

# BMJ Open Quality Engaging community pharmacists in quality improvement (QI): a qualitative case study of a partnership between a Higher Education Institute and Local Pharmaceutical Committees

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## ABSTRACT

**Background** Quality improvement (QI) involves the use of systematic tools and methods to improve the quality of care and outcomes for patients. However, awareness and application of QI among healthcare professionals is poor and new strategies are needed to engage them in this area.

**Objectives** This study describes an innovative collaboration between one Higher Educational Institute (HEI) and Local Pharmaceutical Committees (LPCs) to develop a postgraduate QI module aimed to upskill community pharmacists in QI methods. The study explores pharmacist engagement with the learning and investigates the impact on their practice.

**Methods** Details of the HEI–LPCs collaboration and communication with pharmacist were recorded. Focus groups were held with community pharmacists who enrolled onto the module to explore their motivation for undertaking the learning, how their knowledge of QI had changed and how they applied this learning in practice. A constructivist qualitative methodology was used to analyse the data.

**Results** The study found that a HEI–LPC partnership was feasible in developing and delivering the QI module. Fifteen pharmacists enrolled and following its completion, eight took part in one of two focus groups. Pharmacists reported a desire to extend and acquire new skills. The HEI–LPC partnership signalled a vote of confidence that gave pharmacists reassurance to sign up for the training. Some found returning to academia challenging and reported a lack of time and organisational support. Despite this, pharmacists demonstrated an enhanced understanding of QI, were more analytical in their day-to-day problem-solving and viewed the learning as having a positive impact on their team's organisational culture with potential to improve service quality for patients.

**Conclusions** With the increased adoption of new pharmacist's roles and recent changes to governance associated with the COVID-19 pandemic, a HEI–LPC collaborative approach could upskill pharmacists and help them acquire skills to accommodate new working practices.

## INTRODUCTION

To alleviate the growing demands on the healthcare system and reduce pressure in general practice and secondary care settings, policy-makers and professional bodies have

recognised the potential of community pharmacists to adopt new roles and extended pharmaceutical services.<sup>1,2</sup> Examples of such roles include administration of vaccinations, smoking cessation services and medication reviews.<sup>3–5</sup> However, the adoption of new services often happens largely in the absence of additional pharmacist's resource, organisational support, appropriate education and training and suitable means of remuneration.<sup>6</sup> Research suggests community pharmacists generally perceive their workload to be increasingly contributing to work-related stress and decreasing job satisfaction.<sup>7</sup> Concerns have been expressed about the quality and provision of community pharmacy services. These include low public awareness, expectations and uptake of extended services, perverse incentives leading to 'gaming the system' and under-developed pharmacist–GP (General Practitioner) collaboration with consequential barriers to successful implementation and integration of pharmacy within the wider multidisciplinary team.<sup>8–10</sup>

One strategy to support clinical governance and enhance the quality and delivery of care is through the application of quality improvement (QI). This approach forms part of the UK National Health Service (NHS) healthcare improvement strategy to promote safety, effectiveness and patient experience.<sup>11</sup> Despite an expectation that QI techniques should be an integral part of the culture of professional work, at present there only appears to be isolated examples of good practice.<sup>12</sup> Within community pharmacy QI strategies, its measurement and routine application in daily practice remain underdeveloped.<sup>13</sup> It has been suggested that if QI systems and evidence-based tools are to be implemented in a sustainable fashion, support and funding for appropriate education and training should be made available in the science of safety and quality methods.<sup>14</sup>

This research describes a new collaborative partnership between a Higher Education Institute (HEI) and a cluster of Local Pharmaceutical Committees (LPCs). LPCs in England are responsible for designing, delivering and commissioning health services.<sup>15</sup> LPCs have the potential to play a greater role in pharmacist continuing professional development (CPD) and thereby improve the quality of services delivered. There are approximately 80 LPCs in England, each of which has a direct relationship with pharmacy contractors, and to some extent, with pharmacists' employees. The focus of the research was to describe an innovative HEI-LPC collaboration that co-developed a postgraduate QI module. This was designed to respond to calls for upskilling pharmacists in QI methods. It was anticipated that the enhancement of pharmacist's knowledge of QI would, when effectively applied, facilitate positive practice change across a range of community pharmacy services. The paper also explores pharmacist engagement with the new module, how their knowledge of QI changed and investigates how the learning was applied in practice.

## METHODS

We initially provide a description of how the collaborative process unfolded between the HEI/LPCs. Focus groups were held with pharmacists at the end of the module to assess the impact on pharmacist learning and behaviour.

### Description of the collaboration between HEI/LPC

The Chief Officer (FL) representing Coventry, Warwickshire, Herefordshire and Worcestershire LPCs (consisting of approximately 333 community pharmacies) met with members of the School of Pharmacy (De Montfort University) (SG, TA and NG) in January 2019 to discuss the development and delivery of a postgraduate QI training module that could upskill community pharmacists. The aim of this learning sought to improve the quality of community pharmacy services that is, to promote safety, effectiveness and patient experience. For research purposes, detailed descriptive data about the collaborative process between the HEI and LPC were recorded by FL and SG. This included keeping notes of meetings, emails, phone calls and all interactions and correspondence with the pharmacies and individual pharmacists. Funding for the QI module was via Health Education England (HEE) through the Pharmacy Integration Fund (PhIF). The PhIF is an initiative set up by NHS England to develop pharmacist skills and support the integration of community pharmacy into mainstream primary care practice in order to deliver better outcomes for patients.<sup>16</sup>

Following collaborative discussions, it was decided that the module would be designed to provide pharmacists with methodological training in the principles of QI and that the learning would be 'workplace driven'. During the training, pharmacists would be encouraged to develop critical analysis skills and identify services they deemed to be suboptimal to which appropriate QI tools and methodology could be

applied. This would place the onus on pharmacists to take responsibility through audit assessments in order to uncover areas where they felt QI would most benefit their practice (table 1). This was in keeping with pedagogical principles, specifically adult transformative learning theories (Knowles andragogy), where learners are said to have more say in the direction of learning, are able to build on their existing experience and engage with activities that are of perceived relevance.<sup>17</sup>

Once the training was developed, the LPCs took responsibility for advertising and inviting all community pharmacists within their catchment areas to undertake the module. It was estimated that the time commitment for undertaking the learning would be roughly 10 hours per week. This was made clear in all promotional materials and communications with pharmacists. The module was to be delivered over a 6-month period via an online virtual learning platform with three face-to-face training sessions (delivered by TA and supported by NG and SG). The recruitment target was agreed to be approximately 20 pharmacists. It was envisaged that this number would allow for a close learning relationship with the module leader (TA) and also foster professional networking and peer-to-peer support.

### Focus groups

Using purposive sampling, all pharmacists who had initially enrolled onto the module were made aware of the research and provided with a study information sheet (via email and verbally at the first face-to-face training session) and invited to take part in a focus group discussion. Participants were informed that the purpose of the focus group was to explore their motivation and experience of enrolling onto the QI module, barriers and facilitators to learning and perceived impact (if any), of their learning on professional practice and patient care. Focus groups were employed to create active and dynamic interactions between participants through which ideas and contrary opinions, as well as new areas of understanding, could be generated compared with individual interviews alone.<sup>18</sup> Each focus group lasted approximately 1 hour and were held at a local hotel. For convenience, focus groups were arranged to coincide with the final face-to-face training session. With the participant's written consent, focus groups were audio recorded with detailed field notes taken during and after. The topic guide can be found in Appendix 1.

### Inclusion criteria

Eligibility criteria to participate in the focus group included: (1) registered pharmacist, (2) enrolled onto the QI postgraduate module and (3) willing, consenting and able to take part in the focus group.

### Reflexivity

To minimise bias and avoid influencing participant responses, focus groups were led by two researchers who were not known to the participants and who did not have

**Table 1** Details and learning outcomes of postgraduate quality improvement (QI) module

Module description	QI
Delivered by	Leicester School of Pharmacy (De Montfort University)
Degree level and credit	Postgraduate level 7
Delivery mode	Online distance learning, with tutor support and three interactive face-to-face events.
Duration	Six (6) months
Indicative content/ areas of study	<ul style="list-style-type: none"> <li>▶ Clinical pharmacy management: health policy, healthcare organisation and management.</li> <li>▶ Audit techniques.</li> <li>▶ Clinical governance and how it relates to pharmaceutical services including training and auditing to drive service enhancement.</li> <li>▶ Risk management, dispensing and medication errors, the causes, theory and investigation of medication errors.</li> <li>▶ Service operation and delivery – service improvement, models of pharmacy practice, quality management theory and performance.</li> </ul>
Learning outcomes	<ul style="list-style-type: none"> <li>▶ Critically review, using quality management methods, the provision of a chosen pharmaceutical service or provision.</li> <li>▶ Appraise the strengths and weakness of the current service.</li> <li>▶ Devise a proposal, based on critical review and appraisal, to enable the service to be enhanced. Assess clinical governance principles, risk management and local and/ or national policies and priorities relating to the service.</li> <li>▶ Generate and implement SMART (specific, measurable, achievable, realistic and time-bound), improvements to the chosen service.</li> <li>▶ Plan the assessment or reaudit of the improved service.</li> <li>▶ Critically analyse operational and personal development.</li> </ul>
Assessment	<ul style="list-style-type: none"> <li>▶ 3000-word report</li> <li>▶ Portfolio of evidence</li> </ul>

any involvement in the conceptualising, management or delivery of the QI module. One focus group was led by the lead author AL (male). He has a PhD in pharmacy practice research and extensive experience in qualitative methods. The second was led by a pharmacist educator (male).

#### Data analysis

All data describing the collaboration including planning, development and delivery of the module were collated, diagrammatically charted and finally narrated as activities primarily led by the HEI or those led by the LPC. The focus group discussions were transcribed verbatim and the data imported into the qualitative software package NVivo V.10.<sup>19</sup> Using a constructivist qualitative methodology a thematic analysis was performed by AL which involved a five-stage process as described by Richards and Hemphill.<sup>20 21</sup> This included (1) familiarisation with the data through initial reading and rereading of the transcribed data and preliminary organisation. (2) Open and axial coding and comparison for their internal consistency and boundaries. (3) Emergence of a codebook. The coding tree captured the main themes including codes relating to disconfirming cases. (4) Final coding process and finalising themes. (5) Synthesis and narration of the identified themes. To enhance the consistency of analysis, all the coded data and analysis were reviewed by a separate member of the research team (NG). To enhance the credibility and trustworthiness of the findings, the themes

were then discussed with all members of the research team.

#### Patient and public involvement

This study explored community pharmacist's views of a postgraduate QI educational module. Involving patients/ the public in the design, or conduct was not deemed necessary at this stage.

## RESULTS

### Collaboration and pharmacist recruitment to the QI module

The collaborative HEI–LPC partnership was feasible and deemed to be a success in developing and delivering the QI module. The two organisations worked effectively together to promote the QI module including the development of promotional materials (ie, flyers, marketing videos) and using social media to raise awareness. Details of the types of communication between the HEI and LPC and pharmacists are represented in [table 2](#). Twenty-one community pharmacists expressed an interest in undertaking the QI learning, of which 15 enrolled onto the module (4 pharmacists from independents, 11 from chain pharmacies).

### Focus groups

All of the pharmacists who attended the final training session (total of eight community pharmacists) took

**Table 2** Details of the collaboration and tasks assigned to the Higher Educational Institute (HEI) and Local Pharmaceutical Committees (LPCs)

Month	HEI-led actions	LPC-led actions
January	Initial face-to-face meeting to discuss common interests, process of collaborative working including defining aims and objectives and how to assess outcomes of QI project.	
	Follow-up email/telephone calls to agree actions for HEI–LPC	
	HEI lead has an in-depth discussion with postgraduate team to assess feasibility and management of the QI project.	LPC lead configures an LPC ‘working group’ in order to disseminate QI project plans.
	Emails / telephone calls to agree 1. contents of QI module 2. marketing strategy’ to engage pharmacists.	
February	Development of promotional materials, that is, flyers and student testimonials, (written and video) from other postgraduate students demonstrating benefits of postgraduate learning to practice.	
	HEI–LPC agree contents and design of promotional information.	
March		LPC lead invites sent on a weekly basis (via email) to pharmacy contractors about the QI module using flyer and recorded student testimonial.
		Promotional materials added to LPC website.
	Project promoted on HEI–LPC social media (Twitter, Facebook etc.).	
	Weekly Skype meetings to discuss recruitment numbers and marketing of QI to pharmacies.	
	HEI to communicate with interested students and provide further information and registration details.	
April		Face-to-face promotion of QI module to community pharmacists at four different LPC events.
May	HEI registration information emailed to pharmacists with details of the first training session including the pre-session tasks.	LPC lead relays expressions of interest from pharmacists to HEI.
	Final deadline for recruitment advertised to students.	
	Delivery of first QI training session. Project timeframe and plan agreed with pharmacists.	Dates of training sessions posted on LPC website.
June	Delivery of second QI training session.	
July and August	Email communications on student progress.	
September	Delivery of third training session and conduct of focus group.	
	HEI–LPC discuss outcomes/reflections on the collaboration and provide information about the process for analysis.	

QI, Quality Improvement.

part in one of two focus groups. Three participants were employed by an independent pharmacy and five from chain pharmacies (age range 32–50 years). Three themes emerged based around pharmacist engagement (including barrier to learning), pharmacist knowledge and application of QI and around reflective practice.

#### Pharmacist engagement

Pharmacists were intrigued by the LPC’s invitation to take part in postgraduate education (PGE). The LPC was viewed as a communication conduit between the HEI and themselves. In addition to emails, the invitation was promoted at other LPC training events to raise

awareness and encourage pharmacists to take part. The HEI–LPC model appeared to signal a vote of confidence that gave pharmacists the motivation and reassurance to sign up:

For me personally, if it weren’t for the LPC I certainly wouldn’t be engaging on this module ... they advertised it and brought it forward. [FG1\_Female\_32yrs]

A few pharmacists saw the learning as a means to complete their mandatory CPD or for them to extend their employability, particularly in light of younger ‘newly qualified’



pharmacists who were perceived to be more skilled than themselves:

The newly qualified pharmacists would be more qualified than us ...With the funding cuts and everything, stores closing and so on, I think it's a scary time. So, we just need to up our game. [FG1\_Female\_34yrs]

Most however, reported a desire to acquire new skills and to see the application of QI learning in their practice.

Reflecting on the postgraduate learning, this had been an overall enjoyable experience due to the close working relationships and networks that had developed between fellow pharmacists and the HEI leads. When asked, many were encouraged to pursue further PGE. Of the 15 pharmacists who enrolled onto the QI module, upon completion, 12 registered for further postgraduate modules:

If I was sitting reading my emails before bedtime thinking of "really? Diploma? No", I probably wouldn't have done it. [FG1\_Female\_34yrs]

I thought this would be a good step before I take the full plunge, to just try it out, before I commit to the full postgraduate clinical diploma. [FG2\_Male\_34yrs]

### Barriers to learning

Embarking on the module was daunting for some pharmacists. There was apprehension at the prospect of having to accommodate the new learning and potential to interrupt their work-life balance. Academic writing was a new and challenging skill and there was a consensus that peer support was important:

It is hard, but I think with support and talking with your colleagues, it's helped. And yeah, initially I thought it was going to be really challenging because I haven't done anything like this since university ... [FG2\_Female\_33yrs]

Regarding organisational support, pharmacists reported challenges negotiating time off to attend the face to face training sessions resulting in some resorting to using their annual leave entitlement or taking unpaid leave. Pharmacists did not always feel supported and reported that managers were sceptical of their motives and fearful of losing them because of being 'upskilled':

They had a bit of fear that I'll move into a GP surgery. And that was clear to see from a very frank conversation. [FG1\_Female\_32yrs]

There were also concerns that the analytical skills being taught were not aligned with employers' expectations:

They want more of a faster snap model whereby they can improve quality, so if they see a problem they want a solution within a few days or something like that. [FG2\_Male\_45yrs]

There needs to be a little bit of vision to see we need pharmacists with more skills in our company

to meet the challenges of the future profession. At the moment, you might not find that vision in senior management. [FG1\_Male\_39yrs]

### Knowledge of QI and application in practice

Following the learning, pharmacists reported positive changes in pharmacy culture and practice. They had limited knowledge of QI tools (eg, root cause analysis) or applied these to their practice. They appreciated the value of these skills and described how they were able to be more analytical in their day-to-day problem solving:

One of my technicians came to me and said "we need to do something about these controlled drug prescriptions after they've been handed out". I said "ok". My technician went straight into the solution. I said "right, let me stop you there. I need you to define the problem"; I listened to myself and said [to myself] something's sunk in. [Whereas prior to the module, what would you have done?] I would have said 'Ok, let's run with it' without necessarily giving any thought to whether that was the best solution. [FG1\_Male\_39yrs]

If in the past there was some problem, I'll go straight to the solution. With this I've tried to get the whole team involved more... and it's brought the team together more and understand the problem as a whole. [FG1\_Female\_34yrs]

When asked about the impact on patient care and outcomes, there was a consensus that more time was needed to fully assess this, though it was presumed that an enhancement of service quality would, in the long term, have a positive impact. It was felt that educating and upskilling the pharmacy team in QI would generate more meaningful team conversations that would help patients. Pharmacists appreciated how QI strategies had enabled them to involve other members of the pharmacy team. Not only were they able to identify and provide solutions where services were suboptimal, but the learning appeared to be cascaded to others:

I think by doing this project it's made me feel more confident in leading my team, in terms of bringing about change or improvement in my practice, and they've [staff] also started thinking on that level as well. So instead of just highlighting problems they're now thinking further ... "ok what changes do we need to make, we need to have a discussion about this", so that's the sort of steps that they're taking now in their thought process. [FG2\_Male\_37yrs]

It involved their perspective, because I think when we do an audit we tell them this is what is done. Whereas with the [QI] tools, they were actually engaging the staff themselves to do it which I felt was good, and they contributed more personally. [FG2\_Female\_38yrs]



One pharmacist acquired sufficient confidence to discuss improvement ideas with wider organisational stakeholders to influence service development:

I spoke to service development pharmacists ... because we're looking at different things ... I wouldn't have done that before I'd done this project. I wouldn't have really focused in on those areas to support my idea. [FG1\_Female\_32yrs]

In contrast to those regularly working in one pharmacy, relief pharmacists (who worked in several pharmacies) found it arduous and challenging to apply their learning with staff who they were not routinely working with.

#### The reflective practitioner

There was evidence that the postgraduate QI module had developed pharmacists to be more reflective in their practice. This was attributed to the type of learning they engaged with, which was seen to be different from the previous self-directed CPD they had undertaken. Most considered PGE to be superior to self-directed CPD because of the benefits of peer learning and having specialist input from the HEI.

This is completely different to what I've ever learnt in any other form of CPD, whether its employer led, or LPC led, or everything, it's been different. [FG1\_Female\_34yrs]

Pharmacists reported having an appreciation of the learning process and greater awareness that learning should impact on practice and their personal development. Taking part in the module had prompted one pharmacist to reflect on how he could improve the quality of his future role as an independent prescriber:

My only goal was to become an IP [Independent Prescriber]... I would say my goal changed to becoming a really good IP. So, going through the modules, the diploma, and then having an IP at the end of it, I think will make you a better practitioner than someone who's just gone and done a 6-month course. [FG1\_Male\_39yrs]

## DISCUSSION

This illustrative case study showed that collaborative partnerships between HEIs and LPCs organisations are feasible and that a postgraduate module can improve pharmacist engagement with QI. This collaborative model signalled a vote of confidence that gave pharmacists reassurance to sign up to the module. Despite the benefits of PGE to clinical practice, studies show the uptake of PGE among pharmacists, as with other professionals, remains low.<sup>22</sup> Others have also identified barriers including a perceived lack of time or resource and organisational constraints.<sup>23</sup> Despite the barriers, there were benefits of learning with peers, which is often a drawback identified by CPD that is undertaken in silos.<sup>24 25</sup> There was also evidence that

the QI module had encouraged 'reflective practice' or as described by Mann as "the purposeful critical analysis of knowledge and experience, in order to achieve deeper meaning and understanding".<sup>26</sup>

It has long been acknowledged that professionals learn more from practice than theory alone.<sup>27</sup> The evidence regarding the most effective pedagogical approaches to improve QI training is mixed, with didactic classroom learning less likely to be effective compared with workplace driven QI practices.<sup>28 29</sup> This study supports the work-based driven approach and found that pharmacists' perceptions and experience of the QI learning was positive with reports of the application of QI principles in practice. Experience of effective and relevant PGE, in the absence of perceived barriers, has shown to enhance clinical decision-making and career development, inter-professional working and improvements in patient care.<sup>30</sup> It has also been shown to be the case in other professions where introducing QI learning has been shown to develop skills, understanding and to foster a positive attitude which has the ability to influence clinical practice.<sup>31-33</sup>

#### Strengths, limitations and implications

To our knowledge this is the only UK study that describes LPCs working collaboratively with an HEI to promote QI learning among community pharmacists. We acknowledge several limitations to this study. This was a small scale illustrative case study. There were 15 pharmacists who completed the training and so the views expressed may not be representative of all pharmacists, but rather those who may have been more keen or motivated to engage or who could be described as 'early adopters'. In addition, only 8/15 pharmacists participated in the focus group and so the findings should be viewed with caution as it is uncertain whether data saturation was reached. The wide geographical area some pharmacists would have had to travel for the face-to-face training sessions, may explain in part why more pharmacists chose not to attend. In regards to the transferability of the findings to other settings, we acknowledge the risk of bias in our study. This was an illustrative case study and do not know whether this collaborative model would work in other settings where the working relationship between the HEI/LPC could be different. Furthermore we are unable to validate findings from self-reports or make generalised claims at this stage.

It is also unknown how the QI training had impacted on service quality or patient outcomes in the long term. This is similar to the findings of others. For instance, a QI intervention study in the USA found that after a follow-up period of 2 months, investigators were unable to detect the impact either on quality related events or patient safety attitudes.<sup>34</sup> The impact of a QI learning intervention appear therefore to take time to imbed in practice and that any assessment of patient-related outcomes should acknowledge that outcomes are likely to be gradual or incremental. Others have suggested that regular repetition of QI messages are needed to sustain improvements in practice.<sup>35</sup>

This initiative was funded by HEE who supported fees for pharmacist's enrolment onto the QI module. The results of

this study and another evaluation<sup>36</sup> suggest that the learning has potential to improve community pharmacy service quality and upskill pharmacists in application of QI methods. Professional bodies should consider further investment to ensure the QI module can be offered in a sustainable way. The success of the module has led to this now being offered from De Montfort University and has been integrated into students postgraduate clinical qualifications.

We complete this paper at a time when healthcare systems are in a process of significant transformation in the organisation and delivery of healthcare due to the COVID-19 pandemic. Policy-makers have made rapid changes to reorganise care services to meet the surge in demand of patients with COVID-19, including professional reprofiling and creating new care pathways. Alongside these sweeping changes, there have been reforms to UK community pharmacy contractual arrangements towards and integrated care systems providing extended clinical services.<sup>37–39</sup> There are increased expectations on community pharmacy to help reduce the burden on other areas of the healthcare system, particularly in general practice.<sup>39</sup> These reforms and recent changes in practice have led to unprecedented changes as front line services become refashioned with significant day-to-day practice implications for service delivery and governance. It is yet unclear how pharmacists are responding to such service reconfiguration or how these changes are impacting on the quality of services delivered. If appropriate support or training is not realised, pharmacist risk ‘role overload’ or ‘role strain’ that can contribute to poor quality of services to patients.<sup>40</sup> This research is timely; there is a pressing need to promote QI within community pharmacy to provide assurance that pharmacist and their teams are equipped with the knowledge and skills to maintain patient safety and care.

## CONCLUSIONS

This study illustrates that a HEI–LPC collaboration is feasible and able to engage and upskill community pharmacists through a postgraduate QI module. Despite the barriers to learning, pharmacist demonstrated improved knowledge and application of QI methods and reported using these approaches with their teams to improve practice. With the increased adoption of new pharmacist’s roles and services, promoting QI training should be a priority for policy-makers if service quality is to be maintained in a dynamic and complex healthcare system.

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**Contributors** AL is the chief investigator and made substantial contributions to the overall conception, development and design of the study. NG, SG, FL and TA provided guidance on the methodology and on the qualitative analyses. TA, NG and SG were responsible for running the QI module. All authors contributed to the data analysis and contributed to the write-up. All named authors contributed to editing and approved the final manuscript.

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**Competing interests** AL declares no competing interests. SG, TA NG are employed by De Montfort University and were involved in delivering the Quality Improvement (QI) module. FL is Chief Officer representing the Coventry, Warwickshire, Herefordshire and Worcestershire LPCs.

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**Ethics approval** The study was given a favourable opinion on 22 July 2019 by the Faculty of Medicine and Health Sciences Research Ethics Committee, University of Nottingham (Ref: 258–1906). Written informed consent was obtained from all individual participants included in the study.

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