Potential Clinical Errors Arising from Pathology Result Combination on Clinical Systems

A Briefing and Discussion Paper on some of the contributory factors

Several potentially serious clinical errors have been reported in the UK where the cause appears to be due to test result data being merged on clinical systems. This paper is intended:

- to explain why this is occurring
- to explore some underlying issues
- to open a debate on candidate approaches to solving the problem

Background

What is being observed is not unexpected. It was predicted a decade ago and documented in the Pathology Modernisation reports and in the PMIP project (Pathology Messaging Implementation Project – http://www.connectingforhealth.nhs.uk/systemsandservices/pathology). Thus, the problem has been recognised but hidden to date – a latent error on Reason's error model terminology (1). It has become manifest now because:

- Data is now persisting in clinical databases and being transferred in structured form across systems
- Patients and their data are becoming mobile between acute and primary care sectors
- Patients and their data are moving around geographically dispersed clinical delivery networks
- The control of data display has now become detached from the originators of data breaking down previously coherent and traditional practices
- The results being generated by laboratories are not standardised

The case which has brought this to light though specific is fully generalisable and the paper is an initial attempt to provide workable guidance on how to tackle the issue.

The Index Case

The current reported problem concerns the reporting of PTH (parathormone results). Data on a new PTH result within a single record has been amalgamated for display in a summary table and used in graphical displays. The clinical system already contains data on the patient received from other laboratories which is reported using different units and reference ranges. In order to present the data coherently the software has logically converted the data to common units and thus the converted displayed data in the table differs from the values reported in the primary pathology report. This initially led to a concern of data corruption as the displayed data differs from the reported data but this has not happened. The primary data is conserved and if viewed in isolation matches the primary reported value and units.

Other Cases

This case is not isolated. There have been a number of similar reports of errors arising from data manipulations across a number of clinical systems and no doubt many unreported instances.

Notable ones have included errors in the apparent reporting of folate results where the correct numeric conversion had occurred (from 5.0 ng/L to 0.005 ug/L) but because the display only used 2 decimal places it was seen on screen as 0.00, clearly in error. Similarly, report comments have become detached from results

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and though retained in the systems have been displayed in separate windows causing clinical users to misinterpret results.

Errors in READ code interpretation have been identified on another widely used system where though results displayed correctly diagnostic interpretations were added to records inappropriately. In the most serious case a code for Oestradiol (E2) was misclassified as READ code “E2…” (Mental disorder NOS). This and another 169 similar mis-classifications went unnoticed on 329 systems and in all approximately 115,000 records were contaminated with errors. The clinical consequences of the latter event have never been quantified because many affected records were transferred the traceability of the cases proved all but impossible.

Extent of the Issues

Whilst the index case is linked to primary care, the issue is also latent in other clinical data bases such as those used for patients with Chronic Kidney Disease, Diabetes and Cancer especially chemotherapy. Hence the need for a solution to data combination and transformation is a pressing topic for all of pathology.

Interpretation & Contributing Factors

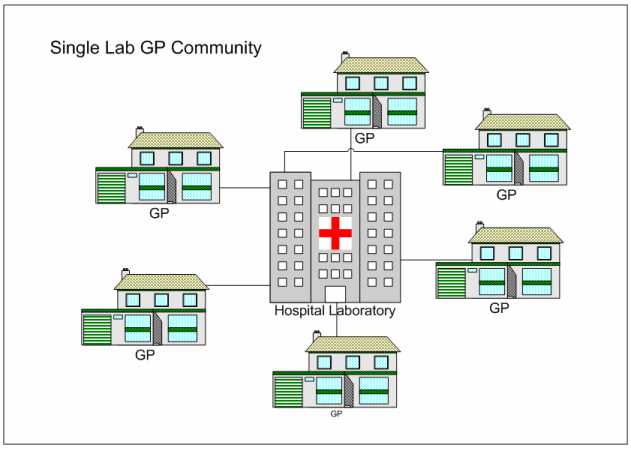
What the current event has highlighted is the lack of standardisation in reported units by laboratories and at a deeper level lack of standardisation of reference ranges. It also exposes questions about the governance of data and of how this should be managed. In an electronically networked world scale and speed of propagation have become significant factors compared to a traditional paper-based service. Any error is now magnified many fold and becomes difficult to unwind.

System Configurations

Over the last decade the landscape of healthcare has changed significantly. Four trends can be identified relating to:

- Consolidation of pathology organisations
- Clinical system development
- Clinical service models
- Patient mobility

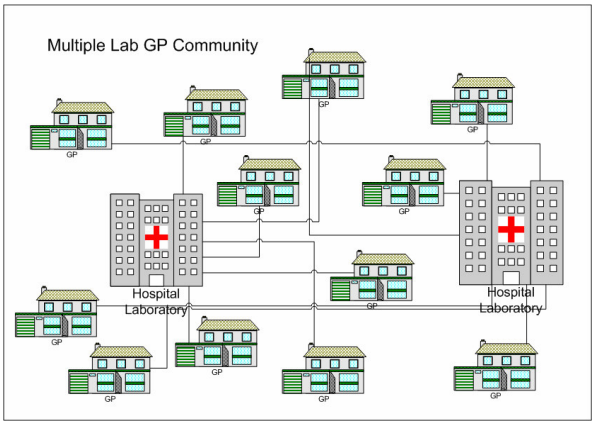
Pathology services were traditionally paper-based and confined to a relatively small geographical footprint. (Figure 1: Single Laboratory GP Community). The early introduction of PMIP was consistent with this model. Data flowed from approximately 200 laboratories into a large number of small GP systems (8,000 across the UK in 2004).

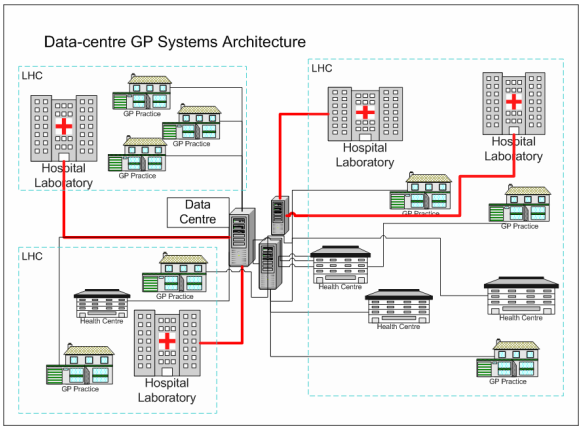


Due to their lack of sophistication it was treated as a text report and rarely subject to further manipulated by the systems. Within this local health community footprint data remained consistent and there was rarely any linkage with data from other health communities. Since all results and reference ranges were derived from a single source data remained coherent and comparable.

With the laboratory consolidations and changes in commissioning boundaries this simple model has altered. This has the effect of mixing data from previously discrete health communities. (Figure 2: Multi-laboratory GP Community). Since data in this model could be derived from different sources where methods were not standardised between the laboratories the potential for conflicting data began to arise. Many local laboratories recognised this possibility and some voluntarily worked towards alignment.

In the intervening decade since PMIP there has been considerable consolidation of GP systems and the continuing trend is towards a data-centre model of system delivery with logical rather than physical separation of the practices. Hence the footprints of health communities now overlap within the information systems (Figure 3: Data-centre Model) and the direct connections between the laboratory and the GP no longer exists.





Data consolidation and transfer

Even for systems that remain scaled at the practice level data transfer, consolidation and conservation has been enhanced. The sophistication of the systems has increased with data being stored within data structures, rather than as text, allowing the development of functions such as cumulative tabular and graphical display and decision support and analysis (e.g. eGFR triggers and QOF reporting). The GP2GP project has been developing to allow data to be transferred between systems when a patient moves practice. This has a similar effect of mixing within a single patient record data derived from multiple laboratory sources.

Clinical Service Delivery

There are additional changes in clinical service delivery which also need to be recognised. Patients are now treated and managed over a wider geographical footprint, for example in cardiac and cancer networks such that their results can be generated at several different locations. Though the potential errors have been manifested in general practice the same issues are present in systems managing specialist clinical networks. Whether these are recognised yet is a moot point.

Population Mobility

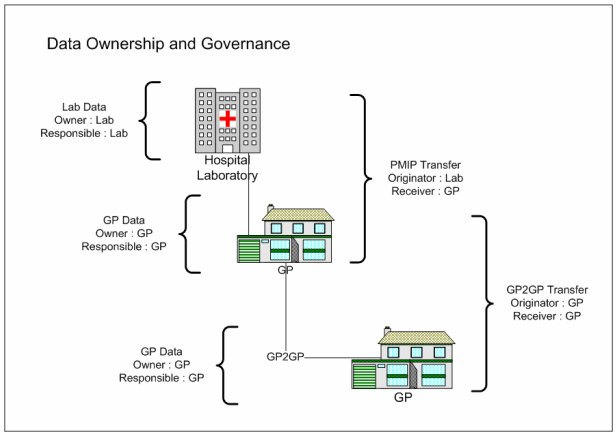
It is possible that the degree of mobility of the population at large has increased with people moving house more frequently. This is exacerbated by the large demographic who are entering retirement, moving to retirement homes and are potentially large consumers of diagnostic services.

Future Trends

As the use of electronic records accelerates the merging of data from disparate sources will increase. This is becoming manifest acutely in the area of pathology where early experience is highlighting many predictable safety and compatibility. Point-of-care testing and home testing will lead to greater diversity of methods and the development of personal health records (see Microsoft Healthvault, http://www-03.ibm.com/press/us/en/pressrelease/26603.wss)

Data Ownership & Governance

These developments all call for clarity in our understanding of who owns and governs data as it passes between systems. This has been most rigorously defined and explored in relation to the Data Protection Act and Caldicott guidelines. However in this context other factors have to be taken into account.



The model to the left shows a very simple schematic of potential data-flows for PMIP reports. The primary transfer from laboratory to GP requester is clearly the joint responsibility of the communicating partners. However the data transfer explicitly passes ownership of the data from the originator to the receiver and the way in which it is handled and used becomes the responsibility of that owner. The originator, in this case the laboratory, might well want to influence how it is used and has a duty of care to minimize misuse but is no longer the data custodian.

Similarly, where an onward transfer occurs, for example, using a GP2GP message, the originator/requestor pair is now the GPs involved and the laboratory is now a further step away from the data ownership.

If this problem is generalised there will be many onward uses of data which is transferred, for example for use in audit, research, decision support and contracting. Furthermore, some of these processes will generate meta-data for example by combining independent datasets originating from different owners. The ownership of meta-data thus may be in hands of as yet unidentified organisations and users. There is a need to clarify these questions so that communicating parties are clear about their responsibilities and boundaries of influence.

Scientific Considerations

From the analysis above combination of data will be an inescapable consequence of current and future e-Health developments. To understand the problem of downstream data manipulation from a laboratory test perspective we need to consider several classes of analytes.

Class 1 analytes

Firstly, there are analytes where the method of reference is to all intents and purposes referenced to a physically verifiable gold standard. Sodium would be such an analyte measured by a technique such as ISE. The value should be the same (within experimental error) on any properly calibrated instrument. Any conversion of units should be safe if appropriate formulae are applied. Reference ranges in many of these cases are physiologically determined and may differ little across populations.

Class 2 analytes

Secondly, there are analytes where an international reference material is available where again if the assays are appropriately calibrated unit conversions should be achievable. Drugs, enzymes, lipids and some hormone assays would fall into this class. Reference ranges may show more variance than in the first class but may be sufficiently coherent to allow conversion.

Class 3 analytes

Thirdly, there are analytes where no reference standard exists and where results are only equivalent within the self-referral system of the method employed. One scientific reason for this is that the methods may rely on immunological techniques where specific antibodies are used to detect and quantify the analyte of interest. PTH is a case in point. Different assays use different antibodies and thus although they all estimate ‘PTH’ they actually detect different physical entities. Within a given assay system abnormality is defined by comparison to a reference population. Thus, for a single patient deviation form normality can be assessed and longitudinal data used in management as the data is internally consistent. However conversion of the data from different assays is not valid and nor is the conversion of reference ranges.

Data Normalisation Methodology

Techniques have been employed to allow normalisation in some instances, the best example being the use of Multiple of the Median which is used to normalise data across methods and populations in prenatal screening. Such efforts have not been applied elsewhere as the need has not yet justified the considerable effort involved.

Other analytes which fall into this call are the tumour markers such as PSA and in many of these cases the significance of misclassification is severe. As indicated above many of these analytes are the very ones which

apply to patients being managed in complex, distributed networks which make it a particularly important problem.

Of particular worry is the projected use of values in automated decision support algorithms such as those represented by Map of Medicine since the threshold values are generally numeric and may be based on false assumptions about data equivalence. Two recent examples were in the published values for PSA in the National Cancer Strategy where a method specific value was naively used without insight to the implications of up to 20% inter-method differences and the eGFR saga where unwarranted assumptions of equivalence lead to very perverse outcomes. The science in this area is also complicated by questions about imprecision in methods such that even though values may be converted the variance may affect the performance of algorithms. These aspects also need attention.

Conclusions

This paper attempts to provide background to stimulate debate on what is an emerging problem in clinical information management as we move into a world of networked patient databases. Several groups will be involved in resolving these issues including the DH, Connecting for Health, professional bodies, IT professionals, suppliers and the wider user community. Some of these groups are currently in active discussion of steps which can be taken to mitigate the risks and ensure that pathology results continue to be transferred and used in a safe, secure and effective way.

Comments can be emailed to the author or posted on NHS Pathology IT community at www.espace.connectingforhealth.nhs.uk.

References

1. Reason J. Human error: models and management. BMJ, 2000;320:768-70

The Yorkshire Centre for Health Informatics

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