Translational Systems Sciences 24

Hironobu Matsushita *Editor*

Health Informatics

Translating Information into Innovation

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Translational Systems Sciences

Volume 24

In 1956, Kenneth Boulding explained the concept of General Systems Theory as a skeleton of science. He describes that it hopes to develop something like a "spectrum" of theories—a system of systems which may perform the function of a "gestalt" in theoretical construction. Such "gestalts" in special fields have been of great value in directing research towards the gaps which they reveal.

There were, at that time, other important conceptual frameworks and theories, such as cybernetics. Additional theories and applications developed later, including synergetics, cognitive science, complex adaptive systems, and many others. Some focused on principles within specific domains of knowledge and others crossed areas of knowledge and practice, along the spectrum described by Boulding.

Also in 1956, the Society for General Systems Research (now the International Society for the Systems Sciences) was founded. One of the concerns of the founders, even then, was the state of the human condition, and what science could do about it.

The present Translational Systems Sciences book series aims at cultivating a new frontier of systems sciences for contributing to the need for practical applications that benefit people.

The concept of translational research originally comes from medical science for enhancing human health and well-being. Translational medical research is often labeled as "Bench to Bedside." It places emphasis on translating the findings in basic research (at bench) more quickly and efficiently into medical practice (at bedside). At the same time, needs and demands from practice drive the development of new and innovative ideas and concepts. In this tightly coupled process it is essential to remove barriers to multi-disciplinary collaboration.

The present series attempts to bridge and integrate basic research founded in systems concepts, logic, theories and models with systems practices and methodologies, into a process of systems research. Since both bench and bedside involve diverse stakeholder groups, including researchers, practitioners and users, translational systems science works to create common platforms for language to activate the "bench to bedside" cycle.

In order to create a resilient and sustainable society in the twenty-first century, we unquestionably need open social innovation through which we create new social values, and realize them in society by connecting diverse ideas and developing new solutions. We assume three types of social values, namely: (1) values relevant to social infrastructure such as safety, security, and amenity; (2) values created by innovation in business, economics, and management practices; and, (3) values necessary for community sustainability brought about by conflict resolution and consensus building.

The series will first approach these social values from a systems science perspective by drawing on a range of disciplines in trans-disciplinary and cross-cultural ways. They may include social systems theory, sociology, business administration, management information science, organization science, computational mathematical organization theory, economics, evolutionary economics, international political science, jurisprudence, policy science, socio-information studies, cognitive science, artificial intelligence, complex adaptive systems theory, philosophy of science, and other related disciplines. In addition, this series will promote translational systems science as a means of scientific research that facilitates the translation of findings from basic science to practical applications, and vice versa.

We believe that this book series should advance a new frontier in systems sciences by presenting theoretical and conceptual frameworks, as well as theories for design and application, for twenty-first-century socioeconomic systems in a translational and trans-disciplinary context.

More information about this series at http://www.springer.com/series/11213

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Preface

This book is an edition in the Springer Translational Systems Science series and an attempt to describe continuing evolution of health informatics, especially in the context of innovation in healthcare. As such, this is the first book that approaches innovation in health informatics from a perspective of translational systems science. Based on such a unique perspective, the purpose of this volume is to present a bird's-eye view to readers on how changes in health informatics will innovate healthcare and how innovation in healthcare will affect health informatics.

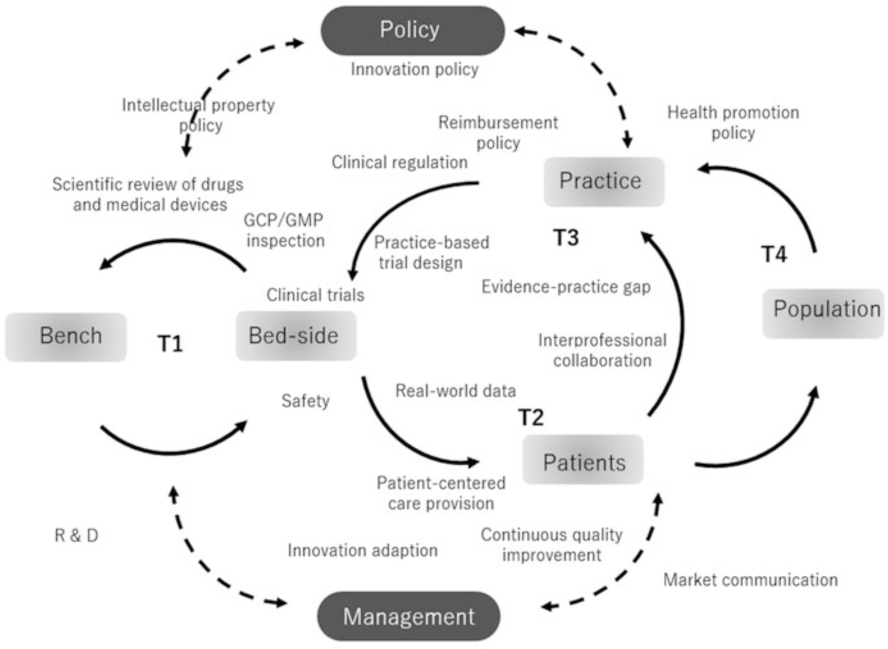
Health informatics is the intersection of information science, medicine, systems science, healthcare delivery systems, management, policy analysis, and health per se. It deals with the resources, devices, and methods required to optimize the acquisition, storage, retrieval, and use of information in healthcare. Moreover, health informatics tools include not only computers but also clinical guidelines, decision support systems, formal medical terminologies, information and communication systems, and data storage systems. As such, traditional books on health informatics, intentionally or unintentionally, have tended to focus on topics such as information management systems, electronic health records, guideline and protocol systems, coding and classification, decision support tools, patient monitoring, population surveillance, bioinformatics, and personalized medicine.

It would not be easy for experts in the field of health informatics to point out that health informatics, as a discipline, has a contradictory characteristic. That is, health informatics has been built on existing health systems, while it seeks to innovate itself to adapt to new health systems. Therefore, there is a potential conflict or dilemma between the conservative direction of maintaining conventional methods and the innovative direction of overriding them and adopting new methods. In simple words, the former is termed tradition, whereas the latter innovation. This book is an attempt to portray that traditional healthcare is being challenged and changed into new forms of healthcare as well as that traditionally used health informatics is being transformed into a new one. In an attempt to do so, this book emphasizes on how to translate information into innovation from a perspective of translational systems science by exploring the horizons of health informatics, introducing cutting-edge practical cases and theoretical frameworks, and including but not limiting to fields such as big data, machine learning, interprofessional collaboration, electronic health records, robotics, telenursing, quality improvement, and safety.

Based on a unique combination of innovative informatics and translational systems science, this volume provides analytics to help readers rethink the relationship between informatics and innovation particularly in healthcare. Technology in the area of healthcare is evolving rapidly, probably with new technology emerging every month. Today, innovation is attracting attention in developed countries, such as Europe and North American countries and Japan, and in many other countries worldwide. In these countries, the realization of innovation in the healthcare field is hailed as a national goal without exception.

For decades, there has been considerable debate about how to effectively and efficiently create breakthroughs and inventions on the bench, or in a laboratory, and share them with clinical settings for implementation on patients; this is called the bench-to-bedside clinical research approach. A bedside-to-bench approach is the opposite approach, where the needs in clinical settings are quickly and accurately captured and shared with laboratories to help scientists improve and realize groundbreaking innovation in healthcare. One of the unique parts of this book is that it proposes a translational view of health informatics and innovation as shown below. In the earlier days, the translational view was centered on the mutual circulation of the bedside and bench. However, we need to extend our horizons to patients, practices, and population, and even to dynamic and systemic interactions between health policies and management. The government has refined the regulation systems to evaluate safety and effectiveness while accelerating innovation policies to enhance the effectiveness of research and development. Newly developed practices that have been confirmed to be safe and effective will be offered to more patients and population by being included in healthcare reimbursement systems. Here, the purposive flow and purposeful co-creation of information, amongst diversified disciplines and practices is key to changing information into innovation. By contrast, hospitals, pharmaceutical companies, medical device manufacturers, clinical trial service providers, and information and communication service vendors, entrepreneurs, and innovative scientists play diversified roles in innovating these pipelines. Here too, the importance of information is increasing significantly.

In other words, healthcare translational systems used to focus on bench-to-bedside (T1) interactions. The research focused here is translational research. However, as health systems have become more innovation-oriented; translationality has expanded from patients (T2) to practices (T3) to population (T4). Now, policy and management, which are becoming more innovation-oriented, are being influential at T1, T2, T3, and T4. All of these effects are achieved through translating data, information, knowledge, and wisdom. Therefore, the new era of innovation-oriented health informatics requires a translational view of health informatics and innovation as proposed in this book.



Translational view of health informatics and innovation

As an introductory part, Chapter 1 by Matsushita, Innovation in Health Informatics, presents propositions or lens of Translational Systems Science. Based on these, this chapter broadly discusses the relationship between informatics, service innovation, and technological innovation in healthcare primarily by descriptively analyzing cutting-age concrete innovative practices.

Chapter 2 by Kawaguchi and Toyomasu focuses on innovation of community-based integrated care and describes the history and the current status of telenursing in Japan. This chapter provides readers with T1, T2, and T3 research and up-to-date systems practices of telenursing where informatics, nursing, computer science, and health policy converge. By approaching such facets, they present innovative aspects of telenursing informatics in comprehensive community care systems.

Chapter 3 by Ikeda et al. outlines topics on innovation in informatics, including information technology and artificial intelligence to improve the quality of life of the elderly. The authors then introduce their own T1 empirical and action research on communication robotics to increase the quality of life of patients staying at long-term care facilities through intervention using artificial intelligence and robotics in the emotional aspects of patients. The study focuses on how to provide mental healthcare to elderly people with dementia, an annually growing population.

In Chap. 4, Taniguchi et al. propose a systematic change in the life course approach by presenting new informatics of trajectory patterns that have been discovered by their longitudinal studies targeted on the Japanese elderly. By exhibiting big data related with T2 and T4, the authors then discuss novel trajectory patterns that should interest public health policy makers, healthcare providers, and each of us.

Chapter 5 dedicated by Nakagami et al. focuses on cutting-edge themes such as real-world data-based care innovation. In this chapter, the authors, based on their state-of-the-art empirical studies concerning T1–T3, introduce translational innovation cases such as automated pressure ulcer prediction model, image-based innovative assessment of pressure ulcers using real-world data, detection technology for deep tissue injury by ultrasonography, early detection of critically colonized wounds by thermography, and detection of wound biofilms. Moreover, the authors discuss the next generation of nursing translational research by integrating informatics and transdisciplinary collaboration with researchers in various fields.

Chapter 6 by Galbrum discusses health informatics from a holistic and translational view that encompasses patients, clinical practices, technology, and their co-innovation processes from T1 to T4. By analyzing innovation in health informatics as a co-innovation phenomenon, he presents an innovation model of health informatics by positioning. This chapter, from an innovation management perspective, then discusses the adoption of health informatics from electronic health records/electronic medical records to advanced visualization and picture archiving communication systems in radiology and cardiology departments.

Chapter 7, Translating Evidence into Practice: An Experience with Interprofessional Education, by Prentice and Salfi discusses how data and information should be used for interprofessional collaboration after they have been transformed into knowledge. In that sense, it is an application area of translational informatics that is closely related to T2 and T3. This chapter will help readers understand the importance of knowledge translation in the practice setting as well as aid practitioners in identifying the facilitators of and barriers to knowledge translation. Moreover, their discussion includes examples of how knowledge translation can be effectively implemented in an interprofessional education teaching.

Chapter 8 by Fujitani et al. introduces a successful case study of clinical bridge research, especially in relation to product development in the Japanese pharmaceutical industry, after overviewing problems associated with T1 or the bench-to-bedside research approach in Japan. The authors also point out various problems such as frustration in filing patent applications, funding challenges, and complicated clinical trial procedures. They also present issues related to the various systems behind health informatics, including the complexity of patent applications, funding challenges, and rigid clinical trial procedures pushed by policy makers. This chapter is suggestive in the sense that health informatics and healthcare systems evolve together.

In Chap. 9, Katsuyama et al. discuss the current status and issues with Japan's community-based integrated care system. They then present the complications regarding the health information system and problems associated with discharge summary, a key media of information that links various professionals and institutions. The authors then provide pragmatic recommendations to resolve such issues from the policy and managerial perspectives.

Although these chapters cover a wide variety of topics, there could be some similarities in the innovation cases and recommendations that appear in each of the chapters. Those similarity aspects include, but not limited to, the following:

– Translationality is a fundamental basis of value co-creation.
– Value co-creation can be affected by translational actors or innovators who spin over systems' boundaries, i.e., disciplines, technologies, and practices.
– Innovators are people who bridge various fields and expertise without being bound by the existing framework.
– New combinations of different competencies, disciplines, technologies, and practices trigger innovation in healthcare.
– Translationality sets the fundamental basis of systemic transition from an existing system into another form of the system.
– The creative combination and fusion of various disciplines, technologies, and contexts initiate with the mutual use of information and knowledge.
– Creative disruption of established frameworks, fixed values, ideas, and systems can serve as a salient key to driving innovation.
– The evolution of health informatics for innovation is an urgent need.

The editor believes that the present volume, as a part of the Translational Systems Science series, will certainly contribute to promoting research on health informatics as well as systems science with insightful findings and implications based on the translational approach.

Chiba-shi, Chiba, Japan Hironobu Matsushita

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This book would not have been possible without the contributions of each of the chapter authors' excellent knowledge, research, and experience. I also thank the editors-in-chief of Translational Systems Science series, Dr. Kyoichi Kijima and Dr. Hiroshi Deguchi, as well as Yutaka Hirachi of Springer Nature for their tough and tenacious encouragement. Thanks to everyone!

Chiba-shi, Chiba, Japan Hironobu Matsushita

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Innovation in Health Informatics

Hironobu Matsushita

Abstract In this chapter, the lens of translational systems science is applied to consider and analyze the ongoing progress of innovation in health informatics. First, this chapter proposes the propositions of translational systems science to help readers understand innovational aspects of health informatics through a perspective of systems thinking. Next, the features of nested translation innovation in ecosystems of health informatics are explained. Based on these, this chapter describes several cases, including imaging and deep learning, and cognitive technologies and extended intelligence. These descriptive analyses reveal that new health innovation comes from the combination and convergence of completely new information. In conclusion, we show that the new era of health informatics is completely different from that of the past and the present.

Keywords Translationality · Innovation · Value-in-context · Contextualization · Converging technologies

1 Introduction

The term "health informatics" first came into use around 1973 (Protti, 1995). Since then, informatics has grown considerably as a clinical discipline in recent years fueled, in part no doubt, by the advances in computer technology (Coiera, 2015). Given that computer technology has enhanced human cognitive competencies in facilitating communication, structuring information, raising questions, and making decisions, informatics inevitably has come to include those functionalities to expand human competencies.

Today, health and medical applications of artificial intelligence (AI) and information and communication technology (ICT), including deep learning and Internet

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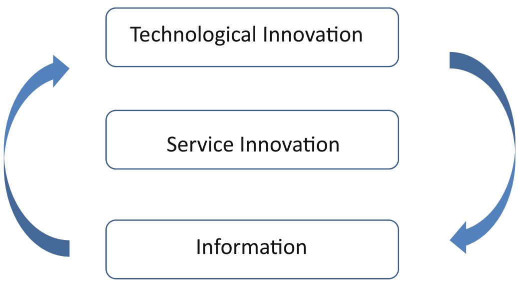
of Things (IoT), are central issues in health informatics. Research and development in this field have been promoted in the past with the focus on the construction of an environment for collecting, storing, and integrally managing various data, such as devices, storage, and Internet technologies. However, in the future, the development of "translational systemization" technology based on transfer learning is strongly demanded. Specifically, it includes individual estimation/prediction of health status by the analysis and mathematical modeling of large-scale health and medical-related data and development of adaptive treatment/intervention methods.

In the future, the health field will evolve in seven directions in line with the evolution of ICT/IoT and AI. (1) Healthcare management will be increasingly dependent on data. (2) Health management and healthcare systems will be systematized for risk control. (3) Health management and healthcare systems will be predictive and immediate. (4) Health policies will be transformed to evidence-based policies. (5) A health information infrastructure will be constructed through standardization of various kinds of health information. (6) Management of healthcare organizations will be redesigned with information as the core in conjunction with policies. (7) Health support will emerge as a strategy for differentiating human resource development in business management. These seven directions are all inextricably related to information and translationality.

It is important to view the vast and infinite world of information in a holistic manner, not in parts. In particular, the following three perspectives (Fig. 1) are important to gain a bird's eye view of health and medical information: (1) obtain new information through technological innovation, (2) transform information into innovation, and (3) embody both as service innovation for a more satisfactory patient service.

Today's health innovation is inextricably linked to the information revolution. Innovation is making obtaining completely new information possible. The ultrafine defects in genes that direct diseases and health in the body are being clarified by innovation that combines ICT and biotechnology, called gene decoding technology. By using the results of innovation of CT scanners that are becoming increasingly sophisticated in recent years, unique and stereoscopic images can be obtained. In addition, the innovation that combines devices worn on the body and ICT provides a mechanism that automatically inputs to electronic medical records vital data such as body temperature, blood pressure, pulse, heart rate, blood sugar level, and

Fig. 1 Health informatics



transcutaneous oxygen saturation. This mechanism is being applied in practical use, and the information thus recorded is transmitted from hospitals, nursing homes, homes, etc., to laboratories, allowing researchers to create new knowledge from the large databases using AI and machine learning.

At the same time, innovation is emerging in the world of health and medical care by leveraging completely new information. Gene deciphering technology has been applied to gene-editing technology, and preemptive medicine now realizes gene manipulation. Until now, the physician interprets and diagnoses planar and stereoscopic images obtained by imaging techniques. However, today, AI loads hundreds of thousands of millions of big data images and substitutes or assists physicians' diagnoses. It has also been clarified that AI, which accumulates certain types of learning than physicians' cognitive functions, has a lower misdiagnosis rate. In addition, the field of visiting nursing care is changing dramatically with the innovation through which sensors attached to patient bodies instantly transmit information related to vital signs to visiting nursing stations.

These are just a few examples of the vast health and medical world of emerging innovation. At least two important trends are evident in this field. People, especially those in developed countries, can benefit from technological innovations and gain new information that has never been known before. At the same time, the information obtained by technological innovations can be transformed into other forms of innovation. However, the evolution of technology and information does not always translate into patient benefits. Therefore, it is crucial to convert technology and information innovation into service innovation in order to benefit patients.

2 On Translationality

The word, "translation" has a wide range of meanings with different contexts. According to Oxford English Dictionary, "translation" has at least the following meanings: Transference; removal or conveyance from one person, place, or condition to another. The action or process of turning from one language to another; also, the product of this; a version in a different language. Transformation, alternation, change; changing or adapting to another use; renovation. Transference of meaning; metaphor. A transfer of property; alternation of a bequest by transferring the legacy to another person (Simpson & Weiner, 1989). The connotation of the word "translation" was more transcendental and even mysterious in the Middle Age than it is today. For instance:

> In Middle English, flowers, bishops, captured peoples, and the relics of saints are all translat from garden to garden, see to see, kingdom to kingdom, shrine to shrine; the soul is translat to God in mystical rapture or at death; and learning, culture, political power, and divine covenant are translat from east to west, pagan to Christian, Old to New Testament, in various manifestations of "translatio studii et imperii," the translation of learning and empire (Watson & Nicholas, 2008).

Today, the term "translation" is used in a variety of ways to reflect the rich connotations of English while at the same time making the implications of each discipline more effective. In philosophy, "translation" means "understanding, interpretation, and hermeneutics." "Translation" is used in linguistics as a term that implies "meaning, conceptualization, interpretation, and metaphor." "Translation" in anthropology means "encounter between others and yourself" (Blumczynski, 2016). When used as "translational research" in the medical field, the *adjective* "translational" refers to the "*translation*" of basic scientific findings in a laboratory setting into potential treatments for disease (Woolf, 2008; Reis et al., 2010; Agency for Healthcare Research and Quality, 2017). The concept of translational research is originated from medical science for enhancing human health and well-being. Translational medical research is often labeled as the "bench-to-bedside" approach. It places emphasis on translating the findings in basic research (at bench) more quickly and efficiently into medical practice (at bedside) (Kijima, 2015).

Thus, the word "translationality" has become a word representing rich metaphor for various disciplines. Hence, the position of this book is to respect the definition of "translationality" in each individual discipline and at the same time to redefine and utilize "translationality" from the viewpoint of systems science. Systems science is an interdisciplinary field that studies the nature of systems, from simple to complex, in nature, society, cognition, engineering, technology, and science itself. To systems scientists, the world can be understood as a system of systems (Mobus & Kalton, 2015).

3 Lens of Translational Systems Science

Translational systems science is a new trend within systems sciences motivated by the need for practical applications that help people by a holistic, comprehensive, and systems thinking on problematic complexity (Kijima, 2015 p40). This book focuses on the aforementioned innovation-oriented health information. Innovations include big data, AI, IoT, neural networks, and brain–computer interface (BCI). The term innovation was conceptualized by Schumpeter. Schumpeter's vision, which regarded the new combination as a source of innovation, has gained a good eye. However, during Schumpeter's time, attention to information was extremely low compared to the present. Therefore, Schumpeter's insights into the importance of the information in the new combination were unfortunately limited.

Let us now complement Schumpeter's discourse. As he stated, the source of innovation is a new combination of existing things (Schumpeter & Opie, 1934). Information and context connect different things. They need to be connected for things to adopt new combinations. A context is a story that incorporates human intentions and goals. Therefore, in many cases, human beings spin the context. However, in recent years, AI has been trying to carry out this human-specific behavior. In a sense, the future where the context is automatically generated even without human intervention is coming up soon.

In other words, it is almost the day when AI takes on a new combination on behalf of humans. However, the essence of this innovation in the traditional "medical informatics" has not been discussed extensively. This book focuses on innovation-oriented health information, as manifested in the subtitle, translating information into innovation. However, it differs greatly from the conventional book in that this book approaches health informatics from the perspective of translational systems science.

The features of translational systems science are the following eight points. Innovation-oriented health informatics and the related many practice cases are best seen through the lens of translational systems science.

3.1 *Three Types of Knowledge—Episteme, Techne, and Phronesis—Coevolve in a Cyclic Translationality in Micro-, Meso-, and Macro-Spheres*

Translational systems science focuses on cross-border flows of knowledge. Knowledge is information that has been interpreted and made meaningful. The exchange of information is fundamental. Innovation-oriented medical informatics also focuses on a circular flow of knowledge. As shown in Fig. 2, technical knowledge (techne), academic knowledge (episteme), and practical knowledge (phronesis) are bridged together in a cyclic manner. As Kijima (2015) argues, core of translational systems sciences comes from much broader translational systems thinking based on the platform underpinned by three domains, i.e., systems concepts/models/theories, systems methodologies, and systems practice. These are applicable in the micro level such as at workplaces and in the macro level such as in industry–academia–government communities as well as to the meso level between them. Service

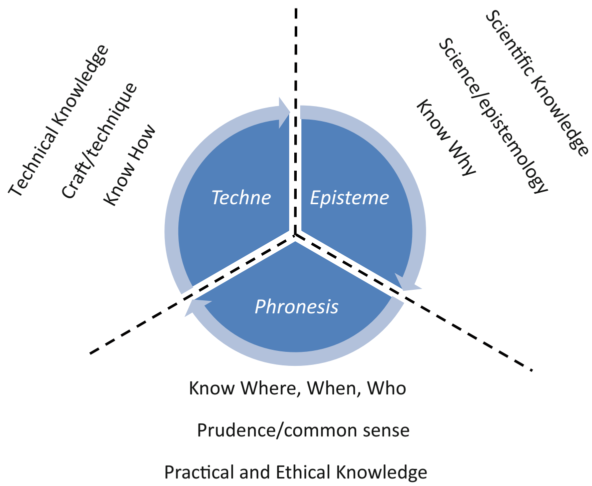


Fig. 2 Three types of knowledge, i.e., episteme, techne, and phronesis coevolve in a translation cycle

innovation is brought to fruition in the technology that causes innovation, the academic knowledge of health informatics, and the place where they are organically connected.

3.2 Translationality Is a Fundamental Basis of Value Co-Creation

In human society, people play different roles such as parents and children, producers and consumers, developers and marketers, professors and students, and the government and taxpayers. They exchange various values according to their roles.

The most obvious is the relationship between producers and consumers who exchange products. In developed countries, however, more than 70% of GDP is recorded through service exchanges. Therefore, in service-dominant logic, we focus on "value co-creation." "Service" in service-dominant logic does not mean intangible goods, but refers to service that exhibits value (use value or experimental value) only when the customer experiences it. In other words, the value of service is generated together with customers, and even for the same service, the values that appear phenomenologically are considered different.

In service-dominant logic, "service is the fundamental basis of exchange." However, the essence of exchange is cross-borderness, and in order for services to exist, cross-borderness of information lies deep within the exchange. Producers and consumers, developers and marketers, students and professors transcend and co-create value across different roles. Therefore, translational systems science defines translationality as a fundamental basis of value co-creation.

3.3 Value Is Phenomenologically Determined by Actors and Beneficiaries in Translational Interaction

In cross-border exchanges, the value is determined phenomenologically by actors and beneficiaries. As mentioned earlier, the combination of new knowledge brought about by the exchange of information is the source of innovation. Such a source need not necessarily be interesting for everyone. The innovator is a person who understands the subtle but delicious taste of an innovation, but whether it is interesting or entertaining to others is subjective to individuals.

Service innovation created by the synergy of technology innovation and information innovation is also essentially grasped only subjectively. Services that are present in "now, here" are perceived and memorized as subjective experiences. In other words, we can only capture value phenomenologically.

Services present themselves in the synergy of heterogeneous roles. Doctors and patients are residents of different worlds. The former spends a long time in the world of medical knowledge and clinical practice, and the latter has limited knowledge of diseases and disorders that are unrelated to them. The two sides cross each other and share a commonplace, resulting in good health care services. Even in an interprofessional collaboration team consisting of doctors, nurses, occupational therapists, pharmacists, etc., patients can be placed in the middle, and each job type can share value only by crossing the boundaries of specialization. Here too, the role information plays is crucial.

3.4 Translational Actors Spin over Systems' Boundaries

Ultimately, to cross and bridge different fields is the basis of value co-creation. If we closely look at the examples of innovation presented in this book and the background of the innovators, we note that none of them has constrained to his or her traditional discipline, industry, or custom. All are masters who have transcended existing specialties. These extraordinary people who traverse to other disciplines are called innovators. A stranger, sometimes called an outsider, in a world of information creates new meaning by transcending this world.

Innovation converge technology, and more precisely, information about technology. It should be noted that the technology itself is a system. Today, the convergence of these technologies or systems is called converging technologies. Converging technology is defined as the "convergence of two or more disparate sciences and technologies to achieve a specific goal." Innovators create value together by converging two or more systems across borders as illustrated in Fig. 3.

Modern people live in the "Age of Transition" of computers, information technology, nanotechnology, biotechnology, etc. In the future, they will exploit these technologies and go beyond the framework of conventional science and technology. Converging technologies will be the key technology for revolutionary technological change and social change. One of them is health informatics.

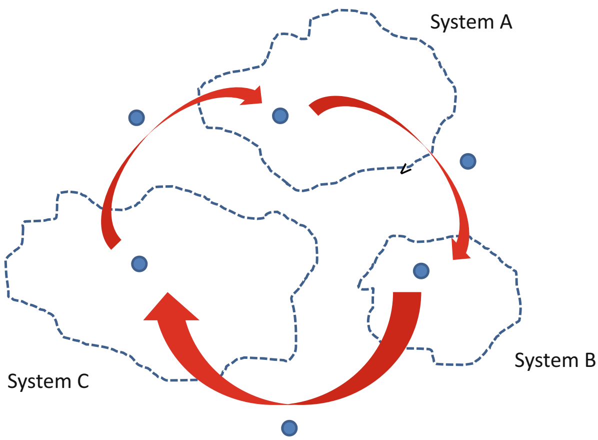


Fig. 3 Translational actors spin over systems' boundaries

3.5 Actors Coproduce Value-in-Context in "Ba," or Shared Context-in-Motion, by Applying Competencies

The study of competency was first conducted in psychology as early as in the 1970s (Maclelland, 1973). Since then, competency has attracted attention in the field of service science, management, engineering, and design (SSMED), an emerging area of study with pioneering research work in the areas of service marketing, service operations, service management, service engineering, service economics, service computing, and other service functions (Chesbrough & Spohrer, 2006; Maglio & Spohrer, 2008). In these areas, many researchers have focused on the human aspect of services. According to Vargo et al., service is "the application of specialized competencies (knowledge and skills) through the deeds, processes, and performance for the benefit of another entity or the entity itself" (Vargo & Lusch, 2004).

A theory of competency models elements such as motives, traits, self-concept, attitudes, values, and skills as well as their dynamic interactions in a hierarchical manner (Boyatzis, 1982); that is, competency is an underlying characteristic of an individual that is causally related to criterion-referenced effective and/or superior performance in a job or situation (Spencer & Spencer, 1993).

It is in "Ba" that human competencies are driven and applied. "Ba" (shared context-in-motion) was first conceptualized by Japanese philosopher Kitaro Nishida (Nishida, 1921). The difference between "Ba" and "place" is that "Ba" accumulates diverse contexts and embeds a self-organization that adheres and generates a lot of information, knowledge, and wisdom. In recent years, the theory of "Ba" has been developed and inherited, and it is positioned at the center of knowledge creation theory in management by Nonaka Ijiro (Nonaka & Konno, 1998). Consequently, actors coproduce value-in-context in "Ba" or shared context-in-motion by applying competencies.

Competency drives in "Ba." Then, the interaction of data, information, knowledge, and wisdom will emerge. Thus, in "Ba" the dynamically moving context is shared, and is sublimated from data to information, from information to knowledge, and from knowledge to wisdom. Thus, learning by experience emerges in "Ba."

3.6 Translationality Sets the Fundamental Basis of Systemic Transition from an Existing System into Another Form of System

Translationality is fundamental to the systemic transition of one system to another. At the first glance, a social system seems to change continuously, but large noncontinuous changes reduce the complexity inside the system, and the system itself transcends different boundaries and changes to another as illustrated in Fig. 4.

Turning to history, the entire society, including the French Revolution in Europe, the American Revolutionary War, and the Meiji Restoration in Japan, can be

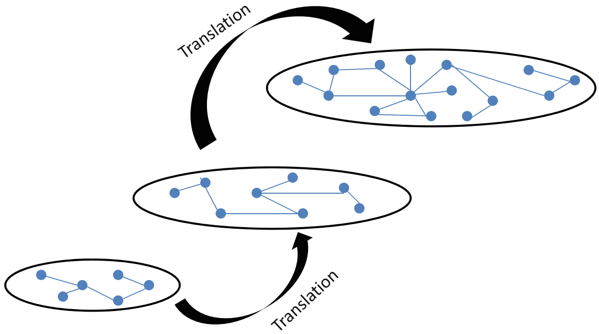


Fig. 4 Fundamental basis of systemic transition from an existing system into another form of system

transformed on a large scale. In addition, even in the past 50 years, considering the devices that people use every day, the society has systemically changed from fixed phones to mobile phones, from mobile phones to smartphones, from smartphones to 3G to 5G, etc.

Translationality, whether in the whole society or a part of it, is the driving force of systemic change. The social impact caused by an innovator becomes pan-social, and when the public obeys it through social communication and control, the social system changes. This is the axiom that applies to every entity: home, business, hospital, community, and country; translationality sets the fundamental basis of systemic transition from an existing system into another form of system.

3.7 Generative Interactions Among Data, Information, Knowledge, and Wisdom Manifest Themselves in a Shared Context-in-Motion in Human Activity Systems

The context is woven like a bunch in "Ba" shared by humans. Data, information, knowledge, and wisdom are generated by people sharing their constantly dynamic context as shown in Fig. 5. A context is shared when multiple people with different

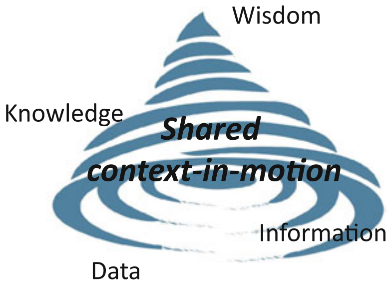


Fig. 5 Generative interactions among data, information, knowledge, and wisdom in a shared context-in-motion

backgrounds, lives, specialties, values, and behavior patterns interact freely; the context in which close friends meet again after a long time and are shared; and a shared context when discussing given ideologies. Context sharing is a very human act.

As described above, “Ba” is a very human act, and without “human interaction,” “Ba” should be difficult to establish. This raises a big question. Can AI produce “Ba”? Can the subtleties of “Ba” interwoven by humans be able to create AI? At present, there are many advantages of humans over AI. One of them would be the creation and sharing of “Ba.”

However, using the findings of Talcott Parsons’s social action theory, the mechanism of “Ba” which appears as a very human-based act at the first glance, is decomposed into four functional prerequisites, namely, adaptation, goal accommodation, integration, and pattern maintenance (Parsons, 1937). If we can make AI learn these functional prerequisites, which may be possible, then “Ba” can be released from the human activity system. This will be one of the challenges of the new era of informatics.

3.8 Value-in-Context Emerges Through Translational Phases Such as Contextualization (Participation), Re-Contextualization (Interpretation), Co-Contextualization (Socialization), De-Contextualization (Objectification), and Trans-Contextualization (Translation)

Data, information, knowledge, and wisdom can only create value when embedded in a specific context. What is valued by context is called value-in-context. How is value-in-context born? A meta value-in-context transformation model presented in Fig. 6 explains this mechanism (Matsushita, 2014).

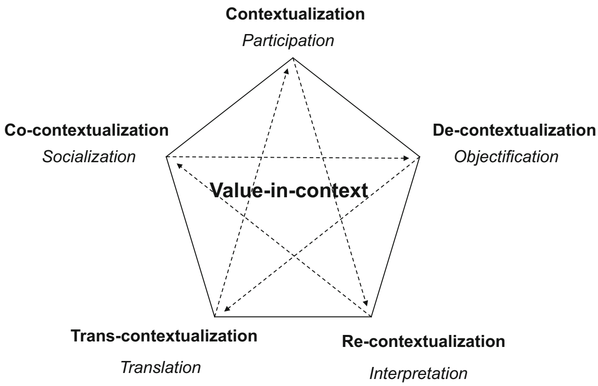


Fig. 6 Meta value-in-context transformation model

It starts from the place and the context of your “current address,” where you have your own field of expertise and a certain track record. When crossing the context of yourself, you encounter various places and contexts, or thrust your head and enter new contexts. This is called “cross border participation” or “contextualization,” because first you jump over and cross borders to capture new contexts.

Next, you reflect on the new places and contexts you encountered. Naturally, the “Ba” varies and contexts are different from the original “current address.” While enjoying a sense of incongruity as well as the difference, you introspect the strange, fresh, and surprising “Ba” and context; this reminiscence is called “re-contextualization.”

Next, you share the introspective context with the new “Ba” and the people in the context. In other words, it is called “socialization.” Those who cross the border usually go across the border alone, but they make friends at the place they travel and share with them the events they reflect on. This point of acting on the context is called “co-contextualization.”

The next action is “objectification.” By objectification one can create a general-purpose solution that can be used beyond such special “Ba” while serving in the context of embedded “Ba.” “Decontextualization” is the refinement of new discoveries, novel business practices, and unique theories by deviating from the original context.

In the “Ba” of a workplace, there is a potential for generalization in problem-solving methods. For example, a certain researcher provides generality to a theory of research and development activities in his or her own work and presents it as an academic dissertation; this is de-contextualization. Trans-contextualization provides an opportunity for transition learning, which means to translate, bridge, and adapt a model learned in one area or “Ba” to another.

Thus, the innovator bridges the diverse contexts with the “Ba” to create a new value and share it with those who share the context with the “Ba.”

4 Innovation in Informatics

Innovation has a profound effect on people’s lives, various communities, business activities, and medical practices in medical institutions. At the same time, if the same word repetition is allowed, innovation has a great impact on the style of innovation.

We attempt to accurately capture the vision of innovation that is emerging in the current and near-future informatics field. To that end, it is necessary to closely see how ICT solutions, which are closely related to informatics, have changed or evolved during the past half century (Table 1).

Table 1 Evolutionary changes of ICT solutions

Era	~1980s	~1990s	~2000s	~2010s	~2020s
Agenda	Increase divisional efficiency	Increase hospital-wide efficiency	Information sharing at hospital	Health information exchange at community	Integrated health information sharing at community
Typical ICT solution	Computerized physician order entry system	Hospital information system	Electronic healthcare record	Electronic health record	Personalized, preemptive and regenerative medicine
Type of innovation	Closed incremental improvement	Closed innovation	Semi-open innovation	Open innovation	Ecosystem-nested translational innovation

4.1 *Closed Innovation*

A common innovation style, except in some advanced organizations, until the 1990s was closed innovation. Closed innovation creates value through the use of internal business resources and technical information consistently from research and development to product development. Certainly, simple execution of closed innovation made management more efficient. Closed innovation had been effective in industries where there is little change in market and technology, accumulation of information and know-how in research and development, and requirement of integral integration.

The Japanese manufacturing industry, which flourished with a standard mass production method based on mass consumption until about the 1980s, adopted a human resource management method, such as seniority and lifetime employment, and closed innovation. The closed innovation-oriented organizations are linear, functional, and inward oriented.

During 1980s, hospitals were in charge of healthcare, not health. Similar to hospitals in other developed countries, Japanese hospitals were still limited in computerization. Nevertheless, ICT solutions such as the computerized physician's order entry system were introduced to increase the work efficiency of doctors, the source of revenue, and to centrally manage medical information mainly by doctors. The hospital agenda was to increase divisional efficiency rather than innovation, exhibiting closed incremental improvement.

4.2 *Open Innovation*

From 1990s, it had become difficult to respond to intensifying competition in the global market and diversifying consumer needs only with product development and service provision by adopting closed innovation. An increasing number of companies were aiming for open innovation that incorporates superior technologies, information, and ideas of external companies from outside without being stuck with in-house development. Open innovation, which is a catchy term, is the creation of value by organically combining internal and external information.

One of the activities for open innovation is to solicit information and ideas from other companies, universities, and research institutes. In addition, using technology intermediaries to search for partners that can solve technical issues is also a practice of open innovation. The same is true of cocreating new business with partners in different fields. Furthermore, in open innovation, the company does not carry out product development itself but provides it to the market in the form of licensing to other companies or spin-off ventures.

The goals of open innovation are diverse, for example, the creation of innovative businesses and products by combining different fields and applying scientific results. In addition, product development is accelerated to cope with shortening of the product life cycle due to intensifying global competition, and large-scale research and development investment is reduced. Organizations that cannot find hope in their inward-looking culture tend to be idyllic for open innovation and aim for open innovation without a strategy. Organizations that are open innovation-oriented tend to be interorganizational and outward oriented. Information is circulated inside and outside as well as back and forth across the organization.

In 2000, information sharing in hospitals, which aimed to share medical information inside the hospital, became a boom. The electronic healthcare records (EHRs) allowed sharing of information across the region that attracted the most attention. The trend until the 1990s was easy-to-use EHRs for doctors at the heart of the medical team.

Since 2000, however, EHRs have come to require new features. They have been required to support interprofessional collaboration that includes not only doctors but also nurses, public health nurses, midwife, pharmacists, physiotherapists, occupational therapists, dietitians, radiologists, and clinical engineers. In addition, the movement to standardize medical interventions also affected the EHR. In providing care based on the clinical pathway, attention was focused on EHR as a tool to record and analyze deviation events from clinical pathway in a standardized language.

In the 2010s, "health information exchange at community" has been advocated across medical facilities, health promotion facilities, and nursing facilities. However, open innovation in healthcare is lagging as far as health information and medical information are concerned. There are 210 regional networks nationwide sharing health information among hospitals. However, the number of registered patients is only 1% of the Japanese population. With public long-term care insurance, which commenced in 2000, it became a policy goal to "seamlessly connect medical care, long-term care, and home care." However, contrary to the policy, information sharing between hospitals and long-term care institutions has not progressed effectively.

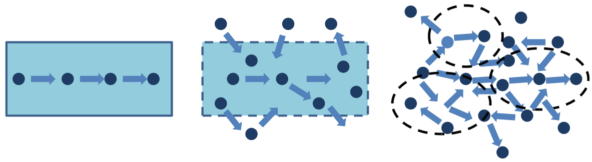
4.3 Ecosystem-Nested Translational Innovation in Health Informatics

What is the next pattern of innovation? This book proposes ecosystem-nested translational innovation. Let us consider the changes in health informatics as an example of ecosystem-nested translational innovation currently emerging in the world of healthcare.

Nowadays, EHRs are evolving by loading the EHR platform with various types of information generated by related technologies. The information that old-generation EHRs handled was no more than conventional text, numerical values, and image information. Current EHRs include color animations, three-dimensional animations, various vital information such as electrocardiograms acquired using sensors, life logs, narratives of patients, cost information on medical fee, divergence from Diagnosis Procedure Combination/Per-Diem Payment System (DPC/PDPS) data, and real-time big data information from patient monitors, which is centrally managed for each patient and stored in Clinical Big Data Repository (CBDR). In addition, EHRs are among the most influential ICT tools that intervene in communication between patients and the interprofessional collaboration team as well as complex communication within the interprofessional collaboration team. As such, innovation of EHRs is evolving in complex ways with other health information system innovations.

These data and information are collected by systems provided by independent vendors. By coordinating the information collected by these vendors and independent vendor systems, the collaboration changes into an ecosystem. This cooperation will foster ecosystem-nested translational innovation. Thus, pan-enterprise interprofessional team collaboration within the industry is the basis of ecosystem-nested translational innovation.

The environment in which such an EHR operates is used routinely and clinically. Moreover, it is possible to translate the information stored in CBDR for various other uses. For example, by combining exploratory matching with machine learning, we can achieve drug side effects matching, process control related to new drug development in post-genome and drug-discovery eras, and analysis of pharmacogenetic drug response characteristics for each patient. In addition, cutting-edge information analysis technologies such as machine learning will be introduced into CBDRs that can be operated over a long period of time to make effective use of stored big data patient information. Thus, health informatics of translational EHRs is emerging (Fig. 7).



Type of Innovation	Closed innovation	Open innovation	Ecosystem-nested translational innovation
Translational Feature	Linear, functional Inward oriented	Inter-organizational Outward oriented	Trans-social sectors Co-creation oriented
Degree of Co-evolution	Low	Medium	High

Fig. 7 Transition of innovation patterns

5 Diagnostic Imaging and Deep Learning

Progress in technologies such as AI and ICT is remarkable, with the wave spreading in the medical field as well. Changes have already begun in both regional and advanced medicine, but how will AI and ICT further evolve and influence the future?

Research on AI began around 60 years ago. Currently, machine learning and deep learning are positioned as the third AI boom. Recently, technologies such as image recognition by deep learning have been developed and are considered to bring innovation to the field of health care. In pathological image analysis such as for blood cancer, chronic shortage of pathologists continues. Currently, one pathologist is responsible for nearly 3000 diagnoses a year, which makes it impossible to arrive at accurate diagnosis. With Japan’s declining birthrate and aging population, labor shortage is accelerating. Therefore, in Japan’s medical industry, collaboration with AI is essential to eliminate labor shortage and maintain economic growth.

There is a pattern of innovation in this area. The innovators combine a variety of devices, including X-rays, computed tomography (CT), magnetic resonance imaging (MRI), and cytology with computer-assisted diagnosis or detection software that implements machine learning and deep learning. The new combination analyzes image and video data and information. To promote the development and clinical application of Computer-Aided Design (CAD) software, it is critical to achieve algorithm development, software implementation, clinical use, feedback of knowledge, improvement of algorithm and software, and circulation of additional clinical use.

In addition to the detection of tumors, outliers can be found from numerous test results. AI can perform inspection that takes 10 days in case of manual inspection. Although humans obtain immense information with their eyes, AI’s image recognition ability and pattern recognition competencies have improved over those of humans. Doctor’s competency is greatly expanded by acquiring AI’s image recognition ability. The amount of work done by physicians performing diagnostic imaging has more than tripled in the past 10 years, with the same number of diagnosticians. That is, image diagnosis supported by machine learning and deep learning is useful to realize efficient image diagnosis.

5.1 Pylori Infection Diagnosis with AI

According to Sotoki Shichijyo et al., AI for *Helicobacter pylori* infection diagnosis exhibits better sensitivity and specificity than the average value of 23 doctors. A 22-layer, deep convolutional neural networks (CNN) was pretrained and fine-tuned using a data set of 32,208 images with either positive or negative diagnosis for *H. pylori* (first CNN). A separate test dataset (11,481 images from 397 patients) was evaluated by the CNN and 23 endoscopists independently (Shichijo et al., 2017). They concluded that gastritis caused by *H. pylori* could be better diagnosed on the basis of endoscopic images compared with the manual diagnosis performed by endoscopists.

In addition, the application of AI has been successful in diagnostic imaging of cancer. A CNN-based diagnostic system was constructed by using a single-shot multiBox detector architecture and trained using 13,584 endoscopic images of gastric cancer. To evaluate the diagnostic accuracy, an independent test data set of 2296 stomach images collected from 69 consecutive patients with 77 gastric cancer lesions was applied to the constructed CNN. The constructed CNN system for detecting gastric cancer could process numerous stored endoscopic images in an extremely short time with a clinically relevant diagnostic ability. It may be well applicable to daily clinical practice to reduce the burden of endoscopists (Hirasawa, Aoyama, et al., 2018).

5.2 Analyzing Endoscopic Images with AI

Colorectal cancer has been on the rise in recent years, ranking number 1 in the cancer death rate in Japanese women and number 3 in men. As a countermeasure, it is known that the mortality from colon cancer can be significantly reduced (53–68%) by removing tumorous polyps that are early cancer and precancerous lesions with colonoscopy (Zauber et al., 2012; Nishihara et al., 2014).

Among polyps, however, there are neoplastic polyps that need to be resected, whereas non-tumor polyps (nonneoplastic polyps) that need not be resected. Physicians need to properly distinguish these polyps during time-constrained examinations. However, the judgment is not easy, as it is strongly dependent on the doctor's intuition and experience. Early detection and treatment of neoplastic polyps using an endoscope have the effect of suppressing colon cancer death.

Under such circumstances, Susumu Kudoh et al. at the Digestive Center of Yokohama City Northern Hospital in Showa University analyzed endoscopic images using AI to determine if the image is a tumor or not. Software that infers a tumor and presents it along with its potential was developed. The safety and efficacy of this method were recognized in December 2018, and approval under the Pharmaceuticals and Medical Devices Act was obtained. The developed software EndoBRAIN® uses a support vector machine for machine learning.

EndoBRAIN® processes the endoscopic image information of the large intestine taken by Olympus's ultra-magnifying endoscope Endocyto. EndoBRAIN® has the ability to output tumor and non-tumor potentials as numerical values from images and thus can assist physicians in predicting and diagnosing lesions. EndoBRAIN® could learn approximately 60,000 endoscope images based on support vector machine. The clinical performance test identified neoplastic polyps and nonneoplastic polyps with an accuracy of 98% and a sensitivity of 97%, which was comparable to that of specialists and exceeded that of nonspecialists (Japan Agency for Medical Research and Development 2019).

5.3 *Detection of Influenza Follicles with AI*

For entrepreneurs, the intersection of healthcare and AI composes one of the attractive and emerging market. For most clinicians, AI is an unknown world. In fact, many doctors view it as a threat that could steal their work. However, as we have discussed so far, the combination of clinical and AI heterogeneity also triggers innovation from the perspective of business start-ups.

The movement to use AI for diagnosis of familiar diseases is also becoming active. If we include patients who rely on self-diagnosis and do not go to the hospital, we may actually have more than 25 million flu cases a year. However, for patients who are given the therapeutic agent Tamiflu 48 h or more after the onset of influenza, no noticeable effect is observed. The current examination method has approximately 60% diagnostic accuracy because it is not sufficient unless 24 h or more have passed since the onset. Note that if a positive case of influenza is incorrectly diagnosed as negative, the carrier may risk spreading the disease, for example, by commuting to school (Chartrand, Leeflang, Minion, Brewer, & Pai, 2012).

Aillis Inc. (Japan Agency for Medical Research and Development 2019), established in November 2017 by emergency doctor Sho Okiyama, aims to support efficient and effective influenza diagnosis by AI. His encounter with a paper in 2013 motivated Dr. Okiyama to start the company. The paper described a flu-specific swelling of the pharynx that could help an expert physician identify the flu with nearly 99% accuracy by examining the flu follicles (Japan Agency for Medical Research and Development 2019).

In influenza patients, a swelling called flu follicles presents in their throat. Although there is a similar swelling in the back of the throat of patients with common cold or even totally healthy people, it was discovered that this follicle has a feature that appears only in the case of influenza. It is a combination of various features such as the color tone and luster of the surface, size, and manner of swelling. For decades, it was known that even objects that inexperienced physicians could recognize as the same would seem to make a big difference in the eyes of veteran physicians. This feature of flu follicles is that which cannot be discerned by just any doctor but only a master doctor. Aillis Inc. is trying to reproduce the "eye of a master" with the power of AI.

The research activity primarily conducted by Aillis has been adopted by a project of the New Energy and Industrial Technology Development Organization (NEDO) and has received financial support. The collection of key data began in 2018, and by obtaining the first-class marketing authorization in 2019 from the Ministry of Health, Labour and Welfare, it became possible for them to manufacture and sell various medical devices. These included not only general medical devices (class I) that could be manufactured and sold under the type III medical device manufacturing and marketing license already acquired but also managed medical devices (class II) and highly managed medical devices (classes III and IV), thus covering all the classifications of medical devices.

5.4 Genomic Medicine and AI

In cancer medicine, research using AI is rapidly becoming essential. We have entered a time when cancer is classified not by the developmental organ or pathological classification but by the essential growth driver, that is, the gene mutation that is essential for cancer growth.

Cancer occurs as a result of a change in nucleotide sequence caused by mutation or a change in genome, resulting in the inability of a gene to function properly. Most cancers are caused by smoking, lifestyle, aging, and other factors, and mutations in certain somatic genes of normal cells give rise to cancer cells. When cancer progresses, this gene mutation is considered to be a source of progression and proliferation only in cancer cells.

Cancer genomic medicine is an attempt to investigate in detail the genes of cancer that do not respond to usual treatment and cannot be removed by surgery and to search for therapeutic agents that respond to changes in the gene. Anticancer drugs called recent molecular target drugs are known to be effective against cancers with certain special genetic changes. Although examining genes does not always lead to treatment, if a drug with a molecular target is found, it may lead to long-term survival or cure rather than continuing traditional treatment.

5.5 Oncogene Panel Test

The oncogene panel test is performed using an analysis device called the next-generation sequencer, which reads large amounts of genome information at high speed using cancer tissues collected through biopsy or surgery. Multiple (several tens to hundreds) genes can be examined simultaneously in one oncogenic panel test.

If a gene mutation is found and there is a drug that is expected to be effective against the gene mutation, the use of the drug will be examined in clinical trials and the like. Preparations are underway from 2019 onward for oncology panel testing to be received in insurance practice.

For example, if there is a specific gene mutation, the analysis result is considered by a committee composed of multiple experts. The doctor will use this as a reference for diagnosis and treatment to see if there is a drug that is expected to be effective for gene mutation. If such a drug exists, consider using that drug, including in clinical trials. If there is no such drug, other treatments will be considered. It is not easy to clear the requirements for the implementation of the cancer genomic medicine that presupposes the oncogenic panel test. The following are the major conditions that must be satisfied.

1. There is a system that can carry out panel inspections, including cooperation with external organizations.
2. There is an interprofessional collaboration team to medically interpret the panel test results.
3. Specialized genetic counseling is possible for patients with hereditary tumors.
4. There are more than a certain number of cases for subjects such as panel examinations.
5. It is possible to collect and manage panel test results and clinical information in an appropriate way with security. In addition, necessary information can be registered at the Cancer Genome Information Management Center.
6. There is a system that allows fresh frozen preservation of surgical specimens, etc.
7. There is an appropriate interprofessional collaboration team to conduct advanced medicine and physician-led clinical trials, including international joint clinical trials.
8. There is an easy-to-understand window for patients to use medical information and provide clinical trial information.

With the advent of increasingly sophisticated sequencers, however, genomic mutations are being discovered one after another (hundreds to millions). When looking at the flow of genomic medicine and personalization of medicine in cancer, the researcher's interpretation and translation become a bottleneck (Good et al., 2014).

6 Cognitive Technology and Augmented Intelligence

By the year 2016, 26 million articles have been registered on PubMed (Medical and Biological Articles Abstracts Database) of the U.S. National Institute of Health. When printed, its thickness is as much as 4000 m, far exceeding the height of Mt. Fuji. As of 2016, the number of articles on cancer alone exceeded 200,000. Since then, the number of papers has been increasing exponentially, and it will reach a height of 100 km, beyond the atmospheric layer, in 2050 (Miyano, 2018).

6.1 Cognitive Computing

What is cognitive computing? IBM's Watson is well known for cognitive computing. What is the difference between cognitive computing and AI? They could be confused but are not similar. In general, while AI mimics the human brain, cognitive computing aims to complement human beings by providing advice to make better decisions and reinforcing human abilities. Such ability is called augmented intelligence.

The word cognitive has the meaning "based on empirical knowledge." Cognitive computing is a system in which a computer not only processes instructions given by humans but also thinks and learns as if it were a human and presents materials that support human decision-making. Cognitive computing can understand not only numbers and simple text but also unstructured data such as natural language, images, sounds, and human expressions. Approximately 80% of the data in the world are said to be unstructured data. Augmented intelligence makes it possible to understand and process much more complex data than ever before. The University of Tokyo Medical Research introduced IBM Watson Genomic Analytics (WGA) in July 2015. It was trained at the New York Genome Center at the time of introduction; subsequently, it read over 20 million Medline data (literature abstract), over 15 million patent data, COSMIC (Catalog of Somatic Mutations in Cancer, UK), ClinVar (Genomic Variation and Information on health, NIH USA), and National Cancer Institute Pathways (NIH USA).

Systems prior to third-generation computing, such as cognitive computing, have mostly dealt with problems that have only one solution; however, cognitive computing addresses questions that have multiple solutions. It has the ability to find the best answer or to answer vague questions. In addition, by receiving feedback on the answers that are derived, it has a deep learning function that allows it to learn on its own and evolve so that accurate answers can be provided.

6.2 Panel Analysis and Whole Genome Sequence Analysis

IBM Watson Genomic Analytics has been introduced as whole genome sequencing (WGS). Laskin et al. (2015) compared the detection rates of actionable mutations with panel analysis and WGS in the terminal cancer patient group in detail. When WGS was used for the terminal cancer patient group, actionable mutations were found in 55 out of 78 patients, and 23 of them were actually treated. By contrast, when the panel analysis was used for the same patient group, 73% of 81 patients had mutations that were informative but not actionable (55% of those mutations were TP53). In addition, 23% of the patients were not found in the panel. The panel reported that nothing was eventually found to lead to an action (Laskin et al., 2015).

Although panel analysis is continuously innovating, as the above-mentioned article points out, whole genome sequencing can be superior if it can be performed efficiently at lower cost. Here is the meaning of utilizing augmented intelligence for whole genome sequence analysis.

7 Conclusion

As outlined in this chapter, biotechnology, nanotechnology, cognitive science, and other fields of epidemiology, internal medicine, molecular biology, public health, nursing, infectious diseases, oncology, and many other disciplines are rapidly converging. Not just the existing field of study converges, but quite diverse combinations are emerging out of the existing framework of this study. The combination and convergence of new findings, which are the basis of innovation, are caused by the combination and convergence of information.

In this chapter, we discussed some translation-oriented scientists and entrepreneurs. All of those dynamic people, who are full of spirit, have gone beyond their existing fields and explored areas unknown to them. Their ethos is creative and ingenious toward creating innovations. All have created their own BA (shared context-in-motion) and a system in which people, goods, money, and information come together. They deal with existing or unknown data and information in a way never before possible. They turn them into knowledge and even raise them to wisdom. That wisdom creates a cycle of creation of new data and information. This represents translation.

The importance of information and the creative circulation of data, information, knowledge, and wisdom have become more important in the present age than ever before. Even tacit knowledge and wisdom that could only previously be used for some skilled doctors are now being replaced by AI. The time has come for more people to gain access to the benefits of wisdom that could only be applied to a fraction of humans. However, it would be premature to call this movement "democratization of wisdom." In modern society, the gap between rich and poor is widening, which also creates a gap in access to information, knowledge, and wisdom.

Nevertheless, information sciences that handle such rapidly evolving information are also in the transition process in response to these changes. Health informatics itself is in the process of transition and translation. In this chapter, we drew upon one part of rapidly changing health information and medical information and analyzed some remarkable trends in the current flow.

As shown in Fig. 8, health informatics will be like a dance hall where all data, information, knowledge, and wisdom from all areas related to health and medical care develop a dance. The dance performed by various dancers who are dressed in elegant costumes, representing AI, IoT, big data, etc., converges on the stage. As a result, more diverse converging technologies will be born in the future. The health informatics of the future will be the stage and platform on which such dancers will step brilliantly. That will be the BA of translational value co-creation.

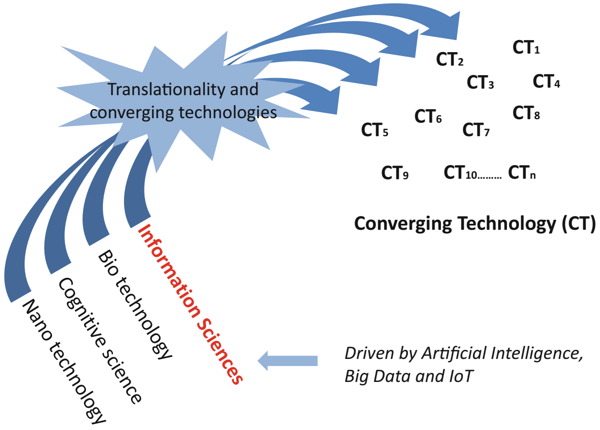


Fig. 8 Translationality and converging technologies

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Innovation of Community-Based Integrated Care: The History and Current Status of Telenursing in Japan

Takayasu Kawaguchi and Keiko Toyomasu

Abstract This chapter defines telenursing as follows: "Telenursing is a nursing practice that uses information and communication technology. This technology is used to understand and educate patients about their health." The elements required to develop a telenursing system are shown in a user-oriented telenursing application based on the structure of personal health records. In recent years, numerous information application tools have been developed for smartphones and incorporated into daily life. The functions necessary for telenursing include information sharing, the structure of medical care, and patients (Doctor to Patient with Nurse [D to P with N]). Telenursing could extend the lifespan through not only the optimization of operations but also interprofessional information sharing and early detection and treatment. Further, telenursing could lead to the reduction in medical expenses while simultaneously providing peace of mind and comfort to people in all situations in hospitals and communities.

Consequently, this chapter is an attempt to identify necessary elements and challenges of a telenursing system primarily from the viewpoint of translational health information sciences.

Keywords Telenursing · Telecare · Home care

1 The Definition of Telenursing

Telenursing can be defined as "nursing practice utilizing telecommunication (electronic/long distance communication)" (American Nurses Association: ANA, Milholland, 1997) (Kumar & Snooks, 2011) or "providing nursing to subjects at physically distant locations by connecting a home or hospital with a mobile terminal using telecommunication techniques" (International Council of Nurses: ICN, Milholland, 2000). Sharpe, a leader in telenursing research, provided the definition

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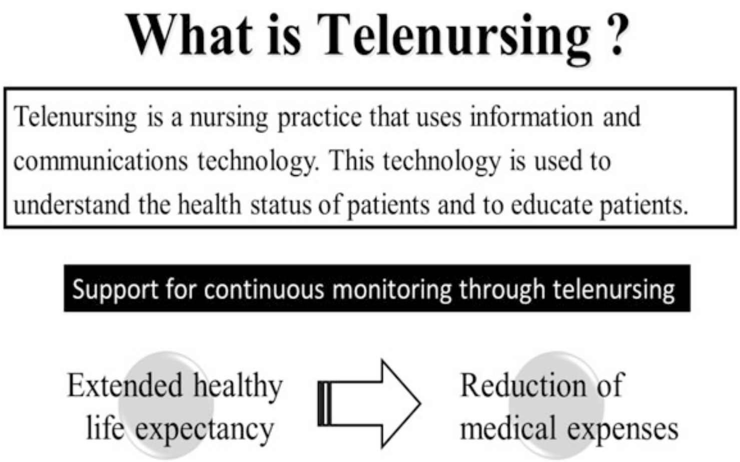

Fig. 1 What is telenursing?

for the American Nurses Association and designated telenursing as a new field that combines nursing science and information science and is a vital nursing practice for the future of medical care (Sharpe, 2001). The authors defined telenursing as shown in Fig. 1. Through the use of information science to manage health and assist in treatment, telenursing is expected to become a major touchstone of future strategic medical policy intended to extend healthy life expectancy and reduce medical expenses.

2 Advances in Information Technology and Japanese Medical Policy

In this section, we briefly outline the history of telemedicine and telenursing in Japan. The Telemedicine Research Group was organized by the Ministry of Health, Labour and Welfare in 1996, and the first Telemedicine Research Conference in Japan was held in March 1997, marking an increase in societal interest in the field.

In December 1997, national and local governing bodies enacted the Long-Term Care Insurance Act responsible for building a community-based, integrated care system. At the same time, a notice from the director of the Health Policy Bureau of the Ministry of Health and Welfare, entitled “Medical Treatment Utilizing Telecommunication Equipment (i.e.) ‘telemedicine,’” ruled that telemedicine did not infringe directly on Article 20 of the Medical Practitioners’ Act (i.e., you may not provide medical examination without face-to-face contact). In addition, the notice stipulated that face-to-face examination would be the general rule and specified the following warnings.

1. Face-to-face examination is mandatory for initial examinations and acute-phase diseases.
2. Telemedicine can be performed only in cases in which the patient's condition is stable (e.g., those with chronic illness).
3. Telemedicine can be performed only in cases in which performing direct, face-to-face examination is difficult (e.g., on isolated islands and in remote areas).

In January 2001, the Cabinet Office established "the Strategic Headquarters for the Advanced Information and Telecommunications Network Society" (abbreviated as IT Strategic Headquarters) and proposed the "e-Japan Strategy," which established an IT environment. The foundation of this strategy was to facilitate reliable information exchange, even in remote areas, through a network and allow patients to receive high-quality medical and care services including response to emergency situations at home. The "e-Japan Strategy II," which was proposed in July 2003, presented seven fields, including medicine, and led efforts to realize a "lively, secure, inspired, and convenient" society.

Goals proposed by this strategy included patient-centered collaboration by medical facilities; health promotion through affordable, secure, and safe medical care; and the provision of telemedical services to remote mountainous areas and isolated islands using IT. The "i-Japan Strategy (Towards Digital Inclusion & Innovation) 2015" was proposed in July 2009. The field of medicine/health was presented as a key pillar of this strategy. Specific goals, including the application of telemedicine technology, maintenance/improvement of physicians' techniques, and realization of community-based medical collaboration, were established to address certain challenges, such as a shortage of community physicians, faced by those in the field of medicine. Proposed plans to realize the implementation of this strategy included the accumulation of data based on the scientific basis for telemedicine, the appropriate use of medical fees, and—for telemedicine technologies that had verified safety/efficacy data—striving for appropriate introduction and expansion of the range of applications.

In February 2013, the "Office of Healthcare Policy" was established by the Cabinet Secretariat, and the "Headquarters for Healthcare Policy" was established in August of the same year. "On the promotion of ICT in the fields of health, medicine, and caregiving" was proposed by the Ministry of Health, Labour and Welfare in March 2014, and the "Health and Medical Strategy Promotion Act" was enacted in May 2014. Accompanying the establishment of the Health and Medical Strategy Promotion Act, the Headquarters for Healthcare Policy adopted a commanding role as headquarters as stipulated in the aforementioned law in June 2014. In the same month, the "Law Pertaining to the Development of Related Laws to Promote Comprehensive Guaranteed Medical Care and Caregiving in the Community" was enacted.

3 Outline of Research on the Implementation of Telenursing

Early research on telenursing in Japan included studies evaluating the outcomes of patients with chronic respiratory failure living at home who received telenursing, assessing nursing triage and telementoring practices through medical interview data from home care patients, investigating the cost-effectiveness of telenursing practices for patients receiving home oxygen therapy (HOT) for chronic obstructive pulmonary disease (Kamei, Yamamoto, Kajii, et al., 2010), verifying the content of and time spent on telenursing for patients receiving HOT living at home (Yamamoto, Kamei, Kajii, et al., 2010), and evaluating nursing techniques through a randomized controlled trial examining the preventive effects of telenursing practice on the acute exacerbation of illness and rehospitalization in home-based monitoring of patients with chronic obstructive pulmonary disease receiving HOT (Kamei, Yamamoto, Kajii, et al., 2013).

Moreover, 2013 saw a randomized comparative study examining telephone-delivered cognitive-behavioral therapy (tCBT) for workers via a remote workplace CBT program (Furukawa & Hayasaka, 2013), a study examining a multimodal, home-based, telephone-delivered care and support system using video calls to patients with diabetes (Kubota, Hosoda, Eguchi, et al., 2013), and research exploring the effects of tCBT on decreased work productivity related to depressive symptoms and the effectiveness of an in-home care system using multifunctional video calls (Nakamura, Koga, & Iseki, 2014). According to a secondary source, research on this topic consisted of several studies before 2014, but the number of studies conducted has since increased (Toyomasu, 2005).

As practical research providing strong evidence continued to expand, accompanied by the country's incremental policy and societal changes related to the development of telecommunication technology, an official notice (10 August 2015, notice from the director of the Health Policy Bureau of the Ministry of Health, Labour and Welfare) was presented in 2015 and proclaimed that it was acceptable to conduct telemedicine in response to patient requests and in combination with appropriate face-to-face examinations. This notification allowed businesses to enter the market to provide full-scale services.

In July 2017, it was ruled that situations in which telemedicine was provided through e-mail or Social Networking Service did not directly violate the Medical Practitioners' Act. In particular, the provision of examination for outpatient smoking cessation through telemedicine alone was permitted on the condition that a physician confirms the performance of regular health examinations/checkups. During the short period from February to March 2018, a review meeting was held to discuss the establishment of guidelines concerning medical care involving the use of telecommunication equipment, resulting in the creation of "Guidelines for the Appropriate Implementation of Online Medical Care."

Japan has a universal health insurance coverage system. Within such system, the calculation criteria for public health insurance are determined by the national fee reimbursement schedule. In the 2018 revision to this schedule, "online medical care" was listed as covered under insurance, meaning that for the first time, online care would be partially covered by public medical insurance if certain conditions were met. In addition, there were limitations on the medical treatment covered by health insurance premiums. Specifically, it covered specific conditions and only treatment provided at emergency medical institutions capable of examination and treatment within approximately 30 min of the occurrence of an emergency.

Accompanying these new stipulations, phone-based reexaminations were reviewed, and fees were calculated under insurance limited to "cases in which necessary instruction was provided when a patient, etc. requested an opinion on treatment." It was ruled that "fees cannot be calculated under insurance for cases carried out with regular medical administration as the goal." Regarding online medical care, care based on a treatment plan and phone-based reexamination were classified as emergency medical care. Because of this and major developments in devices and online information, the "Investigative Commission for the Review of Guidelines for the Appropriate Implementation of Online Medical Care" was established in January 2019.

In the commission's first guideline review, they concluded that, in reality, online medical care was provided through teamwork by D to P and home care nursing during home care visits in home-based medical care settings. Therefore, in addition to establishing a setting for D to P with N (online medical care when the patient is with a nurse), the commission began organizing and reviewing the positions of patients, doctors, and nurses within the guidelines, caution during implementation, and supplementary medical care procedures in which a physician could instruct a nurse.

4 Factors Underlying the Need for Telenursing

In addition to the revision of telemedicine, the information revolution has advanced rapidly, creating a basis for new technological innovation in the realm of information and ICT including cloud, big data, mobile, and Social Networking Service technology. These types of technology were termed the "smart revolution" by the "2012 Telecommunications White Paper." Concerning their effects on society, they have led to a structural transformation in the ICT industry, particularly that of mobile phones. Moreover, the progress of telecommunication technology is accelerating, and remarkable developments in human decision support tools, such as the Internet of Things (IoT) and artificial intelligence (AI), have been achieved. As information evolves, technological innovations that apply this information are expected in the field of medicine, which is steadily becoming more complex.

According to a figure representing the relationship between medical expenses and illness presented by Daniel Kraft, (2011), almost 80% of medical expenses are accounted for by patients with chronic or terminal illnesses who veer beyond the space between health and sickness. The promotion of healthy life expectancy has become important in reducing medical expenses, and bias in medical expenditure and the implementation of personalized medicine through the application of information technology has been proposed as a means via which to achieve this.

The foundation of modern medicine involves the provision of care based on experience, with the goal of universal standardization for all. However, in the future, although standardization (evidence-based practice) will continue to develop, medical care that reflects patients' individuality will also be required. Therefore, it is necessary to ensure that those providing medical care today acquire the ability to predict future care needs through personalized medicine.

5 Telenursing Required for Community-Based, Integrated Care

Figure 2 depicts a future model of community-based integrated care presented by the Ministry of Health, Labour and Welfare (2017). To achieve this, interprofessional information sharing will be vital. Previously, expert opinion was commonly at the forefront of intervention in medicine and caregiving. Consequently, the implementation of a mutual action plan involving two different perspectives: "medical/nursing" shown in the top left and "caregiving/welfare" in the top right of Fig. 2 were the focus, with the "client" often disregarded from start to finish. In other words, conventional medicine at treatment-focused hospitals has progressed as medical care that manages patients. Currently, hospitalization durations are approximately 2 weeks on average; therefore, once the necessary treatment is complete, the patient is discharged and returns to the community when typical nursing care would start. In this situation, hospital nurses perform only duties supporting in-hospital medical care (organizing and communicating observation information), and nursing care, such as lifestyle support or therapeutic care techniques, begins after the patient has

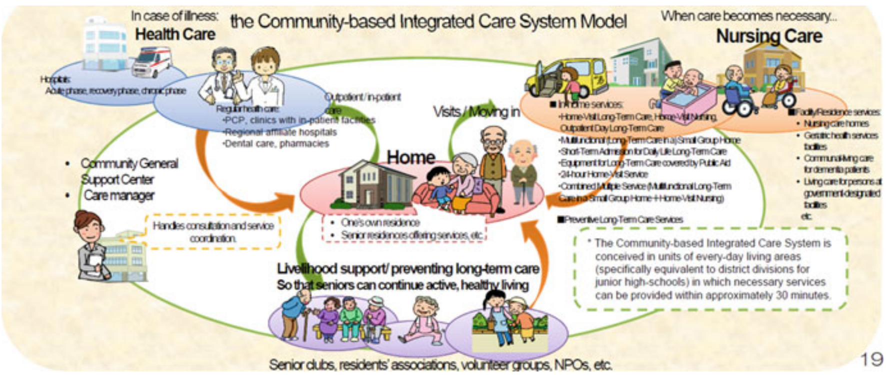

Fig. 2 Establishing the community-based integrated care system. *NPOs* nonprofit organizations, *PCP* primary care physician

returned to the community. Once discharged, patients are out of reach of hospital nurses and begin recuperation with home care/nursing. For community-based medicine in particular, the smooth handover of information from hospital nurses to visiting nurses and other related professionals who take over the responsibility for care is extremely important for the inclusion of "caregiving/welfare" professionals, whose primary duties involve lifestyle support.

In the plan for a community-based integrated care system (Fig. 2), presented by the Ministry of Health, Labour and Welfare (2017), two professions collaborate to provide client-focused care. The present shift from hospital-focused to community-focused medicine indicated that a client-centered approach, which is built upon information sharing between medical/nursing and caregiving/welfare professions, is essential. In community-based recuperation in particular, care does not merely end with the isolated world of the hospital and requires highly personalized observation and nursing support. Given this situation, the application of telecommunication technology is of particular importance in striving to realize a community-based integrated care system. As nurses have become responsible for medical information in hospitals, they are expected to play the role of information coordinators in the community-based integrated care system.

6 The Information Environment Required to Develop a Telenursing System

As shown in Fig. 3, the development of a telenursing system requires four basic functions: "a plan for organizing and managing healthcare information," "sharing and communication of records allowing Interprofessional collaboration," "application of information technology such as AI or robotic process automation to utilize data," and "information literacy in both the professionals managing information and users (clients)." Concerning IoT, the extent to which observation information pertaining to health care can be shared and collected is an important issue for health literacy and the protection of personal information. In the future, all devices used in a client's daily life are expected to be maintained and managed over the Internet; therefore, it will be necessary to use information processing, which accounts for this.

The application of information focused on AI and robotic process automation technology, as shown in the top right section of Fig. 3, is advancing particularly rapidly in the modern day. This field is a vital resource for both the development of health application tools and the realization of personalized medicine. Decisions based on big data, which are essential in predicting health status at an individual level accurately, are also necessary for the realization of personalized medicine.

Considering these issues as prerequisites, rapid research advances, including (1) the development of methods for decision support using AI, including rules engines and machine learning; (2) availability of information (for professionals and clients) through the use of big data; and (3) the development of multilingual,

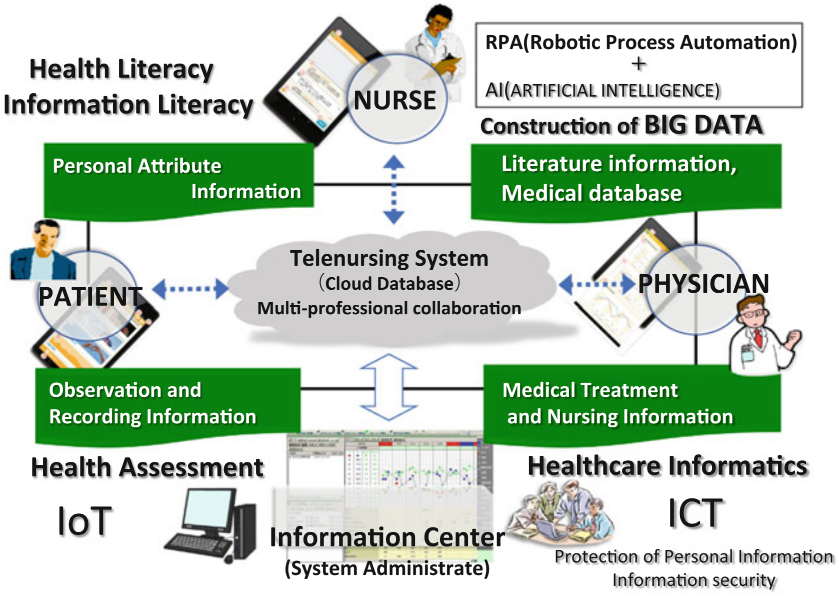

Fig. 3 The information environment required for a telenursing system. *IoT* Internet of Technology

cross-platform software independent of the operating system or hardware will be required for next-generation telenursing. Moreover, the creation of a cloud database from which these data can be managed entirely and working on information security measures are pressing tasks for medical/nursing and related professionals in an age of rapidly advancing information utilization (Kawaguchi, Toyomasu, Imai, 2018).

7 Necessary Elements of and Challenges to the Development of a Telenursing System

The elements required to develop a telenursing system are shown in Fig. 4. Point ① is a user-oriented telenursing application based on the structure of personal health records. In recent years, many information application tools have been developed for smartphones and incorporated into daily life. The functions most necessary for telenursing include information sharing, the structure of medical care, and patients (D to P with N). Concerning information sharing, various systems based on web applications are presently in development for medical use. However, information sharing remains difficult because programs developed for different platforms are used in different ways. In future, it will be essential to develop applications based on a cross-platform structure that is compatible with all platforms. In addition, it will be necessary to develop software that takes ease of use (usability) and use with

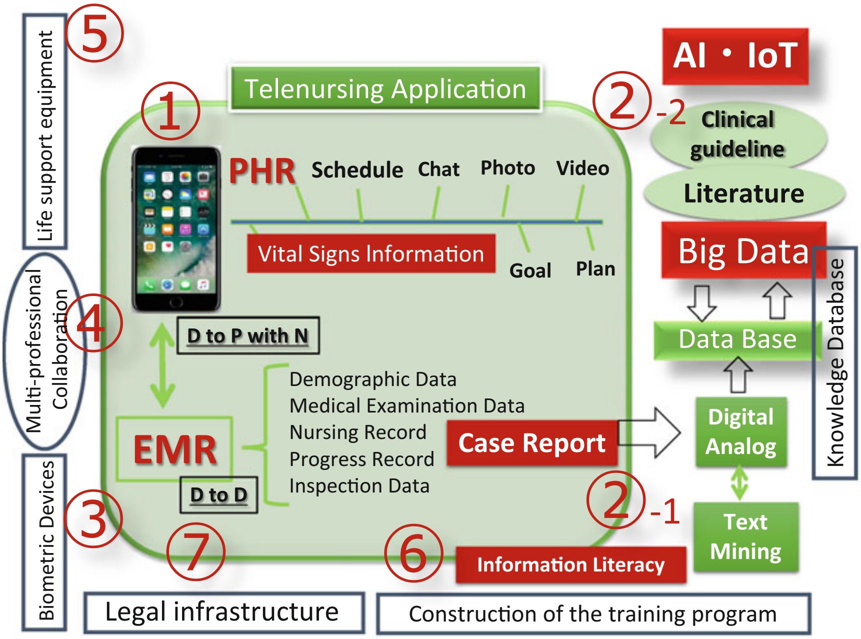

Fig. 4 Elements necessary for telenursing. D = Doctor, N = Nurse, P = Patient

smartphones, which have become a part of the infrastructure of everyday life, into consideration.

Point ② involves the use of databases including AI and IoT. Daily observation data will be accumulated in a database constantly and become a resource for decision-making with future patients. Further, written data sources used as clinical evidence, such as clinical guidelines, in the form of external sources, including numerous research articles and provided through external links, are expected to support decision making by both experts and clients.

Point ③ involves the development of devices that allow remote observation of the body. These devices could contribute considerably to the prediction of risk and support health maintenance through an understanding of day-to-day changes in the body over time. Many studies have examined such devices, but they developed equipment to measure only parts of the body. We remain hopeful that a device will be developed to capture systemic changes and predict health impairments that can be used practically in telenursing.

Points ④ and ⑤ reflect the necessity of information sharing in Interprofessional collaboration. Collaboration with caregiving/welfare professional is particularly important. An advanced electronic medical chart system, which coordinates various medical treatment systems and caregiving service providers rather than individual medical institutions or caregiving facilities, has been proposed, and implementation is underway and aims to provide excellent service that involves central management of health, medical, and caregiving information related to the improvement and maintenance of citizens' health.

Point ⑥ involves the importance of training personnel capable of understanding and handling this type of information system to operate and manage the next generation of telemedicine and telenursing. Moreover, reeducation and a training/licensing system for each profession are necessary. In addition, training in professional skills that will facilitate the use of this type of system will be vital in not only medical education but also basic nursing education to cultivate new expertise for the next generation.

Point ⑦ involves the clarification of legal rules pertaining to these activities. With respect to legislation concerning information security, it will be essential to prepare cybersecurity measures and related legislature, as the system will maintain and manage highly personal information. Further, because the system will require knowledge of information and computer science in addition to medical and nursing science, it will be important to establish certification systems for these fields.

8 Conclusion

In this chapter, we discussed the expected effects of telenursing by introducing research results that should be addressed in the development of a telenursing system. Topics to be addressed in nursing research can be divided mainly into two categories. The first category is "the development of sensing technology capable of observing healthy lifestyle behaviors over time." A multitude of devices and applications are currently being developed, but only partial problem-solving has been possible thus far, and the level of integration necessary for information sharing is yet to be reached. Therefore, initiatives that foster standardization and collaboration between businesses involved in health devices will be necessary. The second category is "the development of an integrated application for the management of health information that is simultaneously useful for day-to-day self-management and allows sharing of health information by hospitals and the community." To achieve this, the development of a multilingual, cross-platform operating system is required. A primary application should be developed to provide a comprehensive link between hospitals and communities.

By addressing the abovementioned challenges, telenursing could extend lifespan through not only the optimization of operations but also interprofessional information sharing and early detection and treatment. Furthermore, telenursing could lead to the reduction in medical expenses while simultaneously providing peace of mind and comfort to people in all situations in hospitals and communities.

Conclusively, this chapter identified necessary elements and challenges of a telenursing system primarily from the viewpoint of translational health information sciences.

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Information Technology/Artificial Intelligence Innovations Needed for Better Quality of Life in Caregiving Homes

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Abstract Among developed countries, Japan has the highest rate of aging, and the population requiring caregiving is increasing annually, along with long-term care service demands. Meanwhile, there are insufficient resources to maintain their long-term care insurance system, and the caregiving industry is facing managerial challenges. Thus, the government proposed a review of the long-term care insurance system and managerial support policies to increase productivity and mitigation of the burden of employees in caregiving homes. Recently, new care approaches utilizing information technology, artificial intelligence, and robot technology for supporting innovation and service in the long-term care facilities have been explored.

Robots are being experimentally introduced in caregiving settings for communication and monitoring older adults, and evidence of the results is being collected. Whether the use of communication robots ultimately improves the users' quality of life is an essential question. Therefore, examining communication robots' effects on older adults is also underway. The introduction of more quantitative and scientific evaluation methods, rather than methods based on an evaluator's experience or subjective opinion, is a challenge of this pursuit.

This research focused on how *mental health care* is provided to older adults with dementia, a population that is increasing annually. We reviewed some studies of the *psychological effects* of communication robots on older adults with dementia. It is best to utilize *noncontact* equipment with older adults with dementia as it causes less psychological and physical stress. In this study, we investigated the effects of a communication robot (Pepper) on the treatment of older adults with dementia and used the Facial Action Coding System to analyze how the older adults felt when communicating with Pepper.

Finally, we will present perspectives concerning the main topic of interest for this chapter: healthcare innovation for providing psychological care to caregiving home residents and daytime care service users through the use of communication robots.

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Keywords Innovation · Caregiving home residents · Daytime care service users · Humanoid communication robot · Emotion analysis · Dementia

1 Introduction: Societal Background and Challenges in Japan's Caregiving for Older Adults

Japan's population is aging at a rapid rate, even among developed countries, and the proportions of the population requiring caregiving and older adults with dementia are growing, leading to the issue of costs related to long-term care. Despite this, an increasing concern is about the shortages of caregivers.

According to the "Annual Report on the Aging Society 2019," Japan's total population as of 2018 was 126.44 million. This includes 35.58 million individuals aged 65 years or older. In other words, 28.1% of the total population consists of older adults (Cabinet Office, 2019, p. 2). The population requiring caregiving has also increased with the number of individuals certified as requiring caregiving (requiring support) roughly tripling over the past 18 years to reach 6.44 million in 2018 (Ministry of Health, Labour and Welfare, Bureau for the Elderly, 2018, p. 4).

The Long-Term Care Insurance Act was enacted in the year 2000. The foundational principle of this act is "support for the independence of older adults." According to the Long-Term Care Insurance Act Chapter I Article 1, individuals who require caregiving "will be provided benefits for necessary healthcare and welfare services to enable the performance of independent activities of daily living in accordance with the possessed abilities" (Ministry of Health, Labour and Welfare, 1997).

The ratio of Japan's social security benefits including benefits for older adults continues to increase, reaching 67.6% in 2015 (National Institute of Population and Social Security Research, 2015). It is anticipated that 2.53 million caregivers will be necessary by 2025, yet a shortage of 377,000 is expected (Ministry of Health, Labour and Welfare, 2015a). Concerning the increasing number of older adults with dementia, in 2015, the Ministry of Health, Labour and Welfare presented the "Comprehensive Strategy to Accelerate Dementia Measures (New Orange Plan)" and has set forth policies such as the "provision of timely and appropriate medical/caregiving in accordance with the condition of dementia" (Ministry of Health, Labour and Welfare, 2015b).

With the enactment of the Long-Term Care Insurance Act, the selection and contracting of care were changed from the conventional contracting method according to a placement system to a free contracting method chosen by the user. However, an environment in which diverse services can be provided based on free competition is yet to be realized in the long-term care market. In fact, there is an "asymmetry of information," and it is not possible for users to obtain advanced and complete information about the quality and content of services when they choose caregiving homes and daytime care services (Ikeda, 2012).

Systemic constraints are further reasons underlying the competition in caregiving industry. The caregiving industry functions based on the long-term care insurance system, and the government is closely involved in it. Caregiving services that operators can provide are predetermined, and their income is dependent on the long-term care fee schedule. In this structure, users receive certification for caregiving and utilize approved services. Each time the long-term care insurance system is improved or the long-term care fee schedule revised, operators need to adapt their practice. They have recently been allowed to provide fully out-of-pocket *non-long-term care services* for users, such as chaperoning travel, in addition to services covered by long-term care insurance. Hence, operators have the right to determine prices, and thus, in these limited areas, competition based on market principles is seen to be possible.

Some caregiving homes have been forced to withdraw from the market due to deterioration of financial conditions and labor shortages. Caregiving includes a variety of tasks and a heavy workload while paying a relatively low wage. As such, the industry has a high rate of turnover and chronic labor shortage. Highly stressful care items for which there is a high demand for improvement from those in the field include transferring (e.g., to a wheelchair), bathing, dementia care, toileting, monitoring, as well as sharing information and maintaining and improving their will to live (Ministry of Health, Labour and Welfare, 2012, p. 37). The most time-consuming caregiving tasks are those concerning sharing information, which have been reported to account for up to 25% of all work hours per employee (Miwa, Watanabe, Fukuhara, & Nishimura, 2014). Accordingly, new efforts aimed at increasing productivity, improving efficiency and the work environment, and resolving labor shortages in caregiving homes are sorely needed.

2 Moving Toward the Use of Information Technology (IT)/ Artificial Intelligence (AI) and the Introduction of Caregiving Robots

The Japanese government has been supporting the introduction of Information and Communication Technologies (ICT), AI, and robot technology to assist innovation in the field of healthcare service (Ministry of Economy, Trade and Industry, Manufacturing Industries Bureau, Office of Robot Policy, 2019). A robot is defined as "an intelligent mechanical system possessing three underlying technologies: sensors, intelligence/control systems, and a drive system" (Ministry of Economy, Trade and Industry, Robot Policy Research Group, 2006, p. 7).

The Ministry of Health, Labour and Welfare and Ministry of Economy, Trade and Industry have indicated "priority areas in the use of robot technology in caregiving" and set forth policies for the active utilization of robots in care. A revision from October 2017 added "communication" as one of the priority areas (Ministry of Economy, Trade and Industry, Manufacturing Industries Bureau, Office of Robot

Policy, 2018). In light of this, development of communication robots as "lifestyle support machinery using robot technology for communication with older adults" and investigation of utilization methods are underway.

Communication robot is "the generic term for a robot used for purposes of or as a means of communication." There are three types: (1) "Status Detection and Response Types" that sense a caregiving home resident's movement in bed, for example, and speak to them to encourage proper movement, (2) "Environment/Operation Responsive Types" that respond to speech or touch from caregiving home residents (CHRs), and (3) "Caregiver Substitute Program Implementing Types" that are used to implement a predecided program during physical exercise or recreation (Ohkawa, 2017, p. 5).

"PARO," developed by the National Institute of Advanced Industrial Science and Technology, is a typical example of a communication robot. According to Sakata (2017), most communication robots are equipped with touch sensors and functions of speech recognition, speech production, facial recognition, and transmission via the internet and are therefore capable of two-way communication. Further, their physical appearances can be broadly classified as either humanoid or animal-like. In addition to verbal communication, some robots are also capable of nonverbal communication through the movement of the hands, feet, body, or eyes. In the care setting, communication robots are expected to be used for psychiatric care concerning the feelings and emotions of older adults (Sakata, 2017). Such robots are also beginning to be used as a user interface for remote viewing and communication.

3 Characteristics of the Caregiving Service Profession and the Importance of Care Oriented to Quality of Life (QOL)

The aim of caregiving is to enhance the QOL. Caregivers provide physical assistance, psychiatric care, and support for social independence to the service recipients. Caregiving homes provide care and support, that is, "service." Service is one "Human activity" provided by humans. Zins (2001) defines service as follows:

> "Human services" is defined here as social services designed to meet human needs that are required for maintaining or promoting the overall quality of life of the prospective populations. (pp. 6–7)

According to Zins (2001), the foundation of a service organization is formed by the relationship between "the provider" and "the recipient" (p. 4). "The needs that the services are designed to meet" (p. 4) are also important. Further, there are "six key elements" common among organizations providing service: "the provider, the recipient, the environment, the organization, the need, and the method" (p. 7). Technology is becoming essential for achieving goals in a service organization. Service providers use "human service technologies" as strategies for fulfilling client needs. Hasenfeld (1983) perceived technology in the following way.

> A human service technology can be defined as a set of institutionalized procedures aimed at changing the physical, psychological, social, or cultural attributes of people in order to transform them from a given status to a new prescribed status. (Hasenfeld, 1983, p. 111)

According to Tao (1995), "The core of technology is formed by the face-to-face interactions between the provider, who distributes the service, and the client, in other words, the recipient. Concrete results are obtained through that interaction" (p. 52). Tao goes on to say that "the targets of technology are humans themselves. Various techniques centered on how to take care of those humans or change them are organized in the form of technology" (p. 52). In the words of Smith (2009, p. 431), this can be interpreted to mean "human services technologies include both what service providers do and how they do it." In short, technology refers to various methods provided in accordance with the status of its targets (clients) and is thought to be concretely captured through an awareness of the problems of "what" to provide and "how" to provide it in real settings.

Caregiving facilities provide "protective care" that is equivalent to Hasenfeld's (1983, p. 143) "people-sustaining" technology. In other words, this corresponds to maintaining the current condition of the service recipient, preventing or delaying deterioration, and assisting with activities of daily living.

Looking at job characteristics, caregiving jobs require collaborations between multiple different occupations (Tao, 1995). "Multi-skilled workers" are a unique characteristic of the business (Sekiguchi, 2015, p. 947) and caregiving home workers (CHWs) act on a foundation of professionalism and volunteerism (Tao, 1995). Concerning care, CHWs have a strongly rooted sense that it "should be done by human hands," as caregiving requires both physical and emotional labor.

Providing "hospitality" (Sekiguchi, 2015, p. 947) and communication are essential in caregiving services. Communication enables older adults to maintain innate human emotional needs, such as the presence of self, a sense of well-being, and a sense of accomplishment (Hamada, Okubo, & Onari, 2006, p. 112). Therefore, *careful listening,* which allows one to build rapport with CHRs, is highly valued. According to Shibata (2017), the sites of damage in the brain differ for each older adult affected by dementia resulting in diverse "core symptoms." Older adults with dementia also have "peripheral symptoms" that arise due to unideal environmental conditions. For example, a bad patient–caregiver relationship can exacerbate these symptoms. Hence, practicing care based on the principles of "person-centered care" and both understanding of and communication with CHRs are essential.

However, the communication aspects of the job can sometimes become a stressor for caregiving home employees (Kanbe, 2015). Communication methods differ depending on the CHWs' skill level and the user's ability. When dealing with older adults with dementia, there are cases in which it is difficult for CHWs to liven things up even during recreation, such as increasing their desire to participate in games. Another issue is that it may be difficult to get older adults with dementia to focus when presenting video content for recreation (Kuwahara, 2015).

Further, amid the complexity of the job and the ongoing labor shortage, upper management demands CHWs to increase their efficiency and productivity.

Consequently, according to CHWs, the quality and amount of communication are decreasing, along with the amount of time spent on recreation. At the same time, recreation and conversations with CHWs are considered vital for increasing the emotional richness of CHRs' lives and working toward an increased desire for social participation and spontaneity. Care duties include a mixture of areas for which it is possible to strive for increased productivity and efficiency, and areas for which this is difficult.

4 The Role of Communication Robots

In the past, Animal-Assisted Therapy (AAT) using real animals has been carried out in medical and caregiving settings. Robots are being used as a tool in place of AAT. In addition to Robot-Assisted Therapy (RAT), the goal of which is treatment, there is also Robot-Assisted Activity (RAA), used for entertainment through games or conversation, and Robot-Assisted Rehabilitation (RAR), used for rehabilitation purposes.

According to Shibata (2017, p. 218), RAT is expected to yield results equivalent to those of AAT and has been shown to have psychological, physiological, and social effects. Commercialization of PARO, a seal-like robot developed by Japan's National Institute of Advanced Industrial Science and Technology, began in Japan in 2005, and there has since been ongoing investigation of its introduction and effects in medical and welfare settings. Since 2009, PARO has been marketed in over 30 countries worldwide and was acknowledged by Guinness World Records as the "World's Most Therapeutic Robot" in 2002. Results of verifying the effects of PARO, the intended users of which are older adults with dementia, confirmed: (1) its ability to "mitigate/control peripheral symptoms such as wandering, violence, or abusive language, and therapeutic effects such as improved/restored conversation ability"; (2) its efficiency in "reducing the burden on caregivers"; and (3) effects of "reduction in the dose of antipsychotic medications" in patients (Shibata, 2017, p. 221).

Meanwhile, Softbank's Humanoid Communication Robot (Pepper) is an example of RAA. Communication with a Humanoid Communication Robot is "psychologically safe" (Sakata, 2019, p. 23) and understood to be simpler and less stressful than communication with another human (Sakamoto & Sakata, 2018). Recently, there has been a trend of utilizing communication robots for physical exercise, recreation, and observation in caregiving homes. Using Pepper to run a recreational application for older adults was found to encourage their participation (Ministry of Health, Labour and Welfare, Bureau for the Elderly, Support for Older Adults Division, 2015, pp. 40–41). According to Kuwahara (2015), incorporating robots into caregiving recreation services will lead to increased QOL in older adults with dementia.

However, cost-effectiveness and insufficient investigation of effective usage methods were problems surrounding the introduction of communication robots. Further, empirical support was necessary due to the need for scientific measurement of effects. Consequently, the Japan Agency for Medical Research and Development conducted an empirical study from a quantitative perspective in 2016.

5 A Theoretical Framework for Realizing Better QOL Through IT/AI Innovations

As seen above, empirical research to reveal effective usage methods for robots and their practical implementation are ongoing. These are examples of innovation in the field of healthcare. It is important to improve healthcare activities while considering how to do so and using which resources with the goals of increasing efficiency and productivity and providing high-quality service in caregiving homes. Figure 1 shows a summary of care initiatives utilizing these kinds of robots from a theoretical perspective.

In caregiving homes, service providers (i.e., CHWs) and service users (i.e., CHRs and daytime users (DUs)) mutually exchange information (Tao, 1995). Consequently, healthcare activities with the goal of increasing QOL are carried out by methods pertinent to the needs of the CHRs/DUs. Healthcare activities are fundamentally those performed by humans and based on specific "technologies." In addition to physical assistance, for example, help with bathing, refers to skills allowing the performance of communication duties, such as conversation with CHRs/DUs. However, these duties have a large physical and psychological burden for CHWs. In situations in which the workload cannot be sufficiently reduced or high-quality service is sufficiently provided with existing technologies, new technologies must be acquired. In these cases, technologies will be introduced by an external organization like a research facility or private corporation in some form, such as IT, big data, AI technology, or robot technology.

Caregiving homes introduce new products developed by external organizations and utilize them in healthcare activities. This corresponds to service innovation. Innovation is a wide concept covering not only the deliverables developed by cutting

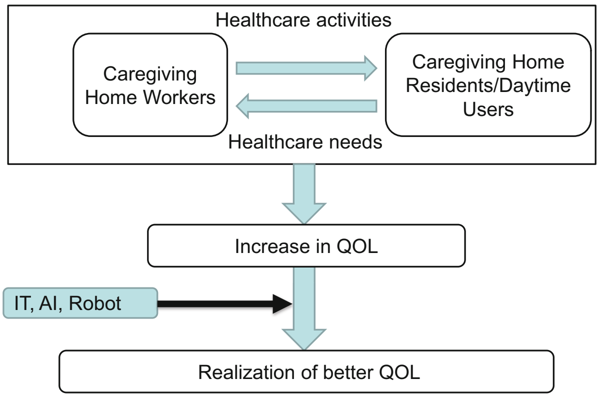

Fig. 1 Information technology (IT) and artificial intelligence (AI) can increase the quality of life of caregiving home residents/daytime users

edge fields of science and technology but also the idea of doing something new. Innovation includes "new 'things' which bring about economic value" (Yonekura & Shimizu, 2015, p. 257), as well as measures for environmental adaptation of an organization (Yonekura & Mckinney, 2005). One should look through a framework of open innovation in order to bring about innovation (Yonekura & Shimizu, 2015). Chesbrough (2006, p. xxiv) stated the following about open innovation:

> Open innovation is a paradigm that assumes that firms can and should use external ideas as well as internal ideas, and internal and external paths to market, as the firms look to advance their technology.

Chesbrough is presenting the perspective that ideas, both internal and external to the business, should be combined to construct a business model and ultimately create value (Chesbrough, 2006). For example, looking at healthcare, caregiving activities that were never seen before can be formulated through the novel utilization of products developed and produced by new technologies, such as AI or robots, in the healthcare service delivery process. This will ultimately lead to providing new value to CHRs/DUs and realization of better QOL. Thus, these initiatives will be referred to as "healthcare innovation."

6 Measuring the Effects of Communication Robots and Problems Therein

One problem concerning the effects of communication robot use is the difficulty of conducting service assessments when there are patients who are older adults with dementia. How are user satisfaction assessments conducted in research on the effects of communication robot use in elderly care facilities? Many studies have used rating scales or descriptive evaluations based on experimenter observation (Kawashima, 2013; Moyle et al., 2017; Obayashi, Kodate, & Masuyama, 2018; Obayashi, Masuyama, Kojima, & Takahashi, 2018; Yokota, Ishiguro, Ohnaka, & Fujita, 2009). Most conduct the evaluation through a written description based on the observer's impressions, but there are others who evaluate using rating scales. For example, Obayashi, Masuyama, et al. (2018) evaluated user's behaviors on a 7-point scale; Hamada et al. (2006) evaluated user's behavior, facial expression, and conversation on a 4-point scale; and Yokoyama, Yamamoto, Kobayashi, and Doi (2010) measured interest using a 4-point scale for whether users wished to continue conversation with the robot. Among behavioral observation analyses, some utilized the observers' descriptive analyses, while others used a method of categorizing and recording user behavior. For example, there are studies demonstrating that introducing a robot led to reduced time spent simply sitting in a chair, increased the frequency of movements such as transferring seats, and increased interaction with the robot (Kagawa, 2012; Watanabe, 2012). In an investigation by Yoneoka (2012), facial expression, behavior, and speech, when responding to a robot, were evaluated on a 5-point scale by an observer. Other research on caregivers involved behavioral observation by video recording and measuring psychological burden through a questionnaire (Obayashi & Masuyama, 2018; Obayashi, Masuyama, et al., 2018). The involvement of the observer's subjective judgment is an issue with methods using observation as the judgment criteria can possibly differ depending on the observer. It is also a problem that the observer's judgments may not match the user's actual level of satisfaction.

Meanwhile, there are also investigations through user self-report with measures of depression such as a scale based on facial expressions or geriatric depression scale (Shibata & Wada, 2011). Although these do have the advantage of directly measuring internal aspects of users, if the survey respondents have dementia, there may be cases in which the reliability of self-reports is questionable.

As for studies using physiological indicators, in an investigation by Iijima, Shibano, Murakami, and Yamaguchi (2010), amylase activity in saliva was used to measure stress. It was found that stress reduced after communication in the form of exercise with a robot. A similar investigation using physiological indicators by Shibata and Wada (2011) utilized measurement of urinary hormone levels. One challenge of studies utilizing physiological methods is the difficulty of measurement in real time. User satisfaction is thought to change over time with physiological changes occurring gradually after the psychological changes and potentially disappearing after a set amount of time has passed.

In light of the above perspectives, there are thought to be advantages to using facial expression analysis tools through noncontact AI as a method for directly measuring CHRs/DU s' psychological states and satisfaction with their lives in real time. Utilizing AI eliminates the influence of an observer's subjective perspective and allows real-time measurement of psychological states from users' own facial expressions.

6.1 Advantages of Facial Expression Analysis Using AI

Previous studies regarding facial expression recognition have typically used still images; however, as facial expressions depend on the movement of the muscles in the face, they must be captured in a fixed time series. For example, it has been reported that not only do the muscles involved differ between spontaneous and intentional facial expressions but the temporal changes when parts of the face move differ as well (Namba, Makihara, Nakao, & Miyatani, 2014; Takahashi, 2002). Using artificial intelligence (AI), which automatically analyzes the movements of parts of the face related to facial expression, can be used to understand facial expression patterns in a time series.

6.2 Facial Action Coding System (FACS) Theory

The AI used to examine the facial expression is developed on the basis of the Facial Action Coding System (FACS). Theoretically, FACS is an analysis tool widely used in research relating to the face, including facial expressions (Ekman & Friesen, 1978). In FACS theory, an action unit (AU) is used as one unit of facial movement. A facial expression is expressed by a combination of several movements on the face, but an AU corresponds to the smallest unit constituting the expression. The parts a face is composed of—the eyebrows, eyelids, cheeks, lips, nose, mouth, chin, etc.—are each further subcategorized and have their specific movements assigned an AU number. For example, the "inner brow raiser" (AU1) and "outer brow raiser" (AU2) have distinct AU numbers, despite being movements for the same general facial feature (the eyebrow), because they account for different parts of it and have different movements. AUs independently do not signify facial expressions; facial expressions are expressed depending on a combination of AUs. For instance, the "cheek raiser (AU6)" and "lip corner puller (AU12)" are the bases of the expression of "happiness" (Kohler et al., 2004) Analyzing facial expressions with FACS requires sufficient proficiency with the FACS theory, and precise analysis is necessary for even slight facial movements. As such, analysis can be a labor-intensive process even with still images. Naturally, analyzing moving images frame by frame is even more difficult.

6.3 Facial Expression Analysis Using Emotion Recognition AI

Having AI perform automatic analysis is useful in facial expression analysis for data like those from videos. CAC Corporation's Kokoro Sensor is an emotion recognition software that uses AFFDEX to perform automatic analysis on facial expressions and moving parts of faces in videos and images (McDuff et al., 2016). AFFDEX is an emotion recognition AI based on FACS theory and developed by a North American company, Affectiva. AFFDEX detects key landmarks on the face to identify facial features and, after extracting a texture model of the skin surface, classifies the surface movements of the face by their AU. These AUs are then used while analyzing the extracted facial model to deduce facial expressions (McDuff et al., 2013, 2016; Senechal, McDuff, & Kaliouby, 2015). AFFDEX creates the output of two types of information from this analysis: the emotion expressed and the facial movements involved. There are seven possible categories of emotions: joy, sadness, anger, surprise, fear, disgust, and disdain. Each of these emotions is given a value of expressiveness from 0 (not expressed at all) to 100 (expressed). Analysis of facial movements takes parts of the face, such as the eyebrows, eyes, nose, mouth, and chin, and further subcategorizes them (e.g., outer part vs. inner part); the output is a value in the range of 0–100, similar to the emotion values. The facial features and movements are described in terms of the algorithm, but they correspond almost exactly to those used in FACS. The facial expression of each emotion mentioned above includes the requisite movements.

7 Examples of IT/AI and Communication Robot Use for Healthcare Innovation

As previously mentioned, the goal of care is to increase QOL. Japan is currently experiencing a rise in the number of older adults with dementia, and mental health care is particularly important for these patients. Accordingly, we will now focus on how to provide mental health care. We will present perspectives on how new technology should be integrated into healthcare activities and ways to advance healthcare innovation. Figure 2 illustrates this perspective. Below, we will also introduce cases of facial expression analysis in older adults with dementia at caregiving homes and their results as examples of the use of communication robots and facial expression analysis software (Ikeda, Kobayakawa, Iseki, & Nakao, 2018).

7.1 An Experiment Using IT/AI and a Communication Robot

In a previous study (Ikeda et al., 2018), 11 users of a caregiving facility located in Tokyo participated in the survey (three men and eight women), with an average age of 83.7 years. They all had dementia.

There were two different conditions: “N condition (No Pepper)”; that is, without the presence of Pepper, and “W condition” (With Pepper.) While the N condition was the normal service condition of the long-term care facility, in the W condition,

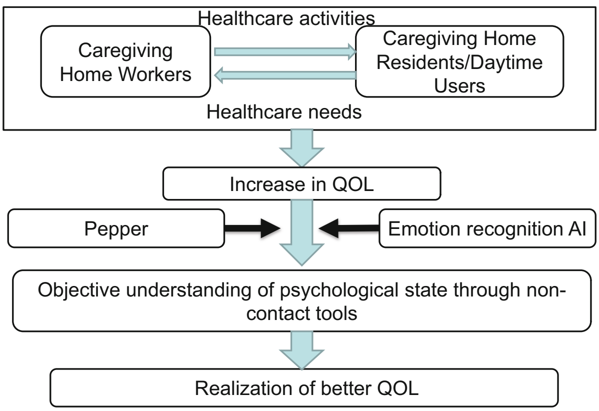

Fig. 2 Technologies and healthcare innovation for better quality of life of caregiving home residents/ daytime users

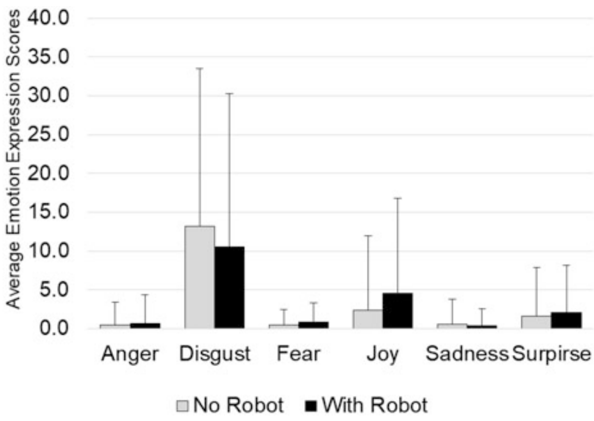

Fig. 3 Evaluation value of each emotion (average of all participants)

Pepper was brought in and reproduced contents of the built-in program, which contains several "brain training games" for elderly people.

Interactions between the Pepper and survey participants were recorded with digital video cameras that were set on a table that the participants regularly used. Recording began when the participant had shortly finished eating a light meal provided by the caregiving facility at around 3:00 p.m. and ended about an hour later. The participant and caregiving staff were not given any special instructions except to avoid touching the camera and to behave as they normally would. Hence, there were intermittent instances in the video where the participant changed seats and her actual time on screen amounted to less than an hour.

The videos recorded with the video camera were analyzed using an emotion analysis software "Kokoro Sensor" developed by CAC Corporation. The software automatically records the result of the captured movement of facial muscles as emotion evaluation values for each frame of the video. The emotion evaluation values were quantified between 0 (not expressed) and 100 (expressed) in terms of joy, sadness, anger, fear, disgust, and surprise.

Figure 3 depicts the results of analysis of the average values of the 11 participants. Overall, the emotions of anger, fear, sadness, and surprise were detected as being very scarce among all participants. Although statistically not significant, the value of disgust was lower, and that of joy was higher in the W condition.

Below is an example of the result of participant A (a 91-year-old woman) with N and W conditions. Figure 4 shows the temporal variation of the value of joy with each condition. While only one peak was observed in the N condition, intermittent peaks were observed in the W condition.

In the N condition, participant A would not smile very often; she would only show an expression of joy when the caregiving staff told her a story about when she wore a Japanese "kimono" wrongly and everyone laughs. Meanwhile, with the W condition, voluntary acts such as "laughing out loud" and "talking" to Pepper were observed many times. For example:

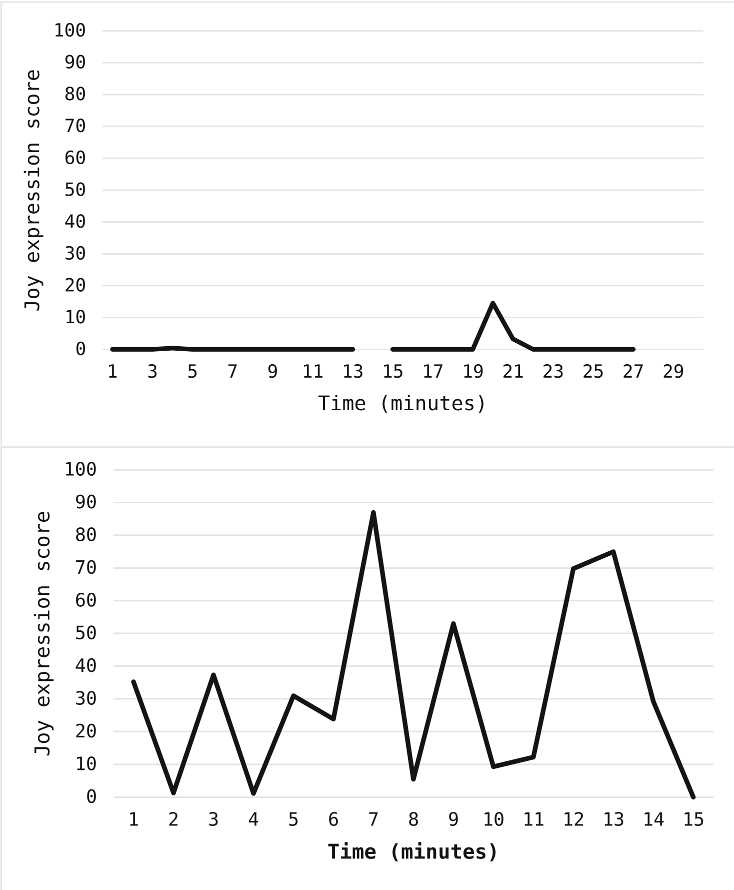

Fig. 4 Temporal variation of joy value (participant A). Upper panel shows the data in the no-robot condition, lower panel with the robot condition. The disconnected part in the line graph indicates missing data due to face recognition error

> When Pepper starts explaining the game, participant A pays attention to it with a smile on her face. However, when Pepper freezes, that expression gradually fades. She responds to Pepper with her hand and smiled (after 3 min). She mumbles "Hello" as a response to Pepper's voice and repeatedly moves her mouth saying, "Pepper" while nodding and laughing. (After 5 min) Pepper asks her, "Are you sleepy?" and she laughs along with the caregiving staff and answers (after 7 min). She replies to Pepper's question, with a smile (after 9 min). In the quiz, all the users around her answer Pepper's questions and laugh together (after 13 min).

Figure 5 indicates the average value of disgust with each condition. While there are two peaks in the W condition, multiple peaks can be seen in the N condition. In the N condition, participant A looks restless and without focus and seems bothered by the garbage and dirt on the table. Disgust was also detected when she listened to the dialogue of the other users, as seen in the example below.

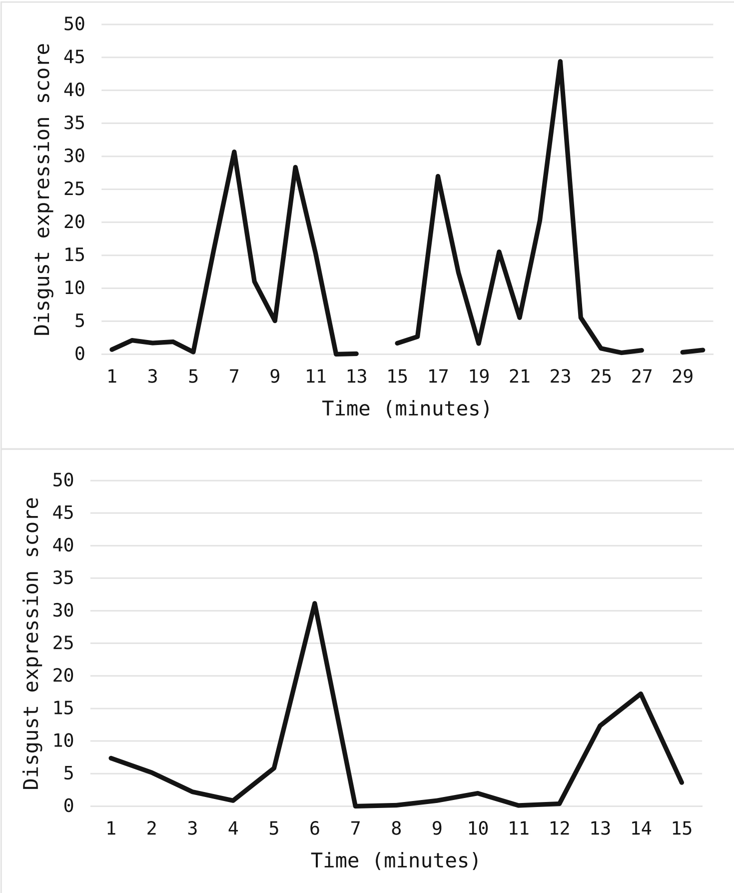

Fig. 5 Temporal variation of disgust value (participant A). Upper panel shows the data in the no-robot condition, lower panel with robots condition

> Participant A is having snacks while listening to pop songs. She looks around for someone to talk to. She then starts making an unpleasant expression. She sees the user beside her requesting something to one of the caregiving staff and asks the staff to respond (after 5 min) She sees that the user beside her has started singing along the music in a hoarse voice (after 7 min). She shows an unpleasant expression when she notices that another user started talking (after 9 min). The same user talks to the caregiving staff with a loud voice again (after 17 min). While listening to the dialogue of other people, she touches the garbage by her hands and tells the caregiving staff to take it away (after 19 min). Finally, she gets annoyed with a speck of dirt in the sheet on the table and tells the caregiving staff to clean it (after 23 min).

On the other hand, in the W condition, she would frequently pay attention to Pepper, without showing disgust to the other users. A specific case is described below.

While organizing the table, she looks uneasy with something in her hands (after 6 min). She hears the voice of the other users between the quizzes and shows an unpleasant expression (after 14 min).

7.2 Effects of IT/AI and Communication Robot Use

Overall, disgust and joy were observed in the participants, with the other emotions being almost undetected. Moreover, in the W condition, the value of disgust was lower and the value of joy was higher than those without the robot, although this was not statistically significant. These findings suggest that the introduction of Pepper evoked positive emotions and reduced the emotions that indicate discomfort.

The value of joy indicated a substantial temporal variation when Pepper was set. Based on the result of the individual case of participant A, the temporal variation in the value of joy is possibly related to the number of peaks of emotions detected. Overall, the temporal change in emotions in this analysis tended to indicate occasional peaks among low values, instead of continuously high values. Considering that the participants were users of a long-term care facility, it is unlikely that they would constantly be expressing their emotions with smiles and unpleasant faces; instead, they presumably maintain neutral expressions that change with the sporadic events around them. Therefore, it is possible that the introduction of Pepper in a long-term care facility, where the users are likely to maintain a neutral expression most of the time, works as an incentive for people to express joyful emotions.

Moreover, the existence of communication robots would encourage users' social communications. Obayashi, Kodate, and Masuyama (2018) introduced a communication robot into a caregiving home and investigated its effects, finding that conversation between older adults and caregivers increased. Hamada et al. (2006) investigated the effectiveness of robot therapy for older adults and reported improvements in their communication, such as in facial expression and conversation. Communication robots may intervene in the conversation and enhance the motivation to communicate with each other.

8 Summary and Conclusions

In this chapter, we discussed the importance of *psychological care* for older adults with dementia in the context of caregiving in Japan as well as the recent trends in the field of healthcare using robot technology. There were challenges in the verification and measurement methods concerning the introduction of communication robots, for example, "what should be used and how? what kind of results can be achieved?" We therefore discussed one study implemented to derive solutions to these issues. Hereafter, it is necessary to continue investigating the status of introducing *things* utilizing IT, AI, or robot technology and to realize new value through healthcare innovation.

Here, we will present perspectives on the focus of this chapter, healthcare innovation for providing psychological care to CHRs/DUs using communication robots, and discuss relationships between the subjects and factors involved. To begin, CHWs are the individuals responsible for care. They are influenced by social and institutional environmental factors. At the same time, they are affected by the organization for which they work and asked to abide by requests to provide high-quality, individualized service to CHRs/DUs and increase productivity and efficiency. Further, they recognize the services needed in the settings in which service is provided through communication with CHRs/DUs.

In order to further advance *psychological care*, in addition to conventional care technologies, it is necessary to consider *what* and *how* to advance in new ways. Accordingly, technologies developed by private companies or research institutions (i.e., IT, AI, and robots) are being incorporated into demonstration experiments and methods of use examined. Facial expression analysis software is being introduced as a new method for scientifically measuring the effects of robot use. Evaluations of communication robot use are being gathered through verbal and nonverbal information from CHRs/DUs in real time. It is necessary to generate information about how to combine humans and *things* in the context of healthcare activities for healthcare innovation in this way through the verification of optimal methods of use for new tools (communication robots) and the accumulation of empirical research by collecting new data and using new analysis tools (Facial expression analysis software). Based on this kind of trial and error in the field, new effective initiatives will lead to the establishment of care methods that can be implemented as routine activities in real settings.

Below, we will discuss this in more depth. An increasing population in need of caregiving and a shortage of labor are environmental factors surrounding caregiving establishments in Japan that lead to magnification of the workload on CHW in the field. Further, an increase in the number of CHRs/DUs with dementia is linked to an increase in individualized care and a larger communication workload.

Evaluation based on economizing due to the demand for increased operational efficiency and productivity is emphasized as an organizational factor for caregiving establishments. This type of evaluation risks inhibiting *hospitality*, the basis of service. Past participant observation performed in caregiving settings captured behaviors toward CHRs/DUs such as *urging them to avoid unnecessary conversation and focus on eating* or *not answering when asked the name of a flower in front of them.* Nonetheless, psychological care for CHRs/DUs is also essential.

Human activities provided by humans form the foundation of care. However, technology is becoming the basis for service-providing organizations (Sandfort, 2009). As previously discussed, technologies can be identified based on "what service providers do" and "how they do it" (Smith, 2009, p. 431). As caregiving service is fundamentally *user-oriented*, it is important that it be guided by *what* is being provided *in what way* while utilizing healthcare technology in accordance with the user's psychological and physical status. Just as "technical skills" (clinical technique and competence as a nurse) and "relational skills" (social skills allowing conversation with others and both accepting and being accepted by others) are important in the field of nursing (Matsushita, 2017, p. 63), the care delivery process in caregiving settings requires the utilization of skills.

This leads to attempts to determine whether *things* using innovative knowledge such as AI, IT, or robot technology can be applied for providing better psychological care to CHRs/DUs. Utilizing *things* that assist humans in the care delivery process is one type of service innovation. Resolving the inconsistency between customization (providing service matching a client's needs) and standardization (increasing the efficiency of service provision) is one challenge in service innovation that may be solvable through the adoption of an open innovation perspective in which clients are involved (Chesbrough, 2011). The sharing of knowledge, including tacit knowledge, between service receivers and providers is necessary if we are to realize service innovation (Chesbrough, 2011). Sharing knowledge is similarly thought to be essential in care settings. In this chapter, these activities are regarded as healthcare innovation, the process of creating new value by combining *things* and human activities with the goal of mental healthcare for CHRs/DUs. Healthcare innovation is achieved when new products or technologies, such as IT, AI, and robots, are introduced from external sources based on the needs and evaluations of CHRs/DUs and used, an appropriate service delivery method is found, and this is shared with CHWs, leading to the creation of value for CHRs/DUs.

As the aim of this chapter was generating value for CHRs/DUs, we did not address perspectives on generating value for CHWs. In this chapter, we presented a case that introduced a method of use for the communication robot Pepper and Facial expression analysis software as an example of healthcare innovation. According to Tao (1995, p. 22), "the subjective assessment of client satisfaction is an important indicator for the evaluation of productivity and efficiency" in service-providing organizations. However, in cases of CHRs/DUs with dementia, communication is often difficult and how CHWs recognize users' psychological state, when they are using services, is a challenge. In this sense, methods for verifying efficiency in the use of communication robots also required a creative solution.

Considering this, it was demonstrated that it would be easier to understand the psychological states of CHRs/DUs with dementia if Facial expression analysis software—a thing resulting from scientific and technological development—could be used to acquire and utilize nonverbal information from facial expressions using noncontact methods. With this, it would be possible to implement individualized care appropriate for older adults with dementia from a comprehensive perspective including both verbal and nonverbal information. There is also a high need for technology that can grasp pathology using facial information in telemedicine (Takahashi, Ito, & Kawaguchi, 2019). It seems that the application of noncontact Facial expression analysis software will become increasingly more important in settings of medicine and caregiving.

Figure 6 presents new perspectives of innovation in the field of health informatics from the above arguments. These involve three processes: (1) translating emotion

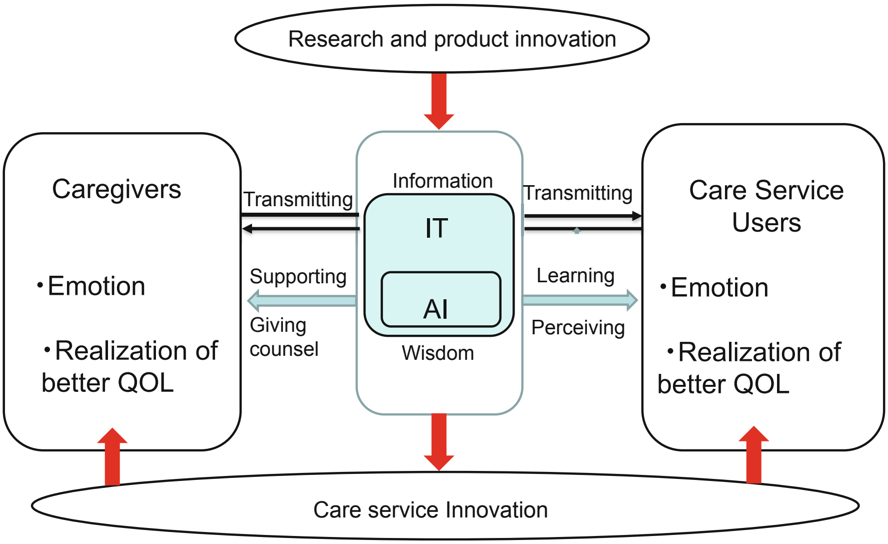

Fig. 6 Translational informatics bridging emotion and QOL

into information, (2) translating information into service innovation, and (3) translating service innovation into increased QOL.

In the past, caregiving involved human care and required CHWs to be able to understand the emotions of CHRs/DUs. With product innovation, robots were invented by combining IT (which involves transmission and processing of information) and AI (which involves discerning, predicting, and executing actions based on obtained information). These technologies can be used to support CHWs. For example, through learning, AI discerns and predicts emotions in CHRs/DUs (emotions that constantly fluctuate, are subconscious to the person themselves, and are difficult to express in words) that CHWs may not fully recognize. It then conveys the needs of the CHRs/DUs to CHWs and suggests a care plan. This allows CHWs to shift from uniform, by-the-book care to care centered on the emotional needs of CHRs/DUs based on suggestions from the AI. It is also possible to utilize service robots equipped with AI in accordance with one's goal. This would reduce the emotional burden (such as anxiety and fear) of CHWs when providing care and allow CHRs/DUs to receive care based on their own emotional needs. Thus, differing from conventional methods, new service providing initiatives utilizing the knowledge obtained from the cooperation of AI and humans can be perceived as care service innovation, which aims to provide better psychological outcomes to CHRs/DUs and CHWs and to ensure a higher QOL.

Finally, to resolve caregiving challenges in Japan as a country with rapid aging, the status of caregiving services, which are advantageous for CHRs/DUs and CHWs, should be explored. Given that CHWs are required to provide services within the economic limits of the management, some CHWs report that they are unable to spare time to provide tailored psychological support to CHRs/DUs in keeping with their needs. However, psychological support for CHRs/DUs is of vital importance and should not be avoided. In reality, providing care that brings about joy in CHRs/DUs is considered one form of remuneration for CHWs who provide devoted care through a high level of expertise and volunteerism. Thus, it is essential to acquire and apply new technologies and to investigate how humans should use *things* as tools in caregiving settings. Further, although this has not reached the stage of investigation, when acquiring and applying new technologies, it will likely be necessary for CHWs, the individuals responsible for service, to play a key role in building relationships with the external businesses or laboratories providing the *things* and the CHRs/DUs receiving the services. For the sake of society as a whole, it will also be important that knowledge gained through an open approach be accumulated, shared, and made usable throughout the caregiving industry in its entirety.

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A New Informatics: Trajectory Patterns in Health Indexes for Japanese Elders and Systemic Change to Life Course Approach

Yu Taniguchi and Hironobu Matsushita

Abstract This chapter discusses intrinsic capacity and functional ability in relation to the framework described in the World Health Organization World Report on Aging and Health. We have investigated health-related trajectories in community-dwelling Japanese older adults. Using data and information from the super-aged society of Japan, the author developed a framework of policy and informatics of healthy ageing that can be applied to ageing societies worldwide. This framework applies to multiple entities, including communities, hospitals, nursing homes, and countries. Translationality is the fundamental basis for the transition away from the existing system.

Keywords Trajectory patterns · Life course approach

1 Introduction

The World Health Organization (WHO) World Report on Aging and Health (World Health Organization, 2015) maintains that putative age-related loss of ability is only loosely related to a person's chronological age. There is no "typical" older person, and the capacities of older adults vary greatly. Some 80-year-olds have physical and mental capacities similar to those of much younger adults, while others experienced substantial declines in capacity much earlier in life. Some 60- and 70-year-olds require help from others to perform basic activities. However, the presence of a

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chronic disease in an older person does not necessarily indicate that he or she is no longer healthy. Many older adults with one or more chronic diseases maintain good functional abilities and report high levels of well-being.

The WHO framework to foster health aging is built around the new concept of functional ability. Intrinsic capacity encompasses physical, emotional, and cognitive capacity as well as vision, balance, and mobility, while functional ability, such as person–environment fit, comprises health-related attributes that enable people to be and do what they have reason to value. This new framework requires that health systems transition from disease-based curative models toward provision of integrated care centered on older adults. It will further require initiation or refinement of comprehensive systems for long-term care. Such a system necessitates a coordinated response from multiple sectors and levels of government and will utilize better ways of measuring and monitoring the health and functioning of older populations.

Besides, care and preventive care are being conducted mainly by older adults. The problems of older adults are considered by different categories based on their functional status, such as community-dwelling older adults, older adults in nursing homes, and hospitalized older adults. Would healthy aging be achieved by such a categorized group based on age and functional limitations? Translationality, in all or part of a society, is needed to systemically change the framework of policy and informatics of healthy aging that can be applied to ageing societies worldwide. This axiom applies to every entity, including communities, hospitals, nursing homes, and countries. Translationality underlies the transition from an existing system to a new system. The present chapter focuses on several health indexes (ie, physical performance, nutritional biomarkers, and cognitive function) that overlap with intrinsic capacity and functional ability, as described in the new WHO concept, and describes health trajectories for aging among community-dwelling older Japanese. This population, which represents the super-aged society of Japan, may be an ideal target for development of health promotion strategies in a global aging society. Using data and information from the super-aged society of Japan, the author developed a framework of policy and informatics of healthy aging that can be applied to aging societies worldwide.

First, I will describe the participants and statistical analysis methods for the studies discussed in this chapter. The participants were from the Kusatsu Longitudinal Study (Shinkai et al., 2016), which recruited residents of Kusatsu town, Gunma Prefecture, Japan. Kusatsu has a population of approximately 7000, and 30% are aged 65 years or older. The main industries are spas and tourism. Under the Health Services for the Elderly Act, passed in 1983, municipal governments in Japan must offer annual preventive health checkups for citizens aged 40 years or older. In conjunction with this service, the Tokyo Metropolitan Institute of Gerontology launched longitudinal studies of aging and health in 2001, in which older participants underwent an additional comprehensive geriatric assessment and a health monitoring survey. All residents aged 65 years or older in Kusatsu town were invited to participate in annual health checkups at the local public health center (Taniguchi, Yoshida, Fujiwara, Motohashi, & Shinkai, 2012) and in health-monitoring surveys by mail or home visit. The Kusatsu Longitudinal Study is ongoing, and the total number of observations in the geriatric assessment is over 10,000. All participants in health checkups provided written informed consent under conditions approved by the Ethics Committee at Tokyo Metropolitan Institute of Gerontology.

The statistical method used in the study series was repeated-measures analysis, such as the group-based semiparametric mixture model analyzed with the SAS macro PROC TRAJ (Jones, Nagin, & Roeder, 2001). This approach uses a multinomial modeling strategy to identify relatively homogeneous clusters of developmental trajectories within a sample population; that is, the modeling strategy allows for the emergence of more than two trajectories. Trajectory parameters are derived by latent class analysis using maximum likelihood estimation. The best-fitting model was determined by comparing the Bayesian Information Criterion values. To assess model fit, posterior probabilities of group membership assignments were calculated for each individual. A high posterior probability of belonging to a single group represents a good fit (Hines, Middendorf, & Aldrich, 2014). In addition, Cox proportional hazards models were used to examine associations of trajectories with adverse health outcomes, such as mortality and incident dementia, while controlling for potential confounders.

The next section will discuss the five health indexes (physical performance, gait function, nutritional biomarkers, cognitive function, and functional capacity) for aging trajectories and trajectories over time among community-dwelling older Japanese.

2 Trajectories of Aging in Physical Performance (Taniguchi et al., 2016)

Physical performance measures for older adults are good predictors of adverse health outcomes, such as disability, hospitalization, cognitive decline and mortality (Taniguchi et al., 2012; Shinkai et al., 2000; Volpato et al., 2011; Rantanen et al., 2003; Cooper et al., 2010). However, no study had used multiple repeated-measures data from a longitudinal study to investigate age-related trends and trajectories of aging in physical performance. This study had two objectives: to identify trajectories of aging and to determine whether potential physical performance trajectories were associated with all-cause mortality after adjustment for important confounders among community-dwelling older Japanese.

The data source for the present study was 1449 adults aged 65 years or older during the period from 2002 through 2010 in the Kusatsu Longitudinal Study. In a sample of the 1449 adults with valid and complete baseline data, 1048 had participated in at least one follow-up assessment by 2011. The average number of follow-up assessments among the 1048 adults was 4.5, and the total number of observations was 4747. Analysis of local registries showed 89 (8.5%) deaths from any cause among the 1048 participants through 2011. The physical performance measures evaluated were handgrip strength (kg) of the dominant hand, as measured with a standard hydraulic handgrip dynamometer and one-leg standing time (s) for the participant's preferred leg until balance was lost (or a maximum of 60 s). At baseline, 57.0% of the participants were women, average (SD) age was 71.6 (5.4) years, and average number of years of education was 9.5 (2.7); 46.4% had no chronic diseases. Average handgrip strength was 25.6 (8.8) kg, and one-leg standing time was 36.5 (23.5) s.

The trajectory patterns of physical performance measures were classified as high, middle, and low (Fig. 1). The posterior probability of allocating each participant into the three groups was 0.84–0.97, indicating a good fit of the model of group trajectories to individual trajectories. Compared to participants in the high trajectory group during follow-up, those in the middle and low trajectory groups for handgrip strength had hazard ratios (HRs) of 2.03 (95% confidence interval [CI], 1.08–3.80) and 2.43 (1.21–4.88), respectively, for all-cause mortality, after controlling for sex, age, and baseline year. For one-leg standing time, the corresponding HRs were 1.66 (0.71–3.86) and 2.46 (1.24–4.91).

This prospective study using repeated measures analysis of data from community-dwelling older Japanese is the first to show that physical performance trajectory patterns and potential physical performance trajectory pattern are independent predictors of all-cause mortality after adjustment for important confounders. Individuals in the low physical performance trajectory groups had a higher mortality risk, which highlights the importance of interventions that maintain or improve physical performance, even among older adults with low physical performance. Moreover, adults younger than 65 years with higher physical performance may have the chance of a high trajectory aging pattern in later life and reduce their all-cause mortality risks.

3 Trajectories of Aging in Gait Function (Taniguchi et al., 2017a)

Among physical performance measures, gait function, for example, gait speed, was reported to be an independent predictor of incident dementia (Verghese, Wang, Lipton, Holtzer, & Xue, 2007; Wang, Larson, Bowen, & van Belle, 2006). In addition to gait speed, step length is a good predictor of future cognitive decline (Taniguchi et al., 2012), and initial gait function is an independent risk factor for dementia and cognitive decline, which suggests that gait speed and step length trajectory patterns, as determined by repeated measures analysis of longitudinal data, might be good predictors of incident dementia. However, no study has investigated these associations. The present study attempted to identify potential gait speed and step length trajectories at usual and maximum paces and determine whether potential gait speed and step length trajectories were associated with incident disabling dementia after adjustment for important confounders among community-dwelling Japanese elders.

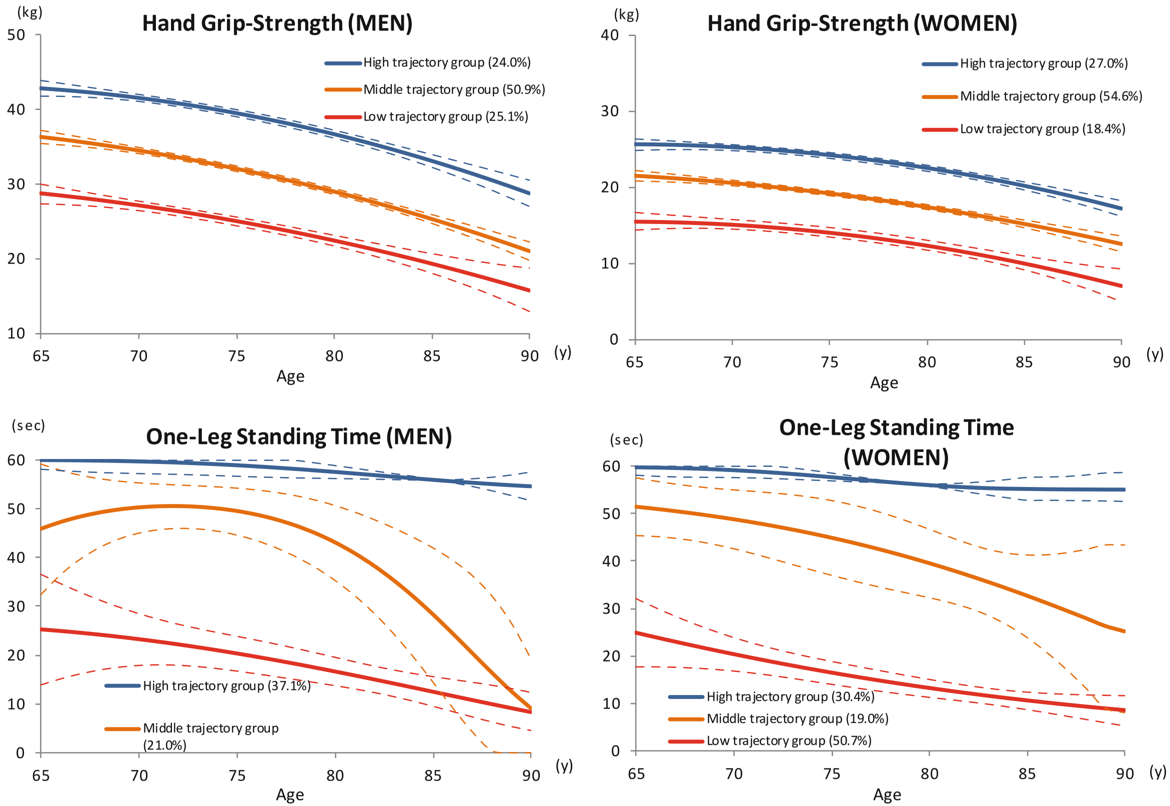

Fig. 1 Trajectories for physical performance measures (grip strength and one-leg standing time). Note: Solid lines are estimated values, and dotted lines are 95% confidence intervals

The data source for this study was 1686 non-demented adults aged 65–90 years who underwent baseline examinations conducted during the period from 2002 through 2014 in the Kusatsu Longitudinal Study. The average number of follow-up assessments was 3.9, and the total number of observations was 6509. There were 196 (11.6%) cases of incident dementia among the 1686 participants during the period through 2014. Gait speed was measured over a straight 5-m walkway on a flat floor. Participants were requested to walk at their usual pace and maximum pace (m/s). Step length (cm) was measured by two staff members. As part of the Japanese Long-Term Care Insurance (LTCI) system, which covers most persons with dementia, the Ministry of Health, Labour and Welfare of Japan requires that a physician provide an observer-based rating for elderly adults with dementia. The categories for the scale are no dementia, some dementia but almost independent in daily life (level I), dementia with some difficulty communicating but with independence in daily living with minimal observation (level II), dementia with some difficulty communicating and a need for partial care (level III), and severe dementia with difficulty communicating and a need for complete care (level IV). In this study, disabling dementia was defined as level II dementia or worse, as this is the level at which applicants are entitled to receive insurance benefits, including institutional, home, respite, and/or day care and loans of equipment. Among men, mean (SD) age was 70.9 (5.2) years, 44.6% had no chronic diseases, and the average number of years of education was 10.5 (2.9) at baseline. Among women, baseline age was 71.4 (5.8) years, 43.3% had no chronic diseases, and average number of years of education was 9.5 (2.5).

Three trajectory patterns—high, middle, and low—were identified for gait speed and step length at usual and maximum paces in men and women (Fig. 2). The average posterior probability of allocating each participant into the three groups was 0.82–0.90, indicating a good fit of the model of group trajectories to individual trajectories. When compared to participants in the high trajectory group during follow-up, those in the middle and low trajectory groups for usual gait speed had HRs of 1.70 (95% CI, 0.96–3.07) and 3.46 (1.88–6.40), respectively, for incident disabling dementia after controlling for important confounders. Participants in the middle and low trajectory groups for usual step length had HRs of 1.00 (0.62–1.60) and 2.12 (1.29–3.49), respectively, for incident disabling dementia, when compared to participants in the high trajectory group. For maximum gait speed, the corresponding HRs were 1.53 (0.78–2.98) and 2.05 (1.02–3.50). Participants in the middle and low trajectory groups for maximum step length had HRs of 1.93 (1.06–3.50) and 2.80 (1.48–5.28), respectively.

This prospective study using repeated measures analysis of data from nondemented community-dwelling older Japanese was the first to show that potential gait speed and step length trajectories are independent predictors of incident disabling dementia, after adjustment for important confounders. Our findings for Japanese elders are consistent with those reported for Western populations (Bohannon & Williams Andrews, 2011) and indicate that gait performance measure trajectories exhibit age-related linear change in later life. There is growing interest in the association between gait performance and degenerative brain lesions. Previous

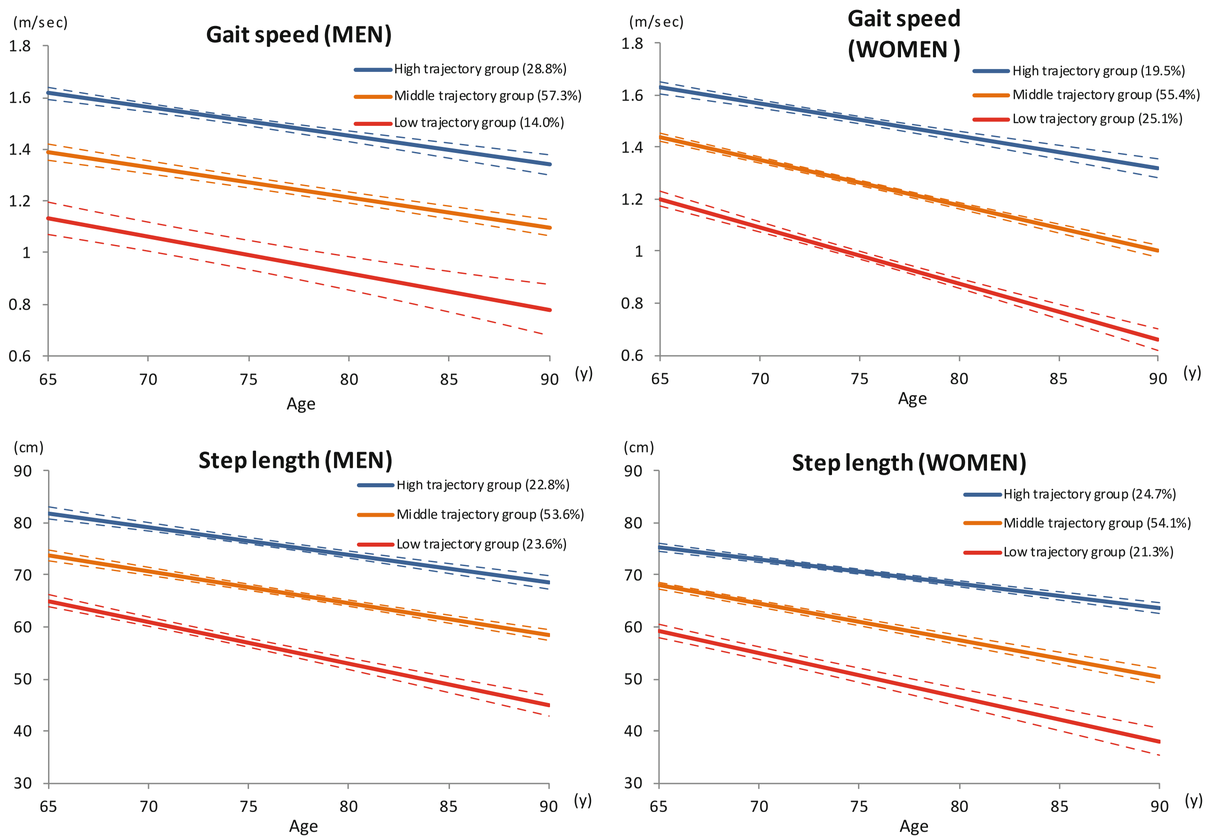

Fig. 2 Trajectories for usual gait speed and step length in men and women. Note: The solid lines are estimated values, and the dotted lines are 95% confidence intervals

studies reported that slower gait speed was associated with lower prefrontal area volume, which is related to slower information processing (Rosano et al., 2012) and lower cerebellar gray matter volume (Nadkarni et al., 2014). Shorter step length was associated with smaller sensorimotor regions (Rosano et al., 2008) and subclinical structural damage of the basal ganglia (Rosano, Brach, Longstreth Jr, & Newman, 2006). Degenerative brain lesions may indeed explain the link between lower trajectories of gait performance and the increased risk of disabling dementia. Individuals in the low gait function trajectory groups had a higher dementia risk that highlights the importance of maintenance for motor function from younger age, in addition to among older adults.

4 Trajectories of Aging in Nutritional Biomarkers (Taniguchi et al., 2019)

Previous studies reported that low albumin levels (Ng, Niti, Feng, Kua, & Yap, 2009; Taniguchi et al., 2014) and low hemoglobin level (Murayama et al., 2017; Shah, Buchman, Wilson, Leurgans, & Bennett, 2011) were associated with cognitive deterioration. Initial serum albumin and hemoglobin levels are independent risk factors for subsequent cognitive deterioration in older adults, which suggests that incident dementia can be strongly predicted by abnormal age-related trajectory patterns in albumin and hemoglobin levels as determined by repeated measures analysis of longitudinal data. However, no longitudinal study had been conducted, and age trajectories of albumin and hemoglobin levels have not been determined. This study attempted to identify potential serum albumin and hemoglobin level trajectories and determine whether these trajectories were associated with incident disabling dementia among community-dwelling older Japanese.

The data source for this study was 2005 adults (average number of follow-up assessments, 4.7; total number of observations, 9330) aged 65 through 90 years during the period from 2002 through 2017 in the Kusatsu Longitudinal Study. There were 278 (13.9%) cases of incident dementia during the follow-up period, and the median (SD) duration of follow-up for incident dementia was 2842 (1647) days. Nutritional biomarkers included albumin (g/dL) and hemoglobin (g/dL). Nonfasting blood samples were collected by standard procedures. In this study, disabling dementia was defined as level II or worse dementia in an observer-based rating for older adults with dementia, as this is the level at which applicants are entitled to receive LTCI benefits, including institutional, home, respite or day care and loans of equipment. At baseline, the mean (SD) age of participants was 71.0 (5.7) years, 57.0% were women, 45.0% were never drinkers, and 56.2% were never smokers. The average number of years of education was 10.3 (2.7), and mean MMSE score was 27.1 (2.8).

Three trajectory patterns for serum albumin and hemoglobin levels were identified (Fig. 3). All three serum albumin and hemoglobin trajectories showed declines

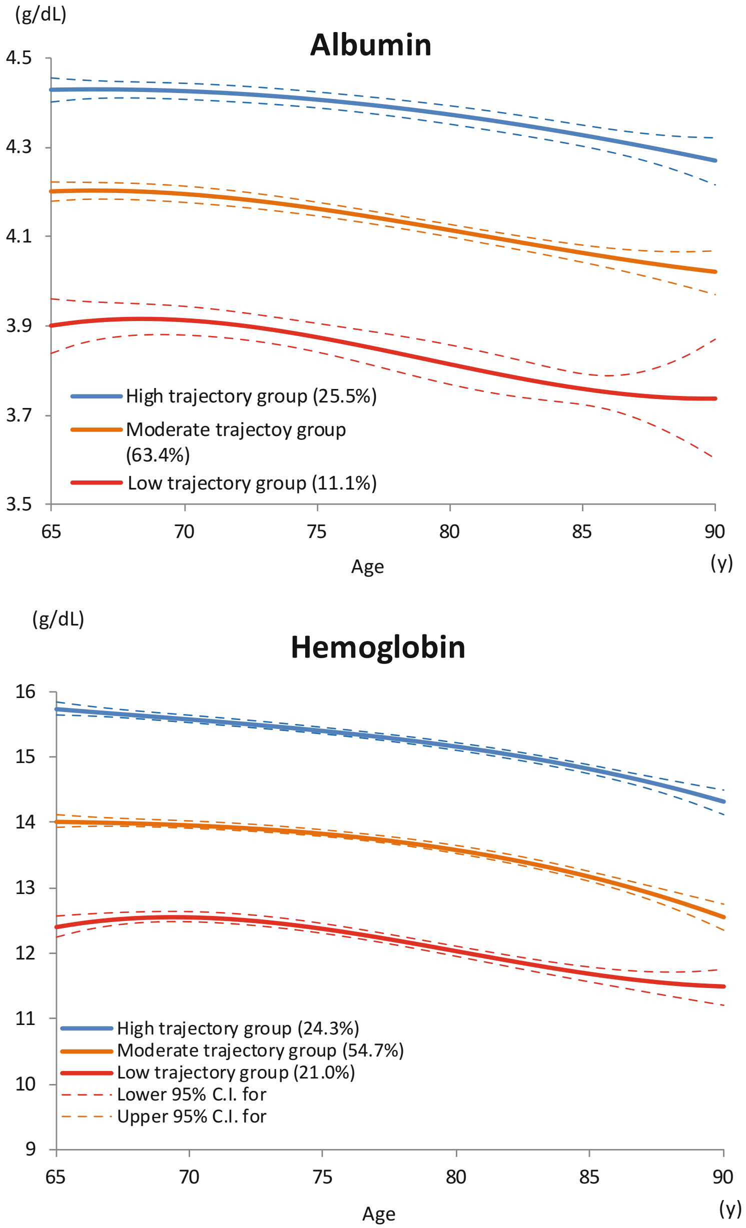

Fig. 3 Trajectories for serum albumin and hemoglobin. Note: The solid lines are estimated values, and the dotted lines are 95% confidence intervals

in values after age 65 years. The average posterior probability of allocating each participant to the three groups was 0.85–0.88 for serum albumin level and 0.88–0.92 for serum hemoglobin level, indicating a good fit of the model of group trajectories to individual trajectories. When compared to participants in the high trajectory group, those in the moderate and low trajectory groups of serum albumin level had HRs of 1.22 (95% CI, 0.92–1.61) and 1.76 (1.21–2.57), respectively, for incident disabling dementia. Participants in the moderate and low trajectory groups for hemoglobin levels had HRs of 1.27 (0.91–1.77) and 1.69 (1.13–2.51), respectively, for incident disabling dementia as compared with those in the high trajectory group.

In this first study to show age trajectories in nutritional biomarkers in a community-based study, three distinct trajectory patterns (high, moderate, and low) for serum albumin and hemoglobin levels were identified among community-dwelling Japanese aged 65–90 years. About 90% of older Japanese (the high and moderate trajectory groups) maintained a serum albumin level higher than 4.0 g/dL in later life. Although 11% of older adults (the low trajectory group) did not reach the cutoff for hypoalbuminemia (Gatta, Verardo, & Bolognesi, 2012), they had a high risk of subsequent LTCI certification and death (Higashiguchi et al., 2008) after age 65 years. With respect to hemoglobin level, about 25% of older Japanese (the high trajectory group) maintained a level higher than 14.3 g/dL in later life, and about half (the moderate trajectory group) had a level higher than 13.0 g/dL until they reached age 87 years. Overall, 21% of older adults (the low trajectory group) had levels consistent with unexplained anemia (10.5–12 g/dL) (Makipour, Kanapuru, & Ershler, 2008) after age 80 years. These findings highlight the importance of interventions that improve nutritional status and management of associated diseases in older adults with low serum albumin and hemoglobin levels. Moreover, it is important to acquire healthy dietary lifestyle from younger age for future dementia prevention.

5 Trajectories of Aging (Taniguchi et al., 2017b) and Trajectories Over Time in Cognitive Function

The MMSE (Folstein, Folstein, & McHugh, 1975) is the most widely used short psychometric test for measuring global cognitive function in epidemiological and clinical studies. No study had used repeated-measures analysis to investigate trajectories of aging in relation to cognitive function. This prospective study of nondemented community-dwelling older adults used repeated measures data from the Kusatsu Longitudinal Study to identify potential MMSE score trajectories of aging among community-dwelling older Japanese and determine whether these MMSE score trajectories were associated with incident disabling dementia, after adjustment for important confounders.

To be eligible for the study, individuals had to be free of dementia at baseline. The data source for the present study was 1724 adults from the Kusatsu Longitudinal

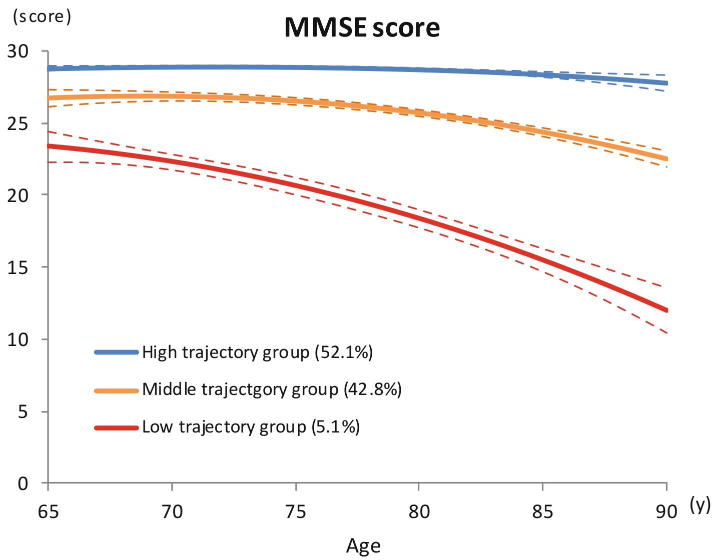

Fig. 4 Trajectories of cognitive function, as assessed by Mini-Mental State Examination Scores. Note: The solid lines are estimated values, and the dotted lines are 95% confidence intervals

Study who were aged 65–90 years and had no dementia during the period from 2002 through 2014. The average number of follow-up assessments among the 1724 adults was 3.9, and the total number of observations was 6755. There were 205 (11.9%) cases of incident disabling dementia among the 1724 participants during the period through 2014. In this study, disabling dementia was defined as LTCI system level II or worse dementia, as this is the level at which applicants are entitled to receive insurance benefits, including institutional, home, respite, and/or day care and loans of equipment. The date of participant application for disabling dementia classification was ascertained by consulting the LTCI system. At baseline, the average (SD) age of study participants without dementia was 71.3 (5.7) years; 56.7% were woman, 43.5% had no chronic diseases and the average number of years of education was 9.9 (2.7).

Three MMSE trajectory patterns were identified as high, middle, and low (Fig. 4). All three groups exhibited MMSE score declines after age 65 years, although the rate of decline varied substantially. The average posterior probability of allocating each participant into one of the three groups was 0.82–0.85, indicating a good fit of the model of group trajectories to individual trajectories. When compared to those in the high-trajectory group, participants in the middle- and low-trajectory groups had HRs of 2.31 (95% CI, 1.68–3.18) and 11.58 (7.57–17.71), respectively, for incident disabling dementia during follow-up.

This prospective study using repeated measures analysis of data from community-dwelling older Japanese was the first to show that potential MMSE score trajectories independently predict incident disabling dementia after adjustment for important confounders, including MMSE score at baseline. Approximately half of participants were classified as having a high MMSE score trajectory—their cognitive function persisted from age 65 to 80 and then slowly declined until age 90. This trend was similar to that for normal aging as reported previously in a 5-year longitudinal study (Jacqmin-Gadda, Fabrigoule, Commenges, & Dartigues, 1997). Cognitive function gradually decreased in the 43% of participants who were classified as having a middle trajectory. Although they remained cognitively intact from age 65 to 75, cognitive function began to decline after age 80 years, and estimated MMSE score was lower than 24 from age 85 to 90 years. Furthermore, the 5% of participants with a low MMSE score trajectory had an estimated MMSE score of 23.4 at age 65 and a more rapid decline until age 90 years. Findings from a previous analysis of cutoff values for incident certified need for care in the LTCI system (Taniguchi et al., 2015) suggested that the present low trajectory pattern is useful for clinical evaluation of elders.

The World Alzheimer Report estimated that the annual global cost of dementia is $818 billion, 85% of which is related to family and social burdens rather than to medical care (Livingston et al., 2017). Declining cognitive trajectories might therefore be associated with increased mortality risk and health-care costs, such as medical and long-term care costs. This prospective study of community-dwelling older adults used repeated-measures data on cognitive function from the Kusatsu Longitudinal Study. The three objectives were to identify trajectories over time in cognitive function among a general population of community-dwelling older Japanese, to determine whether these trajectories were associated with all-cause and cause-specific mortality, and to examine differences in health-care costs (medical and long-term care costs) between trajectories.

To be eligible for the study of a general population of community-dwelling older Japanese, individuals had to be free of disabling dementia at baseline, as assessed by the LTCI system. The data source for the present study was 1736 adults aged 65 years or older from the Kusatsu Longitudinal Study during the period from 2002 through 2014. The average number of follow-up assessments was 3.9, and the total number of observations was 6824 during follow-up. Cognitive function was assessed with the MMSE. The underlying cause of death was coded by using the International Classification of Diseases, Tenth Edition (ICD-10). The relevant ICD-10 codes were I00 to I99 for cardiovascular disease (CVD) and C00 to C97 for cancer; all other codes were classified as "other." Local registries recorded 401 (23.6%) incident deaths among the 1736 participants during the period through 2016. Among the 401 incident deaths, 391 (97.5%) were linked with Japanese national vital statistics (121 CVD deaths, 100 cancer deaths and 170 other deaths). The official medical insurance system includes National Health Insurance and health insurance for older people, and these insurance systems cover almost all medical treatment and medical provider fees. Payments from insured persons to medical providers are made on a fee-for-service basis, in which the price of each service is determined by a uniform national fee schedule. The Japanese LTCI system provides long-term care services, community-based services, and in-facility services. All primary insured persons aged 65 years or older are candidates for care. When insured

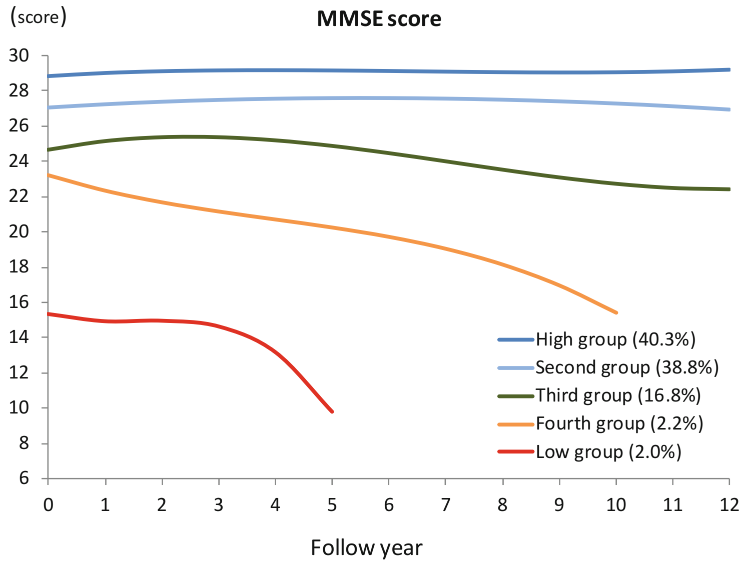

Fig. 5 Trajectories for cognitive function over time, as assessed by Mini-Mental State Examination Score. Note: The solid lines are estimated values

persons need to use LTCI, they submit a request to the municipal government for their primary physicians to assess and evaluate their physical and mental status. Using these results, a local Long-Term Care Needs Certification Board determines eligibility and the care level needed for insured residents. Care services using allotted benefits are coordinated by a care manager, in collaboration with the insured person and their family. Using insurance claims data from the National Health Insurance system, health insurance for older people and data on LTCI beneficiaries, I calculated monthly medical costs and the combined monthly medical and long-term care costs. Costs are expressed in US dollars (1 US dollar = 111.02 Japanese yen). Data from the baseline survey showed that the mean (SD) age of participants was 71.5 (5.9) years and that 56.6% were women. The average number of years of education was 10.0 (2.7).

I identified five trajectory patterns in cognitive function: 40.3% of participants were in the high trajectory group, 38.8% were in the second group, 16.8% were in the third group, 2.2% were in the fourth group, and 2.0% were in the low trajectory group (Fig. 5). The two higher trajectory groups (the high and second groups) had consistently higher scores during the entire follow-up period. Mean MMSE scores in the third group remained relatively constant during the first few years, gradually decreased after 3 years, and were lower than 23 points within 10 years. The two lower trajectory groups (the fourth and low trajectory groups) had an MMSE score lower than 23 points at baseline and exhibited gradual declines during the follow-up period. The average posterior probability of allocating each participant into the five groups was 0.65–0.95, indicating a good fit of the model of group trajectories to

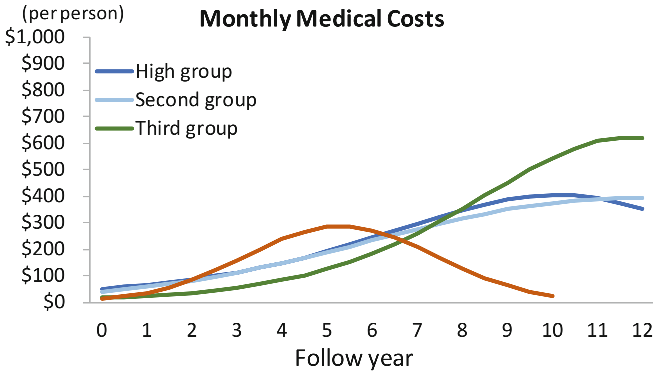

Fig. 6 Cognitive function trajectory—specific trends in monthly medical costs. Note: In the group-stratified Poisson generalized estimating equation models for changes in medical costs, the two smallest groups (the fourth and low trajectory groups) are combined. The solid lines are estimated values

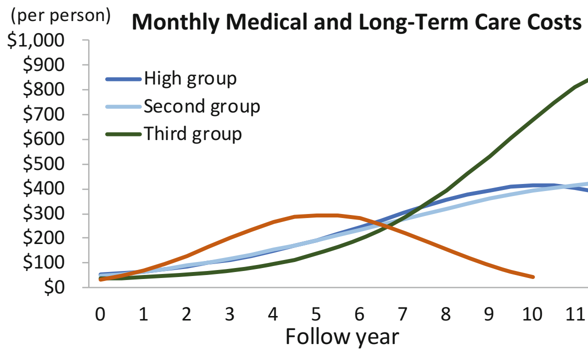

Fig. 7 Cognitive function trajectory—specific trends in monthly medical and long-term care costs. Note: In the group-stratified Poisson generalized estimating equation models for changes in health care costs, the two smallest groups (the fourth and low trajectory groups) are combined. The solid lines are estimated values

individual trajectories. When compared to the high-trajectory group, the second, third, fourth, and low-trajectory groups had HRs (95% CI) of 1.31 (0.99–1.74), 1.38 (0.99–1.92), 1.10 (0.55–2.20), and 2.01 (1.04–3.88), respectively, for all-cause mortality, after adjustment for several covariates. For cause-specific death, the low-trajectory group had a significantly higher HR for CVD mortality. The HRs for other cause mortality (non-CVD death and noncancer death) were significantly higher for the second and third trajectory groups than that for the high-trajectory group.

Generalized estimating equation models showed trajectory-specific changes in monthly medical costs and combined medical and long-term care costs (Figs. 6 and 7). Mean monthly medical costs in the fourth and low-trajectory groups were higher than that in the three higher trajectory groups until 5 years of follow-up but decreased linearly thereafter. In contrast, the three higher trajectory groups exhibited increases in monthly medical costs after the baseline survey; in particular, the third trajectory group had a dramatic increase during the second half of follow-up, and mean monthly medical costs were estimated at $619.6 after 12 years of follow-up. Combined monthly medical and long-term care costs were slightly higher than monthly medical costs alone. Interestingly, mean costs were highest in the third trajectory group, which had the highest monthly medical and long-term care costs after 8 years of follow-up (the combined costs were estimated at $884.8 after 12 years of follow-up).

In this 12-year longitudinal study of 1736 older adults, approximately 80% were classified in the two higher trajectory groups, and they retained higher cognitive function during the entire follow-up period. The cognitive function of the 16.8% of participants in the third trajectory group remained relatively constant for the first few years, gradually decreased after 3 years, and was consistent with dementia within 10 years of follow-up. Both the fourth trajectory (2.2%) and the low trajectory (2.0%) groups had cognitive impairment at baseline and would likely have developed severe dementia had follow-up been longer. Thus, the lower cognitive trajectory might be associated with increased health-care costs. In fact, although the mean monthly medical and long-term care costs were higher in the two lower trajectory groups during the first 5 years of follow-up, they decreased linearly thereafter. The period of decreasing health-care costs in these two groups after 5 years of follow-up overlapped the period when their MMSE scores were below 20. The present third trajectory group had the highest monthly medical and long-term care costs after 8 years of follow-up. Attempts to prevent dementia and reduce social security costs for persons at high risk of dementia should target people with gradual cognitive decline, especially those with an MMSE score lower than 23 points. These findings demonstrated that individuals in the lower cognitive function trajectory groups had higher dementia and mortality risks and their health-care costs were obviously high in later life, which highlights importance of interventions that maintain or improve cognitive function, even among older adults with low cognitive function.

6 Trajectories of Aging in Functional Capacity (Taniguchi et al., 2018a)

The WHO Scientific Group on the Epidemiology of Ageing proposed that autonomy or independence in functioning be used as a health index for elderly adults (World Health Organization, 1984). Functional capacity has been recognized as a hierarchical framework, and Lawton (Lawton, 1972) defined and systemized seven intercorrelated "sublevels" of competence—life maintenance, functional health, perception and cognition, physical self-maintenance, instrumental self-maintenance, effectance, and social role (Fig. 8).

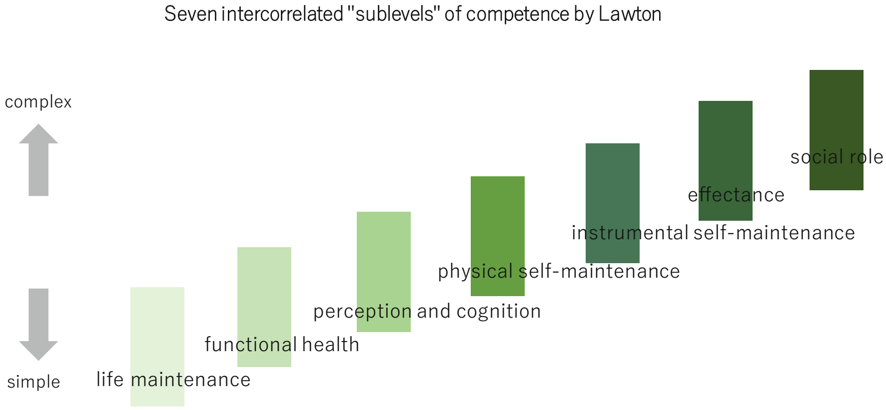

Fig. 8 Functional capacity framework (modification of Lawton's Model)

The Tokyo Metropolitan Institute of Gerontology—Index of Competence (TMIG-IC) (Koyano, Shibata, Nakazato, Haga, & Suyama, 1991) was developed and validated to measure the last three sublevels (instrumental self-maintenance, effectance and social role) of Lawton's model and has been used to assess higher level functional capacity. No study had used multiple repeated measures data from a longitudinal study to investigate aging trajectories in higher level functional capacity. A previous study examined functional state at age 70 years and linked cumulative health-care expenditures by using the Medicare Current Beneficiary Survey from age 70 years until death (Lubitz, Cai, Kramarow, & Lentzner, 2003). Previous findings suggest that elders in the lower aging trajectory of higher level functional capacity have higher all-cause and cause-specific mortality risks and greater medical and/or long-term care costs than do those with normal aging-related declines. This prospective study of community-dwelling older adults used repeated measures TMIG-IC data from the Kusatsu Longitudinal Study. The three objectives of this study were to identify aging trajectories in higher level functional capacity of community-dwelling older Japanese, to determine whether these trajectories were associated with all-cause and cause-specific mortality, and to examine differences in medical and long-term care costs between aging trajectories of higher level functional capacity.

The data source was 2675 adults aged 65–90 years who completed surveys during the period from 2001 through 2011. Primary data were from health monitoring surveys in 2001, 2003, 2005, 2007, 2009, and 2011. Secondary data were from biennial geriatric assessments during 2002 through 2010. The average number of follow-up assessments was 4.0, and the total number of observations was 10,609 during the follow-up period. The TMIG-IC is designed to measure higher level functional capacity in community-dwelling older adults and includes a

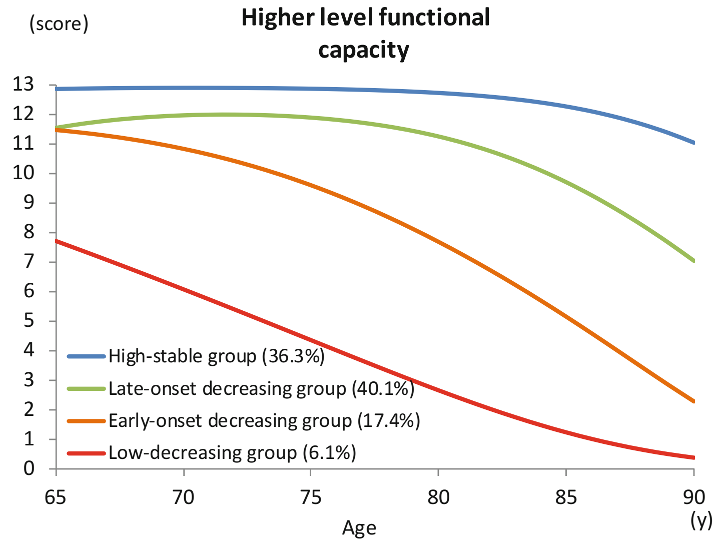

Fig. 9 Trajectories of higher level functional capacity. Note: The solid lines are estimated values

multidimensional 13-item index of competence. The score ranges from 0 to 13, and lower scores indicate lower functional capacity. Deaths from any cause were linked with Japanese national vital statistics during the period through 2015. The underlying cause of death was coded by using ICD-10 codes, and the relevant ICD-10 codes were I00 to I99 for CVD and C00–C97 for cancer. Using data from beneficiaries of National Health Insurance, health insurance for older people, and LTCI, I calculated monthly medical costs, monthly long-term care costs, and the sum of these costs as total cost for each participant for the period 1 year before the follow-up survey from 2001 through 2011. To exclude dramatic increases in medical and care expenditure, monthly medical and long-term care costs were calculated for the period 1 year before the follow-up survey. However, for participants who died within 1 year of survey completion, costs were calculated for the 1-year interval from 2 years to 1 year before the date of death. Costs are expressed in US dollars (1 US dollar = 112 Japanese yen on February 8, 2017). Data from the baseline survey showed that the mean (SD) age of participants was 72.0 (6.2) years; 56.8% were women, 83.7% were able to go out by themselves and 9.3% were independent in their home or neighbourhood but could not travel far by themselves.

Four TMIG-IC trajectory patterns were identified: 36.3% of participants were in the high-stable trajectory, 40.1% were in the late-onset decreasing trajectory, 17.4% were in the early-onset decreasing trajectory, and 6.1% were in the low-decreasing trajectory (Fig. 9). The average posterior probability of allocating each participant into the four groups was 0.73–0.87, indicating a good fit of the model of group

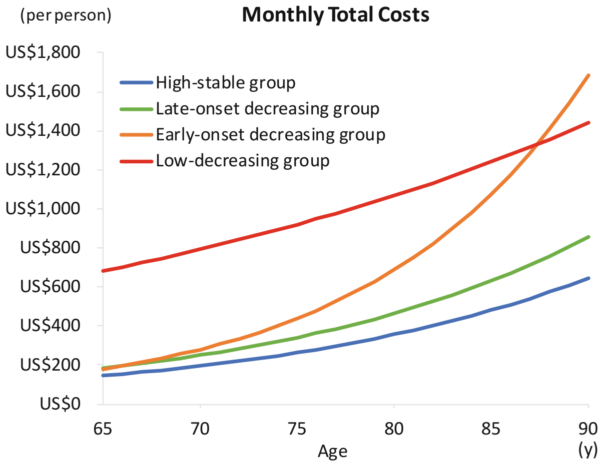

Fig. 10 Higher level functional capacity trajectory—specific age trends in monthly total costs (medical and long-term care costs). Note: The generalized estimating equation models for trajectory group-specific age trends in medical and long-term care costs. The solid lines are estimated values

trajectories to individual trajectories. There were 747 (27.9%) incident deaths among the 2675 participants. The median duration of follow-up for incident death was 2915 days. As compared with the high-stable TMIG-IC trajectory group, the late-onset decreasing, early-onset decreasing, and low-decreasing trajectory groups had HRs (95% CI) for all-cause mortality of 1.29 (1.07–1.56), 2.33 (1.90–2.84), and 4.67 (3.65–5.99), respectively. The analysis of cause-specific death, CVD mortality, and other mortality showed significant associations between the four TMIG-IC trajectory patterns.

Generalized estimating equation models showed significant TMIG-IC trajectory-specific age trends in monthly medical and long-term care costs (Fig. 10). The sum of mean monthly medical and long-term care costs for the low-decreasing trajectory group was estimated at $683.0, which was approximately four times the values for the high-stable ($145.3), late-onset decreasing ($184.2), and early-onset decreasing ($178.9) group at age 65. The sum of medical and long-term care costs increased after age 65 years in the four TMIG-IC trajectory groups. In particular, the early-onset decreasing trajectory group exhibited a dramatic increase after age 75 years, and the estimated costs exceeded those of the low-decreasing trajectory group until age 87 years. Mean total costs later in life were lower for participants with a high-stable and late-onset decreasing TMIG-IC trajectories. This prospective study is the first to show aging trajectories in higher level functional capacity among community-dwelling older Japanese. The trajectory of higher level functional capacity was an independent predictor of all-cause, cardiovascular, and noncancer mortality, and elders with a low-decreasing aging trajectory had higher monthly medical and long-term care costs in later life. These findings highlight the importance of interventions that improve functional capacity in older adults with gradual decline in later life, in addition to low functional level, and focused on the necessity to acquire health literacy from younger age to reduce social burden related to medical and care.

7 Discussion

In this chapter, age trajectories in five health indexes—physical performance, gait function, nutritional biomarkers, cognitive function, and functional capacity—showed that functional changes during old age could be well predicted at age 65 years. Because of their higher reserve capacity, older adults with higher functioning at age 65 maintained this higher level until later in life. They had lower risks of death and disabling dementia and lower medical and long-term care costs.

These findings suggest that, to improve the trajectory of aging, a life course approach that includes younger than 65 years should be combined with traditional concepts such as early detection and early intervention for older adults with lower function. If middle-aged acquire health literacy and healthy lifestyles, the chance of a high trajectory aging pattern in later life might be increased. To acquire such health literacy until middle age may require less resources and effort than receiving intervention in older age. Indeed, young adulthood or middle age might be the inflection point that determines subsequent trajectories. Thus, framework of policy and informatics of healthy aging should be focused that improve the trajectory of ageing at the optimal time between young adulthood and middle age (Fig. 11). A new informatics of healthy ageing might increase longevity and health life expectancy and reduce social security expenses. As such, public health policy at large, and health promotion policy in particular, should pay attention on data sets and discussions provided by this chapter. A new informatics of healthy aging, as discussed above, should be clearly positioned in addressing translational health systems.

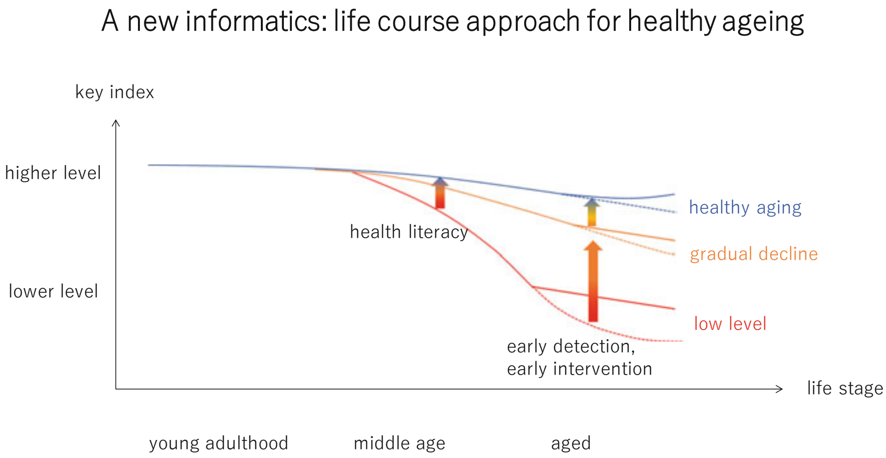

Fig. 11 Conceptual diagram for healthy aging for life course approach with key index. Note: The optimal time between young adulthood and middle age might determine subsequent trajectory in life

This chapter discussed intrinsic capacity and functional ability in relation to the new concept described in the World Report on Aging and Health by using trajectories of five health indexes; however, other health indexes warrant consideration in future studies. Vascular condition (Taniguchi et al., 2018b), which is associated with physical performance, nutritional biomarkers, and certain diseases are important health indexes in later life. Moreover, body mass index may be useful for evaluating a person's health from early childhood to old age. Identifying key indexes during the course of life is clearly an important research concern. Furthermore, the crucial topic of how life stage and level of function, as assessed by a key index, are related to intrinsic capacity and functional ability in later life should be studied in greater detail.

8 Conclusion

Based on the empirical data sets, this chapter discussed trajectories of aging in five health indexes among community-dwelling older Japanese. Because older adults with higher function at age 65 maintain high function until late in life, healthy aging interventions using a life course approach should target adults younger than 65 years. A new informatics for healthy ageing is needed in order to develop a framework of policy that improves trajectory of ageing patterns at optimal time points between young adulthood and middle age. Public health policy, and health promotion policy in particular, should pay attention on data sets and discussions provided by this chapter. A new informatics of healthy aging, as discussed earlier, should be effectively utilized in addressing translational health systems focusing on healthy aging.

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Real-World Data-Based Care Innovation: Lessons Learned from Nursing Science

Gojiro Nakagami, Shinichiroh Yokota, and Hiromi Sanada

Abstract The use of real-world data for clinical applications is rapidly progressing. However, in nursing, the creation of next-generation care based on real-world data has just begun. In this chapter, we introduce various technologies that nursing researchers have developed by working on real-world data analysis in collaboration with researchers in different fields and discuss the next generation of nursing research.

Keywords Artificial intelligence · Bioengineering nursing · Falls · Pressure ulcers

1 Introduction

With the extension of life expectancy, more and more elderly people will live independently. Major changes in human lifestyle, as well as medical and nursing environments, are occurring, along with the emergence of an aging society with fewer children. These changes are causing a global paradigm shift from medical services aimed at curing diseases to those supporting individuals. Such supportive medical or nursing services prioritize assistance in the daily lives of people with various levels of disability, which emphasizes a comprehensive understanding of the individual from a holistic point of view. Furthermore, in the era of Society 5.0 in which the cyber and physical fields are highly integrated, next-generation care is needed where people and advanced technologies coexist and support every

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individual's way of life so that we can create a society where people can pursue their happiness until the end of their lives. To realize this situation, the integration of nursing science and other disciplines is the key.

Evidence-based medicine/nursing and evidence-based practice have been attracting attention for a long time, but most of the evidence in medicine so far has been based on data collected for research purposes. The data collected in this way is "artificial" in a sense and does not necessarily reflect the real-world situation. As a result, an evidence-practice gap has arisen in which the data obtained from research cannot be directly applied to a clinical setting or the research results cannot be used for medical services. Furthermore, in many cases, randomized controlled trials that can most accurately estimate the effects of interventions cannot be performed due to ethical or cost issues, making it difficult to accumulate evidence. Therefore, in recent years, with the progress of information technology and the standardization of medical information, the utilization of electronic health/medical records (EHR/EMR) in the medical field has attracted attention. The EHR/EMR contains the patient's medical records stored in electronic medical record databases, such as prescription orders, injection orders, laboratory test orders, medical records compiled by doctors, nurses, and other medical staff, and so forth, and information is accumulated daily. That is, real-world data is updated daily. In addition, daily clinical work gathers raw data that is hardly available in research. By analyzing this, it is possible to create evidence based on actual data rather than data obtained in an artificial environment. In the field of medicine, various research studies are underway, including automatic discharge summary generation, the development of rare adverse event detection algorithms, the prediction of disease prognoses by machine learning, and the early detection of diseases using artificial intelligence. However, in the field of nursing, we find that real-world data analysis is not fully incorporated. Although research using medical fee data and data from various sensing devices and nursing calls is becoming widespread in the field of nursing, the utilization of electronic medical record data collected and entered by nurses themselves has not been sufficiently advanced.

In this chapter, by introducing "Bioengineering Nursing," which systemizes the process by which nursing fuses with various disciplines to create new care products, and showing how care can be transformed using real-world data, we describe how nursing science can contribute not only to Translational Systems Science (Sanada, Mori, & Nakagami, 2014), but also innovation in health informatics.

2 Bioengineering Nursing: A New Frontier of Nursing Science to Create Next-Generation Care

Nursing has achieved great results by using social science research methodologies to extract and identify health problems as a group. However, there was a situation in which technical development to solve problems was delayed. On the other hand,

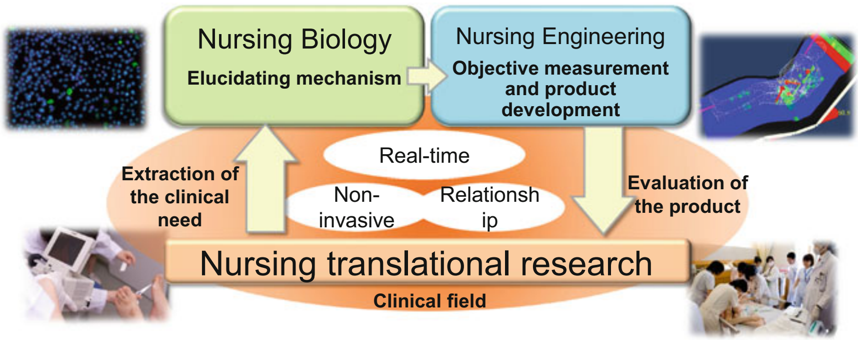

Fig. 1 Bioengineering nursing framework

looking widely at other disciplines, with the development of science and technology, research methods in various fields of life and natural sciences such as molecular biology, genetic engineering, and information science have rapidly developed. These technologies have been applied as effective research tools in various academic fields and have directly and indirectly contributed to the development and improvement of medical care. The authors focused on the current state of application of these technologies in nursing science. However, the elucidation of the pathological conditions caused by human life targeted by nursing science and the mechanism of indirect symptoms and signs caused by disease were not dealt with in other disciplines. As a result, the development of technologies and equipment required for nursing has been delayed, and patients have been inconvenienced. Therefore, we believe that the enhancement of basic research in nursing science will lead to the development of academic fields and the improvement of science, and we are working on the creation of an academic system in collaboration with multidisciplinary researchers.

Figure 1 shows the concept of bioengineering nursing based on the translational flow of related information and knowledge. This figure begins with a detailed depiction of the various clinical questions and problems that nurses encounter. What nursing focuses on most importantly and is good at is understanding the phenomena that occur in the clinical setting. It is clear that any state-of-the-art technology will not produce any benefit if its target is incorrectly identified. Research methodologies to clarify clinical questions are already being established in the research area of nursing, and have successfully incorporated epidemiological and qualitative research methodologies. We think that conventional nursing research, even if it clarified the question, did not elucidate why it would occur, or in medical terms, what its pathophysiological mechanism was. This has led to a delay in the development of new technologies and equipment in the field of nursing. Therefore, in translational research in nursing, we focus on the elucidation of the pathophysiological mechanism as the next stage. Here, we will try to elucidate the pathophysiological condition at the cellular level using the above-mentioned natural science approach, and further verify the mechanism through animal experiments.

Only then can we find a fundamental answer for how to solve that question or problem. An important step in translational research is the realization of technology and equipment in order to adapt the knowledge obtained from this basic research to the real world. It is important to clarify the concept of technology and equipment based on the mechanism and to set and develop basic specifications to achieve it.

In order to conduct such bioengineering nursing research, the involvement of transdisciplinary researchers is essential. The development of each discipline is remarkable, and it is impossible for a single researcher to cover everything. In fact, our laboratory has a team of researchers consisting of not only those with a degree in Nursing and Health Sciences, but also plastic surgeons and specialists in research fields such as molecular biology, agriculture, information science, and mechanical engineering. Insightful organizational learning, or co-creation of data, information, knowledge, and hopefully wisdom, can be initiated by sharing the awareness of the problem both physically and psychologically. To that end, we also collect data at clinical sites where we excel as nursing scientists, creating opportunities for people to feel what perspectives are important to elucidate disease states and develop technologies. A graduate student with a background in nursing is placed under a basic and engineering researcher with a clinical mind, and by promoting their own research themes, students can share their academic perspectives through research guidance.

Here, there are points that have not been fully explained. The point is what kind of uniqueness this cycle of bioengineering nursing can bring to the field. Certainly, the explanation thus far is an analogy of translational research that has developed in the field of drug discovery, and it is unlikely that it is a unique system of nursing, except from the point of view of the clinical problem. We would like to emphasize the next stage of developing new technologies and equipment. In other words, it is important to develop human resources that can adapt to the developed products and systems in actual clinical settings. The questions and issues addressed by nursing are complicated, as mentioned at the outset. In other words, it is necessary to train practitioners with advanced practical skills capable of appropriately using new technologies and equipment and improving patient outcomes. We believe that conducting practitioner training on the same soil as researcher training is unique in nursing science, and we believe that it may be a new path for future nursing research.

As might be expected in the field of medicine, nurses working in clinical settings rarely have a research perspective in the field of nursing. However, with the development of medical care, there will be more opportunities to contend with events that cannot be dealt with only through practice based on old knowledge and experience. In such a case, it is difficult to simply adapt to a medical field that is constantly evolving even after completing the basic training, and even if it trains nurses with specialized knowledge and skills. The ability to develop new nursing skills independently through a sophisticated self-learning system will be required for advanced practiced nurses in the future.

In the following sections, the authors will introduce research examples for new technology development based on real-world data analysis through a bioengineering nursing research framework through collaborations with a variety of researchers from disciplines other than nursing science.

3 Examples of Nursing Research Using Real-World Data

3.1 Fall Prediction Based on Electronic Medical Record Data

The first example of real-world data analysis is the development of a prediction model for falls based on EHR through collaboration with informaticians.

For hospitalized patients, falls are an important incident for nurses to address. It causes increased discomfort and anxiety about the patient's movements, as well as secondary injuries such as fractures and trauma. While falls are preventable, the human and material resources available for prevention are limited, and thus patients at high risk of falls need to be screened. As an existing screening method, there is a method in which a cut-off value is determined by scoring a patient by evaluating their mobility ability, movement, fall history, in-use drugs, complications, mental state, and so forth. These scales have been translated into various languages and are used worldwide. However, it is difficult to easily and objectively evaluate fall risk in a clinical setting. This is because nurses are already very busy checking various risk assessment scales daily to evaluate patients in multiple ways and recording daily nursing practices. There is also the problem of external validity that the performance of scales originally developed in various countries and facilities may not be applicable to hospitals where they work. If it is possible to objectively grasp the patient's condition that can change daily and predict falls with high accuracy, fall occurrences will be reduced.

To solve this problem, Yokota et al., a Japanese research group belonging to the information department of a university hospital, examined whether or not information for fall prediction could be obtained from the hospital database. They attempted to construct a fall prediction model that is highly likely to be collected at any facility and is based on the patient's condition and treatment on a daily basis (Yokota & Ohe, 2016). Yokota and his colleagues used a wide variety of medical information included in the EMR. In addition, information on falls input independently of the EMR was extracted from other databases and linked by patient ID. In this study, the authors defined falls as "an event judged to be a fall for which a fall report was created by medical staff at a clinical site." This definition is the most convenient and clinically objective. As an important predictor, they used the Intensity of Nursing Care Needs. This is an index that substitutes for the severity of the patients that nurses record daily in hospitals throughout Japan. Since nurses are to check the Intensity of Nursing Care Needs daily, for example, regarding the presence or absence of wound care, the degree of independence such as transfer, the presence or absence of assistance, and so forth, there is a feature where information on the patient's condition is updated daily.

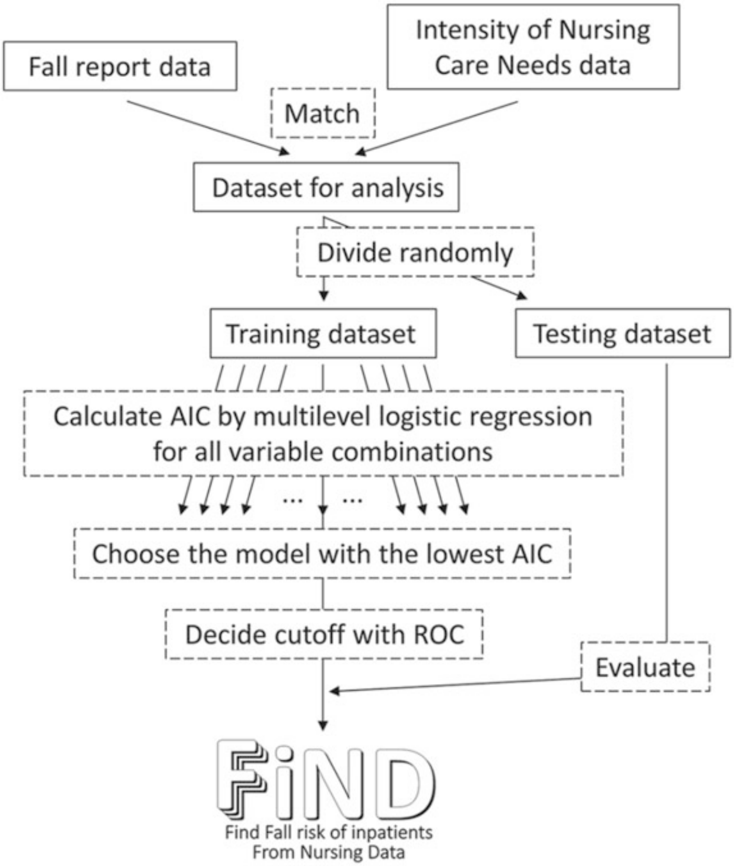

Fig. 2 Flow to construct and evaluate fall risk prediction model FiND (Yokota & Ohe, 2016)

They collected 1,230,604 records from 46,241 patients. Falls occurred in 0.16% of the records. The authors selected electronic medical record data to use this dataset for model construction and verification. That is, half of the data was used for model construction, and the other half for model verification (holdout method). Using the data for construction, 65,536 models were created, and the simplest model was selected according to the Akaike's Information Criterion. Following this, the discriminant performance was calculated for the verification data, that is, data unknown to the model. Finally, cut-off values were determined for balanced sensitivity and specificity. A multi-level logistic regression analysis, which is a method corresponding to repeated measurement data from each patient, was used to construct the model (Fig. 2). As a result, a discriminant model with a sensitivity of 71.3% and a specificity of 66.0% was created. The usefulness of this method is that there is no additional burden on nurses and patients for data collection, and fall prediction can be updated on a daily basis using the information in EMR. In addition, the authors applied machine learning techniques to the model construction to achieve an even higher sensitivity and specificity (Yokota, Endo, & Ohe, 2017).

The authors stated that nursing researchers can generate knowledge through the secondary analysis of the data stored in the EMR, create artificial intelligence by automatically processing the knowledge on a computer, and further utilize artificial intelligence to create higher-level nursing care. It has been argued that the development of artificial intelligence may impair the ability of medical professionals to think, however, we strongly expect that next-generation nurses who can utilize artificial intelligence as a tool will provide high-quality care based on real-world data.

3.2 Real-World Data-Based Effective Pressure Ulcer Prediction and Management

3.2.1 Impact of Pressure Ulcers on the Healthcare System

The following examples are related to technological advances in pressure ulcer management regarding assessment technologies that were achieved through collaboration with molecular biologists and engineers.

Pressure ulcers are major healthcare problems and are most commonly found in elderly patients (Thomas, 2007). The ulcers are associated with prolonged hospital stays (Allman, Goode, Burst, Bartolucci, & Thomas, 1999), decreased quality of life (Gorecki et al., 2009), increased mortality (Khor et al., 2014; Manzano et al., 2014), and increased medical costs (Brem et al., 2010).

We have demonstrated that having pressure ulcers affects not only those burdens, but also the patient's discharge destination (Nakagami et al., 2020). We analyzed medical big-data using the Japanese Diagnosis Procedure Combination (DPC) database, which is a case-mix patient classification system; it was launched in 2002 by Japan's Ministry of Health, Labour, and Welfare, and it covers nationwide inpatient administrative claims and discharge data for acute-care hospitals across the country. Detailed patient data and administrative claims data are collected for all inpatients discharged from participating hospitals. All 82 academic hospitals in Japan are obliged to participate in the database; participation of community hospitals is not mandatory. The database contains data on approximately 50% of all acute-care inpatients. It includes the following: unique identifiers of hospitals; patient age and sex; body mass index; smoking status (non-smoker or current/past smoker); the level of consciousness at admission (classified according to the Japan Coma Scale); type of admission (planned or urgent); use of ambulance service; use of home care before admission; ADL scores on admission; primary diagnoses and comorbidities on admission and adverse events after admission, recorded in accordance with the International Classification of Diseases tenth Revision (ICD-10) codes; procedures and surgeries recorded using original Japanese codes; pressure ulcer stage on admission and discharge based on DESIGN-R classification (Sanada et al., 2011);

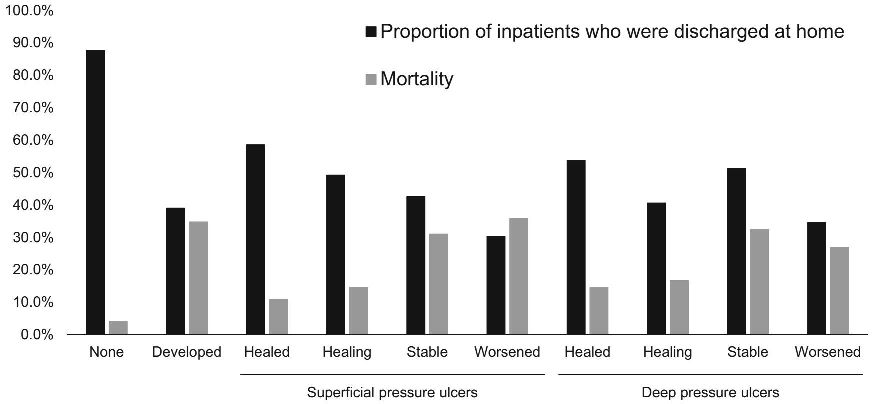

Fig. 3 Proportion of inpatients who were discharged home or died (Nakagami, Morita, et al., 2020)

and discharge destination. Based on the analysis of patients aged 65 years or older who were admitted to hospitals from their homes and discharged between July 1 and 31, 2014 ($N = 340{,}124$), patients with superficial or deep pressure ulcers were less likely to be discharged home. Furthermore, poor pressure ulcer status according to the pressure ulcer severity scale (developed < worsened < stable < healing < healed) was associated with a lower likelihood of home discharge. By graphical presentation in Fig. 3, it is easy to recognize that having pressure ulcers largely affects patient discharge destination.

As represented by this real-world data analysis, the prevention of hospital-acquired pressure ulcers is a top priority for healthcare professionals in acute-care hospitals to increase the likelihood of home discharge. Furthermore, regardless of pressure ulcer severity, ameliorating pressure ulcers by at least one stage, for example, stage three to two is critical for discharge destination. That is, promoting wound healing based on appropriate wound assessment is crucial. Therefore, we have approached those two targets by analyzing real-world data.

3.2.2 Development of an Automated Pressure Ulcer Prediction Model

Nurses are responsible for pressure ulcer risk assessment in hospitals, as well as fall risk assessment. For example, one university hospital screens patients at high risk of developing pressure ulcers using the scheme shown in Fig. 4. However, in acute hospitals, screening is not performed in a timely manner due to rapid changes in patient conditions, and many patients with pressure ulcers are overlooked. In fact, our previous study indicated that 57.8% of new in-hospital pressure ulcer cases do not undergo a scale-based pressure ulcer risk assessment, indicating screening difficulties. Therefore, we examined the possibility of identifying patients at high risk of pressure ulcers using EMR obtained daily by nurses.

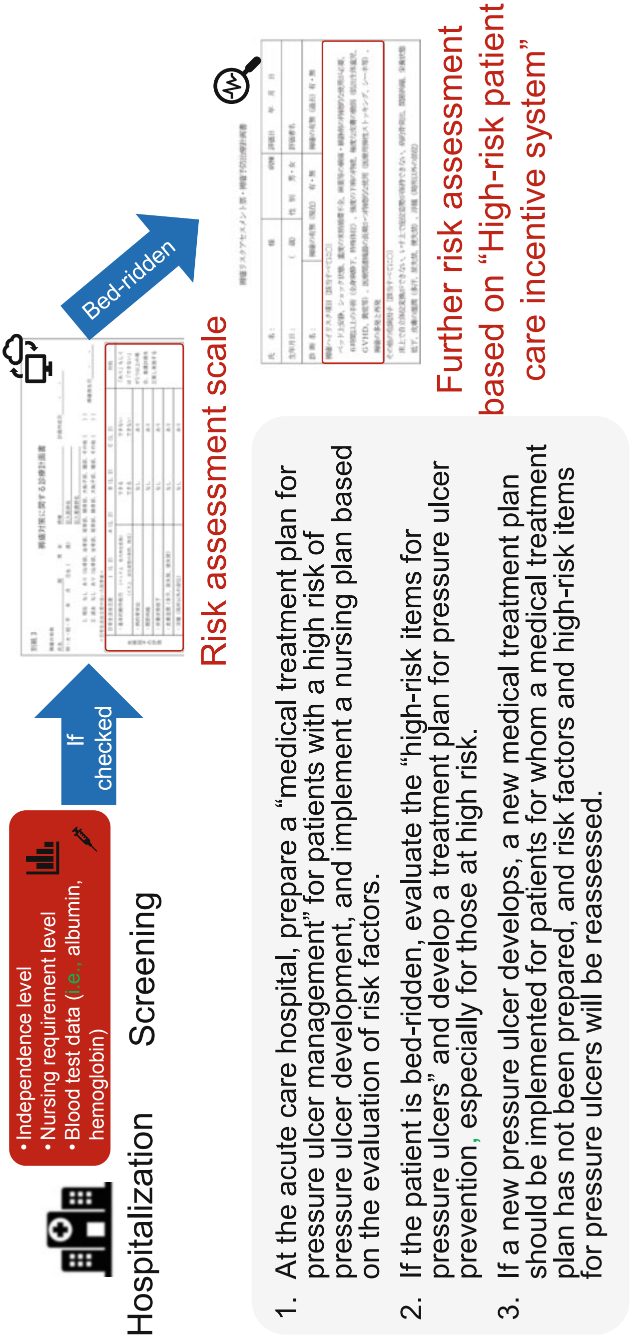

Fig. 4 Pressure ulcer screening scheme in a university hospital in Japan

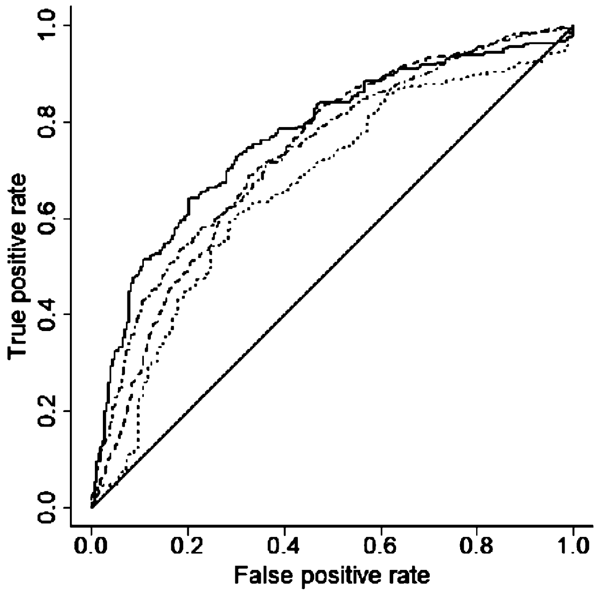

Fig. 5 ROC curves according to outcome types for pressure ulcer prediction (Yokota et al., unpublished data). Dotted line: New occurrence at the frequently occurring sites (AUC = 0.663): Dashed line: New occurrence (AUC = 0.727); One-dot chain line: New occurrence outside the operation department (AUC = 0.734); Solid line: New occurrence outside the operation department at frequently occurring sites (AUC = 0.766)

Of the adult patients who were admitted/discharged to a hospital in Tokyo from 2010 to 2017, a dataset was created by collating the admission/discharge information, basic information on nursing on admission, and the medical treatment plan for pressure ulcer management. Predictive models for the following four types of outcomes were generated: (1) new occurrences; (2) new occurrences outside the operating department; (3) new occurrences at frequently occurring sites; and (4) new occurrence at frequently occurring sites outside the operating department. The frequently occurring sites were defined as the sacrum, coccyx, greater trochanter, iliac, and heel. A 1:1 holdout method was used for learning and verification. A logistic regression analysis was used as the model.

As predictive factors, variables included in the content that nurses input immediately after patient admission were selected. Specifically, gender, age at admission, medical department, ward, poor appetite, restricted diet, presence of dentures, dysphagia, urination method, assisted urination, defecation method, assisted defecation, visual acuity, hearing, speech problems, paralysis, joint contracture, pain, repositioning, standing up, moving around, going up and down the stairs, care assistance, instrumental activities of daily living, cleanliness ability, skin condition, pressure ulcer risk factors, Japan Coma Scale, light reflexes, respiratory problems, and circulation problems were selected. A dataset of 87,771 patients was created, of which 1467 newly developed pressure ulcers. The Area Under the Curve of the Receiver Operating Characteristic curve for each outcome is shown in Fig. 5.

Although it is considered that information obtained by nurses alone cannot yet predict the occurrence of new pressure ulcers with sufficient results, it was suggested that selecting outcomes would improve the results. In addition, the results may be improved by adding disease names, specimen test data, and time-series data, which are not currently included in the predictors. Since it is a prediction model that uses only basic nursing information data that is always input to the electronic medical record, it can be operated without requiring an additional burden on the clinical site when implementing the automatic judgment function on the electronic medical record. Prediction performance may be improved by adding more variables, and the implementation and operation on electronic medical records are the future goals.

Thus, similar to the fall prediction study described above, it is possible for nurses to predict the occurrence of pressure ulcers based on data collected by nurses in their daily work, and that this information is updated daily. By using real-world data, it is possible to perform clinically-based patient assessments that are not bound by existing frameworks. This will improve the quality of nursing care.

3.2.3 Development of an Image-Based Innovative Assessment of Pressure Ulcers Using Real-World Data

In order to properly manage pressure ulcers, it is necessary to understand whether wound healing is progressing normally or being stalled. In the case of stalled wound healing, clarifying the cause for proper management is needed. For this purpose, the DESIGN-R® evaluation scale, a gross pressure ulcer evaluation method, is used. On the other hand, since this evaluation scale is a tool mainly based on gross findings, it is not suitable for the evaluation of damage to deep tissues or invisible inflammation, which is difficult to find from the outside. Therefore, focusing on deep tissue injury and critical colonization, which are the two major problems in the management of pressure ulcers, the authors will introduce emerging methods for evaluating pressure ulcers using ultrasonography, thermography, and a rapid biofilm detection tool developed through translational real-world data analyses.

3.2.4 Detecting Deep Tissue Injury by Ultrasonography

Pressure ulcers can be broadly divided into two types: where the damage progresses from the surface to the deep part, and where the deep damage occurs first and the tissue damage comes to the surface. The latter is called a deep tissue injury (DTI). Although DTI is deeply damaged, it cannot be sufficiently judged by visual inspection or palpation from the surface, and thus treatment such as the sufficient distribution of body pressure is delayed, and a few days later, a deep pressure ulcer becomes apparent. As shown in Fig. 6, even if it appears to be a slight injury to the naked eye, it rapidly worsens, and so early intervention for preventing the progression to deep pressure ulcers is important. Therefore, an ultrasonic imaging device is used as a means of visualizing the state of the deep tissue.

Many pressure ulcer patients are bedridden and are often not easy to move to the examination room, and therefore it is desirable to use a portable ultrasound device if possible. In recent years, the use of ultrasonography in chronic wounds such as pressure ulcers has dramatically increased due to the extremely high image quality

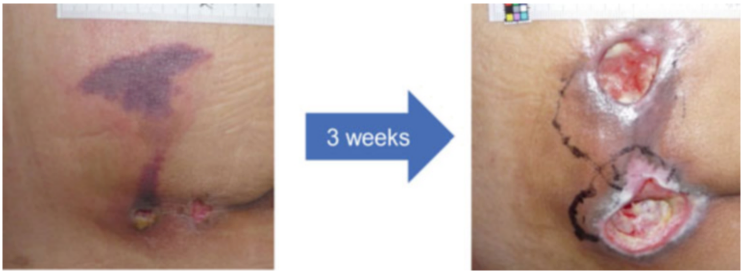

Fig. 6 An example of deep tissue injury in the sacral region

and miniaturization of devices. To date, the multi-disciplinary pressure ulcer round team has been using ultrasonography for approximately 15 years. By analyzing the vast amount of image data in detail, the evaluation viewpoint of pressure ulcer ultrasound was determined, and it became possible to summarize the method of evaluating pressure ulcers by ultrasound in the form of a flowchart (Fig. 7) (Aoi et al., 2009). As can be seen from the normal image, the skin and subcutaneous tissue are composed of layers, and the layer structure can be clearly confirmed by the ultrasound images. If this layer structure is not clear, edema, granulation, necrotic tissue, and so forth are presumed (Fig. 8). Moreover, if the tissue is replaced by scar tissue after healing, the brightness may be increased as a whole. If the patient has a pressure ulcer, the layer structure is often obscured by inflammatory edema. In addition, cobblestone-like signs may be observed when edema findings increase. The low-brightness area with an uneven internal structure is called a "cloud-like image" and is likely to be necrotic tissue (Fig. 9).

The major difference between ultrasonography and other imaging devices, such as CT and MRI, is that you can see only what you want to see. Ultrasonography tends to cause artifacts (virtual images that do not actually exist) and requires the fine adjustment of image quality, which is unsuitable for taking the entire image for retrospective review. On the other hand, the great advantage of ultrasound is the simplicity of the examination, the minimization of patient restraint, and the fact that it can be evaluated in real-time. In addition, with the advancement of the device, it is now much lighter and smaller than before, and the image quality has improved. It has thus become possible to visualize a finer structure by using a high-frequency probe. In this regard, it can be said that this is a novel nursing assessment technology developed from the viewpoint of translational co-creation of information and knowledge between nursing science and engineering. In the future, we are developing technologies to automatically acquire high-quality images and artificial intelligence that automatically analyzes images to determine the degree of damage to deep tissues.

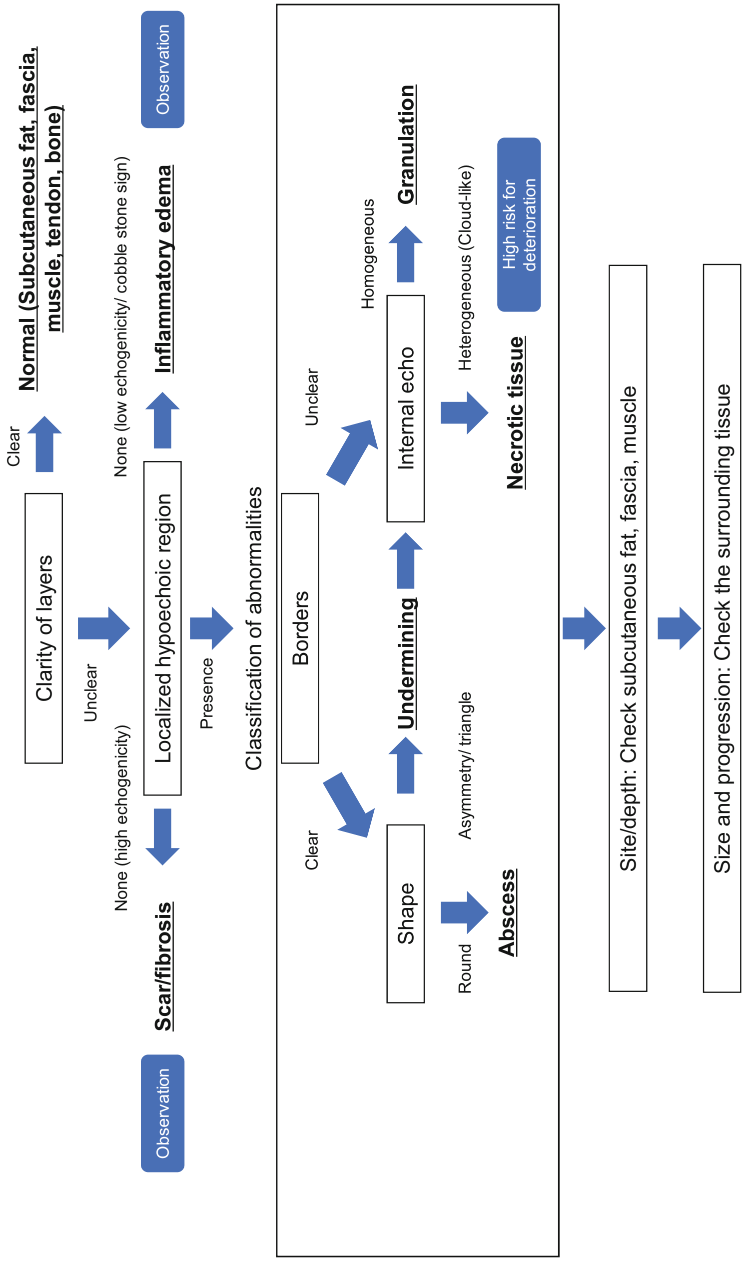

Fig. 7 Flowchart of pressure ulcer ultrasound

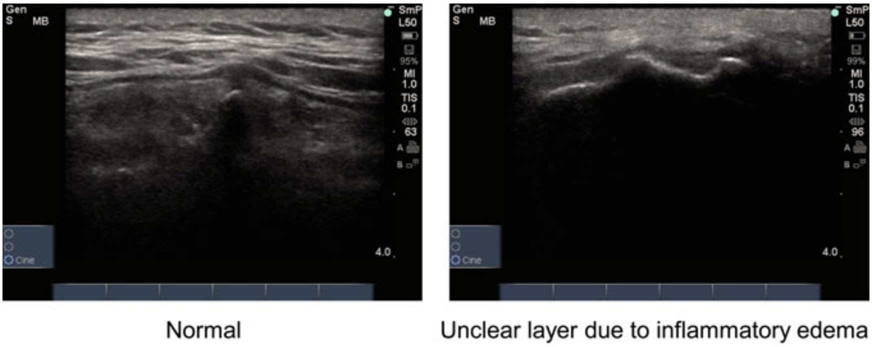

Fig. 8 Unclear layer

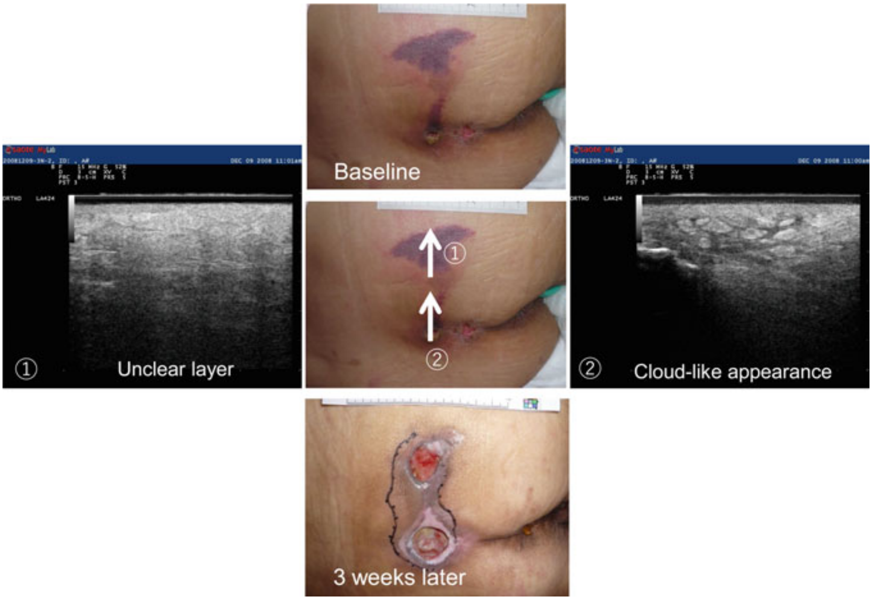

Fig. 9 Ultrasonography for worsening deep tissue injury

3.2.5 Early Detection of Critically Colonized Wounds by Thermography

Chronic wounds, such as pressure ulcers, are always exposed to external pathogens and are prone to delayed healing. Conventionally, the relationship between the host and the bacterium has been thought of as contamination, resident, and infection, but since about 2000, it has been classified into four categories including critical colonization. Contamination is a state in which bacteria are present only in the wound and no growth is observed, and colonization is a state in which bacteria

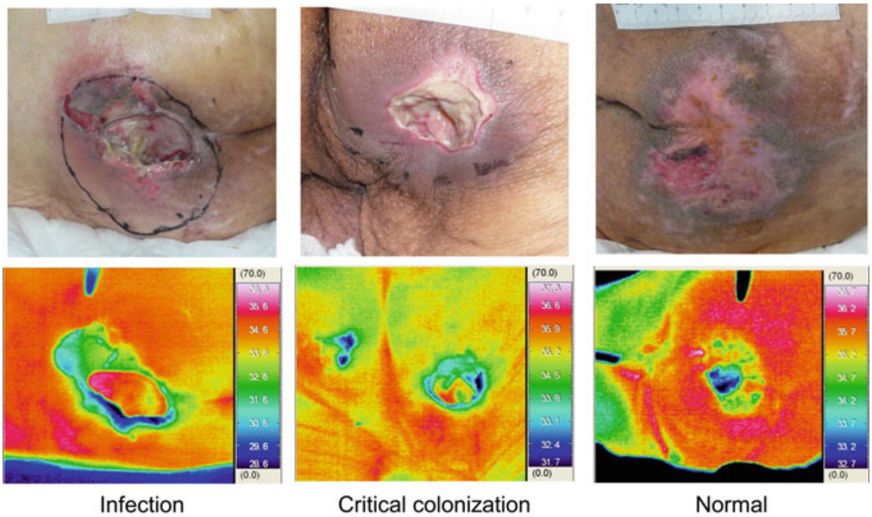

Fig. 10 Detection of inflammation by thermography

capable of growing are attached to the wound but do not harm the wound. On the other hand, critical colonization is a condition that is likely to shift to wound infection, and there are no signs of infection other than the delay of wound healing, but clinical improvement such as the speed of healing is improved with the use of antibiotics. Infection refers to a condition in which growing bacteria enter the tissue and harm the wound. Patients with pressure ulcers are elderly, often undernourished, and their poor immune function has created macroscopically unidentifiable conditions such as critical colonization. The fact that wound healing is delayed despite the lack of gross findings indicates that some host response has occurred after exposure to the bacteria. We thought that capturing invisible inflammation would lead to the identification of critical colonization. As a method for estimating the state of inflammation, we focused on the temperature of the wound site and accumulated clinical data using infrared thermography.

In the case of a physiological test using infrared thermography, preparation of the subject is required, such as habituation for a certain period in a constant temperature room, but it is difficult for pressure ulcer patients to unify such conditions. Further, in most cases, a dressing material is stuck to the wound, and it is difficult to wait until the temperature becomes constant after removing the wound because the burden on the patient is large. In order to solve this problem, the pressure ulcer thermography compared the temperature with the skin around the pressure ulcer and relatively evaluated the temperature distribution.

As shown in Fig. 10, infected wounds have macroscopically obvious signs of inflammation, and thermography shows a hot (red) area at the wound bed. Although no visible inflammation was observed in the critical colonization wound, it showed a high temperature on thermography, and it was judged that subtle inflammation had

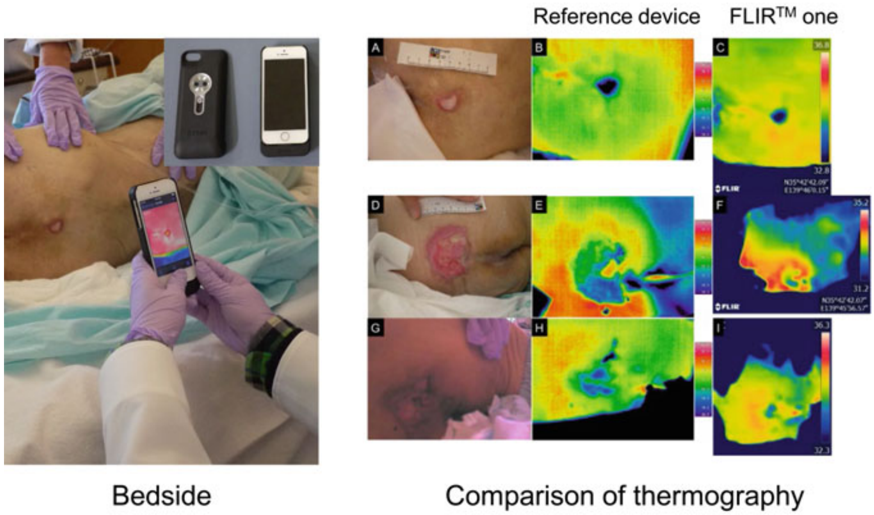

Fig. 11 The use of mobile thermography

occurred. The temperature of the wound bottom is low in a normal healing wound. By capturing the difference between the temperature around the wound and the surrounding area, infrared thermography that originally requires strict temperature control can be used at the bedside (Nakagami et al., 2010). Although it is difficult to use expensive thermography in clinical practice, the use of mobile thermography (FLIR™ one, manufactured by FLIR Systems) makes it possible to evaluate the temperature distribution at a low cost. These cases show a temperature distribution comparable to that of expensive reference equipment (Fig. 11) (Kanazawa et al., 2016).

3.2.6 Integrating Molecular Biology to Nursing Science for Detecting Wound Biofilm

As described earlier, capturing the microscopic inflammation of a wound using thermography leads to the selection of wound treatment. However, wound inflammation is not always caused by infection or critical colonization alone. Wound inflammation occurs, for example, when a strong external force is applied. Therefore, estimating the cause of inflammation will lead to the correct choice of treatment needed for the wound. In recent years, the relationship between biofilm and infection/critical colonization in chronic wounds has been noted. A biofilm is a community formed by microorganisms and contains polysaccharides, proteins, and extracellular DNA as its main components. Biofilms exist as reservoirs of bacteria and express their pathogenicity by forming a population. In addition, it can circumvent the effects of antimicrobial agents and host immunity, causing chronic

Fig. 12 Rapid biofilm detection tool

inflammation and a very strong source of infection. As long as the biofilm exists at the wound bed, neutrophils and other immune cells accumulate, but the biofilm itself cannot be destroyed. Therefore, inflammation is sustained due to the endless production of proteases and reactive oxygen species, and healing is impaired. Therefore, since the latter half of the 2000s, it has been proposed that wound treatment be selected depending on the presence or absence of biofilm as biofilm-based wound therapy. However, it is stated that tissue biopsy, observation with an electron microscope, and observation after special staining are necessary to determine the presence of a biofilm, and it can be said that implementation in general clinical practice is difficult. Moreover, in the case of tissue biopsy, since only a small part of the wound is collected, it is impossible to know how two-dimensionally the biofilm is distributed. In that sense, conventional biofilm detection technology has limited clinical applications.

Therefore, we came up with the idea that the components of the biofilm distributed on the wound surface should be extracted and stained. “Wound blotting,” a technology that can analyze a small amount of protein on the wound surface by staining the membrane by simply pressing a filter paper called a blotting membrane on the wound surface for 10 s, can be routinely performed clinically (Minematsu et al., 2013). We thought that it would be possible to apply this technology to biofilm detection. This makes it possible to determine not only the presence or absence of the biofilm but also which part of the wound surface has the biofilm.

Figure 12 shows the results of staining using a biofilm detection tool developed in collaboration with a Japanese chemical manufacturer and industry-academia collaboration. Alcian blue is used for staining, which specifically stains hyaluronic acid, chondroitin sulfate, pectin, and acidic glycoprotein (acid mucopolysaccharide), which is a component of biofilm. The biofilm can be clearly visualized by washing the wound lightly, applying a blotting membrane moistened with physiological saline to the wound surface for 10 s, and staining with an Alcian blue staining solution. Since the biofilm can be visualized within only 2 min, it has been proposed as a bedside assessment technology or point-of-care biofilm detection tool (Nakagami et al., 2017). This increases the risk of sloughing the following week in the presence of biofilm, and completely removing the biofilm with a debridement reduces the wound area significantly more than if there was a residue (Nakagami et al., 2020). The application of a wound management protocol that removes a biofilm visualized using a device such as ultrasonic debridement can significantly improve the wound healing rate (Mori et al., 2019). Biofilm-based wound care has been practiced in clinical settings.

The methods of assessing pressure ulcers using the ultrasound imaging device, infrared thermography, and rapid biofilm detection tool presented here are all introduced as new technologies in the latest international guidelines. We hope that the accumulation of evidence in the future will become a global standard evaluation method. The fact that various assessment techniques developed by the bioengineering nursing research framework contribute to the world of pressure ulcer care suggests the importance of R & D based on real-world data.

4 Conclusion

Attempts to develop the next generation of nursing care using real-world data have only just begun. However, the knowledge and skills of technology development based on clinical real-world data accumulated through past nursing research will be useful for the development of next-generation care. In fact, with the generalization of the use of ultrasound, nurses can easily measure bladder capacity by ultrasound, and further, a technology for automatically estimating bladder volume from ultrasound images using artificial intelligence has been implemented (Matsumoto et al., 2019). The speed of such innovations has never been imagined before.

The knowledge obtained from real-world data is vast, and the benefits can be enjoyed more widely in nursing, which supports people's lives. In the future, real-world data analysis and artificial intelligence research will advance, and the next world beyond the artificial intelligence generation will definitely come to pass. As in the examples shared in this chapter, further transdisciplinary innovation will be co-created by a new stream of health informatics based on translational systems science that dynamically fuses data, information, knowledge, and wisdom.

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Health Informatics and Co-Innovation: Connecting Patients, Clinical Practice, and Technology

Jérôme Galbrun

Abstract Healthcare has become a growing challenge for many societies in terms of access by the population and cost in the national budget, demonstrating its importance across countries and disease areas. Healthcare systems are under pressure: more of us are living longer and more of us are living with chronic medical conditions, leading to soaring healthcare spending.

To cope with these issues, innovation in healthcare led to the recent emergence of meaningful informatics technology solutions, looking at the adoption of health informatics (HIT), from Electronic Health Records/Electronic Medical Records (EHRs/EMRs) to Advanced Visualization and Picture Archiving Communication Systems (PACS) in radiology and cardiology departments. To understand this underlying technology change in medical practice, we first advocated an evolutionary perspective to analyze this specific innovation, where variation, selection, and retention processes occur based on some empirical evidence.

This directed us to view innovation in health informatics as a co-innovation service model where heterogeneous agents interact to combine technological change and clinical practice into patient-centric solutions. This results in exploring emerging trends such as artificial intelligence and its implication in terms of contributing toward the goal of precision medicine and better outcome for patients.

Keyword Health informatics · Co-innovation · Medical technology · Clinical practice · Artificial intelligence

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1 Introduction

In the interest of patients, most physicians and medical organizations support innovative medicine that preserves health and saves lives. Healing patients, by improving diagnostic and treatment procedures, is the primary motivation of physicians applying new methods and they often use an orderly approach, carefully record conditions and results, and publish the results of their innovative techniques.

Healthcare has become a growing challenge for many societies, in terms of access for the population and of cost for national budgets, exhibiting important variety across countries and disease areas. To cope with it, innovation in healthcare has been supported by the emergence of new diagnostic tools (Gelijns & Rosenberg, 1999) and treatment procedures, recently triggered by the growing influence of patient advocacy groups (Callon & Rabeharisoa, 2008).

From strong empirical evidence, innovation in healthcare has been portrayed as the introduction and the diffusion of new medical devices, drugs, and clinical practices in improving healthcare in general and patient care in particular (Consoli & Mina, 2009; Djellal & Gallouj, 2005). The effort led by service innovation studies in the healthcare sector (Djellal & Gallouj, 2005; Gallouj & Windrum, 2009) has notably considered medical innovation in a more broader and systemic approach. The systemic nature of innovation has been empirically shown by scholars of innovation in various aspects (Edquist, 1997; Malerba, 2004; Lundvall, 1992; Nelson, 1993) and more specifically in healthcare (Consoli & Mina, 2009; Metcalfe, James, & Mina, 2005).

The question of progress in medical technology requires taking into account both low-level details and high-level entities (Consoli & Mina, 2009). Previous scholars approaching healthcare innovation from a systemic perspective (Metcalfe et al., 2005; Mina, Ramlogan, Tampubolon, & Metcalfe, 2007; Consoli & Mina, 2009) have also investigated properties of medical innovation processes occurring at various levels. At one level, the interaction between technology market and scientific community drives possible divergent avenues in terms of medical advances (Consoli & Mina, 2009). At another level, potential constraints such as regulations to assess safety, performance, and cost-effectiveness of new procedures influence the health delivery system and its potential to implement medical innovations (Metcalfe et al., 2005).

This directs us to study in more details the "practical domain" (Consoli & Mina, 2009) where a practicing physician uses technological advances to diagnose or treat a medical condition of a patient.

Doctors, nurses, and surgeons are often the pivotal point around the patient's care. Yet, clinicians in most specialties are reporting increasing rates of workplace burnout, with classic symptoms like fatigue, and doubts about the ability of consistently delivering quality clinical care.[1] Some of the highest rates are from those in critical care, where doctors need to make split second decisions: each patient in these

[1] Medscape Lifestyle Report 2016: Bias and Burnout.

critical care departments generates around 1200 data points per day. As rightfully mentioned by Professor Matsushita in his introduction, since 2000, hospitals have gradually adopted Electronic Medical Records (EMR) or Electronic Health Records (EHR) solutions to address this need of gathering, managing, and sharing patients data in the acute space. Earlier, since 1990, hospitals, private clinics, and radiology centers have been switching from analogical way of working (e.g., printing films of radiology imaging) to digitalizing, storing, and sharing digital images led by the growing usage of advanced radiology imaging devices such as computed tomography (CT) and magnetic resonance imaging (MRI) for the past two decades. These radiology-oriented informatics solutions are named PACS (picture archiving communication systems), usually associated with advanced visualization software tools.

Our empirical investigation focuses on two information technology solutions widely used in hospitals, respectively, Radiology informatics and EMRs, as well as their specific innovation patterns: (1) patient-centric (2) resulting from a co-creation process between technology and clinical users.

2 Discussion

2.1 Medical Technology, Innovative Practice, and Research

Innovation in clinical practice, involving medical technology, requires some further exploration, for instance, by distinguishing innovation in medical practice from research (Eaton & Kennedy, 2007). This implies to identify the boundary between, on the one hand, biomedical and behavioral research, and on the other hand accepted and routine practice of medicine. A patient is the client of the physician and should be able to assume that the physician is acting solely in the client's best interests. The resulting duty of care means that, even though ultimate decision-making rests with the patient, he or she should feel safe in delegating some decisions to the physician. A research subject, in contrast, is a person experimented on and observed by the physician. The research physician has an interest in the subject's welfare but may have even a greater interest in collecting data to serve a larger community of future patients. This aspect is fueling the growing interest of accessing large databases of patients. We will come back to this point when considering the latest advances in radiology informatics and EMRs concerning artificial intelligence (AI) at large.

Innovation in medical technology, as distinct as medical research, involves the complexity of the physician–patient interaction (Eaton & Kennedy, 2007). In cases where several treatments or clinical procedures co-exit, some may be therapy and some may be more like research.

We then aim to consider a broader approach by defining the concept of *innovative practice*. In addition to being a new modality, an innovation in medical technology can be an existing modality used in a new way, in a new dose, or in combination with other new or existing established information technology (IT) solutions. Such evidence criterion deals with a dual variability in medical practice. Variability among patients and variability in manifestations of diseases and injuries[2] require physicians to deviate frequently from standardized procedures. For instance, this kind of medical adaptation lies in every surgical procedure, where innovations are being made daily as an individual surgeon finds improved results with specific changes in operative technique (Moore, 1969; Moore, 2000). Similarly, radiologists and technologists, operating complex medical imaging devices such as computed tomography (CT) and magnetic resonance imaging (MRI), change acquisition parameters, use advanced visualization tools, and constantly improve those to adapt to patient variability (Takahara et al., 2004; Sablayrolles, 2002). Such innovative medicine is a departure from the routine and established practice of routine, producing better patient outcomes.

At the early stage of the computed tomography (CT) development, the X-ray tube rotated around the patient and acquired one slice. Then the table moved, while the X-ray tube and detector went back to their initial position, in order to get the next slice of the patient (Trajtenberg, 1990). In 1990s, Willi Kalendar and Kazuhiro Katada introduced *helical* computed tomography devices, allowing a complete freely rotating motion of the X-ray tube/detector couple around the patient.[3] The table moves while the X-ray tube/detector rotates, resulting in a helical path of the X-ray beam. The slip rings for data transfer and the power supply miniaturization were the key technology enablers for helical CTs. In 1993, the Elscint Company (Haifa, Israel) introduced a dual-detector ring, with a complete rotation in a second: the *multi-slice* CT was born, with the beginning of the race to higher rotation speed and multiple detector rings (2, then 4, then 8). In 2000, the multi-slice CTs were widely distributed as dual-slice CT, four-slice, and eight-slice CT systems. The number of slices is originated by the number of detector lines receiving the X-ray beam, associated with a pivotal characteristic, the sickness of detector lines. Rapid improvement of both characteristics nowadays reveals numerous options for manufacturers for new product development.

Unlike CT, magnetic resonance imaging (MRI) uses no ionizing radiation but a powerful magnetic field (measured in Tesla) to align the nuclear magnetization of hydrogen atoms in water in the patient body. Consequently, MRI provides much more contrast between the different soft tissues of the body than CT does. This medical imaging device is primarily useful in neurological (brain), musculoskeletal (joint), cardiovascular. As it examines chemical and physical properties at the cell level, MRI provides a new means for early detection of disease in care areas such as oncology (cancers) and neurology (neurological degenerative diseases).[4]

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[2]To illustrate this variety, we refer to the measure of disability adjusted life years (DALYs) by cause of death, as shown in the Appendix A.

[3]A useful, more detailed history of this technological development can be found in a PDF document named CT History Technology, accessed at http://www.medical.siemens.com/ siemens/ zh_CN / gg_ct_FBAs /files/brochures/ CT_History_and_Technology.pdf on February 2, 2009.

[4]For readers with a deeper interest on this promising medical imaging device, we recommend to access the international journal of basic research and clinical applications dedicated to MRI, *Magnetic Resonance Imaging*, edited by Elsevier.

While CT provides good spatial resolution and hard tissue visualization with a fast acquisition time, MRI allows comparable resolution with better contrast resolution (the ability to distinguish differences between similar but not identical tissues) requiring longer acquisition time. This MRI ability is directly linked to the complex library of parameters (mainly pulse sequences), each of them being optimized to provide image contrast of a specific chemical component of the body. For instance, depending on the choice by the operator of specific values, for a given sequence (namely T2-weighting), water-containing tissues are bright, whereas fat-containing tissues are dark. In contrast, with another sequence (namely a fluid-attenuated inversion recovery sequence), water-containing tissues are now dark, but damaged tissues developing edema remain bright. Consequently, by variation of MRI scanning parameters (nearly an infinite variety of possibilities), tissue contrast can be altered or enhanced in various ways to detect different features.[5] Alternatively, CT using X-ray attenuation to generate image contrast (Hounsfield units measuring the differences of physical density within the body) is an adequate imaging device for bone and calcification visualization, vessel structure, and blood flow if contrast agents are injected (bolus tracking).

Both imaging techniques are characterized by high versatility in terms of clinical applications and visualization capability (2D or 3D reconstruction from projections). Both devices bear close similarities in terms of data gathering and data processing that can be translated for physicians in their medical practice. In the case of CT, our field study shows a correlated clinical improvement with respect to the enhanced technological capabilities, in terms of accuracy and timeliness as shown in Table 1.[6]

This technological evolution embraces significant clinical improvements, such as CT cardiac imaging capabilities. In medical technology, long-term shifts in the understanding of medical diseases (e.g., cardiac diseases) trigger exploration of new diagnostic avenues (e.g., CT cardiac imaging), and when successful this clinical experimentation generates pressure on the existing set of practices and technologies.

A stimulating factor for innovation in medical technology lies in the permanent search to meet clinical needs in terms of improving patient outcomes, providing safety, increasing utility, and saving time (Metcalfe et al., 2005). Demand by patients and their advocacy group (Callon & Rabeharisoa, 2008) fuels public acceptance of medical innovation. Advocacy organizations in some countries have become a potent force in influencing physicians to provide treatments, third-party payers to cover these procedures, and regulators to support access to them. In generating public acceptance of medical innovation, it is difficult to underestimate the impact of access to the Internet as a growing force in the dissemination of information.

[5]Ibid.

[6]This table is a compilation of data coming from company press releases and company product datasheets, accessed at (alphabetical order): www.gehealthcare.com, www.medical.siemens.com, www.medical.toshiba.com, www.healthcare.philips.com, in the past few years (2006–2016). These data have been cross-checked with the medical imaging community website: www.auntminnie.com, during the same period.

Table 1 Technological change in CT and clinical improvements (source: press releases and product datasheets of CT manufacturers)

Date	Row detector	Wave of technological innovation	Clinical improvements	CT cardiac imaging in seconds
1971	1	Invention		No
1989	1	Helical CT	Exam time	No
1993	2	Dual slice	Exam time	No
1994	4	Multi-slice CT	Exam time	No
1998	8	Multi-slice CT	Angiography	No
2000	16	Multi-slice CT; isotropic view	Cardiac, angiography	12
2001	16	Multi-slice CT; tube power	Obese patients	12
2003	32	Flying focal spot	Image quality	7
2004	40	High-resolution CT	Body coverage	7
2004	64	High-resolution CT	Emergency, cardiac	5
2005	64	Dual-source X-ray; spectral imaging	Cardiac, metal artifact reduction	5
2007	256	Dynamic CT; new detector	Dynamic flows (cardiac, brain...)	2
2007	320	Dynamic CT; new detector	Dynamic flows (cardiac, brain...)	1
2010		New detectors	Lower dose for patients; better image quality	1
2012		Iterative reconstruction	Lower dose for patients	1
2012	640	New detector		0.33
2014		Fractional flow reserve (FFR)	Cardiac	

Websites abound at which patients or potentially patients can learn about all manner of treatments, procedures, both established and experimental.

Advances in medical technology, involving both diagnostics and treatment, have been, at least arguably, a driving force behind the rapid growth of healthcare expenditures (Aaron & Schwartz, 1984; Weisbrod, 1991). One mechanism through which technological change could foster increased expenditures on healthcare would be through its effect on the healthcare insurance system. If a previously untreatable condition becomes treatable, a possible outcome is that an individual patient could encounter a larger medical care expense than was previously the case. In addition to the increased expected demand from individual patients, collective demand is also likely to increase; improving health care, particularly when it has a major effect on life expectancy or quality of life, results in public pressure on government to ensure that the care is available to whomever needs it medically.

Empirical evidence has shown the significant influence of economic pressures on both the rate and direction of medical innovation. This variety of both technologies and techniques tends to limit the promotion of “global standards” in healthcare, some healthcare procedures being refrained in some countries while more rapidly adopted in others, such as national-wide programs for cancer screening and their associated techniques like computer-aided diagnosis tools. Similarly, adoption of EMRs varies a lot country by country[7] linked to multiple factors including funding, existence of interoperability standards, legal concerns around privacy, and security concerns for Personal Health Information storage.

In turn, healthcare systems that prize efficiency create an environment that is favorable for innovative activities driving better outcomes for patients. For instance, percutaneous transluminal coronary angiography (PTCA) has provided alternatives to costly clinical procedures.[8] Medical device technologies raise questions of risk and benefit both to health and to the healthcare systems. These issues about performance and social acceptability of medical technologies (Webster, 2007) now aim to search for better patient outcomes. Then our focus is on the microstate process of generation and diffusion of clinical innovations using medical technologies at the *patient* level. In the radiology informatics domain, we did explore, through a field study, two innovations, virtual colonoscopy, and CT cardiac imaging, as the results of patient-centric cocreated solutions.

2.2 From Scope to Virtual Colonoscopy (CTC)

Colorectal cancer is the third most common cancer in Western countries and the second leading cause of cancer death in the United States.[9] Yet screening rates are low, most likely because current screening methods are invasive and unpleasant for patients. However, almost all colon cancers are essentially preventable. With lung or breast cancer screening, doctors search for the cancer itself. In contrast, colon cancer screening identifies precancerous lesions, which are removed before they become cancer. Consequently, screening is absolutely critical for patients at risk. Computed tomography colonography (CTC), known as virtual colonoscopy, is as accurate in screening for colorectal cancers and precancerous polyps as conventional colonoscopy, the current invasive screening standard. Conventional methods carry a higher risk of perforation and infection than CTC and patients must undergo sedation, which takes them out of action for an entire day. With CTC, patients can be in and

[7]https://www.himssanalytics.org/emram

[8]The designation "percutaneous" is because the physician performing the procedure inserts a catheter through small cuts in the skin and then in blood vessel. The catheters through which tools reach the heart are usually threaded through a cut in the groin, into the femoral artery, and then to the heart vessels. PTCA restores blood supply and oxygen to the heart by opening or narrowed coronary blood vessels using small balloons. In contrast, coronary artery bypass graft (CABG) is a form of open heart surgery in which a detour or "bypass" is created around the blocked part of a coronary artery to restore the blood supply to the heart muscle. The bypass is created using pieces of veins or arteries from other parts of the patient's body.

[9]World Health Organization (2005), International union against cancer. WHO press, Geneva.

out within 30 min, and back to work the same day, with no sedation and no loss of function.

Since 2001, Dr. Danielle Hook, a pioneering researcher in CTC, has trained hundreds of radiologists to perform and interpret CT colonography in Europe (Hock et al., 2008). Dr. Hook by her daily practice demonstrated that CTC uses safe, noninvasive X-ray technology to create detailed two- and three-dimensional images of the colon and surrounding organs in less than minute, in contrast to conventional colonoscopy, which uses a 200-cm long scope inserted in the patient's colon. Dr. Hook did experience CTC with a CT 16-row detector scanner by developing new clinical acquisition protocols for abdomen scans and by designing new post-processing visualization of the colon on her post-processing console. Both improvements were the results of trial-and-error processes, associated with several hundred clinical cases.

Such a clinical experience did drive the development of automate virtual dissection of the colon, based on the doctor's requirements.[10] This collaborative effort did result in features such as 3D virtual endoscopy; 2D reformats in any spatial plane, and auto-dissection of halves in rotation around the long axis of the colon. The professional association, ESGAR,[11] European Society of Gastrointestinal and Abdominal Radiology, did facilitate the rapid expansion, since 2003, through series of workshops or hands-on trainings taught by CTC experts in Rome/Italy (2004), Bruges/Belgium (2005), Edinburgh/U.K. (2006), Pisa/Italy (2006), Nizza/Italy (2007), Malmö/Sweden (2007), Vigo/Spain (2008), Berlin/Germany (2008) (Taylor, Laghi, Lefere, Halligan, & Stoker, 2007). In parallel, this clinical procedure was widely tested in the United States (Yee et al., 2003). Our field study shows that CT colonography rapidly gained acceptance, as shown by the number of occurrence of this term in medical publications from 1997 to 2019 in Fig. 1.

2.3 CT Cardiac Imaging

Coronary artery disease (CAD) is the result of a process called atherosclerosis through which plaque forms on the inner layer of the coronary arteries and impedes the flow of blood to the heart. If untreated, the eventual outcome of the process may be a heart attack.[12] For some years now, cardiovascular disease has been the leading cause of mortality in Western countries. Progress in the field of cardiac imaging has encouraged the development of a reproducible, reliable, noninvasive technique that

[10]For instance, some patent reference can be found under the U.S. Patent 7,274,811 entitled *Method and apparatus for synchronizing corresponding landmarks among a plurality of images* for which Renaud Capolunghi is accredited among the inventers.

[11]As a European Subspecialty Society, *ESGAR* is an institutional member of the European Society of Radiology http://www.esgar.org/

[12]The information about coronary artery disease is primarily from Medline Plus (http://medline.gov/)

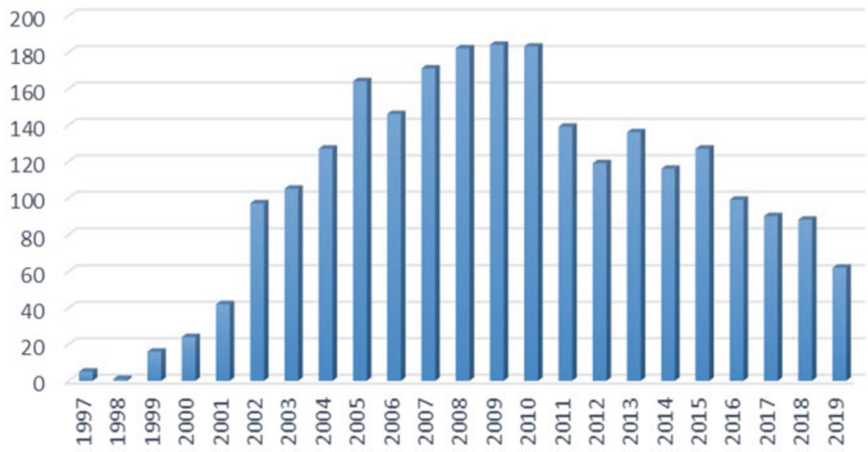

Fig. 1 CT colonoscopy occurrence in medical publications by year (source: PubMed – accessed in January 2020)

provides clinicians and patients with timely relevant clinical information.[13] Multi-row scanners (16 submillimeter slices in one 0.5-s rotation of the tube) made it possible to obtain 2D and 3D images of all cardiac structures and the coronary arteries in one single 20-s ECG-gated volume acquisition with injection of iodine-based contrast medium. This noninvasive imaging procedure did emerge as a solution for early CAD diagnosis. Some pioneers in hospitals did compare these new techniques to current examinations (coronography, myocardial scintigraphy, echocardiography) by intensively exchanging results within their medical organizations and sometimes outside through publications and conferences in medical congresses (Nieman et al., 2001).

In the north of Paris, the "Centre Cardiologique du Nord" (CCN) has been among the early inventers of this new technique in the radiology world since 2000, leading to achieve the challenge of replacing invasive diagnostic coronary angiography by a noninvasive innovation, the CT cardiac imaging (Sablayrolles, 2002). Dr. J.-L. Sablayrolles and his team have developed this technique in the context of close collaboration between internal actors of CCN (radiologists, technicians, cardiologist, and heart surgeons) and external actors (CT device research engineers of the CT manufacturer and contrast media producer). This private clinic did not only validate the performance of new scanners by providing CT manufacturer with clinical cases but also improved acquisition technology and post-processing to validate new cardiac CT applications, so-called clinical applications. This set of innovation is a combination of new acquisition techniques: patient preparation (including oxygen

[13]We refer to an educational brochure from Drs. J.L. Sablayrolles, E. Bouvier, J. Feignoux, Q. Sénéchal (2005) *Cardiac CT: Coronary CTA with 64-MDCT*, Centre Cardiologique du Nord—Saint-Denis—France.

therapy to facilitate breath-holding), acquisition parameters (compromise between spatial and temporal resolution), and injection parameters. This innovation includes post-processing techniques that have been introduced by radiologists on site. At first, CT manufacturers have developed fast, reliable reconstruction software packages, providing 2D and 3D images in any plane, but the extensive clinical experience of the CCN radiologists required new tools to extract all the information contained in this ECG gate, multiphase volume acquisition. With a 64-row detector CT, any cardiac examination represented a set of 2700 images and the radiologists of CCN developed a new workflow in order to cope with this amount of data, while managing the accuracy of the potential CAD assessment.[14] Consequently, they initiated a rigorous multiphase review protocol: (1) morphologic and kinetic study of left ventricular wall and cardiac valves, (2) selection of diastolic and systolic phases for function analysis, (3) selection of the best phases for the right coronary artery and for the left coronary system.

Medical users accumulate through their clinical experience tacit knowledge. The medical device manufacturer or medical software companies possibly capture and codify to bring patient-centric solutions. This transfer process involves numerous interactions between clinical users and software engineering team from heterogeneous organizations.

Innovation of that kind contributes in healthcare to some possible paradigm shift: the CT cardiac imaging enables coronary investigation and a search for myocardial lesions in a single outpatient visit, when its noninvasive dimension and its "protocolization" expand the number of patients who may benefit from this technique.[15] In turn, this new clinical solution being introduced, clinical practitioners face the difficulty of fixing the right indications for its use in specific clinical situations. Prescription of the new examination will depend on not only its clinical relevance but also its freedom from risk, its cost, and the availability of equipment. For some clinical indications, it is complementary to traditional techniques,[16] while in others it can replace them as shown in Fig. 2.

Our field study shows that CT cardiac angiography (measured by occurrence of this term in medical publications) rapidly gained acceptance, from 2006 and still growing with the recent advances such as CT perfusion imaging and fractional flow reserve CT (FFR-CT), as portrayed in Fig. 3.

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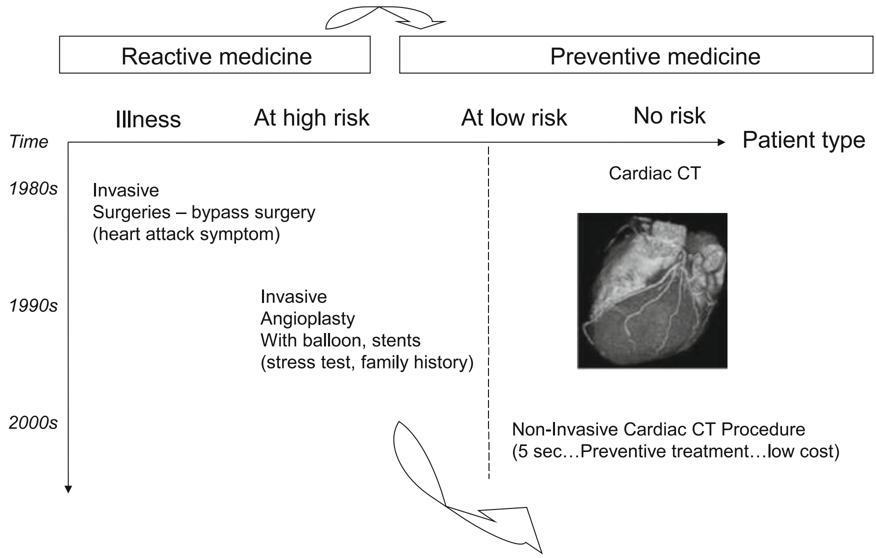
[14] Ibid.

[15] We find protocol examples in a public website dedicated to the Medical Radiology Industry, Aunt Minnie, in a subsection named Cardiac Imaging Community, accessed from http://www.auntminnie.com/ on June 8, 2009.

[16] For instance, balloon angioplasty is a surgical procedure in which a small balloon is inserted and inflated to open narrowed or blocked blood vessels of the heart (coronary arteries). A coronary stent is a semiflexible tube left in place to hold open the previously clogged artery.



Source: Adapted with partial addition and editing from Christensen C. and Raynor M. (2003), *The Innovator's solution,* HBS Press.

Fig. 2 Cardiac CT procedure and disruptive clinical practice

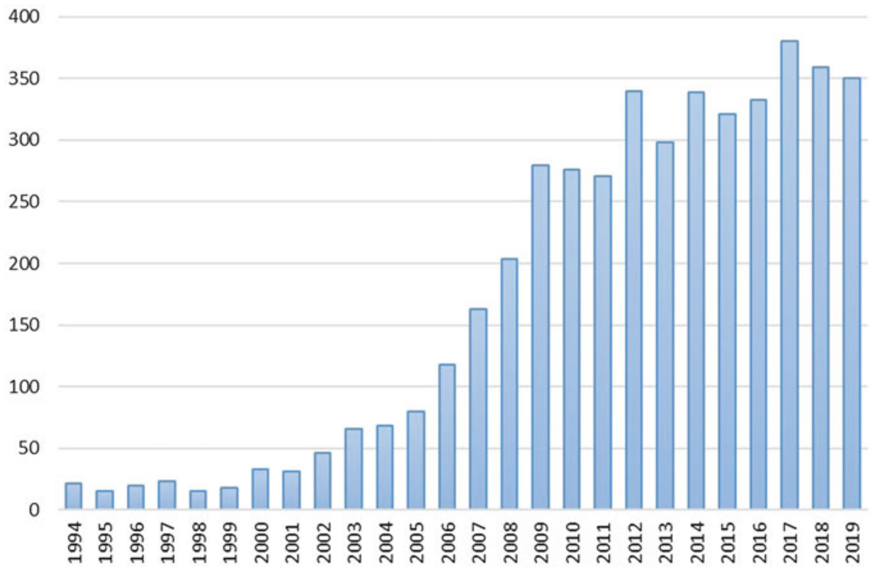


Fig. 3 CT cardiac angiography occurrence in medical publications by year (source: PubMed—accessed in January 2020)

2.4 *Service Science for Understanding Innovation in Clinical Informatics*

Looking at innovation in medical technology in a boarder perspective than product development directs us to consider service and its underlying generation processes. By service we refer to "the application of specialized competencies (knowledge and skills) through the deeds, processes, and performances for the benefit of another entity of the entity itself" (Vargo & Lusch, 2004). It finds its premises in the proposition that the customer is always a cocreator of value (Maglio & Spohrer, 2008) with a focus on the interaction of the customer and the provider in the value-creating processes. Service science is the study of value cocreation interactions among entities, known as service systems.

The meaning of the customer concept has shifted: from a recipient of a service provided, through being one who participates in creating value in service experiences (Prahalad & Ramaswamy, 2004) to the view of being an active actor who cocreates value in close interaction with a provider (Maglio & Spohrer, 2008; Spohrer, Anderson, Pass, Ager, & Gruhl, 2008). In the medical context, service studies have described the patient as exposed and dependent on the immediate environment and seen as an object in medical discourse (Berry & Bendapudi, 2007; Edvardsson, Enquist, & Johnston, 2005; Lovelock & Gummesson, 2004).

The system of innovation places innovation and learning processes at the center of the focus (Edquist, 1997). This emphasis on learning acknowledges that innovation is a matter of producing new knowledge or combining existing elements of knowledge in new ways. Recently, process innovation and service innovation have been studied as an outcome of system of innovation to emphasize this central dimension of knowledge creation or recombination (Lusch, Vargo, & Tanniru, 2009). This is central in our proposed systemic service model.

By considering the medical imaging industry in the frame of the "sectoral innovation system" (Malerba, 2004), it emphasizes the innovation process as an outcome of learning processes by heterogeneous agents (technological change from firms, clinical practice from medical users). These processes are based on a knowledge base spread around patient diagnosis, disease treatment, and availability of technological solutions, taking place in specific institutional settings that greatly influence the involved agents. In turn, this innovation process transforms the various actors, namely *lead users in medical organizations*, *firms*, and *patients* through the introduction and the diffusion of new processes or practice and this substantially changes the *institutional environment* and the current knowledge bases (technological and clinical).

- *Medical users in medical organizations* (public hospitals and private clinics).
  In healthcare, university hospitals play a major role in expanding the range of uses: by testing for safety and efficacy in clinical trials, university hospitals validate the prototypes or upgrades coming from the rapid rate of technological change (Gelijns, 1991). In our model, medical lead users are primary practicing

physicians seeking for optimal clinical solutions based on a dual combination of technology knowledge from firms and clinical knowledge rooted in their own daily use of medical technology. In that sense, innovation in medical technology emerges as a result of complex processes where people and artifacts recursively influence each other.

The involvement of these physicians in user communities such as professional associations allows medical users to shape perceived merits of new clinical technologies for a broader community of practice (Pisano, Bohmer, & Edmondson, 2001).

- *Firms* (medical imaging manufacturers).
  As previously studied, the American, European, and Japanese medical imaging markets are dominated by a small number of large multinational companies (Gelijns & Rosenberg, 1999). The rate of innovative activity is high, resulting in high-performance improvement. At the initial stage of development, manufacturers deliver privileged information to their medical lead users in order to ask them validating from a clinical standpoint any technology innovation, as previously shown for CT and MR (Das & Ven, 2000). Lately, medical imaging manufacturers tend to ask these privileged users to become local, regional, or global "show sites" where the medical imaging system operates in optimized conditions, under the leadership of opinion–leader physicians, in well-known hospitals and clinics, creating a "word-to-mouth" marketing effect, in order to promote firm's technological innovation (Chatterji, Fabrizio, Mitchell, & Schulman, 2008; Mitchell & Kulwant, 1996).
- *Patients* (individuals and emergent concerned groups).
  Patients combine the dual role of end user (consumer) and supplier, by providing physicians with unmet medical needs that may be emphasized by recently emergent concerned groups (Callon & Rabeharisoa, 2008). Medical innovation does follow a specific path in the sense that technological innovation is not self-selected but rather socially shaped (Williams & Edge, 1996). The meaning of technical efficacy and effectiveness is not sufficient for its adoption in healthcare until some clinical relevance has been demonstrated and legitimated by various actors, from medical doctors to patients through regulatory bodies (Pisano et al., 2001). Consequently, technological innovation in healthcare exhibits a "path dependency" where the set of devices and correlated practices is the result of negotiations over competing firms, regulatory, medical instances, and public interests (Webster, 2002). Our framework helps us as well to understand how technological trajectories and path dependencies in healthcare depend on the coevolution of social institutions and patient needs. The variety in lifestyle across countries drives important differences between various national healthcare systems. In our model, patients capture the overall conditions of a given population and its trends, such as aging phenomenon in Japan, as a possible forcing function for clinical innovation among the various stakeholders in multiple areas (Kohlbacher & Herstatt, 2008).

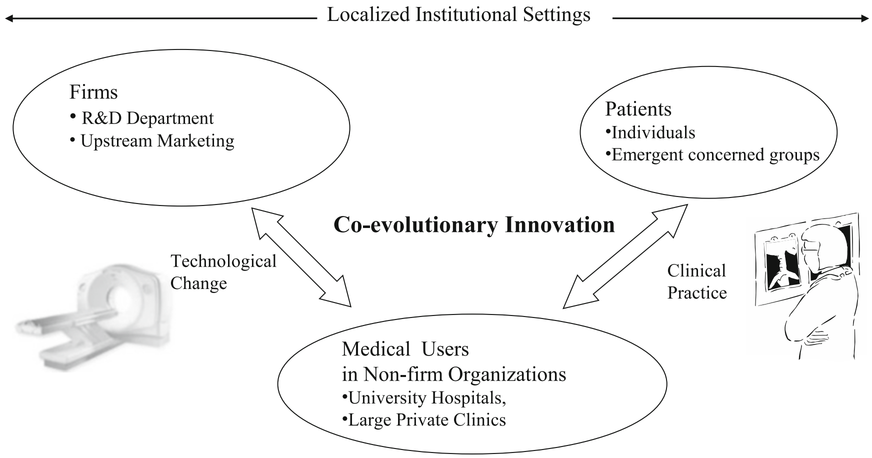


Fig. 4 Description of clinical innovation system

- *Institutions.*
  Localized institutions understood as common rules, norms, laws, and established practices (Edquist, 1997) play a pivotal role to fully appreciate the complexities of medical innovation. Medical innovative solutions are anchored in distinct national healthcare systems that contingent health research and delivery, shaping some diversity from national socialized to private fee-based healthcare systems.

The previous description of the different entities suggests the possibility of a coevolution process in which solution development is generated through interactions between technological change from firms and clinical practice from medical lead users in non-firm organizations that treat patients in localized institutional settings as shown in Fig. 4.

Within the system, agents share some knowledge bases, evolving in time and in location. More fundamentally, we argue that the "clinical innovation system" in healthcare lies at the frontline of patient-care delivery and extends the classical function of clinical researchers, who often assess the impact of basic research and R&D efforts, through clinical trials. Medical users formulate, design, and implement new protocols based on their experience and their history-dependent trajectories of change, clearly spanning across the public-private divide. In turn, they tend to be involved in some paradigm shift occurring in healthcare.

2.5 *Technology in Practice: Clinical Coevolution*

As Nelson argues (2005), technologies are to be understood as involving both a body of practice and a body of understanding. Coevolutionary innovation depends on the contexts of use in which it is embedded and on the differential cost structures generated by the uneven progress of knowledge across pathways of learning in different clinical areas and domains of know-how (Nelson, 2003). The proposed model of innovation suggests that technological advance follows an evolutionary process in the sense that it derives from technological change, clinical practice, and understanding of several actors, beyond a strict planning of a scientific search (Gelijns, 1991). The model presumes that it is determined by consensus of a technological community who are cooperatively involved in advancing the art (Powell, Koput, & Smith-Doerr, 1996) and in exchanging information, as shown in the relational trajectory of medical knowledge through medical publications (Mina et al., 2007).

The coevolution is of firm technology, physicians in non-firm organizations, and unmet patient needs. Because coevolutionary innovation—defined as the joint development and implementation of a new product or service by one firm and at least one medical user to solve patient problems—is characterized by differentiation from firm technological knowledge, accessing medical user knowledge is paramount. This knowledge is difficult to transfer (i.e., “sticky”) because it is rooted in the accumulated experiences of the medical users. More broadly, the model builds on the coevolution of interrelated organizations and the institutional context in which they cooperate in order to produce innovative products and solutions.

The supply-side and the demand-side interact according to a coevolutionary pattern: firms request opinion-leading medical organizations to define their medical-oriented needs. The field study describes the specific elements and some causal drivers of this co-evolution process. This coevolution has two distinct stages or aspects: one, which moves from variation to selection, one from selection to adoption as illustrated in Fig. 5.

This means that the evolution of scanning techniques is essentially interdisciplinary and interinstitutional in nature; that is, it requires the medical profession to create alliances with scientists and technologists, often in industrial firms with expertise in scanning techniques, image processing, and image post-processing. These interactions between clinicians, often in academic medical centers, as illustrated by our field study, and technologists, often in industrial firms, are important for the development of first-generation clinical solutions. Yet in medicine, where research and development (R&D) and adoption are closely linked, the rate and direction of the subsequent improvement process are also linked to the experience of the early medical users and by the effectiveness with which the lead user information is fed back to the device manufacturer.

2.6 Co-Creation Service Innovation Model in Radiology Informatics

This view contributes to bridge service system and lead user innovation in the context of progress in healthcare by focusing on the unique processes linked to user knowledge for incumbent service innovation. Medical users hold potential

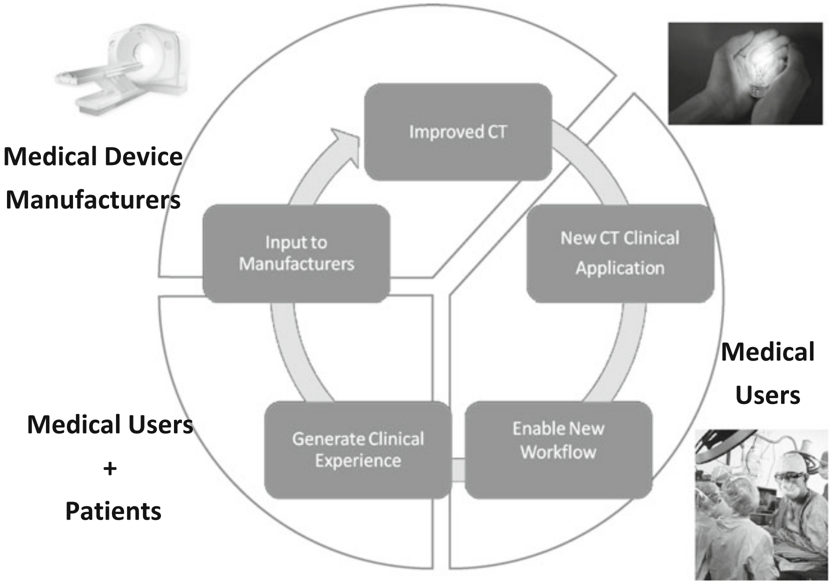


Fig. 5 Coevolutionary process in CT clinical application development

knowledge that is not available from other sources because their knowledge is developed through experience using technological change to treat patients. This knowledge, both in relation to the entity where it is generated and to the interactions among other entities, can impact a firm's future service innovations.

Users have an intimate knowledge of how a product or a service performs in practice (experience), when confronted with the challenges that arise in use, more specifically involving technological change and clinical experience. This may raise issues not envisioned by the technology developers (co-definition), and in turn suggest improvements (co-development), and potential new solutions (co-elevation). We will argue that the service innovation process involving users, namely co-creation of service (Fitzsimmons & Fitzsimmons, 2007) follows two distinct stages: firstly, co-experience and co-definition, secondly co-development and possibly co-elevation, as portrayed in Fig. 6[17]:

Different incentives and organizational routines characterize the heterogeneity of agents involved in the clinical system. For instance, while firms technologically innovate to maximize their profits, medical users may value prestige and patient care as important incentives to clinically innovate. The model supports this variation of incentives as an explaining factor of the existence of the initial phase of co-experience/co-definition. This phase represents the convergence of different incentives through mutual understanding and collaborative efforts: for instance,

[17] Source: Kijima, K, 2009, Tokyo Institute of technology, 18th Annual Conference "Frontiers in Service," Honolulu, HI, U.S.A.

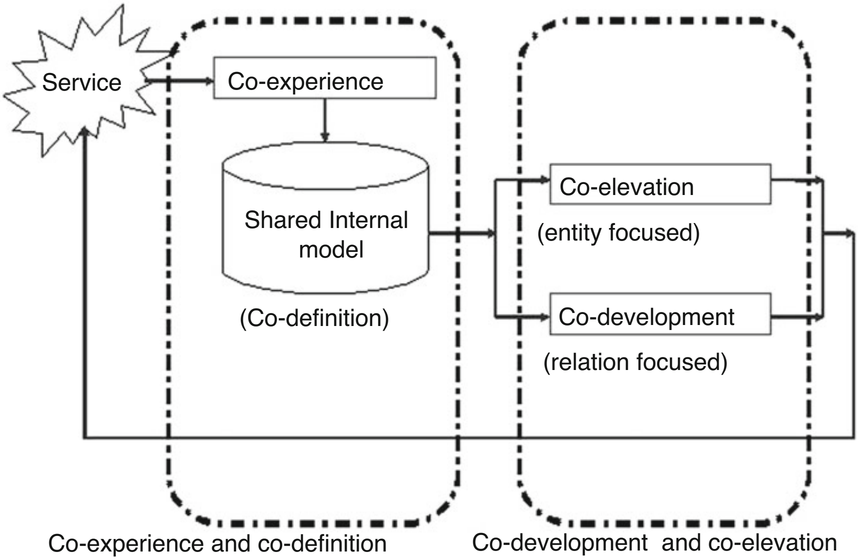


Fig. 6 Service innovation model

clinical efficiency for doctors, transactional efficiency for firm managers, and clinical outcomes for patients.

Technological innovations are shaped not only by firm's history and R&D intensity but also by changes in the public knowledge base triggered by social changes (Williams & Edge, 1996). These changes, often driven by both technology development and new clinical applications, adopted by the masses may be such that the technological foundations of businesses shift dramatically. This may cause the technological knowledge base to converge or diverge. In our medical imaging case, the development of 16-row detector CTs did support the noninvasive CT cardiac imaging procedure by medical lead users in late 2000 (Sablayrolles, 2002), helping the global medical imaging industry to now advocate CT cardiac imaging as a noninvasive routine exam for high-risk patients.

Expanding to a broader range of patients (e.g., low-risk patient, every person), we rapidly face societal challenges such as aging population and more multiple chronic disease burden. For more than two decades, now, electronic health records (EHRs)/ electronic medical records (EMRs) solutions aim to improve the relevance of the diagnosis while increasing the efficiency of the therapy from multiple real-time data sources coming from various actors/systems (devices, IT, clinical inputs. . .) in the acute care setting.

2.7 EMR/EHR as a Future Platform for a Co-Creation Innovation Model?

Clinical data are more than information, and clinical data management at the fingertips of medical professionals drives efficiency and better patient management. Clinically, the next level of integration will drive the development of clinical decision systems targeting a more disease focus through evidence-based medicine including the usage of semantic reasoning engines looking at large databases and the natural language processing capabilities (NLP) transforming unstructured data into structured data. The purpose is to deliver smart, accessible clinically relevant data at the fingertips of the clinicians in various medical areas such as cardiology and oncology. For instance, clinicians will benefit from a “system that automatically get the right relevant information” through context-aware capabilities. This advanced clinical decision support will include clinical pathway management “on the fly,” aiming to cover descriptive and predictive analytics for medical professional.

On the front of the mobility of data, IT technology firms aim to develop new solutions that enable clinicians to focus on their patients, while sharing data across the enterprise. Going beyond the outpatient management, they aim to support the integrated care approach by designing healthcare IT platforms connecting acute care, ambulatory care, and overall care providers. This area of innovation will leverage IT technology components such as cloud deployment and Internet of Things (IoT).

EMRs and EHRs should provide clinicians and patients with all the information they need at the right time, meaning that the IT solution will prepare and present the information easily to be used and digested by the medical professionals. Clinical users expect that IT firms will enrich this information with clinical intelligence and decision support tools, empowering all the different caregivers to make fast and confident diagnosis while actively participating to treatment decisions. This will significantly contribute to the goal of precise medicine, supported by artificial intelligence (AI).

2.8 AI in Healthcare Focusing on People, Not on Pure Technology

Rapid advances in technology are enabling the capture of more data than ever before about the human body and people’s lifestyles, about diseases and their treatments, and about the hospitals and health systems that care for individuals and populations around the globe. However, empirical evidence shows that only a fraction of this data is used effectively to improve the quality and efficiency of care, and to empower people to take control of their own health.

More data do not equal more insight. On the contrary, it can be a burden to people. Consumers with health trackers often do not know what to do with the numbers they are given. With current EMR solutions, clinicians spend more time with machines than face to face with their patients. Additionally, providers are drowning in data but lacking in insights to drive improvements that matter to their patients, staff, and eventually the bottom line for hospitals and clinics. This is where artificial intelligence (AI) can help.

Thanks to advances in computing power as well as inroads in data science, AI methods like machine learning and deep learning are arriving into the mainstream. They can help to make sense of large amounts of data, turning it into actionable insights. However, in healthcare, which is arguably more complex than any other industry, and where lives are at stake, applying AI in a beneficial and responsible way requires more than just heavy number crunching. It also requires an intimate understanding of the personal, clinical, or operational context in which it is used. At the same time, we need to be sensitive to the fact that there is a relentless demand on people—professionals, patients, and consumers alike—to keep adapting to new technology. AI-enabled solutions should make things easier for them, not more complicated.

In medical settings, artificial intelligence combines the power of AI with human domain knowledge to create solutions that adapt to people's needs and environments—helping people to live healthy lifestyles and helping healthcare providers to achieve the *quadruple aim* of improving patient experiences and the work–life of care providers, alongside improved health outcomes for a lower cost of care. Artificial intelligence augments people, rather than replacing them. It acts like a personal assistant that can learn and adapt to the skills and preferences of the person that uses it, and to the situation he or she is in. The technology does not call attention to itself, but runs in the background—deeply integrated into the interfaces and workflows of hospitals, and almost invisibly embedded into solutions for the consumer environment. More and more actors from doctors to firms are shaping a reality today that will become available in the near future from these various research applications.

Firms closely work with clinical partners across the globe—healthcare providers, academia, and hospital networks—to develop AI-enabled solutions that are secure, firmly grounded in scientific research, and rigorously validated in clinical practice:

- Solutions like wearable vital sign sensors with intelligent software that help a hospital to monitor large numbers of patients so that doctors could spot emerging risks.
- Other example, the application that uses algorithms derived from psychological theories of behavior change to help motivate people to stick to their sleep therapy treatments for longer.
- We foresee the development of intelligent dashboards that combine data from various sources, turning them into relevant information that clinicians need to help reduce their cognitive load.

2.9 Toward Population Management and Risk Stratification

Artificial intelligence will also enable clinicians to uncover correlations and patterns in health information to provide predictive care for entire populations. Already today, some cloud-based population IT platforms are developing solutions that can analyze data from patients in a particular town, and recognize which of them should be similar. For example, if a patient does not have a diagnosis code for diabetes, but shows up in a population with similar indicators of diabetes, then that patient might have diabetes.

IT firms are using advanced data science methods to search for patterns and find groups of patients that can be considered similar: IT firms with medical users could then train the algorithm for specific problems to allow clinicians to find the right cluster size and definition.

This population health management (PHM) tool could enable a local doctor to contact their patient in order to advise them on the best course of action, whether that is taking diagnostic tests, or lifestyle changes. In the future, the seamless and effective combination of EMR and PHM solutions could support healthcare systems to deliver value-based care across populations, as well as to gain a greater understanding of potential gaps and inefficiencies.

2.10 Toward Systems of Insights for Physicians and Data Scientists

IT firms support doctors in finding insights in their own healthcare data, if physicians and data scientists want to build their own AI models for medical research. For instance, in radiology, a solution called Philips IntelliSpace Discovery[18] gives them access to advanced analytic capabilities to curate and analyze the healthcare data gathered in their own institution. We know that one of the biggest challenges in implementing artificial intelligence is that up to 75% of healthcare data is unstructured.

Unlike many other industries where the data are relatively clean and normalized, a large amount of clinical information is currently captured in medical notes of various kinds and formats. The lack of interoperability between systems makes it even more difficult to quickly extract the right data. It also poses challenges for the implementation of research solutions into a hospital network.

In radiology departments, this AI-built-in solution, Philips IntelliSpace Discovery is designed to offer an integrated AI solution that enables the entire process of generating new AI applications, providing data integration, training, and deployment in the research setting. The IntelliSpace Discovery Research Suites include tools to

[18] https://www.philips.com.gh/healthcare/product/HC881015/intellispace-discovery

create tailored data analysis and AI solutions in a clinical environment. The easy-to-use research suites for physicians and technicians provide access to state-of-the-art analysis and AI methods, while the integrated development and analytics environments allow direct data access and real-time feedback between physicians and data scientists to enhance collaboration.

In the near future, we may see an extension of this IntellisSpace Discovery solution concept beyond radiology and reaching other clinical domains, leveraging EMR-based enriched data, allowing physicians to get easy access to a whole system of insights.

2.11 Toward Precision Medicine?

Perhaps one of the most promising areas of potential for AI and adaptive intelligence in healthcare is in the field of precision medicine. Since scientists started sequencing the human genome in the 1990s, doctors have predicted the arrival of precision medicine, in which the right patients are matched at the right time with the right therapy to treat their disease.

Such an approach, which is still in its infancy, has particularly far-reaching implications for cancer—a catch-all term to describe a multitude of diseases that will affect one out of two men, and one out of three women worldwide in their lifetime. Scientists are developing an increasingly complex set of options to treat cancer. These range from interventional therapies—such as surgery, radiation, and image-guided therapy—through an increasingly broad range of pharmaceutical therapies, right up to strategies with no or minimal interventions, such as those involving active surveillance or palliative care.

The optimal treatment choice depends on precise diagnosis. Yet in precision medicine, this is critically dependent on the ability to analyze staggeringly large data sets with multiple and diverse parameters—something far beyond any human's ability. This is where AI and big data analytics, coupled with clinical insights can play a crucial role.

To detect the presence of cancer in a patient, they analyze suspicious tissue samples on a glass slide through a microscope to determine if the tissue is malignant. Their typing of the tissue is a crucial component in the staging of the tumor, guiding treatment decisions. With the clinical introduction of digital pathology, it has become possible to implement more efficient pathology diagnostic workflows. This can help the pathologist to streamline the diagnostic process, connect a team, even remotely, to enhance competencies and maximize use of resources, unify patient data for informed decision-making, and gain new insights by turning data into knowledge.

Oncology is a complex medical domain, in which multiple disciplines must collaborate to reach accurate diagnoses and effective treatment plans. Unfortunately, information is frequently lost in communications between specialties and care networks, which can lead to critical information being missed. Prediction models tend to build on nonlocal patient data, which does not accurately reflect the clinical setting. We should foresee future interoperable data platforms able to bring actionable clinical patient information together from disparate data sources, including electronic medical records, lab systems, pathology, and genomics. Although we are at the beginning of our journey into precision medicine, we believe that AI will help clinicians to find insights in the staggering amount of information produced by an individual patient, including their lifestyle, behaviors, physical characteristics, and multiple genetic and nongenetic biomarkers, as well as personal preferences.

Ultimately, we believe this will support an integrated, dynamic healthcare system, in which the patient is a central stakeholder who contributes data and participates actively in shared decision-making. It will allow clinicians at any given time to make a well-informed, confident diagnosis, and—together with the patient—make responsible decisions about the care pathway, designed to yield the best patient outcome.

3 Conclusion

This research investigates the dynamic relationship between health informatics and medical professionals, now and in the future. Drawing upon evolutionary economics and innovation literatures, we propose a co-innovation model that supports the emergence of technology-oriented innovations in the medical device industry. First, we suggest that the *triad* interaction— patient, medical user, and technological change—embedded in the clinical innovation process is the pivotal factor of the innovation itself. Secondly, our research contributes to describe, in a detailed way, the underlying innovation process as a service innovation function, where we define innovation as a service co-creation between heterogeneous agents, namely patients, firm managers, and medical doctors.

Medical innovation is a practice variation to heal patients by improving diagnostic and treatments procedures, fueled by the variability of patients and diseases and supported by technological change, specifically in health informatics.

Faced with an aging population, increasing incidence of multiple chronic diseases, innovative technologies and new powerful drugs, and an unsustainable cost pressure, healthcare stakeholders agree that our global health systems could be improved. Today's healthcare delivery is fragmented, with high levels of clinical waste and unexplained variance in treatment and outcomes—repeat procedures, gaps in information, and long waiting times tell the story of overburdened and under-resourced hospitals. Adding to the challenge are worryingly high staff burnout rates, administrative complexity, and excessive and widely varying prices.

Another complicating factor: our healthcare systems tend to place their focus on acute and emergency episodes—there are limited existing financial incentives for prevention, longitudinal chronic disease management, and population health. Add access constraints and increasingly unhealthy lifestyles in developing and industrialized countries to this mix, and it is clear that healthcare delivery and financing need to change. As a priority, the global healthcare community is urgently seeking strategies and solutions to challenge the status quo—transforming from healthcare systems that are characterized by silos and waste toward integrated, patient-centric and efficient care delivery models.

The future of clinical informatics is centered around addressing the Quadruple Aim—better health outcomes, improved patient experience, improved staff experience, and lower cost of care. In our view, people's health journey should be a seamless, integrated, and highly personalized experience. A journey where every single bit of information adds to a greater body of knowledge which patients, their care professionals, and science and society can benefit from. Our strategy revolves around the health continuum: helping consumers to live a healthy life and take necessary preventive measures when at risk for disease; enabling doctors and providers to make a precise diagnosis and to provide minimally invasive personalized therapy whenever possible; and finally driving monitoring and chronic care in low-cost settings and the home of our patients.

This health continuum needs technology platforms, where interoperability and cloud-based solutions are paramount. Moving forward, strong cloud-based informatics and population health platforms, integrated data management, and adaptive intelligence enable breaking the silos between the different parts of the system, empower patients to take ownership for their own health, and offer new business models to payers. As health systems and medical processes first went digital with electronic health records, clinicians soon found themselves overwhelmed by data that was difficult to understand and interpret.

As shown by our research, health informatics connects clinical practice and patients. With the right configuration and data visualization capabilities, health informatics can enable clinicians to interpret information from multiple sources and inform decision-making in real time. By promoting a co-innovation service approach, our purpose here has been to provide researchers, firm managers, and policy makers with some insights about how innovation develops and about its diffusion. Thinking about these questions, we believe, is an important part of deciding what kind of healthcare we want.

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Translating Evidence into Practice: An Experience with Interprofessional Education (IPE)

Dawn Prentice and Jenn Salfi

Abstract The importance of knowing how to translate knowledge into practice is key for practitioners in clinical settings. The aims of this chapter are: (1) to understand the importance of knowledge translation in the practice setting, (2) to describe the facilitators and barriers to knowledge translation for practitioners, and (3) to provide examples of how knowledge translation was used in an interprofessional education teaching unit.

Keywords Knowledge translation · Interprofessional education

1 Introduction

Today's health care environment is complex with health care services being offered across the continuum ranging from birth to end-of-life care. Inherent in the complexities of the services rendered, is the need for health care professionals to provide quality care based on available evidence, to achieve the best possible outcome. Given the wide availability of information sources, providing evidence-based care is possible, however, discerning the best sources of evidence and knowing how to integrate the findings into practice is the challenge.

2 Knowledge Translation

Discussion about integrating evidence into practice or knowledge translation as it is also known has been around for more than two decades. The Canadian Institutes of Health Research (2016) offers one definition of knowledge translation:

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> Knowledge translation (KT) is defined as a dynamic and iterative process that includes synthesis, dissemination, exchange and ethically sound application of knowledge to improve the health of Canadians, provide more effective health services and products, and strengthen the health care system. (para 4)

The World Health Organization (WHO) (2012) provides another definition of knowledge translation:

> The synthesis, exchange, and application of knowledge by relevant stakeholders to accelerate the benefits of global and local innovation in strengthening health systems and improving people's health. (p. 6)

When examining both definitions certain commonalities are found. Both definitions address synthesis, exchange, and application of knowledge to improve health at the population level, which speaks to the global need to use knowledge to inform and strengthen health care practices and inform policy development.

The language surrounding knowledge translation can be confusing as there are many terms such as research utilization, evidence-based medicine, evidence-based care, and more recently evidence-informed care, which are being used interchangeably. Despite the terminology used, clinicians should be using evidence to inform their clinical decision-making at the bedside.

In Canada, utilizing evidence to inform practice and clinical decision-making is an expectation of all practicing nurses (Canadian Council of Nurse Regulators, 2011; Canadian Nurses Association [CNA], 2018). It is also an expectation that student nurses master this competency during their undergraduate nursing education (Canadian Association of Schools of Nursing, 2015). The intent is to ensure that nursing students understand how to critically appraise research and be able to integrate findings into their clinical decision-making at the bedside, as well as pose research questions based on their practice upon graduation and transition to a novice nurse role.

The Canadian Nurses Association (2018) defines evidence-informed decision-making as:

> . . . the ongoing process that incorporates evidence from research findings, clinical expertise, client preferences and other available resources to inform decisions that nurses make about clients. (p. 1)

The CNA (2018) makes the distinction that evidence-informed decision-making considers more than just evidence. The availability of resources and other contextual factors must also be considered.

3 Importance of Knowledge Translation

Utilizing the most current evidence to provide care contributes to quality care and a decrease in adverse events (Strauss, Tetroe, & Graham, 2009). Moreover, using evidence to inform clinical decision-making has been associated with the development of effective policies and the best use of fiscal resources (Dobbins et al., 2019). Furthermore, the use of evidence-based clinical practice guidelines addresses consistency in patient care and can improve health outcomes (Woolf, Grol, Hutchinson, Eccles, & Grimshaw, 1999).

4 Knowledge Translation: Barriers and Facilitators

Despite the advantages of evidence-based care, there are multiple challenges that must be considered when translating knowledge into practice. These challenges can exist at the individual nurse level, the organization level, or at both levels. At the individual nurse level, barriers to integrating evidence into practice may be attributed to nurses' lack of knowledge in understanding research, interpreting statistical information, or due to a lack of time because of workload pressures in the clinical site (Bradshaw, 2010). Conversely, a nurse's interest in research and regular use of research is a facilitator for using evidence in their practice (Yost et al., 2015).

Yost et al. (2015) found that organizational leadership was a strong theme in the success of implementing knowledge-translation activities. Leaders need to be role models and demonstrate the organization's commitment to implementing evidence-based care (Yost et al., 2015). Furthermore, nurse managers must support a climate that encourages nursing staff to incorporate evidence into their clinical practice (Bradshaw, 2010; Warren et al., 2016), which may entail providing work time for the nursing staff to encourage and integrate best practices (Timmins, 2015).

At the organizational level, there needs to be an easy access to computers and access to databases to facilitate the search of the evidence. In addition, providing staff with in-service education on how to translate evidence into practice may be required (Timmins, 2015; Warren et al., 2016). Warren et al. (2016) further recommend that organizations may need to adopt an evidence-based framework to ensure a successful integration of evidence into decision-making.

5 Knowledge Translation Frameworks

Each day researchers are making new discoveries or interpreting new data that is health care-related and can influence decision-making for patient care. However, moving the research data to a form that it can be widely available for usage in clinical settings and more importantly at the bedside is a challenge. Knowledge translation frameworks provide a process for moving the evidence or research data to the clinical setting. These frameworks provide steps that an organization can use to assist their staff to use the research evidence and incorporate it into their practice setting.

There are many knowledge translation frameworks available to assist with the translation of research into practice. One example is the Knowledge-to-Action Framework developed by Graham et al. (2006) and adopted by the Canadian Institutes of Health Research (CIHR). The Knowledge-to-Action framework outlines three major phases in knowledge creation: (1) knowledge inquiry, (2) synthesis, and (3) products, tools. Seven actions that influence the knowledge creation cycle are also described in the framework. The actions include: (1) identifying the problem/identifying, reviewing, selecting knowledge; (2) adapt knowledge to the local context; (3) assess barriers to knowledge use; (4) select, tailor, implement interventions, (5) monitor knowledge use; (6) evaluate outcomes; and (7) sustain knowledge use (Graham et al., p. 19).

The Promoting Action on Research Implementation in Health Services (PARIHS) (Kitson, Harvey, & McCormack, 1998) is another example of a knowledge translation framework and is based on the idea that knowledge implementation depends on: (1) the type of evidence, (2) the context in which the evidence is being introduced, and (3) the method in which the evidence has been introduced into the practice setting. The PARIHS has been revised and is now known as the i-PARIHS (Kitson & Harvey, 2016). The "i" stands for innovation and describes the focus on implementation. The authors purport that facilitation of evidence uptake in the clinical setting is important to ensure successful knowledge translation implementation (Kitson & Harvey, 2016).

6 Importance of Evaluating Evidence

The benefits of incorporating evidence in health care decision-making at the point of care and at the policy level are evident. Yet there is also the need to evaluate the effectiveness of how the evidence is translated to the practice setting, the methods used to translate the knowledge as well as the outcomes (Bhattacharyya & Zwarenstein, 2009). For example, when planning to implement knowledge transfer interventions, the organization will need to understand what worked, what didn't, and why it didn't. Costs of the intervention should also be considered as part of the knowledge translation evaluation strategy (Bhattacharyya, Estey, & Zwarenstein, 2011). Van Eerd et al. (2011) suggest that organizations carefully consider the measurement properties of the evaluation tools chosen to evaluate the intervention as well as the context in which the evaluation tools will be used. This denotes the importance of having an evaluation plan as part of the knowledge translation intervention strategy (Bhattacharyya et al., 2011).

7 Interprofessional Education—Knowledge Translation in Action

One example highlighting the use of evidence to inform practices in both academic and clinical environments is the implementation of effective interprofessional education (IPE). Research has supported the importance of IPE in developing competencies required for interprofessional collaboration. Effective interprofessional collaboration is essential in the delivery of safe, ethical, and quality health care. Interprofessional collaboration (or interprofessional practice) occurs when a variety of professionals work alongside patients, families, and communities to deliver the highest quality of care, with the ultimate goal of strengthening health and social care systems and improving overall health outcomes (WHO, 2010). Interprofessional education (IPE) aims to develop the competencies required for effective collaboration, namely role clarity, communication, team functioning, and conflict management. These competencies, in addition to an ongoing commitment to provide client-centered care, form the foundation of a collaborative workforce that is prepared to meet the needs and challenges of the current health care environment (WHO, 2010).

8 Interprofessional Education (IPE)

Interprofessional education occurs when students from "two or more professions learn with, from, and about each other to improve collaboration and the quality of care" (Centre for the Advancement of Interprofessional Education [CAIPE], 2002, p. 6). IPE is not a new concept and can be described in the literature as education taking on many different shapes and forms and in a variety of settings. For example, IPE has been successfully delivered via case-based discussions, online and simulation-based learning, and incorporated into anatomy dissection lab environments, as well as into work-based clinical environments. When designing and implementing IPE experiences and opportunities, there are a few key principles that should be considered in order to enhance the effectiveness of interprofessional learning (as identified by CAIPE, 2017). First, IPE should provide the opportunity to learn about one's own scope of practice, as well as that of other professionals. Second, the learning experience should be grounded in mutual respect, and honor the distinct knowledge and expertise that each participant brings to the team from their respective backgrounds. Third, IPE should provide the opportunity for students to develop and refine essential competencies required for collaboration (Centre for the Advancement of Interprofessional Education [CAIPE], 2017).

Another key principle of effective IPE is that it should be integrated throughout a pre-licensure curriculum, and continuously revisited and reinforced as the student progresses through the program and develops as a professional. This continuum should use a variety of pedagogical methodologies, and be planned with intentional, experiential, and shifting goals for each level of the learner (Grice et al., 2018; Salfi, Solomon, Allen, Mohaupt, & Patterson, 2012).

Embedded within these key principles of effective IPE are a variety of competencies (knowledge, skills, and attitudes/behaviors) that are required for interprofessional collaborative practice. IPE competency frameworks aim to provide a common lens through which a variety of professionals can assess, evaluate, and implement evidence-based team practice.

9 IPE Frameworks

There are several frameworks outlining key competencies required for effective interprofessional collaboration that aim to guide and evaluate interprofessional education learning experiences and activities. For the purposes of brevity, we will outline only a couple of these frameworks in this chapter.

On an international level, the WHO (2010) established its commitment to IPE with its publication of the *Framework for Action on Interprofessional Education and Collaborative Practice*, which highlights six key interprofessional learning domains required for collaborative practice: teamwork, roles and responsibilities, communication, learning and critical reflection, relationships with the patient, and ethical practice. Similar to these six learning domains, there are six core competencies outlined in the Canadian Interprofessional Competency Framework (Canadian Interprofessional Health Collaborative (CIHC), 2010), which include team functioning, role clarity, communication, collaborative leadership, conflict resolution, and patient/client/family/community-centered care. Both of these frameworks have been based on research evidence identifying what competencies are required for effective interprofessional collaborative practice, thereby providing viable and sufficient evidence to inform the implementation of effective interprofessional education experiences.

10 Interprofessional Education Experiences

One example of evidence-based practice in IPE, or knowledge translation in action, was the planning and development of an Interprofessional Education Clinical Teaching Unit in a Canadian community hospital. A steering committee comprised of 10 members with representatives from three academic partners and a variety of hospital stakeholders, met together for several months to plan and develop an innovative clinical teaching unit focused on offering effective interprofessional education experiences to a variety of pre-licensure health care students. The main objective of this unit was to integrate interprofessional education into core training for all involved professions in the clinical setting for the purpose of developing competencies required for effective interprofessional collaborative practice, while simultaneously providing high quality, patient-centered care.

The IPE unit provided opportunities for students to work together through various interprofessional activities and dedicated time was provided for the students to learn together. All health professional students participated in interprofessional experiential activities that included daily bullet rounds (team meetings) where all students were expected to share clinical information and discuss their patients. Often these rounds were focused on the discharge of a patient and were facilitated by one of the team members. Another opportunity for interprofessional learning in this clinical unit involved student presentations of cases of observed and/or experienced interprofessional collaboration, in which the group as a whole would then identify and discuss both barriers and facilitators to collaboration in such cases. One final example of a mandatory IPE activity on the clinical unit included regularly scheduled presentations on a variety of professional roles to enhance student knowledge of their team members and each professional's scope of practice.

11 Evaluation of IPE Experiences on the Clinical Teaching Unit

11.1 TOSCE Study

One evaluation tool (also a learning activity) that was used on the IPE unit to assess whether or not the students were acquiring the essential competencies required for interprofessional collaboration was the McMaster-Ottawa *Team Observed Structured Clinical Encounter* (2010) (also known as TOSCE). This tool was developed by the University of Ottawa and McMaster University in 2006. The TOSCE uses a simulated team environment to promote assessment and learning of interprofessional collaborative skills based on the Canadian Interprofessional Competency framework (CIHC, 2010). Through structured simulated team encounters, students involved in TOSCEs can practice and gain skills and receive formative feedback.

Initially, as a learning activity, all of the educational stakeholders agreed to have their students participate in the evaluation of interprofessional competencies using the TOSCE at least once per semester at the end of the students' clinical rotation. Using a cross-sectional design to evaluate students' satisfaction with the TOSCE, a six-item questionnaire was developed for the evaluation study that also included a few open-ended questions (Prentice et al., 2019). Fifty-five students participated over a 2-year period. Ninety percent of the student participants said they would recommend participation in a TOSCE to future students and also recommended that more students were needed for the TOSCEs.

Analysis of the student participants' comments provided the following themes for the strengths of the TOSCE: the ability to consolidate interprofessional knowledge and skills, the TOSCE assisted with understanding the different roles and scopes of practice. Also, participants were satisfied with the TOSCE as a way of evaluating interprofessional competencies.

The student participants noted several difficulties in setting aside time during a busy clinical day to participate in the TOSCE and discussed the need for more details in the TOSCE scenarios. Student participants also wanted the inclusion of other professions, such as dieticians and pharmacy. Moreover, student participants also suggested that the TOSCE scenarios would be more realistic if a simulated patient was part of the TOSCE.

11.2 Staff Perceptions' of IPE

Although there have been studies that examined students' experiences of IPE, there are not many that focus on staffs' perception of interprofessional education. A study that examined staffs' perception of IPE was the first study conducted on the IPE unit (Prentice, Jung, Taplay, Stobbe, & Hildebrand, 2016). The Assessment of Interprofessional Team Collaboration Scale (AITCS) developed by Orchard, King, Khalili, and Bezzina (2012) was used to survey the staff on the IPE unit and collect data on their perceptions of interprofessional collaboration within the unit. The participating staff reported that they respected each other, but felt that they needed more organizational support to further develop their team skills and noted that they needed additional time for team reflection and to make adjustments to team processes. Educational strategies to assist the staff working on the IPE unit were implemented based on the findings from this study (Prentice et al., 2016).

11.3 The Impact of the IPE Unit Study

The aim of this pilot qualitative exploratory case study (Salfi, Prentice, Podwinski, Triemstra, & Hildebrand, 2019) was to enhance understanding of the influence of the IPE unit on the development of collaborative competencies of health and social care students. Grounded by the national collaborative competency framework (CIHC, 2010) this study collected data using a pre/post online open-ended survey measure to assess for change in how students practiced and provided client care (interprofessional approach vs. uni-professional approach). Student participants ($n = 42$) from nursing, rehabilitative sciences, and medicine were recruited using purposeful sampling strategies, and data were analyzed to reveal a number of key findings. First, it was revealed that there were no significant changes in students' approach to care planning and patient care (only in 20% of participants), but there was significant change reported in the use of collaborative language (70%) and change in knowledge regarding the requirements/facilitators for interprofessional collaboration (90%).

Key themes that were revealed from the data in this study described the importance of communication and respect, the importance of dedicated time and opportunities for IPE, the importance of mentors and role modeling in IPE, and the ongoing battle with professional stereotypes despite IPE. The study called for the ongoing investigation of learning outcomes from student experiences on the IPE unit to ensure that the unit is maximizing this unique learning experience for the students and preparing them for effective interprofessional collaborative practice as planned.

12 Conclusion

Interprofessional education is an essential component in developing the competencies required for effective collaboration. This chapter has provided a brief overview of the importance of knowledge translation, using experiences of interprofessional education to highlight the research—knowledge translation—research continuum. The collection of evidence should always precede decisions concerning clinical and educational practices, and once best practices have been implemented, evaluation should continue to collect evidence on its effectiveness, feasibility, and efficiency. This continuum ensures that the best evidence is always informing decisions made on how best to prepare a collaborative workforce that is able to respond to the challenges and complexities of the current health care environment.

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Realities and Challenges of Bridging Research in Japan

Katsumi Fujitani, Takeshi Yamada, Koichi Makimura, Yoko Mano, and Nobuhiko Furuya

Abstract In Japan, bridging research and practice, also referred to as "bench-to-bedside research," has not been actively conducted for many years. In recent years, competition in the medical field has intensified, particularly in the pharmaceutical field, as foreign companies have entered the Japanese market through M&A and Japanese companies have promoted integration and reorganization. In the pharmaceutical industry, small- and medium-sized companies struggle to keep up with the competition due to increased development costs and prolonged R&D periods. This chapter introduces a successful case study of clinical bridge research, especially in relation to product development in the Japanese pharmaceutical industry. We also point out various problems such as frustration in filing patent applications, funding challenges, and complicated clinical trial procedures. The purpose of this study is to clarify the overall status of bridge research in Japan with respect to the issues raised.

Keywords Bridge study · Dermatophytosis · Patent · R&D · Commercialization

1 Introduction

1.1 Background

Translational research (TR), also known as bridge research, selects promising seeds generated from basic research results at universities and other types of research

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institutes, and verifies them in nonclinical and clinical trials to create new commercial products. TR is defined as bridge research that leads to practical applications such as medicines and medical technologies for physical experiments or therapeutic interventions.

In recent years, the development of genome science and regenerative medicine has led to substantial progress in basic research for the realization of new therapeutic methods using genes and cells, but most results have not been put to practical use. We infer that various issues are unique to the system in Japan. This chapter introduces a successful, but challenging, industry-university joint research case in Japan, and highlights the various issues raised from this case.

1.2 Present Situation of TR in Japan

The probability of success in drug development is quite low, and often more than 10 years of research and development (R&D) and more than 100–200 million USD of R&D expenses are required (Ohno, Nagai, & Fukushima, 2010). Patents have a very large impact on R&D. In general, consumer products involve hundreds to thousands of patents per product, and then one basic patent and many peripheral patents are required to bring one product to commercialization. The patent application should be filed before marketing, which inevitably results in increased time and effort because the patent examination period in Japan is extremely long. In the case of pharmaceuticals, therefore, counterfeit products may circulate in the market before patent examination results are obtained. In other words, in the field of drug R&D, the flow of formulating and promoting R&D strategies based on patent strategies is challenging, and under such circumstances, many Japanese pharmaceutical companies face fierce international competition.

A “government initiative” has led to the adoption of treatment themes in various fields in Japan, including research themes for treatment seeds and the establishment of clinical trial bases. However, the government initiative covers therapeutic drugs and treatment methods for a wide range of diseases and fosters an environment that promotes extrapolation into any area from the seeds to patients care, with the proposition of bridging research from basic to clinical. Furthermore, in terms of government funds, the impression that the total budget is relatively small cannot be denied. In today’s internationally competitive environment, the strategy of industry, government, and academia working together to launch new therapeutic drugs, devices, and treatment methods must shift significantly (Tanaka, 2010).

2 Clinical Issues in Basic Medical Research in Dermatophytosis

2.1 Epidemiological Background of Dermatophytosis

Dermatophytosis, which is a common infectious disease of the keratinized tissues in the skin, hair, and nails, is caused by dermatophytes (Osborne, Leitner, Favre, & Ryder, 2005) and affects a large proportion of the population (Vander Straten, Hossain, & Ghannoum, 2003). There are three known genera of dermatophytes: *Epidermophyton*, *Microsporum*, and *Trichophyton.* Among these, *Trichophyton mentagrophytes*, *Trichophyton tonsurans*, and *Trichophyton rubrum* are the most common pathogens, with *T. rubrum* being the most prevalent isolated organism (Osborne et al., 2005). *T. rubrum*, among other dermatophytes, is a major causative agent for superficial dermatomycosis like onychomycosis and tinea pedis (Kemna & Elewski, 1996). These studies suggest that the scattering rate is very high, more than 65.0%, from patients suffering from tinea pedis. Our epidemiological survey targeted 160 people in 2016 and found that the scattering rate of *Trichophyton* species on feet is very high 29.3%, and 55.6% in the elderly population older than 60 years (Suzuki, Fujitani, et al., 2018a, 2018b). Nevertheless, especially in special nursing care homes for the elderly, no appropriate treatment is available, and cases were found in which the wrong antifungal drugs were administered. The potential for the development of drug-resistant fungi that is promoted by misuse of antifungal drugs is a concern.

Overall, clinically, about 20% of the population is reported to have *tinea pedis*, and about 10% have *tinea unguium* in Japan. More than 13% of new dermatology patients have ringworm; the frequency of each type is as follows: foot ringworm is approximately 64%, nail ringworm 20%, body ringworm 7%, and hip ringworm 5% (Onozaki, Makimur, et al., 2009). If limited to foot skin diseases, 40% of cases are tinea pedis. Regarding direct infection from animals to humans, *Trichophyton verrucosum* is found in cattle handlers including dairy farmers, and *Microsporum canis* from cats as companion animals, and *T. mentagrophytes* from rabbits or rodents are present. Body ringworm by animal type and head ringworm are the main problems. A characteristic of ringworm due to estrogenic fungi is that symptoms are often mild or asymptomatic in the host animal (Yamada, Makimura, et al., 2006).

2.2 Emergence of Resistant Fungi

In recent years, filamentous fungi with low sensitivity to antifungal agents have been reported in various countries. NFI5146 shows cross-resistance to naftifine, an allylamine antifungal agent, and butenafine, a benzylamine antifungal agent (Mukherjee et al., 2003). Allylamine and butenafine antifungal agents inhibit squalene epoxidase, which is part of the ergosterol synthesis pathway (Favre & Ryder, 1996). *T. rubrum*, which is less sensitive to terbinafine, was first found in Japan (Suzuki et al., 2018a, 2018b). Allylamine and benzylamine antifungal agents specifically inhibit squalene epoxidase, which is part of the ergosterol synthesis pathway (Favre & Ryder, 1996), and block the synthesis of squalene epoxide from squalene, resulting in accumulation of toxic levels of squalene and decreased levels of ergosterol production, finally leading to rapid fungicidal activity (Leyden, 1998). Like terbinafine, itraconazole, an azole, inhibits the growth of fungi by interfering with the synthesis of ergosterol in the cell wall, but works at a later step than terbinafine and blocks the formation of ergosterol from lanosterol (Leyden, 1998). Thus, the mechanism of action between terbinafine and itraconazole differs, and unsurprisingly, cross-resistance to itraconazole was not observed in terbinafine low-susceptibility isolates. Based on the results of these studies, we suggested that the mechanism of resistance in terbinafine low-susceptibility strains may be due to the loss of sensitivity to squalene epoxidase inhibitors meaning that antifungal drugs with different mechanisms of action may still be effective.

2.3 Purpose of Basic Medical Research

To explore the mechanism for developing antifungal agents against these resistant fungi, application of cloning technology using genetic analysis is the key. For these ringworms, many therapeutic drugs and symptom-relieving methods have been proposed, but eradicating ringworm fungi that have parasitized the skin stratum corneum is difficult, and fundamental treatment methods have not yet been established. The most important issues are the cloning and transformation of genes involved in the invasion factor (pathogenic factor), the regulatory factor of ringworm, and the establishment of gene disruption. In other words, to develop a tool for the creation of animal models of ringworm, pathological and ultrastructural analysis of ringworm can be used to elucidate the pathophysiology and the invasion factors that are possibly involved in the pathogenesis of ringworm and the mechanisms of infection (Yamada et al., 2017).

3 New Technologies

3.1 Challenges and Solutions

Gene disruption is difficult in ringworm because (1) the transformation efficiency of the gene disruption vector is low and (2) the frequency of homologous recombination occurring between the target gene and the vector is low (Yamada, Makimura, et al., 2009). In ringworm, gene destruction and introduction are difficult, and gene function analysis is nearly impossible. In many pathogenic fungi other than ringworm, when analyzing a factor that is thought to be involved in pathogenicity, a mutant strain (gene-disrupted strain) is created in which gene encoding the factor is artificially deleted. Then, a comparative analysis is performed with the wild-type strain. However, creating such a gene-disrupted strain of *Trichophyton* is not easy. No factor has been experimentally shown to be pathogenic, and no etiological factor has been identified. This is the major reason underlying the inability to establish treatment methods (Yamada et al., 2009).

3.2 Features of New Technology and Comparison with Conventional Technology

Yamada et al. isolated a Ku80 ortholog of *T. mentagrophytes* and produced a Ku80 disruption mutant using targeted gene disruption. The Ku80 mutant showed a high frequency of target gene disruption at two independent chromosomal loci, but no phenotypic changes were seen. Therefore, these mutants have great potential for large-scale molecular genetic studies of dermatophytes including *T. mentagrophytes*. With conventional technology, the homologous recombination frequency that occurs between the target gene and the transfer vector is extremely low, and gene disruption and transfer are difficult in ringworm, so analyzing gene function was virtually impossible. The development of a gene-disrupted ringworm (Tmku80) has allowed the introduction of a new gene in ringworm. This enabled analysis of resistance to virulence factors and antifungal drugs (Yamada, Yamada, et al., 2014).

4 Other Issues for the Commercialization (Practical Application Process)

Currently, stable gene disruption and gene insertion are possible for ringworm. However, the method has not been commercialized because the following points need to be resolved ((1)–(3)). Discovery and selection of target molecules by promoting basic research for practical application are needed. Table 1 shows the

Table 1 Historical background from the basic research to the application stage

History of industry–academia collaboration	
1994–2000	Joint research with Toyobo Gene Analysis
1995–2000	Adopted by the New Energy and Industrial Technology Development Organization Commission (Proposal Open Call/Advanced Research and Development Project)
1998–2000	Japan Space Forum selected for public ground research on utilization of space environment in 1998
2007–	Japan Aerospace Exploration Agency joint research on microbiota in the space station
2012–	Joint research with World Geno-matrix
2015–	Joint research with Airy Technology Co., Ltd.

historical background involved in development. Through this research project, it has become clear that industry–university collaborative research in Japan is not open at all but has many closed parts.

(1) R&D tool sales and the analysis service implementation platform are not readily available for use.
(2) No specific drug development candidates have been determined for ringworm or related advanced pathogens.
(3) The matching system, which connects research institutions (academia) and venture companies, is underdeveloped.

5 Barriers to the Commercialization of Pharmaceutical Products

For academia to continue TR and operate independently, the formation of an R&D pipeline is needed that can raise funds. R&D including TR is essentially a patent business and thus funding, commercialization, medicalization, and so on depend on the strength and scope of patents. The success of R&D pipeline formation in academia depends on patents. A researcher at a government-affiliated TR center gave a speech about two international barriers that are present in government policies advocating for science and technology: financial issues and the patent system in Japan.

5.1 Financial Issues

Grants-in-aid: The Japanese government provides financial aid, also called KAKEN (Grants-in-Aid for Scientific Research), which consists of competitive funds intended to significantly develop all scientific research (research based on the free ideas of the researcher), from basic to applied research in all fields, ranging from the humanities and the social sciences to the natural sciences. The grants provide financial support for creative and pioneering research projects that will become the foundation of social development. The research projects are selected using a peer-review screening process (screening by multiple researchers whose field of specialization is close to that of the applicant). However, in Japan, many research funds are managed under the leadership of the government, and the amount is not sufficient. The budget of the "Bridged Research Acceleration Network Program" was implemented by the Ministry of Education, Culture, Sports, Science, and Technology until FY2014, and from FY2015 by the Japan Agency for Medical Research and Development as subsidized and commissioned projects. The total budget executed by the Japanese government is shown below (Table 2). However, the cost of drug

Table 2 Governmental funding in 2012–2016

2012	3.27 billion yen (six sites and support organizations are continuously selected, one site is newly selected, Seeds B 5 issues, and Seeds C 6 issues support issues are newly selected)
2013	2.97 billion yen (newly selected support issues for Seeds B 12 and seeds C 4)
2014	6.51 billion yen, adjustment costs 1.61 billion yen (newly selected support issues for Seeds B 35 issues, Seeds C 24 issues, and two new bases)
2015	6.0 billion yen, adjustment costs 1.62 billion yen (newly selected support issues for Seeds B 30 issues and Seeds C 19 issues)
2016	6.0 billion yen, adjustment costs 1.20 billion yen (as of July 7, newly adopted support issues for Seeds B 12 and Seeds C 11 issues, excluding adjustment costs)

development is estimated to be between 10 billion and 20 billion yen, and these amounts are not expected to be sufficient.

Recent data on the production of scientific papers by the country point to an overall decline in Japan's capabilities to pursue scientific research. A major problem has been that the government's policy toward higher education, particularly cuts to funding for basic expenses, has weakened the foundations of scientific research (News Release: The Japan times, 2017). On the other hand, universities have a negative effect because they neglect education due to heavy pressure to generate research funds (Hunter, 2013). The availability of public research funds not only affects the aspect of promoting research but also relates to the crisis of education itself.

5.2 *Patent System in Japan*

A patent right is the right to protect an invention, and at the same time, the publication of the invention promotes further technological progress and promotes development across an entire industry. Thus, a patent is an extremely important right for the inventor and the company, because it enables the recovery of R&D investment and the reinvestment for new discoveries. In particular, in the case of the pharmaceutical industry, the role and importance of a patent as a means of ensuring technology exclusivity are higher than in other industries.

The term of a patent in Japan is 15 years from the date of publication of the application and is not allowed to exceed 20 years from the date of filing (Fig. 1). On the other hand, the duration of a patent in the United States is 17 years from the establishment of the right, but it is 20 years from the filing date due to revision of the Patent Law (1995). Regarding pharmaceuticals, the duration of a patent right is substantially shortened by the need for a clinical trial or a test for ensuring safety, and thus, the patent right period is extended by a patent right extension system. In Japan, a maximum period of 5 years is allowed for the shorter period "from the clinical trial notification date to the manufacturing approval date" or "from the patent registration date to the manufacturing approval date". Therefore, Japan's real patent validity

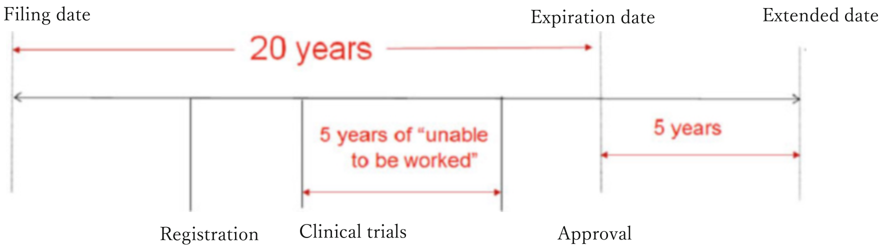

Fig. 1 Japanese patent application system for drugs and other chemicals

period is about 2 years shorter than the United States patent validity period, including the extension period.

Many companies now have patent-specific departments that function as part of their strategy, but Japanese academia does not have such strategic departments or such departments have weak, if any, functions with a few exceptions. Other issues about patent strategy even after filing are also present. Some patent issues include:

- What if the paper was given priority and published before the first application?
- What if the first application is a little late?
- What if I do not make any extra comments after applying?
- What if I do not make an effort to find out what the other party is saying?
- What if a small amount of useful data is added early?
- What if the patent was not granted early?

The problem is that, except for a small number of universities, many local universities (mostly small, private universities) and research institutions do not have any information or knowledge about intellectual property. Many researchers do not know who is available for consulting with them about these issues. The certificate (below) shows that the study cited in this chapter has been fortunate in terms of patent filing. The following patent gazettes of patent applications related to this research are shown as samples (Fig. 2). On the other hand, for companies that put patents into practical use, especially small- and medium-sized venture companies, a business model has not been established as they do not have any pipeline with the universities (Asano et al., 2018).

6 Discussion

Even in this case of bridging research, actual product development has not yet been achieved. We must consider what constitutes real barriers in this respect. In this case, development has proceeded to the stage of stable gene disruption and gene insertion for ringworm, but the developers pointed out the following barriers to commercialization: (1) no platform exists as an R&D tool and (2) drug development of a specific candidate has not been decided. For practical use, discovery and narrowing down of

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(57)【特許請求の範囲】
【請求項１】
白癬菌Trichophyton mentagrophytes TIMM2789株のku80遺伝子ホモログであるTmku80遺伝子を相同組換えによって破壊したTmku80破壊白癬菌＃49株（FERM AP-21532）。
【請求項２】
白癬菌の病原因子を探索する方法であって、請求項１に記載のTmku80破壊白癬菌＃49株（FERM AP-21532）の任意の標的遺伝子を相同組換えによりさらに破壊し、この標的遺伝子破壊白癬菌と野生型白癬菌とを比較して、標的遺伝子破壊白癬菌の病原性が消失または低下した場合に、標的遺伝子がコードするタンパク質を病原因子として特定することを特徴とする方法。

(Original Copy)

Patent Gazette

Japan Paten Office (JP)　Patent No. P4837702
Date of issue:2011.12.14　Date of registration:2011.10.7

Application No.: P2008-111432 Date of Application :2008.4.22 Patent publication No.: P2009-261255A Date of publication:2009-1112	Patent holder: 399086263 Teikyo University (Tokyo) Attorney: 100093230 Nishizawa, Toshio Prior inventor: Makimura, Koichi, Teikyo University Prior inventor: Yamada, Takeshi, Teikyo University Prior inventor: Abe, Shigeru, Teikyo University

Name of Patent: Gene disruption Trichophyton

The scope of patent claims:
Claim 1: Tmku80-disrupted ringworm # 49 strain (FERM AP-21532), which includes homologous recombination of the Tmku80 gene, a ku80 gene homolog of *Trichophyton mentagrophytes* TIMM2789

Claim 2: A method for searching for pathogenic factors of ringworm fungus, further destroying any target gene of Tmku80-disrupted ringworm # 49 strain (FERM AP-21532) according to claim 1 by homologous recombination. A method characterized by identifying a protein encoded by a target gene as a virulence factor when the pathogenicity of the target gene-disrupted ringworm is lost or reduced by comparing the ringworm and the wild-type strain ringworm.

(Translation)

Fig. 2 Japanese patent gazettes

target molecules by further promoting basic research are necessary. Although major research institutes and universities have TR platforms, connecting research results to business by many minor institutes is difficult.

6.1 Platform

Regarding the platform, from the viewpoint of promoting basic research, a data center that collects practical research results will be useful. An example of this is the academic research organization supported by the Japan Agency for Medical Research and Development in Japan (Fukushima, 2016). However, basic research data should not be limited to Japan, but research results from many overseas research institutions should also be collected (Sutton et al., 2019). The creation of such an international consortium should also be considered in the future.

6.2 Project Management

Especially in Japan, universities have a history of avoiding involvement in the business. By definition, educational institutes are not centers for economic activity and are not legally placed to do business. School corporations are non-profit organizations. In recent years, some for-profit organizations have been approved to establish schools (2004), but many universities are still nonprofit organizations. For this reason, few organizations have human resources who can implement project management as a business. Therefore, of course, departments do not exist that support procedures such as connecting research results on campus to businesses. Clearly, researchers with little business experience do not have the skills to perform project management. TR has been defined as the "process of applying ideas, insights, and discoveries generated through basic scientific inquiry to the treatment or prevention of human disease" (Morrison, 2010). According to the TR framework, research is conducted on a collaborative basis with the goal of discovering cures or therapies for patients (Valenti et al., 2016). The process requires various types of specialized knowledge including patent application, product development, production management, and cost calculation. These functions may be difficult at individual universities, and thus, I think that a third-party specialized institution should be developed as a shared facility.

Here, we looked at the actual bridge research situation in Japan by examining one case of research to product development. However, many issues remain to be solved. The many research seeds from small academic institutes are disappearing or being buried, and many venture companies are unable to find the seeds from many academic institutes. The following strategies should be considered:

- Faster priority rules in patent application.
- Faster rights acquisition through an accelerated examination.
- Open resources to academia (deposit to non-profit organizations).
- Development of new basic and applied technologies using funds obtained from a matching system.
- Licensing strategy by industry with the founding venture as a business base.
- Strategy for intellectual property, including publicity for universities that disseminate research results and cross-licensing with competing patents, and so on.

The government, although limited, has spent much effort and time on this issue in recent years. In view of this situation, since 2012, the Japan Science and Technology Agency (JST) has built a new platform and initiated the matching structure (JST (2012): www.jst.go.jp/tt/EN/2012.03). However, because the root of the problem lies in the outlook on higher education in Japan itself, the relationship is complicated, and space limitations preclude a lengthy discussion. One point that needs to be clarified is that in Japan, research administration is under the jurisdiction of the Ministry of Education, Culture, Sports, Science, and Technology, and industrial development is under the control of the Ministry of Economy, Trade, and Industry. Therefore, many barriers are present, including budget issues and patent issues. The TR strategy is not limited to the government's TR strategy. After the establishment of a higher education institution, a graduate school research system, and a flexible pipeline with industry, an R&D pipeline was formed, and revenue from licensing out can be generated. Furthermore, continuing to invest to ensure the stability of specialists and infrastructure development will be possible. For that purpose, student education is important from the viewpoint of securing promising personnel in the future, and the development of a curriculum at the graduate school level is considered effective.

The establishment of a full-scale bridging research system in Japan began in 2005 with the promotion of molecularly targeted drug development for cancer treatment. In 2006, the Basic Act on Cancer Control was enacted, which included the promotion of cancer research. Because about 30% of deaths are due to cancer, and about 50% of people currently suffer from various forms of cancer, this research project was an urgent issue. The government has been increasing the budget for cancer research every year (Fig. 3).

In the United States, on the other hand, the Clinical & Translational Science Awards (CTSA) were launched in 2006 to promote TR for various diseases. In particular, the human genome project, which was completed in 2003 when the genome sequence was revealed, was expected to promote TR for cancer. The cancer genome project, "The Cancer Genome Atlas (TCGA)", was started in 2006 to comprehensively identify genetic mutations that selectively occur in cancer, with a budget of nearly 40 billion yen. In 2014, a large-scale brain project (BRAIN Initiative) was started, with a total budget of about 200 billion yen. The recent cancer genome project has become a major pillar of United States TR in the oncology field to bridge the gap between basic research and clinical trials. Although this is only a comparison between Japan and the United States, the research budget in Japan is quite small because it is almost the same as the research input cost in the

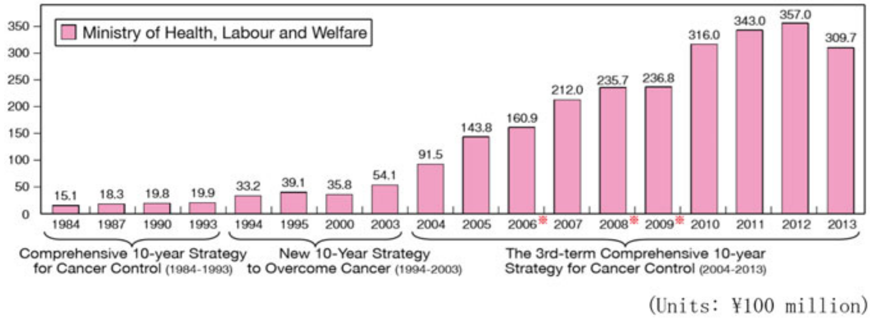

Fig. 3 Trend in the budget for cancer control (Division of Cancer Control and Health Promotion: Health Science Bureau, Ministry of Health, Labour and Welfare)

United States or other OECD countries compared to all government budgets for cancer control. In Japan, the industry–government–academia system is not sufficient.

7 Conclusion

In 2001, the Ministry of Education, Culture, Sports, Science, and Technology created the first TR centers in Japan at Kyoto University and the University of Tokyo. The TR infrastructure development project started in 2002, but project management was not applied until the cancer TR project started in 2004. The path from the development of new drugs and new technologies to commercialization is long and steep. The steps from basic research to clinical research, securing necessary funds, and applying for patents are complex. Application technology, development, and marketing also require careful consideration. Another problem is that no specialists are available who can manage them centrally. Many research institutions and universities lack the necessary human resources for project management. The issue of how to put basic research in academia on the TR track toward product development depends on the establishment of an organization that can promote project management, such as the National Cancer Institute/ Developmental Therapeutics Program (n.d.) (NCI/DTP) in the United States (NHI: NCI/NIH http://dtp.ndi.nih.gov/index.html2019.09). In Japan, the framework for government-led TR is almost complete, but the problem is the promotion of TR led by the private sectors. Industry–government–academia collaboration is not fully functional compared to other developed countries. There are many possible reasons, but one is thought to be due to vertically divided administration. The budget is divided by the executive branch, with academic funding from the Ministry of Education, Culture, Sports, Science and Technology; industry funding from the Ministry of Economy, Trade, and Industry; and medical care funding from the Ministry of Health, Labour and Welfare. In addition, nothing facilitates mutual information exchange. Actually, companies have a lot of information to meet the needs of society, but a limited number of companies have a management department that links collaborative relationships such as conducting necessary basic research based on that information. In conclusion, a third institution should be responsible for project management that connects academia and companies. In the future, we should also consider and discuss how project management should be performed in the area of TR.

As argued in this chapter, a shortage of preparation resources is present, such as platforms to promote TR in life sciences in Japan. More importantly, however, is the lack of a leading development strategy for the entire Japanese industry, and how the industry–government–academia collaboration will be positioned in this process remains unclear. Particularly in the field of pharmaceutical manufacturing, companies face intense global competition. Creating innovative products from the development and production of only one company is almost impossible. For the development of molecularly targeted drugs in cancer therapeutics, information at the gene level is necessary. Regarding genetic information, Merck has released such information, called the "Merck Gene Index", which is generally free to universities and companies for pharmaceutical development. Thus, the term "open innovation" has been used for a long time in the computer program and Internet industries, but "open innovation" is no longer an essential concept in the life science industry. The Merck case just described is an example of "open innovation" (Chesbrough & Appleyard, 2007). Gary also states that Merck's strategy is clear: "Merck expected to capture value in its downstream drug development activities and wanted to create a more open source of inputs in the upstream process of identifying potential areas to investigate."(Pisano, 2006).The idea of open innovation is important when promoting innovative TR. For different types of industries to be integrated into this open innovation platform, the strategic position of both companies and universities needs to be clarified. Even for the case introduced in this chapter, I think it is necessary to develop a strategy from the viewpoint of business continuity and examine what needs to be done. Based on that conclusion, properly determining what technologies companies require and to move compounds into the product pipeline may be possible. In the future, building a data bank and matching system from the viewpoint of open innovation on a private platform that promotes a pipeline that connects research institutions such as universities and product development by companies will be necessary. However, both the university side and the company side will need to carefully engage in strategic thinking about introducing the concept of project management and how to position themselves effectively.

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Current Status and Issues with Japan's Community-Based Integrated Care System: Health Information System and Health Information Exchange System Framework

Kimiko Katsuyama, Ken Kato, Yukinori Murata, Takashi Yoshinaga, Fumiaki Yasukawa, and Akinobu Nemoto

Abstract Despite superior health indicators (life expectancy at birth), Japan's medical care system faces problems of financial burdens and changes in disease structure associated with a declining birthrate and aging population. Reform directions include: (1) maintenance and promotion of health, prevention of disease, and promotion of early detection; (2) promotion of differentiation and collaboration among medical functions (community medicine concept); and (3) establishment of "Community-based Integrated Care System (CICS)." We examine CICS, Health Information Systems, and discharge summary problems. The traditional medical care system has been shifted to home healthcare and nursing care systems for the elderly. Despite Japan's transition to the Electronic Medical Records (EMR) system in 1999, and the introduction of a regional medical network, current systems are vague and costly; standardization of health information content with a simple and affordable system is needed. We focused on transfer and discharge processes. Discharge support nurse managers expressed difficulties preparing discharge summaries due to "differences in values between hospital and home-care nurses," "lack of communication and standardized terminology," and "reduced assessment ability by the Electronic Hospital Information System." The Databank As Solution for your Care and Health (DASCH) project (Ariga, H. *Iryo Business to ICT System [Healthcare Business and IT System]*. Chuo University Press, Tokyo, Japan, 2017) presents solutions via opportunities to emphasize communication in the community.

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1 Introduction

Global health indicators, such as life expectancy at birth, in Japan, are among the best in the world. However, increasing health expenditure resulting from an ageing society and advances in medical technologies exert pressure on the nation's finances. Japan's healthcare expenditure was 10.9% of the gross domestic product in 2016, ranking sixth among 35 Organization for Economic Co-operation and Development (OECD) countries. Furthermore, healthcare costs are expected to increase due to population aging (OECD, 2017).

Currently, major problems of the Japanese medical care system are increased financial burdens resulting from medical demands and changes in disease structure associated with the declining birthrate and aging population. The direction of reform for this system is as follows: (1) maintenance and promotion of health, prevention of disease, and promotion of early detection; (2) promotion of differentiation and coordinated among medical functions (community medicine concept); and (3) establishment of "the Community-based Integrated Care System(CICS)" (Tomiyama, 2017). We discuss the framework of CICS and Health Information Systems and consider the problem of discharge summary for continuing nursing care. Finally, we consider the framework of the new health information exchange system.

2 Community-Based Integrated Care System (CICS)

The increase in financial burden due to medical demand is one of Japan's major problems, to which CICS is expected to be a solution. It is necessary to emphasize home care. It shifts the maintenance period for medical care from the hospital to the home. To realize seamless cooperation at home, interprofessional work is necessary. To facilitate interprofessional collaboration, information sharing is necessary, and a user-friendly system is needed rather than an electronic medical record in a hospital. It is desirable that a two-way network that supports information sharing is available. Regional medical information cooperation networks are rapidly increasing due to the effects of subsidies, however, there are still a few networks that are able to obtain usage fees to cover operating expenses. In order to establish CICS, further progress of information and communications technology (ICT) in the medical and care field is desired. We first discuss the framework of CICS and elaborate on information sharing that is important therein. Subsequently, we outline the present electronic medical records (EMR) system and problems with the regional medical network.

3 "The Long-Term Care Insurance System" and "Community-Based Integrated Care System"

Japan not only has the fastest aging population in the world but also the highest proportion of elderly people. In 1995, the government introduced "the Long-term Care Insurance System," and in 2014, "the Community-based Integrated Care System," which provides seamless community healthcare resources to elderly people with chronic diseases and disabilities (Figs. 1 and 2).

Examining the changes in Japan's demographic makeup reveals that the current social structure consists of 2.6 persons supporting each elderly person. In 2060, with the progression of the aging population and decreasing birthrate, it is estimated that 1.2 persons will be supporting every senior citizen (Japan Ministry of Health, Labour and Welfare (MHLW), 2016).

As society has been aging, the need for long-term care has also been increasing because of the growing number of elderly persons requiring long-term care, lengthening of the care period, and so on. Meanwhile, the trend toward nuclear families and the aging of caregivers in families has contributed to a change in the environment surrounding families. These factors make it difficult to deal with conventional welfare and the geriatric healthcare system. Japan needs a mechanism that enables its society to provide long-term care for the elderly.

After the introduction of the Long-term Care Insurance System, the declining birthrate and aging population necessitated a revision to it. The main contents of the revision to the Long-term Care Insurance System include the following:

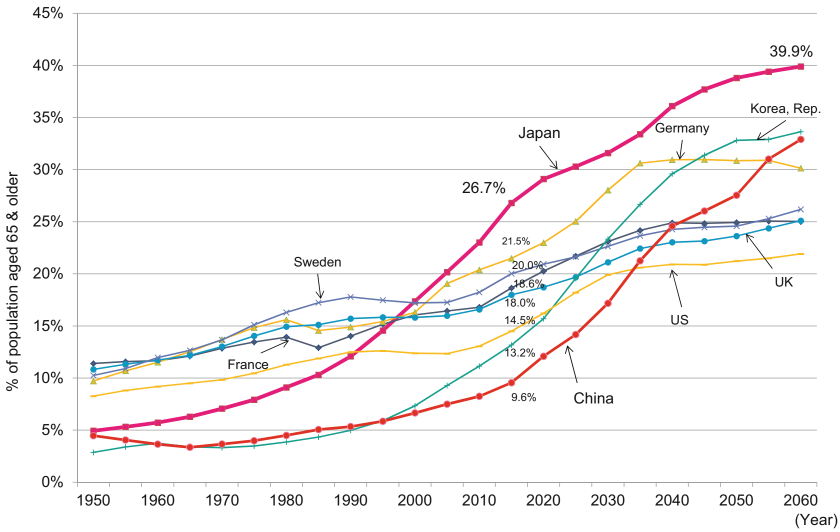

Fig. 1 Changes in the percentage of the population over age 65. Source: Ministry of Health, Labour and Welfare home page (https://www.mhlw.go.jp/english/policy/care-welfare/care-welfare-elderly/dl/ltcisj_e.pdf)

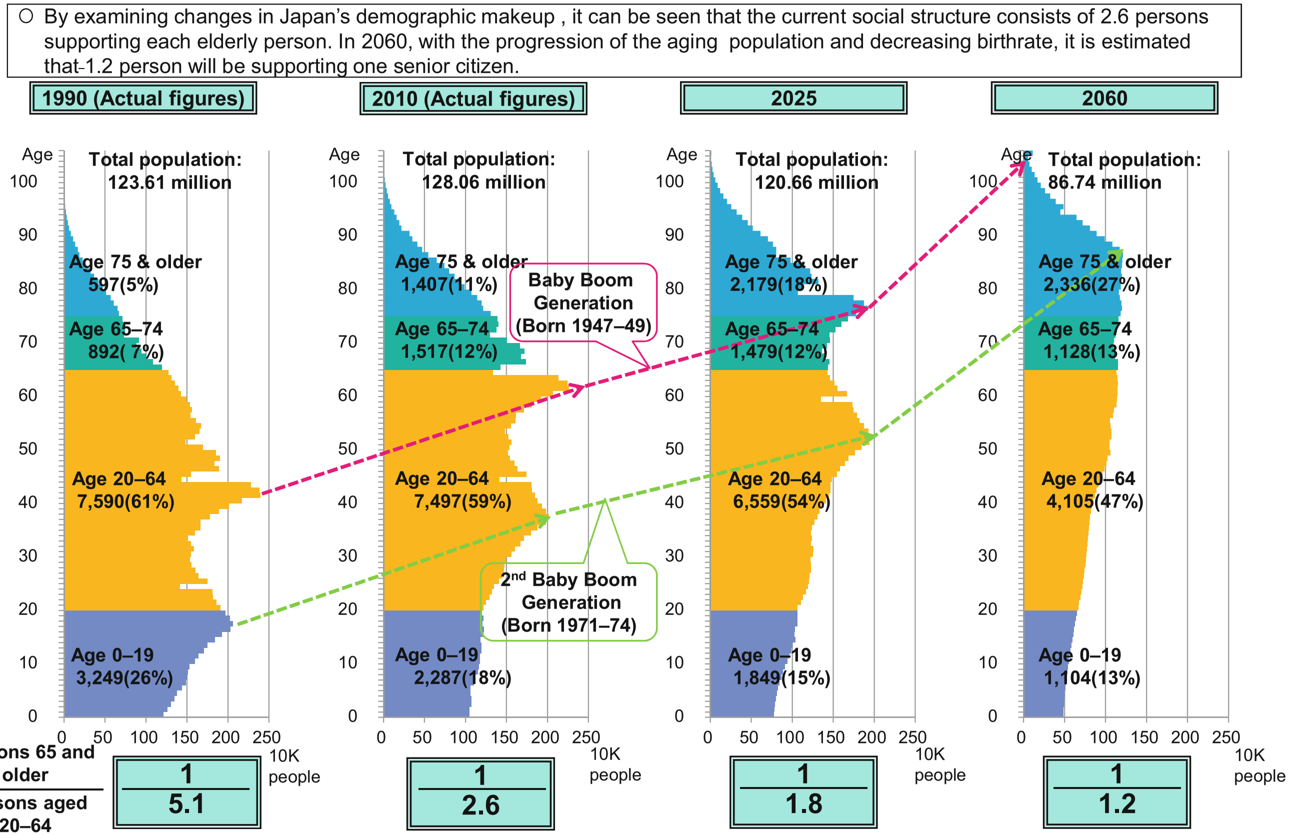

Fig. 2 Changes in Japan's population pyramid (1990–2060). Source: Ministry of Health, Labour and Welfare home page (https://www.mhlw.go.jp/english/policy/care-welfare/care-welfare-elderly/dl/ltcisj_e.pdf)

1. Establishing the community-based integrated care system.
   Enriching long-term care, healthcare, support, and preventive services so that elderly people may continue living in areas they are accustomed to.
2. Making contributions equitable.
   Expanding the reduction of premiums for people with low income and reviewing co-payments of those who have attained certain income levels or who possess certain assets to suppress an increase in premiums (Fig. 3).

4 "The Community-Based Integrated Care System" and Information Sharing

CICS ensures safety, security, and health in daily life. Through this system, medical and nursing care and various life support services, including welfare services, are provided for the community. Thus, the elderly can live the rest of their lives in familiar environments even if they require long-term care. We need a transition from the traditional medical care system to home healthcare and nursing care systems instead of the expansion of healthcare facilities for the elderly. It is necessary to emphasize home care. It shifts the maintenance period for medical care from the hospital to the home. To realize seamless cooperation at home, interprofessional work is necessary. The following are possible examples: unify the way nursing care is provided to ensure appropriate care for patients with dementia, facilitate collaboration between physicians who conduct home visits and visiting nurses and care managers, and ensure collaboration between the regional Community-based Integrated Care Center and daycare centers and the local government's life support department. To achieve effective collaboration and communication, information sharing is very important.

To actually realize information sharing among personnel representing interprofessional for medical care in the home environment, it is necessary to conduct regular conferences and develop regional medical information cooperation networks.

5 Regional Medical Information Cooperation Networks in Japan

In Japan, the transition to the EMR system began in 1999. While the EMR system had previously existed, in 1999, it was recognized for use in maintaining public medical records. As of 2018, large-scale hospitals (800 hospitals with over 400 beds) represented almost 78% of those using EMRs, whereas small-scale hospitals (5498 hospitals with under 200 beds) represented less than 30%. Overall, it has a penetration rate of 38.3%. For clinics, the total rate for use of the EMR system is low (about

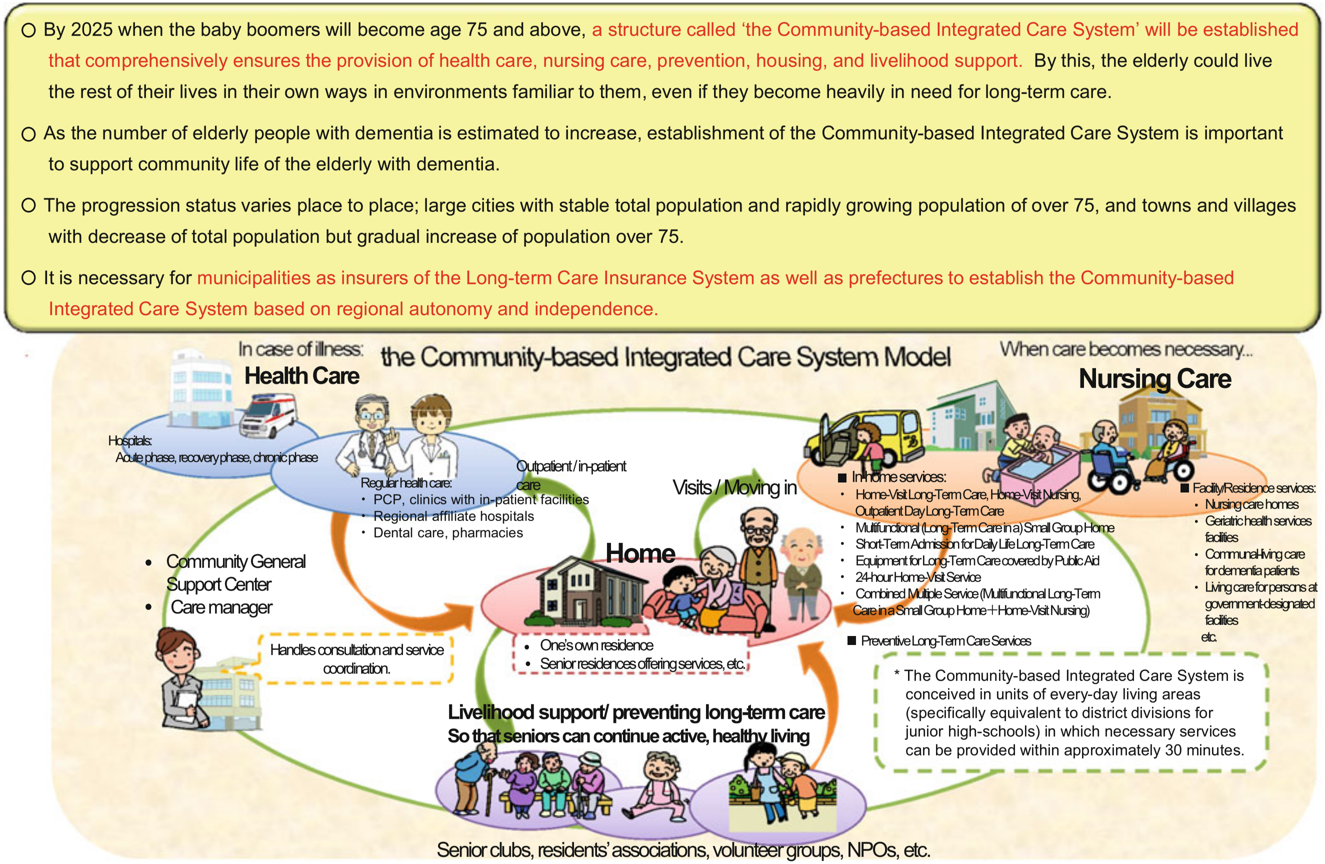

Fig. 3 Establishing "the Community-based Integrated Care System". Source: Ministry of Health, Labour and Welfare home page (https://www.mhlw.go.jp/english/policy/care-welfare/care-welfare-elderly/dl/ltcisj_e.pdf)

30%) (Japanese Association of Healthcare Information Systems Industry, 2019). However, 80–90% of newly opened clinics use the EMR system; in fact, in urban areas, the usage rate is almost 100%. The reason for the delay in implementation in small-scale hospitals is mainly financial. Small-scale hospitals cannot afford the cost of implementing the EMR system (JPY 300,000–600,000 for 100 beds per year) (Japan Hospital Association, 2017). Medical services in Japan are provided mainly by the private sector under a social insurance system; 71% of hospitals and 83% of clinics are private (Japan Ministry of Health, Labour and Welfare, n.d.), and a significant number of private medical institutions are small to medium-sized. Each institution decides whether to introduce an electronic medical record system; the government cannot force them to adopt such systems. Some institutions oppose medical information systems because of their high operating costs.

Regarding the penetration rate for the EMR system, it is still difficult to use ICT for information sharing because of the low penetration rate in small hospitals and clinics, which are intrinsic to the Community-based Integrated Care system. At present, testing is ongoing in hospitals and clinics that are making advanced efforts.

Another factor is that many regional medical information cooperation networks are not yet functioning sufficiently, and there is no mechanism in place to link a patient's ID or manage the viewing authority for medical records. Thus, such deficiencies indicate that there is more work to be done to ensure the effectiveness of these networks.

The framework for regional medical information cooperation networks began with an attempt to share information in a large hospital focused on utilizing electronic records for medical cooperation in the community. Before the implementation of the network, there were some attempts to share information using a common card in the medical arena, but it was not practical. In addition, the government provided subsidies to build a regional medical network from the perspective of reducing medical expenses. A regional medical network was expected to improve efficiency and reduce medical costs resulting from the duplication of tests and prescriptions, support for interpretation, and so on.

In 2005, the retirement age of baby boomers was near, and awareness regarding the situation emerged in 2025. At the same time, the training system for clinical residents changed, effectively meaning that for 2 years, no doctors were supplied. The shortage of doctors became a real problem, and the uneven distribution of doctors was also evident. The number of university medical schools increased, and medical care efficiency was improved by securing local doctors, sharing hospital functions, and cooperating in providing regional medical care. Thus, it was necessary to ensure role sharing among hospitals and build a regional medical network. Since 2009, financial backing has been obtained via a "fund to revitalize the community health care" system five times (Fig. 4).

The regional medical information cooperation network was originally started with the accumulation of centralized patient information for the cooperative sharing of information along a disease-specific clinical pathway. With the consent of the patient, medical information is registered and shared. The second-generation regional medical information cooperation network is a resource for medical

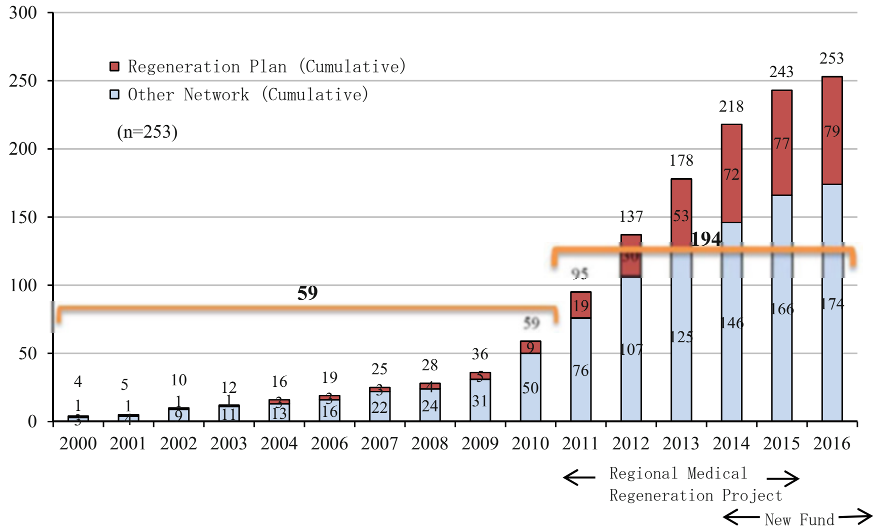

Fig. 4 Changes in regional medical cooperation nationwide (including planned). Source: Watanabe, A., & Ueno, T. (2015). IT wo Riyou Shita Zenkoku Chiki Iryo Renkei no Gaikyo [Overview of National Community Medical Collaboration Using IT]. (No. 368). Retrieved from Japan Medical Association Research Institute website: https://www.jmari.med.or.jp/download/WP368.pdf

information shared by core regional hospitals, small hospitals, clinics, and so on; medical information is shared with the consent of the patient and cooperating institutions in the region by referring to a particular direction or each other. A service center is established to link IDs and control reference authority. As the regional medical information collaboration network expands, technical problems are being resolved through advanced trials, such as the establishment of standard data exchange formats (SS-MIX, SS-MIX2) and a mechanism to link IDs across vendors.

Regarding the medical information cooperation network for the Community-based Integrated Care System, a wide variety of medical and nursing care professionals use it in patient homes, visiting nursing stations, clinics, core regional medical hospitals, and comprehensive community support centers. In addition, regarding the use of a personal computer (PC), tablet, smartphone, or other devices for information sharing, usability deteriorates if access is unobtainable in different operating systems (OS). Therefore, utilization of the Cloud requires the provision of a platform such as SaaS, which is independent of the OS. The regional information cooperation network system in the community-based integrated care system requires not only references but also the ability to provide information in both directions and conference functions for interprofessional work (Fig. 5).

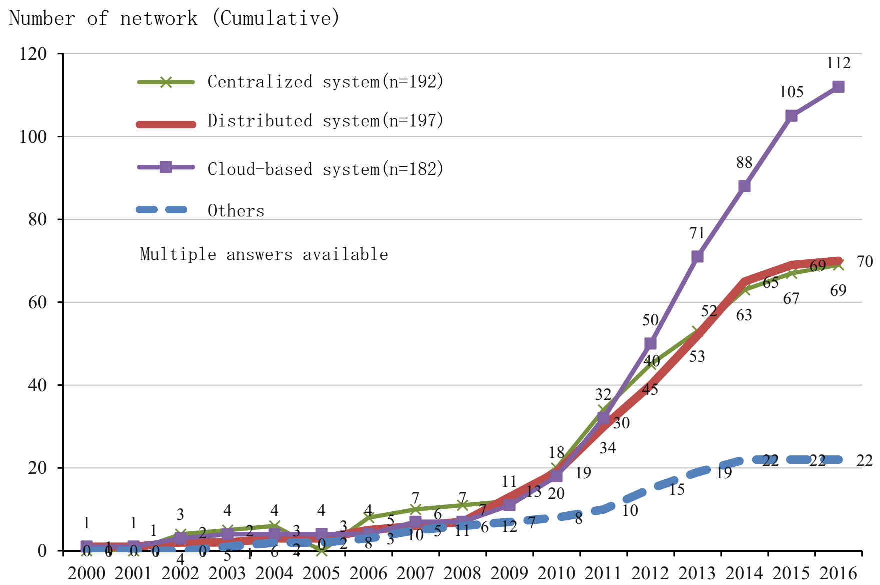

Fig. 5 Changes in information cooperation methods (including planned). Source: Watanabe, A., & Ueno, T. (2015). IT wo Riyou Shita Zenkoku Chiki Iryo Renkei no Gaikyo [Overview of National Community Medical Collaboration Using IT]. (No. 368). Retrieved from Japan Medical Association Research Institute website: https://www.jmari.med.or.jp/download/WP368.pdf

6 Present Conditions and Problems with Regional Medical Information Cooperation

The number of regional medical information cooperation network systems is increasing, and the Community-based Integrated Care System and the "fund to revitalize community health care" have been introduced. Many new networks are formed for utilization in the comprehensive community care system. The number of Cloud-based networks and two-way information exchange capabilities are also increasing. By adopting the Cloud-based approach, the initial investment is lower.

Many networks are growing with the introduction of subsidies, but it is doubtful how far they can cover future operating expenses through usage fees. Some networks were dormant or closed when they were subsidized and bereft of support. The networks that continue to the present have become famous, as have networks perceived by users as possessing merit and those that collect a usage fee as a consideration for use and establish their financial base. In addition, although many networks have been launched, the features required are similar; furthermore, most networks have been built independently (Murata & Kato, 2016). Efficient implementation, operation, and cross-regional collaboration are expected to be necessary, and standardization of functions will be required in the future. According to Nihon Keizai Shimbun (March 15, 2019), although the national and local governments have spent more than JPY 53 billion to curb medical costs and improve patient convenience, only 1% of the nation's population is enrolled in around 210 regional networks (Uebayashi, 2019).

Medical IDs are also being considered for the establishment and use of the Social Security and Tax Number called My Number in the medical field, and it is expected that the effort required to match names will be reduced. The introduction of medical IDs is likely to decrease the threshold for the introduction of regional medical cooperation networks further. In a network in a large city—where there are many users—numerous difficulties in providing medical care and related services can be anticipated. To bring a comprehensive regional medical care system to fruition, a regional medical cooperation network is considered essential, and we hope that an introduction will be promoted, along with clarification regarding the cost burden of operating expenses.

In addition, the Act on the Protection of Personal Information (hereinafter referred to as the Personal Information Protection Law), which came into effect in 2005, has created a climate of caution regarding the sharing of health information although the law does not regulate sharing of health information. Local governments that are not subject to the Personal Information Protection Law established their own ordinances on the protection of personal information to respect the purpose of the law. Consequently, many ordinances were enacted for the protection of personal information, and as these ordinances operate differently, it led to a situation called the "problem on 2000 personal information protection laws" (Suzuki & Yuasa, 2016). In practice, it is difficult for municipal medical institutions, regulated by these ordinances, to share health information. Even if sharing health information becomes technically possible, it is difficult due to the legal system.

Problems of the present health information exchange systems are summarized as follows: (1) The medical information exchange systems have become complicated and are necessary to clarify the information for exchange and operation. (2) The introduction and operating costs of a medical information system are high. (3) It is necessary to establish a system to comply with the Act on the Protection of Personal Information.

To overcome these challenges, it is crucial to focus on constructing a health information exchange system that can be used to support hospitals, clinics, facilities, and providers for transfer and discharge. Standardization of health information content is also necessary for coordinated care, which helps information flow smoothly. In a typical example of collaboration in communities, medical social workers and discharge coordination nurses at the referring acute care hospitals search for receiving hospitals, exchange information by telephone/fax/information exchange systems, and decide on the receiving hospitals. This is the "introduction and acceptance" type where the acute care hospital initiates the transfer. At the time of the transfer, patients bring a referral letter from his/her acute care physicians to the receiving hospital. This referral letter includes information on symptoms, significant laboratory data, medications, medical history, and family structure. The receiving hospital conducts the necessary examinations for the new patient. The treatment decisions are generally made after referring to the results of previous examinations and historical data from the acute care hospital.

Therefore, we discuss the current status of and issues surrounding discharge planning and summaries for nurses in Japanese hospitals and offer suggestions regarding human resource development for nursing staff.

7 Supporting the Transfer of Patients from Acute Care Hospitals to Convalescent and Long-Term Care Hospitals/Facilities

At 17.9 days, the average length of stay of hospitalization for acute care in Japan is longer relative to an average of 6.6 days in OECD countries. This suggests that there is the potential to deliver more care outside expensive hospital settings and closer to people's homes and families. Developing the role of care coordinators in transferring patients from acute care to community settings effectively will be instrumental in achieving this (OECD, 2014). Moreover, discharge nursing summaries are important to coordinate this transition. In practice, it is necessary to support the transfer of patients from acute care hospitals to convalescent and long-term care hospitals/ facilities (Murata, Takahashi, & Yakuwa, 2019).

The main research questions were as follows: What is an excellent discharge summary, and what kind of human resource development programs are required to provide such summaries?

To answer these questions, we reviewed differences in discharge summaries between Japan and other countries and interviewed nursing managers of discharge support centers of Japanese hospitals providing acute care.

8 Discharge Summaries

8.1 What Are Nursing Records?

In the Medical Practitioners' Act (Japanese Law Translation, 2010), a medical practitioner must enter the matters related to the medical treatment that he/she has provided in medical record without delay. However, there is no such a duty for nurses in the Act on Public Health Nurses, Midwives, and Nurses. Nursing records were ordained in the Medical Care Act. In the Medical Care Act (Japanese Law Translation, 2010), hospitals are required to have the following personnel and facilities and prepare the following records pursuant to the provisions of an Ordinance of the MHLW: Records Concerning Medical Treatment. The purpose of nursing records is defined as "proving nursing practice," "guaranteeing continuity and consistency of nursing practice," "evaluating and improving the quality of nursing practice," in the Japanese Nursing Association's "Standards of Nursing Practice" (Japanese Law Translation, 2010). The practice of patient-centered care requires demonstration of nursing practice processes and collaboration with healthcare welfare service providers. It is also evident when a medical accident occurs.

8.2 *What Is Discharge Planning?*

The nursing record guidelines published by the Japanese Nursing Association define the nursing discharge summary as a summary of progress and information regarding the health problems of people who require nursing. The Japan HL7 Association's "Terms and Conditions for Discharge" state the following: "The discharge summary is the effective sharing of information among other departments involved, other medical institutions, and care facilities when an inpatient is discharged, so that the patient's diagnosis, treatment, and care are linked appropriately. It is created at the responsibility of the attending physician in order to be able to do so." In Japan, discharge summaries are created to obtain medical fees, explain them to patients' families, issue them, and affix them to medical records, but they are not handed over to home-care nurses.

Medicare states that discharge planning is "a process used to decide what a patient needs for a smooth move from one level of care to another." The actual process of discharge planning can be completed by a social worker, nurse, case manager, or others. Ideally, and particularly for most complicated medical conditions, discharge planning is performed via a team approach.

Discharge planning involves the following:

Evaluation of the patient by a physician, nurse, home-care nurse, medical social worker, pharmacist, physiotherapist, occupational therapist, case manager, or others.
Discussion with the patient or his/her family representative.
Planning for homecoming or transfer to another care facility.
Determining whether caregiver training or other support is needed.
Referrals to a home-care agency and/or appropriate support organization in the community.
Arranging follow-up appointments or tests.
Coordination of available local and welfare services.

Emphasis placed on discharge planning varies across countries. In the U.S., it is mandatory for hospitals participating in the Medicare and Medicaid program (U.S. Department of Health and Human Services, 2013). In the United Kingdom, the Department of Health has published guidance on discharge practice for health and social care (U.K. Department of Health, 2010). Clinical guidance issued by professional bodies in the United Kingdom (Future Hospital Commission 2013), the United States (U.S. Department of Health and Human Services, 2013), Australia (Lim, Chong, Caplan, & Gray, 2009), and Canada (Health Quality Ontario, 2013) all highlight the importance of planning discharge as soon as the patient is admitted, involving an interprofessional team to provide a thorough assessment, establishing continuous communication with the patient and caregivers; working toward shared decision-making and self-management; and liaising with health and social services, particularly primary care, in the community. In Japan, hospitals are obligated to outline medical fees, but the format and content of the documentation are not stipulated.

The MHLW commissioned the "Comprehensive Research on Electronic Formats and Standardization of Documents Prepared by Medical Institutions" (Yamamoto, 2009) and the Medical Information System Development Center to create a standard for medical care. In addition, we are working on the standardization of terms necessary for records and nursing records. Moreover, NANDA International (NANDA-I) diagnoses books, Nursing Interventions Classification (NIC) books, Nursing Outcomes Classification (NOC) books have been translated into Japanese and installed in Electronic Medical Information Systems. However, the MHLW has not created a standard discharge plan, and such plans are created only by individual prefectures, cities, and hospitals.

8.3 What Are the Issues Surrounding the Standardized Discharge Summary?

The Tokyo Metropolitan Bureau of Health and Welfare in Japan published the "Tokyo Metropolitan Discharge Support Manual" (Tokyo Bureau of Health and Welfare, 2016). In addition, the Agency for Healthcare Research and Quality in the USA created a clinical tool, IDEAL—Discharge Planning Overview, Process, and Checklist—which provides key elements necessary to create a discharge summary (U.S. Agency for Healthcare Research and Quality, 2017).

8.4 Key Elements of IDEAL Discharge Planning

IDEAL is an abbreviation for Include, Discuss, Educate, Assess, and Listen.

Include the patient and family as full partners in the discharge planning process.

Discuss the following five key areas with the patient and family members, to prevent problems at home:

1. Describe what life at home will be like.
2. Review medications.
3. Highlight warning signs and problems.
4. Explain the test results.
5. Make follow-up appointments.

Educate the patient and family members about the patient's condition, the discharge process, and next steps in plain language throughout the hospital stay.

Assess how well doctors and nurses explain the diagnosis, condition, and next steps in the patient's care to the patient and family members and use feedback.

Listen to and honor the goals, preferences, observations, and concerns of the patient and family members.

This process will include at least one meeting to discuss concerns and questions with the patient and family members of their choice. The IDEAL process is very simple and provides the minimum content necessary for a discharge summary.

The Queen's Nursing Institute in the United Kingdom has released the discharge planning for district nurses, which reflects best practice in care transition (The Queen's Nursing Institute, n.d.). These guidelines indicate the need for collaboration between primary physicians, who possess a good understanding of the patient's experience before admission and ways to collaborate with professionals from multiple fields.

Japanese hospitals should consider methods to provide excellent discharge support, by referring to the efforts of other countries.

8.5 Interviews and Analysis

8.5.1 Method

Participants and Setting

The participants were five nurse managers who managed discharge support centers in acute-care hospitals with 300–600 beds in government-designated cities. All participants were women. Interviews were conducted from June to September 2019.

Data Collection

We conducted semi-structured interviews with the participants. The interviews were conducted using an interview guide, which included three questions: "Which situations made you experience negative emotions during discharge planning," "What do you believe to be the reason for that," and "How would you provide good discharge plans in the future?"

The study was described to the participants and informed consent was obtained before conducting interviews, which lasted approximately 30 min; IC recorders were used for recording, and interviews were subsequently transcribed.

Data Analysis

Data analysis transcripts were analyzed according to qualitative methods. Data were coded through three main research questions, central themes and categories were identified, and named. Then, relationships between themes and categories were considered.

8.5.2 Results

Experience of Negative Emotions During Discharge Planning

Participants reported that the following negative emotions occurred during discharge planning:

"A home-care nurse told me that the necessary information was not included in the discharge summary when it was sent from an acute-care hospital."
"I did not know what the home-care nurse wanted."
"We do not know which information patients need for their home-based care."

What Was the Reasoning Behind These Emotions?

Value
"The value of a good discharge summary differs between acute-care hospital nurses and home-care nurses."

"Acute-care hospital nurses think that information about in-hospital treatment processes is important."

"Home-care nurses think that information about treatments, tests, and medicines are important."

Terminology
"The terminology used in creating discharge summaries differs between acute-care hospital nurses and home-care nurses."

"Hospital nurses use the terminology for a 'nursing diagnosis,' while home-care nurses do not use it."

Patients' Everyday Lives
"Acute-care hospital nurses cannot imagine the provision of treatment in the patient's living environment."

What Are Nursing Professionals?
"They are able to use the standardized nursing planning packages for the Electronic Medical Information System easily."

"Nursing care is not based on professional judgment and left to the medical team."

"Hospital nurses cannot explain nursing practice."

What Should Nursing Managers Do?
"Create an opportunity for hospital nurses to watch home-care nurses' practice."

“Hospital nurses should have the opportunity to evaluate discharge support and determine whether it was effective for patients and family members.”

“Establish a system to measure patient outcomes after discharge.”

8.5.3 Discussion on the Interviews and Analysis

Participants were asked to describe their views on the top four barriers that prevented effective discharge planning: “The difference in the sense of value between hospital nurses and home-care nurses,” “lack of communication,” “lack of standardized terminology in creating discharge summaries,” and “the Electronic Hospital Information System reduces hospital nurses’ assessment ability.” Why did these barriers occur? Participants described four reasons. First, most nurses work in hospitals, and nursing procedures differ between home-care nurses and hospital nurses. In addition, hospital teams lacked awareness of both the capability and scope of home-care nurses and challenges faced in relation to issues such as access to drugs and community health equipment loans. Second, although medical fees were paid for the implementation of interprofessional conferences, the time available for such conferences was limited. In the future, we should consider how to ensure that effective conferences are held within a limited time. Third, university nursing education was problematic. Nursing education textbooks describe the importance of interprofessional collaboration and the adjustment of social resources, but they do not provide nurses with comprehensive education regarding what to do. Fourth, standardized terms for connecting hospitals and home-based care are not based on common values. Nurses rely on standardized nursing packages for Electronic Hospital Information System. Nurses should understand and operate the meaning of standardized nursing packages for electronic hospital information systems. Responses from home-based care and hospital administrators were analyzed, and the consistency between the two groups with respect to “effective communication between teams” was most prevalent, with strong similarities also observed for “appropriate care packages” and “interprofessional team working.” Nurses rely on fine discharge information, such as the kind provided in Electronic Hospital Information System, for discharge summaries.

It is necessary to promote effective communication between home-care nurses and hospital nurses through the key elements of IDEAL, rather than a summary using the Tokyo Metropolitan Discharge Support Manual. As hospital and home-care nurses have the provision of patient-centered care in common, it is important to create opportunities for hospital nurses to participate in home-based care to enhance their understanding of home-care nurses’ practices. In addition, it is necessary for hospital nurses to create opportunities to learn about home-care nurses’ values via home-care nursing experience and communicate through discharge summaries. The attainment of experience should focus on the perspectives of hospital nurses concerned with the transfer of care when discharging patients from the hospital to the community and those of community nurses receiving patients into their care. The nursing college curriculum does not provide opportunities for hospital nurses to effectively learn the practices of home-care nurses. The MHLW is currently in the process of deciding on the content of the next curriculum revision. The next curriculum should include opportunities for hospital nurses to learn the values that form the basis of home-care nursing practices, effective interprofessional collaboration, and evaluation with reference to the curricula of districts in the UK.

Significant willingness and commitment to improve patients' experience of care from hospital to home were observed in both hospital- and community-based nurses. It is disappointing that, given the evidence available to support good practice, discharge planning continues to remain a challenge. Both community and hospital nurses were willing to improve the discharge planning process for patients and their family members and caregivers, but it was evident that existing systems and cultures contained barriers to effective discharge, and this should be addressed. It is important that we increase communication opportunities and education to enhance understanding of the diverse values of various occupations using IDEAL.

9 The Future Health Information Exchange System

We focus on the transfer process for better health information exchange in communities. We define the information gathering and analysis processes for the recovery/long-term care hospitals as "support for discharge social work" and standardize them as the databank as a solution for your care and health (DASCH) project (Ariga, 2017). The exchange system proposed under the DASCH project involves an agreement among hospitals and clinics for the type of data disclosed by referring hospitals such as that in the physician's referral letter. Any personally identifiable information is masked and disclosed in accordance with the Personal Information Protection Law(s). The candidate hospital follows the "introduction and selection" system that verifies patient information, determines the acceptability of the patients, and indicates the intention to accept patients. This system can be developed and changed by users without depending on vendors, such as an electronic medical record, at a reasonable price (Murata, 2019). By examining information demanded by nursing care facilities/providers, the system proposed by the DASCH project can be applied in coordination between medical institutions and nursing care facilities/providers.

The health information exchange system was developed as a centralized information exchange system mainly by the vendor of the electronic chart system, which is a complex system intended to please all users. The manufacturing industry has dramatically improved on cost, quality, and delivery by changing their processes from "push" to "pull" production in response to customer orders. The information not requiring urgency should be shared by a pull-type rather than the push-type to protect the receiver of information from information flooding. With the system under the DASCH project, by promoting process improvement from "introduction and acceptance system" to "introduction and selection method," the health information exchange system can share necessary information by a realistic operation method and is advantageous for both patients and hospitals with personal information protection at a reasonable price.

10 Conclusion

The increased financial burden resulting from medical demands and the change in disease structure associated with the declining birthrate and aging population have demanded reforms for Japan's healthcare system including collaboration among medical functions under the concept of "the Community-based Integrated Care System." For elaborating on information sharing advancing collaboration among medical functions, the EMR system and the regional medical network have been introduced. However, present systems tend to be vague and costly. Furthermore, compliance with laws can be crucial in some cases. To overcome these challenges, it is necessary to construct a system that can be simple and affordable. Therefore, the transfer and discharge process was focused on. Standardization of health information content is also necessary for coordinated care, which helps information flow smoothly. Thus, a discharge summary is essential; however, discharge support nurse managers expressed difficulties in preparing a discharge summary due to "the difference in the sense of value between hospital nurses and home-care nurses," "lack of communication," "lack of standardized terminology in creating discharge summaries," and "the Electronic Hospital Information System reduces hospital nurses' assessment ability." The medical information exchange system from the DASCH project focuses on these challenges by not giving a set-up system, rather by giving flexibility through opportunities to emphasize communication in the community.

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