

External Quality Assurance for Cervical Cytology in Developing Countries

Experience in Peru and Nicaragua

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Mortality from cervical cancer in many developed countries has dropped sharply over the last 20 years, and there is now good evidence that a substantial portion of this reduction in mortality is the

outcome of improvements in cervical cancer screening programs.^{1,2} Unfortunately, in developing countries, where mortality rates are often several times higher than in de-

veloped countries and where as much as 80% of patients present with advanced disease,³ these reductions in mortality have not materialized. Failures in developing countries can generally be directly related to failure to achieve adequate quality in ≥ 1 component of a program: definition of the target population, recruitment of women at risk, administration of the screening test, problems at the laboratory level, communication of results to the patient and failure to follow-up (or inadequate follow-up and treatment of) women with positive abnormali-

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ties.^{4,5} By and large, as Miller pointed out,⁵ it is not the test that has failed but other components of the program.

In Nicaragua cervical cancer is the leading cause of death among women aged >35,⁶ and the age-

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standardized mortality rate (15–64) is 18.15 deaths per 100,000.⁷ In Peru, cervical cancer is the leading cause of death in women aged 25–64, causing more deaths among women in this age group than either tuberculosis, maternal conditions or breast cancer.⁸

This article reports on the experience of establishing a proficiency test–based external quality assurance (EQA) scheme for cervical cytology in Nicaragua and Peru based on a system operating in Scotland and Northern Ireland.⁹ It describes how the scheme was adapted to make it acceptable and appropriate for these countries, the difficulties that were encountered in implementation and the strategies used to overcome them. It also asks whether proficiency testing (PT) improves participants' performance and whether PT enables one to identify good and poor performers and assess how good the local panel of experts are at slide selection.

Methods

Problems with the quality of cervical cytology are not peculiar to developing countries. The United Kingdom and New Zealand, to name just 2 developed countries, have experienced serious problems in the quality of cytologic diagnosis that have led to deaths and necessitated recalling thousands of women for repeat smears.^{10–12} In recognition of the difficulties and in response to the problems that have been experienced, many countries, including the U.K., have implemented rigorous EQA schemes for cervical cytology.

The main purpose of such schemes is to ensure that a minimum acceptable standard is maintained and to pursue improvements in quality toward

standards of excellence by a combination of audit and education.¹³ A key element in most EQA schemes is PT, was developed and introduced in laboratories in the United States in 1968 and in the U.K. 20 years later.¹⁴ It involves producing and distributing sets of Papanicolaou-stained cervical smears the diagnoses of which have been agreed by a panel of experts; the sets are examined by all smear-reading staff (primary screener, checkers and pathologists) in the participating laboratories. The tests are marked, and the performance of both individuals and the laboratories as a whole is assessed.¹⁵ The scheme was designed to achieve an unbiased appraisal by an independent external assessor of the performance of all grades of staff who report on cervical smears. Critics of PT question whether the performance of people under test conditions accurately reflects their practice in everyday smear reading. Vooijs and colleagues¹⁶ have pointed out that PT cannot duplicate "normal working conditions" because no "test" can do so. They claim that what is important is the ability to assess and predict the future success of cytopathology personnel to render interpretive and diagnostic decisions based on their current skills. More recent evidence has shown that test performance actually does give some indication of the true performance of screeners.¹⁷ In addition a 14-year longitudinal study of PT results in the Ontario program¹⁸ showed that the degree of reproducibility of reporting was as high as 85–90% and that PT can successfully detect laboratories with suboptimal performance. Although early experience in the U.K. has shown that the scheme is useful at detecting unacceptable levels of performance and specifically is capable of detecting cytologists who consistently perform below an acceptable standard,^{13,19} England has recently abandoned PT.

Neither Peru nor Nicaragua had a functioning EQA scheme before this study commenced. A review of cervical cancer screening in Nicaragua and Peru conducted a year prior to implementation of the program revealed that laboratories in both countries were concerned with the quality of their cytology reading. The heads of the cytology departments and private laboratories claimed that they performed their own internal quality controls, sporadically compared results with colleagues but had no benchmark against which to measure their standards of performance. A random, informal PT round run in 1999 revealed that laboratories had substantial problems with the quality of their read-

ing and that individual and laboratory performance varied enormously between centers.

Development of the PT-Based EQA Scheme in Peru

Meetings with Peruvian Ministry of Health (MoH) officials held in 1999 revealed a strong interest in the creation of a formal quality control mechanism in which the MoH could play a role. However, rather than encouraging the MoH to impose an EQA scheme on laboratories, it was decided to attempt to secure the acceptance of the professionals involved in cytology reading themselves to establish a voluntary scheme. It was assumed that they, more than anybody else, were aware of the problems and were seeking a solution.

Meetings were held with a number of prominent pathologists from Lima and the provinces. These professionals were selected from personal contacts and professional recommendations. The possibility of setting up a PT-based EQA scheme was explained, and this was greeted with enthusiasm. A local panel of experts composed of 4 pathologists and 2 cytologists from 4 institutions was set up with the assistance of the expatriate project staff. The project coordinator also served as the PT facilitator and presided over the meetings of the panel of experts. Before the first round of PT was run, a consultant pathologist from Scotland (then chair of the management committee of PT in Scotland and Northern Ireland) was invited to Peru to provide guidance in establishment of the EQA scheme. Her visit to Peru in 1999 was fundamental in giving credibility to the scheme and in helping the Peruvian professionals understand the process and potential difficulties of establishing an EQA scheme for gynecologic cytopathology. The first round of PT was run in Peru with 10 slides borrowed from the Scottish and Northern Ireland PT scheme and 10 slides selected locally. Subsequently, the panel of experts met before each PT session and selected a local bank slide. This was a difficult task because perception of quality varied enormously between the panel members.

During the panel of experts' regular meeting, the experience with PT was assessed and changes to the scheme made to adapt it to the Peruvian situation. The panel of experts formalized itself, establishing a series of rules for membership in the panel. The panel decided not to formally involve the MoH in the EQA scheme but instead elected to give "ownership" of it to the Peruvian Cytology Society, which, having shown an interest in the scheme and

being a professional scientific organization, was thought to be better placed to support PT and recommend methods and standards of performance.¹⁴ This move granted the scheme a role of professional self-regulation, which created a feeling of real "ownership" among the people involved.

As part of local EQA scheme adaptation, criteria were set for individual and laboratory participation, marking the test and certification. In order to be eligible for certification, laboratories had to comply with the following:

1. All staff members undertake PT.
2. The laboratory must have a minimum annual slide volume of 5,000.
3. At least 1 laboratory member is a pathologist.
4. The laboratory director (pathologist) assumes primary responsibility for evaluating the competency and daily performance of practicing cytologists.
5. The laboratory director takes responsibility for submarginal practitioners.

Staff of laboratories that did not meet these minimum standards were also entitled to participate in PT but on an individual basis. These professionals were entitled to only individual certification, which they could use for employment applications.

Development of the PT-based EQA Scheme in Nicaragua

Nicaragua presents a different scenario from Peru since there is national cervical cancer screening program and cervical cancer represents a lower priority for the MoH. Screening tends to be opportunistic and carried out in conjunction with other reproductive health services. Slides from private/nongovernmental organization clinics are read mainly by individual pathologists rather than registered laboratories, few of which dedicate more than a small proportion of their working time to cervical cytology.

For these reasons it was assumed (incorrectly) that there would be little professional interest in PT or EQA, and therefore it was decided to introduce PT merely as a requisite in the tender for clinical services conducted as part of the broader cervical cancer screening program the project was implementing. However, word quickly spread among pathologists and cytologists, and many laboratories that and individual professionals who did not bid for the cytology services contract asked if they could undergo the test. A formal PT-based EQA scheme was set up in time with a local panel of ex-

perts, which is successfully running to date.

The Test Process

In both countries a complete round of PT consisted of reading 40 slides, some selected by the local panel of experts and some borrowed from the Scottish and Northern Ireland EQA scheme. Tests were carried out twice a year over 2 days, with participants reading 10 slides on each test day. The tests were supervised by the facilitator who initially was the project coordinator and had trained to perform this role in the U.K. Subsequently a local facilitator in both countries was recruited and trained for the job. Individual slide performance was evaluated after every test.

For the purpose of feedback to individuals and certification, performance was assessed from the number of false positives, false negatives and misclassification (only for pathologists) scored in the reading of the 40 test slides. These errors were accumulated, and the matrix used by the Scottish and Northern Ireland scheme⁷ was employed after a complete round of PT to classify participants results as earning a "pass," "borderline" or "fail."

Impact Measurement

To measure the impact of the program over the 3 years (2 in Peru) during which it has been operating, the results from only those individuals with complete PT records were compared. Improvements cannot be measure in terms of changes in sensitivity or specificity in isolation as an improvement in 1 of these parameters may have been made at the expenses of the other. A composite index of performance was created as a weighted average of sensitivity and specificity, giving double the weight to the former, given the greater importance of avoiding false negatives than false positives. The changes in performance between the first and second year (and between the second and the third for Nicaragua) for each participant were simply the difference in the 2 weighted averages, and the overall improvement in program performance was calculated as the mean of individual changes in performance. Change in performance was assessed for statistical significance using a paired *t* test for Peruvian results and a single-sample *t* test for the mean annual change in individual performance for the Nicaraguan results.²⁰

Reliability Analysis

The ability of PT results to enable the identification

of good (and poor) performers was assessed by reliability analysis using Cronbach's α statistic. Again, this tool was applied exclusively to the results of individuals in both countries who completed all tests. Cronbach's α values were calculated for each set of slides in both countries, for each examination session (20 slides) and for each round (40 slides).

Results

Every participant in both countries commented on the difficulties of interpreting U.K. slides because of the much paler Papanicolaou staining used. However, the participants admitted that the U.K. slides were more clear-cut examples of the diagnostic categories. This probably reflects the expertise that U.K. specialists have gained over the years in selecting appropriate test slides. One complete round of PT with 4 examination sessions was run in 2000 and 1 in 2001 in both countries. Nicaragua has an ongoing scheme and has completed its third round of PT.

Experience in Peru

A total of 12 cytology laboratories from the largest hospitals in Peru undertook PT, 6 laboratories in 2000 and an additional 6 in 2001. These laboratories covered the private, public and social security sector. In 2001 PT was also opened to individual participants whose laboratories did not comply with the set requirements. Thirteen professionals from 10 provinces joined the scheme. A total of 92 professionals undertook PT in Peru.

A high level of acceptance of PT was achieved among professionals and is evidenced by requests to enter the EQA process in the 2001 round from 6 new reading centers, all of which process more than 20,000 slides annually. This covered the majority of public and private reading centers in the capital as well as 10 hospitals in the provinces the staff of which had to take the test individually because their laboratories could not qualify for certification.

A major effort has been made in Peru to ensure that the EQA scheme would be sustainable, and 2 strategies were adopted to ensure this. First, the panel of experts decided to grant ownership of the EQA scheme to the Peruvian Cytology Society, which demonstrated great interest in the scheme and was convinced of its utility and acceptability. Second, the panel established that in order to be able to run PT independently, a fee for participation had to be charged to private and social security lab-

oratories. They hoped to convince the MoH to pay the fee for the participation of public sector laboratories.

Discussions were held with the MoH regarding the possibility of formalizing the EQA scheme with official ministerial approval. However, as the project was coming to an end, major political upheavals were occurring in Peru that made further progress on this issue impossible. Since then, the panel of experts in Peru has reinstated PT, and PT is being run through the Society of Cytologists.

Experience in Nicaragua

Twenty-one private and public sector diagnostic centers took part in PT testing between 2000 and 2002. These include tertiary centers, such as the National Reference Center for Cancer (where the bulk of slides from the public sector are read), and many smaller laboratories where cytologists work with no supervision. EQA covers the majority of registered laboratories in the country; to date it is a well-known and respected quality control scheme. A total of 67 professionals have undergone PT over these 3 years, and the institute that currently runs the scheme, the Central American Institute of Health (ICAS), periodically receives new applications to participate in the scheme.

A local panel of experts has been formed by ICAS, and after 2 years of existence it has already changed its membership. The panel meets regularly before the examination to select a bank of slides and after the examinations to evaluate the results. An educational element has been introduced: after each test a review meeting is held where participants can go over each slide under the guidance of the panel of experts.

PT certification seems to have already become a prerequisite of employment in some reading centers and laboratories since candidates are being asked for the results of their PT during interviews.

In addition, MoH has formally contacted ICAS to

discuss the possibility of extending PT to all laboratories serving the public sector in an effort to regulate this field, stimulated perhaps by a new law obliging MoH to implement quality assurance in public laboratories.

Overall Results and International Comparison

Table I provides crude levels of sensitivity and specificity for Nicaragua, Peru and the Scottish scheme over the last 3 complete rounds of PT. The results from all participants in each country were taken into account.

Under the Scottish and Northern Ireland scheme, acceptable performance levels for laboratories are defined on the basis of sensitivity and specificity achieved over 2 rounds of testing (40 slides). The sensitivity and specificity levels for all laboratories together determine the cutoff points for individual laboratory performance in categories of "satisfactory," "intermediate" and "poor." Thus, laboratories achieving sensitivity and specificity within 1 and 2 SD, respectively, of the mean are classified as satisfactory. Intermediate performance is defined as scores lying between 1 and 2 SD for sensitivity and between 2 and 3 SD for specificity. A poor performance grading is given for scores below these cutoff points. Based on these criteria, the two cutoff points for sensitivity in Scotland and Northern Ireland in 2002 were estimated to be 97.8% and 96.0%. For specificity they were 89.4% and 85.5%. During its last 2 rounds of PT (2001), Peru as a whole would have been given an intermediate grading for both sensitivity (96.4%) and specificity (86.7%). Nicaragua as a whole in 2002 would have been graded poor for sensitivity (90.5%) but satisfactory for specificity (92.58%).

In terms of individual performance, the Scottish and Northern Ireland scheme uses a matrix based on the number of false positives and negatives reported in 2 rounds to assess whether individuals have a pass, borderline or fail result.⁷ When apply-

Table I Sensitivity and Specificity Levels in Nicaragua, Peru and the Scottish and Northern Ireland Scheme for 3 Rounds of PT Including All Participants

Country	Year (%)					
	2000		2001		2002	
	Sensitivity	Specificity	Sensitivity	Specificity	Sensitivity	Specificity
Nicaragua	88.94	90.71	89.61	90.84	90.49	92.58
Peru	95.18	88.55	96.39	86.69	—	—
U.K. (mean of all laboratories)	99	96	100	97	99	97

ing this matrix to all 83 participants in Peru in 2001, 53 passed, 11 scored a borderline result, and 19 failed. Of the 31 participants sitting for the 2002 examination in Nicaragua, 14 passed, 8 were borderline, and 9 failed.

Does PT Improve Slide-Reading Performance?

Although it was recognized that some form of continuing education or retraining of professionals is needed to sustain and improve slide reading performance, it was suggested that PT in itself might produce some improvement. Since the project did not include any training component, it was possible to assess this question.

Table II presents mean performance scores (specificity plus twice sensitivity) by country and year for the participants. Although performance increased sharply in Nicaragua between 2000 and 2001, this declined by about the same extent in the following year, leaving no significant overall improvement in performance on either measure ($P = .91$ and $P = .99$, respectively). In Peru, there was no significant change in scores from 2000 to 2001.

Of course, changes in performance could be attributed to differences in the difficulty of the slide sets used. Without reusing slides in successive tests, it is difficult to know whether this is the case. However, an examination of the breakdown of slide diagnoses showed no major variation over time (data not reported).

Can PT Reliably Identify Good Performers?

It has already been pointed out that performance under test conditions does not necessarily correlate with day-to-day work performance. However, it is of interest in any case to know whether the test has any internal consistency. This has been assessed using the Cronbach α statistic, which examines the extent to which individual items in a scale are related to one another. As a rule of thumb, it is usually said that scales with a Cronbach α statistic of $\geq .6$ have reasonable internal consistency.

The Cronbach's α values in Tables III and IV show that the test provides reliable performance in-

dicators only for the reading of 40 slides. The policy of the Scottish and Northern Ireland health schemes to assess performance on this number of slides would appear to be sensible. Cronbach's α values are in fact very low for individual sets of 10 slides, slightly higher for sets of 20 slides (results not shown) and significantly higher for sets of 40 slides. Only Nicaragua's values for sets of 40 slides, however, reach the threshold of .6 (P & Y & B & M with .676; I & V & E & X with .754; and QQ & TT & AA & AB with .743).

Cronbach's α values can also be interpreted in terms of the ability of the panel of expert to select good test slides. The average Cronbach α per set of 10 slides was .467 for U.K. slides but just .292 for slides used in Nicaragua and Peru ($P = .037$).

Discussion

The most clear and important finding from this work was that EQA schemes can be successfully implemented in developing countries. Although it is rather early to assess their impact in Peru and Nicaragua on the quality of cytology, let alone on cervical cancer mortality, important lessons have been learned from the process of adapting the Scottish scheme to a Latin American setting. In particular, 5 factors proved crucial to winning acceptability for the scheme:

1. Voluntary participation (although if the laboratory director agreed to take part, all of its staff were also obliged to).
2. Confidentiality of results.
3. Opportunity to evaluate performance against international standards.
4. Possibility of receiving a certificate issued by distinguished organizations in both countries.
5. Management of PT by a body not linked to any particular laboratory or institution and operating as a form of professional self-regulation rather than being imposed by a regulatory authority.

Given the documented difficulties in adopting a uniform terminology and diagnostic classification worldwide,²¹ at no time was terminology an issue.

Table II Mean Composite Performance Index for Each Year for Each Country and Differences in Performance Scores Between Years

Country	Mean performance score, by year			Change (mean), by year		
	2000	2001	2002	2000-2001	2001-2002	2000-2002
Peru	280.6	281.4	—	0.78	—	—
Nicaragua	273.8	282.5	271.9	9.5	-10.9	-1.0

In both countries professionals are familiar with the cervical intraepithelial neoplasia, World Health Organization and Bethesda terminology. PT was conducted using the British Society for Clinical Cytology (BSCC) terminology²² (translated into Spanish) to start with since the slides borrowed from the Scottish scheme had been diagnosed using this reporting system. The Peruvian panel of experts soon recognized that the BSCC classification offered an advantage over the Bethesda System for the purposes of PT because it has greater number of diagnostic categories available, and so subsequent tests were also carried out using this reporting system.

PT as a quality assurance strategy has advantages over other EQA schemes being introduced into Latin America, such as the Pan American Health Organization-sponsored RED-PAC scheme,²³ because it offers the possibility of evaluating not only laboratories but also individuals' performance within them. PT therefore provides heads of cytology departments with a tool for monitoring the quality of their staffs' work. This is a valuable tool because overall laboratory results all too often mask poor individual performers. The possibility of anonymous comparison of laboratories across the country means that performance can be monitored over time and that overall improvements in standards can be documented. The scheme also allows the countries to compare their performance alongside international benchmarks.

The modifications required for adapting the Scottish and Northern Ireland EQA scheme to Peru were minimal insofar as the PT itself was concerned. What could not be applied was the more general framework of feedback and responsibility between the laboratories, health boards and trusts simply because the health systems in Peru and Nicaragua are structured differently. The EQA scheme does not

Table IV Cronbach's α Values for Nicaragua

Slide set	Origin	Year	Cronbach's α value per set of 10 slides	Cronbach's α value for full set of 40 slides
P	U.K.	2000	.426	.6762
Y	U.K.		.5586	
B	Peru		.3069	
M	U.K.		.2118	
I	Nicaragua	2001	.398	.7544
V	Nicaragua		.2894	
E	Nicaragua		.5036	
X	U.K.		.5323	
QQ	Nicaragua	2002	.2733	.7434
TT	Nicaragua		.1598	
AA	U.K.		.5091	
AB	U.K.		.5656	

prevent standard cytologists from continuing to read smears. Their performance remains the responsibility of the laboratory they work for, and laboratories with standards that fall below acceptable levels are not liable to obligatory suspension as they are (or used to be) in the U.K. Peru is going through a process of slowly creating accreditation systems for the different medical professions, and in time, PT could become part of a laboratory accreditation scheme, as it is in parts of the U.K. with the CPA Ltd. accreditation scheme.

Nicaragua presents a different scenario. Since Nicaragua is a smaller country and the number of pathologists is limited (unofficial figures are 35–40), PT certification is likely to become a prerequisite of individual pathologists and cytologists to be able to practice. The interest the MoH has recently shown in the scheme represents a big step toward implementation of PT at the national level. If this is to happen, it will be important that the EQA scheme remain independently run by an agency that is not part of the MoH (as long as the MoH continues to provide cervical cytologic screening itself).

In what ways has the scheme benefited the participants? Unfortunately, it does not seem to have improved their performance over time. However, most of the professionals involved acknowledged that taking the test and receiving the result made them much more aware of the importance of the accuracy of their reading and gave them a sense of appreciation for their work. This was especially true among cytologists working in remote areas of the country with no technical supervision from a pathologist. Pathologists also commented on the

Table III Cronbach's α Values for Peru

Slide set	Origin	Year	Cronbach's α value per set of 10 slides	Cronbach's α value for full set of 40 slides
P	U.K.	2000	-.0847	.473
B	Peru		.0691	
L	Peru		.0714	
R	Peru		.5822	
DD	Peru	2001	.0326	.5288
KK	Peru		.2889	
HH	Peru		.5919	
SS	Peru		.235	

importance of an external independent evaluation against which to compare their performance since they are the ones cytologists look to for guidance and reassurance. From the beginning it was made very clear to every laboratory involved that there is more to quality control than simply PT and that PT results had to be validated with the everyday performance of individuals in primary screening. Different methods of internal quality control were presented, and 2 laboratories in Nicaragua and 1 in Peru are now experimenting with 100% rapid review of negative cases^{24,25} as an alternative to the revision of 10% of negative slides. In Peru some laboratories have also begun storing negative smears to allow review of the slide in case a patient with a previous negative smear develops cervical cancer. They are also now routinely performing cytohistology correlation.

One danger of a voluntary PT scheme is that participation may be threatened if staff are suspended or fired for failing the test (although it could benefit the patients). There was 1 instance in Peru where a cytologist lost her job as a consequence of poor performance in the first part of the test. There are other cases where professionals have been temporarily suspended because of poor performance. However, these cases have not yet led to a general reaction against PT, perhaps because of the strong support for it from those who pass.

Any quality assurance scheme has to be viewed in a framework of remedial action and training. Probably the largest limitation in the scheme implemented is the fact it was not possible to offer a plan for remedial action for individuals whose performance was not optimal. There is no cytology training center in either country, and the only cytology schools that ever existed in these countries closed in 1997 and 1990, respectively, in Nicaragua and Peru. Refresher courses are not available, and medical school training in cytology is limited. In-service retraining was the only possible recommendation for subperformers. The EQA scheme has highlighted this limitation and inspired the Peruvian Cytology Society to organize refresher courses along the lines of the Scottish practice. Until PT can be offered with the concrete possibility of remedial action, its only advantage is to provide the purchaser of cytology reading services with certification of the quality of their work.

Finally, the ability of local panels of experts to select good slides needs improving: PT is still in its infancy in these countries, and slide selection is ad-

mittedly 1 of the hardest tasks in PT. Given time and guidance, local panels of experts are likely to improve their slide selection.

This experience has shown that the Scottish and Northern Ireland EQA scheme can be successfully adapted to Latin American countries and that it may lead to increased awareness of the importance of monitoring and guaranteeing the quality of cytology services. Despite the initial concerns of some who thought that the scheme might be seen as overbearing or patronizing ("big-brotherish" was a term used by 1 donor), it is clear that there is a tremendous unmet demand from developing-country professionals for the opportunity to engage in continuous professional development of this nature. Assisting them in developing such schemes is a valuable and sustainable use of international development funding.

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