

Opinion Paper

Ian D. Watson*

A patient focused relationship for specialists in laboratory medicine

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Abstract: Technological change is driving individualized healthcare delivery including laboratory medicine. Ensuring patients gain from their empowerment it is essential that they access data that enables them to utilize reliable information. The potential difficulties of comprehension, information retention and imperfect modes of communication can significantly impair utilization of information by patients. Support for understanding and decision-making needs to be clinically competent and integrated within the healthcare team. Specialists in laboratory medicine are well placed to undertake such a role, the issues around this are explored and proposals for better direct engagement with patients made.

Keywords: collaborative healthcare; direct patient contact; improving patient understanding; knowledge management; patient engagement.

Context

Innovation in technology, informatics and infrastructure are revolutionizing society and healthcare in particular; the rapidity of change and development in service models means that the professions delivering them have to change in response; this is illustrated by genomics, in 2012 1000 genomes were mapped [1], now 100,000 are well on the way to being mapped [2] with the expectation that linking such data routinely to patient assessment will revolutionize care. Strategic programs such as the EU Horizon 2020 derived policies for Digital Health for Europe [3]; IT Future of Medicine [4]; Virtual Physiological Human [5]; NIH Human Microbiome Project [6]; all illustrate the investment and expectation from harnessing these technologies.

Genomic diagnostic tests developed by the IVD industry are marketed to physicians and where legally permitted, to patients, indeed individuals are encouraged to have their genome sequenced so they can trace their ancestry through genetic markers, but are also provided with potential clinical risks, enabling individuals to have ownership of their health and identity. Though genomics is seen as the epitome of personalised medicine, there is more to it than that [7]. One could argue that the phenotypic expression as risk factors such as a raised cholesterol or glucose are just as important, or monitoring thyroid replacement therapy is just as relevant to an individual and dealing with each patient's results and circumstances is also personalised medicine.

The paternalistic medical approach adopted hitherto of test requests being made, received and 'owned' by the patient's physician is being overtaken by active patients who research their symptoms/diseases and want access to their medical record and to understand it [8]. However, within this process laboratory medicine as a profession is virtually invisible to the patient, that there is a need for patient education of the significance of laboratory results is not in doubt as evinced by the popularity of Lab Tests OnLine, now available in 13 languages [9]. There is therefore a potential case for individualised comments that are shared between the patient and the specialist in laboratory medicine (SpLM).

Looking at the issue of patients understanding laboratory tests in another way: what do you do if you want to know anything? You search the Internet! Doing this results in a mix of authoritative, dubious or false information. Indeed from such a search you may be encouraged to either do your own tests, by buying point-of-care devices on-line, there are said to be 104 different types of test available for self-testing [10], or send a sample to a laboratory, perhaps not in the patient's country, using non-standard sampling techniques, validation and interpretation. A Dutch survey found that the commonest self-tests were for cholesterol and diabetes, followed by allergies and infection, HIV was the largest in the last group [11]. It is these scenarios that encourage the view that proactive engagement of the SpLM within a healthcare framework for patients is a positive and useful approach [12].

*Corresponding author: Dr. Ian D. Watson, Department of Clinical Biochemistry, University Hospital Aintree, Liverpool, UK, E-mail: iandwat@me.com

Patient comprehension

Patients' reactions to lack of understanding will drive them to seek information; the Gesundheitsstudie [13] found that patients sought information from the following sources: pharmacists 34%, Internet/print 74%, mobile (cell) phone apps 18%, physician friends 41% and television 54%; a spectrum of variable quality information. Government health sources did not seem to figure in this survey, though these are typically of good quality, there are also commercial web pages, supported by advertising, that provide valid information [14].

It has been estimated that approximately 1% of a population will self-test for cancer, typically the worried well, there is a clear impact of psychological morbidity and healthcare demand [15]. Whilst test kit information has been as assessed as moderate to good, it needs to improve and that this may require legislation [16]; this may be particularly pertinent as self-testers have worse health and BMI than the general population, and the reason for such testing appears to be health-related behaviour [11].

Patients have long had the right to have access to their records according to the Alma-Ata declaration [17]. Putting patients at the forefront of a laboratory medicine service needs the recognition of their expectations, they expect all results to be theirs and of the highest quality, expectations undermined by media headlines indicating some failing in detection or diagnosis and while the ISO system may be known by some, there is a need to ensure that compliance with relevant ISOs 15189 and 22870 are highlighted.

There is an inevitable delay in result return and this is a cause of anxiety for the patient, they would wish for any delay to be minimal. There are issues that need managed by laboratorians, for instance, there is variation in adopting the best analytical procedures, e.g. preferring colorimetric over enzymatic creatinine is almost inexplicable to most people. Also patients often see tests as definitive and differences as absolute, there is poor understanding that a test result reflects a probability and that a change needs to be of a certain magnitude to be significant.

However, this is not a one-sided transaction, 15 years ago it was anticipated that the 'good patient' would bring a list of questions expecting clear answers; know and want to be involved in decisions about them and share these with their healthcare providers; have free access to their healthcare records, without demur, request and receive second opinions for major diagnoses and

decisions and of course communicate electronically with their healthcare team [18]; indeed the ePatient is said to have arrived, using their initiative, participating in patient community networks, are engaged in their healthcare and this is to be welcomed as they require less support by the physician who can focus resources on less technology enabled patients [19] providing they are sourcing valid information.

Patients' access to their medical records is now a right within the European Union through the General Data Protection Regulation EU 2016/679 and has been enacted in member states, similar rights are provided in some other countries; professional concerns over patients' access to their records causing patients confusion and anxiety would seem to be misplaced [20], though severity and non-treatability are negatively associated with a willingness to undergo testing and presumably to know the answers [21]; it is also claimed that access to results may not provide the reassurance sought [22].

Technological projects to enable ePatients in Europe have been driven by EU initiatives, the SUSTAINS project in Uppsala over 2012–2014 successfully gave patients access to their electronic patient record (EPR) and informed roll-outs in Estonia, Spain and Italy; all Swedes now have access to their EPR, the current take-up is around 33%. This initiative feeds in to another EU issue of cross-border health, a phone app, DECIPHER, is designed to enable patients to share their data when not in their home country, though it is not clear if/when this will go live.

Access to records provides definitive reference for the patient to review their health data, for the evidence is that oral communication of health information is poorly retained [23, 24] and that even when patients feel informed, they are not. Comprehension can be more difficult for numerate results, this is particularly poor for those with poor education and for whom the language of communication is not their first language [25]. There is a further complexity in that probability of an outcome/event is expressed typically as a fraction, e.g. 1 in 100, 10 in 1000 or as a percentage, e.g. 1%, the numeracy of the individual is relevant to understanding, percentage seemed the best understood verbally [26]; the expression in percentage is better comprehended than as a fraction, older patients have a lesser understanding; more complex values, e.g. $\frac{3}{4}$ or 75% are better comprehended if presented pictorially [27], the type of icon used has an influence [28]. Recall and education are factors that obstruct enablement of effective medical decision making, consequently clinical support is essential [29].

Role of specialists in laboratory medicine

So, this all begs the question would an SpLM be willing to interpret results directly to patients? EFLM created a Working Group on Patient Focused Laboratory Medicine in 2013, which has been considering the issues in this new field. We surveyed the this question in 2015 [30] and found that there was wide variation between countries, in part reflecting national legal requirements and physician relationships with the laboratory; in about 50% of cases interpretive comments when made available to patients were the same for both physicians and patients and supporting patient access to their data. Of course the next question is: do patients want access and do they want comments on their results? As part of the Working Group programme patients from eight European countries were surveyed at medical out-patient clinics [31] there was country to country variation, those wanting comments on results ranged from 50% to 95%; between 15% and 40% said they understood their results, the remainder wanted additional information, a standard description or reference to a website was deemed sufficient by most, but personalization of comments by an SpLM was acceptable to between 40% to nearly 80% of patients, though in only four of the countries was there a willingness to pay for an interpretation and in a further two this was currently illegal.

Providing individualised comments to patients would require a greater volume of report interaction than hitherto for the SpLM, so this would need to be automated. There are software systems that enable an SpLM to build acceptable comments into their library and to generate semi-individualised comments, which can also be fully individualised with a specific individualization; to date such systems have not been widely adopted and where they have been they have only been used to comment to physicians, but this is a clear direction of travel; the costs of implementing such systems are not yet clear, but one would surmise that with widespread adoption costs would be acceptable.

There are a number of unknowns were such an approach to be developed as a strategic goal for empowered patients, laboratory medicine and healthcare in general. The assumption, and anecdotal evidence is that patients do indeed feel ownership of their data and they may better understand their health, but there is, to date, little evidence that this translates into better outcomes [32], lacking such information makes it more difficult to justify associated costs and may be opposed on the basis that while this may be what patients want, is it what they

need? Further, if patients own their results, one has to consider the legal and ethical responsibilities [33], who has the responsibility for acting on or failing to act on results? The concern is that while some patients may seem to be cognizant of the significance of results and feel informed, there is often a genuine lack of comprehension of medical information [29] and so there is a risk through ignorance and/or inability to understand [34]. Given the push by governments to enable patients to access their records, these caveats reinforce the necessity of professional support in enabling clear understanding, and given the pressure that primary care physicians are under they could find managing such a role time-consuming, whereas with the necessary software and agreement of the healthcare team, the SpLM is well placed to deliver such a service.

One major road-block however is the lack of harmonization between, and sometime within, countries of tests used, terminologies and most significantly units of concentration. This reveals the flaws in the ability of laboratory medicine to deliver coherent information: to our detriment! We need to develop and enact standards and harmonisation, for if we do not, someone will do it for us: think on the evolution of eGFR based on a poor test yet mandated by governments [35].

Why and how of implementation

It is clear that there is a need for collaboration and co-operation by an SpLM with physicians, their institutional management and that heuristically a measured, quality, risk-aware approach needs to be adopted to enable the development and delivery of an acceptable service, key points are identified in Table 1.

I would suggest that the value proposition is that:

- Patients are empowered
- Primary care physicians limited time is better utilised
- An SpLM can assist patients understanding
- Patients are better informed
- Improved population awareness of laboratory medicine

And that the unique selling point is that an SpLM's key function is to provide expert comments on results, so it is logical to extend this to patients, with the caveat that collaboration with the physicians dealing with these patients is essential.

I would further suggest that by ensuring that we are the source of knowledge management for clinical laboratory data, that if and when the next disruptive technology

Table 1: Key elements in developing a patient focused laboratory medicine service.

1. Ensure your employer is in agreement with initiating such a service
2. Get the agreement in principle of the physicians responsible for the group of patients
3. Ensure that any IT solution used is sufficiently encrypted to meet local laws and regulations
4. Agree the scope of comments to patients
5. Agree whether comments will go direct to patients with a copy to their physician or will be through their physician
6. If there is a patient group discuss the proposal with them and obtain their support
7. Explicitly agree the competencies of staff who can make comments and their adherence to the protocol(s)
8. The escalation procedure for
 - a. If an unexpected finding is seen
 - b. Patient initiated queries
 - c. If something goes awry
9. Ensure a clear audit trail of all actions
10. Determine the length of record detention
11. Put key performance indicators in place
12. Regularly review the service
13. Publish your experiences

to investigate metabolism arrives, e.g. hand-held MRIs, we would be seen by the core service users, i.e. patients, as the metabolic knowledge management experts: Think about it: do we have the option not to?

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