National Cancer Screening Service

CervicalCheck – The National Cervical Screening Programme

Quality Assurance Standards

International Peer Review Panel Report
12-13 August 2009

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Members of International Peer Review Panel

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- Dr Maire Duggan, Department of Pathology and Laboratory Medicine, University of Calgary, Canada
- Dr Shaun Firth, General Practitioner and Member of UK Advisory Committee on Cervical Screening
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- Mr Tony O'Brien, CEO, NCSS
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- Dr Sheelah Ryan, Chair of National Cancer Screening Service Board
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1. Introduction

On 2 December 2003, the European Council adopted a recommendation to implement population-based screening for cancer of the breast and the uterine cervix in women, and of the colon and rectum in both men and women in all member states of the European Union[1]. In 2004 almost 31,000 women in the EU25 were diagnosed with cervical cancer and 14,000 died from the disease[2]. European data clearly illustrates that cervical cancer remains a considerable public health problem in Europe.

Although the efficacy of cervical cancer screening has never been assessed by randomised controlled trials, there is convincing evidence from observational studies that indicates that screening is effective. The evidence of screening effectiveness was recently reviewed and it was concluded that by careful implementation of a screening policy, the incidence of cervical cancer can be reduced by 80 per cent or more among participating women[3].

There is considerable evidence that indicates the greater effectiveness and efficiency of organised versus non-organised screening. Trend analyses in the Nordic countries have revealed a strong correlation between the decline in the burden of cervical cancer and the geographical extent and the population coverage of organised cytological screening[4]. By improving screening coverage and quality subsequent to setting up a national screening programme in the UK in 1988, the incidence of invasive disease rapidly decreased by 35 per cent[5]. However there are countries, including Ireland, where the impact on mortality has been suboptimal and attributed to the absence of an organised population-based screening programme or the ineffectiveness of an opportunistic approach to screening[6,7].

Continuously improved quality assurance guidelines based on scientifically sound and applicable screening standards are essential to ensuring that population-based programmes of appropriate quality and effectiveness are available to all persons who may benefit from cancer screening. In that context and following a request from the National Cancer Screening Service (NCSS) we agreed to participate in an external international peer-review of the CervicalCheck quality assurance (QA) standards.

The peer-review took place from 12-13 August 2009. The format is outlined in Appendix 1. Given the extent of the discussions and debate that took place, our recommendations to the Board of the NCSS should be interpreted under two general headings. Firstly recommendations in relation to QA standards and secondly recommendations in relation to operational elements of the population screening programme.

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[1] The Council of the European Union. Council recommendations of 2 December on cancer screening. Off J Eur union 2003;878: 34-38

[2] Arbyn M, Raifu AO, Autier P, Ferlay. Burden of cervical cancer in Europe: estimates for 2004. Annals of Oncology 2007;18:1708-1715

[3] IARC. Cervix Cancer Screening. IARC Handbooks of Cancer Prevention. Vol 10, Lyon, France:IARC 2005

[4] Laara E, Day NE, Hakama M. trends in mortality from cervical cancer in the Nordic countries: association with organised screening programmes. Lancet 1987;1:1247-9

[5] Peto J, Gilham C, Fletcher O, Matthews FE. The cervical cancer epidemic that screening has prevented in the UK. Lancet 2004;364;2205-8

[6] Comber H, Gavin A. Recent trends in cervical cancer mortality in Britain and Ireland: the case for population-based cervical cancer screening. Br J Cancer 2004;91:1902-1904

[7] Arbyn M, Raifu AO, Bray F, Weiderpass E, Anttila A. Trends of cervical cancer mortality in the member states of the European Union. Eur J Cancer 2009;45:2640-8

2. Primary Care Standards

2.1 A contractual relationship between CervicalCheck – The National Cervical Screening Programme and smeartakers offers a unique opportunity for targets and performance measures to drive a quality assured national programme.

2.2 The Panel recommends that adherence to primary care QA standards should be a contractual requirement.

2.2.1 References to the smeartaker contract should be removed from the QA standards document.

2.3 The Panel is of the view that, as currently written and defined, a number of 'standards' could more accurately be defined as 'objectives'.

2.3.1 Standards need to be restructured wherever possible in terms of:
- The objective
- The quantifiable measure (that indicates that objective can be met with clear definition of numerators and denominators)
- The minimum standard (acceptable to the programme)
- The target standard (> minimum standard to which all should strive)

2.3.2 The usefulness of '100 per cent' as a standard measure should be reviewed. A 'yes/no' measure may be appropriate in some instances.

2.4 Some standards are likely to be unattainable at the present time as the screening programme is currently in 'start up' phase. It may be more practical for the QA Committee to consider an incremental approach to objectives and associated standards. Programme performance outcomes can then be the basis for raising standards.

2.5 The Panel recommends that smeartaker contract conditions be audited and monitored on an annual basis and should include visits by means of a random sample of (smeartaker) locations registered with the programme.

2.5.1 CervicalCheck should initiate discussions with the Irish College of General Practitioners (ICGP) in relation to developing appropriate external audit methodologies for GP practices involved with the national screening programme.

2.6 It is the view of the Panel that a minimum number of smear tests per year per smeartaker will not necessarily ensure competence.

2.6.1 Technical excellence does not necessarily correlate with the number of smear tests taken.

2.6.2 The programme should focus on training and demonstration of competence.

2.7 The Panel recommends smeartaker training for all registered smeartakers that should be focused on an objective demonstration of competence.

2.7.1 It is recommended that all registered smeartakers should complete the CervicalCheck smeartaker training course during the first three to five years of the screening programme.

2.7.2 It is recommended that all registered smeartakers should participate in Continuing Medical Education (CME) accredited clinical update sessions on a three yearly interval.

2.7.3 It is recommended that for doctors and nurses starting out in practice there should be a set number of training smear tests carried out under observation and also specula examinations.

2.7.4 The Panel acknowledges the important role of GP Vocational Training Schemes in fulfilling a smeartaker training role in Ireland.

2.8 It is the view of the Panel that in the era of liquid based cytology (LBC) a reliance on inadequacy rates alone will not identify the underperforming smeartaker.

2.8.1 The current QA figure of <8 per cent inadequacy rate does not accurately reflect current best practice with LBC.

2.8.2 The programme should review current inadequacy reporting rates and set a more appropriate performance measure in a future contract.

2.8.3 In the interim the Panel recommends that a figure of <2 per cent is a more appropriate performance measure in the era of LBC.

2.9 The Panel recommends that a client satisfaction survey should be developed as another tool to determine the woman's level of satisfaction with the smeartaker and the smeartaking process.

2.10 Notwithstanding the fact that ultimate clinical responsibility rests with the attending GP/Medical Director, the Panel recommends that the roles and responsibilities of all individuals – administration, smeartaker(s), GP practice – needs to be explicitly defined in QA documentation.

2.11 The target population of 25 to 60 years is consistent with international best practice for population screening programmes. Organised call, re-call is critically important to achieving high coverage of the target population.

2.11.1 The Panel recommends that the programme should aim to ensure that 'call' is initiated to women three to six months before they reach the age of 25 years.

2.11.2 The role of opportunistic screening[8] will need to be examined within the first three years of the national programme.

2.11.3 Opportunistic screening is potentially useful if it leads to the screening of women who persistently fail to attend (for whatever reason). However it must also be acknowledged that opportunistic screening can potentially lead to over screening of women and hinder clinical and cost effectiveness.

2.11.4 Analysis of coverage data can inform the development and delivery of 'enhanced' or opportunistic screening activities for the population screening programme.

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[8] Defined as taking advantage of an opportunity to screen an individual who is considered unlikely to respond to a formal invitation to screening e.g. socially disadvantaged, 'hard to reach' populations.

2.12 The Panel recommends that the programme states its preference for the use of single use disposable specula by registered smeartakers as opposed to the conventional reusable metal speculum. The Panel acknowledges that there may be clinical circumstances where this is not possible e.g. certain size of speculum required.

2.12.1 Reusable specula are devices that make contact with intact mucous membrane but do not penetrate sterile tissue. As such the level of decontamination required will be high level disinfection or sterilisation where practicable.

2.13 The Panel noted the explanation of the compilation of the screening programme population register i.e. Cervical Screening Register.

2.13.1 The absence of a unique health identifier is an obstacle and a clear risk to ensuring an accurate and up to date screening register. The Panel would support the introduction of a unique health identifier in the Irish healthcare system.

2.13.2 All opportunities should be taken to ensure an accurate and complete register. In that context GP practices (and other clinics) currently have an opportunity to encourage women to register/check their registration with the screening programme.

2.13.3 In the future, ICT linkages could be developed in GP practices to enable primary care access to the screening register. (The Panel noted the comment that approximately 70 per cent of GP practices in Ireland are computerised).

2.14 The Panel recommended that the feasibility of direct referral (by the programme) to colposcopy on receipt of an abnormal cytology result should be explored and implemented as part of the national screening programme.

3. Cytopathology Standards

3.1 The Panel was of the view that a number of standards as currently defined are 'gold standard' and are likely to be unattainable at the present time as the screening programme is currently in 'start up' phase. The QA Committee is advised that standards may have to be adjusted to take account of the current status of the screening programme.

3.2 As a general comment across all QA chapters, standards may need to be restructured wherever possible in terms of setting out:
- The objective
- The quantifiable measure (that indicates that objective can be met)
- The minimum standard (acceptable to the programme)
- The target standard (> minimum standard to which all should strive)

3.3 The Panel agrees that primary screening workload requirements for cytotechnologists/medical scientists should be carefully evaluated on an annual basis and adjusted according to laboratory outcome data. This will contribute to best outcomes in terms of proficiency, processivity, quality, accuracy and safety.

3.4 At this point in time the Panel is of the view that it is reasonable to recommend the following standards (3.4.1-3.4.4):

3.4.1 For proficiency a minimum number of 3,000 LBC smear tests per year should be screened per cytoscreener/cytotechnologist.

3.4.2 For processivity up to 12,000 LBC smear tests can be screened split between 6,000 primary screens and 6,000 Quality Control (QC) smear tests.

3.4.3 To contribute to quality, accuracy and safety the maximum number of smear tests per day should range between 60-80 LBC slides.

3.4.4 The throughput and workload standards (3.4.1-3.4.3) should be reviewed annually in the context of actual laboratory outcome data that includes test positivity rates, first screen versus reviewing statistics, positive predictive value (PPV) of abnormal cytology for histological outcomes, histological abnormality detection rates and adjusted according to the level of automation.

3.5 The Panel noted the absence of any standard in relation to the workload of the Consultant Cytopathologist.

3.5.1 The Panel recommends that a minimum of 750 screening smear tests for a Consultant Cytopathologist should be incorporated into the QA standards document.

3.6 The Panel acknowledges that the use of automated technology is likely to confer further advantages to the screening process (including impacting on 3.4.2) by making identification of abnormal cells easier. This technology allows cytoscreeners to be directed to locations of concern on a slide by computerised software.

3.6.1 While the results of randomised controlled trials (RCTs) including MAVARIC and CERVIVA are awaited, the Panel is of the view (based on current published evidence to date) that current automation platforms are safe to be considered as a primary screening tool.

3.6.2 The Panel is unable to recommend a maximum number of slides that can be screened on an automated platform. Industry standards should apply until sufficient evidence emerges.

3.7 The Panel noted the current practice of 'double reading'[9] each slide.

3.7.1 'Double reading' is not common practice internationally. Comparability of outcome data with other screening programmes will be difficult.

3.7.2 The Panel recommends that the programme should review laboratory outcome data on this practice (double reading) to determine whether it confers any clinical or quality advantage to the screening programme.

3.7.3 Subject to the outcome of 3.7.2 it is recommended that the programme considers that the second screen range from a 120 second 'rapid review' minimum up to a full rescreen of a portion of the smear tests.

3.8 The key performance indicators (KPIs) are critically important standards to evaluate the performance of the screening programme.

3.8.1 The Panel would require sight of actual laboratory outcome data against KPIs listed to make detailed comment. KPIs listed are consistent with EU QA standards.

3.8.2 The Panel recommends that KPI performance data is collected on a quarterly cumulative basis.

3.8.3 There is a requirement for a clear definition of numerator and denominator values in KPIs.

3.9 The Panel agrees with the QA committee's proposal for the development of a cytopathology atlas as a reference, training and educational tool.

3.10 The Panel recommends the development of formal linkages and reporting pathways between the National Cancer Registry Ireland (NCRI) and the National Cancer Screening Service (NCSS).

3.10.1 The screening programme will ultimately be required to produce (cancer) incidence and mortality data on women on the Cervical Screening Register.

3.10.2 The Panel recommends that the roles and responsibilities of all individuals/laboratories in terms of (cancer) case notification to the NCRI be documented in relation to 3.10.

3.11 The Panel acknowledges that the (current) location of cytopathology services in the United States poses unique challenges that will have to be addressed by the NCSS including:
- Training of Cytotechnologists, Histopathologists, Cytopathologist, Colposcopists
- Maintaining competence of Cytotechnologists, Histopathologists, Cytopathologist, Colposcopists
- Multi disciplinary team (MDT) and Cytological/Histological correlation

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[9] Every slide is fully read by two different cytotechnologists

4. Histopathology Standards

4.1 The Panel noted the current absence of a contractual/governance relationship between the NCSS and histopathology services for the national screening programme. The Panel also noted reference to the reliance on adequate resourcing by the Health Service Executive (HSE) and Hospital Management to ensure the successful implementation of the QA programme.

4.1.1 The Panel recommends that histopathology services are provided by an accredited laboratory.

4.1.2 It is unrealistic to expect the screening programme to function at optimal QA levels until a decision on the provision, location and governance of histopathology services is made.

4.2 As a general comment across all QA chapters standards may need to be restructured wherever possible in terms of setting out:
- The objective
- The quantifiable measure (that indicates that objective can be met)
- The minimum standard (acceptable to the programme)
- The target standard (> minimum standard to which all should strive)

4.3 In the context of cytological-histological correlation the Panel recommends that if a discrepancy[10] arises, a review should be undertaken of the original glass slides and not digitised images.

4.3.1 The Panel recommends that cytopathology and histopathology are reviewed by the same pathologist where a discrepancy arises.

4.3.2 The focus should be on discrepancies that change clinical management decisions.

4.3.3 For clinical demonstration, digitised images are an acceptable alternative

4.3.4 For education or training purposes digitised images should be evaluated by the appropriate training bodies as an acceptable alternative

4.4 The operation of MDT meetings impact across cytology, histopathology and colposcopy services.

4.4.1 The Panel recommends the development and implementation of a standardised operating procedure governing MDT meetings taking account of 3.11 and 4.3 .

4.4.2 The Panel recommends that Histopathology and Colposcopy QA chapters will need to be reconciled to ensure the procedural standards of the MDT meeting are consistent.

4.5 The Panel made some specific comments on the QA document:
- Page 23, section 5.0, line 2 – delete 'when available'
- Page 25, section 8.0 (table) – suggest grading of incidents
- Page 25, section 9.0, line 5 – replace 'recommended' with 'mandatory'

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[10] Discrepancy: equates to one grade or greater difference between cytology and histology result.

- Page 108, Appendix 3A – replace 'number of blocks involved' with 'number of tissue sections involved'
- Page 108-114 – suggest working towards condensing the current three reporting proforma into one

5. Colposcopy Standards

5.1 The Panel was of the view that a number of standards as currently defined are 'gold standard' and are likely to be unattainable at the present time as the screening programme is currently in 'start up' phase. The QA Committee is advised that standards may have to be adjusted to take account of the current status of the screening programme.

5.1.1 As a general comment (for all elements of the programme) the QA committee may wish to consider the following to guide standard development or benchmarking performance:

Performance Quartile 'Benchmark'*	Percentage	Interpretation
1 (lower)	25%	Unacceptable standard
2 (middle)	25%	Minimum standard
3 (middle)	25%	Minimum standard
4 (upper)	25%	Target standard

*E.g. based on the preceding year's performance

5.2 As per the Primary Care and Cytopathology and histopathology chapters, QA standards may need to be restructured wherever possible in terms of setting out:
- The objective
- The quantifiable measure (that indicates that objective can be met)
- The minimum standard (acceptable to the programme)
- The target standard (> minimum standard to which all should strive)

5.3 The Panel recommends that the three Colposcopy sections: Standards; Organisation Guidance and Clinical Guidance be merged into a single chapter.

5.3.1 The Standards section could form the main body of the merged document with appropriate cross references to the organisational and clinical guidance sections.

The Panel made some specific comments:
- 1.5 (a) - QA Committee may need to review whether 15 minutes is sufficient time for a colposcopy appointment slot particularly if treatment is required
- 2.1 (b) - Delete 'and a smear test which suggests underlying CIN'
- 2.2 (b) - The terminology 'select and treat' and 'see and treat' are potentially confusing to the reader and need to be more clearly defined.
- Table 4.4 (c) Clinical Guidance Document – The QA Committee may need to review the use of the word 'discrepancy' in this table to ensure that it is consistent with the terminology used in the Histopathology QA Standards document

5.5 In the context of colposcopy clinic accreditation the Panel noted that legislation is currently in development concerning the accreditation of healthcare facilities in Ireland.

5.5.1 The Panel recommends that colposcopy clinics are visited at least once during the 3-5 year screening interval with an option for a 'spot check' visit if deemed necessary by the progamme.

5.5.2 The Panel recommends the use of an external multidisciplinary panel for QA visits.

5.6 The Panel recommends that a client satisfaction survey should be developed as another tool to determine the woman's level of satisfaction with the colposcopist and the colposcopy process.

5.7 As a future activity the Panel highlighted the opportunity to link maternity outcome data amongst women who have participated in the screening programme and in particular undergone colposcopy treatment(s).

5.8 The Panel recommends that in relation to pregnant women colposcopy should be performed by an experienced colposcopist.

5.8.1 The QA Committee should consider an appropriate definition for 'experienced'.

5.9 The Panel supports the QA Committee's proposal for quarterly multidisciplinary team (MDT) meetings. However the Histopathology and Colposcopy QA chapters will need to be reconciled to ensure the procedural standards of the MDT meeting are consistent.

5.10 The Panel recommends building upon professional linkages with the Irish Society for Colposcopy and Cervical Pathology (ISCCP).

5.11 The Panel noted NCSS plans for the formation of a HPV Testing Implementation Group whose outline function will include:
- Evaluation and prioritisation of testing strategies to be adopted i.e. 'test of cure', triage and primary testing
- Development of clinical management algorithms
- Development of implementation plans for introducing HPV testing strategies into the population screening programme in Ireland

6. Programme and Administration Standards

6.1 As a general comment across all QA chapters standards may need to be restructured wherever possible in terms of setting out:
- The objective
- The quantifiable measure (that indicates that objective can be met)
- The minimum standard (acceptable to the programme)
- The target standard (> minimum standard to which all should strive)

6.2 The usefulness of '100 per cent' as a standard measure should be reviewed. A 'yes/no' field may be appropriate in some instances.

6.3 The Panel would like to reiterate that the absence of a unique health identifier is an obstacle and a clear risk to ensuring an accurate and up to date screening register and ultimately to the success of the screening programme.

6.4 The Panel recommends the insertion of a programme standard in relation to expected impact on cervical cancer incidence and mortality.

6.4.1 As background there was a 20-25 per cent reduction in mortality within six years of commencing the NHS Cervical Screening Programme in 1988.

6.4.2 The often quoted figure of 80 per cent reduction in mortality is among the screened population.

6.4.3 The staging of cancers detected in the first two screening rounds would be a useful marker of programme effectiveness

6.5 The Panel would like to make a general comment that efforts are needed to improve certification of the exact anatomical site of origin in cause-of-death certificates in cases of death from cancer of the uterus.

6.6 The feasibility of direct referral to colposcopy on receipt of an abnormal cytology result should be explored and implemented as part of the national programme.

6.6.1 This would require issuing a combination 'result and referral' letter to the patient.

6.7 The Panel made some specific comments:
- Section 2.4 (Standards) – reference to a 'response time' to client generated complaints may be a more useful and transparent measure
- Section 3.0 (Standards) – the Panel recommends an additional standard in relation to the number of unique women enrolled as a percentage of the eligible population
- Section 3.2 (d) (Standards) – the Panel recommends that reporting the number of women opting off the programme may be a useful programme performance standard
- Key performance indicators for CervicalCheck should be in a format that will allow sharing of data with EU partners

6.8 The Panel would encourage the exchange of information, experience and collaboration with other EU Member States.

Appendix 1
CervicalCheck QA Standards
International Peer Review Panel
Agenda

12 August 2009		
7:30 am-7.40 am	Dr Sheelah Ryan, Chair, National Cancer Screening Service Board Mr Tony O'Brien, CEO National Cancer Screening Service (NCSS)	
7:40 am-7.50 am	NCSS QA Committee on Cervical Screening Mr Simon Kelly, Chair	
7:50am – 8:00am	Cervical Cancer Screening in Ireland Dr Alan Smith, Consultant in Public Health Medicine, NCSS	
8.00 am – 9.30 am	Primary Care Standards*	
9:30 am - 9:45 am	**Break**	
9:45 am – 11:15 am	Cytopathology standards*	
11:15 – 11: 30 am	**Break/overflow session**	
11:30 am - 1:00 pm	Colposcopy standards*	
1:00 pm - 2:00 pm	**Lunch**	
2:00 pm to 3:30 pm	Histopathology standards*	
3:30 pm to 3:45 pm	**Break**	
3.45 pm to 4:45 pm	Programme and Administration standards*	
4:45 pm to 5:30 pm	Overflow session if required	
8:00 pm	**Dinner**	
13 August 2009		
7:30 am to 09:30 am	Private session for peer review panel	
09:30 am to 10:00 am	**Break**	
10:00 am to 12:00 pm	-Follow Up Discussion -Review of Issues -Finalisation of peer review panel conclusions -Wrap Up	
12:00 pm to 1:00 pm	**Lunch**	

* Format: Summary presentation of key areas identified in advance by QA subgroups and peer reviewers followed by round table discussion