

# LA RESPONSABILITÀ MEDICA ADUE ANNI DALLA RIFORMA GELLI

Riflessioni e problemi aperti

13 settembre 2019

Fondazione Bruno Kessler  
Via Santa Croce 77 | Trento

**Responsabilità medica e tecnologie digitali dal punto di vista del medico**  
Gianfranco Gensini

# Strumenti principali della medicina non basata sulle evidenze nel 1990

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- Affermazioni “**ex cathedra**” da parte di “opinion leader” prestigiosi
- **Editoriali**
- Revisioni della letteratura **non** sistematiche
- Linee Guida di Società Professionali stilate per la gloria delle professioni
- **Opuscoli di comunicazione** da parte dei produttori
- **Materiale di marketing** diffuso in incontri medici "scientifici"



centre for  
**Evidence-Based Medicine**  
TORONTO

<http://ktclearinghouse.ca/cebm/>

# 1992: EVIDENCE BASED MEDICINE

EBM is the integration of

- 1. best research evidence** from high quality randomized controlled trials and observational studies in combination with
- 1. clinical expertise** and
- 2. patient values** (wishes and needs of patients)



# What kind of evidence?

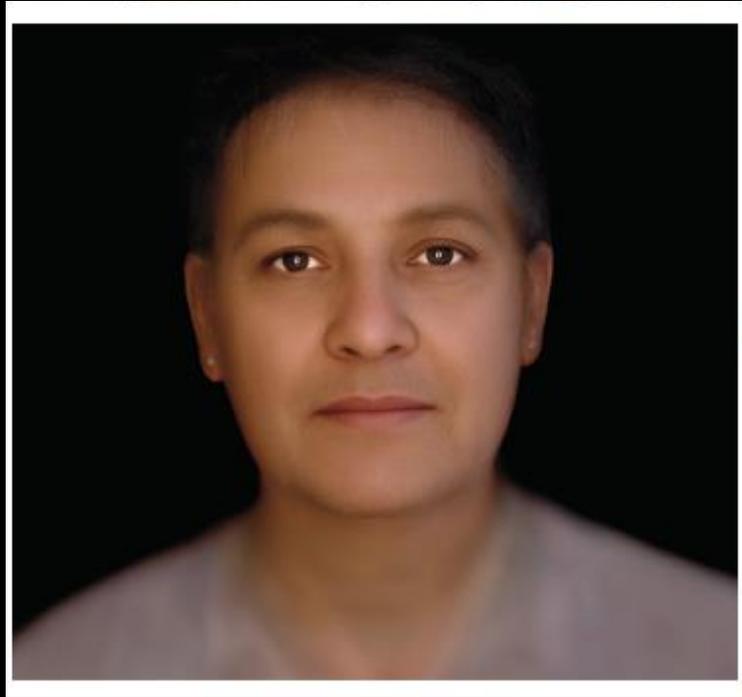
**Simple, disease-related evidence** for the average patient

**4S Study** (Simvastatin): Average age **60**

**SAVE Study** (Captopril): Average age **< 60**

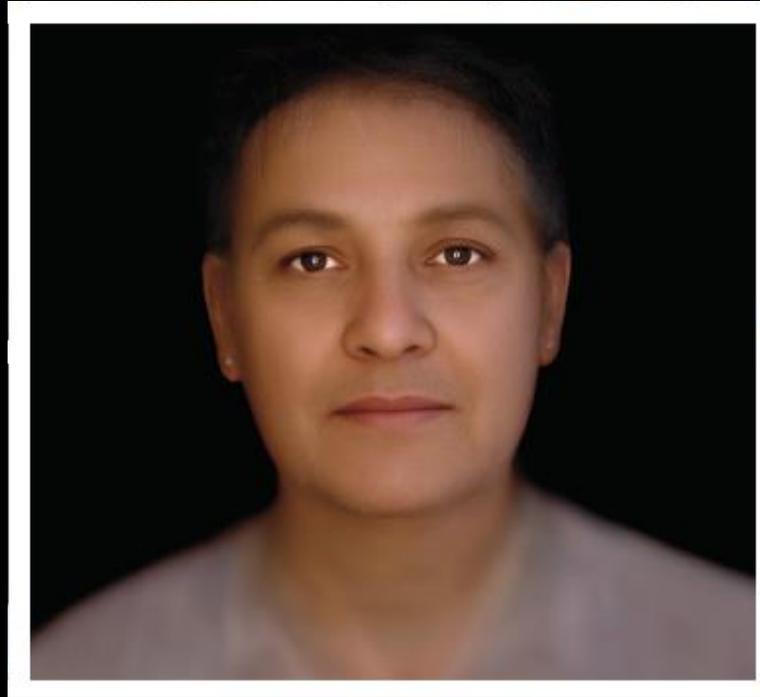
D. Kent

Institute for Clinical Research and Health Policy Studies Tufts Medical Center



D. Kent

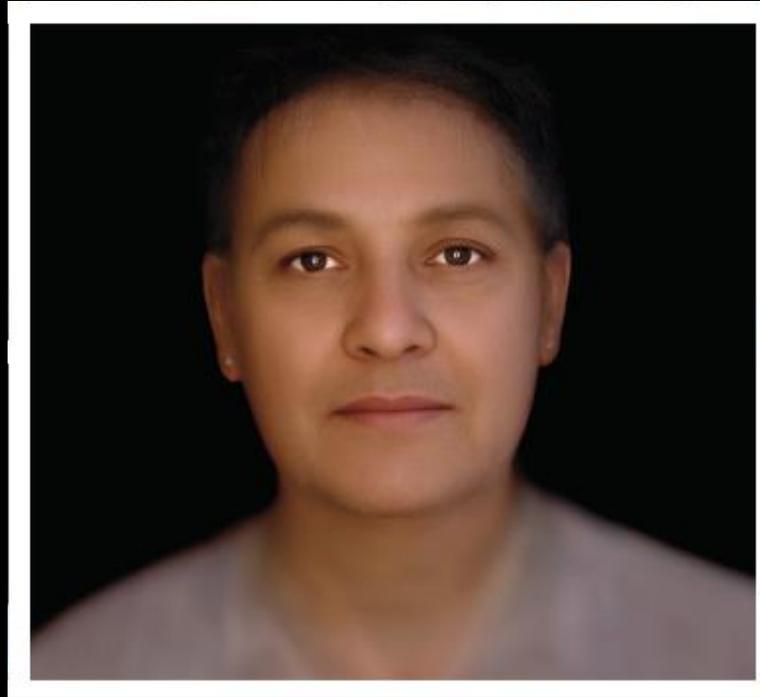
Institute for Clinical Research and Health Policy Studies Tufts Medical Center



**Uomo o donna?**

D. Kent

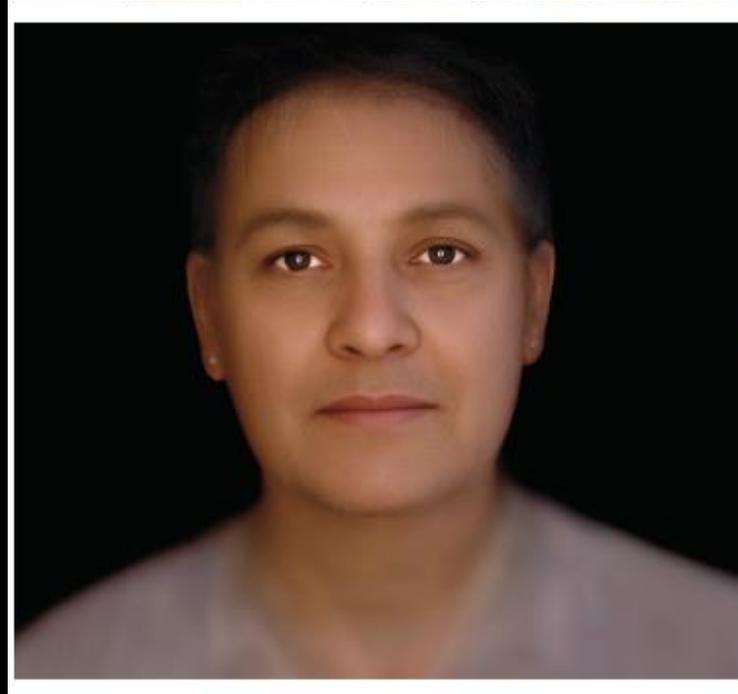
Institute for Clinical Research and Health Policy Studies Tufts Medical Center



**Questa persona non esiste**

D. Kent

Institute for Clinical Research and Health Policy Studies Tufts Medical Center



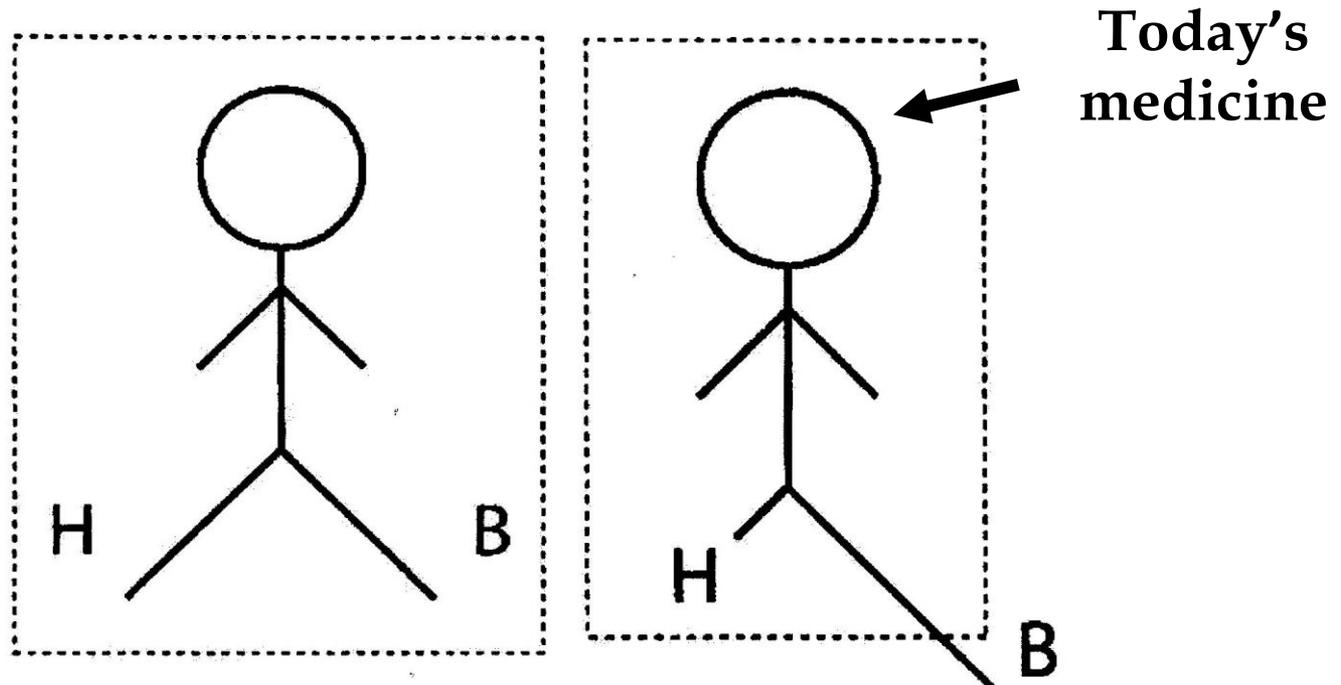
**Questa persona non esiste**  
**E' la persona media delle evidenze**  
**della Medicina Basata sulle evidenze**



# EBM: Groups and Individuals

- Evidence comes from groups of patients;
- Decisions are made by / for individuals.
  
- What's best on average must be best for each individual (??).

# The patient as a person



**B: Biomedical model; H: Humanistic model**

Hetlevik I. Evidence-based medicine in general practice: a hindrance to optimal medical care? *Scand J Prim Health Care* 2004; 22: 136-40



Professor Trish Greenhalgh

# ANALYSIS

## Evidence Based Medicine Renaissance

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### ESSAY

## Evidence based medicine: a movement in crisis?

**Trisha Greenhalgh and colleagues** argue that, although evidence based medicine has had many benefits, it has also had some negative unintended consequences. They offer a preliminary agenda for the movement's renaissance, refocusing on providing useable evidence that can be combined with context and professional expertise so that individual patients get optimal treatment

Trisha Greenhalgh *dean for research impact*<sup>1</sup>, Jeremy Howick *senior research fellow*<sup>2</sup>, Neal Maskrey *professor of evidence informed decision making*<sup>3</sup>, for the Evidence Based Medicine Renaissance Group

<sup>1</sup>Barts and the London School of Medicine and Dentistry, London E1 2AB, UK; <sup>2</sup>Centre for Evidence-Based Medicine, University of Oxford, Oxford OX2 6NW, UK; <sup>3</sup>Keele University, Staffs ST5 5BG, UK

# IMPORTANZA DEL CONTESTO E DELLE RISORSE DISPONIBILI

## Crisis in evidence based medicine?

1

- Evidence based guidelines often map poorly to complex multimorbidity

2

- Producers of evidence summaries, clinical guidelines, and decision support tools **must take account of who will use them, for what purposes, and under what constraints;**

**Actions to deliver real  
evidence based medicine**

*The* NEW ENGLAND JOURNAL *of* MEDICINE

**SOUNDING BOARD**

**Potential Pitfalls of Disease-Specific Guidelines  
for Patients with Multiple Conditions**

Mary E. Tinetti, M.D., Sidney T. Bogardus, Jr., M.D., and Joseph V. Agostini, M.D.

- **Evidence Based Medicine**
- **4P Medicine**
  - Predictive
  - Preventive
  - Participatory
  - Personalized
- **Precision Medicine**

# An Evolving Scenario

*Integrated Care supported by ICT*

- **From Disease-oriented Medicine to Personalized Medicine (4Ps)**
  - **Predictive**
  - **Preventive**
  - **Partecipatory**
  - **Personalized** (superconvergence of data)
- A shift from the **disease and specialty-oriented disciplinary silos** to **knowledge hybridation** (specific answers to complex individual problems)
- Changes in the **extent** (holistically-oriented widening), **depth** (hyperspecialism), **renewal rate** of **knowledge basis**

# Reducing Uncertainty: A fifth P : **PRECISION** MEDICINE

**very large sets of health and disease-related data linked to individual patients.**

These data are also critical for the development of the **Information Commons**, the Knowledge Network of Disease, and the development and validation of the **New Taxonomy**, different from **the usual Disease-based Taxonomy**.

# Personalized medicine

From Wikipedia, the free encyclopedia

Part of a series on

**Genetics**

**Personalized medicine** is a medical model that separates patients into **different groups**—with medical decisions, practices, interventions and/or products being **tailored** to the individual patient based on their predicted response or risk of disease.

The terms **personalized** medicine, **precision** medicine, **stratified** medicine and **P4 medicine** are used interchangeably to describe this concept though some authors and organisations use these expressions separately to indicate **particular nuances**.



The BMJ  SUBSCRIBE NOW

## Richard Smith: Stratified, personalised, or precision medicine

15 Oct, 12 | by BMJ

The simple concept behind **stratified medicine** is that we become smarter at identifying the patients who will benefit. **Stratified** Medicine could be seen as personalised medicine, which I had heard of, rebranded—because **personalised medicine has got a bad name through being oversold**. It's perhaps fairer to say that **stratified medicine** (identifying groups of patients who will benefit from treatments) **is a step towards personalised medicine**, when treatments will be tailored to individuals...



EUROPEAN  
SOCIETY OF  
CARDIOLOGY®



## Universal definition of myocardial infarction

Kristian Thygesen, Joseph S. Alpert and Harvey D. White on behalf of the Joint ESC/ACCF/AHA/WHF Task Force for the Redefinition of Myocardial Infarction

**2007**

# New Universal Definition of Myocardial Infarction

## Applicable After Complex Percutaneous Coronary Interventions?

Didier Locca, MD,\*†|| Chiara Bucciarelli-Ducci, MD, PhD,\*  
Giuseppe Ferrante, MD, PhD,†§ Alessio La Manna, MD,\*¶ Niall G. Keenan, MD,\*  
Agata Grasso, MD,\* Peter Barlis, MD, PhD,†||| Francesca Del Furia, MD,†  
Sanjay K. Prasad, MD,\* Juan Carlos Kaski, MD, PhD,‡ Dudley J. Pennell, MD,\*  
Carlo Di Mario, MD, PhD†

*London, United Kingdom; Rome and Catania, Italy; Lausanne, Switzerland; and  
Victoria, Australia*

**2010**

The new “universal” definition of myocardial infarction (MI) after percutaneous coronary interventions (PCI) is based on the elevation of cardiac markers  $>3 \times$  99th percentile of the upper reference limit (URL) (1,2). Car-

**Conclusions** This study reports the lack of substantial agreement between the new universal definition and CMR for the diagnosis of small-size periprocedural myocardial damage after complex PCI. Baseline levels of CRP or neopterin were not predictive for the development of periprocedural myocardial damage. (J Am Coll Cardiol Intv 2010;3:950–8) © 2010 by the American College of Cardiology Foundation

**EXPERT CONSENSUS DOCUMENT**

# **Third Universal Definition of Myocardial Infarction**

Kristian Thygesen  
Joseph S. Alpert  
Allan S. Jaffe  
Maarten L. Simoons  
Bernard R. Chaitman and

Harvey D. White: the Writing Group on  
behalf of the Joint ESC/ACCF/AHA/  
WHF Task Force for the Universal  
Definition of Myocardial Infarction

**2012**

procedures or after cardiac surgery. The Third Global MI Task Force has continued the Joint ESC/ACCF/AHA/WHF efforts by integrating these insights and new data into the current document, which now recognizes that very small amounts of myocardial injury or necrosis can be detected by biochemical markers and/or imaging.

# 2018!

EXPERT CONSENSUS DOCUMENT

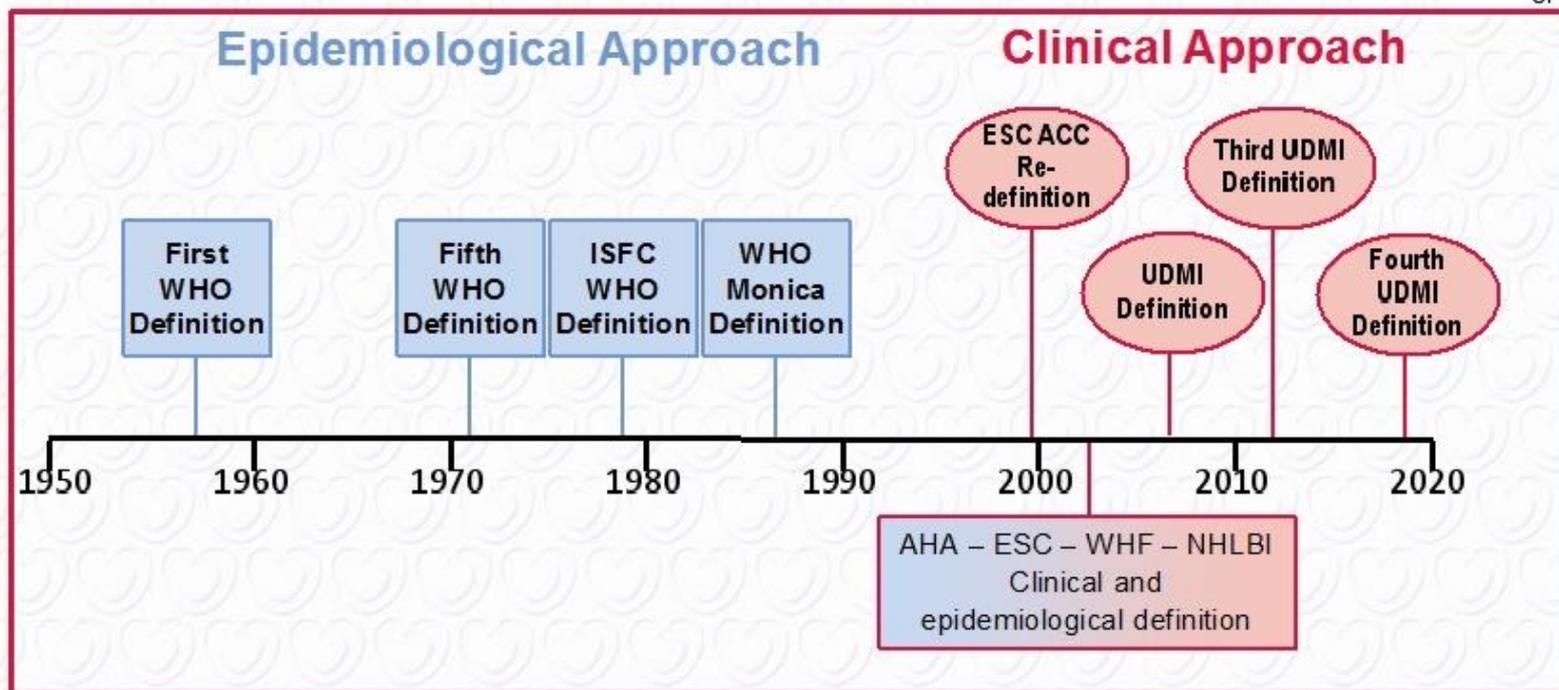
## Fourth Universal Definition of Myocardial Infarction (2018)

Joint ESC/ACC/AHA/WHF Task Force for the Universal Definition of Myocardial Infarction



Fourth Joint ESC/ACC/AHA/WHF Universal Definition of Myocardial Infarction  
European Heart Journal 2019; 40: 237-269 - doi:10.1093/eurheartj/ehy462

# History of Documents on the Definition of Myocardial Infarction



ACC = American College of Cardiology; AHA = American Heart Association; ESC = European Society of Cardiology; ISFC = International Society and Federation of Cardiology; NHLBI = National Heart, Lung, and Blood Institute; WHF = World Heart Foundation; WHO = World Health Organization; UDMI = Universal Definition of Myocardial Infarction

# DIECI COMANDAMENTI !!!

## Ten commandments for the Fourth Universal Definition of Myocardial Infarction (1)



### Myocardial Injury and Myocardial Infarction

- 1) Myocardial injury is defined by the presence of cardiac troponin values (cTn) above the 99<sup>th</sup> percentile of the upper reference limit (URL).
- 2) Myocardial injury may be acute (rise and/or fall of cTn values) as in acute heart failure or chronic ( $\leq 20\%$  variation of cTn values) as in chronic kidney disease.
- 3) Myocardial injury may occur in a variety of situations including after coronary procedural intervention and/or with cardiovascular and non-cardiovascular illnesses.
- 4) Occurrence of acute myocardial injury in the setting of acute myocardial ischaemia defines acute myocardial infarction.

Vision Paper by the Editor-in-Chief

## **“Knowledge-based (personalized) medicine” instead of “evidence-based (cohort) medicine”**

Applying nanoscience and computational science to create an effective, safe, curative and affordable medicine of the future

**Patrick Hunziker**

...a seemingly clear disease entity like **myocardial infarction** is a **continuum**

in:

- **space** (location of infarct related artery),
- **time** (critical relevance of timing of reopening of occluded artery),
- **severity**,
- **individual factors:**
  - degree of **subclinical atherosclerosis** not related to the event,
  - variability of **coagulation system** and **platelet response** to drugs.

# WHY NOW?

The **time is right** because of:

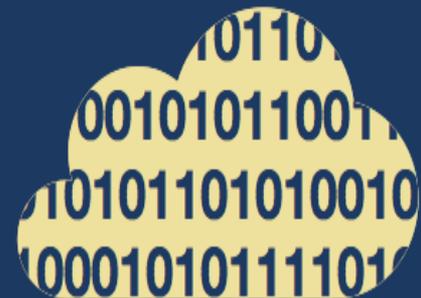
Sequencing  
of the human  
genome



Improved  
technologies for  
biomedical analysis



New tools  
for using large  
datasets



# Watson and healthcare

How natural language processing and semantic search could revolutionize clinical decision support

natural language processing

WATSON

semantic search

HTL High Threshold Logic - NLP Natural Language Processing

The supercomputer has incorporated thousands of sources, including

- scientific **journal articles**,
- national **guidelines**,
- individual-hospital **best practices**,
- **clinical trials**, and even
- **textbooks**.

Watson interfaces with electronic medical records, it has the capability to read and “comprehend” case notes (natural language processing).



“Tonight, I'm launching **a new Precision Medicine Initiative** to bring us closer to curing diseases like **cancer and diabetes** — and to give all of us access to the **personalized information** we need to keep ourselves and our families **healthier.**”

President Barack Obama, State of the Union Address, January 20, 2015



*The* NEW ENGLAND JOURNAL *of* MEDICINE

Perspective  
FEBRUARY 26, 2015

**A New Initiative on Precision Medicine**

Francis S. Collins, M.D., Ph.D., and Harold Varmus, M.D.

... Although the precision medicine initiative will probably yield its greatest benefits years down the road, there should be some notable near-term successes. In addition to the results of the cancer studies described above, studies of a large research cohort exposed to many kinds of therapies may provide early insights into pharmacogenomics — **enabling the provision of the right drug at the right dose to the right patient.**

Opportunities to identify persons with rare loss of function mutations that protect against common diseases may point to attractive drug targets for broad patient populations. And observations of beneficial use of mobile health technologies may improve strategies for preventing and managing chronic diseases. ...

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**Precision Medicine — Personalized, Problematic,  
and Promising**

J. Larry Jameson, M.D., Ph.D., and Dan L. Longo, M.D.

This article was published on May 27, 2015, at [NEJM.org](http://NEJM.org).

NATURE, APRIL 2015

**IMPRECISION**

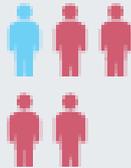
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**MEDICINE**

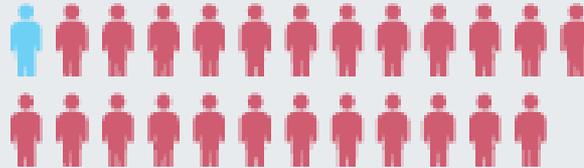
## IMPRECISION MEDICINE

For every person they do help (blue), the ten highest-grossing drugs in the United States fail to improve the conditions of between 3 and 24 people (red).

**1. ABILIFY** (aripiprazole)  
Schizophrenia



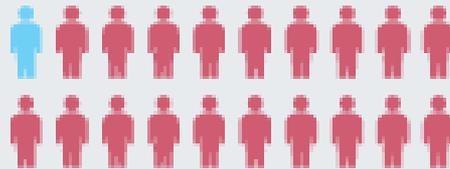
**2. NEXIUM** (esomeprazole)  
Heartburn



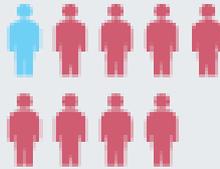
**3. HUMIRA** (adalimumab)  
Arthritis



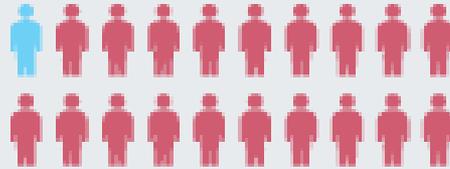
**4. CRESTOR** (rosuvastatin)  
High cholesterol



**5. CYMBALTA** (duloxetine)  
Depression



**6. ADVAIR DISKUS** (fluticasone propionate)  
Asthma



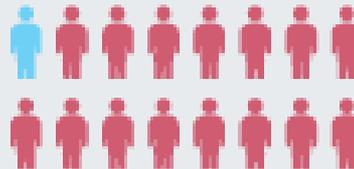
**7. ENBREL** (etanercept)  
Psoriasis



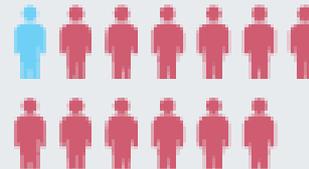
**8. REMICADE** (infliximab)  
Crohn's disease



**9. COPAXONE** (glatiramer acetate)  
Multiple sclerosis



**10. NEULASTA** (pegfilgrastim)  
Neutropenia



Based on published number needed to treat (NNT) figures. For a full list of references, see Supplementary Information at [go.nature.com/4cd78L](http://go.nature.com/4cd78L).

# COMMENT

**STATISTICS** A call to police the whole data-analysis pipeline, not just P values p.012

**SPRING BOOKS** Does Nicholas Stern's global vision admit ground truth? p.014

**SPRING BOOKS** Metaphor pile-up obscures the meaning of junk DNA p.015



**SPRING BOOKS** Grind, politics and dirty tricks in life of polio-vaccine pioneer p.020

SCIENTIFIC ILLUSTRATION BY MICHAEL O'NEILL



## Time for one-person trials

Precision medicine requires a different type of clinical trial that focuses on individual, not average, responses to therapy, says Nicholas J. Schork.

# Design and Implementation of N-of-1 Trials: A User's Guide

N of  
1



**AHRQ**

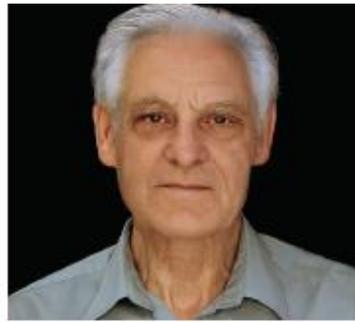
Agency for Healthcare Research and Quality  
Advancing Excellence in Health Care • [www.aahrq.gov](http://www.aahrq.gov)

## Cardiovascular precision medicine: hope or hype?

**Dr Geoffrey S. Pitt** discusses the successes of precision medicine to date and its potential for the future.



A combination of **genomic, epigenomic, transcriptomic, and metabolomics information—a patient's 'panomic' data**—may soon be part of an individual medical record.



## **ALLHAT—All Hit or All Miss? Key Questions Still Remain**

Franz H. Messerli, MD, and Michael A. Weber, MD

... black patients did not do well when randomized to lisinopril; most glaringly, the incidence of stroke was 40% higher than while receiving chlorthalidone.

The American Journal of Cardiology Vol. 92 August 1, 2003

### ***Chlorthalidone vs Lisinopril***

	<b>stroke</b>	<b>BP</b>
<b>(mmHg)</b>		
All patients	- 15%	- 2 mmHg
<b>Blacks</b>	<b>- 40%</b>	<b>- 4 mmHg</b>
effect of race	p<0.01	

ALLHAT Collaborative Research Group. JAMA. 2002; 288: 2981-97

## BI-DIL: An ethnically specific active drug combination

- Subanalysis of the V-HeFT trial revealed an especially **strong effect of hydralazine/isosorbide dinitrate combination vs. prazosin among patients who identified themselves as black**.
- A randomized controlled trial of **hydralazine/isosorbide dinitrate** combination therapy in **black** patients revealed a 43% improvement in survival and led in 2006 to **approval by the US Federal Drug Administration (FDA) of combination therapy (BI-DIL) for heart failure specifically in black patients.**

## Does personalized medicine exist and can you test it in a clinical trial?

Peter A. G. Sandercock

The idea that different patients will respond differently to the same treatment is not new. The recent advances in genomics and laboratory medicine have led to the hope that it will be possible to maximize the benefit and minimize the harms of each medical therapy by using an individuals' biomarker status to 'personalize' their treatment. The selection of treatment for each individual would then be determined, not just by their disease status (or an estimate of the risk of developing a disease or disease progression), but also by their genetic makeup or by other measurable characteristics, such as the level of a particular biomarker in the blood. This review discusses the extent to which personalized medicine might be applied in stroke, and the implications for global stroke health care.

Key words: clinical trials, genomics, personalized medicine, stratified medicine

### Conclusion

Methods for tailoring therapy for the prevention, acute treatment, or rehabilitation of each individual stroke patient are at an **early stage of development**. In the near future, personalized medicine seems **unlikely to make a major contribution** to reducing the

global burden of stroke, and so – as stroke clinicians – we should **focus on**

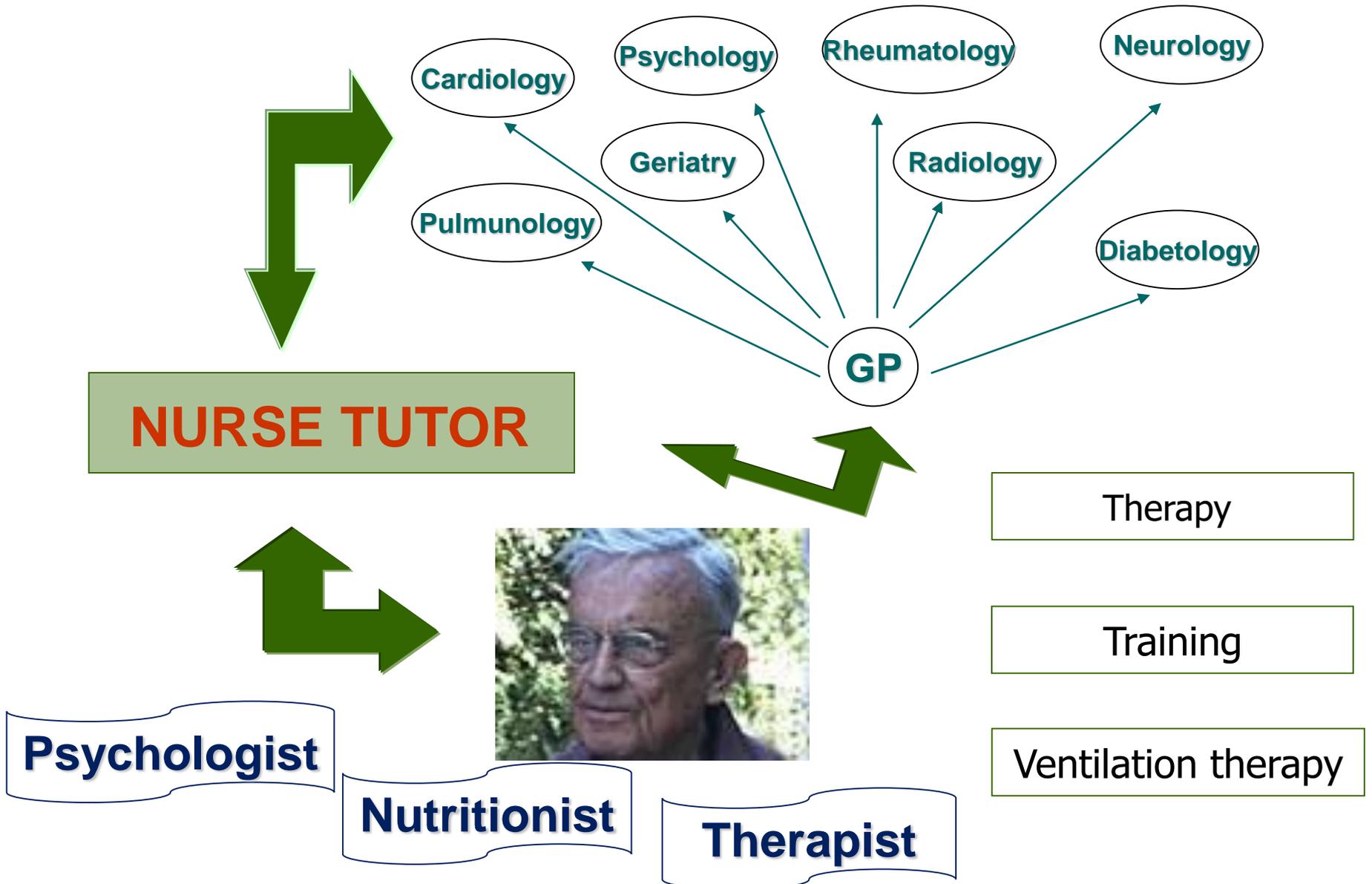
**implementing interventions that are known to be effective**

Drug Administration (FDA) as: 'Using a biomarker to match a patient to a cohort that has exhibited a differential response to a treatment' (6). Precision medicine is an analogous term recently given prominence by President Obama and is 'intended to avoid the implication that medications would be synthesized personally for single patients and to convey a broader concept that would include precisely tailoring therapies to subcategories of disease, often defined by genomics' (7).

### Methods of this review

#### Aims

The aims of this review were to (1) search the literature for papers relevant to stroke, cerebrovascular disorders, and cardiovascular



# Integrated Tele Chronic Care

**PRECISION MEDICINE !**

**PATIENT CENTERED**



**2° opinion  
(pulmonology, cardiology,  
neurology, psychology,  
pharmacy )**

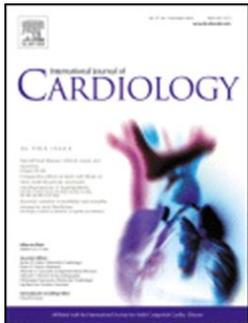


**Devices  
Instruments**



**Basal network:  
GP, patient, call  
center, IP tutor**



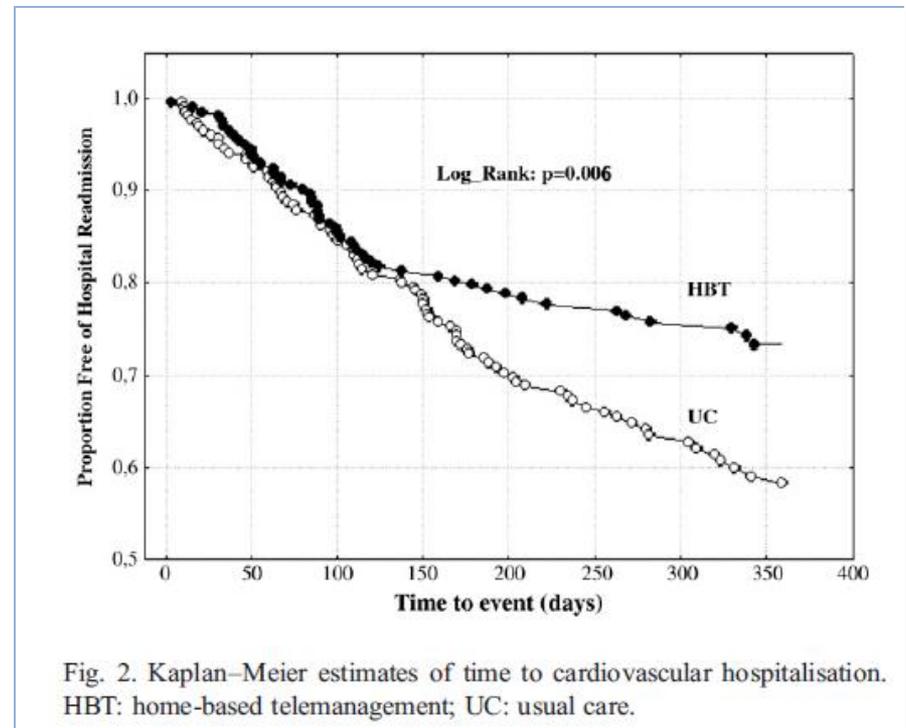


# Multicenter randomised trial on home-based telemanagement to prevent hospital readmission of patients with chronic heart failure

A. Giordano, S. Scalvini, E. Zanelli, U. Corrà, G.L. Longobardi, V.A. Ricci, P. Baiardi, F. Glisenti

International Journal of Cardiology 131 (2009) 192–199

- 230 CHF patients followed for 365 days using telephonic follow-up and ECG monitoring
- 230 patients in the control group
- average age  $57 \pm 10$  y; FE  $27 \pm 6\%$ ;  $VO_2$  13.3 ml/kg/min
- In the “Telemedicine Group” we observed a reduction in:
  - hospitalizations (~ 44%)
  - instabilizations (~ 50%)
  - costs (~ 24%)





# Home-based telemanagement in chronic heart failure: an 8-year single-site experience

Amerigo Giordano\*, Emanuela Zanelli\* and Simonetta Scalvini†

Journal of Telemedicine and Telecare 2011; 17: 382–386

Table 5 Clinical and functional data before and after HBT in the two 4-year periods

	2000–2003 (n = 143)		2004–2007 (n = 95)	
	Before	After	Before	After
NYHA class (SD)	2.4 (0.9)	1.9 (0.8)	2.7 (0.5)	2.3 (0.5) <sup>*†</sup>
LVEF, % (SD)	30 (8)	33 (10)	32 (10)	32 (12) <sup>†</sup>
6-min WT, m (SD)	438 (109)	458 (103)	396 (93)	422 (127) <sup>*†</sup>
MLHFQ score (SD)	28 (20)	21 (17)	39 (20)	26 (21) <sup>*†</sup>
Haemoglobin, mg/dl (SD)	13.3 (1.9)	13.1 (1.8)	12.7 (1.8)	13.6 (1.8) <sup>*†‡</sup>
Beta-blockers, mg/d (SD)	39 (24)	45 (24)	28 (25)	33 (27) <sup>*†</sup>
Beta-blockers, %	92	85	83	87 <sup>*†‡</sup>

\* $P < 0.003$  between groups

† $P < 0.001$  within groups

‡ $P < 0.01$  interaction

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HEART FAILURE

# Optimal postdischarge management of chronic HF

*Simonetta Scalvini and Amerigo Giordano*

Not all strategies for the management of chronic heart failure have been shown to be equally effective in improving outcomes, and the ideal programme has yet to be defined. The WHICH? trial sheds some light on whether a clinical, in-hospital or a home-based strategy of care is superior and cost-effective.

Scalvini, S. & Giordano, A. *Nat. Rev. Cardiol.* advance online publication 20 November 2012;  
[doi:10.1038/nrcardio.2012.161](https://doi.org/10.1038/nrcardio.2012.161)

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In conclusion, the efficacy of postdischarge chronic HF management currently relies on the application of shared, standardized protocols, **rather than the setting of the delivery of care**. Information and communication technologies and remote monitoring systems could provide efficient management for a growing number of patients with chronic HF, **and promote integration between hospital-based and home-based care.**

# Home-Based Telemanagement in Advanced COPD: Who Uses it Most? Real-Life Study in Lombardy



A 6-month home-based telemanagement program (HTP) was offered to **1,074 COPD patients over a 4-year period**.

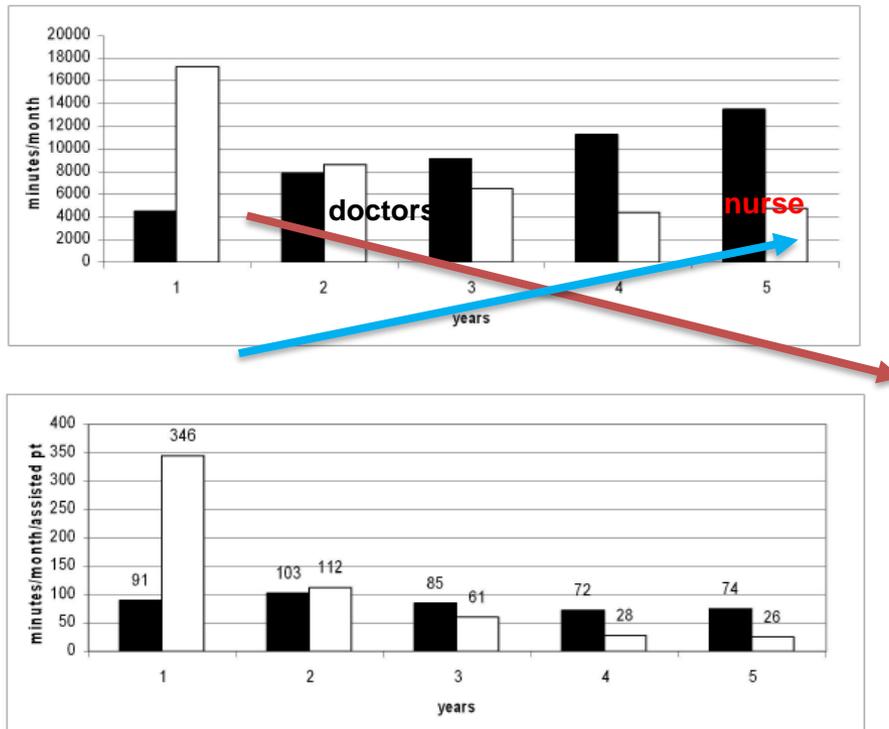
This HTP in Lombardy shows that relapsers, people requiring several ABGs and urgent GP visits are the patient subgroup most likely to consume telemanagement services (scheduled and unscheduled). We propose a patient 'identikit' to improve prioritization for HTP prescriptions.

[Vitacca et Al. : COPD.](#) 2016 Aug;13(4):491-8. doi: 10.3109/15412555.2015.1113243. Epub 2016 Jan 14

**TELE-ASSISTANCE IN CHRONIC RESPIRATORY FAILURE (CRF): PATIENTS' CHARACTERIZATION AND STAFF WORKLOAD OF FIVE-YEAR ACTIVITY.**

TMJ 2009

Michele Vitacca, Abramo Bazza, Luca Bianchi, Sonia Gilè, §Giuliano Assoni, Roberto Porta, Enrica Bertella, Domenico Fiorenza, Luca Barbano, §Laura Comini, §Simonetta Scalvini.

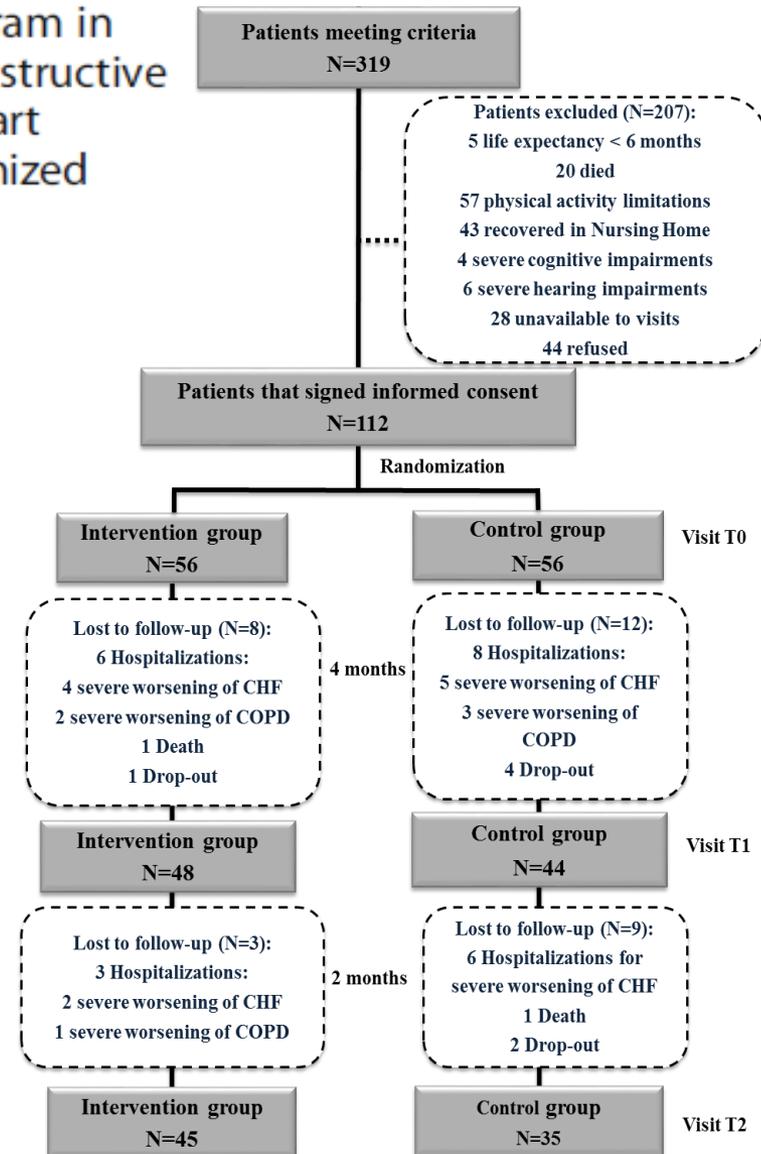


During 5 years of TA activity, doctors time decreased and nurse time increased:  
**rationalitation of costs.**

**Figure 3.** Time course of staff activity (total minutes/month) across years (top) and minutes/month of staff activity adjusted for number of the simultaneously assisted patients (bottom) according to nurse (dark bar) and doctor availability (white bar)

### A multidisciplinary telehealth program in patients with combined chronic obstructive pulmonary disease and chronic heart failure: study protocol for a randomized controlled trial

- ❑ We studied the feasibility and efficacy of an integrated telerehabilitation home-based programme (Telereab-HBP), 4 months long, in **patients with combined COPD and CHF**.
- ❑ The primary outcome was **exercise tolerance** evaluated at the 6-min walk test (6MWT).
- ❑ Secondary outcomes were **time-to-event** (hospitalisation and death), **dyspnoea** (MRC), **physical activity profile** (PASE), **disability** (Barthel) and **QoL** (MLHFQ and CAT).
- ❑ Randomized, open, controlled, multicenter trial.
- ❑ The Telereab-HBP included remote monitoring of cardiorespiratory parameters, weekly phone-calls by the nurse, and exercise programme, monitored weekly by the physiotherapist. All outcomes were studied again after 2 months of a no-intervention period.

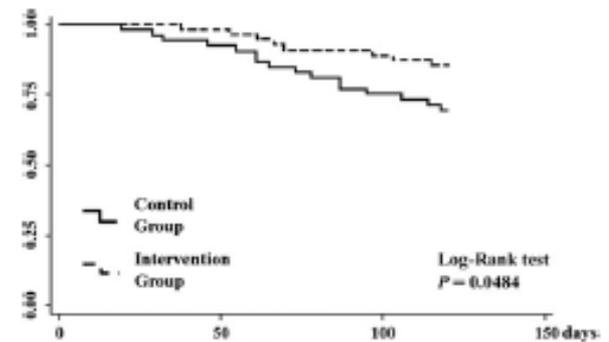
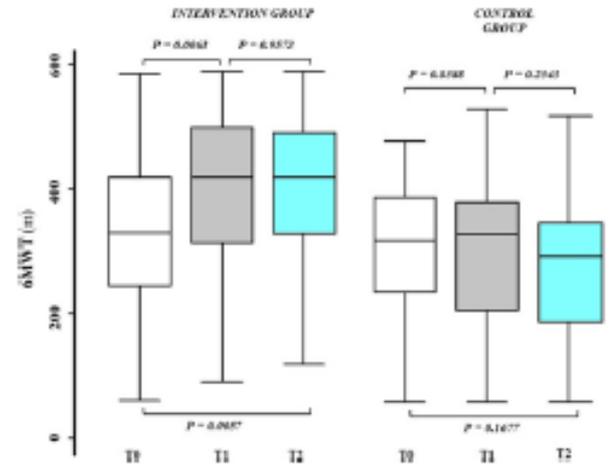




# Home-based telerehabilitation in older patients with chronic obstructive pulmonary disease and heart failure: a randomised controlled trial

PALMIRA BERNOCCHI<sup>1</sup>, MICHELE VITACCA<sup>2†</sup>, MARIA TERESA LA ROVERE<sup>3†</sup>, MAURIZIO VOLTERRANI<sup>4†</sup>, TIZIANA GALLI<sup>2</sup>, DORIANA BARATTI<sup>1</sup>, MARA PANERONI<sup>2</sup>, GIUSEPPE CAMPOLONGO<sup>4</sup>, BARBARA SPOSATO<sup>4</sup>, SIMONETTA SCALVINI<sup>1,5</sup> Age and Ageing 2017

- ❑ 112 patients were randomized, 56 per group, Their age was 70 (9) years, and 92 (82.1%) were male.
- ❑ After 4 months: the IG were able **to walk further than at baseline**: mean (95% CI)  $\Delta$ 6MWT was 60 (22.2,97.8) metres; the CG showed no significant improvement: -15 (-40.3,9.8) metres;  $p=0.0040$  between groups.
- ❑ In IG, the **media time to hospitalisation/death was 113.4 days compared with 104.7 in the CG** ( $p=0.0484$ , log-rank test).
- ❑ MRC ( $p=0.0500$ ), PASE ( $p=0.0015$ ), Barthel ( $p=0.0006$ ), MLHFQ ( $p=0.0007$ ) and CAT ( $p=0.0000$ ) were significantly improved in the IG compared with the CG at 4 months.
- ❑ IG maintained the benefits acquired at 6 months for outcomes.



**HEALTH POLICY STATEMENT**

# 2017 Roadmap for Innovation— ACC Health Policy Statement on Healthcare Transformation in the Era of Digital Health, Big Data, and Precision Health



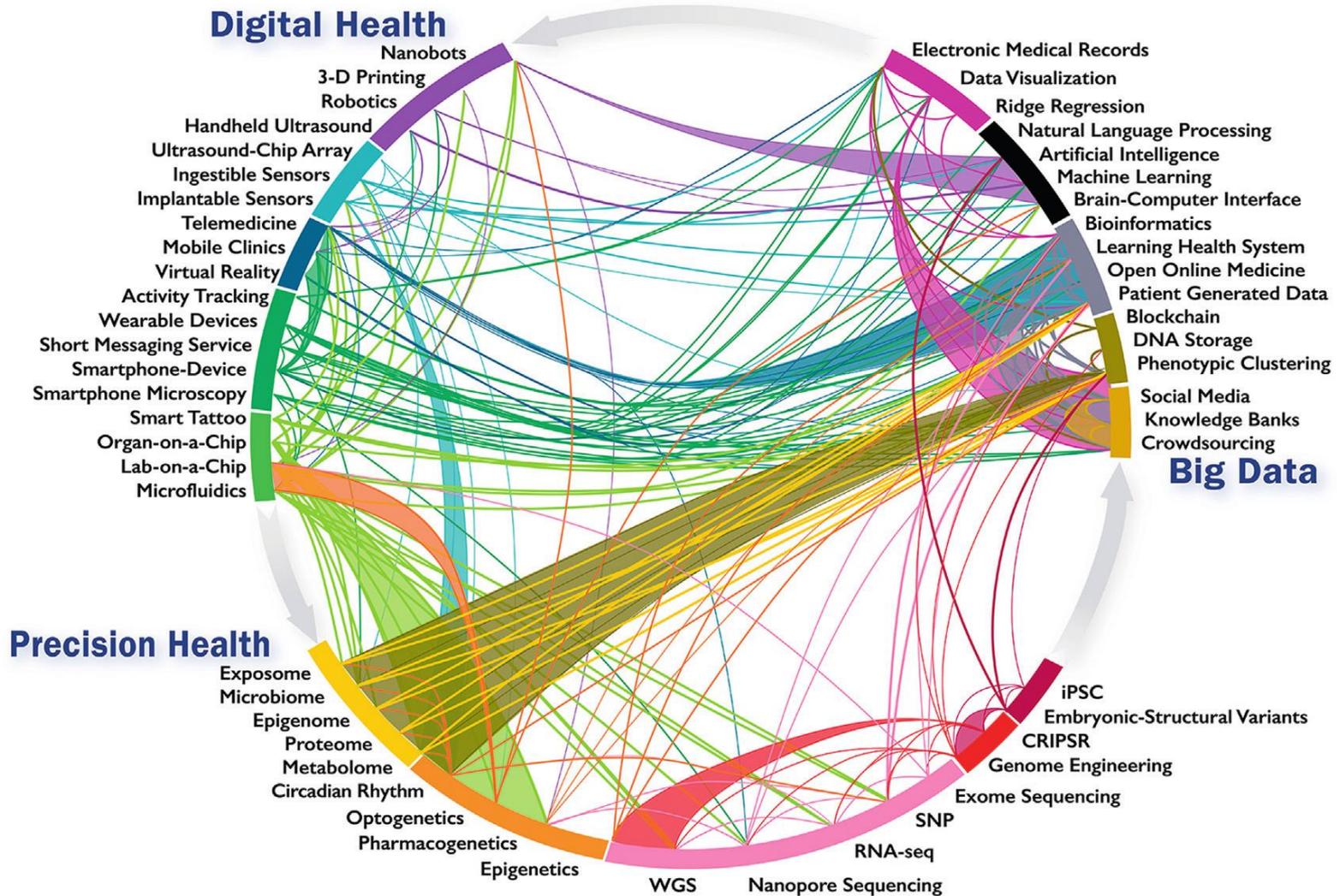
A Report of the American College of Cardiology Task Force  
on Health Policy Statements and Systems of Care

## EXECUTIVE SUMMARY

**Healthcare transformation** is the product of a shared vision between a broad range of stakeholders to establish the future of care delivery and to develop new patient-centered, evidence-driven models in which value is rewarded over volume. Important within this transformation are **newly developed and rapidly evolving technology-based innovations.**

These include: **digital health** with wearable, smartphone, and sensor-based technologies; **big data** that comprises the aggregation of large quantities of structured and unstructured health information and **sophisticated analyses** with artificial intelligence, machine learning, and natural language processing techniques; and **precision-health approaches** to identify individual-level risk and the determinants of wellness and pathogenicity.

**FIGURE 1** New Innovations in Healthcare



Infographic of emerging innovations and developments in digital health (14-32), big data (33-51), and precision health (52-78) and their intraconnections and interconnections. 3d indicates 3-dimensional; CRISPR, clustered regularly interspaced short palindromic repeats; DNA, deoxyribonucleic acid; iPSC, induced pluripotent stem cells; RNA, ribonucleic acid; SNP, single nucleotide polymorphism; WGS, whole genome sequencing.

# Generate Evidence-Based Best Practices for Guideline Consensus and Patient Care

- **...the healthcare community should develop the resources** necessary for administering **digital health, big data, or precision-health services** ...Therefore, priority objectives for the ACC are to:
  - **Review the evidence** that supports the generation of **guideline-based consensus**;
  - **Create working groups** specific to the **development and evaluation of new innovations**;
  - **Solicit input from key opinion leaders**;
  - **Devise and disseminate best-practice models** focused on workflow integration, costs of care, and outcomes;

REVIEW ARTICLE

FRONTIERS IN MEDICINE

# Mobile Devices and Health

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**N Engl J Med 2019;381:956-68.**

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**M**OBILE HEALTH — THE APPLICATION OF SENSORS, MOBILE APPS, SOCIAL media, and location-tracking technology to obtain data pertinent to wellness and disease diagnosis, prevention, and management — makes it theoretically possible to monitor and intervene whenever and wherever acute and chronic medical conditions occur. With 81% of North American adults owning a smartphone,<sup>1</sup> this frontier could be reached in the foreseeable future in the United States and is particularly relevant to the management of chronic diseases. More than 40% of U.S. adults have two or more chronic conditions<sup>2</sup> and chronic conditions

**N Engl J Med 2019;381:956-68.**

**Decentralized clinical trials:**

**Digital biomarkers.**

**Digital diagnostics:**

**Digital patient experience:.**

**Digital therapeutics:**

**Ecologic momentary assessment:**

**Food and Drug Administration (FDA) approval:**

**FDA clearance:**

**Internet of Things:.**

**Medical device:**

**Metadata:**

**Mobile health:**

**Patient-generated health data:.**

**Patient-reported outcome:**

**Software as a medical device:**

**N Engl J Med 2019;381:956-68.**

The transformative potential of mobile health compels clinicians to take an active role in ensuring that this new frontier will be safe, fair, and just for all patients.

N Engl J Med 2019;381:956-68.



Contents lists available at [ScienceDirect](#)

## Technological Forecasting & Social Change



### Big data analytics: Understanding its capabilities and potential benefits for healthcare organizations



Yichuan Wang <sup>a,\*</sup>, LeeAnn Kung <sup>b</sup>, Terry Anthony Byrd <sup>a</sup>

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<sup>b</sup> *Rohrer College of Business, Rowan University, 201 Mullica Hill Road, Glassboro, NJ 08028, USA*

**content analysis of 26 big data implementation cases in healthcare**

# Which is the situation today?

- Healthcare industry has not fully grasped the potential benefits from **Big Data analytics**.
- A better understanding of big data strategic implication is urgently needed.

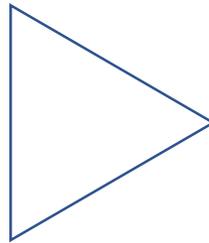
The content analysis of 26 big data implementation cases in healthcare allowed to identify **5 big data analytics**

## The «big» five

1. ***patterns of care*** analytical capability ,
2. ***unstructured data*** analytical capability,
3. ***decision support*** capability,
4. ***predictive*** capability, and
5. ***traceability***.

# Benefits driven by Big Data analytics

- IT infrastructure;
- operational,
- organizational,
- managerial and
- strategic



AREAS

# Which strategies to follow to be successful ?

1. Implementing **(Big) Data governance**
2. Developing an **information sharing culture**
3. **Training key personnel** to use big data analytics
4. **Incorporating cloud computing** into organization's big data analytics
5. **Generating new business ideas** from big data analytics

## Big data analytics: past and present

The term “**big data**” was **first used in 1997** by Michael Cox and David Ellsworth at an IEEE (Institute of Electrical and Electronics Engineers) conference **to explain the visualization of data and the challenges it posed for computer systems** (Cox and Ellsworth, 1997).

## When everything started (1990s)

- **Rapid IT innovations enabled the generation of large amount of data but little useable information in comparison.**
- **Concepts of business intelligence were created to emphasize the importance of :**
  - 1. collection,**
  - 2. integration,**
  - 3. analysis,**
  - 4. interpretation of business information and**
  - 5. how this set of process can help businesses make more appropriate decisions and obtain a better understanding of market behaviors and trends.**

## The evolution (2001 – 2008)

- Ideal stage for the development of big data in terms of 3Vs - **volume, velocity, and variety (3Vs)**, successively evolved into **4Vs - by adding veracity after velocity**
- At the same time, healthcare organizations started to *digitize their medical records and aggregate clinical data in huge electronic data-bases*. This development made health data:
  - **storable,**
  - **usable,**
  - **searchable,** and
  - **actionable,** helping healthcare providers to practice **more effective medicine**

## The revolution – 2009 1/2

- **Big-data computing** become a breakthrough innovation for business intelligence
- **Researchers** predicted that data management and its techniques **were about to shift from structured data into unstructured data**, and from a static terminal environment to a **ubiquitous cloud-based environment**. (Bryant et al 2008,).

## The revolution – 2009 2/2

- **Big-data computing** become a breakthrough innovation for **Big data analytics computing pioneer industries** such as banks and e-commerce were beginning to have an impact on improving business processes and workforce effectiveness, reducing enterprise costs and attracting new customers.
- In regards to **healthcare industry**, as of 2011, stored health care data had reached **150 exabytes** (1 EB =  $10^{18}$  bytes) worldwide, mainly in the form of electronic health records (Institute for Health Technology Transformation, 2013).

The **exabyte** is a multiple of the unit [byte](#) for [digital information](#). In the [International System of Units](#) (SI), the [prefix](#) *exa* indicates multiplication by the sixth power of 1000 ( $10^{18}$ ). Therefore, one exabyte is one [quintillion bytes](#) ([short scale](#)). The unit symbol for the exabyte is **EB**.

Multiples of bytes				
Decimal		Binary		
Value	Metric	Value	IEC	JEDEC
1000	kB kilobyte	1024	KiB kibibyte	KB kilobyte
1000 <sup>2</sup>	MB megabyte	1024 <sup>2</sup>	MiB mebibyte	MB megabyte
1000 <sup>3</sup>	GB gigabyte	1024 <sup>3</sup>	GiB gibibyte	GB gigabyte
1000 <sup>4</sup>	TB terabyte	1024 <sup>4</sup>	TiB tebibyte	–
1000 <sup>5</sup>	PB petabyte	1024 <sup>5</sup>	PiB pebibyte	–
1000 <sup>6</sup>	EB <b>exabyte</b>	1024 <sup>6</sup>	EiB exbibyte	–
1000 <sup>7</sup>	ZB zettabyte	1024 <sup>7</sup>	ZiB zebibyte	–
1000 <sup>8</sup>	YB yottabyte	1024 <sup>8</sup>	YiB yobibyte	–

Orders of magnitude of data

## Library of Congress]

The content of the [Library of Congress](#) is commonly estimated to hold 10 terabytes of data in all printed material. Recent estimates of the size including audio, video, and digital materials start at 3 petabytes<sup>[27]</sup> to 20 petabytes. Therefore, **one exabyte could hold a hundred thousand times the printed material or 50 to 300 times all the content of the Library of Congress.**

## And today? (2019)

- The main trend in the healthcare industry is **a shift in data type from structure-based to semi-structured based** (e.g., home monitoring, telehealth, sensor-based wireless devices) and unstructured data (e.g., transcribed notes, images, and video).
- **The increasing use of sensors and remote monitors is a key factor** supporting the rise of home healthcare services, meaning that **the amount of data being generated from sensors will continue to grow significantly**. This will in turn improve the quality of healthcare services through more accurate analysis and prediction.

# The help of analytics

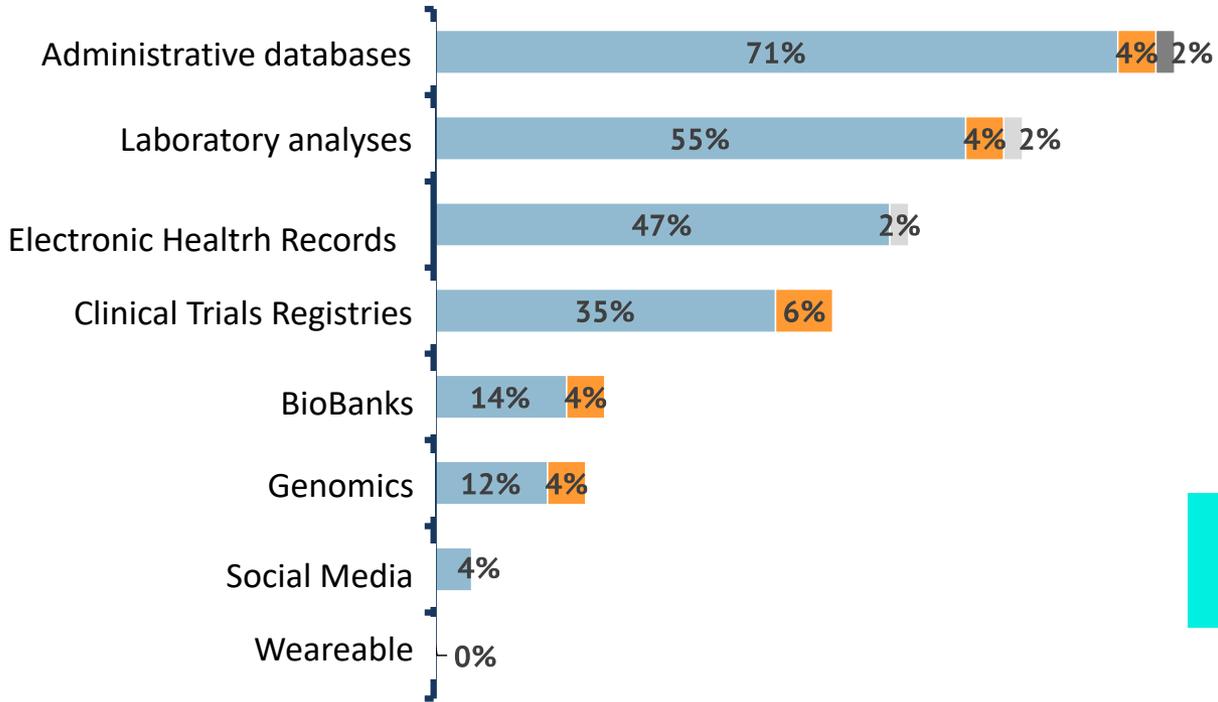
Health facilities could take great advantages by exploiting the huge amount of information that can be collected, analyzed and stored by digital instruments.

**Analytics instruments** may be classified into 4 main categories:

- 1. Descriptive Analytics:**
- 2. Predictive Analytics:**
- 3. Prescriptive Analytics:**
- 4. Automated Analytics**

# MAIN SOURCES OF DATA FOR BIG DATA ANALYTICS AND BUSINESS INTELLIGENCE IN ITALY

■ Descriptive Analytics ■ Predictive Analytics ■ Prescriptive Analytics ■ Automated Analytics



**SAMPLE:  
51 CIOs**

# The most frequent barriers

According to CIOs, the **main problems** in developing Analytics solutions are:

- 1. Limited economic resources available (53%),**
- 2. High complexity in implementing such processes**
- 3. Lack of in-house competencies (33%).**

*Poor maturity of technologies* and/or absence of market solutions (6%) and

*Poor quality of data* (2%), **are not considered** by CIOs relevant **barriers**

# Key takeaways

- Big Data analytics potential still to be fully unleashed
- Right skills and specific competencies still to be fully developed
- Right knowledge and «big data literacy» should be empowered