

Role of re-screening of cervical smears in internal quality control

A Baker, D Melcher, R Smith

Abstract

Aims—To investigate the use of rapid re-screening as a quality control method for previously screened cervical slides; to compare this method with 10% random re-screening and clinically indicated double screening.

Methods—Between June 1990 and December 1994, 117 890 negative smears were subjected to rapid re-screening.

Results—This study shows that rapid re-screening detects far greater numbers of false negative cases when compared with both 10% random re-screening and clinically indicated double screening, with no additional demand on human resources. The technique also identifies variation in the performance of screening personnel as an additional benefit.

Conclusion—Rapid re-screening is an effective method of quality control. Although less sensitive, rapid re-screening should replace 10% random re-screening and selected re-screening as greater numbers of false negative results are detected while consuming less resources.

(J Clin Pathol 1995;48:1002-1004)

Keywords: Rapid screening, cervical screening, re-screening, quality control.

This study examines the quality control of cervical smears as a means of preventing false negative results. Various methods have been described¹⁻⁵ but in most laboratories two methods are used: (1) 10% random re-screening of negative smears, which is the method of choice in most laboratories. It has been suggested for many years,⁶⁻⁸ however, that 10% re-screening is ineffective both for detecting false negative smears and as a means of monitoring staff performance levels. (2) Double screening of smears is effective and undoubtedly the most sensitive method and would probably be the method of choice if it were not so time-consuming and expensive. Many laboratories compromise and re-screen only patients in "high risk" groups.

The lack of an inexpensive and effective method prompted us to evaluate rapid screening as a possible alternative.⁹ Using this method, it is possible to detect a high proportion of abnormal smears in a limited scanning time.¹⁰ Rapid re-screening is particularly effective at detecting high level abnormalities, indicating that this technique would be effective as a method of quality control. In this study, therefore, rapid re-screening was used as a

quality control procedure to examine cervical smears reported as negative by one primary screener. The laboratory provides a screening and diagnostic service for a population of approximately 100 000 women with a three year interval between smears.

Methods

Between June 1990 and December 1994, 142 208 cervical smears were received in the laboratory. During this period cervical smears reported as negative or inadequate were subjected to 10% random re-screening, re-screening for a clinically indicated reason and rapid re-screening. The data produced led this laboratory to discontinue of 10% random re-screening in October 1992.

Rapid re-screening is the examination of a slide using a $\times 10$ objective, covering as much of the slide as possible in 30 seconds. This is achieved by taking bigger steps between fields of view while maintaining the normal pattern of screening and looking at each field for the usual length of time. In our experience about 35 fields are examined per slide (figure).

All cervical smears interpreted as negative, with or without infection, and those reported as inadequate, all having been screened by one screener only, are included. Rapid re-screening can be performed by any competent cytologist. At the end of a working day smears awaiting rapid re-screening are placed together. It is convenient in this laboratory to carry out rapid re-screening as the first task of the day before commencing routine screening. Each screener takes an equal number of slides, and all screen together with one of the screeners calling "start" and "stop" at 30 second intervals. This is performed without knowledge of clinical details. Any smear thought remarkable by the rapid screener is shown to a senior member of staff. Reports can then be modified if necessary before issue.

Results

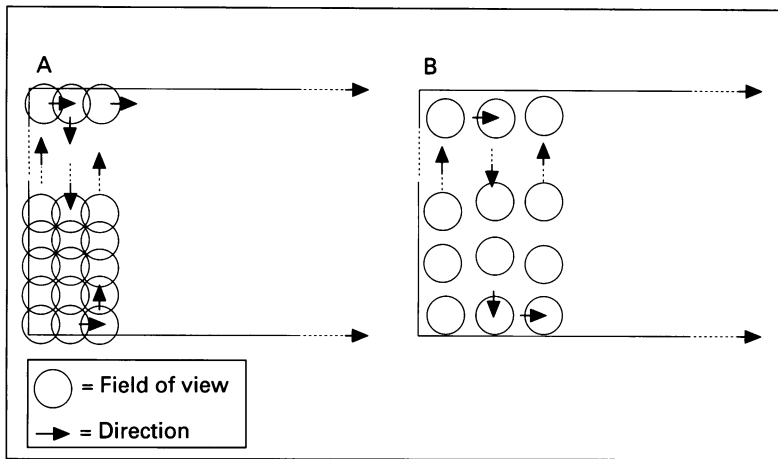
Between June 1990 and December 1994, 142 208 smears were received for screening. Of these, 12 521 were referred to senior staff for checking, of which 9670 were thought to be dyskaryotic. Standard reporting protocols were used.¹¹ Of the total, 5.4% (n=7679) were reported as showing borderline changes or mild dyskaryosis and 1.4% (n=1991) as showing moderate or severe dyskaryosis.

Of the remaining 129 687 negative and inadequate smears, 5437 were fully re-screened for clinical reasons, 24 of which were re-

Department of
Clinical
Cytopathology,
Brighton General
Hospital,
Elm Grove,
Brighton,
Sussex BN2 3EW
A Baker
D Melcher
R Smith

Correspondence to:
Mrs A Baker.

Accepted for publication
24 April 1995



Diagrammatic interpretation of normal (A) and rapid (B) screening.

classified: five as mild dyskaryosis and 19 as borderline changes.

Between June 1990 and September 1992, 10% random re-screening was used routinely in this laboratory. During this period 6360 negative and inadequate smears were re-screened, of which 26 were reclassified: one as moderate dyskaryosis, four as mild dyskaryosis and 21 as borderline changes.

All remaining 117 890 smears were rapidly re-screened, of which 161 were reclassified: five as severe dyskaryosis, nine as moderate dyskaryosis, 27 as mild dyskaryosis, and 120 as borderline changes.

Discussion

We detected a similar error rate on 10% random re-screening and re-screening for a clinically indicated reason. There was no statistically significant difference between the two rates at all confidence levels (see appendix), suggesting that a primary screener is no more likely to miss an abnormality in a smear from a "high risk" patient than from any other. These two methods have therefore been combined and are referred to as a full re-screen. If the detection figures are normalised the false negative rate (FNR), using the standard statistical definition,¹² can be calculated for this laboratory. This equates to 5.3% (all grades including borderline) and 0.50% for moderate and severe dyskaryosis combined. For the purpose of this discussion severe and moderate dyskaryosis will be referred to as high grade dyskaryosis, and mild dyskaryosis and borderline changes with or without evidence of human papillomavirus as low grade dyskaryosis.

The failure of a laboratory to detect high grade dyskaryosis gives most cause for concern, particularly if these women are part of a recall system operating every three to five years. The failure to detect low grade dyskaryosis has debatable importance particularly if women participate regularly in a screening programme. Explanations for false negative results vary, the most likely being scanty dyskaryosis not seen by the screener, incorrect interpretation of the cells on the slide, unexplained breakdown in the reporting procedure—that is, on re-examination of the abnormal slide, the abnormality is obvious and no explanation can be given as to why the abnormality was missed other than that the screener was distracted.

If the above reasons for a false negative report are accepted it is apparent that selected and 10% random re-screening may only detect a small proportion of smears incorrectly reported as negative. In addition, the actual number of missed high grade lesions is likely to be small as they are often easier for the screener to detect on primary screening than low grade dyskaryosis. The abnormal cells often present in larger numbers and morphology is usually distinctive. This is reflected in the FNRs for this laboratory.

Rapid re-screening of the entire negative workload can be performed in roughly the same time as it takes to re-screen fully 10%, less time than 10% re-screening and selected re-screening combined. When this laboratory first began rapid re-screening in 1990 the number of slides extracted and passed to senior staff for checking resulted in a number of these slides being returned as negative. Over time, this has virtually stopped and now most slides passed to senior staff result in the primary screener's report being modified.

We do not suggest that rapid re-screening is a more sensitive method of quality control than full re-screening. If the full re-screening slide numbers are normalised to 117 890, one would expect to detect 505 abnormal cases, of which 10 would be expected to have been high grade dyskaryosis. Rapid re-screening detects only 25% of cases of low grade dyskaryosis and is therefore less sensitive. Rapid re-screening did, however, detect more than the expected numbers of high grade dyskaryosis and suggests a higher FNR of 0.7% for high grade dyskaryosis. When the actual numbers of false negative reports are compared on a cost/time basis, rapid re-screening is far more effective. Three times as many cases of missed low grade dyskaryosis and borderline changes were detected and 14 times as many of high grade dyskaryosis. The primary objective of the rapid re-screening exercise was to detect missed dyskaryosis, particularly high grade. In addition, however, the use of rapid re-screening resulted in the detection of 156 infections missed on primary screening, and 170 smears initially reported as adequate and normal were reassessed as unsatisfactory and a repeat suggested. Five smears reported as unsatisfactory were deemed adequate and normal (table). These incidental findings are not included in the FNR calculations.

Results of re-screening quality control procedures (June 1990 to December 1994)

Result of secondary screen	10% random and selected re-screen (n = 11797)	Rapid re-screen (n = 117890)	Expected (normalised) number in 117890
Borderline changes/mild dyskaryosis	49	147	495
Moderate/severe dyskaryosis	1	14	10
Infection	13	156	
Inadequate	0	170	
Negative (previously inadequate)	0	5	
Total	63	492	

Review of the missed cases of high grade dyskaryosis revealed variable patterns including both small cell and pale cell dyskaryosis. Explanations as to why they were originally missed are not identified. There are a few false negative rates reported in the literature which are difficult to compare as different calculations have been used.^{4,13}

Rapid re-screening detects greater numbers of cases of missed high grade dyskaryosis than any of the other methods examined with respect to the allocation of laboratory resources. What is not apparent is why it is possible to miss dyskaryosis on a full primary screen, but detect it relatively easily in 30 seconds. Screeners do not re-screen their own slides which may account for some interpretative errors. Rapid re-screening is performed as the first task of the day in this laboratory, which may have some bearing, although all staff involved in routine screening take regular breaks, and none spend all of their time in the laboratory at a microscope. Other laboratories in the UK have applied rapid re-screening and have found, although as yet unpublished, similar results.

Rapid re-screening provides valuable data when monitoring laboratory personnel. Melamed⁸ showed that it would take many years to identify a poor screener by accumulation of false negative results detected by the 10% random re-screening technique. Negative smear review, an essential mode of internal quality control, may identify a poor performer¹⁴ but does not prevent the false negative result. The increased number of false negative results detected by the rapid re-screening technique may expedite identification of a poor performer. Individual FNRs can be calculated if accurate records of the individual screeners total output and positive rates are kept and compared. We also keep records of screeners' referral rates to senior staff as together with FNRs these give a guide to the screeners' confidence and competence. The presentation of such data, together with continuous review and correlation, to an individual is a useful educational tool.

In conclusion, 10% random re-screening is an inefficient means of detecting false negative cervical smears, and has been discontinued as a method of quality control in this laboratory. As no significant difference is detected when re-screening selected "high risk" patients, the need to continue this practice is questioned.

This study has shown that rapid re-screening, when compared with 10% random re-screening and selected re-screening, is an effective method of quality control whilst consuming less human resources. It detects higher numbers of false negative results and provides valuable data on the performance of laboratory personnel. Although not the panacea for internal quality control, rapid re-screening should replace 10% re-screening and selected re-screening. When combined with negative smear review and correlated with results obtained, a more effective system of quality control is attained.

- 1 Beilby JOW, Bourne J, Guilleband J, Steele S. Paired cervical smears; a method of reducing the false negative rate in population screening. *Obstet Gynecol* 1982;60:46-9.
- 2 Carney CN. Quality control in cytopathology: A system for simultaneous monitoring of accuracy and education and for proficiency testing. *Acta Cytol* 1984;28:535-45.
- 3 Hindman WM. An approach to the problem of false negatives in gynecologic cytologic screening. *Acta Cytol* 1989; 33:814-18.
- 4 Rohr LR. Quality assurance in gynecologic cytology. What is practical? *Am J Clin Pathol* 1990;94:754-8.
- 5 Wood RJ, Hicklin MD. Rescreening as a quality control procedure in cytopathology. *Acta Cytol* 1977;21:240-6.
- 6 Council on Scientific Affairs. Quality assurance in cervical cytology: The Papanicolaou smear. *JAMA* 1989;262:1672-9.
- 7 Koss LG. The Papanicolaou test for cervical cancer detection: a triumph and a tragedy. *JAMA* 1989;261:737-43.
- 8 Melamed MR. Presidential Address. Twentieth Annual Scientific Meeting, American Society of Cytology. *Acta Cytol* 1973;17:285-8.
- 9 Baker A, Melcher DH. Rapid cervical cytology. *Cytopathology* 1991;2:299-301.
- 10 Boddington MM. Scanning area required for screening cervical smears. In: Evans D, ed. *Cytology automation*. Edinburgh: Churchill Livingstone, 1970:14-23.
- 11 Evans DMD, Hudson EA, Brown CL, Boddington MM, Hughes HE, Mackenzie EFD, et al. Terminology in gynecological cytopathology, report of the working party of the British Society for Clinical Cytology. *J Clin Pathol* 1986; 39:933-44.
- 12 NHS Breast Screening Programme. Publication 22. Guidelines for cytology procedures and reporting in breast cancer screening. London: NHS Breast Screening Programme, 1992:34-5.
- 13 Faraker CA. Partial rescreening of all negative smears: an improved method of quality assurance in laboratories undertaking cervical screening. *Cytopathology* 1993;4:47-50.
- 14 Slater DN. Cervical cytology external and internal quality assurance: a comparative appraisal. *J Clin Pathol* 1995; 48:95-7.

Appendix

Null hypothesis: there is no significant difference between 10% random re-screening and re-screening for a clinically indicated reason. $\chi^2 = 0.092$.

χ^2 values at 1 DF

% Confidence limit	25%	5%	1%	0.1%
χ^2	1.32330	3.844146	6.63490	10.8

$\therefore 0.092 < \chi^2$ at all limits \therefore fail to reject null hypothesis at all levels.