

Saving lives through better communication. Preventing healthcare professionals errors during the donation-transplant process

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ABSTRACT

A shared safety culture among healthcare professionals increases successful donation-transplant outcomes. A perfectly planned integration could reduce the possibility of failed organ transplantation and damage to the patient. Clear and understandable systematic team training projects covering communication aspects linked to practice procedures could improve the quality of the whole process.

Una cultura della sicurezza, condivisa tra i professionisti sanitari, incrementa la riuscita del processo donazione-trapianto. Un'integrazione perfettamente pianificata può ridurre la possibilità di fallimento nel trapianto d'organo e di danno al paziente. Progetti formativi chiari e comprensibili rivolti al gruppo di lavoro, orientati ad aspetti comunicativi e connessi a procedure pratiche, possono migliorare la qualità dell'intero processo.

INTRODUCTION

Healthcare organizations are setting tighter safety requirements and are looking for ways to control quality, safety and efficiency in order to improve health outcomes. They should provide planning procedures and standards for all aspects of critical work and mechanisms for reviewing and monitoring them with an effective supervision in order to identify possible routes of errors from human factors. The objective is to close the gap between the best evidence based practice and what really happens in current practice, which can lead to errors or adverse events. Key elements for the effective organization of health and safety management are communication and cooperation among all team members, the competence of manag-

KEY WORDS

SAFETY CULTURE;
DONATION-TRANSPLANT PROCESS;
QUALITY OF COMMUNICATION;
CLINICAL RISK MANAGEMENT;
HUMAN RESOURCES DEVELOPMENT.

PAROLE CHIAVE

CULTURA DELLA SICUREZZA;
PROCESSO DONAZIONE-TRAPIANTO;
QUALITÀ DELLA COMUNICAZIONE;
GESTIONE DEL RISCHIO CLINICO;
SVILUPPO DELLE RISORSE UMANE.

ers and employees and the supervision of site activities. Furthermore, guidelines, protocols and checklists should be clear and transparent to staff. This is particularly important with regard to organ donation and the transplant process where evidence-based practices have to be monitored, reinforced and implemented at a system-wide level. Especially in this healthcare field, managers and coordinators should be cognizant that they have a vital role in supporting positive health and safety behaviour of professional workers. The multi-disciplinary approach of different professionals in terms of knowledge and competences must be considered a crucial factor in improving the likelihood of donor acquisition.¹ Therefore,

¹ The skills and competences required depend on the role of the different professionals throughout the process.

communicating the right signals from the leadership to employees is highly significant in the achievement of the whole process.

SAFETY CULTURE IN HEALTHCARE ORGANIZATIONS

Of the utmost importance is that healthcare systems change the organizational culture in order to improve patient safety. Safety culture is one element of the organizational culture about which there has been a considerable sociological research. The most commonly used definition of safety culture is the following: "The safety culture of a health organization is the product of individual and group values, attitudes, perceptions, competences and patterns of behaviour that determine the commitment to, and the style and proficiency of an organization's health and safety management."²

Growing interest with regard to safety culture within healthcare organizations has been accompanied by the need for assessment tools focused on the cultural aspects of patient safety improvement efforts. Attention has been paid to understanding the shared attitudes, beliefs, values and assumptions which underlie how people perceive and act on safety issues in their health organizations and the potential relevance of these shared characteristics to initiating fundamental and sustained changes to patient safety. The MaPSCAT advanced some dimensions developed in order

² The definition is from the Advisory Committee on the Safety of Nuclear Installations (ACSNI, 1993) in E. Coles, D. Smith, S. Tombs, *Risk Management and Society*, Netherlands, 2000, p. 11. For a better understanding of this particular topic please see: E.P. Borodzicz, *Risk, Crisis and Security Management*, England, 2005. Common terminology includes safety culture and safety climate with considerable variation in the use of terms and definitions. Safety climate is more specific and refers to the employees perceptions of particular aspects of the organization's culture. In order to evaluate safety climate, Gershon *et al.* published a new healthcare safety climate measurement tool to determine its relationship to safe work behaviours. For an in-depth analysis refer to: M.A. Blegen, A.P. Ginette, J. Rosse, *Safety climate on Hospital Units: a new measure*, in "Advances in patient safety: from research to implementation", Volume 4: Programs, Tools and Products, Agency for Healthcare Research and Quality, US, February, 2005

to reflect increasing generative levels of safety culture in healthcare.³ Leaders could support safety through specific actions and behaviours encouraging all team members to accept responsibility for their safety as well as that of their co-workers and patients. Therefore, an important step in promoting patient safety is the development of a healthy workplace.⁴

To achieve such a culture requires a fundamental improvement in the correct understanding of the values, beliefs and norms about what is important in a health organization and which attitudes and behaviours related to patients safety are expected and appropriate.⁵ From this point of view, the generative organization represents the most advanced state of cultural maturity of a healthcare organization. New ideas are welcomed while failure prompts inquiry rather than cover-up or blame.⁶

David Marx maintains that health professionals would openly admit that they have made a mistake, alert other operators when they see a risk and so participate in a learning culture.⁷ As a result, information about mistakes and near misses⁸ are shared within the

³ The MaPSCAT (Manchester Patient Safety Culture Assessment Tool) is the result of collaboration between researchers in the UK and Canada interested in developing a safety culture tool. Refer to: M.P. Law, R. Zimmerman, G. R. Baker, T. Smith, *Assessment of Safety Culture in a Hospital Setting*, Healthcare Quarterly, Toronto, 13 (Sp) October 2010: 110-115

⁴ For an in-depth analysis see: A. Yassi, T. Hancock, *Building a culture of safety to improve healthcare worker and patient well-being*, Healthcare Quarterly, Toronto, 2005; 8 Special No: 32-8

⁵ Generally, the story of healthcare systems is full of examples of user resistance to the imposition of changes and improvements because values, beliefs and norms are often interwoven with a professional tradition.

⁶ Regarding this topic, Westrum suggests that good information flow and processing have important effects on patient safety, such as a good teamwork and that an open and generative culture means a better uptake of innovations and response to danger signals. For a better understanding refer to: R. Westrum, *Human factors experts beginning to focus on organizational factors in safety*, ICAO Journal, 1996, Oct; 51(8): 6-8, 26-27

⁷ American Society for Healthcare Risk Management, R. Carroll (edited by), *Risk Management Hand Book for Health Care Organizations*, US, 2009, p. 9

⁸ A "near miss" is an event or a situation that could

team, so they can prevent similar situations. This also helps operators to avoid incorrect and reckless behaviour.

An important step in creating a safety culture is to overcome the current fear of punitive outcomes involved in error reporting.⁹ Time and again health operators are concerned with the negative consequences of disclosing errors, such as malpractice litigation, reputation damage, job security and personal feelings. Larson states that breakdowns occur when professionals differ on how to trade goals, do not clearly define rules and responsibilities and fail to communicate updates to a shared plan.¹⁰ He also asserts that it is fundamental to create a common shared vocabulary about safety issues and adverse events,¹¹ which could be used in informal conversation during daily interactions among staff. Moreover, it is important how the feedback to staff on information from an error is used. Besides, effective supervision has to focus on the provision to all employees of instruction, mentoring, training and above all support and mutual reinforcement of safe working

have resulted in an accident, injury or illness, but did not, either by chance or through timely intervention. Because it is caught in time, no harm is caused to the patient. The near miss should be considered as a chance to develop preventive strategies and actions.

9 Some explanations for errors not being reported include: fear of blame from administration, physicians and patients; non supportive management response; and the effort of reporting. Regarding this tool, James Reason suggests that a healthcare safety culture should include adequate reporting systems, action taken on the basis of the reports, flexibility and learning from experience. For an in-depth analysis refer to: J. Reason, *The Human Error*, Cambridge, 1990

10 For a better analysis of this topic, please read: C. Larson, F.M.J. LaFasto, *Teamwork: what must go right/ what must go wrong*, UK, 1989

11 An "adverse event" is a serious incident, therapeutic misadventure, iatrogenic injuries or other adverse occurrences directly associated with care provided. An "error" has to be considered as the failure of a planned action to be completed as intended or the use of a wrong plan with actual or potential negative consequences for the patient. For a better understanding refer to: E. J. Thomas, L.A. Petersen, *Measuring Errors and Adverse Events in Healthcare*, Journal of General Internal Medicine, US, 2003 Jan; 18(1): 61-67

practices.¹² Joint Commission International¹³ asserts that a just culture is not wholly blame-free: it is one that has a clear and transparent process for evaluating errors and separating blameworthy from blameless acts.¹⁴ Obviously, leaders must consistently make safety a top priority in their decision-making. They should play an active visible role to articulate the vision and create the environment evaluating and implementing changes and they should eliminate intimidating behaviour that suppresses the reporting of errors and unsafe conditions.¹⁵ Regarding these issues, the staff members need to believe that safety is taken very seriously by the organization in their own daily work and is focused on evaluating errors and incidents through the development of a framework with common programs and pathways to enhance safety and to achieve high quality standards.

HEALTH CARE STAFF COMMUNICATION

It is recognized that the communication process can affect the safety and quality of patient care. Winya M.K. asserts that efforts to improve health care communication require an increased focus on the systemic and organizational factors that could promote or inhibit patient-physician interactions.¹⁶

12 Regarding this matter, interventions to improve safety culture are interwoven with measurement approaches. The act of measuring sends signals to team members about the value of the organization. For a better analysis in terms of data collection and measurement strategies, see: M.D. Flotter, N. Khatri, G.T. Savage, *Strategic human resource management in health care*, UK, 2010, p. 111

13 Joint Commission Accreditation of Healthcare Organizations, founded in 1994 and based in Illinois, is one of the world's leading non-profit patient safety organizations. Refer to: www.jointcommissioninternational.org

14 Joint Commission International, *Leadership committed to safety*. Sentinel Event Alert, Issue 43, Aug 27, 2009, http://www.jointcommission.org/sentinel_event_alert_issue_43_leadership_committed_to_safety/, web site consulted 10.01.2015

15 For a better analysis refer to: M.R. Chassin, *Improving the quality of healthcare: what's taking so long?*, New England Journal of Medicine, US, 1996, October, 3

16 M.K. Winya, *Making it easier to do the right thing: a modern communication QI Agenda*, Patient Education and Counselling, Ireland, 2012 (Sept), 88 (3): 364-366

The creation of a good donor organ acquisition process depends on all team members involved and a good quality of communication. This, along with sharing of experiences gained in different ways, can improve the mutual understanding of the transplant process. Intensive care staff play a central role in the process of donor organ acquisition in identifying a potential donor, in taking care of the relatives' need for pertinent information and in briefing them on the question of organ donation.¹⁷ Communication failures may occur, particularly with regard to cross-disciplinary interactions. Common causes of errors leading to adverse events include organizational factors such as: lack of communication or miscommunication; lack of attention to safety guidelines and procedures; excessive workload and; insufficient staff members for specified tasks. Many people believe that communication is simply the act of sending a clear message to someone, but just sending a message does not result in action if reception does not occur. Communication is effective when it is in context and linked to the receiver and not only to the transfer of data. Top-down communication has to be replaced by a two-way model which includes feedback to the leadership. Silence about harmful events would be replaced with open disclosure about serious patient safety events which would allow for organizational learning from accidents. In the event of reporting, coordinators would take a non-punitive approach in order to identify problems and work towards their resolution following the logic of learning improvement. Some of the common barriers to reporting errors or accidents include: the limited knowledge about what and how to report; the desire to forget the event and; the fear of reprisals or punishment.¹⁸

Documenting, registering and filing reports of care provided improves communi-

17 K. Meyer, I. T. Bjork, *Change of focus: from intensive care towards organ donation*, European Society for Organ Transplantation, 21 (2008), 133-139

18 In order to overcome these problems leaders could use some strategies to facilitate reporting, such as standard reporting formats immediately available to the team professionals.

cation among health professionals, protects patients against damage, and promotes care continuity and improvement. In addition, records should cover all phases of the transplantation process, ranging from the donation to the hospital discharge of transplant recipients.

Furthermore, the health organizations and teamwork involved in the systematic actions should document incidents and deviations from established procedures and specifications. Documentation would enable all steps and all data affecting the quality and safety of the organs, tissues and cells to be checked and traced, from the donor to the recipient.¹⁹ This is very important because written documentation ensures that work is standardized and also prevents errors that may result from oral communication.²⁰

Priority should be given to investigation and reporting of incidents with demonstrated or potential risk to cause serious adverse events.

According to Politosky G., Coolican M. and Casey K., procedures should be developed through the collaboration of the major organizations involved in the care of donor families and transplant recipients in order to standardize communication practices.²¹

ERRORS AND ADVERSE EVENTS MANAGEMENT

Studies related to medical errors have resulted in growing awareness of patient safety issues within healthcare systems. Global effort has been placed on patient safety in general and, particularly on adverse and sentinel event

19 Council of Europe (edited by), *Guide to safety and quality assurance for the transplantation of organs, tissues and cells*, Strasbourg, 2009, p. 18; website: www.edqm.eu

20 A safety culture exists within an organization which promotes the open reporting of errors and incidents and encourages the consequent improvements in practice that investigations of such events can bring. All team members have to share the responsibility to participate in the evaluation of risk and in the implementation of appropriate strategies for error prevention during the whole donation-transplant process.

21 G. Politoski, M. Coolican, K. Casey, *Perspectives on communication issues among transplant and procurement professionals, transplant recipients and donor families*, US, 1996, Jun, 6 (2): 78-83

management. Generally, errors have been classified by various authors according to task, system and behaviour including diagnostic, therapeutic, and preventive. Many however are actually due to communicative mistakes.

James Reason considers error as “a generic term to encompass all those occasions in which a planned sequence of mental or physical activities fails to achieve its intended outcome, and when these failures cannot be attributed to the intervention of some chance agency”.²²

Reason’s type of error extends Jens Rasmussen’s skill-rule-knowledge model of human behaviour. Rasmussen defines skill-based behaviours as a performance governed by pre-programmed instructions. A primary difference between rule and knowledge-based error is information flow. *Feedback* - what was done and its outcome - represents the control mechanism required to prevent future knowledge-based errors.²³

Human error plays a crucial role where lack of training and knowledge, failure to follow procedures, fatigue and overwork, all contribute to adverse outcomes.²⁴ When an adverse event is identified, the transplant centre must document and notify the event using the case analysis as represented in order to effect changes in policies and practices to prevent repeated incidents.

The most common way to investigate an adverse event is the Root Cause Analysis (RCA)

22 J. Reason, *Human error*, quoted, p. 9.

23 J. Reason correlates types of error with three types of behaviour: *slips*, resulting from a failure of skill by inattention or over attention; *lapses*, which result from a failure of good rules or the application of knowledge; *mistakes*, which emanate from a failure or lack of expertise. For a better understanding of this topic, see: J. Reason, *Human error: models and management*, UK, 2000, Mar 18; 320 (7237): 768-770

24 Adverse events are usually caused by many interrelated factors and some of them are related to the organization and processes, while some are due to human error. Some examples of adverse events during the transplantation process are: the unintended transmission of infectious agents to a recipient; ABO incompatibility between donor and recipient; living donor failure; living donor organs retrieved but not transplanted.

which consists of a process used to discern the underlying reasons for an adverse event in order to prevent the recurrence of a harmful outcome or a near miss. In the organ transplantation process, the possibility to increase safety seems greater using proactive research, mainly centred on organizational process together with a retrospective analysis but not limited to adverse event reports in addition to application of previously shared guidelines and protocols.²⁵ Failure mode and effects critical analysis (FMECA) is used to identify when, where and how processes might fail.²⁶ It also emphasizes prevention rather than reacting to problems or adverse events. A deeper understanding as to why a particular error or adverse event occurred, and with less focus on the individual who made the error, could have positive outcomes.²⁷ The reporting of errors, near misses and adverse events should be encouraged as these are viewed as opportunities to identify and improve processes of care.²⁸ Barriers to reporting are: the fear of disciplinary action; the fear of inappropriate disclosure to others, seen as unnecessary paperwork and not seeing the value in reporting and; especially, the fear of being named in legal action resulting from the error/incident. As for Legal Medical aspects, there are no specific sanctions for healthcare professionals since quality is based on transparency and collaboration as well as efficiency and suitability of all phases of the donation-removal-transplant process. According to European Directives on adverse events it is mandatory to have a quality

25 R. Pretagostini, F. Gabbrielli, P. Fiaschetti, A. Oliveti, S. Cenci, D. Peritore, D. Stabile, *Risk management. Systems for healthcare and safety development on transplantation: a review and a proposal*, 2010, May, 42(4): 1014-6

26 FMECA is made up of four steps: failure modes (what could go wrong?); failure causes (why did the failure happen?); failure effects (what would be the consequences of each failure?); failure prevention (how can we prevent a bad result when there is a failure?). For an in depth analysis see: L. Norris, *Transplant Administration*, US, 2014

27 B. Hoffmann, J. Rohe, *Patient safety and error management. What causes adverse events and how can they be prevented?*, 2010, Feb; 107(6): 92-99

28 J. Reason, *Human Error: models and management*, quoted, 768-770

management system for adverse events notification or for serious reactions. The National Transplant Centre drafted several documents and among them a card for adverse events and adverse reaction notification.²⁹ It is the responsibility of every individual professional to report a patient safety occurrence whether or not it reached the patient and whether or not it caused harm. In this way, simple human errors and behaviours where risk is not recognized will be individually evaluated with the focus on understanding the reasons for errors and so creating the conditions for behavioural modifications.

Personal punishment would be self-defeating since blaming a single individual would hinder collaboration among professionals involved. Sanctions applied to healthcare personnel are mainly generic, as provided by public Hospital Corporations disciplinary codes and by the Penal Code, when the offense is prosecutable *ex officio* or involves legal action by the parties.

All of the above is due to the fact that the very many control systems, both those pre-arranged by applied legislative regulations adopted by the Italian Government, and those following protocols, internal codes and procedures, in the vast majority of cases only report near miss cases or preventable events which do not cause any damage to the patient. Timely communication of an adverse event by healthcare personnel to CRT-FVG³⁰ is of the utmost importance since it reduces or eliminates the consequences of the event itself during all the following stages of the donation-removal-transplant process.

29 Furthermore, to maintain required National quality and efficiency standards some forms of institutional accreditation have been especially set for this kind of surgery. Centro Regionale Trapianti of Friuli Venezia Giulia has set a monitoring and quick reporting system for events and adverse reactions as required by the regulation 2010/45/UE on quality and safety of human organs intended for transplant. For an in-depth analysis of the European Union Directive 2010/45/UE, see: M.G. Ison, J.L. Holl, D. Ladner, *Preventable errors in organ transplantation: an emerging Patient Safety Issue?*, *Am J Transplant*, 2012, Sep; 12(9) : 2307-2312

30 Centro Regionale Trapianti, Friuli Venezia Giulia, Italy.

DONATION-REMOVAL-TRANSPLANT PROCESS: RESEARCH IN FVG REGARDING ADVERSE REACTIONS AND NO DAMAGE TO THE PATIENT.

Donation, removal and transplant activities are presently articulated on three levels: a national level with the National Transplant Centre, a regional and an interregional level with a Regional and an Interregional Reference Centre for Transplant and a Local Coordination level.

The Regional Transplant Centre coordinates data collection and data transmission to patients on the transplant wait list as well as removal activity and communication with resuscitation rooms on the territory; it controls immunological testing prior to transplant, it assigns organs and handles contacts with the interregional centre of reference, with regional and health authorities and with voluntary associations.

Interregional Coordination makes use of three interregional organizations that cover the whole National territory. Each single phase is accompanied by structures that depend both from the National Transplant Centre and the Ministry of Health.

High quality management of coordination centres (locally, regionally and inter-regionally speaking) is a basic premise and a must in order to reach a complete clinical policy of the donation-transplant process. Furthermore, it must offer the highest possible operative guarantee in terms of efficiency and effectiveness to the whole system. Local coordination, in particular, controls and facilitates the whole process leading to organ removal in compliance with National Laws and guidelines. It manages identification of potential donors as well as their suitability and manages relationship with donors' families. It handles all paperwork connected to organ removal and transmission of all potential donors' data to the Regional and Inter-regional Centre.

The transplant process is highly complex, mainly due to the speed that an efficient organization needs while performing all required functions. Therefore, each phase of the process must be meticulously performed. Starting from the required operative process analysis

to identification of professionals, procedures and methodologies to be followed considering that, according to Italian experience, on average we have a 10 hours lapse between donor identification and actual transplant surgery.³¹

S. Venettoni itemizes the whole process into a series of phases and he identifies the professionals involved during each phase as well as critical situations and possible consequences.³² Talking about communication among healthcare professionals he identifies the following steps:

1. Locate potential donor (Local Coordinator, Resuscitator): *Potentially critical situation*: inadequate Local Coordinator integration with hospital diagnostic units; *Consequences*: failure to identify potential tissue and organ donors.

2. Diagnosis, assessment and certification of death (Resuscitator or/and Local Coordinator, committee): *Potentially critical situation*: lack of communication with Healthcare Management or failure to activate Medical Units during death assessment and certification phases; *Consequences*: failure to apply reference standards, loss of potential donor, failure to perform transplant to wait list patients.

3. Notification of potential donor to performing CRT/CIR³³: (Resuscitator and/or Local Coordinator): *Potentially critical situation*: late reporting, notification lacking indispensable information for early evaluation; *Consequences*: donor kept alive beyond established observation period, logistic and organizational problems for organ removal units.

4. Early suitability assessment (Resuscitator and/or Local Coordinator, Coordination,

31 The whole donation-removal-transplant process consists of resuscitation, management, coordination centre, immunology laboratory, diagnostic services, transplant centre, emergency call centre and transport companies.

32 S. Venettoni, *Il processo di donazione-prelievo-trapianto: analisi delle procedure e criticità*, www.salute.gov.it/imgs/C_17_pubblicazioni_645_allegato.pdf, site consulted 22/12/2014

33 Centro Regionale Trapianti/Centro Inter-regionale Trapianti, Italy

second opinion): *Potentially critical situation*: anamnesis, failure to adopt diagnostic preferential operational protocols on potential donor, failure to transmit original medical reports; *Consequences*: need to clarify anamnesis doubts through targeted surveys, delayed procedures and temporary stalemate situation, possible incongruence between what has been transmitted on the phone and/or what has been transcribed by the operator.

5. Maintenance (Resuscitator): *Potentially critical situation*: unsuitable monitoring of requested parameters; *Consequences*: unsuitable donor care, hemodynamic instability.

6. Talking to relatives (Resuscitator and/or Local Coordinator): communication and relationship with potential donor relatives represent one of the most critical points of the whole process. Although each interview is different, it should always be planned with a methodology based on a sequential and clearly phases in any aspect that may influence its result. The request of donation should be stated clearly, directly and in plain and understandable language with an exaltation of values: the donation should be offered as an option, right, privilege, or a possibility of helping others.³⁴ Furthermore, no maximum time for the interview should be pre-established. *Potentially critical situation*: hasty communication using strictly technical language takes place in unprotected environment; proposal for donation is made before clinical death has actually been notified, insufficient amount of time given to family members to ask for explanations and details; *Consequences*: inadequate understanding by family members with temporary stalemate and consequent delays; disoriented and confused family members; disappointment, distrust towards the healthcare system resulting in denied donation.

7. Lymph nodes removal and peripheral blood collection for immunological characterization (Local Coordinator, Local Surgeon, In-

34 Organización Nacional De Trasplantes, *Good Practice Guidelines in the process of Organ Donation*, Madrid, Spain, 2011, page 54

tensive Care Unit personnel): *Potentially critical situation*: lack of information that goes with the material, difficulties and/or not timely biological material transport activation; *Consequences*: procedure errors and mistaken potential donor identification.

8. Consulting assignment lists (Coordination of CIR/CRT, transplant Centres): *Potentially critical situation*: patient list has not been updated with new entries, patient list lacking recent medical information; *Consequences*: failure to select new patient for organ transplant.

9. Summon of transplant receivers

10. Instrumental-diagnostic in-depth analysis (Resuscitator, Local Coordinator, diagnostic services, healthcare personnel).

11. Organ and tissue removal and second suitability evaluation (Surgeons, second opinion): *Potentially critical situation*: several surgical teams are in the operating room at the same time, surgical personnel has not been informed on removal program (i.e. timing, team, organs to be removed), surgical personnel with limited previous experience; *Consequences*: chaotic organization of surgical phases, inadequate organization and management support during surgical procedure.

12. Planned Surgery and third suitability evaluation (Transplant Surgeon, Pathological anatomy): *Potentially critical situation*: failure to transmit organ medical documents especially in cases when the organ has been removed by a medical team other than the transplant team; *Consequences*: failure to evaluate proper organ quality and functionality due to lack of documents, not enough info for the receiver on organ he/she is about to be transplanted with.

13. Transplant (Transplant Surgeon, Diagnostic system): organ transplant is a highly complex surgical procedure and implies great responsibility. It involves the whole transplant system and calls for total collaboration among

all structure internal services. *Potentially critical situation*: selected patient cannot be found, very limited time for patient transportation to transplant centre, insufficient collaboration between support systems within the transplant centre, late communication to intensive care unit for support during forthcoming transplant, lacking or delayed communication to transfusion cent on forthcoming transplant surgery; *Consequences*: transplant may not be performed on selected patient, transplant is performed in a location authorized only for certain types of transplant that may not be the needed one, difficult patient care during the after-transplant phase, no bed available in the intensive care unit, blood units may not be available if transfusion is needed.

14. Follow-up (Transplant centres and/or specialized units located in patient residence area): *Potentially critical situation*: failure to identify person in charge of the follow-up unit, there should only be one doctor instead of several professionals; *Consequences*: irregular relationship between doctor and patient, possible surgery duplication, follow-up phase is not personalized.

15. Logistics aspects regarding equipment and biological material transportation (Coordination centres, transplant centres, transportation systems): poor management of logistics aspects may cause delays and/or serious problems during each phase of the process.

Hereafter, chart Nr.1 lists all adverse events caused by communication and management problems throughout the donation-removal-transplant process in the FVG region during 2011-2013. Chart Nr.2 lists all near miss and non-conformity situations in FVG during the same period.

After collecting all cards for adverse events notification, CRT of FVG creates its own database for further elaboration and information management. Risk evaluation is carried out according to seriousness/consequences (G) and danger/repetition frequency (R). These two variables provide a score (S) that classifies both the event and the procedures to be implemented.

PROCESS PHASE	EVENTS 2011	No	G	R	S	EVENTS 2012	No	G	R	S	EVENTS 2013	No	G	R	S
1						Mistaken risk evaluation	1	severe	rare	10					
2	Inappropriate summons of CAM	1	major	possible	12	Mistaken summons of CAM	2	major	possible	12					
3															
4															
5															
6	Incorrect communication	4	major	possible	12										
7											Incongruity between blood serum sample and patient identification label	1	severe	possible	15
8															
9															
10															
11	Failure to draw up blood sample report	2	moderate	probable	12										
12	Operating theatre organisation	3	moderate	possible	9										
13															
14						Both donor and recipient records in the same chart	1	severe	possible	15					
15						Tissue not used although informed consent	1	severe	possible	15	Restricted information disclosure	1	severe	possible	15

Chart 1 – Signalling adverse events at CRT-FVG, 2011-2013.

PROCESS PHASE	EVENTS 2011	No	G	R	S	EVENTS 2012	No	G	R	S	EVENTS 2013	No	G	R	S
1											Missed BDZ drug monitoring	2	minor	rare	4
2															
3						incorrect organisational communication	3	minor	possible	6					
4															
5															
6						incorrect communication towards relatives	2	minor	possible	6					
7															
8															
9															
10															
11						Failure to draw up blood sample report	3	minor	possible	6	Sample reports incorrectly drawn	6	minor	probable	8
											Operating theatre delayed entry	3	moderate	possible	9
											Histological report missed advice	1	major	rare	8
12						Team not informed in regard to the organisational path	2	minor	rare	4					
13															
14															
15	Lack of procedure	1	minor	possible	6	Donor manager report incorrectly drawn	4	minor	possible	6	Wrong tissue consent report	6	minor	probable	8
	Wrong sample shipping	1	minor	possible	6	Blood sample report delayed	3	moderate	rare	6	Missed signalling to CIR regarding a potential donor	1	minor	possible	6
	Informational system lost data	1	minor	rare	4						Failed communication between CRT and FVG Airport	1	minor	rare	4
											Communication mistake CRT-CIR regarding the organ destination	1	moderate	possible	9

Chart 2 - Near miss and non conformity situations at CRT-FVG, 2011-2013.

RESULTS

According to the above mentioned issues we can see how communication errors are mainly due to mistaken or incorrect use of information, data collection and analysis and difficulties in the use of feedback to better evaluate data received near real time. If we can solve these problems we may guarantee a safer process and will be able to better monitor our activities, avoiding critical situations.

Coordination programs should be instituted in every “organ generating” hospital using highly motivated well-trained professionals who act in compliance with agreed protocols and ethical principles.³⁵ Interventions for the improvement of safety include: team training, leadership walk-arounds, safety audits, event reporting and analysis systems, interactive group briefings and debriefings and performance feedback focusing on how human factors interact with high risk situations. In this regard, Spanish hospitals have introduced a network of healthcare professionals responsible for organ donation and ensuring the involvement of all concerned in the quality of the process, the patient safety and care effectiveness.³⁶ Healthcare professionals can use the research results to transfer evidence to their clinical practice and, furthermore, could improve results and support the approach and monitoring of donors, transplant candidates and recipients. Continuing education, associated with clinical practice, allows operators to progress from learning professionals to expert professionals in critical areas and to become involved in complex decisions.³⁷ Personnel involvement and basic knowledge (glossary, taxonomy, detection technology, analysis,

proactive and reactive intervention) are indispensable for Clinical Risk Management together with use of proper tools for prevention, identification of adverse events, report management, data collecting and widespread use of specific information systems.

A constantly active computerized system monitoring and managing all activity phases, should guarantee data traceability and its transfer to the laboratory located on the donation site, without the need for manual transcription of vital data, thus allowing better technical and clinical evaluation of all gathered information.

A safety culture is characterized by a continual drive toward the goal of maximum attainable safety. The following flow-chart lists the best strategies to avoid communication problems within the coordination system, to improve the relationship between healthcare professionals and patient’s family members, for a safe and successful donation-transplant process.

³⁵ Knowledge and competences are significant factors which could improve a shared understanding of the value of the teamwork.

³⁶ For an in-depth analysis, see: Organizacion Nacional De Transplantes, *Good practice guidelines in the process of organ donation*, quoted, 47-62

³⁷ I. Tonalak, R. Emiroglu, H. Karakayali, N. Bilgin, M. Haberal, *The importance of continuing education for transplant coordination staff*, U.S., 2005, Jun; 15(2): 106-11

LEGEND

Class A: Communication management inside the teamwork itself

Class B: Management of conversation and support of family members

Class C: Training of human resources on clinical risk management during donation-removal-transplant process

	<u>Performance</u>	<u>Possible indicators of wrong behaviour</u>	<u>Indicators of proper behaviour</u>	<u>Professionals involved</u>
Class A	Decision making (A1)	Too many different professionals resulting in incorrect collection of data	Personalized follow-up management / Timely communication of relevant info	Coordinator, surgeons, resuscitator, nurse coordinator, operating theatre personnel, intensive care unit nurses, transportation operators
	Cooperation, exchange and share information (A2)	Distorted communication, logistic and organizational difficulties/ Difficult patient clinical follow up	Proper coordination of activities among operators involved in different phases	
	Management of emotional self-control and conflict solving among operators (A3)	Discontinuous relationship, anxiety and preoccupation affecting organization	Emotional self-control, capacity to mediate and manage conflicts	
	Correct logistics and transportation management (A4)	Delays and possible duplicated action	Respect of delivery times for biological samples and organs to be transplanted	
Class B	Selection of context and information recipients (B1)	Choice of non-protected environment	Adequate environment and guarantee of privacy	Coordinator, resuscitator, psychologist, nurse coordinator, nurse
	Proper skills in managing conversation with family members (B2)	Failure to respect conversation sequence, distorted information received by recipients of the message	Correct data collection / Conversation and information sequences has been respected	
	Use of cultural mediator (B3)	Family members understanding of medical language has been underestimated	Proper evaluation of family members capability to understand medical language	
	Possibility for feedback and clarification (B4)	Unilateral communication	Listening capability, according to feedback timing	
	Activation of psychological -emotional help and support (B5)	Hasty and detached communication finalized at obtaining permission for donation	Establish a help and psychological-emotional support relationship with family members based on trust and respect	
Class C	Knowledge and application of proper procedure/protocol for identification system and clinical risk analysis and prevention (C1)	Insufficient knowledge of all donation-removal-transplant process procedures as well as incorrect information of potential damage events	Knowledge of different phases of the donation-removal-transplant process according to current procedures	Coordinator, surgeons, resuscitator, nurse coordinator, nurses
	Timely communication of near miss situations, adverse events and sentinel events following proper procedure for report sequence (C2)	Failed communication/Blame culture	Proper Training of personnel able to handle immediate event information, according to protocol regarding prevention and GRC	
	Support human resources training development (C3)	Difficult application of knowledge, failure to transfer and improve best practice activity.	Favour participation to audit, briefing and Sea / application of FMECA, RCA, SWA / support educational growth using ECM system	

Flow-chart regarding communication among health care professionals and families towards organ donation.

CONCLUSIONS

The donation and transplantation process requires a progressive change in health culture. A transplant represents the final act of a long, complex, multi-professional and multi-factorial journey. All phases must be systematically coordinated using all available tools for risk identification and evaluation in order to improve the whole process.

Synergy between proper use of tools, logistics, cooperation, efficient verbal and on-line communication, proper training of all professionals involved in all phases, are the premises for a well coordinated and high quality donation-removal-transplant process, keeping safety and high quality standards as a must. All healthcare professionals should receive professional training on donation issues in order to create confidence and proficiency within the whole process.³⁸

Adverse events are unexpected occurrences that may cause unintentional and undesirable damage to the patient. Warning systems set to prevent such events are an indispensable tool to gain a better understanding of causes and risk factors. Based on the “learning from your mistakes” principle, new prevention strategies should be established to improve patient safety. Therefore, the management-organization process plays a crucial role and calls for the utmost professional commitment by all personnel involved at different levels in the donation-removal-transplant process. Roles must be properly assigned to achieve fluidity during each and every phase of the said process although overall culture and safety behaviour can improve the performance and optimize the work flow. A safe clinical environment is strengthened when work processes allow leaders and staff to discuss and learn about safety issues.³⁹ Leaders, at all levels, have to create a

38 Continuous training should be implemented to facilitate effective communication among team members during potential donor cases. Therefore, quality control of patient care is needed as well as communication and cooperation within the staff.

39 Joint Commission International, *Leadership committed to safety. Sentinel Event Alert*, quoted, web site consulted 10.01.2015

culture that supports staff and instils in health operators a sense of ownership of their work processes in order to prevent the clinical risk.

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