The challenges raised - in the era of economic crisis - for research in primary care

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Biomedical Research in an Age of Austerity

- Research as a source of added cost without commensurate clinical value

- Drug and device charges and service fees are borne by insurers and patients, whereas benefits accrue to companies, hospitals, and physicians

- Proven, existing, low-cost preventive and public health measures are preferable in an age of austerity

Moses III et al. JAMA 2012; N Engl J Med. 2010;363(7):601-603

First challenge: funding for research is declining

- Research is a long-term investment, with discoveries requiring 15 to 25 years to mature to clinical application, an interval that has been stable for a century

- Need for making explicit the connection between health and new discovery

Moses III et al. JAMA 2012

Table. Estimated Reduction in Budget Attributable to Sequestration for Select Health and Science Agencies[a]

Agency	Sequester Amount, $ in Billions	Sequester Percentage Range[b]
Centers for Medicare & Medicaid Services[c]	11.9	2.0-8.2
National Institutes of Health	2.5	7.6-8.2
National Aeronautics and Space Administration	1.5	7.6-8.2
Environmental Protection Agency	0.7	7.6-8.2
Health Resources and Services Administration[d]	0.6	2.0-8.2
National Science Foundation	0.6	7.6-9.4
Centers for Disease Control and Prevention	0.5	7.6-10.0
National Oceanic and Atmospheric Administration	0.4	7.6-8.2
Food and Drug Administration	0.3	7.6-8.2
Substance Abuse and Mental Health Services Administration	0.3	8.2
United States Geological Survey	0.1	8.2
Department of Veterans Affairs[e]	0	0

[a] Adapted from OMB Report Pursuant to the Sequestration Transparency Act of 2012 (Pub L No. 112-155).[1]
[b] The resulting sequestration percentage is expressed as a range because each agency's budget varies in the amount of defense vs nondefense spending and discretionary vs mandatory spending.
[c] Most of the Medicare nonadministrative budget is limited to 2% sequestration.
[d] Sequestration on a small proportion of Health Resources and Services Administration spending is limited to 2.0%.
[e] The Department of Veterans Affairs was generally exempt from sequestration.

Moses III et al. JAMA 2012

Funding allocation

- Biologically based research **vs.** research related to health service delivery, information technology, and clinical effectiveness

The current National Institutes of Health (NIH) Roadmap for Medical Research includes 2 major research laboratories (bench and bedside) and 2 translational steps (T1 and T2)

Westfall, J. M. et al. JAMA 2007;297:403-6
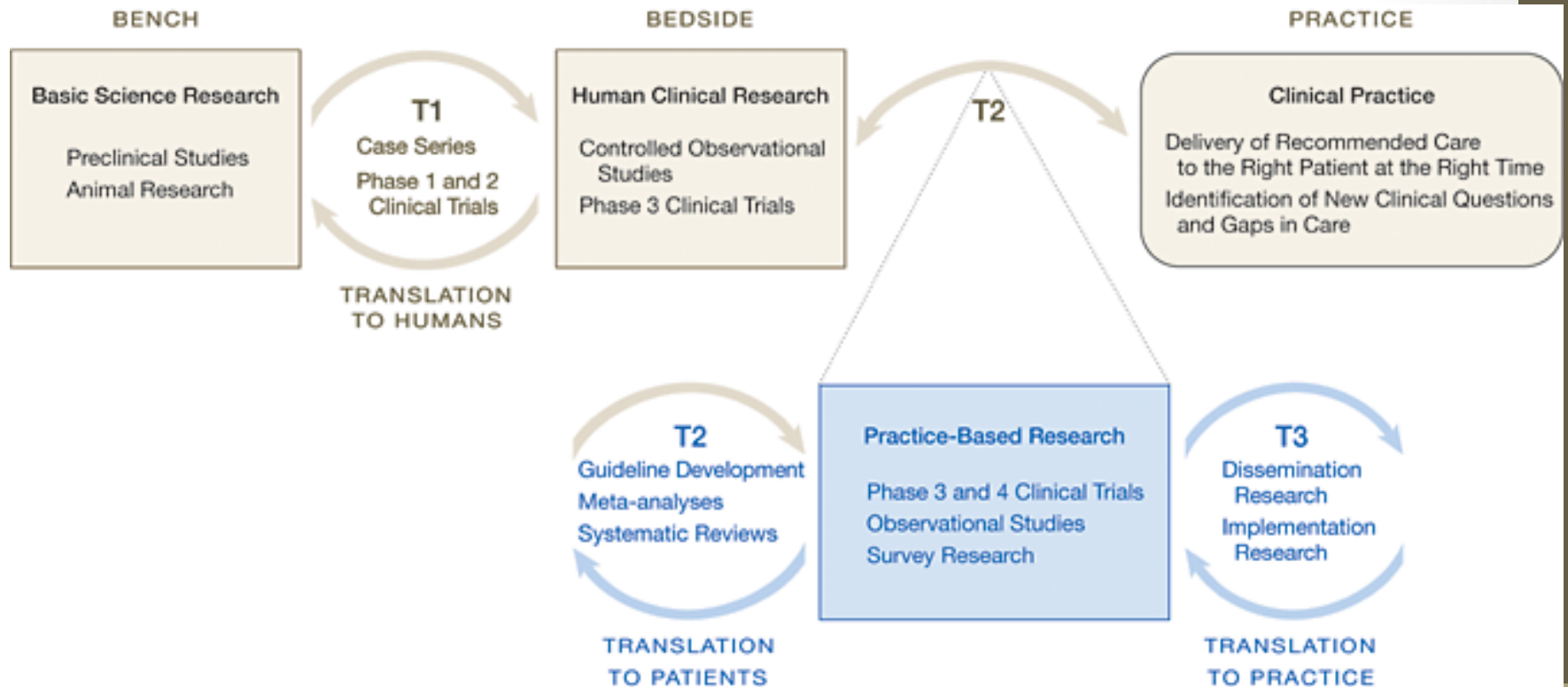
Why translation to practice research in step 3 (T3) is important?

- "Americans only receive 50% of the recommended preventive, acute, and long-term health care."

  McGlynn EA, et al. N Engl J Med. 2003;348(26):2635–2645

- "The overuse of inefficient or potentially harmful interventions is also an important concern."

  Chalmers I et al. Lancet. 2006;367(9509):449–450

What are the purposes for T3 in primary care?

- Identify barriers in everyday health care that increase the gap between evidence based-medicine and practice

- Evaluate the effectiveness of interventions and strategies in primary care settings

- Assess whether specific changes in health care system improve the number of patients who receive evidence-based care

Evidence based medicine

- The conscientious, explicit and judicious use of current best research evidence in making decisions about the care of individual patients

BMJ 1996, 312:71–2

Evidence based products

- Clinical practice guidelines when developed by multidisciplinary teams including methodologists, clinicians, other relevant professional groups, and patients; and when there is use of transparent, well-established processes

Implementation of clinical practice guidelines

- Barriers: knowledge, attitude, behavior

Why Don't Physicians Follow Clinical Practice Guidelines?: A Framework for Improvement

Barriers due to behavior: environmental factors
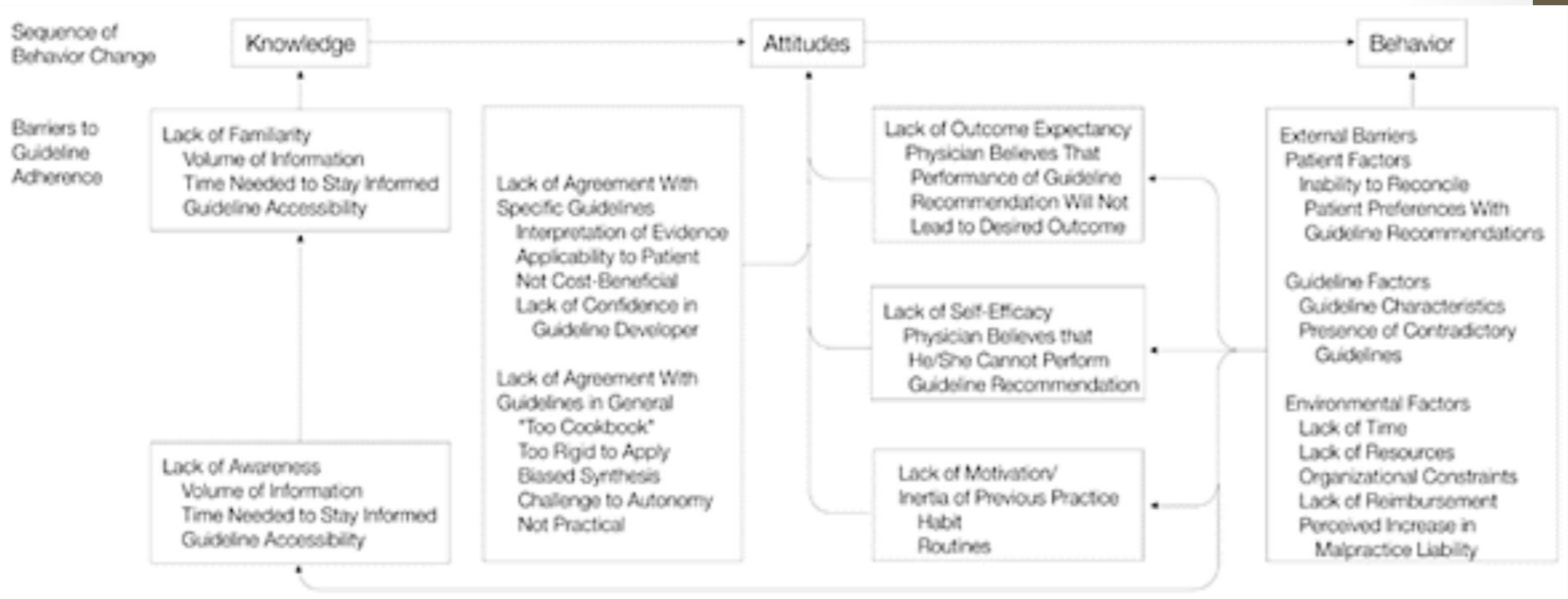
- Lack of resources

JAMA 1999, 282(15):1458-1465

Challenges

- Participation of health care professionals who are charged with implementation in primary care (general practitioners, practice nurses, etc) in research activities

- Research to ensure fidelity: How can we ensure the delivery of an intervention as intended?

- Research to optimize patient adherence: What strategies support patient adherence? What strategies promote shared decision-making?

Effectiveness and primary care – an example

- Prevention of coronary artery disease mortality

- Known risk factors (e.g., hyperlipidemia, hypertension, obesity, diabetes, smoking, lack of physical exercise)

- Intervention strategies: diet, life-style modifications, behavior change

Contribution to the decline of coronary heart disease mortality of risk factor control, medical treatments, and interventions in the US from 1968 to 2000 (*Franco et al. AJM 2011;124:95-102*)
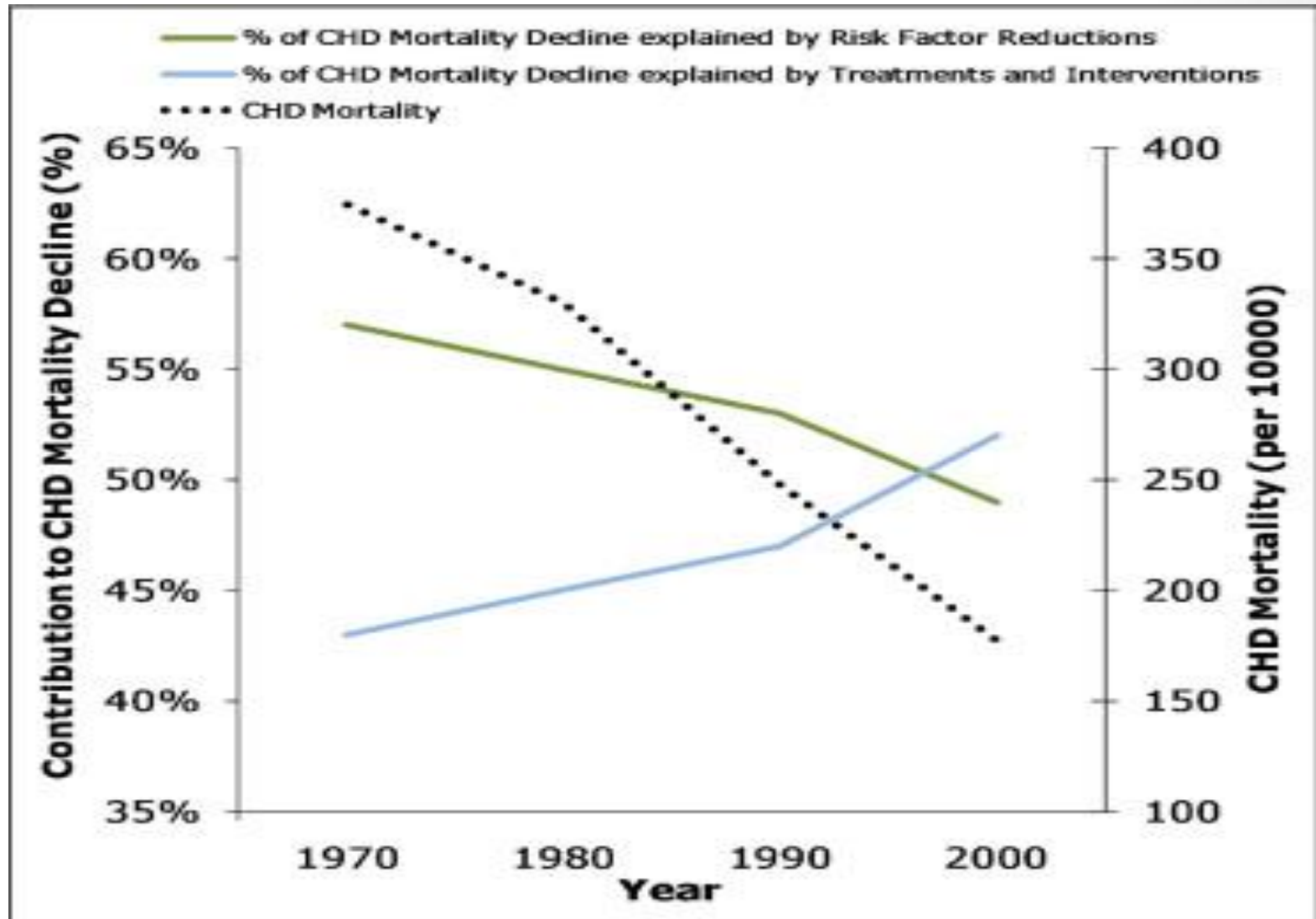
Effective interventions…

- Substantial health gains: reduce mortality

- Health gains due to medical interventions but not due to primary prevention

- What is the role of primary care?

Primordial prevention is yet to be achieved...

- It depends mainly on primary prevention; not on medical interventions

- Absence of risk factors throughout the life of an individual

Stamler J et al. Prev Med. 1999;29(6 Pt 2):S130-S135

Primordial mortality/disability

- 40% is attributed to behavior

- 15% is attributed to social factors

- 10% is attributed to medical interventions

Barnes KA et al. NEJM 2012; 367;891-3

When primary care is considered effective in reducing coronary artery disease mortality?

- When it can reduce primordial mortality/disability beyond this 10% that medical treatments and interventions achieve in patients who already have developed a coronary event

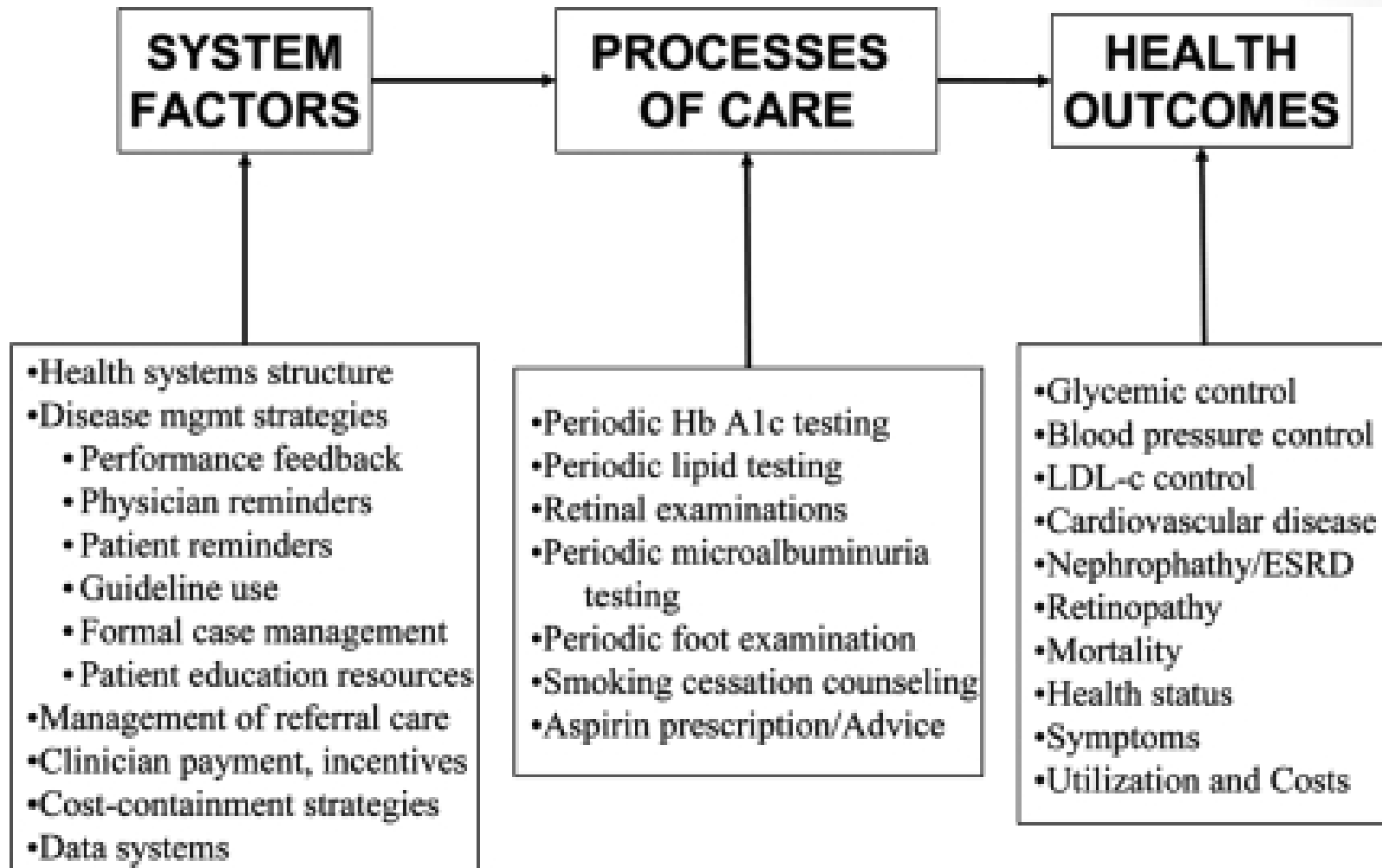*Barnes KA et al. NEJM 2012; 367;891-3*

Challenges

- Design clinical trials that are applicable to primary care

- Increase the external validity of good quality clinical trials for generalizing their results in primary care

- Identify important clinical outcomes to evaluate interventions in primary care

- Evaluate patient reported outcomes /compassionate centered outcomes for the population in primary care

Health system change: the example of type 2 diabetes

- The Translating Research Into Action for Diabetes (TRIAD) study

- Centers for Disease Control and Prevention and the National Institute of Diabetes and Digestive and Kidney Diseases

- multicenter, prospective observational study

- 68 provider groups to deliver primary and specialty care to more than 180.000 diabetic enrollees in 1998

What strategies can affect delivery of care and health outcomes?

| SYSTEM FACTORS | → | PROCESSES OF CARE | → | HEALTH OUTCOMES |

SYSTEM FACTORS
- Health systems structure
- Disease mgmt strategies
  - Performance feedback
  - Physician reminders
  - Patient reminders
  - Guideline use
  - Formal case management
  - Patient education resources
- Management of referral care
- Clinician payment, incentives
- Cost-containment strategies
- Data systems

PROCESSES OF CARE
- Periodic Hb A1c testing
- Periodic lipid testing
- Retinal examinations
- Periodic microalbuminuria testing
- Periodic foot examination
- Smoking cessation counseling
- Aspirin prescription/Advice

HEALTH OUTCOMES
- Glycemic control
- Blood pressure control
- LDL-c control
- Cardiovascular disease
- Nephrophathy/ESRD
- Retinopathy
- Mortality
- Health status
- Symptoms
- Utilization and Costs

Lack of association of system-level factors with delivery of health care processes and patient outcomes

- "More integrated health systems - those implementing more intensive disease management strategies and using financial incentives related to quality - achieved higher levels of diabetes care processes."

- "However, these strategies were not associated with better intermediate outcomes."

The TRIAD study group. Diabetes Care. 2010(33):940-7; Renders CM et al., Diabetes Care 2001;24:1821–33; Landon BE et al., N Engl J Med 2007;356:921–934

In 2005

- Cardiovascular Disease (CVD) Risk Survey focused on patient-level determinants of risk factor control for blood pressure, HbA_{1C}, and LDL cholesterol

- Telephone or mail

- Patients in "good control" (HbA_{1C} <8%, LDL <130 mg/dl, and systolic blood pressure [SBP] <140 mmHg) **vs.** patients in "poor control" of at least two risk factors

Patients' collected data

- perceptions of risks
- self-efficacy
- communication with their providers
- access to care
- cost barriers
- self-reported adherence to a regimen of prescribed medications
- reasons for non-adherence
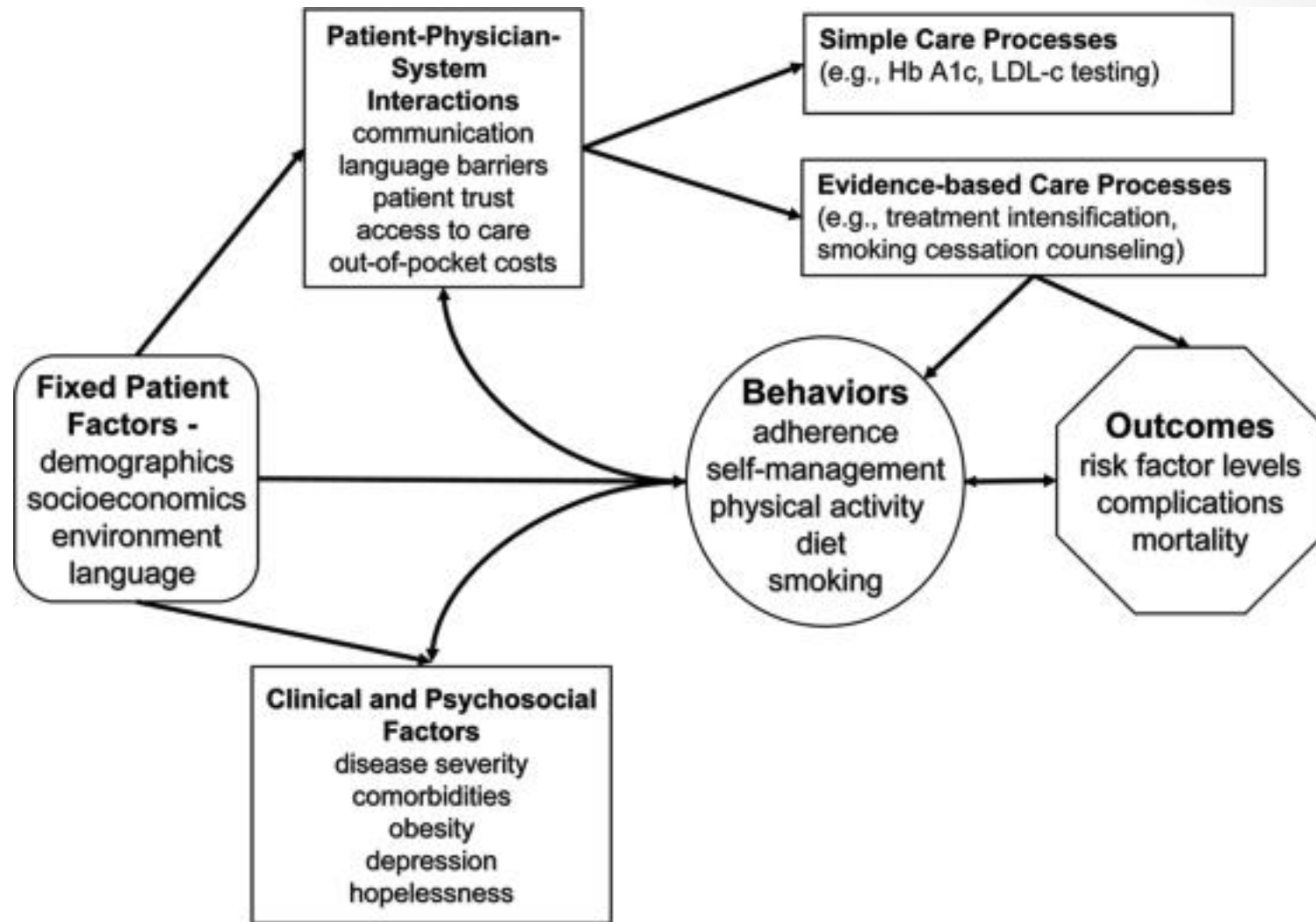
What has TRIAD showed?

- Numerous associations of patient-level sociodemographic, psychosocial, and behavioral factors with both self-care and intermediate outcomes

- Next generation of system-level interventions should be better tailored to meet the needs of diabetic subpopulations

System-level interventions should address disparities

- African Americans and patients of lower socioeconomic status had much poorer control for CVD risk factors, higher rates of obesity, cigarette smoking, undiagnosed and untreated depression, greater sensitivity to out-of-pocket costs, lower trust in physicians, and adverse neighborhood environments

Holman RR et al., N Engl J Med 2008;359:1577-89

Comparative effectiveness of approaches to implement the Chronic Care Model for Type 2 Diabetes

- Very limited evidence

- Care management improves process measures and also improves surrogate outcomes to a trivial extent

- Paucity of data on patient-important outcomes

Egginton JS, et al. MC Health Services Research 2012;12:72

Challenges

- Large scale data: large cohorts, electronic medical records, surveys, qualitative research

- Meta-analysis of individual patient data (consortia)

- Systematic reviews, overviews

- Comparative effectiveness of different system-level interventions to address disparities, multimorbidity, and the appearance of new diseases (e.g., infections)

Evidence based practice
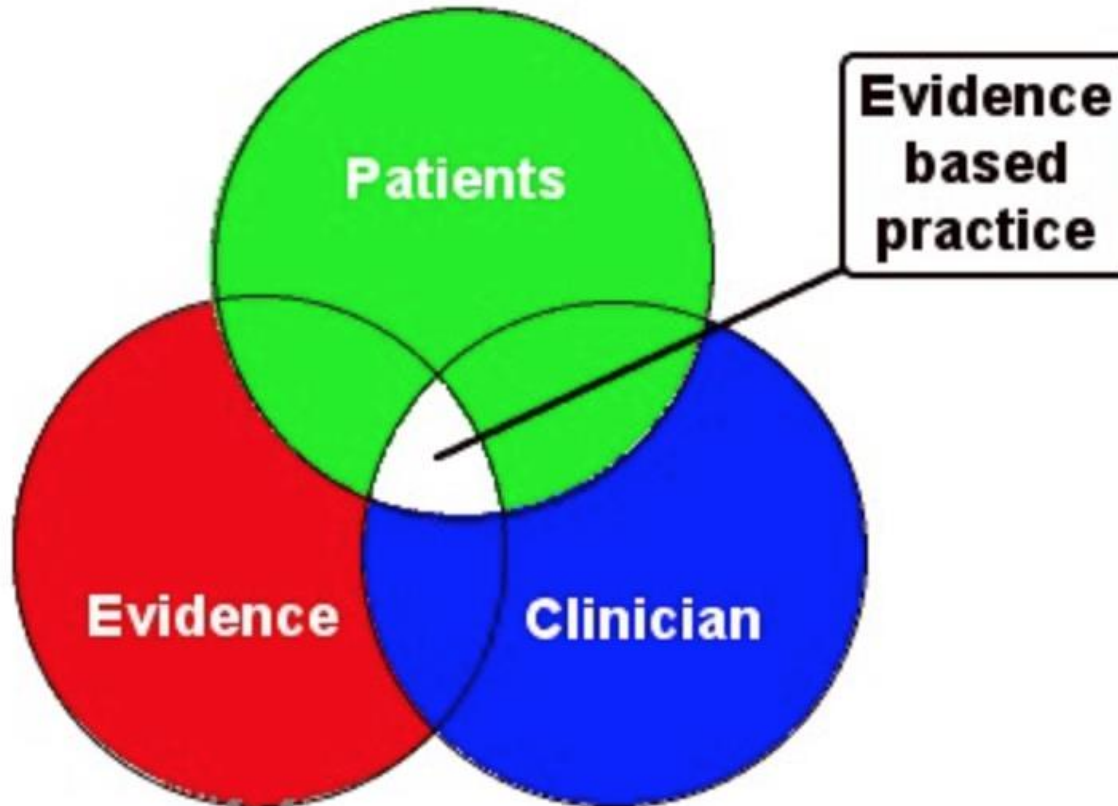
Challenge: medical decision-making in primary care during austerity

- Develop cost-effectiveness analytic models

- Develop cost-utility analytic models: consider cost and patients' priorities and preferences under the new condition of economic recession

Translational research in step 3

- …requires mastery of the "implementation science" of fielding and evaluating interventions in real world settings and of the disciplines that inform the design of those interventions, such as clinical epidemiology and evidence synthesis, communication theory, behavioral science, public policy, financing, organizational theory, system redesign, informatics, and mixed methods/qualitative research.

- …struggles more with human behavior and organizational inertia, infrastructure and resource constraints, and the messiness of proving the effectiveness of "moving targets" under conditions that investigators cannot fully control.
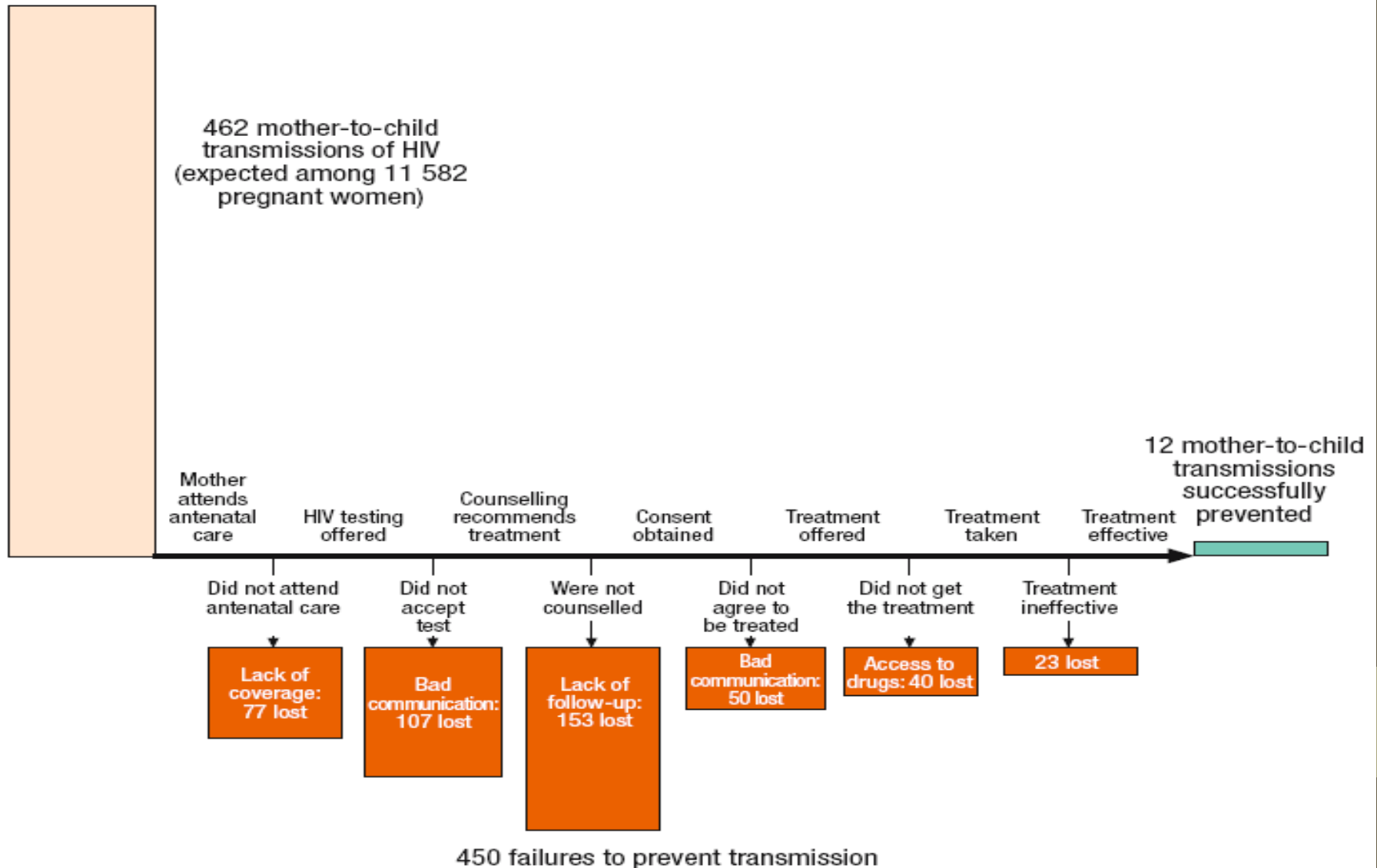
Real world effectiveness

- Population-level outcomes, such as morbidity, mortality, and disability, at the population or at health-care-system level

"The true end point of translational research is not simply institutionalizing effective interventions but improving population health."

Ogilvie D, et al. BMC Public Health 2009, 9:116

Lost opportunities
HIV mother to child transmissions, Ivory Coast (République de Côte d'Ivoire), Africa (*World Aids Day Meeting, Antwerp, Belgium, 2000*)

462 mother-to-child transmissions of HIV (expected among 11 582 pregnant women)

12 mother-to-child transmissions successfully prevented

Mother attends antenatal care — HIV testing offered — Counselling recommends treatment — Consent obtained — Treatment offered — Treatment taken — Treatment effective

Did not attend antenatal care → Lack of coverage: 77 lost

Did not accept test → Bad communication: 107 lost

Were not counselled → Lack of follow-up: 153 lost

Did not agree to be treated → Bad communication: 50 lost

Did not get the treatment → Access to drugs: 40 lost

Treatment ineffective → 23 lost

450 failures to prevent transmission

Actual translation is much more complicated

- private investments in research and development
- policy and legal frameworks
- oversight and regulation
- product marketing
- coverage and reimbursements
- consumer advocacy
- provider awareness
- consumer access

Khoury MJ, et al. Am J Epidemiol. 2010;172:517–524

The paradox of being optimistic in the middle of a crisis

- "It is important to see every crisis as an opportunity in disguise"

Winston Churchill, 1874-1965

Rescue plan?

- Economic recession could provide the impetus for changes that would reduce uncertainty and bolster investment to implementation research