

# Quality indicators for Transfusion Medicine in Spain: a survey among hospital transfusion services

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**Background.** Transfusion services in the European Union must implement quality management systems to improve quality. Quality indicators (QI) play a key role in quality management because they can supply important information about the performance of the transfusion service, which can then be used for benchmarking. However, little is known about the actual use of QI in hospitals. We tried to ascertain the use and characteristics of QI in Spanish hospital transfusion services.

**Materials and methods.** We performed a survey among transfusion services in order to learn which QI they use. We classified indicators into categories and concepts, according to the steps of the transfusion process or the activities the indicators referred to.

**Results.** Seventy-six hospitals (17.9% of the hospitals actively transfusing in the country) reported 731 QI. Twenty-two of them (29%) were tertiary level hospitals. The number of indicators per hospital and by activity varied greatly. QI were assigned to some basic categories: transfusion process (23% of indicators), transfusion activity and stock management (22%), haemovigilance (20%), stem cell transplantation (9%), transfusion laboratory (9%), quality management system (8%), blood donation (3.4%), apheresis and therapeutic activities (2.5%) and immunohaematology of pregnancy (2%).

**Discussion.** Although most hospitals use QI in their quality management system and share a core group of indicators, we found a great dispersion in the number and characteristics of the indicators used. The use of a commonly agreed set of QI could be an aid to benchmarking among hospitals and to improving the transfusion process.

**Keywords:** quality indicator, transfusion, transfusion service, benchmarking, quality management.

## Introduction

William E. Deming showed, in post-war Japan, how a systematic approach to quality management could result in a sustained improvement of quality in all sectors of goods and services production<sup>1</sup>. Along the way, the focus changed from product quality control to quality management and process management. Although the benefits of a systematic quality approach had been demonstrated in the automobile, aerospace and other industries, the movement towards quality management in health care started during the 1980s, and took shape during the following decades, driven by the need for equality in patients' results and by budgetary restraints<sup>2,3</sup>. Quality Indicators (QI) are a key part of this approach, which relies on documentation of activities and collection of objective data in order to verify and judge results and set priorities in the organisations<sup>4</sup>.

The transfusion medicine community assimilated this cultural and organisational change early. In the 1990s the American Association of Blood Banks adopted a "quality systems approach" for its Standards, shifting

from a technical, "questionnaire" approach to quality-based, process-oriented Standards<sup>5</sup>. In the late 1990s the Serious Hazards Of Transfusion (SHOT) scheme highlighted the incidence of transfusion-related adverse events, paving the way for European action on blood safety, achieved through quality management<sup>6</sup>.

In 2002 the European Union passed a Directive aimed at establishing standards of quality and safety, helping to reassure the public that products derived from human blood meet the same requirements across the Union<sup>7</sup>. Blood establishments must set up and maintain quality systems involving all activities that determine the quality policy objectives and responsibilities and implement them by quality planning, control, assurance, and improvement within the quality system, taking into account the principles of good manufacturing practice as well as the European Community conformity assessment system. However, the Directive, apart from safety issues such as the incidence of serological markers among donors or self-sufficiency in the blood supply, does not propose any specific QI that could allow benchmarking of quality standards between the different member states.

The "Optimal Blood Use" (OBU) initiative, supported by the European Union in 2010<sup>8</sup>, defined QI that can be used to monitor and evaluate the quality of the transfusion process or compliance with clinical guidelines. OBU proposes internal and external indicators. Internal indicators are used for quality management and improvement of the clinical transfusion process within an institution. Some countries established a common set of QI for their transfusion services. For example, a shared set of QI was introduced in 2011 in The Netherlands, and has recently been reviewed<sup>9</sup>.

Spain is administratively organised in 17 Autonomous Regions which vary from being a single province or town (i.e. Asturias or Ceuta) to vast swathes of territory (i.e. Castile-Leon). Over time, the central government transferred the power to organise the healthcare system to these Regions. Most healthcare is delivered in publically owned hospitals, which range from high-complexity, university hospitals to small community hospitals. There are also some privately owned, medium- and low-complexity hospitals. Each Region has at least one, publicly owned, regional blood establishment which provides blood components to the hospital transfusion services (HTS). HTS are responsible for compatibility testing and transfusion of components at a hospital level, under the direction of a specialist in Haematology and Haemotherapy. In 1996 the Spanish scientific societies working in the field of transfusion, the Spanish Society of Haematology and Haemotherapy (SEHH) and the Spanish Society of Blood Transfusion and Cellular Therapy (SETS), published Standards of Accreditation, which have currently reached their fourth edition, and created the Transfusion Accreditation Committee (CAT in Spanish). At present about 68% of the whole blood donations collected and about 41% of the units transfused in Spain are performed in regional blood establishments and HTS accredited by CAT<sup>7,10</sup>. However, CAT or International Organisation for Standardisation (ISO) certification is not legally required by health authorities and, therefore, remains a voluntary choice.

The aims of this study were to ascertain which internal QI are being used in HTS in Spain and how they are defined, to determine the impact of these QI on the quality system management, and to gain insight into the QI already accepted by transfusion professionals. For these purposes we sent a survey to Spanish HTS of all levels of healthcare complexity around the country.

## Materials and methods

### Survey preparation

We prepared a survey to gather data about each hospital's complexity and tasks performed and basic facts regarding their existing quality management systems. A pilot group of leaders in transfusion made proposals

for the items in the survey. The Authors collated the answers and a template of the survey was sent back to the pilot group to check the pertinence and relevance of the questions selected. In brief, in the final survey HTS were asked, among other questions, about the scope of their activities, their QI, how these indicators were defined, the accepted control values, and the frequency of analysis. QI were defined as measurement tools based on objective information used to monitor or guide the processes carried out in the HTS. Participants were asked to report the QI they had in place under that name, for all their areas of activity. They were not asked about their current performance according to their QI, because this was deemed out of the scope of the survey. They were also invited to report if they had no QI in place.

### Survey distribution and data collection

The survey was distributed through SETS to physicians in charge of HTS and through the CAT secretariat to physicians working in CAT-accredited HTS. Responses were returned by e-mail or fax.

### Data analysis and classification of quality indicators

Data in the responses were entered into an Excel spreadsheet. We then classified the QI by assigning them to different categories, and to different concepts within each category. Categories and concepts were not predefined, but were created as they arose during data analysis, fitting them as closely as possible to the transfusion process or the clinical activity they described, if the HTS performed tasks other than transfusion (e.g. stem cell collection). For example, within the "Stock management" category we defined one concept about red cell outdating and another about the relationship of the transfusion service with the Blood Centre. If necessary, we contacted the haematologist in charge to clarify the sense or aim of the QI. Categories and concepts are summarised in Table I.

## Results

### Responses to the survey

We received 53 responses to the survey regarding 76 hospitals. The difference between the number of responses and the number of hospitals is due to the fact that two groups of answers were sent as a block by two organisations that share a common set of QI: the Blood and Tissue Bank of Catalonia, comprising eight public hospitals, and Labco, a company running clinical laboratories that include transfusion services in 17 private hospitals. In order to simplify and avoid distortions in the analysis, the QI sent by these organisations were counted only once. When a hospital in these organisations had implemented additional QI for its individual use, those QI were analysed separately.

**Table I** - Quality indicators: numbers by categories and concepts.

| Category                                     | N (%)      | Concepts                                                                            | N (%)     | Examples/explanation                                                                             |
|----------------------------------------------|------------|-------------------------------------------------------------------------------------|-----------|--------------------------------------------------------------------------------------------------|
| 1) Transfusion process                       | 170 (23.2) | Blood utilisation in different medical and surgical settings                        | 28 (17.0) | Analyse blood use in cardiovascular surgery, transplants, etc.                                   |
|                                              |            | Control of the transfusion process with electronic devices or computer applications | 27 (15.9) |                                                                                                  |
|                                              |            | Adequacy of the red cell reserves related to the medical or surgical procedure      | 22 (13.0) |                                                                                                  |
|                                              |            | Percentage of blood components returned to the transfusion service                  | 19 (11.2) |                                                                                                  |
|                                              |            | Ratio plasma/red cells transfused                                                   | 17 (10.0) |                                                                                                  |
|                                              |            | Emergency transfusion                                                               | 15 (8.8)  | Response time, incidence, etc.                                                                   |
|                                              |            | Massive transfusion                                                                 | 9 (5.3)   | Incidence of massive transfusion or compliance with management protocols                         |
|                                              |            | Transfusion rates of blood products per patient                                     | 8 (4.7)   |                                                                                                  |
|                                              |            | Compliance with informed consent for transfusion                                    | 7 (4.1)   | Percentage of transfusions given without the patient giving consent.                             |
|                                              |            | Percentage of patients with autologous donations who receive homologous blood       | 7 (4.1)   | Autologous donation not enough for the patient's needs or not used erroneously.                  |
|                                              |            | Compliance with hospital transfusion guidelines                                     | 7 (4.1)   |                                                                                                  |
|                                              |            | Performance of blood group check at patient's bedside                               | 4 (2.4)   | Compliance with protocol and problem solving.                                                    |
| 2) Transfusion activity and stock management | 160 (22.0) | Percentage of red cell units outdated                                               | 37 (21.3) |                                                                                                  |
|                                              |            | Global transfusion activity                                                         | 32 (20.0) | Number of red cell, plasma or platelet units transfused in a given period.                       |
|                                              |            | Percentage of received platelet units lost due to outdating                         | 27 (17.0) |                                                                                                  |
|                                              |            | Percentage of plasma units lost (not outdated)                                      | 16 (10.0) | Units broken, or returned to the transfusion service but not acceptable, etc.                    |
|                                              |            | Relationship with the Regional Blood establishment                                  | 12 (7.5)  | Response of the Blood Establishment to emergency orders, defective blood products received, etc. |
|                                              |            | Loss of red cells (not outdated)                                                    | 10 (6.3)  |                                                                                                  |
|                                              |            | Autologous units outdated                                                           | 9 (5.6)   |                                                                                                  |
|                                              |            | Breaches of stock                                                                   | 7 (4.4)   | Number of times the transfusion service cannot supply a blood product.                           |
|                                              |            | Platelets lost (not outdated)                                                       | 4 (2.5)   |                                                                                                  |
|                                              |            | Plasma outdated                                                                     | 4 (2.5)   |                                                                                                  |
|                                              |            | Miscellaneous                                                                       | 2 (1.3)   |                                                                                                  |
| 3) Haemovigilance/biovigilance               | 145 (19.8) | Number of errors and near errors                                                    | 38 (26.0) | Raw numbers of errors/near errors                                                                |
|                                              |            | Errors in the blood request document                                                | 34 (24.0) |                                                                                                  |
|                                              |            | Performance of the haemovigilance system                                            | 24 (17.0) | Speed of communication, case solving and corrective action, etc.                                 |
|                                              |            | Adverse effects of apheresis or whole blood donation                                | 20 (14.0) |                                                                                                  |
|                                              |            | Characteristics of transfusion reactions                                            | 15 (10.0) | Description and classification                                                                   |
|                                              |            | Incidents related to the pre-transfusion sample                                     | 12 (8.0)  | Incorrect sample, scarce, incorrectly identified...                                              |
|                                              |            | Miscellaneous                                                                       | 2 (1.3)   |                                                                                                  |
| 4) Transfusion laboratory                    | 68 (9.3)   | Analytical problems                                                                 | 15 (22.0) |                                                                                                  |
|                                              |            | Compliance with red cell compatibility protocols                                    | 14 (20.0) |                                                                                                  |
|                                              |            | Quantitative activity                                                               | 13 (19.0) |                                                                                                  |
|                                              |            | Performance in external quality controls                                            | 12 (18.0) |                                                                                                  |
|                                              |            | Incidents during laboratory work                                                    | 8 (12.0)  |                                                                                                  |
|                                              |            | Response to emergency orders                                                        | 6 (9.0)   |                                                                                                  |

(continued on next page)

**Table I** - Quality indicators: numbers by categories and concepts. (*continued from previous page*)

| Category                                | N (%)    | Concepts                                                             | N (%)     | Examples/explanation                                                                     |
|-----------------------------------------|----------|----------------------------------------------------------------------|-----------|------------------------------------------------------------------------------------------|
| 5) Stem cell procurement and processing | 66 (9.0) | Global activity                                                      | 24 (36.4) | Number of stem cell collections/manipulation processes performed.                        |
|                                         |          | Incidents during stem cell collection or handling                    | 20 (30.3) |                                                                                          |
|                                         |          | Compliance with quality control levels                               | 19 (28.8) |                                                                                          |
|                                         |          | Time to neutrophil or platelet engraftment                           | 3 (4.5)   |                                                                                          |
| 6) Quality management                   | 65 (8.9) | Incidents related to transfusion laboratory management and equipment | 21 (32.3) | Compliance with the training plan, attendance at educational and training sessions, etc. |
|                                         |          | Management of the Quality System                                     | 18 (27.7) |                                                                                          |
|                                         |          | Staff training                                                       | 12 (18.5) |                                                                                          |
|                                         |          | Meetings of the Quality Committee                                    | 6 (9.2)   |                                                                                          |
|                                         |          | Traceability of products.                                            | 5 (7.7)   | Compliance with survey plan and derived actions                                          |
|                                         |          | Client's opinion and satisfaction                                    | 3 (4.6)   |                                                                                          |
| 7) Blood donation                       | 25 (3.4) | Global activity and self-sufficiency of the hospital                 | 8 (32.0)  |                                                                                          |
|                                         |          | Number of autologous donations                                       | 3 (12.0)  |                                                                                          |
|                                         |          | Miscellaneous                                                        | 1 (4.0)   |                                                                                          |
| 8) Apheresis and therapeutics           | 18 (2.5) | Apheresis activity                                                   | 6 (33.3)  |                                                                                          |
|                                         |          | Incidents and process failures                                       | 6 (33.3)  |                                                                                          |
|                                         |          | Quality control                                                      | 3 (16.7)  |                                                                                          |
|                                         |          | Miscellaneous                                                        | 3 (16.7)  |                                                                                          |
| 9) Immuno-haematology of pregnancy      | 14 (1.9) | Prevention of sensitisation events                                   | 4 (28.6)  |                                                                                          |
|                                         |          | Compliance with Rh(D) prophylaxis protocol                           | 4 (28.6)  |                                                                                          |
|                                         |          | Miscellaneous                                                        | 6 (42.9)  |                                                                                          |

Responses came from HTS located in 12 out of the 17 regions in the country. All regions that responded sent at least one answer and in all regions, but one, a tertiary care hospital was included. The characteristics of the responding hospitals are summarised in Table II.

#### Characteristics of the responding hospitals: size and healthcare complexity

Most answers (48/53, 90%) came from public hospitals. The responding hospitals provide all levels of health care as they range from community hospitals to tertiary reference centres. All have emergency departments and maternity wards, except one specialist paediatric hospital. Tertiary level hospitals (>600 beds) provide all kinds of medical and surgical procedures for adult and paediatric patients, including cardiovascular surgery and solid organ and haematopoietic transplantation. Middle-sized hospitals (300-600 beds) usually offer comprehensive care, including autologous hematopoietic and cadaveric renal transplantation but do not perform advanced cardiovascular surgery or other organ transplants. Most responding hospitals (72/76, 96%) are qualified as University Hospitals and take part in specialist training, but not for all specialties.

#### Characteristics of the quality management systems

Ninety-three percent (71/76) of responding HTS have a quality management system, often certified by one or more external agencies. Most of the quality management systems are based on CAT, ISO or both, but some are also certified by FACT-JACIE or EFQM. Three of the five hospitals without a quality management system were considering implementation of such a system (Table II). The number of agencies certifying the quality management systems of the HTS was not associated with the number of QI used by the HTS (*data not shown*).

#### The quality indicators: numbers and use

The 53 responses reported 731 QI. The median number of QI per response was 13 (range: 3-44). Three responses (5%) reported no QI, while 36/53 responses (68%) described between 1 and 20 (Table III).

QI outcome measures were generally reported as percentages or means. For rare episodes (e.g. serious adverse effects of transfusion), HTS tended to use raw numbers. Although most of the HTS collect data monthly, they usually analyse the data every 3 or 4 months. All hospitals reported that their QI have evolved over time, reflecting or causing changes in transfusion policy, hospital practice, or the application of stricter

**Table II** - Hospital characteristics.

|                                                | N.    | %   |
|------------------------------------------------|-------|-----|
| Number of beds/hospital                        |       |     |
| <100                                           | 7     | 9   |
| 100-300                                        | 26    | 34  |
| 301-600                                        | 21    | 28  |
| >600                                           | 22    | 29  |
| Activities of the Transfusion Service          |       |     |
| Transfusion Laboratory                         | 76    | 100 |
| Transfusion in the wards*                      | 60    | 79  |
| Immunohaematology of pregnancy                 | 66    | 87  |
| Autologous donations                           | 54    | 71  |
| Homologous donations                           | 11    | 14  |
| Apheresis and therapeutics                     | 24    | 32  |
| Stem cell transplantation                      | 31    | 41  |
| Accreditation of the Quality Management System |       |     |
| CAT (†)                                        | 10.00 | 13  |
| ISO (‡)                                        | 16.00 | 21  |
| CAT+ISO                                        | 10.00 | 13  |
| CAT + ISO + Others                             | 35.00 | 46  |
| None                                           | 5.00  | 7   |

\*Nursing staff of the Transfusion Service carries out transfusion in the clinical wards. †CAT: *Comité de Acreditación de la Transfusión* (Transfusion Accreditation Committee); ‡ ISO: International Organisation for Standardisation.

**Table III** - Number of indicators by response.

| N. of quality indicators | N. of responses | %  |
|--------------------------|-----------------|----|
| 0                        | 3               | 6  |
| 1-10                     | 19              | 36 |
| 11-20                    | 17              | 32 |
| 21-30                    | 8               | 15 |
| 30-40                    | 3               | 6  |
| >40                      | 3               | 6  |

Percentages have been rounded up.

acceptance thresholds. All HTS spread their results to their staff, the Head of Department and other relevant figures in the hospital.

### The quality indicators: categories and concepts

The analysis showed that QI could be assigned to nine categories, which were then divided into concepts. The categories and concepts are listed in Table I.

All hospitals used at least one QI in the top two categories of indicators: indicators describing the "Transfusion Process" were the most common category in the survey with 170 of the 731 QI reported (23.2%) followed by indicators related to "Transfusion activity and stock management" with 160/731 QI (22%). "Haemovigilance" is the third largest group of

QI: 145/731 indicators (19.8%), appearing in 40/53 responses (75%), followed by "Performance of the transfusion laboratory" with 68 indicators (9.3%) that appeared in 30/53 responses (56%). "Haematopoietic stem cell procurement and processing" is the fifth group of QI, with 66/731 indicators (9%). Although most transfusion services, particularly in the larger hospitals, handle progenitor cells, only 9/53 responses (17%) related to QI in this category. Furthermore, a single hospital provided the largest number of indicators in the category (29/66, 44%). "Quality management" accounted for 65 of the 731 indicators (8.9%) in 17/53 responses (32%). These numbers could be misleading, because most indicators (37/65, 57%) were reported by a group of only four hospitals.

The number of QI for the other three categories, "Apheresis and therapeutics" (18/731 indicators, 2.4%), "Blood donation and processing" and "Immunohaematology of pregnancy" were marginal. Only a few hospitals have indicators for these issues, although a large number of HTS perform the related activities.

## Discussion

In order to learn about the use of QI in transfusion medicine in Spain, we conducted a survey among transfusion services, enabling us to collect information on a sizable sample of transfusion QI. The data render a clear picture of the characteristics and use of QI in transfusion, thanks to the number of indicators reported, the diversity of the hospitals involved, the variety of HTS practices, and the uniformity of indicators included in the categories and concepts that accrued most QI.

### Comments on the method: strengths

We performed this survey among transfusion services, without prior selection of the participants and without knowing whether they had a quality management system in place or not, or the kind of QI they used. In order to increase the pertinence of the questions asked, we did not prepare the survey ourselves, but got help from expert transfusion specialists. A Dutch group recently published a survey based on an alternative approach focused on a previously agreed group of QI throughout the Dutch health system<sup>9</sup>. This approach was waived during our survey design, because there is no formal, country-wide agreement on QI in Spain. Besides, the Dutch QI applied only to transfusion practice, while HTS perform other activities, not always related to transfusion. We considered that our approach would give a truer picture of the situation. We believe that our aim has been achieved, as shown by the diversity of participants, their importance in the national healthcare system and the variety of the situations reported, including some worrying ones, which we comment on below.

### Comments of the method: weaknesses and biases

Some criticisms of our survey and our results can be made. We could not carry out an exhaustive field survey and had to rely on the help of SETS and CAT to reach professionals. Thus, the number of responses was low when compared with the number of hospitals in the country. In the National Haemovigilance Report of 2013<sup>11</sup>, the Spanish National System for Transfusion Safety estimated that there were 368 hospitals in Spain with a HTS. That means that we received responses from only 17.9% of the HTS in Spain. The use of SETS/CAT to spread the survey could have created biases because the main source of information would be hospitals that are committed to quality. Besides, membership of SETS and CAT-accredited transfusion services are irregularly distributed in the country. Although we had expected this situation, the study design and the relatively low response rate precluded comparisons among regions and statistical inference. As a result, we can only make a descriptive report of the situation and our conclusions could be weakened accordingly.

### Comments on the participants

Seventy-six hospitals of all levels of healthcare complexity sent responses. We consider it crucial to have collected data from an important group of tertiary hospitals (22/76, 29% of the hospitals that responded), performing the most complex medical and surgical procedures in the country, acting as referral centres for the whole country and transfusing a substantial proportion of the blood components in Spain<sup>11</sup>. Indeed, those 22 hospitals transfuse 20% of the red cell units in Spain, and most of the platelets and plasma<sup>11</sup>. Taken together, our responding hospitals transfuse about 35% of red cells in Spain. Considering that 173 members of the Spanish Society of Blood Transfusion are physicians working in HTS, the response rate could be 44% (76/173) or higher, because several SETS members work in the same HTS. The regions that did not send any responses account for 17.5% of the Spanish census.

The fact that 63% of responding hospitals are certified by more than one accreditation institution or standard implies a strong commitment to quality in the transfusion community. All hospitals have changed their QI over time, reflecting changes in practices and activities. Again, all HTS share their results with the main stakeholders in their hospitals. We conclude that QI are playing a role in improving performance and also in internal communication and quality perception within the HTS and at different organisation levels.

We previously stated that the main weakness of our study is the relatively low rate of responses, a direct consequence of the way the study was conducted.

However, there is another possible explanation for the low response rate. A small but important number of hospitals (5/76; 6.6%), admitted not having a quality management system, despite European<sup>7</sup> and Spanish regulations<sup>12,13</sup> mandating that transfusion services have such a system. This should be a cause of concern for regional health authorities. The percentage of HTS without a quality management system might be even higher among hospitals that did not respond to the survey or did not receive it. We can only speculate about the causes for this non-compliance, as our survey was not designed to capture this information. Lack of support from the health services is usually mentioned even among those who comply. One should take into account that 57% of the responding HTS in our study were medium- to large-sized hospitals (>300 beds) and such hospitals usually have quality departments. In fact, 33% of the responding HTS belong to just two organisations (Labco and Blood and Tissue Bank of Catalonia) with centralised management, which could indicate that specific leadership and resources are needed for organisation-wide achievements in quality management. In several Regions formed of single provinces, most hospitals participated in the survey, perhaps due to a closer relationship among hospitals sharing a culture of quality.

### Quality indicators: characteristics and interpretation

All HTS had QI related to the top two categories: performance of the transfusion process (23% of QI, 170/731) and overall use of components, stock management and the shelf-life of products (22%, 160/731).

In this latter category, 44% (70/160) of indicators are specifically related to red cells and 19% (30/160) to platelets. This focus is not surprising, given the cost of blood products, their widespread use and their relative scarcity. However, in our opinion, although quantitative measures can be indirect indicators of the performance of a transfusion service, they do not clearly reflect intrinsic characteristics of the transfusion process. This is better addressed by QI in the transfusion process category, such as adherence to transfusion guidelines or standard operating procedures. In fact, quantitative QI could become a hurdle if they consume the precious time of laboratory staff or transfusion officers.

Although many HTS state that they have QI for all their activities, this can be misleading. Not all hospitals have QI covering key categories. For example, QI related to haemovigilance account for only 20% of the total (145/731) and not all HTS use them. More intriguingly, only a small proportion of the QI are related to laboratory performance (68/731, 9.3%) and such indicators are used by less than half the hospitals (30/76). Again, only a small proportion of HTS (8/76, 10%) have QI for their

pregnancy-related immunohaematology activities, even though nearly all perform these activities. This situation is another matter of concern, since it could mean that the quality management systems are not fully developed or properly used.

### Quality indicators as a tool for benchmarking

The variability in the QI used by the HTS makes benchmarking between hospitals difficult. This is the case of the survey. We observed that many different HTS use the same QI, and the two main categories (transfusion process and activity/stock management) account for 45% of all indicators used. Many HTS are using the QI proposed by the OBU initiative. However,

sometimes the definitions of the QI, or the language used, are not the same, creating confusion.

The existence of a set of agreed QI might help in analyses and comparisons between HTS, although care should be taken to avoid the opposite situation: hospitals adopting the same QI even if they are not significant for their quality management, comparing useless pieces of information. Given the difference in the characteristics of the hospitals, some particular QI should exist alongside a set of shared indicators, and probably the acceptance criteria for the shared QI would have to be adapted likewise: for instance, big teaching hospitals should be more stringent regarding product outdates, while remote community hospitals could put up with a higher rate of product loss.

**Table IV** - A proposal set of quality indicators for shared use in Transfusion Medicine.

| Category                                  | Quality indicator(s)                                                                                                                       | Reference |
|-------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| Transfusion process                       | Use of blood components in specific medical or surgical processes                                                                          | 15, 14    |
|                                           | Ratio between plasma and red cell use                                                                                                      |           |
|                                           | Management of massive transfusion                                                                                                          | 15        |
|                                           | Ratio between cross-matched units and transfusions (when serological cross-matching is used)                                               |           |
|                                           | Correct prescription: percentage of transfusion orders that do not comply with institutional transfusion guidelines and/or surgical orders | 8, 9, 14  |
|                                           | Percentage of blood components returned to the Transfusion Service                                                                         | 8, 14     |
|                                           | Percentage compliance with informed consent for transfusion                                                                                | 14        |
| Transfusion activity and stock management | Variation in the use of blood products along time                                                                                          |           |
|                                           | Percentage of outdated products while in stock                                                                                             | 8, 14     |
|                                           | Product loss not due to outdating                                                                                                          | 14        |
| Haemovigilance/biovigilance               | Incidents in blood orders: percentage of blood orders lacking essential detail                                                             | 8, 14, 15 |
|                                           | Severe transfusion reactions: cause and characterisation                                                                                   | 14        |
|                                           | ABO discrepancies due to labelling or sampling errors                                                                                      | 8, 14     |
|                                           | Sampling errors: cause                                                                                                                     | 8, 14     |
| Transfusion laboratory                    | Response time to emergency or urgent transfusion orders                                                                                    | 14        |
|                                           | Blood group discrepancies with previous records due to laboratory errors                                                                   | 8, 14     |
|                                           | Performance in external quality controls                                                                                                   |           |
|                                           | Fulfilment of compatibility guidelines while issuing blood (iso-group, Rh negative to Rh negative, etc.)                                   | 14        |
| Stem cell collection                      | Engraftment data (days to achieve >100 neutrophils/mL, >20,000 platelets/mL)                                                               |           |
|                                           | Quality control of the harvested products (CD34 cells, etc.)                                                                               |           |
|                                           | Rate of failed collection processes and their causes                                                                                       |           |
| Quality management                        | Percentage of units for which there is no record in the hospital blood bank of their final destination                                     | 8, 9, 14  |
|                                           | Incidents related to quality management, other than haemovigilance                                                                         |           |
|                                           | Compliance with staff training programmes and requirements                                                                                 |           |
| Blood donation                            | Incidence of adverse effects of blood donation                                                                                             | 14        |
|                                           | Incidence of positive infectious disease markers                                                                                           | 14        |
| Apheresis                                 | Global activity for each process (plasma exchange, stem cell collection...)                                                                |           |
|                                           | Incidents during the apheresis process                                                                                                     |           |
|                                           | Aphereses that fail their clinical target                                                                                                  |           |
| Immunology of pregnancy                   | Incidence of irregular antibodies in pregnant women                                                                                        |           |
|                                           | Incidence of peri-partum transfusion                                                                                                       |           |
|                                           | Compliance with protocols to avoid transfusion associated red cell sensitisation in fertile women                                          |           |
|                                           | Compliance with Rh sensitisation prevention programmes.                                                                                    |           |

We believe that, as a minimum, the QI proposed by the OBU initiative should be used by HTS, at least in the beginning of their quality management system. These QI cover the main aspects of the transfusion process and are relatively easy to collect and analyse. Based on our data, particularly from the QI used in the hospitals providing the most complex health care and noting that the QI proposed by the OBU initiative and others are already in use<sup>8,14,15</sup>, we put forward a set of QI that could facilitate benchmarking for the transfusion process among hospitals in Spain (Table IV). Of course, this set of indicators should be supported by a consensus of expert transfusion specialists and work as a primary framework for a formal country-wide proposal. Moreover, we propose a more ambitious survey among Spanish transfusion services (and, if needed, services in neighbouring countries) to validate our findings and help build this consensus.

## Conclusions

To our knowledge, this is the first time a survey on the use of QI has been performed among HTS in Spain. The survey shows that a wide range of QI is being used, dealing mainly with the transfusion process and transfusion activities. We also found that some transfusion services do not have a quality management service, despite European regulations. The variability in QI makes it difficult to compare the performance of HTS, but we did find a core set of QI that could serve as a template for further standardisation and a consensus proposal. The existence of an agreed set of QI would facilitate benchmarking between centres, making continuous improvement of the transfusion process more straightforward. Nevertheless, a more exhaustive survey and further work by transfusion quality experts is needed before a consensus can be reached.

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## Authorship contributions

Both Authors contributed equally to designing the study, processing the data, and writing and reviewing the paper.

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