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Contributors

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Foreword

The NHS in Scotland has a strong tradition of providing high-quality, innovative treatment and care. Although we have much to be proud of, we will continue striving to improve the quality of the healthcare services we provide to the people of Scotland. To this end, the Scottish Executive has made the quality of clinical care an explicit statutory responsibility of every NHS body. Clinical governance and clinical effectiveness are now accepted as everyone's business.

This report records leading-edge initiatives aimed at improving the quality of health care provided in Scotland. It aims to provide useful, up-to-date information for all health professionals in Scotland on the work of our national clinical effectiveness bodies. It will be valuable to those who may not be aware of the full range of initiatives aimed at supporting them in improving patient care.

Among the initiatives outlined are the provision of high-quality SIGN guidelines to allow more effective treatment of patients, the work of the recently established Clinical Standards Board for Scotland in developing a national system of quality assurance in the NHS, and a programme of research supported by the Chief Scientist Office to improve the quality of care provided. Central to all these initiatives is the involvement of patients and the public.

Our aim is to use these and other initiatives, together with record levels of investment in the NHS in Scotland, to improve the quality of care provided and the health of people in Scotland.

Susan Deacon MSP
Minister for Health and Community Care

CONTENTS

CONTENTS

SUMMARY

The effectiveness of clinical care and treatment is central to the quality of health care.

Scotland has a well-advanced programme of work on clinical effectiveness, delivered by the co-operative and co-ordinated efforts of a number of bodies – see below for outline of each.

- The Clinical Resource and Audit Group (CRAG) has supported 200 projects since 1989 and promotes systematic programmes of clinical audit at local and national levels.
- The Scottish Intercollegiate Guidelines Network (SIGN) produces multidisciplinary clinical guidelines (46 to date). The development of clinical guidelines and good practice statements provides clinical staff with information about most effective practice.
- More than 40 clinical outcome indicators have already been published.

The more recent introduction of clinical governance (corporate duty of clinical quality) reinforces the importance attached by the Government to the delivery of quality healthcare.

The **Clinical Resource and Audit Group (CRAG)** is the lead body within the Scottish Executive Health Department promoting clinical effectiveness in Scotland. CRAG provides advice to the Scottish Executive Health Department on the development of policies on clinical effectiveness issues. CRAG acts as a national forum to support and facilitate the implementation of the clinical effectiveness agenda.

A **Clinical Effectiveness Strategy Group**, chaired by the Chief Medical Officer, has been established as a forum to draw together the various strands of the quality agenda. It has a strategic and co-ordinating role, gathering together the leaders of all the bodies involved in clinical effectiveness and quality work on a regular basis.

The **Chief Scientist Office** is responsible for encouraging and supporting research to improve the health of the people in Scotland and the services provided by the NHS in Scotland. The CSO has a leading role in establishing the evidence base for health care and its delivery. Much of the work it funds is incorporated into the development of practice within the NHSiS.

The **Scottish Intercollegiate Guidelines Network (SIGN)** aims to improve the effectiveness and efficiency of clinical care for patients in Scotland by developing, publishing and disseminating guidelines which identify and promote good clinical practice based on robust research evidence. Patients' views are represented and SIGN works closely with other national groups and government agencies in the NHS in Scotland. SIGN enjoys international acclaim for the robustness of its methodology in the development of clinical guidelines.

The **Clinical Standards Board for Scotland (CSBS)** is developing and running a national system of quality assurance and accreditation of clinical services in the NHS in Scotland. The role of CSBS is to set standards for clinical care delivery and to support clinical governance by providing an external check but retaining a close link within the NHS family. CSBS is committed to promoting public confidence that ***"every patient, wherever they live, whatever their illness, gets the highest possible standards of care"***.

The recently established **Health Technology Board for Scotland (HTBS)** will advise the NHS in Scotland on the clinical and cost effectiveness of innovations in health care including new drugs and treatment. It will be a single source of national advice, established as a

Special Health Board and independent of health service management. It will work closely with NHS professionals and patient representatives to help ensure that effective innovations and technologies are introduced quickly into mainstream practice and that resources are not wasted on ineffective practices and treatments.

The primary function of **clinical audit** is to improve patient care by informing health care professionals' understanding of their clinical practice. This is usually achieved by measuring performance against specified standards, identifying shortfalls and putting in place any necessary action. Clinical audit in Scotland is a multi-professional activity – supported both locally and by CRAG nationally via effectiveness programmes and national audits. Standards for audit are increasingly drawn from recommendations in SIGN guidelines and on topics selected by CSBS for quality assurance.

The NHSiS has some of the best health service data in the world, and the **Information and Statistics Division (ISD Scotland)** collects, validates, interprets and disseminates information on the national health service in Scotland. ISD Scotland provides a statistical information and intelligence service to a wide variety of customers, creating information that assists in monitoring and evaluating provision of care throughout the NHSiS.

Scotland has been at the leading edge in the use and publication of **clinical outcome indicators** as part of the general drive to use routine information to improve the quality of care. Over the past 10 years, Scotland has made use of its high quality national health data sets to publish a wide range of clinical indicators. Since 1994, over 40 clinical indicators have been published across a wide range of clinical conditions and care settings.

The **Scottish Needs Assessment Programme (SNAP)** assesses the need for interventions to improve health encompassing the need for change in all aspects of living and all professions or services that may be relevant to improving health. SNAP aims to contribute to work on improving health status and building health alliances as well as informing the planning process for health services.

The **Designed Healthcare Initiative** supports well designed and seamless care which minimises waiting times and delays, removes unnecessary hospital visits and provides continuity of care for patients wherever and whenever they need care. The project encourages service providers to consult with patients and other healthcare professionals to achieve improvements to services.

In summary, this report identifies the leading-edge initiatives established to improve the quality of health care provided and highlights how these initiatives fit in to the Scottish Executive's wider Modernisation Programme aimed at delivering a modern, responsive and patient-focussed healthcare service across Scotland. These and other initiatives, together with record levels of investment in the NHS in Scotland, strive to improve the quality of care provided and improve the health of the people in Scotland.

1 Clinical Resource and Audit Group

Introduction

The Clinical Resource and Audit Group (CRAG) provides leadership and a focus for integrating clinical effectiveness activity into clinical services across Scotland.

Clinical effectiveness is an umbrella term describing a range of activities that support clinicians to examine and improve the quality of their care. Probably the best known example is audit but effectiveness stretches beyond this to include standards, guidelines, integrated care pathways, clinical performance indicators and a range of mechanisms to measure and assess quality of care through new information systems and automatic data capture.

Scotland has made great progress in many of these areas and further details on specific initiatives are included in later sections of this report. This first section describes the approach to co-ordination and strategic development of clinical effectiveness, setting this in the context of clinical governance with clear accountability to the public for the quality of care delivered in the NHS in Scotland.

Origins of CRAG

Scotland took a strategic overview of how best to support the effective and efficient use of health care resources as early as 1985, when a group was set up to examine clinical services from a clinical and economic standpoint. In 1989, this became what we now know as the Clinical Resource and Audit Group (CRAG) with an initial remit to act as a national forum for the planning and assessment of clinical resources and a focus for the development of audit (then largely medical audit) across Scotland.

Between 1989-95, there was a major drive to stimulate audit in all clinical disciplines through national audit committees and ring-fenced funding. By 1995, over 120 audits had been funded by CRAG's national projects committee and over £26 million allocated to support this developing activity across Scotland.

In partnership with the Scottish Health Management Efficiency Group (SCOTMEG), CRAG also examined and reported on four key care areas:

- maternity services
- mental illness
- accident and emergency
- services for elderly people.

In 1993, CRAG published *Clinical Guidelines*, confirming the importance of guidelines and protocols in developing evidenced-based practice and high quality clinical care. CRAG supported the establishment of an innovative and collaborative initiative by the joint Scottish Colleges (clinical professional organisations) and in 1993, the Scottish Intercollegiate Guidelines Network (SIGN) began work as a pilot project (see Section 2). Today, CRAG

continues to fund and enjoy a close relationship with this internationally recognised force for clinical effectiveness.

The early work of the Clinical Outcomes Working Group (see Section 3) also dates back to this period, with the first clinical outcome indicators report published in 1994. This group published clinical outcome (largely mortality) information, presented at a named Trust or Health Board level for the first time.

It is a sensitive area of clinical effectiveness and the data can be complex and difficult to interpret. Section 3 discusses the importance of using the data constructively: the reports are not league tables but are an important feedback mechanism for clinicians and managers in their search for opportunities to improve care.

Further details on all CRAG initiatives are available in individual sections of the report, but this brief history serves to illustrate that products and services bearing the CRAG thistle symbol are based on a strong tradition of clinicians working with managers to examine and improve care in Scotland – an inclusive model that fits comfortably with today's emphasis on clinical governance and quality assurance.

CRAG today

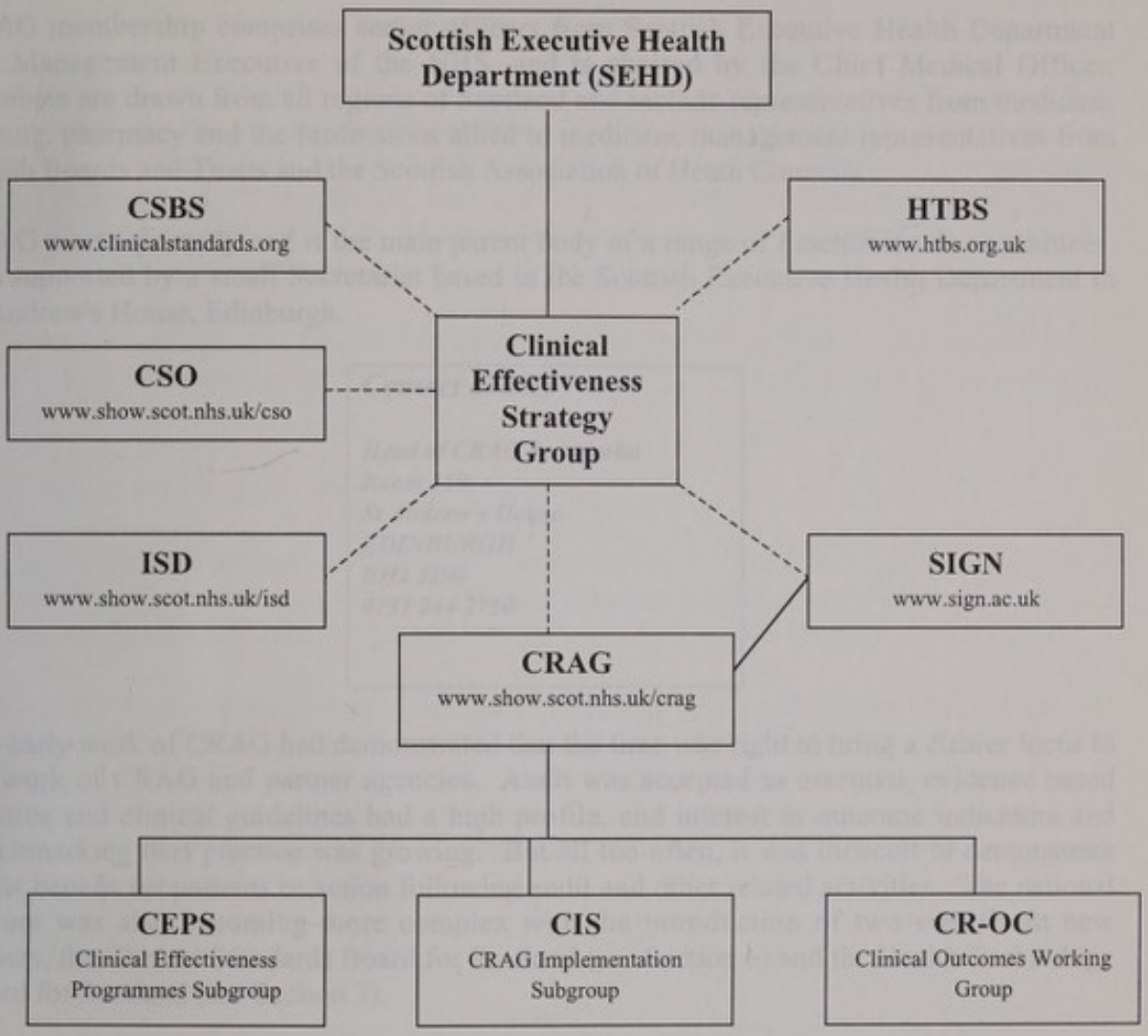
Initially, the main drivers in the system were medical doctors but the focus quickly moved to other professional groups and then to multi-professional clinical effectiveness, reflecting the growing recognition of the importance of working in teams. In essence, CRAG has been charged with facilitating all activities necessary to deliver Section 2 of *Designed to Care*, the White Paper that removed the internal market in the NHS, created the concept of clinical governance, and placed renewed emphasis on clinical and cost effectiveness, quality of care and public involvement.

Following a review of its own role and remit in 1998, CRAG was restructured to reflect the challenges of *Designed to Care* and to build on previous success. It continues to provide strategic advice to Ministers, bringing together key players from the major partner agencies in Scotland and secures essential co-ordination of an increasingly complex system of support. It works through sub-committees and well developed relationships with key partner agencies, each of which have specific responsibilities in Scotland for supporting the clinical effectiveness and public involvement agendas.

Figure 1 illustrates the main components of the CRAG 'family' and relations with other agencies.

Figure 1

CLINICAL EFFECTIVENESS IN SCOTLAND



CSBS Clinical Standards Board for Scotland
HTBS Health Technology Board for Scotland
SIGN Scottish Intercollegiate Guidelines Network
CSO Chief Scientist Office (*part of the Scottish Executive Health Department*)
ISD Information and Statistics Division (*part of the Common Services Agency*)

CRAG's strategic role

CRAG main committee

CRAG membership comprises senior officers from Scottish Executive Health Department and Management Executive of the NHS, and is chaired by the Chief Medical Officer. Members are drawn from all regions of Scotland and include representatives from medicine, nursing, pharmacy and the professions allied to medicine, management representatives from Health Boards and Trusts and the Scottish Association of Heath Councils.

CRAG meets quarterly and is the main parent body of a range of functional sub-committees. It is supported by a small Secretariat based in the Scottish Executive Health Department in St Andrew's House, Edinburgh.

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The early work of CRAG had demonstrated that the time was right to bring a clearer focus to the work of CRAG and partner agencies. Audit was accepted as essential, evidence based practice and clinical guidelines had a high profile, and interest in outcome indicators and benchmarking best practice was growing. But all too often, it was difficult to demonstrate direct benefit for patients or action following audit and other related activities. The national picture was also becoming more complex with the introduction of two significant new players, the Clinical Standards Board for Scotland (see Section 6) and the Health Technology Board for Scotland (see Section 7).

As well as leading the strategic direction, CRAG was asked to:

- deliver a programme of work reflecting the agreed national clinical priorities: cancer, CHD and stroke, and mental health
- focus on implementation of clinical effectiveness.

Strategic direction and co-ordination of clinical effectiveness

The Clinical Effectiveness Strategy Group provides this essential co-ordination by bringing together the leaders of all the organisations represented in Figure 1 to encourage collaboration, ensure integration at a high level and support communication and consultation. This group meets regularly and is proving to be a valuable 'think tank' for CRAG itself, very much reflecting the inclusive development model and improving the pace of change.

CRAG objectives are now delivered through:

- Clinical Effectiveness Programmes sub-group (CEPS)
- CRAG Implementation sub-group (CIS)
- CRAG Outcome Indicators sub-group (CR-OC).

Membership of these groups is drawn from clinical teams from all over Scotland. This secures enthusiasm and appropriate expertise for this work and extends knowledge and ownership of key decisions as individual members report back to their home organisations. Many Trusts and Health Boards will have staff on one or other of these committees and the Chairs of these groups sit on the Strategy Group ensuring clear lines of communication between the strategic and the implementation arms of CRAG.

Other short life groups are convened as required and all report to CRAG: a current example is the group encouraging the use of Information Technology to improve care for patients with diabetes.

Developing and supporting innovation

New ideas and methodologies are stimulated and fostered by CRAG through a programme of national clinical effectiveness projects, offering grants to multidisciplinary groups interested in developing new approaches with the potential for significant health gain.

In line with the challenge to ensure Scotland's clinical resources are strategically aligned to the national clinical priorities, the current portfolio of projects includes commissioned programmes of work in cancer CHD/stroke with new programmes coming on stream later in 2000 in mental health and children's services. These projects are approved and monitored through CEPS, with a budget of £1.7 million (2000/01) of which 20% is reserved for work outside the national priority areas.

Cancer

With cancer as one of three clinical priorities for the NHS in Scotland, a clinical effectiveness programme focusing on patient care is well underway through a range of nationwide prospective clinical audits to study the care pathways for all types of urological and head and neck cancers. A similar study of gastric-oesophageal cancer is complete and an interim final report in preparation. All of these studies have a similar aim – to describe the delivery of investigations and treatment of patients with cancer and to audit these in terms of outcome. Key objectives of each study are to identify variations in clinical practice in the investigation and treatment of each tumour type; e.g. good and inappropriate practice based on clinical outcomes, possible reasons for these and areas which require further investigation.

All studies are undertaken over three years involving 24 months prospective population based audit and a minimum of one year follow up on each patient. All hospitals in Scotland dealing with the diagnosis and/or management of patients with any of the specific tumour types involved are participating in the studies.

Primary Care

The Royal College of General Practitioners has led on a national project on clinical effectiveness in primary care identifying a number of key clinical conditions (including national priorities) for which they have produced agreed audit criteria. This information will be collated and analysed nationally and reported back to participating practices.

More detail on audit in Scotland can be found in Section 4.

Driving change

Supporting quality projects is one part of the story. CRAG recognises the challenge of ensuring that the resources and energy devoted to clinical effectiveness drive change to improve health outcomes.

Lessons learned in one area must be shared widely to improve the pace of change. Teams eager to review their own quality of care must be supported to approach this rigorously and effectively. The CRAG visiting programme offers an opportunity to disseminate best practice, advise Ministers and key partners on progress in this important area of work, and target support initiatives.

Each year, CRAG also runs an annual symposium and a range of more specialised seminars and workshops. It has plans to support a comprehensive programme of specialised workshops around Scotland in partnership with professional organisations and local Health Boards and Trusts.

Using Technology to integrate care – Dunblane September 2000

CRAG held a one-day conference on the uses of technology to improve the delivery of care in the NHS. The conference was largely targeted at the clinical leaders in the service. The aim of this event was to raise awareness of the potential of technology and to share information on the many initiatives that are underway. Topics included telemedicine, using technology to resolve remoteness barriers, data security and indemnity, staffing and technology issues.

Details of all CRAG events can be found on the website; www.show.scot.nhs.uk/crag

Clinical governance

Various definitions appear in articles and official reports and all centre around the corporate or organisational responsibility for clinical quality.

"Clinical governance is the vital ingredient which will enable us to achieve a Health Service in which the quality of health care is paramount. The best definition that I have seen of clinical governance is simply that it means "corporate accountability for clinical performance". Clinical governance will not replace professional self regulation and individual clinical judgement, concepts that lie at the heart of health care in this country. But

it will add an extra dimension that will provide the public with guarantees about standards of clinical care.[1]

Everyone working in the NHSiS has a role in the governance of clinical services by:

- ensuring they are individually capable of delivering care to their patients
- taking part in wider quality assurance systems to measure and monitor care provided by teams
- accepting collective responsibility to ensure services meet expected standards.

There is an individual and collective responsibility placed on clinicians and managers, reinforced by the statutory responsibility now placed on chief executives and which extends their official governance to clinical and corporate issues.

None of this should be new for clinicians. Professional organisations and regulatory bodies require individual healthcare professionals to take responsibility for the quality of care provided to patients and to ensure they take part in continuing professional education to maintain skills in line with the evidence base and emerging technology. What is different is the focus on a systematic approach with explicit standards and an obligation to demonstrate to patients and the wider public that clinical care is the best possible within the resources available.

It is in this new atmosphere that CRAG and other agencies collaborate to support quality assurance systems to deliver high quality health services and promote public confidence in the NHSiS. The following sections of this report describe the aims and objectives of a range of these initiatives and direct the reader to other relevant sources of information (reports and web sites) for people interested in exploring Scotland's approach to improving clinical quality in detail.

Key points on CRAG and the strategic direction for clinical effectiveness

- supports the systematic approach to improving clinical quality - clinical governance
- builds on a strong tradition of clinical effectiveness in Scotland
- provides essential co-ordination of a wide range of related clinical effectiveness activities
- supports a programme of national clinical effectiveness work
- has a new focus on implementation
- compiles outcome indicator reports to provide opportunities to target the search for improvements in care

Head of CRAG Secretariat
Scottish Executive Health Department

Reference

1. *NHS MEL (1998) 75 Clinical Governance. November 1998*

2 Guideline development

Introduction

Clinical guidelines provide recommendations for effective practice in managing clinical conditions where variations in practice affect patient outcomes.

Guidelines are designed to help doctors and other healthcare professionals assimilate, evaluate and implement the ever-increasing amount of evidence and opinion on best current practice. They assist practitioners and patients in making decisions about appropriate and effective health care.

Clinical guidelines have been produced for many years and have been shown to be an effective means of changing the process of health care and improving health outcomes. But they vary in the extent to which they produce the anticipated health gains. Research carried out in Scotland and elsewhere led to the development of standard criteria for assessing the validity of guidelines.

The key elements are that guidelines should:

- be developed by multidisciplinary groups representing all the key disciplines
- be based on a systematic review of the scientific literature
- contain recommendations explicitly linked to the supporting evidence.

In contrast, up to the mid-1990s, guidelines were mostly developed by single specialty groups and based on received wisdom rather than current scientific evidence. The Clinical Resource Audit Group (CRAG) highlighted this problem in the 1993 report, *Clinical Guidelines* (see Section 1).

In response, the Academy of Royal Colleges and their Faculties in Scotland set up the Scottish Intercollegiate Guidelines Network (SIGN) to develop rigorous, multidisciplinary, evidence-based national guidelines for the NHS in Scotland.

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SIGN is a network of clinicians and other healthcare professionals, including all the medical specialties, nursing, pharmacy, dentistry, professions allied to medicine, patients, and health service management. SIGN's aim is to develop clinical guidelines which are both *valid* from a scientific perspective and *valued* by the profession so they can be adopted into practice for the benefit of patients.

SIGN is funded by CRAG, although the employing NHS Trusts and universities make an important contribution to the SIGN initiative by meeting the expenses of most guideline development group members. The member organisations of SIGN also contribute by supporting their representatives on SIGN Council.

How are guidelines developed?

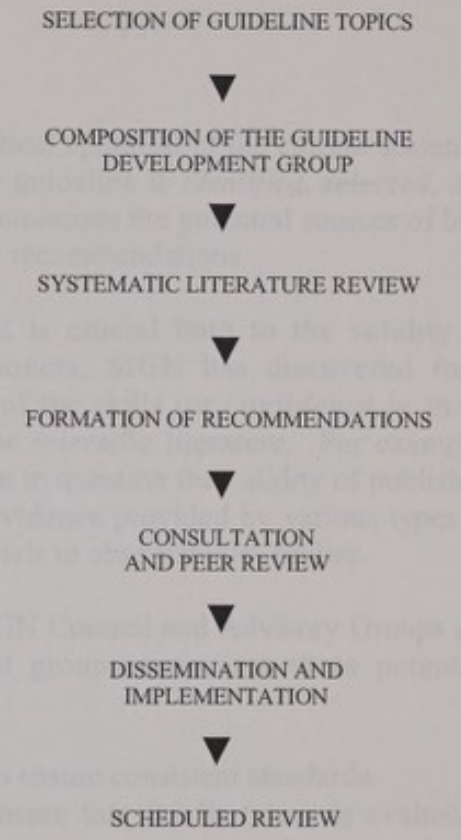
SIGN currently has a programme of 60 evidence-based clinical guidelines – published, in development, or under review – covering a wide range of topics. Many of the SIGN guidelines relate to the NHSiS priority areas of cancer, cardiovascular disease, mental health, child health, and primary care.

Any group or individual can propose a topic for a SIGN guideline. For a topic to be suitable, there must be evidence of variation in practice that affects patient outcomes and a strong research base providing evidence of effective practice.

Selection of appropriate topics for guideline development is crucial. The New Zealand 'Guidelines for Guidelines' Advisory Committee has emphasised that:

- guidelines should address a specific health care need
- there must be an expectation that change is possible and desirable
- there should be potential to improve the quality of care and/or patient outcomes.

The SIGN guideline development process



Multidisciplinary involvement

Representatives of key groups and disciplines affected should be included in the process of developing guidelines. They should not be developed by academics and senior clinicians insulated from the day-to-day pressures involved in providing medical care. Studies have shown that the balance of disciplines within a guideline development group has considerable influence on the guideline recommendations.

> ***"Unless a guideline accurately reflects the routine working practices of most doctors it will act only as a gold standard to be admired."***
> Farmer, BMJ 1993

One of SIGN's great strengths is its ability to call on advice and nominations from all the member organisations in forming multidisciplinary guideline development groups. This ensures that all relevant professions in Scotland have an input and feel ownership over the guideline development process.

Care is also taken to ensure that the groups are balanced geographically, with representatives from across Scotland. Declaration of interests are completed by all guideline development groups members, as well as members of SIGN Council.

Patients and patient representatives are also included in SIGN guideline development groups whenever possible. Patients may have different perspectives on health care processes, priorities, and outcomes from those of health professionals. Involving patients or patient representatives in guideline development is important to help ensure that guidelines reflect patients' needs and concerns. Patients also have a key role in promoting guideline implementation and it is important that they should have access to information on the recommendations of published guidelines.

Systematic literature review

Each guideline is based on a systematic review and critical appraisal of the current scientific literature. This means that the evidence base for the guideline is *identified*, *selected*, and *evaluated* according to a defined methodology. This minimises the potential sources of bias in the guideline and maximises the likely validity of the recommendations.

Although involving users in guideline development is crucial both to the validity of recommendations and their acceptance by practitioners, SIGN has discovered from experience that many clinicians are lacking in some of the skills (or *confidence* in those skills) required to undertake a critical appraisal of the scientific literature. For example, many experienced healthcare professionals are reluctant to question the validity of published studies and unsure of how to evaluate the quality of evidence provided by various types of studies, from meta-analyses of randomised controlled trials to observational studies.

The resources of the SIGN Executive, members of SIGN Council and Advisory Groups are therefore available to assist guideline development groups overcome these potential difficulties. This includes:

- undertaking or overseeing the literature search to ensure consistent standards
- monitoring the critical appraisal process to ensure that the literature is evaluated against rigorous criteria for validity
- ensuring that the systematic review is meticulously documented.

Training in critical appraisal skills is also offered to all members of SIGN guideline development groups. Further advice and support are available throughout the guideline development process.

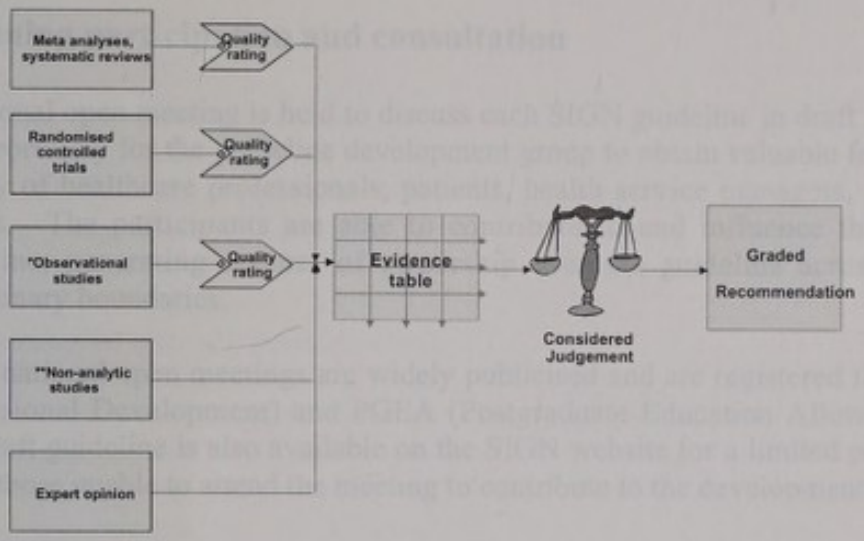
Close liaison with other organisations developing guidelines or undertaking systematic reviews – such as the Cochrane Collaboration or the NHS Centre for Reviews and Dissemination, and more recently the National Institute for Clinical Excellence (NICE) – enables knowledge and experience to be shared and ensures that work is not duplicated.

Deriving and grading recommendations

Guideline recommendations are graded according to the strength of the supporting evidence. This provides groups of practitioners working in the NHSiS with information to help select and prioritise recommendations for local implementation, depending on local needs, priorities, and resources.

Recommendations are graded to differentiate between those based on strong evidence and those based on weak evidence. This judgement is made on the basis of an (objective) assessment of the study design and quality and a (perhaps more subjective) judgement on the consistency, clinical relevance and external validity of the evidence.

Overview of the grading process



It is important to emphasise that the grading does not relate to the *importance* of the recommendation, but to the strength of the supporting evidence and, in particular, to the predictive power of the study designs from which that data was obtained. The grading assigned to a recommendation indicates to users the likelihood that, if that recommendation is implemented, the predicted outcome will be achieved.

Between 1993 and 1998, SIGN used a system for grading guideline recommendations based on the work of the US Agency for Health Research and Quality (AHRQ), formerly the Agency for Health Care Policy and Research (AHCPR). However, SIGN's experience over more than five years of guideline development led to growing awareness of the weaknesses of this grading system:

- some inherent in the system itself
- some relating to its application by guideline development groups
- some to its interpretation by guideline users.

In 1998, therefore SIGN undertook to review and, where appropriate, to refine the system for evaluating guideline evidence and grading recommendations. The objectives of the review were to:

- develop a system that would maintain the link between the strength of the available evidence and the grade of the recommendation, while allowing recommendations to be based on the best available evidence and weighted accordingly

- ensure that the grading system incorporated formal assessment of methodological quality, quantity, consistency, and applicability of the evidence base
- present the grading system in a clear and unambiguous way to allow both guideline developers and users to understand the link between the strength of the evidence and the grade of recommendation.

The new SIGN grading system was piloted and extensively peer reviewed before being implemented in Autumn 2000.

Widening participation and consultation

A national open meeting is held to discuss each SIGN guideline in draft form. This provides an opportunity for the guideline development group to obtain valuable feedback from a wide variety of healthcare professionals, patients, health service managers, and other interested groups. The participants are able to contribute to and influence the form of the final guideline, generating a sense of ownership over the guideline across geographical and disciplinary boundaries.

SIGN national open meetings are widely publicised and are registered for CPD (Continuing Professional Development) and PGEA (Postgraduate Education Allowance) accreditation. The draft guideline is also available on the SIGN website for a limited period at this stage to allow those unable to attend the meeting to contribute to the development of the guideline.

Specialist referees also independently review all SIGN guidelines before publication. This process of extended consultation, although lengthy:

- greatly reduces the risk of bias in the guideline development process
- enhances the validity of the final SIGN guideline
- increases the likelihood that the guideline will be implemented successfully into local practice for the benefit of patients.

Scheduled review

All SIGN guidelines carry a 'sell-by' date which requires that they should be reviewed two years after the publication date and updated to reflect newly published evidence. (SIGN guidelines themselves may act as a stimulus to research: an important subsidiary outcome of the guideline development process is in highlighting gaps in the evidence base.)

The scheduled review will also involve updating the guideline development *process* to reflect advances in SIGN methodology since publication of the first – or previous – edition of the guideline.

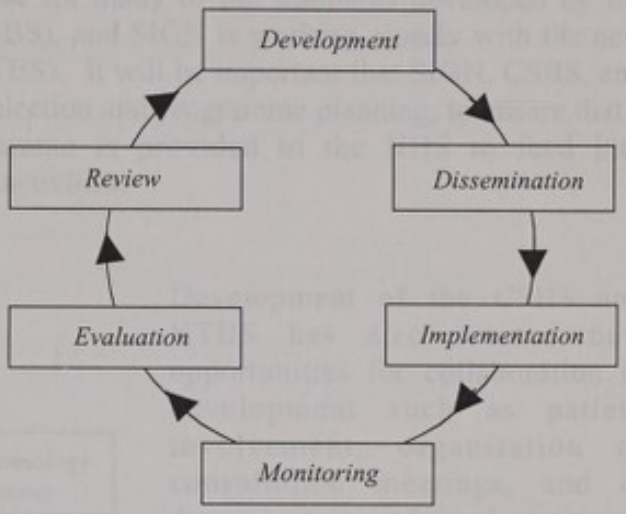
Guidelines due for review are required to reapply for inclusion in the SIGN programme. It must be shown not only that it is necessary to update the guideline due to developments in the evidence base supporting the recommendations, but also that there is a continuing *need* for the guideline. Where possible, evidence relating to the effects of implementing the pilot edition should also be provided. Here in particular, clinical audit provides an essential link between the national guideline and local experience of implementation.

All comments received on published SIGN guidelines, or information on important new evidence in the field, is fed back to the guideline development group for immediate response or for more detailed consideration on review of the guideline.

The 2-year review period is not applied rigidly. Guidelines may be reviewed sooner if there are important developments in the evidence base, or the review may be postponed if, for example, the results of ongoing studies are awaited. Any updates to the guideline that might be required before the scheduled review are noted on the SIGN web site.

How are guidelines used?

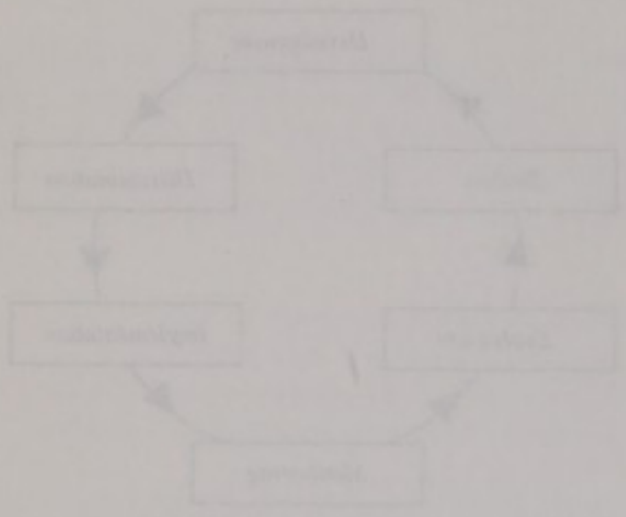
Guidelines can achieve better treatment outcomes for patients, but *local ownership* of the implementation process is crucial to success in changing practice. For this reason, SIGN is responsible for the development of national guidelines, but *not* for their implementation into practice. This is a responsibility of each individual NHS Trust, and is now reinforced by the twin 'levers' of clinical governance and the Clinical Standards Board for Scotland (see below, also section 6).



The guideline cycle

It is also important to emphasise that SIGN guidelines are intended as an *aid* to clinical judgement not to replace it. Guidelines do not provide the answers to every clinical question, nor guarantee a successful outcome in every case. The ultimate decision about a particular clinical procedure or treatment will always depend on each individual patient's condition, circumstances and wishes, and the clinical judgement of the healthcare team.

However, guidelines *are* intended to address variation in practice. Therefore, whilst there is no compulsion to implement any SIGN guideline or individual recommendation, Health Boards, NHS Trusts, clinical teams, and individual practitioners in primary and secondary care should all be able to define the standard of care which they provide, and to justify if necessary why these do not meet nationally agreed recommendations.

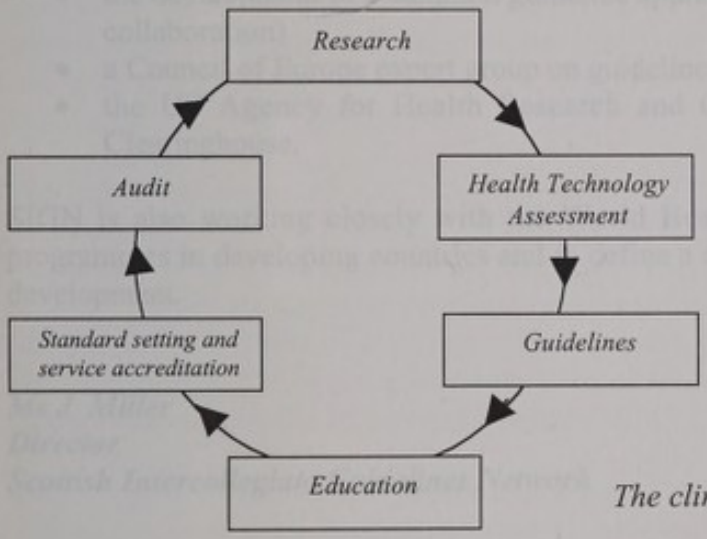


Guidelines and clinical governance

SIGN guidelines are part of a range of complementary activities to translate research into practice, set and monitor standards, and promote clinical excellence in the NHSiS. The highest standards of patient care and improved outcomes are the ultimate goal.

Guidelines are just one piece in the clinical effectiveness jigsaw.

SIGN guidelines provide the evidence base for many of the standards developed by the Clinical Standards Board for Scotland (CSBS), and SIGN is working closely with the new Health Technology Board for Scotland (HTBS). It will be important that SIGN, CSBS, and HTBS liaise closely, particularly in topic selection and programme planning, to ensure that a co-ordinated and comprehensive programme is provided to the NHS to feed into implementation, education, audit, and other activities.



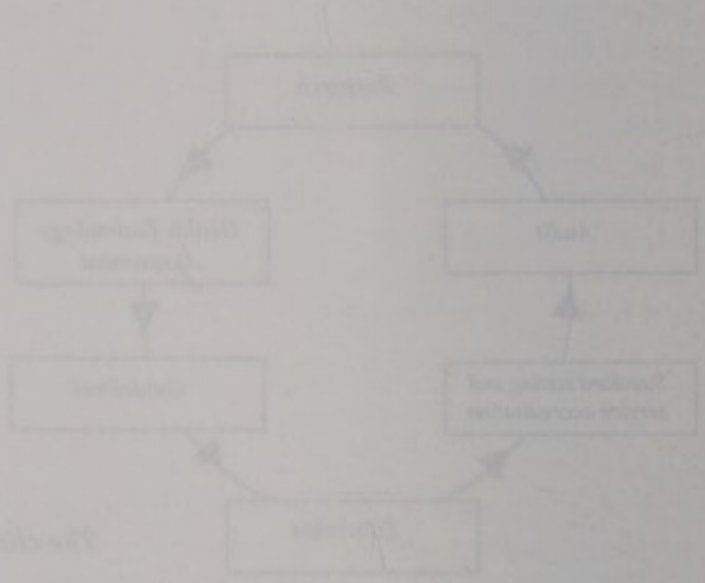
The clinical effectiveness cycle

Development of the CSBS and HTBS has also created new opportunities for collaboration in development such as patient involvement, organisation of consultation meetings, and in dissemination and implementation strategies.

Links with local and national audit projects are also an essential part of guideline implementation, and SIGN has been working closely with the Information and Statistics Division (ISD) to develop the audit component of guidelines and, where possible, to include minimum datasets in guidelines to facilitate prospective audit.

Future developments

To date, SIGN has published 46 evidence-based clinical guidelines and is widely recognised as one of the leading guideline development programmes in the world. SIGN's reputation is based largely on its innovative approach to guideline methodology and the process of constant improvement. Much of this improvement arises from experience gained from working with multidisciplinary groups and seeking practical, but methodologically sound, solutions to problems as they arise.



SIGN is collaborating with other guideline developers, particularly in the UK and Europe, to agree common standards, processes and documentation that will allow the resource-intensive systematic review element of guideline development in future to be shared between national and international initiatives.

SIGN is also looking to use new technologies to deliver guidelines and supporting material in electronic formats. All SIGN guidelines are available on the internet and on a number of NHS Trust Intranets. In October 2000, SIGN published its first CD-ROM, containing all the guidelines published to date. As access to and familiarity with information technology spreads among clinicians, there will also be benefits to be obtained from using intranet-based systems to facilitate the working of guideline development groups.

To this end, SIGN is taking part in a number of Scottish, UK and international initiatives, including:

- the National Electronic Library for Health
- the development of a common guideline appraisal instrument for Europe (the AGREE collaboration)
- a Council of Europe expert group on guideline development
- the US Agency for Health Research and Quality (AHRQ) National Guidelines Clearinghouse.

SIGN is also working closely with the World Health Organisation to support guideline programmes in developing countries and to define a methodology for international guideline development.

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Director
Scottish Intercollegiate Guidelines Network

3 Clinical outcome indicators

Introduction

Scotland has been at the leading edge in the use and publication of clinical outcome indicators as part of the drive to use information to improve the quality of care. The pace of this drive to measure and monitor clinical performance and the outcomes of care has increased in recent years. This report discusses some of these developments, including the work of SIGN on clinical guidelines (see Section 2) and the establishment of the Clinical Standards Board (see Section 6). This section considers the use of national data to support improvements in the quality of care and in particular, the publication of clinical outcome indicators.

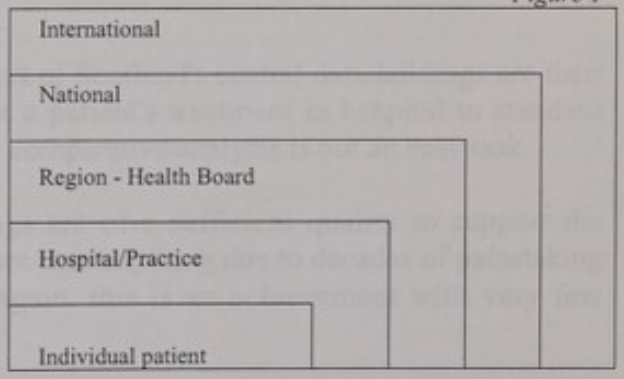
Different information for different purposes

Health care data is needed for a wide range of purposes and to answer many different questions. Inevitably there is a trade off between collecting all the data that might be useful against what is practical and cost effective. Partly as a result of developments in information technology, a great deal of effort is now being devoted to considering how the current data capture systems might be improved.

The primary purpose of data recording in the NHS is to improve the health and aid the treatment of individual patients. The wealth of detailed information recorded for such purposes is held in individual patient case notes and records. Some of this information such as when people are admitted or discharged from hospital and any procedures performed is submitted in the form of standard extracts to the Information and Statistics Division for central collation (see Section 8). In addition, more complex data is often collected to enable clinical audit of specific services (see Section 4).

Over the past 10 years, Scotland has made use of its high quality national health data sets to publish a wide range of clinical indicators. Although the limits of what is possible based on currently available routine hospital discharge data are now being reached, a great deal has been learned which will help inform how clinical information is used in the future. Building on the experience of several pioneering initiatives of the last 10 years, such as the national audits and clinical databases, the next phase will involve collecting and analysing more sensitive data relating to specific conditions. This will allow monitoring, for example, of whether care is being delivered according to the most up-to-date evidence.

Figure 1



The way forward is for clinical activity and clinical outcomes to be monitored using data that is recorded as part of the process of delivering care and fed back as evidence of effectiveness at a range of levels - to the care team, local management and regional clinical networks, and for national and international comparative analysis. Thus, data should be recorded as part of normal clinical practice and then aggregated and used for a range of different purposes.

This approach will require new investment and careful implementation. However, it will improve the quality of the data available at all levels, as well as reducing bureaucracy by minimising the duplication of gathering information for both clinical care and national statistics.

In this way, data which looks at aggregate trends and comparisons such as the clinical outcome indicators will become part of a much wider process, with staff in the NHS in Scotland continuously involved in monitoring and reacting to evidence about their own performance.

Origins

The Clinical Outcomes Working Group was set up by CRAG in 1992 to produce comparative clinical outcome indicators for Scotland (an earlier committee had clarified the desirable characteristics of such indicators). The Group was able to deliver the first clinical outcome indicators relatively quickly because of Scotland's outstanding legacy of high quality national health care data sets:

- in 1993, the first report showed indicators such as mortality within 30 days of admission with stroke at Health Board level[1]
- in 1994, the first indicators at hospital and Trust level were published[2]
- indicators published since 1993 are set out below (see Figure 2)

The basic pattern for Scotland's current configuration of national data sets was laid down in the 1960s. A commitment was made to hold centrally details of all patient admissions to NHSiS hospitals in electronic form, including patient identifiers such as name and date of birth to allow record linkage between different patient admission records. Cancer registration records already held patient identification details and a unique feature of the Scottish initiative was the involvement of the Registrar General for Scotland, which made extracts of death records available for linkage. In this way, there was potential for linkage between hospital admission records (eg to calculate readmission rates) and death records (to calculate mortality rates).

During the 1970s and early 1980s, linkage was carried out primarily as a basis for epidemiological studies. In the late 1980s, it was decided to permanently link Scotland's centrally held data sets to produce summary histories of patient hospital experience and mortality. These patient histories allowed outcome indicators such as hospital survival rates to be calculated. Scotland's centrally held linked health data sets are equalled in very few other places in the world.

The most valuable (but under recognised) aspect of Scotland's central data holdings are their high quality. Condensing the complexities of a patient's treatment in hospital to standard diagnostic and procedural codes that will allow comparative analysis is not an easy task.

The fact that Scotland's national data holdings are of a sufficient quality to support the production of clinical outcome indicators is more than anything due to decades of painstaking work on the part of clinical coding staff. Again, this is an achievement with very few parallels elsewhere in the world.

Clinical outcome indicators 1993-2000

Figure 2

	Clinical outcome indicator	Jun 1993	Dec 1994	Dec 1995	July 1996	Mar 1998	July 1999	Dec 2000
1	Pregnancy under the age of 16		B	B				B
2	Therapeutic abortion rates (▲)		B	B				
3	Childhood incidence of measles		B					
4	Cervical cancer mortality		B	B		B		
5	Suicide rate		B	B			B	
6	Rate of emergency admission for diabetic ketoacidosis		B	B				
7	Longer in-patient stays for children with asthma		B	B				
8	30 day survival after admission for fractured neck of femur	B	T	T			T	
9	Discharge home within 56 days of admission with hip fracture	B	T	T				
10	30 day survival after admission for acute myocardial infarction	B	T	T			T	
11	Re-operation within 1 year of transurethral prostatectomy	B	T	T				
12	Emergency re-admission within 28 days of discharge from medical specialty	B	T	T				
13	30 day survival after admission for stroke		T	T			T	
14	Discharge home within 56 days of admission for stroke		T	T				
15	Psychiatric inpatients: death within 1 year of discharge		H	H				
16	Psychiatric inpatients aged 65+: death within 1 year of discharge		H	H				
17	Psychiatric inpatients: suicide within 1 year of discharge		H	H				
18	Proportion of first births by caesarean section				H			H
19	Vaginal delivery after caesarean section				H			H
20	Babies admitted to a neonatal unit (▲)				H			H
21	28 day emergency re-admission: removal of tonsils/adenoids				T			
22	D & C rates in women under 40				T			T
23	Use of medical methods for early termination of pregnancy				B			B
24	Survival with cancer of the trachea, bronchus and lung				B			
25	Survival with cancer of the large bowel				B			
26	Breast cancer (▲)				B		B	
27	Survival with cancer of the ovary				B			
28	28 day emergency re-admission: elective operation for cataract				T			
29	28 day emergency re-admission: emergency appendectomy				T			
30	28 day emergency re-admission: elective prostatectomy				T			
31	28 day emergency re-admission: elective hysterectomy				T			
32	28 day emergency re-admission: elective total hip replacement				T			
33	Survival with cancer of the stomach					B		
34	Survival with cancer of the cervix uteri					B		
35	Cardiac procedures - standardised procedure ratios for coronary angiography, angioplasty and CABG (▲)					B		
36	Breast feeding (●)							B
37	Smoking during pregnancy (●)							B
38	Registration with general dental practitioner (▲)							B
39	Decayed, Missing and filled teeth in children age 5 years (▲)							B
40	Colorectal cancer (▲)							B
41	Emergency admissions (▲)							B

Level of presentation: B = Health Board; T = Trust; H = Hospital.

▲ - Multiple indicators. ● - Illustrative only. The December 2000 report is in press.

Description and development of the indicators

The indicators are widely varied ranging from:

- true outcome indicators (such as 30 days' survival after admission for heart attack) to process indicators (such as caesarean section rates)
- population indicators (such as teenage pregnancy rates) to specific clinical indicators (such as emergency readmission within 30 days of specific operations such as prostatectomy)

It is not possible here to give a complete technical description of how the indicators are derived and presented, but some general features can be outlined:

- **Time periods**

Even at NHS Trust and Health Board levels, data for a single year for a given condition or procedure may involve relatively small numbers of cases. This would allow random variation to have a significant impact on apparent outcome and so indicators are usually published for periods of 3, or sometimes 5 years.

Earlier reports published data for single 3 year periods. More recent reports have tried to give an idea of trends in outcome by publishing data for successive 3 year periods (see below). Trend data showing rates for single years is available on request and for some of the indicators is distributed as a matter of routine within the NHSiS.

- **Based on linked data**

Many of the indicators are derived from the linked data sets held at ISD Scotland. This allows readmission rates to any NHS hospital in Scotland (not just the initial hospital of treatment) and true 30 days mortality rates (including deaths after discharge as well as in-hospital) to be calculated. The report to be published in December 2000 will contain indicators showing the pattern of patients admitted several times in a five year period across Scotland.

- **Standardisation**

Indicators are standardised for whatever aspects of case mix are appropriate and can be derived from the available data (eg the indicator of survival for 30 days after admission for heart attack is standardised for age, sex and small area deprivation score). It should be emphasised that this is only very crude and partial standardisation for case mix and does not rule out the strong possibility that one hospital may have lower survival than another purely because it admits sicker patients.

- **Confidence intervals**

Indicators are published with 95% confidence intervals to give some indication of the possible effect of random variation (an effect which is greater the smaller the number of patients involved). It is always stressed that the indicators are not published to provide

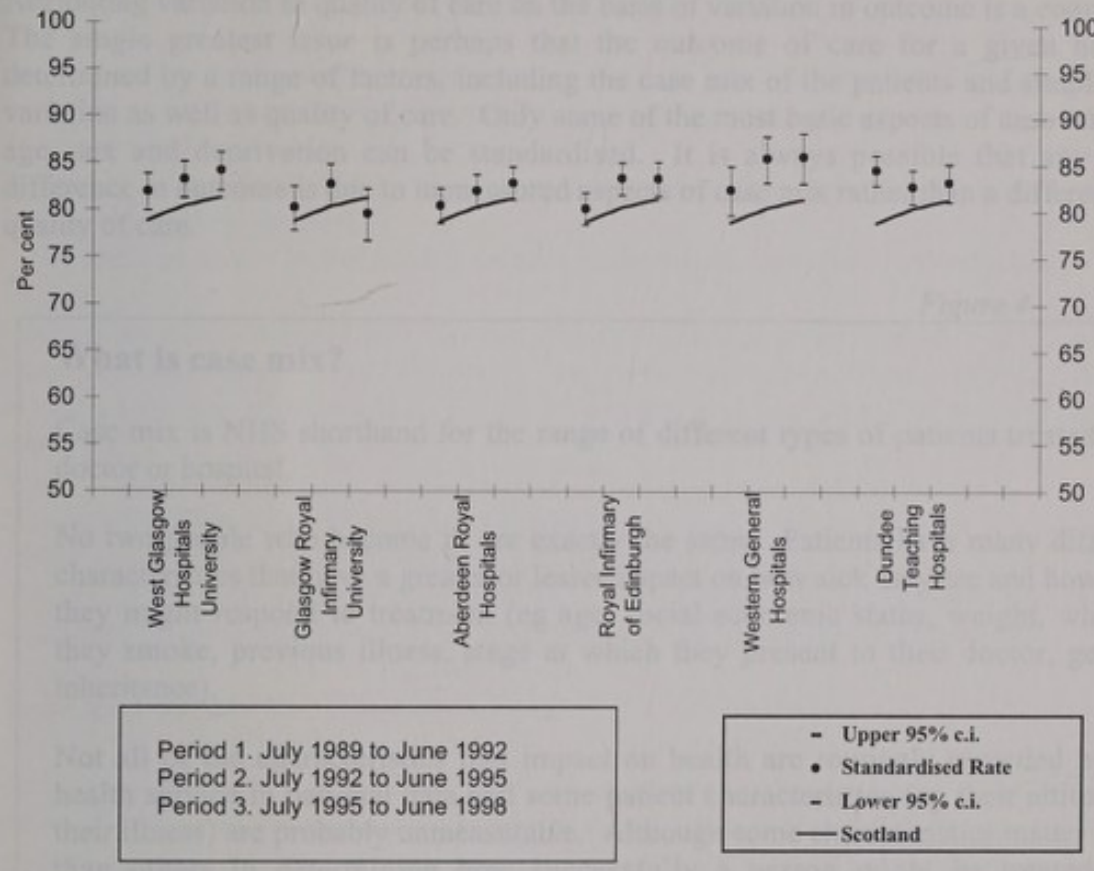
statistical proof of variation in outcome and the confidence intervals do not rigidly divide 'significant' from 'non-significant' results.

Figure 3

AMI: survival for 30 days after emergency admission

Percentage of patients surviving for 30 days following emergency admission with Acute Myocardial Infarction

Teaching Trusts



Clinical Outcome Indicators reports have not been published to a rigid formula or timetable. They reflect a developing and responsive clinical effectiveness agenda. There has been a move towards presenting trend data rather than data for a single period of time and where possible, towards presenting a range of indicators around a given topic rather than just one number:

- the July 1999 Report contained a section on breast cancer with a range of indicators relating to incidence, screening, mortality and survival[3]
- the December 2000 Report will contain a similar section relating to colo-rectal cancer and a section looking at comparative trends in emergency admissions[4].

Purpose of the indicators

Even though the available Scottish data is among the best of its kind in world, it is not a sufficient basis for outcome information that will provide proof, in itself, that the quality of care in one hospital is better than the quality of care in another. Indicators in Scotland have always been seen as contributing one more form of evidence about the quality of health care in the NHS.

Attributing variation in quality of care on the basis of variation in outcome is a complex area. The single greatest issue is perhaps that the outcome of care for a given hospital is determined by a range of factors, including the case mix of the patients and simple random variation as well as quality of care. Only some of the most basic aspects of case mix such as age, sex and deprivation can be standardised. It is always possible that any apparent difference in outcome is due to unmeasured aspects of case mix rather than a difference in the quality of care.

Figure 4

What is case mix?

Case mix is NHS shorthand for the range of different types of patients treated by a doctor or hospital.

No two people who become ill are exactly the same. Patients have many different characteristics that have a greater or lesser impact on how sick they are and how well they might respond to treatment (eg age, social-economic status, weight, whether they smoke, previous illness, stage at which they present to their doctor, genetic inheritance).

Not all of the characteristics that impact on health are routinely recorded by the health service in national data and some patient characteristics (eg their attitude to their illness) are probably unmeasurable. Although some characteristics matter more than others in determining how successfully a person might be treated, the interactions of all the complex factors that make each patient different is not yet fully understood. The ability to calculate how people might be expected to respond to treatment 'on average', still leaves many questions unanswered.

If it was possible to measure accurately the characteristics of the patients it would be possible to statistically adjust outcomes for case mix and so create a 'level playing field'. Then, any variations in the outcome would reflect the quality of the care given rather than the seriousness of the patient's condition or other patient characteristics.

Unfortunately, although adjustments can be made for some things which effect case mix such as patient's age and sex, at present adjustments cannot be made for many aspects of case mix.

Indicators that can now be published reflect other issues that influence the outcome in addition to the impact of the quality of care given.

The indicators have always been published accompanied by a strong 'health warning':

'It is stressed that no direct inferences about quality of care should be drawn from the indicators. They are intended rather to highlight issues which may require further investigation.[5]

The stress on the need for caution was all the more necessary following the decision in 1994 to publish the indicators, rather than distribute them internally in the health service.

The decision was taken only after intense discussion:

- against publication was the fear that it might lead to misuse and misinterpretation of the indicators resulting in potential distress to patients and professionals, or to invalid decisions being taken
- in favour of publication was the need to ensure a free flow of comparative information throughout the NHSiS
- also in favour was a general presumption towards freedom of information

Perhaps the decisive factor was that any system of circulating identifiable but not fully public outcomes information would inevitably lead to partial leaks and scare stories. Publication would allow the information to be put in context and limitations of the indicators to be explained.

Hardly any of the fears relating to publication have been realised. By and large, the Scottish media has been highly responsible in reporting such sensitive material. It could be argued that one of the most valuable contributions of the Scottish clinical indicators was their role in beginning the process of opening up information about effectiveness to the public.

Role and value

Another by-product of publication has been the intense and varied debate about the role and value of outcome indicators. Much more is now known about what they can and cannot do, and this advance has been in large part due to open and informed public debate in Scotland.

Figure 5

Clinical Outcome Indicators: Legitimate Uses do:

- provide useful clues and limited evidence relating to quality of care or performance
- focus attention on variations in outcome which might have remained unsuspected and which may be worth further investigation
- fulfil a 'backstop' monitoring role to highlight potential poor performance
- illustrate past performance that may provide an insight into current practice
- highlight possible examples of good practice
- represent only one component of a comprehensive and concerted effort to provide a high standard of clinical care in the NHSiS

They do not:

- include the patient's views about outcome
- provide definitive proof about performance or quality of care
- constitute a 'league table' of performance
- justify precipitate action in the absence of corroborative evidence

Figure 6

Clinical Outcome Indicators: Benefits and Opportunities

- highlighting operational issues which can be addressed in a straightforward way
- confirming operational problems already suspected on the basis of other information
- encouraging benchmarking to find out why outcomes differ and to identify best practice
- stimulating interest in using and improving the quality of existing data
- spurring further development of new data sources or new measures to overcome perceived inadequacies of current data
- showing the public that quality of care is being monitored

Figure 7

Clinical Outcome Indicators: Limitations and Risks

Limitations of the indicators themselves

- completeness of data and accuracy of coding
- lack of data to adjust sufficiently for differences in case mix
- effects of random or chance variation in patient characteristics
- delay required to provide feedback either because of the need to accumulate sufficient cases, or the need for long-term outcomes (eg 5 year survival times for cancer)
- focus on only one measurable aspect of what is usually a wider spectrum of relevant outcome for a given condition (eg freedom from pain, quality of life)

Risks of inappropriate response to the indicators

- premature and inappropriate action taken on the basis of the indicators without corroborative evidence or further investigation
- manipulation of data to improve apparent outcome
- defensive practice (eg selection of patients to influence apparent outcomes, reluctance to take on difficult cases)
- exclusive focus on fulfilling outcome criteria (eg ensuring patients survive to 30 days regardless of other consideration)
- reinforcing a blame culture rather than a supportive/educational culture
- inappropriate extrapolation (eg an indicator of hip fracture might provide an insight into the work of the orthopaedic unit but would reveal very little about the hospital as a whole)

Use made of the indicators

The indicators provide only one limited form of evidence that there may be an issue to do with quality of care. Their usefulness is entirely dependent on:

- whether the staff concerned take them seriously
- whether the message of the indicators chimes with what is already known or with the results of further investigation
- the ability of staff to do something about any deficiencies of care which are confirmed.

For the first 5 years of their publication, the only generalisation possible about the response to the indicators was its variety: sometimes indifferent or baffled: 'what do we do with them?'

In some instances, the indicators have sparked a formal review process leading to common-sense service changes. In others, they have been the trigger for intensive local audit or involvement in national audit projects. Perhaps most commonly, they have provided reinforcement for a suspicion that something needs to be done about a particular aspect of service provision.

In the first 5 years of publication, requests for updates of the published indicators were relatively uncommon. In the last 6 months that has changed and there are an increasing number of requests for updated indicators. Clinical governance is starting to drive the hunt for evidence.

How informative and useful are the indicators?

There is no doubt that, other things being equal, a hospital with the better outcomes is likely to be providing the better quality of care. But it is not yet known the extent to which 'other things are equal'. It is not yet known precisely how variation in outcome is related to variation in quality of care.

Publication of the indicators has prompted a good deal of debate. Academic publications, attempting to come to a conclusion purely on the basis of the data itself, have tended to be critical. They have argued that there is insufficient data on case mix in the data to enable any definitive conclusions about variation in quality of care to be reached. This largely echoes the 'health warnings' published in the reports themselves.

But a consensus seems to be emerging among people with practical on the ground experience and day-to-day involvement in the delivery of care that outcomes which deviate from the Scottish average often reflect genuine variations in the quality of care.

This contrast would seem to echo what is known about the indicators. In the abstract and in isolation it is very difficult to draw any firm conclusions from them. But combined with local contextual knowledge they can provide useful insights.

Similarly, there is not a great deal of systematic knowledge about how the indicators have been used and how they should best be used. CRAG has funded a Clinical Indicators Support Team (CIST) at ISD Scotland to draw together and disseminate the experience gained in using the indicators.

In the first year, the work will have three main strands:

- statistical validation of the indicators by modelling and linkage to other data sets, including national audits such as the Scottish Hip Fracture Audit. The work aims to give a better understanding of the extent to which variation in outcome can be explained by such factors as case mix or deprivation, or does in fact reflect variation in the quality of care

- a research study investigating the requirements that health boards and trusts have of clinical performance information and the extent to which the clinical outcome indicators meet those needs. A small number of case studies will be carried out to

give an in-depth understanding of the issues, focusing on the clinical indicators as a possible source of information to support clinical governance

- development of a web site-based knowledge base and resource centre. This site will contain regular updates of the work of the team, relevant publications and links to other useful contacts and resources. Users of the site will be encouraged to provide feedback on any aspects of the work of the CIST team and to notify the team of other relevant resources and links. The web site can be found at: http://www.show.scot.nhs.uk/indicators

The CIST team will take a major step forward in understanding precisely what clinical indicators show about variation in quality in the NHS and how they can best be used to improve quality. This work will support the future development and use of clinical outcome indicators but also inform the work of others such as the Clinical Standards Board (see Section 6).

The future

Work is in hand to improve the breadth, quality and timeliness of information available to the Service to allow services to be managed and improved. These improvements will take many forms, most significantly in the information collected and analysed in response to the standards being set and monitored by the Clinical Standards Board.

There will also be changes to the way in which the types of data that already form the basis of Scotland's clinical indicators are fed back to the service. Until now, distribution has primarily been in the form of the published CRAG Clinical Outcome Indicators Reports. In future, these published reports will be supplemented by routine, electronic feedback of performance information. It should soon be possible to provide regular updates of annual trends in outcome indicators on the internet; (allowing Trusts and Health Boards to check the data relating to them before it is put on an entirely public site).

The move towards providing sets of indicators rather than a single indicator for a given condition or area of care will continue. The aim of the indicators is to provide useful evidence and this often comes from different types of complementary information.

Scotland's clinical indicators have tended to focus on acute care. This reflects the fact that data is available in this area. One of the greatest challenges is to extend clinical indicators into primary and community care

The kinds of data that are currently available as a basis for clinical indicators have severe limitations, particularly in terms of detailed information on case mix which would allow more accurate monitoring of quality. One way forward lies with enhancing the standard national data sets with more specialised data relating to specific conditions or types of care, but:

- this information can only be gathered with the full involvement of the staff delivering the care
- this involvement will only happen when the information is seen as useful both in helping to deliver care more effectively and in providing informative feedback about the process and outcome of care.

Several pilots are in hand to develop the best ways of gathering more detailed information, which will be greatly facilitated by the Scottish IM&T strategy for health.

Better data gathered at the point of care will allow a range of feedback loops to be put in place:

- clinical teams will be able to monitor the process and outcome of the care they deliver themselves (eg on a monthly basis)
- regional clinical networks will be able to quickly produce comparative information at the level of clinical teams or individuals
- the current system of national comparative analysis and feedback will become much more timely and sensitive.

Conclusion

The NHSiS will only become as effective as it can be when accurate information is available to alert staff to problems in the delivery of high quality care, and which highlights beacons where the best care is being provided. Scotland has been able to build on its legacy of high quality data sets to take this agenda as far forward as anywhere else in the world.

Clinical governance has provided an even more favourable environment, and the health service is now keen to use whatever information is available as evidence to improve the quality of care.

Much has been achieved in recent years, but measuring and monitoring clinical activity and the outcomes of care is an evolving process and there remains much to do. The Scottish Executive is committed to continuing to improve and extend the information about the quality of care available to NHSiS staff and the public.

The challenge now is to improve the data available for monitoring clinical effectiveness so that monitoring clinical outcomes and reacting to variations in outcome will become a routine part of the day-to-day activities of the NHS in Scotland.

Key points on clinical outcome indicators

- Scotland is among the world leaders in the production and publication of clinical outcome indicators
- since 1994, over 40 clinical indicators have been published across a wide range of clinical conditions and care settings
- this success has been based on Scotland's excellent national information systems
- clinical indicators are an important resource for implementing clinical governance and the drive to improve the quality of care delivered by the NHSiS
- specialist clinical involvement will allow Scotland to lead the way in the next phase of monitoring quality, with detailed information on effectiveness gathered at the point of care fed back quickly, routinely and intelligently to the staff involved
- much has been achieved in measuring and monitoring clinical performance but there remains much to do. The Scottish Executive is committed to continuing to improve and extend the information about the quality of care available to NHSiS staff and the public

Mr D Cline
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Scottish Executive Health Department

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4 Clinical audit

Introduction

Clinical audit is perhaps the best known example of the wider group of clinical effectiveness activities. It may be defined as:

> *'...the systematic and critical analysis of the quality of clinical care. This includes the procedures used for diagnosis and treatment, the associated use of resources and the effect of care on the outcome and quality of life for the patient*[1].

The primary function of clinical audit is to improve patient care by informing healthcare professionals' understanding of their clinical practice. This is usually achieved by setting standards, measuring current performance against those standards, identifying shortfalls and putting in place any necessary action. As standards change, re-audit will become necessary.

Clinical audit is a multi-professional activity that has its origins in medical audit, which was uni-professional and initially involved only doctors. The Clinical Resource and Audit Group was set up in 1989 following publication of the Scottish Working Paper 2 *Implementation of Medical Audit*, which outlined the fundamental principles of medical audit and set out how it would be introduced into the NHS in Scotland. In 1993, audit entered its second stage evolving from uni-professional audit into multi-professional clinical audit.

CRAG has provided a focus for clinical audit work both at national and at local level, issuing guidance to Trusts and Health Boards to support the local application of clinical audit and, subsequently, clinical effectiveness. CRAG does not audit services itself. It sponsors a range or individuals and organisations (such as Royal Colleges, lead Trusts and voluntary agencies) to carry out the work on its behalf.

It is important to distinguish between 'clinical audit' and 'clinical research'. In essence, clinical audit *'...aims to establish the extent to which actual clinical practice compares with best clinical practice. Clinical research aims to establish what is the best clinical practice.'* [2]. Although the two elements are different, it is clearly the case that the one might lead to the other. The outcome of a piece of clinical audit may inform the need for clinical research, and the findings of a piece of clinical research may establish the need to audit clinical practice.

Clinical audit should be seen as a continuous process by which clinical practice and patient care can be improved.

History in Scotland

A brief outline of the history of clinical audit in Scotland is in 'Origins of CRAG' in Section 1. A summary of the key stages in the development of audit includes:

1985 Setting up of the Transfer of Resources Group to examine clinical work by identifying good practice from a clinical and economic standpoint, and disseminating these standards.

1987 First meeting of Clinical Resource Use Group (CRUG) that evolved from the Transfer of Resources Group with an extended membership including chief area medical officers (CAMOs) and clinicians. This was later broadened to include a nurse and a general manager.

1989 Setting up of the Clinical Resource and Audit Group (CRAG). This followed from the White Paper, *Working for Patients* (1989), and the recognition that medical audit could provide an ideal mechanism to secure change. Membership of CRAG was based on that of CRUG with the addition of a postgraduate dean, a regional adviser in general practice and a second nurse. The original remit of CRAG introduced elements of medical audit while maintaining a focus on the effective use of resources.

Those parts of the remit that related specifically to audit were to:

- determine national audit strategy, identify and disseminate good audit practice
- co-ordinate audit practice at national level
- monitor audit training
- receive and scrutinise annual reports of the Area Audit Committees
- consider the need for national and regional studies, external peer reviews, auditing Area Audit Committees
- contribute to the formation of a national register of audit projects.

There was a major drive to implement medical, nursing, dental and pharmaceutical audit and later audit in other professions. CRAG set up four uni-professional audit subcommittees that remained effective until 1992:

- Medical Audit Subcommittee (CRAG-MAS) - December 1989
- Nursing Audit Subcommittee (CRAG-NAS) - October 1990
- Dental Audit Subcommittee (CRAG-DAS) - May 1991
- Pharmaceutical Audit Subcommittee (CRAG-PhAS) - June 1991.

1990 National Projects Committee (NPC) was set up to stimulate and manage a programme of national audit projects.

1993 The National Projects Committee was reconstituted to make the membership more widely representative of the range of interests in the NHSiS. By 1995, over 120 national audit projects had been funded by NPC (which became the Clinical Effectiveness Programmes Sub-group in 1998).

In May, CRAG's publication of The Thomson Report - *The Interface Between Clinical Audit and Management* – led to the development of local audit. The report set out principles for the use of clinical audit, and the roles and responsibilities of health professionals and managers involved in audit. It supported the move to multi-professional clinical audit and recommended the establishment of Area Clinical Audit Committees (ACACs) to oversee the development of audit within Health Boards.

Formation of the Clinical Audit Subcommittee (CRAG-CAS), an amalgamation of CRAG's four uni-professional audit subcommittees.

1994 The Scottish Clinical Audit Resource Centre (SCARC) was set up by CRAG (and based at the University of Glasgow) as a clearing house for information on audit in Scotland. SCARC's remit included education, information and library services, research and development, and support. Details of all local audit projects in Scotland were maintained on a database maintained by SCARC, but funding was discontinued in April 1999.

1995 Development of the Strategic Framework for Clinical Audit in Scotland by CRAG-CAS. The framework document set out to consolidate existing guidance and to complement Boards' local audit strategies. The Implementation Sub-Group replaced CRAG-CAS in 1998.

1998 Internal review of CRAG leading to the establishment of the current structure encompassing:

Clinical Effectiveness Strategy Group (CESG) - set up to provide guidance on the strategic direction of the clinical effectiveness agenda and to improve the co-ordination of the different bodies involved in clinical effectiveness.

Clinical Effectiveness Programmes Subgroup (CEPS) - CRAG's main funding committee with responsibility for developing and supporting new clinical effectiveness programmes and projects in addition to the existing portfolio of national audit projects.

CRAG Implementation Subgroup (CIS) – set up to support the NHSiS in taking forward the clinical effectiveness agenda and promote the output of work sponsored by CRAG, such as clinical guidelines or the findings of national audits.

Funding of clinical audit work

Specific funding for audit was first made available in 1990/91. In the 5 years to March 1995, £26m (including £2m of capital) had been allocated to clinical audit. Two thirds of these funds were allocated to Health Boards for local audit. From 1994/95, funding for audit at local level was included in the general allocations to Health Boards.

Since 1995/96, approximately £2.7m has been allocated each year to support CRAG's work programme. In 1998/99 and 1999/2000, about 60% of the budget was allocated to fund clinical effectiveness projects. Another 30% went to fund clinical guidelines and the CRAG Implementation Subgroup. The remainder is used to support CRAG's other work (eg publications, conferences and committee expenses). The administrative costs of the Secretariat are centrally funded.

Activity levels and range of projects

The range and scope of projects funded through the NPC and more recently through CEPS is extensive, covering a wide range of specialties and disciplines. However, this represents only a small part of the total work that is currently being undertaken in Scotland, with the major part being carried out at local level.

In the early days of audit, the priority was to stimulate interest and involvement in audit. As a result projects funded by NPC tended to be *ad-hoc*, reflecting the interests and needs of the clinicians involved. Since CEPS was set up, the focus has changed towards supporting a number of commissioned programmes concentrating on the national priorities.

These programmes support a range of activity in cancer, CHD and stroke, mental health and children's services. Although, the proposal is to target the majority of funding (currently around 80%) towards these priority areas, CEPS will continue to consider spontaneous applications from all professional groups in Scotland engaged in delivering healthcare services.

Individual projects range greatly in size and scope. Some are tightly focussed on a particular aspect of treatment, for example the Scottish national audit of ECT. Others cover a range of activity under one heading, for example, the Scottish Programme for Clinical Effectiveness in Reproductive Health (SPCERH) and the Scottish Programme for Improving Clinical Effectiveness in Primary Care (SPICE PC).

One of the four complementary roles of SPCERH is to carry out work in the areas of audit and guidelines. SPCERH currently administers the *Confidential Enquiry into Maternal Deaths (CEMD)* and the *Scottish Stillbirth and Infant Death Survey (SSBID)*, both on behalf of the Chief Medical Officer. It also has a commitment to initiate one new topic-based audit each year. Topics covered to date are an *Audit of Pregnancies in Diabetic Women*, an *Audit of Maternity Services in Scotland* and the *Scottish Audit of the Prevention and Management of Emergencies in Labour*.

SPICE PC, led by the Royal College of General Practitioners Scottish Council, aims to assist clinicians in providing effective care and encourage quality improvement in primary care.

In year one, criteria related to quality were developed in seven topics:

- non-insulin dependent diabetes
- continuity of care in mental health
- hypertension
- secondary prevention of ischaemic heart disease following a myocardial infarction
- monitoring of dose critical medication
- management of leg ulcers
- availability.

These identify a baseline measurement from which effective evaluation can be achieved. For further information about SPICE PC, see Section 10.

Current and recently completed projects

Current and recently completed projects can be grouped together in nine broad areas (the number of projects in each area is shown in brackets). Details of current and past projects are available on the CRAG website.

- Cancer (9)
- Children's Services (4)
- Coronary Heart Disease and Stroke (2)
- Diabetes (3)
- Mental Health (3)
- Primary Care (5)
- Renal (2)
- Reproductive Health (1)
- Miscellaneous (6)

In addition, a range of new projects in mental health and children's services is about to begin.

Examples of projects

Cancer - *Scottish Audit of Gastric Oesophageal Cancer*

Aims to:
- identify variations in clinical practice in the investigation and treatment of gastric and oesophageal cancer in Scotland
- identify good and inappropriate practice based on clinical outcomes and identify possible reasons for these
- identify areas which require further investigation.

Expected outcomes are the:
- provision of a population based picture of the management of upper gastro-intestinal cancer in Scotland on which future developments in practice can be based
- start to an ongoing audit of oesophageal and gastric cancer in Scotland to ensure high quality management of these tumour types
- provision of a mechanism via which purchasers can ensure that quality of treatment of upper gastro-intestinal cancer is monitored.

Children's Services - *Early Detection of Surgical Outcome in Cleft Lip and Palate Subjects in Scotland*

Aims to:
- assess the outcome of surgery in children with cleft lip and/or cleft palate
- estimate the potential need for osteotomy surgery in late adolescence by studying standardised models of the child's face taken at age 5 against a recently developed and validated index for the detection of surgical outcome in cleft lip and palate
- improve compliance in the cleft treatment centres in Scotland with the recording of models of the child's face at age 5 in line with national and international recommendations.

Models at age 5 will be those currently available to The Scottish Association for Cleft Lip and Palate (SCALP).

Coronary Heart Disease and Stroke - *Scottish Audit of Carotid Endarterectomy*

Aims to:

- determine the appropriateness of the management of patients undergoing carotid endarterectomy, in terms of patient selection for surgery, whether patients receive preoperative neurological assessment and appropriate investigations, and the time delays from referral to surgery
- compare hospital outcomes in terms of cerebro and cardiovascular events, local complications and deaths
- determine and compare risk adjusted in hospital outcomes
- determine crude and risk adjusted longer term outcomes in terms of re-operation and death through linkage with SMR1 and GRO data

Diabetes - *Clinical Evaluation of Diabetes Care: Use of Innovative IT*

Aims to:

- develop a dynamic and user friendly district diabetes information system

In Tayside and Forth Valley, the grant holders will integrate the hospital-based diabetes systems with dedicated general practice information transfer systems using optical character reader (OCR) technology.

In Lanarkshire, the hospital-based Lanarkshire system will be integrated with general practices using a mixture of paper proformas and electronic data capture to create an efficient register and recall system.

The project will audit the components of locally derived diabetes data set (SIGN 25) before and after the implementation of general practice information transfer system, with comparison between the three regions.

Mental Health - *National Audit of Electroconvulsive Therapy*

Aims were to:

- describe the population receiving ECT in Scotland in terms of age, social class and ethnic origin
- determine which diagnostic groups receive ECT
- describe the practice of ECT in terms of frequency, number of treatments and equipment used
- audit the effectiveness of ECT in the clinical settings utilising standardised outcome measures
- audit ECT in respect of legal and clinical guidelines

Primary Care – *Scottish Leg Ulcer Project*

Aim is to:

- improve leg ulcer care in Scotland

It is a randomised control trial designed to compare the benefits of SIGN guidelines with SIGN guidelines reinforced by a formal structured training programme.

Renal - *Improving the Management of End-Stage Renal Disease*

Aims are to:

- evaluate patient survival and the ability to achieve recommended standards in a one year cohort of new RRT patients in Scotland
- study the influence of co-morbidity on the achievement of these targets

Standards that have an influence on survival and quality of life will be identified and the implementation of changes in practice to achieve them will be discussed with all nephrologists in Scotland. The standards will then be re-measured, in the light of changes made, completing the quality cycle.

Reproductive Health - *Scottish Programme for Clinical Effectiveness in Reproductive Health*

Aims to:

- promote the delivery of clinically effective and evidence-based care in routine clinical practice to ensure ongoing improvements in reproductive health

For further details see above.

Miscellaneous - *Development of Quality Assurance and Audit Systems of ICU in Scotland*

Aims to:

- further develop QA and audit of intensive care units in Scotland
- make the programme suitable for incorporation into overall NHSiS quality assurance arrangements, with data collection based on a minimum core dataset from the CSA's Information and Statistics Division

The objectives and action plan to undertake this work are set out in the SICS Audit Group paper dated February 1999 and will form the basis for monitoring progress.

A number of new projects in the fields of coronary heart disease and stroke, osteoporosis, mental health and children's services will come on stream during the next few months.

Local and national examples

One of CRAG's roles is to review the development of local audit and to do this, each local area is asked to produce an annual report. As audit developed to become a strand of clinical effectiveness, Health Boards were asked to extend their audit activity reports to become

clinical effectiveness reports. CRAG also visits a range of Health Board areas to assess progress against clinical effectiveness goals which are set annually.

Clinical effectiveness reports from different Health Board areas in Scotland vary widely, reflecting the different structures and systems in place and local challenges. Reports generally include an assessment of performance against CRAG goals and a summary of (largely) audit work undertaken in the area during the previous 12 months.

In October 1999, CIS issued new goals for the NHSiS (*Figure 1*), taking account of the impact of clinical governance and changes in the support available for clinical quality improvement.

Goals for 1999/00 onwards take a more strategic view of clinical effectiveness, setting the required direction of travel but leaving operational details to individual Health Boards and Trusts. These new goals were distributed with accompanying guidance notes to the NHS under MEL (1999) 76. The goals provide a template to guide and monitor the development of clinical effectiveness in Scotland.

CIS also considered whether the previous approach to clinical effectiveness visits was appropriate given the reconfiguration of Trusts, the setting up of the Clinical Standards Board for Scotland, and the new focus on clinical governance.

CRAG recognised the benefits of wide consultation with the service over its needs for support in clinical effectiveness, and for following up issues identified in Clinical Effectiveness Reports. It also provided an opportunity to reinforce the new strategic direction of CRAG in general and the clinical effectiveness goals specifically.

Although visits require significant input from both the visiting team and the people being visited, CIS decided that the visits were a valuable opportunity to listen and learn about work at local level, and visited all 15 Health Boards during 1999/00.

A report based on this series of visits is available on the CRAG website. Although the visits highlighted a number of issues that need to be addressed, there was evidence of good and interesting work on clinical effectiveness from every Health Board area.

Figure 1

Goals for clinical effectiveness

These goals are relevant to the whole of the NHS in Scotland. They should be interpreted as applying to primary care, community services, acute hospitals, Health Boards and centrally funded services. To avoid repetition, the goals refer only to 'Trusts'.

- Trusts should have an explicit strategy for clinical effectiveness, which should be part of a broader quality and clinical governance strategy. Organisational arrangements and mechanisms for the systematic monitoring and improvement of the quality of clinical care should be in place.
- Trusts should have an appropriate infrastructure to support clinical audit and clinical effectiveness, and be able to provide evidence of:
    a) systems to monitor clinical effectiveness activity (including clinical audit)
    b) mechanisms to assess and implement relevant clinical guidelines
    c) systems to disseminate relevant information
    d) an IM&T strategy that supports clinical effectiveness
- Trusts should foster a culture in which clinical effectiveness is integral to all clinical care. Developing clinical effectiveness skills should be central to continuing professional education and development, and part of a multidisciplinary systematic approach to continuous quality improvement.
- Clinical effectiveness activities should support priority setting and reflect:
    a) national priority areas identified in Priorities and Planning Guidance
    b) local priorities identified in the Health Improvement Plan
- Trusts should make sure that all operational sub-units have identified programmes of clinical effectiveness activity.
- Trusts should promote clinical effectiveness activities that cross boundaries and support collaboration within and between Primary Care Trusts, Acute Trusts, emerging managed clinical networks and other agencies.
- Trusts should be able to demonstrate an increase in public/patient participation in:
    a) service planning and standard setting
    b) monitoring the quality of care
- Trusts should be able to demonstrate that cost effectiveness issues are being addressed alongside clinical effectiveness.
- Clinical effectiveness should be a prominent feature of the HIP/TIP process - informing commissioning and underpinning service development.
- Trusts should be able to demonstrate that clinical effectiveness activities are:
    a) informing clinical governance
    b) leading to changes in practice and improvements in standards of care
    c) providing best value

September 1999

National audits

One of CRAG's roles is to nurture and develop national systems to audit care. A number of these audits provide a detailed 'snapshot' of a service, allowing problems to be identified and improvements made. In some cases, a decision is taken to maintain the audit over the long term. Four of the audits which were judged to be of national importance were transferred from CRAG to ISD:

- Scottish Hip Fracture Audit
- Scottish Audit of Surgical Mortality
- Scottish Trauma Audit Group
- Scottish Renal Registry.

Scottish Hip Fracture Audit

- set up in 1993/94 – four centres CRAG funded
- locally funded expansion in 1994-99
- all now locally funded
- covers 18 out of 25 orthopaedic units
- audit nurses employed to collect standard data sets and conduct follow-up
- documents hip fracture care in terms of case mix, surgical procedures and complications
- outcomes including mobility, dependency, residential status and mortality
- promotes and evaluates service developments
- links with standardisation of audit of hip fracture in Europe

Feedback is provided:

- six-monthly, in the form of reports to centres
- via ad-hoc reports on specific issues
- in reports to CRAG (four to date)

Scottish Audit of Surgical Mortality

- set up in 1994
- administered from offices in Aberdeen, Dundee, Edinburgh and Glasgow
- covers all surgical specialties, except thoracic, cardiac and obstetric (covered by UK-wide national mortality audits) and almost all consultant surgeons and anaesthetists in Scotland
- identifies all deaths which occur under the care of a surgeon, whether or not there has been an operation
- approximately 4,500 deaths are identified annually

Feedback is provided:

- to individual consultants, on cases they have dealt with where adverse factors in management have been identified
- to all consultants and trainees (anonymised, collated case note assessments received at intervals)
- at hospital or specialty level on request, comparing the selected area with the total data set. This is an area of activity currently being expanded and is seen as a service to Trusts in support of their Clinical Governance responsibilities
- in an annual report highlighting important lessons

Scottish Trauma Audit Group

- set up 1991
- seven centrally funded staff and 25 local co-ordinators funded by health boards
- covers all injured patients admitted to hospital for three days or more or who die
- approximately 7,500 new cases added to database each year
- excludes patients over 65 with an isolated fracture of the neck of femur and/or public ramus
- covers Scottish ambulance service, blood transfusion service, general/orthopaedic/vascular/ cardiothoracic/neuro surgery, intensive care, anaesthetics, radiology and forensic medicine

Feedback is provided:

- daily to medical and nursing staff
- monthly feedback of national standards to A&E consultants
- six-monthly routine analysis to local medical directors
- annually to each Director of Public Health
- three times a year to meetings of regional multi-specialty groups
- national conference every 18 months
- via ad-hoc reports to CMO

Scottish Renal Registry

- collects, collates, analyses and reports on data relevant to improving renal services for patients on renal replacement therapy
- covers all centres and all patients receiving renal replacement therapy for chronic renal failure
- data extracted from the primary clinical record
- patients followed up until death
- based at Royal Infirmary, Glasgow

Feedback is provided:

- to each renal unit showing their performance in relation to the whole country, other renal units and targets, where available
- anonymised results discussed at annual Scottish Renal Association meeting

Annual symposia

Since 1990, CRAG has hosted an annual symposium on clinical audit (and more recently clinical effectiveness) to provide feedback to the Health Service about work being carried out in Scotland.

In the early years, the symposia featured a broad and sometimes eclectic range of examples of work. Presentations included Barium enema audit (1993), Neuroleptic audit in learning disability (1994), Audit of prophylaxis against venous thromboembolism (1996), Play preparation obviating the need for general anaesthesia in children having MRI scans (1997), Time Delay in Fast Track MI – A Nurse Led Audit (1998).

As audit has became more firmly established and the annual meetings increasingly popular, the events have been extended to include themed parallel sessions to allow delegates to hear a

series of presentations around specific topics. In 1999 these included cancer, coronary heart disease, mental health and primary care.

The CRAG meetings have provided an opportunity for people working in audit to present details of their work to a national audience. These symposia have become an important feature of the annual calendar of the NHS, allowing an exchange of information and experiences among a diverse group of people. Approximately 400 people from a wide range of geographical and specialty areas attended the 10th CRAG symposium in December 1999

Exit strategies

Initially, the focus of CRAG's work was to encourage the uptake of audit and evidence-based medicine. But as mentioned in Section 1, although audit was considered essential it was often '...difficult to demonstrate direct benefit for patients or action following audit and other related activities.'[3]

To address this, greater emphasis is now being placed on developing 'exit strategies' for all CRAG-funded projects. Essentially, an exit strategy is the means by which the project findings are systematically disseminated, put into practice, incorporated into service provision or followed up (possibly through re-audit).

Clearly, if a piece of work has shown that, for example, following a set of guidelines on management of patients with a specific condition improves patient outcomes, then the following of these guidelines should become standard practice. This will not happen unless a proactive approach is taken to passing on and incorporating the knowledge that has been gained.

All projects funded by CEPS must address their proposed exit strategies at the outset to be considered for funding. Although it is recognised that the exact nature of the exit strategy may evolve over the course of the project, it is important to consider possible alternatives early on and to plan ahead. The publication of a report is unlikely to impact on clinical practice unless there is some form of positive interaction with those at whom the report is aimed.

The future

The need to measure and evaluate clinical activity against standards, and to revise those standards and re-evaluate the care provided in the face of new evidence, treatments and techniques will ensure that clinical audit retains a central role in the wider arena of clinical effectiveness.

Sharing information on audit activities, whether carried out locally or nationally, is important to allow people in or across professional groups to learn from each other. CRAG will continue to hold national meetings, including an annual symposium, to provide the opportunity for people involved in clinical audit and wider clinical effectiveness issues to meet and discuss their work.

Key summary

- the primary aim of clinical audit is to improve patient care
- clinical audit aims to assess how actual clinical practice compares with best clinical practice, measuring and monitoring performance against standards
- clinical audit is an intrinsic part of the wider clinical effectiveness agenda
- clinical audit should increasingly become an accepted part of everyday work for all health care professionals

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5 Health related research in Scotland

Introduction

The Chief Scientist Office (CSO) was set up more than 25 years ago, and now has an annual research budget of £41m. CSO is responsible for encouraging and supporting research to improve both the health of the people in Scotland and the services provided by the NHS in Scotland.

CSO has a leading role in establishing the evidence base for health care and its delivery, and much of the work it funds is incorporated into the development of practice within the NHSiS.

It takes part in a very broad spectrum of research activities across a diverse range of clinical topics and engages with the academic, research, research funder, policy, and practitioner communities in a variety of ways (summarised below). Further details can be found at www.show.scot.nhs.uk/cso, in CSO's annual reports and newsletters, and in *Research Strategy for the National Health Service in Scotland*, revised in July 1998.

CSO is also the sponsoring body for the Scottish Hospitals Endowment Research Trust (SHERT), set up in 1954 under the terms of the Hospital Endowments (Scotland) Act 1953. This Act empowered the Hospital Endowments Commission to provide SHERT with funds from the endowments of former voluntary hospitals that had been transferred to hospital management boards in accordance with Section 7 of the National Health Service (Scotland) Act 1947. The research fund complements the funding activities of CSO.

Strategic direction of research

The *Research Strategy for the NHS in Scotland* sets out current research priorities for CSO and sets these in the context of the clinical priorities for the NHS. There is also a strong focus on the public health agenda.

The Chief Scientist Committee oversees the overall strategic direction of the work of CSO. Members include the Chief Medical Officer, Chief Nursing Officer, representatives of the NHSiS, the research community, the Medical Research Council (MRC), and the Association of Medical Research Charities. The Scottish Association of Health Councils provides a lay perspective. It is important to co-ordinate research activity with the wider work of the Scottish Executive Health Department and CSO is represented on the CRAG Clinical Effectiveness Strategy Group by both the Chief Scientist and Director.

Increasingly, a culture of research awareness, activity and uptake is evolving and the importance of research for the future development of health and healthcare is now more widely appreciated. Inevitably, our research focus remains more towards the applied or strategic, rather than the basic or fundamental, end of the research spectrum. CSO deliberately seeks to fund studies that are close to application.

CSO not only sponsors research but commissions work in specific areas to ensure a broad portfolio, able to meet the needs of patients and address gaps in our knowledge. Scotland has a strong tradition of research in health care and many of its scientists are at the forefront of

pioneering new developments in this field. It is essential that our funding activity allows this tradition to flourish.

It is increasingly important that all the various professions involved in providing care address complex questions. Research in primary care is a priority across the full range of funding activities and the Support Fund has particularly sought to encourage multi-disciplinary research. Similarly, the Nursing Research Initiative for Scotland was set up in 1994 to encourage non-medical clinical staff to become more actively involved in research.

The current imbalance between the volume of clinical work in primary care and the relative paucity of research evidence has led CSO to assign a particular priority to research in this area. We have developed a range of schemes since 1996 that include: the Primary Care Research Fund; the Research Practice Scheme; and Primary Care Research Networks. CSO is also the major funder of the Scottish School of Primary Care, which aims to bring together multi-professional research teams and 'build capacity' in primary care to increase the evidence base for key clinical issues.

CSO has supported research through three principal mechanisms:

- research units
- grants to individuals and teams
- the NHS R&D Support Fund.

These are currently under review but CSO will continue to support a broad spectrum of work from small projects through to major programmes in priority topics. It must also remain a priority to seek to identify gaps in knowledge and gaps in the skills base.

CSO seeks to address both of these through targeted commissioning of research and a range of research training opportunities, often funded jointly with others such as the Medical Research Council (MRC) and the Scottish Council for Postgraduate Medical and Dental Education (SCPMDE). Both schemes contribute significantly to clinical effectiveness.

Support Fund

The Support Fund was set up in 1998 to meet the costs to the NHSiS of research conducted within it. The Fund is now some £30m. Many of these costs had been met less explicitly from the Associated Costs of Teaching (Research) allocation to teaching boards. A more open allocation mechanism was introduced in 1997 and 28 awards were made, ranging from £5k to almost £5m. Trust amalgamations have led to the largest allocation now being worth over £8m.

The Support Fund has done much to raise awareness of research activity within Trusts and primary care. It has also led to greater recognition of the extent to which research opportunities can help with recruitment, motivation and retention of talented clinical staff. The evidence that centres with a strong tradition of conducting research have better outcomes for their patients also cannot be ignored.

Support funding is used to:

- meet certain costs incurred by providers in supporting non-commercial R&D activity paid for by funders external to the NHSiS (eg Research Councils and Charities)
- support, carry out or commission R&D of direct interest to the NHSiS
- meet the costs of their contribution to the infrastructure and environment in which health and health services R&D can flourish and be well managed
- contribute to the development of the capacity of the NHSiS to identify needs for health and health services R&D
- contribute to the dissemination of the findings of R&D
- contribute to the development and evaluation of techniques for implementing the results of R&D.

Funding is allocated to providers based on applications covering their R&D activities and costs as a whole.

Between 33%-50% of all support funding goes towards non-commercial research that is funded from another source (typically by the MRC, Department of Health, charity or other body). An example of this type of financial support is the Wellcome Trust Clinical Research Facility located largely in the Western General Hospital, Edinburgh. This new £4m unit, dedicated to facilitating clinical research, will provide an optimum environment for the conduct and augmentation of research training in a practical environment.

Wellcome Trust Clinical Research Facility

The primary aims of the new facility are to:

- promote excellence in clinical research
- provide the resources necessary to conduct high quality clinical research
- provide a clinical research infrastructure, available to all clinical investigators with high quality research proposals

CSO plays an integral part in supporting this important development of patient-focussed clinical research in Scotland by contributing to the running costs of the facility.

More generally, a significant proportion of the Support Fund is used to support and undertake research in line with health service priorities. In the 1999-2000 financial year, 57% of expenditure was in support of the priority areas of cancer, mental health, CVD/stroke and public health.

In February 2000, a review group was set up to:

- examine how the allocation system for the Support Fund might be altered to take greater account of NHSiS and other research priorities
- ensure that research quality objectives are more effectively delivered
- make recommendations on how to achieve that flexibility and responsiveness to emerging research priorities.

A consultation paper was circulated in July 2000, and recommendations will be made after the consultation period is complete.

Capacity building: core funded units

It is important that a broad range of research skills and expertise are available to tackle the complex questions that arise in health care. CSO has funded research units from an early stage in its own existence, since they are important contributors to the skills base in their subject. They are also key contributors to the evidence base in their topics.

Units have been supported to meet specific national need, usually reflecting topics important to the NHSiS that were not well covered by the academic community. Such units are reviewed by a visiting group of senior peers at three to five year intervals. They must satisfy the group that the work is of excellent quality and remains of sufficient priority to justify continued support.

Two of our current seven units are co-funded by the MRC and the Health Education Board for Scotland (HEBS) supports a third. All units seek to develop strong links with both the relevant international research community and with local practitioners and policy makers to ensure relevance and topicality. Many units now have an international reputation for excellence.

The seven CSO core funded Units are:

- Health Economics Research Unit, University of Aberdeen (1977)
- MRC Institute for Hearing Research, Scottish Section, University of Glasgow (1978)
- Dental Health Services Research Unit, University of Dundee (1979)
- Research Unit for Health, Behaviour and Change, University of Edinburgh (1983)
- Health Services Research Unit, University of Aberdeen (1987)
- Nursing Research Initiative for Scotland, Universities of Glasgow Caledonian and Stirling (1994)
- MRC Social and Public Health Sciences Unit, University of Glasgow (1998).

CSO invests between £300k and £600k per annum in each of its units. This funding covers research salaries, overheads, and an allowance for travel and other consumables. The funding does not cover direct research costs (eg for fieldwork): the expectation is that units will acquire other external funding based on the CSO investment.

Health Services Research Unit

The Health Services Research Unit aims to improve effectiveness and efficiency in the NHSiS by undertaking and supporting research, working for the implementation of proven change and training health care professionals. The work is focussed within four programmes:

- health care assessment
- mental health research
- effective professional practice
- participation in health care

Health care assessment programme

There is a substantial body of work in the programme on the evaluation of new approaches to surgery, including multi-centre trials of laparoscopic inguinal hernia repair, groin hernia repair and laparoscopic oesophageal reflux surgery.

There is also a body of work associated with orthopaedic trials concentrating on sophisticated imaging in low back pain management, management for the displaced intracapsular hip fractures, a trial of Vitamin D and calcium for secondary fracture prevention and a trial of different types of knee prosthesis.

The Unit also has a leading role in systematic reviews related to incontinence, and undertakes substantial methodological work for example on describing learning curve effects of new technologies.

Mental health programme

The programme is organised around three main themes:

- description of current service provision and practice
- the prevalence, nature, impacts and recognition of mental health problems
- evaluations of differing approaches to the management of mental health problems

Recent projects include studies of *Counselling in General Practice*, *Eating Disorder Services*, *Schizophrenia and Substance Use in Scotland*, *Seasonal Affective Disorder in Primary Care* and *Improving Discharge Procedures*.

Effective professional practice programme

The programme includes four areas of activity:

- systematic reviews of interventions to promote effective professional practice
- rigorous studies of dissemination and implementation activities
- methodological research
- support of service developments (eg methodological support of SIGN and other national initiatives)

This is the largest programme of implementation research in the UK and includes a number of international collaborations. The results should inform health care professionals and policy makers about appropriate methods to promote the uptake of research findings.

Participation in health care programme

The programme is concerned with improving information provision and enhancing patient participation in decision making. There are four main strands:

- improving information for patients
- conceptualising and measuring participation
- evaluating interventions to enhance communication
- participation and external links

MRC Social and Public Health Sciences Unit

The Unit was set up in 1998 through a merger of the MRC Medical Sociology Unit and the CSO-funded Public Health Research Unit. It is one of two CSO Units with a primary focus on public health (the other is RUHBC). Both units are making a key contribution to developing the evidence base for public health policy in the light of the White Paper's stress on tackling inequalities through action on life circumstances and lifestyles, as well as on key health topics such as cancer, CHD and mental health. CSO funds two programmes of work at SPHSU.

One is to develop and apply methods of assessing the impact of non-health sector interventions on health. Health impact assessment (HIA) is seen as one of the key tools for ensuring that all parts of government understand and take account of the effect of their policies and interventions on health. Methods for conducting precise, reliable HIAs remain to be developed, and work is in progress at SPHSU to distil the lessons from past HIAs and related forms of policy appraisal.

The second strand is concerned with developing and applying methods for measuring variations in health and the determinants of health. For example, it will explore the relative importance of individual and higher level factors (eg household, neighbourhood or region) in determining health. That will help to answer questions about the appropriate level at which interventions should be targeted.

Capacity building: other

CSO has run a variety of training schemes to help increase the research skills of people working in health care in Scotland, but the schemes have not always been well taken up. Increasingly, CSO is managing or co-ordinating these schemes more closely and is seeking to develop longer term relationships with the people involved.

This year, CSO has launched (or re-launched) three complementary schemes that should:

- show what the demand is for these kind of initiatives
- how CSO can best serve that demand
- what types of scheme bring most rewards in meeting CSO's overall objectives and providing benefits to the NHSiS.

Postgraduate studentships

These are intended to give graduates in relevant disciplines the opportunity to complete a higher degree in an area of research relevant to the needs of the NHSiS. Staff in higher education institutions are required to submit a proposal for a research project, and to outline the supervision and training arrangements that will be put in place once the individual is appointed.

Research training fellowships

In March 2000, CSO advertised a new flexible scheme open to all health service professionals working in primary, secondary or community care, and all health services researchers. Awards are for a minimum of one year and a maximum of three years, and may be undertaken on either a full time or a part time basis. The scheme is aimed primarily at people who have only a small amount of research experience, and comprises a training programme (which may or may not lead to a formal qualification) and an original piece of research.

Clinical research fellowships

SCPMDE and CSO together have launched a scheme to create six fellowships for doctors and dentists in training. During the first 6 months of the 2 year fellowships, candidates will formulate a full research proposal. A decision will then be made about whether the research is suitable for funding under the CSO small grant scheme. If it is, the second year will be spent undertaking the research, with the cost met by CSO. Salary costs for the research fellows will be met by SCPMDE.

Another innovation is a visiting research fellowship scheme, first advertised in Spring 2000. A number of strong applications were received and the first fellow arrived in October. The scheme is intended to encourage experienced researchers from outside Scotland to bring their expertise to priority public health topics, both by conducting a research project and by developing links with policy-makers, practitioners and researchers in Scotland. It is intended that at least two further rounds of applications will be held.

Each of these schemes will be reviewed and adjustments will be made in the light of experience.

Response mode grants

All CSO funding activity is subject to peer review, and all proposals are shared with policy and other colleagues to comment on relevance. There is currently lay input to proposals on health services research. All project grants awarded have also been peer-reviewed by a CSO advisory committee of senior researchers representing a wide range of professional backgrounds and a great depth and breadth of research expertise.

CSO has two main grants advisory committees, for health services research and biomedical and therapeutics research. Both these areas are defined very broadly:

- health services research covers all research activity associated with health technology assessment, public health, primary care, health care for people with disabilities, health economics, and continuing health care, as well as a range of methodological projects
- biomedical and therapeutics research covers all aspects of clinical and laboratory based research that is relevant to the health of individuals and NHS patients; much recent focus has been in molecular biology and genetics.

A small grant of up to £15k (plus indirect costs) is available for small studies and pilot projects that will take less than a year to complete. A full grant of up to £125k (plus indirect costs) is available for large scale projects taking up to three years to complete.

Large grants are administered through CSO's two main grants advisory committees. At any one time, there are about 90 projects ongoing for each of the two areas, and total expenditure is between £2.5m-£3m a year for each of the two committees.

The projects that are funded are extremely diverse. They lead to a broad portfolio of research activity which covers all the main policy priorities, but which also has room for research on less well developed areas.

Health services research projects include:

- a comparison of delivery methods of cognitive behavioural therapy for panic disorder
- determinants of poor compliance with medication among children
- developing links between primary care and regional cancer genetics services
- randomised controlled trial of low dose aspirin in the prevention of cardiovascular events and death in subjects with asympomatic atherosclerosis
- end of life decision making and elderly patients: the thinking and practices of doctors and nurses
- effect of anaesthetic type and method of repair on patient recovery following primary inguinal hernioplasty
- assessing the impact of trends in maternal age on maternity services in Scotland
- audit-based simulation of hip fracture care to explore major policy options, responses to demographic change and impact of generalisation of best practice guidelines
- the parents' perspective on withholding and withdrawing treatment from neonates.

Examples of biomedical and therapeutics research projects include:

- a pilot study of dose requirements, safety and efficacy of intra-tumoral injection into secondary melanoma of genetically modified herpes simplex virus
- Scottish BRCA1 and BRCA2 founder mutations and modification of genetic cancer risk
- molecular studies of the anti-tumour effect of NSAIDS in colorectal cancer: implications for cancer therapy and prevention
- is the first presentation with a non-cardiac vascular episode an ideal opportunity to detect asymptomatic but treatable left ventricular systolic dysfunction?
- development of a method of quantifying lesion volume and density on scans of patients with lesions
- molecular cytogenetic mapping of the breakpoints of chromosome abnormalities associated with schizophrenia
- carriage of hypervirulent meningococci before and after introduction of Serogroup C conjugate polysaccharide vaccine in the UK
- the role of IL-15 receptor in clinical inflammatory cynovitis
- clinical trial of human pancreatic islet cell transplantation.

Projects are assessed on a range of criteria including relevance and importance of the problem, feasibility of study design, competence of research team, quality of dissemination plans etc.

Commissioned research

CSO, in collaboration with policy colleagues, commissions research to answer specific policy questions. CSO also works in an advisory capacity to colleagues in policy departments who hold their own research budgets but need advice as to how best to organise any tendering or research management process. Recent examples include a literature review to support the Chief Nursing Officer's Review of Public Health Nursing, and the evaluation of the three new demonstration projects announced in the Public Health White Paper.

Examples of ongoing commissioned initiatives include:

- Scottish Cancer Therapy Network
- Primary Care
- Mental Health
- Coronary Heart Disease
- Public Health: Impact of Diet and Nutrition.

The Cardiovascular and Cerebrovascular Initiative

Three projects were supported (only the first has completed):

- the *SCAN* project is a feasibility study to identify and evaluate the costs and benefits of providing a system of coronary heart disease (CHD) monitoring. This work has now reported, revealing that current systems for monitoring CHD in Scotland are not optimal. The system based on MONICA (Monitoring in Cardiovascular Disease) had the most benefits in terms of providing good mortality and hospital data plus population trend data covering disease incidence and prevalence and risk factors.

- *A Randomised Controlled Trial of a Work-book Based Intervention for Stroke Patients: Effects on Disability and Distress in Patients and Partners*. The workbook is a manual that is aimed at reducing disability and distress in stroke patients. It also has sections that may benefit carers and patients. Using the workbook intervention, health outcomes in terms of disability, distress and satisfaction are examined and compared with normal care 6 months after discharge from hospital. This project will report in 2001.

- *The True Incidence, Costs, Health Outcomes and Prognosis of Stroke patients in the Borders of Scotland: A Prospective Study*. This project has been extended for further year to enable more patients to be recruited and a longer period of follow up. It is already apparent that the incidence of stroke in the Scottish Borders is much higher than expected, a finding that may have significant implications for resource allocation. The comprehensive database will provide an invaluable baseline for monitoring the impact of any designed health care initiatives. Completion is expected in 2001.

CSO relationship with CRAG

There is a clear meeting of interests between CSO and CRAG in building the evidence base, and developing protocols and mechanisms to deliver clinical effectiveness. CSO and CRAG have developed a sophisticated understanding about the relationship between research (which is primarily concerned with establishing the evidence base) and audit (which is primarily concerned with the extent to which current practice meets an established standard).

Many projects can be described as 'audit plus', and in these cases, CSO and CRAG are involved in joint funding.

Examples of jointly funded projects include:

- *Turning General Practice Data into Useful Knowledge – a Randomised Controlled Trial of Two Strategies of Feedback to Improve Management of Elderly Hypersensitives Using Computerised Data*
- *Audit-based Simulation of Hip Fracture to Explore Major Policy options, Responses to Demographic Change and Impact of Generalisation of Best Practice Guidelines*
- *A Randomised Controlled Trial of Two Strategies to Improve Adoption of SIGN Guideline on Leg Ulcers.*

CSO's experience of managing research projects, and in conducting reviews of core funded units has been invaluable to CRAG as it developed procedures for managing external commissions.

The future

CSO is currently consulting widely about the best reconfiguration of its funding activities, but aims to focus more explicitly on priority topics while continuing to support a broad portfolio of work relevant to the general needs of the people of Scotland and the NHSiS. An exercise to determine future research priorities in mental health is also under way.

CSO will continue to offer a range of funding mechanisms from those designed to encourage inexperienced researchers through to larger awards to experienced teams. It will also soon be releasing a consultation document on research governance that aims to clarify the expectations of researchers funded by CSO. In future, all recipients will need to comply with these standards. The consultation document is available at www.show.scot.nhs.uk/cso

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6 A national system of quality assurance

Introduction

The Clinical Standards Board for Scotland (CSBS) was established as a Special Health Board in April 1999. Its origins lie in Chapter 8 of the report of the Acute Services Review published in June 1998. It recommended the development of a national system of quality assurance and accreditation of clinical services designed to promote public confidence in the NHS in Scotland. The CSBS will, in partnership with healthcare professionals and members of the public, define standards for clinical services and assess performance throughout the NHSiS against these standards. The standards it adopts will be related to patients' experience as they move through different parts of the NHSiS.

Interface with other organisations

Setting up the CSBS is one of a number of initiatives taken to promote the quality of clinical care. It builds on foundations that have been well established by organisations such as the Clinical Resource and Audit Group (CRAG) and the Scottish Intercollegiate Guidelines Network (SIGN). It will complement other initiatives that have been taken, particularly the duty of the board of each NHS body under the Health Act 1999 to maintain and improve the quality of healthcare which it provides to individuals (clinical governance).

Aims and objectives

CSBS' role is to:

- promote public confidence that the services provided by the NHSiS are safe and that they meet nationally agreed standards
- to demonstrate that, within the resources available, the NHSiS is delivering the highest possible standards of care.

Ways of working

CSBS will develop an annual programme of services to be reviewed, with opportunities for people in the NHSiS and members of the public to put forward suggestions.

It will appoint a multidisciplinary project group for each service, including healthcare professionals and members of the public. These groups will oversee the three parts of the accreditation process:

- setting standards
- undertaking external peer review of performance against these standards
- reporting findings.

A fourth element - self-assessment of performance locally in relation to the standards - is crucial to the effectiveness of the system. It will give the clinicians and managers involved in the service under review opportunities to assess and develop their own practice and systems.

It will also ensure that CSBS' external reviews are part of an ongoing process of continuous quality improvement.

Standards set by the CSBS will:

- focus on clinical issues but not to the exclusion of non-clinical factors that impact on the quality of care
- be written in simple language
- be based on evidence (recognising that levels and types of evidence will vary)
- take account of other recognised standards and clinical guidelines
- be clear and measurable
- focus on improving the outcomes of the care and treatments provided for patients
- be published and widely available
- be regularly evaluated and revised to make sure they remain relevant and up-to-date.

Some standards will be generic to all clinical services, others specific to particular conditions.

Self-assessment:

- each project group will develop and pilot a self-assessment tool for Trusts to use in assessing their own performance against the standards
- this will contribute to CSBSs aim of 'no surprises'
- the outcome of self-assessment will constitute a major component of the evidence provided for the actual peer review visit.

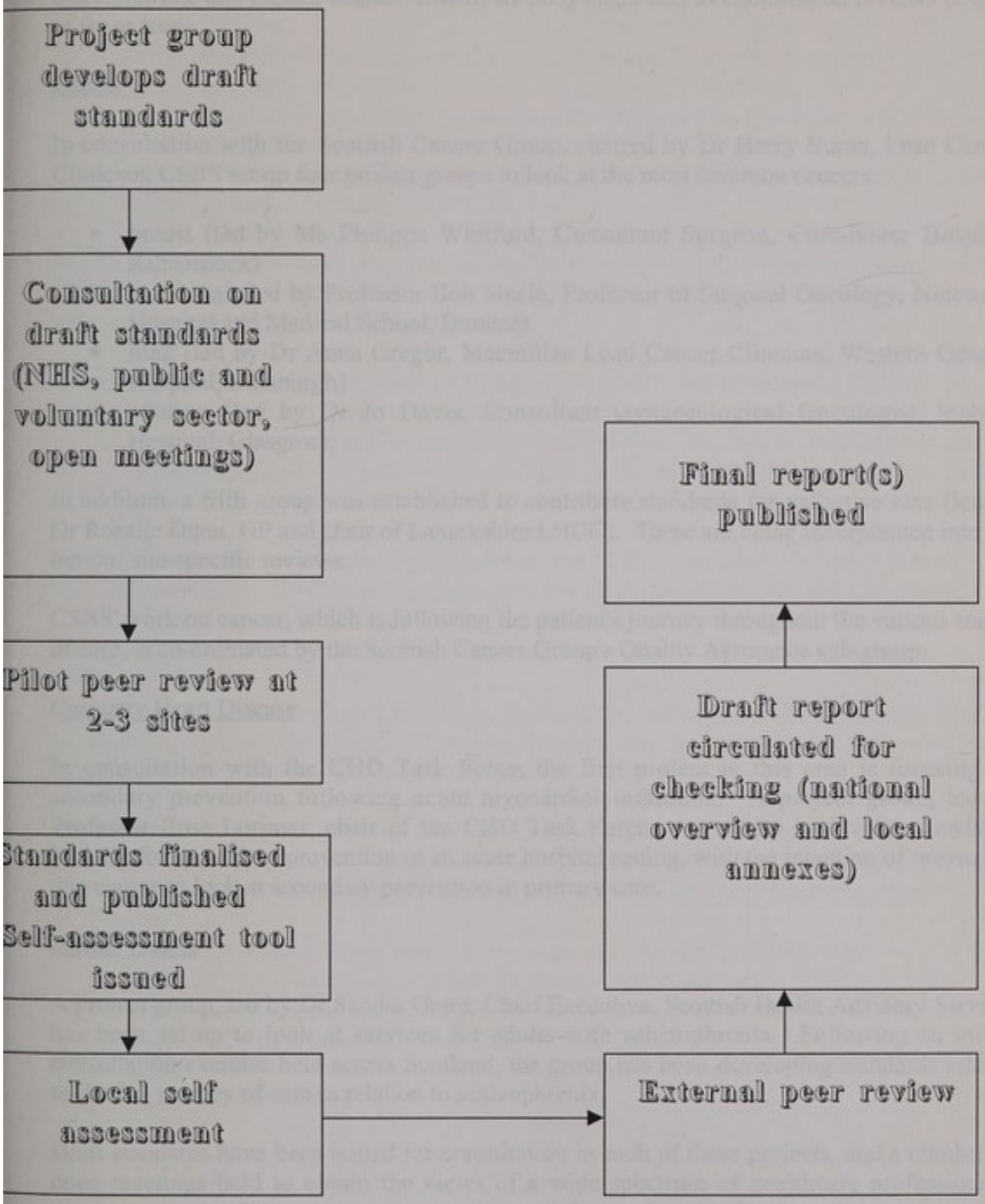
External peer reviews will:

- be based on an objective assessment of written evidence, including the results of self-assessment, and on visits by multidisciplinary teams, including lay people, to the locations where a service is provided
- aim to assess performance in a constructive manner, disseminate good practice and encourage improvements in performance
- take place periodically with follow-up visits if necessary.

Reporting will:

- state clearly whether standards have been met
- include a narrow commentary/narrative on why standards have not been met or how they have been exceeded
- encourage and make suggestions for quality improvement
- be published and widely distributed.

Clinical Standards Board for Scotland



CSBS - Promoting public confidence in the NHS

Progress to date

Initially, CSBS was asked to focus on the national clinical priorities of cancer, coronary heart disease/stroke and mental health. One of its early steps was to commission reviews in each of these areas.

Cancer

In consultation with the Scottish Cancer Group, chaired by Dr Harry Burns, Lead Cancer Clinician, CSBS set up four project groups to look at the most common cancers:

- breast (led by Ms Philippa Whitford, Consultant Surgeon, Crosshouse Hospital, Kilmarnock)
- colorectal (led by Professor Bob Steele, Professor of Surgical Oncology, Ninewells Hospital and Medical School, Dundee)
- lung (led by Dr Anna Gregor, Macmillan Lead Cancer Clinician, Western General Hospital, Edinburgh)
- ovarian (led by Dr Jo Davis, Consultant Gynaecological Oncologist, Stobhill Hospital, Glasgow).

In addition, a fifth group was established to contribute standards for palliative care (led by Dr Rosalie Dunn, GP and chair of Lanarkshire LHCC). These are being incorporated into the tumour site-specific reviews.

CSBS' work on cancer, which is following the patient's journey throughout the various stages of care, is co-ordinated by the Scottish Cancer Group's Quality Assurance sub-group.

Coronary Heart Disease

In consultation with the CHD Task Force, the first project in this area is focusing on secondary prevention following acute myocardial infarction. A project group, led by Professor Ross Lorimer, chair of the CHD Task Force, was set up to develop standards initially for secondary prevention in an acute hospital setting, with the intention of moving in due course to look at secondary prevention in primary care.

Mental Health

A project group, led by Dr Sandra Grant, Chief Executive, Scottish Health Advisory Service, has been set up to look at services for adults with schizophrenia. Following an initial consultation exercise held across Scotland, the group has been developing standards related to the full journey of care in relation to schizophrenia.

Draft standards have been issued for consultation in each of these projects, and a number of open meetings held to obtain the views of a wide spectrum of healthcare professionals, managers, users of the service under review and those who care for them. Pilot peer review visits have been undertaken and the standards are being finalised before roll out of the substantive peer review programme.

Generic standards

CSBS has developed a set of generic standards to:

- assist individual condition-specific project groups by avoiding the need for them to have to reinvent the wheel
- provide useful guidance for people involved in services which are not specifically covered by CSBSs current work programme
- support the service by identifying key issues Boards and Trusts should be addressing in taking forward clinical governance.

In January 2000 a project group was set up, led by the Very Rev Graham Forbes, a CSBS Board member, with multi-professional membership including lay representation. It has developed standards under two broad headings:

- safe and effective clinical care designed to ensure that all patients receive safe and effective care and treatment based on available evidence
- patient focus designed to ensure that all services respond to patients' needs and preferences, and that patients are involved in decisions about their own care through effective two-way communication and information sharing.

In developing these standards, CSBS has worked closely with the Scottish Executive and with the steering group it has set up to promote the implementation of clinical governance.

Primary care

The report of the Acute Services Review stressed the importance of making sure that the primary care component of clinical services is included in the accreditation process, while at the same time recognising its distinctive character.

To pursue these aims, one of the first decisions by CSBS was to establish a Primary Care Reference Group, led by Dr Colin Hunter, chair of the Royal College of General Practitioners (Scotland), with a multi-disciplinary membership including lay representatives. Its role is to:

- serve as a channel of communication between CSBS and primary care
- inform CSBS about quality initiatives already in primary care
- explore how CSBS can build on these initiatives to incorporate standards setting and peer review in primary care appropriately in its work
- advise CSBS on aspects of standards concerned within primary care and its interface with secondary care.

Its first task was to conduct a scoping study of quality assurance initiatives in primary care. In the light of this study, and following an examination of existing accreditation schemes, the group recommended that CSBS should press all Primary Care Trusts and island Health Boards to pursue the accreditation of general practices, using the RCGP's Practice Accreditation Scheme as a starting point.

The group also recommended that CSBS should work with the RCGP and others both to evaluate practice accreditation and to develop a second version with a stronger clinical and

patient focus. The group also signalled its intention to work with Directors of Postgraduate General Practice Education to develop training practice accreditation so that it also meets CSBSs requirements. CSBS endorsed these recommendations at the end of March 2000.

Public involvement

CSBS is committed to effective patient and public involvement in all parts of its work, and to pursuing this objective in a manner consistent with the rigorous approach being adopted to other aspects of its work.

A variety of mechanisms are being pursued to involve lay people who have experience of the services under review either as a user or carer, and the general public:

- 50% of CSBSs own members are drawn from outside the NHS
- lay representatives are included in every project group and review team (initially drawing on nominations from health councils and relevant voluntary and patient organisations)
- CSBS intends to develop as open procedures as possible to enable individuals to put their names forward to take part in its work

CSBS is also exploring different approaches to obtaining the views of patients and members of the public on NHS services:

- it has worked with the National Schizophrenia Fellowship, Scotland and the Scottish Users Network to link with users and carers
- in February 2000 during Scottish Heart Week, it collaborated with Chest, Heart and Stroke Scotland to obtain public views using the media linked to a nurse-answered telephone advice line
- it is also developing an interactive website to facilitate public involvement and links with other organisations.

Looking forward

Building on the foundations laid in its first year, CSBSs priorities for 2000/01 are to:

Initial projects

- finalise the standards in the light of comments received and experience of piloting each set of standards in two or three Trusts
- undertake substantive reviews of performance across Scotland against the standards and to publish a report following the review of each service

Generic standards

- finalise the standards in the light of comments received and pilots in four Trusts
- conduct a baseline review in each Trust and island Health Board.

Primary care

- support Primary Care Trusts and island Health Boards in rolling out practice accreditation to all general practices
- work with RCGP and others to evaluate practice accreditation and produce a revised version with a stronger clinical and patient focus.

New projects

- initiate up to six further projects.

Other priorities

- develop and implement a communications strategy including launching CSBS' website, for communication in the NHS and with members of the public
- develop more open and effective means of involving lay people in CSBS' work
- commission evaluation of CSBS' approach to quality assurance and accreditation.

Key summary

CSBS will:

- involve members of the public and patients in all aspects of its work
- work with and support NHSiS staff in improving standards
- assist NHS Trusts and Health Boards in delivering clinical governance
- base its conclusions and recommendations on the best evidence available
- be open and transparent, publishing all its reports
- seek to avoid duplication of effort, building on the work of other organisations such as CRAG and SIGN
- make sure that its own work is subject to quality assurance and evaluation

Dr D Steel
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Clinical Standards Board for Scotland

September 2000

7 Health Technology Board for Scotland

Background

The Government's key policy document *Designed to Care* acknowledged the potential for better patient care offered by technological advance and recognised that the NHS in Scotland had no agreed way of managing the assessment and introduction of new health technologies.

It proposed the setting up of a Scottish centre to evaluate and provide advice to the NHSiS on the cost-effectiveness of all innovations in healthcare and on existing technologies with questionable cost-effectiveness or variable uptake.

Following extensive consultation (Report of the Implementation Working Group, 1999), the Health Technology Board for Scotland (HTBS) was set up as a special Health Board on 1 April 2000. Together with the clinical guideline and clinical standards initiatives already well established in Scotland (see sections on SIGN and CSBS), HTBS will provide the final component in a comprehensive national framework for quality improvement in the NHSiS.

Remit

HTBS has been set up to provide a single Scottish source of advice on the clinical and cost-effectiveness of new and existing health technologies. A 'health technology' is any intervention used to promote health, to prevent, diagnose or treat disease or for rehabilitation or long-term care. It includes drugs, devices, clinical procedures and health care settings, giving HTBS a wide remit.

HTBS will perform approximately ten high quality Health Technology Assessments (HTAs) a year. HTAs are comprehensive, systematic evaluations of the assumptions for, and consequences of, the applications of health technology. They aim to clarify all relevant consequences of a decision to apply a health technology and should include an evaluation of the technology and relevant alternative technologies (Danish HTA Report, 1996).

The influence of HTBS will depend on its ability to persuade decision makers, through both the scientific rigour and the transparency of its procedures and advice. To ensure scientific rigour, HTBS is seeking to identify best practice in the international arena of Health Technology Assessment and apply it to the Scottish healthcare setting. This will be achieved by employing high calibre assessment staff to perform the appraisal work in-house, by involvement in international HTA initiatives, and by forming 'reference groups' to act as sounding boards on ground breaking issues in methodology, communications and the provision of healthcare services in Scotland.

HTBS will seek to:

- engage and involve the NHSiS, the public, patients and other interested parties in identifying, selecting and assessing topics and dissemination of advice

- address issues of importance to the clinical community and produce timely advice based on a well developed, objective and robust methodological assessment process, which is considered a helpful aid to decision making by policy makers, clinical managers and clinicians
- secure the public and professional 'ownership', and academic and clinical credibility necessary to have its advice put into practice
- react quickly and flexibly to changing circumstances.

Processes for Health Technology Assessment

Health Technology Assessment (HTA) should provide a bridge between scientific evidence, the judgement of health professionals, the views of patients and the public, and the needs of policy makers. But healthcare decision makers have identified several barriers to using HTAs (Millbank Memorial Fund, 2000), including the:

- complex and technical language used
- questionable data quality
- absence of real-world applications
- narrow focus
- late availability of advice.

The processes used by HTBS are being put in place to break down these barriers, so that the advice from their HTAs will lead to robust, defensible evidence based decision-making that supports change and has an impact on the NHSiS.

Current work is focusing on setting up robust processes for choosing topics, for assessment and the assessment process itself. The status of these processes can be seen at http://www.htbs.org.uk

Choice of topics for assessment

Selected topics will undergo a rigorous assessment. HTBS will use open consultation to invite proposals for topics to be assessed. Each topic will undergo a rigorous selection process, judging the likely impact of the HTBS assessment on the NHSiS and the availability of evidence to allow a scientifically robust assessment.

Assessment process

HTBS core staff will produce an evidence report that summarises submissions from all interested parties (patients, professionals and industry), along with systematic reviews, critical appraisals and economic evaluations of the health technology in the particular setting under investigation. This report will be peer reviewed and issued to a topic specific group for discussion.

A topic specific group is a short-life working group that will be created for each assessment, including a wide variety of experts in the field to be assessed. This group will perform an initial assessment of the evidence, taking into account their expert knowledge and the broader implications for the NHSiS.

The Management Board will then work with the topic specific group, performing a quality assurance function and ensuring consistency across assessments. This will result in a report and draft advice about the use of the technology that will be reviewed by interested parties and sent out for general consultation.

Consultation comments will be collated and considered by the topic specific group and the Management Board. Issues will be clarified with interested parties before the Management Board issues a comprehensive report summarising the evidence relating to the clinical and cost effectiveness of the health technology and providing advice on value for money.

The future: communications

HTBS's success will be judged by its impact on the NHSiS and its ability to communicate complex scientific messages openly and clearly to everyone with an interest in health care. Communications will be a key area for future activities in HTBS, linking into patient involvement initiatives and considering new ways for proactive communication of health messages.

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Health Technology Board for Scotland

8 Information systems in Scotland

Introduction

The Information and Statistics Division (ISD) is Scotland's lead agency for health statistics, information technology and related services. NHSiS clinicians and managers, the Scottish Executive, Scottish Parliament and others use ISD's health statistics to inform decision making and to stimulate research and debate.

Data on the health service in Scotland, supplied by hospital Trusts, Health Boards and other healthcare providers, are collected using a number of data schemes that are co-ordinated and managed by ISD.

The Scottish Morbidity Record (SMR) data are the basis of Scotland's health information. Since 1969, SMR data have recorded individual patient contacts with the health service. At present, there are 11 SMR data sets including:

- out-patients
- in-patient and day-cases
- maternity
- waiting list
- mental health
- neonatology.

Data collection for every patient in every hospital in Scotland totals 4.5 million records each year. Details collected for in-patient and day-case record:

- patient's name
- date of birth
- postcode
- details of the hospital
- consultant
- referral route
- diagnosis
- operations or procedures carried out
- when the patient was discharged
- where they were discharged to.

Another 48 data collection schemes are constantly evolving, either through the introduction of new systems or refining and enhancing existing systems. Examples include the Scottish Cancer Registry, NHSiS workforce databases, and summary statistics such as bed numbers and hospital activity. One of the most recent introductions is Continuous Morbidity Recording (CMR) which records patient contacts with their General Practitioner. For each consultation, the GP records whether it is a first contact with a particular condition, a recurrence of a condition, or the continuation of a condition. As the vast majority of contact with the health service experienced by the Scottish population is with their GP, CMR provides a great deal of information that was not available before. CMR is now being developed to incorporate patient contacts with other practice and community nursing staff.

ISD's scope has expanded as a result of the new emphasis on clinical governance in the NHSiS. Both Trust management and the newly formed managed clinical networks need clinical information to underpin their responsibility for the quality of care delivered. The Clinical Standards Board for Scotland (CSBS) needs a mechanism for comparative monitoring of clinical care quality including effectiveness across Scotland. These two strands are linked by clinical guidelines and associated minimum core data sets published by the Scottish Intercollegiate Guidelines Network (SIGN).

ISD has responsibility for co-ordinating and developing certain national clinical audit projects handed on from CRAG (see Section 4), and for encouraging and supporting the development of new national clinical databases. National audits already established are:

- Scottish Trauma Audit Group
- Scottish Audit of Surgical Mortality
- Scottish Hip Fracture Audit
- Scottish Renal Registry.

These individual audits provide highly detailed and specialised information on patient treatment. Clinical priority areas for ISD are cancer, neonatal care, vascular surgery, neurosurgery and elective orthopaedics. New national databases are being developed in these areas. A National Audit Projects Expert Group has been established to establish a coherent strategy for all national clinical audits, including regular reporting and review.

Every item of data collected is subject to a comprehensive and rigorous validation and quality assurance process. This function is managed by the SMR and Standards unit in ISD, working in close co-operation with the NHSiS, taking collective responsibility for raising data standards.

From a very clerically based organisation in the 1970s, ISD has become an expert professional body providing leadership in information services to the NHSiS with a highly skilled and motivated workforce. An increasing emphasis on customer service has helped establish close working relationships with the NHSiS and the Scottish Executive, and extending links outwith the NHSiS.

Scotland's data advantages

Scotland has some of the best health service data in the world. Few other countries have health information that combines high quality data and national coverage. The national database provides an unparalleled opportunity for exploration of the changing patterns of care provision for the population.

One of the most powerful tools in ISD's national database is probability based record linkage. This is a technique for linking together several (episode based) records for the same patient, either in the same data scheme or across several, even if some of the patient's identifiers are not identically recorded.

The patient can then be tracked through the healthcare system, wherever and whenever they were treated in Scotland. Patient based analyses are set to become central to health information as a result of the increasing emphasis on clinical effectiveness in the health

service, and the requirement to monitor outcome. It is important to note that strict confidentiality rules govern all of ISD's analysis and patient-identifiable information is never published.

Quality initiatives for the health service in Scotland depend critically on information of this detail and calibre.

Role and remit of ISD Scotland

ISD's principal role in supporting Scotland's health and health service is:

- to provide information and statistical services to the NHSiS, central government and other public sector organisations, members of the public, and voluntary and commercial organisations
- complement analytical services with interpretation and / or statistical advice

To achieve this, ISD must:

- collect and maintain a wide range of national health service data sets to a high standard
- further the overall aims of the NHSiS through the best use of information technology.

Behind this lies a wide range of tasks aimed at delivering a responsive, impartial service to the many organisations and individuals who need access to quantitative information on health and social care.

Strategic direction

Delivery of health care to patients is continually evolving, guided in part by policy review documents and in part by changes in clinical and management practices. Routinely collected information, previously skewed towards management needs, is shifting significantly towards the developing needs of clinicians. National information and information services must keep abreast of these clinical and service changes to remain relevant.

ISD's strategic development areas are:

- supporting clinicians
- utilising technology where appropriate
- enhancing primary care information.

ISD is increasing its involvement with clinicians in using national databases and ISD's statistical and information skills and services. ISD plans to continue to support national audits and their evolution, supporting the development of new national databases in clinical priority areas.

Advancing technology offers better ways of capturing and disseminating information. ISD seeks to develop the opportunities afforded by technology through extensive use of NHSnet for data transfer, capturing national data from clinical information systems, and offering greater accessibility to NHS users of non-confidential data by web publishing.

ISD is developing and enhancing the collection of primary care information by working with primary care trusts, local health care co-operatives and GPs to identify information requirements and develop systems to satisfy these.

Uses of information

ISD publishes and provides information derived from the data sets in five main ways:

Regular publications

All ISD publications are currently accessible through ISD's website, ISD Online. Major regular publications include:

- *Scottish Health Statistics*
- *Costs Book*
- ISD's *Health Briefings*
- *Cancer registration statistics.*

Electronic packages

ISD has created a number of packages that can be installed by customers on their own computer systems. These allow customers to generate information and analyses according to their individual requirements, without having to involve the ISD *ad hoc* service (see below):

Scottish Key Indicators for Performance (SKIPPER)

- provides analyses of health information nationally, allowing for comparisons across groups and monitoring of performance over time, using a predetermined set of indicators. (Indicators were selected by the SKIPPER Steering Group, drawn from staff throughout the NHSiS.)
- includes analyses on coronary heart disease, primary care services, cancer, finance, workforce, public health, child health, mental health and waiting times
- is aimed at all levels of the health service including SEHD, Trust chief executives, Health Board general managers, clinicians, information managers and public health medicine specialists.

Case mix and Benchmarking System (CABS)

- provides a system of comparative patient based statistics
- contains data from the general and acute in-patient and day-case SMR submissions
- currently aimed at Acute Trusts (each Trust can only identify their own data). The system is being developed to offer similar functionality for Primary Care Trusts.

Summary Health Information Pages (SHIP)

- provides easy access to high-level aggregate health information for Scotland
- designed in response to a request from SEHD
- SHIP is now available to a wider audience through ISD Online.

'Ad hoc' enquiries and Parliamentary Questions

The ISD Customer Support Desk answers one-off information queries from a wide variety of sources including the general public, clinical and academic staff, and NHSiS staff.

ISD regularly provides information to answer Parliamentary Questions, from both the Scottish and UK Parliaments.

Special projects / consultancy service

More complex inquiries often become special projects. Examples include:

- cancer cluster investigations (eg cancer incidence on Benbecula, bladder cancer around an oil refinery)
- special report on Deprivation and Health in Scotland
- development of clinical outcome indicators.

ISD is setting up a dedicated information and analytical consultancy service to respond to enquiries commissioned by Trusts and Health Boards, which are outwith ISD's core work programme.

A recent example is providing information to support the development of an Ambulatory Care Centre for a major Scottish Trust. The project reviewed data for all specialties from 1996/97 to date and projected forward 10 years using population statistics from the General Register Office for Scotland. The aim was to establish the most appropriate services for patients in an ambulatory care setting and determine the effect that the introduction of the centre would have on the activity patterns within the hospital.

IT link

ISD's role in IT is to support the NHSiS to find better and more effective ways of working, using the most appropriate technology available.

ISD is responsible for the following systems:

- General Practice Administration System for Scotland (GPASS)

GPASS has been successfully and comprehensively redeveloped as an award winning Windows based clinical system from software originally developed by David Ferguson, a Glasgow GP. It is now used in over 84% of practices in Scotland. GPASS is at the core of Scottish Primary Care IT strategy and forms a major component of the overall NHSiS IT strategy.

- Scottish Health on the Web (SHOW) (www.show.scot.nhs.uk)

SHOW is a website available to the public containing links to all health related web sites in Scotland. Users can find information on Trusts, Health Boards and other NHSiS organisations, details of national initiatives and many other links. SHOW is widely used, currently visited approximately 3 million times a month.

- Scottish Care Information (SCI) and Electronic Clinical Communications Implementation Programme (ECCI). ISD Scotland is a joint partner in these systems with the SEHD Management Executive.

SCI is an integrated programme of IM&T developments aimed at delivering NHSiS-owned products and standards for use across Scotland to support clinical communication and Electronic Patient Record (EPR) and Electronic Health Record (EHR) development.

ECCI is a Scotland wide programme to develop electronic clinical communications and provide greater integration between primary and secondary care throughout the NHSiS. By 2003, it is expected that extensive implementation of clinical communications will be in place, including:

- widespread clinical email including seeking consultants' opinion
- co-ordinated referral information
- electronic booking - protocol based where appropriate
- test ordering and results receiving
- discharge letters and summaries and clinic letters
- information in support of shared care.

ECCI is not primarily an IT project. It is a programme aimed at improving the delivery of clinical care, enabling services to become more patient centred and provide a more seamless service.

Training and staff development are key to its success and a vital part of planning ECCI projects. Staff in primary and secondary care will be helped with introducing the new ways of working and trained in the new technologies involved.

The five lead sites - Argyll and Clyde, Grampian, Highland, Tayside, West Lothian - are all now starting to implement their ECCI programmes. Second phase sites - Borders, Dumfries and Galloway, Forth Valley, Ayrshire and Arran, Western Isles, Orkney, Lanarkshire - will start later this financial year. Third phase sites - Greater Glasgow, Lothian, Fife, Shetland - will get underway in 2001.

IT systems capability in support of ECCI is being strengthened by the Scottish Care Information (SCI) programme. SCI will create a range of applications based on modern software that will enable clinical information to be communicated electronically throughout the NHSiS.

The future

The national datasets have huge potential to support the health service's information needs. ISD's customers, in particular in the clinical community, are only just beginning to recognise this potential and ISD will respond to the increased demand for information by developing the following key areas.

Accessibility of information

ISD expects that the internet will be central to increasing the accessibility of information. Currently ISD's web publications provide processed data and do not allow direct access to the underlying data sets. 'Data warehousing' is currently being investigated as a tool to allow customers to access the unprocessed data (taking full account of patient confidentiality and the Data Protection Act). The data would be available online, using web browser technology.

Consultancy team / customer services team

These teams will become increasingly important as ISD moves its focus from routine reporting towards customised information provision.

Data quality control

Data quality is the key to ISD's business and its Standards team plans to extend the accreditation of local data processing within Trusts.

New data sets and enhancements to existing data sets

ISD must remain responsive to NHSiS priorities with the development of new data sets as required by SEHD and organisations such as CSBS and the emerging Managed Clinical Networks. Information for primary care is a key development area.

IM&T strategy

ISD is closely involved in the information part of the NHSiS Information Management and Technology strategy. This relationship will be strengthened with the introduction of the SCI and ECCI programmes.

Other sources of information

Scottish Health on the Web (www.show.scot.nhs.uk) offers links to health websites for Scotland, including:

ISD Online : www.show.scot.nhs.uk/isd
GPASS : www.show.scot.nhs.uk/gpass
SKIPPER : www.show.scot.nhs.uk/isd/Scottish_Health_Statistics/subject/Skipper/home
CABS : www.show.scot.nhs.uk/isd/isd_services/cabs.htm
SHIP : www.show.scot.nhs.uk/isd/isd_services/SHIP/home.htm

ISD Customer Support Desk	0131 551 8899
ISD Customer Services Team	0131 551 8615
ISD Consultancy Service	0131 551 8972

Key summary points for clinical outcomes and quality

ISD Scotland and Information Systems:

- holds key information which can be used to underpin research into and monitoring of clinical outcomes and quality
- is developing new data sets as NHSiS priorities change, in collaboration with clinical staff, CSBS and SIGN
- information is readily available to the NHSiS and improving accessibility is a key priority
- can be commissioned for special projects where complex analysis and interpretation are required
- supports data quality improvement through accreditation and appropriate uses of IT

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9 Clinical effectiveness programme in practice based primary care

Introduction

'The effectiveness of clinical care and treatment has always been and will remain central to the quality of health care. The development of clinical guidelines and good practice statements provides clinical staff with information, based on available evidence about most effective practice. Their impact is evaluated through clinical audit and the development of clinical outcome indicators which allow critical reviews of performance.'

Paragraph 20 'Designed to Care'[1]

In June 1998, the Royal College of General Practitioners Scottish Council produced a discussion paper *Promoting Good Practice*[2] which sets out some initial thinking behind the term clinical governance, including a number of principles (Box 1). Other professional organisations, including the British Medical Association and the Royal College of Nursing, produced similar key principle statements.

Box 1: Key principles
Clinical Governance in Primary Care should embrace:

- the ethos in the GMC Duties of a Doctor: Good Medical Practice
- ownership of any system developed by all professional groups working in the primary care sector to whom the system will apply
- a multi-disciplinary approach
- personal and professional development of individual primary healthcare workers
- recognition of service provision by primary healthcare teams within the resources available
- development and maintenance of standards of service provision through clinical audit and professional performance review
- a culture of continuous quality improvement
- an appropriate balance between education, guidelines and indicators
- facilitation of improvement for practices which fail to meet minimal standards
- the continuance of professional self regulation

Background

Further to this paper, the RCGP hosted a multi-disciplinary Clinical Governance Reference Group for Primary Care, which was convened with representation from key professional groups. It met on six occasions and considered a number of presentations from different perspectives.

The Group agreed to produce a paper which it hoped would provide useful practical advice to clinicians and managers working in the Primary Care setting. *Practical Guidance on the Implementation of Clinical Governance in Primary Care in Scotland* was published in March 1999 and distributed to every General Practitioner in Scotland; Chief Officers of the Scottish

Executive Health Department, ME, CRAG, Chief Executives, Medical and Nursing Directors of Trusts; Health Board General Managers and LHCCs. The document is available on the web at *www.show.scot.nhs.uk/dtc*

Subsequent to this paper, the College prepared a successful proposal to CRAG's Clinical Effectiveness Programmes Sub-Group for a 3-year grant to deliver the Clinical Effectiveness Programme in Practice Based Primary Care. The Programme provides a focus for the development of quality initiatives in practice based primary care and is monitored by a Steering Group (CEPSTEG) drawn from the original Clinical Governance Reference Group but incorporating further multi-disciplinary involvement. See table below for membership.

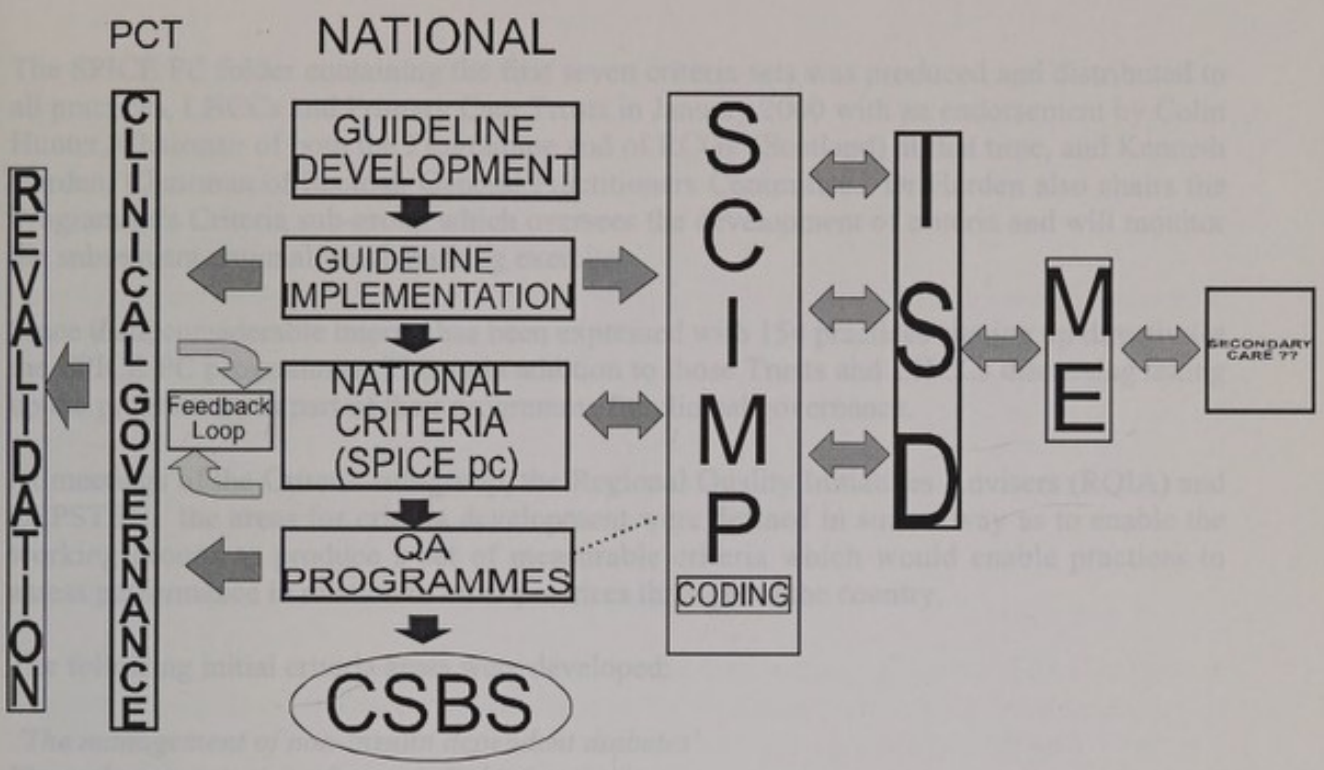
Mr George Brechin – Medical Director	Ms Nicola Ring – NMDU
Dr Gordon Stone – HB General Manager	Mr Andrew Gardiner - SAHC
Dr Hugh Whyte – SMO SEHD	Ms Tracey Nairn – Vice Chair NPAC
Ms Lesley McLay – Director of Nursing	Dr Colin Hunter – Programme Chairman
Prof Lewis Ritchie–Aberdeen University	Mrs Heather Ross - SPNA
Dr Mike Winter – Medical Director	Dr Bill Taylor – Director of QAI
Dr Kenneth Harden – Chairman SGPC	Dr David Watts – SGPC
Dr Murray Lough – PGGPE	Ms Liz Nicol – IHM
Dr Chris Johnstone – RCGP	Dr Malcolm Campbell – Director QS
Dr Robert Milne - PCCIU	Ms Beatrice Cant – CRAG
Dr Libby Morris – Chairman SCIMP	Ms Margaret Dolan – Chief Pharmacist

The personnel involved in the Programme consist of the Chairman (one session), two GP Directors (two sessions each), six GP Regional Quality Initiatives Advisers (one session each), Quality Initiatives Manager, Administrative Assistant and IT Officer.

At the outset, the key elements of the programme were:

- development and implementation of quality standards
- development and implementation of quality initiatives
- implementation of SIGN Guideline initiatives.

Whilst these still form part of the core work of the Programme, it has become apparent that this work impacts on other initiatives both in terms of primary care services and the continuous professional development of individual GPs. For example, the introduction of the Clinical Standards Board for Scotland (CSBS), revalidation and IT initiatives allow for closer collaboration with the Programme's objectives. The following diagram shows the interaction between the principal professions/organisations.



Where are we now?

Over the past 18 months, significant progress has been achieved and is outlined as follows.

Quality Standards

Overall Objectives

Following a consultation exercise, it was agreed that this area of the Programme should be labelled with the catchy acronym of SPICE PC – Scottish Programme for Improving Clinical Effectiveness in Primary Care. The aim of the initiative is to provide practices and LHCCs with a programme designed to help them answer three important questions in relation to effective performance. These are:

- what are we doing?
- what should we be doing?
- how does our performance compare with other practices and LHCCs?

These objectives are achieved by providing practices with copies of the criteria sets developed by the criteria working groups, by analysing practice data to measure the practices' performance in relation to the criteria set, and by feeding back to the practices comparative data.

The data collection is done using either GPASS or a stand alone data entry system and is designed to happen as automatically as possible. Negotiations continue to encourage non-GPASS software suppliers to produce data entry screens compatible with SPICE PC.

Developing and Agreeing Criteria

NATIONAL
GUIDELINE DEVELOPMENT
GUIDELINE IMPLEMENTATION
NATIONAL CRITERIA (SPICE pd)
CSBS

The SPICE PC folder containing the first seven criteria sets was produced and distributed to all practices, LHCCs and Primary Care Trusts in January 2000 with an endorsement by Colin Hunter, Chairman of both the Programme and of RCGP (Scotland) at that time, and Kenneth Harden, Chairman of Scottish General Practitioners Committee. Dr Harden also chairs the Programme's Criteria sub-group which oversees the development of criteria and will monitor the subsequent national benchmarking exercise.

Since then, considerable interest has been expressed with 154 practices signing up directly for the SPICE PC programme. This is in addition to those Trusts and LHCCs discussing taking up the programme as part of their programme for clinical governance.

At meetings of the Criteria sub-group, the Regional Quality Initiatives Advisers (RQIA) and CEPSTEG, the areas for criteria development were defined in such a way as to enable the working groups to produce a set of measurable criteria which would enable practices to assess performance in relation to other practices throughout the country.

The following initial criteria areas were developed:

'The management of non-insulin dependent diabetes'
'Secondary prevention of myocardial infarction'
'Hypertension detection and management'
'The monitoring of potentially hazardous drugs'
'Availability'
'The management of leg ulcers'
'Continuity of care in mental health'.

Working to the general principles laid down by CEPSTEG each criteria group was constituted so as to provide a broad range of appropriate input. The specific composition of each group was set out in the individual working group reports. Five of the working groups were convened by an RQIA, one (diabetes) by the Director of Quality Standards and one (leg ulcers) by a district nurse with specific expertise in the area to reflect the multi-disciplinary nature of this particular data set. Each group worked autonomously. Most groups met at least once and some met on several occasions. In addition, email was used to good effect with frequent communication among the members of the groups and the director.

Some of the criteria areas were relatively easy to progress in that they were straightforward clinically with abundant evidence to work on. Others such as Availability and Drug Monitoring were more challenging. The development of mental health criteria was minimal to allow the Programme's work to tie in with that of CSBS on standards for Schizophrenia. The overall principle was that existing evidence including SIGN Guidelines was collated and reviewed. From this the groups attempted to develop a set of criteria which were acceptable to all, evidence based where possible and achievable.

The central secretariat has handled a large volume of enquiries and comments. In addition the RQIAs have been active in running meetings and dealing with local opinion leaders. The project has also gained national publicity as the subject of articles in *Update*, *Doctor* magazine and the recently published first edition of *Scottish Practice*. SPICE PC was also presented at a national symposium funded by CRAG and at the Institute of Healthcare Management Annual Conference.

The production of a second set of criteria is now underway and criteria groups have been set up under the following areas:

Management of Asthma
Management of Pernicious anaemia
Management of Epilepsy
Diagnosis and Management of Left Ventricular Systolic Dysfunction related to Ischaemic Heart Disease
Monitoring of Prescribing for Hypothyroidism
Peer review Group of these six areas

All criteria groups are following the CEPSTEG guidelines on membership, in particular that there should be an identified representative from an LMC on each group.

Development of the information collection and analysis systems

The development of these systems has taken longer than initially planned. The College had developed a stand-alone access database system for recording data – this proved necessary as an interim measure until all practices in Scotland had been upgraded to GPASS Version 4 which included the newly created Care Management Screens.

It was also necessary to ensure compatibility between the stand-alone system and Care Management Screens and to ensure that the extraction software being developed by the Primary Care Clinical Informatics Unit at the Department of General Practice, University of Aberdeen was capable of extracting data from both systems. In addition, it has been necessary to work closely with SCIMP (Scottish Clinical Information Management in Primary Care) to ensure that SCIMP approved Read codes are used. Further details on SCIMP can be found later in this report. ISD has been helpful in assisting the college IT officer. The first data extraction uplift is expected to take place in October 2000 and initially six monthly thereafter.

Liaison with other bodies and organisations

Because of the need to work closely with others involved in developing clinical effectiveness programmes, the team has been closely involved with the CSB Primary Care Reference Group and Generic Standards Group, the Bi-collegiate Steering Group of the Scottish Colleges of Physicians, the GPASS programme board, SCIMP, and the RCGP website group. In addition, the programme has been undertaken in liaison with the CHD Taskforce and the Scottish Asthma Management Initiative in ensuring a cohesive approach to developing standards.

The programme is on course to deliver a useful contribution to clinical effectiveness in primary care.

Quality Initiatives

These initiatives attempt to raise the quality of patient care by assessing individuals or organisations. They use experience that the RCGP has gained over the years starting with What Sort of Doctor. They combine the submission of written material with a visit.

Practice Accreditation is suitable for the majority of practices while the Quality Practice Award is suitable for the more developed practice. Membership by Assessment of Performance is a process where a doctor who is not a member of the RCGP can join without doing the MRCGP exam. Fellowship by Assessment is for doctors who are members of the RCGP who wish to demonstrate they are providing a high quality of care for their patients.

The Quality Initiatives Centre (QUIC) was established at the RCGP office in Edinburgh to provide a central 'one-stop shop' to better support these initiatives. QUIC also co-ordinates visits and the training of assessors. In addition, six Regional Quality Advisers assist many local advisers and assessors.

Practice Accreditation

There has been a great deal of interest in this initiative. The system originated in England and following evaluation and consultation it was adapted so that it could be piloted in Scotland. To date, 10 Trusts and two Islands' Health Boards have signed up to deliver this system. There still may be more to follow. Training of assessors has occurred in six areas and is due to happen in the remainder soon. The first visit for real is awaited.

In June 2000, CSBS announced its endorsement of Practice Accreditation as a useful starting point and urged Primary Care Trusts and Island Health Boards to support the process of accrediting practices in their areas. CSBS will have an input to Version II by being involved in the Multi-professional Criteria Development Group. It is proposed that Version II would be published in summer 2001 and that there should be an incremental change from version one. The Primary Care Reference Group would then make the final recommendation to the Board on its suitability.

Evaluation of version one now being used in Scotland is being explored so that it can inform any changes required for the next version.

Quality Practice Award

This Award is a process which demonstrates a high level of quality of care delivered by all members of the practice Team. It is criteria based, involves submission of an extensive portfolio of evidence followed by an assessment visit by a team of four.

There are now 13 practices in Scotland who have achieved the award. A further 31 practices have notified their intent to apply. On 22 March a workshop was held for participating practices in Scotland, which was well attended by many disciplinary groups from each practice. Generic training for people who make assessment visits of any type has been carried out in three regions of Scotland. Version IV was published in August 2000. The training and introduction of lay assessors will be carried out during the course of the year.

Membership by Assessment of Performance

There is a scattered albeit small amount of interest for this throughout Scotland with 11 candidates. This initiative offers candidates a route to Membership of the College by assessment of performance rather than by examination, but is by no means viewed as an easy option having proved just as rigorous a process.

The process involves submission of a series of video consultations followed by a portfolio of written evidence and subsequent assessment by a team of two. There are active groups in the East and North East and others beginning in the West. Support for the candidates in making their video of consultations will be important and is being addressed in different ways locally, regionally and nationally.

Fellowship by Assessment of Performance

This is an award which demonstrates excellence in clinical care by an individual doctor. As with the others, it involves video examination of consultations, substantial portfolio of written evidence and full day assessment by a team of three. The process is currently encouraging lay assessment and this has already taken place in Scotland. There are now 26 Fellows by Assessment in Scotland and eight have notified their intent to apply.

Quality Assurance for Out-of-Hours

Following the Scottish Executive Out-of-Hours Review in 1988, the College was successful in a bid to the Primary Care Development Fund for a grant to develop a scheme of Quality Assurance for Out-of-Hours.

A Working Group of key organisations and individuals was set up and has drawn up draft criteria for out-of-hours care initially for co-operatives and deputising services. The first draft criteria set went out for a Delphi type consultation in the summer and results have been collated. Currently, pilot sites are being recruited to test that the criteria are robust whilst being fair and achievable. Additionally, potential assessors are being recruited which will include GPs, Managers, Triage nurses and patients. Following this a pilot version will be created which will be rolled out across Scotland. This may also be piloted in the rest of the UK.

Guideline Initiatives

The RCGP guideline initiatives aim to encourage GP participation in the development of SIGN guidelines and to promote the implementation of SIGN guidelines in primary care. The GP Advisory Group to SIGN has representation from all the RCGP faculties as well as SGPC and helps to plan and co-ordinate these activities.

SIGN was set up in 1993 and gradually over the years has gained respect from the professions. Through wide participation in the development process a sense of ownership has been nurtured and the recent external review of SIGN has emphasised the wide acceptance of SIGN guidelines.

One of the key factors of SIGN's success is that it is professionally led –"By us, for us" in Scotland. CRAG has decided, following the review, that SIGN will remain an intercollegiate

organisation linking strongly with the CSBS and HTBS as well as networking with other organisations.

The purpose of guidelines is not only to summarise the evidence and reinforce good clinical practice but also to promote change in professional practice where and when appropriate. The main challenge is in the implementation of the recommendations in the guidelines to improve the quality of patient care across Scotland. This process must be supported by a multi-faceted approach, involving a variety of tools and education, audit and feedback to help us all do the right thing at the right time. Guidelines will remain an integral part of quality initiatives. However, it is recognised that implementation requires time and resources to achieve changes in outcome.

GP involvement in the development of SIGN guidelines:

Topic Selection:

The GP Advisory group has been concerned that topics selected by SIGN with GP representatives this year for the development of guidelines have been focused in secondary care. Through consultation, two topics were identified from general practice to work up for proposals to SIGN. Multi-disciplinary focus groups were used to develop the proposals which were presented to SIGN on Otitis Media and Osteoporosis. Further efforts will be made to ensure that topics for guideline development are suggested from primary care in the future.

GPs on SIGN Guideline Development Groups:

Thirty-five SIGN guidelines are currently under development or review and at least two GPs are in each group. There are now also GP chairmen of SIGN groups, e.g. Obesity, and Otitis Media. GPs are reimbursed by SIGN for locum and travel expenses for attendance at meetings throughout the development process.

National meetings and peer review:

GPs actively participate in the national open meetings when draft guidelines are discussed. In the last year over 150 GPs attended these meetings. Six GPs at each national meeting are invited to prepare a report on the discussions which then helps the GPs on the development group to redraft the guideline taking into account the views of colleagues. Locum fees and travel expenses are paid by SIGN for GPs who prepare these reports. Once the final draft guideline is prepared GPs are invited to act as peer reviewers and comment on the content and presentation of the guideline. Every guideline is reviewed by at least two GPs and again a session payment is made by SIGN for this work. Finally, the RCGP also participates in the Editorial Board.

Initiatives to Promote Implementation:

Signet website:

This website can be accessed from the RCGP Scotland site and has links with the SIGN site. It contains information about all the guideline initiatives and how GPs can become involved.

The site is kept up-to-date with information about SIGN as well as tools, tips and tactics to help implementation of guidelines. The site can be found at *www.rcgp-signet.co.uk*

Quick Guides:

The primary care summary cards are developed by a multi-disciplinary team interpreting the SIGN recommendations and presenting the key messages in a user-friendly format. They have been well received and are now widely distributed to GPs, nurses, PAMs, Pharmacists and GP registrars. They will continue to be kept up-to-date and distributed free of charge. Extra folders are available from the RCGP offices.

SPACE:

The Scottish Practice based Accreditation in Clinical Effectiveness pilot project was funded by the Primary Care Development Fund and has been running in South East Scotland – Borders, Lothian and Fife. It has been evaluated by Edinburgh University on behalf of SCPMDE. It is hoped that the programme, with a workbook for practices and audit facilitators, will be rolled out to the rest of Scotland later this year.

Guideline Specific Tools:

Heart Pack:

The Heart Pack was launched in February by Susan Deacon as a collaborative venture with SHARP (Scottish Heart Arterial disease Risk Prevention) to promote the implementation of the SIGN guidelines 40 and 41. Copies of the video and resource pack were distributed widely throughout Scotland with frequent requests for more copies. As a result, a CD ROM version of the Heart Pack has been developed and is now available from the RCGP office. The CD not only contains the original resource directory and video but also the SIGN guidelines and Risk Assessment calculator, as well as links to websites.

Asthma Pack:

The asthma video has received a BMA education award. Links with the National Asthma Audit project have been established, and if practices want help in looking at the organisation and management of their patients with asthma, a meeting with a local facilitator can be organised through the RCGP using the Asthma Pack resource material.

IT Tools:

Guideline decision support is being explored through SCIMP, which is looking at ways in which key recommendations from SIGN guidelines can be incorporated into computer software to help remind GPs at the point of contact with patients. Care Management screens in GPASS and the CDSS (Clinical Decision Support System) present opportunities for IT support of implementation of guidelines.

SCIMP

In The Beginning

The introduction of the concept of Clinical Governance for General Practice coincided with a huge proliferation of initiatives designed to help doctors and nurses working in Primary Care to establish and demonstrate a high standard of care for their patients.

SIGN Guidelines, Quality Initiatives from the RCGP, and prescribing and referral guidelines from hospital specialities were produced at a phenomenal rate. One estimate was that there were 850 'guidelines' available to GPs in 1998. Computer technology could be utilised to implement guidelines and quality standards. It is impractical to expect doctors to read and familiarise themselves with the volume of paperwork that encompasses all the protocols that they might need, and one way of making them readily accessible would be to have them on the computer, in the consulting room and instantly available.

Background

At the conference *Making the Best Use of your Computer* in Edinburgh in June 1999, attended by representatives of SGPC, RCGP, SIGN Guidelines, Quality Initiatives and all the user groups of the major software systems used by GPs in Scotland, there was widespread agreement to amalgamate all the work already done and agree on a Scottish standard for the recording, implementation and comparison of markers of care in general practice.

There was a need for a mechanism to ensure a consistent and standard approach to monitor performance and take the clinical governance agenda forward. It was widely acknowledged that a huge opportunity existed to agree on common standards for chronic disease management in primary care, creating the potential to influence quality of care, demonstrate and compare standards across the whole of Scotland, and make an enormous contribution to reducing the workload of GPs.

Support for the government's IM&T strategy

The Scottish Executive was fully supportive of an initiative to provide clinical input to an area that needed to be co-ordinated and validated in order to be accepted by Primary Care.

The stated aims of the IM&T strategy include:

- to ensure continuity and co-ordination
- to ensure the accuracy of a patient's identity and records and avoid the need to repeatedly obtain the same information
- to support clinicians in choosing best practice by giving easy access to professionally approved care guidelines and by offering alerts and reminders
- allow clinicians to audit and compare their own practice to that of their peers based on 'like with like' data.

The Way Forward

A group was set up to act as a central point of contact for all groups wishing to contribute to the debate on selection of agreed standards and protocols. Membership of SCIMP can be found on the SCIMP website and its aims are to:

- co-ordinate activities which use IM&T to support the clinical process.
- encourage use of IM&T in the consultation where there is potential to improve patient care
- encourage common clinical coding across Scotland
- publicise the benefits of a shared approach
- enable the implementation of Guidelines
- make it easier to do the right thing.

Clinical Input

GPASS is the software system designed and developed by the Scottish Executive for use in practices in Scotland and currently used by over 80% of Scottish practices. Originally, it was purely an administrative system, but at the request of clinicians has recently added a consulting room module with an easily adaptable 'Care Management Screen' (CMS) which can be configured at practice level to record chronic disease care.

Users can design screens on any aspect of clinical care including morbidity, health promotion and prescribing using coding of their own choice. Other GP software systems (eg EMIS, Vision, Torex and Exeter) are developing similar facilities. The CMSs present the clinician with a checklist of minimum care criteria, which not only remind GPs of essential elements of the consultation, but also empower nurses to deliver high quality care as an integrated part of the practice team. By incorporating SIGN guidelines and quality criteria into the CMSs, clinical governance can be delivered as a by-product of the consultation, and not as an additional activity.

Avoidance of Chaos

Successful delivery of clinical governance and quality initiatives is critically dependent on the quality and standardisation of the routine information available. The Scottish IM&T strategy emphasises the need to base data collection systems on data useful in routine clinical work which improves patient care. The mechanism for collecting and extracting this information has already been developed by PCCIU at Aberdeen University, where it is collated and made into reports for individual, practice, LHCC or Scottish use.

Progress

The first task was to establish a core set of codes by which diseases and their management could be recorded consistently. Most software systems currently used in Scotland use Read version 2 to record morbidity and management. The resulting list was circulated to all LHCCs in Scotland, and the suggestions and criticisms were incorporated to produce a list of 800 codes. These codes were then checked by ISD, who mapped them to ICD10 (the coding most frequently used by secondary care in Scotland).

This list was published on the web site www.show.scot.nhs.uk\scimp and the top 300 codes as currently recorded by practices using the Electronic Questionnaire were published separately and sent to every practice.

The wider picture

SCIMP's website on SHOW (Scottish Health on the Web) acts as a resource for clinicians to access information about coding, and a forum for those wishing to contribute to the debate. There are direct links to RCGP, SIGNet and the user groups of GPASS, EMIS and VISION. This reinforces the position of SCIMP as the key element in the network which links primary care groups with quality initiatives. An organisational chart has been produced to clarify the relationships between all of the different bodies.

Two major projects are currently being piloted by the Scottish Executive. Scottish Care Information (SCI) is an integrated programme of IM&T developed to support clinical communication and electronic patient record development. It is a joint initiative by Trusts, Boards, primary care and ISD to link primary and secondary care electronically. Electronic Clinical Communications Initiative (ECCI) is linked with SCI and aims to set up electronic links between primary and secondary care to include 'Second Opinion' by email, protocol driven referrals, booked appointments and results reporting. SCIMP will continue to liaise at every level, and encourage integration of all initiatives in order to ensure that GPs will be assisted by IM&T in order to deliver high standards of patient care.

Key Points on the Clinical Effectiveness Programme

- to be effective in improving the quality of care, clinical effectiveness has to be relevant to the patient
- the national programme should facilitate practitioners and practices to fulfil the clinical effectiveness and clinical governance agenda
- professional ownership is a key feature
- a key element is to ensure future IT developments enhance clinical effectiveness
- there is an issue of time for all primary care clinicians to actively engage in the clinical effectiveness and clinical governance agenda
- future development of Practice Accreditation should take cognisance of the needs of revalidation for health professionals and the objectives of the Clinical Standards Board
- there is a continued need to disseminate good practice and provide opportunities at a Scottish level for shared learning between lead clinicians

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Chairman – Clinical Effectiveness Programme
Royal College of General Practitioners (Scotland)

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10 Scottish Needs Assessment Programme

Introduction

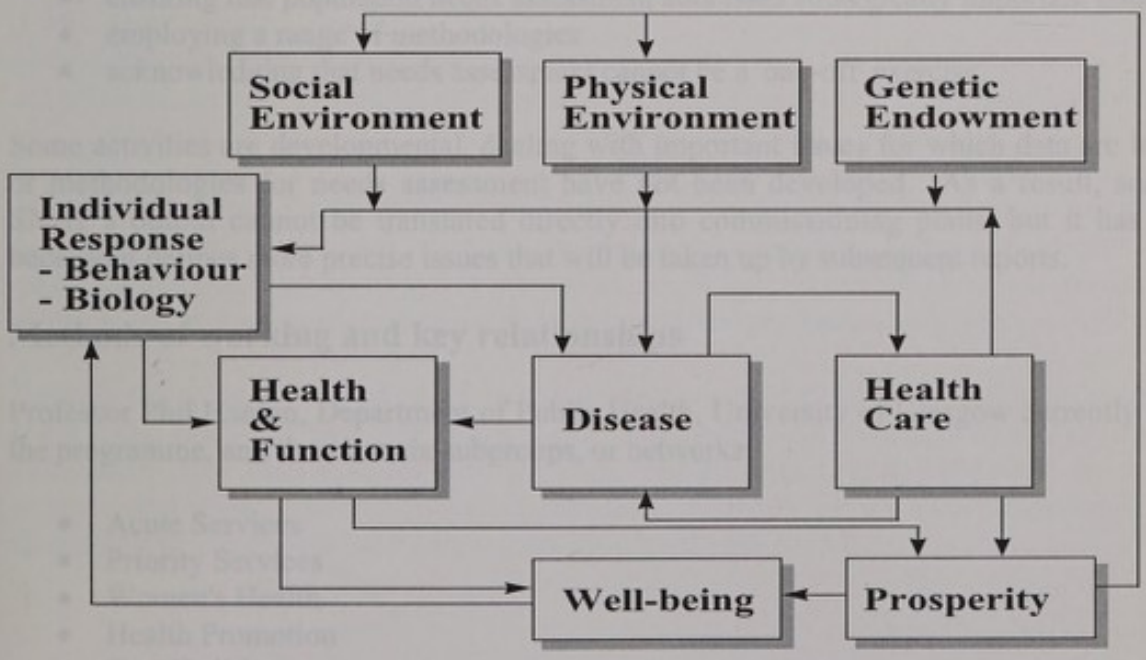
Although the Scottish Needs Assessment Programme (SNAP) is not a part of the CRAG remit, it is an integral part of the quality initiative in Scotland. Its key words are health, populations, need, and multi-agency interventions.

As a public health network, its focus is on assessing health as well as health care and on the population level rather than that of the individual patient. It assesses need for interventions to improve health rather than solely to meet demand for care. It encompasses the need for change in all aspects of living, and all professions or services that may be relevant to improving health. Its work reflects the framework of the White Paper and the wider model developed by Evans and Stoddart some years ago (see figure 1).

The definition of needs assessment that SNAP has adopted is that it is 'a process whereby opportunities for increasing health gain are identified and appraised', and it includes both needs for which no intervention exists and needs for which there is evidence of an effective intervention.

It is important to recognise that needs assessment is not equivalent to measuring clinical effectiveness. The key difference is that individuals, communities and populations have 'needs' while treatments and interventions are assessed on 'effectiveness'. Defined populations (eg people in a given locality or individuals who share a similar characteristic) are the proper focus for needs assessment, while treatments and interventions are the starting point of the study of clinical effectiveness.

Figure 1: Evans and Stoddart Model



The main target for SNAP reports is toward policy and planning but everyone, from public interests to clinicians, uses them.

Origins of SNAP

The 1991 National Health Service and Community Care Act led to the separation of the purchaser and provider functions, and Health Boards were charged with the task of commissioning health care based on a formal assessment of need. SNAP was set up in 1992, under the auspices of the Scottish Forum for Public Health Medicine, as a self-help network for Consultants in Public Health Medicine (CPHMs).

CPHMs had been given formal responsibility for population needs assessment as a basis for their own Health Board strategies, but they found that there was substantial value in collaboration with colleagues charged with similar responsibilities throughout Scotland. It soon became clear that much could be achieved through a central co-ordinated approach, using a wider range of skills and staff than could be available locally.

The original agenda was established by consulting the networks about needs assessment priorities at local level. These views were supplemented by discussions at a national level (eg with general managers). This created a 'first round' of SNAP reports that addressed national priority issues such as stroke and accidents, and confronted other issues that were highlighted because of 'grass roots' concerns (eg breast feeding and teenage pregnancy). In 1994, the Management Executive provided funding for two core staff and this has continued, but the contribution of members of topic groups is voluntary. In 1997, responsibility for SNAP was transferred to the Office for Public Health in Scotland (OPHIS).

Aims and objectives

SNAP aims to contribute to work on improving health status and building health alliances as well as informing the planning process for health services. This is done by:

- ensuring that population needs assessment addresses strategically important issues
- employing a range of methodologies
- acknowledging that needs assessment cannot be a 'one-off' exercise.

Some activities are developmental, dealing with important issues for which data are lacking or methodologies for needs assessment have not been developed. As a result, some of SNAP's output cannot be translated directly into commissioning plans, but it has value because it defines more precise issues that will be taken up by subsequent reports.

Methods of working and key relationships

Professor Phil Hanlon, Department of Public Health, University of Glasgow currently chairs the programme, and there are six subgroups, or networks:

- Acute Services
- Priority Services
- Women's Health
- Health Promotion
- Oral Health
- Primary Care.

SNAP's programme and strategy is managed by the SNAP Core Group, which consists of the leaders of each of the networks and representatives from academic public health and the Directors of Public Health Group. Network members contribute the main resources (time and expertise) required to produce a SNAP report and in this sense Health Boards and other organisations are the main contributors to SNAP.

SNAP negotiates its programme of work on an annual basis with the Scottish Executive Health Department, and consults with Health Board departments of public health to determine which topics they feel SNAP should address.

When the Core Group has agreed the work programme, individual consultants in public health medicine in Health Boards are identified to take the lead on a particular topic. They also have responsibility for taking this forward with other relevant health professionals and users of the service.

All reports are produced with the support of the SNAP Secretariat. Under a public health umbrella, there is a wide range of contributors and the mix for each report depends on the nature and impacts of the topic. The disciplines of epidemiology, demography, statistics, health promotion, social science, health economics, health service management and the voluntary sector regularly combine to create a public health perspective. SNAP recognises that improving the quality of future work depends on the involvement of key groups outside service public health medicine.

Each report should contain sections on:

- the epidemiology of specific diseases and their impact on health, disease and need for services
- an evaluation of current interventions from prevention through to rehabilitation or continuing care
- current provision of interventions including content and coverage
- an economic appraisal
- patient satisfaction and consumer views
- implications and recommendations for HIPS and the commissioning of health services.

The SNAP Editorial Committee and the Directors of Public Health Group review all drafts to guarantee a consistent level of quality guidelines for reports. During the course of the programme it has become clear that there is no single best method of assessing health needs: different issues and questions require different methods, approaches and degrees of detail.

Because the epidemiology of risk factors is complex - and the fact that many exist outside the NHS - the evidence base for associations and for the effectiveness of interventions is necessarily less than that for clinical interventions that can be subjected to rigorous experimental trials. This creates a methodological challenge that is addressed by the Editorial Group and by occasional research projects associated with SNAP.

Key deliverables

SNAP is committed to providing reports across the full spectrum of topics of public health concern. Initially, the agenda was dominated by topics in acute medical care, such as hip replacement and heart surgery, reflecting the relative importance of acute services at that time within health boards.

When the Common Core Work Programme designated mental health as a priority area for the NHSiS, SNAP produced a Mental Health Portfolio to complement the Framework for Mental Health Services in Scotland. This portfolio, published in 1997, comprised eight reports on public health aspects of mental health. It aimed to help the NHSiS to take forward the essential tasks of developing mental health services in the 21st century and to promote the attainment and maintenance of the best mental health possible in the population.

With the purchaser-provider split in 1991, fundholding general practitioners as well as Health Boards took on responsibility for assessing need. During 1996, SNAP undertook a research project with funding from CSO to determine the contribution of needs assessment to health service planning in Health Boards and in general practice.[1]

The research showed that general practitioners varied greatly in their experience of needs assessment and that many would welcome guidance in this task. As a result, the SNAP Primary Care Network set to work on its *Needs Assessment in Primary Care: a Rough Guide.*

This gave practical step-by-step advice to primary care teams on how population needs assessment can improve both the health of their practice communities and the effective use of practice budgets. More than 3,000 copies were distributed to health professionals in Scotland and there is a steady demand for this SNAP report following the introduction in 1999 of co-operative planning and a focus on public health issues within local health care co-operatives.

A key aim for SNAP is to raise awareness of health needs which the public or even Health Boards might not have recognised, and provide evidence as to why they are important issues: the SNAP Women's Health Network advocated the need to recognise the problem of domestic violence and, in October 1997, produced the SNAP report on domestic violence.

The report highlighted the extent of the problem in Scotland and the importance of the issue for the NHSiS. It attracted a great deal of interest both in the media and from organisations in England, and the Department of Health in London requested copies for distribution to all health authorities in England. The findings were presented at a WHO conference in Copenhagen in December 1997 and at a joint Scottish Office/HEBS/SNAP/COSLA conference when the setting up of the Scottish Office task force to tackle domestic violence in Scotland was announced.

In recent years, the tasks undertaken by SNAP have widened. For example, SNAP used its experience in networking to pilot and gain experience in conducting health impact assessments (HIAs) in response to the Government's identification of health impact assessment in 1998 as a key task for health boards.

The case studies were used to examine the methodological issues as well as to produce recommendations on the specific topics. They reflected the public health emphasis on the wider determinants of health and looked at the impact of housing strategies and transport policy on the health of specific groups within the affected communities.

SNAP concluded that HIA should be seen as one element in the range of partnership work to promote health and consider health in planning. There is no single 'blueprint' for HIA that will be appropriate for all circumstances, and different approaches and methods will be required in different situations, requiring a range of skills and disciplines.

The need for accurate assessment of population health needs, current and future, presents an ongoing challenge. Some of the service based needs assessments which are currently being conducted (eg for cardiac rehabilitation and multiple sclerosis) are addressing issues of fundamental service redesign that resonate with themes set out in the White Paper *Designed to Care*.

Projections and predictions of need and demand, such as in the Hepatitis C report just completed, are notoriously susceptible to unforeseen changes in both epidemiology and interventions. SNAP measures its success by the extent to which its reports are used to inform resource allocation decisions.

The evaluation project[1] showed that all Health Boards wanted to use population needs assessment as the basis for purchasing health care, and found the SNAP reports useful to this end. The key users and local interpreters are the directors of public health, and they have continued to give strong support to SNAP, both in principle and through the release of CPHM and other staff time to take part in the production of reviews.

Future directions for SNAP within public health generally

The role of SNAP should continue to be in providing expert and evidence-based recommendations to inform the planning process for health-improving interventions.

All public health professionals (medical and non-medical, inside and outside Health Boards) have a stake as participants in and users of this work. The Scottish Executive and Scottish Parliament have a role in setting the agenda and using the output.

Although the concept of a self-help network remains intact, the size of the network has to be widened, new mechanisms of leadership evolved and all those with a legitimate stake in the endeavour involved appropriately if the new agenda is to be met. This will include the development of health impact assessment methodology and reports as outlined in the *Review of the Public Health Function*[2].

SNAP has been taken as the model for the public health networks that are now to be established as part of the new Public Health Institute for Scotland. This provides an opportunity to create a more formal and exciting collaborative approach to working of the nature that SNAP has pioneered.

The common gain network methodology will be used to address key strategic issues that are of obvious relevance to Health Boards, Trusts, local authorities, the Scottish Executive and the people of Scotland. The output from this work should be documents that are of practical

value to stakeholders, and represent pieces of work that would have been required at local level anyway but that can be completed more quickly, and at a higher quality, by pooling resources.

Given the creation of the Institute, and its resourcing for such purposes, the volume of reports will almost certainly increase. It is crucial that the quality of the methodology is developed in parallel.

Key Summary Points

- SNAP's role should continue to be in providing expert and evidence-based recommendations, based on assessment of need, to inform the planning of health interventions, including health services.
- The work programme of needs assessment should continue and develop to reflect both the national public health agenda of the Scottish Executive and 'grassroots' issues channelled through CPHMs.
- The public health networks that have worked well for SNAP should be further developed as a broader networking mechanism for public health in Scotland, resourced through the new Institute of Public Health.
- The networks should expand their repertoire of work to include work on health impact assessments, patient experience of disease, short reports and other developments.

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References

1. *Scottish Needs Assessment Programme. A study to determine how needs assessment can increase the health benefits of purchasing within Scotland. SNAP, 1996.*
2. *Scottish Executive. Review of the Public Health Function. HMSO, 1999*

11 Other linked initiatives

Designed Healthcare Initiative

The Designed Healthcare Initiative is targeted at supporting review and redesign of the patient's end-to-end journey. The aim is to develop well designed and seamless care which minimises waiting times and delays, removes unnecessary hospital visits and provides continuity of care from the GP's surgery to hospital, where necessary, and back into the community.

In February 1998, Ministers announced they would be providing £3m in funding over a 3-year period to assist the health service in redesigning care and to support a number of demonstration sites.

Designed healthcare pilots

In the first round of bidding, £2m was allocated to support 30 projects, including two large rolling programmes of service redesign at Ayrshire and Arran Acute Hospitals NHS Trust and Lothian University Hospitals NHS Trust. Over £1 million has been allocated in the second round of bidding to support a further 14 projects.

The Initiative is supporting a 5-10 year change agenda.

Scottish Design Network

The Initiative is supported by the Scottish Design Network, which provides a forum for exchanging ideas and information on service redesign. Membership of the Network has now expanded to include 25 Trusts and 11 Health Boards, the Marie Curie Centre and the Scottish Prison and Ambulance Services.

Training and development programme

A training and development programme aims to support the development of a Scotland-wide change capability. Topics covered in the programme include:

- accelerated redesign
- basic tools and techniques
- team coaching
- clinical governance
- patient involvement
- continuous quality improvement.

A comprehensive training programme provided by Leicester Royal Infirmary NHS Trust, one of the leaders in the field of service redesign, underpins the work of the Initiative workshops.

Achievements to date

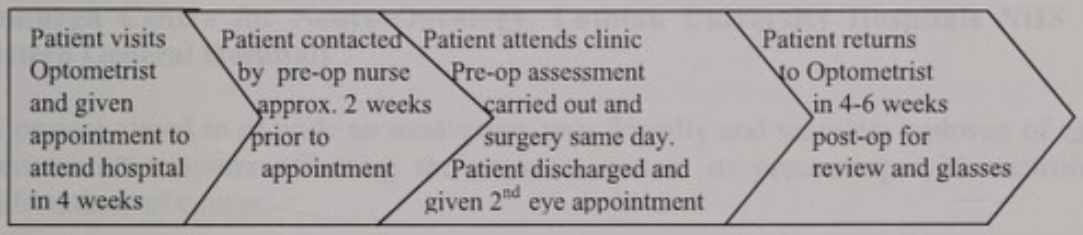
One Stop Cataract Surgery Service, Ayrshire and Arran Acute Hospitals NHS Trust

The Cataract Project started on 7 September 1998 and is the first of 12 in a 3 year rolling programme. The service was redesigned over a 6 month period. The main characteristics of the new service include:

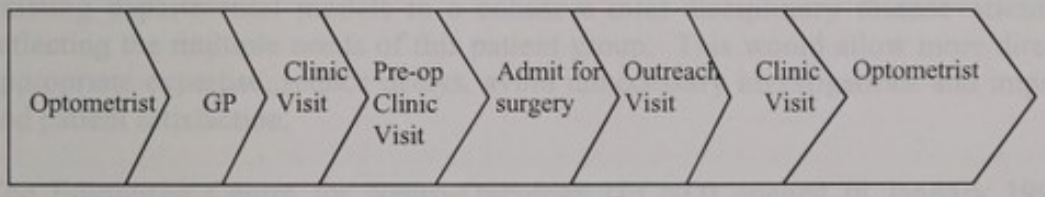
- direct Optometrist referral of cataract patients to dedicated cataract clinics
- consultation, pre-operative assessment and surgery, if indicated, on the same day (one stop surgery)
- post-operative review by Optometrist in line with the move towards shared care supported by the Royal College of Ophthalmologists
- development of team working across primary and secondary interface
- devolved management and decision making.

The newly designed service has resulted in a single visit to hospital for cataract patients. The 'One Stop Cataract Surgery' model has proved very successful in reducing the total length of time required for diagnosis and treatment. The waiting time for surgery has been significantly reduced. Streamlining of the service has also reduced the number of visits to different agencies from seven to three and the number of visits to hospital from four to one.

New process map



High level previous process map



Evidence based care

The model has involved the development of guidelines/protocols for referral and follow-up of patients by Optometrists, the introduction of a care pathway, the development of patient information booklets and GP/Optometrist information packs.

One Stop Hand Rehabilitation Service, Ayrshire and Arran Acute Hospitals NHS Trust

The redesign hand clinic started in November 1999. Previously, patients were referred by the GP to a consultant outpatient clinic at the Ayr Hospital. They were then referred on to the physiotherapy waiting list for pre-op assessment, to be followed at a later date by surgery. The waiting list for physiotherapy assessment before redesign was 6 to 8 weeks. Following surgery patients waited several weeks before commencing treatment.

Following redesign, the service has been streamlined with a 'One stop clinic' before surgery. Generic therapeutic assessment now takes place at this clinic visit, removing the need for the pre-assessment clinic. Therapeutic intervention is initiated within 24 hours of surgery by an identified generic therapist. The Occupational Therapist and Physiotherapist alternate weekly to carry out the generic assessment. If required, either therapist can be contacted to attend.

One Stop Colorectal Clinic, Dr Gray's Hospital, Elgin

The development of a Rapid Assessment Clinic in Morayshire arose from the perceived need to provide a service that reduced the time to diagnosis for serious colorectal disease.

The project started on 1 December 1998. Introduction of the 'One stop clinic' has resulted in a reduction in the number of visits to hospital, fewer episodes of preparation for investigation, and principally a very substantial reduction in the time to diagnosis. The median time from referral by the GP to diagnosis was reduced from 19 weeks to 4 weeks.

Edinburgh Centre for Neuro-Oncology, Lothian University Hospitals NHS Trust (Western General Hospital)

This project aimed to provide an innovative, user friendly and seamless pathway of care for patients with tumours affecting the nervous system or presenting with neurological manifestations of cancer.

The reconfiguration involved radically redesigning pathways of specialist care from the existing departmental models to a cohesive inter-disciplinary disease orientated model reflecting the multiple needs of this patient group. This would allow more direct access to appropriate expertise, reduce delays, avoid unnecessary investigations and improve quality and patient satisfaction.

The Edinburgh Centre for Neuro-Oncology (ECNO) opened in January 1999 and was officially launch by Sir David Carter in June 1999. The Centre provides a clinical and administrative hub for the service and easily identifiable central point for referral, which has resulted in:

- easier GP access by centralising administration
- increase in patients referred for expert advice
- patient centred consultation, with treatment and management plans where patients are well informed of disease, prognosis and treatment options
- fewer needless visits to hospital
- use of telephone advice options

- quality of care delivered improved by no duplication of care processes and compliance with the Royal College of Physicians guidelines.

Redesign of Oncology Day Case Services, Lanarkshire Acute Hospitals NHS Trust (Law Hospital)

The aim of this pilot was a fundamental restructuring of the provision of Day Case Oncology services at Law Hospital for patients suffering from breast, lung and colorectal cancer. The pilot addressed issues of patient access, quality and continuity of patient care from the initial stage of referral, the further stages of inpatient stay up to and including discharge to the primary care sector.

Achievements include:

- cancer patients who previously attended the Beatson Oncology Centre, Glasgow are now having their care provided locally in the Day Case Oncology Suite at Law Hospital, removing the journey time from Law to the Beatson
- total patient wait time has been reduced from 3 to 5 hours for 79% of patients being seen and treated within two and a half hours
- the Trust expects to exceed the original target moving from a baseline of zero to over 600 day cases a year

Shared Care Glaucoma Clinic, Highland Acute Hospitals NHS Trust (Raigmore Hospital)

The aims of this project included:

- reducing the number of attendances by glaucoma patients to the general eye clinic by introducing a shared care glaucoma clinic
- reducing the number of visits to hospital by combining visual field testing and clinic attendances
- providing written and verbal information to promote the patient's understanding of their condition
- freeing time at the general eye clinic to allow medical staff to see other patients
- extending the role of the nurse and orthoptist giving more job satisfaction and improving morale.

The clinic opened in March 1999 and has proved very successful. On average, 40 patients are seen each month.

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Telemedicine Initiative

Telemedicine refers to any application of information and communications technology that removes or mitigates the effect of distance in healthcare. In Scotland, the Scottish Telemedicine Initiative, led by Professor Ray Newton, has been funded by the Scottish Executive Health Department to promote the implementation of telemedicine. The initiative is backed by a £5m budget and is guided by the Scottish Telemedicine Action Forum (STAF).

STAF is a group of clinicians, academics, managers and technologists with a remit to oversee the development of telemedicine in Scotland by:

- gathering information about past and present telemedicine activity in Scotland and in other countries, and identifying individuals and groups that are active in the field
- developing a strategy for implementing telemedicine
- promoting telemedicine in the NHSiS and disseminating information about its potential through workshops and conferences
- setting up and supporting a number of demonstrator projects
- advising on funding projects
- encouraging Health Boards and Trusts to consider the application of telemedicine in their improvement plans
- identifying and promulgating standards relating to telemedicine.

The telemedicine initiative remains at a very early stage. Two projects have been funded to date - in Grampian (*Role of Telemedicine Provision in Emergency Care in Remote Communities*) and in Argyll and Clyde (*Royal Alexander Cardiovascular Health Electronic Links*). A third project to support the West of Scotland Cancer Managed Clinical Network is due to be funded shortly. Over 50 initial applications were submitted for consideration by STAF and a number of these have been invited to submit a full proposal. It is hoped that some of these projects will be able to start before the end of 2000/01.

An example of the kind of work that is being supported is the £1.1m project in Grampian. This project will:

- link 14 community hospitals in Grampian with the A&E department in Aberdeen;
- allow the community hospitals to call on the advice and expertise of the central department, resulting in fewer patients having to make the journey to Aberdeen; and
- improve the communications infrastructure and so open up opportunities for training and for staff networking.

Telemedicine is a rapidly developing field with great potential to improve access to high quality care irrespective of distance. Along with other aspects of information technology, the equipment is improving all the time, opening up new possibilities and opportunities for redesigning services. Realising the potential of telemedicine will require a concerted effort by many people. Ultimately it can only be fully effective with the active support of healthcare staff and their willingness to adopt new skills and new ways of working.

Significant investment is being made to ensure that Scotland develops the necessary knowledge base and expertise to take full advantage of advances in telemedicine. Evaluation

of the projects funded by the Scottish Telemedicine Action Forum will provide evidence about which telemedicine applications are sufficiently effective, efficient and robust to deserve wider implementation.

The Scottish telemedicine website - http://www.show.scot.nhs.uk/telemedicine - is intended to become a vehicle for sharing information about telemedicine activity in Scotland and elsewhere, and as a means to facilitate networking.

Mr D Cline
Scottish Telemedicine Development Manager
Health Gain Division
Scottish Executive Health Department

Electronic Clinical Communications Implementation

Electronic Clinical Communications Implementation (ECCI) is a Scotland wide programme to develop electronic clinical communications between primary and secondary care throughout the NHSiS. By 2003, it is expected that extensive implementation of clinical communications will be in place, including:

- widespread clinical email including seeking consultants' opinion
- co-ordinated referral information
- electronic booking – protocol based where appropriate
- text ordering and results receiving
- discharge letters, summaries and clinic letters
- information in support of shared care.

It is important to recognise that ECCI is not primarily an IT project. It is of greater significance as a programme aimed at improving the delivery of clinical care, enabling services to become more patient-centred and facilitating the provision of a more seamless service through the greater integration of primary and secondary care.

Training and staff development are key to the success of ECCI and these issues are a vital part of planning the ECCI projects. Staff in both primary and secondary care will be assisted with introducing the new ways of working associated with communicating electronically and will be trained in the new technologies which are involved.

ECCI lead sites

Invitations to become ECCI lead sites were issued by the SEHD in March 2000. Five lead sites were selected in May from bids received from the NHSiS. The lead sites are Argyll and Clyde, Grampian, Highland, Tayside and West Lothian. All the lead sites have detailed plans for their electronic clinical communications programmes and implementation is now starting in these areas.

Second and third phase sites

The ECCI programme will be implemented in three phases. It is intended that second phase sites (Borders, Dumfries and Galloway, Forth Valley, Ayrshire and Arran, Western Isles, Orkney and Lanarkshire) will start later this financial year and will progress ECCI just behind the lead site programme. The third phase (Greater Glasgow, Lothian, Fife and Shetland) will get underway in 2001.

Information Technology support

IT systems capability in support of ECCI is being strengthened by a programme of work entitled Scottish Care Information (SCI). This programme will create a range of applications based on modern software that will enable clinical information to be communicated electronically throughout the NHSiS.

Mr K Brewer
Head of Division
Electronic Clinical Communications Implementation
Scottish Executive Health Department

Managed Clinical Networks

Managed Clinical Networks bring together all the health professionals responsible for providing a particular service so that they can work together across administrative and professional boundaries in a new way. The aim is to give patients more uniform access to a service of the highest quality, while at the same time making the best use of resources. The focus is on patients and services rather than organisations and buildings.

One of the main strengths of the concept is its flexibility. It can be applied to many different situations in response to the interests of the patient. However that flexibility has meaning only if the operation of each Network is governed by core principles. These were set out in MEL(1999)10. A key principle is representation of patients' organisations in the management arrangements of each Network.

A wide range of MCNs is now either in existence or being developed, at local, regional and national level. Pilots are under way in different parts of the country, involving different diseases and conditions. This work will continue, and each pilot will be carefully evaluated in terms of the benefits it brings to patients.

Mr W Scott
Head of Branch
Health Care Policy Division
Scottish Executive Health Department

Coronary Heart Disease Task Force

The Task Force was established, following the publication of the Acute Services Review Report, in August 1998. It is led by Professor Ross Lorimer and consists of a small core group of members including a general practitioner, a research fellow in cardiac nursing, a statistician, a patient and members of the Department.

The overall aim of the Task Force is to develop a clinical network for cardiac services in Scotland. To achieve this, the Task Force has been assigned the following remit :

- to investigate and quantify the scope for increased intervention rates within the four current cardiac surgery centres in Scotland, and to address known inequity of access. Waiting list issues will also be addressed
- to build on existing work to develop a national database, in conjunction with ISD
- to provide advice on strategic direction for the organisation of adult cardiology services, with particular emphasis on CHD. Primary, secondary and tertiary care will be covered, and the vascular template adapted for CHD to clarify who is responsible for what, and where
- in light of the above, the Task Force will examine new and developing cardiological techniques with particular emphasis on effectiveness, resource implications, and avoidance of unnecessary duplication of high cost equipment
- to ensure implementation and audit of relevant SIGN guidelines.

Over the past 2 years, the Task Force has been looking at the full range of issues relating to CHD and is now in the process of producing a National Plan for CHD.

The Task Force has been involved in the primary prevention project 'Have A Heart Paisley', and the lessons from the project will be rolled out across Scotland.

A national database for CHD will be created, based on routine management of patients in primary care, to make sure that patients with CHD get their treatment in the most efficient and co-ordinated way. A national waiting time will be set which covers the entire patient journey from first seeing a GP about chest pain to the time of any intervention needed.

The Task Force has also been working with the Clinical Standards Board for Scotland to determine standards for secondary prevention after a heart attack. The standards are now being monitored across the country. Managed Clinical Networks at local level for investigation and diagnosis, linked to a national Network for intervention, will be the mechanism by which all of these developments will be drawn together.

The Task Force has also been turning its attention to stroke services in Scotland, in particular to issues such as access to imaging, the development of stroke units across the country and thrombolysis. It will be working alongside the Clinical Standards Board for Scotland to develop standards for Stroke Services.

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Appendix I

Key Contacts

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Appendix II

GLOSSARY

A & E	Accident and Emergency
ACACs	Area Clinical Audit Committees
AGREE	Appraisal of Guidelines Research and Evidence for Europe
AHCPR	Agency for Health Care Policy and Research
AHRQ	US Agency for Health Research and Quality
BMA	British Medical Association
CABS	Case mix and Benchmarking Systems
CDSS	Clinical Decision Support System
CEMD	Confidential Enquiry into Maternal Deaths
CEPS	Clinical Effectiveness Programmes sub-group
CEPSTEG	Clinical Effectiveness Project Steering Group
CESG	Clinical Effectiveness Strategy Group
CHD	Coronary Heart Disease
CIS	CRAG Implementation sub-group
CIST	Clinical Indicators Support Team
CMR	Continuous Morbidity Recording
CMS	Care Management Screen
COSLA	Confederation of Scottish Local Authorities
CPD	Continuing Professional Development
CPHM	Consultants in Public Health Medicine
CRAG	Clinical Resource and Audit Group
CR-OC	CRAG Outcome Indicators sub-group
CSA	Common Services Agency
CSBS	Clinical Standards Board for Scotland
CSO	Chief Scientist Office
ECCI	Electronic Clinical Communications Implementation
ECNO	Edinburgh Centre for Neuro-Oncology
ECT	Electroconvulsive Therapy
EHR	Electronic Health Record
EPR	Electronic Patient Record
ISD	Information and Statistics Division

GMC	General Medical Council
GP	General Practitioner
GPASS	General Practice Administration System for Scotland
HEBS	Health Education Board for Scotland
HIA	Health Impact Assessment
HIP	Health Improvement Plan
HMSO	Her Majesty's Stationery Office
HTA	Health Technology Assessment
HTBS	Health Technology Board for Scotland
OHM	Institute of Healthcare Management
IHM	Institute of Healthcare Management
I M & T	Information Management and Technology
IL-15	Interleukain 15
ISD	Information and Statistics Division
LHCC	Local Healthcare Co-operative
LMC	Local Medical Committee
MCN	Managed Clinical Networks
ME	Management Executive
MEL	Management Executive Letter
MONICA	Monitoring in Cardiovascular Disease
MRC	Medical Research Council
MRCGP	Member of the Royal College of General Practitioners
NHS	National Health Service
NHSiS	National Health Service in Scotland
NICE	National Institute for Clinical Excellence
NMDU	Nursing and Midwifery Practice Development Unit
NPAC	National Paramedical Advisory Committee
NPC	National Projects Committee
NSAIDS	Non-steroid Anti-inflammatory Drugs
OCR	Optical Character Reader
OPHIS	Office for Public Health in Scotland
PAMs	Professions Allied to Medicine
PCCIU	Primary Care Clinical Informatics Unit

PGEA	Postgraduate Education Allowance
PGGPE	Post Graduate General Practice Education
QAI	Quality Assurance Initiatives
QS	Quality Standards
RCGP	Royal College of General Practitioners
R & D	Research & Development
RQIA	Regional Quality Initiatives Advisers
RUHBC	Research Unit in Health and Behaviour
SAHC	Scottish Association of Health Councils
SASM	Scottish Audit of Surgical Mortality
SCALP	The Scottish Association for Cleft Lip and Palate
SCAN	Scottish Coronary Assessment Network
SCARC	Scottish Association of Health Councils
SCOTMEG	Scottish Health Management Efficiency Group
SCIMP	Scottish Clinical Information Management in General Practice
SCPMDE	Scottish Council for Postgraduate Medical and Dental Education
SEHD	Scottish Executive Health Department
SGPC	Scottish General Practitioner Committee of the BMA
SHARP	Scottish Heart Arterial disease Risk Prevention
SHERT	Scottish Hospitals Endowment Research Trust
SHIP	Summary Health Information Pages
SHOW	Scottish Health on the Web
SIGN	Scottish Intercollegiate Guidelines Network
SKIPPER	Scottish Key Indicators for Performance
SMR	Scottish Morbidity Record
SNAP	Scottish Needs Assessment Programme
SPACE	Scottish Practice based Accreditation in Clinical Effectiveness
SPCERH	Scottish Programme for Clinical Effectiveness in Reproductive Health
SPHSU	Social and Public Health Sciences Unit
SPICE PC	Scottish Programme for Improving Clinical Effectiveness in Primary Care
SPNA	Scottish Practice Nursing Association
SSBID	Scottish Stillbirth and Infant Death Survey
STAF	Scottish Telemedicine Action Forum

STAG	Scottish Trauma Audit Group
TIP	Trust Implementation Plan
WHO	World Health Organisation