Methodological issues in the use of guidelines and audit to improve clinical effectiveness in breast cancer in one United Kingdom health region

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Aims: To develop a system to improve and monitor clinical performance in the management of breast cancer patients in one United Kingdom health region.

Design: An observational study of the changes brought about by the introduction of new structures to influence clinical practice and monitor change.

Setting: North Thames (East) Health region, comprising seven purchasing health authorities and 21 acute hospitals treating breast cancer.

Subjects: The multi-disciplinary breast teams in 21 hospitals and an audit sample of 419 (28%) of the breast cancer patients diagnosed in 1992 in the region.

Interventions: Evidence-based interventions for changing clinical practice: regional guidelines, senior clinicians acting as ‘opinion leaders’, audit of quality rather than cost of services, ownership of data by clinicians, confidential feedback to participants and education.

Outcome measures: Qualitative measures of organizational and behavioural change. Quantitative measures of clinical outcomes compared to guideline targets and to results from previous studies within this population.

Results: Organizational changes included the involvement, participation of and feedback to 16 specialist surgeons and their multidisciplinary teams in 21 hospitals. Regional clinical guidelines were developed in 6 months and the dataset piloted within 9 months. The audit cycle was completed within 2 years. The pilot study led to prospective audit at the end of 2 years for all breast cancers in the region and a 15-fold increase in high quality clinical information for these patients.

Changes in clinical practice between 1990 and 1992 were observed in the use of chemotherapy (up from 17–23%) and axillary surgery (up from 46–76%).

Conclusions: The approach used facilitated rapid change and found a balance between local involvement (essential for sustainability within a hospital setting) and regional standardization (essential for comparability across hospitals). The principles of the approach are generalized to other cancers and to other parts of the UK and abroad.

Key words: breast cancer; audit; guidelines; cancer registry; changing practice.
Introduction

Within the UK, one of the recommendations of the national Expert Advisory Group on Cancer (EAGC) in 1995 was that health purchasers should develop cancer-specific contracts as part of a re-organization and improvement of cancer services, aiming to provide uniform care for all patients and to improve survival. Contracts should include guidelines for the management of the cancer and measures for assessing the performance of cancer units. Guidelines and performance indicators were not used systematically at that time, nor were data suitable for measuring performance collected systematically. There were various sets of guidelines covering different aspects of care, for screened and symptomatic breast cancer. Evidence-based guidelines for breast cancer were published in the following year, 1996, by the Clinical Outcomes Group (COG) of the UK Department of Health.

Improving the quality of care of cancer patients requires not only commitment to high standards but also measurement against the standards and implementation of changes in clinical practice. In this study we set out to develop a system which would be capable of improving practice across a UK administrative health region with 3.8 million population, which would monitor changes in practice against performance targets, and which would also be achievable and sustainable within the resource-limited health service.

There is a considerable body of published evidence on the factors which facilitate change in clinicians’ practices. Our system to improve clinical performance aimed to incorporate these: the effective factors are guidelines which are local rather than national, involvement and ownership by the clinicians, awareness-raising through education, respected senior colleagues as opinion leaders, regular feedback of results to clinicians and an overall emphasis on quality rather than cost of care. Consumer pressure may be also effective. To ensure comparability across the hospitals in the region, the measurement of clinical performance had to be based on a standard dataset. The cancer registry was used as the central coordinating point, partly because of its neutral position in the health service market, but mainly because cancer registries have experience in the conduct of population-based audits for common cancers in the UK, across Europe and in the USA. Retrospective audits of breast cancer management have demonstrated variations in treatments and outcomes between hospitals and surgeons, for patients diagnosed between 5 and 15 years ago.

Materials and methods

The study commenced in 1994. The regional Cancer Registry (Thames) data showed that about 2000 new breast cancers were diagnosed annually in the regional population-base of 3.8 million people in North Thames East region. Treatment took place mainly in 21 hospitals, including seven screening centres and three non-screening University hospitals and numerous other small units, including many private clinics. There were more than 80 surgeons operating on breast cancer patients. The system for improving and monitoring clinical practice comprised seven elements as follows.

The steering group

The work was steered by a professor of surgery with a specialist interest in breast cancer (IT), who chaired the Clinical Advisory Board described below, and two representatives of health care purchasing bodies (IB, AP). Three health service researchers at the Cancer Registry set up and co-ordinated the study.

Clinical Advisory Panel

A multidisciplinary Clinical Advisory Panel developed regional clinical standards for the management of breast cancer. The Panel was broad-based with 19 members, comprising consultant clinicians, nurses and other health professionals representing all aspects of the hospital-based breast cancer services: radiology, surgery, pathology, oncology and patient support.

Guidelines

Regional clinical guidelines were based mainly on existing national guidelines and authoritative evidence, and fully referenced. National UK guidelines for the management of breast cancer were reasonably well developed by 1994 particularly through the national Breast Screening Programme (BSP). There were published surgical guidelines from the King’s Fund, the British Association of Surgical Oncology (BASO) and the British Breast Cancer Group. There was guidance on oncology from the Joint Council for Clinical Oncology and the Lancet overview; and on patient support. National guidelines were then only partially evidence-based; the truly evidence-based breast cancer guidelines from the Clinical Outcomes Group were not available until 1996.

The Clinical Panel was divided into subgroups for each speciality and set quantifiable targets based on findings from previous studies and the clinicians’ assessment of current performance (see Surgical Guidelines in Table 1; the minimum target was intended to be achievable, the ideal was the goal to be reached ultimately).

Over a 3 month period, the Panel took the guidelines and targets through three cycles of discussion, amendment and re-circulation, the guidelines were then considered to be a pragmatic consensus view. The Panel members were reminded of the research evidence at each stage. Some issues on which there was no consensus, such as the need for axillary node surgery were excluded because while there was a BSP standard, there was no comparable BASO guideline for symptomatic disease. The final draft version of the regional guidelines is available from the authors.

The draft guidelines were widely discussed with surgeons with a special interest in breast cancer, through professional educational structures, district seminars and regional conferences.
### Table 1. North Thames East R&D study of breast cancer management

<table>
<thead>
<tr>
<th>Draft Standards: Surgery*</th>
<th>Minimum</th>
<th>Ideal</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Referrals from GP</td>
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<tr>
<td>a. Women attending for diagnostic purposes will be seen at a breast clinic and at least once by a consultant (or a senior registrar) with expertise in breast disease*</td>
<td>90</td>
<td>100</td>
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<tr>
<td>b. All women should have access to a consultant with expertise in breast disease</td>
<td>100</td>
<td>100</td>
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<tr>
<td>2. Waiting time for outpatient appointments</td>
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<tr>
<td>a. New referrals will be seen within 14 working days</td>
<td>50</td>
<td>75</td>
</tr>
<tr>
<td>b. Urgent referrals will be seen within 7 working days</td>
<td>75</td>
<td>90</td>
</tr>
<tr>
<td>3. Clinical standards—diagnosis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>a. Diagnosis will be via a Triple Assessment (clinical assessment, radiology and cytology)*</td>
<td>80</td>
<td>90</td>
</tr>
<tr>
<td>b. Women with a palpable abnormality will be given a diagnosis and treatment plan within 10–14 working days of the first outpatient appointment</td>
<td>50</td>
<td>90</td>
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<tr>
<td>c. Patients who have newly diagnosed breast cancer should have at least a second attendance in which the surgeon should discuss diagnosis and treatment options with the patient</td>
<td>80</td>
<td>100</td>
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<tr>
<td>d. Diagnosis and treatment options should be discussed in the presence of a Breast Care Nurse</td>
<td>50</td>
<td>100</td>
</tr>
<tr>
<td>e. Management should be determined by a multi-disciplinary diagnostic group (cytologist, radiologist, surgeon) prior to treatment</td>
<td>50</td>
<td>100</td>
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<tr>
<td>4. Surgery</td>
<td></td>
<td></td>
</tr>
<tr>
<td>a. Women with a diagnosis of breast cancer will be admitted for surgery within 14 days after being informed of the need for surgical treatment</td>
<td>90</td>
<td>95</td>
</tr>
<tr>
<td>b. A Specialist Breast Surgeon consultant will perform or closely supervise surgery*</td>
<td>50</td>
<td>90</td>
</tr>
<tr>
<td>c. In breast conserving surgery, cavity wall biopsies should be performed to provide evidence of complete excision</td>
<td>75</td>
<td>100</td>
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<tr>
<td>d. Women with invasive tumours less than or equal to 15 mm in diameter (pathological measurement) should be treated with breast conservation; Mastectomy may be advisable for large tumours (&gt;4 cm), central tumours, multicentric tumours, small breasts or if the patient wishes it</td>
<td>–</td>
<td>90</td>
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<tr>
<td>e. If node sampling is performed, no less than 3 lymph nodes will be sampled. If axillary clearance is performed, no less than 8 lymph nodes will be excised</td>
<td>–</td>
<td>95</td>
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<tr>
<td>f. Post operative complication rate should be low</td>
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<td></td>
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<tr>
<td>*Wound infection, haematoma</td>
<td>40</td>
<td></td>
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<tr>
<td>*Seroma rate &lt;20</td>
<td></td>
<td></td>
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<tr>
<td>*Lymphoedema &lt;5</td>
<td></td>
<td></td>
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<tr>
<td>g. Women will be seen by a Breast Care Nurse during admission for surgery</td>
<td>90</td>
<td>100</td>
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<tr>
<td>5. Post-operative follow-up</td>
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<tr>
<td>a. Cases will be reviewed by a multi-disciplinary group (Surgeon, Radiotherapist, Pathologist) prior to follow-up, to confirm the diagnosis and discuss further management</td>
<td>50</td>
<td>100</td>
</tr>
<tr>
<td>b. Women will be reviewed in a dedicated multi-disciplinary combined Clinic (Surgeon and Oncologist/Radiotherapist) within 10–14 days of discharge, to consider adjuvant therapy</td>
<td>50</td>
<td>95</td>
</tr>
<tr>
<td>c. Women will be seen at the first follow-up Clinic with a Breast Care Nurse</td>
<td>50</td>
<td>100</td>
</tr>
<tr>
<td>d. There should be opportunity for patients to have reconstructive surgery</td>
<td>80</td>
<td>100</td>
</tr>
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### Clinical involvement and ownership

Wide clinical involvement was facilitated by the NHS Breast Screening Quality Assurance networks: surgical, radiological, pathology and nursing networks existed in the region. Sixteen breast surgeons were the nominated contacts for the 21 acute hospitals. There were 21 breast specialist nurses involved and 11 histopathologists. (The pathologists were asked to ensure complete registration of breast cancers in their Hospital Units, before the sample for audit was taken). The surgeons and nurses facilitated the audits and helped to develop the guidelines.

### Measurement and audit

The audit set out to measure practice and services against the guideline standards. The guidelines covered three areas: (a) the clinical management of individual patients, (b) infrastructure—the organization and facilities of the unit and (c) patient support. Three different surveys were used to collect these data. The sources of these data were, respectively, the patients’ case-notes, interview with the breast surgeon and a postal survey of the specialist nurses. The forms for the first survey, Clinical Management, were developed from clinical audit forms in use in individual hospital units and the form used in the Eurocare study.1422

The pathology page was based directly on the Breast Screening Pathology Form already in use by laboratories. The forms were tested on five sets of patients’ case-notes. Ethical permission was obtained from the nine district Research Ethics Committees, seven of whom passed the study on Chairman’s action without committee discussion. The Clinical Management audit was piloted in 1994–95 using a retrospective sample of patients diagnosed in 1992.
A stratified design was used to explore differences between hospital types. A stratified random sample of all patients diagnosed in 1992 in the area was taken. A sample size of 50 patients in each strata was required for a statistical power of 80% to detect differences of 20% between hospital types, with a 95% significance level. Hospitals were categorized by type, according to volume (or caseload), that is the total number of new breast cancer patients diagnosed in 1992 and registered at the cancer registry. There were four categories of hospital volume: high (>99 patients per year), medium (50–99), low (11–49) and very low (<10). The (three) non-screening University hospitals were considered as a separate category because of their research activity and different case-mix.

For each patient in the random sample, data were abstracted from hospital case-notes by two researchers from the cancer registry and input to a central database. The data analysis comprised a comparison between the regional guideline targets and actual care and services in the region, according to hospital type.

The infrastructure survey collected the organizational information about the breast units using a semi-structured interview with the breast surgeon. The questions covered team working, facilities, manpower, protocols and equipment of the breast units. The third survey on Patient Support utilized a postal questionnaire which was developed in collaboration with a small group of nurses and sent to all the breast care nurses. Both these surveys were carried out in 1995.

**Feedback of audit results**

Clinical audit data were collected from the case-notes by researchers from the Cancer Registry and collated centrally for analysis. Comparative results by anonymized hospitals were produced and fed back to all participating surgeons. An example is given in Figure 1. Discussion was encouraged both informally and through local and regional conferences.

**Educational outreach**

The study design included one-to-one contact with individual participants in the Trusts to inform and educate them about the rationale and conduct of the study, in order to encourage participation initially and to close the audit loop finally. The study team visited each of the 21 hospitals and contact surgeons at least once, and most several times, during the 1-year study period. These visits maintained involvement and dialogue, and facilitated data collection.

**Results**

The changes observed during the study period were both organizational and clinical. While the organizational changes were directly attributable to the study, the causality of the clinical changes cannot be established because the study interventions were not randomized.

**Organizational change**

The study facilitated quite rapid change in the region’s ability to monitor treatment outcomes against guidelines in a comparable way across the hospital units. The initial structures—Clinical Advisory Panel and collaboration between the breast care teams and the cancer registry—enabled measurement and audit to be tested right through the audit cycle within 2 years. Regional draft standards were drawn up by the Clinical Advisory Panel within 6 months, a standard dataset was defined and agreed within 9 months; data collection in Units, data analysis centrally by the Registry, and feedback of results on a region-wide scale were completed within 2 years.

At the end of the 2-year pilot, the 15 purchasing health authorities in North Thames made participation in the prospective audit part of the process of accreditation of cancer units. The audit was implemented prospectively for all breast cancers in 29 acute hospital units in 1996/97. They jointly commissioned the Cancer Registry to facilitate implementation and channelled NHS audit monies to fund the data collection within Units. It was the first region-wide prospective audit of breast cancer in England. The prospective audit now collects data on about 3000 cases per year, sufficient to study quality and (later) outcomes in depth.

**Measurement and audit**

Prior to the audit, only four of the 15 centres were collecting a small and non-standard dataset on their patients; others
had invested considerable resources in system developments which were unsatisfactory. During the pilot phase, an audit database was set up on a PC at the Registry. Copies of the program were offered to all participating breast units if they wished to implement audit prospectively in their clinics. During the pilot study, one of the screening centres fully implemented the audit dataset for all breast patients prospectively, using its own database, and seven centres tested the registry’s audit software. Within the first prospective year, 14 of the 15 hospital units had fully implemented prospective audit and it took a further year to implement audit prospectively in all 29 hospital units. More than half the hospital units used the free software provided by the Registry. Significant delays were mainly in finding resources for data collection and input. The pilot study has led to a 15-fold increase in the collection of good quality clinical audit data on breast cancer management in the study area.

Clinical effectiveness

The clinical findings of the pilot audit are reported elsewhere.\textsuperscript{1,4,3} The random stratified sample of patients comprised 419 (28%) of the 1480 eligible patients. The main clinical findings were that overall in the Region most guideline targets were met. The results suggested that a minority of women were under-treated: 15% (95% CI = 6–25%) of the node positive pre-menopausal women did not receive chemotherapy and 10% (95% CI = 6–14%) of patients did not receive radiotherapy after conservative surgery. There were few differences between high and low volume hospital units. The performance of high-volume units was significantly better in certain respects: the use of FNA for diagnosis, adequate axillary sampling (more than two nodes excised if sampling was done), and access to a high volume (skilled) surgeon and a specialist breast care nurse. All hospital units met the waiting time target that 50% of patients should be seen in hospital within 14 working days of GP referral. However, 15% of patients in the region waited more than 5 weeks.

The results of 1992 were compared with those from the Eurocare survey for 1990.\textsuperscript{4} There were some improvements between 1990 and 1992, but causality remains unproven. Between 1990 and 1992, the proportion of patients given chemotherapy rose from 17% to 23%. (Chemotherapy use in the 1980s was even lower at under 10%\textsuperscript{3}). The use of axillary surgery increased dramatically from 46% to 76%, the proportion of patients having surgery rose from 83% to 95% between 1990 and 1992.

Survival outcomes, based on Registry data over a longer timescale, show an upward trend. The 5-year relative survival rate in Thames\textsuperscript{4} increased steadily from 52% for patients diagnosed in 1960–64, to 68.7% (95% CI = 68.1–69.3) in 1986–90.

The organization survey produced data on the infrastructure of breast cancer services in 1995. We found the semi-structured interview was a rather soft tool. However it revealed that only 12 of the 15 hospital units had a specialist nurse and only five had a lymphoedema clinic. This was supported by data from the Nurses Survey, which also emphasized the lack of resources for important patient support facilities such as information material and lymphoedema and prosthetics services. The organization survey duplicated in part the much more detailed work of the Breast Screening QA team. In recognition of this, some health authorities in the region are now using this team to survey the infrastructures of both screening and symptomatic services.

Confidential feedback

The confidential feedback packs of results were sent out to the 16 contact surgeons. Three surgeons requested a presentation of their results, with interpretation of the comparative data for a local clinical audience. Anonymized results were also presented at regional meetings.

Attitude changes

While the surgeons in 1994–95 were aware of the BASO guidelines, few were aware of the Calman–Hine recommendations and the changes they implied. The audit network was helpful in spreading awareness. The surgeons recognized the importance of knowing their workload accurately and being able to substantiate claims of good practice. Consequently the audit, which could have been perceived by surgeons both as an extra workload and as threatening their position, was seen as a benefit.

Attitude to the Cancer Registry also changed. Several clinicians commented that for the first time the Registry was producing information of relevance to them and to clinical practice in cancer. A network of clinicians actively working with the cancer registry should improve the completeness, quality and utility of cancer registration.

Conclusion

The study was designed to set up and test an effective process for monitoring and improving clinical performance. The pilot study demonstrated that a region-wide approach by consensus among hospital teams could be implemented quite quickly; clinicians appreciated the benefits of standard data on clinical outcomes, provided that professional sensitivities were respected in disseminating the results.

There are many alternative models that are being developed for monitoring clinical performance on a local and regional basis but in our view, the important features are as follows:

1. the area should be large enough to contain several hospitals of each type—including oncology centres, high volume units and low volume units—in order to make it relevant to consultants at all types of hospital;
2. local involvement of and ownership by clinical teams is essential in order for the audit to become self-sustaining in hospitals;
3. the audit must benefit the clinicians—the dataset must help them in organizing their unit or in managing patients;
4. a standard dataset must be collected in all units with common definitions, codes and training notes;
(5) in coordination of the study across hospitals a balance needs to be found between a prescriptive approach, which can threaten ownership, and a devolved approach, which can lead to fragmentation;

(6) truly comparative data are valuable to purchasers and are best collated by a neutral agency such as a cancer registry.

There are several improvements that could be made to our model. The purchasers of cancer services are important stakeholders and, subsequent to this pilot study, they became more actively involved and funded on-going development. We would also recommend having representation of family practitioners and patients on the Panel, to guide the study. Professional networks are extremely helpful—we utilized those networks set up for the UK NHS breast screening programme; further networks are needed to involve (a) oncologists and (b) cancer data managers more closely.

Data on the activity of the specialist nurses was difficult to capture and further development is needed to reliably obtain qualitative and quantitative data in the area of patient support. Data collection is the most expensive part of audit, particularly as the data collectors need to be specially trained and their work quality assured to ensure that the audit is accurate and reliable. The cost per case audited in the pilot was about £100 (154 EUROS, US$158) which included all the development costs of the process, the database development and the feedback. Prospective audit will be less than £50 (77 EUROS, US$79) per case. While this is a small fraction of the cost of cancer treatment, creative ways of minimizing the cost need to be found if prospective audit is to become sustainable in hospitals. One possible approach is to develop structured case-notes for the clinicians to complete. Clinicians routinely record most of the relevant patient information, usually in free text in the case-notes. Subsequent abstraction of these data onto a structured proforma means collecting the data twice. In order for audits as envisaged by the recommendations for specialization and clinical governance to become economically sustainable in hospitals, clinical data will almost certainly need to be collected in a structured way in the clinic, either on paper or electronically.

Following a UK Government discussion in 1998 ‘suddenly, improved clinical information is central to modernizing the NHS.’ The population-based Cancer Registry played a vital role in setting up this audit region-wide and in giving objective, independent, confidential results. The region-wide dataset has other benefits, such as comparable staging data for evaluation of screening programmes. High quality clinical databases have great potential for outcomes research. The clinical networks established by region-wide audit should aid rapid dissemination of new research evidence, improving clinical effectiveness.

The model developed in this study could be generalized to any cancer, and to other regions of the UK and abroad. The Cancer Registry’s database expertise, its neutral position in the purchaser-provider split and a region-wide, population-based perspective would be even more important for cancers managed largely in primary care or in hospitals outside the NHS. Regional cancer registries are a key part of the strategy for high quality clinical information to support clinical effectiveness in NHS cancer care.

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References

18. Sainsbury JRC, Rider L, Smith A, McAdam WFA. Does it


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