

# **Ethical Challenges for Genomics and Personalized Medicine**

Michael Kalichman  
Research Ethics Program, UC San Diego  
Bioengineering 183  
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# College Bound, DNA Swab in Hand by Tamar Lewin (5/18/10)

- “Instead of the usual required summer-reading book, this year’s incoming freshmen at the University of California, Berkeley, will get something quite different: a cotton swab on which they can, if they choose, send in a DNA sample.”

# College Bound, DNA Swab in Hand by Tamar Lewin

- “The university said it would analyze the samples, from inside students’ cheeks, for three genes that help regulate the ability to metabolize alcohol, lactose and folates.”

# College Bound, DNA Swab in Hand by Tamar Lewin

- “Berkeley’s program for the class of 2014 is the first mass genetic testing by a university. Jasper Rine, the professor of genetics who is leading the project, said it was designed to help students learn about personalized medicine and identify their own vulnerabilities.”

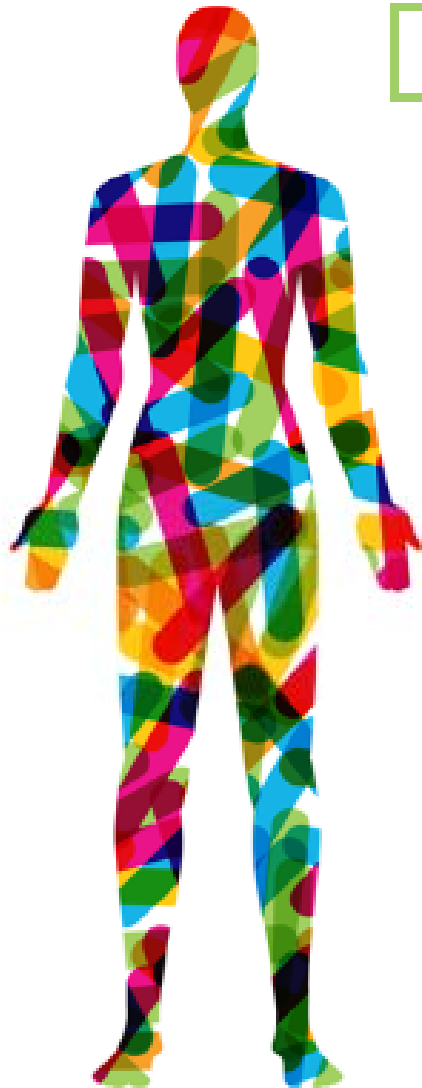
# College Bound, DNA Swab in Hand by Tamar Lewin

- “ ‘They may think these are noncontroversial genes, but there’s nothing noncontroversial about alcohol on campus,’ said George Annas, a bioethicist at the Boston University School of Public Health. ‘What if someone tests negative, and they don’t have the marker, so they think that means they can drink more? Like all genetic information, it’s potentially harmful.’ ”

New York Times, May 18, 2010

# Getting Serious About Personal Genomics' Risks (9/8/10)

- "...the California Department of Public Health (CDPH) ruled that if Berkeley wanted to return personalized genetic data to some of its freshmen, the testing must be conducted at the direction of a physician and performed by a licensed clinical laboratory."



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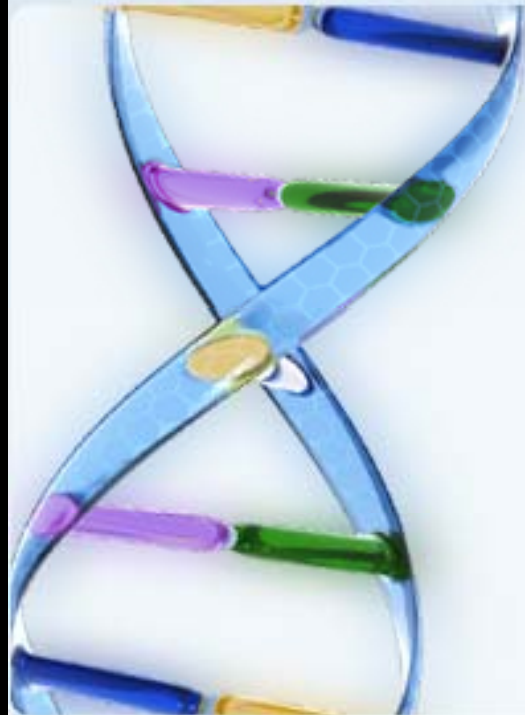
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# Ethics

- Choices, how we act
- What counts?
- Who decides?
- How do we judge ethical decisions?
  - Post hoc
  - A priori
- Predicting Outcomes

# Benefits of Testing

- “increased knowledge about disease risks and predispositions”
- “more tailored drug therapy”
- “Increased knowledge can result in medical or lifestyle changes that reduce risks, or it can affect the patient’s life decisions or strategies for coping.”

Ormond KE et al. (2010): Challenges in the clinical application of whole-genome sequencing. *The Lancet* 375:1749-51.

# Risks of Testing

- “might reveal information about risks for sensitive issues, such as psychiatric disorders or behavioural traits.”
- “In view of the predicted frequency of recessive mutations in the population, every patient will learn that he or she is a heterozygous carrier of more than one serious or lethal autosomal recessive disease.”

Ormond KE et al. (2010): Challenges in the clinical application of whole-genome sequencing. *The Lancet* 375:1749-51.

# Costs to Society

- "...large increase in testing by cautious physicians to rule out false-positive results."
- "Who will provide skilled interpretation of whole genome sequence to millions of patients?"

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# Personalized Genomics – ethical challenges

- Where are the harms?
- Risks
  - Probability
  - Severity
- Individual
  - Disease
  - Parentage
  - Privacy
- Understanding of risk (lifetime, cumulative)
- Validity / false positives / false negatives

# Probability: What determines risk?

- Accuracy of the test?
- Reliability of the test?
- Meaning of the test result?

# Severity: How is it determined?

- Mortality?
- Pain and Suffering?
- How soon? How often? For How long?

## Preventable: What can be done?

- Lifestyle changes?
- Pharmacological intervention?
- Surgical intervention?



## Treatable: What can be done?

- Lifestyle, pharmacological, or surgical intervention?
- Decreased risk of mortality?
- Decreased severity of morbidity?

# What would you want to know?

	Probability	Severity	Preventable	Treatable
Low				
High				

# Empirical Data?

- 3640 study participants
- 49.7%: “overall concerns about undergoing testing”
- “None ...indicated that they would definitely not want to know their risk”
- “82.4% indicated that they would want to know.”

Bloss CS (2010): Consumer perceptions of direct-to-consumer personalized genomic risk assessments. *Genetics in Medicine* 12(9):556-566.

# “Knowledge is Power”

- Francis Bacon
- *Religious Meditations, Of Heresies*
- 1597
  
- “As academics, we often assume that information is good and more information is better. But more information can sometimes be counterproductive.”

Ormond KE et al. (2010): Challenges in the clinical application of whole-genome sequencing. *The Lancet* 375:1749-51.

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**UC San Diego Research Ethics Program**  
**<http://ethics.ucsd.edu/research.html>**  
**[kalichman@ucsd.edu](mailto:kalichman@ucsd.edu)**

Michael Kalichman  
Research Ethics Program, UC San Diego  
Bioengineering 183  
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