

NICE Clinical Guidelines: involving patients, sharing decision-making, considering cost effectiveness

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Key messages

- Patient involvement can lead to recommendations that address issues of key concern to patients.
- Guideline recommendations should be written so they promote shared decision making.
- Cost effectiveness is important as clinicians make decisions about use of resources at individual patient level.

The UK's National Institute for Health and Clinical Excellence (NICE) has now published over eighty evidence-based clinical guidelines covering a wide range of clinical areas in primary and secondary care since 2002. In 2006 the World Health Organisation (WHO) considered NICE to be 'one of the largest, most productive and best organized developers of clinical guidelines in the world.'¹ NICE commissions standard guidelines from four National Collaborating Centres (NCCs), three of which are hosted by medical Royal Colleges, and since 2007 has had its own short clinical guideline programme. NICE is continually developing and refining its methods and has a comprehensive *Guidelines Manual*² for its guideline developers. While NICE guidelines share many features of other national guidelines there has been a particular emphasis on stakeholder engagement (through a rigorous public consultation process), user involvement (through the recruitment

Samenvatting

Stokes T. NICE Clinical Guidelines: involving patients, sharing decision-making, considering cost effectiveness *Huisarts Wet* 2010;53(1):20-1.

NICE is een onafhankelijk instituut binnen het Verenigd Koninkrijk. NICE ontwikkelt onder andere richtlijnen voor medisch handelen voor de National Health Service. Anders dan de standaarden van het NHG besteden de NICE-richtlijnen expliciet aandacht aan kosten-effectiviteit en gezamenlijke besluitvorming van dokter en patiënt. NICE betreft gebruikers (zowel patiënten als mantelzorgers) actief bij het opstellen van richtlijnen.

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Mogelijke belangenverstrengeling: niets aangegeven.

of patient members to all guideline development groups), shared decision making and the need to explicitly consider cost effectiveness as well as clinical effectiveness when making recommendations. NICE is also currently developing methods to link research evidence to guideline recommendations through GRADE evidence profiles.³ This commentary specifically reviews the way in which NICE clinical guidelines involve patients, ensure shared decision making and address cost effectiveness when drafting guideline recommendations as these are areas that are likely to be of most interest to a Dutch audience.

The involvement of patients

Patient involvement in NICE clinical guidelines is achieved in two ways.⁴ First, the public consultation process at each stage of a clinical guideline's development ensures that patient stakeholder organisations can shape the clinical content of the guideline through commenting on the guideline's scope and on its draft version before publication. Second, at least two patient and carer (people who look after patients with the relevant condition) members sit on each multidisciplinary guideline development group (GDG). NICE has a dedicated Patient and Public Involvement Programme (PPIP) that helps recruit patient and carer members of GDGs and also supports them through the guideline development process. Patient and carer members have equal status to professional members and their key role is to ensure that the views, experiences and interests of patients inform the GDG's work. This may include: 1. identifying issues of concern to patients or carers to help develop the guideline's review questions; 2. reading summaries of the research evidence from a patient or carer perspective to judge – for example, whether or not the identified papers address issues that patients and carers consider important; 3. making sure that patients and carers' perspectives are taken into account when the group draws up recommendations for clinical practice and when it considers stakeholders' comments made during the consultation process and 4. helping produce a patient version of the guideline ('Understanding NICE guidance' booklet). The integration of relevant patient experiences into each review question helps to make the question patient-centred as well as clinically appropriate. For example, a review question that looks at the effectiveness of chemotherapy for a terminal cancer is more patient-centred if it integrates patient views on whether it is preferable to prolong life or to have a shorter life but of better quality. Review questions can also focus specifically on key aspects of the

patient experience. For example, the NICE postnatal care guideline conducted a literature review to determine whether there are cultural differences that need to be considered in delivering information and support on breast or bottle-feeding. In such reviews qualitative research is increasingly being used by guideline developers⁵ alongside reviews of randomized controlled trials.

Shared decision-making

Shared decision-making means that information exchange is a two way process in the consultation and both deliberation and decision are made by both health care professional and patient. This is in contrast to a 'paternalistic' model where information is given to the patient and deliberation and decision are made by the health care professional or an 'informed' model where information is given to the patient and the patient makes the deliberation and decision.⁶ NICE has promoted shared decision making through ensuring that its clinical guidelines address issues of importance to both patients and health care professionals and by highlighting the need to ensure the patient's agenda is addressed. For example, the NICE antibiotic prescribing for respiratory tract infections guideline makes a specific recommendation that patients' or parents'/carers' concerns and expectations should be determined and addressed when agreeing the use of the three antibiotic prescribing strategies (no prescribing, delayed prescribing and immediate prescribing) for respiratory tract infections in primary care. NICE has also issued guidance that has a specific focus on shared decision-making about medicines: the medicines adherence guideline. This guideline makes a set of specific recommendations that address how health care professionals can increase patient involvement in decisions about prescribed medicines and how they can support patients to increase their adherence with prescribed medication. It emphasizes that the purpose of assessing adherence is not to monitor patients but rather to find out whether patients need more information and support. The guideline was developed using standard NICE methods,² but the developers carried out a thorough review of the relevant social science as well as medical literature on shared-decision making about medicines.⁷

Considering the cost effectiveness of diagnostic tests and treatments

Arguably the most important differentiating feature of NICE clinical guidelines is their brief to consider cost effectiveness as well as clinical effectiveness when making recommendations on 'which test?' or 'which drug?' It should be noted that NICE's Technology Appraisal (TA) programme uses health economic evaluation in its assessment of selected new and established health technologies for the NHS in England and Wales.⁸ Health economics is about improving the health of the population through the efficient use of resources and it does apply at the level of individual clinical decisions. While health care professionals already take resources and value for money into account when making clinical decisions the incorporation of good-quality health-economic evidence into clinical guidelines can help to make this more consistent. NICE's

clinical guidelines may incorporate and contextualize recommendations on the use of specific drugs already recommended by NICE as being cost effective through its TA programme. For example, NICE issued a TA on the use of statins which stated that they should be used as part of the management strategy for the primary prevention of cardiovascular disease (CVD) for adults who have a 20% or greater 10-year risk of developing CVD and that therapy should usually be initiated with a statin with a low acquisition cost. The accompanying lipid modification clinical guideline helps implement this recommendation in UK primary care through specifying how cardiovascular risk should be assessed and discussed with the patient and through recommending that treatment should be initiated with a specific low acquisition cost statin: simvastatin (40mg). Alternatively, NICE's own guideline developers may carry out de novo health cost effectiveness analysis when no appropriate health economic evaluation exists. For example, the coeliac disease guideline developed a model to estimate the cost effectiveness of serological test strategies for detecting coeliac disease in patients presenting with signs and symptoms which was used to inform the specific clinical guideline recommendations.

Conclusion

In conclusion, NICE clinical guidelines have strong patient involvement, promote shared decision-making and make cost effective recommendations. The challenge, as with all national guideline programmes, remains their effective implementation.

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