

Quality Control Assurance in National Screening Programmes for Cervical Cancer

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Abstract

The United Kingdom established a centrally controlled formal screening programme for cervical cancer in 1988. The programme has been an unprecedented success, with the incidence of cervical cancer falling by an accelerated rate of 7% a year. Underlying the success of the programme is a rigorous system of quality assurance at all levels of activity. Quality assurance assessment is performed for coverage of the target population, cytology reporting laboratories and colposcopy services. Each component in the system is examined annually by mandatory returns, and by regular on-site review of the clinical services by independent authorities. Processes also exist to establish and maintain the competency of all clinical and non-clinical staff involved in the programme. Using nationally published figures from the financial year 2001/2002, the different quality assurance strategies are described. The future development of quality assurance in the programme is then discussed.

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Introduction

The National Health Service (NHS) was established in the United Kingdom (UK) in 1948, against a post-war background of poverty and ill health. The aim was to provide healthcare based on need to all citizens of the UK, free at the point of delivery. The service has expanded and evolved dramatically over the last 50 years, and currently has an annual budget of £44.8 billion (US\$73.9 billion) and a staff of over 1.2 million, with funding derived from general taxation and mandatory national insurance contributions.¹ With parliamentary devolution in the UK, the NHS now comprises 9 district health regions in England, which are subdivided into 99 Health Authorities. In 1989, the government published a White Paper entitled *Working For Patients*. It was passed into law as the Community Care Act in 1990, in which an internal market was created within the structure of the NHS.^{2,3} This established the role of general practitioners (GPs) and Health Authorities as service “purchasers” and hospitals as service “providers”. By 1995, all NHS hospitals assumed independent fiscal responsibility and were called “hospital trusts”. Later, further autonomy was also encouraged for GPs to form “primary care trusts”, with the role of the Health Authority being the development of strategies for the provision of healthcare locally and the assessment of performance for the Department of Health. The expectation is that primary care trusts will eventually control 75% of the NHS budget

in these “purchaser” agreements.⁴ Under a different government, the focus has shifted away from this internal market to a more collaborative approach, the so-called “partnerships in health”,^{5,6} and a focus on quality and equality across the country.

In the UK, cervical screening was first performed in the 1960s. Screening programmes were promoted at a local level by Medical Officers of Health and cytologists. By the 1980s, however, the incidence of cervical cancer was unaffected and remained in the middle of the continental range. It was clear, that in the UK, cervical screening was not an effective or well-managed programme; it lacked clear objectives. There was a notable lack of screening of women at greater risk and some of the women who were screened were not followed up appropriately. In 1987, an intercollegiate working party advised that Papanicolaou smears be repeated every 3 years in all women aged 20 to 64 years.⁷ In 1988, the Department of Health required each Health Authority in England to introduce a cervical screening programme “for all women aged 20 to 64 to have a smear at least every 5 years”. It also published guidelines to facilitate its implementation.⁸ Consequently, the incidence of cervical cancer in the UK has fallen more than that of any other cancer: 26% between 1992 and 1997, with mortality falling at an accelerated rate of 7% a year.⁹ In 1992, the government published its ambitious goals for reduction in the rates of a number of cancers in the UK, including

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cervical.¹⁰ The cervical screening programme has achieved and surpassed these targets (Table I), and cervical cancer is an increasingly uncommon disease in the UK.

Operational Strategy of the UK Cervical Screening Programme¹¹

The operational strategy of the programme has developed with the changes in healthcare delivery described above. At present the service is contracted from cytology and colposcopy services by primary care trusts and GPs, under the direction of the Health Authority. The process is summarised below.

- Commissioners based within primary care trusts contract the service locally.
- All women aged between 20 and 64 years are invited for screening at least once every 5 years.
- The call/recall system, based at the Health Authority, maintains the process by which women are invited to attend a smear test.
- The GP practice or clinic is where women attend their smear test, have their questions answered and receive advice or counselling, if necessary.
- The smear test is sent to the laboratory, where it is “read”.
- If a woman requires colposcopy, she is offered an appointment at the department from whom the GP has contracted the service.

Quality Assurance

While the success of the screening programme has been impressive, there is no room for complacency. A small number of well-publicised lapses in the integrity of the service have led not only to heightened awareness of the need for quality standards in cytopathology and colposcopy, but have also contributed to changes in the structure of provision of public healthcare nationally. To this end, quality assurance was incorporated into the programme structure, and is now a fundamental part of the UK practice. This occurs at a number of levels, and is summarised in Figure 1. The National Health Service Cervical Screening Programme (NHSCSP) is responsible for the setting of standards and achievable targets for clinical services engaged in the cervical screening programme. These are

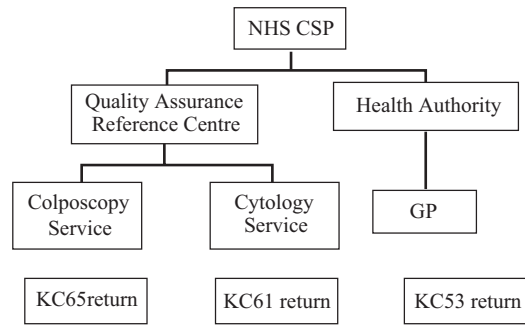


Fig. 1. Structure of Quality Assurance in Cervical Screening. (see text for full explanation of terms)

The NHSCSP produces directives regarding target population and coverage for health authorities, and quality standards for colposcopy and cytology services. The QARC performs a triennial on-site review of colposcopy and cytology services. Additional review of cytology is performed as part of the CPA procedure (see text). Mandatory Korner Community (KC) returns are provided for assessment of activity in each area of screening. These are examined by the centre returning the data, the QARC and the NHSCSP directorate for quality assessment.

published from working parties comprising representatives from the British Society of Colposcopy and Cervical Pathology (BSCCP), British Society for Cervical Cytology (BSCC), Royal College of Pathologists and Association of Genitourinary Medicine (AGUM), and were organised and co-ordinated by the NHSCSP. They are incorporated into practices in the UK, and each individual unit and practitioner is responsible for the implementation and regular internal audit of their practice. A formal process of “quality assurance” is performed from regional Quality Assurance Reference Centres (QARCs) in each NHS Executive region in England, in addition to further independent assessment as part of the triennial review of hospital trusts by the Commission for Health Improvement. For cytopathology services, registration and external assessment from Clinical Pathology Accreditation Ltd (CPA) is also available. All these measures help to maintain minimum standards and to improve the performance of all aspects of the cervical screening programme. Finally, the BSCCP, Health Professions Council and NHSCSP provide accreditation for clinical and non-clinical staff involved in the programme following proof of exposure to a required level of clinical workload in recognised units. The BSCCP also requires demonstration of exposure to a minimum workload for re-accreditation of clinical staff practising colposcopy in the screening programme.

Korner Data Set Returns

Data regarding aspects of UK health performance are returned under a series of data sets, known as Korner returns. The three types of return are community (KC), therapy (KT) and activity (KA), relating to different areas of public healthcare. Cervical screening is examined in 3 mandatory returns: KC53 examining coverage of the target population; KC61 examining activity of cytology services; and KC65 examining colposcopy service activity. These

TABLE I: CHANGES IN INCIDENCE AND MORTALITY FROM CERVICAL CARCINOMA OVER TIME

Year	Incidence (per 100,000 population)	Mortality (per 100,000 population)
1971	376	190
1975	300	143
1979	225	100
1983	230	103
1987	250	103
1991	240	85
1995	215	53

will be considered with respect to each area of quality assurance in the programme.

Call/Recall and KC53 Returns

The most significant change proposed from the 1988 instruction was the establishment of the call/recall system in the NHS screening programme. The success of any national screening programme is seen in its coverage of the target population. Every woman in the target population who is not suspended from recall will be sent an appointment for a smear test at the GPs clinic, triggered off by the Health Authority. Each of the 99 regional Health Authorities in England has a database of eligible women registered with GPs within the district with respect to cytology history. Quality assurance for screening coverage operates at the level of the Health Authority, which is required to provide information regarding coverage of the target population from the last day of each financial year in the annual KC53 return. In addition, ad hoc reports are required for local monitoring purposes and these may be randomly requested by the Department of Health for any time period. The department then publishes these figures to show national coverage, coverage by district and, finally, by Health Authority.¹²

While coverage has remained fairly constant over the last 5 years, data from KC53 returns are used to establish if increased activity is required to improve service quality. An example would be improved strategies for the London district, where coverage is consistently 5% below the national average. In stratifying by age, it has been noted that there has been a fall in women <50 years old who attended routine smear examination, while those in the age group 50 to 64 years have witnessed improved coverage year on year, suggesting the need to target the former group in future promotional material.

Quality Assurance in Cytology and KC61 Returns

Pathology laboratories involved in the screening programme not only perform cytology, but also recommend action on the basis of smear results. Consequently, the programme, at a local level, can be seen to focus on the cytology laboratory. The laboratories are responsible for the determination of protocols and referral patterns, utilising published guidelines from the NHSCSP. Effective analysis, reporting and clerical activity of these services are a key priority for quality assurance in the UK screening programme. The Department of Health, NHSCSP, regional QARCs and referring trusts require information from the laboratories regarding cytology results and outcomes of referrals. This information is also used in expenditure negotiations and resource allocation. At the basic level, the laboratory is required to provide the KC61 return annually. The first part relates to the number of smears examined and stratified according to result. In the second part, these are

expressed by source of smear and age of patient. It is assumed that smears supplied by community clinics and GPs will represent the majority sourced from the “call/recall” system, and not those taken for clinical reasons, such as symptoms or previous cytological/pathological abnormality.

With no obvious “gold standard” for particular performance indicators, 10th and 90th centiles are established. Laboratories that returned numbers which fell outside these ranges (so-called “outliers”) are investigated for possible causes of these differences. Remedial action is taken, if required, with the assistance of their QARC. With the additional return of stratification by age, this return also allows monitoring of changes in pattern of disease as the programme progresses.

The third part of these national returns relates to internal quality control. The latest guidelines published by the NHSCSP identify it “as an essential component of laboratory quality assurance”. All abnormal smear results returned in the first 3 months of the reported year are correlated with histology results, where available, following treatment or directed biopsy. This allows calculation of positive predictive values for the cytology service itself, and for individual cytoscreeners. Positive predictive values of between 44% and 94% for all abnormalities were reported in the 2001/2002 returns. A sensitivity of 90% for cervical intraepithelial neoplasia (CIN) 2 and above, for all smears returned as moderate dyskaryosis and above, was recommended following these returns.

Internal quality assurance is also achieved by 2 processes of smear result review. In “rapid review”, all negative and inadequate smears are re-examined within the department to check the primary screening result before it leaves the laboratory. Full “rescreening” is performed on all abnormal smears. With the final result from both pathologists and “checkers” used as the gold standard, it is possible to produce statistical data for the primary screening process within the unit, specifically the negative and positive predictive values, respectively. This not only allows the performance of the department to be reviewed internally, but also for individual screening profiles to be established for each cytoscreener. This is used to establish which individuals need extra support, with the screener being withdrawn from the screening process until performance is improved. The current recommendation is >90% of all smear abnormalities to be identified, and for >95% of all high-grade abnormalities to be identified in the primary screening process.

External quality assurance (EQA) of screening laboratories is performed from 2 services in the UK. First, a non-profit seeking company, the CPA certifies the entire laboratory service, including all aspects of pathology and cytology. A team of CPA inspectors assesses the laboratory

on a 4 yearly basis and, between inspections, the company must be informed of any major changes in staffing, service provision, organisation, resources or EQA performance. Cytology services are also reviewed as part of the triennial QARC visits, which require prior submission of modified KC61 data to examine the performance of the laboratory. Besides these visits, over the last year, each laboratory was sent 10 sample slides that included good examples from each one of the 8 classifications recognised by the BSCC: negative, inadequate, borderline, three grades of dyskaryosis, invasive squamous carcinoma and glandular neoplasia. All personnel involved in “reading” the smears are required to submit to the QARC their opinion on the 10 slides, and the results will be relayed to the screening centre to aid in performance review.

Multidisciplinary Teams

The liaison between cytology, histology and colposcopy is an important component of local screening programmes. To this end, quality assurance is improved by the multidisciplinary work of colposcopy, cytology and histopathology staff. Regular meetings were held among the 3 groups to allow exchange of information on individual cases and outcomes. They also serve as a forum for discussion of changes in referral strategies and guidelines on cytology reporting.

Quality Assurance for Colposcopy

In 1996, the NHSCSP published a document,¹³ written in collaboration with the BSCCP, Royal College of Obstetricians and Gynaecologists and AGUM, which established the guidelines for colposcopy services in 2 areas: the identification of activities that can improve quality and the setting of standards against which quality can be measured. Examples of these standards are shown in Table II.

The National Quality Assurance Group, Visits and KC 65 Returns

EQA is established by triennial visits of every screening programme unit by the QARC. This consists of teams of clinicians and administrative staff nominated from the regional QARC, and the visits are performed alongside the assessments of cytology and histopathology services by clinical staff in these fields. In addition to visiting the unit and assessing the facilities, these teams are also provided in advance with the performance figures of the units with respect to the standards document, excerpts of which are shown in Table II. By reviewing the 3 aspects of the service, they provide the trust executive with an impartial overview of current performance and suggest remedial action, if required. The National Quality Assurance Group, with representatives from every regional centre and representation from the NHSCSP and BSCCP, meets twice

a year to discuss the implications of quality assurance in the screening programme and to provide feedback to the screening programme directorate on the practical implications of new proposals.

The performance of colposcopy services is reviewed on an annual basis by the return of KC65 data from each unit within the screening programme. This information is used at 3 levels: locally for internal quality assurance, regionally for the QARC to examine the broad overview of each unit’s activities, and nationally by the Department of Health to examine the provision of the service. The data are taken from the initial 3 months of the preceding financial year, which is representative of clinic activity. It examines 5 parameters:

- Number of women referred to colposcopy by indication
- Time from referral to first offered appointment
- Outcome from first appointment, e.g. treatment, diagnostic biopsy
- Time from biopsy to patient being informed of results in writing
- Types of biopsies taken and results

Two sets of returned data from the authors’ unit are shown in Tables III and IV.

Certification and Training in Colposcopy

The certification and training committee of the BSCCP introduced certification in colposcopy into the UK practice in 1998. It requires all clinicians to attest that they have achieved the recommended basic training standards, including seeing at least 50 new patients a year, performing audit of their own practice and attending 1 recognised national colposcopy meeting triennially. Subsequent to this registration they are required to:

- Have a basic medical qualification, except where nursing practitioners apply for certification in an extended role.
- Have attended a basic training course approved by the BSCCP, including theoretical and practical modules.
- Undertake training in a unit which has been recognised by the BSCCP for training purposes.
- Perform 50 colposcopies under direct supervision, of which 20 must be new presentations; 10 of these must be high-grade disease.
- Perform 100 colposcopies under indirect supervision; at least 30 must be new presentations, of which 15 must be high-grade disease.
- Present 10 case summaries (up to 500 words) reflecting the training experience.
- Apply to the BSCCP for accreditation.
- Apply for a separate treatment module which requires the trainee to observe 10 large loop excision of the transformation zone (LLETZ) and perform 10 LLETZ under supervision, and then perform 5 extended LLETZ/ cone biopsies.

TABLE II: STANDARDS FOR THE COLPOSCOPY SERVICE

Objective	Example of measure	Target
Ensure women are adequately informed about colposcopy and treatment	Proportion of results and management plans communicated to women	≥90% within 14 days of attendance at clinic
Provide an adequate clinic environment	Clinics should have a suitable couch, colposcope and other equipment	All clinics
Provide appropriate clinic staff	Clinics should have a named clinic nurse with appropriate skills and without concurrent outpatient duties	All clinics
Ensure appropriate and accurate data collection	Clinics should be able to prove a basic data set	All clinics
Reduce default	Minimal default on appointments	≤15% of women fail to attend their first/follow-up appointment
Reduce failure of diagnosis of early cancers	Women who require treatment for an abnormal cervical smear should have prior colposcopic assessment	
Improve quality, accuracy and timeliness of diagnosis	- Waiting time for colposcopic assessment for all referrals	≥90% in <8 weeks
	- Waiting time for colposcopic assessment for women with moderate/severe dyskaryosis smears	≥90% in <4 weeks
	- Proportion of biopsies adequate for histological interpretation	≥90%
	- Accurate reporting of colposcopic findings	≥90%
	- Evidence of CIN on histology	≥85%
	- Colposcopist's accuracy in predicting high-grade lesions or worse	≥70%
Ensure appropriate selection for and quality of treatment	- Women who need treatment should give written or verbal consent	
	- Proportion of women managed as outpatients under local analgesia	≥80%
	- Proportion of outpatient treatments completed in <10 minutes from commencement of treatment	≥85%
	- Proportion of cases admitted as inpatients due to treatment complication	≤5%
	- Proportion of women with no dyskaryosis on cytology at 6 months	≥90%
Ensure appropriate and adequate follow-up	- Proportion of treated patients who have follow-up smear within 6 to 8 months following treatment	≥85%
	- Proportion of confirmed (histological) treatment failures within 12 months of treatment	≤5%
Ensure adequate communication with referring practitioner	- Proportion of results and management plans communicated to the referring practitioner	≥90% within 14 days of patient's attendance at clinic
Maintain skill levels	- Number of new cases managed by an individual colposcopist per annum	≥100%
	- If the unit is training colposcopists, number of cases directly supervised by an individual colposcopist per annum	≥50%

CIN: cervical intraepithelial neoplasia

The trainer must be a registered BSCCP colposcopist. For each trainee, the department should have a minimum of 300 cases per annum, 100 of which must be new cases.

The unit should be adequately equipped for training; ideally, it should have video facilities and a full range of diagnostic and therapeutic facilities. The unit should meet

the minimum standards stipulated in the above document.

Colposcopists are required to re-certify on a triennial basis, and must have seen at least 50 new patients a year. While information is provided on the grading of the referral smears and accuracy of impression with respect to histology findings, at present there is no requirement of diagnostic

TABLE III: WOMEN REFERRED FOR COLPOSCOPY, ACCORDING TO CLINICAL INDICATION

Indication	Inadequate	Borderline	Mild dyskaryosis carcinoma	Moderate dyskaryosis	Severe Dyskaryosis	Severe/ Invasive	Glandular neoplasia	Other smear	No referral	Total
Screening smear	17	32	62	41	17	0	0	0	0	169
Clinical Indication	0	0	0	0	0	0	0	0	52	52
Total	17	32	62	41	17	0	0	0	52	221

TABLE IV: TIME INTERVAL BETWEEN REFERRAL AND FIRST APPOINTMENT, ACCORDING TO CLINICAL REFERRAL INDICATION

Interval	Inadequate	Borderline/ Mild dyskaryosis	Moderate/ Severe dyskaryosis	Severe/Invasive carcinoma/ Glandular neoplasia	Other	Clinical indication	Total no. referred
≤2 weeks	0	1	7	0	0	8	16
2 to 4 weeks	1	5	15	0	0	3	24
4 to 8 weeks	8	63	23	0	0	26	120
8 to 12 weeks	6	17	10	0	0	8	41
≥12 weeks	2	8	3	0	0	7	20
Total	17	94	58	0	0	52	221

accuracy for re-accreditation. The clinician is responsible for this and it will be reflected in the data produced for the visiting QARC team.

Documentation in Colposcopy

Included in the NHSCSP publication titled *Standards and Quality in Colposcopy* is a minimum data set requirement for documentation following colposcopy examination. The requirement is that ≥90% of all colposcopy visit records should record:¹³

- Whether the colposcopy was satisfactory
- The position of the squamo-columnar junction in relation to the cervical os
- Whether a lesion was seen and, if so, its site
- The opinion of the colposcopist
- Actions taken and/or interventions

While there is no specific advice given as to how this information is recorded, most units now use both hard copy and computer-based records, allowing easy access to data for audit and quality review processes.

The Future

The final step in quality assurance for the NHS service is the review of smear-taking practices for screening purposes. At present, guidance is provided by the BSCC on smear-taking but there is no formal requirement for training or review of smear-taking ability. The regional QARCs are in the process of establishing quality assurance reviews at the primary care level. When implemented, this vital aspect of the screening programme will be addressed.

With the increasing rarity of invasive cervical cancer in

the UK, it has been proposed that an independent review of every new case of invasive cancer should be performed. Currently, the majority of cytology services will perform a review of smear history in cases of cervical carcinoma, as an objective review of quality. In future, the patient or their representative will be formally involved in the review process with the reporting of errors or omissions. This is thought to be not only important in maintaining public confidence in the programme but also has far-reaching implications for the service in terms of accountability and medico-legal consequences.

REFERENCES

1. House of Commons (UK) Department of Health Resource Accounts 2001-2002. London: HMSO, 2003:363.
2. Department of Health (UK). Working for patients. London: HMSO, 1989. Document no. Cm 555.
3. Department of Health (UK). Community care in the next decade and beyond. London: HMSO, 1990.
4. Department of Health (UK). The NHS explained. Accessed 2 May 2003, at <http://www.nhs.uk/thenhsexplained.asp>.
5. Department of Health (UK). Health of the nation. London: HMSO, 1990. Document no. Cm 1523.
6. Department of Health (UK). The NHS plan. London: HMSO, 2000. Document Cm 4818-I.
7. Royal College of Obstetricians and Gynaecologists (UK). Report of the intercollegiate working party on cervical cytology screening. London: RCOG Press, 1987.
8. Department of Health and Social Security (UK). Health services management: cervical cancer screening. Heywood: DHSS, 1988.
9. Quinn M, Babb P, Jones J, Allen E. Effect of screening on incidence of and mortality from cancer of cervix in England: evaluation based on routinely collected statistics. *BMJ* 1999; 318:904-8.
10. Department of Health (UK). The health of the nation. London: HMSO, 2000. Document no. Cm9986.
11. Oxford Cancer Intelligence Unit (UK). The NHS cervical screening programme. Accessed 2 May 2003, at <http://www.ociu.org.uk>.
12. Lancucki L, editor. Cervical screening programme, 2001-2002. Statistical Bulletin 2002/21. London: Crown Publications, 2002:2-13.
13. Luesley D, editor. Standards and quality in colposcopy. NHSCSP Publication No. 2. Sheffield: NHSCSP Publications, year of publication?:5-23.