Open access Original research

BMJ Open Quality

Implementation of a quality management system in a liver transplant programme

Yolanda López-Púa , ¹ Miquel Navasa, ² Antoni Trilla, ³ Jordi Colmenero, ⁴ Raquel García, ² Eva López, ² Anna Durà, ² Ana Guash, ² José Ríos ⁵

To cite: López-Púa Y, Navasa M, Trilla A, *et al.* Implementation of a quality management system in a liver transplant programme. *BMJ Open Quality* 2023;**12**:e002440. doi:10.1136/bmjoq-2023-002440

➤ Additional supplemental material is published online only. To view, please visit the journal online (http://dx.doi.org/10. 1136/bmjoq-2023-002440).

Received 2 June 2023 Accepted 7 September 2023



Check for updates

© Author(s) (or their employer(s)) 2023. Re-use permitted under CC BY-NC. No commercial re-use. See rights and permissions. Published by BMJ.

¹Quality Unit, Biomedical Diagnostic Center, Hospital Clinic de Barcelona, Barcelona, Catalunya, Spain ²Liver Transplant Unit, Hospital Clinic de Barcelona, University of Barcelona, Barcelona, Catalunva, Spain ³Preventive Medicine Unit, Hospital Clinic de Barcelona, University of Barcelona, Barcelona, Catalunya, Spain ⁴Liver Unit, Hospital Clinic de Barcelona. IDIBAPS, CIBERehd, University of Barcelona, Barcelona, Catalunya, Spain ⁵Department of Clinical Farmacology, Hospital Clinic de Barcelona, Hospital Clinic and Medical Statistics Core Facility, IDIRAPS Biostatistics Unit School of Medicine, Universitat Autònoma de Barcelona,

Correspondence to Yolanda López-Púa; yolopez@clinic.cat

Barcelona, Catalunya, Spain

ABSTRACT

Background The management of liver transplantation has become a complex process involving different healthcare professionals. Teamwork, standardisation and definition of the best practices are essential for success, patient satisfaction and society's favourable perception of transplantation programmes.

ISO 9001:2015 certification provides the necessary elements to help implement a quality management system (QMS) to ensure that patient care is performed with the highest guarantees of clinical quality and safety. The aim of this study is to describe the steps, strengths and limitations in the implementation of a QMS in a liver transplant programme (LTP).

Project management method This included analysing the starting point, setting up a working group, training, defining the scope of certification, preparing documentation, and conducting an internal and external audit, which culminated in the ISO 9001 quality certification award. The scope of QMS includes all the processes of LTP, from referral of candidates to long-term follow-up after transplantation.

Results The project was structured in seven phases that took place between 2008 and 2011. The implementation of QMS led to the generation of all the necessary documentation to meet the requirements of the standard, including internal and legal requirements related to the transplant activity. The establishment of indicators to measure the effectiveness of processes, risk management and the identification of incidents allows us to implement measures devoted to avoiding the deficiencies and to meet the established objectives.

Conclusion ISO 9001:2015 certification has contributed to the adaptation of a new quality and safety culture focused on the patient. All activities are protocolised, everything is recorded, measured, and verified, and all steps are taken as planned. Work is carried out in terms of continuous improvement. This has led to less variability in daily clinical practice and a better understanding of work dynamics.

INTRODUCTION

The effectiveness of the quality and safety of healthcare processes, as well as the satisfaction of patients and professionals involved, continues to arouse growing interest from healthcare organisations and institutions, and in general, from a society that is increasingly

WHAT IS ALREADY KNOWN ON THIS TOPIC

Government health policies encourage and promote the provision of comprehensive healthcare with high levels of quality, as well as the implementation of quality management systems (QMS) to ensure that patient care and the processes involved are efficient and with maximum guarantees of clinical safety.

WHAT THIS STUDY ADDS

It provides a practical insight into the experience of implementing a QMS in a liver transplantation programme.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ By encouraging liver transplant units to implement a useful QMS with the aim of promoting quality and safety in patient care, and establishing the standard requirements for liver transplant units.

demanding of healthcare services. ^{1 2} The WHO, ^{3 4} the guidelines set by the European Union ⁵ and Spanish legislation ^{6 7} emphasise the provision of comprehensive healthcare by ensuring high levels of quality and the implementation of quality systems that are evaluated by independent bodies. As a consequence of the application of these policies, the implementation of a quality management system (QMS) in clinical units has been increased in recent years with the aim of ensuring that patient care and the processes involved are efficient and have the greatest guarantees of quality and clinical safety.

ISO 9001,Quality Management Systems Requirements,⁸ is the global reference for QMS adopted by millions of organisations worldwide, providing the criteria for a QMS supported by a process model and the PDCA (Plan-Do-Check-Act) cycle to achieve desired outcomes and customer satisfaction. The first ISO 9001 international standard was issued in 1987 and reviewed in 1994 to clarify preventive and mandatory documentation requirements.



The following ISO 9001 edition was issued in 2000, adopting the process approach, and was subject to a mild revision in 2008 to clarify certain requirements. Finally, in 2015 the present version of ISO 9001 was published, emphasising the need to monitor the context and evaluate the stakeholders that influence the organisation and the process approach with more flexibility and less focus on documentation. ⁹⁻¹¹ Implemented QMS Standards such as ISO 9001 can be audited and certified by independent third-party organisations (the certification body) to assess if the QMS complies with the applicable requirements and if the intended results are achieved. ¹¹

The implementation of a QMS in accordance with ISO 9001:2015 involves the establishment of an organisational structure, the integration of responsibilities, definition of processes, protocolisation and standardisation of activities, and ensures that processes are properly resourced and managed. The objective is to provide tools that help organisations to achieve better results through the application of continuous improvement, ensuring compliance with the customer and conformity with regulatory requirements. Consequently, the focus is on increasing the efficiency of the processes, preventing deficiencies, and seeking a benefit for the patient. ¹³ ¹⁴

The liver transplant programme (LTP) of the Liver Transplant Unit from the Institute of Digestive and Metabolic Diseases at Hospital Clinic, Barcelona, has been a benchmark programme since its creation in 1988, both for the number of transplants carried out to date (2460) and for the excellent short-term and long-term results obtained. The probability of patient survival is 94% in the first year and 80% in the fifth year.

The programme was certified according to the international ISO 9001 standard in 2011 and according to the Spanish UNE 179008, the QMS for liver transplantation units, standard ¹⁵ in 2017.

The aim of this paper was to describe the design, implementation and certification process of a QMS in an LTP and to explore its applicability and usefulness in a liver transplant unit.

PROJECT MANAGEMENT METHOD

The process of adaptation to the ISO 9001 standard started in November 2008. Two fundamental aspects were considered for the planning and implementation of the QMS in the LTP. The main premise was that the QMS should be applied to all medical interventions performed by the programme, regardless of whether the patient was a potential transplant candidate, a transplant candidate on the waiting list or a patient who had a transplant. The second premise was that the system should be focused

on providing a useful tool for professionals. With this approach, it was essential to homogenise care practices and clinical criteria so that the care offered to the patient would be carried out in the same way, with all the guarantees of quality and safety, regardless of the professional attending the patient.

It was also intended that the QMS would help to retain the clinical care knowledge acquired over the years by the most senior professionals. For this reason, the QMS orientation was intended to be entirely clinical. The major challenge and complication of the project was mainly adapting the complex activity of liver transplantation to a non-specific standard outside the clinical setting without losing its clinical care orientation. The team responsible for planning and developing the project consisted of the following professionals: the head of the liver transplant unit, an external quality manager, hepatologists, surgeons, anaesthesiologists, an intensive care and ward nurse coordinator, an outpatient and anaesthesia nurse, and administrative staff. All of them received training in the ISO 9001 standard.

A quality committee was also set up to monitor the QMS, and its composition and functions were defined, as well as the frequency of meetings.

Seven project phases were identified and planned (figure 1).

First phase: Analysis of the starting point

The status of the programme was analysed in terms of compliance with the requirements of ISO 9001. This analysis focused on the process approach, the documentation required, continuous improvement through the analysis of results and the implementation of adequate measures, the recording and resolving of incidents and nonconformities, the assessment of customer satisfaction, management responsibilities, competencies and training of professionals, the maintenance of facilities and equipment involved in processes, and the implementation of corrective actions.

Second phase: Establishment of the working group

A multidisciplinary working group was created to plan and develop the project, composed of hepatologists, surgeons, nurses and administrative staff.

Third phase: Training

The team responsible for the project was trained in the requirements of the ISO 9001 standard.

Fourth phase: Scope of certification

To establish the scope of the QMS in a coherent manner, all the processes involved in liver transplant were mapped



Figure 1 Project phases.



out with the help of all the professionals involved in the transplant process.

Fifth phase: Creating and updating documentation and implementation of the QMS

A standard operating procedure for the control of documentation and control of records was created to establish the bases for the documentation format, content layout, coding, drafting, review and approval, identification of changes, distribution of current versions, and management of obsolete documents.

The implementation of the QMS was carried out simultaneously with the elaboration of the documentation.

Sixth phase: Conducting the internal audit

An internal audit was carried out to determine the degree of adherence of the QMS to the ISO 9001 standard and to internal, legal and regulatory requirements. Nonconformities, observations and opportunities for improvement were detected and corrected.

Seventh phase: Conducting the certification audit

The certification body was chosen, and the certification audit was carried out.

Data relating to customer satisfaction, results of audits, indicators, the relationship with internal suppliers, and the effectiveness of actions proposed to address non-conformities and reduce risks are reviewed and analysed quarterly in order to assure the compliance with the QMS and to monitor the continuous improvement.

After the implementation and evolution of our QMS, we wanted to go to a step further and to promote the development of a specific standard for liver transplant units in Spain.

We proposed this project to the Spanish Association for Standardisation and Certification (AENOR) and it was successfully approved. AENOR established the working group AEN/CTN 179/GT12 'Liver transplantation',

dependent on the AEN/CTN 179 committee 'Quality and safety in healthcare centres'.

The project had a high level of participation of public institutions, including the Spanish Ministry of Health, Transplant Coordination of the Spanish autonomous communities, the National Federation of Liver Patients and Transplant Recipients, the National Transplant Organization, the Spanish Society of Liver Transplantation, and more than 10 Spanish university hospitals. As a result of this work, the UNE 179008 standard was elaborated.

RESULTS

First phase: Analysis of the starting point

At the starting point, there were many documents, protocols and policies describing the tasks involved in the LTP, as well as indicators of the performance of the programme. However, in most cases these documents did not comply with all the requirements of the ISO 9001 standard.

Second phase: Establishment of the working group

The working group was established, as shown above in the Project management method section.

Third phase: Training

The working group received training from an external quality manager. In addition, this person was always present during the development of the project.

Fourth phase: Scope of certification

The scope of the QMS was defined, and the process map was drawn up. The process map allowed us to visualise the relationships between the different types of processes defined: strategic processes, focused on the fulfilment of our policy, mission and objectives, key processes, directly related to the patient, and support processes, necessary

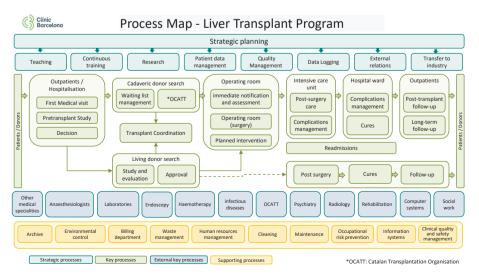


Figure 2 Process map.



to carry out the activity. The processes defined are shown in figure 2.

Fifth phase: Creating and updating documentation and implementation of the QMS

Documentation was generated to meet the requirements of the standard, the internal and legal requirements related to transplant activity. The quality policy, quality manual, organisational chart, job descriptions and quality objectives were elaborated.

Twenty-three general procedures related to processes were created, 13 of which were medical, nursing or administrative procedures related to the evaluation of transplant candidates, assistance in hospitalisation units and follow-up in outpatient clinics. The other procedures were related to quality management, such as documentation control, audit performance, incident management, corrective actions, staff training, patient satisfaction monitoring, equipment and facilities maintenance, purchasing, and management relations with suppliers (online supplemental appendix 1 (General Procedures)).

Twenty-seven standard operating procedures and 28 care protocols were developed, 18 of which were medical protocols and 10 were nursing protocols (online supplemental appendix 2 (Standard Operating Procedures), online supplemental appendix 3 (Protocols)). Seventy-three specific forms were also created to record the performance of the activity, and 45 indicators to monitor the effectiveness of the processes were established. Indicators were extracted from the recommendations and consensus documents of the scientific societies and, alternatively, we defined some indicator ad hoc for specific needs of our programme (table 1). Objectives (targets) were set for process and programme indicators.

A system for recording incidents in outpatient consultations, intensive care units, hospitalisation units and operating rooms was established in order to detect problems, failures or errors that could hinder the work of professionals and patient recovery. Several safety checks were established to control critical key points in the processes, as it was detected that a significant number of incidents occur at device changes (arrival in the operating room, intensive care unit and hospital ward), admission of the living liver transplant donor and recipient patient, admission of the cadaveric donor recipient patient, immediate presurgical assessment, inpatient discharge information and referral to outpatient clinics.

Patient satisfaction was assessed. For this purpose, a satisfaction survey is offered to all patients immediately before hospital discharge. In 2015, we introduced the evaluation of family/caregiver satisfaction.

According to the ISO 9001 standard, an annual planning of continuous training for staff to improve the skills needed to adapt to changes and innovations in their daily work was established. In addition, the effectiveness of the training received by all staff was evaluated.

Sixth phase: Conducting the internal audit

When the QMS was implemented, an internal audit was carried out to determine the degree of adherence to the standard. It was necessary to correct four non-conformities for improvement. After 3 months, the certification body was chosen, and the external certification audit was carried out.

Seventh phase: Conducting the certification audit

After the correction of the non-conformities detected, the certificate of compliance was obtained in August 2011. Since the implementation of the QMS, the quality committee has met quarterly to review process performance and assess continuous improvement.

After the publication in 2015 of the last version of the ISO 9001 standard, the QMS was adapted to the new requirements. The major changes were the following:

- ▶ Determining the context of the organisation by conducting a SWOT (Strengths, Weaknesses, Opportunities and Threats) analysis to identify and address potential risks to the programme and improve processes, considering internal strengths and external opportunities.
- ► Inclusion of process risk management. The tool used for risk analysis was the FMEA (Failure Mode and Effect Analysis). Improvement actions were defined and monitored to minimise the risks found.
- ► Consideration of the needs and expectations of all stakeholders, creating opportunities for improvement and objectives aimed at meeting the needs detected and satisfying expectations. The transplant unit identified the relevant stakeholders, including patients, relatives, transplant unit professionals from LTPs in Spain, non-transplant referral hospitals, national and regional transplant organisations, several patient associations and scientific societies.

Following the publication of the Spanish standard UNE 179008 QMS for liver transplantation units in October 2016, the QMS was adapted to include the requirements of this standard, which is based on ISO 9001:2015 and includes specific requirements for liver transplant units. The main changes made to implement it were the assessment of the risks of the processes focusing on patient safety, reinforcing the competence of nursing staff, optimising the coordination between multidisciplinary teams (eg, to reduce the time from graft availability notification to recipient transplantation) and the establishment of effective communication channels with all stakeholders involved in the transplantation process.

In October 2017, the certificate of compliance with this standard was obtained, making our programme the first in Spain to achieve this recognition.

Activity of the LTP since ISO 9001 certification until today

The activity of the LTP since obtaining the ISO 9001 compliance certification in 2011 until today, and the result of some process indicators, are shown in table 2.



Table 1 Liver transplant programme indicators	
Liver transplant programme indicators	
Pretransplant	Intensive care unit/surgical intervention
% Compliance with available signed and filled informed consents	% Compliance with the checklist of the recipient (medical)
% Compliance with available signed and filled informed transfusion consents	% Compliance with the recipient checklist (nurse)
% Of patients visited within 15 days from the request of the first visit	% Completion of the intensive care unit (ICU) admission repo (medical)
% Patients presented in transplant committee in less than 90 days after referral	% Compliance with the checklist on arrival at the ICU (medical)
Rate of spontaneous visits to the pre-liver transplant nurse's office	% Completion of the ICU transfer report (medical)
% Patients who had transplants with preanaesthetic report	Mean number of packed red blood cells
% Living donors undergoing full study and evaluation in less than 60 days	% Completion of surgical report
% Completion of checklist: preoperative evaluation of living donors (nurse)	% Completion of anaesthesia report
% Completion of checklist: preoperative evaluation of recipients (nurse)	% Completion of nursing report
% Completion of checklist: preoperative evaluation of recipients (hepatologist)	% Appearance of primary graft malfunction
% Completion of checklist: preoperative evaluation of living donors (surgeon)	
Immediate post-transplant	Outpatient follow-up
% Patients with post-transplant infections	% Patients visited by the doctor in 15 days or less postliver transplant
% Perioperative mortality (≤24 hours after surgery)	% Patients visited by nursing staff in 15 days or less postliver transplant
% Early liver retransplantation rate (≤7 days post-transplant)	% Early postliver transplant mortality (first month post transplant)
Late liver retransplantation rate (except those in the first week)	% Patient readmitted to ICU after liver transplant (index hospitalisation)
Early re-intervention rate (unscheduled intervention 15 days postliver transplant)	% Patient re-admitted within 1 month after liver transplant discharge
% Completion with the nursing discharge report	% Emergency room admission less than 1 month after liver transplant discharge
Other indicators	% Patient survival after liver transplantation: 1 year, 3 years, 5 years and 10 years
Satisfaction of the patients who had a transplant	% Graft survival after liver transplantation: 1 year, 3 years, 5 years and 10 years
Average hospital stays after liver transplant	
Average ICU stay after liver transplant	
Average stay in the ward after liver transplant	

DISCUSSION

The current study shows the steps, strengths and limitations in the implementation of a QMS in an LTP. Working under the requirements of a QMS in the LTP over these years has contributed to the adaptation to a new quality and safety culture focused on the patient. Activities are clearly protocolised; everything done is recorded, verified done as planned and is done under the perspective

of continuous improvement. The implementation of a QMS has led to changes in both the approach and the working method. The standardisation and protocolisation of processes led to less variability in daily clinical practice. For example, the introduction of a checklist at key moments such as the immediate preoperative assessment ensures that all necessary preoperative activities are carried out. The systematisation of all activities allows

% Patients visited within 15 days of request for first visit Patients initiating evaluation Average days in evaluation			80								2021	277
	81	82)	83	98	88	98	93	92	94	06	89
	193	211	240	223	178	168	123	163	173	143	144	152
	95	142	160	142	130	153	140	147	197	136	129	110
SD days in evaluation	89	112	147	128	145	177	165	153	183	127	124	06
Median days in evaluation	84	109	130	115	26	86	104	113	182	109	94	26
Patients included on waiting list	93	93	66	98	72	78	52	81	80	77	78	89
Patients included on waiting list in <3 months	53	39	34	37	34	37	22	32	25	31	37	32
% Patients on waiting list in <3 months	54	42	34	38	47	47	42	40	31	40	47	47
% Patients with preanaesthesia report	20	59	75	87	26	93	68	88	87	87	100	98,6
Median MELD (Model for End-stage Liver Disease) Score	21	20	22	23	21	22	22	21	20	23	23	23
(range)	14–23	12-22	15–25	17–26	14–26	18–25	17–24	18–25	15–26	17–24	21–30	18–26
Transplanted patients	73	72	74	99	29	29	28	64	81	29	54	75
% Patients with post-transplant infections	22	34	28	45	33	30	32	19	23	30	22	30
% Perioperative mortality (<24hours after surgery)	4.1	0	4.1	1.5	1.5	1.5	0	1.6	0	1.4	0	6.7
% Early liver retransplantation rate (≤7 days post-transplant)	4.1	4.1	4.1	1.5	2.9	0	1.7	1.6	0	0	0	0
% Early post-liver transplant mortality (first month post-transplant) C	0	0	2.8	က	3.1	က	3.5	3.2	1.2	2.9	7.4	5.3
% Patient survival after liver transplantation: 1 year	95.5	91.4	94.1	95.4	9.96	91.9	92.3	94.7	96	93.9	92.5	ı
% Patient survival after liver transplantation: 3 years	89.4	87.1	8.98	93.9	91.4	85.5	80.8	93	91	ı	ı	ı
% Patient survival after liver transplantation: 5 years	84.9	80	79.4	89.2	7.68	80.7	6.97	I	ı	ı	ı	I
% Patient survival after liver transplantation: 10 years	65.2	71.4	ı	ı	ı	I	ı	I	I	ı	I	ı
% Graft survival after liver transplantation: 1 year	90.4	88.9	89.2	93.9	91	91	91.4	89.1	93	92.5	2.06	ı
% Graft survival after liver transplantation: 3 years	84.9	84.7	7.67	89.4	85.1	82.1	79.3	89.1	98	ı	ı	ı
% Graft survival after liver transplantation: 5 years	79.5	76.4	71.6	84.9	82.1	9.77	75.9	I	ı	ı	ı	ı
% Graft survival after liver transplantation: 10 years	57.5	69.4	ı	ı	ı	ı	ı	ı	ı	ı	ı	ı
Average hospital stays after liver transplant (days)	20.5	20.2	22.5	20	18	18.7	21.5	16.6	19.4	19	15.7	18.9
Patient satisfaction (% with score of 9/10 or 10/10)	92	96	91	100	92	80	92	100	92	98	92	92
Family/caregivers satisfaction (% score of 9/10 or 10/10)	ı	ı	ı	ı	26	89	100	100	100	96	92	92



for greater professional autonomy and helps new staff to become more familiar with the work dynamics, leading to a shorter adaptation period. The record of incidents has allowed the detection of problems or errors in daily assistance. Through the analysis of these incidents, corrective measures have been applied, and some risks have been identified and addressed.

The incorporation of indicators into process monitoring makes it possible to evaluate the effectiveness of improvement actions. In the current study, it was observed that some indicators apparently worsened or at least did not improve. Several reasons may explain this lack of improvement: (1) An increased detection and recognition of protocol violations that were already present but unrecognised before the implementation of the QMS, (2) Very high values in some indicators, almost impossible to improve (eg, survival at 1 year) and (3) The increase of the associated pathologies that require a more complex evaluation, prolonging the period of time before the inclusion on the waiting list.

Moreover, it should be considered that the saturation of the hospital services that perform the complementary tests requested for the evaluation of patients can alter the activity of the programme. The QMS has tools to identify these disruptions and implement actions to mitigate them. It is helpful to identify those responsible for these services and establish fluid communication channels with these professionals to resolve these disturbances.

Indicators related to the per cent of compliance with safety checklists are not shown because they stopped being monitored in 2015 due to the target value being reached in all of them a few years earlier. It is possible that the QMS has played a significant role in the maintenance of these high-quality standards. Although the major challenge and complication of the project was to adapt the complex activity of liver transplantation to a non-specific standard outside the clinical setting without losing its clinical care orientation, we believed and confirmed by our experience that we got over this limitation.

The implementation of a continuous training programme is also an important consequence of the QMS, particularly for nursing staff, updating and increasing of knowledge in relation to the transplant process. Regarding the content of the training sessions, the professionals are asked for topics they find most interesting and/or useful for their job. The continuous evaluation of the teachers and alumni allows a measurement of the effectiveness of the training, and the information is tailored to the needs of the professionals.

Attending to the needs and expectations of patients and their families by providing feedback from satisfaction surveys and patient complaints allows us to improve our service. The results, in terms of overall satisfaction from families' responses, are very similar to those reported by patients. We found some differences between patients and families/caregivers regarding the identification of areas with room for improvement. While the main concerns of patients focused on the taste of the food,

aspects of comfort (eg, noise in the ward) and the information received regarding medication and its side effects, families focused on the provision of more psychological support to patients, the small size of the rooms and the lack of single rooms. During the COVID-19 pandemic, families and caregivers also complained about the restriction of visits.

We have established continuous feedback with patient associations by providing satisfaction surveys of hospitals that refer patients for transplantation, educational actions (meetings) and information (videos, booklets) on the care of patients on the waiting list and patients who had transplants, with participation in meetings and webinars led by patient associations.

Although all governmental health policies encourage and promote the provision of comprehensive healthcare to achieve high-quality standards and the development and implementation of quality systems,^{3–7} the scarcity of resources in public health organisations can be a limiting factor for the implementation of a QMS. This lack of resources leads to a greater effort on the part of professionals, which can lead to rejection and lack of commitment, precluding the certification of a clinical unit. At the start of the project, the main barriers were the number of hours spent on document preparation and implementation, the financial costs of quality consultants (although this should be seen as an investment rather than expense) and the reluctance of some team members regarding the expected effect of the QMS. Another reason that could limit the implementation of a QMS is the lack of specific standards. In the absence of specific models for certifying activities carried out in the healthcare field, except for the Joint Commission, 17 the most widely used model for the implementation of a QMS is currently offered by the ISO 9001:2015 standard. Although the ISO 9001 standard can be applied to any type of organisation, and healthcare professionals may consider its adaptation to health processes to be complex, the UNE 179008:2016 standard may help liver transplant units to adhere to the QMS systems. A specific limitation of the study is that it shows the process in a specific country (Spain). The main limitation of our study refers to the applicability of our experience to other hospitals. Our QMS integrates European and Spanish legislation on liver transplantation, recommendations of Spanish scientific societies, and is adapted to the conditions and guidelines of the hospital, and the UNE 179008 standard is only recognised in Spain. Another limitation is the changing context of liver transplantation, especially in Spain, with a very high rate of organ donation. Therefore, several process and outcome indicators and risk-based strategies are likely not applicable to other countries, especially to non-public healthcare LTPs and possibly not useful elsewhere. The study has limitations as to whether the results and the QMS proposed are fully acceptable for the LTPs in other countries.

For future studies we plan to include some patientrelated measures as performance indicators: *Patient*



Reported Outcome Measure and Patient Reported Experience Measure with our Patient Experience Group, including some focus-group meetings with patients, and with the goal to create patient-centred outcome measures for liver transplantation in the context of the International Consortium for Health Outcomes Measures.

We would like to emphasise that the implementation of the QMS has been associated with a substantial change in the working style, opening participation in clinical protocols and updating guidelines or in the choice of quality objectives to all staff, becoming aware of key aspects of patient safety, comfort and perception of treatment. We would also like to highlight that the updating and creation of clinical protocols and working procedures has contributed to the retention of the knowledge acquired over the years by the senior and experienced professionals, which translates to the application of the best clinical practices and the achievement of better results. In addition, it has led to an increase in the commitment of our professionals, an essential aspect that has allowed us to maintain our certification from 2011 to the present. We can conclude that it is possible to adapt the complex activity of liver transplantation to a non-specific standard such as ISO 9001 without losing its clinical care orientation, and that this implementation has helped us to improve the performance of our activity.

We encourage liver transplantation programmes to implement a QMS to improve the efficiency of their processes, promote quality and safety in patient care, and achieve a greater satisfaction among the professionals involved in liver transplantation.

Twitter Jordi Colmenero @ColmeneroJordi

Acknowledgements Dr Marta Arias, Dr Gabriela Gutiérrez, Dr Mercè Brunet and Mrs Magalí Castella.

Contributors Conceptualisation, methodology, investigation, writing-review and editing: YLP, MN, AT, JR and JC. Data curation and review: YLP, MN, JC, RG, EL, AD, AG and JR. Formal analysis, validation, writing original draft, supervision: YLP, MN and AT. All authors approved the final submitted manuscript. Guarantor: YLP.

Funding The work by JC had support from Agència de Gestió d'Ajuts Universitaris i de Recerca (AGAUR, grant SGR 2021) and Carlos III Institute of Health (ISCIII, Ministry of Economy and Competitiveness, Spain cofunded by EU, grant PI22/01234).

Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Ethics approval Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement All data relevant to the study are included in the article or uploaded as supplementary information.

Supplemental material This content has been supplied by the author(s). It has not been vetted by BMJ Publishing Group Limited (BMJ) and may not have been peer-reviewed. Any opinions or recommendations discussed are solely those of the author(s) and are not endorsed by BMJ. BMJ disclaims all liability and responsibility arising from any reliance placed on the content. Where the content includes any translated material, BMJ does not warrant the accuracy and reliability of the translations (including but not limited to local regulations, clinical guidelines, terminology, drug names and drug dosages), and is not responsible for any error and/or omissions arising from translation and adaptation or otherwise.

Open access This is an open access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited, appropriate credit is given, any changes made indicated, and the use is non-commercial. See: http://creativecommons.org/licenses/by-nc/4.0/.

ORCID ID

Yolanda López-Púa http://orcid.org/0009-0001-5741-8577

REFERENCES

- 1 Lorenzo S, Joaquín Mira J, Sánchez E. Gestión de Calidad total Y Medicina Basada en La Evidencia. Medicina Clínica 2000;114:460–3.
- 2 Ferlie EB, Shortell SM. Improving the quality of health care in the United Kingdom and the United States: a framework for change. Milbank Q 2001;79:281–315.
- 3 WHO Working Group. The principles of quality assurance. International Journal for Quality in Health Care 1989;1:79–95.
- 4 WHO. Quality of care. Available: https://www.who.int/health-topics/quality-of-care#tab=tab_1 [Accessed May 2023].
- 5 Bottaro S, Garel P, Agra Y. European network for patient safety and quality of care: PaSQ. Revista de Calidad Asistencial 2016;31(S):1–3.
- 6 Ley 14/1986, De 25 de Abril, General de Sanidad. BOE Núm. 102, De 29/04/1986. BOE-A-1986-10499. n.d. Available: https://www.boe.es/eli/es/l/1986/04/25/14
- 7 Ley 16/2003, De 28 de Mayo, De Cohesión Y Calidad del Sistema Nacional de Salud. BOE Núm. 128, De 29/05/2003. BOE-A-2003-10715. n.d. Available: https://www.boe.es/eli/es/l/2003/05/28/ 16/con
- 8 International Organization for Standarization. ISO 9001:2015 quality management systems. Requeriments, 2015. 2015. Available: https:// www.iso.org/standard/62085.html)
- 9 Astrini N. ISO 9001 and performance: a method review. *Total Quality Management & Business Excellence* 2021;32:5–32.
- 10 Fonseca L. From quality gurus and TQM to ISO 9001:2015: a review of several quality paths. *International Journal for Quality Research* 2015;9:167–80.
- 11 Fonseca L, Domingues P, Nóvoa H, et al. ISO 9001:2015: the view from the conformity assessment community. Total Quality Management & Business Excellence 2023;34:558–79.
- 12 Shaw CD, Groene O, Botje D, et al. The effect of certification and accreditation on quality management in 4 clinical services in 73 European hospitals. Int J Qual Health Care 2014;26 Suppl 1:100–7.
- 13 Enders C, Lang GE, Lang GK, et al. ISO 9001:2015 certification in quality management. Klin Monbl Augenheilkd 2017;234:886–90.
- 14 Shaw CD. External quality mechanisms for health care: summary of the expert project on visitatie, accreditation, EFQM and ISO assessment in European Union countries. *International Journal for Quality in Health Care* 2000;12:169–75.
- 15 Spanish Association for Standardization. UNE 179008:2016 quality management systems for liver transplantation units. 2016. Available: https://www.une.org/encuentra-tu-norma/busca-tu-norma/norma?c= N0057288)
- 16 Sociedad Española de Trasplante Hepático (SETH). Consensus document of the Spanish society of liver transplantation. waiting lists, liver transplantation and quality indicators. *Gastroenterol Hepatol* 2009;32:702–16.
- 17 Joint Commission International standard. n.d. Available: https://www.jointcommissioninternational.org/standards/