# Chapter 1
# Pharmacy Practice Research: Evidence and Impact

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**Abstract** This chapter summarises the current challenges that exist when matching increasing demand for health-care services to available capacity and funding. This has led to a drive to implement new services and redesign existing services in line with evidence of their clinical and cost-effectiveness. These principles are then translated into the context of pharmacy with consideration of the quality of the evidence available for pharmacy and related medicines services. Finally, there is an examination of the interplay between practice, policy and research, and examples are given of four different ways in which research can inform policy. The chapter concludes with a summary of the remaining challenges that need to be addressed to ensure that in pharmacy we can deliver an evidence-based service.

## 1.1 Evidence and Evidence-Based Health Care

It is important in 'health-care decision making' that both populations and individual patients are given a treatment that is likely to work and represents value for money. This is especially important at a time when in most of the countries in North America, Europe and Australasia (that is the majority of what is known as the developed world), the demand on health care is increasing. This is due largely to changing demographic profiles with a greater proportion of older people than previously. As age increases, there is an equivalent chance of poorer health and thereby requirement for treatment. This will therefore be a cost to countries, regardless of how their health-care systems are funded—i.e. whether they have a Beveridge-based approach such as in the taxation-funded universal health care offered under the NHS in the UK, or a Bismarck system, whereby health-care costs are covered by third party insurance systems, such as Germany or the USA.

To ensure limited budgets are used efficiently, the central question is which treatments are, and which treatments are not, both clinically- and cost-effective.

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This knowledge can inform decisions taken at both country wide level by policy makers and at individual patient level by the health-care professional in partnership with the patient. Indeed, the current drive towards more joint decision making at patient level is driven by research findings which suggest that this leads to better clinical outcomes and more satisfied patients who are likely to adhere to treatments.

### *1.1.1 Multiplicity of Research*

There is already much research conducted to address questions about clinically-and cost-effective health care. Such studies range from pharmaceutical industry pre-licensing studies and post marketing surveillance, often not reported in peer reviewed journals, through to rigorous independently conducted substantive studies. However, these often only address the 'big' questions; a classic example would be the early studies demonstrating the value of reducing lipid levels in reducing morbidity and mortality from heart disease. Many conditions of lower prevalence remain under researched, although taken together, they represent a large proportion of the health care delivered.

However, there remains a challenge even when answering the big question. Is there a generic way of accessing, collating and interpreting results from the multiplicity of research reports in the peer-reviewed literature which can help 'answer' the question of finding the 'best treatment' for a particular population suffering a particular condition. Furthermore, whilst at a first glance the published literature may seem to offer some understanding, studies often report conflicting results and may not be conducted in the exact context for which information is required. For example, do results of a study conducted in North America with a largely Caucasian population aged averagely 50-years translate to a community in an area of Australia with a population of mixed ethnicity and ages over 65-years.

### *1.1.2 Quality of Research*

The way research is conducted can also influence the bottom line as reported, potentially leading incorrect conclusions to be drawn. For example, a study conducted to explore whether taking an antidepressant relieves symptoms of depression, conducted without a control group could lead to a gross overestimation of the effect of the medication, because of the now well-documented size of the placebo effect. Randomised controlled studies, regarded as the best study design, cannot, however, automatically always be judged as rigorous. For example, it is important that all participants allocated to a treatment group are analysed in that group, and that those unable to be contacted for whatever reason at follow-up are classified as treatment failures. A good example of this would be smoking cessation studies, where those who are successful in stopping smoking are more likely to

come back for follow-up assessment than those who have failed, leading to an overestimation of the effect of the smoking cessation intervention, be it a pharmacological or behavioural one. Therefore, in deciding to what extent a single piece of research can contribute to informing policy, the study design and conduct of the study must all be critically evaluated.

### *1.1.3 The Evidence-Based Medicines Movement*

The conundrum, therefore, is how to develop techniques which allow the 'true' answer of what is the most clinically- and cost-effective choice to be distilled and synthesised from the literature, then to be understood, articulated and translated into practice at the front line of service delivery.

#### 1.1.3.1 The Cochrane Collaboration

One of the first people to think through the above issues systematically was Archie Cochrane, founder of the Cochrane Collaboration[1] and one of the fathers of evidence-based medicine. In later parts of this chapter, we will talk more specifically about evidence-based pharmacy, but for now the principles of evidence-based medicine apply equally to evidence-based pharmacy.

The classic logo of the Cochrane Collaboration[2] illustrates the dilemma that people face when trying to understand what a multiplicity of research reports tell us about a specific question. The Cochrane Collaboration logo is itself a schematic representation of one of the first questions answered by the collaboration. This was to identify the right way to manage a woman with a history of repeated premature births, to prevent this happening in subsequent pregnancies. Each of the horizontal lines in the logo represents the outcome of a trial in which pregnant women were treated with varying doses of corticosteroid and the confidence limits around the estimated odds ratio of a successful outcome. The vertical line is the line through an odds ratio of 1, namely that there is no effect of treatment. Thus of the eight trials depicted, three show a benefit of using steroids. However, the diamond at the bottom shows the overall beneficial effect of this treatment in reducing premature births when all the studies are combined as if in one big trial. In this technique, now known as meta-analysis, all the individual studies are treated as one big study and one big population; increasing sample sizes in this way means the confidence interval around the estimated effect size is narrowed, and the robustness of the estimate is greater. Until this approach was understood, use of corticosteroids in

[1] www.cochrane.org/ accessed 27 Oct 2014.

[2] http://www.cochrane.org/about-us/history/our-logo accessed 16 Oct 2014.

pregnancy was only 20 %. It steadily rose thereafter reducing rates of premature births, preventing much human suffering and reducing NHS costs.

The Cochrane Collaboration itself is now an international group of health-service researchers, information scientists, statisticians and others who on a voluntary basis agree to conduct reviews of published literature to answer topical questions of relevance to health-care providers. There are Cochrane groups specific to different conditions, e.g. a Urology group, and those for more general topics such as what is the best way to encourage health-care professionals to change their behaviour—the Cochrane Effective Practice and Organisation of Care group.

#### 1.1.3.2 Systematic Reviewing and Critical Appraisal

Accepting that meta-analysis is the solution to synthesising the literature and informing policy decisions about the best treatment, it becomes critical to ensure that prior to any meta-analysis, all eligible studies are identified. This has led to an understanding of the way to search the electronic databases of published research in the topic area. Gone are the days of manually searching journals until sufficient articles had been identified which made the required point. In a systematic review, the aspiration would be to find and include all relevant papers, regardless of their final conclusion, although the reality is often somewhat different. Even highly skilled information scientists cannot find everything, but if there are omissions, these should be by chance and not by intent. Once papers are identified, they also have to be critically appraised. One of the issues to consider is the extent to which it is valid to combine the individual studies into one big virtual study. Are the studies similar enough in terms of characteristics of the population, the health service in which they were delivered, the co-morbidities and risk factors of the participants, the outcomes used and the follow-up period. All of this has to be taken into account when looking at the value of the final figure and its applicability to any single setting. Furthermore, as mentioned earlier, what was the quality of the research that was done, were non-responders included in the follow-up, was an intention to treat analysis undertaken and were the assessors blind to group allocation. Perhaps of greatest importance is the study design. Ideally to compare two treatments, a randomised controlled trial design should be used, to allow for the multiple confounders that might spuriously suggest a treatment will work when assessed by a simple before and after analysis.

#### 1.1.3.3 Grades of Evidence

The Cochrane Collaboration has devised a set of quality rules and standards which, as far as they can, allow for the limitations in published studies to be systematically examined and reported. There are Cochrane standards for the conduct of studies of different study designs, including most recently standards for assessing qualitative research and combining the results using meta-ethnography. There are even

checklists for assessing systematic reviews of systematic reviews! These widely accepted quality tools therefore allow a review to be judged or graded, both on the rigour of the study designs and the quality of the studies. Amongst individual study designs, randomised controlled trials are the gold standard, followed by controlled trials, cohort studies, case studies and case reports. Both quality and study design can then be taken into account when assessing the importance which can be attributed to the bottom line finding.

### *1.1.4 Using Evidence to Influence Practice*

Since the founding of the Cochrane Collaboration, the model of systematic reviewing and critical appraisal of the existing research have become the accepted approaches to inform health-care decision making, and 'an evidence-based service' has become the mantra. The Cochrane Collaboration is an international movement, and reviews are driven by researcher led groups. Therefore, in addition to Cochrane, individual countries have realised the need to develop their own organisations to undertake such reviews, answering questions driven by national priorities.

So, for example, in England and Wales, NICE (National Institute for Health and Care Excellence formally National Institute for Clinical Excellence)[3] was established in 1999. NICE undertakes and commissions reviews of the evidence, which are often directed at major issues such as whether or not a newly launched drug for a particular condition should be used. Initially, most interest was focussed on synthesising the evidence for choice of pharmacological agent. Given increasingly constrained budgets and demands on the health service, there has also been a steady move towards considering not only effectiveness but costs. In order to compare different treatments for cost, the concept of the quality-adjusted life year (QALY) was born. The QALY is a measure of disease burden, including both the quality and the quantity of life lived and provides a common standardised measure to allow comparisons between treatments, for example, between a new and an established treatment. It provides an objective measure of the additional cost of the new treatment and can demonstrate whether possibly marginal health gains come at an unaffordable cost. The synthesis of the evidence to support NICE decisions may need to be commissioned. One centre which often undertakes this synthesis is the NHS Centre for Reviews and Dissemination[4] based at the University of York.

Similarly, the Scottish Medicines Consortium[5] was established in Scotland in 2001, prompted by a need to remove replication of decision making across the then 15 individual Health Boards and to promote consistency in medicine use across

[3] www.nice.org.uk/ accessed 27 Oct 2014.

[4] www.york.ac.uk/inst/crd/ accessed 27 Oct 2014.

[5] https://www.scottishmedicines.org.uk/ accessed 27 Oct 2014.

Health Board boundaries. The SMC has been credited with providing more timely advice than NICE, but in practice the two groups work in tandem and complement each other's activities. In adopting evidence-based decision making in this way, the UK is reflecting practice in other countries such as Canada and Australia. For example, there is a pan-Canadian process [CADTH Common Drug Review (CDR)][6] which reviews the clinical effectiveness and cost-effectiveness of drugs and provides recommendations for Canada's publicly funded drug plans. In Australia, the Pharmaceutical Benefits Advisory Committee (PBAC)[7] recommends new medicines which can be provided under the Pharmaceutical Benefits Scheme (PBS) (medicines subsidised by the Australian Government). No new medicine can be listed unless the committee makes a positive recommendation. Reassuringly, a recent academic publication (Clement et al. 2009) demonstrated that conclusions about effectiveness and cost-effectiveness across the three countries were consistent, but that there was also variation in final recommendation because of differences in other contextual factors such as agency processes, ability for price negotiation and social values.

As well as high level use of evidence to inform policy, individual practitioners also need evidence-based guidance on managing individual patients with a particular condition, when they may be faced with a plethora of management and pharmacological treatment options. In Scotland, the Scottish Intercollegiate Guideline Group[8] undertakes wide ranging disease-based reviews, recognising that in some areas, the level of evidence is not as strong as in others and making this clear in the final recommendations. The development groups include clinicians, researchers and lay representatives, and findings are disseminated as guidelines to inform practice, with an accompanying quick reference guide for professionals and good practice points highlighted. Condition specific guidelines are also produced by specialist societies, e.g. for pain or hypertension.

## 1.2 Evidence-Based Pharmacy

### *1.2.1 From Drugs to Services*

As noted above the original focus of evidence-based medicine was mostly about the choice of drug. There was an increasing recognition that similar techniques could also be applied to choices about different procedures or diagnostic tests and perhaps most recently about choice of personnel actually delivering the service. These developments and the need for appropriate methodologies to apply when moving from

[6] http://www.cadth.ca/ accessed 27 Oct 2014.

[7] http://www.health.gov.au/internet/main/publishing.nsf/Content/Pharmaceutical+Benefits+Advisory+Committee-1 accessed 27 Oct 2014.

[8] www.sign.ac.uk/ accessed 27 Oct 2014.

clinical research and studies of medicines contributed to the development of the discipline of Health Services Research (HSR).[9] HSR investigates 'how social factors, financing systems, organisational structures and processes, medical technology and personal behaviours affect access to health care, the quality and cost of health care and quantity and quality of life. Compared with medical research, HSR brings together social science perspectives with the contributions of individuals and institutions engaged in delivering health services'. It is a relatively new discipline whose methodologies are continually developing and becoming more sophisticated. Initially, HSR focussed more on the different ways of understanding and delivering patient care from the perspective of the effectiveness of the medical workforce, in both secondary and primary care. However, crucially it was not about whether a doctor could do something in a more effective or efficient way than another health-care professional but more about the optimal way a doctor should work. For example, should a surgeon use technique 'a' or technique 'b' or should stroke patients be cared for in specialist units or community units.

### *1.2.2 Pharmacy Practice Research*

In applying an evidence-based approach to pharmacy, a sub-speciality within health services research has been developed known as pharmacy practice research. Its focus is on exploring how and why people access pharmacy services, the costs of pharmacy services and the outcomes for patients as a result of these services, and comparison of these costs and outcomes compared to the same or similar services delivered by other providers. Its aim is to support evidence-based policy and practice decisions where pharmacists are employed or medicines are prescribed or used.[10] Pharmacy practice research often challenges traditional professional boundaries, reflecting the shift in the balance of care currently observed in health-care delivery. For example, many conditions that were once primarily managed solely in a hospital setting are now managed in primary care settings, and many roles, particularly those delivered previously by doctors, are now being delivered by other health-care professionals including pharmacists. Pharmacy research aims to understand the clinical, humanistic and economic impact of these changes from the perspectives of pharmacists, patients and other health-care professionals.

#### 1.2.2.1 Quality of Research

The approaches taken in pharmacy research can be summarised under the broad areas of understanding and describing the way care is accessed and delivered,

[9] http://en.wikipedia.org/wiki/Health_services_research accessed 25 Sept 14.

[10] http://en.wikipedia.org/w/index.php?title=Pharmacy_research&redirect=no accessed 25 Sept 2014.

identifying areas for improvement and evaluating new service models using rigorous research approaches. However, we should spend a moment now to reflect on the need, as in medicine, for rigorous approaches and to be critical of using research, to inform practice, which is not conducted to such standards.

As pharmacy practice research has developed, it has become inextricably linked to the move to change the whole paradigm of pharmacy from a technical supply function to a cognitive-based profession exploiting the unique expertise pharmacists have about medicines and their use, alongside the worldwide need to address the increasing demands on health care, financial constraints and predicted workforce shortages. Unfortunately, enthusiasm to demonstrate the contribution pharmacists can make to a wider role in health care has resulted in a multiplicity of small studies which were designed with the *a priori* assumption that a pharmacist could deliver a role effectively, for example, they could improve a patient's medication regime or increase their adherence, compared to current usual care. Critical also was the fact that with a few notable exceptions, much of the research was done by pharmacists themselves, generally with little insight into the increasingly sophisticated methodological approaches being used in HSR more generally. It is not surprising therefore that this body of research was widely criticised by the wider Health Services Research community and dismissed as not generating the necessary evidence for policy change. In response, in the UK, the Pharmacy Practice Research Resource Centre (based at the University of Manchester) commissioned a review of pharmacy practice research from Nicholas Mays, then Director of the Health and Health Care Research Unit at the Queens University Belfast. The results of the review were disseminated at a conference in 1994, but they made for uncomfortable reading for the majority of the pharmacy practice research community. The review concluded that the discipline of pharmacy practice research was largely immature, was limited to small descriptive and feasibility studies and most damningly that it was mostly designed and conducted by pharmacists with an apparent aim of demonstrating the value of pharmacy *per se*. The outcome was a plethora of studies interesting in that they could be used as proof of concept studies, but of little value in providing generalisable data, often only reporting intermediate process outcomes rather than clinical or humanistic patient outcomes and with health economic input extremely rare. In summary, in an evidence-based age, such research could not inform policy.

A core recommendation made in the review by Nicholas Mays referred to above was that as pharmacy practice research integrates several research paradigms and perspectives, it should be delivered by multidisciplinary groups including not only pharmacists and other members of the clinical team but also statisticians, health psychologists, social scientists, health economists and epidemiologists, among others.

#### 1.2.2.2 Systematic Reviews of Pharmacy-Related Research

Just as in other areas of science, evidence from pharmacy practice research should be formally collated using a systematic review approach, involving comprehensive identification of all papers addressing a topic, selecting them against predefined inclusion and exclusion selection criteria, quality assessing them and reporting them. Ideally for quantitative studies, this should be in a meta-analysis. The critical quality review is really important for highlighting deficiencies in studies which may tend to favour more positive outcomes such as lack of an objective outcome measure, evaluation of the study by the same person who delivered the intervention, small numbers, failure to follow up non-responders or failure to use an intention to treat analysis. A relatively recent paper in Annals of Pharmacotherapy has emphasised the value of systematic reviews for pharmacy practice (Charrois et al. 2009) and gives good guidance on searching, evaluating, interpreting and disseminating the findings. Systematic reviews of pharmacy roles are increasing but readers need to critically consider the quality of the review method and the quality of the study inclusion criteria before quoting any conclusions. To take the profession forward, only the highest level of evidence should be cited.

Conducting a systematic review is a piece of research in its own right, often referred to as 'secondary' research. Just as primary studies can be done to differing levels of quality so can a systematic review. As noted earlier, there are quality criteria for assessing reviews, and even for reviews of reviews. Publishing a systematic review through the Cochrane Collaboration is beneficial on several counts. First, all Cochrane reviews have a certain status; they are also easily found by those searching for evidence as one of the first actions is always to search the Cochrane library. Second and linked to the above is the fact that there is knowledge that Cochrane reviews have been conducted to the highest standards; in order to publish a review under the Cochrane banner, a detailed protocol must first be submitted and approved through a peer review and editorial process. Finally, Cochrane reviews have a finite life and if not updated at regular predefined intervals, they are no longer considered valid.

There are already several systematic reviews relevant to pharmacy practice in the Cochrane library. Importantly, they often involve multidisciplinary teams of researchers and are therefore less likely to have any bias in favour of pharmacy in the interpretation and reporting.

One of the earliest was a review of the effect of outpatient pharmacists' non-dispensing roles on patient outcomes and prescribing patterns (Nkansah et al. 2010). Publication of the third update of this review is pending. In the most recent update in the public domain (2010), the authors comment that many of the studies show improvements but these are not statistically significant. The authors also comment that because of heterogeneity across the studies, no overall conclusion is possible.

In an evidence-based age, non-significant findings, however positive, cannot be claimed as evidence. Studies do not only need to be well designed but also to have

included an appropriate sample size calculation to ensure they are not underpowered. Indeed the importance of undertaking an iterative approach to intervention design and testing is now well accepted[11] by the research community who follow the MRC guidance on developing and evaluating complex interventions. Pilot work to assess likely effect size and provide factual data to guide the power calculation for the definitive study is now *de rigueur*, and without this publication of studies in the leading journals is unlikely.

Similarly in 2012, a Cochrane review on polypharmacy and the elderly (Patterson et al. 2012) including a range of study designs showed a reduction in inappropriate prescribing and drug-related problems but conflicting results on hospital re-admissions,i.e. making a difference only to process rather than to a clinical outcome. The conclusion was, therefore, that it was unclear whether interventions to improve appropriate polypharmacy, such as pharmaceutical care, resulted in clinically significant improvements to patients.

Finally, a 2013 review (Alldred et al. 2013), again on improving prescribing but this time in care homes only, could not come to a definitive conclusion due to heterogeneity in design intervention and outcomes. This review could have had the potential to be considered a stronger more robust review, as it only included RCTs. However, individually few if any of these RCTs got high scores on the quality assessment. All of the eight studies, remaining after selection from 7,000 hits, included a pharmacist as the main deliverer of intervention.

Systematic reviews are of course published in many places, additional to the Cochrane library. They are printed by academic Journals, after going through appropriate peer review, and are prized by Editors as they get cited frequently. Holland et al undertook a review of papers evaluating the outcomes of pharmacist-led medication review in the elderly (Holland et al. 2008). Only RCTs were eligible for inclusion, and there was a meta-analysis for the main outcome of unscheduled hospital admissions. The authors comment on the steadily increasing quality of pharmacy practice research but once again were not able to provide a definite answer on changes if any in the 'clinical outcome of hospital re admission or mortality'. Some process improvements, e.g. patient knowledge and adherence were noted.

Finally, a review of the views of pharmacists, their staff and the public on a public health role for community pharmacy (Eades et al. 2011) concluded that overall whilst pharmacists were positive about providing public health services, these were secondary to medication-related and dispensing roles. Support staff were less confident and positive about providing a public health role, and whilst consumers were positive in principle about pharmacists providing such a service, they did not expect it and had rarely been offered it in practice. This review has identified descriptive studies such as surveys which are methodologically less challenging to conduct than an intervention studies, yet the authors of the review once again comment on the poor quality of the studies.

[11] http://www.mrc.ac.uk/documents/pdf/complex-interventions-guidance/ accessed 13 Oct 2014.

Small studies can of course be done to the highest quality, but to conduct a strong study eligible for any of the reviews cited above would require an experienced team and a substantive grant. Accessing such funds for pharmacy-related research is becoming easier, but it still represents a formidable challenge if pharmacy-related studies are being assessed for prioritisation against studies of, for example, a new surgical intervention. It is also sometimes difficult to get pharmacy colleagues in clinical practice to take part in research because they themselves are already very busy, and many funding arrangements do not pay for pharmacists' time. In Australia, there have been moves to integrate pharmacy practice and research, and the community pharmacy contract global sum includes money to fund pharmacy-related research. An excellent example of how this has been put to good effect follows in the next section.

### *1.2.3 Importance of Right Outcome*

In their Cochrane review, Nkansah et al. commented on the heterogeneity of many components of the research including variation in the types, intensity and duration of interventions or differences in timing of follow-up measurements. They also comment on the lack of detail in the papers on the development processes of the interventions or how staff were trained to deliver the intervention or what constituted successful delivery of the intervention—what is sometimes referred to as fidelity. All of these are important things for any researcher to consider in designing, conducting and reporting a study.

The uncertainty around many of the aforementioned items could account for the conflicting results observed and also make it difficult to combine studies in a meta-analysis.

However, the main area of heterogeneity that the authors identify as requiring attention in the future is the need to select an appropriate outcome measure. At the study design stage, it should be possible to provide a theoretical reason for why the intervention in question is likely to change the selected primary outcome and whether the measure selected is likely to be sensitive enough to identify any changes. The gold standard choice of outcome to assess the clinical cost-effectiveness of intervention in general is a quality of life measure such as the SF36 or EQ5D which can be converted into QALY. Thus, NICE and equivalent organisation can compare diverse interventions on the basis of a common unit—the QALY, to which they can also attach a price.

However, in delivering pharmaceutical care we need to realistically ask ourselves the likelihood of changing these broad brush measures which have several domains. For example, the EQ5D, now the favoured measure in the UK, has five domains covering mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Whilst there is a youth version there is no older people's version, and the scale itself has not been validated in every disease to which it has been applied. Nkansah et al. comment that in older people their likelihood of co-morbidities

means that even improving outcomes in one of their conditions may not be sufficient to change the global assessment of overall quality of life and they call for a new universal, easily applied, valid and reliable outcome to be developed to use in these populations, who because of polypharmacy regimes often comprise the majority of participants in pharmaceutical care interventions.

In a study of community pharmacist-led medicine management for patients with coronary heart disease (The Community Pharmacy Medicines Management Project Evaluation Team (C. Bond Principal Investigator) 2007), there was no change in the primary outcome measure of patient quality of life as measured by the SF36 in the intervention group compared to the control. Yet there was significant increase in the patient satisfaction score for the care they received from the pharmacists. This leaves a conundrum of what is driving that increased satisfaction. Indeed, there is a general move to begin to consider the use of more patient-centred outcomes such as discrete choice experiments to value of what it is that the patient liked about the intervention. Early work has suggested that a DCE can be used to quantify and value the pharmacy input and reverse the take-home policy message to be more positive (Tinelli et al. 2010).

However, whilst the pharmacy profession and the research community all see the logic of this argument, the new pharmacy-delivered intervention is competing for funds with other new exciting developments, and the rationale for the EQ5D and SF36 QUALY were that they could bring a heterogeneous mix of interventions down to a single common unit of benefit. At this present time it is unclear how policy makers would view an alternative set of outcomes, and it remains unclear whether they would be prepared to pay for more satisfied patients.

## 1.3 The Policy, Practice and Research Triangle in Pharmacy

In 1986, the Nuffield report (Nuffield 1986) was the first to clearly identify in the UK that community pharmacists could play a more central role in health-care delivery. It was particularly important because it was seen to be an objective pronouncement by opinion leaders outwith the pharmacy profession who would have little, if any, vested professional interest in its recommendations.

The overall message of Nuffield was embraced in the context of health care in general. It was immediately adopted by policy makers in a succession of publications, which iteratively have been more ambitious in widening the scope of pharmacy practice and for changing a profession from having a predominantly technical medicine supply function to being a clinical profession with interfaces with both patients and other health-care professionals. The extent of change in the intervening years has been ground breaking. Whilst the UK has in many ways led the implementation of the extended role, this has also been happening elsewhere, most notably in Australia and Canada. In an evidence-based health-care system, it is

interesting then to reflect on what has driven that change and to what extent it has been informed by research.

The reality is that to effect a change in role as significant as the one seen in pharmacy requires more than research evidence. For such a change to happen, it has to be acceptable to society—the public, fellow health-care professional and the pharmacy profession itself; it has to meet a policy need and there has to be some evidence of feasibility and benefit.

Applying these ideas specifically, and as noted earlier in this chapter, demographic changes will mean an inevitable increased future demand for health care. Furthermore, technological advances mean that many conditions previously treated surgically and requiring long stays in hospital can now be managed medically with pharmacotherapeutic approaches or as day cases. So there is a secondary care–primary care shift moving care out of hospitals. At the same time there are medical workforce shortages, a move to have longer consultation times reducing patient throughput, and a changing cultural expectation of the need to see a doctor for relatively minor symptoms, increasing demand although arguably not needed. The potential for other health-care professions including pharmacy to fill that capacity gap has been recognised, and the ambition for pharmacy to extend its role has actually coincided with a policy need. Furthermore, pharmacists have increasingly taken on new roles informally, for example, in hospitals advising medical staff of the best medicine regime for a patient, in the community issuing repeat prescriptions in advance of receipt of the formal form in the interest of continuity of supply for the patient, and pursuing the long-held traditional role of providing advice to patients on the management of minor ailments. Today it is a formal role in many countries for pharmacists to prescribe prescription only medicines; to prescribe on the NHS or equivalent pharmacy medicines rather than patients paying for them; to manage repeat dispensing; to advice on adherence; to provide a clinical medication review and make changes to drug regimens; to provide a multiplicity of public health roles including formal intensive advice to stop smoking, issuing emergency hormonal contraception, screening for chlamydia, giving brief interventions to address hazardous drinking and administering flu vaccinations to give but a few examples.

Practice research can be categorised under four broad areas with respect to its role in relation to policy. The first category is where **research has informed policy** and has been the trigger for innovation (e.g. smoking cessation, repeat dispensing, new medicines service) and where it was conducted before any service rollout. The second is again where the research was undertaken before service rollout but after a policy decision had been made, that is it was to **support a planned policy** (e.g. medicine management). Third is research that has been conducted after a new service had been introduced to **confirm the appropriateness of implemented policy**, (e.g. pharmacist prescribing). The final category is where it has been used to evaluate an innovation or service in order to **understand the processes in place**, identify good and less good aspects and make recommendations for the future (e.g. evaluation of the new English community pharmacy contractual framework). Each of these will be considered in turn, but it will be clear as the descriptions are

read that there is some overlap between groups and in many ways it is a continuum. Because much of the professional change has been spearheaded in the UK, and because the author is UK based, there is no apology that the following examples are all from that country.

## *1.3.1 Research Informing Policy*

### 1.3.1.1 Smoking Cessation

In 1991, as part of a progressive trend in many countries to widen safe and convenient access to medicines, the first nicotine replacement therapy (NRT) (nicotine gum 2 mg) was deregulated in the UK from a prescription-only medicine to a pharmacy medicine. Since then many other nicotine-replacement therapies at higher strength and in different formulations have been deregulated and many are now freely available as a General Sales List medicine. The wider availability of NRT made it possible for pharmacists to take on a very clear public health function of supporting smoking cessation. This led to the idea that pharmacists and their staff could be trained to provide a formal smoking cessation service. A randomised controlled trial was designed and funded to test whether the smoking cessation outcomes of people attending trained pharmacies were any different than those attending community pharmacies providing advice on smoking cessation as per usual practice. In other words, could the quality of the service provided by community pharmacists be enhanced by training. A 2-h training package was developed for pharmacists and their staff based on the theory of behavioural change. Smokers were followed up at 1 month, 4 months and 9 months after their first pharmacy visit. The study showed that smoking cessation rates at all three time points were better for those people attending trained compared to untrained pharmacies (Sinclair et al. 1998), and the cost of intensive pharmacist support was £300 per quitter and £83 per year of life gained (Sinclair et al. 1999). Despite this good evidence of benefit, endorsed by a Cochrane review (Sinclair et al. 2008), it was some time before smoking cessation advice became a core role for all community pharmacists in Scotland with appropriate recognition and a professional payment. First small local contractual arrangements were entered into, fighting professional turf wars on the way. Gradually, pharmacists demonstrated that as a profession they could deliver on smoking cessation, and in 2008, the service became embedded in the national contract. Today in Scotland, 70 % of all quit attempts go through community pharmacy, and thus community pharmacy is tackling one of the biggest public health problems of this, and the last, century. It is salutary to emphasise this long time line between the generation of the evidence and implementation into policy, and also to remember it was not just the research that led to the change. It also happened because society was ready to stop smoking and because smoking was suddenly identified as a priority public health policy issue.

#### 1.3.1.2 Repeat Dispensing

With a similar time frame and in a similar way, a randomised controlled trial of pharmacists managing repeat dispensing conducted in the mid 1990s (Bond et al. 2000) led to repeat dispensing by pharmacists becoming embedded in both English and Scottish community pharmacy contractual frameworks. In the original RCT, when pharmacists managed repeat dispensing, they detected more medicine-related problems than were detected in the control group of usual care, they reduced the annual costs of drugs prescribed per patient in the system and GPs, managers and patients liked the service. Once again in the years following the academic publication, small pilot projects of the service were implemented widely in various local areas and ultimately the service became standard for all pharmacists.

#### 1.3.1.3 New Medicines Service

The final example in this category is of the New Medicines Service recently introduced and evaluated in England. It is generally accepted that many people who are prescribed a new medicine do not necessarily take it for a range of reasons. Many people may even not take the first dose. A study published in 2006 (Clifford et al. 2006) showed that when patients prescribed a new medicine for a chronic condition were followed up by phone there was an improvement in their positive beliefs about taking the medicines, there was reduced non-adherence and reduced problems compared to a control group who did not receive the follow-up call. This research underpinned the New Medicines Service introduced into English community pharmacy contracts on a 1 year pilot basis in 2012 and now set to continue after an ongoing positive evaluation report. Thus, the New Medicines Service could also in fact fit into the next category of research confirming the appropriateness of a policy, especially as the way the service was implemented in practice was not through the centralised telephone service used in the trial but through individual pharmacists.

### *1.3.2 Research to Support a Planned Policy*

In the early 2000s, new community pharmacy contracts were being developed in the home countries of the UK to reflect the aspirations of policy documents to move the pharmacy profession to a more cognitive role. Whilst most of the professionals believed at the time that this was the future for the profession, whilst contractual payments were driven by volumes of items dispensed, it was unlikely that the focus of community pharmacy services would change. Building on the success of the practice-based primary care pharmacists, it was believed that community pharmacists could deliver at least some of these roles from their community pharmacy

base, by delivering a holistic pharmaceutical care service. In pharmaceutical care, pharmacists would take responsibility for the management of a patient's medicines and their associated drug-related needs. Research was commissioned by the Department of Health to derive evidence of the benefits of a community pharmacy-led pharmaceutical care service for patients with coronary heart disease. At the time there was evidence from published studies of the benefits of individual components of a pharmaceutical care or medicine management service (e.g. life style advice, blood pressure monitoring, adherence support), but there had been no studies of the whole service. A large definitive randomised controlled trial was conducted. This study has been previously referred to in this chapter as the one in which choice of outcome measure was critical. The study failed to show that there was an increase in appropriateness of treatment or patient quality of life although as noted earlier, there was increase in patient satisfaction and observed individual improvements in prescribing. However, whilst some community pharmacists identified many areas of improvement, others were less successful, so on average there was little change (Krska et al. 2007). When the new contract was implemented, it was emphasised that the Medicines Use Review component was about supporting the patient and not about improving appropriateness of care. This study also shows the challenges of generalising from small trials with self-selected participants to larger studies involving whole populations. The former are more likely to give positive results as the participants will be those who are more likely to have an interest in and commitment to the project. The larger whole population studies are more likely to reflect subsequent national implementation but may be more conservative in their estimate of benefit.

### *1.3.3 Research to Confirm the Appropriateness of Implemented Policy*

Research defending policy is often commissioned as a formal evaluation after a service has been introduced. In the UK, this has been the case, for example, after the introduction of non-medical, including pharmacist prescribing.

#### 1.3.3.1 Pharmacist Prescribing

Non-medical prescribing was introduced in the UK after the Crown review (Department of Health 1999), a group established to review the supply and administration of medicines, recognising that much current practice was operating on the edge of the current regulations and legal frameworks. The Review recommended the implementation first of non-medical supplementary prescribing in which trained nurses or pharmacists with the agreement of patients and medical staff could continue to prescribe specified drugs for a patient, altering them as necessary within

an agreed clinical management plan. Supplementary prescribing, introduced in the UK in 2003 was quickly followed by independent prescribing (2007), which gave trained nurses and pharmacists the right to prescribe any drug they wanted within their areas of professional competence including controlled drugs. More recently other health-care professionals such as podiatrists and opticians have also been given some prescribing rights. Newly agreed accreditation criteria for undergraduate pharmacy degrees in the UK, to be introduced from 2015, will provide all pharmacy graduates with the requisite competencies to prescribe. These significant changes were introduced without prior research evidence of safety or benefit. The rationale might have been that the stepwise introduction starting with supplementary and then followed by independent prescribing allowed a staged opportunity to reflect on the rollout supported by commissioned evaluations (Department of Health 2011). These evaluations focussed mostly on experiences and safety aspects and did not include evidence of effectiveness or efficiency compared to traditional approaches. There is now a considerable body of subsequent research on non-medical prescribing, mostly focused on nurses and pharmacists. However, the bulk of this research has been descriptive exploring the extent of implementation and the medical specialities where most non-medical prescribing is delivered, the views and experiences of patients, medical doctors and the new prescribers themselves. A few studies have looked at the clinical outcomes of non-medical prescribing. One exploratory study (Bruhn et al. 2013) showed that in the field of chronic pain, pharmacist prescribing compared to traditional GP led care for patients with chronic pain led to significantly improved pain outcomes at 6 months (as measured using the validated Chronic Pain Grade) but interestingly only some effect on the mental health sub-scale of the SF36. This again reflects earlier discussion in this chapter on the importance of choosing the right outcome measure.

#### 1.3.3.2 Primary Care Pharmacy

In the late 1990s and early 2000, the value of a pharmacist working closely with a general practitioner based in the practice became apparent. The role was purely advisory, and based on the clinical pharmacy role then well established in the hospital setting. It included for most early post holders reviewing practice prescribing and looking at a practice level at trends in prescribing, adherence to guidelines and formularies and making recommendations for changes to improve efficiency and effectiveness, at both practice and individual patient level. At individual patient level, some posts involved the pharmacist having face-to-face consultations with patients (McDermott et al. 2006), but until the advent of pharmacist prescribing (see previous example) any recommended changes had to be mediated by the medical prescriber.

The pharmacists working in general practice in the UK came to be known as primary care pharmacists, and over the course of approximately 10 years, the pharmacy profession evolved from being split into hospital and community pharmacists to having a third significant group of pharmacists delivering a clinical

service. No large-scale definitive study was ever published of the added value that pharmacists brought to the practice team, although small uncontrolled studies and case reports appeared to confirm that the pharmacists saved money for practices and brought prescribing into line with current guidelines. This is a very interesting example of a sea change in the pharmacy profession which emerged on the basis of a slowly building body of descriptive evidence and local roll out rather than a big study and national implementation. However, reassuringly, a systematic review of practice-based pharmacy services (Fish et al. 2002) including studies from North America (7), the UK (5), Australia (2) and Sweden (1) showed that most published RCTs suggested benefits from the roles although studies were generally very small, not powered and did not include measures of cost-effectiveness.

### *1.3.4 Research to Inform Future Service Review*

In this final category, the value of research in giving constructive feedback to providers and policy makers on how a service could be improved to support improved efficiency and effectiveness is illustrated. In 2005, a programme of work was commissioned to evaluate the introduction of the new Community Pharmacy Contractual Framework in England. As mentioned earlier, this new contract represented a significant change from earlier contracts as it was structured to formalise and recognise through remuneration professional advisory services alongside traditional dispensing roles. The emphasis of the evaluation[12] was to describe implementation processes and provide constructive recommendations on addressing identified barriers to optimal service delivery. So for example, one option introduced in the contract was for local organisations to commission advanced services from accredited community pharmacists. One such service was the Medicine Use Review (MUR) service. The research, which adopted a mixed methods approach, showed great variation in rate of uptake of the service in different local areas and by different pharmacists. The qualitative data revealed that there was a misunderstanding on the part of general practitioners, pharmacists, patients and commissioners about the purpose of the MUR. GPs either expected and pharmacists delivered a full clinical review rather than providing supportive communication with the patient. There was also concern about the record keeping, inability to assess quality and communication with the GPs. Thus the report could highlight these areas and allow local solutions to address these to be put in place. Subsequently small studies of MURS have been able to demonstrate the benefits

[12] http://www.pharmacyresearchuk.org/waterway/wp-content/uploads/2012/11/National_evaluation_of_the_new_community_pharamcy_contract.pdf accessed 14 Oct 2014.

they can confer,[13] and the service has continued to be delivered by increasing numbers of pharmacists.

### *1.3.5 An Integrated Example*

In Australia, the introduction of Home Medicine Reviews provides an interesting comparator and an example of excellent integration between service provision and research. Since the mid-1990s, the global sum allocated to fund professional pharmacy services under the 5-yearly Community Pharmacy Agreements (CPA) has increased from $5 million in the second CPA (1995–2000) to $663 million in the fifth CPA (2010–2015). Several Commonwealth-funded research projects undertaken to evaluate the impact of pharmacist involvement in medication review for consumers living at home were conducted in the late 1990s, following a successful randomised controlled trial within the nursing home sector. This research subsequently informed negotiations within the third CPA to fund pharmacist and GP involvement in the Home Medicines Review (HMR) Programme. An HMR[14] involves a comprehensive medication review conducted by an accredited pharmacist. The process begins with a referral from the patients' GP to either their preferred pharmacy or pharmacist. The pharmacist then conducts an interview with the patient, usually in their own home, before writing a report to the referring GP, documenting specific medication review findings and recommendations. The GP then meets with the patient to develop a medication management plan based on the pharmacist's report. This successful programme has been developed and iteratively refined by research, much led by Professor Chen of the University of Sydney, Prof Gilbert from the University of South Australia and Prof Roberts from the University of Queensland. It is a real example of policy makers and researchers working together for the benefits of an improved service to patients.

## 1.4 Challenges

In the last decade the volume of good quality research on the cost effective and clinically effective prescribing, supply and use of medicines has increased exponentially. Nonetheless there remain challenges to bridging the policy research divide, and it is frustrating for researchers when policy is introduced for which there is no evidence, or where there is evidence that does not seem to have been

[13] http://www.pharmaceutical-journal.com/news-and-analysis/news/inhaler-technique-murs-significantly-improve-outcomes/11107200.article

[14] http://5cpa.com.au/programs/medication-management-initiatives/home-medicines-review/

taken into account. Some of these challenges and reasons for them are considered briefly below.

### 1.4.1 Expertise, Time and Money!

A robust study that generates gold standard evidence requires an experienced team, appropriate iterative developmental and pilot work and substantive funding. All of these remain challenges for those working in the field of practice research. Capacity and expertise are being developed in Universities and in the workforce but it is a steep learning curve until a researcher would be judged 'a safe pair of hands' to lead a programme of work. Doctoral and post-doctorial experience are core to a research career as is the ability to network and link with those from relevant complementary disciplines. Commissioned research programmes addressing a national priority can often seem to have short deadlines between the initial call and its submission date, unrealistic objectives to be addressed within the funding envelope and tight time-scales for when results should be available. It is better to argue the case to do part of the commission well than to spread efforts, expertise and resource too thinly.

### 1.4.2 Engaging Colleagues

Research of relevance to pharmacy frequently depends on peers in practice collecting data, recruiting participants or delivering a new service, often referred to as an intervention. It is important that in all these roles, adequate training and monitoring are in place to ensure accurate and consistent recording of data, non-biased recruitment or delivery of the new service in the planned way. This requires patience from those on the research team and commitment from colleagues for whom maintaining services represent an ever increasing workload to say nothing of the increased regulatory hurdles that are introduced.

### 1.4.3 Changing the Status Quo

Many new pharmacy roles are not new roles per se but are new to pharmacy. They will most likely have been delivered previously by medical colleagues, and there will be some resistance from those colleagues to another professional taking them on, especially if a transfer of funding would be implied. This attitude is slightly surprising, given that it is acknowledged by all, including the medical colleagues that they currently do not have the capacity to deliver all that is demanded and that new ways of working need to be identified. Further, there may initially be resistance from patients if they think that the move to transfer care is to 'save money' or that

the new provider is not as well as qualified. Finally other non-medical colleagues may also be aspiring to take on the role that is being devolved, as in prescribing. The role of research therefore is to generate the evidence that shows that patients are not getting second best care, and to design the new service with stakeholder input so all concerns are addressed, and the new service is not seen to fail for the wrong reasons, for example, in the case of medication management that GPs are not referring patients to the service.

### *1.4.4 Negative Findings*

Negative findings can be challenging to reveal especially if positive results had been central to implementation of a new service. This is where it is important at the design stage to think about incorporating a parallel strand of research which does not just focus on outcomes but is explanatory. For example, was the training sufficient to give the pharmacists the skills to deliver the new service, was the new service acceptable to patients, did the GPs implement the recommendations? Identify what, if anything, went wrong and provide recommendations for change. Most importantly, difficult though it might be, do not be persuaded to hide the negative findings, and ensure that at the project start the researchers have independence to publish findings.

### *1.4.5 Funding*

Securing adequate funding is also a challenge. Whether applying to a dedicated call or applying for response mode funding (i.e. getting your own ideas funded) will always be within a competitive context. In general, pharmacy specific funds are modest so it is wise to try and access other funding streams and to collaborate with colleagues from other disciplines. Persuading grant giving bodies to prioritise funding on services such as aspects of medicine management (e.g. improving adherence or improving appropriateness of prescribing) or symptom management compared to developing a new cancer treatment may also appear challenging. However, at a time when patient safety is high on everyone's agenda, reducing prescribing errors is central, improving adherence is also a facet of medicines safety, and non-adherence leads to costs both in terms of medicines wastage and sub-optimal treatment. Finally, appropriate symptom management in the community pharmacy could lead to improved earlier diagnosis of serious diseases such as cancer and COPD, which when treated earlier have a better prognosis.

### 1.4.6 Duplication of Research

Finally, to what extent is it necessary to repeat research done in one country in another country? Will policy makers acknowledge the relevance of generalising from a different health-care setting, with different ethnic populations, different cultural attitudes? The answer to this is not simple, as it will depend on the exact intervention or development in question, but nonetheless it is important to learn from others and draw on their experiences. A good example of this is the interest in North America in the HMR service introduced in Australia. Whilst recognising that the evidence in the US about the value of extending pharmacists' roles in relation to medication management is increasing, authors of a recent paper have also explicitly drawn on evidence from elsewhere, namely Australia (Zagaria and Alderman 2013). The authors highlight that 'it is instructive to look at how similar practice models have been established and evolved in other countries'. This is an interesting example of where local research has been complemented by selected research from elsewhere generating a stronger body of evidence for the US than could have otherwise been achieved in the same timescale.

### 1.4.7 Communicating with Policy Makers

There is, as noted at the start of this chapter, a need to reconfigure health services if future need is to be managed within an affordable budget. Those interested in generating evidence that identifies a role for pharmacy in this service redesign must reflect not only the quality of their research but also on improving the way these findings are communicated to policy makers. This may not be just about recycling academic papers as policy briefings but is also about building real and virtual networks, and using the social media to promote awareness and disseminate findings widely.

## 1.5 Conclusion

Pharmacy has come a long way in the last three decades in becoming a truly clinical profession. A recent paper (Mossialos et al. 2013) has described the expanded role for pharmacy as 'policy making in the absence of policy relevant evidence' and claims further research is needed. We would not argue with this but also would assert that there is a building body of evidence confirming the value to patients of this paradigm shift. However, as we move forward more consideration need to be given to improving the quality of the evidence, ensuring that cost effectiveness as well as clinical effectiveness is considered, making sure the right outcomes are

chosen, and finally opening up better lines of communication with policy makers to ensure greater partnership in planning a research strategy fit for the future.

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