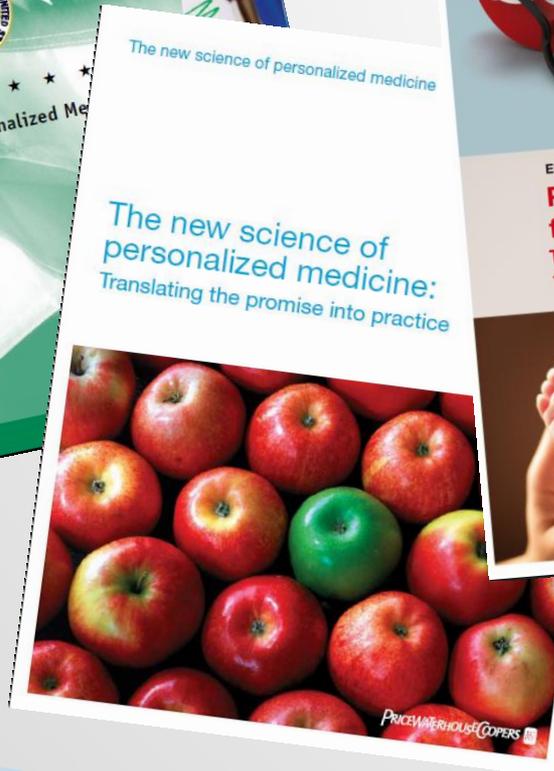


Personalized Medicine

March 2015

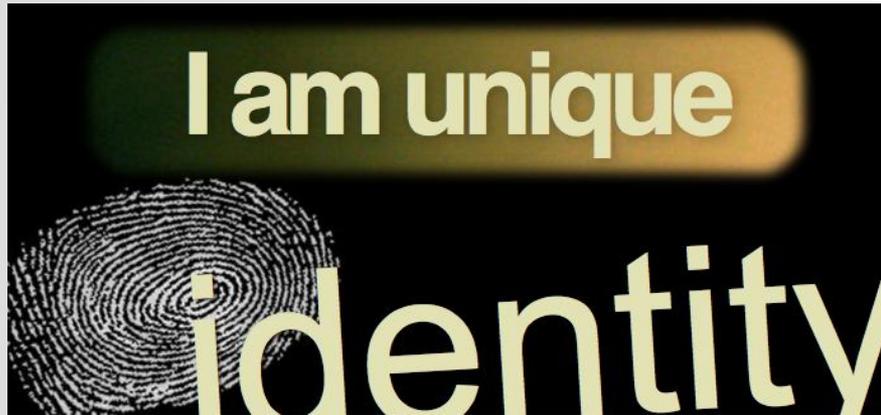
David Levine
President and CEO
D.L. Strategic Consulting

Personalized Medicine: A Question of Health Around the World



Individualized Medicine

Personalized medicine



Precision Medicine

Biomarkers
Genomics

Patient Centered
Approach
Personalized
Health
Care



A Definition

- ▶ Personalised medicine is a new approach to **classifying, understanding, treating, and preventing disease** based on **data and information** on individual biological and environmental differences. It seeks to integrate data on the entire dynamic biological makeup of each individual as well as the **environment and lifestyle factors** that interface with this makeup to generate complex, individual phenotype.¹

1) Personalized Medicine for the European Citizen

Personalized Medicine Is Impacting Patient Care in Many Diseases. For Example...

...in Breast Cancer:

One of the earliest and most common examples of personalized medicine came in Herceptin (trastuzumab). About 30% of patients with breast cancer have a form that over-expresses a protein called HER2, which is not responsive to standard therapy.

Trastuzumab was approved for patients with HER2 positive tumors in 1998 and further research in 2005 showed that it reduced recurrence by 52% in combination with chemotherapy.

Personalized Medicine Is Impacting Patient Care in Many Diseases. For Example...

in Cardiovascular Disease:

The primary method for managing heart transplant rejection was the invasive technique of endomyocardial biopsy – a heart biopsy.

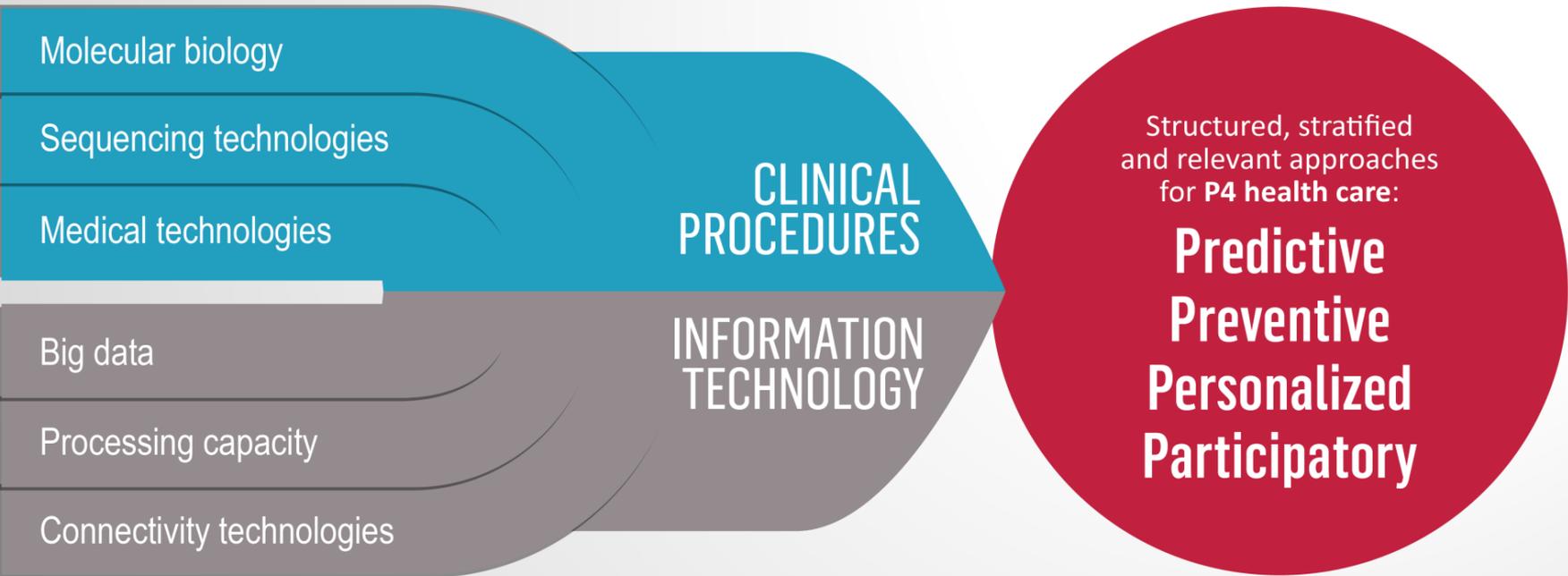
Today, a genetic diagnostic test is performed on a blood sample, providing a non-invasive test to help manage the care of patients post-transplant.

Personalized Medicine

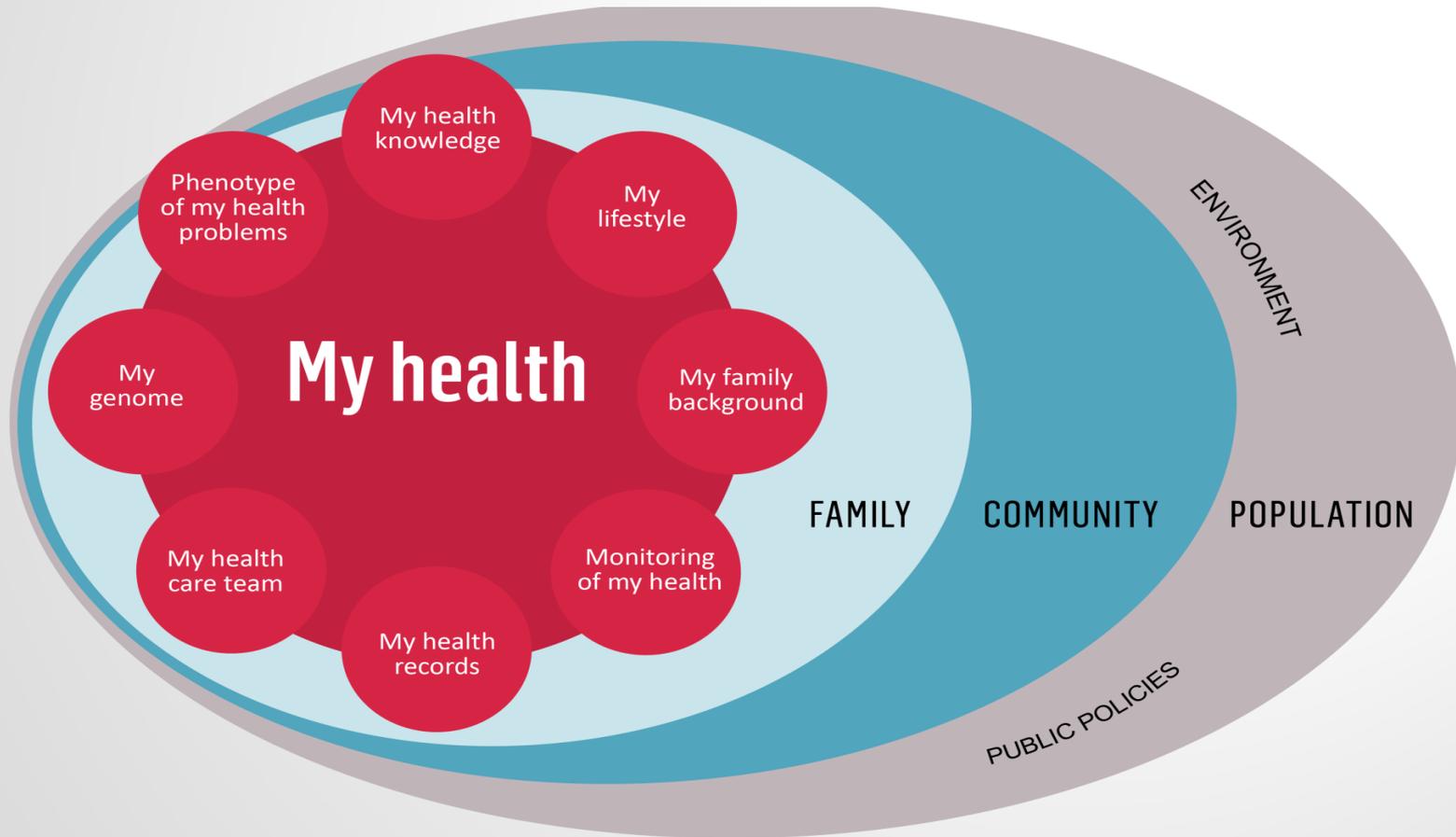
The full implementation of personalized medicine encompasses:

- ▶ Risk Assessment: Genetic testing to reveal predisposition to disease
- ▶ Prevention: Behavior/Lifestyle/Treatment intervention to prevent disease
- ▶ Detection: Early detection of disease at the molecular level
- ▶ Diagnosis: Accurate disease diagnosis enabling individualized treatment strategy
- ▶ Treatment: Improved outcomes through targeted treatments and reduced side effects
- ▶ Management: Active monitoring of treatment response and disease progression

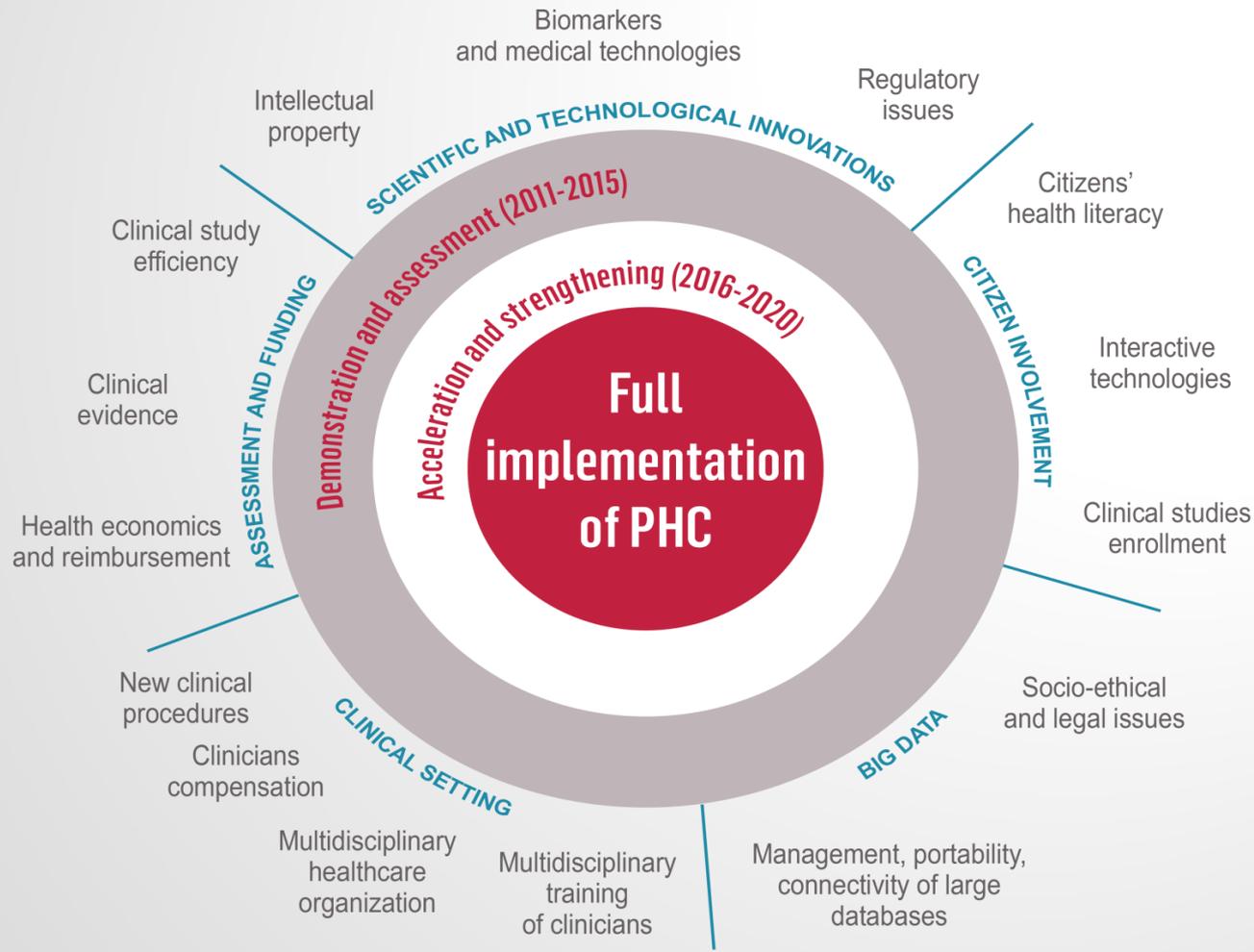
Scientific and technological innovations driving a revolution in Healthcare Management



The PHC paradigm shift: The citizen fully engaged in personal health management



Framework to leverage the benefits of the PHC revolution



PERSONALIZED MEDICINE BY THE NUMBERS

Cost of sequencing a human genome

2001 (2)	2014 (2)
\$300,000,000	\$1,000

30% of all treatments in late clinical development rely on biomarker data (6)

50% of all treatments in early clinical development rely on biomarker data (6)

60% of all treatments in preclinical development rely on biomarker data (6)

34% reduction in chemotherapy use would occur if women with breast cancer receive a genetic test of their tumor prior to treatment (8)

17,000 strokes could be prevented each year if a genetic test is used to properly dose the blood thinner warfarin (9)

\$604,000,000 in annual health care cost savings would be realized if patients with metastatic colorectal cancer receive a genetic test for the KRAS gene prior to treatment (10)

PERSONALIZED MEDICINE BY THE NUMBERS

- ▶ 30% of all biopharmaceutical companies surveyed require all compounds in development to have a biomarker (7)
- ▶ 50% of all clinical trials collect DNA from patients to aid in biomarker development (7)
- ▶ 75% increase in personalized medicine investment by industry from 2006–2011 (6)

137 FDA–approved drugs have pharmacogenomic information in their labeling (5)

155 pharmacogenomic biomarkers are included on FDA–approved drug labels (5)

TODAY

- ▶ *A patient has late-stage non-small cell lung cancer .*
- ▶ *She has gone through a number of treatments, but none were able to stop the cancer's spread.*
- ▶ *A newly approved drug called Xalkori® (crizotinib) might offer hope.*
- ▶ *Only about 5% of patients whose tumors have the anaplastic lymphoma kinase (ALK) gene rearrangement can potentially benefit.*
- ▶ *A newly approved diagnostic test determines that the patient has the gene rearrangement and that the drug is a treatment option for her. After starting to take Xalkori®, the tumors begin to respond.*

The Future: A Doctor in His office

- ▶ *A series of studies have demonstrated a connection between multiple rare mutations found in 10 percent of people and the likelihood that they might convert to type 2 diabetes.*
- ▶ *Patients have had their entire genome sequenced and entered into their electronic medical record – a process that takes only a week and costs a few hundred dollars.*

A quick search of the patient database finds that about 4% are at risk.

Half of those patients are given a strong reminder and advice on diet and lifestyle choices they can take to avoid the disease.

To the other half, whose medical records reveal pre-diabetic symptoms, he sets up appointments to consider more proactive treatment with drugs that can prevent the onset of disease.

The US Research Project

The survey found that:

- ❑ A large majority of people have not heard of personalized medicine but react positively when it is described to them.
- ❑ Most feel excited about the potential benefits of personalized medicine, including choosing a treatment that is most likely to work for them and the potential to prevent illness.
- ❑ A large majority also recognize the value of these technologies and believe that they should be covered by insurance



Benefits of Personalized Medicine

The information could...



■ Major benefit ■ Minor benefit ■ Not a benefit ■ Not sure

"I'm going to read you a list of some of the benefits of personalized testing. For each one, tell me if that would be a major benefit, a minor benefit, or not a benefit for you personally."

GENETICS: CLINICAL APPLICATION



More than 90% of doctors show a positive attitude toward genetics.



Accessibility to tests remains the principal barrier.



72% of doctors feel that they do not possess the resources, knowledge or skills necessary.



Almost 70% of doctors say that they are not sufficiently informed about the usefulness and accessibility.

Obama Personalized Medicine Initiative January 30, 2015

- ▶ More and better-tailored treatment for cancer
- ▶ Creation of a voluntary national research patient cohort
- ▶ Commitment to protecting privacy
- ▶ Regulatory modernization–FDA Next Generation Sequencing Technologies
- ▶ Private public partnerships

Introducing Personalized Medicine into the Canadian Health Care System

1. Scientific innovation and technology
2. Evaluation of the clinical efficacy of the innovation
3. Evaluate the model of financing
4. Determining clinical implementation (education of professionals)
5. Insuring an appropriate regulatory environment
6. Managing large volumes of data
7. Citizen participation

The Statistics

1. 41% of Canadians are currently taking a prescription medication
2. 25% of Canadians are on 2 or more prescription medications
3. 60% of Canadians on prescription medication are unhappy
4. Employees on high-risk medication have 69% more healthcare visits, 3 times more sick days and 4 times more disability claims
5. 95% of all adverse drug reactions go unreported
6. Up to 75% of people are non-responsive to their medication and do not even know it.

Personal Prescribing

- ▶ Personal prescribing identifies eligible employees' individual compatibility with over 50 commonly prescribed medications so their doctors can prescribe them the right dose of the right drug to avoid adverse drug reactions and non-effects.

Advantages of a Personalized Prescription Plan

An employee benefit package is now being offered to help reduce drug waste and keep employees healthy and productive

1. Saves Money on medication waste
2. Less employees on short and long term disability
3. Less medication-related absenteeism
4. Increased productivity and morale

Thank you