Challenges of producing a new external quality assurance program

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Introduction

Laboratory Medicine has seen extensive and fast-paced growth in the availability of new tests for diagnosis, monitoring and patient management. Pathology laboratories face the challenges of having to bring these tests to market in a timely manner. One of the requirements for validation and subsequent accreditation of a new test or analyte in many laboratories is the availability of an accredited external quality assurance (EQA) program.

In 2019 RCPAQAP began a lean six sigma (LSS) project to reduce the turnaround time to introduce a new accredited EQA program. This process improvement project was driven by the need to meet customer demands for EQA program availability for new and upcoming tests. The aim of the project is to assess the capability of the current process and identify areas of improvement to design a process to meet customer demands and deliver timely EQA programs to advance outcomes.

Method

A Voice of Customer (VoC) survey was distributed to gather customer requirements for having EQA availability at the time of introducing a new test.

A desktop audit was conducted and documented data was reviewed and collected for 14 pilot programs in serology and immunology dating from 2006. Total cycle time from initial interest in a new program until the accreditation date of that program was captured in days.

A SIPOC (Suppliers, Inputs, Processes, Outputs and Customers) analysis as well as detailed process mapping was done to identify key areas in the development of a new EQA program. There were 6 key phases identified; program selection, sample sourcing, program planning, program preparation, report generation and accreditation.

Interviews were conducted to perform a root cause analysis for each phase of program development and to identify areas where time delays occurred in each of the identified phases.

Data analysis was carried out on the following programs: Anti-Saccharomyces antibodies (AS), Cyclic Citrullinated Peptide (CCP), Drug Allergens (DU), HS-CRP (HC), IgD (ID), Neuronal Antibodies (NU), Liver Antibodies (LA), Procalcitonin (PC), Memory B cells (MB), RSV PoC (RSV), Influenza PoC (FLU), QuantiFeron TB (TB), Lyme Disease (LYM), Strongyloides (SG).

Results

Figure 1. Voice of Customer (VoC) survey results.

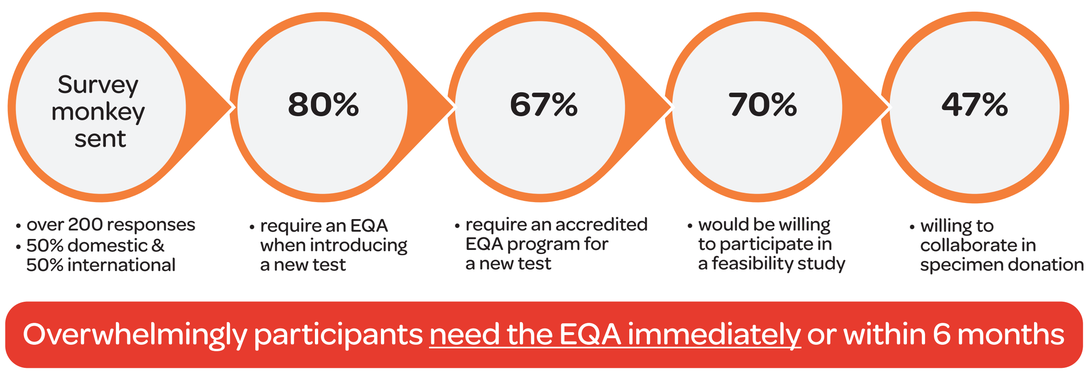

Figure 1 shows the data gathered from the VoC survey on customer requirements for an EQA program for a new test. When asked "How long after validation of a new test would your laboratory take to enrol/ look into EQA participation?", of the 221 responses collected, 85% needed an EQA program within 6 months. The majority, 171/221 (77%) wanted the EQA before or immediately after validation. The remainder noted up to 12 months after validation.

Figure 2. Total cycle time in days of time taken to accredit a new EQA program.

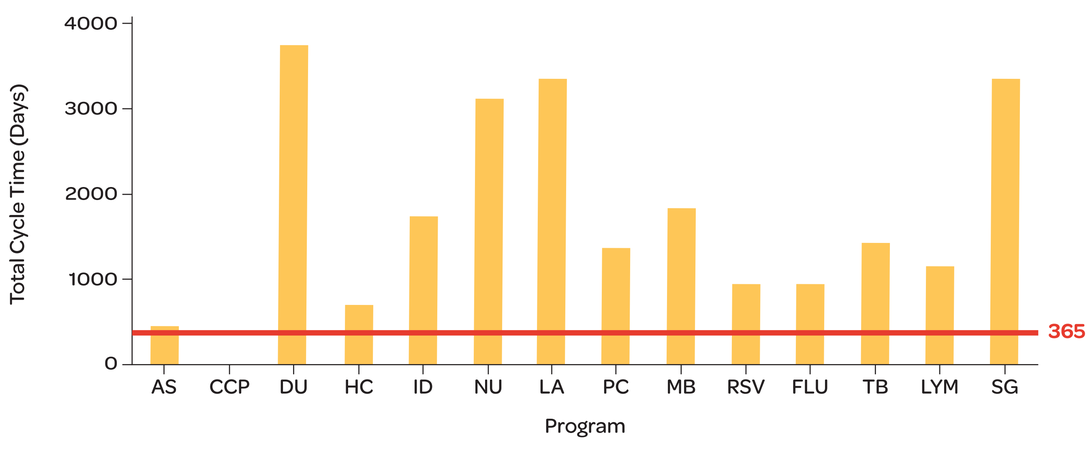

Figure 2 shows the total cycle time (in days) taken to accredit 14 new programs in serology and immunology since 2006. The red horizontal line (12 months) denotes maximum customer expectation to achieve accreditation. The mean cycle time was 1449 days (approximately 4 years) to achieve accreditation. Accreditation date for CCP was unavailable as it was split from an existing accredited program hence no bar graph is displayed for this program.

Root cause analysis showed 6 areas which caused time delays; time delays in gathering customer interest for a new program, selecting a program to go to pilot, compiling program specific information such as methods, sourcing appropriate samples, manual report generation and completing the accreditation requirements. Data is displayed in Figure 3.

Figure 3. Areas which cause delays in introducing a new EQA program.

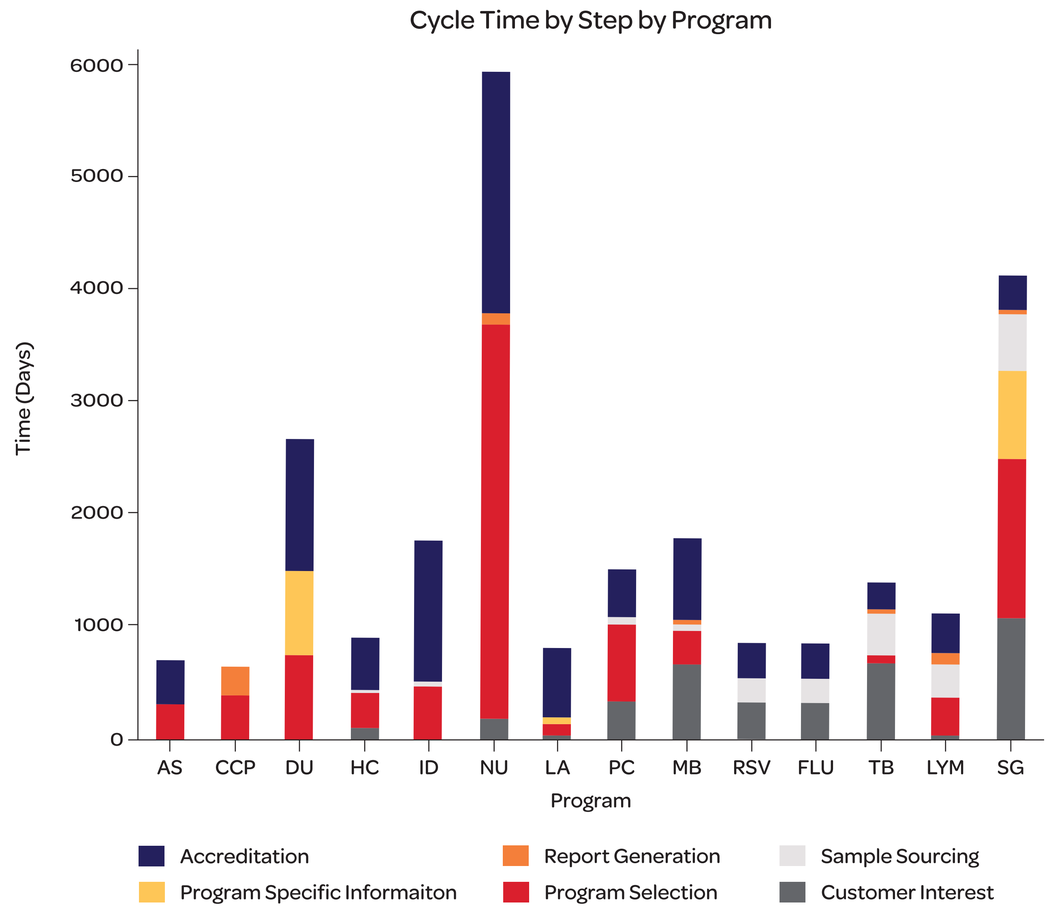

Figure 3 shows that report generation caused the least amount of time delays. Selecting a program to pilot caused the most delays, followed by accreditation. Capturing customer interest and sample sourcing also contributed to increasing the turnaround time of achieving accreditation of a new program.

Discussion

EQA and proficiency testing providers from all over the world undertake pilot studies. The complexities of producing these new EQA programs are not well documented. Pilot studies can often take years before becoming a formal program, with this appearing to be a normal time frame[1].

Laboratories are now requiring EQA programs for new tests in a much shorter period than EQA providers are currently offering. Even more so when the test is an emerging disease of public health concern[2].

The LSS project undertaken by RCPAQAP has highlighted areas which cause significant time delays in producing a new accredited EQA. The data and evidence from this project will be used to change the current processes to expedite the development of new programs. One key outcome is a move away from performing multiple pilot studies to conducting a feasibility study and then advancing straight away to a full program, where possible . A feasibility study can be conducted to evaluate the capability, practicality, data analysis and assessment requirements for introducing a new program.

Other areas of improvement include better collection of customer requirements from the initial customer interest to help design the program. Moving away from 18 monthly scheduled audits towards having new programs accredited as soon as the feasibility study is completed will also speed up the accreditation process of a new program.

References

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2. Sung, H., Yoo, C. K., Han, M. G., Lee, S. W., Lee, H., Chun, S., ... & Min, W. K. (2020). Preparedness and Rapid Implementation of External Quality Assessment Helped Quickly Increase COVID-19 Testing Capacity in the Republic of Korea. Clinical Chemistry.

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