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RODRIGO ALVES SARLO

IMPLEMENTATION OF ORGANIZATIONAL INNOVATIONS IN THE PROCESS OF ORGAN AND TISSUE DONATION

Rio de Janeiro

2020

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A thesis presented to the Instituto COPPEAD de Administração, Universidade Federal do Rio de Janeiro, as part of the mandatory requirements for the degree of Doctor of Sciences in Business Administration (D.Sc.)

Advisor: Eduardo Raupp de Vargas

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To my beloved family
Gabi, Dudu, Biel and Carol

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ABSTRACT

SARLO, Rodrigo Alves. **IMPLEMENTATION OF ORGANIZATION INNOVATIONS IN THE PROCESS OF ORGAN AND TISSUE DONATION**. 2020. 113f. Tese (Doutorado em Administração) - Instituto COPPEAD de Administração, Universidade Federal do Rio de Janeiro, Rio de Janeiro, 2020.

Since the demand for transplants is greater than the supply, countries and regions need to establish strategies to implement efficient transplant systems. (MARTIN *et al*., 2019) Given that the main limiting factor for carrying out the procedures is the availability of organs and tissues, the central strategy is to optimize organ and tissue donation process, obeying the ethical and legal principles Some countries are recognized for having consolidated transplant systems and this was only possible by establishing a focus on the donation process, especially in the brain-dead donor.(R. Matesanz *et al*., 2017).Transplant surgery is usually performed in hospitals far from those where the potential donor is located. Thus, a process is demanded where multiple professionals and institutions are involved since the identification, diagnosis of brain death, family request, surgery for recovery, allocation and distribution of organs are highly complex steps and not necessarily coupled.(MANYALICH *et al*., 2011). Unlike organ donation that can only occur while there is blood circulation, tissue donation can be performed within a few hours after the circulatory arrest. (Muraine, 2002).Two models of procurement have become more implemented around the world and therefore have greater adherence, study and scientific publications: the “Spanish model” based on in-house transplant coordinators (IHC) and the “American model” based on organ procurement organizations (OPO). The basic difference between these models refers to the management of the process and the location of the professional specialist in donation. (RUDGE *et al.*, 2012) The Brazilian transplantation law allows the adhesion of the 2 models for procurement in the national territory. The practical observation of innovations implemented in the state of Rio de Janeiro since 2010 motivated the beginning of a series of studies and local research in order to understand these phenomena and seek to improve the local process and extend these findings.(LENZI *et al*., 2014; BONFADINI *et al*., 2014). We sought to study organizational innovations from a theoretical perspective, for research that could add knowledge in an original way to the area of organ and tissue donation within the innovation implementation organization theories. We identified many similarities between the role of IHC and realized that their activities fit perfectly into the middle managers models described in literature.(S. A. BIRKEN *et al*., 2012) Throughout the 3 papers that compose this thesis, we will present an association between the role of IHC and middle managers. The process of implementing the IHC program will be presented in the context of organ and tissue donation to bring a wide list of activities and strategies carried out by transplant coordinators, which can assist the future implementation of IHC in other units at the local level, but also in several other regions and countries. This work will also provide a theoretical contribution to middle managers theory, by the identification of a new domain in which in-house transplant coordinators influence sustainability of the system.

Keywords: Innovation, Implementation, Healthcare, Donation, Transplantation

RESUMO

SARLO, Rodrigo Alves. **IMPLEMENTATION OF ORGANIZATION INNOVATIONS IN THE PROCESS OF ORGAN AND TISSUE DONATION**. 2020. 113f. Tese (Doutorado em Administração) - Instituto COPPEAD de Administração, Universidade Federal do Rio de Janeiro, Rio de Janeiro, 2020.

Como a demanda por transplantes é maior do que a oferta, países e regiões precisam estabelecer estratégias para implementar sistemas de transplantes eficientes. (MARTIN *et al*., 2019). Tendo em vista que o principal fator limitante para a realização dos procedimentos é a disponibilidade de órgãos e tecidos, a estratégia central é otimizar o processo de doação de órgãos e tecidos, obedecendo aos princípios éticos e legais. Alguns países são reconhecidos por ter sistemas de transplante consolidados e isso só foi possível estabelecendo um foco no processo de doação, principalmente no doador com morte encefálica. (MATESANZ *et al*., 2017). A cirurgia de transplante geralmente é realizada em hospitais distantes daqueles onde o potencial doador está localizado. Assim, é exigido um processo onde múltiplos profissionais e instituições estão envolvidos, pois a identificação, diagnóstico de morte encefálica, solicitação familiar, cirurgia de recuperação, alocação e distribuição de órgãos são etapas de alta complexidade e não necessariamente acopladas. (MANYALICH *et al*., 2011). Ao contrário da doação de órgãos, que só pode ocorrer enquanto houver circulação sanguínea, a doação de tecidos pode ser realizada algumas horas após a parada circulatória. (MURAINE, 2002). Dois modelos de doação têm se tornado mais implementados em todo o mundo e, portanto, têm maior adesão, estudos e publicações científicas: o “modelo espanhol” baseado em coordenadores internos de transplantes (IHC) e o “modelo americano” baseado em organizações de procura de órgãos (OPO). A diferença básica entre esses modelos refere-se à gestão do processo e à localização do profissional especialista em doação. (RUDGE *et al*., 2012) A legislação brasileira de transplantes permite a adesão dos 2 modelos de doação em território nacional. A observação prática das inovações implementadas no estado do Rio de Janeiro a partir de 2010 motivou o início de uma série de estudos e pesquisas locais com o objetivo de compreender esses fenômenos e buscar aprimorar o processo local e ampliar esses achados. (LENZI *et al*., 2014; BONFADINI *et al*., 2014). Buscou-se estudar as inovações organizacionais a partir de uma perspectiva teórica, para pesquisas que pudessem agregar conhecimento de forma original à área de doação de órgãos e tecidos dentro das teorias de implementação da inovação organizacional. Identificamos muitas semelhanças entre o papel do IHC e percebemos que suas atividades se enquadram perfeitamente nos modelos de gerentes intermediários descritos na literatura. (BIRKEN; LEE; WEINER, 2012) Ao longo dos 3 artigos que compõem esta tese, apresentaremos uma associação entre os papeis do IHC e os gerentes intermediários. O processo de implementação do programa de IHC será apresentado no contexto da doação de órgãos e tecidos para trazer um amplo rol de atividades e estratégias realizadas pelos coordenadores de transplante, que podem auxiliar na futura implementação do IHC em outras unidades em nível local, mas também em várias outras regiões e países. Este trabalho também fornecerá uma contribuição teórica para a teoria dos gerentes intermediários, pela identificação de um novo domínio no qual coordenadores de transplante internos influenciam a sustentabilidade do sistema.

Palavras-chave: Inovação, Implementação, Sistema de saúde, Doação, Transplante

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LIST OF ABBREVIATIONS

ADD: Actual Deceased Donor
CICI: Context and Implementation of Complex interventions
CFIR: Consolidated Framework For Implementation Research
DBD: Donation after brain death
EBHI: evidence-based health care innovation
EBP: evidence-based practice
ED: Emergency Department
ETPOD: European Training Program on Organ Donation
GDP: Gross domestic product
HEAPN: *Hospital Estadual Adão Pereira Nunes*
HEAS: *Hospital Estadual Albert Schweitzer*
HEAT: *Hospital Estadual Alberto Torres*
HEGV: *Hospital Estadual Getúlio Vargas*
ICU: Intensive Care Unit
IHC: in-house transplant coordinator or transplant coordinator
MeSH: Medical Subject Headings
NHS: National Health Service
NWCC: North West Change Centre
OPO: Organ Procurement Organization
OTPD: Organ Transplanted per Donor
PET: *Programa Estadual de Transplantes*
PMP: Per Million Population
PTD: Potential Tissue Donor
TPM: Transplant Procurement Management
TMT: Top management team
UK: United Kingdom
US: United States of America
WHO: World Health Organization

SUMMARY

1 INTRODUCTION

Establishing a solid transplant system is a worldwide challenge. Countries and regions must seek to increase de quantity and improve quality of transplant procedures with equity and transparency.(MARTIN *et al*., 2019; MULLER *et al*., 2019)

The implementation of efficient organ and tissue procurement models, aiming at higher deceased donation rates may increase supply, allowing more organs to be transplanted. In contrast, an implementation failure can lead to a huge impact with waste of organs and loss of thousands of lives. (RUDGE *et al*., 2012).

Spain has established an efficient donation model, in which the in-hospital transplant coordinator (IHC) is responsible for setting up all activities related to the donation process. They may “increase the quantity, quality, and effectiveness of organ and tissue donation by training and advising healthcare professionals in the major steps of the donation process”. IHC need to “be skilled in personal and professional relationships to be locally accepted and acknowledged, supported by hospital managers, and paid for their work.” (MANYALICH *et al*., 2011) They are allocated in the middle of the organization.

Middle managers and their roles have been the subject of study by several authors. They are subordinated to top managers, usually hospital directors, and need to be in constant contact with all healthcare professionals in their units. (NEALEY; FIEDLER, 1968) and have been considered important in the implementation and maintenance of policies and practices within the organization.(DRESSLER, 1978)

These professionals are able to transmit the strategy formulated by the executives and take them to employees, implementing change and improving organizational performance.(WOOLDRIDGE; FLOYD, 1990; FLOYD; WOOLDRIDGE, 1992; FLOYD; WOOLDRIDGE, 1997)

Recently, there has been an increase in research interest related to the role of middle managers, regarding their influence on organization change context and how they impact innovation implementation.(CHUANG *et al*., 2011) It has been hypothesized

their impact in healthcare innovation implementation by diffusion information, synthesizing information, mediating between strategy and day-to-day activities, and selling innovation implementation. (S. A. BIRKEN *et al*., 2012)

A systematic review was carried out to assess middle managers' role in healthcare evidence-based practice (EBP) implementation. One hundred and five studies were selected after searching MEDLINE/PubMed and EBSCO databases from 1996 to 2015. Authors stated that there was still "little understanding regarding middle managers' role in EBP implementation". Among the selected articles, there were none that addressed organ and tissue donation field. (S. BIRKEN *et al*., 2018).

In the State of Rio de Janeiro, a series of managerial measures aimed at organ and tissue donation process culminated in improvements in the local transplantation system. These practical measures led to the development of local research in order to understand these phenomena and seek to improve the local process, aiming at increasing the quantity and quality of the organs harvested and thus, the number of local transplants performed. (LENZI *et al*., 2014; BONFADINI *et al*., 2014)

The objective of this thesis is to investigate an association between in-house transplant coordinators activities and their role as middle managers, seeking to describe the process of the implementation of practices towards organ and tissue donation improvement in four hospitals in Rio de Janeiro, Brazil.

Within the seven-year period of IHC activities as managers fully dedicated to the organ and tissue donation process, we sought to investigate whether the implementation of this innovation was effective; the strategic actions with IHC intermediation between directors, executives and employees; and the possible association between the activities developed to improve the donation process with middle managers' role addressing the innovation implementation literature.

The first article of this thesis describes the period of implementation of these managers in four public hospitals and the defined criteria for this choice, analyzing the impact of activities developed from these professionals on organ donation: *Impact of the*

introducing Full-time in-house coordinators on referral and organ donation rates in Rio de Janeiro Public Hospitals: a Health Care Innovation Practice

IHC are supposed to “increase the quantity, quality, and effectiveness of organ tissue donation by training and advising healthcare professionals in the major steps of the donation process” (MANYALICH *et al*., 2011, p.274). Therefore, healthcare professionals must adhere to the activities developed by the IHC and this requires an effective implementation.(KLEIN; SORRA, 1996)

The following article entitled: *Project of Cornea Donation in Rio de Janeiro: Analysis of the Implementation of an Organization Innovation Practice,* provides the description of a tissue donation team in order to improve cornea donation, under OPO coordination, through intermediation of the IHC, in one of the previously selected hospitals.

Support from top managers has been described as a way to increase middle management commitment. The knowledge and involvement of these professionals in strategic planning has been attributed to positive implementation outcomes. (URQUHART *et al*., 2014; S. A. BIRKEN *et al*., 2015; HOVLID; BUKVE, 2014; VARSI *et al*., 2015)

The last article of this dissertation entitled: *The role of in-house transplant coordinators as middle managers in organ donation rates in Rio de Janeiro: from implementation to sustainability,* provides a deeper overview of the activities and strategies carried out by the IHC, in order to have a broader and more detailed approach to the implementation process.

A quantitative analysis was performed, using two statistical methods: bootstrap analysis and T-test (Students' test), using a retrospective control group in which the innovation was not implemented, in order to verify whether the presence of the IHC has a significant impact on results, from 2011 to 2018.

A qualitative analysis was also performed through semi-structured interviews with IHC that were involved in the implementation project, aiming to assess their role as middle managers, addressing the four domains described by Birken *et al* (2012): information

diffusion, synthesizing information, mediating between strategy and day-to-day activities and Selling innovation implementation.(S. A. BIRKEN *et al*., 2012)

For discussion, a literature review was carried out after the description of theoretical gaps in a recent systematic review publication on the role of middle managers in the implementation of EBP.(S. BIRKEN *et al*., 2018) The additional files were evaluated to guide a search in two scientific databases: MEDLINE/PubMed and EBSCO. It was possible to identify two new Medical Subject Headings (MeSH) in PubMed database which were included in the search.

In order to assess and review the role of middle managers in the process of implementing healthcare innovations, the following MeSH topics were included in the search: organizational innovation; knowledge management; models, organization; diffusion of innovation; change management and implementation science. Some additional studies were identified as relevant for the theoretical discussion after evaluating the reference sessions of previously selected articles, according to the search methodology.

This dissertation aims to provide a theoretical contribution, through the application of theories from innovation implementation with organ and tissue donation field, positioning the IHC as middle managers, addressing their role in middle management and proposing a domain of influence on the sustainability or maintenance of innovation.

With the quantitative and qualitative results presented, it aims to bring a practical contribution to management strategies, with several actions carried out by the coordinators aimed at improving the organ and tissue donation process.

1.1 ORGAN DONATION AND TRANSPLANTATION SYSTEMS

World Health Organization (WHO) established ethical principles in order to provide guidance for the establishment of transplantation systems around the world. Since the demand for transplants is greater than the supply, countries and regions need to establish strategies to implement efficient transplant systems. (MARTIN *et al*., 2019)

Given that the main limiting factor for carrying out the procedures is the availability of organs and tissues, the central strategy is to optimize organ and tissue donation process, obeying the ethical and legal principles established by the WHO in conjunction with the affiliated international societies and seeking to offer the greatest possible security to potential recipients. (RUDGE *et al*., 2012; DOMÍNGUEZ-GIL *et al*., 2016)

Some countries are recognized for having consolidated transplant systems and this was only possible by establishing a focus on the donation process, especially in the brain-dead donor.(MATESANZ *et al*., 2017).

Brain death is the irreversible loss of all functions of the brain, including the brainstem. Essential findings include coma, absence of brainstem reflexes, and apnea. Brain death diagnosis may vary through countries or even regions, but when a patient is declared brain dead, he is clinically and legally dead. A potential organ donor is a patient who met the criteria for brain death with no absolute contraindication to organ donation.(SHEEHY *et al*., 2003)

Transplant surgery is usually performed in hospitals far from those where the potential donor is located. Thus, a process is demanded where multiple professionals and institutions are involved since the identification, diagnosis of brain death, family request, surgery for recovery, allocation and distribution of organs are highly complex steps and not necessarily coupled.(MANYALICH *et al*., 2011)

Unlike organ donation that can only occur while there is blood circulation, tissue donation can be performed within a few hours after the circulatory arrest. Corneas are the tissues most widely procured and after the recovery, they are not transplanted directly into the patient. Tissues are sent to a tissue bank in order to be processed and stored, then after days they are distributed to potential recipients.(MURAINE, 2002)

Two models of organ procurement have become more implemented around the world and therefore have greater adherence, study and scientific publications: the “Spanish model” based on in-house transplant coordinators (IHC) and the “American model” based on organ procurement organizations (OPO). The basic difference between

these models refers to the management of the process and the location of the professional specialist in donation. The Spanish model is based on intra-hospital coordination, where the donation specialist is based, executes and reports all his activities and the American model is based on extra-hospital coordination, and the specialist performs the same activities, but it is based on an extra-hospital unit – OPO.(RUDGE *et al*., 2012)

Spain has become the country with the best donation rate over many years due to the organization of procurement at the hospital level, and one of the main reasons for this performance is associated with IHC role on donation activities.(MATESANZ *et al*., 2017)

IHC may “increase the quantity, quality, and effectiveness of organ and tissue donation by training and advising healthcare professionals in the major steps of the donation process”. IHC need to “be skilled in personal and professional relationships to be locally accepted and acknowledged, supported by hospital managers, and paid for their work.” (MANYALICH *et al*., 2011) They are allocated in the middle of the organization.

Becker *et al.* have studied by a qualitative approach the organizational differences between 4 countries in Europe and how they impact organ donation rates. Semi-structured interviews were conducted with healthcare professionals and summarized recommendations for a systematic improvement of organ donation systems, from donor evaluation, family approach, public initiatives and cooperation between hospitals and stakeholders. Even so, the availability of resources and support by qualified IHC was pointed as one of the most important interventions.(BECKER *et al*., 2020)

Witjes *et al.* (2019) conducted a systematic review to identify interventions aimed at healthcare professionals that positively affected the number of organ donors. Among the 22 selected studies, the interventions that had a positive influence were training and education, adoption of electronic support for identification and/or referral of donors, collaborative pathway, donation request and/or family support by trained professionals.(WITJES *et al*., 2019)

The Brazilian transplantation law allows the adhesion of the 2 models in the national territory. It will be up to the manager responsible for coordinating this process regionally to define the best donation model. This must be done by the state health departments.(PORTARIA 2600/2009, 2009)

In the state of Rio de Janeiro, there was an option to adopt a hybrid model for donation that enabled the implementation of a series of innovations at national level, through the creation of a remodeled OPO, in the year of 2010.

The practical observation of the implementation of innovations in Rio de Janeiro, Brazil, motivated the beginning of a series of studies and local research in order to understand these phenomena and seek to improve the local process and extend these findings to other regions and countries for a broader contribution. (LENZI *et al*., 2014; BONFADINI *et al*., 2014)

1.2 HEALTHCARE INNOVATION IMPLEMENTATION

According to Klein and Sorra (1996, p.1055), “implementation within an organization is the process of gaining targeted employees’ appropriate and committed use of an innovation…and presupposes adoption”. Implementation effectiveness refers to “the consistency and quality of target organizational members’ use of a specific innovation”. The climate is shaped by resources of the organization and strategies are determined by top managers.(KLEIN; SORRA, 1996, p.1058)

For Rogers (1995), the innovation-decision process is described as “an information-seeking and information-processing activity, where an individual is motivated to reduce uncertainty about the advantages and disadvantages of an innovation”. Implementation is the stage is this process where the transition between planning and execution takes place. Managers and employees have to deal with uncertainties until the new idea becomes institutionalized.(ROGERS EM, 1995)

The implementation process is challenging for organizations, which must deal with different issues, especially interpersonal, cognitive and emotional ones. (SHORTELL

et al., 1998). Implementation failure leads to multiple consequences, especially social and financial.(KLEIN; KNIGHT, 2005)

Durlak and DuPre emphasizes that “the level of implementation achieved is an important determinant of program outcomes”. Thus, effective implementation has an impact on the maintenance and sustainability of innovation, but also brings individual benefits to those involved. They also have selected five categories: innovation, providers, communities, the prevention delivery systems (*i.e: features related to the organization)* and the prevention support center (*i.e: training and technical assistance*).(DURLAK; DUPRE, 2008, p.334)

Although the implementation is not necessarily linear, some models separated the process into phases such as: pre-implementation, implementation and maintenance or sustainability of the innovation.(FIXSEN *et al*., 2009; MENDEL *et al*., 2008; AARONS *et al*., 2011) have categorized the outer and the inter setting and them, mapped constructs in each domain through implementation phases: exploration, adoption decision (preparation), active implementation and sustainment. Such approach could provide a “better understanding of the challenges likely to be presented during implementation phases”, including the predecessor period.(AARONS *et al*., 2011, p.15)

A systematic review was conducted by Chaudoir *et al*. (2013) in order to identify most relevant factors that affect successful implementation of evidence-based healthcare innovations. These were similar to the previous ones, but authors proposed a relationship with the following implementation outcomes: adoption, fidelity, implementation cost, penetration and sustainability. Authors identified 62 measures that can be used to access constructs in the selected domains: structural, organizational, provider, patient and innovation levels. (CHAUDOIR *et al*., 2013)

Wutzke *et al*. (2016) addressed how managers and employees have experienced the implementation of innovations from their personnel experience and which factors have positive impact on sustainability. The main findings were: to have a strong business case, be prepare for the change process, promote the change by engagement of all

stakeholders involved and develop the right structures and process to support implementation.(WUTZKE *et al*., 2016)

The effect of environmental, organizational and top managers' characteristics on initiation, adoption decision and implementation were examined in a survey performed in 1200 public organizations in the United States. The authors emphasize the importance of both external and internal resources for organizational innovativeness, the importance of financial resources linked to human resources and the influence of top managers in the allocation of these resources.(DAMANPOUR; SCHNEIDER, 2006)

Many attempts to innovate fail as a result of implementation failure, leading to high economic and social impacts. Klein and Knight (2005) performed a review research and they highlighted critical factors that shape the process and outcomes for implementation. They outline the role of top managers, especially for a supportive behavior towards employees.(KLEIN; KNIGHT, 2005)

To predict innovation effectiveness, a field study was conducted in a consumer product industry to examine two stages of innovation: adoption (decision to use innovation) and implementation (consistent use of innovation). Top managers were still the main force at implementation phase, but employees were found as a significant driver of implementation, especially if they recognize the innovation as a way to improve their performance.(SUNG *et al*., 2011)

The deepening of research on factors that lead to the success or failure of implementations led to the identification of multiple variables, bringing the notion of very complex interactions at the interpersonal, organizational and system factors level. Despite this, interpersonal aspects were identified as determinants in this process. Among some of these aspects, that of middle managers has received special attention in the last decade.(URQUHART *et al*., 2014)

Despite the wide research about the implementation process, there is an increasing recognition in the literature about the need for follow-up and monitoring, in order to identify factors that influence the sustainability of innovation. This may provide an in-

depth view of innovation across its entire scope. Shediac-Rizkallah and Bone (1998) have conceptualized sustainability as long-term maintenance programs.(SHEDIAC-RIZKALLAH; BONE, 1998)

There is a paucity of research in the sustainability, especially when compared to the implementation literature. Nevertheless, sustainability should be face as an outcome of an effective implementation. Schreier and Dearing (2011, p.2060) have defined it as “the continued use of program components and activities for the continued achievement of desirable program and population outcomes”.

A review of 125 studies found divergences in the definitions and terminologies of sustainability. For a temporal definition, there was a categorization in 3 ranges: 12 months, 12 to 24 months and above 24 months. In addition, the methodology for assessing and establishing that an innovation was considered sustainable over a period varied widely between the studies surveyed, applying quantitative, qualitative and mixed methodologies.(STIRMAN *et al*., 2012)

In the case of public health, the concern with the sustainability of innovation becomes more relevant, since public health programs only deliver benefits to society when they do so in a sustained manner over time. Another series raised 85 relevant studies and proposed a framework with 9 domains that affect the sustainability of a program: political support, funding stability, partnerships, organizational capacity, program evaluation, program adaptation, communication, public health impacts and strategic planning.(SCHELL *et al*., 2013)

The use of theoretically informed approaches to guide the design, development, implementation, evaluation and sustainability was recommended in a recent survey, within the scope of public health.(WALUGEMBE *et al*., 2019)

1.3 ROLE OF MIDDLE MANAGERS ON INNOVATION IMPLEMENTATION

Middle managers and their roles have been the subject of studies by several authors over the years.

Nealey and Fiedler (1968) highlighted the importance of developing middle managers towards comprehensive training focused on the company, and not specializing in a single role, in order to prepare these professionals for managerial functions and leardership development. They impact the organization's performance through administrative actions, such as training and face-to-face interactions with employees, distinguishing different levels of performance, in comparison to executives or top managers. (NEALEY; FIEDLER, 1968)

Dressler (1978) classified as middle managers: ward chief, clinic director, or program coordinator which “develops procedures for implementing institutional policies and is responsible for the operation of a particular service element or elements”. Their intermediate position allows for the interpretation of organization policies and communication to staff or employees, in addition to promoting feedback to the directors. Thus, through leadership and relationship skills, they become relevant to the implementation process. The lack of authority and high turnover were pointed out as one of the issues of this position.(DRESSLER, 1978, p.358)

Kanter (1982) addressed the influence of middle managers together with employees, by proving greater organizational commitment, promoting change and innovation. Through their involvement in the operation, they can perform tasks, suggest and put the strategy of the directors into practice.

A typology of middle managers involvement in strategy was developed by Floyd and Wooldridge (1990) (fig 1.1). The two-dimension framework represented the direction of influence upon strategy (upward or downward) and the extent to which their influence impacts organization’s concept of strategy and improve its performance.(WOOLDRIDGE; FLOYD 1990; FLOYD; WOOLDRIDGE, 1992; FLOYD; WOOLDRIDGE, 1997). Some of the roles that would be later categorized by Birken (2012) in the implementation of innovations were introduced, but with a focus on innovation. (S. A. BIRKEN; LEE; WEINER, 2012)

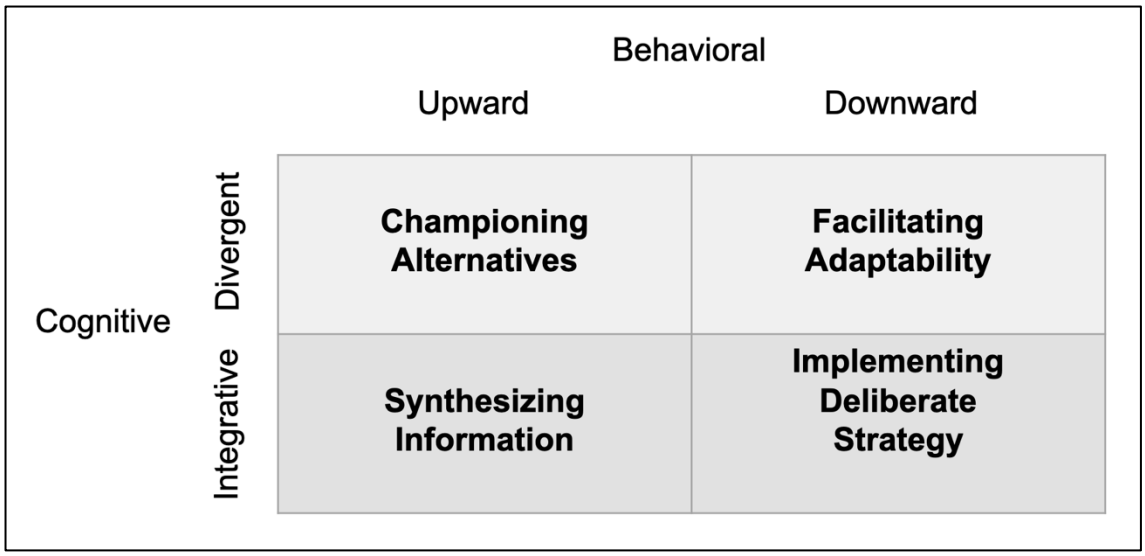

Figure 1.1: Typology of middle management involvement in strategy. Adapted from (FLOYD & WOOLDRIDGE, 1992)

Castelani (1992) reported issues related to the implementation in an article that examined lessons learned from the closing of 6 large institutions in New York. The ability to generate a connection between strategy and routine, mediating political decisions, dealing with the community and various stakeholders and negotiating contracts, provide a broad look, with an important social role of middle managers.

A survey was performed in order to identify the relationship between the managerial strategy of middle management and nurse commitment in Australian hospitals. The study reported a degree of distrust of nurses, relating to centralized decisions made by top managers. The increased commitment of these professionals was related to the involvement of their participation in decision making process, provided by the middle managers mediation.(BREWER; LOK, 1995). This research reiterates the strategic role and capacity for change that these professionals can bring to the organization

Miller described the process of converting a nurse manager to an interdisciplinary team leader, during the implementation of a patient-centered care model in New York City. The study reports positive outcomes through the development of leadership skills for the benefit of the organization and the patient. Coordination by nurses shortened the length of stay and improved communication between staff members.(MILLER, 1999)

The strategic alignment as part of a public policy in the United Kingdom (UK), focusing on middle managers was described by Clifford (2001). The North West Change Centre

(NWCC) programmes “were designed, in part, to provide middle managers with a context in which to place modernization for both local government and the NHS (National Health Service)”. In addition to the introduction of the proposed modernization agenda, partnership and collaboration are made with seniors managers and management theories and techniques are introduced.(CLIFFORD, 2001). A framework was created to illustrate relationship between professionals and their organizations (fig 1.2). These programs demonstrate the relevance of middle managers to the process of large-scale change to the healthcare system.

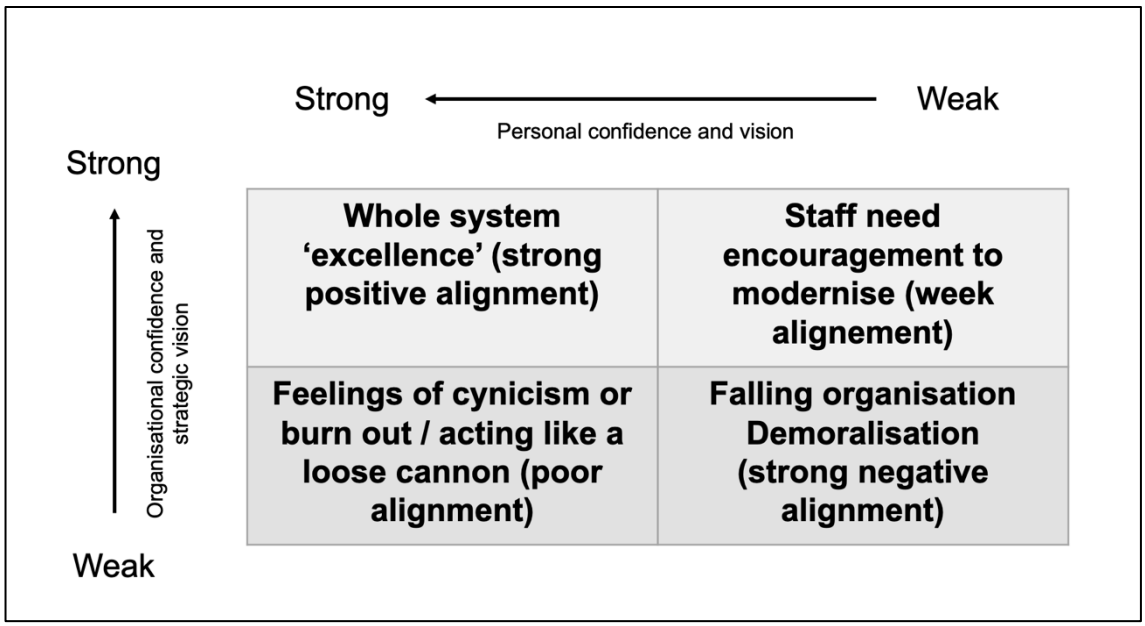

Figure 1.2: Strategic alignment between middle managers and their organizations. Adapted from (CLIFFORD, 2001).

Information, training and empowerment were identified as key elements of the implementation of a Quality System in three clinical laboratories, assessing constructs as leadership, goals, client focus, management by fact and process improvement. Despite identifying an important role for middle managers in the dissemination of information, the study attributed the responsibility of leading the change to top managers. (SILOAHO *et al*., 2001)

To address a deeper comprehension of interactions between upper and middle managers and how they affect decision-making process, Pappas *et al*. (2004) performed a survey with a middle-management team in one hospital with 386 beds and 2000 employees. Results indicated that middle managers exert significant

influence upon top managers through championing new ideas and synthesizing information. Authors defined this construct as the “interpretation and evaluation of information that alters top management perspective.”(PAPPAS *et al*., 2004, p.9). Later, Birken *et al*. expanded and included employees in this spectrum. (S. A. BIRKEN *et al*., 2012)

Middle managers may facilitate the changing process within employees through the developing of new strategies and shaping the organizational culture. Ham stated that this could be made by the “engagement of clinicians to bring about changes, developing and strengthening of clinical leadership, and provision of professionals with the time, resources, information, and skills needed to achieve change”(HAM, 2003, p.1980). Top managers should empower middle managers to help them create a leadership climate and this may improve delivery of care.(VALENTINO, 2004; CARNEY, 2006)

Dopson and Fitzgerald (2006) also advocated empowerment for middle managers, when their role was assessed in the implementation of evidence-based healthcare. But the authors added that these professionals also need to be proactive and “negotiate credible power, in a multiprofessional setting by working in collaboration with a key clinician on a desired innovation”. They have a role in diffusing innovations and ideas through professionals and organizations.(DOPSON; FITZGERALD, 2006)

Since the influence of middle managers and their roles are fundamental to the implementation process, their resistance to it can be a huge obstacle to change. A qualitative study based on semi-structured interviews and focus group with 92 middle managers in 17 healthcare units found a greater support from middle managers when innovation meets their needs and priorities, rather than organization as a whole.(CHUANG *et al*., 2011) The lack of support from top managers and a top-down behavior may also influence resistance from managers, implying a barrier to innovation.(BROOKS *et al*., 2011)

In order to address the role of middle managers in healthcare innovation implementation, Birken *et al* (2012) presented 4 domains by which the professionals “may bridge the gaps in the information that employees need to effectively implement

healthcare innovations". Its hierarchical position allows the perfect assimilation of innovation and its diffusion. They are able to synthesize information and sell the idea to employees, creating an appropriate climate for the implementation effectiveness. (S. A. BIRKEN *et al*., 2012, p.4-5)

Birken *et al* (2012) applies in their theory many of the elements that were presented in the literature about the role of middle managers, but the approach focused on implementation and the reunion of these 4 constructs representing the bridge between top managers and employees, shaping the implementation climate was an original contribution. (S. A. BIRKEN *et al*., 2012)

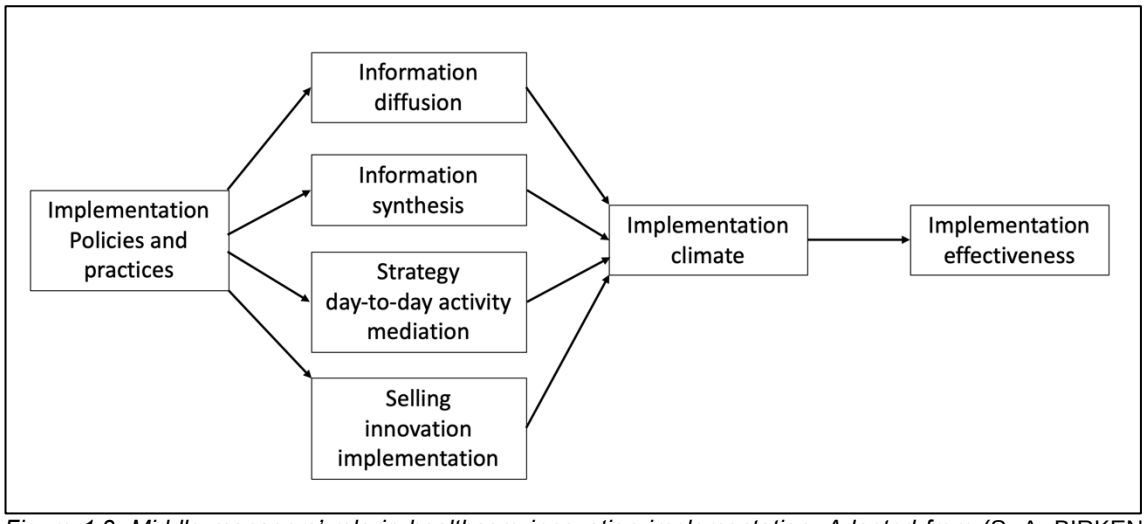

Figure 1.3: Middle managers' role in healthcare innovation implementation. Adapted from (S. A. BIRKEN *et al*., 2012)

- Information diffusion consist on dissemination of facts by middle managers in order to give employees relevant information about the innovation implementation;
- Information synthesis consist on integration and interpretation of facts by middle managers, to reinforce the importance of implementation to employees and the organization;
- Strategy / Day-to-day activity mediation refers to the identification of tasks required for implementation, giving employees the tools necessary to implement them.
- Selling innovation implementation means the justification of innovation implementation and encouraging employees to consistently and effectively.

Previous studies discussed below have already considered the participation of middle managers as relevant members to the organization's strategy (KANTER, 1982; WOOLDRIDGE; FLOYD, 1990; FLOYD; WOOLDRIDGE, 1992; CASTELLANI, 1992; FLOYD; WOOLDRIDGE, 1997;) but their influence on healthcare implementation was first assessed by Birken *et al*. (2012). Authors concluded that “executives may encourage proactivity among middle managers by creating climates in which proactivity is rewarded, supported and expected. (S. A. BIRKEN *et al*., 2013, p.9).

Support from top management can increase middle management commitment, by demonstration on how innovation is important for organization.(S. A. BIRKEN *et al*., 2015). This can be achieved through their involvement in formulating the strategy. (Hovlid & Bukve, 2014). Through participation in the implementation planning, managers can create their own perceptions of the benefit of innovation (VARSI *et al*., 2015)

Urquhart *et al*. (2014) examined the key interpersonal, organizational, and system level factors that influenced implementation and use of complex innovations in cancer care. Five factors were identified as influential to implementation. Among them, authors have highlighted the role of managers promoting stakeholder’s involvement, management of the changing process, leading and championing, in addition to administrative and managerial support. Middle managers played an important role, especially in relation to interpersonal aspects of implementation.

Studies have reported implementation failures related to poor communication between executives and middle managers. This may be due to a lack of training and preparation, in addition to a poor strategic alignment between high and medium level, reflecting a high sense of responsibility for managers. (DAINTY; SINCLAIR, 2017) Rapid and top-down changes associated with a feeling of lack of autonomy can lead middle managers to lose the potential to act as agents of change.(JAVANPARAST *et al*., 2018; URQUHART *et al*., 2018)

To understand their commitment and motivation is also a way to improve effectiveness of implementation. Another study performed by Urquhart *et al*. (2019) found that middle managers’ perception of the ease of implementation and the identification of benefit

for patients have a positive effect on their work. In addition, they highlighted the importance of education of middle managers about the potential benefit of the innovation and their involvement in the planning phase.(URQUHART *et al*., 2019)

Austin *et al.* (2020) sought to identify the readiness of middle managers to change in a qualitative case study, since these professionals "must lead the change" determined by the top managers. Despite this, they also experience changes and, thus, the identification of factors that impact, positively or negatively, their readiness can be a way to improve their motivation and therefore, the employee's commitment to implementation.

1.4 ORGANIZATIONAL INNOVATION ON ORGAN DONATION

Even the leading countries in the donation process have evolved year after year, implementing more efficient systems that reduce losses and failures, and seek to improve safety for all involved, especially recipients.

As stated above, despite the excellent performance, failures have been observed in these procurement systems, bringing opportunities for improvement in recent years. In addition, some countries tried to implement some of these models, such as Germany, and were unsuccessful, resulting in implementation failures and loss of financial and human resources, such as organs that could not be recovered. (TACKMANN; DETTMER, 2019)

Despite all the development of the donation and transplantation area, there are few published studies related to the theme of implementation and sustainability or maintenance over time.

A systematic review was performed with studies that addressed innovation and donation/transplantation research published between 2006 and 2016. Among the thirty-one selected studies, it was found that most had a clinical approach, with a focus on transplantation. Only seven studies had a managerial approach associated to theme of innovation. (SIQUEIRA, 2019)

Publications found through bibliographic research for innovation or implementation associated with the field of organ and tissue donation did not reveal any association with the implementation science approach until the beginning of research related to this thesis.

From analysis of all additional files from a recent systematic review (S. BIRKEN *et al*., 2018), that selected one hundred and five studies, in order to assess middle managers' role in healthcare evidence-based (EBP) practice implementation, there were none that addressed organ and tissue donation field.

Thus, a theoretical gap was identified and an opportunity to apply an area of knowledge, which is the science of implementation of organizational implementation of innovations in order to improve stages of the organ and tissue donation process.

The role of in-hospital coordinators acting as middle managers in the process of organ and tissue donation for transplantation was defined as the subject of study for this thesis.

1.5 CONTRIBUTIONS, ORIGINALITY AND VALUE

The organ donation area is essentially public around the world, and the same applies to Brazil. Our country has a public system with broad healthcare coverage, but it faces serious financial constraints. However, the national system is widely recognized for its values as equity and integrality.(GARCIA *et al*., 2015)

The implementation of an in-house transplant coordinators program is one of the most successful strategies described at national level, but there is a lack of information about the role IHC in the implementation phase and their impact on sustainability of the program, which is reflected by its maintenance. (LENZI *et al*., 2014; SILVA *et al*., 2015; MOURA *et al*., 2015; TONDINELLI *et al*., 2018; ANDRADE; FIGUEIREDO, 2019)

Therefore, we seek to provide an association of in-house transplant coordinators (IHC) and their activities within the implementation of organ and tissue donation local systems with middle managers' role found in innovation implementation literature review among different areas in healthcare as cancer care, quality improvement, primary, mental care and others.

As middle managers, IHC are also subordinated to top managers as hospital directors and/or OPO Directors and need to be in constant contact with all healthcare professionals in their units. We want to assess whether they could be considered important in the implementation and maintenance of policies and practices within the organization in organ and tissue donation, to improve quantity, quality and effectiveness of donation through training and advisory. (MANYALICH *et al*., 2011)

The first article to be presented in Chapter 2, entitled: *Impact of the introduction of full-time internal coordinators on reference and organ donation rates in public hospitals in Rio de Janeiro: a practice of health innovation, the implementation of a Organizational Practice* describes the period of implementation of these managers in four public hospitals and the defined criteria for this choice, analyzing the impact of activities developed from these professionals on organ donation.

It has brought a major impact on the local system, improving indicators related to donor detection, conversion rates and finally, organ donation rates. An innovation of this type was implemented at the local level (Rio de Janeiro state), which was the develop of in-house transplant coordinators fully dedicated to organ donation activities in four public hospitals, through a regional coordination (OPO) and with government support (state health secretary)

IHC roles in management of organ and tissue donation fits with Dressler's classic classification and positioning at organization level: ward chief, clinic director or program coordinator which "develops procedures for implementing institutional policies and is responsible for the operation of a particular service element or elements".(DRESSLER, 1978, p.358)

The term middle management was associated with in-house transplant coordinators for the first time in the literature, since we assume similarity between these activities. Despite this, we were unable to delve into the activities of these professionals in the light of the theory of innovation implementation and the role of middle management. (S. A. BIRKEN *et al*., 2012)

By empirical observation, the implementation of the inhouse coordinator program would result in improvement of organ donation rates in a few years. For that to happen, it is assumed an effective implementation to takes place. (KLEIN; SORRA, 1996)

The second article of this thesis will be presented in Chapter 3, entitled: *Project of Cornea Donation in Rio de Janeiro: Analysis of the Implementation of an Organization Innovation Practice.* The study provides the description of a tissue donation team in order to improve cornea donation, under OPO coordination, through intermediation of the IHC, in one of the previously selected hospitals.

It was described the process of implementation through interaction the IHC as middle managers with the top managers (OPO and hospital directors) and we analyzed this process throughout this paper, from the perspective of tissue donation and in light of science implementation theory.

Floyd and Wooldridge have developed a typology of middle management involvement in strategy. (WOOLDRIDGE; FLOYD, 1990; FLOYD; WOOLDRIDGE, 1992; FLOYD; WOOLDRIDGE, 1997)

Clifford has published UK experience based on alignment of a local government (NHS) modernization agenda focusing on middle managers as changing agents aiming at employees. (CLIFFORD, 2001). In Brazil, and in most countries, donation and transplantation are mostly public activities.

Top managers can increase the commitment of the middle managers through support, and involvement of IHC in the formation of the strategy and implementation of tissue donation activities and planning may promote this support (HOVLID; BUKVE, 2014; VARSI *et al*., 2015; S. A. BIRKEN *et al*., 2015)

Urquhart *et al* (2014) identified relevant roles for middle managers that influenced implementation as role of managers promoting stakeholder's involvement, management of the changing process, leading and championing, in addition to administrative and managerial support. They highlighted an important role regarding interpersonal aspects of implementation.

Some successful initiatives have been documented in our country with good results when strategic planning at the central level is aligned with interventions
such as those previously described: training and education, development of tools for donor identification and/or referral, and family support by trained professionals. (LENZI *et al*., 2014; SILVA *et al*., 2015; MOURA *et al*., 2015; TONDINELLI *et al*., 2018; ANDRADE; FIGUEIREDO, 2019)

Finally, during the third article entitled: *The role of in-house transplant coordinators as middle managers in organ donation rates in Rio de Janeiro: from implementation to sustainability,* provides a deeper overview of the activities and strategies carried out by the IHC, in order to have a broader and more detailed approach to the implementation process

We reported the performance of the IHC project over the 8 years and when comparing it with a control group of hospitals with similar characteristics, we sought to bring a theoretical and practical contribution from the adoption of this innovation.

A quantitative analysis was performed, using two statistical methods: bootstrap analysis and T-test (Students' test), using a retrospective control group in which the innovation was not implemented, in order to verify whether the presence of the IHC has a significant impact on results, from 2011 to 2018.

A qualitative analysis was also performed through semi-structured interviews with IHC that were involved in the implementation project, aiming to assess their role as middle managers, addressing the four domains described by Birken *et al* (2012): information diffusion, synthesizing information, mediating between strategy and day-to-day activities and Selling innovation implementation.(S. A. BIRKEN *et al*., 2012)

This dissertation aims to provide a theoretical contribution, through the application of theories from innovation implementation with organ and tissue donation field, positioning the IHC as middle managers, addressing their role in middle management and proposing a domain of influence on the sustainability or maintenance of innovation.

With the quantitative and qualitative results presented, it also brings a practical contribution to management strategies, with several actions carried out by the coordinators aimed at improving the organ and tissue donation process.

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2 IMPACT OF INTRODUCING FULL-TIME IN-HOUSE COORDINATORS ON REFERRAL AND ORGAN DONATION RATES IN RIO DE JANEIRO PUBLIC HOSPITALS: A HEALTH CARE INNOVATION PRACTICE

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BACKGROUD

Establishing an organization to promote organ donation and a good organ procurement team assure quality and improve performance on organ donation rates. Brazil's organ procurement structure is based on 2 models disseminated worldwide: the "Spanish model," based on in-house coordinators, and the "American organ procurement organization (OPO) model," with extra-hospital coordinators. In 2006, Brazil's Federal Government had formally introduced the in-house coordination model for every hospital equipped with a mechanical ventilator bed. In January 2012, the Rio de Janeiro State OPO, *Programa Estadual de Transplantes*, introduced an innovation in the organization of the in-house coordination model in 4 selected public hospitals with high organ donation potential. It consisted in launching full-time in-house coordination teams, with ≥ 1 physician and 2 nurses per hospital fully dedicated to organ procurement.

OBJECTIVES

The objectives were to observe the impact of this innovation in referral and organ donor conversion rates and to analyze the importance of middle managers in health care innovation implementation.

METHODS

Comparing the year before implementation (2011) and the year of 2014 showed that this innovation led to an overall increase in referrals - from 131 to 305 per year (+132%) and conversion rates - from 20% to 42% per year resulting in an increase in number of donors from 26 to 128 per year (+390%).

CONCLUSION

Despite wide variations among hospitals in the outcomes, our results seem very encouraging and express a positive impact of this model, suggesting that dissemination to other hospitals may increase the number of donors and transplants in our region.

2.1 INTRODUCTION

Organ shortage is a worldwide issue, and the pursuit for maximization of the number of organ donors is an effort that every country should do, according to the World Health Assembly.(WORLD HEALTH ASSEMBLY, 2010) For many years, countries have adopted different strategies to achieve this goal, but whether a strategy is ethical and acceptable is also an important concern.

For this reason, worldwide specialists and different members of society gathered in a meeting at Istanbul from April 30 to May 2, 2008, according to the World Health Organization Guiding Principles on Human Cell, Tissue, and Organ Trans- plantation (*World Health Organization. Guiding principles on human cell, tissue, and organ transplantation*, n.d.), “to address the urgent and growing problems of organ sales, transplant tourism, and trafficking in organ donors in the context of the global shortage of organs”.(“The Declaration of Istanbul on Organ Trafficking and Transplant Tourism,” 2008)

According to these principles established, most countries have focused their attention on increasing organ transplants through obtaining more deceased donors. For this purpose, 2 models became more frequently adopted worldwide: 1) the “Spanish model,” based on in-house transplant coordinators (IHCs) where the donation staff is located directly within the donor hospitals (MATESANZ, 2003)·(MANYALICH *et al*., 2011)·(MATESANZ *et al*., 2011) ; and 2) “the American model,” based on organ procurement organizations (OPOs) where the coordinators are located in facilities outside of the hospitals.(NATHAN *et al*., 2003)

Whether one model is more efficient than the other is a matter of deep analysis and discussion, owing to different characteristics among countries and regions resulting in wide variation in organ donation rates.(DONATION & TRANSPLANTATION INSTITUTE, 2014)

In Brazil, a developing country, both models have been accepted since October 2009, when new regulation was approved from the National Transplant System, applying the current National Transplant Law.(Portaria 2600/2009, 2009) At that time, despite the

possibility of implementation of any of these models, most State OPOs were presenting low organ donation rates.(ASSOCIAÇÃO BRASILEIRA DE TRANSPLANTE DE ÓRGÃOS, n.d.)

In 2010, the State of Rio de Janeiro adopted a new organizational model for organ donation, combining strategies and design of both models in a more efficient way through innovation practices after launching the remodeled State OPO, *Programa Estadual de Transplantes* (PET).(LENZI *et al*., 2014) Some reports have shown that this practice had a positive impact on donor detection, through OPO referral and conversion rates when the OPO model was already established.(SALIM *et al*., 2007),(SHAFER *et al*., 2003)

The aim of the present study was to analyze the impact of IHCs working as middle managers on referrals, conversion rates, and number of donors.

2.2 METHODS

As part of an isolated initiative, in January 2012, one of the 160 hospitals in the OPO area, *Hospital Estadual Adão Pereira Nunes* (HEAPN) placed 1 nurse as full-time IHC. This innovation, a new organizational practice, led to an 88% increase in the number of brain-death referrals and a 200% increase in the number of organ donors in the 1st year in that facility.

In February 2013, the OPO directors met the Secretary of Health of the State of Rio de Janeiro to set up a program of IHCs in 4 public trauma hospitals that appeared to have high potential for organ donation, with more than 150 beds and neurosurgical service.

As part of these 4 hospitals, HEAPN would improve the IHC service in the following years with 1 physician and 3 nurses, as well as the other 3 selected facilities (Hospital Estadual Getúlio Vargas, Hospital Estadual Albert Schweitzer, and Hospital Estadual Alberto Torres).

Evaluation of the IHC performance was made comparing the year before its implementation (2011), when no intervention was made, and the year of 2014, when all hospitals had the IHC implemented. All data were obtained from the PET database.

2.3 RESULTS

Table 2.1 summarizes results obtained after the implementation of IHCs at the 4 hospitals selected since 2011, when none of these units had IHCs implemented and the OPO (PET) assisted all cases of potential organ donors.

Comparing the year 2011, the sum of brain-death referrals in the 4 hospitals accounted for 131 potential organ donors and 26 effective donors. At the end of 2014, all hospitals together accounted for 305 brain-death referrals and 128 effective donors, an increase of 132% and 390%, respectively. The conversion rate also increased from 20% to 42%.

Table 2.1: Performance of hospitals from 2011 to 2014

	HEGV		HEAPN		HEAT		HEAS		All Hospitals	
YEAR	Donors	CONV (%)	Donors	CONV (%)	Donors	CONV (%)	Donors	CONV (%)	Donors	CONV (%)
2011	14	19	9	29	1	17	2	66	26	20
2012	21	26	27	28	3	33	1	17	52	27
2013	26	32	30	34	10	25	1	4	67	28
2014	30	43	49	55	41	39	8	20	128	42

Fonte: Author

Abbreviations: HEGV, Hospital Estadual Getúlio Vargas; HEAPN, Hospital Estadual Adão Pereira Nunes; HEAT, Hospital Estadual Alberto Torres; HEAS, Hospital Estadual Albert Schweitzer

2.4 DISCUSSION

For the organization, set-up, and management of an organ procurement system, multiple aspects must be evaluated in terms of successful existent models and tools available. No less important, local and cultural characteristics must be understood and analyzed, owing to the peculiarities of each country and region.

In fact, innovation is defined as “an idea, practice, or object that is perceived as new by an individual or another unit of adoption”.(ROGERS EM, 1995, p.11) After 2010, PET implemented a few innovations in the State of Rio de Janeiro considering variables listed above, including a benchmarking strategy with others states in Brazil and other countries.

Because education and training are 2 of the most common interventions for obtaining an efficient organ procurement model (MATESANZ *et al*., 2011), (LENZI *et al*., 2014), (MULVANIA *et al*., 2014), PET adopted the Transplant Procurement Model (TPM) training for its 1st 4 years, when 200 transplant coordinators where trained.

Because a local experience resulted in an increase in brain-death referrals, conversion rates, and number of organ donors in a single hospital, when in 2012 HEAPN had placed a nurse as fully dedicated procurement staff, and with evidence already shown that combining both the Spanish and the American models could be successful,(SHAFER *et al*., 2003; SALIM *et al*., 2007), a strategic plan was set to place IHCs in hospitals with high potential for organ donation, where ≥1 physician and 2 nurses, with advanced training (TPM) and full dedication, would be part of the procurement staff.

Because scientific data suggests that hospitals with more than 150 beds and the presence of a neurosurgical service are correlated with the number of potential donors (SHEEHY *et al*., 2003), 4 public hospitals were selected with these characteristics with the use of data obtained from Hospital Development at PET.

Considering the importance and need for rapid change in the scenario of organ donation in the state, the implementation of this innovation needed to be efficient. The strategic plan and goals planned by the Secretary of Health and the OPO directors would be implemented by the IHCs, acting as middle managers and disseminating all over each hospital. Besides, it was also important for the IHC to bring value to all brain-death patient families and hospital employees.

Observing the impact of an IHC on referrals, conversion rates, and number of donors, we concluded that this hybrid model should be considered for regions where high-potential hospitals are located and low performing.

In addition, we wanted to analyze the implementation period, where these professionals, classified as middle managers, would help the diffusion of the information and mediation between strategy and day-to-day activities, and selling innovation implementation, as shown by theory. We assumed that this level of management was related to the fast results obtained.(BIRKEN *et al*., 2012)

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3 PROJECT OF CORNEA DONATION IN RIO DE JANEIRO: ANALYSIS OF THE IMPLEMENTATION OF AN ORGANIZATION INNOVATION PRACTICE

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BACKGROUD

For many cornea disorders, transplantation can be the treatment of first choice. In Brazil, there is a disparity in the number of transplants between regions due to the lack of an oriented system for cornea procurement. The aim of this study was to analyze the implementation of a system exclusively oriented toward the improvement of cornea recovery in the Rio de Janeiro State Organ Procurement Organization (OPO) area. With this system, all cornea donation activities were coordinated by the OPO after telephone referrals following asystolic death. From the perspective of health care innovation, we will discuss the role of the main participants and their interactions following the implementation phase.

METHODS

One hospital was chosen to host the project following the first 2 years of the implementation of the State Cornea Donation System. We retrospectively analyzed all deaths between January 1 and December 31, 2016, using the hospital death records and the OPO referrals record. The strategic plan, documents, and interviews were carried out for the analysis of the implementation of this innovation in our region.

RESULTS

Of 1720 deaths in 2016, 1093 (63.5%) were referred to the OPO following asystolic death for assessment and screening, but 819 of these potential tissue donors (PTDs) were not eligible for donation due to medical contraindications. The remaining 274 (25.1%) fulfilled the PTD criteria. Less than half of the families (n 1⁄4 128) of these PTDs could be contacted requesting donation, but 50% consented. Finally, corneas were pro- cured from 58 patients. The interactions between in-house coordinators and top managers were mandatory for the success of program implementation.

CONCLUSION

For the first time in our country, cornea recovery took place following asystolic death with OPO coordination at a central level. The PTD rate could be estimated, and an analysis of the role of stakeholders could be made for the implementation phase of this innovation in our system.

3.1 INTRODUCTION

Cornea transplantation is reported as one of the oldest transplant procedures, with the first surgeries performed in the 1930s.(GARCÍA-SOUSA *et al*., 1999) Despite corneal transplantation being the most frequent surgery among all types of transplants, cornea diseases are still the major cause of vision loss, producing psychological and economic consequences for the individual and society as a whole.(WHITCHER *et al*., 2001)

In many countries the number of corneas procured is insufficient to meet the demand for transplants for several reasons. These include poor identification and referral of potential tissue donors (PTDs), medical contraindication, and family refusal and logistical issues, with the last one representing the main cause of inefficiency.(MURAINE, 2002),(GAIN *et al*., 2002),(BREDEHORN *et al*., 2002)

In Brazil, the number of corneal transplants has been decreasing since 2012, as has the number of patients on the waiting list. In 2014, 13,000 (68.3 transplants pmp) were performed, while the estimated annual demand was more than 17,000 (89 transplants pmp). There is still a disparity in the number of transplants between regions in Brazil, varying from 136.6 pmp (Brasília, Federal District) to 14.7 pmp (state of Rondônia).(ASSOCIAÇÃO BRASILEIRA DE TRANSPLANTE DE ÓRGÃOS, 2014)

An improvement in organ donation has taken place in Rio de Janeiro since 2010, with the deceased donor rate increasing from 5.1 pmp in 2010 to 17.0 pmp in 2014. This shift was due to a new organizational model for organ procurement through the launch of a remodeled State Organ Procurement Organization (OPO) - the *Programa Estadual de Transplantes* - but the strategy to increase the number of brain-dead donors (DBDs) was unable to meet the demand for corneas and other tissues.(Sarlo *et al*., 2016),(BONFADINI *et al*., 2014). Until 2014, all transplants were performed from tissues recovered from DBDs. In the same period, 301 cornea transplants were performed (18.8 pmp), while the estimated demand was more than 1400 surgeries.(ASSOCIAÇÃO BRASILEIRA DE TRANSPLANTE DE ÓRGÃOS, 2014)

The objective of this study was to analyze the implementation of a system exclusively oriented toward the improvement of cornea recovery and the results of the system

following the first 2 years. From the perspective of health care innovation implementation, we will discuss the role of the main participants and their interactions from conception through implementation effectiveness.

3.1.1 Implementation of a State Cornea Donation System

In 2014, a strategic plan was made to implement a cornea donation system in the state of Rio de Janeiro, with the first goal being to increase cornea recovery and transplantation through donation following asystolic death. The main stakeholders were identified: the OPO, tissue banks, and general hospital staff.

The objective was to set up an innovation in the local health care system that consisted of telephone referrals from local hospitals to the OPO of all deaths following cardiac arrest. Thus, the OPO should coordinate at the central level all tissue donation activities. Every PTD should be identified - that is, any deceased person with no medical contraindication for tissue donation and from whom blood samples could be obtained for serologic tests.(PONT *et al*., 2003)

Since it has been demonstrated that the PTD rate varies from 18% to 40% among all hospital deaths, it was hypothesized that this strategy could maximize cornea donation across the state. (PONT *et al*., 2003), (BARBOZA *et al*., 2007),(MELLO *et al*., 2010) In fact, timely referral to an OPO following asystolic death already a standard practice in some procurement organizations worldwide, but it had never been done in Brazil with this level of commitment. It has been demonstrated that this practice provides an efficient cornea recovery system.(BREDEHORN *et al*., 2002), (CARAMICIU *et al*., 2014)

The OPO Cornea Team started operating on January 1, 2015. Ten professionals, including physicians, nurses, and social workers, were admitted to the team to work in 24-hour shifts as OPO transplant coordinators, doing assessment and screening by phone of all deaths reported by hospitals. When a PTD is identified, the OPO must coordinate the interface between the hospital staff, through its in-house coordinator

(IHC), and the tissue bank that will perform the recovery. Two ophthalmologists were responsible for training, education, and supervision of nonmedical staff.

At the hospital level, one of the main trauma centers in the state, *Hospital Estadual Adão Pereira Nunes* (HEAPN), was chosen to host the pilot project due to its characteristics and high performance in organ donation in the past years. In this hospital, 4 IHCs were working fully dedicated to organ donation as a result of a health policy implemented a few years before.(SARLO *et al*., 2016)

In fact, there was a previously unsuccessful project for cornea retrieval in progress at the hospital, which had been implemented in January 2013. By that time, the tissue bank had set up a cornea recovery team to work inside the hospital in 24-hour shifts to detect PTDs and to recover corneas. No corneas were recovered from cardiac-arrested patients; they were recovered only from brain-dead patients. There was little engagement of hospital staff in cornea procurement and no relationship between the recovery team and the hospital's director board beyond a formal consent to the activities.

Considering the poor performance and the need for improvement, it was assumed that the engagement of the IHCs with a higher level of support from the top managers would be crucial. In April 2015, the tissue bank cornea recovery team was dismissed, and several meetings between the top managers from the OPO, the tissue bank (*Banco de Olhos do Hospital São João Batista*), and the hospital were held to implement the innovation. The initial aim was to sell the innovation to the hospital's top management team (TMT) and get their commitment in the assimilation process. It was assumed that this would help to effectively implement the innovation.(PANZANO *et al*., 2012)

With TMT support, all IHCs were highly involved and trained for adequate assessment of PTDs, physical examination of tissue samples, and obtaining blood samples after cardiac arrest from a central vein or the heart, if necessary. At the same time, lectures and basic training were held for all hospital staff with the aim of engagement toward cornea donation. A protocol was established for referral of all deaths in real-time to the OPO.

3.2 MATERIAL AND METHODS

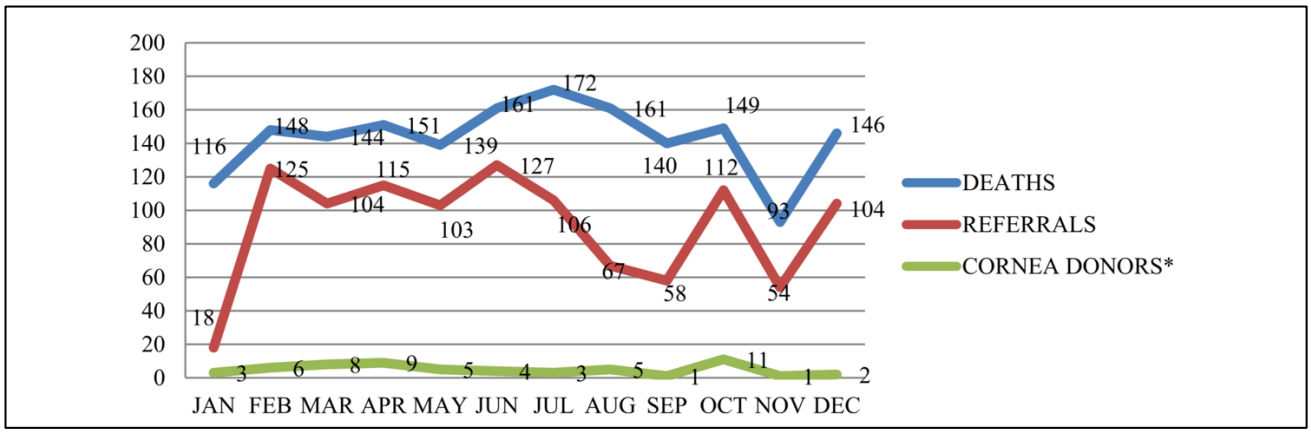
We retrospectively analyzed all deaths between January 1 and December 31, 2016, using the hospital death records and the OPO referrals record. The hospital death records worksheet inputs were name, hospital ID number, age, time of death, department, and cause of death. The IHC also registered whether a family request was made and, if no donation was made, the reason for that. The OPO record had the same inputs, but it was limited to deaths referred from hospital staff.

A comparison of hospital death records with OPO referral records was made to identify missed referrals. For estimating the number of PTDs and the potential of the hospital for cornea donation, death causes were grouped into 6 categories: infectious, neoplasia, cardiovascular disease, trauma, undetermined, and others.

The strategic plan and other relevant documents were gathered. The main participants from the IHCs, OPO, and tissue bank were interviewed to clarify their interactions and roles in the project during the implementation phase.

3.3 RESULTS

Figure 3.1 summarizes the number of cornea donors from January to December 2016 at HEAPN procured by this protocol. The main steps of innovation implementation described above are also summarized. Of 1720 deaths in this period, only 1093 (63.5%) were reported to the OPO for assessment and screening by phone, with subsequent physical examination and family approach by either the IHC or tissue bank staff.



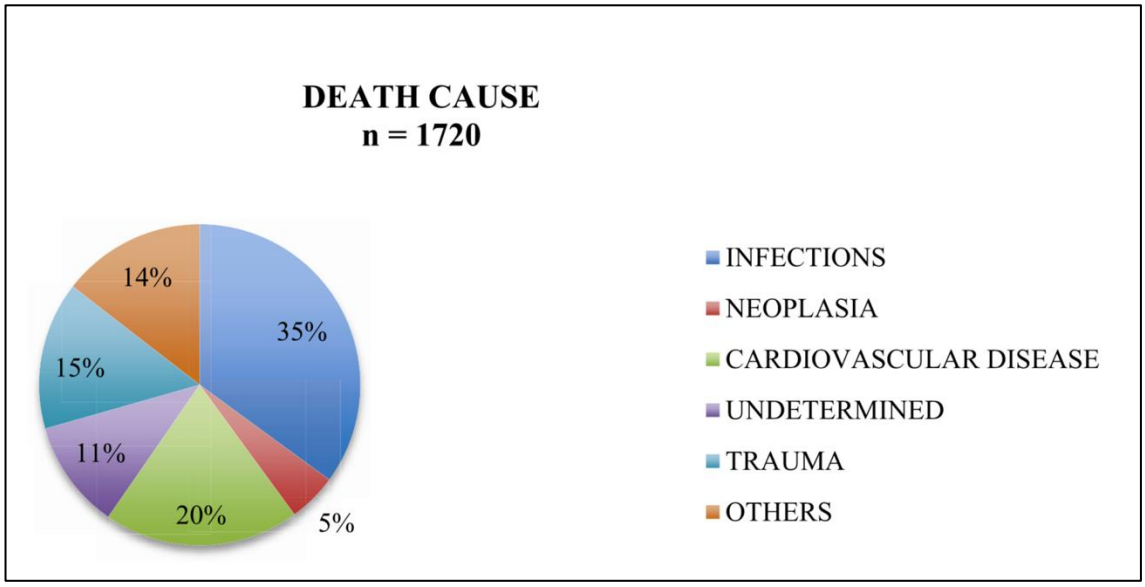
*Graphic 3.1: Number of deaths, referrals to the OPO, and cornea donors from January to December 2016 at the hospital (HEAPN). *Corneas procured from brain-death donors are not included in this figure, as this activity is not influenced by the protocol examined in this report.*

From the 1093 deaths referred to the OPO, 819 were not eligible for donation due to a medical contraindication (74.9%), having been assessed clinically by a transplant coordinator or staff from the tissue bank. The remaining 274 patients (25.1%) fulfilled the PTD criteria.

Of the 274 PTDs assessed, 102 families did not receive requests for tissue donation due to lack of infrastructure, and in 44 additional cases, the family could not be found. In total, 128 families received requests for donation, and 50% of them consented for cornea donation. From the 64 authorizations obtained, corneas were procured from 58 patients.

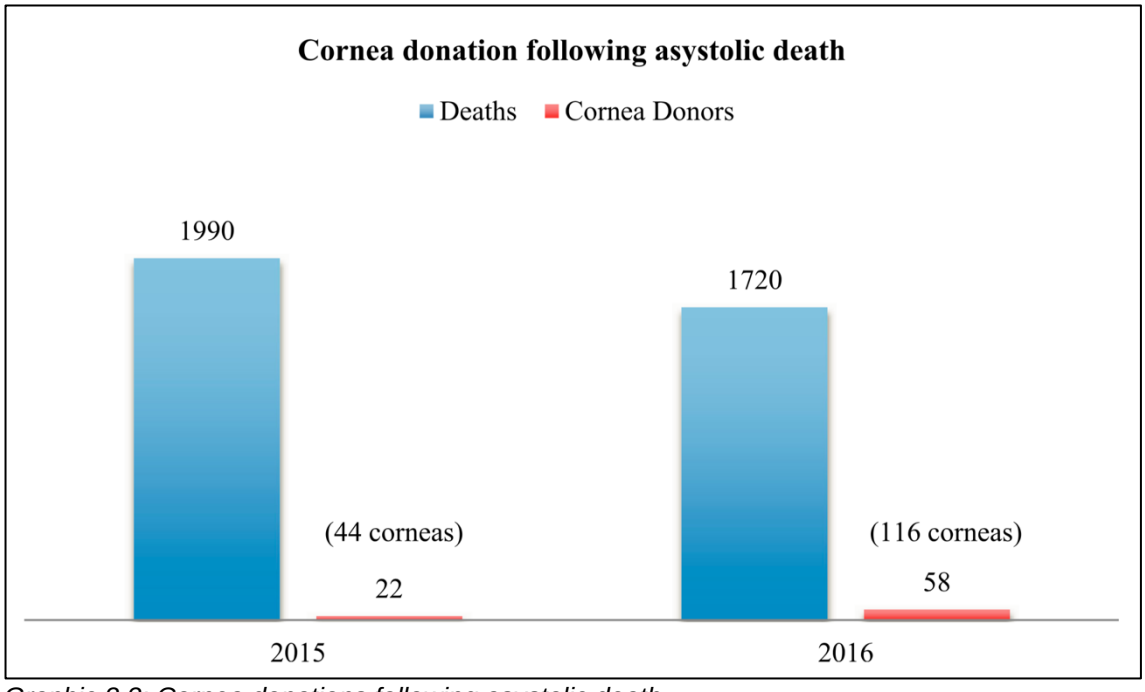
We retrospectively analyzed all deaths (n = 1720) from the hospital death reports to estimate the losses due to missed referrals. From this analysis, 1027 patients (59.7%) had a clear medical contraindication for cornea donation, including sepsis, some specific types of cancer or risk group, or infection with human immunodeficiency virus or hepatitis B or C virus. The 693 remaining patients classified as PTDs would be, in theory, eligible for cornea donation.

Figure 3.2 summarizes the main causes of death at HEAPN during 2016. The main cause was infection of any type (n = 595, 35%), following by cardiovascular disease (n = 334, 20%) and trauma (n = 253, 15%).



Graphic 3.2: Main death causes at the hospital (HEAPN) in 2016

Figure 3.3 demonstrates the number of cornea donors during the first 2 years of the project. In 2014, no corneas were retrieved from cardiac-arrested patients despite the maintenance of the tissue bank cornea recovery team. In 2015, 44 corneas were retrieved from 22 donors following asystolic death, and the following year showed a growth of 163%, with 116 corneas retrieved from 58 donors following asystolic death.



Graphic 3.3: Cornea donations following asystolic death

3.4 DISCUSSION

A shortage of tissue grafts, as corneas, skin, vessels, and bones, is a reality worldwide. The lack of donor tissue procured is the limiting factor for treating many diseases. Endothelial abnormalities and keratoconus represent the leading indications for cornea transplantation.(DAPENA *et al*., 2009),(DUMAN *et al*., 2013)

Apparently, the lack of a tissue donation-oriented system seems to be the main reason for the inefficiency in many countries and regions, due to its peculiarities. In the state of Rio de Janeiro, the OPO launched in 2010 was initially focused on maximizing the number of DBDs, from whom both organs and tissues can be recovered. There was a substantial increase in the number of cornea transplants when 2009 is compared to 2014, with 88 (5.7 pmp) procedures performed in 2009 and 301 (18.8 pmp) in 2014 [6,8]. The number of surgeries was still below the necessity, however, as it had already been demonstrated that the number of brain-dead patients was insufficient to meet the demand for corneas. Brain death is a rare event, representing only 0.5% to 1% of all deaths in a population.(SHEEHY *et al*., 2003),(HOYERT *et al*., 2001)

Studies have demonstrated a considerable variability in the rate of PTDs (any deceased person with no medical contraindication for tissue donation and from whom blood samples can be obtained for serologic tests) in different regions, varying from 18% to 40% among all deaths, ac- cording to hospital profiles.(PONT *et al*., 2003), (BARBOZA *et al*., 2007), (MELLO *et al*., 2010) So, except for medical contraindications, logistical issues represent the main cause for inefficiency in this process. These include low or no referral of deaths to the IHCs or the OPO, early removal of the body from the morgue, inability to cool the body in proper temperature, unavailability of the recovering room due to autopsy; unavailability of the recovering team in time for the procurement, and inability to contact or meet the family of the deceased patient.(GAIN *et al*., 2002)

Implementing a cornea donation system oriented toward detection, screening, and adequate timely assessment of PTDs is a challenge, especially in our reality, where the main hospitals are public and most of their staff are unaware of this activity. This is the main reason that we wanted to perform this study, to describe the steps of the

implementation and the results and correlate them with the literature of health care innovation implementation so that new theoretical constructs can be identified and applied to clinical practice in the future.

As mentioned before, HEAPN is one of the main trauma centers in the state of Rio de Janeiro. Since 2012, the hospital has been developing strategies to improve organ and cornea donation rates. In that facility, there is a highly skilled and fully dedicated IHC team composed of 1 physician and 3 nurses. Despite this, performance with regard to cornea donation following asystolic deaths was negligible. Cost had increased in 2013 when the tissue bank decided to hire professionals, but the results were still unsatisfactory.

In 2015, the OPO was involved together with hospital top managers, and, finally, the IHC work routines were rebuilt, especially with the designation of one of the nurses for cornea donation activities. Then, as shown earlier, the cornea donation rates improved, and cost was reduced at the hospital level. At the OPO level, a highly specialized team was settled on in anticipation of a bigger demand in the future, when more hospitals and activities should be integrated to generate more corneas for transplantation.

It is important to highlight that missed referrals from HEAPN accounted for the loss of detection of more than 400 PTDs, since 36.5% of all deaths were not reported to the OPO. Lack of infrastructure is still a major cause of the lower conversion rate following PTD identification. Thus, with optimization of referral activity and performance improvement, it may be possible to reach up to 300 cornea donors every year.

As a result of the change in mentality throughout the whole system, the number of transplanted corneas in our region increased from 301 (18.8 pmp) in 2014 to 575 (34.7 pmp) in 2016. The State Cornea Donation System resulted in an improvement of more than 90% in cornea transplantation following the first 2 years of implementation.

3.4.1 **Analysis from a healthcare innovation implementation perspective**

Innovation is defined as “an idea, practice, or object that is perceived as new by an individual or another unit of adoption”.(ROGERS EM, 1995, p.11) Health care is rich in evidence-based innovations, yet despite a successful implementation in one facility, many cases of innovation may disseminate slowly.(BERWICK, 2003)

For organ and tissue transplantation, a huge effort has been made worldwide toward the dissemination of best practices through benchmarking and innovation implementation.(WORLD HEALTH ASSEMBLY, 2010) In spite of this effort, there is still a huge difference among countries, with multiple factors influencing donation and transplantation activities, such as economics, politics, and sociocultural behavior, which are also affecting other innovations in health care.(DONATION & TRANSPLANTATION INSTITUTE, 2014)·(DENIS *et al*., 2002)

This study aimed to analyze the implementation period, which is “the transition period [during] which targeted organizational members ideally become increasingly skillful, consistent, and committed in their use of an innovation”.(KLEIN; SORRA, 1996) Considering that the proposed innovation (the implementation of a protocol for interaction between the hospital [HEAPN] and the OPO [*Programa Estadual de Transplantes*]), came from an outsider organization, the assimilation process was assumed to be a crucial step. Assimilation is defined as an organizational process that 1. begins when organizational decision-makers first become aware of an evidence-based health care innovation (EBHI), 2. can lead to the adoption of the EBHI, and 3. may culminate in the EBHI’s routinization or institutionalization by adopter organizations.(YIN, 1977)

Studies have been published to identify particular factors that may influence the implementation phase and stakeholder involvement, management of the change process, championship behavior, and administrative and managerial support, and the most relevant innovation attributes recently have been described.(URQUHART *et al*., 2014) A qualitative analysis would be an elucidating tool for identification of these factors in our project.

After involvement of the TMT and their assimilation with subsequent support behavior, the death referral protocol has been started. The interaction between hospitals' TMTs and the local IHC teams acting as middle managers in this scenario possibly influenced positively the implementation process. TMTs may increase middle managers' commitment in many ways, such as by directly conveying to them that innovation implementation is an organizational priority, allocating implementation policies and practices, and even encouraging middle managers to leverage performance reviews and human resources to achieve innovation implementation.(BIRKEN *et al*., 2015)

In fact, the role of the IHCs as middle managers in this innovation should be better understood, since these professionals, as nurses, social workers, and intensive care unit doctors, have a strategic location between the TMT and frontline employees. Since the IHCs are the specialized donation professionals, their role in implementation with sensibilization and diffusion of the innovation may be considered as fundamental.(BIRKEN *et al*., 2012)

From what we know, our study is the first to document the implementation of a regional system exclusively oriented toward cornea recovery in Brazil, reporting a complex interaction between managers. The approach and analysis from the innovation implementation point of view is also original and can bring ideas to other projects within the organ and tissue donation field, but also for the health care system as a whole.

3.5 CONCLUSION

From our analysis of the data obtained from hospital and OPO administrative registers and comparison of these data with previous articles published, it is clear that a better result could be obtained. First of all, only 63.5% of all deaths were referred to the OPO, which limited the number of PTDs available for screening and assessment. In addition, logistical problems such as lack of infrastructure at the hospital or lack of a specialized professional also played an important role in the final results.

This study contributed to the estimation of PTDs in our population, since no data were available until now in the Rio de Janeiro State OPO area. At HEAPN, there may have

been up to 693 PTDs (that would be eligible in theory for donation), and with a performance improvement, it may be possible to reach up to 300 cornea donors every year.

An integrated system with specific policies and practices for cornea donation is critical to achieving satisfactory results. In Rio de Janeiro, the engagement of all stakeholders was possible due to a solid strategic plan from top managers and an efficient execution from middle managers.

Further studies will be needed to measure the implementation effectiveness and improve the number of cornea and tissue donors, but this study can bring an optimistic vision for the health care and transplant system in our region.

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4 THE ROLE OF IN-HOUSE TRANSPLANT COORDINATORS AS MIDDLE MANAGERS IN ORGAN DONATION RATES IN RIO DE JANEIRO: FROM IMPLEMENTATION TO SUSTAINABILITY

BACKGROUD

The implementation of an innovation is a complex process and is influenced by multiple factors. The role of different level of managers have been subject of many studies through last years.(S. BIRKEN *et al*. 2018)

The Spanish model for organ and tissue donation has become one of the most successful, since an in-house transplant coordinator (IHC) is responsible for setting up all activities related to the donation process. Despite this, some have failed to implement it, with a lower than expected number of donors and fewer transplants as a result. Thus, poor implementation of an organ procurement program can lead to a huge economic and social impact.

Since IHC fit into the categorization of middle managers from implementation science's perspective, we sought to analyze their impact on implementation phase within the hospital, in donation and transplantation field.

METHODS

For this study, we performed both quantitative and qualitative analysis.

For the quantitative analysis, a bootstrap and a T-Test (Students' test) were made to compare retrospectively a group of 4 hospitals where a full-time IHC project was implemented with a control group of 4 hospitals with similar characteristics, but without an IHC fully dedicated program. We aimed to assess whether the presence of the IHC has statistical significance in organ donation rates within an 8-year period (2011 to 2018)

For qualitative approach, semi-structured interviews were performed with 8 IHC that were involved with the implementation of the project. Thematic coding was applied to seek association with the domains from the theory of middle managers role on innovation implementation, but also to identify activities performed by these managers as IHC and to search for domains not previously identified or described.

RESULTS

During the study period, the intervention group had 711 organ donors, while the control group had 232 organ donors. The implementation of an IHC project led to a performance improvement between 20 and 33% in this sample (95% CI). We found that up to 340 organ donors could be obtained in the control group, resulting in almost 800 organs transplanted, if this group had implemented the project.

The interviews allowed to identify crucial activities of IHC for the implementation and address them to middle managers' role on innovation implementation theory (S. A. BIRKEN, Lee, and Weiner 2012), but also to detect a new influence domain for these

managers, positively influencing the sustainability of this innovation, at least in donation field.

CONCLUSIONS

The implementation of IHC optimize the donation process and increase organ donation rates.
The comprehension of IHCs role, in the light of the theory of middle managers can improve this process in regions with already consolidated results, in addition to offering a perspective of reversing implementation failures in unsuccessful cases.

4.1 INTRODUCTION

Establishing a solid transplant system is a worldwide challenge. Most regions that have reached this level have done so by implementing efficient organ procurement systems, targeting high deceased organ donation rates, with a direct impact on the increase in the number of transplants.

The Spanish model has become one of the most successful, since an in-house transplant coordinator (IHC) is responsible for setting up all activities related to the donation process. The transplant coordinator's main goal is "to increase the quantity, quality, and effectiveness of organ and tissue donation by training and advising healthcare professionals in the major steps of the donation process". They need to "be skilled in personal and professional relationships to be locally accepted and acknowledged, supported by hospital managers, and paid for their work."(MANYALICH *et al*., 2011)

Middle managers are professionals that have the ability to establish an effective connection between the strategy designed by top managers and the execution performed by employees. (S. A. BIRKEN, *et al*., 2012) These professionals were identified as highly relevant to the successful implementation of innovations and have been the object of study in several fields, but in a very superficial way in donation and transplantation field.(R. Sarlo *et al*., 2016; S. BIRKEN *et al*., 2018; R. A. SARLO; VARGAS, 2019)

Failure to implement an organ procurement program can lead to an impact that is difficult to measure, with waste of organs and loss of thousands of lives

The implementation of an innovation is a complex process and is influenced by multiple factors. Since IHC fit into the categorization of middle managers from implementation science's perspective, we sought to analyze their impact on implementation phase within the hospital, in donation and transplantation field.

For this study, we performed both quantitative and qualitative analysis. For the

quantitative analysis, we compare retrospectively a group of 4 hospitals where a full-time IHC project was implemented with a control group of 4 hospitals with similar characteristics, but without an IHC fully dedicated program, using a bootstrap analysis. We aimed to assess whether the presence of the IHC has statistical significance in organ donation rates within an 8-year period (2011 to 2018)

For the qualitative approach, semi-structured interviews were performed with 8 IHC that were involved with the implementation of the project. Thematic coding was applied to seek association with the domains from the theory of middle managers role on implementation, but also to identify activities performed by these managers as IHC and to search for domains not previously identified or described.

We will present a discussion about organ donation, focusing on in-house transplant coordinators and then on implementation theory, focusing on middle managers.

After these sessions, the results will be presented followed by the discussion and final conclusion

4.2 ORGAN DONATION

According to World Health Organization (WHO), ethical principles should guide healthcare leaders to provide equitable and transparent transplant systems worldwide, pursuing quality for the process and safety to all people involved.(MARTIN *et al*., 2019) Despite cultural and socioeconomical differences between countries and regions, in addition to local legal issues, all strategies to improve donation and transplantation must be in line with international standards.(MULLER; DOMINGUEZ-GIL; MARTIN 2019)

As organ donation is an altruistic act, most efforts to maximize the number of transplants should focus on building an efficient system for procurement of deceased donors.(RUDGE *et al*., 2012; HALLDORSON; ROBERTS, 2013; DOMÍNGUEZ-GIL; MURPHY; PROCACCIO, 2016) A more broad approach should consider developing policies to prevent chronic diseases progression, expand donor utilization criteria, consider implementation of nonheart-beating donation program, develop new

techniques through research & development and improve graft survival.(ROELS; RAHMEL, 2011; DOMÍNGUEZ-GIL *et al*. 2011)

Nevertheless, the practice with the higher quantitative impact for transplantation is still the optimization of procurement of brain-dead donors.(KAZEMEYNI; AGHIGHI, 2012; R. MATESANZ *et al*., 2017) Two organizational models have become more accepted worldwide and although both have highly skill professionals, advanced training programs and protocols, they differ in relation to the role of the transplant coordinator: procurement at the Organ Procurement Organization (OPO) level, known as “the American Model”, or at the hospital level (or in-house), known as “the Spanish Model”.(RAFAEL MATESANZ, 2003; MANYALICH *et al*., 2011; NATHAN *et al*., 2003)

In the past years, both models have been implemented and adapted around the world, or even used in combination with optimized results.(SALIM *et al*. 2011; LEE; KIM, 2009; GARSIDE *et al*., 2012; R. SARLO *et al*., 2016; ANDRADE; FIGUEIREDO, 2019;) Some have recognized the potential for improvement in the application of these models and proposed it as a way to improve their local transplant systems.(DEGHEILI *et al*., 2020; SOYAMA; EGUCHI, 2016) In fact, studies performed both in the United States and Spain have already reported satisfactory results after the adoption of a hybrid and combined model for donor procurement. (SHAFER *et al*., 2003; SALIM *et al*., 2007; BOFILL-RÓDENAS *et al*., 2019)

In fact, Spain has become the country with the best donation rate over many years due to the organization of procurement at the hospital level, combined with a set of public policies established at the national level, being continually reassessed to improve country's performance. The main character of Spanish Model is the in-house transplant coordinator (IHC).(R. MATESANZ *et al*., 2017)

Transplant coordinators are supposed to “increase the quantity, quality, and effectiveness of organ and tissue donation by training and advising health care professionals in the major steps of the donation process: detection and evaluation of potential and tissue donors, brain death diagnosis, donor maintenance, family approach for organ donation, organ retrieval and allocation, tissue procurement,

processing storage and clinical applications, and quality assurance of the entire process".(MANYALICH *et al*., 2011)

Becker *et al*. (2020) have studied by a qualitative approach the organizational differences between 4 countries in Europe and how they impact organ donation rates. Semi-structured interviews were conducted with healthcare professionals and summarized recommendations for a systematic improvement of organ donation systems, from donor evaluation, family approach, public initiatives and cooperation between hospitals and stakeholders. Even so, the availability of resources and support by qualified IHC was pointed as one of the most important interventions.(BECKER *et al*., 2020)

Witjes *et al*. (2019) conducted a systematic review to identify interventions aimed at healthcare professionals that positively affected the number of organ donors. Among the 22 selected studies, the interventions that had a positive influence were training and education, adoption of electronic support for identification and/or referral of donors, collaborative pathway, donation request and/or family support by trained professionals.(WITJES; JANSEN, *et al*., 2019)

In Brazil, the public healthcare system (*Sistema Único de Saúde*) was designed to provide assistance for all citizens in an integral and equitable manner. Despite having a developing private healthcare system, transplantation has around 90% of all procedures financed by the public system, from surgical transplant procedures through complete clinical follow-up and medications.(GARCIA *et al*., 2015)

Brazilian organ (and tissue) donation activities are strategically planned, regulated and financed by government agencies. Organ Procurement Organizations (OPO) are predominantly public and their interaction with hospitals, whether public or private, aims to maximize donor procurement in their defined area.(R. A. SARLO; VARGAS, 2019)

Some successful initiatives have been documented in our country with good results when strategic planning at the central level is aligned with interventions such as those

previously described: training and education, development of tools for donor identification and/or referral, and family support by trained professionals.

The implementation of an in-house transplant coordinators program is one of the most successful strategies described at national level, but there is a lack of information about the role IHC in the implementation phase and their impact on sustainability of the program, which is reflected by its maintenance.(LENZI *et al*., 2014; SILVA *et al*., 2015; MOURA *et al*., 2015; R SARLO *et al*., 2016; SILVA *et al*., 2016; TONDINELLI *et al*., 2018; ANDRADE; FIGUEIREDO, 2019)

Although many studies have reported the efficiency of these procurement models in different countries, their adoption does not necessarily imply in positive or even sustainable results over time. In Germany, the implementation of inhouse transplant coordinators model and changes in legislation were made in 2012, but has resulted in a decrease in the number of donors.(TACKMANN; DETTMER, 2019). In 2017, 53% of United States OPO failed to meet the proposed donation rate standard and new standards have been proposed, in order to avoid decertification of most of these organizations.(SNYDER *et al*., 2020)

Understanding the factors that lead to effective implementation of inhouse coordinators programs can optimize results in other regions or countries and contribute to perform sustainable public transplantation policies, since there is a scarcity of studies with this approach in the literature

4.3 IMPLEMENTATION OF INNOVATIONS AND ITS SUSTAINABILITY

Rabin *et al.* (2008) have categorized the innovation process into 5 stages: diffusion, dissemination, implementation, adoption and sustainability. Effective implementation is a result of the complex interaction of all these stages.

The implementation science is the scientific study of implementation in a variety of health settings with the goal to establish a connection between theory and practice. While implementation is about the process and the transition from adoption to

routinization, the implementation science is the scientific study of the methods that influence this practice. (HOLAHAN *et al*., 2004; RAPPORT *et al*., 2018; VOTOVA *et al*., 2019)

The categorization of innovation as multiphasic and multidimensional allowed the development of research in each specific phase, the analysis of the correlation and transition between them, including the examination of the antecedents.(WOLFE, 1994) The disparity between countries and regions also may impact results due to economic, political and sociocultural differences.(DENIS *et al*., 2002)

For Rogers, the innovation-decision process is described as “an information-seeking and information-processing activity, where an individual is motivated to reduce uncertainty about the advantages and disadvantages of an innovation”. Implementation is the stage is this process where the transition between planning and execution takes place. Managers and employees have to deal with uncertainties until the new idea becomes institutionalized.(ROGERS EM, 2003)

The Normalization Process Theory was proposed by May and Finch (2009) to approach the social context by the interaction of people involved, organization structure and process within the implementation and the mechanisms by which it is operationalized. The study seeks to understand why some processes are effectively implemented and therefore institutionalized while others are not. While Rogers’ Diffusion of Innovations Theory focused on the final stage of diffusion and adoption, May and Finch provided “a framework for analyzing the dynamic collective work and relationships involved in the implementation and social shaping of practices.” The theory emphasizes the need for continuous investments by agents over time.

Several factors can impact implementation outcomes and therefore, scholars and practitioners have sought to identify and categorize them.

Damschroder *et al*. (2009) proposed a development in the understanding of the social role, with a broader approach Five major domains that interact, and impact implementation effectiveness were categorized: intervention characteristics, outer setting, inner setting, characteristics of the individuals involved, and the process of

implementation. Authors identified different constructs for each domain and proposed the Consolidated Framework For Implementation Research (CFIR) as “a means by which to see far; a road-map for the journey of accumulating an ever more rich understanding of the complexities of implementation, and a more predictable means by which to ensure effective implementations”.

Seeking to identify constructs and their relationship with categorized domains allows better planning of the implementation process. Damschroder *et al*. (2009) mapped several constructs from the review of theories, as complexity, cost, implementation climate and engaging, for example.

Table 4.1: adapted from Damschroder et al: Consolidated Framework For Implementation Research (CFIR)

DOMAIN	CONSTRUCTS
Intervention	intervention source, evidence strength and quality, relative advantage, adaptability, trialability, complexity, design quality, cost
Outer settings	patient needs and resources, cosmopolitanism, peer pressure, external policies and incentives
Inner settings	structural characteristics, networks and communications, culture, implementation climate
Characteristics of individuals	knowledge and beliefs about the intervention, self-efficacy, individual stage of change, individual identification with organization, other personal attributes
Process	planning, engaging, executing, reflecting and evaluating

Fonte: Damschroder *et al*., 2009

Durlak and DuPre (2008) emphasizes that “the level of implementation achieved is an important determinant of program outcomes”. Thus, effective implementation has an impact on the maintenance and sustainability of innovation, but also brings individual benefits to those involved. They also have selected five categories: innovation, providers, communities, the prevention delivery systems (*i.e: features related to the organization)* and the prevention support center (*i.e: training and technical assistance*).

Although the implementation is not necessarily linear, some models separated the process into phases such as: pre-implementation, implementation and maintenance or sustainability of the innovation.(MENDEL *et al*., 2008; FIXSEN *et al*., 2009) Aarons *et al.* (2011) have categorized the outer and the inter setting and them, mapped constructs in each domain through implementation phases: exploration, adoption decision (preparation), active implementation and sustainment. Such approach could

provide a “better understanding of the challenges likely to be presented during implementation phases”, including the predecessor period.(AARONS; HURLBURT; HORWITZ, 2011, p.15)

A systematic review was conducted by Chaudoir *et al.* (2013) in order to identify most relevant factors that affect successful implementation of evidence-based healthcare innovations. These were similar to the previous ones, but authors proposed a relationship with the following implementation outcomes: adoption, fidelity, implementation cost, penetration and sustainability. Authors identified 62 measures that can be used to access constructs in the selected domains: structural, organizational, provider, patient and innovation levels. (CHAUDOIR; DUGAN; BARR, 2013)

Pfadenhauer *et al*. (2017) proposed a broader approach including the context in which implementation takes place. The Context and Implementation of Complex interventions (CICI) framework encompasses three dimensions: context, implementation and setting. For a practical perspective, a checklist was developed to address “questions regarding which factors of a respective dimension (i.e., context, implementation, setting) exert their influence, and how this influence affects implementation success and, ultimately, intervention effectiveness.(PFADENHAUER *et al*., 2017) It may allow the application of theoretical models to real cases during the innovation planning phase.

A systematic review was undertaken to identify implementation frameworks of innovations in healthcare published from 2004 to 2014. Six concepts that should be considered for successful implementation were identified: those related to the process of implementation (stages and steps), the innovation to be implemented, the context involved (domains), influencing factors, strategies and evaluations.(MOULLIN *et al*., 2015)

Wutzke *et al* (2016) addressed how managers and employees have experienced the implementation of innovations from their personnel experience and which factors have positive impact on sustainability. The main findings were: to have a strong business case, be prepare for the change process, promote the change by engagement of all

stakeholders involved and develop the right structures and process to support implementation.(WUTZKE; BENTON; VERMA, 2016)

The effect of environmental, organizational and top managers' characteristics on initiation, adoption decision and implementation were examined in a survey performed in 1200 public organizations in the United States. The authors emphasize the importance of both external and internal resources for organizational innovativeness, the importance of financial resources linked to human resources and the influence of top managers in the allocation of these resources.(DAMANPOUR; SCHNEIDER, 2006)

Many attempts to innovate fail as a result of implementation failure, leading to high economic and social impacts. Klein and Knight (2005) performed a review research and they highlighted critical factors that shape the process and outcomes for implementation. They outline the role of top managers, especially for a supportive behavior towards employees.

To predict innovation effectiveness, a field study was conducted in a consumer product industry to examine two stages of innovation: adoption (decision to use innovation) and implementation (consistent use of innovation). Top managers were still the main force at implementation phase, but employees were found as a significant driver of implementation, especially if they recognize the innovation as a way to improve their performance.(SUNG; CHO; CHOI, 2011)

Urquhart *et al.* (2014) examined the key interpersonal, organizational, and system level factors that influenced implementation and use of complex innovations in cancer care. Five factors were identified as influential to implementation. Among them, authors have highlighted the role of managers promoting stakeholder's involvement, management of the changing process, leading and championing, in addition to administrative and managerial support. Middle managers played an important role, especially in relation to interpersonal aspects of implementation.

The role of middle managers at multiple levels was first described in 2012 by Birken *et al*. (2012) as crucial to the success of the implementation, since these professionals

have the ability to establish an effective connection between the strategy designed by top managers and the execution performed by employees. Its hierarchical position allows the perfect assimilation of innovation and its diffusion. Middle managers are able to synthesize information and sell the idea to employees, creating an appropriate climate for the implementation effectiveness.

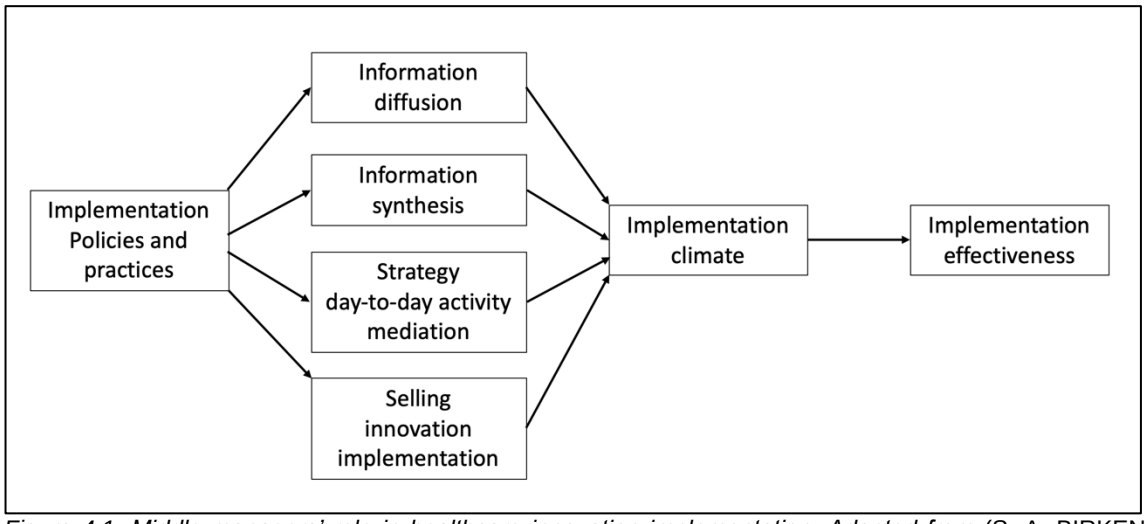


Figure 4.1: Middle managers' role in healthcare innovation implementation. Adapted from (S. A. BIRKEN; LEE; WEINER, 2012)

- Information diffusion consist on dissemination of facts by middle managers in order to give employees relevant information about the innovation implementation;
- Information synthesis consist on integration and interpretation of facts by middle managers, to reinforce the importance of implementation to employees and the organization;
- Strategy / Day-to-day activity mediation refers to the identification of tasks required for implementation, giving employees the tools necessary to implement them.
- Selling innovation implementation means the justification of innovation implementation and encouraging employees to consistently and effectively.

Birken *et al*. (2015) performed a survey with 63 middle managers to assess the four main roles of these professionals in implementation process, according to their opinion. Diffusion and synthesizing information were rated as the most important activities, while selling innovation implementation as the least important. The study brings an important contribution regarding the differentiation between middle managers and champion: "whereas champions may give frontline employees the motivation to

implement an innovation, middle managers may give frontline employees the means to do so with practical information, tools, and assistance.” (S. A. BIRKEN *et al*., 2015, p.4)

Middle managers commitment and their influence on implementation effectiveness was assessed by Fryer *et al*. (2018) in an exploratory cross-sectional survey of nurse managers from 30 United States (U.S) hospitals. The study concluded that middle managers commitment has a positive impact on implementation, through the perception of perceived support from the frontline worker for the improvement program. Five key drivers were identified: having a clear implementation plan, being held accountable for program results, having adequate financial resources for program implementation, having adequate personnel resources for program implementation, and having senior manager support to overcome implementation challenge.(FRYER; TUCKER; SINGER, 2018)

In order to have a deeper understanding of middle managers role influence in organizations, Engle *et al.* (2017) identified 14 promising practices of middle managers through data collected from 30 hospitals, obtained through semi-structured interviews. These findings provide practical examples of how these professionals carry out their activities in the 4 main roles proposed by Birken's theory.

A qualitative study was performed by Urquhart *et al.* in order to examine the role of middle managers in the implementation process of cancer-related innovations. Fifteen middle managers were interviewed, and data were analyzed through constant comparative approach. Five main roles were identified: planner, coordinator, facilitator, motivator and evaluator. Authors also found that they have are additional responsibilities within the organization and “have limited decision-making power with respect to implementation”. So, their role during implementation must be aligned with the determinations of the top managers. (URQUHART *et al*., 2018)

To understand their commitment and motivation is also a way to improve effectiveness of implementation. Another study performed by Urquhart *et al*. (2019) found that middle managers’ perception of the ease of implementation and the identification of benefit for patients have a positive effect on their work. In addition, they highlighted the

importance of education of middle managers about the potential benefit of the innovation and their involvement in the planning phase.

Austin *et al*. (2020) sought to identify the readiness of middle managers to change in a qualitative case study, since these professionals "must lead the change" determined by the top managers. Despite this, they also experience changes and, thus, the identification of factors that impact, positively or negatively, their readiness can be a way to improve their motivation and therefore, the employee's commitment to implementation.(AUSTIN; CHREIM; GRUDNIEWICZ, 2020)

A recent literature review evaluated 105 articles published in different scenarios of healthcare in several countries, corroborating the capacity that these professionals have to shape the implementation climate. However, despite the number of studies reviewed, there was still little understanding of the determinant actions in the role of middle managers for this purpose. There was no mention towards organ and tissue donation or transplantation activities in this review.(S. BIRKEN *et al*., 2018)

The role of middle managers on implementation climate was investigated by Bunger *et al*. (2019) in a qualitative study. Since middle managers share the belief that implementation is expected, supported and rewarded among employees, they are able to shape the implementation climate.

Despite the wide research about the implementation process, there is an increasing recognition in the literature about the need for follow-up and monitoring, in order to identify factors that influence the sustainability of innovation. This may provide an in-depth view of innovation across its entire scope. Shediac-Rizkallah and Bone (1998) have conceptualized sustainability as long-term maintenance programs.

There is a paucity of research in the sustainability, especially when compared to the implementation literature. Nevertheless, sustainability should be face as an outcome of an effective implementation. Schreier and Dearing (2011, p.2060) have defined it as “the continued use of program components and activities for the continued achievement of desirable program and population outcomes”.

A review of 125 studies found divergences in the definitions and terminologies of sustainability. For a temporal definition, there was a categorization in 3 ranges: 12 months, 12 to 24 months and above 24 months. In addition, the methodology for assessing and establishing that an innovation was considered sustainable over a period varied widely between the studies surveyed, applying quantitative, qualitative and mixed methodologies.(STIRMAN *et al*., 2012)

In the case of public health, the concern with the sustainability of innovation becomes more relevant, since public health programs only deliver benefits to society when they do so in a sustained manner over time. Another series raised 85 relevant studies and proposed a framework with 9 domains that affect the sustainability of a program: political support, funding stability, partnerships, organizational capacity, program evaluation, program adaptation, communication, public health impacts and strategic planning.(SCHELL *et al*., 2013)

The use of theoretically informed approaches to guide the design, development, implementation, evaluation and sustainability was recommended in a recent survey, within the scope of public health.(WALUGEMBE *et al*., 2019)

4.4 INNOVATION IMPLEMENTATION IN ORGAN AND TISSUE DONATION

IHC need to constantly interact with healthcare professionals, mainly physicians, nurses, psychologists and social workers, who are at the frontline of care for critically ill patients and support their families. So, in the light of science implementation's perspective, we assume that these professionals act as middle managers, since a IHC should be "skilled in personal and professional relationships to be locally accepted and acknowledged, supported by hospital managers, and paid for their work." (BOURNE; WALKER, 2005; MANYALICH *et al*., 2011)

Andrade and Figueiredo (2019) reported an improvement in organ donation rates in Santa Catarina over a 13-year period, with an increase of 172.5% in ADD, as a result of an OPO's strategic planning with local hospitals. Education and training were identified as the main measures, in addition to the implementation of a network of

inhouse transplant coordinators. In other sites, as Germany, the implementation of IHC model lead to negative outcomes, with a decrease in the number of donors over the years. (TACKMANN; DETTMER, 2019)

Silva *et al*. (2016) reported the implementation of an in-house coordinator project in 9 selected hospitals in the State of Sao Paulo, Brazil, from 2003 to 2012. They highlighted the importance of IHC in the improvement of brain death referrals, conversion rates and finally, organ donation rates. Despite this, among all the selected hospitals, only 4 of these achieved results with statistical significance in the measured outcomes. The authors reported some issues that resemble implementation failures to explain the group of undesired performance, such as nurses who quit their job.

The experience of implementing the in-house coordinator project was also reported by Sarlo *et al*. when the hiring of teams fully dedicated to organ procurement in 4 public hospitals resulted in a increase of 390% in the number of donors, comparing the pre-implementation period (2011) with that of effective implementation (2014). It was assumed that IHC act as middle managers, since they need to constantly interact with healthcare professionals at the institution and implement a strategy formulated by directors and top managers. (R. SARLO *et al*., 2016)

There is a scarcity in the literature on innovation, implementation and sustainability with a focus on management of the organ and tissue donation process. A systematic review was performed with studies that addressed innovation and donation/transplantation research published between 2006 and 2016. Among the thirty-one selected studies, it was found that most had a clinical approach, with a focus on transplantation. Only seven studies had a managerial approach associated to theme of innovation.(SIQUEIRA, 2019)

A workshop was held in the United States in 2018 to engage stakeholders from donation and transplantation field. The goal was to “develop approaches to stimulate transformative change in organ transplantation as measured by increased innovative practices, improving access to transplantation services, improving organ quality and long-term graft and patient survivals, enhancing the quality of patient lives, and improving the efficiency of clinical transplantation.” The proposed management

measures towards organ donation were related to data collection and analysis within the Organ Procurement Organizations (OPOs) and reassessment of goals between OPOs and transplant centers.(FISHMAN; GREENWALD, 2018)

It is possible to notice in recent publications a propensity and a concern related to the process of implementation and/or sustainability in organ donation field, although there is still low correlation with the implementation science's theories described above.

Czewinski *et al.* (2016) have described the impact of the implementation and sustainability of ETPOD, an organ donation educational program in 31 hospitals in Poland. They reported an improvement in the number of effective donors within the first 3 years (period of the study). It was not possible to identify a correlation with the theory of innovation and implementation, despite the same tipology.

Another research published in 2019 reported the implementation of a multidisciplinary approach in six hospitals in Netherlands with the objective to improve potential donor identification in emergency department (ED) and consequently, organ donation rates. The collaboration between ED and medical teams was reported as a determine factor in positive outcomes. There was no mention of the role and impact of other managers in the implementation process.(WITJES; KOTSOPOULOS, *et al*., 2019)

Once Organ Donation is highly influenced by the public's healthcare systems, besides being a subject of much debate in society and have different results around the world, we wanted to analyze the impact of IHC in light of middle managers theory on implementation phase within the hospital, which has never been done before.

4.5 MATERIALS AND METHODS

This study has as its main objective to evaluate the role of the IHC addressing their role as middle managers on innovation implementation.

The implementation of a full-time internal coordinator program in four hospitals in the state of Rio de Janeiro, Brazil aimed to improve the organ and tissue donation process.

A literature review was carried out after the description of theoretical gaps in a recent systematic review publication on the role of middle managers in the implementation of EBP.(S. BIRKEN *et al*., 2018) The additional files were evaluated to guide a search in two scientific databases: MEDLINE/PubMed and EBSCO. It was possible to identify two new Medical Subject Headings (MeSH) in PubMed database which were included in the search. Among the selected articles, there were none that addressed organ and tissue donation activities.

In order to assess and review the role of middle managers in the process of implementing healthcare innovations, the following MeSH topics were included in the search: organizational innovation; knowledge management; models, organization; diffusion of innovation; change management and implementation science. Some additional studies were identified as relevant for the theoretical discussion after evaluating the reference sessions of previously selected articles, according to the search methodology.

We carried out a literature search that address the innovation implementation theory with focus on middle managers' role into organ and tissue donation activities but we could not identify a relationship in strictly theoretical terms between the

Therefore, it was decided to perform a quantitative and qualitative analysis described below with the aim of providing an original theoretical-practical contribution through a connection of these 2 areas of knowledge.

4.5.1 Quantitative analysis

We retrospectively analyzed organ donation performance in four public trauma hospitals where a full-time in-house coordinator project was implemented (*HEAPN, HEAS, HEAT and HEGV)*. Four hospitals with similar characteristics, but without a specific donation program were chosen as a control group

Both groups had similar characteristics: total number of beds, ICU beds, in addition do an emergency room and neurosurgery service. The total number of beds and ICU beds from each hospital are presented in Table 4.2.

Data were obtained from OPO database after authorization, but hospitals in control group were not identified. The period defined for the study were the years between 2011 and 2018.

We applied the Bootstrap analysis method for the comparison of the 2 groups (intervention and control) between the years of 2011 and the year of 2018. The application of this technique aims to assess whether the presence of the IHC has statistical significance in organ donation rates, over the years.(EFRON, 1979)

Bootstrap allows to estimate the variation that will be used in the confidence intervals. It is an important technique as resampling allows you to analyze how a point estimate can vary. Bootstrap, in a way, is based on the law of large numbers, which attests that with an adequate set of observations, the empirical distribution will be considered a good approximation for the true distribution.(EFRON, 1979)

Resampling cannot improve our point estimate and even with a large size of observations, the correspondence between the real and the empirical distributions is not perfect, that is, there may be an error in the average estimate. However, the variation in estimates is much less sensitive to these differences between the real and the empirical distribution. When reasonably close, both the empirical and the real distribution show similar variations. Thus, in most cases, the bootstrap is more robust when approaching the distribution of relative variation than when approaching absolute distributions.(EFRON, 1979)

A T-test (Students' test) was also performed, since a linear regression found no trend. The comparison between both group, with the averages of organ donation rates (year by year) was performed: with IHC (intervention) and without IHC (control), from 2012 (start of implementation) and 2018 (last observation).

Table 4.2: Hospitals characteristics (total number of beds and ICU beds). Intervention group: HEGV

	HEGV	HEAPN	HEAT	HEAS	TOTAL
BEDS (total)	287	326	214	384	1211
ICU BEDS	47	25	75	45	192

	Hospital 1	HMMC	HMSF	HMFM	TOTAL
BEDS (total)	414	345	300	170	1229
ICU BEDS	27	50	20	40	137

Fonte: Autor

(Hospital Estadual Getúlio Vargas), HEAPN (Hospital Estadual Adão Pereira Nunes), HEAT (Hospital Estadual Alberto Torres), HEAS (Hospital Estadual Albert Schweitzer). Control group: hospitals were not identified

4.5.2 Qualitative analysis

For a qualitative analysis, we performed semi-structured interviews with 8 IHC (2 from each of the following hospitals where the innovation was implemented).
Professionals who worked in the first phase of implementation were eligible for this interview, that is, in the first and second year of activities.

The interviews were transcribed, analyzed and compared to apply the Thematic coding method. After the first case analysis, thematic domains linked to the individual cases were crossed. Respondents had their identities preserved anonymously and are presented in the form of numbers, as are hospitals. It will not be possible to identify the hospital or the interviewee through their numbers.

The objective of this qualitative analysis is to identify activities and assess the role of the IHC as middle managers, relating to the four domains described by Birken *et al.*: information diffusion, synthesizing information, mediating between strategy and day-to-day activities and Selling innovation implementation.(S. A. BIRKEN, *et al*., 2012) We also wanted to seek for any domains related to middle managers role not previously identified or described. The analysis of the supplementary material by Engle *et al* (2017), was used to base the questions of this interview.

The list of questions asked are presented in Table 4.3.

Table 4.3: List of questions asked to IHCs

How did you get involved with organ donation in the hospital?
How was the invitation to work as an inhouse transplant coordinator? What were your motivations?
How was the implementation process, the start of activities? How much time has elapsed between the invitation and the start of activities?
Did you attend any meeting with any director before the start of operations?
Was there a goal for the first months or during the first year? How was the interface with the directors of the hospital and the OPO? How was your work monitored by directors?
What activities did the team carry out with the hospital staff? List these activities and their frequency. Why were they defined like this?
Was there a preferred team or unit? How was that defined? Was anyone responsible for these teams previously contacted? Was there a meeting with the team leaders before these contacts?
Has any activity been carried out on your own initiative? If so, how was this need identified?
How is the relevance of organ donation presented to hospital professionals? What were the main strategies launched to encourage hospital staff to adhere to organ and tissue donation activities?
In addition to healthcare professionals, were there any activities with other professionals or family members? If so, why?
Did you undergo any complementary training related to organ donation during your period as IHC? If so, which one and why?
Do you associate any relationship between your activities and the maintenance of the project?

Fonte: Autor

4.6 RESULTS

4.6.1 **In-house transplant coordinatos impact on donation**

Between 2011 to 2018, 4 hospitals where the innovation was implemented showed an increase in the number of donors and, therefore, they became more relevant to the OPO over the years.

In 2011, the year before implementation of the innovation, there were 121 actual deceased donors (ADD) in the State of Rio de Janeiro and the 4 selected hospitals performed 26 ADD, which represented 21% of all OPO actual deceased donors.

From 2011 to 2015, there was an improvement in the organ donation rates in all OPO area, but it was greater in the 4 hospitals selected for the IHC project. In the year prior to implementation, this sample accounted for 21% of all ADDs and their participation increased to 46% in 2015 when the OPO achieved the best performance rate within the 8-year period.

In the following years, there was a global drop in the organ donation rates in the state of Rio de Janeiro, but the hospitals in the intervention group remained more relevant that they were in the pre-implementation period.

In the control group, the percentage of actual deceased donors remained stable in relation to the OPO total number of ADD during the follow-up years. In 2018, however, the number of donors in that group fell, accounting for only 7% of all OPO donors.

Table 4.4. Organ donors from 2011 to 2018

YEAR	OPO DONORS (TOTAL - STATE RJ)	HEGV	HEAPN	HEAT	HEAS	TOTAL INTERVENTION GROUP	PERCENTAGE OF DONORS IN RELATION TO OPO DONORS
2011	121	14	9	1	2	**26**	**21%**
2012	221	21	27	3	1	**52**	**23%**
2013	225	26	30	10	1	**67**	**30%**
2014	272	30	49	41	8	**128**	**47%**
2015	303	31	47	46	14	**138**	**46%**
2016	226	20	35	41	7	**103**	**46%**
2017	246	22	32	37	9	**100**	**40%**
2018	261	16	31	45	5	**97**	**37%**
TOTAL	1875	180	260	224	47	711	

YEAR	OPO DONORS (TOTAL - STATE RJ)	Hospital 1	Hospital 2	Hospital 3	Hospital 4	TOTAL CONTROL GROUP	PERCENTAGE OF DONORS IN RELATION TO OPO DONORS
2011	121	6	4	5	6	**21**	**17%**
2012	221	9	13	2	7	**31**	**14%**
2013	225	8	9	8	3	**28**	**12%**
2014	272	10	16	4	6	**36**	**13%**
2015	303	9	8	14	10	**41**	**14%**
2016	226	7	12	4	5	**28**	**12%**
2017	246	14	7	2	6	**29**	**12%**
2018	261	6	3	2	7	**18**	**7%**
TOTAL	1875	69	72	41	50	232	

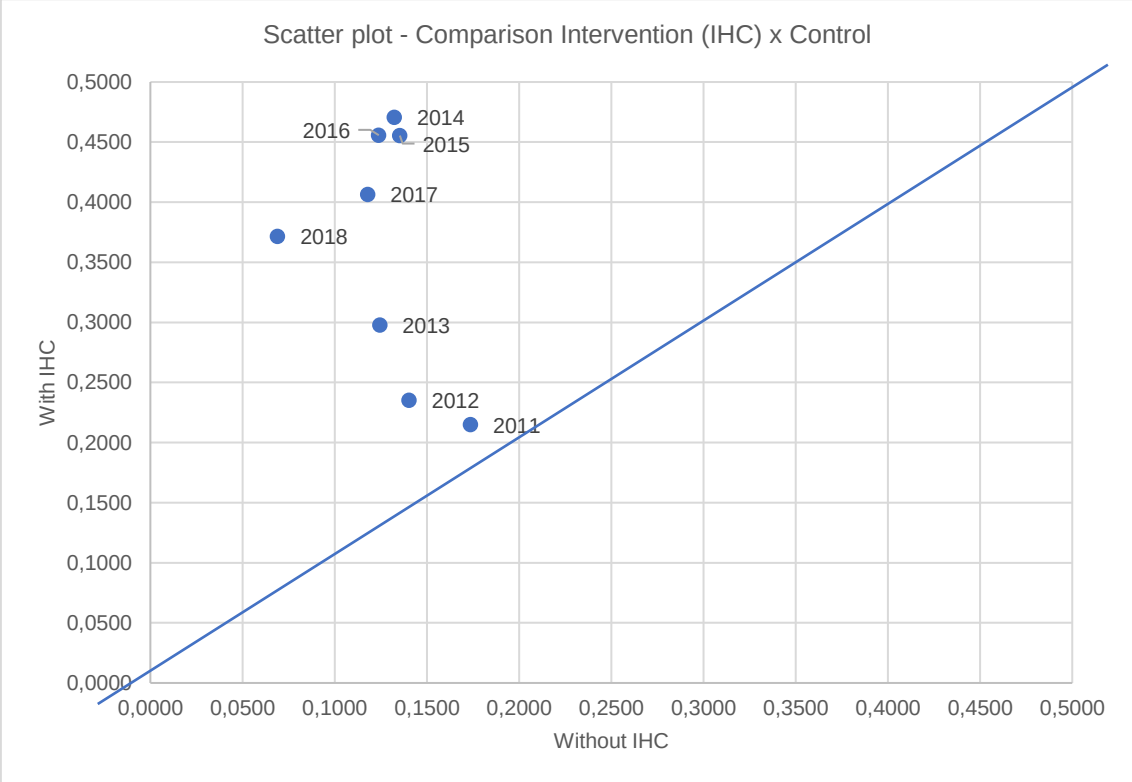
Fonte: Author

Intervention group: HEGV (Hospital Estadual Getúlio Vargas), HEAPN (Hospital Estadual Adão Pereira Nunes), HEAT (Hospital Estadual Alberto Torres), HEAS (Hospital Estadual Albert Schweitzer). Control group: Public hospitals with similar characteristcs, but without an in-house transplant coordinator (IHC) program

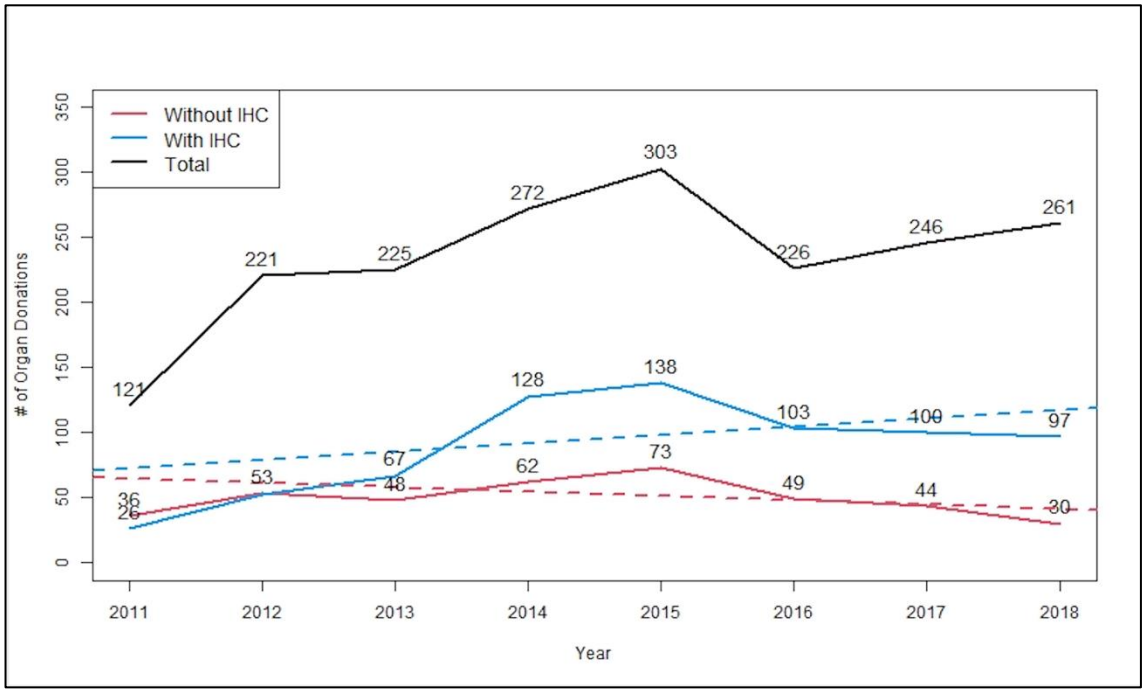
Applying the Bootstrap analysis, we observed that the average percentage of increase is greater than zero, with an interval between 0.20 to 0.33 (95% CI). This implies that the implementation of an inhouse coordinator project led to a performance improvement between 20 and 33%, after a 10^6 of resampling. The distribution of the difference results is not symmetrical, and this is reflected in the CI, which is applied for individual difference and not for average difference. This makes the result even more powerful.

Graphic 4.1 shows that for all years, the presence of transplant coordinators reflected in better performance, when compared to the control group, where they were absent. All observations are at the top of the bisector, reiterating the positive impact of organizational innovation on organ donation rates through all

A T-test (Students' test) was also performed, since a linear regression found no trend. The comparison between the averages (year by year) between the groups using T-test reached statistical significance (p = 0.005), demonstrating that the implementation of the IHC has a positive impact on the outcomes (Graphic 4.2)



Graphic 4.1.
Scatter plot analysis: comparison between the intervention group (inhouse coordinators: HEGV, HEAPN, HEAT and HEAS) and the control group (without inhouse coordinators)



Graphic 4.2
Comparison of intervention group (with IHC) with control group (without IHC) with T-Test (Students' test)

4.6.2 **In-house transplant coordinators activities and their role as middle managers**

The interviews made it possible to identify crucial activities of IHC for the implementation and thus, fit into the domains of the theory of middle managers. It was possible to observe the presence of activities related to all domains described by Birken *et al*, through the analysis of the content of the interviews.(S. A. BIRKEN, *et al*., 2012)

All relevant activities related to the implementation phase are listed below and distributed according to the most appropriate domain. The IHC were randomly listed from IHC 1 to IHC 8, so they could not be identified.

A further analysis from each domain will be made in the discussion session

Table 4.5: Categorization of activities and their relationship with the domain described by Birken et al. (2012)*, obtained by analyzing the content of the interviews. Information and Diffusion*

D1: INFORMATION DIFFUSION

TEAM AWARENESS TO GET SUPPORT	*"When we started the project, one of the initial objectives was to raise awareness among all hospital staff to support the project...So we presented the project on several sites to introduce them to what was going on"*	IHC 1
ORGANIZATIONAL CULTURE DEVELOPMENT TOWARDS INNOVATION (ORGAN DONATION)	*"Sporadically over the months we took pictures and delivered promotional materials, like brochures and stuff", and people liked it a lot. We wore shirts encouraging donation, visited hospital departments and usually spent around 5 minutes with healthcare teams taking pictures while asking questions: "you already know the process? Do you know about organ donation, what can you do as a professional? Would you be a donor?",*	IHC 2
ONLINE DISSEMINATION OF THE ONGOING PROCESS FOR HEALTHCARE TEAMS	*Whether there was a suspected brain death patient, all hospital employees were notified e involved in the process: medical staff, nurses, psychologists, social workers, and respiratory care teams.*	IHC 3
TO PROMOTE THE ASSOCIATION OF PROFESSIONAL ADHERENCE WITH POSITIVE OUTCOMES	*"One thing we have developed over the years is the issue of effective communication. So, when we try to show the professional that when he communicates and support the donor family, the impact of this is very significant"*	IHC 4
APPROACH TO HEALTHCARE TEAMS IN ORDER TO PREPARE, CUSTOMIZE AND SCHEDULE TRAINING	*We met all teams, especially Intensive Care (ICU) and trauma center, but also their supervisors and we used to announce training agenda, but also to be "around"...*	IHC 5
FORMAL, INSTITUTIONAL AND INNOVATION ROUTINE PRESENTATION	*"There was an admission lecture at the hospital, and we managed to get into that lecture. They had lectures from all sectors and services of the hospital and there was the moment that transplant coordinators also spoke and explained about our work"*	IHC 2

Fonte: Birken *et al.* (2012)

Information diffusion consist on dissemination of facts by middle managers in order to give employees relevant information about the innovation implementation.

All IHCs reported a series of activities related to this domain, since the donation process requires the involvement of several hospital teams. The potential organ donor, for example, is under the care of an intensive and emergency teams, since these patients are in brain death, requiring critical care support. For this reason, most activities related to the dissemination of information aim to bring as much information as possible to healthcare professionals.

They reported from strategies aimed to build culture in favor of donation, such as visits with informative materials, to informal visits to present their work during the initial phase or scheduling training, in addition to formalization with institutionalization, as in the case of the inclusion of IHC in admission lectures.

D2: INFORMATION SYNTHESIS

Table 4.6 Categorization of activities and their relationship with the domain described by Birken et al. (2012)*, obtained by analyzing the content of the interviews. Information Synthesis*

ACCESS THE TOP MANAGERS FOR THE PRESENTATION OF POSITIVE RESULTS	*"It was us who were looking for the directors to demonstrate our results and I always liked to show our perfomance, our results. So, it was not hospital directors that demand the results, in the beginning..."*	IHC 5
CUSTOMIZATION OF THE GLOBAL STRATEGY FOR LOCAL NEEDS	*"I believe that in the first moment, in the first or second year, we proposed the work methodologies obviously aligned with the OPO work process. So we felt free to customize it the way we understood it was important to adapt it according to hospital's needs"*	IHC 4
MAINTENANCE OF A CONTACT FLOW ON RELEVANT FACTS WITH THE TOP MANAGERS	*"I had a close of contact with the directors board and always when I had a brain death case, I reported to them... I had a very open channel with all directors at that point, in the early stages. We also had monthly meetings with OPO managers, and yes, they had goals settled and needed to report data, indicators and results"*	IHC 6
IDENTIFICATION OF OTHER ACTIVITIES WITH VALUE ADDITION POTENTIAL	*I had a monthly control of all the organs that we were able to recover and which were transplanted ... and even in terms of financial income we used to do. That was something we created "*	IHC 3
PUBLIC AND TRANSPARENT DEMONSTRATION OF PERFORMANCE AND THE IMPACT ON END-USER (*TRANSPLANTED PATIENTS*)	*"we created a hall with several posters, several tributes related to the issue of organ donation. So, everyone ... it was like a living mural, everyone saw everything and we did monthly: number of trainings, brain death referrals and how many people were helped"*	IHC 3

Fonte: Birken *et al.* (2012)

Information synthesis consist on integration and interpretation of facts by middle managers, to reinforce the importance of implementation to employees and the organization.

IHC are highly trained professionals in their activity, which is to manage the complex organ and tissue donation process. Given this complexity, they need to synthesize and simplify technical issues within employees and directors.

In addition, they report to both hospital directors and OPO directors. For this reason, the IHC needs to be able to understand the global strategy outlined by all these managers.

Regarding to hospital directors, because they do not have technical knowledge about donation and transplantation, IHC identified the need to report their results and monitor their indicators, as a way to maintain good access and support from them, as outline by IHC 6.

Regarding to OPO directors, these are technically qualified professionals in the field of donation and transplantation, but they are unaware of the local reality of each hospital. Thus, IHCs need to understand OPO strategy and goals, but adapt them to the nuances of their own hospital.

Table 4.7: Categorization of activities and their relationship with the domain described by Birken et al. (2012)*, obtained by analyzing the content of the interviews. Strategy / Day-to-day activity mediation*

D3: STRATEGY / DAY-TO-DAY ACTIVITY MEDIATION

PERFORM ESTABLISHED TASKS OF THE DONATION-TRANSPLANTION PROCESS	*"Initially my role as transplant coordinator was to detect (=possible donor), to mobilize hospital staff not only from intensive care and emergency room, but to identify the cause of brain death ... to track deaths from neurological causes ... and referral all deaths for tissue donation evaluation"*	IHC 7
MONITORING OF INDICATORS AND DESIGING OF LOCAL FLOW CHARTS	*"We did a monitoring of deaths and evaluated it by creating a flowchart to assess possible cases of tissue donation."*	IHC 7
ADEQUACY OF TRAINING TO LOCAL LIMITATIONS OR SPECIFIC DEMANDS	*"... and the other trainings, we were practically doing inside units. We always tried to focus on units (ICU and emergency room) and not use the auditorium because it was always very hard for gather a bunch of people during shifts to an inner place. So we had to bring the knowledge to where the teams were"*	IHC 6
STIMULATE EMPLOYEES CO-PARTICIPATION AND BE ABLE TO ASSIST THEM	*"Whenever there was a case, we would gather the entire ICU team to assist, open the brain death protocol together, so when I was doing the tests, I would always explain the tests out loud for them to understand how those tests worked. "*	IHC 6
OFFER TECHNICAL AND EMOTIONAL SUPPORT (TO HEALTHCARE PROFESSIONALS)	*"Many intensive care physicians do not feel secure in interrupting life support. So, as a nurse, I carried federal legislation, on my cell phone to show them. Because sometimes they were insecure, since they were not clarified. In addition, we were there to support them in difficult moments, of emotional instability"*	IHC 7

Fonte: Birken *et al.* (2012)

Strategy / Day-to-day activity mediation refers to the identification of tasks required for implementation, giving employees the tools necessary to implement them.

From IHCs' point of view most part of these activities was related to training and education. These measures are widely addressed during professional training to become HCIs and all reinforced the importance of these activities. The way in which training was performed varied from hospital, according to the perceived need for the respective IHC.

We notice that only IHC from 2 hospitals reported activities related to tissue donation, while all reported activities related to organ donation

Table 4.8. Categorization of activities and their relationship with the domain described by Birken et al. (2012)*, obtained by analyzing the content of the interviews. Selling innovation implementation*

D4: SELLING INNOVATION IMPLEMENTATION

EMPLOYEES INVOLVEMENT THROUGH ACKNOWLEDGMENT AND RETURN ON OUTCOMES TO JUSTIFY THEIR PERFORMANCE	*"I had the idea of creating a social network for us. For every brain death case in the unit, we would like to thank the people in that place and give feedback about the procurement and organs destination. This is something that seemed like a good thing and meant a lot to people in the hospital, they felt really valued. "*	IHC 5
EMOTIONAL APPEAL ON THE IMPACT USE (OR WASTE) OF INNOVATION (= DONATION)	*I encouraged people to see the other side, so that they have an idea ... They thought that this patient was going to overload the shift and that, they could leave this patient aside ". So I showed the other side, where we could save up to 8 or 10 lives...*	IHC 5
DEMONSTRATE BENEFITS NOT RELATED DIRECTLY TO THE USE OF INNOVATION	*One thing I learned from my former supervisor, is that I need to promote my work. So it is important for society, it is important for the hospital and it also has a positive financial impact for the hospital... we can free a bed occupied with a brain-dead patient who will not become an effective donor"*	IHC 7

Fonte: Birken *et al.* (2012)

Selling innovation implementation means the justification of innovation implementation and encouraging employees to consistently and effectively.

For this domain, we were only able to list 3 types of activities. In addition, among the 8 IHC interviewed, only 4 reported activities in this domain. It is interesting to note that the coordinators who reported activities in this area were the most experienced.

Furthermore, a relationship was identified between some activities carried out by middle managers and the maintenance of innovation, the project of in-house transplant coordinators. Since some of these activities were not related to the previously identified domains and there was a positive correlation between a set of activities and the sustainability of the project, we have proposed a new domain for middle managers, termed ‘transition to sustainability’. The activities related to this domain are listed in Graphic 3.

Table 4.9: Categorization of activities related to sustainability of the innovation

D5: TRANSITION TO SUSTAINABILITY

USE OF COMMUNICATION TOOLS TO IMPACT MIDDLE MANAGERS (= IHC) IN OTHER HOSPITALS	*"with the social network, we reach professionals from the hospital itself, but today we have friends and colleagues from many other hospitals ... people come to ask questions and acknowledge, they are grateful for the work we do. I think the social network was one of the main factors"*	IHC 5
STRENGTHENING TRUST WITH PATIENTS' FAMILIES	*"What can I really contribute to the relief of these people here? Then that question is there with those answers, the organ donor garden, family support ... and then families call me and create a circle of trust. "*	IHC 8
APPROACH AND PARTNERSHIP WITH PRESS TO EXPOSE RESULTS TO SOCIETY	*"The reflection of that was when the media came here, the TV stations, the newspapers and everything, so we started to become very well known, with a nationally acknowledge work"*	IHC 8
NEIGHBORHOOD AND LOCAL COMMUNITY INVOLVEMENT	*"Sometimes, educational strategies were also carried out in schools ... It is important to expand this to the neighborhood and develop partnerships with community leaderships. There were religious meetings and local leaders were invited. "*	IHC 7

4.7 DISCUSSION

Organ and tissue donation is a field of huge challenges and pursuit for continuous improvement, since the demand for transplants is often greater than donors supply. For the past 3 decades, Spain has established itself as a transplant leading country due to the innovations in the donation field. All of this occurred due to a sustained national public policy oriented towards this purpose.(R. MATESANZ *et al*., 2017)

In Brazil, transplantation has gained special attention within the public healthcare system, but the differences and disparities between regions resulted in inequitable outcomes. The central and northern regions have a similar number of inhabitants, for example, but in the first the GDP per capita is twice that of the second. As a result, the number of donors is thrice, and the number of transplants is twice between central and north regions.(GARCIA *et al*. 2015; GÓMEZ; JUNGMANN; LIMA, 2018) As in other countries, lowest donation rates lead to fewer transplants performed.

The years that followed this period were very unstable for Brazil and the state of Rio de Janeiro, since a deep economic and political crisis took place. There was a negative impact on the number of deceased donors and organ transplants in almost all the national territory, and the state of Rio de Janeiro was one of the most affected.(ASSOCIAÇÃO BRASILEIRA DE TRANSPLANTE DE ÓRGÃOS, 2016)

The adoption of cost-effective public policies is a fundamental measure for any healthcare system, especially in developing countries, which are more susceptible to crisis. For some pathologies, such as liver failure, transplantation may be the only definitive therapeutic option. In other cases, such as kidney failure, transplantation generally offers the best quality of life at a lower cost, especially in relation to dialysis.(WADSTRÖM *et al*., 2017; FU *et al*., 2020)

The improvement in organ and tissue donation rates by the IHC in the state of Rio de Janeiro is an example of cost-effective practice for the health system, since the increase in organ supply positively impacts the number of transplants.

Table 4.5, 4.6, 4.7 and 4.8 shows the evolution of the number of donors between the years 2011 and 2018 in the 4 public hospitals where the innovation was implemented. It is possible to see that these units have acquired greater relevance in the OPO area, which covers 230 hospitals. The hospitals that hosted the project were responsible for 47% of all actual deceased donors in 2015 and despite the crisis, they maintained an excellent performance in the following years.

Among all the other hospitals in the OPO area, at least 12 other hospitals were identified as units with a high potential for obtaining ADDs. For the control group, 4 main hospitals were selected, which in addition to having characteristics and infrastructure similar to the intervention group, had the best performance in donation rates in 2011.

The comparison between the control and intervention groups shows in the bootstrap analysis that the adoption and implementation of innovation had a positive impact in all years of the study, as show in graphic 4.1. While in the intervention group there were 711 actual deceased donors during the study period, in the control group there were only 232 actual deceased donors, in the same period.

If the performance in this group were the same as in the intervention group, following the implementation of IHC through 2012 to 2018, it would be possible to obtain up to 572 ADDs in this group, which would lead to an additional 340 donors. Such a

performance would add between 700 to 800 solid organ transplants in the same period, considering the State of Rio de Janeiro Organ Transplanted per Donor (OTPD) yield. This would have a huge social and financial impact, saving hundreds of lives. The quantitative results are consistent with other studies that reported the implementation of IHC programs.

Salim *et al*. (2007) have reported the effect of an in-house transplant coordinator program in 2 trauma hospitals at an OPO area, in California, United States). The comparison of the 3-year pre-IHC period with the 3-year post-IHC period showed a 17% increase in donation rates, which was mainly attributed to family support and the relationship between the IHC and hospital professionals.(SALIM *et al*., 2007) It was not possible to identify a wide range of activities from IHC, which may explain suboptimal results.

In another retrospective study, Salim *et al*. (2011) have reported the successful implementation of another IHC program, with a better family consent rate and higher conversion rates (death referral / actual donor). Authors also documented an increase in death referrals, but also in organs transplanted per donor ratio. The cost of the project was presented as a limiting factor for its maintenance.

Shafer *et al.* (2003) reported the impact of IHC in 2 trauma hospitals, in Texas, United States. Managers duties included: to provide early referrals and evaluation of potential donors, a coordinated and planned family approach, specialized donor management, education and training initiatives, administrative and quality support. Positive results were attributed to these strategies, but there was no mention of the relationship between IHC and senior management, as directors. Major financial limitations were also cited, which we assume have impacted the project's continuity.

At the national level, the results reported by Andrade and Figueiredo (2019) over a 13-year period in Santa Catarina are one of the most long-standing success stories in our country. A very well coordinated plan coordinated by the OPO, consisting of a strategy based on education and training lead to an increase of 172.5% in ADD was reported during the study period. It was not possible to understand the role of coordinators in

relation to other activities and whether they could maintain their respective programs without the full support of the state OPO.

Some other implementation failures, such as those reported by Silva *et al.* (2016), who, despite reporting good results, only obtained significant results in 4 of the 9 hospitals selected for the implementation of IHC program, reinforce the need for a better understanding of this intervention.

In other regions, as previously mentioned, the implementation of this model has almost completely failed. In Germany, for example, the result was a reduction in the number of donors. The reasons for this failure have not yet been properly identified.(TACKMANN; DETTMER, 2019)

Therefore, the interviews provided additional understanding on the role these inhouse coordinators since their activities in organ and tissue donation field fit with the science implementation's definition for middle managers.

According to Manyalich *et al.* (2011, p.274)., the main goal of the transplant coordinator is to "increase the quantity, quality, and effectiveness of organ and tissue donation by training and advising healthcare professionals in the major steps of the donation process". They need to "be skilled in personal and professional relationships to be locally accepted and acknowledged, supported by hospital managers, and paid for their work."(MANYALICH *et al*., 2011, p.274)

It was possible to identify a series of activities and strategies of the IHC that are related to Birken's domains: diffusion of information, synthesizing information, mediating between strategy and day-to-day activities, and selling innovation implementation. Table 4.5, 4.6, 4.7 and 4.8 provides the list of examples obtained after thematic codification.(S. A. BIRKEN *et al*., 2012)

The analysis of each domain will be presented above, according to Birken *et al.* (2012) middle managers theory.

D1: INFORMATION DIFFUSION

1. Definition:

Dissemination of facts by middle managers in order to give employees relevant information about the innovation implementation

2. List of activities identified:

- team awareness to get support; organizational culture development towards innovation (organ donation); online dissemination of the ongoing process for healthcare teams; to promote the association of professional adherence with positive outcomes; approach to healthcare teams in order to prepare, customize and schedule training; formal, institutional and innovation routine presentation

3. Discussion:

Information diffusion was the domain where the largest list of activities was found, with a wide range of strategies described by almost all IHC. Although heterogeneous, the common objective of informing the team or even preparing for educational activities reinforces the need for IHC to be close to hospital teams.
The strategies contributed to the establishment of a culture focused on organ donation, which helped on several occasions to motivate hospital staff.

On some occasions, even an informal approach was taken to establish a stronger link with the teams, as informed by IHC2:
“Sporadically over the months we took pictures and delivered promotional materials, like brochures and stuff", and people liked it a lot. We wore shirts encouraging donation, visited hospital departments and usually spent around 5 minutes with healthcare teams taking pictures while asking questions: "you already know the process? Do you know about organ donation, what can you do as a professional? Would you be a donor?",

The survey performed by Birken *et al.* (2015) to assess the four main roles of middle managers in implementation process found that diffusion and synthesizing were the

most important activities. This corroborates the need for IHC to be communicative individuals with the ability to establish partnerships.(MANYALICH *et al*., 2011)

This is also in line with the findings of Fryer *et al*. that reported a positive influence of middle managers commitment. Authors stated that: “middle manager commitment is an important driver of perceived implementation success, in part, because it positively influences perceived frontline worker support for the improvement program.(FRYER; TUCKER; SINGER, 2018)

As previously pointed, the donation process requires the involvement of several hospital teams. Donors are under the care of multidisciplinary teams and an integrated approach is essential for a successful outcome.

Andrade and Figueiredo (2019) reported some interventions with this purpose as: involve intensive care doctors in transplant coordination, develop donation and transplantation process, training programs with an emphasis on family interview and potential donors identification, brain death diagnosis and donor management.

D2: INFORMATION SYNTHESIS

1. Definition:

Integration and interpretation of facts by middle managers, to reinforce the importance of implementation to employees and the organization

2. List of activities identified:

- access the top managers for the presentation of positive results, customization of the global strategy for local needs, maintenance of a contact flow on relevant facts with the top managers, identification of other activities with value addition potential, public and transparent demonstration of performance and the impact on end-user (*transplanted patients*)

3. Discussion:

All IHC reported activities in this domain. We noticed that the proximity to the directors was one of the elements that these professionals gave more importance.

The pursuit for maintaining close contact was cited in different scenarios, such as in the initiatives to present results to directors, in order to strengthen support.

The identification of activities that add value also reinforces this view, as in the excerpt cited by IHC3:

"*I had a monthly control of all the organs that we were able to recover and which were transplanted ... and even in terms of financial income we used to do. That was something we created"*

These findings are in line, at least partially, with Urquhart *et al*. conclusions of a qualitative study. They concluded that middle managers must maintain an alignment with top managers, since they have limited decision-making power for implementation, needing to keep working according to the parameters programmed by top managers.(URQUHART *et al*., 2018)

Despite this, other statements revealed that the coordinators also had the autonomy to define activities, as long as they respected the general guidelines and ethical principles. IHC 4 stated:

"I believe that in the first moment, in the first or second year, we proposed the work methodologies obviously aligned with the OPO work process. So we felt free to customize it the way we understood it was important to adapt it according to hospital's needs"

This domain then also applies properly to the role of the IHCs as middle managers. The complexity of their work demands synthesizing to simplify technical issues for both employees and directors

As they report to directors from different structures, like OPO and hospital, they need to be able to understand the OPO strategy and promote alignment with hospital strategy. Sometimes they need to customize to the local reality.

D3: STRATEGY / DAY-TO-DAY ACTIVITY MEDIATION

1. Definition:

Identification of tasks required for implementation, giving employees the tools necessary to implement them

2. List of activities identified:

- perform established tasks of the donation-transplantation process, monitoring of indicators and desiging of local flow charts, adequacy of training to local limitations or specific demands, stimulate employees co-participation and be able to assist them, offer technical and emotional support (to healthcare professionals)

3. Discussion:

This domain, in the case of the present study, was identified mainly from an operational perspective, where the coordinators listed their day-to-day activities. In addition, all reported providing training and the majority, monitoring performance indicators.

"Initially my role as transplant coordinator was to detect (=possible donor), to mobilize hospital staff not only from intensive care and emergency room, but to identify the cause of brain death ... to track deaths from neurological causes ... and referral all deaths for tissue donation evaluation"

For Manyalich *et al.* (2011) "the transplant program lies in professionalizing donation and sharing responsibilities". According to the author, IHC "need to be skilled in personal and professional relationships to be locally accepted and acknowledged, supported by hospital managers and paid for their work". Moreover, they need to "work for and provide a service to everyone, they must be staff members and hierarchically under the responsibility of the medical director so as to maintain their independence within the hospital."(MANYALICH *et al*. 2011)

The understanding then of this role and the support of the managers allowed all IHC to understand the importance of the training, but they did it according to the particularities of their hospitals

D4: SELLING INNOVATION IMPLEMENTATION

1. Definition:

Justification of innovation implementation and encouraging employees to consistently and effectively use innovations.

2. List of activities identified:

- employees involvement through acknowledgment and return on outcomes to justify their performance, emotional appeal on the impact use (or waste) of innovation (= donation), demonstrate benefits not related directly to the use of innovation

3. Discussion:

This domain was mentioned by a smaller number of IHC, which is also in line with the study by Birken *et al*., in which this was also the one that the middle managers gave less importance.(S. A. BIRKEN *et al*., 2015)

Despite this, the possibility of reaching and reaching outside with other professionals, in addition to the emotional appeal, brings a perspective of adding value, as mentioned by the IHC 5.

“I had the idea of creating a social network for us. For every brain death case in the unit, we would like to thank the people in that place and give feedback about the procurement and organs destination. This is something that seemed like a good thing and meant a lot to people in the hospital, they felt really valued.”

“I encouraged people to see the other side, so that they have an idea ... They thought that this patient was going to overload the shift and that, they could leave this patient aside ". So I showed the other side, where we could save up to 8 or 10 lives...”

These statements are in agreement with the findings of Urquhart *et al*. in which the identification of benefits for patients was attributed as a positive factor for the work of middle managers.(URQUHART *et al*., 2019) Since this work, in our study, is related to the donation of an organ in a moment of family fragility due to the loss of a beloved one, this seems to become particularly more relevant.

As mentioned above, in results section, we only detected 3 types of activities related to this domain. We found that among 8 IHC interviewed, only 4 reported activities in this domain. We believe that the activities related to this domain require a deep understanding of the role and a wide experience. This can be corroborated by the fact that only the most experienced reported activities in this domain

D5: TRANSITION TO SUSTAINABILITY

1. Definition:

Influence of middle managers on the maintenance and sustainability of innovation

2. List of activities identified:

- use of communication tools to impact middle managers (= IHC) in other hospitals, strengthening trust with patients' families, approach and partnership with press to expose results to society, neighborhood and local community involvement

3. Discussion:

Middle managers have the possibility to use a wide range of tools, especially in the case of activities with social appeal.

"with the social network, we reach professionals from the hospital itself, but today we have friends and colleagues from many other hospitals ... people come to ask questions and acknowledge, they are grateful for the work we do. I think the social network was one of the main factors"

The involvement of multiple actors in society provides a sense of protection and maintenance of the project, which can at least in theory, keep these professionals motivated and stimulate the virtuous cycle of approaching different spheres of society

“The reflection of that was when the media came here, the TV stations, the newspapers and everything, so we started to become very well known, with a nationally acknowledge work”

Urquhard *et al.* (2018) have already outlined that the identification of benefit for patients was related to a positive effect on middle managers' work. Despite this, there is still no report of the impact of middle managers on families or society.

We believe that this scope in the external environment serves as a motivational factor for IHCs, but it also makes their program more solid.

This hypothesis was raised after these interviews' analysis, but it still needs to be better studied in future works. According to Schreier and Dearing (2011, p.2060), sustainability should be face as an outcome of an effective implementation and they have defined it as "the continued use of program components and activities for the continued achievement of desirable program and population outcomes".

Durlak and DuPre (2008) also pointed that an effective implementation has an impact on the maintenance and sustainability of innovation, and also brings individual benefits for everyone involved.

With the results presented, it was possible to verify the relevance that the IHC project assumed in the local scenario, since in quantitative terms, they positioned four hospitals with a very high relevance before a number of more than 200 hospitals across the State of Rio de Janeiro.

The analysis of the content of the interviews allowed to identify a series of activities carried out by these professionals over the years. IHCs believes that promoting social involvement can change the perception of innovation, bringing an idea that it belongs to society, being on another plane.

Our study has some limitations, as it reflects the implementation in a local setting with a limited sample. In addition to dealing with a retrospective control group, not randomized, the interviews were conducted only in the intervention group, since the implementation was restricted to that group.

4.8 CONCLUSIONS

The implementation of IHC optimize the donation process and increase organ donation rates. Two statistical models applied in this analysis justify the presence of in-house transplant coordinators with exclusive dedication to the process of organ donation.

IHC can be classified as middle managers, based on their mid position within the organization since they are subordinated to the directors and need to articulate with all healthcare professionals in their facilities. Their roles during the implementation of activities towards the improvement of organ donation were assessed in this study, addressing Birken *et al*. domains (S. A. BIRKEN; LEE; WEINER, 2012)

It was possible to correlate the various activities carried out targeting organ and tissue donation system implementation during the past years with all domains described: information diffusion, information synthesis, strategy / day-to-day activities and selling innovation implementation.

From these collected and presented data, the different successful strategies implemented by hospitals are presented here and can be taken as an example to facilitate the implementation of future projects on other sites.

We also observed that, at least in the case of organ donation, it was possible to identify 1 other domain in which mid-level managers positively influence the sustainability of the implementation, which reflects in the maintenance of the program in all hospitals until the publication of this article.

The comprehension of IHCs role, in the light of the theory of middle managers can improve this process in regions with already consolidated results, in addition to offering a perspective of reversing implementation failures in unsuccessful cases.

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5 CONCLUSIONS

Organ and tissue donation is a very challenging field, where for developed countries it has been applying complex strategies in order to improve their performance sequentially. For developing countries this challenge is harder, as they need to deal with multiple difficulties, in addition to financial constraints.(RUDGE *et al*., 2012)

Regardless of social, political and economic issues, each country and region face particular problems and needs to adopt different strategies, sometimes adapted from some existing model or if necessary, to implement original measures.(DOMÍNGUEZ-GIL; MURPHY; PROCACCIO, 2016; BECKER *et al*., 2020)

In the State of Rio de Janeiro, a series of managerial measures into organ and tissue donation process culminated in improvements in the local transplantation system. It has led to the development of local research in order to understand these phenomena and seek to improve performance, aiming at increasing the quantity and quality of organs and tissues procured and thus, the number of local transplants performed. (LENZI *et al*., 2014; BONFADINI *et al*., 2014)

At the local level, hiring professionals fully dedicated to donation activities represented an organizational innovation for the State healthcare system. The adoption of the Spanish model in four public hospitals aimed to increase rates, in units with high potential for organ donation. As in-house transplant coordinators (IHC), the managers are supposed to “increase the quantity, quality, and effectiveness of organ and tissue donation by training and advising healthcare professionals in the major steps of the donation process” (MANYALICH *et al*., 2011).

IHC are allocated in the middle of organization and need to “be skilled in personal and professional relationships to be locally accepted and acknowledged, supported by hospital managers, and paid for their work.” (MANYALICH *et al*., 2011)

Middle managers are subordinated to top managers, usually hospital directors, and need to be in constant contact with all healthcare professionals in their units. (NEALEY;

FIEDLER, 1968) and have been considered important in the implementation and maintenance of policies and practices within the organization.(DRESSLER, 1978)

Middle managers are important for implementing changes and improving the organization's performance.(FLOYD; WOOLDRIDGE, 1997). There is a growing scientific interest in research that assess the role of middle managers in healthcare innovation implementation.(CHUANG; JASON; MORGAN, 2011). Despite this, there is still “little understanding regarding middle managers’ role in EBP implementation”.(S. BIRKEN *et al*., 2018)

The similarity of managerial functions between IHC and middle managers role was assumed for this dissertation. Birken *et al.* (2018) performed a systematic review to identify studies reporting on middle managers’ roles in healthcare EBP implementation and its determinants. Among one hundred five records selected, from 1996 to 2015, there was none that addressed organ and tissue donation field.(S. BIRKEN *et al*., 2018)

The objective of this thesis is to investigate an association between in-house transplant coordinators activities and their role as middle managers, seeking to describe the process of the implementation of practices towards organ and tissue donation improvement in four hospitals in Rio de Janeiro, Brazil.

Within the seven-year period of IHC activities as managers fully dedicated to the organ and tissue donation process, we sought to investigate whether the implementation of this innovation was effective; the strategic actions with IHC intermediation between directors, executives and employees; and the possible association between the activities developed to improve the donation process with middle managers’ role addressing the innovation implementation literature.

The first article of this thesis documents the period of implementation of the Spanish model of in four public hospitals and the defined criteria for this choice, analyzing the impact of activities developed from these professionals on organ donation: *Impact of the introducing Full-time in-house coordinators on referral and organ donation rates in Rio de Janeiro Public Hospitals: a Health Care Innovation Practice*

The paper describes the strategic plan, the criteria for selecting hospitals and the composition of donation teams. From 2011 to 2014, the IHC provided (in the four hospitals) an improvement of the main performance indicators of organ donation, since there was an increase of 132% in brain death referrals, an improvement of donor conversion rates from 20 to 42% and finally, an increase in the number of donors from 26 to 128 donors, fulfilling Manyalich *et al*. (2011) propositions.

From this publication, the innovation in the local transplant system was documented, featuring an effective implementation process. (KLEIN; SORRA, 1996). Despite the association between IHC with middle managers' roles it was not possible to address it from a theoretical perspective.

The second article of this dissertation, entitled *Project of Cornea Donation in Rio de Janeiro: Analysis of the Implementation of an Organization Innovation Practice,* provides the description of a tissue donation team in order to improve cornea donation, under Organ Procurement Organization (OPO) coordination, through intermediation of the IHC, in one of the previously selected hospitals.

To set up an efficient tissue procurement system, all stakeholders should be involved within the strategic plan. (MURAINE, 2002; CARAMICIU *et al*., 2014; BONFADINI *et al*., 2014). In tissue donor screening, all deaths must be evaluated and there are several additional logistical problems for tissue harvesting, in addition to more rigorous criteria for donor validation.(PONT *et al*., 2003)

This paper describes the development of the tissue donation system, where the coordination and strategic design were developed by the top managers (the OPO and hospitals' directors) and IHC mediated the strategy within healthcare professionals. Results obtained were reported, which were possible through adherence and commitment. Following the first year of this project, 116 corneas were procured, which represented an increase of 163% over the previous year.

Scholars have highlighted the influence of middle managers with employees in the change process through strategy, where their involvement can improve the

organization's performance, especially if they are involved in decision-making processes.(FLOYD; WOOLDRIDGE, 1997; BREWER; LOK, 1995)

The strategic alignment between top managers and middle managers can be part of public policies and organ donation in Brazil is properly applied to this scope.(CLIFFORD, 2001)

Middle managers may strongly influence organization’s performance, especially if they are empowered, facilitating the diffusion of innovation. (DOPSON; FITZGERALD, 2006). The results obtained in such a complex process seems to reflect this element.

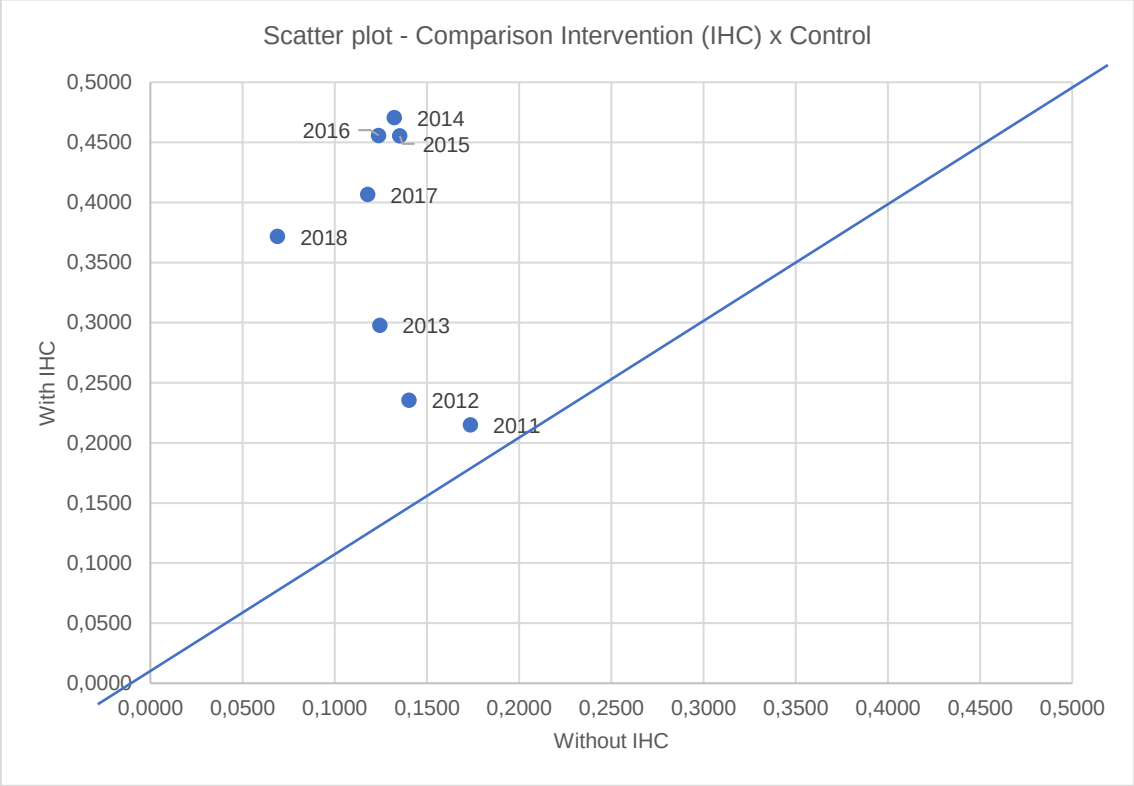
Support from top managers has been described as a way to increase middle management commitment. The knowledge and involvement of these professionals in strategic planning has been attributed to positive implementation outcomes. (URQUHART *et al*. 2014; S. A. BIRKEN *et al*., 2015; HOVLID; BUKVE, 2014; VARSI *et al*., 2015) The results achieved in this series were attributed to executives support in association with IHC commitment with implementation.

The last article of this dissertation entitled: *The role of in-house transplant coordinators as middle managers in organ donation rates in Rio de Janeiro: from implementation to sustainability,* provides a deeper overview of the activities and strategies carried out by the IHC, in order to have a broader and more detailed approach to the implementation process through their roles as middle managers.

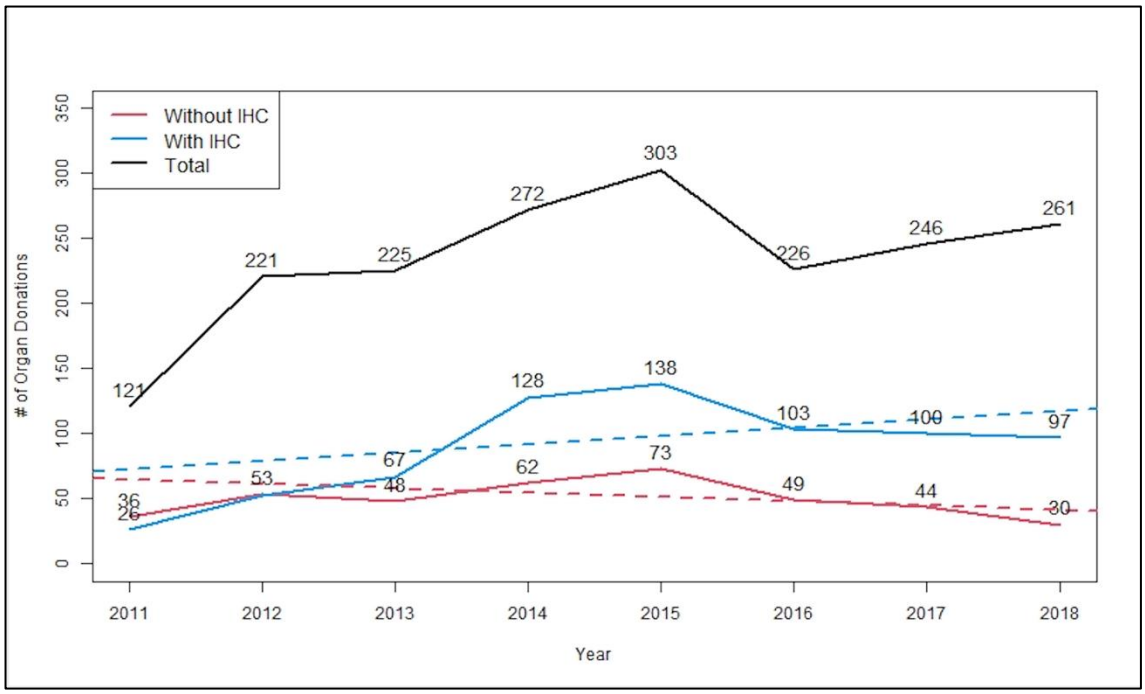
Two statistical methods were carried out for a quantitative analysis: bootstrap analysis and T-test (Students' test), using a retrospective control group in which the innovation was not implemented, in order to verify whether the presence of the IHC has a significant impact on results, from 2011 to 2018. The year of 2011 precedes the implementation of the innovation.

The control group consisted in four hospitals with total number of beds, ICU beds, in addition do an emergency room and neurosurgery service, that is, high potential for organ procurement.

The results found through the two statistical tests: T test and Bootstrap analysis, confirm that the implementation was effective and the presence of the IHC was statistically significant.



Graphic 4.1.
Scatter plot analysis: comparison between the intervention group (inhouse coordinators: HEGV, HEAPN, HEAT and HEAS) and the control group (without inhouse coordinators)



Graphic 4.2
Comparison of intervention group (with IHC) with control group (without IHC) with T-Test (Students' test)

Semi-structured interviews with eight IHC were performed for a qualitative analysis, in order to assess their role as middle managers in the implementation period, addressing the four domains described by Birken *et al.* (2012): information diffusion, synthesizing information, mediating between strategy and day-to-day activities and selling innovation implementation.

Through the qualitative analysis it was possible to identify several activities carried out by the IHC over the years and to relate these activities to the domains investigated. A relationship was identified between the activities of these managers and the maintenance or sustainability of the donation teams

This dissertation aims to provide a theoretical contribution, through the application of theories from innovation implementation with organ and tissue donation field, positioning the IHC as middle managers, addressing their role in middle management and proposing a domain of influence on sustainability or maintenance of innovation, at least in organ and transplantation field.

The quantitative and qualitative results presented can provides a practical contribution to management strategies towards organ and tissue donation improvement, with several actions carried out by IHC.

This study has some limitations, such as being restricted to a single region, which was the State of Rio de Janeiro, Brazil. Financial crisis in the country has negatively impacted donation rates from 2015 to 2018, but an attempt was made to neutralize this effect by comparing it to a control group with similar characteristics.

A limitation, which can be considered for a future research is a qualitative approach of all stakeholders involved is the donation process: OPO directors, hospital directors, employees, families, transplanted recipients and transplant teams

The study of transplant coordinators with an approach focused on middle management can open up a wide range of possibilities, allowing theoretical contributions for innovation implementation, but it can also bring management practices strategies and insights to improve the donation and transplantation process, allowing more lives to be saved.

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