Personalized Risk Assessment Promises, Pitfalls and the Path Forward

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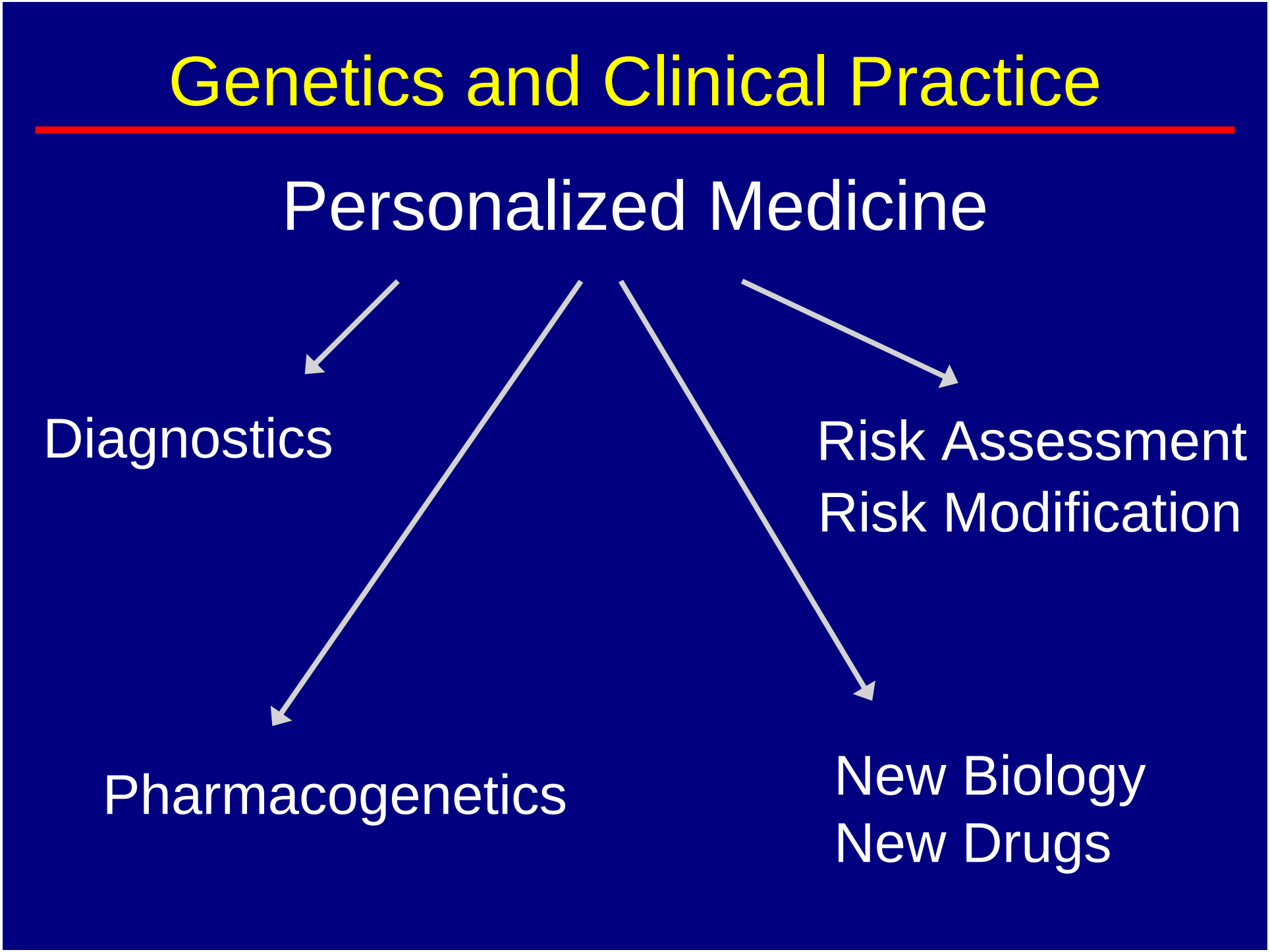
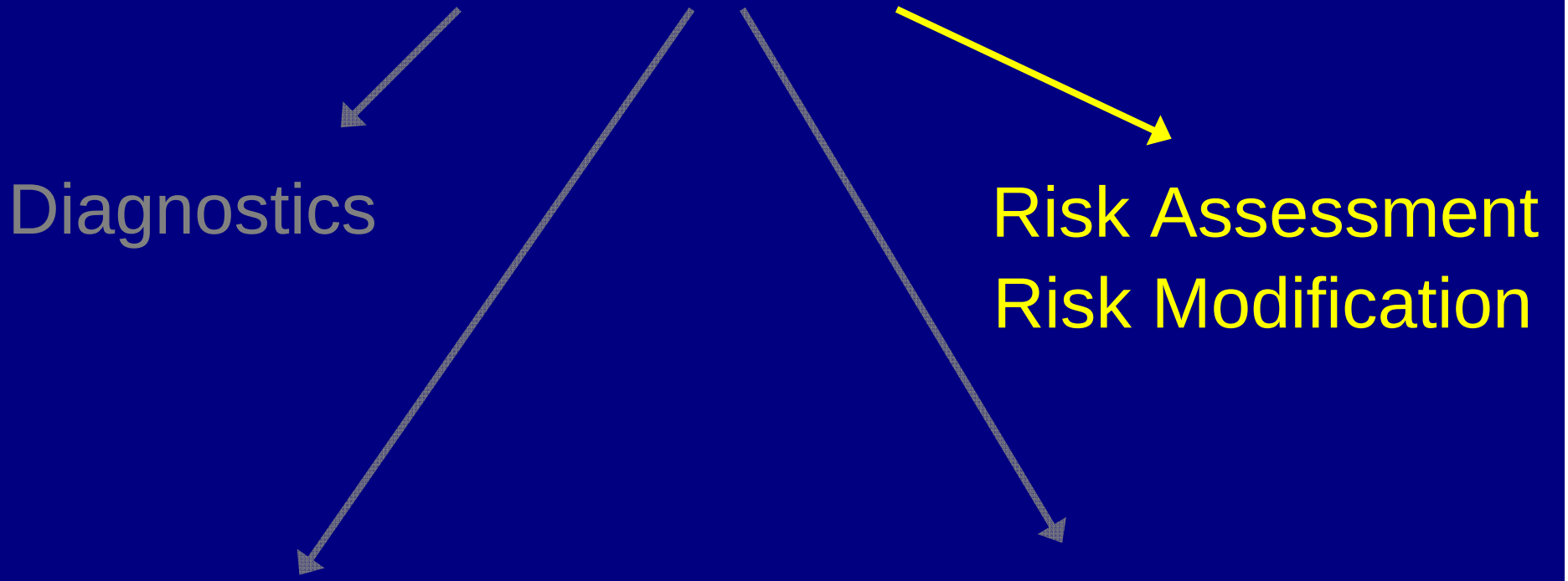
Genetics and Clinical Practice



Genetics and Clinical Practice

Personalized Medicine



Promises

- Genetics will revolutionize medicine
- Personalization will improve treatment and prevention
- Individuals will control their health information

Promising Interventions

- Early lung cancer detection - chest x-rays
- Chemoprevention - beta carotene, vitamin E
- Back pain - disc surgery
- Breast cancer treatment - autologus bone marrow transplants

Genetic Risk Factors for Common Diseases

Should individuals be told about their risk profile?

Yes!	No!
The future is now!	It is too early!

Yes!

- Evidence base: robust
- Prevention
- Knowing thyself
- Family history inadequate
- Empowering
- Motivating
- Resource efficiency

No!

- Evidence base: weak
- Genes/environment not understood
- Risk levels too weak
- Family history is just as good
- Not understandable
- Unproven clinical utility

Resolving Debates

- Duel
- Shout louder
- Change the rules
- Deploy *ad hominem* argument
- Design experiments, collect data

Pitfalls

- Move forward - in all directions at once
- Fail to collect data
- Selectively collect data

Research Questions

- What types of conditions should be included in research testing?
- How do we educate individuals about the limitations of genetic testing?
- How should we deliver genetic test results in ways that are both understandable and in context?
- How will an individual's interpretation of their test results evolve through time?

Research Questions

- What is the potential impact on the lives of individuals receiving these test results?

- Will knowing that an “at risk” allele is carried in a family impact family interaction?

- As new information on genetic variants is obtained, how do we inform individuals that the state of science has changed?

- How do we apply genetic risk prediction to clinical practice?

Genetic Risk Factors for Common Diseases

Approach: Create transdisciplinary team to address research questions focused on delivering risk information to patients.

Multiplex Project

- Who will be interested in and request genetic testing?
- Will individuals understand their test results?
- Will test results influence information seeking?

Long term: Did the test make a health difference?

Multiplex Project

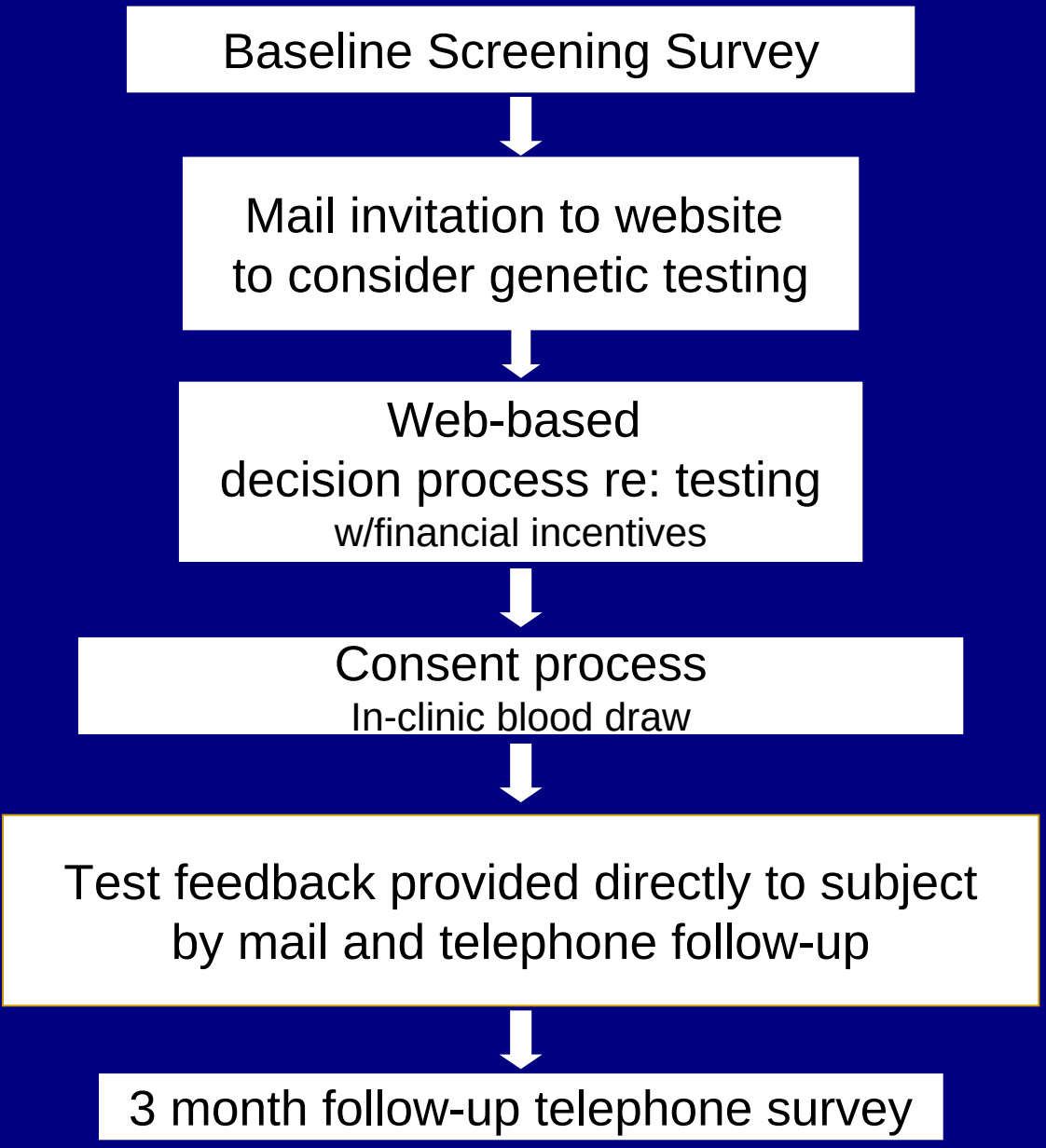
Genomics/Genetics Applied to Public Health

- Henry Ford Health System - ~2,000 participants
- Stratified sampling - age, health status, ethnicity, education and income

Multiplex Prototype Test
8 Health Conditions & 15 Genes

- Diabetes
- Heart Disease
- High Cholesterol
- Hypertension
- Lung cancer
- Colon Cancer
- Skin Cancer
- Osteoporosis

Multiplex Study Design



The Multiplex Initiative

This report will tell you whether you have versions of genes that raise your chances of getting some common health conditions.

My Results

And What they Mean

Understanding Your Test Results

Remember these points when reading your test results.

1. Having risk versions of genes means that you are more likely to get the health condition than people who do not have risk versions.
2. Most people will have between 4 and 10 risk versions of the genes on the Multiplex Genetic Test.
3. Having risk versions does not mean that you will certainly get any of these health conditions.

For more information about your results, see the enclosed document "Important Points to Keep In Mind."

Overview of Your Results

You have one or more risk versions that raise your chances of getting:

Heart Disease
High Cholesterol
High Blood Pressure
Type 2 Diabetes
Osteoporosis
Lung Cancer
Colon Cancer
Skin Cancer

Look inside this booklet and throughout this packet for more about what your results mean for YOUR personal risk.

What is a risk version?

Genes can come in more than one version. When you have a risk version it means that you have a version of a gene that raises your chance of getting a health condition.

Go to http://multiplex.nih.gov for more information about:

Health conditions • Genes for each health condition

Personalized Medicine: Conclusions

- Promises
  - Significant potential for healthcare impact at population level
- Pitfalls and Challenges
  - Failure to learn from practice
  - Reaching segments of the population may be difficult
- Path Forward
  - Support research aimed at exploring testing
  - Significant opportunity for public / private partnerships

Multiplex Project

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