National Colorectal Screening Programme

International Peer Review Panel Report of Quality Assurance Standards
10-11 March 2011
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• Shane Neary

• Dearbhla Reid
1. Introduction

Colorectal cancer is the most common malignant tumour in Europe with more than 400,000 new cases and over 200,000 deaths reported each year.\(^1\) As in many European countries incidence and mortality in Ireland are much higher than in most other regions of the world.\(^1,2\)

In Ireland, colorectal cancer is the second most common newly diagnosed cancer among men and women. Each year over 2,000 new cases of colorectal cancer are reported. The number of new cases is expected to increase significantly over the next 10 years, due mainly to an increasing and ageing population. Colorectal cancer is currently the second most common cause of cancer death in Ireland and about 50 percent of colorectal cancer patients die from the disease.\(^1,2\)

Studies show that colorectal cancer screening is an effective tool for cancer control. Early detection permits more effective treatment than if the disease is diagnosed later, once symptoms have appeared; and early treatment and removal of pre-malignant lesions also reduces the incidence of colorectal cancer by preventing cancer developing.\(^3\)

Screening is performed on predominantly asymptomatic people. Effective quality assurance is required to maintain an appropriate balance between benefit and harm in the large numbers of people eligible to attend cancer screening programmes. Following a request from the National Cancer Screening Service (NCSS) we agreed to participate in an international peer-review of the draft quality assurance (QA) standards that will govern the national colorectal cancer screening programme, due to commence in 2012. This process took place on Thursday 11 and Friday 12 March 2011. The format is outlined in Appendix 1. Our recommendations are presented here.

The discussions and debate that took place were wide-ranging and somewhat inevitably extended beyond quality assurance of the screening programme. Our recommendations to the NCSS should be interpreted under two general headings. Firstly recommendations in relation to QA standards and secondly recommendations we consider most important in relation to operational elements of the population screening programme and their wider impacts on endoscopy, histopathology, radiology and surgical services for colorectal cancer in Ireland.

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2. **Faecal Immunochemical Test (FIT)**

2.1 The international panel would agree with the choice of the FIT test as the screening tool of choice for a population-based screening programme.

2.1.1 Automation is a distinct advantage.

2.1.2 Brings analytical sensitivity to the detection of haemoglobin (Hb) and provides the opportunity with an appropriate device of setting the concentration (of Hb) to use to define positivity.

2.1.3 By monitoring detection rates for cancers and adenomas the positivity threshold for the test can be adjusted (a) to achieve an appropriate balance between sensitivity and specificity and (b) maintain an acceptable flow of referrals to screening colonoscopy services

2.2 The panel noted the intention of the NCSS to obtain, by means of competitive tenders, (a) the supply and distribution of the FIT test and (b) laboratory services.

2.2.1 A close relationship with the FIT manufacturer/supplier is essential to ensure that supply lines and product (FIT test) quality can be guaranteed.

2.2.2 The contracted laboratory is an integral part of a population screening programme and leadership of laboratory services at consultant level is vital.

2.2.3 The laboratory should have at least two analytical instruments to process the FIT tests.

2.2.4 The panel understands that it is currently the intention to contract a single laboratory but that this position may change.

2.2.5 The quality of the programme will be enhanced if those involved (at the laboratory) can see and where possible be involved in the whole process. The laboratory needs to see that it is contributing to saving lives and not just producing positive results.
2.3 Hb denatures whilst in buffer solution held by the device used to collect faecal samples. The rate of denaturation will be influenced by factors including the preservative properties of the buffer solution, the chemical and microbiological composition of the individual faecal sample, the length of time in transit and the ambient temperature.

2.3.1 Ideally the sample (FIT test) should be received by the laboratory within 10 days of use by the client. It should be either analysed on receipt or stored at a temperature to minimise further deterioration of the sample. Clearly this is not totally within the control of the programme and requires action on the part of the client.

2.3.2 One sample has been proven to be sufficient for a population programme and is likely to maximise uptake amongst the eligible population. Using more than one sample introduces problems with return postage and sample deterioration. The ability to change the positivity threshold for the test means that an appropriate balance between sensitivity and specificity can be maintained using a single sample approach. Italy introduced a one-sample approach in its regional programmes several years ago and they have published data to demonstrate the effectiveness of this protocol.

2.4 External quality assessment and laboratory internal quality control is critical to the success of these population programmes and is particularly critical for FIT tests. The NCSS may wish to consider appointing an independent/external reviewer to advise on laboratory performance issues.

2.4.1 External quality assurance schemes for FIT exist but are in their infancy.

2.4.2 Continuous monitoring of outcomes and laboratory protocols will be necessary.

2.5 The labeling and packaging of the device and instructions for use is critical.

2.5.1 Needs to be easy for people to provide the actual sample e.g. individuals with arthritis, poor sight, etc.

2.5.2 The date of the sample must be recorded e.g. England and Scotland have a policy whereby their national programmes do not process a sample without a date. Samples received beyond an agreed collection-receipt elapse period must also be rejected. Criteria for rejection need to be determined.

2.5.3 Barcodes (possibly 2 barcodes – one for tube and one for user) offer considerable advantages for logistics and ICT purposes.
2.6 The panel noted that the programme has modelled for six per cent positivity with FIT.

2.6.1 The programme may wish to consider a slightly lower and more conservative three-four per cent programme start-up for the first screening round. This will enable the actual positivity rate to be determined in the local population without compromising the service (if the positivity rate proves to be higher than expected), to ensure that (a) screening colonoscopies can be provided in a timely fashion without adversely affecting the symptomatic (diagnostic) service and (b) all elements of the invitation process, FIT and laboratory services are operating in a consistent, reliable and quality assured manner.

2.7 Editorial comments on draft FIT standards chapter:

- 7.2.4 The sample cannot be stable during transport unless it is kept close to 0 degrees centigrade.
- 7.2.6 Suggest the second sentence should state ‘Should be free from analytical interference from drugs’.
- 7.3.2 A qualified clinical chemist is too vague. In the UK it is defined as a consultant pathologist or scientist.
- 7.3.3 Second line. Suggest ‘required’ as opposed to ‘encouraged’.
- 7.4.2 The method should be easy and reliable to undertake/perform.
- 7.4.3 The word ‘user’ crops up several times (7.4.5). Requires a definition or better term.
- 7.4.6 The idea of duplicate measurement is good. Preferably measured not in the same ‘run’ or batch but this will depend on the analytical system.
- 7.4.6 I think that a more sensitive measure for FIT would be the mean and a dispersion parameter SD of SEM for the measured Hb concentration. Weekly would probably be a good idea. CUSUM could also be measured and monitored. The critical issue is what to do with the numbers that are generated. An independent advisor on laboratory quality assurance (QA) matter could be considered.
- 7.4.7 and 7.5.5 Excellent audit activities.
- 7.5.1 Insert ‘into’.
- 7.5.1 Suggest two working days based on my experience. Clients are clearly worried and have reported back their appreciation of a fast turnaround time.
- 7.5.2 Not clear what collective reports this is describing. Need examples.
- 7.5.4 More a statement than a standard.
- 7.5.5 Second paragraph needs to be rewritten.
3. **Endoscopy & Radiology**

**Endoscopy**

3.1 The panel was of the view that exclusion criteria for entry into the screening programme should be kept to a minimum. Colonoscopy has a miss (pathology) rate of between 1-10 per cent and therefore it would be difficult to justify the exclusion of someone on the basis of a previous colonoscopy.

3.2 The panel recommended that those with an absent bowel or in treatment for colorectal cancer should be in the exclusion categories.

3.2.1 Individuals within the target population have the option of checking with their own GP as to their suitability for participation in the programme. The programme may wish to utilise this option in its communication materials.

3.3 The panel recommended a nurse-led approach to the issue of consent (for colonoscopy/CT colonography). This is the approach adopted by the colorectal screening programme in England i.e. specialist screening practitioners (SSPs). Part of their job is to ‘exclude’ clients on health, mental capacity grounds and/or seek further medical advice before proceeding.

3.4 The panel noted the NCSS explanation of the planned role for advanced nurse practitioners (ANPs) in obtaining consent.

3.4.1 The panel emphasised the importance of ‘training’ for the ANPs to allow them to have the confidence to know when to seek help/advice on all matters related to obtaining consent.

3.4.2 Consent for colonoscopy should include a clear and realistic explanation of the procedure, possible discomforts, the risks and benefits and a clear relevant discussion of potential adverse events.

3.4.3 A possible auditable outcome for units to consider is ‘how often does the ANP obtain consent without having to seek further advice from a senior colleague’. Having 15 screening colonoscopy units will allow for cross-unit comparison and to share best practice.
3.5 The panel recommended that, while no direct evidence currently exists on which to base targets, all sedation used should be recorded to permit a subsequent audit of practice i.e. an auditable outcome.

3.5.1 The panel recommended that propofol should not be used in a screening colonoscopy unit.

3.6 The panel recommended that the use of reversal agents should be recorded to permit a subsequent audit of practice i.e. an auditable outcome.

3.7 The panel recommended that patient comfort should be of central importance to meet a key principle for a screening programme of creating as good an experience as possible. The modified Gloucester comfort score should be used to record patient comfort scores.

3.8 The panel would like to acknowledge that the generic issue of accreditation of endoscopists is beyond the remit of the NCSS. The panel made the following comments:

3.8.1 The endoscopy service in association with professional bodies must develop a competency framework/mechanism.

3.8.2 The Royal College of Physicians of Ireland and the Royal College of Surgeons of Ireland should play a central and leading role in developing such a framework.

3.8.3 A number of challenges will arise including identifying an appropriate accreditation test, defining how the process will work and critically dealing with poor performance.
3.9 The panel recommended that consideration may need to be given to the centralisation of what have been termed ‘Level 3’ and ‘Level 4’ endoscopy competency skills.

3.9.1 Level 3: Removing smaller flat lesions (<20mm that are suitable for endoscopic therapy, larger sessile and polypoid lesions with more difficult access). Some flat lesions <20mm with poor access might be unsuitable for this level. Any person doing colonoscopy for positive FOBT in a screening programme should have this level of competency.4

3.9.2 Level 4: ‘Removing large flat lesions or other challenging polypoid lesions that might also be treated with surgery. This is the type of lesion that would not be removed at the first colonoscopy because of time constraints, if applicable, or because the surgical option needs to be discussed with the patient. If the patient chooses to have endoscopic therapy then he/she should be referred to a Level 4 competent endoscopist. This level of competency would be expected of only a small number of regionally-based colonoscopists.’

3.10 The panel recommended that there needs to be a clear referral pathway from screening colonoscopy units to a designated cancer centre in the context of Level 4 procedures.

3.11 The recording of adverse outcomes following a colonoscopy needs careful consideration and planning. Consideration should be given to a proactive and robust mechanism for detecting, grading and recording adverse events especially those that occur after patients leave the endoscopy unit. For example a 30 day ‘close out’ contact/questionnaire with the patient.

3.11.1 The impact of the events on the patient should be assessed and priority given to the most critical adverse events.

3.11.2 When reporting adverse events, the sample size/denominator should always be presented.

3.12 A robust approach for dealing with poor performance needs to be created within the population screening programme. The panel recommended that poor performance should be managed by the lead clinician at the relevant screening colonoscopy unit in the first instance with escalation to the clinical lead for the programme if unresolved or requiring their involvement for another reason.

3.13 There is evidence that endoscopic proficiency increases with the number of procedures performed. Low numbers of procedures are associated with a greater risk of complications. Although the number of procedures performed annually is not a reliable measure of quality, achieving an adequate volume is essential to maintaining skills and effectively monitoring performance.

3.13.1 Endoscopists in the English Bowel Cancer Screening Programme (BCSP) must perform $>150$ BCSP colonoscopies per annum.

3.13.2 The panel agreed with the population screening programme’s standard that each endoscopist participating in the colorectal screening programme should undertake to perform at least 300 procedures per year of which 150 should be screening programme colonoscopies.

CT Colonography

3.14 The panel recommended CT colonography (CTC) as a supplementary test for those patients in whom it is deemed ‘not clinically safe’ to proceed with colonoscopy. However:

3.14.1 The CT colonography service must be of high quality. The training and experience of consultant radiologists is critical.

3.14.2 Referral of patients deemed unfit for colonoscopy for CT colonography is a clinical decision.

3.14.3 The patient must be fully informed of all possible outcomes. There is a possibility that such patients may require a subsequent procedure/investigation for which they may not be fit.

3.14.4 The total number of all referrals from colonoscopy pre-assessment for CT colonography should be $\leq 10\%$. The existence of 15 screening colonoscopy units allows for inter-unit comparison and the development of standardised referral protocols and sharing of best practice, thereby maximising best outcomes for patients.
3.15 The panel noted that the location of CT colonography centres has yet to be determined. The panel noted:

3.15.1 Appropriately trained and experienced consultant radiologists in CT colonography are required.

3.15.2 The minimum number of CT colonography cases read per consultant radiologist per year should be ≥100.

3.15.3 Centralised, co-ordinated administrative support for the booking of appointments, follow-up and QA will ensure that safe processes are in place to ensure best outcomes for patients.

3.16 The panel recommended that, while no clear evidence currently exists on which to base standards, the following key performance outcomes by a CT colonography service should be recorded to permit a subsequent audit of practice and the setting of standards in the following areas i.e. defined as auditable outcomes.

- Major complication rate
- Prevalence of extra-colonic findings, categorised as to whether requiring additional work-up or not. For example, additional tests recommended or referral required versus incidental finding requiring no additional work-up.
- Percentage of abnormal studies i.e. adenoma detection rate and cancer detection rate.
- Positive predictive value for large adenomas and cancer.
- Negative predictive value for cancer (utilising cancer registry data).

3.17 Based on current knowledge and experience the panel recommended the following standards:

- Completion (examination adequacy) rate of ≥95%. The panel recommended that CT centres consider the routine use of faecal tagging to improve examination adequacy.
- Perforation rate of <1 per 3000 studies
3.18 The panel commented that CT colonography reporting and data system (CRADS) was developed for CT colonography as a primary screening test in the USA. The panel recommended using polyp size categories so that the whole of the (screening programme) team can understand the findings i.e. small or large lesion rather than C3 or C4.

3.19 The panel would endorse recently published CT colonography standards⁵ and recommend a separate ‘Guidance document for the use of CT Colonography,’ drafted by the RCSI, Faculty of Radiologists.

3.19.1 The setting of QA standards should be an objective process and not be influenced by operational or resource issues.

3.19.2 A guidance document would have the scope to outline how a CT colonography service in an Irish healthcare setting should be structured and delivered at both national and local level.

3.19.3 A guidance document would allow the radiology profession to develop appropriate clinical protocols e.g. guidance on the investigation of extra colonic findings, use of buscopan (if not contraindicated), tagging (reduced laxative regimens), same day examinations, use of CO2 insufflators etc.

3.20 The panel recommended that a QA committee should include a consultant radiologist representative to support the delivery of high quality CT colonography focused on outcomes, performance and patient experience within the national colorectal screening programme.

4. **Histopathology**

4.1 The panel explained the background to the EU guideline classification system of neoplasia versus dysplasia/intramucosal cancer terminology.

4.1.1 The current grading systems are problematic and the EU QA guidelines have sought one that is clinically useful and pathologically accurate. Low grade and high grade neoplasia are simple terms that describe the condition. The EU group believed it was not appropriate to use the term of ‘intramucosal carcinoma’ because of its lack of clinical value and the potential to increase resection rates and lead to increased post-operative mortality.

4.2 The panel recommended the adoption of the terms ‘low grade’ and ‘high grade’. The panel accepted the programme’s preference to retain the term ‘dysplasia’ at this point in time as opposed to ‘neoplasia’.

4.3 The panel recommended that the terms ‘intramucosal carcinoma’ and ‘carcinoma in situ’ should not be used.

4.4 The panel explained the exclusion of the pathological feature of ‘tumour budding’ in the ‘EU Guidelines for Quality Assurance in Colorectal Cancer Screening and Diagnosis’.

4.4.1 pT1 tumours will provide many difficulties in a screening programme and the current evidence base for management of these lesions is poor.

4.4.2 The EU group’s deliberations were driven by the evidence-base and the need to minimise post operative mortality and morbidity in a fit and well population and minimise the potential harms of a population screening programme.

4.4.3 EU QA guidelines document has not included it, as firstly, there are multiple classifications involving the ‘budding’ term. Secondly the more prognostic factors that are used the greater the resection rate and thirdly, it is not clear whether ‘budding’ is a feature that is independent of other factors.
4.5 The panel recommended that the term ‘budding’ should not be used as a histopathological prognostic indicator.

4.6 The panel explained the adoption of the term ‘sessile serrated lesions’ (SSL) in the ‘EU Guidelines for Quality Assurance in Colorectal Cancer Screening and Diagnosis’.

4.6.1 The EU QA document recognises that the natural history of these lesions is poorly understood, that the pathological differentiation of these lesions is imprecise with poor reproducibility and that the terms used should be understandable. As a result the EU QA document adopted four mutually exclusive categories for classification of serrated lesions (hyperplastic polyp, sessile serrated lesion, traditional serrated adenoma, mixed lesion or mixed polyp).

The term sessile serrated lesion (SSL) includes sessile serrated polyps (SSP) and sessile serrated adenomas (SSA); it encompasses all non-dysplastic serrated lesions except hyperplastic polyps.

4.7 The panel recommended the adoption of the terms ‘sessile serrated lesions’ (SSL).

4.8 The panel recommended that serrated lesions do not warrant colonoscopic surveillance unless there is evidence of adenomatous tissue present.

4.9 The panel recommended that the programme should consider establishing a three member ‘national panel’ for interpreting difficult cases.
4.10 The panel recommended the use TNM Version 7 and cautioned that supporting ICT needs to be adaptable as staging versions are generally rewritten every five years.

4.11 The panel recommended that the screening programme adopt a central audit approach to histopathology.

4.12 The panel recommended that high grade dysplasia (HGD) should be less than 10 per cent for FIT positive clients in a screening programme.

4.13 The panel recommended participation in a national external quality assurance scheme for histopathology. The UK programme covering England, Wales, Scotland and Northern Ireland provides a ready made external quality assurance (EQA) scheme which Ireland could join (fee payable).

4.14 The panel recommended that the programme should minimise the number of histopathology sites involved with the screening programme to develop and enhance colorectal histopathological expertise.
5. Surgery

5.1 The panel was of the view that the main purpose of tattooing is to mark the site of removal of a large lesion that may turn out to be a polyp (i.e. pT1) cancer. This is to allow careful inspection of the site of removal at follow-up colonoscopy and also to allow identification of the site of the lesion (by intra-operative colonoscopy) when completion colectomy is deemed to be necessary.

5.2 The panel urged caution when tattooing is used to mark the site of a small or soft lesion with a view to making the location easily identifiable at surgery. This is considered to be particularly important for laparoscopic surgery as it is not possible for the surgeon to palpate the colon. A problem may arise with this approach in that sometimes tattooing can lead to the spread of ink throughout the peritoneal cavity making it extremely difficult to identify the original tattoo site. A tattoo mark may also be hidden by a thick mesentery.

5.3 The panel recommended that if there is any doubt about where a lesion is during a surgical resection (laparoscopic or open) then a pre-operative CT colonography (CTC) should be performed to establish the exact anatomical location of the tumour. Alternatively intra-operative colonoscopy can be performed and it follows that such patients should have full bowel preparation before surgery.

5.4 The panel recommended that a standardised and consistent approach to tattooing should be in place within each hospital performing colorectal cancer surgery.

5.5 The panel recommended that the surgical management of all screen-detected colon and rectal cancers should be concentrated in the designated cancer centres in Ireland.
5.6 The panel recommended that the screening programme offers an opportunity to embed a uniformity of approach to the management of early rectal cancers. The National Cancer Control Programme (NCCP) would have the unique opportunity to set international best practice standards in this area.

5.6.1 The panel recommended the concentration of expertise for non-standard endoscopy and surgery for the local excision of difficult polyps and early rectal cancers i.e. combination of advanced endoscopic techniques, surgery (TEMS) in two of the designated cancer centres.

5.6.2 Radiology expertise including MRI and endorectal ultrasound should be available in these designated cancer centres.

5.7 The panel was of the view that a 30 per cent abdomino-perineal resection rate was too high and the programme should consider a figure closer to 25 per cent.
6. Programme and Administration

6.1 The panel noted the explanation and reassurance that a ‘foreword’ would be part of the final QA guidelines document. The panel was informed this would include:

6.1.1 The governance and accountability structure.
6.1.2 Clinical and organisational responsibilities.

6.2 The panel endorsed the collaborative approach adopted by the NCSS with the professional bodies, Royal College of Physicians of Ireland, Royal College of Surgeons in Ireland and (other parts of) the HSE. This confers a number of advantages.

• Managing expectations.
• Defining roles and responsibilities.
• Maximising the impact of the screening programme e.g. improving endoscopy services, concentration of surgical services for colorectal cancer, maximising best outcomes for patients.

6.3 The panel recommended strong clinical leadership across all the (specialty) domains for the national colorectal screening programme.

6.4 The panel noted the intention for the national programme to commence at the start of 2012 and recommended the following be in place before commencement.

6.4.1 A robust ICT system to capture the flow of data during each screening event (laboratory/endoscopy/histopathology/radiology/surgery/central office).
6.4.2 A strong QA governance structure.
6.4.3 Risks to clients/patients must be minimised.
6.4.4 Best clinical outcomes for patients must be maximised.
6.4.5 Introduction of the screening programme should not adversely affect the symptomatic (diagnostic) service.
6.5 The panel recommended that the NCSS must be satisfied that the factors listed in 6.4.1-6.4.5 are met before the commencement of a national programme.

6.6 The panel recommended an annual multidisciplinary meeting for all those involved with the delivery of the national programme.

6.7 The panel recommended that a QA ‘monitoring’ function should be implemented across all elements of the screening pathway.

6.8 The panel noted the explanation that the mortality reduction figure emanated from a health technology assessment. The panel was of the view that a mortality reduction of 36 per cent was optimistic and recommended that the programme should initially aim for a reduction in mortality between 15-24 per cent consistent with the original randomised controlled trials on colorectal cancer screening.

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6 HIQA, Health Technology assessment (HTA) of a population based colorectal cancer screening programme in Ireland (25 March 2009).
## Appendix 1  International Peer Review

### Agenda

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<th>Time</th>
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<tr>
<td><strong>Thursday 10 March 2011</strong></td>
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<tr>
<td>7:45 am-7:50 am</td>
<td>The National Cancer Screening Service (NCSS)</td>
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<td>Mr Tony O’Brien, Director</td>
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<td>7:50 am-8:00 am</td>
<td>NCSS QA Committee on Colorectal Screening</td>
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<td>Mr Simon Kelly, Chair QA Committee</td>
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<td>8:00 am – 8:15 am</td>
<td>Population Colorectal Cancer Screening – outline of programme</td>
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<td>Dr Alan Smith, Medical Director – Screening Policy</td>
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<td>8:15 am – 9:30 am</td>
<td>The Faecal Immunochemical Test (FIT)*</td>
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<td>9:30 am - 10:45 am</td>
<td>Endoscopy and Radiology* (Endoscopy session)</td>
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<td>11:00 am – 12:15 am</td>
<td>Endoscopy and Radiology* (Radiology session)</td>
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<td>12:15 pm – 1:00 pm</td>
<td>Histopathology*</td>
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<td>2:00 pm - 2:45 pm</td>
<td>Histopathology ctd*</td>
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<td>2:45 pm – 4:00 pm</td>
<td>Surgery*</td>
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<td>4:15 pm – 5:15 pm</td>
<td>Programme and Administration *</td>
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<td>5:15 pm</td>
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<td>5:30 pm to 6:00/6:30 pm</td>
<td>QA Committee Meeting</td>
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<td><strong>Friday 11 March 2011</strong></td>
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<tr>
<td>8:00 am to 10:30 am</td>
<td>Private session for International Peer Review panel</td>
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<td>11:00 am to 1:00 pm</td>
<td>- Follow Up Discussion</td>
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<td>- Review of Issues</td>
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<td>- Finalisation of peer review panel recommendations</td>
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<td>- Wrap Up</td>
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* Format: Summary presentation (5 mins) of key areas/themes identified in advance by QA subgroups and peer reviewers followed by round table discussion
The National Cancer Screening Service is part of the Health Service Executive National Cancer Control Programme. It encompasses BreastCheck – The National Breast Screening Programme and CervicalCheck – The National Cervical Screening Programme.

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