

# Beyond the evidence of guidelines

H. Wollersheim

Scientific Institute for Quality of Healthcare, Radboud University Nijmegen Medical Centre, Nijmegen, the Netherlands, e-mail: H.Wollersheim@iq.umcn.nl

## INTRODUCTION

Clinical guidelines should support health care providers and patients with appropriate recommendations for daily practice to enable both to make better informed decisions. Preferably, the recommendations are based on the best available evidence, supplemented with clinical expertise.

In former days guidelines were often developed by the so-called 'Good Old Boys Sat Around the Table' (GOBSAT) method. Nowadays, this expression refers to the unstructured manner by which a group of self-selected experts discuss their (often subjective) opinions, which are written down by one of them.

Gradually it became clear that this informal procedure has major limitations.

The scientific basis of the resulting guideline may be poor. Dominant and influential persons may push through their preferences or limit ideas about optimal care by considerations of what they suppose is achievable in daily practice (required skills, instruments, money, time, staff, patient preferences). The group often tried to draw attention to themselves to strengthen their position within a clinical area.

There was a lack of uniformity in the guidelines developed by the 'GOBSAT method'. They were not updated on a regular basis and as most professionals and their representing bodies were not involved in the end product, wide acceptance was lacking, resulting in poor compliance.

Because of these flaws, guideline development was gradually professionalised. The development procedures were standardised. The recommendations were provided with a sound scientific basis and developed in a rigorous systemic way by a balanced working group which incorporates clinical and methodological expertise, adequate technical support to carry out searches and health economic analyses and an agreed work plan with well-organised meetings.<sup>1</sup>

First a representative and multidisciplinary group of six to 15 experts from relevant organisations are invited. Besides clinical and methodological experts, patient representatives, policy makers, insurers and managers should be involved.

The skills of the chairman are crucial, to stimulate discussion while ensuring an effective and efficient group process. Existing (international) guidelines on websites and systematic reviews or meta-analyses (for example within the Cochrane library) are identified. Subsequently a literature analysis (search and a qualitative analysis of the findings) and a formal group process with structured consensus discussion according to the Delphi methodology should be started.

Formulation of recommendations with their evidence grading<sup>2</sup> has to be performed by a democratic voting procedure after extensive discussions of all the information obtained.

## FORMAL CONSENSUS METHODS

The RAND-modified Delphi procedure<sup>3,4</sup> is a formal consensus method that is derived from the Delphi method. It is especially suitable to select recommendations for problems where evidence is scarce. A panel of experts forms opinions about the appropriateness of different treatments in a large number of cases. These cases are paper patients with certain diagnostic characteristics (for example disease or disease stage, age, complaints, abnormal findings) that have been shown to influence treatment decisions. The judgement of appropriateness is determined by the advantages (effectiveness, rapidity and duration of the treatment response) and disadvantages (invasiveness, side effects and complications) and is scored by all panel members on a 0-9 scale. In a plenary session all scores are compared and differences discussed. Subsequently the scoring is repeated and a treatment is considered appropriate if the median score is in the 7-9 scale.

## BEYOND EVIDENCE

Weak or absent evidence is not exceptional as for more than half of the questions or choices there will be no<sup>5,6</sup> or

conflicting evidence. Even if an explicit search strategy is used guideline groups may end up with different evidence findings due to a different search strategy and inclusion and exclusion criteria. For example, less than 11% of the evidence was shared between Dutch and German guidelines for breast cancer.<sup>7</sup>

Even if evidence is found, the relevance and quality of the studies may be disputed or the findings may be in selected populations that differ from those seen in routine care. Especially in the elderly, comorbidity may lead to conflicting evidence.

If controversies occur, normative and cultural opinions about the risk-benefit ratio of a recommendation play an important role.<sup>8,9</sup> This is all right, as long as these implicit norms and values are made explicit and are in agreement with those within the target groups, especially the health care providers and patients involved.

## DECISION-MAKING

Medical decision-making in individual patients uses the findings of population-based evidence in guidelines, but the recommendations should be translated to an individual patient with unique needs and preferences.

Moreover, personal experiences and interests of the health care provider and ethical principles together with economic and political considerations influence the ultimate decision. These factors cannot be quantified against each other, as they are difficult to balance. The World Health Organisation recognises this dilemma<sup>10</sup> and advises that value judgements should be explicit and be influenced by patients in particular.

## HIDDEN ETHICAL VALUES

In the article by de Kort *et al.* in this number of the Journal, hidden value judgements in the formulation of recommendations in palliative oncology care were found.<sup>11</sup> These value judgements may account for many of the variations between guidelines.<sup>12</sup> For example, a preference to prolong life without considering the quality of life that can be expected when no curative options

are available or for doing something instead of watchful waiting was found.

As patient's and doctor's value judgements may differ and these judgements are not made explicit in the guideline report, they may be taken as evidence. Instead they should be a tool to discuss the pros and cons of an option with the patient. To support these discussions they suggest a meaningful checklist of potential values that may support the decision process. I feel that the suggestion to imagine that one of your parents is sitting in front of you is the most important.

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