New paradigms for quality in primary care

Barbara Starfield

Introduction

THERE is no longer any doubt of the importance of primary care as the key to an effective and efficient health service. Primary care, defined in terms of the achievement of its four functions, can be measured and its quality assessed.

But, as in all forms of human endeavour, science and society change over time, providing primary care with new challenges. The science of quality measurement is, at best, still in its adolescence.[1] For the most part, current approaches to assessing quality of care are based on models developed a half-century ago. At that time, the techniques of medical audit of the processes of care were developed to assess the extent to which generally recognised features of care, such as preventive procedures, indicated screening tests, and appropriate management strategies for specific conditions, were performed by practitioners. These are still the stock-in-trade of virtually all quality assessment schemes today with relatively minor modification. First, evidence for appropriateness is increasingly sought as the basis for making judgments about indicated interventions. Secondly, satisfaction surveys have been added to the armamentarium of quality assessments, although these types of assessments are arguably more useful for marketing of competing health plans than for assessing the quality of care. Outcomes of care, as characterised by self-reported functional assessment instruments, are increasingly recognised as important measures of quality; however, there have been no serious proposals to set standards for adequacy of outcomes and there are no well accepted standards of assessing health status.

There are good reasons for moving beyond conventional approaches to assessing quality of care and there are now tools available to focus on the new challenges that face health services systems in general and primary care — the cornerstone of health systems — in particular. These challenges include:

- the increasing importance of person-focused assessments rather than disease-focused assessments, deriving largely from the recognition that co-morbidity is the rule rather than the exception, and that discomfort, dysfunction, and disability result not only from specific medical conditions but from a variety of circumstances, including social conditions as well as medical conditions;
- the increasing dangers of medical interventions, including diagnostic and therapeutic technology and medications, with the consequent heightened risk of adverse effects on the health of people;
- the increasingly recognised effect of the mode of delivery of health services on the health of individuals and populations; and
- the explosion of interest in equity as an important outcome of health services systems, wherein inequity is defined as systematic disadvantage in health experienced by sexually defined population subgroups.

Health is determined by a spectrum of antecedents, including the social and political context in which people find themselves (Figure 1). Although we may continue to think of health as mainly determined by genetic and biological predispositions, it is a fact that these predispositions are heavily conditioned by the context in which they are located. An entire new literature documents the importance of many types of determinants of health, some never previously recognised. A parsimonious depiction of the variety of types of 'causes' of ill health divides them into the political context, the social context, personal exposures and characteristics, and genetic and biological characteristics, as well as the pathophysiological mechanisms through which they operate to increase or decrease risks to illness. Any simple categorisation such as this misses the innumerable interactions that undoubtedly exist between and among these types of depicted characteristics. Unrecognised in such a two-dimensional framework is the influence of time and trajectories over the life course. The influence on adult health of events in very early life and continuing through childhood is now undeniable, although the mechanisms of the trajectories are still unclear. Does early damage always increase risk of subsequent pathology and under what conditions might it not? Might the effects of early insults be occult, only to be manifested later? Are they mostly gradually accumulating,

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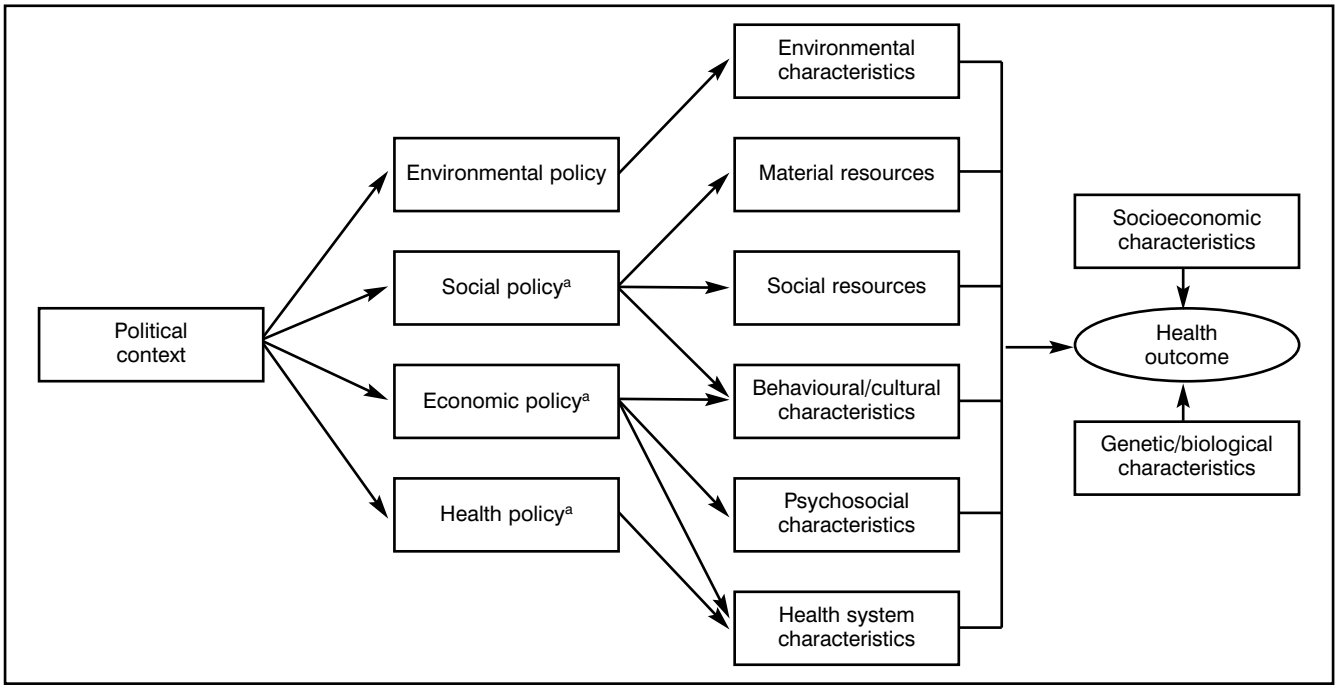

Figure 1. A conceptual framework of health determinants: individual model. [a]Reflects a country's approach to the distribution of power (political jurisdiction).

with each increment leading to progressively greater risks to health later on? Or are there vulnerable 'incubation' periods during which individuals are particularly susceptible to incurring risks that will be manifested later on? We are also beginning to suspect that the pathway of determinants does not act in the same way in all countries, all cultures, and in all population subgroups. We should take them into account in considering the quality of health care if we are serious about improving health.

Co-morbidity

Increasing likelihood of survival owing to scientific and technological advances will result in larger proportions of people with continuing morbidity and disability and with more co-morbidity as new diseases are accrued on top of already existing ones. Co-morbidity is now the rule rather than the exception. The following examples will provide the evidence for thinking of morbidity as co-morbidity, not in terms of single diagnoses.

- Roos *et al*[2] showed that, in an entire population of Canadian adult patients with hypertension, only one-third of visits made by these patients in any one year are for that diagnosis. The next most common reason for their visits was diabetes, which accounted for 3% of visits. Thus, 63% of visits made by patients with hypertension are for a large number of reasons, with no single one of them accounting for more than 1% of visits. It clearly does not make sense to limit considerations of quality of care for patients with hypertension to care of their hypertension, or even to care of their hypertension and their diabetes.
- Clouse and Osterhaus[3] demonstrated that adults with a diagnosis of migraine have 33% greater costs for conditions unrelated to migraine than other patients matched for age, sex, and length of enrolment in a managed care plan.
- Similarly, one-eighth of the costs of asthma and chronic otitis media and eustachian tube disorders are attributable to diagnosis and treatment of just one co-morbidity — sinusitis — rather than the indicator condition.[4]
- In children with chronic illness, the observed co-prevalence for the most common pairs of childhood chronic conditions is one and one-half to four times greater than predicted on the basis of random distribution of these conditions.[5]
- Insights about the demonstrated relationships of low-grade and largely asymptomatic systemic infections or even low birth weight[6] and subsequent coronary heart disease provide powerful evidence of the inter-relationships among apparently unrelated types of morbidities, and extend these observations even further to considering the impact of clustering of morbidity over the lifespan from fetal health to old age.[7] In other words, diseases cluster in a whole variety of different ways in different individuals.
- The average number of diagnosed conditions in adults over the age of 60 is two. Over 80% of females aged 65 to 85 years have at least one chronic condition; 50% have more than one, and 25% have three or more.
- For the United States population as a whole, 41% have one type of morbidity, 33% have two to three types, 6% have four to five types, and 1% have six to nine types — these data are based on diagnoses made in medical visits and thus under-represent the extent of co-morbidity as it exists in populations.
- US national data show that, when considering the co-occurrence of obesity, hypertension, diabetes, and

hypercholesterolaemia alone, 75% of US adults are sick.[8] Almost one-third of the US adult population have two of these conditions, one-seventh have three, and 3% have all four — and that is just for these four conditions alone!

The reasons that we need to think more broadly about determinants of health and about co-morbidity have to do with three features of disease, originally borrowed from the field of genetics but more broadly applicable. First, many causes of disease may be present in an individual, but with no disease being present. This is called penetrance. Secondly, some causes (or predispositions) to disease are associated with different diseases. This is called pleotropism. Thirdly, some diseases can result from one or more of several causes or predispositions to disease. This is known as etiologic heterogeneity.

If these three phenomena exist (and they do), then it is not difficult to see why we must be concerned about various types of determinants of disease and why co-morbidity has to be among our concerns for the quality of care. A disease-by-disease focus, which has occupied our attention up to this time, will not continue to serve us well. Existing clinical guidelines apply to individual diagnoses and even the best ones derive from clinical trials that exclude people with co-existing illnesses. For example, a recent study[9] showed that the sensitivity and specificity of a test for *Helicobacter pylori* was very much lower when tested in primary care practices than the published values, which came from studies in specialty care. At least two other recent studies have confirmed the inappropriateness of guidelines developed by academic investigators, working primarily in tertiary medical centres. Research collaborations among practising physicians have shown the inappropriateness of guidelines for common conditions, such as otitis media, headaches, or hypertension, and research collaborations of primary care paediatricians are showing that the following of professionally developed guidelines for management of febrile infants leads to no better outcomes[10-14] Evidence-based medicine is surely a desirable approach to assuring the quality of practice; however, existing evidence is not, for the most part, appropriate for primary care. The criteria by which the quality of evidence is based rely heavily on elegance of research methods and the quality of internal validity, particularly as manifested by the randomised controlled clinical trial. Unfortunately, the requirements for external validity, or the generalisability of the findings to populations other than the ones studied, have not been the major criteria for judging the adequacy of guidelines. Individuals with co-morbidity are usually excluded from participation in clinical trials and the average rate of participation in these trials, even among eligible individuals, is about 15%. Thus, there is now no good evidence base for diagnosis and intervention in primary care, where the nature of the problems and the extent of co-morbidity make irrelevant the application of most clinical guidelines.

The increasing danger of medical interventions

The variability in use of technology among western industrialised nations is extraordinary. In Japan, there are 69.7 CAT scanners per million population; in the UK there are 6.3. In Japan, there are 18.8 magnetic resonance imagers per million people; in Canada there are 1.3. The cascade effect of diagnostic technology is well documented but poorly recognised. For each diagnostic intervention there is a finite possibility of an adverse effect, even death. The burgeoning use of technology can only increase the number of adverse effects, even if the rate of each decreases owing to safer individual ones. It has been determined, for example, that if each prospective jogger is subjected to a diagnostic work-up to assess the likelihood of occult cardiac diseases, then more people will be killed by the cascade effect of tests than would die simply from unexpected death during jogging.

Per capita expenditures on pharmaceuticals range from $352 per person per year in France to $207 in New Zealand. Since 1990, the rate of introduction of new medications has skyrocketed, with most of the new medications adding little to improve health but much to increased costs of health care systems. The US Institute of Medicine estimated that somewhere between 44 000 and 98 000 deaths per year in the US result from errors in hospitals.[15] Deaths owing to medication errors are rising rapidly.[16] Adverse effects of medications owing not to medical error but, rather, to unanticipated ill effects, is calculated to be somewhere between the fourth and sixth leading cause of death in the US today. When iatrogenic causes of death associated with unnecessary surgery, errors in medication administration, other errors in hospital care, and nosocomial infections (infections acquired in the hospital) are added to the toll of death, then iatrogenic causes amount to the third leading cause of death — 225 000 deaths annually — in the United States, after heart disease deaths and cancer deaths, and more than cerebrovascular diseases and all other causes. These figures are, however, underestimates, since they derive primarily from studies in hospitals and exclude adverse effects that lead to discomfort and disability rather than death. The dangers of iatrogenic illness are not well recognised. The routes by which harm may occur are many.[17] No current quality assessment programme is designed to systematically monitor ill effects from medications, although much anecdotal evidence, particularly in the elderly, indicates that symptomatic side-effects are frequently worse than the symptoms from the underlying condition for which the medication is prescribed.

Primary care in other countries

The powerful effect on health of health system organisation and delivery characteristics is still not well recognised, despite the efforts in the past 10 years at health services reform. We know very little about the impact of other specific aspects of health systems; for example, referral rates, although we know that these vary widely across and within countries.[18] Why should referrals for medical problems vary from about 25% of all consultations in Norway, Italy, and Denmark to between 10% and 15% in France and Ireland, and why should referrals to surgical specialists vary from about 10% to about 40% of consultations in European countries? Which indicates better quality of care and why?

What we do know is how important primary care adequacy is in influencing health. In a major cross-national comparison performed in the late 1980s, and again five years

later, countries with strong primary care systems were found to have lower health care costs than those countries with weaker primary care infrastructures. Although there is not a linear relationship between the strength of primary care and health outcomes, and many other types of factors influence both overall levels of health as well as equity in distribution of health across population groups, it is apparent that a focus on primary care is an important feature of health systems. In this particular study, strength of primary care was assessed by scoring 15 components of health systems that are conducive to primary care. Nine of these characterise the system's focus on primary care (e.g. professional earnings of primary care physicians relative to specialists), and six rate the achievement of practice characteristics of primary care (e.g. person-focused care over time, comprehensiveness of care). The optimum balance of these 15 features in predisposing to good outcomes is unknown, as is the relative importance of each. However, in concert, they provide a good basis for assessing the primary care orientation of a health system.

Countries with a poor primary care orientation have, on average, poorer health outcomes (Tables 1–3),[19] although there are important caveats depending on other characteristics of the countries.[20]

Even within countries, the impact of primary care remains strong on various manifestations of health. For example, states in the USA that have more primary care resources have better health outcomes for just those indicators that would be expected to respond to primary care alone (without also involving specialty care),[21] even when income inequalities within the states are taken into account. The opposite is the case when the supply of specialists is concerned: health levels are worse with a greater ratio of specialists to population. While income inequality is significantly related to higher total mortality, higher infant mortality, lower life expectancy, and higher low birth weight ratios, primary care physician availability is independently associated with lower total mortality, lower infant mortality (which is primarily owing to its very significant effect on postneonatal mortality), and higher life expectancy (Figure 2). The effect of primary care is quite strong; each additional primary care physician reduces total mortality by 34 per 100 000, in the state-level analyses. We have confirmed these conclusions with analyses from the 283 metropolitan areas in the United States, although the effect is much greater for white populations in these areas than for the black populations, for which income inequality is the overwhelmingly important determinant of mortality. We have also confirmed the findings in 60 communities in the US for which we have data on self-reported health. Clearly, primary care cannot solve all of the adverse effects of an inequitable society but it can do much to reduce their ill effects.

A study conducted in Spain showed the effect of primary care reform on mortality rates for several major causes of death.[22] The researchers divided Barcelona into zones based on how early primary reform was implemented. Theory about the impact of primary care would suggest that deaths associated with hypertension and stroke would be responsive to primary care alone, whereas death from perinatal causes, cervical cancer, and cirrhosis would also require improvements in specialty care for mortality to be reduced. Ten years after the reform was implemented, death rates associated with hypertension and stroke in those zones in which reform was implemented first fell the most. For perinatal causes, death rates fell, but not more in the zones with earlier primary care reform. The same was the case for deaths associated with cervical cancer and cirrhosis. For tuberculosis, rates in all three zones decreased consistent with a city-wide public health campaign to address the problem.

A recent report from the United Kingdom demonstrated the high salience of the primary care physician to population ratio in the case of in-hospital standardised mortality rates. This factor was more important than the percentage of patients admitted as emergencies, the number of hospital doctors per 100 hospital beds, and the admission ratio.[23] Thus, where it has been examined, primary care makes a major contribution to reductions in mortality in populations.

Primary care to population ratios affect the rate of hospitalisations for six ambulatory care-sensitive conditions among adults in the US.[24] There is no relationship between the internists (adult medical doctors, most of whom have not been specifically trained in primary care) to population ratio and the rates of hospitalisation for these conditions (which are thought to be preventable by good primary care), but there is a strong and very significant negative relationship between the family physician to population ratios and hospitalisation rates for these conditions, such that the higher the ratio, the lower the hospitalisation rate. The case is the same for children. In other words, there is no relationship between the paediatrician to population ratio and the rates of hospitalisation for the two ambulatory care-sensitive conditions that were studied; however, there was a strong and significant negative relationship between the family physician to population ratio and the rates of hospitalisation for these conditions.

Another recent national study of the impact of primary care on health showed that adults in the United States with a primary care physician rather than a specialist as their personal physician had one-third lower costs of care, and were one-fifth less likely to die (after controlling for the effects of age, sex, income, insurance, smoking, perceived initial health, and 11 major conditions).[25]

A summary of the evidence regarding the value of a 'primary care-led' health system indicates substantial benefits (Box 1). Countries with strong primary care have lower costs and generally healthier populations. Within countries, areas with higher primary care physician to population ratios (but not specialist to population ratios) have healthier populations by a variety of measures, and have fewer social inequalities in the health of their populations.

The imperative for equity

What is equally or even more striking is that greater primary care physician availability produces a greater effect in areas with high income inequality. That is, primary care has an equity-producing effect on health, at least for those measures of health that are especially responsive to primary care, such as postneonatal mortality, stroke mortality, and self-perceived health.[26]

Table 1. Average rankings (best level of health indicator = 1; worst level of health indicator = 13) for health indicators in infancy, for 13 countries grouped by primary care orientation.

Primary care orientation	Low birth weight (1993)	Neonatal mortality (1993)	Postneonatal mortality (1993)	Infant mortality (1996)
Lowest (Belgium, France, Germany, USA)	9.5	7.8	11.5	8.8
Middle (Australia, Canada, Japan, Sweden)	7.3	5.3	5.5	6.0
Highest (Denmark, Finland, Netherlands, Spain, UK[a])	4.8	7.8	4.6	6.4

[a]England and Wales only.

Table 2. Average rankings (best level of health indicator = 1; worst level of health indicator = 13) for health indicators, years of potential life lost (total and suicide) in 13 countries grouped by primary care orientation. (Source: OECD Tapes, 1998.)

Primary care orientation	All deaths except suicide		Suicide		All deaths except external	
	Female	Male	Female	Male	Female	Male
Lowest (Belgium, France, Germany, USA)	9.5	10.8	7.3	8.3	8.8	10.8
Middle (Australia, Canada, Japan, Sweden)	3.8	2.8	7.0	7.3	3.8	3.5
Highest (Denmark, Finland, Netherlands, Spain, UK[a])	7.6	7.4	6.8	5.8	8.2	7.0

[a]England and Wales only.

Table 3. Average rankings for health indicators for countries grouped by primary care orientation: World Health Report, 2000. Highest ranking country = 1. (Source: calculated from WHO World Health Report [Health Systems: Improving Performance] *2000.)*

Primary care orientation	DALEs[a]		Child survival equity[b]		Overall health	
Lowest (Belgium, France, Germany, US)	16.3		22.5		36.3	
Middle (Australia, Canada, Japan, Sweden)	4.8	11.0	16.5	15.8	26.0	29.1
Highest (Denmark, Finland, Netherlands, Spain, UK)	16.0		15.2		31.6	

[a]DALE = disability adjusted life expectancy (life lived in good health). [b]Child survival: survival to age five years, with a disparities component. Overall health =

$$\frac{\text{(DALE) minus (DALE in absence of a health system)}}{\text{(maximum DALE for health expenditures) minus (maximum DALE in absence of a health system)}}$$

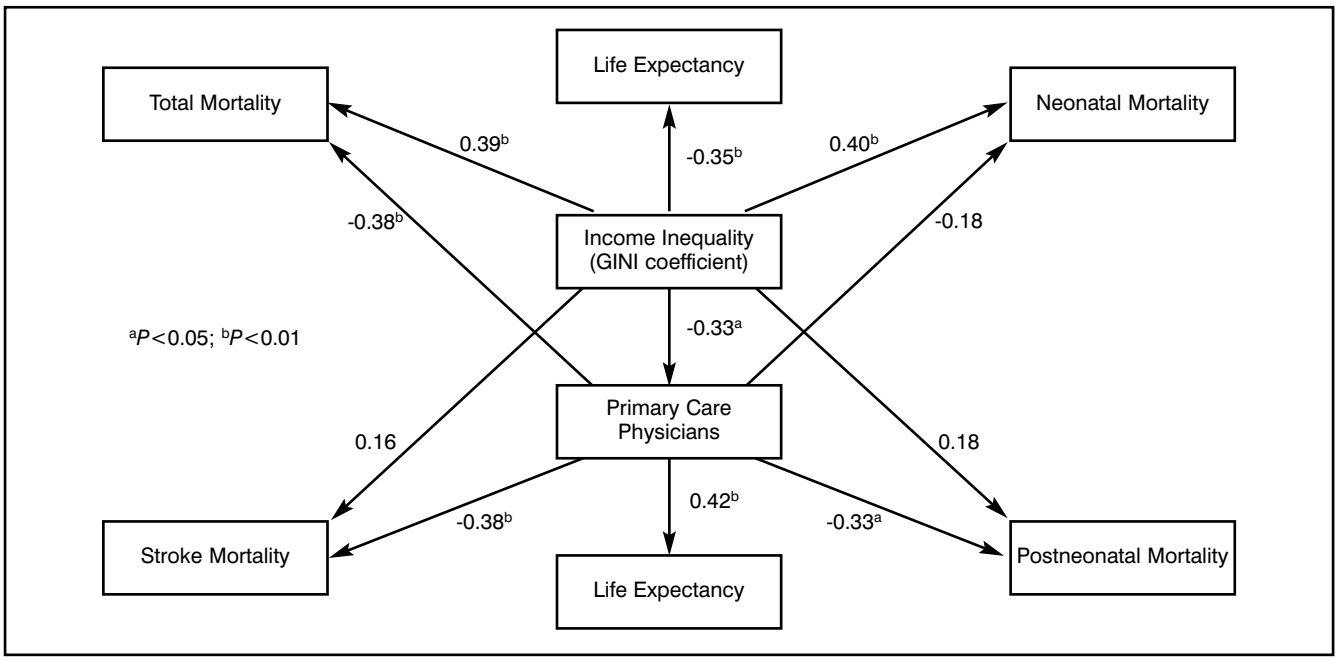

Figure 2. Path coefficients for the effects of income inequality and primary care on health outcome: 50 states in the USA, 1990.[21]

Countries with strong primary care:
- have lower overall costs
- generally have healthier populations

Within countries:
- areas with higher primary care physician availability (but not specialist availability) have healthier populations
- more primary care physician availability reduces the adverse effects of social inequality

Box 1. Benefits of primary care: evidence-based. Based on numerous studies cited in reference 18.

The increasing recognition of the multiple causes of illness, the predominance of co-morbidity, and the dangers of medical interventions should make us take much more into consideration than simply the processes of clinical care for specific conditions. We know, of course, that appropriate clinical care for a specific condition is better than inappropriate care, and we are correct to pay attention to that. But we need to expand our vision of inappropriate care. What we do in the health system can contribute much of benefit to people's health — but it also can contribute harm. It can also do much to reduce inequalities and inequities across population subgroups. Income inequality continues to be associated with poorer health outcomes; however, primary care resources reduce its ill effects.

We have much to do to prepare for these new challenges to health systems in general and to primary care in particular. The necessary tools are available.

1. Co-morbidity can be represented by techniques such as the adjusted clinical group (formerly ambulatory care groups) (ACG) system developed at the Johns Hopkins University.[27] This system takes all diagnoses made on each individual in a year and combines them in such a way as to provide a 'burden of morbidity' pattern unique to each individual, or aggregated to describe a population of people.
2. The International Classification of Primary Care[28] is a well developed and well tested system of coding and classifying symptoms and signs that could be put to good use in documenting and monitoring the occurrence of adverse effects of interventions, including medications.
3. Every evaluation of effectiveness of an intervention should include among its study variables important characteristics of the health delivery system, including the level of care at which the intervention is provided (specialty care or primary care), the type of practitioner prescribing the intervention, and the duration and nature of the relationship between the practitioner and the patient, as these have been amply demonstrated to influence the outcome of care. All evaluations of the quality of care should include consideration of the adequacy of primary care characteristics as well as clinical characteristics. Validated instruments, such as the Primary Care Assessment Tool (PCAT),[29] which is available in comparable form for adults, children, and the providers, make it possible to do this in a standard way.
4. All studies of the determinants of disease, including conventional epidemiological investigations, should include variables that reflect the ecological context in which the research subjects live. At the very least, information should be obtained to make it possible to link the subject's characteristics with area characteristics from census and other data, with due regard for the assurance of confidentiality and security of the data. Only in this way can we really address the imperative to understand inequity and develop policies and practices that reduce its adverse effects on population health.

All four considerations are relevant for the design of clinical trials. The gold standard for evaluating the quality of care — the randomised controlled clinical trial — suffers from poor external validity.[30] Three major flaws in the design of these trials, no matter the extent of the internal elegance of their design, make them of uncertain utility for primary care practice. Hence, clinical guidelines that derive from the results of these trials may not be applicable in primary care practice. First, these trials generally exclude people with co-morbidity — just the sort of people who are the most frequent attenders in primary care practices. Secondly, they almost never take into account the nature of the health care that people are receiving while they are in the trial. Of particular relevance in primary care practice is the absence or presence of a relationship with a source of primary care, which itself can be expected to influence the outcome of medical interventions.[19] Thirdly, most clinical trials, no matter how elegantly designed, are almost always of insufficient size to capture adverse effects, especially as they might occur in everyday practice. It is critical that post-marketing surveillance of new interventions be made a part of medical practice, with systematic attempts to detect adverse effects of all types. Fourthly, clinical trials rarely, if ever, consider the possibility that new interventions may have different effects in different population groups. Their results, therefore, may not represent the likelihood of benefit (or risk) to different population groups and may lead to increased inequity in health from differences in response to the tested intervention.

At the very least, we should begin quickly to consider the new priorities and imperatives in quality assessments in designing evaluations of interventions, in developing standards and guidelines for practice (including primary care practice), and in devising approaches to ongoing monitoring of the effects of medical practices on the health of patients and populations.

Primary care is well poised to take the lead in addressing these challenges. It has already demonstrated its role in improving overall health of populations for those aspects of health that are primarily in its purview. Primary care is the only level of services in a position to understand and deal with co-morbidity. With better attention to systematic descriptions of the existence and distribution of multiple diagnoses within individuals and within disadvantaged population groups, primary care can make unique contributions to knowledge of the nature and correlates of morbidity. Through its integrating and person-focused functions it can play an important role in the documentation of adverse effects of all interventions, in the characterisation of their nature and course, and in descriptions of the magnitude of

their impact on peoples' health. The worldwide imperative to reduce the extraordinary disparities in health across and within countries will also be served by a concerted effort to build a strong foundation of primary care services in every health care system.

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