



Applying process mining in health technology assessment

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Abstract

Objective Propose a process mining-based method for Health Technology Assessment.

Methods Articles dealing with prior studies in Health Technology Assessment using Process Mining were identified. Five research questions were defined to investigate these studies and present important points and desirable characteristics to be addressed in a proposal. The was defined method with five steps and was submitted to a case study for evaluation.

Results The Literature search identified six main characteristics. As a result, the five-step method proposed was applied in the radical prostatectomy surgical procedure between the robot assisted technique and laparoscopy.

Conclusion It was demonstrated in this article the creation of the proposal of an efficient method with its replication for other health technologies, coupled with the good interpretation of the specialists in terms of comprehensibility of the discovered patterns and their correlation with clinical protocols and guidelines.

Keywords Process mining · Health Technology Assessment · Cost analysis · Value-base health care · Real-world evidence

1 Introduction

New, modern technologies have been progressively incorporated in healthcare, resulting in increased medical and hospital products and services. Moreover, the new items incorporated repeatedly incur excessively, and frequently unnecessary, use of these resources, thereby failing to meet the criteria of cost-effectiveness and budget impact prescribed by Health Technology Assessment studies [1, 2].

Health Technology Assessment comprises techniques applied to assess healthcare interventions considering their potential effects and consequences on the healthcare system, the sector economy, and society. This Assessment involves monitoring when a given healthcare technology should be included or excluded at a faster or slower rate, thus providing information to support healthcare managers'

decision-making. Health Technology Assessment is also defined as an interdisciplinary, multi-science activity that aims to provide sufficient input for the definition of priorities for the healthcare system and decisions regarding disease prevention, diagnosis, treatment, and rehabilitation [3, 4].

A major effort can currently be observed in scientific production in connection with Health Technology Assessment for healthcare management purposes. Nevertheless, there is still much to be investigated regarding new healthcare techniques, which requires enabling the creation of processes and appropriate methodologies adapted for dealing with individual countries' context and address the reality of individual environments. This implies developing and applying new Health Technology Assessment techniques to support healthcare decisions [2, 5].

Some authors cite the difficulty of incorporating outcomes of Health Technology Assessment studies undertaken in other countries due to reproducibility and replicability, i.e., variations in the effectiveness of alternatives, costs, use of resources in the healthcare system, epidemiological issues, among others. To mitigate that limitation, the authors suggest producing studies using clinical data and information on the actual region's use in question [6–8].

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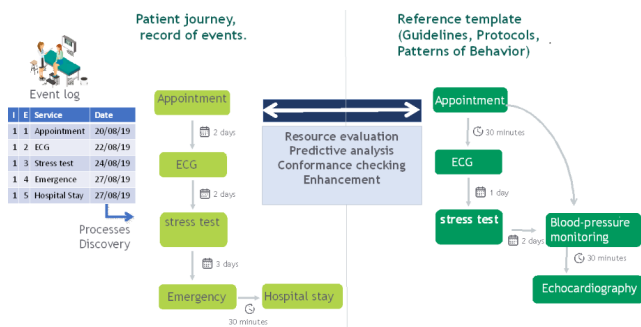


Fig. 1 Example of using Process Mining in Healthcare

Randomized clinical trials are widely accepted and used in Health Technology Assessment. They have long been regarded as the technique that best provides scientific evidence, the “gold standard” for Health Technology Assessment. However, one of their main features, and actually a limitation, is that they are applied to specific populations within targeted environments, which often differ from each country’s clinical or social realities. Therefore, they may fail to provide sufficient evidence on the effectiveness of given healthcare technology, in particular, due to the profile of patients whose comorbidities and demographics frequently differ from those of the subjects used in randomized clinical trials [9].

This need led to the emergence of the concept of real-world evidence (RWE), a decision-making support methodology in Health Technology Assessment [10]. Over the past decade, countries have developed healthcare records and managerial approaches capable of providing quality data for Health Technology Assessment in a more agile and dynamic manner [11].

Real-world evidence studies require inputs known as real-world data. These are used to support decision making in the healthcare industry and are collected from traditional Health Technology Assessment studies but under an approach of non-experimental and uncontrolled observational research [10]. Real-world data provide useful information on the comorbidity profile of a target population. They can be used to confirm decisions in connection with a market choice or new investment options. Therefore, derivative studies may provide supporting evidence on interventions’ financial value to patients, government healthcare agencies, and payers [12].

The use of real-world data is similar to the concept of event logs or transaction records comprising the description of the activity, the date of execution, and the record’s identification key, all of which apply to the concept of process mining [13] - a term that consists of robust methodologies which use data mining and machine learning for pattern recognition in the data analyzed, enabling automatic extraction of models representing the process flow, its timing, resource

evaluation, conformance checking, process improvement and prediction analyses [13–15].

Based on the event log for a given patient, applying the Process Mining algorithm results in the most frequent pattern being discovered and indicated through the flowchart with activities being represented in boxes and arrows indicating the path sequence to be followed. This flow also enables the identification of some metrics that may be associated, such as case frequency, timing between activities, costs, among others, as shown in an example in Fig. 1.

Along with this technique for process model discovery, Process Mining concepts allow comparative analyses between the models discovered and customary reference models, such as medical protocols or clinical guidelines. Figure 1 shows an example for a hypertensive patient in which the left-hand side shows the process model discovered using patient data, and the right-hand side shows the reference model representing the typical journey for patients with this disease, i.e., a clinical guideline or care protocol for the management of this ailment.

In the article [16], which deals with a review of process mining and patient journey applications, describe the potential of the use of this technology applied for conformity assessment to follow the trajectory of a patient in the face of his disease, and thus generating an understanding of patterns that can be useful in the formulation of protocols and the build on medical domain knowledge [16].

There is a rapid evolution of health technologies that have an impact on the health segment, with the demand for a medicine focused on the patient’s needs and in a personalized way, and thus, process mining can develop techniques to efficiently assess the suitability of a particular treatment process for a patient with a specific profile [17].

In a brief review of studies that apply real-world evidence in health technology assessment, we can see applications that use natural language programming (NLP) [18] and techniques for the use of sentiment analysis to evaluate the effectiveness and safety of health technologies [18, 19], which can add value to the proposed technique associated with the assessment of health outcomes through the interpretation of information obtained from social media data or evaluation of device used.

Therefore, recognizing a set of events for a given procedure and ordering may help formulate rules and apply smart processes for Health Technology Assessment. A potential can be perceived here and an opportunity to apply process mining in Health Technology Assessment studies using real-world evidence methodology.

Difficulties occur in applying traditional Health Technology Assessment studies, randomized clinical trials due to adaptability issues, time for implementation, high costs, and exposure of patients in research [9, 11, 20]. This gives

rise to an opportunity to create new models and methods, enabling the use of concepts from Real-World Evidence studies in integration with data from healthcare information systems [6, 20–23]. Discovery, comparison, and improvement of process models in the healthcare area differ from other areas of their characteristics, i.e., high variability, complexity, security and privacy issues, and their activities' multidisciplinary nature [14, 24–26].

Therefore, this paper defends the proposal of applying a Health Technology Assessment method based on Real World Evidence concepts using Process Mining. This study aims to review recent literature for possible applications of process mining in Health Technology Assessment, specifically within the concept of real-world evidence, identifying the main characteristics and their limitations, with the goal of proposing a new technique for Health Technology Assessment using process mining concepts.

2 Methods

2.1 Research strategy

The method used in this quantitative and qualitative review and comprehensive search strategy was developed to capture the maximum number of relevant articles in each database. The following databases were used to select the papers: PUBMED, ACM Digital Library, IEEEExplore, ScienceDirect, and SpringerLink by applying the following extensive search expression: (“Process Mining” AND “Health Technology Assessment”).

As for the time period covered, the initial year of selection was 2002 - an important reference year for the subject of process mining due to the creation of the Alpha or α -miner algorithm, an algorithm that, besides being the first one created, also made the subject of process mining more relevant. The review period ended in June 2020.

2.2 Criteria for study selection and scope

For the research, two inclusion criteria and three exclusion criteria were used, namely:

First inclusion criteria: The papers were published and found using the search expression between 2002 and June 2020.

First exclusion criteria: Elimination of duplicate papers.

Second exclusion criteria: only articles on Health Technology Assessment (Analysis Methodology using Process Mining) were selected, and, with the following points of interest being used as a way of analyzing the papers selected:

Question 1: In what healthcare environment was the assessment applied? / What technology was used?

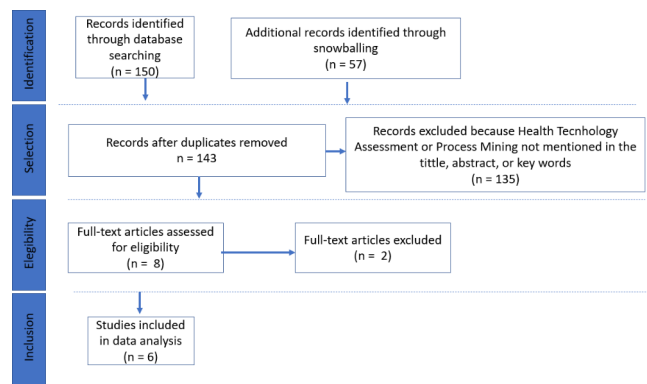


Fig. 2 Article selection process – PRISMA flow diagram [27]. Source: author

Question 2: What strategy/algorithm was adopted?

Question 3: What assessment metrics/measures were used?

Question 4: What difficulties/limitations were found?

Question 5: What was the study's main contribution?

Study analysis To map process mining applications, methodologies, and techniques used in healthcare and evaluate their significance in Health Technology Assessment studies that used the respective technique.

To identify the assessment strategy and metrics used in Health Technology Assessment studies and the difficulties and limitations encountered in applying the technique. Additionally, the analysis also aims to identify important characteristics adopted to support the study and discussion to develop new Health Technology Assessment techniques based on process mining.

3 Results

A total of 150 articles were obtained after executing the search strategies, and 57 records from subsequent snowballing were used to expand the study sample, to verify the existence of other studies published, using a search in the Google Scholar database applying the following search expressions: “Health Technology Assessment” and “Process Mining” (Fig. 2). After duplicates were removed, 143 records remained. Of these, 135 were excluded because they did not mention process mining and health technology assessment in the title, abstract, or keyword. Two of these were excluded because they did not describe empirical applications. In total, six articles were included in the analysis.

Despite the comprehensive selection applying HTA using PM as the topic, only 6 articles were identified until June 2020. The most recent article was published in 2017,

demonstrating the knowledge gap and the researcher's interest in this approach, whose application requires specialized knowledge.

Answers to the research questions were obtained by reading the six articles selected, shown in Table 1.

The answers highlighted a few prominent points and desirable characteristics to be addressed in a proposal for a Health Technology Assessment method using process mining.

First characteristic Process mining should be considered a possible and important strategy to design a Health Technology Assessment technique based on real-world data.

Second characteristic Models based on this proposal should be replicable and reproducible for any Health Technology Assessment, using algorithms and tools specifically tailored to this purpose. Most of the related works used PROM [36] - an open-source framework provided by the University of Eindhoven [37]. The software was created to support various techniques and algorithms to experiment with the process mining technique within the academic community. Still, it is not suitable for its professional application.

Third characteristic Given the limitations and proposals raised, there is a desire for robust tools that provide integration and dynamism in Health Technology Assessment processes. However, to meet this requirement, new process mining algorithms must be considered. There already are many available that are capable of interpreting more complex models;

Fourth characteristic Another need identified relates to automatic forms of comparability among the models discovered, to reduce the dependency of Health Technology Assessment on professionals specialized in process mining techniques;

Fifth characteristic Building a knowledge-based repository capable of storing models discovered for comparative use with new models extracted seems to us to be an important requirement for a smart Health Technology Assessment proposal;

Sixth characteristic Using concepts provided by Health Technology Assessment specialists, design a tool that includes the indicators targeted and charts in the assessment should be considered a relevant feature for a proposal.

Based on the characteristics identified, we suggest a Health Technology Assessment method using process mining, illustrated in Fig. 3, addressing the following steps:

In the first step of the method, clinical data and information undergo a process of integration. Whenever possible, the data is obtained directly from the healthcare institutions' management system, thus enabling the automatic and dynamic assessment of the outcomes achieved through the healthcare technologies.

The data pre-processing step is fundamental to address issues connected with high variability of events and differences in granularity and the quality and initial assessment of the data.

In the parameter and search definition step, like in any economic analysis study, the study design strategy must be drafted according to the PICO process (Patient or Population, Intervention, Comparison, and Outcomes) [35]. Still, at this step, HTA assessment is continuous for the patients' health services, without neglecting the patients' characteristics, healthcare resources, and other environmental factors that may influence care options in terms of the quality of the healthcare provided.

Thus, HTA specialists will set the parameters for the tool in terms of indicators or outcome metrics capable of expressing healthcare technologies' efficacy and effectiveness. One example of this is the readmission rate, rate with relapse, survival, length of hospital stay, and differences in costs of the technologies used. The representation of the process models will include the definition of the event sequence and organized by time. These are then linked to the interpretation of the events' variability through macro-activity and activity groupings, thereby enabling the extraction of the most frequent paths [25, 37]. The temporal analysis should be considered to determine the average or mean duration of activities between events and the possibility of selecting the metric of average activity cost to provide inputs of economic analyses.

In this step, processing using the PM technique is suggested, based on the Fuzzy Mining algorithm [37], the discovery of two process models (Model HT1 and HT2), for each health technology to be evaluated.

This allows a high-level view of the process and preserves the aggregate details, abstracting a behavior pattern of the most significant process tasks and relationships in the healthcare area added to the multilevel approach to solve issues due to the high variability of events [25]. In the expert evaluation step, a dashboard will be developed, allowing the application of the metrics defined in the research strategy, with the differentiation between the two process models discovered and adding indicators and charts for outcomes, rendering the tool interactive and intuitive for HTA specialists and helping them to visualize the analysis.

As far as the economic analyses, it will be possible to apply cost-minimization analysis (CMA). This basically is the difference in costs involved between techniques and

Table 1 Articles and questions. Source: author

Author and Year	1 - In what health-care environment / What technology was used?	2 - What strategy /algorithm was adopted?	3 - What assessment metrics/measures were used?	4 - What difficulties /limitations were found?	5 - What was the study's main contribution?
Mans et al. 2013 [28]	Use of a process-oriented methodology to evaluate the impact of the application of new technologies. CAD/CAM (Digital) techniques were used compared to the conventional technique used in dental implants.	Process discovered using process mining. The study obtained detailed information of the process model for its evaluation, using PROM software version 5.2 as a tool, with the establishment of a Petri net using the heuristic miner algorithm.	Assessment of the techniques used (conventional and digital) focused on three perspectives: evaluation of process flow, resources used and duration of activities.	One limitation relates to the process mining algorithm used to obtain other information to support more complex analyses, which greatly restricted the view of a more detailed Health Technology Assessment. The authors also mention the intention of obtaining other perspectives of analysis in future studies, such as: cost and accuracy and other information on outcome assessment.	By comparing technologies, the authors demonstrated the potential of technology driven assessment using real world data to represent how processes are performed in both methods evaluated.
Huang et al. 2014 [29]	To assess the current steps in medical-hospital process-oriented care as compared to the patient-oriented model of a health promotion and disease prevention program, specifically in the population of pregnant women with diabetes, through process mining.	The process flows of both models were discovered by means of the PROM tool, generating a Petri network with the heuristic miner algorithm.	The authors merely present the possibility of comparison between both care protocols in each step.	The authors merely evaluated the two process models without employing the protocol's assessment metrics. They mention the intention of matching parameters automatically and performing dependency inferences in future studies.	The contribution of this work reflects an important concern in dynamic care protocol and guideline analyses, thus providing quality and cost-effective healthcare.
Cho et al. 2017 [30]	Assessment of the effect of best practices to redesign healthcare processes using evidence-based research in a Korean hospital with approximately 1400 beds and 40 surgery rooms.	The authors use the heuristic miner algorithm to generate a Petri net with LTL-CHECKER conformity assessment and indicator generation through Originator by task matrix, all algorithms available in PROM. They also mention the discovery of process models for behavior analysis (patterns) to compare assessments to improve.	The authors propose indicator dimensions related to variations in duration, cost, quality, and flexibility.	They merely analyze variations in the current and proposed processes, with results being positive, negative, and neutral for outcomes desired. They further state that the form of application and definition of indicators needs to be validated and that these were based solely on a literature review and the authors' knowledge.	The possibility of applying some indicators from different perspectives is a strength of this work; however, this must be aligned with Health Technology Assessment metrics.

Table 1 (continued)

Author and Year	1 - In what health-care environment / What technology was used?	2 - What strategy /algorithm was adopted?	3 - What assessment metrics/measures were used?	4 - What difficulties /limitations were found?	5 - What was the study’s main contribution?
Dunkl et al. 2011 [31]	Analysis and assessment of cutaneous melanoma medical guidelines, demonstrating the variability and implications in therapy.	The assessment strategy was adopted by the PICO scheme and by the analysis of the therapy process according to the clinical guideline. The process was discovered using RWD in the PROM tool, generating a Petri net.	The author does not provide details of the metrics used but merely mentions that PROM tool reports will enable the production of reports summarizing therapy outcomes, including death, healed, no show, and kept appointment according to age matching and other conditions of the population.	The authors prove that integration between identifying process models discovered through patient data and better modes of comparison between clinical guidelines is a major challenge.	A study using process mining with different perspectives of Health Technology Assessment is a very positive point of the study. Formalization of the representation of clinical therapy processes for an outlook of medical evidence processes. Formalizing clinical therapy processes and clinical guidelines make a more accurate re-establishment of the concept of process conformity possible. Assessment of conformity guided by evidence-based data highlights the compatibility of implementations proposed in the guidelines.
Baumgärtel et al. 2014 [32]	Technology analysis is based on simulations obtained by process flow, using a case for stroke patients.	To discover the process flow, the authors used an algorithm of their design based on the heuristic algorithm described in the paper.	The study assesses the process flows estimates with cost and time metrics.	The models discovered were executed manually, and the authors additionally commented that they worked only with cost and time metrics and intend to apply new assessment metrics in the future.	The proposal uses an algorithm’s definition, and this was the major contribution; however, transforming it in more dynamic ways will require using pre-processing steps to refine the models.
Rovani, 2014 [33]	Analysis of the procedure to treat cryptorchidism surgically as compared to clinical guidelines, defined by the use of the Declare tool, manually.	To discover the process flow, the authors used PROM to generate the Petri net and the process assessment was performed through comparison with the guideline and performed using the Declare software.	Although the authors mention the goal of Health Technology Assessment, they do not use assessment metrics, only comparison of process models.	They mention the difficulty of an integrated information process and the application of the technique in various segments of the healthcare sector. One of the difficulties presented was the manual construction of guidelines.	A proposal for applying health process assessment in Health Technology Assessment, demonstrating the difficulties regarding processes of integration and dynamism in obtaining those process models.

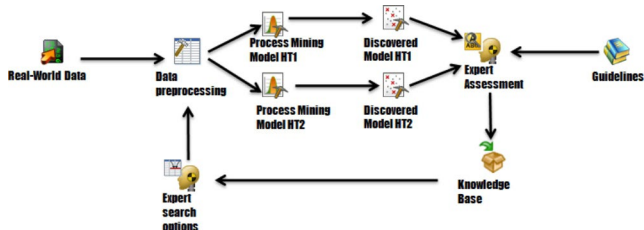


Fig. 3 Proposal for a Health Technology Assessment model using process mining. Source: author

incremental cost-effectiveness ratio (ICER) [38–40]. The expression treats differences in costs concerning the difference in effectiveness between techniques. For the social (accessibility), ethical (confidentiality and privacy of information), and legal (regulation) [4] dimensions, information capable of supporting these considerations were addressed in the integration process. However, this analysis was not

carried out in this study due to the limitation of obtaining reliable data for research purposes.

The knowledge base will be populated in two ways; saving the data patterns discovered recognized by the assessment or by manual definition by the specialist in BPMN (Business Process Management Notation).

3.1 Study case

With the technique performed by laparoscopy or robot-assisted (Da Vinci robot), the radical prostatectomy surgical procedure will be used as a trial for evaluating experimentally the method proposed.

The research project was submitted and approved by the research ethics committee under the number 3,326,942 of the proposing institution: Hospital Erasto Gaertner in Curitiba, Parana, Brazil.

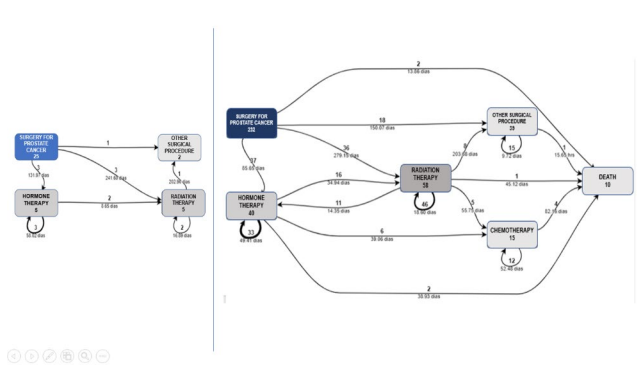


Fig. 6 Process model discovery on the left robot assisted n=25 – and on the right, laparoscopic n=232, post-surgical care

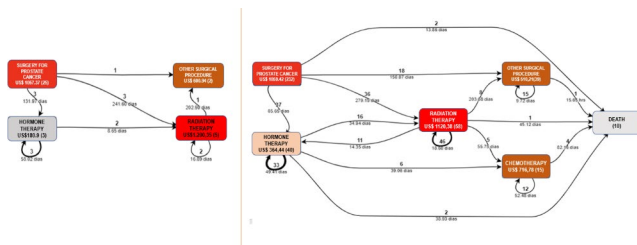


Fig. 7 Economic analysis on the left robot assisted n=25, and on the right laparoscopic n=232, post-surgical care

The economic analysis based on the models discovered after surgery can be performed by changing the activity metrics to average cost, applying the cost-minimization analysis (CMA) calculations, and the incremental cost-effectiveness ratio (ICER) as described below. Cost-Minimization Analysis (CMA) For calculation of the total cost amount, the sum of the costs of all activities is carried out, multiplied by their frequency, according to the formula and calculation below, based on the information from the model discovered in Fig. 7:

$$C_1 = \sum (\text{average cost} * \text{frequency}) / n = 1367.23$$

$$C_2 = \sum (\text{average cost} * \text{frequency}) / n = 1517.23$$

$$CMA = (C_1 - C_2) = 150.00$$

Incremental cost-effectiveness ratio (ICER) The study of the incremental cost-effectiveness ratio was used to consider the assessment of outcomes, which indicates the cost differentiation for the difference in the effectiveness of the techniques. Based on the outcome of readmissions, wherein the robot-assisted technique (n=25), there were 2 cases (92%

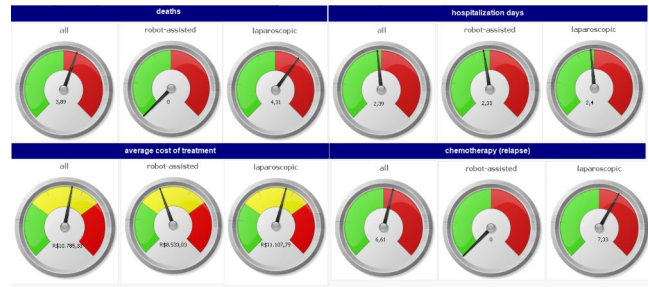


Fig. 8 Dashboard Health Technology Assessment. Source: author

of effectiveness), and in the laparoscopic (n=232), there were 39 cases (83,19%). We have the following calculation:

$$ICER = (C1 - C2)/(E1 - E2) = (1367.23-1517.23)/(0.9200-0.8319) = -1702,61.$$

It is important to note that in this case, there is no differentiation of values for the surgical procedure since the health institution participating in the research does not have a differentiated charging table for the robot-assisted technique, thus having the CMA and the ICER favorable for the robot-assisted technique, as its outcome is more effective and with less use of resources. Step four Develop a dashboard that makes it possible to apply distinguishing metrics between the two process models by adding key performance indicators (KPI) and graphs that make the tool visual and interactive with experts to support decision making. In the method proposed, the construction of a dashboard is included to broaden the specialists’ analysis in the comparison of health technologies. Figure 8 presents a suggestion of some indicators that may serve as a basis for Health Technology Assessment, but other indicators may be added.

Step five Set up an area for the development of the knowledge base – which supports the expert with information from guidelines and protocols stored as process models – on the application of technology in healthcare and which will serve, in other assessments, to support the specialist’s work and decision-making.

After discovering the process model, it will be possible to store it as a reference model in the knowledge base, as shown in Fig. 9, allowing it to be maintained concerning medical guidelines and protocols.

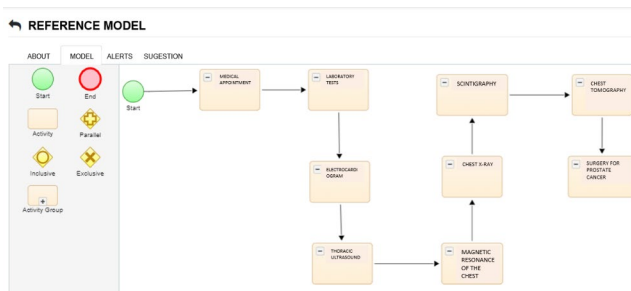


Fig. 9 Reference model for prostatectomy surgery in both techniques

4 Discussion

The drive to design and develop new processes and methods in Health Technology Assessment corroborates the opinions of the Latin American Health Technology Assessment International (HTAi) forum in 2018. Another important factor identified in this research relates to the underuse of process mining in Health Technology Assessment, with only 1,1% of studies applying this healthcare technique. That reveals a gap and an opportunity to develop an instrument to optimize Health Technology Assessment processes.

Regarding Health Technology Assessment, the process mining proposal is appropriate. It integrates with new approaches that operate with real and online data, also called real-world data, used in real-world evidence studies, thus enabling a more cost-effective healthcare process thanks to faster and more practical analyses, allowing managers to dedicate themselves to acquiring a more global view of the healthcare process, consequently creating conditions to provide the most cost-effective use of health resources and, especially, to reduce adverse events and life-threatening situations [11, 12, 41].

The possibility of using the proposed technique in various technologies in healthcare and situations that can be transposed to any other environment is a distinctive feature, as the real-world evidence technique using process mining will solve difficulties related to reproducibility and replicability, i.e., the ability to apply the analyses to different scenarios and on time, usually in real-time.

One of the major challenges for developing this proposal will be the creation of characteristics to address the high variability and differences in the granularity of patient data regarding the evaluated technologies. Therefore, it will be necessary to create robust data preprocessing steps coupled with process mining algorithms to address and minimize such issues.

The adoption of specific Health Technology Assessment metrics and measures should be incorporated in the comparison of Health Technology Assessment process models, giving the tool a robust possibility of analyses and enabling

the instruments to support experts' decisions in choosing and formulating new analyses.

Due to the scant use of instruments in applying process mining in Health Technology Assessment, knowledge about the specification or choice is still poor. Still, Health Technology Assessment specialists' support should help define indicators and metrics that enable their incorporation, thus providing greater dynamism in analyses and evaluations.

The integration proposed with electronic health records will allow the adoption of assessments based on clinical data and, thus, the possibility of direct relationships with each technology's outcomes and the identification of factors that provide better characteristics regarding the application of healthcare technology.

In a future study, the aim is to apply in the instrument proposed an assessment of radical prostatectomy surgery using laparoscopy and robotics, enabling experts to set parameters for indicators to express efficacy and effectiveness, for example, in this case: urinary function, erectile function, non-relapsing biochemical rate, quality-adjusted life years (QALY) for an outcome assessment, survival, length of hospital stay and cost differentiation.

5 Conclusion

The main contribution of this study relates to a proposal to design an instrument to dynamically analyze not only healthcare technology but the environment in which it is applied and the human resources that use such technology, thus making it possible to use it more effectively and provide a higher quality of service to patients.

An important justification for the use of this proposal can be exemplified with the crisis that we are experiencing today concerning COVID-19, wherewith the integration of data from different health services, the deployment of procedures and administration of medications to patients could be dynamically assessed to determine the best outcomes, making the results dynamic and available in real-time to support clinical research regarding the discovery of clinical protocols and treatments.

It is proposed in future work, to add data on the patient's experience and satisfaction in relation to the use of health technology, through the collection of quality of life research data and, through the techniques of sentiment analysis, thus enabling the evaluation of patient experience and satisfaction outcomes.

Author contributions All authors contributed to the study conception and design.

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Declarations

Competing Interests This manuscript has not been published and is not under consideration for publication elsewhere and We have no conflicts of interest to disclose.

Ethics approval The research project was submitted and approved by the research ethics committee under the number 3,326,942 of the proposing institution: Hospital Erasto Gaertner in Curitiba, Parana, Brazil.

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