HTA AND MARKET ACCESS ISSUES FOR A COMPLEX INTERVENTION

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UNDERSTANDING TODAY'S PRACTICE TO SHAPE A SMART TOMORROW

- Opportunity for you and us to
  - Get an impression of how HTA and Payers concretly collaborate with Industry today – based on one medical device example - and the challenges around it
  - Get a view on what that means to you
  - Get a view of what that means to industry
  - Discuss new ways of working with Medical Devices Companies
  - Include that thinking into future steps

HEART FAILURE - THE FORGOTTEN DISEASE...

In Europe

Over 15 million PATIENTS, 3.5 million NEW PATIENTS EVERY YEAR

IT IS CLOSE TO 10,000 NEW DIAGNOSES PER DAY

THE LEADING CAUSE OF HOSPITALISATION IN THE AGE GROUP 65+

1 in 4 PEOPLE WILL DIE IN THE 1st YEAR

HF ACCOUNT FOR AT LEAST 2% of TOTAL HEALTHCARE EXPENDITURE

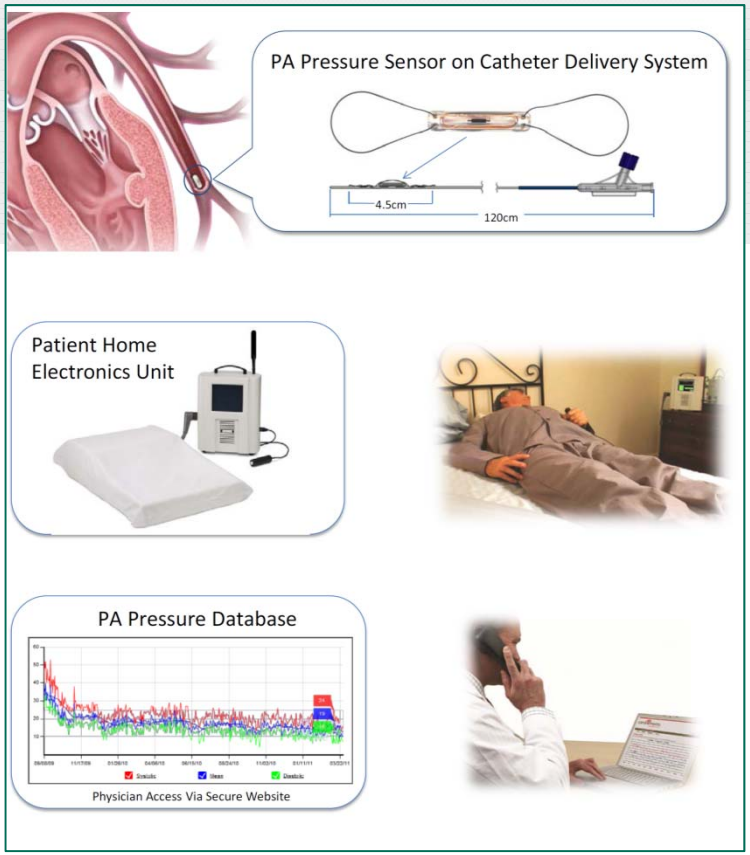
MORE THAN 1.6 million HF HOSPITALIZATION PER YEAR, EACH ADMISSION COST €10,000

IN-PATIENT CARE IS RESPONSIBLE FOR 75% OF HF COSTS.

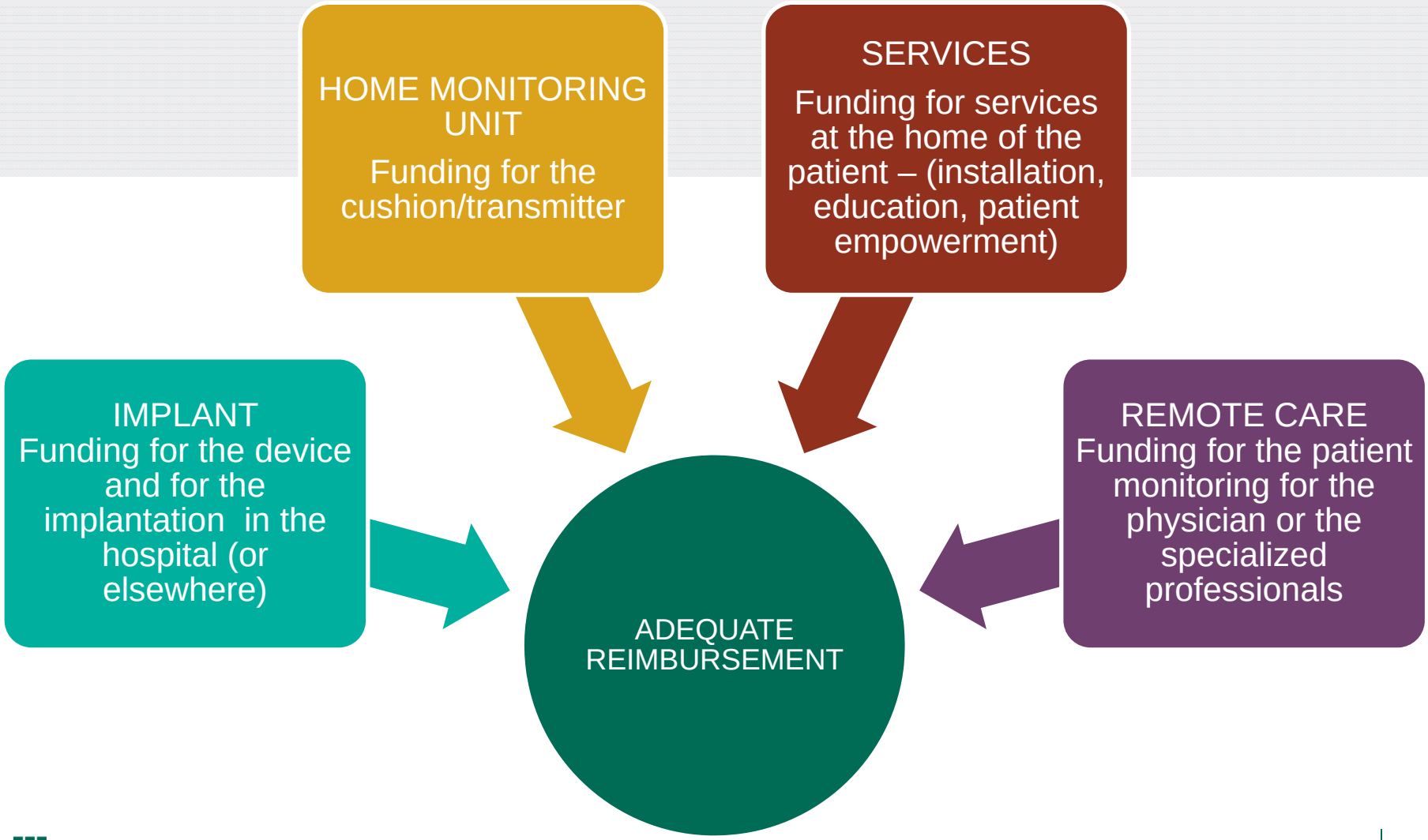
* Data from European market

HEART FAILURE PATIENT MONITORING

- The CardioMEMS Case
  - Is a diagnostic, non-active implant that monitors Pulmonary Artery Pressures of Heart Failure Patients
  - The information the implant sends via a home monitoring system unit allows physiancs to adopt the treatment before patients become symptomatic
  - RCT data shows reduction in HF re-hospitalizations by 37%
  - Improves quality of life
  - CardioMEMS is intended to monitor a limited group of patients and not all HF patients (NYHA Class 3, previously hospitalized)



CHALLENGE: PATIENT ACCESS FOR CARDIOMEMS IS COMPLEX, COMPLICATED AND UNPREDICTABLE…



MARKET ACCESS CHALLENGES: THE CARDIOMEMS CASE

Theory

Facts & activities → Should lead to → Patient Access

Reality

- Champion RCT
- FDA approval on May 28, 2014
- CE marking in 2011 and certification from BSI on 1st May 2014
- January 2015: Seed Panel on CardioMEMS
- October 2015: European Payer Roundtable on CardioMEMS

But it doesn't →

- No patient pathways
- No funding for telemonitoring
- No funding scheme for home based components
- Local evidence still needed

OUR SEED EXPERIENCE

- SEED gave us
  - A Challenge within our company to engage with external Stakeholders at an early stage
  - Views on what additional Evidence would be needed in many European countries from an HTA perspective

- What did we decide after SEED?
  - We are pursueing CED programs to generate additional evidence needed
  - We are considering Real Word Data collection and an additional RCT

- SEED did not give us
  - A clear Market Access Pathway
  - A committment of when we do all things recommended that we would be better off and gain Market Access more easily
  - We still need to approach each country individually

OUR EXPERIENCE WORKING WITH NOKC

- Clear and fair timelines
- Good preparation via life meetings
- Outlook that this engagement truly has an impact on market access in two ways
  - Market Access Outlook as the Norwegian regional health leaders play a role
  - Procurement Outlook as the Assessment will be considered by the national Procurement body

- Engagement is worth pursueing
- Increases business predictability

OUR PAYER ROUNDTABLE EXPERIENCE

- We were able to attract public and private Payers and HTA from
  - Belgium
  - Germany
  - France
- Discussions were focused on
  - The management of the disease: it requires patient empowerment and support of the patient self-management, a multidisciplinary approach working in teams, and a high level of commitment. Each patient is different hence HF management needs to become more personalized.
  - Financial barriers: slow access to innovation and lack of interoperability between different health care providers. Static financial schemes prevent
  - Different needs: scientific community, patients, industry, payers and institutions all have different views and needs
- Conclusion
  - Access to Innovation should become more predictable to ensure patients access at an earlier stage through definition of data requirements from both parties (scientific and ecoomic) based on achievable expectation which consider the necessity for SME to be payed/ financed for innovaiton while developing evidence

OUR MARKET ACCESS APPROACH

- CED (Coverage with Evidence Development) opportunities
  - Which countries offer these schemes?
  - What level of engagement is needed?
  - What is the experience so far?

- Patient Monitoring Funding
  - Not funded in most European countries
  - Multi-Stakeholder Discussions to see whether there is a willingness to change that – very challenging

- Registries
  - Can we utilize Patient Registries to better identify patients that would benefit from CardioMEMS or similar technologies
  - Can Registries (national and/or European) contribute to RWD data collection, e.g. Compare different ways of how patients are monitored and treated (Devices and Drugs)

CONCLUSIONS FOR US

- Patient and Market Access have become very challenging for true medical device innovations
- Time to market and time to Patient Access has increased severly
- Without special payment schemes or routine Reimbursement innovations are not being used by hospitals
- Without local experience with a new medical technology there is hardly any chance to get the technology utilized

CONCLUSIONS *IF CARDIOMEMS WOULD HAVE REMAINED AN SME*

- SME would most likely focus in the first years on 1-2 markets only (e.g. Norway and Switzerland) – meaning no access across Europe
- Huge workload associated with Market Access today – increased budget needed
- Experts and Consultants needed even for large companies
- SME may run out of funding during CED

HOW CAN WE CHANGE THAT?

- Do we need to overcome the speechlessness and routine reaction to new medical devices?
- A role for the HTA-N / Member states to identify promising technologies and see if e.g. a technology like this is relevant for more than one MS?
- Develop jointly defined evidence development schemes and value based assessments supported by the joint HTA cooperation
  - HOW: Early Joint Dialogue between Payers, HTA, Physicians, Hospitals and Industry – multi-stakeholder meetings to discuss how this fits into the Health Care System
  - Agreements on how we can introduce a therapy and diagnostics into a Health Care System – avoiding frustrations at all ends
- Reflect via a dedicated Multistakeholder HTA-N Platform for medical technologies how this could look like and work and therefore ensure relevant technologies of interest to MS are assessed by the EU cooperation for adoption within their jurisdiction.

MARKET ACCESS PROPOSAL FOR INNOVATIVE MEDICAL DEVICES IN EUROPE