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QUALITY ASSURANCE PROGRAMMES IN TRANSFUSION SEROLOGY

R. W. BEAL

Chairman, Australian Red Cross Transfusion Service, Adelaide, South Australia

INTRODUCTION

An external Quality Assurance Programme (QAP) in Blood Transfusion Serology (TS) has a number of featureswhich make it different from other QAPs. An awareness of these distinctive differences is essential for the success of a TS QAP.

Unlike those programmes which require machine-based measurement of analyte levels and numerical reporting, TS is a discipline which is essentially manual and subjective. A compounding feature is the lack of uniformity in methods of reporting results, which makes comparison of performance of laboratories difficult, if not impossible.

These matters must be taken into account in the design of a TS QAP and in the assessment of reporting by participating laboratories.

RANGE OF TESTS

Any TS QAP, however basic, must include ABO and Rh grouping and demonstration of compatibility between materials purporting to come from donors and potential recipients. Within the ABO system, occasional exercises in recognition of A variants have been useful. Most TS QAPs include exercises in detection and identification of atypical red cell antibodies, and an increasing number of participants attempt this part of .the programme concerned.

Some exercises include an antenatal workup, which may incorporate ABO and Rh grouping, antibody screening (and identification where appropriate), haemoglobin estimation, and the results of screening for significant transmissible disease (syphilis, etc.).

An important part of this kind of exercise (and indeed most others) is the interpretation of the findings to the referring party. Excellence in laboratory performance is not necessarily matched by comparably sound interpretation of the data available. The assessment of quality assurance involves both competence at the laboratory level and proficiency in interpretation and reporting.

Although the range of test procedures in TS is relatively small in comparison with other disciplines, changes can be rung through these tests to ensure satisfactory and useful participation.

Because of its vital importance in transfusion practice, emphasis on recognition and detection of clerical error should feature regularly in TS QAPs.

Another useful exercise which emphasises the importance of reproducibility, is to send out identical material in the same or subsequent survey, so that participating laboratories act as their own controls.

SOURCES AND MATERIAL

Organisers of TS QAPs rely considerably on the goodwill and thoughtfulness of colleagues in the field to ensure the continuing availability of material which will permit an interesting and educational series of programmes to be maintained.

The principal requirement is for plasma/sera which contain an antibody (or antibodies) in reasonably high titre. At times, the goodwill of colleagues and donors may permit a significant volume of material to be obtained by plasmapheresis, while in other situations, dilution with inert material may be necessary for sufficient volume to be obtained to allow all participants to receive a reasonable aliquot for testing. In a survey involving 200 participants, a minimum of 200 ml. of plasma would be required. In smaller surveys, a wider range of antibodies may be included, bearing in mind that not all persons who make antibodies are willing or able to provide their plasma in volume for these purposes.

Finding sufficient blood (either whole blood or red cell concentrate) for use with antibody containing sera in compatibility testing presents less of a problem, and transfusion services are usually willing to provide red cells of an appropriate group in sufficient volume to ensure that participants have reasonable amounts of material with which to work.

As with all materials of human origin used in QAPs, it is essential that plasma/serum included in TS QAPs be negative on screening for

Address for reprint requests: Dr. R. W. Beal, Director, Red Cross Transfusion Service. South Australian Division, Adelaide. South Australia.

syphilis, HIV antibody, hepatitis B surface antigen and CMV antibody. All laboratory staff handling material (both organising and participating) must be made aware of these requirements and of the need to treat all such material as potentially infectious, in the absence of a test for non-A non B (NANB) hepatitis.

LOGISTIC ASPECTS

When the materials for a particular round of a QAP have been identified and collected, the work of the organising laboratory really begins.

Appropriate sterile leak proof containers (not as easily obtained as might be anticipated) are prelabelled and the materials *dispensed* carefully, avoiding any risk of aerosol exposure to the staff concerned, and ensurmg that there is no external contamination of the container?. *Packaging* is to some extent governed by postal regulations and by IATA regulations covering consignment of human materials by air. Conforming with these regulations will ensure the safety of the exercise, at considerable cost in terms of time and materrals.

Consignment

Time spent in discussion with postal authorities regarding the most expeditious and economic means of despatch is usually time well spent. In order to assess the effects, if any, of transit time and conditions. it is customary for the originating laboratory to arrange with one or two of the recipients to accept delivery of a duplicate set of materials and to return it forthwith to the sender, who is then able to assess the effects of transit at first hand. Comments on the state of the material on arrival are often sought from referees and in some cases from all participants.

The ***timing*** of despatch should endeavour to avoid public holidays, etc, and (if possible) transport strikes. A deadline for return of results should be set which is long enough to allow the staff to do the work, but brief enough to minimise the possibility of collusion.

REPORTING

Participants should be advised that the greatest value is derived from a QAP when material is handled in a completely routine manner. (Like much good advice, it may not be accepted or acted upon).

Careful instructions covering the precise methods of reporting should be given to participants to ensure the validity of the information or individual assessment and comparative purpose . A sensibly short deadline is important (see above).

Before materials are despatched, the coordinating laboratory should have defined criteria of assessment either in a numerical or qualitative fashion, based on the known material included and possibly modified by referees' reports. Although some forms of survey can be automated TS QAP returns probably require individual assessment, particularly where interpretation of the data obtained is concerned.

To ensure the greatest possible benefit to participants, some farm of written feed-back is required within a relatively short period after the closing date for returns, and certainly before the returns have been fully assessed. This initial feed-back may sometimes include an offer for the provision of additional material where it is obvious or likely that a number of participating laboratories have experienced difficulties with a particular investigation.

Definitive feed-back will usually include the collated results of that particular round of the survey and a commentary on them. In TS QAPs, it is not customary for comments to be sent to individual laboratories about their individual performances, although it is possible to write computer programmes which will highlight the results of the individual laboratory by number, and compare its performance with that of all participants.

Frorn time to time, originating laboratories may offer to provide practical assistance to a participating laboratory by entering into dialogue on points of methodology or by directing them to nearby reference centres for assistance. In some programmes, such as those in the UK and New Zealand, laboratories are regionalised, and central laboratories within each region take formal responsibility for smaller participatiang laboratories, whose results are routinely forwarded to the regional reference laboratory. In Australia where participation m QAPs remains voluntary (for the present at least), and where there is seldom a formal link between laboratories in a region, such follow-up requires delicate handling.

In certain instances, where analyses are sent, they may he accompanied by a commentary on a particular aspect of the exercise, either clinical or methodological. The scope in TS QAPs is somewhat more restricted than with conventional haematology, but the opportunities nevertheless exist for a didactic document to be produced.

MAINTENANCE OF INTEREST

As stated above. tlie range of materials and scope of the tests performed have a somewhat limiting effect on the variations possible on tlie transfusion serology theme. From time to time, it is possible to offer, on a request only basis, material which is available in small volumes, in order to allow larger reference type laboratories to undertake somewhat more esoteric investigations than are appropriate or possible in a larger survey. A case in point was a modest volume of serum from a factor VIII deficient middle aged man, who had at least five detectable antibodies.

Maintenance of interest also involves public presentation of the survey findings at appropriate and relevant meetings. These presentations should not be confined to annual meetings of the sponsoring organisation, but should include any forum where participants meet. The mutual feed-back and discussion possible in such personal contacts is valuable and justifies the effort and expense involved.

CONFIDENTIALITY

QAPs run for many years by the Royal College of Pathologists of Australasia (RCPA) have involved voluntary participation only and for this reason, the requirement for confidential handling of results has received considerable attention. In order to achieve confidentiality, planners of QAPs undertake to document information by number only, which number can be identified by the participating laboratory and the organisers of the programme alone. Information concerning RCPA QAP results is not supplied to any third party, including governmental agencies.

With laboratory accreditation now a fact of life in much of Australia. satisfactory performance in an appropriate QAP will become a criterion of registration. In this regard, confidentiality will be preserved by ensuring that the only information made available to an accrediting authority about QAP performance will be provided by the laboratory itself. and not by the QAP organiser or sponsor.

EDUCATIONAL EFFECTIVENESS

Although it is sometimes difficult on a short time base to measure any perceptable education and benefits, it is possible over a longer term to identify more positive benefits occurring to individual practitioners and to the practice of TS generally. These benefits include:

(I) the outlawing of inadequate techniques, such as the PVP crossmatch, which was shown by RCPA surveys in the early 1970's to be unsatisfactory;
(2) the assessment of new and modified techniques, on a local or wider basis;
(3) tlie adequacy (or otherwise) of certain reagents in common use, including batch to batch variation;
(4) the capacity of unsatisfactory performers to remedy the situation and to sustain such improvement;
(5) the increased awareness of the importance of recognising clerical errors, and their relationship to satisfactory overall performance.

Is is possible, through the cooperation of participants, to evaluate in a semi-formal fashion, the various methodologies in current use by means of questionnaire. With programmes of modest size, these data can have a significant role in influencing policy and practice in a regional area.

The setting up and running of a TS QAP is a time-consuming and exacting task, not to be attempted without appropriate staff being available for involvement. The rewards may be intangible, but are considerable, including the knowledge that the laboratory which takes on board such responsibilities contributes significantly to the improvement of their art and to the increased safety of transfusion practice.