

“Tooling” Communities to advance Community Resilience; Through Open innovation environments

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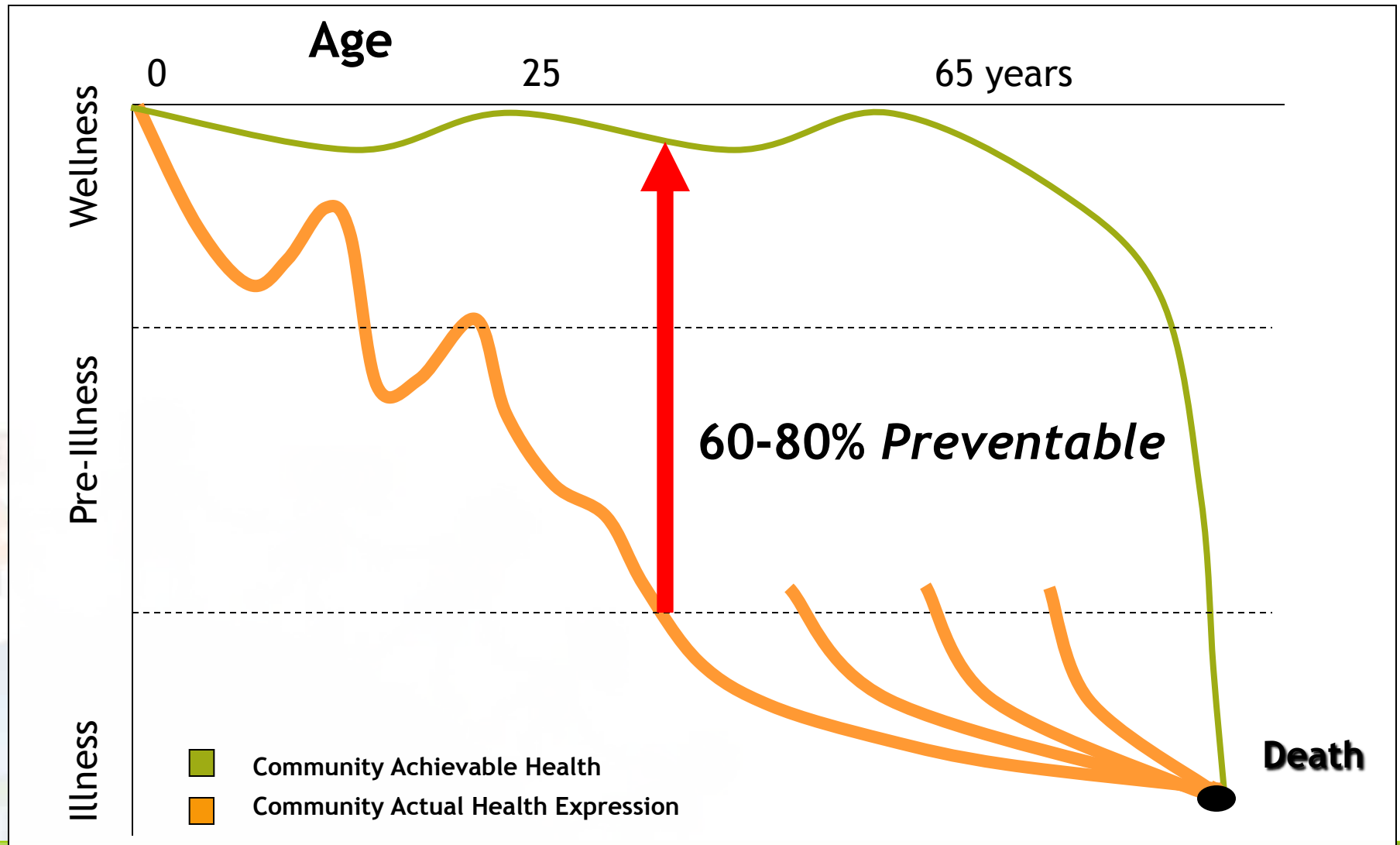
2010 January FDA workshop



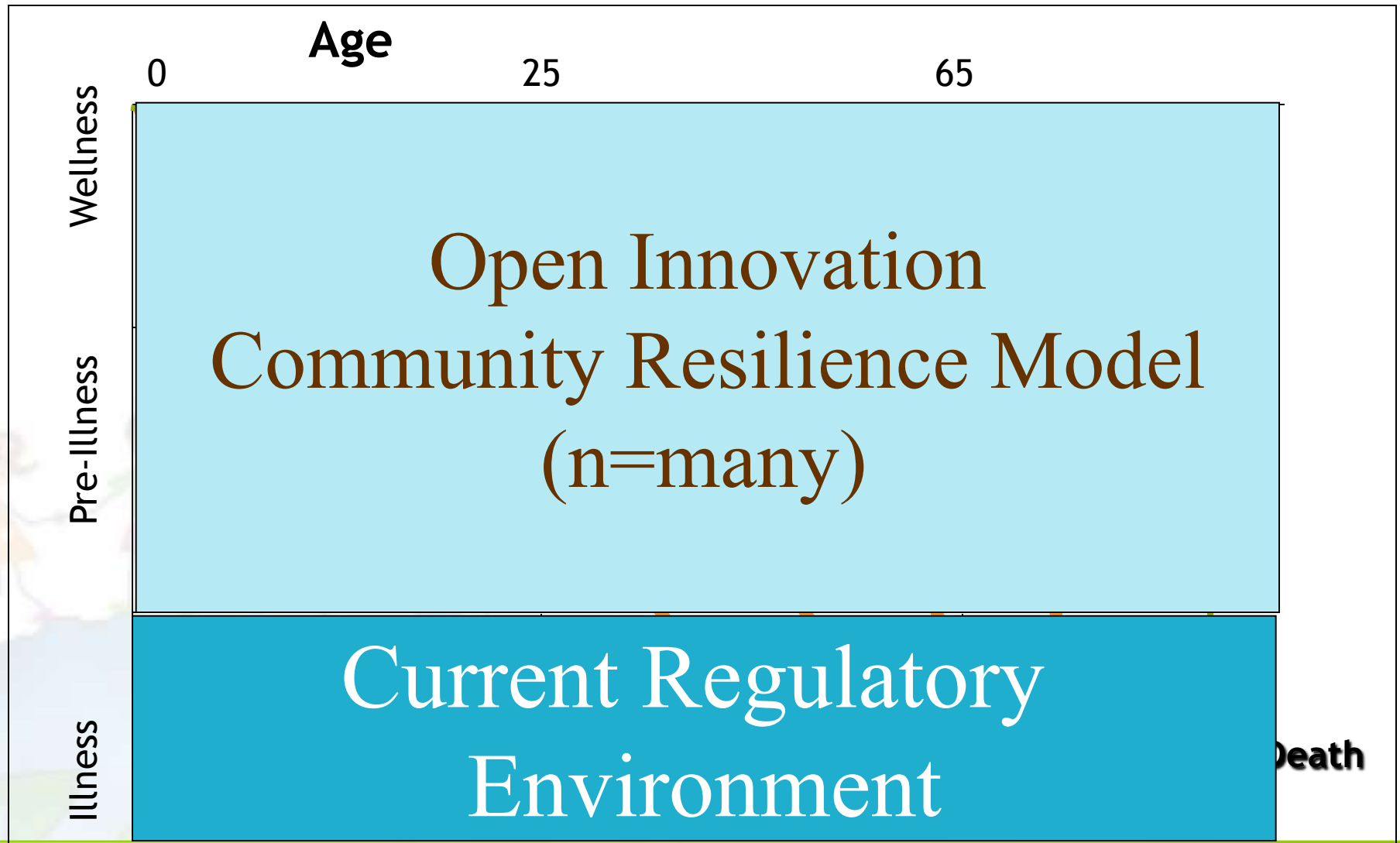
FDA value proposition

- ▶ **FDA support of the 2010 Nation's First Health Security Strategy**
 - Broadly sharing responsibility
 - Proactive community voice
- ▶ **Connectivity across Crowds (n= many) provides for a new era in safe and effective *proactive resilience***
 - Maximize the resolution of pre-endpoint experience
 - Identify clinically relevant co-occurrences
 - Example: Progressively effective H1N1 resilience
- ▶ **Outcomes requested**
 - FDA agreement to support advancing/operationalizing this model
 - FDA commitment to build a functional template that defines stakeholder responsibilities in open innovation models.

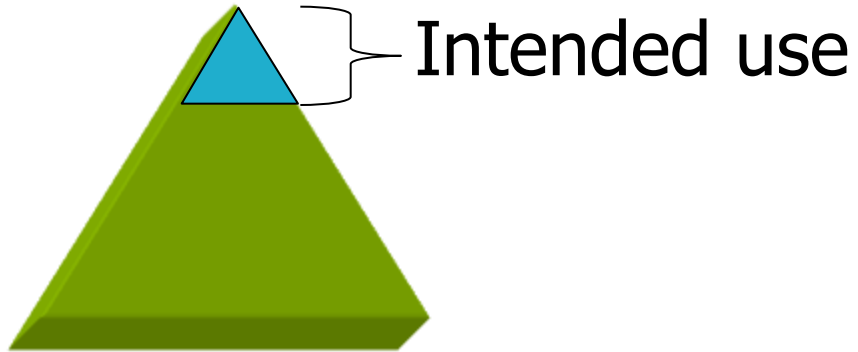
Community Health Landscape



Effective Segmenting of Landscapes



Current Regulatory Environments



**High Confidence,
narrow intended use**

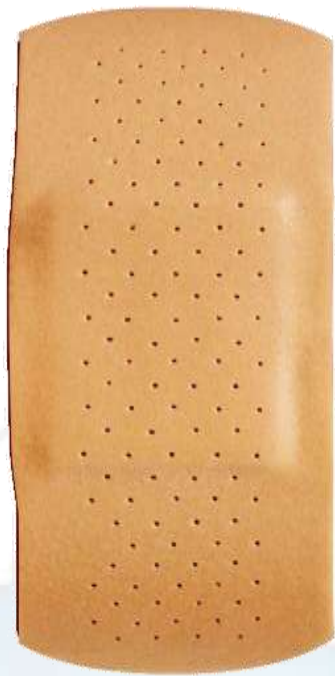


How does the “Community Resilience” Model work?

1. Identify the **health outcome** one wishes to target (to avoid the avoidable)
2. Search the medical literature/clinical experience for clues to the **avoidable contributors** to this outcome
3. Build the technology environment to **support user** tracking of avoidable contributors
4. Accumulate data to generate *sufficient correctness* (to be defined)
5. Adjust environment (**choice architecture**) to reduce/eliminate contributors
6. Repeat the cycle given the new information.

In a *H1N1* world...

Sufficient Confidence;
Flexible Intended Use



Temp, O₂ sat, HR

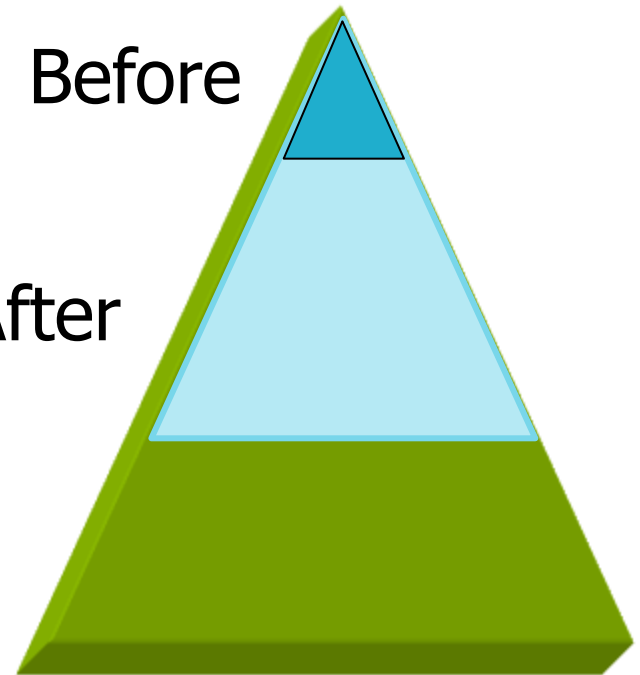


Integrated Disposable Pulse Ox

Meaningful use

Before

After



Benefits & Challenges

- ▶ Privacy and security spectrum ...default set at max
- ▶ Communities/individuals own the raw data
- ▶ Regulatory paradigms: defining effective regulatory boundaries
- ▶ Crowd-assisted verification and validation
- ▶ Useful boundaries/definitions for *flexible* intended use
- ▶ Accumulated data can be utilized to fosters next phase innovation

Tomorrow's resilience >> Yesterday's resilience

In a nut shell...

**Upon this gifted age, in its dark hour,
rains from the sky a meteoric
shower of facts ... they lie
unquestioned, uncombined.
Wisdom enough to leech us of our ill
is daily spun, but there exists no
loom
to weave it into fabric.**



01010
001101
00111000111
001101010010
011010101000011111

Edna St Vincent Millay

Millay E StV. *Collected sonnets*. New York: Harper and Row, 1988: 140.

Thank you!

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*“In a **Connected world**, we are no longer responsible for what is reasonably known, we become responsible¹ for what could have been reasonably known had we collected and organized the data appropriately.”*

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Thank you!

US Obesity Trends

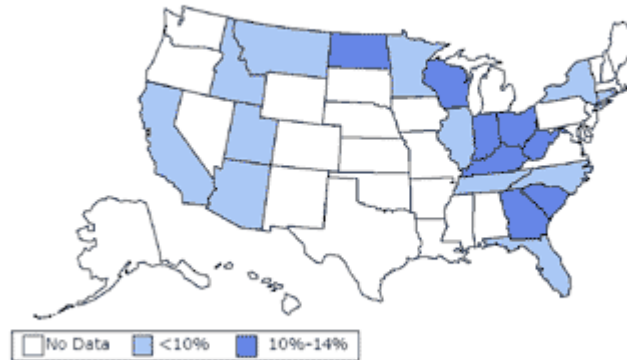
Key Mediators of
Crowd health
adjustment

1) Activity

2) Nutrition

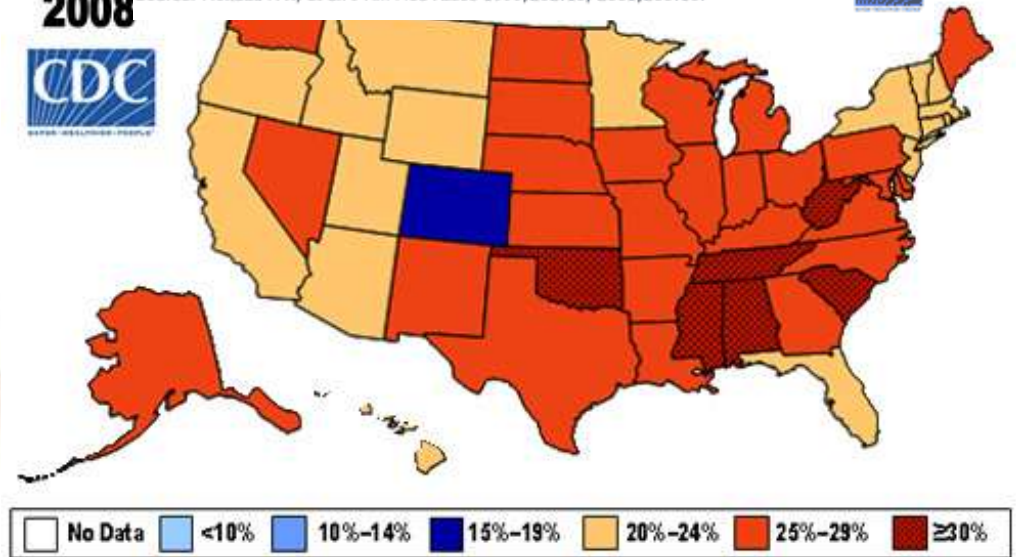
Obesity Trends* Among U.S. Adults
BRFSS, 1985

(*BMI ≥ 30 , or ~ 30 lbs overweight for 5'4" woman)



2008

Source: Mokdad A H, et al. *J Am Med Assoc* 1999;282:16, 2001;286:10.



“1980 Continua solution”

Device Interface

XHR Interface



Wireless
Ultra Low Power
Ultra low cost



Secure



Problems to solve with Continua...

- ▶ **Connectivity across user experience will link clinically relevant co-occurrences.**
- ▶ **Barriers to participation will plummet**
- ▶ **Compelling reason to share data**
- ▶ **Citizen becomes the ultimate insurer of value**
- ▶ **Knowledge density in wellness and pre-illness will set the backbone for financial density**
- ▶ **Health adjustment will be linked to future health cost adjustment**
- ▶ **Advance the fabric of evidence-based investment in health**