Reducing errors in the pre-analytical phase

The total testing process (TTP) incorporates not just the analytical phase in the laboratory, but also the pre and post analytical phases (1). As laboratory professionals we have worked tirelessly for decades to document and improve analytical performance to the point where only a very small proportion of errors actually occur during analysis. The preanalytical phase was first mentioned in the literature in the 1970s but took a further 20 years before it was recognized as an area that needed improving. This need to improve has recently been re-enforced by statements in ISO 15189:2012 detailing that the preanalytical phase must be monitored and improved from the laboratory. The laboratory has an obligation to improve these processes, despite many of them occurring outside the laboratory, as it is the only department that can collect and assess data on errors occurring in the preanalytical phase. In 2012 the EFLM WG-PRE (European Federation of Laboratory Medicine Working Group for the Preanalytical Phase) was established to coordinate efforts to improve quality and standardization in this area (2). At the time of establishment there were only 3 nations with a national working group for the preanalytical phase; this has grown in the 6 years since to over 20. However, establishing working groups is just the first step; it is what working groups achieve that is important. In order to improve the pre-analytical phase, you must first be able to measure it. In Lippi *et al.*'s paper they reference two quotes that are very relevant here.

The first by Peter Drucker states '*you cannot manage what you cannot measure*' and the second by Galileo Galilei states '*you should measure what can be measured, and make measurable what cannot be measured*' (3). Taken together they indicate that in order to improve something you must first be able to monitor it. Cornes and Shetty discuss the various mechanisms of measuring quality indicators. They explore options from manual audits through to automated processes. Automated processes are the most robust mechanism, however the key requirements are that monitoring is performed regularly and that there are procedures in place to act when poor performance is identified; measurement alone is not enough (4).

Cadamuro and colleagues look at the next stage in the process of collecting quality indicators from the preanalytical phase. They review a practical mechanism to collate the data into a format that is easy to evaluate and feed back to users. As with Cornes *et al.*, they go on to state how important it is to ask what the data means and how can it be used to improve error rates and therefore patient outcome. A key part of this is to not only know how a particular quality indicator is performing but also how it is changing with time. You must have the ability to 'drill down' into the data to target particular clinical areas that are seeing changes in error rates or are outliers. Both of the above papers state the essential requirement to have a standard operating procedure to clearly define how you will measure, process and act on quality indicators for the preanalytical phase (5).

Although much of the work on preanalytical quality indicators and how to collect and act on them has originated from Europe, the work produced is highlighting the issue around the globe. Bouzid and colleagues review how their work in Tunisia is improving error rates (6). They set up a manual audit process, which was both simple to use and robust, and collected data on all samples with an error over a 1-month period. Crucially they then acted on this data. Their mechanism of action involved a continuing program of re-education combined with regular feedback of errors to re-enforce the training received. This continuous communication between the laboratory and its users is important if you want to make improvements and have users understand the reasons why. Without this engagement and collaboration change will be difficult to achieve.

However, with all this data collection, standardization and recommendations the real question is have the EFLM WG-PRE and other working groups in the area achieved what they set out to do? In his paper in this special edition of the *JLPM*, Giuseppe Lippi, a founding member of the working group, and colleagues set out to review whether or not quality in the preanalytical phase is improving or whether we are just better at documenting it. They acknowledge that the answer to this question is very challenging to determine. They do however show that laboratories who have been monitoring and intervening for prolonged period have seen significant improvements. They conclude by stating that we are seeing an improvement in the preanalytical phase, but we are also picking up more errors. It is this more comprehensive detection of errors though that is leading to this improvement. We should view better detection of errors not as a growing problem, but as a growing opportunity to improve patient safety (3).

The initial part of the preanalytical phase is sometimes called the pre-analytical phase. This deals with the part in the

process where the clinician and the patient determine the clinical question, and what test would best aid them in patient management. Salinas and colleagues systematically look at this problem from the point of defining it through causes and solutions. They crucially make the important statement that it is not just the clinician that is responsible for test inappropriateness. There is also influence from patients, the laboratory and economics; all must come together if we are to ensure the right test is performed to produce the best patient pathway and outcome. There are numerous strategies possible to improve appropriateness which are reviewed in the article but it is important to highlight that this is not about reducing tests but increasing appropriate testing (7). Equally any interventions made should be audited to ensure they have the desired impact on patient outcome. An interesting future development in this area could be in the field of machine learning. Hoffmann and colleagues, look at a case study using machine learning to guide appropriateness. They do this by training a computer system to guide outcome or direct testing based on a dataset where the inputs and outputs are already defined. Once trained the system can take new inputs and produce the trained output and over time the system can learn and improve the algorithm. Given the large amounts of data in modern laboratories machine learning is likely to play a large part in the future of laboratory diagnostics (8).

If we are to truly reduce errors and improve harmonization in the preanalytical phase it would be logical to look at the process that makes up the largest part of this phase venous phlebotomy. Previous studies have shown harmonization and compliance with guidelines is poor and the risk to patients can be high (9). Bölenius and Nilsson review what variations there are in venous blood collection and importantly why there is this variation. They make the important point that a key reason for errors in this process is the human factor; humans make mistakes no matter how good they are, we are all fallible. However, there are many other drivers for variation in the process from national and local guidelines through to culture in the workplace. Having identified the causes, they also discuss how they can be a source of variation (10).

Taken together this special issue looks at how we are, and should be, collecting data on quality in the preanalytical phase. It also looks at what the sources of poor quality can be and how we should be going about improving. It also demonstrates how far we have come and looks at what the future might hold in this important area of the TTP where there is still much work to be done.

Acknowledgments

Funding: None.

Footnote

Provenance and Peer Review: This article was commissioned by the editorial office, *Journal of Laboratory and Precision Medicine* for the series "Reducing errors in the pre-analytical phase". The article did not undergo external peer review.

Conflicts of Interest: Both authors have completed the ICMJE uniform disclosure form (available at http://dx.doi.org/10.21037/jlpm.2018.07.04). The series "Reducing errors in the pre-analytical phase" was commissioned by the editorial office without any funding or sponsorship. Michael Cornes served as an unpaid Guest Editor of the series and serves as an unpaid editorial board member of *Journal of Laboratory and Precision Medicine* from December 2016 to November 2018. Jennifer Atherton served as an unpaid Guest Editor of the series. The authors have no other conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Received: 09 July 2018; Accepted: 29 July 2018; Published: 30 July 2018.
doi: 10.21037/jlpm.2018.07.04
View this article at: http://dx.doi.org/10.21037/jlpm.2018.07.04

doi: 10.21037/jlpm.2018.07.04
Cite this article as: Cornes M, Atherton J. Reducing errors in the pre-analytical phase. J Lab Precis Med 2018;3:63.

