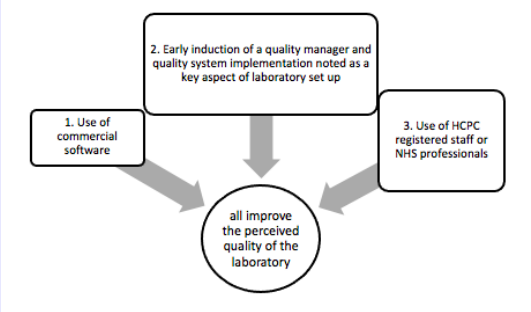
# Identifying an Efficient Quality Management System: Comparisons of Lighthouse Laboratories

Felicity Newman-Webb

Roanna George, Giulia Getti

## AIM

**To identify an optimal quality management system (QMS) by comparing systems created for the lighthouse laboratories (LHLs) stood up for the SARS-CoV-2 pandemic.**
**This study also tested three hypotheses:**




## BACKGROUND

**A QMS is a defined set of management processes employed to help assure quality in an organisation. There are scarce published reviews of comparisons of quality systems and often focus on technical quality management rather than the framework for the laboratory to function accurately and safely. Quality systems are often very complex and hard to compare due to subjective understanding of the standards and having non-standardised assessment outcomes.**

**In late 2019 cases of pneumonia were noted caused by a novel coronavirus, later named SARS-CoV-2. These cases rapidly spread round the globe resulting in the Department of Health and Social Care outlining the need for high throughput SARS-CoV-2 testing laboratories called LHLs. During set up the quality of these laboratories were called into question by colleagues and the media, so a request was made for them to be accredited to ISO standards.**

**These independently created LHL's and their quality systems provided an opportunity for comparison. Eleven bespoke LHLs were created, including one here at University Hospitals Plymouth (UHP).**

## METHOD

**A survey of 33 questions was sent out to LHL Quality Managers to compare the LHL quality and laboratory structure, QMS design process and additional questions to test the hypotheses.**

**Available quality dashboards were reviewed for objective metrics indicating the ability of the quality system such as number of serious incidents reported.**

**Interviews of responding Quality Managers to gather qualitative data beyond the survey responses as well as a comparison of the QMS structure to the primary site managed by University Hospitals Plymouth.**

## RESULTS

**There were four responses from the original 11 laboratories surveyed, plus a further three LHLs not previously identified resulting in a 64% response rate. These laboratories have been listed as sequential letters (A, B, C, D, E, F and G) to provide anonymity.**

| Laboratory | A | B | C | D | E | F | G |
|---|---|---|---|---|---|---|---|
| Type of laboratory | Private | Private | NHS | NHS | NHS | Private | Collaboration |
| Number of samples/day | 20,000 | 100,000 | 65,000 | 50,000 | 40,000 | - | 18,000 |
| Number of staff (range) | 51-150 | 601-1000 | 601-1000 | 301-600 | 301-600 | - | 51-150 |
| Midpoint of HCPC staff ratio (%) | 4.9 | 1.2 | 1.2 | 0.8 | 0.8 | - | 12.8 |
| Commercial QMS software used | No | Yes | Yes | Yes | Yes | - | Yes |
| Quality Manager at project start | Not Known | Yes | Yes | Yes | Yes | Not known | Yes |
| Quality system identified as a key aspect of laboratory set up | Yes | No | Yes | Yes | Yes | Not known | Yes |
| ISO standard for laboratory set up | 17025 | N/A | 15189 | 15189 | 15189 | 15189 | 15189 |
| Quality/Management findings from UKAS (number) | >12 split between QMS and technical | 20 | 0 | N/A | N/A | Not known | 0 |
| Technical findings from UKAS (number) | | 2 | 2 | N/A | N/A | Not known | 0 |

## CONCLUSION

**The overall aim of the study to identify an efficient streamlined QMS was not achieved due to a reduced interaction with the study and the survey design was flawed. Several sites declined further interview resulting in all the available data being recovered from the survey which was insufficient in its design.**

**Hypothesis one: Data indicated that further review is needed as all sites used commercial software apart from one (Laboratory A) . Laboratory A and B appear to have comparable findings indicating the use of software had no effect. However, significantly the sample size is too small and unable to fully test the hypothesis.**

**Hypothesis two: Laboratory C indicated early employment of a Quality Manager and early implementation of a QMS and had few UKAS findings, whilst laboratory B indicated early implementation of a QMS was not identified as a key aspect and laboratory A does not indicate an early employment of a Quality Manager and both had the highest findings. This superficially indicates the hypothesis is true, however, laboratory B had significant QMS restructuring and there was qualitative discussions with the laboratories which indicated members of the Quality Teams were seconded to the LHLs to aid early set up which could affect the results.**

**Hypothesis three was tested and indicted that use of HCPC registered staff is unlikely to affect the perceived quality of the laboratory. However, the second part of the hypothesis indicated favourable outcomes by utilising NHS professionals, particularly by using an established laboratory as their main QMS with an extension to scope to the LHL.**

**This study has served as a preliminary review of the LHL network and its quality systems and if the study was repeated with key improvements could help identify a streamlined and efficient QMS as two sites (C and G) indicated elements of a streamlined QMS due to the number of documents they have and the reduced number of UKAS findings.**

**To develop this study in the future the below could be considered:**

**1.Restructuring of the survey and increasing response rate of the survey by making it mandatory or enlisting the DHSC to act as an authoritative body to request UKAS assessment data**

**2.Increase time to review the data and build relationships with LHL staff**

**3.Expand the group for review by surveying the pathology network for data**