

Quality Management Systems and Accreditation in Blood Services

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There are many different configurations of blood services. Some countries, mostly high resource, have fully centralised national blood services for collection testing and distribution of blood, components and products to hospitals. Others have blood centres run by different organisations in different states or regions, and by government, military or commercial organisations. In lower-source countries the situation is often more complex, with many also having local collection in hospitals and clinics.

Although the work patterns and regulatory requirements are different, there are many benefits of a Quality Management System (QMS) in any setting. Working to guidelines and quality standards in a system where there is external accreditation, an effectively implemented QMS and a workplace culture with an understanding of the value of quality, significantly improves practice. Document control and well-designed standard operating procedures improve consistency, helping to prevent problems occurring and saving costs as fewer errors/mistakes need to be investigated and corrected. Ongoing monitoring through internal audit identifies areas for improvement.

External audit as part of accreditation and regulation uses recognised standards where available, e.g., ISO15189 for transfusion laboratories undertaking clinical work, or EU Blood Safety and Quality Regulations (BSQR) for blood establishments. Haemovigilance incidents and External Quality Assessment can also reveal problem areas. Error management, including trending, investigating the root causes (not allocating blame) and acting on non-conformances brings continuous improvement with a

safer and more effective service for donors and patients. The QMS also protects staff, encompassing working conditions, training, competency and management support. WHO publish guidance on implementation of a quality system in blood establishments.

Ideally, accreditation fits within a national or regional blood system and is undertaken by a regulator appointed by a ministry of health, sitting outside the organisation(s) delivering blood services, but with enough expertise to understand the relevance of the standards and to appoint effective assessors. However, any recognised accreditation programme will still help to promote quality and give confidence in blood services. Accreditation standards for blood services are often designed for high resource countries, with stringent requirements that are not easy to meet in lower resource countries. Standards can also be adapted for the setting and level of development of blood services to which they are to be applied, balancing safety and achievability, e.g. the African Society for Blood Transfusion (AfSBT) Stepwise accreditation programme. This approach encourages resource limited blood services to embark on accreditation that would perhaps otherwise seem out of reach and stimulates incremental improvement focussing on priorities to improve blood safety.

The importance of commitment by management to instil a “quality culture” at all levels cannot be underestimated. An understanding that quality is everyone’s responsibility, and of its purpose and benefits, drives motivation to invest the time and effort required to realise the full benefits of a QMS and other quality initiatives.

Disclosure

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