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Review

Patient blood management implementation in light of new Italian laws on patient's safety

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ABSTRACT

The present work aims to analyze the impact - from legal and medical perspective - of the recent Italian legislative provisions on the subject of healthcare safety, and how these affect current transfusion practices, also in light of the accumulation of evidence deriving from the implementation of the Patient Blood Management (PBM) program.

The scientific evidence shows that PBM is a bundle of care that improves patient outcomes including mortality and morbidity, improves the quality of life of patients and the population, reduces healthcare costs and decreases consumption of blood components. These aspects should be largely sufficient to carry out an urgent implementation of PBM in Italian hospitals. However, it is now also possible to indicate a further incentive for implementation which is made up of medico-legal aspects and is characterized by the need to decrease the intrinsic risks of the use of blood products so as to protect doctors and hospitals from possible future medico-legal disputes regarding adverse transfusion events that could be effectively avoided.

1. Introduction

The subject of improving safety and quality in healthcare while resources are increasingly limited has become a challenge in the health systems of advanced countries in recent decades. Continuous commitment to patient safety is one of the fundamental vectors for the development of clinical governance policies. Patient safety is the basis for quality healthcare [1]. The fact that a medical and health treatment can be detrimental, rather than cure or treat, is the reason for viewing patient safety as the core element of quality of care.

For these reasons, organizational pathways have been implemented that are aimed at the renewal and evolution of healthcare in line with the most current scientific evidence. Clinical risk management (CRM) is a necessary organizational approach that purports to improve the quality and safety of health services by identifying the circumstances that can put patients at risk and eliminate or at least reduce the existing risks deriving from medical activities.

Through the multidisciplinary contribution of the various specialists on the subject and the competences of legal medicine centered on clinical aspects, it is possible to identify potentially risky medical practices and to report the profiles of medical professional liability before the latter materialize [2]. By applying CRM with an analytical and organizational approach, it is possible to considerably improve patient's safety [3,4] also in the field of transfusion medicine.

In Italy, the urgent need to increase the safety of care provided to patients comes after the enactment of Law No. 24 of 8th March 2017 entitled: "Provisions on patient care safety and professional liability of healthcare professionals".

In the field of transfusion medicine, in recent years, we have witnessed profound changes at the global level in the approach to the blood utilization [5–7] through international Patient Blood Management (PBM) programs.

The present work aims to analyze the impact in legal and medical terms of the recent Italian legislative provisions concerning the safety of care that affect modern transfusion medicine, also in light of the accumulation of evidence deriving from the implementation of the PBM program.

2. Italian law on the safety of care

Italian Law No. 24/2017, referred to as the Gelli or Gelli-Bianco law, named after the speakers in the Chamber of Deputies and the Senate, regulates various aspects of the professional activity in health care. Among these, Article (Art.) 1, entitled "Healthcare safety",

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governs the safety of care and the appropriate use of resources and reporting: "(1) The safety of care is a constitutive part of the right to health and is pursued in the interest of the individual and the community. (2) Care safety is also achieved via the combination of all the activities aimed at the prevention and management of the risk connected to the provision of health services and the appropriate use of structural, technological and organizational resources. (3) All personnel, including freelancers working under the agreement with the National Health Service, are required to contribute to risk prevention activities implemented by public and private health and social and healthcare facilities".

The law focuses primarily on the responsible action of the physician and of health professionals in order to allow the provision of quality healthcare and only subsequently on the possible sanctions to be adopted for negligent health professionals and organizations [8]. It immediately assumes that the safety of care is part of the right to health guaranteed to citizens by the Italian Constitution in its Art. 32 and shows that this security is achieved with a set of activities, which all personnel must complete, characterized by a multi-disciplinary framework of structural, technological and organizational resources.

This innovative regulatory reference is also the consequence of important indications provided by European Union bodies over the last decade. The European Commission is committed to supporting Member States in order to improve strategies and programs for promoting quality of care in all care facilities, ensuring the coordination of activities to guarantee patient's safety. An example is afforded by a regulation of the European Parliament and of the Council of Europe No. 282/2014, which launched the third health action program from 2014 to 2020, to support Member States with the objective, inter alia, of developing tools to improve the quality and safety of care.

Alongside these supranational provisions, European case-law was also incorporated by the European Court of Human Rights. The Court ordered that the right to health should have an ever-increasing space and legal recognition, putting the citizens in a position to appeal to the Strasbourg Court to protect their rights. In particular, the Court considers the protection of health and safety of care stemming from the Charter of Fundamental Rights of the European Union, specifically from Art. 2 (right to life, individual psychophysical integrity) and 8 (respect for private family life). Thus, the authorities of the Member States are obliged to conform to these principles, actuating substantial measures such as legal mechanisms to sanction harmful and procedures means to ensure compensation to patients for damage suffered. Alongside these obligations, the Member States also have the burden of adopting preventive measures, in order to contain the risks to life and health of those undergoing medical treatment. Accordingly, the Court could be asked to assess situations in which patients' health is endangered or compromised due to the failure to provide for appropriate precautionary organizational measures to prevent and reduce adverse events. It is interesting to observe the Court's position with regard, not so much to the individual health worker, but rather to the authorities endowed with decision-making power within the hospital and responsible for the organizational liability of medical activities.

In multiple rulings on this subject [9], the European Court has stated that: "It cannot be excluded that the acts and omissions of the authorities in the field of health services may result in their liability pursuant to article No. 2 of the Charter of Fundamental Rights of the European Union". The Court has also ruled on the fault attributable to State bodies for failure to adopt sufficient measures to prevent or reduce the risks of managing health services [10] by stating: "knowledge of the facts and errors possibly committed in the administration of medical care is essential to allow hospital facilities and medical personnel to remedy potential shortcomings and prevent similar errors".

In accordance with these principles, the new indications provided by Italian legislation appear as an innovation of paramount importance in the organizational vision of national hospitals. There is no longer a vision determined only by the repercussions for a healthcare professional who acts causing harm to the patient, but there is a wider organizational responsibility of the national health directorates that must have a central focus on the responsible action of professionals to increase patient safety.

The fundamental principles of European legislation and case-law in these areas appear to be promoted within the clinical practice by Law No. 24/2017. The content of Art. 5 of the law on the choice of medical treatments and compliance with the guidelines is of particular interest in this discussion.

This article, entitled "Guidelines on Good Clinical Practice and recommendations included in the guidelines", states "1. Health professionals, in the execution of health services with preventive, diagnostic, therapeutic, palliative, rehabilitative and legal medicine purposes, adhere, without prejudice to the peculiarity of specific cases, to the recommendations provided for by the guidelines published in pursuance of paragraph 3 and processed by public and private bodies and institutions as well as scientific societies and technical-scientific associations of the health professions registered in a special list established and regulated by decree of the Minister of Health, to be issued within ninety days from the date of entry into force of this law, and to be updated every two years. In the absence of the aforementioned recommendations, health professionals adhere to good clinical practices".

This article requires compliance with specific guidelines in professional healthcare practice or, in the absence thereof, with good clinical practices. It presents entirely specific guidelines, to be implemented according to a structured procedure divided into several successive stages. In any case, in the absence of guidelines structured according to the specific provisions of the law, doctors must adhere to "good clinical practices."

However the definition of this concept is far from simple and differently interpreted by the various authors, it clearly includes [11,12] professional practices oriented towards the protection of health, as based on scientific evidence; behaviors recommended in documents, provided they are consistent with scientific evidence and processed with a stated methodology that can be reconstructed.

Although the Law No. 24/2017 contains an array of other aspects of interest with regard to professional liability and to settle disputes, the two mentioned articles appear to be of particular interest in transfusion medicine in relation to the new evidence on this subject.

3. Patient blood management: a new approach in transfusion medicine

In order to reduce the significant risks of blood transfusions such as infectious and non-infectious risks, human errors, etc., research has largely focused on the safety of blood products in areas such as improving collection, storage, cataloguing, transport and administration [13–17]. These activities have contributed to increasing the safety of the product, however, without eliminating somewhat incompressible risks, since they are biological material [18].

With these activities an improvement in patient safety was achieved through improved product safety. However, it was assumed that the transfusion represented, in the case of anemia, an indispensable or irreplaceable therapy, therefore a risk to live with.

The introduction and application of PBM at the global level has produced a necessary change in this assumption. PBM shifts the attention in transfusion medicine from a product focus to a patient focus and to managing the patient's own blood [19]. PBM is an evidence-based, patient-specific medical and surgical concept that employs a multidisciplinary multimodal team approach to optimize the patient's red cell mass, minimize blood loss and exploit and optimize the patient's physiological tolerance of anemia.

Each pillar of PBM reduces the need for allogeneic blood components [20,21]. The use of blood transfusion is therefore not in many cases, necessarily absolute or inevitable, but on the contrary, can be considered modifiable via the application of the three pillars.

Anemia and bleeding are key risk factors, predicting up to 97.4% of transfusion decisions in elective surgical settings [22]. By the strict application of PBM, it is possible to reduce or even eliminate transfusion, sheltering the patient from the risks associated.

The standardized application of PBM programs has shown that large reductions in the utilization of blood products is possible. A systematic review and meta-analysis of PBM [23] programs with more than 200,000 patients has shown that the implementation of PBM has significantly reduced transfusion rates by 39%.

In conjunction with the decrease in blood component transfusion, there is a reduction in the direct risks of administration, specifically the eventualities that represent the main causes of death and serious transfusion damage [24–27] such as transfusion-associated circulatory overload (TACO) (1 case in 100 transfusion events), transfusion-related acute lung injury (TRALI) (1 case in 10,000 transfusion events), transfusion errors whereby an incorrect blood component is administered to the patient, creating an ABO incompatibility, and bacterial contamination of the component.

The reduction and control of the direct risks of transfusions via the implementation of PBM are associated with the direct reduction of probabilistic mortality and morbidity risks or any associated negative outcomes, including mortality and morbidity.

PBM focuses on the safety of care and the appropriate use of resources, in accordance with Law 24/2017. This is the first reason supporting the duty to apply the PBM.

It can be stated that PBM procedures must be viewed as “good clinical practice” according to any interpretation of the terms employed by the legislator.

Furthermore, 1) some interpreters identify good clinical practice with the “conventional” guidelines; accordingly, the guidelines that are inspired by the PBM are to be applied; 2) the guidelines of the National Blood Centre [28], fully consistent with the principles of the PBM, transposed by ministerial decree of January 2017 and approved with a similar procedure – even if not identical to the ones provided by Law 24/2017 – are in fact enforceable.

In light of the previous legislative references, the medico-legal methodology and the best clinical practices in transfusion medicine, it is possible to assert that when an adverse event occurs following the inappropriate or avoidable administration of a blood product – perhaps in the absence of the establishment by the health authorities of the hospital of an organized PBM program or the failure by the healthcare professionals to observe the guidelines and recommendation documents regarding the PBM - a profile of professional liability organizational in nature for the health departments and possibly of direct liability for the prescriber and enforcer could be established.

Despite this, data published by the National Blood Center (ISTISAN report) suggests blood use in Italy has not changed significantly since the issuance of the new law. For example, when comparing data between 2016 and 2018 there were no significant changes in the use of red blood cells, although plasma transfusions recorded a small decrease. [29–31] While data for 2019 are not yet available, it is likely that the wide variation in PBM implementation across Italy will persist.

To date, the Italian Society of Orthopedics and Traumatology (SIOT) [32] and the Italian Society of Anesthesia Analgesia Intensive Care and Intensive Care (SIAARTI) [33] have produced recommendations around PBM initiatives. However, more work is needed to increase awareness of the clinical and legal implications of PBM. Until there are PBM guidelines in other specific clinical settings, there is the possibility of using international guidelines like those produced in Australia [34]. After a comprehensive systematic review of the literature the National Blood Authority of Australia published six PBM guideline modules covering the following clinical settings: critical bleeding/massive transfusion, perioperative, medical, critical care, obstetrics and maternity, and neonatal and paediatrics. These guidelines are freely available.

4. Conclusions

The scientific evidence shows that PBM is an extraordinary tool allowing for decreased utilization of blood components, improving the clinical results of patients, reducing healthcare costs, improving the quality of life of patients and of the population. These elements should be largely sufficient to carry out an urgent implementation of the PBM in Italian hospitals. However, it is now also possible to indicate a further incentive for implementation made up of medico-legal aspects on the subject and characterized by the need to effectively decrease the intrinsic risks of the use of blood products in order to protect health authorities from possible future medico-legal disputes regarding adverse events in the transfusion area of inquiry that could be effectively avoided. For these reasons, it appears currently necessary to stimulate the national, regional and local health authorities, in order to provide the utmost boost to the widespread and effective implementation of PBM programs.

Declaration of Competing Interest

The authors declare no competing financial interests.

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