

Lean thinking and brain-dead patient assistance in the organ donation process

PENSAMENTO *LEAN* E CUIDADO DO PACIENTE EM MORTE ENCEFÁLICA NO PROCESSO DE DOAÇÃO DE ÓRGÃOS

PENSAMIENTO *LEAN* Y CUIDADO DEL PACIENTE CON MUERTE ENCEFÁLICA EN EL PROCESO DE DONACIÓN DE ÓRGANOS

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ABSTRACT

Organ donation is a complex process that challenges health system professionals and managers. This study aimed to introduce a theoretical model to organize brain-dead patient assistance and the organ donation process guided by the main lean thinking ideas, which enable production improvement through planning cycles and the development of a proper environment for successful implementation. Lean thinking may make the process of organ donation more effective and efficient and may contribute to improvements in information systematization and professional qualifications for excellence of assistance. The model is configured as a reference that is available for validation and implementation by health and nursing professionals and managers in the management of potential organ donors after brain death assistance and subsequent transplantation demands.

DESCRIPTORS

Brain death
Organ donors
Patient assistance management
Nursing assistance
Quality management

RESUMO

A doação de órgãos é um processo complexo que desafia os profissionais e gestores do sistema de saúde. Este estudo objetiva apresentar um modelo teórico de organização do cuidado ao paciente em morte encefálica e o processo de doação de órgãos, balizado pelas principais ideias do pensamento *Lean* que possibilitam a melhoria da produção a partir de ciclos de planejamentos e criação de um ambiente propício para o sucesso da sua implementação. O pensamento *Lean* pode tornar mais eficaz e eficiente o processo de doação de órgãos e contribuir com a sua melhoria, a partir da sistematização das informações e capacitação dos profissionais para a excelência do cuidado. O modelo apresentado configura-se como um referencial disponível para validação e aplicação pelos profissionais e gestores de saúde e enfermagem na prática da gestão do cuidado ao paciente potencial doador de órgãos em morte encefálica e respectiva demanda por transplante.

DESCRITORES

Morte encefálica
Doadores de órgãos
Administração dos cuidados ao paciente
Cuidados de enfermagem
Gestão de qualidade

RESUMEN

La donación de órganos es un proceso complejo que desafia a profesionales y gerenciadore del sistema de salud. Se objetiva presentar un modelo teórico de organización del cuidado al paciente con muerte encefálica y el proceso de donación de órganos, orientado por las principales ideas del pensamiento *Lean* que posibilitan la mejora de producción mediante ciclos de planificación y creación de ambiente propicio para el éxito en su implementación. El pensamiento *Lean* puede mejorar eficacia y eficiencia del proceso de donación de órganos y contribuir a su mejora, a partir de la sistematización de informaciones y capacitación de los profesionales para la excelencia del cuidado. El modelo presentado configura un referencial disponible para validación y aplicación por parte de profesionales y administradores de salud y enfermería en la práctica de la gestión de cuidado al paciente potencial donante de órganos con muerte encefálica y las respectivas solicitudes de transplantes.

DESCRIPTORES

Muerte encefálica
Donadores de tejido
Manejo de atención al paciente
Atención de enfermería
Gestión de calidad

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INTRODUCTION

Organ transplantation starts with organ donation. This process is a safe and effective therapy for several diseases that lead to organ or tissue failure, such as kidney or heart failure. Organ transplantation improves the quality and perspective of life of people affected by such diseases. Donation is the removal of viable organs from the bodies of cadavers or live donors. In the case of brain-dead individuals (cadaver donors), their organs will replace the inefficient organs of other people (recipients). The organ donation process is complex and involves a set of actions and procedures to convert a potential donor into an effective donor⁽¹⁻²⁾.

This transformation from a potential to an effective donor generally takes place in intensive care units (ICUs) or Emergency Services, and a qualified and prepared multidisciplinary team is required to address this situation in both the technical-scientific and humanistic dimensions that are inherent to nursing assistance. Late brain death identification may lead to infection, hemodynamic instability or cardiorespiratory arrest, leading to the loss of potential donors and of the hope of bringing life to other patients.

Providing assistance to brain-dead patients is considered a challenging situation from an ethical and professional point of view because it requires actions and major responsibilities *where nothing can go wrong* with regard to meeting the family and knowledge of and assistance to potential donors⁽³⁾. Family members living through the donation process suffer when they receive the brain death notice, particularly when there is a lack of information or a delay in releasing the body. Therefore, professionals should pay more attention to the family and think about strategies to make this process less distressing, bureaucratic and tiresome⁽⁴⁾.

Based on the above details and the numerous procedures (or lack of them) that may make the donation process unfeasible, we were interested in applying lean thinking, or lean production, to the organ donation process and analyzing the implications for brain-dead patient assistance. We started with the assumption that organ donation may be interpreted as a production system and may be associated with current production system ideas in the search for quality, efficient and efficacious assistance.

Lean thinking or lean production may add knowledge to production processes and make them into sustainable business models. Until the late 1990s, this model was primarily applied to manufacturing. However, lean production concepts may be applied to any other productive sector, including services such as healthcare, because this approach enables high quality levels, lowers costs and allows adequate delivery time. Organizations use lean practices and tools to generate value

for their clients, that is, goods and services with higher quality and fewer defects. Based on the Toyota methods, lean thinking leads to better results with less effort, space, money and time, compared to the traditional mass production system⁽⁵⁾.

Lean thinking adds some principles that should be considered by companies: fully solve consumer problems; assure that all services work together; do not waste consumer time or effort; and provide exactly what consumers want, where they want it and when they want it⁽⁶⁾.

In healthcare, services are provided and consumed. Assistance aims to reestablish human health as the *end product*. In the organ donation process, the objective of the services provided is specifically the protection and perfusion of organs. The priority is to assure the best possible physiological support to improve the success of transplanted organs⁽⁷⁾.

One characteristic of such services is variability, as the services differ depending on who provides them and where they are processed. This variability makes it difficult to control quality and requires major investments in training/qualification and standardization⁽⁵⁾. Considering the level of complexity of the organ donation process, a multiprofessional team must be able to meet the needs of potential donor and must have updated knowledge that allows for a fast and safe approach.

However, it is necessary to emphasize that there is an increasing imbalance between the number of patients on the waiting lists for organ transplantation and the availability of such organs. There are some limiting factors to this process. These limiting factors include the lack of notification about patients with Brain Death (BD) to Organ Notification, Procurement and Distribution Centers; the lack of health professionals qualified with regard to the donation-transplantation process through continuing education; and

family refusal⁽¹⁾.

Several issues have arisen in trying to improve and minimize the imbalance in the organ donation process. For example, how can we improve the assistance to potential organ donor patients with brain death and help shorten the transplantation waiting list? Additionally, could lean thinking principles improve the organ donation process?

Therefore, we decided to introduce a theoretical model to organize the assistance to brain-dead patients and the organ donation process using lean thinking ideas to improve this process.

Organ donation process

in 1991, the Federal Council of Medicine (CFM) defined the diagnosis of brain death (BD), which is a condition for multiple organ donations, as the irreversible situation of

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all respiratory and circulatory functions, or the irreversible cessation of all brain functions, including functions of the brainstem. The CFM also stated that BD has to be the consequence of an irreversible process of known origin⁽⁸⁾.

BD patients are primarily identified in ICUs and Emergency Services (ES). These services generally see patients with acute severe neurological injuries, such as brain hemorrhage, brain trauma and ischemic injury, which often evolve to BD⁽⁹⁾.

The detection of BD has two stages: the clinical diagnosis and a complementary graphic exam. The former must be performed at a time interval that depends on the potential donor age group: a) seven days to two incomplete months, repeating the exam every 48 hours; b) from two months to one incomplete year, repeating every 24 hours; c) from one year to two incomplete years, repeating every 12 hours; d) and above two years, repeating the exam every 6 hours⁽⁸⁾. It is important to emphasize that the clinical exams should be performed by different physicians who must not be part of the removal and transplantation team and that one of the exams must be performed by a neurologist.

The next step involves specific brain death tests, which include motor tests, evaluation of the pupillary responses, evaluation of the oculocephalic reflex (*doll's eyes* phenomenon), evaluation of the oculovestibular reflex (thermal test with chilled water), evaluation of the corneal reflex, evaluation of cough and nausea, and the apnea test. Tests to confirm BD include complete brain angiography (to check the absence of brain blood flow), radioisotope brain angiography, EEG, transcranial Doppler, CT with contrast or xenon, and SPECT (single photon emission computerized tomography to study pre- and postsynaptic neurons), among others. The observed clinical and complementary data should be recorded in the brain death declaration form^(2,8,10).

After confirming brain death and discarding clinical contraindications that are risks to organ receivers, patients are considered to be potential organ donors. It is important to highlight that for the organ donation process to be feasible, it is necessary to confirm the BD diagnosis and notify the potential donor.

After detecting BD, it is necessary to optimize organ tissue perfusion and assure organ viability. In this stage, the recommendations include the continuous monitoring of the heart rate, oxygen saturation, blood pressure, central venous pressure, hydroelectrolytic and acid base balance, urinary output and body temperature⁽¹⁾.

It is important to adequately manage potential donors with the same effort and dedication provided to any other ICU patient because these patients should not be viewed as dead and no longer needing assistance. This human being *should not stop being unique to become an object*⁽¹¹⁾ because a single potential donor who is in good condition may benefit more than ten patients with transplants⁽¹²⁾. Thus, it is important that these patients are treated as someone who is/was inserted in a social, family and cultural context.

After confirming BD, the physician in charge should communicate with the family regarding the irreversibility of the patient's situation. At this moment, if the hospital has more than eighty (80) beds, ICU or ES professionals should communicate with the Intra-Hospital Committee of Organ and Tissues Donation for Transplants (CIHDOTT), which in turn communicates with the Organ Notification, Procurement and Distribution Center of the State or of the Federal District (CNCDO) and informs them of the potential donor in the hospital. If there are fewer beds, communication is made directly to CNCDO^(9,13). It is important to stress that this notification is compulsory and does not depend on family willingness or on the clinical condition of the donor to become an effective donor.

CNCDO will send a health professional to carry out the organ and tissue donation interview with the family. If the family agrees with the donation, they will sign the Consent Form in the presence of two witnesses. As part of this process, the family may decide which organs will be donated.

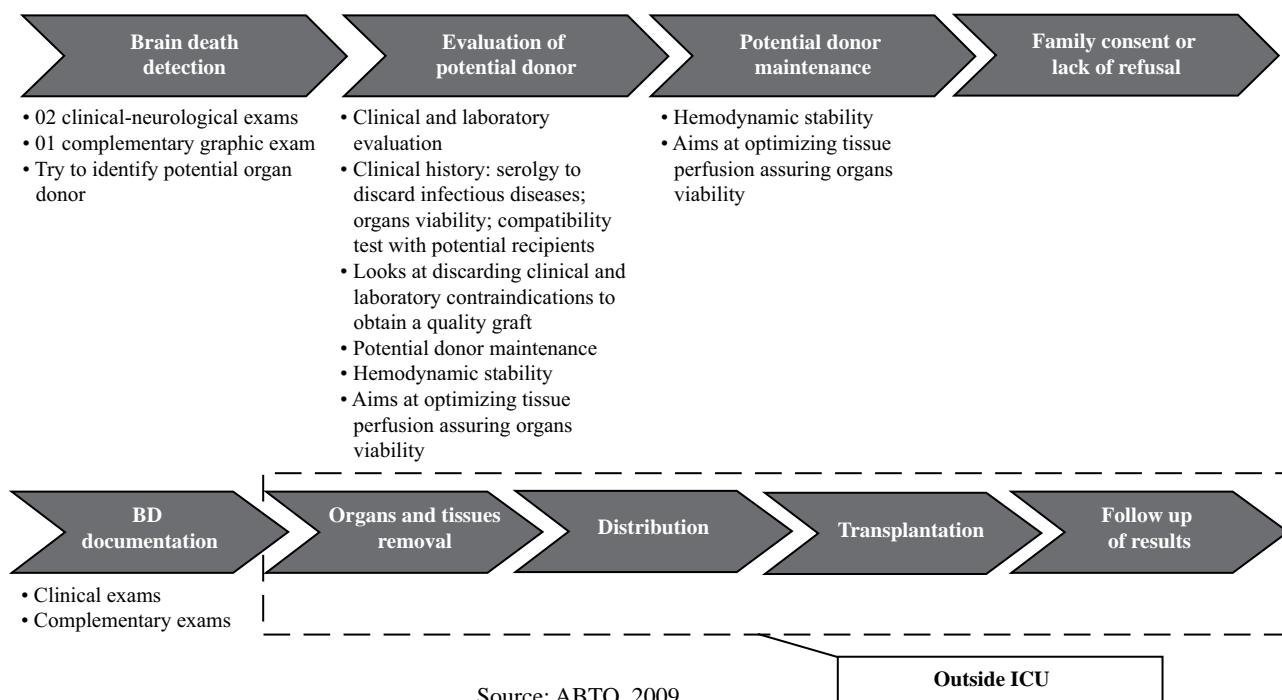
Figure 1 shows the organ donation process.

There are many obstacles to organ donation that contribute to the increase in the number of patients on the waiting lists for organs. These obstacles include a lack of understanding of the concept of brain death by family members and even by some health professionals; the lack of credibility of real organ donation and transplantation benefits; logistical difficulties in maintaining potential donors; the irreversible cardiac arrest of potential donors during the donation-transplantation process; medical contraindications for potential donors; non-identification or late brain death determination; and family refusal^(1,14).

Relating some lean thinking or lean production ideas to the organ donation process

The term lean, more commonly referred to as lean thinking (lean mentality, in Portuguese) refers to the search for value maximization by eliminating waste through the practice of continuous improvement. Thus, one may say that lean is a type of tool, the management theory of which is based on Toyota Production System practices and results^(6,15-16).

Lean production is an integrated set of activities designed to obtain high volume production using the minimum amount of raw-material inventory, in-process inventory and finished goods inventory. Pieces approach the workstation *just-in-time*, are completed and pass rapidly through the operation. Thus, it is understood that lean production is a practice to improve production through planning cycles, enhancing the ability of managers to create a favorable environment for successful implementation^(16,17). Simply stated, lean production is a way to produce more with increasingly less (less human effort, less equipment, less time and less space) and, at the same time, offer clients increasingly more of what they want⁽¹⁰⁾.



Source: ABTO, 2009

Figure 1 – Organ donation process.

The lean approach is based on a series of principles that orient the operations of a company in the search for higher quality added to higher efficiency, which has yielded excellent results in terms of operational excellence and profitability to several sectors in which it has been applied, such as computers, cars or steel. Some studies have used lean thinking for healthcare services^(5,17,19).

In healthcare services, patients expect and/or demand increasingly better assistance with higher quality and resolution and, therefore, more investments in service training / qualification are needed. Health institutions should examine their operations to ensure that their

processes generate value for the clients / users as a quality product, meeting patients', families', governmental and societal expectations.

A product is the result of a production system that is offered to consumers; it may be a good or a service. In the health area, the product is a service, and specifically in nursing, the product is assistance. A service is characterized as work performed by one person to benefit another, is intangible and immaterial, and cannot be stored.

The chart below relates some lean thinking ideas to the organ donation process (Chart 1).

Chart 1 – Relating some Lean thinking ideas to the organ donation process.

Ideias Lean	Significado Lean	Significado no processo de doação de órgãos
Maintenance	Company should provide a reliable and quality service for clients. As such, the company should invest in maintenance, especially preventive maintenance, aiming to always have the machine ready to perform its functions without failure. In lean thinking, this preventive maintenance is shared by employees and there is no single person in charge of this task.	Hospitals must have reliable equipment, such as multiparameter monitors, artificial breathers, infusion pumps, and beds, among others, to give quality assistance to potential organ donors. In healthcare, preventive maintenance is mandatory because the detection of a defect at the moment the equipment is being used may lead to the patient's death. It is believed that this preventive maintenance may be shared in healthcare, involving employees using these pieces of equipment in addition to the hospital maintenance area.
Setup	Setup is the period a machine remains shut down, interrupting the production, so that manufacturing machines are adjusted. It is the preparation of the machine for the next step or task. Expected setup time, that is, shutdown time, is zero, to minimize company costs and useless time.	When setup time is related to the healthcare sector, and more precisely to the organ donation process, one has to think about minimizing useless time. One may imagine a situation of taking a patient suspected of brain death to a complementary exam to diagnose BD. At this moment, it is necessary that machines are available and reliable so that time is not wasted and there is no damage to the patient's condition. An example may be a portable artificial breather not working correctly. In addition to compromising the patient's condition, this issue generates useless time. A similar situation is waiting for a BD patient to undergo brain angiography. This delay, in addition to generating wasted time and damaging the patient's condition, may increase hospital costs. Therefore, it is important to minimize the setup time.

Continue...

Continuation...

Ideias Lean	Significado Lean	Significado no processo de doação de órgãos
Information system	Develop an information system that is readily available, reliable and easy to interpret.	From the moment a potential donor is identified, both in the ICU and ES, professionals should be fully aware of the protocols, routines and flow because they should act with technical, scientific and humanistic competence and be able to integrate/articulate this knowledge among themselves. The BD protocol should be started as soon as brain death is suspected. Two clinical neurological exams are needed; one must be performed by a neurologist and the other by an intensivist. After the neurological exam, if it is positive for BD, the nurse should inform the Intra-Hospital Committee for Organs and Tissues Donation for Transplants (CIHDOTT). This information system is well defined for professionals to help the donation process and prevent wasted time and misinformation or wrong information.
Training / qualification Multifunctionality	Training / qualifying employees so that they are polyvalent and have a systemic view of the organization and its processes to master different functions.	The donation process is complex and relatively recent in healthcare. Thus, it requires that professionals are constantly updated and qualified / trained to assist both the organ donor and receiver. The multifunctionality of health professionals is slightly more difficult because assistance to the potential donor is multiprofessional and, for the assistance to the potential donor to be of quality, every professional must be able to promptly act with competence and technical precision within their sphere of activity. Nurses, as part of the multiprofessional team, manage a brain-dead patient's assistance and carry out important actions to procure organs, primarily acting in the identification of donors, hemodynamic maintenance, and in the communication with transplantation centers and family members to make the organ donation process feasible. It is also important that ethical and human relation issues involved in organ donation are contemplated during the qualification process.
Multifunctional machine	Machines that are able to perform several functions.	During brain-dead patient assistance, potential organ donors are connected to several multifunctional machines that are used to help and more judiciously monitor the assistance. A multiparameter cardiac monitor is a machine that performs different functions. It determines the heart rate, respiratory rate, blood pressure and temperature, among other parameters that help professionals preserve and maintain organ donors and receivers. Even with this technological armamentarium, welcoming and humanizing the assistance to BD patients and their families is indispensable.
Automation / Automatic	Machines interpret situations and automatically adapt.	A future scenario in healthcare may include machines that will be programmed to identify a specific situation or problem and immediately correct it. One may imagine a multiparameter monitor identifying a patient's hemodynamic instability and automatically adjusting the medication. Even if these highly qualified machines are invented, it is believed that they will never replace humanized assistance.

Based on the above relationships, we have developed a theoretical model to organize assistance to brain-dead patients and the organ donation process based on the main lean thinking ideas (Figure 2).

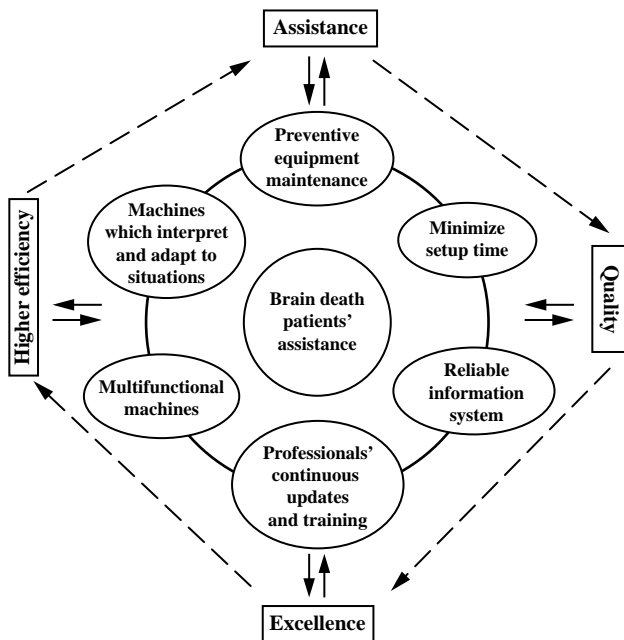


Figure 2 – Theoretical model to organize assistance to brain-dead patients and the organ donation process based on the main lean thinking ideas

The understanding of the process and the adequate implementation of its stages lead to safer and higher quality organs, potentiate brain death diagnosis and donor organ procurement, and allow for expedited packaging and transport to the recipient of the organ transplantation. This improvement comes from planning and organizing patient assistance, the preventive maintenance of machines, minimal setup time, effective information systems, and qualified and knowledgeable professionals. As a result, it is possible to improve assistance efficiency, quality, and excellence. This situation assures that continuous improvements in this process benefit both health professionals and the family members of the donors and recipients.

Each of these concepts may induce specific improvement efforts. Collective and interactive actions among health team members, in addition to the understanding of operational management, will enable the interpretation of lean concepts and their association with favorable health production system efficiency with respect to organ donation.

CONCLUSION

This study enables a better understanding of the organ donation process and the main lean thinking ideas. It was possible to put into context the donation process and this new thinking, which has been used in healthcare and

which attempts to obtain better results with less effort. The following main lean thinking ideas were used: lean, maintenance, setup, information system, training / qualification / multifunctionality, multifunctional machine, and automation / automatic.

Transposing the main lean thinking ideas onto the organ donation process was a challenge because this model was primarily developed for manufacturing. However, from a theoretical perspective, it was possible to apply the model at different levels of the organ donation process. It should be stressed that lean thinking may make the organ donation process more effective and efficient and contribute to improvements in information systematization and the qualification of professionals. This method assures quality assistance to patients without *freezing* the approach. Instead, it provides information on how to act in different

situations. In this sense, this theoretical model may make contributions to aspects related to humanization, communications, linkages and ethics. These aspects should be considered because they are indispensable for the relationship with patients and family members involved with the organ donation process.

We believe that this study may encourage new academic studies in healthcare using lean production because this area, as with all other production systems, should be open to continuous improvements. Within health assistance, these ideas may improve the organ donation process. Stages of this process should be considered in detail, and specific solutions may be generated under these broader concepts to potentiate improvements in multiprofessional team activities.

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