



Medical technology

Medical technology is a broad term that refers to a variety of **solutions**, **products**, and **services** that can be utilized to save and improve people's lives. Effective and sustainable methods for managing these technologies, to ensure that their essential requirements (in terms of both safety and performances) remain under control throughout their whole life cycle, are essential.



Health Technology Management

To ensure access to appropriate medical devices, proper **management** and use of medical equipment over its life cycle must be considered [...] The process consists of good procurement practices, appropriate donation solicitation and provision, logistics of delivery and installation, inventory management, **maintenance**, safe use and training, and measurement of clinical effectiveness.

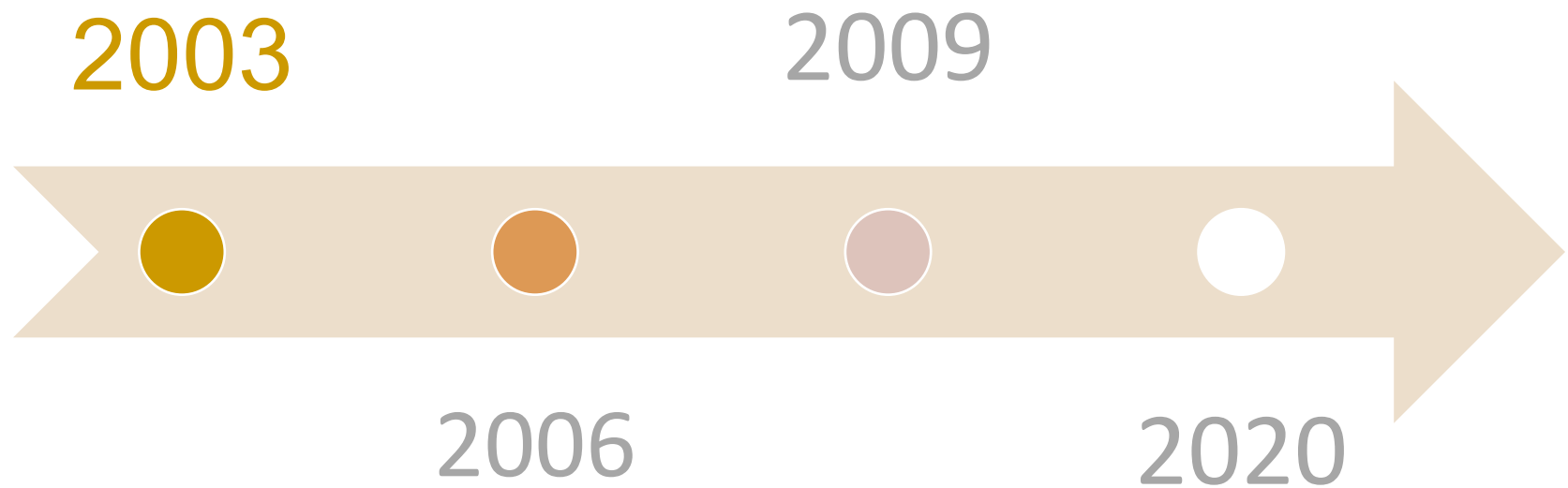
<https://ced.ifmbe.org/resources/ce-html-definitions.html>



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Measuring performances through Key Performance Indicators (KPIs)



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2003

The screenshot shows the IEEE Xplore digital library interface. At the top, there are navigation links for IEEE.org, IEEE Xplore, IEEE-SA, IEEE Spectrum, and More Sites, along with a SUBSCRIBE button. The main header features the IEEE Xplore logo, navigation menus for Browse, My Settings, and Help, and an Institutional Sign In button. Below the header, a search bar shows the word 'All'. The article title 'A new proposal of quality indicators for clinical engineering' is prominently displayed, followed by the publisher 'IEEE'. Action buttons for 'Cite This' and 'PDF' are visible. The authors listed are E. Rodriguez; A. Miguel; M.C. Sanchez; F. Tolkmitt; E. Pozo. On the left, statistics show 2 Paper Citations and 165 Full Text Views. The abstract section is titled 'Abstract:' and contains the text: 'As we know from Stiefels paper "...we want to do our work right the first time and better the next time. But we really don't know whether we have done it right, or are doing it better, unless we have a measurement system for quality." Unfortunately, there is little agreement in the standardization of indicators used for evaluation of organizations related to medical equipment management. And those that do the first steps, always walk on thin ice. With this paper, we suggest a set of five quality indicators for the control and the evaluation of management for medical equipment maintenance. The indicators proposed allow the organization, that applies them, to easily correct and adjust their management programs, with a strive for improvement in results and quality and broadening their experiences. The selection of the indicators was executed according to those that are most used among leading health care organizations. Sometimes the indicators are labeled differently but the basic idea is the same, and therefore the results can be compared competitively and the potential of an organization can be displayed.'



E. Rodriguez, A. Miguel, M. C. Sanchez, F. Tolkmitt and E. Pozo, "A new proposal of quality indicators for clinical engineering," Proceedings of the 25th Annual International Conference of the IEEE Engineering in Medicine and Biology Society (IEEE Cat. No.03CH37439), Cancun, 2003, pp. 3598-3601 Vol.4, doi: 10.1109/IEMBS.2003.1280931.



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E. Rodriguez, A. Miguel, M. C. Sanchez, F. Tolkmitt and E. Pozo, "A new proposal of quality indicators for clinical engineering," Proceedings of the 25th Annual International Conference of the IEEE Engineering in Medicine and Biology Society (IEEE Cat. No.03CH37439), Cancun, 2003, pp. 3598-3601 Vol.4, doi: 10.1109/IEMBS.2003.1280931.

In this paper, we propose **a set of five indicators** which are used to control and evaluate the management of **maintenance in clinical engineering**.

The indicators allow comparison among equal institutions and open the doors to have active effects on the quality of management and make necessary changes to adjust a program.

They also permit to improve the results, broaden the experience in the use of quality indicators and to calculate to the potential of an organization.



1.- Availability

The availability of medical equipment is based on the time each medical equipment in a hospital should be available, and its relation to the time, it is available.

$$I_A[\%] = \frac{T_A}{T_{PA}} * 100$$

For example, if a clinical laboratory usually uses a medical equipment from **8:00am to 11: 00am** every workday, the equipment should be available **15h** per week, and therefore $15h \times 52 = 780$ horas per year.

In case the equipment is **down from Friday 10:00am to the following Monday 9:00am**, the none-availability of the equipment is 5 hours and the indicator is calculated to be: $I_A[\%] = 775/780 * 100 = 99\%$.

An availability of medical equipment of over 90% is considered good.

2.- Compliance with the Plan of Preventive Maintenance

This indicator refers to the compliance with the planned maintenance for one year. It is calculated for

1) the **hours spent on preventive maintenance** vs. the hours planned for preventive maintenance

and

2) the **number of preventive maintenance interventions** vs. the number of planned interventions.

This quality indicator is also displayed as a percentage, whereas a percentage of **95% is considered to be good.**

$$I_{CtP}^h [\%] = \frac{T_{TM}}{T_{TM_plan}} * 100$$

$$I_{CtP}^l [\%] = \frac{N_{TI}}{N_{PI}} * 100$$



3.- Effectiveness and the use of Time

This indicator refers to the **effectiveness of productiveness** of a department. It reflects the use of time for corrective and preventive maintenance. The effectiveness should be over 70%, in order to be competitive.

$$I_{EoP} [\%] = \frac{T_{TM}}{T_H} * 100$$

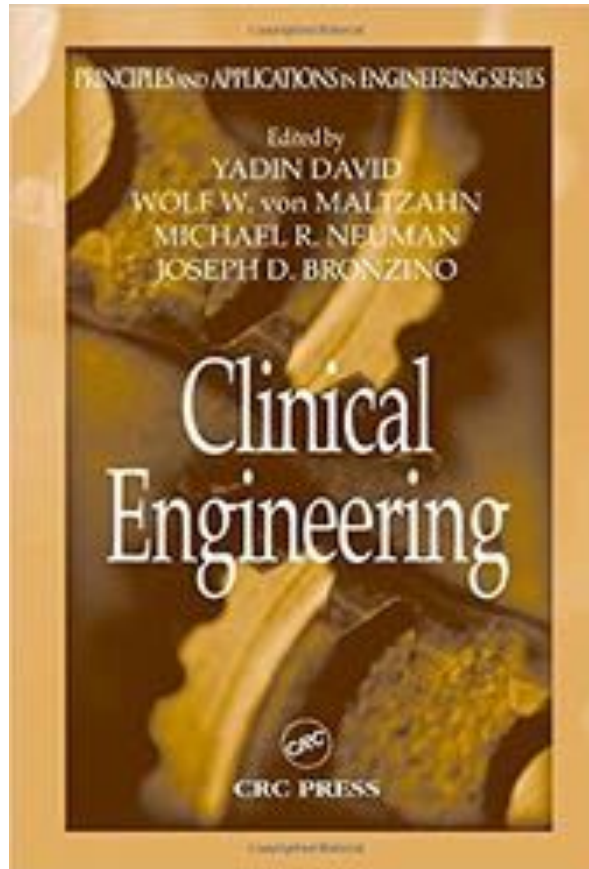
According to the definition, the term effectiveness describes the ability of achieving a goal, reaching a consequence or accomplishing an objective. In our case, this means that **the majority (more than 70%) of time available should be used for preventive and corrective maintenance activities.**

**Back in 2003 clinical engineering
was still a matter of screwdrivers...**



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4

Clinical Engineering Program Indicators

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Dennis D. Austin
Dybanics, Inc.

Robert L. Morris
Dybanics, Inc.

The role, organization, and structure of clinical engineering departments in the modern health care environment continue to evolve. During the past 10 years, the rate of change has increased considerably faster than mere evolution due to fundamental changes in the management and organization of health care. Rapid, significant changes in the health care sector are occurring in the United States and in nearly every country. The underlying drive is primarily economic, the recognition that resources are finite.

Indicators are essential for survival of organizations and are absolutely necessary for effective management of change. Clinical engineering departments are not exceptions to this rule. In the past, most clinical engineering departments were task-driven and their existence justified by the tasks performed. Perhaps the most significant change occurring in clinical engineering practice today is the philosophical shift to a more business-oriented, cost-justified, bottom-line-focused approach than has been generally the case in the past.

Changes in the health care delivery system will dictate that clinical engineering departments justify their performance and existence on the same basis as any business, the performance of specific functions at a high-quality level and at a competitive cost. Clinical engineering management philosophy must change from a purely task-driven methodology to one that includes the economics of department performance. Indicators need to be developed to measure this performance. Indicator data will need to be collected and analyzed. The data and indicators must be objective and defensible. If it cannot be measured, it cannot be managed effectively.



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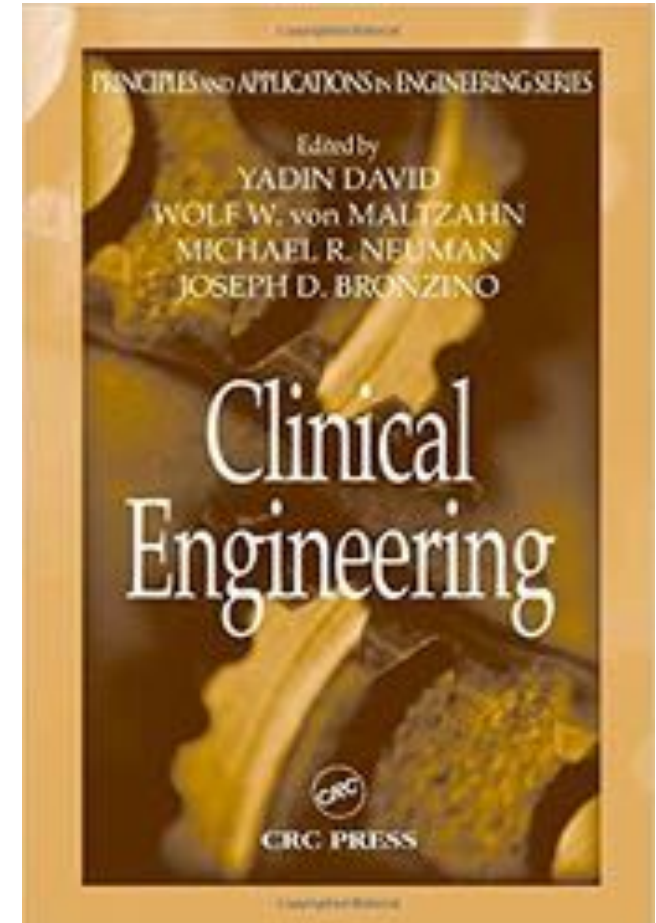


4.2 Standard Database

In God we trust...all others bring data!

Florida Power and Light

Evaluation of indicators requires the collection, storage, and analysis of data from which the indicators can be derived. A standard set of data elements must be defined. Fortunately, one only has to look at commercially available equipment management systems to determine the most common data elements used. Indeed, most of the high-end software systems have more data elements than many clinical engineering departments are willing to collect. These standard data elements must be carefully defined and understood. This is especially important if the data will later be used for comparisons with other organizations. Different departments often have different definitions for the same data element. It is crucial that the data collected be accurate and complete. The members of the clinical engineering department must be trained to properly gather, document, and enter the data into the database. It makes no conceptual difference if the database is maintained on paper or using computers. Computers and their databases are ubiquitous and so much easier to use that usually more data elements are collected when computerized systems are used. The effort required for analysis is less and the level of sophistication of the analytical tools that can be used is higher with computerized systems.



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How can I define an indicator?

4.5 Indicator Example 1: Productivity Monitors

Defines Indicators. Monitor the productivity of technical personnel, teams, and the department. Productivity is defined as the total number of documented service support hours compared with the total number of hours available. This is a desirable rate-based outcome indicator. Provide feedback to technical staff and hospital administration regarding utilization of available time for department support activities.

Establish Thresholds. At least 50% of available technician time will be spent providing equipment maintenance support services (revolving equipment problems and scheduled IPMs). At least 25% of available technician time will be spent providing equipment management support services (installations, acceptance testing, incoming inspections, equipment inventory database management, hazard notification review).

Monitor Indicator. Data will be gathered every 4 weeks from the equipment work-order history database. A trend analysis will be performed with data available from previously monitored 4-week intervals. These data will consist of hours worked on completed and uncompleted jobs during the past 4-week interval.

Technical staff available hours is calculated for the 4-week interval. The base time available is 160 hours (40 hours/week \times 4 weeks) per individual. Add to this any overtime worked during the interval. Then subtract any holidays, sick days, and vacation days within the interval.

CJHOURS: Hours worked on completed jobs during the interval

UJHOURS: Hours worked on uncompleted jobs during the interval

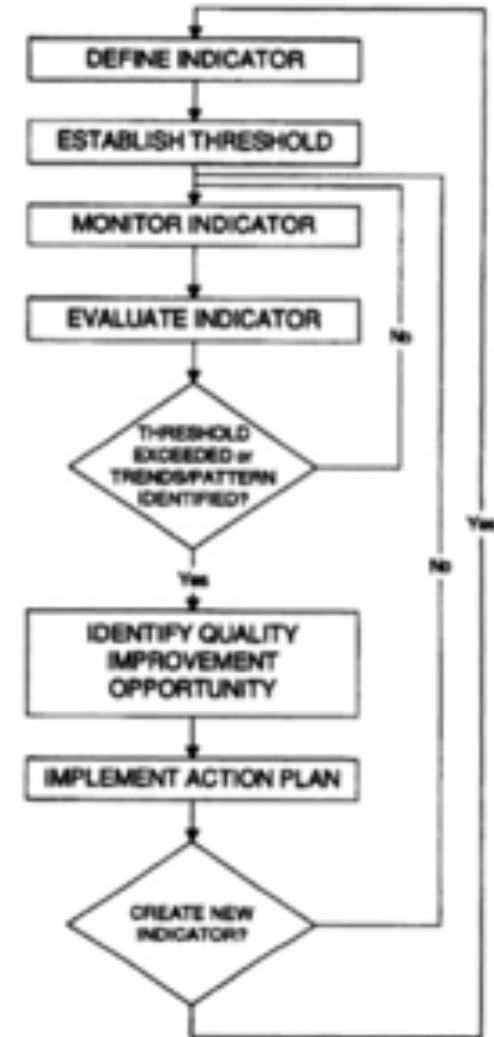
AHOURS: Total hours available during the 4-week interval

Productivity = (CJHOURS + UJHOURS)/AHOURS

Evaluate Indicator. The indicator will be compared with the threshold, and the information will be provided to the individual. The individual team member data can be summed for team review. The data from multiple teams can be summed and reviewed by the department. Historical indicator information will be utilized to determine trends and patterns.

Quality-Improvement Process. If the threshold is not met, a trend is identified, or a pattern is observed, a quality-improvement opportunity exists. A team could be formed to review the indicator, examine the process that the indicator measured, define the problem encountered, identify ways to solve the problem, and select a solution. An action plan will then be developed to implement this solution.

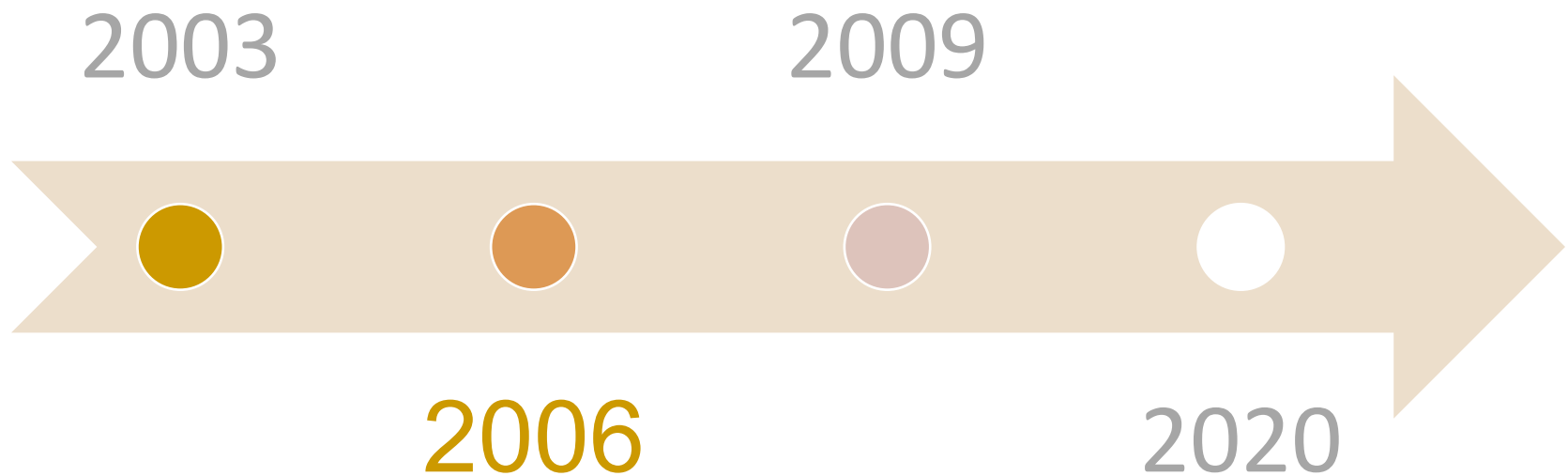
Implement Action Plan. During implementation of the action plan, appropriate indicators will be used to monitored the effectiveness of the action plan.





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Evolution of the discipline: KPIs and evidence



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2006



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Conferences > Proceedings of the IEEE 32nd ...

Benchmarking Performance Improvement Indicators for the Clinical Engineering Department

Publisher: IEEE Cite This PDF

P. Kitcher All Authors

2 Paper Citations 131 Full Text Views

Abstract

Document Sections

- > Introduction
- > Method
- > Results
- > Conclusion

Authors

Abstract:
Performance measurement and Benchmarking have become an integral component of all sectors and the Clinical Engineering (CE) department can not be overlooked. The optimum goal of Benchmarking Performance indicators in the CE department is to continuously strive to improve the quality of the CE department's services upstream, which will consequently lead to a better financial performance downstream. To be successful in this work, I identified mainstream performance indicators essential in making the adjustments needed for improvement of the department's performance. As to the selection of these indicators, an in-depth survey was sent out to over sixty CE directors. The response was analyzed to reveal the top three mainstream performance indicators to be: (a) CE service cost as a percentage of CE inventory value; (b) Total number of preventive maintenance (PMs) completed per month versus total number of PMs scheduled in a month; (c) CE service cost over the last fiscal year versus the total productive (worked) staff hours in that fiscal year. Upon further mathematical analysis of CE department

P. Kitcher, "Benchmarking Performance Improvement Indicators for the Clinical Engineering Department," Proceedings of the IEEE 32nd Annual Northeast Bioengineering Conference, Easton, PA, USA, 2006, pp. 137-138, doi: 10.1109/NEBC.2006.1629790.

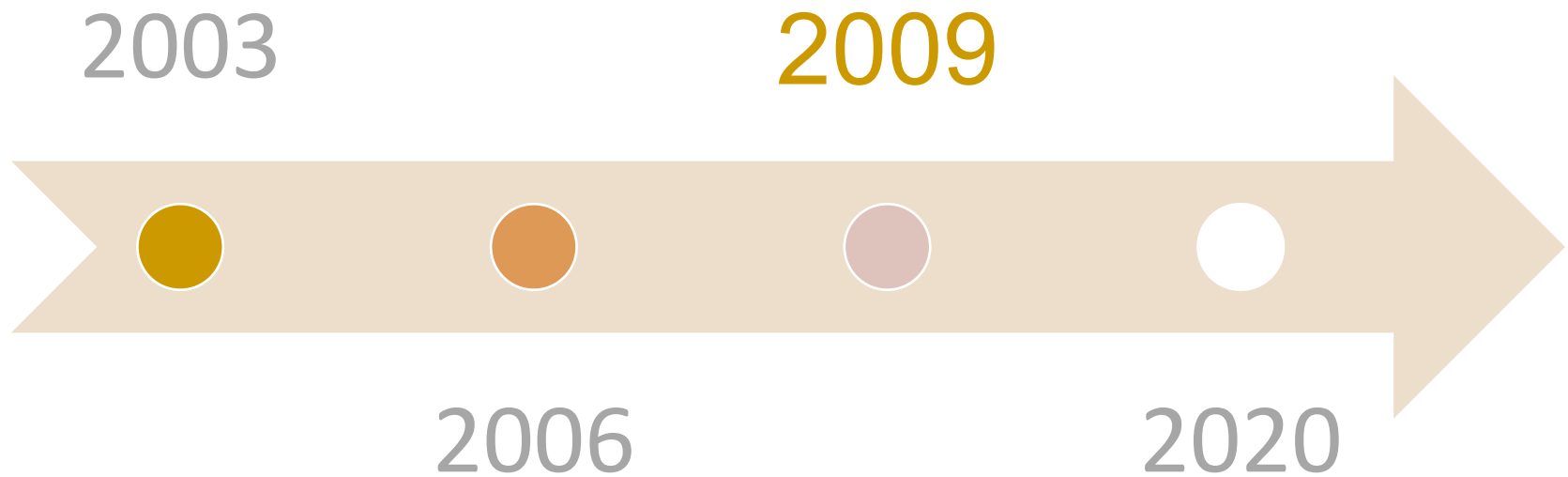


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Evolution of the discipline: KPIs and evidence



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2009



Joachim H. Nagel



[World Congress on Medical Physics and Biomedical Engineering, September 7 - 12, 2009, Munich, Germany](#) pp 397-400
[| Cite as](#)

Indicators for Evaluating and Measuring the Impact of Healthcare Infrastructure and Technology Management on Investments, Service Delivery and Quality of Care

Authors

[Authors and affiliations](#)

J. H. Nagel, M. Nagel

Conference paper

445

Downloads

Part of the [IFMBE Proceedings](#) book series (IFMBE, volume 25/12)

Abstract

Modern health care heavily relies on a whole range of health technologies that should be efficient, safe, cost effective and available to all people without causing a financial burden to the health care systems that would make them unachievable or unsustainable. Resources are often wasted on investments in health technologies that do not meet priority needs or are too complex, incompatible with the existing infrastructure and services, or too costly to maintain.

Nagel J.H., Nagel M. (2009) Indicators for Evaluating and Measuring the Impact of Healthcare Infrastructure and Technology Management on Investments, Service Delivery and Quality of Care. In: Dössel O., Schlegel W.C. (eds) World Congress on Medical Physics and Biomedical Engineering, September 7 - 12, 2009, Munich, Germany. IFMBE Proceedings, vol 25/12. Springer, Berlin, Heidelberg.
https://doi.org/10.1007/978-3-642-03893-8_115



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INDICATORS

There are different motivations and goals to use indicators in a study and, consequently, the indicators being used must be optimized to achieve the specific aims of the study. In this project we have three different questions to be answered:

1. the degree to which health care infrastructure and health technology management have been established on **local, regional and country levels**,
2. what the **impact is of healthcare infrastructure and technology management on investments, service delivery, quality of care and patient safety**, and
3. **how the functioning** of healthcare infrastructure and technology management as well as their impact on the quality of care **can be measured and improved**.

EVIDENCE!

Nagel J.H., Nagel M. (2009) Indicators for Evaluating and Measuring the Impact of Healthcare Infrastructure and Technology Management on Investments, Service Delivery and Quality of Care. In: Dössel O., Schlegel W.C. (eds) World Congress on Medical Physics and Biomedical Engineering, September 7 - 12, 2009, Munich, Germany. IFMBE Proceedings, vol 25/12. Springer, Berlin, Heidelberg. https://doi.org/10.1007/978-3-642-03893-8_115



Indicator Development Process

A literature search for published, commonly cited and accepted indicators for evaluating and measuring the impact of healthcare infrastructure and technology management on investments, service delivery and quality of care was done without much success.

Thus, a whole new set of indicators was developed by the authors.

Looking at the aims and goals of this project it becomes obvious that there should be four different baskets of indicators for:

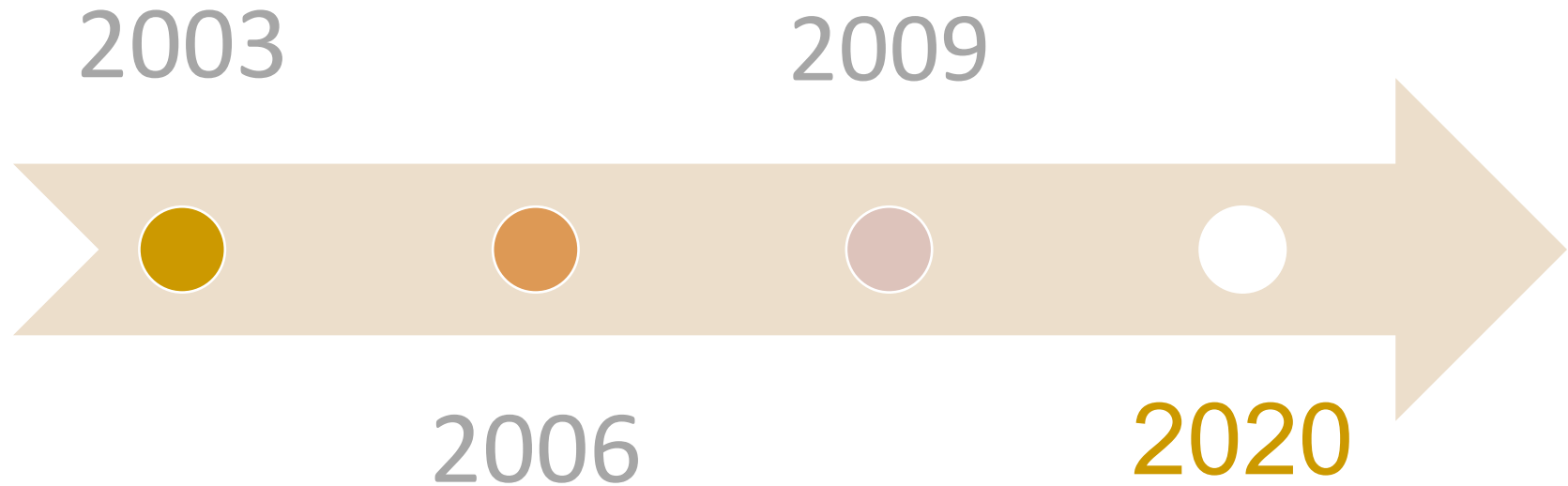
1. the implementation of HTM,
2. the quality of HTM,
3. the impact of HTM on the investment / use of resources, and
4. the impact of HTM on the quality of care and patient safety.

Nagel J.H., Nagel M. (2009) Indicators for Evaluating and Measuring the Impact of Healthcare Infrastructure and Technology Management on Investments, Service Delivery and Quality of Care. In: Dössel O., Schlegel W.C. (eds) World Congress on Medical Physics and Biomedical Engineering, September 7 - 12, 2009, Munich, Germany. IFMBE Proceedings, vol 25/12. Springer, Berlin, Heidelberg. https://doi.org/10.1007/978-3-642-03893-8_115



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Evolution of the discipline: KPIs and evidence



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2020

EDITOR-IN-CHIEF
ERNESTO IADANZA

CLINICAL ENGINEERING HANDBOOK

SECOND EDITION



Chapter 41

CE-HTM indicators

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Update

The 2004 first edition clinical engineering (CE) handbook focused on individual CE department performance improvement indicators or measures of performance, as are utilized in a typical first world country. The second edition focuses on CE-health technology management (HTM) indicators used by developing countries at the national Ministry of Health (MoH), central, and local facility levels. This update is primarily based on a World Health Organization (WHO)-The Pan American Health Organization (PAHO) study in 2009.

Background (Nagel et al., 2009)

There are ways to measure positive effects on the availability, access, capability, and perceived quality of healthcare services.

- These physical advances have often not been matched by an equal advancement of
- related policies, institutional capacities, planning, managerial and technical aptitudes, and recurrent operating budget
- This undermines major capital investments and technical contributions at country level.
- This is one of the most critical system-wide barriers to scaling up priority health interventions and achieving the WHO's Millennium Development Goals (MDGs).

- Recommend and implement system changes and operational improvements including
 - institutional and technical capacity development,
 - ongoing support to healthcare infrastructure and technology policy implementation,
 - institutionalization of HTM seamlessly integrated into the overall health system and services policy, planning, and management.

Objective (Nagel et al., 2009)

The objective is to define and develop models to assess and predict the impact of healthcare infrastructure, technology allocation, and investments at local and country levels. Indicators:

- Implementation of CE and HTM process indicators.
- Quality of CE-HTM outcome indicators

Definitions (Health Technologies Resource, 2016)

Health technology (HT)

Application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures, and systems is developed to solve a health problem and improve the quality of lives (https://www.who.int/healthsystems/WHA60_29.pdf).

Evidence Based Maintenance (EBM)

EBM proposed definition by Binseng Wang (2010):

“A continual improvement process that analyses the effectiveness of maintenance resource deployed in comparison to outcomes achieved previously or elsewhere, and makes necessary adjustments to maintenance planning and implementation”





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A set of indicators for management and maintenance of medical technologies



Evidence-based medical equipment management: a convenient implementation

Ernesto Iadanza, Valentina Gonnelli, Francesca Satta & Monica Gherardelli

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ORIGINAL ARTICLE



Evidence-based medical equipment management: a convenient implementation

Ernesto Iadanza¹ · Valentina Gonnelli¹ · Francesca Satta² · Monica Gherardelli¹

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Abstract

Maintenance is a crucial subject in medical equipment life cycle management. Evidence-based maintenance consists of the continuous performance monitoring of equipment, starting from the evidence—the current state in terms of failure history—and improvement of its effectiveness by making the required changes. This process is very important for optimizing the use and allocation of the available resources by clinical engineering departments. Medical equipment maintenance is composed of two basic activities: scheduled maintenance and corrective maintenance. Both are needed for the management of the entire set of medical equipment in a hospital. Because the classification of maintenance service work orders reveals specific issues related to frequent problems and failures, specific codes have been applied to classify the corrective and scheduled maintenance work orders at Careggi University Hospital (Florence, Italy). In this study, a novel set of key performance indicators is also proposed for evaluating medical equipment maintenance performance. The purpose of this research is to combine these two evidence-based methods to assess every aspect of the maintenance process and provide an objective and standardized approach that will support and enhance clinical engineering activities. Starting from the evidence (i.e. failures), the results show that the combination of these two methods can provide a periodical cross-analysis of maintenance performance that indicates the most appropriate procedures.

Keywords Evidence-based maintenance · Health technology management · Key performance indicators · Medical equipment · Clinical engineering

1 Introduction

Today's rapid and continuous technological evolution, which affects most production sectors, also involves healthcare. Indeed, healthcare technologies have become an essential part of the provided services, as they play increasingly significant roles in the diagnosis and treatment of patients.

The complexity of the technological assets found in healthcare facilities, in terms of number and diversity, is reflected in the complexity of technology management, which must be efficient so that the equipment can always be used safely and appropriately. From this perspective, maintenance

is a key process throughout the life cycle of every medical device. Maintenance planning requires the assessment of a number of parameters, including how a piece of equipment is used, how often it is used, its intended use, risk associated with its usage and its failure rates.

There are two main types of maintenance required for medical equipment in all hospitals: scheduled maintenance (SM) and corrective maintenance (CM). SM, in compliance with the manufacturer's instructions, includes the operations performed at scheduled times to reduce deterioration from use (often referred to as "preventive maintenance") or the occurrence of functional failures. CM comprises the repair of the equipment's functions (i.e. its restoration) as well as its replacement when repair is not feasible due to costs or obsolescence [15].

Maintenance is also a crucial aspect of the activities in a hospital's clinical engineering (CE) department because it involves significant human and financial resources. Therefore, the assessment of the effectiveness of any maintenance programmes is strictly linked to the optimization of the use of available resources in CE departments [20].

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We needed data
(evidence!) for proving
the EBM approach

- *University Hospital of CAREGGI
(Florence)*
- 1500 beds
- **16200 pieces of equipment**
- 5600 employees
- 54000 hospital admissions
- 128000 access to the emergency
room



Data analysis

13 classes of medical equipment analysed

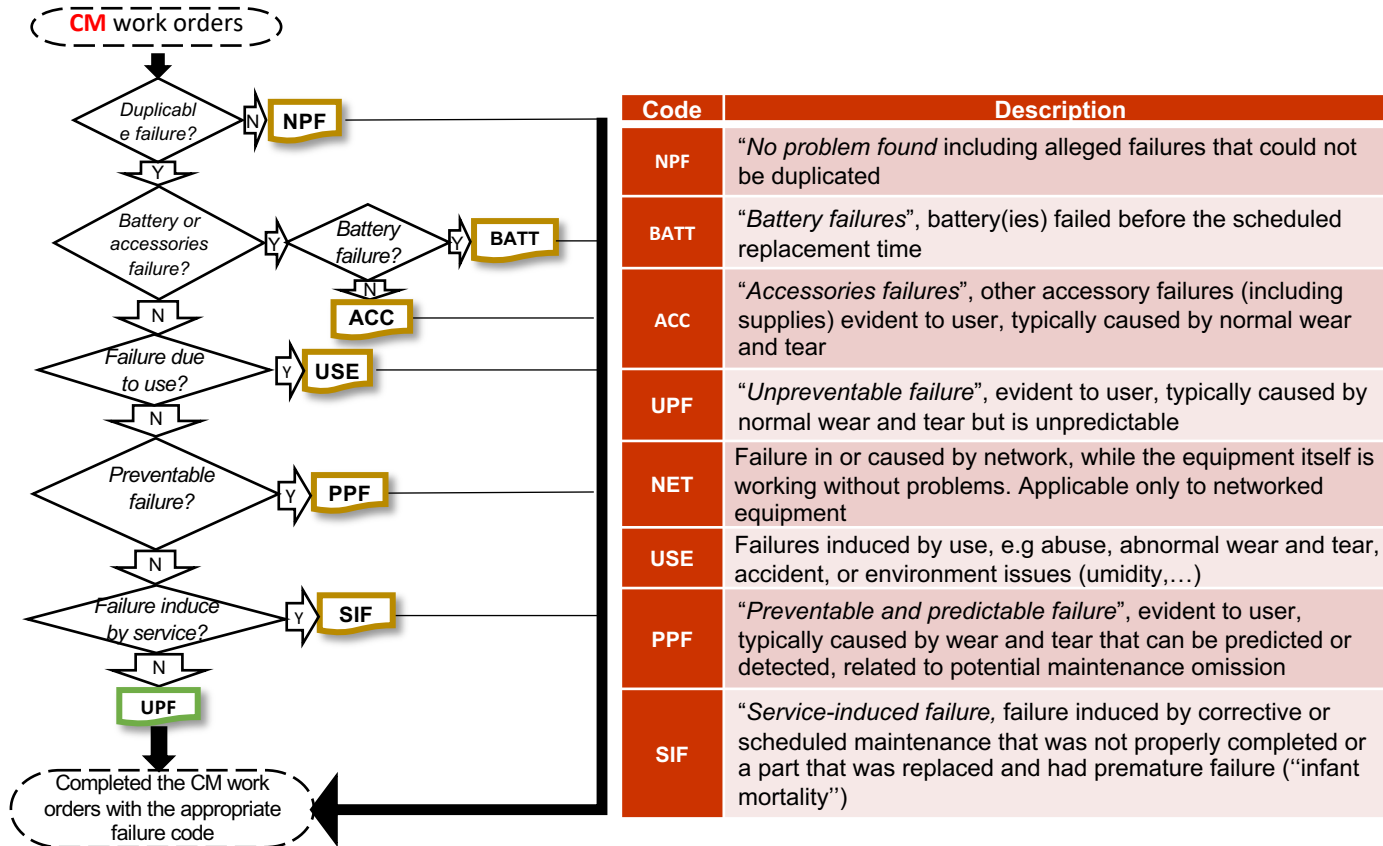
2 critical areas: Operating Room (**OR**) and Intensive Care Unit (**ICU**)

Time span: 5 years

Medical equipment	CIVAB class	Units	Total CM work orders	Total SM work orders	OR & IC work orders (CM)	OR & IC work orders (SM)	CM work orders coded	% of CM eliminated
Anesthesia machine	ANS	87	802	491	668	444	593	11,23%
Aspirator	ACH	183	160	287	25	42	20	20,00%
Monitoring central	CMO	44	212	147	120	87	114	5,00%
Defibrillator	DEF	282	1.463	2.036	559	709	438	21,65%
Electrosurgery unit	ELB	109	287	408	219	342	181	17,35%
Electrocardiograph	ECG	236	1.384	947	170	148	155	8,82%
Surgical lamp	LSC	241	411	1.222	264	987	239	9,47%
Monitor	MON	669	1.294	3.337	599	1.794	547	8,68%
Ceiling mounted unit	PSO	291	284	522	242	386	165	31,82%
Pulse Oximeter	OOR	445	557	1.120	120	297	110	8,33%
Surgical table	TOP	65	520	382	435	211	349	19,77%
Telemetry	UTC	78	99	142	61	51	59	3,28%
Ventilator	VPO	142	796	831	685	748	611	10,80%
TOT		2872	8269	11872	4167	6246	3581	14,06%

Classification of maintenance work orders: Assigning Failure Codes

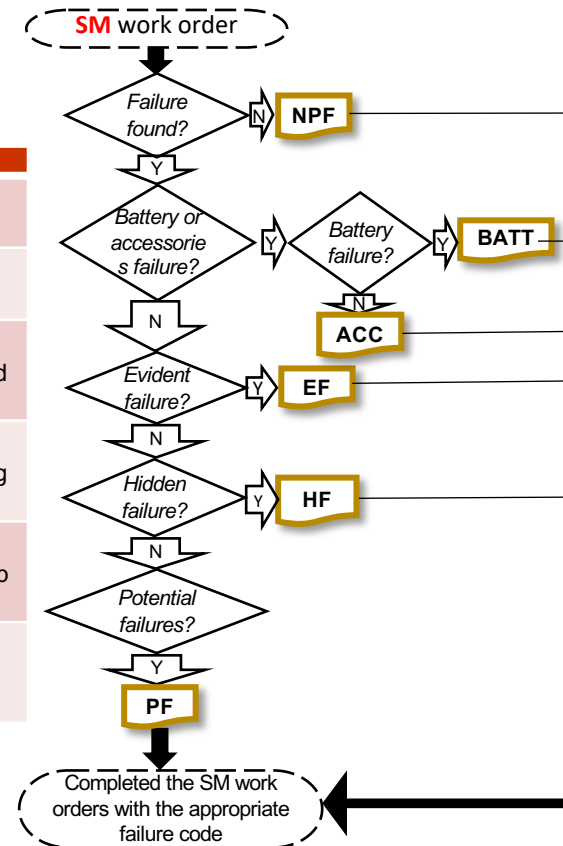
[Wang B, Fedele J et al. (2010) Evidence-based maintenance: part I-measuring maintenance effectiveness with failure codes. *Journal of Clinical Engineering*]

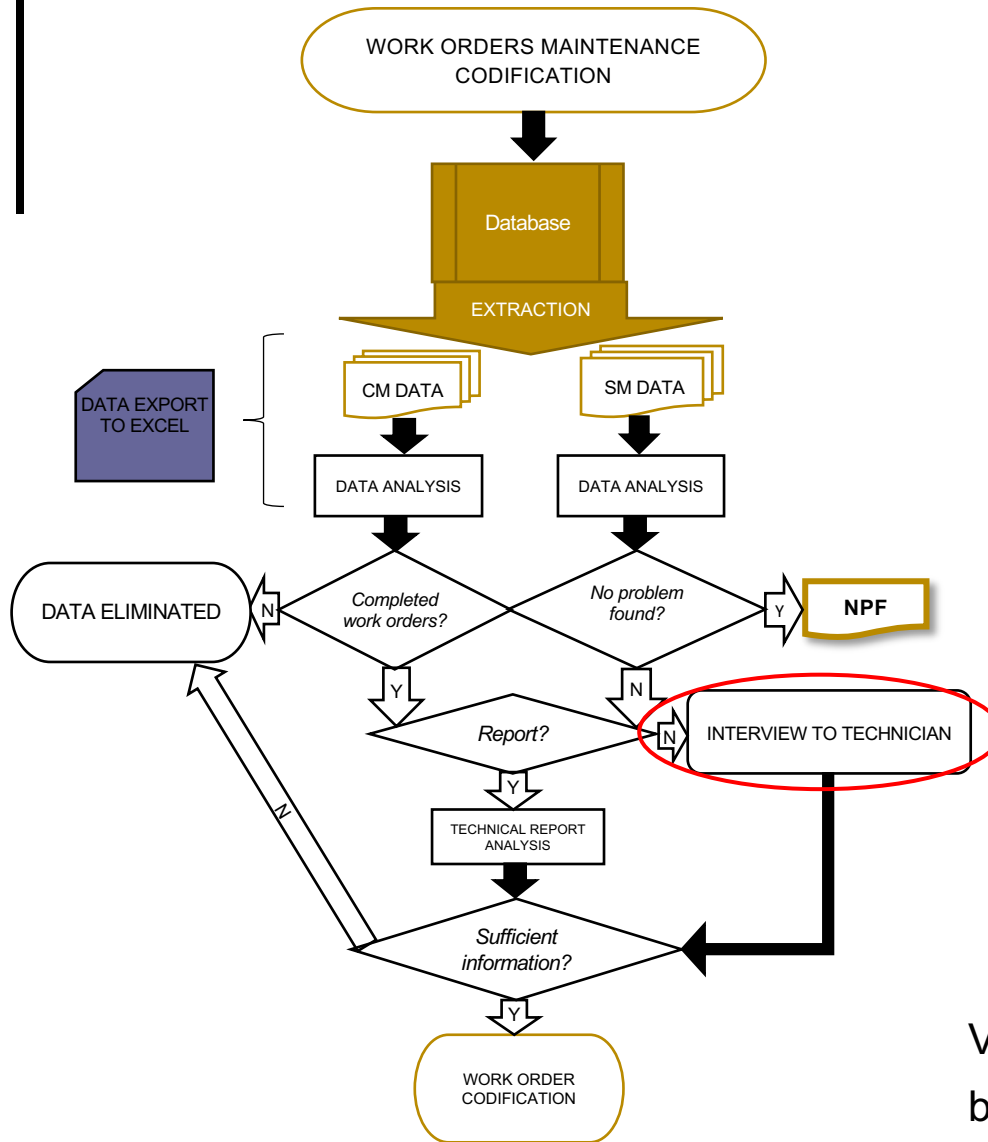


Classification of maintenance work orders: Assigning Failure Codes

[Wang B, Fedele J et al. (2010) Evidence-based maintenance: part I-measuring maintenance effectiveness with failure codes. *Journal of Clinical Engineering*]

Code	Description
NPF	"No problem found" including alleged failures that could not be duplicated
BATT	"Battery failures", battery(ies) failed before the scheduled replacement time
ACC	"Accessories failures", other accessory failures (including supplies) evident to user, typically caused by normal wear and tear
EF	"Evident failure", a problem that can be detected but was not reported by the user without running any special tests or using specialized test/measurement equipment
PF	"Potential failure", failure is either about to occur or in the process of occurring but has not yet caused equipment to stop working or problems to patients or users (frayed power cord)
HF	"Hidden failure", a problem that could not be detected by the user unless running a special test or using specialized test/measurement equipment (out of calibration, failed EST)





Valentina Gonnelli, MSc,
beatification ceremony 🙏



A set of 20 KPIs was defined (Financial, Technological, Organizational)



Original Article | [Open Access](#) | Published: 10 August 2019

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Medical & Biological Engineering & Computing 57, 2215–2230 (2019) | [Cite this article](#)

Technological

KPI 1 DOWNTIME	KPI 3 MTTR	KPI 5 CLASS FR
KPI 2 UPTIME	KPI 4 MTBF	KPI 6 GFR
KPI 7 AFR		

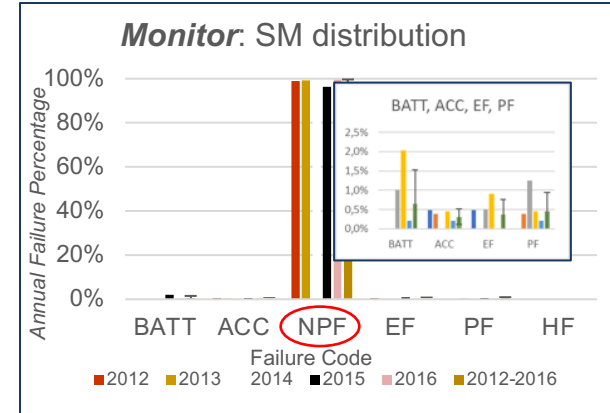
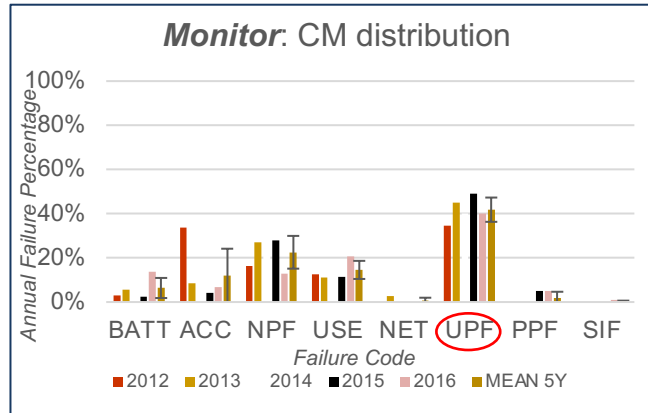
Organizational

KPI 8 NEGLIGENT WO	KPI 9 1 DAY WO	KPI 10 SM WITH PROBLEM
KPI 11 COVERAGE RATE OF SM	KPI 12 FALSE FAILURES	KPI 13 N° DEVICES PER TEC
KPI 14 CM HOURS VS SM HOURS		

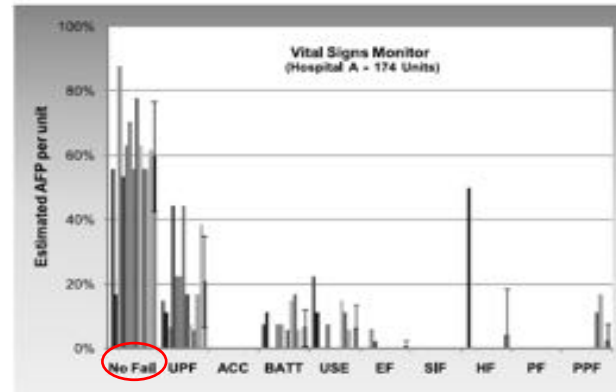
Financial

KPI 15 COSR	KPI 16 IN HOUSE MAINT	KPI 17 EXT MAINT
KPI 18 CM COST	KPI 19 SM COST	KPI 20 SPARE PARTS COST

Results compared to literature



[Iadanza E et al. (2019) Evidence-based medical equipment management: a convenient implementation. Medical & Biological Engineering & Computing]

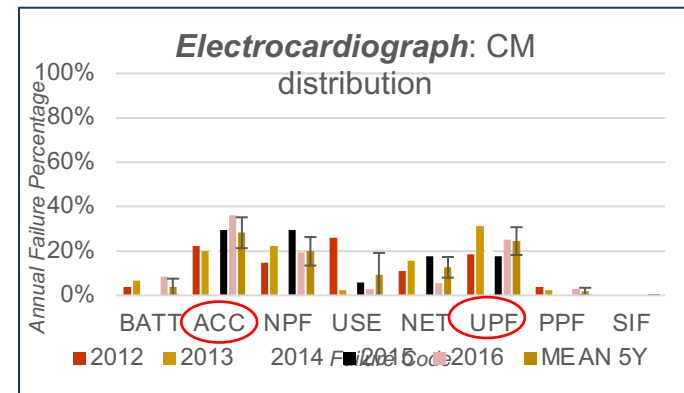
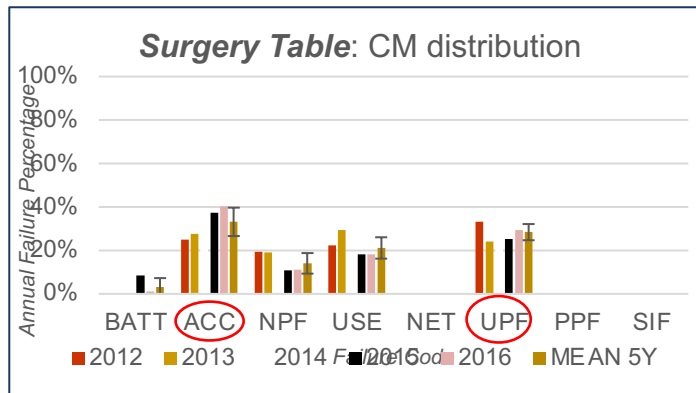


[Wang B, Fedele J et al. (2010) Evidence-based maintenance: part I-measuring maintenance effectiveness with failure codes. Journal of Clinical Engineering]



Plan supply chain and SM activities according to evidence from CM!

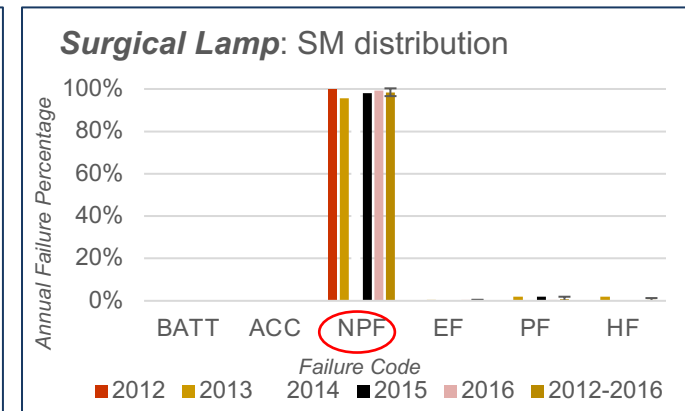
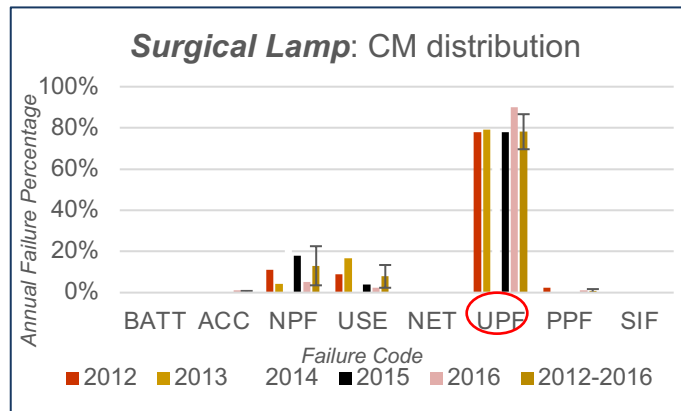
E.g.: Evidence for surgery tables and ECGs shows that most failure are unpreventable (UPF) or related to accessories (ACC):



[Iadanza E et al. (2019) Evidence-based medical equipment management: a convenient implementation. Medical & Biological Engineering & Computing]

Plan supply chain and SM activities according to evidence from CM!

E.g.: Evidence for surgical lamps show that most failures are unpreventable (UPF) and not encountered during scheduled maintenance (NPF):



[Iadanza E et al. (2019) Evidence-based medical equipment management: a convenient implementation. Medical & Biological Engineering & Computing]



EBM starts to be proposed in CE public tenders for global services

1. Metodologia di EVIDENCE BASED MAINTENANCE (EBM)

Al fine di implementare un metodo di lavoro che consenta di monitorare costantemente e di fornire alla stazione appaltante una completa fotografia in *real-time* delle prestazioni di manutenzione preventiva e correttiva, il RTI adotterà l'approccio denominato *EVIDENCE BASED MAINTENANCE* (EBM).

[...]

Questo approccio, proposto a livello mondiale da Wang et al. nel 2010 e riproposto con una applicazione pratica in Italia nel 2019 da Iadanza et al. consiste nella raccolta di evidenze durante le operazioni di manutenzione preventiva e correttiva e nella successiva analisi di un set di indicatori di prestazione, o *Key Performance Indicators* (KPI) al fine di mantenere sempre sotto controllo il processo, ma anche di pianificare eventuali azioni correttive quali per esempio il progetto e realizzazione di interventi formativi mirati o l'approfondimento di situazioni critiche insieme il SIC, agli utilizzatori ed eventualmente ai fabbricanti.

Il RTI propone l'implementazione di tale metodologia con un doppio approccio:

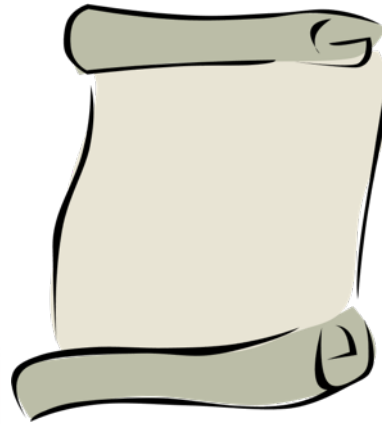
Wang, B., Fedele, J., Pridgen, B., Williams, A., Rui, T., Barnett, L., ... & Poplin, B. (2010). Evidence-based maintenance: part I: measuring maintenance effectiveness with failure codes. *Journal of Clinical Engineering*, 35(3), 132-144.

Iadanza, E., Gonnelli, V., Satta, F., & Gherardelli, M. (2019). Evidence-based medical equipment management: a convenient implementation. *Medical & biological engineering & computing*, 57(10), 2215-2230.





EBM starts to be proposed in CE public tenders for global services



Code	Description	CM/SM
NPF	No problem found	both
BATT	Battery failure	both
ACC	Accessory failure (including supplies)	both
NET	Failure related to network	CM
USE	Failure induced by use (i.e. abuse, accident, environment conditions)	CM
UPF	Unpreventable failure caused by normal wear and tear	CM
PPF	Predictable and preventable failure	CM
SIF	Induced by service (i.e. caused by a technical intervention not properly completed or premature failure of a part just replaced)	CM
EF	Evident failure (i.e. evident to user but not reported)	SM
PF	Potential failure (i.e. in process of occurring)	SM
HF	Hidden failure (i.e. not detectable by the user unless special test or measurement equipment)	SM

- ✓ Integrazione delle funzionalità di GAEM 2.0 con la possibilità di classificazione dei guasti alla chiusura dell'intervento da parte del tecnico, conformemente al seguente schema di codifica internazionale², dove con SM si indica la manutenzione preventiva (*Scheduled Maintenance*) e con CM la correttiva (*Corrective Maintenance*):

Received March 15, 2021, accepted April 23, 2021, date of publication April 28, 2021, date of current version May 7, 2021.

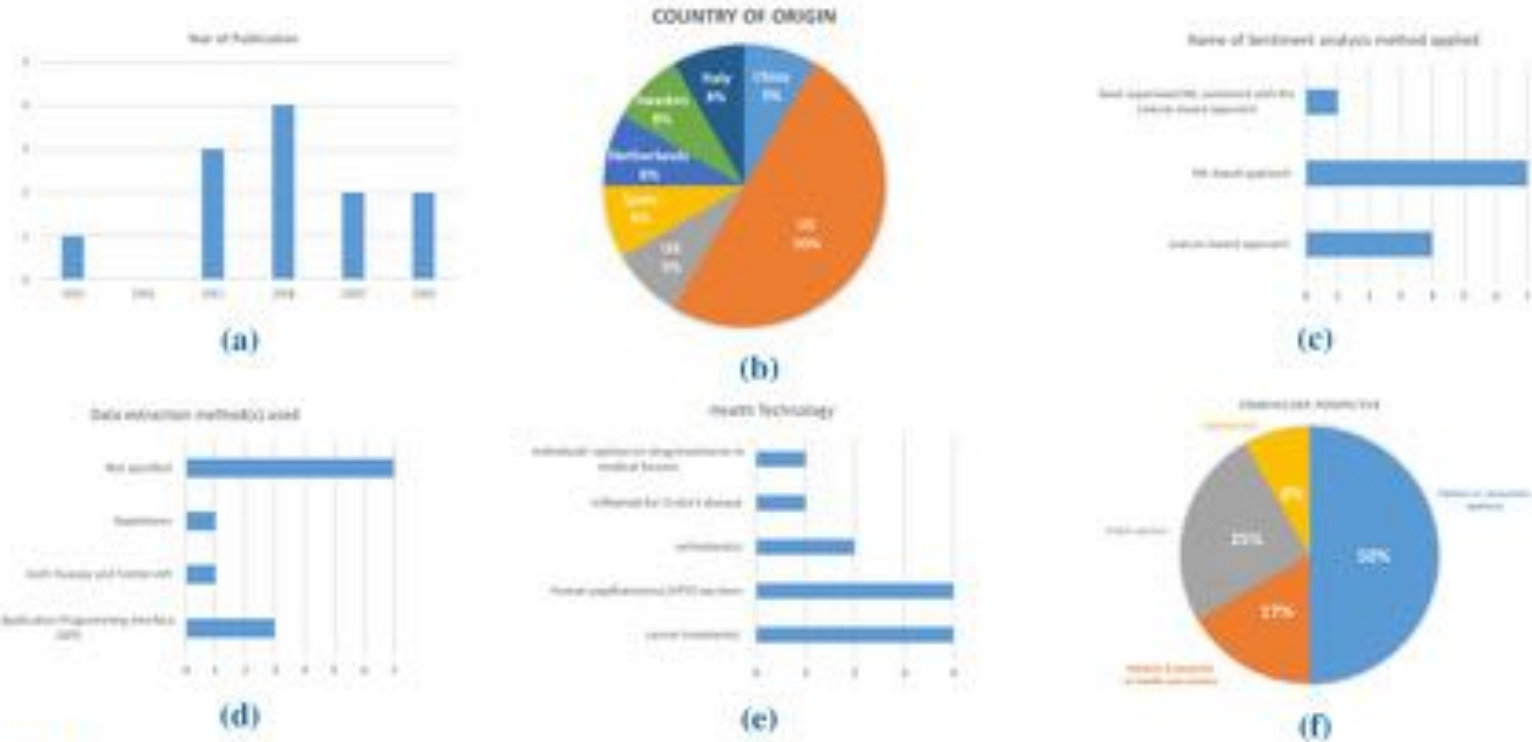


FIGURE 2. Graphical analysis of results. (a) The histogram presents the number of publications between 2015 and 2020. (b) The pie chart presents the country of publication of the selected studies. (c) The histogram illustrates the SA methods/techniques applied by the authors. (d) The histogram shows the data extraction method(s) used. (e) The histogram presents the health technologies assessed in the included studies. (f) The pie chart illustrates the proportion of stakeholder perspectives presented across the studies.



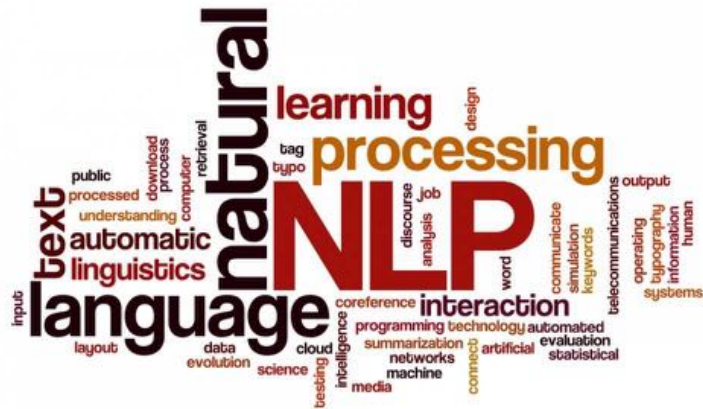
FIGURE 2. Graphical analysis of results. (a) The histogram presents the number of publications between 2015 and 2020. (b) The pie chart presents the country of publication of the selected studies. (c) The histogram illustrates the SA methods/techniques applied by the authors. (d) The histogram shows the data extraction method(s) used. (e) The histogram presents the health technologies assessed in the included studies. (f) The pie chart illustrates the proportion of stakeholder perspectives presented across the studies.

online and social media, and healthcare materials for applications that range from marketing to customer service to clinical medicine.

https://en.wikipedia.org/wiki/Sentiment_analysis



Natural Language Processing can be used to extract knowledge from text docs



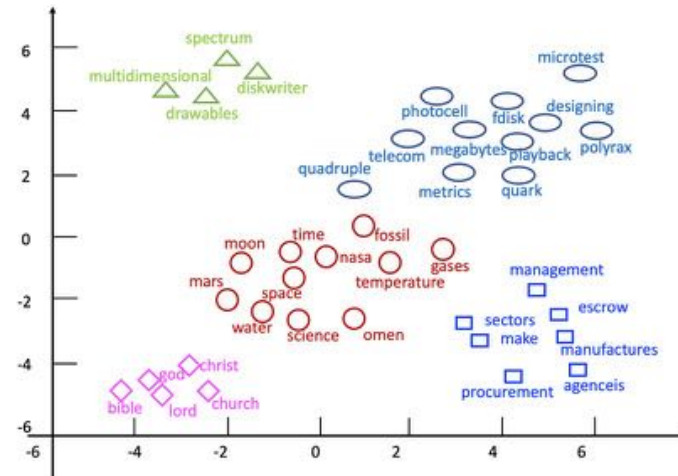
Clinical Entity Recognition	Clinical Entity Linking	Assertion Status	Relation Extraction
<p>40 UNITS DOSE of insulin glargine DRUG at night FREQUENCY</p>	<p>Suspect diabetes SNOMED-CT 40222008 Linking to MC Diabetes 11838 Hyponatremia ICD-10 E870</p>	<p>Fever and sore throat → PRESENT No stomach pain → ABSENT Father with Alzheimer → FAMILY</p>	<p>Admitted for Review due to Chemo Documented Examination Treatment AFTER CAUSED BY</p>

Natural Language Processing

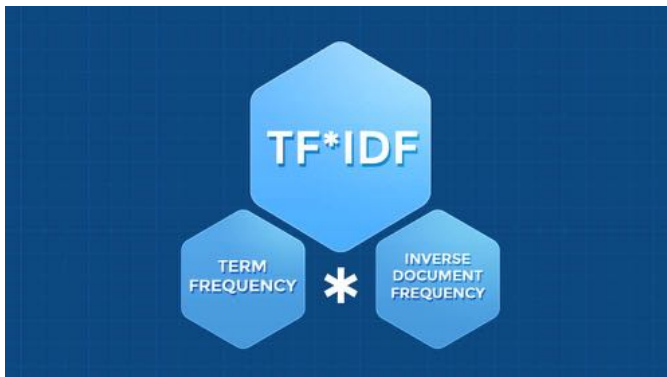
Bag of Words



Word Embedding



Term Frequency – Inverse Document Frequency



Language Models





UNIVERSITÀ
DI SIENA
1240

Spontaneous Reporting Systems



VAERS

stands for

Vaccine Adverse Event
Reporting System

FAERS

stands for

FDA Adverse Event Reporting
System

MAUDE

stands for

Manufacturer And User
facility Device Experience
database



MHRA
Regulating Medicines and Medical Devices



EUDAMED
EUROPEAN DATABANK ON MEDICAL DEVICES



XLI Annual School 2022 – Biomedical
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MAUDE Adverse Event Report: SMITH & NEPHEW, INC. SPATIALFRAME.COM SOFTWARE SOFTWARE FOR DIAGNOSIS/TREATMENT



◉ FDA Home ◉ Medical Devices ◉ Databases



31990 | De Novo | Registration & Listing | Adverse Events | Recalls | PMA | IDE | Classification | Standards
CFR Title 21 | Radiation-Emitting Products | X-Ray Assembler | Medical Reports | CLIA | TPLC

SMITH & NEPHEW, INC. SPATIALFRAME.COM SOFTWARE SOFTWARE FOR DIAGNOSIS/TREATMENT

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Catalog Number 71070401

Device Problem Application Program Problem (2880)

Patient Problem No Clinical Signs, Symptoms or Conditions (4582)

Event Date 02/08/2021

Event Type malfunction

Manufacturer Narrative

The device, used for treatment was not returned for evaluation, reporting event could not be confirmed. A complaint is for the iadjust mobile application, which is a component of taylor spatial frame software, therefore no devices will be returned for evaluation. No screenshots or log files, used in treatment, were provided for review. There is no information that would suggest the device/software failed to meet specifications. A relationship, between the device/software and the reported incident could be corroborated. This event has been communicated to the taylor product development engineer for their consideration. No further investigation is warranted for this event. Possible cause could include but is not limited to software not programmed correctly. Based on this investigation, the need for corrective action is not indicated. If additional information is received, the complaint will be re-opened. This investigation is considered closed.

Event Description

It was reported that the surgeon wanted to use software for treatment of the taylor spatial frame software. The surgeon navigated to www. Spatialframe. Com at the beginning of a surgery case, because the surgeon wanted to use the chronic mode in the software to ensure he was building an optimized frame. Both the surgeon and the sales representative were unable to login. The incident occurred prior to logging in. The login screen was not available. There was a delay greater than 30 minutes for the adverse event. No injury reported.

[Search Alerts/Recalls](#)

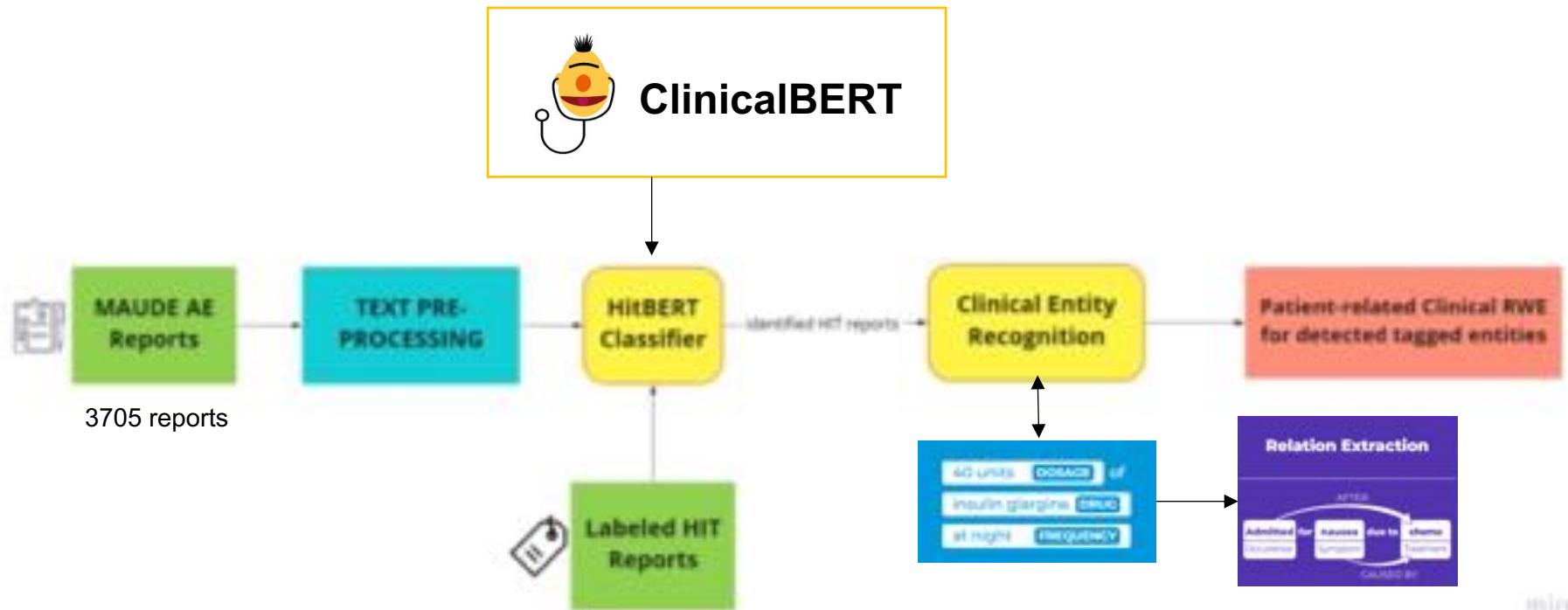


Health Information Technology (HIT) Adverse Events

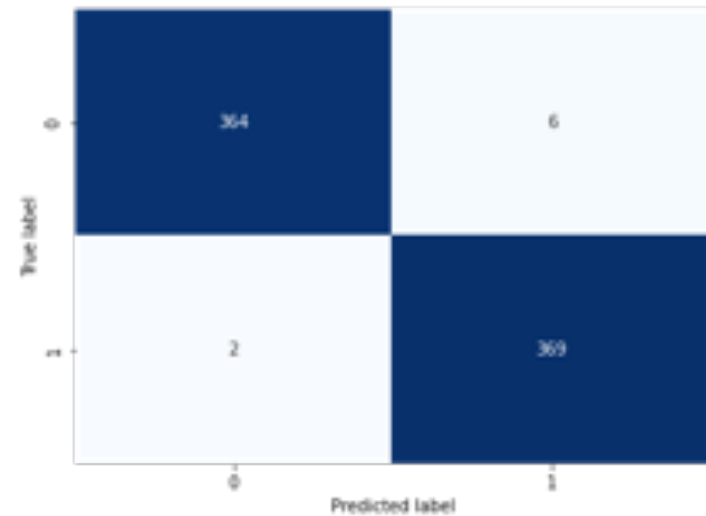
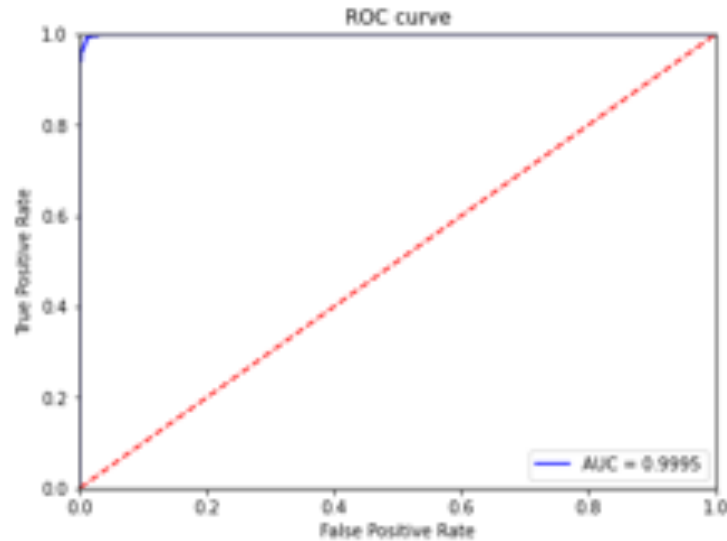


Kang, H., Gong, Y., *Creating a database for health IT events via a hybrid deep learning model*, *Journal of Biomedical Informatics*, Volume 110, 103556, 2020, <https://doi.org/10.1016/j.jbi.2020.103556>.

Identifying fault causes from HIT reports



Preliminary results for HIT classification with NLP



Testing metrics:

- Accuracy: 0.9892
- Precision: 0.9840
- Recall: 0.9946
- Specificity: 0.9838
- F1 Score: 0.9893

Classification accuracy using BERT Fine Tuning (MCC): 97.85%