

Systems Thinking and Synergy

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Safety: An Example of Why We Need a Global System for Clinical Research and Healthcare



Statistics on Air Transport Safety With a Global System

System based on 10,500 Universally Applied Standards and Recommended Practices**

# of Airline Passengers (2014)*	3.3 billion
# of Accidents (2014)**	402
# of Passenger Deaths (2014)**	761

* IATA "Strong Demand for Air Travel Rises in 2014"

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Statistics on Drug Safety when Clinical Research and Healthcare are Conducted Without a Global System

Non-System resting on Non-integrated, Inconsistently Applied ICH Guidance, Best Practices and GCPs

# of Prescriptions Written (USA2014)***	4.0 Billion
# of Serious Adverse Events(USA2014)****	807,270
# of Resulting Patient Deaths (USA-2014)****	123,927

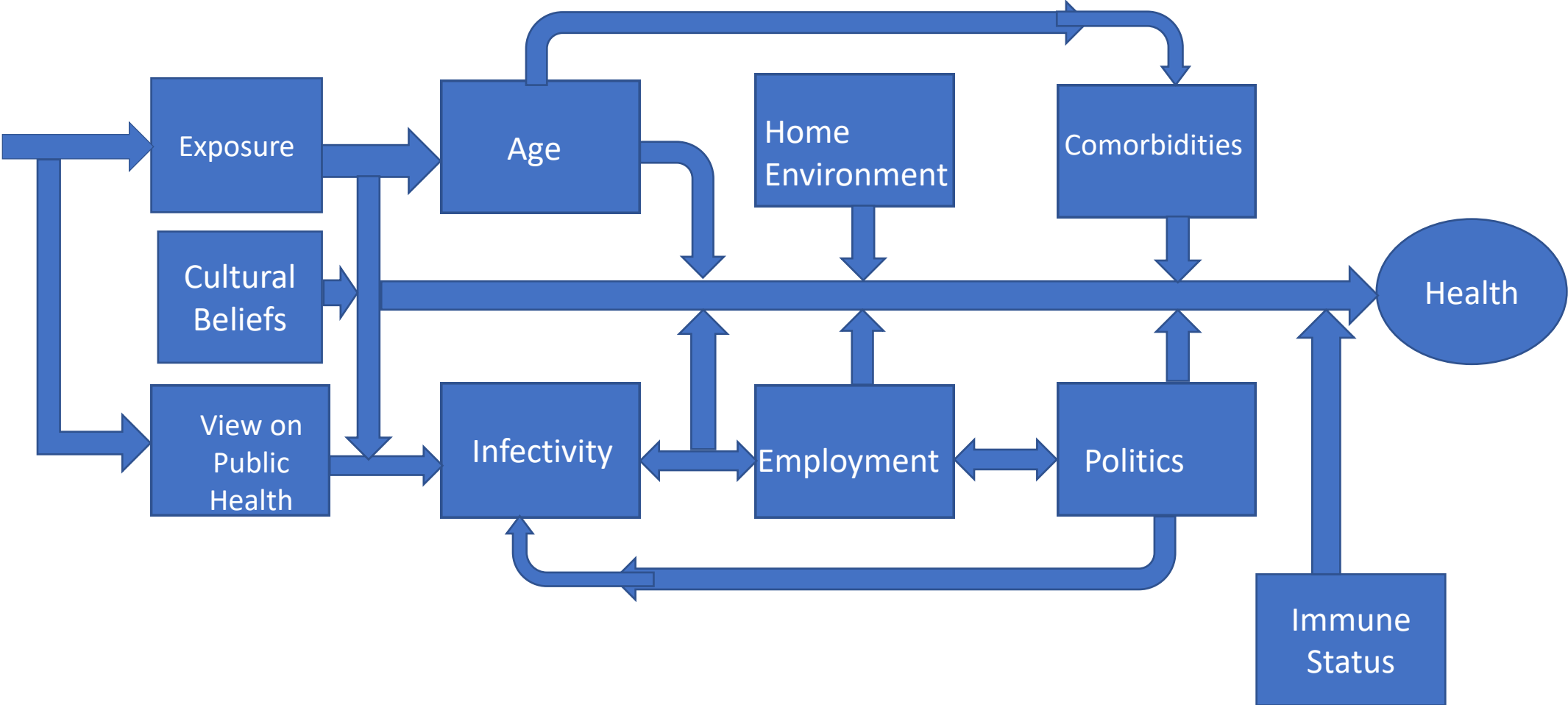
*** Estimates are USA represents 50% of prescriptions written

****FDA FAERS Reporting by Patient Outcomes by Year

Healthcare is a Complex System

- Simple – easy to manage with existing methods
- Complicated – difficult, but amenable to rules and procedures
 - *Outcome of randomized control trial*
 - *Safety procedures – contact tracing, checklists*
- Complex –
 - *very difficult, too many unknowns, unpredictable interactions*
 - Lack of response to preferred treatment
 - Fix one thing, another breaks (anti-stall feature of 737MAX)
 - *Possible solution*
 - Empirical observation to quantify components of your model
 - AI to identify patterns for study and inference
 - Progressively include more data types to approach personalization

Health System Map



System Thinking and Personalized Decisions

- Personalized healthcare decisions – study the influence of all components of your system model on the outcome
 - *Better manage patients with multiple chronic diseases*
 - Most guidelines are disease oriented
 - No controlled studies for treating patients with multiple problems
 - *Define longer term outcomes – healthier patient in 5 years*
 - *Decision support is, in part, prediction*
 - Who will benefit from this intervention, who will have an adverse response
 - Who will have a beneficial immune response to Covid19, who will have a cytokine storm

To Be Continued In 2021

ACRES Synergy II Conference

***Continuing the Discussion on the
Application of Systems Approaches
To Health Care and Clinical Research***

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