Michel Wensing
Charlotte Ullrich *Editors*

Foundations of Health Services Research

Principles, Methods, and Topics

Springer

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Part I
Introduction to Health Services Research

Chapter 1
Description of Health Services Research

Michel Wensing and Charlotte Ullrich

Abstract Health services research (HSR) aims to contribute to the improvement of healthcare by addressing challenges in real-world healthcare settings. It is centred around the values, needs and interests of people who are (potential) users of healthcare (i.e. individuals and populations). HSR complements life sciences and clinical research as a third pillar of health research by analysing structures, processes and outcomes of health services. A large part of HSR can be described as healthcare epidemiology (description and exploration of current status of healthcare delivery) or evaluation research (focused on interventions in healthcare). The specific approach of HSR involves empirical research and analysis that is informed by different scientific disciplines. This chapter provides an introduction into the field of HSR and its characteristics. It also locates HSR within the broader field of health-related sciences.

1.1 Introduction

How can the unnecessary prescribing of opioids be reduced? Does counselling of patients match with their preferences, needs and abilities? How can patients' discharge from hospital be coordinated with ambulatory care? All three are typical questions of health services research (HSR) as they address current problems in healthcare. Perceived or anticipated problems and challenges in healthcare are often the primary driver of HSR, not the development of scientific theory or the ambition to make discoveries per se. Nevertheless, scientific knowledge is required to systematically address these issues.

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In the broad field of health research, HSR has a specific position. Scientific research related to human health can be categorised into three broad fields. (a) *Life science research* (also described as fundamental research) is research that aims to provide insight into health and disease in humans. It focuses on cells, organs and other biological (and psychological) systems and is typically conducted in research laboratories. (b) *Clinical research* is research that aims to provide insight into the cause, diagnosis, prognosis and treatment of disease. This research is done in individuals and populations in designs that span a spectrum from highly controlled conditions to real clinical practice. (c) *Health services research* is research that aims to provide insight into the organisation, delivery and outcomes of healthcare to individuals and populations, including interventions to improve them. This research is mostly done empirically in healthcare settings or on the basis of data from such settings. In this sense, HSR focuses on real-world healthcare practice, rather than healthcare under extraordinary conditions, such highly specialised treatment centres, research under controlled conditions or research in laboratories.

The three fields of health research share the goal of improving health outcomes and are interconnected; knowledge from the life sciences may be transferred to clinical and epidemiological research, and then to HSR. This flow of knowledge has been described as 'from bench to bed to practice' (Westfall et al. 2007). To improve healthcare, there is (ideally) a flow backwards and forwards. For instance, HSR may provide insight into factors that influence the effectiveness of clinical interventions, such as patient adherence to treatment. HSR thus complements life sciences and clinical research by providing unique knowledge to understand healthcare practice, organisation and outcomes in routine care settings. This knowledge is crucial for optimising the health of individuals and populations.

HSR aims to provide scientific knowledge that contributes to the improvement of healthcare, particularly its outcomes for patients and populations. This intention to contribute to improvement applies to the field as a whole, not necessarily to each single study. HSR is a response to the needs of healthcare policy-makers and other stakeholders who face challenges that are not addressed by fundamental and clinical research. HSR has gradually developed into an independent academic field, which differs from the contributing disciplines and from fields of application in healthcare. The field is an established scientific subject in some countries, while it is still developing in other countries. Since the 1960s dedicated structures for HSR have emerged in healthcare systems and in the academic world, such as professorships, academic journals, conferences and educational programmes. These developments started in the English-speaking world and have subsequently spread to other, primarily high-income countries, which is reflected in the growing diversity of the field.

Along with the development of the field, different definitions of HSR have been proposed over the years (e.g. Lohr and Steinwachs 2002; Plochg et al. 2007). While most commonly used definitions of HSR point in the same direction, they show subtle differences. For example, in the Anglo-American context, HSR leans towards a focus on the structure and performance of healthcare systems. A systems approach of HSR is also found in other definitions (e.g. Pfaff and Schrappe 2011). In the German-speaking world, *Versorgungsforschung* (usually translated as health

Table 1.1 Key features of health services research

– A focus on challenges and problems in real-world healthcare with the intention to contribute to improvement
– Analysis of problems in terms of structures, processes and outcomes, with a focus on the perspectives of (potential) users and other stakeholders
– Use of multidisciplinary, systematic and data-driven approaches

services research; Pfaff 2003, p. 13) includes most research outside research laboratories, varying from research on healthcare systems to clinical research on interventions in healthcare practice.

For the purpose of this book, we see HSR as a research field that aims to contribute to the improvement of healthcare by addressing challenges in real-world healthcare settings. HSR is centred around the values, needs and interests of people who are (potential) users of healthcare (i.e. individuals and populations). This focus leads to an emphasis in HSR on what matters to these users: accessible, safe, effective, patient-centred, efficient and coordinated healthcare. Consequently, HSR concerns the behaviours of healthcare professionals, clinical and preventive interventions in settings and the contribution of technologies, organisations and systems in healthcare. It uses multidisciplinary empirical research and analysis from stakeholder and system perspectives to address these challenges and point to possibilities for improvement. Table 1.1 summarises the key features of HSR.

HSR is a research field that is primarily defined through its objective. HSR uses concepts and methods from several scientific disciplines, assuming that healthcare problems can be better addressed in this way than by a monodisciplinary approach. Several scientific disciplines and fields contribute concepts and methods to HSR, particularly medicine, public health, epidemiology and behavioural and social sciences. These disciplinary approaches have to be combined and adapted to healthcare to meet the aims and focus of HSR. In this sense, the approach of HSR is multidisciplinary. Whether these concepts and methods have been truly integrated (i.e. interdisciplinary approach) is a topic for debate. Although there is no exclusive unified understanding of concepts or methods for HSR, particular perspectives and research methods have been proven suitable for addressing HSR research questions. Against this background, within this chapter, we will address the scope and perspective of HSR (Sect. 1.2), give an overview of study designs and methods (Sect. 1.3), introduce the fields within HSR (Sect. 1.4) and contextualise HSR as a scientific field among other fields of health research (Sect. 1.5).

1.2 Scope and Perspective of Health Services Research

HSR looks at both outcomes and determinants in healthcare. HSR typically addresses its topics at three different levels of aggregation (SAMW 2014): a) the *micro level of interactions* between patients and healthcare providers and patients'

behaviours in relation to healthcare; b) the *meso level of healthcare institutions*, such as hospitals and ambulatory care practices; and c) the *macro level of healthcare systems* on the regional, national or international scale. HSR emphasises the connections between factors and processes at different levels of aggregation in (complex) systems (e.g. how macro level conditions influence care at the micro level). HSR takes a broad perspective on what healthcare comprises, for instance, including mental healthcare and social care.

The focus on outcomes does not mean that every single study is focused on outcomes in individuals and populations but that the overall long-term perspective of HSR is on improving such outcomes. Debates may arise about what relevant outcomes are, what counts as 'better' and which outcomes should be prioritised. For instance, single individuals may have priorities that differ from the population or society. HSR tends to favour a societal perspective on the importance of outcomes rather than the perspective of single specific individuals or specific stakeholders. Health outcomes are of course of interest in HSR, usually as one among several outcomes, but outcomes of interest in health services cannot be reduced to health alone. Several perspectives have influenced the types of outcomes typically considered in HSR.

From an economics perspective, outcomes of interest include *healthcare utilisation*, *healthcare costs*, *health benefits* and the *equity* of the distribution of costs and benefits. The *efficiency* of healthcare is the balance between healthcare benefits and resource utilisation (costs or investments). From this perspective, healthcare benefits are primarily defined in terms of survival and health-related quality of life in populations. While the health economics approach treats healthcare practice largely as an unknown 'black box' (with inputs and outputs), this 'box' is opened in other approaches to health research. Important aspects of quality of care are safety, effectiveness, patient-centredness, timeliness, efficiency and equity (Institute of Medicine 2001). Quality of care has been defined as "the expected ability to achieve the highest possible net benefit according to the valuations of individuals and society" (Donabedian 1980). It is context dependent; thus, the meaning of these aspects of quality differs according to time, place and stakeholders.

Besides description, HSR aims to identify and examine the determinants of outcomes (including causes, preconditions and provoking factors). These may be summarised as 'associated factors' because the exact role is often unclear in HSR. Insight into these factors often helps in understanding the current state of affairs and thus in developing policies and programmes to address problems and challenges in healthcare. A wide range of factors are associated with outcomes and are thus of interest to HSR. Lohr and Steinwachs (2002) provide the following categories of factors:

- *Social factors*, such as the culture in a healthcare profession, the functioning of a clinical team or the network of healthcare professionals emerging from sharing patients
- *Financing systems*, such as the reimbursement system, financial risk for healthcare providers and co-payment for patients
- *Organisational structures and processes*, such as the type of leadership, the design of work processes and the available resources in an organisation

- *Health technologies*, such as information technology infrastructure and buildings
- *Individual behaviours* (e.g. of patients and professionals), covering competences, routines, attitudes and other cognitions

Depending on the topics of interest, two more categories need to be added to this list:

- *Characteristics of diseases and health conditions*, such as their complexity, predictability and prevalence
- *Characteristics of clinical and preventive interventions*, such as their evidence base, safety, effectiveness and cost

HSR may also consider societal factors (e.g. wealth or cultural orientation of a society) and environmental factors (e.g. air pollution or social deprivation), but these are not primary topics as they are examined in other scientific fields and disciplines (e.g. public health).

1.3 Study Designs and Methods in HSR

Empirical research, based on systematically collected data from healthcare practice, is the central methodology in HSR. The field shares its research methods, such as randomised trials and qualitative studies, with other scientific fields and disciplines. Widely used methods for data collection in HSR are interviews, questionnaires and abstraction from patient records and claims data (Section III). Other methods, which are used less frequently, include direct observation, extraction from digital devices and computer laboratory experiments. In terms of what is actually done, a large part of HSR can be classified into one of the following two fields:

- *Healthcare epidemiology*: Observational research on healthcare structures, processes and outcomes, with a focus on documenting and exploring the variations between providers, populations and jurisdictions
- *Evaluation research*: Data-based assessment of the outcomes, processes and costs of implementation strategies; healthcare delivery models and health-related policies; evaluations in HSR use experimental and observational designs

While most HSR uses quantitative methods, qualitative research is used as well (Chap. 7). HSR also includes *validation research* (to provide validated measures, such as questionnaires), *systematic reviews* (to synthesise studies) and *conceptual analysis* (to provide hypotheses and interpretations). Table 1.2 describes the purposes for which the different types of data are mainly used in HSR.

For the examination of the effects of interventions and factors on specific outcomes, studies with experimental and observational designs are used in HSR (Grimes and Schulz 2002). In studies with experimental designs (trials), participants are purposefully assigned to one of two or more study groups that are differently exposed to an intervention. In randomised trials, the assignment to study

Table 1.2 Main relations between study purposes and types of data in Health Services Research

Types of data / *Main purposes*	Interviews, observations and documents	Written and online surveys	Data that are routinely collected in healthcare practice	Published studies
Description and exploration	Describe and explore individual perspectives and contexts of healthcare	Describe and explore individual perceptions, experiences and outcomes	Describe and explore healthcare utilisation and performance	Systematic reviews of descriptive and explorative studies
Evaluation of interventions	Develop interventions, evaluate intervention processes	Evaluate processes, outcomes and costs of interventions	Evaluate outcomes and costs of interventions	Systematic reviews of intervention studies
Measurement validation	Develop content of measures and test prototypes	Examine validity and properties of measures	Examine validity and properties of a measure	Systematic reviews of validation studies

groups is based on randomisation. Outcomes are measured after exposure to the intervention and frequently also before the start of the intervention. In studies with an observational design, one or more existing study groups are analysed with respect to the outcomes of interest. Determinants and outcomes may be measured at the same moment in time (cross-sectional design) or at different moments (cohort study, case-control design).

While some laws and regulations on health research do not apply to HSR as opposed to clinical research on health interventions and medical devices, it is generally recommendable to adhere as closely as possible to the principles of *Good Clinical Practice* in HSR for interventions. In addition, laws and regulations on data security apply to HSR: all data containing personally identifiable information (personal data) has to be protected. In particular, health data of vulnerable patients need consideration from the planning stage of studies onwards. Obtaining external ethical approval before conducting a study is a common requirement for HSR studies (Chap. 4).

1.4 Fields Within Health Services Research

HSR covers research on a wide variety of topics, varying from shortages of healthcare workers and resilience of healthcare regarding disasters to digitalisation of work processes and data-driven decision support in clinical practice. The different topics of HSR can be categorised in the following four fields: (a) patient perspectives, (b) healthcare providers, (c) organisation of care and (d) healthcare performance. Table 1.3 summarises these fields (Chap. 2).

Table 1.3 Fields of health services research

– *Patient perspectives*, focusing on issues such as self-management of disease, healthcare utilisation, patient-centredness of care, patients' feedback and patient involvement in healthcare planning
– *Healthcare providers*, covering issues such as availability, accessibility, allocation of roles, resilience and retention
– *Organisation of healthcare*, covering patient care teams, healthcare institutions, professional bodies and healthcare provider networks
– *Healthcare performance*, covering practice variation, real-world impact of clinical interventions and improvement strategies

Patient perspectives. The focus on patients' perspectives is one of the hallmarks of HSR. In recent decades, the role of patients has increasingly changed into that of active participants in healthcare planning and delivery. This change was motivated by various ideologies, varying from initiatives to enhance humanness in healthcare to economic approaches, which see healthcare as an economic market. Consequently, patients have been renamed as service users, consumers or co-producers of health. In this book, we largely stick to the conventional term 'patients' for convenience of reading. Various concepts have been launched to integrate patients' perspectives in health, such as patient engagement, patient involvement and patient perspectives. Interventions such as communication training and decision aids aim to contribute to the implementation of these concepts in practice. In addition, patients may be involved in activities such as the planning of healthcare institutions and activities in healthcare.

Healthcare providers. In the Western world, modern healthcare has developed over centuries from the work of craftsmen and churches in the past. Modern healthcare is provided by various healthcare providers, such as physicians, nurses, midwives, pharmacists, psychologists and allied health professionals. In high-income countries, healthcare systems employ about 10% of the working population, and in many countries, it uses about 10–15% of the gross domestic product. Many healthcare providers are professions that are characterised by a distinct body of knowledge, regulated access to the occupation, moral duties and societal legitimacy (Freidson 1989). The degree of professionalisation varies across healthcare professions and is overall highest for physicians, who tend to be in positions of greatest power in healthcare. Nurses are the largest group of healthcare professionals in terms of numbers. The capacity, quality and outcomes of healthcare strongly depends on the availability, accessibility and performance of healthcare providers (Chap. 19).

Organisation of healthcare: Many patients do not receive healthcare in one-off contacts with a healthcare provider, but in a series of contacts with a range of providers over a period of time. Ideally, the healthcare received is seamless over time and across different healthcare providers. This has been described in terms of continuity of care, which has many positive effects, e.g. lowered mortality (Pereira Gray et al. 2018) and increased feelings of security and confidence among patients (Haggerty et al. 2003). The conceptualisation of healthcare coordination is

challenging as it is not consistently defined and definitions overlap with other concepts, such as interprofessional collaboration, continuity of care and integrated care. Modern healthcare systems are fragmented and under economic pressure, thus posing challenges for healthcare coordination (Chaps. 21 and 22).

Healthcare performance: Healthcare is knowledge intensive, resource intensive and subject to changing societal expectations. Scientific discoveries (e.g. penicillin, the first antibiotic in 1928) have fundamentally changed healthcare and will continue to change it. There is a continuous flow of new health-related knowledge, which results in new treatments and technologies, evidence-based guidance and new healthcare delivery models. Many studies have shown that aspects of performance can be improved because this knowledge is not fully adopted in practice. The impact of clinical and preventive interventions in healthcare settings is influenced by the context in which they are applied and influenced by strategies, such as quality improvement, safety management and knowledge transfer.

1.5 Health Services Research as a Scientific Field

Several scientific disciplines and fields contribute concepts and methods to HSR. A particular study in HSR may also fit in other fields or disciplines, such as health economics, health psychology, medical sociology or computational science. Consequently, there are no strict boundaries between HSR and other scientific fields or disciplines. Nevertheless, it may be clarifying to explore the boundaries to other scientific fields for a better understanding of the field (see Table 1.4).

There is little overlap between HSR and the life sciences, but overlaps with *clinical and epidemiological research* exist. Clinical research is often conducted under controlled conditions (e.g. strict inclusion criteria for participants, specially trained healthcare professionals). In some clinical studies, these controls are loosened to reflect real healthcare (e.g. pragmatic clinical trials), which poses overlap with HSR. For instance, studies on the implementation of evidence-based practices are part of clinical research as well as HSR.

The research activity of the *health professions* (e.g. surgery or nursing) may include HSR, but the larger proportion is typically clinical research. From the perspective of the health professions, HSR is a cross-cutting field. Some disciplines (such as family medicine, paediatrics and geriatrics) have a high affinity with HSR because they share an interest in specific topics. For instance, family medicine/general practice defines itself essentially in terms of accessibility for all patients and all health problems, a patient-centred approach, comprehensive medical care and responsibility for healthcare coordination (Starfield et al. 2005). These features are all key topics of HSR, although it does not postulate them as given values.

The *social and behavioural sciences* contain a range of fields and subdisciplines that focus on health. Examples are medical sociology, health psychology, medical anthropology and health economics. These subdisciplines usually remain dedicated to the underlying discipline with respect to aims, concepts and methods used. In

Table 1.4 Summary of research fields that are close to HSR

	Primary aim	Main approach	Main methods	Relevance for HSR
Health professions	Develop and strengthen health professions	Practice-based and politically driven prioritisation of topics	Methods from life sciences, clinical research and HSR	Provide topics for research
Social and behavioural sciences	Accumulation of knowledge on human behaviour	Design and testing of concepts in cyclic research processes	Conceptual analysis and empirical research, often within traditions	Provide concepts, interventions and research methods
Clinical and epidemiological research	Provide knowledge to support clinical decision-making	Structured measurement and analysis of data within standardised study designs	Epidemiological concepts and methods	Provide research methods, clinical research evidence, collaboration in real-world studies
Public health	Enhance the health of populations	Identify health risks, evaluate preventive interventions and health systems	Epidemiological and health economics research	Provide topics in prevention, collaboration in health systems research

contrast, HSR applies concepts and methods from different disciplines in a single study. Also, social and behavioural science research do not necessarily aim at contributing to improvement of healthcare, as it may primarily aim to contribute to the accumulation of scientific knowledge within their domain. HSR is therefore primarily positioned in the health sciences.

Public health concentrates on the health populations with a focus on the prevention of disease and health risks (e.g. vaccinations and health promotion). It considers a broad range of determinants, including many outside the healthcare system (e.g. air pollution and water quality). Preventive care is an important field of healthcare, which can be the topic of HSR. The field of public health also comprises research on the structure and performance of health systems, which overlaps with HSR.

1.6 Aim and Focus of the Book

The motivation for realising this book emerged from our teaching on HSR. We felt a need for a comprehensive introduction to the field, which focuses on principles, methods and topics of HSR. To the best of our knowledge, such a book did not yet exist. Therefore, we decided to write this book, building on our experience in a

Master's programme on HSR at Heidelberg University, Germany since 2015. The book aims to provide an introduction and overview of HSR, especially for students and newcomers to HSR. We intend to write for a broad international audience, but it is likely to be more closely oriented towards high income countries.

This book places emphasis on healthcare practice and (potential) users of healthcare, thus the micro level of healthcare. Healthcare institutions (at meso level) and healthcare systems (at macro level) are considered insofar as they influence healthcare practice. While *healthcare practice research* might be a more accurate term, within this book we retain the established term 'HSR' to avoid inflation of concepts.

Chapter 2 *Fields of HSR* will describe the four fields (a) patients' perspectives, (b) healthcare professionals, (c) organisations of care and (d) healthcare performance in more detail, providing typical themes and examples.

Section II focuses on established principles for providing robust and relevant research on healthcare practices, such as the integration of theories (Chap. 3) and procedures to enhance scientific integrity (Chap. 4). Distribution of research findings to a central stakeholder is crucial for any applied field; therefore reporting (Chap. 5) and research dissemination (Chap. 6) are central to HSR.

The quality of the research practices and methodologies determine the value of HSR to a large extent. Poorly designed or poorly conducted studies do not contribute to science or practice and may do harm. *Section III* therefore focuses on the principles and methods of research. This part of the book first elaborates on frequently used methodological approaches, which are primarily defined by data type: qualitative research (Chap. 7), survey research (Chap. 8) and data extraction from electronic patient records (Chap. 9). Each of these chapters elaborates on general principles, methods for sampling, data collection and data analysis. A separate chapter focuses on social network analysis (Chap. 10). The development and validation of measures, especially questionnaires, is important in any field of science, including HSR (Chap. 11).

The remaining chapters of Section III focus on the development and evaluation of interventions, which is an important purpose of many studies in HSR. Intervention is a broad concept, which comprises, for instance, implementation strategies and healthcare delivery models. The chapters on intervention research are organised by the primary purpose of the study: intervention development (Chap. 12), process evaluation (Chap. 13), outcomes evaluation (Chap. 14) and economic evaluation (Chap. 15). The final chapter in Section III focuses on methods for systematic review of intervention studies (Chap. 16).

As healthcare practice constantly changes, so do topics of HSR. *Section IV* of this book introduces eight exemplary emerging topics of HSR. These refer to the four research fields mentioned above. New developments in the field of patient empowerment (Chap. 17) and, as an example, personalised mental health (Chap. 18) are addressed. The evolving field of health professions (Chap. 19) and, as an example, community pharmacies (Chap. 20) concern the field of healthcare providers. Continuity of care (Chap. 21) and, as an example, coordination of healthcare for refugees (Chap. 22) address the field of organisation of care. Concerning health

performance, the book elaborates on digitalisation in healthcare (Chap. 23) and climate change (Chap. 24).

Each chapter provides an outline of central themes and developments of the respective topic as well as examples. Throughout the book, boxes are used to highlight example studies and summarise key points. Reading suggestions are provided for further interest.

We would like to thank our students whose critical enquiries made us aware of the need to explain the principles, methods and topics (and what HSR actually comprises) in more detail. A big thanks goes to Alexandra Valdez for a thorough language check and Alicia Armbruster, Janina Bujan Rivera and Claudia Trickes for checking the literature references. All remaining errors and unclarities are obviously our responsibility.

With this book we intended to provide useful material for teaching and learning programmes on HSR. However, it neither provides practical 'hands-on' guidance nor is it fully comprehensive on its own. Instead, we hope that the book offers perspectives and source for critical engagement in HSR, alongside lectures, readings and exercises. In this respect, this book should be understood as an invitation to HSR rather than a final word on its realm.

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Chapter 2
Fields of Health Services Research

Michel Wensing and Charlotte Ullrich

Abstract Health services research focuses on a broad spectrum of problems and challenges in healthcare. These topics can be categorised in four fields: (a) patients' perspectives, (b) healthcare providers, (c) organisation of healthcare and (d) healthcare performance. *Patients' perspectives* influence their self-management of health and diseases, utilisation of and involvement in healthcare and their feedback on healthcare. Healthcare is dependent on the availability, accessibility, competencies and resilience of *healthcare providers*. *Organisation of healthcare* is the backbone of healthcare delivery, especially for patients, for whom healthcare has to be coordinated over time and across different healthcare providers. Variation in and improvement of *healthcare performance* across geographic areas and healthcare providers, including the implementation of innovations, are traditional topics of health services research.

2.1 Introduction

Health services research (HSR) studies perceived or anticipated challenges in healthcare. This chapter will broadly describe these challenges and present illustrative examples of health services research. Four fields of interest can be distinguished: (a) patient perspectives, (b) healthcare providers, (c) organisation of healthcare and (d) healthcare performance. In each of these fields, healthcare epidemiology (descriptions and explorations of issues) and evaluation research (of healthcare delivery models and other interventions) can be found. In all research fields, a variety of study designs and research methods are used. The development

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Table 2.1 Main fields of HSR

Field	Topics
1. Patients' perspectives	Self-management of health and disease Utilisation of healthcare Involvement in healthcare Feedback on healthcare received
2. Healthcare providers	Availability of healthcare providers Accessibility of healthcare providers Allocation of professional roles Resilience and retention of healthcare providers
3. Organisation of healthcare	Interprofessional collaboration Coordination in healthcare institutions Integrated care Coordination in healthcare systems
4. Healthcare performance	Practice variation and real-world impact of interventions Programmes and policies to improve healthcare

of concepts, theory and methods is increasingly seen as a necessary foundation of HSR. (Chap. 3). This chapter will describe these research fields outlining classic research topics (Table 2.1), describing central research findings and presenting illustrative examples.

2.2 Patients' Perspectives

Patients' perspectives influence their self-management of health and diseases (2.2.1), utilisation of healthcare (2.2.2), involvement in healthcare (2.2.3) and their feedback on healthcare received (2.2.4). The order of these topics reflects the typical patients' pathway through healthcare. All these topics have been extensively studied in HSR.

2.2.1 Patients' Self-Management of Disease

For a substantial part, the health of individuals and populations is related to living conditions (e.g. housing, pollution), life-styles (e.g. smoking) and biological factors (e.g. genetic predispositions). The health of individuals and populations is thus largely determined outside the healthcare system. Most individuals manage most their health conditions themselves, using self-care and social support. Self-care or self-management has been defined as "the care taken by individuals towards their own health and wellbeing: it comprises the actions they take to lead a healthy lifestyle; to meet their social, emotional and psychological needs; to care for their long-term condition; and to prevent further illness or accidents" (Department of Health 2005). Studies within this field typically focus patients' perspectives on self-management and on interventions to support patients' self-management.

For instance, a German study in a large sample of primary care patients examined self-care in common health issues such as sore throat, cough and back pain (Parisius et al. 2014). It found that patients were prepared to use an average of 18 remedies, with highest scores for inhalation (80% would use this), hot lemon drink (76%), honey (76%), chamomile tea (73%) and chicken soup (72%). Self-management programmes teach and support individual patients with respect to disease-related problem-solving (e.g. interpreting symptoms, maintaining activities), managing medications (e.g. adherence, adversities, barriers), cognitive symptom management (e.g. relaxation, distraction, reframing), exercise, management of emotions (e.g. emotions as symptoms, fear, self-doubt), communication skills (e.g. building partnership with physician) and use of community resources (Holman and Lorig 2004). Most of these aspects require individual behaviour change; albeit other approaches have emphasised the role of social support for self-management capabilities (Koetsenruijter et al. 2016). Support tools for self-management include software devices, such as applications for smartphones.

Patients' adherence to treatment (also described as treatment compliance) can be understood as a specific aspect of self-management, which has a research tradition that precedes that of self-management (Britten et al. 2002). Interventions to increase treatment adherence can be classified as technical, behavioural, educational and/or affective (Van Dulmen et al. 2007). These interventions can effectively increase treatment adherence, but none is consistently effective, and it is difficult to predict whether a specific intervention for enhancing treatment adherence will be effective in a specific target group (Van Dulmen et al. 2007). An example of a technical intervention is electronic monitoring of medication use, using a device attached to the inhalator of asthma medication that is wirelessly linked to the patients' smartphone and monitored by community pharmacists (Kuipers et al. 2017). Box 2.1 presents a study on the implementation of a self-management support intervention in routine primary care.

Box 2.1: Personalised Support for Self-Management in Primary Care (Eikelenboom et al. 2016)

This randomised trial tested a personalised approach to enhancing self-management in primary care. Based on extensive preclinical research, a list of individual needs regarding self-management support was composed. These included, for instance, self-efficacy, computer skills and depression. These needs were measured and visualised as an individual profile for healthcare professionals, who had received training on counselling patients on the basis of these profiles. A total of 646 patients from 15 primary care practices were included in the final analysis. No effect on patient activation at 6 months (the primary outcome) was found, but more patients performed self-monitoring and used individual care plans (secondary outcomes). These findings suggest specific aspects of self-management were better taken up, albeit by a minority of patients, but a comprehensive change of patients' self-management approach was not achieved.

2.2.2 Healthcare Utilisation

Patients' perspectives on health and healthcare determine not only self-management of disease but also whether an individual seeks healthcare in the first place. Beyond the individual interpretation of bodily and mental symptoms, there is a large range of factors that influence individuals' utilisation of healthcare: sociocultural, sociodemographic, social-psychological, organisational and social systems-related (Anderson 1973; Andersen 1995). Studies within this field typically focus on determinants of healthcare utilisation for specific conditions and on interventions to change (increase or decrease) healthcare utilisation.

For instance, a study showed that the decision to attend primary care among middle-aged and older men with lower urinary tract symptoms was predominantly determined by advice from others and information in the media. The number or seriousness of health symptoms was less relevant for this decision (Wolters et al. 2002). Interventions such as educational leaflets, reminders, media campaigns and changes in co-payment have been used to increase or decrease healthcare utilisation. Box 2.2 provides an example.

Box 2.2: Educational Flyer to Enhance Healthcare Utilisation Among Elderly Patients (Van Eijken et al. 2004)

Many elderly patients have symptoms that remain unnoticed, although they could be ameliorated by treatment. Examples are hearing impairment, visual impairment, urinary incontinence, lower urinary tract symptoms and mild depression. A written leaflet was developed to provide information on these symptoms and stimulate individuals to seek healthcare. However, a randomised trial in 760 patients did not identify effects on the number of consultations in primary care in the subsequent 3 months (the primary outcome).

The aggregated result of individual decisions on healthcare utilisation can be evaluated with respect to efficiency and equity at population level. Low healthcare utilisation as compared to similar populations (e.g. in a different geographic region) may be interpreted as inequity, assuming that it reflects unmet health needs or 'underuse' that is related to poor access to healthcare. High healthcare utilisation, on the other hand, may be interpreted as inefficiency, assuming that health needs do not match with the expressed healthcare utilisation.

2.2.3 *Patient-Centredness in Interactions with Healthcare Providers*

After an individual has decided to seek healthcare, a healthcare provider is chosen and contacted, the interaction is prepared (e.g. questions for the provider are listed), the provider is attended and there may be follow-up after the contact. Attendance can be short, e.g. consultations of a few minutes, or extended over a period of time, e.g. during hospital stays. In all phases, information and communication are crucial. Patient-centredness is a central concept in this context. Patient-centred care has been described in terms of "patients are known as persons in context of their own social worlds, listened to, informed, respected and involved in their care—and their wishes are honoured (but not mindlessly enacted) during their health care journey" (Epstein and Street 2011). Patient-centredness has five aspects (e.g. biopsychosocial perspective; 'patient-as-person'; sharing power and responsibility; therapeutic alliance and 'doctor-as-person') (Mead and Bower 2000). Many related concepts have been coined, such as patient engagement, patient involvement and patient activation.

Much health services research has focused on patient-centredness in the provider-patient communication. Associations between patient-centred communication and various outcomes were found, most particularly with patient satisfaction with care and patients' self-management behaviours, while the associations with clinical quality were mixed (Rathert et al. 2012). Box 2.3 provides an example.

Box 2.3: Decision-Making in Routine Cancer Care (Hahlweg et al. 2017)
This qualitative study used participant observation to examine clinical decision-making in one cancer treatment centre in Germany. A total of 54 consultations were observed. In most cases, patients were not actively involved. Patients who were 'active' (i.e. asked questions, demanded participation, opposed treatment recommendations) facilitated shared decision-making. Time pressure, frequent alternation of responsible physicians and poor coordination of care were the main observed barriers for shared decision-making. There is was much variation in decision-making behaviour between different physicians as well as the same physician with different patients.

Interventions such as decision aids, question prompt lists and training of patients have been applied to enhance the uptake of shared decision-making in routine care. Decision aids are paper-based or computerised tools that convey information on treatment options, their benefits and harms, and they elicit patient values and preferences. Question prompt sheets help patients to specify questions and can be used by patients to prepare for consultations with healthcare providers (Albada et al. 2012). Such interventions can have effects on healthcare delivery and patient-reported outcomes, such as enhanced shared decision-making (Légaré et al. 2018).

2.2.4 Feedback on Patient Experiences in Healthcare

When patients give voice to their experiences in healthcare, they can contribute to the planning, delivery and improvement of healthcare. Patients' experiences relate to the performance of healthcare providers (e.g. their effectiveness and competence) and the organisation of care (e.g. accessibility and continuity). The measurement and use of patient experiences is an important topic of health services research. Various methods for eliciting patients' views have been developed, most of which are based on questionnaires or interviews. Examples are written surveys in samples of patients to provide feedback to healthcare providers, focus group interviews with patients to include their views in clinical guidelines and documentation of patient-reported outcomes (PROMs) to monitor effects of treatment. Such methods need to be assessed in terms of validity, effectiveness and implementation in the context of application (Wensing and Elwyn 2003; Coulter et al. 2014).

Patient experiences can be classified as preferences, reports or evaluations (Wensing and Elwyn 2003). Preferences are patients' ideas about what should happen in individual treatment or in healthcare generally. Reports represent objective observations of the organisation, process or outcomes of healthcare. Evaluations are patients' assessments of these observations.

Patient experience measures tend to be weakly correlated with measures of clinical quality indicators that measure adherence to clinical recommendations (Llanwarne et al. 2013). A large range of questionnaires for functional health status, health-related quality of life or evaluations of healthcare delivery have been developed. There is substantially less research on the effectiveness and implementation of the use of patient experiences for the planning, delivery or improvement of healthcare practice. The small body of research on patient feedback showed limited impacts (Baldie et al. 2018). Approaches that go beyond the consultation of patients and involve patients as partners in the design of healthcare services at organisational level can result in specific products or activities and increased perceptions of being involved (Bombard et al. 2018) (Box 2.4).

Box 2.4: Involving Patients in Setting Priorities for Quality Improvement (Boivin et al. 2014)

In this study, communities in a Canadian region were invited to set priorities for improving chronic disease management in primary care. Patients were consulted in writing, before participating in face-to-face deliberation with providers. In a pragmatic cluster-randomised trial, this approach was compared to communities, in which providers set priorities among themselves. A total of 172 individuals from 6 communities were involved: 83 patients and 89 healthcare providers. The involvement intervention enhanced mutual influence between patients and providers, which resulted in a 41% increase in agreement on common priorities, which was statistically significant. Priorities established by providers alone placed more emphasis on the technical quality of single disease management. Patient involvement increased the costs of the prioritisation process and required more time to reach consensus on common priorities.

2.3 Healthcare Providers

Healthcare is dependent on the availability, accessibility, roles and retention of healthcare providers. It makes little sense to consider organisation or performance of healthcare, if there are no healthcare providers to attend, if they are not accessible or do not take on specific roles or if they are not resilient and do not remain in their functions. Planning, recruitment, training and retention of healthcare providers are therefore important topics of HSR, especially given the current and anticipated workforce shortages.

2.3.1 Availability of Healthcare Providers

The numbers of healthcare providers vary substantially across the world and over time. The number of physicians increased in previous decades to an average of 3.5 per 1,000 inhabitants in the 36 OECD countries in the year 2017 (OECD 2019, p. 175). There is substantial variation across countries. For instance, the figure was 4.3 physicians per 1,000 inhabitants in Germany, 2.8 in the UK and 2.6 in the USA. Likewise, the number of nurses varies across countries. Per 1,000 inhabitants, it was 12.9 in Germany, 7.8 in the UK and 11.7 in the USA (mean across countries: 8.8 nurses per 1,000 inhabitants) (OECD 2019, p. 181). The required or optimal numbers of health providers is estimated with a view on planning of admissions to training for the health professions in a healthcare system. However, this is challenging, because the supply and demand of healthcare is influenced by many factors and the estimations require data that may not be available (Lopes et al. 2015). Workforce shortages may exist in specific healthcare sectors and geographic regions, such as rural areas and deprived neighbourhoods (see Box 2.1). Besides studies of supply and demand for healthcare, health services research can evaluate health policies to address imbalances in the availability of healthcare providers. These may target the access to education programmes (e.g. increase numbers of students), adapt regulations (e.g. allow enhance scope of practice), provide financial incentives (e.g. higher wages) or personal support (e.g. better living conditions) (Kuhlmann et al. 2018) (Box 2.5).

Box 2.5: Long-Term Care for Patients with Dementia (Forstner et al. 2019)

The number of patients with dementia is increasing, mainly because of ageing populations. Therefore, it is important to estimate the required healthcare capacity, such as nursing home care, informal care and respite care. Health insurance claims in a German state were analysed to explore variations in healthcare supply and healthcare utilisation in small geographic areas. The study found differences between districts in the utilisation of long-term care for dementia, which were largely explained by the composition of the population within the districts (in terms of age, sex and level of care dependency). An exception was the utilisation of respite care, which was higher in districts which had higher supply of this type of care.

2.3.2 Accessibility of Healthcare Providers

Research on the accessibility of healthcare providers considers factors such as geographic distance, financial cost, waiting times and length of consultation time. For instance, individuals may be willing to travel longer to attend a preferred provider (Zander et al. 2019). Another aspect is patients' co-payment in relation to use of healthcare, which varies substantially. A randomised trial, classic in health services research, compared different levels of co-payment and showed that patients reduced their use of both effective and noneffective services in case of co-payment (Newhouse 1993). Another topic is consultation times in primary care, which were found to vary from 2 to 22 min across countries, with a trend towards longer consultations in countries with higher expenses on healthcare and higher density of primary care physicians (Irving et al. 2017). Health services research has also focused on interventions to reduce waiting times, such as open access scheduling, triage of patients, interventions to promote self-management, consultations by telephone or email and involvement of nurse practitioners (Ansell et al. 2017).

2.3.3 Allocation of Professional Roles

After initial education and training, healthcare providers can fulfil many roles. These include, for instance, providing specialised expertise, performance of technical procedures, counselling of patients and coordination of care. There is large variation within and across countries with respect to what roles are fulfilled by professional with a specific vocational training. For instance, nurses may provide a range of services under the responsibility of physicians, but they may also have more autonomy up to independent diagnosis and treatment decisions. If the boundaries of activities between providers are unclear, issues may emerge regarding the division of roles between health professions (Cramer et al. 2018). Studies in this field typically focus on the feasibility, safety, costs and implementation of revisions of professional roles (e.g. the introduction of nurses in primary care). Reallocation of professional roles occasionally leads to the emergence of new professions. An example provides 'physician assistants', who emerged in the USA to address physician shortages and have then been introduced in some other countries as well. Physician assistants are nonphysician clinicians (e.g. licensed nurses) who received additional training (typically 3 years at master-level) to work in specific medical domains.

2.3.4 Resilience and Retention of Healthcare Providers

Job satisfaction, job stress and burn-out among healthcare providers are important challenges in healthcare. Research in this field examines these issues in specific healthcare providers and evaluates interventions and policy measures to enhance their resilience and retention. For instance, a study in primary care physicians in 11 countries found that job dissatisfaction was lowest in Norway (8% of physicians) and highest in Germany (37%) (Cobidon et al. 2019). Higher job dissatisfaction was related to being middle-aged, working in urban areas, working alone, high workload, heavy administrative burden, long delays in hospital discharge information and limited possibilities to offer same-day appointments. Having computerised medical records and a practice manager were associated with lowered dissatisfaction. As a response to recruitment and retention problems in specific healthcare professions in specific countries, various interventions have been applied. Examples including changes in the training programme, financial incentives and new ways of working to facilitate a different work-life balance (Marchand and Peckham 2017).

2.4 Organisation of Healthcare

For many patients, healthcare has to be coordinated over time and across different healthcare providers. A variety of structures and activities specifically aim at enhancing healthcare coordination, such as interprofessional collaboration (2.4.1), coordination in healthcare institutions (2.4.2), integrated healthcare systems (2.4.3) and coordination in healthcare systems (2.4.4). Effective coordination of healthcare is not only important for the outcomes and experiences of individual patients and the job satisfaction of healthcare providers but also for the costs, equity and resilience of the healthcare system. An organisational perspective is therefore required in HSR.

2.4.1 Interprofessional Collaboration

Physicians, nurses and other healthcare providers collaborate (at micro-level) in teams, hospital departments and ambulatory care practices. The collaboration is usually based on the exchange of information regarding individual patients and involvement of the various providers in clinical decision-making. Research on the collaboration between healthcare providers has identified many factors that influence interprofessional collaboration, such as the content of the exchanged information, available guidance (e.g. clinical protocols), healthcare providers' competencies and views on collaboration (Chap. 19). Their interaction patterns influence healthcare delivery and outcomes in ways that are complex. Collaboration between

healthcare providers can be measured and analysed as social networks (Tasselli 2014); Box 2.6 provides an example.

Box 2.6: Collaboration for Cardiovascular Primary Care (Heijmans et al. 2017)
This observational study was linked to a randomised trial of a programme to improve cardiovascular risk management in primary care. It involved 180 healthcare providers from 31 primary care practices, who completed a written questionnaire. Data on healthcare processes were extracted from the patient records of 1620 patients. The study found that higher adherence to evidence-based guidelines for cardiovascular risk management was associated with the presence of an opinion leader in the practice and high consistency of views among the physicians, nurses and practice assistants in a primary care practice. Interaction frequency did not show associations.

Many interventions to enhance healthcare coordination have been developed and examined in research. For instance, a healthcare professional may delegate or transfer specific tasks and responsibilities to other healthcare providers. As an example, primary care physicians may be substituted by nurses in specific domains of their work. The available research showed that such substitution was associated with lowered mortality and similar or better outcomes for aspects of health status, patient experience, quality of care and healthcare utilisation (Laurant et al. 2018). For a good interpretation of these findings and their transferability to other settings, the context of the studies has to be considered.

Another intervention to improve healthcare coordination is the enhancement of patient care teams, for instance, by training members regarding teamwork, changes in communication procedures or by adding team members with specific expertise, such as pharmacists. These interventions can improve aspects of collaboration and outcomes of healthcare, but the effects across studies are mixed and overall modest (e.g. Reeves et al. 2017). A variety of contextual factors influence the implementation and effectiveness of these interventions. For instance, previous experiences regarding collaboration and mutual trust appeared to be important factors in the collaboration between physicians and pharmacists (Löffler et al. 2017).

2.4.2 Coordination in Healthcare Institutions

Healthcare providers are embedded in healthcare institutions (e.g. hospitals, ambulatory care practices), which coordinate their activities. Many of these organisations can be described as professional bureaucracies, which implies that they combine hierarchical structures with high autonomy of healthcare professionals (Mintzberg 1996). Organisational leaders can influence the organisational climate by the way

they allocate attention, respond to incidents, allocate resources and rewards, show exemplary behaviour, offer coaching and select new staff (Aronson et al. 2014). The involvement of physicians in leading roles has been described as key for effective coordination. Studies in this field have explored correlations between organisational characteristics and aspects of healthcare performance, patient experiences or job satisfaction. For instance, a study of 370 German hospitals found that hospitals with physician-leaders have lower mortality rates (for pneumonia) and higher patient satisfaction with care (Kaiser et al. 2020). Leadership influences research use among the nursing and allied health professions (Gifford et al. 2018). While medical professionals in hospitals have been studied with a view on the power dynamics between physicians and institutional managers, there is much less research on leadership roles of ambulatory care physicians.

The transferability of research on healthcare institutions across healthcare settings and countries is an issue, because they differ in many ways. For instance, they have different organisational cultures. Culture is a body of shared knowledge, norms and values of which individuals may not be particularly aware. Specific aspects of organisational culture may influence how healthcare coordinated. For instance, a flexible, innovation-centred culture was found to be associated with a better uptake of quality improvement activities and with better health outcomes (Shortell et al. 1995). The approach to behaviours that deviate from the norm is another aspect of culture, which influences the coordination of healthcare. Box 2.7 provides an example. It may be possible to change aspects of organisational culture, for instance, by 'walk arounds' by organisational leaders (Morello et al. 2013).

Box 2.7: Healthcare Coordination in Organ Donation (Pohlmann 2019)
In Germany, organ donation is strictly regulated in order to maintain a fair allocation of scarce organs. The allocation is based on detailed scoring of individual patients, which is done by physicians involved in organ transplantation. In the years 2010–2012, there proved to be large-scale 'upcoding' by these physicians to enhance the likelihood of receiving an organ for specific patients on the waiting list. The estimates of the prevalence of upcoding were between 10% and 20% of patients in the waiting list for organs. Research on the basis of interviews, law suits and other documentation provided little evidence for direct financial benefit of individual physicians. Qualitative research suggested that the upcoding behaviour was embedded in widely shared behavioural patterns of physicians. They dealt with a complex, externally imposed administrative system for reimbursement in ways to maintain financial viability of the hospital as well as their professional autonomy in deciding which patients would get the available organs allocated. Unrelated policies of health insurers to motivate physicians to optimise the coding of diagnoses – which had financial benefits to insurers in the risk adjustment scheme – seemed to have prepared the ground for these practices.

2.4.3 Integrated Care

Healthcare may also be coordinated across different healthcare institutions, such as hospitals and primary care practices. Integrated care is a short generic name for purposefully designed, structured healthcare for a defined population of patients, which involves coordination across relevant healthcare providers. Many studies in this field focused on examples of integrated care programmes and examined their implementation and effectiveness. A well-known example is probably the *Chronic Care Model*, which specifies key components of structured healthcare for patients with chronic disease in six domains: self-management support, clinical information systems, delivery system redesign, decision support, healthcare organisation and community resources (Bodenheimer et al. 2002). *The Chronic Care Model* has guided many policy-makers across the world, and it has been the topic of much research. For instance, the degree of its implementation in primary care practice in Europe has been examined (Van Lieshout et al. 2011). A review of studies concluded that models of integrated care may enhance patient satisfaction, increase perceived quality of care and enable access to services, while the evidence for other outcomes including service costs remained unclear (Baxter et al. 2018).

2.4.4 Coordination in Healthcare Systems

The coordination of healthcare is also be influenced by the healthcare system (at macro-level), because these systems determine the finances, structure and governance of healthcare (Chap. 21). Across the world, many policy interventions in healthcare systems have been applied to enhance healthcare coordination, or which impacted on healthcare coordination. Studies in this field focused on reforms in specific countries or compared healthcare systems across countries to explore impacts and contributing factors. For instance, competition between healthcare providers and other market principles were assumed to enhance the efficiency of healthcare services in recent decade. Research found that enrolled individuals were less positive about their healthcare experience and about healthcare insurers (Bes et al. 2017). Another example is the body of research on strong primary care, which is defined as ambulatory care that provides the first point of access to healthcare for most people and most health issues, a patient-centred approach, high continuity of care over time and coordination across healthcare providers. Studies found associations between strong primary care, better health outcomes and lowered healthcare costs. Some countries have adopted strong primary care (e.g. Denmark, The Netherlands and the United Kingdom). Box 2.8 provides an example of a study in this field.

Box 2.8: Introduce Strong Primary Care in a Healthcare System (Wensing et al. 2019)
A programme to enhance primary care (Hausarztzentrierte Versorgung) started in 2008 in Baden-Wuerttemberg, a state in South Germany with approximately 11 million inhabitants. Patients remained free choice of physician, which is a legal right in Germany, but they could voluntarily participate in a programme that involved many aspects of strong primary care and emphasised structured management of patients with chronic diseases. Likewise, primary care physicians could voluntarily join, which the majority of them has done in the subsequent decade. The implementation of the primary care model was facilitated by financial incentives for physicians, data-based performance feedback and political lobbying by stakeholders. Evaluations showed that patients in the primary care programme had more visits in primary care, and fewer non-referred visits to other providers, as compared to a control group. A comparative evaluation with about one million patients and 5-year follow-up showed that enrolled patients had somewhat lowered mortality as compared to a control group, adjusted for confounding factors (Hazard Ratio: 0.978; 95% CI: 0.968; 0.989). It was concluded that the primary care model is safe and potentially beneficial in terms of patients' survival.

2.5 Healthcare Performance

Variation in healthcare performance across geographic areas and healthcare providers is a traditional topic of health services research. Performance is a broad concept and covers, for instance, clinical effectiveness, patient safety, equity, cost and patient experiences. A large body of research examined the variation in performance across different settings or the impacts of clinical and prevention interventions in the real world (2.5.1). Another field of HSR focuses on programmes and policies to improve aspects of performance, including quality improvement, safety management and knowledge transfer (2.5.2). These programmes and policies are also interventions, but they are often described as strategies to distinguish these from clinical and prevention interventions.

2.5.1 Practice Variation and Real-World Impact of Interventions

Research on the variation in quality of care, provider performance and outcomes across geographical regions, healthcare providers or populations is a classic topic of health services research. It started several decades ago with Wennberg and Gittelsohn's studies of geographic variations in Vermont, USA, regarding resource inputs (number of physicians, numbers of procedures) and utilisation of services

(Wennberg and Gittelsohn 1973). These studies suggested inequalities in access and use of healthcare between geographic areas, which may be related to clinical uncertainty (lack of guidance recommended practices) and supplier-induced demand (mechanism that more resources lead to higher numbers of procedures). Researchers across the world have continued to do similar studies, which largely confirmed the presence of practice variation in healthcare performance in many countries and medical domains. The interpretation of practice variation is complex, because it may reflect true differences in healthcare needs between populations. Research on practice variation considers geographic areas or healthcare providers as units of analysis, whereas clinical decisions are mostly made by clinicians. Research at this lower level of aggregation is required to provide insight into the nature and mechanisms of practice variation.

While clinical research examines the effectiveness and safety of interventions under controlled conditions (e.g. restricted inclusion criteria, standardised interventions), HSR examines the effectiveness of clinical and prevention intervention under real-world conditions. The real-world impacts of many clinical and preventive interventions are influenced by characteristics of healthcare providers, patients' perspectives and healthcare organisations. In practice, some studies may be qualified as clinical research and as HSR. For instance, the efficacy of medication depends on healthcare providers' competence in delivering it as recommended and the impact of efforts to enhance patients' adherence to the treatment regime. Specific parts of a clinical study may therefore be described as health services research.

2.5.2 Programmes and Policies to Improve Healthcare

Strategies and policies to improve healthcare include quality improvement, safety management and knowledge transfer. From a methodological perspective, these are interventions that can be evaluated with respect to effectiveness. Some strategies have been extensively studied in randomised trials and other rigorous study designs (e.g. audit and feedback for physicians (Ivers et al. 2012), but a large number of studies focused on user experiences rather than outcomes, or used weaker study designs (e.g. before-after comparisons).

Quality improvement has (under various names) become part of healthcare practice. For instance, medication prescribing data or complication rates after surgical procedures may be collected and reported back to practitioners. Many hospitals are required to participate in accreditation procedures, which have a similar focus. Quality of care has been described as the "expected ability to achieve the highest possible net benefit according to the valuations of individuals and society" (Donabedian 1980, p. 22). Much research in this domain has focused on the development and use of measures for performance assessment, such as quality indicators (Box 2.9 provides an example). Short-cycle improvement (using the plan-do-check-act or PDCA-cycle) is a widely used approach to quality

improvement, in which specific methods and tools have been embedded (e.g. pareto-diagrams and fishbone-charts).

Box 2.9: Primary Cardiovascular Care and Health Outcomes (Kontopantelis et al. 2015)
In the UK, primary care was financially incentivised for better quality of care since 2004. Performance measures comprised of quality indicators, which were related to evidence-based clinical guidelines and based on data from computerised patient records. Data from 8647 practices in England were used to analyse performance in cardiovascular care. All-cause mortality and mortality from six cardiovascular conditions (diabetes, heart failure, hypertension, ischaemic heart disease, stroke and chronic kidney disease) were taken as outcomes. Data were aggregated in 32,482 neighbourhoods. Higher mortality was associated with greater area deprivation, urban location and higher proportion of a non-White population. There was little relationship between practice performance on quality indicators and all-cause or cause-specific mortality rates in the practice locality. Premature death seemed unrelated to the quality of cardiovascular primary care in neighbourhoods.

Patient safety was added to the political and research agenda in the 1990s. It focuses on the absence of 'incidents' in healthcare. Incidents have been defined as unintended events or circumstances that could have resulted, or did result, in unnecessary harm to a patient ('unnecessary' implies that it is potentially avoidable) (Runciman et al. 2009). A systematic review of studies estimated that a median 9.2% of hospitalised patients experienced at least one adverse event; if an adverse event was experienced, the total number was 11.2 on average; of all these events, about half were considered avoidable (De Vries et al. 2008). The mean number of safety incidents per 100 patient records in primary care was 12.6; a mean of 30.6% of incidents was associated with severe harm; a mean of 55.6% of incidents was considered preventable (Madden et al. 2018).

Since the 1980s, quality and safety management has been introduced in healthcare across the world. It has various schools, which all share focus on systems rather than individual performance, emphasise analysis the determinants of quality and safety problems, data-based performance feedback and the role of organisational culture and leadership in achieving improvements (Berwick 1989). The effectiveness of quality and safety management, and how to enhance, has been a topic of many studies (Dixon-Woods 2019). Box 2.10 presents strategies that were perceived to promising for improving patient safety in primary care (Gaal et al. 2011).

Box 2.10: Strategies for Improving Patient Safety in Primary Care (Gaal et al. 2011)

An international panel of 58 primary physicians and researchers from 8 countries assessed 38 specific strategies for improving patient safety in primary care regarding importance and use. The strategies concerned facilities in the practice, patient safety management, communication and collaboration, education on patient safety and generic conditions. High importance scores (80% or more agreed) were yielded for computerised medical record system, which is adequately kept; education on patient safety in the vocational training of GPs; and the availability of a clinical guideline on patient safety.

Knowledge transfer is another approach to improving healthcare, which is linked to evidence-based healthcare movement. It refers to the implementation of recommended practice into clinical and preventive care, thus closing gaps between evidence and practices (including stopping practices that are not, or no longer, evidence-based) (Grimshaw et al. 2012). Research on knowledge implementation in healthcare has been described as implementation science (Eccles and Mittman 2006). Implementation science is characterised by a focus on the outcomes of implementation strategies, and a key idea is that these should be tailored to target groups and settings (Grol and Wensing 2004). Barriers and facilitators for implementation need to be identified to facilitate such tailored implementation. Many frameworks, theories and models of implementation science are available to design and evaluate implementation strategies (Nilsen 2015). Box 2.11 provides an example. The transfer of scientific knowledge as products or services (e.g. new medication) to a commercial market can also contribute to the implementation into clinical and preventive care, but approval and reimbursement is not necessarily sufficient for actual adoption in healthcare practice.

Box 2.11: Performance After Stopping an Implementation Programme (Minchin et al. 2018)

The study by Minchin et al. (2018) refers to the pay-for-performance systems for implementation of (largely evidence-based) guidance in primary care. It examined what happened after stopping parts of the programme by removing specific quality indicators, an underexplored topic. Data from computerised patient records in 2,819 primary care practices (covering more than 20 million patients) were available for the years 2010–2017. Financial incentives were removed for six quality indicators in 2014. Interrupted time series analysis of patient record data showed that the removal was associated with immediate decline in performance scores, with highest decreases for indicators on counselling of patients. In contrast, there was little change in performance for six indicators that remained financially incentivised.

2.6 Conclusion and Perspectives

This chapter described a number of topics of health services research to give readers orientation of what it comprises. New themes will continue to emerge within and outside these fields (see also Section IV on emerging topics). In research on patient perspectives, we anticipate much attention for the role of modern information technology to deliver various interventions to influence patients' behaviours and experiences in relation to healthcare. An emerging topic in research on healthcare providers is the introduction and possible replacement of humans by technologies for healthcare delivery, such as robotic devices in nursing and applications of artificial intelligence. Regarding organisation of care, research has emerged that focuses on the collaboration of health and social care. The impact of a climate change on healthcare is another important topic for future HSR (Chap. 24). Research designs, methods and concepts for HSR have developed and will continue to develop (Chap. 3). For instance, the specification of study protocols and the use of reporting guidelines have become standards in HSR. Also, implementation science has emerged as a subfield within HSR (and within clinical research), which provided new perspectives and conceptual frameworks (Wensing et al. 2020).

Recommended Readings

Orientation on the field of health services research is provided on the websites of professional organisations, such as AcademyHealth (https://academyhealth.org/), DNVF (https://www.dnvf.de/) and HSRUK (https://hsruk.org/)

Journals in particular provide further orientation to the field, such as *BMC Health Services Research*, *Journal of Health Services Research and Policy* and *Frontiers in Health Services*.

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Part II
Principles of Health Services Research

Chapter 3
Use of Theories in Health Services Research

Michel Wensing and Charlotte Ullrich

Abstract A scientific theory is a set of ideas that coherently describes selected phenomena in the world. Theories in health services research align with empirical research data and aim at providing interpretations and explanations of findings. Theory can be practically used in research to formulate research questions, derive measures, develop interventions and predict their outcomes. The use of theories also helps to make assumptions of a study explicit. In health services research, the explicit use of theory in studies is recommended but not common practice. Different types of theory can be described in terms of scope, aggregation level, aims, format, content and empirical basis. Given the interdisciplinary character and scope of health services research, considering a range of theories is often a fruitful approach.

3.1 Introduction

In colloquial use, 'theory' is often contrasted to 'practice' as an imagined or hypothetical world versus reality. In science, theory refers to a set of ideas that coherently describes phenomena in the world with the aim of providing interpretations and explanations of the phenomena at hand as well as generalisable understanding. In contrast to nonscientific theories, which are often implicit and unstructured ideas, scientific theories are logically coherent and informed by systematic empirical research. Thus, theory can be described as "an organized,

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heuristic coherent, and systematic articulation of a set of statements related to significant questions that are communicated in a meaningful whole […] for the purpose of providing a generalisable form of understanding" (Iceberg 2006). In health services research (HSR), theory may relate to many different questions, such as 'how to support patients?' 'how to improve self-management of health?' and 'what contributes to the retention of nurses in healthcare?'

The explicit use of theory can strengthen empirical research in various ways. It can guide the choice of relevant topics for research, the selection of measures and the development of interventions. It can also provide interpretations for findings. For instance, theory on professional bureaucracies can help us understand how hospitals function and point to the power dynamics of physicians and managers, which influence the uptake of innovations. Most HSR is focused on providing knowledge on concrete problems or challenges in healthcare. Beyond direct relevance for a particular study, HSR as a scientific field could accumulate knowledge more efficiently (e.g. comprise fewer noneffective interventions and rejected hypotheses) if it were systematically guided by theory. This helps reduce the number of studies that unnecessarily replicate previous research and point to promising new perspectives. Nevertheless, there are few examples of systematic, stepwise knowledge accumulation over a period of time within HSR.

This chapter will first provide an overview of the types of theories that may be relevant to HSR (3.2), then elaborate on various ways to use theories in HSR (3.3) and the choice of theory in HSR (3.4). The chapter ends with conclusions and perspectives (3.5). We do not promote a particular theory because it is often fruitful to consider a range of theories. While we will distinguish between different types of theories in the next section, we use the term 'theory' to refer to all these types broadly (e.g. including models and frameworks).

3.2 Types of Theories

In science, the available theories differ in many ways from each other. They can be distinguished on the basis of features such as scope, level of aggregation, content, aims, format and empirical basis (see Table 3.1). Understanding these features helps characterise a specific theory and position it in relation to other theories.

Table 3.1 Features of theories

Features	Available options
Scope	Scientific paradigm, grand theory, mid-range theory, situation-specific theory
Aggregation level	Macro (e.g. social structures, institutions), meso (e.g. populations, organisations), micro (e.g. individuals, social interactions)
Content	Classification, causal mechanisms, (sensitising) concepts
Aims	Aiming at prediction and testability, aiming at providing interpretation
Format	Conceptual framework, models, constructs, theories (in the narrow sense)
Empirical basis	Untested, some confirmation, substantial confirmation

Theories can be distinguished in terms of scope or generalisability (Iceberg 2006; Davidoff et al. 2015). A *scientific paradigm* is a set of broad assumptions that are applied to the world at large (e.g. evolutionism to explain dynamics of life). A *grand theory* is a broad theory that encompasses a wide range of phenomena across various populations, settings and time (e.g. social systems theory). A *situation-specific theory* has the narrowest range of interest and focuses on phenomena in a narrowly defined population and setting (e.g. an intervention theory). Many of the theories in HSR can be described as *mid-range theories*, which are between grand theories and situation-specific theories (e.g. a theory to explain individual health utilisation). Mid-range theories go beyond a specific setting and population but do not apply to all domains of reality (e.g. they do not go beyond healthcare settings or even beyond a specific healthcare sector). They integrate the findings of empirical research across settings and populations as well as concepts from grand theory.

Following the social sciences, three levels of aggregation can be distinguished in HSR. Macro-level theories relate to large-scale social processes, structures and systems (e.g. the healthcare system). As an example, social systems theory is a grand theory that largely applies to this macro-level, e.g. to research the relation of healthcare systems to other political or economic systems. Meso-level theories relate to populations, communities or organisations, such as hospitals (e.g. theory on professional organisations). Micro-level theories relate to individuals and their interactions, for instance, patients and healthcare providers (e.g. social network theory on social support). In HSR, the linkages between the different aggregation levels are often of interest. For instance, studies may explore how interactions at micro-level are shaped by the healthcare organisation at the meso-level and healthcare system at the macro-level.

The content of theories varies. Some theories are *classifications* (e.g. types of interventions or barriers for change), while other theories provide concepts that specify *causal mechanisms*. Causality implies correlation and time order (the cause precedes the consequence), but it is challenging to examine empirically and thus fundamentally a theoretical construct (Moser et al. 2020). Like in many other scientific fields, causes are rarely deterministic for outcomes in HSR. This means that repeated studies of specific phenomena (e.g. effects of a specific intervention) typically show a variation of findings, of which the average may be the closest to the truth. Causes (e.g. interventions) in HSR tend to have probabilistic impacts, which may be nonlinear and influenced by contextual factors. For instance, counselling of patients does not consistently improve self-management, and it is difficult to predict which patients will benefit.

In the natural sciences, scientific theories are supposed to be explicit, logically coherent, testable and predictive. This means that they define phenomena in a structured way, which facilitates quantitative analyses. This ideal is also present in large parts of the behavioural and social sciences. However, in some cases, theory aims to

provide interpretations of phenomena, but not necessarily explanations and predictions. Sensitizing concepts match with this approach. Also, the emphasis on empirical testing varies across scientific disciplines. Experiments in controlled laboratory conditions are standard practice in some fields, but case studies or illustrative examples are common in others. In HSR, all these approaches can be found. Overall, the field leans towards explanation, prediction and hypothesis testing, mostly in field research settings rather than laboratory experiments.

Theories can also be distinguished by format. Conceptual frameworks and models are concepts that are closely related to theories (Nilsen 2015). A *framework* provides an overview of descriptive categories or even of the relations between them, which are presumed to account for a phenomenon. Frameworks may be linked to one of the more formal theories, but these linkages are often loose and implicit. They are widely used in HSR, for instance, to plan, evaluate and explain the implementation of innovations (Strifler et al. 2020). *Models* specify theories in a mathematical format, which facilitates testing and prediction. These are rare in HSR but may emerge in the coming area of big data and artificial intelligence. Some authors use a different definition and consider models to be descriptive theories for narrowly defined phenomena (Nilsen 2015). *Theories* in a narrow sense are narrative accounts of phenomena. Finally, theories include *constructs*, which can be understood as 'mini-theories' that refer to specific factors, processes or states in the world (e.g. health-related quality of life, professional autonomy, organisational readiness for change, health literacy). In HSR, constructs rather than theories are more frequently applied than full theories. In the context of empirical research, constructs need to be operationalised into variables and (validated) measures in order to be useful (see also Chap. 11 on validation of measures). Alternatively, some provide 'sensitising concepts', which need to be filled with content in their application in research.

Last but not least, theories differ with respect to the degree of empirical testing. Some scientific theories are largely untested ideas, albeit reasonably explicit and logically coherent (otherwise they would not be scientific). Ideally, these theories will be tested in subsequent empirical research. Other theories have been extensively tested in a range of domains and have received substantial confirmation. An example is the theory of planned behaviour, which explains individual behavioural intentions on the basis of attitudes, social norms and self-efficacy. A study found that the theory of planned behaviour (operationalised in a questionnaire) explained up to 42% of behavioural intentions in studies of clinicians (Eccles et al. 2012). Most theories fall on the continuum between these two extreme options: They have some confirmation in empirical research, but the evidence is limited, conflicting or only partly generalisable.

3.3 Use of Theories in Research

Research does not happen in a vacuum but is shaped by the assumptions and interests of the researchers and the research field. Referring to theories facilitates explication of these assumptions and interests. More practically, theories help develop relevant research questions, derive measures, develop interventions and predict their outcome, analyse data and facilitate interpretation and explanations. Ideally, the choice and operationalisation of theory for use in a study is a careful process, which requires a substantial amount of time before data can be collected. Given the applied nature of HSR, however, this process is often short and pragmatic. Occasionally, theory-guided secondary analysis of collected data can add to the use of theory, for instance, in the context of a doctoral thesis.

Theories can be used in HSR in various ways. Theory may be used to provide interpretations that complement descriptive and data-driven explorations. This use of theory tends to identify a range of factors and processes, while their relative importance or impact remains to be examined in further studies. This type of research is often descriptive, usually by categorising items within a theoretical framework. It may also be more analytical, using theories to interpret data in relation to associations or mechanisms that are specified by the theories. Ideally, the findings of research stimulate the refinement of theories. This requires that theories be used to 'theorise' about the data and initial results of data analysis (Kislov et al. 2019). This 'theorising' approach requires extensive knowledge of theories, which not all health services researchers might have. As a consequence, theories tend to become reified rather than continuously refined and improved on the basis of research findings (see Box 3.1 for an example).

Box 3.1: Reducing Hospital-Induced Infections (Dixon-Woods et al. 2012)

A study by Dixon-Woods et al. (2012) used ethnographic methods (e.g. 122 interviews and 855 h of observation in intensive care units) to explore practices around performance measurement in England. Led by a social constructivist approach, it suggested that differences in reported infection rates may reflect underlying social practices in data collection and reporting and variations in clinical practice. These practices were related to inclusion and exclusion criteria for the programme, the data collection systems they established, practices in sending blood samples for analysis, microbiological support and laboratory techniques and procedures for collecting and compiling data on possible infections.

Table 3.2 Terms related to causal mechanisms in Health Research

Mechanism	Process or event through which an intervention operates to affect desired intervention outcomes
Precondition	Factor that is necessary in order for an intervention mechanism to be activated
Intervention	Method used to achieve change in behaviours or processes in healthcare
Determinant	Also referred to as 'barrier' or 'facilitator', a factor that enables or hinders the intervention from eliciting the desired effect
Mediator	Intervening variable that may account for the relationship between the intervention and the outcome
Moderator	Factor that increases or decreases the level of influence of an intervention
Proximal outcome	The product of the intervention that is realised because of its specific mechanism of action; the most immediate, observable outcome in the causal pathway
Distal outcome	Outcome that the intervention processes is ultimately intended to achieve; not the most immediate outcome in the causal pathway

Adapted version of Lewis et al. (2020)
The original table is focused on implementation strategies, which is adapted to generalise to interventions in healthcare

Another strategy for the use of theory comprises the identification of constructs of interest, which are then measured in a study (e.g. using questionnaires), followed by analysis of hypotheses that relate to these constructs. An example is a study in diabetes care, which measured aspects of organisational culture and team climate and confirmed associations with aspects of diabetes care (Bosch et al. 2008). This type of theory use is usually related to the exploration of causal mechanisms. A distinction can be made between moderators and mediators of the effects of interventions or observed factors. *Mediators* are intermediate steps in a causal chain (e.g. training results in better skills, which then improves behaviours; skill is the intermediate factor). *Moderators* are not part of the causal chain but influence the causal process (e.g. the training may be most effective in young people; thus, age is a moderating factor). In practice, HSR may examine a range of theory-based factors, only a few of which usually show effects on relevant outcomes with overall limited predictive power. Box 3.2 provides an example and Table 3.2 defines a number of key terms in this context.

Box 3.2: Psychological Determinants of Clinical Behaviours (Presseau et al. 2014)
This study postulated that clinical behaviours are determined by impulsive (automatic) and reflective (motivational) processes. These may operate in parallel ('dual processes') or sequentially (first automatic, later reflective). Questionnaires were sent to general practitioners and nurses in 99 UK primary care practices, measuring reflective (intention, action planning and coping planning) and impulsive (automaticity) predictors for six

guideline-recommended behaviours (e.g. blood pressure prescribing and providing weight advice). The dual process model was supported for three of six behaviours, while a sequential reflective process was supported for four behaviours. The percentage of variability in the clinical behaviours, which was explained by these psychological factors, varied from 14% to 28% (except for feet examination, where it was 58%).

3.4 Choice of Theories

Many theories may be used in HSR. Table 3.3 presents a number of grand theories that may be relevant for HSR. The choice of theory is guided by the research objective. For instance, the behaviour of individual clinicians may be explained by psychological behaviour theory, the collaboration between health professionals by sociological theory and the health policy by theory from political science. In practice, the background of the research team (e.g. psychology or economics) heavily influences the choice of theory. Many researchers have a strong preference for a specific theory, and they may choose research topics to which it can be applied. Furthermore, there seem to be discipline-specific theoretical preferences as well as fashions in the choice of theories within disciplines. An example is the increased interest in organisational culture and organisational learning in healthcare institutions in HSR in some parts of the world in the years 2000–2010. In addition, theoretical preferences within a field might differ not only across time but also from country to country.

From a scientific perspective, criteria for the choice of scientific theory within HSR include:

- Clarity and logic: Is the theory understandable and inherently plausible?
- Validity: Is the theory grounded in empirical research, which is generalisable to the population and setting of interest?
- Parsimoniousness: Is the theory as simple as possible?
- Informativeness: Does the theory cover different phenomena, populations and settings?
- Feasibility: Can the theory easily be applied, e.g. regarding measurement and training of researchers?

In HSR, there have been several efforts to provide an overview or synthesis of theoretical approaches. Advocating the proactive use of theoretical approaches, these attempts aim at making theory more easily accessible and quickly applicable for researchers. Some studies have focused on the choice of theory in research practice. An empirical study in implementation researchers in health (Birken et al. 2017)

Table 3.3 Grand theories used in Health Services Research

Grand theories	Disciplines of origin	Central idea	Possible areas of application in HSR
Cognitive theory	Psychology	Decision-making is determined by individual cognitive processes	Learning by health professionals; design of computerised decision support systems
Behaviour change theory	Psychology	Individual cognitions determine (change of) behaviour	Counselling on health-related lifestyles, change of health professionals' behaviours
Social-constructivist theory	Anthropology, sociology	Ideas and behaviours are influenced by social processes	Collaboration between health professionals; patients' behaviours in interactions with health professionals
Social networks theory	Sociology	Connections between individuals' influence and cognitions and behaviours	Teamwork of health professionals; spread of innovations; patient referral between providers
Social exchange theory	Sociology	Repeated exchange determines behaviours	Coordination of healthcare; management of healthcare institutions
Rational choice theory	Economics, sociology	Individual benefits and risks determine behaviours of populations	Reimbursement of healthcare providers; job satisfaction of health professionals
Organisation theory	Organisational science	Resources, structures and processes in organisations influence outcomes	Performance of healthcare organisations; implementation of innovations
Social systems theory	Sociology, organisational science	Social structure, processes and outcomes are closely associated	Performance of healthcare institutions; quality and safety management
Social conflict theory	Political science	Power determines processes and outcomes in systems	Health policy decision-making; collaboration between health professions

showed that they used over 100 different theories from various scientific disciplines, mainly to identify determinants, inform data collection, enhance conceptual clarity and guide intervention planning. The criteria used by most respondents to select theory included: analytic level, logical consistency, plausibility, empirical support and description of a change process. Another study in researchers and practitioners showed that barriers to the selection of theory included inconsistent terminology, poor fit with the implementation context and limited knowledge about and training in existing theories. Facilitators to the selection of theory included the importance of clear and concise language and evidence that the theory was applied in a relevant health setting or context (Strifler et al. 2020).

While in some disciplines recombining theoretical approaches are seen as an integral part of each research project, within health sciences, it is often emphasised that a pragmatic approach to theories is needed to rapidly provide results that are relevant for application. Therefore, available consolidated integrations of theories are taken off the shelf and used in a research project. Different attempts have been undertaken to consolidate theoretical approaches concerning a certain research field. The use of ontologies (standardised terminology) for theoretical constructs has been proposed to overcome the inconsistent definitions in the literature (Michie and Johnston 2017; Leeman et al. 2019). While some theories have been successfully summarised in an ontology (e.g. behaviour change psychology), it remains to be seen whether this is possible and sensible for all research topics and types of theories that are relevant to HSR. Another example is the larger number of integrative frameworks for implementation science to categorise factors associated with the uptake of innovations in healthcare practice (Esmail et al. 2020).

3.5 Conclusion and Perspective

In HSR research, the explicit and critical use of theory in studies is not common practice. Although some academics are sceptical (Oxman et al. 2005), many have argued for more and better use of theory in health research (Alderson 1998). Given the applied character of HSR, theory may be used pragmatically as an instrument in research, particularly to guide the choice of measures and provide interpretations of findings. A more theory-oriented HSR is needed to accumulate and systematise research more efficiently as a basis to develop the field. In the coming area of big data and advanced data analysis, an increasing number of theories may be mathematical models. The use of theory in research has benefits, but also risks. For instance, the theory may be too vague to be of practical use, or it may be simply incorrect for the topic at hand. Also, it is often time-consuming to identify and understand relevant theories. Given the limited predictive power of most theories in HSR, it seems wise to keep an open mind and consider a range of theories as well as observations of healthcare practice, rather than take a narrow approach from the outset.

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Chapter 4
Scientific Integrity in Health Services Research

Charlotte Ullrich and Michel Wensing

Abstract Scientific integrity or research integrity builds the backbone of good research practice. In health services research (HSR), there is no binding and shared set of rules for scientific integrity, but many principles and guidelines for science in general and health research more specially apply to this field. Surveys among researchers suggest that there is room for improving the integrity of HSR. This chapter addresses research integrity as an immanent part of all activities in research, from choosing an objective to presenting results. Central aspects that are relevant to HSR concern data protection and ethical approval, conflicts of interests, integrity of teamwork and reporting research.

4.1 Introduction

Scientific integrity or research integrity (the terms are often used interchangeably) builds the backbone of good research. It refers to values, norms and principles that guide and regulate scientific practice. When scientific integrity is compromised, the quality and usefulness of scientific results are also compromised. General legal regulations (e.g. concerning data protection) apply to research, but scientific integrity is mainly safeguarded by voluntary commitments. Although it is currently under pressure, the academic freedom to choose topics and methods of scientific research is protected in most nations (UN 1966). In most European countries, it is seen as a core principle of democratic societies (EU 2020). The freedom of research comes with the responsibility for trustworthiness (DFG 2019).

While there is no universal set of rules that applies across disciplines, several core values can be identified. Often, the four Mertonian norms (sometimes acronymised as CUDOS) with their principles of (a) communism (also referred to as

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communalism), (b) universalism, (c) disinterestedness and (d) organised scepticism serve as a central reference point (Merton 1973). In the early 1940s, sociologist Robert K. Merton described the ethos of modern science as regulated by these four idealised imperatives: Research findings are *'communal'*. This means they are common property to the whole scientific community; an important aspect as scientific progress relies on sharing results publicly. Scientific claims must aim to be *'universal'* and exclusively based on validity, independent of status or personal attributes of researchers. Research should be *'disinterested'*, that is, motivated by expanding knowledge rather than personal or institutional benefit. All research claims have to be subject to *'organised scepticism'*, assessing scientific contribution and rigour before being accepted. In more practical terms, the consequences are that researchers are committed to work according to state of the art ('lege artis'), meaning in accordance with standard practices, document results, critically scrutinise all results, maintain strict honesty regarding contributions of partners and competitors and avoid and prevent scientific misconduct. The responsibility to ensure research integrity through individual attitudes and behaviours as well as organisational procedures and regulations lies in research communities, research teams and individual researchers.

In a scientific community, academic consensus is achieved through scholarly debate, e.g. at conferences, during the publication process or in defining research standards. Academic societies, funding bodies and publishers often shape and provide guidelines regarding what good research practice entails. However, these guidelines only offer general orientation; within each research project, they must be applied and weighed on a case-by-case basis. As an interdisciplinary field, health services research (HSR) is informed by ideas about research integrity from various scientific fields. Biomedical research is the main point of reference. Derived from the experience with human experimentation under National Socialism as judged in the Nuremberg Trials and formulated in the Declaration of Helsinki, a set of rules for medical research was established internationally (WMA 2013). Based on the key principles of self-determination, beneficence, non-harm and justice, the ethical evaluation of research involving human subjects balances the general gain of knowledge against the individual physical integrity of the research participants in biomedical research (Beauchamp and Childress 2019). Although direct physical or mental harm from research activities is rarely an issue in HSR, it must consider its broader impact on people's lives and society. For instance, the application of questionnaires or interventions by researchers can imply risks of harm, such as psychological distress and burden for participants. Responsible research must therefore consider the balance between effort (e.g. time and money), risks and benefits of the planned research.

In HSR there is no binding and shared set of rules for scientific integrity, but many principles and guidelines for health research generally apply in this field. This chapter addresses research integrity as an immanent part of all activities in research, from choosing an objective to presenting results. It provides an overview over central aspects that are relevant to HSR, outlining data protection and ethical approval, mapping conflicts of interests and describing established measures to ensure research integrity (Box 4.1).

Box 4.1: Examples of Guidance for Scientific Integrity in HSR
- General values: Communism, universalism, disinterestedness, organised scepticism
- Legal and professional regulations: *Good Clinical Practice* guidance and related laws, data protection laws, professional laws, ethical approval requirements
- Specific mechanisms: Reporting guidelines, disclosure of conflict of interest, statement of authorship

4.2 Data Protection and Data Management

In HSR, data is typically obtained from patients, healthcare providers, experts or other stakeholders. All data containing personally identifiable information (personal data) must be protected according to prevailing laws and regulations. Within the European Union, the *General Data Protection Regulation* (GDPR 2016) regulates the collection and processing of personal data from individuals living in the EU (even beyond research GDPR 2016). Mandatory safeguards for processing personal data for research include informed consent, technical and organisational procedures, data minimisation and pseudonymisation. Particularly with regard to patients, the vulnerability of participants needs to be considered from the planning stage onwards. Health data are data that need particularly strong protection. According to the GDPR, they fall into the same category as, for example, data on ethnic origin, sexual orientation and religious conviction. In general, only information and data that is needed and will be used within the research project should be gathered (data minimisation). All data must then be stored as safely and securely as possible, ensuring data protection and minimising data sharing. Data should not be kept longer than necessary. Legal retention periods may apply, and after such periods elapse, the information must typically be destroyed using approved methods.

Information that could allow subjects to be identified needs to be removed from the data as soon as possible. This holds true not only for direct identifiers (e.g. names, address) but also for indirect identifiers (e.g. illness) that could identify a person when used in combination with other information within a dataset. When using data that are rich in context, e.g. in qualitative research, special measures, such as masking or omission, must be taken to prevent identifiability. When fully anonymised, the data no longer count as personal data.

Consent of the research participants must be voluntary, informed and specific. In HSR, consent forms are typically used when general information is being given and consent is being asked for (a) taking part in the research (including purpose and type of the research, voluntary nature and procedures for withdrawal, risks and benefits) and (b) the use of collected data (including storage, maintaining confidentiality, archiving, reuse). Today, written forms are used to document explicit consent in most studies. In some cases, an audio-recorded agreement might be used. Explicit

informed consent may not be required for most surveys, as questionnaires are completed and returned anonymously, and this is interpreted as consent to participate. Also, no informed consent is required in studies that are based on anonymised databases.

4.3 Ethical Approval

Obtaining external *ethical approval* before conducting a study is a common requirement for studies in the field of HSR, but there is some debate about how to conduct appropriate ethical reviews (Goldstein et al. 2018; Schrag 2011). In order to get ethical approval, the planned research must be described in some detail, with specific attention to the informed consent procedures, measurements and interventions for participants. In practice, ethical approval is often a prerequisite for funding of studies and publications in journals. Medical research ethic committees oversee clinical research to ensure accordance with professional ethical principles (e.g. Helsinki Declaration), laws and regulations. Specific regulations for studies of medical interventions (e.g. based on Good Clinical Practice) are rarely applied to studies in HSR, although the scope of what clinical trials are has broadened substantially over time and would include many studies of interventions in HSR. Even if Good Clinical Practice guidance and related laws do strictly not apply to a study, they outline many characteristics that can strengthen its scientific integrity. Depending on the country, institutional context and research design, ethical approval for HSR may be required from ethic committees located at professional organisations, scientific associations, universities or university departments. The aim of ethical review is to independently review, assess and monitor research involving humans with respect to safeguarding their rights, safety and wellbeing according to national and international laws, regulations and professional codes.

Ethical approval must be obtained before research participants are approached, data collection begins and interventions are applied. Therefore, sufficient time must be planned for the preparation of the documents and the approval process. Within larger collaborative research projects, approval may be needed from different national or international ethical review boards. Researchers should also monitor and document the process of conducting research because changes in the planned activities may have ethical implications. The exact amount of time required for ethical approval differs widely between jurisdictions: from several weeks to a year or longer (Eichler et al. 2019; White et al. 2016). Regardless of ethical approval, researchers remain ethically responsible for their research activities. In other words, the ethical responsibility cannot be delegated, but rather remains with the researchers at all times. This may mean that specific procedures may be applied, although the ethics committee does not strictly require them (e.g. monitoring of adverse effects of an intervention, although the intervention is not qualified as medical) or that specific

practices are avoided, e.g. questionnaires on sensitive topics, even though the ethics committee would provide approval.

4.4 Conflict of Interest and Questionable Research Practices

In scientific research, many individuals and organisations have multiple interests – e.g. scientific pursuit, improving societal problems, enhancing academic career and maintaining financial livelihood. *Conflict of interest* describes a situation in which a person is subject to two (or more) coexisting interests that are in direct conflict with each other. Following the widely used concept by Thompson (1993), primary and secondary interest can be distinguished: "A conflict of interest is a set of conditions in which professional judgment concerning a primary interest (such as a patient's welfare or the validity of research) tends to be unduly influenced by a secondary interest (such as financial gain)" (ibid.). Thus, the conflict of interest begins with the risk of influence, not only when such undue influence has taken place. It is now a common requirement that conflicts of interest are disclosed in statements that are included in research reports. Beyond disclosure, researchers need to reflect on their conflicts of interests and integrate these reflections in their decisions on whether and how to study specific topics.

Conflicts of interest can lead to questionable practices in research. Increasingly, there are empirical data on the occurrence of breaches of research integrity. Research has shown, for example, that research misconduct and questionable research practices come in many forms and happen more often than assumed (Aubert Bonn and Pinxten 2019). A study focused on HSR found a median of six questionable research practices in publications of HSR from the Netherlands, such as conclusions that did not adequately reflect the results and poor documentation of conflicting evidence (Gerrits et al. 2019). The (perceived) pressure to create societal impact was found to be associated with questionable research practices in the reporting of messages and conclusions in publications on HSR (Gerrits et al. 2020; see Box 4.2).

Box 4.2: Questionable Research Practices in Science

A survey on the prevalence of responsible and questionable research practices among academic researchers in the Netherlands in 2020 across all scientific disciplines reported (Gopalakrishna et al. 2022) that about 8% of the 6831 respondents indicated committing misconduct (4.3% fabrication, 4.2% falsification) and over 50% researches indicated frequently engaging in at least one questionable research practice (17.5%), including non-publishing of valid negative studies (17%), underplaying a study's flaws and limitations and insufficient supervision and mentoring (15%). Scientific norm subscription and perceived likelihood of detection were associated with less misconduct. Publication pressure increased the odds of frequent questionable research practice. Concerning the prevalence of responsible research practices, most respondents declared that they avoided plagiarism, while only a minority preregistered study. The study suggests that responsible research practices are affected negatively by publication pressure and might be motivated by mentoring, scientific norm subscription and funding pressure.

A key area of questionable research practices is authorship. Authorship of academic publications serves as a core measure of research productivity and influences academic advancement. While disciplinary cultures and conventions differ, substantial intellectual contribution and accountability are premises for legitimate authorship in academia. Studies show, however, that in practice authorship credit is also influenced by hierarchical power relations (Macfarlane 2017). The so-called honorary or ghost authorship exists, with estimates ranging from 25% to 50% of publications within medicine (Basford et al. 2014). Unwarranted authorships, granted irrespective of input, include authorships as a favour or tribute to superiors (such as institutional leads) to meet strategic goals or as an attempt to increase the likelihood of publication. A study on 201 articles submitted to a general medical journal found that more than two-thirds of 919 corresponding authors disagreed with their co-authors regarding the contributions of each author (Ilakovac et al. 2007).

In HSR, different interests need to be balanced. As applied research, HSR often involves different stakeholders, such as health policy-makers, health insurers, healthcare providers and health industry. Conflicts of interests may especially occur if researchers are linked to specific stakeholders (e.g. a health profession) and conduct research on topics that are central to those stakeholders. Research in HSR is largely based on projects with external funding. A research agenda set by political stakeholders does not always reflect scientific priorities and may lead to neglect of specific topics. Maintaining academic independence, e.g. in choosing objectives and research designs, while depending not only on funding but also on cooperation with stakeholders in healthcare (e.g. for field accesses), poses challenges. For instance, stakeholders may not be interested in rigorously designed evaluation studies as these may show that a preferred intervention has little effect. In addition, in HSR, most studies are conducted by teams of researchers who might have different and conflicting interests, e.g. concerning academic pursuit.

4.5 Reporting and Publishing Research

The output of science is multifold and includes, for instance, technologies, training of individuals and advice to decision-makers. In health research, there is a great deal of emphasis on scientific publications as an important medium of academic discourse and the main vehicle for reporting, discussing and challenging research. Scientific publications are characterised by peer review and indexing. Review by peers (colleagues in the field) usually leads to revisions before publication, which helps maintain and optimise the quality of research. Indexing implies that research publications can be found, for instance, in databases with search facilities, such as PubMed®. Besides journal articles (the dominant type of publication in HSR), books and reports can be considered scientific publications if they have been subject to peer review and are trackable in a public database.

Planning and writing scientific publications are crucial components of many research projects. The identification and writing of relevant publications are precious

skills that require training, talent and extensive reading of the scientific literature. As most research publications are targeted at scientific journals, researchers should familiarise themselves with the main journals in their field. However, the purpose should not be to write as many publications as possible, for instance, by 'salami-slicing' the collected data into many papers, but to write sound reports that reach the target audience and convey relevant findings. Some studies may be better combined in a comprehensive report than spread over multiple papers in different scientific journals.

Preprint servers (e.g. medRxiv, F1000research), which have become more popular since the COVID-19 pandemic in 2020, provide the opportunity to peer review while the manuscript is directly available online. On the one hand, this raises the issue of whether such manuscripts can carry the label 'scientific'. On the other hand, preprint servers increase the speed of the publication process, and they may help address the 'publication bias': the problem that a substantial number of health-related studies are never published, typically those with unspectacular findings.

In health research, there is a wide and diverse range of scientific journals. Nearly all journals have an online version, and some are 'open access', which means they are freely accessible on the Internet. At the same time, multiple online 'predatory journals' that fail to have adequate peer review procedures also exist (Grudniewicz et al. 2019). The journal impact factor indicates the number of citations of publications in a journal, but it would be inappropriate to focus on this factor exclusively when choosing a journal for the submission of a manuscript. The use of impact factors for assessment of research individuals, teams or institutions has been criticised as fundamentally flawed (Seglen 1997). Among the problems is the large variation of values between different research fields (e.g. high in neuroscience, much lower in surgery) and the skewed distribution of citations within a journal (few publications attract many citations). As a response, the DORA-movement of research institutions and publishers (www.sfdora.org) has taken initiatives to reduce the emphasis on impact factors, such as the presentation of a range of indices rather than the impact factor alone (e.g. number of downloads from the journal). Also, assessment of research should not solely be based on the number of scientific publications but on a wider range of indicators that reflect quality and impact of the research.

The (traditional) publication process involves a manuscript being critically examined by colleagues ('peers'), usually revised by the authors (possibly in multiple rounds) and finally published. Critical examination of research during and after peer review requires a complete report on the study and, ideally, access to the data. Analyses of the health literature have repeatedly shown that many published research papers are incomplete (Mc Cord et al. 2022). As a response, reporting guidelines have been developed and promoted by many major health journals. Examples are CONSORT for randomised trials, PRISMA for systematic reviews and COREQ for qualitative research (see www.equator-network.org for these and other reporting guidelines). These guidelines list the items that should be included in research reports. While designed for reporting, they are often also used to inform the design and conduct of studies.

Registration and publication of a study protocol is generally recommended and obligatory for some study designs (e.g., randomised trials) in many health-related journals. This makes transparent what aspects were included in a study later, after its conception and design. Post-hoc measurements and analyses are often associated with increased risk of bias, which means that they need to be interpreted carefully. In practice, there is a great deal of overlap between the drafting of the study protocol, registration in a recognised database, application for ethics approval and use of reporting guidelines (Box 4.3).

Box 4.3: Open Science
Open science is a movement to 'open up' science by accessibly sharing knowledge, including data, publications and software. It compromises practices such as open access publications, open review (review with disclosure of reviewer names) and open data (making data available for use by other scientists). Many public research funders have promoted aspects of open science or made these obligatory (e.g. DFG in Germany). The proponents believe that open science is consistent with public funding and that it enhances the quality and integrity of science. Critics argue that it is not compatible with cultures in some parts of the world and that it may not be inclusive for some academics. In addition, parties with commercial or other nonscientific interests (e.g. publishers of journals) may resist open science.

4.6 Mentoring and Authorship in Research Teams

In HSR, most studies are conducted by teams of researchers. These typically involve one or two early career researchers, who may be doctoral students or postdocs; one or more mentors/supervisors, who may be more and less actively involved in the research; and others, such as methodological experts, study nurses and students in paid or nonpaid roles. This constellation implies that teamwork is of crucial importance. Two important aspects of the integrity of teamwork in research teams concern mentoring and authorship.

Mentoring refers to guidance and facilitation of the professional development of team members, typically of less experienced team members. Particularly doctoral and other students are entitled to receive mentoring; it can be seen as part of the compensation for their contributions. This implies that mentors should be easily accessible for mentees and have regular meetings with them. In practice, many mentors are project leaders, supervisors of doctoral theses and/or institutional heads. Mentors should be aware that their mentees are dependent on them for their jobs and careers and regularly reflect on the integrity of their approach. In addition, specific strategies can be used to prevent or manage conflicts between mentoring and other roles. These include the involvement of at least two (senior) mentors (e.g. as supervisors of a doctoral thesis) and the appointment of an independent advisor or

ombudsperson who is not member of the research team. Some research institutes have made these strategies obligatory for doctoral students.

Within research teams, authorship on scientific publications is a sensitive topic because it influences careers and funding chances. All authors are expected to contribute substantially to the research and provide substantive comments to the manuscript in order to qualify as author. Many journals demand a statement that specifies the contribution of every author. The International Committee of Medical Journal Editors (ICMJE) issued a widely used guideline (the 'Vancouver Rules') that defines the criteria for authorship credit (Box 4.4). The Contribute Role Taxonomy (CRediT) is a tool to determine authors' contributions to a specific paper (Allen et al. 2019). In practice, it is difficult for scientific journals, research funders or others to check the legitimacy of authorship. It is therefore the primary responsibility of the research team, particularly the principal investigator, to assure legitimate authorship on publications.

Box 4.4: Criteria for Authorship (ICMJE)

- Substantial contributions to the conception or design of the work; or the acquisition, analysis or interpretation of data for the work
- Drafting the work or revising it critically for important intellectual content
- Final approval of the version to be published
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved

In HSR, multi-authorship is common. While in some disciplines, authors are often listed in alphabetical order, in HSR authors are usually listed by their relative contribution. The author listed first is usually the person who has made the most significant contribution to the publication in terms of designing the study, literature search, acquiring and analysing data and writing the manuscript. The status of the first author is reflected in their visibility, not least because of citation conventions. The author listed last is usually the supervisor or principal investigator of a research project. In HSR, the first or last author may also be corresponding authors and the primary contact for inquiries from journal editors and readers. Beside their genuine and identifiable contribution, all authors are expected to agree on the final version of the paper to be published and share responsibility for its publication.

Due to the different interests and the potential impact of authorship, listing authors may lead to conflicts. For instance, the principal investigator may want to be first author on a manuscript, even though a junior researcher did most of the intellectual and practical work. Some team members may want to involve individuals as co-authors for strategic or relational purposes even though they do not qualify as authors. As a general rule and given the dependent position of early career researchers, the principal investigator has the responsibility of deciding authorship according to scientific standards in such cases. Nevertheless, it is desirable that all potential

authors can openly express their views in the research team and be able to report misconduct to trusted persons in their institutions. Heads of departments and research groups should engender and incentivise a culture that facilitates these practices of scientific integrity.

4.7 Conclusion and Perspective

Research integrity is a central prerequisite in scientific research that influences all of its components. While there are regulations and recommendations for enhancing research integrity in place, the responsibility of individual researchers and research teams remains essential. As a consequence of several high-profile cases of data fabrication and fraud in science, the awareness of research integrity has grown in recent years. Initiatives such as open science and the DORA-movement have started to address the system-related incentives that enhance questionable practices.

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Chapter 5
Presentation of Quantitative Research Findings

Jan Koetsenruijter and Michel Wensing

Abstract Valid and clear presentation of research findings is an important aspect of health services research. This chapter presents recommendations and examples for the presentation of quantitative findings, focusing on tables and graphs. The recommendations in this field are largely experience-based. Tables and graphs should be tailored to the needs of the target audience, which partly reflects conventional formats. In many cases, simple formats of tables and graphs with precise information are recommended. Misleading presentation formats must be avoided, and uncertainty of findings should be clearly conveyed in the presentation. Research showed that the latter does not reduce trust in the presented data.

5.1 Introduction

A clear presentation of study results is essential to convey the information that is provided by a study. However, the importance of clear reporting is often overlooked by researchers. The findings of quantitative studies are usually presented in tables and figures, but other formats are occasionally used (e.g. visual graphics). In many fields (e.g. education, journalism and politics), graphs, charts and tables are used to tell a story, to explain complex information and to persuade people in the target audience. In science, the way of presenting research findings should be influenced by an understanding of the information needs of the target audience, knowledge of how readers actually read study results and ideas about how uncertainty in research is best conveyed. Ideally, the chosen formats are valid, clear and attractive for the target audience.

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Insights from research on reading behaviours provides clues to the design of tables and graphs. One might assume that users read through the whole report, but this is seldom the case. Indeed, there is a wide variety among potential users in how they read scientific papers and data reports. Differences in experience and skills, e.g. statistical skills or the ability to deal with uncertainty, are related to this variation. Studies on reading behaviour have indicated that reading is often performed selectively and that certain sections in reports and papers receive disproportionally more attention. For example, the abstract and the conclusion are often read first, and less attention is paid to the methods section (Lavis et al. 2005; Wronski et al. 2021). As a consequence of less attention being paid to the methods, methodological limitations of claims on health interventions are sometimes neglected (Aronson et al. 2019). This reinforces the principle that important aspects of a study should be clearly highlighted, for example, in the discussion section.

Not only is there a difference in how much attention is put on certain sections, also there is variation in how well these are understood. On the one hand, the interpretation of numerical information may depend on features of the format (Oudhoff and Timmermans 2015). On the other hand, differences in numeracy and graph literacy among users explain this variation. For example, visual aids such as graphs and bar charts may aid accurate understanding of probabilities, although they could also lead to overestimations of low probabilities and underestimations of high probabilities (Trevena et al. 2013). Studies showed that clinicians find it hard to correctly interpret the information on treatment effects from meta-analyses (Johnston et al. 2016). Likewise, nurses and midwives often interpreted probabilistic screening information falsely (Bramwell et al. 2006; Lopez et al. 2016). This stresses the importance of how research findings are presented, even for a relatively well-educated target group. To reach both users with low numeracy and users with low graph literacy, visual displays for communicating statistical information and numbers could be included (Trevena et al. 2013).

This chapter discusses some general principles of how (quantitative) study results can be reported. We will focus on how study results can be presented in tables and graphs, as these are most commonly used. They are a quick and effective way to communicate large amounts of complex information that would be complicated to explain solely in text. Also, many readers will first look at the presented tables and graphs, which makes them important for attracting readers. The chapter will not only discuss how studies can be presented but also focus on the side of the receiver: How is scientific work read by potential users? The chapter will mostly focus on general principles of the presentation of quantitative research findings.

5.2 Tables

Tables are widely used for the communication of research findings because they can summarise large amounts of data. Compared to graphs, tables are the better choice when the exact values are of interest and when the relationships between the constructs are relatively simple (Boers 2018b; Few 2005; Wensing et al. 2017). Also,

including data in tables rather than text helps to reduce the length of the text. Nevertheless, not all numbers should be presented in a table. We will discuss various types of tables that are commonly used in health services research (HSR), provide some general guidelines for designing a good table and discuss what information a table should contain.

Two main types of tables can be distinguished: (1) descriptive tables that present frequencies and percentages and (2) tables that present relations between constructs, often based on regression analysis or similar methods. A descriptive table can be seen as a lookup table and usually has a simple design. It is intended to quickly show data that are associated with specific measures or variables (Boers 2018b). A classic first table in many publications is a simple descriptive table of the study population with the number of participants and their characteristics presented in frequencies and percentages (see Table 5.1 for an example). Also, a more extensive description of an important variable in a study can be presented in a descriptive table. By convention, variables or measures are presented in the rows and the total or subgroups in columns (e.g. intervention and control group in a randomised trial). Whereas descriptive tables contain frequencies and percentages, tables used to convey relationships in the data present measures of an association, e.g. regression coefficients or odds ratios (Table 5.2 is an example). Although graphs can also be used for conveying relations between variables, the advantages of a table are that estimates are reported with high precision and that many relations can be included. Whenever possible, absolute numbers that underly percentages or coefficients should be presented in tables. Tables should add additional information to what is already captured in text.

Concerning the design of a table, an overarching rule is that tables should be self-explanatory, i.e. a reader should be able to understand it without having to read the methods or results sections for clarification. Readers often scan a paper and try to interpret a table or figure before reading the whole text. It is advised that there

Table 5.1 Hypothetical example of a table describing a study population

	Control (n = 189)	Intervention (n = 201)	Total (n = 390)
	Mean (SD)/%	Mean (SD)/%	Mean (SD)/%
Cluster level (general practices)			
Number of practices	10	10	20
Average number of physicians per practice	2.3 (0.6)	2.5 (1.1)	2.4 (0.9)
Practices with a diabetes nurse (%)	80.0	90.0	85.0
Individual level (patients)			
Age (%)			
<65	28.2	34.7	31.6
65–80	36.7	39.4	38.1
>80	35.1	25.9	30.3
Sex (%)			
Male	55.2	48.3	51.1
Female	44.8	51.7	48.9
Charlson Comorbidity Index	3.4 (2.3)	3.2 (2.6)	3.3 (2.5)

Table 5.2 Hypothetical example of a table presenting relations between variables and measures, based on regression analysis

	Continuity of care		Hospitalisation	
	Beta	95% CI	OR	95% CI
Physician characteristics				
Age	0.14	(−0.04, 0.32)	0.60*	(0.34, 0.86)
Sex (ref: male)	0.06*	(0.02, 0.15)	0.85	(0.42, 1.59)
Involvement in DMP	0.21**	(0.12, 0.30)	1.38	(0.73, 2.51)
Patient's characteristics				
Age	0.24**	(0.22, 0.26)	1.06**	(1.03, 1.09)
Sex (ref: male)	0.07	(−0.04, 0.18)	1.73*	(1.05, 3.01)
Charlson Comorbidity Index	−0.83**	(−1.44, −0.22)	1.64**	(1.43, 1.84)
Enrolled in DMP	0.17*	(0.10, 0.25)	0.82	(0.58, 1.22)

**sign. <0.01, *sign. <0.05

Table 5.3 Recommendations for a well-designed table (Springer 2022)

Recommendations	
Clear and concise legend/caption	Provide clear, informative titles; table and figure titles should not be vague. Give each column a short or an abbreviated heading
Data divided into categories for clarity	By dividing the data into clear and appropriate categories, relevant differences between groups can be identified
Sufficient spacing between columns and rows (declutter)	This prevents the layout from making the table look messy or crowded and ensures that the table is easy to read
Units are provided, e.g. age in years, cost in EUR	Although self-explanatory, an oft-forgotten part
Readable font type and size	Tables can be fully packed with categories and variables, but this should not be at the expense of readability

should always be a minimum of white space around a number for easy reading (Boers 2018b). If the reader needs to make comparisons, it is easier when the corresponding numbers are presented close together and preferably horizontally, as it is easier to read than when they are arranged vertically. Similar to guidelines for graphs, it is recommended to maximise the data (information) to ink (text, numbers, elements, etc.) ratio and thus to keep them as simple as possible. Table 5.3 provides a number of recommendations for a well-designed table. More specific guidance for tables can be found on the websites of various scientific publishers.

The exact information that should be presented in a table highly depends on the aim of the study and thus the message to be conveyed; however, some recommendations apply in nearly all cases. Descriptive tables should not only present measures of centrality (mean, median) but preferably also an indication of the variation (e.g. standard deviation). When continuous variables are categorised, the category boundaries should be reported. For tables in which the results of a regression analysis are presented, the variation of the numbers to be presented is higher. For ordinary least square (OLS) regression, one must specify whether the standardised (beta) or

unstandardised (B) regression coefficients are presented. The former has the advantage that effect sizes are comparable among each other and even between different models. The downside, however, is that the presented coefficient is only an abstraction as it presents the change in standard deviation and does not refer to the original scale. This is the advantage of choosing unstandardised coefficients in which a change reflects the original scale, e.g. a change in life expectancy in years or increase in costs in EUR. When a logistic regression is performed, the most commonly used parameters are the effect size expressed in log odds (B) or an odds ratio (OR), with the latter being used more often. While the OR presents the ratio of two odds, which is not an intuitive scale for many, relative risks or marginal effects can be more appropriate when the aim is to transmit risks (Norton et al. 2018; Schmidt and Kohlmann 2008). For scientific use and understanding the relations between phenomena, the OR may be the better choice. When categorical variables are included, it is important to mention the reference category, list the number of cases included in the analysis and, in the case of a multilevel model, include the intra-cluster coefficient (ICC). In all situations, one should not only present point estimates but also estimates of their precision, e.g. 95% confidence interval, and an indication of their significance.

A debated topic is whether to include nonsignificant effects in a (regression) table. An important reason to include such results is that the reader will be able to see not only which measures are related to the outcome of interest but also the tested measures that were not related. Furthermore, nonsignificant effects should be reported to contribute to systematic reviews and meta-analyses of studies in a domain. Even if nonsignificant effects are excluded from the table, it should be clear from the text of the report that these effects were actually statistically tested. If only a few of many coefficients are significant, one may consider presenting them only in text rather than in a table, provided that the report specifies in clear detail which analyses were done (i.e. how many coefficients were statistically tested). In this context, the specifications of the analytical procedures should be specified. (One should not rely on the default option in the statistical software.)

5.3 Graphs

The use of graphs in research presentation and the communication of results makes it possible to synthesise large amounts of data and enables users to comprehend the information more easily than if it were presented in mere words or numbers (Cukier 2010). Tufte (1983) refers to well-designed graphics as instruments for reasoning about quantitative information and considers them the most powerful way to communicate statistical information. Graphs are also considered to be aesthetically pleasing and give your work a professional appearance (Springer 2022). Compared to tables, a graph is better at showing patterns of relationships between multiple variables. Nevertheless, this does not automatically mean that graphs are always preferable to tables. While graphs seem to be better in transmitting the essential

aspects of a message, numerical tables might better present the precise quantities and are therefore preferred by many scientific journals (Boers 2018b; Trevena et al. 2013).

Box plots, bar plots and line graphs are three frequently used figures (see Figs. 5.1, 5.2 and 5.3 for examples). A box plot presents the variation in a single continuous variable including an indication of variation (e.g. standard deviation or interquartile range). Box plots can also be used to compare variation in relation to subgroups of a population. A bar plot presents the variation in a continuous variable in relation to the categories of a categorical variable. It might suggest that a physical mass or volume is conveyed, which is often not the case. To avoid this when data represent more abstract constructs like perceived pain, a dot plot can be considered. A line graph presents the variation in a continuous variable in relation to another continuous variable. Line graphs are used to convey the relation between two continuous variables and often used to illustrate variation over a time range.

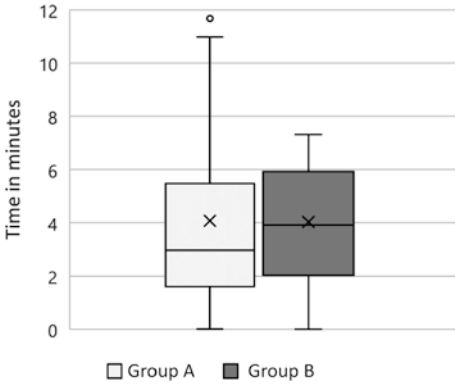

Fig. 5.1 Example of a box plot

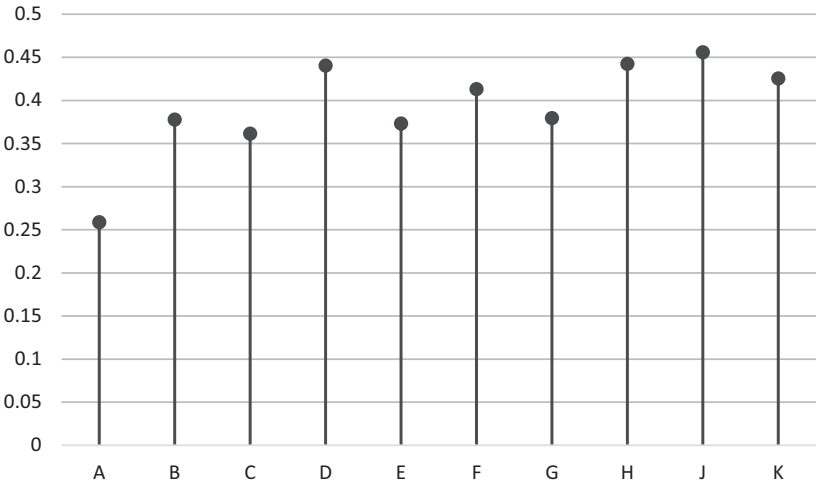

Fig. 5.2 Example of a bar plot

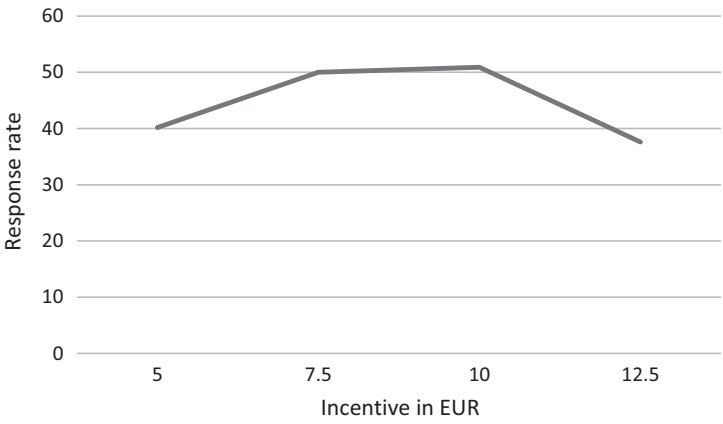

Fig. 5.3 Example of a line graph

Designing a valid, clear and attractive graph is not always easy, and many books and articles address this topic. This chapter will present some general principles for informative and effective graphs on research findings. Many of these principles apply to tables as well.

The first principle is *know your audience*. Knowing the message you want to convey and to whom you want to convey it is essential, as whom the figure is intended for matters. For example, in a scientific journal, a graph can be designed differently than figures in an information leaflet for patients (Rougier et al. 2014). Just as important is knowing your message. What exactly should a specific figure tell the reader? Each graph should be tailored to its primary communication purpose (Duke et al. 2015). Once this purpose is identified and the target group is clear, they should be used to guide design of an effective graph. This can be done, for example, by putting items the reader needs to compare close together (Duke et al. 2015). Box 5.1 presents a study that focused on the interpretation of a quantitative data report by a specific population.

Box 5.1: How Are Research Findings Read? (Wronski et al. 2021)
The QuantEV project aimed at understanding how research findings in a quantitative report were used by potential decision-makers. By using a range of data collection methods, including eye-tracking, participants were observed while reading a report. The study found that the participants had different reading strategies and that, on average, participants paid less attention to the methods section. Putting the methods section into greater focus by adding a structured box with a summary of the methods attracted the readers' attention but did not increase the overall time spent reading it. Based on interviews, the study showed that some of the participants tend to use the report to confirm their own ideas, rather than being open for or critical towards the information provided in the report. These findings illustrate the need to think carefully about how best to convey the most important message of your research.

A second principle is that graphs should be kept as simple as possible. This principle is mentioned by many authors in the field of visualisation and links to the principle of maximising the data-to-ink ratio. This is the idea that one should aim to convey the maximum amount of information with the lowest number of elements necessary to create a complete graph (Duke et al. 2015). Rougier uses the word *chartjunk* to illustrate the use of unnecessary colours, too many labels, coloured backgrounds, useless grid lines, etc. (Rougier et al. 2014). This also means that it is recommended to use the simplest plot appropriate for the information to be displayed (Duke et al. 2015; Tufte 1983). The graph designer should resist the temptation to include many colours or extensive formatting, as 'message trumps beauty'; functionality is more important than looks (Rougier et al. 2014). In the end, the best graph is one that needs the least cognitive burden to interpret. Partly following from these rules, it is generally advised to avoid the following graph types as they are less effective or often prone to misinterpretation: pie charts, stacked bars and area, spider and three-dimensional graphs (Boers 2018a; Tufte 1983). Although it is advisable to keep graphs as simple as possible, this does not mean that supporting text and captions can be omitted. In order to guide the viewer through a graph, legends, titles and axis labels should be included (Khasnabish et al. 2020; Rougier et al. 2014).

A third principle relates to the validity of presented information. A clear warning is given in the literature that although a graph should communicate a message, misleading visual perception should always be avoided, and 'graphical integrity' should be maintained (Duke et al. 2015; Rougier et al. 2014; Tufte 1983). An example of a potentially misleading graph is when a nonzero baseline is used in a bar chart, thereby exaggerating the differences between categories and/or groups. The (not recommended) use of (three-dimensional) pie charts is also potentially misleading, as the position of a category influences the perceived proportion. To avoid misunderstanding, colleagues could be consulted for their interpretation of a graph. For further practical guidance, Kelleher and Wagener (2011) provide an overview of 10 guidelines in which they address issues like meaningful and similar axis ranges, graphical objects and attributes, visualising patterns and the use of colour.

5.4 Uncertainty

It is inherent to any scientific study that generated research findings are subject to some level of uncertainty. In HSR, the uncertainty tends to be moderate to high. For reasons that are discussed in Chap. 6, it is important to convey the uncertainty of research findings. Here we will discuss different types of uncertainty and focus on how this can be conveyed in the context of tables and figures.

Generally, three different types of uncertainty can be distinguished: uncertainty resulting from probability, ambiguity or complexity (Han et al. 2011). For HSR, ambiguity is especially relevant, as it is related to the random and systematic errors in research and is reflected in the impreciseness of the findings (e.g. a 20–40%

improvement by an intervention). Random error (uncertainty due to the use of a sample, imprecise measurements or random fluctuations in phenomena) is usually expressed as confidence intervals. These show a range in which the true value of an estimate is most likely to fall. Confidence intervals are presented in tables, in addition to a point estimate, e.g. an effect size (see Table 5.2). In a line graph, for example, uncertainty can be visually represented by a dotted line below and above the main estimate. In HSR, the convention is to present the 95% confidence interval. In addition to the information provided in a point estimate and p-value, confidence intervals provide information on the ranges within which the point estimate is likely to vary. This helps the reader to understand that every study comes with uncertainty, resulting in estimates that are not as precise as they are often interpreted to be.

In addition to random error, there is often also a risk of systematic error (bias) that causes uncertainty of research findings. For instance, dropouts that are not random, confounding factors that are missed or external developments in the healthcare setting that may influence the study results. This bias is not captured in p-values and confidence intervals and might therefore be overlooked. Some of these issues can be handled in sensitivity analyses, which are analyses that use purposefully changed assumptions (e.g. a different baseline risk of an event). The results of such sensitivity analyses may be presented in tables and graphs, similar to the primary analysis in a study. Alternatively, one may consider providing some kind of quantification of the uncertainty arising from systematic errors. This is done with a credibility interval which could appear as follows: *I am XX% certain that the true value is between X and Y* (Fischhoff and Davis 2014). If not captured in a sensitivity analysis or credibility interval, potential sources of bias should at the least be mentioned in the discussion section.

Although there is no question that it is important to report on uncertainty in research findings, it might influence readers' interpretation of these findings. It has been shown that communicating uncertainty related to the study design and conduct is generally perceived positively, e.g. a higher perceived trustworthiness; however it is also linked to lower competence perceptions (Gustafson and Rice 2020).

5.5 Conclusion and Perspective

This chapter provided an introduction to the use of tables and graphs for the presentation of quantitative research findings. These should present data in a valid, clear and possibly attractive way to the audience and in a way that addresses their uncertainty and reading habits. In many cases, this means that relatively simple tables and graphs are preferred. Alternative formats for the presentation of study findings, such as podcasts and infographics, are increasingly being used in an effort to reach the audience more effectively. This poses new challenges in the presentation of quantitative research findings, which need attention in the future.

Recommended Readings

Designing tables: (Boers, 2018b) (from an article series in BMJ Heart).
Practical guidelines for designing graphs: http://www.perceptualedge.com (Stephen Few).

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Chapter 6
Dissemination and Utilisation of Research Findings

Michel Wensing and Charlotte Ullrich

Abstract The utilisation of research findings in healthcare practice and policy is a central purpose of health services research. Strategies for dissemination of research results must therefore be considered in every research project. In health services research, such activities go beyond scientific publications and may include, for instance, lectures for various audiences, podcasts and policy briefs. Trustworthy communication on research should openly convey uncertainties associated with the research findings. Stakeholders such as patients and clinicians can be informed and involved in studies at various stages, including the preparation and conduct of studies and the interpretation of findings. Active involvement of stakeholders in early stages of research has potential benefits but comes with additional risks and responsibilities for researchers.

6.1 Introduction

While science may have value in itself, it is ultimately its value for people and societies that determine its relevance. This certainly applies to health services research (HSR), in which most studies focus on problems or challenges in healthcare that are high on the political agenda. Therefore, a range of parties ('stakeholders') may have interest in the findings: the general public, patients, healthcare providers, managers, public policymakers, healthcare insurers and health-related industry. Many studies in HSR claim to provide knowledge that be directly used to influence specific outcomes, such as patient experiences in healthcare or retention of

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healthcare workers. This is called *instrumental use*. Classic examples of instrumental use relate to clinical trials that determine the admission and reimbursement of clinical interventions, such as medication. In HSR, direct instrumental use is less common. In some fields, research findings may be protected by patents and made available in an economic market. Examples of patent-protected outputs of HSR are scarce, but occasionally, research findings are transferred to specific tools or services that can be sold (e.g. hospital accreditation programmes).

The use of findings of studies in HSR is often better described as *conceptual use*: knowledge that helps to understand phenomena in healthcare and provides orientation to decision-makers, but not straight solutions. Most examples of the conceptual use of HSR relate to studies that explore the nature of problems or challenges in healthcare or the impacts of interventions. Systematic reviews of published research play a prominent role in this type of use because they provide knowledge that is more robust than single studies (Chap. 16). While instrumental use may be possible in relatively short time periods (e.g. months), conceptual use tends to require more time (e.g. years).

A third type of use is *strategic use* of research findings, which refers to the application of knowledge to meet political aims of a stakeholder, such as the postponement of a decision or the enhancement of credibility for a given decision. The link between research content and consequences in practice is loose or absent. The strategic use of research is rarely directly evident from scientific publications. Box 6.1 provides examples of the use of HSR in policy and practice.

Box 6.1: Examples of Research Utilisation

- *Instrumental use:* An evaluation of practice accreditation in primary care practices showed little added value of written plans for quality improvement (Nouwens et al. 2014). This finding contributed to the decision of the Dutch College of General Practitioners to reduce the administrative components of the accreditation procedure.
- *Conceptual use:* A programme for strengthening primary care in Germany was designed as a contract of health insurers for primary care practices. In a scientific study, this contract was systematically mapped onto an existing framework for strong primary care (Wensing et al. 2016). In this way, the German programme could be related to the international body of research literature, which helped policymakers connect to this vast international literature.
- *Strategic use:* The evaluation of a large and expensive programme for quality improvement in healthcare in the Netherlands was commissioned, but it was not made possible to apply a strong evaluation design and comprehensive measurements. It was only possible to document and explore a few aspects of the activities (Versteeg et al. 2012). The evaluation had been the result of external pressure, but there was no real interest among leading stakeholders in knowing the effectiveness of the programme.

Dissemination of research refers to activities to inform audiences about research, including scientific papers but also other activities, such as oral lectures for audiences and news items in social media. Dissemination of research findings is a precondition for their utilisation, but it may not be sufficient for actual adoption in practice and policy. The involvement of stakeholders in various stages of a research project may help to enhance its practical relevance in various ways. This chapter will first elaborate on dissemination (Sect. 6.2) and the communication of research findings (Sect. 6.3) and then focus on stakeholder involvement in various phases of research (Sect. 6.4). The chapter ends with conclusions and perspectives (Sect. 6.5).

6.2 Dissemination of Research

For research utilisation, it is required that potential users be aware of and understand research findings. Scientific publications may reach researchers, but they rarely reach stakeholders in healthcare practice, management and policy. Beyond scientific publications, other strategies can be used to enhance the utilisation of research findings in healthcare settings, such as policy briefs for decision-makers, news items in the media (including social media) and integration of research findings in clinical guidelines. Conferences and other events may be used to launch press releases, which are picked up by journalists and thus lead to items in the public or professional media. A systematic 'marketing' approach to the communication of research findings would mean that the target groups are identified and analysed for them to be reached most effectively. For instance, some groups largely depend on credible peers (rather than written reports), while others can be reached by news items in social media.

Various terms are used to describe the spread of information in a population. *Dissemination* is the activity of an individual or organisation to spread information, while *diffusion* refers to the observed spreading of information and practices in a population over time. Dissemination aims at increasing awareness and knowledge, but not necessarily at change in individual behaviours or organisational performance. This is distinguished from *implementation*, which refers to the actual uptake of knowledge in professional behaviours and the performance of healthcare organisations. Related terms are *knowledge transfer*, *knowledge translation*, *research transportation* and *research utilisation* (Graham et al. 2006). While these concepts differ in subtle ways, they largely refer to the same phenomena, namely, the communication of research findings to potential users. *Integrated knowledge translation* is a somewhat different concept, however, as it refers to the active, ongoing relationship between researchers and decision-makers from the start of a research project in order to optimise its impact on decision-making (Gagliardi et al. 2016).

Research utilisation is a broader concept than dissemination. Several activities can contribute to the utilisation of research findings, of which dissemination is one. Besides the production of relevant research and the transfer of research findings to relevant groups ('push'), these include efforts to enhance and facilitate interest in research findings ('pull') and the exchange between researchers and research users

(Lavis et al. 2006). The 'push' approach essentially involves the identification of actionable messages, the use of credible messengers, tailoring of messages to different audiences and possibly also the development of dissemination skills of researchers. While dissemination is thus far an understudied topic, experiences of researchers and decision-makers have provided experience-based recommendations (see Box 6.2). The 'pull' approach to research utilisation may include the creation of one-stop shopping for research users, the establishment of rapid-response units and the development of research skills in knowledge users. The 'exchange' approach to research utilisation aims at building relationships between researchers and research users, which may include a role for trusted individuals or organisations ('knowledge brokers') (Lavis et al. 2006). Ideally, these dissemination activities are embedded in a broader structure, which also includes activities to enhance the research climate and to evaluate of research utilisation activities.

Box 6.2: Practice Recommendations by a Policy Advisor (Whitty 2015)
An experienced health policy advisor provided a number of experience-based recommendations for research dissemination that apply to HSR generally. First and foremost, the research report should be timely: better 80% right and before a decision is made than 95% right after the decision. The policy topic should be presented upfront; this makes the item easily identifiable in a search on the topic. The methods should be explicitly described, so that they can be considered (and possibly graded) in decision-making. According to this author, it is a misconception that decision-makers do not like randomised trials. On the contrary, he argues that they are clear and easy to understand by decision-makers. Systematic reviews of studies are considered most helpful by decision-makers. Figures are appreciated by many decision-makers, and data on costs are often of central importance. Interpretations, recommendations or advocacy is best avoided in research reports.

6.3 Communication of Research Findings

In order for research findings to have an impact, decision-makers and other research users need to trust them. Many factors influence trust in information, including the perceived credibility of the source, the relationship between research users and researchers and the way the findings are presented. For instance, a study that used eye-tracking in a computer laboratory setting found that academic readers had mixed, but overall limited interest in reading about the methods section in a data report for planning health services (Wronski et al. 2021). This study demonstrated a discrepancy between the focus on rigour of research methods in the research world, which is considered the primary determinant of the validity of research findings, and the limited interest and understanding of research methods among many recipients of research.

Nevertheless, it is important that the degree of uncertainty of research findings is explicitly communicated for informed decision-making. In HSR, the certainty of

many research findings is moderate at best because most studies have methodological limitations. Publication in a peer-reviewed journal or book provides some protection against misleading claims, but there are also examples of peer-reviewed studies that proved to be misleading, inadequate or fabricated (Chap. 4). Several training programmes and tools have been developed to specify the risk of bias in research in a reasonably standardised way. Although it might be assumed that the communication of uncertainty reduces trust in research findings, a study actually found that it did not reduce trust in the presented numbers and the trustworthiness of the source (Van der Bles et al. 2020). It seems possible to communicate research findings and associated uncertainty without losing impact. In principle, most people can learn to assess the certainty of research evidence (see Box 6.3).

A widely used approach for assessing the certainty of research evidence is GRADE (Schünemann et al. 2013). Although this grading system is primarily designed for the assessment of research on clinical interventions in the context of clinical practice guidelines, its principles are also relevant for intervention studies in HSR. In short, GRADE assesses the research evidence for each important or critical outcome across all available studies. It fundamentally distinguishes between randomised trials, which provide a high certainty of findings, and observational studies, which are considered to provide a low certainty. On the basis of specific

Box 6.3: Teaching Lay People to Assess the Certainty of Health Claims (Nsangi et al. 2017)

The public receives many claims about what improves or harms health. People need to be able to assess the reliability of these claims. This study examined a short course to teach primary school children (aged 10–12 years) to assess claims about the effects of treatments. A representative sample of 120 eligible schools in Uganda were randomly allocated to either an intervention or control group. Intervention schools received the Informed Health Choices primary school resources (textbooks, exercise books and a teachers' guide). Teachers attended a 2-day introductory workshop and gave nine 80-minute lessons concerning twelve concepts essential to assessing claims about treatment effects and making informed health choices. The primary outcome, measured at the end of the school term, was the mean score on a test with two multiple-choice questions for each of the twelve concepts and the proportion of children with passing scores on the same test. Data on 6,383 pupils and 76 teachers in the intervention group and 4,430 pupils and 67 teachers in the control group were available. The mean score in the multiple-choice test for the intervention schools was 62.4% compared with 43.1% for the control schools (95% CI 17.3–22.7). In the intervention schools, 69% children passed the test compared with 27% children in the control schools (95% CI 44–55). The study shows that a short course effectively taught primary school children to assess the reliability of health claims.

methodological criteria regarding the conduct of the studies in practice, the certainty of evidence may be downgraded for randomised trials or upgraded for observational studies. Study design is the primary determinant of the research quality, but aspects of the conduct of a study can strengthen or reduce this quality. In the final step of GRADE, the certainty of evidence is combined with other considerations (balance of benefits/harms, values and preferences, feasibility, equity and resource use) to define a recommendation for practice and policy. Thus, decisions in practice and policy are never based on research findings alone.

6.4 Stakeholder Involvement in Research

While dissemination relates to stakeholders after a study has produced results, stakeholders can also be involved in earlier phases of research. There are a number of potential benefits of the involvement of stakeholders in various phases of a study: (a) It helps to identify relevant topics and questions that have priority for research, (b) the support of key stakeholders often increases the likelihood of receiving funding for a study, (c) it facilitates access to individuals in a healthcare domain for interventions and data collection while the study is being conducted, (d) it supports the interpretation of research findings and (e) it helps to convey research findings to relevant audiences. In practical terms, stakeholders can be involved in many ways, varying from advisory boards and panels for consultation to being members of the research team in all phases of a research project. In health research, it is also common for researchers to be representatives of stakeholders (e.g. physicians or nurses who do research). There is no evidence to suggest that any particular approach is superior, and this is an area of ongoing development.

While stakeholders are involved in many studies in HSR as objects of research, they can also be involved as subjects in designing, conducting and interpreting research. Stakeholder involvement in research has been described in various ways, including ‘patient and public involvement’, ‘participatory research’, ‘action research’, ‘integrated knowledge translation’ and ‘inclusive research’ (Hoekstra et al. 2020). Although these concepts are not entirely the same, they have much in common. Essential aspects of these concepts include the central role of the relationship and communication between researchers and stakeholders, active and meaningful involvement of stakeholders in the planning and conducting of studies, co-production of knowledge through involvement in the design and interpretation of research and the need for capacity building and support of stakeholders for their role in research (Hoekstra et al. 2020).

While stakeholder involvement in research is often described in positive terms, there are also risks: (a) stakeholder involvement may increase the time and resources needed for research, (b) stakeholders may make proposals that contradict scientific knowledge, (c) researchers may lose independent judgement and take the side of one of the stakeholders or (d) researchers may ‘hide’ themselves behind the stakeholders and thus fail to make an independent professional assessment. As a consequence, the involvement of stakeholders in a study poses additional responsibilities

for researchers. The involvement of stakeholders does not preclude the responsibility of the researchers to analyse the data in a balanced way and interpret the findings adequately in the context of the broader body of scientific research. For instance, it remains important to recognise and convey methodological limitations and apply strategies to overcome these. Also, it is important to contextualise research findings in the broader scientific literature, even if this literature contradicts with specific views of stakeholders. For instance, a stakeholder's views on an issue may hide important considerations, such as claiming that there is a shortage of physicians but ignoring the possibility of role revisions of healthcare workers. Box 6.4 describes a particular approach to involving stakeholders in research.

Box 6.4: Embedding Researchers in Health Service Organisations (Wolfenden et al. 2017)

Embedding researchers in healthcare delivery organisations that are the topic of the research is a method to be close to key stakeholders while research is conducted. The expectation is that an embedded coproduction approach makes policy and practice-relevant research immediately available to end users, accelerating the use of evidence in decision-making of health and other services. Examples of this approach exist across the world and include, for instance, Collaborations for Leadership in Applied Health Research and Care (CLAHRC) in the UK and Quality Enhancement Research Initiative (QUERI) of the Veterans Administration in the USA. These and other initiatives have indicated a number of factors that may be associated with the effectiveness and sustainability of research-practice partnerships. These include (a) embedding of researchers in service delivery teams and organisational governance positions, (b) financial contributions from both sides, (c) production of benefits for both sides and (d) sufficient time, as the benefits accrue over time.

6.5 Conclusion and Perspective

Dissemination and utilisation of research findings have become of greater interest because it justifies the societal investments in scientific research. The wish to have an impact on decision-making is intrinsically felt by many health researchers and research institutions. It is also a moral responsibility for researchers to contribute to dissemination and uptake of research findings, particularly if they have been funded by public organisations and have depended on cooperation of patients or other persons for conducting their research. They may also contribute to strategies for enhancing the implementation of research findings into practice and policy, but in many cases, this is the primary responsibility of other parties and authorities in healthcare (Wensing et al. 2021).

The use of social media by health researchers is relatively new and may help reach a larger audience, faster and with more impact (Dol et al. 2019). However, it also has risks, such as an unwanted focus on single studies and a reinforcement of

homogeneous views at the expense of conflicting research evidence. A further development in dissemination is the publication of studies before they are reviewed by scientific peers, which was reinforced during the COVID-19 pandemic (from 2019 onwards). While this is faster than the traditional publication process, it also involves a higher likelihood of errors. Nevertheless, HSR as a field has a special obligation to think about new and creative way to enhance dissemination and utilisation of research findings.

Recommended Readings

Hoekstra, F., Mrklas, K. J., Khan, M., et al. (2020). A review of reviews on principles, strategies, outcomes and impacts of research partnerships approaches: a first step in synthesising the research partnership literature. *Health Research Policy and Systems*, 18(1), 51.

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Part III
Research Methods in Health Services Research

Chapter 7
Qualitative Research Methods in Health Services Research

Charlotte Ullrich and Regina Poß-Doering

Abstract Qualitative research offers a unique contribution to health research by providing the opportunity to gain detailed insight into real-life situations, people's experiences, perceptions, beliefs, behaviours and contextual factors. It can be conducted as a stand-alone study or as part of larger studies. Frequently used qualitative data collection methods include interviews, focus groups and observation. While there is a range of qualitative data analysis methods available, most overlap in combining inductive and deductive approaches. Typical challenges of qualitative research concern the sample size, saturation, interview guide, reach, maintaining anonymity and choice of analytical strategy. Strategies to address these issues are described in this chapter.

7.1 Introduction

Qualitative research is a methodology that aims to understand people's perceptions, experiences, beliefs and behaviours as well as contextual factors. It collects communicative, nonnumerical data to gain meaningful, detailed insight into the 'how' and 'why' of real-life situations. Thus, qualitative research offers a unique contribution to health research by providing methods to gain an in-depth understanding of practices and habits in healthcare settings that explore (a) tacit factors such as social norms, professional status, experience and behavioural patterns and (b) structural factors such as organisational and further contextual factors. In health services research (HSR), a broad spectrum of qualitative research methods is used to explore the

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perspectives of patients, healthcare professionals and other actors to gain insights into healthcare practice, health policy and health interventions. Research design, methods for data collection and data analysis depend primarily on the research questions of interest. To explore and map aspects that may impact healthcare delivery, data collection methods can be interviews, focus groups and observations. This chapter provides:

(a) An overview of key characteristics of methods of sampling, data collection and data analysis of qualitative research in HSR
(b) A description of typical challenges and strategies to address them

Methods of qualitative data collection have similarities to everyday actions, such as observing situations or conducting conversations. Qualitative methods use these everyday experiences and strategies but differ from them in their methodologically conscious, controlled and reflected use. They also differ from clinical methods such as 'clinical interviews', as they do not aim to diagnose or treat but to provide analytical insights into aspects of reality.

In health research, the qualitative research process is characterised ideally by an interplay of inductive and deductive approaches. Sampling, data collection and data analysis are informed by background literature, existing concepts and theory (deduction). At the same time, the exploratory nature of the research design is upheld by proximity to the research field, recursive reformulation of research questions, adaptation of study designs and grounding analysis in data (induction). Although qualitative research is characterised by an inductive approach, deductive components based on concepts and previous research can strengthen a qualitative study by guiding data collection and enriching data analysis.

7.2 The Qualitative Research Design

Qualitative research is field research, that is, research in real-world settings. It can be conducted in the context of stand-alone studies or as part of larger studies, for instance, the evaluation of an intervention programme. When formulating a research design, the first question is what kind of data are needed to answer a (perhaps initially vague) research question. In HSR, a range of qualitative study designs are used, including case studies, grounded theory and ethnography. Mostly, individual and focus group interviews are used for data collection, and approaches that combine induction and deduction are used for data analysis. A combination of different methods in data collection and analysis is possible and is often instructive.

Qualitative research often starts with a relatively explorative research aim that anticipates unexpected aspects *(openness)*. This means that the collected data are usually semi-structured, and quantification is not necessarily sought. During the data collection phase, the study design can be adapted to emerging empirical insights and characteristics of the field: Interviews could be complemented with observations, a sample enlarged with an additional group or – more commonly in HSR – interview guides might be revised (*recursivity*). Over time, this leads to determination of both methods and research questions. However, especially in

third-party-funded research projects, there may be little flexibility to adapt the research focus and design. Nevertheless, openness and recursivity as well as step-by-step focussing can be maintained, for instance, through interlinking data collection and analysis. The emergent nature of the research design calls for sound planning and thorough documentation (Box 7.1).

Box 7.1: Strategies in Planning a Qualitative Study in HSR

- Ensuring research question specific field access – adequate data collection includes consideration of potential obstacles.
- Allowing for extra time and sufficient funding reflects the emerging nature of qualitative research (e.g. change in participant group, number of interviews, methods of data collection).
- Planning for specific resources, such as transcription and data analysis software, travel or publication budgets or participant compensation promotes trouble-free work.
- Budgeting at least 50% of the time for data analysis and write-up supports timely finalisation.
- Reporting guidelines (e.g. Tong et al. 2007; O'Brien et al. 2014) are helpful tools for planning and documenting a qualitative study.

During planning stages and beyond, vulnerability and dependency need consideration with regard to patients, healthcare professionals and other research participants. *Informed consent* is a necessary starting point. Especially within a longer process, renewed and ongoing consent may be needed. Discretion and anonymity are ethical desiderata. Ensuring data protection without losing analytical insights is a particular challenge. Besides pseudonymisation, masking as a practice to conceal or distort identifying details about people and research sites can be used to protect privacy and prevent exposure and harm as a result of participating in research.

7.3 Sampling Strategies

All approaches in qualitative research need good field access and a suitable sampling strategy (Green and Thorogood 2018). Commonly used in health research are *theoretical* and *purposive sampling* techniques that involve the researchers applying their expertise to select a sample that best fits the research purpose. Theoretical sampling was developed within grounded theory as a strategy to develop a 'new theory' based on data. Interlinking sampling and analysis, additional data or participants are included based on insights from the initial analysis of a first data set – often choosing deviant cases that could challenge previous findings. It might be used when there are no strict criteria for recruitment and flexibility in the research timeline. For purposive sampling to be effective, clear criteria and rationale are

defined to gain insights into the phenomenon of interest (e.g. perceptions and experiences of healthcare providers regarding screening programmes).

Another commonly used strategy is *convenience sampling*, which involves the inclusion of individuals who are easily accessible to the researchers (for instance, all healthcare professionals in an intervention arm in a randomised trial). This can be used as an inexpensive way to collect initial data to gather ideas about a particular phenomenon within a specific group (e.g. asking a group of students in one academic programme about their general view on vaccinations). *Snowballing* as a sampling technique can be used effectively when targeted groups or individuals of interest are vulnerable and not easily accessible (Ghaljaie et al. 2017). When this technique is applied, the first participant provides one or multiple contacts of potential further participants.

All sampling approaches are followed until themes of interest can be illustrated, no new insights emerge from the data and deviant observations as well as consistency of findings facilitate assessment of data sufficiency and indication of saturation. Higher numbers of participants could allow for broader analysis; however, data sufficiency and saturation are rather grounded in content that appropriately illustrates categories or themes defined in the analysis. While there is no shared definition of data saturation, different forms have been described: (1) *Theoretical saturation* refers to dimensions of an emerging theory being fully reflected in the data. (2) *Thematic saturation* is assessed when no new themes emerge to further illustrate the data. (3) *Data saturation* refers to the level of new data repeating what was expressed in previous data. (4) *Meaning saturation* refers to the richness and quality of data when no additional information emerges from the data (Saunders et al. 2018; Sebele-Mpofu 2020). This implies that there is no pre-set ideal sample size in qualitative research. However, there is some research and experiential knowledge to refer to: Depending on the scale and aim of the research, 9–17 interviews in homogenous study populations, for instance, may be sufficient to explore a field (Hennink and Kaiser 2022). When personal perspectives are the focus, more interviews are recommended, while institutional knowledge of experts may be focused on in smaller numbers. When the number of total interviews is limited, fewer study populations with sufficient numbers should be targeted. Independent of the sampling approach, a detailed description of factors that could shape the findings indicates the extent to which these may be applied to other contexts or settings. Data saturation is therefore not primarily determined by the number of participants but rather by intrinsic features of the study at hand (Vasileiou et al. 2018)

7.4 Methods of Data Collection

In qualitative research designs, data collection is seen as communication and is often set up to mimic real-life interaction: Individual interviews illuminate subjective perceptions. Group interviews deliver insights into shared norms and opinions. Direct observations facilitate understanding of behaviours in healthcare practice. Other forms of data collection include questionnaires based on open questions;

Table 7.1 Key qualitative data collection methods in HSR

Methods	Analytical focus	Research examples
Individual interviews	Individual perceptions, attitudes and experiences (usually in-depth)	Expert views of care providers and stakeholders, evaluations of interventions and technical solutions
Focus group interviews	Group view, shared norms and opinions	Care provider group perspectives on processes, interventions and requirements determination
(Participant) Observation	Processes and behaviours in practice	Uptake of measures in daily routines, as-is status determination

think-alouds to test questionnaires, aids or tools and collecting documents to explore discourses and (self-)representations, e.g. analysing medical records. Traditionally, data collection is done face-to-face. Increasingly, media are used, such as telephone and online conference tools for single interviews and for focus groups. Generally, formal interviews are audiotaped and fully transcribed. Additional written jottings and protocols are useful to keep track of emerging topics for further investigation and to document information and impressions during or after data collection. This is especially important when using observation (Table 7.1).

7.4.1 Individual Interviews

In qualitative research, the extent to which the researcher directs the interviews is one dimension by which qualitative interviews can be classified. At one end, there are *informal interviews* often used in ethnographic research, compromising natural, often opportunistic conversation in the field. A fully *structured interview*, at the other end, is a rather rigid interview style, strictly adherent to content and often order of the interview guide with little to no additional questions asked (Green and Thorogood 2018). In HSR, the most commonly used interview type lies between these two poles. In *semi-structured interviews*, core topics of interest are set, but at the same time, the interview follows the course of conversation and probes the participant for additional detail (e.g. Witzel 2000). The interview guide provides a tentative order and wording of open-ended questions and serves as a compass balancing pre-set topics and the interviewee's accounts rather than dictating a questions-answer scenario. While core topics of interest are set (deductive element), the interviewer aims at evoking narratives and follows the course of conversation (inductive element). The term semi-structured interview is commonly used for this type of data collection; however, in-depth or narrative interview might also be used since these interview types emphasise allowing time and space for the interviewee's stories.

All participants in qualitative interviews are included due to a specific expertise. However, within the methodological debate, a differentiation is made between interest in personal or biographic experiences and more generic expert experience. Within *expert interviews'*, experts are identified by virtue of their specific

knowledge of a field, their position or their status. Within these interviews, participants are addressed primarily in regard to their expert role rather than as a whole person. Thus, in HSR, interviews with healthcare professionals, for example, typically focus on their professional views on healthcare delivery and their perspective of patients' experiences (Bogner et al. 2009).

Preparing an interview guide that reflects these ideas and is feasible (see Box 7.2) is as crucial for a successful conversation as one's mode and mindset while conducting the interview. It is key to have an attitude of genuine interest, expressed through probing and connecting follow-up questions as well as a reserved demeanour, shown, for example, by the ability to tolerate pauses and silence. The way questions are asked influences the responses. Using everyday language rather than technical or analytical terms (e.g. facilitators, barriers) and avoiding leading and judgemental wording invites the interviewees to open up and share their perspective.

Box 7.2: Strategies for Developing Semi-structured Interview Guides

- Developing a fitting interview guide needs time, reflection and about 3–5 rounds of revision
- Common structure: (a) opening question, (b) 3–5 main topics with 2–5 follow-up questions and (c) 1–2 closing questions
- Ideally 1–2 pages for an interview length of 30–45 minutes
- Provide narrative impulses: use open questions, ask for examples and specifications
- Avoid asking directly about your research question(s)

7.4.2 Focus Group Interviews

A group interview is a discussion with a small number of participants on a specific topic (Green and Thorogood 2018). In group interviews, a situation is provided where people are invited to consider their own views, perspectives and experience in the context of the views of others. Therefore, the group interaction is explicitly used to produce data, e.g. to reveal consensus and dissent or shared experiences and values among the participants. Group interviews are used in a broad spectrum of disciplines, marketing and media research in particular that differentiate subtypes and use various labels such as (focus) group interviews and group discussion. In HSR, *focus groups interviews* (sometimes just 'focus groups') are frequently used to gather a broad range of perspectives as well as shared viewpoints from a number of participants at a specific time and location (Krueger and Casey 2014; Kühn and Koschel 2011) (Box 7.3).

Box 7.3: Exploration of Perceptions Regarding Patient-Centred Care (Brickley et al. 2020)
This Australian study explored perceptions and experiences of patient-centred care through involving both patient advocates and general practitioners. Purposive sampling was used to recruit participants for separate focus group sessions. All sessions followed the same protocol: After a short briefing, a moderator posed questions defined in a structured guide and added probing questions to encourage elaboration of initial ideas. Generated data were subjected to thematic analysis using a constant comparative approach. Researchers familiarised themselves with the data, engaged in coding and derived initial ideas of thematic concepts to explore in subsequent focus group sessions. After the first sessions and initial analysis, theoretical sampling and inclusion of additional probing questions were guided by a theory-based model. Supported by field notes, the iterative and reflective process enabled assessment of thematic saturation.

In HSR, participants of focus groups are typically a relatively homogenous group of people, such as patients, healthcare providers or health policy experts. The intention of focus groups is the exchange of viewpoints and discussion among participants, and the basic setup is similar to that of an interview. Participants are asked to reflect on themes and questions initiated by an interviewer. Focus groups can be conducted in closed rooms that provide enough space for participants and moderators to sit around grouped tables or chairs, enough light to support video documentation (if used) and little noise to ensure quality audio recording. When conducting online focus groups, data protection can be ensured by selecting an appropriate platform and the use of aliases for participants when logging in for anonymity.

Focus groups differ from individual interviews, and conceptual and methodological challenges need to be considered. While structuring and the natural course of conversation should be balanced just like in interviews, there are also two intertwined conversation processes to be upheld: conversation between the moderating researcher and conversation between any number of participants. Administrative efforts can be demanding as participants, moderators, location and technical equipment need to be coordinated. For groups with 8–10 participants, a less extensive interview guide may be appropriate to ensure a balanced participant speaking time. Good moderating practice entails detailed content and context-related preparation, concentrated, yet reserved listening to the group conversation, facilitation of a relaxed atmosphere and sound teamwork. During data analysis, individual aspects need to be studied in relation to the collective discussion (Box 7.4).

Box 7.4: Strategies for Conducting Group Interviews in HSR
- Typical length 60–120 minutes.
- 6–10 participants.
- (At least) two moderating researchers: One leading, one documenting.
- Moderator: Introduce the topic, engage participants in the conversation, practice active listening, provide prompts and narrative impulses and apply flexibility to the interview guide.
- Planning and scheduling efforts consider appropriate setting and sample for the topic.
- Familiarising oneself with related background information enables moderators to provide narrative impulses.
- Audio recording: Protocols of (anonymised) participants, times and verbatim of beginning of statements support assignment of speakers during transcription.
- Use video cautiously (due to data protection) and preferably only when nonverbal aspects will be analysed.
- Budget sufficient time for data collection and analysis.

7.4.3 Observation

The value of ethnographic methods such as observation in studying healthcare practices is gaining renewed methodological attention (Cubellis et al. 2021; Cupit et al. 2018; Dixon-Woods 2003; Vindrola-Padros and Vindrola-Padros 2018). Although only used by some researchers in HSR, participant observation offers additional insights into healthcare practice. While interviews can highlight perceptions and opinions, observation focusses on what is actually done.

Observation can focus on regular or extraordinary events, short situations or longer periods, ascribed and formal roles, social relations, social structures of groups and organisations and certain locations, lifestyles and subcultures (Lofland and Lofland 1995). Depending on the objective, observation can tailor the extent of participation, overtness and directedness: (a) The extent of participation can range from attending a few meetings (e.g. to gain field access) to full-time immersion. Alternating between intense and moderate participation is common. In HSR, the researcher is often more an observer than a participant. Required time for observation varies. (b) As 'undercover research' is the exception (not least due to ethical concerns), open research comprises information about and consent for observation. (c) Within open observation, little to no pre-fixed categories are used with the aim to record all events, actions, expressions, etc. of apparent relevance. More directed observation could use observation grids for a more focused perspective.

When using observation in HSR, two methodological characteristics are considered. (1) *Balancing proximity and distance*: Qualitative observation is characterised by a constant tension between field participation and analytical detachment.

Especially within longer field visits, at first, acquiring an insider perspective is the central aim. However, this involvement – sometimes called 'secondary socialisation' – is accompanied by the danger of adopting the perspective of the field ('going native') and losing scientific distance. (2) *Recording fleeting moments*: In contrast to interviews, observations are often not audio- or video-recorded and focus on non-verbal data as well. Thus, different forms of field notes are central tools: *head note*s (written during participation) and *scratch notes* (brief jottings), both of which inform *full notes* (immediate write-ups), which contain detailed descriptions of events. These full notes should be intelligible to someone who was not involved in the research and form the basis for the developing analysis (Emerson et al. 2011). From the beginning, detailed descriptions of observable behaviour should be distinguished from interpretations (e.g. by using two separate columns).

7.5 Methods for Data Analysis

While a wide spectrum of methods for data analysis is used in HSR, reaching from primarily inductive grounded theory to primarily deductive forms of highly directed content analysis (in Germany, especially (Mayring 2000)), most qualitative research questions are based on previous findings and have an explorative character. Examples are thematic analysis (Braun and Clarke 2022) and framework analysis (Gale et al. 2013). Although the analytical process is described differently and the use of key terms (such as codes, categories and themes) is inconsistent between methods, there is considerable overlap in key procedures of methods that combine inductive and deductive approaches towards data analysis.

Aiming at synthesising findings, qualitative analysis usually alternates between working on two interlinked levels going back and forth between data work and conceptual work. Within a recursive process, a *basic approach to qualitative data analysis* comprising four essential stages: (1) During *familiarisation*, the researcher reads and rereads transcripts and fieldnotes to establish an overview and deep knowledge of the data. (2) Within *open coding*, close line-by-line reading initially identifies themes of interest from the data. These may have the form of codes but can also be diverse and disparate. Categorising small segments – without regard to how or whether those ideas will ultimately be used – opens up avenues of inquiry by breaking data open. Open coding primarily aims at understanding 'what is going on' rather than labelling. (3) *Focused coding* (also thematic coding) often includes multiple rounds of focused fine-grained, line-by-line analysis based on already identified themes of particular interest. While open coding may consist of more informal pen-and-paper notes or jottings, using qualitative data analysis software (such as atlas.ti or MAXQDA) is often a helpful tool during focused coding to manage data and capture analytical insights. This step is characterised by revising and redefining codes until, gradually, a more defined set of categories and subcategories is developed. (4) Ultimately, researchers search for *analytical themes* – associations and patterns, concepts and explanations within the data – to answer the research

Box 7.5: Antibiotic Prescribing Decisions in Primary Healthcare (Poss-Doering et al. 2020)
This theory-based study aimed at identifying factors associated with primary care physicians' decision-making processes to explain deviations from rational antibiotic prescribing for acute noncomplicated infections. Within a process evaluation, 27 semi-structured interviews were conducted with primary care physicians. A framework analysis based on the Tailored Implementation for Chronic Disease Checklist (TICD) identified themes of interest deductively a priori as well as inductively de novo from the data. Similarities and differences were sought across and within interviews to ensure representation of different perspectives. The dual process theory was applied to facilitate understanding of the scope of individual factors that induce inappropriate antibiotic prescribing or promote rational prescribing. A model was developed to provide transparency as to how prescribing decisions occur and describe that educational interventions may result in active rational rather than routine-based decision-making.

question (Box 7.5). Data analysis can be described as work on uncertain terrain, approaching insights in narrowing circles.

Within the outlined basic approach, steps may overlap (e.g. familiarisation might coincide with open coding), may be split (e.g. differencing additional steps such as axial and selective coding in grounded theory) and may be reversed or repeated at a different pace for different categories. It can be combined with additional tools (e.g. memos, grounded theory coding paradigm). A set of strategies has been proven both practical and fruitful in HSR projects (see Box 7.6).

Qualitative data analysis can start more inductively, deriving initial themes de novo from the data. Alternatively, it can start more deductively with predefined categories, theories or frameworks, which could then be expanded upon inductively. Often, by combing deduction and induction, initial themes can be identified a priori and informed by background literature as well as from open coding. In HSR, often pre-existing frameworks (e.g. CFIR and TICD, TDF, see example in Box 7.5 and Chap. 3) inform the study design, e.g. in respect to interview guides and data analysis (Nilsen 2015). For instance, a study on determinants of acute thrombolysis examined the applicability of a pre-existing framework in a qualitative study, using the TICD framework to inform the interview guide and data analysis (Skolarus et al. 2019). A study on user perception of an electronic patient record applied framework analysis as a method identifying themes deductively from the interview guide and inductively from the data (Poss-Doering et al. 2018).

During data analysis, methodological strategies aim at minimisation of potential bias and a reduction of the risk of overlooking relevant content. Involving more than one researcher supports rigour in analysis. Independent double coding by two researchers has been described as a gold standard by some researchers. However, independent coding of all data might only be feasible in some contexts. In

Box 7.6: Strategies in Qualitative Data Analysis

- *Case vignette memos*: After familiarisation with first transcripts and notes, short case vignettes (1–2 pages) are useful to describe the course of the interview or observations and 3–5 key issues raised by participants. They also support comparison of interviews and adapting the interview guide as well as prepare for focused coding.
- *Successive coding*: Coding interviews or observations in batches is a common strategy for adapting the research design, sample and interview guide to emerging analytical insights. After the first batch of interviews is conducted (3–5 or max 1/3 of the planned number), a first familiarisation with the data through open coding and case vignettes is recommendable.
- *Comparative analysis*: Coding per subgroup (e.g. first patients, then practitioners) or data types (e.g. interviews or focus groups) facilitate insights into target-group-specific themes. Comprehensive analysis of the complete data set, inclusion of deviant cases and comparisons between and within cases facilities are sound practice.
- *Documenting code development*: Code memos and codebooks document ideas, insights and connections throughout analysis. Codebooks include definitions of these codes along with examples. As a clearer sense of ideas to pursue is developed, code definitions and memos take a more focused character and might integrate previously separate pieces of data or analytical ideas.

general, continuous consultations between researchers are often fruitful to reflect the emerging nature of qualitative data analysis. Additional researchers can also be involved in coding (parts of) the data jointly with the primary researcher or reviewing (parts of) the coding. In addition, peer feedback can be obtained while presenting preliminary results at conferences, regular research workshops or colloquia. Engaging research participants in data analysis (e.g. via communicative validation) can contribute to reducing potential bias. Employing theoretical concepts and frameworks can support comparability across studies.

7.6 Presenting Results

In qualitative research, snapshots of ever-changing conditions of real-live settings are investigated, and researchers are expected to use all of their professional experiences and abilities within data collection and data analysis. Subjectivity of researchers is therefore more apparent than in other research designs. Researchers can mitigate bias and strengthen transferability of findings by combining induction and deduction, involving additional researchers, triangulation of methods and data sources, heavily using contextually relevant literature, being transparent in case selection and study limitations as well as reflecting on their own role.

A broad variety in *presentation of qualitative data* in HSR can be observed. However, for any chosen form of presentation, the use of direct quotes from the data supports transparency regarding the data groundedness of findings. Quotes can be embedded within the text and/or presented within (additional) tables. Although debated, a general indication of typicality of accounts or the frequency of themes might support arguments and counter notions of anecdotalism, but does not convey statistical relevance. Data management software features may offer relevant overviews. In presenting results, data protection becomes especially crucial as research participants could be identifiable due to rich context information, making careful consideration of pseudonymised wording essential. This includes critically assessing whether to disclose or mask research sites, locations and other potentially identifying characteristics as well as omitting potentially exposing statements when choosing data quotes for illustration. Presentation of results ideally also includes a statement regarding data storage and potential data availability. Following reporting guidelines (such as COREQ or SRQR) generally supports best practice reporting.

7.7 Conclusion and Perspectives

Highlighting concepts and shared strategies of qualitative research, this chapter indicates when, why and how to apply qualitive research methods in HSR. Emerging topics such as online research, meta-synthesis and secondary data analysis present additional approaches. Digitalisation offers sites of qualitative research such as blogs, electronic health records and patient forums as well as the need to adapt research strategies when conducting online interviews or analysing data using video conferencing tools and cloud-based software. Qualitative meta-synthesis is a way to aggregate findings across different qualitative studies. Secondary analysis that reuses existing qualitative data from previous studies reflects the mandate of data minimisation and data avoidance, reduces burdens on participants and offers opportunities for pragmatic and quick availability of data and, thus, results. However, analysing secondary data proposes substantial challenges, such as fit to the (new) research question and missing relevant contextual knowledge. In addition, practical problems such as limited consent for secondary data use and maintenance of data protection need to be considered. These upcoming topics present opportunities to reflect and enhance the contribution of qualitative methods to the development of the field of HSR.

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Chapter 8
Survey Methods in Health Services Research

Jan Koetsenruijter and Michel Wensing

Abstract Survey studies use questionnaires in samples of individuals (e.g. patients or healthcare providers) to measure phenomena in the world. The collected data are structured, which facilitates quantitative data-analysis. Typically, a sample (rather than all members) of a study population is included. Generalisation of findings to the study population is possible if the sampling is (close to) random and if the response rate is sufficiently high. The questionnaire can be administered as a paper-based tool, online or in interviews settings. It typically contains several sets of questions with prestructured answering categories (e.g. a five-point scale). Ideally, these sets are previously validated instruments. Data-analysis involves description, data-reduction, analysis of associations and effects and sensitivity analysis.

8.1 Introduction

Survey studies use structured questionnaires to collect data from people, such as nurses or patients. Survey research has been defined as "a study field which uses the collection of data by using a sample from a well-defined population through the use of questionnaires" (Visser et al. 2000) or more broadly as "a set of scientific procedures for collecting information and making quantitative inferences about populations" (McColl et al. 2001). In this chapter, we focus on survey research on the basis of questionnaires that are completed by study participants. The questionnaire may be paper-based, administered online or used by interviewers in face-to-face or

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Table 8.1 Steps in a survey study

	Key items of attention
1. Preparation of a survey study	Define the aim and objectives of the study, which may include hypotheses for testing
	Review the current state of knowledge on the topic
	Determine which concepts and phenomena are of interest
2. Decide on study design, study population and sampling procedure	Cross-sectional or longitudinal study design, using repeated or recurring measurements
3. Design and pilot test the questionnaire	Choose the questionnaire format, e.g. paper-based, telephone-based, online administrated
	Select or develop questions
	Pilot test the questionnaire
4. Conduct data collection	Invite the study sample to participate
	Administer questionnaires
	Arrange data management
5. Data analysis and reporting	Data analysis according to plan
	Scientific reporting

telephone interviews. Completion of the questionnaires generates new data, which are analysed quantitatively with respect to description, comparison of groups, change over time, associations between variables and regression of outcomes on predictors (McColl et al. 2001).

Survey research has a long tradition in the social sciences, going back to market research and election polling in the early twentieth century. Survey studies are widely used today because they are flexible and efficient and the findings are (under specific conditions) generalisable (Story and Tait 2019). Survey studies are also widely used in health services research (HSR). Designing and conducting a high-quality survey study requires substantial expertise and resources: Not all 'surveys' (data collection with questionnaires) are scientific survey research. Advantages of survey research are their versatility (as they can be used in many settings and topics) and their efficiency (by using sampling and structured data collection). Disadvantages concern the risks associated with the use of non-validated questions and selection bias caused by suboptimal sampling procedures and nonresponse. Survey studies can be used to measure constructs such as opinions, knowledge or experiences, which are often hard to grasp by other approaches. They have also been criticised because they reduce complex phenomena to simple numbers (e.g. between 0 and 5). The use of additional open-ended questions may help to provide a deeper or broader insight.

The remainder of this chapter is structured along the typical steps in a scientific study (see Table 8.1), as each step contains survey study specific content.

8.2 Preparation for a Survey Study

Before a questionnaire can be designed, the aims and objectives of a survey study must be outlined. These are based on an understanding of the topic and the existing gaps in knowledge, which is usually informed by scientific literature, conversations

with stakeholders and/or practical experience. While the study aim is usually broad, the objectives (or research questions) are more specifically defined in terms of concepts or phenomena of interest. The research questions may be phrased in terms of hypotheses that are to be tested. The research objectives or questions provide clues for the required measurement instruments, such as sets of questions in the questionnaire. Adequate phrasing of the research objectives or questions is crucial for a study because they link the study design, methods and measures to a scientific purpose and context for interpretation of the findings. Table 8.2 specifies a number of methodological terms that are often used in the context of survey research. Box 8.1 provides an example of a survey study in six countries.

Table 8.2 Terminology in survey research

Survey (study)	Study based on a sample and using questionnaires
Questionnaire	Measurement tool in survey research
Concept	Theory-informed expression of phenomena. For measurement, abstract concepts need to be operationalised into concrete measures
Measure	The operationalisation of a concept. It can refer to a questionnaire or to a set of items within a questionnaire
Variable	Measured concept or phenomena that can show variation. Variables can be based on one or multiple items, and most studies include several variables
Instrument	Tool to measure a concept or phenomena. In survey research, it consists of a set of items. Most questionnaires include several instruments
Scale	Set of questions to measure (a domain of) a concept. An instrument can contain several scales. Note that this does not refer to 'answering scale' (e.g. five categories from 'agree' to 'disagree')
Item	Smallest unit of measurement, e.g. a single question in a questionnaire

Box 8.1: An International Survey Study on Patients' Self-Management (Koetsenruijter et al. 2015a)

The EUWise project is a study on how social support within networks from patients with diabetes can contribute to their health status and wellbeing. As study design, a survey study was chosen because the relevant concepts were not possible to measure using other methods, e.g. the use of claims data or direct observations. First, a theoretical model was developed in which the relevant concepts were defined. Next, a questionnaire was designed in order to measure the variety of relevant concepts. To measure the concept of health status, the validated instrument SF-12v2 was chosen. The SF-12v2 is a patient-reported measure of health status developed to measure disease burden and consists of 12 items. In the SF-12v2, health status is divided into two domains: a mental domain and a physical domain. To calculate a patient's score on both domains, six items per domain are combined into one scale. These scales are used in the further analysis to generate the study results.

8.3 Study Design, Study Population and Sampling

Survey studies can be used in all designs for empirical research in human populations, varying from cross-sectional studies to randomised trials. Many survey studies have a cross-sectional design, i.e. observational research in a defined study population at one point in time. For instance, nurses' views on patient safety may be examined in a one-off survey study. Many cross-sectional survey studies are descriptive, but some are analytical in the sense that they are guided by theory and may involve testing of hypotheses. In some cases, the study is repeated in the same study population, which means that the study is no longer cross-sectional but rather longitudinal. The latter design includes repeated measurements in the same individuals, recurring measurement in the same study population but different individuals, or a combination of the two. Survey research can also be used for the evaluation of interventions to provide data on primary and secondary outcomes, on potential confounders or on descriptive variables. For instance, patient-reported quality of life may be the primary outcome in the evaluation of a health intervention.

Typical for survey research is the inclusion of a sample of individuals instead of the whole population of interest. When designed and analysed well, this sample can be used to make inferences about the study population. The choice of study population follows directly from the study objectives, usually with additional restrictions for practical reasons. For instance, a study may aim to generalise to all physiotherapists in a country but then be restricted to a specific region from which they are actually recruited. The sampling frame describes the concrete source of names for recruitment (ideally as close to the study population as possible). The study sample describes the individuals who actually participated in the study by completing the questionnaires.

It is important to understand the statistical theory behind sampling participants into a survey study. Random selection from a sample frame (list of names) provides the best guarantee that the actual sample is representative of the study population. Besides fully random sampling, the sampling may be random within predefined subgroups or strata of the population (stratified random sampling) or purposefully oversampled in specific subgroups, for instance, if low participation rates are expected in a subgroup (probability sampling). In addition, it is relatively common for specific clusters to be included (e.g. hospitals) in which participants (e.g. patients or healthcare professionals) are sampled randomly (clustered random sampling). These are all variations of probability sampling.

In practice, random sampling is not always possible, for instance, if patients have to be approached over time when they attend a healthcare professional. It is important to carefully consider how the sample can be selected in such a way that it is still representative of the study population and no (selection) bias is introduced. For instance, patients who are frequent attenders of healthcare or patients with good experiences in healthcare may be included more often. If random sampling is not possible, alternative sampling approaches can be applied. Closest to random

sampling is systematic sampling: the selection of individuals from a list according to a pre-set structure (e.g. every second person). Other sampling methods include, for instance, sampling all attending patients after a randomly chosen point in time or sampling all health workers in randomly sampled healthcare organisations. Finally, convenience sampling may be applied (e.g. through close colleagues), which is most distant from random sampling and usually not generalisable. In many situations, it is helpful to collect descriptive data in order to compare the study sample with the study population.

Apart from the chosen sampling method, the size of the sample should also be defined. From an ethical and economic point of view, the aim is to include as many subjects in a study as necessary (and no more) to draw a valid conclusion. Before the study is conducted, a sample size calculation should be performed. Generally, a sample size calculation is dependent on the variation in the sample, desired level of accuracy and (in the case of hypothesis or intervention testing) the expected effect size and desired statistical power. In HSR, a statistical power of 80% is often considered acceptable, as is a significance level of $p < 0.05$. The variation in a sample is not always known upfront, but in some cases, it can be derived or estimated from other studies.

In addition to the statistical considerations in determining the number of participants in a study, the expected response rate should be considered. Low response reduces the statistical accuracy and power and often involves risk of selection bias. What a realistic response rate is strongly differs and depends on the study population and topic of the study. In general, response is higher among patients than it is among healthcare professionals (Meyer et al. 2020). There seems to be a trend of response rates in health research dropping (Cook et al. 2009; Galea and Tracy 2007). In patient populations, response rates vary roughly between 50% and 70% (Meyer et al. 2020; Sitzia and Wood 1998), while among physicians rates are generally lower ranging from 10% to 60% (Creavin et al. 2011; Cummings et al. 2001; Cook et al. 2009).

Generally, face-to-face and telephone interviews have higher response rates than postal questionnaires (McColl et al. 2001). In addition, there are a considerable number of ways to improve participation in survey research. For instance, small monetary incentives can improve response rates considerably, both prepaid and conditional upon participation (David and Ware 2014; Edwards 2002; Jemal et al. 2011; Koetsenruijter et al. 2015b). Other options to improve response rates are informing participants upfront about a study as well as following up with contacts and sending reminders (Edwards 2002; McColl et al. 2001). Short questionnaires and questionnaires that were of more interest to the participants also tend to have higher response rates (Edwards 2002). For healthcare professionals, pre-notifications and follow-ups have also proven to be effective (Brtnikova et al. 2018), as were incentives (Pit et al. 2014; VanGeest et al. 2007). Also, consider offering the survey instrument both on paper and online to offer the most convenient option to every potential participant (VanGeest et al. 2007).

Nevertheless, most studies will not reach a 100% response rate, and therefore, it is important to think about how to deal with nonresponse in advance. Statistical methods allow for differences between study sample and population to be adjusted, but the validity of those methods strongly depends on what information is available on the nonresponders and/or population of interest. At the very least, some background characteristics should be available on how the study sample relates to the population of interest. Ideally, some of those characteristics are also known for the nonresponders, so the researcher can check if the characteristics differ from the people who participated. Many interventions can be used to enhance response rates in surveys; Box 8.2 provides an example.

Box 8.2: Increasing Response Rates (Koetsenruijter et al. 2015b)
A proven strategy to increase response rates is monetary incentives. Participants receive a small amount of money when they return a completed questionnaire. However, the appropriate amount is not so easy to define. In a randomised controlled trial, four different monetary incentives (5.00 EUR, 7.50 EUR, 10.00 EUR and 12.50 EUR) were offered to patients with diabetes for completing a questionnaire. The results showed that response was highest among the 7.50 EUR and 10.00 EUR intervention arms and was lower for the 5.00 EUR and 12.50 EUR arms. This means that in certain situations higher monetary incentives are not only inefficient but also less effective.

8.4 Design and Pilot Test the Questionnaire

The questionnaire is the central tool in a survey study, so its design is of vital importance. The first task is to find out what concepts or other items need to be measured to address the aims of the study. This seems trivial, but there are usually several instruments (i.e. sets of questions) for a specific concept, and clarity on the concept helps in finding and selecting the relevant instrument. The time required for careful selection or development and pilot testing of a questionnaire is easily underestimated. For a typical study on health services, this requires several weeks to several months. In this section, we will not go into detail about how to design and validate questionnaires (see Chap. 11 for this topic), but we will discuss some key aspects and provide general rules that should be considered when designing or selecting a survey instrument.

The use of validated instruments is preferred over newly developed sets of questions, particularly for concepts that are central in a study. Some instruments are used frequently and are considered a gold standard in certain fields, e.g. the EQ-5D when measuring QALYs (quality-adjusted life years; Greiner et al. 2003). If no validated instrument yet exists, a non-validated but previously used instrument can be used, or (as a last option) a new set of questions must be designed. Many instruments have already been developed; therefore, it is a good advice to do a

thorough search before deciding to develop a new set of questions. There is no single database containing all survey instruments; therefore, getting an overview of the available instruments can be complicated. Apart from exploring existing databases (e.g. https://inn.theorizeit.org, https://guides.lib.uw.edu/hsl/measure), looking up similar studies and the instruments they used is a good way to start. Some questionnaires are validated in a different population and setting, so a judgement of its validity and applicability for the targeted study population and setting needs to be made. The latter task is not that straightforward and is highly dependent on the researchers' assessment.

In the design of a questionnaire, it is important to keep the targeted population in mind, for instance, regarding background knowledge and level of reading skills. Many questionnaires are too difficult for the targeted population. Apart from the wording in your survey, the layout can also contribute to the readability and ease of completing your questionnaire. Relating to the structure, it is advised not to start with the most sensitive questions to prevent respondents from dropping out. A safe start is asking for background characteristics like age, gender and other such items that might be relevant for your study. Also, some interesting topics could be addressed in the beginning of the questionnaire to foster the interest of the participant. Thematically organised sets of questions can also be used within a questionnaire to provide structure. By putting similar kinds of questions together, the respondent knows what they can expect in the block. For example, one block of questions could be related to health and comorbidities, whereas a second block might ask about social support.

After finishing the questionnaire, it is highly recommended to conduct a pilot test in the targeted population, even if the instruments have been previously validated or used. Any practice test, even in just a few individuals, is better than no test. A first test can be done, for example, by colleagues, but some testing should also be done in the population that will be aimed at in the study. Methods that can be used are normal completion of the questionnaire followed up by a debriefing session or the 'think aloud' method in which respondents verbalise the thoughts they have while answering the questions (see Chap. 11 for more information).

8.5 Data Collection and Data Management

Assuming that ethics approval has been received, the next logical step is to collect data by administering the questionnaire and integrating the data in an appropriate database. The administration of a survey can either be guided by a researcher as an interview or be self-administered by the respondent in an online or paper-based questionnaire. The advantage of a guided interview is that more complex questions can be included, whereas self-administered surveys need to be self-explaining. For example, in a study on social support networks, in a face-to-face interview, graphical prompts were used to map the support networks (Koetsenruijter et al. 2015a). Alternative to an in-person interview, a telephone interview can provide some of the

advantages of a guided interview at a lower cost and might therefore be more feasible. Although guided administration modes can have advantages, the majority of questionnaires in HSR research are self-administered. Traditionally, paper-based surveys are often used as they are low in cost and can reach almost all populations by mail or by hand delivery, for example, in GP practices. Online administration modes are becoming increasingly popular and offer some additional features to paper-based surveys. Among other things, they can reach a large population without much extra effort and without necessarily increasing costs. Data entry is not necessary as the results will be stored in a digital format, and web-based surveys allow for greater flexibility in the design of a questionnaire, e.g. including graphics and audio or personalising a questionnaire based on a respondent's previous answers.

It is good to be aware that the method for collecting data should be related to the population of interest as some methods are more suited for specific populations than others. For a young population, web-based questionnaires might be suitable, whereas in an older population, an in-person interview may be more feasible. Note that there are large differences regarding the usefulness of online surveys across countries. Also, one should consider how the questionnaire can be distributed. An online questionnaire is often distributed by sending invitations through e-mails. However, there are also examples where potential participants can access the questionnaire without a personal invitation. When using a paper-based version, the most common way is to send it by mail; however, it can also be done face-to-face or over the telephone by an interviewer. When the sample is selected through GP practices, one might have access to participants' home addresses but not e-mail addresses, thus restricting the mode of data collection. Table 8.3 provides a summary of the advantages and disadvantages of several modes of data collection.

After the data has been collected, answers should be entered in a digital format which can later be used to analyse the data. When a digital data collection format was used, the used software most often provides output in SPSS, CSV or Excel format. If a paper-based format was used, the answers have to be entered into a database either by hand or using a software programme to scan questionnaires. The

Table 8.3 Modes of data collection

Administration mode	Platform	Advantage	Disadvantage
Self-administered by participant	Online (browser/app)	Large samples; low costs; no data entry necessary	Limited access in specific populations, (computer) literacy required
	Paper-based	Large samples, wide reach to all populations	Complexity of questions limited, literacy required
Administered with guidance of research associate	Telephone or video call	Allows more complex questions; personal contact	Relatively expensive
	In-person interview	Allows complex questions; personal contact	Expensive

use of a codebook is recommended at all times to define which values relate to which answer category. In the simplest form, the resulting database contains one participant in every row and a new variable in every column. Unique identifiers should be used for every respondent. If clusters, e.g. practices, are relevant, an identifier should also be entered for every practice.

The last step before your dataset is ready for further analysis is the data cleaning. In this step, errors and irregularities in the dataset are identified and, if possible, corrected. If errors are not solvable because they are related to the answer given by the respondent, they should be considered missing values. Chapter 9 provides many recommendations on the design and validation of databases for research purposes, which also apply to survey research. As a general rule, study participants should always remain in the data file, and recoding of invalid or unlikely values must be avoided in the source file. Respondents who only answered a few questions (e.g. less than 5% of all questions) might be considered nonresponders and removed from the database. As with other steps, all changes made in this process should be documented. This phase of data management should provide a consolidated database that provides the starting point for all data analysis.

8.6 Data Analysis and Reporting

After collecting and cleaning the data, data analysis can start. We will present a global description of the approach in order to get started, distinguishing between descriptive and inferential statistics. The aim of this section is not to give a full introduction to the topic of quantitative data analysis but to sketch the most common analyses that are used for survey research.

It is good practice to start data analysis with a plain descriptive analysis of the collected data by calculating frequencies. In addition, indicators of central tendency (e.g. mean or median values) and dispersion (e.g. standard deviation, minimum and maximum values) are determined. Inferential statistics (for generalisation to a larger study population) do not play a role in this descriptive analysis. In some studies, the descriptive figures are the main result. In other studies, it helps the researcher to familiarise themselves with the data in order to prepare for further analysis. In addition, it provides a description of the study sample (the typical first table in research papers). A further aspect is the exploration of the presence of missing values, which have an impact on the strategies in further analysis.

The second step of data analysis may consist of data reduction to a lower number of variables, particularly of (multiple) items into (one or a few) predefined scales. Methods such as factor analysis and reliability analysis can be used to examine the validity and reliability of scales in the observed data. Many existing scales have predefined algorithms for the calculation of composite scores, some of which involve weighting of observed scores. It may be noted that data reduction does not imply validation because this requires dedicated research with samples that are not used for purposes other than validation.

The third step concerns the analysis of associations between variables and/or comparisons between groups, using quantitative methods such as regression analysis in combination with inferential statistics to generalise to the study population. The planned primary analyses are increasingly documented and registered before the start of data analysis to enhance the integrity of research. Many studies in HSR use a type of regression analysis that is a quantitative method to predict the values of a dependent variable ('outcome') on the basis of chosen independent variables ('predictors'). A major strength of regression analysis is that it allows one to rule out the (confounding) influence of other factors apart from the variables of interest. Most studies in HSR use frequentist statistics, but an increasing number of studies use Bayesian statistics. When interpreting the results of regression analysis, the effect size should be meaningfully interpreted rather than only testing the statistical significance. While statistical significance (using p-values) of effects and associations remain widely used, it is actually better to focus on confidence or credibility intervals as they express the uncertainty of findings more accurately.

The final step in data analysis is sensitivity analysis, which replicates the main analysis with smaller or larger changes in the baseline values of variables or assumptions. In this way, the robustness of the findings of the main analysis is examined.

Reporting on a survey study is the logical last step in conducting a study. As in all studies, it is recommended to use reporting guidelines that match the chosen study design (e.g. STROBE for observational research). In survey studies, it is particularly important to describe the questionnaire in sufficient detail (e.g. answering categories for all questions), to report the response rate and to interpret the findings in relation to the risk of selection bias. Finally, it is good practice to make the scripts for data analysis available for external review (e.g. as a supplement to the research report).

8.7 Conclusion and Perspective

Survey studies are widely used in HSR because they can provide insight into the opinions, knowledge and experiences of a population. The time and effort that is needed to design and conduct a survey study may be underestimated if the time to design the questionnaire is short, data are not well managed or the data analysis is only descriptive. A relatively new development is the use of smartphone-based data collection, which provides new opportunities (e.g. tailored questionnaires) as well as risks (e.g. unclear sampling frame). If a survey is simply put online and respondents participate by self-selection, the risk of selection bias is especially high, and there are strong limitations on the inferences that can be made. This practice of non-probability sampling is also under development, but as of this writing, the methods to generate reliable results are limited (Baker et al. 2013). The methods for quantitative analysis are also being continuously developed. Newer approaches include, for instance, the use of Bayesian statistics for the assessment of the accuracy of estimates.

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Chapter 9
Use of Electronic Patient Records for Health Services Research

Gunter Laux

Abstract An electronic patient record (EPR) is the systematised collection of a patient's digitally stored health information, usually supplied by healthcare professionals. Claims data are extracted from EPRs and are collected for the reimbursement of healthcare providers. EPR and claims data can be used for health services research. However, there are some immanent pitfalls that must be considered and managed when using claims data for research. One vital issue is that the use of claims data for HSR must be in accordance with current data protection law. Furthermore, claims data in research are secondary data, which means the data were not collected for answering a particular research question. Limitations that may be prevalent in particular claims data sets – especially in terms of validity – should be critically addressed.

9.1 Electronic Patient Records

A patient record is a repository of information about a single patient. This information is usually generated by healthcare professionals as a direct result of interaction with a patient or with individuals who have personal knowledge of the patient (or both). Among other things, it documents a patient's health problems and the treatments provided. Only in some settings, patients may add information to their records themselves. In most countries, patient records are now computerised. Patient records have a vital function in healthcare, particularly for enhancing information continuity in patient care (see Chap. 19) (Dick et al. 2022).

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The American Institute for Healthcare Management (AMIHM) defined five main functions of patient records (AMIHM 2022): (a) planning *patient care*, (b) *communication* among healthcare providers, (c) *legal documentation*, (d) verification for *billing and reimbursement* and (e) sources for *research and quality management*.

The disadvantages of paper-based documentation are obvious (Uslu and Stausberg 2008), and in the third decade of the third millennium most providers – with very few exceptions – use 'electronic patient records' (EPRs) that require computer software and hardware. Admittedly, computer software and hardware are a cost factor. Moreover, the skills for the correct handling of EPRs must be learned. From a technological point of view, EPRs are special applications to collect and store patient-related information of healthcare and associated services. A graphical user interface and a database backend are the minimum requirements of an EPR. Moreover, relevant classifications of information items (see Sect. 9.2.2) are available for use within EPRs.

Personal health records (PHR) can be generally defined as "electronic and lifelong records of health-related information that is provided and can be managed by an individual" (Park and Yoon 2020). Most PHRs are not integrated with EPRs, but they may allow for the transfer of information to EPRs. In a few settings (e.g. primary care in the Netherlands since the year 2020), patients can add information to their EPR themselves. PHRs enable individuals to take a more active role in their own health. Modern 'eHealth' approaches use state-of-the-art information and communication technology for trans-institutional healthcare purposes. Important subtopics of eHealth are health data sharing and telemedicine (Knaup et al. 2020). However, this chapter focuses on EPRs rather than PHRs.

The next section on 'claims data' addresses the data extracted from EPRs that are related to healthcare delivery costs. Mostly, these extractions are mandatory for healthcare providers in order to obtain reimbursement for their interactions with patients and the services delivered. It is important to remain aware of the fact that claims data are a subset of the data usually available in an EPR. An EPR contains additional items that would be of special interest for HSR (e.g. family anamnesis, detailed information on the course of diseases and laboratory values). However, these data are usually not exported for reimbursement purposes. Studies based on an entire information set available in EPRs pose a specific challenge: Different export interfaces for different EPR systems must be used, and the exported data have different structures. Thus, it is often laborious to export data at the level of every single practice or hospital. Finally, using this detailed information available in EPRs for HSR is difficult to apply without patients' individual consent.

9.2 Claims Data

EPRs are one of three widely used types of data in HSR (the other two are questionnaires and interviews). Basically, we can distinguish between 'primary data' and 'secondary data'. *Primary data* are generated by the researchers themselves via surveys, interviews or direct observations and are specially designed for addressing a particular research question. *Secondary data* are commonly defined as data not

collected for the purpose of answering a predetermined research question (Laux et al. 2014, Johnston 2014; Trinh 2018). 'Claims data' are a specific type of secondary data. Broadly speaking, *claims data* are administrative data on healthcare and are collected in the context of documentation of healthcare delivery costs (NICHSR 2020). This can be a shortcoming. For example, if only the occurrence of a patient at a particular healthcare provider is available but not the content of the consultation, obviously information is lost.

In Europe, healthcare expenses of many citizens are covered by relatively comprehensive health insurance or by general taxes. Therefore, these organisations play a major role in collecting and providing claims data. Numerous initiatives aim to enhance the availability and use of claims data for research purposes. For instance, the project 'Towards European Health Data Space' (TEHDAS: https://tehdas.eu/project) has the ambitious aim of developing joint European principles for the secondary use of health data (TEHDAS 2022). The work currently involves 25 countries. The cross-border sharing of health data has so far been project based, and there are no legal bases or common practices for the secondary use of health data in Europe. A lack of clarity and differing interpretations of the General Data Protection Regulation (GDPR) means that health data is being underused in research and decision-making. The project's vision for the future is that European citizens, researchers and communities will benefit from secure and seamless access to health data regardless of where it is stored.

In the following, we address general vital issues that should be considered by researchers in using claims data for their research.

9.2.1 Research Questions and Study Designs

Typical research questions in HSR that can be answered with claims data depend on the availability and the quality of data (Table 9.1).

Claims data are not sufficient to answer all questions in HSR (or health research broadly). Questions that concern the views of patients or healthcare professionals are not captured by claims data. For instance, it is usually not possible to use a suitable proxy for patient satisfaction in claims data. The availability and quality of health data in claims data is mostly limited, which reduces their usefulness for

Table 9.1 Examples of research questions that may be answered by claims data

Domain in HSR (2)	Research questions
Patients' perspectives	To what extent have the vaccination offerings for COVID-19 been used?
Healthcare providers	Is there a possible undersupply of medical specialists in a particular area, given geographical variations in the incidence of health problems?
Organisation of healthcare	How many different healthcare providers do patients see and is this associated with hospital admission rates?
Healthcare performance	Which treatment for a given disease is the most cost effective?

answering clinical research questions (e.g. the effectiveness of clinical interventions on specific health outcomes).

Data from EPRs can be used in various study designs. They have frequently been used in observational studies, such as cohort studies, case-control studies and cross-sectional studies. These may or may not involve the evaluation of interventions. They can also be used in randomised trials of interventions. The validity and feasibility of EPRs (and claims data derived thereof) need to be considered on a case-by-case basis.

9.2.2 Data Material and Measures

In many cases, claims data sets are available at the individual level. This is very advantageous compared with data from statistical offices that are mostly aggregated at regional or national levels. In comparison to studies based on primary data, the sample is already available, and there is no need for data collection. Typically, a sample size calculation is not an explicitly mandatory work step during the study. Nevertheless, often it is necessary to take a look at the number of potentially available cases in order to assess the size of the target sample. This can occur when the inclusion criteria for a particular study are very strict and the resulting sample is rather small. It may also be necessary if the time window of observation is rather large and dropouts during the observation reduce the sample size considerably.

Usually the claims data provided for HSR are highly structured because data structuring was done in the course of documentation for reimbursement purposes. The researcher usually starts the work by understanding the data structure and the underlying semantics. If data structure and semantics are recognisable, the researcher identifies – if not yet done – the part of the data material that is necessary for answering the research question.

Some data components are coded with well-defined classifications or nomenclatures. Whenever these are international, e.g. the ICD (International Classification of Diseases) (ICD 1993) for diagnoses or the ATC (Anatomical Therapeutic Chemical) classification (ATC 2022) for pharmaceuticals, research results can be directly interpreted internationally without mapping country-specific classification codes. SNOMED-CT (Systematized Nomenclature of Medicine-Clinical Terms) is an internationally standardised, multilingual vocabulary of clinical terminology that is used by physicians and other healthcare providers for the electronic exchange of clinical health information. The main difference between nomenclature and classification is that nomenclature involves naming organisms, while classification involves organising organisms in hierarchical series of groups. In brief, nomenclature and classification are two important aspects of taxonomy. For reimbursement of medical services, specific billing classifications may be applied. However, those are country specific, like OPCS (Office of Population Censuses and Surveys) used for

coding interventions and procedures within the NHS (National Health System) in Great Britain.

While classifications and nomenclatures have obvious advantages, they can also present problems. Misclassification and misnaming are ubiquitous problems that mostly occur when a particular classification/nomenclature does not fully reflect reality or when the coding/naming was simply done incorrectly. The research should explore the comprehensiveness and validity of the available data as thoroughly as possible before using them in research. This may be done within the available data set (e.g. check for pregnancies in men) and by interviewing experts, ideally health professionals who have filled the EPR with data.

There is no typical measure that is associated with data analysis based on claims data. The measures derived from claims data are determined by the research question. Many measures in claims data studies relate to one of the following categories: patients' health problems (e.g. diagnoses), services provided (e.g. tests, treatments, hospital admissions) and healthcare utilisation (e.g. number of interactions with healthcare providers). The measures for data derived from claims data are typically scaled at the nominal, ordinal, interval or ratio level (Table 9.2).

Examples

1. **How severe is a patient's heart insufficiency (HI)?** We would ideally be able to obtain this information from the ICD code that corresponds to the NYHA (New York Heart Association) stages:

   (1) 'No limitation of physical activity', (2) 'Slight limitation of physical activity', (3) 'Marked limitation of physical activity' and (4) 'Unable to carry out any physical activity without symptoms'. This is a typical example of an ordinally scaled measure.

2. **Which of three equivalent pharmacotherapy options is the most cost effective?** Based on the assumption that the three pharmacotherapy options would be equivalent in terms of effects, side effects and application, we would simply measure cost-effectiveness on the basis of manufacturing costs (e.g. in €). This is a typical example for a ratio-scaled measure. Statements like 'Option 1 is three times more cost effective than option 2' would then make sense.

Table 9.2 Scales of measures

Scale	Description	Type	Mathematical operations
Nominal	Names or categories without ordering scheme	Discrete	Counting and calculation of percentages
Ordinal	Data have an ordering scheme, but sums or differences do not make sense	Discrete	Counting and calculation of percentages
Interval	Data have an ordering scheme and sums or differences can be calculated. However, there is no true zero, and therefore, the calculation of ratios does not make sense	Continuous	Calculation of percentages, addition and subtraction
Ratio	An extension of interval level data with a true zero; calculation of sums, differences and ratios does make sense	Continuous	Calculation of percentages, addition, subtraction, multiplication, division and ratios

Claims data primarily relate to the presence and number of services, but in some cases these volumes can be used to construct measures of the quality of care. For this purpose, quality indicators may be developed. According to the AHRQ (Agency for Healthcare Research and Quality)

> Quality Indicators (QIs) are standardized, evidence-based measures of health care quality that can be used with readily available hospital inpatient administrative data to measure and track clinical performance and outcomes. (AHRQ, 2022)

Usually, quality indicators have a denominator that refers to a defined patient population or set of events and a numerator that relates to the number of desirable or avoidable events.

Examples

- The proportion of adult patients with diabetes mellitus type 2 who had at least four visits to the attending physician in the previous year (a recommended practice)
- The proportion of patients with analgesics who received opioids in the previous year (a practice preferably avoided)
- The proportion of patients with chronic heart failure who were admitted to hospital in the previous year (an event that may be avoided if ambulatory care has high quality)

9.2.3 Risk of Bias

Bias is a ubiquitous phenomenon in research and is not limited to using claims data for research. A violation of the *internal validity* occurs when a study result does not adequately reflect reality, e.g. due to incorrect documentation or imprecise measurement. Bias is also present when a study result (e.g. an explanatory model or statistical figure) is unrepresentative of the study population. Then the *external validity* is violated. There are many sources of bias and several ways of categorising them

(Pannucci and Wilkins 2010). This section elaborates on the types of bias that are most typical for HSR based on claims data.

Selection bias is an error that occurs due to the selection process of the sample when data is not representative of the target population. This issue is more likely the rule rather than the exception in claims data sets. If a big claims data sample is available, there are options to construct representative subsamples for the underlying research question. These methods are described in detail elsewhere (Milanzi et al. 2015; Dumicic 2011).

Example: A team of HSR scientists wants to obtain a representative overview on pharmacotherapy for patients with depressive disorders in primary care in Germany. For this, a claims data set of a big statutory health insurance would exist. The problem then is that the population of a particular health insurance normally differs from 'the average German population' (e.g. in terms of age, gender and socioeconomic characteristics). Moreover, privately insured patients are not represented.

As the name says, *misclassification bias* occurs whenever entities are classified incorrectly. In our context, misclassification occurs whenever individuals are assigned to a different category than the one they should be in. This can lead to incorrect associations being observed between the assigned categories and the outcomes of interest. Misclassification and measurement bias are usually not amenable to correction in claims data sets. It is therefore all the more important to be proactive in avoiding misaligned incentives that have the potential to lead to incorrect classifications.

Example: In order to report patients' health problems, well-defined diagnoses are used. Misclassification in terms of diagnoses is very frequent. Labelling a particular patient with a wrong diagnosis can occur due to misaligned incentives whenever reimbursement is linked to a certain morbidity level of patients (Schubert et al. 2010). Another type of misclassification can occur in off-label prescriptions. For particular drugs, specific indications – mostly defined by specific diagnoses – are necessary. The doctor wants to help the patient with the off-label prescription. Therefore, the doctor gives the (wrong) diagnosis in order to the justify the off-label prescription.

Measurement bias is most recognisable as a faulty measurement outcome from a faulty machine or device such as a computer or piece of electronic equipment. This type of bias is ubiquitous in research and not only restricted to HSR with claims data. However, the following example illustrates why this bias type can occur often in our research context. Uniform, adequate standards for diagnostic testing are a prerequisite to avoid measurement bias in our context.

Example: As shown above, data on patients' morbidity based in diagnoses are vital elements in HSR based on claims data. For many diagnoses, diagnostic tests are necessary (e.g. DNA testing) whereby medical laboratories are involved. In claims data sets, we often have situations in which different patients have received their diagnoses from different laboratories with different devices and maybe different quality standards. In contrast to experimental studies, where the researcher can control for the measurement quality, there is an increased risk for measurement bias in claims data sets.

9.2.4 Data Preparation and Analysis

Before data can be analysed, they must be properly prepared. The following steps are usually performed in the given order.

Obtaining Data: The organisation that provides claims data and the organisation that performs analyses in order to answer the research question in HSR are usually not the same. Frequently, a particular health insurance provides the data to a scientific institute, e.g. a department of a university. The claims data provider and the organisation performing the analyses have to clarify in detail the following questions:

What is the 'minimum data set' (MDS) in order to answer the research question? The MDS contains the data that is available and necessary to answer the research question but not more. This is essential beyond the background of required data economy.

What is the format of the claims data? In the third decade of the third millennium, we assume without reservation that data are available digitally. Both organisations have to determine in which format the data will be exchanged. Ideally, both organisations use the same type of database, and database dumps can be delivered. However, this is the exception rather than the rule. Still very common are 'flat files' as a format for data exchange, e.g. files with comma-separated values (csv), whereby data fields are separated by a predefined character. XML (eXtensible Markup Language) data formats are more sophisticated since structures and types of data are well-defined. Moreover, there are techniques to check data consistency with XML-based techniques (XML Schema). Regardless of which format is chosen, this has to be clearly agreed upon between the participating organisations.

Developing a database structure: The database structure determines the data storage for the study so that it can be accessed adequately in subsequent data analyses. There are generally two main options for storing data digitally: database programmes and statistical programmes. Usually database programmes are more complex to learn and operate, but they allow the analyst greater flexibility in manipulating the data. Independently from the form of storage, there should be a 'codebook'. A codebook describes the data and indicates where and how it can be accessed. At the minimum, the codebook should include the following items for each variable:

- Name
- Type (e.g. decimal number or string)
- Format (e.g. decimal with number with two decimal places or string with maximum length of 16)
- Description

Example: Let a claims data set consist of patient data and their diagnoses. Then we would define two database objects: 'Patient' and 'Diagnosis'. Generally, these objects are displayed as table within the codebook (Tables 9.3 and 9.4).

Perhaps one wonders why we use two tables and do not integrate both patient and diagnosis data into one table. The main reason is that patients do not have a predefined number of diagnoses. Some patients could have more than 10 diagnoses and some patients could have no diagnosis. Therefore, it is better to use two tables. The 'PatID' from the table 'diagnosis' references the patient in the table 'Patient'. This design avoids unnecessary null values as well as redundancies. The reader interested in database design can find easy-to-understand literature on websites or in books, e.g. from M. J. Hernandez (Hernandez 2020).

Table 9.3 Patient

Name	Type	Length/format	Description
PatID	String	32	Unique patient identification code
YearOfBirth	Integer	YYYY	Patient's year of birth
Gender	String	1	Patient's gender; m: male, f: female
ZIPcode	String	5	ZIP code of patient's place of residence

Table 9.4 Diagnosis

Name	Type	Length/format	Description
PatID	String	32	Unique patient identification code
DiagDat	Date	MM-DD-YYYY	Date of diagnosis
Diag	String	A##.##	Diagnosis coded in ICD-10

Importing data: Importing the data from the claims data provider into the database structure for analyses is a technical process and depends on the data format to be imported and the target database. Researchers unfamiliar with data management usually get support from data managers. It is important that all import steps are completed without errors or warnings. Therefore, the import process should be monitored. Normally, 'log files' are generated during the data import process. These files contain information on potential problems or successes and should be checked carefully by the person responsible for them.

Data quality assessment: Askham et al. proposed six primary dimensions for data quality assessment (Askham et al. 2013). These dimensions are also applicable to the verification of the data quality in claims data (see Box 9.1).

Box 9.1: Dimensions of Data Quality

- *Completeness* is defined as the proportion of stored data against the potential of '100% complete'.
- *Consistency* of data is defined as the absence of difference, when comparing two or more representations of a particular object against a definition.
- *Accuracy* is defined as the degree to which data correctly describes the 'real-world' object being described.
- *Validity* of data is given, if data conform to the syntax (format, type, range) of their definition.
- *Uniqueness* is given, if nothing was recorded more than once based upon how a particular thing is identified. It is the inverse of an assessment of the level of duplication.
- *Timeliness* is defined as the degree to which data represent reality from a certain point in time.

If possible, all six of these dimensions should be checked during the data quality assessment. However, the checks are more or less feasible.

Examples: Completeness can only be checked, if it is clear, what '100%' means (e.g. the total number of insurants in the data set). Consistency can normally be checked by rules. If, for example, a patient died in a particular year, there should be no more diagnoses for this patient in the following year. Accuracy is difficult to test in claims data since we assume that data more or less represents the real world. Only obvious flaws can be detected, e.g. a female patient with prostate cancer. If syntax including format, type and range of data element are clear, validity checks can easily be implemented. Therefore, we could, for example, exclude a patient with an age of <15 or an ICD-10 code not beginning with a letter. Uniqueness is quite easy to check by identifying erroneous multiple entries. The corruption of data timeliness is not easy to detect, unless obvious flaws can be detected in the claims data set (e.g. timestamps in the future).

Transforming data: Data transformation means to alter the structure and format of raw data as needed for data analysis. Transforming data also means to derive new information out of the existing data. Transforming data can be more or less complex. Usually statisticians or data managers are responsible for transforming data.

Examples: Let us assume that we would have a data set containing ICD-10 diagnoses up to the five-digit level. For our analyses, this could be too complex, and a three-digit level would be fully adequate. Then, a new truncated variable should be created. The variable with the five-digit level should persist in the database, if only to make the consistency comprehensible. Another example is to use mathematical functions for data transforming, e.g. to use log(costs) instead of costs, since cost data usually have a skewed distribution that may cause problems in analysing data.

Data analysis is the process of systematically applying statistical and/or logical techniques to describe and illustrate, condense and recap and evaluate data (RCR 2021). According to Shamoo and Resnik (2003), various analytic procedures 'provide a way of drawing inductive inferences from data and distinguishing the signal (the phenomenon of interest) from the noise (statistical fluctuations) present in the data'. For claims data analysis in HSR there is no 'typical' data analysis method. The best choice of methods depends on the research question, the study design and the characteristics of the available data (e.g. measurement level and presence of missing data). In descriptive studies, the distribution of possible values of measures is determined and described, ideally with indication of the accuracy of the descriptive figures (e.g. using confidence intervals). In most quantitative studies, however, associations between measures or differences between subgroups are examined with the purpose of testing hypotheses. In this situation, hypothesis testing techniques are relevant, such as regression analysis.

For instance, two or more subpopulations with different exposures and outcomes may be compared. Adjustment for potential confounders is vital in order to validly measure the association between exposures and outcomes. Multivariable regression techniques (Hidalgo and Goodman 2013) or matching procedures (Rosenbaum and Rubin 1983; Sekhon 2011) then can be considered. For longitudinal research questions with multiple measures over time, longitudinal data analyses methods should be applied (Das 2014). Moreover, there are numerous more or less complex data analysis methods that refer to specific research questions, e.g. survival analysis (Clark et al. 2003). HSR based on claims data should often consider that the data is clustered. Typically, patients are treated by doctors, and doctors work within an organisation (hospital, practice). Variance analyses must take this clustered structure into account (Lohr 2014), for instance, by using random-coefficient regression analysis.

9.2.5 Practical Aspects

9.2.5.1 Data Security

Data security aspects are not limited to EPRs and claims data. Whenever we deal with personal data, we must comply with current data protection regulations (see Chap. 4). The General Data Protection Regulation (GDPR) in Europe is indeed one of the toughest privacy and security laws in the world (GDPR 2018):

> Though it was drafted and passed by the European Union (EU), it imposes obligations onto organizations anywhere, so long as they target or collect data related to people in the EU. The regulation was put into effect on May 25, 2018. The GDPR will levy harsh fines against those who violate its privacy and security standards, with penalties reaching into the tens of millions of euros.

When processing process data, the researcher must do so according to seven protection and accountability principles outlined in Article 5.1–2:

1. *Lawfulness, fairness and transparency*: Processing must be lawful, fair and transparent to the data subject.
2. *Purpose limitation*: You must process data for the legitimate purposes specified explicitly to the data subject when you collected it.
3. *Data minimisation*: You should collect and process only as much data as absolutely necessary for the purposes specified.
4. *Accuracy*: You must keep personal data accurate and up-to-date.
5. *Storage limitation*: You may only store personally identifying data for as long as necessary for the specified purpose.
6. *Integrity and confidentiality*: Processing must be done in such a way as to ensure appropriate security, integrity and confidentiality (e.g. by using encryption).
7. *Accountability*: The data controller is responsible for being able to demonstrate GDPR compliance with all of these principles.

These principles are sensible and usually relatively easy to implement. However, there is an additional, explicit regulation in the GDPR that makes dealing with claims data considerably more difficult in comparison to the time before the GDPR came into force: You must adhere to strict new rules about the *consent from a data subject* to process their information.

- Consent must be ‘freely given, specific, informed and unambiguous’.
- Requests for consent must be ‘clearly distinguishable from the other matters’ and presented in ‘clear and plain language’.
- Data subjects can withdraw previously given consent whenever they want, and you must honour their decision. You cannot simply change the legal basis of the processing to one of the other justifications.
- Children under 13 can only give consent with permission from their parent.
- You need to keep documentary evidence of consent.

Example: Let us assume that we would have a claims data set containing data of 8 million insurants from a big health insurance in Germany. If these insurants did not give explicit consent to use their data, it will be – at first glance – not possible to use these data. So, what can we do?

There are two main options to use claims data without explicit consent from the particular individuals: 1. *Data aggregation*: Data is not delivered at the individual level, but aggregated, e.g. on the level of medical practices or at the level of certain age groups. However, aggregation leads to a loss of statistical power for quantitative analyses. 2. *Data anonymisation*: Fully anonymised data also prevent the consideration of the individual. Recital 26 of the GDPR specifies that data protection principles should not apply to anonymous information or to personal data rendered anonymous in such a way that the data subject is no longer identifiable. At first glance, this seems to be a good 'way out'. However, omitting names, addresses and other contact data is not enough.

Example: Let us assume that we would have a claims data set with names, addresses and other contact data omitted. Therefore, it is not possible – at least at first glance – to identify single patients. However, if we had individuals' diagnoses in the data set, then a patient with two rare health problems in combination with age and gender would be 'identifiable'.

9.2.5.2 Data Linkage

Claims data have the potential to provide a full picture based on data used for the reimbursement of healthcare costs. Nevertheless, researchers face certain limitations, e.g. lack of clinical data or patient reported outcomes. Also, similar data may be spread over different data sets (e.g. different health insurers). To overcome these limitations, claims data can be linked to other primary or secondary data sources (Jacob et al. 2017).

For many studies, a linkage to other primary or secondary data sets can be very important to close information gaps in order to adequately answer a particular research question.

However, rules on data protection can make data linkage a real challenge (see Sect. 9.2.5.1). It must be proven for each single use case if and how data linkage is possible and how it can be done.

Example: Let us assume that we would have a claims data set where data are aggregated or anonymised. Then a data linkage at the individual level is obviously not possible.

9.2.5.3 Handling Big Data Sets

One definition of 'Big Data' is data *so large, fast or complex that it's difficult or impossible to process using traditional methods* (SAS 2022). Therefore, we would not define most claims datasets as 'Big Data', since the handling of even very big claims data sets (e.g. millions of records) is not really a problem with existing hardware and software systems for the purpose of answering research questions properly.

Example: Let us consider 100 million individuals with overall 1 billon related diagnoses and 2 billion related prescriptions. This can be handled with sophisticated – but still traditional – IT methods.

Admittedly, in many cases, a database specialist should be involved in order to propose adequate components for scientific data management within the given context.

9.2.6 Reporting

Secondary data analyses – especially based on claims data – in health research have become more and more important. Therefore, explicit recommendations for standardised, transparent and complete reporting of secondary data analyses are important.

Between 2009 and 2014, the first proposal for a specific reporting standard for secondary data analysis was developed (Swart et al. 2016). Parallel to this national process in Germany, an international reporting standard for routine data analysis was initiated in 2013 with RECORD (Reporting of studies Conducted using Observational Routinely collected health Data) (Benchimol et al. 2015). The explicit aim was

> to improve reporting to ensure that readers, peer reviewers, journal editors, and other consumers of research can assess its internal and external validity. By improving the quality of reporting of research using routinely collected health data, we seek to reduce unclear research reports and achieve the tenets of the scientific process: discovery, transparency, and replicability.

RECORD proposes a checklist of 22 items, extended from the STROBE statement, which should be reported in observational studies using routinely collected health data.

Example: RECORD-ITEM 13.1 'Describe in detail the selection of the persons included in the study (i.e. study population selection), including filtering based on data quality, data availability, and linkage. The selection of included persons can be described in the text and/or by means of the study flow diagram'.

HSR researchers should take a look at the work of Swart et al. (2016) and Benchimol et al. (2015) for inspiration on adequate reporting based on routinely collected health data.

9.3 Conclusions and Perspective

Using 'claims data' for HSR can be very advantageous for the researcher, but they have limitations and pitfalls that should not be underestimated. While the data are available from the start of a study, it often requires a substantial amount of work to check and prepare the data for analysis. Moreover, using claims data must be in accordance with current – quite strict – data protection law. Already existing derogations for research should be sensibly expanded in order to guarantee both the use of data for research at the individual level and data protection for individuals. For the future, it can be assumed that health-services-related patient data will be recorded more extensively and in more detail. Therefore, we expect that claims data will even become more important for HSR. In conclusion, claims data should be used, analysed and interpreted in HSR as what they are: administrative data on healthcare that can shed light onto particular research questions that are eligible to be answered with those same data – no more, no less.

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Chapter 10
Social Networks Analysis in Health Services Research

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Abstract Social networks research has gained popularity in health services research in recent years. Social networks are one way to conceptualise and examine the role of social context in shaping phenomena. The connections between individuals (e.g. patients or healthcare providers) have been examined with a view on their structure, determinants and consequences. Studies found that network factors such as density of connections relate to health-relevant phenomena, such as the uptake of recommended practices by healthcare providers and health behaviours in patients. Social network research has specific features, which differ from many other quantitative studies. This chapter complements previous chapters by focusing on aspects of sampling, measurement and data analysis that are particularly relevant or unique for networks research.

10.1 Introduction

Healthcare providers, patients and other parties in healthcare transfer information, and they may collaborate in patient care. The transfers and interactions may be formally arranged in organisational structures (e.g. within a hospital), but many remain non-formalised and not directly visible, although they may be stable over long time periods. For instance, a physician may care for patients who are referred by a selected

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number of other physicians over many years of practice. Concepts and methods of social network analysis can be used to measure, map out and analyse the connections between individuals or organisations. Social networks analysis can be used to examine structures and processes of networks of patients, health workers and healthcare organisations as they pertain to health-related and other outcomes.

Research on the consequences of social networks is one way of examining how social factors influence healthcare practice and health outcomes. Social networks research can be used to examine the structure of connections between individuals (or other entities), their determinants and their consequences. The content of these connections may vary from transfers of information (e.g. a referral letter of one physician to another) to face-to-face interactions in a multi-professional patient care team. Relevant outcomes include, for example, patients' health status, health workers' job satisfaction and efficiency of healthcare delivery. The sources of data and methods for data collection are similar to other health services research (e.g. surveys, interviews and administrative databases), but the concepts, measures and (quantitative) data analysis methods are specific for social networks research. In addition, social network concepts have been used as 'sensitizing concepts' in a qualitative research design. This chapter, however, will largely focus on a quantitative approach to social networks, which was originally developed in mathematical sociology.

Section 10.2 will elaborate on concepts of social network research, which have been applied in health services research. Section 10.3 will highlight aspects of sampling of participants in social networks research. In the context of health, social network methods can be applied to healthcare providers (Sect. 10.4) and patients (Sect. 10.5). Data analysis in social networks research is described in Sect. 10.6. The final Sect. 10.7, provides conclusions and perspectives.

10.2 Theories and Concepts

The role of social networks has been conceptualised in different ways. Following Snijders et al. (2010), we would suggest that individuals and networks co-develop over time and influence each other mutually. Individuals create and adapt networks by starting and dissolving connections, which is usually an incremental process over a period of time. The emerging networks influence individuals' ideas and behaviours in several ways, which have been specified by a range of theories and concepts for social network research. The following theoretical notions theories seem particularly relevant for health services research:

1. *Contagion theory* specifies how ideas and behaviours spread in social networks, such as smoking behaviours in a population (Christakis and Fowler 2013). The mechanisms underlying contagion are related to social interaction and include, for instance, imitation of successful others, role modelling and social comparison. Social networks influence the impacts of these behavioural mechanisms through characteristics such as density, hierarchy and the presence of opinion leaders. In this approach, individuals tend to be considered passive recipients of social influences. Box 10.1 provides an example in the health field.

Box 10.1: Contagion of Health-Related Behaviours (Christakis and Fowler 2007)
Data from a longitudinal health-related cohort study in 1 city, covering 12,067 people over 30 years (1971 to 2003), were analysed to examine the spread of obesity (body mass index >30) in the population. A person's risk of becoming obese increased by 57% if they had a friend who became obese in a given time interval. Persons of the same sex had higher influence on each other than those of the opposite sex. As opposed to smokers, who moved to the boundaries of the social network in the city, obese people remained firmly embedded throughout the network.

2. *Negotiation theory* specifies how individuals make decisions in situations that involve uncertainty of outcomes and dependency on others, such as the decision of task allocation in a patient care team. The underlying mechanisms are specified by theories on social exchange and social games, which provide concepts such as mutual trust, altruism and free riding. Specific network characteristics (e.g. reciprocity and stability of connections) influence decision-making in these situations (Nowak 2012). This theory considers individuals as active decision-makers, who are constrained by external factors.
3. *Social capital theory* specifies individuals' access to valuable sources of information, emotional support, practical help or other resources from others (Song and Chang 2012). Social capital is the potential of an individual's network to provide such access. The role of weak ties (loose or indirect connections with people) in getting access to resources has been highlighted in this context. It considers individuals as actors who can actively seek information, emotional support, confirmation of individual identity or practical help. This theory has been used to examine social support of people, but it may also be relevant in other contexts.

The quantitative approach to social networks, which is grounded in mathematics, focuses on the structure and dynamics of connections rather than their content, meaning or value. Nevertheless, a meaningful interpretation of social networks depends on insight into the nature of the transfers between individuals. For instance, the members of a clinical team may all communicate with each other, but exchange of clinical information may be limited to a few members. The mechanisms that explain the effects of social networks on specific outcomes are not directly observed in social network research but tend to be assumed. In studies of human behaviour, these include comparison with relevant others and imitation of successful others. Table 10.1 provides a number of frequently used network measures. Network measures may be related to individuals (e.g. the size of an individual network), in which case the elicitation of values for measures is conventional. However, the added value of network research is primarily in the concepts that go beyond individual characteristics and relate to the wider network. The elicitation of values for such measures

Table 10.1 Examples of network measures

Measure	Description	Interpretation
Network size	Total number of individuals (or other units of interest) in a network	Indication for access to resources. Large networks may provide many resources but are costly to maintain.
Network density	Proportion of connections of all possible connections in a network	High density may enhance contagion of ideas and behaviours and coordination in dense networks might be better.
Betweenness centrality	Number of times an individual acts as a bridge along the shortest path between other individuals	Central persons have more social influence.
Homophily	Degree to which network members share common features	Based on contagion and selection mechanisms, network members tend to become more similar over time.
Opinion leadership	Individual who is frequently mentioned as opinion leader in a network	Opinion leaders can influence individuals' decision-making.

Freeman (1978) and Glegg et al. (2019)

typically requires a two-step procedure: Data are measured in individuals (or other lower-level units of interest), and then aggregated at network level to elicit values.

10.3 Study Population and Sampling Methods

The social networks of patients or healthcare providers have variable size, and their boundaries can be difficult to determine. One option is to focus on individuals' ego-networks (personal networks of directly connected individuals) and measure connections between the named others as perceptions of the included individual. This approach has been frequently used in population-based surveys. While the approach is certainly more feasible than studies that include a complete network, it does not use the full potential of social networks. An alternative is to define network boundaries pragmatically by focusing on visible units, such as a primary care practice or hospital department. This approach has the advantage that the network relates to a recognisable unit, such as a clinical department or home care organisation. A disadvantage of this approach is the exclusion of persons who might be relevant for the members in a unit but do not belong to it. A third option is to define network boundaries empirically, using snowball sampling (iterative sampling) until the network is completely covered. If a full dataset on connections is available, such as claims data that cover a large population, it may be possible to identify networks empirically through empirical analysis of clustering.

The data collection in studies of networks often requires that named individuals (or other units of interest) can be linked to other named individuals. This means that data collection cannot be done pseudo-anonymously, as this would make it

impossible to determine such linkages. Therefore, many studies of social networks require the participants to have a high degree of trust in the research team that the data will not be misused. Another challenge in network research is to achieve high participation rates because a high number of nonrespondents obviously reduces the possibility of establishing full networks. While nonresponse can be corrected in traditional methods, this is more of challenging in network research. For these reasons, it can be attractive to use existing datasets that include anonymous individual identifiers, such as administrative databases (see Box 10.2 for an example).

Box 10.2: Uptake of New Medication (Arnold et al. 2021)
This study used health insurance claims data in a longitudinal observational study to examine the effects of patient-sharing networks on physicians' uptake of a new ingredients' combination in the treatment of heart failure patients. Here, a network with physicians from different specialty groups as nodes and connections across five shared patients could be represented. After data extraction, social network analysis was conducted using statistical software R package igraph. Binary logistic regression with the outcome prescribing the new drug in the year 2018 and following network-related predictors – degree, betweenness centralisation, constraint and number of links to prescriber – showed that physicians with more connections to prescribers in the year 2017 were more likely to prescribe the new drug the following year. In addition, many connections to other physicians who were not mutually connected, as measured by constraint, positively influenced prescription. A strength of this study was that the sample size was the whole network of physicians practising in the state with few missing values of the individual variables. Limitations were related to the absence of information on the medical indication for prescribing the drug in claims data.

10.4 Research on Healthcare Providers' Networks

Besides description of the structure and characteristics of healthcare providers' networks, many studies on healthcare providers focus on the consequences of their networks for the uptake of (recommended) practices, the coordination of healthcare delivery or patient-relevant outcomes. Many studies in this field are observational and cross-sectional (Glegg et al. 2019). Frequently used network measures are degree centrality, tie characteristics (e.g. homophily, reciprocity) and whole network density (Glegg et al. 2019). Very few studies of provider networks are designed

as randomised trials, an exception being studies on the involvement of clinical opinion leaders in continuing education programmes (Flodgren et al. 2019).

An example of a study that explores the impact of healthcare provider networks is a study on patients with chronic heart failure who had been in hospital (Geva et al. 2019). It found that high provider connectedness was associated with lowered rates of rehospitalisation. This study was based on claims data on 1429 patients, of whom 333 had a rehospitalisation within 30 days after discharge from hospital. Provider connectedness (normalised degree) was the number of connections from a provider to other providers in the region divided by the number of other providers (excluding the index provider) in the region, expressed as a percentage. A logistic regression model was applied to adjust for comorbidities and other potential confounders.

10.5 Research on Patients' Networks

Social network research has been applied in many populations of patients or individuals at risk, including patients with infectious diseases (e.g. HIV) and patients with non-communicable diseases (e.g. diabetes; Valente and Pitts 2017). It has been used in public health research to examine various health behaviours, such as smoking and use of contraceptive medication. This body of research showed that network characteristics and health behaviours are correlated, but the causality is difficult to determine as most studies have been observational. Studies that used advanced quantitative modelling (e.g. stochastic actor-orientated models) suggested that contagion of ideas and behaviours and the incremental selection of network members underly homogeneity of health behaviours (e.g. the observation that most people in specific network smoke or do not smoke; Valente and Pitts 2017). Other studies have taken a social capital approach to the analysis of patients' networks; Box 10.3 provides an example.

Box 10.3: Social Capital of Diabetes Patients (Koetsenruijter et al. 2015)
This international study examined the impact of different types of support on health and health-related behaviours in patients with type 2 diabetes in six countries: Bulgaria, Greece, the Netherlands, Norway, Spain and the United Kingdom. An observational study (using interviews and questionnaires) was conducted, involving a sample of 1692 type 2 diabetes patients. Outcomes were patient-reported health status, physical exercise, diet and smoking. Random coefficient regression models were used to examine linkages with individual networks, community organisations and neighbourhood type (deprived rural, deprived urban or affluent urban). Patients had a median of three support connections, and 35% participated in community organisations. Controlled for patients' characteristics, large emotional support networks were associated with a decrease in non-smoking. Large practical support networks were associated with worse physical and mental health and less physical activity. Participation in community organisations was associated with better physical and mental health and, in patients with low income, with more physical activity. The consistent association between participation in community organisations and health status provides a clear target for interventions and policies.

Network interventions for patients or citizens specifically use or alter the characteristics of social networks to generate, accelerate or maintain health behaviours and positive health outcomes. These interventions may accompany other interventions and strengthen their impacts. A systematic review identified 27 randomised trials of social network interventions in health and 10 evaluations with other evaluation designs (Hunter et al. 2019). Four types of network interventions were identified: individual network interventions (use of network data to identify certain individuals to be recruited to act as proponents of behaviour change), segmentation network interventions (interventions directed towards groups of people clustered in a network), induction network interventions (activation of existing social ties in a social network to diffuse information or healthy behaviours) and alteration network interventions (changing the structure of the network by the addition of new members or breaking existing ties). A relatively large number of these studies on interventions were related to substance use or sexual health; positive effects were mainly found in the sexual health domain. It was difficult to separate the effects of the network interventions from the effects of other aspects of the interventions.

10.6 Data Analysis in Social Networks Research

The quantitative analysis of social networks often involves specific methods of data analysis that are not used in other domains of health services research. This is related to the specific structure of data in social networks research, which are essentially comprised of matrices in which both rows and columns represent individuals (or other units of interest), and the cells indicate whether a connection of interest is present. In most other types of health services research, rows represent individuals and columns represent measures (variables). The exception is survey research on ego-networks, which applies the conventional data structure (e.g. health surveys that include questions on social support). As a consequence, specific software for analysis of social networks is required, such as UCINET or R packages such as statnet and igraph.

A first step in social network analysis (some studies may not go beyond this) is the description and visualisation of a specific network. Network measures such as density can be calculated for each network. This step does not involve statistical testing of network characteristics, but the findings can inform interpretation and be used in further analyses that involve statistics. Figure 10.1 provides an example of a network visualisation. The density of an individual support network may be included as a predictor of health status, using regression analysis. Such analysis should consider the multilevel structure of the data.

Further analyses of social networks require specific expertise in advanced quantitative data analysis and are only briefly outlined here. Some studies involve network data and data on affiliations (e.g. memberships of organisations or participation in events). If repeated measurements of a network are conducted,

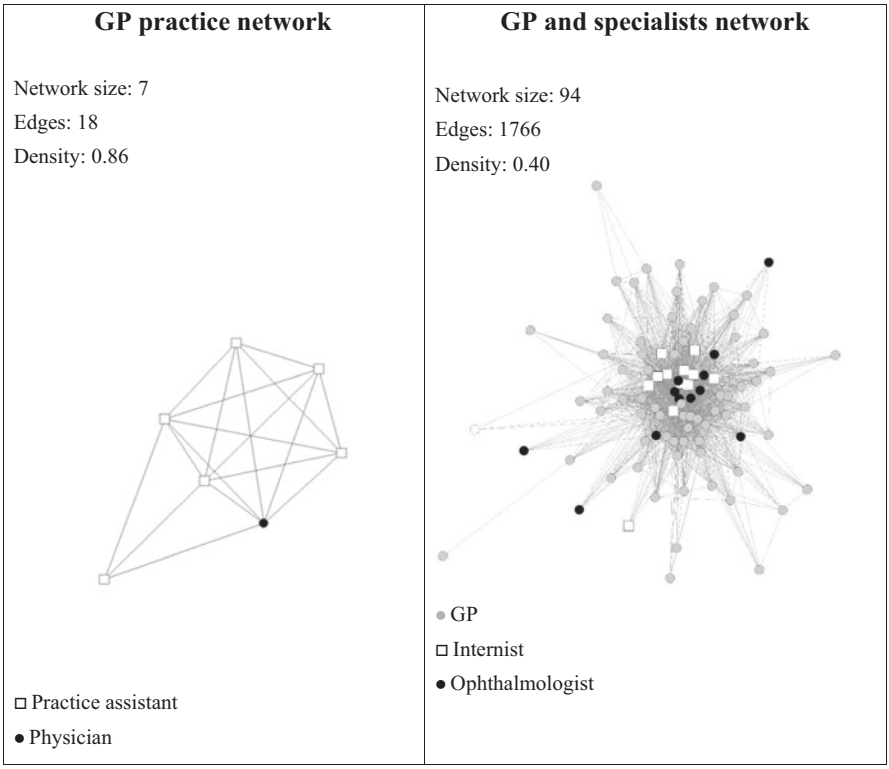

Fig. 10.1 An example of a network visualisation

changes in network structure and network effects over time may be analysed using advanced methods, e.g. exponential random graph models (ERGM). As opposed to the methods used for network description and visualisation, these and other methods involve statistical testing.

10.7 Conclusion and Perspective

Social networks research in health has gained increasing interest in recent years. Many studies in this field are observational, but there is a growing body of research on network-related interventions, mainly for improving health behaviours in patients and populations (Smit et al. 2020). Future research should focus more on the mechanisms underlying the impacts of networks in health by using quantitative analysis methods and randomised trials of network interventions. In this context, it is crucial to consider the content and meaning of the transfers between individuals on which the networks are based. For this purpose, future research should build on substantive

fields, such as conceptual frameworks for knowledge implementation or for social support of patients' self-management.

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Chapter 11
Development and Validation of Questionnaires in Health Services Research

Katja Krug and Michel Wensing

Abstract Most health services research is based on structured measures, particularly questionnaires, that facilitate quantitative analysis. To arrive at scientifically sound results, these measures should be valid and reliable regarding the concepts or phenomena to be measured. Although there are many validated measures available, studies may require new tools with a more precise focus on the particular objective. Validation requires systematic empirical research, which involves both qualitative and quantitative research methods. Validity is essentially the ability to measure what is intended to be measured, while reliability (a precondition for validity) is the ability measure something consistently. Sensitivity of a measure to (real) change has been described as a third important measurement property.

11.1 Introduction

In health services research (HSR), many studies aim at describing the status quo or detecting impacts of an intervention, i.e. in health-related quality of life of patients, in quality of care or in service providers' cooperation. To that purpose, measures that generate structured and quantifiable data are needed. Measures include questionnaires (i.e. for self-reported or by-proxy assessment of subjective topics) and data-extraction protocols (i.e. documents, queries for evaluating quality of care) and data generated by technical applications (i.e. using electronic medication packaging to assess medication adherence). The focus of this chapter will be on the

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development and validation of structured measures for HSR, especially questionnaires. Related topics, such as sampling and data collection procedures, are covered in Chaps. 8, 9 and 10.

As a first orientation, Box 11.1 presents key characteristics of good measures. Fundamentally, the quality of measures needs to be considered with respect to the purpose of a specific study. For instance, the primary outcome in an intervention study needs to meet different (potentially higher) standards than a measure of one of the background factors.

Box 11.1: Characteristics of Good Measures
- The measure addresses relevant topics in the study.
- The measure adequately reflects what it is supposed to measure.
- The measure provides precise data.
- The interpretation of the data is straightforward.
- The data allow an answer to the research question.
- The measure detects relevant changes in the outcome or the factors of interest.
- The measure is available and easy to apply and analyse.

HSR uses methodological concepts from psychology and epidemiology to describe criteria for measurement quality. Main quality criteria for measures, also called properties, primarily relate to validity and reliability. Other criteria, such as sensitivity to change, may be relevant in specific contexts of application.

Validity

Within the last decades, the concept of validity has evolved to a general standard which subsumes various approaches. Now, validity generally "refers to the degree to which evidence and theory support the interpretations of test scores for proposed uses of tests" (AERA et al. 2014, p. 11). Thus, validity of a measure is not given per se but connected to the purpose of the measurement. Validation is an ongoing process. Applying a measure for a new purpose or in a population not yet observed calls for new validity evidence. Otherwise, consequences drawn from the results need to be interpreted cautiously. Evidence for validity of a measure has at least three main aspects: content validity, criterion validity and the internal structure of the measure.

Validity evidence related to content refers to a comprehensive illustration of the aspect of interest. Considering content-related validity evidence is of major importance in developing a measure. It involves consultation with experts and stakeholders (e.g. in qualitative studies) to examine content validity of measure.

Test-criterion relationships may cover different aspects: convergent or discriminant validity evidence and concurrent or predictive validity evidence. Convergent validity evidence refers to measures assessing a similar aspect of interest; discriminant validity evidence allows distinctions between concepts. Concurrent validity evidence applies if the aspect of interest occurs at the same time (concurrently) as the measurement. Predictive validity evidence applies if the aspect of interest occurs in the future (after

the measurement). In HSR, concurrent validity evidence plays a major role in assessing structures and processes, i.e. waiting times in practices and hospitals or documentations, which are easier to assess by questionnaire than by (the more accurate) direct observation. Predictive validity evidence is of paramount importance in identifying facilitating aspects and risk factors for events in the future, i.e. the degree of compliance with patients' wishes in the presence of a DNR (do not resuscitate) order.

Internal structure of a measure refers to the domains of content, which are hypothesised and empirically verified. For instance, a measure of patient experience in healthcare may cover two domains: the experience with a particular healthcare provider and the experience with the organisation of care. The example illuminates that this criterion is close to content validity.

Reliability

Reliability describes the precision of a measurement. It "refers to the consistency of scores across replications of a testing procedure" (AERA et al. 2014, p. 33). Reliability is a necessary, but not sufficient, prerequisite for validity. The interpretation of the results of a measure as intended (validity) can only be trustworthy if those results are precisely assessed. On the other hand, reliability does not guarantee validity.

Reliability is usually described as coefficient based in classical test theory (CTT) or item response theory (IRT). In CTT, the assessed score consists of the true score and random error. The smaller the random error, e.g. when scores in replications are similar, the higher the reliability. IRT uses functions that classify single items from which a conclusion about the extent of a latent trait ('ability') can be drawn. For high reliability, replications of the identified function would lead to a similar conclusion.

Sensitivity to Change

Sensitivity to change (sometimes described as responsiveness to change) is the ability of a measure to identify actual changes and is most relevant for measures that are used to detect anticipated changes or effects of an intervention.

The remainder of the chapter describes the main issues to be considered during the process of developing and validating a measure, focusing on questionnaire development and validation. Although the example of patient-reported outcome measures (PROMs) is often used for illustrative purposes, the principles apply to all questionnaire-based assessments, i.e. clinical outcome assessments (COAs), observer- and clinician-reported outcome measures or measures for implementation outcomes (Mettert et al. 2020).

11.2 Development

11.2.1 Preliminary Aspects

Since the development and validation of new measures is a task not easily undertaken, a thorough literature research for already available measures is mandatory. Before developing a new measure for a specific question, a thorough review of

available and validated measures is recommended. For example, for patient-reported outcomes, PROQOLID, the *Patient-Reported Outcome and Quality Of Life Instruments Database* (https://eprovide.mapi-trust.org/about/about-proqolid) and the Consensus-based Standards for the selection of health Measurement Instruments (COSMIN) initiative (https://www.cosmin.nl/) provide overviews of available measures.

Even if relevant measures exist, additional validation research may be necessary, for example, in cases where:

- Initially no validation was done. No information on precision and validity evidence is given. Results of the measure cannot be interpreted with respect to the purpose of assessment.
- Crucial parts of the validation are not up-to-date, e.g. theoretical assumptions or models on which the purpose of the measure is based were developed further.
- The measure is applied in another format, e.g. web-based instead of paper-based, which may lead to a different precision in assessment.
- A different target population is assessed, e.g. a measure was developed and validated with general practitioners but is now intended to be used with trainees.
- The measure has to be translated from another language. Translation processes may lead to imprecision and shifts in meaning. Additionally, cultural adaptations may be necessary. Depending on the purpose of the measure, the setting also has to be considered, e.g. different healthcare systems when assessing aspects related to health services.

If the decision is made to develop a new measure, its aims need to be clearly defined. At the beginning of the process of developing a new measure, defining the aim of the measure involves answering the following questions: What exactly is intended by applying the measure? How can the aspect of interest and/or its extent be observed? For some aspects of interest, these questions are easier to answer than for others, depending on their complexity. For example, compared to sociodemographic characteristics, i.e. age and gender, more complex issues, i.e. health-related quality of life, need an explanation and definition. A common understanding of the issue to be measured is a prerequisite for assessing validity evidence.

Content-related validity is crucial in the development of a new measure. To achieve a comprehensive understanding of the aspect of interest, a conceptual framework needs to be identified or defined, published relevant research extensively reviewed and qualitative research with experts and stakeholders conducted. A well-conducted design process improves content-related validity, e.g. to avoid construct underrepresentation, which can lead to important aspects of the desired outcome being missed. Box 11.2 provides an example of a questionnaire based on a theoretical model. The Patient Assessment of Chronic Illness Care (PACIC) assesses chronic care based on the Chronic Care Model (CCM Wagner et al. 2001).

Box 11.2: Example of a Questionnaire with Underlying Predefined Dimensions

The Patient Assessment of Chronic Illness Care (PACIC, Glasgow et al. 2005) for assessing chronic care defined by the Chronic Care Model (CCM, Wagner et al. 2001)

CCM dimension	Definition
Health system/ organisational Support	Create a culture, organisation and mechanisms that promote safe, high-quality care
Clinical information systems	Organise patient and population data to facilitate efficient and effective care
Delivery system design	Assure the delivery of effective, efficient clinical care and self-management support
Decision support	Promote clinical care that is consistent with scientific evidence and patient preferences
Self-management support	Empower and prepare patients to manage their health and healthcare
Community resources	Mobilise community resources to meet needs of patients

PACIC scale	Definition	Example item
		When I received care for my chronic illness over the past 6 months, I was
Patient activation	Actions that solicit patient input and involvement in decision-making	given choices about treatment to think about.
Delivery system/ decision support	Actions that organise care and provide information to patients to enhance their understanding of care	shown how what I did to take care of my illness influenced my condition,
Goal setting	Acquiring information for and setting of specific, collaborative goals	encouraged to go to a specific group or class to help me cope with my chronic illness,
Problem-solving/ contextual counselling	Considering potential barriers and the patient's social and cultural environment in making treatment plans	helped to plan ahead so I could take care of my illness even in hard times,
Follow-up/ coordination	Arranging care that extends and reinforces office-based treatment and making proactive contact with patients to assess progress and coordinate care	contacted after a visit to see how things were going.

Even if a specific explanation and definition is given, people may still have varying objectives associated with the same issue. For a patient with lung cancer, breathlessness is a more important aspect of health-related quality of life than for a patient with diabetes. Therefore, it is worthwhile to not only define the aim of the measure ('what?') but also to identify the target population ('to whom should the measure apply?').

11.2.2 Item Development

The challenge of measuring constructs, theories or models lies in their operationalisation: translating definitions into observable and measurable units. These units may cover one or more dimensions leading to unidimensional or multidimensional measures.

Based on the definition of the measurement aim and the dimensions covered, an extensive item pool of potential questions for the measure is generated. The item pool should comprehensively cover all aspects of interest. At this stage, probable repetitions of content due to different wording increase the likelihood of choosing the most appropriate expression later. While gathering potential items, precise and unambiguous wording needs to be considered; the item should cover only one issue and negative formulations should be avoided. For users, imprecise wording and multiple aspects in one item leave room to unintentionally focus on the answer options and thus provoke unwanted measurement error. Observing these 'rules' for item formulation (i.e. precise and unambiguous wording), a standardised application and instructions for scoring and interpreting the results support precise measurement, minimise measurement error and thus enhance reliability.

For example, answering an item like 'I do not take the medication prescribed by the general practitioner because I have experienced side effects' with 'I do not agree' may refer to behaviour related both to medication use (i.e. 'I do not agree because I always take the medication'), the prescriber (i.e. 'I do not agree because the general practitioner did not prescribe my medication') and other experiences with medication (i.e. 'I do not agree because I have not experienced side effects but am not able to swallow the pills'). Depending on the aspect of interest to be measured, the question might be split in multiple questions covering one aspect each.

The user's interpretation of item wording can be observed in a 'think-aloud' protocol, also called cognitive debriefing or cognitive interview. Potential users of the measure are asked to verbalise their thoughts while filling out the questionnaire. Thus, different foci and interpretations across users can be identified and items rephrased for clarity and unambiguity. It is recommended to include five to eight persons in cognitive debriefing (Wild et al. 2005); if more adaptions are necessary, the sample for cognitive interviews may be larger (Boateng et al. 2018).

11.2.3 Answer Options, Instructions and Layout

A measure consists not only of the items themselves but also of item-related response options and instructions. The choice of response options triggers the analysis of the measurement and potential conclusions which can be drawn from the results. In healthcare research, two kinds of response options are most frequently

used: numerical scales and free-text response. *Numerical scales* offer a range of prestructured display options. The most commonly used are categorical response scales and numerical rating scales, especially Likert-type scales, but other scales use rankings or counts (e.g. the number of healthcare assistants working in a practice). Categorical scales include binary answer options ('yes'/'no') and multiple categories for which one or more options can be chosen. Most sociodemographic variables, i.e. gender, educational level or income, are assessed by picking one option out of several offered. Multiple responses ('please choose all that apply') are used to assess items such as comorbidities, medications used or healthcare providers contacted by patients.

A numerical rating scale in a questionnaire implies a subjective assessment. There are usually no right or wrong answers; the focus lies in most cases on the individual experience or attitude of the respondent (performance tests pose an exception). As a subtype of numerical rating scales, Likert-type scales allow distinct responses on an interval scale. There are equal distances between the response options which allow the calculation of means and sums for analysis. Typically, Likert-type scales only provide anchors at the extremes (i.e. 'not at all' – 'always') without labelling the answer options in between. In recent years, scales with all answer options labelled (i.e. 'not at all' – 'often' – 'always') are also called Likert-type scales. In this case, the use and interpretation as an interval scale are part of the validation process.

Free-text responses can be used for questions which ask for a more elaborate answer (i.e. in addition to a numerical scale, 'please give reasons for your answer'). They also provide an option if a categorical response scale does not include a category that fits for the respondent (i.e. 'other – please specify'). While free-text responses allow respondents more detailed answers, their analysis may be effortful. Depending on the research question, free-text responses should be used sparsely as other qualitative methods may have more merit for answering the research question (also see Chap. 7).

11.3 Validation of Measures

11.3.1 Item Selection for (Pre)Final Version

Before focusing on reliability and validity evidence of a measure, the measure needs to be refined. Approaches to ensure content validity (definition of constructs, conceptual frameworks, literature review, qualitative research) are used to gather a pool of suitable items. The item pool generated during the item development phase usually comprises more items than necessary for achieving the goal of measurement. Several items will cover the same aspect using different phrases. The item selection phase aims to select items for the final questionnaire. Developers have to find the balance between identifying the items needed for a reliable and valid measurement of the aspect of interest and providing an acceptable measure which meets user

needs, i.e. practicability, time constraints and resources. Pilot studies with a sufficient number of participants are needed at this stage.

Analytical approaches to select items based on CTT include the analysis of item descriptive statistics, internal consistency and item-total correlation. A sufficient sample of users from the target population needs to provide answers to the item pool. Descriptive statistics can be made for all numerical scales. Depending on the scale level, this includes absolute and relative frequencies, mean with standard deviation and/or median with interquartile range. Items with strong floor and/or ceiling effects may be deleted; items covering the whole spectrum of answer options may be selected for the final version of the questionnaire. Internal consistency describes the mean intercorrelation of all items of a (sub)scale on interval level (i.e. Likert-type scales). The parameter for the whole scale can be compared to the internal consistency of the scale without the respective item. Items which worsen consistency values when included are potentially less precise than the other items concerned and may be excluded from the final version. A similar approach is the analysis of item-total correlations. Each item is correlated with the sum (or mean) score of its respective (sub)scale. Items with low correlations contribute less and could potentially be deleted. Low correlations also hint to imprecise expressions and ambiguity in the items.

Questionnaires that are based on IRT are mainly performance measures, such as knowledge tests. They are mostly based on multiple-choice items leading to dichotomous answers (Baker and Kim 2017). Each item has its item characteristic curve depicting the probability of 'solving' the item depending on the 'ability' of the person answering the item. Easier items have a higher probability of being solved; for more difficult items, a higher person ability is necessary. Next to item difficulty, the ability of the item to discriminate between less able and more able persons can be drawn from the steepness of the curve: the steeper it is, the higher the item discrimination. Items that are too simple (everyone can solve them) or too difficult (no one can solve them) do not inform about the ability of the person. Those items could potentially be deleted from the final version. Still, the questionnaire should comprise items of varying difficulty to allow discrimination at the extremes. In addition, items with a high item discrimination are preferably included in a measure. Higher item discrimination allows for a more precise differentiation between ability groups.

After the analysis and before usage and further validation, the prefinal version should again be piloted with cognitive debriefing in a sample of the target population. Any changes to items, answer options and instructions ideally lead to an iterative process of re-evaluating the questionnaire. The focus of the validation process lies on determining reliability and validity evidence of the measure for the intended purpose. Other issues could be important depending on the aim of the measure, i.e. for a diagnostic test, sensitivity and specificity are of paramount importance, while the user of a clinical outcome measure is interested in detecting improvements over time due to an intervention.

11.3.2 Assessing Validity

For the validation process, the validation sample is drawn from the target population and optimally representative for the population. The sample size needed depends on the method used (examples are given in the text). Validation studies aim at providing evidence for the reliability of a measure and the validity of the data assessed for a specific purpose. Data assessed in validation studies do not allow for conclusions to be drawn about the content of the findings since they have a different focus, e.g. the validation of a quality-of-care questionnaire in hospitals and general practices does not include assessment of differences between practices and hospitals. While content validity aspects were discussed for the development of a measure, test-criterion relationships and the internal structure are the focus of providing validity evidence before usage of a measure.

The test-criterion relationship can be assessed by examining the association between the scores obtained by the newly developed measure and the criterion of interest which could be assessed by observation (did/did not occur) or by an already established and validated measure, the gold standard for measuring the aspect of interest. A strong association between measure and criterion indicates high validity evidence. Since the maximum validity level achievable corresponds with the reliability of both measures used, the observable validity of the newly developed measure may be lower than the actual validity for the intended purpose – if the gold standard is less reliable than the measure to be validated. Concurrent criterion validity can be assessed in cross-sectional studies; predictive criterion validity calls for a longitudinal study design.

The internal structure of a measure developed based on a theory or a model (construct) can be assessed by comparing the observed empirical model with the theoretical model using regression analysis, e.g. structural equation modelling (SEM), or confirmatory factor analysis (CFA). The theoretical model comprises the items and their relation to underlying factors. High validity is observed if the structure of the theoretical model is mirrored in the empirical data. The goodness of fit of the model to the data is assessed by various indices, i.e. the comparative fit index (CFI), Root Mean Square Error of Approximation (RMSEA). Factor analyses require a larger sample size. Recommendations differ: from 200–300 participants to at least 10 participants per item to at least 1000 participants to achieve excellent results (Boateng et al. 2018). SEM requires large sample sizes depending on the complexity of the model (Wolf et al. 2013).

The validity of a measure developed based on the collection of various aspects of a topic (content) can also be explored using exploratory factor analysis (EFA) or other methods. These methods do not require a predefined internal structure but use statistical criteria to identify the internal structure. EFA allows the identification of the newly developed questionnaire as a unidimensional or multidimensional measure. In multidimensional measures, each item refers ideally to one dimension (factor). Items loading on the same factor are connected in their empirical values. High content validity based on an EFA additionally needs content justification: Under

which heading can the items of one factor be summarised? A heterogenous mixture of items in one factor may be indicative of an arbitrary and random factor solution due to the sample used. Confirming the structure found by EFA in a second independent sample using CFA strengthens validity claims.

11.3.3 Assessing Reliability

For test-retest reliability, assessments in the same sample with the same measure at two time points are required (cohort study). The coefficient to be calculated depends on the scale level used in the measure. For measures used in HSR, intraclass correlation coefficients (ICC) or Pearson correlation coefficients (r) are the most frequently reported test-retest reliability parameters. For determining reliability via a retest, the aspect of interest needs to be stable over time. For an unstable characteristic, a low correlation between test and retest results may be due to an actual change in the characteristic or to a low reliability of the instrument (high proportion of measurement error if the characteristic did not change after all). To interpret test-retest reliability, the time interval between tests is crucial. If the interval is too long, the aspect of interest might have changed in the meantime; if the interval is too short, training or memory effects may influence response behaviour. Memory effects occur if participants remember their responses from the first assessment with the measure.

In contrast to test-retest reliability, a measure can also be required to show sensitivity to change. Sensitivity to change is also assessed in cohort studies. For patient-reported outcomes, patients can give either a subjective impression of how they experienced the development of the aspect of interest between first and second assessment, or they can give objective parameters indicating the aspect of interest that is assessed concurrently to the measure to be validated. Experiences and differences between assessments can be correlated with the observed differences in the measure to analyse sensitivity to change (Box 11.3).

Box 11.3: Sensitivity to Change of the MYMOP (Measure Yourself Medical Outcome Profile) (Hermann et al. 2014)

The MYMOP aims at assessing therapeutic effects for medical concerns defined individually by the patient. As part of the questionnaire, patients evaluate their concerns on seven-point Likert scales. To evaluate its sensitivity to change, patients were asked to evaluate their concerns and give an overall impression of how they had improved four weeks later. In a sample of 476 patients in primary care, a mean change of 0.5 points indicated no change, 1.3 points little improvement and 2.2 points large improvement.

A further commonly used reliability indicator is internal consistency (already described in the context of item selection, see Sect. 11.3.1). For reliability purposes, it is mostly given as Cronbach's alpha. Internal consistency can be assessed for unidimensional and multidimensional measures. Cronbach's alpha is usually calculated and reported for each dimension separately. Alternatively, the more robust McDonald's omega coefficient is increasingly applied for assessing reliability (Dunn et al. 2014). An advantage of reporting internal consistency for reliability is that it can be determined in cross-sectional studies. In any case, a sufficient sample size is needed for assessing reliability depending on the reliability coefficient aimed at and the related study design (cohort or cross-sectional study).

Another important type of reliability is rater agreement. Inter-rater or intra-rater agreement applies to clinician- and observer-reported outcomes, especially for diagnostic tests. The result of a diagnostic test is usually the decision about the allocation to a predefined category (i.e. infected/not infected, no/mild/severe expression of a disease). High concordance of category allocation between different raters (inter-rater agreement) or repeated allocation of the same raters (intra-rater agreement) suggest high reliability of the category system. Concordance is assessed by Cohen's kappa or intra-cluster correlation coefficients.

11.3.4 Population-Based Measures: Norms/Standardisation

Usually, the separate items of a questionnaire are combined into one or a few scores. To interpret results of a newly developed questionnaire, calculation of the score may be set and norms for comparison defined. The calculation of the score is part of the validation process. Most often, simple sum or mean scores are used. There are examples of more elaborated weighted sum scores that include all items weighted according to their relevance or prognostic ability. Prominent examples are the quality-of-life questionnaire Short Form SF-12 Health Survey and the EuroQol instrument EQ-5D (Coons et al. 2000) (Boxes 11.4 and 11.5).

Box 11.4: SF-12
The SF-12 comprises 12 items on two dimensions (physical and mental summary score). The items were selected from the item pool of the SF-36 and are not simply summed up but weighted to highly correlate with the original SF-36 physical and mental summary score (Ware et al. 1996). Regression models to identify items and weights differ slightly across countries (Gandek et al. 1998).

Box 11.5: EQ-5D
The EQ-5D is a preference-based measure covering five aspects (mobility, self-care, usual activities, pain/discomfort, anxiety/depression). Originally providing three answer options to each aspect, a five-answer-option version was developed to address ceiling effects. Answer options are combined to a health state including the individual answers, e.g. '11111' for the best health state possible or '31211' with limitations in mobility and usual activities. To allow comparisons with population-based norms, value sets were created using time trade-off and discrete choice experiments for both EQ-5D versions (Devlin et al. 2018).

The definition of norms depends on the purpose of the measure. For diagnostic measures, cut-offs are defined based on known groups (i.e. patients with and without depression) and providing sensitivity and specificity values. The optimal cut-off value can be defined using receiver operating characteristic (ROC) curves. Other measures refer to norms as what is common. For these norms, a representative sample provides the values with which individual scores and study results can be compared. For subgroups, differentiated norms are available, i.e. for quality of life (SF-12) in special patient groups. The norms may be revised from time to time.

11.3.5 Other Measurement Properties

In addition to the properties described, other aspects may also be relevant during the development and validation of a measure. These include (but are not restricted to) practicability, reasonability, cost and usefulness. Most of these issues can already be considered during measure development. Assessing practicability and reasonability are part of pilot studies. Costs and usefulness are topics in validation studies.

Practicability refers to the ease of use for the people applying the measure; in HSR, this is most often healthcare staff. A practical measure needs little to no training and explanation to be applied. Practicability comprises the ease of instructions to be given, analysis of the measurement data and interpretation of the results. *Reasonability* refers to the effort needed from the persons filling out the questionnaire, e.g. for PROMs these are patients. Especially in vulnerable patient groups, questionnaires are kept shorter to minimise demand on patients. Generally, filling in long questionnaires may be tiresome and lead to less precise results. *Costs* apply for both the measure itself and its application. Developing a paper-and-pencil questionnaire requires different resources to designing a similar web-based version. Filling in web-based questionnaires requires technical equipment, which may have to be provided. For some questionnaires, a fee has to be paid, which also leads to costs for the application. *Usefulness* refers to the conclusions which can be drawn from the measurement results. This also includes certainty of the results, which is strongly related to validity and reliability.

11.4 Conclusions and Perspective

The use of valid measures is of paramount importance to any scientific field, including HSR. While validity and reliability are always relevant criteria to be fulfilled by a measure, the importance of other aspects depends on the potential use of the measure. In HSR, it is often important to consider the practicability and utility of a measure to be used in a study: the effort for achieving results should be low; participants should not need training to fill in measures; the questions should be self-explanatory.

The validation of a measure is a continuous process, meaning that a measure is hardly ever validated for all purposes, populations and contexts. Information on the validation process helps critically appraise the measures used and guide researchers in outcome assessment and analysis. Knowledge of the development and validation process allows a critical appraisal of available measures and identification of the most suitable measure for a given research question. The Consensus-based Standards for the selection of health Measurement Instruments (COSMIN) initiative provides both recommendations for selecting an appropriate PROM for a study (https://www.cosmin.nl/) and reporting guidelines for validation studies (Gagnier et al. 2021). The translation and cultural adaptation process could follow the guidelines provided by the International Society for Pharmacoeconomics and Outcomes Research (ISPOR; Wild et al. 2005).

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Chapter 12
Development of Interventions in Health Care

Michel Wensing and Cornelia Straßner

Abstract Interventions in health services research cover a variety of goal-orientated activities, including treatments of patients, healthcare delivery models and health system reforms. The development of interventions is usually based on a mix of several ingredients, including the analysis of real-world problems and needs, previously performed scientific research, use of theory or frameworks, involvement of intervention users and other stakeholders and pilot research of the interventions. A systematic, stepwise approach increases the transparency and replicability of the process and possibly also the effectiveness and implementation of interventions. The design of interventions is a science in development. We recommend reporting and reflecting on the political, commercial and other interests that influence the development of interventions.

12.1 Introduction

Health services research (HSR) examines a variety of interventions, such as clinical treatments of patients, health technologies, healthcare delivery models and health system reforms. Many interventions in HSR concern changes in the organisation and delivery of healthcare that aim to improve outcomes for individuals and populations. These interventions may be described as programmes, strategies, solutions or policies to distinguish these from clinical interventions. The efficacy of clinical interventions (e.g. medication) is the subject of clinical research, but clinical interventions that are delivered in a real-world healthcare context can be the subject of

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HSR. Many interventions are complex: They have multiple interacting components, they relate to a high number of behaviours in those delivering or receiving the intervention, a high number of groups or organisational levels are targeted, there are many and various types of outcomes and there is flexibility or tailoring in delivering the intervention (Craig et al. 2008). Interventions of interest to HSR are delivered in settings that provide organisational, financial and legal constraints that differ from the optimised world of clinical trials of intervention efficacy.

This chapter focuses on methods for the development of interventions. The classic path for the development of clinical interventions treatments starts with fundamental ('discovery-orientated') biomedical research, followed by clinical studies: Phase 0 is the first research in humans, Phase 1 aims at finding the intervention dose with lowest possible side effects, Phase 2 is for testing safety and potential effects, Phase 3 is efficacy research and Phase 4 focuses on long-term and rare side effects. Following this logic, a similar stepwise approach to the development and testing of interventions in HSR has been proposed: theory development, intervention modelling, explorative trial, definitive randomised trial and long-term implementation (Campbell et al. 2007). In HSR, later authors have described the development and evaluation of interventions as a cyclic process, in which development and evaluation are conducted iteratively. For instance, a widely used framework for the development and evaluation of complex interventions in health specifies four components, which are not listed in a fixed order: (a) development or identification of the intervention, (b) engagement of stakeholders, (c) feasibility and acceptability testing and (d) evaluation (Skivington et al. 2021).

In practice, interventions are developed in various ways and can be characterised in terms of:

- The extent to which a stepwise, systematic approach is applied
- Whether and how research evidence is considered
- Whether and how scientific theory and frameworks are used
- Whether, how and when intervention users and other stakeholders are involved
- Whether and how the uptake in practice is anticipated, for instance, by exploration of barriers and facilitators for implementation
- The extent to which empirical pilot and feasibility research is conducted
- How political, commercial and other interests are handled

This chapter will elaborate on these topics in Sects. 12.2 through 12.6, followed by conclusions in Sect. 12.7. It will not provide a cookbook recipe for intervention development, but it will describe the main ingredients that can be used.

12.2 Stepwise Approaches for Intervention Development

Many guidelines for systematic, stepwise development of interventions have been published. An example is *Intervention Mapping*, which was originally developed for health promotion programmes and has been applied across other domains (see Box 12.1; Bartholomew et al. 2001).

Box 12.1: Steps of Intervention Development According to Intervention Mapping (Bartholomew et al. 2001)

- *Needs assessment*: The problem is phrased in terms of behaviours that need to be changed and targets that need to be reached.
- *Specification of determinants of (current) practice*: Determinants that may influence practice are identified, as these are potential targets for interventions.
- *Definition of proximal programme objectives*: Determinants and performance objectives are then mapped onto each other in a matrix.
- *Assessment of theoretical methods and practical strategies*: Potentially suitable methods and strategies are identified and evaluated.
- *Programme design*: Strategies are chosen and organised into a deliverable programme, which is then pretested.
- *Monitoring and programme evaluation*: The final phase concerns the assessment of whether programme targets are reached.

Intervention mapping provides a generic structure for intervention development but few clues for its content (e.g. what type of factors, objectives or strategies may be considered) and operational procedures (e.g. how to go from analysis to selection of strategies). The same applies to many other structured approaches to intervention development. In practice, the use of intervention mapping and related approaches can be time-consuming as it often requires weeks or months to go through all steps up to intervention design.

Design thinking is another systematic approach to intervention development that has gained some popularity in healthcare in recent decades. This approach specifies three steps, which are repeatedly taken until a satisfactory solution is found (Altman et al. 2018): (1) thorough analysis of the needs of the targeted users, using empirical research and conceptualisation; (2) intervention development, comprised of rapid cycles of ideas generation, prototype development and testing; and (3) implementation in practice, evaluation of impact and scale-up. Design thinking has been successfully applied in the context of health research (Altman et al. 2018).

Regardless of the methodological approach, experience suggests that a large number of ideas may emerge during activities for developing interventions (Wensing 2017). Therefore, setting priorities and making choices is a crucial aspect of intervention development. Structured methods for priority setting, such as voting procedures with stakeholders, may be applied. Intervention designers may also use their experience and preference to make choices in the development of interventions, such as what phenomena are targeted and which activities are planned. Obviously, this approach has low transparency and replicability. In practice, a mix of explicit and implicit approaches may be applied (Box 12.2 provides an example). Practical considerations, such as, available time, resources and competences, play a role in the choices as well.

Box 12.2: Stepwise Development of an Implementation Programme (Bonner et al. 2019)
The assessment of individual risk is a key component of recommended cardiovascular prevention, but it is not always implemented. An Australian project used a stepwise procedure, which involved a theoretical framework and stakeholders (i.e. primary care physicians) to develop a programme to address this. Stage 1 involved the identification of potential strategies, using the behaviour change wheel framework, informed by previous research involving 400 general practitioners and 600 patients/consumers. Stage 2 co-developed website content with general practitioners, and Stage 3 piloted a prototype website at a national conference for general practitioners. Stage 4 iteratively improved the website based on 'think aloud' interviews with practitioners and patients. Stage 5 was a feasibility study to evaluate potential effects, acceptability and demand. The latter study showed that most physicians involved intended to use the website for cardiovascular risk assessment. Nevertheless, the invitation to provide feedback also provided a number of suggestions for further improvement, such as integration with practice software and more resources for people with low literacy skills.

12.3 Use of Evidence and Theory

Recommendations for intervention design (O'Cathain et al. 2019) state that research evidence and theory should play a role in the development of interventions. Examples of this exist, for instance, in the development of interventions to change professionals' behaviours (Colquhoun et al. 2017). Ideally, research evidence and theories are systematically and repeatedly reviewed during the intervention development process. This serves several purposes:

- The identification of interventions that proved to be effective in other settings, which may thus be considered for use
- The identification of interventions that failed to be effective in other settings, which should be avoided
- The generation of hypotheses on how interventions might work, what effects they might have and under what conditions these effects are optimised

In the evaluation of published research, it is often challenging to assess the transferability of its findings to the targeted group and setting. For instance, an intervention for optimising antibiotics prescribed in primary care may not be useful for prescribing of other medication or antibiotics prescribed in hospitals. Differences between targeted groups and settings do not suggest that research findings from elsewhere are never applicable (the latter would exclude the possibility that knowledge accumulates over time). It requires in-depth knowledge of the intervention and the setting in which it should be applied to assess the applicability of research findings from other settings. The analysis of the transferability relates not only to the effectiveness of interventions (e.g. what are the core intervention components that

are required to have an impact) but also to the implementation (e.g. whether the core intervention components can be implemented in the targeted group and setting) (Movsisyan et al. 2019). Such analysis may result in purposeful adaptations of published interventions or the conclusion that these cannot be used in a targeted group and setting. In addition, modification of interventions may be required with respect to language and culture.

In addition to the results of empirical research, theories and frameworks can guide the development of interventions. In HSR, however, most interventions are not developed on the basis of theories or frameworks. If theory is applied, it often concerns broad notions about human behaviour, such as 'learning is a social process' (social constructivism) or 'behaviour change depends on financial incentives' (economics theory). Collaboration across disciplines and fields may be required, which can be challenging. For instance, relevant concepts may come from psychology, engineering and medicine, while most individuals are only trained in one of those fields. Furthermore, it is usually difficult to link intervention components to specific determinants of behaviours with high probability of effective change (Waltz

Box 12.3: Using the Health Belief Model to Design a Campaign to Improve the Use of Medication Lists

Medication lists are an important document especially in the care of elderly, multimorbid patients. However, medication lists are frequently unavailable, incomplete, not updated or not readable, which may result in serious adverse drug reactions (ADR). The aim of the project *MeinPlan* was to improve the use of medication lists among all citizens aged 65 years or older of a defined region with permanent medication. For this purpose, a population-based campaign was designed (Straßner et al. 2020) using the health belief model as guidance (Janz and Becker 1984). The model hypothesised that the likelihood of engaging in a health-promoting behaviour (e.g. *using a complete and comprehensible medication list and keeping it on hand*) was influenced by specific determinants that were targeted by the campaign. According to the model, important influencing factors are the perceived threat of not engaging in the health-promoting behaviour, which is again determined by the perceived susceptibility (e.g. *the perceived likelihood of experiencing an ADR*) and the perceived seriousness (e.g. *the expected consequences of experiencing an ADR*). The campaign targeted these determinants by spreading information about drug safety via several channels. Furthermore, the campaign tried to reduce barriers for the desired behaviour by offering a platform allowing the generation and regular update of an electronic medication list. According to the health belief model, cues to action, i.e. internal and external triggers for the desired behaviour, are important. The campaign provided these by distributing posters, brochures and medication list templates. Demographic and sociopsychological variables were considered by providing templates and information in several languages.

et al. 2019). An exception is a framework of behaviour change techniques (BCTs), which can be used to develop interventions for individual behaviour change (Carey et al. 2019). The framework specifies 93 BCTs, 70 of which were linked to 25 (of 26 prespecified) 'mechanisms of action' (i.e. cognitions such as 'beliefs about capabilities') in 277 studies of behaviour change in patients (Carey et al. 2019). This framework is particularly relevant in the development of interventions for individual behaviour change.

Regardless of the approach, it is recommended to describe the 'theory of the intervention'. This specifies how interventions may work, what effects they have and under what conditions these effects are optimised. Box 12.3 provides an example. This topic is further elaborated on in Chap. 13, which is on process evaluation.

12.4 Co-design and Stakeholder Involvement

In addition to research evidence and theory, potential users of the interventions and other stakeholders can be involved in the development of interventions (Colquhoun et al. 2017; O'Cathain et al. 2019). This is known under various names, such as codesign, user-centred design and stakeholder involvement. Many specific activities are subsumed under these labels, such as focus group sessions with intervention users, development of experience models and prototype testing with users (Dopp et al. 2019). The boundaries with process evaluation are thin. Codesign tends to refer to earlier phases in the life cycle of an intervention that might have more fundamental impact on the interventions than process evaluation.

Codesign and related approaches have been promoted because they are expected to contribute to interventions that are more likely to be effective and implementable (Van Dijk-De Vries et al. 2020). However, codesign requires substantial time investment by many people, which needs to be balanced with the assumed positive impacts (Oliver et al. 2019). Comparative research on the usefulness of different approaches to codesign and stakeholder involvement in health research is scarce. A notable exception is a study that compared different methods for involving stakeholders in the identification of barriers for implementation (Krause et al. 2014). The study showed that survey, interview and brainstorming methods for involving stakeholders all provided unique information. In this study, brainstorming with healthcare professionals seemed most be productive and time efficient of all methods to involve stakeholders in the intervention design (Box 12.4 presents another example).

Box 12.4: Implementation of Video-Based Mental Healthcare (Hoffmann et al. 2020)
Video-based mental healthcare demonstrates comparable effectiveness to face-to-face treatments, but its implementation is a challenge in some countries. Focus group interviews with mental healthcare professionals, primary care physicians and patients were used to explore their views and use these to optimise the interventions. The mental healthcare professionals (11 in total) highlighted the importance of a trusting relationship between the patient and the therapist and doubted whether such a relationship could be established through video consultations. Nevertheless, they considered mental health specialist video consultations to be suited for patients in rural areas, those with impaired mobility and those who may otherwise remain untreated. Furthermore, they expected that the collaboration with primary care physicians would improve. Finally, they identified scheduling of consultations, duration of the consultations and financial reimbursement as preconditions for implementation. On the basis of these findings, the video consultations were planned at fixed time slots which general practice staff and therapists will have agreed upon. At the beginning of each consultation, a practice team member escorts the patient to the room designated for video consultations, sets up the widescreen computer tablet and the videoconferencing platform and addresses the patient's questions. The content of the psychotherapy was determined by prevailing research evidence and clinical experience.

12.5 Pilot and Feasibility Research

Testing interventions in practice is another component of intervention development, which logically follows after design of a prototype of an intervention. In practice, a variety of approaches are used (Levati et al. 2016). Ideally, members of the targeted group of users are invited to apply the interventions in realistic conditions, and data are collected to document the acceptance, practicality and potential effects of the interventions. Alternatively, the intervention is described rather than made available for use, but this entails that the experience being hypothetical rather than real. The data collection is usually simple and comprises observations, interviews and written surveys. Instead of targeted users, others may be involved, particularly if the users are difficult to recruit for a study. Also, the conditions may be artificial rather than realistic, such as a computer laboratory. Pilot and feasibility research can serve different purposes, including:

- Examination of the acceptance of the interventions among the targeted group of users and the practicality of using interventions
- Optimisation of the interventions with respect to contents, formats and doses
- Estimation of the possible effects on relevant outcomes, which thus informs the required sample size for a subsequent evaluation study
- Examination and optimisation of methods for evaluation in a subsequent study, typically a randomised trial

In some cases, proxy measures of outcomes are used in pilot and feasibility research. For instance, professional behaviours may be self-reported rather than observed and extracted from documentation. In this context, it is important to consider the predictive value of the measures for real-world behaviours as this is often limited. A wide range of factors influence the likelihood that proxy measures reflect actual behaviours in a health setting. In a systematic review, these were categorised into characteristics of decision-makers (e.g. their openness to experiences), cognitive factors (e.g. social desirability) and task factors (e.g. high stakes) (Hayes et al. 2020). Context factors (e.g. regulations, cultural beliefs) may be added to these categories. Ideally, proxy measures are validated against optimal measures of behaviours before being put to use. Box 12.5 describes an example of a pilot study.

Box 12.5: Pilot Study of a Triage System in Out-of-Hours Care (Roth et al. 2020)

The implementation of a software-based instrument for standardised initial assessment in German out-of-hours care aims to support healthcare professionals and steer patients toward the right healthcare provider. An early qualitative process evaluation on the basis of interviews was carried out alongside the implementation in 26 outpatient emergency care services within 11 federal states in Germany. Participants were 30 healthcare professionals who work with the system either at the joint central contact points of the outpatient emergency care service and the emergency departments of hospitals or at the initial telephone contact points of the outpatient emergency care service. Matrix-based framework analysis was applied to analyse the interview data. Healthcare professionals perceived that workload increased initially, due to additional time needed per patient. When using the system more frequently and over a longer time period, its use became more routine, and the time needed per call, per patient, decreased. The system was perceived to support decision-making regarding urgency for medical treatment, but not all types of patients were eligible. Technical problems, lack of integration with other software and lack of practicability during peak times affected the implementation.

12.6 Guidance on Intervention Development

Political, commercial and academic interests often influence the development of interventions in healthcare because individuals and organisations invest resources (e.g. time, reputation). Transparency on these interests is a minimum requirement for scientific intervention developers and commonly required in scientific publications. We recommend that intervention developers also reflect on the incentives for intervention development, and lobby for change if these are not aligned with

healthcare needs and priorities. For instance, a research team may depend on a positive pilot study for future funding, a stakeholder in healthcare (e.g. health insurer) may have invested reputation in an intervention, or a firm may have plain commercial interests. Full reporting on intervention development is obviously important. Reporting guidelines for complex interventions in healthcare are available, such as the TIDieR checklist (Hoffmann et al. 2014). Interventions of interest to HSR tend to be named inconsistently and vaguely (e.g. 'break through' is a method for quality improvement). For a detailed, standardised labelling of interventions, content-specific taxonomies are available. An example is the behaviour change techniques for individual behaviour change (see Carey et al. 2019).

12.7 Conclusions and Perspective

A systematic, methods-based approach to intervention development enhances the transparency, replicability and transferability of the activities. From a scientific point of view, these are desirable features. It may also enhance the effectiveness of interventions and the likelihood that they can be implemented by the targeted users. Nevertheless, there has been much less interest in the development of interventions in HSR than in their evaluation. This may explain the lack of standardised, well-specified and validated methods for intervention design. In practice, the most challenging aspect of intervention development is likely the step from problem analysis to choosing interventions. This step requires creativity, intuition and collaboration across disciplines and fields, knowledge of intervention users and experience in the design of interventions.

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Chapter 13
Process Evaluation in Health Services Research

Michel Wensing and Regina Poß-Doering

Abstract Process evaluations aim to provide insight into how and why interventions have impact on outcomes or not. Methods of observational research are used to explore processes and factors related to the delivery and impact of interventions. Examination of the fidelity and adaptation of interventions ('has it been delivered as planned?') is the core of process evaluation. The challenges of process evaluation are mainly in the conceptualisation, analysis and interpretation of data. While process evaluations can be largely descriptive accounts, full potential is achieved if the evaluation is guided by theory. Participatory approaches to the evaluation of interventions are a special type of process evaluation in which the researchers actively involve themselves and stakeholders in the research process.

13.1 Introduction

Many types of interventions are of interest in health services research (HSR). These include, for instance, medical treatments, prevention programmes, continued education in health professionals and changes in the organisation of healthcare delivery. The outcomes of interest are equally multifold and include, for instance, aspects of patients' health or quality of healthcare. Process evaluation refers to research on processes and factors associated with the delivery and impact of interventions. The distinction between process and outcomes evaluation of interventions is partly a matter of perspective: Specific items may be outcomes in some studies and processes in other studies (e.g. health professional's adherence to clinical guidance).

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The type of interventions and outcomes of interest determine the focus of a process evaluation, i.e. the research questions (see Box 13.1).

Box 13.1: Potential Research Questions for Process Evaluations

- Have the targeted individuals and populations been exposed to the interventions?
- Have they effectively been reached by the interventions?
- Have the interventions been delivered as planned, or have they been adapted?
- Which intervention components have contributed to outcomes?
- What contextual factors (organisational, physical, cultural) have influenced outcomes?
- What are the mechanisms of change or the absence of it?
- What have the consequences of the interventions been, positive or negative, beyond the anticipated outcomes?
- What were participants' experiences with the interventions?
- Can the interventions be sustained over time?
- Can the interventions be transferred to other settings?

In recent decades, there has been growing interest in the study of processes and factors that influence the outcomes of many types of interventions in healthcare (Moore et al. 2015). The expectation is that process evaluations contribute to the development of more effective interventions. Process evaluations have most value to science and practice if their results can be contextualised with respect to the intervention outcomes. In other words, process evaluations convey little beyond description if it is not clear whether the interventions of interest had an effect on targeted outcomes.

This chapter will first elaborate on the conceptualisation of interventions (Sect. 13.2) and their fidelity (Sect. 13.3). Sampling and data collection will be described in Sect. 13.4 and data analysis methods in Sect. 13.5. The chapter concludes with a section on guidance for design and reporting of process evaluation (Sect. 10.6), followed by conclusions (Sect. 10.7).

13.2 Conceptualisation of Interventions

In HSR, it seems that many interventions fail to be grounded in explicit ideas on how they might work. They may be designed according to what has been labelled the ISAGIATT principle ("it seemed a good idea at the time" (Martin Eccles, personal communication)). The explicit use of explanatory models (e.g. logical models (Rehfuess et al. 2018) and theories of change (De Silva et al. 2014)) have been promoted for a long time (Blettner et al. 2018). In essence, intervention theories make explicit (in various degrees of detail) which factors and processes are assumed

Table 13.1 Intervention theory for implementation of polypharmacy recommendations

Interventions	-> Determinants addressed	-> Recommendations targeted	-> Effects of recommendations
Training Practice concepts Presentation of pathways in quality circles Checklist Template Tablet PC Poster/flyer	Expert knowledge Routine Availability of medication lists at interfaces Definition of target group Feasibility of checklists Self-management abilities of patients Language barrier Difficulties of comprehension Standardisation of medication lists	Structured medication counselling provided Up-to-date medication lists available Reduced potentially inappropriate medication	Improved clinical outcomes

Adapted from Jaeger et al. (2013)

to be affected by an intervention, how this impact is influenced by the context of its application and how the intervention ultimately results in changes in targeted outcomes. Ideally, intervention theories are built on available research knowledge and sound theories of behaviour and organisation. Table 13.1 provides an example of a pragmatic intervention theory of a programme for improving medication management in primary care practices.

The interventions of interest in HSR have increasingly been considered 'complex' (Skivington et al. 2021). Complexity involves more than having many components. The lens of complexity (labelled in various ways, e.g. 'complex adaptive systems' and 'complexity theory') assumes that changes (e.g. outcomes after applying an intervention) are difficult to predict because they are influenced by multiple factors in non-linear ways, and linkages between connected factors and random fluctuations play an important role in their impact. As yet, it is unclear whether interventions informed by complexity theory are more effective than other interventions (Brainard and Hunter 2016).

Interventions that are provided as a package can be composed in different ways, which should be specified in an intervention theory. For instance, one format is to choose interventions on the basis of individual needs and preferences. As a consequence, the use of interventions may vary across the targeted individuals. Alternatively, interventions may be related in a chain: An educational programme for healthcare professionals (step 1) may intend to induce change in patient treatments, which are provided by these professionals (step 2) with the intention to improve health outcomes in patients. If health outcomes failed to improve, it would be inappropriate to conclude that the interventions in step 2 were not effective if their effectiveness had been proven in previous research. In other situations, the

absence of health impacts may be related to the clinical interventions, the strategies for their implementation or both.

Similar to the interventions, targeted outcomes may be connected in different ways. This should also be part of the intervention theory. In HSR, patients' health outcomes and health professionals' behaviours are usually of most interest. In addition, individual cognitions (e.g. knowledge, attitudes, intentions), skills and routines, and organisational characteristics (e.g. resources, governance structure and organisational culture) may be of interest. The number of potential outcomes is high. For instance, a review identified 67 indicators for implementation outcomes (Willmeroth et al. 2019), many of which may also be considered factors that mediate the impact of an intervention on outcomes.

13.3 Fidelity and Adaptation of Interventions

Intervention fidelity is the correspondence between the planned and the realised intervention. In HSR, interventions are seldom realised completely as planned. For instance, health professionals may not attend all planned sessions of an educational programme, or patients may not adhere to all aspects of a self-management programme. The assessment of intervention fidelity is the core of process evaluation because it is crucial for a sound interpretation of intervention outcomes. Lowered intervention fidelity may reduce the effectiveness because not all ingredients are provided at the required dose. The reverse is also possible: Adaptation of interventions may actually increase their effectiveness because they are better tailored to local needs and conditions. The actual relation between intervention fidelity, adaptation and effectiveness is a question for empirical research. In the context of efficacy research (such as randomised trials), the aim is usually to optimise intervention fidelity (Bellg et al. 2004). In most cases in HSR, however, intervention fidelity is an observed variable. There is ample room for better reporting on intervention fidelity in published research (Slaughter et al. 2015).

The assessment of intervention fidelity requires, firstly, specification of the planned intervention as a starting point. In reality, not all interventions are specified in great detail, so this may require research and conceptualisation (see also Sect. 12.2). Intervention developers and stakeholders may be interviewed to get a good understanding of the planned interventions. Secondly, it is necessary to choose or develop measures for intervention fidelity. It needs to be specified whether intervention fidelity relates to the provision, exposure or use of intervention components. There are few standardised measures for intervention fidelity, but frameworks to guide the development of tailored measures exist (Carroll et al. 2007). Thirdly, the evaluation of intervention fidelity requires an assessment of whether deviations from the planned intervention are (random) fluctuations or purposeful adaptations or modifications. An extensive framework for intervention adaptations and modifications is available (Wiltsey Stirman et al. 2019). Besides the categorisation of changes to the planned interventions, it documents aspects such as when and how the modification was made, whether the modification was planned/proactive (i.e. an adaptation) or unplanned/reactive, who determined that the modification would be made, the reasons for the modification and contextual factors that influenced the decision.

Box 13.2: Intervention Fidelity of a Structured Communication Approach in Oncology Care (Bossert et al. 2020)
The Heidelberg milestones communication approach (MCA) is delivered by a specifically trained interprofessional tandem of hospital physician and nurse to terminally ill patients. It consists of four milestone conversations (MCs) at pivotal times in the disease trajectory. Its implementation is facilitated by communication training for the healthcare professionals, changes in the workflows in the hospital and continuous promotion by the clinical management. This study aimed to assess to what extent the MCA was implemented as planned and consolidated in specialised oncology practice. All written records of the conversations, which are part of the routine documentation during MCs and follow-up calls, were analysed. Adherence to key aspects of the manual was documented on structured checklists at the beginning of the implementation of the MCA and after six months. The analysis was largely descriptive. A total of 133 MCs and 54 follow-up calls (t1) and of 172 MCs and 92 follow-up calls (t2) were analysed. The analysis showed, for instance, that advance care planning was discussed in 26 (13%) of the second conversations in the respective assessment periods; in 31 (47%) of these conversations, prognostic awareness was recorded. The authors concluded that the implementation of a trajectory-specific communication concept was successful, although room for further improvement was also identified.

13.4 Sampling and Data Collection

The empirical research for process evaluation is often straightforward. In the context of an intervention study, data may be collected once (typically at the end of the intervention period) or repeatedly (e.g. at start and end of intervention period). Repeated data collection can provide better insights, but one must consider that data collection for process evaluation may have unwanted (positive or negative) impacts on individuals, leading to over or underestimation of intervention effects.

In many cases, all participants in a study are included (full census), but sampling may be applied if the study is very large or resources are limited. Estimations of a required sample size for process evaluation are not commonly done, and the actual sample size is often pragmatically chosen. In some studies, it can also be important to provide insight into individuals who did not receive or use the interventions of interest. Also, participants may be purposefully selected for in-depth analysis, for instance, contrasting groups such as high and low performers.

In HSR, the participants of interest include patients, health professionals, managers and other stakeholders. They may be requested to answer questions (interviews, surveys) or be observed (directly or using documents such as patient records). In some cases, relevant content-specific measures are available, but in most situations, new measures are developed and applied.

13.5 Data Analysis

Many process evaluations in HSR conduct descriptive analyses only, such as frequency distributions, correlations and summaries of statements or observations. The results of these analyses are relevant and often helpful to decision-makers. However, descriptive analysis does not use the full potential of process evaluation. This section elaborates on additional approaches to data analysis, which seem particularly useful for providing more in-depth understanding (Table 13.2 provides an overview).

In quantitative studies, factors associated with intervention outcomes can be examined in *multivariate data analysis approaches*, such as regression analysis. Ideally, such analysis is based on well-developed intervention theories and data collected in longitudinal study designs. Relevant factors may mediate or moderate the impact of the intervention on outcomes (see Fig. 13.1 for an illustration). Mediators are intermediate outcomes that influence primary outcomes of interest. For instance, education may influence knowledge (the mediating variable) and thus behaviour. Moderators are factors that change the impact of an intervention on outcomes. For instance, the effect of an intervention may be different for men and women, in which case gender would be a moderator. The approach to the statistical analysis of potential mediators and moderators differs.

A second approach provides qualitative research, particularly *qualitative framework analysis*. In fields that have been thoroughly studied, such as studies of barriers for implementation in clinical practice, studies should build on the available body of knowledge. A framework summarises the findings of previous research and can be used to guide a deductive qualitative analysis (see Chap. 7). This may be helpful in considering a broader range of issues than a purely inductive analysis and highlight issues that were not found despite their importance in previous research. It can also help further develop the framework if the study provided issues that were not previously identified, and in this way, enhance science. Box 13.3 provides an example.

Table 13.2 Overview of approaches to data analysis in process evaluation

	Short description	Key assumptions
Multivariate analysis	Quantitative analysis to identify mediators and moderators of change	Processes and associated factors can be quantified
Framework analysis	Qualitative analysis to map data onto a conceptual framework	Relevant conceptual framework is available to classify data
Realist evaluation	Identification of context-mechanism-outcome configurations	Context and mechanisms interact to bring about outcomes
Mixed methods	Triangulation of quantitative and qualitative methods	Qualitative and quantitative methods strengthen each other
Participatory research	Researchers are actively involved in designing and conducting interventions	Researchers' interventions are beneficial to both research and practice

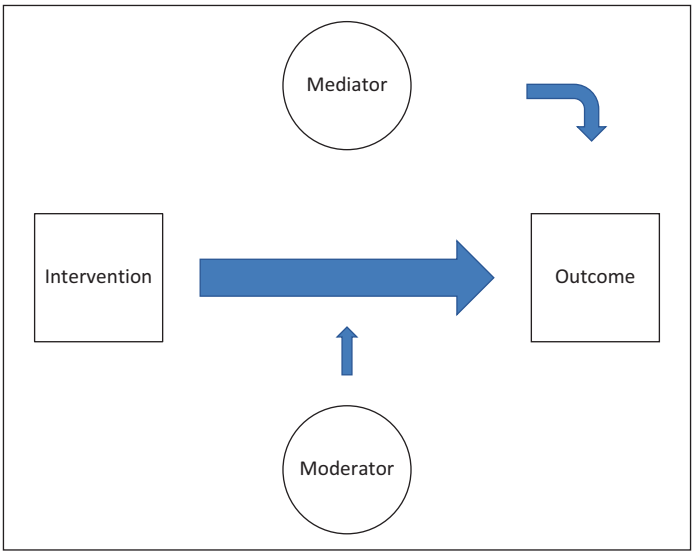

Fig. 13.1 Mediators and moderators of intervention outcome.

Box 13.3: Framework Analysis for Understanding Antibiotics Prescribing (Poß-Doering et al. 2020)

In the ARena study (sustainable reduction of antibiotic-induced antimicrobial resistance), 14 primary care networks in two federal German states aimed to promote appropriate antibiotics use for acute non-complicated infections. A comprehensive quality improvement programme was applied for this purpose. This study aimed to identify factors associated with outcomes. Audio-recorded telephone interviews were conducted with physicians, non-physician health professionals and stakeholder representatives (n = 45 in total). The pseudonymised verbatim transcripts were coded applying a thematic framework analysis based on the Tailored Implementation for Chronic Disease (TICD) framework which uses seven domains to classify determinants of implementation (guideline factors, individual health professional factors, patient factors, professional interactions, incentives and resources, capacity for organisational change and social, political and legal factors) (Flottorp 2013). The predefined categories of the TICD were used to identify determinants of practice regarding potential changes in health professional practice concerning the appropriate use of antibiotics in acute non-complicated infections in primary care. Given the predominance of social influence processes (social support, social learning, social normative pressures and social contagion), additional inductive analysis focused on these domains.

Another option is the use of *realist evaluation* (Bonell et al. 2012). This approach starts from the perspective that context and mechanisms determine outcomes and then postulates that specific patterns of context, mechanisms and outcomes (CMO) can be identified. The result of a realist evaluation is a list of CMO combinations. The particular strength of realist evaluation is that it can provide insight into the working mechanisms of interventions. Mechanisms that are distant from the intervention become context at some point; thus, the distinction between context and mechanism can be difficult (Shaw et al. 2018). While realist evaluation has a background and tradition in constructivist social science and qualitative research, there is no pertinent reason to refrain from quantitative and confirmatory methods in its application. There is, however, a debate on whether mechanisms in realist evaluation only refer to conscious, active individual actions or also other mechanisms that are not perceived by individuals (Shaw et al. 2018).

In process evaluations that used qualitative and quantitative methods, a *mixed methods approach* can be applied to strengthen data analysis. This implies that data from different methods are used to assess the same factor or relation between factors (triangulation). For instance, a process evaluation used written surveys and interviews with cardiologists in ambulatory care to examine the implementation of a coordinated ambulatory cardiology care programme (Hennrich et al. 2019). It showed that most components of the programme regarding medical care were well-implemented, but arrangements to enhance fast access and procedures for communication were only partly implemented. In practice, there is room for improving the quality of 'mixed methods' studies in HSR (O'Cathain et al. 2008; Fàbregues et al. 2021).

A final approach described here is *participatory research*, which is known under various names, including 'embedded research', 'engaged scholarship', 'research partnerships', 'integrated knowledge translation' and 'action research'. In participatory research, researchers are actively involved in the design, delivery or adaptation of interventions. For instance, researchers may become members of healthcare delivery teams or executive teams for the delivery of interventions (Marshall et al. 2014). Researchers may also be involved in decisions on the research in research partnerships (Hoekstra et al. 2020). Key features are co-creation, reciprocity, trust, fostering relationships, respect, co-learning, active participation and shared decision-making in generation and application of knowledge (Nguyen et al. 2020). Proponents believe that participatory research helps increase the relevance and impact of studies through the engagement of target groups and users (Vindrola-Padros et al. 2017).

13.6 Guidance on Process Evaluation

Reporting on process evaluations should be accurate and comprehensive, like any other type of research. Process evaluation is essentially observational research in populations, so reporting guidelines such as STROBE apply to process evaluation

(see: www.equator.com). In addition, specific guidance for the design and reporting of process evaluation may be used to provide comprehensive reports. A framework for process evaluations in cluster randomised trials emphasised that reporting should be comprehensive for the cluster level (e.g. hospital or ambulatory practice) as well as the individual level (e.g. patients) (Grant et al. 2013). This framework considers the recruitment of clusters and individuals within clusters, the delivery of interventions to them and their response to intervention. A consensus guideline for process evaluation for research in rehabilitation provides 29 specific items, most of which seem to apply in other fields as well (Masterson-Algar et al. 2018).

13.7 Conclusions and Perspective

Process evaluation of interventions is an important type of HSR that can contribute to the development and optimisation of interventions. While process evaluation can address many other questions, it is wise to restrict a particular process evaluation to what is feasible and necessary to provide valid results (Odendaal et al. 2016). Sampling and data collection for process evaluation may be straightforward, although most measures have to be newly developed and actual data collection can be time-consuming. The challenges of conceptualisation and data analysis in process evaluation may often be underestimated, which leaves much of the potential of process evaluation unused. The development and validation of the methods of process evaluation are needed to enhance the quality of research.

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Chapter 14
Outcomes Evaluation in Health Services Research

Michel Wensing and Jeremy Grimshaw

Abstract This chapter focuses on the evaluation of the outcomes of interventions in health services research. The study designs for outcomes evaluation can be globally classified as experimental or observational. Experimental designs (i.e. randomised trials) are best for the assessment of the effectiveness of interventions, that is, the 'pure effects' as compared to a relevant comparator. In addition, a wide range of observational evaluation designs are available that may use components of experimental designs. Observational designs can be used for the examination of change and goal attainment. Outcomes evaluation in health services research typically includes samples of participants in the range from several dozens to hundreds or thousands. In many cases, a variety of outcome measures across different domains are included, covering aspects of healthcare delivery and/or health outcomes.

14.1 Introduction

This chapter focuses on research methods for the evaluation of the outcomes of interventions in health services research (HSR). Many interventions of interest to HSR are changes in the structure or process of healthcare delivery that aim to improve the quality and outcomes of healthcare for individuals and populations. Examples vary from the introduction of a question prompt sheet for patients in

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clinical practice and education programmes for healthcare providers to large-scale healthcare system reforms. As opposed to natural developments or trends, interventions are purposefully applied and have a specific starting point. In HSR, most interventions are complex; they have many components that interact with each other in their application, resulting in outcomes that cannot easily be predicted.

If an intervention is applied, the expectation is that it has benefits and little (or acceptable) harm for the targeted individuals and populations. This expectation may be based on beliefs, experience, theory or research. For outcomes evaluation, there should be a degree of uncertainty regarding this expectation, warranting research. Not all interventions are 'ready' for outcomes evaluation. Some interventions are not yet sufficiently elaborated, so further intervention development and pilot research is needed first. Other interventions are proven effective, so it would be unnecessary and unethical to withhold these from people who would benefit. Outcomes evaluation is indicated if there is 'equipoise' regarding benefits of an intervention, that is, it seems plausible that it will be effective, but it is not sufficiently certain. In practice, many other considerations also influence a decision to conduct an outcomes evaluation, such as political views and costs of the required research (Baier et al. 2019).

This chapter provides a general introduction and broad overview of the methods for outcomes evaluation with a particular focus on HSR. Section 14.2 elaborates on study designs. Sampling and measurement are discussed in Sect. 14.3, followed by data analysis in Sect. 14.4. Section 14.5 briefly discusses guidance specific to outcomes evaluations. The final section, 14.6, provides conclusions and perspectives.

14.2 Study Designs

A study design describes the structure of a study. It specifies aspects such as the allocation of participants to study arms and the timing of measurements and intervention. For instance, a randomised trial is a study design in which participants are randomly allocated to (at least) two study arms, (at least) one of which gets the intervention of interest, and outcomes are measured after the intervention has been started (and potentially also before the intervention is applied). As compared to other study designs, the randomised trial is generally considered a strong study design because it is associated with low risk of bias. The choice of study design largely determines the type of questions that can be answered with reasonable certainty by a specific study. For outcomes evaluations, a distinction can be made between (a) goal attainment, (b) change and (c) effectiveness. Table 14.1 relates these three research objectives of outcomes evaluations to study designs.

Evaluation designs are broadly classified as experimental or observational. Experimental designs, or randomised trials, are designed to assess the effectiveness of interventions, i.e. the degree to which changes can be causally attributed to an intervention. The risk of bias in this assessment is minimised by several features of the study design, of which randomisation is very important: the random allocation of study participants, who receive different interventions, to two (or more) arms.

Table 14.1 Possible research questions for outcomes evaluations

Research objectives	Definition	Possible study designs
Goal attainment (Have the goals of the intervention been reached?)	Degree of meeting defined goals, regardless of whether this implies change or intervention effectiveness	Cross-sectional, post-intervention only design
Change (Has there been change in outcomes after the start of the intervention?)	Change in relevant outcomes over time, regardless of what has caused this change	Longitudinal observational design, uncontrolled before–after comparison
Effectiveness (Has the intervention contributed to a change in outcomes?)	Change in relevant outcome over time that can be attributed to an intervention	Randomised trial, controlled before–after comparison, interrupted time series analysis design

Randomisation enhances the comparability of different study arms at baseline regarding factors that may influence the outcome. This protects against confounding in the assessment of intervention effectiveness. Several other features of experimental designs provide further protection against bias, such as standardisation of interventions and measurements, optimisation of the delivery of the planned interventions, application of specific inclusion criteria for participants and control (or selection) of the context in which the interventions are applied.

The strength of internal validity of experimental designs may come with limitations for the external validity (i.e. the generalisability of findings). If participants have to meet strict inclusion criteria and high fidelity of a standardised intervention is enforced, then the healthcare practices in the trial may differ substantially from routine healthcare. To overcome this limitation, many randomised trials in HSR are pragmatic. This implies that they apply random allocation to study arms, but otherwise have relatively loose inclusion criteria and control mechanisms, which better reflect the situation in routine healthcare practice (Schwartz and Lellouch 2009). PRECIS-2 is a structured instrument to assess the degree of pragmatism of a trial (see http://rethinkingclinicaltrials.org).

Although some randomised trials are relatively cheap and fast, in many cases, a substantial amount of time and resources is required. Also, it may be perceived as unfeasible to randomise individuals to study arms. There is a range of quasi-experimental designs that apply aspects of randomised trials but do not randomly allocate participants to study arms. The term ‘quasi-experimental’ is used variably, so it is clearer to describe these non-randomised designs as observational studies. It should be noted that ‘clinical trial’ is a broad concept that essentially covers all health-related studies of interventions in humans (regardless of the presence of randomisation). Despite the higher risk of bias, non-randomised designs can provide reasonably convincing results if the design is close to a randomised trial (e.g. a parallel control group is included) and well-conducted. In addition, the trustworthiness of findings is higher if the effect sizes are large, appropriately adjusted for confounders and found to be dependent on the dose of intervention (Schünemann et al. 2013).

Other observational designs for outcomes evaluations are more distant from the design of a randomised trial and therefore less able to assess intervention effectiveness. They can, however, provide insight into change and goal attainment. These can be listed from low to high protection for bias:

- *Cross-sectional studies*: Measurements are conducted once after the intervention has been introduced. This design can show whether goals are met, but whether change happened remains uncertain.
- *Before–after comparisons*: Measurements are conducted before and after the intervention has been introduced. This design can show whether change occurred, but attribution of the change to the intervention remains uncertain. If repeated measurements before and after the intervention are done, interrupted time series analysis can be used to enhance the certainty of causal attribution.
- *Controlled before–after comparisons*: Measurements are conducted before and after the intervention has been introduced as well as in a non-randomised control group without this intervention. This design may allow change to be attributed to the intervention, but the certainty of this attribution depends on the degree that selection bias is controlled. Again, interrupted time series analysis can enhance the certainty of attribution.

There is a wide range of non-randomised designs available for outcomes evaluation, which have been described under different labels. In particular, a variety of (non-randomised) controlled designs have been described that are associated with various risks of bias (Cook and Campbell 1979). Table 14.2 describes several frequently used designs for outcomes evaluation from an epidemiological perspective. Comparative case studies and developmental research are other designs (coming from the social sciences) that may provide insight into the impacts of interventions, but we consider these primarily process evaluations (see Chap. 13).

Table 14.2 Designs for outcomes evaluation

Design	Focus	Key features
Randomised trial	Intervention effectiveness	Prospectively conducted; random allocation of participants to arms; inclusion of control group
Controlled trial	Intervention effectiveness	Prospectively conducted; non-random allocation of participants to arms; inclusion of control group (also called controlled before–after comparison)
Case-control study	Changes in participants, potential intervention effectiveness	Prospectively or retrospectively conducted; control cases are matched to cases using predictors of outcomes
Cohort study	Changes in participants	Prospectively or retrospectively conducted; continuous, repeated measurements in observed period; may include observed cohort for comparison (may be strengthened by interrupted time series analyses)
Cross-sectional study	Goal attainment	Retrospectively conducted; data collection once, usually after the intervention

Table 14.3 Risks of bias in randomised trials

Risks of bias	Explanation
Bias arising from the randomisation process	Inadequate random sequence allocation (selection bias); lack of allocation concealment (selection bias)
Bias due to deviations from intended interventions	Lack of blinding of study participants (performance bias)
Bias due to missing outcome data	Incomplete accounting of patients and events (attrition bias)
Bias in the measurement of outcome	Lack of blinding of assessors (detection bias)
Bias in the selection of the reported result	Selective outcome reporting (reporting bias)

Higgins et al. (2019)

It is important to consider carefully what is provided to participants in the control arm because this poses the basis for the comparison in the analysis and interpretation. Control arms with a placebo intervention (standard in medication trials) are rare in HSR. The participants in the control arm or comparison cohort usually receive one of the following: (a) no intervention (which often denotes 'usual care') or (b) a less-intensive version of the intervention of interest. The primary purpose of the control arm in a study is to control for secular trends ('natural developments'), concurrent initiatives (e.g. similar interventions) and non-specific intervention effects (e.g. 'Hawthorne effect', the effect of receiving attention due to participation in the study). Measurements before the start of interventions cannot control for these sources of bias in the estimation of intervention effectiveness. In practice, these issues (secular trends, concurrent initiatives and Hawthorne effects) are very common in HSR. Changes in values of outcomes are usually observed in control groups, which reinforces the importance of a control group in the design of outcomes evaluations. Many sources of bias have been specified for randomised trials (see Table 14.3); most also apply to non-randomised controlled designs.

14.3 Sampling and Data Collection

Many outcomes evaluations in HSR involve a study population of healthcare professionals (physicians, nurses, allied health professionals, etc.), healthcare managers or healthcare policy makers. They may be the primary or the only study population, but many studies in HSR also involve a study population of patients (or individuals at risk for disease). Outcomes of interest may relate to patients, e.g. their knowledge or experiences. In some cases, patients are used to provide data on the behaviours of healthcare providers. In another category of outcomes evaluations, patients are the primary or only study population. These studies may marginally fall within the scope of HSR if the focus is primarily on clinical or public health outcomes.

Study participants can be sampled from a population in different ways, which influences the generalisability of study findings. Random sampling provides the best generalisability, but a low participation rate reduces this advantage. In many studies, healthcare providers, patients and others are recruited pragmatically, for instance, on the basis of existing networks or (in case of patients) consecutively after attending a hospital or practice. In some situations, it is possible to use anonymised data (e.g. collected for reimbursement purposes), which can enhance the representativeness of the sample. The sample sizes typically vary from several dozens to hundreds or thousands of individuals, but the samples of healthcare professionals are usually much smaller than those of patients and limited by the number of healthcare professionals who are available in a setting.

The sample size that is required to detect relevant effects can be calculated using methods that are used across the population sciences. Many outcome evaluations in HSR use clustered data (e.g. patients within practices and teams within hospitals), which needs to be taken into account in the calculation of statistical power and in the data analysis. This usually means that larger samples are needed than in non-clustered studies.

In order to get a comprehensive view of the outcomes of an intervention, it is usually best to include a variety of measures across different domains. In outcomes evaluation, the following categories of measures can be distinguished:

(a) Measures of intended outcomes of the interventions, such as providers' adherence to recommended practices and patients' experiences with healthcare
(b) Measures of potential confounders, factors which bias the estimation of intervention effectiveness, such as patients' characteristics (disease severity, health literacy, etc.)
(c) Measures that describe the study populations (e.g. years of experience of providers), which are not outcomes but help to assess the generalisability of the findings of the study

Various types of measures can be used, such as:

(a) Extraction of data from existing clinical or administrative records, which are often in computerised systems
(b) Questionnaires for patients, healthcare professionals and healthcare managers, preferably comprised of validated measures
(c) Other measures, such as direct observation, visits by simulated patients and the extraction of user data from computer applications

All measures have their strengths and weaknesses with respect to validity, feasibility and cost (see Chaps. 7, 8 and 9). Box 14.1 provides an example. The use of a mix of measures in a study can ameliorate the limitations of a specific approach.

Box 14.1: Example of a Primary Outcome in a Randomised Trial in Health Services Research

In a cluster randomised trial of a programme to improve cardiovascular risk management in general practice (Huntink et al. 2013), the primary outcome concerned the clinical behaviours of nurses. It was measured on the basis of data in the computerised patient records and scored positive if one of the following conditions was met:

1. There is a record in the patient's medical file, or other healthcare provider-based records, that the patient has received advice on at least one lifestyle item as specified in prevailing guidelines of CVRM; diet, smoking or physical exercise, and which are relevant for the individual patient in the previous 6 months. Also, at least one target for improving an aspect of lifestyle is recorded. This target is maximised 15 months previously. When a patient has a perfect lifestyle, then that will be recorded.
2. There is a notation in the patient's medical file that the patient has none, mild or major depressive symptoms and that the patient has been referred to E-health, a physical exercise group, or depression treatment respectively.

The study included a range of secondary outcomes, including patients' cardiovascular health (assessed from data in patient records), patients' health-related lifestyles (assessed in written questionnaires) and nurses' counselling skills (assessed from audiotaped consultations with patients, using a validated scoring form).

14.4 Data Analysis

The methods for data analysis in outcomes evaluation are quantitative. Pre-specification of the data analysis plan strengthens the scientific integrity (Hiemstra et al. 2019). In particular, the primary analysis of the primary outcome should be pre-specified. This is the outcome for which the study is statistically powered to detect a meaningful effect. Most outcomes evaluations include secondary outcomes, some of which will show significant effects by chance. The pre-specification of a primary outcome provides protection against the overinterpretation of these chance-based significant effects. In cross-sectional post-intervention only designs, the data analysis is descriptive. In studies without a control group but with repeated measurements, the focus is on within-group changes.

In studies with a control arm or comparison cohort, the primary focus of the analysis is on the comparison between study arms or cohorts after (the start of) the intervention. This comparison is expected to reflect (on average) the true effectiveness of an intervention when adequately controlled for influences such as natural trends, concurrent initiatives and receiving attention as a study participant. The study arms may be unequal from the start, particularly in non-randomised trials and

small randomised trials. Therefore, the comparison between groups is often adjusted for features of participants in a study that are expected to influence the primary and secondary outcome. Main candidates for these adjustments are the baseline measurements (measurements before intervention start) of the primary and secondary outcomes. The adjustment is usually implemented through a technique for multivariate analysis, using methods such as propensity scores, synthetic controls and multiple imputation of missing values, which are not elaborated here. Data analysis of outcomes evaluations requires a high level of quantitative data analysis skills. Box 14.2 presents an example.

Box 14.2: Example of Data Analysis Approach in a Randomised Trial (Schmidt et al. 2016)

In a randomised trial of the effectiveness of intensified case management of post-intensive care patients in primary care (Schmidt et al. 2016), the data analysis approach can be summarised as follows. The primary aim of the study was to detect a difference at 6 months of five points or more in mean Mental Component Summary of the Short-Form Health Survey 36, since this amount of change is thought to be clinically meaningful. The confirmatory test for the primary outcome was a t-test for independent groups, which was run in the intention-to-treat population. The effect of clustering and missing values was explored with linear mixed models and imputations. All secondary outcome analyses were exploratory and not adjusted for multiple tests. A confirmatory and exploratory two-sided significance level of $\alpha = 0.05$ was applied, and effect size estimates with 95% confidence intervals were reported.

14.5 Guidance for Outcomes Evaluation

The design, conduct and reporting on randomised trials have received much attention, and many sources of guidance are available. Many outcomes evaluations in HSR are not strictly required to follow Good Clinical Practice and related regulations, but approval by an independent ethics committee or institutional board is nearly always required. Nevertheless, we would recommend adhering to these regulations in HSR because its aims and principles generally apply to outcomes evaluations in health. In addition, we would recommend registration of intervention studies (or publication of the study protocol), even though this is not necessarily expected if the design is not a randomised trial. Examples of reporting guidelines that may be relevant for outcomes evaluations in HSR are SQUIRE (Standards for QUality Improvement Reporting Excellence) and CHEERS (Consolidated Health Economic Evaluation Reporting Standards). These and other reporting guidelines for research can be found at https://www.equator-network.org/.

14.6 Conclusion and Perspective

The evaluation of the outcomes of interventions is an important component of HSR, which has great practical relevance for decision-makers and can contribute to the accumulation of knowledge. The availability of increasing amounts of data in healthcare and new methods of data analysis (e.g. 'machine-learning') may facilitate outcomes evaluations in the coming years. For instance, the instrumental variables approach (from economics) can occasionally be applied to create unbiased comparisons (Hamad et al. 2019), although the number of applications seems limited in practice. The limited availability of data for HSR is currently the limiting factor for the application of advanced data analysis methods, but this may change in the future.

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Chapter 15
Economic Evaluation in Health Services Research

Stefan Listl and Michel Wensing

Abstract Resources for healthcare are scarce, so choices need to be made about how to get the best possible health outcomes given the available resources. Economic evaluation is often integrated into broader evaluation studies (e.g. randomised trials of interventions), in which specific measures of costs and economically relevant outcomes are added. The building blocks of economic evaluation include the choice of framework (e.g. cost-effectiveness or cost-utility analysis), decision-making perspectives, time horizons, discounting of costs and outcomes and decision analytical models (e.g. decision tree or Markov model). Economic evaluation frequently uses specific (quantitative) methods for estimating the efficiency of interventions, such as incremental cost-effectiveness ratios. In addition, economic evaluation in HSR explores the variation of costs and efficiency across healthcare providers and underlying factors.

15.1 Introduction

Newly developed clinical interventions are usually expected to have greater clinical effectiveness or fewer side effects than currently existing interventions. This applies to medication, nursing procedures, physiotherapy interventions and other clinical

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interventions. It also applies to medical devices, such as diagnostic tests and information technologies. However, many newly developed clinical interventions and medical devices involve higher costs. For example, the costs of cancer drugs at the time of approval have increased substantially (Bach 2009). While improvements in treatment are generally desirable, the overall resources that can be devoted to healthcare are limited (Drummond et al. 2015). As a consequence, choices have to be made about clinical interventions and medical devices as to whether the health outcomes generated justify the associated costs (Listl et al. 2019). Economic evaluation is required to support decision-making on the reimbursement of (new) clinical interventions and medical devices from the collective cost reimbursement system (e.g. health insurance). The economic concept 'efficiency' refers to the balance between cost and health benefits of a clinical intervention.

In routine healthcare delivery, the actual use of (approved and reimbursed) clinical interventions and medical devices is subject to decision-making by clinicians, patients and others. The clinical effectiveness and economic efficiency of an intervention in routine practice may be lower than those found in clinical trials that led to approval and reimbursement of the intervention in the first place. In addition, healthcare delivery models and programmes for quality improvement and implementation may be applied to improve specific aspects of healthcare. Economic evaluation is also relevant for evaluation studies of such models and programmes in health services research.

Informing choices in routine healthcare delivery, i.e. seeking to maximise people's health and well-being given available resources, falls within the remit of health economics. More specifically, economic evaluation has been described as 'ensuring that the value of what is gained from an activity outweighs the value of what has to be sacrificed' (Williams 1983). In order to determine whether the benefits produced by a particular treatment exceed 'what has to be sacrificed' (also called opportunity costs), a method of measuring and comparing outcomes versus costs is required. Widely used methodological frameworks for health economic evaluation include cost-minimisation analysis (CMA), cost-effectiveness analysis (CEA), cost-utility analysis (CUA) and cost-benefit analysis (CBA) (Drummond et al. 2015).

This chapter provides an introduction into frameworks and methods for economic evaluation in health services research, provides concrete examples of applied cost-effectiveness analysis and highlights some methodological and practical challenges.

15.2 Standard Frameworks for Economic Evaluation

There are four standard frameworks for economic evaluation that can be useful for health services research (Drummond et al. 2015):

Table 15.1 Typical characteristics of economic evaluation approaches

	Outcome measures	Decision criterion used
Cost-minimisation analysis (CMA)	Health benefits of compared interventions are identical	Lowest costs
Cost-effectiveness analysis (CEA)	Effectiveness in natural units (e.g. survival rates, diagnostic accuracy, etc.)	Incremental cost-effectiveness ratio
Cost-utility analysis (CUA)	Utility, e.g. quality-adjusted life years (QALYs)	
Cost-benefit analysis (CBA)	Health benefit expressed in monetary units (e.g. EUR, GBP and USD)	Benefit – Costs = net benefit

- Cost-minimisation analysis (CMA)
- Cost-effectiveness analysis (CEA)
- Cost-utility analysis (CUA)
- Cost-benefit analysis (CBA)

While these frameworks all consider costs in monetary units (e.g. in EUR, GBP or USD), they rely on different types of outcome measures and different decision criteria to identify the preferred treatment alternative(s). An overview of their key characteristics is shown in Table 15.1.

In CMA, the treatment alternatives under comparison have identical health benefits. Hence, the economic evaluation can be simplified to a comparison of all relevant intervention costs and choosing the alternative with lowest cost.

CEA and CUA represent the most frequently used approaches to economic evaluation in healthcare. They use identical methods, except for how they measure health outcomes. CEA incorporates clinical effectiveness in terms of natural units such as survival rates, blood pressure or dental implant survival (see Box 15.1 for an example of CEA). In health services research, effectiveness may also be measured differently, such as adherence to clinical guidance or incidence of unsafe practices. On the other hand, CUA incorporates health benefits as expressed through more generic and patient-centred utility measures, such as quality of life as expressed on a scale between 0 (worst health status) and 1 (best health status). Often, CUA combines patients' duration and quality of life into a composite measure, such as quality-adjusted life years (QALYs). The advantage of CUA over CEA is that its generic way of measuring health outcomes makes it amenable for prioritisation of treatments across various domains of healthcare. However, the responsiveness of health-related utilities to changes in healthcare practice may be low, which reduces its relevance for health services research. Both CEA and CUA usually rely on the incremental cost-effectiveness ratio (ICER) as a commonly applied decision criterion. The ICER describes the difference in costs divided by the difference in health outcomes of one therapy as compared to another therapy:

$$\text{ICER} = \frac{Cost_A - Cost_B}{\text{Outcome}_A - \text{Outcome}_B}$$

CBA measures both the intervention costs and the health outcomes in monetary units and establishes a net benefit of the clinical intervention(s) under consideration. Methods such as contingent valuation are designed to determine the monetary value of various health states from the patient perspective. If the net monetary benefit of a clinical intervention is positive, the respective intervention is prioritised. The underlying assumption is that a patient will only be willing to pay for something if they can derive a higher benefit than under current resource use.

If the purpose is to increase efficiency in resource use, the additional effects produced by an intervention must exceed the effects forgone by the most productive alternative use of the same resources. This means that considerations about the efficiency of a treatment also need to take account of information on other alternatives using the same resources. To this end, Integer Programming (IP) provides a method to rank alternative interventions according to efficiency under a resource constraint (Birch and Donaldson 1987). However, IP comes with substantial data requirements because it necessitates detailed information about the costs and effects of all interventions as well as resource constraints. Yet another and more pragmatic approach to maximise health gains from available resources is Program Budgeting Marginal Analysis (PBMA; Peacock et al. 2010). In PBMA, decision-makers select interventions that are considered in the context of a prespecified budget. Subsequently, the decision-makers recommend disinvestments to free up resources for new investments.

15.3 Building Blocks of an Economic Evaluation

Many economic evaluations are integrated in outcomes evaluations (e.g. alongside RCTs), but they may also be conducted as stand-alone studies. For example, CEA and CUA can be accommodated into clinical trials via standardised evaluation templates to assess outcomes and intervention costs. Alternatively, CEA and CUA can be carried out as modelling studies that draw upon synthesis of existing evidence. The specific methodological characteristics of CBA means that the latter type of economic evaluation is often better accommodated as a distinct study.

To derive recommendations for decisions about the efficiency of clinical interventions, an economic evaluation needs to incorporate various types and layers of information. Leaning on Drummond et al. (2015), the following building blocks, listed in sequential order of how an economic evaluation is conducted, can be distinguished:

Specification of the decision problem: This is the definition of all relevant options available for evaluation, the recipient population and the geographical location and setting in which the options are being delivered.

Decision-maker's perspective: Defining the decision-maker's perspective is relevant because different decision-making perspectives mean that different types of costs and health outcomes are incorporated for evaluation. Frequently used perspectives are as follows: (i) societal decision-maker, (ii) ministry of health, (iii) healthcare payer and (iv) patient (Drummond et al. 2015). For example, a societal decision-maker would consider all occurring costs from a population-wide perspective, whereas a patient might not consider treatment costs that are covered by the

general public. One should also note that different countries or settings may involve context-specific effectiveness and costs of interventions.

Time horizon: For how long should the costs and health benefits of a treatment be considered? For example, the caries-related cost-effectiveness of sugar-sweetened beverage taxation could be considered for a time horizon of 10 years or across the entire lifecycle (Jevdjevic et al. 2019).

Development of decision analytical model: In CEA and CUA, this serves to determine how the treatment(s) under consideration translate into differential pathways of care, health outcomes and/or costs (Petrou and Gray 2011). Two widely used approaches are:

1. *Decision tree*: The treatment alternatives are represented by a series of pathways or branches (see Box 15.1 for an example). The first point in the tree, the decision node, represents the options between a choice that must be made. The pathways that follow each treatment alternative represent a series of logically ordered consequences of each treatment option. The end points of each pathway indicate the health benefits and costs emanating from the respective treatment.
2. *Markov model*: In this type of model, patients are assumed to have one particular health state from among various alternatives at any point in time and to transition with a certain probability between these health states over a series of predefined time cycles (e.g. weeks, months or years). Costs and health benefits are assigned to each health state. Treatments typically affect the transition probabilities between various health states. Markov models simulate the transition of people between various health states over time and allow for the aggregation of the health benefits and costs due to different treatments (see Box 15.2 for an example of a Markov model).

Box 15.1: Economic Evaluation Alongside a Clinical Trial to Enhance Implementation of Guidelines for the Management of Urinary Tract Symptoms (Wolters et al. 2006)

This study assessed the costs and patient outcomes of an implementation strategy designed to enhance uptake of guidelines for initial management of lower urinary tract symptoms in primary care. A cluster randomised trial in 187 older male patients compared costs and outcomes in the intervention group (= strategy to enhance guideline uptake) and the control group (= guideline provision only). A healthcare perspective and a 3-month time horizon were adopted in the economic evaluation. The primary health outcome was patient-reported urinary symptoms at 3 months. The clinical study found that patient-reported urinary symptoms at 3 months did not differ significantly between the study groups. The mean total costs per patient were lower by 28.15 EUR in the intervention group compared to the control group. These findings suggest that the intervention did not substantially change health outcomes but reduced costs in the first 3 months after an initial consultation.

Box 15.2: Economic Evaluation of a Maximum Care Model for Urinary Tract Infections Using a Markov Modelling Technique (Harmsen et al. 2009)

This probabilistic modelling study used a Markov model to assess the cost-effectiveness of a maximum care model for urinary tract infections in children (= more diagnostic testing and antibiotic treatment) versus standard practice in primary care in the Netherlands. The model input parameters were derived from a systematic literature review. Probabilistic sensitivity analysis was performed by means of Monte Carlo simulation. The findings of the study indicate that, over 30 years, maximum care gained 0.00102 (males) and 0.00219 (females) QALYs (quality-adjusted life years) and saved 42.70 EUR (males) and 77.81 EUR (females) compared with current care. This suggests that maximum care provides a higher quality of life at lower costs, which was largely explained by the health and cost impacts of the few cases of renal failure.

Identification of input data for model parameterisation: Various information sources can be useful for model parameterisation. Economic evaluations alongside randomised trials draw directly upon primary information from trials. Other information sources include evidence synthesis on the basis of previously published literature, claims data (particularly for utilisation rates and treatment costs), price lists for pharmaceutical or medical products, reimbursement rates or expert opinions. Depending on the decision-maker's perspective, various types of costs can be relevant, such as direct costs for treatment and indirect costs caused by absence from work/school due to disease (Drummond et al. 2015).

Discounting of future costs and health outcomes: People generally value future costs and health benefits less the more distant in the future they occur. Economic evaluations that look into the future therefore need to adjust the value of costs and benefits for the time at which they occur. Guidelines for discounting in economic evaluations differ between countries and over time. Most guidelines recommend discounting costs and effects at the same rate, with 5% or 3% being the most common discount rates (Attema et al. 2018).

Decision criterion: Choosing between treatments is trivial when a treatment costs more and produces fewer effects than another treatment (or the opposite, if a treatment costs less and produces more effects than another treatment). More frequently, however, a treatment costs more and produces more effects than another treatment. Hence, a decision criterion such as the ICER is needed. In CEA, an alternative approach to the ICER is the net health benefit criterion (Stinnett and Mullahy 1998).

Sensitivity analysis: Uncertainty about the value of model input parameters is common in economic evaluation. To check the robustness of results, there are two main types of sensitivity analysis. In deterministic sensitivity analysis, the impact of

uncertainty in model parameters is explored by 'trying out' different input values. In probabilistic sensitivity analysis, model input parameters are sampled from their distributions and processed via simulations to determine the probability with which the treatments under consideration will be efficient (Jain et al. 2011).

In addition to the conventional components of economic evaluation described above, another approach is budget impact analysis . While economic evaluation usually provides information about the *average* costs and health benefits of a treatment, budget impact analysis seeks to estimate the *aggregate* budget implications of adopting a treatment for an entire population. Such an analysis is relevant in order to understand the full financial implications of adopting a new treatment and the extent to which other treatments might need to be replaced as a consequence of adopting this new treatment (Sullivan et al. 2014). This information is needed to assess the financial affordability of a new intervention in a healthcare system.

15.4 Measures and Data Collection

Various measures of costs and outcomes are used in economic evaluation. For cost measures (see Table 15.2), a broad distinction can be made between highly detailed resource use items (micro-costing) and aggregate resource use items (gross costing). In addition, data collection at the organisational level (top-down) and at the individual patient level (bottom-up) can be distinguished. In practice, the choice of methods for economic evaluation is influenced by practical issues, such as the feasibility of the inclusion of measures and the level of technical competence that is required and available (e.g. higher for modelling studies).

For health-related outcomes, a broad range of generic utility measures and disease-specific instruments exist. Examples of disease-specific instruments are the Headache Impact Test (HIT-6) or the Oral Health Impact Profile (OHIP-5). Widely used generic measures are EQ-5D (see Box 15.3) and SF-6D. Both are

Table 15.2 Costing methodologies

	Level and type of data collected		
		Expenditure data collected at organisational level (e.g. *cost centre)*	*Resource use data collected for each individual patient and then multiplied by unit cost to estimate the expenditure*
Level of identification of resource use items	*Highly detailed resource use items are identified*	Top-down micro-costing	Bottom-up micro-costing
	Aggregate resource use items are identified	Top-down gross costing	Bottom-up gross costing

Source: Špacírová et al. (2020)

preference-based instruments, but EQ-5D was developed by means of a time trade-off (TTO) approach whereas SF-6D was developed by means of a standard gamble (SG) approach. Despite the generic nature of both EQ-5D and SF-6D, limitations have been described for both instruments (see e.g. Brazier et al. 2004). Box 15.4 provides an example of the use of these measures for economic evaluation.

Box 15.3: Description of Domains in the EQ-5D

Under each heading, please tick the ONE box that best describes your health TODAY:

Mobility

- I have no problems in walking about.
- I have some problems in walking about.
- I am confined to bed.

Self-care

- I have no problems with self-care.
- I have some problems washing or dressing myself.
- I am unable to wash or dress myself.

Usual activities (e.g. work, study, housework, family or leisure activities)

- I have no problems with performing my usual activities.
- I have some problems with performing my usual activities.
- I am unable to perform my usual activities.

Pain/discomfort

- I have no pain or discomfort.
- I have moderate pain or discomfort.
- I have extreme pain or discomfort.

Anxiety/depression

- I am not anxious or depressed.
- I am moderately anxious or depressed.
- I am extremely anxious or depressed.

Box 15.4: Cost-Effectiveness and Cost-Utility of a Home-Based Exercise Programme in Geriatric Patients with Cognitive Impairment (Eckert et al. 2021)

This economic evaluation was conducted alongside a randomised placebo-controlled trial. In the intervention group, 63 geriatric patients with cognitive impairment received a home-based, individually tailored exercise programme to increase physical performance. Patients in the control group (n = 55) received unspecific flexibility training as a placebo control. The incremental cost-effectiveness of the exercise intervention compared to the placebo was calculated with respect to improvement of (i) physical performance as assessed by the short physical performance battery (SPPB) and (ii) quality-adjusted life years (QALYs based on EQ-5D-3L). After 24 weeks, the intervention group scored significantly better than the control group with respect to physical performance but not for health-related quality of life. The average cost to implement the home-based exercise intervention was 284 EUR per patient. For an assumed willingness-to-pay threshold of 500 EUR per SPPB point, the probability of the intervention to be cost-efficient was 92%. For an assumed willingness-to-pay threshold of 5000 EUR per QALY, the probability of the intervention to be cost-efficient was 85%. These findings suggest that the home-based exercise intervention represents good value for money in terms of physical performance. Findings for quality of life were less robust.

15.5 Limitations of the ICER Approach

Many economic evaluations in healthcare practice research rely on the ICER as a decision criterion. However, the ICER approach is not without limitations (Birch and Gafni 2007). The ICER calculates an average cost per additional unit of health outcome, which implies that treatments are assumed to be perfectly divisible into individual units of health outcomes. In reality, however, the assumption of *perfect divisibility* of a treatment is often unrealistic, particularly in health services research. For example, a manager must purchase an entire magnetic resonance imaging (MRI) machine and cannot divide it into piecemeal fractions that might align better with the decision-maker's budget. In addition, the ICER assumes *constant returns to scale*, i.e., that for each and every additional unit of investment, the same impact will be yielded. In reality, however, the 'dose–response relationship' of a treatment depends on the extent of previous applications of that treatment. For example, the additional health benefit of the prescription of a smoking cessation programme is likely to depend on whether the patient participated in the smoking cessation programme before. Thus, the ICER approach is subject to simplifying assumptions which can eventually result in CEA and CUA (which widely rely on the ICER) not leading to efficiency improvements (Birch and Gafni 2003; Listl et al. 2019). Several alternative methods to identify efficiency improvements have been proposed. The complexities of economic evaluation in health services research are demonstrated in Box 15.5.

Box 15.5: Cost-Utility Study Embedded Within a Multicentre, Matched-Controlled Study on the Substitution of Inpatient Care from Medical Doctors (MDs) to Physician Assistants (PAs) (Timmermans et al. 2017)
A total of 2292 patients from across 34 hospitals in the Netherlands were followed from admission until 1 month after discharge. In the matched control group, patients were subject to a traditional approach in which only MDs provided inpatient care. In the intervention group, patients were subject to a mixed model in which PAs provided care in addition to MDs (PA/MD model). No significant difference between the intervention and control groups was found in terms of QALYs (based on EQ-5D). While total costs per patient did not significantly differ between the groups, the costs per items differed between the MD model and the PA/MD model. Personnel costs were lower for the PA/MD model, but the MD model had lower costs per length of stay. These findings suggest that the cost-utility in wards jointly managed by PAs and MDs is similar to the care in wards with traditional house staffing. The involvement of PAs may reduce personnel costs, but not overall healthcare costs. However, the heterogeneity of patient populations and hospital settings made it difficult to draw firm conclusions.

15.6 Conclusion and Perspective

Economic evaluation has become a mainstay of health research, and the number of publications keeps increasing. In this chapter, we have presented key concepts of economic evaluation and highlighted associated opportunities and challenges for health services research. Neglecting comprehensiveness in conducting, reporting and publishing economic evaluation studies poses substantial risks in terms of wasting resources and jeopardising the quality and safety of healthcare. Future healthcare practice research is recommended to adopt a pragmatic approach to economic evaluation, while being mindful of the limitations of the applied methods.

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Chapter 16
Systematic Reviews of Health Care Interventions

Manuela Bombana

Abstract Systematic reviews of interventions aim at synthesising evidence from studies on interventions to provide guidance for decision-making and further research. Systematic reviews use prespecified methods, mapped in a review protocol. A systematic search strategy is applied to identify studies by searching electronic databases and possibly other sources. After reviewers reach consent on the included primary studies, they systematically record detailed information on each study in the data extraction process. Each study is described and assessed regarding key descriptive features, risk of bias and the certainty of the evidence, and its findings. Finally, results from the included primary studies may be combined by pooling data in the context of a statistical meta-analysis or other type of synthesis.

16.1 Introduction

Clinical decision-making and health policy development should be informed by the best available research evidence. This applies to clinical treatments as well as healthcare delivery models, implementation programmes and other complex interventions. A systematically consolidated evidence base on a specific research question has higher certainty than single studies. Systematic reviews follow systematic, replicable methodological approaches to search, synthesise and critically appraise the available evidence on a defined research question. Single studies may be biased, resulting in misleading conclusions. This results in inadequate, potentially unstable action, which may cause more harm than necessary.

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Historically, the statistical approach of 'meta-analysis' (as a relevant part of data synthesis in the context of systematic reviews) emerged prior to the broader methodological approach of a systematic review. In 1904, Karl Pearson was the first to publish pooled results, and with his publication, he sustainably influenced the development of meta-analysis. The development of the concept and technique of meta-analysis and the word itself were coined by Gene Glass in 1976 (Bohlin 2012; Glass 1976). The methods were adopted and further developed in the health sciences, covering (among others) systematic methods for searching studies and the methodological assessment of included studies. Today, the conduct of meta-analysis as part of systematic reviews is an important tool in evidence-based medicine (EbM) (Greco et al. 2013). There is a broad consensus that reviews are required to reduce research waste and support decision-makers with the best available evidence. The number of systematic reviews in health and the methodology for conducting systematic reviews have developed enormously in recent decades. Thirty years ago, very few systematic reviews were conducted, and it was considered to be a new methodological approach. Prior to the year 2000, only about 3000 systematic reviews had been indexed in MEDLINE. Now, about 10,000 systematic reviews of health research are published annually (Clarke and Chalmers 2018).

Systematic reviews with homogenous included studies provide the highest level of evidence and are therefore, compared to other study designs, superior regarding the certainty of the evidence (Howick et al. 2011). The systematic review methodology seeks to provide unbiased evidence by applying a systematic and transparent research methodology. Cochrane Reviews are internationally considered the gold standard of systematic reviews, particularly for randomised trials (and related designs) of interventions. Cochrane Reviews are based on an extensively elaborated and largely standardised set of methods (Higgins et al. 2021). These standards are also captured in the PRISMA 2020 statement (Page et al. 2021). Systematic reviews of interventions are also relevant in health services research (HSR), as this covers the evaluation of healthcare delivery models, implementation programmes and other interventions in real-world healthcare.

Besides the Cochrane style of systematic reviews, there are other types, such as scoping reviews, rapid reviews and qualitative syntheses. *Scoping reviews* aim to map out the available research in a chosen domain to identify knowledge gaps, clarify concepts, scope literature or investigate research conduct. They also are conducted to serve systematic reviews to confirm eligibility criteria or research questions (Munn et al. 2018). *Rapid reviews* are conducted in a shorter timeframe than systematic reviews. There is no common methodological approach to conduct a rapid review, and thus, they often differ from each other in the methodologies utilised (Harker and Kleijnen 2012). Specifically, policy makers need a synthesis of the evidence to derive policy actions in short time frames, i.e. within some weeks or months. Rapid reviews often serve this purpose as systematic reviews take at least 12 months (Ganann et al. 2010). *Qualitative syntheses* focus on the qualitative research evidence for a topic, focusing on types of phenomena, processes or working mechanisms rather than their numbers. Some Cochrane Reviews are syntheses of qualitative studies.

This chapter provides an introduction to the methods of systematic reviews, focusing largely on reviews of studies on the effects of interventions. To guarantee that methods are applied as initially planned and to reduce publication bias, all steps of a systematic review are ideally documented in a protocol that is published prior to the conduct of the review itself (Chandler et al. 2021). Further steps of a systematic review include (1) defining a research question; (2) writing a review protocol; (3) developing and applying a systematic search strategy; (4) conducting title, abstract and full text screening; (5) extracting data; (6) assessing the risk of bias; (7) grading the quality of the evidence (GRADE); and (8) synthesis of findings, which may imply statistical meta-analysis. The approach differs across the study design of included studies in the systematic reviews; i.e. non-randomised studies need different risk of bias assessments and data extraction tools compared to randomised controlled trials (RCTs).

16.2 Defining a Research Question and Writing a Review Protocol

Defining the focus of a systematic review by generating a research question is one of the very first steps of a systematic review. The scope of a systematic review is either broad or narrow and is reflected in the research question. A broad research question covers a wide range of topics (e.g. interventions), which may enhance broad relevance, whereas a narrow research question only addresses one topic or a few topics, which may enhance concrete relevance. The scope, either broad or narrow, also depends on time, resources and instructions, among other factors. Systematic reviews aim to support clinical and policy decision-makers and identify knowledge gaps that require further research. The research questions need to be both answerable and not yet answered. The development of a well-formulated research question is time-consuming and needs expert knowledge in the research field of the intended topic of the systematic review. It is recommended to involve relevant stakeholders and apply tools for priority setting to ensure that the review considers all relevant aspects in the field of research. In Cochrane Reviews, research questions are formulated as objectives (Thomas et al. 2021). The James Lind Alliance (JLA) offers priority setting methods for health research. The priority setting process involves patients, clinicians and carers in a priority setting partnership. The JLA developed a detailed guidebook for everyone who wants to establish such a partnership and conduct the process of priority setting in health research (Cowan and Oliver 2013).

Specifically, for systematic reviews of interventions, the application of the 'PICO' scheme is recommended, i.e. the PRISMA checklist suggests using the PICO scheme if the systematic review aims to investigate the effects of an intervention (Page et al. 2021) (Box 16.1 provides an example).

Box 16.1: Example of PICO
When investigating whether the application of media in gynaecological care is effective in improving health behaviours during pregnancy, it is recommended to define a research question according to the PICO scheme: Is the application of media in gynaecological care (intervention) as compared to no media application in gynaecological care (comparator) effective in bringing about improvement in health behaviours (outcome) in adult pregnant women (population)?

PICO (**P**opulation/**P**atient, **I**ntervention, **C**omparison/**C**ontrol, **O**utcome) is a tool to define the breadth of the review and to set the anchor for the inclusion criteria. Applying the PICO criteria for the definition of the research question means addressing all components of PICO in the research question. One might ask the following questions to define the PICO elements:

- Population/patient: What are the characteristics of the patient or population of interest, e.g. gender, age, etc.? What is the condition or disease of interest (and its severity)? In HSR, the population additionally or primarily concerns healthcare providers.
- Intervention: What is the intervention of interest for the patient or population regarding its effectiveness? In HSR, interventions may also be healthcare delivery models, strategies for improving aspects of care and other typically 'complex interventions'.
- Comparison/control: What is the alternative to the intervention? In systematic reviews including clinical trials, the comparator usually consists of clinical alternatives to the intervention, e.g. placebo, different drug and surgery. In HSR, the comparator to the intervention is mainly usual care or alternative strategies.
- Outcome: What are relevant outcomes with regard to the condition and intervention? In HSR, a wide range of outcomes may be considered, reflecting aspects of healthcare delivery, costs and health outcomes.

Based on the PICO elements, review authors define eligibility criteria for inclusion of studies. Therefore, each element of PICO needs to be defined in sufficient detail, and review authors need to consider the pros, cons, necessity, relevance and consequences of each restriction and allowance, meaning each exclusion and inclusion criteria.

After the research question has been developed, the methods of the systematic review should be described in a study protocol. This protocol elaborates on the methods in the phases that are presented in this chapter. It is recommended to apply the PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist for recommended items to address in a systematic review protocol (Moher et al. 2015). This checklist can be applied as a guideline for the writing of a review protocol.

16.3 Search and Select Studies

To identify relevant primary studies for inclusion in a systematic review, it is necessary to develop a systematic search strategy that meets the review's eligibility criteria as closely as possible. The balance between accuracy and comprehensiveness in literature searches usually leans towards the latter, which means that as many relevant studies as possible are included in order to reduce selection bias. Systematic review authors need to search various sources, such as electronic databases (see Box 16.2), grey literature databases, internet search engines, trial registers, targeted internet searches of key organisational and institutional websites and other sources. Searching systematic reviews on similar topics and reference lists of included studies is a relevant aspect of the search for eligible studies.

Box 16.2: Databases for Literature Searches
Most relevant databases include Medline (via Ovid or PubMed), EMBASE (Excerpta Medica Database), Cochrane Database of Systematic Reviews, CENTRAL (Cochrane Central Register of Controlled Trials), CINAHL Plus (Cumulative Index to Nursing and Allied Health), Nursing Reference Center Plus, Scopus, Web of Science, PsycINFO, HSTAT (Health Services/Technology Assessment Text), TRoPHI (Trials Register of Promoting Health Interventions), LILACS (Latin American and Caribbean Health Science), AIM (African Index Medicus), CCMed (Current Contents Medicine Database of German and German-Language Journals) and RAND-Health and Health Care.

The selection of relevant databases also depends on the topic of the systematic review as there are many further databases on specific topics, such as sexually transmitted diseases or different aspects of toxins. The review authors need to check the relevance of each database for conducting the systematic review. It is strongly recommended to consult or involve an information specialist to support the development of a search strategy and to conduct searches of electronic databases. The search strategy should at least be peer-reviewed by an information specialist or a librarian before it is run (Lefebvre et al. 2021).

The development of a search strategy for a systematic review of interventions needs to be tied to the main concepts of the review as defined by the PICO scheme. For each concept, it is helpful to identify synonyms, related and international terms, alternative spellings, plurals, etc. and select relevant text words and controlled vocabulary. The application of truncations (used to replace multiple characters, e.g. protect* = protects, protective, protection, etc.) and wildcards (used to replace single characters, e.g. te?t = test, text, etc.), is recommended. The concepts are connected to one search strategy by the application of different Boolean operators (and, or, not). The search strategy reflects the review's eligibility criteria.

For each database search, the date of search, the search period and the retrieved records need to be documented. The search dates ideally should not be older than 12 (better 6) months prior to publication of the systematic review. Thus, the review team needs to schedule the search and if necessary, update it according to the project timeline and the scheduled submission date.

In addition to electronic database searches, review authors should conduct searches on relevant organisational and institutional websites, on grey literature databases, in search engines and in trial registries. Also, it is recommended to hand search references of included studies.

In the next step, duplicates from the different searches need to be removed. Practical experience in HSR suggests that searches may result in 1000–10,000 database hits, 'records', with about 0–100 eligible studies. The deduplicated records are screened, ideally by at least two review authors. There are various technical possibilities to screen the titles and abstracts of the records; e.g. Covidence is a recommendable digital screening tool. The full texts of potentially relevant records need to be assessed for eligibility. At least two review authors need to check and decide on their eligibility by screening the full texts. Disagreements in the title, abstract and full text screening should be solved with a third review author as an arbiter.

16.4 Data Extraction

Data extraction is the structured collection of data from studies that are included in the systematic review. The following categories of data are usually covered: (a) descriptive information on the study (e.g. author and year of publication), (b) information on study design and methods, (c) main findings and (d) other information (e.g. description of the study setting). It is recommended to use a data extraction form to ensure that all relevant data are extracted by the review authors. The application of a data extraction form simplifies the comparison of extracted data between two review authors. Data can be extracted in paper forms, in electronic forms or in data systems. Regardless of the format, data extraction forms need to be "easy-to-use forms and collect sufficient and unambiguous data that faithfully represent the source in a structured and organized manner" (Li et al. 2021). Data extraction forms should be piloted and adapted before its application in the data extraction process of the review. A well-designed data extraction form captures all relevant details of the study, and in the ideal case, the review authors no longer need to check the original paper in the further process of the review conduct. The Cochrane Collaboration provides data extraction forms for various types of designs.

16.5 Assessment of Risk of Bias and Grading of Certainty

All studies suffer from a degree of bias, which results in deviations from 'the truth'. As the truth is often unknown, we can only assess the risk of bias based on known characteristics of the included studies. For instance, non-randomised comparisons

of intervention outcomes between study groups run the risk that the groups may be different from the start. Many types of risks of bias in studies have been described. They are primarily determined by the study design (e.g. randomised trials involve lower risk of bias by design), but specific aspects of the conduct and analysis of studies can compensate to some extent for weaknesses in study design or increase bias in well-designed studies. Higher risk of bias results in lower certainty of the veracity of the study results. The assessment of the risk of bias and thus the certainty

Table 16.1

Bias	Content	Explanation
Selection bias	Random sequence generation	The sequence of allocation to the intervention or control group should be generated randomly, e.g. a computer-generated randomisation sequence.
	Allocation concealment	Concealment of allocation to the intervention or control group is relevant to prevent selection bias by participants or personnel.
Performance bias	Blinding of participants and personnel	Knowledge of the received intervention or control may affect participants and personnel. Therefore, blinding of participants and personnel is recommended.
Detection bias	Blinding of outcome assessment	Knowledge of the received intervention or control may affect outcome assessment. Therefore, blinding of outcome assessors is recommended.
Attrition bias	Incomplete outcome data	Incomplete outcome data occur when participants drop out during the study. Severe differences in the dropout rate across intervention and control group affect reliability in the results.
Reporting bias	Selective reporting	Reporting bias results from reporting of selected results, e.g. reporting only statistically significant results.
Other bias	Other forms of bias (e.g. confounding bias)	Results are subject to further bias, e.g. inadequate control for confounders.

of findings is a key component of systematic reviews.

The domains of assessment, its contents and its labelling differ across study designs. In randomised controlled trials (RCTs), for instance, the risk of bias assessment focuses on seven domains (Sterne et al. 2019) (Table 16.1):

After the identification of specific risks of bias, a structured method may be used to determine an overall assessment of the risk of bias. For instance, the Cochrane Handbook describes a stepwise approach. Using a checklist of domains for risk of bias, each domain receives a judgement on the risk of bias: low, moderate (some concerns) or high. If the judgements across all domains is ‘low risk of bias’, the overall judgement is ‘low risk of bias’. If at least one domain is judged as ‘moderate risk of bias/some concerns’, the trial is judged as ‘moderate risk of bias/some concerns’. Similarly, if at least one domain is judged as ‘high risk of bias’ or several domains are assessed as ‘moderate risk of bias/some concerns’, the overall judgement is ‘high risk of bias’ (Higgins et al. 2021).

Systematic reviews may include study designs other than RCTs. In several research fields, specifically in HSR, evidence needs to be derived from non-randomised studies of interventions as there are few RCTs. According to the GRADE working group, individual cross-sectional studies with consistently applied reference standards and blinding, inception cohort studies and observational studies with large effect sizes can provide a similar evidence level as RCTs (Schüneman et al. 2013). Well-executed observational studies may provide a high certainty in evidence. Non-randomised studies of interventions are 'observational studies'. These include different study designs, such as cohort studies, controlled before-and-after studies, case-control studies, interrupted-time-series studies (ITS) and controlled trials (Sterne et al. 2016). Several tools exist to assess the risk of bias for non-randomised studies of interventions. However, the domains of assessment differ across risk of bias assessment tools. A prominent tool – recommended by the Cochrane Collaboration – to assess the risk of bias in non-randomised studies of interventions is the ROBINS-I tool. The ROBINS-I tool also consists of seven domains, including bias due to confounding, bias in selection of participants for the study, bias in classification of interventions, bias due to deviations from intended interventions, bias due to missing data, bias in measurement of outcomes and bias in selection of the reported result (Sterne et al. 2016, 2019). Further information and a detailed guidance on the usage of the ROBINS-I tool and updates in risk of bias tools can be found on the internet on www.riskofbias.info.

To assess the certainty of the total body of evidence (rather than individual studies) regarding intervention outcomes, it is recommended to grade the evidence. GRADE is an internationally and widely used system, which involves an evaluation of the evidence on health interventions for each of the relevant outcomes regarding risk of bias, consistency of effects, directness of comparisons, publication bias and imprecision. The certainty of the evidence can be assessed as very low, low, moderate or high. While a systematic review do not go further, developers of guidance for decision-makers will also consider other factors beyond certainty of evidence, such as cost and implementability of an intervention. Details on the performance of GRADE are made available by the GRADE working group via the internet www.gradeworkinggroup.org.

16.6 Synthesis of Studies

The synthesis of studies is a procedure in which data from all included studies in the systematic review are collected to generate an overall body of evidence from the relevant and included evidence. When the review includes results from two or more studies, the review authors should consider a statistical synthesis of the numerical results. This is only valid if the interventions in included studies are sufficiently homogeneous, which requires expert judgement. The statistical synthesis to estimate the overall intervention effect is conducted by the application of a meta-analysis (Deeks et al. 2021; McKenzie et al. 2021). From a statistical point of view, a meta-analysis provides a weighted average value of the effect estimates as derived

from the included studies. Simple counting of studies with 'positive effects' can be highly misleading and should not be applied.

In some cases, conducting a meta-analysis may not be relevant or possible for several reasons and instead, a narrative synthesis of the results is necessary; e.g. when there is limited evidence (no studies or only one study), the reported outcome estimates are incomplete, the effect measures are different and cannot be equalised, there is a huge concern of bias in the evidence or there is large statistical heterogeneity across studies (McKenzie and Brennan 2021). The narrative synthesis is typically a textual description of the effect estimates. The reporting of systematic reviews without meta-analysis should follow the Synthesis Without Meta-analysis (SWiM) guideline. The guideline consists of nine items to improve transparency in reporting (Campbell et al. 2020).

In other types of synthesis, the results of each study are systematically categorised according to prespecified or post hoc developed categories and then described separately as a narration. There are also further statistical methods to synthesise the evidence, e.g. summarising effect estimates, combining p-values and vote counting based on the direction effect. Those alternative statistical methods result in a more limited body of evidence than meta-analysis. However, compared to narrative approaches, these statistical approaches may be superior.

Systematic reviews that integrate qualitative studies need a qualitative evidence synthesis. In qualitative synthesis, the focus is on identification of issues rather than quantifying them using qualitative methods of analysis.

16.7 Practical Aspects of Systematic Reviews

When conducting a systematic review, it is recommended to build a team with different areas of expertise and previously establish a project plan where the team defines which persons will be involved in the different stages of the review conduct. One person should take the lead and the coordination of the project, supervise the timeline and manage the team and the tasks. For the team members, it is important to have one contact person in charge of the review conduct. As indicated earlier, it is highly recommendable to have an information specialist in the project team who has access to many databases.

It is recommended to meet up regularly with the team (in person or virtually) to manage and update the project plan, discuss how to proceed, clarify the next steps and solve open issues. It is recommended to work with a GANTT chart to track progress and development and identify potential problems in the progress of the project. Setting fixed deadlines for the finalisation of the single working packages is very helpful. As the team will work together for up to several years, it is helpful to consider elements of team building. When conducting a review with the Cochrane Collaboration, authors have the possibility to contact the review advisory groups, which support Cochrane authors from the beginning of their projects.

Conducting a systematic review is time-consuming. A Cochrane Review may take between 2 and 5 years, depending on the records received, the workforce available to conduct the review and the overall progress of the project. Therefore, it is recommended to check the available tools, test them, agree within the team on which ones are helpful in the context of the specific review, and adapt and apply the tools that ease the process (as exemplified in each section).

16.8 Conclusions and Perspective

Systematic reviews are often used by decision-makers in clinical practice and health policy, and thus, systematic reviews may have an impact on the health services system, clinical practice guidelines and intervention programmes in healthcare. The methodology for systematic reviews has developed enormously in recent decades. For intervention research, the methodological guidance of the Cochrane Collaboration provides the gold standard, which also applies to HSR. For instance, the Cochrane Effective Practice and Organisation of Care (EPOC) group has conducted many reviews in this field. The COVID-19 pandemic has reinforced the need for high-quality research and systematic reviews. The quality of systematic reviews may be further improved by methodological developments, such as the natural language processing methods for literature searches, tools for specification of complex interventions and Bayesian methods for statistical pooling of data from studies.

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Part IV
Emerging Topics in Health Services Research

Chapter 17
Novel Interventions for Patient Empowerment

Michel Wensing and Katja Krug

Abstract Patient empowerment, a classic topic of health services research, places patient perspectives on health and healthcare in the centre of interest. Many studies have examined patient–provider communication and patients' experiences in healthcare. Relatively novel interventions for patient empowerment are as follows: education of lay people to critically assess health information; the implementation of shared decision-making and other models for patient-centred communication in routine practice; providing patients with access to their computerized health records; support of patients' self-management of health and disease; and the involvement of patients in healthcare planning and the development of clinical guidelines. Studies found that various interventions for patient empowerment can effectively improve the alignment of healthcare with patients' perspectives.

17.1 Introduction

Patient empowerment is characterised by patients' needs, values and preferences playing a central role in the delivery and organisation of healthcare. The concept draws attention to a broad range of aspects of care that are important to patients, beyond mere survival and cure of disease, such as being informed about health and treatment, retaining a sense of control and feeling cared for. Patient-centred healthcare has been studied for several decades, particularly with respect to patient–provider communication and patients' experiences in healthcare. This has led to a proliferation of related concepts, such as patient satisfaction, shared decision-making, patient

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activation, patient engagement, patient involvement and patient empowerment. In this chapter, we use the final term as an umbrella concept for the involvement of patients' perspectives in healthcare planning and delivery. The phrase 'patient' has been debated, and alternatives, such as service users, consumers or people, have been proposed. In this chapter, we stick to the conventional term 'patient'.

Despite the research and initiatives in practice, studies show that the degree of patient centredness of healthcare could be further improved. For instance, an international survey among older adults (>65 years) in 2017 in 11 high-income countries showed (Osborn et al. 2017):

- 23–64% reported difficulties in getting out-of-hours care without going to the emergency department (e.g. 54% in the UK).
- 15–40% of elderly with the highest medical needs experienced high emotional distress (e.g. 37% in the Netherlands).
- 13–43% of elderly with the highest medical needs reported care coordination problems (e.g. 36% in Switzerland).

The attention to patients' perspectives on health and healthcare has led to a proliferation of questionnaires to measure health-related quality of life, functional status and patients' experiences in and evaluations of healthcare (Wensing and Elwyn 2003). For instance, many clinical trials of medical treatments now include measures of patient-reported health; thus, there is a large need for validated questionnaires. Patient-reported outcome measures (PROMs) and patient-reported experience measures (PREMs) have been developed to monitor the quality of healthcare. The actual use of questionnaires for patients in routine patient care and performance measurement systems remain relevant topics of research. Many interventions for patient empowerment have been proposed and applied, varying from communication training for healthcare providers to information platforms to guide patients' choice of providers and treatments.

In short, patient empowerment is a flourishing field of activities in healthcare, which needs to be guided by health services research (HSR). This chapter will elaborate on several interventions to enhance patient empowerment that are relatively novel. It does not claim to provide a comprehensive review of the vast literature on the topic.

17.2 Training of People to Assess Health Information

'Patient education' is a short name for many interventions to enhance patients' knowledge and understanding of health and healthcare. Overall, patient education in the context of healthcare delivery has positive effects on outcomes that are relevant for patients (Fønhus et al. 2018). A relatively novel topic of research is training of patients, or lay people, to critically assess health information. The need for such training was demonstrated by a review of studies that assessed the quality of health information (Oxman et al. 2022). It showed that only a few sources of health information (e.g. leaflets or websites) mention conflicts of interest, alternative interventions, potential harms, costs, quantitative information on effects and absolute effects. Box 17.1 presents an interesting example of an effective training programme, focused on school children in Africa. Similar studies are needed in other countries.

Box 17.1: Critical Appraisal of Health Claims (Nsangi et al. 2017; Aronson et al. 2019)
This study was based on the assumption that the public is exposed to many claims on health interventions that are incomplete, overstated or wrong. Concepts for critical evaluation of health claims are available and can be taught, but it was unknown whether lay people could effectively learn them. In a randomised trial with about 10,000 African school children at 120 schools, the ability to assess health claims critically was effectively taught. The programme was based on a framework of principles:

– Regarding claims about intervention effects: Claims should not assume that interventions are safe, effective or certain. Seemingly logical assumptions are not a sufficient basis for claims. Trust in a source alone is not a sufficient basis for believing a claim.
– Regarding comparisons of interventions: These should be fair, for instance, involve similar groups and outcomes. Syntheses of studies should be reliable. Descriptions should reflect the size of effects and the risk of being misled by chance.
– Regarding choices: Problems, options and goals should be defined. Available evidence should be relevant. Expected benefits should outweigh risks and other disadvantages.

17.3 Shared Decision-Making

The concept of shared decision-making proposes that informed preferences of patients plays a major role in decision-making in healthcare practice (Elwyn et al. 2017). It involves more than listening empathically to the patient or receiving informed consent because it partly transfers decision-making power from providers to patients. It involves the communication of the best available research evidence on benefits and harms of options and the clarification of patients' values and preferences in relation to this information. One framework suggests that shared decision-making has three main components (Elwyn et al. 2017):

- Team talk: Work together, describe choices, offer support and ask about patients' goals
- Option talk: Discuss alternatives using risk communication principles
- Decision talk: Get to informed preferences, and make preference-based decisions

Patient decision aids are information tools (in written or computerised formats) that are used for a structured presentation of the benefits and risks of treatment options, the elicitation of patients' values and preferences, and providing support in choosing options that match with individual values and preferences. Decision aids for patients have been extensively studied. For instance, a systematic review with

104 randomised trials found that they decreased patients' decisional conflict and feelings of being uninformed and reduced the use of major elective invasive surgery (Stacey et al. 2017). The direct impacts on professional performance and health outcomes seem to be limited. The median effect on length of consultations was 2.6 min longer if a decision aid was used in routine practice.

While the effects of shared decision-making remain a topic of debate and research, the interest of HSR has shifted towards their implementation into routine healthcare practice (Box 17.2 provides an example). The development of decision

Box 17.2: Implementation of a Decision Aid for Patients with Advanced Cancer (Laryionava et al. 2021)

The project PETUPAL (Decision Aid to Support Advanced Cancer Patients) aimed at developing and implementing a decision aid for cancer patients for whom the provision of best supportive care was an equal alternative to tumour-targeting therapies. For these patients, the likelihood that curative treatment would have clinical effects was usually very low. The decision aid was planned to be applicable across different types of cancers, which meant that no quantitative information on treatment benefits and harms was prespecified in the decision aid. Part 1 of the decision aid elicited individual values, desired information items, and views on the desired involvement in clinical decision-making. Part 2 presented the treatment options, their potential benefits and disadvantages (e.g. side effects of the treatment and many hospital visits) and a global indication of the potential clinical effects (e.g. impact in 10 or 20 out of 100 patients, to be pointed out by the attending physician). The decision aid was carefully developed on the basis of a scoping review of topics relevant for patients, focus groups with patients and (separately) with healthcare professionals, and pilot testing of prototypes of the decision aid in patients.

While the development of the decision aid was relatively straightforward, the planning of its use in routine clinical practice proved to be challenging. The pilots with the decision aid showed that in one large cancer treatment centre hardly any eligible patients were identified in a 3-month period. This led to a more detailed elaboration of the clinical eligibility criteria for patients in terms of diagnoses and treatment stages. While part 1 of the decision aid could, in principle, be handed out long before (only) best supportive care would become a viable option, this was not feasible as it might take several months or years before the use of part 2 of the decision aid would become relevant. Therefore, parts 1 and 2 were planned to be used in combination and allow for flexibility in the exact logistic procedures used. Finally, it was planned to evaluate the implementation of the decision aid continuously during the project, given the uncertainties around the best approach for its implementation in routine clinical practice.

aids and publication of studies on their effects have not led to wide-scale uptake in healthcare practice. Strategies to enhance the implementation of shared decision-making include educational programmes for healthcare providers and training of patients. A systematic review with 87 evaluations of these implementation interventions (mainly from the USA, Canada, Germany and the Netherlands) concluded that it is uncertain whether they are effective (Légaré et al. 2018). There is thus a need for further research on the topic. A review of research draws attention to the role of organisational and system-level characteristics that influence the implementation of shared decision-making (Scholl et al. 2018). These characteristics include, for instance, organisational leadership, culture, resources and priorities, as well as teams and workflows. Providing a better understanding of the context in which shared decision-making is implemented is an important topic in future HSR.

17.4 Patient Access to Health Records

In various jurisdictions across the world, patients have access to their computerised health records to be able to read the information documented by healthcare providers and add comments. For instance, patients in the Netherlands have access to their medical records in primary care practices and most hospitals. The first studies on this intervention were published by pioneers in North America in 2010. A survey among about 136,000 patients by the same researchers seven years later showed that about 20% of the invited patients were interested in accessing their records (Walker et al. 2019). Patients who accessed the records felt that reading the records helped them take better care of their health, remember treatment plans better and feel more in control. Patients from deprived backgrounds (less educated, non-white, non-native speakers) were most likely to report these benefits. A survey among clinicians who had applied patient-accessible health records (with 27% response rate) found that most (74%) felt that providing access to health records for patients was a good idea (DesRoches et al. 2020). About a third (37%) reported to spend more time on documentation.

Further HSR on the effects and implementation of patient-accessible health records is needed. While some countries have implemented this, its uptake is more limited in other countries. It seems plausible that this does not primarily have a technological reason but is related to cultural, legal, organisational and other factors. For instance, a qualitative study among experts in Germany found that barriers for implementation were related to prevailing processes of the paper-based bureaucratic paper world, the plurality of actors and electronic systems and the lack of clear political regulations and political incentive structures (Pohlmann et al. 2020). The COVID-19 pandemic has pushed the implementation of information technologies in health, which may also have an impact on open health records.

17.5 Support of Patients' Self-Management

Most patients with chronic conditions receive recommendations regarding their lifestyles and adherence to treatments. Their self-management of health and disease was originally conceived as an individual competency that focused on narrowly defined medical objectives. For instance, a study tested the use of a questionnaire for patients and an online platform for providers to identify barriers for self-management in primary care and found that it improved some concrete behaviours (Eikelenboom et al. 2016). In recent decades, the concept of patient self-management has been broadened by including the role of social support and a broader range of outcomes, such as patients' sense of control and ability to manage disease. Social support and self-management capabilities are associated (Koetsenruijter et al. 2016) and may thus strengthen each other, but insight into the exact working mechanisms is limited. Interventions to enhance social support for self-management of disease and health have been developed and tested, but their impact seems modest. For instance, a 'whole systems approach' to enhance social support for patients with chronic diseases in primary care practices did not impact self-care activities, enablement, functional status or psychological well-being (Kennedy et al. 2013). Innovative and evidence-based approaches to support of patients' self-management of health and diseases are needed.

17.6 Patient Involvement in Healthcare Planning

Some funders of projects in healthcare request that patient and public involvement (PPI) be considered in grant applications. In the UK, the National Institute for Health and Care Excellence (NICE) published a patient and public involvement policy in 2013. Patients can be involved in the planning of healthcare in various ways, such as consultation of user panels in surveys or representation of patients in committees or programmes for planning healthcare. While involvement of patients meets ethical imperatives, it should also be considered in terms of benefits, risks and feasibility of various approaches to the involvement of patients. HSR can contribute to this. One example is the involvement of patients in priority setting for quality improvement, which was examined in a randomised trial and a qualitative process evaluation (see Box 17.3).

Related to healthcare planning, patients are increasingly involved in the development of guidelines in research projects and healthcare regulation (Wiig et al. 2020). Still, involving patients poses challenges. Patients may not be able to understand and interpret highly specified health terminology (Rashid et al. 2017). The recruitment and selection of suitable and representative participants is crucial (Lander et al. 2019). The role of 'qualification', i.e. scientific literacy, of involved patients is discussed controversially: Do patients need to be trained to take part in guideline development or would that impair their lay status? (Rashid et al. 2017) Although strongly recommended, there is a paucity of identified effects; the impact of

Box 17.3: Priority Setting for Quality Improvement (Boivin et al. 2014a, b)
The study involved 83 chronic disease patients and 89 health professionals in a two-arm randomised trial in Canada. Priorities established with patients were more aligned with components of structured care management, such as access to primary care, self-care support, patient participation in clinical decisions and partnership with community organisations. Priorities established by professionals alone placed more emphasis on the technical quality of single disease management. Patient involvement increased the costs of the prioritisation process and required 10% more time to reach consensus on common priorities. A related qualitative process evaluation highlighted the role of the combination of small-group deliberations, wider public consultation and a moderation style focused on effective group process to level out the power differences between professionals and the public (Boivin et al. 2014b).

involving patients in guideline development on healthcare, patients' health literacy, and shared decision-making is yet unknown. How to best involve patients in research and guideline development is an ongoing topic of debate and research, primarily on the role patients can adopt, from passively being informed (i.e. in lay summaries of research projects) to acting as consultants to taking an active part in co-production (Price et al. 2022).

A step further is taken by Priority Setting Partnerships of the James Lind, where patients are directly involved in setting a research agenda. In considering research topics deemed important by groups of patients and healthcare professionals, health services researchers ensure that they address patient-related and relevant objectives. In more than 60 of over 150 healthcare areas where research topics were identified, research questions were subsequently addressed in studies and analyses. As an example, in 2015, for end-of-life care, the highest priority for research was given to providing out-of-hours palliative care and supporting patients in being cared for at a place of their choice. This has led to studies focusing on the description and improvement of out-of-hours services in palliative care (Mason et al. 2020).

17.7 Conclusions and Perspective

Concepts such as patient empowerment and patient-centred healthcare are historically associated with attention to humaneness in the doctor–patient relationship and communication training for healthcare professionals. Today, a variety of interventions and tools have been developed and tested to enhance patient empowerment, of which several were described in this chapter. The approaches should be assessed with respect to benefits, harms and feasibility in routine healthcare practice. Furthermore, impacts on equity need to be considered as interventions, and tools for

patient-centredness may not be equally accessible or effective for all subgroups in the population. Thus, rigorous designs and methods for empirical evaluation in realistic healthcare settings are needed.

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Chapter 18
Mental Health Reform, Ecological Translation and the Future of Public Mental Healthcare

Ulrich Reininghaus and Inez Myin-Germeys

Abstract In recent three decades, mental health has evolved towards a predominance of community-based care, guided by ideas on how context influences individual health and well-being. This development is a specific example of increased responsiveness to patients' needs and preferences. More recently, the trend is amplified by digital health applications, such as those for Ecological Momentary Assessment, which are installed on smart phones and used in the places where people live. Health services research is needed to examine the implementation and outcomes of these applications and models for community-based mental healthcare. These need to be tailored well to the needs and competencies of users (patients and healthcare providers) and to the settings in which they are implemented.

18.1 Introduction

For much of the latter half of the twentieth century, efforts in mental health research have focused on the management and care of those with common and severe mental disorders. These disorders have complex aetiologies and poor long-term functioning

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and social outcomes and generate a high burden for patients, carers and society (Tamminga et al. 2021). Indeed, recent years have seen evidence continue to accrue on the complex socio-environmental risk architecture of mental ill-health with life events, urbanicity, migrant and ethnic minority status, cannabis use, bullying victimisation, childhood adversity (abuse, neglect, household discord) and social disadvantage/isolation being among the most pervasive risk factors for developing a range of mental disorders (Tamminga et al. 2021). There is also evidence on the complex temporal interplay of socio-environmental adversity across the life course and how adverse social contexts in daily life may impact mental ill-health in a rapid momentary vicious cycle (Klippel et al. 2021; Morgan et al. 2014). In addition, whilst the initial surge for the molecular genetic basis of mental disorders was characterised by slow progress and methodological concerns, recent years have seen more rapid advances through large-scale collaboration in genome-wide association studies (GWAS) (EU-GEI et al. 2014; Tamminga et al. 2021). However, heritability estimates of the overall contribution of common genetic variants based on molecular genetic data are considerably smaller than heritability estimates from twin studies. There are several potential explanations that may account for these findings, but, given the consistent evidence that socio-environmental factors confer substantial risk, it seems reasonable that gene–environment interactions play an important role (EU-GEI et al. 2014). Finally, much aetiological research has focused on identifying the neurobiological mechanisms through which the social environment impacts individuals and interacts with genes to increase risk for mental disorder (EU-GEI et al. 2014; Tamminga et al. 2021).

This complexity in aetiology illustrates that interventions and services need to be multifaceted and address various levels of explanation and causation, including the neurobiological, psychological and social (Reininghaus and Morgan 2014). Whilst there is broad consensus that such interventions and services need to be evidence-based and provided by a multi-professional team, precisely how they are best configured and delivered to reach service users and their families to provide them with high-quality care remains subject to ongoing debate.

This chapter aims at providing an overview of how mental healthcare and mental health services research has evolved over the past decades to deliver primarily community-based services today, how developments in ecological psychology and eco-epidemiology converge with principles of community-based care and how the shift to providing care in context is accelerated by the opportunities provided by novel technologies for ecological translation of treatment and services. On this basis, the chapter will discuss challenges for mental health services research, which may inform future directions of mental health services research and how they might evolve over the decades to come.

18.2 From Mental Health Reform to Public Mental Health Provision

Following major mental health reforms and the process of deinstitutionalisation since the 1960s, community mental health services have become a central feature of mental healthcare systems in many countries of the Global North (Bhugra et al. 2017; Priebe and Finzen 2002; Thornicraft et al. 2016). Mental health reforms and the process of deinstitutionalisation and the accompanied release of long-stay patients from large asylums to the community have required organisational mechanisms to coordinate and integrate an emerging variety of services for people with mental disorder. This development from large asylums to community-based care was not a consistent linear trend, and several challenges emerged with regard to the implementation of community mental healthcare. Some countries successfully addressed these challenges, and a relatively refined system of both multi-professional community mental health teams and specialist mental health teams developed subsequent to deinstitutionalisation (Bhugra et al. 2017; Thornicroft et al. 2016). Historically, community-based care comprised all services outside large asylums, but since these asylums have largely disappeared, a broad definition of community mental healthcare means that effective services are delivered to a defined local population in collaboration with other local agencies (see Box 18.1) (Bhugra et al. 2017; Priebe and Finzen 2002; Thornicroft and Tansella 1999).

Box 18.1: Definition of Community-Based Mental Health Services
A community-based mental health service is one which provides a full range of effective mental health care to a defined local population**,** and which is dedicated to treating and helping people with mental disorders, in proportion to their suffering or distress, in collaboration with other local agencies (Thornicroft and Tansella 1999).

In line with this, a variety of models of service delivery have been proposed, determining the service components depending on the need of care and level of available resources, where (1) at a low level of resources, there is a focus on primary care with mental health specialist back-up (e.g. for training, consultation and in-patient treatment), (2) at a medium level of resources, this shifts to providing mainstream mental healthcare including generic community mental health teams, acute in-patient care, outpatient clinics, rehabilitation and long-term community-based residential care and (3) at a high level of resources, there are specialist mental health services, including early intervention, crisis resolution, home treatment and assertive outreach, which are primarily geared towards prevention and management of acute crisis and reduction of chronicity (Thornicroft et al. 2016; Thornicroft and Tansella 1999). Importantly, these components from low to high resource levels build on each other and are inextricably intertwined. For example, Tom Craig (Craig 2019) has recently documented how the introduction of early intervention, crisis

resolution, and assertive outreach services in the UK was accompanied by simultaneous disinvestment, rebadging and reconfiguration of mental health rehabilitation services that had followed the closure of asylums in the UK (Craig 2019). This, in turn, resulted in a substantial increase in supported housing, with service users often having little choice as to where they live (e.g. close to family and friends) (Craig 2019). Indeed, in many European countries the number of involuntary admissions, places in supported housing institutions, forensic beds and people with mental health problems in prison have increased since the 1990s, which has been referred to, and controversially debated, as a process of reinstitutionalisation or transinstitutionalisation (Craig 2019).

Further challenges that currently remain in mental healthcare are a substantial unmet need for care in the population and continued limited access to, and use of, mental health services. This may result in a long duration of untreated illness, which is an important marker for a poor prognosis (Malla et al. 2016). One area of mental healthcare in which these shortcomings have become particularly evident is child and adolescent mental health services (Malla et al. 2016). Whilst most mental disorders emerge in adolescence and young adulthood and are a leading cause of disease in youth in high-income countries, mental health services remain difficult for them to access (Malla et al. 2016). Many countries (incl. Australia, the UK, Denmark, Ireland and the Netherlands) have sought to address this by providing new forms of youth mental health services geared towards low-threshold early intervention and prevention at selected demonstration sites (Malla et al. 2016). However, establishing these services at a national level with a sufficient level of integration with local services remains a challenge.

In addition, given the evidence that mental health is distributed as continuous rather than categorical phenotypes in the population and in line with the broad definition of mental health by the World Health Organization (World Health Organization 2014) that mental health is much more than the absence of psychopathology (see Box 18.2), it has become increasingly evident that a more fundamental reform and a shift towards more comprehensive public mental health service delivery is required. This builds on the seminal population strategy by Geoffrey Rose (Rose 1992), who demonstrated that, for health problems that are continuously distributed in the population, a small shift in the population mean is associated with a substantial reduction in the prevalence of disorder. For reforming mental health service delivery, this involves adopting a population perspective and not only focusing on those with disorder but also aiming to improve mental health at the population level through the delivery of public mental health services that address the full spectrum of mental ill-health, including (1) mental health promotion, mental health literacy and stigma reduction; (2) indicated, selective and system-level prevention targeting high-risk individuals, subpopulations and living environments, respectively; and (3) evidence-based, interdisciplinary mental health service delivery for people with mental disorder (Reininghaus et al. 2022). This requires comprehensive assessment, monitoring and surveillance of mental health, including the incidence of disorder at the population level, to assess public mental health measures geared towards preventing the occurrence of new cases (in a defined population over a specified time period) (Reininghaus et al. 2022). However, in many countries, including in Germany and Belgium, there is

an absence of up-to-date evidence on incidence of mental disorders, which suggests that evidence-based planning of public mental health services remains limited.

Box 18.2: Definition of Mental Health by the World Health Organization (WHO 2014)
A state of well-being in which an individual realizes his or her own abilities, can cope with the normal stresses of life, can work productively and is able to make a contribution to his or her community.

18.3 Increasing Impact of Ecological Psychology: Translating Interventions and Services to Daily Life

In parallel to major mental health reforms and deinstitutionalisation since the 1960s, and perhaps inspired, to a degree, by a similar zeitgeist, the scientific discipline of ecological psychology and eco-epidemiology emerged. Whilst different in emphasis on subjective experience and ecological systems, respectively, at the very heart of both ecological psychology and eco-epidemiology is the assumption that our experience and behaviour are situated in context (Myin-Germeys et al. 2018). In other words, these approaches posit that if we want to understand and explain experience and behaviour, we need to consider and investigate the context in which it occurs as well as the interaction between experience and context. From this, new research methodologies, such as the experience sampling method (ESM; synonymously, ecological momentary assessment), emerged and have recently gained momentum through the rapid advances in digital technologies. ESM is an intensive longitudinal data collection method that allows us to measure moment-to-moment variation in experience and behaviour in context and, hence, reflects an essential part in investigations of ecological psychology (Myin-Germeys et al. 2018). The ESM has been widely used to measure cognitive, affective and behavioural processes, symptoms, social functioning, quality of life and important contextual factors in mental health research (Myin-Germeys et al. 2018). This method has been also used and evaluated for tracking and monitoring mental health and, on this basis, providing service users and clinicians with personalised feedback through reporting systems (Myin-Germeys et al. 2018).

More recently, this field has developed further, and ecological momentary interventions (EMIs) have been proposed (Myin-Germeys et al. 2016) and are currently receiving an upsurge of interest. EMIs emphasise that if experience and behaviour are indeed situated in context, then it is precisely in this context that they are most amenable to change (Reininghaus 2018). EMIs therefore intend to translate preventive and therapeutic principles and techniques into daily life and tailor them to individuals' needs in a given moment and context, based on ESM assessments (see Fig. 18.1), thereby, achieving more sustainable change under real-world conditions, a process referred to as ecological translation (Reininghaus 2018; Schulte-Strathaus et al. 2022). Some evidence-based interventions have been

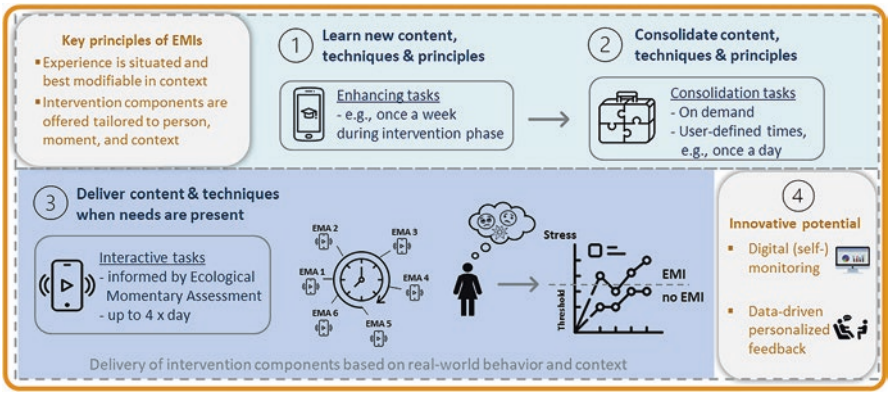

Fig. 18.1 Components and principles of ecological momentary interventions (EMIs)
Note: Simplified illustration of key principles and delivery schemes for ecological momentary interventions (EMIs) based on the EMIcompass intervention (Schick et al. 2021). EMIs consist of three types of tasks: (1) enhancing, (2) consolidation and (3) interactive tasks. During the intervention period, enhancing tasks are used to introduce new techniques and principles once a week, whilst consolidation tasks are delivered once a day for practising techniques at user-defined time points or on-demand. Interactive tasks are tailored to what individuals need in a given moment and context through interactive sampling (e.g. when scores of momentary stress or negative affects exceed certain thresholds) using ecological momentary assessment (EMA). EMIs enable ecological translation of therapeutic principles into daily life and can be supplemented by other digital forms of service delivery, including (4) monitoring of symptoms in real-time to generate and offer personalised feedback on subjective experience and behavioural patterns

transformed into EMIs, including personalised techniques and exercises frequently used in (third-wave) cognitive behavioural therapy (Schulte-Strathaus et al. 2022). These interventions show great promise, especially when adherence is supported in the context of blended care approaches (Rauschenberg et al. 2021; Schulte-Strathaus et al. 2022). Developed from basic research on experience and behaviour from an ecological perspective using ESM, EMIs are now researched across a range of mental health domains, including depression, anxiety, attention deficit/hyperactivity disorder, psychosis, substance misuse and eating disorders (Rauschenberg et al. 2021; Schulte-Strathaus et al. 2022). The use of EMIs is now also increasingly tested in routine care settings, but effectiveness, cost-effectiveness, implementation, uptake and reach of most EMIs have yet to be established (Rauschenberg et al. 2021; Schulte-Strathaus et al. 2022) due to the nascent and innovative nature of this approach.

18.4 Digital Mental Health: Opportunities for Accelerating Ecological Translation in Mental Healthcare

The rapid advances in the digital world provide us with plenty of opportunities to achieve adaptive, personalised, real-time and real-world transfer of interventions and services and have contributed to a renaissance of ecologism. Ecological translation of treatment and services dovetails with the original intention of community-based mental healthcare to provide services to the population in local context and real-world living environments. Indeed, ecological translation has gained much wider interest in psychiatry, including through a push towards mobile or smart sensing (Schulte-Strathaus et al. 2022), i.e. passively collected multimodal data from built-in or add-on mobile sensors (e.g. accelerometer, Global Positioning System and electrocardiogram) to assess other variables such as mobility, physical activity, heart rate variability and sleep (Schulte-Strathaus et al. 2022). Such passive or sensor-based intensive longitudinal data collection methods have received increasing attention. These methods ask individuals either to carry a dedicated sensor or use sensor-equipped mobile devices (e.g. smartphones and smartwatches) in order to collect rich data on behaviour, location, contextual changes and log device usage data to assess contextual, socio-environmental, physiological and behavioural momentary markers without requiring active user input (Schulte-Strathaus et al. 2022). It has been argued that passive or sensor-based methods allow for capturing 'digital phenotypes' that may allow for predicting risk of transition to or relapse of mental disorder using advanced statistical methods (Schulte-Strathaus et al. 2022).

Whilst this appears intuitively appealing, evidence on safety and effectiveness of this approach remains very limited. What is more, passive methods of digital phenotyping may be viewed as reinforcing the role of service users as passive recipients of, rather than active and empowered partners in, mental healthcare, and concerns have been raised by service users and mental health professionals that digital tools may create new barriers to accessing care. Further, the uptake of digital monitoring tools informed by passive and active intensive longitudinal data collection methods remains slow and disparate across European countries, which may be due in part to the limited availability of, and evidence on effective strategies for implementing digital tools in routine mental healthcare. The *Implementing Mobile Mental health Recording Strategy for Europe* (IMMERSE) consortium has recently been formed to address this issue in a two-phase, prospective implementation study. This consists of a participatory mixed-methods field study in phase I and a cluster randomised controlled trial (cRCT) in phase II with the aim of developing, optimising and investigating strategies, contextual factors, processes, outcomes and costs of implementing a Digital Mobile Mental Health intervention (DMMH) in routine mental healthcare in four European countries (i.e. Belgium, Germany, Scotland and Slovakia) (see Fig. 18.2). This DMMH intervention is strongly rooted in the ESM, which is used for tracking symptoms, therapy goals, key problem areas, mood, momentary quality of life, activities and social context and, thereby, geared towards ecological translation through (a) strengthening service user engagement and

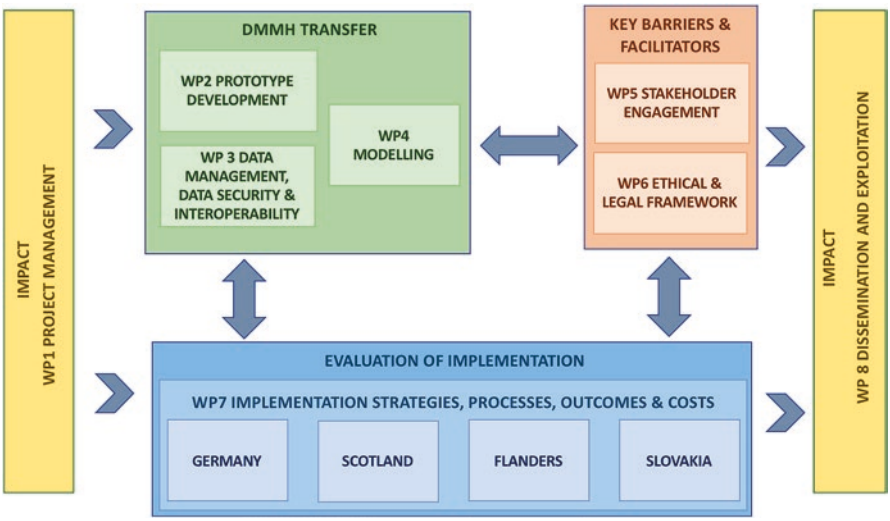

Fig. 18.2 Overall strategy of the IMMERSE consortium
Note: The overall strategy of IMMERSE is to transfer DMMH from a research tool to a clinical prototype ready for use in clinical practice (Project area DMMH TRANSFER, WPs 2, 3 and 4), to identify key barriers and facilitators for implementation of DMMH in routine mental healthcare practice (Project area KEY BARRIERS AND FACILITATORS, WPs 5 and 6) and to run an implementation study in four EU countries evaluating the implementation processes, outcomes and costs (Project area EVALUATION OF IMPLEMENTATION, WP 7), whilst also developing a tailored plan for further dissemination and exploitation, scaling up DMMH to the wider mental clinical health market (Project area IMPACT, WPs 1 and 8). IMMERSE, Implementing Mobile MEntal health Recording Strategy for Europe. DMMH, Digital Mobile Mental Health; WP, Work Package

empowerment in context, as it identifies the service user as the expert of their experience, making them active partners in their own treatment; (b) improving service users' self-management and recovery in daily life, as it provides the service user with a tool to manage their own mental health problems in their living environment; (c) providing goal direction in clinical assessment and management of care beyond appointments in the clinician's office; and (d) enhancing shared decision making, as it provides the highly relevant day-to-day information that is needed for service users and clinicians to make treatment joint decisions that are relevant to service users' real lives. Alongside the implementation strategies that are developed and evaluated in the IMMERSE consortium, this provides an enormous opportunity for accelerating ecological translation in mental healthcare practice. In line with this, others have started to compile a comprehensive set of implementation strategies to address challenges specifically to implementing digital *mental health* interventions in healthcare settings, which may contribute to closing the research-to-practice gap (Graham et al. 2020). Overall, the rapid developments in digital mental health and its implementation in routine care may substantially influence how mental health services will be shaped in the decades to come.

18.5 Current Challenges and Future Developments

Among the most pressing challenges in mental healthcare is the absence of robust assessment, monitoring and surveillance systems that form an essential basis for evidence-based service planning. Given the recent shift in focus to early intervention (Harvey et al. 2007; Malla et al. 2005; McGorry et al. 2008; Rauschenberg et al. 2021), prevention as a tangible goal (Rauschenberg et al. 2021) and promoting positive mental health (WHO 2015; Orpana et al. 2016), mental health services research needs to encompass the entire continuum of mental health – ranging from positive mental health and well-being via high-risk states to full-threshold mental disorder (see Reininghaus et al. 2022 for further detail) – to broaden its scope beyond the management, care and long-term outcomes of severe mental disorders (Morgan et al. 2021; Tamminga et al. 2021). Implementing broad assessment, monitoring and surveillance systems will, in turn, provide the basis for transforming the mental health field so that it can deliver care across all domains of public mental health services, including mental health (literacy) promotion, mental disorder prevention and evidence-based, interdisciplinary mental health service delivery. The challenge for mental health services research will be to inform the fundamental reforms that this will require and address important and intriguing questions in terms of how these services will be configured, structured and delivered in public mental healthcare practice (Reininghaus et al. 2022).

Digital mental health and, in particular, ESM-based tracking tools, reporting systems and EMIs rooted in ecological psychology and eco-epidemiology are promising evidence-based innovations that may contribute to transforming mental healthcare practice in the future. Uncertainties with regard to safety, effectiveness and implementation remain to be addressed for these innovations to realize more fully their potential. Mental health services research needs to address these uncertainties in rigorous and innovative research that develops not only digital tools as technology-enabled services in stakeholder-centred designs but also effective implementation strategies to improve acceptance, reach and uptake from the outset. This will provide enormous opportunities for delivering accessible, low-threshold services and translating interventions to where they matter, namely, the daily lives and living environments of users, thus enabling the achievement of what has been a central goal in different areas of mental health research and practice for some time now, i.e. the ecological translation of public mental health care.

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Chapter 19
Dynamic Landscapes of Health Professions

Charlotte Ullrich, Cornelia Mahler, Sandra Stengel, and Michel Wensing

Abstract Patients receive healthcare from various healthcare providers such as physicians, nurses, pharmacists, physiotherapists and psychologists. Across time and space, realms of and relations between healthcare professions show many differences (e.g. the professional autonomy of registered nurses). Variation, e.g. in respect to vocational training, approaches towards healthcare and autonomy of health professionals, needs to be considered in research and development in this field. Healthcare professions are therefore a classical domain of health services research. This chapter addresses three fields of research: (a) development within healthcare professions, considering increasing specialisation and allocation of tasks across professions; (b) interprofessional collaboration and education; and (c) work experiences and retention of health workers, particularly in underserved areas.

19.1 Introduction

As healthcare is dependent on the availability, accessibility, roles and retention of healthcare providers, healthcare occupations are a classical domain of health services research (HSR) (see Chap. 2). Vocational training and professional development of health workers are the basis of healthcare provision. This has been the topic

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of a large body of educational and implementation research in health. The planning and recruitment of the required number of health workers is central to the assessment of health needs in populations as well as to the allocation of tasks to specific healthcare providers. For example, tasks of physicians may be transferred to other professions, such as nurses or pharmacists. HSR has examined the consequences of such task transfers for health outcomes, work experiences, costs and the number of workers required. Another topic is the retention of health workers, which is closely related to issues of job satisfaction, workload and working conditions.

Across time and space, realms of and relations between healthcare professions show differences. Variation, e.g. in respect to vocational training, approaches towards healthcare and autonomy of health professionals, needs to be considered in research and development in this field. In Europe, 14.7 million people were employed in health occupations in 2019, representing about 7% of all persons employed and about 3% of all inhabitants. These occupations include: (a) nurses, midwives and nursing aids (4.5 million); (b) (paid) home-based personal care workers (4.1 million); (c) medical doctors (1.9 million); and (d) other health professions (4.1 million), such as physiotherapists (0.5 million), pharmacists (0.4 million) and dentists (0.3 million). In 2019, the majority of health workers were female (78%), over one-third were over 50 years old (Eurostat 2020). These health workers practice in hospitals and other healthcare institutions, ambulatory care practices and in long-term care institutions (e.g. nursing homes).

Although many differences in the health workforce can be found, three broad trends can be identified across many countries. First, healthcare occupations tend to develop towards increasing differentiation and specialisation, which is associated with changes in status and autonomy as well as technological developments (such as digitalisation and robotics). Second, there has been increasing attention for the quality and efficiency of interprofessional teamwork because it is central to modern healthcare and influences outcomes as well as work satisfaction and work experience. Thirdly, shortages in the health workforces exist in many places, partly as imbalances across healthcare sectors and geographic areas. This chapter will elaborate on these three trends with a focus on Europe and highlight themes for HSR.

19.2 Differentiation and Specialisation Within Healthcare Professions

While all health occupations aim at treatment and care of health problems of people, they differ in their approaches. These differences correspond with differences in education, self-conception and social status. While the definition of what constitutes a profession is somewhat contested (Bollinger 2018; Brint 1993), it is usually characterised as a specific form of occupation that requires a formal qualification based on prolonged, specialised academic training and a specialised body of knowledge and skills (see Box 19.1). Next to divinity and law, medicine belongs to the traditional professions. Since the nineteenth century, medicine has been successful in

developing a dominant position in the provision of healthcare (Freidson 1970; Light 2000). This was related not only to discoveries in the natural sciences, which provided life-saving treatments such as antibiotics, but also to the legitimisation and reimbursement of the medical profession by public agencies (e.g. health insurers).

Professions typically have extended autonomy to regulate their practice; they are often largely governed by professional ethics and codes, partially linked to professional law and predominantly monitored by collegial control. Professionalisation of a health occupation is therefore reflected in extended power to control professional affairs (e.g. through establishing regulative bodies) as well as enhanced status, power, and pay and better work conditions.

Similar development as that seen in medicine, although less pronounced, can be observed in other health occupations in the second half of the twentieth century (Whitcombe 2005), albeit the differences between countries and occupations remain substantial. For instance, the training and autonomy of registered nurses differs widely across countries. Educational programmes for some health occupations (e.g. nursing and midwivery) have developed from occupational training to university qualification. Alongside expanding professional training, research activities are typically initiated to enhance the systematic scientific knowledge base of a health profession. This knowledge centres around clinical interventions for diagnosis, treatment and care of patients.

Box 19.1: Characteristics of a Profession
- Specific form of occupation
- Formal qualification based on prolonged, specialised academic training
- Specialised body of knowledge and skills
- Often associated with (altruistic) work in public service
- Specific status, prestige and power
- Extended autonomy to regulate their education and practice

Increasing differentiation of health professions and within health professions is a general trend, which is related to growing specialisation within healthcare. For instance, within their postgraduate medical education and subsequent area of expertise, physicians increasingly focus on specific subdisciplines of medicine. Examples are additional training in diabetology, emergency medicine or palliative care; experts for specific operations for surgeons; and experts for electrophysiology for cardiologists. This also holds true for general practitioners who may develop additional clinical and nonclinical competencies (Wensing and Braspenning 2017). Within nursing, specialisation within healthcare settings and medical disciplines are common, e.g. in the areas of intensive care nursing, paediatric nursing, oncology nursing and cardiac nursing.

In addition, new health professions have emerged. For example, medical engineers have entered healthcare as a new health profession in some countries. In the Netherlands, they hold a university degree in technical engineering and are at the same time registered health professionals who closely collaborate with physicians

in surgery or rehabilitation care. Some existing occupations have altered their professional approaches. For instance, physiotherapists have shifted from technical applications to exercise behaviours and pharmacists from mere medication dispensing to clinical management of patients (van de Steeg-van Gompel et al. 2010). Furthermore, healthcare workers increasingly qualify for specific roles within the healthcare system, such as case or care management for patients, middle management in organisations or specific technical procedures.

Many such additional qualifications can be obtained by different health professions. For example, a case manager may be a physician, nurse or have another health profession. In order to fulfil a task that needs be performed, the development of the competency profile is more important than a specific health profession. The COVID-19 pandemic accelerated additional changes in the allocation of professional tasks. For example, in Germany, pharmacists were newly allowed to vaccinate against COVID-19 after completing a brief training course.

As a consequence of these developments, the tasks and roles of health workers provide a complex and dynamic setting for patient care: Patients in hospital may be attended by medical specialists, medical residents, nurses with various specialisations (e.g. intensive care and cardiology) and various competence levels (e.g. advanced practice nurses) of which one may act as case manager and possibly also by pharmacists, physiotherapists, psychologists, etc. In practice, it can be hard for patients to distinguish the different professions and roles. HSR is needed to document stakeholders' views on these developments and to examine their impacts on healthcare delivery and outcomes (see Box 19.2 for an example).

Box 19.2: A New Profession: Physician Assistants in Hospitals (Timmermans et al. 2017)

Physician assistants (PAs) are nonphysician clinicians (often nurses with a bachelor's or master's degree in nursing or another health profession other than medicine) who have qualified to perform medical procedures in a specific medical domain. In recent decades, they have practiced in the United States and in some European countries. Their emergence has been controversially discussed by both physicians and nurses. In the Netherlands, physician assistants complete a 2-year postgraduate training programme after an initial 4-year training in nursing or an allied health profession. A matched-controlled study (Timmermans et al. 2017) with 34 hospital wards compared teams that included physician assistants with traditional teams comprised of physicians only. Analysis of 2307 medical records showed similar length of hospital stay and scores for quality of care. A survey among patients showed that patient experience was more positive in wards with physician assistants. Employing well-trained PAs seems to be safe and may lead to better patient experiences. However, many studies on physician assistants are small and from the United States, so more well-designed and large evaluations in European countries are required.

The implications of the ongoing integration of information technology applications and robot technology in healthcare, including applications of artificial intelligence, is a further area of interest, as it has implications for the planning and training of healthcare providers. Evaluation studies in this field are often challenging because the stakes for the involved professions are high and the research settings usually involve practical restrictions, such as large differences across sites and the availability of only a few newly trained professionals. This means that researchers need to be diplomatic as well as creative in the design and conduct of studies.

19.3 Interprofessional Collaboration and Education in Healthcare

Interprofessional teamwork is central to healthcare. However, each profession looks at the patient and their healthcare problems through its own professional lens and therefore also sets different goals for and with the patient, ideally involving care givers. It is therefore necessary not only to train health professions in their profession specific competencies but also for them to acquire interprofessional competencies to improve patient care (see CIHC 2010). Within the healthcare literature, two concepts have received increasing attention in recent decades (Xyrichis 2020): interprofessional collaboration (IPC), referring to teamwork between health workers from various professional backgrounds, and interprofessional education (IPE). A large number of research topics within IPE and IPC concern issues regarding patient safety (Howarth et al. 2022), communication and teamwork (Baik and Zierler 2019), staff and patient satisfaction with care (Will et al. 2019) and organisational changes or hierarchical issues (Braithwaite et al. 2016). Within interprofessional education, the concurrent development of both professional and interprofessional competencies is an important topic for research and development. Alongside research evaluating outcomes of the interprofessional competencies, often as defined by IPEC (2016), the development of instruments to measure these outcomes are challenging and still under way (e.g. Nexusipe). Further research addresses attitudes towards interprofessional learning (Pollard et al. 2004), aspects of (interprofessional) socialisation within the various health professions (King et al. 2016) and stereotyping.

The highly influential US-based Institute of Medicine report (1999) points out that patient safety is often at risk due to misunderstandings and lack of communication between different health professions. A strategy to overcome this issue is to train health professionals together from the very beginning of their undergraduate training (see CAIPE 2016). This requires a change from mono-professional to interprofessional collaboration in the healthcare system and the need to develop interprofessional competencies from early on in professional training (Frenk et al. 2010). In medical and postgraduate medical education, changes can be observed over the last years and decades. In Germany, for example, interprofessional competencies are increasingly anchored in the associated competency-based frameworks with defined objectives. Among others, the CanMEDS Framework (Frank et al. 2015),

Box 19.3: Key Terms and Frameworks for Interprofessional Healthcare

- Successful *interprofessional collaboration* according to the *Canadian Interprofessional Health Collaborative* (CIHC) is a "A partnership between a team of health providers and a client in a participatory, collaborative and coordinated approach to shared decision-making around health and social issues" (CIHC 2010).
- *Interprofessional education* occurs according to the UK *Centre for the Advancement of Interprofessional Education* on "occasions when members or students of two or more professions learn with, from and about each other to improve collaboration and the quality of care and services" (CAIPE 2016).
- The *IPEC framework* issued by the *Interprofessional Education Collaborative* describes four central interprofessional competencies relevant for interprofessional education (a) values and ethics, (b) roles and responsiblities, (c) interprofessional communication and (d) teamwork (IPEC 2016).
- A *National Interprofessional Competency Framework* (2010) issued by the *CIHC* describes six interprofessional competencies relevant for interprofessional education and collaboration (a) role clarification, (b) interprofessional conflict resolution, (c) team functioning, (d) collaborative leadership and two overarching competencies, (e) interprofessional communication and (f) patient/client/family/community-centred care (CIHC 2010).
- The *CanMEDS Framework* formulated by the *Royal College of Physicians and Surgeons of Canada* that describes the roles and competencies physicians require to address healthcare needs. Interprofessional competencies are integrated within the roles of the communicator and the collaborator (Frank et al. 2015).

which was originally developed in Canada in 2005 for postgraduate medical education (see Box 19.3), has influenced this progress. In the meantime, the framework has been used in many countries around the world also for undergraduate medical education, and it additionally guides health professions such as nursing, midwifery and physiotherapy (e.g. in Switzerland (Herion et al. 2019)) in the definition of competencies to be acquired during their undergraduate training. Interprofessional competencies are central to the roles defined within this framework – e.g. the roles of collaborator and communicator.

The implementation of interprofessional training wards began in Sweden in 1996 and in the meantime has evolved into an innovative strategy combining interprofessional educational and collaborative activities (see Box 19.4). Preliminary results are promising regarding professional and interprofessional competency

development (Mink et al. 2021; Oosterom et al. 2019) and also demonstrate that patient safety is not violated by it (Kuner et al. 2022). Research on long-term sustainable effects of competency development as well as cost-benefit analyses still needs to be undertaken.

Box 19.4: Heidelberg Interprofessional Training Ward (HIPSTA) (Mink et al. 2021, 2022)

Interprofessional training wards have the potential to develop interprofessional competencies alongside professional competencies by exposing students from various health professionals in a real-life clinical setting during a clinical placement. In Heidelberg, Germany, medical students and nurses in vocational training experienced a 4-week placement on the Heidelberg Interprofessional Training Ward HIPSTA, facilitated by nurse and physician educators to support and guide the interprofessional teams in collaborative practice and in medical and nursing care. Results of the longitudinal quantitative study showed significant positive short-term results on interprofessional competencies directly after the placement. Long-term effects three months after the placement still showed positive effects on interprofessional socialisation and collaboration (Mink et al. 2021). Group discussions at the end of the placement showed differences between the different student/learner teams regarding their interprofessional socialisation process pointing out the need for more research in the field in the development of interprofessional competencies (Mink et al. 2022).

In general, interprofessional collaboration seems to work well where no (or little) competition between health professionals arises and a common goal and vision regarding patient-centred care exists: An example would be complementary and naturopathic non-pharmacological interventions and counselling which are conducted by physicians as well as allied health professionals (Homberg et al. 2021; Valentini et al. 2022). A further pressing topic in need of successful interprofessional collaboration is sustainable healthcare or planetary health, a research area overcoming not only professional but also disciplinary boundaries (see Chap. 24).

Research in this field not only addresses educational and collaborative issues within healthcare but also has the aim of showing that successful interprofessional education has an impact on healthcare and outcomes. However, the link showing how or if interprofessional education has a direct impact on patient outcomes is challenging. Due to the emerging character of the field, there is a need to define terminology so that concepts can be identified, evaluated and compared (Mitzkat et al. 2016); frameworks need to be developed and studies conducted. To date, two Cochrane reviews of intervention studies address the effects of interprofessional education on professional practice and healthcare outcomes (Guraya and Barr 2018; Reeves et al. 2013; Reeves et al. 2016) and interprofessional collaboration to improve professional practice and healthcare outcomes (Reeves et al. 2017). Both

reviews see the growing number of studies in the field as encouraging and, at the same time, state the difficulty of drawing conclusions due to the heterogeneity of interventions, frameworks, evaluation methods and outcomes applied. Therefore, there is a need for rigorous studies based on a sound framework, the evaluation of interventions and their short and long-term outcomes, and qualitative research methods examining processes, which change according to organisational (meso-level) and healthcare policy (macro-level). Last but not least, cost-benefit analyses are needed to show the necessary return of investment such a (fundamental) change in practice entails.

Overall, to achieve all these innovative and necessary changes in healthcare, a change of paradigms in the healthcare system is necessary. On an organisational level, team-based collaborative leadership/partnership is required rather than a profession specific intra or interprofessional hierarchy between health professionals (Orchard et al. 2017). New organisational models need to be implemented and evaluated, education of healthcare professionals needs to be adapted and graduates prepared for the challenges within the healthcare system.

19.4 Healthcare Labour Market: Job Satisfaction and Workforce Mobility

Healthcare delivery depends on the availability of trained and motivated health workers, but shortages and imbalances across healthcare sectors and geographic areas exist in all countries. The shortages are particularly high in nursing, which is the largest health profession overall. The assessment of physician shortages partly depends on the allocation of tasks across professions (e.g. whether a physician is required for blood pressure measurement or injections). In addition, there are disbalances within professions (e.g. too few physicians in primary care and geriatrics) and geographical regions (e.g. too few providers in rural areas). Although the increasing use of technology (e.g. robotics in nursing) may reduce the need for health workers, it is likely that future healthcare will remain largely dependent on health workers.

HSR has explored issues such as job satisfaction and work experiences of health workers, and it has examined the impact of strategies to enhance recruitment and retention of health workers. For instance, an international study on work satisfaction of primary care physicians found variations across 34 mostly European countries, with the highest scores in Denmark and the lowest in Spain. Favourable to physician work satisfaction were performing technical procedures, providing preventive care, feedback from colleagues, patient satisfaction and working fewer hours (Stobbe et al. 2021). Work–life balance has become an important ambition for health workers and thus a topic for HSR. As a result, reduced working time of physicians has been observed internationally (Lachish et al. 2016). This raises the question to what extent these developments influence the quality of patient care (Panattoni et al. 2015; Stengel et al. 2021), address the workforce shortage or provide an approach

for offering appealing working-models to attract general practitioner trainees (Lambert et al. 2017).

The recruitment and retention of health professionals in the health workforce, and in underserved rural areas and deprived urban areas in particular, is a related topic of HSR. Many determinants have been identified, which can be categorised as (1) financial, (2) career and professional, (3) working conditions, (4) personal, (5) cultural and (6) living condition factors (Mohammadiaghdam et al. 2020). A qualitative study in nurses identified (a) push factors, i.e. factors that may push nurses to consider leaving the profession included limited career prospects, generational barriers, poor public image of nursing and workplace pressures, and (b) pull factors, i.e. factors that nurses desired and could keep them in the profession included professional pride, improved remuneration, recognition of nursing, professionalisation and improving the image of nursing as a profession (Roth et al. 2022). The mobility of health workers, also across national borders, is another topic that relates to workforce shortages. An example is a study on the experiences with nurses who were trained in another country (see Box 19.5). Further research is required to provide analysis and interpretation of the findings of the numerous descriptive studies, followed by the development and evaluation of interventions and policy measures to enhance work experiences and retention of health workers (as an example: Mulfinger et al. 2019).

Box 19.5: Perceptions of Internationally Trained Nurses (Roth et al. 2021)

The recruitment of nurses from other countries is one of the strategies to reduce the shortage of nurses in a country. The views of these nurses and the host nurses were explored in a cross-sectional survey study with 167 participants, using validated measures of safety culture, work engagement and work–life balance. Both groups expressed moderately positive views on safety culture and work engagement and moderately negative views on work–life balance. Host nurses reported higher workload and worse work–life balance. Nevertheless, substantial room for improvement existed in both groups.

19.5 Conclusion and Perspective

The delivery of healthcare largely depends on the human workforce, and it seems unlikely that technology will drastically change this, although it may help to increase labour productivity. HSR is required to support the planning, recruitment, training, performance and retention of health workers. Workforce shortages may be considered the biggest challenge for healthcare in the coming decades, given the ageing populations in many countries. Future research should go beyond description and identification of factors associated with work experience and retention. It should offer analysis and interpretation, as well as evaluate interventions and policy

measures in this field. A distinct analytical perspective on professions can help to identify underlying assumptions to understand characteristics, changes and (potential) conflicts within and between healthcare professions.

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Chapter 20
Community Pharmacies as Healthcare Providers: New Developments in Medication Management and the Role of Information Technology

Hanna Seidling and Robert Moecker

Abstract Community pharmacies make a major contribution to patient care, yet they have been underrepresented in health services research. They provide an example of nonphysician providers with expanding roles. With new services such as patient education, vaccination services and medication review becoming increasingly common, the role of pharmacies goes beyond dispensing medication. This requires, among other things, appropriate clinical competency and access to necessary patient data. Clinical training, digitalisation of procedures and interprofessional collaboration facilitate pharmacy services. Among the most commonly provided and effective services are medication review and medication management, which are approaches to enhance medication safety. However, the generalisability and implementation of these approaches need to be examined in future studies.

20.1 Introduction

Pharmacies play an important role in supplying the population with medicines and providing information and support to enhance appropriate drug usage. Generally, pharmacies are part of primary care – most often as on-site, community pharmacies, but a smaller fraction are mail-order pharmacies. Alternatively, they are associated with hospitals to support inpatient and outpatient care. These two types of pharmacies differ concerning the range of medicines that are typically provided, the legal

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framework, and the staff of the pharmacies. These differences are related to the type of patients attending hospitals or primary care. This chapter focusses on community pharmacies and their contribution to healthcare in Europe, highlighting three emerging topics: (a) the role of community pharmacies in primary healthcare, (b) medication review and management and (c) the role of information technology in medication management.

20.2 Community Pharmacy as an Important Pillar in Primary Healthcare

Community pharmacies are important places to obtain medicines but also to seek advice regarding minor ailments. Usually, community pharmacies are easily accessible due to a relatively dense network of facilities. Depending on international and also regional differences, i.e. rural versus urban, the average number of community pharmacies in European countries per 100,000 inhabitants ranges from 7 in Denmark to 88 community pharmacies in Greece with an average of 29 community pharmacies per 100,000 inhabitants in OECD25 countries (Organization for Economic Co-operation and Development) (OECD 2020). These numbers also depend on the extent to which hospital pharmacies and physicians are involved in dispensing medicines, the number of subsidiaries allowed and which over-the-counter medicines (OTC, not requiring a prescription) can be purchased in drugstores or supermarkets. For example, in Spain, pharmacists can privately own only a single pharmacy; while in Germany, they can have up to three subsidiaries; and in the UK, larger chain pharmacies are allowed (Benrimoj and Fernandez-Llimos 2020).

Irrespective of the exact number of pharmacies, community pharmacies – like general practitioner practices – are characterised by a high frequency of patient contacts. In Germany, for example, 3.3 million individuals visit a community pharmacy every day, adding up to 1 billion patient contacts per year, compared to 1 billion visits to general practitioner practices per year (ABDA – Bundesvereinigung Deutscher Apothekerverbände e. V. 2020; Kassenärztliche Bundesvereinigung (KBV), 2021).

Community pharmacists are academically trained medication experts. They primarily collaborate with physicians and play a major role in checking and filling medication prescriptions. Besides the traditional task of dispensing medicines, community pharmacies offer increasingly patient-centred and clinical services, i.e. professional pharmacy services (Mossialos et al. 2015) (Box 20.1).

Providing these services requires that pharmacists have clinical and communication skills to establish constructive relationships with patients and prescribing physicians.

Also, pharmacists need to become even more engaged with health services research in the community pharmacy setting in order to accumulate evidence on the effectiveness and implementation of pharmacy services. Promising examples of engaging pharmacists in health services research are practice-based research networks, such as the Danish Network for Community Pharmacy Practice Research and Development (NUAP) and the Utrecht Pharmacy Practice network for Education

Box 20.1: Professional Pharmacy Services (Moullin et al. 2013)
Professional pharmacy services are delivered in the community pharmacy setting and aim to improve health outcomes and the value of healthcare by optimising the process of care. Examples for internationally available professional pharmacy services that target a specific disease or health problem are:

- Pharmaceutical care programmes, e.g. management of diabetes or hypertension
- Cessation and withdrawal/deprescribing programmes, e.g. tobacco or opioids
- Point-of-care testing, e.g. hepatitis B/C or HIV, blood pressure and glucose
- Medication review and medication management programmes
- Vaccination
- Education of patients, e.g. inhaler technique

and Research (UPPER) (Burghle et al. 2021; Koster et al. 2014). Pharmacists show great willingness to contribute to the development of community pharmacy practice in these networks and have expressed that research networks foster the exchange of knowledge among researchers and practitioners and contribute to the development of clinical pharmacy and health services research in pharmacy.

20.3 Prerequisites for Medication Reviews and Management

A widely applied example of comprehensive and complex professional pharmacy services is medication review (MR). "MR is a structured evaluation of the patient's medicines with the aim of optimizing medicines use and improving health outcomes. This entails detecting drug-related problems and recommending interventions" (Griese-Mammen et al. 2018). If followed by continuous monitoring, i.e. periodic follow-ups, medication review becomes medication management (MM). The aim is to continuously monitor the patient's drug therapy and prevent potential drug-related problems should drugs be added or the patient's health deteriorates as patients become more multimorbid with age.

The effectiveness of MR has been explored in numerous studies. For instance, a systematic review and meta-analysis on MR interventions in the community setting showed positive effects on blood pressure and HbA1c in patients with diabetes and on total cholesterol in patients with hyperlipidaemia (Al-Babtain et al. 2022). Interestingly, services in these studies were often a package of pharmaceutical care of which MR was just one part.

In order to determine the effectiveness of MR, rigorous evaluation research is required (Beuscart et al. 2018), and the effects of MR must be distinguishable from those of other parts of a service package. For example, Blalock et al. (2020) screened people for increased fall risk and compared the effectiveness of an information and

gait training intervention with and without MR. People who screened positive for a high risk of falling showed a higher decrease in the mean drug burden index than the control group or those who screened negative. However, among those who screened positive, the amount of decrease did not differ between those who received a MR and those who did not, indicating little to no added value of MR, compared to a targeted gait training intervention for this target group. On the other hand, Lapointe-Shaw et al. (2020) showed in a propensity score matched cohort study that patients who received a community-based medication reconciliation and adherence review, called MedsCheck in Canada, after discharge had a lower risk of 30-day death or readmission.

Driven by potentially positive effects, MR has become more common and established in Europe and elsewhere, such as Australia, Canada and the United States. Today, most European countries offer MR to some extent. Some countries have implemented government-driven, standardised and reimbursed MR services and reached national coverage. Other countries rather have chosen to launch local MR programmes which were rolled out and upscaled (Imfeld-Isenegger et al. 2020). The 'type' of MR offered varies across countries from simple to advanced. For simple MR, only information from the medication history is available. In intermediate MR, the medication history is available together with a patient interview or clinical data. In advanced MR, all three types of information are available, allowing for the most comprehensive assessment (Griese-Mammen et al. 2018). In addition, and despite the above-mentioned classifications, MR practices differ among European countries but also internationally. Simple MRs, including elements such as drug-drug interactions, duplications or treatment costs, are performed least consistently, while advanced MR seems to be performed most consistently across countries (Bulajeva et al. 2014). There are also differences with regard to how MR is implemented (Imfeld-Isenegger et al., 2020) and how it is evaluated. Table 20.1 gives examples of MR and MM studies that address the evaluation of MR and MM services differently.

In Germany, local projects such as ATHINA ('Arzneimitteltherapiesicherheit in Apotheken', 2012), ARMIN (Arzneimittelinitiative Sachsen-Thüringen, 2014) and Apo-AMTS (2012) were initiated to test and promote MR in community pharmacies. These projects were primarily initiated by pharmaceutical organisations, and patient information was collected in community pharmacies through patient interviews. In ARMIN, physicians are regularly involved in the medication review process enabling an advanced MR. Furthermore, patients' medication data could be exchanged via an online server. Also, communication between physicians and pharmacists was fostered and facilitated by electronic communication via this online server.

In the UK, precursory services such as MUR (medicines use review, since 2005) and NMS (new medicine service, since 2011) were implemented and funded by the government. Both services are not a full clinical review like an MR. Nevertheless, MUR and NMS focused on specific aspects which are also part of MR, i.e. addressing the patients' understanding of their medicines and improving the medication adherence. Both are preparatory services that have contributed to paving the way for structured medication reviews (SMRs). SMRs were planned to be implemented in 2020/2021 as part of the new general practice contract framework in the UK. SMR can be provided within the interprofessional setting

Table 20.1 Exemplary medication review projects and their evaluation

	REVISA project (medicines use review service) (García-Agua Soler et al. 2021)	DREAMeR-study (clinical medication reviews) (Verdoorn et al. 2019)	Medication review with follow-up (Varas-Doval et al. 2020)	ARMIN (Arzneimittel-initiative Sachsen-Thüringen) (Meid et al. 2023)
Country	Spain	Netherlands	Spain	Germany
Study	Implementation, cross-sectional multicentre study; interviews, questionnaires	Multicentre RCT	Hybrid effectiveness	Retrospective, propensity score-matched cohort study
Population	(1) Community pharmacies (N = 64) (2) Patients (N = 495) with complex medication, high risk medication or polymedication (≥5 drugs)	Patients (≥70 years) with polypharmacy (≥ 7 long-term medications (N = 629)	(1) Community pharmacies (N = 135) (2) Patients (≥65 years) with polymedication (≥5 drugs) (N = 844)	Patients (N = 5033) with polymedication (≥5 drugs)
Service	Medicines use review service	Clinical medication review focused on patients' personal goals	Medication review with follow-up	Systematic, structured interview by pharmacist and by physician, follow-up every 3 months
Outcomes	Medicines use review-related time, cost, satisfaction and willingness to pay	Health-related quality of life (EQ-5D-5L and EQ-VAS), number of health problems	Implementation outcomes: progress, reach, fidelity and integration; number of emergency visits and hospitalisation, health-related quality of life	Mortality, hospitalisation, drug–drug interactions, potentially inadequate medication, adherence, healthcare utilization, amongst others
Special feature of the study	Assessment of time needed to perform service to gauge reimbursement/price per intervention	Multicentre RCT providing highest level of evidence	Assessment of implementation *and* effectiveness outcomes	Comparably large sample size which allows for assessment of hard outcomes

Table 20.2 Exemplary barriers in the implementation of MR (Michel et al. 2021)

CFIR domain	Barriers
Intervention characteristics	Lack of transparency regarding achieved outcomes Costly implementation Long and complex documentation
Outer setting	Low awareness of MR and low willingness to participate Lack of adequate remuneration Difficult relationship between pharmacists and physicians Lack of official mandate from health authorities
Inner setting	No support from colleagues No private space for counselling, small pharmacies MR was not aligned with pharmacy's mission or staff's view Lack of resources (e.g. training, time and money) No leadership engagement Difficult integration of MR in pharmacy workflow
Characteristics of individuals	Lack of confidence, partly due to insufficient clinical training Lack of motivation
Process	Few/limited description of planning how to implement MR

of primary care networks (PCNs). PCNs are comprised of various healthcare providers (HCP), including general practitioners, clinical pharmacists and district nurses, typically covering 30,000 to 50,000 patients (Pharmaceutical Services Negotiating Committee 2021).

Outside Europe, there are countries that have already implemented MR at the national level and remunerate it accordingly. In Australia, for example, MedsChecks, home medicines reviews (HMR) and residential medication management reviews (RMMR) are offered. All services aim at checking a patient's medication and improving drug therapy. While MedsChecks are services that can be initiated by community pharmacists and have to be provided in the community pharmacy, HMR and RMMR are provided upon referral from a physician and take place in the patient's home or aged care facility, respectively (Australian Government – Department of Health 2021).

Besides effectiveness, the implementation of MR in real-world healthcare settings has been examined. Various factors influence the successful implementation of interprofessional MR, as results from a review on barriers in the implementation of MR from the pharmacists' perspective using the Consolidated Framework for Implementation Research (CFIR) show (see Table 20.2).

To examine and optimise the effectiveness and implementation of MR, further research is required. While the implementation of MR has been examined, many studies are only observational and qualitative. In addition, the MR under investigation is mainly without the involvement of physicians. The goal in practice should be to establish MR in collaboration with pharmacists and physicians, i.e. an interprofessional setting. Hence, further areas for research are comprehensive and easy access to patient data for HCPs, clinical training of pharmacists, pharmacist-physician collaboration and the cost-effectiveness of MR.

20.4 Potential Role of Information Technology (IT) in Fostering Medication Management

Pharmacies are an essential component of any healthcare system. Yet, there are substantial differences in the degree to which pharmacies are integrated into health systems' IT networks. Hospital pharmacies can typically access and exchange information with clinics electronically via the hospital's information system. In contrast, in some countries, community pharmacies do not have interconnected software systems, leaving them as singular organisations that are neither interlinked with other pharmacies nor with other HCPs (Thiel et al. 2019). In the UK, for example, the differences between community pharmacies and hospital pharmacies (which have had central systems for some time) or physicians (whose IT infrastructure has been specifically funded) become clear as community pharmacies are separated from other parts of the NHS (Goundrey-Smith 2018). Communication and the exchange of information across sectors also continue to be a major challenge. Reasons for this include diverging attitudes towards data ownership and a lack of technical standards and infrastructure for electronic interoperability. In many countries, digitalisation efforts are currently underway and will probably be rolled out within the coming years.

The process of prescribing and dispensing medicines by physicians and pharmacists, respectively, is facilitated by electronic prescription; i.e. pharmacies can retrieve prescriptions electronically. European countries are at different stages of implementing e-prescriptions. While some countries have just started to pilot e-prescriptions, other countries like Denmark, Estonia, Finland, Portugal, Spain and Sweden have e-prescription coverages of >90% (OECD 2018). The European Commission's goal is to implement e-prescriptions in 25 European countries by 2025, thereby harmonising and digitalising prescribing and dispensing across borders, bringing physicians and pharmacists closer together and relieving the patient in the process of carrying paper-based prescriptions from one HCP to another.

As community pharmacists' activities are shifting from dispensing medicines to providing healthcare services in the form of professional pharmacy services, such as MR and MM, these services require an appropriate skill set, which includes strong clinical knowledge and communication skills on the one hand and hands-on practice and experience on the other. Also, in this context, new digital tools might help to foster skills and competencies and support the implementation of MR and MM services.

O'Sullivan et al. (2020) interviewed pharmacists about 'Essential Attributes for the Community Pharmacist as Care Provider'. They identified:

- Three key attitudinal-behavioural attributes: Forward thinking, patient-centric and provider mentality
- Five skill-related attributes: Organisational competence, communication, building relationships, patient care and management and leadership
- Two knowledge-related attributes: Treatment guidelines and regulatory and payer requirements

Besides having knowledge, a pharmacist needs to have a variety of soft skills to be a care provider rather than a product dispenser. While pharmacists can gain clinical expertise, such as interpreting diagnostic results and applying guidelines, by reading and studying, they might need training on communication, building relationships or practising a (new) service.

This section elaborates on three examples where IT might play a major role in promoting MR services and highlights how health services research can endorse this process. To simulate practice or to provide support in practice, extended reality applications are increasingly being used. An example of such an application is the "Augmented reality for risks management in injectable drugs preparation in hospital pharmacy" (Othman et al. 2021). One of the main difficulties in preventing medication errors when preparing doses for administration is providing information without disturbing the person at work. Othman et al. (2021) developed augmented reality glasses which provide different instructions to the operator to reduce medication errors. Further pharmaceutical areas of use for extended reality applications might include situations in which a patient is usually needed or where training usually requires physical presence (Coyne et al. 2019). In future pharmacy practice, potential examples include training communication skills, simulating medication reviews or adherence education. Extended reality applications have great potential to enhance digital training and education, provide immersive training experience and support pharmacists in daily work. However, there are still challenges, such as costliness and the availability of content for those applications, for example, training scenarios which have to be developed and tested (Coyne et al. 2019).

Second, for pharmacists to perform their role as HCPs and conduct clinical services effectively and efficiently, they need easy access to patient data (including recorded diagnoses and diagnostic test results). For example, if they want to perform a comprehensive MR, they also need clinical data, which usually reside with physicians. Being able to access such data would make pharmacists' workflows more efficient. Hohmeier et al. (2017) have shown that integrating health information exchange in pharmacy workflow can enhance pharmacy services (see Box 20.2).

Box 20.2: Integration of Health Information Exchange in Community Pharmacy Workflow (East Tennessee Health Information Network) (Hohmeier et al. 2017)

With health information exchange (HIE) networks, different HCPs can share medical and prescription data across separate settings. For example, physicians, clinics, diagnostic centers and hospitals share patient medical data within the East Tennessee Health Information Network. Hohmeier et al. (2017) investigated the participation of the first community pharmacy in this network. The community pharmacy participated to enhance its services. For the transitional care service, the use of HIE allowed for simple patient identification and easily obtainable medication lists. In 60% (n = 15) of the cases, the medication list could be obtained via HIE. Patients had 15 medications on average, and all patients (100%) had at least one discordant medication. Subsequently, pharmacists could contact prescribers for clarification to prevent medication errors.

Third, pharmacy services should be made easily available for all patients but especially those who live in rural areas or who are particularly vulnerable, such as patients discharged from hospital or nursing home residents. Bridging the physical gap between HCPs and patients using telehealth may have advantages regarding improved accessibility, timeliness and cost-effectiveness. Studies indicate there are benefits to MR with regard to frequently studied process evaluation outcomes, such as patient uptake of the service, number of pharmacists' recommendations and patient and HCP satisfaction (Shafiee Hanjani et al. 2020). Medication-related outcomes, costs and clinical outcomes were analysed less often. Hence, such findings need to be confirmed in further research – ideally randomised controlled trials.

20.5 Conclusion

Community pharmacies are an important pillar of healthcare that will likely become even more relevant in the coming years. In Europe, there is considerable variation in what services are offered and how well community pharmacies are networked with other HCPs. While MR and MM are among the emerging services in community pharmacies, their uptake still needs to be facilitated. The role of IT in pharmacy care cannot be overestimated. It can help train pharmacists by employing innovative applications, such as extended reality. IT facilitates interconnectivity and interoperability, which is required for efficient information exchange in healthcare. IT can help make patient care provided by pharmacists more easily accessible by using telehealth services. Health services research is needed to evaluate the effects and implementation of specific tools and interventions in order to support decision-making by pharmacies, the pharmacists' bodies and public agencies. Besides medication-related, patient-related and clinical outcomes that have been studied for some services, relating these outcomes to costs and potential savings as well as identifying the patients who potentially benefit most, are crucial to negotiating and establishing professional pharmacy services. The uptake of pharmacy services into routine practice poses another important topic of future research, which should focus on the impacts of strategies for implementation (e.g. external facilitation of community pharmacies).

Recommended Readings

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Chapter 21
Continuity of Care: New Approaches to a Classic Topic of Health Services Research

Johanna Forstner and Christine Arnold

Abstract Continuity of care refers to the degree to which healthcare provision is a consistent and interconnected process. It has three dimensions: relational continuity, informational continuity and management continuity. Continuity of care impacts on healthcare utilisation and health outcomes. Patients, especially those with multiple or rather complex healthcare needs, value continuity of care in terms of forming a longitudinal and trusting relationship with health professionals. In health systems, several strategies aim at achieving high continuity of care, such as case management, advanced nursing practice and integrated care. Future studies may focus on the role that patients can and want to play in enhancing continuity and how it can be optimised in fragmented healthcare systems.

21.1 Introduction

Continuity of care (CoC) is a classic theme of health services research. It has been described as "the degree to which a series of discrete health care events is experienced by people as coherent and interconnected over time and consistent

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with their health needs and preferences" (WHO 2018, p. 8). CoC is particularly relevant for patients with complex healthcare needs that require the involvement of many different health professionals. This becomes even more relevant in highly fragmented health systems, which are characterised by strong separation between hospital care and ambulatory care (Wright and Mainous 2018). CoC is highly valued by patients, particularly those with many chronic conditions (Pandhi and Saultz 2006). CoC is considered to be one of the core elements of primary care (Uijen et al. 2012).

The first use of the term 'continuity of care' dates back to the 1950s and focussed on the personal relationship of a patient with a health professional. Since then, and especially within the last 20 years, the term has increasingly been used in the scientific literature. From the 1970s on, CoC has been considered as a multidimensional concept. Various definitions of the concept of CoC have been used, and they are not consistently distinguished from related concepts such as coordination of care (Uijen et al. 2012). What the various definitions have in common is that they distinguish several dimensions and consider different points of view (e.g. patients and health professionals). For this chapter, we will use the definition of the dimensions of CoC proposed by Haggerty et al. in 2003 (see Box 21.1).

Box 21.1: Definition of Continuity of Care According to Haggerty et al. (2003)

- *Relational continuity* refers to having a trusting and longitudinal relationship with a health professional.
- *Informational continuity* implies that a health professional has all relevant information on the patient and their medical history on hand.
- *Management continuity* means that if care is provided by (many) different health professionals, their approach is consistent with that of others and is congruent with the patient's needs.

The effect of CoC on healthcare utilisation and health outcomes, such as mortality, hospital (re-)admissions or quality of life, has been investigated in many studies. Baker et al. (2020) showed that high relational CoC was associated with lowered all-cause *mortality*. Furthermore, Wensing et al. (2021) compared patients participating in a strong primary care programme in Germany, regardless of age and indication, with a control group, using several relational CoC measures. They observed higher CoC in patients participating in the programme and a lowered risk of *hospital admission*, *readmission* and *hospital admission because of ambulatory care sensitive conditions*. Facchinetti et al. (2020) conducted a meta-analysis of randomised controlled trials of CoC interventions for preventing hospital readmissions

of older people with chronic conditions. Approximately 9000 individuals were included in the analysis, and the interventions were shown to have a positive effect on short-term readmission. When looking at long-term readmissions, the evidence was inconclusive. Furthermore, interventions were most effective when all dimensions of CoC were addressed. Chen et al. (2017) conducted a meta-analysis of the effect of CoC on *quality of life* in older adults with chronic conditions. Their analysis of 1400 patients found CoC to have a significant impact on quality of life, measured by using the SF-36 instrument.

In this chapter, we will first elaborate on the patients' and relatives' perspectives on CoC (Sect. 21.2) and then turn to three selected approaches to enhance CoC that have been the topic of health services research and which increase in complexity: (a) case management, (b) advanced nursing practice and (c) integrated care (21.3). Subsequently, new developments in health services research on CoC will be considered (21.4), and finally, some future perspectives are offered (21.5).

21.2 Patients' and Relatives' Perspectives on Continuity of Care

The definition of CoC from a patients' perspective according to Reid et al. (2002, p. i) is "one patient experiencing care over time as coherent and linked". From the perspective of patients and relatives, relational CoC seems to be the most recognised and most highly valued out of the three core dimensions of CoC. In most cases, patients would like to see the same health professional over a long period of time and on a regular basis, thereby building a trusting relationship. Seeing the same health professional is also preferred over receiving healthcare provided by a team with various health professionals. However, not all patients value and wish for CoC. It is generally most valued by patients with complex healthcare needs who experience the consequences of a fragmented healthcare system: elderly patients, parents of young children, females and people with lower levels of education. Furthermore, life-changing experiences that are shared with a health professional can raise the perception of the importance of CoC and help to build trust as well as a long and ongoing relationship with a health professional (Pandhi and Saultz 2006; Waibel et al. 2012).

The need and desire to reach CoC also depend on the prevailing health problem. Ehman et al. (2017) conducted a study with an anonymous survey of 770 individuals, comparing multimorbidity patients and healthy adults from family medicine centres. They found that both healthy participants and multimorbidity patients prefer CoC for routine check-ups regarding their chronic conditions or for preventive care appointments, while they are more likely to forgo this continuity for acute problems if it means they can get in touch with a physician more quickly. Yet, in acute situations, patients with multimorbidity prefer to wait longer to be seen than healthy adults if this means that they can be seen by their primary care professional instead of another member of the same care team (Ehman et al. 2017). Although the

majority of patients prefer to see their own primary care physician on a regular basis and thus knowingly or unknowingly increase relational CoC, not everyone is able to do so. Aboulghate et al. (2012) found that this possibility is less likely for women, younger patients, patients without chronic or mental conditions, and 'non-white' patients.

In contrast to relational CoC, it is more difficult to inquire whether patients perceive and value informational and management CoC. Patients are often only confronted with the concept of CoC when they experience gaps in CoC, such as obvious deficits in information transfer between health professionals. Many patients assume that CoC takes place in the form of information transfer or communication between health professionals and the availability of shared care plans (Haggerty et al. 2013).

In practice, many patients and their relatives contribute to informational and management CoC by taking on a coordinating role. They may not do so voluntarily but rather out of necessity as they have the impression that no one else is assuming this responsibility (Bossert et al. 2020). Some patients take on a 'patient-as-professional role' (Phillips et al. 2015) and coordinate their care proactively (such as by involving other health professionals). Whether a patient wants to take on an active and coordinating role in care depends on factors such as individual attitudes, cultural beliefs, familiarity with the health system and health literary (Phillips et al. 2015; Haggerty et al. 2013). Health services research is needed to explore which patients can and want to be actively involved in healthcare and where the limits to this lie.

21.3 Strategies to Enhance Continuity of Care

As a response to low CoC, various strategies have been applied to enhance CoC. *Case management* is an approach to manage the care of people with complex health and social problems and has been established in nursing and social care since the 1960s. It provides support and CoC in a fragmented healthcare system, resulting in individualised management of treatment and care across specialised health professionals. A case manager enhances CoC by offering coordination of treatment and care over time and between health professionals. Case managers are also expected to help patients access care and take charge of their care planning (Uijen et al. 2012). The role is often performed by dedicated nurses or social workers. Case management can reduce all-cause mortality and hospital readmission in specific populations, for instance, in patients with chronic heart failure (Takeda et al. 2019). It can also improve patients' quality of life, for instance, in cancer patients (Yin et al. 2020). However, case management is not universally effective, and it involves additional resources; thus, the cost-effectiveness of healthcare may be at stake (WHO 2016; Takeda et al. 2019). Also, the involvement of a case manager (usually a role with little decision-making power) may alleviate problems of lowered CoC, but it usually does not address causes that are inherent to a fragmented healthcare system.

Another strategy in which a key person takes over the coordination of care and address management continuity is the *Advanced Nursing Practice (ANP)*. ANP has been developed and used in the United States and Canada since the 1960s. The reasons

for its development are numerous, such as the shortage of physicians, especially in primary care, and the increasingly complex care and specialisation of nurses (e.g. community health, primary care or mental health; Schober 2016). The use of community health nurses as an ANP concept in the area of community care has been common practice for a long time. In Scandinavia, the UK, the United States and Canada, they are deployed in primary healthcare. They are highly specialised nurses, who are the first point of contact in primary care for health and disease-related issues. They work autonomously and take over medical tasks and coordinate care in their specialties. With regard to qualification, there are differences across nations (Hamric et al. 2013). Most community health nurses in ANP have a master's degree. In hospitals, ANP often falls under the concept of *primary nursing*. They are considered the point of contact for the patient and other professional groups involved, and they coordinate care in the hospital. This strategy can promote CoC and patient satisfaction (Manthey et al. 1970). ANP can contribute to CoC in settings which are characterised by fluctuations of physicians and other health professionals. The adoption of ANP is mixed across countries. An example of a health services research project in ANP is shown in Box 21.2.

Box 21.2: Example Advanced Nursing Practice (Laurant et al. 2018)
In their systematic review of 18 randomised trials, Laurant et al. (2018) investigated the extent to which nurses working as substitutes for primary care doctors impacted: patient outcomes, processes of care and utilisation of care, including volume and cost. Study findings suggest that care delivered by nurses (e.g. first contact care or follow-up examinations for chronic diseases such as diabetes), compared to care delivered by physicians, possibly generates similar or better health outcomes for a broad range of patient conditions. For example, nurse-led primary care may lead to slightly fewer deaths among certain groups of patients, compared to doctor-led care. The evidence was rated as low to moderate. Laurant et al. (2018) concluded that nurse practitioners or advanced practice nurses can perform physician tasks, such as consultations in primary care. Nurse-led consultations may lead to higher patient satisfaction. Overall, visits are of longer duration. However, it remains unclear how nurse-led consultations affect healthcare costs and what level of nurse education leads to the best patient outcome.

Another approach to improving CoC is *integrated care*, a concept that is not consistently defined and interchangeably used with related terms such as 'coordination', 'disease management' and 'case management'. Integrated care is purposefully designed healthcare for a defined population (e.g. diabetes patients), to provide healthcare that is coordinated across healthcare professionals and informed by the best available evidence (WHO 2016). Especially in the context of the increase in multimorbidity and complex care, programmes that overcome the fragmentation of the healthcare system, managed care and accountable care are necessary and have become popular since the year 2000. Today, variations of integrated care can be found in all countries, and there is a large body of health services research on the implementation and effectiveness of integrated care. An example of a study is shown in Box 21.3.

Box 21.3: Example Healthy Kinzig Valley Integrated Care (Schubert et al. 2021)
The Kinzig valley in southwestern Germany is a best-practice model region that has implemented an integrated care concept on a large scale ('Healthy Kinzig Valley Integrated Care'; German: *Integrierte Versorgung Gesundes Kinzigtal*). The aim is to overcome the fragmentation of the healthcare system and promote CoC. It is a network of general practitioners, specialists and clinicians, psychotherapists, care facilities and physiotherapists that plans and coordinates treatment for those insured by the AOK (German: *Allgemeine Ortskrankenkasse*) Baden-Württemberg and the Social Insurance for Agriculture, Forestry, and Horticulture. Despite some positive effects in the first 5 years, the elaborate 10-year evaluation of the programme showed neither an improvement nor a deterioration in the quality of healthcare compared to structurally similar control regions. Early evaluations suggested cost savings due to higher efficiency of healthcare delivery.

21.4 New Developments Regarding Continuity of Care in Health Services Research

Health services research on CoC is traditionally based on interviews and surveys in patients and health professionals (Schang et al. 2013). A method to measure CoC from the patients' perspectives is to use the Nijmegen Continuity Questionnaire (NCQ), which was developed in the Netherlands. This questionnaire includes 28 items within three subscales: 'personal continuity: care provider knows me', 'personal continuity: care provider shows commitment' and 'teams/cross-boundary continuity' (Uijen et al. 2011).

With the increasing availability of routine data, which are often derived from computerised clinical and administrative patient data, interesting computational approaches to research CoC have emerged. For instance, widely used measures of CoC are the Bice–Boxerman Continuity of Care Index, the Herfindahl Index, the Usual Provider of Care Index (UPC) and the Sequential Continuity of Care Index (SECON). The Bice–Boxerman Index, the Herfindahl Index and UPC are all indices that measure the rate of all provider contacts with the same provider (usually the general practitioner). As they all depict the same construct, they are highly correlated. All indices are simplifications of a complex construct and should only be seen as proxies, which should be interpreted carefully (Pollack et al. 2016) (Box 21.4).

Box 21.4: Example Measuring Continuity of Care (Forstner et al. 2023)
In patients with chronic obstructive pulmonary disease (COPD), hospital readmission rates are very high. Reasons are, amongst others, a high burden of comorbidity and frequent exacerbations. Therefore, in a study focusing on the impact of provider connectedness on CoC after hospital discharge and readmission rates, Forstner et al. (2023) calculated the SECON to measure CoC. This index, unlike other indices, does not depict the share of contacts that are with the same provider but considers whether consecutive consultations are with the same provider or with another as the previous consultation. Thus, the SECON does justice to the fact that patients with a high burden of comorbidity need to see several healthcare providers to receive appropriate treatment for their conditions. The index can take on values between 0 and 1 with 1 indicating perfect CoC. In their study, patients with COPD had a mean SECON of 0.73 in the year after hospital discharge. The authors found provider connectedness to impact on CoC and readmission rates but other factors appeared to be more important.

21.5 Conclusions and Future Prospects

This chapter focusses on CoC, a classic topic of health services research. CoC is highly valued by many patients, and it contributes to health outcomes. A range of approaches to enhance CoC are applied in healthcare settings and have been the topic of many evaluation studies. Future studies may focus on the role that patients can and want to play in enhancing CoC.

More fundamentally, one may consider how much CoC is desirable. High provider CoC can develop a positive doctor–patient relationship that gives patients confidence and security (Wilfling et al. 2021). On the other hand, such a relationship can also be inhibited if sensitive issues are to be addressed. In these cases, some patients might choose to actively interrupt CoC. While high provider CoC and relationship CoC can achieve high-quality patient care and patient satisfaction, this can be especially stressful for health professionals. A good and trusting relationship with the patient can cause the work–life balance to falter and can be emotionally distressing. New generations of health workers tend to favour a different work–life balance than previous generations, which inevitably involves reduced relational CoC. Care models that include high relational CoC thus might be beneficial for the patient, but it remains to be seen whether it is viable in the long run.

Furthermore, it remains an open question whether CoC can and should be an aim in a healthcare system that involves high specialisation (Wright and Mainous 2018). Increasing numbers of patients have various morbidities that require the involvement of different specialists from time to time. A balance or combination of high CoC and involvement of specialised health professionals needs to be found and would be a topic for future research.

Recommended Readings

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Chapter 22
Access to, Continuity and Coordination of Healthcare for Refugees: Emerging Challenges and Topics for Health Services Research

Kayvan Bozorgmehr and Andreas W. Gold

Abstract In light of rising numbers of refugees worldwide, refugee health has gained growing scientific attention. Health research in this field has mainly focused on disease prevalence, social conditions and related health risks. However, the organisation and delivery of healthcare for refugees as an important topic of health services research has been sidelined, despite the inherent challenges of providing effective and high-quality care for this population. A first issue concerns barriers in the access to health services for refugees that arise at different levels of the cascade of healthcare provision. Other issues are the continuity and coordination in healthcare for refugees, who tend to move between locations in unpredictable ways. Healthcare for refugees is to some extent delivered by separate health system structures, in which generic problems of the overall healthcare system are exacerbated.

22.1 Health Services Research and Refugees

Health research in the context of refugees has long been primarily disease-oriented. It has aimed to study the morbidity of refugees by establishing estimates of prevalence or incidence of a given health condition among this heterogenous population. Such research tends to be concerned with infectious diseases or mental health (Bozorgmehr et al. 2020c) and gives less consideration to the broad spectrum of

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conditions, including noncommunicable chronic conditions, that can be encountered in contemporary refugee populations (Abubakar et al. 2018). Even less studied are aspects of health systems and health services delivery. While much research has dealt with legal regulations on access to healthcare or utilisation of health services, few studies tend to focus on organisation, governance, financing, quality, equity or efficiency of healthcare. As a result, knowledge remains orientated on individuals and their medical needs, while system-level solutions, barriers, and facilitators to high-quality care for refugees, including perspectives from health services research (HSR), remain sidelined (Bozorgmehr et al. 2016a, 2020c). However, a perspective from HSR has a lot to offer to address and respond to the health needs of refugees. In this chapter, we use the example of coordination of healthcare for refugees to highlight the added value of this lens.

By the term migrant, we mean all those who leave their place of habitual residence, whether within a country or across an international border, temporarily or permanently, and for various reasons (IOM 2019). A relevant subgroup under this term are forcibly displaced migrants, which we refer to as refugees. The term refugees in this chapter is not used as a purely legal term, but rather as umbrella term for asylum seekers, persons whose asylum application has been rejected, and persons whose claim for asylum has been accepted and refugee status has been granted according to the Geneva Convention or on humanitarian grounds as well as those in irregular situations crossing national borders in search of international protection. For a detailed description and definition of the different groups and legal frameworks, we refer to glossaries on international migration law (IOM 2019).

Migrants tend to be healthier than their host population due to the 'healthy migrant effect'. This effect relates to the fact that migrants are a selective population of their country of origin and (in comparison to that 'source population') are usually healthier as they have the physical, social and financial means to migrate. Meanwhile, this effect has also been described for comparisons between migrants and populations in their host country (Razum 2009). However, such a health benefit does not always hold for the group of refugees (Abubakar et al. 2018). Refugees disproportionately suffer from mental health problems (Priebe et al. 2016; Satinsky et al. 2019; Steel et al. 2009), health consequences from external causes like attacks or accidents (Jahn et al. 2021), and are at higher risk of acquiring infectious diseases due to the crowded conditions in camps and poor hygiene in the peri-migration phase (Greenaway and Castelli 2019), but at the same time they are not 'different' from non-refugee populations in suffering from all common, severe and non-severe, conditions that can be encountered in primary care as 'daily business' (Bozorgmehr et al. 2016a). From these health needs, two main requirements arise for healthcare: first, ensuring good access to timely and effective primary care in order to identify health needs, initiating acute and longer-term care, and facilitating access as gate opener or gatekeeper to specialised services based on underlying need, and second, providing adequate specialised services that are accessible, acceptable and responsive to, e.g. the mental health or complex somatic needs of refugees.

This chapter will first elaborate on barriers to refugees accessing health services, then we will deliberately focus on the aspects of continuity and coordination of

care. Using this example, we seek to highlight emerging challenges and topics for HSR and identify areas in which it can generate knowledge that informs solutions to improve healthcare and, ultimately, health of refugee populations.

22.2 Barriers in Access to Health Services for Refugees

The availability, accessibility, acceptability and responsiveness of health services are often limited for refugees due to a wide range of formal and informal barriers. Formal barriers refer primarily to healthcare entitlements. Many European countries restrict the access of refugees to healthcare (Bradby et al. 2015; Lebano et al. 2020). In Germany, for example, the *Asylum Seeker Benefits Act* limits the entitlements of services to acute and painful conditions, with the exception of vaccination, care provided for pregnant women, and victims of torture and sexual or physical violence (Gottlieb and Schülle 2021). Further barriers exist in terms of the requirement of a healthcare voucher to visit a physician (Bozorgmehr and Razum 2020). Informal barriers can arise from individual health literacy and the associated knowledge of and ability to navigate a complex healthcare system (Kickbusch et al. 2013; Spura et al. 2017). Low-threshold support services to help refugees find their way through the new health system are often not available. Moreover, service providers and the structures of healthcare are often not adapted to refugees as patients. This is reflected, among other things, in the uncertainty of service providers about refugees' healthcare entitlements, which can lead to under-provision of care despite an existing entitlement to healthcare services (Führer 2020; Razum et al. 2016). Some of these barriers are 'generic', meaning that they potentially affect every patient and are not linked to a migration or refugee background. Other barriers are 'migration-specific', i.e. of concern in other migrant populations, and can, for example, also turn up among international students, international workers or other populations on the move. Some are 'refugee-specific', i.e. attributable to the particular legal situation and the consequences for health and healthcare that arise solely due to the act of seeking international protection (see Table 22.1).

22.3 Continuity and Coordination of Healthcare for Refugees

Continuity and coordination of healthcare are important areas for improvement across many health systems. They are desirable features of healthcare delivery as a lack of continuity and uncoordinated care is expected to result in over- and under-provision of healthcare and inefficient as well as ineffective delivery of care interventions.

Continuity of care considers three dimensions across the continuum of care for patients across both time and space (Haggerty et al. 2003) (see Chap. 21) (Box 22.1):

Table 22.1 Barriers for refugees to access health services

Level	Generic barriers	Migration-specific barriers	Refugee-specific barriers
Individual	Health-seeking behaviour Health literacy	Language discordance with healthcare provider; insufficient knowledge about healthcare system, rights, entitlements and processes of care	Frequent relocations between and within federal states, counties and communes Lack of trust of healthcare workers (e.g. based on negative premigration or peri-migration experiences) Dispersal to isolated housing facilities with reduced physical accessibility to service providers
Provider	High time pressure in daily treatment routines The additional time required for complex treatment processes often cannot be charged	Lack of knowledge about ways to involve trained interpreters/bilingual health workers when needed Low intercultural competencies, lack of awareness about somatising patient presentation style Limited knowledge on travel medicine/migration-related health problems	Lack of knowledge about legal situation of refugees, entitlements to care and prevailing health problems Lack of time to deal with administrative issues involved in care for refugees
Healthcare organisational	Poor intersectoral coordination Fragmentation and insufficient integration of services Mismatch between need and demand for special services (e.g. psychotherapists) Weak primary care systems	No routine availability/use of health interpreters/bilingual health workers and ad hoc use of untrained interpreters (other clinic/ward staff, family members, social networks)	No special healthcare unit charged with the responsibility to provide care for refugees
Health system	Limited sensitivity to diversity aspects	Country-specific regulations on healthcare entitlements for non-nationals	Specific restrictions for refugees

Box 22.1: Three Types of Continuity as Proposed by Haggerty et al. (2003)

- *Relational continuity* refers to having a trusting and longitudinal relationship with a healthcare professional.
- *Informational continuity* entails a healthcare professional having all relevant information on the patient and their medical history on hand.
- *Management continuity* means that if care is provided by (many) different healthcare professionals, their approach is consistent with that of others and is congruent with the patient's needs.

Coordination is an important aspect to ensure continuity of care. However, there is a lack of consensus on what the term 'coordination' encompasses (Schultz and McDonald 2014). A review on this topic identified 57 heterogeneous definitions of the term 'care coordination' (Schultz and McDonald 2014). Following the identification of both common and unique themes among them, the authors of the review (Schultz and McDonald 2014) propose the consolidated definition provided in Box 22.2.

Box 22.2: Definition of Care Coordination

"*Care coordination* is the deliberate organization of patient care activities between two or more participants (including the patient) involved in a patient's care to facilitate the appropriate delivery of healthcare services. Organizing care involves the marshalling of personnel and other resources needed to carry out all required patient care activities and is often managed by the exchange of information among participants responsible for different aspects of care". (McDonald et al. 2007)

This definition involves proactive organisation of care activities of different participants (institutions or individuals, including the patient) to reach an appropriate level of care by means of resource allocation and exchange of required information.

Both continuity of care, and its related aspect of coordination of care, are important aspects in the area of refugee health. For example, the high-level meeting on refugee and migrant health of the World Health Organization Regional Office for Europe calls upon its member states to take appropriate measures to promote continuity and quality of care for migrants and refugees (WHO, Regional Office for Europe 2015). At the same time, existing evidence shows that continuity and coordination of care appear to be particularly at stake in the context of healthcare delivery for refugees in Europe (Bradby et al. 2015). The reason for this is that the concepts of continuity, including coordination, have yet to be considered in scenarios in which a patient with a fixed place of residence encounters healthcare providers in a geographically circumscribed region. The concepts, and the underlying health systems

delivering the services, are however not yet prepared for 'a world on the move' (Abubakar et al. 2018), i.e. for people travelling (forced or voluntarily) within and between countries in irregular forms, as will be elaborated and highlighted below.

22.3.1 Lack of Continuity and Coordination of Care

Continuity of care is particularly challenging in the context of healthcare provision for refugees. Considering the migration trajectory with its pre, peri and post-migration phase (Zimmerman et al. 2011), ensuring continuity of care as defined above appears to be – at first glance – an impossible task for health systems. When people flee their homes due to violence, conflict, war, political persecution, natural disasters or economic collapse, they often also leave behind a health system that has been largely dysfunctional, limited in scope and quality or provides services only in the scope of humanitarian aid, e.g. through international organisations serving large camps of internally displaced people. Such care is often constrained by limited resources and deviates from recommendations of clinical guidelines as the specific contexts of camps do not allow for care to be delivered in conformity with common evidence-based recommendations (Blundell et al. 2019). What is still poorly understood is how existing clinical and evidence-based guidelines can be adapted especially to the peri-migration phase, which is often characterised by bureaucratic hurdles and encampment policies. Such an adaptation is required in order to meet the healthcare needs of refugee populations and avoid 'good care' being postponed to an undetermined future when people have resettled.

Health records (e.g. on vaccination during childhood), if they ever existed, are often left behind or lost; medication and treatment is disrupted, and access to services is at stake. Refugees from countries with functional health systems also leave behind trusted service providers with whom they may have built relationships over years. They also leave a system whose operating norms, rules and culture may have not been perfect (if such a thing as a perfect health system exists) but were at least well known to them.

During flight, in the peri-migration phase, refugees often cross several borders on an irregular basis. Access to healthcare services is often precarious, denied by countries of transit due to the irregular and clandestine situation of the refugees, or provided in a humanitarian manner with limited or *ad hoc* scope. Little research has been conducted on the peri-migration phase, but existing evidence suggests that the responses are framed as emergency care leading to chaotic and fragmented approaches (Chiarenza et al. 2019). Furthermore, narrative evidence suggests that especially refugees with chronic conditions discontinue their medication due to lack of access to medicines, bearing the risk of, e.g. exacerbation of conditions such as diabetes. In countries of transit, health screenings are sometimes performed (Zenner et al. 2020b). However, they mostly focus on infectious diseases and are driven by securitisation perspectives and (provenly unfounded) fears that dangerous infectious diseases are 'imported' by incoming refugees (Voss et al. 2020). A study on health services provision on infectious disease services to refugees in countries of arrival, transit and

destination found that services are often poorly coordinated within and between countries, lack continuity of care with respect to fundamental health information (e.g. results of health screenings or vaccination records) and are organised in a haphazard way (Bozorgmehr et al. 2019). It remains unclear which organisational concepts may improve such coordination and how governance within and across countries needs to be organised to avoid disrupted care and over- or under-provision.

Even if the scope of such screening is kept broader and includes assessment for other health needs, the information collected is usually not passed on to other health service providers on the migration route or to the refugees in a way that would ensure continuity of information. Often, health records are either not existent or established in formats that do not allow exchange between providers between or even *within* countries (Zenner et al. 2020a). This leads to interrupted flows of information, repeat history taking at each stage of the migration trajectory, repeat diagnosis (e.g. undergoing chest X-rays for tuberculosis several times), overprovision of services (e.g. being vaccinated several times against measles), under-provision of services (e.g. late treatment with insulin due to unknown diabetic condition) and treatment errors (e.g. treating patients with kidney disease with pain killers such as ibuprofen). The discontinuity of care and the disrupted exchange of information is exacerbated by language barriers that refugees often face in both countries of transit and countries of arrival. Ensuring cross-country transfer of health-related information in conformity with data protection laws to ensure informational continuity is still an unresolved technical, social and organisational challenge.

An exception is resettlement programmes managed by the International Organization of Migration (IOM) or the United Nations High Commissioner for Refugees (UNHCR), which include standardised pre-departure assessments of health status, structured recording of health-related information and exchange of information between predeparture settings (e.g. camps in the country of origin) and the destination country (Zenner et al. 2020a). However, such resettlement programmes cover only a tiny fraction of those forcibly displaced globally. The majority settle in other countries based on individual agency or are subject to dispersal, e.g. between or within countries of arrival, based on administrative reasons of the host country to better 'manage' the flows of incoming refugees. Such policies, however, barely consider the health-related dimension, including informational or management continuity. For example, dispersal programmes within Germany often lead to discontinuity of information as medical information is not passed on when refugees are transferred to other federal states within the country (Bozorgmehr et al. 2016b). Relational continuity is also often disrupted, for example, when refugees are transferred from central camps to peripheral communities without follow-up treatment, e.g. care for traumatised patients, being organised or provided (Nikendei et al. 2019). Disruptions in all three dimensions of continuity also occur in the case of forced or voluntary repatriation, as linkage to care back in the countries of origin is far from self-evident and not proactively coordinated.

While healthcare professionals have a particular responsibility to ensure continuity in care and coordinate delivery of services, the task is barely accomplished at the micro-level of patient-doctor encounters. Measures at the level of healthcare facilities as well as at the organisation level of authorities and agencies in charge

of reception of refugees need to improve governance and healthcare coordination for refugees. This includes the definition of clear responsibilities at different administrative levels within countries, but it also entails the establishment of new structures and forms of cooperation that ensure cross-border governance of healthcare for refugees to ensure continuity with respect to management, information and service provision (Dara et al. 2012, 2017). This is accompanied by questions of how organisational (and administrative) change can be facilitated, which intersects with sociological research on organisations but also with political science perspectives on facilitating policy and institutional change.

22.3.2 Interventions to Improve Continuity and Coordination of Care

To improve coordination, care management approaches, which work well in other areas of healthcare (see Chap. 21 in this book), could be introduced in the context of refugees as well. Especially integrated care approaches are important to establish interdisciplinary, low-threshold services on site in camps (Bozorgmehr et al. 2018).

In order to improve the continuity of care, interventions are necessary at various levels. HSR can measure the effects of interventions at individual and organisational levels and provide scientific support for implementations. In this way, HSR can contribute to finding solutions to improve the often insufficient coordination and continuity of healthcare for refugees.Here, we briefly point to a selection of possible interventions according to the three aspects of Continuity of care (CoC):

To improve relational continuity:

- Establish a long-term relationship with a primary care team that is preferably trained on the specific needs and requirements of a migrant patient group (O'Donnell et al. 2016).

To improve informational continuity:

- Patient-held health records, which improve intersectoral availability of information after transfer to different camps and increase doctors' satisfaction with the information they need (Jahn et al. 2018; Straßner et al. 2019)
- Electronic medical records that allow digital exchange of health-related information between service providers in different countries (Chiesa et al. 2019) or of providers at different sites and camps within countries (Jahn et al. 2021)

To improve management continuity:

- Quality circles that help to identify barriers and facilitators at the level of healthcare facilities (Straßner et al. 2017)
- Cross-sectoral meetings of stakeholders involved in reception of refugees (authorities, camp service providers, healthcare professionals and social workers) to coordinate needed care in terms of resource allocation, proactive planning and deliberate decision-making (Nikendei et al. 2017)

A general overarching intervention to improve access to healthcare, especially for marginalised populations, is to strengthen primary care services as a system-wide intervention for all groups of a population (WHO & UNICEF 2018). Specific interventions to improve the healthcare quality of refugees and asylum seekers in countries of resettlement focus mainly on four aspects: approaches to strengthen integration between existing systems and services in healthcare and social care, interventions to enhance communications services and interventions to upskill health professionals in primary care as well as care of refugees (Iqbal et al. 2021).

An approach to meeting the health needs of a refugee population at the primary care level and linking them to regular health services is the 'beacon clinics', which have been established in various locations in recent years (Kay et al. 2010; Kohler et al. 2018). Their team is multidisciplinary and typically includes general practitioners, nurses, social workers and administrative staff. Typical roles and responsibilities of 'beacon clinics' are described in Box 22.3.

Box 22.3: 'Beacon Clinics' for Refugee Populations

"Beacon clinics are outcomes-focused, providing initial health assessments for refugees with onsite interpreter services and patient education materials available in multiple languages. Beacon practices provide initial, transitional PHC for refugees during the first six months from acceptance, as a gateway service to full registration in the local health system. Patients receive a patient-owned medical record, and the beacon practice subsequently links patients with local providers for ongoing primary care and provides information about other health services in the community.

Roles of beacon clinics include planning and facilitating optimal and patient-centric care in a primary care environment, sharing best practice knowledge with providers in the community, and supporting research to improve primary care for refugees.

Beacon clinics provide information and resources about infectious diseases, immunisation needs, and policies, which help to up-skill community clinics and providers in their capacity to deliver care to refugees locally. As the beacon clinic helps community providers and clinics in improving their confidence in offering quality care to the refugee community, it also helps build trust between the local refugee community and community practices.

A typical role held by these clinics during care transition points could include: a first visit may be offered from the beacon staff to support successful transition into community practice; discussion of specific issues with medical and administrative staff of the accepting clinic to support better understanding of common and specific challenges related to the patient and the refugee population in general; information may also be provided to administrative staff about access to booking interpreters and other relevant resources in the community to improve experience of medical appointments and the overall ongoing care." (Kohler et al. 2018)

Since primary care in many countries is struggling with a shortage of physicians, there have been discussions about alternatives for physician-only models of care and new tasks and roles for non-physician healthcare professionals (Kringos et al. 2015; Maier and Aiken 2016). 'Refugee Health Nurses' (RHNs) are another example of how primary care services can address the specific needs of a refugee population. Desmyth et al. (2021) describe key roles and possible tasks of RHN working in countries of resettlement as follows:

> "Key roles of the refugee health nurse are providing primary care that is culturally responsive, promoting health literacy and empowerment and advocating for our patients within healthcare systems. Refugee nursing offers care across the life span and includes comprehensive physical assessment, mental health assessment, immunisation history and catch-up, family planning, oral health, nutrition, torture and trauma sequela, infectious, parasitic, and vaccine preventable disease and chronic disease recognition and management." (Desmyth et al. 2021)

Nurses are central and independent actors – either in multidisciplinary teams or in nurse-led services – as systematic literature reviews of models of care for refugees in primary care have shown (Ho et al. 2019; Joshi et al. 2013; Robertshaw et al.

Box 22.4: Integrated Healthcare Service for Refugees

"The Monash Health Refugee Health and Wellbeing Service Model (MHRHW) service model aims to provide holistic care for asylum seekers and refugees with complex health needs. The integrated service is resourced by a multidisciplinary team comprising: general practitioners, refugee health nurses, infectious disease physicians, paediatricians, bicultural workers, community development workers, psychiatrists, counsellors, physiotherapists, pharmacists and administration staff. A 'Refugee Health Nurse on Triage' service is available each day to support local agencies requiring refugee health information, and assist services with client referrals.

The MHRHW service model does not intend to replicate universal services. Rather, the service provides intensive transitional care to asylum seekers and refugees experiencing high levels of vulnerability, restricted access to Australia's universal healthcare system, Medicare, and complex health needs. […]

The four key components of the MHRHW service model include:

1. *Primary healthcare*:
   The primary healthcare component involves health assessments of physical, social and mental health, which consider migration history and prior medical care. Assessments are undertaken by refugee health nurses, […]. Refugee health nurses provide immunisations and referrals as required, and offer complex case management for clients with higher needs. General practitioners and allied health professionals, including counsellors and physiotherapists, also provide coordinated and integrated multidisciplinary primary healthcare.
2. *Specialist services […],*
3. *Capacity building and secondary consultation […]*
4. *Community development* […]." (McBride et al. 2016)

2017). In many cases, RHNs are described as 'system navigators' for refugees. Consequently, assessment, care coordination and case management are often important tasks for them. An example for the involvement of RHNs in an integrated healthcare service for refugees is shown in Box 22.4.

22.4 Further Research Needs and Conclusions

Health systems research with a focus on health of refugees is a relatively new and emerging field of research. While we have growing evidence on this topic, some of which we have presented in this chapter, further research and scientifically guided development of interventions are needed.

More research is needed in particular on the healthcare needs of refugees during transit and the health consequences of discontinued care. Specifically, effective modes of collaboration to improve cross-border governance deserve more attention. In countries of resettlement, effects of not only individual but also organisational interventions to improve coordination and continuity of care should receive more focus in research. Important aspects of research and development in this context are:

- Implementation of care management in refugee contexts
- Medical records systems and their role in ensuring/facilitating informational continuity as well as management continuity
- Involvement of interprofessional team members in providing effective refugee/migrant health
- Models of delivering healthcare for refugees and strategies for integrating refugees into regular healthcare structures.

Therefore, long-term and longitudinal studies of refugee resettlement are needed to provide information on how challenges and opportunities change over time. To this end, refugees' experiences with various aspects of healthcare must also be surveyed on a regular basis.

Consequently, health research on refugees should not only focus on individual health conditions and the burden of disease but also needs to take a closer look at organisational and system-related aspects. Ensuring access to healthcare that also addresses the specific needs of refugees proves to be particularly challenging. HSR can help find solutions to improve the often lacking coordination and continuity of healthcare provision for refugees. While we have pointed to a selection of possible interventions, much more evidence and research is needed to guide and inform the development of interventions and reforms to achieve responsive and high-quality healthcare for refugees.

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Chapter 23
Digital Technology for Information and Communication in Healthcare

Aline Weis and Sabrina Pohlmann

Abstract All areas of healthcare are highly dependent on the exchange of clinical and administrative information. This requires a technological infrastructure and tools for documenting and communicating information between healthcare providers, patients/citizens, healthcare payers and others. In recent decades, these infrastructures and tools have been increasingly based on digital technology. Examples include computerised patient records in hospitals and primary care practices, video conferencing for meetings of clinicians and online platforms for transfer between healthcare organisations. Implementing digital technologies in healthcare needs to reflect system-related conditions such as political, cultural, financial and organisational factors. Furthermore, skills of potential users must be considered from the development stages of digital tools up to the evaluation in routine settings.

23.1 Introduction

Since about the turn of the millennium, documentation and information transmission practices in healthcare have changed. Like in other sectors of society, the predominantly analogue tools have increasingly been supplemented or replaced by digital applications. This process started with the switch from handwritten records to PC-based documentation in healthcare facilities.

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Modern information and communication technologies (ICT) already offer a wide range of possibilities, which are increasingly integrated in a variety of processes. During an inpatient stay, for example, it is possible to merge patient data from the documentation systems of the various specialist disciplines (e.g. laboratory, operating room, nursing and radiology) that help capture and store patient information digitally. By merging these systems into a comprehensive clinical patient record, all attending healthcare providers are equipped with all relevant information about the respective patient. For example, by merging documentation systems, interprofessional coordination processes could be supported in order to overcome communication breakdowns and thus avoidable delays in action and decision-making (Holderried et al. 2020).

In ambulatory care, digital practice information systems are gradually replacing analogue record management in some countries, while this transformation has been completed in other countries. Data exchange between outpatient and inpatient facilities can be facilitated by a uniform data interface and enable more comprehensive recording of health-related patient data. One example is the use of regional digital platforms to facilitate information sharing between primary care and local hospitals in the Netherlands. Such efforts and developments are generally referred to as eHealth, which is used as an umbrella term for healthcare practices comprising, for example, electronic data capture and communication and information processing, both for administrative purposes and with regard to medical care and documentation in the healthcare sector (see also (Lux 2020) and Box 23.1).

Box 23.1: Terminology and Definitions in Digital Healthcare
The terminology in the field of digital technology for information and communication in healthcare is developing rapidly. Overarching terms are 'eHealth' and 'digital health' or – the by now rather outdated – term of 'health telematics' (Fischer et al. 2016, p. 5f). The demarcation between the different fields of application, user groups and the associated concepts is often difficult, and the boundaries are fluid (Fischer et al. 2016, p. 8f). This considerably complicates finding clear definitions in these areas. What all concepts have in common is the endeavour to enable or improve digital exchange and communication in healthcare with the overarching goal of increasing the quality of care (Elmer 2016). In addition to communication between individuals and organisations, the concept of digital health also comprises other tools such as computerised clinical decision support systems, digital versions of decision aids to enhance shared decision-making with patients, and robots in care or surgery.

While the collection of patient data *within* a healthcare institution in computerised patient records and for administrative purposes is already 'lived practice' in many countries, the digital *exchange* of health information *between* different actors and healthcare institutions seems to be the exception rather than the rule in many countries. The implementation of such overarching digital structures and interventions apparently poses a major challenge for healthcare systems. Nevertheless, there

are several examples of specific tools for information exchange that are becoming increasingly common in healthcare worldwide, such as digital cross-sectoral health and patient records or e-prescription services. Specialist consults or patient-doctor discussions via video conferencing as well as a wide range of healthcare applications such as interactive online-based self-help programmes for treatment of patients with depression or other conditions are already established. The use of computers, smartphones and tablets has become an important part of today's healthcare practice – both for healthcare providers and for patients (Fischer et al. 2016, p. 7ff.).

The COVID-19 pandemic has shown how important digital structures and procedures are for the maintenance of health services (e.g. physicians using video calls with patients) and for the collection of health data as a basis for medical and political decision-making, for example, the real-time recording of virus spread, available intensive care beds and ventilators, the acceleration of reporting channels for infections and the real-time display of vaccination rates. Against this background, the digitalisation of information exchange and communication structures may be one of the most significant and challenging transformations in healthcare in recent times. However, the effects of the use of many digital tools are unknown. Adverse outcomes cannot be excluded, e.g. poorer access to healthcare for specific patients and lower job satisfaction for health workers due to, for example, higher documentation burdens for healthcare workers. With this in mind, it is also worth questioning whether digital tools, often presented as 'digital solutions', are generally associated with improved quality of healthcare (Elmer 2016). In short, from the perspective of health services research (HSR), when, how and whether digitalisation leads to improvements in healthcare is an important topic for empirical research.

This chapter focuses on two major areas of interest that can be distinguished from HSR perspective: (a) analysis of the preconditions for digitalisation of information and communication in healthcare and (b) the evaluation of digital innovations in this domain. The first concerns the healthcare system-related conditions for the establishment of digital infrastructures and the adoption of digital communication tools in healthcare. The second domain concerns the evaluation of the impacts of specific digital tools in routine care settings, such as smartphone applications to document symptoms and forward them to healthcare providers.

23.2 Healthcare System-Related Conditions

Digitalisation and implementation of digital interventions for information transmission and communication in healthcare is a topic of much debate and political decision-making in most countries around the world and their healthcare systems. It has also led to the emergence of an industry of technology developers and consulting companies.

Certain conditions must be met before digital interventions can be implemented in healthcare settings. The required information technology (e.g. computers and software applications) needs to be available and affordable. This condition is usually fulfilled in high-income countries, although technical adaptation and scaling-up may pose technical and economic challenges. Nevertheless, the availability of a

technology does not automatically lead to its adoption in practice. This is also illustrated by the very heterogeneous status of different countries in terms of their eHealth implementation successes. This is especially true for broader implementation (on a supra-regional, national level) that are applicable on both a cross-sector and cross-institutional basis and increasingly include patients in this exchange (e.g. the cross-institutional patient record) (see Box 23.2).

HSR can help make the specific contextual conditions of the digital interventions understandable as well as identify and overcome the implementation challenges related to the health system and their dynamic interplay (see also Greenhalgh et al. 2017). For the implementation and evaluation of digital interventions, the inclusion of the 'broader institutional and sociocultural context' of healthcare organisations (macro level) plays an important role (Greenhalgh et al. 2017). In addition to the specific contextual conditions at the macro level, typical challenges in healthcare facilities such as hospitals and doctors' practices also play a role at the meso-level. These include political, financial and organisational factors as well as resistance by and insufficient skills of potential users. These will be highlighted in the remainder of this section.

Box 23.2: Digitalisation Level of Patient Documentation

A study in Germany shows that 58% of medical practices (excluding psychotherapists) have almost completely digitalised their patient documentation. By contrast, only 4% of medical practices continue to keep their patient documentation almost entirely in paper form (Kassenärztliche Bundesvereinigung [KBV] 2020). However, it is also the case that electronic files or their contents mostly remain within an institution and are not shared with third parties (Thiel et al. 2018). Results of the HIMSS-Annual European Digital Health Survey and the KBV PraxisBarometer for 2019 show in this context that 93% of physicians still communicate in paper form with hospitals, and applications, such as electronic health records, are used by just 44% of all healthcare facilities, e.g. hospitals, outpatient physician practices, medical care centres, etc. (KBV 2020; McKinsey and Company 2020). At the same time, research in this area clearly shows that the degree of digitalisation varies greatly from country to country and that it has a correspondingly different status in their respective healthcare systems. The Digital Health Index, for example, measured the degree of digitalisation in the healthcare systems of selected EU and OECD countries in 2018. The Bertelsmann Foundation study shows that the overall index scores of the individual countries vary widely. According to the study, Estonia had the highest level of digitalisation in the healthcare system with an index value of 81.9 points. Germany ranked second to last with an index value of 30 (Thiel et al. 2018).

23.2.1 Political and Cultural Factors

In health systems around the world, (political) strategies are being developed to promote the implementation of digital interventions in healthcare (see also WHO 2021). Digitalisation is discussed in terms of its contribution to improving patient care in general. Other key topics of care are also associated with the potential of digitalisation (Ross et al. 2016). These include the topics of patient participation, patient autonomy, intersectoral and interdisciplinary collaboration and their qualitative enhancement. The development and impact of such strategies is an important topic for HSR.

Especially regarding interventions that are applied on a supra-regional or national level and thus affect the entire healthcare system, political strategies are considered relevant. This is associated with the broad use and unrestricted exchange of health information across spatial borders. For a sustainable implementation of digital interventions, it is necessary to consider different requirements for the institutions of healthcare systems.

In this context, the development of health telematics and the availability of technically and semantically interoperable standards and systems are important prerequisites for the implementation and sustainable use of digital interventions, such as in the case of the cross-institutional electronic health record (Shull 2019). The WHO defines interoperability in its Global Digital Health Strategy 2020–2025 as "the ability of different applications to access, exchange, integrate and cooperatively use data in a coordinated manner through the use of shared application interfaces and standards, within and across organizational, regional and national boundaries, to provide timely and seamless portability of information and optimize health outcomes" (WHO 2021). Interoperability thus represents a central principle in the realisation of digital health.

These preconditions often follow a politically driven digital strategy combined with legal regulations for data protection and data security when dealing with highly sensitive health information from and about patients. A legal and ethical framework should ensure patient safety, data security, appropriate use and ownership of health data when using digital systems and services (WHO 2021). This equally includes telemedical applications and the implied virtual contact between doctors and patients (Nittari et al. 2020) and the application of artificial intelligence (Amann et al. 2020). In addition to the general misuse of patient data by third parties (such as health insurance companies or employers), legal regulations should also clarify questions of liability and therefore responsibility in dealing with digital applications (Ross et al. 2016).

One main challenge for sustainable implementation of digital interventions is reconciling patient involvement with the demand for usability and data protection, as well as medical meaningfulness paired with professional ethical standards (Pohlmann 2021). This means that for the development and use of digital applications appropriate technical and everyday usability is necessary to be able to realise any amount of patient participation (Kunz et al. 2016). For this purpose, and in relation to corresponding data protection concepts, the inclusion of the lived reality of patient groups becomes relevant (cf. also Sect. 23.3). This means that the structure,

content and associated options for dealing with the applications must be understandable and comprehensible. It is also necessary to protect the handling of highly sensitive health data from misuse. In this context, data protection and data security solutions should mirror the security needs of patients and thus be able to assume a realistic position in the implementation process (Pohlmann et al. 2020). These requirements for usability and data protection or data security also become relevant in relation to the different organisational circumstances of care. In this context, the consideration and integration of medically necessary routine processes and actions during implementation are just as important as professional ethical normative requirements. This essentially relates to the acceptance of the different service provider groups (hospital doctors, general practitioners, specialists, nursing, etc.) within the care system, which is central to the implementation of digital health (Kunz et al. 2016). Among other things, this involves the question of how and to what extent patient participation can be implemented digitally in order to continue being able to make medically necessary decisions appropriately and implement treatments in a targeted manner. What knowledge base can be used to provide information and make decisions?

How respective (political) strategies differ in different countries to meet these requirements and what potential contribution they can make to the implementation success of eHealth applications is evaluated in various comparative studies (Thiel et al. 2018) (see also Box 23.3).

Box 23.3: eHealth in Germany: The Role of Political and Cultural Factors

The importance of a consistent digitalisation strategy supported by the clear will of political decision-makers is demonstrated by a study exploring barriers to digital health in Germany. A total of 18 representative healthcare experts were interviewed in the qualitative study. It was shown that, despite the shared ambition to enhance digitalisation in healthcare, conflicting aims and expectations of different policymakers hinder development. The principle of self-government, which is typical of Germany, is a cultural prerequisite for such diversity of interests being taken into account. Data protection (as a legal and ethical requirement) was used by some interest groups to influence the political decision-making process (Nohl-Deryk et al. 2018).

Another study, which examines the prerequisites and barriers for implementing a patient-oriented, cross-sector electronic health record based on 33 semi-structured interviews (23 with different healthcare professionals and 10 with key players in the German healthcare system), also describes a tendency to simply transfer analogue structures and processes into digital formats instead of redesigning them after considering an overarching digitalisation strategy and the associated opportunities and limitations. Similarly, the administrative apparatus, with its complex administrative structures and heterogeneous (digital) systems, makes the exchange of health data difficult due to compatibility and data protection problems (Pohlmann et al. 2020).

23.2.2 Financial and Organisational Factors

The extent to which digital innovations can be integrated and regularly used in healthcare organisations depends on different prerequisites. It is important to strive for a high degree of fit between eHealth interventions and healthcare organisations in order to generate and maintain acceptance of their use among the various healthcare provider groups. This also addresses the integration of systems and services into the usual care process (Ross et al. 2016).

The potential and real positive effects of digital applications are relevant in connection with user acceptance. For instance, much research in this area shows that when eHealth systems fit well or are perceived to fit well, within the workflow and work practices of healthcare organisations, this facilitates their use (Granja et al. 2018; Ross et al. 2016). The same is true for application usability and the associated minimisation of workflow disruption during implementation (Ross et al. 2016). This also pertains to limited availability of time. Information on the benefits and drawbacks of eHealth systems as well as learning relevant system functions via different training formats are described as positive influencing factors in this context (Ross et al. 2016; Wensing et al. 2019).

Similarly, in addition to the usability of the applications, ethical normative principles of professional practice become relevant for the acceptance and use of digital care concepts by healthcare providers and for interprofessional collaboration. Existing roles and the associated understanding of roles in the doctor–patient and doctor–doctor constructs as well as forms of interaction, participation and communication represent structural starting points for planning, implementation and evaluation. Paternalistic views and professional values, documentation routines and systems and the bureaucratic processes oriented around them can stand in the way of the use of innovative technologies (Pohlmann 2021). For instance, the implementation of eHealth systems may also affect established professional roles and associated responsibilities, thus disrupting established work styles. Research often cites that anxiety, dissatisfaction or uncertainty about new roles and responsibilities arise from the introduction of eHealth systems and hinder their implementation (Ross et al. 2016).

The costs of eHealth systems are a key factor for their sustainable implementation. Therefore, financing models that provide security for organisations in the introduction and use of such interventions become relevant (Ross et al. 2016). If the implementation of digital interventions in healthcare fails because important framework conditions of the healthcare environment are not taken into account, this leads not only to the frustration of potential users but also to financial risks for healthcare organisations (Kunz et al. 2016). The risk, represented by monetary costs of acquiring and maintaining digital interventions, is rarely assumed, especially when there is little evidence of the added value generated by such interventions for users. The funding of different digital applications, especially when a national claim is envisaged, varies greatly and usually depends on the respective healthcare financing systems (Thiel et al. 2018).

With regard to the financing of eHealth, a country comparison study shows that, due to the high dynamics of change and the need for further development of eHealth, project funding is generally less suitable for creating a reliable financing basis. Based on this country analysis, an appropriate and sustainable financial framework was found to be more promising (Thiel et al. 2018).

Financial incentives as innovation drivers for eHealth adoption by insurers and government agencies are potential promoters of the decision to adopt. Financial incentives include the provision of seed capital to cover up-front costs, reimbursements for deployment and performance-based funding. These incentives generally relate to the initial phase of implementation and are intended to ensure that as many users as possible adopt the digital systems and services as quickly as possible and transfer them to widespread use (Ross et al. 2016; Thiel et al. 2018).

23.2.3 Attitudes and Skills of Users

One cornerstone for the successful implementation of digital technologies in healthcare is the willingness and skills of users (healthcare providers and patients) to adopt digital tools in their daily routines (micro level). Various studies in professional contexts have already shown that trying out and independently learning to use new technologies increases acceptance and the sustainability of skills and abilities (Fuchs-Frohnhofen et al. 2018; Rösler et al. 2018). To date, however, there is a lack of knowledge about the specific support needs of users of innovative digital technologies and about possible training formats (Vaportzis et al. 2017). In addition, studies on physician IT use show that training and support measures may be sparsely used by clinicians (Wensing et al. 2019). Therefore, it is necessary to consider how training or support offers can be designed attractively for patients, healthcare providers and citizens to gain a broader acceptance.

Interviews with healthcare and nursing staff in the Netherlands showed that individuals who had little previous experience in dealing with digital technologies had a great reluctance to increase the use of ICT in their work environment. However, training in the work environment and support from colleagues with higher digital skills in particular proved to be beneficial in reducing this reluctance (Leeuw et al. 2020). This finding regarding learning preferences can also be applied to patients who are confronted with the use of digital technologies because they might need the support of their physicians or representatives of other healthcare professions in case of difficulties in using the digital health technologies. This assumes that these professionals are appropriately familiar with the relevant technologies (Hefner et al. 2017) (Box 23.4).

Box 23.4: Comprehension Problems and Training Opportunities (Walker et al. 2018)
The patient portal MyChart Bedside (MCB) was developed specifically for inpatient care at a large Midwestern academic medical centre in the United States and provides patients with various information related to their hospital stay. An analysis of user experiences indicated that there were recurring comprehension problems on the patient side, which in turn caused anxiety and uncertainty. In addition, the research allowed conclusions to be drawn that users of the portal had different ideas about how they would like to learn about MCB. The authors noted that, in addition to video tutorials and handouts, in-person training is particularly important for learning how to use a patient portal like MCB.

23.3 Development and Evaluation of Digital Tools

Digital tools in the context of healthcare (e.g. smartphone applications) are interventions that need to be carefully developed and evaluated in order to optimise their benefits and minimise harms. The development and evaluation of digital tools is a growing domain of HSR. Some digital tools (e.g. computerised medical records) are infrastructures that have a broad range of long-term impacts, which makes it challenging to conduct evaluation research. Hence, it is important to distinguish between specific tools (that can be evaluated with respect to specific benefits and harms) and the underlying infrastructure.

23.3.1 User Involvement in the Development of Digital Tools

The involvement of users in the design and development of digital tools is widely believed to enhance their uptake in healthcare practice and people's lives. For instance, Zhong et al. (2020) concluded that potential barriers to using patient portals should be identified and eliminated as early as possible in the planning stage to make the technology usable for those who can benefit most from it. The authors therefore underline the relevance for aligning the needs of patients and providers in terms of patient portal functionalities to ensure effective, patient-centred care. A large number of potential users may be considered in the design of digital tools, including patients/service users, their relatives, healthcare professionals (physicians, nurses, etc.) and healthcare managers.

Despite the growing consensus that involving users as co-scientists or in form of user-led research is an important starting point for successful technology development processes, it is still not being implemented extensively (Joss et al. 2016). Methods for stakeholder involvement in intervention design are available (see Chap.

Box 23.5: Engaging Patients and Family Members in Health IT Projects (Leung et al. 2019)

Leung et al. (2019) explored in their scoping review whether studies exist that try to improve outcomes of health IT projects by engaging patients and family members of patients. Furthermore, they searched for practical strategies that healthcare organisations can use in order to engage patients and caregivers. The focus of the review lies in ways to involve patients and their family members in the health service planning and delivery context.

They identified two articles meeting the inclusion criteria that presented frameworks dealing with patient engagement in the health IT context. According to the results of the review, there were studies that showed positive impact when patients and family members became effectively engaged in health IT projects. However, from the authors' point of view, none of the identified frameworks were able to capture all relevant strategies and considerations for engaging patients and family members. Therefore, they state that further research is needed to evaluate and validate the existing strategies.

12), but they need further development. Studies conducted to date often provide little information about the problems that occur when future users apply the technologies. However, knowing about those challenges is highly relevant for evaluating and establishing digital technologies in real-world healthcare (O'Connor et al. 2016) (Box 23.5).

23.3.2 Evaluation of Digital Tools

Although user-centred development of digital tools adds value, it does not automatically mean that the tools are implemented in the real world and that they have positive effects. Like all interventions, they may have positive and negative effects, and they may be adopted in full, in part or not at all (Mathews et al. 2019). Therefore, evaluation research is required. The effects of many digital tools for information and communication in healthcare have in fact been evaluated (for instance, in randomised trials), but the generalisability of study findings needs to be carefully considered.

In the United Kingdom, all digital health technologies that are being considered for procurement in the health and social care system need to be checked using an evidence standards framework (National Institute for Health and Care Excellence (NICE) 2018). The Medical Device Regulation of the EU also applies to health-related digital tools. Also, the German legislature has set the course for digital health applications (DiGAs) to quickly become an integral part of healthcare with their Digital Healthcare Act. Subsequently, since 2019 all German citizens insured in a statutory health insurance have the right to receive a prescription of DiGA. Particular

attention was paid to ensuring that there are reliable specifications for procedures and methods that must be used before DiGAs enter the market in order to provide evidence of positive care effects. However, from the health providers' perspective, the creation of acceptance and trust in a reliable, producer-independent quality inspection of DiGA still needs to be consolidated (Gerlinger et al. 2021). To date, the systematic observation and evaluation of healthcare effects end with the approval for cost coverage by the statutory health insurance, which leads to a quite limited evaluation period.

Generally, the impact of pharmaceutical technologies on healthcare is measured using health technology assessment (HTA), which might also offer tools to assess the impact of digital tools (Vis et al. 2020). However, HTA frameworks mostly focus on clinical effectiveness of eHealth services and their economic consequences. They do not standardise technical requirements or functionalities, nor do they assess consequences on the organisational, ethical or legal level. Therefore, impacts on the healthcare system in general possibly remain unknown (Vis et al. 2020) (Box 23.6).

Box 23.6: The Concept of Adherence in the Context of Digital Health Interventions (Kernebeck et al. 2021)

None or limited participation in the usage of digital tools is one of the main limiting factors in the effectiveness of these interventions. Therefore, adherence to digital interventions – meaning the extent to which the software or digital tool is utilised by the patients in the way it was designed – is becoming increasingly important. Consequently, transparent reporting regarding adherence to digital interventions must be introduced in order to understand, interpret and compare the results of studies. According to the authors of the manuscript, process evaluations conducted in the wake of intervention studies enable evaluation of adherence more specifically. Nevertheless, the evaluation of adherence should also be considered after implementation.

23.4 Conclusions and Perspective

As an evolving field, digital health is an important subject of HSR that poses specific methodological and ethical challenges. On the one hand, digitalisation information is available more quickly and often more extensively (including diagnoses dating further back, etc.). In addition, standardised data interfaces increasingly bridge information gaps, for example, between different institutions involved in the provision of care. On the other hand, the growing amount of data makes it more difficult to filter out the relevant information for the current care situation. This situation also serves as a starting point for further developments, such as the use of machine learning and artificial intelligence in the medical context, for example, to

support patients in rural areas with triage and diagnostic information (Baker et al. 2020). For many potential user groups, such developments harbour the risk that personal communication in the doctor–patient relationship will diminish and be replaced by purely digital data sources. Nevertheless, especially in the inpatient sector, the course is being set for the comprehensive digitalisation of processes, which is to result in 'smart hospitals'. The aim of this endeavour is not only to sustainably serve the well-being of patients and provide them with rapid access to care but also to create improved working conditions for employees, especially in nursing, in particular through digitally supported documentation and up to the use of robotics in patient care.

These profound changes in healthcare as we have known it make understanding the underlying processes essential to guide the penetration of digital technologies in this complex field. However, digitalisation must not be understood as an end in itself, but rather it is one of the future tasks of HSR to oversee the consequences of increasing application of digital technologies in healthcare. Consequently, it might also become a role of HSR to clarify where it does not seem reasonable to replace historically grown analogue processes with digitalised ones.

With regard to healthcare, this means that processes must be analysed strategically and – most importantly – in a user-centred manner. Furthermore, it is important to recognise that not only digital technology but also organisational change plays a vital role in any resulting transmission processes. Therefore, an extensive role of HSR may be to examine workflows, clinical processes and work practices to be supported by digital applications to improve their fit and facilitate implementation.

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Chapter 24
Climate Change as a Topic for Health Services Research

Nicola Alexandra Litke

Abstract Climate change is one of the greatest health threats of our time. Hence, healthcare faces new challenges which require adaptation to manage and prevent health impacts of climate change. Healthcare should prepare better for surges of disease due to disasters, such as heat, flooding and pandemics. This means that capacity planning must be reconsidered with a view on flexible adaptation to the required need. As the global health sector itself is one of the highest contributors to climate change, its working processes with respect to emissions and use of scarce resources must be critically assessed. Examples for mitigation strategies include the reduction of energy use, waste management and prudent use of materials in healthcare. Most of the mitigation strategies involve reducing greenhouse gas emissions while also providing health co-benefits.

24.1 Introduction

Climate change is one of the greatest health threats of the twenty-first century (Karliner and Slotterbeck 2019). Environmental changes associated with climate change have direct and indirect *impacts on population health* such as increases of heat-related illness, mental health disorders, allergies and respiratory diseases, vector-borne diseases and diseases related to poverty, migration and other social consequences of climate change (Haines and Ebi 2019). Thus, health systems face new challenges that require adaptation to manage and prevent health impacts of

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climate change to protect vulnerable groups and maintain a high quality of care *(adaptation)*. Health systems and health services need to prepare for and address these emerging challenges, thus building *climate resilience* (Prior et al. 2018; Tong and Ebi 2019; World Health Organization (WHO) 2015). These requirements imply that health workers need to gain the competences to identify and treat emerging health threats and prepare for surges in these threats.

Healthcare systems not only have to manage the consequences on our health, but also have to reduce their impact on climate change *(mitigation)*. As the global health sector itself has a large impact on climate change, it is necessary to significantly reduce its emissions and use of scarce resources (Watts et al. 2020). Examples for mitigation strategies include the reduction of energy use, waste management and prudent use of materials (Karliner and Slotterbeck 2019; Quam et al. 2017). Most of the mitigation strategies involve reducing greenhouse gas emissions while also providing health benefits. These *health co-benefits*, such as through a sustainable diet (e.g. meat reduction and ecological agriculture) and active transport (e.g. riding a bicycle or walking), contribute to improved health outcomes (Quam et al. 2017).

Health services research is needed to provide the knowledge and means for adaptation and mitigation of climate change with respect to the structures and processes of healthcare delivery in institutions, practices and communities. Regarding adaptation, the contribution of health services research primarily relates to the development of the resilience of health professionals and healthcare organisations to the impacts of climate change. Regarding mitigation, health services research can contribute to the design and evaluation of climate-orientated strategies, which address the working processes in healthcare. This chapter will first summarise the health impacts of climate change, then it will provide ideas for adaptation and mitigation as well as perspectives for health services research (Fig. 24.1).

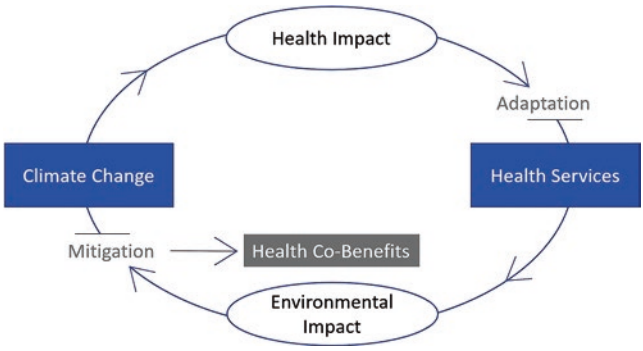

Fig. 24.1 Climate Change and Health Services

24.2 Health Impacts of Climate Change

Human well-being and life expectancy have always been influenced by the quality of the physical environment (Yassi et al. 2001). In previous centuries, the environmental impact on human health was primarily traced back to poor housing, dangerous working conditions, poor drinking water, lack of sanitation and poor nutrition. Climate change in recent years, which is being caused by human action, has put the ecosystems' balance at risk and is associated with direct and indirect health threats. These include increases in: (a) heat-related disorders, (b) respiratory disorders, (c) infectious diseases, (d) food security, (e) mental health disorders and (f) others.

Morbidity and mortality are increasing due to extreme weather events, such as heatwaves, floods and drought (Haines and Ebi 2019; Kipp et al. 2019; Watts et al. 2017). Especially elderly people are threatened by heat-related illness, such as heat stroke and heart failure (Zacharias et al. 2015; Herrmann and Sauerborn 2018). The global average heat-related mortality per year in people aged over 65 years or over, for example, has increased by 53.7% since the year 2000. In Germany this resulted in 20,200 deaths in 2018, which is the third highest number of heat-related deaths globally for that year (Watts et al. 2020). Furthermore, hospitalisation rates increase on warm days due to kidney diseases, diabetes, exsiccosis and heat stroke.

There have also been increases in allergies, asthma, COPD and other associated respiratory diseases due to longer and more intense production of pollen and other allergens as well as environmental pollution, such as air pollution (Haines and Ebi 2019; Ghazali et al. 2018; Patz et al. 2014).

Rising temperatures and heavy rainfall increase the occurrence of vector-borne, foodborne and waterborne diseases (Haines and Ebi 2019; Altizer et al. 2013; Caminade et al. 2019). As the prevalence of vector-borne diseases, such as dengue, malaria and Lyme disease, rises and changes geographically, an additional increase in the risk for pandemics and epidemics is predicted due to a lack of immunity among local residents (Pecl et al. 2017; Patz et al. 2014).

Indirect impacts also emerge from extreme weather events, which have an influence on agriculture and therefore the quantity and quality of nutrition. Undernutrition is especially seen as one of the most significant concerns related to climate change (Patz et al. 2014).

Mental health disorders such as anxiety and depression due to emotional processing of climate change information and post-traumatic stress disorder following climate-related disasters cause major morbidity. Mental health is also threatened by climate-related displacement (Haines and Ebi 2019; Patz et al. 2014). Other health impacts include death, poverty, loss of livelihood or hunger due to natural disasters such as floods, droughts or hurricanes (Haines and Ebi 2019). In some regions this implies dislocations, resulting in stress, undernutrition, violence, sexual abuse and mental illness of refugees (Patz et al. 2014).

24.3 Building Climate Resilience in Healthcare

Healthcare providers need to be prepared for and adapt to emerging health threats, to protect vulnerable groups and provide safe healthcare of high quality. This has been described in terms of the resilience of healthcare. According to the WHO, "a climate resilient health system is one that is capable to anticipate, respond to, cope with, recover from and adapt to climate-related shocks and stress, so as to bring sustained improvements in population health, despite an unstable climate" (WHO 2015, p. 8). This has direct consequences for health professionals and healthcare organisations, such as hospitals and ambulatory practices.

On one hand, health systems need to understand how climate change will affect health and service delivery and evaluate healthcare procedures and structures under diverse climatic conditions to provide their effectiveness under varying circumstances. In order to *anticipate* climate change-related health risks, awareness and knowledge of health professionals as well as an accessible surveillance system and adequate risk management are crucial (Paterson et al. 2014; Blanchet et al. 2017). Currently, knowledge and awareness of health professionals about climate change fall short of this ambition. A qualitative study including general practitioners' (GP) perceptions of heat health impacts in Germany concluded that it is necessary to raise awareness among German GPs for heat-related illness (Herrmann and Sauerborn 2018). Although education of health workers is included in macro-level plans, health professionals did not receive any kind of education focused on health impacts of climate change. While the awareness of climate change impacts on health by health professionals is high, the self-assessed knowledge is described as low (Hathaway and Maibach 2018). Kotcher et al. (2021) identified several barriers in engaging health professionals in educational and advocacy activities. These included time constraints, insufficient knowledge, belief that their actions would not make a difference, little support from peers, perception of the topic being too controversial and perception that their engagement in the activities will bring a certain risk for them personally and professionally (Kotcher et al. 2021). Research is needed to explore how the implementation of professional education and other measures can address these barriers. Furthermore, patients and the public, especially vulnerable groups that are most endangered by the health threats, need to be educated and protected. Studies are required to evaluate programmes in this field. One of the groups that are affected by climate change impacts is elderly people. Protective behaviours, a back-up in medication supply, personal strength, social support, connectedness and their physical environment such as green spaces, are described as determinants of their individual resilient capacity. Emerging from this is a new field of investigation which has been dubbed climate gerontology (Leyva et al. 2017).

In order to *respond to* climate change, healthcare needs a certain adaptability to cope with uncertainties and surges of disease. For this, adequate capacity as well as access to flexible and adaptable resources is required (Paterson et al. 2014; Blanchet et al. 2017). This starts with strengthening the health workforce forms and includes informed and well-trained health professionals, a shifting number of health professionals to respond to locally increased demand for services and

diversified professions that are able to communicate both across disciplines and institutions (WHO 2015). Flexibility in the allocation of professional roles (e.g. operation assistants who can also work in intensive care units) is one topic that needs to be studied. Furthermore, health professionals themselves need to be strengthened to cope with stress and crisis situations. Organisational resilience depends on the resilience of each individual and their interactions as a team within this organisation.

One example for *coping with* climate change is the implementation of indoor-climate management in hospitals to prevent heat-related illness (Lenzer et al. 2020). Heating, ventilation and air conditioning have shown potential in improving vital signs, reducing cardiac stress, accelerating recuperation and increasing physical activity of inpatients in hospitals. Consequently, shorter stays for patients with respiratory diseases and a reduction of mortality for heat illness patients could be observed.

Despite the existence of several frameworks and concepts to promote and assess the resilience of healthcare facilities, the adoption of specific programmes in clinical practice is limited (Achour et al. 2015). A systematic review of Biddle et al. (2020) pointed at a lack of operationalisation of resilience concepts in empirical studies. Health services research is needed to identify knowledge deficits of health professionals and patients towards health threats, develop adaptation strategies and implement these into routine practice in order to *bring sustained improvements* in health. Furthermore, health services research is necessary to strengthen networks and communications between health professionals as a means to increase the knowledge and skills of health professionals through the (peer) exchange of information and coping strategies. Additionally, these networks optimise infrastructure and access to resources in the face of health crises arising from the effects of climate change (WHO 2020). Moreover, health services research can identify lack of support of vulnerable groups affected by climate change-related health threats and develop targeted interventions to protect these groups and increase quality of care in a changing environment. Box 24.1 provides an example of a study that focused on resilience in ambulatory care practices.

24.4 Reduction of the Environmental Impact of Healthcare (Mitigation)

When building climate resilience, healthcare needs to find ecologically sustainable ways to provide healthcare and reduce its impact on climate change at the same time. The health sector is one of the drivers of climate change, as it releases greenhouse gases, consumes large amounts of energy and water and produces large amounts of waste, among other things. In total, the health sector is responsible for more greenhouse gases than the flight and the shipping sector (Karliner and Slotterbeck 2019). The impact is primarily caused by supply chains, production and transport of goods, purchased electricity, heating and cooling systems,

Box 24.1: Example: Research Project 'RESILARE' (Litke et al. 2022)
The project 'RESILARE', conducted by the Department of General Practice and Health Services Research at the Heidelberg University Hospital and the aQua Institute, Germany, aimed to develop and evaluate quality indicators for German primary care facilities to promote their resilience in crisis situations related to climate change, such as heat waves, and to reduce the environmental impact of the outpatient health sector. The preliminary results pointed to many aspects that facilitate crisis management in practice, including team communication, awareness of the employees, resilience and motivation of the individuals, interaction and networking between health facilities and on the community level, immediate and proactive leadership and following clear structures, such as action plans. Specific examples were:

- Providing (at least weekly) team meetings respecting and considering the mental health state of all employees, frequent team building actions and providing transparent and comprehensible information for all team members.
- Identifying various scenarios of potential crisis situations that could occur in an individual practice and preparing concrete and feasible action plans on how to respond to those specific crisis situations.
- Constant reflection and evaluation of past time periods within the team with the end result being a change processes/structures within the practice. Complaint management (for patients and staff) as well as open and constructive error management is seen as crucial.
- Being aware of the practice capacities and not overusing them in 'regular' healthcare as a crisis is mostly linked to an overload of resources.
- Optimising communication with patients, for instance via social media, a homepage, telephone hotlines, signs within the practice, information sheets and/or comprehensive explanations given in person. This can help increase patient compliance and therefore the implementation of action plans within the practice.

transportation of employees, patients and visitors, healthcare provision itself and its downstream activities, such as the use of products, their disposal and financial investments. Several disciplines and fields can contribute to climate change mitigation. The specific contribution of health services research concerns the analysis and change of working processes in healthcare, particularly in patient care. For instance, a new clinical or prevention intervention would not only need to be designed and evaluated according to health-related and economic outcomes, and possibly regarding health equity, but also regarding its environmental sustainability. Specifying this, health services research might contribute to mitigation by focusing on the environmental sustainability of care delivery. For instance, critical use of medication (e.g. antibiotics) and imaging tests (e.g. MRI) are two examples of topics for health services research.

Mitigation of climate change has parallels with rationing of healthcare and related concepts, such as value-based healthcare and de-implementation of low-value practices. Lower use of resources is often positive for the climate, although the time horizon may differ between these different approaches (short-term for rationing, long-term for climate change). Further research is required to explore the compatibility of these approaches in practice as well as the effects and risks of specific interventions. If decisions to use resources are made by health professionals, the possibility of underuse or overuse of services should be addressed (Gray 2017).

Evaluating processes and reflecting on them in regard to their sustainability needs to trigger innovations, such as the reorganisation of medication use through reverse logistics and a new end-of-use and end-of-life management. Reassignment of care flows, new technology and infrastructure to reorganise life cycles of medical goods and resources are asked to save resources and to adequately allocate existing resources (de Campos et al. 2021). Additionally, this can be important not only for the reduction of the ecological footprint but also regarding unforeseen crisis situations, like the COVID-19 pandemic, where medical goods importation or production needed to be stopped, leading to shortages.

A good example is the use of medication and anaesthetic gases in patient care. Desflurane, for example, is one of the hazardous gases that affect the ozone layer. A reduction or even a replacement of desflurane by other anaesthetic gases in operation rooms can significantly reduce hospital emissions without compromising patient safety (MacNeill et al. 2017; Schuster et al. 2020). Also, the conversion to dry-powder inhalers together with the education of patients on its correct usage is another way to reduce the carbon footprint of care delivery and in-use emissions from pharmaceuticals (Tennison et al. 2021). This demonstrates that it is necessary to evaluate medication prescription, such as inhalers, antibiotics and medication in general, according to their sustainability, their disposability and the overall necessity of a prescription itself. As several medications achieve the same medical effect, their sustainability should be included in the decision process of prescription.

Other aspects of sustainability (e.g. shown in Box 24.2) need to be considered for a transformation towards ecologically sustainable health institutions.

Besides the aim of reducing emissions of health services, the mitigation actions also entail health benefits or what is referred to as health co-benefits. Hospitals built according to the green hospital approach can improve productivity, staff satisfaction and quality of care. This is demonstrated by researchers in a children's hospital in Pittsburgh, USA, which conducted a longitudinal assessment while building a new green hospital (LEED certification) (Thiel et al. 2014). In addition to observed reductions of energy and water consumption, mortalities of the children decreased by 19%. Because of aspects like increased staff satisfaction, employee turnover decreased significantly and the vacancy rate in registered nurses decreased by 30%. Regarding the limited resources of health workforce, green hospitals should be considered as one building block in the complex response to skills shortages.

When it comes to health co-benefits on the patient level, mobility and diets are named as the most popular approaches. Climate-friendly mobility, like walking and bike riding, decreases morbidity and mortality and reduces air pollution at the same

Box 24.2: Green Hospitals and Green Practices as an Example of Implementing Mitigation Measures (Litke et al. 2020; Litke 2022)

As an example of how to implement mitigation measures in health institutions, the concepts of green hospitals and green practices have evolved. Elements of green hospitals include:

(a) Green buildings: The planning and construction of buildings need to be as efficient and economical as possible. This includes the use of sustainable materials, the integration of natural ventilation and light, as well as green roof terraces and embedding the buildings into their natural environment. This should allow for green recovery paths and spaces for patients and staff, cycle paths and easy access via public transportation.
(b) Energy efficiency: Care processes and buildings need to be efficient and save energy. At the same time, the required electricity should come from regenerative energy sources. Behaviour change in energy consumption is also necessary, such as switching off computers or medical devices when not in use or efficient planning of patient routes and occupancy of operational theatres.
(c) Waste management: Managing and reducing waste means separation and adequate disposal of (medical) waste as well as avoiding products causing waste in the first place. Using reusable products instead of single-use plastics and disposables is a starting point.
(d) Water management: To save water, preparation of rainwater or used water for flushing toilets or similar applications is a possible approach.
(e) Transportation/mobility: In order to provide sustainable transportation of patients and staff, cycle paths, walking pathways and public transportation need to be provided. For business trips and patient transfers, sustainable alternatives need to be utilized such as e-mobility or telemedicine.
(f) Food supplies: Regional, seasonal and plant-based food needs to be increased in cafeterias and in patient care. This can also provide better health outcomes and improve patient recovery.

The named elements of green hospitals can also be transferred to smaller health institutions such as practices. Smaller health institutions bring advantages in the implementation of mitigation measures, as they often can be employed faster. Furthermore, communicating objectives and implementing behavioural changes can be processed more immediately.

time (Wolkinger et al. 2018). Furthermore, reducing the consumption of red meat and processed meat is estimated to not only decrease emissions but also reduce the risk of cancer (Herrmann et al. 2019).

24.5 Discussion and Perspectives

To address climate change and healthcare, two areas for health services research have been described (Karliner and Slotterback 2019): identifying starting points to increase climate resilience of health facilities and (Haines and Ebi 2019) evaluating the implementation of interventions to increase ecological sustainability of health services.

Interventions aiming to build climate resilience, especially in vulnerable groups such as elderly people, need to be developed, implemented and evaluated in order to protect those groups, prevent harm and save resources. Scenario projections might be one of the emerging methods that help identify future challenges and develop tailored interventions to prepare health facilities. As frameworks and concepts already exist, the development of specific interventions, their implementation and their evaluation in everyday healthcare becomes even more important.

Sustainability needs to become a key criterion in the evaluation and development of interventions. Evaluation outcomes in health services research should include environmental or resource-linked outcomes to obtain sustainability of healthcare and new implemented interventions. Often, climate-friendly interventions bring health co-benefits and therefore not only save resources (and costs on a long-term perspective) but also improve healthcare and respond to current issues in health services, such as skills shortages and the burden of increasing care demand.

To achieve this, it is recommended to view climate change not as a new topic that needs to be implemented 'on top' of other aspects, forming a new delimited scientific field. Rather, climate change adaptation and mitigation need to be considered in all fields, similar to aspects like patient-centredness and cost-effectiveness.

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Michel Wensing and Charlotte Ullrich

Correction to:
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Owing to an unfortunate oversight on the part of production, the diagonal line was placed incorrectly in Table 1.2 of Chapter 1. This has now been updated.

A comma was missed in the title of Chapter 22. The title of this chapter has been changed from 'Access to Continuity and Coordination of Healthcare for Refugees: Emerging Challenges and Topics for Health Services Research' to 'Access to, Continuity and Coordination of Healthcare for Refugees: Emerging Challenges and Topics for Health Services Research' after the initial publication.

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