

# Standard setting in the Netherlands: impact of the human factor on guideline development

**M**EDICAL guidelines are becoming increasingly popular. The main impetus has come from the United States of America<sup>1</sup> but they are now used in many other countries.

Doctors are ambivalent about guidelines: on the one hand they feel that working according to guidelines gives a higher degree of professionalism but on the other hand, guidelines are seen as a threat to personal autonomy imposed by non-professional outsiders. In 1987, the Dutch college of general practitioners, *Nederlands Huisartsen Genootschap*, decided to keep abreast of developments and to start its own standard setting programme. A 'standard' gives a set of guidelines for one subject, such as otitis media, and is a blend of an algorithm, reference material and teaching aid.<sup>2</sup> The document's format follows the usual way a general practitioner thinks and acts when in contact with patients.

There are four main features of the standard setting programme. Development of guidelines uses a 'bottom up approach' meaning by general practitioners rather than specialists. Standard setting is being incorporated into a nationwide comprehensive system of quality assurance, comprising an already existing system for continuous medical education and a developing system of audit. Participation in any of these quality assurance activities is strictly voluntary. The implementation of the programme is being monitored; the first results show that acceptance is high.<sup>3</sup> The standard setting programme is independent of both the government and the insurance system even though the programme has become fully subsidized.

The theory of guideline development for general practice has previously been described in the *Journal*.<sup>4</sup> In 1993 many practical experiences were presented at the WONCA-SIMG conference on quality of care (World Organization of Family Doctors and *Societas Internationalis Medicinæ Generalis*) at the Hague. One presentation focused on the influence of the human factor on standard setting in the Netherlands. Although theory tells us that scientific evidence must form the basis of guideline development,<sup>5</sup> that evidence is usually insufficient.

Medicine is not a science, it is more like an art. This means that medical guidelines are highly influenced by the human factor — feelings, behaviour, values, needs, rationality and subjectivity. This influence can be illustrated by looking at the four steps of the standard setting procedure that were designed as stages in internal and external quality control. All four stages are supported by staff of the Dutch college of general practitioners.

The first step is selection of an appropriate subject for standard setting by an independent advisory board. This uses four criteria: availability of sufficient scientific material, preferably from general practice; importance of the subject in terms of incidence or prevalence or of a high degree of suffering; feasibility of formulating unambiguous guidelines; and ability to improve the quality of care. Although these criteria seem logical, there is no arithmetical weighting system to assist the board in its decisions. The board takes balanced decisions, but sometimes the human factor is felt acutely. In one such instance, the board had decided that prevention of osteoporosis was not a suitable subject for a standard in view of the many uncertainties surrounding the subject, thus it would not be possible to make unambiguous guidelines. This was not well understood by many general practitioners who pointed to the need for guidelines because of the general public's misunderstanding of the large inter-doctor variation in its treatment.

The second step in the standard setting procedure is the development of standards by working parties. Each working party comprises four to eight general practitioners who have a mixture of scientific and practical experience. Individual members scrutinize parts of the literature and write a first outline for a guideline; these drafts are then combined to form a standard. Lack of scientific evidence and thus room for the human factor is felt in many practical ways. The need for guidelines is usually felt most strongly in areas where scientific evidence is conflicting. An example is acute otitis media, where research from the United Kingdom and from the Netherlands has suggested diametrically opposed treatment strategies.<sup>6,7</sup> Even when there is ample evidence, many practical questions cannot be solved. For example, although the benefits of treatment of hypertension are well established, it is not known what levels of risk can be accepted without treatment. Research from general practice is often lacking, meaning that data from less comparable hospital-based populations have to be used.

All these shortcomings frequently lead to the use of the consensus method. In the process of reaching consensus human beings argue. This arguing is fed not only by rationality, but also by other mechanisms such as personal authority (real or imagined), assertiveness (easily confused with knowledge), strategic considerations, culturally based arguments and, last but not least, the basic values of general practice. At the Dutch college these factors are addressed. Working parties are asked to exemplify all decisions, scientifically based or not, in a separate document called the scientific justification. Staff members receive training in group dynamics so that they can manage problems such as assertiveness, self appointed authority and strategic consideration. An example from the last category comes from the working party on problematic use of alcohol, in which two different lines of thought were represented: one psychologically oriented and the other more tailored to the needs of general practice. Both groups feared their particular line of research was being threatened and that they would lose support. Both had made protocols for other purposes, which they defended fiercely. In the end, a well justified consensus was reached.

The other factors influencing consensus decisions, culturally based arguments and basic values of general practice, are usually implicit. For participants in the development of guidelines these often form blind spots. Outsiders such as general practitioners working in countries with different socioeconomic situations tend to recognize them immediately. However, their views are not regularly sought (as the standards are published in Dutch). Besides the usual basic values, Dutch general practitioners tend to subscribe to certain points of view: when the results of a treatment are the same, whether done by general practitioners or by specialists, treatment in general practice is preferred, for example the care for patients with non-insulin dependent diabetes; prescription of drugs has to be limited; systematic preventive actions can only be justified when definite proof of benefit exists; when in doubt abstain. While this final value is not new, it tends to be overlooked. Practical examples can be found in many standards, such as watchful waiting being the treatment of choice in cases of threatened abortion, and in acute sore throat and acute otitis media it is advised that no antibiotics be prescribed, except in specified circumstances.

The third step in the development of standards is the comment phase. Here, the draft standard is sent to 50 randomly selected general practitioners and to a number of specialists. These people give valuable feedback for future implementation. For example, after the comment phase the post coitum test was scrapped from the standard on subfertility because the general practitioners in the survey found this test too difficult to implement.

The last step of standard development is the authorization procedure. This consists of one lengthy session in which the working party has to defend its product before a critical college of wise men and women. Their wisdom is derived from various academic chairs of general practice and from long involvement in college activities. Most standards pass with only slight alterations. On two occasions, however, standards were rejected: in one case this was owing to inadequate presentation of the scientific evidence and in the other the proposed guidelines were too vague.

The conclusion from these experiences is that development of guidelines for general practice can benefit from the human factor. The most prominent of these benefits is the possibility of reaching consensus on a multitude of questions important for the day to day functioning of general practitioners. The potentially negative sides of the human factor, such as subjectivity, can be curtailed by a rigid development procedure.

SIEWERT THOMAS

Head of Department of Standard Setting,  
Nederlands Huisartsen Genootschap

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### Address for correspondence

Dr S Thomas, Department of Standard Setting, Nederlands Huisartsen Genootschap, Postbox 3231, 3502 GE Utrecht, Netherlands.

## Fraternizing with fringe medicine

**F**EW in mainstream medicine want to give offence by seeming to ridicule patients or healers anxious to believe that fringe medicine — increasingly demanded by the population of many countries<sup>1,2</sup> — can cure illness. So why should we not fraternize with almost anyone who shares our own wish to give hope and comfort, at least whenever nothing better is available?

However, we may be going too far in our anxiety to be less critical than in the past. Perhaps we should not be quite so afraid of being called arrogant or patronizing. The recent report from the British Medical Association<sup>1</sup> tries to be polite about all of the various beliefs and theories that make up fringe medicine, even such things as iridology, which claims to be able to make diagnoses from looking into the eyes, and reflexology, which claims the same from looking at the feet. None of these therapies are endorsed by the British Medical Association, but neither are they criticized. All those on the list are thanked for the information they have sent in, and given a credibility that would have been unthinkable a few years ago.

A firm distinction must surely be made between fully trained, qualified and registered medical practitioners (who are taught differential diagnosis and encouraged to follow, whether in diagnosis or therapy, where the evidence leads) and unqualified healers with fixed beliefs who feel no need to make any such effort.

Do we really want to give the impression that we approve equally of all claims and remedies, no matter how little evidence there is that they are anything more than placebo? Nobody, it seems, dares make the point that in medicine there are a whole range of situations where it is virtually impossible for a remedy,

however worthless, not to have many grateful patients. The history of medicine teaches us that there are many circumstances where everyone involved — patients, relatives, doctors, healers — may sincerely believe that there has been a real objective effect on the disease process, when in retrospect this is not true. Those who think that they have been helped may even have been harmed.

Gratitude is an unreliable index. Many patients feel better because of one or more types of placebo: the personality of doctor or healer, the relief at starting a new and exciting remedy, the use of strong verbal suggestion that there will be benefit, tablets of a striking shape or colour, needles, enemas and so on. Another factor that is equally important is that gratitude is often based on the false premise that without the remedy there would have been no improvement. It can also be wrongly assumed that without the treatment relapse would have occurred. Alternatively, those expressing gratitude may be essentially healthy, but may have been persuaded that it is only alternative medicine that keeps them that way.

Those who believe that an unorthodox herbal remedy is more likely to help them than an orthodox herbal remedy (digitalis, for example) must be free to choose. However, nobody can be happy about choice based on misinformation or lack of information.

Too much fraternization can confuse the public and suggest that we have lost confidence in rational thought and pragmatic problem solving. We risk encouraging the damaging and misleading idea of two equally respectable systems, two schools of thought, two valid cultures. If it is felt that weighing evidence is