Institute of Biomedical Science 12 Coldbath Square, London EC1R 5HL

Tel: 020 7713 0214 • Fax: 020 7837 9658 E-mail: mail@ibms.org Website: www.ibms.org



Chief Executive Jill Rodney

26 February 2016

Mr Phil Hudson Managing Director Beeston Consultancy Ltd.

Dear Phil

Pathology Quality Assurance Dashboard

Thank you for sending the latest draft of the PQAD and the accompanying documents. The IBMS has reviewed Version 10 and feels that there are still matters that need further consideration before the project goes 'live'. The opinion is that the concerns below are highly pertinent and reflect the realities of implementation.

1. The proportion of clinically relevant tests agreed between the requestor and provider as 'urgent' reported within locally agreed turnaround times (from receipt to authorisation).

The 'urgent' caveat needs clarity about what is actually classified as urgent

2. The proportion of diagnostic cytology and histopathology cases that are reported, confirmed and authorised within 10 calendar days of the procedure taking place.

The inclusion of authorisation in this Cytology and Histology indicator may be problematic as this is something of a bottle neck that can be outside of laboratory control if reliant on other parties to deliver the whole pathway

3. The number of results/reports not available within 42 days of request

We understand that the Genetics Dashboard is not expected to recommence in April as had been anticipated. Genetic services are going out to tender in March, and we now expect the pathology dashboard to be part of that exercise. It is our understanding that implementation will commence once the contracts have been awarded and will be part of the contract monitoring and linked with actual payments.

In view of this, the IBMS believes that a 42 day limit for availability of results or reports is very ambitious and, at present, likely to be impossible. A 42 day limit with a target of zero outliers will make any hospital that does the more specialist work fail the target consistently. If the target were to be 90 or 95% of total workload then there is no issue as these tests are tiny numbers in comparison to full blood counts or urea & electrolytes. It is essential that there is a clear statement to confirm whether genetics is in or out of this exercise and, if out, some definition of molecular testing, which is now undertaken in respect of specific tests in the 'traditional' pathology services and not only in genetics departments.

4. The proportion of departments providing pathology services that are accredited to ISO 15189:2012 standards or equivalent

Recent discussions between accredited laboratories and UKAS has produced the agreement that it would be based on a minimum percentage of repertoire, to get round the "let's just take it out of scope" issue. It is felt that in respect of indicators 4, 5, and 6 there should be (at least) some guidance to allow for:

- Tests where no ISO15189 accredited EQA is available,
- Tests under development/as research
- A "good Samaritan" clause to allow for a test to be used "off accreditation" in extremis

It should also be noted that EQA schemes are accredited to ISO17043 not ISO15189

Tests carried out in rare disease diagnosis and management will unlikely be accredited. This is of particular relevance to molecular diagnostics (section 5, see below)

5. The proportion of requests referred to third party pathology providers that are accredited to ISO 15189:2012 standards or equivalent

Again there is the subtlety of a laboratory that may be accredited but not for a highly specialised referral test (see comment above).

11. The number of serious incidents requiring investigation recorded by pathology.

Some clarity on the definition of a serious incident is required.

All recorded incidents should be investigated not just "serious" ones and what defines a "serious" incident? Actual harm to the patient? RIDDOR reportable? Near miss? Safeguarding breach? Failure to follow protocol? This would benefit from some accompanying definition notes.

There are occasions where "serious" incidents occur with no harm to patients but which are in fact a near miss for which an RCA should be generated

12. The proportion of Pathology staff whose annual appraisals have been completed on time

Neither the Royal College of Pathologists or the IBMS or ISO 15189:2012 standard mandate 92% rather than 90%; the closer the target to 100% the higher the incentive is to just fiddle it with the net result of devaluing the indicator as a measure of quality.

13. The number of consultant planned activities undertaken by locum/agency resources

1 WTE is 10PA a week. It is not made clear the time frame for which the target of <20 PA applies - a month or a quarter, and how does the same target make sense for the largest and smallest trusts in the Country.

14. The number of days undertaken by qualified (non-Consultant) locum/agency resources

Again, as for 13, the timeframe over which this is measured is not made clear. A putative target of less than 20 days in a month is less than a single WTE across all disciplines in Pathology. This is a totally unrealistic target (if this interpretation is correct) and is frankly unsustainable. A target of absolute number is inappropriate bearing in mind the difference in size of departments and Trusts. Percentage locum usage would be more appropriate with the "benchmark" being "Progressive decrease in usage" in context to local usage

15. The proportion of staff who interpret results whose annual appraisal included a discussion about their participation in interpretive EQA schemes (where they are available)

The value of this metric is questionable - what does it prove, what benefit is gained? Furthermore, annual appraisals are confidential between the appraisee and the appraiser, so it is not clear how meaningful information could be obtained.

The 100% target has the potential to devalue the whole process; a well thought out, well prepared and followed up appraisal at 13 months would be considered failure, whereas rushed, badly prepared paperwork exercise at 11 months and 3 weeks would be considered success.

16. The number of amendments correcting reports issued (not the number of results affected).

What is an amendment? Is it a correction of a mistake/reinterpretation or the updating of a report? In histopathology and cytopathology this is not an uncommon occurrence; it is entirely possible and absolutely correct that in certain cases where specialised tests such as molecular markers or genetic profiling or even just antibodies not performed in a particular department are sent away to a centre of expertise, for there to be multiple supplementary reports added onto the original report on an on-going basis. Is that an amendment? It is a change to the original report, but that is clinically sound practice as the initial report needs to be issued pending the specialised testing results coming back to allow timely management of the patient to commence. Amendments/additions may also follow a subsequent MDT meeting when a further course of investigation may be agreed.

Furthermore, a target of less than 3 amendments on reports a month, in an environment such as clinical chemistry where several 100,000 results a month are being produced, seems unrealistic. Many tests in chemistry/haematology and increasingly microbiology are done in large batches or flows; a system failure could generate 100's or more corrections. Perhaps a better indicator would be to measure the number of significant incorrect reports impacting on patient safety.

18-20 - Users

What is the 90% target – is this all good/v good responses or what? There is concern that this indicator target will encourage laboratories to avoid surveying areas of the service where they know they have issues or problems. The RCPath KPI's state that a RCPath standardised questionnaire should be used. Perhaps the satisfaction survey needs to be defined. If "net promotor" style surveys are used then this could be a challenge.

Finally, frequency of reporting: biannually in respect of both trust Board and Pathology Directorate. Is this a typographical error and should trust Board be show biennial reporting?

Council is very aware of the tight deadlines but feel these points merit serious consideration ahead of sign-off.

We look forward to welcoming you to our Council strategy session next Friday and are pleased to have the opportunity to hear directly from you about the PQAD and also the recent Carter report in respect of the pathology elements.

Kind regards

Sarah May

Deputy Chief Executive