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Multi-criteria decision analysis as an effective and reliable tool for integrating Hospital RWD from different data sources

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Event Website: https://www.globalcea.org/icehtmc

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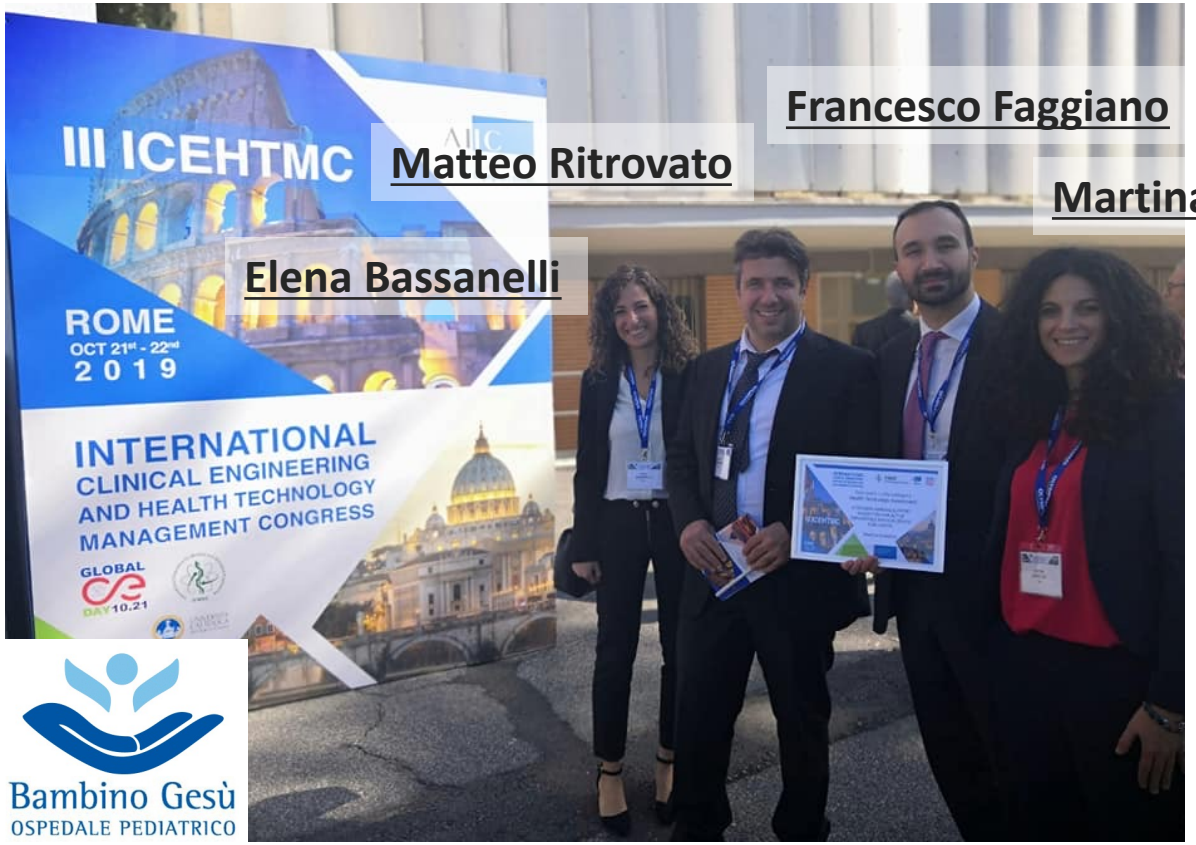

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Real World Data for Hospital-Based Health Technology Assessment

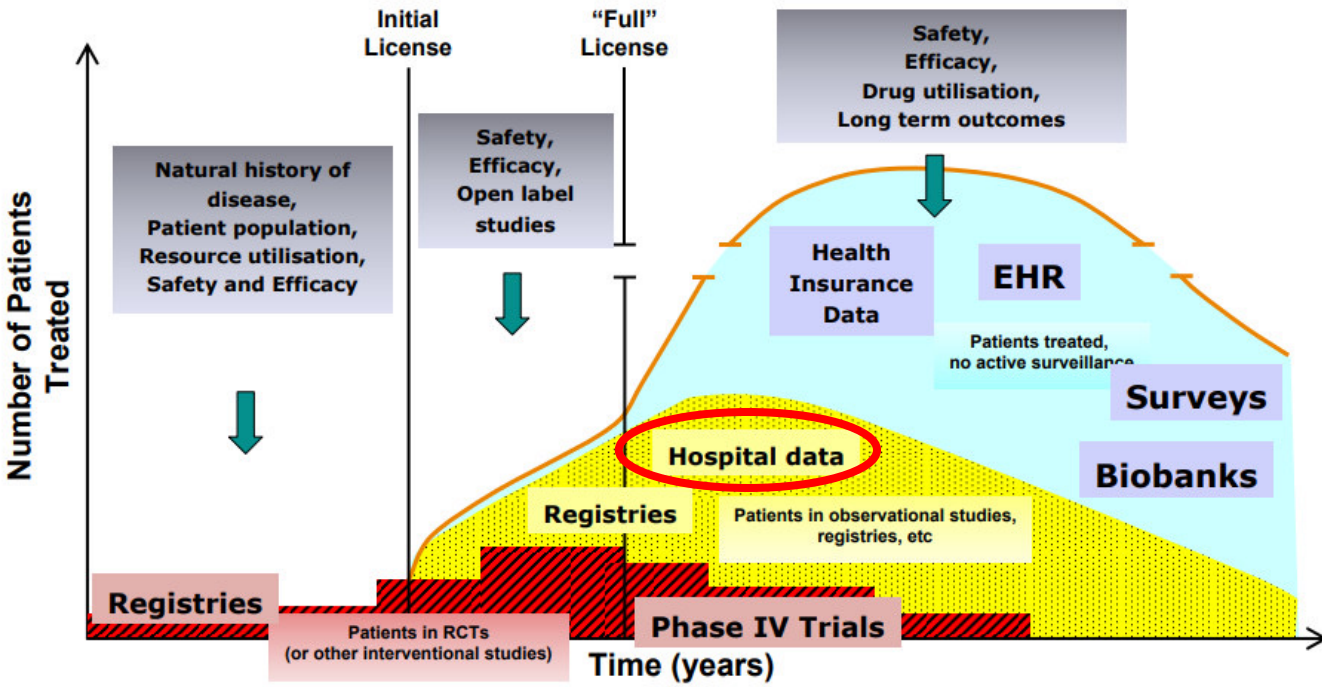
THE CLUE TO WHY RWD IS AN IMPORTANT COMPONENT OF ANY ESTIMATION OF COST-EFFECTIVENESS IS IN THE NAME: THE DEFINITION OF EFFECTIVENESS, AS OPPOSED TO EFFICACY, REFERS TO THE MEASUREMENT OF EFFECTS IN THE REAL-WORLD, RATHER THAN UNDER THE CONDITIONS OF EXPERIMENTATION REQUIRED FOR THE UNBIASED MEASUREMENT OF EFFICACY.

Real World Data relevance in Hospital Setting

RWD are relevant in Hospital to:

- Carry out Health technology Assessment Processes that are dependant on RWE when outcomes are not available from RCTs
- Conduct more precise economic analyses (Cost-effectiveness Analysis, Budget impact analysis,…)
- Evaluate health product implication on patient management in real-life setting

Hospital Real World Data



Variables	RCTs	RW studies
STANDARD OF EVIDENCE	Gold standard	Supplementary to RCTs
VALIDITY	High internal validity	High external validity (generalizability to real-world practice)
STUDY GROUP	Homogeneous highly selective population: patients are based on stringent inclusion and exclusion criteria	Heterogeneous population in clinical practice (patients at high risk of adverse events, pregnant women, children and elderly people, patients with comorbidities, those who receive different medications for other morbidities)
SAMPLE SIZE	Limited	Larger
ADVERSE EVENTS	Reveal the more frequent adverse events	Can reveal less frequent adverse events and those that can occurred after long exposure
FOLLOW UP	Designed, short period and highly controlled follow-up	In clincal pracrtice, long follow-up period able to assess rare, long-term adverse events
PURPOSE	Efficacy: identify the causal relationship between intervention and changes in clinical conditions	Effectiveness: doesn't show whether the technology works but if it can work in actual clinical practice
SETTING	Experimental setting	Real world setting
COMPARATOR	Placebo	Many alternatives intervention/non-treatment users
STUDY DESIGN	Prospective	Retrospective/Perspective
TYPE OF STUDY	Experimental/Interventional	Observational/non-interventional
OUTCOMES	Clear sequence	Wide range
RANDOMIZATION	Yes	No
BLINIDING	Yes	No
COSTS	Expensive to develop and conduct	Low if the study is retrospective, comparable to RCTs if the study is perspective
CONFOUNDERS	Standardized, controled	Bias: selection, information, recall, detection
APPROVAL OR CLEARANCE OF NEW MEDICAL DEVICE PRODUCT	Gold standard, when feasible for new device approval	Can complement RCT findings, accepted for new device indications, might ease post-marketing surveillance of adverse events
LEARNING CURVE	Not considered	Could be controlled if it is konwn the intial physiscian experience
EHICAL ISSUES	It is strictly required	Mostly regards patient's privacy

Enterprise Content Management Systems

SURVEY
(HEALTH PROFESSIONALS, PATIENTS)

EMERGING TECHNOLOGIES
(WEARABLES, IOT, ETC..)

CLINICAL REGISTRIES

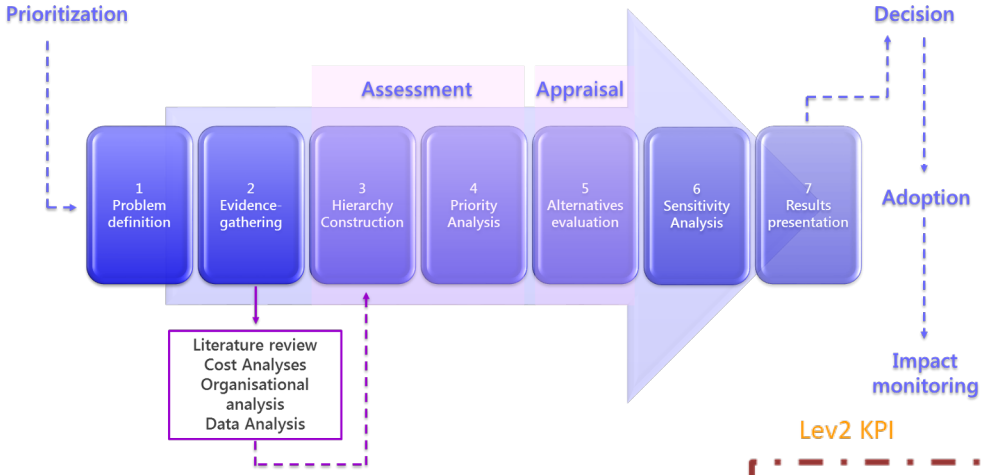
ELECTRONIC HEALTH/MEDICAL RECORDS

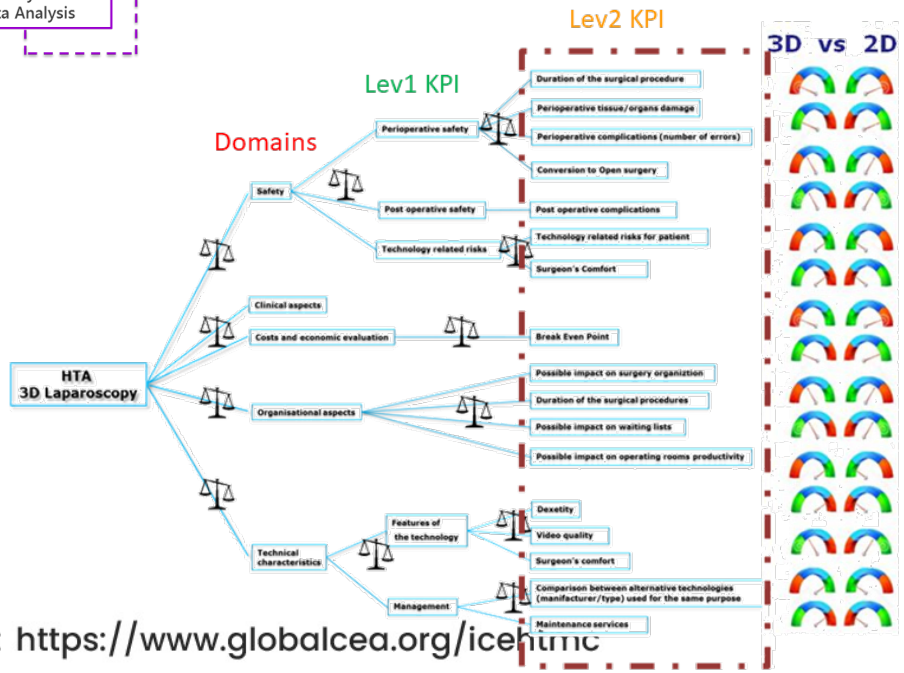
ADMINISTRATIVE/CLAIMS DATA

Objective

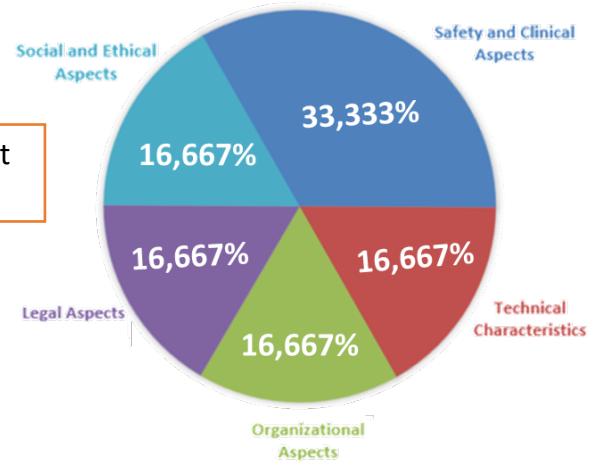
The aim of this work is to show a new approach to integrate, throughout Multi Criteria Decision Analysis based, different kind of Hospital Real-World Data, to obtain univocal and reliable results about the introduction of a new technology in a hospital setting.

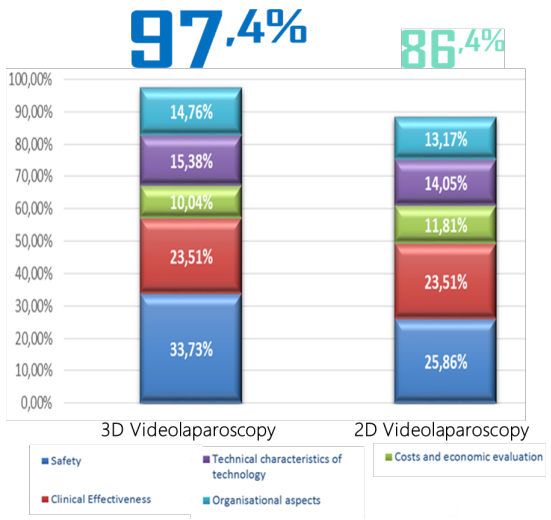
Decision oriented HTA (Do-HTA)





Overall Weight System





Performances Evaluation

Decision oriented HTA (Do-HTA)

SAFETY AND EFFECTIVENESS DATA

- Data from scientific literature
- Electronic Health Records
- Key Enabling Technologies (Wearables, IoT, etc..)

ORGANIZATIONAL AND ECONOMIC DATA

- Historical Time series from Hospital registries and databases (Administrative data)

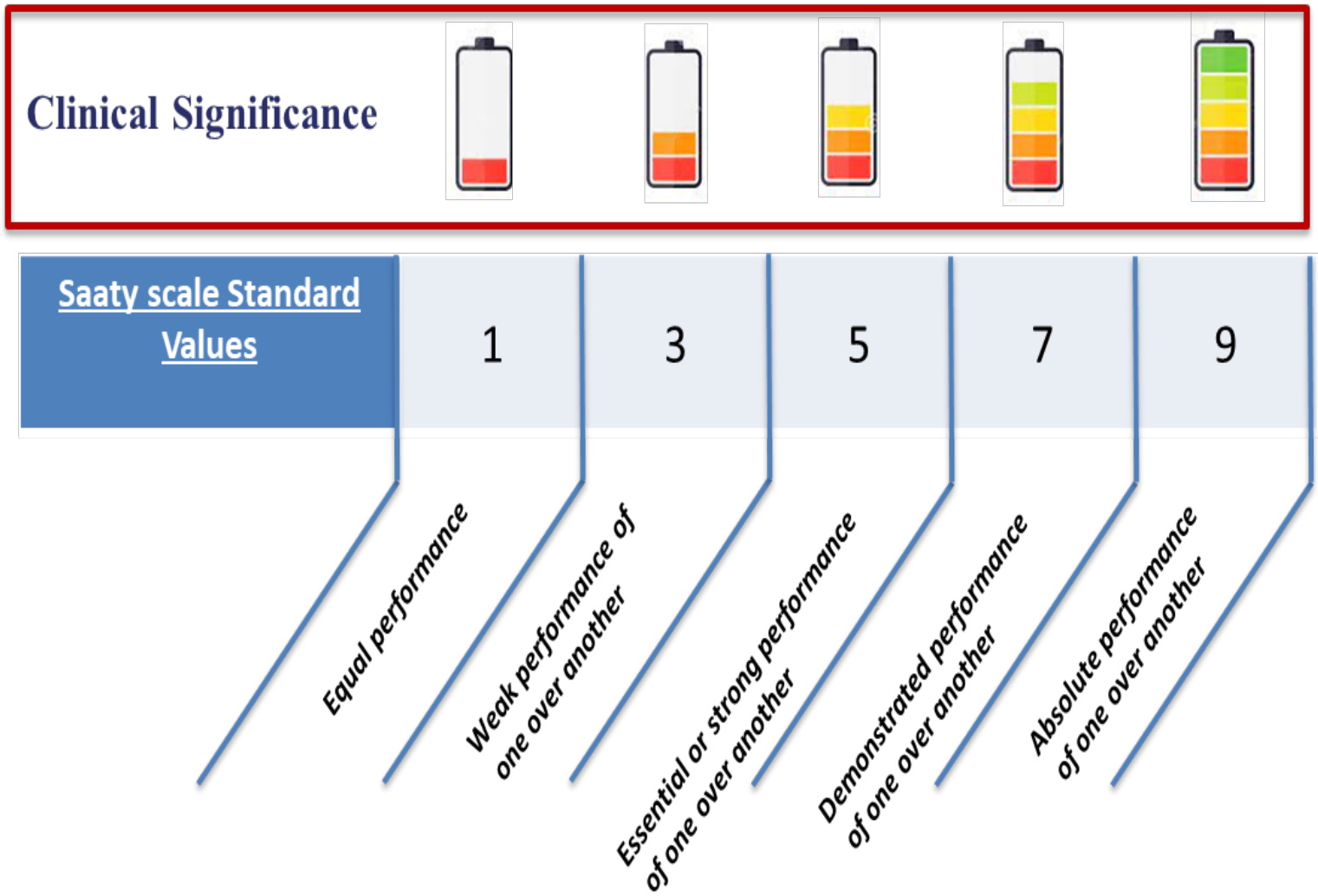
PATIENTS PERSPECTIVE AND SOCIAL ASPECTS

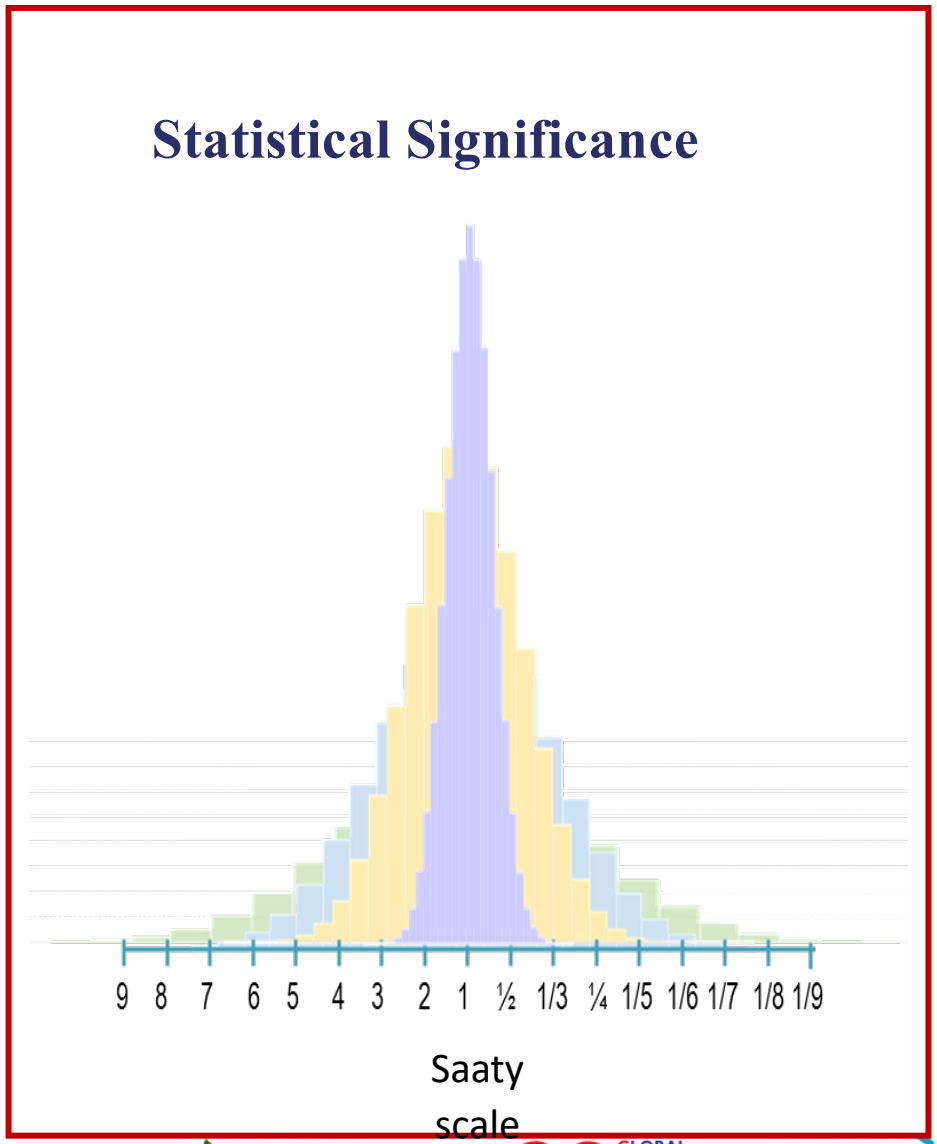
- Surveys
- Quality of Life

Clinical Significance & Statistical Significance

- **Statistical significance** implies that the **difference** seen in the sample also exists in the population.
- **Clinical significance** implies that the **difference** between treatments in effectiveness is **clinically** important, and it is possible that **clinical** practice will change if such a **difference** is seen.

Clinical Significance & Statistical Significance



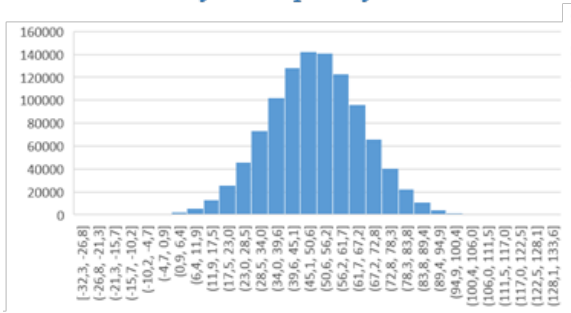


Evaluating Data Quality for Clinical Significance

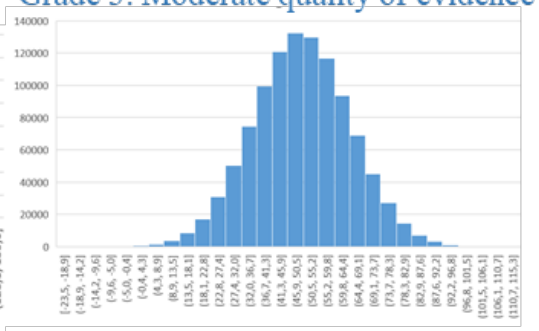
Data from scientific literature → GRADE Approach
Grading the Quality of Evidence

GRADE	Max probability	Standard deviation
1	0,2	1,99
2	0,43	0,92
3	0,67	0,598
4	0,9	0,44

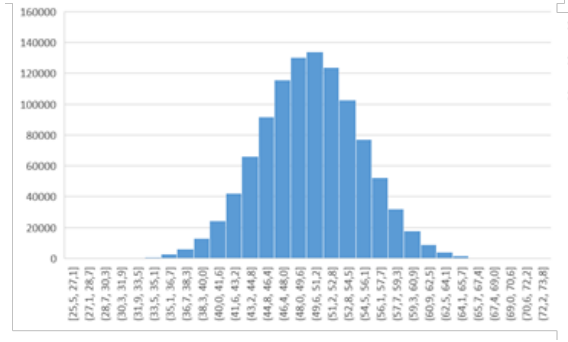
Grade 1: Very low quality of evidence



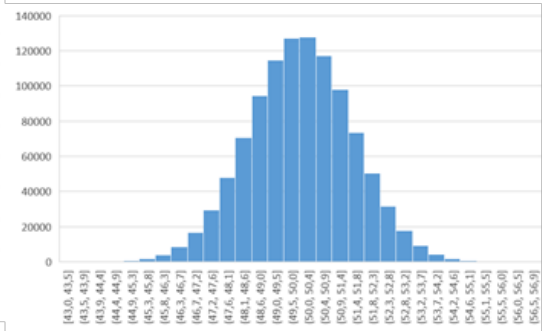
Grade 3: Moderate quality of evidence



Grade 2: Low quality of evidence



Grade 4: High quality of evidence



Standard Density Probability Functions:

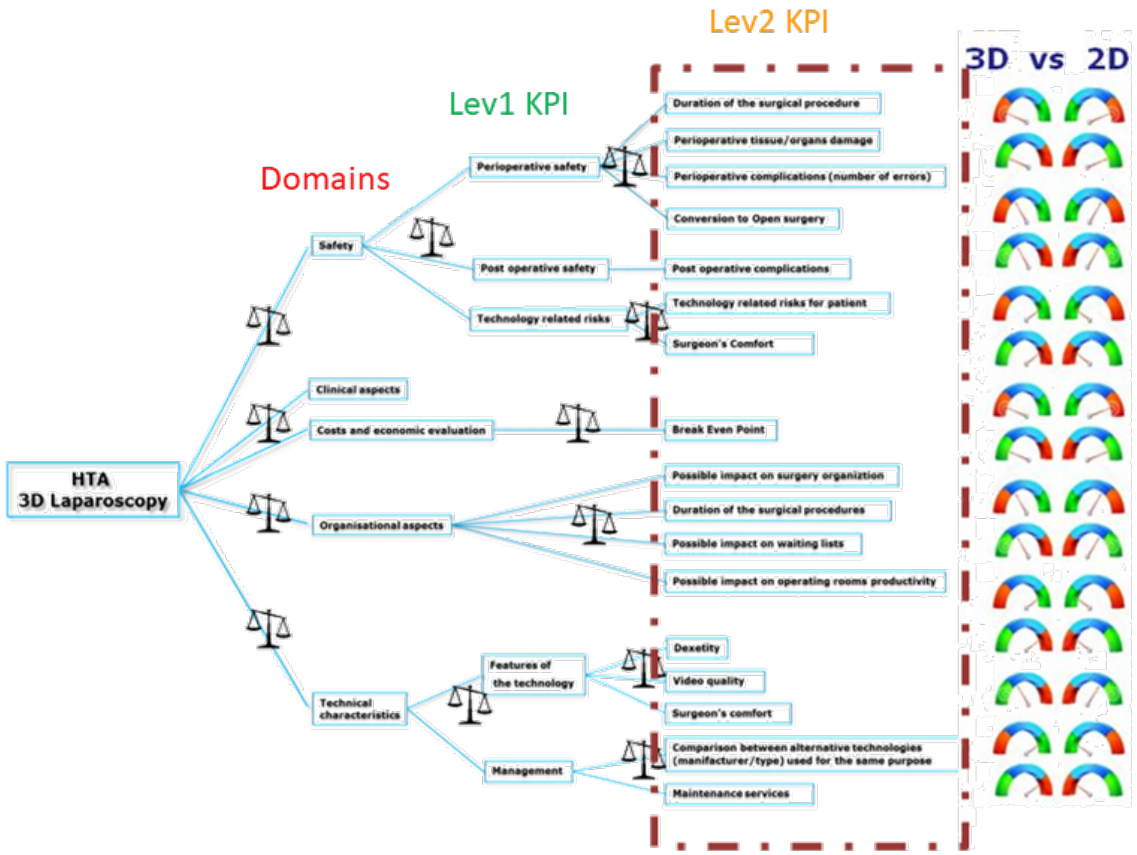
μ = performance value

$\sigma \propto (\text{Grade level})^{-1}$

$$f(x) = \frac{1}{\sigma\sqrt{2\pi}} e^{\frac{-(x-\mu)^2}{2\sigma^2}}$$

With $x = \mu$

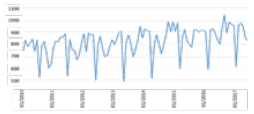
Integrating Data Quality into decision-making processes



- Depending on the indicator's data quality, a proper GRADE level and, consequently, the related probability density function are associated to each performance indicator.
- Thanks to this approach it is possible to modulate the final performances values proportionally to their robustness.

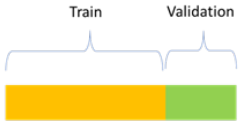
Forecast Analysis

Data collection



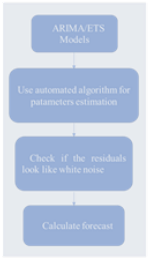
- Monthly inpatients admission at General Surgery department
- Monthly revenues of General Surgery department between January 2010 to December 2018

Pre-elaboration



- Data from January 2010 to December 2017 were used for parameters estimation and model construction
- Data from January 2018 to December 2018 were used for the algorithm validation

Models definition



- ARIMA parameters' estimation
- ETS parameters' estimation

Fitting errors and forecasting accuracy assessment

- Akaike information criterion (AIC)
- Bayesian information criterion (BIC)
- Root mean square error (RMSE)
- Mean absolute error (MAE)
- Mean absolute percentage error (MAPE)

Model construction

The final objective is to obtain a hybrid model ETS-ARIMA that benefits of the advantages of both methods. The best EST model (or models) was then combined with the ARIMA model (if it exists).

$$X_t = l_1\widehat{X_t^1} + l_2\widehat{X_t^2}$$

$\widehat{X_t^1}$ *and* $\widehat{X_t^2}$ are the values estimated by the ETS and ARIMA models respectively at time t. X_t is the expected value of the hybrid model. l_i is a weight factor of the related model.

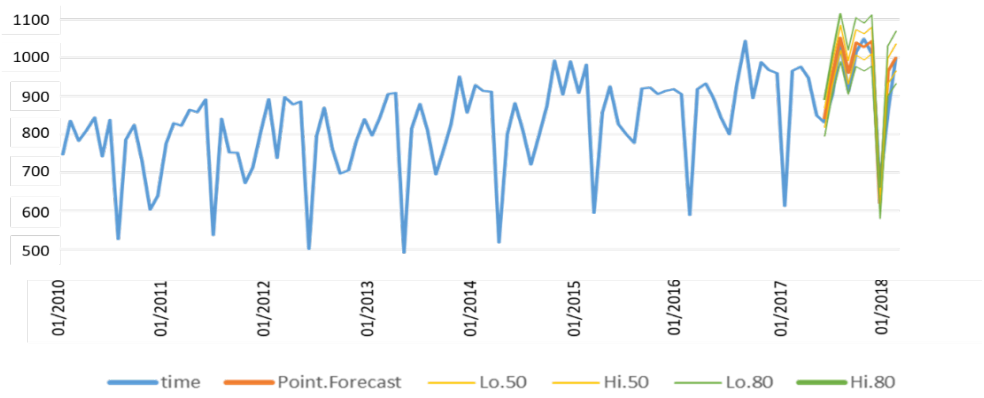
$$l_i = \frac{E_i^{-1}}{\sum_{i=1}^{2} E_i^{-1}}$$

where $l_1 + l_2 = 1$ and $E_i = \sqrt{\sum_{i=1}^{n} e_i^2}$, is the quadratic sum of the residuals of the single model. The lower E_i the higher the accuracy of the model, resulting in higher weight (l_i) in the hybrid model.

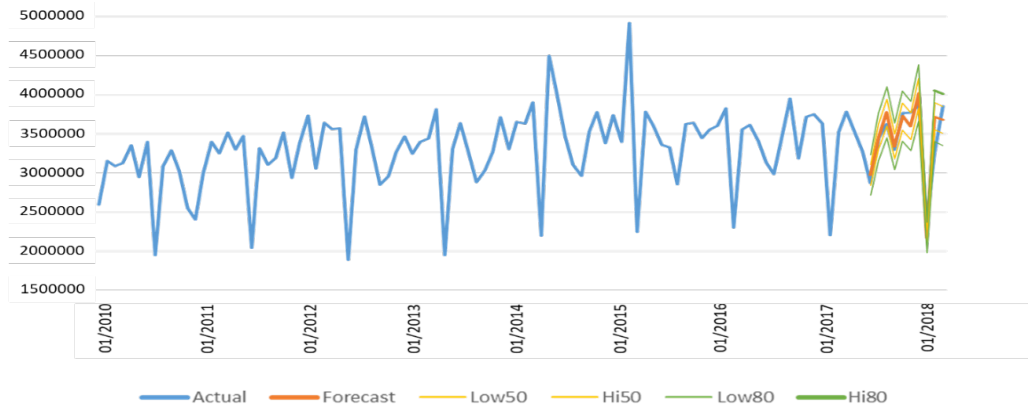
Model validation

To evaluate the performances of the method proposed, accuracy of each model was assessed comparing the original data from the last year of the time series (from January 2018 to December 2018) with the predicted values on months 1, 3 and 12.

$$Accuracy_{month(n)} = \left(\sum_{i=1}^{n} \frac{X_i^{simulated}}{X_i}\right)$$

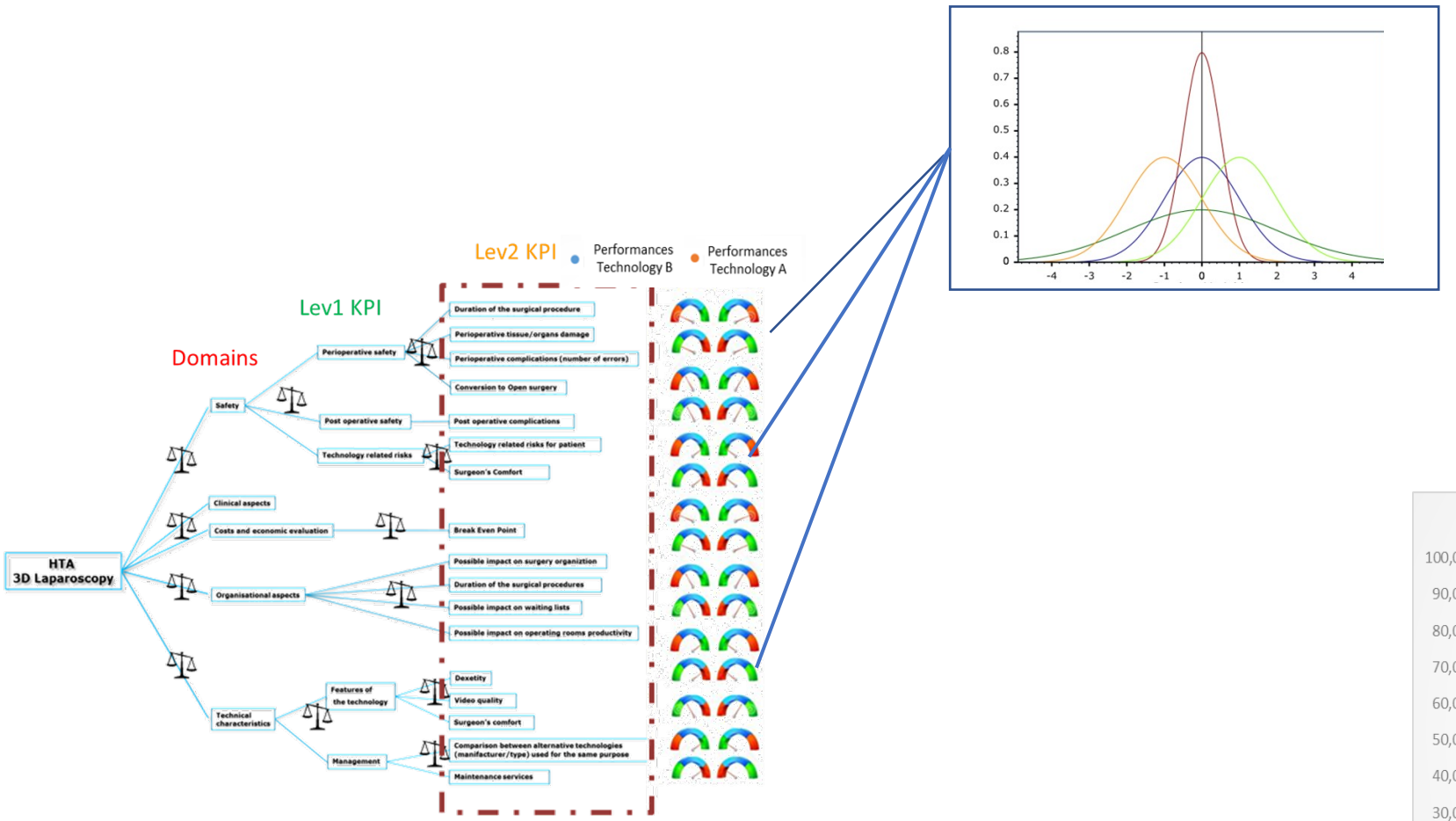


Inpatient Admission

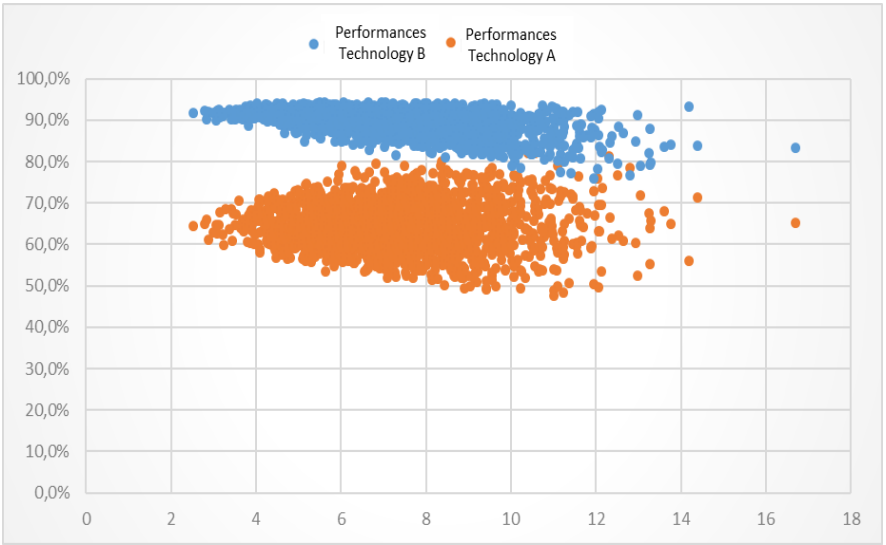


Revenues

Integrating Real World Data into Multicriteria Decision Analysis



Montecarlo Simulation Results



Performances Technology B
Performances Technology A

Conclusions and Remarks

- Despite the promise RWD are bringing, there is still not a general agreement on the best way to maximize potentialities and benefits of using RWE in health care decision-making processes and which could be their proper use during the lifecycle of health technologies.
- Mathematical elaborations of RWD in Hospital Based Health Technology Assessment, providing structured and reliable outcomes, drastically increase the reliability of previsions giving evidence of errors and uncertainty of results.
- RWD and RWE appear particularly suitable in supporting decision making processes at hospital level, where context analysis and the decision-makers expertise play a crucial role for the process.

Thank you for your attention

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