

A MEDICAL MICROBIOLOGY QUALITY ASSURANCE PROGRAMME

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OBJECTIVES OF A MICROBIOLOGY QUALITY ASSURANCE PROGRAMME

While the objectives of a microbiology quality assurance programme (QAP) would appear to be self-evident, in fact careful consideration needs to be given to the aims of the programme since these will have a major bearing on its design. Most such programmes have as their basic objective the monitoring of the performance of microbiological examinations by laboratories to define a standard of adequate performance, and to identify laboratories whose performance is significantly inferior. The first decision that needs to be made is whether the programme should concentrate on the common procedures in the microbiology laboratory, or whether the ability to detect uncommon but important pathogens should be given priority. Quite apart from their scientific merit, the "uncommon" pathogens serve the function of stimulating interest in the participating laboratories. The importance of regularly including materials to check coagulase testing of staphylococci is undeniable, but such materials do not generate much enthusiasm. The programme should stimulate interest and discussion in participating laboratories, and therefore ideally it should attempt to cover both common and uncommon pathogens.

Consideration also needs to be given to the scope of the programme. While a microbiology programme will obviously be centred on bacteriology, other aspects of the laboratory's work, such as mycology, serology and antibiotic assays, also warrant inclusion.

Because of the problems involved in the preparation of materials, many programmes have been based on sending out pure cultures of strains for identification and sensitivity testing only. This however covers only one facet of the laboratory's activities, and it is probably more realistic to be concerned about the laboratory's ability to isolate pathogens from mixed cultures even though this entails considerably more effort in the preparation of the test materials. Even more difficult is the preparation of materials to satisfactorily

test selective and enrichment media for fastidious pathogens, but this is clearly a very valid objective of a microbiology external quality assurance programme. Similarly, while a purely regulatory programme is only concerned with the correctness or incorrectness of the participants' responses, an educational programme needs to be concerned with the causes of incorrect responses, with the aim of eliminating them. The identification of faulty techniques, media or reagents requires considerable data from the participants and of course the facilities to analyse this data.

Even a programme based solely on sending out pure cultures for examination involves a lot of organisation. Any objectives requiring more complex materials and questionnaires need to be carefully assessed before they are embarked upon.

ORGANISATION OF A PROGRAMME

Frequency and Content of the Despatches

Cost will be the major determinant of the frequency with which materials will be despatched. In general terms the more frequently materials are sent out the better, since familiarity will tend to diminish the tendency by participants to subject these to "special treatment", and the results are thus more likely to reflect the routine operation of the participating laboratories. The Microbiology Quality Assurance Programme of the Royal College of Pathologists of Australasia (RCPA) sends out eight despatches per year, at intervals of approximately six weeks. We have looked at the possibility of sending less frequent despatches containing more materials to reduce costs, but we have rejected this on the grounds that a larger despatch would impose too great a burden on some of the smaller participating laboratories. For an external quality assurance programme to be of maximal value to a laboratory it must be possible to readily integrate the programme's materials into the daily routine.

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The individual items in each despatch are designed to achieve a satisfactory blend of the requirements for examining the standard of common laboratory procedures, the ability of participating laboratories to isolate pathogens from mixed cultures and the ability of laboratories to correctly identify recognised pathogens which are uncommon in their experience. Thus the bacterial isolates in the most recent despatch included three strains for catalase testing and Lancefield grouping (where relevant), a mixture of *Bacteroides fragilis* and *Enterobacter cloacae* in simulated pus for isolation, identification and sensitivity testing and a strain of *Corynebacterium diphtheriae* for identification. We also make available programmes in mycology, serology and parasitology for those laboratories which undertake these activities.

Preparing the Materials

A Quality Assurance Programme is clearly under an obligation to ensure that all participants receive identical materials. This poses special problems in microbiology, where we are dealing with living organisms. Most programmes have had the chastening experience of sending out material which some of the participants found to be non-viable, and this is especially troublesome when media-testing is the objective of an item. These problems are exacerbated when participants are scattered over a considerable distance. The RCPA QAP for example sends materials to participants up to 4,000 miles away from the distribution centre. Inevitably delays may occur, and sometimes extremes of temperature conditions may be involved. We have found that we must be able to ensure the stability of our materials for at least three weeks. When we first started we used "wet" methods for transporting materials – agar slopes, tubes of transport medium etc. These "wet" methods are satisfactory for *staphylococci* and *Enterobacteriaceae*, and it is even possible, with some ingenuity, to send out relatively simple mixed cultures. However the behaviour of individual components in such a mixture is unpredictable, and fastidious organisms always present problems. We have found that the only way that we can meet the requirements for reliable and stable materials is to produce freeze-dried specimens. When mixed cultures or very fastidious organisms are to be distributed it is essential to do careful preliminary work to ensure that the organisms will remain viable for the required period. These, often lengthy,

preliminary studies mean that items must be planned well ahead. Even when preliminary runs have proved satisfactory it is necessary to retain a representative sample of the freeze-dried specimens for sampling at intervals to demonstrate continued viability. This is particularly important with items where low inocula of fastidious organisms are despatched to test the quality of participants' selective or enrichment media. Quality assurance of a quality assurance programme is vital.

We have found with fungi that sending the organisms out on agar slopes gives the most satisfactory results.

Designing the Questionnaire

Our experience has been that analysis of the sources of error can usually only be successfully carried out if the data returned by the participants is presented in a uniform manner. This virtually never occurs if participants are asked to report their test results in a free text form. To carry out this very important educational aspect of the programme we have found that a "tick box" format is essential to ensure that the data we require is returned to us. This requires considerable care in the design of the questionnaire. Often several attempts may be required to come up with a satisfactory questionnaire format. Once the number of participants reaches a certain size then a computer becomes essential for adequate data analysis, but data entry remains a very time-consuming business.

Laboratory Safety

A meaningful microbiology programme must include pathogens amongst the materials distributed and participants need to be reminded of the potential infectivity of the "unknown" items that they will be handling. We are aware, for example, of three cases of shigellosis attributable to materials distributed as part of our programme. As a matter of policy certain pathogens (e.g. *Legionella pneumophila*, *Salmonella typhi*) are eschewed.

Transport of the Despatch

A variety of different transport modes are used to deliver the materials to participants but inevitably air transport is the most important. As a matter of policy, airlines, and indeed all other types of carriers, actively discourage the shipment of pathogenic microorganisms. Shipment of our materials therefore comes under the International Air Transport Association regulations for shipping dangerous

goods. These rather complex regulations must be strictly adhered to, and preparation of the necessary paperwork (for each despatch seventy three different shipping manifestos are prepared) and packaging of the materials takes a lot of labour. Even so delays occur as a result of idiosyncratic interpretation of these regulations by various transport and customs officials. Industrial action by unions has also been a cause of considerable difficulty in the past.

Analysis of Results and Feedback to the Participants

To maintain the interest of the participants and for the programme to achieve maximum benefit it is essential to carry out analysis and get the results back as soon as possible while the items are still fresh in the minds of the staff involved. To achieve this objective we send out preliminary results at three weeks after the date of despatch to those laboratories who have returned their questionnaires, and final results after six weeks. We have in the past produced detailed discussions on the sources of error in specific items for inclusion with the final results. While these discussions have been very useful, their production time is lengthy, and thus we now send them out after the results.

REVIEW OF THE OBJECTIVES

Participating laboratories should be reminded that subscription to an external quality assurance programme is only one component of the process of quality assurance. The reliability of the results of the programme in terms of quality assurance will obviously be very dependent on the nature of the items which were included and on the way in which individual participants approach the programme. Because of these factors the results of the programme can only be taken as an indicator of whether a laboratory's performance is satisfactory or inadequate. We cannot attempt to distinguish between laboratories whose performance is merely satisfactory and those whose performance is excellent.

Subscription to the RCPA Microbiology QAP has been voluntary, and strict confidentiality of the results has always been maintained. In the past this need for confidentiality has been interpreted as precluding the specific identification of laboratories whose performance was inferior. It was hoped that those partici-

pating laboratories whose performance was sub-standard would realise this themselves and take appropriate steps. It is apparent however that this has not **happened in some cases**, and therefore, while confidentiality is being maintained, more active measures are being taken to draw individual participants' attention to the quality of their work and to suggest corrective steps. We believe that for a participating laboratory to gain maximal benefit from the programme the results should be openly and freely discussed by the staff of the laboratory. Even when a laboratory's performance has been satisfactory there is benefit to be obtained from discussing the nature and sources of errors that other participants may have made.

As part of the educational function of the programme we have attempted to identify methodology which is unreliable. Such identifications however need to be done with care. We have noted for some years now that there is a consistently high error rate associated with the slide coagulase test for the identification of staphylococci. While this information might be interpreted as indicating that the slide **coagulase** test is an intrinsically unreliable procedure, closer analysis shows that a relatively small number of laboratories were responsible for most of the errors. In the hands of many participants slide coagulase testing was error-free. Thus in any analysis of sources of error, care must be taken to distinguish between poor methodology and poor technique. Similar problems can arise when attempts are made to assess commercial media and reagents. We have found, for example, that some of the recently-introduced kits for rapid identification of staphylococci appear very reliable in distinguishing between *S. aureus* and *S. epidermidis* but give equivocal results with *S. saprophyticus*. Any assessment of such products should therefore only be attempted if a full range of the isolates that they are likely to be used on has been tested. One must also be wary of assessing commercial kits which are only used by a small minority of participants. It can be very difficult to determine whether the errors that may be seen are due to intrinsic faults in the kits or whether they are due to faulty technique on the part of the users.

Organising a microbiology quality assurance programme is a fascinating experience, but it involves considerable time and effort, attention to detail and constant careful experimentation to provide a worthwhile service.