

# What patients think of 'molecular diagnostics'

IOM

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Patient Advocates In Research (PAIR)

# Promises: are we there yet?


 **Few** successes

 HER2

 **Real life** issues

 Most drugs stop

“...nearly a **decade** since distinct breast cancer genotypes...  
5 years since the first multiparameter gene expression  
assays...

 Although there is compelling evidence regarding the clinical  
validity of these assays in providing prognostic information  
about distant disease recurrence, there is **little information**  
**about their clinical utility**—that is, how does the test result  
influence clinical **decision making**, and **do patients benefit**  
from that change?”

- Sporano et al. JCO 2010

Defining the Clinical Utility of Gene Expression Assays in Breast Cancer: The Intersection of Science and  
Art in Clinical Decision Making

# We HAVE to get this right

***Data ≠ Knowledge ≠ Results***

## ***Dangers of not doing this well....***

- Un-validated biomarkers kill products
- What do False +/- do to people?
- Ethnicities?
- Rare cancers?
- **Wastes time/\$\$\$,  
erodes trust,  
& costs lives**

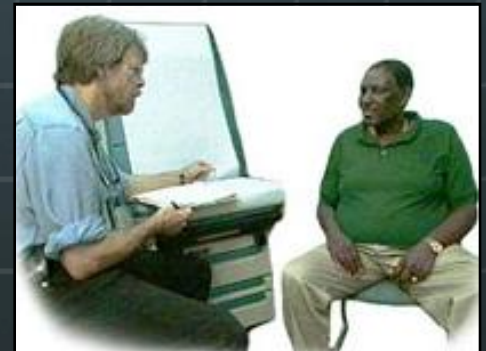


# Who is the real end user?

People  $\Rightarrow$  Public  $\Rightarrow$  Patients

People/patients want...

- True prevention, but not at all costs
- To reduce risk of cancer &/or recurrence
- Maintain lifestyle
- Believe the 'cure' hype
- A safe system
- Worried well:
  - Lower risk, absolutely!



# What do diagnostics mean to people?

Nothing

Fear

RISK

Vulnerability

Hope

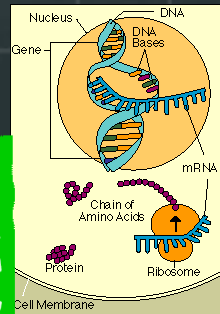
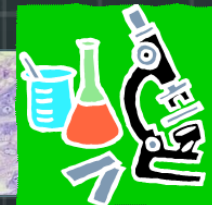
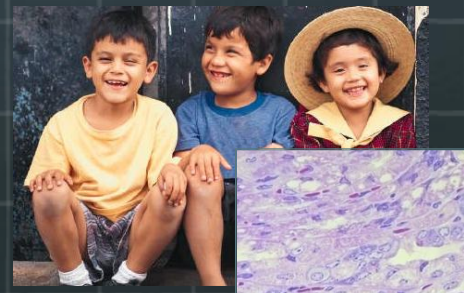
Loss of self, family,  
culture, community,  
privacy

Knowledge

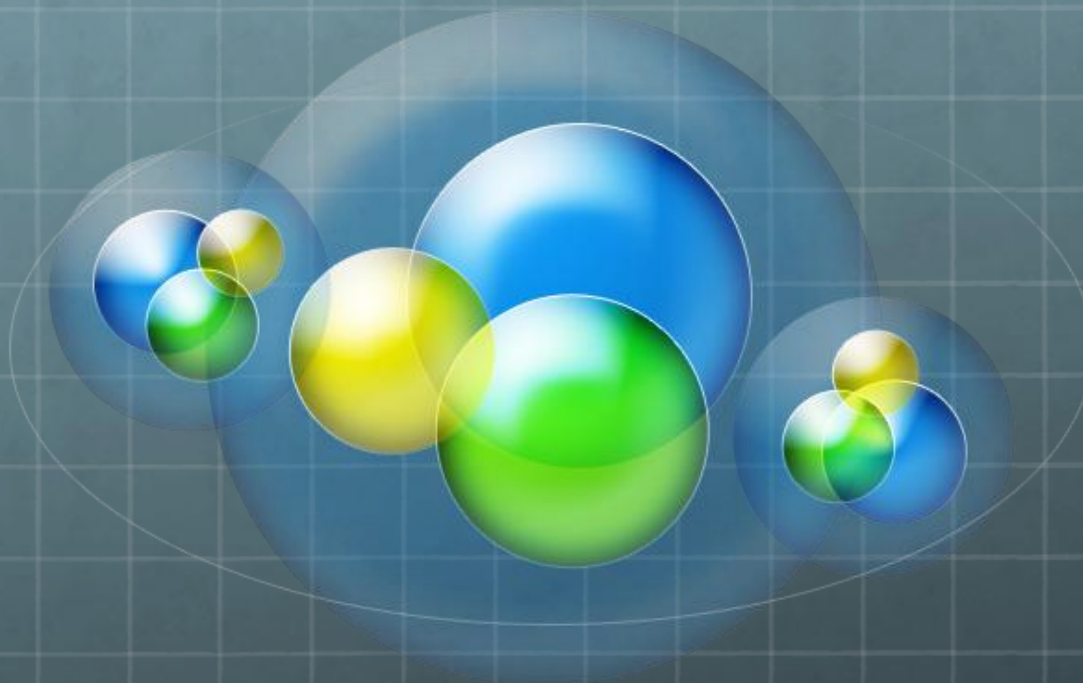
Disease

Family genetics

\$\$ Cost \$\$



*"Words  
Matter"  
series*



# RISK

## To me (absolutely)

## Relative to population

# Which risk strategy is used?

1. Google?
2. Abdication?
3. 2<sup>nd</sup>, 3<sup>rd</sup>, 4<sup>th</sup> opinions?
4. Statistical equations?
5. Gut?
6. Clinical trials?
7. Dice?
8. Family?



# For patients, it isn't about the test!



🌐 It's a **life** decision, not just medical

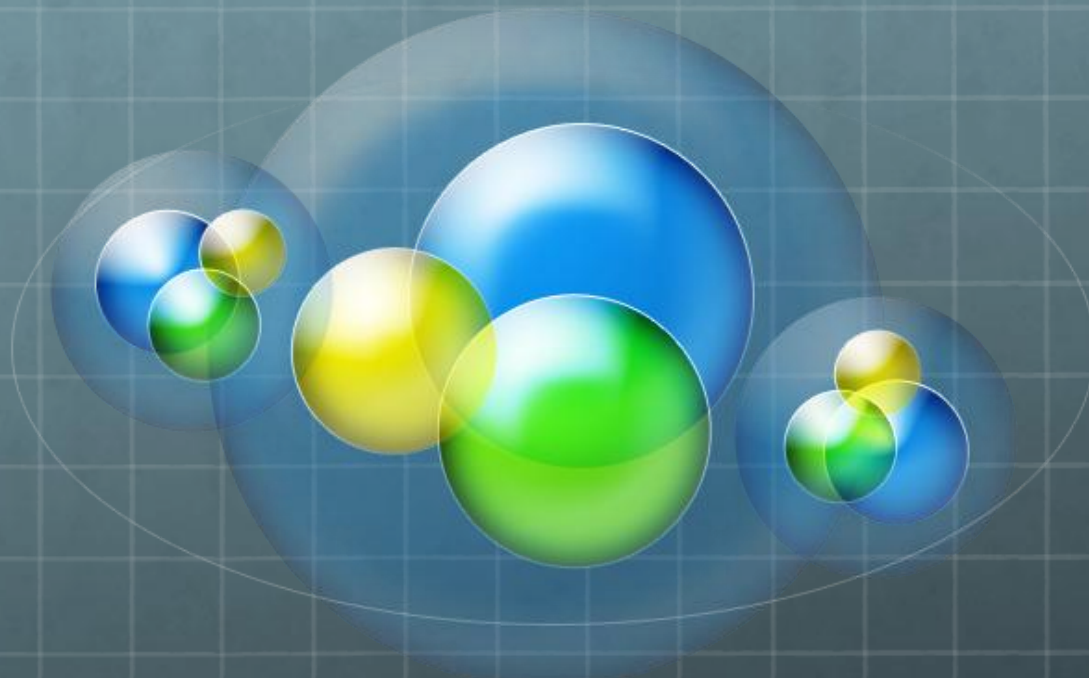
1. Extra procedures, pain/suffering?
2. What do test results mean?
3. Something to prevent/lower risk?
4. Hereditary?
5. Will options remain open, or close?
6. What about work, family, social life?
7. Am I protected against misuse?
8. 'Personalized medicine'???? Where?

# What is 'clinical utility' to Aunt Mildred?

- Reliability
  - Treatment response in <x> cancer + ramifications
- Focus on true indicators (i.e. not LVEF)
  - Concrete numbers v. spectrum v. variance
- Convey test results clearly and simply
  - What is most important?
  - Quick updates to ALL
- Part of the whole
  - Other diagnostic tools?
- If it's genetic...
  - Give me counseling



*"Words  
Matter"  
series*



# CLINICAL UTILITY

## Personal guidance

Acceptable v. out-of-range results,  
relevance of intervention

# Clinical utility? -or- PERSONAL UTILITY?



# Personal utility = reality

- 🌐 Getting test results in reasonable timeframe
- 🌐 Results explained clearly in plain language
- 🌐 Doctors/HCPs comfortable interpreting test info
- 🌐 Something you can do about it
- 🌐 Ability to say yes or no to receiving test results
  - 🌐 Some people want to know even if no intervention is available
  - 🌐 ...and some don't



# Levels of evidence? Value?

- People/patients like registries!
- CTs + QOL + observational studies + outcomes
- Clinical settings useful
- Impact on life and family
  - Physical
  - Financial
  - Emotional
  - Social
  - Etc.



# Don't make the screening mistake



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NEWS

[Featured Article: Chemoradiation May Help Some Patients with Bladder Cancer Avoid Radical Surgery](#)

A Closer Look



Crunching Numbers: What Cancer Screening Statistics Really Tell Us

...tion about cancer screening has started to ... as ovarian cancer, the



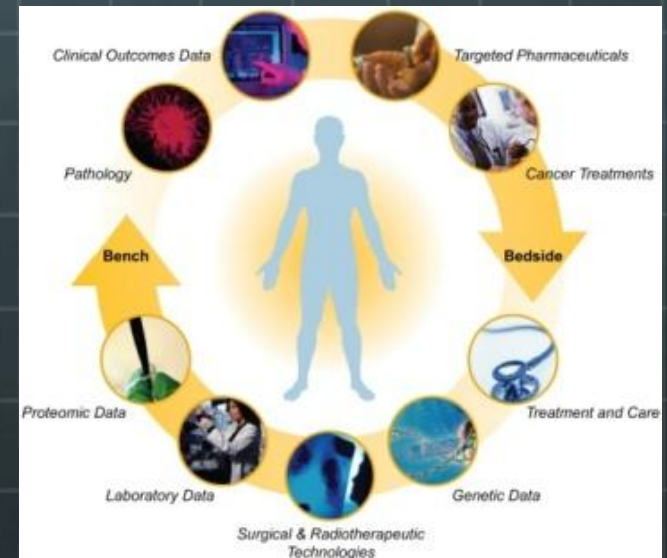
Reader suggested

Clear messages needed,  
not confusion

[Exercise Guidelines](#)

# Rethink our approach

- Human body = integrated circuit
- Pay attention to ALL at once
  - Gen- + prote- + metabol- + other- OMICS together
  - Multiple pathway interactions
  - Microenvironment
  - Immune system
  - Adverse events
  - QOL
- RCTs can't do it all



# Include past lit & recs, e.g.

- FDA changes to medical device advisory committee deliberation
- Joint NIH-CDC Workshop on
- Secretary's Key message:  
Need **new INFRASTRUCTURE** that enables by clinicians while doing their daily work!  
[http://oba.od.nih.gov/SACGHS/sacghs\\_home.html](http://oba.od.nih.gov/SACGHS/sacghs_home.html)
- CLIA for Genomic Applications in Practice and Prevention  
<http://www.egappreviews.org/about.htm>
- “Evaluating the utility of personal genomic information”  
Foster et al. <http://www.ncbi.nlm.nih.gov/pubmed/19478683>

# Requests from patients & advocates

## 1. Honor **true** meaning of “patient-centered”

- 🌐 Mean what you say
- 🌐 Risk? Be absolute, not relative

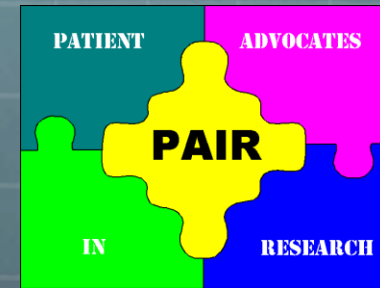
## 2. Resolve IP issues, get to work & **share**

- 🌐 Data, biospecimens, updates, results

## 3. “Nothing about us **without** us”



# Thank you...



## ● Patient Advocates

- PAIR advocates (~200)
- SPORE advocates (~220)
- NCI CARRA advocates (~170) and DCLG (15)
- Cooperative Group advocates (~80)
- FDA advocates (~20)
- Many others

● Experienced:  
for creating new opportunities

● New:  
for fresh ideas & energy

● And to those who made a  
difference before their death

## ● Research teams for

- Dedication
- Efforts
- Collaborations

*Thanks for all you do for  
cancer patients  
and their  
families*

- For more information,  
contact  
[Deborah@tumortime.com](mailto:Deborah@tumortime.com)