

The President's Precision Medicine Initiative

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Precision Medicine:

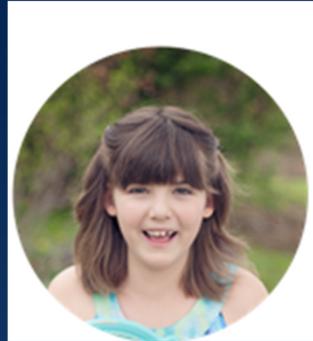
- An emerging approach for disease prevention and treatment that takes into account people's individual variation in genes, environment and lifestyle.
- Not a new concept
 - Medicine has always been “personalized”
 - Consider prescription eyeglasses, blood typing...
- However, most therapies available today are designed for an “average patient.”
- PM is about moving away from this “one-size-fits-all” approach.



Precision Medicine Success Stories



William Elder Jr.



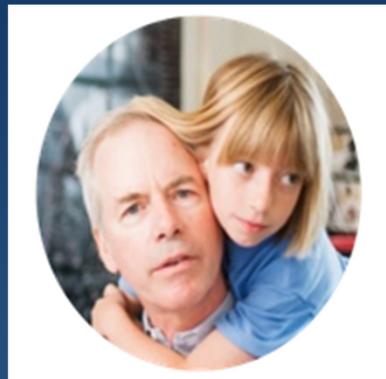
Emily Whitehead



Elana Simon



Melanie Nix



Hugh and
Beatrice Rienhoff

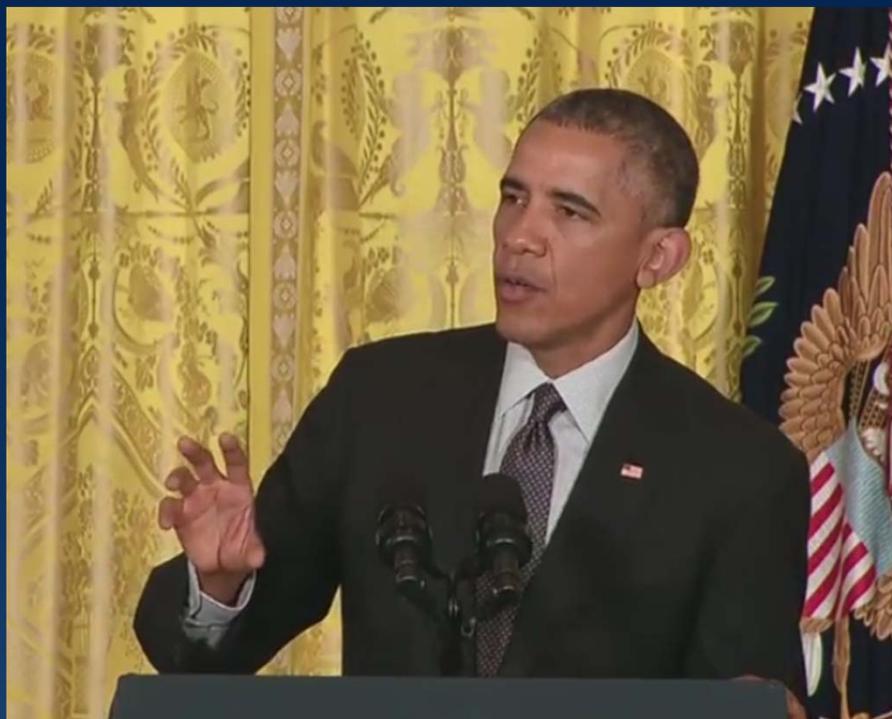


Kareem
Abdul-Jabbar



Noah and
Alexis Beery





“And that’s why we’re here today. Because something called precision medicine ... gives us one of the greatest opportunities for new medical breakthroughs that we have ever seen.”

President Barack Obama
January 30, 2015



Precision Medicine Initiative (PMI)

Mission Statement

To enable a new era of medicine through research and technology that empowers patients, researchers, and providers to work together toward development of individualized treatments.



Precision Medicine Initiative: Why Now?



Genomics



Data Science



EHRs



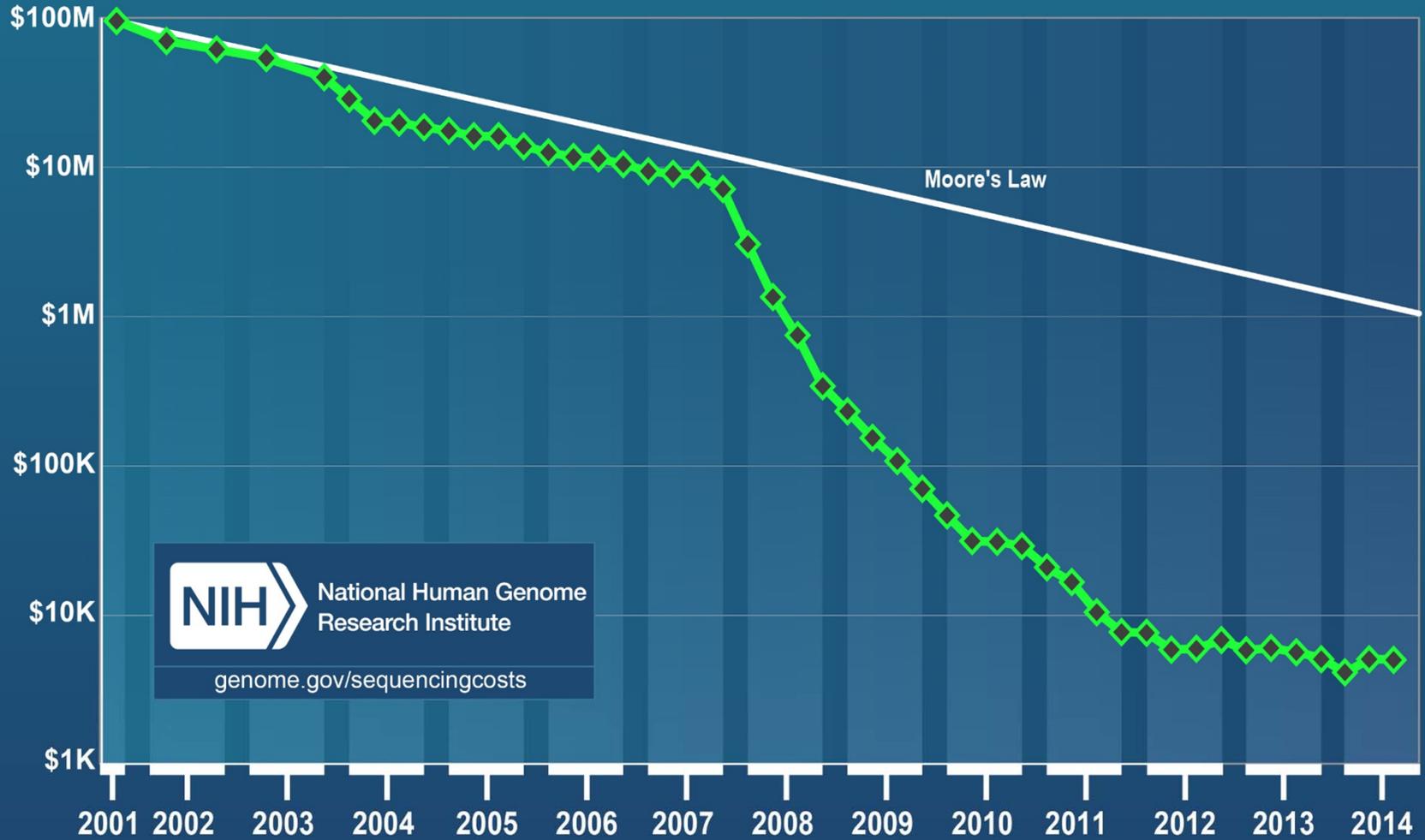
Technologies



Patient Partnerships



Cost per Genome



NIH National Human Genome Research Institute
genome.gov/sequencingcosts



Precision Medicine Initiative: Timing is Everything

	Ten Years Ago	Now
Cost of sequencing a human genome	\$22,000,000	\$1000 - \$5000
Amount of Time to Sequence a Human Genome	2 years	<1 day
Number of smart phones in the United States	1 million (<2%)	160 million (58%)
EHR Adoption (% providers)	20-30%	>90%
Computing Power	n	n x 16



Precision Medicine Initiative

Vision: Build 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.

- **Near Term:** apply the tenets of precision medicine to a major health threat – cancer
- **Longer Term:** generate the knowledge base necessary to move precision medicine into virtually all areas of health and disease



PMI: Core Components

- Cancer component (NCI)
 - Expand genetically-based clinical cancer trials
 - Explore fundamental aspects of cancer biology
 - Identify new cancer subtypes, therapeutic targets
 - Create a “cancer knowledge network” to generate and share new knowledge to fuel scientific discovery and guide treatment options.
- Creation of a national research cohort (NIH, others)
 - One million or more Americans who volunteer to participate in research.
 - Participants to have the opportunity to contribute diverse sources of data (e.g., medical records; genetic information; environmental and lifestyle data; data from mobile *devices*)
 - Broadly accessible to qualified researchers
 - Forge new model for scientific research that emphasizes engaged participants and open, responsible data sharing
- Regulatory modernization
 - Identify and support changes to advance precision medicine and protect public health
 - Development of a new approach for regulating NGS technologies (FDA)



Core Activities

Cross-government working groups

- Participant engagement
- Stakeholder outreach
- Data infrastructure
- Regulatory modernization
- Privacy

NIH Advisory Committee Working Group

- Recommendations on Cohort Design



PMI and Privacy

Goal: Establish a framework for protecting the privacy and security of participants' information in PMI

- Develop a set of privacy principles to guide the development of the PMI cohort
- Identify gaps and other issues in current privacy and security protections, and propose policy changes to address those gaps.



Questions?

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