

# Scottish Intercollegiate Guidelines Network: the first 15 years (1993–2008)

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**ABSTRACT** The Scottish Intercollegiate Guidelines Network (SIGN) was established in 1993. One of the first national programmes of evidence-based clinical practice guidelines, it has played a lead role internationally in many of the developments in guideline methodology. The challenges faced from the beginning of the organisation up to its integration into the National Health Service and how they were addressed are set out and related to SIGN's contribution to the Scottish tradition of medical education.

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**KEYWORDS** Clinical practice guidelines, evidence-based medicine, Scottish Intercollegiate Guidelines Network, SIGN

**DECLARATION OF INTERESTS** No conflict of interests declared.

The Scottish Intercollegiate Guidelines Network (SIGN) was established in 1993 to sponsor and support the development of national clinical practice guidelines for Scotland on a multi-professional basis.<sup>1,2</sup> By the end of 2009 SIGN had published 112 guidelines (new and revised) on clinical practice and guideline methodology. In its first 15 years SIGN has established a unique place in international guideline development and this paper offers a brief historical record.

## SIGN COUNCIL AND EXECUTIVE

In the early 1990s, there was growing interest in evidence-based medicine (EBM) and its application – through the development of clinical guidelines – to improve the process and outcomes of healthcare. Guidelines were defined as ‘systematically developed statements to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances’.<sup>3</sup> In Scotland, the Royal Colleges were keen to play an active role in their development.

In 1993, the Clinical Resource and Audit Group (CRAG),<sup>4</sup> the lead body for clinical effectiveness policies of the then Department of Health for Scotland, recommended that Scotland should develop national clinical practice guidelines and that these should be developed by the Royal Colleges and their Faculties in Scotland.<sup>3</sup> The Chief Medical Officer for Scotland wrote:

I and my colleagues on CRAG are very keen to stimulate and support this activity, but CRAG

cannot do all the work itself and in any case that is not desirable. We look rather to working in collaboration with the Royal Colleges, the specialist associations of the health care professions and relevant educational bodies.<sup>3</sup>

As a result, Scotland was almost unique in developing a national guideline programme that was publicly funded but professionally led and politically independent. Justification for this approach came when a systematic review of guidelines produced by specialist societies (the norm before the establishment of SIGN and similar organisations) found that few if any of these guidelines used a robust methodology.<sup>5–7</sup>

SIGN initially established a Council with representatives of all Royal Colleges and their Faculties in Scotland, which reported annually to their coordinating body, the Academy of Royal Colleges and their Faculties in Scotland. While this body included only medical Colleges, by the time SIGN published its first guideline in 1995,<sup>8</sup> membership had been extended to representatives from all other healthcare professions (see online material at <http://www.rcpe.ac.uk/journal/issue/41-2.php> for SIGN Council members since 1993).

## DEVELOPMENT

The first meeting of the Scottish Intercollegiate Group on Clinical Guidelines (renamed SIGN Council in 1994) was held in February 1993 and convened jointly by the Royal College of Physicians of Edinburgh (RCPE) and the

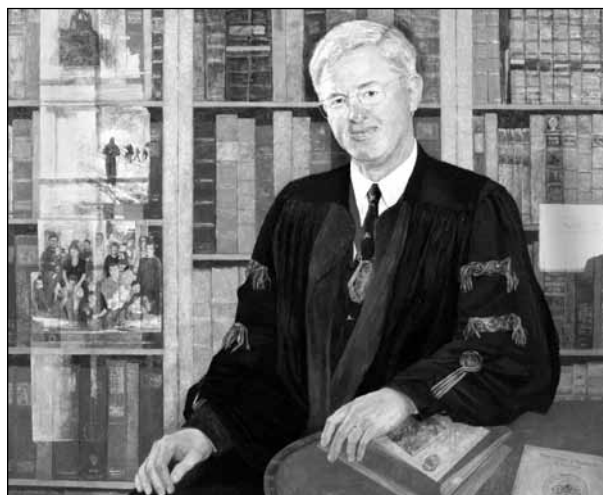
Scottish Council of the Royal College of General Practitioners (RCGP). In 1994 Jim Petrie (Figure 1) became Chairman. Working with members of CRAG and other Royal Colleges in Scotland, he was instrumental in setting up SIGN Council (for professional leadership) and SIGN Executive (to provide administrative support). Initially, the Executive comprised two members of the RCPE's education and audit department, headed by Christina Pottinger.

In 1995, SIGN published its remit,<sup>1</sup> a methodology manual<sup>2</sup> and a pilot national guideline.<sup>8</sup> In its first publication, SIGN set out the draft criteria by which it would appraise clinical guidelines for recommendation for national use in Scotland.<sup>2</sup> The first national guidelines were envisaged as 'broad statements which relate to an optimal level of care in which current knowledge and experience are balanced against the constraints of available staff and other resources. These should then be critically reviewed and modified to produce local protocols – more detailed developments of these broad principles – for local application.'

This publication also noted that SIGN would facilitate the implementation of local arrangements and monitor and evaluate the impact of SIGN-sponsored guidelines. It then provided detailed criteria for the membership and declaration of interests of guideline development groups, the identification and grading of evidence and for appraising the validity of the guideline development process. The issue of declarations of interests is now widely seen as being of major importance. Current SIGN requirements for the completion of declarations of interests are set out in Section 2.4 of SIGN 50,<sup>9</sup> and these procedures are kept under constant review to ensure they comply with best practice. While SIGN Council had agreed to receive and appraise guidelines from other bodies, it soon realised that SIGN could not approve guidelines which did not meet its own criteria.

The body's first guideline underwent much revision between 1993 and 1995, as SIGN's processes, including criteria and guideline format, evolved. The guideline group was encouraged to be brief, provide a succinct quick-reference guide and limit references to 20. Interestingly, when this guideline was revised in 2008–10, the process still took two years and the number of references had increased tenfold. The first guideline included a statement, drafted by CRAG and the Central Legal Office for the National Health Service (NHS) in Scotland, that SIGN guidelines were not standards of care. This remains the case 15 years on.

In 1997, SIGN Executive became a separate organisation based in the RCPE, which provided support services. Petrie became President of the RCPE in 1997 and, until his untimely death in 2001, continued to chair SIGN Council. In 2002, Gordon Lowe succeeded Petrie as Chairman of



**FIGURE 1** Jim Petrie, SIGN chairman from 1994 to 2001. Portrait by Victoria Crowe (RCPE collection).

SIGN Council and Sara Twaddle replaced Juliet Miller as Director of SIGN Executive. By this time staff numbers had increased to 20. The constitutions and procedures of SIGN Council and SIGN Executive were revised and a Senior Management Group formed. In 2003, CRAG was incorporated into NHS Quality Improvement Scotland (NHS QIS), which then funded SIGN.

By 2004 SIGN's management, processes and relationships with guideline development organisations in other countries had been stabilised. The Colleges wished to retain professional leadership but were concerned about their liabilities for staff and legal responsibilities in guideline development. It was agreed that staff should transfer to NHS QIS, but that SIGN Council would remain the guardian of SIGN methodology and retain professional leadership. This has preserved SIGN's key features – professional leadership and public funding – and facilitated the implementation of its guidelines.

#### **Relationships with other guideline organisations**

Following the development of clinical practice guidelines for England and Wales by the National Institute for Health and Clinical Excellence (NICE) from 1999, informal meetings between SIGN and NICE were held to discuss mutual interests. It was recognised that Scotland's health service had developed differently from England's and, since devolution of health and education in 2001, was rapidly becoming even more different. Furthermore, NICE's guideline development processes and ownership had also evolved differently. From 2003 the relationship was formalised and a joint statement of principles on working together was issued.<sup>10</sup> Since then there has been a regular exchange of search strategies and evidence tables between SIGN and the National Collaborating Centres working on NICE guidelines.

Internationally, SIGN has been a major player in guideline development, participating, for example, in the European

Cancer Guidelines Collaboration and promoting the formation of the Guidelines International Network (GIN).

## METHODOLOGY

It was always the intention that guidelines in Scotland would be evidence-based, as set out in the CRAG report of 1993.<sup>3</sup> This was a major step at a time when EBM was still a relatively new concept and most existing guidelines were developed by methods that would now be regarded as highly susceptible to bias.

At the same time as Petrie was convening a meeting of the Royal Colleges to decide whether to go ahead with a joint guideline initiative, Jeremy Grimshaw, the Programme Director at Aberdeen University's Health Services Research Unit, and Ian Russell, of Aberdeen University's Department of General Practice, wrote a paper highlighting the vital importance of three aspects of guideline development:<sup>11</sup>

- A systematic review of the literature.
- Multidisciplinary development groups.
- Direct links between evidence and recommendations.

Grimshaw presented a summary of this paper at a meeting of Royal Colleges and advocated the use of these principles as the basis for the new guideline development organisation. This proposal was accepted with comparatively little discussion. Whether those at the meeting fully appreciated what they were taking on is perhaps doubtful, given that it took several more years to work out how to apply these principles in practice. However, these principles have stood the test of time and are still fundamental to the way in which SIGN works.

With the principles agreed, the first guideline groups were gathered together and a start was made on recruiting a core staff. In the early days doctors joining a guideline group could be taken aback on being told that years of experience in their field were now seen as the lowest possible level of evidence and in future had to be supported by stronger evidence, preferably randomised controlled trials (RCTs).

At this time Petrie was active at meetings across the country 'selling' the new approach to guideline development and the importance of a rigorous methodology. This effort, combined with Petrie's strong support of staff, was invaluable in getting the fledgling organisation accepted by professional groups across the country. At the same time EBM was becoming more widely accepted, helped by contributions from powerful advocates such as Iain Chalmers (one of the founders of the Cochrane Collaboration) and David Sackett (founder of the Oxford Centre for Evidence-Based Medicine) and the growing strength of the Cochrane Collaboration. As SIGN's reputation began to grow and

the benefits of a robust methodology became clearer, the conflicts reduced and within a few years the process was widely accepted.

During these early years Grimshaw retained concerns about the extent to which SIGN was actually performing to its stated standards. Many of the earlier guidelines were inherited and it proved very difficult to 'retrofit' the methodology. Only after a few years when skills had developed did the performance on new guidelines begin to match expectations.

Part of the skill development process was due to training, something that SIGN emphasised from the beginning. A series of courses on critical appraisal of the medical literature was provided for members of guideline groups to ensure that all members had at least a basic grasp of the concepts fundamental to EBM. These courses were initially led by the Health Services Research Unit at Aberdeen University. Later, SIGN staff took on part of this role and eventually it became one of SIGN's core services.

As expertise in guideline development grew, SIGN staff also began to run courses on the practicalities of the development process. These were originally offered to guideline group members but later became popular for a wider audience and are now regularly run for other organisations in the UK and abroad.

### Grading of evidence and recommendations

From the beginning of evidence-based guidelines there has been a need to set a level of evidence (to establish the methodological quality of individual studies) and grades of recommendation (to provide an indication of how reliable the overall body of evidence supporting a recommendation is). For the first few years SIGN used the then widely accepted system developed by the US Agency for Health Care Policy and Research with a hierarchy of evidence based on study type, and recommendations graded from A to C.<sup>12</sup> It became clear, however, that this system had substantial weaknesses and did not really address the variations in evidence quality that were being encountered.

In 1998 a working group was set up to review the grading system and come up with proposals for a new scheme. The final system owed a lot to that developed by Les Irwig and his group in Australia.<sup>13</sup> It sought to improve flexibility and allow finer judgements on the overall quality of evidence, as well as give more weight to trials other than RCTs. The scheme also saw the introduction of 'considered judgement': the issues that a guideline group takes into account when interpreting evidence to produce a graded recommendation. It was the first scheme to have incorporated this explicitly into the process, with the aim of increasing the transparency of decision making.

In 1999 the working group's recommendations were accepted and the new scheme was subsequently published.<sup>14</sup> It was first used in SIGN publication 48<sup>15</sup> in 2000 and has continued to be used by SIGN largely unchanged up to the time of writing (December 2010). It has also been adopted or adapted by a number of other guideline developers internationally. The Grading of Recommendations Assessment, Development and Evaluation (GRADE) group has since taken the question of how best to grade evidence further.<sup>16</sup> In June 2009 SIGN Council agreed to adopt the GRADE approach and to amend the grading system accordingly. It is worth noting, however, that as recently as 2008 the SIGN approach was still seen as a valid approach in particular contexts.<sup>17</sup>

It has to be accepted that there will be clinical questions for which there is no good, evidence-based answer. SIGN has worked with the Scottish Government Chief Scientist's Office to promote topics for future research, and in recent years has amended the methodology to ensure such issues are noted in the UK Database of Uncertainties of the Effectiveness of Treatments.

### **Involving patients**

SIGN has always recognised the importance of involving patients and their carers in developing guidelines. Early efforts could fairly be described as 'tokenistic', but as the need for patient input became clearer, methodology was developed for making full use of the patient contribution. This eventually led to the appointment of a full-time member of staff with a remit to support patient involvement in guidelines.

The growing scope of patient involvement can be seen by comparing the comparatively brief comment on patient involvement in SIGN 39<sup>18</sup> with full coverage of the topic in SIGN 50,<sup>9</sup> and eventually production of SIGN 100<sup>19</sup> – a patient version of the full guideline manual. In 2007 the first in a series of patient versions of guidelines was published.<sup>20</sup> These versions aim to present the key points from the guideline in plain English, in a format that will be more easily understood by a lay reader.

### **Documenting and evaluating the process**

A core principle of SIGN is that everything it does should be transparent and measurable against external standards. At the time that SIGN was established, Grimshaw was working with Françoise Cluzeau, and Peter Littlejohns, of St George's Hospital Medical School's Health Care Evaluation Unit, London, on producing a critical appraisal instrument for guidelines. This later provided the foundation of the Appraisal of Guidelines Research and Evaluation (AGREE) instrument that is now widely accepted as the standard method of evaluating clinical practice guidelines.<sup>21</sup>

The appraisal instrument formed the basis for the AGREE collaboration and, as a partner, SIGN participated

in the work of further developing the instrument. When the final version was published, SIGN and the AGREE Collaboration produced a web-based tool that provides the background to each of the AGREE criteria and uses the SIGN process to illustrate how these should be applied in practice.<sup>22</sup> A manual to aid guideline developers was first published in 1999 and briefly outlined the processes used for developing a guideline and related them to the relevant AGREE criteria in advance of the publication of the first edition of the AGREE instrument.<sup>18</sup>

The publication of the 50th SIGN guideline was taken as an opportunity to produce what was hoped to be a landmark document, and so SIGN publication 50 became the SIGN manual for guideline producers.<sup>9</sup> First published in 2001, it is now a web-based publication which is regularly updated to reflect changes in the methodology. It provides considerably more detail than SIGN 39 and includes copies of all documentation used in the process of developing a guideline. It is in fact a 'kit' for anyone to use for guideline production, and as such it has been taken up by a number of organisations around the world.

As guideline development has become more sophisticated, the focus has shifted from development methodology to patient involvement and supporting implementation, and much remains to be done in both areas.

The work of the GRADE group will influence future methodological development and has already raised issues regarding resource implications, burden of care and social context. The increasing internationalisation of guideline production will also influence future development, as SIGN continues to play its part in initiatives such as GRADE, the ADAPTE Collaboration on adapting existing guidelines and the GIN Evidence Tables Working Group, which aims to standardise evidence tables to facilitate work sharing between guideline developers.

## **BUILDING UP THE GUIDELINE PROGRAMME**

When SIGN was launched, a number of guidelines were already in the process of being developed by the Colleges, which had set up working parties in co-operation with Government or specialist societies. Most of these were published under the SIGN banner. This resulted in a rapidly developing publication programme, with eight guidelines published in 1996, the first full year of operation, despite limited resources.

As mentioned above, there were concerns about the methodology used in these early guidelines, which were described as 'pilot editions' (with a clear implication that improved versions would follow later) and 'SIGN Publications' rather than guidelines. In one case the lack of evidence was such that the document was presented as a report on good practice rather than a guideline.<sup>23</sup> Each iteration of a guideline has used improved



methodology compared with its predecessor, and the quality gap between 'generations' of guidelines has narrowed considerably since these early days. Despite these limitations, even the earliest guidelines contain many of the features that are still regarded as important today: graded recommendations, sections on audit and implementation, cost implications for the service and a description of the methodology.

### Topic selection

SIGN uses a 'bottom up' approach to topic selection, with guideline topics proposed by individuals or teams actively working in NHS Scotland. As awareness of SIGN grew, the number of topic proposals increased substantially and a process to select topics worth developing was required. A pro-forma was developed for proposers to submit topics. This covered various criteria that were seen as essential for a topic to be suitable for a SIGN guideline, most importantly:

- Evidence of variation in practice that influences patient outcomes.
- Evidence that the topic affected a substantial number of patients in Scotland.
- Existence of an evidence base sufficiently large to support a guideline.

Proposals were initially sifted by senior Executive staff in consultation with relevant members of SIGN Council. Those that passed this hurdle were considered by Council, both through specialised subgroups and at a full Council meeting, which then made the final decision. The successful topics were submitted to CRAG for final agreement of funding. Once SIGN became part of NHS QIS, this process underwent a number of changes. The basic process remains the same, but with the addition of new factors such as NHS Scotland priority areas for healthcare and the need to integrate with the rest of the NHS QIS programme.

### Problems of scale

As resources grew, the production of new guidelines continued apace and by the end of 1999 40 guidelines covered the major health areas affecting the Scottish population (cardiovascular disease, cancer, mental health and child health) as well as other serious issues such as obesity, diabetes, asthma and hip fracture in the elderly. To keep up with the production rate, staff numbers continued to expand until the total number of employees stood at around 20. It was becoming apparent, however, that this work rate could not be sustained indefinitely. The number of existing guidelines that needed updating was increasing and from 2000 onwards the issue of new guidelines slowed. The programme became a mixture of new topics and reviews of existing work. Today, the majority of the guidelines on the programme at any one time are updates rather than new topics.

Looking ahead, it seems clear that there will be major changes in the development of guidelines. SIGN has already decided to stop printing hard copies of guidelines and emphasise electronic publications instead. Apart from cost savings, this offers the opportunity to update guidelines more quickly.

Throughout the history of SIGN the length of time required to produce a guideline has remained relatively static at around two years. Apart from a few outliers, the time between publication and update or withdrawal averages around 4.5 years. There is growing pressure for this to be cut substantially. Future guidelines will also need to be much more focused. The days of full guidelines that cover all aspects of a topic are almost certainly over.

### Implementation

Guidelines are pointless unless implemented. During its early history, SIGN was specifically excluded from implementation activity, but it has now been recognised that this is not a viable approach. In 2002 SIGN organised a conference around the impact of its guidelines, based on a survey conducted by CRAG.<sup>25</sup> Following on from this there has been substantial growth in activities to support implementation by both SIGN and NHS QIS, which has been substantially influenced by the work of the Cochrane Effective Practice and Organisation of Care group.

## CONCLUSIONS

Over the past two decades, the collaboration of the Scottish Royal Colleges with all healthcare providers (and patients and carers) across Scotland, to develop and promote evidence-based clinical practice guidelines, has continued a long tradition of promoting quality and equality in healthcare. SIGN has been a pioneering example of the application of medical science to Scottish healthcare and of national collaboration. Its worldwide recognition continues the Scottish tradition of international medical education.

**Acknowledgements** We thank many current and former members of SIGN Council and Executive, and SIGN advisors, for contributing their recollections to this history, including James Beattie, Tricia Donald, Keith Donaldson, Lesley Forsyth, Jeremy Grimshaw and Christina Pottinger. We also thank former members of CRAG (Eillen Barnwell, Willie Farquhar and Derek Maclean). We dedicate this history to the memories of Professor Jim Petrie (first Chairman of SIGN Council) and Christina Pottinger (first head of SIGN Executive).

## REFERENCES

- 1 Petrie J, Grimshaw J, Bryson A. The Scottish Intercollegiate Guidelines Network initiative: getting validated guidelines into local practice. *Health Bull (Edin)* 1995; 53:354–8.
- 2 Scottish Intercollegiate Guidelines Network. *Clinical guidelines: criteria for appraisal for national use*. Edinburgh: SIGN; 1995.
- 3 Clinical Resource and Audit Group. *Clinical guidelines: report by a working group*. Edinburgh: Scottish Office; 1993.
- 4 *The history and development of CRAG*. Edinburgh: CRAG; 2002. Available from: <http://www.crag.scot.nhs.uk/topics/facts/history.htm>.
- 5 What is a systematic review? In: Higgins JP, Green S, editors. *Cochrane handbook for systematic reviews of interventions*. Chichester: Wiley-Blackwell; 2008. p. 6.
- 6 Grilli R, Magrini N, Penna A et al. Practice guidelines developed by specialty societies: the need for a critical appraisal. *Lancet* 2000; 355:103–6. doi:10.1016/S0140-6736(99)02171-6
- 7 Miller J, Petrie J. Development of practice guidelines. *Lancet* 2000; 355:82–3. doi:10.1016/S0140-6736(99)90326-4
- 8 Scottish Intercollegiate Guidelines Network. *Prophylaxis of venous thromboembolism: a national clinical guideline*. Edinburgh: SIGN; 1995.
- 9 Scottish Intercollegiate Guidelines Network. *SIGN 50: a guideline developer's handbook*. Edinburgh: SIGN; 2008.
- 10 *Updated partnership agreement between the Scottish Intercollegiate Guidelines Network and the National Institute For Health And Clinical Excellence*. Edinburgh, London: SIGN, NICE; 2003. Available from: <http://www.sign.ac.uk/about/niceandsign.html>
- 11 Grimshaw J, Russell I. Achieving health gain through clinical guidelines. 1: developing scientifically valid guidelines. *Qual Health Care* 1993; 2:243–8. doi:10.1136/qshc.2.4.243
- 12 Acute pain management: operative or medical procedures and trauma. Rockville, MD: US Department of Health and Human Services. Agency for Health Care Policy and Research; 1993.
- 13 Liddle J, Williamson M, Irwig L. *Method for evaluating research and guideline evidence*. Sydney: New South Wales Department of Health; 1996.
- 14 Harbour R, Miller J. A new system for grading recommendations in evidence based guidelines. *BMJ* 2001; 323:334–6. doi:10.1136/bmj.323.7308.334
- 15 Scottish Intercollegiate Guidelines Network. *Management of early rheumatoid arthritis*. Edinburgh: SIGN; 2000.
- 16 Guyatt GH, Oxman AD, Vist GE et al. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. *BMJ* 2008; 336:924–6. doi:10.1136/bmj.39489.470347.AD
- 17 Baker A, Young K, Potter J et al. *A review of grading systems and critical appraisal tools for use by specialist medical societies developing evidence-based guidelines*. London: NHS Plus, Royal College of Physicians of London; 2009.
- 18 Scottish Intercollegiate Guidelines Network. *SIGN Guidelines: an introduction to SIGN methodology for the development of evidence-based clinical guidelines*. Edinburgh: SIGN; 1999.
- 19 Scottish Intercollegiate Guidelines Network. *SIGN 100: a handbook for patient and carer representatives*. Edinburgh: SIGN; 2008.
- 20 Scottish Intercollegiate Guidelines Network. *Stable angina for patients*. Edinburgh: SIGN; 2007.
- 21 The AGREE Collaboration. *The Appraisal of Guidelines for Research & Evaluation (AGREE) Instrument*. London: AGREE Trust; 2001. Available from: <http://www.agreecollaboration.org>
- 21 *Appraising the quality of clinical guidelines: the SIGN guide to the AGREE appraisal instrument*. Edinburgh: SIGN; 2007. Available from: <http://www.sign.ac.uk/methodology/agreeguide/index.html>
- 23 Scottish Intercollegiate Guidelines Network. *Report on good practice in the care of children and young people with diabetes*. Edinburgh: SIGN; 2006.
- 24 Clinical Resource and Audit Group. *Implementation of SIGN guidelines in NHSScotland*. Edinburgh: CRAG; 2002.

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