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**NORTHROP GRUMMAN**

# Applying systems engineering to improve healthcare

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# “Bottom-line up front”

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- Systems engineering offers tools and methods that can solve important societal problems
- Healthcare appears to offer opportunities for significant improvements through systems engineering
- One example of how this might work is offered, and its feasibility discussed

The “triple aim” for healthcare (my paraphrasing):

- (a) better health outcomes
- (b) lower costs
- (c) better experience for healthcare consumers

Bisignano & Kenny, “Pursuing the Triple Aim: Seven Innovators Show the Way to Better Care, Better Health, and Lower Costs”, 2012

# How does systems engineering add value?

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- Sometimes, it does so by managing the introduction of new technologies
- But more often, it is focused on improving the work-flow through which a task is accomplished
  - The introduction of technology then becomes a 2<sup>nd</sup>-tier effect
- Accomplished by finding the “leverage points”
  - Then use the engineering results to build consensus
  - Address the social, as well as the technical and operational, aspects of the mission
  - Things will be in conflict; systems engineering provides methods to bring balance to all of these conflicting tendencies, desires, and stakeholder opinions

## Example: combating fraud in public-paying systems

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- Fraud in such systems is a **big deal**
- Historical approach is to pay claims, find fraudulent transactions after the fact, and chase the bad guys
  - Almost nothing is ever recovered
- One obvious “leverage point”: do the fraud detection **before** making the payment
  - Lots of issues: cannot slow down payments on average, little tolerance of false-positives
  - Because of these issues, the Government always considered this infeasible
  - But having identified it as a leverage point, we attacked the problem . . . and it is working

# The healthcare problem

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- > 17% of U.S. GDP, and growing faster than inflation<sup>1</sup>
- Really good interventions and outcomes for a small portion of society, but very high levels of variation (leading to injury and death, and significant costs)
  - My friend David<sup>2</sup> estimates that **40%** of healthcare costs in the U.S. are due to unjustified variation
  - Per Wheeler<sup>3</sup>, high levels of variation is a **key indicator** of a weak system-level design
- Organized for the convenience of the practitioners, not for that of the customers
  - Induced costs (e.g., time off of work to see doctors, to talk to paying agents, etc.) is very high
  - High levels of dissatisfaction
- No indications of convergence for cost, no material improvements in outcomes, no decrease in variation

<sup>1</sup> Centers for Medicare & Medicaid Services, National Health Expenditure Data

<sup>2</sup> David Lawrence, M.D., IoM, former chairman of Kaiser Healthcare System

<sup>3</sup> Donald Wheeler, "Understanding Variation", SPC Press, 2000 (2<sup>nd</sup> edition)

# What is being tried?

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- Significant effort to bring automated information systems into healthcare
  - Electronic patient records
  - Electronic transfers of prescriptions from doctors to pharmacies
  - Billing and payment systems
  - A material effort: 10's of billions of dollars
- But . . . according to the National Academy<sup>1</sup>, it has all been for naught
  - No improvement in outcomes
  - No decrease in cost (or even a reduction in the rate of increase!)

<sup>1</sup> "Why Health Information Technology Doesn't Work", Elmer V. Bernstam and Todd R. Johnson, The Bridge – the magazine of the U.S. National Academy of Engineering, Fall 2009

# My assessment

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- Much of this healthcare IT was introduced at the wrong places into the process, and
  - Without tying decision-making to measurements
  - Without trying to understand the root-causes of variation in healthcare (and Wheeler will tell you that you cannot improve the average until you have reduced variation)
- In other words . . . **without** having done the up-front systems engineering
- One example:
  - Most of this information technology – 10's of billions of dollars worth of it – is aimed to give information to healthcare practitioners, healthcare administrators, and payers
  - But my friend David had an interesting insight:
    - According to him, the critical decision is the one of “when do I seek sick-care?”
    - The critical decision is therefore made by **us** – the healthcare consumer
    - According to this insight, most of the healthcare IT spend is going to be low-leverage . . . because almost **none** of it helps the person who actually makes this decision – us – make more accurate or more timely decisions to this question!

# How this allows variation

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- Some enter the sick-care system too early
- Some enter late
- Some enter at the wrong place
- Whenever we enter, we enter with little hard data available for the doctor
  - Yet there is intense pressure on the doctor at the point and time of entry to make a near-instant diagnosis; in combination with current test technology (most current tests look for **one** thing) that in essence requires the doctor to guess what you have, lots of mistakes – another type of variation! – result
  - If the doctor's guess turns out to be wrong, the test (usually) comes back negative, and it all starts all over again
- Poor understanding and characterization of the false-alarm rates of the existing tests.
  - Little effort to use even available test results to lower these false-alarm rates.



# Another thought

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- Healthcare protocols are, in large part, driven by averages, rather than by the patient's actual, personal condition
  - “Schedule-based maintenance”, rather than “condition-based maintenance”
- In other problem domains, transitioning to **condition-based maintenance** has led **both** to better outcomes and very significant cost savings

# What might a “systems-engineered” healthcare system look like?

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- Low-cost, low-intrusion, **periodic** testing that gathers information across a **broad range** of potential conditions and issues
- Use of those data to create individual **longitudinal** records – which the experts\* will tell you is the proper rigorous basis for separating “signal from noise”, and decreasing the false-alarm rates from these tests.
- Continuous, unprompted analysis of these data – yours, your family’s, those who live near you, those who work in the same building as you, those who are served by the same water-treatment plant as you, etc. – for off-nominal indications.
- When there is either a risk or an opportunity, we send you a post-card asking that you come visit a particular healthcare practitioner. When you arrive, the doctor has all of the right information right away.
- It will prompt you to enter the sick-care system at the right time and place, but also prompt you to enter the well-care system, to deal with life-style issues, etc.

\* such as Professor Kazeef

- This is clearly very different than today's healthcare system
  - Anywhere
- Note that – according to this analysis – the question of who pays for healthcare is not likely to drive major improvements in the healthcare system

But is this feasible in any reasonable time-frame?

# Creating the closed-loop

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- Data<sup>1</sup> now indicate that protein concentrations in your body change rapidly in response to aging, onset of illness, etc.
  - These may be the sensor of choice; already “seeing” 10x better than current methods<sup>2</sup>
- Proteomics-based causality “cases” are already being created and validated<sup>2</sup>
  - Pancreatic cancer, lung cancer, renal cell carcinoma, cardiovascular risk, ALS, diabetic retinopathy, others
- A 1-drop blood test (no phlebotomist required!) can already assay ~1,000 proteins (and soon, ~3,000) over a billion-fold range of concentrations . . . and provide the information needed for the causality cases<sup>3</sup>
  - No need to do this at a doctor’s office
- Gather all of the data, secure it, process it against the causality cases, notify you and your doctor(s)<sup>4</sup>
- Learn from additional data, e.g., diagnoses, outcomes of various treatments, etc.
  - Even automatically discover new causality cases<sup>5</sup>
- Your longitudinal data will create insight that might motivate improvements in life-style, too<sup>2</sup>.

<sup>1</sup> Gold, Larry: Somascan longitudinal studies, 2013

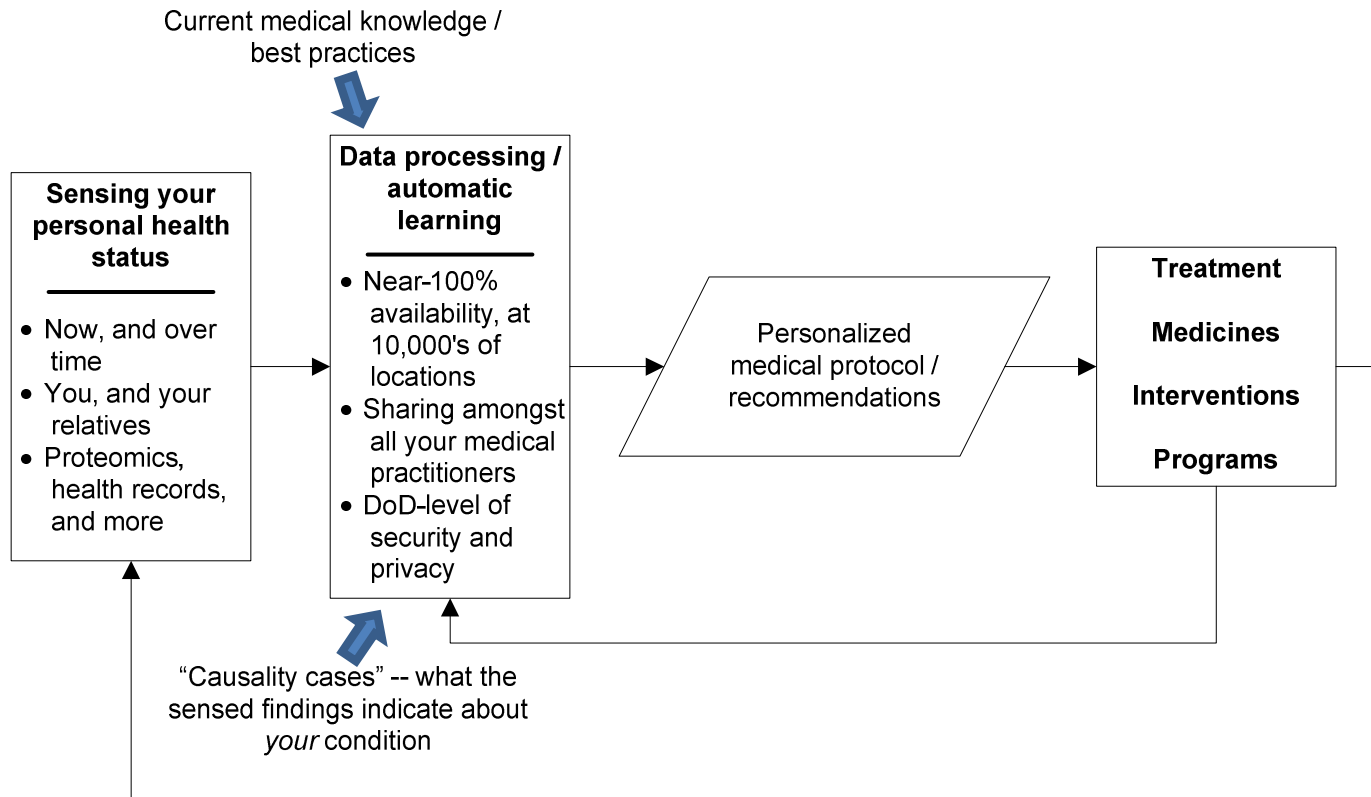
<sup>2</sup> Williams, Steve: Aphrodite and Medusa: Portraying the beauty of biology and the Gorgon of disease, 2014

<sup>3</sup> Gold et al, Aptamer-based multiplexed proteomic technology for biomarker discovery, 2010

<sup>4</sup> Gold, Larry & Siegel, Neil: Closed-loop healthcare data processing system, November 2014

<sup>5</sup> Shekar et al, “Discovering Neuroblastoma”, 2014

# The “closed-loop”



A closed-loop system – “condition-based health care” – will save costs, improve outcomes, and achieve a better balance between acute treatment and prevention

Shift from the current medical model of being reactive to disease, to a more proactive approach to treatment and prevention

Patent pending – “Learning Health Systems and Methods”, Siegel, Shekar, Yu, filed 2013

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# Why is this difficult?

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- The need to sense and classify large quantities of health data consistently
- The need to combine those measurements with several other types of data, so as to provide decision-making guidance in a largely-automatic, yet highly-credible manner (if not largely automatic, the processing would overwhelm the available personnel; if not credible, the recommendations would not be used)
- The need to find small signals embedded in lots of “noise”, and to create actionable information that are often not directly present, but must be synthesized by combining available data into higher-level abstractions
- The need to provide highly-secure and highly-credible access controls to these data; balanced against the need, at the same time, to provide those results to a wide range of appropriately-authorized personnel at a large number of points-of-presence
- The need to cope with an immense data ingest rate
- The need for the system to have essentially 100% availability, never to lose data, and to provide consistent user response times
- The need to stay on-line, yet also accommodating considerable adaptation over a very long system life-time
- The need to recognize that there will resistance to adoption

High quality requirements.  
Small stumbles will discourage adoption.

# Progress

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- Multiplexed sensing, at a target cost, over large range of concentrations (which allows for small sample sizes)
- Formation of an initial set of medically-credible causality cases
- Initial indications that this sensing construct can quickly detect changes in life conditions
- Demonstrated operation of computing systems that display the requisite characteristics of number of points of presence, security, availability, transaction rate, ingest rate, total data volume and total number of records, and other computer-science measures of system operations
- We have demonstrated significant progress on the problems associated with display of the resulting information both to patients and healthcare providers, so that these data can facilitate effective, transparent, and timely decision-making.



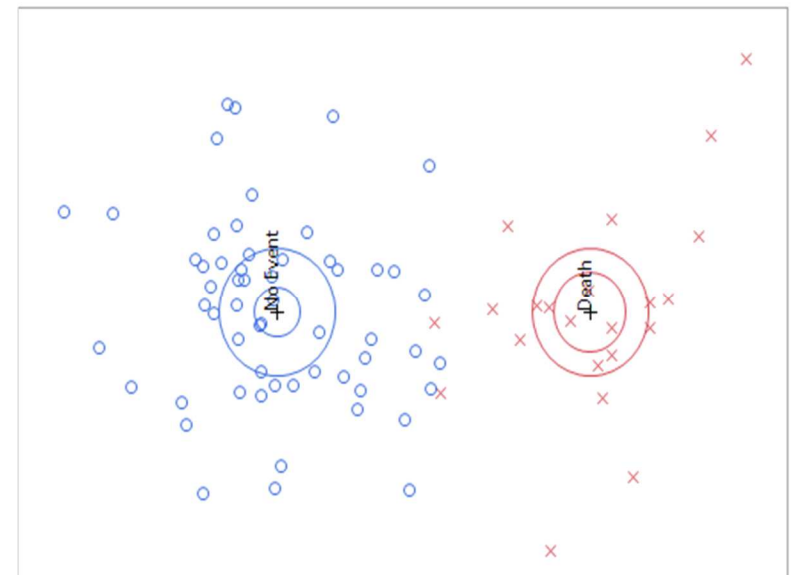
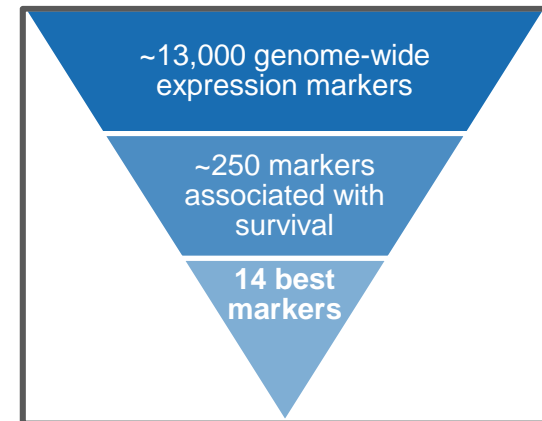
# Example of creating the causality cases

## Clinical Problem

- Neuroblastoma (NB)
  - Pediatric cancer with poor outcome
  - Heterogeneous patient population

## Personalized Health Solution

- We used machine-learning analytics to identify predictive markers of **survival** and **tumor stage**
  - Use complete genomic measurements patients
  - Perform robust analytics on integrated clinical and molecular data
- **From ~13,000 genomic and clinical markers, we identified 14 markers that – in combination – were highly predictive of survival**
  - No “seeding” by clinicians
- Truth data from tumor biopsies
- No false positives; ~5% false negatives



**Large-scale analytics *is going to work!***

# Benefits, if & when we succeed

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- Allow healthcare consumers to know accurately – based on objective data – **when** they need to enter the sick-care system
- “One test / many markers” permits the healthcare practitioner at the patient’s point-of-entry more precisely to evaluate changes and off-nominal conditions in the patient across a wide range of factors
- Longitudinal data can decrease false-alarm rates from medical tests
- Materially reduce unjustified variation in healthcare practice, by joining detailed diagnostic information with evidence of clinical effectiveness applied to specific patient strata
- Increase efficiency of healthcare system by more proactively identifying and monitoring sick people earlier in their disease course, and perhaps motivating life-style improvements
- Enable practitioners and healthcare systems to become more efficient and effective in clinical practice through periodic incorporation of new “causality cases”

# Integrating into the healthcare system

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- ***Different than the way we do it now*** – Creates new and potentially substitutive diagnostic / therapeutic methods and approaches within current healthcare system – there will be perceptions of “winners” and “losers”
- ***New interfaces*** – Computer / human & data / human
- ***Social*** – The delicate balance between providing “recommendations”, versus “direction” for healthcare personnel
- ***Cultural*** – Portends change in roles, value, and relationships among healthcare personnel and institutions
- ***Non-traditional evaluation*** – Likely to be most valuable at a “system” level, versus traditional single-test / single-condition clinical trial and publication process

# Summary

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- We believe that a true data-based / systems-engineering approach to healthcare is likely necessary in order to achieve major improvement in outcomes, while also achieving cost-reductions
- Providing data to the patient – helping them decide when they need to enter the healthcare system
- Periodic tests that measures 1,000's of parameters, and trigger hundreds of causality cases, rather than single-focus tests upon the onset of symptoms.
- The data are already there when you arrive at the doctor. No “random walk” through the healthcare system.
- Leverage on the life-style / wellness portion of the problem

“Condition-based health care” can lead to better outcomes, materially-lower costs, and a better experience for healthcare consumers

# Questions / discussion

# Meet the author

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