

Cervical Screening **Wales**
Sgrinio Serfigol **Cymru**

CERVICAL SCREENING WALES

A Report on the Implementation
of Liquid Based Cytology
in Wales

July 2004 - December 2005

OCTOBER 2007



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Executive Summary

Cervical cancer is a malignant disease occurring in the neck of the womb – the uterine cervix. The disease may be prevented by microscopically detecting early pre-malignant cellular changes, through a process known as cervical screening; these changes may then be treated to remove the abnormality, thereby preventing the development of cancer.

Cervical Screening Wales offers a regular cervical smear test to check the health of the cervix as part of an organised screening programme, and if necessary, further evaluation and treatment as part of a clinical examination called colposcopy, before any changes detected can become an invasive cancer.

Cervical screening has for many years relied upon conventional cytology utilising the Papanicolaou Smear to detect these changes; however, more recently a new method of screening called Liquid Based Cytology (LBC) has been developed and introduced to the programme.

Introduction of this technology was recommended by the National Institute for Clinical Excellence (NICE) and the recommendation has been accepted by the National Assembly for Wales.

This report describes the roll-out process of LBC technology in Wales and presents an initial assessment of the performance of the new technology and its impact on the cervical screening programme in Wales.

The formal roll-out of LBC to the cytology service in Wales required a successful procurement, an organised implementation plan, comprehensive conversion training of 2,600 sample takers and 119 laboratory personnel, the implementation of a supporting infrastructure, and the development of a co-operative interactive approach to screening from all service professionals.

The analysis of performance information gathered post LBC implementation shows a reduction in inadequate samples, an improved Positive Predictive Value (PPV), maintained primary screener sensitivity and specificity, a reduction in colposcopy referrals, a reduction in laboratory turnaround times and potentially a more efficient use of staff and resources.

LBC technology provides a basis for continued improvements and development within the programme, including Computer Assisted Screening, 'reflex or adjunct' testing, the development of cytology diagnostic networks and the improvement of quality assurance procedures and audit.

The implementation of LBC to the cervical screening programme in Wales was achieved within budget and in twelve months which was within the target timescale.

This evaluation has concluded that the technology is safely established, functioning well, providing acceptable results and will provide a robust platform for the future development of the cervical screening programme.

1. Introduction

The aims of the cervical screening programme in Wales are to reduce the incidence of and the morbidity and mortality from invasive cervical cancer. The screening programme is considered effective and the numbers and rates of cases of invasive cervical cancer have halved since the establishment in the late 1980's of regular invitations to women for cervical screening. Now about 160 cases of invasive cancer are newly diagnosed each year in Wales. The fall in the incidence of cervical cancer is also reflected in the fall in the number of deaths from cervical cancer seen over the last 20 years.

Cervical screening involves a laboratory test to check the health of the cervix and, if necessary, to enable treatment to be offered if there are early cellular changes, before they become an invasive cancer.

Cervical Screening Wales (CSW) is responsible for the whole of the cervical screening programme provided to women resident in Wales. This responsibility includes:

- programme management and coordination
- call and recall arrangements
- cervical cytology services
- cervical histology services
- colposcopy services

CSW is responsible for inviting women aged between 20 and 64 years who live in Wales, to attend for a cervical screening test every 3 years. About 220,000 women each year accept an invitation to have this test (around 80% of the eligible population between 25-64 years have been tested at least once in the last five years). The sampling and examination of the test, handling of results and coordination of recall and follow up care, including treatment, is managed by CSW.

The screening test requires the removal of a small number of cells from the woman's cervix (sampling) and examination of these cells in a laboratory (cervical cytology services). Women who have defined cellular changes reported by the laboratory are referred for a diagnostic procedure (colposcopy) and if required, appropriate treatment is then offered. The screening programme is based on a three yearly test cycle to look for any abnormal cell changes. Although the programme reduces the risk of cervical cancer, not all cervical cancers are prevented; as with all medical tests and procedures false positive and false negative results are unavoidable.

Before the introduction of Liquid Based Cytology (LBC), the sampling process used in cervical cytology had remained largely unchanged for over fifty years. A wooden spatula was used to obtain cells from the cervix, which were then spread onto a glass slide before processing and subsequent microscopical examination in the laboratory. This conventional smear test was simple, easily performed and relatively inexpensive.

The established sampling procedure was, however, potentially open to variation and inconsistencies at all stages of the collection including the sampling, transfer, spreading and fixation processes required for each cervical sample. It is considered that inadequate sampling and the sample transfer methods required by the conventional technique may have been an important reason for false negative results, which is why some women had abnormalities that were not detected.

The development of commercially available LBC systems offered an improved method of collecting and processing the cells from the cervix.

LBC utilises an improved sampling device, the Rovers[®] Cervex-Brush[®], to collect the cell sample from the cervix. Following sampling, the head of the brush sampler is immediately transferred to a vial containing a preservative fluid (a collection and transport medium). This simpler method of collecting the cells in a preservative fluid, rather than spreading the sample on to a glass slide enable samples to be processed in the laboratory where greater control over the quality of the finished slide can be achieved. This process reduces the number of samples that have an inadequate number of cells for reporting. To improve sampling in specific cases additional sampling implements (an endocervical brush or occasionally extended tip plastic spatula) may be used.

The labelled sample is sent to the laboratory for processing. The cell sample is re-suspended in the sample vial as part of the laboratory process to release the cells from the brush and evenly distribute them throughout the sample fluid. A portion of this sample is then used to prepare a thin layer of cells on a microscope slide for subsequent examination. This has the benefit of ensuring that the sub-sample presented on the slide for examination is representative of the whole sample and increases the likelihood of abnormal cells being included on the slide.

Using the evidence from previous research and from the Welsh and other UK pilots, it was anticipated that certain outcomes would improve with the introduction of LBC.

These were:

- A reduction in the number of samples which were inadequate for screening in the laboratory (inadequate samples)
- An improvement in primary screening sensitivity leading to improvements in detection of abnormalities
- Service efficiency gains including:
 - A reduction in the number of repeat tests due to inadequate sampling
 - Increased automation, leading to more efficient working procedures
 - Increased specificity, which would reduce the number of women requiring follow up investigation

1.1 Main considerations

The formal roll-out of LBC to the cytology service in Wales required a successful procurement, an organised implementation plan, the implementation of a support infrastructure and a co-operative approach from all service professionals. The roll-out planning of LBC was influenced by a number of factors. Information gained from the CSW LBC pilot assessment has been invaluable in informing the process. For logistical reasons processing facilities were introduced to all laboratories as part of the implementation plan. The development of Pathology networks was considered in the process, however, the advantages of single site processing in the rapid implementation and consolidation of LBC across the service outweighed the potential delays that would have been implicit in the negotiation of equipment sharing agreements between laboratories. This was the most cost effective option at the time and supported the maintenance of locally based screening and reporting functions.

1.2 Screening and reporting

As far as is possible the maintenance of locally based screening and reporting functions is a central principle of the screening programme in Wales. This enables local clinical access to pathology results, and direct input to Multi-Disciplinary Team meetings (MDT) and the CSW systems of patient management. However, changes in service delivery models and technology developments may require that this approach is re-evaluated in the future.

The implementation of LBC provides a basis for continued development within the screening service (e.g. HPV testing and Computer Assisted Screening).

1.3 Other considerations

The need for a robust system for monitoring the service during and following roll-out was identified, reliable data must be available to monitor all aspects of performance. Close scrutiny of service performance indicators was essential in the post implementation assessment phase.

Reliable data were required from laboratories to enable comparative assessment of conventional and LBC technologies, before and after implementation. These data informed the assessment of both sample taking and laboratory technology issues.

Initial difficulties were experienced in the supply and requisition of consumables by the primary care sector. Information on the usage rate of consumables was essential in the establishment of practice minimum stocking levels and establishing reliable distribution processes.

2. Background

Cervical Screening Wales (CSW), which is part of Velindre NHS Trust, manages the cervical screening programme in Wales. The programme is well established and since April 1999 has been organised as a managed clinical network. Approximately 220,000 women accept an invitation to attend for cervical screening each year and on average approximately 80% of eligible women aged 25-64 resident in Wales have attended for a cytology test and have been adequately screened at least once in the last five years.

In June 2000, the National Institute for Clinical Excellence (NICE) issued guidance on the use of Liquid Based Cytology (LBC) within the NHS Cervical Screening Programme (NHSCSP) in England and Wales. The NICE concluded that:

"Research evidence suggests that Liquid Based Cytology (LBC) could provide significant and important benefits. However, the quality of the evidence is variable and some areas of uncertainty remain. Although there is insufficient evidence to justify the nationwide introduction of LBC technology at this time, it is likely that LBC will have the effect of reducing the number of false negative test results as well as the number of unsatisfactory specimens. In addition, it may decrease the time needed for examination of specimens by cytologists.

In order to establish its contribution, a programme of pilot implementation projects of LBC should be undertaken, accompanied by a full review of the results at each stage. This should be done before consideration is given to the general introduction of this technology nationally. These projects should evaluate all the effects, costs and practical implications of introducing LBC technology into the cervical screening programme."

In response to the NICE guidance, the National Assembly for Wales (NAfW) decided to commission CSW, with funding, to undertake a pilot implementation project between October 2001 and September 2002.

As part of this pilot, an evaluation of the effects, costs and practical implications of introducing the LBC technology was undertaken. A report on the project was produced on behalf of the LBC Project Steering Board and the lessons learned from the pilot were taken forward in the planning of the full implementation. Two other independent pilot assessments looking at the implications of introducing LBC were undertaken in Scotland and England at about the same time.

The effect on test results was as expected with a significant reduction in the number of inadequate samples. A fall in the number of women referred to colposcopy was also noted, not just due to the reduced inadequate rate but for high-grade referrals as well. This reduction was significant for one Cervical Screening Administration Department (CSAD) and the numbers of referrals continued to reduce following completion of the pilot phase. The potential causes of this anomaly may be multifactorial, and include, cross screening-boundary referral issues and pre-pilot workload management (backlog recovery).

Also, during the course of the pilot phase, minor amendments were made to colposcopy referral criteria on an all-Wales basis for samples categorised as having borderline changes. This may have had an impact on the referral rate within the pilot assessment.

The CSW pilot evaluation report recommended that:

- A procurement process is completed for the supply and installation of processing and ancillary equipment and the necessary laboratory and sample taking consumables required to roll-out the new technology to the whole of Wales
- The continuing allocation of additional funding required to support the roll-out process should be confirmed
- A firm commencement date for the roll-out process was agreed
- The current level of conversion within the pilot assessment areas should be maintained and supported with 'bridging' funding, pending completion of the procurement process and the subsequent implementation of LBC
- Discussions with local services and trusts be commenced to establish appropriate service configurations for the location of processing equipment
- Further preparatory development should be undertaken, particularly in relation to training in both the primary care and laboratory sectors, developing a generic approach to LBC training and to ensure that an efficient implementation can be achieved
- A small management group be established within CSW to act as a focus point for negotiations and to oversee the development and management of the implementation and roll-out process

Following a subsequent review of the LBC technology, including information from these pilots, The NICE published technology appraisal guidance on the use of Liquid Based Cytology for Cervical Screening (number 69), which was issued to the NHS in October 2003.

The guidance recommended:

" that liquid-based cytology (LBC) is used as the primary means of processing samples in the cervical screening programme in England and Wales."

The guidance considered two technologies for providing LBC and concluded:

"There is currently insufficient evidence to recommend one LBC product over another."

Following these announcements and after discussion with the Welsh Assembly Government and Health Commission Wales, additional funding of £1.168m was agreed to implement an improved cervical screening programme for Wales using liquid based cytology.

This report has been written to:

- Describe the roll-out process of LBC technology in Wales
- Present the initial findings on the performance of the new technology
- Describe the impact of the roll-out process on the cervical screening programme in Wales.

The report has utilised data from a number of sources including:

- Costs and activity information from CSW and participating laboratories
- Laboratory returns and raw data extracts sent electronically to CSW
- Information extracted from Cervical Screening Administration Departments through the *National Health Applications & Infrastructure Services (NHAIS)* or 'Exeter' system
- Information from the ISCO Colposcopy Information System (ISCO-CIS)
- Information from Welsh Health Supplies information systems
- Information from Medical Solutions plc

3. LBC Implementation Plan

3.1 Introduction

An implementation plan for the phased introduction of LBC for all cervical screening samples was developed. The implementation plan was managed by a small team within CSW, led by the All-Wales Programme Manager. The implementation team was accountable to the Director of Screening Services for the progress and completion of the project. The team included:

- All-Wales Programme Manager
- Screening Services Business Manager
- CSW Senior Nurse Manager
- CSW Programme Co-ordinators
- Director Welsh Cytology Training School
- Manager of the Welsh Cytology Training School

The implementation plan was, of necessity, flexibly arranged around local service availability and requirements, including local circumstances such as planned laboratory refurbishments.

The implementation or roll-out plan covered:

- The co-ordination and arrangements for conversion of primary care sectors and laboratories, delivered to a defined time line
- Support for interim screening arrangements (Pap smears)
- Training requirements for sample takers and laboratories
- Establishment of the supporting infrastructure, including the consumables distribution processes through Welsh Health Supplies
- Establishment of contracting arrangements (supply, orders and deliveries) with the LBC supplier
- Establishment of contract surveillance and review
- The introduction of monitoring processes for usage rates and expiry dates of consumables
- The establishment of transport arrangements for inter service sample transfer and other facilities required to handle samples (bags, racks, containers etc)

Interim assessment and progress feedback arrangements were in place to enable CSW to advise the Welsh Assembly Government and Health Commission Wales on the progress of the implementation plan.

3.2 System procurement

Following an exacting and detailed 'OJEC' procurement, CSW placed the contract for the conversion of all cervical screening with Medical Solutions plc utilising the SurePath™ LBC technology. The technology produced by TriPath Imaging™ Inc, which is now part of BD Diagnostics - Diagnostic Systems, is distributed in the UK by Medical Solutions plc. This decision required a change of supplier as

ThinPrep® LBC technology supplied by Cytoc UK Ltd was the product used in the pilot assessment project.

Despite the rigorous procurement process, the change of supplier and the need for some retraining of laboratory personnel was controversial for some laboratory staff who were involved in the initial pilot.

The pilot project envisaged that full implementation of LBC in Wales would require the adoption of a 'hub and spoke' arrangement. In this arrangement, screening laboratories are retained at their current location, with samples being redirected from the primary reception laboratory (spoke laboratory) to a central processing laboratory (hub laboratory), which would subsequently return the processed samples to the primary reception laboratories for screening and reporting.

The hub and spoke arrangement proved to be a successful innovation during the piloting of LBC and was initially expected to be the model for the roll-out of LBC to the wider service. However, it was recognised at an early stage that a modified approach was advisable based on technological differences in the LBC system chosen.

The development of processing networks was properly considered within the implementation planning phase, however, the advantages of single site processing in the rapid implementation and consolidation of LBC across the service outweighed the potential delays that would have been implicit in the negotiation of equipment sharing agreements between Trusts and laboratories.

In addition, to establish a processing network, it is essential that specific pre-requisites are in place, in particular a reliable transport service. Initial enquiries established that most Trusts did not have suitable transport arrangements in place. As the establishment of suitable arrangements would have introduced additional 'open-ended' costs, and the chosen technology was suitable for single site processing as an alternative to network processing, this option was selected to enable immediate progress on implementation.

The implementation process was planned to start promptly following the signing of contracts on 14th July 2004.

3.3 Training processes

The progress of roll-out was dependant on the success of the training programme. Training was, therefore, a rate limiting factor.

There were two parallel training phases in the plan:

- Primary care / Sample taker training
- Laboratory training – technical, scientific and medical staff

Comprehensive training arrangements were necessary to ensure a successful roll-out. The roll-out plan required careful scheduling of the completion of training processes. Training convergence of the two phases was required to

enable completion of roll-out in a defined area. The roll-out could not proceed if training schedules were not met; the two training phases were subject to specific rate limiting influences:

- Primary care training was an extended process due to the number of individuals requiring training and the organisational complexity of arrangements, although individual training events were relatively quick to complete
- Laboratory training was very intensive and rate limiting in the time required for individuals to complete the process

3.4 Laboratory training

3.4.1 Background

The LBC laboratory training was provided in two parts:

- **Technical training**; which relates to the installation, calibration, running and maintenance of the processing equipment used in the application. This was provided for Biomedical Scientists (BMS) and Medical Laboratory Assistant (MLA) support staff
- **Morphology training**; which relates to the microscopy processes of screening and reporting of LBC samples. This was provided for Cytoscreeners, Biomedical Scientists (BMS), Advanced BMS Practitioners and Cytopathologists

Technical Training

All technical training was provided by the suppliers Medical Solutions plc. The training was provided within the laboratories by the company's technical specialist, following equipment installation and in most cases spanned two days.

The training covered instrument calibration and running procedures, routine maintenance procedures, fault recognition and trouble shooting processes and basic minor repairs procedures.

The training was provided to nominated staff members, including the designated supervising BMS. Staff completing the training were accredited by the company as proficient system operators.

Morphology Training

Morphology training was delivered through the Welsh Cytology Training School (WCTS). To meet differing operational needs, two categories of courses were provided:

- a) Full conversion training was based on a three-day induction course of lectures and practical microscopy sessions at the Welsh Cytology Training School to introduce staff to the principles and practice of LBC, followed-up by the

examination of consolidation slide sets and performance review slides at the base laboratory.

- b) Abbreviated conversion training was developed for staff already trained in LBC during the pilot project using the ThinPrep® system. This modified 'cross-over training' was based on a one-day LBC System Conversion Course at the Welsh Cytology Training School, to introduce staff to the principles and practice of SurePath™ LBC technology, followed up by the examination of consolidation slide sets and performance review slides at the base laboratory.

By 11th January 2006, 119 staff out of 122 had successfully completed this training in 12 laboratories across Wales. This is considered the effective laboratory training completion date, as the remaining outlying staff did not affect LBC operational performance.

Conventional Papanicolaou cytology has now been completely superseded, and all new staff are now trained solely in LBC as they start work in laboratories.

3.4.2 Course content

The core training developed for laboratory staff was common to pathologists, biomedical scientists and cytoscreeners and was based upon the NHS Cervical Screening Programme model delivered through the Liverpool Cytology Training School by Dr L Turnbull. Initially the course structure consisted of a three-day induction phase, a consolidation phase, an interim assessment and performance review. However, from the experience gained in the LBC pilot project, the interim assessment was deemed inappropriate and removed from the training schedule. Training involved the microscopical evaluation of at least 540 slides over an eight-week period. The slide mix was prepared to enable the evaluation of sensitivity and specificity. A minimum sensitivity of 95% was required for satisfactory completion of the training.

Biomedical Scientists and cytoscreeners underwent the full training programme, consisting of the induction course, consolidation phase and performance review phase.

Senior laboratory staff (checkers) were also expected to undergo the full training programme as they are expected to show competence in the primary screening of slides.

Cytopathologists, and clinical cytologists (ABMSP) whose job plan does not include checking and/or primary screening, completed the induction course and consolidation phase only; they were not required to undertake the performance review. Clinical cytologists who do undertake checking and/or primary screening were required to complete the full conversion training programme.

All staff were issued a certificate of achievement by the WCTS, recognising their proficiency, on successful completion of the training.

The induction course introduced participants to the concept of LBC and the additional microscopy skills that are required. No formal assessment was included at this stage.

The consolidation phase involved the screening of a minimum of 200 unknown LBC slides. These were heavily seeded with abnormal slides (40-50%) to allow interpretative ability and observer sensitivity to be assessed. A minimum sensitivity of 95% was identified as the standard for progression to the performance review phase.

The performance review phase required the examination of a further 200 slides. These were seeded with a low percentage of known abnormal samples (around 10%), enabling an accurate measure of the observer's screening sensitivity.

BMSs and cytoscreeners who achieved a final overall sensitivity of 95% were acknowledged as proficient LBC screeners.

Staff who did not achieve the overall sensitivity standard were required to examine a further set of performance review slides; their performance figures were recalculated against the supplementary assessment slides. A small number of staff (six individuals) required this additional assessment.

Three members of staff did not complete the training programme. None of these individuals are currently reporting cervical cytology; one resigned from employment during the training period, one did not complete the required number of slides and withdrew from screening, and one failed to achieve the required sensitivity following supplementary training and again, withdrew from screening.

3.4.3 Course delivery

The training programme was organised by the Manager of the Welsh Cytology Training School, Mr Andrew Evered, under the direction of Dr Nick Dallimore, Welsh Cytology Training School Director. Local Training Supervisors were identified to provide on-site support during the conversion process; these trainers were Mr David Nuttall, Head BMS, Ysbyty Glan Clwyd; Mrs Christine Davies, Head BMS, Singleton Hospital and Mrs Lynne Williams, Chief BMS, West Wales General Hospital.

Training was delivered at the WCTS training centre in Cardiff and at the North Wales 'WCTS Satellite Training Centre'. Local microscopy training was also delivered in Carmarthen and Pembrokeshire.

CSW purchased two multi-headed teaching microscopes to facilitate the training programme and to support the development of ongoing update training/teaching for LBC and cytology.

All but a small number of staff were trained in the initial roll-out training which was completed by January 2006. Figure 1 details dates of site conversion training. Training for the small number of staff who missed the initial training phase due to unavoidable absence was completed later.

Because many of the screening and professional staff completed the training very promptly, wherever possible the LBC technology was rolled out at an accelerated pace.

Figure 1: Training sites and period of training

Laboratory	2004						2005												2006	
	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12	1	
BND	■	■																		
GLM	■	■	■	■																
LLD			■	■	■	■														
SIN					■	■	■	■												
YGC						■	■	■	■	■	■	■	■							
GWY						■	■	■	■	■	■	■	■							
WXH						■	■	■	■	■	■	■	■							
WWG							■	■	■	■	■	■	■	■	■	■	■	■	■	■
WBH							■	■	■	■	■	■	■	■	■	■	■	■	■	■
RGH								■	■	■										
PCH													■	■	■	■	■	■	■	■

Note: See Table A.1.1 in Appendix 1 for key to laboratories

3.4.4 Observations on laboratory training process

The training schedule was organised to correspond with the roll-out conversion plan; this ensured continuity in experience between training and practice and the implementation of the new technology.

To be effective, training must be supported by adequate resources, especially in the development of training slide sets. Effective work based morphology training required the need to identify and develop local based trainers.

An unexpected difficulty in laboratory training was encountered by those laboratory staff that had been trained on the ThinPrep® system during the LBC pilot. In many cases, these staff found the cross-over conversion to SurePath™ technology more challenging than those who had no prior experience of screening LBC.

The unexpected effect of retraining staff to use the alternative LBC technique required additional time and training costs. This contingency should be included in the assessment criteria for the next procurement process currently due to be initiated in 2009.

3.5 Primary care training

Sample taking is undertaken by a variety of trained staff, most of whom are General Practitioners or Practice Nurses working in general practice or in NHS community clinics. Some sample taking will also be undertaken in Hospital Trusts, notably in colposcopy departments.

In Wales there are 2,600 registered sample takers operating out of approximately 700 locations. The locations included every GP practice in Wales,

community clinics, health centres and colposcopy units at various hospitals, both acute and community based. Due to the number and diversity of sites, the delivery of primary care training was complex and sometimes difficult to organise.

The LBC implementation plan ensured that colposcopy clinic staff were trained and converted to the new technology as soon as their local laboratory had completed training. This provided sufficient workload for the laboratory staff to maintain the skills learnt during training and maintain their LBC screening competency. Once the local colposcopy clinic was established as a user of LBC, training was focused on a rapid conversion of the local primary care sector.

3.5.1 Organisation of sample taker training

The sample taker training process was planned, supervised and co-ordinated by the CSW Senior Nurse Manager, Ms Ruth Lawler.

Sample taker training was led locally by the CSW Programme Co-ordinators, and implemented by the CSW Nurse Co-ordinators. The process was centred on the 5 screening divisions of CSW. The order of training was co-ordinated to develop in parallel with laboratory training development:

- Gwent fully converted in pilot
- Bro Taf 60% converted in pilot
- North Wales full conversion training required
- Morgannwg full conversion training required
- Dyfed Powys full conversion training required

Training of all 2,600 registered active sample takers in Wales was completed within 16 months, between September 2004 and December 2005, with over 230 training events.

3.5.2 The primary care training programme

Training was delivered locally on site at practices and clinics or at other suitable local facilities; wherever possible, group training was arranged to include multiple practices.

Organisation of the process was generally practice or clinic based. All individuals that take cervical samples were asked to attend for training. Cascade training was not deployed.

The process was controlled through the sample taker register. All sample takers in Wales must be registered with CSW and are issued with a personal identification number. Sample takers are required to provide evidence of initial training and completion of regular update training for inclusion and retention on the register. Samples received from un-registered sample takers may be rejected at the laboratory.

A team based approach was taken to primary care training, the team included:

- Programme Co-ordinator and/or Senior Nurse Manager
- Nurse Co-ordinator
- A 'senior' Biomedical Scientist from the local laboratory
- The CSW Programme Manager provided the 'laboratory input' where local BMS representation was not available.

The training included formal lectures on the LBC sample taking process and the background to the benefits, development and principles of LBC, including laboratory perspectives.

This was followed up with a practical session utilising a dummy patient and prosthetic cervix teaching aids.

An element of update training was included in the LBC training sessions to maximise the value to practitioners as part of the process of CPD/CME. The training programme included a 'programme update' to ensure an enhanced service benefit for registrants.

Sample takers who had been trained in ThinPrep[®] technology during the pilot assessment were asked to attend for retraining in SurePath[™] protocols. This was required as there are distinct differences in the way the sample is handled and collected into the sample vial. This process is fundamental to the collection of a satisfactory sample, if not completed properly laboratories are required to report deficient samples as inadequate. The handling and packaging of samples is also modified and ancillary information relating to risk management is different due to the use of a different preservation fluid.

Sample takers completing the course were issued with certificates for their CPD portfolios.

To encourage and promote participation and to ensure that there was limited impact on clinical sessions, many of the training sessions were held during lunch time.

Many Local Health Boards were highly supportive of training arrangements, designating protected training time for the LBC conversion sessions, assisting in the identification and funding of suitable premises and providing financial support for refreshments.

A number of the training sessions not supported by LHBs were supported by Pelican[®] Healthcare, providing financial support for refreshments for course participants. Pelican[®] Healthcare also supplied disposable speculae in support of all of the training sessions.

CSW developed special training support materials for the training process, including training resource packs, training videos and DVDs, and prosthetic training aids.

Medical Solutions plc provided assistance and support in the development process and underwrote the development costs of these materials as part of the product support offered in supplying the LBC system.

Information leaflets and materials, produced by CSW for women who are invited for screening, were updated to reflect the new test.

Ongoing annual refresher training and training of new sample takers will continue as part of the routine CSW management of the service.

3.6 Installation of processing equipment

The preliminary implementation plan envisaged that laboratories would be grouped together in processing partnerships, based on the successful model adopted in the pilot assessment process – hub and spoke processing.

In planning the roll-out implementation schedule, and in discussion with laboratories, it became clear that on further consideration of technological differences in the SurePath™ equipment and other considerations including logistics and transport arrangements, that a modified approach was necessary.

It was subsequently agreed that the conversion process would be facilitated by providing all laboratories with processing equipment if a rapid implementation was to be achieved.

3.6.1 Systems installation

The SurePath™ processing system prepares, processes and stains slides in an integrated system. The system uses density gradient centrifugation to separate diagnostic material from obscuring material and utilising a multi-vial vortex mixer and centrifuge, a cell enrichment processor - the PrepMate™, and a processing platform - the PrepStain™ Slide Processor which includes a discrete slide staining process. The finished stained slide is then separately cover-slipped. CSW provided additional funding for automated cover-slipping devices as part of the procurement process.

Some laboratories required minor structural alterations, or additional or altered benching to ensure that efficient processing work flow patterns were in place. CSW made funding available where necessary to support these works; Medical Solutions plc also provided assistance in a number of these site improvements. One laboratory was in the planning stages for relocation and requested deferment of implementation to conclude planning processes. The implementation schedule was planned to take account of the logistical factors affecting laboratories.

The installation of the integrated processing system was completed by Medical Solutions plc. The process included equipment installation, functionality and system 'beta' testing, and on site training of laboratory designated system supervisors and operational and support staff.

In establishing the procurement assessment criteria, CSW took into consideration the need for additional technical support for the processing function and additional funding was made available to laboratories for 0.5 WTE MLA assistance.

3.6.2 Systems monitoring procedures

To ensure consistency of performance across Wales, a technical external quality assurance (TEQA) scheme is in place. The TEQA process is organised and run by CSW and managed by the CSW TEQA Facilitator – Mr Nigel Boucher, based at Llandough Hospital, Cardiff.

Laboratories operate to common, company approved protocols which were discussed and agreed as part of the implementation plan. Considerable initial work was done on defining optimal process settings to ensure consistent and reliable results and an interactive technical support group has been established by the CSW TEQA Facilitator. The TEQA Facilitator acts as a local technology support specialist for CSW, and has received additional technical training from Medical Solutions plc.

System failure and downtime is an important consideration in the screening programme. The equipment has proved reliable in routine use, and the response of Medical Solutions plc and their sub-contracted support service (Grifols UK Ltd) to service call-outs has been very good. The performance history of the technology is logged by laboratories and the information is collected and collated by the LBC Co-ordinator as part of the contract monitoring process.

A gynae-morphology external quality assurance (GEQA) scheme has also been introduced to ensure that standards are maintained in screening and reporting processes. This process is also organised and run by CSW and managed by the GEQA Facilitator – Mrs Jane McRea, who is also based at Llandough Hospital.

The two EQA schemes are run under the direction of the EQA Schemes Organiser, Mr Bryan Rose, CSW All-Wales Programme Manager.

3.7 Supplies and logistics

The need for specialised packaging was recognised to comply with transport and postal regulations for samples (UN 602). CSW and Medical Solutions plc co-operated in the development of primary and secondary packing that fulfilled the requirements and specifications.

The primary packing is based on a combined HMR Request Form/sample bag designed to hold one sample vial. The bag is attached to the form and has a self sealing edge. CSW produces the HMR Request Form/sample bags, which are supplied to Medical Solutions plc for including in the sample kits for sample takers. The packaging includes absorbent pads to contain spillage if damaged in transit. The format of the request form is based on a modification of the HMR/101 format.

Medical Solutions plc provides specially commissioned secondary packing that is printed with the CSW logo and location details; this ensures that samples dispatched to laboratories that have the outer enclosure packaging damaged can be safely forwarded to CSW. The sample transit bags hold multiple primary package HMR Request Form/sample bags - up to five samples per package.

3.7.1 Supply of consumables

Effective consumables supply control is essential to limit supply problems and contain the costs of LBC.

The consistent and reliable supply of the consumables required for LBC to sample takers in primary care, to hospital clinics and to laboratories was initially problematic and has required considerable managerial effort by CSW. The challenges included:

- Establishing the supplies infrastructure, distribution and transport arrangements
- Extending supplies arrangements across the service
- Negotiating implementation arrangements with suppliers
- Negotiating implementation arrangements with consumers
- Monitoring usage rates and expiry dates of consumables
- Liaising and troubleshooting supplies arrangements with
 - primary care
 - laboratories
 - distribution centre
 - suppliers

To provide administrative assistance an LBC co-ordinator was appointed. This was initially a temporary appointment, but the continuing need for an LBC co-ordinator to manage and support the supplies process was identified and the post has now been consolidated within the CSW management structure.

CSW has made arrangements with Welsh Health Supplies (WHS) for the warehousing and distribution of consumables. The LBC co-ordinator liaises with WHS on the ordering supply and distribution of consumables. The requisition process is controlled by CSW, with all orders directed through the LBC co-ordinator.

3.7.2 Supplies to primary care

An initial stock level was established based on the activity levels of individual sample takers. However, the service experienced a major problem in meeting the supply demands of sample takers during the implementation phase. This was due to unexpected and inconsistent ordering patterns from primary care in establishing their working stock levels. LBC consumables have a specified shelf life, which can lead to out-of-date wastage. Despite instructions in training to manage stock levels to avoid wastage, there were a number of occasions where the stock levels held by WHS were not sufficient to meet the initial peak in

demand from Primary Care caused by overstocking. Consequently additional supplies were ordered from Medical Solutions plc.

In response to the over ordering of supplies by the primary care sector experienced in the roll-out process, which lead to stock shortages, supply control procedures were introduced to reduce over stocking and consumables wastage which is an inevitable consequence of over ordering.

A formal arrangement is now in place with WHS to manage the delivery of consumables to primary care and colposcopy units, controlled by the LBC Co-ordinator.

3.7.3 Supplies to laboratories

CSW arranges the direct delivery of laboratory consumables from the supplier to the laboratory.

During the roll-out phase a standing order arrangement using WHS was implemented for laboratory consumables. This was not effective in practice, due to variations in workflow patterns. Laboratory supply arrangements have consequently been returned to a demand-led requisition process.

Laboratories requisition supplies through the LBC co-ordinator, who then arranges the supply from Medical Solutions plc warehousing, direct to laboratories. The control of stocks is particularly important for laboratory supplies as these are high value consumables, which have a shorter shelf life than sample taker consumables. This system of direct management of laboratory supplies enables both CSW and Medical Solutions plc to avoid holding large stocks, which improves efficiency and the cost effective use of resources.

Consumables ordering and supply is centrally controlled by CSW through the dedicated LBC Co-ordinator. The monitoring of the efficient usage of consumables is a key post implementation function.

4. Implementation Report

Data on the progress and performance of cervical screening are routinely extracted from a number of sources and held centrally by CSW to provide routine performance reports for the service. These data were used in the assessment and analysis of the LBC implementation.

4.1 Effect of LBC technology on laboratory throughput

An analysis of laboratory throughput and productivity was undertaken based upon all samples authorised. All LBC samples (including vaginal/vault samples) were included in the analysis.

Data held on the CSW server was verified with all Welsh laboratory information systems to confirm that the data extracts were complete and accurate. Samples that were unlabelled, lost or broken in transit and not reported were excluded from the results. Samples reported at English laboratories were excluded from this analysis, as we do not have complete data from these laboratories.

4.2 Introduction of LBC technology to laboratories

Four Welsh laboratories began using LBC technology in October 2001, as part of the LBC pilot project (previously reported by Cervical Screening Wales, Ref: Pilot Project Report November 2003). ThinPrep[®] technology was used during the pilot assessment and was replaced as part of the implementation process.

It must be noted that Cytoc UK Ltd acted very responsibly during the cross-over process, agreeing to temporary extension of equipment leasing contracts and providing continuing product support, enabling a smooth transition for the pilot laboratories and sample takers in those areas.

Laboratories began reporting SurePath[™] LBC samples between February 2004 and November 2005. The analysis of data was concentrated on the time period from six months before the first reported SurePath[™] LBC sample to December 2006. The data is presented in three and six month periods running from October 2003 – June 2007 for comparison with published KC statistics.

Table A.1.1 gives the date when each laboratory began reporting LBC samples as part of the pilot (using ThinPrep[®]) or as part of the full roll-out (using SurePath[™]). Note that three of the four laboratories involved in the pilot project did not convert 100% of their workload to LBC at that time.

The data presented is for all LBC samples and includes the ThinPrep[®] LBC samples still being reported by the four laboratories that were predominantly converted during the pilot project.

4.2.1 Laboratory workload and use of LBC

The number of LBC samples authorised by each laboratory increased during 2005 as more sample takers and laboratory staff were trained, (table A.1.2 shows samples from all sources and table A.1.4 shows GP and NHS community clinic sources). By mid 2006, very few conventional samples were being received at any Welsh laboratory.

4.2.2 Comparison of workload before and during conversion to SurePath™

Comparison of the total number of tests reported by the laboratories during the conversion to SurePath™ LBC showed that the overall number of samples reported by the laboratories for the six month period April 2004 to September 2004, were comparable to the previous six months. (Table A.1.3 shows samples from all sources and table A.1.5 shows GP and NHS community clinic sources).

The numbers were slightly lower during October 2004 to March 2005 when the majority of laboratories were receiving their SurePath™ LBC training and LBC samples began to be reported.

4.2.3 Cytology turnaround times

After a sample is collected, it is expected that it will arrive in the screening laboratory within 7 days of collection, processed within 7 days and reported on within 14 days. The CSW standard requires that:

80% of women receive their results within 4 weeks and that 100% of women receive their results within 6 weeks from the date that the sample was taken.

Turnaround times:

The time taken from receipt of a sample to the date that the report was authorised, are monitored on a monthly basis for all Welsh laboratories.

These are grouped into periods of samples being reported:

- within 4 weeks
- between 4 and 6 weeks
- those taking more than six weeks to be reported

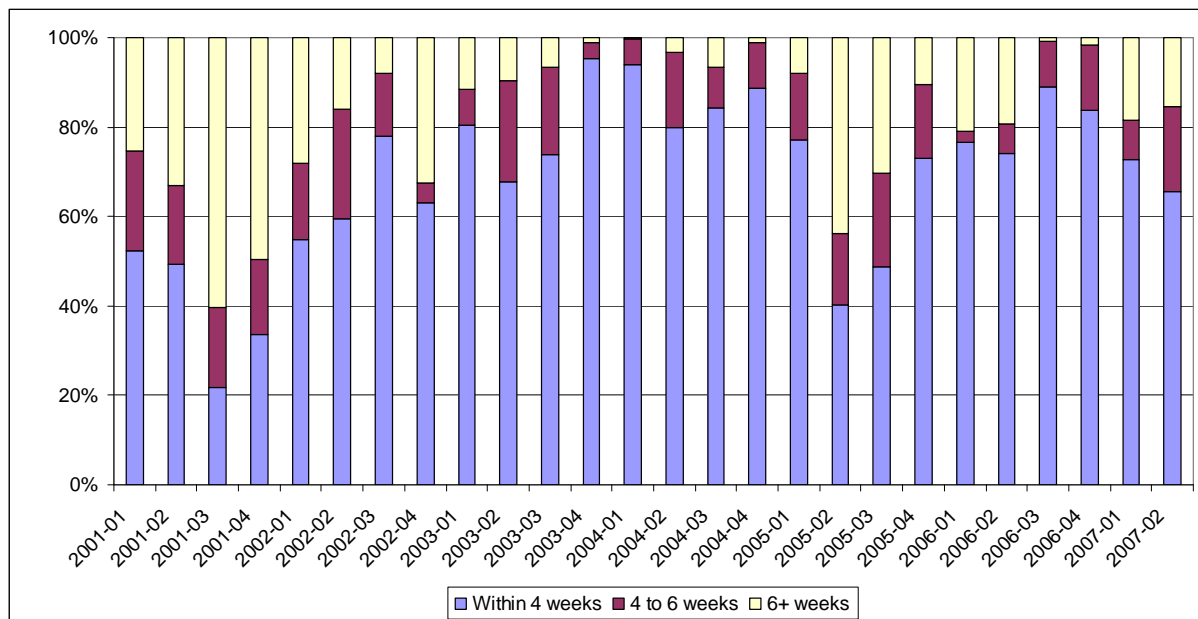
It was anticipated that the change in technology to LBC, although beneficial in the longer term, would have a short-term effect of extending laboratory turnaround times.

Figure 2 shows the proportion of samples that were authorised (date reported by laboratory) within four and six weeks from the date of receipt in the laboratory, six months before the LBC pilot started in August 2001 until June 2007.

The increased turnaround times from autumn 2004 reflects the time period when many laboratories began training or reporting LBC samples. By Oct 2005, the proportions of samples reported within four and six weeks of receipt at laboratory have increased again, indicating an improved turnaround time.

It may be observed that recent figures (2007-01, 2007-02) have shown a downturn in turnaround times; this is not attributed to difficulties with the LBC technology. A number of laboratories have experienced staffing difficulties in this period which are due to extended sickness absences, maternity leave, and the failure of Trusts to fill staff vacancies. CSW has taken action to assist laboratories to restore their performance to 'within standard'.

Figure 2: Cytology turnaround times for Welsh Laboratories; within 4 weeks - 4 to 6 weeks - and more than 6 weeks



4.2.4 Laboratory reporting rates

Laboratories assess sample adequacy according to agreed criteria. If the sample is inadequate a further sample is requested. For all adequate samples, the sample result is graded as negative or abnormal, using the standard national codes.

The laboratory reporting rates are the test results expressed as a proportion of all samples which were accepted as being satisfactory for screening. These rates were monitored before, during and after conversion to SurePath™ LBC. Note that four laboratories were already reporting LBC samples.

A reduction in the inadequate sample rate was an anticipated benefit of the new technology.

4.3 Effect on test results

4.3.1 Inadequate sample rates

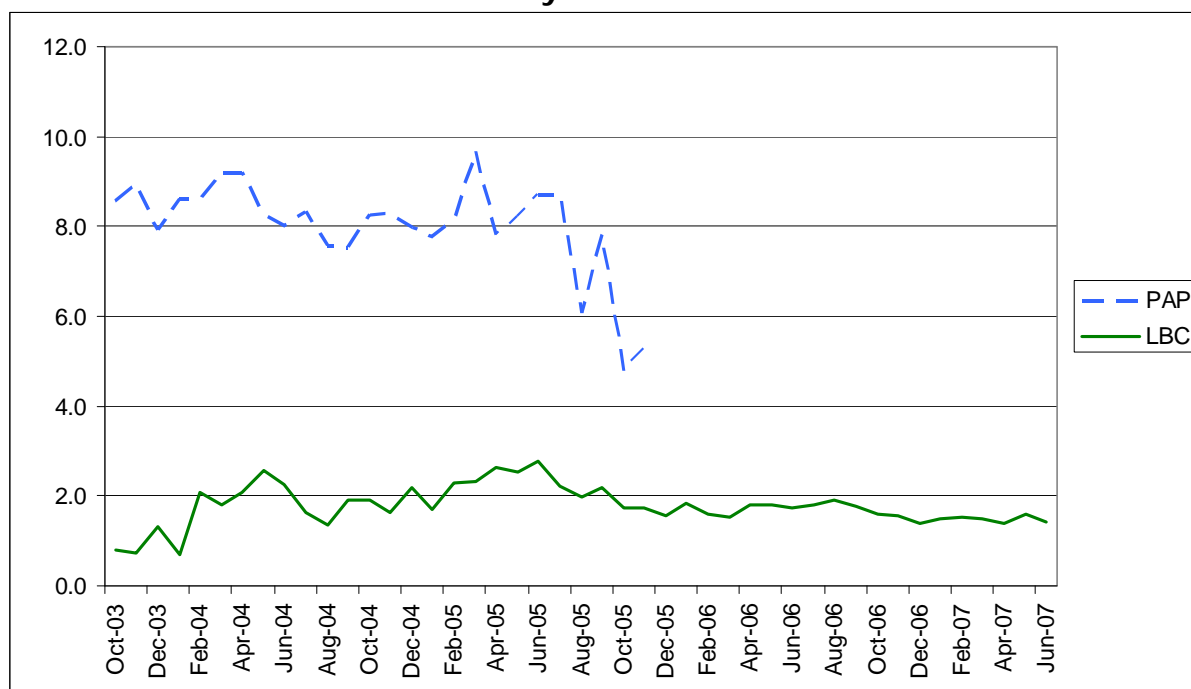
Table A.1.6 shows the inadequate sample rates by month for conventional and LBC screening tests received from GP and NHS community clinic sources from October 2003 to June 2007 inclusive.

The overall inadequate rate (for conventional samples and LBC) fell from around 6% to under 2% as LBC was introduced to all services in Wales. This is a statistically significant reduction. The inadequate rate has remained below 2% for the past 21 months.

4.3.2 Comparison of conventional and LBC inadequate rates

Inadequate rates in conventional samples received from GP and NHS community clinics (NHSCC), did not appear to reduce substantially as LBC training was rolled out, reducing from 8.2% in April 2004 – March 2005 to 7.9% and in April 2005 – March 2006 (table A.1.6). This reduction is not statistically significant. Figure 3 shows the comparative figures by month. The drop seen in the conventional inadequate rate after August 2005 is due to the small number of conventional samples being reported.

Figure 3: Inadequate rates for conventional and LBC samples, GP and NHS community clinic sources



4.3.3 Inadequate rates by age

Comparison of the inadequate rates from screening tests received from GP and NHS community clinic sources, by age group, over the year before and during conversion to LBC (table A.1.7) show that the biggest decrease in inadequate rates was seen in the 20-39 year age groups.

4.3.4 Inadequate rates before and after LBC training

When LBC training was first introduced in 2000 as the LBC pilot project began, a comprehensive programme of sample taker training courses was conducted across Wales for all sample takers. At that time a significant reduction was noted in the inadequate rate in conventional samples being reported by sample takers who had received the LBC update training course. Although a significant reduction in the inadequate rate was not seen during the roll-out of the sample taker training prior to the implementation of LBC across Wales in 2005, most sample takers would have already benefited from the training set up in 2000.

Every sample taker involved with cervical screening in Wales has been issued with a unique personal identity code by CSW. This is stored, confidentially, on a central database which details their place of work and training status, including update courses undertaken and LBC conversion. The Welsh pathology systems and the NHAIS administration system (*Exeter*) also capture the ID code for every cytology test and result entered.

It was, therefore, possible to compare inadequate rates before and after LBC training for each individual sample taker. Some sample takers continued to use the conventional method as well as LBC after their training as they worked in two different locations.

Around 3,600 sample takers are recorded on the database as having received training in LBC over the past five years. Some of them, however, are not currently active in taking LBC samples; around 3,400 sample takers have taken an LBC sample, at some time, which was sent to a Welsh laboratory for screening. Comparison of the inadequate rates during the year before and year after the sample takers first recorded LBC training date, shows a slight increase in the inadequate rate for conventional samples from 7.8% to 8.2%, but this is not statistically significant.

The inadequate rate for LBC and conventional samples combined, fell from 4.0% during the year before sample takers were LBC trained to 2.3% the following year, this is statistically significant. This significant reduction reflects the increase in the number of LBC samples taken after training that have a lower inadequate rate.

4.3.5 Effect on adequate rates

Tables A.1.8a and A.1.8b show the overall Welsh reporting rates (numbers and percentages) for all adequate samples from all sources, by quarter, since April 2000. The adequate result rates for LBC and conventional samples are shown combined as well as 'LBC samples only' for comparison. Note that the high reporting rates for LBC samples only, shown in 2000-2001, are due to the small numbers of LBC samples reported whilst LBC technology was first being introduced during the pilot project.

Tables A.1.9a and A.1.9b show the similar Welsh reporting rates (numbers and percentages) for all adequate samples from GP and NHS community clinic sources only, by quarter, since April 2000.

It should also be noted that samples taken in hospital in gynaecology and colposcopy departments were the first to be converted to LBC; as these women have been referred in due to abnormal screening cytology, these by nature, have a higher proportion of abnormal results.

4.3.6 Rates of low-grade disease

The rates of low-grade disease, from April 2000 were compared for all samples and LBC samples only from all sources (tables A.1.8a and A.1.8b) and from GP and NHS community clinic sources (tables A.1.9a and A.1.9b).

Figure 4 shows the comparative low-grade rates for all samples and figure 5 for LBC samples only.

Figure 4: Percentage of low-grade samples reported - all samples

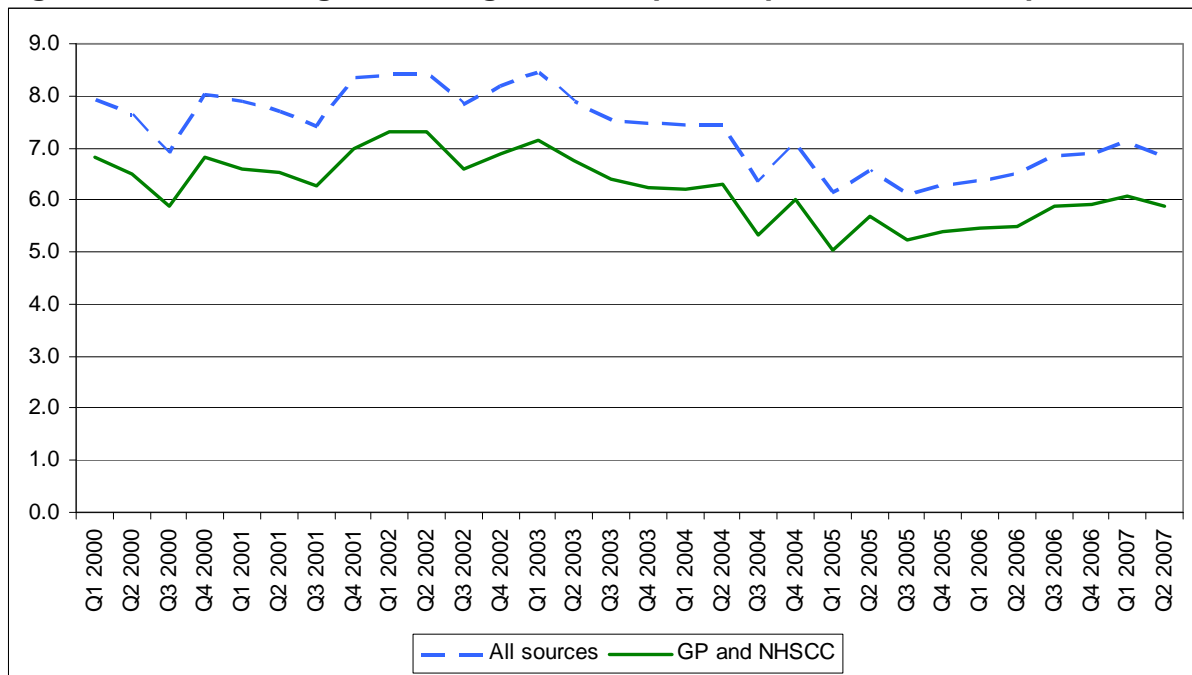
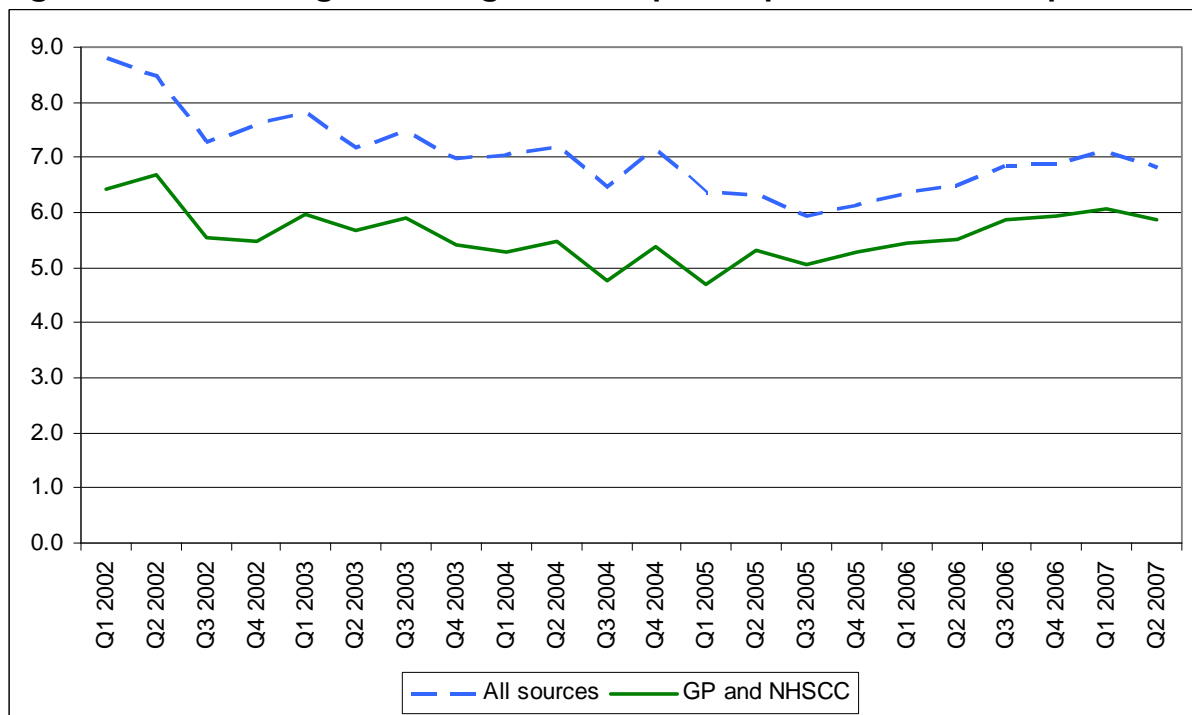


Figure 5: Percentage of low-grade samples reported - LBC samples



Trends were analysed for overall low-grade reporting rates for all samples reported from April 2000 to June 2007. Figure 6 shows the trend of all samples from all sources; figure 7 shows the trend of all samples from GP and NHS community clinic sources only.

The slope of the fitted regression line shows a statistically significant decrease on both graphs.

Figure 6: Percentage of low-grade samples reported - all samples, all sources

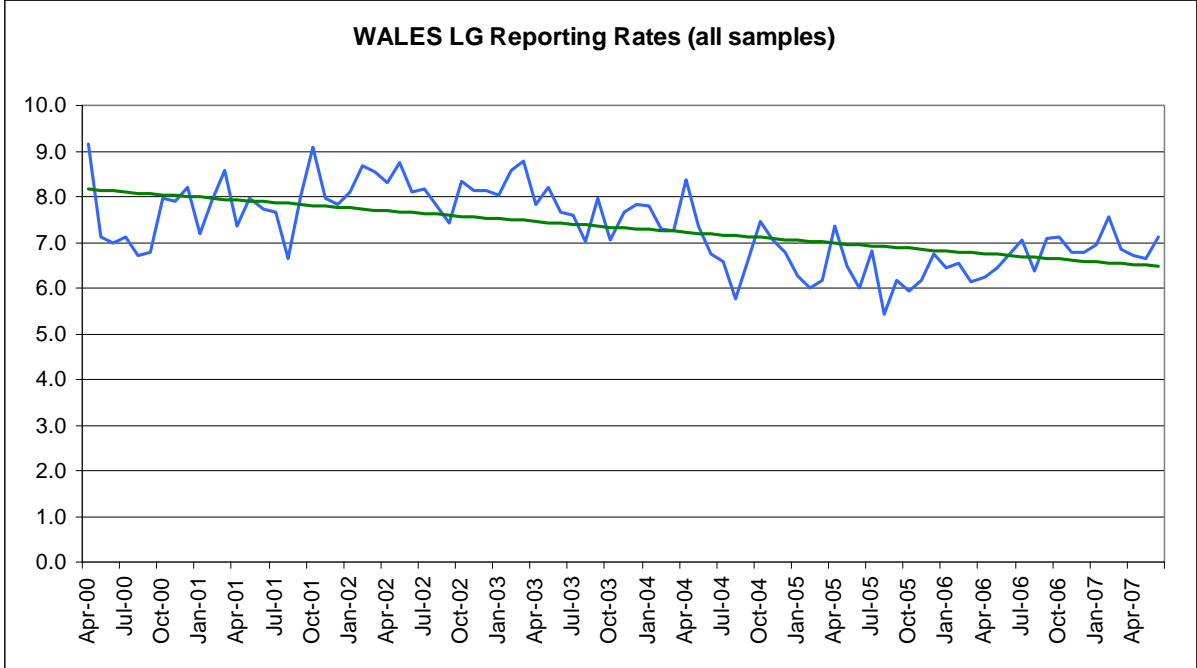
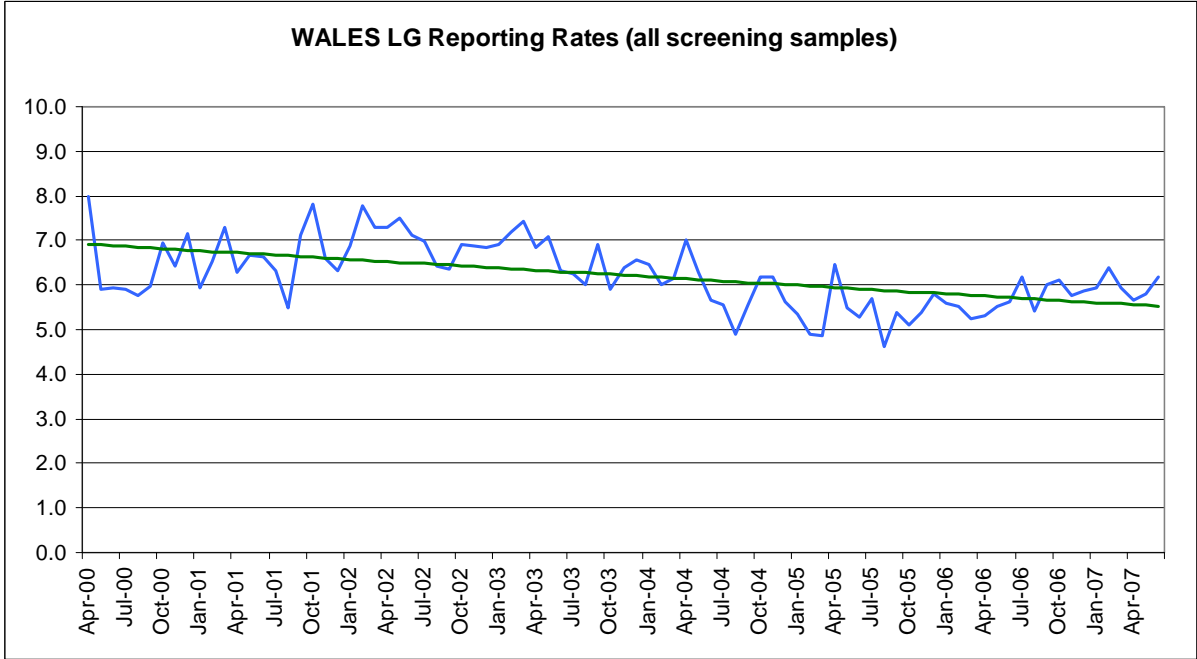


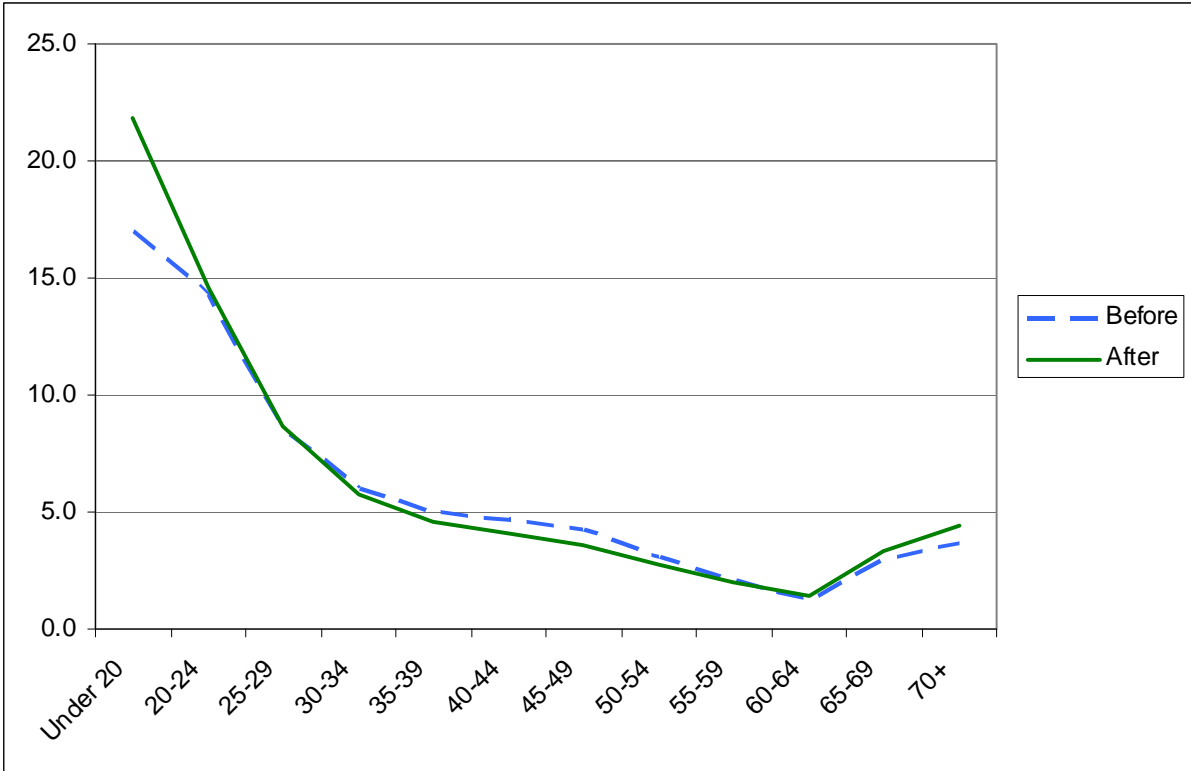
Figure 7: Percentage of low-grade samples reported - all samples, GP and NHS community clinic sources



A Comparison of the low-grade reporting rates by age group, before and after the implementation of SurePath™ LBC was made (table A.1.10a and figure 8). April 2004 to March 2005 was defined as the year before SurePath™ LBC began to be reported, April 2005 to March 2006 was taken to be the year after SurePath™ LBC was introduced.

There was a significant difference in the overall low-grade reporting rates and also in the age groups 40-44 years and 45-49 years.

Figure 8: Percentage of low-grade samples reported by age group, GP and NHS community clinic sources



4.3.7 Rates of high-grade disease

The rates of high-grade disease, from April 2000 were compared for all samples and LBC samples only from all sources (tables A.1.8a and A.1.8b) and from GP and NHS community clinic sources (NHSCC) (tables A.1.9a and A.1.9b).

Figure 9 shows the comparative high-grade rates for all samples and figure 10 for LBC samples only.

Figure 9: Percentage of high-grade samples reported – all samples

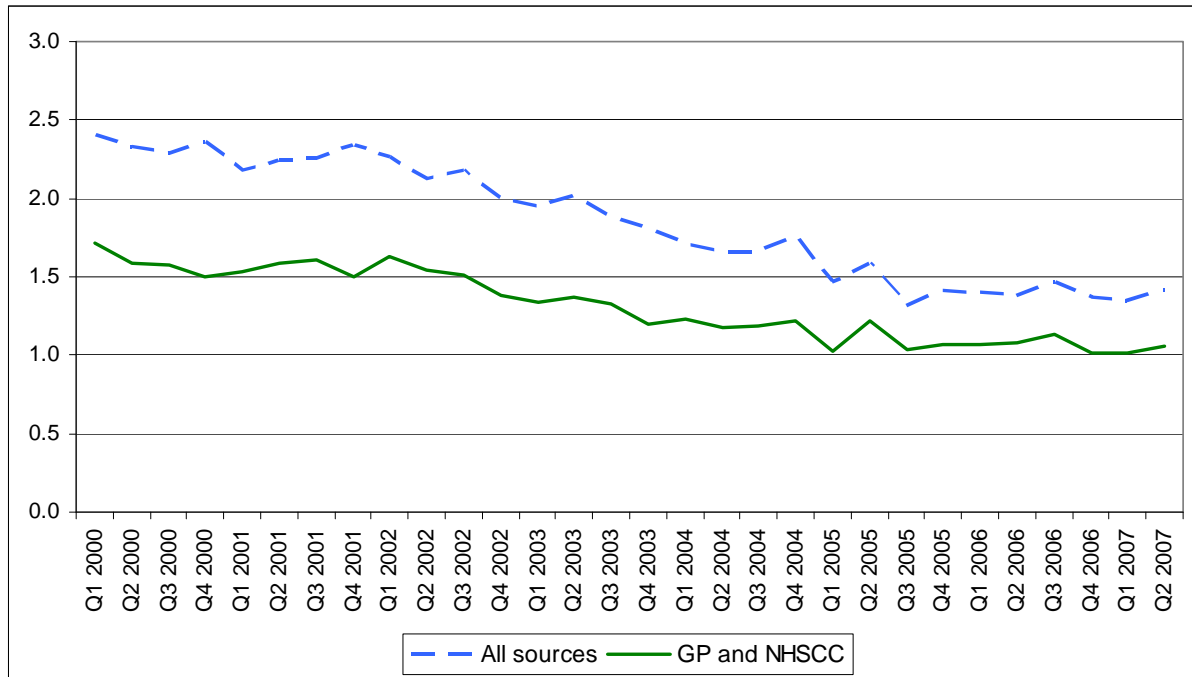
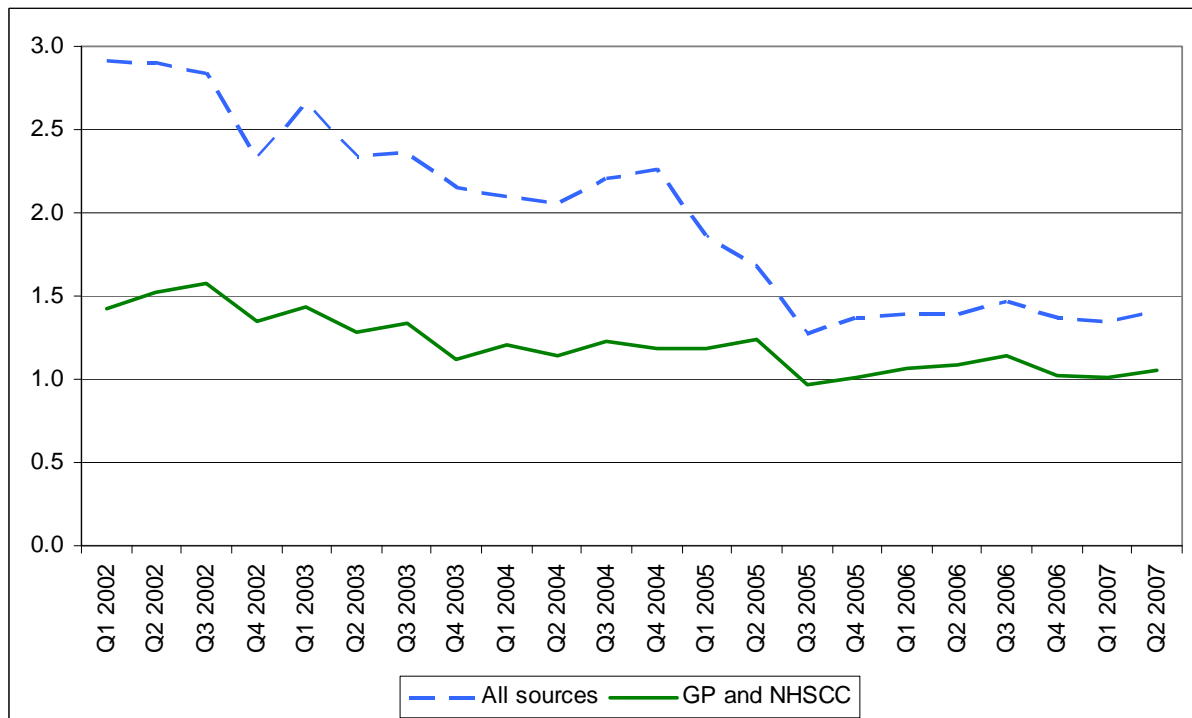


Figure 10: Percentage of high-grade samples reported – LBC samples



In January 2005 CSW confirmed a change in screening policy (Ref: CSW Colposcopy Quality Manual SOP C.90.5) to recommend that a repeat cytology sample need not be taken at a first colposcopy visit, following the completion of evidence based research, published later in 2006 (Ref: Rieck et al, 2006).

Trends were analysed for overall high-grade reporting rates for all samples reported from April 2000 to June 2007. Figure 11 shows the trend of all samples

from all sources; figure 12 the trend of all samples from GP and NHS community clinic sources only.

The slope of the fitted regression line shows a statistically significant decrease on both graphs.

Figure 11: Percentage of high-grade samples reported - all samples, all sources

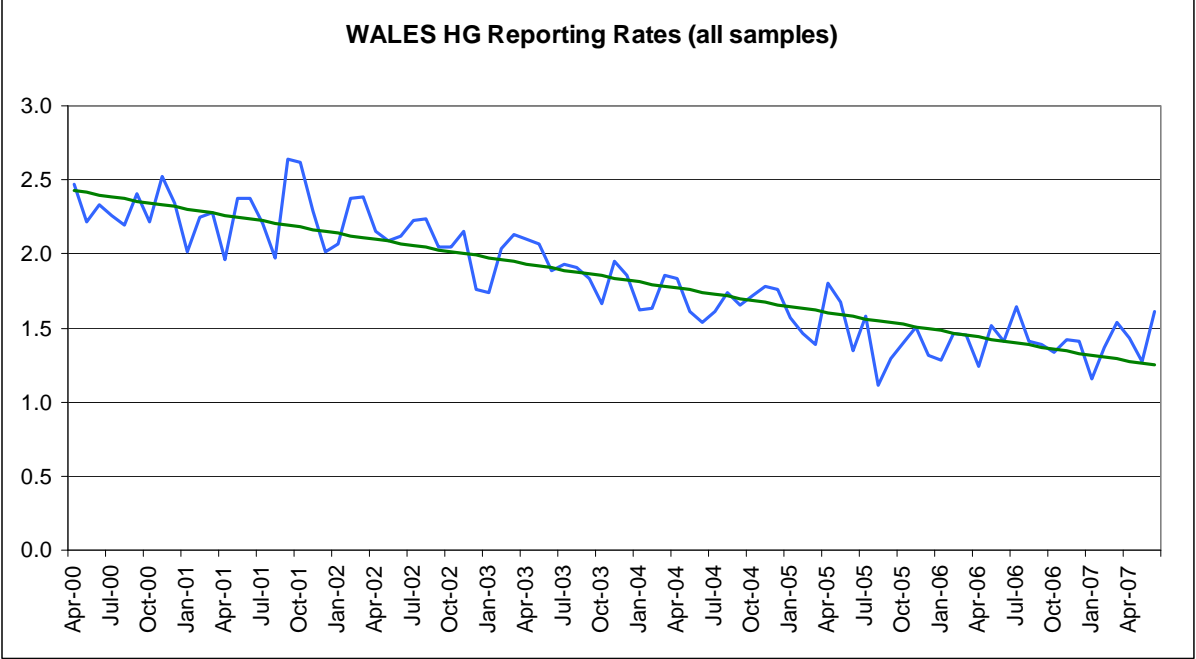
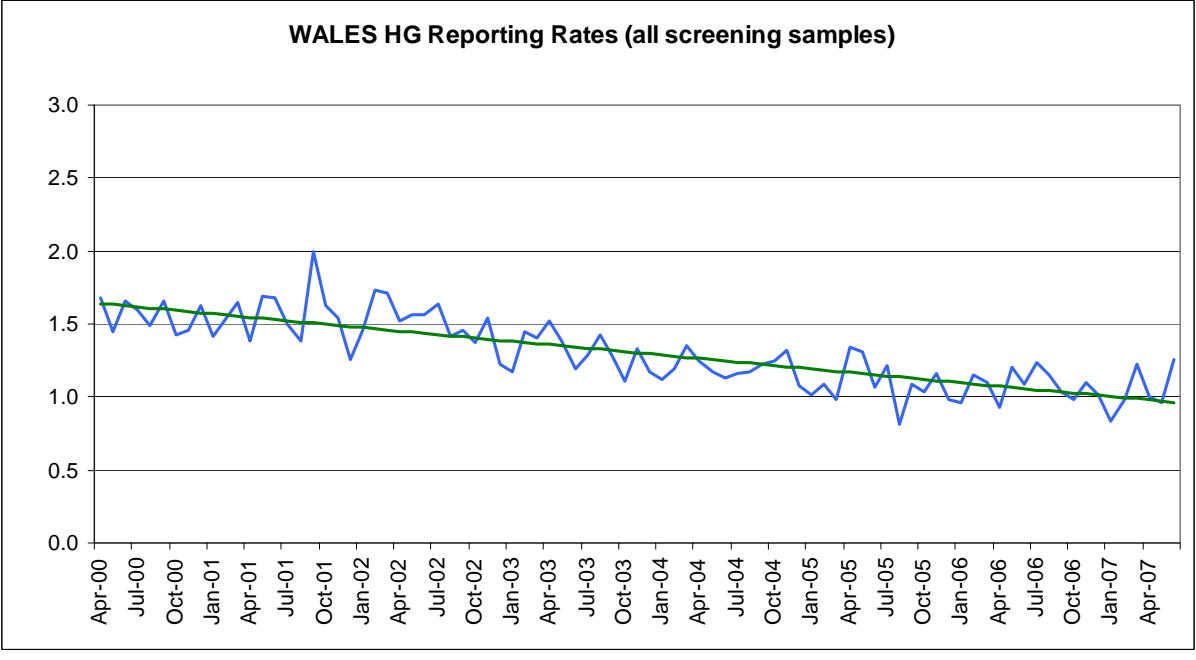


Figure 12: Percentage of high-grade samples reported - all samples, GP and NHS community clinic sources



A Comparison of the high-grade reporting rates by age group, before and after the implementation of SurePath™ LBC was made (table A.1.10b and figure 13).

April 2004 to March 2005 was defined as the year before SurePath™ LBC began to be reported, April 2005 to March 2006 was taken to be the year after SurePath™ LBC was introduced.

There was no significant difference in the overall high-grade reporting rate, but there was a significant difference found in the age group 50-54 years.

Figure 13: Percentage of high-grade samples reported by age group, GP and NHS community clinic sources

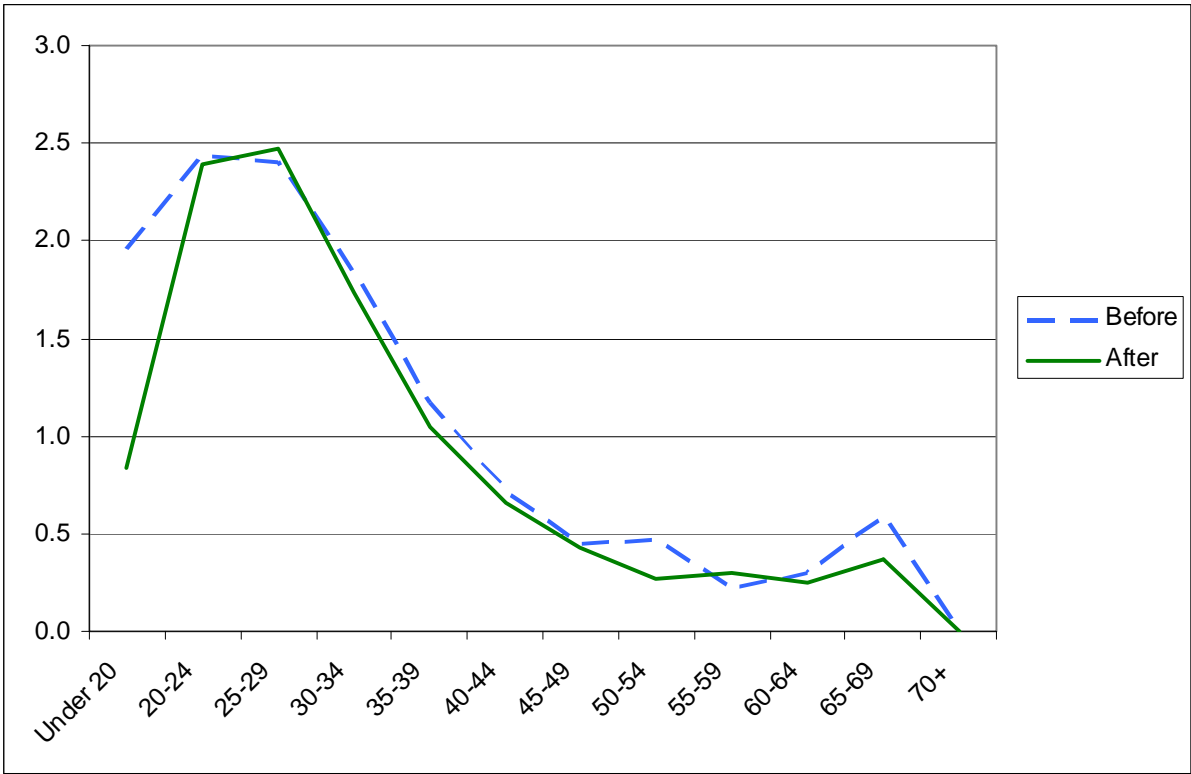
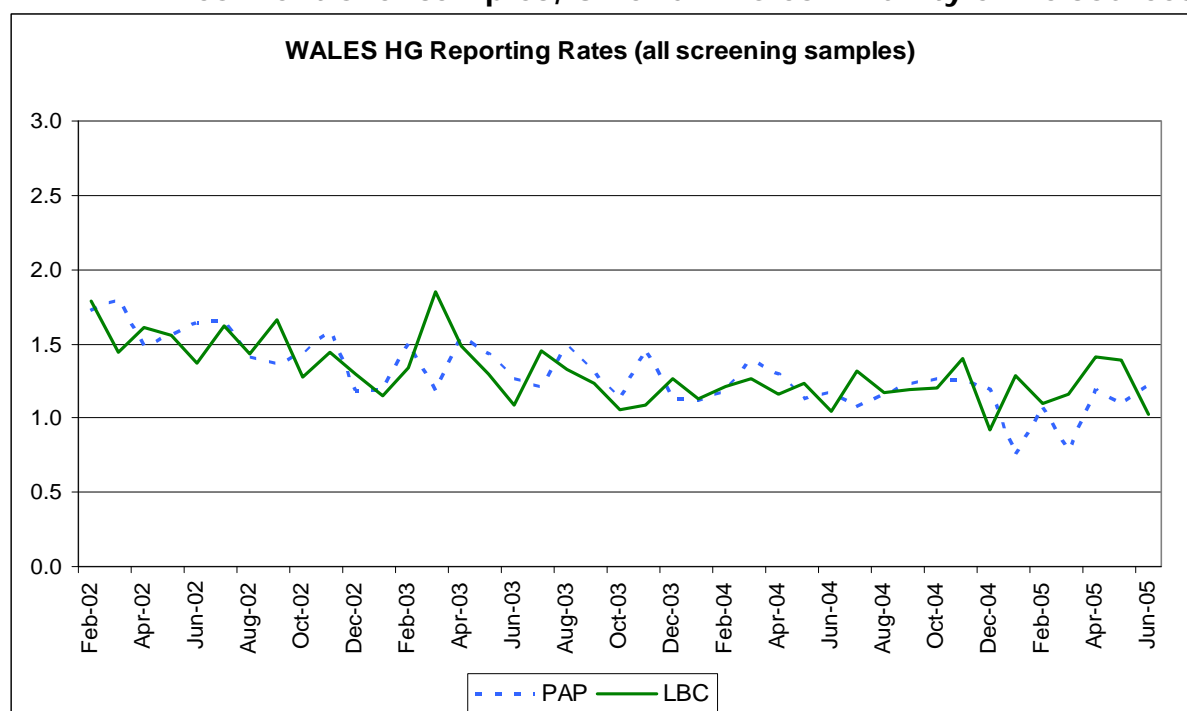


Figure 14 shows the high-grade reporting rates plotted for LBC samples alongside conventional cytology samples from GP and NHS community clinic sources up to July 2005, after which time the small number of conventional cytology samples reported by laboratories caused erratic reporting rates.

The decreasing reporting rates were similar for both sample types. Analysis of both low-grade and high-grade reporting rates (figures 6, 7, 11 and 12) show that the decline is present for conventional cytology (Pap) samples and figures have been steadily decreasing over the past seven years, long before LBC was introduced in Wales.

Figure 14: Comparison of high-grade reporting rates for LBC and conventional samples, GP and NHS community clinic sources



4.3.8 Positive predictive values

The positive predictive values (PPV: see Glossary for definition) for all high-grade referral results over the past seven years, were summarised for all Welsh laboratories, (table A.1.11), as published in the CSW annual KC statistical publication. The summary for Wales is shown below in Table 1.

Table 1: Positive Predictive Values for Wales by year

	2000/01	2001/02	2002/03	2003/04	2004/05	2005/06	2006/07
WALES	76%	72%	72%	76%	78%	79%	83%

Note that for 2000/01 and 2001/02, figures were based upon referrals made during the first three months of that year, i.e. April to June 2000 and April to June 2001 respectively. From 2002/03 onwards, figures were based upon referrals made during the previous twelve months, i.e. the figures from the 2005/06 report show the referrals made during April 2004 to March 2005, which were made before SurePath™ LBC was fully implemented across Wales.

4.3.9 Sensitivity of primary screener

The effect of the introduction of LBC technology on primary screening at all Welsh laboratories was investigated by looking at primary screening sensitivities and false negative cytology rates for LBC and conventional samples separately. Data for April 2004 – March 2005 is shown in tables A.1.12a and A.1.12b, the data for April 2005 – March 2006 is shown in tables A.1.13a and A.1.13b.

These figures should be treated with caution as they are for all samples from all sources and it should be noted, therefore, that there might be an effect of population and clinical case mix. Figures include different proportions of women by age group, deprivation and previous cytology results.

In 2004-05, sensitivity and specificity for LBC and conventional cytology were similar. In 2005-06 the sensitivity and specificity for LBC samples was maintained. This level of reporting of primary screener sensitivity and specificity has continued in 2006-07.

The difference in the sensitivity rates of 92.9% for screeners reporting LBC samples compared to 90.3% for screeners reporting conventional samples during 2005-06, was significant.

4.3.10 Referrals to colposcopy

Referrals to colposcopy in Wales are mainly from two sources: direct referrals by CSW when indicated by abnormal cytology and referrals from primary care when an abnormality of the cervix may be suspected following clinical examination.

Baseline rates of referral to colposcopy from 1st April 2001 were derived from the CSW Safety-Net system located in the CSADs and were verified against the colposcopy database (ISCO-CIS). Data was analysed for the five CSAD areas in Wales, by month of referral to colposcopy and referral test result, split into low-grade and high-grade referrals. Figures 15 and 16 show the number of low-grade and high-grade colposcopy referrals respectively, for Wales since April 2001.

It should be noted that some women may have more than one referral to colposcopy, where they may prefer to attend a different clinic a second referral is made. As this is a small number of additional referrals it does not affect the trends seen in Figures 15 and 16.

The downward trends in both the low-grade and high-grade referrals to colposcopy are statistically significant.

Figure 15: Low-grade direct referrals to colposcopy

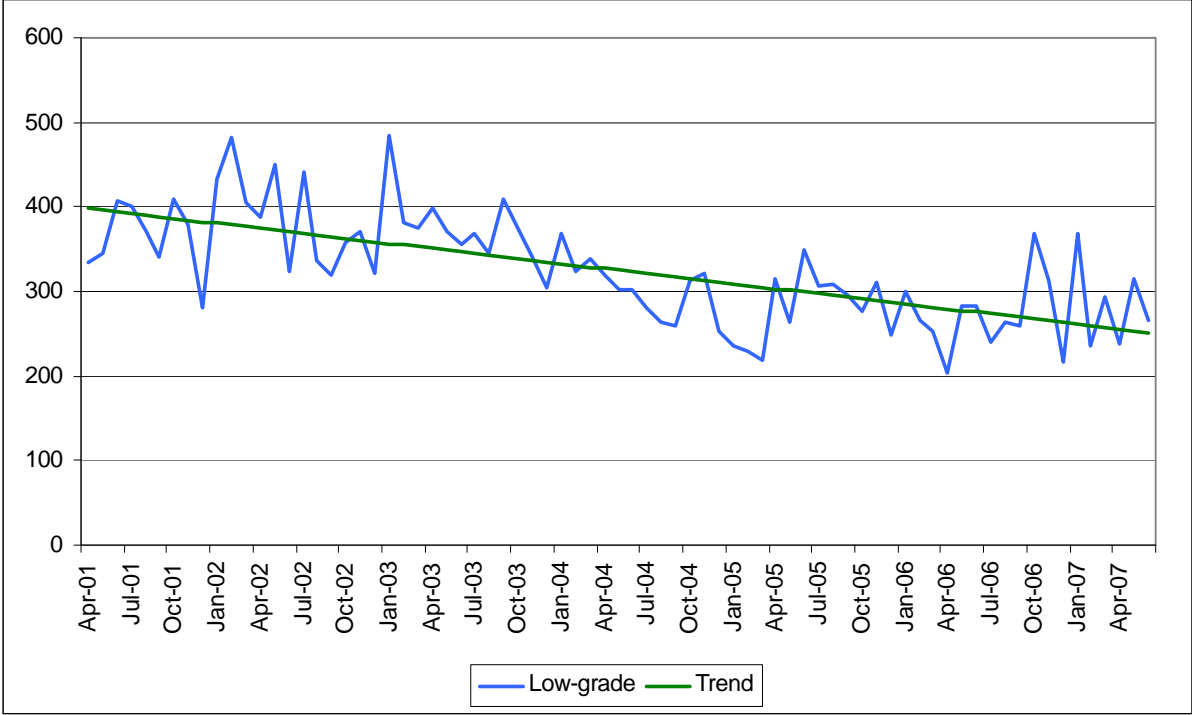
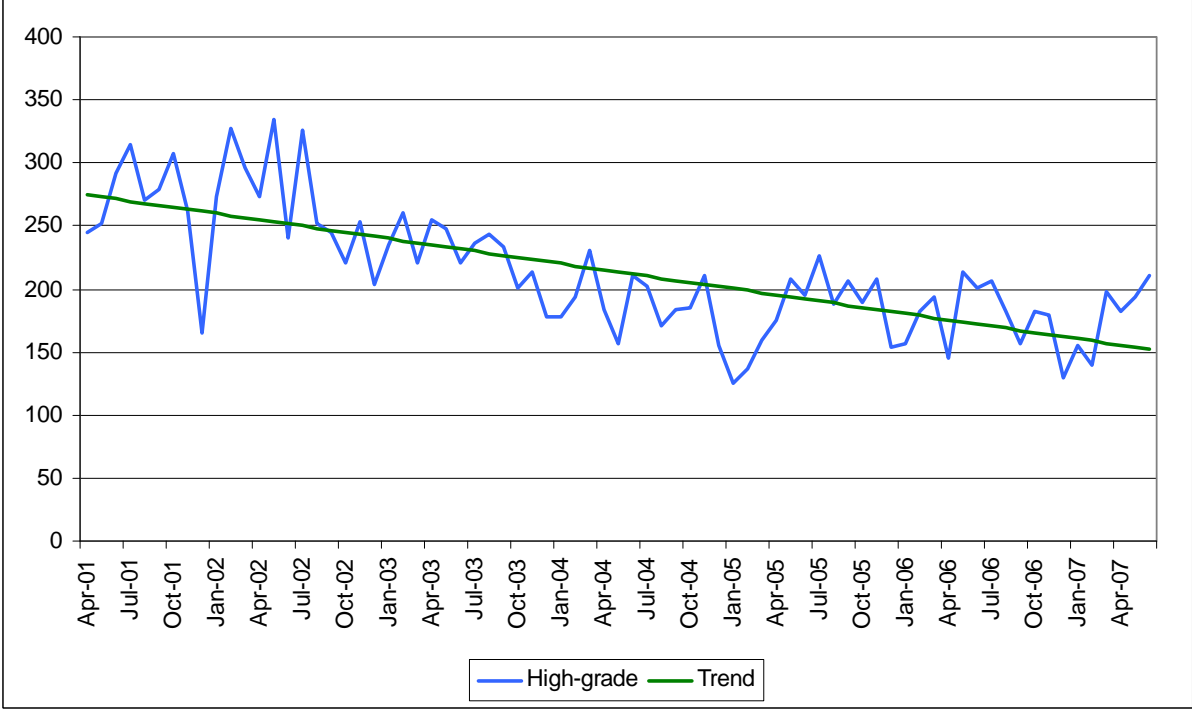


Figure 16: High-grade direct referrals to colposcopy



5. Implementation and Service Costs

The direct costs of converting the cervical screening programme in Wales to Liquid Based Cytology and rolling out the technology were £210,500 broken down as:

Capital Investment:

- Teaching equipment and multi-headed microscopes £ 30,000
- Reporting software and printers £ 49,000
- Automated Coverslippers £100,000

Non-recurring revenue:

- Consultant Training £ 24,000
- Hire of venues £ 5,200
- Travel and subsistence £ 2,300

The major costs were the purchase of consumables to support the new technology, which amounted to £620,000 in part implementation year 2004, and has recurring implications.

These costs do not include CSW and other NHS staff time, which was a major factor in achieving the implementation efficiently, without major disruption to the screening programme and without compromising other essential and routine functions.

5.1 Finance and costing

Cervical screening funding is directed through CSW. Additional funding for the roll-out, approved by the National Assembly for Wales, was provided to CSW, through Health Commission Wales (HCW), to support the implementation process. This funding supports the initial equipment costs, and ongoing additional consumables costs for primary care and laboratories.

Despite the recommendations of the NICE assessment, it was clear that additional resources were required to support the roll-out, these costs were borne from the annual running costs of the first year.

No additional funding was made available for these resource implications which included all management costs for the roll-out. All project management and other resource costs critical to the success of LBC implementation were absorbed by CSW.

Costs were arranged within the £1.168m annual running cost figure to address:

- conversion processes, including all training
- provision of equipment
- ongoing support and running costs
- supply of sample taking and laboratory consumables

The initial overall additional funding of £1.168m has been uplifted annually.

The additional funding provided for LBC is 'ring fenced' in common with the principle laid down in the National Service Framework for the Cervical Screening Programme in Wales.

LBC funding arrangements have subsequently been integrated into the general funding agreements with Trusts. Trusts were, however, expected to identify the recoverable costs associated with conventional sample taking and processing to offset the increased costs of LBC. This was accounted for by CSW in its cost estimates prepared for and agreed with HCW as part of the total funding agreement.

The following table (table 2) shows the offsetting of these additional manpower costs through CSW recovering efficiency gains from provider laboratories.

Table 2: Consumables Offset costs

TRUST	PROCESSING SUPPORT (first full year cost active from 2006/07)	CONSUMABLES RECHARGE (Active from 2006/07)
	£	£
Gwent Healthcare NHS Trust	20,365	17,658
Cardiff & Vale NHS Trust	20,365	16,410
North Glamorgan NHS Trust	7,332	4,732
Pontypridd & Rhondda NHS Trust	7,332	10,307
Bro Morgannwg NHS Trust	7,332	5,312
Swansea NHS Trust	7,332	12,574
Carmarthenshire NHS Trust	7,332	9,851
Pembrokeshire & Derwen NHS Trust	7,332	4,360
North West Wales NHS Trust	7,332	8,248
Conwy & Denbighshire NHS Trust	7,332	7,738
North East Wales NHS Trust	7,332	6,815
Total all-Wales figure	£106,718	£104,005

6. Observations and Conclusions

The formal roll-out of LBC to the cytology service in Wales required a successful procurement, an organised implementation plan, comprehensive conversion training of sample takers and laboratory personnel, the implementation of a support infrastructure and a co-operative working arrangement with all service professionals.

6.1 Summary of the implementation activities

The rapid conversion of Wales to LBC technology over a twelve month period within the allocated budget, which involved a diverse geographical area, a large number of sample takers and many different locations, integrated with an intensive programme of laboratory personnel training, is a major achievement. Although the roll-out process was completed within twelve months, the final conversion of the few remaining untrained personnel took a further six months; this did not affect the conclusion of implementation as all areas had adopted LBC within twelve months.

The rapid and efficient conversion to the new technology is a credit to the efforts of all CSW staff and supporting Trusts as well as the efficient response and support by Medical Solutions plc to installation and training requests.

6.2 Key achievements

It was expected from previous research findings and from the LBC pilot assessment project that certain outcomes would improve with the introduction of the new LBC technology. These achievements include:

6.2.1 Reduction in the inadequate samples rate

An inadequate test is reported when the cytology laboratory is not able to screen a cervical sample and issue a result. This could be for technical reasons such as too few cells on the slide or problems in the collection and preservation of the cell sample on the slide, or for clinical reasons such as inflammatory cells obscuring the cervical cells, preventing full examination of the sample.

Previously, using conventional cytology collection methods, if a sample could not be screened, the woman would require an early recall for a repeat sample to be collected. With LBC, if a slide cannot be screened further slides can be prepared from the residual sample of cellular material; in some instances this may eliminate the need to take another sample from the woman.

This technological improvement removes additional anxiety for the woman, decreases the workload for the sample takers and laboratories by reducing repeat tests, and decreases the time that the woman has to wait for her result.

6.2.2 Primary screening sensitivity

The primary screening sensitivity is the measure of the accuracy of the primary screener's opinion compared to the final reported test result. Analysis of the figures for 2004-05 shows that sensitivity and specificity for LBC and conventional cytology were similar. In 2005-06 the sensitivity and specificity was maintained for LBC samples. Figures for 2006-07 show that this level of performance has continued.

For the year April 2004 to March 2005, the sensitivities for LBC and conventional samples were similar (93.2% and 93.0% respectively).

In the following year April 2005 to March 2006 the sensitivity rate for screeners reporting LBC samples remained at 92.9%, but the sensitivity for conventional samples dropped to 90.3%.

6.2.3 Improvement in screening specificity

Improved PPVs have been observed for all laboratories, this is particularly notable in the latest screening figures for 2006-2007.

Improvements in the PPV indicate that fewer women are unnecessarily being referred to colposcopy, with the confirmation of more abnormalities and reductions in the number of women 'over-treated' in relation to unnecessary referrals and follow-up.

6.2.4 Improvements in outcome

The overall number of cytology samples taken has decreased, resulting in a reduction in the number of colposcopy referrals.

Sensitivity and specificity have been maintained.

The Positive Predictive Value of the cytology results has improved.

6.2.5 Overall service efficiency gains

Laboratory efficiency has been improved by the introduction of Liquid Based Cytology.

The change of technology has seen a reduction in the number of samples being processed by the laboratory, resulting in a reduced turnaround time for laboratories in issuing a result.

Also, LBC samples may be screened more quickly than conventional samples as there is a reduced sample area to examine and cells are presented as a thin layer. This has enabled laboratories to reduce the pressure on screening staff

and further resulted in a significant improvement in turnaround times. These factors also enable improvements to be introduced in Internal Quality Control procedures.

CSW remains committed to the principle of the maintenance of locally based screening and reporting functions within the screening programme in Wales, enabling local clinical access to pathology results and input to multi disciplinary team (MDT) or Clinico-Pathological Conference (CPC). The implementation of LBC has taken place at a time when MDT reviews were being recommended for difficult cases. The efficiency gains should enable pathology and colposcopy staff to take advantage of resource gains, undertaking MDT reviews without the need for additional resourcing. It is also anticipated that efficiency gains will support the development of the CSW audit of cervical cancers (CSWACC) which began in 2006 and will be further developed and fully implemented in 2007.

6.3 Service developments

The successful completion of the implementation of LBC provides opportunities for the consideration of further service developments based on LBC technology.

6.3.1 Computer Assisted Screening

The implementation of LBC provides a basis for continued development within the screening service. The option to assess Computer Assisted Screening (CAS) technology was included in the contracting process. An assessment of the BD Diagnostics, Diagnostic Systems, TriPath CAS technology – the Focal Point / Location Guided Screening device is currently underway and will be reported separately.

6.3.2 Reflex testing

The capacity for reflex or auxiliary testing of residual samples is also under assessment; this could also affect cytology reporting processes. Discussions with the supplier, Medical Solutions plc are currently underway to assess the use of 'cell markers' in the screening process. The role of HPV testing in the screening process, which is the subject of a number of major studies in the UK, will also be evaluated.

6.3.3 Developments in processing

For logistical reasons processing facilities were introduced to all laboratories as part of the implementation plan. This was the most cost effective option at the time and supported the maintenance of locally based screening and reporting functions.

Reorganisation within the health service together with proposals for the modernisation of pathology may require a re-evaluation of processing

arrangements. The need for processing on all sites will be considered, possibly in conjunction with the potential introduction and integration of CAS technology without additional reorganisation of the screening/reporting infrastructure.

6.4 Conclusions

The implementation of LBC throughout Wales has been achieved within budget to a reasonable timescale, and this evaluation has concluded that the technology is now functioning well and providing results that meet the criteria established by the National Institute for Clinical Excellence.

The technology is safely established and may provide a platform for future development within the cervical screening programme.

Glossary of Terms

CSAD	Cervical Screening Administration Department
Primary Screener Sensitivity	Number of samples where primary screener opinion is abnormal and result is abnormal, as a proportion of all abnormal results for that primary screener
Primary Screener Specificity	Number of samples where primary screener opinion is normal and result is normal, as a proportion of all normal results for that primary screener
False Negative	Number of samples where primary screener opinion is normal and result is abnormal, as a proportion of all abnormal results for that primary screener
Positive Predictive Value (PPV)	Histological confirmation of a high grade reported sample resulting in recommendation for gynaecological referral. The number of high grade referral samples with histological outcome of CIN2 or worse, as a proportion of all high grade referral samples with a known histological outcome.
HPV	Human Papilloma Virus
ISCO-CIS	Information System for Clinical Organisations – Colposcopy Information System, is the computer system used to manage colposcopy referrals, appointments and capture clinical data for all women who are seen in colposcopy
low-grade	Includes cytology results reported as borderline changes and mild dyskaryosis
high-grade	Includes cytology results reported as moderate dyskaryosis, severe dyskaryosis, ?glandular neoplasia and ?invasive carcinoma
CSW Safety-Net System	The computer system which is used to fail-safe all women who require a direct referral to colposcopy

Appendix 1: Result Tables

Table A.1.1: Commencement of LBC Reporting

Laboratory	Laboratory Name	Reporting of LBC commenced (pilot using ThinPrep®)	Reporting of LBC commenced (full roll-out using SurePath™)
BND	Princess of Wales Hospital, Bridgend	May 2002	Aug 2004
GLM	Royal Glamorgan Hospital, Llantrisant	April 2002	Aug 2004
GWY	Ysbyty Gwynedd, Bangor		March 2005
LLD	Llandough Hospital, Cardiff	Oct 2001	Sept 2004
PCH	Prince Charles Hospital, Merthyr Tydfil		Nov 2005
RGH	Royal Gwent Hospital, Newport	Dec 2000	March 2005
SIN	Singleton Hospital, Swansea		Feb 2004
WBH	Withybush Hospital, Haverfordwest		March 2005
WWG	West Wales General Hospital, Carmarthen		Nov 2004
WXH	Wrexham Maelor Hospital, Wrexham		June 2005
YGC	Ysbyty Glan Clwyd, Rhyl		Dec 2004

Table A.1.2: LBC samples authorised by each laboratory (all sources)

Laboratory	Oct 2003 – Mar 2004	Apr 2004 – Sept 2004	Oct 2004 – Mar 2005	Apr 2005 – Sept 2005	Oct 2005 – Mar 2006	Apr 2006 – Sept 2006	Oct 2006 – Mar 2007
BND	1741	1919	3356	5479	5443	5070	5116
GLM	4479	4679	6960	11801	9406	10019	10318
GWY	0	0	65	8880	7783	7359	6926
LLD	11530	11971	15969	17190	17779	16038	17361
PCH	0	0	0	0	3219	4417	3914
RGH	19082	17902	15163	18891	17019	19698	16108
SIN	153	470	1632	15116	14378	12304	15877
WBH	0	0	9	1645	5124	4389	3670
WWG	0	0	461	7463	9998	8179	8726
WXH	1	0	2	3682	7101	7901	6894
YGC	0	0	18	7638	6817	5863	6052
TOTAL	36986	36941	43635	97785	104067	101237	100962

Table A.1.3: Total samples authorised by each laboratory (all sources)

Laboratory	Oct 2003 – Mar 2004	Apr 2004 – Sept 2004	Oct 2004 – Mar 2005	Apr 2005 – Sept 2005	Oct 2005 – Mar 2006	Apr 2006 – Sept 2006	Oct 2006 – Mar 2007
BND	5150	5070	5245	5486	5452	5073	5118
GLM	9637	10255	10397	11825	9413	10021	10320
GWY	8249	8982	6692	9491	7909	7361	6976
LLD	16610	17119	17140	17200	17784	16041	17363
PCH	4606	4999	4281	5398	4516	4431	3914
RGH	19083	17906	15163	18892	17019	19698	16109
SIN	15541	13650	12095	15665	14385	12304	15877
WBH	4253	4822	3305	3839	5142	4413	3678
WWG	9480	9944	8109	11123	9999	8180	8727
WXH	6100	7433	6355	8181	7108	7913	6894
YGC	8842	7119	6717	8624	6822	5869	6053
TOTAL	107551	107299	95499	115724	105549	101304	101029

Table A.1.4: LBC samples authorised by each laboratory (GP and NHS community clinic samples)

Laboratory	Oct 2003 – Mar 2004	Apr 2004 – Sept 2004	Oct 2004 – Mar 2005	Apr 2005 – Sept 2005	Oct 2005 – Mar 2006	Apr 2006 – Sept 2006	Oct 2006 – Mar 2007
BND	1433	1592	3047	5136	5114	4758	4855
GLM	3877	4170	6436	11210	8912	9483	9700
GWY	0	0	51	8568	7457	7053	6574
LLD	9994	10451	14300	15523	16290	14667	15940
PCH	0	0	0	0	2909	4005	3535
RGH	17272	16237	13525	17348	15409	18204	14538
SIN	0	4	755	13769	13466	11350	14814
WBH	0	0	0	1302	4858	4106	3436
WWG	0	0	63	6780	9339	7494	8044
WXH	1	0	1	3342	6553	7445	6385
YGC	0	0	18	7293	6418	5482	5669
TOTAL	32577	32454	38196	90271	96725	94047	93490

Table A.1.5: Total samples authorised by each laboratory (GP and NHS community clinic samples)

Laboratory	Oct 2003 – Mar 2004	Apr 2004 – Sept 2004	Oct 2004 – Mar 2005	Apr 2005 – Sept 2005	Oct 2005 – Mar 2006	Apr 2006 – Sept 2006	Oct 2006 – Mar 2007
BND	4828	4724	4933	5143	5123	4760	4857
GLM	9033	9745	9869	11232	8919	9485	9702
GWY	7570	8379	6182	9141	7575	7055	6622
LLD	15008	15502	15444	15532	16293	14670	15942
PCH	3892	4365	3775	4869	4096	4016	3535
RGH	17272	16240	13525	17348	15409	18204	14539
SIN	13912	12048	10592	14297	13472	11350	14814
WBH	3884	4446	2977	3441	4875	4129	3443
WWG	8377	8939	7155	10410	9339	7495	8045
WXH	5544	6919	5876	7547	6558	7456	6385
YGC	8213	6595	6564	8207	6422	5487	5670
TOTAL	97533	97902	86892	107167	98081	94107	93554

Table A.1.6: Inadequate rates by month; GP and NHS community clinic samples

Year	Month	Conventional			LBC			ALL samples		
		Inad	Total	% Inad	Inad	Total	% Inad	Inad	Total	% Inad
2003	10	1052	12256	8.6	52	6652	0.8	1104	18908	5.8
2003	11	951	10617	9.0	39	5356	0.7	990	15973	6.2
2003	12	770	9729	7.9	58	4417	1.3	828	14146	5.9
2004	1	877	10214	8.6	34	4839	0.7	911	15053	6.1
2004	2	879	10201	8.6	111	5296	2.1	990	15497	6.4
2004	3	1096	11939	9.2	108	6017	1.8	1204	17956	6.7
2004	4	943	10245	9.2	113	5474	2.1	1056	15719	6.7
2004	5	804	9743	8.3	128	4973	2.6	932	14716	6.3
2004	6	967	12083	8.0	136	6068	2.2	1103	18151	6.1
2004	7	997	11970	8.3	95	5876	1.6	1092	17846	6.1
2004	8	795	10491	7.6	66	4834	1.4	861	15325	5.6
2004	9	822	10916	7.5	99	5229	1.9	921	16145	5.7
2004	10	829	10048	8.3	88	4589	1.9	917	14637	6.3
2004	11	854	10320	8.3	114	6988	1.6	968	17308	5.6
2004	12	649	8121	8.0	114	5252	2.2	763	13373	5.7
2005	1	544	6987	7.8	114	6641	1.7	658	13628	4.8
2005	2	494	6051	8.2	161	7072	2.3	655	13123	5.0
2005	3	693	7169	9.7	178	7654	2.3	871	14823	5.9
2005	4	361	4632	7.8	248	9420	2.6	609	14052	4.3
2005	5	359	4368	8.2	277	10928	2.5	636	15296	4.2
2005	6	389	4473	8.7	404	14545	2.8	793	19018	4.2
2005	7	145	1664	8.7	387	17373	2.2	532	19037	2.8
2005	8	50	823	6.1	395	19813	2.0	445	20636	2.2
2005	9	73	936	7.8	398	18192	2.2	471	19128	2.5
2005	10	35	732	4.8	271	15583	1.7	306	16315	1.9
2005	11	27	511	5.3	318	18394	1.7	345	18905	1.8
2005	12	8	69	11.6	217	13833	1.6	225	13902	1.6
2006	1	1	18	5.6	312	17119	1.8	313	17137	1.8
2006	2	1	14	7.1	234	14786	1.6	235	14800	1.6
2006	3	0	12	0.0	257	17010	1.5	257	17022	1.5
2006	4	0	17	0.0	253	14033	1.8	253	14050	1.8
2006	5	0	15	0.0	306	16990	1.8	306	17005	1.8
2006	6	1	11	9.1	310	17890	1.7	311	17901	1.7
2006	7	0	7	0.0	284	15728	1.8	284	15735	1.8
2006	8	0	4	0.0	269	14115	1.9	269	14119	1.9
2006	9	1	6	16.7	269	15291	1.8	270	15297	1.8
2006	10	1	5	20.0	280	17442	1.6	281	17447	1.6
2006	11	6	51	11.8	257	16308	1.6	263	16359	1.6
2006	12	0	2	0.0	183	13070	1.4	183	13072	1.4
2007	1	1	3	33.3	236	15983	1.5	237	15986	1.5
2007	2	0	3	0.0	221	14471	1.5	221	14474	1.5
2007	3	0	0	0.0	242	16216	1.5	242	16216	1.5
2007	4	0	0	0.0	206	14931	1.4	206	14931	1.4
2007	5	0	0	0.0	303	18897	1.6	303	18897	1.6
2007	6	0	1	0.0	243	16895	1.4	243	16896	1.4
TOTAL		16475	197477	8.3	9388	528483	1.8	25863	725960	3.6

Note: Inad = Inadequate result

Table A.1.7: Inadequate rates by age group; GP and NHS community clinic samples

Age Group	April 2004 - March 2005			April 2005 - March 2006			% Difference
	Inad	Total	% Inad	Inad	Total	% Inad	
Under 20	21	379	5.5	7	245	2.9	2.7
20-24	1562	21649	7.2	644	23432	2.7	4.5
25-29	1269	19013	6.7	633	21591	2.9	3.7
30-34	1549	23145	6.7	729	24617	3.0	3.7
35-39	1650	25731	6.4	786	27597	2.8	3.6
40-44	1441	24379	5.9	774	27635	2.8	3.1
45-49	1038	20719	5.0	627	23516	2.7	2.3
50-54	894	18175	4.9	382	20126	1.9	3.0
55-59	843	17725	4.8	311	20177	1.5	3.2
60-64	499	12681	3.9	260	15095	1.7	2.2
65-69	27	1053	2.6	10	1088	0.9	1.6
70+	4	139	2.9	4	118	3.4	-0.5
Total*	10797	184788	5.8	5167	205237	2.5	3.3

* Note: There are 6 ages unknown in April 2004 – March 2005 and 11 ages unknown in April 2005 – March 2006 which appear in the total

Table A.1.8a: Number of adequate samples from all sources, by quarter

Year	Quarter	All samples			LBC samples		
		Neg	Blinc / mild	Mod +	Neg	Blinc / mild	Mod +
2000	1	39432	3482	1057	0	0	0
2000	2	39645	3365	1027	0	0	0
2000	3	42411	3210	1066	0	0	0
2000	4	37602	3360	990	56	22	11
2001	1	43414	3812	1053	361	222	60
2001	2	43266	3695	1080	338	186	76
2001	3	48331	3971	1206	482	215	70
2001	4	45460	4254	1190	2131	480	192
2002	1	49334	4654	1252	9557	954	315
2002	2	50062	4701	1187	13636	1306	447
2002	3	49036	4261	1186	15781	1276	499
2002	4	47722	4356	1058	16649	1403	429
2003	1	47440	4472	1036	16009	1401	475
2003	2	47127	4133	1054	17890	1420	463
2003	3	47628	3966	994	17346	1436	454
2003	4	46211	3807	924	16686	1280	395
2004	1	45520	3720	857	16440	1272	380
2004	2	45512	3733	830	16617	1323	377
2004	3	46666	3215	844	16239	1149	392
2004	4	42660	3322	822	17136	1348	427
2005	1	40150	2675	638	21820	1515	443
2005	2	46392	3312	800	34459	2368	629
2005	3	56868	3759	811	53817	3446	735
2005	4	47917	3246	734	46725	3101	690
2006	1	47776	3299	724	47695	3293	720
2006	2	47666	3361	717	47591	3352	716
2006	3	43717	3265	702	43668	3265	700
2006	4	45790	3440	686	45723	3436	684
2007	1	45349	3518	667	45344	3518	667
2007	2	49212	3657	759	49210	3657	759

Table A.1.8b: Percentage of adequate samples from all sources, by quarter

Year	Quarter	All samples			LBC samples		
		Neg	Bline / mild	Mod +	Neg	Bline / mild	Mod +
2000	1	89.7	7.9	2.4	0.0	0.0	0.0
2000	2	90.0	7.6	2.3	0.0	0.0	0.0
2000	3	90.8	6.9	2.3	0.0	0.0	0.0
2000	4	89.6	8.0	2.4	62.9	24.7	12.4
2001	1	89.9	7.9	2.2	56.1	34.5	9.3
2001	2	90.1	7.7	2.2	56.3	31.0	12.7
2001	3	90.3	7.4	2.3	62.8	28.0	9.1
2001	4	89.3	8.4	2.3	76.0	17.1	6.8
2002	1	89.3	8.4	2.3	88.3	8.8	2.9
2002	2	89.5	8.4	2.1	88.6	8.5	2.9
2002	3	90.0	7.8	2.2	89.9	7.3	2.8
2002	4	89.8	8.2	2.0	90.1	7.6	2.3
2003	1	89.6	8.4	2.0	89.5	7.8	2.7
2003	2	90.1	7.9	2.0	90.5	7.2	2.3
2003	3	90.6	7.5	1.9	90.2	7.5	2.4
2003	4	90.7	7.5	1.8	90.9	7.0	2.2
2004	1	90.9	7.4	1.7	90.9	7.0	2.1
2004	2	90.9	7.5	1.7	90.7	7.2	2.1
2004	3	92.0	6.3	1.7	91.3	6.5	2.2
2004	4	91.1	7.1	1.8	90.6	7.1	2.3
2005	1	92.4	6.2	1.5	91.8	6.4	1.9
2005	2	91.9	6.6	1.6	92.0	6.3	1.7
2005	3	92.6	6.1	1.3	92.8	5.9	1.3
2005	4	92.3	6.3	1.4	92.5	6.1	1.4
2006	1	92.2	6.4	1.4	92.2	6.4	1.4
2006	2	92.1	6.5	1.4	92.1	6.5	1.4
2006	3	91.7	6.8	1.5	91.7	6.9	1.5
2006	4	91.7	6.9	1.4	91.7	6.9	1.4
2007	1	91.6	7.1	1.3	91.6	7.1	1.3
2007	2	91.8	6.8	1.4	91.8	6.8	1.4

Note: Inad = Inadequate result
 Neg = Negative result
 Bline / mild = Borderline changes or mild dyskaryosis (low-grade) results
 Mod + = Moderate dyskaryosis or worse (high-grade) results

Table A.1.9a: Number of adequate samples from GP and NHS community clinic sources only, by quarter

Year	Quarter	All samples			LBC samples		
		Neg	Blinc / mild	Mod +	Neg	Blinc / mild	Mod +
2000	1	36239	2700	679	0	0	0
2000	2	36756	2596	635	0	0	0
2000	3	39214	2495	668	0	0	0
2000	4	34132	2541	558	0	0	0
2001	1	39757	2850	663	0	1	0
2001	2	39933	2840	691	0	0	1
2001	3	44856	3054	784	6	0	0
2001	4	41922	3194	685	1064	84	6
2002	1	45656	3663	816	8276	577	128
2002	2	46395	3723	787	12063	878	200
2002	3	45465	3270	748	13892	831	236
2002	4	43822	3287	662	14643	861	211
2003	1	43483	3403	634	14263	917	221
2003	2	43678	3205	650	16315	992	225
2003	3	44201	3069	637	15758	1001	227
2003	4	42671	2882	552	15206	878	183
2004	1	42027	2817	557	14849	841	192
2004	2	42094	2865	536	15058	883	184
2004	3	43412	2481	549	14723	748	193
2004	4	39579	2569	522	15424	886	196
2005	1	37001	1984	405	19684	983	247
2005	2	43122	2639	567	31732	1808	422
2005	3	53766	2994	593	50931	2740	527
2005	4	45124	2608	514	44036	2480	473
2006	1	45014	2626	514	44956	2624	512
2006	2	44920	2644	520	44863	2639	520
2006	3	41215	2604	504	41179	2604	504
2006	4	42937	2736	470	42879	2733	469
2007	1	42712	2795	465	42707	2795	465
2007	2	46499	2936	529	46498	2936	529

Note: Neg = Negative result
 Blinc / mild = Borderline changes or mild dyskaryosis (low-grade) results
 Mod + = Moderate dyskaryosis or worse (high-grade) results

Table A.1.9b: Percentage of adequate samples from GP and NHS community clinic sources only, by quarter

Year	Quarter	All samples			LBC samples		
		Neg	Bline / mild	Mod +	Neg	Bline / mild	Mod +
2000	1	91.5	6.8	1.7	0.0	0.0	0.0
2000	2	91.9	6.5	1.6	0.0	0.0	0.0
2000	3	92.5	5.9	1.6	0.0	0.0	0.0
2000	4	91.7	6.8	1.5	0.0	0.0	0.0
2001	1	91.9	6.6	1.5	0.0	100.0	0.0
2001	2	91.9	6.5	1.6	0.0	0.0	0.0
2001	3	92.1	6.3	1.6	100.0	0.0	0.0
2001	4	91.5	7.0	1.5	92.2	7.3	0.5
2002	1	91.1	7.3	1.6	92.2	6.4	1.4
2002	2	91.1	7.3	1.5	91.8	6.7	1.5
2002	3	91.9	6.6	1.5	92.9	5.6	1.6
2002	4	91.7	6.9	1.4	93.2	5.5	1.3
2003	1	91.5	7.2	1.3	92.6	6.0	1.4
2003	2	91.9	6.7	1.4	93.1	5.7	1.3
2003	3	92.3	6.4	1.3	92.8	5.9	1.3
2003	4	92.6	6.3	1.2	93.5	5.4	1.1
2004	1	92.6	6.2	1.2	93.5	5.3	1.2
2004	2	92.5	6.3	1.2	93.4	5.5	1.1
2004	3	93.5	5.3	1.2	94.0	4.8	1.2
2004	4	92.8	6.0	1.2	93.4	5.4	1.2
2005	1	93.9	5.0	1.0	94.1	4.7	1.2
2005	2	93.1	5.7	1.2	93.4	5.3	1.2
2005	3	93.7	5.2	1.0	94.0	5.1	1.0
2005	4	93.5	5.4	1.1	93.7	5.3	1.0
2006	1	93.5	5.5	1.1	93.5	5.5	1.1
2006	2	93.4	5.5	1.1	93.4	5.5	1.1
2006	3	93.0	5.9	1.1	93.0	5.9	1.1
2006	4	93.1	5.9	1.0	93.1	5.9	1.0
2007	1	92.9	6.1	1.0	92.9	6.1	1.0
2007	2	93.1	5.9	1.1	93.1	5.9	1.1

Note: Neg = Negative result
 Bline / mild = Borderline changes or mild dyskaryosis (low-grade) results
 Mod + = Moderate dyskaryosis or worse (high-grade) results

Table A.1.10a: Number and percentage of low-grade results by age group, GP and NHS community clinic sources only

Age	April 2004 - March 2005			April 2005 - March 2006			Significant Difference?
	Bline /Mild	Adequate	% Bline /Mild	Bline /Mild	Adequate	% Bline /Mild	
Under 20	61	358	17.0	52	238	21.8	No
20-24	2855	20087	14.2	3316	22788	14.6	No
25-29	1516	17744	8.5	1812	20958	8.6	No
30-34	1289	21596	6.0	1364	23888	5.7	No
35-39	1207	24081	5.0	1233	26811	4.6	No
40-44	1070	22938	4.7	1087	26861	4.0	Yes
45-49	832	19681	4.2	812	22889	3.5	Yes
50-54	534	17281	3.1	542	19744	2.7	No
55-59	345	16882	2.0	400	19866	2.0	No
60-64	154	12182	1.3	208	14835	1.4	No
65-69	30	1026	2.9	36	1078	3.3	No
70+	5	135	3.7	5	114	4.4	No
TOTAL*	9898	173991	5.7	10867	200070	5.4	Yes

Table A.1.10b: Number and percentage of high-grade results by age group, GP and NHS community clinic sources only

Age	April 2004 - March 2005			April 2005 - March 2006			Significant Difference?
	Mod+	Adequate	% Mod+	Mod+	Adequate	% Mod+	
Under 20	7	358	2.0	2	238	0.8	No
20-24	488	20087	2.4	544	22788	2.4	No
25-29	426	17744	2.4	518	20958	2.5	No
30-34	396	21596	1.8	415	23888	1.7	No
35-39	281	24081	1.2	280	26811	1.0	No
40-44	165	22938	0.7	178	26861	0.7	No
45-49	89	19681	0.5	98	22889	0.4	No
50-54	81	17281	0.5	53	19744	0.3	Yes
55-59	37	16882	0.2	59	19866	0.3	No
60-64	36	12182	0.3	37	14835	0.2	No
65-69	6	1026	0.6	4	1078	0.4	No
70+	0	135	0.0	0	114	0.0	No
TOTAL*	2012	173991	1.2	2188	200070	1.1	No

* Note: There are 6 ages unknown in April 2004 – March 2005 and 11 ages unknown in April 2005 – March 2006 which appear in the total

Note: Bline / mild = Borderline changes or mild dyskaryosis (low-grade) results
 Mod + = Moderate dyskaryosis or worse (high-grade) results

Table A.1.11: Summary of Positive Predictive Values (%)

Laboratory	2000/01	2001/02	2002/03	2003/04	2004/05	2005/06	2006/07
BND	94	81	78	80	83	85	88
GLM	82	74	74	66	77	81	79
GWY	76	87	76	84	82	84	92
LLD	65	66	71	78	84	80	81
PCH	87	63	60	66	67	64	73
RGH	83	81	74	85	86	86	87
SIN	56	67	69	72	72	72	82
WBH	82	88	84	79	86	82	84
WWG	61	73	68	69	68	69	81
WXH	63	65	66	81	81	85	84
YGC	79	58	70	73	66	74	90
TOTAL	76	72	72	76	78	79	83

Table A.1.12a: Sensitivity of primary screening for each laboratory, LBC samples, April 2004 – March 2005

Laboratory	Total primary screened	Specificity %	Sensitivity %	Sensitivity moderate or worse %	False negative %	False Negative moderate or worse %
BND	5259	97.6	91.4	95.3	8.6	4.7
GLM	11639	96.6	94.3	96.5	5.7	3.5
GWY	65	100.0	100.0			
LLD	27940	95.8	92.4	98.0	7.6	2.0
PCH						
RGH	33065	95.1	94.2	96.2	5.8	3.8
SIN	2102	94.0	93.8	98.8	6.2	1.2
WBH	9	100.0	100.0	100.0		
WWG	461	94.5	85.3	94.4	14.7	5.6
WXH	2	50.0				
YGC	18	100.0				
TOTAL	80560	95.7	93.2	97.0	6.8	3.0

Table A.1.12b: Sensitivity of primary screening for each laboratory, conventional samples, April 2004 – March 2005

Laboratory	Total primary screened	Specificity %	Sensitivity %	Sensitivity moderate or worse %	False negative %	False Negative moderate or worse %
BND	5029	97.6	93.8	100.0	6.3	
GLM	9010	97.5	93.4	91.7	6.6	8.3
GWY	15590	98.9	95.4	99.4	4.6	0.6
LLD	6319	97.3	90.3	96.9	9.7	3.1
PCH	9235	92.5	85.9	93.3	14.1	6.7
RGH	4	100.0				
SIN	23643	96.2	94.4	97.9	5.6	2.1
WBH	8114	97.3	88.0	94.8	12.0	5.2
WWG	17281	98.4	97.8	99.0	2.2	1.0
WXH	13610	90.9	93.9	99.2	6.1	0.8
YGC	13806	97.4	94.1	97.8	5.9	2.2
TOTAL	121641	96.4	93.0	97.1	7.0	2.9

Table A.1.13a: Sensitivity of primary screening for each laboratory, LBC samples, April 2005 – March 2006

Laboratory	Total primary screened	Specificity %	Sensitivity %	Sensitivity moderate or worse %	False negative %	False Negative moderate or worse %
BND	10879	98.0	91.2	96.3	8.8	3.7
GLM	21199	97.5	92.6	97.4	7.4	2.6
GWY	16617	99.0	95.1	98.3	4.9	1.7
LLD	34969	94.3	93.9	98.4	6.1	1.6
PCH	3211	97.4	85.8	94.3	14.2	5.7
RGH	35910	94.6	93.8	97.1	6.2	2.9
SIN	29494	97.7	90.5	96.2	9.5	3.8
WBH	6763	96.5	93.8	100.0	6.2	
WWG	17425	98.0	91.2	96.7	8.8	3.3
WXH	10671	92.0	95.6	99.3	4.4	0.7
YGC	14444	96.7	93.8	96.7	6.2	3.3
TOTAL	201582	96.3	92.9	97.5	7.1	2.5

Table A.1.13b: Sensitivity of primary screening for each laboratory, conventional samples, April 2005 – March 2006

Laboratory	Total primary screened	Specificity %	Sensitivity %	Sensitivity moderate or worse %	False negative %	False Negative moderate or worse %
BND	13	100.0	100.0			
GLM	29	100.0	100.0			
GWY	680	96.9	96.7	100.0	3.3	
LLD	15	100.0	50.0	100.0	50.0	
PCH	6679	95.2	86.2	96.5	13.8	3.5
RGH	1		100.0			
SIN	556	94.2	95.1	92.9	4.9	7.1
WBH	2209	95.6	87.7	96.4	12.3	3.6
WWG	3648	98.2	93.8	96.2	6.3	3.8
WXH	4463	92.9	95.9	100.0	4.1	
YGC	991	97.5	93.5	100.0	6.5	
TOTAL	19284	95.5	90.3	97.2	9.7	2.8

Note: A very small number of samples during this time period are missing the primary screener opinion and are not included in the tables above.

References

National Institute for Clinical Excellence (2000). Guidance on the use of liquid based cytology for cervical screening. NICE Technology Appraisal Guidance No. 5. London: National Institute for Clinical Excellence.

National Institute for Clinical Excellence (October 2003). Guidance on the use of liquid based cytology for cervical screening. NICE Technology Appraisal Guidance No. 69. London: National Institute for Clinical Excellence. (www.nice.org.uk)

Cervical Screening Wales, Liquid Based Cytology Pilot Project, Project Report, November 2003.

Rieck GC, Bhaumik J, Beer HR, Leeson SC. Repeating cytology at initial colposcopy does not improve detection of high-grade abnormalities: A retrospective cohort study of 6595 women. *Gynecologic Oncology* 101 (2006) 228-233.

IATA packing instruction 602 (class 6.2). International Air Transport Association(1998) Dangerous Goods Regulations. 39th edition. Montreal; Geneva: IATA.

Cervical Screening Wales Quality Manual, Colposcopy Standard Operating Policies and Procedures, v2 18th Jan 2005, Section C.90 Indications for Treatment, Sub-section C.90.5 Management Plan for Patients Presenting with Abnormal Smears.

Cervical Screening Wales Statistical Report, Cervical Screening Programme Wales: 2000/01, published January 2002.

Cervical Screening Wales Statistical Report, Cervical Screening Programme Wales: 2001/02, published January 2003.

Cervical Screening Wales Statistical Report, Cervical Screening Programme Wales: 2002/03, published January 2004.

Cervical Screening Wales Statistical Report, Cervical Screening Programme Wales: 2003/04, published November 2004.

Cervical Screening Wales Statistical Report, Cervical Screening Programme Wales: 2004/05, published July 2005.

Cervical Screening Wales Statistical Report, Cervical Screening Programme Wales: 2005/06, published August 2006.

Cervical Screening Wales Statistical Report, Cervical Screening Programme Wales: 2006/07, published August 2007.

Statistical reports available from: www.screeningservices.org/csw

National Service Framework for the Cervical Screening Programme in Wales:
March 1999, Cardiff, Welsh Office