Past Papers (All Candidates)

This file contains 6 laboratory management problems which have been presented to candidates for the Part 2 MRCPath oral examination in Clinical Biochemistry. Candidates are given half an hour to prepare their answers to this problem and a laboratory scenario or clinical case.

After each case, the notes for the examiners have been provided by the examiner who set the question. These are not intended to be exhaustive but provide some background for the case. More importantly, they provide some insight for candidates into what the examiners are looking for.

Note that the scenario will usually be set in the context of the UK or English health service organisation. However, the questions are usually general and candidates from health services with a different administrative organisation should still be able to discuss the principles involved in the management issue and the solutions available which are local to the candidate.

Note also that examiners are most interested in candidates showing a logical progression from the diagnosis of the problem and the delineation of the principles involved, to appropriate management. They will be less interested by candidates that simply give a list of possible solutions culled from a management textbook. Some issues may require fairly delicate negotiation with colleagues, others a more robust response to avoid the laboratory being disadvantaged by hospital management. As candidates will be hoping to become senior members of the laboratory team in the near future they should imagine themselves in this position and how they would deal with the sensitivities involved.

In some scenarios, some issues need attention before others. Failure to recognise the importance of those that immediately affect patient management as the first matter requiring attention will count against candidates as the examiners are looking for evidence of safe practice.

Note that the cases provided may be complex and there will usually be several ways of tackling them. The ones given below may not be the only ones, or even the best, but should provide the basis for a discussion. In the ideal scenario, with candidates who are on top of the issues, the discussion should end up as a dialogue with the examiners who may also be looking for help with a difficult problem!

In preparing for this part of the examination, there is no substitute for regular discussion about laboratory issues with senior consultant staff and, if possible, trying to arrange “mock” oral examinations with senior colleagues.

Question 1

You are a fairly recently appointed head of Chemical Pathology in a district general hospital.

Since arriving you have implemented major changes in equipment and working practices. Results for almost all tests can be available within an hour or so of the sample arriving in the laboratory (depending only on how many other samples arrive at the same time), at any time of the day or night.

What difference, if any will this make to the way you clinically validate results?

Question 1: Notes for Examiners

As with most management questions, there is no definitive right answer to this one - at least, not until NICE tells us there is.

However, candidates should realise that there is a balance to be struck between holding back results for clinical validation and the amount of time they are prepared to spend validating. Factors which may influence this balance include:

- What happens to the results once they are clinically validated (eg. immediate electronic transmission to wards and GPs *vs* printing and sending out on the next working day).
- The number of people in the Department who are appropriately trained and qualified in clinical validation. (Might this include technical staff following established protocols?).
- The presence of modem links to permit clinical validation from home in the evenings and at weekends. (Should staff who do this receive additional remuneration?).
- The clinical needs of any specialist clinical units the DGH may house.

Whatever the local solution, two points seem clear:

- There is little point in improving analytical turnaround times to this extent if the results are all held back for clinical validation on the next working day.
- Releasing all results with no clinical validation stage raises some interesting questions about the role of the consultant chemical pathologist/clinical scientist.

Question 2

You are Head of Chemical Pathology Services in a large District General Hospital. Your Clinical Director is approached by the local Mental Health Trust who wish to discuss long term support for their urine drugs of abuse (DOA) screening service.

The current situation in the Mental Health Trust is:

- they have a workload of 250 samples/week (200 from day clinics; 50 from inpatients.
- they currently analyse all samples on site in the Drug Dependency Unit using nursing staff trained by the instrument company.
- they have a recently procured dedicated immunoassay system (throughput 50 samples/hr) and have entered into a favourable 3 year reagent rental contract covering service, support and training.
- they require a Monday-Friday with same day results for IP samples and next day results for clinical samples.
- they feel unable to support the above situation indefinitely and are worried about 'quality issues'.
- they wish to negotiate MLSO staffing for their on-site analysis and associated quality support from Chemical Pathology.

The Directorate supports the above in principle and you are asked to advise the Business Manager on the key issues in respect of any future Service Level Agreement with the Mental Health Trust. In doing this:

1. What further information would you require about the current situation?

2. What would be the key cost elements in the proposed 'staff quality' package?

3. What quality standards might be incorporated into the agreement and how could they be monitored?

Question 2: Notes for Examiners

1. Extra information on current situation could include:

   - DOA profile required
   - Policy for any confirmatory analyses (if required)
   - Peaks and troughs of workload
   - Transport arrangements
   - Report validation procedures
   - Mode of transmission of reports
   - Standard of 'laboratory' facilities in the Drug Dependency Unit.

2. Cost Elements could include:

   - MLSO staffing:
     - state registered staff will be needed (working unsupervised)
     - workload suggests half-day commitment on M-F basis is necessary
     - cost of 0.5 wte MLSO 1 is approximately 8K pa + on-costs
   - Quality Support:
     - QC materials and documentation (if not in reagent contract)
     - EQAS participation costs
   - Requirement for consultant advice (if any)
   - Financial agreement for accommodating growth/reduction in workload

3. Quality Standards and Monitoring

   Important to realise that both parties can incorporate these.

   User (Mental Health Trust) may include:
   - Provider laboratory CPA status
   - Turn around times (how define??) – including any requirement for urgent analysis
   - EQAS performance

   Provider (Pathology) may include:
   - Minimum acceptable ID for samples and request forms
   - Deadline for sample delivery (to meet agreed TAT)

   Monitoring Arrangements
   - Monthly Report (activity; standards compliance etc.)
   - Audit of specific aspects as necessary

Candidates may well wish to propose a longer term strategy of performing the work in the central laboratory rather than a POCT exercise.

In making their response, candidates should show an awareness of the guidelines of the Joint Working Party or Quality Assurance (POC Testing) and the CPA standard requiring compliance with these.

Question 3

You receive a call from the 'Customer Services Manager' of your hospital saying that she has received a formal written complaint from the parents of a child being treated by the oncology firm. It concerns the clinical chemistry laboratory and she needs some information.

The gist of their complaint is that their son had to remain in hospital for an additional night because the result for a specimen sent to the laboratory, for a Methotrexate analysis, was not received in the late afternoon, when they had been promised it, but the following day. The medical staff had told them that the specimen, which had been taken in the early morning, would be analysed that day and that if the result was within their acceptable target range, as they expected, their son would be discharged. The lateness of the result had caused great distress to both the child and the parents together with the added inconvenience of an extra night at the hospital and the additional expense.

Methotrexate analyses are not performed by your laboratory but sent to a neighbouring hospital about 5 miles away, usually by taxi. Your preliminary investigation reveals that the specimen was received by your specimen reception at 09.15h on the morning in question but had not been sent to the referral laboratory. It had been discovered in a refrigerator in the late afternoon after a phone call from the requesting doctor who was trying to obtain the result. The specimen had been sent for analysis the following morning, and the result was within the target range.

What further information would you require to investigate the complaining in more depth?

What steps would you take to ensure that the same problem did not happen again?

You will be expected to draft a letter on behalf of the Chief Executive, who replies to all of the formal complaints received by the hospital. How will you word this letter?

Question 3: Notes for Examiners

1. Further information

- What was the standard procedure for sending Methotrexate specimens away?
- Was there a written protocol?
- Who had the responsibility for sending the specimen?
- Why had the specimen not been sent away?
  - Too busy
  - Inexperienced staff
  - Poor training
  - Etc
- Was the area being supervised?
- Why was it placed in the refrigerator?
- At the end of the investigation, what actually did go wrong?

2. Preventing a repeat of the problem

- Ensure correct training for all who undertake specimen reception.
- Written procedures for all specimens sent away.
- Adequate supervision for this crucial area.
- Reminder to all staff of the vital nature of the work in specimen reception.
- Sharing of the complaint with all staff, avoiding a 'who's to blame' approach.

3. Chief Executive's letter

- Apologise for the error, since the laboratory was to blame.
- Explain in outline what went wrong.
- Give mitigating circumstances if there were any.
- Explain that procedures have been put in place to prevent it happening again.
- Offer to talk to the parents or show them around the laboratory.

There are many avenues that can be explored with this case.

- Methotrexate treatment and regimes.
- 'No blame' culture vs. the witch-hunt.
- The response of the individual who made the mistake.
- The likelihood of the mistake happening again.
- Errors often being a combination of circumstances.
- Completing an 'incident report'.
- Who should perform the investigation?
- Learning from mistakes.
- Etc.

Question 4

You are three months into your Consultant appointment at a large District General Hospital. Thus you are perceived by your Clinical Director to be 'new blood' and are asked to be one of two Pathology representatives (the other is a Consultant Histopathologist) on the Trust's established General Practitioner (GP) Liaison Group. This meets every two months to review clinical and support services provision by the Trust.

After two meetings it is clear that there is general dissatisfaction with the Pathology services and Chemical Pathology seems to be singled out for much non-specific criticism. ('Too slow' and 'unhelpful' are familiar comments from the more vociferous GP's).

In subsequent discussion with the Clinical Director you express your concerns and 'volunteer' to conduct a formal review of user satisfaction among the GP's as the basis for changes in service provision.

In planning this exercise:
What approaches to gathering the required information would you consider and why? From your experience, what do you feel will be the key aspects of the services to GP's on which you will need to seek opinion?

Question 4: Notes for Examiners

It is likely that we would all have slightly different approaches to this problem but candidates might consider the following points:

Approaches to Gathering Information

Background
Existence of any current service agreement and standards.
Previous audits (if any) of service to GP's
Formal log of complaints from GP's (general or discipline specific)

New Information
Audit of current service
Questionnaire – validity? Design?
Visits to selected GP's (possibly with questionnaire)
Views of laboratory staff

Aspects of Service for User Opinion/Level of Satisfaction

May include:
Access ('opening hours')
Request form design (personalised; multidisciplinary)
Phlebotomy Services (?domiciliary visits)
Turnaround times
Transport of Samples and Reports
Availability of Consultant advice
Electronic Data Interchange
POCT Support
Management data on Pathology usage by practice
CPA Status (awareness!)
Participation in Clinical Audit

Pathology handbook/Information sheets/CD (covering much of the above information)

Some of the above will require an overall opinion, others (eg. consultant advice) may require discipline specific information.

Question 5

You are informed by the Laboratory Manager that the Trust is suffering long 'trolley waits' and is reorganising its Medical Admissions Unit (MAU) to enable better patient management. A Nurse Consultant has recently been appointed as part of this initiative. She has stated it is necessary for MAU to have a "machine that does D-Dimers and Troponins" to enable early discharge.

Develop your view of this information. What are the implications for patients, the Trust and the laboratory?

The Medical Policy Board decides that it needs the laboratory perspective. You are asked to attend one of their monthly meetings to inform them prior to their making a decision. Draft your submission highlighting the points to be made.

Question 5: Notes for Examiners

While a number of approaches are possible reflecting local practice the essential components of the candidate response should focus around recent National (MDA guidance) and publications on the utility (or otherwise) of such testing.

The candidate should be aware that:

- The Medical Devices Agency have issued guidance on point of care testing (POCT) which informs current practice.
- There are cross-discipline issues and they need to liase with their Haematology colleagues.
- The need to tactfully approach the Nurse Consultant as the information is indirect.
- Clinical decisions are ultimately the responsibility of the Medical Consultants and they therefore need to elicit their views. They need to obtain their perspective of the MAU.
- Issues such as turnaround time and IT (patient records, contiguity, the electronic patient record) are high relevant.
- The impact on the laboratory service of supporting POCT training, maintenance and supervision.
- The economics of the proposal (at different levels: direct cost, impact on unit, impact on Trust, societal implication)
- The need for a concise response setting out the position adopted incorporating timeliness, cost, staffing and training implications.
- The need for the use of management structures to effect input.
- Risk and Clinical Governance issues underpin such decisions.

Question 6

As the newly appointed head of clinical biochemistry you are called to see your clinical director. The contract for your main endocrine immunoassay analyser system is due for renewal in a year's time. Under pressure to make cost savings, the Pathology Directorate decides to take this opportunity to amalgamate the immunoassay functions of all the departments. As a result of a "process re-engineering study", the director has taken the irrevocable decision to undertake all the immunoassays formerly performed in the separate departments of haematology, clinical biochemistry, immunology, virology and microbiology in one laboratory area on the minimum number of new analysers. You are charged with drawing up a specification for the clinical chemistry analytical performance and implementing the changes. Indicate how you will deal with this within the time frame. What important elements must be retained to ensure service quality is not compromised by the new arrangements?

Question 6: Notes for Examiners

In a sense this is a gift to anyone who has had a part in change management, or works in immunoassay. However, candidates need to be able to see the bigger picture and work logically, even if they have never met the situation suggested in this scenario. There are a number of aspects to this question.

Specifying and selecting analytical system within time frame.
Need to draw up specification – workload, turnaround, speed of analysis, minimum volume, analytical performance (CV, EQA data, calibration frequency, etc), random access, add on tests, stats, assay list (which Troponin, hCG specificity) etc, etc.
Needs to be tendered through European Journal advert (for candidates from EEC!).
Timeframe should include allowance for seeing systems in hospitals, testing system etc.
Need for redundancy in number of analysers to avoid downtime (?critical assays – troponins, hCG, etc).

Need to produce test script to test responses to tender against specification. How to deal with special tests – eg. IGF, GH, vitamin D, bone markers, rarer steroids etc not on standard platforms.
Need to define show-stoppers in terms of what is impossible (eg. workload incompatible with proposed configuration, (unable to perform stat hCG or Troponin for example.

Suitability of cross-discipline platforms
Compatibility of sample types.
Any precautions for high risk work (virology, etc) in mixed samples.
Ability to work random access or pseudo-batch.
Best of breed for all disciplines possible?

Arrangements for cross-discipline working
Working practices in each department, (eg. add-on-tests, follow-up tests).
Numbering systems and booking samples in.
Grade and training of staff operating analysers.
QC and calibration practices.
Sample storage (eg. paired sera for virology).
Authorising results from analyser and finished reports – different practices in different departments.

Implementing the change
(This is the key) – need for clear leadership and management structure for both implementing change and running new section.
Perhaps need to question idea of changing laboratory practices and analysers at the same time (forced to by resources but better not both at once).
Dedicated, experienced leadership essential at BMS and senior management level.
Training needs.
Visiting successful combined laboratories eg. The Netherlands, USA.
Communication, communication, communication!