Criterion for reimbursement of medical technology

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Within the scope of
Federal Ministry of Health

Agenda

- What is the starting point of a medical technology
- What are the legal backgrounds of reimbursement
- Who is the customer/purchaser of a medical technology
- How to prove to be good
- How to get integrated into health services

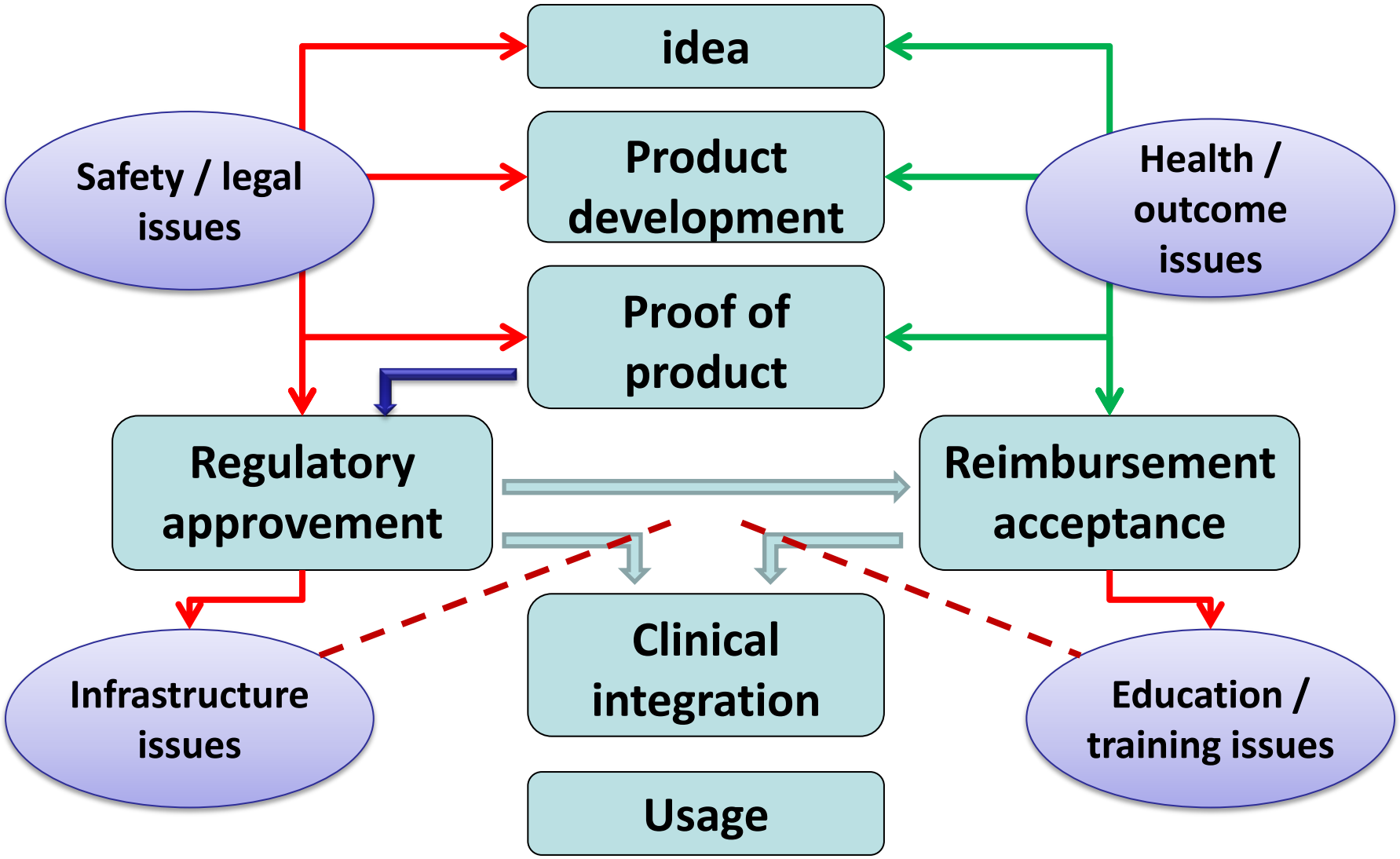
What is the starting point of a medical technology

When you assess an idea and decide about investment,

check for:

- Regulatory needs
- Reimbursement needs
- Technical needs

The pathway to get implemented



What are the legal backgrounds of reimbursement

- We have 27 national health care systems
- We have additional regional health care authorities
- We have additional European regulations with national/regional variations on the implementations

→Do you think „one size fits all“ is a good expectation?

Time strain in the development and implementation process

- There are principles of health care ideas
- There are concrete topics when a technology is entering the market

As closer you are to get into the market –

as more concrete the legal and reimbursement backgrounds and topics are.

Who is the customer/purchaser of a medical technology

Three customers exists:

- the citzen and patient
- the health care system
- the health care provider

The principles of European health care systems I

– The patient centred approach means:
– Show the added value of a medical device out of the patient‘s perspective

- Instead of: 0,1l of lung volume
- Test: 50 m more walk without a problem

The principles of European health care systems II

- Do not compare a technology against nothing (placebo)
- Show the benefit of a technology compared to the actual standard ot medical treatment

The principles of European health care systems III

- Use only valid surrogat parameters in case that you need a surrogate

- Be aware: Quality of life criterias are difficult to handle and are not accepted in the same way everywhere. QoL is depnding on cultural and societal issues.

The principles of European health care systems IV

- The systems are moving towards each other. But this will take some more time.

- The systems are trying to survive. By this they are able to change the rules of the game during the time of your development.

How to approach the legal requirements

- First step to get reimbursement:

  Get regulatory approvement

- Be in line with European regulations first of all (Free trade of products)
- Concentrate on one regulation (where your company is placed)
- Get the approvements of this region and by this get access to the European market

Regulatory approvement

- Develop the needed evidence
  (eg. register studies if this is required due to the nature of the specific device)
- Software is a device too
- Think about the vigilance procedure if this is needed for your device
- Get the CE sign and the regulatory approvement
- Contact the local responsible authority

Regulation principles for the future

Depending on the time frame of your development:

- As longer it will last as closer regulation will be in accordance to pharmaceutical products
- Prove safety in studies and in real life
- Prove that the device is able to keep the promises

How to prove to be good

- Actual situation: RCT based knowledge for reimbursement
- Trends: change from hierarchy of evidence to the best kind of evidence depending on the technology related topic

Level	Therapy / Prevention, Aetiology / Harm
1a	SR (with homogeneity*) of RCTs
1b	Individual RCT (with narrow Confidence Interval"¡)
1c	All or none§
2a	SR (with homogeneity*) of cohort studies
2b	Individual cohort study (including low quality RCT; e.g., <80% follow-up)
2c	"Outcomes" Research; Ecological studies
3a	SR (with homogeneity*) of case-control studies
3b	Individual Case-Control Study
4	Case-series (and poor quality cohort and case-control studies§§)
5	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"

The starting point of the evidence tables

Produced by Bob Phillips, Chris Ball, Dave Sackett, Doug Badenoch, Sharon Straus, Brian Haynes, Martin Dawes since November 1998. Updated by Jeremy Howick March 2009.

Oxford Centre for Evidence-Based Medicine 2011 Levels of Evidence

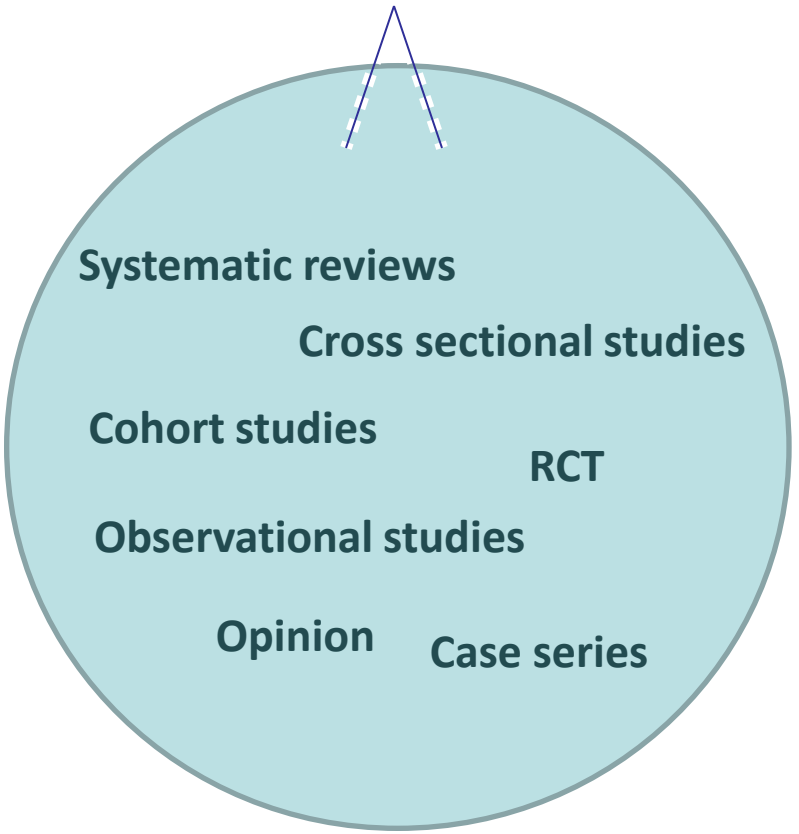
Question	Step 1 (Level 1*)	Step 2 (Level 2*)	Step 3 (Level 3*)	Step 4 (Level 4*)	Step 5 (Level 5)
How common is the problem?	Local and current random sample surveys (or censuses)	Systematic review of surveys that allow matching to local circumstances**	Local non-random sample**	Case-series**	n/a
Is this diagnostic or monitoring test accurate? (Diagnosis)	Systematic review of cross sectional studies with consistently applied reference standard and blinding	Individual cross sectional studies with consistently applied reference standard and blinding	Non-consecutive studies, or studies without consistently applied reference standards**	Case-control studies, or "poor or non-independent reference standard**	Mechanism-based reasoning
What will happen if we do not add a therapy? (Prognosis)	Systematic review of inception cohort studies	Inception cohort studies	Cohort study or control arm of randomized trial*	Case-series or case-control studies, or poor quality prognostic cohort study**	n/a
Does this intervention help? (Treatment Benefits)	Systematic review of randomized trials or *n*-of-1 trials	Randomized trial or observational study with dramatic effect	Non-randomized controlled cohort/follow-up study**	Case-series, case-control studies, or historically controlled studies**	Mechanism-based reasoning
What are the COMMON harms? (Treatment Harms)	Systematic review of randomized trials, systematic review of nested case-control studies, *n*-of-1 trial with the patient you are raising the question about, or observational study with dramatic effect	Individual randomized trial or (exceptionally) observational study with dramatic effect	Non-randomized controlled cohort/follow-up study (post-marketing surveillance) provided there are sufficient numbers to rule out a common harm. (For long-term harms the duration of follow-up must be sufficient.)**	Case-series, case-control, or historically controlled studies**	Mechanism-based reasoning
What are the RARE harms? (Treatment Harms)	Systematic review of randomized trials or *n*-of-1 trial	Randomized trial or (exceptionally) observational study with dramatic effect			
Is this (early detection) test worthwhile? (Screening)	Systematic review of randomized trials	Randomized trial	Non -randomized controlled cohort/follow-up study**	Case-series, case-control, or historically controlled studies**	Mechanism-based reasoning

OCEBM Levels of Evidence Working Group*. "The Oxford 2011 Levels of Evidence".
Oxford Centre for Evidence-Based Medicine. http://www.cebm.net/index.aspx?o=5653
** OCEBM Table of Evidence Working Group = Jeremy Howick, Iain Chalmers (James Lind Library), Paul Glasziou, Trish Greenhalgh, Carl Heneghan, Alessandro Liberati, Ivan Moschetti, Bob Phillips, Hazel Thornton, Olive Goddard and Mary Hodgkinson*

Evidence

From *hierarchy* of evidence to *needed* evidence in medical science

- Define the question you would like to get an answer
- Define the area you are working in
- Define the group you would like to give the answer
- Describe the area of health services you would like to go into



How to get integrated into health services

- But even if you can overcome all the issues in relation to:
  - Regulation
  - Reimbursement

  You have to get **acceptance** and **trust** within a system to be used