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The United Kingdom national microbiological quality assessment scheme

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SUMMARY A comprehensive microbiological quality assessment scheme for the benefit of all clinical microbiological laboratories in the United Kingdom was established in 1974. The main emphasis of the scheme has been on the supply of simulated clinical material for proficiency testing. Of 494 laboratories currently participating in the scheme, 84 are abroad and over 500 specimens have been distributed between 1974 and 1980. A wide variety of specimens are issued. These include specimens for: general bacteriology including isolation, sensitivity testing and serology; mycobacterial bacteriology; syphilis serology; virus isolation; general viral serology; rubella serology; hepatitis B antigen detection; electron microscopy; mycology; parasitology; antibiotic assay; public health specimens including milk and water. Laboratories are requested to examine the specimens using their routine procedures and report their results to the Microbiological Quality Control Laboratory (MQCL). The reports are analysed at MQCL and the summarised results of each distribution are sent to all participants. Each participant receives details of his individual performance on current specimens and an analysis of the previous 6 months, cumulative performance. The performance of all laboratories is reviewed twice yearly and laboratories with results significantly worse than those of their peers are offered the opportunity to seek advice and help from a National Advisory Panel of their professional colleagues. The Scheme is confidential and its main role is educational.

Quality assurance programmes in pathology laboratories were for many years the exclusive domain of the clinical biochemists who rapidly developed the concepts, materials and statistical methods for quality control within their laboratories and external quality assessment schemes.[1] The quantitative values derived from biochemical analyses are amenable to statistical analysis and widespread automation has facilitated reproducibility of results, reduced the number of methods in use and allowed inclusion of adequate numbers of controls.

The situation in microbiology is more complex. Some microbiological entities may be readily available in pure form—for example, bacteria and viruses, but others may not be—for example, antibodies. Whereas two batches of urea, if sufficiently pure, should behave similarly, two pure strains of bacteria of the same species may commonly differ in growth characteristics and other properties. Bacteria and viruses tend to be unstable in biological specimens and change, both in absolute and relative numbers in a specimen. This, and the wide range of specimens examined in bacteriology makes it difficult to produce control material.

Automation is uncommon in microbiology; a wide variety of methods are used and much of the work is labour intensive, precluding the use of numerous controls. Finally, it is difficult to separate technical procedure from interpretation in microbiology, as in the isolation of micro-organisms the two processes are inherently linked. For these reasons quality assurance programmes in microbiology have been slower to develop than in clinical biochemistry. Quality assurance is not simply a process by which the quality of the final product—that is, the satisfactory performance and interpretation of tests, is measured. Quality assurance is as stressed by Bartlett[2] a total and continuous monitoring of staff, equipment, methods and reagents. Much of the day to day quality assurance work is best conducted within the laboratory and various comprehensive approaches to internal quality control have been described.[2-6] However, the success of the internal quality control procedures in assuring the quality of

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the final product is best assessed by the examination of quality assessment (proficiency testing) samples supplied by an independent laboratory.

External quality assessment programmes for clinical microbiology were first developed in the USA where the wide variety of laboratories examining clinical material caused concern over lack of adequate standards of performance. Since 1966, laboratories which examine any specimens from outside their own state have been required by Federal Law to participate in a recognised quality assessment programme. In addition, most states require such participation by indigenous laboratories. Quality assessment schemes are organised by the Center for Disease Control,[7] the College of American Pathologists,[8] and various state health departments.[9] Quality assessment schemes in Canada[10] and Australia[11] have also been described.

This report describes the development and operation of the UK External Quality Assessment Scheme and presents results from distributions of simulated specimens for bacteriology. Results from distributions of other categories of specimens such as virology and antimicrobial sensitivity testing will be reported elsewhere.

Development of the Scheme

HISTORY OF THE SCHEME

Quality assessment trials in the UK were first organised on a regular and comprehensive basis by the Public Health Laboratory Service (PHLS) in 1971. These early trials, with about 90 laboratories participating, were organised by a number of individual interested microbiologists, with co-ordination, record keeping and computing being provided by the PHLS at the Epidemiological Research Laboratory, Central Public Health Laboratory, Colindale.

Three important though not unexpected findings emerged from these trials: errors in isolation, identification and sensitivity testing occurred; laboratories differed in their overall success rate; most laboratories found participation a useful and stimulating exercise. In view of these findings the Department of Health and Social Security provided funding, through the PHLS, to establish a full time Microbiology Quality Control Laboratory to serve all clinical microbiology laboratories.

The MQCL was established in 1974. Administratively part of the Central Public Health Laboratory at Colindale, the MQCL is situated in the grounds of Neasden Hospital, The staff presently consists of a medically qualified director and his deputy, a chief medical laboratory scientific officer, a graduate principal grade microbiologist, three junior medical laboratory scientific officers and secretarial and maintenance staff. Central service units at Colindale provide facilities for data preparation and processing and the reproduction of documents. Between 1974 and 1979 MQCL functioned as an independent laboratory within the PHLS. However, in 1979 the laboratory was administratively merged with the Standards Laboratory at Colindale to form the new Division of Microbiological Reagents and Quality Control.

FUNCTIONS OF THE MQCL

Possible functions for a microbiological quality control laboratory are:

1 To provide simulated specimens for examination by clinical microbiology laboratories as part of an external quality assessment scheme.

2 To monitor the performance of laboratories in examination of simulated specimens and to identify laboratories whose performance is significantly worse than their peers.

3 To identify faulty techniques and reagents by correlating these factors with the results of examination of simulated specimens.

4 To initiate educative programmes to remedy deficiencies revealed by the examination of simulated specimens.

5 To encourage the development and introduction of standard methods where poor results are shown to be associated with a wide diversity of methods.

6 To help develop and produce manuals and materials for use by laboratories in their own individual quality control procedures.

7 To monitor and assess the performance of commercially produced media and reagents.

Until recently MQCL has been fully occupied with the first two activities. Where this quality assessment has occasionally revealed deficiencies in media, methods or reagents, the problems have been investigated. However, any large scale consistent involvement in this field is at present outside the resources available to MQCL.

The Standards Laboratory at Colindale performs quality control on their own range of reagents and to a limited extent on commercially produced reagents. The merging of Standards Laboratory and MQCL into a single Division provides opportunities for the development of quality control of reagents.

General bacteriology distributions

PARTICIPANTS IN THE SCHEME

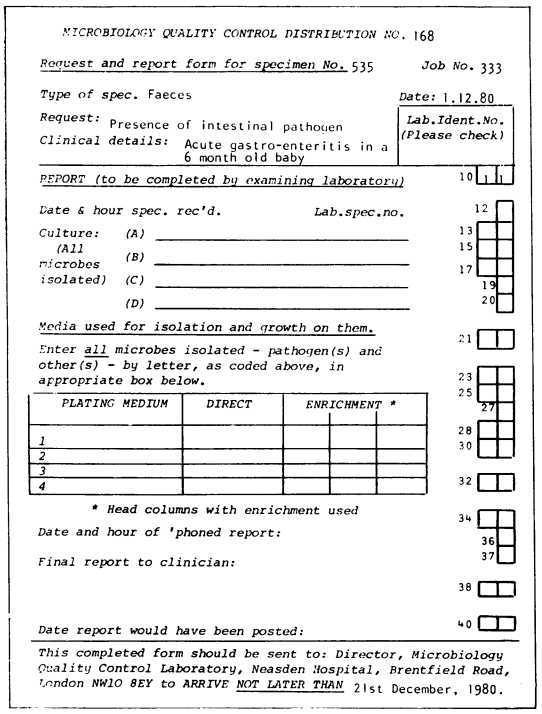
The number of laboratories currently participating in the Scheme is 494. The Scheme is intended primarily for the benefit of public health and clinical

microbiology laboratories in the UK, and 321 of the laboratories are in England, 30 in Wales, 38 in Scotland and 13 in Northern Ireland. Ninety-two of the laboratories are foreign, mainly in Europe. Of the participants, 353 are hospital laboratories, 58 are public health laboratories including 52 PHLS laboratories of which 50 are associated with hospitals, 13 are university laboratories, 19 are armed forces laboratories and 51 represent a miscellany of commercial, veterinary and water board authority laboratories.

To preserve confidentiality each laboratory, on joining the Scheme, is allocated a unique MQCL code number for all filing and computer operations within MQCL.

OUTLINE OF THE GENERAL BACTERIOLOGY SCHEME

Simulated specimens are prepared at MQCL and despatched by post to participants. Normally three specimens are included in each monthly distribution. Requests and Report forms (Fig. 1) accompany the specimens together with an instruction sheet which also gives prominent warning of the possible presence of pathogenic bacteria in the specimens.



MICROBIOLOGY QUALITY CONTROL DISTRIBUTION NO. 168

Request and report form for specimen No. 535 Job No. 333

Type of spec. Faeces Date: 1.12.80

Request: Presence of intestinal pathogen

Clinical details: Acute gastro-enteritis in a 6 month old baby

Lab.Ident.No. (Please check)

REPORT (to be completed by examining laboratory)

Date & hour spec. rec'd. Lab.spec.no.

Culture: (A) _____

(All microbes isolated) (B) _____

(C) _____

(D) _____

Media used for isolation and growth on them.

Enter all microbes isolated - pathogen(s) and other(s) - by letter, as coded above, in appropriate box below.

PLATING MEDIUM	DIRECT	ENRICHMENT *		
1				
2				
3				
4				

* Head columns with enrichment used

Date and hour of 'phoned report:

Final report to clinician:

Date report would have been posted:

This completed form should be sent to: Director, Microbiology Quality Control Laboratory, Neasden Hospital, Brentfield Road, London NW10 8EY to ARRIVE NOT LATER THAN 21st December, 1980.

Fig. 1 *Request and report form from a general bacteriology distribution.*

The participating laboratories are asked to examine the specimens according to their routine procedures and return the completed reports to MQCL within a specified period. The details on the report forms are then translated into numerical codes suitable for computer analysis and transferred to punched cards. The data is then analysed by computer and various tables are produced. Selected information on the overall results of the distribution is condensed into a summary which is sent to all participants. Each participant also receives a computer produced printout (Fig. 2) showing details of their individual current and past performance. Twice a year the previous six months results are analysed in order to find laboratories whose performance is significantly worse than average. Laboratories participate in the Scheme under conditions of strict confidentiality and the educational aspects of the Scheme are foremost.

SIMULATED SPECIMENS FOR ISOLATION OF BACTERIA

The majority of simulated specimens for isolation and identification of bacteria are mixed cultures of a recognised pathogen and one or more commensals. Although single strains are sent when appropriate—for example, from blood cultures, urines or cerebrospinal fluid, these pure cultures mainly test identification procedures and should present no problem in isolation. Mixtures of bacteria test the isolation media used and the ability to recognise and isolate pathogens from a mixture. The stringency of the test can be varied according to the ratio of pathogen to commensal and the relative sensitivity of the two to selective agents.

The strains used in the preparation of simulated specimens are originally isolated from clinical material. They are kept as freeze-dried cultures in the MQCL and are thoroughly characterised to ensure that they are typical strains by all commonly used diagnostic criteria.

Until recently the majority of specimens have been prepared in a semisolid transport medium consisting of 0·156% (wt/vol) sodium dihydrogen orthophosphate in deionised water, neutralised with N NaOH and semisolidified with 0·3% (wt/vol) agar. This method of preparation is inexpensive in terms of materials and apparatus and provides adequate preservation of many of the enterobacteria and hardier Gram-positive organisms. The physical appearance of the specimen approximates to that of some types of patients' specimens received in the laboratory and facilitates the treatment of quality assessment specimens as routine. However, there are a number of serious drawbacks associated with preparation of simulated specimens in transport media. All simulated specimens must survive the

MICROBIOLOGICAL QUALITY CONTROL

Laboratory xxx Distribution 168, 1st December 1980

Specimen numbers	533	534	535
Microbes isolated	Staph.aureus	Proteus	EPEC+prob.contam
1st identification	Staph.aureus	not relevant	EPEC 0128
2nd identification			
Your result judged	Right	Wrong	Right
Reason if wrong	Not applicable	Microbes isolated	Not applicable

Your sensitivity results

Specimen number 536

Ampicillin	S2	Cephaloridine	S2	Gentamicin	S2
Sulphonamide	S2	Trimethoprim	S9	Cotrimoxazole	S9

2 indicates a correct result, 0 an incorrect result, 9 means not scored. For the 5 specimens you have recently been sent for sensitivity testing you have scored 42 (095%) out of your possible total of 44.

18 specimens have been submitted to your laboratory recently. You have had 14 right (93 % of those reported on) and 1 wrong. An average laboratory examining the same specimens as you would have had 13.28 right. Your score is 0.6 .

You have stated that you do not usually examine 00 of the recently despatched specimens. 00 of your reports arrived late. No reports whatever was received for 03 specimens.

Fig. 2 *Computer produced print-out showing details of an individual laboratory's current and past performance.*

normal postal journey with an additional margin allowed for delays in transit. From analysis of postal delivery times it is calculated that specimens must remain in good condition for at least seven days and longer if they are sent to laboratories abroad. Some of the more delicate bacteria—for example, *Neisseria* and *Haemophilus*, showed poor survival experimentally and could not be included in simulated specimens. Apart from gross loss of viability, some strains declined in numbers during storage and others multiplied thus altering relative numbers of pathogen and commensal in mixtures and presenting a different level of difficulty depending on when the specimen was received.

Quality control of these simulated specimens in the MQCL was difficult as they had to be prepared shortly before despatch and where deficiencies were revealed there was usually insufficient time to replace the specimens. To overcome these problems, freeze-drying of specimens containing the more delicate pathogens was introduced in 1978 and this method is now used for all simulated bacteriology specimens. Individual strains of bacteria or mixtures are freeze-dried in butyl rubber capped vials in a 5% (wt/vol) inositol/horse serum suspending medium.[12] The long term stability of these freeze-dried specimens has yet to be established but can at least be measured in months rather than days. Thus adequate time is available for quality control before despatch and all participants receive comparable specimens. This stability also allows issue of replicates of simulated specimens on request to laboratories who failed to obtain the correct answer on the first testing. An additional advantage of freeze-dried specimens for quality assessment is that the material, although stable in the dry state, deteriorates rapidly after reconstitution. This prevents laboratories from making an unrealistic number of repeated attempts on the specimen after initial failure to isolate any pathogens.

The main disadvantage of freeze-dried specimens is the complete lack of resemblance to patients' specimens and the consequent difficulty of ensuring that they do not receive special attention in the laboratory. A further problem is that some strains of various species show atypical growth characteristics on reconstitution. It is therefore necessary to select strains that appear to be least affected by freeze-drying.

POSTAGE OF SPECIMENS

Each distribution and each specimen is given a unique MQCL number. After preparation and quality control the specimens are packed into Post Office approved cardboard boxes together with request and report forms and instruction sheets.

Addressed labels are produced by computer only for laboratories registered as wishing to receive the particular category of the distribution. The computer produces a list of the MQCL code number of these laboratories allowing the receipt of returned reports to be recorded. Five laboratories distant from the MQCL receive duplicate specimens of which one set of each is posted back to the MQCL and examined as a check on survival of the specimens in the post.

DISTRIBUTION

Each specimen is accompanied by a request and report form (Fig. 1) which is labelled with the unique MQCL code number of the laboratory to which it is sent. Various colours of forms are used matching the colour of the specimen labels to reduce the chances of transposition of the specimens in the MQCL and the recipient laboratories. The nature of the simulated specimen, the investigation required and a brief clinical history are given. The amount of detail given in the clinical history and the specificity of the request vary according to the nature and content of the specimens. With specimens such as faeces or wound swabs where a wide range of pathogens would normally be sought, a short clinical history and general request such as "? pathogens present" is usual. If the specimens contain bacteria infrequently encountered in the UK, mention that the patient had been abroad would be made. With rarer pathogens and those causing specific diseases such as *Corynebacterium diphtheriae* and *Clostridium tetani*, a more specific history and request would be given. Laboratories are requested to record details of the microbes isolated according to media and, in some cases, methods used, and the form of the report that would be made to a clinician. For most specimens, approximately three weeks are allowed between despatch of the specimens and the date up to which reports are accepted at the MQCL. Although recognised as an unrealistically long period, giving laboratories the opportunity to spend longer than normal time on the specimens, it is necessary to allow this period for delays in transit of specimens and reports. The receipt of each returned report form is recorded on a computer-produced list of laboratories receiving the specimens. At the end of the stipulated period a brief statement of the intended result is sent to all participants and reports received subsequently are not analysed. Selected information from each report form is translated into a numerical code by the MQCL staff and each report is assessed as right or wrong. All reports are individually assessed by a senior microbiologist before the coded results are transcribed to 80 column punched cards.

ANALYSIS OF RESULTS

Data are processed using a Hewlett Packard 9830A minicomputer with 4 kilobytes of Ready Access Memory and 2·4 megabytes of hard disc memory. Software is written in BASIC. The analysis of results is essentially in two parts: data from the current distribution are sorted and tables and listings are produced giving details of overall results for the distribution; various cumulative files are up-dated to provide long-term computer-stored records. These records are searched automatically by the computer to assess, and provide monthly statements of each individual laboratory's cumulative performance over a selected time span. A summary of the overall results of the distribution is written. Details are recorded of organisms isolated, identification levels reached and results according to the various methods or media used. Any points of interest arising are discussed as are common sources of error if these can be identified. These summaries are sent to all laboratories taking part in the distribution.

Each participant receives a print-out (Fig. 2) showing details of their own individual results. The first part of the print-out shows details of the participant's results for the three specimens in the current distribution. The names of the microbes isolated and the identification made are printed together with the MQCL assessment of the result. If the result is judged wrong, a brief reason is given—for example, wrong organism(s) isolated or wrong identification.

The second section of the print-out shows results of antibiotic sensitivity tests. General bacteriology distributions used to include one specimen for which sensitivity tests were requested on the pathogen included, but the large number of discrepancies obtained has prompted the introduction of a new trial sensitivity scheme to be fully considered elsewhere.

The third section of the print-out shows details of the participant's performance in specimens distributed over the previous six months. The specimens included in this analysis change after each distribution, with results from the current three specimens replacing results from the earliest three. The number of specimens sent to the laboratory in the previous six months is stated together with the number for which the participant was judged as right and wrong. The number of correct results that would have been achieved by a hypothetical average laboratory examining the same specimens is given, together with the participant's score (see later). Finally, the number of late and non-returned reports and specimens not examined is given.

ASSESSMENT OF PARTICIPANTS' RESULTS

The criteria and the level of assessment used in

scoring participants as right or wrong have a profound effect on the apparent performance standards of participants. In general both recognition of the presence of an entity namely, isolation of a pathogen, and subsequent qualification—that is, identification of a bacterium, are assessed. Thus in specimens for isolation of bacteria an attempt is first made to evaluate which organisms have been isolated by the participant, regardless of subsequent identification. Failure to isolate the intended pathogen or stated isolation of a pathogen not present in a specimen are both regarded as incorrect results. Where the intended pathogen has apparently been isolated, the identification of the isolate is evaluated as right or wrong. Thus successful isolation of *Corynebacterium diphtheriae* with subsequent misidentification as *C xerosis* results in the laboratory being scored as incorrect. The setting of a level of acceptability of identification raises some problems. The level of identification attempted will vary between laboratories according to the genus of the pathogen and the stated site of isolation. The decision on the degree of identification necessary or desirable for any group of bacteria is in many cases a subjective judgement based on the individual interests of microbiologists and clinicians. Even where a consensus exists as to the level of identification necessary, it may be the practice of laboratories to refer isolates after preliminary screening tests. In the past MQCL has accepted each individual participant's assessment of the level of identification necessary and he has been held accountable only to the level at which he has elected to identify the strain. Thus identifications of a *Shigella flexneri* type 1a as *Shigella* sp, *Shigella flexneri*, *Shigella flexneri* type 1 and *Shigella flexneri* type 1a would all be judged correct whereas identification of not a *Shigella*, *Shigella* sp, other than *flexneri*, *Shigella flexneri* type other than 1 and *Shigella flexneri* type 1 sub type other than 1a would all be judged as wrong.

Although this method of assessing results is relatively simple to apply and relieves the MQCL from having to make value judgements for each specimen, it does suffer from two major disadvantages. Firstly, a laboratory making the trivial (from the clinical viewpoint) error of identifying a strain of *Shigella flexneri* type 1a as *Shigella flexneri* type 1b, is marked wrong together with those who failed to either isolate or recognise the shigella. The second disadvantage of this method of assessment is that laboratories achieving a very minimal level of identification are marked as correct together with those achieving a much more detailed level of identification. Although the adequacy of an identification of unnamed *Shigella* sp from a stool sample is arguable, presumably few would regard an identification of unnamed *Neisseria* sp from a urethral swab as acceptable. In order to overcome these deficiencies a quantitative scoring system (see later) is currently being assessed for future use.

Identification of poor performers

Twice yearly the results of the previous six months' 18 or so specimens are analysed by computer to identify laboratories whose performance is significantly worse than the average. Only the results of general bacteriology specimens have so far been included in the analysis. Only specimens considered fit for interlaboratory comparisons are included, with obvious unsatisfactory specimens being excluded. The statistical analysis, which has been discussed by Tillett and Crone,[13] is carried out in two parts. Firstly, the modified χ^2 test of Cochran[14] is applied, to give assurance that the differences in the success rates between laboratories cannot reasonably be ascribed to chance. A second stage is then carried out to identify laboratories with poor performance.

The performance of laboratories cannot be compared simply on the basis of numbers of correct and incorrect results as specimens differ in difficulty and not all laboratories will have reported on all the specimens distributed. Some 3% of laboratories do not report on a given type of specimen routinely and some simply do not return the report forms or return them too late for analysis. The performance of each laboratory is therefore assessed by comparison with the results that would have been achieved by the hypothetical average laboratory examining the same specimens. A score for each laboratory is calculated according to the formula:

$$\text{Score} = \frac{\text{Number of specimens correct} - \text{Number correct by average laboratory}}{\text{Standard error of the number correct by average laboratory}}$$

The score thus calculated expresses a laboratory's results in terms of numbers of standard errors above or below the results of the average laboratory. Thus positive scores indicate results better than average and negative scores indicate results worse than average. By convention, scores are considered significant at the 95% confidence limits and laboratories with scores below $-1{\cdot}96$ are considered as poor performers.

As the Scheme is purely educational and entirely confidential a considerable amount of thought has been given to the problems involved in offering advice and assistance to a poorly performing laboratory and the following protocol has been adopted. A National Advisory Panel for Microbiology has been established and comprises repre-

sentatives from the Royal College of Pathologists, the Association of Clinical Pathologists, the Institute of Medical Laboratory Sciences and the Pathological Society of Great Britain and Ireland. This Panel exists solely to offer advice and assistance to laboratories experiencing problems with their performance. The Panel is notified by the Director of the MQCL of any laboratories with scores of less than −1·96 in a single six month period by their unique code numbers. The Panel is provided with a record of the scores of the laboratory over previous six month periods together with a detailed computer produced record of the participant's results in the six month period currently under review (Fig. 3). The Panel may then decide to write to the director of the laboratory concerned, advising him of the laboratory's poor performance and inviting him to contact any member of the Panel for advice and help. This letter is prepared and posted from the MQCL and it should be emphasised that the Panel remains ignorant of the identity of the laboratory concerned. If poor performance persists over the next six month period without the director seeking advice of the Panel then the laboratory's record is again examined by the Panel and if found necessary the identity of the laboratory is revealed to the Panel. At this stage the Chairman of the Panel makes a personal approach to the director of the laboratory concerned.

The number of poor performers in the UK clinical laboratories between 1977 and 1980 is shown in Table 1. The number concerned is very small, at present accounting for only 0·6% of clinical laboratories in the UK. As poor performance is defined in terms of standard error, the total number of poor performers (including UK clinical laboratories and all other categories) will remain approximately constant, allowing for such factors as irregularities and skew in the distribution and will not be affected by the difficulty of the specimens. There is therefore a suggestion of relative improvement in the performance of UK laboratories between 1977 and 1980 although the numbers involved are too small to justify any firm conclusions.

Results of distributions of simulated specimens for bacteriology

The percentage of laboratories with correct results in the various specimens is shown in Tables 2-4. Little importance can be attached to the results of individual specimens as successive specimens may vary in difficulty, both by design, and in the case of specimens in transport media, by accident. The degree of difficulty of a specimen may be controlled by altering the relative numbers of pathogen and commensal, and in specimens where selective media would normally be used, by inclusion of commensals of various degrees of resistance to the selective agents used. In the case of specimens in transport media,

Laboratory number xxx

Specimen number	Assessment of report	Reason if wrong	Pathogen included	Other organisms	Percent correct
490	right		Staphylococcus aureus	Proteus	99
491	right		No pathogen	acinetobacter+micrococcus+Strep.	98
492	right		Shigella flexneri type 4	hafnia+E.coli	79
493	wrong	isolation	Streptococcus pyogenes	proteus	97
494	wrong	identification	Staphylococcus aureus	Clostridium sordelli	69
495	right		Salmonella paratyphi B	coliforms	96
502	right		Haemophilus influenzae type B	Staph. albus	93
503	right		No pathogen	C. xerosis/neisseria/strep	88
504	right		Shigella boydii	E.coli	95
517	right		Listeria monocytogenes		95
518	right		Clostridium perfringens	proteus/ strep/ staph	97
519	wrong	identification	Vibrio cholerae	E. coli	94
526	right		Streptococcus group A	S.albus/S.viridans/N.pharyngis	99
527	wrong	isolation	N.gonorrhoeae	E.coli/S.albus/S.viridans	93
528	wrong	isolation	No pathogen	providence/coli/klebsiella	98
533	right		Staph. aureus	Staph. albus/micrococcus	99
534	wrong	isolation	Bacteroides melaninogenicus	Proteus	32
535	excused		E.coli 0128	E.coli	83

Fig. 3 *Computer produced print-out showing results of a laboratory in the previous six months' specimens.*

Table 1 *The number of laboratories in the UK showing poor performance between 1977 and 1980*

	1977		*1978*		*1979*		*1980*
	Jan-Jun	*Jul-Dec*	*Jan-Jun*	*Jul-Dec*	*Jan-Jun*	*Jul-Dec*	*Jan-Jun*
No of poor performers	8 (2·6%)	7 (2·2%)	3 (0·9%)	6 (1·7%)	7 (2·0%)	3 (0·8%)	2 (0·6%)

Numbers in parentheses are the number of poor performers expressed as a percentage of the total number of UK clinical laboratories in the scheme during the appropriate six month period.

unintentional variation in difficulty may arise, due to decline in numbers of the pathogen or increase in numbers of the commensals during transportation. The introduction and subsequent growth of unintended contaminants—undetected by the limited predespatch quality control possible is another uncontrolled factor affecting the difficulty of specimens in transport media. The results of specimens that were known to have been grossly unsatisfactory have been omitted from the Tables but it is possible that some of the poorer earlier results of specimens before the introduction of freeze-drying are due in part to these uncontrolled factors.

GRAM-POSITIVE BACTERIA (Table 2)

Gram-positive cocci

The general standard of performance for this group of bacteria is good. The lower success rates with certain of the specimens containing *Staphylococcus aureus* and *Streptococcus pyogenes* are associated with failure to isolate the pathogen from mixtures containing *Proteus* sp. Failures with specimens containing group B streptococci were equally distributed between failure to isolate the streptococcus and incorrect identification. Failures with specimens containing group C streptococci were mostly associated with misidentification, usually as group A streptococci.

Clostridia

Difficulties with *C tetani* were mostly associated with failures in isolation. *C perfringens* was usually easily isolated and identified with the exception of a strain not producing lecithinase, with which only 81% of laboratories succeeded. With *C oedematiens*, failures were equally distributed between failure to isolate and misidentifications, the most common of which was as *C perfringens*.

Bacillus cereus

This organism was sent in simulated faeces from a queried case of food poisoning. Most failures with this specimen were due to failure to isolate the strain, probably due to many laboratories not considering this organism as likely to have caused the symptoms described and therefore not using appropriate media.

Listeria monocytogenes

Failures with this species were mainly due to failure to isolate the strain. This apparently hardy species has on occasions shown inexplicable and irregular loss of viability in transport medium.

Corynebacterium diphtheriae

Failures with *C diphtheriae* were almost equally divided between misidentification of species and

Table 2 *Percentage of laboratories with correct results in successive specimens containing Gram-positive bacteria distributed between 1974 and 1980*

Gram-positive bacteria	*Percentage of laboratories correct in successive specimens. Results from unsatisfactory specimens have been omitted*	*Average % correct*
Staphylococcus aureus	79,* 99, 100, 75,* 97, 96, 97, 98, 96, 91, 82,* 99, 98, 99, 99	94
β-haemolytic streptococcus group A	92, 71,* 90, 85,* 87, 97, 97, 70,* 89,* 92, 99, 97, 99	90
β-haemolytic streptococcus group B	77, 66, 83, 84	78
β-haemolytic streptococcus group C	93, 83, 95, 87	90
Streptococcus pneumoniae	98, 98, 99	98
Streptococcus sanguis	98	98
Clostridium tetani	84, 85, 97, 89, 94	90
Clostridium perfringens	83, 98, 97, 97, 81,† 97, 98, 98, 97, 99	95
Clostridium oedematiens	58, 70	64
Bacillus cereus	64	64
Listeria monocytogenes	95, 76, 98, 92, 77, 95	89
Corynebacterium diphtheriae	79, 88, 85, 92, 92, 91	85

*These specimens also contained *Proteus* sp.
†The strain of *Clostridium perfringens* in this specimen did not produce lecithinase.

Table 3 *Percentage of laboratories with correct results in successive specimens containing Gram-negative bacteria distributed between 1974 and 1980*

Gram-negative bacteria	*Percentage of laboratories correct in successive specimens. Results from unsatisfactory specimens have been omitted*	*Average % correct*
Bacteroides fragilis	98, 87, 95, 92, 88	92
Salmonella spp	99, 85, 89, 80, 86, 94, 96, 79, 95, 99, 96	91
Salmonella indiana (lactose positive)	42	42
Shigella sonnei	95, 92, 91, 96, 77, 97, 89, 98, 98, 97	93
Shigella flexneri	98, 90, 63, 90, 89, 94, 79, 79	85
Shigella boydii	86, 84, 90, 82, 91, 95	88
Shigella dysenteriae	27, 36	32
Vibrio cholerae	90, 93, 83, 94	90
Enteropathogenic *E coli*	91, 95, 78, 97, 94, 94, 95, 83	91
Yersinia enterocolitica	90, 76, 88, 92, 93	88
Vibrio parahaemolyticus	70	70
Shigella + *Salmonella* mixture	51, 75, 80	67
Pseudomonas aeruginosa	100, 96, 95, 81, 88, 98	93
Pasteurella multocida	97, 97	97
Serratia marcescens	93	93
Haemophilus influenzae	90, 94, 93	92
Neisseria meningitidis	89, 94	92
Neisseria gonorrhoeae	75, 81, 93	83
Bordetella pertussis	66, 77, 85	76

Table 4 *Percentage of laboratories with correct results in successive miscellaneous negative specimens distributed between 1974 and 1980*

Specimens	*Percentage of laboratories correct*	*Average % correct*
Negative faeces	98, 97, 98, 96, 95, 99, 97, 98, 99, 98	98
Negative urethral swabs	88, 99, 98	95
Negative nasal swab (*S aureus* queried)	87	87

ailure to demonstrate toxin production by laboratories testing this property.

GRAM-NEGATIVE BACTERIA (Table 3)

Enteric pathogens

Simulated faeces may vary enormously in difficulty of isolating the pathogen depending on the relative numbers of pathogen and coliforms and the degree of growth of the coliforms on selective media. Laboratories are mainly successful with specimens containing enteropathogenic *E coli*, salmonellas and *Shigella sonnei* although specimens containing mixtures of salmonella and *Shigella sonnei* cause problems despite strong hints contained in the clinical details. The majority of laboratories failed to recognise the presence of a lactose fermenting salmonella, *S indiana* in one specimen. Shigellas other than *Sh sonnei* prove more difficult. In cases where other non-lactose fermenting coliforms were included in the mixture, it is not always possible to ascribe failure to isolation of identification. Two different strains of *Shigella dysenteriae* presented particular problems. The first strain was distributed in transport medium and the high failure rate was assumed to be due to deterioration or the specimen. However, the second specimen was freeze-dried and the repeat high failure rate would appear to indicate a genuine difficulty with this species, which is seldom encountered in the UK. Most laboratories were successful in growing and recognising *Vibrio cholerae* and *Yersinia enterocolitica*.

Other Gram-negative bacteria

Of the remaining Gram-negative bacteria, *Bordetella pertussis* and *Neisseria gonorrhoeae* presented the most difficulty, failures in both being mainly associated with isolation. Preparation of satisfactory specimens containing these species is not easy as both tend to be damaged by freeze-drying and growth directly after reconstitution may be atypical.

NEGATIVE SPECIMENS (Table 4)

The number of negative specimens reported as containing pathogens is a cause for concern. Serious errors were found with a simulated urethral swab containing *Moraxella phenylpyruvica*, which 12% of laboratories identified as *Neisseria gonorrhoeae*. Even more surprising was the fact that 13% of laboratories identified a coagulase negative, DNAase negative *Staphylococcus albus* as *Staphylococcus aureus*. Pathogens are often found in negative simulated faeces and these have included *Shigella boydii*, *Shigella dysenteriae*, *Shigella sonnei*, *Sal-*

Table 5 *Level of identification of pathogens reached by participants examining simulated specimens*

Pathogen in specimen	*Percentage of laboratories identifying to level stated**
Bacteroides fragilis	Anaerobic Gram-negative rod 1, *Bacteroides* sp 37, *B fragilis* 62
Bordetella pertussis	*Bordetella* sp 3, *B pertussis* 97
Clostridium oedematiens	*Clostridium* sp 65, *C oedematiens* 35
Clostridium perfringens	*Clostridium* sp 3, *C perfringens* 97
Clostridium tetani	*Clostridium* sp 3, *C tetani* 97
Corynebacterium diphtheriae	*Corynebacterium* sp 4, *C diphtheriae* 96
Enteropathogenic *E coli*	untyped "EPEC" 4, polyvalent 5, 0 type 91
Haemophilus influenzae type B	*Haemophilus* sp 5, *H influenzae* 59, type B 36
Listeria monocytogenes	*Listeria* sp 3, *L monocytogenes* 97
Mycobacterium tuberculosis	AFB 30, *Mycobacterium* sp 20, *M tuberculosis* 50
Neisseria gonorrhoeae	*Neisseria* sp 3, *N gonorrhoeae* 97
Neisseria meningitidis group B	*Neisseria* sp 3, *N meningitidis* 73, group B 24
Pasteurella multocida	Gram-negative bacillus 1, *Pasteurella* sp 6, *P multocida* 93
Pseudomonas aeruginosa	*Pseudomonas* sp 12, *P aeruginosa* 88
Miscellaneous *Salmonella* species	*Salmonella* sp 31, 0 group 23, single H phase 13, both H phases 23
Salmonella typhimurium	*Salmonella* sp 15, 0 group 11, single H phase 5, both H phases 69
Serratia marcescens	Coliform 5, *Serratia* sp 32, *S marcescens* 63
Shigella boydii	*Shigella* sp 2, *Sh boydii* 82, type 16
Shigella dysenteriae	*Shigella* sp 1, *Sh dysenteriae* 34, polyvalent 37, type 28
Shigella flexneri	*Shigella* sp 3, *Sh flexneri* 43, type 35, subtype 19
Shigella sonnei	*Shigella* sp <1, *Shigella sonnei* 100
β-haemolytic streptococcus group A	β-haemolytic streptococcus 4, group A 96
β-haemolytic streptococcus group B	β-haemolytic streptococcus 8, group B 92
β-haemolytic streptococcus group C	β-haemolytic streptococcus 10, group C 90
Yersinia enterocolitica	*Yersinia* sp 1, *Y enterocolitica* 99
Vibrio cholerae eltor	*Vibrio* sp 4, *V cholerae* 78, eltor 18

*Percentage values are largely averages from several specimens.

monella spp (various) *Salmonella typhimurium*, *Salmonella paratyphi* C, *E coli* 0125, *E coli* 0127, *Yersinia enterocolitica*, *Vibrio cholerae* and *Vibrio parahaemolyticus*.

LEVELS OF IDENTIFICATION

The levels of identification achieved by laboratories for various species are shown in Table 5. The level of identification varies according to both genus and species. In general, the most frequently encountered pathogens of a genus are fully identified whereas less commonly encountered pathogens are partially identified. The wide availability of reference facilities for some organisms—for example, salmonella, encourages a low level of identification with later referral. Smaller laboratories may refer many of the less commonly isolated pathogens to parent laboratories. However, it is surprising that such common pathogens as *Streptococcus pyogenes*, *Clostridium perfringens*, *Neisseria meningitidis*, *N gonorrhoeae*, *Haemophilus influenzae* and *Pseudomonas aeruginosa* are not universally identified to species level.

Discussion

Simulated specimens supplied by the MQCL now form a regular and reliable means for individual laboratories to monitor the effectiveness of their internal quality control procedures.

The general standards of performance of public health and clinical laboratories are apparently good. However, the level of success measured by the Scheme is almost certainly artificially high. Specimens from the MQCL are clearly identifiable and are almost certainly given special attention in most recipient laboratories as directors are concerned that their laboratory should score well in the Scheme. This motivation passes down the chain of command from the chief medical laboratory scientific officer to the juniors working at the bench, each anxious to avoid recrimination in the event of failure. Results obtained by individual laboratories are often corroborated through an unofficial telephone network of colleagues in other laboratories. It may be argued that such special attention to simulated specimens is not necessarily counterproductive as it enables laboratories to identify and investigate problems immediately rather than waiting until results are available from the MQCL. Some laboratories split simulated specimens into two aliquots, with one being examined by the junior working on the appropriate routine bench and the other by a senior member of staff. This may be a useful approach as failure by the junior and success by the senior probably indicates inadequacies in staff training and failure by both may indicate problems with media or methods. A few particularly conscientious participants adopt this approach but report to MQCL only the results obtained by the routine examination.

The implications of the special attention given to simulated specimens are twofold. Firstly, it must be accepted that the success rates obtained, in general

reflect the best that laboratories can achieve rather than the average standard of performance. This has been demonstrated elsewhere by LaMotte *et al.*[15] who found large differences in the success rates for detection of drugs of abuse achieved with identical samples submitted blind through clinics and posted as known quality assessment samples. The second consequence of the high success rates achieved is a general feeling of complacency about standards of performance. This is well illustrated by the low number of laboratories requesting repeat specimens after obtaining incorrect results even though this service is explicitly offered to participants on every summary. For a recent 31 specimens 1063 incorrect results were reported and yet only 126 (12%) requests for repeat specimens were received. The apparently high standard of results is also due in part to the rather generous criteria applied in marking results as right or wrong. Thus a laboratory reporting a strain of *Clostridium perfringens* as *Clostridium* sp has been accepted as correct, although many would consider this to be an inadequate response. A new marking system is being developed whereby a participant's result is marked on a scale of -1 to 2 according to the level of identification reached rather than on a right or wrong basis. To achieve full marks for a specimen, a previously defined level of acceptable identification will have to be reached. It is hoped that this will help to raise standards in microbiology. A previous failing in the scoring system has been that laboratories could escape being scored for any particular specimen by the simple expedient of not returning the report form to MQCL. A laboratory failing to isolate a pathogen from a specimen might therefore be tempted to "lose" the report form. This contingency will be catered for in future by scoring as "wrong" all laboratories failing to make a return. It is essential that the standards set by the MQCL are seen to be relevant to the clinical responsibilities of the participant laboratories. To this end the MQCL is guided by a PHLS Standing Committee on Microbiology Quality Control, the members of which are active and eminent microbiologists.

Identification of poor performance on the basis of standard error has the advantage for the MQCL that the selection is free from subjective influences and is apparently fair in comparing performance with that of the average laboratory. Although empirically, the method does select laboratories with below average performance, it is open to criticism in that the distribution of results is not normal and is markedly skewed. In addition, this method of evaluation will always result in a fixed proportion of laboratories being identified as poor performers even though general standards of performance improve. In view of these factors there is a need to develop non-parametric statistical evaluation techniques for defining and identifying poor performance. The main activity of the MQCL has been restricted to quality assessment. Considerable interest has been expressed in the possibility of increased involvement in the assessment of commercially prepared reagents and media. The DMRQC is already involved on a limited scale in the assessment of serological reagents and this involvement will doubtless increase. In some cases deficiencies in reagents have been revealed through participants' responses to the simulated specimens and a limited number of investigations into the quality of these reagents have been carried out. However, any systematic attempt to control the quality of commercial products would be an enormous undertaking. A survey undertaken in 1977 into the use of kits in microbiology revealed the use of 135 types of kit. A more recent survey on varieties of desoxycholate media used revealed 40 commercially produced products. For the two most popular products there were 28 and 19 different batches in use respectively.

The first five years of the MQCL have established the usefulness of the Scheme, which is apparently widely appreciated by microbiologists. The future must bring further developments to resolve the many remaining problems.

Many people have freely given large amounts of their time to the cause of microbiological quality assurance and the MQCL has relied heavily on their expert advice and in many cases on the provision of specimens. The early quality assessment trials and the subsequent establishment of the MQCL owe much to the efforts of Drs Joan Stokes, Robert Blowers and John Abbott, and Mr Bill Fletcher who as records officer concerted these early efforts. Our sincere thanks must be given to Dr Peter Crone who was the first Director of the MQCL and who developed the Scheme. Various people too numerous to acknowledge individually provided gifts of strains. Particular thanks must go to Mrs Gwen Smith who has kept records in order and organised the considerable volume of printed paper that flows from the MQCL. The efforts of the staff of the MQCL both past and present are acknowledged. Lastly, thanks are due to all participants whose willing co-operation has made the whole scheme possible.

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