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CLINICAL

# Guidelines in the era of realistic medicine

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The Scottish Chief Medical Officer set a number of challenges to the medical profession in her Annual Report.[1] A number of these challenges relate to clinical guidelines. These challenges were welcomed and are currently being addressed by many guideline organisations including the Scottish Intercollegiate Guidelines Network (SIGN).

SIGN was established in 1993 by the Academy of Medical Royal Colleges and their Faculties in Scotland.[2,3] As such, it was one of the first national guideline organisations and pioneered many of the processes that were subsequently adopted by other guideline organisations and a detailed manual describing how it produces guidelines has been published.[4] SIGN has many strengths. These include making use of the wide expertise of multidisciplinary guideline development groups, which include patient representatives, to carefully consider the evidence and apply considered judgement when translating the evidence into recommendations. SIGN is keen to liaise with interested parties over proposed guidelines topics. Clinicians or government may consider they know what guidance is required, but there is considerable merit in our system that ensures guideline requests from patients are given the same consideration.

SIGN is a constantly evolving organisation and is therefore addressing the challenges of modern medicine. One challenge is to reduce the burden and harm that patients experience from over-investigation and over-treatment. This challenge was recognised by the *British Medical Journal*'s *Too Much Medicine* Campaign.[5] Guidelines should be able to provide recommendations that balance the benefits and harms of investigations and interventions. An historical problem with recommendations made by guideline organisations was that the evidence was very heavily dependent on randomised clinical trials, leading to so-called Grade A recommendations.[6] This did not necessarily mean that the magnitude of effect was particularly significant; it merely reflected the high methodological quality of the trial evidence. An unexpected consequence of providing evidence grading from A to D was that it was often assumed that Grade A evidence should always be adopted. This has undoubtedly led to over-treatment, and also to ignoring more important recommendations based on other types of evidence. To solve this problem, SIGN now provides 'strong' or 'conditional' recommendations. These are based on the potential benefit and harm to the patient as well as the quality of the underlying evidence. For 'strong' recommendations that 'should' be carried out we can be confident that, for the vast majority of people, the intervention will do more good than harm, and for 'conditional' recommendations that should be 'considered', the intervention will do more good than harm for most patients.[7,8] This type of recommendation 'allows' the patient and clinician to decide not to follow the guidance, even when the evidence is strong and the benefit significant. Some patients may chose, for many valid reasons, not to have a particular treatment or investigation.

It is a strength of guidelines that they provide guidance but do not mandate a course of action. A good example is the recently published SIGN guideline on osteoporosis.[9] In the early years of evidence-based medicine, the pressure was to achieve as much adherence to guidelines as possible. Now, the challenge is to build flexibility into the guidance and provide the evidence for the options.

The best example of whether, after careful consideration, guideline recommendations should be followed is when multimorbidity complicates the issue for individual patients. If the recommended course of action would only provide a small or perhaps considerably delayed benefit, it may be perfectly acceptable to not follow the guidance for reasons of life expectancy if there was little chance of achieving the benefits of the treatment.[10]

It would be surprising if a management plan agreed between a patient and a clinician followed every recommendation and it is for this reason that SIGN has always opposed arbitrary targets for guideline adherence. However, it would be more concerning if a guideline does not influence a management plan because many of the recommendations are uncontroversial and cover only current practice in investigation, management and follow up.

Additionally, explicit consideration of the balance of benefits and harms of an intervention can lead to an explicit strong or conditional recommendation not to do something. This approach also has considerable merit. An example of this is the *Choosing Wisely* campaign in the USA[11] which seeks to reduce unnecessary investigation. Recently the American Cancer Society updated their breast cancer screening guidelines to recommend starting screening later and to recommend less frequent screening based on the evidence of the balance of benefit and harm.[12] Such recommendations are frequently met with adverse publicity and accusations of rationing of healthcare. This is a valuable role for guideline organisations with rigorous and transparent methodology because they are ideally placed to produce credible and implementable recommendations to do less.

A related problem to multimorbidity is polypharmacy. Many prescriptions are not based on evidence-based clinical guidelines and many prescriptions occur despite guidelines advising to the contrary. In a number of recent SIGN guidelines, a minority of recommendations are for drug therapy and many of these advise not to give a drug or to reduce the dose. Even in some conditions such as heart failure, where drugs are the mainstay of treatment, nearly half the recommendations do not concern drug therapy.[13] Despite guidelines often recommending alternatives to medication or advising caution, it is inevitable that many patients will end up on several medications.[10] This carries significant risk. The most notable risks are the possibility of drug-drug interactions enhancing or reducing the efficacy of the drugs or increasing side effects. Much comorbidity is predictable, with certain conditions occurring frequently in combination. Future SIGN guidelines will identify these frequently associated conditions and highlight any likely drug-drug interactions.

The Chief Medical Officer also challenged healthcare professions to reduce unwarranted variation in clinical practice to achieve optimal outcomes for patients. Guidelines were developed for this purpose and continue to fulfil this role. Variation in practice is unlikely to be justified when a national guideline provides a clear recommendation that a treatment or investigation is superior in terms of desired patient outcomes. When clear superiority of outcomes is demonstrated it is usual for managed clinical networks to adopt the recommendations and for national standards to be based on these recommendations. Many cancer clinical networks follow SIGN guideline recommendations. An example of guidance changing practice relates to the surgical management of oesophageal cancer.[14] This guideline recommended that oesophageal and gastric cancer resection surgery should be carried out in high-volume specialist surgical units by frequent operators,[14] and was based on demonstrably better outcomes with centralisation of services. This was then followed by a service reconfiguration and significant improvements in outcome.

Trials usually have end-points of interest to the clinician, the healthcare provider or a regulatory body. In contrast, what matters to a patient may be very different and it is important we encourage trials to measure things that matter to the patient. In addition, it is important to ensure that the patient voice is heard throughout the guideline process. We therefore have patient representatives on the SIGN Council, the decision-making body of SIGN. Patient representatives are also members of the Guideline Program Advisory Group (GPAG), which assesses all guideline proposals. This is an active process where the specific clinical questions that the guideline will address are discussed and refined in collaboration with the proposer. All guideline development groups have patient representatives as full members of the group and patients can also contribute to peer review. SIGN also produces patient versions of each guideline, which summarise, in patient-friendly style, the recommendations from the guideline. Therefore, a patient can readily access the same information as the clinician and understand the recommendations and the outcomes that are sought. These electronic patient booklets are designed to ensure that the patient can be fully informed about what management options are likely to be offered and lead to an informed discussion with their clinician about preferences.

While topics for guidelines have traditionally been made by clinicians, we have changed our proposal process and application form to make the process simple and transparent.[15] Applications from patients are encouraged and SIGN undertakes to support patients who wish to make a proposal by helping to complete and revise the application.

SIGN recognises the need to provide value for public money and prevent waste. We understood that there were considerable risks for SIGN in costing recommendations and in performing health economic evaluations. This could have led to accusations of rationing healthcare. In addition, health economic evaluation is complex and requires considerable expertise. As a result of the integration of SIGN into the larger organisation, Healthcare Improvement Scotland, a shared health economics expertise is now available. We apply health economic evaluation selectively during

guideline development, when such considerations are important in fully understanding whether a recommendation would be in the best interests of the Scottish public.

Guideline development is expensive and SIGN is a relatively small organisation, but it is supported by considerable contributions of time and expertise by the healthcare professionals and the public in Scotland. The budget for SIGN is small compared to guideline organisations in other comparable countries but we are still required to justify the costs. SIGN therefore selects topics on the basis of the likely benefit of the guideline in Scotland. One important consideration has been that most guidelines contain many recommendations that reflect current practice. Having a guideline that supports current practice may be reassuring but it does not lead to a significant impact or improvement in care. Therefore future SIGN guidelines will focus on the important but challenging questions where practice varies or the evidence requires careful evaluation. This will mean the guidelines are shorter, may be based on a variety of evidence sources, may contain more consensus recommendations and fewer key clinical questions, but they are also likely to produce the greatest effect on practice. There is no intention to change our established methodology, or the involvement of patients, or to move away from the provision of guidelines rather than protocols or standards of care.

In the era of realistic medicine, SIGN guidelines should be the starting point for decision-making at the clinician-patient interface, and should inform the joint decision, not dictate a particular course of action.

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