

IMPACT HTA

Improved methods and actionable tools for enhancing HTA

Deliverable 8.2

Toolkit of instruments to identify the clinical variability and its impact on the use of health technology

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Executive summary

The IMPACT HTA project (Improved Methods and Actionable Tools for enhancing HTA) is a Research and Innovation Action (RIA) funded under the Horizon 2020 programme that looks at new and improved methods across ten thematic areas aiming at: (1) understanding variations in costs and health outcomes within and across countries, and (2) integrating clinical and economic data from different sources to improve methods in economic evaluation in the context of HTA and health system performance measurement.

In particular, the purpose of WP8 is to identify which and to what extent organizational/contextual factors influence the effectiveness of use of medical technologies and might cause clinical variation in their implementation, affecting hospital performance. In fact, the utilization of health technologies can generate an increase or a decrease in patient benefit. Effectiveness and appropriateness are factors able to increase patient value, while inappropriate use, overuse or underuse of health technologies can generate a decrease in the same benefit. In particular, an inappropriate use of health technologies due to a 'Non-Evidence-Based Medicine' approach by physicians can reduce the clinical and the organizational performance of doctors and healthcare organizations.

In this view, WP8 developed a toolkit aimed at analysing the different factors (i.e. behaviour of healthcare professionals and organizational issues) further to the technical characteristic of technology that contribute to clinical variability. In particular, the toolkit mainly relies on an analytical tool aimed at assessing the clinical variation due to the use of health technologies, with a specific focus on the impact of clinical variation on the allocative and technical efficiency of hospitals.

Such analytical tool allows to calculate either economic and technical efficiency gains deriving from: (1) policies aimed at reducing purchasing prices of medical devices or equipment, (2) organizational interventions aimed at reducing the resource used for operational surgeries (i.e. duration, health professionals involvement, etc.), and (3) interventions aimed at reducing administrative and hospitality costs.

The report is structured as follows: (1) a description of the context and the rationale of developing such analytical tool; (2) an overview of the analytical tool to assess the clinical variation of hospital technologies which has been developed by WP8 (3) a detailed description of the data and sources used to populate the analytical tool; (4) a user manual explaining how to use the tool with a demo including sample data.

1. Context and problem definition

Hospitals are under constant pressure to provide high quality services in an era of limited financial resources and increasing expectations from patients, government and society (1). The adaptation of innovative health technologies (HT) can offer solutions to help meet these demands. However, depending on the implementation and use of new HTs they can either generate an increase or a decrease in health benefits and costs (2). Effective and appropriate use are factors able to increase patient value and performance, while inappropriate use, overuse or underuse of health technologies can generate a decrease in the same benefit, reduce the performance for both healthcare professionals and the healthcare organizations while at the same time increase budget spending.

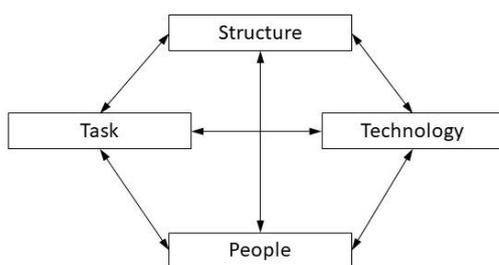
Even though structured guidance on how health technologies should be introduced, used and disseminated exists and is distributed in hospitals, the operational uptake and implementation of evidence-based practice is often insufficient to change clinical behavior and reduce clinical variability (3). Unfortunately, production and diffusion of Health Technology Assessment (HTA) recommendations or national guidelines for the appropriate use of technologies does not automatically produce a change in clinical practice even in the most effective and efficient health care organizations which can affect the performance (4). In fact, one of the greatest challenges in HTA is the operational implementation of HTA recommendations in clinical settings. Hospitals are complex organizational systems and the performance of health professionals and the way they utilize HTs are largely dependent on the local-organizational contexts of the hospital in which they practice (5,6,7,8,9,10,11). This holds particularly true if we think of the variety of items and dimensions that constitutes the “uniqueness” of a hospital, such as the physical, structural, managerial and possibly cultural identity of a hospital. These are all dimensions that are likely to affect the ways of utilizing HTs. Prior studies have primarily focused on the behavior of the individual professional in this process and therefore organizational factors’ influence on effective implementation and proper use of health technologies remains poorly understood (12). While the maturity of a technology is measured in relation to if it has been in use long enough for most of its initial faults and inherent problems to be removed or reduced by further development, the “maturity” of a hospital when receiving a new technology, and whether its organizational and managerial features (i.e. its contextual factors) enable the technologies to concretely produce health in the long run, is rarely discussed. It is therefore not clear whether hospital contextual factors only are affected by health technologies (HT) or if (and how) hospital contextual factors affect the use of HTs’. Although it is well acknowledged that a clear understanding of the organization in which technologies are introduced is crucial (13), this is not the same as having full awareness of the extent to which the organization is capable of using the

technology concretely in order to possibly enhance the performance (13). In other words, although a technology may be highly recommended in an HTA report, it is unclear which contextual factors may enable its optimal utilization and how. Therefore, there is a clear need to investigate the impact of contextual factors on the actual use of HTs and the clinical variability of use and therefore to standardize an approach to analyze, measure and manage the clinical variability and its relationship with organizational models.

Theoretical framework

In order to explore the role of organizational conceptual factors influence on clinical evidence-based decision-making and how this relationship might influence the uptake of technologies, Harold J. Leavitts 1965 Organizational System Model (15) has been used as an inspiration to identify and select the variables that are central to the analysis of the interaction (figure 1).

FIGURE 1. LEAVITT'S SYSTEM MODEL (1965)



The model is based on a dynamic and system-oriented organizational perspective that views organizational changes in a holistic perspective. This means that changes in an organization (in this case a hospital) can be described by the interdependent interaction between four main components: Tasks, people, structure and technology. Task is the organizations purpose to provide a service, it involves all the things that need to be done in order to achieve a certain goal at the organizational, departmental, or individual level. People are those who carry out the task within an organization. This component also pertains to all skills, competencies, knowledge, and efficiency that employees bring. Technology is a very broad concept and can for example include tools and computers (in this case medical technologies). Structure is the workflow, communications and decision-making authority within an organization. It also involves the mutual relations between departments and employees, the coordination between various levels of management, and communication patterns. Any type of change or redesign in one component will affect the other three.

This report focuses on how organizational factors might influence clinical evidence-based decision-making and how this relationship might influence the uptake of technologies. Therefore, the focus of the Leavitt's System Model will be on the interaction between structure, people and technology.

Contextual organizational factors effect on the use of technologies

Through a literature review performed as part of Task 1 in WP 8 (for more information see Deliverable 8.1 of the Project) the effect of hospital contextual factors on the use of technologies was examined through a literature review. PubMed, Scopus, Web of Science, Econlit and Ovid were searched to retrieve studies published in English from 1st January 2010 to 31st May 2018. A total of 33 studies were included mostly addressing information and communication technologies (ICTs). Four main contextual domains were highlighted as likely to affect the concrete use of health technologies within hospitals. The four domains were: Hospital infrastructure and architecture; Hospital's availability of financial resources; Leadership styles; Human resource management tools.

The results from the review suggested that several contextual factors play a major role in health technologies actual utilization and effectiveness at hospital level, even though data are mostly referred to ICTs and not to the whole spectrum of health technologies. Although numerous items should be evaluated when considering the uptake of health technologies at hospital level, the impression is that a full awareness of some of these and of their concrete effects may be missing. Moreover, evidence concerning medical and surgical health technologies is lacking and future research should attempt to fill this gap.

Contextual organizational factors effect on evidence-based clinical decision-making

A second literature review examined how organizational contextual factors might influence clinical decision-making and how it can affect the use of evidence-based practice (EBP). A search was conducted in the three electronic databases: MEDLINE/PubMed, Web of Science and Scopus covering the period from 1st January 2000 to 1st October 2018. The search included four groups of search terms: 1) Organizational factors, 2) Decision making factors, 3) Evidence-based practice and 4) Hospitals. The search included subject headings (Mesh terms in PubMed) for the four groups of search terms as well as a targeted "keywords search" for the same four groups. The same search was repeated for the three electronic databases: MEDLINE/PubMed, Web of Science and Scopus. Furthermore, a hand search of articles retrieved was performed in order to find further references. A specific focus was put on locating organizational/ managerial barriers and facilitators that effectively influence evidence-based clinical decision making in hospital settings.

A total of 30 articles were included in the analysis. Based on a narrative summary of the results of the selected article the following three themes emerged from the systematic review (as fully described in Deliverable 8.1 of the Project):

1. Resources
2. Leadership
3. Organization

This analysis showed that hospital administrations have a great responsibility in order to create an environment and culture that support and endorse coherency between hospital policies, evidence-based knowledge and practice in the whole organization. Teamwork across units and collaboration between staff and leaders at all levels, as well as clear communication and goal setting are all important aspects in order to support a strong culture where research is valued and EBP is a common goal of the institution and its members. In addition, hospitals should ensure sufficient time for training and implementation, financial support, proper additional staffing in order to implement EBP.

The influence of contextual organizational variables on clinical evidence-based decision-making

In order to explore how organizational factors might influence clinical evidence-based decision-making and how this relationship might influence the uptake of technologies, two case studies have been performed examining two different technologies:

1. diagnostic use of high sensitivity troponin and its impact on NSTEMI myocardial infarction; (Non-ST elevation myocardial infarction) diagnosis and treatment in emergency departments
2. clinical use of robotic surgery with Da Vinci Robot in different clinical areas. (45)

The logic that guided the choice of case studies for the research was to identify examples that could contain, in different care settings, those context variables that could influence the variability of use of health technologies in order to better explain, describe and explore events or phenomena in the everyday contexts in which they occur.

The first case study was chosen since the use of high sensitivity troponin for predictive diagnosis of NSTEMI myocardial infarction in hospitals' emergency departments, is still very heterogeneous. Indeed, its overuse, as often happens with the diffusion of the technology, combined sometimes with an inappropriate timing of use due to organizational problems, increase the risk of having many false positive patients to the test (46,47). This implies that a certain number of patients will be directed towards the performance of invasive procedures such as coronary angiography even if not necessary. Coronary angiography, like all invasive procedures, involves a risk/benefit ratio in which, although

fortunately rare, adverse events may occur, even of a severe nature such as pseudoaneurysms, stroke, or cerebral hemorrhage, severe cardiac arrhythmias, etc. On the other side the underuse of this test, instead, results in increasing number of false-negative patients that may also be discharged with a heart attack in progress that it has not completely manifested, potentially leading to death.

A correct use of this test, on the other hand, contributes to an earlier diagnosis, allowing a better therapeutic approach and a reduction in the time spent by patients in the emergency room with a consequent reduction in costs.

The second case study was chosen since the different clinical use of the Da Vinci Robots in different clinical area (from prostatectomy to cardiac surgery and gynecological surgery) associated with different organizational model of robot utilization (hub system or decentralized system) and different surgical technique (use of different numbers – from 2 to 4 – and kinds of surgical harms for the same surgical intervention) produce different performances in different hospitals that do the same type of surgery. These variables, linked in particular to the organizational aspects of robotic surgery activities, have an impact on the quality of the service provided as well as on waiting times and on the level of specialization of both the centers and the professionals. Greater specialization allows you to create and exploit a wealth of common knowledge (social capital) as well as fostering a professional culture of cooperation. More purely organizational are the advantages identified in the optimization of the logistics function and administrative which can create greater allocative efficiency and rationality in planning / management activities. (28)

In both cases, the initial idea was to investigate the significance of various conceptual organizational aspects of technology uptake using objective data collected from publicly available official websites such as hospital websites and ministerial websites. This method was used for case study 1 on the use of high sensitivity troponin for predictive diagnosis of NSTEMI myocardial infarction where information regarding organizational conceptual factors was collected from the webpages of the relevant hospitals and official ministerial online documents. However, the study showed that there is limited data publically available on organizational aspects. Therefore, method for data collection for case study regarding the clinical use of the Da Vinci Robot was altered to solely rely on self-reported survey data with key stakeholders at hospitals. Questions in the survey covered all subtopics of the four conceptual organizational domains identified in the first literature study as well as the four components of the Leavitt's System Model.

Case study on the diagnostic use of high sensitivity troponin for predictive diagnosis of NSTEMI myocardial infarction in emergency departments

Cardiovascular diseases (CVD) are the leading cause of death in the European Union (EU) causing over 1.8 million deaths each year, which is equivalent to 37% of all deaths in the EU (16,20). The most common form of CVD is the myocardial infarction which is responsible for over 15% of mortality each year (16). Myocardial infarction (commonly known as a heart attack) is a life-threatening condition that occurs when blood flow to the heart muscle is abruptly cut off (ST-elevation myocardial infarction, STEMI) or partially blocked with severely reduces blood flow (non-ST-elevated myocardial infarction, NSTEMI), causing tissue damage to the heart muscle (17).

Together with presentation of symptoms and an electrocardiogram (ECG) test, troponin testing is an essential component of the diagnostic workup and treatment of myocardial infarction. An elevated cardiac troponin I and T in serum or plasma indicate a damage to the heart muscle and therefore plays a critical role in the timely diagnosis of heart attacks or for the use of a 'early rule out protocol'. In Europe, the vast majority of cardiac troponin assays are sensitive (i.e. allow for detection of cardiac troponin in 20–50% of healthy individuals) or high-sensitivity (detection in 50–90% of healthy individuals) assays. The guidelines of the European Society of Cardiology from 2015 (21) recommends high-sensitivity assays over less sensitive ones. However, the majority of currently used point-of-care assays cannot be considered sensitive or high sensitivity assays and a heterogeneous use of high sensitivity troponin for predictive diagnosis of NSTEMI myocardial infarction in emergency departments have been observed (21).

The operational uptake and implementation of evidence-based practice is often insufficient to change clinical behavior and reduce clinical variability. Inappropriate use of a health technology, such as high sensitivity Troponin, due to a non-evidence-based approach can cause delay in diagnosis, longer hospitalization, reduce the patient outcome and the performance of staff as well as the healthcare organization while increasing costs.

The purpose of this case study is to describe differences and similarities in the hospital organizational models and examine the influence of contextual organizational variables affect on the use of High-sensitivity cardiac troponin assays as a biomarker of cardiomyocyte as recommended by the guidelines of the European Society of Cardiology from 2015.

The case study incorporates clinical data collected as a part of the Italian TROCAR 2017 study with structural conceptual organizational data collected from webpages of the relevant hospitals and official ministerial online documents. In particular, the TROCAR 2017 study (22) (CARDiacus TROponin for the diagnosis of NSTEMI in the setting of clinical practice in First Aid Medicine in the national territory) is a multi-center observational survey, conducted in a sample of Italian hospital Emergency

Departments (ED). The main objective of the study was to perform a clinical and pharmaco-economic evaluation of currently available cardiac troponin dosage methods in a population of patients admitted due to suspected acute myocardial infarction and electrocardiographic negativity (NSTEMI). The study was performed by the National Centre for Health Technology Assessment of the Istituto Superiore di Sanità from January 2018 to May 2019 at 12 Italian emergency departments, uniformly distributed throughout Italy (4 in the north, 4 in the center and 4 in southern Italy). Participants were found eligible for the TROCAR 2017 study if they complied with all of the following criteria:

1. Age ≥ 18 years;
2. Clinical suspicion of AMI and electrocardiographic negativity (NSTEMI), ie with chest pain of suspected cardiac origin (or angina equivalent) and ECG negative for STEMI. By negative ECG for NSTEMI infarction we mean: normal ECG, non-specific non-specific ECG, ECG with other ischemic changes (negative T waves or ST segment substructure);
3. Had performed at least one cardiac troponin determination test;
4. Filled in a informed consent form.

Patients who refused to provide informed consent form, had cross-elevation of the ST / pathological Q-wave / inverse T-wave path to the electrocardiographic pattern, were breastfeeding or pregnant, or had any other clinical condition that would make them incompatible with participation was excluded from participation in the study.

The study collected data using a questionnaire specifically constructed for the study as the main tool in order to gather information on demographic data, patient's medical history, routine and specific laboratory tests performed, main risk factors; cardiological evaluation, instrumental examinations performed, administered therapy, 30-day evaluation.

In addition, an analysis grid was developed in Excel, including all four conceptual organizational domains and sub topics identified in the above section "Contextual organizational factors effect on the use of technologies"). The webpage of each hospital as well as official ministerial online documents was searched in order to find as many conceptual organizational information as possible.

Results

Data from 2913 patients were collected from 12 different Emergency Departments in the study period considered. Excluding patients who did not meet the inclusion criteria, the sample was composed of 2868 patients. Each Emergency Department were asked to enroll 500 patients each. The following Table 1 shows the participating centers in the TROCAR 2017 study and the actually number of patients that was enrolled. For privacy reasons, further results from individual hospitals will not be shown in this case study.

Of the included patients in the study 60.6% were males and 85.6% were Caucasian. The median age was 61 years (min: 18 years - max: 99 years), 32.8% were employed, 27.3% were retired, 4.2% were housewives and 4% were unemployed (30.7% of the population had missing information regarding employment status).

The distribution of baseline characteristics and demographic information according to use of high sensitivity troponin did not show large variation between groups, indicating homogenous patient groups. Baseline tables according to type of troponin use can be viewed in Appendix 1.

In general, 14.6% of patients enrolled in the study were hospitalized (rule in) while 85.4% were discharged (rule out) from the emergency department. The median residence time at the Emergency Department was 5.9 hours, 85.3% of patients remain in the emergency room for more than 3 hours.

TABLE 1. PARTICIPATING CENTERS IN THE TROCAR 2017

Hospital	City	Number of patients enrolled
PRONTO SOCCORSO UO - Presidio Spedali Civili di Brescia	Brescia	133
Dipartimento di Pronto Soccorso e Medicina d'Urgenza - AOU Novara	Novara	354
Azienda Ospedaliero Universitaria Arcispedale "S.Anna"	Ferrara	469
Azienda Ospedaliero - Universitaria "Policlinico - Vittorio Emanuele"	Catania	519
Ospedale Maggiore Policlinico	Milano	121
Azienda Usl Toscana Nord Ovest	Livorno	374
Policlinico Umberto I	Roma	159
Policlinico Ospedale Giovanni XXIII	Bari	93
Azienda Sanitaria Universitaria Integrata	Trieste	40
Ospedale Sant'Andrea	Roma	132
AOR San Carlo	Potenza	64
Azienda Ospedaliera di Padova	Padova	410
Total		2868

Table 2 shows the distribution of organizational factors according to whether or not the department used high sensitivity Troponin. If information were not able to be located for at least 50% of the hospitals it was not included in the table.

TABLE 2. DISTRIBUTION OF ORGANIZATIONAL FACTORS ACCORDING TO USE OF HIGH SENSITIVITY TROPONIN AT DEPARTMENT LEVEL

	Use of high sensitivity troponin, frequency (N = 6)	Use of contemporary troponin, frequency (N = 6)
Hospital infrastructure and architecture		
University hospital?	6	6
Ownership of hospital?		
Public	6	6
Private not-for-profit		
Private for profit		
Architectural type of hospital		
Pavilion hospital	1	3
Single-block hospital		

	Use of high sensitivity troponin, frequency (N = 6)	Use of contemporary troponin, frequency (N = 6)
Multi-block hospital	4	3
Vertical tower	1	
Number of staffed beds in the hospital?		
<500	2	
500-999	2	4
1000-1500	2	1
> 1500		1
Current number of employees in hospital?		
<2000	3	1
2000-3900	1	3
4000-5999	2	1
>6000		1
Yearly number of hospital admissions		
<20.000	2	
20.000 – 29.999	1	4
30.000 – 39.999	2	
40.000 – 49.999	1	1
>50.000		1
Yearly number of inpatient discharges performed at hospital?		
<2500		1
2500-2999		2
30000-3499		
>3500	3	1
Number of yearly acute hospital visits to the ED		
<50.000		
50.000-100.000		4
> 100.000	3	
Opening hours of ED 24H	6	6
Roles of hospital in the uptake territory?		
1. Hub	3	3
2. Spoke		
3. Hub AND spoke depending on activity	3	2
4. Does not belong to a hub and spoke network		
Which specific clinical pathways and itineraries for patients' categories exists? (more than one answer possible)		
Emergency Pathway	6	5
Orthogeriatric pathway	6	3
Mother and child Pathway	6	3
Cancer pathway	6	4
Is Health Technology Assessment activities mentioned?		
Yes	3	3
No		
Leadership styles		
Organizational chart of hospital		
Vertical model driven by specialties		2
Horizontal model driven by pathways		
Model based on progressive patient care	1	
Mixed model (matrix)	5	4
Which patient pooling approach(es) is used in order to group patients within ward units? (more than one answer possible)		
Clinical specialties	5	5
Intensity and complexity of care	1	
The age/sex of patients		
Clinical processes		
Mixed approach		

Six out of the 12 ED used high sensitivity troponin and 6 ED used a lower sensitivity troponin at the beginning of the study (results not shown). During the study period, 3 of the centers who were using a lower sensitivity troponin switched to a high sensitivity troponin. For the purpose of this study, they will however remain in the group with low sensitivity troponin given the fact that organizational factors are less likely to change over short periods of time and therefore affect the change.

The results of the web-based search (Table 2) showed that only a limited number of information regarding organizational contextual factors were able to be located on the hospital web pages or ministerial official web pages. Most often information regarding “Hospital infrastructure and architecture” and some “Leadership information” were located. However, no differences between hospitals using different troponin assay was detected. No information regarding “Hospital’s availability of financial resources” or “Human resource management tools” were located on the web pages.

Information located doing the online search regarding organizational conceptual factors showed more similarities between emergency departments with different Troponin use than differences (Table 2). All Emergency Departments participating in TROCAR 2017 were located at public university hospitals and all had 24 hours opening hours. They were all located at relatively large hospitals with more than 2000 employees, having between 500 and 1500 staffed beds, a yearly number of inpatient discharges performed at hospital of more than 2500 patients, and more than 500.000 acute hospital visits to the Emergency Departments. Hospitals with emergency department using high sensitivity Troponin seemed more often to describe clinical pathways and itineraries for specific patients’ categories such as Orthogeriatric pathways, Mother and child Pathways, and Cancer pathways than hospitals with emergency department using contemporary Troponin. Regarding the organizational chart most hospitals described a mixed model matrix and a patient pooling approach based on clinical specialties in order to group patients regardless the type of Troponin use.

This case study shows that only a limited number of conceptual organizational factors was identified through publicly available official websites from the hospitals and ministerial websites. The fact that hospitals are very conservative in their approach or willingness to share organizational descriptive information with the public could maybe also be part of the reason why this aspect is so limitedly covered in the literature. It would require a dedicated survey to collect information regarding organizational conceptual factors which is both expensive and time consuming.

Nevertheless, two families of contextual factors emerge as relevant in possibly affecting the hospitals’ propensity to adopt the innovative technology. The first is related to the hospitals’ dimension, which, is suggested in the literature should ideally be of medium size. Hospitals which are too small are likely

to lack a sufficient experience and may also be inefficient because the fixed infrastructural and administrative costs are shared across too small a caseload, thereby pushing up the cost of an average hospital visit. On the other hand very large hospitals may imply too high complexity which is difficult to manage in a structured and orderly way, with possible negative effect on the swiftness of procedures concerning the uptake of a new technology.

The second family of contextual factors concerns the presence of integrated clinical pathways. It seems that hospitals which have more elaborated clinical pathways are more likely to be pioneer in the adoption of high sensitive troponin. This could depend on the fact that they are more aware of the long-term effects of the technology in terms of value produced for patients and also for the system as a whole given the lower cost of treatment in the cycle of care.

Case study on the clinical use of the robotic surgery with Da Vinci Robot in different clinical areas

Robot assisted surgery has progressed rapidly over the last decade to approximately 877,000 surgical procedures being performed worldwide with the da Vinci Surgical Systems in 2017 (23). The da Vinci surgical system mostly focus on the five surgical specialties: gynecologic surgery, urologic surgery, general surgery, cardiothoracic surgery, and head and neck surgery. The most common procedures performed are being hysterectomy and prostatectomy (23). Despite the rapid growing utilization of robot surgery, there is currently no common organizational model or organizational guidelines for the structural organization of robotic surgery and therefore no national or international golden standard to be uphold as a measure of comparison for whether or not evidence-based practice is being followed in regards to utilization of the da Vinci Robot (26).

The purpose of this case study is to uncover European experiences in organizing robot assisted surgery using the da Vinci Robot and to uncover differences and similarities in the hospital organizational models. The analysis combined results from two literature reviews, one HTA literature search and a survey study consisting of responses from healthcare professionals including both surgeons and nurses from hospital departments using the da Vinci Robot as well as information regarding conceptual organizational aspects of the hospital which will be collected from hospital management from the hospitals involved. The method and analytical approach as well of the full results of the case study are presented in Appendix 2 of the document.

Discussion

The results show that there is currently no common organizational model or organizational guidelines for the structural organization of robotic surgery and therefore no national or international golden standard to be uphold as a measure of comparison for whether or not evidence-based practice is being

followed in regard to utilization of the da Vinci Robot. However, some general recommendations have been identified in the literature including:

- high volume for robot surgery both for the department as a whole and for each of the surgeons performing robot assisted surgery;
- centralization of the robot surgical activities in dedicated robot centers;
- sharing the da Vinci Robot between multiple specialties using the same robot where one specialty alone can't fill the robot's capacity;
- dedicated operations team only performing robot surgery (nurses, anesthesiologist);
- a structured training program with a combination of preclinical theoretical and practical training as well as clinical practical training;
- a standardized and structured training program for the whole operational team including teamwork and communication.

The literature study explicitly points out the importance of high volume of robot surgeries at both department level and surgeon level and is suggesting to secure this by centralizing surgeries and by limiting robotic surgery to dedicated, smaller 'robot teams' in order to increase routine and experience and increase outcome for both patients and safety as well as productivity. In all the included departments robot surgery is limited to a small number of surgeons. However, it is also noticed that for some of the specialties only very few surgeries are performed using robot surgery (below 20 per year) which could compromise the routine and experience level among the affected surgeons. The survey showed, that top management was involved in deciding the volume of operations performed with the da Vinci Robot however it could be questioned whether this is enough to secure a substantial volume for all specialties and surgeons.

According to the literature, a large operating room or center dedicated only to robotic surgery is a prerequisite for the successful use of robotic technology. In none of the participating departments is this structural premise fulfilled which might explain why availability of operating rooms and medical equipment as well as management of schedules are listed as a high barrier by most of the surgeons in the survey. In the department's robot surgery is characterized by several specialties sharing the same robot between them, which probably can be explained to some degree by the fact that most of the individual specialties cannot fill the robot's capacity alone. By sharing they therefore optimizes the capacity utilization even though it seems to complicate the organizational structure. In the literature it has been suggested that to ensure the optimization of operations in the organization model where the same robot is being shared between different specialties a tighter and more central coordination of management of the operation planning is recommended.

Internationally, it has been recommended that specific training and credentialing requirements are developed for those involved in robot-assisted surgery so that patients receive safe care. Though all surgeons included in the case study indicated that simulation training activities were systematically provided by their hospital only half of the surgeons indicated that theoretical training was required and less than half that a validation test in robotic console proficiency was obligatory in order to perform surgery with a Da Vinci Robot. The training of nurses for assisting in robot surgery seemed more structured as they all indicated that they received 3-4 days of official training in the da Vinci robot system which included instructor-based training and observation of surgical teams using the robot. Since all surgeons included in the case study work in the same hospital, however in different departments, the diversity in the answers regarding training and requirements for performing robot surgery could either reflect a lack of clear overall regulations of robot surgery requirements at a hospital level, or that rules and guidelines have not been distributed in an transparent way throughout the organizational structure of the hospital. The same pattern was also seen in regards to use of guidelines, protocols and checklist where answers from surgeons regarding checklist use varied within the same department from rarely to always and for protocol use from never to frequent within the same department. Whereas all nurses indicated always or frequently using all of the requirements.

The result of the analysis contributes to knowledge about how hospital conceptual organizational factors might influence the organization and utility of robotic surgery using the da Vinci Robot in a European perspective including internationally experiences identified in the literature. Furthermore, possible consequences of the organizational models were examined by including information on barriers related to the organizational model which are aspects that are relatively under-emphasized in the international literature. However, some methodological challenges should also be pointed out, which should be considered in future studies. Firstly, both the literature study and the survey analysis have primarily had a descriptive focus, the purpose of which was to describe hospital conceptual organizational factors, the organization of robotic surgery and to some extent the impact hereof. Given it is “only” a case study, including a relatively low number of participating European hospitals the results should only be considered as an insight into how hospital structural conceptual factors might influence the organization of robotic surgery and to a limited extent the impact that this organization has on the utilization of the da Vinci Robot. For future studies it is suggested to include additional information regarding how the organizational aspects of surgery with the da Vinci Robot influence the performance aspects. Such knowledge requires a more systematic examination of the association between organizational models and performance indicators in relation to for example workflows, productivity, economically aspects and patient outcome. Furthermore, it should be noticed that all the participants included in the survey used robotic surgery and therefore must be

considered relatively positive about the technology. Thus, there may be bias in the assessment of the consequences of the organizational aspects of robotic surgery, as well as the experienced barriers of the participants compared to using more objective observations. Lastly, it should be pointed out, that the studies included in the internationally HTA reports on robotic surgery are based on a relatively unclear data material, which makes it difficult to assess the reliability and validity of the study's results and conclusions. This means that the recommendations regarding organizational aspects of robot surgery from the literature must be interpreted cautiously.

Despite these limitations, the analysis is a first step on the path to understanding how structural organizational factors at both hospital and department level might affect the utilization of technologies such as the da Vinci Robot.

Rationale of developing an analytical tool aimed at assessing the clinical variation due to the use of health technologies

Hospital contextual organizational factors is describing the environment or setting in which a health technology is to be implemented or adopted in. Although classical Health Technology Assessment and other evaluation models assay a wide spectrum of domains when analyzing the effects of technologies (among which organizational aspects), the inverse relationship, i.e. how organizational/contextual factors may affect the implementation and use of the health technology, is surprisingly unexplored.

Case studies highlighted how the efficient use of resources is a key driver in order to reduce clinical variation, when high cost technologies require an optimized structural, human and cultural setting. Moreover, the structural dimension of a hospital is important in order to pursue scale and scope economies. Again, contextual factors describing the environment or setting in which a health technology is to be implemented or adopted in can have a crucial impact on decision making and affect either economic and technical efficiency.

In order to pursue economic efficiency, it is considered crucial the adoption of measures aimed at increasing the purchasing power of the hospital in the acquisition process involving medical equipment. Instead, technical efficiency can be achieved with a more appropriate use of hospital resources, involving for example: the duration of a surgical operation or a diagnostic procedure, the involvement of health professionals, the optimization of administrative and hospitality costs.

Indeed, the literature reviews described above, have showed that contextual characteristics that may influence the adoption of a technology in an hospital include infrastructure and architecture; availability of financial resources; leadership styles; human resource management, culture, time available, funding, proper staffing, equipment and dedicated time for implementation. For example,

in regard to the availability of financial aspects, it does not come as a surprise that a hospital with more resources has an advantage in implementing the use of HTs. However, the internal distribution of resources and their coherence with organizational units' technological assets could have consequences on the use, if misaligning between HTs and budgets within or across organizational units exist.

However, the evidence emerging from the case studies only partially matches the content of the literature reviews. The impression is that the affecting factors detected in the case studies belong to the most accessible types of information available. In other words, many of the dimensions emerging from the reviews may not be concretely analyzable because of a scarce propensity of hospitals to share this information. Domains such as leadership style or role ambiguity may constitute confidential information. Moreover, an important criticism regards the access to granular information about:

- operating times;
- health professionals involvement;
- prices of medical equipment and components purchasing;
- administrative costs;
- hospitality costs.

This information is crucial in order to implement an analytical system based in Activity Based Costing that enables to estimate either economic and technical efficiency as key drivers to pursue an improvement in clinical variation. In this view, the case studies have shown that, where granular data about the uptake of resources are collected, there is still a high heterogeneity in the mode of data management, storing and gathering (different procedures, IT systems with no interface...) which make very difficult to implement an homogeneous analytical system involving a comparison between different organizational units (i.e. hospitals or emergency departments).

Although in the initial stages of the project the choice of the two case studies was made according to either the relevance of technologies and thus the chance of collecting datas to populate the analytical tool to assess economic and technical efficiency, the results of the surveys did not enable to use quantitative information regarding Troponin and Da Vinci Robot. However, important information on how some common key elements affecting clinical variation can be detected, undepending on the kind of HT and that can be applied also to other technolgies.

On the other side, access to pre-existing datasets was available for hip and knee replacement prosthesis across three hospitals in Marche region.

For these reasons, the chance of accessing micro costing data about knee and hip replacement, allowed to test an analytical tool aimed at assessing the clinical variation due to the use of health

technologies. In presence of data, the tool that is presented in this report can be used in order to assess economic and technical efficiency associated with the adoption and implementation of diverse hospital technologies.

2. Development of an analytical tool to assess the clinical variation of hospital technologies

In a context in which it is necessary to face the public health sustainability crisis, it is important to adopt strategies to rationalize spending and strategies aimed at obtaining better results from the resources invested (which lead to waste reduction and increase in value).

Considering that the purchase of medical technologies and devices represents a substantial part of the expenditure of the public health structures of the Servizio Sanitario Nazionale (Italian National Health Service), the availability of an analytical tool becomes fundamental for identifying and eliminating the most expensive technologies with the same efficacy and safety.

In the 2014 Report on the expenditure recorded by the public health structures of the NHS for the purchase of medical devices drawn up on the basis of a study by the Ministry of Health for monitoring the consumption of medical devices, it is clear that the expenditure for implantable prosthetic devices and products for osteosynthesis accounts for 22.3%.

The analytical tool below described, which has been created by WP8 and relies on a decision model, represents a methodology aimed at assisting, supporting, advising and recommending political decisions in the field of medical devices by increasing the set of information available. It is in fact an analytical study, carried out with a critical and evidence-based approach that allows the development of a structured assessment of health technologies with the aim of providing input for those who are responsible for the role of decision-makers. The model allows decision-makers to formulate divestment strategies applied to medical devices through a cost minimization analysis.

This report will analyse the specific case of disinvestment of hip and knee prostheses, but the analytical tool can also be applied to other procedures.

Foreword: focus on hip and knee prostheses

During the 100th Congress of the Italian Society of Orthopedics and Traumatology it emerged that in Italy over 200,000 prostheses are implanted every year, of which: over 100,000 hip, just over 85,000 knee and about 15,000 shoulder, elbow and ankle prosthesis and currently, the demand for prostheses is increasing especially in subjects with high functional demand. The range of implants has expanded thanks to the improvement in the quality of materials, surgical techniques, anesthesiology and general medicine. The National Epidemiology Center of the Italian National Institute of Health (Istituto Superiore di Sanità) has calculated that in the years 2001-2014 there was a considerable increase in the number of prosthetic implants.

Replacement of the hip prosthesis

The replacement surgery of hip prosthetics constitutes an increasingly widespread solution for many disabling pathologies, such as arthrosis, the rheumatoid arthritis and fractures of the femoral neck, conditions that mainly affect older people. (48)

The patient usually draws great advantages and benefits from surgery, which resolves painful symptoms, restores autonomy of movement and leads to a significant improvement in the quality of life.

Episodes of hip fractures occur mainly in patients over the age of 65 and account for approximately 87%. In Italy, every year, between 70,000 and 90,000 femoral fractures are estimated, in Europe, more than 600,000. Female subjects seem to be more predisposed to this type of episode, representing about 75% of cases (94% of these concern women over 65); the age of subjects with a hip fracture ranged from 66.0 to 72.4 years. (48)

The hip prosthesis replaces the natural joint, which is no longer functional. There are three types of prostheses (50):

1. The total replacement or arthroplasty (intervenes on both joint components: the femur and the acetabulum);
2. partial replacement or endoprosthesis (preserves the acetabulum);
3. partial prosthesis (it preserves the neck of the femur and can only be used in young patients and in the absence of osteoporosis).

The hip prosthesis is made of different materials. The stem and cup are of a metal alloy; the insert and the head, on the other hand, can be in metal, plastic or ceramic. The materials used to construct the prosthesis affect its durability and wear. The cemented prosthesis is made with acrylic cement, used to firmly fix the cup and the head of the stem, creates a strong weld, making it difficult and problematic to remove the prosthesis, when it has worn out. The cementless prosthesis is based on a pressure mechanism, which involves the use of prostheses with very small holes on the stem. These allow the bone to grow inside, further anchoring the prosthesis. The uncemented prosthesis, unlike the first, has the advantage of easier removal.

There are more than 60 different models of hip replacements. However, less than ten are actually used (49).

The choice of the most appropriate prosthesis is up to the surgeon. Before any intervention it is essential to make considerations relating to (49):

- Age of the patient;

- Body weight and fragility of some materials (ceramic);
- Any allergies of the patient to the materials (metals) of the prosthesis;
- Kind;
- Basic pathology.

The types of prostheses used by the previously indicated companies, as regards hip surgery, are MOM, MOP, COP and COC.

MoM

The MoM prostheses are metal-on-metal hip prostheses. Named MoM from the English Metal on Metal, they are a type of prosthesis characterized by the coupling of two metal joint components, one femoral and the other acetabular.

MoM prostheses have been placed on the international market since the late 1990s with the intention of offering a series of advantages and benefits compared to traditional implants, which can be briefly summarized in the points:

- less wear of mechanical surfaces compared to systems with conventional coupling (metal-polyethylene; ceramic-ceramic; ceramic-polyethylene; ceramic-metal);
- less chance of implant mobilization;
- less chance of prosthetic breakage;
- in MoM surface prostheses (HRA), greater anatomical and functional preservation of the hip joint which makes them particularly suitable for use in younger and more active subjects.

As explained by the Ministry of Health, it is necessary to consider that, in the face of these advantages, in this type of prosthesis, wear of the articular surfaces can occur, leading to the production and accumulation of metal ions (metallosis from cobalt and chromium) and debris (debris) at the level of the peri-prosthetic. These phenomena may be at the origin, in some patients, of local inflammatory reactions which in turn cause the appearance of symptoms affecting the hip which can result in implant failure and the need for a surgical revision of the same. In addition, the local release and absorption into the circulation of the aforementioned metal ions may be the cause in some patients of adverse reactions affecting various target systems / organs, such as:

- general hypersensitivity reactions (skin rashes);
- neurological symptoms also affecting the sensory organs (auditory or visual alterations);
- alterations in the psychological state;
- cardiomyopathy;
- changes in kidney function;

- thyroid dysfunction.

MoP

MOP prostheses they are hip prostheses made in polyethylene and metal on polyethylene.

Polyethylene is a high-quality metal-free plastic, and the acetabulum is usually made of this plastic. In addition, other components can be made of metal and covered with plastic. When a cavity is plastic and the sphere is metal it is considered MOP. Total prostheses with metal head and acetabular cup in polyethylene or with acetabular cup in metal with polyethylene insert are the least expensive and have been the most used over time. (50)

In addition to standard polyethylene, cross-linked high-strength polyethylene has been in use for many years, but its advantage in reducing wear compared to standard polyethylene has not yet been well documented (48, 49, 50) (48-52).

CoP

The COP prostheses are hip prostheses of ceramic on polyethylene. Prostheses with ceramic femoral head and polyethylene acetabular cup appear to have a lower percentage of wear than metal-on-polyethylene ones.

CoC

Finally, COC prostheses are ceramic-on-ceramic hip prostheses. These prostheses appear to have the lowest wear rate compared to the others, but are generally the most expensive (Clarke et al 2015). Ceramic parts are very durable and are no more fragile than metal components. Today's ceramics are destined to surpass metallic materials.

Replacement of the knee prosthesis

Regarding the knee replacement surgery, the first prosthetic implants adopted the hinge concept and included a hinge connection between the components. More recent implants, recalling the complexity of the joint, attempt to replicate the most complicated movements and exploit the support of the ligaments.

There are many types of prostheses available for TKR on the market, but they all have the following in common:

- a femoral component, consisting of a large block used to cover the surface of the distal part of the femur. The metal component surrounds the bone and has a groove within which the patella can slide up and down so that the knee can flex and extend;
- a tibial component, represented by a flat metal surface which is fixed on the proximal part of the tibia by means of a central stem or pins;
- a plastic insert (polyethylene), which allows the femur to articulate with the tibia. It can have a complex profile that mimics the natural joint surface and can have a central cam;
- a patellar component, consisting of a small dome-shaped "button" of plastic material (polyethylene) that recalls the shape of the patella.

In addition, in this case, the choice of prostheses must be evaluated on the characteristics of the patient (e.g. age, weight, physical activity), on the characteristics of the implant (e.g. models, materials), on the experience of the surgeon and on his familiar with the device.

Objective of the model

The objective of the model is to carry out a cost minimization analysis and provide an efficiency assessment using regional benchmark frontiers, where the organizational units are the public health structures that provide, in this specific case, hip replacement services. and knee replacement.

This cost minimization model takes into consideration the efficiency frontiers that are constructed considering the minimum cost incurred for each item of expenditure by the health structures included in the analysis. The expenditure items considered are: consumables (which include the various components of the prostheses and other consumables), staff, the operating room and other direct costs (including drugs).

The model allows for the construction of disinvestment strategies through the application of decrease coefficients, expressed as a percentage, on each cost item considered, with particular reference to the different components of the prostheses. In this report the case of hip replacement will be considered with particular reference to the difference between MoM, MoP, CoP and CoC.

Model structure

The data used to show the validity and functioning of the model come from public health facilities in the Marche region (Italy), in particular ASUR, AOU ANCONA and ASL MARCHE NORD.

The model allows to evaluate, following the implementation of a divestment strategy, how the positioning of the various healthcare facilities included changes with respect to the efficiency frontier and the value of the DRG rate, which in the case of hip replacement is equal to € 8,837.

The model consists of a deterministic and a probabilistic part. The deterministic part allows you to observe the effects in terms of efficiency increase of a single divestment policy, while the probabilistic part, estimates the stochastic efficiency frontiers and allows you to observe a complete picture of all the possible combinations constituted by the various divestment scenarios.

3. Data and sources used to populate the analytical tool

The analytical tool described in the previous section of the document was populated and tested using data relating to hip and knee prosthesis operations in the years 2017 and 2018 performed in the Marche Region (Italy). It is noteworthy to clarify that these data were gathered for a previous project involving on one hand the Marche Region and on the other one (among others) the Italian National Institute of Health.

The analysis performed refers to three sets of data, and in particular:

- data relating to hip and knee prosthesis interventions in the years 2017 and 2018 already provided to the Italian National Institute of Health as part of the RIAP (Registro Italiano Artroprotesi – Italian Registry of Arthroprosthesis) project.
- SDO (Schede di Dimissione Ospedaliera – Hospital Discharge Reports) data relating to hip and knee replacement operations carried out from 1 January 2017 to 30 October 2019 in the regional context, including active mobility flows, and passive mobility data for the same period which were made available by Marche in the same period in order to allow internal comparisons on the overall activity of the Region.
- the purchase data of prosthetic material for the years 2017 and 2018, through the flow of Medical Devices (AREAS) relating to the materials included in the CND classes P0908 and P0909.

It is noteworthy to mention that the data provided to the RIAP by the Marche Region does not currently allow reflections on the quality of individual prostheses and / or surgical approaches and / or methods of fixing the components, because a sufficiently large historical series is not available. However, literature suggests that a more precise analysis would be possible if we had broader time horizons, up to reaching an optimal result with an amplitude of about ten years. In this sense, it is recommended to improve adherence to the RIAP by extending it to all structures and all interventions carried out in the Region.

The combination of the three sets of data has allowed a series of analyzes aimed at verifying the behavior of the various structures in the Marche region (in particular with reference to public or private status) to allow comparisons between the different types and between those who feed the RIAP flow more completely and those who participated to a lesser extent in feeding the RIAP.

In particular, analyzes were carried out on:

- Type of patients treated (by gender, age and case history identified through the ICDs), also by stratifying the analysis by type of provider (public vs private).
- Outcomes of the interventions in relation to the length of stay.

- Type of devices purchased (medical devices flow) and level of fragmentation (variety of suppliers and price) with respect to the structure that purchases.

The data were then processed in a descriptive analysis that traces the analysis model of the RIAP and then in an inferential analysis aimed at showing the different behaviors of the structures that provide data for the RIAP and, where possible, between these and the complex of activities of the Marche Region.

In order to make the analyses consistent with the benchmarks identified in the ALTEMS report, in some cases aggregations were made according to criteria different from those of the RIAP, and in particular in relation to: age classes for surgery and materials used in prostheses.

The elaborations carried out have been grouped into three areas:

1. The first is entirely dedicated to analyses carried out on SDO tracks.
2. The second relates to the data entered in the RIAP. This part is further divided into two sections: the first, as far as possible, presents structured data as in the RIAP reports, while the second presents data structured in a specific way to investigate phenomena not discussed in the RIAP reports.
3. The third is dedicated to analyzes carried out on AREAS data.

The results are shown separately for hip replacement surgery and for knee replacement surgery, respecting the above scheme for both. A summary of the main findings is reported below whereas the full outcomes are described in Appendix 3 of this document.

Hip replacement surgery

As regards hip replacement surgery, the most relevant elements of the analyzes carried out highlight the following.

Source SDO

- about 72% of the interventions are carried out by public structures, with therefore a large theoretical space for rationalization interventions
- the average age of operated patients is 74.9 years, but with significant differences between patients in public facilities (77.2 years) and those in private facilities (69.4 years)
- the average length of stay is 11.9 days overall, with significant differences between public (13.7 days) and private facilities (7.7 days)

The need for organizational intervention is evident with the aim of allowing more timely discharge and within acceptable thresholds. However, the differences are partly inevitable due to the

aforementioned different age of the patients and the cause of the interventions, which in the public mainly resides in rupture of the femur, which is rarely operated in private. It is probable that public facilities are also used as long-term care and rehabilitation facilities to the detriment of the appropriateness of hospitalizations.

The regional territory is characterized by a strong passive mobility. In 2017 and 2018 it involved 873 and 888 interventions respectively (therefore 26.1% and 26.5% of the total interventions carried out in the Marche region, including active mobility and passive mobility). It is clear that the recovery of this significant share of patients residing in the Marche Region appears to be a first important area of intervention for a divestment aimed at avoiding the flight of resources to other regions and the improvement of the supply of services within the Marche Region.

Passive mobility is directed almost exclusively towards private structures and not only towards neighboring regions. The flight to Lombardy is particularly high.

An analysis was also carried out on the attractiveness of the structures of the Marche Region. The overall values of the three-year period (899 cases) show that the attraction is mainly exercised by private structures, which cover 72.4% of the total.

Source RIAP

The compilation of RIAP forms in the Region is still partial, although increasing. The percentage covered by the RIAP is therefore 30.5%.

The analysis relating to access routes shows important differences with respect to the national reference behavior, in particular due to the almost total absence of anterolateral accesses and the high use of posterolateral accesses in the Marche region.

The variety of behaviors in the choice of the access route is not a guarantee of appropriateness, it would therefore be useful to define shared clinical guidelines to be developed through boards of the reference scientific societies, at least at national level.

A sort of adverse selection of patients emerges in private structures that favor older patients and a less complex case history (see SDO data).

In the public sphere, there is a greater use of cemented prostheses. The reasons are not entirely clear: in fact, in addition to the different type of patients treated in relation to age (cemented prostheses would be more appropriate for the elderly), the personal preference of individual operators emerges.

Source AREAS

The 2018 expenditure is not proportional to the number of interventions carried out in the same year traced through the SDOs. In particular, the cost per intervention at the AOU Ancona is significantly lower than the other two companies (ASUR and Marche Nord) which instead have similar results. It appears probable that AOU Ancona has used material in stock since 2017, consequently an area of possible divestment is related to warehouse management.

The differences in the purchase prices, relating to the materials identified by specific CND code, would allow a theoretical overall saving of about 13.5%, or 342,000 euros per year, if everyone bought at the lowest price. The tracks examined, however, do not allow to give information on the quality of the products purchased, which could have an impact on the different prices paid.

Knee replacement surgery

As regards knee replacement surgery, the most relevant elements of the analyzes carried out highlight the following.

Source SDO

- about 34% of the interventions are carried out by public structures.
- the average age of operated patients is 71.2 years, but with little difference between public (72.3) and private (70.7) facilities.
- the average length of stay is 7.9 days overall, with significant differences between public (10.6 days) and private facilities (6.5 days).

The need for organizational intervention is evident with the aim of allowing more timely discharge and within acceptable thresholds. It is probable that public facilities will also be used as long-term care and rehabilitation facilities to the detriment of the appropriateness of hospitalizations. The age difference of the patients is small and therefore has no significant impact on the length of hospital stay.

The regional territory is characterized by a strong passive mobility. In 2017 and 2018, it involved 969 and 1,037 interventions respectively (therefore 33.5% and 34.4% of the total interventions performed in the Marche region, including active mobility and passive mobility). It is clear that the recovery of this significant share of patients residing in the Marche Region appears to be a first important area of intervention for a divestment aimed at avoiding the flight of resources to other regions and the improvement of the supply of services within the Marche Region.

Passive mobility is directed almost exclusively towards private structures.

An analysis was also carried out on the attractiveness of the structures of the Marche Region. The overall values of the three-year period (1,314 cases) show that the attraction is mainly exercised by private structures, which cover 91.7% of the total.

Source RIAP

The compilation of RIAP forms in the Region is still partial, although increasing. The percentage covered by the RIAP is therefore 45%.

The access route analysis shows important differences with respect to the national reference behavior, in particular a large use of surgical techniques using quad-sparing access and the scarce use of midvastus techniques.

The variety of behaviors in the choice of the access route is not a guarantee of appropriateness, it would therefore be useful to define shared clinical guidelines to be developed through boards of the reference scientific societies, at least at national level.

Source AREAS

The 2018 expenditure is not proportional to the number of interventions carried out in the same year traced through the SDOs. In particular, the cost per intervention at the AOU Ancona is significantly lower than the other two companies (ASUR and Marche Nord) which instead have similar results. It appears probable that AOU Ancona has used material in stock since 2017, consequently an area of possible divestment is related to warehouse management.

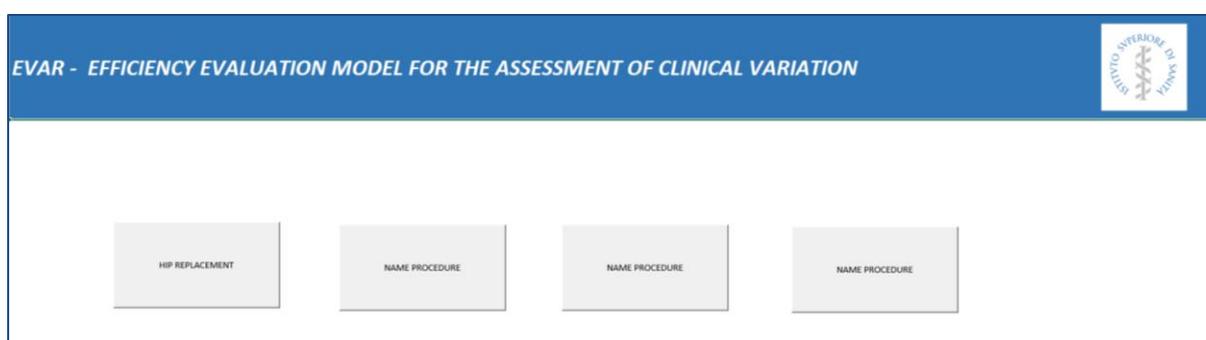
The differences in the purchase prices, relating to the materials identified by specific CND code, would allow a theoretical overall saving of about 27%, or 331,496 euros per year, if everyone bought at the lowest price. The tracks examined, however, do not allow to give information on the quality of the products purchased, which could have an impact on the different prices paid.

4. Analytical tool user's manual

This section illustrates step by step how to use the model up to the final output (efficiency frontiers) which provides a unitary vision of the different divestment scenarios allowing an immediate evaluation that goes beyond a simple analysis of costs.

In the first screen represented in figure 2, "disinvestment model", "start" page, it is possible to select "hip replacement" if you intend to proceed with the cost analysis for the replacement surgery of the hip prosthesis or "knee replacement" if you want to use the model for the evaluation of knee prostheses.

FIGURE 2. TEMPLATE OPENING SCREEN



The explanation of the model in this report will follow the example of hip replacement.

Deterministic settings

Following the first step, a second screen will open and then a second page called "deterministic settings", represented in Figure 3.

FIGURE 3. DETERMINISTIC SETTINGS. MANAGEMENT CONTROL TRACK

CO.GE REPORT	delivery	personnel costs	consumption materials	operating room costs	other direct costs
hip replacement	ASUR1	FALSO	FALSO	FALSO	FALSO

It is possible to observe the starting layout resulting from a management control report which for each procedure provides the data relating to the different cost items.

The model allows to consider the tracings of the various health structures included in the analysis, or an average in the case of missing values at the level of a single structure.

The screen in figure 4 shows the case in which such data is missing. In fact, in the absence of data available at a single facility level, if "MEDIA", but "ASUR", "AOU ANCONA" or "ASL MARCHE NORD" is not selected under the heading "delivery", the model will give "FALSE" and will estimate the "virtual" layout of the individual ASLs based on a system of re-proportioning of the various cost items starting from the number of days of average hospitalization. In the absence of a differentiation in the mean hospital stay, the model will consider the trace with the mean values.

FIGURE 4. MANAGEMENT CONTROL LAYOUT, SILGLE HEALTH DELIVERIES

CO.GE REPORT	delivery	personnel costs	consumption materials	operating room costs	other direct costs
hip replacement	ASUR1	FALSO	FALSO	FALSO	FALSO

In the "set strategy" section, the "materials" table shows the price of the individual components of a prosthesis, namely:

- cup;
- domes;
- ceramic inserts;
- metal inserts;
- polyethylene inserts;
- stems, ceramic heads;
- metal heads;
- other.

In particular:

- the cost of the MoM prosthesis is obtained by adding the costs of the cup, domes, metal inserts, stems, metal heads and other costs;
- the cost of the MOP prosthesis includes cup, domes, polyethylene inserts, metal head stems and other costs;
- the cost of the COP prosthesis, on the other hand, concerns cups, domes, polyethylene inserts, stems, ceramic inserts and other costs;
- the cost of the COC prosthesis is based on cup, domes, ceramic inserts, stems, ceramic heads and other costs.

These costs are available at the individual facility level and are included in the "materials" item of the management control layout. In the absence of tracings at the level of a single structure, therefore, a first differentiation will concern the costs of the individual components of the prosthesis.

The model makes it possible to formulate a strategy that provides for a percentage decrease, which varies from 0% to 80% at the price of each component.

As shown in figure 5, the user is enabled to set the percentage decrease to be applied to each component ("set discount (%)") columns) using a drop-down menu. On the other hand, the starting costs of the single components ("cost / piece" columns) cannot be changed by the user directly, as they are stored in the starting dataset (visible to the user by discovering the "Data settings" worksheet). In this specific simulation, 10% was set for each item.

FIGURE 5. CONSTRUCTION OF THE DISINVESTMENT STRATEGY BASED ON A REVISION OF THE COSTS OF THE PROSTHETIC COMPONENTS

SET STRATEGY						
MATERIALS	ASUR	AOU ANCONA	ASL MARCHE NORD	ASUR	AOU ANCONA	ASL MARCHE NORD
	SET DISCOUNT (%)			unit costs		
other	10%	10%	10%	223 €	241 €	640 €
cup	10%	10%	10%	771 €	882 €	920 €
domes	10%	10%	10%	131 €	112 €	111 €
ceramic inserts	10%	10%	10%	464 €	574 €	75 €
metal inserts	10%	10%	10%	476 €	651 €	694 €
polyethylene inserts	10%	10%	10%	286 €	230 €	187 €
stems	10%	10%	10%	790 €	837 €	626 €
ceramic heads	10%	10%	10%	388 €	395 €	466 €
metal heads	10%	10%	10%	203 €	154 €	170 €
COST DRIVERS	ASUR	AOU ANCONA	ASL MARCHE NORD	ASUR	AOU ANCONA	ASL MARCHE NORD
	SET DECREASE (%)			cost		
length of stay	10%	10%	10%	12	15	10
operating theater (minutes)	10%	10%	10%	135	135	135
TARIFFS	ASUR	AOU ANCONA	ASL MARCHE NORD	ASUR	AOU ANCONA	ASL MARCHE NORD
	SET DECREASE (%)			cost		
personnel (daily cost)	10%	10%	10%	174 €	174 €	174 €
other direct costs (daily tariff)	10%	10%	10%	43 €	43 €	43 €
operating theatre (cost per	10%	10%	10%	5 €	5 €	5 €

The same principle applies to the other drivers that allow simulating the full cost of the procedure for the purpose of evaluating the margin with respect to the DRG reimbursed or its possible overrun. The drivers considered by the model are: the length of stay (in days) and the duration of the surgical operation (expressed in minutes) as shown in figure 6.

Finally, figure 7 shows the model screen which enables the user to include in a divestment strategy also the modification of the cost per day of hospitalization of the staff, of the direct costs and of the operating room.

FIGURE 6. CONSTRUCTION OF THE DIVESTMENT STRATEGY BASED ON A REVIEW OF THE LENGTH OF STAY AND OF THE OPERATING ROOM

COST DRIVERS	ASUR		AOU ANCONA		ASL MARCHE NORD	
	SET DECREASE (%)	cost	SET DECREASE (%)	cost	SET DECREASE (%)	cost
length of stay	10%	12	10%	15	10%	10
operating theater (minutes)	10%	135	10%	135	10%	135

FIGURE 7. CONSTRUCTION OF THE DISINVESTMENT STRATEGY BASED ON A REVIEW OF PERSONNEL COSTS AND OTHER COSTS PER DAY OF HOSPITALIZATION, AND COSTS PER MINUTE OF OPERATING ROOM

TARIFFS	ASUR		AOU ANCONA		ASL MARCHE NORD	
	SET DECREASE (%)	cost	SET DECREASE (%)	cost	SET DECREASE (%)	cost
personnel (daily cost)	10%	174 €	10%	174 €	10%	174 €
other direct costs (daily tariff)	10%	43 €	10%	43 €	10%	43 €
operating theatre (cost per minute)	10%	5 €	10%	5 €	10%	5 €

In the right margin of the “deterministic settings” screen there are four ordered buttons that allow the user to proceed sequentially in the simulation (figure 8). Respectively:

- BACK TO START allows you to return to the first screen of the model, where you can decide between the "hip replacement" and "knee replacement" option
- GO TO COST ACCUMULATOR
- GO TO DETERMINISTIC OPTIMIZATION
- GO TO PROBABILISTIC SETTINGS

FIGURE 8. DETERMINISTIC SETTINGS. INITIAL SETTINGS AND BUTTONS FOR THE DIFFERENT SIMULATION OPTIONS

DETERMINISTIC SETTINGS

BACK TO START
GO TO COST ACCUMULATOR
RUN DETERMINISTIC OPTIMIZATION
GO TO PROBABILISTIC SETTINGS

SET STRATEGY						
MATERIALS	ASUR			ASL MARCHE NORD		
	SET DISCOUNT (%)	unit costs	ASUR	AOU ANCONA	ASL MARCHE NORD	unit costs
other	10%	223 €	223 €	241 €	640 €	640 €
cup	10%	771 €	771 €	882 €	920 €	920 €
domes	10%	131 €	131 €	112 €	111 €	111 €
ceramic inserts	10%	464 €	464 €	574 €	75 €	75 €
metal inserts	10%	476 €	476 €	651 €	694 €	694 €
polyethylene inserts	10%	286 €	286 €	230 €	187 €	187 €
stems	10%	790 €	790 €	837 €	626 €	626 €
ceramic heads	10%	388 €	388 €	395 €	466 €	466 €
metal heads	10%	203 €	203 €	154 €	170 €	170 €

COST DRIVERS	ASUR		AOU ANCONA		ASL MARCHE NORD	
	SET DECREASE (%)	cost	SET DECREASE (%)	cost	SET DECREASE (%)	cost
length of stay	10%	12	10%	15	10%	10
operating theater (minutes)	10%	135	10%	135	10%	135

TARIFFS	ASUR		AOU ANCONA		ASL MARCHE NORD	
	SET DECREASE (%)	cost	SET DECREASE (%)	cost	SET DECREASE (%)	cost
personnel (daily cost)	10%	174 €	10%	174 €	10%	174 €
other direct costs (daily tariff)	10%	43 €	10%	43 €	10%	43 €
operating theatre (cost per	10%	5 €	10%	5 €	10%	5 €

CO.GE REPORT	delivery	personnel costs	consumption materials	operating room costs	other direct costs
hip replacement	ASUR1	FALSO	FALSO	FALSO	FALSO

Deterministic accumulator

Clicking on the "GO TO COST ACCUMULATOR" box opens a third screen called "deterministic accumulator", shown in figure 9, which represents an accumulator that estimates the full cost of each procedure at the level of each individual health facility and reports the DRG margin, calculated using the difference between the DRG rate and the full cost ("total" column).

The accumulator considers the estimated average costs of personnel, materials, the operating room and other direct costs for each type of MoM, MoP, CoP and CoC prosthesis, the costs of which per component are included in the item "materials".

It is noteworthy how, in the case considered, the only costs that vary according to the type of prosthesis applied are those of consumables, given the fact that in this analysis it was not possible to have differentiated data for each type of prosthesis on the use of the room staff and other direct costs. Consequently, the accumulator reports the same costs for each type. It is understood that, in the presence of a cost differentiation that can be deduced from the dataset present in the hidden "Data settings" sheet, the accumulator will report different estimates for each of the items present in the layout.

FIGURE 9. DETERMINISTIC ACCUMULATOR. RESULTS OBTAINED BY SELECTING THE "MEDIA" OPTION IN THE "DETERMINISTIC SETTINGS" SHEET, IN THE MANAGEMENT CONTROL LAYOUT.



type	delivery	personnel	materials	op theatre	other dir costs	total	DRG margin
MOM		1.920,42 €	3.334,36 €	653,06 €	523,91 €	6.431,75 €	2.405,25 €
MoP	MEDIA1	1.920,42 €	3.228,61 €	653,06 €	523,91 €	6.326,00 €	2.511,00 €
COP		1.920,42 €	3.348,97 €	653,06 €	523,91 €	6.446,36 €	2.390,64 €
CoC		1.920,42 €	3.407,23 €	653,06 €	523,91 €	6.504,63 €	2.332,37 €

BACK TO DETERMINISTIC SETTINGS

Figure 10 presents an additional accumulator screen showing the cost estimate of a single healthcare facility (ASUR). This must be selected in the "deterministic settings" page even if / without considering that the model will give a "FALSE" response (see Figure 3).

FIGURE 10. DETERMINISTIC ACCUMULATOR. RESULTS OBTAINED BY SELECTING THE “MEDIA” OPTION IN THE “DETERMINISTIC SETTINGS” SHEET, IN THE MANAGEMENT CONTROL LAYOUT.



DETERMINISTIC ACCUMULATOR

type	delivery	personnel	materials	op theatre	other dir costs	total	DRG margin
MOM		2.161,96 €	3.281,55 €	725,63 €	589,80 €	6.758,94 €	2.078,06 €
MOP	ASUR1	2.161,96 €	3.170,62 €	725,63 €	589,80 €	6.648,00 €	2.189,00 €
COP		2.161,96 €	3.278,94 €	725,63 €	589,80 €	6.756,33 €	2.080,67 €
COC		2.161,96 €	3.364,99 €	725,63 €	589,80 €	6.842,38 €	1.994,62 €

BACK TO DETERMINISTIC SETTINGS

Deterministic optimization model

By clicking on "GO TO DETERMINISTIC OPTIMIZATION", again from the "deterministic settings" screen page shown in figure 8, a further screen opens that represents an optimization model represented in figure 11. It allows the user to calculate an efficiency coefficient with reference to the costs incurred for the prostheses, for the staff and for the operating room.

The efficiency coefficient is equal to the ratio between the cost incurred by the single ASL and the minimum cost incurred at the regional level for the single cost item. The coefficient varies from 0 to 1, where 1 indicates the maximum efficiency and will be attributed to the ASL which bears the minimum cost for each item.

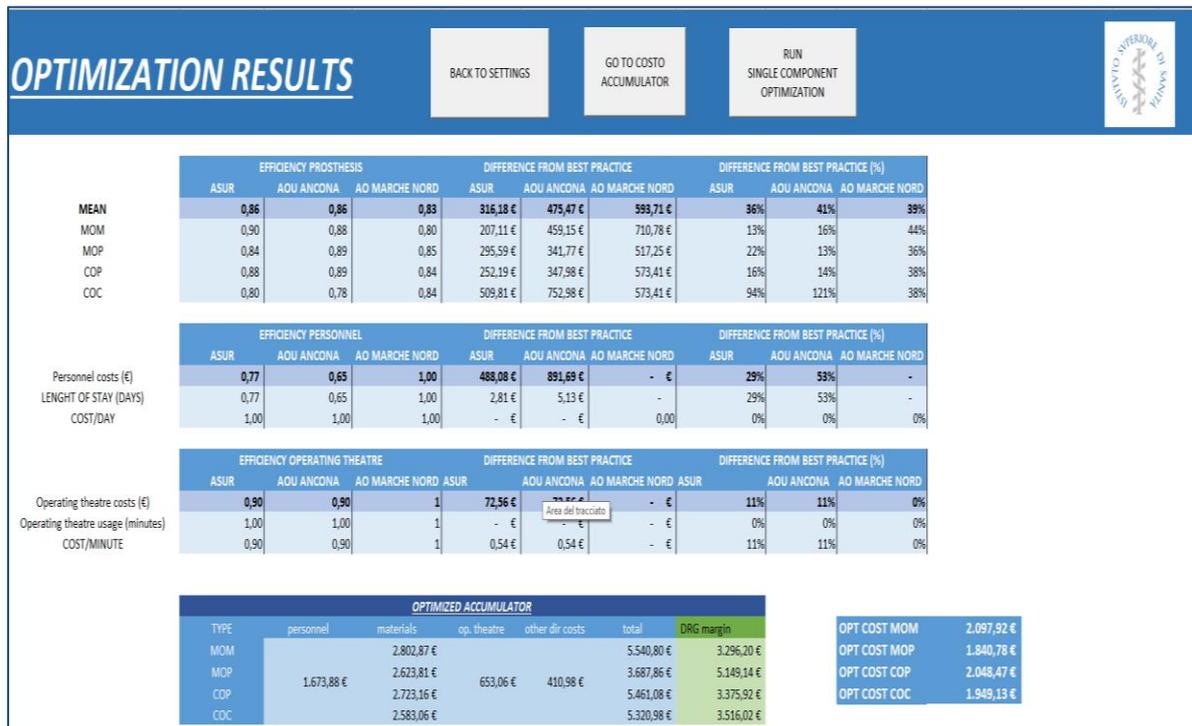
The costs taken into consideration are those indicated in the "deterministic settings" screen.

The model also calculates the difference in both monetary and percentage terms between the costs incurred by each structure and the "best practice", or the lower cost incurred by one of the companies.

The efficiency coefficient can be calculated with reference to:

- the cost of the prostheses;
- the number of days spent in hospital;
- the cost of personnel per day of hospitalization;
- direct costs per day of hospitalization;
- the number of minutes in the operating room;
- the cost per minute of the operating room.

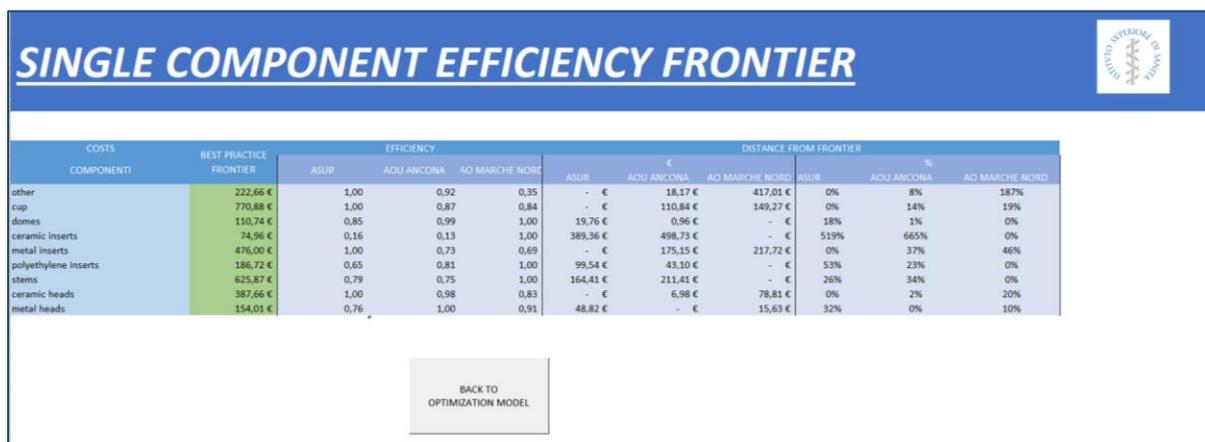
FIGURE 11. RESULTS OF THE DETERMINISTIC OPTIMIZATION MODEL



As shown in figure 11, the model also indicates the optimized cost accumulator, and the lower cost and therefore the reference cost for each type of prosthesis, chosen among the different structures and the optimized cost for each type of prosthesis.

The coefficient of efficiency of the prostheses is also elaborated on the basis of the costs of the components of the individual prostheses: MoM, MoP, CoP, CoC and their average for each healthcare facility, through the "RUN SINGLE COMPONENT OPTIMIZATION" command (top right of the Figure 10). In this case, the model allows to elaborate an efficiency frontier which is defined by the minimum cost per single component of the prosthesis sustained at the regional level (figure 12).

FIGURE 12. ESTIMATE OF THE EFFICIENCY COEFFICIENTS FOR EACH SINGLE COMPONENT (BORDER IN GREEN)



The "BACK TO SETTINGS" button allows the user to return to the initial deterministic settings. The "GO TO DETERMINISTIC ACCUMULATOR" button, on the other hand, allows you to view the starting cost accumulator, resulting from the initial settings (not optimized).

Probabilistic settings

By clicking on the "GO TO PROBABILISTIC SETTINGS" button from the "Deterministic settings" screen (figure 8), the user gets the screen that presents the settings of the probabilistic model which, like the deterministic one, considers:

- the materials (cup, domes, ceramic inserts, metal inserts, polyethylene inserts, stems, ceramic heads, metal heads and more);
- the drivers (length of stay in days and the duration of the surgery expressed in minutes);
- rates (cost of staff, costs per day of hospitalization and the cost per minute of the operating room).

This model, shown in figure 13, allows to attribute a probability to each disinvestment scenario that provides for the attribution of discounts as shown in the "Deterministic settings". To do this, each discount percentage is assigned a standard deviation, a maximum and a minimum that can be modified as desired by the user (figure 13).

FIGURE 13. PROBABILISTIC SETTINGS OF THE MODEL

The screenshot shows the 'PROBABILISTIC SETTINGS' interface with the following components:

- Buttons:** BACK TO DETERMINISTIC SETTINGS, RUN FRONTIERS SIMULATION, RUN BUDGET IMPACT SIMULATION.
- Logo:** UNIVERSITÀ INFERRIORE DI TORINO
- Materials Table:**

MATERIALS	ASUR				AOU ANCONA				AO MARCHE NORD			
	BASE CASE DO NOT CHANGE	SET PARAMETERS (SD, MIN, MAX)			BASE CASE DO NOT CHANGE	SET PARAMETERS (SD, MIN, MAX)			BASE CASE DO NOT CHANGE	SET PARAMETERS (SD, MIN, MAX)		
other	10%	3%	2%	80%	10%	3%	2%	80%	10%	3%	2%	90%
cup	10%	3%	2%	80%	10%	3%	2%	80%	10%	3%	2%	80%
domes	10%	3%	2%	80%	10%	3%	2%	80%	10%	3%	2%	80%
ceramic inserts	10%	3%	2%	95%	10%	3%	2%	95%	10%	3%	2%	80%
metal inserts	10%	3%	2%	80%	10%	3%	2%	80%	10%	3%	2%	80%
polyethylene inserts	10%	3%	2%	80%	10%	3%	2%	80%	10%	3%	2%	80%
stems	10%	3%	2%	80%	10%	3%	2%	80%	10%	3%	2%	80%
ceramic heads	10%	3%	2%	80%	10%	3%	2%	80%	10%	3%	2%	80%
metal heads	10%	3%	2%	80%	10%	3%	2%	80%	10%	3%	2%	80%
- Drivers & Tariffs Table:**

DRIVERS & TARIFFS	ASUR				AOU ANCONA				AO MARCHE NORD			
	BASE CASE DO NOT CHANGE	SET PARAMETERS (SD, MIN, MAX)			BASE CASE DO NOT CHANGE	SET PARAMETERS (SD, MIN, MAX)			BASE CASE DO NOT CHANGE	SET PARAMETERS (SD, MIN, MAX)		
Length of stay (days)	10%	4%	10%	80%	10%	4%	10%	80%	10%	5%	10%	80%
Operating theatre (minutes)	10%	4%	10%	80%	10%	4%	10%	80%	10%	5%	10%	80%
Personnel (daily costs)	10%	4%	10%	80%	10%	4%	10%	80%	10%	5%	10%	80%
Other direct costs (daily tariffs)	10%	4%	10%	80%	10%	4%	10%	80%	10%	5%	10%	80%
Operating theatre (cost per minute)	10%	4%	10%	80%	10%	4%	10%	80%	10%	5%	10%	80%

These are used to associate a random distribution of Beta type to each discount parameter, in line with the Ispor guidelines (48) which suggest attributing distributions to the rates that allow the extraction of values between 0 and 100%. The stochastic equations used to construct the distributions, together with the related scale and shape parameters, are reported in the "Distributions" worksheet hidden from the user. However, these equations can be acted on indirectly by modifying in the sheet

represented in figure 13. The columns under the item "SET PARAMETERS" for each ASL, that is: "SD" (Standard Deviation), "MIN" (Minimum) and "MAX" (Maximum).

Montecarlo simulations

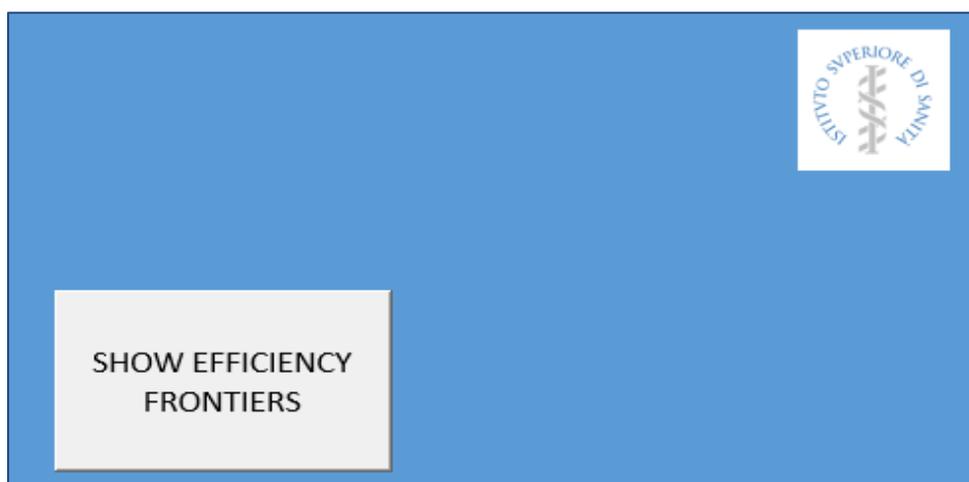
The probabilistic model returns the results in terms of scenario through two Monte Carlo simulations.

Frontiers simulation

The first Monte Carlo simulation is launched by clicking the "RUN FRONTIERS SIMULATION" button located in the "Probabilistic setting" screen / page, as shown in Figure 13.

Once the Monte Carlo simulation has stopped, it is necessary to click the "SHOW EFFICIENCY FRONTIERS" button (figure 14) which will appear at the end of the procedure to obtain the efficiency frontiers graphs.

FIGURE 14. BUTTON FOR BUILDING EFFICIENCY FRONTIERS



The model shows graphs (figure 15) that represent the efficiency frontier (blue line) for each type of MoM, MoP, CoP and CoC prosthesis and the different cost scenarios resulting from the different disinvestment strategies that can be formulated using the settings provided in the "PROBABILISTIC SETTINGS" sheet (Minimum, Maximum and Standard Deviation). Each point on the graph represents the result of each divestment strategy and its distance from the blue line measures the level of inefficiency. The points that are placed on the efficiency frontier indicate the scenarios that would lead to acquiring a level of "full" efficiency (equal to 1).

The usefulness of the simulations consists in the possibility of observing the outcome, in terms of cost minimization, of a set of strategies within a given range of possibilities (determined by the percentage variations of costs). Obviously, once this range has been determined, through the settings on the

“PROBABILISTIC SETTINGS” sheet it will be possible for the user to observe as a whole, what would be the results of any disinvestment strategies implemented.

By way of example, figure 15 shows an “as is” situation in which all the average values are the starting ones (ie those present in the dataset contained in the hidden “Data settings” sheet). A standard deviation of 5%, a minimum of 2% and a maximum of 60% was applied to these costs.

This scenario, therefore, does not envisage a homogenization of the costs of the three structures observed. The differences between the costs therefore remain unchanged, since they have varied uniformly. It is possible to observe how:

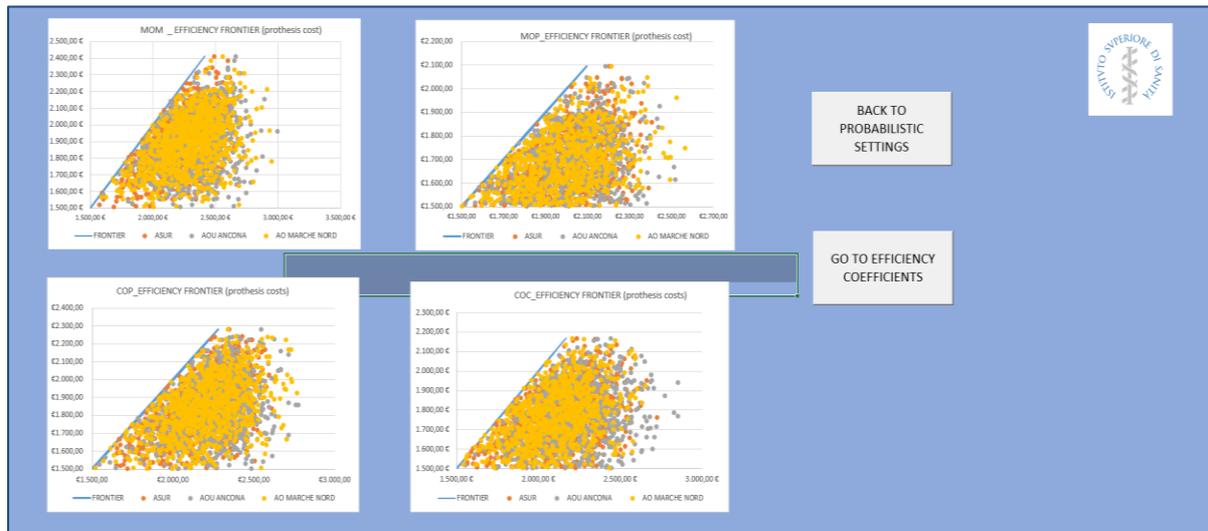
- the AO Marche Nord has structurally higher costs than the other companies, since the relative scenarios are the most distant from the efficiency front. These results are valid for all types of prostheses considered, except in the case of the CoC where the costs of the individual structures seem to overlap;
- the procedure that involves the use of the CoC prosthesis is the one that, in general, is less efficient, being, for all three Healthcare Structures, the one whose costs are furthest from the efficiency frontier, and which therefore, apart from effectiveness and safety with the others, is destined to be discontinued, in the absence of efficiency measures that reduce the costs of the procedure.

FIGURE 15. SIMULATION WITH THE USE OF STOCHASTIC EFFICIENCY FRONTIERS. SITUATION "AS IS"



Figure 16, on the other hand, shows the results of a divestment intervention which consists in homogenizing the costs of the different types of prostheses, so that the costs of the components purchased by the individual structures are as close to the minimum regional purchase cost (represented by the border).

FIGURE 16. SIMULATION WITH THE USE OF STOCHASTIC EFFICIENCY FRONTIERS. DIVESTMENT STRATEGY BASED ON THE HOMOGENIZATION OF THE PURCHASE COSTS OF THE PROSTHESIS COMPONENTS.



It is possible to observe that, following such an intervention:

- the costs of the Marche Nord AOU, which in the previous simulation were the highest, overlap those of the other health facilities;
- the procedure that involves the use of the CoC prosthesis sees its inefficiency reduced.

Finally, by clicking on the “GO TO EFFICIENCY COEFFICIENTS” button (figure 16), the model returns the percentiles relating to the efficiency coefficients (maximum 1) relating to each structure for each of the procedures considered (figure 17). The "BACK TO FRONTIERS" button allows you to return to the screen shown in figure 16.

FIGURE 17. PROBABILISTIC SIMULATION. COEFFICIENTS OF EFFICIENCY



Budget impact simulation

The second Montecarlo simulation is obtained by clicking the "RUN BUDGET IMPACT SIMULATION" button in the "probabilistic settings" screen (see figure 14).

At the end of the Monte Carlo Simulation, the "GO TO BUDGET IMPACT" generator button appears (figure 18) on which to click to elaborate a graph of the budget impact analysis of all health facilities (figure 19).

FIGURE 18. BUDGET IMPACT GRAPH GENERATOR BUTTON

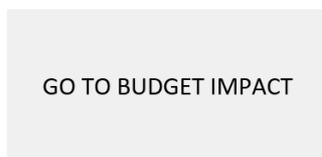
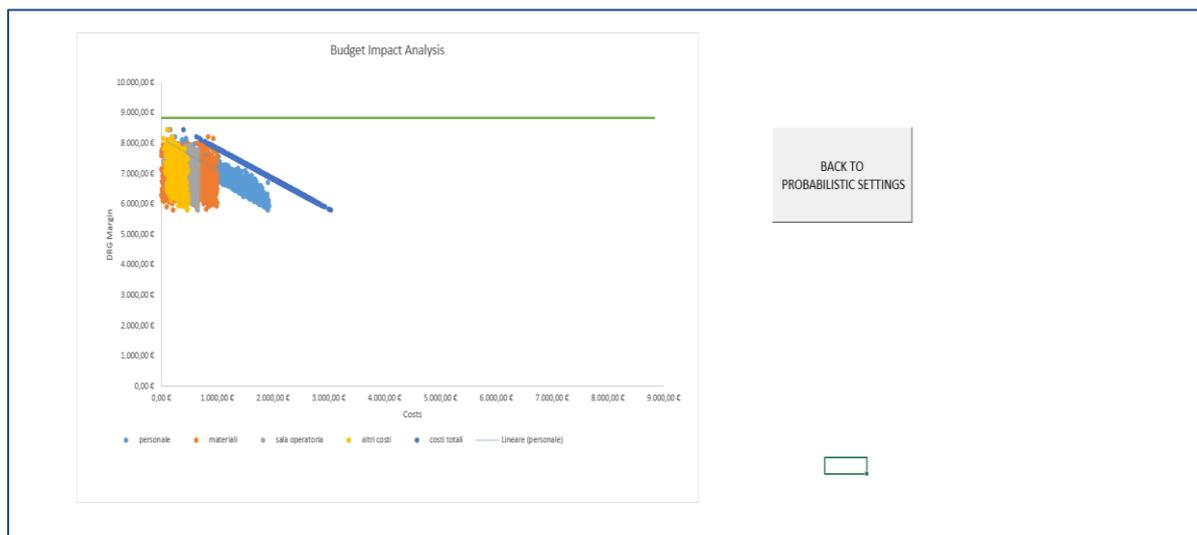


FIGURE 19. BUDGET IMPACT ANALYSIS CHART



The line parallel to the abscissa axis (in green) represents the DRG, set at € 8,837.00 for each operation / surgery to replace hip prostheses.

The changes in personnel costs, materials, operating room and other costs, according to the probabilistic settings, are represented on the X-axis.

Conclusions

The model not only allows to identify the least convenient technology for each healthcare facility but, by homogenizing the costs of the different technologies, so that the costs of the components purchased by the individual facilities is as close to the minimum regional purchase cost (represented by the border) make usable even those technologies that were previously inefficient.

A reason for concern represents the chance to apply this model to different settings either at regional and national level.

The toolkit has been designed in order to be suitable for all the Italian healthcare deliveries. As a matter of fact, in order to be populated, it requires data that are produced by the administrative offices of the Italian healthcare deliveries on a routine basis (i.e. management control data as for example the personnel cost, operating theatre costs etc...) and on the basis of homogeneous institutional guidelines. On the other side the prices of the single components and of the prostheses are well known in each setting. As a matter of fact, the toolkit gives also the opportunity of running the evaluation of the efficiency by estimating an efficiency frontiers. These are based on data coming from different healthcare deliveries, which means that, in order to perform this analysis, different organizations should have access and should produce the same kind of data and at the same level of detail.

Moreover, sensitivity analysis is suitable so that it is possible to account for variation in the costs and prices of different settings. This tool could be a useful support in order to support the new-born Italian "Centrali di Acquisto Regionali", agencies in charge of governing the purchasing process on a regional basis (materials and technologies are acquired at the same purchasing price for all the healthcare deliveries within the same region).

However, in order to make this toolkit available and suitable for different national jurisdiction, some adaptations have to be made. In particular, the input data sheet should be modified in order to be compliant with the standard format of the economic reports that are produced by the healthcare delivery. It should be verified whether an homogeneous format exists so that data are comparable across different organizations. If this would not be the case, further adaptations would be needed. By the way, the model is feeded with information that can be also collected without being uploaded from the standard reports, for example by considering metadata or making assumptions from expert opinions or from literature.

Independently of the technical adaptations of the model described above, which are however necessary when tools and models are applied to different socio-organizational contexts, the validity

and exportability of the model in other contexts is given by the principles on which the same model is based. In fact, the model fully incorporates the theoretical foundations for which organizational factors are able to influence clinical evidence-based decision-making and that this might influence the uptake of technologies (see Section 1 of the document).

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Appendix 1. Baseline tables according to type of troponin use

TABLE 1. BASE LINE CHARACTERISTICS ACCORDING TO USE OF HIGH SENSITIVITY TROPONIN AT DEPARTMENT LEVEL

	Use of high sensitivity troponin, N = 1293 - N (%)	Use of contemporary troponin, N = 1607 - N (%)
Age		
<45	254 (19,64)	259 (16,12)
45-54	248 (19,18)	328 (20,41)
55-64	273 (21,11)	326 (20,29)
65-74	234 (18,1)	321 (19,98)
75-84	220 (17,01)	282 (17,55)
>=85	64 (4,95)	91 (5,66)
Gender		
Male	767 (59,18)	993 (61,64)
Occupation		
In work	575 (50,48)	382 (43,13)
Student	22 (1,93)	3 (0,34)
Housewife	35 (3,07)	90 (10,20)
Retired	460 (40,39)	338 (38,32)
Unemployed	47 (4,13)	69 (7,82)
Missing	157 (13,78)	729 (82,65)

TABLE 2. CO-MORBIDITIES ACCORDING TO USE OF HIGH SENSITIVITY TROPONIN AT DEPARTMENT LEVEL

Anamnesis	Use of high sensitivity troponin N= 1296 - N (%)	Use of contemporary troponin N = 1611 - N (%)
Previous ischemic heart disease	412 (25,57)	279 (21,53)
Hypertension	589 (45,45)	862 (53,51)
Diabetes	153 (11,81)	297 (18,44)
Other major pathologies	590 (45,52)	563 (34,95)

Appendix 2. Methods and results of the case study regarding the clinical use of the robotic surgery with Da Vinci Robot in different clinical areas

Methods

In order to examine organizational contextual factors effect on the clinical use of the Da Vinci Robot the following analysis combines results from a literature search of HTA reports on the use and organization of robotic surgery, which was performed by browsing websites of major HTA agencies and health sites and a semi-structured online questionnaire study. The data sources complement each other in relation to securing more valid analyzes of the different aspects of contextual organizational variables affect on clinical evidence-based decision-making. Where the literature search provides an overview of general international research experiences on robotic surgery, the questionnaire examines how organizational factors affect the utilization of the da Vinci Robot in an European context. Conclusions and themes from the literature search have also been used as a basis for the development of the online survey. The sections below describe the development of the survey, how data was collected as well as analyses used.

The Survey development

A specific search for evidence and information regarding organizational aspects, implementation and the use of robot surgery was conducted on websites of major HTA agencies and health sites collecting information on HTA reports, such as: The International Network of Agencies for Health Technology Assessment, NIHR Dissemination Centre at the University of Southampton, Cochrane Database of Systematic Reviews, Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effects (DARE). Especially information regarding organizational/ managerial barriers and facilitators that effectively influence evidence-based clinical decision making in hospital settings as well as surveys and interview guides used to gather information on organizational aspects, utility, barriers, enablers and performance of robotic surgery were of special interest. The questions in the survey were constructed based on results from the two literature reviews described in section 1 of this document and results from the HTA report search. The survey was structured according to the components included in the Leavitt's organizational model described in section 1. Before finalizing the survey, all questions were sent to an expert panel for validation. The final questionnaire was addressed to managers, physicians and nurses, and investigated both hospital and department contextual factors as well as physicians' and nurses' perceptions of barriers and enablers to the uptake of the da Vinci

Robot. The participants were selected as they represented different levels and / or perspectives on the organization of robot surgery, and thus overall contributed to a more holistic perspective on the utilization of robotic surgery.

Setting, data collection and participants

The semi-structured questionnaire was distributed to 9 hospitals in 5 European countries (Italy, Poland, Slovenia, Spain and Portugal). Hospitals were nominated by the participating partners and invitations were sent out to hospitals where a preliminary examination had shown, that the da Vinci Robot was being used. For the collection of data, the survey used self-administered questionnaires delivered in an electronic format via a link in an E-mail to the online survey portal SurveyMonkey. For each participating hospital a contact person was appointed by the consortium partners who was in charge of distributing the link to different key actors (managers, physicians, nurses) of the hospitals.

Analysis

Initially, a summary of the main results collected from websites of major HTA agencies and health sites are presented, after which the results from the online survey with professionals at hospital level are analyzed. Results collected from the online survey will be structured according to Leavitt's organizational model described in section 1 of this document and will be presented as a narrative summary analysis.

As mentioned earlier, Leavitt's organizational model is based on four components that define an organization: technology, tasks, structure and people. In relation to the current analysis, the technology deals with the robot technology itself and its characteristics. It describes the technique and the administrative procedures and work processes associated with the robot. The structural aspects relate to the structural and formal organization of robotic surgery as well as conceptual organizational aspects of the hospital. Finally, the people dimension concerns strategies for training and learning curves as well as cultural conditions such as collaboration and communication. Since the analysis is focusing on exploring contextual organizational variables affect on clinical evidence-based decision-making the component Task in the Leavitt's model which includes the use of the robot technology and the operations that the personnel have to perform when using the technology will not be dealt with in details.

Results

Results from literature on the use and organization of robotic surgery

In the section below, the use of the Da Vinci Robot as well as international experiences of organizing robotic surgery according to identified HTA reports are presented. The analysis includes results from Canada, the USA, Ireland, Germany, Belgium, Italy and Denmark (see references 24-34). It varies how much the four dimensions of Leavitt's organizational model are included in the HTA reports. A major part of the literature touches on the People dimension, including robot surgery training and learning curve, and secondary communication and collaboration. Conversely, the literature only highlights to a limited extent the structural dimension. Since all HTA reports identified focuses on robot surgery in general and not only on surgery performed with the da Vinci Robot the technology section below includes information from other sources than HTA report in order to give a description of the da Vinci Robot.

Technology

The Da Vinci surgical system is a robotic system that utilizes computational, robotic, and imaging technologies to enable improved patient outcomes compared to other surgical and non-surgical therapies. The da Vinci surgical system was developed by the American company "Intuitive Surgical" and was approved in 2000 by the American Drug and Food Administration (FDA) for surgery (23). The da Vinci Surgical System operates on a *master-slave* principle, where the surgeon sits at a console (master) connected by cables to the robot (slave). The robot part is entirely dependent on surgeon activity. Surgeon hand movements are transmitted to laparoscopic surgical instruments, which directly reproduce the surgeons hand activity reversible (26-30).

As a general rule, the Da Vinci robot consists of the following three separate but interconnected sections (see figure below):

- 1) The surgical console where the surgeon is placed and controls the robot by observing a stereoscopic monitor creating an enlarged (approximately 10-15 times) three-dimensional (3D) image of the surgical area which makes the tissue structures appear very clear. The surgeon manages the robot's arms by moving two joysticks each with space for two fingers.
- 2) The patient-side cart with robotic arms which are controlled by a computer that recreates the surgeon's movements in real time. Prior to placing the robotic instruments in the patient, up to six small openings are typically made of about 1 cm's width through which so-called working gates are placed. Through these gates camera and surgical instruments can be inserted.
- 3) The vision cart which consists of a monitor where the clinical staff can monitor the surgery.



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Structure

Only a limited amount of literature describes structural or organizational issues regarding the utilization of the Da Vinci Robot. The following issues have been identified in the sections regarding organizational aspects in national HTA reports on robot surgery.

Large volume of operations is highlighted in several studies as a prerequisite, although no studies specifies how many operations 'large' refer to. The recommendation is based on several parameters. First, large surgical volume can contribute to the development and maintenance of the surgeon's and other surgical staff's skills, experience and routine, which may help improve surgical flow, length of operation, and the quality of the patient outcome after surgery (36, 37). In addition, it reduces operating expenditure per operation, which causes a greater return on the investment in robot technology compared to low operational volume (24). The literature points to two structural aspects that could support a large operation volume and thus economic optimization. The first aspects is a centralization of the robot surgical activities in dedicated robot centers where only robot surgery is performed. Besides optimizing the financial implications and resource utilization, it is expected to increase the patient safety and outcome due to increased competence level and experience among the operating staff. Second, it is highlighted that in cases where one specialty alone can't fill the robot's capacity the utilization will be optimized by letting multiple specialties use the same robot (24, 35). However, it should be emphasized that the arguments are not based on quantitative statements.

By having an operating theater only dedicated to robotic surgery it would also avoid that robots are being moved between operating rooms risking to damage the robot and/or the operating personal. Furthermore, robot surgery also demands greater space in the operating room compared to conventional laparoscopy and open surgery as a consequence of a larger setup in the form of operating console, the robot itself, monitoring apparatus, etc. Lastly, a dedicated operations team is highlighted as a third and final structural prerequisite for an appropriate implementation and

utilization of robotic surgery. A limited group of motivated surgical staff experienced in robotic surgery is pointed out to have positive outcomes for both surgeons, hospital administration and patients. Examples include potential improvements in patient outcome, increased productivity and efficiency, as well as greater staff satisfaction (35, 38). However, the conclusions must be taken with caution as they are not based on systematically collected knowledge.

People

As described above, part of the literature is about people-related consequences of robot-assisted surgery, special training and learning curve, but also communication and collaboration.

Robot surgery is highlighted in many studies as associated with a significant learning curve for surgeons. However, there is no consensus on the length of the learning curve. This is partly due to disagreement on what parameters or outcome that the learning curve should be determined by, and partly because the learning curve is dependent on several related factors, such as the complexity of the procedure, surgeon-dependent factors (experience with similar procedures / technology and surgical procedures), hospital-related factors (available operating time at operating room and operating volume) (36,37,39,40,41,42). In the literature, there is general agreement that the learning curve is associated with both a significant financial costs and potential negative consequences for patient outcome and should therefore be optimized. In the literature, surgical training is recommended as a structured, objective and skill-based training program, as it is expected to reduce the learning curve and thus the costs and negative outcomes. Recommendation is given to designing the structured training program as a combination of preclinical theoretical and practical training as well as clinical practical training (37,39,40,42). However, the literature does not specify clear and uniform guidelines for the recommended duration and detailed organization of the training program's sub-elements, nor does it appear that official and standardized guidelines for robotic surgical training exist, apart from brief guidelines from the robot's manufacturer (Intuitive Surgical) (37,35,40,42).

Robot surgery also requires that other surgical staff (i.e. surgical nurses) receive training in robot surgery, as the level of competence for all the staff is crucial for both patient safety and efficiency (operation time and surgical flow). In addition, insufficient training in robotic technology and components has been shown to lead to inappropriate handling of the technology as well as communication and collaboration difficulties in the operating room. Therefore, a standardized and structured training program for the operational staff is also expected to streamline the training period and improve the results of the training. According to the literature, such a program should at least include theoretical instruction in technology, practical training in handling the technology and in problem solving. As for the surgical training, the scope and design of the training is not further

specified and as for the surgeons official and standardized guidelines for training is missing except for brief guidelines of Intuitive Surgical.

Compared to other types of surgery, collaboration and communication between the surgical staff in robotic surgery is emphasized to bring better results in terms of efficiency, patient outcome and patient safety. This is partly due to the fact that robotic surgery must be regarded as team surgery to a greater extent than both open surgery and conventional laparoscopy based on the position of the operating surgeon at the console (43,44). As a consequence, the importance of organizational support is emphasized such as good cooperation and good communication in the operating room. In some studies, it is recommended that preoperative briefings should be used by the operating staff in order to clarify the division of work tasks as well as to ensure a common understanding of the operation and work processes of the operation (38). In other studies, it is emphasized that experience and routine across the surgical staff is an essential prerequisite, which is why it is recommended that the size of the surgical staff be adjusted to the volume of surgery (37, 45). Finally, some studies highlight how structured training of the operating staff is essential for well-functioning collaboration and communication. It is emphasized that team training by the overall operations team in this regard can be a recommended supplement to the training programs for the individual subject groups (37,38).

Results from online survey with European hospitals

The total number of hospitals involved in the case study so far, has been quite lower than what was expected. At the time being only 1 hospital has given an adequate response to all the aspects of the survey and as a consequence the data collection period has been extended until 31st of January 2020, in order to collect data from 3 more hospitals. Furthermore, the project partners have been asked to reconnect with their appointed contact person for each of the selected hospitals in order to have more surgeons and nurses using the da Vinci Robot to answer the survey. As a last precaution, partners at hospitals that previously have been involved in the European project AdHopHta has also been invited to participate in the survey. For this reason, the following section will only be showing preliminary results from a case study of one hospital. Since hospitals have been guaranteed anonymity, the name and country of origin of the included hospital will not be included.

The results include responses from 1 hospital, 4 different departments (Gynecology, Urology, Otorhinolaryngology and Thoracic surgery), 8 different surgeons and 2 nurses all using or assisting with the Da Vinci Robot for surgery as well as an representative from hospital management.

Description of hospital

The hospital included in the case study is a research hospital which provides public services however funded privately. The architectural type of the hospital can best be described as a pavilion hospital

with separated buildings which are not directly connected to each other. The hospital has 850 number of staffed beds, 4.000 employees, around 44.000 yearly number of inpatient admissions and more than 2.000.000 outpatient visits performed. In the uptake territory the hospital both play the role of a hub and a spoke depending on the activity.

Technology

In the hospital technology-innovation priorities are set by top management and middle management of the hospital and it is top management and CEO who take the final decision in reference to the adaptation/purchase of a new technology. In the uptake process of the technology it is however only physicians /healthcare personnel together with middle management who are systematically involved.

In regards to the use of the da Vinci Robot hospital, management has made restrictions or requirements for the volume of surgeries performed and also for the type of surgeries that can be performed. Two different models of the da Vinci robot are utilized in the hospital, the Da Vinci XI Surgical system and the Da Vinci SI Surgical system. It varies across specialty and department which specific model is used, which may reflect the time of purchase of the robots and the year in which robot surgery was introduced for the specialty. Further description of the Da Vinci robot technology can be viewed in the technology part of the previous section.

Structure

HOSPITAL STRUCTURAL / ORGANIZATIONAL FACTORS

At admission patients are being grouped within ward units based on intensity and complexity of care. About 70% of the patients treated in the hospital is involved in a clinical pathway such as emergency pathway, orthogeriatric pathway, cancer pathway or neurological pathway.

The hospital uses activity-based cost management tools and departments hold an annual budget which is broken into monthly budgets. The budget is defined by top management but with the opportunity for negotiation with the clinical setting. Job evaluation activities are systematically carried out for physicians, managers and nurses using score and factor comparison methods. Furthermore, people evaluation activities in regards to competence dictionary and performance evaluation activities for are carried out for physicians, managers and nurses. Also potential human resources is systematically evaluated. The hospital uses ICT tools to collect and exchange patient information regarding medical images, lab results and discharge notes and a combination of paper registers and ICT tools for diagnosis and clinical problems and patients' procedures. However, the ICT tools are only fully integrated and coordinated at a clinical ward level. Most managerial/administrative data, such as financial data, patient flows, logistics and procedures, is collected and exchanged only through ICT

tools with the exception of clinical guidelines which is exchanged through a combination of paper registers and ICT tools. The hospital does not have a dedicated Health Technology Assessment unit, but HTA activities does take place in order to support managerial decision-making processes.

STRUCTURAL / ORGANIZATIONAL FACTORS IN RELATION TO THE DA VINCI ROBOT

Out of 5 departments using the Da Vinci Robot, 4 departments were included in the survey. One of the departments had been performing surgeries with the da Vinci Robot for more than 10 years while the other 3 departments introduced the da Vinci Robot 4-5 years ago. The survey showed, that in all 4 of the departments the Da Vinci Robot was placed in a general operating theater where also conventional surgery was performed. The included departments had between 5 and 10 surgeons but only around half (between 2 to 4) of the surgeons in each department perform surgery using a Da Vinci Robot. For most departments the da Vinci Robot was being used 1 day a week for between 6-10 hours. Only one department used the da Vinci Robot 5 days a week for about 7-8 hours a day. The number of surgeries performed per year per department also varied from around 20 to around 450 per year. For the nurses it was indicated that 10 out of 50 scrub or theater nurses were assisting in surgery with the da Vinci Robot. The nurses worked in cross-disciplinary surgical teams assisting in surgery for several specialties assisting both in surgery with the da Vinci Robot as well as conventional surgery.

In relation to the degree of barriers to the full implementation of the da Vinci Robot 3 out of 8 respondents answered that barriers generally were frequent or high, 4 out of 8 that barriers were limited and 1 answered that barriers were not existing. When asked about specific structural barriers all of the participating surgeons indicated that device cost and the reimbursement system caused high barriers to the full use of the da Vinci Robot. Other high barriers to the use included: Availability of medical equipment and operating room (5 out of 8), management of schedules (5 out of 8) and general organization at hospital level (4 out of 8).

People

EXPERIENCE

All of the 8 surgeons included in the case study had finished their specialist training more than 5 years ago and two of the surgeons finished their specialist training more than 20 years ago. Both nurses had finished nursing school more than 10 years ago. The number of surgeries performed per year per surgeon varied from under 10 surgeries in one department to more than 100 surgeries per surgeon in another department.

TRAINING

All surgeons indicated that simulation training activities were systematically provided or required by their hospital before being entitled to perform surgery with a Da Vinci Robot and most surgeons also indicated that the hospital provided or required mentorship and training in surgical team work and team communication. Half of the surgeons indicated that theoretical training was required and only 3 surgeons answered that a validation test in robotic console proficiency was required in order to perform surgery with a Da Vinci Robot. Nurses would officially receive 3-4 days of official training in the da Vinci robot system which would consist of instructor-based training and observation of surgical teams using the robot. The training would include basic laparoscopic understanding, team communication and team-based training, preparation of computer system and fitting of surgical instruments. No peer-to-peer education or mentoring program was mentioned. When asked about specific barriers to the full use of the da Vinci Robot nurses mentioned difficulties in receiving continued training for already certified robotic nurses as a challenge for nurses assisting in surgery with the da Vinci Robot.

CONSULTATION OF SAFETY PROCEDURES

Out of the 8 surgeons, 6 indicated that protocols was frequently used, 5 indicated that guidelines were frequently or always used and 5 indicated that checklists were always or frequently used. Two surgeons answered that guidelines were rarely used and 2 that protocols never or rarely was used and 3 surgeons that checklists were rarely or never used. Answers regarding checklist use could vary within the same department from rarely to always and for protocols from never to frequent within the same department. Nurses indicated that both guidelines, protocols as well as checklist was used frequently or always.

Appendix 3. Study on hip and knee replacement procedures in the Marche Region (Italy)

The Marche Region has made available to the project the data relating to hip and knee prosthesis operations in the years 2017 and 2018 already provided to the Istituto Superiore di Sanità as part of the RIAP (Registro Italiano Artroprotesi – Italian Registry of Arthroprosthesis) project. The data correspond exactly to what was provided for the RIAP project, which has already published the 2017 data in aggregate form (RIAP Annual Report 2018) but not yet those of 2018. The record layouts of 2017 and 2018 are not structured in a totally overlapping manner, for which in some cases it was not possible to present the overall data of the two years except in a separate or partial form. Whenever possible, to give greater robustness to the information extracted, the data were presented in aggregate form between the two years and compared with the RIAP data published in the 2018 report (relating to 2017).

In addition, SDO (Schede di Dimissione Ospedaliera – Hospital Discharge Reports) data relating to hip and knee prosthesis interventions carried out from 1 January 2017 to 30 October 2019 in the regional context, including active mobility flows, and passive mobility data for the same period were available. In the same period in order to allow internal comparisons on the overall activity of the Region.

A further series of data is linked to the prosthetic material purchased in the years 2017 and 2018, flow traced through an extraction from the Medical Devices flow (AREAS) relating to the materials included in the CND classes P0908 and P0909

The complex of available data has allowed a series of analyzes aimed at verifying the behavior of the various structures in the Marche region (in particular with reference to public or private status) to allow comparisons between the different types and between those who feed the RIAP flow more completely and those who participated to a lesser extent in feeding the RIAP.

In particular, analyzes were carried out on:

- Type of patients treated (by gender, age and case history identified through the ICDs), also by stratifying the analysis by type of provider (public vs private)
- Outcomes of the interventions in relation to the length of stay
- Type of devices purchased (medical devices flow) and level of fragmentation (variety of suppliers and price) with respect to the structure that purchases

The data were then processed in a descriptive analysis that traces the analysis model of the RIAP and then in an inferential analysis aimed at showing the different behaviors of the structures that provide

data for the RIAP and, where possible, between these and the complex of activities of the Marche Region

In order to make the analyses consistent with the benchmarks identified in the ALTEMS report, in some cases aggregations were made according to criteria different from those of the RIAP, and in particular in relation to: age classes for surgery and materials used in prostheses.

The elaborations carried out are grouped into 3 distinct paragraphs:

1. The first entirely dedicated to analyses carried out on SDO tracks
2. The second relates to the data entered in the RIAP. This part is further divided into two sections: the first, as far as possible, presents structured data as in the RIAP reports, while the second presents data structured in a specific way to investigate phenomena not discussed in the RIAP reports.
3. The third is dedicated to analyzes carried out on AREAS data

The results are shown separately for hip replacement surgery and for knee replacement surgery, respecting the above scheme for both.

Results

Hip replacement surgery

DESCRIPTIVE ANALYSIS OF HIP PROSTHESIS INTERVENTIONS IN MARCHE (SDO DATA)

The analysis of the SDO flow, including active mobility, made it possible to verify that approximately 2,470 hip replacement operations are performed annually in the Marche Region, including both primary implants and revisions. The value is stable over time both as an absolute value and in relation to the distribution in the individual structures.

TABLE 1: NO. OF HIP PROSTHESIS INTERVENTIONS, BY STRUCTURE

STRUCTURE	2017	2018	2019 *
SINGLE HOSPITAL CENTER AV1	117	100	41
SINGLE HOSPITAL CENTER AV2	373	400	222
SINGLE HOSPITAL CENTER AV3	312	305	214
SINGLE HOSPITAL CENTER AV4	194	180	133
SINGLE HOSPITAL CENTER AV5	183	175	136
NURSING HOME VILLA IGEA	212	206	179
NURSING HOME VILLA PINI SANATRIX GESTION	204	222	176
RITA SRL VILLAVERDE PRIVATE NURSING HOME	288	244	269
AO HOSPITALS RIUNITI MARCHE NORD	276	291	215
AOUOSPEDALI RIUNITI - ANCONA	315	337	250
TOTAL	2,474	2,460	1,835

* 2019 data refer to SDOs closed by 30 October, projection values are comparable with previous years

The distribution of hip replacement operations between public and private structures is constant over time: around 72% of total operations are performed in the public

TABLE 2: DISTRIBUTION OF INTERVENTIONS BY TYPE OF STRUCTURE (PUBLIC / PRIVATE)

TYPE OF STRUCTURE	2017	2018
public facilities	1,770	1,788
private facilities	704	672
% interventions in public structures	71.5%	72.7%

The operations performed are, as expected, mainly on women, who represent an average of 62.9% of the operations in the three years. However, it should be noted that private structures tend to operate a lower than average percentage of women as opposed to public structures. Overall in the three-year period, 65.2% of public structures worked for women, compared to private structures that worked for 57.4% of women (the data is constant over time and also refers to individual structures rather than to the aggregate)

The following table presents the distribution by age group of hip replacement operations.

TABLE 3: NO. OF HIP REPLACEMENT OPERATIONS, BY AGE GROUP AND YEAR

Age class	2017		2018		2019	
<45	30	1.2%	26	1.1%	31	1.7%
45-54	111	4.5%	113	4.6%	99	5.4%
55-64	253	10.2%	283	11.5%	219	11.9%
65-74	625	25.3%	632	25.7%	497	27.1%
75-84	929	37.6%	883	35.9%	645	35.1%
85+	526	21.3%	523	21.3%	344	18.7%
Total	2,474	100%	2,460	100%	1,835	100%

As expected, most of the interventions focus on the older age groups, and in particular in the 75-84 age group. In the three years there seems to be a dynamic in which the percentages of intervention in the younger groups seem to grow, albeit in a limited way, a possible sign of a clinical behavior that favors early interventions.

The following table shows the distribution by structure of the different age groups of patients on whom hip replacement surgery is performed. The table summarizes all the interventions of the three-year period, the green color shows percentage values that are more than 20% lower than the average,

RITA SRL VILLAVERDE PRIVATE NURSING HOME	68.2
AO HOSPITALS RIUNITI MARCHE NORD	78.6
AOUOSPEDALI RIUNITI - ANCONA	75.6
Public	77.2
Private	69.4
Total	74.9

An in-depth study was then carried out in relation to the length of stay in relation to the different structures and different age groups, with the aim of identifying reference benchmarks.

The data analysis clearly shows a different behavior between public and private structures. While the former are characterized by prolonged hospitalizations, an average of 13.7 days for the public (the only exception being Marche Nord with a value slightly below the overall average), the latter are characterized by generally short hospitalizations, an average of 7.7 for the private individual (with the Villa Igea Nursing Home which appears to have significantly lower length of stay than all other structures).

TABLE 6: AVERAGE HOSPITAL STAY BY FACILITY. OVERALL DATA 2017/19

Structure	Days hospitalisation
SINGLE HOSPITAL CENTER AV1	13.9
SINGLE HOSPITAL CENTER AV2	12.8
SINGLE HOSPITAL CENTER AV3	14.0
SINGLE HOSPITAL CENTER AV4	14.1
SINGLE HOSPITAL CENTER AV5	14.3
NURSING HOME VILLA IGEA	5.1
NURSING HOME VILLA PINI SANATRIX GESTION	9.8
RITA SRL VILLAVERDE PRIVATE NURSING HOME	7.9
AO HOSPITALS RIUNITI MARCHE NORD	10.7
AOUOSPEDALI RIUNITI - ANCONA	16.4
Public	13.7
Private	7.7
Total	11.9

The difference between the two types of structure is even more evident by setting a cut-off within which hospitalization can be considered physiological and verifying what the percentage of hospitalizations is below the threshold value. The following table shows the behavior of the different structures with respect to the threshold value of 10 days of hospitalization. The value of 10 days represents the median value of the complex of public and private hospitalizations.

TABLE 7: NO. OF CASES WITHIN AND OUTSIDE THE THRESHOLD (10 DAYS) BY FACILITY. OVERALL DATA 2017/19

Structure	cases in max 10 days	cases over 10 days	% within 10 days
SINGLE HOSPITAL CENTER AV1	58	200	22.5%
SINGLE HOSPITAL CENTER AV2	368	627	37.0%
SINGLE HOSPITAL CENTER AV3	284	547	34.2%
SINGLE HOSPITAL CENTER AV4	169	338	33.3%
SINGLE HOSPITAL CENTER AV5	140	354	28.3%
NURSING HOME VILLA IGEA	589	8	98.7%
NURSING HOME VILLA PINI SANATRIX GESTION	435	167	72.3%
RITA SRL VILLAVERDE PRIVATE NURSING HOME	746	55	93.1%
AO HOSPITALS RIUNITI MARCHE NORD	501	281	64.1%
AOUOSPEDALI RIUNITI - ANCONA	244	658	27.1%
Public	1,764	3,005	37.0%
Private	1,770	230	88.5%
Total	3,534	3,235	52.2%

A further analysis conducted by structure and age group confirms the constant difference between public and private, regardless of the age group taken as a reference. As expected, a generic increase in hospitalization correlated with the increase in the age group is also observed.

TABLE 8: AVERAGE HOSPITAL STAY BY STRUCTURE AND AGE GROUP

Structure	Age group						total
	<45	45-54	55-64	65-74	75-84	85+	
SINGLE HOSPITAL CENTER AV1		13.8	13.4	14.2	14.0	14.0	14.0
SINGLE HOSPITAL CENTER AV2	10.2	10.0	10.8	11.9	12.9	14.4	12.8
SINGLE HOSPITAL CENTER AV3	9.8	11.5	11.0	11.5	14.7	16.3	14.0
SINGLE HOSPITAL CENTER AV4	5.0	10.8	10.8	12.1	15	15.9	14.1
SINGLE HOSPITAL CENTER AV5	13.0	11.9	12.8	13.5	14.3	16.2	14.3
NURSING HOME VILLA IGEA	4.8	4.8	4.8	5.1	5.4	5.4	5.1
NURSING HOME VILLA PINI SANATRIX GESTION	8.9	8.9	8.8	9.8	10.3	12.8	9.8
RITA SRL VILLAVERDE PRIVATE NURSING HOME	6.9	7.4	7.9	7.8	8.3	8.3	7.9
AO HOSPITALS RIUNITI MARCHE NORD	12.7	9.6	11.9	9.9	10.7	10.9	10.7
AOUOSPEDALI RIUNITI - ANCONA	13.2	13.7	12.4	14.5	17.4	19	16.4

The need for organizational intervention is evident with the aim of allowing more timely discharge and within acceptable thresholds. A significant part of the differences in the length of hospitalization is explained by the different type of cause of the interventions between public and private structures, this phenomenon is analyzed in the following chapter dedicated to the analysis of RIAP flows, and in particular in table 19. This difference also emerged in comparison with the Advisory Board. Another factor that presumably impacts on prolonged hospitalization in public facilities is that these are in fact used as long-term care and rehabilitation facilities to the detriment of the appropriateness of hospitalizations. Further targeted analyzes would be appropriate to verify suitable corrective actions. A third reason, but less impactful than the previous ones, is that public structures admit patients with a higher average age.

Mobility

The regional territory is characterized by a strong passive mobility. The available data concern only the years 2017 and 2018 and show that in the two years they involved 873 and 888 interventions respectively (therefore 26.1% and 26.5% of the total interventions carried out in the Marche region, including active and passive mobility). It is clear that the recovery of this significant share of patients residing in the Marche Region appears to be a first important area of intervention for a divestment aimed at avoiding the flight of resources to other regions and the improvement of the offer of services within the Marche Region.

A further element of analysis concerns the places towards which the flow of passive mobility is directed

The following table shows the Regions that exercise the greatest attraction to passive mobility and the structure that attracts the most within the individual Regions (values referring to the two-year period 2017/2018).

TABLE 9: PASSIVE MOBILITY - MAIN STRUCTURES. OVERALL DATA 2017/2018

Region	freq per Region	+ attractive structure	Freq. Struct. + attractive
Umbria	122	LAMI SPA (SAGISC - MADONNA DEGLI ANGELI) - Perugia	53
Lazio	29	SAN FELICIANO NURSING HOME - Rome	4
Abruzzo	88	NURSING HOME VILLA SERENA - Città Sant'Angelo	70
Emilia Romagna	1,040	VILLA MARIA CECILIA HOSPITAL - Cotignola	234
Lombardy	389	IST.CLINICO S.SIRO SPA-MILAN	262
Italy	1,761		

Overall, it is highlighted that mobility is concentrated exclusively towards private structures and in particular towards Emilia Romagna which alone absorbs 59% of mobility, among other things attracting not only in the main reference structure (Villa Maria Cecilia Hospital in Cotignola) which represents 22.5% of the attractiveness of the Emilia-Romagna region. The opposite is true for the attraction exercised by the Lombardy Region, which overall represents 22.1% of mobility, in which the center of greatest attraction (Istituto Clinico San Siro di Milano) alone absorbs 67.4% of those who turn to Lombardy region to receive hip prostheses. Mobility therefore cannot be explained exclusively on the basis of territorial contiguity (the high number of patients operated on in Lombardy is underlined).

An analysis was also carried out on the attractiveness of the structures of the Marche Region. The overall values of the three-year period show that the attraction is mainly exercised by private structures, which cover 72.4% of the total, mainly concentrated at the Villa Verde nursing home.

TABLE 10: ACTIVE MOBILITY - MAIN STRUCTURES. OVERALL DATA 2017/2018

Structure	No. of interventions	%
SINGLE HOSPITAL CENTER AV1	11	1.2%
SINGLE HOSPITAL CENTER AV2	42	4.7%
SINGLE HOSPITAL CENTER AV3	22	2.4%
SINGLE HOSPITAL CENTER AV4	16	1.8%
SINGLE HOSPITAL CENTER AV5	56	6.2%
NURSING HOME VILLA IGEA	75	8.3%
NURSING HOME VILLA PINI SANATRIX GESTION	64	7.1%
RITA SRL VILLAVERDE PRIVATE NURSING HOME	512	57.0%
AO HOSPITALS RIUNITI MARCHE NORD	24	2.7%
AOUOSPEDALI RIUNITI - ANCONA	77	8.6%
attraction public facilities	248	27.6%
attraction private structures	651	72.4%
total attraction	899	100.0%

DRG encoding

As regards the coding and therefore the DRG attributed to the interventions, the behavior is rather uniform, with DRG 544 "Replacement of major joints or reimplantation of the lower limbs" which represents a total of 91.8% of the interventions and DRG 545 "Revision replacement of the hip or knee" which represents 6.8% of the series. The use of other DRGs is occasional (1.4% of cases), however consistent with hip prosthetic interventions.

TABLE 11: DRG FREQUENCY BY FACILITY

Structure	DRG frequency			Total
	DRG 544	DRG 545	Other DRGs	
SINGLE HOSPITAL CENTER AV1	232	20	6	258
SINGLE HOSPITAL CENTER AV2	902	79	14	995
SINGLE HOSPITAL CENTER AV3	763	48	20	831
SINGLE HOSPITAL CENTER AV4	464	37	6	507
SINGLE HOSPITAL CENTER AV5	461	23	10	494
NURSING HOME VILLA IGEA	557	37	3	597
NURSING HOME VILLA PINI SANATRIX GESTION	574	28	0	602
RITA SRL VILLVERDE PRIVATE NURSING HOME	742	58	1	801
AO HOSPITALS RIUNITI MARCHE NORD	711	53	18	782
AOUOSPEDALI RIUNITI - ANCONA	807	79	16	902
TOTAL	6,213	462	94	6,769

DESCRIPTIVE ANALYSIS OF THE INTERVENTIONS INCLUDED IN THE RIAP

Section 1

The cards relating to hip replacement operations, provided as part of the RIAP by the Marche Region in the period under review, totaled 1,503, an increase in 2018 compared to the previous year. The increase is consistent with the indications of the ISS to make the compilation of the forms mandatory, however the level of compilation reached is still insufficient, as a total of 4,934 interventions were carried out in the same period in the Region. The percentage covered by the RIAP is therefore 30.5%.

Most of the tables presented below are constructed with the same criteria as the RIAP, in order to make an immediate comparison between the data possible. However, in some cases the trace available in the Marche Region did not allow the extraction of completely overlapping data and therefore some data are presented in a different way compared to the RIAP reports.

TABLE 12: RIAP COMPILATION FREQUENCY BY FACILITY

STRUCTURE	2017	2018	total
NURSING HOME VILLA PINI SANATRIX GESTION	191	180	371
NURSING HOME VILLA IGEA	193	164	357
UNICO HOSPITAL CENTER ZT11	124	85	209
UNICO HOSPITAL CENTER ZT5	0	154	154
ZT4 HOSPITAL - SENIGALLIA	79	64	143

UNICO HOSPITAL CENTER ZT6	57	68	125
AOUOSPEDALI RIUNITI - ANCONA	53	43	96
RITA SRL VILLVERDE PRIVATE CARE HOUSE	0	25	25
NURSING HOME 'VILLA SAN MARCO'	1	13	14
UNICO HOSPITAL CENTER ZT8	5	3	8
NURSING HOME 'VILLA ANNA' SRL	0	1	1
TOTAL	703	800	1,503

The overall percentage of compilation of the forms in the two-year period, comparing private and public structures, is substantially overlapping (51% vs 49%), however it should be noted that in 2017 private structures completed more forms (54.7% of total) while in 2018 the highest value is related to public structures (52.1%) which are obviously gradually adapting to the indications of increased compilation of forms. Since the analysis of the overall SDOs of the regional structures showed that the percentage of interventions in public structures is about 72%, it is however evident that over the years an adequate compilation of the RIAP records has not yet been obtained, and therefore an intervention of promotion in this sense.

TABLE 13: RIAP COMPILATION FREQUENCY BY TYPE OF STRUCTURE

	No. of forms completed 2017-2018		
	2017	2018	TOTAL
Private	385	383	768
Public	318	417	735
Total	703	800	1,503

The interventions included in the RIAP are almost all provided under the election regime, regardless of the public / private type of the providing structure.

TABLE 14: FREQUENCY OF INTERVENTION TYPE (ELECTION / URGENCY) BY TYPE OF STRUCTURE

Type of structure	2017		2018	
	Election	Urgency	Election	Urgency
Public	313	5	nd	nd
Private	383	2	383	0

The distribution by age and type of intervention is available for 2017 only and is presented in the following table. Direct comparison with RIAP data is not possible and is presented separately by patient gender. However, the distribution appears consistent. In particular, in both cases for total replacement the most represented classes are those between 65 and 84 years, while partial

replacements are more often dedicated to patients over 85. The distribution of revisions (which also include removals and replacements of spacers) have a very limited series, however consistent with the RIAP data.

TABLE 15: FREQUENCY BY AGE GROUP AND TYPE OF INTERVENTION. YEAR 2017

age class	total replacement		partial replacement		revision		Total	
	n °	%	n °	%	n °	%	n °	%
<45	15	2.4%				0.0%	15	2.1%
45-54	31	5.0%			2	6.9%	33	4.7%
55-64	82	13.2%			1	3.4%	83	11.8%
65-74	214	34.5%	1	1.9%	9	31.0%	224	31.9%
75-84	224	36.1%	11	20.8%	11	37.9%	246	35.0%
85+	54	8.7%	41	77.4%	6	20.7%	101	14.4%
not available	1	0.2%				0.0%	1	0.1%
Total	621	100%	53	100%	29	100%	703	100%

The laterality of the intervention, presented in the following table, sees a slightly higher percentage for the right than for the left, these values are consistent with the national RIAP data (53.3% right, 45.4% left).

TABLE 16: LATERALITY BY TYPE OF INTERVENTION. YEAR 2018

Laterality	Total replacement	Partial replacement	Total overhaul	Total	%
Right	379	27	17	423	52.9%
Bilateral prosthesis:	1			1	0.1%
Left	331	23	22	376	47.0%
Total	711	50	39	800	100%

The analysis relating to access routes shows important differences with respect to the national reference behavior, in particular due to the almost total absence of anterolateral accesses and the high use of posterolateral accesses in the Marche region. The variety of behaviors in the choice of the access route is not a guarantee of appropriateness, therefore it would be useful to define shared clinical guidelines to be developed through boards of the reference scientific societies, at least at national level.

TABLE 17: ACCESS ROUTE BY TYPE OF INTERVENTION. OVERALL FIGURE FOR 2017/2018

Access route	Total replacement	Partial replacement	Revisions	Total	%	% national
Other	1	1		2	0.1%	0.9%
Front	120	1	1	122	8.1%	12.9%
Anterolateral	2			2	0.1%	13.8%
Lateral	380	47	21	448	29.8%	23.6%
Postero-lateral	828	55	46	929	61.8%	48.9%
Total	1.331	104	68	1,503	100%	100%

The distribution by primary cause is consistent with the national trend, with primary osteoarthritis and fracture of the neck and / or head of the femur together making up over 90% of the total

TABLE 18: FREQUENCY OF CAUSE OF INTERVENTION (TOTAL OR PARTIAL REPLACEMENTS). OVERALL FIGURE FOR 2017/2018

Cause of intervention (total or partial replacement)	Frequency	Distribution%	% RIAP distribution
Primary osteoarthritis	939	65.4%	62.2%
Post-traumatic arthrosis	17	1.9%	1.1%
Rheumatic arthritis	4	0.3%	0.2%
Neoplasm	1	0.1%	0.2%
Aseptic femoral head necrosis	40	2.8%	2.6%
Outcomes of congenital dysplasia or dislocation	17	1.2%	1.8%
Outcomes of Perthes disease or epiphysiolysis	4	0.3%	0.2%
Fracture of the neck and / or head of the femur	408	28.4%	31.4%
Other	5	0.3%	0.3%
Total	1,435	100%	100%

The analysis of the causes of intervention relating to the different type of public / private structure shows particularly relevant differences, as shown in table 18. In particular, almost all interventions for

fracture of the neck and / or head of the femur are concentrated in public structures . This difference certainly has a large impact on the length of stay, which is greater in public facilities, as already highlighted in the analyzes relating to the SDOs of the Marche Region and as also highlighted by the Advisory Board which reviewed this document.

TABLE 19: FREQUENCY OF INTERVENTION (TOTAL OR PARTIAL REPLACEMENTS) BY TYPE OF STRUCTURE. OVERALL DATA FOR 2017/2018

Cause intervention (total or partial replacement)	Public attendance	Frequency private
Fracture of the neck and / or head of the femur	395	13
Primary osteoarthritis	258	681
Aseptic femoral head necrosis	27	13
Post-traumatic arthrosis	5	12
Outcomes of congenital dysplasia or dislocation	3	14
Outcomes of Perthes disease or epiphysiolysis	3	1
Other	2	2
Rheumatic arthritis	1	3
Neoplasm	1	0
Neck fracture pseudarthrosis	1	0
Total	696	739

Analyzing the possible presence of a previous intervention in relation only to replacements (total or partial), it is clear that in the Marche region almost all interventions are not preceded by other interventions (98.3%). The comparison with the general data of the RIAP shows that in Italy the average value is equal to 92.8%.

TABLE 20: FREQUENCY OF PREVIOUS INTERVENTION (TOTAL OR PARTIAL REPLACEMENTS). OVERALL FIGURE FOR 2017/2018

Previous intervention	Frequency	%	% RIAP reference
Nobody	1.411	98.3%	92.8%
Osteosynthesis	21	1.5%	1.1%
Osteotomy	2	0.1%	0.3%
other	1	0.1%	5.8%
Total	1,435	100%	100%

As regards the causes of intervention in the event of a revision, the frequency distribution shows some differences with respect to the RIAP reference data, however it should be emphasized that the overall sample of the Marche region appears to be small (68 cases) so the statistical robustness of the it is limited. The largest difference compared to the RIAP reference is found in the percentage of prosthetic fractures which in the Marche is equal to 33.8% while in the RIAP it is 13.3%

TABLE 21: FREQUENCY OF CAUSE OF INTERVENTION (REVISION). OVERALL FIGURE FOR 2017/2018

Cause of the intervention (revision)	Frequency	%	% RIAP reference
Implant removal results	1	1.5%	1.7%
Other	2	2.9%	1.7%
Periprosthetic fracture	23	33.8%	13.3%
Infection	3	4.4%	7.8%
Dislocation	8	11.8%	12.6%
Aseptic mobilization of the cup	9	13.2%	22.0%
Aseptic mobilization of the stem	7	10.3%	10.4%
Total aseptic mobilization	4	5.9%	10.7%
Osteolysis from debris	2	2.9%	2.0%
Painful prosthesis	5	7.4%	6.3%
Rupture of the implant - neck	2	2.9%	4.9%
Wear of materials	2	2.9%	6.5%
Total	68	100%	100%

The following table presents the 2017 data in relation to the methods of fixing. It is not possible to refer to a RIAP benchmark as the data published on the RIAP report is aggregated in a different way

TABLE 22: METHODS OF FIXATION OF THE ACETABULAR AND FEMORAL COMPONENTS. YEAR 2017

2017 Method of fixation of the acetabular component	Method of fixation of the femoral component			
	Cemented	Not cemented	Not applicable	Total
Cemented	53	39	1	93
Not cemented	31	524	5	560
Not applicable	7	36	7	50
Total	91	599	13	703

The year 2018 shows some changes in relation to the use of fixation methods for the cemented acetabular component (equal to 22.3% of the total, compared to 13.2% in 2017), while the use of fixation methods for the non-acetabular component decreases. cemented (72.4% vs 79.7% in 2017).

A similar analysis relating to the method of fixation of the femoral component sees the cemented one go from 12.9% in 2017 to 23.4% in 2018 and a reduction in the use of non-cemented fixation which goes from 85.2% in 2017 to 75.3 % of 2018.

TABLE 23: FIXATION MODALITIES OF THE ACETABULAR AND FEMORAL COMPONENTS. YEAR 2018

2018	Method of fixation of the femoral component			
	Cemented	Not cemented	Not applicable	Total
Method of fixation of the acetabular component				
Cemented	142	32	4	178
Not cemented	31	544	4	579
Not applicable	14	26	3	43
Total	187	602	11	800

The RIAP reports a series of data relating to:

- type of joint coupling by type of intervention (MoM, MoC, CoC, CoP)
- type of stem (modular, non-modular straight or anatomical or with conservation)

It is not possible to extract such data from the tracks of the Marche region

SECTION 2

The average age by way of fixation of the acetabular component of the prosthesis, for the year 2017, shows an association between cemented prosthesis and older age

TABLE 24: MEAN AGE OF PATIENTS BY TYPE OF FIXATION (ACETABULAR COMPONENT). YEAR 2017

2017	Cemented	Not cemented	Not applicable	Total
Average age of patients	78.9	70.9	85.0	72.9

The survey was further developed by aggregating patients by age group, as also proposed by the RIAP. The summarized data with reference to the average age are confirmed and, from the following table,

it is clear that, even if all age groups can make use of cemented rather than non-cemented fixation methods, the increase in the age group is more frequently associated with cemented fixation.

TABLE 25: DISTRIBUTION BY AGE GROUP AND METHOD OF PROSTHESIS FIXATION (ACETABULAR COMPONENT). YEAR 2017

Age class	Cemented		Not cemented		Not applicable		Total	
	Frequency	%	Frequency	%	Frequency	%	Frequency	%
<45	3	3.2%	12	2.1%			15	2.1%
45-54			33	5.9%			33	4.7%
55-64	3	3.2%	79	14.1%	1	2.0%	83	11.8%
65-74	11	11.8%	211	37.7%	2	4.0%	224	31.9%
75-84	39	41.9%	191	34.1%	16	32.0%	246	35.0%
85+	36	38.7%	34	6.1%	31	62.0%	101	14.4%
not available	1	1.1%					1	0.1%
Total	93	100%	560	100%	50	100%	703	100%

The same distribution examined in the two following tables, dividing between public and private structures, does not seem to highlight significant differences in behavior, except for the presence of the elderly (85+) who in the private sector represent 6% of the total, against 24.5 % of the audience. It therefore seems that there is a sort of adverse selection of patients in private structures that favor older patients, which presumably represent less complex case studies.

TABLE 26: DISTRIBUTION BY AGE GROUP AND METHOD OF PROSTHESIS FIXATION (ACETABULAR COMPONENT), BY TYPE OF STRUCTURE. 2017, PUBLIC FACILITIES

Public Age class	cemented		not cemented		Not applicable		Total	
	Frequency	%	Frequency	%	Frequency	%	Frequency	%
<45	3	4.4%	1	0.5%			4	1.3%
45-54			11	5.4%			11	3.5%
55-64	3	4.4%	25	12.3%	1	2.2%	29	9.1%
65-74	10	14.7%	71	34.8%	1	2.2%	82	25.8%
75-84	28	41.2%	72	35.3%	13	28.3%	113	35.5%
85+	23	33.8%	24	11.8%	31	67.4%	78	24.5%
Unavailable	1	1.5%					1	0.3%
Total	68	100%	204	100%	46	100%	318	100%

TABLE 27: DISTRIBUTION BY AGE CLASS AND METHOD OF PROSTHESIS FIXATION (ACETABULAR COMPONENT), BY TYPE OF STRUCTURE. 2017, PRIVATE STRUCTURES

Private	cemented		not cemented		Not applicable		Total	
	Frequency	%	Frequency	%	Frequency	%	Frequency	%
<45			11	3.1%			11	2.9%
45-54			22	6.2%			22	5.7%
55-64			54	15.2%			54	14.0%
65-74	1	4.0%	140	39.3%	1	25.0%	142	36.9%
75-84	11	44.0%	119	33.4%	3	75.0%	133	34.6%
85+	13	52.0%	10	2.8%			23	6.0%
Total	25	100%	356	100%	4	100%	385	100%

The following table shows, for 2017, the distribution of the fixation modality of the acetabular component by comparing public and private structures. A difference emerges relative to the lower use of cementless prostheses in the public (possible indicator of patients on average younger) but also of greater presence of "not applicable" (without cup implant)

TABLE 28: DISTRIBUTION OF THE FIXATION MODALITY OF THE ACETABULAR COMPONENT BY TYPE OF STRUCTURE. YEAR 2017

Method of fixation of the acetabular component	Private facilities		Public facilities	
	Freq.	%	Freq.	%
Cemented	25	6.5%	68	21.4%
Not cemented	356	92.5%	204	64.2%
not applicable (without cup implant)	4	1.0%	46	14.5%
Total	385	100%	318	100%

A similar reflection, but based on the relationship between surgeon and fixation modality (possible only on 2018 data) shows the high association between the surgeon and the choice of modality.

TABLE 29: SURGEON ASSOCIATION - METHOD OF FIXATION OF THE ACETABULAR COMPONENT. YEAR 2018

Surgeon	Cemented		Not applicable		Not cemented		Total
	Freq.	%	Freq.	%	Freq.	%	Freq.
to	7	16.3%	7	16.3%	29	67.4%	43
b	4	25.0%	1	6.3%	11	68.8%	16
c	9	33.3%	2	7.4%	16	59.3%	27
d	6	14.3%	6	14.3%	30	71.4%	42
is	106	68.8%	6	3.9%	42	27.3%	154
f	18	11.0%	3	1.8%	143	87.2%	164
g	1	50.0%			1	50.0%	2
h	1	8.3%	4	33.3%	7	58.3%	12
the	4	14.3%	7	25.0%	17	60.7%	28
L	7	43.8%	1	6.3%	8	50.0%	16
m	1	25.0%			3	75.0%	4
n					1	100.0%	1
or			1	33.3%	2	66.7%	3
p	3	4.4%	3	4.4%	62	91.2%	68
q	7	8.3%	1	1.2%	76	90.5%	84
r			1	1.0%	95	99.0%	96
s					25	100.0%	25
t					1	100.0%	1
u	4	30.8%			9	69.2%	13
v					1	100.0%	1
Total	178	22.3%	43	5.4%	579	72.4%	800

In practice, the greater use of cemented in the public sphere, as shown in the following table, would not be a behavior dictated by the type of structure, but by the fact that the surgeon “e” (public surgeon) preferentially uses cemented. Similarly, the highest percentage of cementless in the private sector could depend on the choices of the main surgeons operating in these structures (“f”, “p”, “q”).

TABLE 30: METHODS OF FIXATION OF THE ACETABULAR COMPONENT BY TYPE OF STRUCTURE. YEAR 2018

Structure type	Cemented	Not applicable	Not cemented	Total
Private	29	5	349	383
Publish	149	38	230	417
Total	178	43	579	800

The following table concerns the association between the cause of the surgery and the method of fixation of the acetabular component (year 2017, only total or partial replacement operations). The data show that for most causes the cementless modality is used exclusively, while in particular for the fractures of the neck and / or of the femoral head it is possible to use any modality

TABLE 31: CAUSE OF INTERVENTION AND METHOD OF FIXING THE COMPONENT. YEAR 2017

Cause intervention	cemented	not cemented	Not applicable
Primary osteoarthritis	30	426	2
Post-traumatic arthrosis		9	
Rheumatic arthritis		1	
Aseptic femoral head necrosis	1	14	
Outcomes of congenital dysplasia or dislocation		7	
Outcomes of Perthes disease or epiphysiolysis		2	
Fracture of the neck and / or head of the femur	58	87	34
Neck fracture pseudarthrosis	1		
other		2	
Total	90	548	36

ANALYSIS OF THE "AREAS" TRACKS - PURCHASED MATERIALS (HIP PROSTHESIS)

An indispensable premise for the analyzes proposed in this section is that the AREAS flow refers to the purchase of prosthetic materials, divided by year, but cannot be linked to actual consumption nor does it allow to verify when the materials in question have actually been used and on which patients. Furthermore, the data are aggregated by pharmacy that made the purchase, which does not necessarily correspond to the structure providing the service.

A first element analyzed is the 2018 expenditure, which is not proportional to the number of interventions carried out in the same year traced through the SDOs. In particular, the cost per intervention at the AOU Ancona is significantly lower than the other two companies (ASUR and Marche Nord) which instead have similar results. It appears probable that AOU Ancona has used material in stock since 2017, consequently an area of possible divestment is related to warehouse management.

TABLE 32: COSTS AND INTERVENTIONS BY COMPANY. YEAR 2018

Company	Total expenditure 2018	Interventions 2018	Cost / Intervention
ASUR	€ 1,855,052	1.160	1,599
AOU ANCONA	€ 191,321	337	568
AO Marche Nord	€ 487.280	291	1,674
Total	€ 2,533,653	1,788	1.417

A different explanation for the phenomenon would also be possible, based on a hypothesis in which AOU Ancona pays much less for materials than other companies. This hypothesis is denied by the precise analysis of the cost per piece purchased, aggregating the pieces on the basis of the type identified through CND. The following table shows this information in relation to the behavior of the three reference companies. The green color identifies a cost per piece that is at least 10% lower than the regional average reference value, while the red identifies a cost that is at least 10% higher than the regional average reference. In practice, therefore, these are virtuous or critical areas on which individual companies could intervene.

The paths examined do not allow to give information on the quality of the products purchased, however it is clear that in terms of mere cost, activities aimed at divestment would be possible.

TABLE 33: COSTS PER PIECE PURCHASED BY COMPANY. YEAR 2018

Tipologia materiale	ASUR			AOU Ancona			AO Marche Nord			totale		
	costo tot	n° pezzi	costo * pezzo	costo tot	n° pezzi	costo * pezzo	costo tot	n° pezzi	costo * pezzo	costo tot	n° pezzi	costo * pezzo
altro	€ 47.254	191	€ 247	€ 16.591	62	€ 268	€ 30.562	43	€ 711	€ 94.408	296	€ 319
componente acetabolare	€ 7.016	8	€ 877							€ 7.016	8	€ 877
cotile	€ 507.068	592	€ 857	€ 56.822	58	€ 980	€ 131.888	129	€ 1.022	€ 695.778	779	€ 893
cupole	€ 52.636	363	€ 145	€ 1.117	9	€ 124	€ 11.689	95	€ 123	€ 65.443	467	€ 140
inserti ceramica	€ 51.591	100	€ 516	€ 4.462	7	€ 637	€ 40.481	49	€ 826	€ 96.533	156	€ 619
inserti metallo	€ 32.791	62	€ 529	€ 1.447	2	€ 723	€ 7.708	10	€ 771	€ 41.947	74	€ 567
inserti per componenti acetabolari	€ 1.886	10	€ 189							€ 1.886	10	€ 189
inserti poietilene	€ 152.990	481	€ 318	€ 15.066	59	€ 255	€ 36.099	174	€ 207	€ 204.155	714	€ 286
steli	€ 730.573	832	€ 878	€ 67.913	73	€ 930	€ 152.991	220	€ 695	€ 951.477	1.125	€ 846
teste ceramica	€ 152.479	354	€ 431	€ 24.994	57	€ 438	€ 57.013	110	€ 518	€ 234.486	521	€ 450
teste metallo	€ 118.768	527	€ 225	€ 2.909	17	€ 171	€ 18.848	100	€ 188	€ 140.525	644	€ 218
Totale complessivo	€ 1.855.052	3.520	€ 527	€ 191.321	344	€ 556	€ 487.280	930	€ 524	€ 2.533.653	4.794	€ 529

Overall, if all materials were purchased by all companies at the lowest price, an overall saving of about 13.5% would be possible, or 342,000 euros per year.

The following table shows, in line with what has already been reported above, that there is a relatively wide variety of suppliers and that individual companies tend to purchase from different suppliers. Hence probably the price differences found.

TABLE 34: PARTS AND VALUE DISTRIBUTIONS BY SUPPLIER AND COMPANY. YEAR 2018

Supplier	ASUR		AOU Ancona		AO Marche Nord		Total	
	pieces	value	pieces	value	pieces	value	pieces	value
ACTIVA SRL	78	€ 45,510	15	€ 5,460	3	€ 3,432	96	€ 54,402
ADLER ORTHO SPA	81	€ 59,734	199	€ 116,004	74	€ 45,492	354	€ 221,230
ARTHREX ITALIA SRL	36	€ 31,644					36	€ 31,644
CORMAN HOSPITAL SRL	525	€ 388,539	75	€ 54,642	487	€ 361,619	1087	€ 804,801
DIMED SRL					11	€ 13,996	11	€ 13,996
DEKA MELA SRL					4	€ 5,173	4	€ 5,173
INTRAUMA SPA	9	€ 10,146					9	€ 10,146
LIMA SM SPA	3	€ 406					3	€ 405
LIMACORPORATE SPA	507	€ 81,602	35	€ 5,594	350	€ 56,553	892	€ 143,749,
LINK ITALIA SPA	131	€ 43,360					131	€ 43,360
MED SYNERGY BIO SRL	37	€ 18,747			1	€ 1,016	38	€ 19,763
MEDACTA ITALIA SRL	278	€ 192,856					278	€ 192,856
MEDCOM TECH ITALIA SRL	1	€ 416					1	€ 416
NEW TECH SRL			2	€ 188			2	€ 188
PERMEDICA SPA	306	€ 96,747					306	€ 96,747
SMITH & NEPHEW SRL	623	€ 323,107					623	€ 323,107
STRYKER ITALIA SRL	320	€ 211,888					320	€ 211,888
ZIMMER BIOMET ITALIA SRL	585	€ 350,350	18	€ 9,433			603	€ 359,783
Total	3,520	€ 1,855,052	344	€ 191,321	930	€ 487,280	4,794	€ 2,533,653

Knee replacement surgery

DESCRIPTIVE ANALYSIS OF KNEE PROSTHESIS INTERVENTIONS IN THE MARCHE (SDO data)

The analysis of the SDO flow, including active mobility, made it possible to verify that approximately 1,947 annual average knee prosthesis operations are performed in the Marche Region. The value is stable over time both as an absolute value and in relation to the distribution in the individual structures.

TABLE 35: NO. OF KNEE PROSTHESIS INTERVENTIONS, BY STRUCTURE

STRUCTURE	2017	2018	2019
SINGLE HOSPITAL CENTER AV1	29	30	24
SINGLE HOSPITAL CENTER AV2	190	205	124
SINGLE HOSPITAL CENTER AV3	146	139	121
SINGLE HOSPITAL CENTER AV4	36	38	14
SINGLE HOSPITAL CENTER AV5	40	35	15
NURSING HOME VILLA IGEA	584	665	443
NURSING HOME VILLA PINI SANATRIX GESTION	258	277	188
RITA SRL VILLVERDE PRIVATE NURSING HOME	403	378	346
AO HOSPITALS RIUNITI MARCHE NORD	178	156	98
AOUOSPEDALI RIUNITI - ANCONA	56	51	36
TOTAL	1,920	1,974	1,409

* 2019 data refer to SDOs closed by 30 October, projection values are comparable with previous years

The percentage of knee replacement operations in public structures compared to private ones appears to have decreased slightly over the years (even the partial value for 2019 is decreasing): about 34% of total operations are performed in the public. This percentage is absolutely different from what happens in hip prosthesis operations, where the public part covers about 75% of the total.

TABLE 36: DISTRIBUTION OF INTERVENTIONS BY TYPE OF STRUCTURE (PUBLIC / PRIVATE)

Type of structure	2017	2018
public facilities	675	654
private facilities	1.245	1,320
% interventions in public structures	35.2%	33.1%

The operations performed are, as expected, mainly on women, who represent on average 65.5% of the operations in the three years. The difference between public and private is very small: public 64.3% of women against private 66.1%.

The following table presents the distribution by age group of knee replacement surgeries.

Most of the interventions focus on the age groups between 65 and 84 years, while it is a rare event in the over 85 population. The values show a limited annual variability.

TABLE 37: NO. OF KNEE REPLACEMENT SURGERIES, BY AGE GROUP AND YEAR

Age class	2017		2018		2019	
<45	15	0.8%	2	0.1%	3	0.2%
45-54	58	3.0%	49	2.5%	44	3.1%
55-64	273	14.2%	318	16.1%	217	15.4%
65-74	830	43.2%	868	44.0%	611	43.4%
75-84	714	37.2%	711	36.0%	506	35.9%
85+	30	1.6%	26	1.3%	28	2.0%
Total	1,920	100%	1,974	100%	1,409	100%

The following table shows the distribution by structure of the different age groups of patients on whom knee replacement surgery is performed. The table summarizes all the interventions of the three-year period, the green color shows percentage values that are more than 20% lower than the average, while the red one represents values that are more than 20% higher than the average. The overall data that emerges is that public structures tend to operate older patients than private structures, however this different behavior is less evident than what happens for hip prostheses. Moreover, the limited number of cases in the extreme classes is strongly influenced by chance factors.

TABLE 38: NO. OF KNEE REPLACEMENT SURGERIES BY STRUCTURE AND AGE GROUP. OVERALL DATA 2017/19

Structure	Age class												Total
	<45	45-54		55-64		65-74		75-84		85+			
SINGLE HOSPITAL CENTER AV1		0%	1	1.2%	4	4.8%	43	51.8%	33	39.8%	2	2.4%	83
SINGLE HOSPITAL CENTER AV2	1	0.2%	9	1.7%	55	10.6%	208	40.1%	233	44.9%	13	2.5%	519
SINGLE HOSPITAL CENTER AV3		0.0%	13	3.2%	60	14.8%	173	42.6%	159	39.2%	1	0.2%	406
SINGLE HOSPITAL CENTER AV4		0.0%		0.0%	5	5.7%	31	35.2%	51	58.0%	1	1.1%	88
SINGLE HOSPITAL CENTER AV5		0.0%	2	2.2%	10	11.1%	34	37.8%	44	48.9%		0.0%	90
NURSING HOME VILLA IGEA	9	0.5%	49	2.9%	294	17.4%	769	45.4%	538	31.8%	33	2.0%	1692
NURSING HOME VILLA PINI SANATRIX GESTION	3	0.4%	10	1.4%	93	12.9%	319	44.1%	288	39.8%	10	1.4%	723
RITA SRL VILLAVERDE PRIVATE NURSING HOME	3	0.3%	48	4.3%	211	18.7%	506	44.9%	346	30.7%	13	1.2%	1127
AO HOSPITALS RIUNITI MARCHE NORD	4	0.9%	12	2.8%	53	12.3%	172	39.8%	183	42.4%	8	1.9%	432
AOUOSPEDALI RIUNITI - ANCONA		0.0%	7	4.9%	23	16.1%	54	37.8%	56	39.2%	3	2.1%	143
Total	20	0.4%	151	2.8%	808	15.2%	2.309	43.5%	1,931	36.4%	84	1.6%	5.303

The same information is also obtained from a precise analysis of the average age of the patients by structure and in aggregate by public / private type.

TABLE 39: AVERAGE AGE OF PATIENTS BY STRUCTURE OVERALL DATA 2017/19

Structure	middle age
SINGLE HOSPITAL CENTER AV1	73.4
SINGLE HOSPITAL CENTER AV2	73.0
SINGLE HOSPITAL CENTER AV3	71.1
SINGLE HOSPITAL CENTER AV4	75.2
SINGLE HOSPITAL CENTER AV5	72.4
NURSING HOME VILLA IGEA	70.5
NURSING HOME VILLA PINI SANATRIX GESTION	72.2
RITA SRL VILLAVERDE PRIVATE NURSING HOME	70.0
AO HOSPITALS RIUNITI MARCHE NORD	72.0
AOUOSPEDALI RIUNITI - ANCONA	71.1
Public	72.3
Private	70.7
Total	71.2

An in-depth study was then carried out on the length of stay in relation to the different structures and different age groups, with the aim of identifying reference benchmarks.

The data analysis clearly shows a different behavior between public and private structures. While the former are characterized by prolonged hospitalizations, an average of 10.6 days for the public (the best value is that of "Marche Nord", however higher than the overall average), the latter are characterized by generally short hospitalizations, average for the private sector 6, 5 days (with the Villa Igea Nursing Home which appears to have significantly less hospital stays than all other structures).

TABLE 40: AVERAGE HOSPITAL STAY BY FACILITY. OVERALL DATA 2017/19

Structure	days deg
SINGLE HOSPITAL CENTER AV1	12.0
SINGLE HOSPITAL CENTER AV2	11.2
SINGLE HOSPITAL CENTER AV3	10.6
SINGLE HOSPITAL CENTER AV4	10.6
SINGLE HOSPITAL CENTER AV5	11.3
NURSING HOME VILLA IGEA	4.5
NURSING HOME VILLA PINI SANATRIX GESTION	9.5
RITA SRL VILLAVERDE PRIVATE NURSING HOME	7.7
AO HOSPITALS RIUNITI MARCHE NORD	8.7
AOUOSPEDALI RIUNITI - ANCONA	12.6
Public	10.6
Private	6.5
Total	7.9

The difference between the two types of structures is even more evident by setting a cut-off within which hospitalization can be considered physiological and verifying what the percentage of hospitalizations is below the threshold value. The following table shows the behaviors of the different structures with respect to the threshold value of 8 days of hospitalization. It is therefore confirmed that private structures are able to standardize their interventions more extensively. In particular, at the Villa Igea Nursing Home, over 98% of the interventions lead to discharge within 8 days. The value of 8 days represents the value immediately above the median (median value 7), and includes within it approximately 2/3 of the interventions, therefore being above this threshold represents an evident critical element.

TABLE 41: NO. OF CASES WITHIN AND OUTSIDE THE THRESHOLD (8 DAYS) BY FACILITY

Structure	cases in max 8 days	cases over 8 days	% within 8 days
SINGLE HOSPITAL CENTER AV1	17	66	20.5%
SINGLE HOSPITAL CENTER AV2	165	354	31.8%
SINGLE HOSPITAL CENTER AV3	90	316	22.2%
SINGLE HOSPITAL CENTER AV4	33	55	37.5%
SINGLE HOSPITAL CENTER AV5	20	70	22.2%
NURSING HOME VILLA IGEA	1663	29	98.3%
NURSING HOME VILLA PINI SANATRIX GESTION	366	357	50.6%
RITA SRL VILLAVERDE PRIVATE NURSING HOME	880	247	78.1%
AO HOSPITALS RIUNITI MARCHE NORD	258	174	59.7%
AOUOSPEDALI RIUNITI - ANCONA	32	111	22.4%
Public	615	1146	34.9%
Private	2909	633	82.1%
Total	3524	1779	66.5%

In this case, contrary to what happened for hip prosthesis operations, it is not necessary to deepen the analysis according to the age groups, as there are no significant differences in the age groups in which public structures intervene compared to private ones.

The need for organizational intervention is evident with the aim of allowing more timely discharge and within acceptable thresholds. Public facilities are probably used as long-term care and rehabilitation facilities to the detriment of the appropriateness of hospitalization. Further targeted analyzes would be appropriate to verify suitable corrective actions. A possible further explanation is linked to the age of the patients, which is lower in private structures, probably an indicator of lower complexity. During the Advisory Board no indications emerged on how to verify whether more complex cases are being dealt with in the public (in the case of the hip a check was made on the causes of intervention, finding that the fractures are operated almost exclusively in public facilities).

Mobility

The regional territory is characterized by a strong passive mobility. The available data concern only the years 2017 and 2018 and show that in the two years they involved 969 and 1,037 interventions respectively (therefore 33.5% and 34.4% of the total interventions carried out in the Marche region, including active mobility and passive mobility). The passive mobility for knee prostheses is therefore higher than that for hip prostheses, which has a value of just over 26%. It is clear that the recovery of this significant share of patients residing in the Marche Region appears to be a first important area of intervention for a divestment aimed at avoiding the flight of resources to other regions and the improvement of the supply of services within the Marche Region.

A further element of analysis concerns the places towards which the flow of passive mobility is directed.

The following table shows the Regions that exercise the greatest attraction to passive mobility and the structure that most attracts within the individual Regions (values referring to the two-year period 2017/2018).

TABLE 42: PASSIVE MOBILITY - MAIN STRUCTURES. OVERALL DATA 2017/18

Region	freq per Region	more attractive facility	Freq. Struct. + attractive
Umbria	235	LAMI SPA (SAGISC - MADONNA DEGLI ANGELI) - Perugia	102
Lazio	26	SAN CARLO DI NANCY HOSPITAL - Rome	4
Abruzzo	159	NURSING HOME VILLA SERENA - Città Sant'Angelo	137
Emilia Romagna	1.331	VILLA MARIA CECILIA HOSPITAL - Cotignola	307
Lombardy	149	POLICLINICO SAN PIETRO SPA Ponte San Pietro-Bg	41
Italy	2,006		

Overall, it is highlighted that mobility is concentrated exclusively towards private structures and in particular towards Emilia Romagna which alone absorbs 66% of mobility, among other things attracting not only in the main reference structure (Villa Maria Cecilia Hospital in Cotignola) which represents 23% of the attractiveness of the Emilia-Romagna region, and is geographically close to the regional borders. The opposite is true for the attraction exercised by the Lombardy Region, which overall represents 7.4% of mobility, in which the center of greatest attraction (Policlinico San Pietro di Ponte San Pietro-Bg) alone absorbs 27.5% of those they turn to the Lombardy region to receive knee prostheses.

An analysis was also carried out on the attractiveness of the structures of the Marche Region. The overall values of the three-year period show that the attraction is mainly exercised by private structures, which cover 91.7% of the total.

TABLE 43: ACTIVE MOBILITY - MAIN STRUCTURES. OVERALL DATA 2017/2018

Structure	No. of interventions	%
SINGLE HOSPITAL CENTER AV1	4	0.3%
SINGLE HOSPITAL CENTER AV2	40	3.0%
SINGLE HOSPITAL CENTER AV3	13	1.0%
SINGLE HOSPITAL CENTER AV4	1	0.1%
SINGLE HOSPITAL CENTER AV5	8	0.6%
NURSING HOME VILLA IGEA	475	36.1%
NURSING HOME VILLA PINI SANATRIX GESTION	51	3.9%
RITA SRL VILLVERDE PRIVATE NURSING HOME	679	51.7%
AO HOSPITALS RIUNITI MARCHE NORD	5	0.4%
AOUOSPEDALI RIUNITI - ANCONA	38	2.9%
Attraction public facilities	109	8.3%
Attraction private facilities	1,205	91.7%
Total attraction	1.314	100.0%

DRG encoding

As regards the coding and therefore the DRG attributed to the interventions, the behavior is rather uniform, with DRG 544 "Replacement of major joints or reimplantation of the lower limbs" which represents a total of 95% of the interventions and DRG 545 "Replacement review hip or knee "which represents 4.6% of the cases. Occasional use of other DRGs (0.4% of cases).

TABLE 44: DRG FREQUENCY BY FACILITY

Structure	Freq. DRG			total
	DRG 544	DRG 545	Other DRGs	
SINGLE HOSPITAL CENTER AV1	77	2	4	83
SINGLE HOSPITAL CENTER AV2	498	18	3	519
SINGLE HOSPITAL CENTER AV3	391	13	2	406
SINGLE HOSPITAL CENTER AV4	86	2	0	88
SINGLE HOSPITAL CENTER AV5	86	2	2	90
NURSING HOME VILLA IGEA	1,635	55	2	1,692
NURSING HOME VILLA PINI SANATRIX GESTION	671	52	0	723
RITA SRL VILLVERDE PRIVATE NURSING HOME	1055	71	1	1127
AO HOSPITALS RIUNITI MARCHE NORD	417	13	2	432
AOUOSPEDALI RIUNITI - ANCONA	123	15	5	143
Total	5,039	243	21	5,303

DESCRIPTIVE ANALYSIS OF THE INTERVENTIONS INCLUDED IN THE RIAP

The data sheets relating to knee replacement operations, provided as part of the RIAP by the Marche Region in the period under review, totaled 1,753, an increase in 2018 compared to the previous year. The increase is consistent with the indications of the ISS to make the compilation of the forms mandatory, however the level of compilation reached is still insufficient, as overall in the same period 3,894 interventions were carried out in the Region. The percentage covered by the RIAP is therefore 45%.

TABLE 45: RIAP COMPILATION FREQUENCY BY FACILITY

STRUCTURE	2017	2018	total
RITA SRL VILLVERDE PRIVATE CARE HOUSE		36	36
NURSING HOME VILLA IGEA	486	435	921
NURSING HOME VILLA PINI SANATRIX GESTION	232	227	459
NURSING HOME 'VILLA SAN MARCO'	4	22	26
UNICO HOSPITAL CENTER ZT2	2		2
ZT4 HOSPITAL - SENIGALLIA	62	41	103
UNICO HOSPITAL CENTER ZT6	21	43	64
UNICO HOSPITAL CENTER ZT8	4	6	10
UNICO HOSPITAL CENTER ZT11	21	22	43
AOUOSPEDALI RIUNITI - ANCONA	13	5	18
UNICO HOSPITAL CENTER ZT5		71	71
TOTAL	845	908	1,753

The overall percentage of compilation of the forms in the two-year period, comparing private and public structures, shows that private structures compile the RIAP forms much more (private structures 82.3% of the total vs public structures 17.7%) even if in 2018 the overall behavior of public structures improved. Since the analysis of the overall SDOs of the regional structures showed that the percentage of interventions in public structures is about 34%, it is evident that over the years an adequate compilation of the RIAP records has not yet been obtained, and therefore a promotion intervention is necessary in this sense.

TABLE 46: RIAP COMPILATION FREQUENCY BY TYPE OF STRUCTURE

	No. of forms completed 2017-2018		
	2017	2018	TOTAL
Private	722	720	1,442
Public	123	188	311
Total	845	908	1,753

The interventions included in the RIAP are almost all provided under the election regime, with only occasional urgent hospitalizations in public structures.

The table showing the distribution by sex and age, as well as by type of intervention, relative to 2017 alone, does not show significant differences compared to the national RIAP benchmark. Women make up about 2/3 of the total number of interventions, and the prevailing age group for both sexes is that between 65 and 74, followed by that between 75 and 84.

TABLE 47: NUMBER OF INTERVENTIONS BY GENDER AND AGE GROUP OF PATIENTS AND BY TYPE OF INTERVENTION. YEAR 2017

	Primary				Revision		TOTAL	
	total		single compartment		n°	%	n°	%
	n°	%	n°	%				
Kind	732		104		9		845	
Males	238	32.5%	45	43.3%	2	22.2%	285	33.7%
Females	494	67.5%	59	56.7%	7	77.8%	560	66.3%
Age groups by gender								
Males	238		45		2		285	
middle age	70.8		63.9		52		69.6	
<45	5	2.1%	2	4.4%			7	2.5%
45-54	4	1.7%	5	11.1%	1	50%	10	3.5%
55-64	39	16.4%	15	33.3%	1	50%	55	19.3%
65-74	101	42.4%	17	37.8%			118	41.4%
75-84	84	35.3%	5	11.1%			89	31.2%
85+	5	2.1%	1	2.2%			6	2.1%
Females	494		59		7		560	
middle age	71.8		67.4		71.8		71.3	
<45	5	1.0%		0.0%			5	0.9%
45-54	7	1.4%	4	6.8%			11	2.0%
55-64	59	11.9%	18	30.5%	2	29%	79	14.1%
65-74	228	46.2%	23	39.0%	3	43%	254	45.4%
75-84	186	37.7%	13	22.0%	2	29%	201	35.9%
85+	9	1.8%	1	1.7%			10	1.8%

TABLE 48: LATERALITY BY TYPE OF INTERVENTION. YEAR 2017

Laterality	Primary		Revision	Total	%
	totals	single compartment			
Right	772	133	17	922	52.6%
Bilateral prosthesis:	15			15	0.9%
Left	698	105	13	816	46.5%
Total	732	104	9	1,753	100%

The laterality of the intervention, calculated on the whole of the two annuities, sees a slightly higher percentage for the right than for the left, these values are consistent with the national RIAP data (52.6% right, 46.5% left).

TABLE 49: ACCESS ROUTE BY TYPE OF INTERVENTION

Access route	Primary				Revision		Total		Ref.
	totals		single compartment		2017	2018	No.	%	RIAP
2017	2018	2017	2018						
medial paratellar	726	738	86	68	9	21	1,648	94.0%	85.6%
lateral patellar	2	5	7	2			16	0.9%	2.6%
midvastus	3	3					6	0.3%	5.4%
minimally invasive midvastus			3				3	0.2%	3.8%
quad-sparing			8	63			71	4.1%	0.2%
subvastus		7					7	0.4%	0.9%
minimally invasive subvastus				1			1	0.1%	0.3%
tibial tuberosity osteotomy	1						1	0.1%	0.1%
Total	732	753	104	134	9	21	1,753	100%	

The analysis of the access routes shows important differences with respect to the RIAP reference behavior, in particular for the widespread use of quad-sparing access (4.1% vs 0.2% RIAP). However, this value depends almost entirely on the 2018 values, which are not present in the RIAP benchmark relating to 2017 alone. There are also differences with regard to patellar accesses because in the Marche the medial ones are used more often, while the lateral ones are almost absent. Lastly, midvastus access (0.3% vs 5.4%) and minimally invasive midvastus (0.2% vs 3.8%) are used in the Marche region. The variety of behaviors in the choice of the access route is not a guarantee of appropriateness.

The distribution by primary cause is consistent with the national trend, with primary osteoarthritis covering over 90% of cases. In 2017, 4.8% of the forms in which the "cause" field was not filled in should be reported. This denotes poor data entry quality. The problem is not present in 2018, a sign of an increased compilation quality.

TABLE 50: CAUSE OF INTERVENTION BY TYPE OF PRIMARY INTERVENTION (TOTAL / SINGLE COMPARTMENT). YEAR 2017

Cause intervention	Primary				TOTAL		Ref RIAP
	totals		one-compartment		n °	%	%
	n °	%	n °	%			
primary osteoarthritis	665	90.8%	96	92.3%	761	91.0%	94.9%
post traumatic arthrosis	17	2.3%	1	1.0%	18	2.2%	1.1%
rheumatic arthritis	5	0.7%	0	0.0%	5	0.6%	0.5%
neoplasm	0	0.0%	0	0.0%	0	0.0%	0.1%
osteonecrosis	4	0.5%	7	6.7%	11	1.3%	0.9%
other	1	0.1%	0	0.0%	1	0.1%	2.6%
not available	40	5.5%	0	0.0%	40	4.8%	
Total	732	100%	104	100%	836	100%	100%

TABLE 51: CAUSE OF INTERVENTION BY TYPE OF PRIMARY INTERVENTION (TOTAL / SINGLE-COMPARTMENT). YEAR 2018

Cause intervention	Primary				TOTAL		Ref RIAP
	totals		one-compartment		n °	%	%
	n °	%	n °	%			
primary osteoarthritis	729	97.2%	123	91.8%	852	96.4%	94.9%
post traumatic arthrosis	12	1.6%	0	0.0%	12	1.4%	1.1%
rheumatic arthritis	3	0.4%	0	0.0%	3	0.3%	0.5%
neoplasm	0	0.0%	0	0.0%	0	0.0%	0.1%
osteonecrosis	3	0.4%	11	8.2%	14	1.6%	0.9%
other	3	0.4%	0	0.0%	3	0.3%	2.6%
not available	0	0.0%	0	0.0%	0	0.0%	
Total	750	100%	134	100%	884	100%	100%

The analysis of the presence of previous intervention referring to primary implants does not reveal any significant discrepancies with respect to the RIAP reference, although within a certain variability between 2017 and 2018. In general, it is confirmed that about 90% of interventions are not preceded by other interventions, as per RIAP reference.

TABLE 52: NUMBER OF PRIMARY INTERVENTIONS BY TYPE OF PREVIOUS INTERVENTION AND TYPE OF INTERVENTION. YEAR 2017

Previous intervention	Primary				TOTAL		Ref. RIAP
	Totals		single compartment		n °	%	%
	n °	%	n °	%			
Nobody	634	86.6%	83	79.8%	717	85.8%	90.9%
Arthrodesis	3	0.4%	0	0.0%	3	0.4%	0.1%
Osteotomy	13	1.8%	2	1.9%	15	1.8%	0.6%
Arthroscopy	26	3.6%	18	17.3%	44	5.3%	2.6%

Previous intervention	Primary				TOTAL		Ref. RIAP
	Totals		single compartment		n °	%	
	n °	%	n °	%			%
Other	56	7.7%	1	1.0%	57	6.8%	5.7%
TOTAL	732	100%	104	100%	836	100%	100.0%

TABLE 53: NUMBER OF PRIMARY INTERVENTIONS BY TYPE OF PREVIOUS INTERVENTION AND TYPE OF INTERVENTION. YEAR 2018

Previous intervention	Primary				TOTAL		Ref. RIAP
	totals		single compartment		n °	%	
	n °	%	n °	%			%
Nobody	722	95.9%	123	91.8%	845	95.3%	90.9%
Arthrodesis	1	0.1%	0	0.0%	1	0.1%	0.1%
Osteotomy	8	1.1%	0	0.0%	8	0.9%	0.6%
Arthroscopy	19	2.5%	11	8.2%	30	3.4%	2.6%
Other	3	0.4%	0	0.0%	3	0.3%	5.7%
TOTAL	753	100%	134	100%	887	100%	100.0%

As regards the causes of intervention in the event of a revision, the cases of the Marche Region are particularly limited (29 cases in the two years) therefore the statistical significance is scarce. However, the distribution appears to be consistent with the RIAP reference, with the most represented causes coinciding.

TABLE 54: NUMBER OF REVISION SURGERIES BY CAUSE OF INTERVENTION. YEARS 2017 AND 2018

Cause of the intervention	Revision		
	n °	%	ref RIAP
Aseptic mobilization of several components	8	27.6%	27.8%
aseptic mobilization of the tibial component	6	20.7%	10.1%
Wear of materials	1	3.4%	2.2%
Prosthetic dislocation	2	6.9%	2.6%
Instability	2	6.9%	5.1%
Infection	4	13.8%	18.9%
Disease progression	1	3.4%	2.2%
Painful prosthesis	3	10.3%	16.5%
Other	2	6.9%	3.0%
Total	29	100%	

As regards the fixation method of the femoral component, the behaviors relating to the two-year period 2017 and 2018 are substantially overlapping, with extensive use of the cemented method (over 93%).

TABLE 55: METHOD OF FIXATION OF THE FEMORAL COMPONENT BY TYPE OF INTERVENTION

Method of fixation of the femoral component	Primary				revisions	
	totals		one-compartment		2017	2018
	2017	2018	2017	2018		
Cemented	680	732	104	134	8	16
not cemented	23	18				
Not applicable	29	3			1	5
Total	732	753	104	134	9	21

Also as regards the method of fixing the tibial component, the two-year data can be superimposed.

TABLE 56: METHOD OF FIXATION OF THE TIBIAL COMPONENT BY TYPE OF INTERVENTION

Method of fixation of the tibial component	Primary				revisions	
	totals		one-compartment		2017	2018
	2017	2018	2017	2018		
Cemented	699	735	104	134	8	19
not cemented	7	15				1
Not applicable	26	3			1	1
Total	732	753	104	134	9	21

For the method of fixation of the patellar component, the high number of observations "not applicable" is due to the fact that not all interventions involve the patella, for the rest the absolute prevalence of the use of cemented fixation remains confirmed

TABLE 57: METHODS OF FIXATION OF THE PATELLAR COMPONENT BY TYPE OF INTERVENTION

Method of fixation of the patellar component	Primary				revisions	
	totals		one-compartment		2017	2018
	2017	2018	2017	2018		
Cemented	125	213		2	2	2
not cemented	6	7	2	2		
Not applicable	605	533	102	134	7	19
Total	736	753	104	138	9	21

No further investigations were made on the RIAP data, in addition to those already presented above since it was considered that the data organized and commented on according to the RIAP report model are sufficient for an adequate description of the phenomena.

ANALYSIS OF THE "AREAS" TRACKS - MATERIALS PURCHASED (KNEE PROSTHESES)

An indispensable premise for the analyzes proposed in this section is that the AREAS flow refers to the purchase of prosthetic materials, divided by year, but cannot be linked to actual consumption nor does it allow to verify when the materials in question have actually been used and on which patients. Furthermore, the data are aggregated by pharmacy that made the purchase, which does not necessarily correspond to the structure providing the service.

A first element analyzed is the 2018 expenditure, which is not proportional to the number of interventions carried out in the same year traced through the SDOs. In particular, the cost per intervention at the AOU Ancona is significantly lower than the other two companies (ASUR and Marche Nord) which instead have similar results. It appears probable that AOU Ancona has used material in stock since 2017, consequently an area of possible divestment is related to warehouse management.

TABLE 58: COSTS AND INTERVENTIONS BY COMPANY. YEAR 2018

Company	Total expenditure 2018	Interventions 2018	Cost / Intervention
ASUR	€ 958,151	447	€ 2,144
AOU ANCONA	€ 31,853	51	€ 625
AO Marche Nord	€ 255,671	156	€ 1,639
Total	€ 1,245,675	654	€ 1,905

A different explanation for the phenomenon would also be possible, based on a hypothesis in which AOU Ancona pays much less for materials than other companies. This hypothesis is denied by the precise analysis of the cost per piece purchased, aggregating the pieces on the basis of the type identified through CND. The following table shows this information in relation to the behavior of the three reference companies. The green color identifies a cost per piece that is at least 10% lower than the regional average reference value, while the red identifies a cost that is at least 10% higher than the regional average reference. In practice, therefore, these are virtuous or critical areas on which individual companies could intervene. The paths examined do not allow to give information on the quality of the products purchased.

Looking at the table, it is clear that AOU Ancona certainly does not pay less for some items than other companies, but in 2018 it did not buy what was necessary for its interventions. It should also be noted that AO Marche Nord spent more than other companies for some types of materials. Since these are small quantities, the hypothesis is that it is qualitatively different and therefore more expensive.

TABLE 59: COSTS PER PIECE PURCHASED BY COMPANY. YEAR 2018

Type of material	ASUR			AOU Ancona			AO Marche Nord			total		
	total cost	n ° pieces	cost * piece	total cost	n ° pieces	cost * piece	total cost	n ° pieces	cost * piece	total cost	n ° pieces	cost * piece
FEMORAL COMPONENTS FOR CEMENTABLE TWO-COMPARTMENT PRIMARY IMPLANT	€ 26,223	23	€ 1,140							€ 26,223	23	€ 1,140
FEMORAL COMPONENTS FOR CEMENTED TWO-COMPARTMENT PRIMARY PLANT	€ 406,083	294	€ 1,381	€ 4,709	7	€ 673	€ 127,936	96	€ 1,333	€ 538.727	397	€ 1,357
NON-CEMENTED FEMORAL COMPONENTS FOR BICOMPARTMENTAL PRIMARY IMPLANT	€ 8,796	6	€ 1,466	€ 13,520	10	€ 1,352				€ 22,316	16	€ 1,395
FEMORAL COMPONENTS FOR REVISION KNEE PROSTHESES	€ 47,372	24	€ 1,974							€ 47,372	24	€ 1,974
FEMORAL COMPONENTS FOR SINGLE-COMPARTMENT KNEE PROSTHESES	€ 9.776	11	€ 889				€ 1,248	1	€ 1,248	€ 11,024	12	€ 919
PATELLAR COMPONENTS	€ 1,628	1.015	€ 2							€ 1,628	1.015	€ 2
FITTONS FOR KNEE PROSTHESES	€ 8,497	19	€ 447				€ 1,312	2	€ 656	€ 9,809	21	€ 467
TIBIAL INSERTS FOR FIXED BICOMPARTMENTAL PRIMARY IMPLANT	€ 93,050	276	€ 337	€ 3,900	15	€ 260	€ 12,574	30	€ 419	€ 109,523	321	€ 341
TIBIAL INSERTS FOR FURNITURE TWO-COMPARTMENT PRIMARY IMPLANT	€ 47,025	100	€ 470				€ 15,600	30	€ 520	€ 62,625	130	€ 482
TIBIAL INSERTS FOR FIXED REVISION KNEE PROSTHESES	€ 2,018	3	€ 673							€ 2,018	3	€ 673
TIBIAL INSERTS FOR REVISION FURNITURE KNEE PROSTHESES	€ 624	1	€ 624							€ 624	1	€ 624
TIBIAL INSERTS FOR SINGLE-COMPARTMENT KNEE PROSTHESES	€ 2,187	9	€ 243							€ 2,187	9	€ 243
TIBIAL PLATES FOR BICOMPARTMENTAL PRIMARY IMPLANT FIXED CEMENTED	€ 106,791	129	€ 828	€ 9,724	12	€ 810	€ 50.606	58	€ 873	€ 167,121	199	€ 840
TIBIAL PLATES FOR BICOMPARTMENTAL PRIMARY IMPLANT FIXED NOT CEMENTED	€ 3,848	4	€ 962							€ 3,848	4	€ 962
TIBIAL PLATES FOR BICOMPARTMENTAL PRIMARY IMPLANT CEMENTABLE FURNITURE	€ 12,373	14	€ 884							€ 12,373	14	€ 884
TIBIAL PLATES FOR BICOMPARTMENTAL PRIMARY IMPLANT CEMENTED FURNITURE	€ 46,319	53	€ 874				€ 37,658	37	€ 1,018	€ 83,977	90	€ 933
TIBIAL PLATES FOR BICOMPARTMENTAL PRIMARY IMPLANT FURNITURE NOT CEMENTED	€ 1,968	1	€ 968							€ 1,968	1	€ 1,968
TIBIAL PLATES FOR FIXED REVISION KNEE PROSTHESES	€ 88,812	98	€ 906							€ 88,812	98	€ 906
TIBIAL PLATES FOR SINGLE-COMPARTMENT KNEE PROSTHESES	€ 17,563	21	€ 836				€ 416	1	€ 416	€ 17,979	22	€ 817
KNEE PROSTHESES - OTHER	€ 2,965	2	€ 1,483				€ 8,138	1	€ 8,138	€ 11.103	3	€ 3,701
KNEE PROSTHESES - OTHER ACCESSORIES	€ 7,079	32	€ 221				€ 184	2	€ 92	€ 7,263	34	€ 214
THICKNESSES FOR KNEE PROSTHESES	€ 17,154	29	€ 592							€ 17,154	29	€ 592
Total	€ 958,151	2,164	€ 443	€ 31,853	44	€ 724	€ 255,671	258	€ 991	€ 1,245,675	2,466	€ 505

Overall, if all the materials were purchased by all the companies at the lowest price, an overall saving of about 27% would be possible, or 331,496 euros per year, attributable almost exclusively to the materials contained in the CND FEMORAL COMPONENTS FOR CEMENTED BICOMPARTMENTAL PRIMARY PLANT

The following table shows, in line with what has already been reported above, that there is a relatively wide variety of suppliers and that individual companies tend to purchase from different suppliers. Hence probably the price differences found.

TABLE 60: PARTS AND VALUE DISTRIBUTIONS BY SUPPLIER AND COMPANY. YEAR 2018

Supplier	ASUR		AO ANCONA		AO Marche Nord		total	
	pieces	value	pieces	value	pieces	value	pieces	value
3M ITALIA SRL	1	€ 2,562					1	€ 2,562
ACTIVA SRL	169	€ 152,966			141	€ 128,690	310	€ 281,656
ARTHREX ITALIA SRL	1	€ 406					1	€ 406
CORMAN HOSPITAL SRL	11	€ 33.004					11	€ 33.004
HENRY SCHEIN KRUGG SRL	1	€ 99					1	€ 99
JOHNSON & JOHNSON MEDICAL SPA	2	€ 1,296					2	€ 1,296
KALTEK SRL	2	€ 1,098					2	€ 1,098
LIMACORPORATE SPA	7	€ 1,042					7	€ 1,042
LINK ITALIA SPA	106	€ 69,671			5	€ 9,633	111	€ 79.304
MEDACTA ITALIA SRL	18	€ 13,416					18	€ 13,416
MEDTRONIC ITALIA SPA			1	€ 3,565			1	€ 3,565
MICROPORT SCIENTIFIC SRL	6	€ 5,096					6	€ 5,096
PERMEDICA SPA	136	€ 105,570					136	€ 105,570
SMITH & NEPHEW SRL	153	€ 129,217			104	€ 112,736	257	€ 241.953
STRYKER ITALIA SRL SOLE SHAREHOLDER	10	€ 7,977					10	€ 7,977
ZIMMER BIOMET ITALIA SRL	491	€ 434.731	38	€ 28,288	4	€ 4,612	533	€ 467.632
Total	1.114	€ 958,151	39	€ 31,853	254	€ 255,671	1,407	€ 1,245,675

Discussion and conclusions

The analyzes carried out allowed to highlight some critical issues on which improvement interventions could be carried out. These are always potential interventions of an organizational nature that could have the objectives of reducing the length of hospitalization in public structures, reducing passive mobility and strengthening the centralization of purchases of prosthetic material. With a view to "HTA and divestment", these measures allow for potential recoveries of resources to be reinvested to enhance services. Of course, reinvestment can also involve different structures, for example by strengthening the rehabilitation capacity outside acute hospitals.

The data provided to the RIAP by the Marche Region does not currently allow reflections on the quality of individual prostheses and / or surgical approaches and / or methods of fixing the components, because a sufficiently large historical series is not available. The literature analyzed in previous deliverables of this project by other operating units suggests that a more precise analysis would be possible if we had broader time horizons, up to reaching an optimal result with an amplitude of about ten years. In this sense, it is recommended to improve adherence to the RIAP by extending it to all structures and all interventions carried out in the Region.