

CLINICAL GOVERNANCE

Bulletin

Editorial: Innovations and new techniques

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Over the last 10 years, the delivery of health-care has undergone a major transformation. New technologies, techniques and therapies have revolutionised the way care is given; at the same time, patient safety has received greater attention. How can we meet the challenge of fostering both innovation and a culture of dynamic modernisation while ensuring that patient safety is not compromised? This requires a partnership between managers and clinicians, with medical and clinical directors working together to ensure that:

- parameters are set for the safe introduction and monitoring of new techniques;

- clinicians practise only in fields in which they have been properly trained and accredited;
- new techniques are evaluated and appropriate accreditation programmes developed.

This issue of CGB begins with W E G Thomas's overview of the issue of innovation and patient safety; other topics include research governance, quality assurance in the private sector, cancelled operations in orthopaedics and quality indicators in paediatrics. Future issues will revisit clinical audit and its benefits, as well as out-of-hours services. We are looking forward to receiving your contributions.

Fostering innovation without compromising safety

W E G Thomas

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There is a danger that the current litigious society in which medicine and surgery are practised could compromise the introduction of new and novel forms of therapy. Therefore there is a need to create an environment in which innovations can be encouraged without in any way endangering patient safety. The responsibility for the control of such innovative activity is both national

and local. Aspects of this control must include:

- the ethical aspects of any research project;
- the assessment of potential benefits to patient care of any new form of treatment;
- the assurance of clear informed consent;
- the careful audit of outcome.

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Unless all these are clearly addressed, the practitioner, the institution where the treatment is carried out and the NHS are at risk of litigation.

National process

The UK is the first country to have established a system of monitoring the introduction of new procedures. The National Institute for Clinical Excellence (NICE) requires all clinicians to report any new technique or procedure, following which a review of all relevant research literature relating to it is undertaken. Advice is taken from those deemed specialists in that sphere. The Interventional Procedures Advisory Committee considers the safety aspects of a new treatment and subsequently issues guidelines for its use, in particular regarding any specific restrictions or limitations. A similar process is followed for new technical advances, which are referred to the NICE Technology Appraisal Programme.

Following review, the introduction of any new procedure must be followed by careful audit of its outcomes, and if necessary the guidelines are modified. This process should allow innovation to prosper and yet prevent a cavalier approach to patient safety.

Local process

For the practical delivery of this programme, NICE depends on local arrangements and the careful execution of a local clinical governance

policy. Hospitals therefore must not only be aware of any new technique being used within the area of its responsibility, but also monitor, audit and control the introduction of any new techniques. Medical directors and clinical directors need to introduce local clinical governance policies that will encourage innovation but in a way that does not compromise patient safety. A process that is too cumbersome, too rigorous or too demanding in its restrictions will deter clinicians from innovative thinking and this will not be in the long-term interest of the clinical service or patient care. The clinical governance team of a trust should introduce a process that captures the information that will allow the clinical director to decide whether the new technique is in the patient's interest, is safe and is acceptable within NICE guidelines.

Appraisal form

In many trusts a form has been designed to enable clinicians to capture and report information relating to the introduction of new techniques, procedures, interventions, diagnostic equipment or pharmacological agents. Once completed, the form is sent to the clinical director, who will study the rationale for the innovation, why it is being introduced and how it would relate to the long-term development of the clinical service in his/her area of clinical responsibility. Therefore the appraisal document should cover such issues as the following:

- Is the development of proven benefit? An assessment of the relevant literature should be appended to the appraisal document and it should make reference to any systematic review. An evaluation of the new technique's cost-effectiveness is also desirable.
- What is the target condition or patient population? This should include an estimate of the numbers involved.
- Is there any information regarding the perceived need for this particular service? This should include an estimate of need both locally and nationally.
- What will be the effect on the existing service? Will the introduction of this new service, intervention or procedure have a negative or a positive effect on any existing service and will any other treatment of necessity be stopped as a result of introducing the new treatment?
- What will be the cost of introducing this new procedure? There may need to be assumptions made with regard to this, but as accurate an estimate and business plan as possible is required.
- What will the expected outcome measures be? What will be regarded as an appropriate or satisfactory outcome?
- Will there be any effect on other services or directorates? Any new technique that replaces an existing intervention provided by another directorate or clinical service will have a knock-on effect on that service.

Conclusion

The introduction of any new procedure, intervention or agent must of necessity be subject to close scrutiny. However, many operative procedures have never been subjected to randomised trials, and indeed it would now be impossible ethically to do so for many tried and tested therapeutic interventions. Although there is a desire to practise 'evidence-based medicine', many current operative procedures are not supported by such data. Nonetheless, the introduction of a new operation must be accompanied by clear evidence that the procedure will in all probability improve quality of care for the patient.

With most new techniques, there are commercial interests involved. However, it is important not to allow

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these to dictate the introduction, or the rate of introduction, of a new technique. Financial motives, although very strong, must not be the fundamental reason for introducing treatment options; nor should media or public pressure be the predominant factor. This tended to occur, for example, with the introduction of laparoscopic surgery in the early 1990s, and thus when certain problems arose the technique was saddled with a bad reputation. It has only been after careful audit, training and clear evidence of clinical benefit that these procedures have become widely accepted. If a careful

protocol had been followed for the introduction of such a new form of surgery, several patients would have been spared a great deal of suffering and the technique could have been introduced without the negative phase of public reaction. Ironically, it was early public pressure and commercial expediency that drove the process and this must not be allowed to happen again.

The introduction of any new interventional procedure must therefore be controlled within the bounds of clinical governance protocols that have been well thought through; the procedure must have been

clearly shown to be ultimately in the patient's best interest. However, we need to be mindful that innovative thinking is what drives the practice of medicine and surgery forwards. We must not stifle such progress, but at the same time we must not allow maverick clinicians or commercial interests to drive this process. Clear audit and national databases will help in the monitoring of the outcomes of new techniques, and should not only encourage innovative clinicians to continue to strive for excellence but also reassure the public that such innovations are being introduced in a safe and responsible manner.

Awareness of research governance within a district general hospital

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- Dissemination of information regarding key policies such as research governance, in large, complex health-care organisations is a challenge.
- Health-care organisations need to put in place appropriate systems to vet and register all research projects.
- The need to obtain ethical approval before research can start must be emphasised.
- Health-care organisations should consider assessing the effectiveness of their communication in the field of research and development.

There has been much discussion of both research governance and ethics with regards to research carried out involving humans in the UK¹. Much of this has considered the importance of gaining ethical approval and the time taken to do so². There is, however, potentially a more basic problem: some researchers do not seem to know that if their research involves access to NHS patients, samples, staff or premises, then they must seek ethical and trust approval before commencing. This is worrying and must be addressed as a priority.

In relation to the NHS, the Department of Health has produced a Research Governance Framework³.

NHS trusts have been required to produce a research governance local implementation plan (RGLIP) with Board approval to ensure the development of appropriate systems and controls. The RGLIP sets clear targets for the development of systems and capacity to ensure that the risk associated with research is assessed and managed.

Local experience

A key assumption is that NHS organisations can effectively communicate new policies and procedures with their staff. This is a challenge. For example, at Mid Essex Hospital Services NHS Trust (MEHT) (a district general hospital with a regional burns centre) there are approximately 4000 staff. How can the new way of doing things be disseminated and how does one assess whether the associated research governance has improved?

All NHS trusts are required to approve research before it goes ahead. At MEHT, it is policy that all proposed research involving the trust's patients, staff or premises is registered and reviewed, and research is not allowed to proceed without written trust approval from the Director of Research and Development (R&D). This policy is

in place to protect the participants, researchers and the trust, and has been disseminated through a variety of means (formal briefing of managers, letters to key staff and researchers, R&D newsletters and via the staff magazine) for over two years.

The registration process for research projects involves sending a completed form and accompanying documents such as the protocol, ethics application and ethics approval letter to the R&D Department. Project registration instructions and documentation are internally available in easy-to-access electronic format. The R&D Department provides assistance with the registration process if required.

Method

An exercise was carried out to assess the knowledge of MEHT staff in relation to research governance. A questionnaire was felt to be an effective way of gathering the required information because a larger number of people could be sampled anonymously. After piloting, the final version of the research questionnaire comprised three main sections:

- questions to allow the categorisation of the staff respondents;

- questions to assess their research awareness;
- space for comments.

A total of 369 questionnaires were sent out; there was no reminder letter. The sampling used three strata: those who had attended internal R&D training, researchers and others. This was to assess whether these groups had different levels of understanding of research governance. Awareness was assessed objectively through the number of correct or appropriate responses given by each respondent.

Results

The questionnaire was returned by 154 members of staff (a response rate of 42%): 29 had attended training, 46 were researchers and 79 were neither researchers nor had received training. There was no statistical difference ($P > 0.05$, ANOVA) in awareness of research governance between the groups who had been trained (mean score 7.3, 95% confidence limits, CFL, 6.5–8.2) and researchers (mean score 7.2, 95% CFL 6.3–8.0), but both these mean scores were significantly greater ($P < 0.001$, Bonferroni *post hoc* test) than that of the other group (mean score 4.7, 95% CFL 4.0–5.3). A breakdown for three key questions is given in Table 1.

It was noted that there was a significant relationship (linear regression, ANOVA, $P < 0.01$, $r^2 = 0.97$, $n = 4$ categories) between mean perceived level of awareness (good, mean 8.5, $n = 18$; moderate, mean 7.0, $n = 79$; poor, mean 4.4, $n = 40$ and not applicable, mean = 1.3, $n = 15$) and their objective scores.

The written comments were reviewed and the general picture was that staff considered approval for research to be too complex; further,

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while some thought that research was important, the majority reported that they did not have sufficient time to undertake it.

Discussion

To appreciate the implications of this survey in full, it is necessary to consider who the researchers are in this context. The Department of Health has defined research as a process to gain 'new generalisable information'. Research can, therefore, vary from randomised controlled trials of medicinal products to staff or patient surveys which NHS trusts are required to complete by the Department of Health. Consequently, research is carried out by a diverse range of staff, from clinical to those with administrative and clerical duties, and for a number of different reasons. It is perhaps not surprising that some staff do not identify with

the requirement for trust and ethical approval for a survey of staff attitudes, for example. (The questionnaire described in this letter was reviewed by the South Essex Local Research Ethics Committee and was approved by the MEHT.)

If the data obtained here are representative of other NHS trusts, then this reinforces the need for building research capacity for all categories of staff. Measures at MEHT to address the issues raised have included:

- letters to all researchers;
- the promotion of R&D training;
- a re-examination of our communication strategy.

If more organisations assessed the effectiveness of their R&D communication then this would benefit patients, researchers, NHS trusts and other research partner organisations.

Table 1. Percentages of three groups of staff responding affirmatively (correctly) to three key questions ($n = 154$)

	Non-researcher and untrained (n = 79)	Trained (n = 29)	Researcher (n = 46)
Were you aware that the trust has an R&D policy before reading this questionnaire?	80	100	85
Do all proposed R&D projects need approval by an appropriate research ethics committee?	53	79	72
Do all proposed R&D projects need trust approval issued by the Director of R&D?	49	83	72

References

- 1 Pattison J, Stacey R. Seeking a balance: response from the Department of Health and COREC. *British Medical Journal* 2004; 329:622
- 2 Wald SD. Bureaucracy of ethics applications. *British Medical Journal* 2002;329:282–4
- 3 Department of Health. *Research Governance Framework for Health and Social Care: Implementation Plan*. London: DoH, 2001. Available from: www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4008777&chk=dMRd/5

Quality assurance in a private hospital

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- Comprehensive quality assurance programmes must be clinically driven.
- Quality assurance programmes should include assessments of clinical outcomes.
- Hospital performance must be assessed at more than one level.

There are major differences between independent and NHS acute health-care provision in the UK. Although some 12% of all operations are performed in the independent sector (a figure which will increase dramatically as the NHS purchases more care in private hospitals) the range of service provision is comparatively restricted. There is a limited emergency component in the private sector, the service is consultant based, the information technology (IT) services are fully integrated, the management structure is slimmer and the service is not focused on nationally driven targets.

The Healthcare Commission plans convergence of standards and inspection between the private and public sectors¹. While approaches may have to be adjusted to account for some of the more obvious differences between the sectors, we believe that the programme we have developed has application in both settings.

Quality assurance programme

Our quality assurance (QA) programme has been put in place at the largest independent hospital in the UK, the Wellington in London. Unusually, but by no means uniquely, for the private sector the Wellington provides a range of tertiary services and is of a size comparable to a small district general hospital. However, staff numbers are different – 740 consultants hold practising privileges at the hospital.

Quality assurance programmes in health-care should be supported only if they increase clinical efficiency and demonstrate this with hard data and outcomes. Quality is not easily defined and there are many different perspectives on it (Table 1).

A quality assurance programme for a health-care institution must attempt to address all these aspects with relevance and validity. Our programme looks at both hospital and professional performance at different levels:

- broad generic indicators (e.g. unplanned returns to theatre, unplanned readmissions, in-hospital mortality);
- specialty-specific audits (e.g. those conducted by the British Cardiology Interventional Society);
- professional quality assurance led by the Medical Advisory Committee (MAC).

Some of these are statutory obligations required by the Healthcare Commission, which regulates all independent hospitals under the Care Standards Act 2000. Others are voluntary and have been developed with the help of the MAC and consultant staff.

Generic indicators

In common with many other independent hospitals in the UK, the Wellington Hospital supports the international Quality Improvement Project (QIP)², which provides sets of clearly defined clinical performance indicators. The hospital may choose which of these to use. The following are the core data-sets currently in use (and also defined within the national minimum standards):

- in-hospital mortality;
- perioperative mortality;
- unplanned returns to theatre;
- unplanned readmissions;
- unplanned transfers to another hospital;

- surgical site infections for specified procedures.

Others have also been adopted but are more specific to individual hospital services (e.g. day case patients who convert to overnight stay).

These indicators are not intended to be the basis for league tables but they allow for trend analysis and thus lead to a dynamic quality improvement programme.

Specialty-specific audits

Comparing hospital performance requires risk adjustment to address differences between both patient population and hospital provision. We therefore support a number of specialty-specific audits, at both a national and a more local level. This enables us to capture clinically rich data and provides valid feedback on our performance and outcomes. Some of the national audits that we support are:

- the Central Cardiac Audit Database (CCAD);
- the Intensive Care National Audit Research Centre (ICNARC);
- the Nosocomial Infection National Survey (NINS).

Other audits and measures function at a regional level (e.g. London Health Observatory for cardiac revascularisation) or at unit level (e.g. spinal unit reviews of surgical outcome). All these audits provide us with specific comparative outcomes and allow us to benchmark our performance. Patients are pleased to hear that infection rates are very low and that survival in the intensive

Table 1. Quality perspectives

Perspective	Area of interest in quality
Government	Regulatory compliance, cost-effectiveness, efficiency, transparency
Professional	Clinical effectiveness, technical perfection, consistently good clinical outcomes
Patient	Safety, individualised care, best personal outcome, expectations met, trust

care department is above average. Such questions are being increasingly posed by the public.

Professional quality assurance

The involvement of the medical staff is paramount in developing a good quality assurance programme that will demonstrably affect patients in a positive fashion. The MAC, together with the chief executive, must take the lead in engaging the consultant staff and specialist units. However, this is a participative process and nothing is imposed. Consultants are motivated by the feedback on outcomes and performance, and this has led to the development of specialty and multidisciplinary team meetings and the formation of specialist groups ('chambers').

Overall professional quality assurance is the responsibility of the chief executive, who is advised by the MAC. A clinical governance group involving ancillary staff, chaired by a consultant and with another lead consultant in clinical audit, is responsible for reviewing all deaths and clinical incidents.

The MAC itself has several functions:

- It recommends the granting of practising privileges for those who are able to demonstrate their com-

petence in their defined scope of practice. Demonstration of this competence requires professional references and performance information.

- It monitors performance via the audits outlined above and the reporting of adverse incidents. In addition, behavioural issues are considered (via complaints and incident reporting) and medical note keeping is audited on a rolling programme.
- It takes action when a significant event (critical incident, adverse outcome) occurs. Although this would usually relate to internal peer review, sometimes an external panel of experts (drawn from Royal Colleges or specialist societies) may be brought together to consider specific cases.

Such functions are now relatively commonplace in the independent sector. They provide the main protective mechanism for the patient and, because of the reliable clinical information and integrated IT systems, there is a rapid response time to incidents and complaints.

Conclusion

We have outlined a comprehensive quality assurance programme, which

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functions at both institutional and individual clinical level. This feeds into our clinical governance programme, which also encompasses our regulatory compliance.

This is a clinically driven programme, which arguably may be more achievable in the private sector, where there is a more focused range of services. It has been generated and continues to evolve because of the enthusiasm of the clinicians. A positive impact on patient outcomes is the hallmark of an effective programme.

References

- 1 See <http://consultation.healthcarecommission.org.uk/download/Assessment%20for%20improvement.pdf>
- 2 See www.ncl.ac.uk/qip

A study of cancelled operations in an orthopaedics department

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- An audit showed that most cancellations of orthopaedic operations were by the patients.
- All patient cancellations should be considered avoidable.
- Improved patient communication can reduce the number of cancellations.

Background

Cancellations of operations often make headlines. It is well known that patients can suffer inconvenience and distress when confronted with their operation being cancelled. There have been many

reported cases of people's health being affected by a delay in getting the treatment they require¹, but today hospitals are required to offer the patient a rescheduled operation within 28 days of the initial date, to avoid such complications. However, cancellations of operations will often result in wasted NHS resources, as theatre sessions may go unused², and will hinder reductions in operation waiting lists.

Department of Health figures³ show a rise in the total numbers of operations cancelled for non-clinical reasons, from 60,242 in 1999–2000 to 77,818 in 2000–01 and 81,743 in

2001–02. In an attempt to curtail this trend, the government launched an £8.5 million initiative in 2002, to pay for hospital management dedicated to reducing the number of cancellations⁴. More recent government figures have shown cancellation rates at 67,254 for the year 2002–03 and 66,303 for the year 2003–04.

The study reported here took a detailed look at operations cancelled in the orthopaedics department of a district general hospital. Doctors analysed their own department's data to see whether recommendations for improvement in this area could be made.

Method

Audit 1

Initial data were collected retrospectively, from the Critical Care Directorate, for operations performed or cancelled over the 13 months from 1 October 2001 to 31 October 2002 in the Orthopaedics Department. The cancellation data had previously been recorded by the Critical Care Directorate at the time of each cancellation. The data included the type of operation (day surgery, elective, trauma or emergency), the date and the reason for the cancellation.

We then categorised each of the cancellation records into one of the following broader categories:

- hospital reasons;
- clinical reasons;
- patient cancellation.

After these initial findings were analysed, a report with recommendations was presented to the Orthopaedics Department and two of the recommendations were implemented.

Audit 2

Fifteen months later, a further sample set of six months' cancellation data was obtained and compared with the initial data from Audit 1, to see whether the implementation of the recommendations had reduced the operation cancellation rates. The comparison was based on a 12-month data sample, after the 13-month data sample (Audit 1) and 6-month data sample (Audit 2) had been accordingly adjusted.

Results

Audit 1

The initial 13 months of operation cancellation data revealed that one in six (16%) of all operations scheduled were cancelled (545 cancelled out of 3390 scheduled). The proportion of operations cancelled rose from 14% (38 in 277) in the initial month, October 2001, to 29% (88 in 300) in the final month, October 2002.

The data were grouped by three main categories of cancellation (Table 1):

- hospital reasons – 227 (42% of total cancellations);
- clinical reasons – 186 (34% of total cancellations);
- patient reasons – 112 (21% of total cancellations).

Table 1. Audit 1: operation cancellations over 13 months

Reason for cancellation	Number of cancellations
<i>Hospital reasons (n = 227)</i>	
Rescheduled	105
No beds in ward	53
Session overran	37
Administrative error	17
Cancelled after arrival	8
Surgeon or anaesthetist not available	5
Food or drink on ward	2
<i>Clinical reasons (n = 186)</i>	
Unfit for anaesthetic	93
Unfit for surgery	39
Operation not necessary	37
Cancelled at pre-assessment	9
Cancelled by consultant	5
Laceration on operation site	3
<i>Patient reasons (n = 112)</i>	
Patient cancelled	32
Did not arrive	22
Refused operation	16
Rescheduled	12
Did not attend pre-assessment	9
Sick (self-certified)	6
Holiday	6
Work	5
Food or drink	3
Unprepared	1

Twenty records (4% of total cancellations) did not have sufficient data to classify the reason for cancellation.

Cancellations due to bed shortages, included in the 'hospital reasons' category, made up 53 of the 545 cancellations (10%). In October 2001, 12 out of 277 operations (4%) were cancelled due to bed shortages, but by October 2002 this problem had been resolved, and the rate had fallen to 1 in 300 (<1%).

Recommendations and implementations following Audit 1

Hospital management will always have the complex task of juggling overstretched resources to meet demand, and clinical reasons for cancelling operations are often unavoidable. The recommendations in these areas were:

- to implement realistic operation scheduling;

Table 2. Audit 2: operation cancellations over follow-up 6 months

Reason for cancellation	Number of cancellations
<i>Hospital reasons (n = 69)</i>	
Rescheduled	42
No beds in ward	0
Session overran	12
Administrative error	10
Cancelled after arrival	1
Surgeon or anaesthetist not available	1
Food or drink on ward	2
Instruments not available	1
<i>Clinical reasons (n = 57)</i>	
Unfit for anaesthetic	29
Unfit for surgery	10
Operation not necessary	11
Cancelled at pre-assessment	4
Cancelled by consultant	3
Laceration on operation site	0
<i>Patient reasons (n = 24)</i>	
Patient cancelled	8
Did not arrive	12
Refused operation	1
Rescheduled	0
Did not attend pre-assessment	0
Sick (self-certified)	2
Holiday	0
Work	0
Food or drink	1
Unprepared	0

- to have dedicated resources for trauma and emergency operations;
- to organise hospital routines so that an operation was scheduled only after the patient had been assessed as fit for anaesthetic and surgery.

After the initial audit, the process of booking patients in for emergency operations only after clinical assessment was implemented. In addition, preoperative clinical assessment at 12 weeks was implemented, for elective surgery, before the operation was booked.

A significant finding was that 21% of cancelled operations were related to the patient, all of which could be seen as avoidable if there had been better communication with patients. During the period following Audit 1, patient communication was improved as a result of the 12-week

pre-assessment, since the patient would have the chance to discuss the operation date, to ensure that it was convenient, and also to make sure that any worries were addressed.

Audit 2

The follow-up audit (six months of operation cancellation data) was undertaken 15 months later, after the changes had been implemented. It showed operation cancellations at a rate of 1 in 11 (150 cancelled out of 1639 scheduled).

The data were again grouped by the three main categories of cancellation (Table 2):

- hospital reasons – 69 (46% of total cancellations);
- clinical reasons – 57 (38% of total cancellations);
- patient reasons – 24 (16% of total cancellations).

Comparison of Audits 1 and 2

The annual cancellation rates (data adjusted to 12 months) were calculated from the two data-sets and compared (see Tables 3 and 4). Overall, there had been a 42.9% drop in the operation cancellation rate.

Each category of cancellation had seen a drop in cancellation rates. Hospital cancellations saw a 38% drop in cancellations, mostly due to the resolved problem of 'No beds in ward', which had already seen an improvement at the end of the first audit period. Clinical cancellations saw a 33% fall, as a result of the earlier clinical assessment of patients before booking them in for an operation. Patient cancellations were reduced by 54%, as a result of the improved patient communication.

Discussion

The issue of patient cancellations is a topic that has previously been highlighted by the press in relation to missed appointments with general practitioners⁵, although it is a topic that appears to have been neglected in discussions about cancelled operations. All patient cancellations should be looked upon as avoidable. At least an operation that is rescheduled to make way for an emergency case does not result in a wasted theatre session. However, when a patient cancels at the last minute, the theatre session, with all its paid for resources, will often go unused, as it can be difficult to find

Table 3. Comparison of the annual (adjusted) rates of operation cancellation between the two audits

	Audit 1	Audit 2	% change
Operations scheduled	3129	3278	+4.8%
Operations performed	2626	2978	+13.4%
Operations cancelled	503	300	-40.4%
Cancellation rate	1 in 6 (16.1%)	1 in 11 (9.2%)	-42.9%

Table 4. Comparison of annual adjusted rates of operation cancellation, by category, between the two audits

	Audit 1	Audit 2
<i>Hospital reasons</i>		
Total	210	138
Rescheduled	97	84
No beds in ward	49	0
Session overran	34	24
Administrative error	16	20
Cancelled after arrival	7	2
Surgeon or anaesthetist not available	5	2
Food or drink on ward	2	4
Instruments not available	0	2
<i>Clinical reasons</i>		
Total	171	114
Unfit for anaesthetic	86	58
Unfit for surgery	36	20
Operation not necessary	33	22
Cancelled at pre-assessment	8	8
Cancelled by consultant	5	6
Laceration on operation site	3	0
<i>Patient reasons</i>		
Totals	105	48
Patient cancelled	30	16
Did not arrive	20	24
Refused operation	15	2
Rescheduled	11	0
Did not attend pre-assessment	8	0
Sick (self-certified)	6	4
Holiday	6	0
Work	5	0
Food or drink	3	2
Unprepared	1	0

In Audit 1, 20 (4%) of the operations did not have sufficient data to classify the exact reasons of cancellation and are therefore not included here; in Audit 2, all operations cancelled were categorised.

a replacement operation at short notice.

One suggestion to resolve the issue of missed appointments with general practitioners was to introduce fines for the offending parties⁶. A similar approach could also be applied to the case of missed operations. Another idea is to introduce a system whereby a patient pays a deposit on booking an operation, which would be refunded on arrival for the operation. However, the introduction of an element of punishment for the patient would surely result in a decline in

relationships between patients and practitioners. If the NHS were to fine the public for cancelled operations, it would most certainly be faced with an increase in law suits over its own shortcomings.

Before patients are blamed for cancellations, health services should look at the way they communicate with patients as a first step to reducing the rate.

A study entitled 'What patients really think of the NHS' by KPMG Consulting, based on interviews with a sample of 2012 adults in

February 2002, reported that one in 12 respondents admitted to a missed outpatient appointment in the previous five years, many of whom simply forgot⁷. In the report, KPMG recommend the introduction of a national best practice of pre-appointment reminders by post, telephone, email or text message.

As patients embark on a course of treatment, which could be a frightening experience, a friendly point of contact, easily accessible and able to discuss any concerns in the run-up to the operation, could make all the difference. As in a number

of other areas in medicine, good communications would seem to be paramount in running an efficient, effective and satisfactory service.

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Development of indicators of clinical quality in a paediatric setting

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- A clinical indicator is a means by which the quality of health-care services can be understood and improved.
- In the paediatric setting, relatively few clinical indicators have been established.
- The development of clinical indicators can be facilitated by considering measures of quality in terms of patient experience, physical measures of outcome, and measures of process.
- In conjunction with the National Clinical Governance Support Team, the development of clinical indicators has been piloted in a large specialist children's NHS trust.
- For the full commitment of clinical teams, the emphasis must be on the use of clinical indicators to support service improvement.

Background

An essential component of effective clinical governance is the ability to innovate and make continuous improvements to the quality of patient care. To identify where service improvement is necessary, and then monitor and assess the effectiveness of change, it is important that there is both a clear understanding of what 'quality' means and a mechanism for measuring it.

The concept of indicators of clinical quality (henceforth referred to as clinical indicators) is becoming an important feature of the way in which NHS services are to be monitored.

In some adult-based services, for example neurology and neurosurgery, meaningful clinical indicators have been developed and are used as a tool with which to monitor and improve services¹. By contrast, few such indicators have been developed in services for children and young people. The recent Green Paper *Every Child Matters: Change for Children* includes an outcomes framework² that might be used as the basis for high-level indicators that relate to a range of services for children and young people, including health-care. However, these indicators are more relevant to public health than to providers of acute, secondary and tertiary services. This article describes work carried out to date at Royal Liverpool Children's NHS Trust towards the development of clinical indicators for children's and young people's services.

The overall vision is to develop a series of paediatric clinical indicators to use both as a means for improving services and as a mechanism for objectively demonstrating the quality of services. Specific objectives include:

- the development of 5–10 clinical indicators in two pilot specialty areas;
- the identification of core clinical indicators that can be used in most specialties.

Method

The project team

The work was carried out in collaboration with the National Clinical Governance Support Team, and was led by a steering group comprising:

- consultants in paediatric surgery, paediatric gastroenterology and paediatric accident and emergency medicine;
- a nurse specialist;
- a physiotherapist;
- the clinical governance lead;
- the information manager.

The specialties selected as pilot sites for the work were gastroenterology and accident and emergency, and the programme of work was guided by facilitated events with the relevant clinical teams and the steering group.

The process

The process is outlined in Figure 1. The first step was to identify the key patient groups. For each pilot

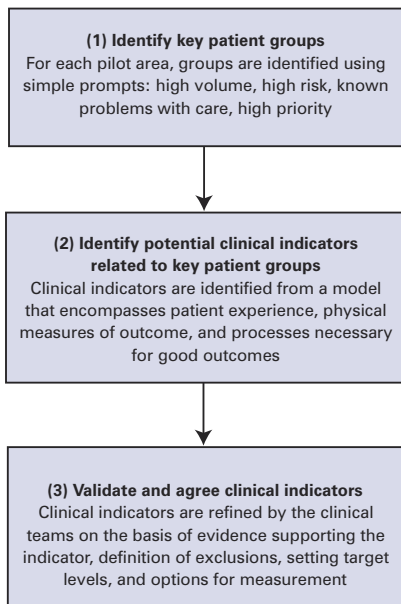


Figure 1. The process of developing the clinical indicators.

area, this was done by using simple prompts:

- high volume;
- high risk;
- known problems with care;
- high priority.

The second step was to identify potential clinical indicators related to these key patient groups. These were developed on the basis of a model (Figure 2) for clinical indicators that encompasses three dimensions of outcomes of care: patient experience, physical measures of outcome, and processes necessary for good outcomes. The model accounts for variation between specialties in the ease of definition of indicators across the three dimensions.

The third step was to validate and agree clinical indicators. Proposed clinical indicators were then refined by the clinical teams to produce a final list. The criteria for refinement included:

- evidence supporting the indicator (e.g. research, expert opinion);
- definition of exclusions;
- setting target levels where appropriate;
- options for measurement.

Results and lessons learnt

The model and materials used for the generation of clinical indicators facilitated the development of 10 indicators in accident and emergency

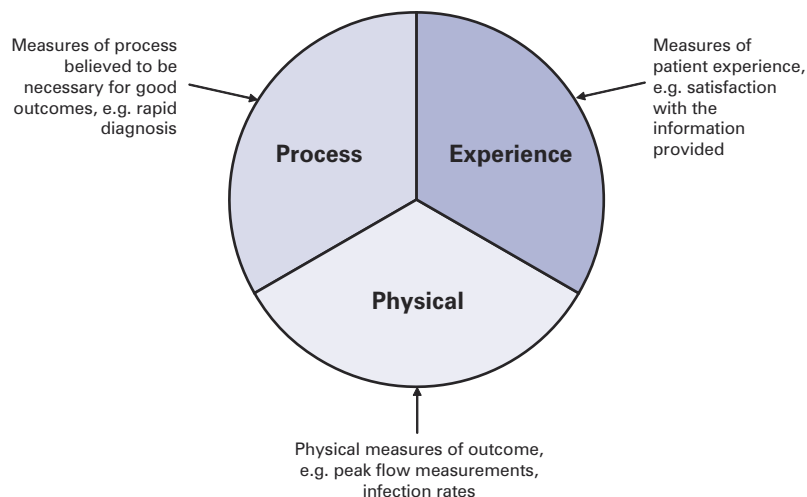


Figure 2. Dimensions for measures of clinical indicators of quality. The model is general and applies to medical as well as surgical specialties, for example.

paediatrics and six indicators in paediatric gastroenterology. An example of an agreed clinical indicator within accident and emergency care is shown in Table 1. The clinical teams involved were supportive of the model and method employed in this programme of work, and further specialty teams will be engaged in the process. The steering group attempted to use the model to identify trust-wide clinical indicators (applicable to many specialties) with limited success. Trust-wide clinical indicators may emerge from

a bottom-up approach, where there is congruence across several clinical specialties, as opposed to the use of a top-down method.

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Table 1. Example of clinical indicator measurement matrix developed for analgesia for cases of paediatric trauma

Element of matrix	Target/means of measurement
Short description	Percentage of trauma patients with a pain score of ≥ 3 at presentation who receive appropriate analgesia within 20 minutes
Reason for this indicator	Standard set by British Association for A&E Medicine Clinical Effectiveness Committee
Full indicator description	100% of children who present with a pain score of ≥ 3 should be offered appropriate analgesia within 20 minutes of pain assessment
Definitions	Trauma patients not on trauma sheet (level 3) Appropriate analgesia as specified in departmental guidelines
Target	100%
Measurement method	Patient identified from hospital information system with trauma code and pain score ≥ 3 Time of prescribed analgesia entered on to database and retrieved by pain team audit clerk
Sample	50 patients
Frequency of measurement	Twice yearly
Additional actions	Increase awareness of clinical indicators in pain team and department Suggest concurrent information about number of patients not having pain score entered but with evidence of moderate pain from audit of senior house officers

Is there clinical governance after the new GP contract's Quality and Outcomes Framework?

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- Rushcliffe Primary Care Trust has an established and effective quality programme for general practice that has a five-year track record.
- The new General Medical Services (nGMS) contract introduces a Quality and Outcomes Framework with financial incentives to encourage practice participation.
- Comparison between the clinical governance framework and the Quality and Outcomes Framework highlights the continued need for an all-embracing quality framework.

Background

A successful quality programme has been established in the 18 general practices in Rushcliffe Primary Care Trust (PCT) over the past five years, consisting of interdependent elements to support a cycle of continuous improvement (see Figure 1):

- a locally developed clinical governance (CG) matrix, which serves as a framework to facilitate and map quality development¹;
- quarterly meetings of a multi-professional, multi-practice quality improvement forum to share good practice, influence the local quality agenda and develop the framework;
- self-assessments and practice non-reciprocal 'buddy' visits to review progress against the matrix and enable practices to share experience and provide mutual support and learning.

Practice assessments against the Rushcliffe CG matrix have demonstrated year-on-year progress in quality development, identified good practice and highlighted areas for further development for practices and the PCT.

The new GP contract

The new General Medical Services (nGMS) contract for general prac-

tice, implemented in April 2004, includes a Quality and Outcomes Framework (QOF) to measure achievement (scored in points) against quality standards. Practices agree an annual point score against four domains – clinical, organisational, additional and patient experience – which enables them to secure income based on the number of points achieved in addition to their global sum. This involves an annual visit by a PCT visiting team consisting of a clinician (usually a GP), PCT QOF lead and lay person.

The QOF is a substantial and detailed framework and although participation is voluntary, practices derive a substantial part of their income via the QOF. This will ensure practices participate and invest effort and resources to achieve the points to which they aspire.

Clinical governance and the QOF

A strong focus on the QOF as a cornerstone of the new contract has created some confusion over the continuing relevance of existing clinical governance systems. Detailed exami-

nation, however, reveals that much of the QOF concentrates on outcome measures and does not support the development of quality 'systems and processes'. Comparison of Rushcliffe's CG matrix with the QOF (Figure 2) confirms that clinical governance is a much broader, all-embracing framework and there is a danger that important aspects of quality could be neglected if the QOF is seen as the definitive quality framework for general practice.

There is clearly a continued need for a framework to support the development of systems and processes to enable the delivery of outcomes and to promote the fundamental principles of clinical governance. This is reflected in the contractual and statutory requirements of the nGMS contract for practices to have an effective system of clinical governance². This is a system over and above the QOF, indicating that the QOF does not replace the statutory duty of clinical governance placed on practices as organisations that provide patient care in the NHS³ and allowance is made within the global sum for protected time to support activities such as clinical governance.

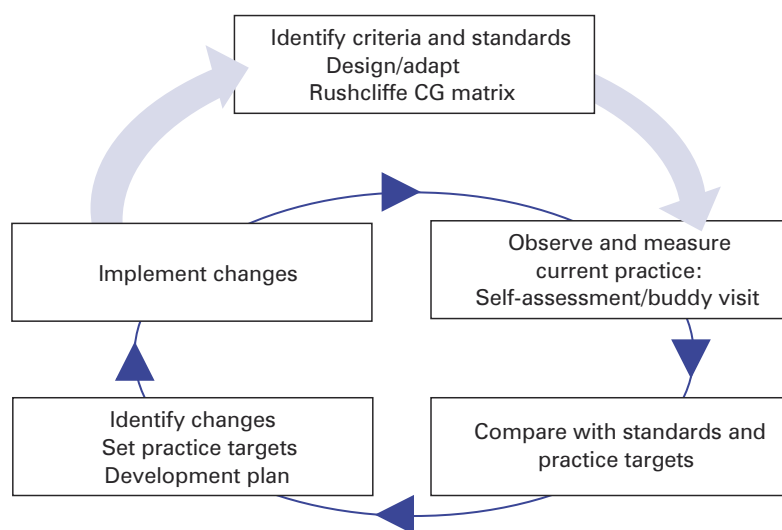


Figure 1. Diagram illustrating the Rushcliffe cycle of continuous improvement for general practice. © 2005 Rushcliffe PCT.

The QOF provides new and substantial financial incentives for practices. The challenge for PCT governance teams is how to continue to engage and convince practices that clinical governance is a much broader responsibility that deserves and demands continued development at a time of competing priorities.

CG matrix review

Consistent with the principles of the clinical governance matrix as part of a cycle of continuous improvement (see Figure 1), review of the matrix was required to support the nGMS contract and other new priorities, for example GP appraisal and revalidation. In consultation with practices a new version of the Rushcliffe GP CG matrix has been produced.

Direct overlaps between the CG matrix and QOF have been identified and cross-referenced; where overlaps exist these have been checked and amended to ensure consistency between the two. To exclude overlaps from the matrix would have caused fragmentation and loss of coherence.

Clinical governance and QOF review visits

With the introduction of annual QOF review visits to confirm practice activity as part of the nGMS contract monitoring arrangements, practices expressed concern about the number of visits that they have to prepare for and be involved with. It was apparent, however, that local GPs valued the collaborative approach of the clinical governance buddy visits established in Rushcliffe over the last few years, and expressed a desire to continue to have contact with local clinicians.

The quality cycle has been extended from two to three years, to provide more realistic timescales for practices to make progress on their CG development plans and enable some streamlining of future clinical governance buddy visits and QOF review visits. Some integration of the clinical governance and QOF review visits in year 3 should be practicable, as the QOF review process will be well established and more focused.

There is clinical governance after QOF!

The QOF is a substantial and detailed quality framework for

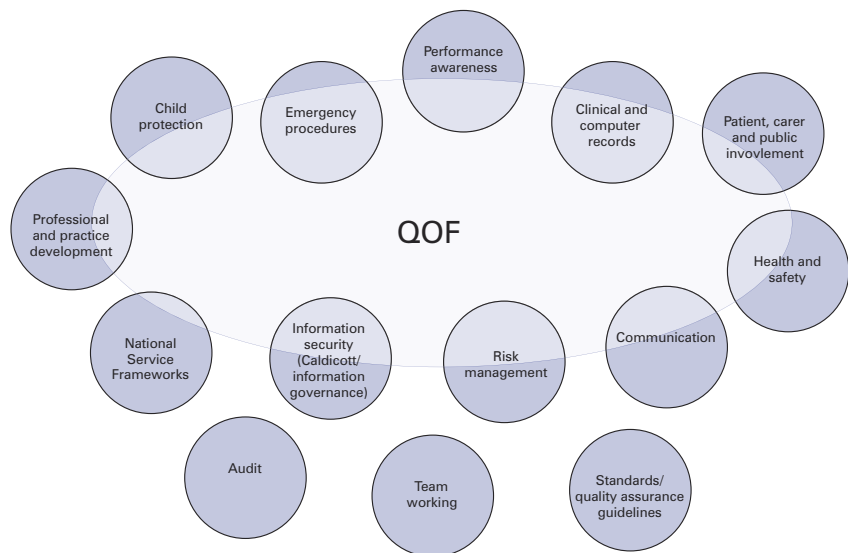


Figure 2. Diagram illustrating the direct overlaps between the categories in the Rushcliffe clinical governance matrix (small circles) and the standards in the nGMS contract's Quality and Outcomes Framework (QOF) (large oval). Audit, for example, falls outside the QOF. © 2005 Rushcliffe PCT.

general practice driven by financial incentives. However:

- participation is voluntary;
- it does not support many important aspects of quality development;
- participation in clinical governance remains a contractual requirement for practices.

The Rushcliffe CG matrix and quality programme established over the last five years continues to be relevant, supporting the breadth of the quality agenda in practices, including the development of systems and processes, such as the QOF and other national and local priorities.

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