Medtronic & COVIDIEN

Welcoming Covidien to Medtronic

Health Technology Assessment For Medical Devices

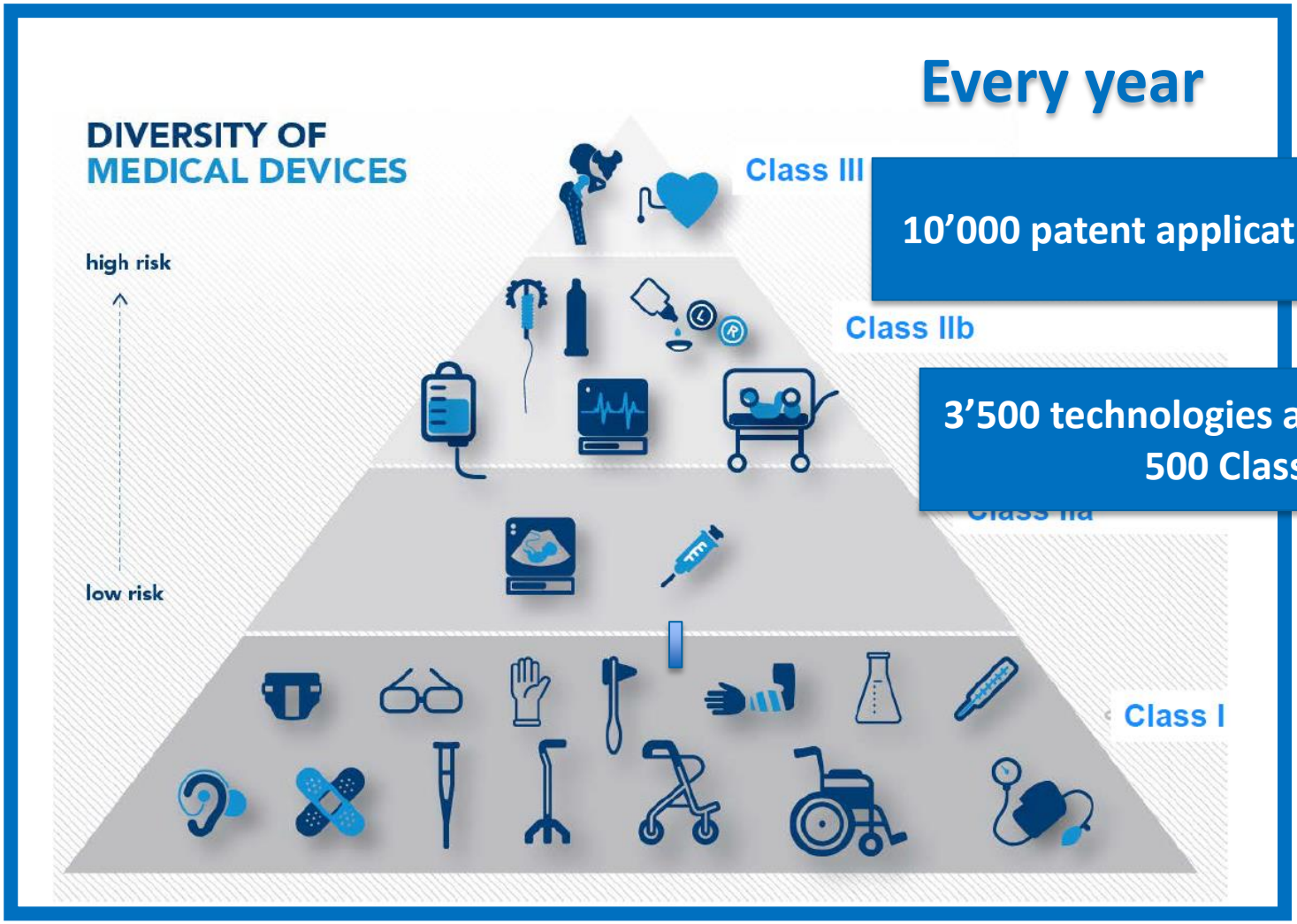
Pascale Brasseur

June 23rd 2015

Agenda

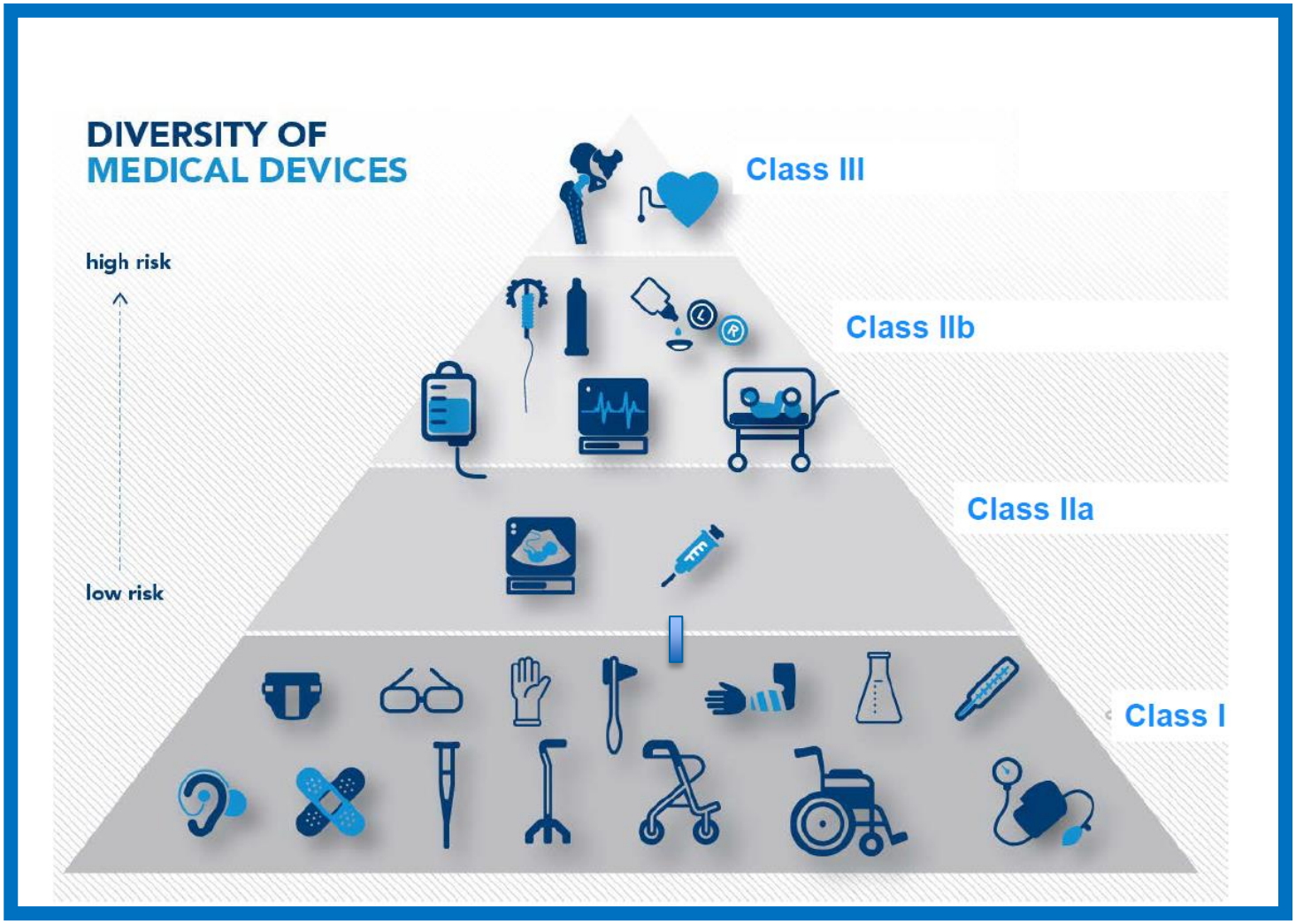
- A few facts about Medical Devices
- HTA of Medical Devices
- Market Access Jigsaw
- Initiatives at European level

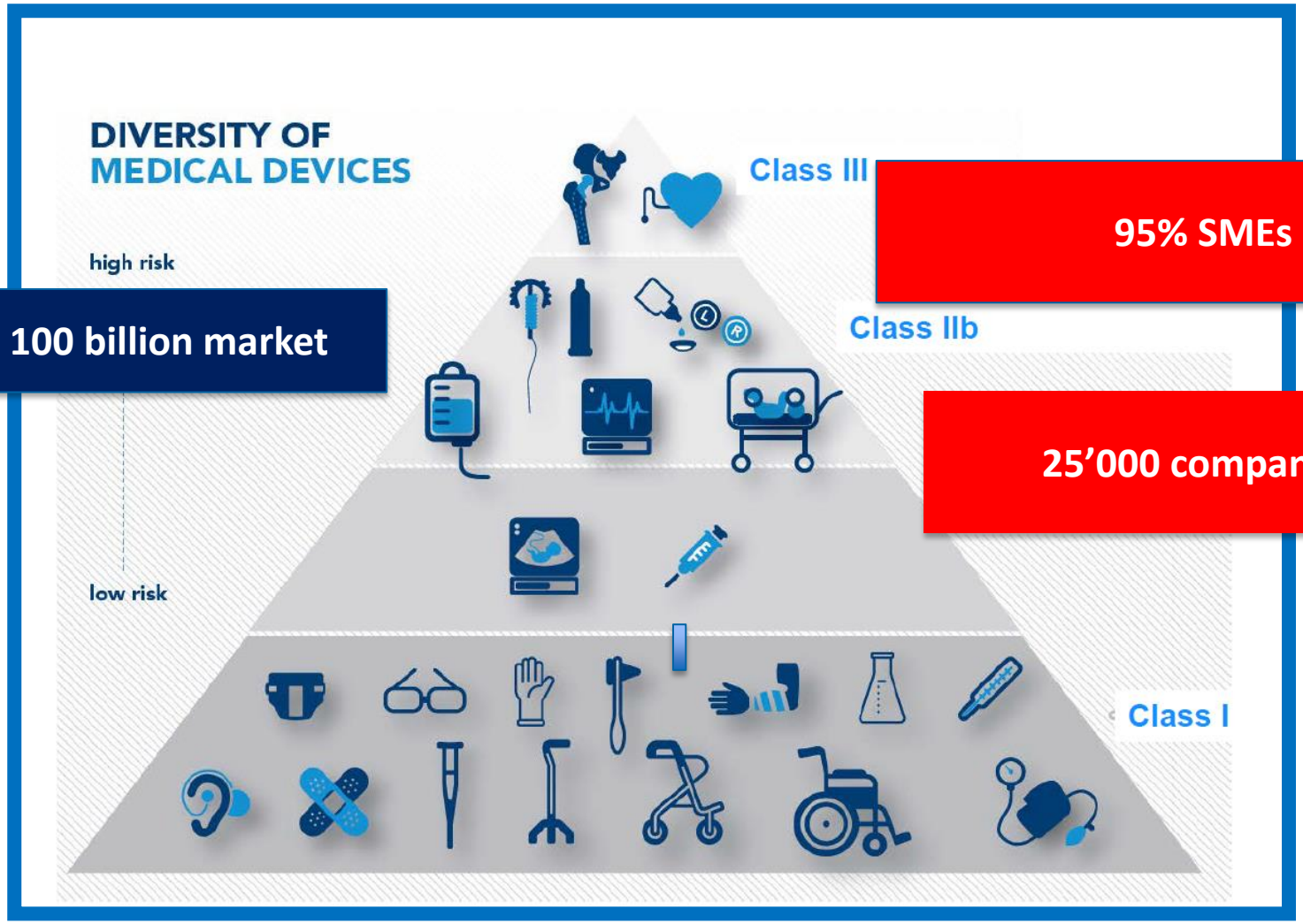
Every year



10’000 patent applications to EPO

3’500 technologies approved in EU
500 Class III

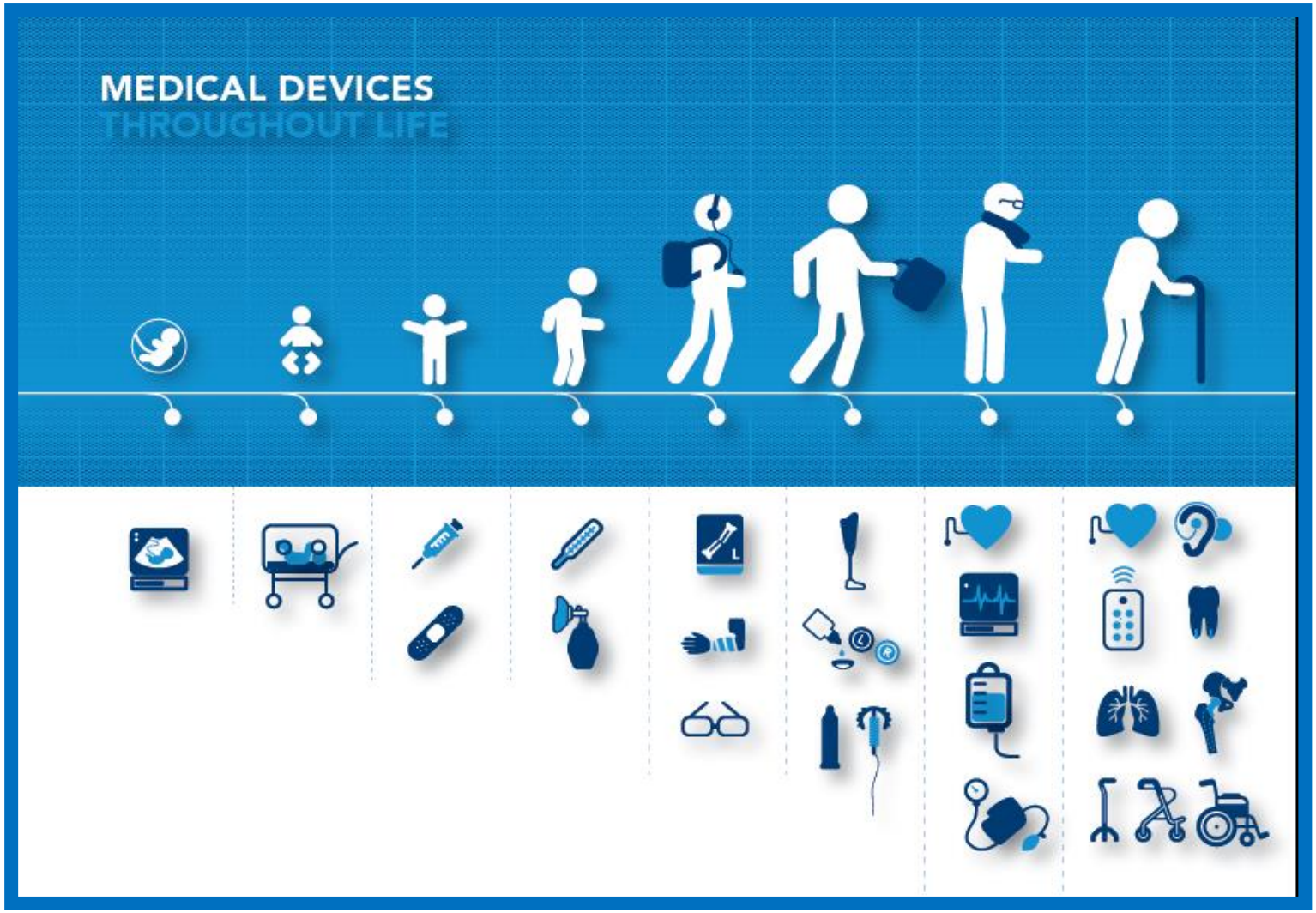

DIVERSITY OF
MEDICAL DEVICES
high risk
low risk
Class III
Class IIb
Class IIa
Class I



$ 100 billion market

95% SMEs

25’000 companies in EU


MEDICAL DEVICES
THROUGHOUT LIFE

MedTech Europe
from diagnosis to cure

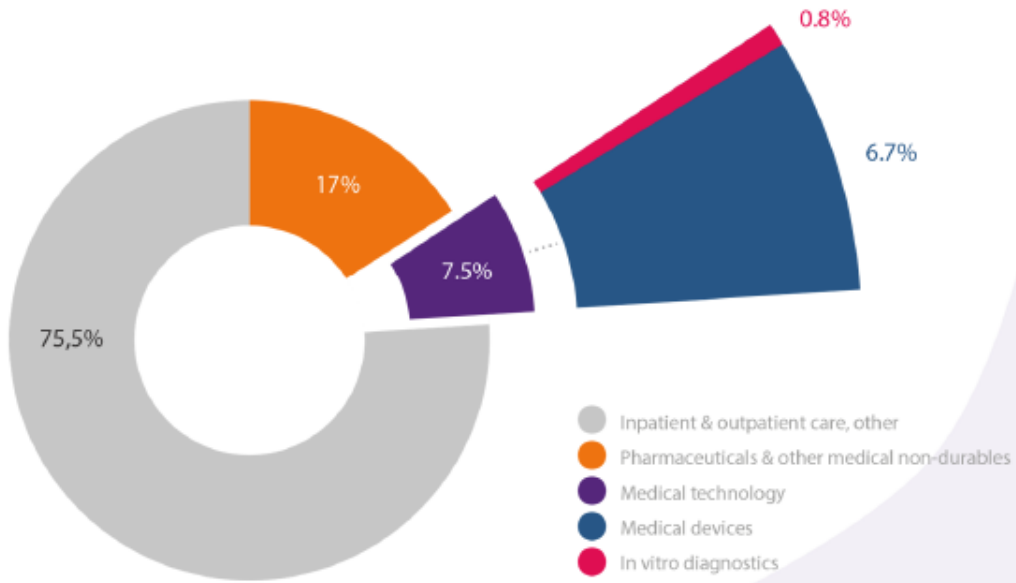
Expenditure on MedTech

It is estimated that only around **7.5 %** of total European healthcare expenditure is attributed to MedTech.

The spending on medical technology varies significantly across European countries, ranging from around **5% to 10%** of the total healthcare expenditure.

MedTech Europe
from diagnosis to cure

Breakdown of total healthcare expenditure in Europe



Europe refers to EU + Switzerland, Norway. MedTech data – latest year available, healthcare expenditure data – 2010.
Source: WHO, Eurostat, EFPIA, EDMA, Eucomed calculations.

HTA

Health Technology Assessment

Specificities for HTAs on Medical Devices

Volume ** • Number ** • **
VALUE IN HEALTH

Economic Evaluation for Devices and Drugs—Same or Different?

Michael Drummond, PhD,[1] Adrian Griffin, MSc,[2] Rosanna Tarricone, MSc, PhD[3]

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Assessing the Clinical and Cost-Effectiveness of Medical Devices and Drugs: Are They That Different?

Rod S. Taylor, MSc, PhD,[1] Cynthia P. Iglesias, MSc, PhD[2,3]

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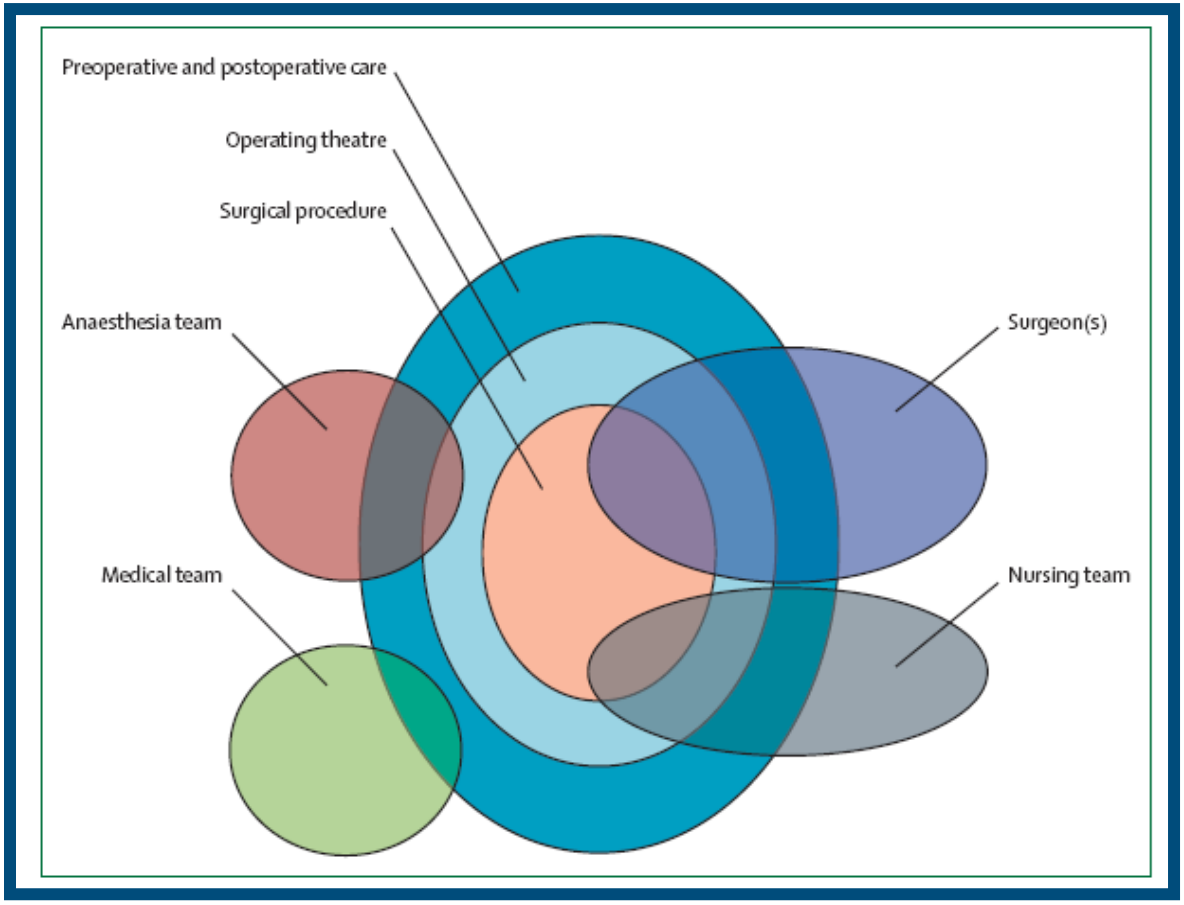
Specificities for HTAs on Medical Devices

http://www.ehti.info

Specificities for HTAs on Medical Devices

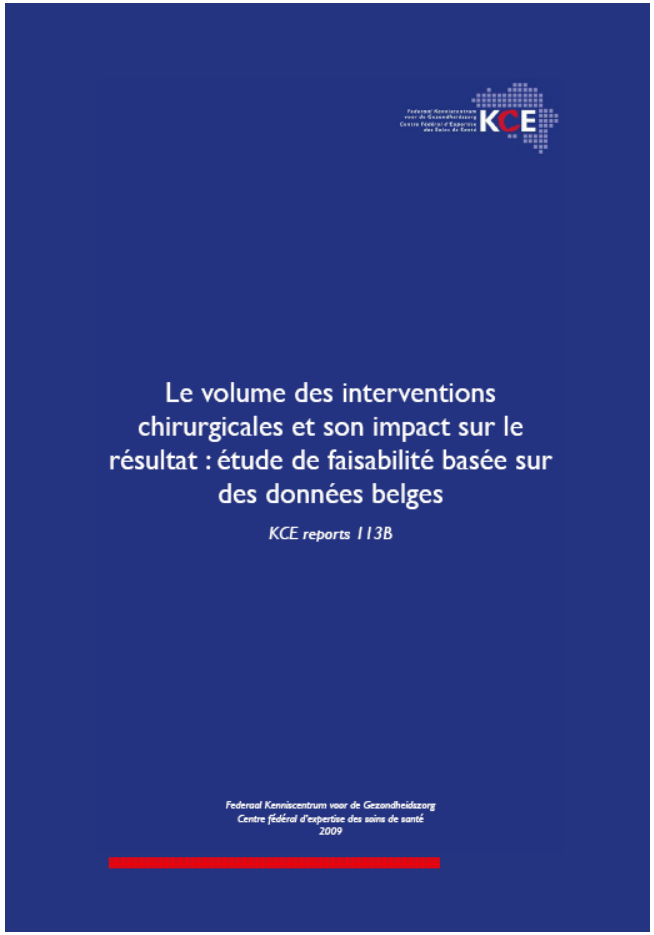
- Problems in conducting clinical studies
- Learning curve
- Generization - Class effect
- Accounting for the wider organizational impacts

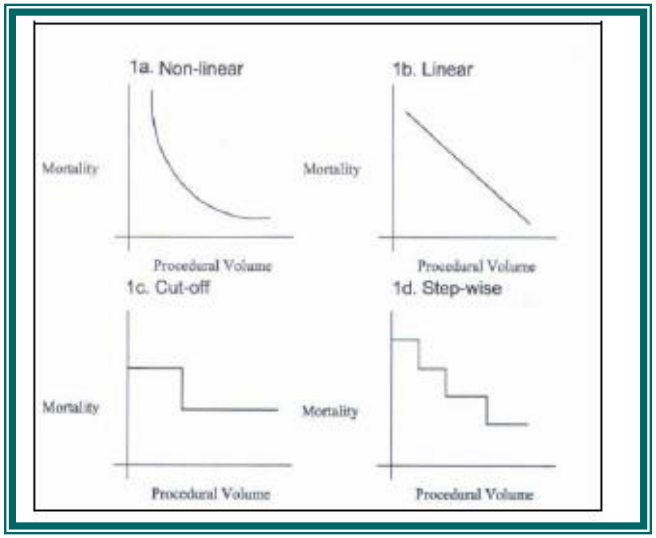
Learning curve



Source : Ergina P et al, Surgical Innovation and Evaluation 2- Challenges in evaluating surgical innovation Lancet – Vol. 374 – September 2009

Assessing the impact of volume of interventions





Source : KCE report 113 – 2009

Assessing the impact of volume of interventions

The NEW ENGLAND JOURNAL of MEDICINE

SPECIAL ARTICLE

Hospital Volume and 30-Day Mortality for Three Common Medical Conditions

Joseph S. Ross, M.D., M.H.S., Sharon-Lise T. Normand, Ph.D., Yun Wang, Ph.D., Dennis T. Ko, M.D., Jersey Chen, M.D., Elizabeth E. Drye, M.D., Patricia S. Keenan, Ph.D., Judith H. Lichtman, Ph.D., M.P.H., Héctor Bueno, M.D., Ph.D., Geoffrey C. Schreiner, B.S., and Harlan M. Krumholz, M.D.

ABSTRACT

BACKGROUND

The association between hospital volume and the death rate for patients who are hospitalized for acute myocardial infarction, heart failure, or pneumonia remains unclear. It is also not known whether a volume threshold for such an association exists.

METHODS

We conducted cross-sectional analyses of data from Medicare administrative claims for all fee-for-service beneficiaries who were hospitalized between 2004 and 2006 in acute care hospitals in the United States for acute myocardial infarction, heart failure, or pneumonia. Using hierarchical logistic-regression models for each condition, we estimated the change in the odds of death within 30 days associated with an increase of 100 patients in the annual hospital volume. Analyses were adjusted for patients' risk factors and hospital characteristics. Bootstrapping procedures were used to estimate 95% confidence intervals to identify the condition-specific volume thresholds above which an increased volume was not associated with reduced mortality.

RESULTS

There were 734,972 hospitalizations for acute myocardial infarction in 4128 hospitals, 1,324,287 for heart failure in 4679 hospitals, and 1,418,252 for pneumonia in 4673 hospitals. An increased hospital volume was associated with reduced 30-day mortality for all conditions (P<0.001 for all comparisons). For each condition, the association between volume and outcome was attenuated as the hospital's volume increased. For acute myocardial infarction, once the annual volume reached 610 patients (95% confidence interval [CI], 539 to 679), an increase in the hospital volume by 100 patients was no longer significantly associated with reduced odds of death. The volume threshold was 500 patients (95% CI, 433 to 566) for heart failure and 210 patients (95% CI, 142 to 284) for pneumonia.

CONCLUSIONS

Admission to higher-volume hospitals was associated with a reduction in mortality for acute myocardial infarction, heart failure, and pneumonia, although there was a volume threshold above which an increased condition-specific hospital volume was no longer significantly associated with reduced mortality.

N ENGL J MED 362;12 NEJM.ORG MARCH 25, 2010

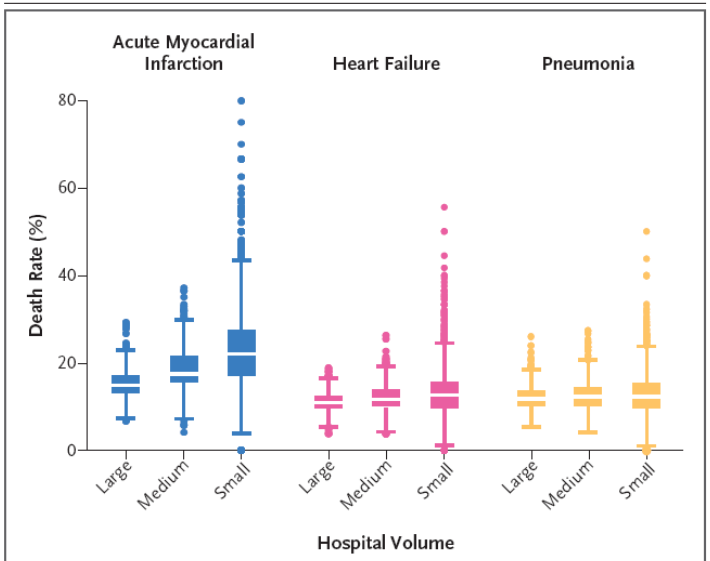


Figure 1. Frequency Distribution of 30-Day Rates of Death, According to Medical Condition and Hospital Volume.

The upper boundaries of the boxes represent the 75th percentile, the white horizontal line within each box represents the median or 50th percentile, and the lower boundaries of the boxes represent the 25th percentile. Individual data points represent outliers. The I bars represent the highest and lowest values within 1.5 times the interquartile range.

Source : Ross et al, Hospital Volume and 30-day Mortality for 3 Common Medical Conditions , NEJM ; March 25, 2010, 362; 12, 1110-1118

Example of evaluation report (France)

Eléments conditionnant le SA : - Spécifications techniques : - Modalités de prescription et d'utilisation :	Aucune exigence supplémentaire par rapport aux spécifications techniques proposées par le fabricant *Composition du plateau technique* Les pré-requis indispensables à l'implantation de valves pulmonaires par voie veineuse transcutanée ont été définis comme suit : - le centre médico-chirurgical doit regrouper sur le même site et dans le même bâtiment, les plateaux techniques de cardiologie interventionnelle congénitale et de chirurgie cardiaque congénitale dans le cas où une conversion en urgence est nécessaire ; - l'acte doit être réalisé dans une salle de cathétérisme conforme à un bloc opératoire en termes d'asepsie avec une salle de réveil à proximité ; - la nécessité d'une définition optimale d'images radiographiques pour la réalisation des procédures de cathétérisme et de contrôle radiologique ; - la possibilité de réaliser dans le centre une circulation extra-corporelle. D'autre part, l'accès à un capteur biplan est recommandé. *Composition de l'équipe pluridisciplinaire* Pendant l'intervention, en salle de cathétérisme doivent être présents deux cardiologues interventionnels ayant l'expérience des cardiopathies congénitales et un anesthésiste réanimateur habitué à la chirurgie à cœur ouvert et à la prise en charge des patients ayant des cardiopathies congénitales. Dans le centre, doit également être présent un chirurgien cardiaque ayant l'expérience du traitement des cardiopathies congénitales. *Formation et expérience requises* Pour prétendre à l'implantation d'une valve pulmonaire par voie veineuse transcutanée, les praticiens doivent : - avoir une formation de cathétérisme cardiaque interventionnel congénital ; - avoir acquis, dans le cadre d'une formation initiale spécifique aux dispositifs implantés dans le centre, la connaissance nécessaire à cette activité et la maintenir ; - avoir une formation pratique à la technique effectuée par compagnonnage. *Nombre de centres pouvant réaliser l'implantation et volume d'activité* Pour une répartition géographique optimale, entre 7 à 10 centres en France peuvent prétendre à l'implantation des valves pulmonaires par voie veineuse transcutanée. Chaque centre implanteur ne doit pas réaliser moins de cinq procédures par an.

Prerequisites of technical platform

Composition of multidisciplinary team

Required training and expertise

Authorized centers – required volume

Source: CNEDIMTS assessment report – Percutaneous pulmonic valve

Internal Validity of non randomized studies Guideline by EUnetHTA

Summary and table with main recommendations

The inclusion of non-randomised studies (NRS) in HTA may be useful in specific circumstances, but leads to several challenges in terms of internal validity assessment. The aim of this guideline was to recommend tools or checklists that are suitable for assessing risk of bias (RoB) in NRS evidence.

RoB tools were identified from previous systematic reviews and own systematic literature searches. Key criteria, such as coverage of relevant bias domains, were used to evaluate the tools. In addition, tools were required to be free of items on reporting quality and external validity (or applicability). Literature findings concerning reliability and ease-of-use were used as additional criteria.

A total of 11 tools were identified and assessed in detail. Two tools emerged as the currently best instruments for assessing RoB in NRS: ACROBAT-NRSI (A Cochrane Risk of Bias Assessment Tool) and RoBANS (Risk of Bias Assessment Tool for Nonrandomised Studies). As both tools have been developed only very recently, data on reliability are sparse, but it is clear that adequate training is required before assessing NRS evidence. Because ACROBAT-NRSI offers endpoint-specific assessments, requires a summary rating and comes with detailed instructions and documentation guides, this tool is recommended as primary RoB tool for assessment of NRS.

Market Access Jigsaw

The Market Access Jigsaw

- **Regulatory:** Always
- **HTA:** Sometimes
- **Reimbursement:** More often by procedure

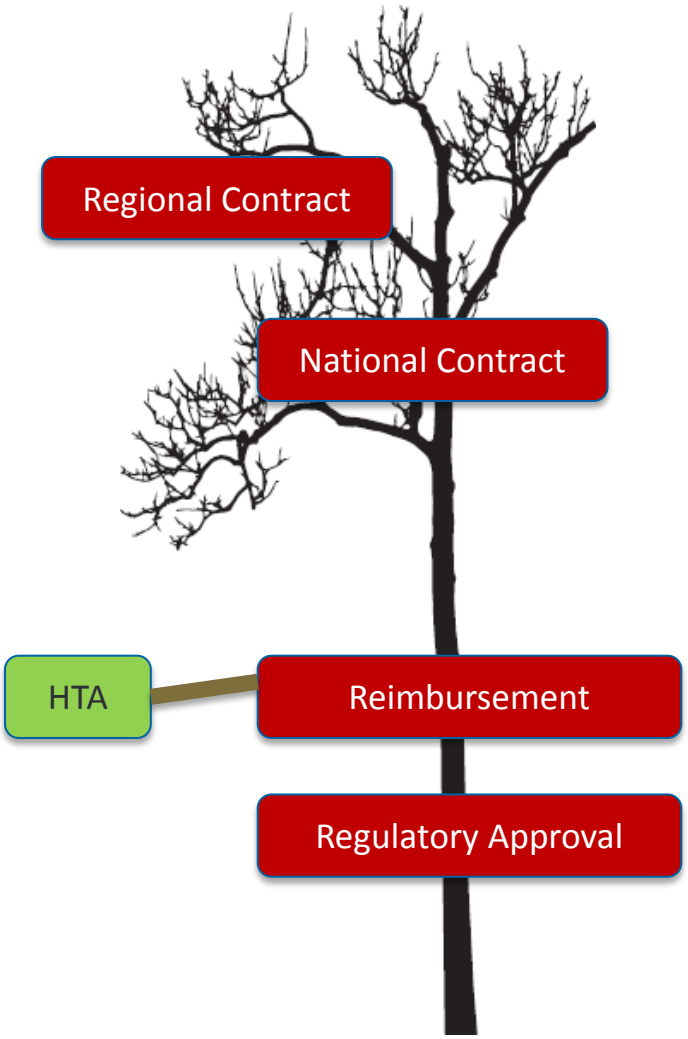
  In-patient / Out-patient / Community Care

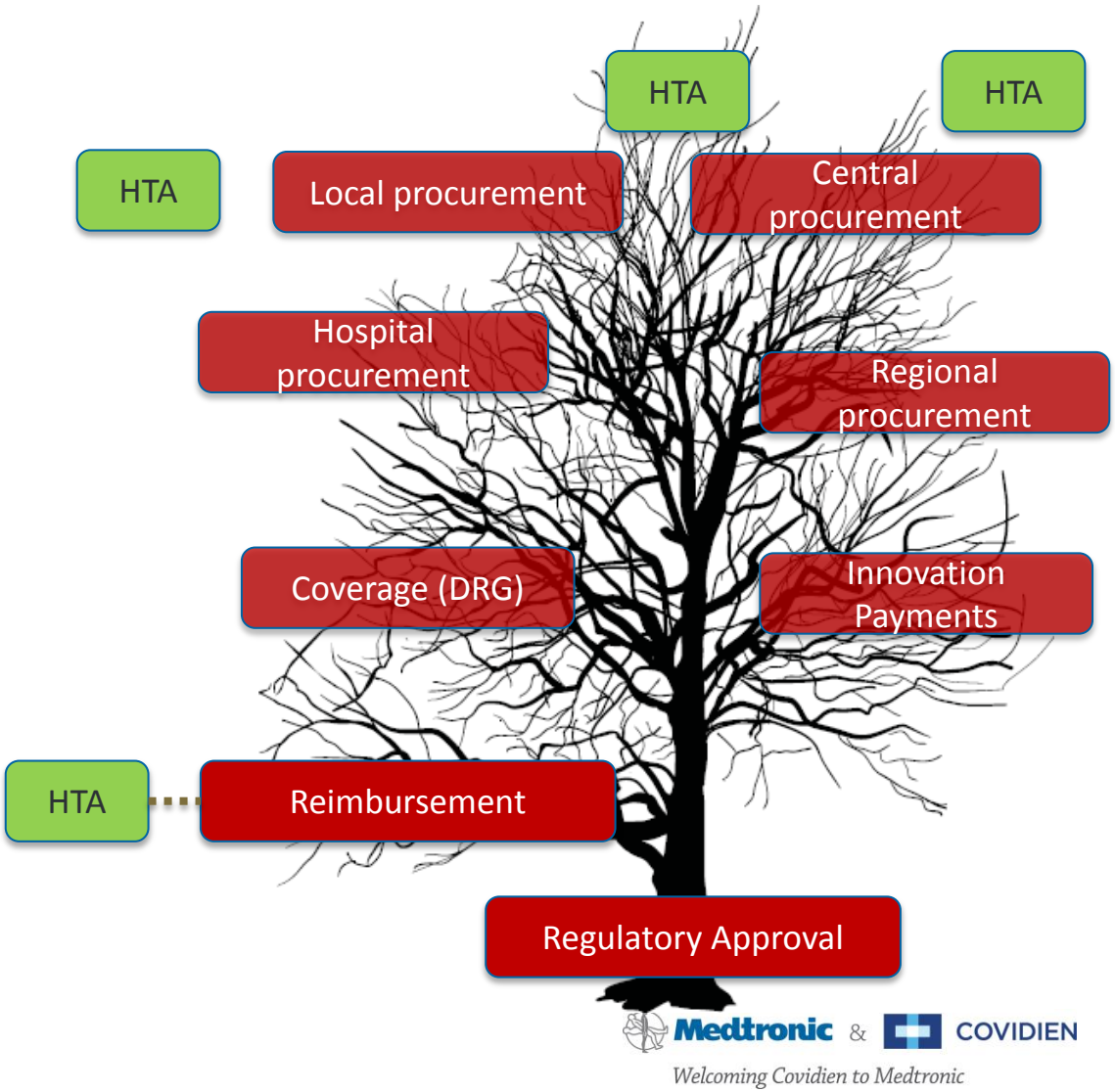
  Implantable / non-implantable

  Class / single brands

- **Procurement:**

Where HTA Informs the Route to Market





HTA for Medical Devices across EU

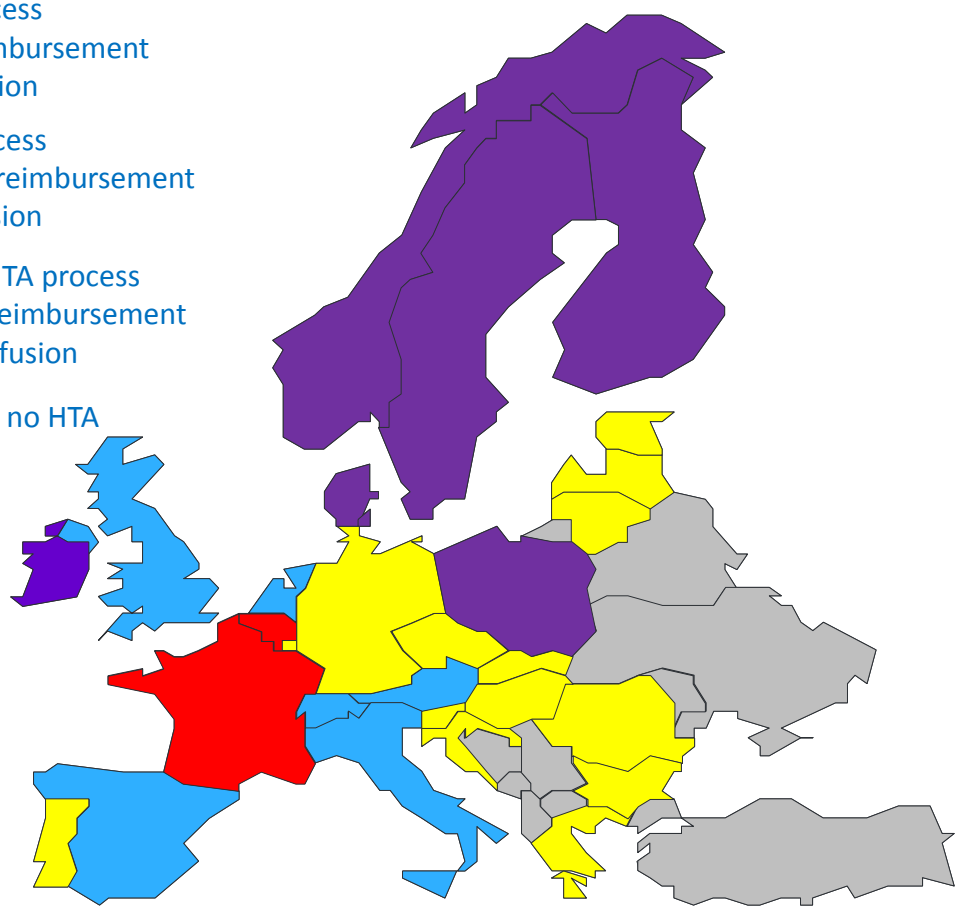
Formal HTA process
Clear link to reimbursement
Impact on diffusion

Formal HTA process
No clear link to reimbursement
Impact on diffusion

Some kind of a HTA process
No clear link to reimbursement
No impact on diffusion

Very sporadic or no HTA

No information



A few numbers

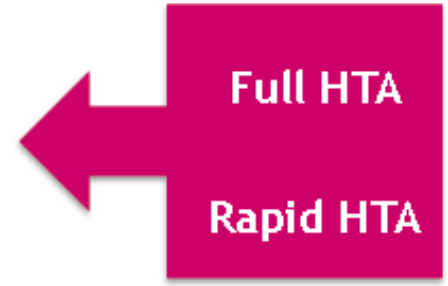
- About **365 HTA reports** involving medical technologies in 2014
- 12 countries
- 80% of these HTA reports were published in **4 Countries** (France, Spain, UK, and Sweden)
- **50%** of these HTA reports were published in **France**

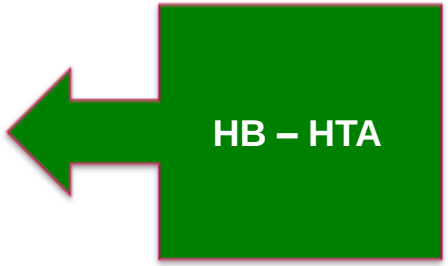
Different types of HTA

- National level

- (Regional level)

- Local (hospital level)





Hospital-based HTA

Provide decision-makers with contextualised assistance on how to make sound investment decisions on innovations, thus ensuring that good-value innovative health technologies reach clinical practice.

- Tailoring HTA to specific hospital circumstances (comparators, how care is organised in the hospital, BIA,…)
- Keeping a sharper focus on technologies that are of specific interest for the hospital
- Timely adjustment to hospital context
- In collaboration with “decision makers” (end users)

Hospital-based HTA

Five most important domains in decision-making by type of manager

Domains of the AdHopHTA survey	Clinical manager	Hospital manager
D1: Health problem	74%	51%
D2: Technology characteristics	16%	19%
D3: Safety	82%	77%
D4.1: Clinical outcome effect size	84%	74%
D4.2: Quality of evidence	74%	72%
D5.1: Economic - societal point of view	24%	23%
D5.2: Economic - hospital point of view	42%	61%
D6: Ethical	24%	19%
D7: Organizational aspects	11%	30%
D8: Social	11%	5%
D9: Legal	26%	21%
D10.1: Strategic	26%	35%
D10.2: Political	0%	7%

Hospital-based HTA and EUnetHTA domains

Domain	HTA Core model: EUnetHTA	HB-HTA Core model: AdHopHTA
D1: Health problem and current use	✓ relevant	✓✓✓ most important
D2: Description and technical characteristics	✓ relevant	✓ relevant
D3: Clinical effectiveness	✓ relevant	✓✓✓ most important
D4: Safety aspects	✓ relevant	✓✓✓ most important
D5: Costs and economic evaluation	✓ relevant	✓ relevant
D5.1 Societal point of view		
D5.2 Hospital point of view		✓✓✓ most important
D6: Ethical aspects	✓ relevant	✓ relevant
D7: Organizational aspects	✓ relevant	✓✓✓ most important
D8: Social aspects	✓ relevant	✓ relevant
D9: Legal aspects	✓ relevant	✓ relevant
D10: Political and strategic aspects		✓ relevant
D10.1 Political aspects		
D10.2 Strategic aspects		✓✓✓ most important

HTAs performed on Medical Devices

- More or less assessments ?
- Different evaluation pathways?
- Different methodologies?
- Different requirements in terms of evidence?

HTA-related initiatives at EU level

1. Permanent HTA network (October 2013)
2. EUnetHTA JA2 (January 1, 2013 - September 30, 2015)
3. AdHopHTA (October 2012 – September 2015): Hospital HTA
4. MedtechHTA (July 2012 – June 2015): HTA for Medical Devices
5. INTEGRATE-HTA (2013 – 2015): Evaluating Complex Technologies
6. ADVANCE-HTA (January 2013 – December 2015): HTA for Diagnostics

* LYG and outcome weighted survival metrics, DALYs / QALYs

In summary

Key principles for the conduct of HTAs:

- **scientific rigour**
- **timeliness**
- **inclusiveness**
- **transparency**
- **review**
- **support for implementation**

- **specificities of medical devices (commensurate evidence – learning curve)**

A few websites

- http://www.eucomed.org
- http://www.eunethta.eu
- http://www.adhophta.eu
- http://www.advance-hta.eu
- http://www.integrate-hta.eu
- http://www.medtechta.eu/wps/wcm/connect/site/medtechta/home

Medtronic & COVIDIEN

Welcoming Covidien to Medtronic

Thank you !