CRM Devices and Telemonitoring – Where the industry stands today

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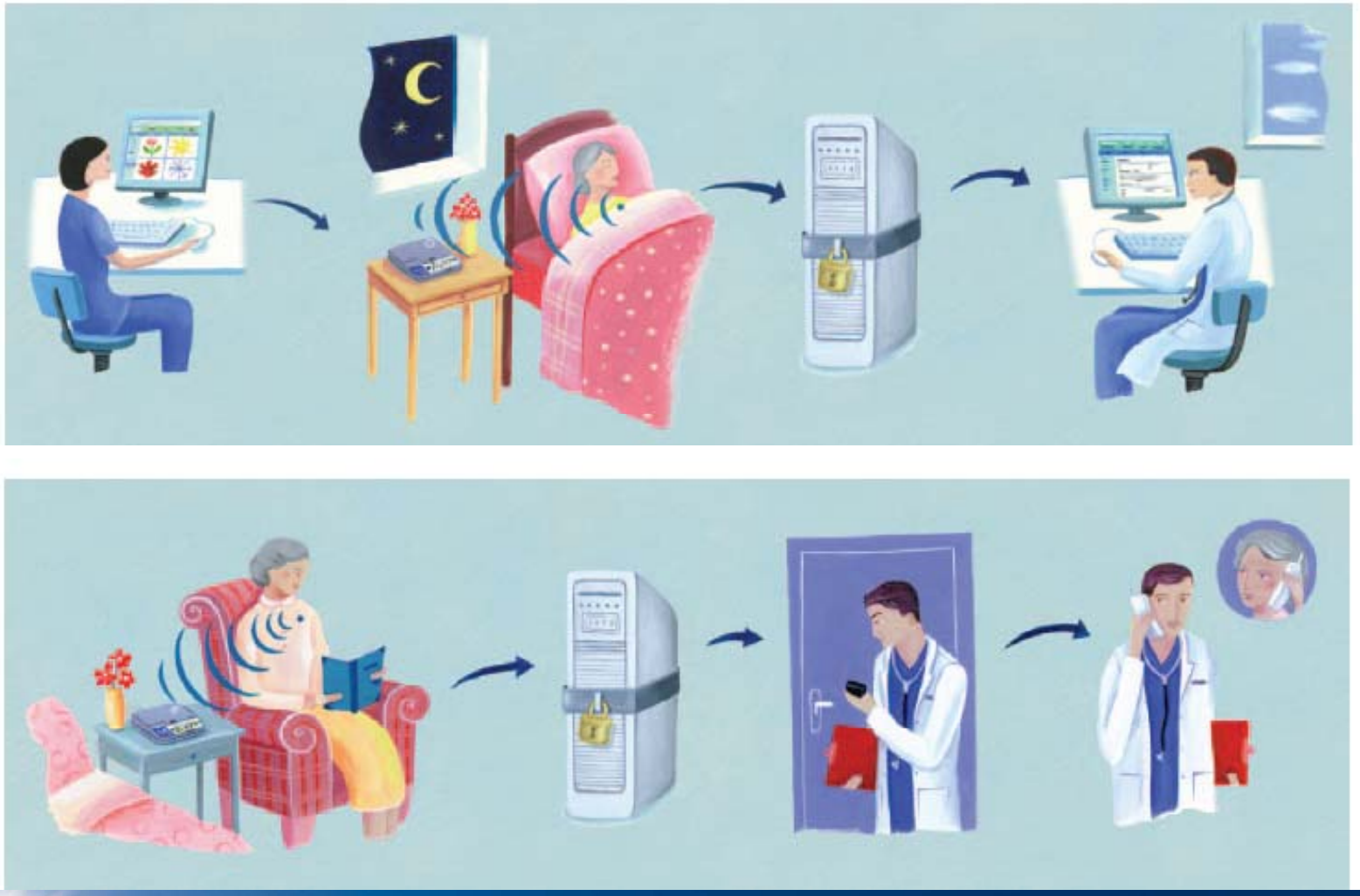
CareLink®. Your Life.

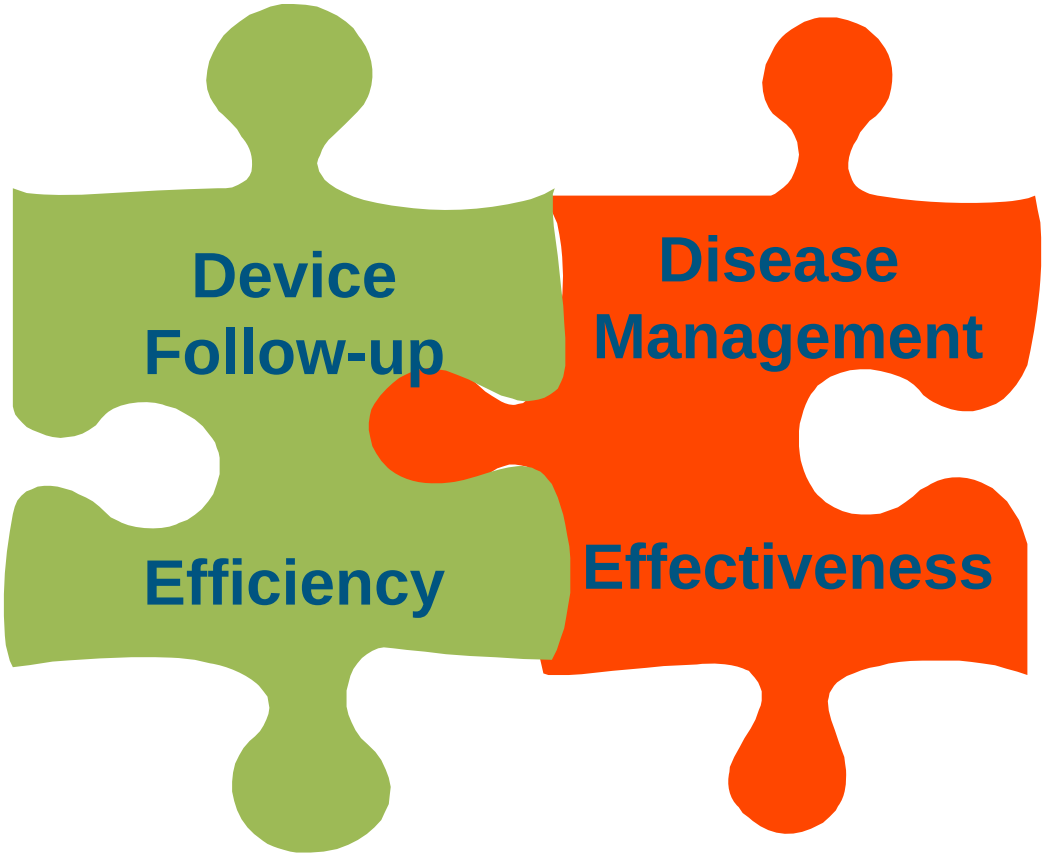
CareLink Status worldwide

- More than 450.000 patients in > 4000 clinics
- > 30 countries
- 9 years of experience
- Adoption keeps accelerating in Europe

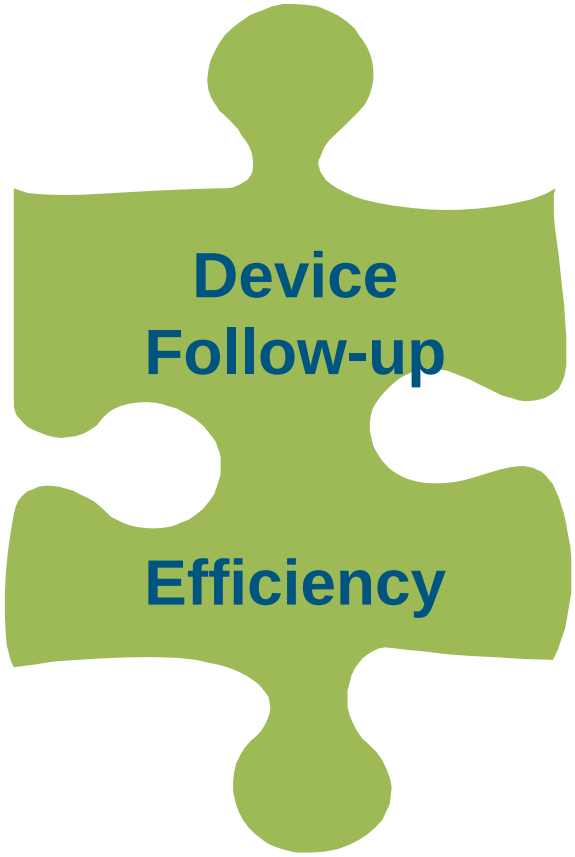
CareLink usage



CareLink Value Propositions

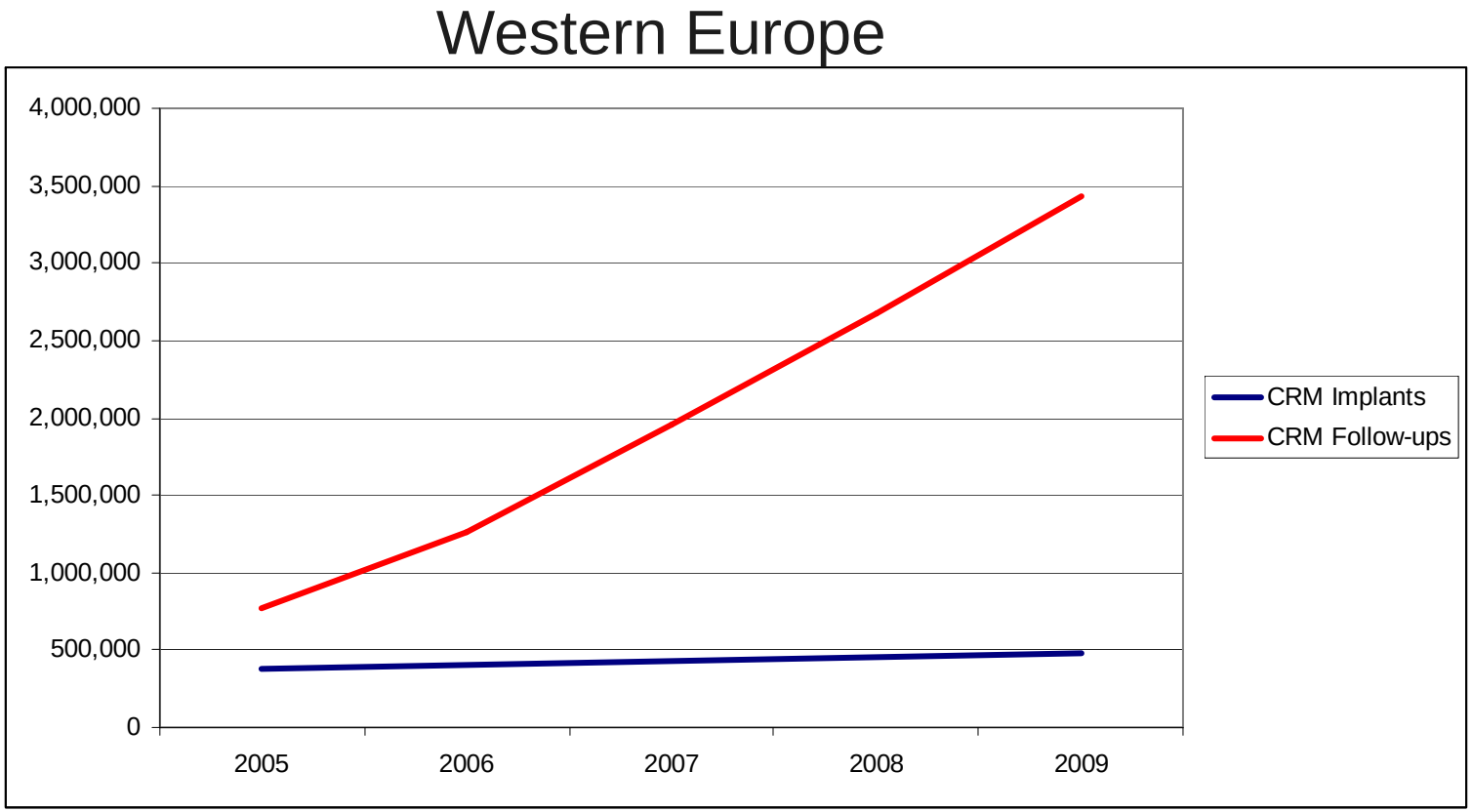


CareLink Value Propositions

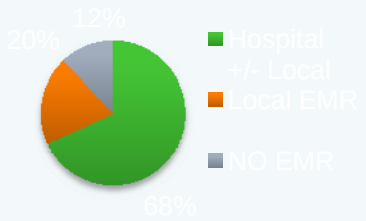
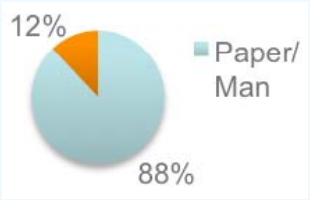
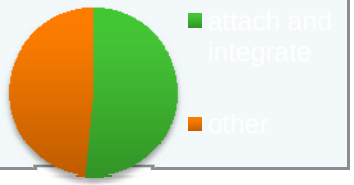


- Improved care and reduction of unscheduled visits
- Reduction of follow-up burden
- Connection to EMR systems
- Facilitation of Quality Control and auditing

Follow-up burden increases exponentially



EMR systems are becoming more common in Europe and drive connectivity needs

Topic	Key Messages	Data
Type of EMR	88% of clinics use **electronic system**; 60% have hospital EMRs	
Storage of Patient data	**88% clinics use paper filing and manual entry**	
Connectivity needs	**51%** respondents say they will need to **'attach/Integrate' data** in <12 months	

CareLink Value Propositions

- Our devices include important disease-related information:
  - Optivol
  - HRV
  - Patient daily activity
  - Resting heart rate
  - AT/AF episodes

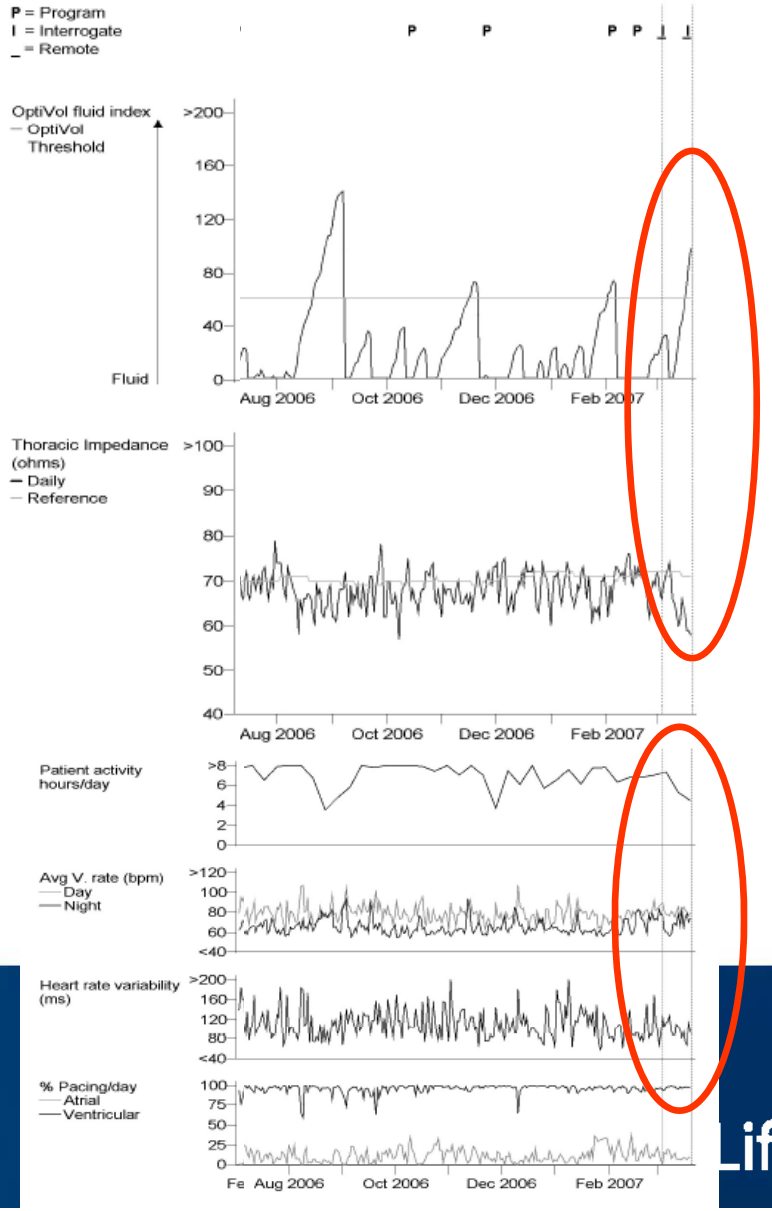
CareLink Disease Management

CareAlert for an episode of possible fluid accumulation associated with a reduction of the patient activity.

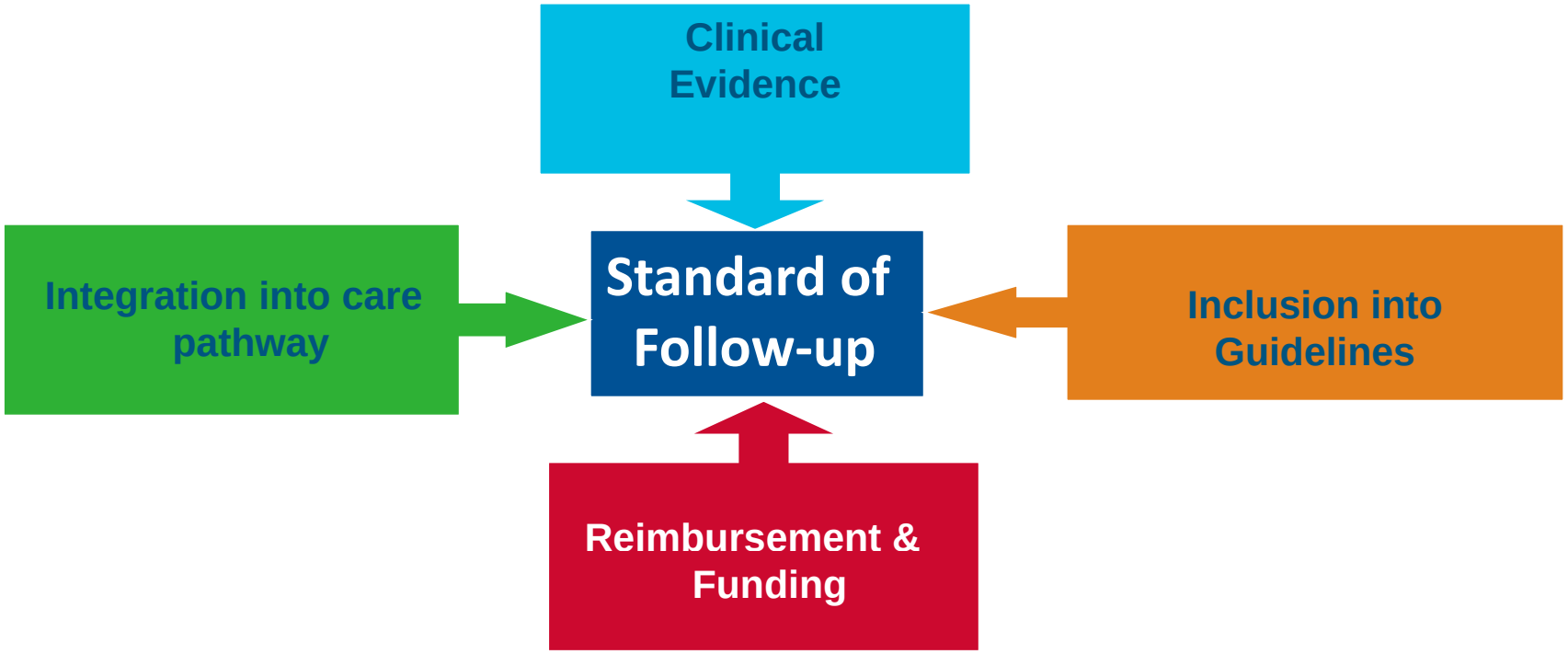
Contacted by phone, the pt reported a worsening of HF symptoms.

The diuretics dosage was increased.

The review of device data after 1 week permitted to observe the normalization of fluid and activity indices.



Establishing remote monitoring as standard of care



Liability Data Privacy Security

The rise and rise of evidence requirements – Medtronic studies completed & on-going

Device Follow-up

- **REMOTE ICD** (174 patients)
  J Cardiovasc Electrophysiol 2009
- Non-randomised observational studies:
  - **Finland** (41) *Europace 2008*
  - **Italy** (67) *PACE 2008; Journal of Telemedicine and Telecare 2008*
  - **US** (59) *PACE 2004*
  - **Australia** (225) *Presented HRS 2008*

Disease management

- **PREFER IPG** (980 patients)
  Trials 2008; J Cardiovasc Electrophysiol 2009
- **CONNECT US** (1997 patients)
  American Heart Journal 2008; Heart Rhythm Volume 5, Issue 5, Supplement 2008 ; Accepted Late Breaking Clinical Trials 59th Annual Scientific Session of the American College of Cardiology
- **OPTILINK** (1000 patients) *On-going*
- **MORE-CARE** (1721 patients) *On-going*

Result Highlights

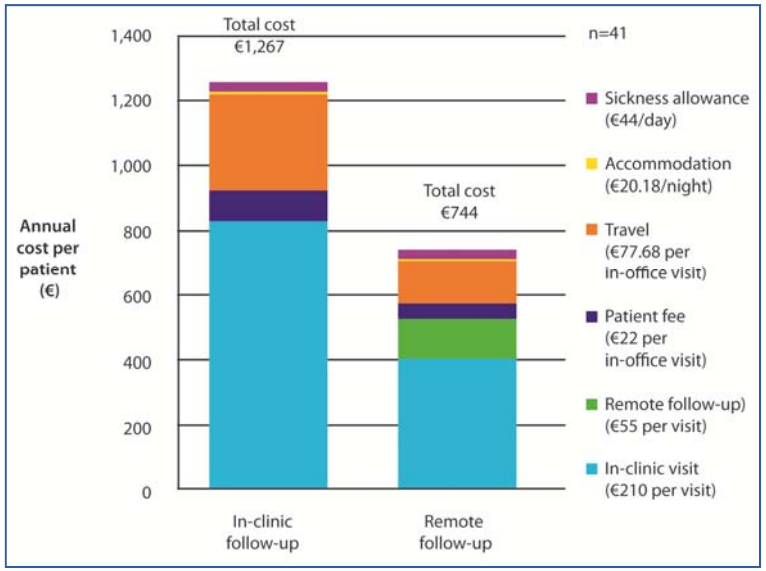
Device Follow-up

- **REMOTE ICD** (174 patients)

  No significant difference in mortality, no negative effect on the patient Health-related quality of life

- **Non-randomised observational studies (~400)**

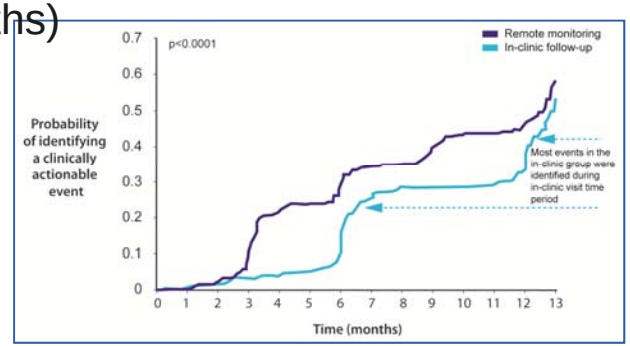
  Cost and time saving



Disease management

- **PREFER IPG**

  The mean time to first diagnosis of clinically actionable events was earlier in the Remote arm (5.7 months) than in the Control arm (7.7 months)



- **CONNECT US**

•Time from clinical event (arrhythmias, cardiovascular disease progression, and device issues) to the physician's clinical decision was 22 days versus 4.6 days for patients in the remote monitoring group

• 18% reduction in LOS for cardiovascular hospitalization

Guideline and Consensus Paper

ESC: HF Guideline , 2008

Remote monitoring

Remote monitoring can be summarized as the continuous collection of patient information and the capability to review this information without the patient present. The collection of this information may require patient participation for measures such as weight, BP, ECG, or symptoms. Newer implanted devices provide access to information such as heart rate, arrhythmia episodes, activity, intracardiac pressure, or thoracic impedance without the need to actively involve the patient.

Continuous analysis of these trends can activate notification mechanisms when clinically relevant changes are detected, and therefore facilitate patient management. Although unproven, remote monitoring may decrease healthcare utilization through fewer hospital admissions for chronic HF, fewer heart failure-related re-admissions, and more efficient device management. Ongoing trials will assess the clinical utility of such an approach.

Class of recommendation IIb, level of evidence C

Expert Consensus on the Monitoring of Cardiovascular Implantable Electronic Devices:

Table 3 Minimum frequency of CIED in person or remote monitoring*

Pacemakers/ICDs/CRT

- Within 72 hours of CIED implantation (In Person)
- 2–12 weeks post implantation (In Person)
- Every 3–12 months pacemaker/CRT-P (In Person or Remote)
- Every 3–6 months ICD/CRT-D (In Person or Remote)
- Annually until battery depletion (In Person)
- Every 1–3 months at signs of battery depletion (In Person or Remote)

*More frequent in person or remote monitoring may be required for all above devices as clinically indicated.

Where to focus evidence development for HTA and funding bodies

Device Follow-up and Disease management

HTA

Funding bodies

<u>Payer Advisory Board Recommendation:</u>

- High level evidence (RCT) required to establish a therapy
- Remote device follow-up and remote disease management is different – heavy **connection to local healthcare practices** and infrastructure, much greater need for “local” proof

How to improve Reimbursement for physicians

Device Follow-up

- France, Belgium, Italy, Netherland, Norway, Denmark, Finland, Switzerland
- Spain, Greece
- Partnership: physician/manufacturers with Regional/National payers

Disease management

- Need to go with a pathway and protocol
- Partnership with physicians/local payers where
- Link to current disease management programs: UK, Italy, Germany

Integration into care pathway

EP – Device clinic

Patient

Cardiologist HF Specialist

General Practioner

Home Care

Integration into future care pathway

Therapeutic
OptiVol, Activity, HRV, NHR, AT/AF, VT/VF, V Rate during AT/AF, % Pacing

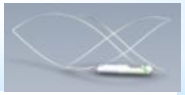
CRT & ICD

Rhythm
Reveal: Activity, HRV, NHR, AT/AF, VT/VF, V Rate during AT/AF

SubQ Micro Monitor

Hemodynamic
PA Pressure

P.A Pressure Monitor



Non-invasive
Philips, HomMed, Corventis Symptoms, Weight, BP, INR, O_2, Medication, Depression, Lifestyle

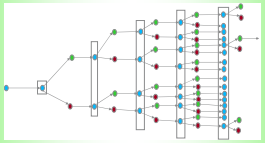
Patch Monitor

Patient

Acute Tests

Integrated Diagnostics

Flexible & Expandable Intelligent Algorithm



Patient Triage

HF Hospitalization Risk Contributing Factors

Remote Pt Management

Clinician

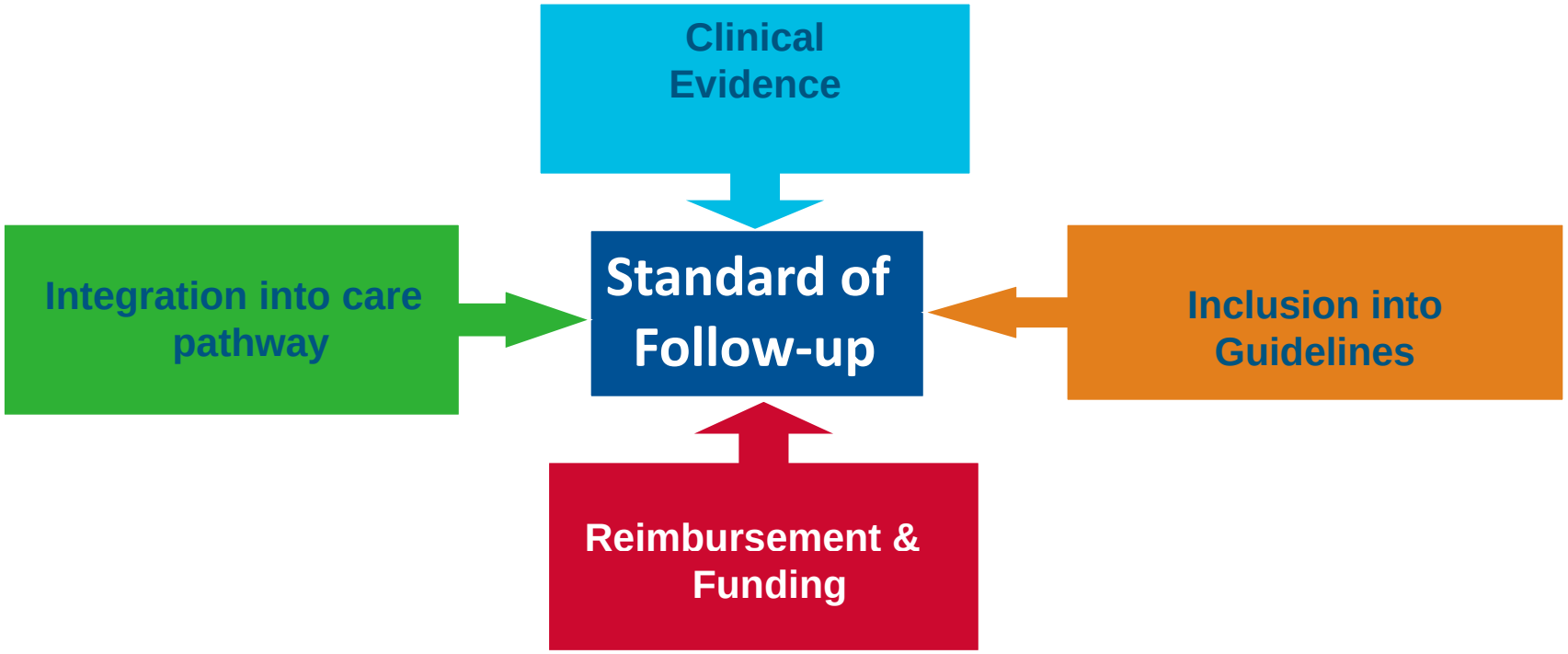
Increased Patient Adherence
Simple Interpretation
Next Step Treatment Actions
Reduced Hospitalizations
Chronic & Acute Solutions

Patient

Feedback
Instructions
Therapy Support

Medtronic

Establishing remote monitoring as standard of care



Liability Data Privacy Security

Thank you for your attention

Reimbursement update

Physician/ hospital payment	Countries	Commets
	Germany, UK, Portugal, Sweden	In UK the tariff is not specific for remote device check. Centre of Evidence-Based purchasing in UK is going to publish a Buyers Guide
	Italy, Netherland, Norway, Denmark, Finland	Physician support needed for a tariff for remote care
	France	Law was recently changed so remote care can be reimbursed. Tariff not yet finalized. A **Premium price recognized to the device + monitor from the Government**
	Belgium, Switzerland	By law, in-person evaluations is mandatory to get reimbursement. KCE in Belgium is going to publish a mini-HTA • FOPH in Switzerland is working on a report submitted by the local trade association to accept the remote services in the list of Health Services
	Spain	Identify and garner physician believers and advocates for remote care. Global budget system can facilitate payment.

The PREFER study

- 980 US patients implanted with pacemaker enrolled
- Prospective, randomized, parallel, unblinded, multicenter, open-label clinical trial
- Primary endpoint: utility of quarterly remote interrogation to determine the earlier diagnosis of clinically actionable events (CAEs) compared with the existing practice and routine office visits

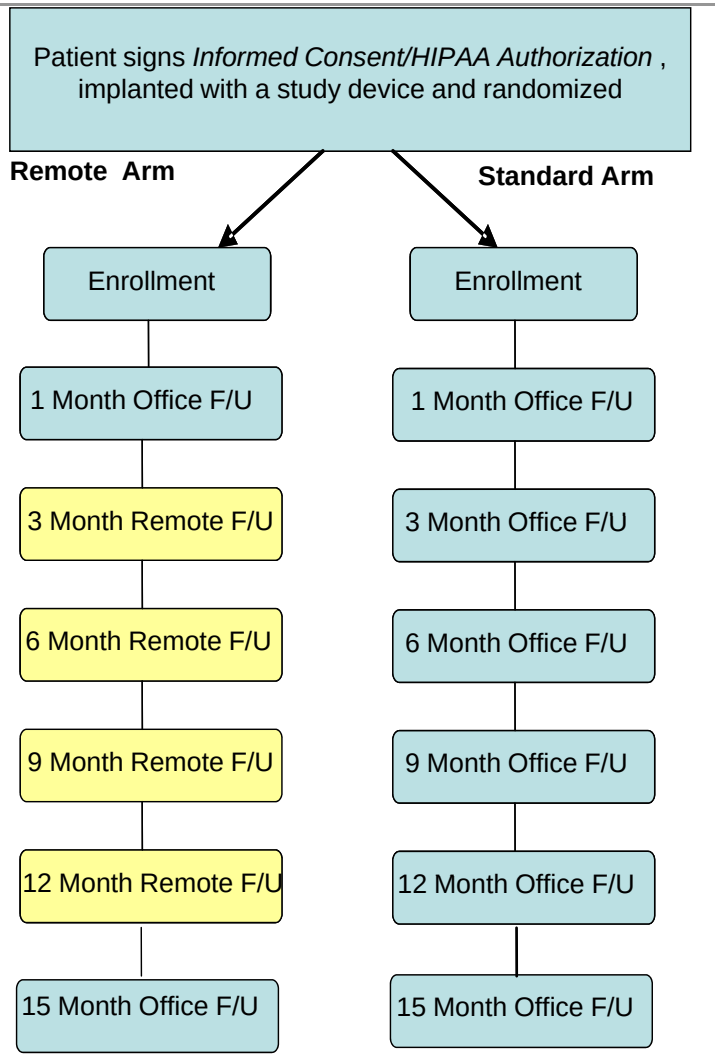
  GOAL: Early identification > early intervention > impact on clinical
- Remote arm: 3 remote transmissions and one in-clinic visit at 12 months
- Control arm: 2 in-clinic visits at 6 and 12 month

Jane Chen et al; *Trials* 2008, **9**:18; Crossley GH et al. J Am Coll Cardiol 2009;54:2012-9

The CONNECT Study

- 150 US centers
- **1,997 Pts**. CRT/ICD
- **Randomized 1:1**
- First Enrollment: Nov. 2006
- FU Complete: Aug. 2009
- Database Locked Sept. 2009

- Treatment arms are balanced and representative of the general ICD/CRT-D population



Crossley GH et al. American Heart Journal Volume 156, Number 5

CONNECT: Study Objectives

Primary Objective:

- Remote Management reduces time to clinical decision

Secondary Objectives:

- Reduces Healthcare Utilization (hospitalizations, ER visits)
- Remote Management reduces patient and caregiver burden
- Characterize clinic satisfaction with wireless ECG
- Measure Patient Well Being (anxiety, depression, quality of life)
- Show Left Ventricular Capture Management (LVCM) variability
- Evaluate the compliance with scheduled CareLink transmissions

OptiLink

- **OptiLink HF**: Prospective, multi-center, unblinded, 1:1 randomized, controlled study (ICD or CRT-D)
- The objective of the study is to establish whether the use of event-triggered HF-disease management through Medtronic's OptiVol® fluid status monitoring with an automatically generated wireless CareAlert® notification of the clinician via the Medtronic CareLink® Network can reduce cardiovascular related hospitalizations and the number of deaths in a subject population with HF and ICD / CRT-D treatment as compared to standard clinical assessment.
- **1.000 patients** followed up for 18 months (Germany)
- Start Date: September 2008
- Estimated Completion Date: October 2013

MORE-CARE: MOnitoring REsynchronization in CARdiac patiEnts

- **MORE-CARE**: International, prospective, multi-center, randomized, controlled trial (CRT-D). First enrollment April 2009

- Phase 1. Demonstrate that the remote management system reduces the time from device detected event onset to clinical decision for arrhythmias, cardiovascular disease progression, and system issues compared to patients receiving only in-office care. (June 2012)

- Phase 2**.** Demonstrate that the remote monitoring strategy in CRT-D patient management reduces the occurrence of death from any cause, cardiovascular and device-related hospitalization (at least 48-hour stay) in the Study Group with respect to the Control Group (Dec 2013)
- **1721 patients** followed up for 24 months in: Italy, Spain, Switzerland, Israel Hungary, Czech Republic, Sweden, Denmark, Benelux, UK, Portugal, France

The FAST project

This tender is led by MedCom, Denmark, in partnership with the:

1. Norwegian Centre for Integrated Care and Telemedicine (NST)
2. Department of Applied Social Science, University of Stirling
3. the Norwegian Knowledge Centre for the Health Services
4. a panel of international expert advisers, in business, economics, health policy analysis, Health Technology Assessment, and medicine
5. stakeholders in telemedicine including patient groups together with the WHO Observatory, EU commission

Aims

The project aims to provide a benchmark document (the ‘MethoTelemed Guidance’) which will:

- Provide systematic documentation of the manner and extent of telemedicine applications in healthcare systems
- Provide a structured framework for assessing the effectiveness and contribution to quality of care of telemedicine applications.