

QA VISIT REPORT
Cambridge & Huntingdon
Breast Screening Service
26 February 2009

The East of England QA Reference Centre has taken the utmost care to ensure that the statements of fact included in this Report are true and accurate and that, where an opinion of the QA peer review team who conducted the quality assurance visit is expressed, such opinion is honestly held by the team, based on true and accurate information and has been arrived at in good faith and without malice.

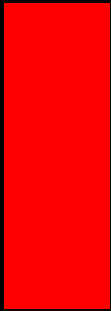
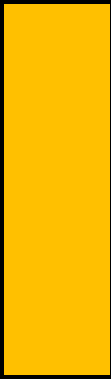
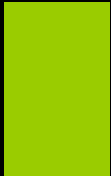
NOTES ON QA REPORT AND TABLE OF RECOMMENDATIONS

Each professional lead has provided a report and made a number of recommendations based upon data submitted in advance of the QA visit and their observations on the day.

All the QA recommendations made in the body of the report are presented in a table at the beginning and have been colour coded to give an assessment of the risk of the current process or practice at the Unit and consequences of the Service failing to mitigate this risk.

In making this assessment of risk, the QA Team have exercised a judgement based upon the input from the expert QA advisors and the wider experience across the NHSBSP.

Colour Key

	<p>A recommendation has been coded red if, either, unaddressed it could lead to significant risk of harm to women seen by the service, or where due to an absence of data or evidence the quality of the Unit cannot be assessed because the QA process cannot be conducted satisfactorily.</p> <p>We acknowledge that there are occasions when a recommendation may be allocated a high risk grading even though the probability that an adverse event will occur is small. This is because even though the occurrence may be rare, the event would have a significant impact on the patient.</p>
	<p>A recommendation has been coded amber when a process or practice does not meet the expected standard or the recommended practice of the NHSBSP but does not lead to direct clinical risk to individual women. Many of the NHSBSP standards are designed to ensure the acceptability of the screening programme, the maintenance of the value of screening by adhering to professionally-agreed performance standards and quality measures to reduce the anxiety of users.</p> <p>Units should be aware that there is significant political, social and reputational damage to the Unit and the NHSBSP of failure to meet the required standards of the Programme.</p>
	<p>A recommendation has been coded green when it carries no risk to the women seen by the service but which, if implemented could enhance the performance of the Unit and/or the experience of the women screened.</p>

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ACKNOWLEDGEMENTS

The East of England Quality Assurance Team would like to record their thanks to Dr Barter and all staff working in the Cambridge & Huntingdon Breast Screening Service for welcoming the visiting team.

LIST OF VISITORS

QA Director	Jem Rashbass
QA Co-ordinator	Jo Slater
QA Facilitator	Beverley Collins
QA Admin & Clerical	Janet Skeys
QA QMS	Barbara Dawes
QA Radiographer	Monica Dale
QA Physicist	Claire Skinner
QA Radiologists	Jill Wilkie Roger Whitney
QA Pathologist	Salam Al-Sam
QA Surgeon	Neil Rothnie
QA Breast Care Nurse	Philippa Dooher

LIST OF SCREENING PERSONNEL ATTENDING THE QA VISIT

Consultant Radiologists	Sue Barter (Director of Screening) Matthew Wallis Peter Britton Ruchi Sinnatamby Matthew Gaskarth
Administration/Clerical	Judith Fatibene (Administration Manager) Ruth Mynott (Acting Deputy Administrator Manager) Heather Couzens Judith Skinner Mary Garner Kim Pye Carol Stephen
Radiographers	Barbara Knighton (Supt Radiographer) Mary Hunt Jane Killick Sue Fitzsimmons Paula Willsher Christine Ogilvy Sam Newton Latch Raghubans Lesley Rowlands Angela Freeman
Advanced Practitioner	Kathryn Taylor
Assistant Practitioners	Rita Stewart Val Hopkins
Radiographer Assistants	Luzel Carandang Jenni Wilkinson
Breast Care Nurses	Dawn Chapman Joanna Rowley Sharon Iddles
Pathologist	Elena Provenzano (Lead Pathologist)
Surgeons	Gordon Wishart (Lead Surgeon) John Benson Parto Forouhi

East of England Radiation Service Oliver Morrish

Cambs Primary Care Support Services Liz Hewson

1. Introduction and Summary

This is an outstanding Breast Screening Unit, serving a population of around 55,000, that meets or exceeds all significant performance metrics required by the NHS Breast Screening Programme. All major recommendations from the previous QA visit have been addressed.

Uptake is high at just under 78% (KC62 07/08) and the screening round length (SRL) data demonstrate that the percentage of women offered an appointment within 36 months of their previous screen has consistently exceeded the NHSBSP target of >90%; in the last quarter was almost 98%. The proportion of women receiving a normal result within two weeks of attendance is 98% and the service has radically improved performance against the target of >90% within 3 weeks for screen to assessment in the first three quarters of 2008/2009, although they are still not quite meeting the target. However, review of the figures for date of screen to date of first offered appointment for assessment shows performance that exceeds 90%. These results are a reflection of the dedication and hard work of the entire breast screening team.

All disciplines are highly motivated although there remains significant understaffing in the both the radiography and administration & clerical teams. The combined activity with the very busy symptomatic service creates significant pressures on the team and, based upon the screening population, the office should have a further 2.5 whole time equivalent members of staff and the radiography team a further 1.9 wte. It is entirely due to the industry and diligence of the existing staff that they are managing to support this service but the current situation is not sustainable, even in the medium term. The understaffing needs to be addressed within the next three months as it significantly jeopardizes the continued efficient functioning of the service.

Although the individual processes and protocols that support the service are generally well documented and there appears to be good overall communication and governance of the practices of the programme, an integrated quality management system (QMS) is not present. Without this, despite the best efforts of the staff, it is difficult to create a unified framework for ensuring quality across the entire programme. The Service would benefit significantly from formal introduction of the QMS process as recommended by the NHS Breast Screening Programme and this would require an additional resource of 0.6 QMS lead to support the integration across the entire service.

The large radiology team function exceptionally well and the cancer detection rates are excellent, particularly the prevalent round rate which is twice the national target. The benign biopsy rates are slightly above target levels which is a reflection the unit's use of vacuum assisted biopsy and the policy for managing B3 lesions. The practices have been the subject of detailed audit.

The surgical team are to be congratulated on providing an excellent surgical service to the breast screening unit and women benefit from high standards of care and excellent outcomes.

The radiology and surgical teams are supported extremely well by the cohesive team of breast care nurses who deliver a high standard of care to screening patients attending for assessment and beyond diagnosis.

Consideration needs to be given to the available space at the breast unit which will not be sufficient with the increased activity that will result from the extended screening age range.

In line with the previous QA recommendations, the pathology team has reduced in number from 8 to 5. They offer an excellent service with only a minor recommendation to label nipple margins for cases of DCIS.

Jem Rashbass

Jo Slater

2. Summary Table of Recommendations

1. Management

Recommendation No	Details	Owner	Risk	Date for resolution
1.1	That the Breast Screening Unit in conjunction with the Commissioners develop a tariff based model for screening that can be used to ensure that current service delivery as well as population growth, age extension and high risk screening are appropriately funded.	Director of Screening/ Commissioning Lead for PCT		Within 3 months

2. Admin & Clerical

Recommendation No	Details	Owner	Risk	Date for resolution
2.1	Review the screening and symptomatic work load against staffing levels and recruit accordingly.	Administration Manager/Director of Screening		Immediate
2.2	An audit of ceased women now and then annually.	Administration Manager/PCT		Immediate and ongoing
2.3	Implement the recommendations made by QA and CfH relating to batch selection when published in April/May 2009.	Administration Manager/PCT		When final report is published

3. QMS & Right Results

Recommendation No	Details	Owner	Risk	Date for resolution
3.1	<p>Following a serious untoward incident at the West of London Breast Screening Service (WoLBSS) when the service had failed to recall women for assessment and had instead issued a 'normal' result, the CHI report of the investigation concluded that:</p> <p>There was no robust and comprehensive operational protocol to ensure that women who had been screened received the correct results despite the fact that, following a similar incident in 1994, national guidelines had been produced. WoLBSS was not compliant with these guidelines. This was an unacceptable and avoidable failure.</p> <p>The director of each breast screening service is responsible within the framework of clinical governance for ensuring that a 'right results' procedure is in place and is audited regularly (NHSBSP publication No.55 May 2003).</p> <p>This report includes a detailed analysis of both your quality management system (QMS) and the 'right results' procedure and a number of recommendations have been made to help you to improve these systems in order to minimise the risk of a screening incident.</p>	Director of Screening		See detailed reports

4. Radiography

Recommendation No	Details	Owner	Risk	Date for resolution
4.1	Increase radiographic staffing to support the screening service	Director of Screening / Superintendent Radiographer	High	Within 6 months
4.2	Reinstate a regular formal programme of self and peer review of images	Superintendent Radiographer	Medium	Immediate
4.3	Develop a system of peer review for digital images	Superintendent Radiographer	Medium	Immediate
4.4	Consider a more inclusive schedule of staff meetings	Superintendent Radiographer	Medium	Within 6 months
4.5	Work with HR to band the Advanced Practitioner for her whole contract at band 7	HR / Director of Screening / Superintendent Radiographer	Medium	Within 3 months
4.6	Develop the Deputy Superintendent Role	Director of Screening / Superintendent Radiographer	High	Within 6 months
4.7	Improve access to facilities at mobile sites	Superintendent Radiographer	Medium	Immediate
4.8	Arrange a clinical update for the department	Superintendent Radiographer	Medium	Within 3 months

5. Medical Physics

Recommendation No	Details	Owner	Risk	Date for resolution
5.1	Equipment Handover form to be revised.	Superintendent Radiographer and Physicist	Medium	Within 3 months

5. Medical Physics (continued)

Recommendation No	Details	Owner	Risk	Date for resolution
5.2	"Fineview" processing package is automatically applied on one of the digital units but not on the other. This should be investigated and the units matched according to the radiologists' preferences.	Radiologists and Physicist		Within 3 months
5.3	The new reporting room should be used for all reporting so far as is practicable.	Radiologists and Superintendent Radiographer		As soon as is practicable
5.4	Local Rules to be clarified regarding the Controlled Area and protection for staff in the room.	Superintendent Radiographer and Physicist		Within 3 months
5.5	The signs on the doors should indicate the radiation risk (i.e. external radiation).	Physicist		Within 3 months
5.6	"IRMER" documentation to be revised when new national guidance is published.	Superintendent Radiographer and Physicist		When new guidance is published
5.7	The work instruction for suspension of X-ray equipment needs to be revised to make clear who should be informed when remedial or suspension levels are exceeded. This work instruction needs to be referred to on the QC record sheets, and be readily available, so that staff performing tests act accordingly.	Superintendent Radiographer and QA Radiographers		Within 3 months

5. Medical Physics (continued)

Recommendation No	Details	Owner	Risk	Date for resolution
5.8	Up to date remedial and suspension limits, taken from the tolerances given in NHSBSP Publication 63, need to be in place for all radiographer QC tests. Tolerances must be given in the form of ranges (rather than e.g. "+/- 5%") on all QC record sheets, along with baseline and/or target values. Tolerances must also be marked on all graphs used for recording results. When a new graph is started the tolerances must be transferred across immediately. For mobile units it is particularly important that remedial and suspension levels for mAs are available and acted upon since films are not processed until the next day. Detailed requirements are given earlier in this report.	QA radiographers		Within 3 months
5.9	Work instructions to be amended to reflect the changes to tolerances.	Superintendent Radiographer and QA Radiographers		Within 3 months
5.10	Work instructions to include requirement to plug in the densitometer, since it is believed that readings may be unreliable when run off the battery.	Superintendent Radiographer and QA Radiographers		Within 3 months
5.11	Baseline values should be reviewed on a monthly basis.	QA radiographers		Within 3 months

5. Medical Physics (continued)

Recommendation No	Details	Owner	Risk	Date for resolution
5.12	For digital units, revise tolerances in line with national requirements; ensure that all QC results are recorded on disk; and reinstate SMPTE phantom and dead pixel map.	QA radiographers and Physicist		Within 3 months
5.13	Investigate why image quality parameters often fail NHSBSP 63 tolerances.	QA radiographers and Physicist		Within 3 months
5.14	Spare 24x30 cassettes at base should be moved to the van to ensure that there are 8 available at each location.	Superintendent Radiographer and QA Radiographers		Within 3 months
5.15	New test required for uniformity post-engineer visit.	QA radiographers		Within 3 months
5.16	X-ray spillover at chest wall edge could be tested with Gafchromic self-developing film post-mobile move.	QA radiographers		Within 6 months
5.17	For the Mammotome stereo localisation accuracy protocol, include the need to use a lower needle guide in the work instruction. Regularly check the test needle to ensure it is not bent and replace if necessary.	Superintendent Radiographer and QA Radiographers		Within 3 months
5.18	A work instruction is needed for the localisation QC test with FNA needle.	Superintendent Radiographer and QA Radiographers		Within 3 months

5. Medical Physics (continued)

Recommendation No	Details	Owner	Risk	Date for resolution
5.19	Record actual errors in x, y and z in mm rather than recording ticks for stereo tests	QA radiographers		Within 3 months
5.20	Ensure all radiography staff trained to use the stereo unit perform tests sufficiently frequently to maintain their skills – consider refresher training from GE.	Superintendent Radiographer		Within 6 months
2.21	SLA for Physics services to be put in place as soon as is practicable.	Superintendent Radiographer and Physicist		As soon as is practicable
5.22	Physics tests to include a measurement of high contrast spatial resolution in magnification mode.	Physicist		Within 3 months

6. Radiology

Recommendation No	Details	Owner	Risk	Date for resolution
6.1	Procure facility for specimen x-rays	Director of Screening		Within 12 months
6.2	Replace damaged ultrasound couch	Director of Screening		Within 3 months

7. Pathology

Recommendation No	Details	Owner	Risk	Date for resolution
7.1	Labelling nipple margin specially for cases of DCIS	Surgeons		Within 3 months
7.2	Screening / symptomatic split is not given by clinicians	Surgeons		Within 3 months
7.3	Her2 technician needs support, appointment of part time person to help	Pathology Department / Management		Within 6 months

8. Surgery

Recommendation No	Details	Owner	Risk	Date for resolution
8.1	Adequate facilities for specimen imaging should be available	Trust		Within 6 months
8.2	I would fully support the appointment of a Breast Fellow to this Unit	Lead Surgeon / Trust		Advisory
8.3	Ensure that adequate facilities are available to support planned age extension.	Trust		To be included in the planning of age extension
8.4	Adequate support needs to be made available for data collection, in particular for all of the compulsory national audits.	Trust		Advisory

9. Breast Care Nurse

Recommendation No	Details	Owner	Risk	Date for resolution
9.1	No recommendations			

3. Management Report

This is an extremely well managed unit under the Directorship of Dr Barter, supported by the Superintendent Radiographer and Administration Manager, both of whom have been with the service for many years.

Roles are documented and lines of accountability both within the department and in the wider Trust are made clear in the organisational chart. The service is well integrated into the Trust Clinical Governance programme and incidents are reported according to Trust policy as well as to the RCR breast group scheme.

Team communications appear to be good and regular, if not frequent, breast screening team meetings are held. It is unfortunate that some of the radiography staff feel that communication in the breast team as a whole has deteriorated recently. The vast majority of staff are part-time and this causes particular challenges in ensuring that everybody is up-to-date and aware of what is going on in the Unit. Unit 'Away days' are held twice per year and are an excellent opportunity for all staff to contribute to the strategic as well as the day-to-day organisation of the Unit.

Symptomatic and screening services are operated separately on a day-to-day basis, but there is a need to increase staffing levels in the areas of radiography and A & C to properly maintain both services. The funding is not separately identified and, although there has been a one off uplift in funding for age extension (65 – 70 yr olds), this has led to problems in negotiating for funding for the general increase in the screening population.

Communications with the PCT commissioners are good and regular meetings are held to discuss service delivery, including performance, but it has still not been possible to develop a tariff-based model to support the service. This is unfortunate, as significant changes in the Service over the coming years will require an increase in funding. Even though the current relationship between the provider and commissioner may be based around a block contract, it should be possible to create a notional tariff based model for the Breast Screening Service This would allow current funding needs as well as future predictions of population growth, including age extension, to be appropriately funded. *Both parties would benefit from a clear and transparent funding formula on which to base negotiations for future development of the service.*

Service level agreements are in place with the PCT call/recall services but not with the commissioning arm of the PCT.

The transition to digital technology is progressing well, with two FFDM units in operation on the Addenbrooke's site and advanced plans to extend this technology to the mobile units.

The Trust is supporting plans to develop a static screening site at Trumpington which will enable the service to introduce an extended working day, essential if the requirements of age extension are to be met without an increase in the screening round length.

Discussions with the PCT about implementing screening for high risk women have been taking place for some time and the service hope to offer mammographic and MRI screening in line with national recommendations once funding from the PCT has been secured.

The service is aware that they need to implement QMS, but this too will require fully funded support.

Recommendations

Within 3 months

- That the Breast Screening Unit in conjunction with the Commissioners develop a tariff-based model for screening that can be used to ensure that current service delivery as well as population growth, age extension and high risk screening are appropriately funded.

Jem Rashbass

Jo Slater

4. Administration and Clerical Report

The Cambridge & Huntingdon Breast Screening Service breast screening to approximately 55,000 women aged 50 to 70 across five PCT's. The service screens its population with 2 mobile units at 11 sites and at the static unit.

Staffing levels

The service currently has 8.39 wte staff, although when this is reviewed against the symptomatic workload and long term sickness and the vacant post is taken into account, the number of staff left for screening is actually 1.97 wte. NHSBSP guidelines (publication 47: Quality Assurance Guidelines for Administration and Clerical Staff) recommend 1 wte A&C staff for every 12,000 eligible women invited for screening which leaves a shortfall of 2.5 wte.

Despite this severe understaffing, the administration & clerical team work very well together and provide a good service.

The office is adequate for purpose.

The Administration Manager attends regular Regional Office Manager Meetings, and the staff have regular meetings within the unit. All other staff have adequate training and are offered the opportunity to study for NVQ's in-house.

Morale

The morale of the A & C staff is very good they are very supportive of each other and are very loyal to the Administration Manager. Some of the staff, including the Administration Manager, work occasionally on Saturday mornings but this is not a situation that is sustainable. The problem of understaffing should be addressed urgently if the level of service is to be maintained.

Responsibilities

The Administration Manager oversees the general office administrative duties for the screening and symptomatic services. She is responsible for the screening round plan, clinic scheduling, enters abnormal results and oversees the collection of KC62 and BASO data. Detailed screening round plans are available to all staff.

Workload and Compliance

The screening population at present is 55,000 and rising. In common with the other 6 services across Norfolk, Suffolk & Cambridgeshire, the service calls by 'failsafe' batches, which is outside NHSBSP standard procedure. However, the QARC and Connecting for Health has recently reviewed this practice and a report will shortly be published. 'True' failsafe batches are run quarterly. Round length is at present 98%, the current uptake rate is 78%, screen to normal 98% and screen to assessment 82%.

Protocols and Procedures and Work instructions are work in progress.

Customer Care

All women with special needs are flagged up and offered an appropriate appointment at the static unit. Women who wish to withdraw are managed appropriately although this should be audited regularly (see recommendation below).

Computer System

The service has successfully implemented the NBSS system. The hardware is managed by the Trust's IT dept with whom the breast screening team have a good working relationship. The software is managed by the nationally agreed contract. The crystal reporting software is available only on the Administration Managers PC.

GP's

Prior to screening, the unit communicates with GP's by letter and posters to practices.

Call/Recall

There are SLA's in place and these will be updated as per the new national template at review date. There is good communication between the Unit and PCT agencies and in the future will be meeting on a regular basis to discuss any issues.

All analysis jobs received from the PCT's are acted upon, however an audit of ceased women should be carried out on both the NBSS system and NHAIS system to ensure that eligible women are invited for screening or that they have been ceased appropriately.

The Administration Manager uses the AJ-BCE to provide population counts for planning purposes.

Analysis Jobs used:-

- BCE (screening coverage)
- BCNS (unscreened women)
- BCO (open episodes)
- BCR (count/select batched women)
- BCX (deducted women)
- BGEN (GP details)
- BSCW (ceased women)
- BSBD (date of birth changes-PCT)
- BSFF (Failsafe for nearly 53 year olds)
- KC63 (DoH annual returns – PCT)
- PHGC (GP/Partnership changes)
- PHRC (registration changes – electronically)

Recommendations:

Previous recommendations

The recommendations from February 2006 have all been completed.

Recommendations following this visit are as follows:

Immediate

- Review the screening and symptomatic work load against staffing levels and recruit accordingly.
- An immediate audit of ceased women to then be repeated annually.

When regional review is completed

- Implement the recommendations made by QA and CfH relating to batch selection when published in April/May 2009.

Janet Skeys

5. QMS & Right Results Reports

The responsibility for the co-ordination, implementation and maintenance of the QMS is divided between key members of the team without the allocation of dedicated time and resources; the Administration Manager and the Superintendent Radiographer share most of the responsibility.

Responsibility and the Organisational Chart

The Director of Screening supports the QMS but does not have ultimate responsibility.

There is an organisational chart showing hierarchy but the QMS is not represented.

The Surgical, Pathology and Nursing roles within screening are currently excluded from the QMS.

QMS Documentation

A Quality Plan has not been produced to show the current structure of the QMS and the aims and objectives planned for future implementation and maintenance.

NHSBSP guidelines require the documentation to be produced according to three categories in the form of a policy, a set of procedures and a set of work instructions.

The Administration Manager and the Superintendent Radiographer have both produced a folder labelled "Policies and Procedures"; each folder contains master copies of QMS documentation but the organisation of the folders and the format of the documentation are different. For example, one "Policies and Procedures" folder has a comprehensive index and has been divided into core process sections, the other does not and one folder has most documentation written in the style required for a procedure whilst the other has most documentation written in the style required for a work instruction.

The documentation does not have a QMS Policy signed by the Director of Screening.

Work Instructions

The format of the work instructions could be improved. Some do not have a header section that includes a reference number, the responsible person/s and a summary of the purpose of the work instruction and some do not have a footer section that includes the issue number and issue date, the date the work instruction is due for review, the number of pages in the document, the person who issued the work instruction and the person who authorised the work instruction.

There is a referencing system, but it is in need of review to enable a clear distinction to be made between the policy, a procedure and a work instruction and to reflect the core process section the document should be filed in.

Examples of documents referred to in a work instruction are not listed at the end of each work instruction but examples of some documents are available for reference.

A large number of work instructions are written in the style required for a procedure and some are incomplete and inexplicit. For example, staff explained how film sets with a normal result are removed from the viewer but the related work instruction 8.1 "Procedure for Processing Normal Results" does not include an explicit set of instructions that cover all of the processes reported to be undertaken to perform the

task and 1.4 “Daybook” does not include the reported practice of recording a clinical recall.

The master copy of a current work instruction is not marked to confirm it is the original copy.

The Implementation of New Work Instructions

A new draft of a work instruction is written by a member of staff responsible for performing the task covered in the work instruction. The Administration Manager or the Superintendent Radiographer then format and issue the work instruction.

Compliance

A system is not in place to monitor compliance with QMS documentation.

Discrepancies

A system is not in place to log discrepancies.

Document Control

A system to control the circulation of QMS documents is not in place.

QMS Meetings

Multi disciplinary QMS meetings attended by the Director of Screening are not held.

Audit

An ongoing programme to audit all work instructions at least once a year has not been established.

Archived Documents

Out of date QMS documents are destroyed and are not archived.

Confidentiality and Disclosure Policy and Information Security Policy

It was reported that five members of staff are still to sign up to PIAG.

Induction Programme for New Staff

There is an induction programme for new staff.

Conclusion

It is mandatory for all breast screening services within the NHS Breast Screening Programme to have a Quality Management System.

It is clear that the service supports the concept of Quality Management and the basic foundations for the implementation of a Quality Management System are in place.

However, despite the best efforts and dedication of the Administration Manager and the Superintendent Radiographer over a number of years, a QMS has not been implemented.

It is unrealistic to expect senior managers with very heavy workloads to be able to fully implement and maintain a QMS. It will not be possible to achieve full implementation and ongoing maintenance of the QMS without the allocation of dedicated time.

Without a systematic approach to the management of quality and the implementation of a full Quality Management System the ability for the service to maintain its current high standards is at risk.

Recommendations

Recommendation No	Details	Owner	Date for Resolution
3.1	The Director of Screening should have ultimate responsibility for the QMS.	Director of Screening	Immediate
3.2	Ensure all staff sign to confirm they have read and understood the PIAG guidelines.	Administration Manager	Immediate
3.3	File master copies of the current QMS documentation in one folder and circulate copies for reference throughout the department and mobile units.	Administration Manager / Supt Radiographer	Within 3 months
3.4	Mark the current master copy of a procedure or work instruction as "original" and a cancelled document as "cancelled".	Administration Manager / Supt Radiographer	Within 3 months
3.5	Produce a Quality Plan to show the current structure of the QMS and the aims and objectives to cover future implementation and maintenance.	Director of Screening / Administration Manager / Supt Radiographer	Within 3 months
3.6	Establish a system for document control.	Administration Manager / Supt Radiographer	Within 3 months
3.7	Establish and maintain a comprehensive record of discrepancies and the action taken to resolve them.	Administration Manager / Supt Radiographer	Within 3 months
3.8	Hold Quality Management Meetings attended by the Director of Screening at least once every three months.	Director of Screening / Administration Manager / Supt Radiographer	Within 3 months
3.9	Allocate 2 or 3 days a week of dedicated time for the implementation and maintenance of a QMS.	Director of Screening	Within 6 months
3.10	Produce a screening service organisational chart to show hierarchy and the links between the QMS Co-ordinator and the team	Director of Screening	Within 6 months

Recommendation No	Details	Owner	Date for Resolution
3.11	In consultation with the QARC, plan and implement a review of all QMS documentation and aim to produce a policy signed by the Director of Screening and complete procedures and explicit work instructions that comply with national guidelines within a manageable timescale.	QMS Co-ordinator	Within 6 months
3.12	Keep a copy and a record of archived QMS documentation	QMS Co-ordinator	Within 6 months
3.13	In consultation with the QARC, ensure the QMS documentation reference numbers and format are in line with national guidelines	QMS Co-ordinator	Within 9 months
3.14	Ensure the header section of the QMS documentation identifies the reference number, the responsible person/s and a summary of the purpose of the work instruction.	QMS Co-ordinator	Within 9 month
3.15	Ensure the footer section of the QMS documentation identifies the person it was issued and authorised by, the issue and review dates and the individual page numbers alongside the total number of pages.	QMS Co-ordinator	Within 9 months
3.16	List the documents referred to in a procedure or work instruction at the end of the document and provide copies of the documents for reference.	QMS Co-ordinator	Within 9 months
3.17	Introduce a system whereby the person/s responsible for undertaking a task sign a form to confirm they have read and understood the related work instruction.	QMS Co-ordinator	Within 9 months
3.18	Include all disciplines involved with breast screening in the Quality Management System.	QMS Co-ordinator	Within 12 months
3.19	Plan and initiate an ongoing annual schedule to audit all procedures and work instructions and confirm compliance.	QMS Co-ordinator	Within 12 months

Barbara Dawes

Right Results

Background

New national guidelines for the Right Results will direct QA Teams to review and report on the arrangements for the implementation of the Right Results for the breast screening services within their region at least once every three years.

Representatives from the East of England Breast Screening Programme QA Team visited all screening services within the region in 2008 to review their Right Results; subsequent review of the Right Results will form part of the three yearly QA audit visit schedule.

The initial walk through of the Right Results for the Cambridge and Huntingdon Breast Screening Service was undertaken on 14th May 2008; all recommendations made following the walk through have been considered by the service and a number have been implemented.

This report is a summary of the walk through of the Right Results undertaken on 25th February 2009 as part of the QA Visit; it summarises current practice, associated risk and related recommendations.

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1. Clinic Preparation

	Current Practice	Associated Risk	Recommendation
1.1	Screening clinics are held on two mobile units. Two copies of the Clinic Control Sheet listing all women invited to attend are produced for each clinic. One copy is kept in the office and is used to pull the packets for the clinic and then destroyed. The other copy accompanies the clinic to the mobile unit and is kept at reception.		
1.2	Duplicate names are identified from the NBSS duplicate names list. A clerical officer highlights duplicate names on the Clinic Control Sheet, bar code labels for film reading and the address labels for the Screening Sheet.		
1.3	A Screening Sheet (Client Form) is produced by the Service for each woman who attends.		
1.4	Previous screening films from other screening services are obtained in advance of the clinic.		

1. Clinic Preparation (continued)

	Current Practice	Associated Risk	Recommendation
1.5	<p>A set of four labels is produced for each woman invited to attend a screening clinic. When a woman attends the set is used as follows:</p> <ul style="list-style-type: none"> • The first is placed on a pink slip and used to confirm identification details at reception. <p>The label on the pink slip is also used to mark the film set with identification details on one of the two mobile units</p> <ul style="list-style-type: none"> • The second is placed on the Screening Sheet and used to confirm identification details and record a telephone number • The third has a bar code and is placed on the bottom of the Screening Sheet and used to enter screening details in the Daybook • The fourth has a bar code and after processing will be placed on a corresponding film for film reading 		
1.6	An encrypted memory stick accompanies the clinic for the Daybook.		
1.7	The transfer of a clinic from one site to another adheres to PIAG guidelines.		

2. Clinic Reception

	Current Practice	Associated Risk	Recommendation
2.1	At the beginning of the day the radiographers count the number of women listed on the Clinic Control Sheet and record the total after the last entry on the list.		
2.2	Each woman is asked to state her full name at reception and her response is checked to match a name printed on a set of labels.		
2.3	<p>A label is selected and placed on a pink slip. The woman is asked to read the name and date of birth recorded on the label and to sign and date the slip to confirm they are correct.</p> <p>The pink slip also contains questions about current breast symptoms and the woman is asked to answer the questions.</p>		
2.4	<p>Attendance is recorded on the Clinic Control Sheet by highlighting the appointment time and screening number next to the woman's name.</p> <p>A number is allocated to each woman in order of arrival and the number is marked on the Clinic Control Sheet against her name and on the pink slip.</p>		

2. Clinic Reception (continued)

	Current Practice	Associated Risk	Recommendation
2.5	<p>A woman who attends and is not screened is:</p> <ul style="list-style-type: none"> • Marked on the Clinic Control Sheet by recording "Attended not Screened" against her name • Recorded on the Daybook as "Attended not Screened" <p>The corresponding unused bar code label intended for film reading is placed on the back of the Clinic Control Sheet.</p>		
2.6	<p>A woman who attends and has an incomplete screen is:</p> <ul style="list-style-type: none"> • Marked on the Clinic Control Sheet as attended • Recorded on the Daybook as attended 	<p>The tracking, monitoring and audit system is less effective.</p>	<p>Mark the Clinic Control Sheet and the Screening Sheet to confirm that a woman has attended and had an incomplete screen.</p>
2.7	<p>A woman who does not attend is marked on the Clinic Control Sheet by recording DNA against her name.</p> <p>DNA is written on the unused bar code label intended for film reading the unused label is then placed on the back of the Clinic Control Sheet.</p>		

2. Clinic Reception (continued)

	Current Practice	Associated Risk	Recommendation
2.8	<p>At the end of the clinic the highest allocated number recorded on the Clinic Control Sheet is used to confirm the total number of women screened. The number is recorded on the Clinic Control Sheet.</p> <p>The number of film packets for women screened is not counted to confirm it is the same as the number of women marked as attended on the Clinic Control Sheet.</p>	<p>Using the highest allocated number for this check may result in a mistake because the allocated numbers will not be recorded in order and the actual highest number could be missed.</p> <p>The chance to identify a discrepancy at the earliest opportunity is missed</p> <p>The effectiveness of the monitoring system is reduced.</p>	<p>At the end of the clinic, count the number of women marked on the Clinic Control Sheet as attended and screened to confirm the total number of women screened.</p> <p>At the end of the clinic, count the number of film packets for women screened and check the total matches the number of women marked on the Clinic Control Sheet as attended and screened.</p>
2.9	<p>The number of women marked as DNA on the Clinic Control Sheet is counted to provide the total number of DNA's. The number of DNA's is recorded on the Clinic Control Sheet.</p> <p>The number of unused bar code labels placed on the back of the Clinic Control Sheet is not counted and checked to match the number of women marked as DNA on the Clinic Control Sheet</p> <p>The name and screening number of each woman marked as DNA on the Clinic Control Sheet is not checked to match the name and screening number on an unused bar code label placed on the back of the Clinic Control Sheet.</p>	<p>The chance to identify a discrepancy at the earliest opportunity is missed.</p> <p>The effectiveness of the monitoring system is reduced.</p> <p>The chance to identify a discrepancy at the earliest opportunity is missed.</p> <p>The effectiveness of the monitoring system is reduced.</p>	<p>Check the number of women counted and marked as DNA on the Clinic Control Sheet match the number of unused bar code labels placed on the back of the Clinic Control Sheet.</p> <p>Check the name and screening number of each woman marked as DNA on the Clinic Control Sheet match the name and screening number on an unused bar code label placed on the back of the Clinic Control Sheet.</p>

2. Clinic Reception (continued)

	Current Practice	Associated Risk	Recommendation
2.10	<p>The numbers of women marked on the Clinic Control Sheet as screened, attended not screened, cancelled and DNA are totalled and checked to equal the number of women booked into the clinic.</p> <p>The number of women who attended and had an incomplete screen is not recorded on the Clinic Control Sheet.</p>	<p>The effectiveness of the monitoring system is reduced.</p>	<p>Record the number of women who attended and had an incomplete screen on the Clinic Control Sheet.</p>

3. Mammography

	Current Practice	Associated Risk	Recommendation
3.1	<p>Identity is verified before mammography. The woman is asked to state her name, date of birth and the first line of her address and her response is checked to be the same as the details recorded on the main identification label on the Screening Sheet.</p>		
3.2	<p>The number of films taken per woman is recorded on the Screening Sheet and the Daybook.</p>		

3. Mammography (continued)

	Current Practice	Associated Risk	Recommendation
3.3	A system is not in place to confirm identification details on a set of films taken on a mobile unit if it is discovered at processing that the identification marker failed.	A film set could be marked with incorrect identification details.	Discuss the options with the QA Radiographer and develop a system to confirm identification details on a set of films taken on a mobile unit should it be discovered at processing that the identification marker failed.
3.4	The Daybook is used.		
3.5	A radiographer alerts the film readers to a symptom that either she has noticed or the woman has reported to her by marking and highlighting a cross in a dedicated box on the corresponding Screening Sheet and by recording a Radiographer Alert on the Daybook. Supporting information is recorded on the Screening Sheet and Daybook.	This practice is an example of good practice. The risks associated with a radiographer alert are: <ul style="list-style-type: none"> • A film reader could miss the cross marked on the Screening Sheet • The radiographer could forget to record the alert on the Daybook 	Support current good practice by marking an alert (for example, a coloured dot) on the bar code label that will be placed on a film for film reading. At daybook importation or when loading the viewer, check that a film reader alert marked on a Screening Sheet has been uploaded onto the "current" NBSS record.

4. SAPE End of Clinic

	Current Practice	Associated Risk	Recommendation
4.1	SAPE is undertaken by a clerical officer at the same time as the film sets from the clinic are being processed.		

4. SAPE End of Clinic (continued)

	Current Practice	Associated Risk	Recommendation
4.1	The number of DNA'S recorded on the Clinic Control Sheet is checked to match the number of unused bar code labels on the back of the Clinic Control Sheet.		
4.2	The name and screening number on each unused bar code label on the back of the Clinic Control Sheet is checked to match the name and screening number of each woman marked as DNA on the Clinic Control Sheet. Each unused bar code label is ticked to confirm the check.		
4.3	The Daybook is imported.		
4.4	The number of DNA'S recorded on the Clinic Control Sheet is checked to match the number of unused bar code labels on the back of the Clinic Control Sheet.		
4.5	The list of women in the Daybook at importation is not printed to check it matches the women listed as attended on the Clinic Control Sheet.	A woman could be closed as DNA by mistake.	Print the list of women in the Daybook at importation and check they match the women listed as attended on the Clinic Control Sheet.
4.6	The tick on each unused bar code label on the back of the Clinic Control Sheet is crossed through to confirm a DNA letter has been produced.		

4. SAPE End of Clinic (continued)

	Current Practice	Associated Risk	Recommendation
4.7	The total number of attended, DNA's and attended not screened is checked to match the number of women booked in to the clinic.		
4.8	The Reporting Flowchart (Clinic Tracking Sheet) is issued after SAPE is complete. The number booked into the clinic, the number screened and the number of DNA's is recorded on the Reporting Flowchart.		

5. Film Processing

	Current Practice	Associated Risk	Recommendation
5.1	The Reporting Flowchart is married with the clinic in the processing room.		
5.2	The number of processed film sets married with corresponding film packets is counted. Reference is made to the Reporting Flowchart to confirm the total is the same as the total number of women screened. The number of film sets processed is not recorded.	The effectiveness of the monitoring system is reduced.	Record the number of film sets processed to confirm the check that the number of film sets processed matches the number of women screened.

5. Film Processing (continued)

	Current Practice	Associated Risk	Recommendation
5.3	The bar code label for film reading is placed on the corresponding left MLO. The name and screening number on the bar code label are checked to ensure they match the name and screening number on the film it is placed on.		
5.4	Technical Recalls identified during processing remain with the clinic and are loaded onto the viewer.		

6. Film Loading

	Current Practice	Associated Risk	Recommendation
6.1	A clinic is not taken from the processing room to the viewer room until it has been married with its corresponding Reporting Flowchart.		
6.2	The film packets are not counted before the clinic is loaded onto the viewer to confirm the total is the same as the number of women recorded on the Reporting Flowchart as attended because they were counted after processing. The check is made after the clinic is loaded.	The film packets could have been miscounted at processing and a discrepancy will not be identified at the earliest opportunity when the ability to resolve the discrepancy is likely to be easier.	Count the film packets before loading a clinic onto the viewer to: <ul style="list-style-type: none"> • Confirm the total is the same as the number of women recorded on the Reporting Flowchart as attended • Identify a discrepancy at the earliest opportunity

6. Film Loading (continued)

	Current Practice	Associated Risk	Recommendation
6.3	A record is made on the Reporting Flowchart and on a white board to identify where the clinic is loaded.		
6.4	It was reported that checks are made to confirm the name and screening number on the film set, bar code label, Screening Sheet and film packet are the same.		
6.5	The whole clinic is kept together.		
6.6	The film packets are counted after the clinic is loaded onto the viewer to confirm the total is the same as the number of women recorded on the Reporting Flowchart as attended.		
6.7	Film sets, from a variety of clinics, requiring previous films for film reading are married with their corresponding previous films, loaded on the viewer together and tracked on a "Various" Reporting Flowchart.		

7. Film Reading

	Current Practice	Associated Risk	Recommendation
7.1	<p>During the previous Right Results walkthrough in June 2008 it was reported that the film readers swiped the bar code label placed on the left MLO film to identify a woman on NBSS before swiping a "result" bar code.</p> <p>At this visit it was reported that there is variation in practice; some readers swipe the bar code label placed on the left MLO film and some swipe the bar code label on the Screening Sheet.</p>	<p>Swiping the bar code label on the Screening Sheet to identify a woman on NBSS increases the chance of a woman receiving the wrong result because the risk of the paperwork being in a different order to the order of the films on the viewer is greater than the risk of the wrong bar code being placed on the wrong film.</p>	<p>Swipe the bar code label placed on the left MLO film to identify a woman on NBSS before swiping a "result" bar code.</p> <p>Maintain a rigorous checking mechanism throughout the Right Results process to ensure the correct bar code label is placed on the correct film.</p>
7.2	<p>Film Reader 1:</p> <ul style="list-style-type: none"> • Inputs their opinion on the computer • Does not record an opinion on the Screening Sheet for those women reported as Routine Recall (RR) • Records their opinion of Recall to Assessment (RC) as "A" on the corresponding Screening Sheet and marks the breast diagram 		

7. Film Reading (continued)

	Current Practice	Associated Risk	Recommendation
<p>7.2 (cont)</p>	<ul style="list-style-type: none"> Does not record the name and screening number of each woman they report as RC on the Reporting Flowchart. This task is undertaken by Film Reader 2 	<p>Because film Reader 1 does not record the name and screening number of each woman they report as RC on the Reporting Flowchart Film Reader 2, the person unloading the viewer and the Clerical Officers issuing the result letters are unable to use the Reporting Flowchart to its full capacity to identify and confirm a discrepancy.</p> <p>For example:</p> <ul style="list-style-type: none"> Reader 2 reports the film set as RR and saves RR on NBSS <p>Reader 1 reported the same film set as RC and intended to save RC on NBSS but by mistake saved RR</p> <p>As both readers have saved the result as RR, NBSS will save the result as RR on the Session List checked by Reader 2. Therefore, if Reader 2 does not see "A" (RC) recorded on the Screening Form the discrepancy will be overlooked.</p>	<p>Film Reader 1 should record their opinion of RC on the Reporting Flowchart. This could be achieved without disturbing the format of the Reporting Flowchart by Film Reader 1 using the reverse side.</p>

7. Film Reading (continued)

	Current Practice	Associated Risk	Recommendation
<p>7.2 (cont)</p>	<ul style="list-style-type: none"> • Records their opinion of TR on the corresponding Screening Sheet <p>Records the name and screening number of the film sets they have reported as TR on the Reporting Flowchart in the "TR" section, removes the film set from the viewer, marries the films with their film packet and puts the packet in the labelled TR basket</p> <p>Records the name and screening number of the film sets they require previous films for before they can issue a result on the Reporting Flowchart in the "Previous Films Requested" section, removes the film set from the viewer, marries the films with their film packet and puts the packet in the labelled Previous Films Request basket</p>		
<p>7.3</p>	<p>Film Reader 2:</p> <ul style="list-style-type: none"> • Inputs their opinion on the computer • Does not record an opinion on the Screening Sheet for those women reported as RR • Records their opinion of RC on the corresponding Screening Sheet and marks the breast diagram 		

7. Film Reading (continued)

	Current Practice	Associated Risk	Recommendation
<p>7.3 (cont)</p>	<ul style="list-style-type: none"> Records their opinion of TR on the corresponding Screening Sheet and manages the film set in the same way as Film Reader 1 (7.2) <p>Manages a film set they require previous films for in the same way as Film Reader 1 (7.2)</p> <ul style="list-style-type: none"> Records the names and screening numbers of the women that both film readers 1 and 2 have reported as RC on the Reporting Flowchart in the "Recall" section 	<p>Because film Reader 1 does not record the name and screening number of each woman they report as RC on the Reporting Flowchart the risk that Film Reader 2 could miss a discrepancy is increased.</p> <p>For example:</p> <ul style="list-style-type: none"> Reader 2 reports the film set as RR and saves RR on NBSS <p>Reader 1 reported the same film set as RC and intended to save RC on NBSS but by mistake saved RR</p> <p>As both readers have saved the result as RR, NBSS will save the result as RR on the Session List checked by Reader 2. Therefore, if Reader 2 does not see "A" (RC) recorded on the Screening Form the discrepancy will be overlooked.</p>	<p>Film reader 1 should record their opinion of RC on the Reporting Flowchart. This could be achieved without disturbing the format of the Reporting Flowchart by Film Reader 1 using the reverse side.</p>

7. Film Reading (continued)

	Current Practice	Associated Risk	Recommendation
7.3 (cont)	<ul style="list-style-type: none"> Removes the films agreed by Readers 1 and 2 as RC from the viewer, marries them with their film packet and puts the film packet in the basket labelled "Recall" Records the names and screening numbers of the women where the opinions of Film Reader 1 and Film Reader 2 do not agree on the Reporting Flowchart in the "Discussion" section 	<p>Because film Reader 1 does not record the name and screening number of each woman they report as RC on the Reporting Flowchart the risk that Film Reader 2 could miss a discrepancy is increased.</p> <p>For example:</p> <ul style="list-style-type: none"> Reader 2 reports the film set as RR and saves RR on NBSS <p>Reader 1 reported the same film set as RC and intended to save RC on NBSS but by mistake saved RR</p> <p>As both readers have saved the result as RR, NBSS will save the result as RR on the Session List checked by Reader 2. Therefore, if Reader 2 does not see RC recorded on the Screening Form the discrepancy will be overlooked.</p>	<p>Film Reader 1 should record their opinion of RC on the Reporting Flowchart. This could be achieved without disturbing the format of the Reporting Flowchart by Film Reader 1 using the reverse side.</p>

7. Film Reading (continued)

	Current Practice	Associated Risk	Recommendation
7.3 (cont)	<ul style="list-style-type: none"> Removes the films reported as RC by one reader and as RR by the other reader from the viewer, marries them with their film packet and puts the film packet in the basket labelled "Discussion" Refers to the NBSS Session List to confirm that all film sets that do not have a final action of Routine Recall (RR) have been removed from the viewer 	<p>This is an example of good practice, but the check could miss a discrepancy if either one of the film readers has saved a routine recall result by mistake instead of a recall to assessment result.</p>	<p>Film Reader 2 should refer to the Screening Sheets, the NBSS Session List and a record of recommended actions of recall to assessment made by both Film Reader 1 and Film Reader 2 on the Reporting Flowchart to confirm they have removed the correct film sets from the viewer.</p>
7.4	<p>After the completion of the second film read the film sets with a Routine Recall result remain on the viewer.</p> <p>The Reporting Flowchart remains with the Routine Recall Results.</p>		
7.5	<p>The film/s for a woman who attended and had an incomplete screen are loaded on the viewer with their clinic and reported by Film Readers 1 and 2.</p>	<p>This is an example of good practice; the films from an incomplete screen should be reported by two film readers.</p>	<p>Continue to film read and report the film/s from an incomplete screen.</p>

7. Film Reading (continued)			
	Current Practice	Associated Risk	Recommendation
	The film readers record a result on NBSS.	A result is being saved on NBSS on the basis of an incomplete screen.	The QARC is seeking advice from the National Office with regard to how a result for a woman who has had an incomplete screen should be recorded and will inform all screening services of the response in the near future.
7.6	<p>The Consensus Read: The final action from the consensus read is recorded by a Film Reader on:</p> <ul style="list-style-type: none"> • The computer system • The corresponding Screening Sheet by writing RR (routine recall) or ASS (recall to assessment) <p>The outcome from a Consensus Read is not recorded on the Reporting Flowchart by a Film Reader. The Office Manager records the outcome on the Reporting Flowchart when she is producing the result letters.</p>	<p>The opportunity for the film readers to confirm at the end of the consensus film read that they have discussed all film sets listed on the Reporting Flowchart as requiring a consensus film read is not available.</p> <p>The opportunity for the clerical staff to cross reference a result recorded by the film readers on the computer system, screening sheet and Reporting Flowchart has been removed. As a result the monitoring system is less effective.</p>	<p>A copy of the Reporting Flowchart should remain with and accompany the Consensus Read.</p> <p>A film reader at the Consensus Read should record the outcome for each film set discussed on the Reporting Flowchart to enable discrepancies to be identified and an effective monitoring system and audit trail to be maintained.</p>

7. Film Reading (continued)

	Current Practice	Associated Risk	Recommendation
7.6 (cont)	Each film set is removed from the viewer and married with its film packet. All film packets are placed in the basket labelled "Post Discussion".		

8. Unloading the Viewer

	Current Practice	Associated Risk	Recommendation
8.1	The SIRR List is printed.	If the SIRR List is printed after assessment appointments have been booked or the consensus read has taken place it may not reflect the true status of the clinic at the end of the second film read.	Ensure the SIRR List is printed after the second film read, before assessment appointments have been booked or the consensus read has taken place
8.2	The film sets with a routine recall result are unloaded from the viewer before the film sets already removed from the viewer by the film readers are checked.	A discrepancy will not be identified at the earliest opportunity when the ability to resolve the discrepancy will be easier.	Before unloading the film sets with a routine recall result from the viewer check the names and screening numbers recorded on the Reporting Flowchart match the names and screening numbers on the Incomplete SIRR List and the final actions of Assessment on the Complete SIRR List. Then confirm that the corresponding film packets have either been placed in a labelled basket in the viewer room or taken to the office.

8. Unloading the Viewer (continued)

	Current Practice	Associated Risk	Recommendation
8.3	The film packets for film sets with a Routine Recall result are not counted before the film sets that remain on the viewer are unloaded.	A discrepancy will not be identified at the earliest opportunity when the ability to resolve the discrepancy will be easier.	Count the film packets before and after unloading the routine recall result film sets from the viewer to confirm the total is the same as the number expected.
8.4	The name and screening number on each film set unloaded is checked to be the same as the name and screening number on the corresponding Screening Sheet, bar code label on the left MLO and film packet.		
8.5	The final action section of each Screening Sheet is checked to be blank to support a Routine Recall result.		
8.6	<p>The film packets are counted after the film sets have been removed from the viewer.</p> <p>The number of film sets with a routine recall result unloaded from the viewer is recorded on the Reporting Flowchart in the "No. Unloaded – Normal" section.</p> <p>The number is added to the number of "No. Unloaded Other" and the combined total is checked to equal the number of women screened.</p>		

8. Unloading the Viewer (continued)

	Current Practice	Associated Risk	Recommendation
8.7	<p>After the routine recall results have been unloaded from the viewer the names and screening numbers recorded on the Reporting Flowchart are highlighted on the Complete and Incomplete SIRR Lists.</p> <p>The total number of film sets in each result category is recorded on the front page of the SIRR List.</p>	<p>Highlighting the names and screening numbers recorded on the Reporting Flowchart on the Complete and Incomplete SIRR Lists is an example of good practice but the effectiveness of the check is limited because it is undertaken after the routine recall results have been unloaded making it more difficult to resolve a discrepancy.</p>	<p>Before unloading the film sets with a routine recall result from the viewer check the names and screening numbers recorded on the Reporting Flowchart match the names and screening numbers on the Incomplete SIRR List and the final actions of Recall to Assessment or Technical Recall on the Complete SIRR List.</p> <p>Continue to highlight the names and screening numbers recorded on the Reporting Flowchart on the Complete and Incomplete SIRR Lists to confirm the check.</p>

8. Unloading the Viewer (continued)

	Current Practice	Associated Risk	Recommendation
8.8	Film sets with a Routine Recall result are taken to the Office. The Reporting Flowchart and SIRR List accompany the Routine Recall results.		
8.9	<p>When unloading the viewer, very occasionally a discrepancy is identified whereby a film reader has married a film set with the wrong film packet.</p> <p>This is becoming more difficult to resolve with the occasional use of digital mammography for screening because it could be assumed that the films are not available in hard copy.</p>	<p>A film set could be lost.</p> <p>When a film reader marries a film set with the wrong packet there is an increased risk of an incident at assessment; however this risk is reduced because there is a check when the assessment appointment is booked to confirm that the name and screening number on one film in the packet matches the name and screening number on the accompanying Screening Sheet (9.3).</p> <p>A discrepancy could be overlooked.</p>	<p>When placing a film set in a packet the film reader should check the name and screening number on the film set, Screening Sheet and film packet match.</p> <p>Mark the Screening Sheet and Clinic Control Sheet when digital screening images are taken.</p>

9. Routine Recall Results (RR) from the Second Film Read

	Current Practice	Associated Risk	Recommendation
9.1	<p>The Recall to Assessment results from a clinic arrive in the office after film reading in two stages:</p> <ul style="list-style-type: none"> After the completion of the second film read, the Office Manager collects the Recall to Assessment results from the "Recall" basket in the viewing room. <p>Sometimes this is done before the routine recall results have been unloaded from the viewer.</p> <ul style="list-style-type: none"> After the completion of the Consensus Read. The Office Manager collects the Recall to Assessment results from the "Post Discussion" basket in the viewing room 	<p>The ability to identify and resolve a film reading discrepancy at the earliest opportunity is reduced.</p> <p>The tracking system is less effective.</p>	<p>Before removing a film packet from the viewing room check the name and screening number and the result match on the screening sheet, Reporting Flowchart and NBSS SIRR List. This will enable a discrepancy to be identified at the earliest opportunity when it is easier to resolve.</p>

9. Routine Recall Results (RR) from the Second Film Read (continued)

	Current Practice	Associated Risk	Recommendation
9.2	Film packets removed from the viewing room before the Routine Recall results are unloaded from the viewer are not tracked.	Staff could assume they know the whereabouts of a film packet but in reality it could be lost or mislaid.	Track film packets removed from the viewing room before the routine recall results are unloaded from the viewer.
9.3	A check is made when the assessment appointment is booked to confirm that the name and screening number on one film in the packet matches the name and screening number on the accompanying Screening Sheet.		
9.4	The final action of recall to assessment recorded on the Screening Sheet is checked to be the same as the result recorded on NBSS. This is an example of good practice.		
9.5	The agreed final action of recall to assessment (from the first and second film read) recorded on the Screening Sheet and on NBSS is not cross referenced with the result recorded on the Reporting Flowchart to confirm they match.	The ability to identify and resolve a film reading discrepancy at the earliest opportunity is reduced. The tracking system is less effective.	Before removing a film packet from the viewing room to book an assessment appointment check the name, screening number and the result match on the screening sheet and the Reporting Flowchart.

9. Routine Recall Results (RR) from the Second Film Read (continued)

	Current Practice	Associated Risk	Recommendation
9.6	The final action of Recall to Assessment from the Consensus Read is recorded on the Reporting Flowchart by the Office Manager and not by a Film Reader.	The opportunity for the clerical staff to cross reference an RC result from the Consensus Read between the results recorded on the computer system, the Screening Sheet and the Reporting Flowchart to confirm they match is not available. As a result the monitoring system is less effective which increases the chance of a discrepancy being overlooked	A film reader at the Consensus Read should record the outcome for each film set discussed on the Reporting Flowchart to enable the clerical officer issuing the result to maintain an effective monitoring system and identify a discrepancy.
9.7	The assessment appointment date is recorded on the Reporting Flowchart.		

10. Recall to Assessment Results

	Current Practice	Associated Risk	Recommendation
10.1	The Office Manager collects the Technical Recall results from the Technical Recall basket in the viewing room before the routine recall results have been unloaded from the viewer.	The ability to identify and resolve a film reading discrepancy at the earliest opportunity is reduced. The tracking system is less effective.	Before removing a film packet from the viewing room check the name and screening number and the result match on the screening sheet, Reporting Flowchart and NBSS SIRR List. This will enable a discrepancy to be identified at the earliest opportunity when it is easier to resolve.
10.2	Film packets removed from the viewing room before the Routine Recall results are unloaded from the viewer are not tracked.	Staff could assume they know the whereabouts of a film packet but in reality it could be lost or mislaid.	Track film packets removed from the viewing room before the routine recall results are unloaded from the viewer.

10. Recall to Assessment Results (continued)

	Current Practice	Associated Risk	Recommendation
10.3	The final action of Technical Recall recorded on the Screening Sheet is checked to be the same as the result recorded on the NBSS. This is an example of good practice.		
10.5	The final action of technical recall recorded on the Screening Sheet and on NBSS after the first or second film read is cross referenced with the result recorded on the Reporting Flowchart to confirm they match. This is an example of good practice.		

11. Technical Recall Results

	Current Practice	Associated Risk	Recommendation
11.1	The Reporting Flowchart and SIRR List accompany the Routine Recall results and are referred to when the Routine Recall results from the second film read are checked by a Clerical Officer.		
11.2	The number of film packets is not counted to check it matches the number of Routine Recall results recorded on the Reporting Flowchart.	A discrepancy will not be identified at the earliest opportunity when the ability to resolve the discrepancy is likely to be easier.	Count the film packets containing film sets with a Routine Recall result to confirm the total is the same as the number of Routine Recall results recorded on the Reporting Flowchart.

11. Technical Recall Results (continued)

	Current Practice	Associated Risk	Recommendation
11.3	A routine recall result is confirmed by checking that the Reader 1 and Reader 2 sections of the Screening Sheet are blank.		
11.4	SIBC is used to close the episodes.		
11.5	The name and screening number on a Screening Sheet is checked to match a name and screening number listed on the complete SIRR List as a Routine Recall result. The screening number is highlighted on the complete SIRR List to confirm the check.		
11.6	The Routine Recall result letters are printed.		
11.7	The name and screening number on each letter is checked to match a name and screening number listed on the complete SIRR List with a Routine Recall result. The name is highlighted on the complete SIRR List to confirm the check.	The person performing the check described in 11.5 may highlight a screening number by mistake without having referred to a Screening Sheet. Such a mistake increases the chance of a woman receiving the wrong result.	Before sending a routine recall result letter, check the name and screening number on the letter match the name and screening number on a blank screening sheet and a name and screening number listed on the complete SIRR List with a Routine Recall result

11. Technical Recall Results (continued)

	Current Practice	Associated Risk	Recommendation
11.8	The number of film packets is counted and checked to match the number of routine recall result letters.		

12. Routine Recall Results (RR) from the Arbitration Film Read

	Current Practice	Associated Risk	Recommendation
12.1	The Routine Recall results from the Consensus Film Read are issued by a senior clerical officer.		
12.2	The computer screen and the final action section of the Screening Sheet are checked to confirm the result is Routine Recall.		
12.3	The final action of Routine Recall from the Consensus Read is recorded on the Reporting Flowchart by the Office Manager and not by a Film Reader.	The opportunity for the clerical staff to cross reference an RR result from the Consensus Read between the results recorded on the computer system, the Screening Sheet and the Reporting Flowchart to confirm they match is not available. As a result the monitoring system is less effective which increases the chance of a discrepancy being overlooked	A film reader at the Consensus Read should record the outcome for each film set discussed on the Reporting Flowchart to enable the clerical officer issuing the result to maintain an effective monitoring system and identify a discrepancy.

13. Batch Reconciliation

	Current Practice	Associated Risk	Recommendation
13.1	SASP5 is checked twice a week to ensure there are no missing results. This is an example of good practice.		

6. Radiography Report

All but one of the recommendations from the last QA visit report have been achieved:

- Consider rescheduling at least one MDTM to allow radiographers to attend

The sessions allocated for the MDT meetings are fixed, however the Superintendent has willingly offered staff TOIL if they choose to attend these in their own time.

Standards of Mammography

An assessment on fifty sets of screening films in both projections based on three main categories was undertaken:

1. correct identification
2. whole breast imaged
3. overall technical quality

Films were generally of a good standard with acceptable image quality and some were noticeably better than those taken 3 years ago. A large number of the films reviewed showed an obvious run-back artifact along the chest wall edge of each film extending up to two cm into the breast. This was especially noticeable on lower density images and had not been identified either when the films were processed and collated or when the viewer had been loaded. This type of run-back artifact is usually a progressive problem caused by hardening of the rollers. Vigilance by the radiographers and assistant practitioners could have identified this at an earlier stage and Carestream asked to replace the rollers. This was brought to the attention of the Superintendent at the time.

Technical repeat and recall rates continue to be monitored regularly and individuals are given their own figures on a quarterly basis. The figure for the last quarter was 2.01% and the overall figure for the last four quarters was 1.88%, which is within the national target of <2% of total examinations. An audit in 2005 looked at the consistently higher than average TR rate of the unit at that time and a programme of regular peer review of images was introduced. This has not been continued as regularly as before due to staffing constraints and I would recommend its reintroduction.

The unit is extremely fortunate in having two FFDM units and although only limited screening takes place on these at the moment; one session per week for special needs and implants, a programme of digital image peer review should also be developed to ensure that quality is maintained.

Technical Aspects

QA time at the base unit is available to both QA radiographers and is identified on the rota. All the radiographers and assistant practitioners are responsible for performing daily equipment quality control. Data for the analogue machines is not entered on to the windense system but is recorded on paper. Data for digital machines is recorded on units and on paper. Fault report forms are completed and sent to the Regional Physicist for forwarding on to the National Office. All equipment is either under warranty or covered by fully comprehensive maintenance contracts.

Business cases have been written to replace both analogue mobile vans. The service plans to run only one FFDM mobile, replacing the other mobile with a new FFDM static site at Trumpington. Both ultrasound machines are in the three year capital

equipment replacement plan and are scheduled for replacement in 2010 and 2011 respectively.

Radiation Protection and Health & Safety

There is no named Health & Safety representative as such. The Superintendent is the risk officer and carries out departmental risk assessments.

The Superintendent is also the radiation protection supervisor. Local rules were updated recently and are displayed on the backs of the doors in all the x-ray rooms.

There is a named first aider in the unit and a link manual handling assessor.

Management and organisational issues

Population size for the current screening round is 55,000. Uptake for the screening round 2007 – 2008 was 77.4% but this has dropped for the current year (April 08 – March 09) and is currently 75.1%.

The percentage of self-referrals has also decreased from 5% in 2007-2008 down to 3.6% for the nine months between April – December 2008.

Recommended staffing levels for this population and uptake are; 55,000 x 1.3 wte per 10,000 women = 7.1 wte.

National Guidance recommends that when calculating the wte for mammographic staffing of screening, the time spent on advanced practice should be excluded. It is important that if the Superintendent has a major managerial responsibility with minimal clinical input she is also excluded from the radiographic staffing calculation for clinical service delivery. Assistant practitioners may spend no more than 0.6 wte per week screening and the remainder of their time should be occupied with other tasks, ie. viewer loading/chaperone duties.

There are a total of 10.75 wte advanced practitioners, radiographers and assistant practitioners in post. Of this only 5.2 wte is available to deliver screening once the time spent on delivering the symptomatic service and other duties has been taken out of the calculations.

There is therefore a significant shortfall of 1.9 wte in the imaging sessions necessary for the delivery of screening as shown in more detail on the table below.

	Supt radiographer	Specialist/ Advanced practitioners	Radiographer	Assistant Practitioner	Imaging Assistant
wte	1.0	.53	7.72	1.6	1.54
Screening wte	-	-	4.4	0.8	-
Total wte available for screening	5.2				
Wte for other duties	3.3 symptomatic, .53 Advanced Practice 1.8 chaperone, film loading etc				

Age extension will increase the eligible population by 22,000, giving a total of 77,000 at which time the unit will need at least a further 3.0 wte mammographic staff to deliver screening bringing the total number required up to 10.0 wte. If the uptake improves to over 75% overall then 11.5 wte staff will be needed.

In common with the situation in other Breast Units across the region the symptomatic service has developed considerably. The radiographic staffing necessary to sustain this level of activity is 3.3 wte per week, which places a significant burden on the delivery of screening.

There is current documentation relating to patient /client identification, PIAG compliance is monitored at annual appraisals and signed consent is obtained prior to all interventional procedures.

The Superintendent is joint Programme Manager along with the Screening Office Manager. The Deputy Superintendent does not have any management duties formally delegated to her and is not allocated management time on the rotas. The development of a structured Deputy role would undoubtedly benefit the unit considerably. Succession planning for the eventual retirement of the current Superintendent needs to be considered and cover for annual leave and sickness should be more robust. The deputy appears to be a very capable individual and the unit would benefit from developing her further.

Teamwork

The radiographers and assistant practitioners display a strong team spirit, supporting each other particularly well. As a team in general, they do not feel very visible within the unit and partly attribute this to their non attendance at the MDT meetings. They are keen to raise their profile collectively as a group and are demonstrating their willingness to achieve this by looking for ways to integrate themselves more into the team. Pre-assessment image review by the team before each assessment clinic is carried out in other units: this review promotes team discussion generally, facilitates CPD, is useful for clinical reasons too and might be worth considering here if time allows.

Staff meetings are held at about 6 week intervals for the last half of an afternoon session. Attendance at these is very limited as clinical work on the mobiles is not cancelled, the day of the week is not varied and, therefore, some staff never have an opportunity to attend. Minutes are produced and circulated via e-mail and the agenda is open to contributions from all staff. There is one joint staff meeting per year between the radiographers and the A&C staff. There is a six monthly away day for the whole team where research and audit results are presented and protocols and policies discussed.

The vast majority of staff are part time and this causes particular challenges in ensuring that everybody is up to date and aware of what is going on in the unit.

Communication in the breast team as a whole is perceived to have deteriorated recently and, while the radiographers are keen to improve the service, they have not always understood the reasons behind some of the changes that have been implemented in the department.

Multiple concerns were raised on the difficulty of hand-washing due to lack of fresh running water and distances to toilet facilities at some mobile sites. Every effort should be made to ensure that staff can access these facilities easily. Concerns were also raised again regarding the scheduling of mobile appointments and the difficulties

of the recent “long day” trial were debated. Staff were encouraged to respond to the Superintendent with constructive suggestions on how the long day could be improved.

There are no links with radiographers in the main department and local cancer network meetings do not involve the radiographers.

Training & Development

All radiographers and assistant practitioners hold a recognised qualification in mammography and have a good knowledge of the NHSBSP policies. 5 radiographers attended Symposium Mammographicum in 2008 and seven are due to attend the Cambridge Conference in 2009. All available staff attend ‘Away Days’, study days and radiology audit sessions.

All radiographers, advanced / assistant Practitioners and radiographic dept assistants have had an appraisal within the last six months and all have documented PDP’s. They are encouraged to undertake CPD activities but are not routinely given time back or allocated time during working hours to do this. The last departmental clinical update was more than two years ago.

There is a relatively low level of advanced practice amongst the radiographers for a unit of this size. One radiographer undertakes ultrasound and interventional procedures and another is training in ultrasound. There is not seen to be any need for further radiographic advanced practice and radiographer film readers are not required due to the number of radiologists in the unit.

The qualified advanced practitioner is in the unfortunate position of having a split contract paid at two different bands; she is band 7 for only those sessions per week where she performs advanced practice and band 6 for time spent screening. Split contracts such as this are not acceptable under Agenda for Change terms and conditions and this situation should be rectified as a matter of urgency.

Client Satisfaction and Acceptability

The unit received 52 written compliments during the last year. There were 14 complaints made during the same period, 12 minor, mainly about the parking on the Addenbrooke’s site and 2 reported through the PALS department which have been resolved. There is a visitors’ book in reception and the “Your Views Count” leaflets are used to record compliments and complaints. A quarterly patient satisfaction survey is being developed by QARC which will be adopted in the unit once the Trust Audit Department have confirmed they are happy with it. Letters and cheques are regularly received by the unit. ??Complaints were made last year. The Breast Unit has a bi-annual Clinical Governance Meeting

There is no funded health promotion activity.

Radiographic Performance

Staff consistently achieve good quality images. Individual TR/TP rates are monitored and have been formally acted upon in the past where necessary.

The impression I received during my visits was of a strong, committed team of radiographers and assistant practitioners who provide a high quality screening and symptomatic mammography service to their women.

Actions and Recommendations

Immediate

- Reinststate a regular formal programme of self and peer review of images
- Develop a system of peer review for digital images
- Improve access to facilities at mobile sites

Within 3 months

- Work with HR to band the advanced practitioner for her whole contract at band 7
- Arrange a clinical update for the department

Within 6 months

- Increase radiographic staffing to support the screening service
- Consider a more inclusive schedule of staff meetings
- Develop the Deputy Superintendent role

Monica Dale

7. Medical Physics Report

Introduction

This report is based on visits to the Cambridge Breast Screening Service at Addenbrooke's Hospital on 24th and 26th February 2009. The documentation reviewed included recent physics reports for the X-ray and ultrasound units, radiographers' QA data, and compliance with radiation protection legislation (IRR99 and IRMER). Local policies, procedures and records were compared with national guidelines. The audit visit followed the format given by NHSBSP publication No.40. Discussions took place with the following members of staff:

Barbara Knighton (Supt Radiographer)

Mary Hunt (Local QA Radiographer)

Angela Freeman (Local QA Radiographer)

Oliver Morrish (Local Physicist)

Equipment

Cambridge Breast Screening Service (BSS) uses three analogue and two digital mammography X-ray units. Static units at base comprise one GE Senographe DS full field digital unit, one GE Senographe Essential full field digital unit and one Siemens Mammomat 3000 Nova. Mobile units comprise one Lorad MIV and one Siemens Mammomat 3000 Nova. The GE Senographe DS incorporates a stereo unit. There is one Kodak (Carestream) film processor. Kodak Min R EV film and Min R cassettes with EV-150 screens are used.

There are two Toshiba Aplio 80 and one Toshiba Aplio XG ultrasound units.

There are no significant problems with the X-ray, ultrasound or processing units.

Equipment servicing

X-ray, ultrasound and processing equipment is serviced regularly by the manufacturer's service engineers. The Equipment Handover form should be revised – a new version is available from Physics.

Radiation Dose, Film Density (or Pixel Value) and Image Quality

Mean glandular dose to the standard breast, film density (or pixel value) and image quality are assessed as part of routine Physics quality assurance surveys at intervals of 6 months for each X-ray unit. Film density (or SNR for digital units) is monitored daily, and image quality weekly, by the BSS radiography staff. These performance parameters generally meet NHSBSP standards for all units. Film density for the analogue units on occasion exceeds the upper limit of 1.9 due to slight increases in processing speed, but is corrected by adjustment of the fine density control and reduces again when the speed decreases.

The “crossover” points at which programme settings change on the Siemens units have recently been adjusted according to new Regional guidance, and the new settings should result in improved image quality. At the audit the image processing settings on the digital units were examined. It appears that the “Fineview” processing package is automatically applied on one of the units but not on the other. This should be

investigated and the units matched according to the radiologists' preferences. The "Premiumview" processing can be added or removed at the reporting workstation.

The location of the reporting monitors for the GE Senographe DS means that control of ambient lighting and reflections is difficult. The new reporting room should be used for reporting so far as is practicable.

Radiation Protection

Local Rules are available for each X-ray room. These include all essential elements and are up-to-date. However the Local Rules should clarify that the entire room is the Controlled Area whilst the unit is connected to the mains; that staff should remain behind the protective screen at the console where possible; and that if their presence is required elsewhere in the room they should wear appropriate lead clothing. Currently the wording is a little ambiguous. The signs on the doors should ideally indicate the radiation risk (i.e. external radiation).

The IRMER documentation is incomplete and requires revision. However, new national guidance on IRMER in the NHSBSP is about to be published, so it is recommended that any revision is postponed until the new guidance is available.

Radiographer Quality Assurance

The equipment QA programme is generally of a high standard and the QA Radiographers are clearly very dedicated to ensuring that this high standard is maintained. All tests are being carried out on all units at the required frequency. There are several points of good practice, including a good system for displaying QC results on A3 charts; and an excellent ultrasound QA system which includes phantom measurements. Staff are working very hard to comply with QA requirements and are given sufficient time for QC testing. For many tests however, remedial and suspension levels need to be put in place or need revising in order to meet the standards of NHSBSP Publication 63. Work instructions are being updated and further revisions are needed. In particular the following is required:

- The work instruction for suspension of X-ray equipment needs to be revised to make absolutely clear who should be informed when remedial or suspension levels are exceeded. This work instruction needs to be referred to on the data sheets used for recording QC results, and be readily available, so that staff performing tests act accordingly.
- Up to date remedial and suspension limits, taken from the tolerances given in NHSBSP Publication 63, need to be in place for all QC tests. Tolerances must be given in the form of ranges (rather than e.g. "+/- 5%") on all QC record sheets, along with baseline and/or target values. Tolerances must also be marked on all graphs used for recording results. It is important that when a new graph is started the tolerances are transferred across immediately. In particular, the following need to be in place:
 - Sensitometry
 - Speed and Contrast (+/-0.1 remedial, +/-0.2 suspension)
 - Base plus fog (0.23 remedial, 0.26 suspension)
 - Developer temperature (+/-0.5° from baseline remedial, +/-1.0° suspension)
- Daily and weekly Perspex block tests:

- Remedial and suspension levels of mAs given as a range for each unit and Bucky along with baseline values (Daily: +/-5% remedial, +/-10% suspension; weekly +/-10% remedial).
- Target density, and expected filter and kV, to be stated on QC record sheets.
- For weekly tests, an additional remedial level is required to ensure density at all thicknesses is within the range 0.3. This could be achieved by setting the required densities to be within 0.15 of the target i.e. 1.55 – 1.85. Refer to NHSBSP 63 for density suspension levels.
- For mobile units it is particularly important that remedial and suspension levels for mAs are available and acted upon since films are not processed until the next day.
- A column for the fine density setting is needed on all QC record sheets.
- Work instructions to be amended to reflect the above.
- Work instructions to include requirement to plug in the densitometer, since it is believed that readings may be unreliable when run off the battery.
- Physics can supply a foam spacer for achieving Programme 4 with 7cm Perspex on Siemens units.
- Baseline values should be reviewed on a monthly basis.
- Digital units:
 - Tolerances in line with national requirements rather than GE's expectations to be developed in conjunction with local Physics service.
 - Ensure that QC results are recorded on disk.
 - Reinstate availability of SMPTE phantom and dead pixel map
- Weekly image quality tests:
 - The tolerances given in NHSBSP 63 for the various test details need to be observed as well as the IQIN number. Results indicate that some test details often fail to meet these tolerances. This could be due to poor image quality at chest wall edge due to chemical runback in the processor. Local Physics service to investigate this.
- Cassette sensitivity and film screen contact:
 - Tolerances are required for mAs (+/-5% of mean value) and density (+/-0.10 OD of mean). Physics can provide a spreadsheet for calculating this.
 - Spare 24x30 cassettes at base should be moved to the van to ensure that there are 8 available at each location.
- Monthly magnification AEC test: tolerances are required
- Post-engineer visit checks:
 - New test required for uniformity. A sheet of aluminium can be provided by Physics.

- Post-mobile move checks:
 - X-ray spillover at chest wall edge could be tested with Gafchromic self-developing film. Local Physics service to investigate.
- Stereo localisation accuracy:
 - For the Mammotome protocol, include the need to use a lower needle guide in the work instruction.
 - Regularly check the test needle to ensure it is not bent and replace if necessary.
 - A work instruction is needed for the localisation QC test with FNA needle
 - Record actual errors in x, y and z in mm rather than recording ticks
 - Ensure a log of QC results is recorded on disk
 - Ensure all radiography staff trained to use the unit perform tests sufficiently frequently to maintain their skills – consider refresher training from GE.

Physics Services

Physics services are provided by Addenbrooke's Hospital. The Physics service is very good and the BSS is satisfied with the standard of service they receive. There is an excellent relationship between Physics and the BSS, and Physics is consulted appropriately. All units are visited twice yearly. It is understood that an SLA is being developed – this should be put in place as soon as is practicable. The Lead Physicist has made considerable efforts to update protocols and to ensure the QA visits are kept up-to-date. However, staff resources are barely adequate for routine mammography and there is little time for research and development, though standards are still generally being met. Just 0.95 WTE clinical scientists are involved in NHSBSP work whereas NHSBSP publication 33 requires 2.8 WTE. Reports are clear and comprehensive and are produced in good time. Action is taken on the reports by the BSU. All staff are trained appropriately and undertake CPD where required.

Physics Quality Assurance

The Excel spreadsheets used at QA visits have recently been redeveloped by the Lead Physicist. The new spreadsheets are excellent and incorporate all the recommendations given at recent audits at other centres regarding updating tests and tolerances and comparing with baseline values. The only additional recommendation is that Physics tests include a measurement of high contrast spatial resolution in magnification mode. Comprehensive work instructions are also being developed.

Recommendations from previous audit

Recommendations were made on the previous audit visit and have been addressed as follows:

- *Software replacement for Lorad to bring in Rh filter for 6cm Perspex:* The engineer queried whether this was technically possible. The current auditor does not perceive it to be a problem, since a recent patient dose audit indicated that doses comply with national DRLs, there are no reports of blurred images and image quality will be better using the Mo filter for 6cm.

- *QC protocol for testing accuracy of stereo to be improved:* Done, some additional recommendations given here.
- *Windense tolerances to be amended:* Windense is no longer being used.
- *Radiographers to initial that QC tests are within tolerance:* Done.
- *Procedure for action to be taken when QC is outside tolerance to be documented:* Done, some additional recommendations given here.
- *QC of Fischer display monitor and UPS for Fischer table:* N/a, Fischer unit has been replaced.

Summary of recommendations:

As soon as is practicable

- The new reporting room should be used for all reporting so far as is practicable.
- SLA for Physics services to be put in place as soon as is practicable.

When new guidance is published

- “IRMER” documentation to be revised when new national guidance is published.

Within 3 months

- Equipment Handover form to be revised.
- “Fineview” processing package is automatically applied on one of the digital units but not on the other. This should be investigated and the units matched according to the radiologists’ preferences.
- Local Rules to be clarified regarding the Controlled Area and protection for staff in the room.
- The signs on the doors should indicate the radiation risk (i.e. external radiation).
- The work instruction for suspension of X-ray equipment needs to be revised to make clear who should be informed when remedial or suspension levels are exceeded. This work instruction needs to be referred to on the QC record sheets, and be readily available, so that staff performing tests act accordingly.
- Up to date remedial and suspension limits, taken from the tolerances given in NHSBSP Publication 63, need to be in place for all radiographer QC tests. Tolerances must be given in the form of ranges (rather than e.g. “+/- 5%”) on all QC record sheets, along with baseline and/or target values. Tolerances must also be marked on all graphs used for recording results. When a new graph is started the tolerances must be transferred across immediately. For mobile units it is particularly important that remedial and suspension levels for mAs are available and acted upon since films are not processed until the next day. Detailed requirements are given earlier in this report.
- Work instructions to be amended to reflect the changes to tolerances.
- Work instructions to include requirement to plug in the densitometer, since it is believed that readings may be unreliable when run off the battery.

- Baseline values should be reviewed on a monthly basis.
- For digital units, revise tolerances in line with national requirements; ensure that all QC results are recorded on disk; and reinstate SMPTE phantom and dead pixel map.
- Investigate why image quality parameters often fail NHSBSP 63 tolerances.
- Spare 24x30 cassettes at base should be moved to the van to ensure that there are 8 available at each location.
- New test required for uniformity post-engineer visit.
- X-ray spillover at chest wall edge could be tested with Gafchromic self-developing film post-mobile move.
- For the Mammotome stereo localisation accuracy protocol, include the need to use a lower needle guide in the work instruction. Regularly check the test needle to ensure it is not bent and replace if necessary.
- A work instruction is needed for the localisation QC test with FNA needle.
- Record actual errors in x, y and z in mm rather than recording ticks for stereo tests.
- Physics tests to include a measurement of high contrast spatial resolution in magnification mode.

Within 6 months

- Ensure all radiography staff trained to use the stereo unit perform tests sufficiently frequently to maintain their skills – consider refresher training from GE.

Claire Skinner

8. Radiology Report

Background

The Cambridge and Huntingdon Breast Screening Service offers screening to a population of 55,000 women. The unit continues to achieve consistently high performance and maintains an enviable position as a centre of excellence both regionally and nationally.

Since the last visit, Dr. Sue Barter and Dr. Matthew Wallis have joined Dr Peter Britton, Dr Ruchi Sinnatamby and Dr Matthew Gaskarth, maintaining the strength and depth of radiology expertise. The unit has also appointed an advanced practitioner, Mrs. Kathryn Taylor, who performs ultrasound examinations and ultrasound guided procedures. Training opportunities continue to favour medical staff and two specialist registrars are currently attached to the unit.

The transition to digital technology is progressing well, with two FFDM units in operation on the Addenbrooke's site and advanced plans to extend this technology to the mobile units. This means that the unit is well placed to introduce the next phase of age extension and it is disappointing to learn that, having been selected as a pilot site, funding has not yet been made available to get this started.

Recommendations of the 2006 QA report

- All readers should achieve the recommended reading volume of greater than 5000 mammograms.
- Reading volumes are now reaching NHSBSP standards for all readers.
- Policies and practices reviewed to avoid mixing of symptomatic and screening women attending for either results or clinical recall.
- The unit accepted the premise, but has been unable to implement the suggestion, as this would require more surgical manpower than can realistically be provided.
- Updated written assessment protocols should be produced in line with the new NHS BSP guidelines for assessment.

This has been done.

Radiological performance

The KC62 returns from 2007/08 demonstrate that the unit has maintained excellent overall performance, exceeding NHSBSP targets in virtually all domains. Cancer detection rates are consistently high and the unit achieves its high SDR without a recall rate penalty, which is to be commended. Benign biopsy rates do stray above target levels, just exceeding the minimum standard in the case of the prevalent round rate. This does reflect the unit's use of vacuum assisted biopsy coupled with their policy for managing B3 lesions, and has been the subject of detailed audit. Similar increases in benign biopsy rates have been observed in other high performing units and reflect a national change in practice.

Staffing

The unit maintained excellent staffing levels, with five highly experienced consultant radiologists, leaving limited need or opportunity for the development of advanced practice. The team is currently supported by one advanced practitioner, who is fully

trained in ultrasound and ultrasound guided procedures, and is undergoing training in film reading. A second advanced practitioner has commenced training and there are two specialist registrars, one of whom has completed her fellowship, but continues a weekly commitment to the unit, and a second still in training.

This limitation of opportunity for personal development through advanced practice may have a detrimental effect on morale within the core radiographic team and the unit management need to be aware of the need to include and encourage this group so that they continue to feel valued and motivated.

Questionnaires were returned by all members of the team, showing satisfactory training and levels of CME activity (as often on the faculty as in the audience!), including participation in PERFORMS and Interval Cancer Peer Review meetings.

Screen reading

Screen reading is performed by the consultant radiologists, and two specialist registrar fellows perform a third read. Mrs Taylor is currently undergoing training in film reading. Annual film reading figures have been compiled and these indicate that most readers reach or nearly reach the recommended 5000 mammograms per year. There is a reasonably equitable distribution of reading between the film readers. All films are double read, and two consensus meetings operate a week, after each of the MDT meetings, when all readers present review each discordant case. Decision-making is clearly recorded on the pro forma, and entered directly on to NBSS.

Assessment Clinics

The number of assessment clinics has increased since the last visit from three to four clinics per week, carried out on a Monday afternoon, Tuesday morning and afternoon, and Thursday afternoon. This has accommodated increases in the screened population and NHS BSP screen to assessment times are now being achieved. Six to eight patients are seen in each clinic, with all biopsies where possible carried out at the time of assessment. Comprehensive new sets of written assessment protocols have been compiled since the last visit. All radiologists are involved in assessments. Breast care nurses are not present in the initial assessment, but are called upon in the event of a likely positive diagnosis.

All calcification is sampled using an 11 G Mammotome, though the prone table has made way for one of the digital sets, and all ultrasound guided sampling is performed with a 14 G biopsy. The unit would benefit from a facility for x-raying biopsy samples. We also noted that one of the ultrasound couches has a damaged surface, presenting a potential infection risk; this needs replacing.

Axillary lymph nodes are sampled according to protocol, with excellent written instructions including illustrations which are mounted on the wall. Fine needle aspiration is no longer performed due to change in the pathology cytology expertise available.

There are three results clinics per week, with all biopsies reviewed at one of the two MDT meetings. Explained by manpower issues, it has not been possible to separate symptomatic and screening women attending for results. With support and early explanation from breast care nurses, the unit does not feel that this provides any detrimental effect on the women involved.

Multi disciplinary team at meetings

We attended the MDT meeting on Thursday 26th of February. The meeting was well attended by all medical staff, with the notable absence of the radiography team. This was explained by the early start of the MDT at 8 o'clock meaning that for personal reasons the radiographers were unable to attend on a regular basis. The meeting took place in the new research block, where audiovisual facilities are excellent. Each woman was clearly presented, healthy discussion ensued, and decision-making processes were clear and precise. Decisions were recorded electronically.

Peer review of screening cases

Films were reviewed by JW and RW on Wednesday the 25th of February. Professor Peter Britton, Dr Ruchi Sinnitambay, and Dr Matthew Wallis were present.

Cases	No.	Comments
Assessment clinics (All consultants) Random selection by QA radiologists	17	Assessments followed the unit's very clear protocol and documentation was comprehensive. There was some difficulty retrieving some digital images during the review, but we were assured that these were stored somewhere. The unit policy is to repeat all 4 views on a digital set for clients recalled to assessment following an analogue screen, and it was interesting to see that this was often the only action needed to clarify an abnormality.
Ca diagnosed at ER	1	This case involved a very small cluster of microcalcification, that was not accessible to prone table biopsy. Early recall was performed at one year, and an MRI which was normal. Eventually a biopsy was successful revealing high-grade DCIS. There are no criticisms of the management of this case.
ER x 2	1	Following the therapeutic vacuum excision of a papillomatous lesion, this woman was placed on ER to ensure a one-year follow-up. In future such cases will not be categorised as ER.
ER in past year	6	One of these involved a surgical follow-up for nipple discharge, and we were assured that in future such cases will not be classified as ER. Apart from one biopsy demonstrating B2 with calcification placed on ER, other cases were appropriately recalled.
Interval Cancers	5	One of the 5 cases showed some asymmetry which might have prompted a recall; the home team agreed and will put the case forward to the Regional ICPR meeting.

Interval cancers

All interval cancers are reviewed locally at the end of the consensus meetings, and any not deemed normal/benign taken of the regional review. ICPR meetings are well attended by all members of the team. Interval cancers have historically been recorded on a cardex system. Protocols and training are awaited in order to be able to record interval cancers on NBSS. Data has been sent to the unit from the cancer registry in May 2008, and analysis of this has revealed that out of a total of 146 potential interval cancers, only seven have been found to be Addenbrooke's patients.

Audit and education

All radiologists have completed sufficient CME and CPD, and are regularly attendees at the regional interval cancer peer review meeting. They all take part in PERFORMS on a regular basis. With close links to the University of Cambridge, the unit continues its ongoing considerable contribution towards audit and research.

High risk screening

The unit has been in talks with Cambridge Primary Care Trust for some time in order to secure funding for the implementation of breast screening of those women at high risk of developing breast cancer due to a strong family history, as advised by NICE guidelines. The PCT are apparently ready to fund 'high' risk women, but not those categorised as being at 'intermediate' risk. With the current practice of double reporting breast MRIs, and the implementation of a breast MRI biopsy service, the unit is well positioned to implement this development.

Summary

The unit has continued to develop and improve since the last QA visit. Its enviable radiological staffing expertise, and the hard-working commitment of all members of the team have secured its position as a national centre of excellence. The presence of radiology trainees and fellows enhances an ongoing commitment to audit and research. The downside of this, however, is the obvious accompanying lack of opportunities for the development of the advanced practice. It is therefore essential to include and maintain the interest and commitment of all other members of the team and to value them in other ways, in order to avoid demotivation, and to maintain quality recruitment and retention.

Recommendations

Within 3 months

- Replace damaged ultrasound couch

Within 12 months

- Procure facility for specimen x-rays

Roger Whitney

Jill Wilkie

9. Pathology Report

1.0	Introduction	
1.1	Who is the designated lead pathologist for the local breast screening service?	Elena Provenzano
1.2	Who deputises for the designated lead pathologist?	Merche Jimenez-Linan
1.3	How many pathologists report cyto and histopathology specimens generated by the local breast screening service?	Histopathology – 5 Cytology – 6
1.4	Are all pathology samples from the local breast screening service reported in your laboratory? If not why not? How many cancers / annum?	Yes Q There are 310 cancers ; annum No mention on form case split Screening or symptomatic

2.0	Workload	
2.1	General What is the total pathology WTE establishment?	There are 1.6 WTE pathologists reporting breast, not including cytology. Specific allocation for screening is not available.
2.2	What is the current pathology staffing WTE in post?	Current staffing: Medical - Consultants 30 (20 WTE) ST1's 4 SpR's 5 Locum for service 1 BMS – Band 8 = 7 Band 7 = 19.6 Band 5/6 = 24 Trainees = 9 Band 4 = 13 Band 3 = 5.3 Band 2 = 10.7

2.0	Workload (continued)	
2.3	How many specimen requests are reported per annum* in total? *financial year 01 - Apr to 31 - Mar	98, 379 including cytology and external referral cases (excluding PMs, paediatric and neuropathology cases)
	(i) Cytopathology service - No. of gynecological specimen requests reported per annum	55306
	No. of non-gynae specimen requests reported per annum. Any breast specimens?	5164 (7078 including seminal fluids) Q -Breast non-gynae specimens ?
	No. of WTE cyto-pathologists	3
	(i) Histopathology Service - No. of specimen requests reported per annum	35995
	- No. of WTE pathologists	20
	(iii) - Autopsy Service - No. autopsies per annum	477 adult and 324 paediatric
2.4	Breast How many breast specimens are reported per annum? (i) Breast FNAC Approximate screening/symptomatic split	22 (not available)
	(ii) Wide bore needle core biopsies Approximate screening/symptomatic split	1158 – approximately 36% screening (417 screening/ 714 symptomatic)
	(iii) Surgical specimens Approximate screening/symptomatic split	1053 dealt with by 5 consultants, one advanced practitioner and 10 juniors
	(iv) Frozen sections Approximate screening/symptomatic split	Very rarely performed for breast – perhaps 2-3 per annum

3.0 Staffing/Accreditation		
3.1	Do the number of medical staff sessions in the laboratory in general comply with RCPATH/CPA guidelines?	Yes
	If not, why?	-
3.2	What is the status of CPA accreditation: (i) Full	Yes
	(ii) Conditional (please state reason)	
	(iii) Referred (please state reason)	
3.3	Is the laboratory CPA accredited for histopathology and Cytopathology?	Yes
3.4	Review date of CPA accreditation	2010
3.5	How many sessions have been allocated for breast work?	Approximately 16 PA's per week are allocated to breast work (including the HER2 testing service and management)
3.6	Is the laboratory/secretarial staffing satisfactory?	Laboratory currently short-staffed as unable to fill posts. Secretarial staffing satisfactory following appointment of breast PA.

4.0 Laboratory Process		
4.1	Who reports (i) breast cytopathology samples?	Stuart Coghill, Maria O'Donovan, Penny Wright, Alison Marker, Aileen Patterson, Robin Moseley
	(ii) breast histopathology samples?	Elena Provenzano, Victoria Bardsley, Merche Jimenez-Linan, Penny Wright, Victoria Phillips
4.2	Is immediate breast cytology reporting undertaken?	No
4.3	Who performs the aspirations?	Clinicians
4.4	Are adequate specimen transport facilities available?	Yes

4.0	Laboratory Process (continued)	
4.5	What are the average turnaround times for screening cases? (i) breast cytology samples	3.3 days including weekends Core biopsy 48 hours WLE and mastectomy 6.5 days Reports authorized after ER/PR results entered
	(ii) breast needle biopsy	3.0 days (2.5 excluding weekends). Includes mammotomes and needle core biopsies. Reports for cancers are not authorised until ER results available.
	(iii) open biopsies (including localisation biopsies)	6.5 days for all surgical breast specimens (unable to calculate specifically for open biopsies) – includes weekends and is skewed by number of highly complex cases such as post chemotherapy specimens
4.6	Do you receive specimens in the appropriate state for examination?	Yes
4.7	Identification of mammographic abnormalities (i) is there easy access to specimen radiography	Yes
	(ii) when is specimen radiography used?	Specimen radiography initiated by histopathology is used for mastectomies performed for DCIS
	(iii) are copies of specimen radiographs supplied with specimen?	In the majority of cases
	(iv) are the national guidelines for macroscopic examination and sampling of specimen followed?	Yes
	(v) are you satisfied with the quality and maintenance of laboratory equipment with respect to breast screening specimens?	Yes
4.8	Do you routinely record specimen weight? If not why not? Q Specimen Photograph	Yes – part of our macro proforma Specimens are not routinely photographed No Shave margins Nipple margin not labelled

5.0 Communication		
	Are you satisfied with the level of communications with the following staff? (i) radiologists	Yes
	(ii) surgeons	Yes
	(iii) breast screening staff	Yes
	(iv) oncologists	Yes
5.2	Are multi-disciplinary meetings dealing with patient management held regularly? (i) prospectively	Yes
	(ii) retrospectively	Yes
	(iii) how often?	Twice weekly

6.0 Data Collection		
6.1	Do pathologists provide the RCP breast screening histopathology national minimum data set? If not, why?	Yes – incorporated into our reporting proforma
6.2	Do they use the recommended diagnostic categories for cytology and needle biopsy specimens? If not, Why?	Yes

7.0 Quality Assurance		
7.1	Do the pathologists participate in the National Breast Screening Histopathology EQA Scheme? (Confirmation of participation should be obtained from the Scheme Secretarial)	Yes
	(i) Please provide a listing of pathologist participation in each EQA round since the last QA visit.	EP is officially participating for the first time this round as she has only just been appointed to a substantive post, but has been reviewing the slides informally for the past 3 years VP recently completed her training and has participated in the two most recent EQA rounds since qualifying

7.0	Quality Assurance (continued)	
7.2	Is the laboratory involved in internal audit regarding (i) breast cytopathology?	No
	(ii) breast histopathology?	Yes – regular audit of turnaround times and HER2 results including proportion of HER2 2+ FISH positive cases, current audit of B3 atypia final excisional biopsy findings
	(iii) other pathology?	Yes
7.3	What procedures are employed?	Cores reported by 2 pathologists in tricky cases
7.4	What results were obtained and what changes made as a consequence?	High 2+ rate with low FISH positivity rate. Regular multiheader review meetings of 2+ cases with FISH results introduced. Trial of new antibodies.
7.5	Does the laboratory participate in any technical EQA schemes? If so, which ones?	NEQAS Breast pathology (Hormone receptor and HER2), General pathology, Lymphoid pathology, Neuropathology and Alimentary tract pathology

8.0	Training/CME	
8.1	Have pathologists reporting breast specimens attended any breast screening update courses since the last visit?	Yes, only one of the five pathologists reporting breast has not attended a breast update course over the past 3 years.
8.2	(i) List details and dates of courses attended by each pathologist?	<p>MJL – Non-operative breast pathology course, Nottingham, March 2006</p> <p>BDIAP Symposium on breast pathology, London, June 2006</p> <p>Breast pathology update, Udine, Italy, November 2007</p> <p>Breast pathology update course, Leeds, November 2008.</p> <p>PW – Non-operative breast pathology course, Nottingham, March 2006</p> <p>Non-operative breast pathology course, Nottingham, April 2008</p> <p>VP – Advanced Histopathology Course, Edinburgh, September 2005.</p>

8.0	Training/CME (continued)	
8.2	(i) List details and dates of courses attended by each pathologist? (continued)	<p>EP – British breast group, January 2006</p> <p>Non-operative breast pathology course, Nottingham, March 2006</p> <p>BDIAP Symposium on breast pathology, London, June 2006</p> <p>British breast group, June 2006</p> <p>IAP International Congress, Montreal, September 2006</p> <p>Optimal management of intracranial metastases from breast cancer, London, November 2006</p> <p>British breast group, January 2007</p> <p>British breast group, June 2007</p> <p>Brighton breast cancer day, Brighton, July 2007</p> <p>West of Scotland Breast Screening Service Radiology Update Meeting, Glasgow, September 2007</p> <p>Nottingham international breast cancer conference, September 2007</p> <p>British breast group, January 2008</p> <p>NEQAS meeting, Coventry, June 2008</p> <p>British breast group, June 2008</p> <p>Galway/ Nottingham international breast cancer conference, Galway, June 2008</p> <p>Errors in pathology, RSM London, September 2008</p> <p>IAP International Congress, Athens, October 2008</p>

9.0	Performance Assessment/Peer Review	
9.1	Are the quality assurance statistics satisfactory? (i) cytology – CQA	Insufficient numbers – 3 FNAs over 3 year period
	(ii) needle core biopsy - BQA	Absolute sensitivity – 94% Complete sensitivity – 97.4% Specificity – 22.1% Full specificity – 80.1% Positive predictive value (B5) – 99.7% PPV for B4 – 62.5% PPV for B3 – 12.3% False negative rate – 2.4% False positive rate – 0.3% Inadequate – 4.8% Inadequate rate for cancers – 0.3% Suspicious rate – 8.1%
	(iii) non-operative diagnosis (cytology and core combined) - NDQA	As per BQA
	(iv) histology - HQA	Results for screening period 01/04/2005 – 31/03/2008 Benign/ normal = 50 Radial scar = 4 (15) Atypical hyperplasia = 25 Carcinoma in situ = 72 Microinvasive = 3 Invasive carcinoma = 322 Details not recorded = 8

9.0	Performance Assessment/Peer Review (continued)	
9.1	(iv) histology – HQA (continued)	<p>Breakdown of invasive cancers:</p> <p>NST = 250 Tubular = 15 Lobular = 24 Mucinous = 7 Medullary = 0 Tubular mixed = 3 Other mixed = 22 Other primary = 1 Other malignant = 11</p> <p>Size range of invasive cancers: 1-10mm = 90 >10-15mm = 99 >15-20mm = 52 >20-50mm = 68 >50mm = 12 Size unknown = 1</p> <p>Grade: I = 80, II = 151, III = 73 No assessment = 16, Not specified = 2</p> <p>Nodal status: Node negative = 227 Node positive = 87 Not sampled/ cleared = 8</p> <p>Vascular invasion: Not present = 198 Present = 39 Not specified = 85 Not sampled</p>
9.2	How complete are 10 randomly selected reports compared with RCPATH minimum dataset standards?	Good
9.3	Issues identified during multi-disciplinary peer review or during MDM component of QA visit	Problems with addenda – obvious in printed formats but not in online format seen via HISS JCIS system – web based reporting

10.0	Previous Recommendations	
	Have the recommendations from the previous QA visit been addressed satisfactorily?	<p>New proforma including macro that is easier to read</p> <p>Improvement in turnaround times, related to advanced practitioner role and restructuring of laboratory workflow</p> <p>Appointment of an advanced practitioner in breast pathology – James Neal</p> <p>Total number of pathologists reporting breast cases has been reduced from eight to five</p> <p>Appointment of PA for breast pathology services, Ellen Strachan</p> <p>New offices for consultant staff have been approved, estimated completion date April 2009</p>
	Sentinel lymph node	<p>No intra-operative assessment</p> <p>Histology and immunohistochemistry when indicated.</p> <p>No Molecular</p> <p>No cytology or frozen sections</p> <p>Rarely get more than 3 lymph nodes</p> <p>2mm sections on which 3 levels are taken with spares for immunohistochemistry</p>

11.0	Actions to be undertaken (to be completed at QA visit)	
	(i) 3 month recommendations	<p>Labelling nipple margin specially for cases of DCIS</p> <p>Screening / symptomatic split is not given by clinicians</p>
	(ii) Longer term recommendations	Her2 technician needs support, appointment of part time person to help

12.0	Points of Good Practice	
		<p>Advanced practitioner made a difference to turn around time</p> <p>Web based proforma used for reporting</p> <p>Subspecialisation – consistency</p> <p>Double reporting</p>

Salam Al-Sam

10. Surgical Report

This report should be read in conjunction with the Quality Assurance Visit Questionnaire as completed by Professor Gordon Wishart, Lead Surgeon for the Screening Unit.

On the day of the visit (26.2.09) I was able to attend a multidisciplinary meeting and meet with three surgeons involved in the breast screening service – Professor Gordon Wishart, Mr Parto Forouhi and Mr John Benson. I also undertook a review of 10 sets of notes from women initially referred from the screening programme. We also discussed matters arising from the ABS at BASO screening audit data over the last 3 years.

Matters arising from previous QA Report

There were no major issues identified on the previous QA report, although a number of recommendations were made.

- Purchase of a Faxitron machine for specimen imaging in theatres.
- Following the introduction of the PACs system the surgeons felt that this was no longer necessary as they were able to obtain specimen imaging on the PACs system. This was an acceptable response at the time. However, it is apparent that some form of improved specimen imaging system is now required in theatres. I would therefore recommend the purchase of a specimen imaging system within 6 months.
- A review of the surgical assessment clinics has been undertaken and the timing for the surgical assessment clinics has been altered to improve efficiency.
- Pathology reporting times have improved and are now available within 10 working days.
- The Nurse Practitioner was made up to Nurse Consultant level.
- There has been a recent increase in the availability of reconstructive slots.
- Further clinics and surgical staff have improved surgical throughput.

QA Visit Questionnaire

The three Consultants provide an excellent surgical service to the breast screening unit. Cover is in place for annual leave and good team working means that waiting time targets for treatment are all met. This unit would provide an excellent training opportunity for surgical breast trainees and there is ample opportunity for research. I would fully support the consultants' wish to appoint a breast fellow.

The arrangements for assessment are very satisfactory and patients are seen promptly after full MDM discussion. There is excellent breast care nursing support. There are a limited number of clinic rooms, in particular for breast care nurses to see women in a degree of privacy. With the changeover to digital mammography consideration should be given to allocating more space to breast care nurses.

The surgeons are satisfied with the guidewire localisation availability and the accuracy of the wire placements.

It is important that with age extension adequate planning and facilities are available for the increased work load.

The protocols for the management of benign, indeterminate, in situ and invasive malignancies are all within national guidelines. There are also well established and appropriate follow up protocols. The team should be congratulated on their work in reducing the number of follow up appointments for low to moderate risk patients.

ABS @ BASO Audit Data

I was able to review this unit's BASO data and the only major issue arising was the apparently high repeat operation rate. The team are to be congratulated on auditing this from the period of 2004-2007. Most of the high level is due to re-operation on positive sentinel node biopsy cases. The figures presented by the Unit were entirely acceptable.

Data Collection

The Unit is soon to appoint a Data Manager who will give 15% of their time to the clinical service, the remainder being for research. A considerable amount of data is collected on the joint clinical information system (JCIS). In addition the Unit was able to produce an audit of survival and local recurrence for their breast cancer patients. These outcome data were excellent and were all within the ABS at BASO (2008) Guidelines. The surgeons should be congratulated on having this analysis available.

Multidisciplinary Meeting

This appeared to run extremely smoothly. The decision making was entirely appropriate and the facilities for discussion and projection of information were excellent.

Decisions were recorded at the time of the multidisciplinary meeting and were available the same day in the clinic.

Trials Entry

There is an excellent record of trials entry from this Unit.

Professional Development

All three surgeons have been able to partake in adequate CPD over the last year. It should be noted that the Trust's consultant study leave budget is low, particularly when compared to other Trusts (£690 per annum).

Notes Review

The general standard of the notes was excellent. All the appropriate information was recorded. In one case of a guidewire wide local excision procedure there was no recording that a specimen x-ray had been done or that the lesion was confirmed to be seen on the x-ray. In all other operation notes this information was available.

Summary

Professor Wishart and his colleagues are to be congratulated on providing an excellent surgical service to the breast screening unit. The standards of care appear to be extremely high and there is evidence of good team working. The team also have an excellent set of protocols ensuring an even standard care to all patients in the unit. Excellent outcome and data are available. I can find no significant fault with the service and indeed there are many areas of excellent practice which could be shared amongst other units in the region.

Recommendations

Advisory

- I would fully support the appointment of a Breast Fellow to this Unit – advisory.
- Adequate support needs to be made available for data collection, in particular for all of the compulsory national audits.

To be included in the planning of age extension

- Ensure that adequate facilities are available to support planned age extension.

Within 6 months

- Adequate facilities for specimen imaging should be available

Neil Rothnie

11. Breast Care Nurse Report

Nurses present at the QA visit:

Dawn Chapman Nurse Consultant Band 8b (35 hours)
(Lead BCN but not involved directly with NHSBSP screening women)

Joanna Rowley Band 7. 1WTE

Sharon Iddles Band 7. 1 WTE

Nurses not present at the QA visit:

Vanessa Shackleton Band 7. 1 WTE

Alison Hallett Band 7. 0.8 WTE

Hilary Harte Band 7. 0.6 WTE

Pat Skelly Band 7. 1 WTE

Visiting Quality Assurance Breast Care Specialist Nurse:

Philippa Dooher

Staffing

The Nurse Consultant is lead for the team and provides strong leadership and support but it not involved in the NHSBSP due to the management components of the Nurse Consultant role and the requirements of the symptomatic service. Some of the nursing team members are Breast Care Nurses/Practitioners and some are Practitioners/Breast Care Nurses. The resources within the team meet the screening needs of the service and do not require further investment in posts. The Nurse Consultant now has a management role for the secretaries and there is adequate provision for the team.

The Breast Care Nursing Service

The team meet the needs of the women attending the NHSBSP programme and deliver a high standard of care to women attending the assessment clinics. Contact prior to attending an assessment is available with the details of the nurses incorporated in to the invitation leaflet. Two nurses are allocated to a clinic and meet the women on arrival and are available throughout the appointment to address both information and psychological needs. The team have also been trained to provide Entonox during biopsies for pain relief if needed. There is not a dedicated counselling room but clinical rooms for privacy are always allocated. In house and charity written information is provided to support verbal information. A nurse is present when both a benign or cancer diagnosis is given. Formal psychological support was available for a short period but the post has not been replaced and the team reported that they have not identified this as a service delivery need at present.

Lymphoedema management, prosthetic fitting, seroma drainage, ward visits, home visits, individual appointments, an open door invitation once a week, pre assessment appointments, end of treatment support group, telephone help line and triage access back to clinic are provided by the team. There are a team of oncology nurses, research nurses and a reconstruction nurse who work closely with the team.

The team attend the MDT meeting and state that they are able to take part in the MDT decisions. They stated that they are encouraged to develop the service by the MDT

and are supported to enable the delivery of the new developments. Each member of the team now works one day a month on the ward on a supernumerary basis to provide teaching in relation to the care needs of patients with a breast disorder to the ward staff. The team wear a uniform which has been accepted by the women/patients but the Nurse Consultant uniform has been noted to cause distress to patients due to being the colour black, thus providing a negative image of the role.

Clinical supervision is available and the team have regular team meetings, an annual away day and seek peer support when needed.

The team did not have concerns in relation to office space, stated that they have access to clinical rooms and have a designated prosthetic fitting room.

Education and Development

The team are able to access educational updates and all have a Breast Care Nursing Qualification (Certificates checked apart from Vanessa Shackleton). Members of the team have or are registered to attend the Advanced Communication Skills Training Course. One nurse Practitioner/BCN is completing a master's programme and further education will be available to other team members subject to service requirements. Only one nurse has a counselling qualification but the majority of team members have completed counselling/communication skills modules within degree/masters programmes.

The team have developed an invitation only support group for end of treatment and awarded the trust "over and above" achievement award. They have obtained a Macmillan Cancer Support Grant to produce a booklet and DVD which will contain the information covered during the session to reinforce the teaching or for those who cannot attend the group. The Group is held in a support centre with complimentary therapies available with the aim of the women attending the centre in the future.

The Nurse Consultant has been awarded an M.B.E. for her contribution to Breast Care Nursing and has an honorary contract with Anglia Ruskin University to teach on the Advanced Breast Practitioner Module at Masters Level.

The team are piloting an integrated care pathway for breast patient's surgical care.

Research/Audit

The team have completed a survey of the women/patients which covers the whole service and also to evaluate the new model of end of treatment support session, named "Recoup your equilibrium". They participate in the mastectomy/reconstruction audit and are actively recruiting patients to specific clinical trials. They have completed GCP training.

The team are evaluating the patient led follow up programme with further audit in relation to changes in this cohort of patient's pathway since discharge from attending regular follow up clinics and are presenting the findings at a conference in 2009.

Previous Report Recommendations

- Improve physical resources: - counselling room, office and secretarial support – achieved recommendations
- Reinstate formal clinical supervision – achieved recommendations.
- Ensure provision of specialist psychological support in order to comply with NICE Guidelines for Supportive Care – partially achieved as addressed with a post but it was short term. The majority of needs the team state are met by

Present Recommendations

None

Area of Good Practice

- Support Group/session
- Resources allocated to meet the NHSBSP nursing requirements
- Continuity of care with the provision of treatment needs throughout the pathway

Summary

This well resourced team are meeting the Nursing Guidelines for the NHSBSP and are enthusiastic to develop and deliver changes to the service which is commended. The team are aware that if they have resource issues in the future they will need to review the extensive service they provide, this would be detrimental to the whole breast service. It has been noted that the colour of the Nurse Consultant uniform does have a negative image for women attending the unit or for those who have a cancer diagnosis and then have care delivered from this nurse; this may have a psychological impact for women and their families attending the unit.

Reference:

Quality Assurance Guidelines for Clinical Nurse Specialists in Breast Cancer Screening. Fourth Edition. NHSBSP Publication No 29. January 2008.

Philippa Doohar

12. Appendix 1: Key for KC62 Data

	Met Standard/Target
	Reached Standard but failed Target
	Failed Standard/Target

13. Appendix 2: KC62 Summary 2004-2007

Objective	Criteria	Calculation	Minimum Standard	Target	2004/05	2005/06	2006/07	2007/08	
1 To maximise the Number of eligible women who attend for screening	The percentage of eligible women who attend for screening	Tables: A+B+C1+C2	≥ 70% of invited women attend for screening	80%	78.03	77.93	78.28	77.64	
		Age: 50-64			76.35	77.16	77.61	77.35	
		Age: 50-70							
		Table: A							
		Age: 50-64				73.04	74.50	72.69	71.04
		Age: 50-70				72.07	73.32	71.51	70.30
		Table: B							
		Age: 50-64				27.96	28.67	21.63	24.67
		Age: 50-70				23.87	22.44	20.77	23.72
		Table: A+B							
Age: 50-64				60.53	63.79	57.23	57.76		
Age: 50-70				56.32	56.58	55.60	56.43		
Table: C1									
Age: 50-64				89.98	90.26	89.59	89.11		
Age: 50-70				90.08	90.61	89.36	89.09		
Table: C2									
Age: 50-64				66.09	61.99	51.80	61.19		
Age: 50-70				71.37	64.49	50.98	59.71		
Table: C1+C2									
Age: 50-64				87.35	86.40	86.14	86.13		
Age: 50-70				85.07	84.77	85.49	85.62		
2 To maximise the number of cancers detected	a) The rate of invasive cancers detected in eligible women	Table: A	Prevalent screen ≥ 2.7 per 1000	Prevalent screen > 3.6 per 1000	5.65	4.22	4.46	7.25	
		Age: 50-52							
		Table: C1	Incident screen ≥ 3.0 per 1000	Incident screen ≥ 4.0 per 1000	4.42	5.57	5.31	5.72	
		Age: 53-64							
		Table: C1	Incident screen > 3.1 per 1000	Incident screen > 4.2 per 1000	4.67	5.65	5.48	5.67	
		Age: 53-70							
	b) The rate of cancers detected which are in-situ carcinoma	Table: A	Prevalent screen > 0.4 per 1000			2.17	0.42	1.78	1.61
		Age: 50-52							
		Table: C1	Incident screen > 0.5 per 1000			1.92	1.44	1.08	0.74
		Age: 53-64							
	Table: C1	Incident screen > 0.5 per 1000			2.00	1.88	0.98	0.77	
	Age: 53-70								
	c) Standardised detection ratio	Tables: A+B	Prevalent screen ≥ 0.75	Prevalent screen ≥ 1.0		1.78	1.32	1.05	1.74
		Age: 50-64							
		Table: C1	Incident screen ≥ 0.75	Incident screen ≥ 1.0		1.19	1.39	1.29	1.48
Age: 50-64									
Tables: A+B+C1		Overall ≥ 0.75	Overall ≥ 1.0		1.37	1.37	1.24	1.54	
Age 50-64									
Tables: A+B	Prevalent screen > 0.85	Prevalent screen > 1.0		1.77	1.19	1.03	1.69		
Age: 50-70									
Table: C1	Incident screen > 0.85	Incident screen > 1.0		1.23	1.34	1.32	1.44		
Age: 50-70									
Tables: A+B+C1	Overall ≥ 0.85	Overall ≥ 1.0		1.38	1.30	1.26	1.50		
Age 50-70									
3 To maximise the number of small invasive cancers detected	The rate of invasive less than 15mm in diameter detected in eligible women invited and screened	Table: A	Prevalent screen ≥ 1.5 per 1000	Prevalent screen > 2.0 per 1000	3.91	2.11	1.78	2.82	
		Age: 50-52							
		Table: C1	Incident screen > 1.65 per 1001	Incident screen > 2.2 per 1000	2.21	2.69	2.07	2.75	
		Age: 53-64							
Table: C1	Incident screen > 1.7 per 1000	Incident screen > 2.5 per 1000	2.40	3.35	2.29	2.79			
Age: 53-70									
7 To minimise the number of women screened who are referred for further tests	a) The percentage of women who are referred for assessment	Table: A	Prevalent screen <10%	Prevalent screen <7%	8.56	8.06	8.97	7.41	
		Age: 50-52							
		Table: C1	Incident screen <7%	Incident screen <5%	4.25	3.54	3.70	3.52	
	Age: 53-64								
	Table: C1				4.31	3.58	3.65	3.52	
	Age: 53-70								
b) The percentage of women screened who are placed on short term recall	Table: T	<1.0%	<0.25%		0.15	0.04	0.06	0.06	
	Age: 53-64								
	Table: T	<0.5%	<0.25%		0.15	0.06	0.06	0.07	
Age: 53-70									
8 To ensure that the majority of cancers, both palpable and impalpable, receive a non operative tissue diagnosis of cancer	The percentage of women who have a non operative diagnosis of cancer by cytology or needle histology after a maximum of 2 visits	Table: T	>80%	>90%	95.40	86.36	91.92	96.97	
		Age: 50-64							
Table: T				96.52	89.84	92.04	96.36		
Age: 53-70									
9 To minimise the number of unnecessary operative procedures	The rate of benign biopsies	Table: A	Prevalent screen < 3.6 per 1000	Prevalent screen < 1.8 per 1000	4.78	2.95	4.46	3.62	
		Age: 50-52							
		Table: C1	Incident screen < 2.0 per 1000	Incident screen < 1.0 per 1000	1.77	0.90	0.99	1.27	
		Age: 53-64							
Table: C1	Incident screen <2.0 per 1000	Incident screen < 1.0 per 1000	1.60	0.94	0.98	1.15			
Age: 53-70									