MANAGING TRANSPLANTATION PROCESSES THROUGH LEAN PRINCIPLES

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INTRODUCTION

The gap between organ supplies and demands has been studied in several countries, from the technical and managerial standpoints (Matesanz, 2009; Roza *et al.*, 2010). In Brazil, restructuring organ transplantation activities after the promulgation of the Transplants Act (Law No. 9.434 of 1997) and Technical Regulations (Edict No. 2.600 of 2009) provided leverage for studies in this field. The reasons behind this gap are based on two issues: 1) low organ supply and 2) inefficient use of available organs.

Inefficient use of organs is understood in terms of structure and time. Flaws are apparent in the organ procurement and distribution stages, such as the identification of potential donors (Clausell *et al*., 2001; Conceição *et al.*, 2005), the notification of cases involving suspected brain deaths (Conceição *et al.*, 2005; Mattia *et al*, 2010), the maintenance logistics for potential donors (Pestana, *et al.*, 2013), interviews with families (Clausell,*et al.*, 2001; Mattia *et al.*, 2010) and coordination with all those involved (Clausell, *et al*., 2001; Van Gelder *et al*, 2008). Time constraints permeate the entire transplant process, with ischemic time playing a particularly decisive role in the use of donated organs (Fuzzati, 2005; Genç, 2008).

The Brazilian Organ Transplantation Association (ABTO) oversees the organ donations and transplants process nationwide and in each Brazilian state. During the first six months of 2014, only 28.3% of potential donor notifications were transformed into effective donors. Among these effective transplants, 92% of the cases resulted in the implantation of donated organs in patients on waiting lists (Registro Brasileiro de Transplantes [RBT], 2014). On the bottom line, losses of 73.9% potential donors are noted throughout the entire process.

Faced by this context of severe organ loss, it has become crucial to enhance the effectiveness of transplantation procedures. Among management approaches pursuing greater efficiency, particularly through fine-tuning cost and quality factors, the lean philosophy is particularly noteworthy. Its implementation extends through a variety of sectors, including healthcare institutions (Bushell *et al*., 2002; Wysocki, 2004; Jones & Mitchell, 2006; Decker & Stead, 2008; Toussaint & Berry, 2013).

However, from the standpoint of organ transplants, there are few studies addressing the macro-process. In the Brazilian scenario, studies in this research field are incipient since the available works

(Monteiro, 2011; Pestana *et al.*, 2013; Toledo *et al.*, 2013) apply the lean methodology to only some of the stages of organ transplantation workflow. The Monteiro (2011) study was limited to the logistic activities in the process. Pestana *et al.* (2013) addressed only the organ donation stages, while Toledo *et al.* (2013) explored only the post-transplant monitoring stage.

The purpose of this study is to ascertain the applicability of lean philosophy grounded on the five-step thought process – identify value, map value stream, create flow, establish pull and seek perfection – within the organ transplantation context in Brazil. The applicability of this philosophy will be investigated through an analysis of the existence of convergence among lean philosophy practices and the procedures adopted by State Coordination Units with high effective transplant scores.

This survey is relevant for the academic world, insofar as the purpose of the study is to encompass the entire organ transplantation process (donations and transplants *per se*) from the standpoint of lean management within the Brazilian context. The body of scientific theory on lean will be widen by the proposed conceptual framework on lean practices in organ transplantation. Furthermore, the public health sector also benefits from this study, as the main expected outcome consists of enriching activities focused on attaining good quality universal healthcare supply targets.

ORGAN TRANSPLANTATION MACRO-PROCESS IN THE BRAZILIAN CONTEXT

Brazil's National Transplant System (SNT) is a federal entity that plans, organizes, coordinates and controls all transplantation operations and strategy nationwide. The single transplant waiting list model was adopted with a single recipient registry that ensures fair, free and universal access to available organs. This registry consists of State lists classified by different organ types. The organ distribution follows the registration order and compatibility between donors and recipients nationwide, as in States where notifications are presented, unused organs are made available to the national listing (Law No. 9.434 of 1997).

At the State level, the implementation of organ logistics and distribution coordination activities in the donation and transplantation process is handled by the Organ Notification, Procurement and Distribution Centers (CNCDOs). State Transplant Centers are responsible for managing lists of potential recipients, as well as receipt of brain death notifications and the organization of the organ logistics and distribution in their operating areas (Edict No. 2.600 of 2009). Organ Procurement Organizations (OPOs) and Intra-Hospital Organ and Tissue Transplant Donation Commissions (CIHDOTTs) were set up to assist the CNCDOs. The establishment of these CIHDOTTs is mandatory in hospitals with more than eighty beds, among other criteria. The OPOs work mainly at the regional level, organizing donor procurement logistics, while the CIHDOTTs work under organ donation assistance protocols in healthcare establishments. When there are no CIHDOTTs in place, the OPOs accumulate the functions inherent to the Intra-Hospital Commissions. Some of these activities are the promotion and organization of special reception rules in hospitals for donor families during the entire donation process and the training of the healthcare professionals for dealing with families, understanding the brain death concept and maintaining the donor (Edict No. 2.600 of 2009).

In operating terms, the workflow for implementing the transplantation macro-process consists of the following stages: detection, assessment and maintenance of potential donors, family notification, logistic aspects (organ allocation), harvesting organs from donors, physical distribution

of organs and tissues, organ implantation in recipient(s) and overseeing outcomes (Pereira *et al.*, 2009; Cinque & Bianchi, 2010).

The identification of patients meeting the clinical criteria for brain death is the starting point, with OPOs actively seeking out potential donors by visiting hospitals throughout their region (Edict No. 2.600 of 2009). The medical staff of ICUs, ERs and A&Cs, together with the CIHDOTTs, assist the OPOs in these active searches in their respective hospitals. Suspected brain death notification is mandatory, and must be forwarded to the CNCDOs by OPOs, CIHDOTTs or the practitioners at the hospitals. Diagnosis of brain death as defined by the Federal Medical Counsel (CFM) consists of two clinical and neurological examinations conducted by two hospital physicians and a supplementary graph test that, depending on the age bracket, may be an electroencephalogram, transcranial doppler, radiography or others (Pereira *et al.*, 2009).

Having completed a diagnosis confirming brain death, the physician on the hospital staff attending the patient must notify the family of the irreversibility of the patient´s clinical status. The potential donor must be kept hemodynamically stable by physicians and be assessed regularly through clinical and laboratory examinations. Should there be no absolute counter-indications (as established by the CFM), the potential donor may become an effective donor once the family authorizes the donation. The family interview stage addressing organ donation must be conducted by trained practitioners who are CIHDOTT members or are referred by the CNCDO. This phase is designed to provide support and clear up any doubts that may arise regarding the possibility of donating the organs of the deceased relative.

Once there is the family consent, the practitioner in charge of the process, together with the CNCDO, begin to take the steps needed to make the potential donor into effective. More specifically, the team in charge of the notification (CIHDOTT, OPO or the hospital itself) notifies the CNCDO with respect to the donated organs, the donor´s clinical and laboratory condition and the planned starting time of the harvesting procedures (Pereira *et al.*, 2009).

Sending the organs to their recipients is the responsibility of the CNCDO, which must use the Brazilian Computerized Management System (SIG). For each available organ, a correlation must be drawn up between the anthropometric, immunological, clinical and serological characteristics of the deceased donor and the corresponding Single Technical Registry, using the criteria specific to each organ type in order to list potential recipients by precedence (Edict No. 2.600 of 2009). With the list of potential receipts on hands, the harvesting and transplantation teams must be identified and contacted. The means of transportation (by air or land) are defined by the CNCDO.

Once harvested, the donated organs are taken to the transplant center, where they are packed in cooler boxes with ice and a preservation solution appropriate for each organ. The transplant team then handles the implantation surgery for the recipients. The CNCDOs are involved mainly during the donation and transplantation phases.

LEAN PRINCIPLES IN THE ORGAN TRANSPLANTATION PROCESS

Lean healthcare refers to the field of lean philosophy applied to the healthcare area. An approach based on the five-step lean thinking process – identify value, map value stream, create flow, establish pull and seek perfection -- is frequently used to implement a lean system for healthcare

institutions in order to avoid waste, including barriers to communication, inaccurate information, wrong or unsuitable tools, inefficient movement and redoing work (Bushell, *et al*., 2002).

A scenario characterized by higher healthcare costs (Wysocki, 2004; Daniel, 2005; Ferro, 2005; Womack, 2007), poor quality services (Daniel, 2005; Jones & Mitchell, 2006; Joosten, Bongers, & Janssen, 2009; Kissoon, 2010; Toledo *et al.*, 2013; Toussaint & Berry, 2013), long waiting times for patients (Womack, 2007) and more limited resources (Jones, 2011) is driving healthcare organizations to reconfigure patient care services and the use of resources, grounded on lean philosophy.

Within the organ transplantation context, there are few studies adopting a lean approach (Monteiro, 2011; Pestana *et al.*, 2013; Toledo *et al.*, 2013), although this standpoint is brought to the fore in other hospital and clinical activities (Bushell, *et al*., 2002; Wysocki, 2004; Ferro, 2005; Jones & Mitchell, 2006; Decker & Stead, 2008; Araujo *et al*., 2009).

In order to underpin and extend the field of research into organ transplantation management, lean elements were proposed related to the five principles in the organ transplantation context, grounded on good practices noted in the donation and transplantation process in national reference systems – USA (Goodman *et al.*, 2003; Goodman *et al.*, 2007) and Spain (Organización Nacional de Trasplantes [ONT], 2011) – and lean healthcare practices *(*Bushell, *et al*., 2002; Wysocki, 2004; Jones & Mitchell, 2006; Kollberg *et al*., 2007; Kissoon, 2010; Simon & Canacari, 2012; Toussaint & Berry, 2013).

Identify value

According to Simon and Canacari (2012), all stakeholders must be taken into consideration when identifying values. Consequently, within the transplantation context, demands to be addressed encompass healthcare practitioners engaged in the procedures, donor families and patients waiting for organs.

Map the Value Stream

Activities adding value must be identified, as waste is eliminated throughout the healthcare process (Bushell, *et al*., 2002; Jones & Mitchell, 2006; Kollberg *et al*., 2007). As a result, the value stream encompasses stages that add value for healthcare practitioners, donor families and recipient patients (Simon & Canacari, 2012).

Create Flow

The non-stop flow must be gentle, continuously focused on those involved in the process. In other words, it is recommended that barriers hampering access for patients who are transplant candidates should be lifted, as well as simplifying workflows for the supply of more efficient treatments (Goodman *et al.*, 2007).

Establish Pull Production

The trigger for the transplantation process consists of the existence of patients awaiting transplants. The pull system ranges from efforts at the start of the flow encouraging donations (Goodman *et al.*,

2003) through to the final stage of successful transplant surgery (Goodman *et al.*, 2007), thus saving or enhancing the life of a patient (Manyalich *et al.*, 2011).

Seek Perfection

A state of perfection will be reached as the culture of continuous improvement is disseminated throughout all institutions and practitioners involved (Allway & Corbett, 2002).

LEAN PRACTICES IN THE ORGAN DONATION AND TRANSPLANTATION PROCESS

The following Table presents the practices related to each of the lean thinking principles within the organ transplantation context.

Table 1: Lean practices applied to the organ donation and transplantation process based on the principles of lean thinking:

Lean Thinking Principles	Lean practices in the organ donation and transplantation process
Identify Value	Healthcare practitioners require access to appropriate human and material resources in order to perform their activities (Goodman *et al.*, 2007); professional acknowledgement (Goodman *et al.*, 2003; Goodman *et al.*, 2007; ONT, 2011) and a pleasant workplace with exchanges of information, good organizational climate and teamwork (Goodman *et al*, 2003; Goodman *et al.*, 2007; ONT, 2011). Donor families need good quality care for their loved ones, together with ongoing transparent contacts with healthcare practitioners regarding the status of hospitalized relatives (Roza, 2005; Edict No. 2.600 of 2009; Toledo *et al.*,2013), Patients waiting for compatible organs under favorable clinical conditions with low ischemic time (Goodman *et al.*, 2007; Pereira *et al.*, 2009) and complication-free surgery (Goodman *et al.*, 2007).
Value Stream	Initiatives focused on enhancing the effectiveness of the organ transplantation process are: 1) Notification of all brain deaths to the State Transplant Centers (Edict No. 2.600 of 2009) through hospital coordinators monitoring neuro-critical patients (ONT, 2011); frequent supply of brain death diagnosis guidelines, with this topic included in healthcare practitioner routines (Goodman *et al.*, 2003) and regular audits conducted in order to monitor the effectiveness of sending possible donors to the ICU (ONT, 2011). 2) Conversion of 100% of notifications into donations and subsequently into transplants. To do so, brain death diagnoses must be reached correctly (Conselho Federal de Medicina [CFM], 1997); there should be no maintenance problems with potential donors, thus avoiding cardio-respiratory arrest (Pereira *et al.*, 2009; Westphal *et al*, 2011); the team has a microbiology and pathological anatomy laboratory available (ONT, 2011); prior preparation with family interviews is in place (Goodman *et al.*, 2003; Roza, 2005; ONT, 2011); the logistic planning has been drawn up for organ distribution (Monteiro, 2011) and the ischemia and operating times are monitored in order to ensure the feasibility of the transplant and lesser complications for recipients (Goodman *et al.*, 2007).
Create Flow	The smooth flow of transplantation activities results from: 1) Links among the various stages of the process, grounded on two issues. First, the trust relationships established and maintained among the coordination teams, healthcare practitioners and other institutions involved (Goodman *et al.*,

Lean Thinking Principles	Lean practices in the organ donation and transplantation process
	2003; ONT, 2011). Second is by building up the capacities of practitioners in order to understand the organization and processes, particularly ethical issues, human relationships and coordination activities (Goodman *et al.*, 2007; ONT, 2011; Pestana *et al.*, 2013). 2) A decentralized decision-taking process based on a functional tiered organizational structure with several decision-taking levels (Goodman *et al.*, 2007; Monteiro, 2011; ONT, 2011) and multi-disciplinary teams (Goodman *et al.*, 2007). 3) Team size tailored to hospital requirements (ONT, 2011). 4) Workplaces designed to ensure easy access to working tools: means of communication (Goodman *et al.*, 2007), machines and equipments (Pestana *et al.*, 2013) and information technology systems specific for transplants (Goodman *et al.* 2007).
Pull Production	The pull system for transplants is identified in three ways: 1) Generating supply (start of the process) in order to provide more organs. High limits are set for rejecting organ supplies (Goodman *et al.*, 2007), seeking early notification for all suspected brain deaths, even if doubtful (Goodman *et al.*, 2003). With regard to early notification, the following are required: a) supply of training and guidelines on clinical signs resulting in brain death (Goodman *et al.*, 2003; ONT, 2011); b) appointing contact persons in hospitals to handle organ donations, monitoring neuro-critical patients (Goodman *et al*, 2003; ONT, 2011); c) overseeing the effectiveness of sending possible donors to ICUs (ONT, 2011) and; d) organizing marketing actions to boost organ supplies, such as awareness-heightening campaigns (Goodman *et al.*, 2007). 2) Keeping the waiting list constantly updated, properly administered and fine-tuned (Goodman *et al.*, 2007). 3) Defining the transplant team and the respective hospital, as well as procedures related to the implant operation (scheduling and preparing operating theaters) may begin even before the transplant team reaches the hospital (Monteiro, 2011).
Seek Perfection	1) Commitment from the senior management of the hospital in terms of the resources needed to grow the transplant program, and for hospitals with higher donation potential, strategic planning and quality committees (Goodman *et al.*, 2003; Goodman *et al.*, 2007). 2) Standardization of work processes – transplant protocols (Goodman *et al.*, 2007). 3) Establishment of quality circles with the entire transplant team attending regular meetings to discuss the program and ways of upgrading it, eliminating practices that no longer work and learning from peers (Goodman *et al.*, 2003; Goodman *et al.*, 2007). Furthermore, surveys must be conducted with hospital practitioners on points for improvement, providing hospital practitioners with feedback on each donation and its recipient (Goodman *et al.*, 2003). 4) Establishment of process controls through instructions on the goals and outcomes expected from practitioners, reviewing and monitoring performance data for all stages of the process (Goodman *et al.*, 2003; Goodman *et al.*, 2007), development of a process for addressing faults, analyzing the root causes of problems (Goodman *et al.*,2003). 5) Conducting studies and surveys on developing good practices and the establishment of benchmarking (Goodman *et al.*, 2007).

Lean Thinking Principles	Lean practices in the organ donation and transplantation process
	6) Supply of refresher and training courses for healthcare practitioners on new activities (ONT, 2011; Pestana *et al.*, 2013).

METHODOLOGY

This survey examines the existence of an alignment among the management procedures used at certain State Transplant Centers and lean thinking practices. Once this convergence has been confirmed, the management of the Brazilian transplant system can be enhanced. Consequently, the general question set for this survey is: "How can the donation and transplantation process coordinated by the Organ Notification, Procurement and Distribution Centers (CNCDOs) in Brazilian States be better managed through applying lean thinking principles, in order to boost the effective organ transplantation rate?". The following questions were proposed as extensions of the initial question:

- What are the demands of the people involved (healthcare practitioners, donor families and recipient patients) in the organ donation and transplantation process? (identify value)
- How does the organ donation and transplantation process take place? What are the stages adding value? (value stream)
- Is the organ donation and transplantation process effective? (value stream)
- How does the continuous donation and transplantation flow take place without interruptions? (create flow)
- How does the flow of donation and transplantation activities begin? (pull production)
- How can organ supplies be managed? (pull production)
- How can the culture of seeking perfection be disseminated by institutions involved in the organ donation and transplantation process ? (seek perfection)

The case study method was adopted for this research project, as it complies with the three criteria proposed by Yin (2005). First, the question that the survey attempts to answer is "how" the transplantation process can be better managed. Second, there are no requirements related to behavioral events, and finally, the focus is on contemporary occurrences. According to the classification proposed by Vergara (2005), the investigation is exploratory, as it was noted that poor knowledge has been built up and systematized on transplantation process management.

Three cases were selected for this study. The analysis units were defined through interviews with practitioners in the field involved in transplantation activities and with some managerial knowledge of this topic. As a result, it was decided that the focus of the survey would be the State Transplant Center (CNCDOs). The selection of the Rio de Janeiro (RJ), São Paulo (SP) and Santa Catarina (SC) State Centers was steered by the fact that they play leading roles in the Brazilian Transplant System, with some of the best donation and transplantation statistics disclosed and overseen by the Brazilian Organ Transplantation Association (ABTO).

The data were collected through in-depth individual interviews, with prior planning through a semi-structured guide that was drawn up on the basis of the lean practices conceptual framework, within

the organ transplantation context. Other data sources, such as observations during interviews, support documents provided by the respondents and visits to CNCDO websites, were used to supplement the case descriptions and analyses.

This survey examines only the standpoint of healthcare practitioners represented by the coordinators of the CNCDOs – the subject of the survey – without exploring the views of recipients or donor families.

The cases were analyzed in compliance with the lean practices conceptual framework in the organ donation and transplantation process (Table 1).

The constraints of the study refer to the strategy adopted ("case study"), the researcher and the respondents. Yin (2005) stresses the impossibility of generalization for the entire population when using the case study method. The researcher may introduce a bias into the data collection and the respondents may also offer subjective opinions when presenting the facts.

CASE STUDIES

Reports and observations during the interviews with each of the coordinators of CNCDOs in RJ, SP and SC were synthesized in order to present relevant aspects for analyzing the cases. In order to do so, categories (sub-items) were created related to lean thinking, as set forth below.

CNCDO Organization Chart and Support Structures

In RJ, the Center has five areas: Operations (including intensive care physicians), Family Coordination, Hospital Relationship, Research and Education, and Quality. There are fifty CIHDOTTs and five OPOs.

In SP, there are four internal areas: Technical (organ distribution only), System, Quality and Administration, in addition to support provided by fifty CIHDOTTs and ten OPOs.

The SC Center consists of four areas: Technical, Information, Audits and Regulation, and Administration. The coordination is shared between a Technical Coordinator and an Administrative Coordinator. There are 45 CIHDOTTs supporting the operations of this Center with the OPOs under development, although their activities have already been defined.

Types of Transplants Handled

All the studied States handle heart, liver, kidney and pancreas-kidney transplants, with São Paulo also engaged in lung and pancreas transplants.

General Targets, Breakdown of Targets for Each Team and Performance Monitoring

The general guideline for CNCDOs in RJ, SP and SC is to step up the number of transplants while ensuring quality and efficiency for these operations. In Rio de Janeiro, the focus is on maintenance and a family-based approach. In SP, transplant system management is most important, while in SC, the efforts focus more on recognizing brain death and assisting donor families.

With regard to the breakdown of targets for each team and the respective oversight activities, specific targets have been established in RJ for the internal teams, OPOs and CIHDOTTs, together with performance indicators. The Quality sector is in charge of controlling the activities of the

internal team, while the Hospital Relationship division oversees the activities of the OPOs and CIHDOTTS. The transplant teams are not monitored; there is merely an indicator reflecting their activities. Regular meetings are held with each team (internal, CIHDOTTs and OPOs) as well as general meetings that discuss the progress of the activities and present the outcomes, together with proposed improvements. Presentations grounded on a “lives saved” approach spotlight the end-goal of the transplant process more clearly.

In SP, they defined the targets, with oversight of the activities performed by the OPOs, CIHDOTTs and transplant teams. However, there is no formal monitoring of in-house activities at the Centers. Meetings are held sporadically with discussion of issues related only to organ procurement and transplantation, not including the activities performed by the internal team. This Center focuses on the topic of seeking perfection through upgrading management software (SIG).

The CNCDO in SC has set specific targets for the internal team, the OPOs and CIHDOTTs. The Information sector manages the internal indicators (some are in the final preparation stage). The procurement indicators are managed by the Information sector as well as by the OPO Coordination units depending on the type of indicator. The transplant teams are not monitored, there is merely an indicator reflecting their activities. Meetings are held with the internal team and organ harvesting practitioners in order to examine institutional performances, present problems and propose improvements. A close relationship has been established between this Center and some Notifying Hospitals, with weekly meetings at these institutions.

Professional Acknowledgement and Motivation

Strategic positions are offered in RJ to outstanding practitioners as a type of professional acknowledgment. Although there are no initiatives of this type in SP. SC acknowledges its practitioners by awarding prizes to the best-performing individuals and institutions, as well as offering additional remuneration to organ procurement practitioners.

With regard to motivation, RJ organizes events where experiences are exchanged. Practitioners in SP are motivated through exchanging ideas and stimuli generated in the course of their work. SC obtains commitment from its employees through 1) good relationships between the procurement teams, hospitals and the CNCDO; 2) the example of the Technical Coordinator acting effectively in the operation, and 3) arranging well-organized educational events in pleasant settings.

Registry of Patients on the Waiting List

Only the RJ Center does not monitor updates of the recipient waiting list. In contrast, SP and SC monitor these lists and request the transplant teams to provide missing information.

Operating Process

Members of the CIHDOTTs and OPOs (when established) handle the identification of potential donors. Furthermore, in RJ, the Center operating team assists at this stage.

In order to diagnose brain death, the CNCDOs may assist in the graph test. This examination takes place in Notifying Hospitals and, when some item of equipment or human resources are required, the Centers establish partnerships: the Fundação Saúde healthcare foundation in RJ; agreements

with companies in SP and in SC, material resources (equipment) are available in-house, and the physicians are partners of the Center, going to the Notifying Hospital.

With regard to the maintenance of potential donors, RJ allocates intensive care physicians (CNCDO Operations Division) who provide support for practitioners at the CIHDOTTs and OPOs. In SP, maintenance is the full responsibility of the OPOs and CIHDOTTs, with no influence from the Center. In SC, in addition to members of donation institutions (OPOs and CIHDOTTs), there are physicians on stand-by for providing assistance.

The laboratory tests for assessing potential donors are usually conducted at Notifying Hospitals. If necessary, RJ outsources these tests to an outside laboratory, and in SP they may be conducted at the OPO hospitals.

The most stringent organ acceptance criteria are in SP, where this Center does not accept all the expanded criteria, as they reject donors with Chagas disease and / or hepatitis.

OPOs or CIHDOTTs members conduct the family interviews in all studied Centers. The Family Coordination division in RJ supports the more complex interviews.

The supply of organs is handled by the Centers in compliance with the ranking of recipients generated in the SIG. The transplant teams accept the organs (or not) and notify their patients of the operation. In SP, heart and lung supplies are speeded, with the top three transplant hospitals being notified, instead of merely the first of them.

In order to harvest organs, the liver and heart extraction teams in RJ are the same as the transplant teams, as this is a way of assessing organ quality macroscopically. The same system is used in SP by the heart, lung and liver teams, and in SC with the pancreas and pancreas-kidney teams. SP has established a six-hour deadline for notifying the organ harvesting team of the extraction times. In SC, tiered planning contacts the harvest teams; plan A covers multi-organ surgeons, while plan B includes kidney harvesting surgeons in situations where donors are unstable; and plan C consists of contacts with the OPO in Rio Grande do Sul State, which harvests kidneys.

At all Centers, the organs are generally packed in cooler boxes with ice and preservation solutions. Furthermore, there are latest-generation portable kidney perfusion machines in RJ that ensure better kidney conservation.

Decisions taken by the Centers on the mode of distribution are based on a planned structure. The means of transportation are by land (short distances) and by air (long distances). For overland transportation, RJ has its own vehicle supported by Military Police outriders when necessary. SP uses vehicles outsourced from a contracted company by the Municipal Healthcare Bureau, and SC has its own vehicles and drivers, supported by Military Police and Civil Police outriders. For air transportation, RJ has a helicopter available during the day and a Brazilian Air Force aircraft for night flights; SP has the following options: regular flights, Brazilian Air Force aircraft, Highway Police helicopter and air taxi, while SC has set up partnerships with the Chief of Staff, Military Police, Civil Police, Fire Department, Emergency Mobile Care Service (SAMU) and an air taxi company.

Communication Tools

The usual means of communication at the Centers are telephone, fax or email. RJ set up a hotline – *Disque Transplante* – while SC has introduced a specific email for exchanging information on the operating process.

Capacity-Building and R&D

Only RJ has a specific Research and Education area. In terms of R&D, RJ has conducted studies on transplants, seeking the best methods and good practices in the literature (still incipient), while SP has conducted studies only on procurement.

With regard to training, all the Centers run courses to enhance the performance of the practitioners in their respective activities. Furthermore, RJ offers complete courses at different levels to all healthcare practitioners, and is implementing the EPET ongoing education system, that is designed to review protocols, align new types of conduct and eliminate faults. This State is also investing in building hospital coordination capacities for donations through the Master Alianza Program (Spain) and is engaged in benchmarking with the Philadelphia OPO.

In SP, practitioners at the CIHDOTTs and OPOs receive training in clinical matters and communication techniques; there are no capacity-building activities for practitioners in the entire process, with guidelines provided on new routines as alterations are introduced into the process.

In SC, in-house training sessions (Center) and outside courses are held regularly, and also on demand, addressing the issue of donations – with an intensive course on delivering bad news – as well as the complete process. There are also courses conducted in-house through programs run by tutors from Spain. Refresher course in processes and the respective training sessions for new practices are scheduled as they arrive. The Master Alianza Program in Spain also welcomes practitioners from this State. Finally, there is a CIHDOTTs visits program in transplantation hospitals that helps its practitioners to learn more on the process.

Standardization of Work Processes

RJ and SC standardized the activities of their internal teams, the OPOs and the CIHDOTTs as protocols, standard operating procedures (SOPs) and conduct handbooks. In RJ, this responsibility is assigned to the Quality area, while in SC, there is a professional in charge of standardization coordination. At the moment, SP does not document operating procedures.

Addressing Faults

In RJ, this process is passive, structured and centralized in the Quality sector. Final approval is given by the RJ CNCDO coordinator. In SP, the process is active, structured and centralized in the Quality area of the CNCDO. However, it does not encompass in-house faults. In SC, the process is both active and passive, structured and decentralized (any area may prepare a report). The final decision on the steps to be taken lies with the CNCDO coordinator. The non-conformity report is a standardized tool in this process.

Planned Initiatives

In the near future, RJ intends to implement the following initiatives: 1) a Hands On course; 2) centralized medical records of the donor; 3) more active approaches adopted by the hospital relationship sector; 4) more active process for addressing faults, with an analysis routine and; 5) running donation campaigns. In SP the following are planned: 1) setting up exclusive CIHDOTTs; 2) acknowledgement of harvesting practitioners through assorted awards and financial incentives (medals, etc); 3) use of new technologies (smartphones) for forwarding donor information to the transplant teams and; 4) supply of refresher and broader-ranging courses (full process) to the in-house team. In turn, SC plans to: 1) implement a strategic plan; 2) set up a Quality area; 3) develop SIG software for the pre-distribution and post-transplant stages; 4) develop a tool for viewing the CIHDOTTs targets; 5) negotiate with the Santa Catarina State Blood Network on transferring quality technology and; 6) formulate other sector indicators for the Center.

FINDINGS

The findings of the analysis confirmed the existence of a level of alignment between the procedures adopted by these State Transplant Centers and lean thinking practices. The specific questions posed by this survey were answered from the standpoint of the CNCDO coordinators, as set forth below.

What are the demands of the people involved (healthcare practitioners, donor families and recipients) in the organ donation and transplantation process?

It was noted that the CNCDOs tried to respond to the demands of each of their stakeholders. Starting with the resources made available to healthcare practitioners, all the Centers provide equipment, means of communication and other tools, either in-house or through partnerships. The partnerships are set up with laboratories, other hospitals and companies rendering logistic services. In terms of human resources, only SP has physicians for all types of transplants.

Professional acknowledgement is found only among procurement practitioners and members of the in-house teams of the CNCDOs, consisting of job promotion (RJ), productivity rewards (SC) and additional remuneration (SC). SP does not offer any type of initiative in this area.

Evidence of collaborative contexts consists of partnerships (RJ, SP and SC), good relationships among institutions (RJ and SC) and the involvement of all employees in proposing improvements (RJ, SP and SC).

Considering transplant institutions, all the CNCDOs strive to ensure that organs remain in good condition through supplies compliant with ischemic times and logistics planning for their distribution. More specifically the RJ CNCDO allocates intensive care specialists to Notifying Hospital teams in order to keep donors hemodynamically stable, using renal perfusion machines that ensure better kidney conservation. The requirements in São Paulo are more stringent in terms of the expanded criteria, as well as monitoring the performance of transplant teams through the post-transplant conditions of grafts and their recipients, in order to pinpoint possible faults.

Donor families are well served, as the CNCDOs provide training in how to deliver bad news to all practitioners involved in the family approach stage. RJ centralizes aspects related to families in a Family Coordination area, while SC invests heavily in practitioner education focused on the human aspects of the process, bringing in tutors from Spain.

How does the organ donation and transplantation process take place? What are the stages adding value?

From the standpoint of the stakeholders, the vale-added stages are: 1) identification of suspected brain deaths followed by the notification of these suspected cases to the CNCDOs; 2) brain death diagnoses conducted in compliance with the CFM; 3) assessment and maintenance of potential donors; 4) family interviews and 5) sending out organs. Transportation of blood samples (for ranking generation) and organs does not add value to the flow, although it is essential for completing the process. Consequently, efforts are expended in transportation focused on minimizing the time spent at this stage.

Is the organ donation and transplantation process effective ?

Despite the selection of CNCDOs with high effective transplant rates, there is still some wastage. The actions taken by the Centers are focused on reaching an effective transplant rate of 100%.

In order to identify potential donors, all the CNCDOs encourage the monitoring of neuro-critical patients by members of the CIHDOTTs and OPOs, running brain death recognition courses.

The correct diagnosis of brain death is assured by the CNCDOs through the supply of trained practitioners and equipment, available either in-house or through partnerships with companies specializing in graph tests.

In terms of the assessment and maintenance of potential donors, all the Centers regularly monitor the clinical status of potential donors. RJ and SC provide conduct handbooks at hospitals and also offer practitioners outside the hospital to assist in caring for potential donors. Furthermore, RJ has set up a partnership with a laboratory for processing laboratory tests, if necessary.

For approaching families, the practitioners in the donation teams are trained in techniques for delivering bad news in all the States studied, with practitioners in RJ and SC also consulting a family interview guide that is available at Notifying Hospitals.

Actions were noted in SP and SC focused on enhancing the effectiveness and efficiency of harvesting logistics: SP has set a deadline for the harvesting teams to notify the time and the harvest surgery, which SC has introduced tiered planning to call the harvesting teams into action.

With regard to organ distribution all CNCDOs have established distribution structures through partnerships with a wide variety of institutions. While SC trims cycle duration by using peripheral blood, sending off blood samples to serology and typing laboratories well in advance, SP hectares adopted the practice of early supply of critical organs to the first three hospitals in the ranking. In turn, RJ works with a high-technology structure for kidney packaging and conservation.

How does the continuous donation and transplantation flow occur, without interruptions?

The fluidity of this process is assured through 1) links among the parties involved in the process, 2) decisions are taken on decentralized basis, 3) teams are sized in compliance with as local requirements and 4) practitioners are provided with all work tools.

In order to ensure links among all stages of the process, all the CNCDOs have set up partnerships with institutions for conducting tests and transporting organs, investing in building up the capacities

of their employees for understanding the entire process (except the in-house team of the CNCDO in SP). Furthermore, RJ and SC run specific donation process coordination courses. In particular, SC has set up agreements with the directors of some Notifying Hospitals and organizes CIHDOTT visits to transplantation hospitals. RJ has strengthened its relationship with families and Notifying Hospitals through setting up in-house areas at the CNCDO; organizing events fostering interactions among practitioners: and adopting a "lives saved" approach in presentations that underscores the final goal of the process.

The decentralization of decision-taking processes is clearly apparent in the Brazilian transplant system structure: CIHDOTTs and OPOs head up donations. SP is a special case, as the activities of its CNCDO are tightly focused only on organ distribution. In terms of the team multi-functionality, all the Centers are engaged in setting up donation, in-house and transplant teams that perform multiple activities.

Team size is dictated by the need of each CNCDO. RJ found it necessary to se up exclusive divisions for family coordination and hospital relationships, while SP felt that the activities of this Center must be more tightly focused, with greater independence for other organizations (OPOs and CIHDOTTs). In contrast, SC established two coordination positions, one technical and one administrative.

All work tools are available to healthcare practitioners at all the CNCDOs studied. The Computerized Management System is crucial for generating the recipients ranking and ensuring transparency and trustworthiness for organ distribution. Some additional practices were noted in RJ and SC. Particularly noteworthy in RJ, was a direct communication channel – the *Disque Transplante* hotline – and the use of a renal perfusion machine for packaging and preserving kidneys. In SC, a specific email address has been established for exchanging information on the operating process.

How does the flow of donation and transplantation activities begin ?

The existence of patients requiring organs is the trigger for this process. In operating terms, the use of pull techniques moves in two directions: prior maintenance of the waiting list and supply management, with the latter being addressed in the following question. Activities related to booking and preparing operating theaters immediately after the definition of the transplant teams are not analyzed in this paper.

The CNCDOs in SP and SC work actively with prior maintenance of the waiting list, monitoring updates of the data on potential recipients, seeking out inconsistencies and taking steps as required.

How can organ supplies be managed?

The number of donors increases as organ supplies are managed in two ways: establishing high organ rejection cut-off points and stepping up the number of suspected brain death notifications.

The expanded criteria constitute the organ rejection ceiling, and are not adopted fully by the SP Center.

An increase in the number of suspected brain death notifications is being pursued by the CNCDOs – as mentioned in the question of the effectiveness of the process – through active searches in hospitals by CIHDOTTs and OPOs, as well as running courses with brain death recognition modules. Furthermore, SC monitors CIHDOTT performance in order to identify sub-notifications and address

faults. In future, with the implementation of the Hands On course in RJ, more practitioners will be trained in suspected brain death identification.

How can a culture of seeking perfection be disseminated by institutions involved in the organ donation and transplantation process?

The dissemination of this culture includes commitments from the CNCOs to allocate resources and time. Setting up a Quality area is a practice noted in RJ and also in SC, in the near future. Meetings to discuss improvements are encouraged and arranged by the CNDAs in São Paulo, where improvements focus on organ distribution.

The State Centers in RJ and SC are well aware that the foundations of a perfection-seeking culture include the standardization and formal establishment of processes. This survey does not encompass the standardization of transplantation activities.

The establishment of quality circles was noted at the CNCDOs; in RJ and SC, regular structured meetings are attended by everyone, while they are held sporadically in SP, addressing only matters related to procurement.

Performance goals and their respective monitoring must be established for all practitioners (procurement, at CNCDOs and transplant). However, SP has not yet defined and does not monitor the performance of the in-house team at the Center. RJ and SC have also not defined goals for the transplant teams, having only a partial overview of their performance based on a single management indicator.

The process for dealing with faults was established at all CNCDOs, with differences related to process centralization and its scope. RJ and SC do not have a centralized structure, while the faults control process in SP is centralized in a single area, with the scope of its activities limited to specific stages. It is worthwhile stressing the use of non-conformity reports, which are standardized and formalized throughout the organization in SC.

Encouragement for benchmarking and developing new practices is noted in full in RJ, while SP is focused on studies of innovation during the procurement phase, and SC works only with international benchmarking activities, fostering interaction with international reference institutions.

Capacity building for new activities is provided by all the CNCDOs studied, with refresher courses offered in RJ and SC, but not in SP.

Ideal coordination model from the lean standpoint, adapted to the Brazilian transplant system

Through an analysis of the practices found at each of the CNCDOs studied, an ideal coordination model may be proposed from the lean standpoint. Its preparation requires input from all the State Transplant Centers studied, with no single CNCDO standing out across the board. The specific characteristics of each case are now the extension, completeness and scope of a necessary set of practices to be implemented by the organizations administering the transplantation process in Brazil – CNCDOs.

CONCLUSIONS

Returning to the main question explored by the survey, this study concluded that the organ donation and transplantation process could be better managed in Brazil through applying lean principles. The procedures adopted by the studied CNCDOs (RJ, SC and SP) are aligned with lean principles presented in the literature review.

The demands from healthcare practitioners, donor families and recipient patients were identified by the CNCDO coordinators, bearing in mind that value-adding stages may also be diagnosed.

All the Centers take steps to ensure that procedures are handled correctly, with no wasted resources and compliant with the requirements of the end-users of the process – patients who are transplant candidates. Observation of the daily routines for conducting this process was not included in the scope of this survey. There are no data proving the effective implementation of the actions mentioned in the interviews, although it is suggested that the adoption of these initiatives is subject to alterations during operating routines, explaining the existence of waste throughout the process stages.

Much of the effort is expended at the start of the process, during the donation phase. A possible justification may be due to awareness among the State Centers that the main shortfall is located precisely at the start of the process.

The main contribution offered by this survey is the possibility of building up an ideal transplant coordination model tailored to the Brazilian context and grounded on practices noted at the RJ, SP and SC CNCDOs. Consequently, it may be said that this study adds value to the efforts from public administrators.

Taking into consideration the constraints of this paper, it is suggested the following topics be studied using lean methodology: 1) outlook of donor families and patients who are transplant candidates 2) complete process – donation, transplant and post-transplant monitoring 3) activities related to tissue transplants, and 4) macro-process for transplanting organs harvested from live donors.

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