La Gestione Remota dello Scompenso Cardiaco tra Benefici Clinici, Difformità di Accesso e Tracciabilità della Prestazione

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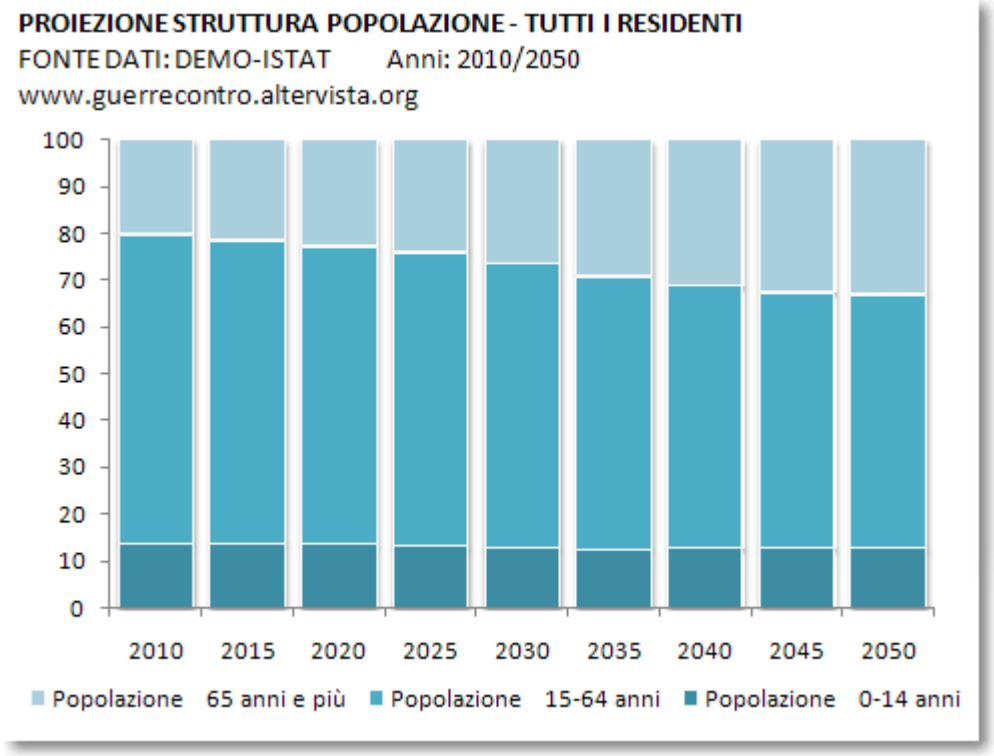
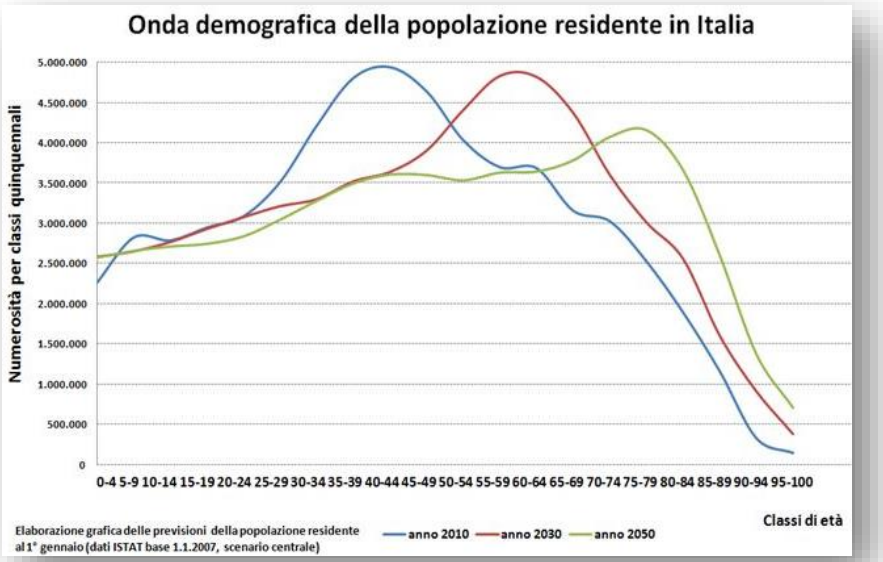
La Popolazione Italiana





- Incremento longevità
- Incremento quota over 65 anni

La popolazione anziana è quella più esposta a patologie croniche tra le quali:

- **Scompenso cardiaco (SC)**
- **Fibrillazione atriale (FA)**

Leading Causes of Death

By AMERICAN HEART ASSOCIATION NEWS

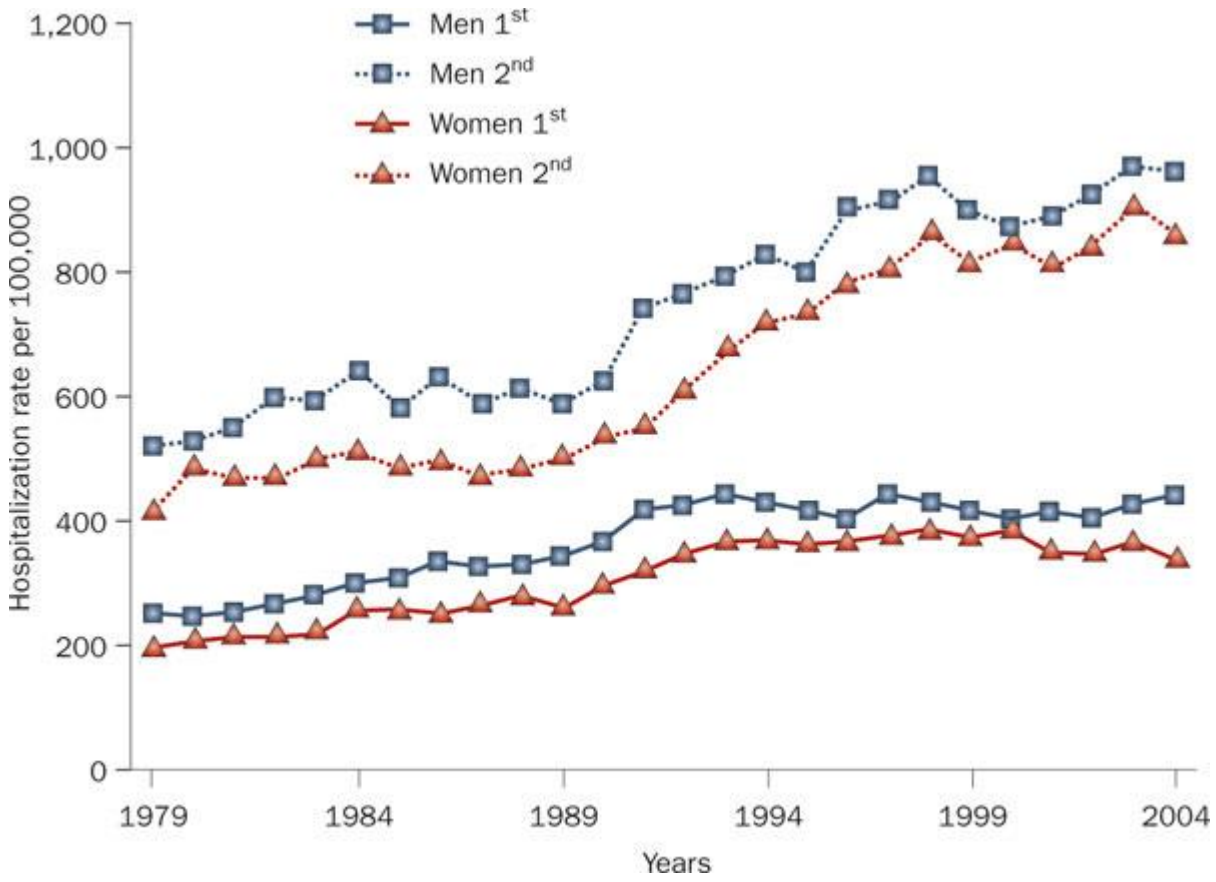
Heart disease continues to kill more Americans than any other cause, followed by stroke at No. 5, according to 2015 federal data.

	Total Deaths	Share of Total
Heart disease	633,842	23.4%
Cancer	595,930	22%
Chronic lower respiratory diseases	155,041	5.7%
Accidents	146,571	5.4%
Stroke	140,323	5.2%
Alzheimer's disease	110,561	4.1%
Diabetes	79,535	2.9%
Flu, pneumonia	57,062	2.1%
Kidney disease	49,959	1.8%
Suicide	44,193	1.6%

Source: Centers for Disease Control and Prevention

Published Dec. 8, 2016

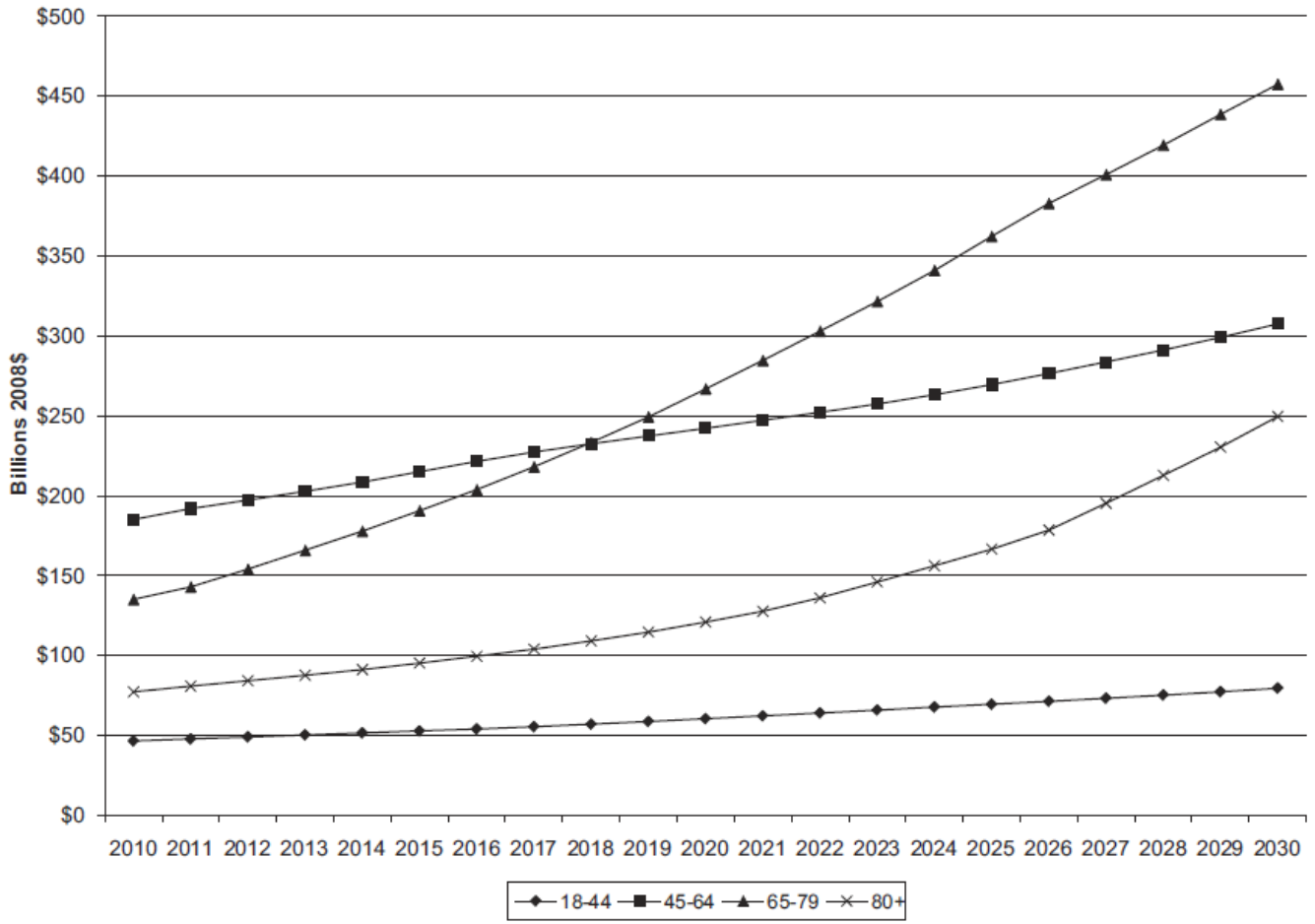
Ricoveri per Scompenso Cardiaco



AHA Policy Statement

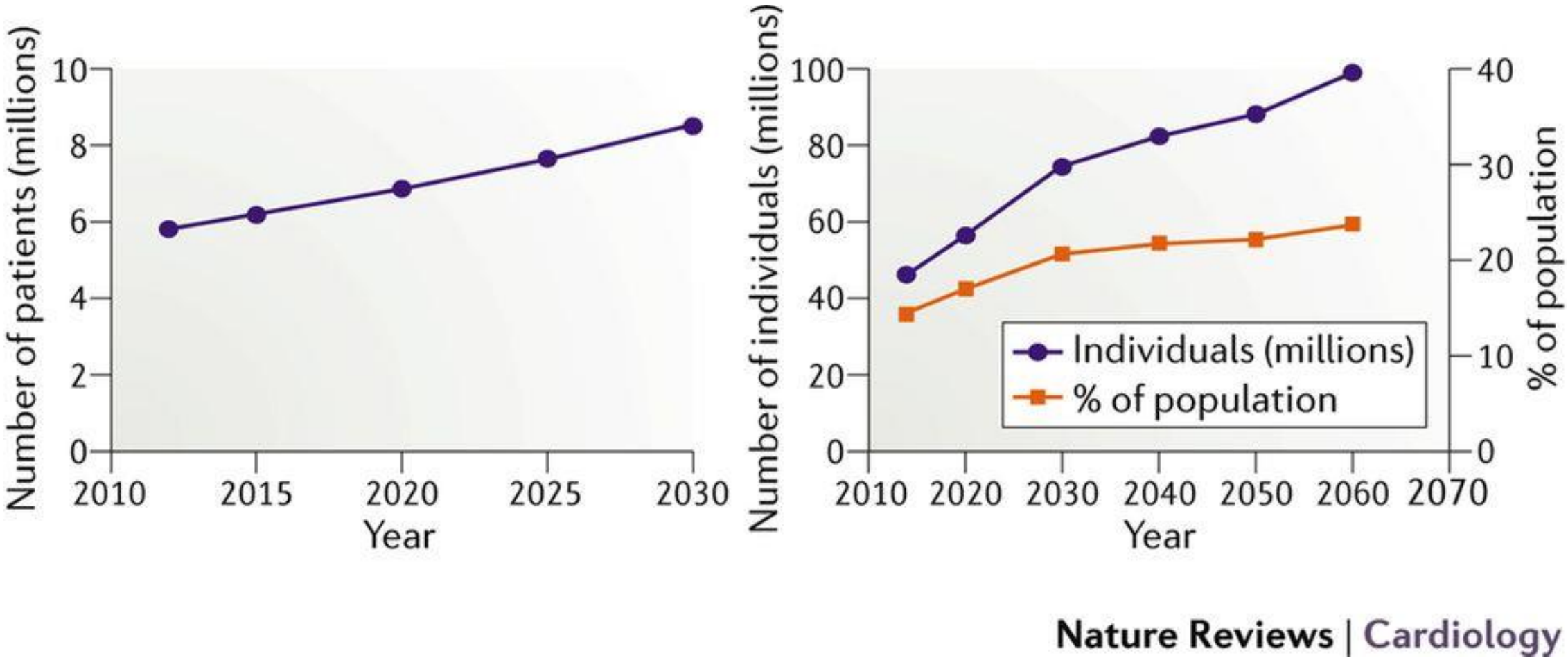
Forecasting the Future of Cardiovascular Disease in the United States

A Policy Statement From the American Heart Association



Circulation. 2011;123:933-944

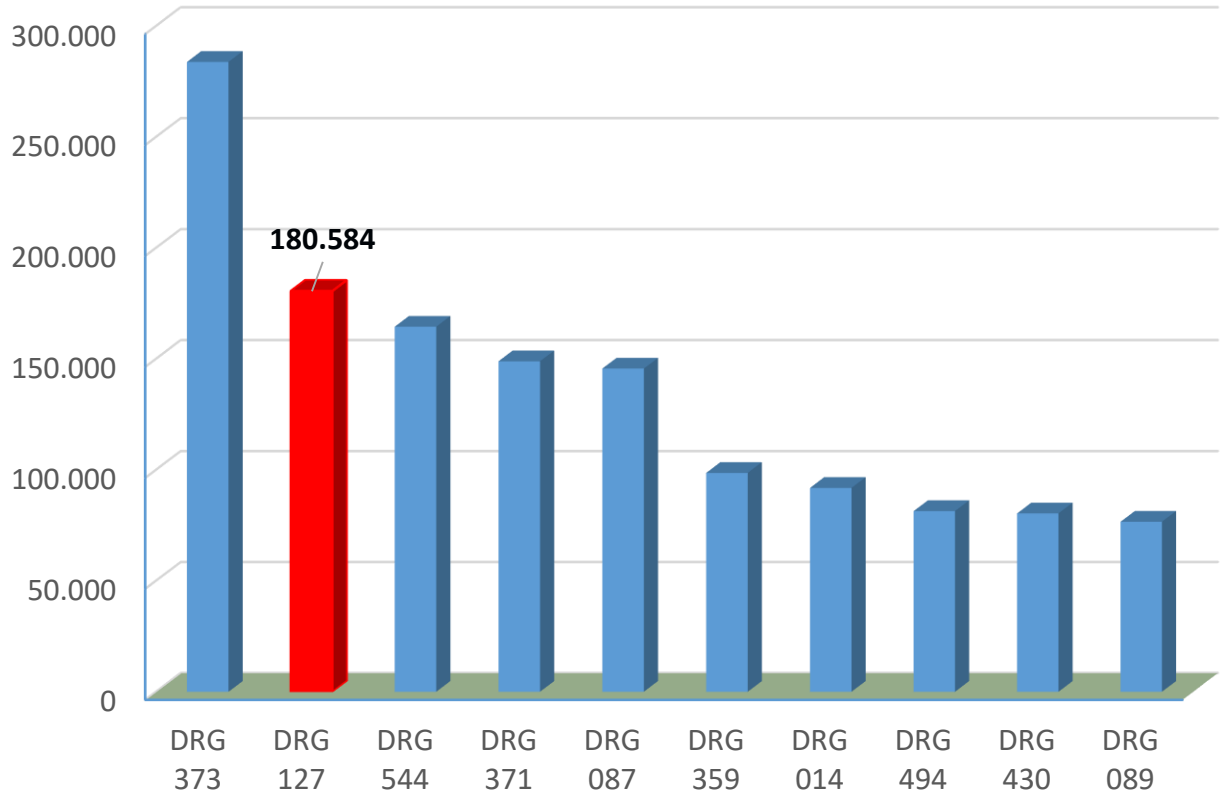
Projected population burden of heart failure in the USA



Nature Reviews Cardiology 2017 **volume14**, pages591–602

ITALIA: Primi 10 DRG per numerosità dimissioni

Attività per acuti Regime Ordinario – Anno 2016 (Dati SDO Ministero Salute)



DRG 373: Parto vaginale senza diagnosi complicanti

DRG 127: Insufficienza cardiaca e shock

DRG 544: Sostituzione di articolazioni maggiori o reimpianto degli arti inferiori

DRG 371: Parto cesareo senza CC

DRG 087: Edema polmonare e insufficienza respiratoria

DRG 359: Interventi su utero e annessi non per neoplasie maligne senza CC

DRG 014: Emorragia intracranica o infarto cerebrale

DRG 494: Colecistectomia laparoscopica senza esplorazione del dotto biliare comune senza CC

DRG 430: Psicosi

DRG 089: Polmonite semplice e pleurite, età > 17 anni con CC

*Rapporto annuale sull'attività di ricovero – Dati SDO 2016. Ministero della Salute

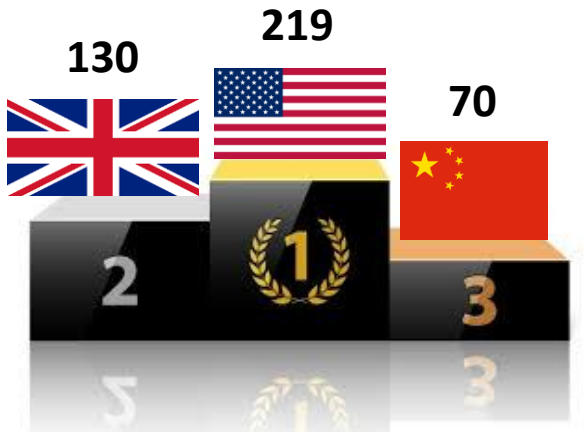
Scompenso Cardiaco: problema di Salute

PREVALENZA

- 62 milioni di adulti affetti da HF nel mondo – stima prevista in aumento

INCIDENZA

- Nuovi casi per 100.000 per anno



CRESCITA

Prevalenza dei Fattori di Rischio in Aumento

Scompenso Cardiaco PREVALENZA

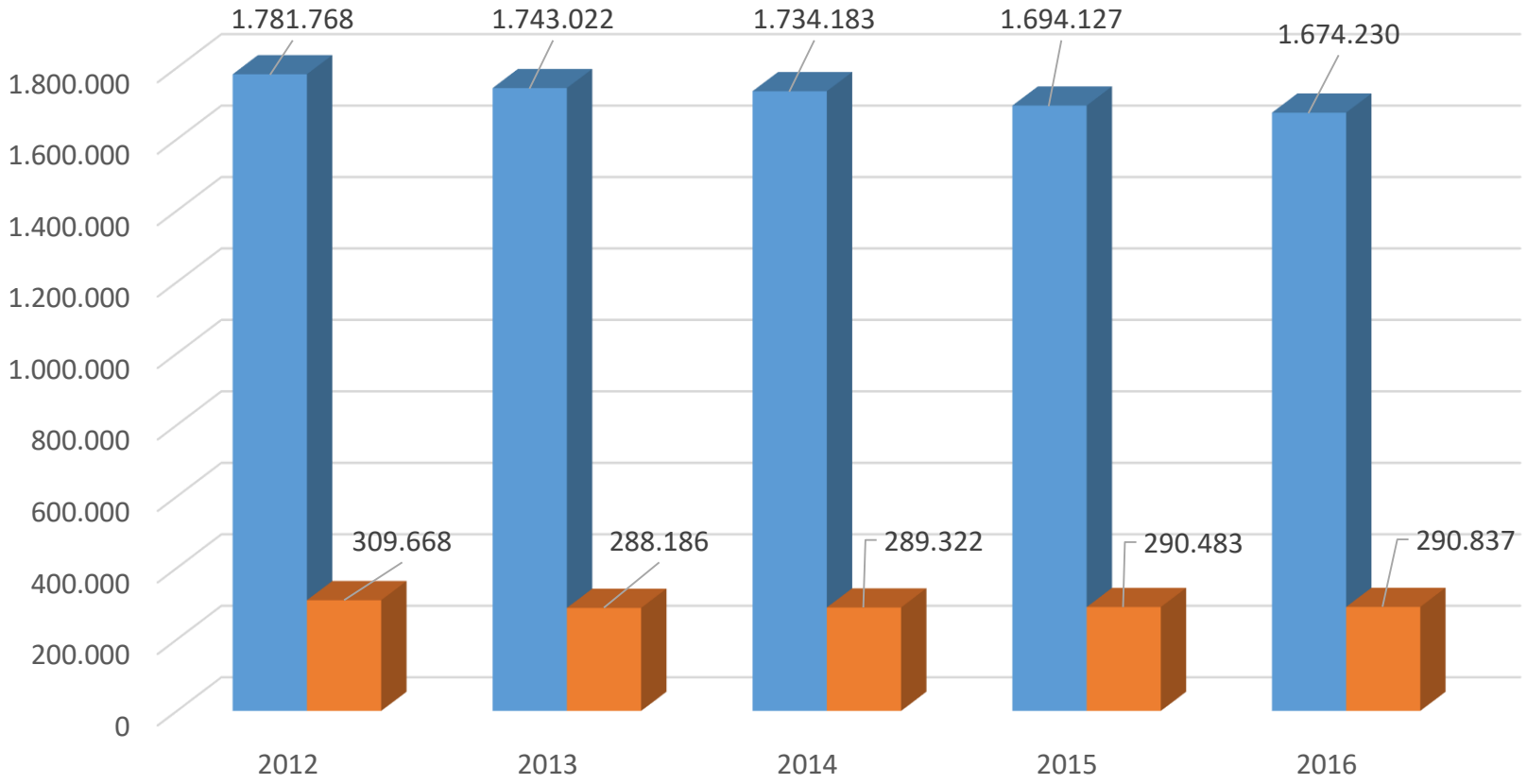
Sopravvivenza post-IMA Migliorata

Invecchiamento della Popolazione

Più del 50% muore entro 4 anni dalla diagnosi: il 40% dei ricoverati entro 1 anno dal ricovero

Giorni Degenza e Oltre Soglia negli ultimi 5 anni

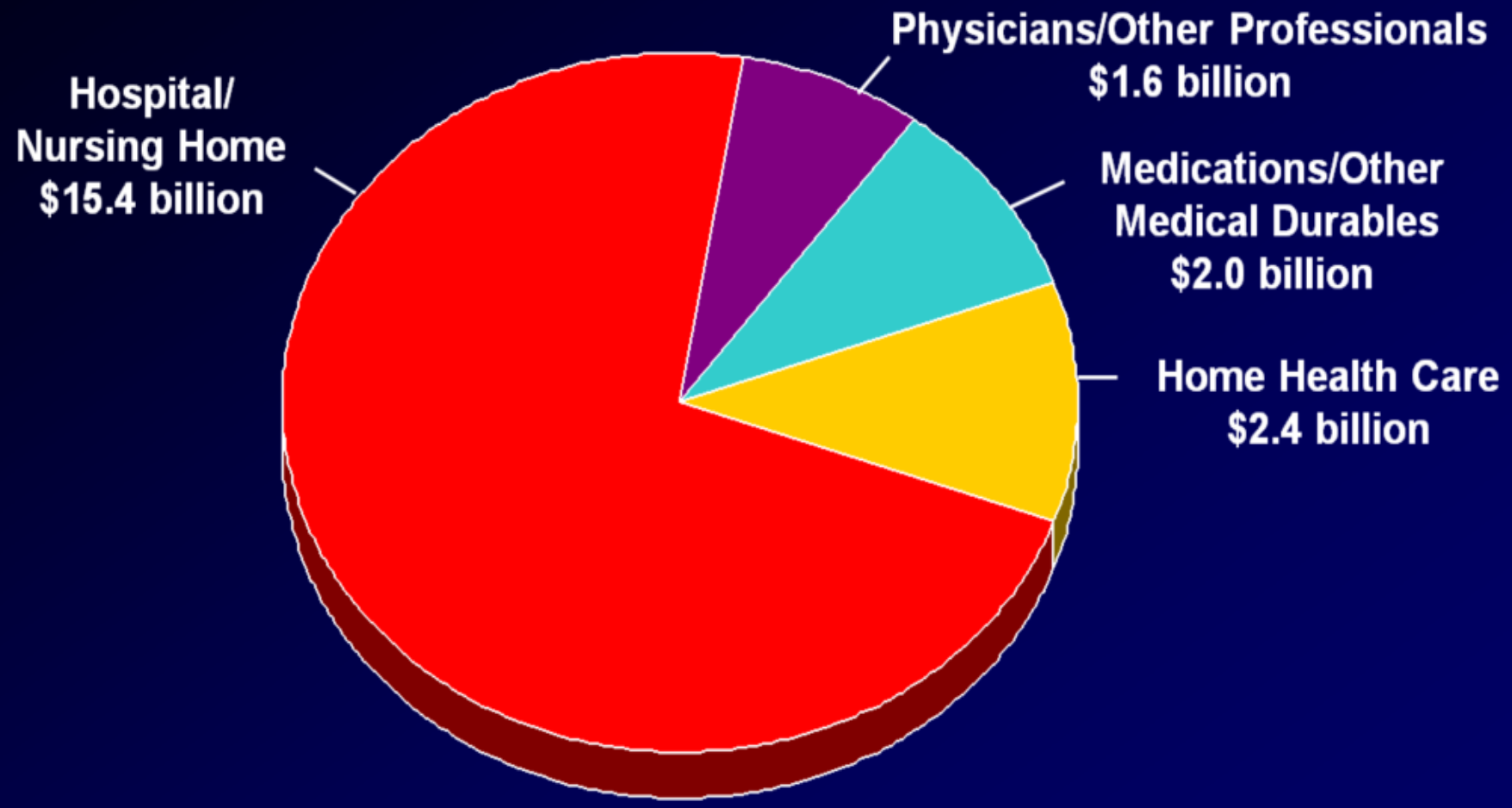
Dati SDO anni 2012 – 2013 – 2014 – 2015 – 2016
(Regime Ordinario – Giorni di degenza e Oltre Valore Soglia)



Valore soglia = 21 giorni

*Rapporto annuale sull'attività di ricovero – Dati SDO. Ministero della Salute

Estimated Total Direct Costs of Heart Failure in the United States

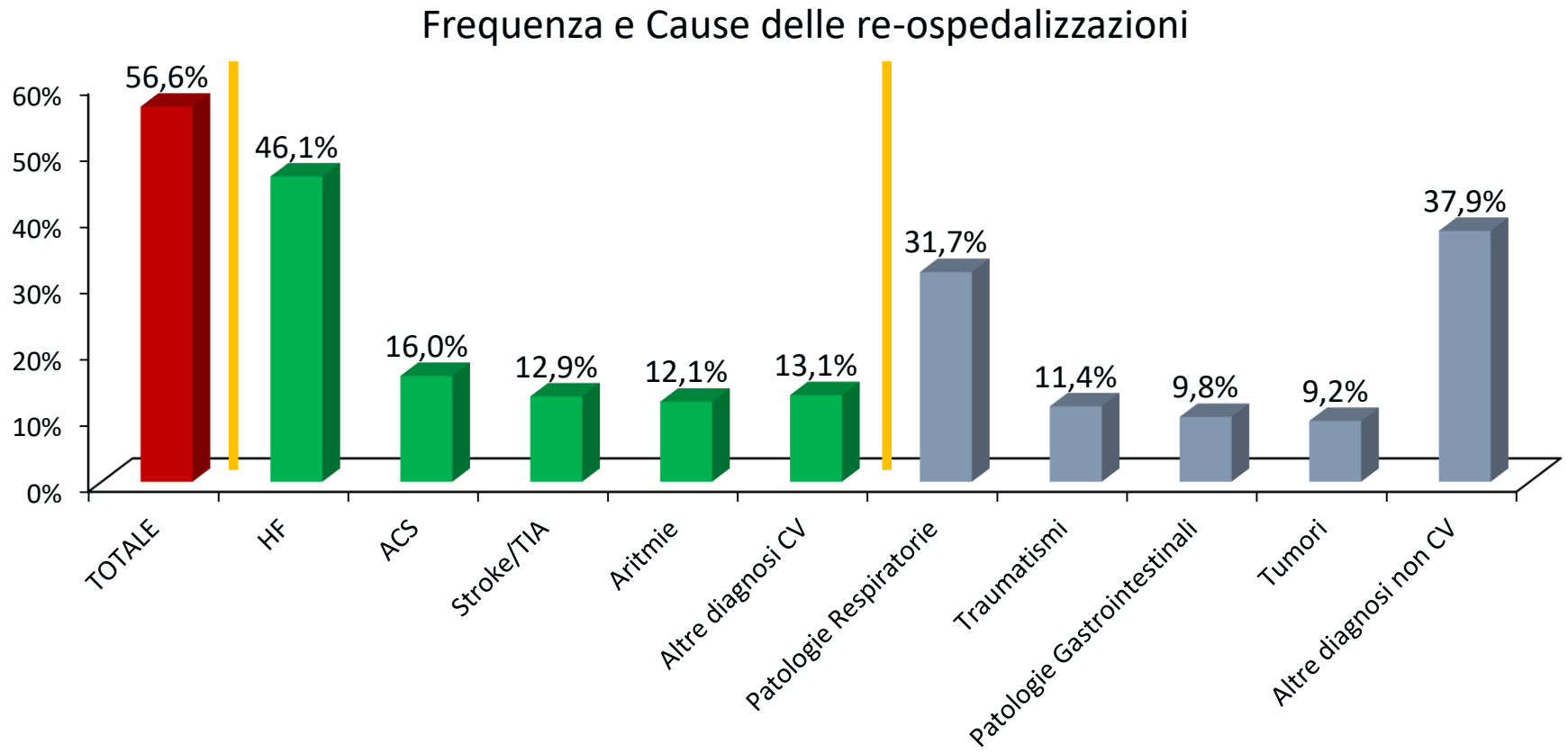


Total cost = $21.4 billion

American Heart Association. *2003 Heart and Stroke Statistical Update.*

Scompenso Cardiaco: Le Re-ospedalizzazioni in Italia

Il **56% dei pazienti dimessi** ha necessità di almeno **1 ricovero nell'anno successivo** alla dimissione. Più o meno la metà dei ricoveri ha cause NON-cardiovascolari ne consegue la necessità di un atteggiamento **multidisciplinare**.



Dati: Osservatorio ARNO - 2015

La Cronicità in Italia

Le Malattie Croniche nel 2017 hanno interessato quasi il 40% della popolazione Italiana:

- **24 milioni i malati cronici**
- **di questi 12,5 milioni affetti da multi-cronicità**

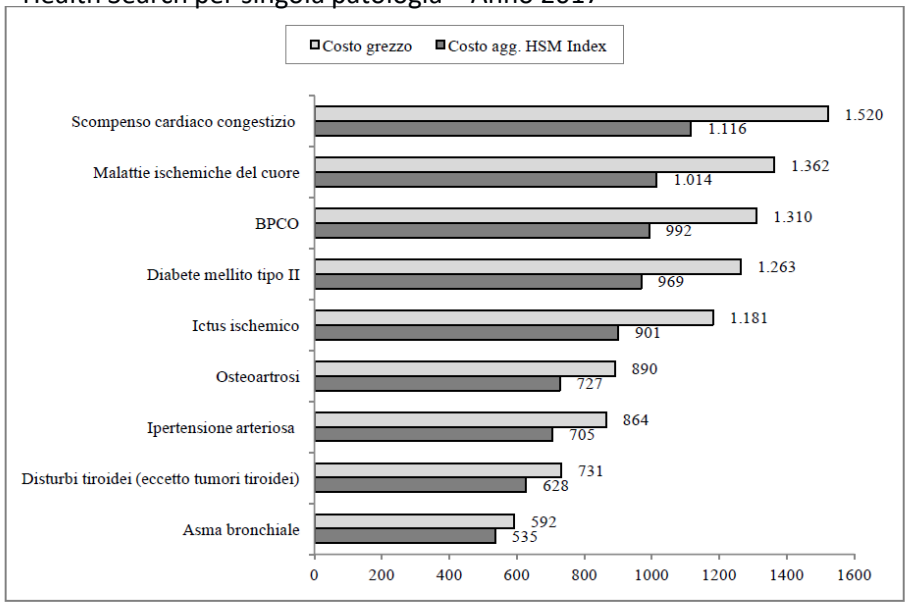
Persone (assoluti in migliaia) per presenza di patologie croniche e tipologia di patologia - Anno 2017 e proiezioni anni 2028 e 2038

Tipologia di patologie	2017	2028	2038
Persone con almeno una malattia cronica	**24.040**	**25.233**	**25.589**
Persone con almeno due malattie croniche	12.578	13.907	14.673
Diabete	3.411	3.634	3.908
Ipertensione	10.702	11.846	12.523
Bronchite cronica	3.553	3.731	3.856
Artrosi/artrite	9.723	10.803	11.506
Osteoporosi	4.772	5.279	5.757
Malattie del cuore	2.499	2.689	2.926
Malattie allergiche	6.428	6.313	5.940
Disturbi nervosi	2.732	2.925	2.978
Ulcera gastrica o duodenale	1.435	1.586	1.611

Fonte dei dati: Elaborazioni Osservasalute su dati Istat - Indagine Aspetti della vita quotidiana.

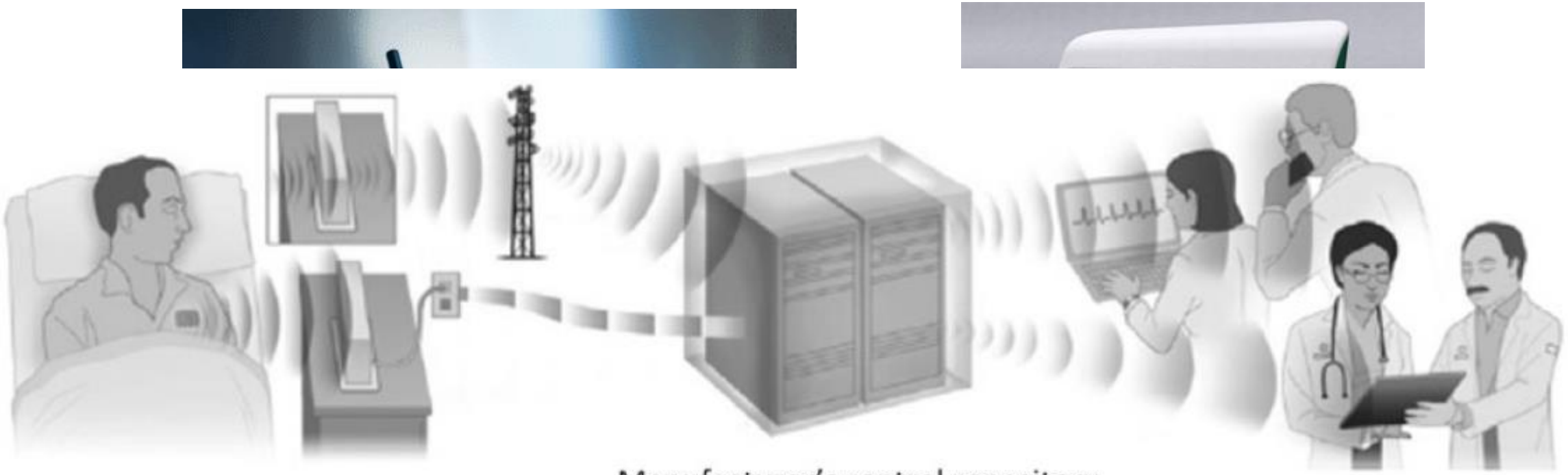
I costi per la gestione della Cronicità ammontano a 66,7 miliardi di Euro nel 2017

Costo (€) medio annuo (grezzo e aggiustato mediante l'Health Search Morbidity Index) dei pazienti assistiti dai MMG aderenti al network Health Search per singola patologia - Anno 2017

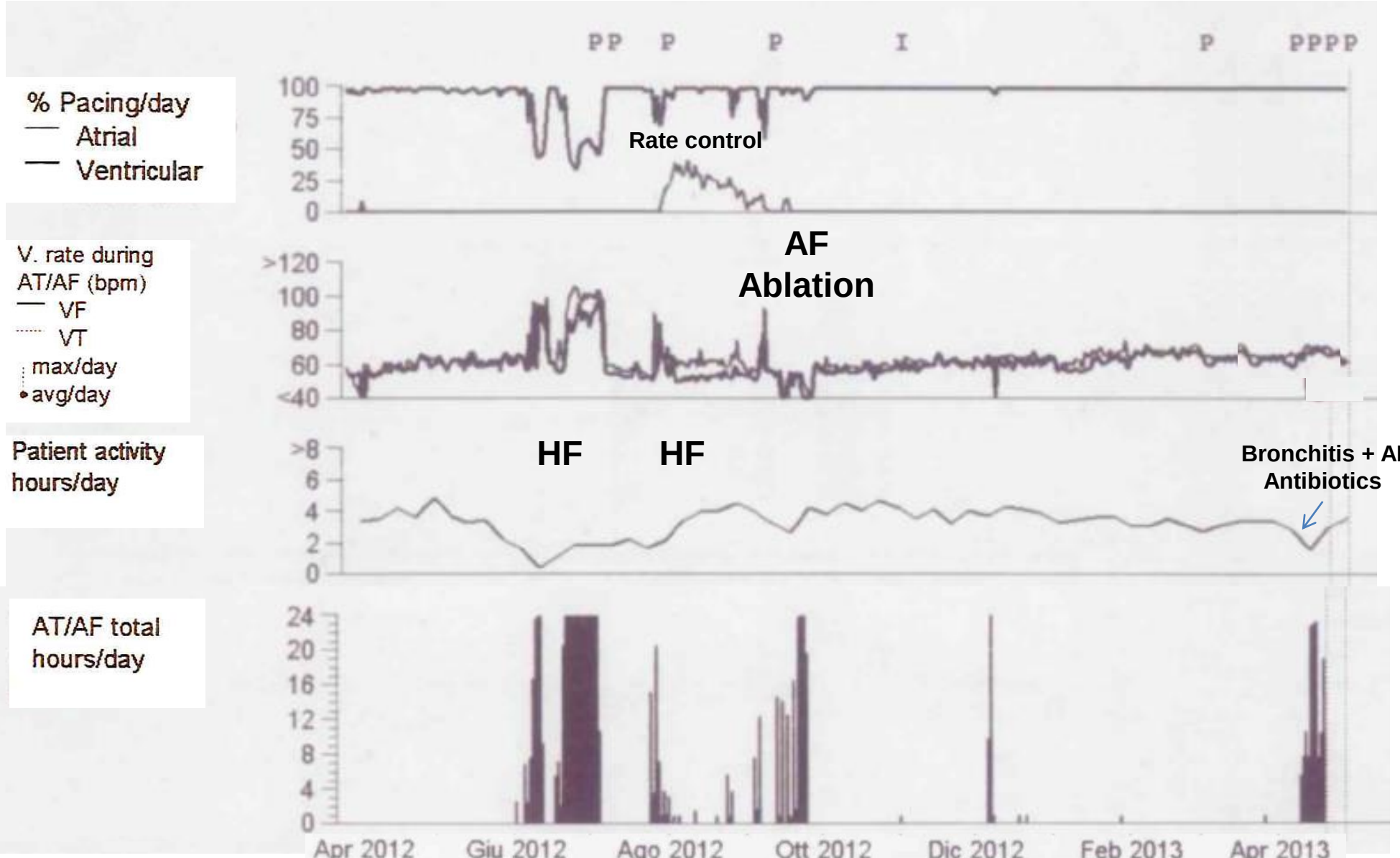


Fonte dei dati: Health Search - IMS LPD. Anno 2017.

REMOTE CIED & Patient MONITORING is the Landmark of TELEMEDICINE



• AF & HF management by REMOTE: decision is taken for AF ablation

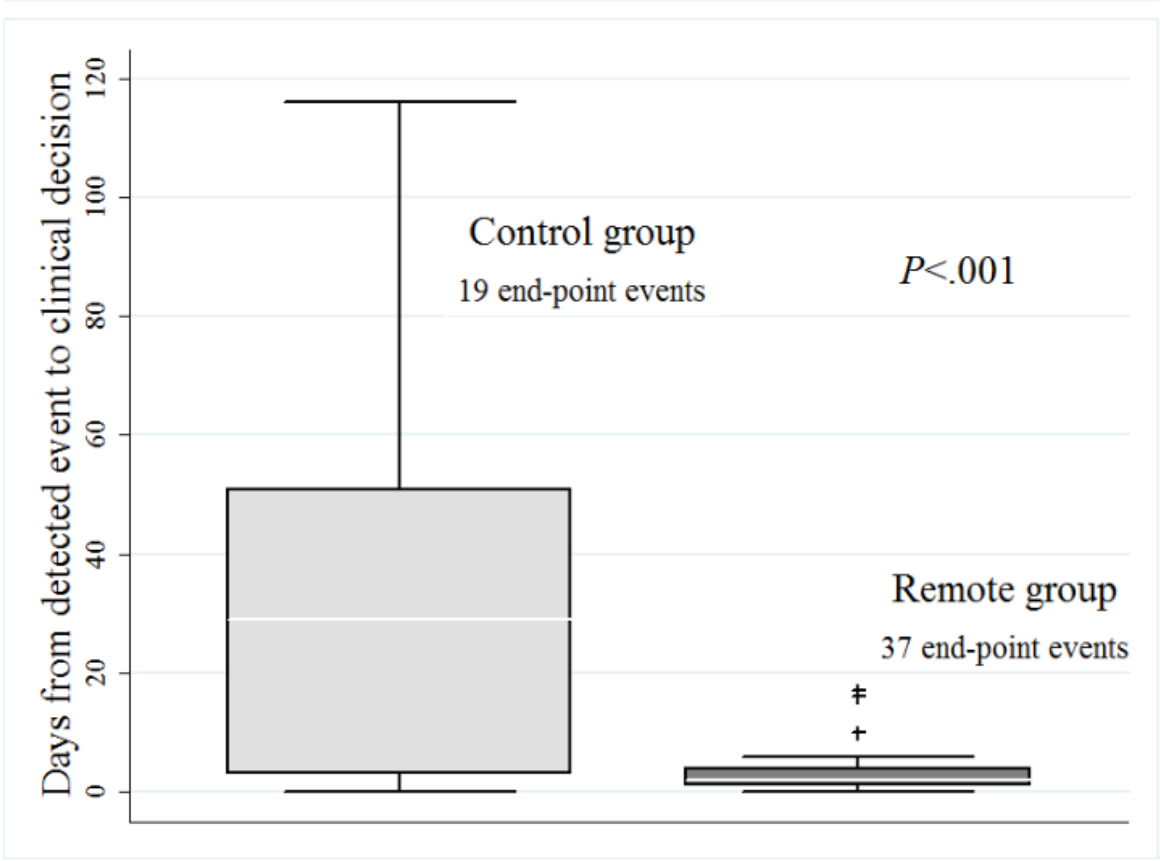


HOW to make Medical Care Sustainable ?

- Proficient USE of MANPOWER
  (Medical, Nursing and Technical staff)

- Early Intervention to Decrease Hospitalizations

The MORE CARE Trial : TIME to Decision



Boriani G, Burri H, et al JMIR 2013

The IN-TIME Trial
Home Monitoring significantly increases survival !!!!

Study Results

Modified Packer Score

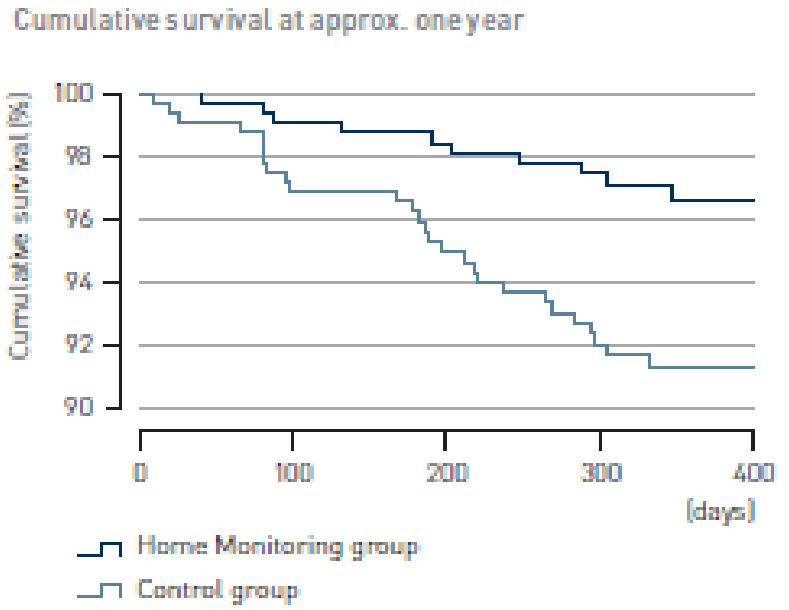
- In 18.5% of patients in the Home Monitoring arm clinical status worsened, versus 27.5% in the control arm
- Significant: P<0.05

All-cause mortality

- Reduction from 8.7% in the control arm to 3.4% in the Home Monitoring group*
- Hazard Ratio: 0.356 (95% Confidence Interval: 0.172–0.735)
- Highly significant: p=0.004

Cardiovascular mortality

- Hazard Ratio: 0.367 (95% Confidence Interval: 0.162–0.828)
- Highly significant: p=0.012



* from the Kaplan-Meier curve 1 year after randomization

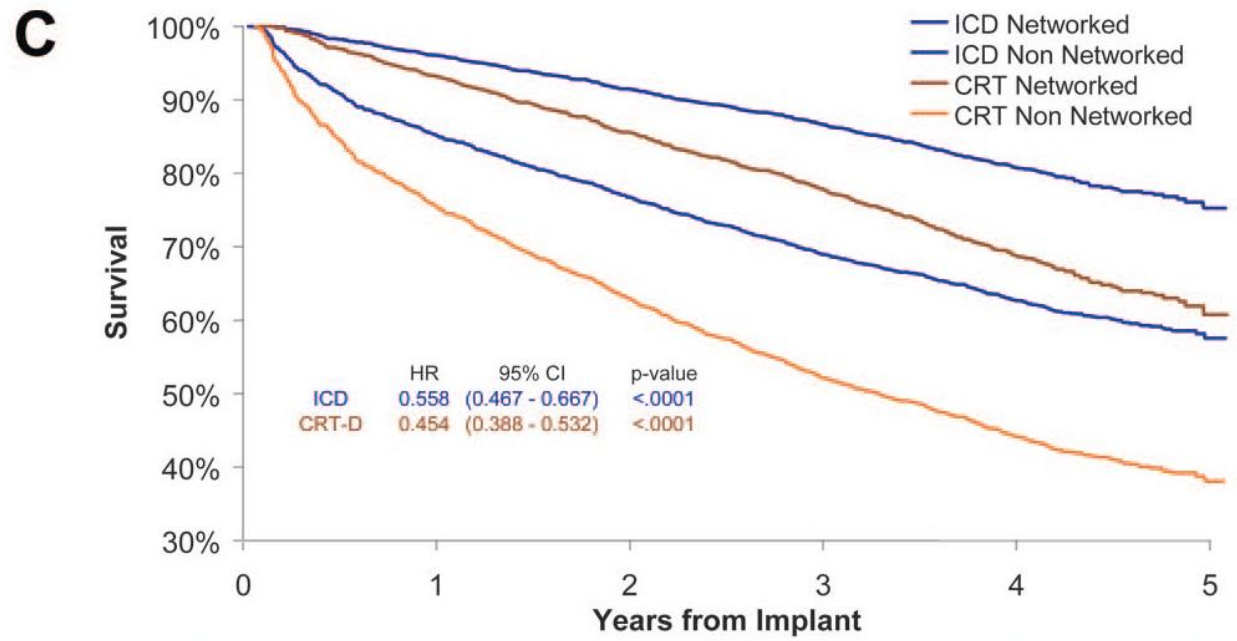
Hindricks, *Lancet 2014*

MILESTONES of Sustainable Medical Care

- REMOTE PATIENT MANAGEMENT (TELEMEDICINE)
- PATIENT EMPOWERMENT

Long-Term Outcome After ICD and CRT Implantation and Influence of Remote Device Follow-Up

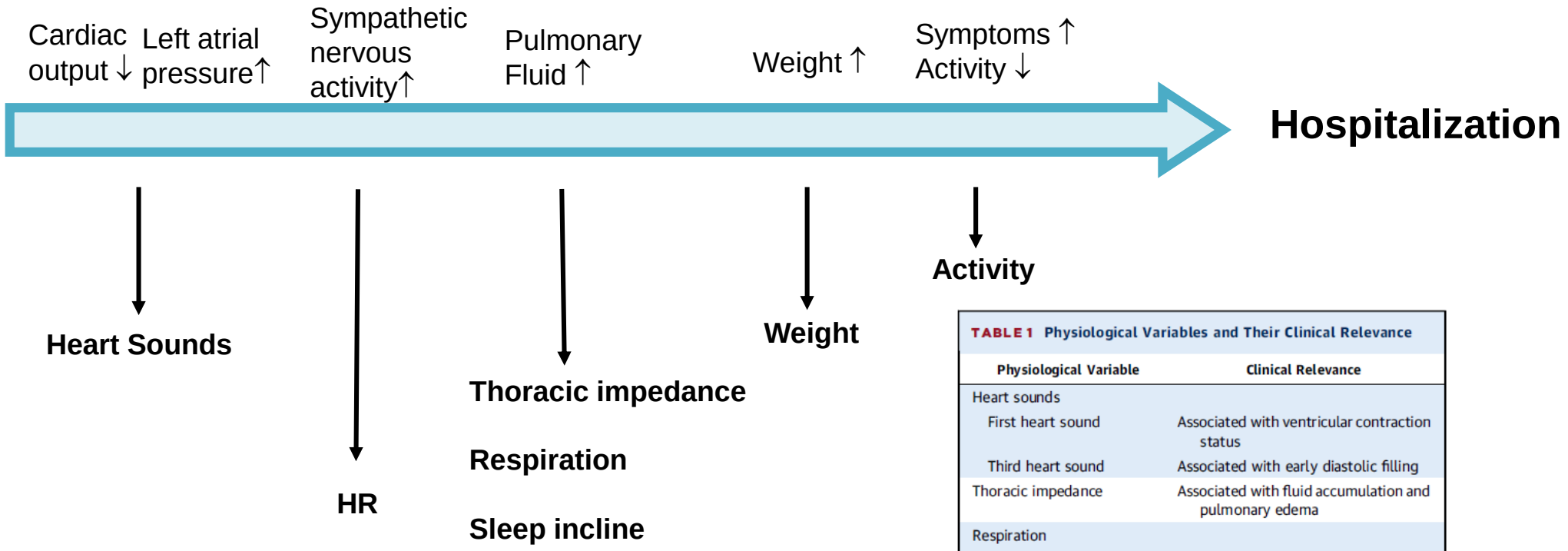
The ALTITUDE Survival Study



Networked	ICD	3,026	2,651	2,034	1,353	554	31
	CRT-D	2,110	1,913	1,479	1,065	470	20
Non-Networked	ICD	3,026	2,592	1,988	1,304	530	34
	CRT-D	2,110	1,813	1,407	1,003	452	26
Networked	ICD		96%	92%	87%	81%	75%
	CRT-D		93%	86%	78%	69%	61%
Non-Networked	ICD		85%	77%	69%	63%	58%
	CRT-D		76%	63%	52%	44%	38%

Circulation. 2010;122:2359-2367

Heart Failure can be reliably predicted by integration of device-detected and non-invasive measurements



There is a large individual variability in presentation and time course, even for the same patient. Thus, several patterns may precede a decompensation.

TABLE 1 Physiological Variables and Their Clinical Relevance

Physiological Variable	Clinical Relevance
Heart sounds	
First heart sound	Associated with ventricular contraction status
Third heart sound	Associated with early diastolic filling
Thoracic impedance	Associated with fluid accumulation and pulmonary edema
Respiration	
Respiration rate	Rapid shallow breathing patterns associated with shortness of breath
Ratio of respiration rate to tidal volume	
Heart rate	Indicator of cardiac status
Activity	Global patient status and fatigue

Boehmer JP, et al. A Multisensor Algorithm Predicts Heart Failure Events in Patients with Implanted Devices: Results From the MultiSENSE Study. *J Am Coll Cardiol HF* 2017; 5:216-25.

Sensor Measurements

Heart Sounds
S1 & S3

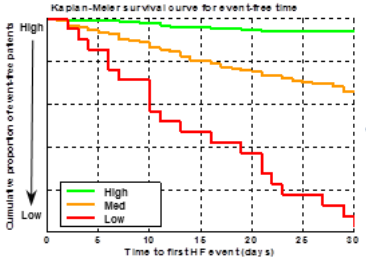
Impedance
Thoracic

Respiration
Rate & Volume

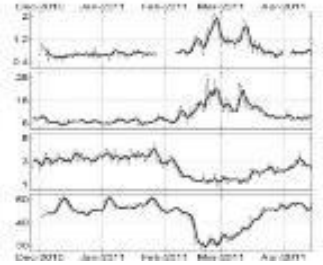
Activity
Time Spent Active

Heart Rate
Night time

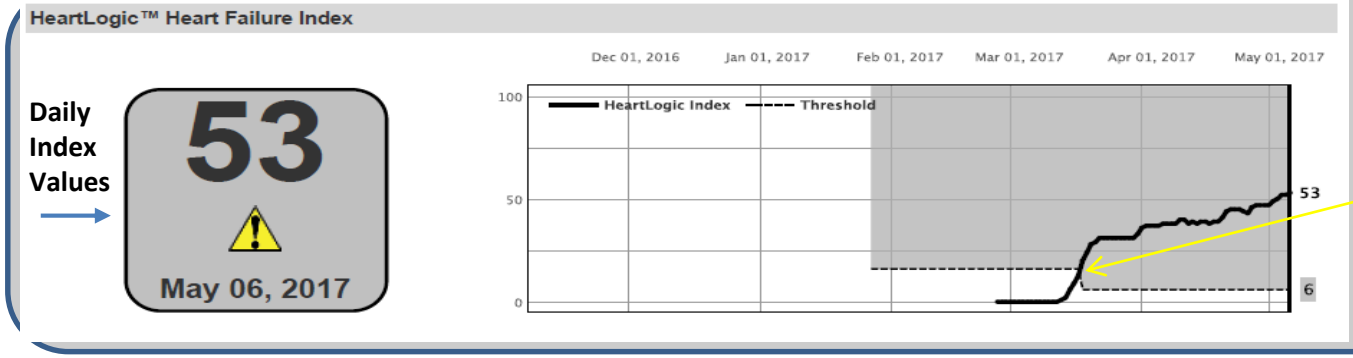
Assess patient risk for worsening HF



Evaluate changes from patient baseline



Combined into a single, simple index with alert



Physician programmable threshold

Alert issued when index crosses threshold

JACC: HEART FAILURE VOL. 5, NO. 3, 2017
ISSN 2213-1779
http://dx.doi.org/10.1016/j.jchf.2016.12.011

A Multisensor Algorithm Predicts Heart Failure Events in Patients With Implanted Devices

Results From the MultiSENSE Study

John P. Boehmer, MD,[a] Ramesh Hariharan, MD,[b] Fausto G. Devecchi, MD,[c] Andrew L. Smith, MD,[d] Giulio Molon, MD,[e] Alessandro Capucci, MD,[f] Qi An, PhD,[g] Viktoria Averina, PhD,[g] Craig M. Stolen, PhD,[g] Pramodsingh H. Thakur, PhD,[g] Julie A. Thompson, PhD,[g] Ramesh Wariar, PhD,[g] Yi Zhang, PhD,[g] Jagmeet P. Singh, MD, DPhil[h]

Empowerment of CIED patients

National Standards for Diabetes Self-Management Education

bjh guideline

Patient self-testing and self-management of oral anticoagulation with vitamin K antagonists: guidance from the British Committee for Standards in Haematology

Ian Jennings,[1] Dianne Kitchen,[1] David Keeling,[2] David Fitzmaurice[3] and Carl Heneghan[4] on behalf of the BCSH Committee

[1]UK NEQAS (Blood Coagulation), Sheffield, [2]Oxford University Hospitals, Oxford Haemophilia and Thrombosis Centre, Churchill Hospital, Oxford, [3]The University of Birmingham, Primary Care Clinical Sciences, Edgbaston, Birmingham, and [4]Department of Primary Care Health Sciences, Oxford University, Oxford, UK

Devices available for point-of-care testing

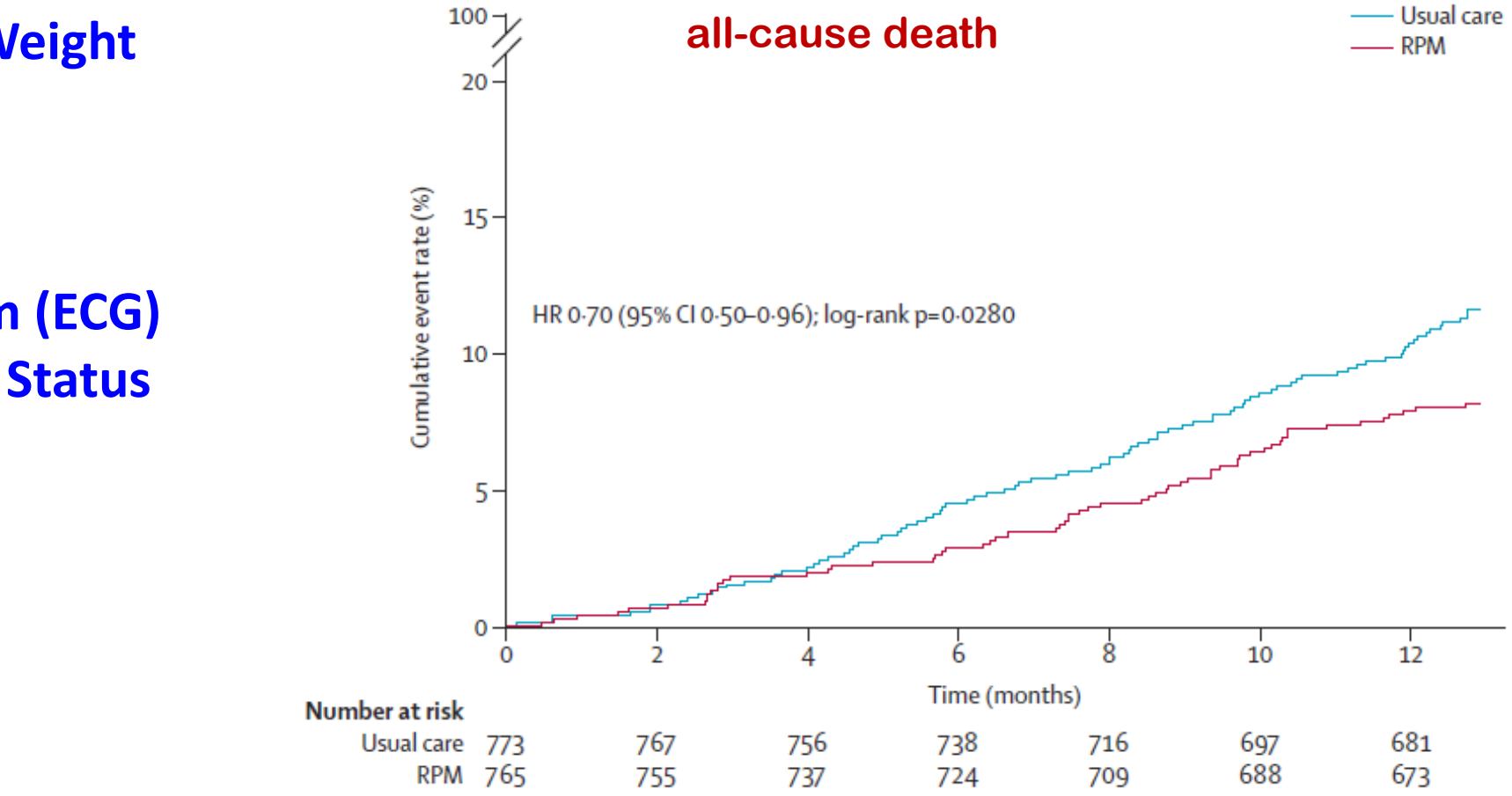
Several devices are available for POCT by healthcare professionals (for a review see National Health Service [NHS] Purchasing and Supply Agency 2008). However, not all POCT devices are suitable for PST/PSM. Consideration for selection of a device for patient use should include: size; portability; ease of use; single analyte device; volume of capillary (fingerstick) blood required; test strips/cuvette storage; display and cost.

Cost-effectiveness of self-testing and self-management

The evidence for PST and PSM demonstrates improved quality of oral anticoagulation therapy compared to standard monitoring (Garcia-Alamino *et al*, 2010; Heneghan *et al*, 2012). The current costs of suboptimal oral anticoagulation should not be underestimated and are substantial. A US economic model reported that if 50% of those currently receiving warfarin had optimal anticoagulation, 9852 emboli would be prevented at a saving of US$ 1·3 billion (Caro, 2004). Yet, despite the growing evidence of effectiveness for PST/PSM, it is often not a funded option across different healthcare systems. This partly reflects concerns over the costs of metres and test strips, which together may prevent wide-scale uptake (Shah *et al*, 2013).

Efficacy of telemedical interventional management in patients with heart failure (TIM-HF2): a randomised, controlled, parallel-group, unmasked trial

Body Weight
BP
HR
SpO2
Rhythm (ECG)
Health Status



Lancet 2018; 392: 1047–57

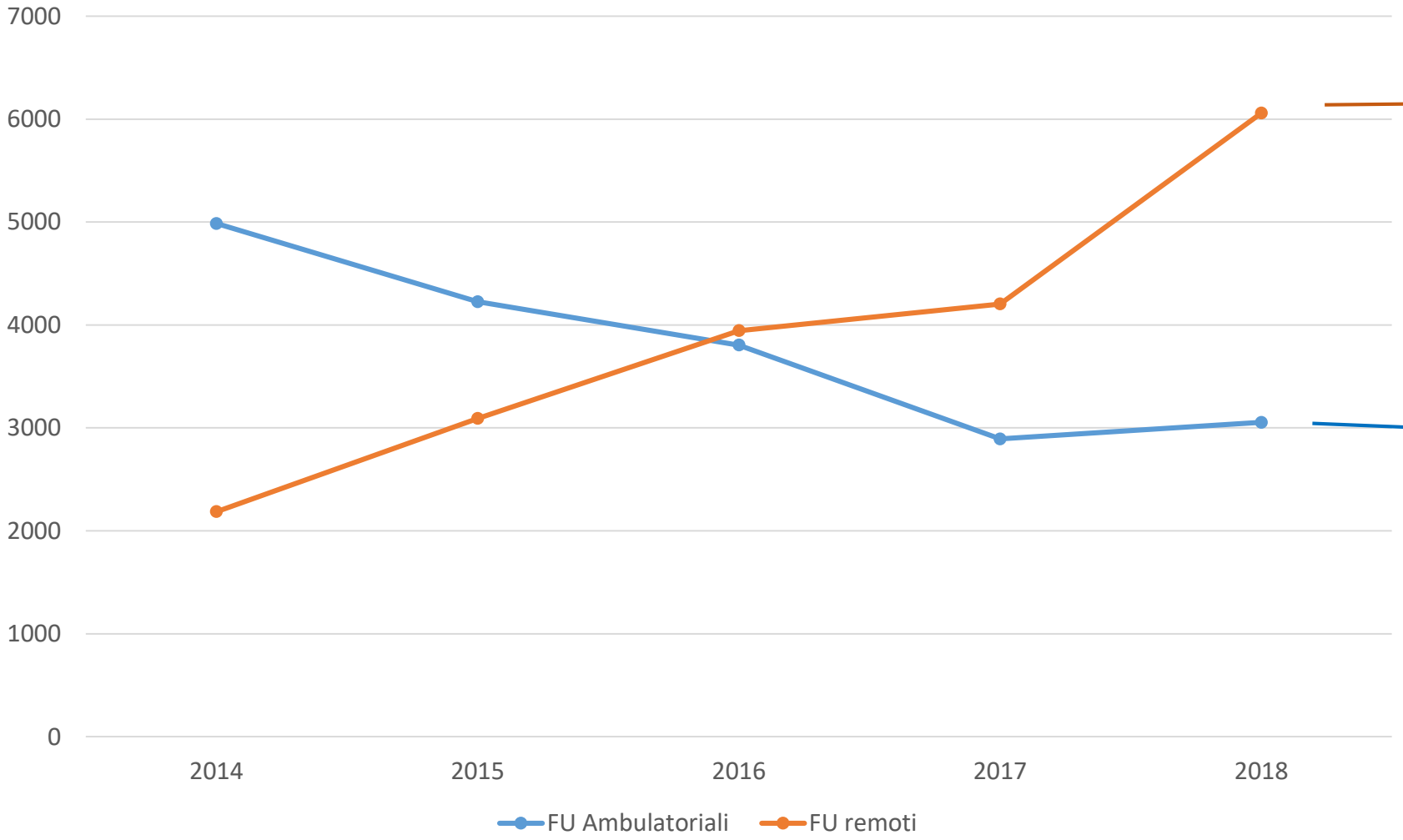
Why Do We need TELEMEDICINE ?

- Population INCREASING & AGEING Worldwide
- SHIFT from ACUTE to CHRONIC DISEASE models (Hypertension, diabetes, heart failure, oncologic diseases …)
- Disease Management is becoming non-sustainable Worldwide
- State-of-the-Art Medical Care at risk of becoming a LUXURY GOOD in the near future

Risorse invariate

Pazienti in aumento

Pazienti trattati con CIED



NON Generano rimborso

NON possono aumentare

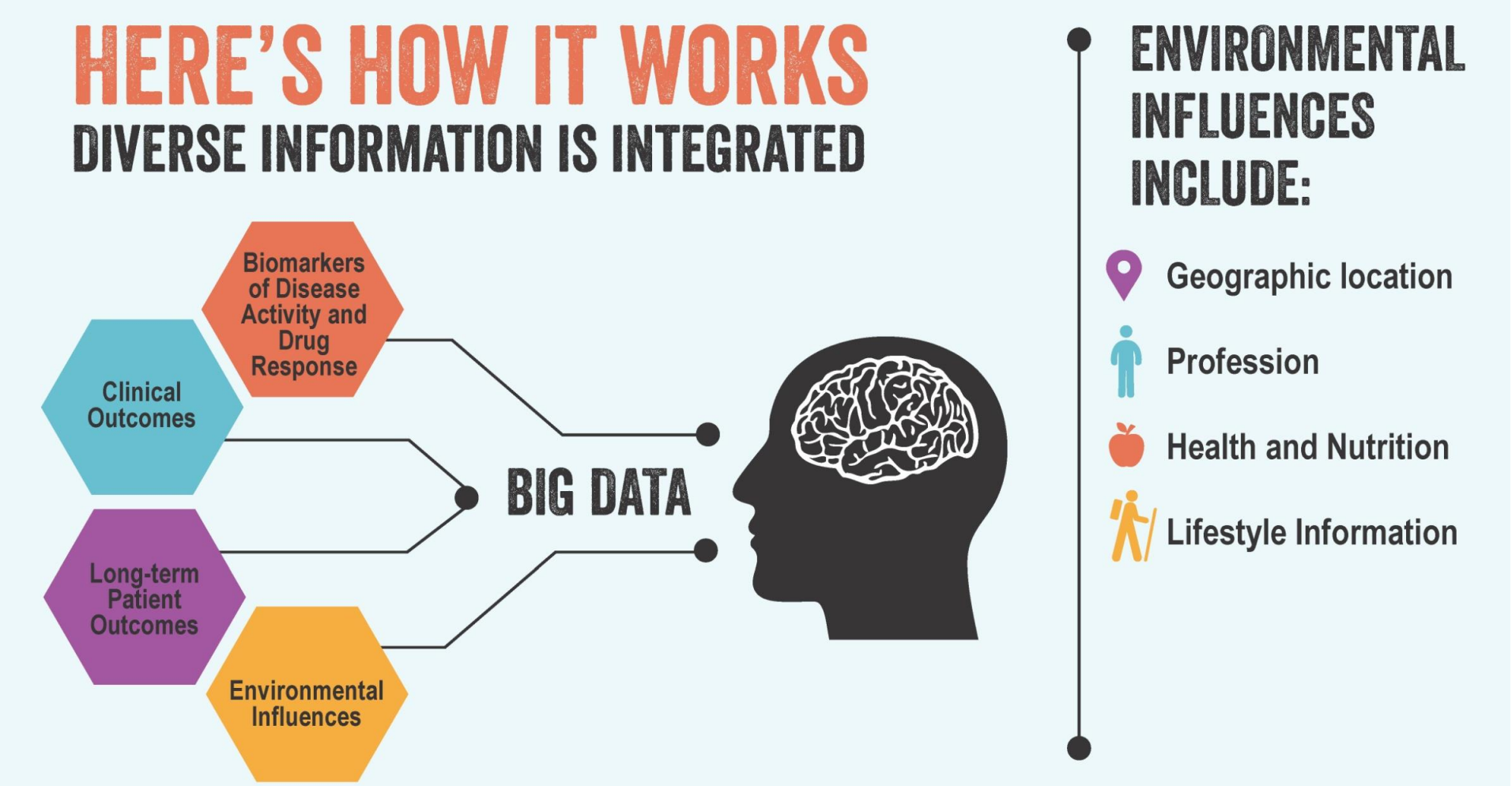
A Change of Health Systems paradygm is urgently needed

Gestione della cronicità: le decisioni inderogabili

- Integrazione medicina generale-HF clinic nel progetto di Telemedicina: flusso dei dati, teleconsulto
- Accesso rapido alla diagnostica di base (es: point of care) HOME CARE
- Uso efficiente delle risorse umane : abolizione dei processi duplicati, valorizzazione delle professionalità, Remote Job
- Patient Empowerment : Educazione della popolazione a partire dalla scolarità elementare

Health Care Management : Information Flow, Connectivity,

Telemedicine



Allocation of financial resources in Europe

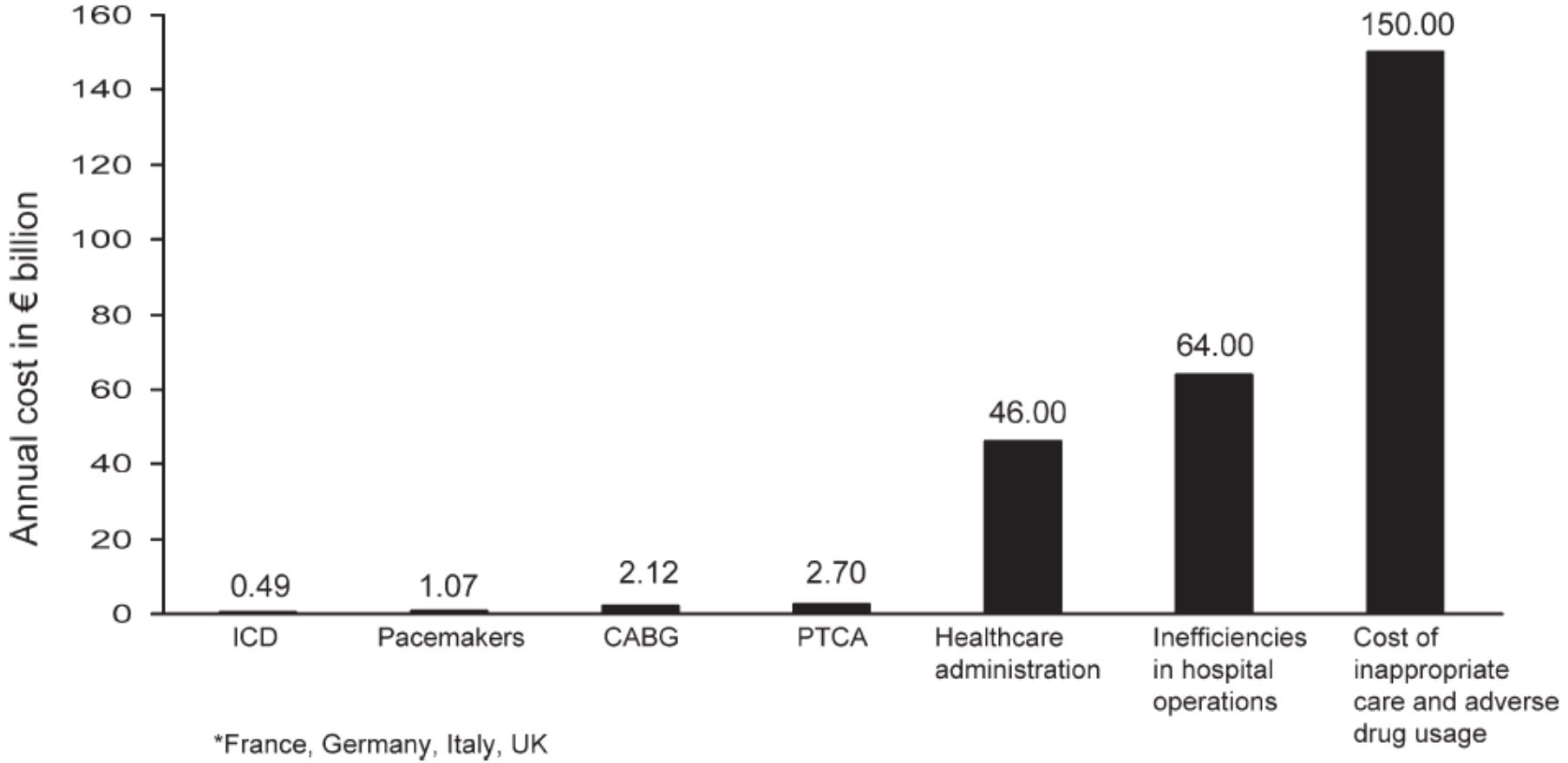


Figure 4 Total annual costs for the indicated therapies,[30–35] compared with healthcare administration, inefficiencies, and inappropriate care and adverse drug usage.[36,37] 'Inappropriate care and adverse drug usage'[37] includes not following clinical guidelines/pathways, double diagnostics, lack of appropriate referrals, and so on. Adverse drug usage includes over-prescribing of drugs and so on. 'Inefficiencies in hospital operations' have been taken from a McKinsey report,[36] based on better planning/scheduling of case loads, improved use of information technology, and organizational restructuring in the hospital.

European Heart Journal (2007) **28**, 392–397

KEY POINTS of Disease MANAGEMENT

- MANPOWER is the most expensive resource in Disease management
- Manpower is Inefficiently used in Health Care Systems
- Administrative processes are the most inefficient activity in the Health Business Management

Patient immediate feedback

Multi-Sensor Surveillance for Elderly Care

What is a CIED Follow up ?

- 2 hours travel + 20 to 40 minutes check in and rescheduling
- 2 to 10 minutes in ambulatory DEVICE check
- NO CLINICAL work up
- HALF to FULL day lost for any accompanying person
- Travel and parking costs

Always remember the Boriani lesson ….

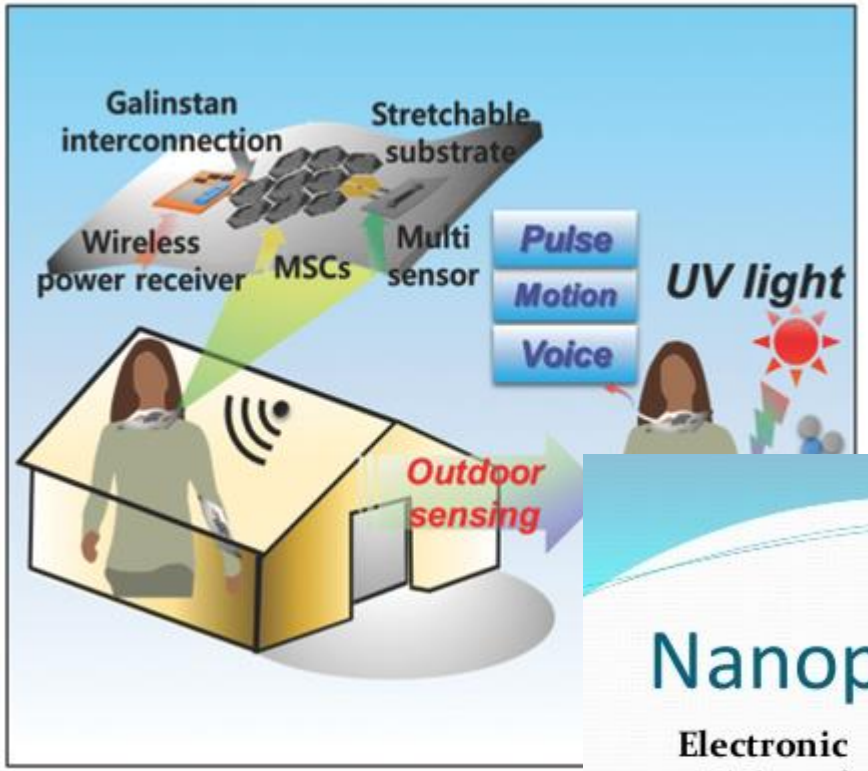
EUROPEAN SOCIETY OF CARDIOLOGY®

Europace (2011) **13**, ii32–ii38
doi:10.1093/europace/eur079

Cardiac resynchronization therapy: a cost or an investment?

Giuseppe Boriani[1]*, Lorenzo G. Mantovani[2], Mauro Biffi[1], Martin J. Schalij[3], Cristian Martignani[1], Christophe Leclercq[4], Jeroen J. Bax[3], and Angelo Auricchio[5]

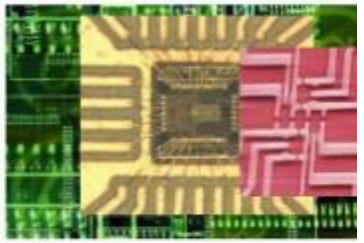
[1]Institute of Cardiology, University of Bologna, Azienda Ospedaliera S.Orsola-Malpighi, Via Massarenti 9, 40138 Bologna, Italy; [2]Faculty of Pharmacy, CIRFF/Center of Pharmacoeconomics, University of Naples Federico II, Napoli, Italy; [3]Leiden University Medical Centre, Leiden, The Netherlands; [4]Service de Cardiologie et Maladies Vasculaires, CHU Rennes, Rennes, France; and [5]Division of Cardiology, Fondazione Cardiocentro Ticino, Lugano, Switzerland



Nanoparticle Applications

Electronic

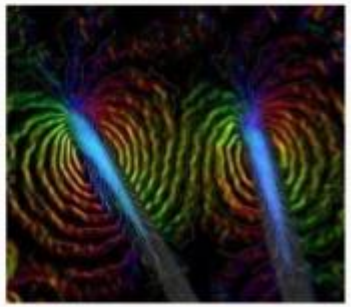
- High performance and smaller components,
- High conductivity materials.
- e,g, capacitors for small consumer devices such as mobile phones



Nano-Chips

Magnetic

- Increased density storage media.
- Nanomagnetic particles to create improved detail and contrast in MRI images.
- Scanning probe microscope systems from Nano Science instruments.



Heart Rhythm Society℠

A publication from the Heart Rhythm Society

Welcome, Mauro (201368) March 21, 2016 Donate

Consensus Statement Webinar: Remote Interrogation & Monitoring of Cardiovascular Implantable Electronic Devices (CIED)

Wireless remote monitoring has fundamentally changed the paradigm of care for patients with CIEDs. Randomized clinical trials have demonstrated that remote monitoring is superior to a calendar-based schedule of periodic in-person device interrogations. Yet the rate of adoption of the technology into clinical practice has varied widely.

This webinar summarizes the key clinical trials highlighting the superiority of remote monitoring and presents the new paradigm for managing CIED patients with continuous remote monitoring and event-triggered in-person evaluations.

Access Activity

Complimentary for HRS members
$29 USD for non-members

Learning Objectives

After completing this activity, participants will be able to:

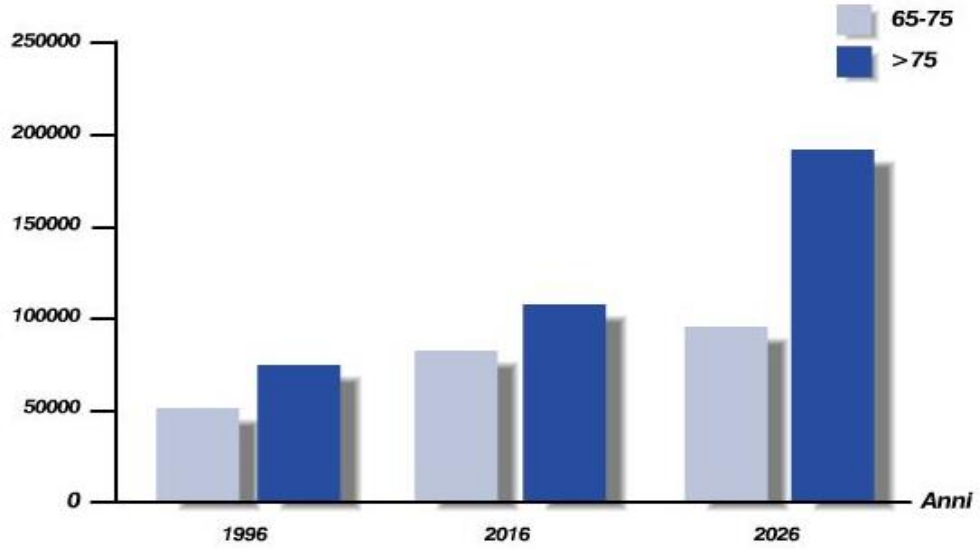
- Develop and implement a strategy for remote CIED monitoring and interrogation, including patient education
- Offer remote monitoring as an option to all CIED patients
- Recognize when to refer patients to an appropriate center that provides this capability

Overview

In 2015, HRS released the *Expert Consensus Statement on Remote Interrogation and Monitoring for Cardiovascular Electronic Implantable Devices*. In this 60-minute webinar, the document Chair, David J. Slotwiner, MD, FHRS, and Co-Chair, Niraj Varma, MD, PhD, in collaboration with writing group member Renato Pietro Ricci, MD, present highlights from the expert consensus statement. They are joined by Bruce L. Wilkoff, MD, FHRS, CCDS, Chair of the *2015 Expert Consensus Statement on Optimal ICD Programming and Testing.*

I numeri dello Scompenso Cardiaco

- Più di **1.500.000** pazienti affetti da SC*
- **170.000** nuovi casi ogni anno*
- **500** ricoveri/giorno dovuti a SC*
- Incremento del **40%** del numero di ricoveri negli ultimi 5 anni*
- Incidenza aumenta all'aumentare della classe d'età del paziente
- Numero di persone affette da SC raddoppia entro il 2030*



Modificato da *Kelly Circ.* 1997

*R. Cappato - G Ital Aritmol Cardiostim 2005;3:155-159