Best practice recommendations

Managing the clinical authorisation workload associated with laboratory medicine reports

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Foreword

Best practice recommendations (BPRs) published by the Royal College of Pathologists should assist pathologists in providing a high standard of care for patients. BPRs are systematically developed statements intended to assist the decisions and approach of practitioners and patients about appropriate actions for specific clinical circumstances. They are based on the best available evidence at the time the document was prepared. It may be necessary or even desirable to depart from the advice in the interests of specific patients and special circumstances. The clinical risk of departing from the BPR should be assessed and documented.

A formal revision cycle for all BPRs takes place every 5 years. The College will ask the authors of the BPR to consider whether the recommendations need to be revised. A review may be required sooner if new developments arise or changes in practice necessitate an update. A full consultation process will be undertaken if major revisions are required. If minor revisions or changes are required, a short note of the proposed changes will be placed on the College website for 2 weeks for members' attention. If members do not object to the changes, a short notice of change will be incorporated into the document, and the full revised version will replace the previous version on the College website.

This BPR has been reviewed by the Professional Guidelines team. It will be placed on the College website for consultation with the membership from 17 August to 14 September 2026. All comments received from the membership will be addressed by the authors to the satisfaction of the Clinical Director of Quality and Safety.

This BPR was developed without external funding to the writing group. The College requires the authors of BPRs to provide a list of potential conflicts of interest. These are monitored by the College's Professional Guidelines team and are available on request. The authors of this document have declared that there are no conflicts of interest.

Executive summary

Clinical authorisation workload, including the provision of interpretative comments, has risen by much more than the human resource available to provide the service.

Options for managing increasing workload relative to clinical resource include the following.

- Ensuring existing demand optimisation techniques have been implemented to help ensure appropriate test requesting, such as the introduction of minimum retesting intervals and the Getting It Right First Time initiatives.
- In conjunction with service users, reviewing which tests would benefit requesters and patients most by having interpretation added, and in what circumstances. Considerations include the complexity of test interpretation as perceived by different report recipients, the clinical acceptability of any delay in results that authorisation might introduce and whether this advice could be provided in ways other than through manual reporting.
- Providing test reporting guidance to service users, perhaps through report web links, either in addition to or in lieu of interpretative reporting. Patient-targeted guidance may also form part of this.
- Optimising other uses of information technology (IT) to determine which test results most require manual review before/after reporting.
- Encouraging test recipients to contact laboratory clinical staff for interpretative advice rather than relying solely on report comments. In time, this ‘test recipient’ group might include patients themselves. Resource released by managing the clinical authorisation workload could help facilitate this development.
- Advocating initiatives that educate service users in the appropriate use and interpretation of laboratory medicine tests.
- Considering the retirement of manually added comments from test results where the aforementioned steps have been successful in significantly reducing or negating their worth. This will usually require a risk assessment as well as a need to inform or consult main service users.

- For the remaining clinical authorisation work, ensuring a suitable environment exists for reporting, separating this duty from any concurrent clinical and non-clinical tasks that could be provided by colleagues, including alternate staff groups.

1 Introduction

Medical laboratories undertake a wide scope of practices as part of delivering a clinical service. Among these, most laboratory medicine services in the UK add an interpretation to certain test results where it is thought that this might assist the requester to better diagnose or manage their patient.[1] This often forms part of the clinical authorisation/clinical validation process, aimed at also identifying test results that may, for various reasons, require further scrutiny. Such clinical authorisation is frequently provided by a consultant-led service, involving clinical scientists and medically trained laboratory staff.[1] It is a process that is distinct from the technical authorisation/validation of tests, which aims to help ensure the analytical validity of results.

Advice already exists on best practice when providing interpretations on laboratory medicine reports,[2] but the balance between the demand for comments and the resource available to provide them has shifted markedly since most interpretative services were originally conceived. This document is intended to provide advice on steps that can be taken to safely accommodate changes in authorisation workload relative to the number of clinical laboratory staff.

Much of what is suggested will already be part of the continual service development of many laboratories, but other aspects, such as providing written interpretative guidance to requesters, exploring means of reducing the scope of a clinical authorisation service or encouraging more direct contact with users, may not be as widespread.

1.1 Target users and health benefits of this guideline

Primary target users are all clinical staff working within laboratory medicine. Intended benefits include improving the ability to manage changing laboratory workload relative to clinical staffing, and to consider alternative ways of providing a clinical authorisation service.

2 The need to manage clinical authorisation workload

2.1 Rising demand for laboratory medicine testing

Initiatives to improve the appropriateness of test requesting have only been partially successful in limiting the rising demand for laboratory services.[3–5] The growing needs of an ageing population, better identification of chronic long-term conditions such as diabetes, hypertension, hyperlipidaemia or chronic kidney disease, and more guideline-driven testing of patients with these and other health problems are all contributory.[6] Other initiatives incentivising systematic testing, such as the Quality and Outcomes Framework, have also promoted an increased use of diagnostics.[6]

Between 2000–2001 and 2015–2016, the UK's average annual increase in primary care laboratory test workload was 8.7%, representing a 3.4-fold increase in testing per capita over the period,[7] although there is a suggestion these rises were plateauing in the years immediately preceding COVID-19.[6] Data on secondary care laboratory demand is not as readily available, but it is known outpatient appointments in England have more than doubled in the last 20 years[8] and A&E admissions have increased by 38% since 2010–2011.[9] There is no reason to suggest that similar rises in secondary care workload have not also occurred in the devolved nations of the UK.

Over the same periods, there has not been a similar proportionate increase in clinical staffing within the laboratory. While improvements in automated analytical technology have helped mitigate some of the pressures associated with increasing test demand, this does not necessarily modify the more direct relationship between rising workload and the increased time required to add interpretative comments.

This may, in turn, contribute to why the majority of pathologists from all disciplines feel they have insufficient time to get through their daily workload[10] and, presumably not coincidentally, why 40% wish to reduce their contracted hours in the next 5 years and approximately a quarter intend to retire earlier than previously planned.[11] Since roughly half of all pathologists are already aged 50 years or over, it means that there is a potential staffing 'cliff edge' within the next decade,[11] which would only further exacerbate the ability to meet the clinical demands of the service, including clinical authorisation provision.

One of the aims of the RCPath Workforce Strategy is to support the pathology workforce by reforming ways of working to help manage the pathology workload.[12] This document

aims to stimulate laboratories to review their current work practices in relation to clinical authorisation to prepare for future changes in workload relative to clinical resource.

3 Options for managing increasing workload relative to clinical resource

3.1 Implementation of demand optimisation measures

Demand optimisation is defined as the process by which diagnostic test use is optimised to maximise clinical care and promote efficient use of resources.[13] It is one of the RCPath's Key Assurance Indicators aimed at assuring service quality[14] and is a cornerstone of the Getting It Right First Time initiative.[4] While some tests may be under-requested by some services, on balance many of the optimisation processes – such as reducing unnecessary repeat testing,[3] ensuring appropriate test repertoires and reducing diagnostic over-requesting[13] – will likely have the net result of reducing laboratory test demand. However, it is often difficult to be sure what this would have been without any intervention.

3.2 Choosing tests to clinically authorise

Specific guidance exists on which test results should be communicated urgently to a requester,[15] and there is existing best practice advice on the provision of interpretative comments,[2] although not in the context of managing this workload.

3.2.1 Evidence of interpretative reporting value

While there is evidence that test requesters appreciate the inclusion of result interpretation,[16,17] data showing that they influence patient outcomes is more limited and inconsistent. For example, with thyroid function test reporting among patients receiving levothyroxine replacement, a retrospective study showed an apparent change in clinician behaviour after interpretative comments were instituted,[18] while a more recent placebo-controlled study showed little difference between a laboratory that added thyroid comments compared to one that did not.[19] A separate study investigating reflective testing found that adding tests on to existing GP requests could lead to improved patient management.[20]

This paucity of evidence means identifying which tests would benefit service users and patients the most by the addition of interpretation is not straightforward and is often based on a subjective judgement of the likely value added to a requester's existing knowledge of the test; for example, a doctor in training might benefit more from interpretation than a

hospital specialist. Added to this is the fact that many patients are now able to receive the results themselves and so may wish to know what the results mean for them.

3.2.2 Factors to consider when deciding to manually add interpretative comments

Weighing the benefits and risks associated with adding interpretative reporting for a particular test(s) is complex. The following lists some of the factors to consider.

The benefit to patients of test results including an interpretative comment

- Test results that are complex to interpret.
  - It seems self-evident that, for test results that most requesters would not be expected to be able to interpret for themselves or cannot be understood from simple thresholds, an interpretative comment will be necessary. This might include tests which by their very nature are not numeric, such as serum electrophoresis or xanthochromia, or complex profiles of tests such as plasma amino acids or other metabolic tests.
- Test results that are less complex to interpret.
  - For other less esoteric tests, as mentioned above in relation to thyroid testing, it is more difficult to be sure of the value added by the laboratory including an interpretation.
  - These tests that are less complex to interpret are the ones best placed to reconsider if or how interpretative advice might be provided (see sections below).
- Tests with unusual or unfeasible results.
  - Irrespective of the complexity of a test, there may be instances where results for a patient are not feasible physiologically or are strikingly different to those found in them previously. Processes at the analytical stage prior to clinical authorisation may be able to address many of these situations, such as due to sample contamination or interference caused by haemolysis, icterus or lipaemia. Others might require clinical review, either to ensure the identification of a genuine marked change in a result from the same individual, or to avoid releasing improbable results without further attention.
  - It should be noted that the positive predictive value of delta checks in identifying the ‘wrong blood in tube’, by comparing current against previous results in the same patient, has likely diminished over time as systems to reduce pre-analytical

error have been introduced,[21] as has the ability to investigate samples suspected of being mixed-up if the only identifier is an electronic sample label.

The risk to patients of test results including an interpretative report

The addition of a manual clinical authorisation step to test reporting might not always be beneficial, even if there is sufficient resource to include interpretative comments. Circumstances including the following require consideration.

- Delay to result reporting.
  - Manual addition of comments before reporting a result necessarily introduces a delay that might vary throughout the day and week, assuming this service is not delivered 24/7. If clinical authorisation is limited to only those results that are abnormal, as is commonly the case, then the delay could be to the very ones most clinically relevant to immediate patient care. Thus, the clinical benefit of the comment has to be weighed against the clinical risk of delaying its reporting, which will vary between tests and clinical situations.
  - An alternative process to clinically authorising results before release is to subsequently review those that have already been reported, at least provisionally, to the requester. It is not known how valuable the subsequent re-reporting of some results might be or whether they are acted on any differently to those reported prospectively.
- Providing incorrect advice.
  - This is always a risk in any healthcare situation. Even with highly competent reporting staff, this can occur where insufficient or incorrect clinical information is provided. This might include, for example, not knowing a patient was receiving thyroid treatment when interpreting thyroid function tests or, even if known, in suggesting levothyroxine overreplacement while not knowing the patient had previous thyroid cancer that is at high risk of recurrence. Even with wider access to electronic health records, the time required to understand the complete clinical context of every patient may make clinical authorisation of the existing workload unfeasible.
  - The clinical consequences of incorrect advice can vary, but if the laboratory feels the requester requires interpretation on the report to fully understand a particular test result, presumably this means the wrong advice could be especially detrimental to the patient.

- An added complication is the knowledge that the patient may now see a result at the same time, or even before, the test requester. Incorrect advice could then prove to be confusing or distressing to them.

4 Providing test reporting guidance to service users

It is already recommended that the addition of standardised (also known as 'coded' or 'set') comments onto a report, based on agreed criteria, is an option to aid interpretation.[2] However, this approach is limited in the amount of information that can be included in a report and might still need considerable manual intervention to ensure, as much as possible, that the comment added is the one appropriate to the clinical situation.

Another option is to follow the lead of most clinical services outside of pathology. When following national or local guidelines related to the commonest conditions seen by their own medical speciality, they often share this guidance in adapted form with patient referrers, such as GPs, to help educate non-specialists and to guide future patient management or referral.

Laboratories frequently already have their own internal reporting guidance to help harmonise the advice provided for test results in specific clinical circumstances. However, it is less usual for these reporting guidelines to be shared with service users, meaning that a test requester may not be fully aware why particular comments are used in different situations.

Inclusion of reporting guidance on the test report could be a means of supplementing or replacing existing interpretative comments. Ideally, this would be written in a way that would be as clear and informative as possible to the test requester. Feasibly, this could be as a web link to a controlled document that features flow diagrams providing advice for the commonest clinical situations related to the reported test(s). Such approach could reduce the likelihood of clinical laboratory staff inadvertently providing mistaken interpretative advice because, for instance, a patient's health condition was only partially known or the information provided by the requester was inaccurate.

Sharing reporting guidance might also help educate the service user regarding the intended use(s) of the test, its limitations and which criteria or clinical guidelines are used to help determine the choice of a particular interpretative comment. This latter point could stimulate discussion with experienced test users about the further development of the guidance.

In respect of patients, who now also frequently receive their blood results, similar links to authoritative patient information sources, such as LabTestOnlineUK (https://labtestsonline.org.uk/) may also be of value. There is also emerging evidence that providing patients with automatically generated interpretations of abnormal test results (as opposed to no recommendations) can lead to a higher probability these will subsequently be followed up.[22]

5 Optimising the use of information technology

One mitigating feature that has helped accommodate the rising demand for interpretative reporting has been developments in IT. Within the laboratory, the increasing functionality of laboratory information systems have provided more flexibility in limiting clinical authorisation to only those test results that require most attention, or perhaps only those requesters who do not already have specialist knowledge of the test. External to the laboratory, rapid electronic transfer of most test results directly to the requester – and now the patient – has been able to speed clinical decisions and adds assurance that the results have been reviewed.

Nonetheless, these IT developments have also changed the expectations of service users who are often themselves under pressure to assess patients more quickly. In this environment, clinicians may feel that any delay to result reporting introduced by clinical authorisation is now less acceptable and makes the choice of whether the addition of human interpretative comments outweighs these delays more difficult, either for specific tests or for specific clinical services, such as for primary care versus emergency departments.

Undoubtedly, it is advisable for there to be a scheduled review of the electronic criteria used to decide which results add most clinical value during clinical authorisation.[2]

5.1 Artificial intelligence

There is evidence the laboratory community largely expects and supports the use of artificial intelligence (AI) within laboratory medicine,[23] and numerous AI tools have already been applied to different aspects of the discipline.[24] However, many are still at a development or evaluation stage, so currently their ultimate impact is unclear. However, it is becoming apparent that by incorporating numerous sources of demographic, clinical, pharmacy and laboratory data, they have the potential to be providing advice based on

information that few clinical authorisers in the laboratory could credibly collect or assimilate.

5.2 Clinical decision support tools

In contrast to AI tools, clinical decision support tools usually implement GOFAI (Good Old-Fashioned AI), relying on more traditional statistical, rule-based and programming techniques to aid decision making, with or without incorporating information from the electronic patient record. Tools such as those to identify acute kidney injury or to implement the kidney failure risk equation are in common use,[25] but there is potential to influence many other disease conditions. In regard to helping with interpretative comments in laboratory medicine, commercial 'expert' systems have been available since the 1990s in other countries[26] but have not been widely implemented in the UK as yet.

6 Encouraging contact with laboratory clinical staff

Requesting clinicians already frequently contact laboratories for clinical advice but, because of its unpredictability, responses are often fitted around other, more planned, activities. Some service users may not even realise there are experienced clinical staff available to help them.

Laboratory clinicians themselves might be wary about being too successful in promoting their availability if there is insufficient time to deal with more questions or are fearful any service would quickly become another means of communicating operational rather than clinical queries.

Grasping the opportunity to evolve a clinical laboratory service from a comment-generating service to being a less faceless, more consultation-based service, while at the same time addressing the concerns already mentioned, is no easy task. Some services already mimic other non-pathology medical specialities by having 'Advice and Guidance' email addresses that allow responses at planned times for non-urgent questions and will reject non-clinical queries. It is hoped that some of the measures in this document might also release time to allow services to advertise other direct-contact initiatives with less concern about being overwhelmed.

There is an argument, albeit still somewhat controversial, that such direct contact be extended to patients. At this stage, such a development would need to be piloted in a controlled way that ensured patient safety while at the same time allowing the benefits and

risks to patients to be studied. However, other professional groups within healthcare, such as clinical pharmacists, have already developed a vision to shift from a hospital role mainly supporting other professionals to one where they themselves help manage the care of patients.[27] Aspects of their plan for the future could equally apply to laboratory medicine.

7 Education of service users in the use of laboratory services

Educating the local healthcare community in the appropriate use of tests and the laboratory service is second nature to most laboratory clinical staff. The unmet educational need has risen over time as the number and complexity of tests has increased, the teaching of laboratory medicine in medical schools has diminished and the breadth of healthcare staff using the laboratory service has widened.[28]

Maintaining an ongoing clinical educational programme remains challenging for many, either because of a reduction in the time that can be devoted to teaching and/or the difficulty in obtaining access to health staff who have competing priorities. However, although firm evidence of these initiatives may be thin, few involved in the process are likely to regard it as not being beneficial or rewarding.

8 Considering retirement of manually added comments

Clinical authorisation services in the UK have usually developed over several decades. While IT advances have helped manage some of the increasing quantity and complexity of the existing service, it is natural that the thought of expanding clinical authorisation further through choice or necessity – even if the changes in workload cannot obviously be managed – is easier to consider than actively proposing contraction. Several of the suggestions in this document may make retirement of manually clinically authorised tests much more feasible, thereby releasing resource to pursue alternative means of providing a clinical service, or to allow other aspects of a quality service to be further developed. For some laboratories, consideration of taking this path may be less of a choice.

If it is thought that mitigations, such as the availability of reporting guidelines to test requesters, have sufficiently reduced any risk of interpretative comment removal to an acceptable degree (through a formal risk assessment), and consultation with experienced and less experience users of the test concurs, then users can be informed of the planned removal of manual comments.

9 Clinical authorisation in a suitable environment

Common to all diagnostic disciplines, there is a need for any remaining clinical authorisation work to be performed in an environment that is suitable to allow the clinician to wholly concentrate on the task. This means being in a quiet area minimising external interruptions, such as telephone calls or concurrent additional tasks, which could be covered by clinical or non-clinical colleagues.

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