Task Group Health

Tobias Schaeffter

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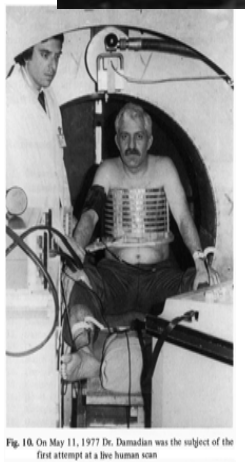
TG Health – Group Members

Members:
Adriaan van der Veen (VSL),
Baki Karaböce (TUBITAK),
Beat Jeckelmann (METAS),
Helen Parkes (LGC),
Ian Severn (NPL),
Mariapaola Sassi (INRIM),
Sophie Vaslin-Reimann (LNE),
Tobias Schaeffter (PTB),
Ulrike Ankerhold (PTB)

Two face2face meetings per year + additional web-based meetings

History of Medical Physics

1896	Publication “X-Strahlen” (**W.C. Röntgen**)
1898	Clinical and other application
1900	Nobel-Prize Röntgen
1903	Radioactivity Bequerel, Curie
1920	Radioactive Tracer for Diagnosis (**Hevesy**)
1931	Tomography (Ziedses des Plantes & Vallebona)
1942	Transmission Ultrasound on Head (Dussik)
1946	NMR-Spectroscopy
1952	Nobel Prize: **Purcell, Bloch**
1958	Anger-camera for scintigraphy
1963	PET (Kuhl)
1971	CT (**Hounsfield**) first head scan
1974	CT first body scan
1973	MRI (**Lauterbur**)
1979	Nobel Price: **Hounsfield, Cormack**
1978	Balloon dilatation (**Grüntzig**)
1991	Nobel Prize, **R. Ernst**
2001	Nobel Prize, **K. Wüthrich**
2003	Nobel Prize, **P. Lauterbur** & **P. Mansfield**



Innovation Context

1. Benefits of new technology must be demonstrated
2. Regulatory hurdles
3. Driving Forces:
   - Ageing Population,
   - “Omics Era” – Precision Medicine
   - Evidence-based Medicine
   - Personalized Medicine (“Big Data”),
   - Cost Reduction.
   - …

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.

“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

President Obama has long expressed a strong conviction that science offers great potential for improving health. Now, the President has announced a research initiative that aims to accelerate progress toward a new era of precision medicine (www.whitehouse.gov/precisionmedicine). We believe that the time is right for this visionary initiative, and the National Institutes of Health (NIH) and other partners will work to achieve this vision.

The concept of precision medicine — prevention and treatment strategies that take individual variability into account — is not new[1]; blood typing, for instance, has been used to guide blood transfusions for more than a century. But the prospect of applying this concept broadly has been dramatically improved by the recent development of large-scale biologic databases (such as the human genome sequence), powerful methods for characterizing patients (such as proteomics, metabolomics, genomics, diverse cellular assays, and even mobile health technology), and computational tools for analyzing large sets of data. What is needed now is a broad research program to encourage creative approaches to precision medicine, test them rigorously, and ultimately use them to build the evidence base needed to guide clinical practice.

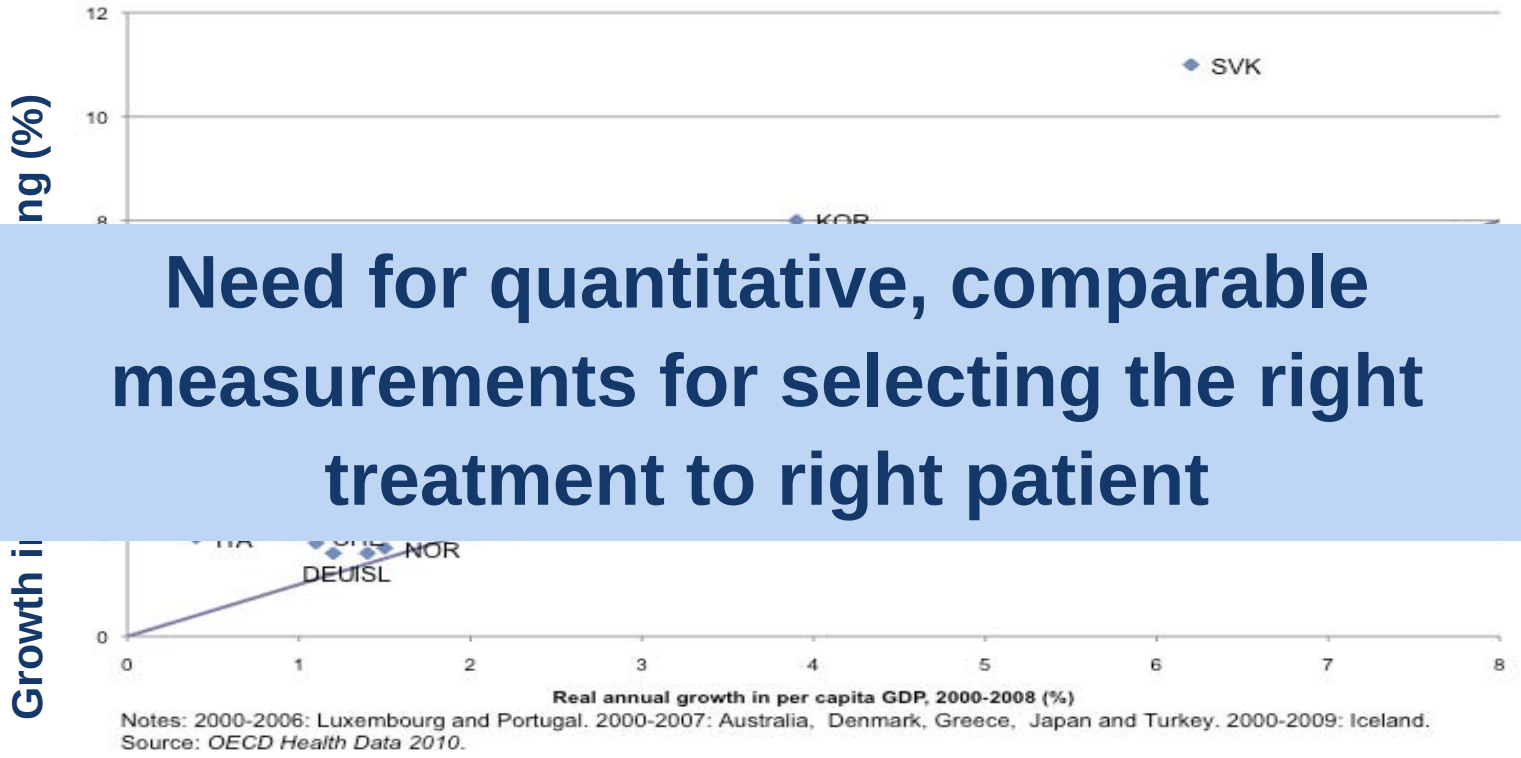
The proposed initiative has two main components: a near-term focus on cancers and a longer-term aim to generate knowledge applicable to the whole range of health and disease. Both components are now within our reach because of advances in basic research, including molecular biology, genomics, and bioinformatics. Furthermore, the initiative taps into converging trends of increased connectivity, through social media and mobile devices, and Americans’ growing desire to be active partners in medical research.

Oncology is the clear choice for enhancing the near-term impact of precision medicine. Can-

Socio-Economic Context

Healthcare Costs are growing faster than the GDP due to

- Increasing costs of treating chronic disease
- New more expensive treatments
- Currently population based treatments



Need for quantitative, comparable measurements for selecting the right treatment to right patient

TG Health – Objective

The aim of the Task Group is to form a coherent approach on metrology for health by

- complementing the work of EURAMET's TC
- Liaising with the Joint Committee for Traceability in Laboratory Medicine (**JCTLM**) and other groups
- Supporting the **development of standards**, measurement methods and measurement structures
- Develop the **Strategic Research Agenda (SRA)** for EMPIR
- **Propose research topics** for joint research projects and to elaborate road maps for future R&D
- **Disseminate expertise and knowledge** on metrology for health through seminars, guides and conferences

Outline

1. EMRP – Outcome
2. EMPIR projects
3. EURAMET Strategic Research Agenda (SRA)
4. Healthcare Challenges
5. Consolidation of European Metrology in Health

TG Health – EMRP

EMRP – Topics of the 11 funded Health projects

- 5 in vitro diagnostics (IVD) related
- 2 radiation therapy related
- 1 MRI safety
- 1 therapeutic ultrasound
- 1 drug delivery
- 1 hearing safety

TG Health – EMRP 2014/2015

EMRP - Outcome

- Increased collaborative work between NMIs
- Initiation of new & changed standards
- Impact in Clinical Practice could be stronger (integration of more clinical partner required)
- Impact stories to demonstrate importance for EU-Commission
- Showcase Meeting in June (stronger support for Paula Knee needed)

TG Health – EMRP 2014/2015

EMRP

- Topic selection often from a metrology perspective
- Stakeholder input could be improved
- Impact in clinical practice could be stronger (integration of more clinical partner required)
- Role of standards for clinical practice
- Clinical guidelines of high importance

TG Health – EMPIR

Debriefing EMPIR-Health Call 2015

- 1st phase less transparent than 2nd phase
- Different evaluation groups with different assessors
- Need for external experts to register as referees
- Cutoff at 9 Projects due to same score of 10/11th project:
  - 2 IVD related
  - 2 neurodegenerative related
  - 2 radiation therapy related
  - 1 Quantitative Imaging
  - 1 Hearing related
  - 1 Additively manufactured implants
- Some projects have some overlap and can form clusters

Health ranked list			
1	15HLT01	JRP-h02	MetVBadBugs
1	15HLT02	JRP-h11	ReMIND
1	15HLT03	JRP-h22	Ears II
4	15HLT04	JRP-h13	NeuroMet
5	15HLT05	JRP-h09	PerfusImaging
5	15HLT06	JRP-h18	MRTDosimetry
7	15HLT07	JRP-h01	AntiMicroResist
7	15HLT08	JRP-h15	MetMRgRT
9	15HLT09	JRP-h04	MetrAMMI
10		JRP-h17	SafeBlood-MET
11		JRP-h19	MeRTH
12		JRP-h08	Breath Analysis
12		JRP-h12	MetroNucMed
14		JRP-h03	METVES II
15		JRP-h07	BioIMET
16		JRP-h16	DECART
17		JRP-h20	Prometheuis
18		JRP-h05	MycoSAFE
19		JRP-h14	ImplantsMRI
20		JRP-h10	PQImage
21		JRP-h21	BioReMIR

TG Health – EMPIR

“Speed Dating” of projects 23-May-2016

- Web-based meeting for potential project collaboration (1 hour)
- 6 min presentations

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7	15HLT08	JRP-h15	MetMRgRT
9	15HLT09	JRP-h04	MetrAMMI

- Only 5 projects have registered and send material
- Fruitful discussion between projects on neurodegenerative disease
- collaboration on exchange of reference material initiated

TG Health – EMPIR

EMPIR Health - 2015

- Impact in Clinical Practice must be demonstrated
- Showcase Meeting with Stakeholders

EMPIR Health - Call 2018

- New Topics?
- How can we create critical mass ?
  - Larger projects
  - Formation of project cluster
  - Themes rather general call?
  - Prioritization through stakeholder meetings
  - Links to H2020

SRA Document Healthcare Challenges

Healthcare Grand Challenges

- Personalizing healthcare, ageing population and the related rise in chronic diseases including cancer, neurodegenerative disorders and cardiovascular disease.
- Costly technological advances in screening, diagnostics and therapies.
- More knowledgeable patient demands, and a shifting paradigm from diagnosis and cure to predict and prevent.

2.1 Health Grand Challenge

2.1.1 Key challenges

Healthcare is considered one of the major European Challenges and a strategic cornerstone in almost all EU R&D programmes. In the upcoming decade healthcare will remain a top priority politically as well as socio-economically, and its importance will even be intensified due to demographic change and spiraling costs that put even the richest nations under pressure.

Total expenditure on health in the European region is 9.0% of GDP (2011)(7.9% in 2000) [11]

"Healthcare costs are rising faster than levels of available funding"[12]

Notably, the EU is required by its founding treaty to ensure that human health is protected as part of all its policies, and to work with the EU countries to improve public health, prevent human illness and eliminate sources of danger to physical and mental health (EU Health Strategy "*Together for H*ealth"[13]).

"As cancer is one of the major causes of ill health in the European Union, associated with a considerable cost to society, it is essential to invest in Europe's future health by taking long-term and sustainable actions to tackle cancer."[14]

A number of significant EU, World Health Organization (WHO) and other policy drivers[15,16,17,18,19,20] and foresight studies[21,22,23] highlight future healthcare challenges, and requirements for supporting research and technology development. Identified healthcare challenges within Europe include:

- Personalizing healthcare, an ageing population and the related rise in chronic diseases including cancer, neurodegenerative disorders and cardiovascular disease.
- Costly technological advances in screening, diagnostics and therapies.
- More knowledgeable patient demand, and a shifting paradigm from diagnosis and cure to predict and prevent.

Horizon 2020 Priorities

- Understanding health, ageing and disease
- Effective disease prevention
- Improving diagnosis, treatments and technologies
- Active and healthy ageing
- Integrated, sustainable, citizen-centred care
- Improving **health information, data exploitation** and providing an evidence base for health policies and regulation

Healthcare Challenges

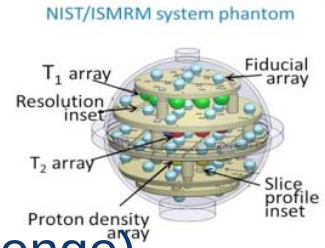
- Modern medical diagnostics relies on variety of multi-parametric data, such as
  - In-Vitro Diagnostic (IVD), DNA, Vital Signs (blood-pressure, ECG, Respiration, Temperature)
  - Multi-modal Imaging,
  - Patient history (Anamneses).

- Full potential of data not exploited due to:
  - Lacking networks,
  - Lacking interoperability,
  - Lacking data security,
  - Lacking comparability and standards

US-Activities

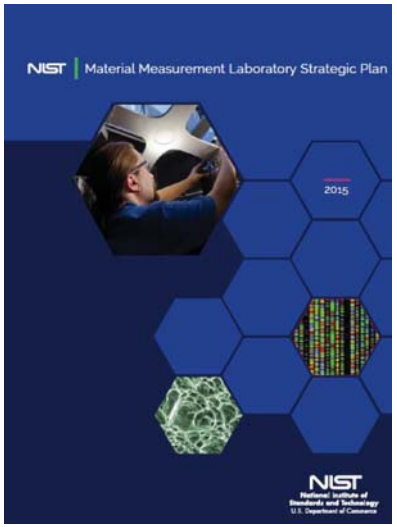
NIST Activities

- Quantitative PET-CT Imaging
- Quantitative MR standard
- Evaluating image processing methods (Biochange challenge)
- Statistical Methods for Quantitative Imaging
- Reference material for precision medicine
- Close links with clinical societies:
  RSNA, SNM, ISMRM,ACR
- Close links with federal government: FDA, NIH
- Running grant programs with clinical opinion leaders



Future NIST Activities

- Complex Biotherapeutics
- Reproducibility of Biomedical Research
- Provide validated data and informatics tools
- Precision medicine-specific guide on IT-security



Pathways to Impact

- Standards vs Clinical Guidelines
- Showcase Meeting with stakeholders (clinical opinion leaders)
- Engagement with clinical societies
- Develop a coherent European Approach, ie Critical mass by
  - Larger Projects within EMPIR?
  - Links to other programs (H2020)
  - Project Collaboration (Program Themes)
  - Network/Clusters of Excellence
  - Avoid duplicating work
  - …..