# Clinical Care and Research: Are There Global Bioethical Standards?

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To answer our question, and really to phrase it differently and better, we need to answer another basic question first:

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# What is the nature of the human being?

# What does it mean to be "human"?

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*A definition from britannica.com*

Human being, a culture-bearing primate classified in the **genus Homo**, especially the **species H. sapiens**. Human beings are anatomically similar and related to the great apes, but are distinguished by a more highly developed brain and a resultant capacity for articulate speech and abstract reasoning .

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1. Biological "Machine"
   (variable genomics –
   "individuality"; but population
   commonality – human
"species")

2. Biological Machine + Cognitive Function
   (computation capability for analysis of sensory input and, thereby, appropriate action)

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3.  Biological Machine + Cognitive Function + Abstract Thinking (Tool Making) + Language

4.  Biological Machine + Cognitive Function + Abstract Thinking  + Emotion (Compassion, Love, Joy, Sadness)

5.  All of the above plus creativity – art, music, literature, poetry, science, engineering, architecture....

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6.     All of the above through #5 plus a "spiritual"   dimension? (vs human self-sufficiency –                machine)
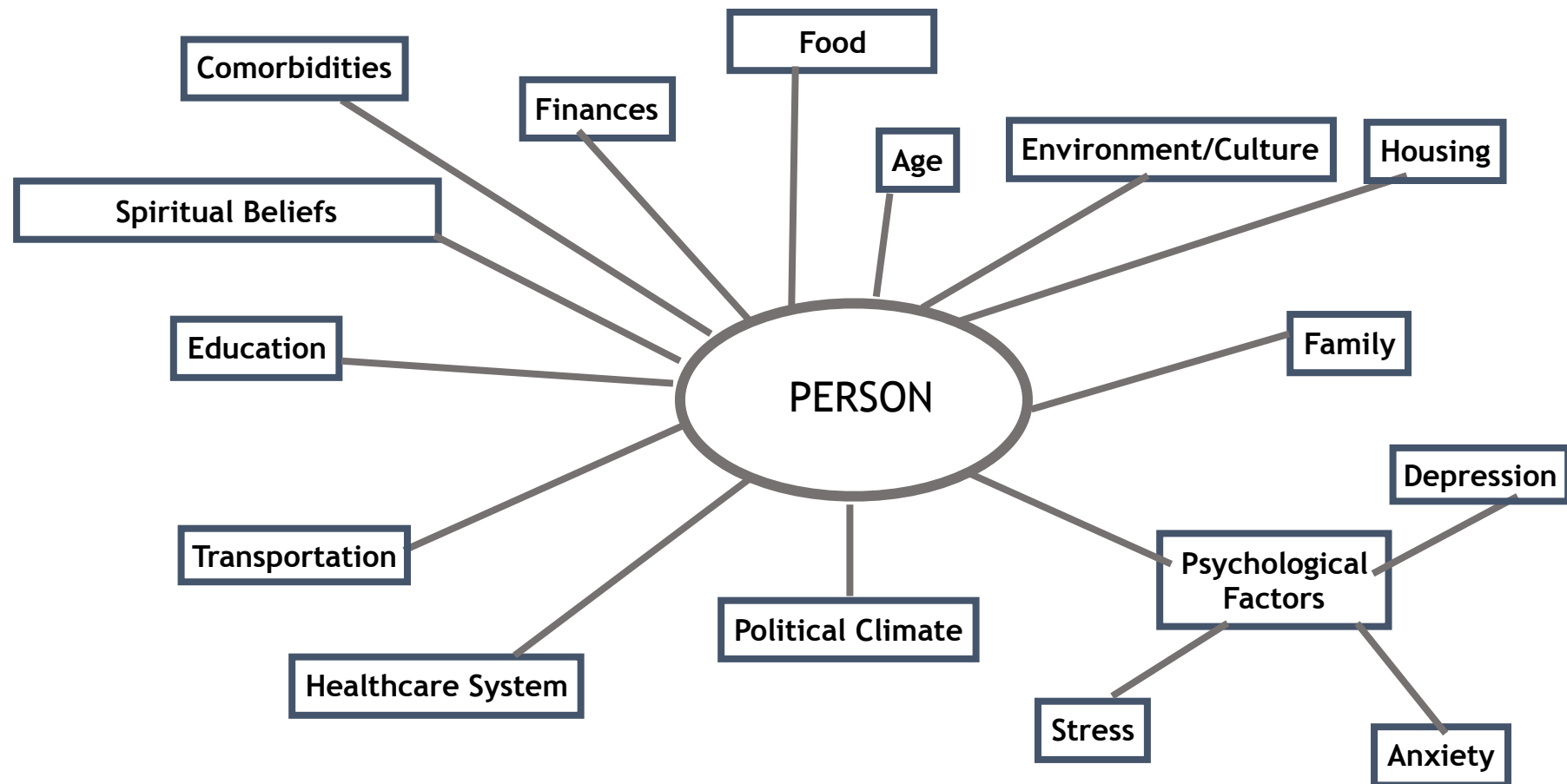
Abrahamic faiths – Judaism, Christianity, Islam

Buddhism

Hinduism

Taoism

….

*Metaphysical need – divinity? Higher*

# The Human Being (and Health) as a Complex Product of Biology and Societal/Other Factors

# Clinical Care and Research: Are There Global Bioethical Standards?

What are the implications of what we have just considered about the nature of the human being for the design of healthcare systems and the clinical research needed to improve that care?

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## The U.S. Example:
## U.S. spent 17.8% of GDP on its healthcare in 2015;
## 19.9% in 2025



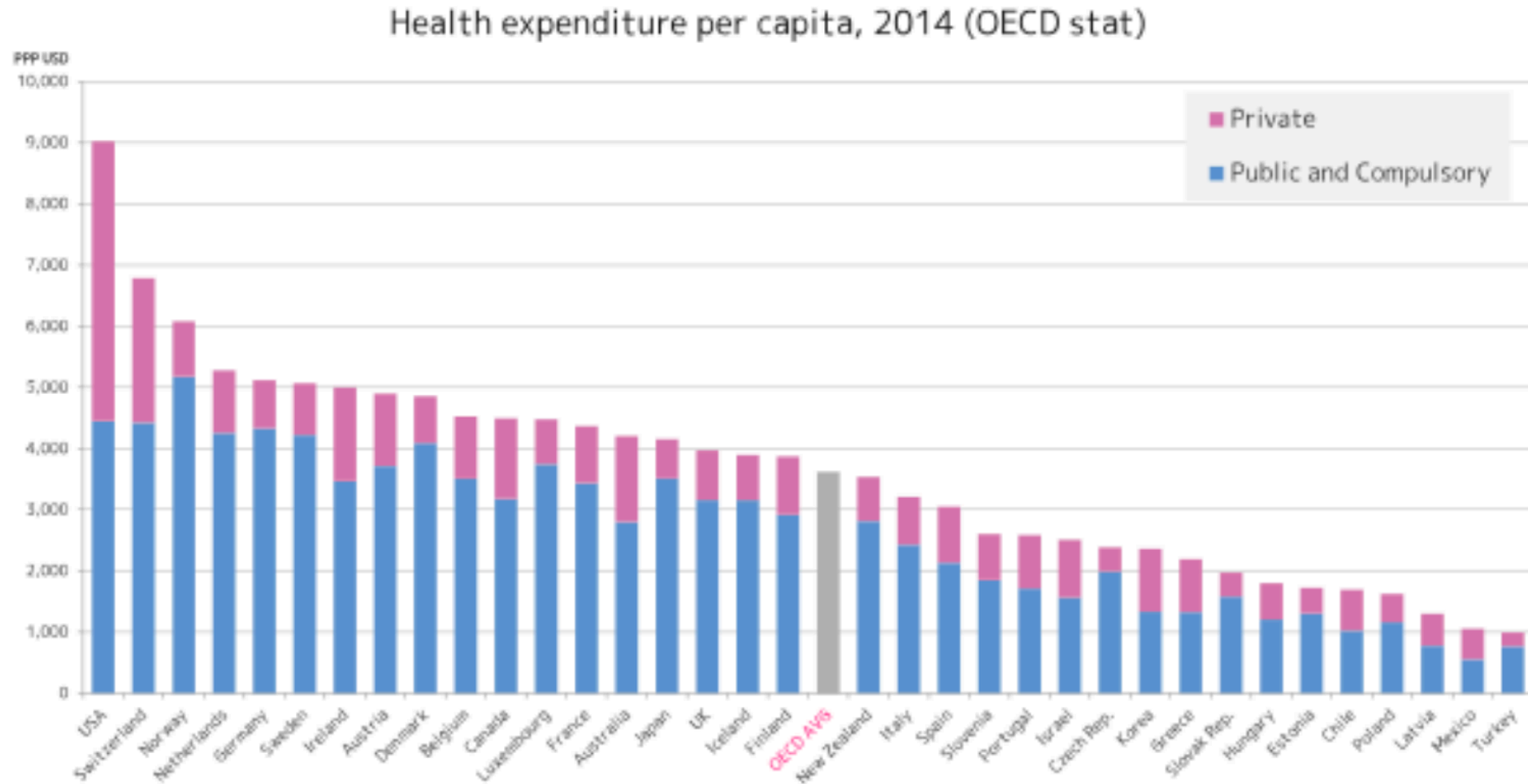Health Care Spending as a Percentage of GDP, 1980–2013
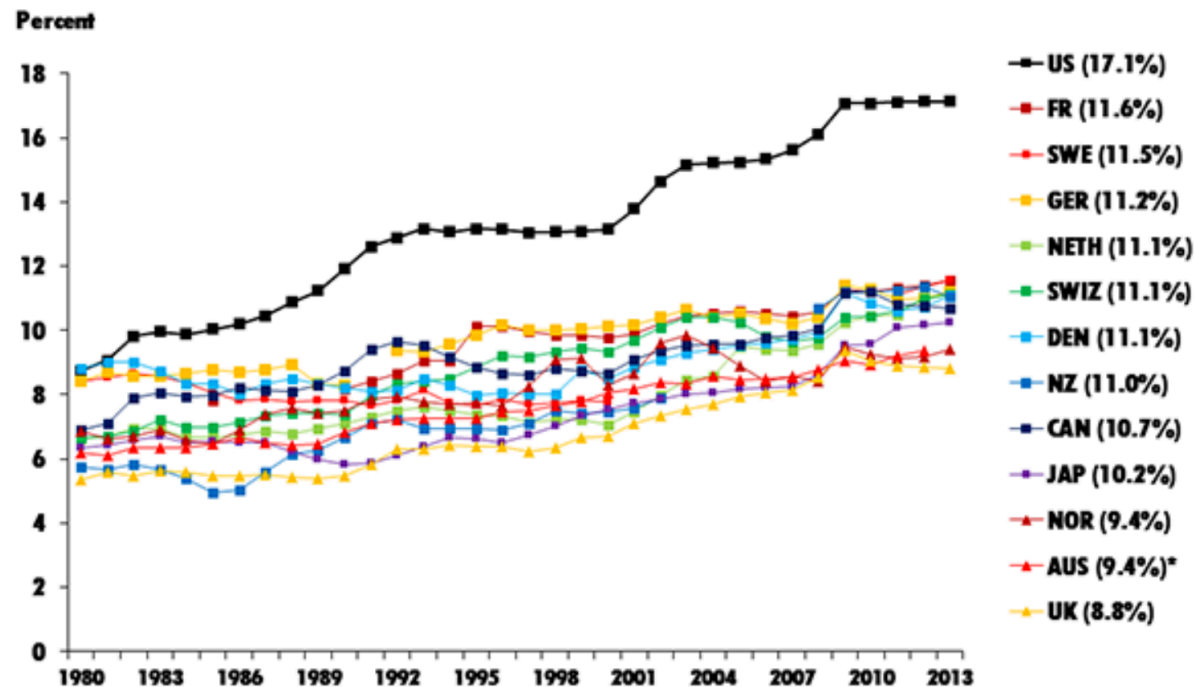
* 2012.
Notes: GDP refers to gross domestic product. Dutch and Swiss data are for current spending only, and exclude spending on capital formation of health care providers.
Source: OECD Health Data 2015.

# Per Capita Healthcare Spending Around the World



Health expenditure per capita, 2014 (OECD stat)

# Examples of Per Capita Healthcare Spending
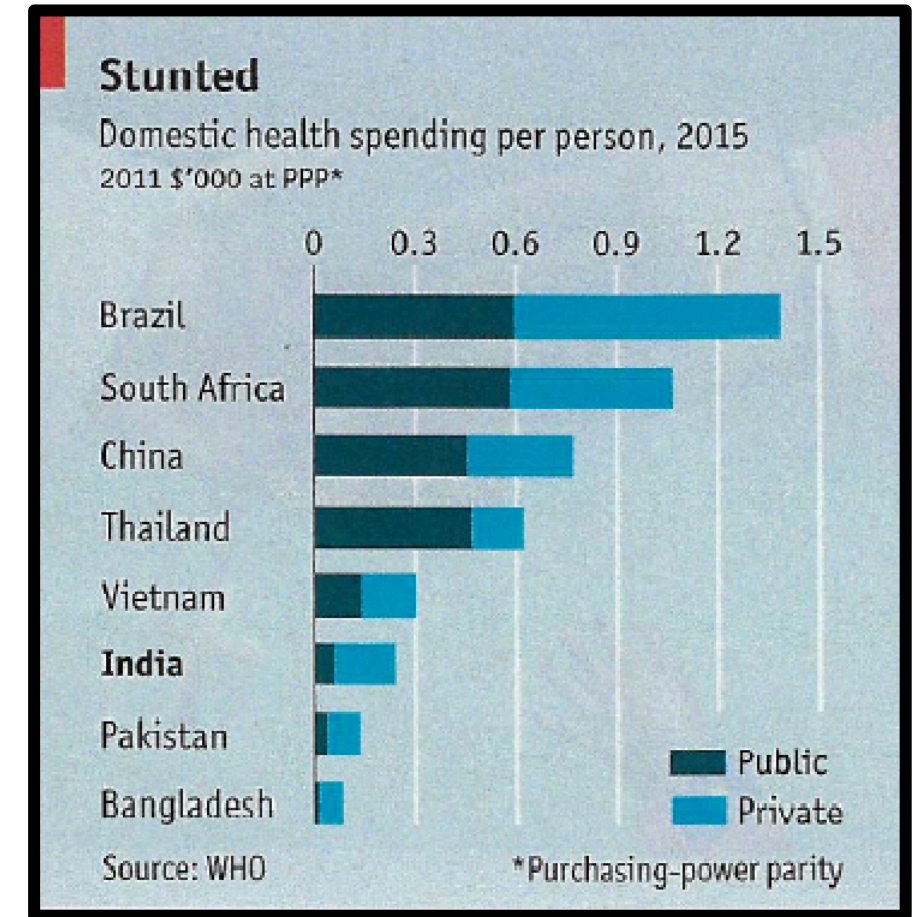
High-Income Countries:   $10,802 pppy

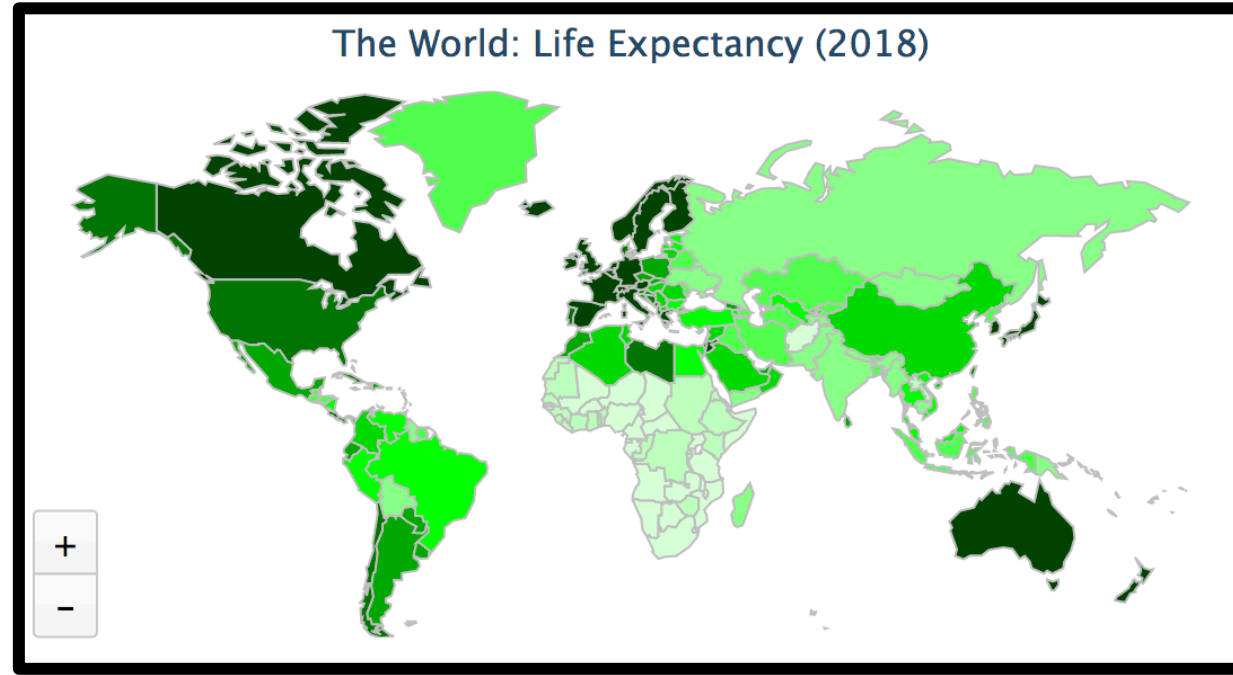Low-Income Countries:    $15-329 pppy

Another view:

61 high-income countries: 81% THC spending, but only 16.6% world popln

U.S. alone spends 41.7% of THC – with 4.4% global popln



Economist 9/29/2018

# Lack of Correlation of Spending with Life Expectancy



The World: Life Expectancy (2018)

U.S. #53 @79.25 yrs; China #111@ 75.93
Monaco #1@89.37; South Africa #228@50.64

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# U.S. Life Expectancy



Life expectancy depends a lot on where you live

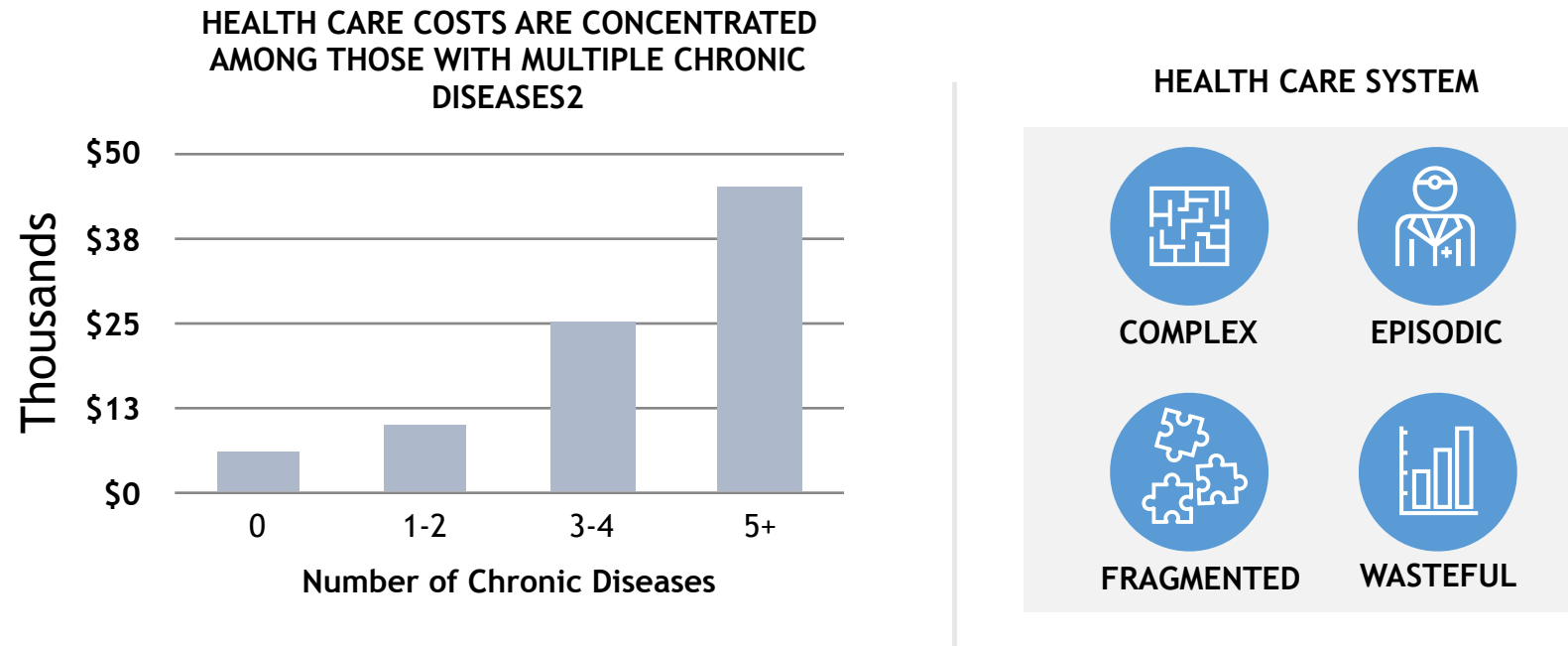Source: The State of US Health, 1990-2016, JAMA
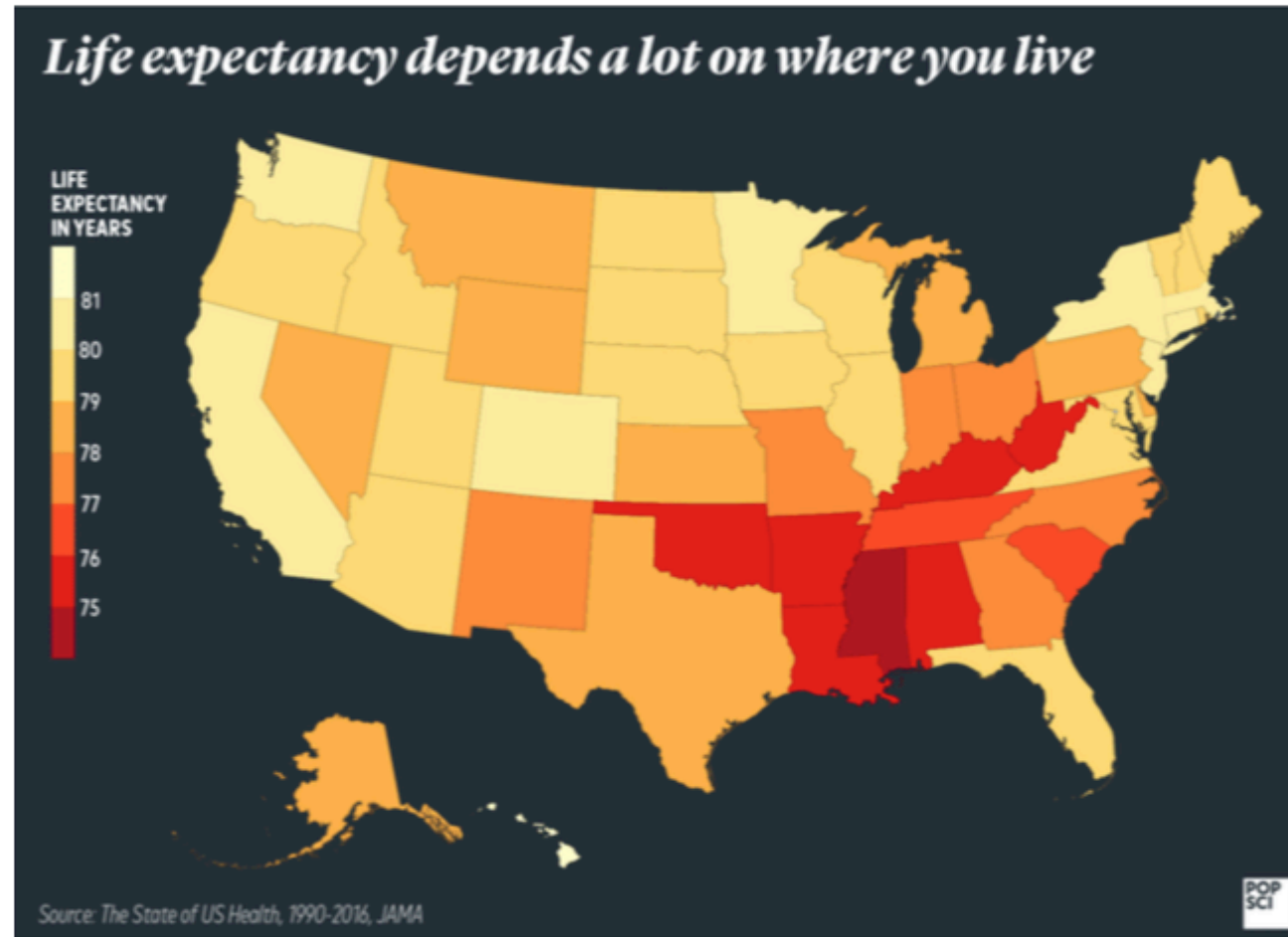
# Global System Failure

- **Focus on disease and not wellness**
- Failure to take whole human being into account and see health as a product of total society –not a thing unto itself
- Unsustainable costs worldwide
- Complex Chronic Illness –cost and QOL burden
- Lack of coverage for all China>U.S.
- Inequities in all systems
- Suboptimal quality-of-life outcomes
- Too few primary care doctors
- Costs to individuals and families

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# Chronic illness as a big and growing problem.

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# The Impetus for Healthcare System Change

## SPENDING ON HEALTH CARE ACCOUNTS FOR ~ 18% OF GDP IN THE U.S.[1]

### HEALTH CARE COSTS ARE CONCENTRATED AMONG THOSE WITH MULTIPLE CHRONIC DISEASES[2]



Thousands (y-axis): $0, $13, $25, $38, $50

Number of Chronic Diseases (x-axis): 0, 1-2, 3-4, 5+

### HEALTH CARE SYSTEM



COMPLEX    EPISODIC

FRAGMENTED    WASTEFUL

## Obesity, diabetes, hypertension, chronic kidney disease

1. Mitchell E. and Machlin S. Concentration of Health Expenditures and Selected Characteristics of High Spenders, U.S. Civilian Noninstitutionalized Population, 2015. Statistical Brief #506. AHRQ, 2017.
2. Cohen, SB. The concentration and Persistence in the Level of Health Expenditures for the U.S. Population, 2012-2013. Statistical Brief #481. AHRQ, 2015.

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# Obesity

## Body Mass Index

Weight/height squared:

kg/m$^2$   (2.2lbs/kg; 2.54cm/inch)

| | |
|---|---|
| Underweight: | $\leq$18.5kg/m$^2$ |
| Normal: | 18-25 |
| Overweight: | 25-30 |
| Obese: | $\geq$30 |

# Obesity

- More than 60% of Americans are overweight (including "obese"):

- Of all the developed economies, US has highest rate of obesity –
75% predicted by 2020

- Up to 400,000 U.S. deaths per year
- Annual societal cost: $117 billion ($2.5

Prevalence of obesity highest in Americas and lowest in SE Asia

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# Hypertension:

- Enormous global problem:  972 million in 2000; 1.56 billion by 2025
- China: Prevalence 27.8% of Chinese people (increases steeply with age); overall control  9.7% (Yichong et al, Intl J Cardiol, 2017)
- U.S.  23.4%  or 76.2 million people
- 18% of global deaths; 162 million years of life lost

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# Diabetes Facts:

- Worldwide, no. of diabetics has risen from 108 million in 1980 to 422 million in 2014.
- Prevalence of diabetes among adults >18 over 18  has risen from 4.7% in 1980 to 8.5% in 2014.
- Rising more rapidly in middle- and low-income countries.
- Diabetes: major cause of blindness, kidney failure, heart attacks, stroke and lower limb amputation.

WHO, 2017

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# Type 2 Diabetes in the U.S.A.



FIGURE 1 | Number and Percentage of U.S. Population with Diagnosed Diabetes, 1958-2015[2]
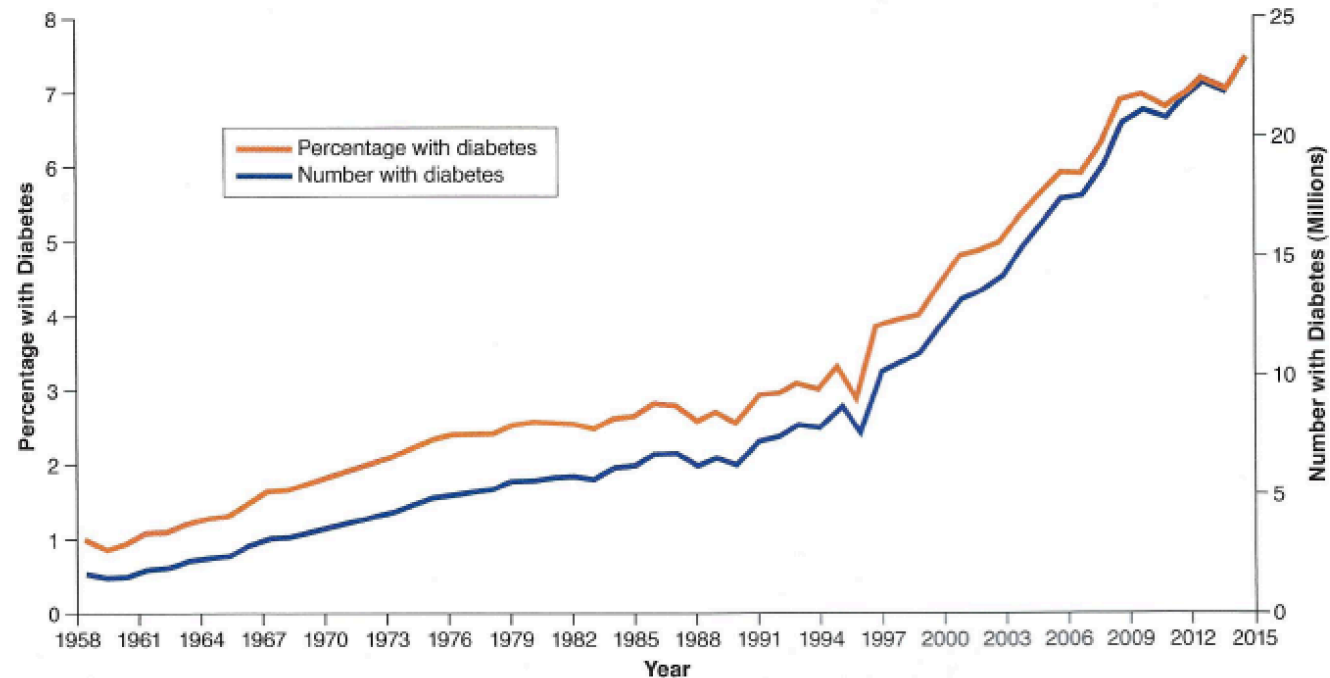
From Centers for Disease Control and Prevention, Division of Diabetes Translation. United States Diabetes Surveillance System, available at: http://www.cdc.gov/diabetes/data.

# Health:

"a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity."

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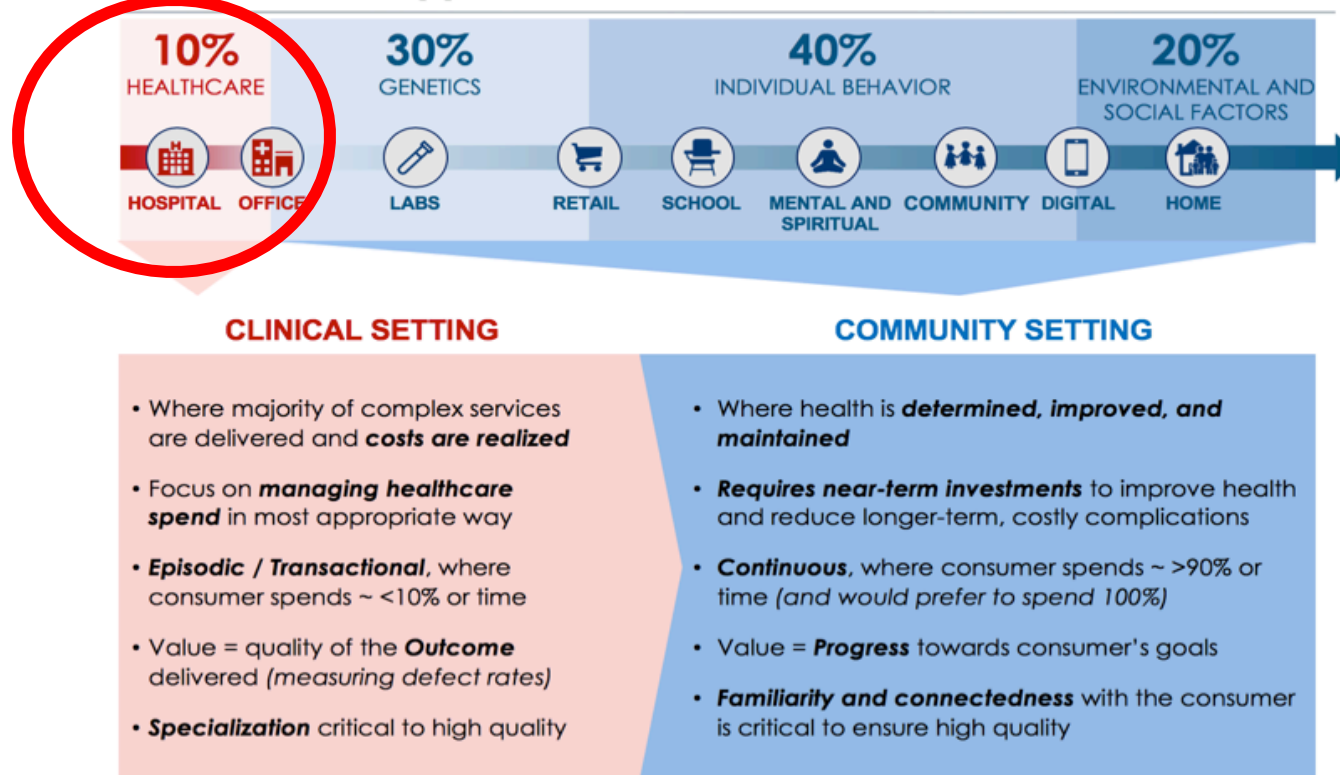
What can we do about it?
We **MUST** solve the problem!
The situation is wrong (bio)ethically
(*and not sustainable*)
We need a new model!!

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## Recognizing that Health is a Product of Society and not a "thing" unto Itself!



**Disruption requires new models based on delivering services where health happens…**

| 10% HEALTHCARE | 30% GENETICS | 40% INDIVIDUAL BEHAVIOR | 20% ENVIRONMENTAL AND SOCIAL FACTORS |
|---|---|---|---|
| HOSPITAL  OFFICE | LABS | RETAIL  SCHOOL  MENTAL AND SPIRITUAL  COMMUNITY  DIGITAL | HOME |

**CLINICAL SETTING**

- Where majority of complex services are delivered and **costs are realized**
- Focus on **managing healthcare spend** in most appropriate way
- **Episodic / Transactional**, where consumer spends ~ <10% or time
- Value = quality of the **Outcome** delivered (measuring defect rates)
- **Specialization** critical to high quality

**COMMUNITY SETTING**

- Where health is **determined, improved, and maintained**
- **Requires near-term investments** to improve health and reduce longer-term, costly complications
- **Continuous**, where consumer spends ~ >90% or time (and would prefer to spend 100%)
- Value = **Progress** towards consumer's goals
- **Familiarity and connectedness** with the consumer is critical to ensure high quality

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Waldeck, 2019

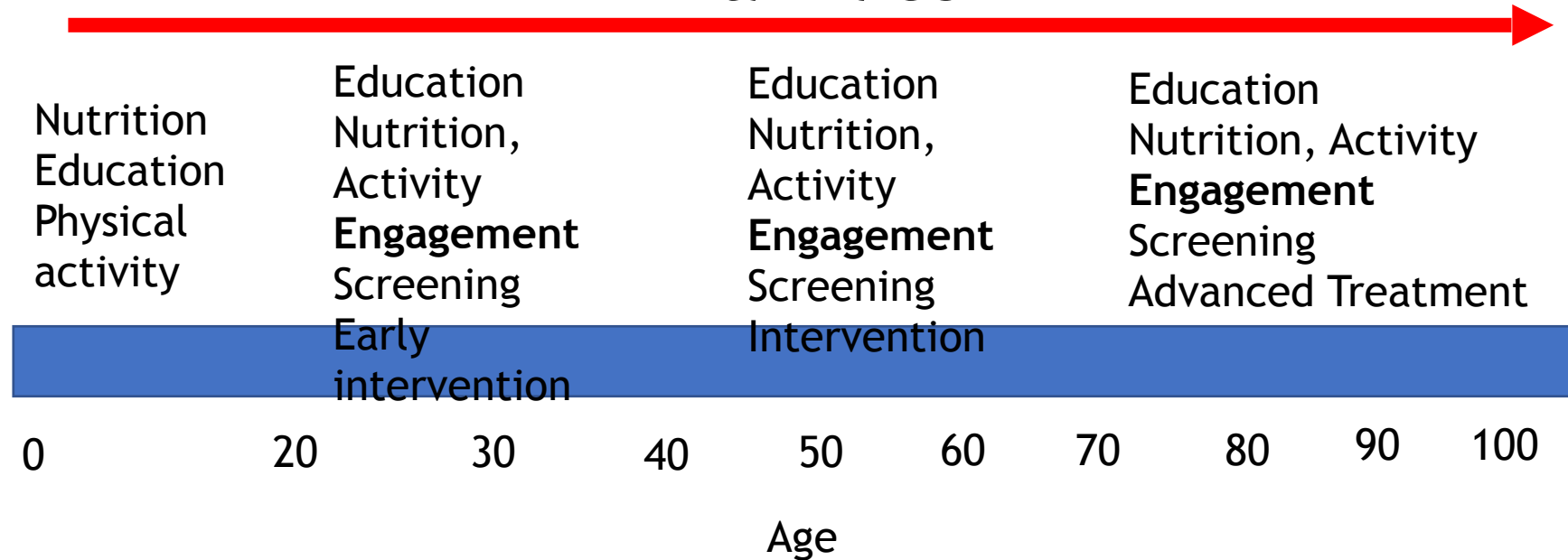Rogosin Institute

# A New Model
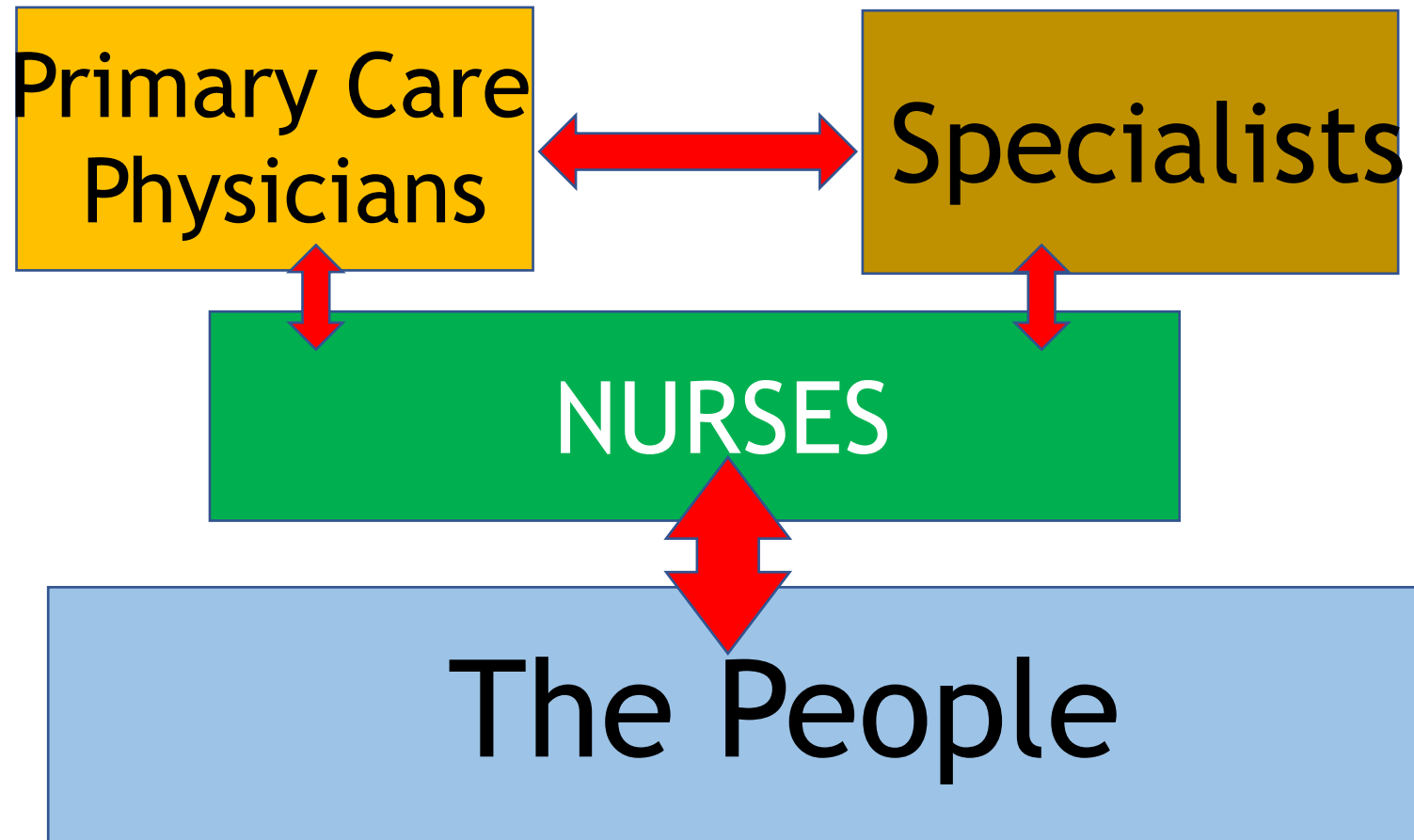
## Integrated

Focus on **wellness and QOL!**

- education(school); good nutrition; activity
- public health prevention
- screening and early detection/ intervention
- treatment and prevention of progression
- advanced compassionate care when

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# The Model

## Wellness and QOL Continuity Across the Lifetime of Individuals and Families

Nutrition
Education
Physical activity

Education
Nutrition, Activity
**Engagement**
Screening
Early intervention

Education
Nutrition, Activity
**Engagement**
Screening
Intervention

Education
Nutrition, Activity
**Engagement**
Screening
Advanced Treatment

0    20    30    40    50    60    70    80    90    100

Age

# What Else is Needed?

**WHOLE**
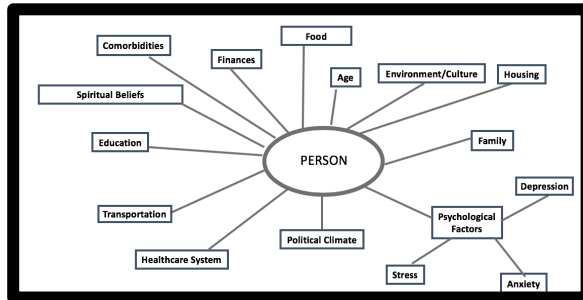


**PEOPLE**

- Registry/Electronic Health Record
- Machine Learning/Artificial Intelligence – Stratify Risk
- A Health/Wellness System that Learns
- Supportive local and national policies
- Shared Risk
- Measurable Outcomes
- Empathy/Compassion/ Professionalism
- Engagement by All

# Stratify Risk!
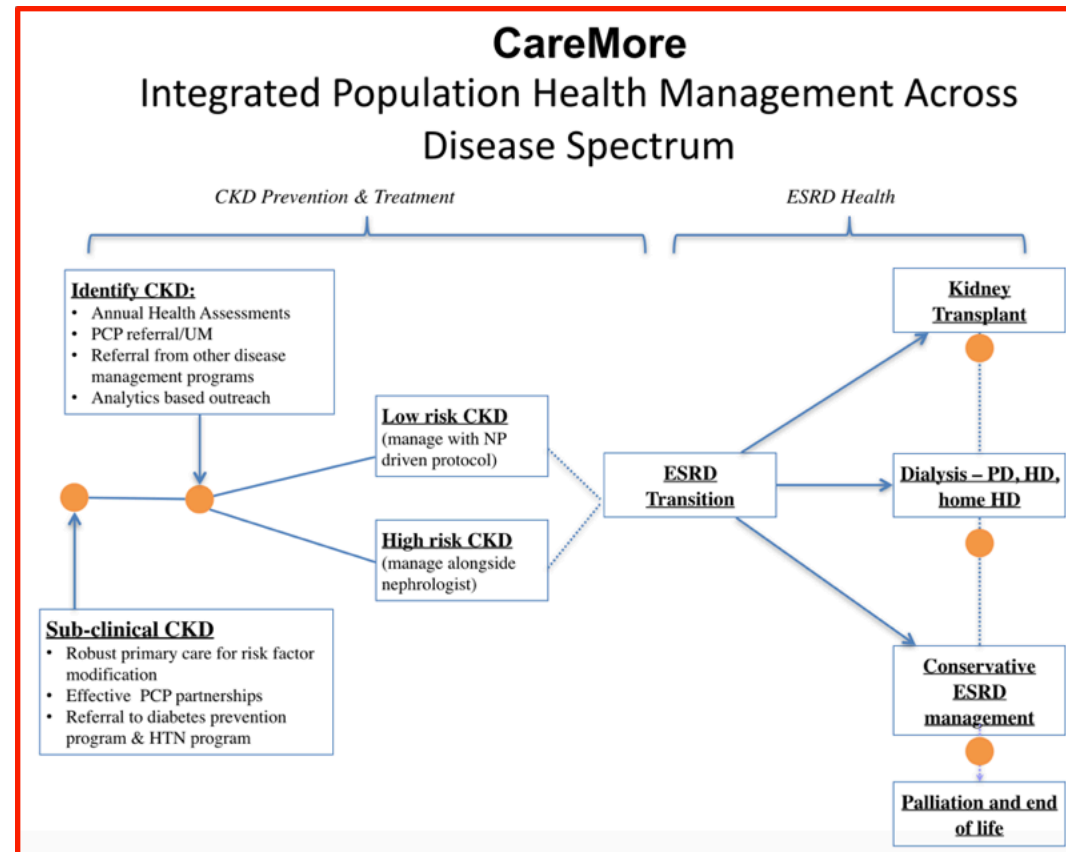
# The Rogosin Institute

Independent, Non-Profit (501c3)
Clinical Care and Research Institute closely affiliated with

# The Kidney

Waste removal system; blood pressure control; red blood cell control

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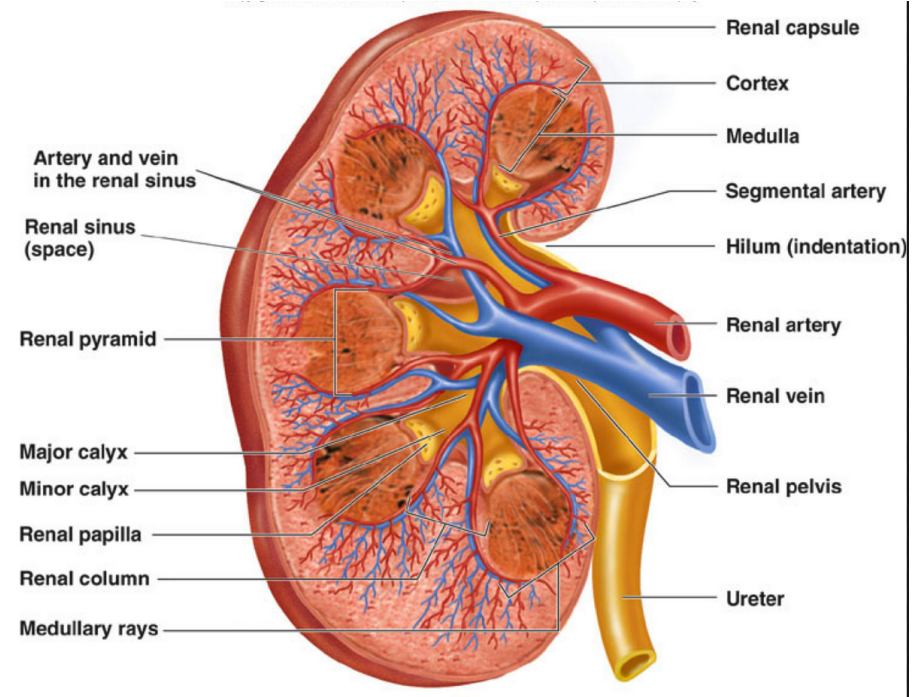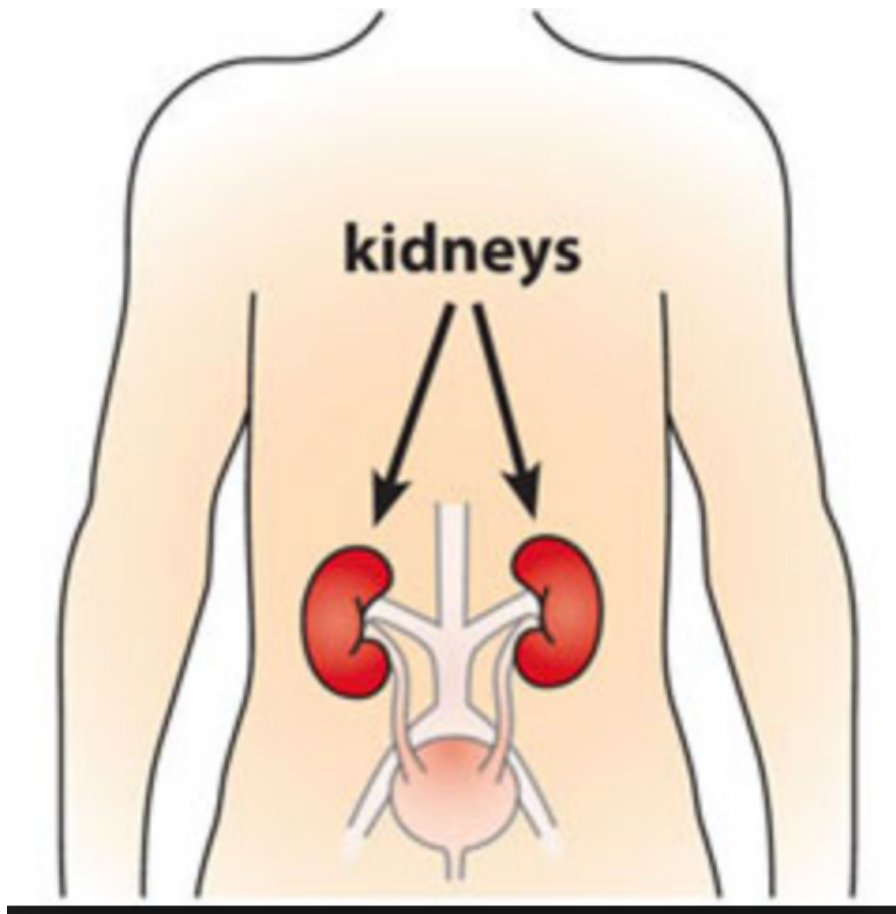
# Kidney function is vital to the proper functioning of all body systems:

Every day, our two kidneys:

- Filter about 120 to 150 quarts of blood to produce about 1 to 2 quarts of urine
- Regulate body fluid volume
- Regulate sodium, potassium, phosphorus
- Remove wastes (urea, ammonium....)
- Regulate blood pressure, remove waste and water, hormones
- Help make red blood cells
- Regulate calcium absorption via calcitriol
- (bone structure and function)

# The Rogosin Institute
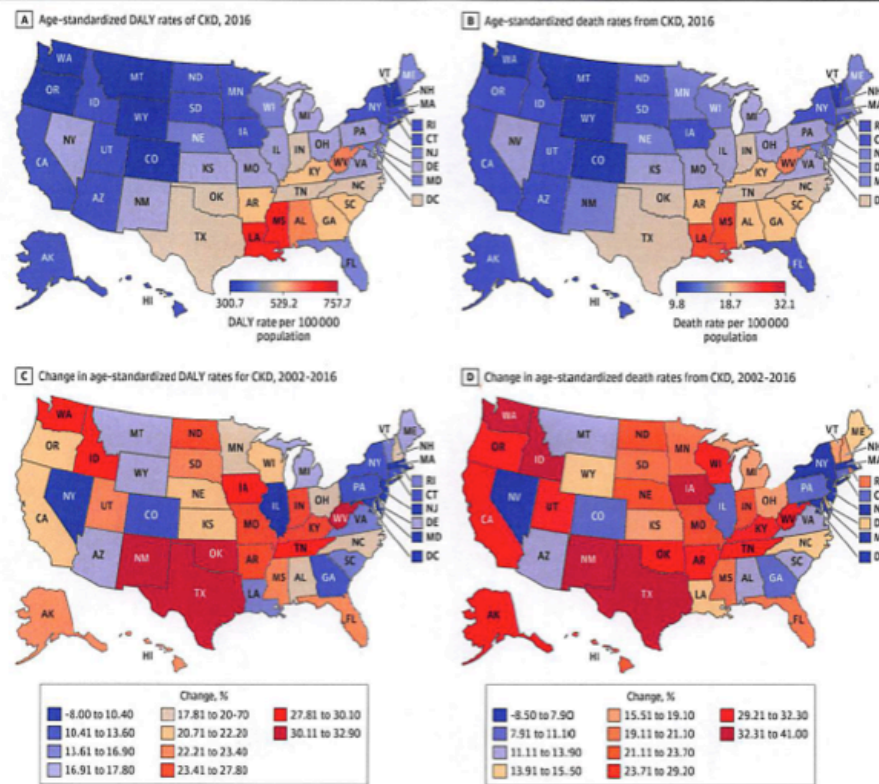






Normal Glomerulus
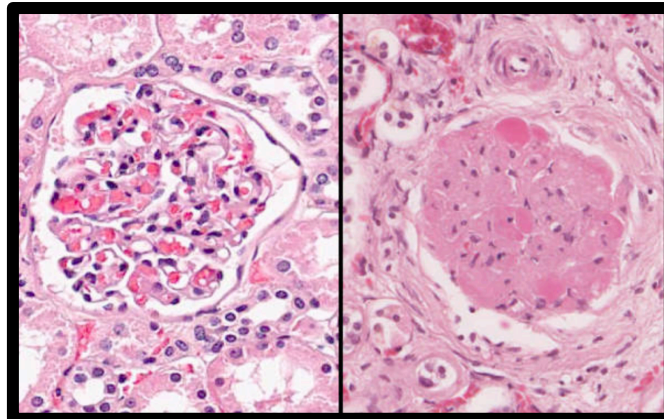
End-Stage Diabetic Glomerulus

## 2002-2016

30,000,000 Americans – 96% not aware of their CKD



Figure 1. Maps of Age-Standardized Disability-Adjusted Life Years (DALYs) and Death Rates Due to Chronic Kidney Disease (CKD) in 2016, and Percentage Change From 2002 to 2016

Age-Std CKD DALYs:
Vermont: 321
Mississippi: 697
(per 100,000)
Overall: +18.6%
Death: +58.3%
(Ages 20-54: 25.6% - CKD DM

DALY increase risk factors:
Metabolic (DM): 93.8%
Dietary: 5.3%

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# A National Problem: Chronic Kidney Disease

More than **1** in **7**

15% of US adults are estimated to have chronic kidney disease—that is about 30 million people.

CDC

**1** in **2**

About 1 in 2 adults aged 30-64 is expected to develop chronic kidney disease in their lifetime.

CDC

Centers for Disease Control and Prevention. National Chronic Kidney Disease Fact Sheet, 2017. Atlanta, GA: US Department of Health and Human Services, Centers for Disease Control and Prevention; 2017.

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# Costs of Kidney Disease

## Hypertension and Diabetes as the Leading Causes of CKD and ESRD in the World

**USA:** CKD Prevalence: 14%; ESRD >0.03%
Expensive: 1% ESRD take 7% Medicare budget
CKD 3: $23,680 per year
CKD 4: $33,374 per year
CKD 5: $36,147 per year
CKD 5 on Dialysis: $84,645 per year
*Source: 2013, 5% Medicare Claims Data Set*

**China**: CKD prevalence**:** 10.8%
(estimated at over 100 million **Chinese**)
and **ESRD,** 0.03%.

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# A Global Problem Chronic Kidney Disease (CKD)

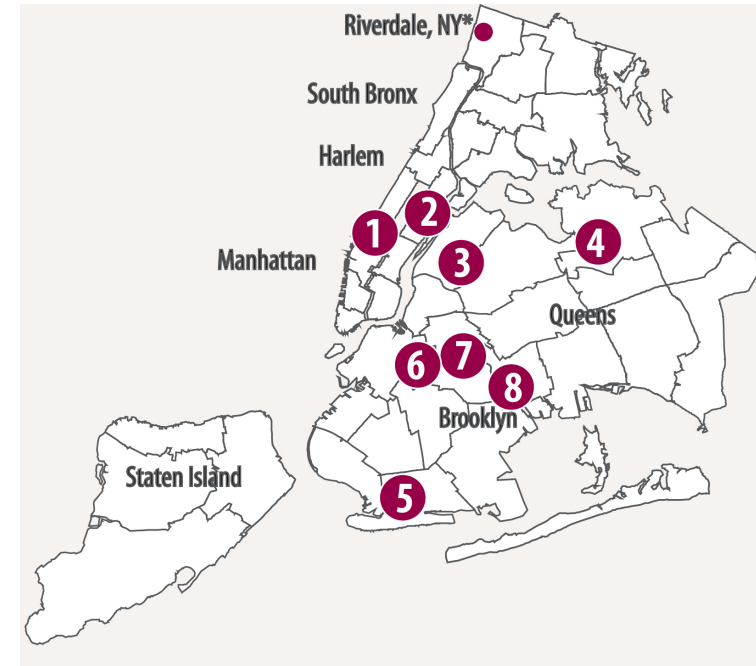**1 in 10 people live with CKD worldwide**

**CKD Risk Factors:**

- Diabetes
- Hypertension
- Family history of kidney disease, diabetes, hypertension
- Certain ethnicities (African American, Hispanic, Asian, Pacific Islander, American Indian)
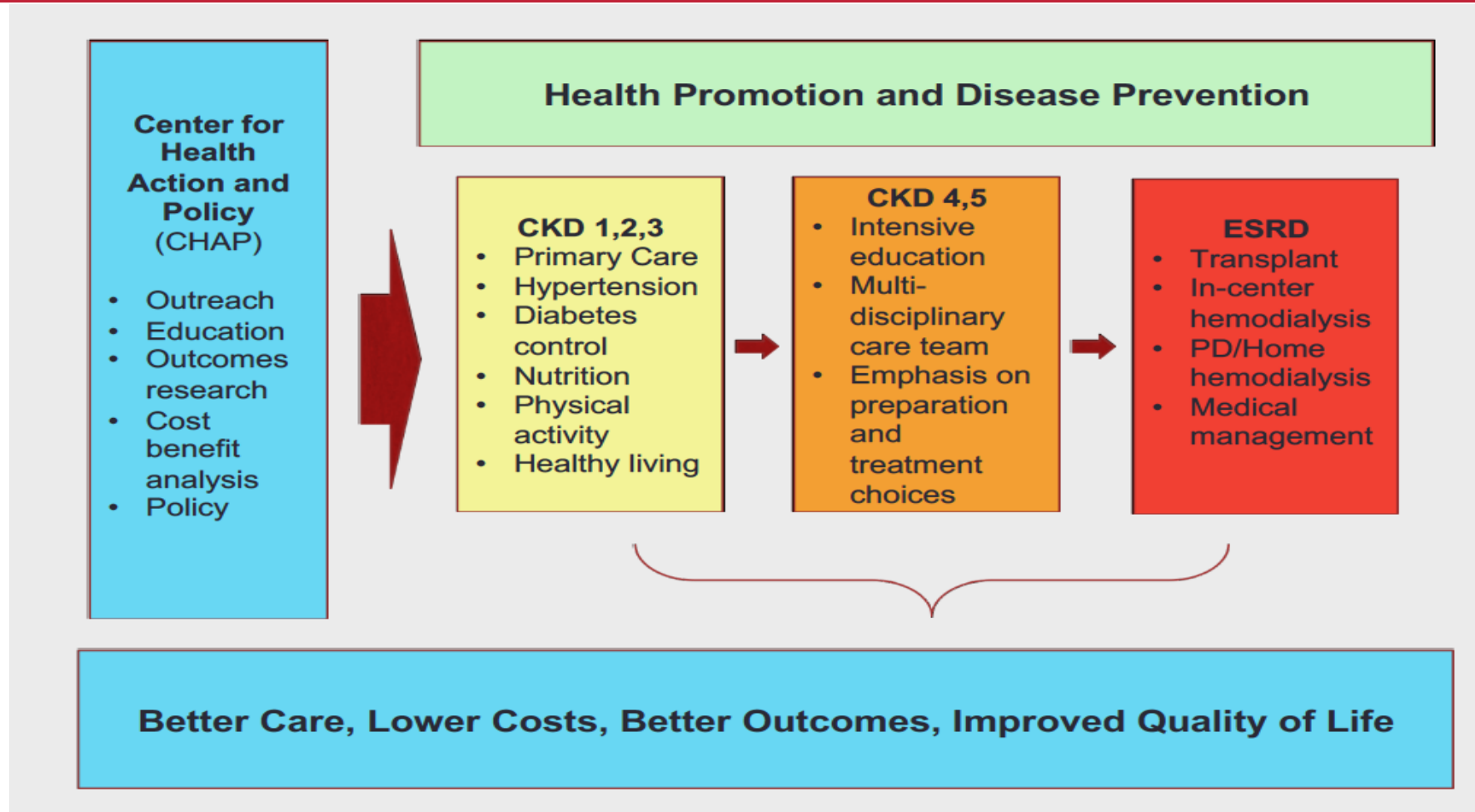- Age: Older than 60

# The Rogosin Institute: 510 people serving NYC (110 Nurses)

- 8 dialysis units in NYC (1,600 patients)
- Chronic Kidney Care
- Clinical research
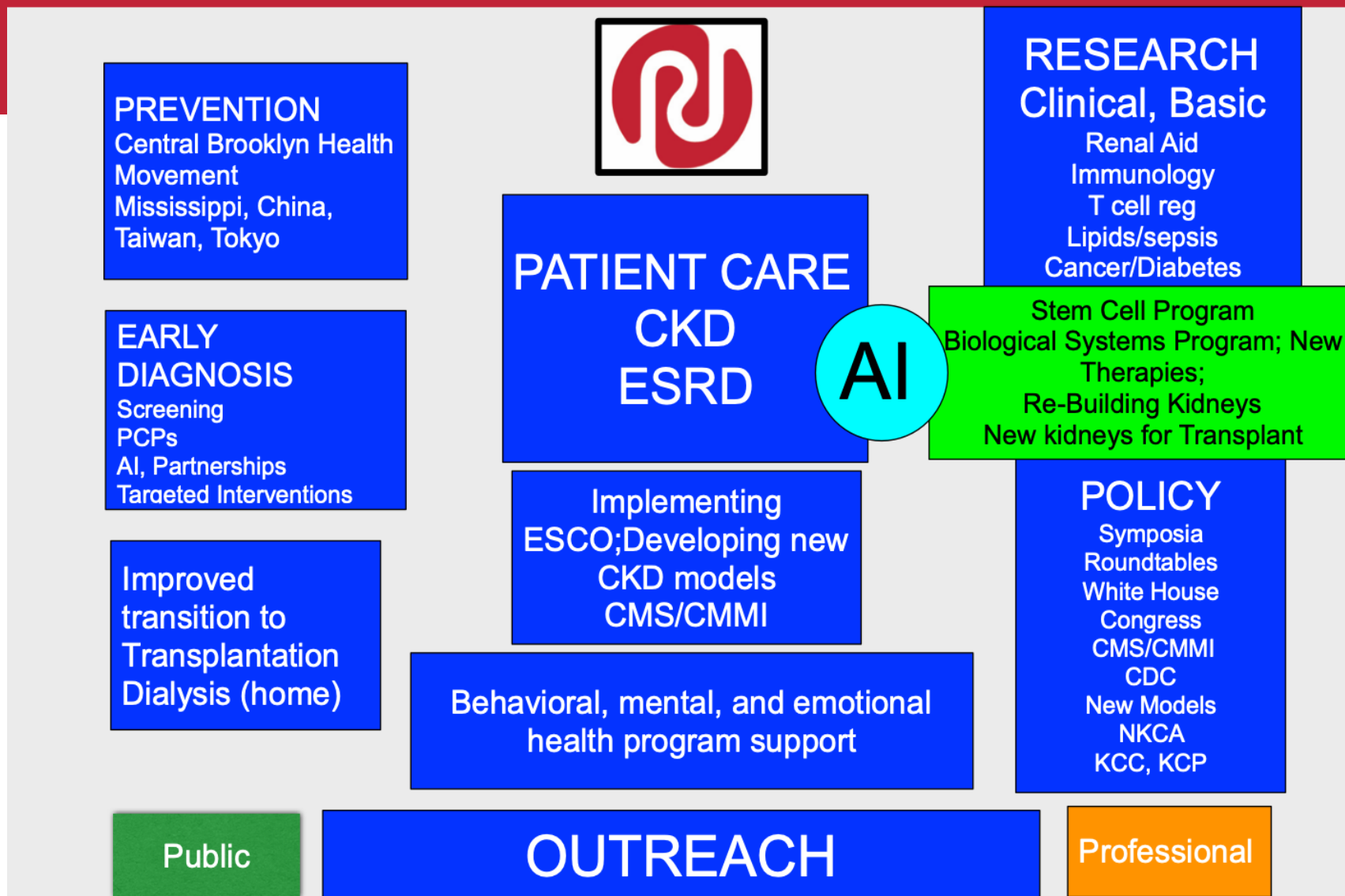- Kidney transplant program
- Center for Health Action and Policy

# The Rogosin Kidney Care Model

# The Rogosin Institute, June 2019



**PREVENTION**
Central Brooklyn Health Movement
Mississippi, China, Taiwan, Tokyo

**EARLY DIAGNOSIS**
Screening
PCPs
AI, Partnerships
Targeted Interventions

**Improved transition to Transplantation Dialysis (home)**

**PATIENT CARE CKD ESRD**

**AI**

Implementing ESCO;Developing new CKD models
CMS/CMMI

Behavioral, mental, and emotional health program support

**RESEARCH Clinical, Basic**
Renal Aid
Immunology
T cell reg
Lipids/sepsis
Cancer/Diabetes

Stem Cell Program
Biological Systems Program; New Therapies;
Re-Building Kidneys
New kidneys for Transplant

**POLICY**
Symposia
Roundtables
White House
Congress
CMS/CMMI
CDC
New Models
NKCA
KCC, KCP

Public

**OUTREACH**

Professional

Confidential

X

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# The Rogosin Institute

Central Brooklyn Health Movement
Primary Prevention,
Education, Screening
Early Intervention

PEAK PROGRAM
Patient Education in
Advanced Kidney Disease
(Stage 4, 5)

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# The Rogosin Institute-pulseData collaboration

| Numbers for 2014-2016 | |
|---|---|
| Total patient cohort | 109,028 |
| Patients in dataset who progress to an eGFR <20 | 2,416 |
| Patients who continue on to an eGFR <10 | 241 |
| Patients who received an AV fistula in the six months prior to their decline to an eGFR <10 | 17 |
| Patients identified by the model (at the top risk quintile) in the six months prior to a decline to an eGFR <10 | 181 |

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# Who Makes This Happen?
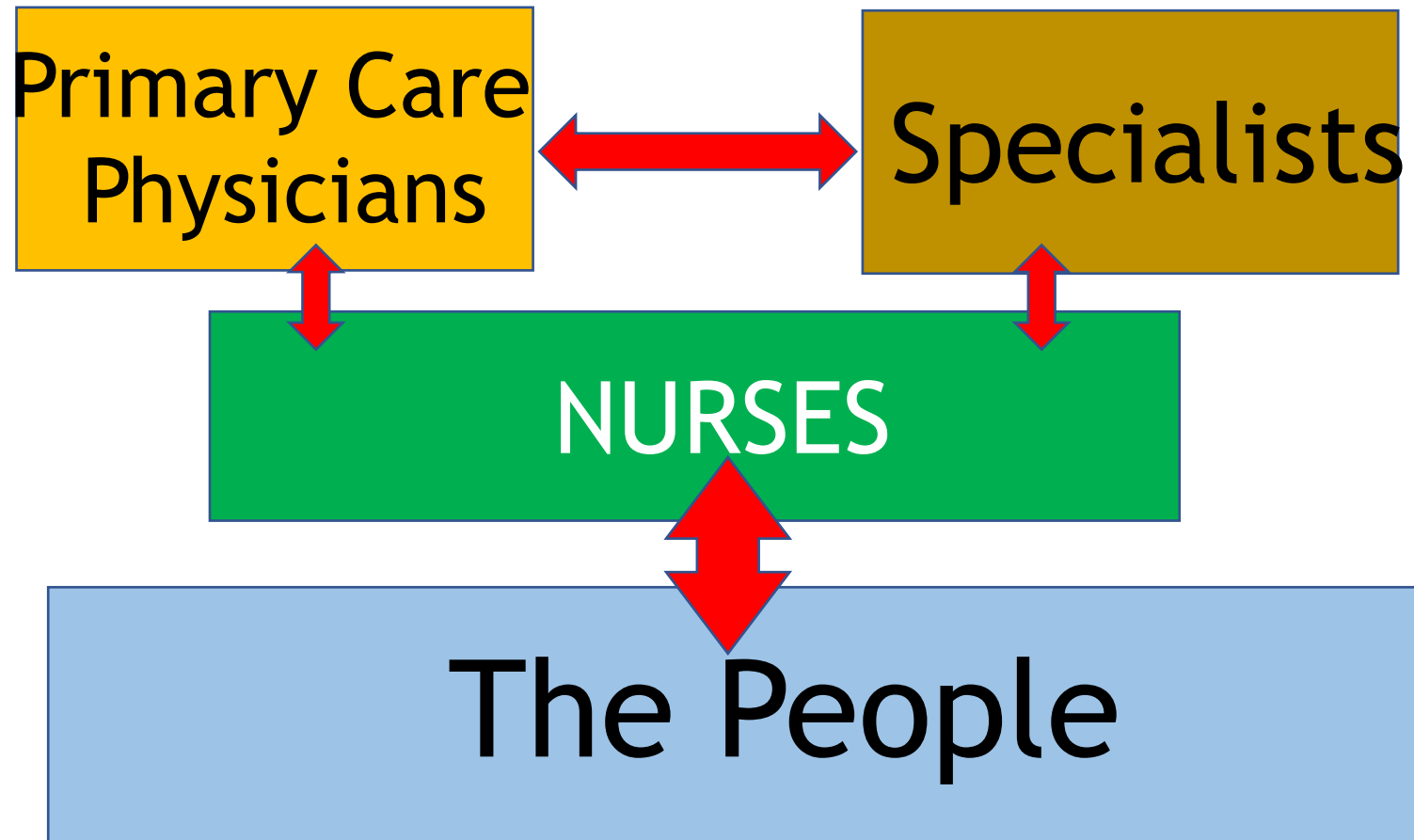
# The PEOPLE as a critical missing ingredient in the new healthcare system

# The People as Partners

Rogosin has over 25 years of experience in community outreach and mobilization utilizing the *Problem Solving for Better Health® (PSBH®)* methodology

- Implemented in 32 countries
- Over 60,000 participants, and 40,000 health promotion projects

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# Prevention Succeeds with Community Involvement

The people with the problems are not the problem; they are the solution when equipped with the right tools!




Releasing Human Potential!!!

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# Central Brooklyn Health Disparities

Significant differences in health outcomes between Brownsville and other parts of



**Obesity** (percent of adults)

| | |
|---|---|
| BROWNSVILLE (RANKS 11TH) | 32%* |
| STUYVESANT TOWN AND TURTLE BAY (RANKS 59TH) | 8% |
| BROOKLYN | 27% |
| NYC | 24% |

NYC DOHMH, Community Health Survey, 2011-2013
*Interpret estimate with caution due to small sample size

**Diabetes** (percent of adults)

| | |
|---|---|
| BROWNSVILLE (RANKS 6TH) | 15% |
| STUYVESANT TOWN AND TURTLE BAY (RANKS 59TH) | 3% |
| BROOKLYN | 11% |
| NYC | 10% |

NYC DOHMH, Community Health Survey, 2011-2013

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# Central Brooklyn Health Disparities

Central Brooklyn neighborhoods:
East New York, Brownsville,
(~270,000 residents)
Health disparities:

- Infant mortality rate is 8x as high as Manhattan's Upper East Side
- Premature mortality rate is 5x that of Manhattan's Financial District
- 1 in 6 adults has Type 2 Diabetes



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Who can make us all healthier?

YOU!!

**The current statistics are unacceptable! We won't take it anymore!
You can be the ones to change the way things are and turn America around!!!**

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# Obesity and Diabetes as Complex Problems

More than medical: also emotional and societal



M.S. Sahoo, MedLife, Dec. 2018

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# NO EXCUSES!!!!!

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**A movement of, by, and for the people!!**

# Achieving Better Health

The Centers for Disease Control and Prevention estimates that 80% of chronic Illness could be eliminated with attention to these four basic health factors:

<div style="color:red; text-align:center">

Better nutrition

More physical activity

Moderate to no alcohol use

No tobacco

</div>

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# Nutrition:

## Just how important is it?

## How should we be thinking about it?
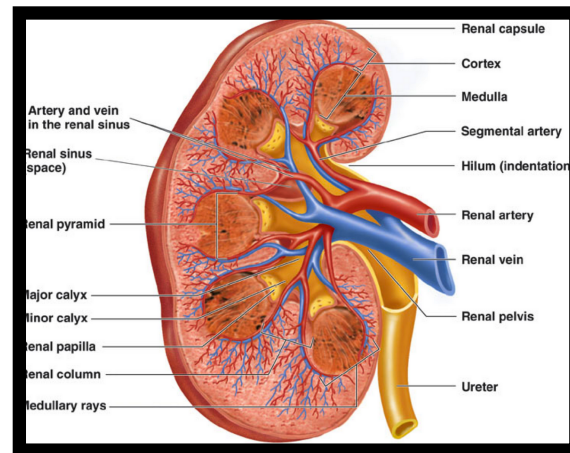
The human body
as a
finely-tuned machine

INPUT → ← OUTPUT

Food
Physical activity
Medication
Environment
(stress, etc)

Feeling good!
Optimal mental
and physical
function
Positive emotional
state

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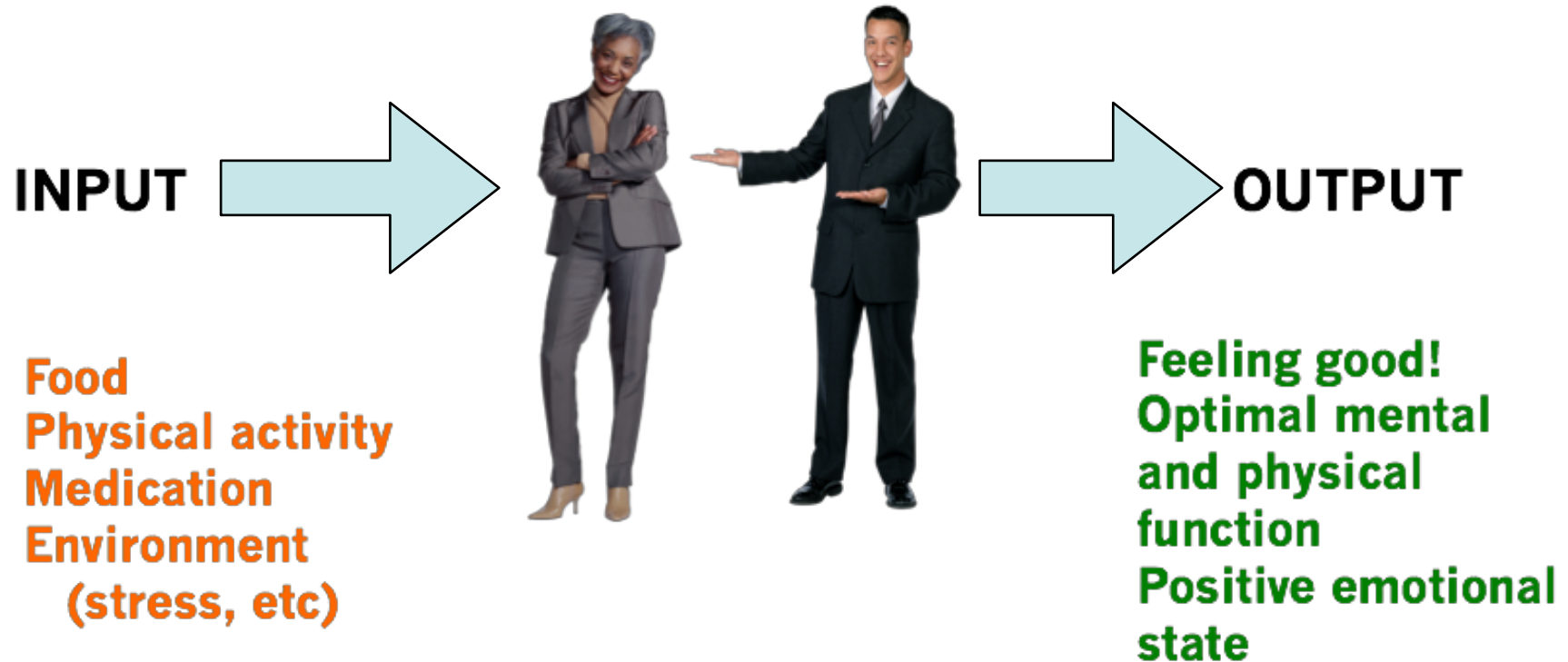
# The Human Being (and Health) as a Complex Product of Biology and Societal/Other Factors
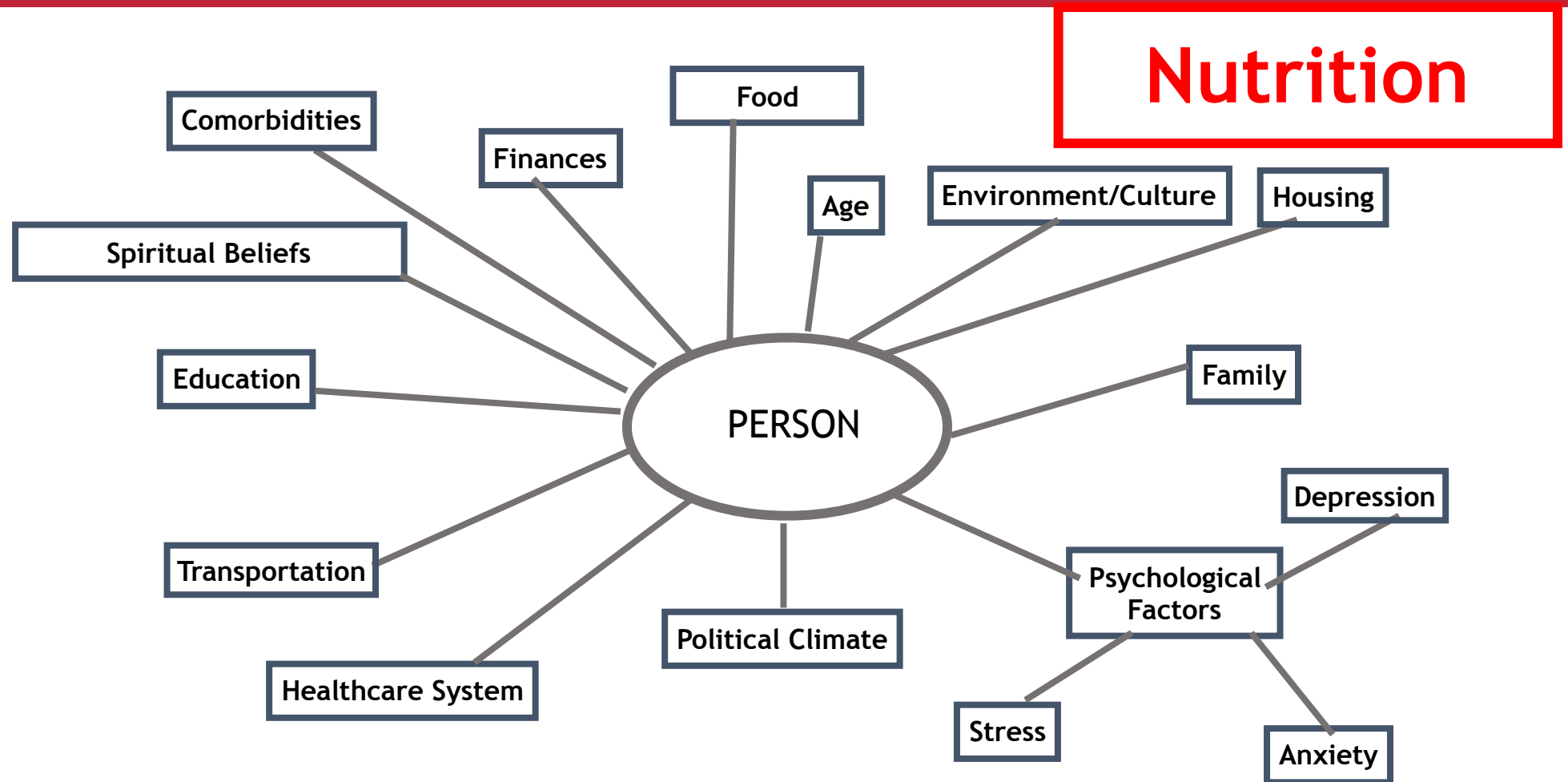
# FOOD AS MEDICINE

The most important "medication" we all take is the food we eat on a daily basis

- Proteins
- Carbohydrates
- Fats

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# Mixing the Fuels

## RECOMMENDED FUEL PORTIONS

### Carbohydrates

**Starches**: breads, cereals, grains, rice, pasta

Dried **beans**, peas, lentils

**Fruits**

**Vegetables** - corn, peas, winter squash, lettuce, leafy greens

**Milk**, yogurt

**Sugar**, sweets, desserts

### Protein

**Meats** - beef, pork, lamb, poultry, fish, shellfish

**Eggs**

**Cheese**

**Tofu**

### Fats

Oils

**Margarine**

**Animal fats** - dairy, poultry fish, shellfish

**Nuts**
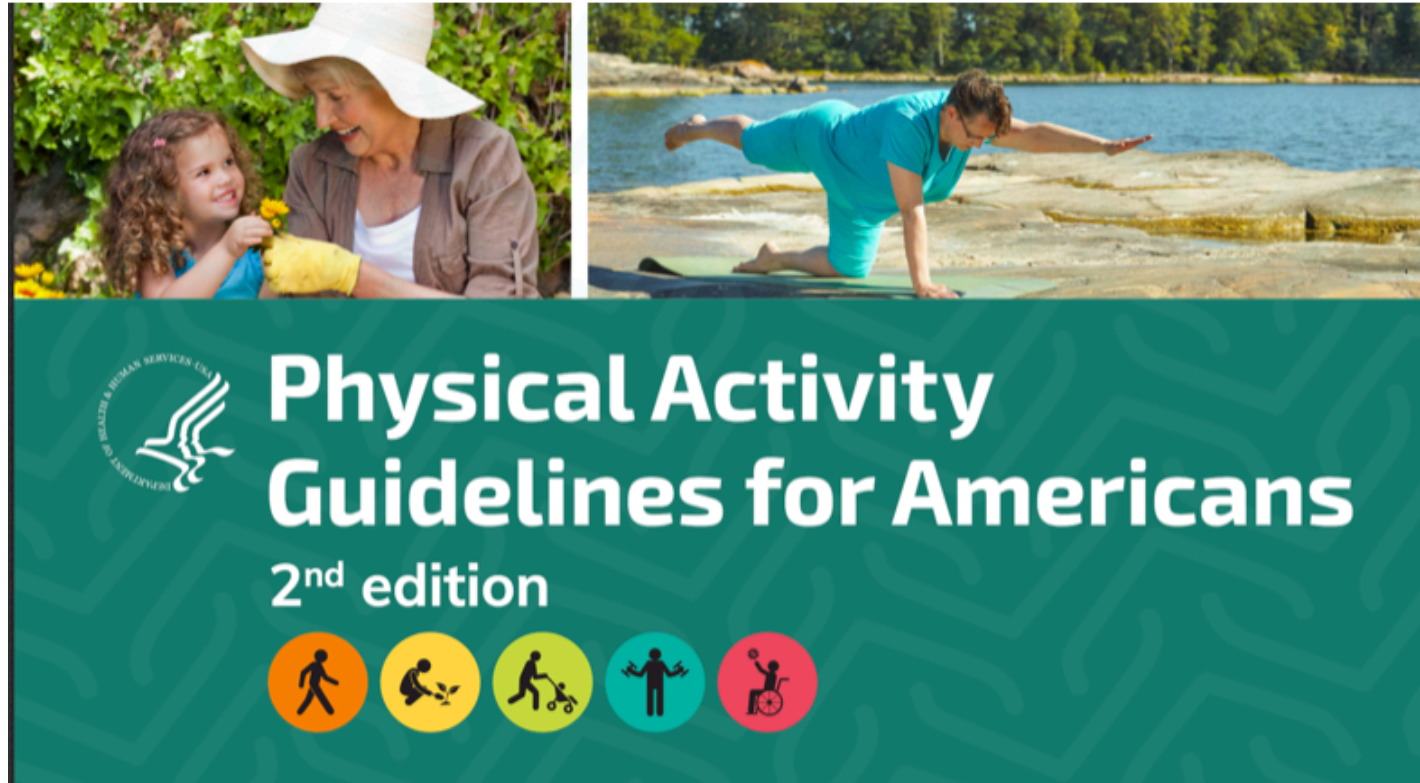


**about 50%**     **25%**     **25%**

# Physical Activity

## Table 2-2. Components of Physical Fitness

| | |
|---|---|
| **Cardiorespiratory Fitness** | The ability to perform large-muscle, whole-body exercise at moderate-to-vigorous intensities for extended periods of time. |
| **Musculoskeletal Fitness** | The integrated function of muscle strength, muscle endurance, and muscle power to enable performance of work. |
| **Flexibility** | The range of motion available at a joint or group of joints. |
| **Balance** | The ability to maintain equilibrium while moving or while stationary. |
| **Speed** | The ability to move the body quickly. |

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# Some examples

# Activity and Mortality



Risk of all-cause mortality decreases as one moves from red to green.
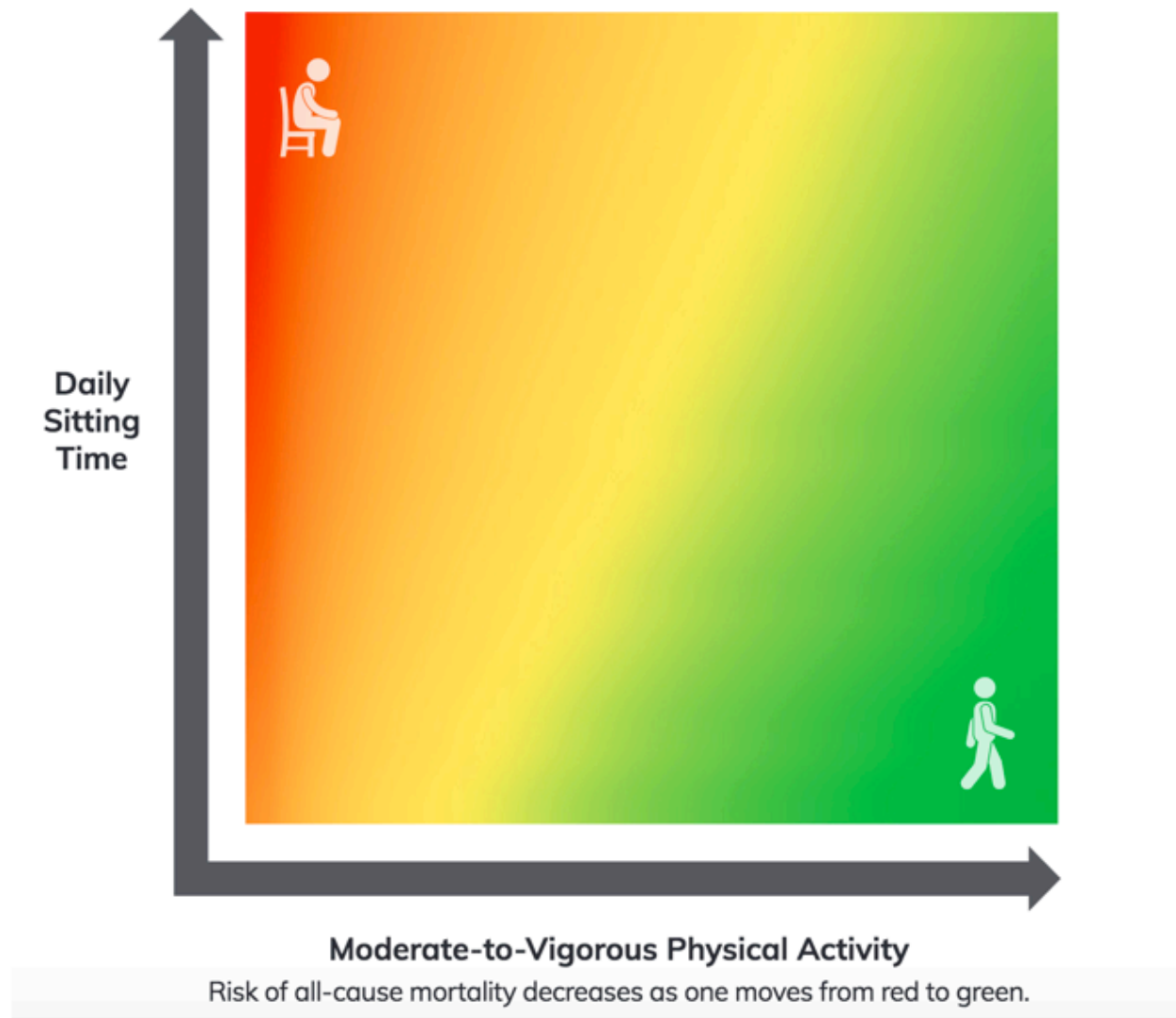
# No-to-light alcohol use

# No Smoking
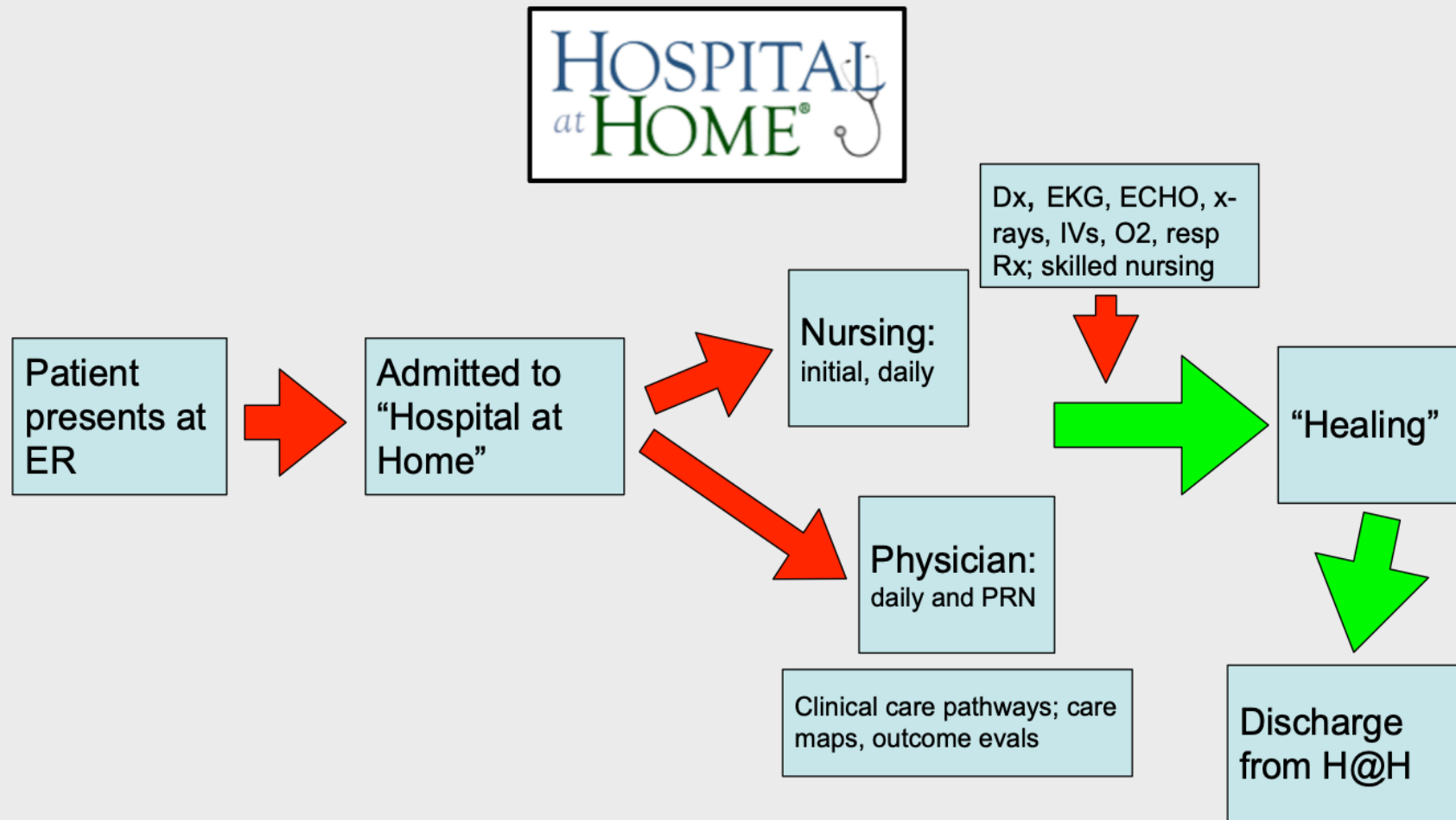
# The new system must pay for **WELLNESS** and not **SICKNESS**!!

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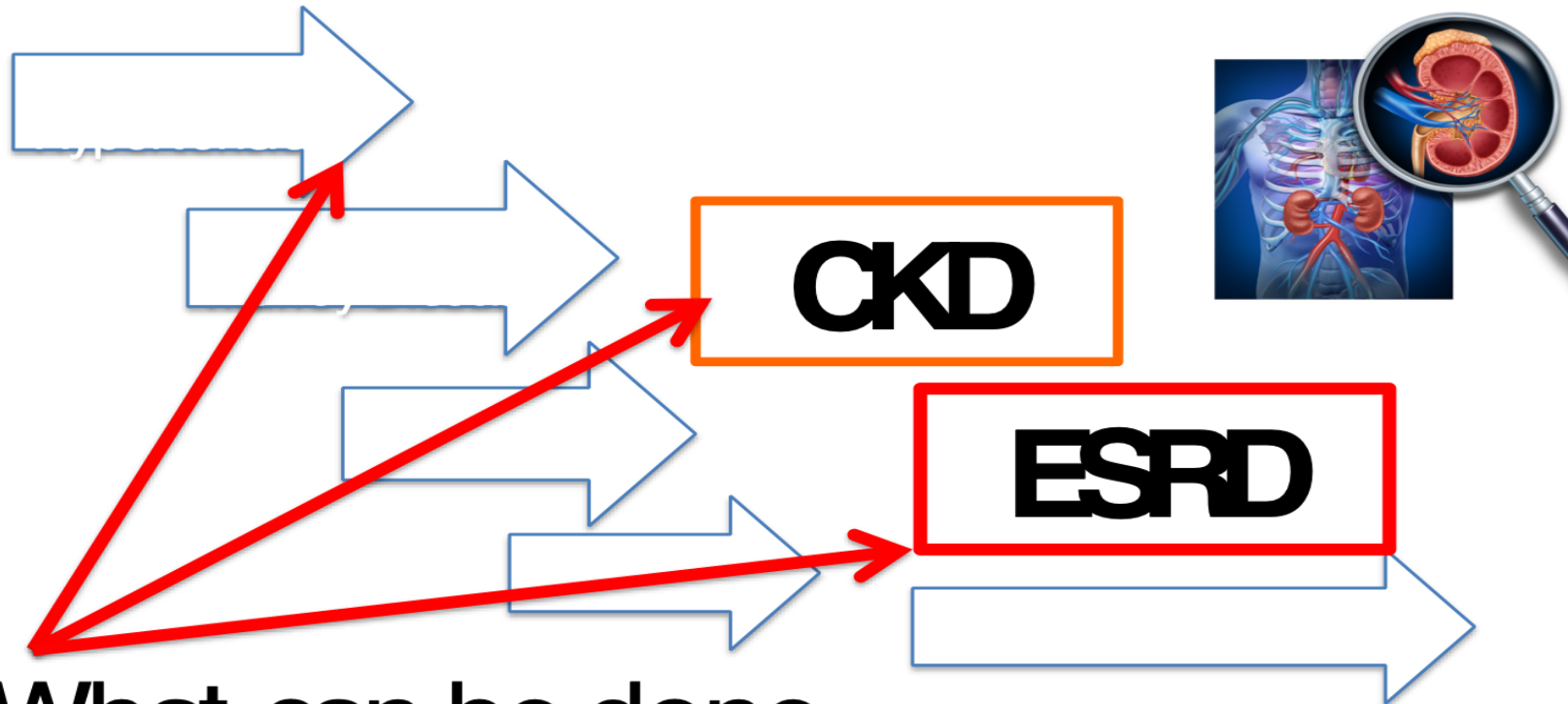
# The Human Being (and Health) as a Complex Product of Biology and Societal/Other Factors
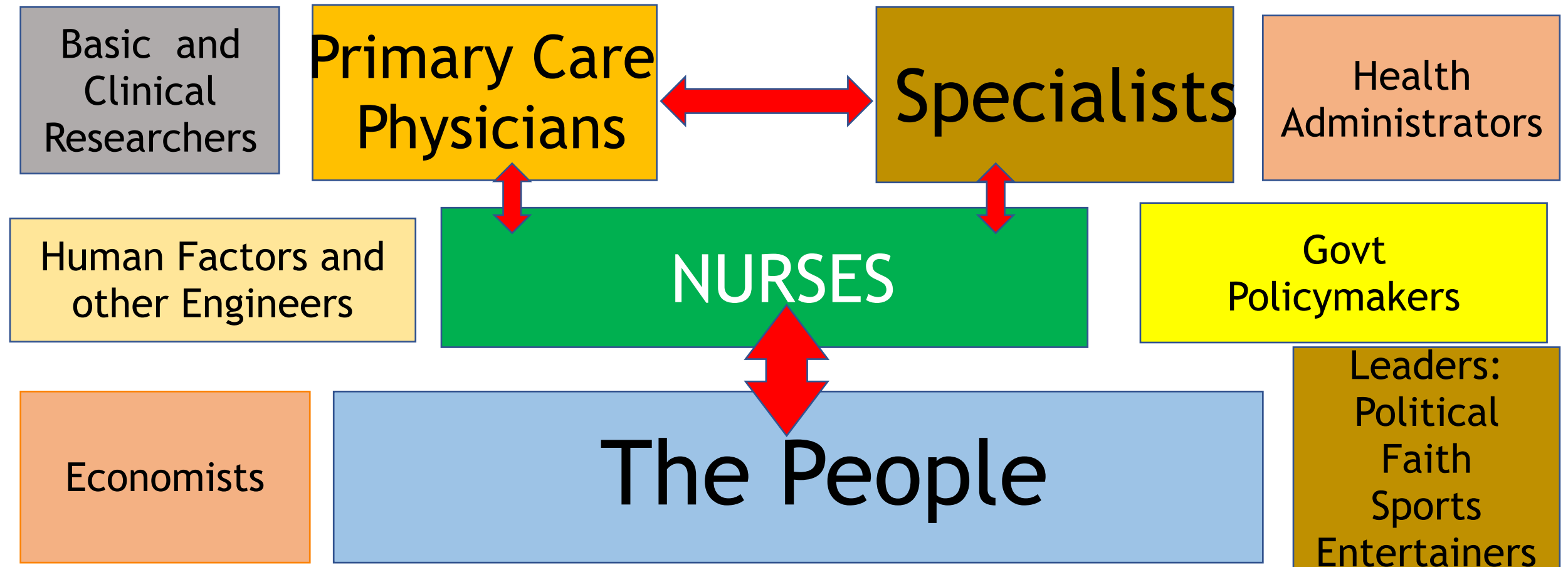
# Back to the Future

# The Critical Issue

The principles of Bioethics, **derived from our understanding of what it means to be human**, demand that our healthcare system be radically transformed:

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# Do we, collectively, have the will to make this happen - to meet our bioethical responsibilities?

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# Who Makes This Happen?

Basic and Clinical Researchers

Primary Care Physicians ⟷ Specialists

Health Administrators

Human Factors and other Engineers

NURSES

Govt Policymakers

Economists

The People

Leaders: Political Faith Sports Entertainers

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