

CERVICAL CANCER SCREENING REVIEW OF CERVICAL CYTOLOGY LABORATORY PROVISION

Cervical Cytology Laboratory Review Group

Baseline Information paper

Summary

This paper provides baseline information and statistics to help inform the review group in the decision making process regarding the laboratory provision of cervical cytology. It highlights future trends in technology and continuing manpower changes which require planning to ensure a smooth migration to a delivery model which can adapt to the significant changes expected within the discipline over the next 10 years.

1. Introduction

- 1.1 The Scottish Executive Health Department (SEHD) has commissioned through the Scottish Cervical Cytology Review Group a review of cervical screening laboratory service delivery and its future provision, taking into account models of service delivery, management, manpower planning and technology changes.
- 1.2 This paper is designed to give the review group an overview of the current provision of laboratory based cervical cytology. It was commissioned at a preliminary meeting at SEHD in January 2007 where the decision was made to evaluate the current provision of laboratory based cervical cytology and determine if the current delivery would meet future requirements and presented best value both from a quality and financial perspective.
- 1.3 The remit for the production of this paper was to establish baseline information on the activity and delivery of the current service. Information on the manpower provision including skill mix, and technological challenges was to be included in the paper which would also highlight areas of strength, weakness and constraints in the delivery of service. Information sources were to include data currently published through the national screening programmes and ISD. Further primary data on demographics and activity would be established using a short questionnaire to laboratories.
- 1.4 The paper will set out the detail which will allow the review group to consider some options for how cervical cytology laboratory provision could look in the future. The paper will consider the current provision and potential alternatives both in delivery and national organisation. The paper will also scope out what future workload may look like and how technology, such as the cervical imager, could impact and potentially improve and enhance current performance.
- 1.5 The group minute from January 2007 stated that this information would provide a baseline for understanding the scale and demand for cervical cytology provision in the future and could be used to inform a migration plan from the current 11 centre model, to a new rationalised model if required

2. Background

- 2.0 The Scottish Cervical Screening Programme (SCSP) was introduced to allow early diagnosis of pre-invasive changes which may lead to cervical cancer. As part of the programme women in the 20-60 year age group are invited for a routine cervical smear once every three years. Across Scotland this equates to 406000 smears per year. The workload is spread across 11 laboratories with varying workloads from 18500 in Highland through to 76500 in Lothian. The programme has been successful and there has been a reduction in incidence of cervical cancer by 36% and a decrease in deaths from 199 in 1986 to 100 in 2002

- 2.1 Liquid Based Cytology (LBC) a new method of preparation was introduced throughout Scotland in 2003/04 after successful piloting. The effect of the introduction of LBC has been to provide a 20-30% productivity gain in primary screening and has reduced the workload from 489000 in 1997/98 to 406000 in 2004/05 by the reduction in inadequate preparations. There has also been a significant countrywide improvement in turnaround time of cervical smear reporting dropping from a country wide mean of 18 days in 00/01 to a mean of 13 days in 04/05
- 2.2 This required a significant investment in capital equipment and revenue costs across Scotland with the capital costs of £2.75m funded centrally and Boards funding the additional revenue costs of approximately £1.5m pa
- 2.3 This technology along with changing skill mix and other emerging newer technologies will further impact on the organisation and delivery of cytology laboratory services and it is clear that a national strategic approach is required to guide and help Boards and laboratories in decision making.
- 2.4 In the roll out of liquid based cytology in Scotland the decision was made to retain both the processing of cervical smears and screening of the smears in all of the centres. A change in delivery and a reduction in the number of laboratories processing cervical smears was debated at the time. It was decided that to stay within the project plan for the roll out of the new technology and in view of the lack of a facility/process to agree a new model of delivery that there should be little change in the organisation of the laboratory delivery.
- 2.5 It was recognised that as the new system became more embedded further discussion would be required. Within the roll out in England a number of the regions have developed a model of processing and staining smears in centres, with the stained slides sent out to screening centres for reporting in a 'Hub and Spoke' model
- 2.6 More recently within the NHS in England, practice based commissioning has highlighted a more market driven direction with one cervical laboratory recently losing its contract to an adjacent region after tendering with a significant human resource impact.

3. Laboratory Role in the Cervical Screening Programme

- 3.1 All of the laboratories across Scotland work on a similar workflow system. This involves close working practice with GP Practices, Clinics and Colposcopy. Normally a woman will be called via the call recall system (managed locally at present but about to be replaced by the national Scottish Cytology Call Recall System (SCCRS)) to attend her GP or Clinic. The woman's cervix is sampled using a sampling brush either by a medical practitioner or nurse and the brush is washed in a special preservative solution within a uniquely identified specimen container to free the collected cells from the brush. The container and a corresponding laboratory request form with the woman's identification and recent relevant clinical details are sent to the laboratory.

- 3.2 On receipt the identification minimum dataset and clinical details are checked and the specimen is given a laboratory identification number and either entered into the lab system or into the local/regional cervical system which runs call recall. This is usually carried out by the medical laboratory assistant (MLA) but can be carried out by biomedical scientists (BMS), cytoscreeners or clerical staff
- 3.3 The specimen is processed through the Liquid Based Cytology Processor (LBC). This through a pressure and filter system allows the cells within the container to be attached to the surface of a filter. The filter is then placed against the surface of a slide and the cells attach to the slide.
- 3.4 The slide is removed from the system and is subsequently stained with dyes to allow the cells to be visualised. A fine glass protective coverslip is placed over the slide to allow the cells to be retained permanently.
- 3.5 The slides are then viewed microscopically either by a cytoscreener or a biomedical scientist. They will review the slide fully and come to a decision. If that decision is negative or the slide is deemed unsatisfactory, the slide is then rescreened by rapid review (quick review over 2-3 minutes) by another cytoscreener or biomedical scientist. (Some labs carry out the rapid review prior to full assessment of the slide.) If an abnormality is detected either initially or at rapid review, the opinion of the cytoscreener/biomedical scientist is recorded and passed to the medical staff or advanced practitioner for reporting. If the cytoscreener/biomedical scientist detects areas of concern of which they are not sure, the slide can be passed to a senior biomedical scientist for comment before referral.
- 3.6 All results are recorded either using a paper based system and transferred onto computers systems or recorded directly by the screening staff onto the system.
- 3.7 The admin and clerical staff have various roles and can be involved in entering the details and clinical history into the computer system through to running the call/recall system ensuring that women due a smear are called at the appropriate time.
- 3.8 Most if not all of the labs have other responsibilities within the wider spectrum of histopathology and cytology and these include processing and diagnosis of other fluids and cells sent to the laboratory. Cytology's main application is in the diagnosis of cancer. Many of the staff are also involved in the histopathology service and this is discussed further in manpower planning.

4. Organisation & Management Structure

- 4.1 The laboratory service is consultant led usually via a local lead consultant with nominated responsibility for cervical cytology. All of the current cytology labs except one are managed in conjunction with the clinical lead for histopathology services and are usually held within the laboratory service directorate of the local acute hospital.

- 4.2 The budget for the service is usually held within the overall pathology budget. The expenditure and payroll systems may not be defined to the detail of allowing separate and identifiable cervical cytology costs and this impacts in attaining robust financial information for the review group.
- 4.3 The local strategic direction and planning for laboratory provision are decided within the local Departmental structures. This includes budgeting, planning, activity and local implementation. Since the move to Liquid Based Cytology, funding was supplied centrally for capital purchase/ 1st year lease costs of LBC equipment and then the additional revenue costs for service devolved to local Boards.
- 4.4 The Cervical screening programme differs from the 2 other major cancer screening programmes namely breast and colorectal where organisation is centrally funded through National Services Division. There is a similar national management of cervical cytology within the Welsh system which changed from local Health Authority to national control in 1999/2000.

The review group may want to consider the question of whether the management of cervical cytology would benefit from being organised and budgeted nationally or continue under local Board auspices. This would require further information on the benefits and implications and data on cost analysis probably based on the Welsh Model

- 4.5 Cervical cytology is reliant on major primary care input in organisation, call and follow up of women in the programme. This historically has involved the acute laboratory sector more in the complete NHS journey for the screening population and in Public Health Medicine in comparison to other areas of laboratory medicine.

5. Quality

- 5.1 Quality standards across the screening programme are very high in comparison with other laboratory provision. Reassurance of quality is inherent within the programme and is supported through accreditation, external quality assessment and internal quality assurance. Cytology has arguably the most checks and balances of any discipline within the clinical setting. National advice and guidance is through the National Screening Advisory Group.

Accreditation

- 5.2 Laboratories require to be registered within the Clinical Pathology Accreditation (CPA) Scheme. This involves running a quality management system and meeting the requirements of CPA including ISO standard 15189. This also involves a series of internal audits and recording and actions measured against the CPA Standards.
- 5.3 To maintain full accreditation the laboratory is visited and reviewed by peer and full time assessors. The review involves audit and assessment against the standards. Currently all Scottish cytology laboratories hold accreditation or conditional approval either through the pathology department or within their own right and are included in the CPA register.

NHS Quality Improvement Scotland (NHS QIS)

- 5.4 NHS QIS published comprehensive quality standards in 2002 which covered all aspects of the cervical screening programme including the laboratory provision. The reports from the original visits in 2003 and the follow up visits in 2006 to each health board region are available.¹ The report from 2006 was highly complimentary of the screening programme as a whole and in the laboratory provision in particular stating that ‘unnecessary recalls and the time it takes to get smear test results are both down. (in comparison to 2003)
- 5.5 Quality standards are also defined at UK level by the NHS Cervical Screening Programme (NHSCSP) which published its most recent set of Achievable Benchmarks in 2000.² Other NHSCSP guidelines also contain quality standards which are applicable in Scotland and are reviewed by the Scottish Cervical Cytology QA groups. These include histology/cytology correlation and assessment against national norms for specificity and sensitivity.

External Quality Assurance

- 5.6 The Scottish Cervical Cytology External Quality Assurance Scheme is funded centrally by NSD. It oversees and runs 3 complementary schemes which assess reporting ability and technical standards and provide educational material to all laboratories to encourage standardisation of reporting. The scheme is currently registered with CPA and is awaiting assessment
- 5.7 All staff who report cervical cytology participate in routine interpretative assessment (proficiency testing) This involves reviewing and reporting a number of slides with normal or abnormal cell content under supervised conditions. This is carried out 3 times over 2 years. Within this scheme persistent poor performance is followed up by supportive training and education. All screening staff are required to attend refresher/update courses at predefined times. The courses and other training and education requirements are supplied by the Scottish Cervical Cytology Training School.

Internal Quality Assurance

- 5.8 Every screened slide is re-screened by the previously described rapid preview or review methodology which provides an independent rapid assessment of whether the preparation is negative or not and can also highlight possible areas of weakness which may need review and or retraining.
- 5.9 Individual screening staff reporting profiles and the overall laboratory profiles are reviewed and compared with national rates of pick ups of abnormality.

¹ www.nhshealthquality.org

² www.cancerscreening.nhs.uk/cervical/publications

- 5.10 The quality of preparations is reviewed by internal controls and by the technical EQA scheme run by the cytology QA group

The review group will be required to consider the impact of any changes to the overall quality of the screening programme.

6. Activity

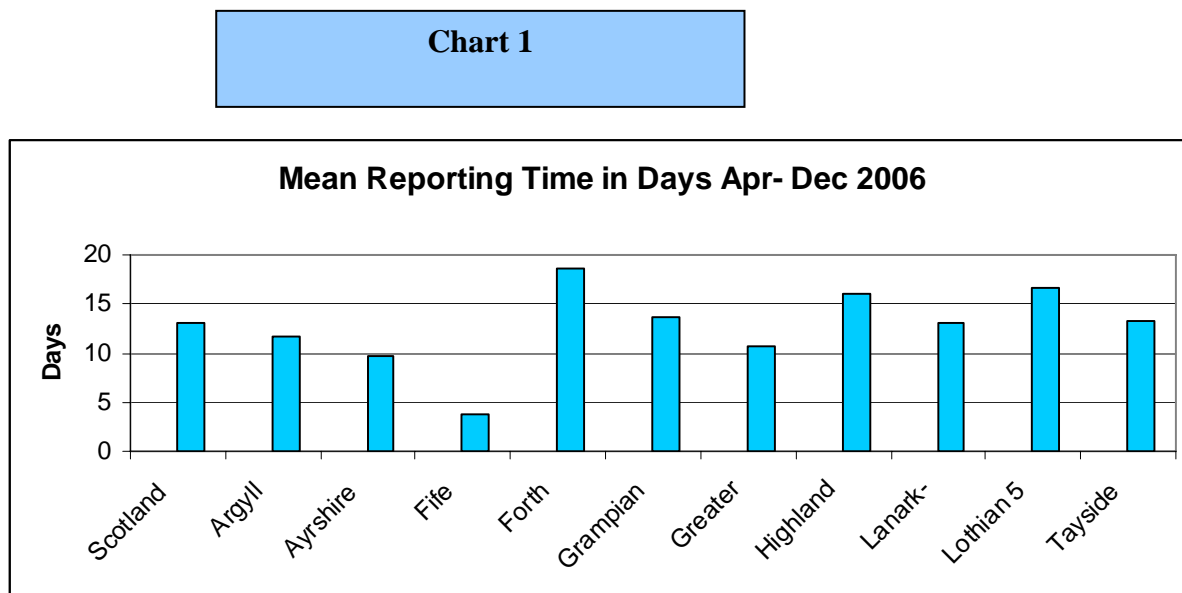
- 6.1 The laboratory aspect of cervical cytology is delivered across the country from 10 Boards and 11 laboratories with 2 laboratories in Glasgow. Dumfries and Galloway contract out the laboratory aspect of cervical cytology to Lanarkshire and a similar arrangement exists between Borders and Lothian. Highland report smears from the Western Isles and Grampian report those from Orkney and Shetland.
- 6.2 ISD collects and publishes data in relationship to the screening programme and this includes activity, reporting patterns and turnaround time. **Table 1** highlights the activity in 05/06 in comparison to 1995/96 and shows a significant drop in activity. This is partly due to the introduction of LBC in 2003 which would account for 5-10% of the reduction but there is also a slight decline from 2000 in the percentage of woman attending for smear.

Table 1

Board	No of Smears 2005-06	No of Smears 1995-96	% Reduction
Ayrshire & Arran	26824	34880	23
Clyde Division	36166	42818	16
Fife	28821	34272	16
Forth Valley	26240	29934	12
Glasgow (Over 2 Labs)	67195	79946	16
Grampian	45113	51142	12
Highland	18822	23376	19
Lanarkshire * Incl D&G	53999	60113	10
Lothian	76940	84342	9
Tayside	30121	36805	18

- 6.3 Reporting times, defined as the date of receipt of the smear in the laboratory to the date of authorised report, have dropped significantly since the introduction of LBC. In 99/00 the mean reporting time was 19 days and this had dropped to 13 days in the latest statistics to Dec 06. During one quarter in 1999/00 the reporting time in one Board reached 44 days. The reduction in reporting times has reduced women's anxiety during the screening process

6.4 As can be seen in **Chart 1** average reporting times from Apr 06 to Dec 06 vary across the country from 4 to 18 days. From the published statistics it is difficult to determine the cause of this variance but longer reporting times are usually related to staffing.



The review group will be asked to consider the impact of the drop in activity and the variance in reporting times and what effect any future development/changes may have on this trend

7. Technology

Liquid Based Cytology (LBC)

- 7.1 LBC has produced a number of significant effects including the reduction of the inadequate sample rate which has reduced the number of repeat smears. (This was commented on in the 2006 NHSQIS report.) It has also produced a 20-30% productivity gain through the screening of a much smaller slide area and the clarity of the final preparation.
- 7.2 LBC has been used both in pilot since 2001 and full implementation from 2003 and the overall effect to the screening programme has been positive. Most Laboratories have both a Cytoc T3000 processor and a T2000 processor with an overall capital purchase cost of £160k per laboratory. The original purchase or lease for the laboratory was supplied through NSD funding or had previously been funded from other sources.
- 7.3 The oldest T3000's are approximately 6 years old and the bulk were purchased or leased in 2002/03. With a notional 7 years write off period a number of the instruments will require replacement over the next 3 years.

- 7.4 Laboratories who leased (Ayrshire and Arran and Tayside) will have the revenue lease costs incorporated into local budgets but other labs will either require capital funding to replace the instruments or lease/rental revenue costs. When replacement comes there may be value in considering a national contract again possibly through National Procurement and possibly through a managed service contract.
- 7.5 This efficiency gain has driven other healthcare systems to review the cytology provision and initiate greater centralisation of services and the introduction of various models of delivery including hub and spoke. (Particularly in England).
- 7.6 In Scotland at the time of introducing LBC there was no driver for change. Current services were retained across 11 laboratories with 10 of the laboratories utilising Cytoc's T3000 processor which has the capacity to prepare between 60 and 80k preparations per year. This gives a technology preparation capacity of at least 600k for a workload of approx 400k.in a normal 8 hour working day.

The review group may consider this capacity, its hours of utilisation, possible replacement costs and the current delivery over 10 Boards and 11 labs may require further in depth study.

Cervical Cytology Imager

- 7.7 As a further development of technology Cytoc has introduced electronic imaging of the LBC preparations. This reduces the manual screening input by the cytoscreener and has been shown to provide improvements in standardisation of screening. It is now used in over 250 labs worldwide and has attained full U.S. FDA approval for diagnostic use.
- 7.8 Its method of operation is to analyse the LBC preparation and detect the most abnormal fields by assessing DNA content The fields are electronically marked and made available at a review station microscope for the screener to view. This reduces the number of fields to be viewed by the screener from a mean of 120 fields of view to 22 fields
- 7.9 Opinions vary on the efficacy of this technology which is currently being reviewed as part of the Mavaric trial ³ taking place on behalf of NHSCSP in Manchester and due to report 2008/09
- 7.10 Cytoc have indicated their willingness to take part in a feasibility study of their new imaging system in Scotland and may be willing to fund part of a study to ascertain its effectiveness within the Scottish screening programme.

³ www.cancerscreening.nhs.uk/cervical/research.html

- 7.11 The specificity and sensitivity of the imager have been assessed in a number of papers most of which support the argument that it is at least the equivalent of manual screening. ⁴
- 7.12 Improved efficiency with less screener time used for each slide was apparent across most of the studies reviewed and this was supported by a trial by Bolger in Ireland. In this study there was discussion about the published increase in efficiency of between 55% and 180% which had been achieved in various US studies but this would be difficult to translate without evaluation to the UK system. Bolger suggests an average of 20 negative slides per hour was reasonable in the Irish experience compared with an average of 10-12/ hour in their laboratories. ⁵
- 7.13 Outline costs would indicate that the implementation of this technology on a lease basis would range in cost from £1.70/test excl VAT to £2.90/test contingent on the number of centres of delivery. This would be additional to the current revenue costs and does not take account of any potential efficiencies in delivery. Assessment of cost/benefit would require a more detailed business case.
- 7.14 Cytoc have recently developed a 'remote connectivity' module for the imager. This functions by allowing LBC specimens to be processed and scanned in a centre and the coordinates of the 22 fields stored to CD or other electronic environment. The prepared slides can then be transported to any lab for reviewing.
- 7.15 This technology could be useful if the outcome of the review is to concentrate laboratory cervical cytology in fewer centres or as a means to distribute work amongst labs during times of pressure. There is the potential for the centres to become the hub with spoke labs continuing to review slides. Again this option would require further detailed costings and impact/risk assessment.
- 7.16 Initial discussions with Cytoc have indicated the possibility that the system could be developed further possibly in conjunction with the SCRRS system and uplifted to any lab. This may provide the basis of a suitable migration plan if the number of centres processing LBC drops. There is the potential to use this technology to reduce the impact of staff redeployment.

The review group may want to consider whether the current technology is used efficiently and the feasibility of utilising new imaging technology and the impact of this on service delivery

Information Technology and E Health

Scottish Cervical Call Recall System (SCCRS)

- 7.17 SCCRCS is new national integrated and standardised computerised call recall system which is being introduced throughout Scotland in May 2007. It is based on electronic requesting from the smear takers creating a paperless system in the laboratories. Its

⁴ Roberts et al Diagnostic Cytopathology 2007 v35 No 2

⁵ Bolger et al Acta Cytologica v50 No 5 Sep-Oct 2006

integrated database, accessible from all laboratories will facilitate the movement of processing and reporting across laboratories and thus has great potential for facilitating collaborative working.

- 7.18 Within the laboratory, the disappearance of booking in patient demographics, and creating and issuing paper reports is expected to impact most heavily on clerical staff. Online reporting and inbuilt monitoring and quality assurance systems will simplify working practice for screening and reporting staff.

Further assessment of the effect of SCCRS will be carried out after its implementation and should inform future discussions within the review group.

8. HPV Testing and Vaccination

- 8.1 Virtually all cervical cancers and the majority of pre-cancers are caused by infection with high risk (HR) types of HPV. There are around 18 genotypes that have been classified as high-risk but types 16 and 18 are commonest, accounting for approximately 70% of cervical cancers (1). HPV infection is very common but is usually cleared naturally, yet it is evident that chronic or persistent infection with the same HR-HPV type highlights individuals at greatest risk of disease and disease progression. Conversely absence of HR-HPV provides reassurance that disease progression is unlikely.
- 8.2 Several randomised controlled trials of HPV testing have shown that HPV is more specific for detection of high grade cervical disease and might be more appropriate than cytology as a first line test. Recent reviews have suggested that there is a role for HPV testing for triage of women with low grade cytological abnormalities to reduce referrals to Colposcopy, in following up women who have been treated for CIN and in ceasing women from screening at age 50. Several countries such as the USA and Norway are establishing national guidelines on the use of HPV in triage and others recognise the need to move from cytology to HPV testing.
- 8.3 Commercial HPV screening assays have been available for about 10 years and many of the large diagnostic companies are now entering the market. There are several methodologies which can be carried out on the same sample as cytology providing type specific, generic, quantitative and qualitative testing. The Specialist Virology Centre in Edinburgh has been involved in several of the HPV trials and provided the Quality Assurance materials to the NHSCSP pilot and is already accredited for HPV testing by CPA. It has the skills and expertise to play a key role in defining and providing appropriate services in Scotland.
- 8.4 There are 2 HPV vaccines currently on the market, one already licensed for use in Europe and the other expected to be licensed later this year. Both are effective against HPV 16 and 18. They are given intramuscularly in a three dose schedule (0, 1 and 6 months) and will be first licensed for girls aged 9-26. Both show almost 100% efficacy over 5 years against development of infection with the types they contain. Nevertheless, there is little evidence to date of cross protection and lesions due to other HPV types will still develop. HPV testing will be required to monitor the effectiveness of the vaccination programme.

- 8.5 Cytology screening will remain essential for at least a generation for those women who have not been vaccinated. It is also important for those who have been vaccinated in order to detect the 30% of cervical cancers and pre-cancers caused by other high risk HPV types. It is difficult to predict accurately the timing and extent of the impact of HPV testing and vaccination on the current cervical screening programme but flexibility will be required to adapt to the change in diagnostic services.

The review group may want to consider what affect the design of HPV testing and the impact of vaccination may have on the programme

9. Manpower Planning

- 9.1 The cytology laboratory normally consists of 5 groups of staff including medical staff, advanced practitioners and biomedical scientists, cytoscreeners, medical laboratory assistants and clerical Staff. Each of these groups is faced with challenges in delivering the future service model for cytology.
- 9.2 The number of staff involved on the provision of the service are outlined in **Table 2**. This information has been collected in a recent survey of all labs and has **not been validated** (e.g. calculation of wte allocated to cervical cytology is subjective in some instances)
- 9.3 There are approximately 215 staff delivering the laboratory aspect of cervical cytology. Many of the staff listed will carry out a number of duties including histopathology and non gynaecological cytology.

Table 2

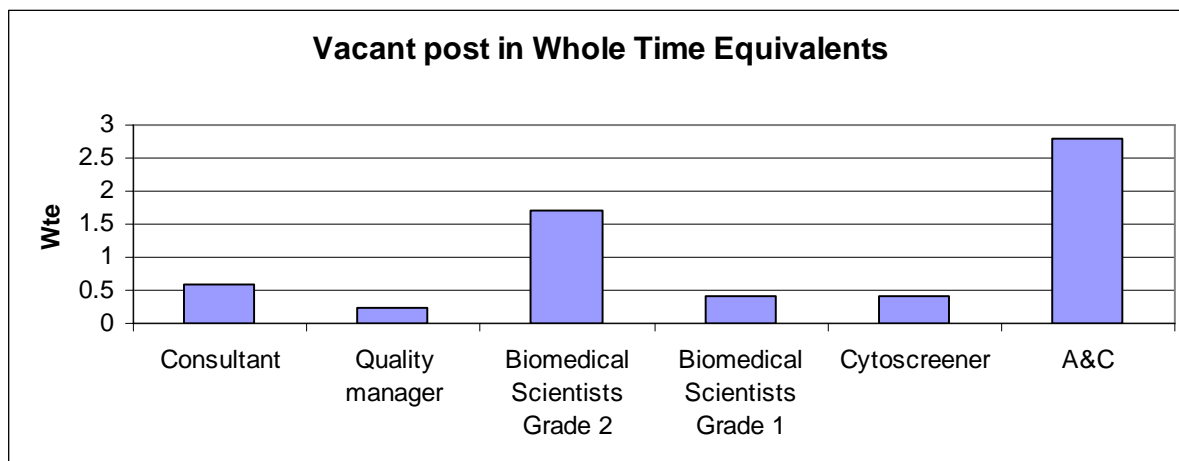
Staff Group	Staff Numbers	Whole time equivalent (wte)/programmed activities (pa) for Cervical Cytology
Consultants	25	52pa
Medical Staff Other	5	18.5pa
Advanced Practitioners	4	2.65wte
Biomedical Scientists	79	51.81wte
Number of Cytoscreeners	40	27.75wte
Medical Laboratory Assistants	23	17.36wte
Admin and Clerical	39	25.75wte

Vacancies

- 9.4 Vacancies are outlined in **Chart 2** and show vacancy rates which are relatively low overall. The consultant post had the longest period of vacancy 32 months and was attributed to consultant shortages. The A&C staff have been affected by the delay in

implementation of SCCRS with a cautious management approach awaiting assessment of the reduction of administrative requirement SCCRS may bring.

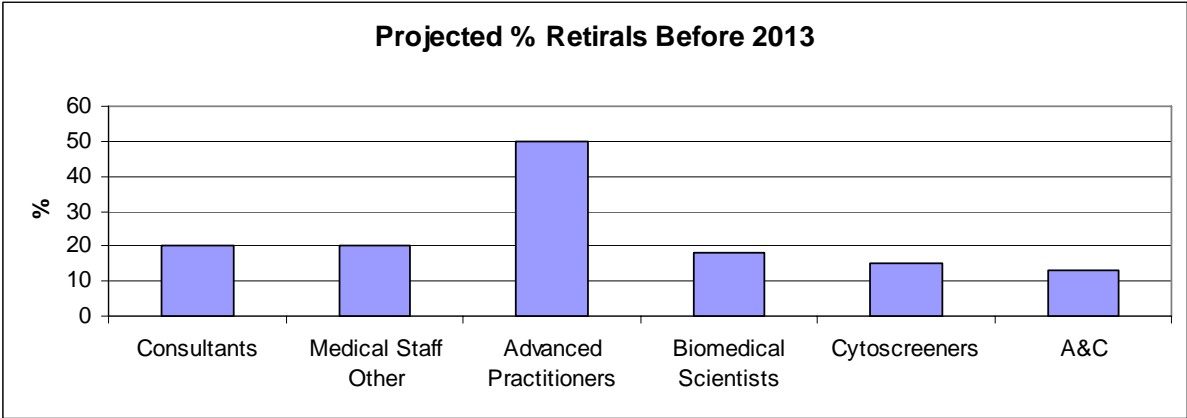
Chart 2



Retirals

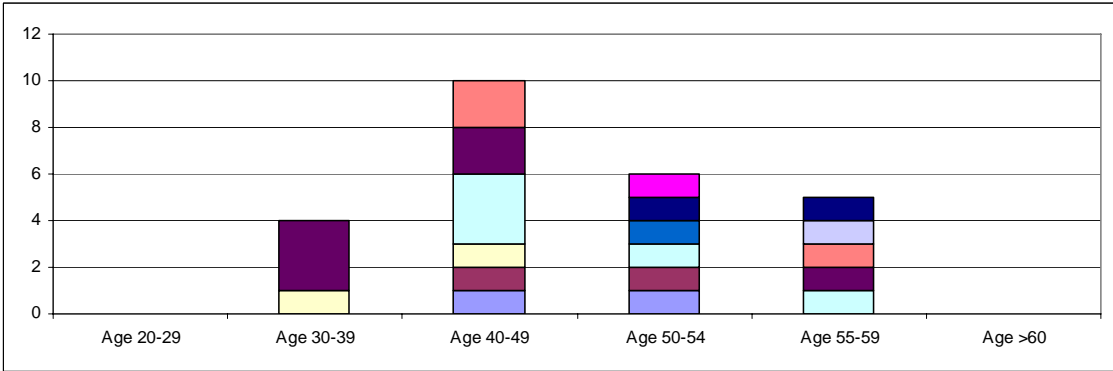
- 9.5 Projected retirals before 2013 are highlighted in **Chart 3** and fit in with the demographic pattern of the staff concerned. Possibly the most obvious comment is that 50% of the Advanced Practitioners will have retired. This is to be expected, as they are recruited from the more senior biomedical scientists in the profession. The figures are skewed because of the limited number of posts to date in Scotland.
- 9.6 Five of the consultants are projected to retire and the total clinical time for their current contract equate to approximately 11 PA's of direct clinical contact time with only one of the consultants showing more than 2 PA's for cytology.
- 9.7 Within the Biomedical Scientist group 14 out of 79 are expected to retire which is not outwith projections and given that the integrated degree produces the 100 or so biomedical scientists per year there would be sufficient HPC registered practitioners to recruit. A restricting factor is that HPC registered integrated degree graduates are likely to require 2 further years of training before sitting a Certificate of Competence for Cervical Cytology
- 9.8 The Cytoscreener group show a fairly low attrition rate and should be sustainable from the current recruitment sources.
- 9.9 A&C Staff demographics show no evidence of problem. The factors which need to be taken into consideration looking at future establishment figures for A&C staff would include the impact of SCCRS and the likely requirement for less staff.

Chart 3



9.10 In the original scoping paper there was anecdotal evidence of a difficulty in both filling vacant consultant posts and the age demographics were showing that a number of medical staff were aged 50 or above. From the recent survey, there are 25 consultants with sessions accredited for cervical cytology. They are committed to 52 programmed activities and provide diagnostic input to over 27000 cases per year. The age demographics are shown in chart 4 below indicating a fairly robust age profile with the majority of consultants in the age 40-49 age group.

Chart 4
Consultant Age Demographics

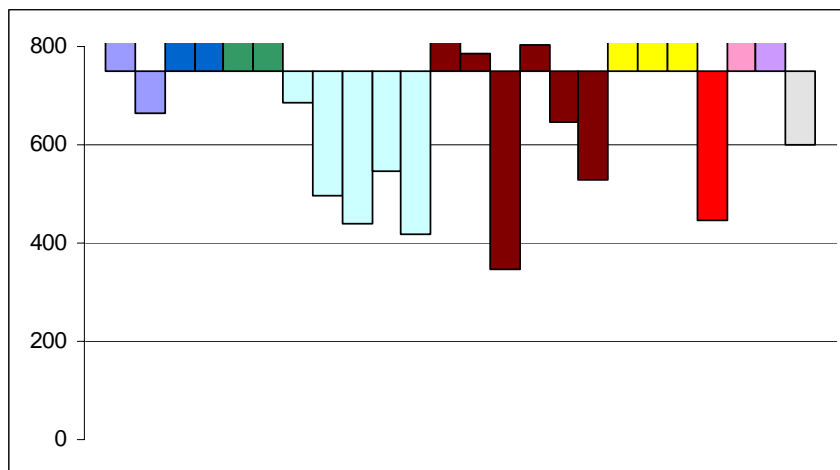


9.11 Traditionally, cytology laboratories in Scotland have been led by a consultant specialising in cervical cytology. Some areas also employ highly experienced non-

consultant medical staff: other labs distribute medical reporting across larger numbers of staff. Three laboratories have introduced Advanced Practitioner posts which allow for non medical reporting of abnormal smears. The latter, in conjunction with evolving changes in categories of smears requiring a medical opinion, has led to a reduction in the number of smears requiring medical reporting.

- 9.12 While recruitment may pose a problem and few trainees are indicating cervical cytology as a preferred career pathway, the new consultant contract and specialisation allow for including cervical cytology (e.g. in gynaecological pathology) and ensuring that appropriate sessional/PA commitment is allocated.
- 9.13 The original NHSCSP Guidelines (ABC2) indicated a minimum number of 750 cases should be reported to ensure sufficient spread of clinical presentations could be seen. This figure has been subject to debate but remains the published standard although likely to change in the future. The NHSCSP Laboratory Quality Assurance Group suggest that the medical input should not drop below 1 programmed activity to maintain practice. From **Chart 5** below there is a clear indication that there are some labs where consultant staff have limited programmed activities in cervical cytology and see significantly fewer than 750 cases.
- 9.14 NHSCSP and CPA currently have as a standard that a cytology laboratory must be directed by a medical consultant. CPA are considering a change this standard to widen the statement to include staff with the appropriate competencies.
- 9.15 Other medical staff are involved in the delivery of the service and are usually graded as associate specialists. They carry out a similar role to the consultant pathologist and are currently employed in 4 health board regions supporting the laboratory service.

Chart 5
Cases per consultant Colour Coded per laboratory



- 9.16 Advanced Practitioners in Cervical Cytology are a small group of staff recruited from experienced biomedical scientists who have been trained and examined in reporting abnormal cervical smears.⁶ To date, there have been 4 appointments in Scotland. The current role of Advanced Practitioners is clearly defined through professional guidance and an HDL but their potential future role in the development of the service needs discussion.⁷
- 9.17 Biomedical Scientists have been identified as having recruitment and retention issues and the Biomedical Scientist Modernisation Board has helped in the development and funding of integrated degrees.⁸ It should be within the remit of the review group to report on the manpower planning and development of this group within cervical cytology taking account of UK wide direction as appropriate.
- 9.18 The number of cytology screeners has remained relatively static with only a small reduction in numbers post liquid based cytology implementation. Recruitment of qualified screening staff is extremely difficult and there is very little movement of Cytology screeners between laboratories. Within this group as with Medical Laboratory Assistants there has been little opportunity to develop beyond this grade. With the modernisation agenda for NHS staff and the developing health care scientist career pathway how could future educational direction affect this group?
- 9.19 Clerically the service is in a state of change with the assessment of the impact of SCCRS still to be realised. Anecdotally there have been significant effects on laboratory turnaround when there have been shortages within the clerical group. They can be a difficult group as far as recruitment and retention are concerned particularly in geographical areas of high employment.

The review group may want to consider the most effective structure and manpower planning arrangements taking into consideration any possible change in service delivery

Education and Training

- 9.20 Training for Cytology Screeners and biomedical scientist staff in Scotland and the rest of the UK is co-ordinated by the National Cervical Cytology Education and Training Committee (NCCETC) which reports to the NHSCSP. Training is delivered at

⁶ Advanced Specialist Diploma in Cervical Cytology www.ibms.org

⁷ NHS Circular: PCS(PTB)2002/1

⁸ HDL (2004) 28

Cytology Training Schools across the UK; the Scottish School is based at Edinburgh Royal Infirmary. The training is a combination of formal training school based teaching and laboratory based training. The training schools are all externally assessed by the NHSCSP UK Cytology training Schools assessment scheme.

The exit examination is currently the NHSCSP Certificate in Cervical Cytology (CCC) but this qualification will soon be replaced by the City and Guilds Diploma in Cervical Cytology which is open for registration in June 2007 with the first examination scheduled for mid-2008 at the earliest. The new Diploma exam will only be available three times a year.

- 9.21 Training is intensive and standardised across the UK. Biomedical scientists can sit the CCC after eighteen months training; Cytology Screeners require a minimum of two years. In practice in Scotland both staff groups are trained for two years before they can sit the exam. Trainees staff cannot sign out negative samples until they have obtained the CCC therefore are “un-productive” in cervical cytology as all their screened slides are “double-screened” by qualified staff.
- 9.22 A minimum of 5000 slides must be screened during the training period before trainees can sit the CCC. This target may prove to be a barrier for biomedical scientists who traditionally are involved in other aspects of the laboratory’s workload. This may extend the training period. In operational terms it often takes up to two and a half years from appointment to obtaining the CCC.

10 Conclusions

- 10.1 This baseline briefing is based on collection of both primary and secondary data and was designed to help inform the review group in relationship to the future delivery of this service. It is, given the timescale, incomplete and further in depth analysis is required
- 10.2 From the information supplied it is clear that there are important drivers for change organisationally, technologically and in manpower planning. There has also been some anecdotal information which has either been supported or challenged in the collection of the baseline statistics.
- 10.3 It is anticipated that the review group may want to consider at a general level the options for design/management of the service based on this information and possibly start the process of a fuller option appraisal. They may also want to consider how that option appraisal would be carried out.
- 10.4 There will be further questions the review group will require answers to after the first review group meeting and it is hoped that information can be collected in time for consideration at the September meeting.

Questions

The review group may want to consider the question of whether the management of cervical cytology would benefit from being organised and budgeted nationally or continue under local Board auspices. This would require further information on the benefits and implications and data on cost analysis probably based on the Welsh Model?

Is the current model of delivery the most effective in delivering cervical cytology in the medium to long term?

What impact will technology changes have on the future delivery of service? How do you assess the impact of the technology?

Is the current skill mix robust enough to meet the future needs and changes within the screening programme? The review group may want to consider the most effective structure and manpower planning arrangements taking into consideration any possible change in service delivery?

If an option appraisal is carried out what should the scope of this be?

What further information does the review group require to make evidence based decisions?