External Clinical Service Review

Directorate: Clyde: Surgery and Anaesthetics

Date of Review Period: Approx 2001 - 2007

Date of Review: July / Aug 2007

Report Prepared by: Professors AM Thompson and WD George

Date: 21st September 2007

The aims of this service review are:

- To review the procedures and protocols for the management of breast patients in Inverclyde Royal Hospital (IRH).
- To review the specific allegations and complaints of patient mismanagement.
- If necessary, to undertake a systematic review of patient care to determine the extent, if any, of patient mismanagement.
- To make any recommendations on how the delivery of the breast services in Inverclyde could be improved.

It is important to note that whilst acknowledging the professional responsibility and accountability of all staff and departments involved in this review, it is **NOT** the purpose of this report to apportion blame.

Review Group Membership:

- Prof. W.D. George, Consultant Breast Surgeon, NHS GG&C.
- Prof. A.M. Thompson, Professor of Surgical Oncology, University of Dundee.
- Mrs. L. Meikle, Head of Nursing, Surgery & Anaesthetics Directorate, NHS GG&C.
- Mrs. K. Cormack, Clinical Risk Manager, NHS GG&C.

Staff who met with the review group (in order of consultation):

- Tim Cooke, Associate Medical Director, Surgery & Anaes Directorate, NHS GG&C
- Philippa Whitford, Chair of the West of Scotland Breast Cancer MCN
- Liz Jordan, Associate Medical Director, Clyde Directorate, NHS GG&C
- Iain Morrice, Consultant Surgeon, IRH, NHS GG&C
- Iain Watt, Consultant Surgeon, IRH, NHS GG&C
- Stephen Dahil, Consultant Pathologist, Clyde Directorate, NHS GG&C
- Noelle Edwards, Breast Care Nurse Specialist, IRH, NHS GG&C
- Isabel Hardie, Outpatient Nurse Manager, IRH, NHS GG&C
- Linzi Binnie, Nurse Specialist/ previous OPD sister, IRH, NHS GG&C
- Elfatih Eltahir, Consultant Surgeon, Clyde Directorate, NHS GG&C
- Katherine Krupa, Consultant Surgeon, Clyde Directorate, NHS GG&C
- Richard Jones, Clinical Oncologist, NHS GG&C
- Mike McKirdy, Surgical Clinical Director, Clyde Directorate, NHS GG&C
- Frank Kelly, Consultant Radiologist, IRH, NHS GG&C
- Marzi Davies, Consultant Radiologist, RAH, NHS GG&C

Process & Data Gathering:

- Documentation review of information produced from the West of Scotland Managed Clinical Network, Breast Cancer.
- Consideration of the CSBS Breast Cancer Standards and IRH assessment.
- Consideration of SIGN 84: Management of Breast Cancer in Women.
- Case note review of 4 individual patients identified from previous screening exercise in June 07 of all patients (1600) who had previously attended the service since Jan 06.
- Case note review of 31 individual patients identified by the Clinical Director.
- Discussion with all appropriate stakeholders on 17th and 18th July 2007 & 8th August 2007.

Executive Summary:

- Extensive internal and external peer review of patient management and processes has been employed in conducting the review of patients with breast conditions managed at IRH. This included case note review, interviews with clinical staff and review of regional hospital data.
- The quality of the IRH hospital notes is generally good with clear documentation of procedures and results.
- Staff at IRH are passionate about delivering an innovative, high quality, service, accessible to the local population.
- It is noted that there remains a commitment to provide an excellent clinical service to all patients in Inverclyde. Past innovative developments at IRH, meeting all CSBS minimum standards, are noted and the level of service in recent years has moved towards and in some cases exceeds desirable CSBS standards.

- Four patients were said to have a new diagnosis of cancer following the internal review. It is the opinion of the external team that the clinical management of 2 of these patients was reasonable prior to the internal review. A more stringent diagnostic approach may have led to an earlier diagnosis in the remaining 2 patients.
- One major criticism was of insufficient needle sampling of breast lesions (and hence insufficient attention to preoperative diagnosis). However, the preoperative diagnosis rate at IRH has consistently exceeded the 70% essential CSBS standard and in 2006 approached the desirable standard of 90%. Despite this, criticism is appropriate for some individual cases and this should be borne by the whole team.
- There is a need in future to ensure that needle biopsy of breast lesions is pursued appropriately and in conjunction with radiological colleagues.
- Poor interpersonal relationships and communication difficulties have undermined the development and delivery of the highest quality Clyde wide service.

- The Clyde-wide MultiDisciplinary Team (MDT) meeting should be encouraged with all relevant parties in attendance, actively participating and being heard. The MDT meeting must be appropriately chaired, given sufficient time with accurate record keeping, provide onward transmission of information to primary and secondary care and thus act as a pivotal point in the working week.
- Most team members in all disciplines should aim to work Clyde-wide and not be employed solely to practice in one hospital.
- Increasing interdisciplinary working and information sharing is required and recent reorganisations and recruitments show great promise in this direction.

- Those who deliver breast services to patients in Inverclyde should look confidently to the future. With the staff changes that have already occurred and with the Clyde-wide multidisciplinary team working effectively, IRH should offer and deliver an excellent service to the community.

Background:

Setting

Argyll & Clyde breast cancer services were reviewed by the Clinical Standards Board Scotland (CSBS) visit in 2001.The management of breast cancer has been laid out in the SIGN guidelines (Currently SIGN: 84 Management of Breast cancer in Women 2005).

Since the peer review visit in 2001 there have been multiple reviews/ongoing reorganisations of Clyde (formerly Argyll and Clyde) services including the complexity of multi-site surgical services. These rapid and repeated changes appear to have had an unsettling effect on service provision.

The Inverclyde Royal Hospital (IRH) breast service

The Inverclyde Royal Hospital (IRH) service has been generally forward thinking with innovations such as a one stop clinic, Macmillan Nurse Specialist appointment and a Multidisciplinary Team (MDT) meeting all operational for over a decade, ahead of many larger institutions. High quality audit with comprehensive data collection has been active since 2000.

A functioning breast service is established and provides a one stop service with immediate information back to the patient with a copy to the GP.

The one stop breast service provides in clinic mammography and ultrasound; FNAC in the clinic is prepared by an MLSO and results are available within 30 minutes. Patients requiring surgery are generally operated on within 2 weeks based on H north ward, IRH. Immediate reconstruction is problematic due to time and geographical constraints with Glasgow Royal Infirmary reconstructive services and there has been little collaboration to develop immediate reconstruction within Inverclyde. However it is reported that immediate and delayed reconstruction have been made available to some individual patients.

Pathology services have been consolidated on the RAH site, but continue to offer an excellent cytology and pathology service to IRH.

Developments in radiological technical services in the last year and the move to a single department model have allowed for the opportunity to undertake guided biopsy procedures since mid 2006, and the introduction of double reporting.

Outreach services from the Beatson have been in place for some time but multiple changes in personnel and the evolution of specialist practices has made delivery at IRH challenging.

Staff reported they have very little or no time available for CPD, for example attendance at meetings and the opportunity to keep updated.

This review

Greater Glasgow and Clyde Health Board initiated an internal review which has been subsequently followed by an externally led review. In the initial internal review process the case records of all new patients referred to the breast clinic for the previous 18 months to June 2007 were reviewed by 8 surgeons over 2 days in June 2007. A total of 1600 case records were examined and this resulted in the identification of 194 patients in whom clinical review was deemed advisable. These 194 patients were recalled and re-examined. Relevant investigations were carried out when this was deemed necessary and all results were discussed in multidisciplinary team meetings. As a result of this internal review, 4 patients with breast cancer were highlighted (see below).

Any retrospective review of clinical practice might identify actions that on reflection may have been conducted differently. SIGN Guidelines (as with other guidelines) require a degree of interpretation for local implementation and are to be considered in the context of the wider clinical practice on the basis of all clinical data available on each individual case.

Services elsewhere in Scotland also have to pause and reflect from time to time, though ideally proactively and not in the public eye causing the associated, undesirable, patient and community anxiety.

Managed Clinical Network data (albeit at least a year behind real time) and Clinical Standards Board for Scotland/ NHS Quality Improvement Scotland (CSBS/QIS) standards demonstrate that IRH practice currently exceeds all essential standards and for most aspects of the breast service meets the higher, desirable, standards.

One standard which has received particular attention is the preoperative diagnostic rate (essential CSBS standard 70%). The preoperative diagnostic rate at IRH has shown audited improvement from 74% in 2003 to 87% in 2006. The proportion of patients undergoing breast conservation and those receiving adjuvant therapy have also improved such that with all other standards IRH is well in the midst of (and indeed for some standards exceeds) the performance of other breast teams in the West of Scotland.

Issues identified:

The oral and written evidence, individual and group perceptions and order of events vary significantly between individuals. The Clinical Director who had raised concerns about the service and the Associate Medical Director who advised on the need for a process of internal review also participated in the internal review of all patients seen between January 2006 and June 2007.

Interactions reported and evidence of written language between individuals in the Clyde Breast Team suggest interpersonal conflict and suboptimal communication have been a major contributor to the break down in trust within the service.

The main patient-centred issues that have been raised include:

- The preoperative diagnosis rate
- The use of repeat needle sampling (including sampling under radiological guidance)
- Tumour bed re-excision
- Offering patients conservation rather than mastectomy
- Offering patients reconstruction

Review of 35 case notes:

Independent case note review suggests, even in retrospect, a reasonable course of action was followed for a number of these patients. Several patients highlighted had atypical presentations or were not straightforward. In other patients, some of the issues that have been raised were decisions of the MultiDisciplinary Team (MDT) as a whole rather than decisions taken by individual clinicians. The external review group was asked to consider 4 complaints, however these patients fell into the group of patients covered by the internal review and were therefore reviewed as part of the 35 case records.

We found that in some patients the diagnostic procedures employed were incomplete and more widespread use of needle biopsy, particularly image guided needle biopsy, should have been considered. In the same way and in a small number of patients the MDT decisions regarding the use of post operative radiotherapy and the prescription of adjuvant endocrine therapy did not conform to Scottish guidelines.

Findings from the external review were as follows:

- Cooperation and coordination between clinical, radiological and cytopathology findings was generally good but could have had a lower threshold for repeating tests and alternative diagnostic approaches. This could have led to swifter diagnoses.

- There has been discussion around the appropriateness of re-excision v mastectomy (some appropriate from the notes, but the outcome of MDT discussion documented in the patient's case notes would have been helpful for other patients). It is difficult to criticise in retrospect the actual decision made on a patient by patient basis from the evidence available.

- Aromatase Inhibitor use – the IRH breast team did not follow Scottish agreed protocols for 3 patients. This should have been evident at the MDT.

- Access to reconstruction, both immediate and delayed, was not actively promoted.

- Mammographic surveillance protocols – there was no evidence of breaches by the surgical IRH team from the evidence presented.

- Timing and availability of preoperative staging results – this requires development of a protocol with radiological services.

Included in the 35 patients were four patients said to have a new diagnosis of cancer following the internal review.

One of these 4 cancers had been diagnosed prior to the internal review and in our view managed appropriately. The remaining 3 cancers were all atypical in their presentation and presented diagnostic challenges. However, the external team concludes that whilst one of these was managed appropriately, a more stringent diagnostic approach (needle biopsy in one case and a repeat image guided needle biopsy in the other) may have led to an earlier diagnosis. However, the external review team do not expect that the outcome for either of these 2 cases will have been prejudiced by the diagnostic delay.

Recommendations:

Recent recruitment to the Clyde breast service in surgery, radiology and oncology provides comfort that future practice will continue to evolve in a positive direction. While acknowledging aspects of good practice in the existing service, the future service must incorporate the following elements:

- Protocol and SIGN Guideline based, quality assured service. There was evidence that preoperative staging was carried out but surgery progressed prior to availability of results which may have influenced clinical management. This requires development of a protocol with radiological services to allow timely investigations and reporting.

- Provision of a high quality one stop diagnostic service (clinical, radiology, cytopathology).

- Provision of staff for 3 sites (and the relevant job plans) needs to be reviewed. With regard to the surgeons, it is recommended there should be a surgical lead for each site with involvement of the current other multidisciplinary breast team members at each site. The Health Board should give very careful consideration to which surgical personnel will deliver the future service at the IRH. With 3 Consultant Breast Surgeons for circa 200 new breast cancer cases per year in Clyde there should be sufficient resource for cross-Clyde surgical provision at the 3 surgical sites.

- Review of the job plans for all three consultant breast surgeons is required and should include contingency plans to deliver the service during planned or unplanned leave.

- There is a need to include in the planning of future services all relevant staff in IRH who are well versed in the running of a service.

- The Breast Care Nurse Specialists in Clyde should work as a team providing cover for each other at all three sites at times of planned and unplanned leave.

- Liaison should be optimised between breast clinicians and radiology services in the clinic, particularly with regard to radiologically guided needle sampling.

- To ensure adequate support, equipment and personnel, are available to deliver the service for the volume of patients attending the clinic with particular reference to mammography, breast ultrasound and radiologically guided needle sampling,

- To increase the use of image guided (ultrasound, mammogram) needle (FNAC or preferably core biopsy) at the one-stop clinic, particularly where the first attempt has given pathology data at variance with the clinical/radiological impressions.

The IRH service ultimately requires: two one stop clinics per week, one follow up clinic per week, and one whole day (2 session) operating list per week (which might also incorporate IRH based endocrine practice). This service should be delivered by a lead consultant breast surgeon at IRH over 2 consecutive days: an operating day followed by a clinic day.

Multidisciplinary working:

Multidisciplinary Team Meetings (MDTs) serve to ensure up to date best practice with discussion of all relevant information for each patient. Multiple representations from each discipline promote challenging inter-disciplinary debate and learning.

- The MDT needs to be chaired appropriately allowing time for all voices to be heard and sufficient discussion to occur to include all relevant views and information. The chair should be rotated to promote inclusiveness.

- There is a need to ensure recording of MDT decisions (and where unusual decisions have been taken documentation of the rationale).

- The outcome of MDT discussions should be documented in the patient's case notes.

- The Clyde wide MDT as the sole MDT requires job plan time set aside to do this (minimum 1-2 hours for attendance, additional time for pre MDT preparation for radiology and pathology).

- Patients should be discussed at the sole MDT meeting by all clinicians responsible for their care negating the need for discussion at ad-hoc meetings risking different outcome decisions.

- The Clyde wide MDT may be in person or by video linking.

***Wider implications**:*

Updating staff on current practice improvements and continued professional development of all clinical team members is essential and should be appropriately resourced.

MCNs generally need to flag up variances from desirable QA levels; how this should be acted upon and by whom remains unclear at present to those involved in clinical practice and requires central guidance. How seriously the information is taken, whether it is pursued, who has responsibility for closing the loop and whether they should reply to the MCN to say how they will attempt to improve on shortfalls needs to be clarified.

The future of reconstructive services for patients in Clyde needs to be clarified. It seems likely that this service should be offered either at RAH or the Canniesburn Unit at GRI and discussion with Plastic and Reconstructive surgeons on this topic would be advisable.

There is a need to ensure provision of mentoring, learning and education to support clinical managers in developing the required leadership skills.

There may be wider implications for multidisciplinary, multi-site working for Greater Glasgow and further afield.

Signed…… (AM Thompson)

Signed…… (WD George)

Signed…… (L Meikle)

Signed …… (K Cormack)

for the Review Group. Date: 21/9/07