The need for research in primary care

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Making evidence from scientific studies available to clinical practice has been expected to directly improve quality of care, but this expectation has not been realised. The notion of quality of care is complex, and quality improvement needs medical, contextual, and policy evidence. In primary care, research is needed that takes into account the specific characteristics of its population and the presentation and prevalence of illness and disease. The context of the doctor-patient encounter plays a major part, and needs better understanding. At the policy level, issues of equity must be addressed. The knowledge base for family practice must be expanded by integration of multiple methods of comprehension, so we can bridge the gap between evidence and practice.

In his 1972 report, Cochrane concluded that to improve quality, the clinical sector of the UK National Health Service (NHS) should be controlled by science, in particular by wide use of randomised controlled trials. Dissemination of the results of these trials would directly change patients' care. 30 years later, Cochrane’s approach clearly enhanced the number of published papers, but it has had rather limited effect on clinical practice and policies—even when applying the most sophisticated electronic techniques. In this paper, we explore the complexity of the notion of quality of care, then analyse limitations of contemporary ideas about evidence-based medicine, and look at the need for medical, contextual, and policy evidence. From this research, opportunities for primary care will be looked at.

Quality of care and caring for quality: a theoretical framework

Demonstration of quality has become increasingly important, and doctors can no longer self-proclaim their work and services to be of high quality. The Institute of Medicine’s definition of quality is widely accepted up to today:

“Quality of care is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.”

Figure 1 shows the complex picture of determinants of quality, starting from the Donabedian-triangle of structure, process, and outcome, and gives a theoretical framework that enables analysis of quality of care.

Structure consists of three interrelated components: society, the individual, and the health-care system. Society presents a so-called epidemiological community, characterised in terms of morbidity, socioeconomic status, employment, housing, and other variables; a cultural community (an anthropological frame of reference); and a support community, with formal, informal, and professional networks. At the level of the individual, biopsychological status, knowledge (about the functioning of the body), skills (coping, self-care), and attitudes (health perceptions and health beliefs) affect clinical care. For the health-care system, organisational aspects (accessibility, continuity) and characteristics of health-care providers (competence, empathy) affect quality of care.

Process refers to all interventions and interactions between patients and providers. Process quality largely depends on adequate communication, medical decision-making, and management of care. Guidelines, protocols, and algorithms that underpin process are increasingly based on scientific evidence. Structure and process are inextricably linked in continuous interaction. Quality of communication between patients and doctors, for instance, will be determined not only by the skills of the doctor but also by patients’ characteristics (eg, health beliefs) and by community characteristics—eg, importance of integration of cultural-anthropological factors in communication with immigrants. Medical decision-making will interact with the patient’s expectations and beliefs—eg, it is difficult to make clear to a patient who has unrealistic faith in medical technology that a CT scan is not needed for diagnosis of acute sinusitis. Both structure and process will establish the final outcome.

Outcome is decided by how patient and doctor perceive health and disease, and this perception has shifted from problem-orientation to goal-orientation. As a result—eg, for a patient with chronic pulmonary disease—the patient’s ability to participate in social life is more important than their change in lung-function test. This consideration results in a range of relevant outcome indicators that can be measured, from signs and symptoms, physical functions (eg, blood pressure, blood-glucose, peak-flow), quality of life (functional status), patient’s satisfaction, and social equity. But in figure 1, we emphasise the complexity of the different components of quality, and the picture is certainly incomplete, or why a linear mechanistic approach is not able to improve quality.

Evidence-based medicine must not be overestimated in the quality debate (figure 1). Its role is restricted to improvement of the scientific rigour of guidelines and protocols. An essential aspect of quality of care that has been triggered by findings of research is the need to value outcomes. Evidence-based medicine then allows analysis of effectiveness and efficiency of pursuing these outcomes.
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a definite yes-no decision in a particular patient—more uncertain certainty in Richards’ words. A bigger difficulty, however, is the availability of evidence. A basic assumption in guideline development is that clinical research follows clinical relevance. In reality, much research is driven by commercial interests. Moreover, the pharmaceutical industry could actively be involved in the so-called making of a disease, as in the case of female sexual dysfunction. As a result, more evidence is published on pharmacological treatments than on the effects of interventions aimed at changing health behaviour. For example, in the secondary prevention of cardiovascular events, there is detailed knowledge of the effect of drug treatment, but hardly any on the substantial effects of smoking cessation through non-pharmacological interventions. As a result, there is a danger of evidence-based medicine to pursue what is possible and available rather than what is relevant.

**Contextual evidence**

Contextual evidence is necessary to assist doctors to address the challenge of how to treat a particular patient in a specific situation. This need refers back to the principles of good doctor-patient communication to create trusting interpersonal relationships, exchange of pertinent information, and negotiation of treatment-related decisions. Good communication includes both instrumental and affective behaviours, but there is no blueprint to guarantee a favourable outcome. Factors that affect communication are related to the character and personality of doctor and patient and their personal history (continuity of care), disease characteristics (life-threatening diseases, depression, chronic pain), and family, socioeconomic, and cultural circumstances. Conflicts in the Middle East, for example, affect Western doctors’ communication with patients of a specific ethnic origin.

The underlying issue is that what comprises a diagnostic method—communication to establish a history or convey a diagnosis—is at the same time an intervention. Here, translation of study findings becomes a difficulty when a randomised controlled trial needs rigorous standardisation of history taking, diagnosis, and patients’ information. Trial design first excludes part of the regular intervention to assess the effects of the innovative, experimental one, and introduces the danger of overvaluing the new method over the established one. Another drawback relates to selective study dropout: patients from lower socioeconomic status—in itself a barrier to use of certain diagnostic and therapeutic strategies—might most frequently be lost to follow-up in randomised controlled trials. Usually, little information is given about the socioeconomic characteristics of patients in the dropout groups, which hampers extrapolation to regular patients’ care.

Extrapolation from research to practice presumes that patients are open to a rational approach, take responsibility for their own health, and make their own informed decisions. Evidence-based medicine depends in part on these factors, but many patients attribute their health status to external factors beyond their control (external health locus of control). When research offers probabilities and numbers needed to treat, patients expect certainty from their doctor, wanting to know whether treatment is successful for them. One way or another, doctors have to cope with this expectation, which brings ethical deliberations into the arena. While promoting best evidence care, doctors could be caught in a conflict between their obligation to promote health and respect for the patient’s autonomy. To pursue medical benefits over the patient’s autonomy can be valued as solidarity with the patient, but also as overprotection and paternalism. Similarly, respect of patients’ wishes for self-determination can be viewed as indifference to their medical needs. As the (family) doctor has to include these factors in every consultation with a patient, understanding contextual evidence is necessary to bridge the gap between efficacy—what works in isolation in an ideal setting—and effectiveness (what works in routine practice). In view of its different constituent elements, a multifaceted approach to implementation is needed, which is explored in the first paper of this series.

**Policy evidence**

The health-policy environment decides every meeting of (family) doctors and their patients, and therefore there is a need to enrich practice with more policy evidence, which entails efficiency, equity, and rationing. Achievement of individual evidence-based treatment benefits is in itself not the final word for promotion of that treatment for all patients. An assessment of therapy in chronic obstructive pulmonary disease stressed this:

“Although the evidence suggests that improved compliance with guideline-recommended practice will improve symptoms and disease-specific quality of life, further work needs to be done to establish the cost-effectiveness of chronic therapies for COPD [chronic obstructive pulmonary disease] relative to other chronic conditions. Without such data, managed care organisations will be reluctant to allocate scarce resources to expensive guideline implementation programs for individuals with this condition.”

Maynard stressed the implications of resource allocation in more general terms. When there are two treatment options—option A, leading to 5 years of good quality-of-life survival, and option B, leading to 10 years—an obvious evidence-based choice would favour option B. However, when limited resources are taken into account, and option B is the most expensive option, option A may produce more years of good quality of life than option B at the level of the population. From a population perspective, the evidence-based choice is option A. A clinician prescribing option B uses resources

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**Figure 2: Three types of evidence to improve quality**

**Medical evidence** (evidence-based medicine)

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improving quality of practice needs integration of education have an effect on doctors' and patients' behaviour, which goes beyond the limits of the health-care gatekeeping, reimbursement, and payment, regulations for advertising of medicines, and continuing medical education have an effect on doctors' and patients' behaviour, which goes beyond the limits of the health-care system. For instance, in case of asthma, to change working conditions would be the most logical intervention for the patient. But out of fear of losing their job, patients might prefer symptomatic treatment without notifying the employer of their diagnosis. Figure 2 shows how improving quality of practice needs integration of conclusions from the three types of evidence.

The research we need

The scope

In 1961, White and colleagues showed—in the ecology of medical care model—that only a few adults having symptoms consult a doctor, and only about 1% receive care in hospital in an average month. An update of this ecology model—despite major changes in the organisation and financing of medical care in the USA—was remarkably similar. In a population of 1000 adults and children in an average month, about 800 report symptoms of some sort, 327 consider seeking medical care, 217 actually visit a doctor's office (about 113 to primary-care doctors and 104 to specialists), 65 visit a complementary or alternative medical-care provider, 21 visit a hospital outpatient clinic, 13 visit an emergency department, eight are admitted, and fewer than one individual is admitted at an academic medical centre. Since medical research has been mostly hospital-based and focused on molecular mechanisms, there could frequently be a mismatch between primary care-based questions and hospital care-based answers. An investigation linking prevalence in primary care to available evidence from research could be the first step in identification of the main priorities for primary-care research. Clinical trials should be redirected towards the primary-care setting. Only through studying patients who visit their family doctor with symptoms and signs, and associated interfaces with other health-care settings, will enable design of high performance health-care systems. In this process, family practice-based research networks can play the important part of a laboratory for research activities in real practice.

The domains

Clinical research has tended to emphasise the therapeutic side of health care. Treatment interventions are preceded by diagnostic procedures and decision-making. Many new diagnostic techniques have become available in primary care during the past decades. Few publications focus on diagnostic processes, and methods of diagnostic research lag behind those for treatments. Formal requirements for adoption of diagnostic tests in routine care are practically absent. Even less researched is the value of history taking and clinical examination in the diagnostic process. Diamond and Forrester have shown that a decision aid consisting of three questions about precordial pain can greatly increase the pretest probability of coronary ischaemia, and thus lead to most adequate and efficient use of additional diagnostic testing. An essential feature of the diagnostic process in family practice is the low incidence and prevalence of severe diseases (low probability), and this aspect must be integrated in assessment of tests. Because a large part of diagnostic decision-making takes place in primary care, including selection and referral of patients, diagnostic tools must be investigated in a primary-care setting.

More trials in primary care are needed, starting not only from well established diagnoses with inclusion and exclusion criteria but also from usual complaints and symptoms. Diversity in the study population can be an advantage, because it could help differentiate between important subgroups and preclude overoptimistic estimates of intervention benefits. Large randomised clinical trials are not always feasible, and most of the time they are very costly. Therefore in primary care, investigators will probably continue to cope with the contradiction that the rigour of inclusion criteria and patients' selection needed for a randomised controlled trial is completely opposite to daily practice, in which variation and comorbidity is the prevailing situation, certainly in the growing population of patients older than 65 years of age.

The importance of psychosocial factors (socioeconomic status, health locus of control) and ethnocultural factors is increasingly acknowledged, but the effects of access to health information and services (information-rich vs information-poor) have not been studied thoroughly. There is much to learn about the genetic dimension of disease (such as predisposition for cancer or coronary heart disease) and treatment response—eg, racial differentiation of response to hypertensive treatment with calcium-channel blockers or disparities in incidence of diabetes-related complications in various ethnic groups. The genetic revolution depends in part on careful characterisation of clinical events, and benefits of genetics for family practice will arise in particular in their complex expressions in common morbidity.

Fundamental research at the primary-care level is needed to understand the clinical usefulness of the biopsychosocial idea. The question why so many carriers of Helicobacter pylori do not develop an ulcer indicates this difficulty. What other factors or experiences does it take to evoke clinical symptoms? And how can we explain the placebo effect seen in clinical research and practice? Di Blasi and colleagues reviewed published work on the effect of context on health outcomes and reported evidence for an effect (although small) of the doctor-patient interaction, more specifically of enhancing patients' expectations through positive information about the treatment or illness and reassurance. Fishbein has suggested the importance—in changing health behaviour—of beliefs and self-efficacy on outcome, and provided a theoretical basis for these findings. Doctor-patient meetings are especially important opportunities for putting clinical evidence into practice, and therefore, research on the effect of the doctor-patient relationship can help practitioners appreciate its value and use it in evidence-based management of patients. Research restricted to biomedical processes is insufficient; patients' care is more than diagnosis and treatment. McWhinney investigated the natural history of disease and illness. Natural history has more or less been restricted either to patients' immune system taking care of an intruding bug or to his or her self-control getting the better of worry-induced somatisation. In fact, an essential part of natural history is the possibility of
RESEARCH INTO PRACTICE II

Summary of trial characteristics in primary health care and family medicine

- The research question focuses on frequently encountered problems in primary health care
- The problem definition is closely related to the reason for meeting in clinical practice (compared with diagnosis-based)
- The diagnostic and therapeutic strategies studied are relevant to primary health care and incorporate the patient’s perspective with respect to acceptability and feasibility
- Multimorbidity (especially in elderly people) is taken into account
- Context variables, such as sex, socioeconomic status, and cultural and ethnic characteristics are measured and reported, contributing to adequate extrapolation of the results in daily practice
- The cost-utility—including patient preferences and values, with special emphasis on equity—is part of the analysis

compensation for lost functions, which can range from physical training to compensate loss of a limb, to re-definition of personal goals and objectives in life. Compensation is a special strength of living organisms, and for that reason in clinical practice there is a need for a model of the affected organ rather than of the mechanism of illness and disease. Such a notion allows association of illness and health with the full biopsychosocial situation of a patient, and helps to give clinical research a more holistic focus, which fits well with the specific characteristics and natural predisposition of family medicine, where medical, contextual, and policy factors all must be integrated into management of patients.

Conclusion

To address all these issues, the knowledge base for family medicine must be expanded by integration of self-reflective practice by clinicians; involvement of the patient in generation of research questions and interpretation of data; inquiry into the systems affecting health care and investigation of disease events; and diagnostic approaches and treatment effects in patients over time. This research will look at the many aspects of quality of patient care, as investigation of disease events; and diagnostic approaches and treatment effects in patients over time. The panel summarises how this work could be interpreted into characteristics of research trials to make scientific evidence more useful and applicable to primary care and family practice.

The fundamental question remains how this research will contribute to best health and wellbeing for all patients. We have argued that we need three sources of evidence: medical evidence to prevent, cure, and care for diseases; contextual evidence to make medical research work in daily practice; and policy evidence to contribute to equity on a worldwide scale. This research will support family medicine and family doctors to continue to contribute to health and wellbeing of patients in the community, based on accessibility, equity, and respect for the authenticity of the patient.

Conflicts of interest statement

None declared.

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