

Hospital-based Health Technology Assessment applied to bloodstream infection diagnosis

Dr Gregoire Mercier and Dr. Iñaki Gutiérrez-Ibarluzea

Who are we?



Dr. Gregoire Mercier

- Head of the Economic Evaluation Unit, Montpellier University Hospital, France
- The presenter declares that has no conflict of interest regarding this presentation



Dr. Iñaki Gutiérrez-Ibarluzea

- Knowledge Manager
- Basque Office for HTA. Ministry for Health. Basque Government
- The presenter declares that has no conflict of interest regarding this presentation

Objectives

- To introduce the concept of Hospital-Based Health Technology Assessment (HB-HTA)
- To give an overview of how the HB-HTA process is organized in some European countries
- To apply HB-HTA to an innovative technology aimed to diagnosis bloodstream infections (IRIDICA)

Outline

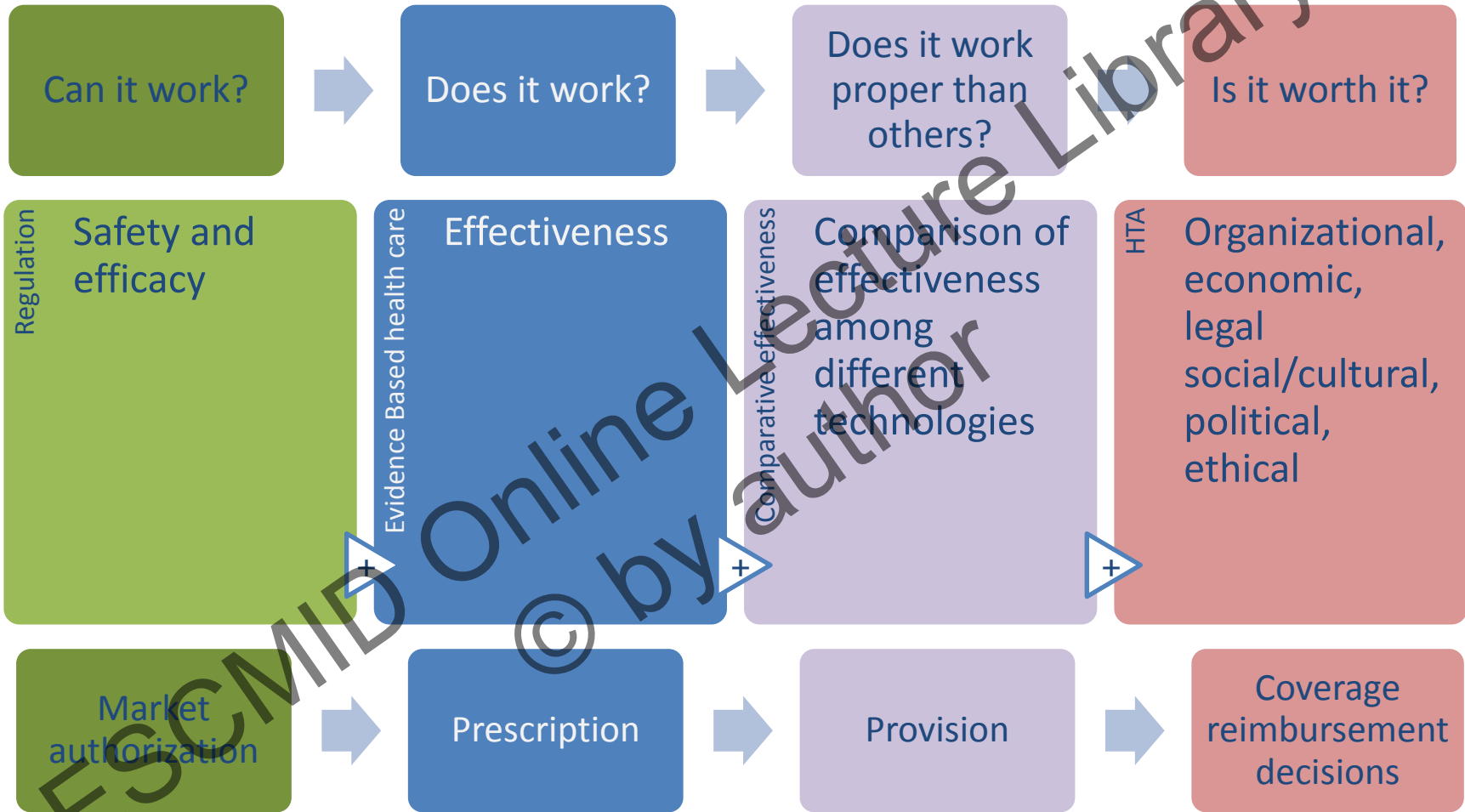
- What is HB-HTA?
- How is HB-HTA organized?
- Application of HB-HTA to IRIDICA
- Take-home messages
- Discussion with the audience

Outline

- **What is HB-HTA?**
- How is HB-HTA organized?
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What is HTA

- Health Technology Assessment is:
 - “The systematic evaluation of the properties and effects of a health technology, **addressing the direct and intended effects** of this technology, as well as its **indirect and unintended consequences**, and aimed mainly at informing decision making regarding health technologies.”



Decisions and levels

- Informing decisions is crucial at any level
 - Prescription relates to **micro** decisions
 - Provision relates to **meso** decisions
 - Coverage and reimbursement relates to **macro** decisions.

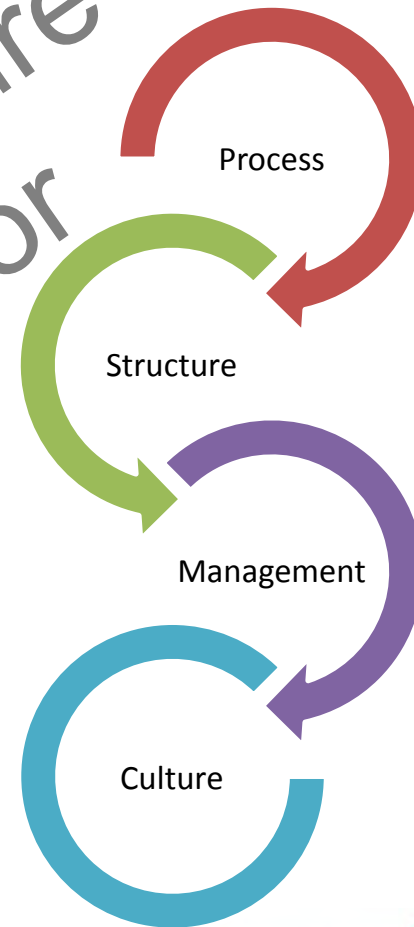
What is HB-HTA

- HB-Health Technology Assessment is:
 - “The application of HTA principles to inform decisions at the meso and micro levels within hospitals.”
- Hospital-based Health Technology Assessment (HB-HTA) means performing HTA activities tailored to the hospital context for managerial decisions. It includes the processes and methods used to produce HTA reports “in” and “for” hospitals.



What makes different to HB-HTA

- Context in which technology will be implemented (applicability)
- Context influences results and thus, value
- Special features to bear in mind within hospitals:
 - Organisational aspects
 - Comparators, how care is organised in the hospital, budget impact analysis,...



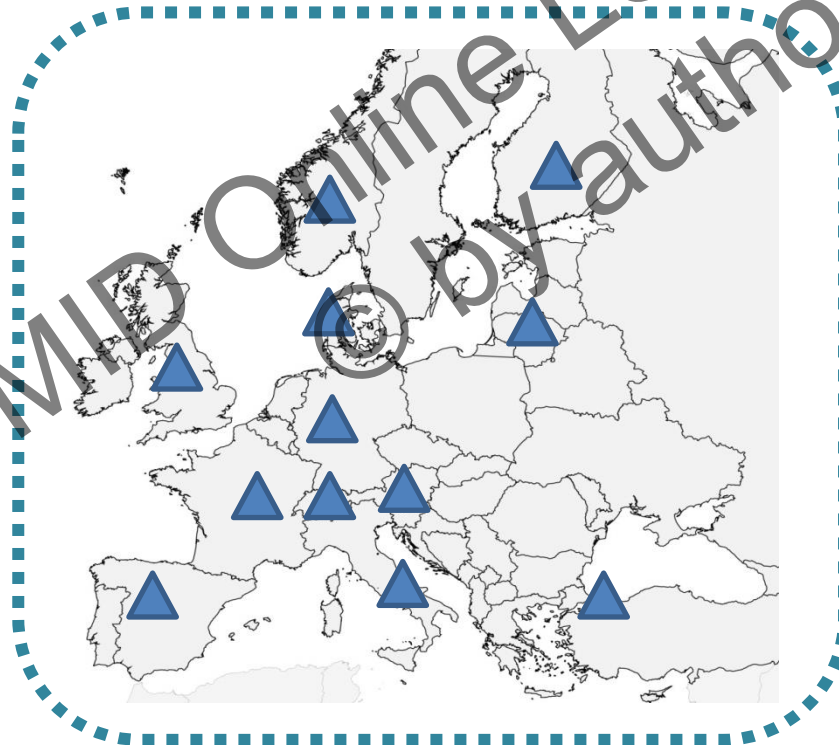
Reality in the case of hospitals

- Standards of practice (comparator)
- Characteristics of the staff members
 - Competences
- Structure of services (who deals with what?)
- Culture (how personal values and personal interactions are influencing the adoption of the technologies, where the hospital is based and which community they are servicing)

Diffusion of HB-HTA across Europe

So far, HB-HTA programs have been set up by hospitals in Norway, Denmark, Finland, UK, Italy, Spain, Switzerland, Austria, Germany, Estonia, Turkey and France.

Most of these countries are involved in the European AdHopHTA project.



[AdHopHTA Handbook, 2015]



Osteba

Centro de Evaluación y Tecnología Sanitaria
Euskal Herriko Unibertsitatearen
Ezkerreko Zuzenbidea

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How is HB-HTA organized?

- Everything started... in a hospital and in France
- CEDIT, 1982

CEDIT ASSISTANCE PUBLIQUE HOPITAUX DE PARIS



Main differences with classical HTA agencies

- Run by health professionals, managers, quality management professionals or financial departments at hospitals
- Combined with other duties
- Organised around commissions that deal with decisions on procurement



Some examples...

- Individual units
 - Clinic Hospital. Barcelona
 - Gemelli Hospital. Rome
- Hospital Consortiums
 - CEDIT. Paris
- Coordinating offices
 - AETSA. Andalusia GANT
 - INESS. Quebec



Osteba

Two main big hits



HTAi Health Technology Assessment international

Home | HTAi | News & Events | Membership | Meetings | Policy Forum | **Interest Groups** | Journal | Resources | Search...

Interest Groups

- Access to HTA
- Registration Programs
- Investment and Early Awareness
- Early Career Network
- Ethics
- Hospital Based HTA**
 - IG Materials
 - HTA in Developing Countries
 - Impact of Public Health Interventions
 - Information Retrieval
 - Patient and Citizen Involvement
 - Regulatory Interactions & Conditional Coverage

Hospital Based HTA

HTAi Interest Group on Hospital Based HTA

Purpose

This Interest Group has been established to provide an area for members of HTAi who are developers and users of Health Technology Assessment (HTA) in hospital settings to share information, insights, and work on collaborative projects. This group is also open to all members of HTAi with an interest in HTA in a hospital setting.

Please visit the file area of this IG for more information about this group and the work they have undertaken.

- Access IG files and resources

Join this IG

IG co-chairs: Americo Cicchetti and Marco Marchetti

All members of HTAi are welcome to participate in this IG. To join, simply log in to the website and return to this page. A link to join the IG mailing list will appear automatically.

Would you like to join this IG? [Become a member of HTAi.](#)

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Application of HB-HTA to BSI diagnosis

- Clinical background:
 - Burden/severity of disease
 - Role of the microbiological diagnosis
 - Current practices and emerging technologies

Application of HB-HTA to BSI diagnosis

At the hospital level, the question is « ***Shall we implement this new technology in our hospital?*** »



HB-HTA process

The diagram illustrates the HB-HTA process, which is enclosed in a dashed blue border. It consists of three stacked, rounded rectangular boxes. The top box is green and labeled 'Clinical impact'. The middle box is orange and labeled 'Economic impact'. The bottom box is blue and labeled 'Organizational impact'. A blue arrow points downwards from the top of the diagram towards the text 'Shall we implement this new technology in our hospital?' above.

Clinical impact

Economic impact

Organizational impact

Caveat

- HB-HTA is evidence-based management, NOT medicine.
- It might be difficult to disentangle the impacts of the technology (i.e. IRIDICA) and of the organizational features of the hospital and laboratory.
- The decision depends on:
 - The national/regional context: Hospital payment; reimbursement of lab tests.
 - The hospital context: choice of the comparator, target population, current organizational features.
- However, there are some common trends

IRIDICA



IRIDICA

- **Technology:** IRIDICA BAC BSI assay (PCR + Electrospray Ionization ToF Mass Spectrometry)
- **Indication:** To diagnose bacteriemia and fungemia in patients with hematologic malignancies/solid tumors undergoing chemotherapy with a neutropenic fever
- **Comparator:** Conventional blood cultures +/- MALDI-TOF MS
- **Outcomes:**
 - **Clinical impact:** diagnostic accuracy; mortality
 - **Economic impact:** budget impact; cost effectiveness
 - **Organizational impact:** Time to detection; time to treatment; change in treatment plan; LoS

IRIDICA: clinical impact

Evidence

IRIDICA vs. BC:

#1: Stevenson et al (4 studies):

→ **Sensitivity:** 0.81 (95%CI 0.69 to 0.90)

→ **Specificity:** 0.84 (95% CI 0.71 to 0.92)

#2: Desmet et al:

→ **Sensitivity:** 0.41

→ **Specificity:** 0.93

→ **Mortality rate:** 29% (no comparative data)

Estimated impact: **-4.6%**

Clinical impact

→ **Diagnostic accuracy: mixed evidence**

→ **Mortality: experts advice only**

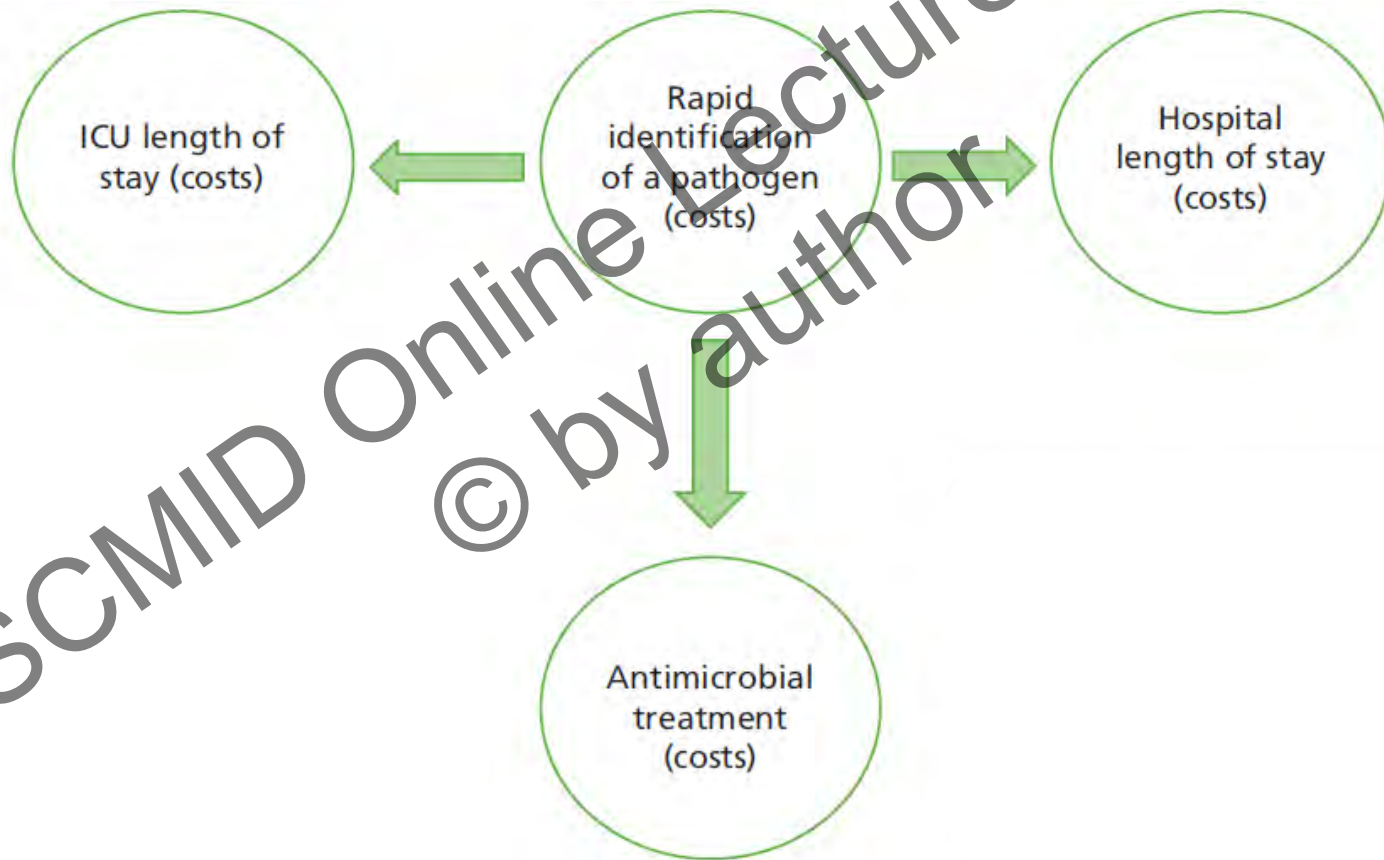
[Desmet 2016; Stevenson 2016]

Additional data from Metzgar 2016

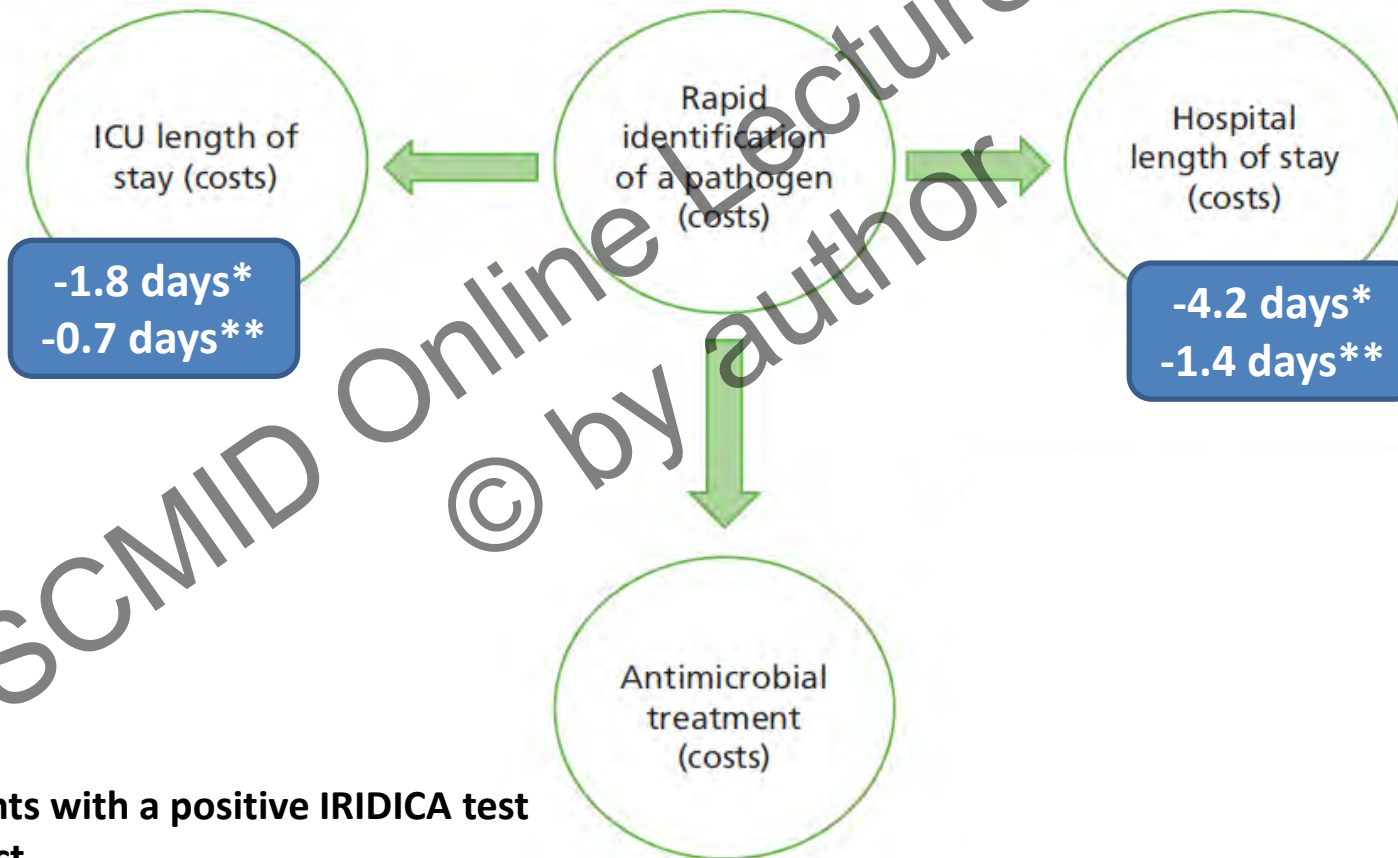
Table 3. Comparison of IRIDICA BAC BSI Assay and standard-of-care culture results in clinical blood specimens from patients with suspected bloodstream infections, summarized by organism group (details in Table 4).

Organism Group	Matched Positive	BAC BSI Assay +/ Culture -	BAC BSI Assay-/ Culture +	Matched Negative ^B
Gram-positive (including Mycoplasma)	15	11 ^{A(5)}	2	207
Gram-negative	13	21 ^{A(4)}	3	207
Unidentified bacteria	0	1	0	207
Yeast	2	1	0	207
Potential Contaminants (details in Table 4)	2	12 ^{A(2)}	3	207
Other reportable organisms excluding potential contaminants (n = 550)	0	0	0	207

IRIDICA: economic impact



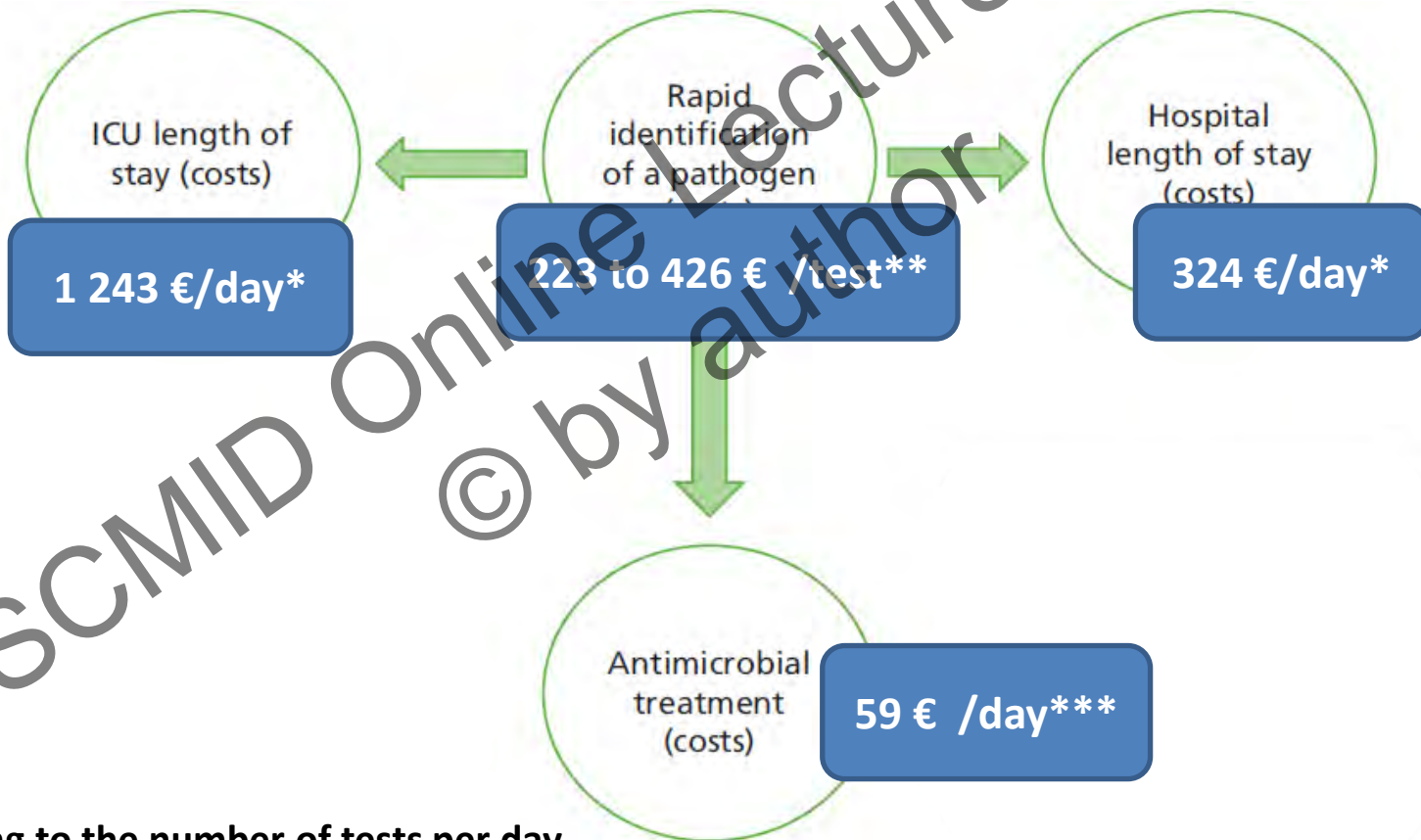
Hypotheses (vs. BC)



*: For patients with a positive IRIDICA test

** : Net effect

Costs



*: NHS data

** : According to the number of tests per day

*** : Empirical treatment for sepsis Expert advice

[Stevenson 2016]

Incremental cost per annum

Assumption	Machinery to be purchased	No machinery
2.4 samples/day	86 000 €	41 000 €
17 samples/day	-199 000 €	-244 000 €
68 samples/day	-793 000 €	-974 000 €



Fixed + variable costs

IRIDICA: economic impact

Economic impact

- Treatment cost:
 - IRIDICA+ & BC+: -14%
 - IRIDICA+ & BC-: -37%

- Hospital budget impact:
-41 to + 974 k€ par annum



Fixed + variable costs

- Cost-effectiveness:
DOMINATING

IRIDICA: Organizational impact

Evidence

Organizational impact

IRIDICA vs. BC: (Stevenson 2016)

- **Time to result:** no data
- **Time to treatment:** no data
- **Changes in treatment plan:** 41% of cases (experts advice)

→ **Organizational impact: limited evidence**

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HB-HTA of IRIDICA

Clinical impact

→ Diagnostic accuracy: mixed evidence

→ Mortality: experts advice only

Economic impact

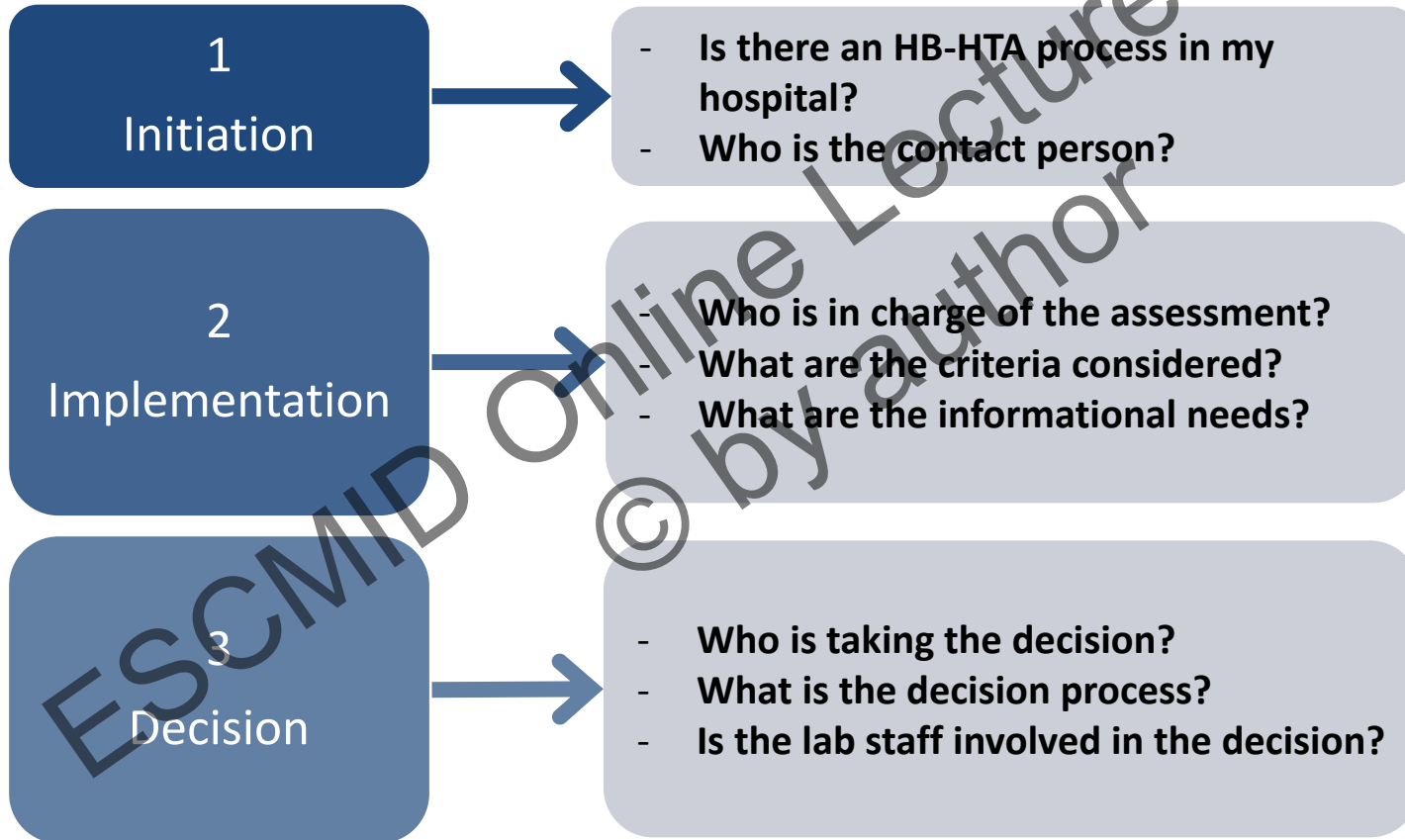
→ Hospital budget impact:
-41 to + 974 k€ par annum

→ Cost-effectiveness:
DOMINATING

Organizational impact

→ Limited evidence

Practical issues for the laboratory team



Role of the laboratory team

1 Initiation

- **Contacts the HB-HTA unit** and fills in the form to **request the assessment**
- **Conducts local clinical trials**

2 Implementation

- **Assists the HB-HTA unit with its clinical expertise** during the process:
 - Reviews the clinical evidences
 - Defines the impact of the new technology on patients management

3 Decision

- **Promotes the strategic impact** of the new technology according to the hospital's priorities

Take-home messages

- HB-HTA is a process aimed at supporting **hospital-level managerial decisions**.
- New technologies (including diagnostic ones) are expected **to be increasingly assessed through HB-HTA**.
- Laboratory staff **plays a key role** in HB-HTA initiation and implementation
- In a given hospital, the decision **depends on the current practice**.
- Although the transferability of HB-HTA results from a setting to another should be cautious, **common trends exist**.

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References

Stevenson M, Pandor A, Martyn-St James M, Rafia R, Uttley L, Stevens J, Sanderson J, Wong R, Perkins GD, McMullan R, Dark P. Sepsis: the LightCycler SeptiFast Test MGRADE®, SepsiTest™ and IRIDICA BAC BSI assay for rapidly identifying bloodstream bacteria and fungi - a systematic review and economic evaluation. *Health Technol Assess.* 2016 Jun;20(46):1-246. doi: 10.3310/hta20460.

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