

Human Learning Systems: A practical guide for the curious

CASE STUDY

Learning as management strategy: Pathology in the English NHS

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Introduction

This case study is an example of 'learning as a management strategy' in practice.

It has been created to illustrate the work in two different ways:

- The story of the work to enact learning as a management strategy
- The illustration of the work to enact learning as a management strategy as connected Learning Cycles. This representation of the work helps connect the case study with the core concepts in the guide.

An illustration of this work as connected Learning Cycles can be found <u>here</u>.

The story of the work...

This case study describes how work to understand and improve the pathology (medical diagnostics) system in North Devon led to significant performance gains, influencing national priorities and the approach to pathology accreditation.

Overview

Approximately 80% of patient interactions with the NHS involve pathology services, equating to about 200 million requests per year.[1] In North Devon, this translates to about 5.5 million tests per year for a population of approximately 180,000. Monitoring for chronic conditions accounts for a large proportion of this testing (for example over 50% of biochemical tests[2]). While some of this testing was supported by evidence-based guidelines, this was not universally the case. In fact, prior to the changes we describe, there was increasing evidence that around 25% of these tests may be unnecessary.[3] This issue is not unique to North Devon. The NHS Atlas of Variation has demonstrated that significant geographical variability in primary care pathology testing rates in the UK[4][5] cannot be accounted for by differences in socio-demographic or other descriptive indicators of GP practices.[6]

These indications of excess and inappropriate testing are material. The potential for diagnostic tests to cause harm is increasingly recognised, and has led to initiatives such as "Choosing Wisely". [7] Despite this, the focus of laboratory accreditation standards has been on whether tests are conducted repeatably and in well-controlled environments, not whether tests are necessary or appropriate for patients. There has also been a strong focus in England on reducing the cost-pertest in order to improve efficiency. Moreover, a significant proportion of the primary care testing associated with chronic disease monitoring has been influenced by the requirements for payment via the quality and outcomes framework (QOF) of the General Medical Services (GMS) contract, which was introduced in 2004.[8] Most chronic diseases listed in QOF require some element of blood monitoring, usually on an annual basis. There has been little or no requirement to ensure that this monitoring is confined to tests that are necessary and sufficient to provide care. This combination of factors has led to a tangible disconnect between what matters to patients and the de facto focus of performance management in the pathology system.

In order to better understand these issues and how to act on them, an initial group of partners in North Devon pathology services undertook a series of experiments. Latterly, this collaboration grew to include national partners, leading to experiments at different levels of system scale. The outcomes have included:

- Significant, measurable reductions in unnecessary activity, cost and harm
- The systematic integration of an alternative quality framework for North Devon pathology, linking the local laboratory and primary care via learning-led governance
- The adoption of this quality framework within NHS England's national GIRFT (Getting It Right First Time) report for pathology
- Collaboration with the pathology accreditation authority (UKAS) to integrate this quality framework within the national accreditation approach.

Story of change

Defining purpose

To begin to explore what matters to patients undergoing diagnostic tests, the North Devon team interviewed a small number of patients attending routine phlebotomy clinics. They found that, in general, although patients trusted healthcare professionals to do what was necessary to keep them safe and well, patients were not aware of what tests were being done. In addition, they found that patients wanted testing to tell them if they were "normal" and, if not, what needed to happen to return them to "normal". These findings are in line with larger studies,[9] and from these a statement that reflects the purpose of laboratory medicine was derived: "To help citizens, and those supporting them, make informed decisions about their health and care."

Understanding the system

(i) Making the system visible

Initial interviews showed that the current approach to pathology in North Devon was not meeting this purpose. The team met patients who had received results for tests they did not know were being done, and conversely met patients who had gained false reassurance from tests that had not been done. They saw numerous examples of tests that were not necessary to answer the clinical question being asked, often leading to significant harm from "treating the result". Conversely, they saw evidence of delayed and suboptimal decision-making due to a failure to carry out appropriate tests. Results generated by the laboratory were often presented in ways that obscured meaning and were prone to being misunderstood. In addition, results tended to reflect what is normal for a population. They rarely clarified what was abnormal for the individual.

(ii) Building relationships & trust

Recognising that these finding were significant and challenging, the team felt it was important to define the scale of the issues with reference to how they impacted other motivators for key actors in the system, such as local GPs, primary healthcare teams and commissioners. This included understanding the impacts on clinical workload, patient safety and system cost. They elected to focus initially on two pilot GP practices. This enabled the team to ensure that the stories and data they gathered were specific, relevant and meaningful to those who would work to pilot initial changes. Having two practices also allowed them to understand and differentiate between the generalisable and what may be highly context-specific.

Clinical workload and system cost

In 2012, there were 81,465 primary care requests that generated at least one result that was outside a reference limit in full blood count (FBC) and liver function tests (LFT). Approximately 25% of these came from chronic disease monitoring. As a preliminary exercise, the team examined the consequences on primary care workload of an alanine aminotransferase (ALT) result outside reference ranges arising from chronic disease monitoring (this is a blood test that checks for liver damage). They reviewed the case notes of 45 patients with chronic disease from the two practices in whom the ALT was above the reference range. They found:

- 34 patients had the "abnormal" result filed with no further action
- 7 patients had the test repeated, which was within the reference range
- 4 patients were seen again in a GP appointment to discuss the results
- 1 patient received an ultrasound of the liver, identified as fatty liver (adding nothing to the management of a patient who could be seen to be obese)
- 1 previously well patient saw the GP 14 times in a year, with multiple repeat tests while a further patient had several GP appointments and referral for onward investigation. Neither of these patients had significant pathology that altered management.

The team also looked for secondary care referrals in the year prior to the changes we describe below. These were from one of the pilot practices (list size 11,000 patients) and were generated as a result of an FBC that had been requested as part of chronic disease monitoring. The team identified 7 patients who fitted these criteria. These generated 1 haematology appointment, 4 gastroenterology appointments, 1 MRI head scan, 1 CT of the colon, 4 gastroscopies, and 4 colonoscopies. 2 patients did not attend their appointments. No significant pathology was found in any patient. 2 patients had benign polyps. The estimated cost of these investigations is about £10,000. Extrapolating to the whole North Devon locality, the cost would be £200,000.

Patient safety

The team interviewed a patient who described the effect on her life of detection of an incidental mild anaemia, and as a result produced a video in which she describes her experiences.[10] Other cases showed how a mildly elevated ALT can turn a citizen who is an infrequent user of medical services into a patient with high levels of dependence with multiple follow-up appointments. At one extreme, a patient had 14 follow-up appointments within a year, despite having no symptoms that would have suggested the need to check liver function in the first place. Another patient eventually stopped attending secondary care referrals as they were becoming so anxious about the investigations that had been put in train from a result just above the ALT reference range.

(iii) Establishing shared purpose

Sharing these data and patient stories provided a powerful foundation for engagement and the opportunity to share perspectives, surface differences, and formulate further shared lines of enquiry with the GP practices.

Practices were keen to learn from others before taking action, and so the team reviewed the content of local chronic disease monitoring recommendations held by the 20 general practices served by the North Devon laboratory. They found that no two practices recommended the same set of tests.

Next, they turned to National Institute of Health and Care Excellence (NICE) guidance but found that little of this guidance was based on robust evidence. This surfaced differences of perspective within the group of learning partners, especially about the role of some specific tests that were not recommended in some clinical contexts but that were traditionally requested. This was particularly true for FBC and LFTs.

To resolve this, they started to reframe the reasons for testing into clinical questions as they would be seen from the perspective of the patient. For instance, "annual blood monitoring for hypertension" became, "are my kidneys OK? Is there any evidence I am suffering side effects from my medication?"

From this, the partners were able to reach significant consensus about which tests would be necessary and sufficient to answer specific clinical questions, providing a useful touchstone for interdisciplinary discussion and learning, and a route to action.

Co-Design

Building on this insight (i.e. that framing requirements for testing through the lens of a clear clinical question, anchored to the patient perspective), partners developed a number of "care sets" for chronic disease management. These were clusters of pathology tests which could be ordered as a set with confidence that they were necessary and sufficient to answer the specific clinical question at hand.

Partners recognised that these needed to be tested, initially within the pilot practices, then if successful on a broader basis to understand how transferrable the learning would be across contexts. This led the partners to continue their exploration through a series of action learning cycles or experiments.

Experimentation/exploration and System Stewardship

First Learning Cycle: developing monitoring measures and pilot study

Practices had historically requested FBC and LFTs in most chronic disease monitoring schedules but, through the co-design process, it had been agreed to remove these from most of the pilot care sets. This meant that partners were able to use requesting data for these tests from the pilot practices to monitor uptake of the new approach. They used haemoglobin as a marker test for FBC and bilirubin as a marker test for LFT. To test acceptability of the new care sets they were initially introduced to the two pilot practices.

GP leads were identified within the pilot practices, who ensured that all staff were

aware of the pilot intervention. The local laboratory IT team worked closely with healthcare assistants (HCAs) in the practices to ensure they could request the test groups using a single click in the primary care electronic ordering system. In both pilot practices there was a rapid and significant fall in haemoglobin and bilirubin requesting rates (Figures 1 and 2). Partners concluded that care sets were an effective and acceptable way of changing test ordering practices.

Figure 1: Monthly test requests for haemoglobin and bilirubin for chronic disease monitoring in pilot practice 1



Figure 2: Monthly test requests for haemoglobin and bilirubin for chronic disease monitoring in pilot practice 2



Second Learning Cycle: using electronic ordering to pilot the new care sets at scale

Based on the findings of the first Learning Cycle, partners shared the new care sets with all practices. They developed presentations to show the variation in current requesting practices, the harms caused by current approaches to testing, the rationale for the new care sets, and the effect of these on requesting volumes in the pilot practices. They then gave a talk to North Devon GPs in a half-day educational forum.

The partners found that GPs were very supportive of the new testing protocols and they had good feedback on the approach. However, over the next three months they saw only a slight drop in testing requests. To understand the barriers to uptake, partners visited practices to discuss with GPs, nurses and HCAs. They found that in some practices (including in the pilot practices) the HCAs and nurses were using the protocols but then starting to add back on the usual tests that they had been requesting for years. This can be seen, for instance, in the after-pilot uptick in haemoglobin requesting seen in Figure 1 and Figure 2. Partners learned that HCAs and nurses had thought that the new care sets had been introduced purely to save money. They also learned that in other practices, even though clinicians were keen to use the protocols, the internal practice systems had not been changed as doing so required time and commitment and these practices had other priorities.

Partners concluded that their laboratory requesting data was a good way to monitor uptake, surface learning, and target specific support to practices to improve uptake. They noted that educational events had not been an effective way to deliver sustained change across their whole health system and hypothesised that it would be important to:

- Design new forums for ongoing dialogue, ideally involving whole healthcare teams and not just lead GPs.
- 2. Assist local clinical leadership with practical support.

Third Learning Cycle: creating a pathology optimisation forum for peer-led improvement

Based on findings from the second cycle, partners set up a pathology optimisation forum for practice HCA and GP leads. The goal was to provide peer-led learning with input from laboratory staff. Funding was secured to release these people for a half-day event every quarter.

At the first forum practice, uptake of the new care sets was discussed by showing data on haemoglobin and bilirubin test volumes by individual practice. This showed a drop in testing in eight practices, but that 12 practices still did not appear to be using the protocols. There was discussion about barriers to implementation and a number of themes emerged:

- Doing the right thing for patients and reducing workload are the key drivers for clinicians in primary care
- A reluctance to let go of previous individual practice protocols
- A worry that new diagnosis could be missed
- Not appreciating the harm that can occur from de facto screening
- Concerns about the rigour of the evidence review.

Partners were challenged to add a test (thyroid function) that was deemed missing from a testing protocol (new diagnosis of type 1 diabetes). They reviewed the updated NICE guidance on this topic, which suggests thyroid-stimulating hormone (TSH) is measured at annual review in these patients. As a result, they changed the test group, improving upon their initial work, increasing ownership outside of the project team, and demonstrating how this approach facilitates keeping testing algorithms up to date.

They were also challenged to remove annual cholesterol testing from cardiovascular protocols, which would be in line with NICE guidance. However, partners chose to keep this in their care sets as this was an area that many felt uncomfortable with, and which it was agreed could be an additional barrier to change when there was still some reluctance to let go of FBC and LFT.

Fourth Learning Cycle: responding to feedback with patient stories and test-requesting data

At the next meeting of the Pathology Optimisation Forum, partners aimed to address the concerns raised at the initial meeting. They presented stories of how unnecessary testing leads to harm, including a video of a patient with incidental detection of anaemia describing the anxiety and disruption it caused in her life. They showed their data on how unnecessary testing creates additional workload, and they showed that reductions in LFT had not significantly reduced the detection of pathologically raised ALT, suggesting that, under the new approach, disease was not being missed. Talking, listening and bringing back this further information to the forum levered the biggest change during implementation. In the following months, North Devon saw the biggest drop in test-requesting as a further 10 practices implemented the new testing protocols. This left just two practices that were not consistently using the new care sets. These two remaining practices were recognised as requiring individual practice meetings to further discuss and understand their local context and barriers.

Impacts

On requesting volumes

In 2012, blood tests that could be easily identified as part of chronic disease monitoring from clinical details accounted for 26% of renal profiles from primary care; 18% of FBC requests from primary care; and 26% of LFTs from primary care. The rolling annual average test volumes for chronic disease per 1,000 registered patients in North Devon are shown in Figure 3.

Figure 3: Estimated changes in common analyte requests for chronic diseases between April 2012 and March 2017 (rolling annual test volumes)



The effects of the interventions are clearly visible when viewing overall primary care requesting. There has been a small rise in renal profile requesting (563 sodium tests per 1,000 patients in 2013, 601 sodium tests per 1,000 patients in 2016; 6.7% increase; p<0.0001) that was in line with secular trends. This contrasted with large drops in the overall number of primary care requests for FBCs (555 haemoglobin requests per 1,000 patients in 2013; 476 haemoglobin requests per 1,000 patients in 2016; 14% decrease; p<0.0001) and LFTs (436 bilirubin tests per 1,000 patients in 2013; 338 bilirubin tests per 1,000 patients in 2016; 22% decrease; p<0.0001).

On costs

Approximately 95% of primary care requests to the North Devon laboratory are now received electronically. Using laboratory cost data, the intervention is estimated to have reduced marginal (or reagent only) costs by approximately £18k per year. However, using NICE reference costs,[11] this is nearer to £200,000 reduction in actual annual testing costs (Table 1). Table 1: Estimated cost-savings associated with test reductions in FBCs and LFTsperformed for chronic disease monitoring between 2012 and 2016

Year	2012	2016
Approximate number of LFT and FBC for chronic disease monitoring	18,000	2,000
Total marginal cost (£1.10 per test)	£20,000	£2,000
Total reference cost (£12 per test)	£220,000	£24,000

On primary care workload

Between 2012 and 2016, North Devon saw a 13% reduction in primary care requests that generated at least one result that was outside a reference limit in the FBC or LFTs (81,465 in 2012 to 70,949 in 2016; p<0.01). In their study of harm, partners had examined how abnormal ALT results created downstream workload. Between 2012 and 2016 there was a 19% drop in the overall number of ALT results that are outside reference range, from 43 per 1,000 patients per year to 35 per 1,000 patients per year (p<0.0001). In contrast, the number of results that are elevated to levels that are likely to reflect pathology (3 times upper limit of normal) has not changed significantly; from 3.7 per 1,000 patients per year in 2012, to 3.4 per 1,000 patients per year in 2016 (8% drop; p>0.1). This suggests that the new approach does not miss significant pathology as a result of the interventions.

Embedding and influencing

Through the course of these initial Learning Cycles, a new lingua franca for collaboration around pathology had emerged. This became known as "The Clean Framework" and provided a way of describing what good testing looks like, so that partners could evaluate and improve current practice across the full range of pathology tests, not just those used for chronic disease monitoring.

Box 1. The Clean Framework

Clean In

Requests

- Ask a well-formulated and valid clinical question
- That the test is capable of answering
- As a consequence of patient informed choice
- Arriving at the point of testing in a state that allows the question to be answered

Clean Through

Tests

- Are produced within known variation
- On time to answer the question or otherwise enable optimal care

Clean Out

Results

- Are provided in a format that enables accurate understanding and appropriate use
- Describing the consistency (or uncertainty) of the result
- With reference to what's normal for the patient
- Including narrative as necessary to faciliting informed choice

Supported by the new Pathology Optimisation Forum, this framework provided a systematic way to rapidly identify the point and nature of intervention required for improvement. For example, applied to wound swab requesting the framework facilitated a shift to using ankle brachial pressure index (ABPI) tests instead. The volume of wound swabs being requested reduced to 1/4 of the previous level while heal rates improved from a baseline of 56 weeks average and 20% ongoing to 60% within 12 weeks, 20% within 24 weeks and 20% >24 weeks. This work also released nurse capacity (c. 22 nurse appointments per week per practice) and GP time.

Viewed in the round, applying this framework across North Devon and for a range of high-volume test types has reduced demand into pathology to pre-2004 levels where it has stabilised, despite previously growing at 5% per year.

Connecting Learning Cycles at different levels of system scale

The Learning Cycles undertaken within North Devon were already operating at different levels of system scale, providing insights about what good pathology looks like to individual patients and patient cohorts, GP practices and practice clusters and what this meant for local commissioners and, as the local pathology services provider, for the local acute hospital foundation trust.

However, learning was also emerging that had relevance to regional and national priorities and strategy. For example, while the national Carter review of pathology services [3] was emphasising the opportunities to reduce cost per test and variation in testing practices through the consolidation of local pathology services into regional mega-labs, North Devon's learning suggested that cost-per-test could be a misleading measure¹ and that the primary levers to affect variation sat on the demand side of pathology (i.e. in the requesting practices of clinicians), much less so on the supply side of how labs operate. A similar insight had emerged about the role of pathology accreditation, which has traditionally focused on standardising practice within pathology labs but without systematic regard for what happens up and down stream. This had led to a quality culture within pathology which tended to be self-contained, with little impetus for outreach to effect changes in clinical practice.

It's relevant to note, however, that North Devon's learning didn't contradict the recommendations of the Carter Review or question the value added by accreditation. These could both be seen to provide useful and important lenses on pathology. For example, in the language of The Clean Framework the existing accreditation approach had shown remarkable success in supporting labs to achieve the requirements of "Clean Through". The North Devon insight, therefore, was that broadening focus to see the pathology system end-to-end, from the perspective of patients and so incorporating "Clean In" and "Clean Out", enabled even more effective interventions and access to the key levers for change.

To pursue this, partners from North Devon chose to re-enter the cycle of "Understand the System", this time to strengthen their relationships with national actors and other local labs by:

- Building relationship and trust
- Establishing shared purpose
- Making the system visible.

In practice, this manifests as a discipline of:

- Connecting to key actors
- Carefully listening to them to understand their context and what matters to them (e.g. what were their priorities, what impact were they seeking to achieve, how were they measuring success and what did they feel responsible and accountable for?)
- Sharing the North Devon learning and data
- Inviting perspectives on this learning and its implications, including seeking out alternative views and data, understanding and seeking to fill gaps, exploring uncertainties. and making links between the implications and what mattered to the various actors.

¹ Partners had seen that doing only necessary and appropriate testing reduced the total volume of testing. Set against a number of fixed overhead costs this meant that cost-per-test went up while system cost reduced.

This engagement had notable parallels to the way partners in North Devon had learned to work together within the Pathology Optimisation Forum: listening, learning, iterating and taking the time to seek out where there could be shared energy to take action. In time, what started as quite low key and exploratory conversations led to more structured opportunities such as:

- Liaison with The Nuffield Trust led to the publication of a report on The Future of Pathology Services[12]
- Close consultation with The Royal Colleague of Pathologist led to several national learning events
- Connection with the organisers of the annual Frontiers in Laboratory Medicine (FiLM) conference led to keynote presentations, panel discussions and workshop sessions at consecutive annual events
- Direct engagement with UKAS led to collaboration within a community of practice focused on the future of regulation and accreditation.[13]

As connections built further opportunities opened up until, in 2018, Tom Lewis (the microbiologist who had anchored much of the work in North Devon) was recruited to helm NHS England's GIRFT programme for pathology, alongside colleagues Marion Wood and Martin Myers.[14] This programme provided the platform for a step change in national engagement. With the backing of NHS England, the GIRFT Team had the time, legitimacy and access to consult deeply with actors across the national system, including systematic engagement with local pathology services and lab providers across the whole country. Again, modelling the cycle of Understand

the System, this consultation facilitated a national conversation about the future and focus of pathology, the outputs of which have been captured in the GIRFT report for pathology, formally launched in January 2022 to a record number of attendees for the whole GIRFT programme.[15]

Looking ahead

As the story of this work in pathology arrives into 2022 an exciting new scale of opportunity is emerging. The GIRFT report - with The Clean Framework as its centrepiece has been well received and its recommendations are enjoying strong engagement. For example, UKAS is actively developing its approach to integrating the up and downstream insights of Clean In and Clean Out within its approach. Care sets and test profiles are being embraced as a valuable approach to simplifying and improving the appropriateness of pathology requesting across clinical networks. Reference ranges, which help to describe what's normal for patient populations, are being revisited to improve their consistency and their fidelity to what matters to patients.

"There are extraordinary, and challenging, times ahead. But we are hugely encouraged by the resilience, adaptability and openmindedness that we witnessed throughout this remarkable year. If we can harness the tenacity and creative energy that we saw in abundance during our visits [to engage actors across the pathology system], we are sure that pathology will meet those challenges head on."

Dr Tom Lewis, Dr Marion Wood and Dr Martin Myers (The clinical team for GIRFT Pathology)

Next Steps: download the full guide

If this case study and the <u>illustration</u> of this case study as a connected learning cycle have been all the information you need to begin your experiment, go for it! (And we'd love to hear how it goes).

If you want more detailed information about the work required to undertake the different elements of Learning Cycles, at each of the different system scales, there is more detail in the full "how to" guide <u>here</u>, together with connections to a range of different tools and methods that different organisations have used. If you are looking for a summary version of the guide, you can find that <u>here</u>.

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