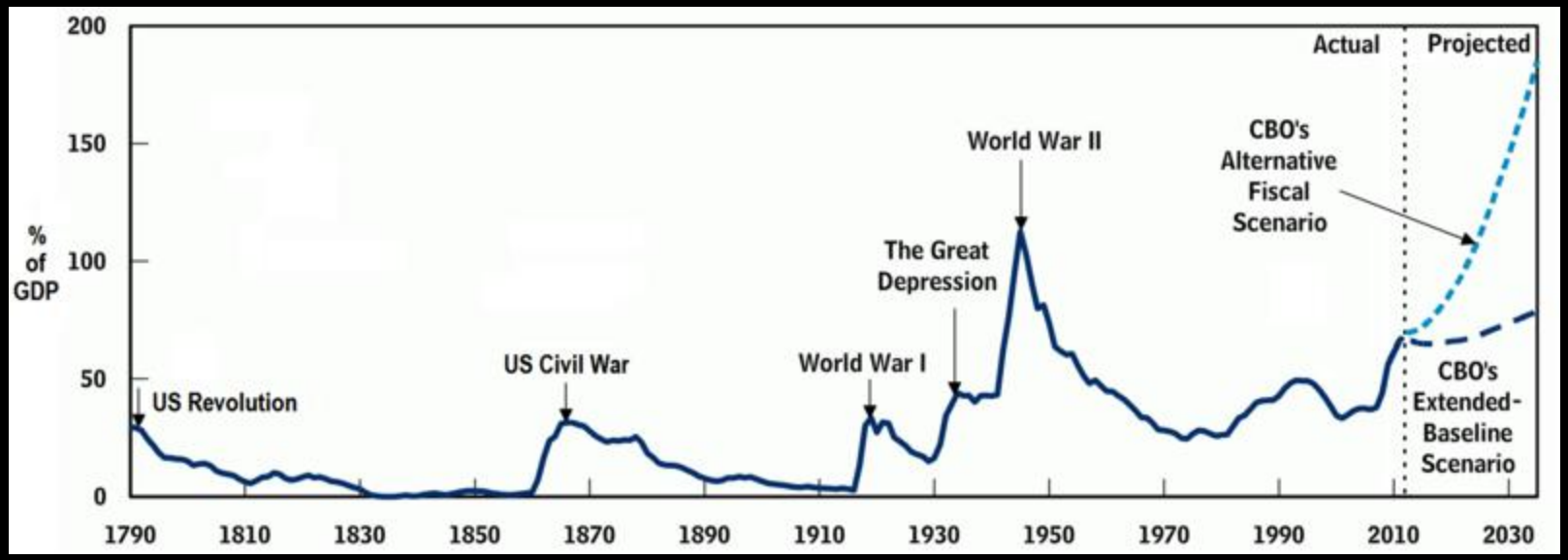
Fred V. Plapp, MD PhD

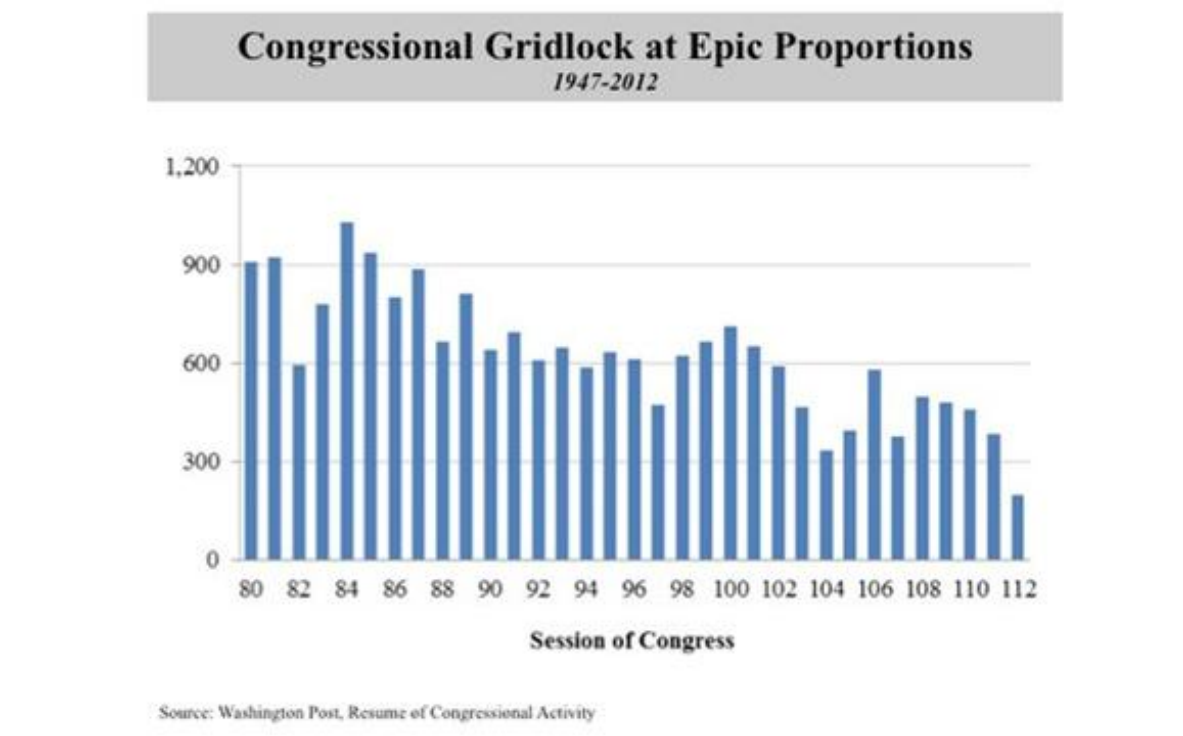
FUTURE OF TRANSFUSION MEDICINE & BLOOD BANKING

Government Debt to GDP



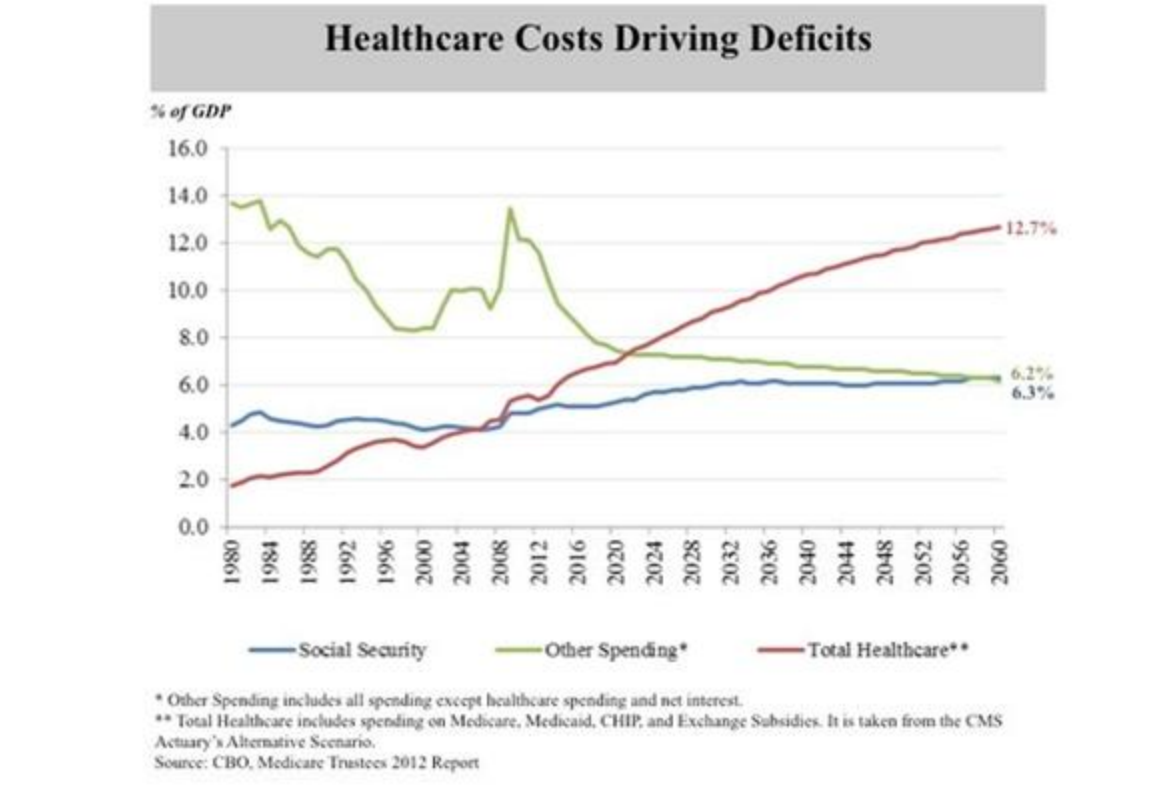
- Debt:GDP was 36% in 2007 & 73% in 2012
- Tax cuts, recession, terrorism, 2 wars, stimulus, health
- Expected to rise to >80% in next decade
- If ratio exceeds 90%, economic growth stagnates

Congressional Gridlock



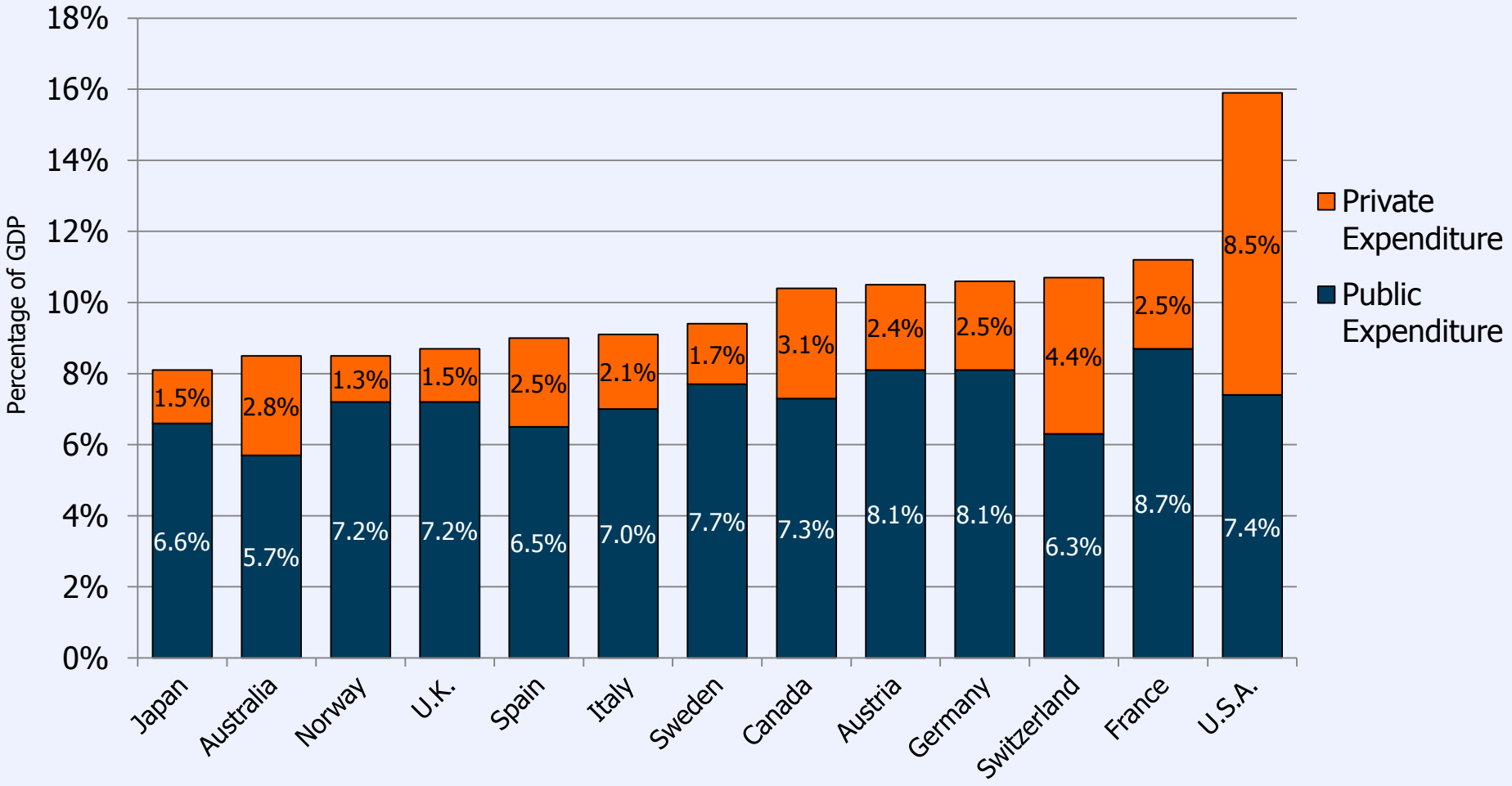
112th Congress only passed 200 laws, mostly housekeeping
One third of average of preceding 32 Congresses
Congress more polarized than any time since 1879

Healthcare Driving Debt



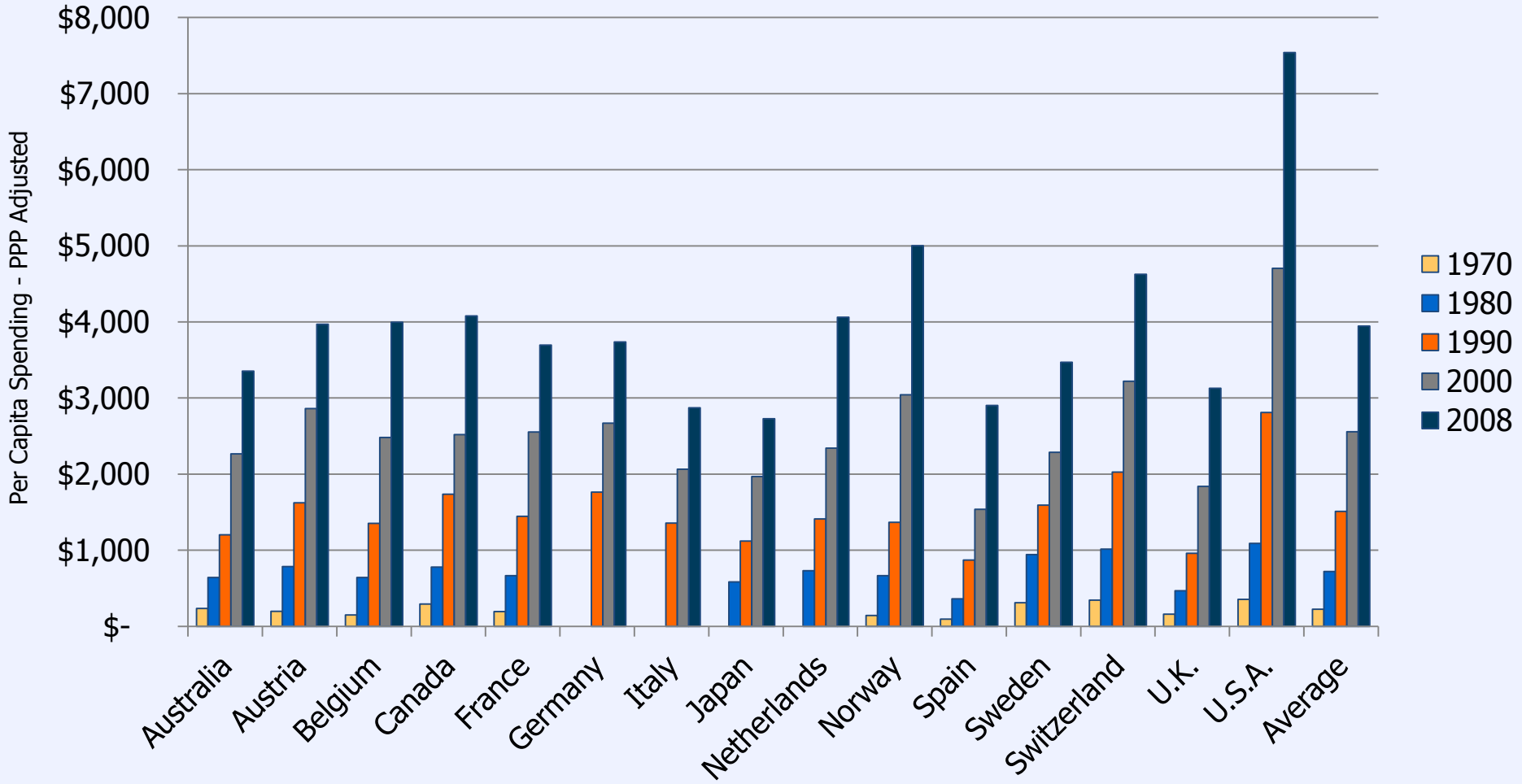
- $1.8 T in 2004, $2.8 T in 2012 & $3.4 T in 2015
- 14% of GDP in 2000, 18% in 2012, 25% by 2037
  - ACA & aging of population

Public and Private Health Expenditures as a Percentage of GDP, U.S. and Selected Countries, 2008



Source: Organisation for Economic Co-operation and Development (2010), "OECD Health Data", *OECD Health Statistics* (database). doi: 10.1787/data-00350-en (Accessed on 14 February 2011).
Notes: Data from Australia and Japan are 2007 data. Figures for Canada, Norway and Switzerland, are OECD estimates. Numbers are PPP adjusted.

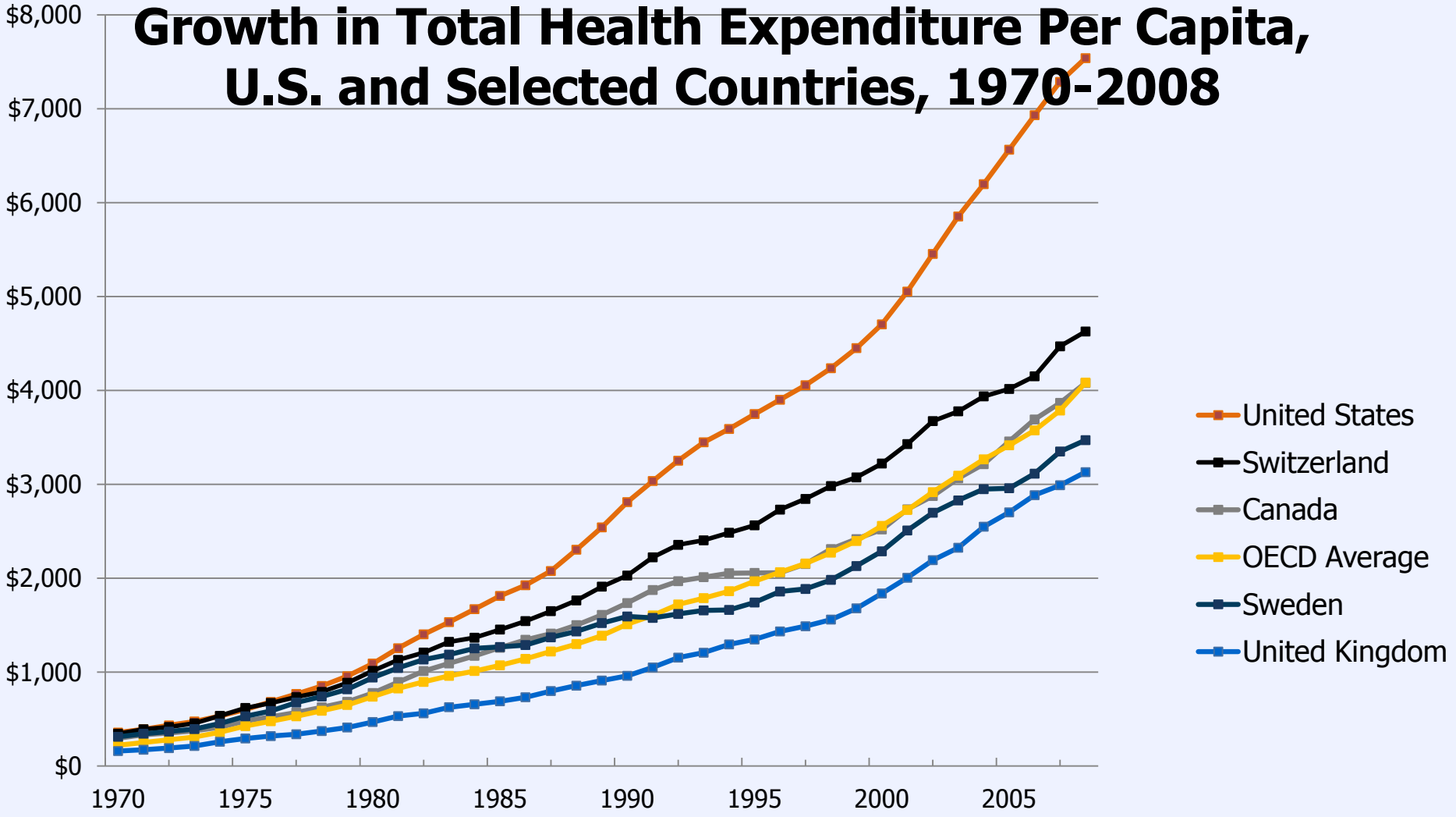
Total Health Expenditure Per Capita, U.S. and Selected Countries, 1970, 1980, 1990, 2000, 2008



Source: Organisation for Economic Co-operation and Development (2010), "OECD Health Data", *OECD Health Statistics* (database). doi: 10.1787/data-00350-en (Accessed on 14 February 2011).

Notes: Data from Australia and Japan are 2007 data. 2008 figures for Belgium, Canada, Netherlands, Norway and Switzerland, are OECD estimates. 2000 figured for Belgium are OECD estimates. Numbers are PPP adjusted. Break in Series AUS (1998); AUSTRIA(1990); BEL(2003, 2005); CAN(1995); FRA(1995); GER(1992); JAP(1995); NET(1998, 2003); NOR(1999); SPA(1999, 2003); SWE(1993, 2001); SWI(1995); UK (1997. Starting in 1993 Belgium used a different methodology.

Growth in Total Health Expenditure Per Capita, U.S. and Selected Countries, 1970-2008



Source: Organisation for Economic Co-operation and Development (2010), "OECD Health Data", *OECD Health Statistics* (database). doi: 10.1787/data-00350-en (Accessed on 14 February 2011).

Notes: Data from Australia and Japan are 2007 data. Figures for Belgium, Canada, Netherlands, Norway and Switzerland, are OECD estimates. Numbers are PPP adjusted. Break in series: CAN(1995); SWE(1993, 2001); SWI(1995); UK (1997). Numbers are PPP adjusted. Estimates for Canada and Switzerland in 2008.

Exhibit ES-1. Overall Ranking

Country Rankings	
	1.00–2.33
	2.34–4.66
	4.67–7.00

	AUS	CAN	GER	NETH	NZ	UK	US
OVERALL RANKING (2010)	3	6	4	1	5	2	7
Quality Care	4	7	5	2	1	3	6
Effective Care	2	7	6	3	5	1	4
Safe Care	6	5	3	1	4	2	7
Coordinated Care	4	5	7	2	1	3	6
Patient-Centered Care	2	5	3	6	1	7	4
Access	6.5	5	3	1	4	2	6.5
Cost-Related Problem	6	3.5	3.5	2	5	1	7
Timeliness of Care	6	7	2	1	3	4	5
Efficiency	2	6	5	3	4	1	7
Equity	4	5	3	1	6	2	7
Long, Healthy, Productive Lives	1	2	3	4	5	6	7
Health Expenditures/Capita, 2007	$3,357	$3,895	$3,588	$3,837*	$2,454	$2,992	$7,290

Note: * Estimate. Expenditures shown in $US PPP (purchasing power parity).
Source: Calculated by The Commonwealth Fund based on 2007 International Health Policy Survey; 2008 International Health Policy Survey of Sicker Adults; 2009 International Health Policy Survey of Primary Care Physicians; Commonwealth Fund Commission on a High Performance Health System National Scorecard; and Organization for Economic Cooperation and Development, OECD Health Data, 2009 (Paris: OECD, Nov. 2009).

The NEW ENGLAND JOURNAL of MEDICINE

Volume 348(26) 26 June 2003 pp 2635-2645

The Quality of Health Care Delivered To Adults In the United States

McGlynn, Elizabeth A.: Asch, Steven M.: Adams, John: Jeesey, Joan: Hicks, Jennifer: DeCristofaro, Alison: Kerr, Eve A.

BACKGROUND

We have little systematic information about the extent to which standard processes involved in healthcare—a key element of quality—are delivered in the United States.

METHODS

We telephoned a random sample of adults living in 12 metropolitan areas in the United States and…received written consent to copy their medical records…to evaluate performance on 439 indicators of quality of care for 30 acute and chronic conditions as well as preventative care…

RESULTS

Participants received 54.9 percent of recommended care.

CONCLUSIONS

The deficits we have identified in adherence to recommended processes for basic care pose serious threats to the health of the American public. Strategies to reduce these deficits are warranted.

U.S Ranks Near Bottom in 9 Health Care Areas

- Infant mortality & low birth weight
- Teenage pregnancies & STD
- Injuries & homicides
- Disability
- Prevalence of HIV & AIDS
- Drug related deaths
- Obesity & diabetes
- Heart disease
- Chronic lung disease

U.S. Health Care Quality

- Medical errors 6th leading cause of death
- 46% patients don't receive recommended care
- 33% patients harmed during hospital stay
- 20% Medicare patients readmitted w/in 30 d
- 4044 surgical never events each year
  - Wrong body part, wrong procedure, foreign object
- 20% med records not transferred in timely manner

Health Care Waste

- $2.8 Trillion spent on health care
- 1/3rd or $750 Billion is waste
  - $75 B - fraud
  - $105 B - prices set too high
  - $130 B - inefficiently delivered services
  - $190 B - excessive administrative costs
  - $210 B - unnecessary services

Estimates by Institute of Medicine & America's Health Insurance Plans

Other Causes of High Cost

- Health care lobbyists spend 3.5x more than defense/aerospace & 4x more than oil/gas
- MC can't negotiate pricing of prescription drugs, durable med goods & med devices
- Americans see more specialists
- MC physician reimbursement cuts rescinded
- Regulations – HIPAA, MU & billing
- Malpractice & defensive medicine
- Executive compensation
- Information not shared – XS testing
- Lack of pricing transparency

How to Save $910 Billion

- Adopt best care processes
- Coordinate fragmented care
- Stop overtreatment with antibiotics, surgery, intensive care at end of life
- Simplify administration, rules & billing
- Price medical products & services transparently to make a fair profit
- Decrease illegal fraud & abuse

Berwick JAMA 2012

Medicare

- Growing at unsustainable pace
  - Influx of baby boomers
    - >65 yr increase from 40M to 72M by 2030
    - >65 yr increase from 14% to 25% of population
    - 7000 baby boomers eligible each day
    - Rapid increase in over 80 population
    - Health care demand will increase
  - Working age will shrink from 63% to 57%
    - % population paying for Medicare & SS decreasing
  - Price increases for everything
  - Expensive new technologies
- Need to shift from fee for service to value based purchasing

Value Based Purchasing

- CMMS withholds % payment for DRG
- Hospitals have to earn it back by meeting quality metrics
  - Process of care measures
  - Patient satisfaction surveys
  - Readmissions
  - Mortality
  - Hospital acquired conditions
  - Patient safety
- 10% of payment will be at risk by 2017
  - Average hospital profit margin is 3%

Hospital Quality Transparency

- Hospital Consumer Assessment of Healthcare Providers & Systems (HCAHPS)
  - CMMS
  - Hospitalcompare.gov
- Leapfrog group's Hospital safety score
  - Business initiative to grade hospitals
  - Mobile app available to public
- Healthgrades Inc
  - Mortality & complication rates for 27 procedures
  - 26 measures publicly available data
- US News & World Reports
- Consumer Reports

Medicaid

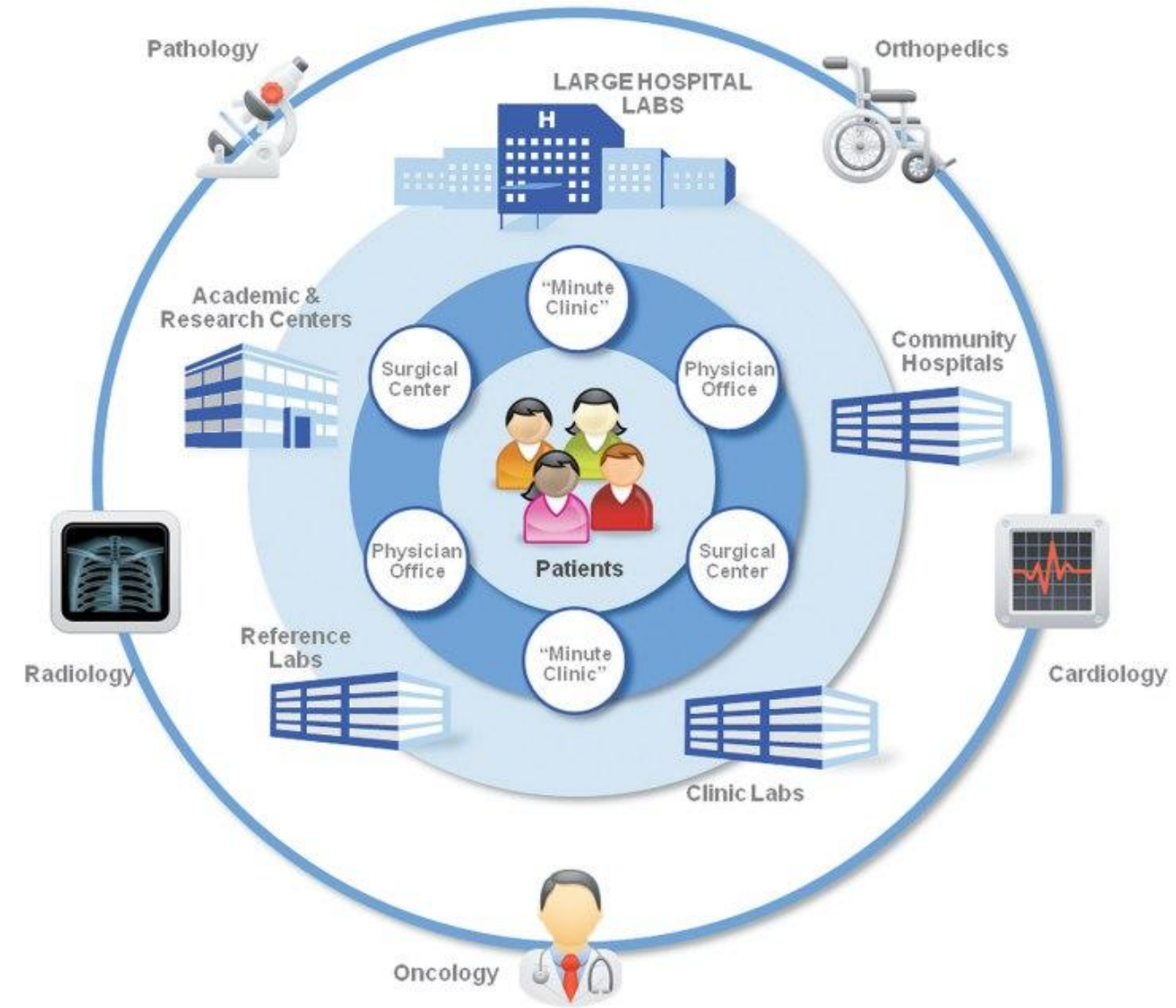
- ACA sought to extend Medicaid to additional 21 million people (138% of poverty level)
- Fed pay 100% until 2016 & 90% by 2020 for new enrollees
- Supreme court ruled expansion optional
- Hospitals agreed to lower payment rates in exchange for more insured patients
- If states don't expand Medicaid hospitals will have lower payment & same # uninsured

Affordable Care Act

- Major Goals
  - Reduce waste
  - Slow cost spiral
  - Improve quality of health
- Transition of payment model from fee for service to capitated or global model
  - Bundled payment programs for episode care
  - Global payment model for population
  - Accountable Care Organizations

Accountable Care Organizations

- Clinical integration thru continuum of care
  - 450 formed in 49 states
  - Medicare & private insurance ACOs
- Lower cost, improve quality, improve patient care experience
  - Physician ACO keeps patients out of hospital
  - Hospital ACO coordinates care
- Shared savings if meet performance and quality metrics



Hospitals

- Spending on EHR, physician employment & construction
- Emphasis on cost cutting
- Low margin businesses consolidate to survive
- Health systems merging with others
  - Gain economies of scale in IT, purchasing, billing, human resources
  - Negotiate higher reimbursement from payers
  - Coordinate care to participate in ACO
- Insurers buying hospitals
- Health systems offering own insurance plans

Laboratory Test Growth

- $70B spent on 7B tests
  - 4% Medicare expense
  - $25B overuse or overpricing
- 4-6% growth per year
  - Population growth
  - Aging population
  - More insured patients
  - Prevention emphasized
  - Esoteric tests

Laboratory Test Reimbursement

- Clinical Lab fee schedule frozen 10/12 years
- Lab CPI update permanently reduced
- Lab reimbursement cut to pay for physicians
- Decreased reimbursement for molecular Dx
- Clin lab fee schedule will be cut $10 B over 10 yr
- Medical device excise tax of 2.3%
  - Vendors will pass expense to laboratories
- Other potential cost saving targets?
  - Lab copayments for Medicare
  - Competitive bidding for lab services
  - Bundled payments

Laboratory Quality

- Variation & poor communication
- 30% tests do not provide new diagnostic information or alter therapy
- 20% patients report test results not transferred in time for appointment
- 25% tests repeated unnecessarily
- 50% patients reported failure in result notification

Other Influences on Lab

- Private insurance may adopt Medicare fee cuts
- Higher test volume due to ACA but decreased reimbursement per test
- Hospital squeeze means less capital for lab
- Lab must support ACO & reduce unnecessary testing
- Patients with HSA will seek low cost lab
  - Will demand price transparency
  - Immediate access to lab results

Education Anxiety

- Quality of U.S. education
  - 25th in math, 17th in science & 14th in reading
  - 77% HS graduation rate (rank 22/27 countries)
  - <40% college freshmen graduate in 4 years
    - 57% complete degree in 6 years
  - Only 5% bachelor degrees in math & science
  - Grade inflation (average GPA risen from 2.5 to 3.1)
- Student debt has doubled in last 15 years
  - $1 Trillion in student debt
  - Average debt is $26,000 for undergraduate
  - Two thirds take out loans & 30% default

More Education Anxiety

- Universities spending beyond their means
  - Driven by need to compete for college rankings
  - Student loans, teacher pensions & benefits
  - Campus building & infrastructure boom
  - Spend more on facilities & administration than instruction
- States cutting back on financial aid
- College graduates have fewer high paying job prospects

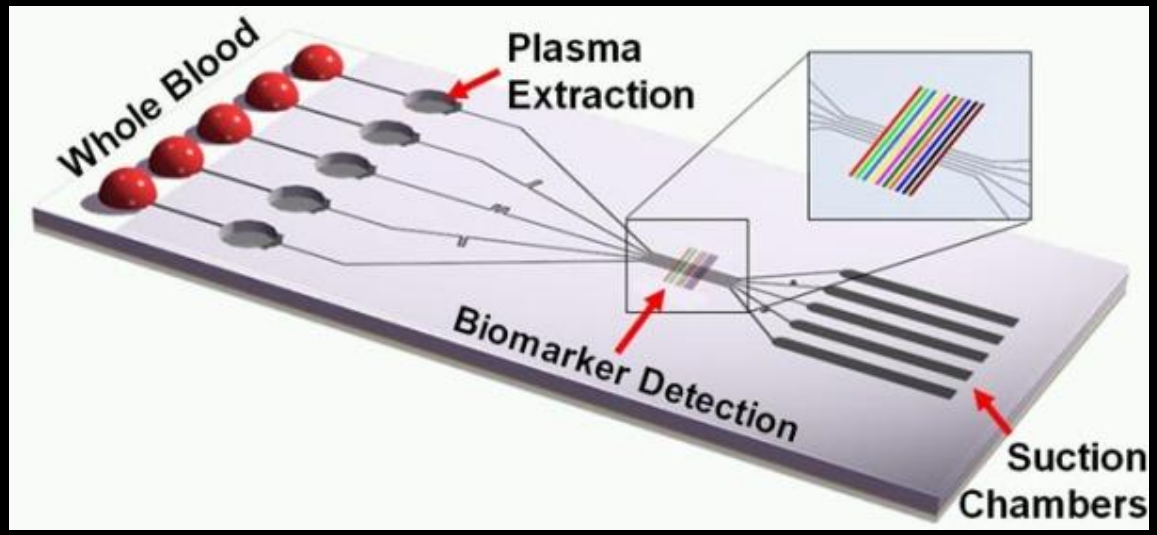
Education Must Change

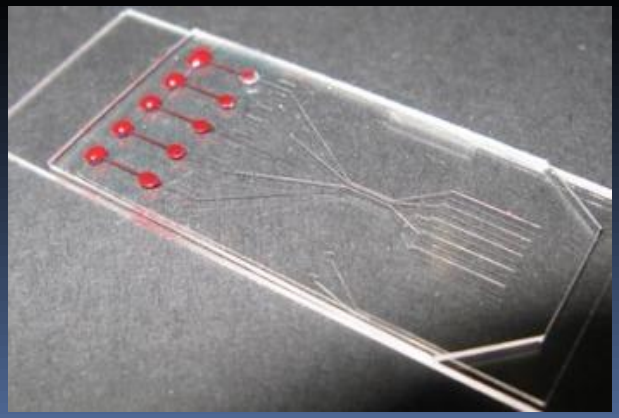
- Colleges must lower costs
- Time required for degree must decrease
  - Measure competency not classroom hours
- Time spent on campus will decrease
  - Less need for classrooms and campus facilities
  - Smaller & more productive teaching staff
- Increased use of online education
  - 6M students took at least 1 online course in 2011

Technological Revolution

- Driverless cars
- Robotics
- Dr. Google - Online medical information
- Implantable or wearable biosensors
- Home biosensors
- Medical tricorder
- QR codes for medical records
- Wireless lab on a chip

Lab on a Chip

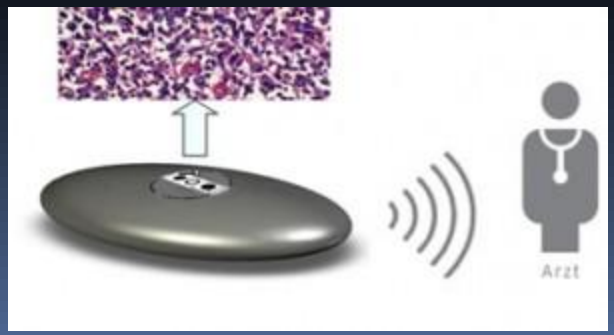

Whole Blood
Plasma Extraction
Biomarker Detection
Suction Chambers



Mobile Health

- Hyperconnected world
  - Smart phones, pads, high speed bandwidth, wireless, Skype, cloud computing, super computers, big data, social media
- 6 billion active smart phones worldwide
  - Smartphone or pad will become hub of medicine
- 140 million health apps downloaded by 2016
  - Manage chronic illness & accountable care
  - Move health from hospital to home
  - Increase transparency

Examples of Smart Phone Lab



Personalized Medicine

- Whole genome sequencing
  - Genetic profile will become routine test
  - Will replace newborn screening
  - Mutations, disease risks, Rx response
- Multiplex microarrays
- Proteomics
  - MALDI-TOF mass spectrometry
  - Silico-peptide microarray
- Metabolomics

Transparency

- Lack of price transparency
  - Hip replacement varies $11k to $125k in U.S.
  - CBC varies from $11 to $157 in midwest
- Payment transparency
  - Negotiated discounts
  - Out of pocket expenses
  - Aetna & UHC apps available for members
- Medical record accessibility
  - Personal EMR apps
  - QR code storage
  - Not prohibited by HIPPA
- Patients will demand total transparency

February 26, 2013

How Will These Forces Affect Blood Center Operations?

Increased Demand for Blood

- Aging of population
  - 10% of >65 yr are anemic
  - 45% RBCs go to >65 yr
- More anticoagulant and antiplatelet medications
- Population growth
  - More disease
  - More MVA
  - More violence

Decreased Demand for Blood

- Another recession
  - RBC use fell 5% 2008-2011
- Health care reform
  - Cost containment pressure
  - ACO & blood management
  - High deductible insurance
- Better technology
  - Minimally invasive surgery
  - Endovascular repair
  - Safer anticoag & antiplatelet
  - Less toxic chemotherapy

Decreased Blood Collections

- Aging of Donor Base
  - Donors between 24-49 yr less likely to donate
  - Relying more on repeat donors >50 yr
    - Aging & illness will limit donations
    - Will switch from donors to recipients
- Additional donor screening tests
  - Higher deferral rate
- More rigorous blood donor safety standards
  - Increase Hgb standard to 13.0 or 13.5 g/dL
  - Limit donations of 16 yr old females
  - Increased inter-donation interval from 56 to 84 d

Blood Inventory Challenges

- Demand for fresh blood
  - 18 of 23 studies suggest adverse effects of older blood
  - 3 major clinical trials; results in 2-4 years
  - CTS & critical care may demand <14 d RBCs
- More difficult supply chain management
  - Younger RBCs reserved for critical patients
  - Shelf life reduced from 42 to 21 days?
  - Better preservative or rejuvenation solutions?
    - Apply proteomics & metabolomics to storage lesion

Blood Inventory Challenges

- Platelet wastage
  - Extend storage time @ RT by eliminating risk of bacterial contamination
    - MALDI-TOF for rapid bacterial detection
    - Pathogen inactivation
  - Use metabolomics to block cold storage lesion
    - Store platelets in cold for extended periods
  - Thrombosomes
    - Lyophilized platelets stored at RT

Blood Safety Policy

- Current policy is blood safety at any cost
  - More screening for increasingly rare agents
  - Well intentioned but economically irrational
    - HTLV screening costs $59M per QALY
- Decision to screen often based on availability of approved test
  - Test availability guided by IVD market & profit
- We will need to rethink this policy as money gets tighter!

More Transfusion Transparency

- 1 in 7 hospitalized patients transfused
- Much variability in transfusion practice
  - CABG blood use varies from 50 to 100%
- U.S. Biovigilance Network only tracks complications of donation & transfusion
- Need national database of all transfusions
  - Assess efficacy, outcomes & variability
- Price transparency
  - Process fee is 30% of actual cost of transfusion

Need for Consolidation

- Slim operating margins of 1-2%
- Costs rising more than revenue
  - Compliance costs are 30% of total expenditures
  - Donor recruitment, collection, testing, shipping costs
- Demand for transfusion is slowing
  - Decreased revenue from voluntary donations
- Geographic variability in supply & demand
  - Lack alignment collection & hospital utilization
- Ability to serve mega-merged health systems
  - Competitive bidding in future?

Consolidation Activity

- ARC has consolidated testing
- 3 largest blood centers in Florida merged
  - OneBlood Inc
  - 200 hospitals served
- Blood Center of Wisconsin
  - Merged with Heartland Blood Center in Chicago
  - Serve 103 hospitals in IL,IN & WI

Alternative Model

- Current system collects blood, tests donors & then has to defer donor & quarantine unit
- Future technology would allow POC testing
  - Masimo transcutaneous hemoglobin
  - Lab on a Chip donor screening tests in real time
  - Defer immediately
  - Cut out waste of collecting & processing unacceptable units

How Will These Forces Affect Transfusion Services?

- Cost & patient safety pressure to decrease transfusions
  - More emphasis on blood management programs
- Public disclosure of transfusion volume, # RBC per patient, transfusion reactions, mistypes, cost
  - Hospital Compare already includes mismatches
  - Will hospital acquired infections be linked to Tx?
  - Hospitals rewarded for lower transfusion rates?

Shift to Outpatient Transfusion

- ACOs will shift care to outpatient setting
  - Blood center processing fees are higher than Medicare outpatient reimbursement
  - Cost pressure to avoid transfusion
    - Screen all patients for anemia
      - Noninvasive continuous Hgb biosensor
        - Avoid iatrogenic anemia
    - Upload wirelessly to smart phone & BM team
    - Anemia management through continuum of care

Transfusion Service Supply Chain Management using Amazon Model

- Blood centers ultimately merge into dozen large regional centers
- Cloud computing with national DB of blood types, genotypes, special processing, etc
- Tx service orders blood online from whichever center has best pricing & inventory
  - Groupon-like incentives to unload short dates
- Antigen matched blood ordered based on genomics or proteomics
- Blood delivered same day by drone or next day by Google driverless vehicle

Transfusion Service Compatibility Testing

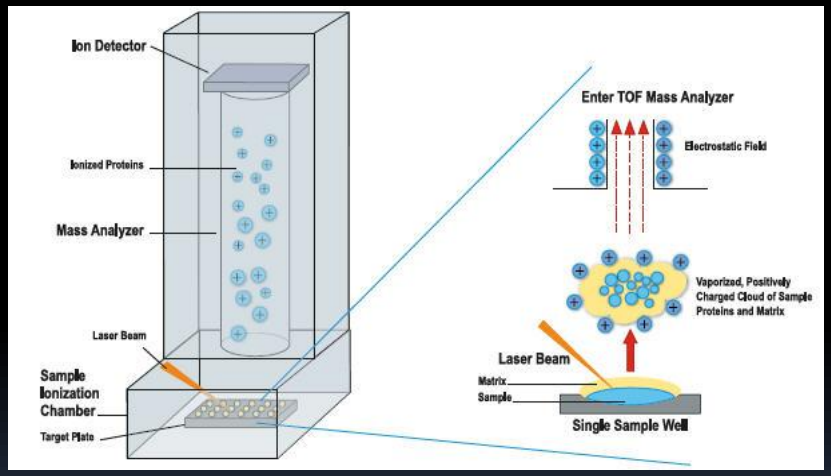
- Replace antigen/antibody testing with genomics & proteomics
  - MALDI-TOF for RBC antigen typing
  - Whole genome sequencing for RBC genotype
- Transfuse only antigen matched RBCs
- Eventually eliminate positive antibody screens

MALDI-TOF Advantages

- Microbiology
  - ID 1600 species
  - 20 Ribosomal proteins
  - 10 uL sample size
  - 1 minute analysis time
  - <$1 reagent cost/test
- Blood Typing
  - ID RBC antigens
  - ID RBC antibodies

MALDI-TOF Mass Spectrometry

Matrix Assisted Laser Desorption Ionization Time of Flight

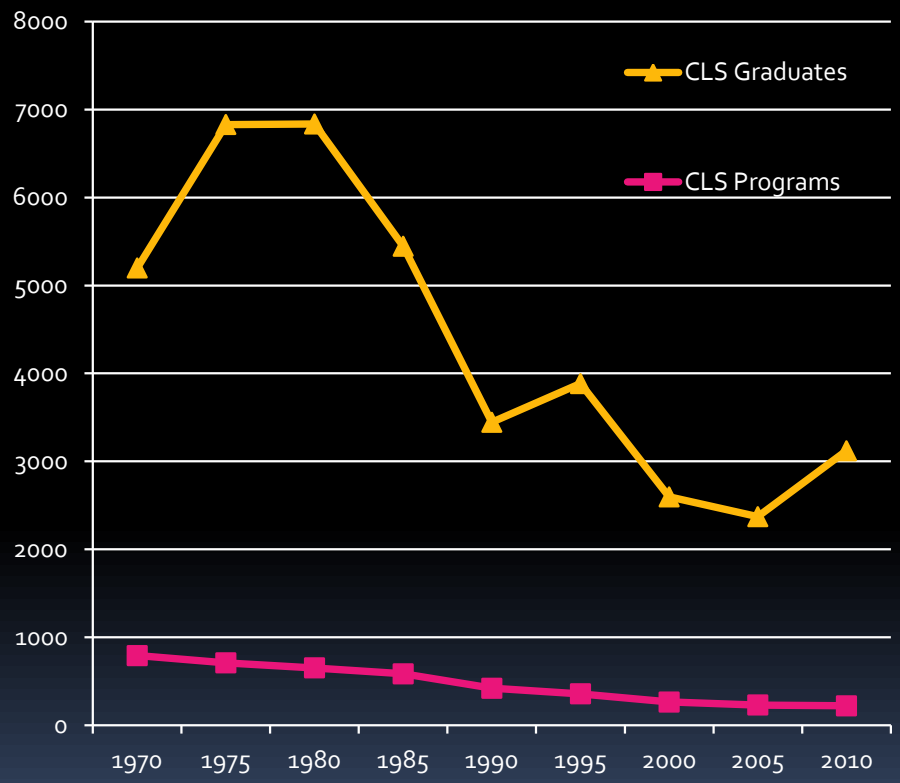


- Add whole cells
- Add organic matrix
- Ionize & vaporize proteins with laser
- Apply voltage gradient
- Time of Flight tube
- Proteins separate by mass – smallest travel fastest
- Mass spectrum generated
- Protein profile obtained
- Compare to protein DB

Transfusion Service Prenatal Workup

- Eventually will know complete gene sequence of all newborns
  - Maternal serum screening replaced by whole genome sequencing of cell free DNA
    - Already used for RhD genotyping
  - Newborn screening will be replaced by WGS
- Genotype contains most RBC genes
- Info available in community HIE
  - Available to any BB or transfusion service
- Transfuse only antigen matched blood
- Eliminate alloimmunization

Education of MLS



6500 to 1800 to 2900

791 to 220 programs

Blood Banker Education

- Transfusion services and blood centers will need more lab specialists in proteomics, genomics, big data & mhealth
- Adopt MOOC model of education
- Create MOOC blood bank courses

Massive Online Open Courses

- Democratization of education
  - Universal access to low cost, high quality
- Download world's best lectures on any topic
- Thousands to millions students per course
- Exams monitored by webcam & mouse clicks
- Learning outcomes data analysis
- More educator feedback
  - Hire only best teachers, not necessarily professors
- Certificates of completions for nominal fee
- Universities accept outside credits
- Professors & text books may become obsolete

The Future will be Exciting!