Artificial intelligence in transfusion medicine and its impact on the quality concept

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1. What is on?

In the blood supply and clinical consumption there are currently two main directions for the future of manufacture or procurement, and patient care. One is determined by the state of the art in the advanced world with by and large strong and stable infrastructures, where systems have developed and are in the process of refining and strengthening the customer relationships, quality of care and related marketing principles. These include social marketing to create a solid and sustained access to the unique source material - human blood and blood components, and clinical advocacy and marketing to advance the quality and specificity of stochastic dynamic programming of transfusion practices at the bedside. To enable this strategy to be implemented, the process of manufacturing the source material in new and specific cellular blood products is certainly a challenge. However, the infrastructure on which the system is built needs to be solid and complete, and to progress in its structural elements might need introduction of artificial intelligence and stochastic dynamic programming. The aim is to compute a policy and strategy prescribing how to act and perform optimally in the face of uncertainty.

The second direction is the acceleration of synergised efforts to bridge the gaps existing to various degrees in the large developing part of the world. This involves the infrastructure and governance at the national level to economy of scale, leadership, competence of professionals, education and appropriate environmental conditions at the local and regional level. Although in principle the same developmental stages have to be followed, the pace of development could be accelerated to allow a faster narrowing and shallowing of the distinguished gaps [1,2]. Here artificial intelligence and in particular stochastic dynamic programming seem far in this instance but might turn out to be a blessing in disguise!

2. Reliable data bases

A wider introduction and application of stochastic dynamic programming [3] and artificial intelligence will play a major role through the creation of reliable quality data bases (big data), and the use of these ‘big data’ bases through a network of algorithms, deep learning and machine learning processes. This would allow better management of the vein-to-vein manufacture and clinical application of blood and blood components, based on stochastic dynamic programming, computer simulation and algorithmic consumption and production predictions that would allow an optimal use of source material, equipment, consumables, and above all, professional staff [4,5]. More advanced and sophisticated robotics will be introduced to standardise a growing number of production processes and procedures, controlled by an advanced system of communication through information technology including automated alert systems to detect early trends in deviation from the standards. As a consequence waterproof documentation is paramount. The human work force has to be educated in such environment and quality culture to be able to handle and act appropriately and oversee the processes and procedures in a different way. The prime objective, however, excellent customer satisfaction through personalised transfusion therapies, remains the same, based on the old Hippocrates adagio ‘Primum est non nocere’.

3. Pharmaceutical principle

Blood products have a supportive therapeutic purpose and should therefore be considered to be produced according to pharmaceutical principles. Because in many cases a regulatory framework for biologics came into existence to regulate the manufacture of pharmaceuticals, applying GMP rules requires understanding the similarity and differences between blood products and pharmaceuticals. [6] The procurement or manufacturing of the active starting material – whole blood, a unique living tissue – is completely different from the bulk purchasing of active ingredients for medicinal products. Human blood or plasma is collected under aseptic conditions and these have to be guaranteed during processing. The batch size of blood and blood components is limited to each single whole blood donation and the production of a few blood components thereof. In the pharmaceutical industry, in general, the starting materials are raw and bulk, and need to be processed step-wise into aseptic finished products through usually large batch sizes. Quality assurance is done by batch sampling, which given the one unit only collection and production in the blood supply is virtually impossible.

To produce a product a well-defined process (series of procedures) of
manufacturing the product from an input, a source material into an output, a quality finished product is needed. That means there is a flow from input through the manufacturing or processing steps (procedures) to produce the desired output or product. Each of the elements of the manufacturing system needs to be described (process descriptions) and meet national and/or international quality requirements (standards). The output in quantity and quality of the product or products is determined by the need of the customers, and regulated by governmental rules and guidelines. So, there needs to be in place a customer oriented marketing structure (clinical interface). The data or information collected is then determining the intensity of the manufacturing flow and the magnitude of the input to guarantee the volume of the output required. In other words manufacturing systems need an overarching quality system management to control and assure each of the processes and procedures from purchase of source material to quality and quantity of finished products and customer satisfaction. Also when these products are being used or consumed. Key elements are in technology and methodology of each of the steps – selection and purchase of the source material; equipment and other tools for the manufacturing of the product; quality assurance through in-process quality control, monitoring and evaluation and technical and operational maintenance of each of the steps/procedures; documentation and deviation or adverse event management; sustained infrastructure with a technical and administrative environment, supportive processes and appropriate steering of the complete and integral manufacturing system. These elements could be optimised and secured through a well-designed artificial intelligence based algorithmic structure.

4. Project setting needed?

In the blood industry and supply we deal with human blood to be donated on a voluntary and non-renumerated principle (altruism). Each whole blood donation is a complete and sterile source material produced by a suitable and well-motivated human being. Purchasing this source material is in principle a non-for profit process, where the origin, the selected human being, is not paid for providing his source material (batch), but duly recognised and appreciated.

Management processes in a manufacturing system provide the foundation to ‘do it right.’ The core or primary processes are typically well understood and documented, and will support sound planning and effective control. However, for the more complex operations, specialist processes such as system engineering and ICT, may be needed to enable effective management. It is crucial that the set of supportive management processes selected are appropriate to the challenges created by a specific manufacturing process. Sound planning is key to communicating the current status and work to be done. It is essential to clear understanding and communication of the work to be done and its current status. This starts with the top-down planning for the process design to introduce and implement artificial intelligence and its algorithms. An effective planning process will continuously reconcile these top-down plans and milestones with the detailed bottom-up plans that are developed as the main processes evolve. This ‘big-picture/out of the box thinking’ is needed to look for the best structures and identify and manage the implications of key interactions during the manufacture and consumption chain. In the future artificial intelligence might indeed be a valued asset starting off in a well-designed project setting and selection.

5. Project Selection

Project selection has an enormous impact upon operational performance in a manufacture setting since this ensures that the organisation puts its resources in the optimum portfolio of investments (short term as well as long term elements). This plays a role, not only when projects are initially selected for investment (e.g., introduction of pathogen reduction and inactivation, cellular engineering, development and introduction of artificial intelligence), but also in enabling rapid algorithmic decision-making (machine learning) once the project is up and running, including closing down a project that is no longer delivering what is wanted by the organisation to properly manage the related processes. In this way, successful project-based blood establishments promote a robust portfolio management discipline that continuously addresses the question of which projects best satisfy the strategic objectives and what processes need to be in place to achieve excellence in the manufacture of human blood, particularly in emergency situations (e.g., humanitarian emergencies, pandemics).

6. Reflection

Times keep changing and so do culture and opportunities. Vigilance systems, as assessment and surveillance tools depending on a meticulously designed and implemented documentation system, are still under development to trace mishaps and deviations from the set standards – haemovigilance. This triggers the reawakening of the essence of the blood supply – the customer in the hospital: the patient. Attention and awareness is shifting back to the bedside of the vein-to-vein transfusion chain with the institution of patient blood management systems (PBMs) and personalised patient care to secure evidence-based and rational use of manufactured blood and blood products in a well-prepared clinical environment and based on the three-pillar concept of PBMs. These are important developments that form a perfect opportunity and culture ground for nurturing artificial intelligence through deep learning and eventually mechanical learning tools.

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References


