PRECISION MEDICINE VERSUS PERSONALIZED MEDICINE

A BRIEF DISCUSSION PRESENTATION

PRECISION VS. PERSONALIZED MEDICINE PRESENTATION

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TOPIC DISCUSSION AGENDA

- Subject matter historical timeline
- Definitions of Personalized and Precision medicine
- Legislation of Personalized and Precision medicine
- Examples of each form of treatment
- Benefits of each form of treatment
- Impacts and Influences; ie, Pharma, Cost, Politics, etc

DEVELOPMENT OF PERSONALIZED TO PRECISION MEDICINE

1900-1990

Disease and critical genetic Dysfunction treated with a narrow range of options and pharmaceutical compounds This form of medicine defined as PERSONALIZED.

1985-2010

Evolutions of Pharmaceutical testing and enhancements, with an acceptable 50% positive response rate

1990-2003

The Human Genome Project Thirteen Years and $3B Breakthrough evaluation of Individual process treatments

2010

Genomic medicine categorized as Personalized medicine. Focus of personalized treatments:
Diabetes and Cancers
PMI established 2015

2020

Legislation and debate. Insurance, politics and health Care administration driven. Evaluation of personal data integration.

H.R.4393 - Advancing Access to Precision Medicine Act

PRECISION & PERSONALIZED MEDICINE

- The result of “personalized” Medicine treatment is a "one-size-fits-all" approach to medicine that is based on broad population averages (in most cases less than a 50% positive success rate). This traditional practice often misses its mark because each person’s genetic makeup is slightly different from everyone else’s, often in very important ways that affect health. The Human Genome Project of 1990-2003 offered data and insight for development of new protocols.
- Called the “anywhere for everyone” format of treatment.
- Personalized medicine involves a more interactive, intimate, and interview process, which includes history and feedback from the patient and family. It is often thought of tailoring medical treatment to the individual characteristics, needs, and “preferences” of a patient during all stages of care, including prevention, diagnosis, treatment and follow up
- The advent of precision medicine is moving us closer to more precise, predictable and powerful health care that is customized for the individual patient. Our growing understanding of genetics and genomics — and how they drive health, disease and drug responses in each person — is enabling doctors to provide better disease prevention, more accurate diagnoses, safer drug prescriptions and more effective treatments for the many diseases and conditions that diminish our health.
- Precision medicine involves the evaluation and review of human genomics, environments and lifestyles.
- Health care administration, the requirements for cost efficiency and the lure of more targeted, efficient treatments have driven the acceleration to embrace and support new PRECISION based treatment protocols.
- Tailoring health care to each person’s unique genetic makeup – that’s the promising idea behind precision medicine, also variously known as individualized medicine, personalized medicine or genomic medicine.

PRECISION MEDICINE TRANSITION OR SIMPLE ADDITION?

- Addresses the “one size fits all” concerns
- Offers evaluations at the molecular level
- Personalized medicine based on PRECISION
- Use of genetic codes, to offer insights
- Driven by innovation, diagnostics and cost
- Enhanced health care management:
  - Genetics and comprehensive study versus symptoms and therapeutics

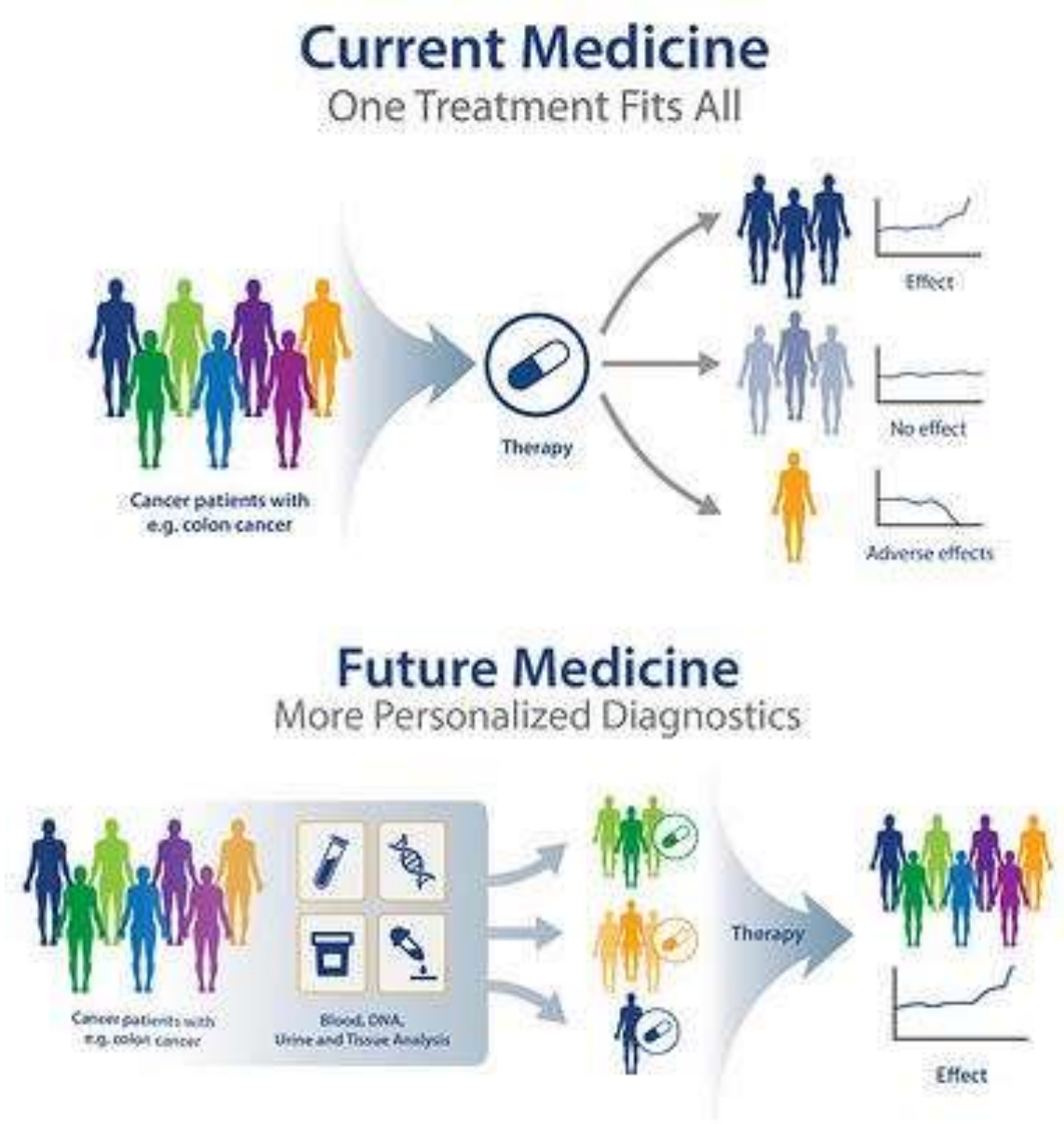


Photo & Illustration credit: PDX and Personalized Medicine., by Jody Barbeau PhD, June 5, 2018 at 01:30 PM | Tags, https://blog.crownbio.com/pdx-personalized-medicine

Twenty years ago, on June 26th 2000, those running the public Human Genome Project and its private-sector shadow, a firm called Celera Genomics, decided to declare victory. In a simultaneous breasting of the tape, each published a "working draft" of the genome. The broker, Bill Clinton, hosted the chief scientists at the White House. Hyperbolic comparisons were made to the Apollo project to land people on the Moon.

Unlike Apollo, though, this announcement marked a beginning rather than an end. Genomics is now so embedded in biology that it is hard to recall what things were like before it. Those first human sequences cost billions of dollars to obtain. Today, with the advent of new technologies, a full sequence costs about $200, and less detailed versions are cheaper still. It is as if, to use Apollo as the analogy, regular shuttles to the Moon had become available at prices an average family in the West could afford—and the more adventurous might now be considering a trip to Mars.

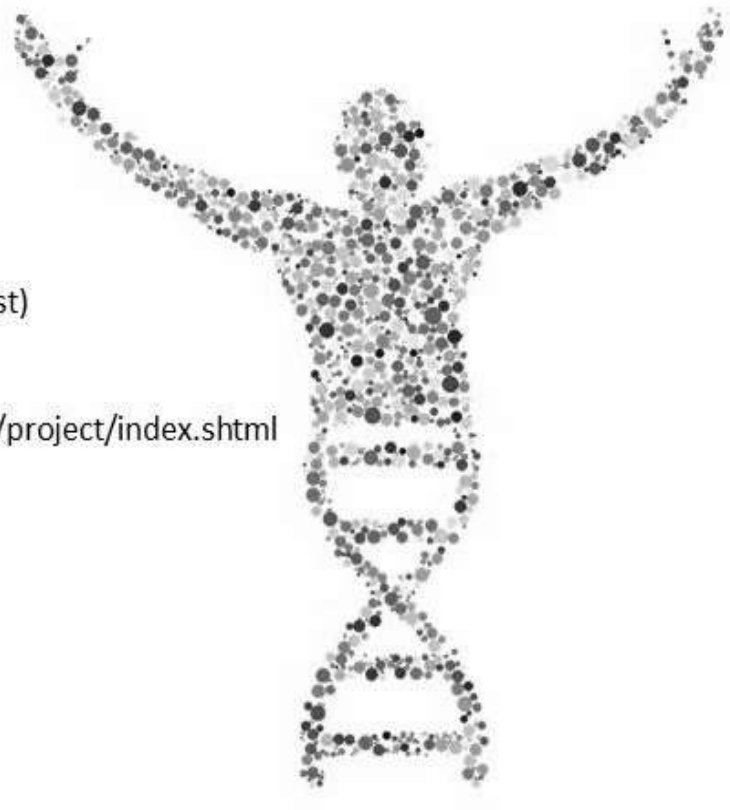
And I was there:

Human Genome Project (special assignment)
US Government Stanford University/USC

March 1997-June 1999 (Military exit transition technologist)

Under Dr. Michael Giesen @
https://web.ornl.gov/sci/techresources/Human_Genome/project/index.shtml

- Identify genes in human DNA
- Sequence chemical base pairs
- Catalog into databases
- Develop tools for analysis
- Translate from academia to public sector
- Evaluate ethical, legal and social issues of the project



I WAS THERE FROM THE START:

DAWN OF AN ERA

THE HUMAN GENOME PROJECT TRANSFORMED BIOLOGY AND MEDICINE.

IT IS HARD TO REMEMBER WHAT SCIENCE WAS LIKE BEFOREHAND.

Sponsor: Rep. Swalwell, Eric [D-CA-15] (Introduced 09/18/2019)

H.R.4393 - Advancing Access to Precision Medicine Act 116th Congress (2019-2020)

House - Energy and Commerce

Latest Action: House - 09/19/2019 Referred to the Subcommittee on Health.

LEGISLATION

- PURPOSE: To facilitate access to government funding for the advancement of PRECISION based HC initiatives.
- EXECUTION: To amend title XIX of the Social Security Act to provide for a State option under the State Medicaid plan to provide DNA sequencing clinical services for certain children, provide for a study by the National Academy of Medicine on the use of genetic and genomic testing to improve health care, and for other purposes.
- DELIVERABLES: Leveraging funding, resources and laboratory reporting requirements to accelerate program initiatives and comply with the CARES Act Section 18115pdf icon, and to amend https://www.congress.gov/bill/116th-congress/house-bill/4393/all-info?r=7&s=1

CLINICAL TESTING EXAMPLES & TALKING POINTS OF EACH

- Personalized evaluation and therapeutics medicine has been the standard for over 200 years.
- Laboratories and diagnostics:
  - Laboratories that perform clinical diagnostic testing under CLIA,
  - PGX- Pharmacogenomic tests look for changes or variants in these genes that may determine whether a medication could be an effective treatment for you or whether you could have side effects to a specific medication.
  - CGX- Cancer Genomics is a test to determine if you are at risk for hereditary cancer! Hereditary Cancer Marker Screening can identify if you carry genes that are known to be associated with certain cancers. CGx, which tests for genetic predisposition to cancer, and are considered to be LESS accurate.
- Addressing complex, multiple diseases
- Combinations of conditions
- Social and situational backgrounds
- Achieving outcomes tailored to the aged individual
- Determining the individual patients wants and needs
- Personal variables

ADVANTAGES AND DISADVANTAGES OF PRECISION MEDICINE

- Ability to use patients' genetic information
- Predict treatments that will work
- Understand underlying disease mechanisms
- Prove the prevention, diagnosis and treatment of various diseases
- Improved integration of EHRs

- Infrastructure Requirements
- Healthcare Cost
- Legal issues
- Required education regarding molecular genetics and biochemistry
- Understanding the relevance of the information
- Relaying results to the patients in ways they understand

POTENTIAL IMPACT

1. Leverage existing technologies and interfaces
2. Share information seamlessly across departments for the benefit of the patient
3. Integrate test results within individual patient records and the clinical decision-making workflow
4. Futureproof the organization's precision medicine program (Dixon, B., 2018)

EXECUTION PITFALLS & CHALLENGES

Most asked QUESTIONS:

- Are these platforms legal/ethical?
- How does the transition affect patient intimacy?
- Are patient information security protocols sufficient?
- Will facilitators be required to ask AOE questions?
- What protocol is to be used in reporting AOE information?
- Does the historical and clinical data support integration theory?
- Will the current technology platforms support the operational transition?
- How will network providers extract from clinical reporting and CLER data?
- Have LOINC codes been assigned to these test and the testing protocols?
- How will the data reported to state and jurisdictional entities be used and monitored?

SUMMARY

- The current Health Care systems technology, integration and security protocols are not suitable.
- Does a transition in treatment plan integration lead to loss of patient intimacy?
- The existence of multiple and dysfunctional laboratory create communication barriers.
- Electronic options are in the process of standardization. Electronic reporting options are available to reduce the burden on providers reporting test results. Laboratories that are not currently reporting electronically to the Laboratory Reporting Working Group at eocevent405@cdc.gov.
- How do we measure success: in quality of care, quality of life, cost savings, efficiencies or a combination of all?
- In summary, the precision medicine process transition promoters will state the following:
  - Promotes an understanding of the difference between precision and accuracy
  - Applies informatics to the collection and analysis of big data
  - Puts things into perspective
  - Provide data that has clinical relevance at the patient level
  - Presents data in a way that makes it easier for the clinician and end-user to interpret
  - Relevant data used in the decision-making process

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