Under-Diagnosis and Under-Treatment of Osteoporosis and the Importance of Outcomes and Effectiveness Research

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COERE

Disclosures

- Sources of Research Funding:
  - NIH (NIAMS, NCATS, NCMRR), AHRQ, PCORI
  - Industry: Amgen, Mereo, Radius
- Past president, Board of Trustee, National Osteoporosis Foundation
- Consultant: Amgen, Radius, Roche
- Royalties: UpToDate

Overview

- How bad is the problem?
- What is the possible impact?
- How do we define quality?
- What has been tried to improve practice in osteoporosis?
  - Provider-directed interventions
  - Patient-directed interventions
  - System interventions

The New York Times

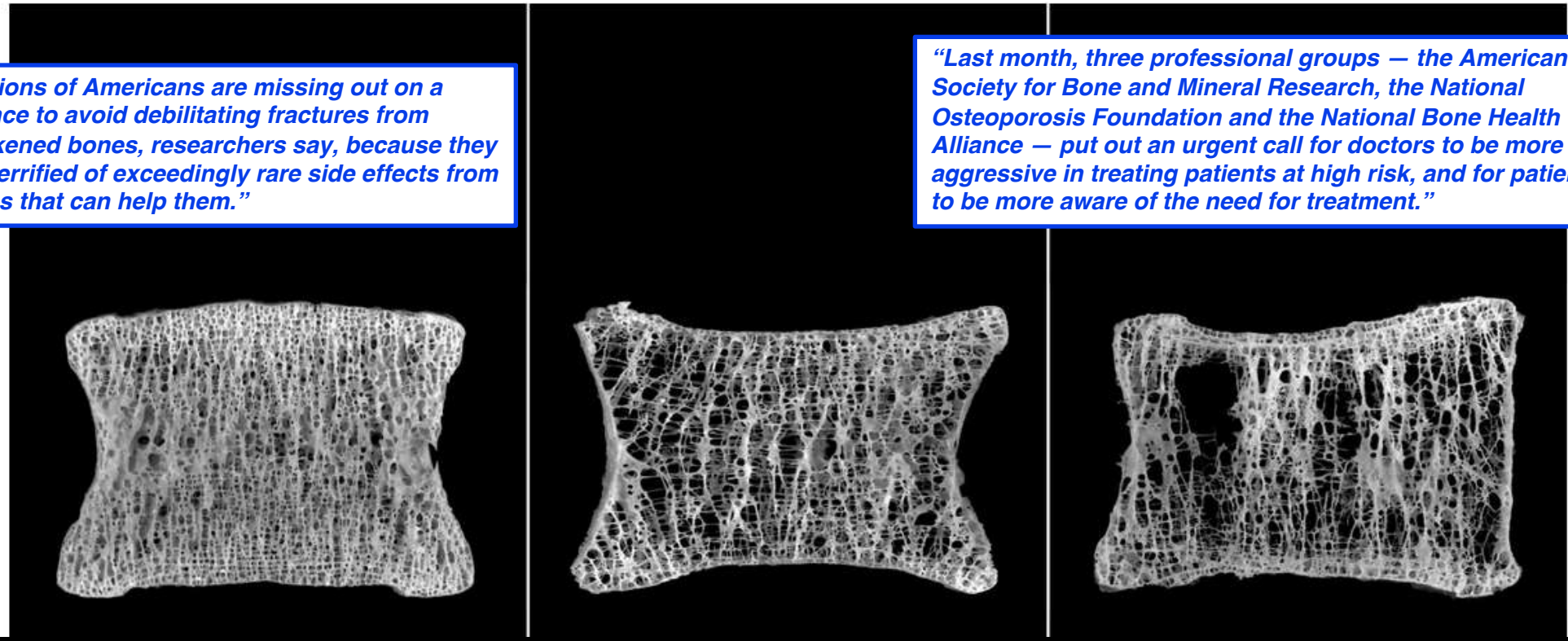
HEALTH

Fearing Drugs' Rare Side Effects, Millions Take Their Chances With Osteoporosis

By GINA KOLATA JUNE 1, 2016

"Millions of Americans are missing out on a chance to avoid debilitating fractures from weakened bones, researchers say, because they are terrified of exceedingly rare side effects from drugs that can help them."

"Last month, three professional groups — the American Society for Bone and Mineral Research, the National Osteoporosis Foundation and the National Bone Health Alliance — put out an urgent call for doctors to be more aggressive in treating patients at high risk, and for patients to be more aware of the need for treatment."



EDITORIAL

JBMR®

A Crisis in the Treatment of Osteoporosis

Khosla and Shane, 2016

The Washington Post

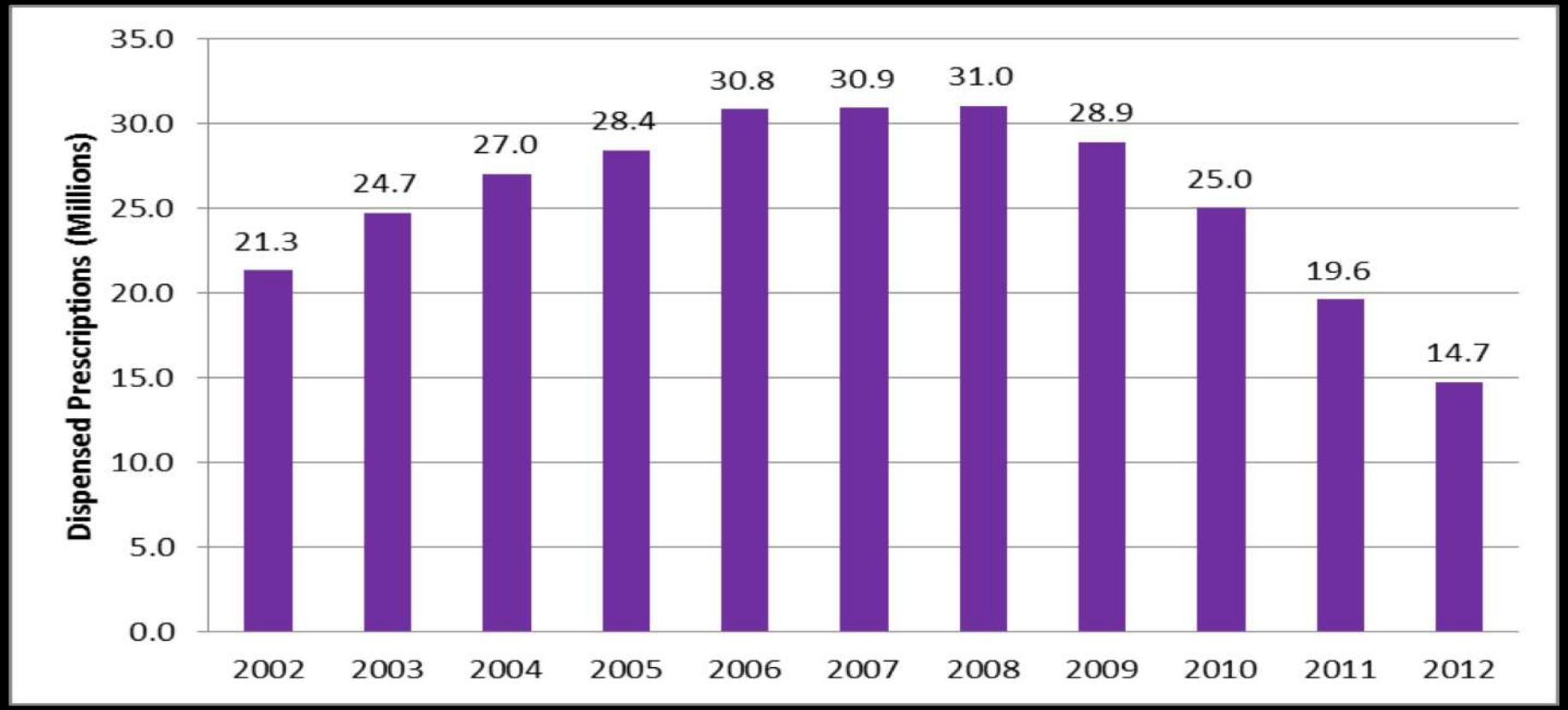
Health & Science

Why some women are afraid to treat osteoporosis

By Marlene Cimons October 17

My neighbor Arlyn Riskind, who is 53, has premenopausal osteoporosis, diagnosed nine years ago. She takes low-dose birth control pills to preserve her bone mass and postpone menopause. But after menopause, she knows she "may be soon faced with some decision-making." And she is quite anxious about it.

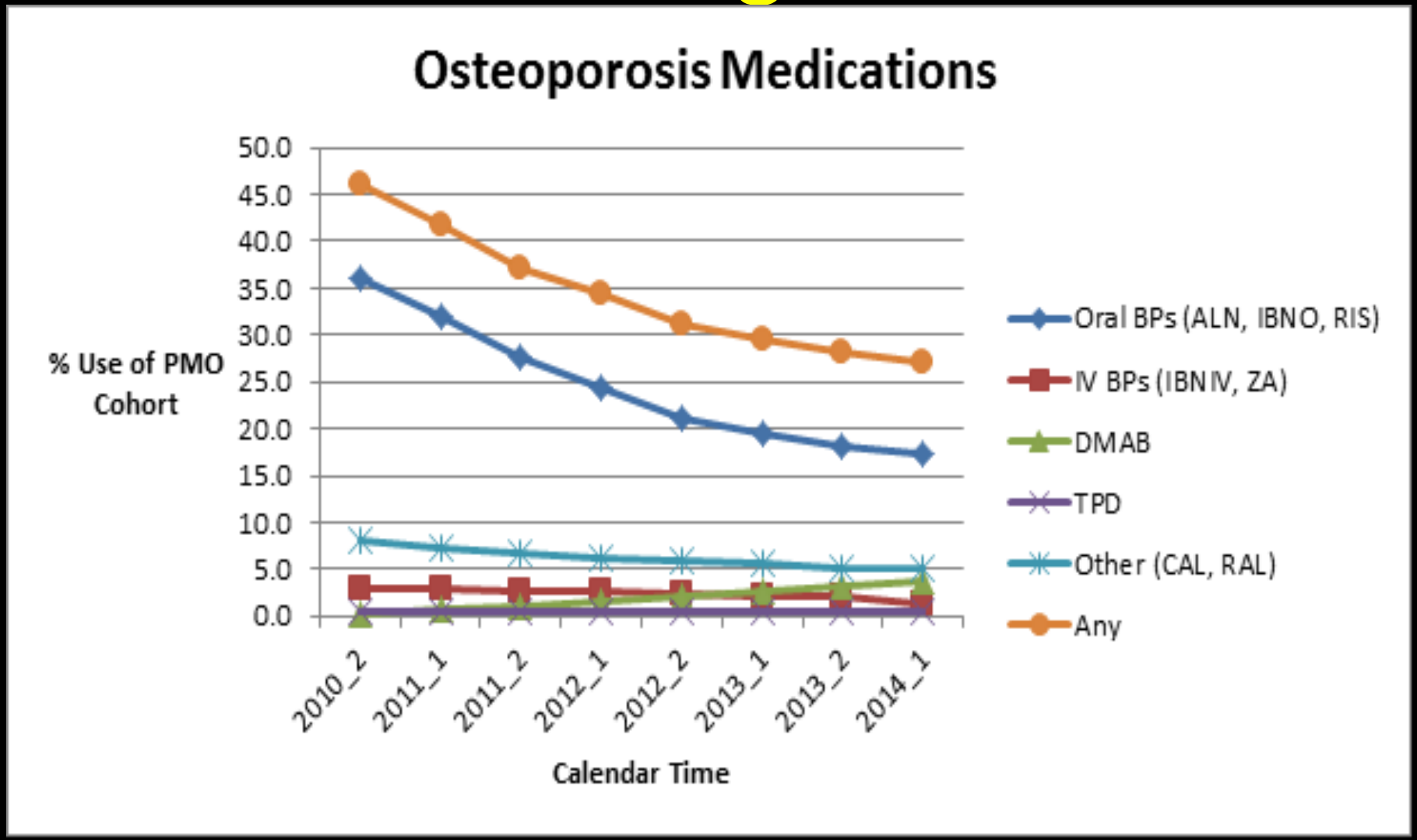
Oral Bisphosphonates Use is Declining (alendronate, risedronate, and ibandronate) Use in USA, 2002-2012



Source: IMS Vector One: National, Years 2002-2012 Data Extracted February 2013

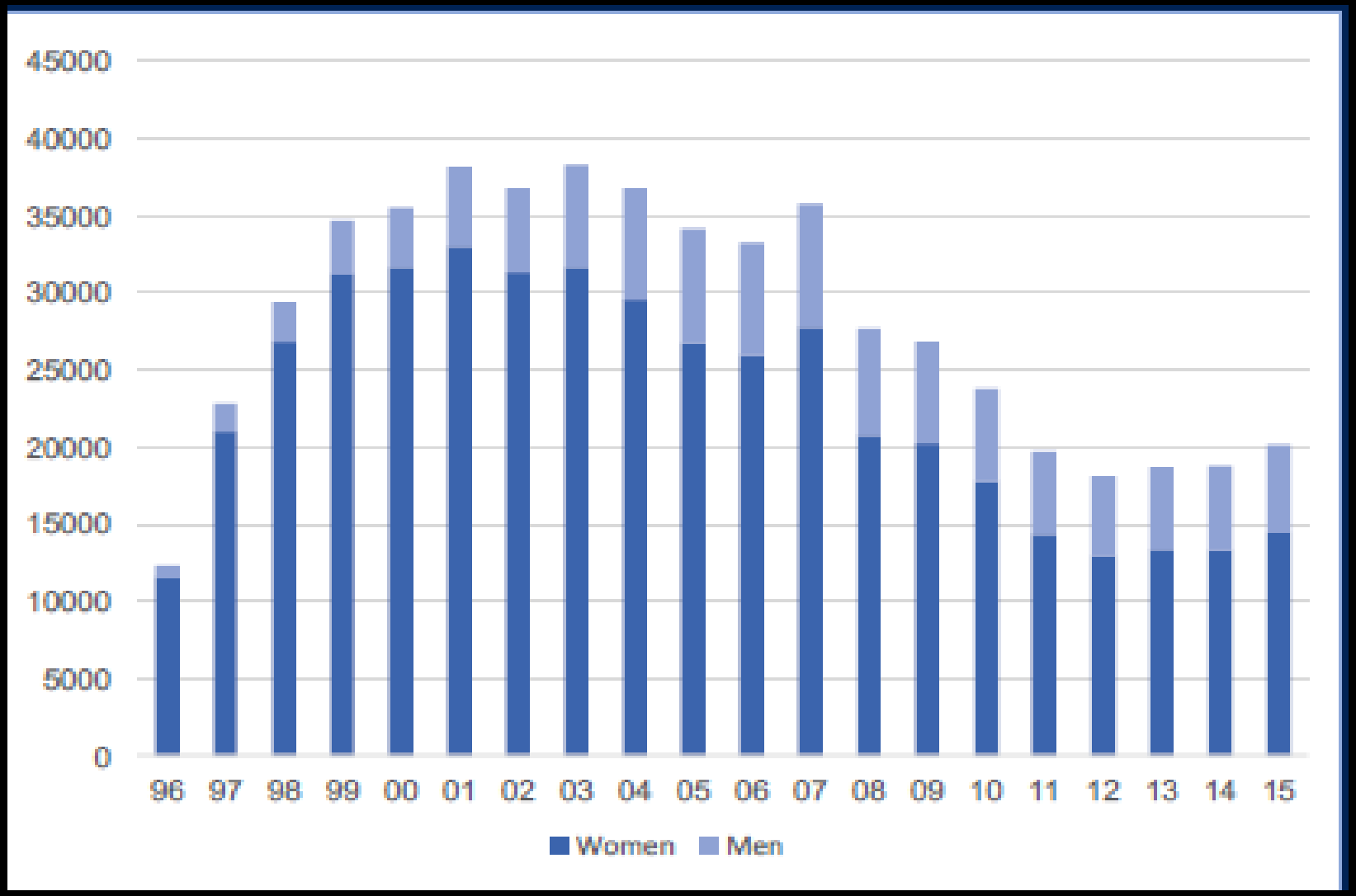
Wysowski D. *Bone* 2012;57: 423

Updated Medicare Data on Drug Rx



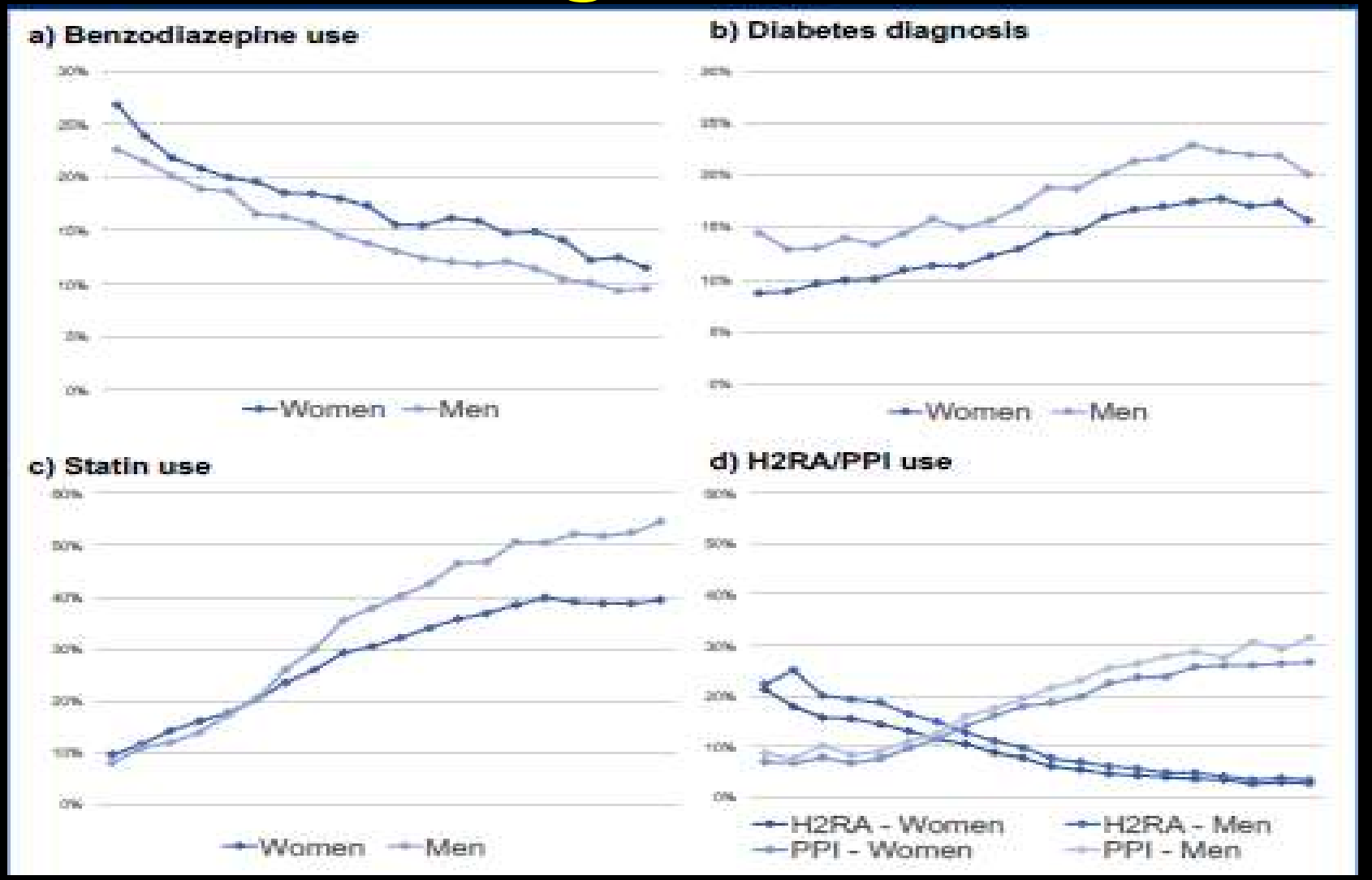
Curtis J. et al, personal communication

Declining Bisphosphonate Use in Ontario, CA



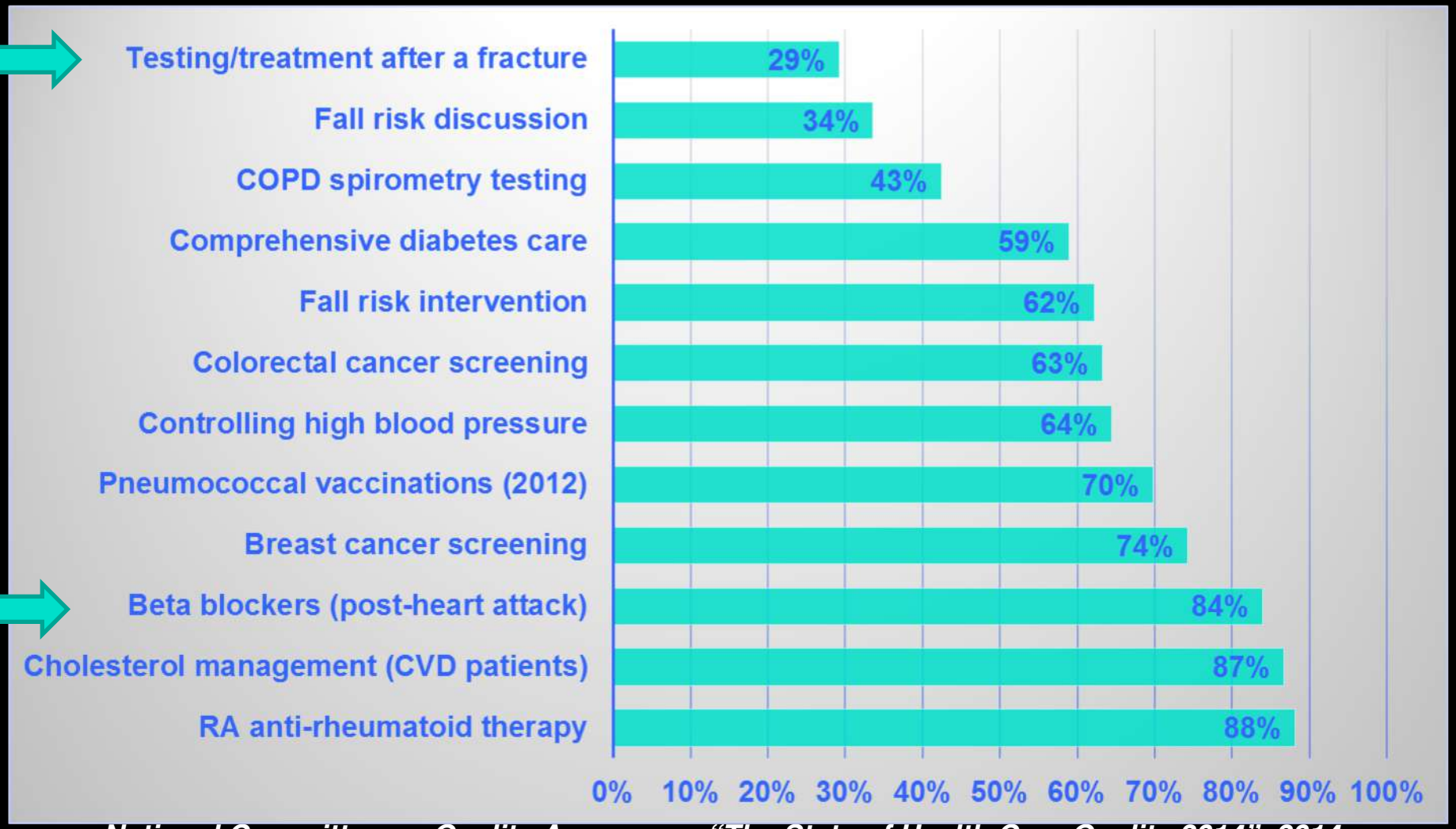
Hayes KN ASBMR 2018

Changing Patterns of Chronic Disease Drug Use in Ontario



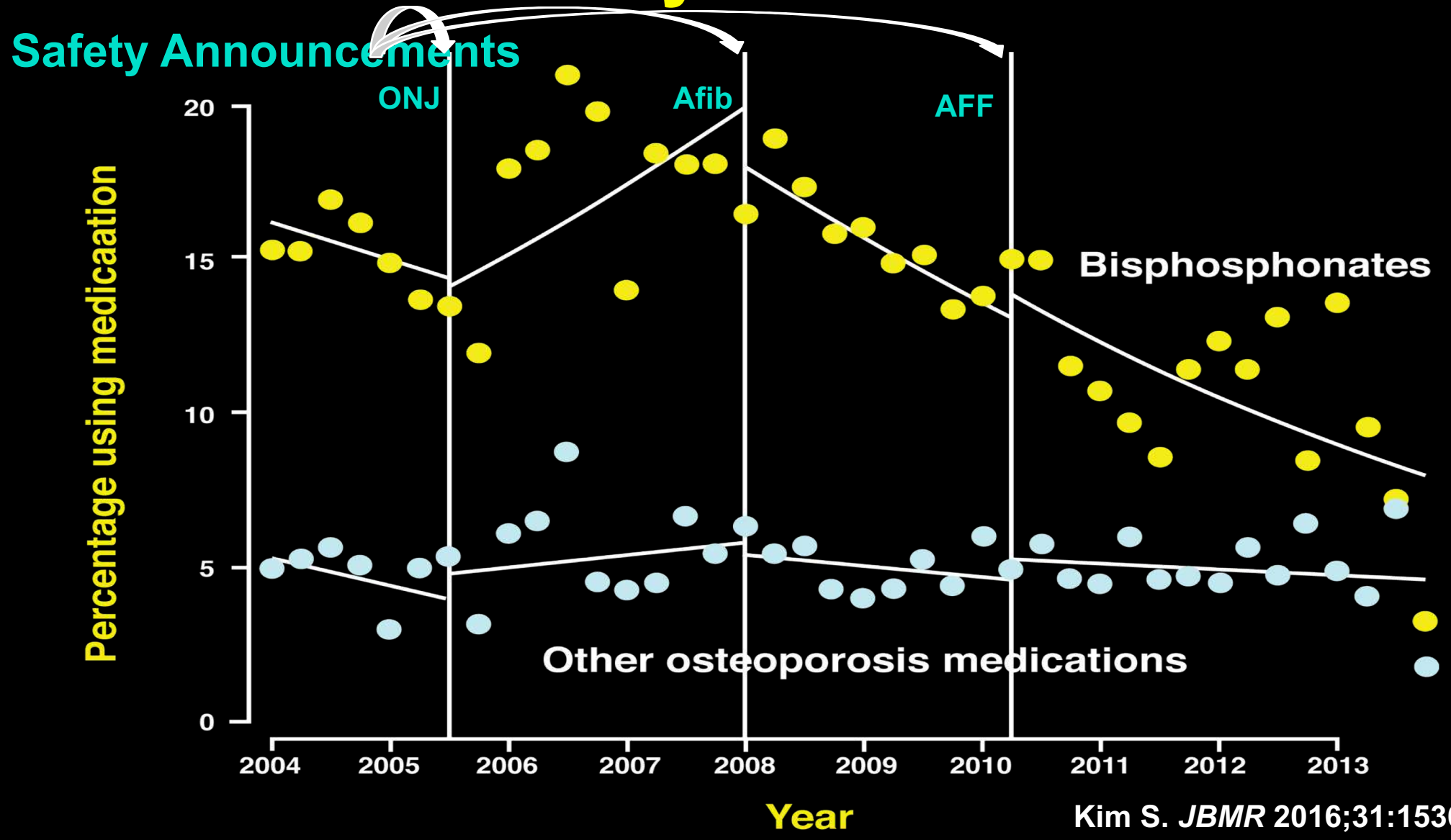
Hayes KN ASBMR 2018

Osteoporosis Care Lags Behind Other Major Diseases/Conditions (2013 HEDIS HMO data)



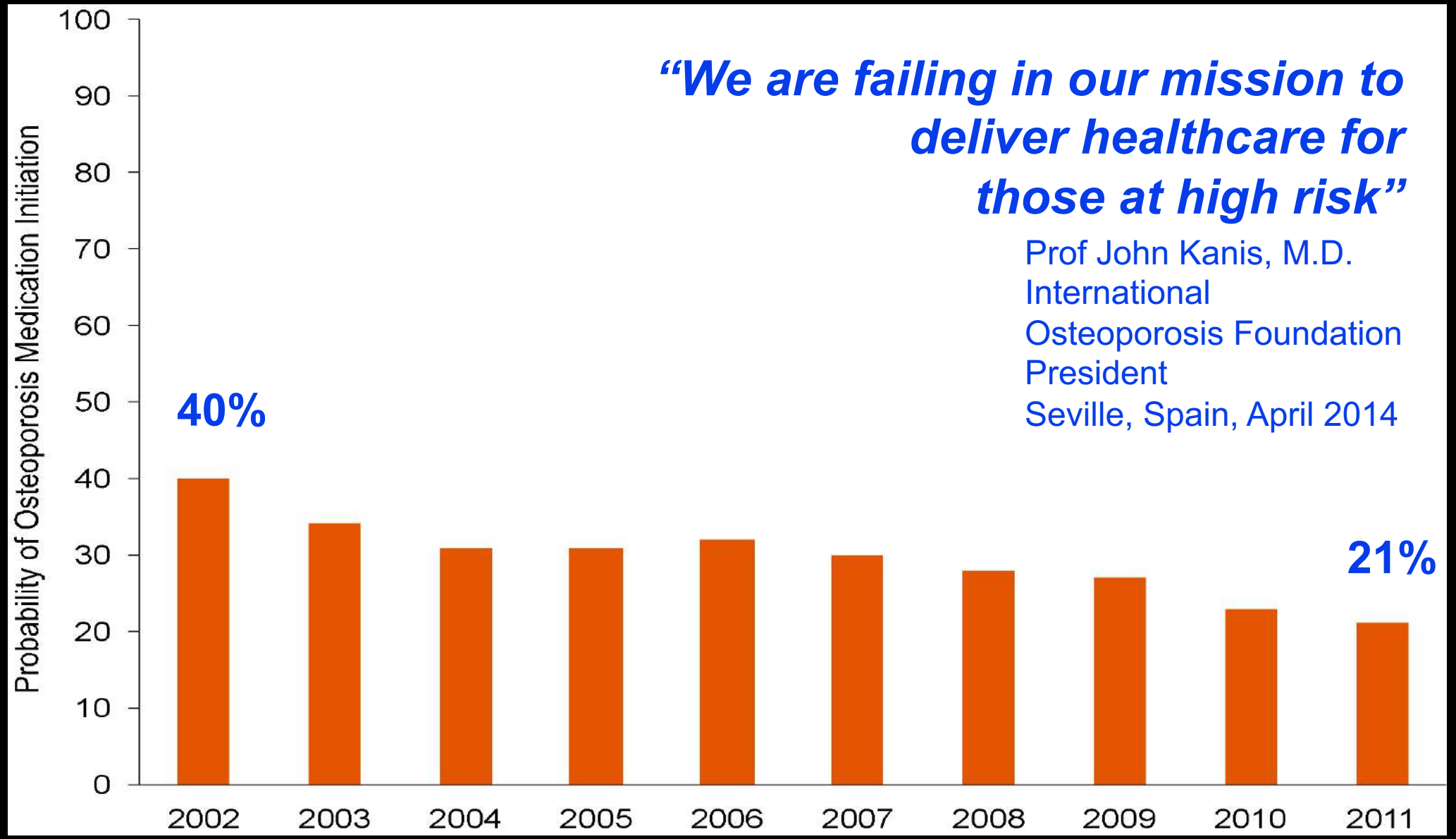
National Committee on Quality Assurance, "The State of Health Care Quality 2014". 2014.

Temporal Trends in Bisphosphonates vs. FDA Safety Announcements



Kim S. *JBMR* 2016;31:1536

Treatment Post-fracture is Declining

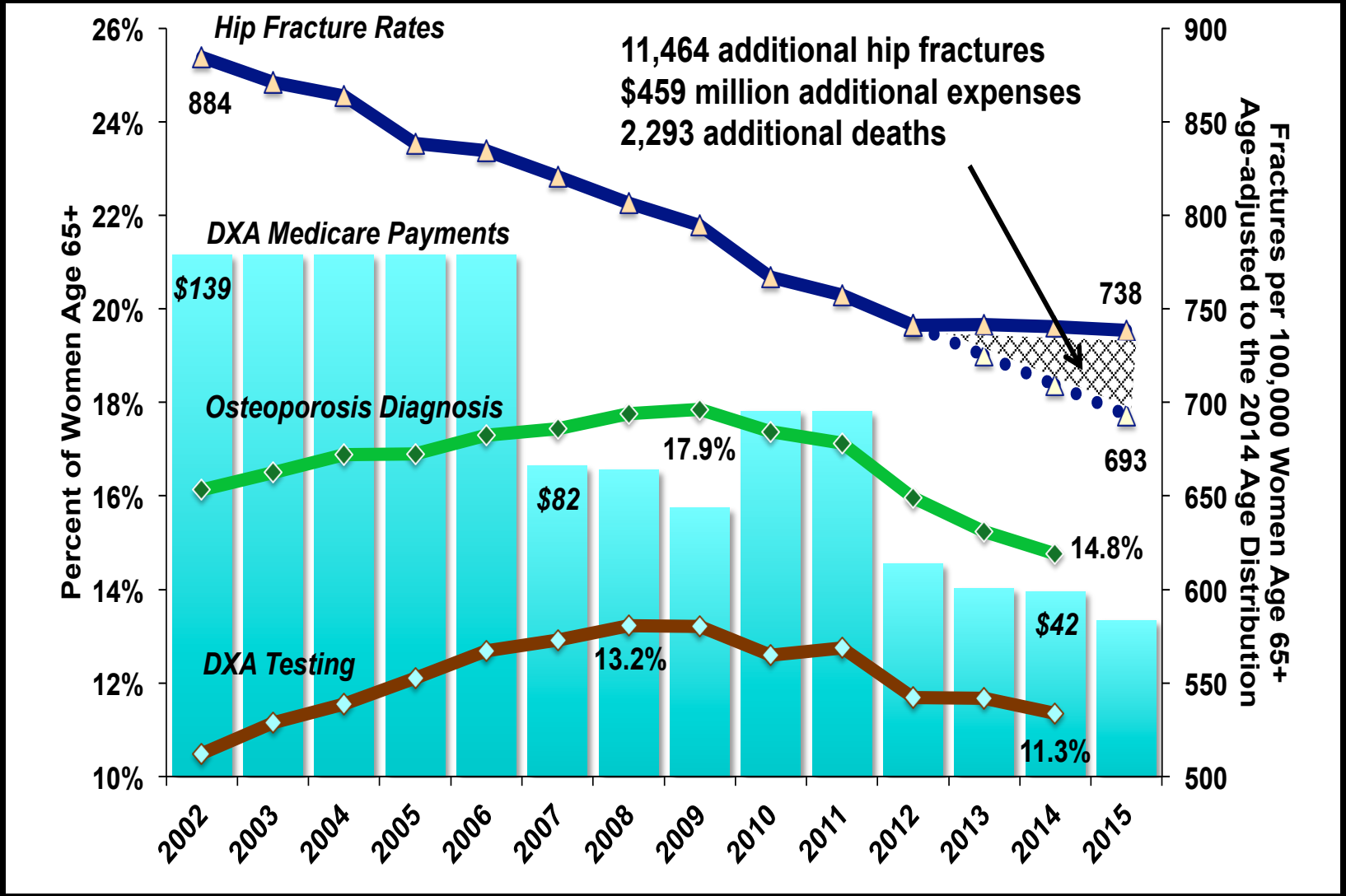


"We are failing in our mission to deliver healthcare for those at high risk"

Prof John Kanis, M.D.
International
Osteoporosis Foundation
President
Seville, Spain, April 2014

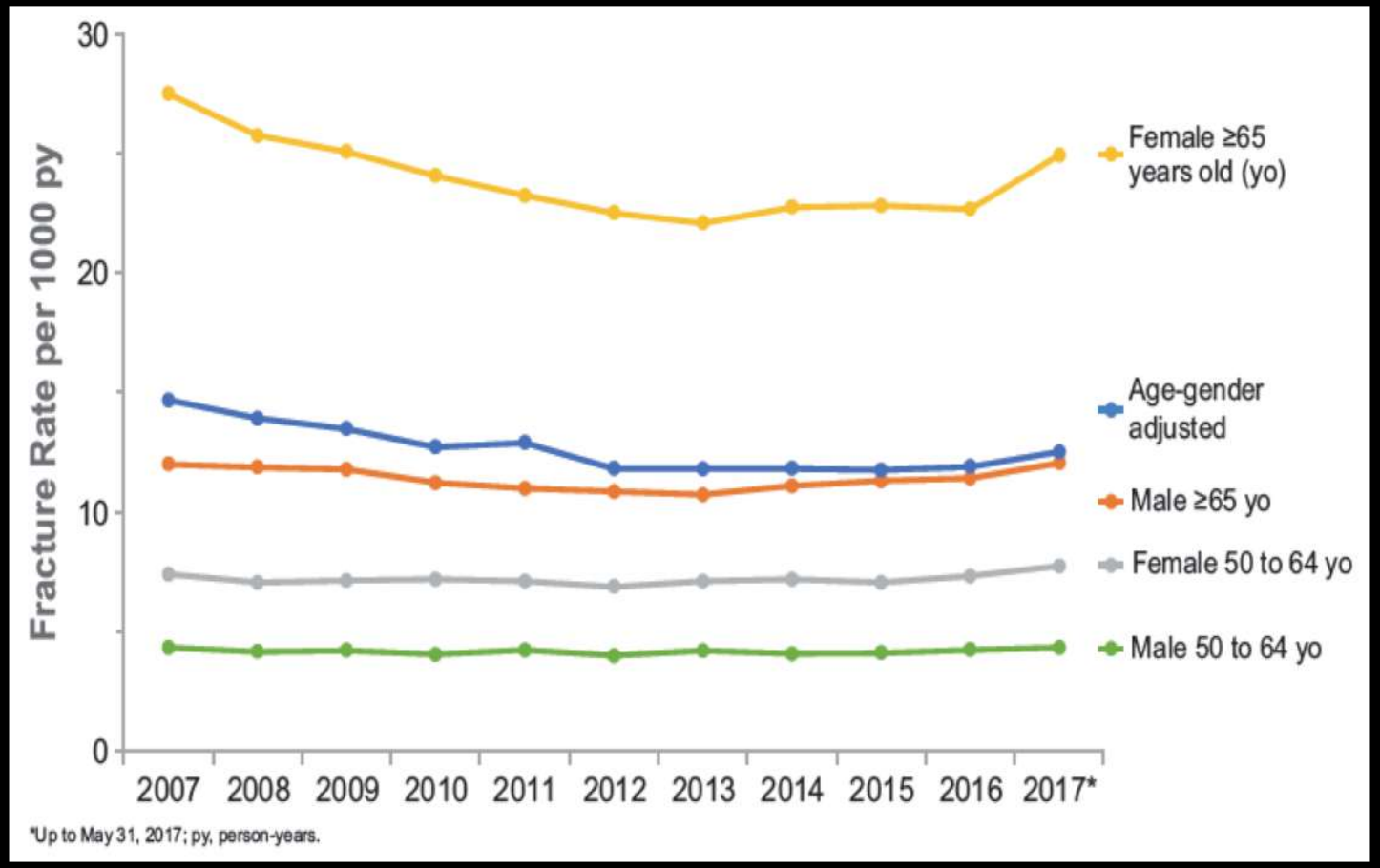
Solomon D. *J Bone Min Res* 2014;29:1929

Recent Changing Testing and Fracture Rates in US



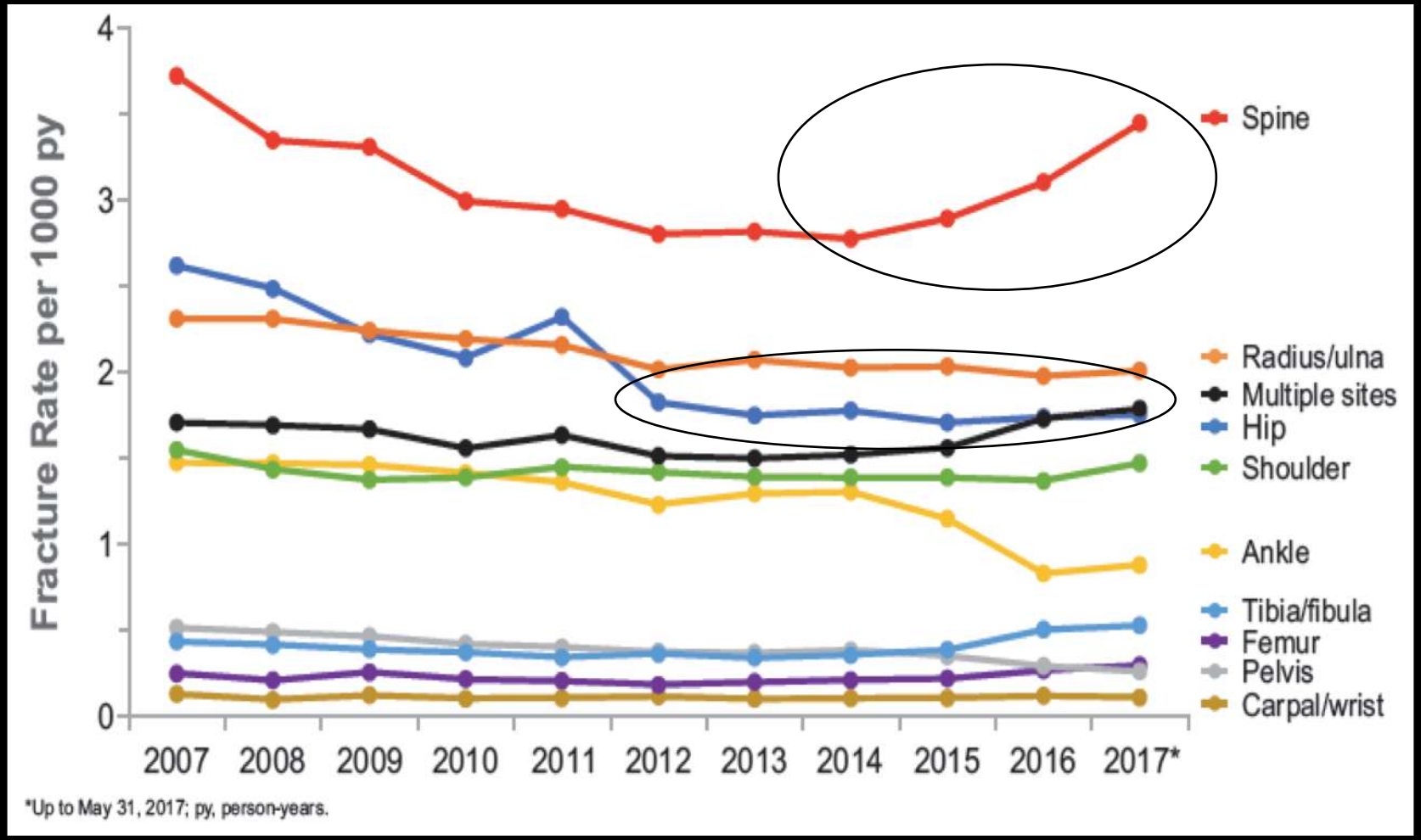
Lewicki M. *Osteo Int* 2018;29:717

More Recent Fracture Trends in US Managed Care Enrollees



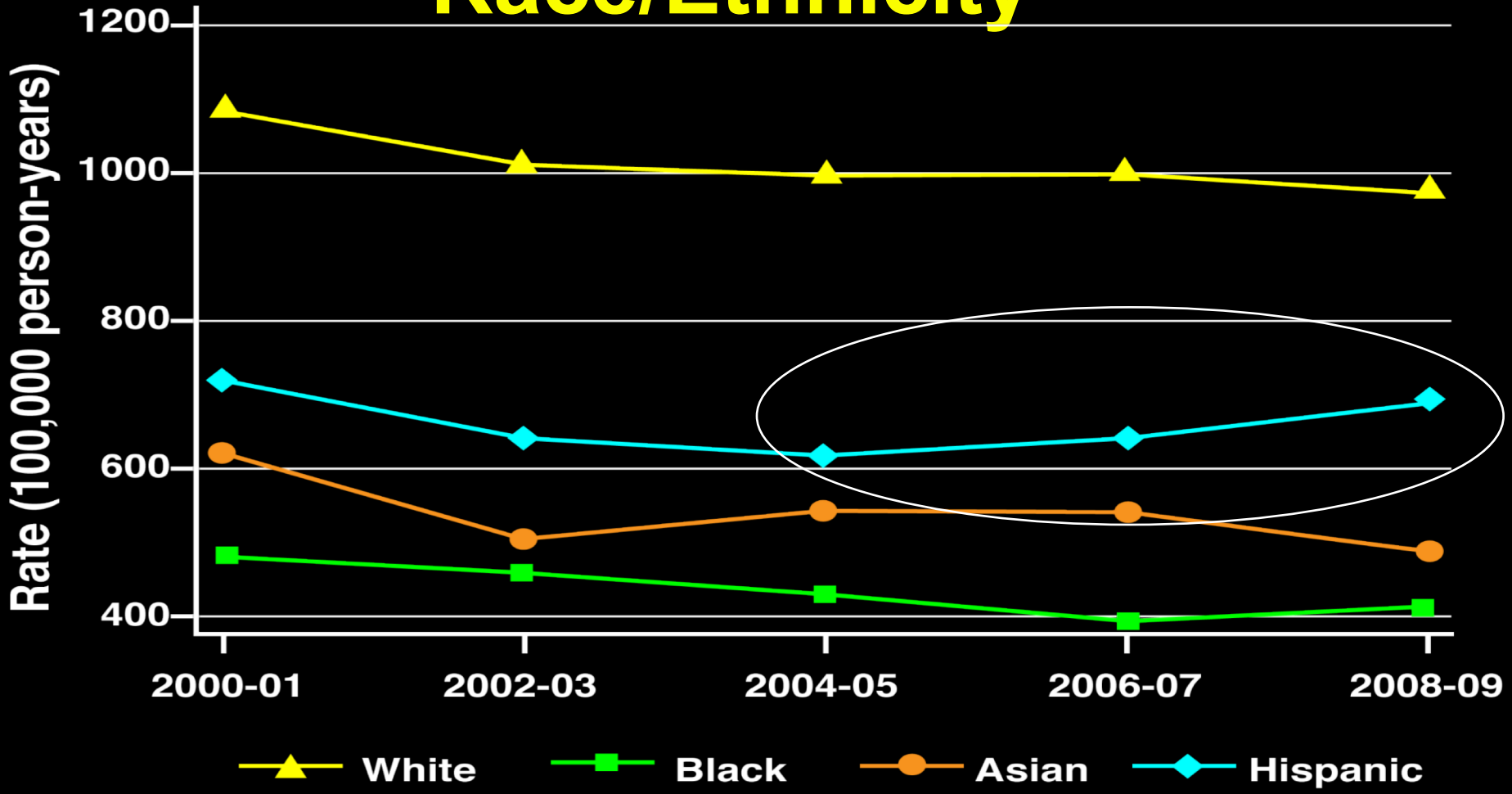
Lewiecki EM et al. ASBMR. 2018. Abstract 0742

Increasing Rates of Spine, Femur, and Tib/Fib Fractures in Recent Years



Lewiecki EM et al. ASBMR. 2018. Abstract 0742

Age-Standardized US Hip Fracture Incidence Rates in Women by Race/Ethnicity*

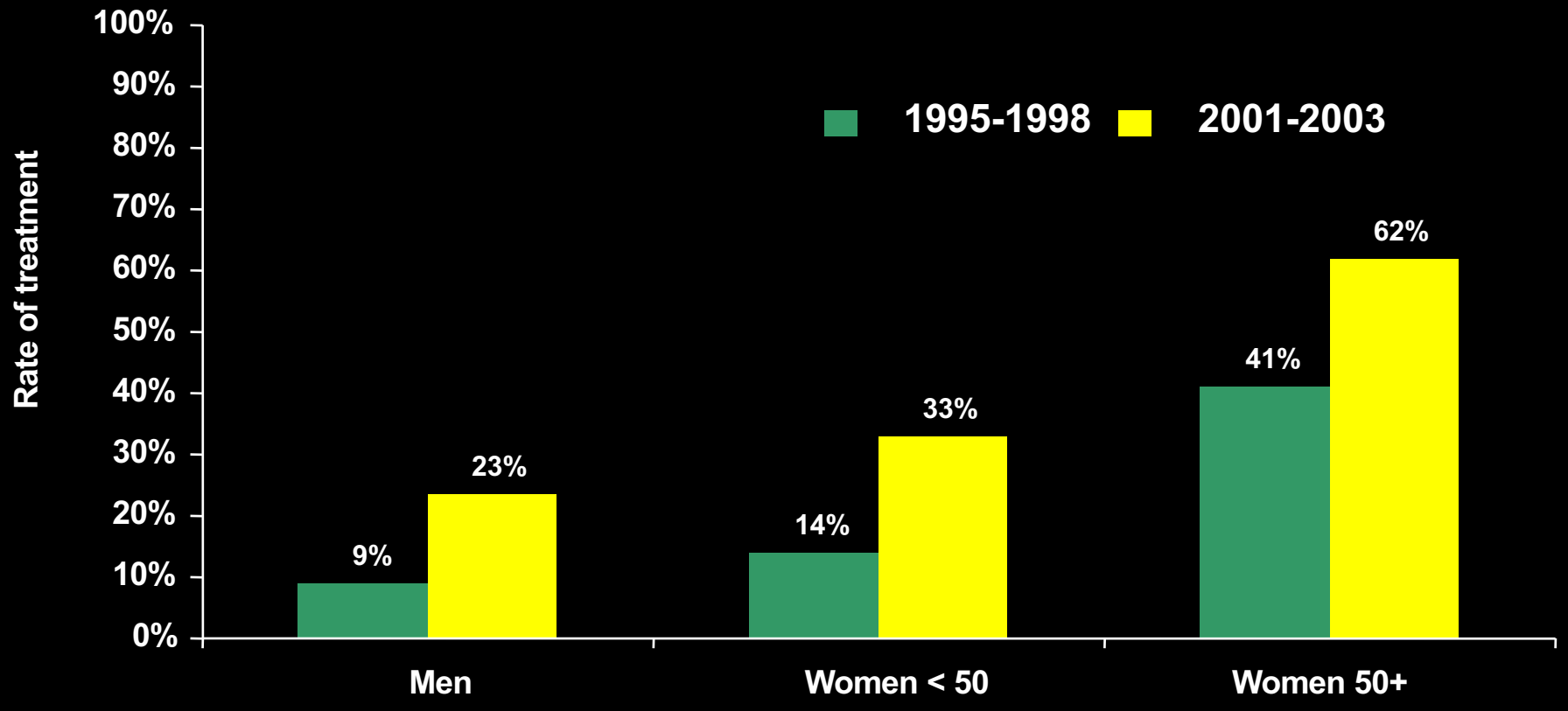


* Standardized to the 65+ population using 2010 US Census data

Wright N. *JBMR* 2012;27:2325

Changing Patterns of Glucocorticoid Induced Osteoporosis (GIOP) Rx- US

HRT + Prescription Bone Rx among New Glucocorticoid Users (n = 5,471)

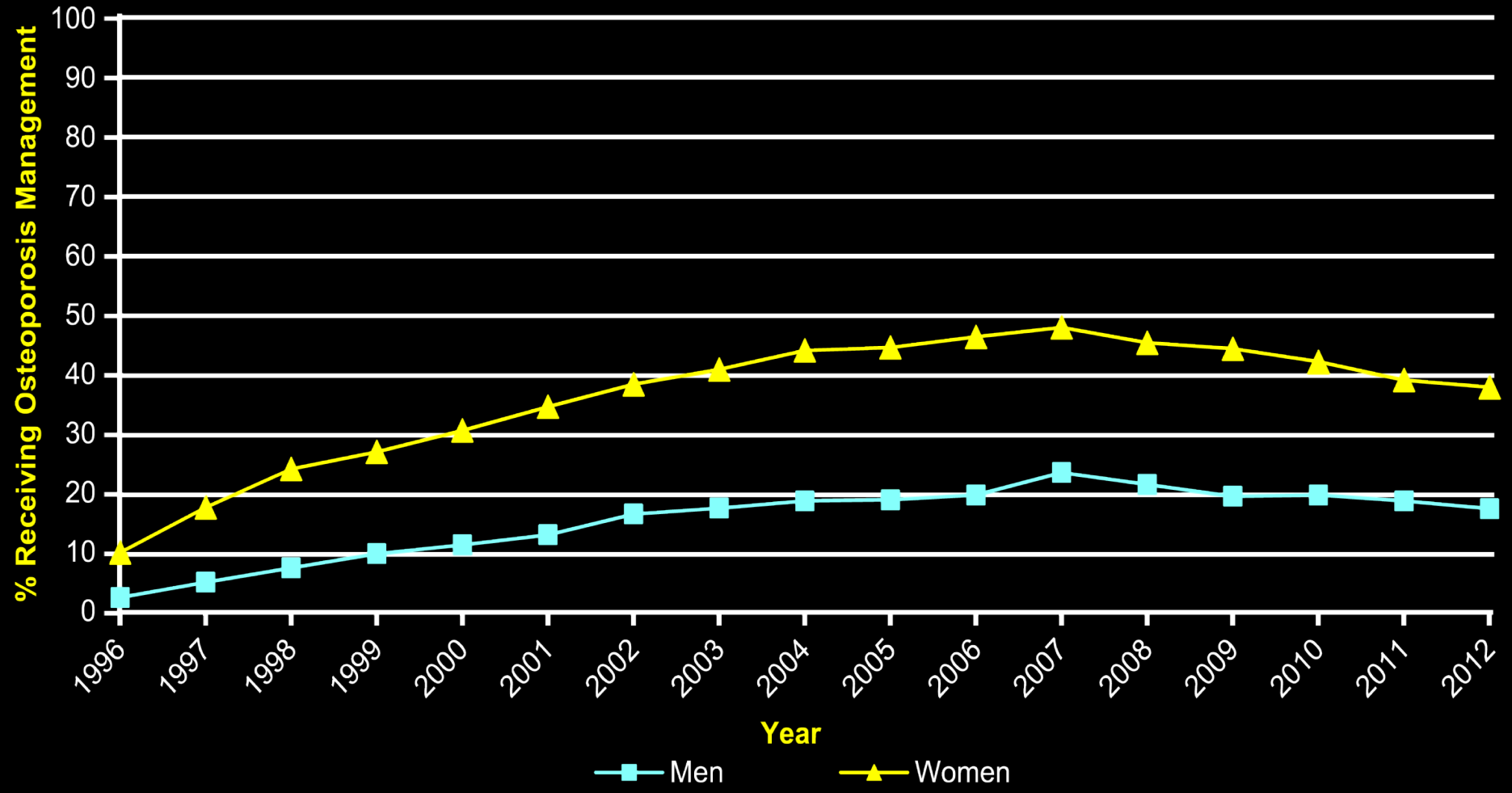


p < 0.01 for all comparisons

Curtis JR. *Arth Rheum* 2005;52:2485

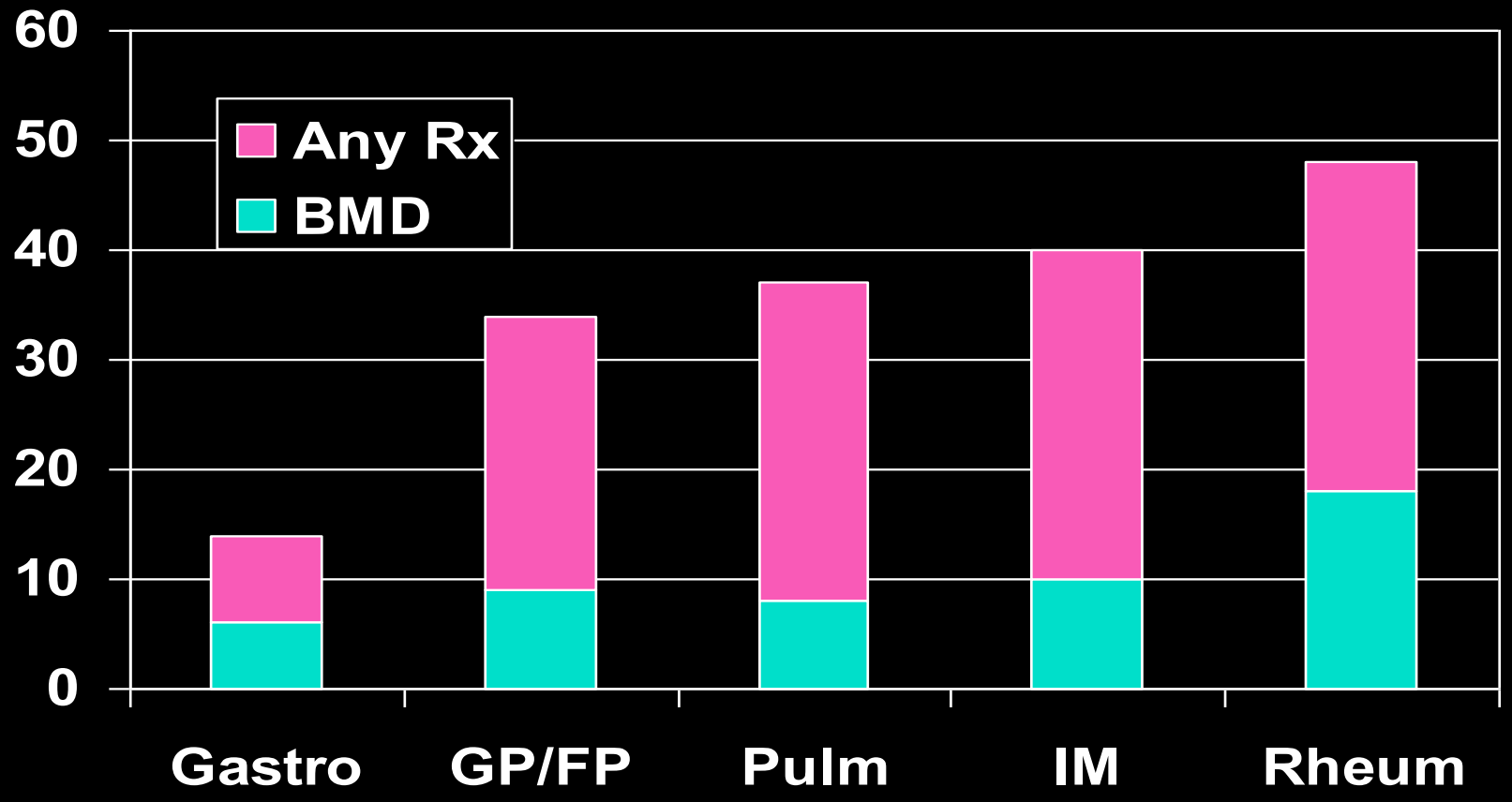
Temporal Pattern in Osteoporosis Treatment in GIOP in Canada

Low Rates of Rx



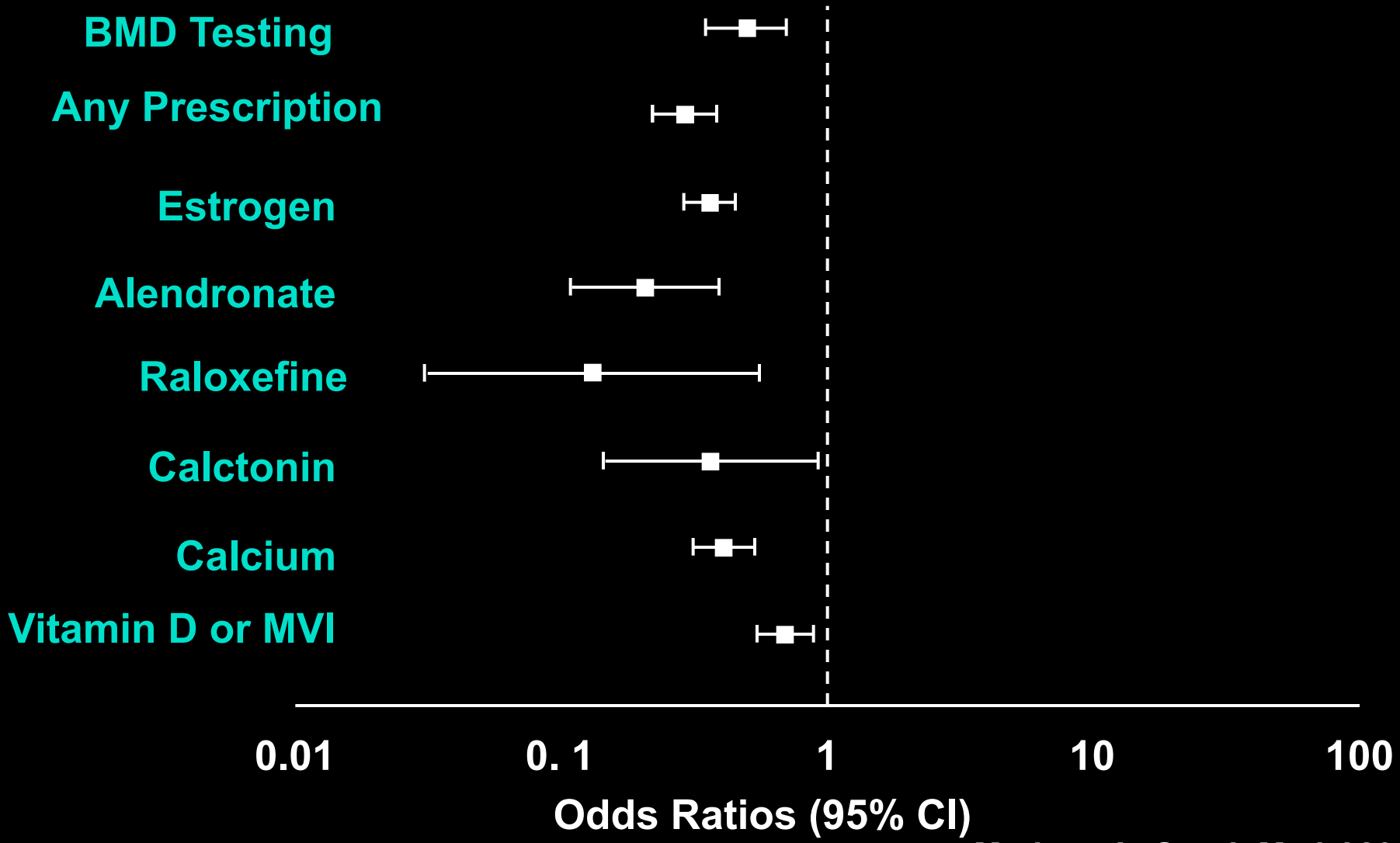
Albaum JM. *Osteo Int* 2015;26:2845

Practice Pattern Variation in GIOP Prevention



Mudano A, *J Rheumatol*, 28:1298, 2001

Osteoporosis Care Lower Among African American Women with Prior Fractures Compared to Caucasians



Mudano A, *South Med J* 2003;96:445

How Can We Improve Quality in Osteoporosis?

- New uses for older drugs (efficacy)
- Improve safety of older drugs (safety)
- New(er) drugs/biologics (efficacy)
- Better ways to translate research into practice (effectiveness)

How Can We Improve Quality in Osteoporosis?

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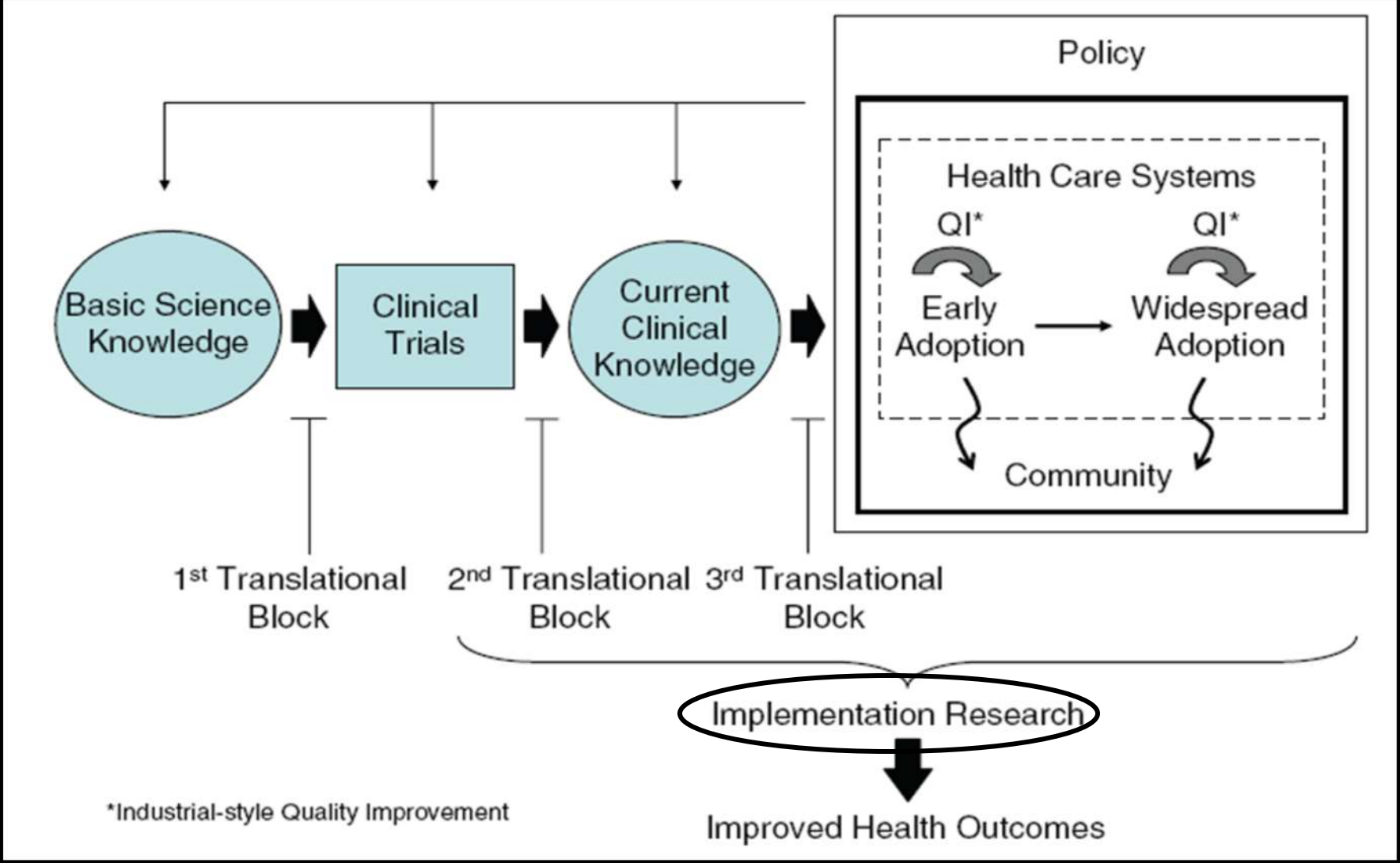
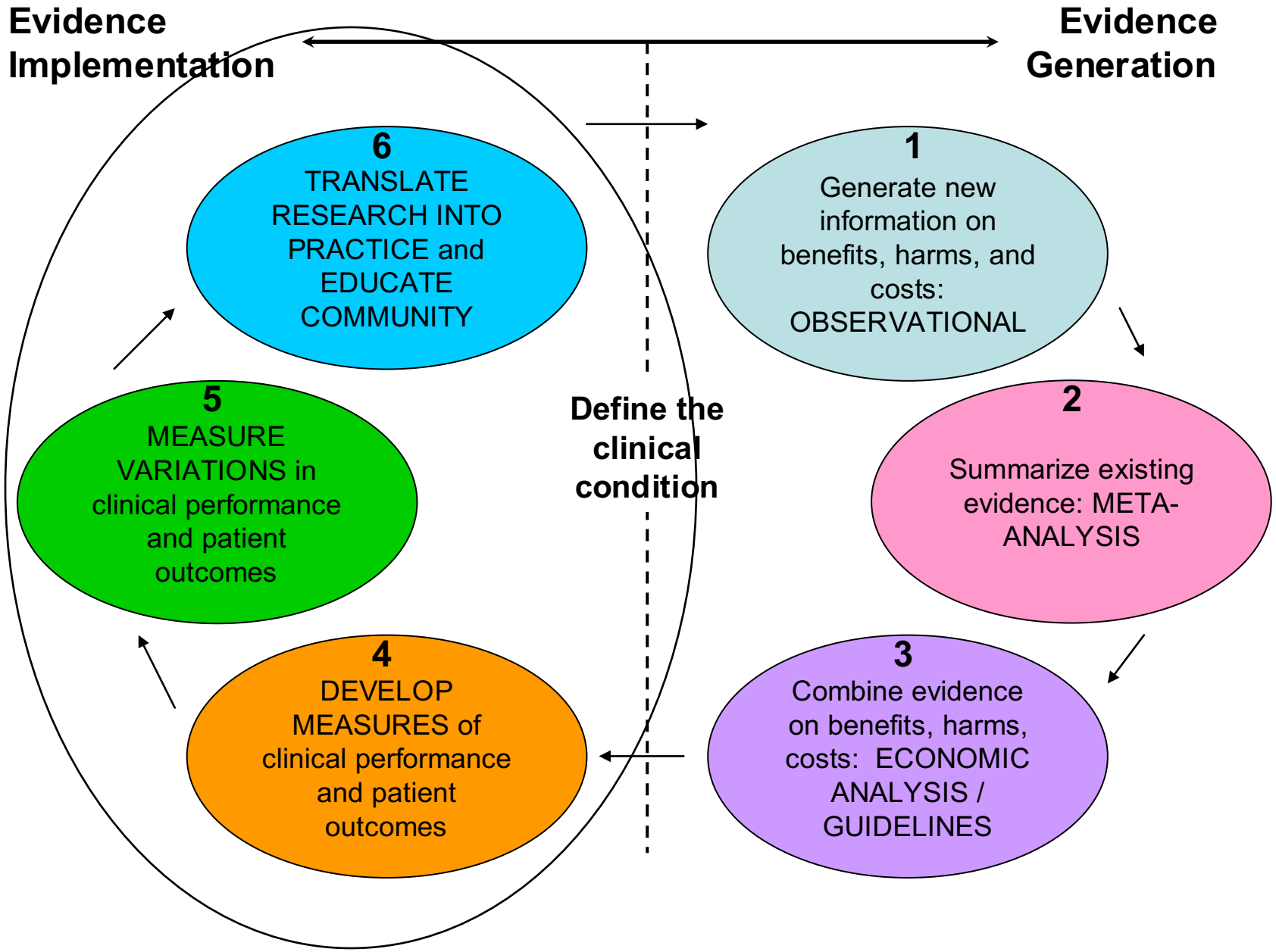
T2, T3 Research Conceptual Model



Salanitro, Estrada, Allison. In Glasser, Essentials of Clinical Research. 2008.


Evidence Implementation
Evidence Generation
6
TRANSLATE RESEARCH INTO PRACTICE and EDUCATE COMMUNITY
1
Generate new information on benefits, harms, and costs: OBSERVATIONAL
5
MEASURE VARIATIONS in clinical performance and patient outcomes
Define the clinical condition
2
Summarize existing evidence: META-ANALYSIS
4
DEVELOP MEASURES of clinical performance and patient outcomes
3
Combine evidence on benefits, harms, costs: ECONOMIC ANALYSIS / GUIDELINES

Defining Quality

"Quality is like obscenity:
I'll recognize it when I see it"

Ringel and Vickrey, Arch Neurology, 1997

What Do We Know About Health Care Quality?

- Quality can be measured
- Health care systems must be accountable for quality
- Measurement AND accountability drive improvement
- Consumers want and use information about health care quality

Definition of Quality
Institute of Medicine

- Health services for individuals and populations
- Increase the likelihood of desired health outcomes
- Consistent with current professional knowledge

Institute of Medicine, 2001

The NEW ENGLAND JOURNAL of MEDICINE

VOL. 348 NO. 26

ESTABLISHED IN 1812 JUNE 26, 2003 WWW.NEJM.ORG

The NEW ENGLAND JOURNAL of MEDICINE

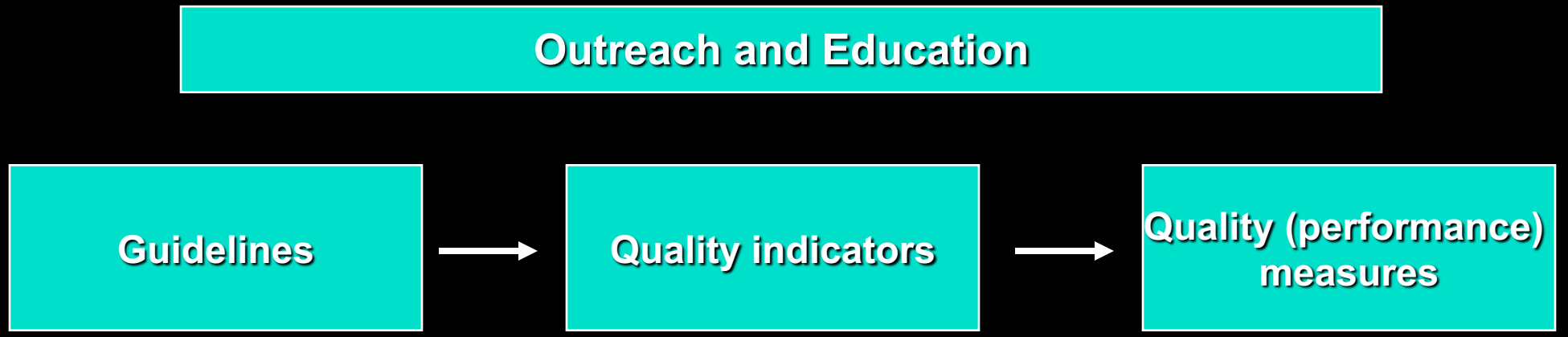
SPECIAL ARTICLE

The Quality of Health Care Delivered to Adults in the United States

Elizabeth A. McGlynn, Ph.D., Steven M. Asch, M.D., M.P.H., John Adams, Ph.D., Joan Keesey, B.A., Jennifer Hicks, M.P.H., Ph.D., Alison DeCristofaro, M.P.H., and Eve A. Kerr, M.D., M.P.H.

"Adults received 55% of recommended care according to 439 process-of-care measures."

Quality Indicator Development Process

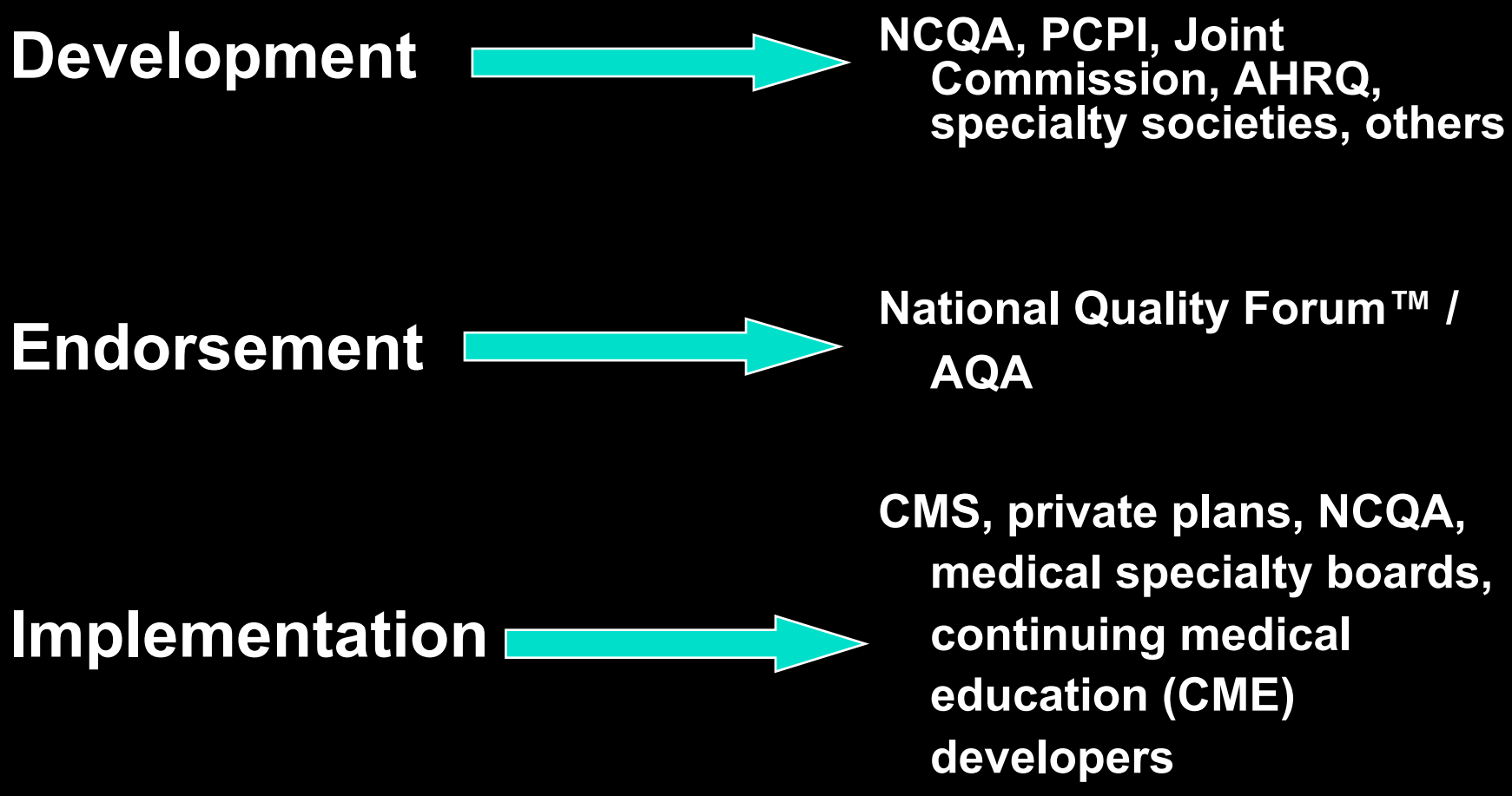


Anatomy of a Quality Measure

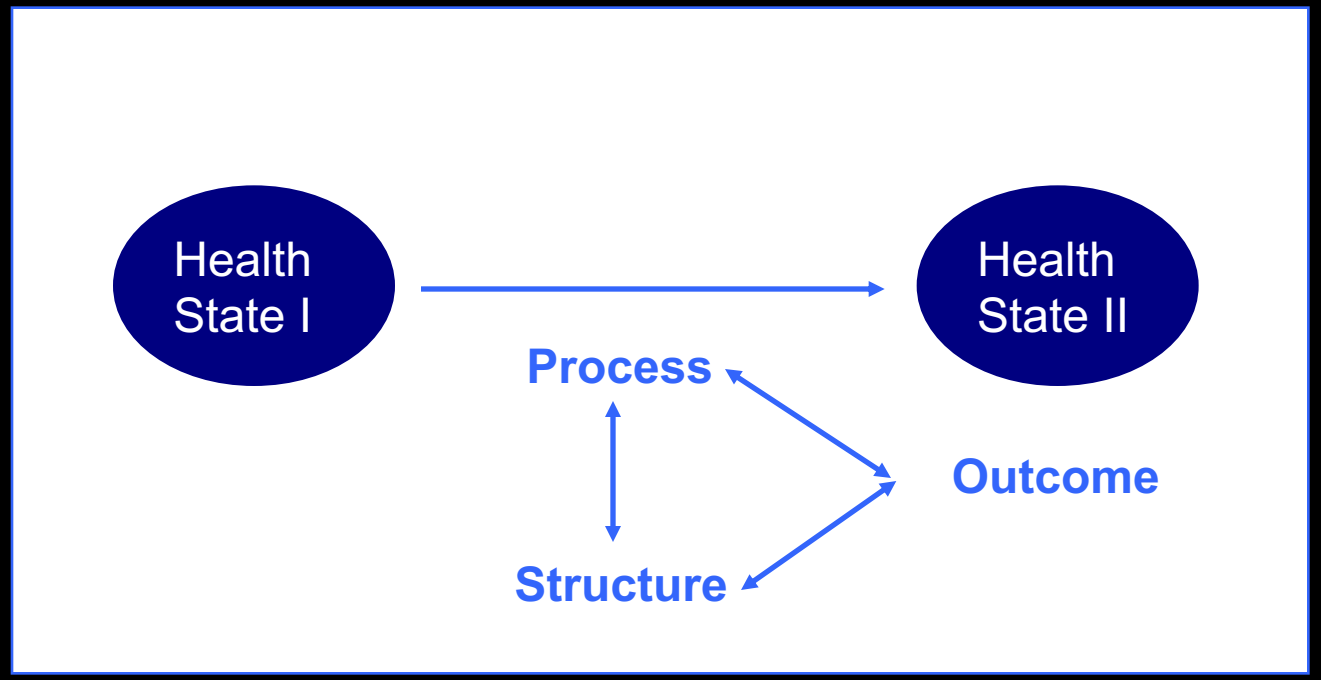
The Core

- Numerator – what outcome or process of care is the measure trying to address?
- Denominator – what population is the measure focused on?
- Exclusions
  - Medical (contraindication)
  - Patient (patient choice)
  - System (vaccine unavailable)

Quality Measure National Landscape



Targets for Health Care Quality Improvement



Donnabedian. *Milbank Quarterly* 1996; 44:166
Clancy CM, Eisenberg, JM. Outcomes research: Measuring the end results of health care. Science. 1998; 282:245

HEDIS® Measures for Osteoporosis
Low Rates of Follow-up Intervention

- **HEDIS: A set of measures used to assess performance on key measures of clinical effectiveness[1]**
  - Process and outcomes measures
  - Standardized member satisfaction survey
  - Used by commercial, Medicare, and Medicaid plans alike
  - Allows plan-to-plan comparison
- **Osteoporosis Measure: % of women > 67 years of age who received either a BMD test or an osteoporosis medication within 6 months of fracture[2]**

1. National Committee for Quality Assurance. Available at: www.ncqa.org/communications/publications/publications/hedispub.thm.
2. The National Committee on Quality Assurance. NCQA Washington, D.C.

Osteoporosis HEDIS

Trends, 2003 - 2016	
Year	Medicare (PPO)
2003	18%
2007	18
2009	18
2011	19
2013	22
2015	33
2016	34

Quality ID #418 (NQF 0053): Osteoporosis Management in Women Who Had a Fracture

2018 OPTIONS FOR INDIVIDUAL MEASURES: REGISTRY ONLY

MEASURE TYPE

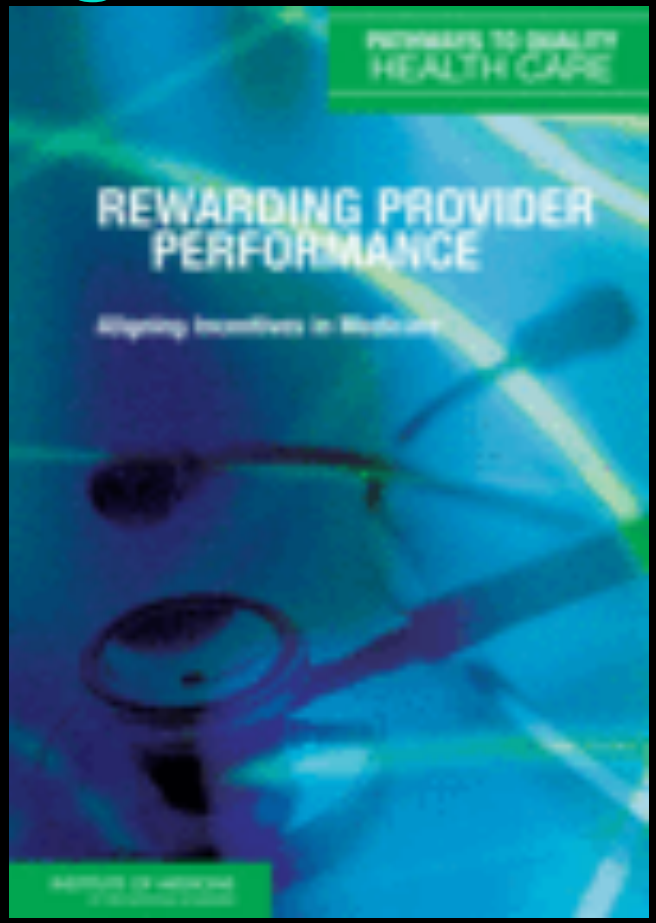
- % women age 50-85 who fracture and who either had:
  - 1) Bone mineral density test or
  - 2) Prescription for a drug to treat osteoporosis in the six months after fracture

- Submitted after each fracture
- Anticipated that clinicians who treat any fracture except fractures of the finger, toe, face or skull will submit measure
- Fracture identified by either an ICD-10CM diagnosis code for fracture and a CPT service code OR an ICD-10-CM diagnosis code for fracture and CPT procedure code for surgical treatment of fractures

Globalize the Evidence, Localize the Decision

Meeting the Challenge

"Performance measurement is a necessary but not sufficient foundation to drive and sustain improvements in patient care. Improvements in the quality and affordability of care will occur only when this information is actually used."

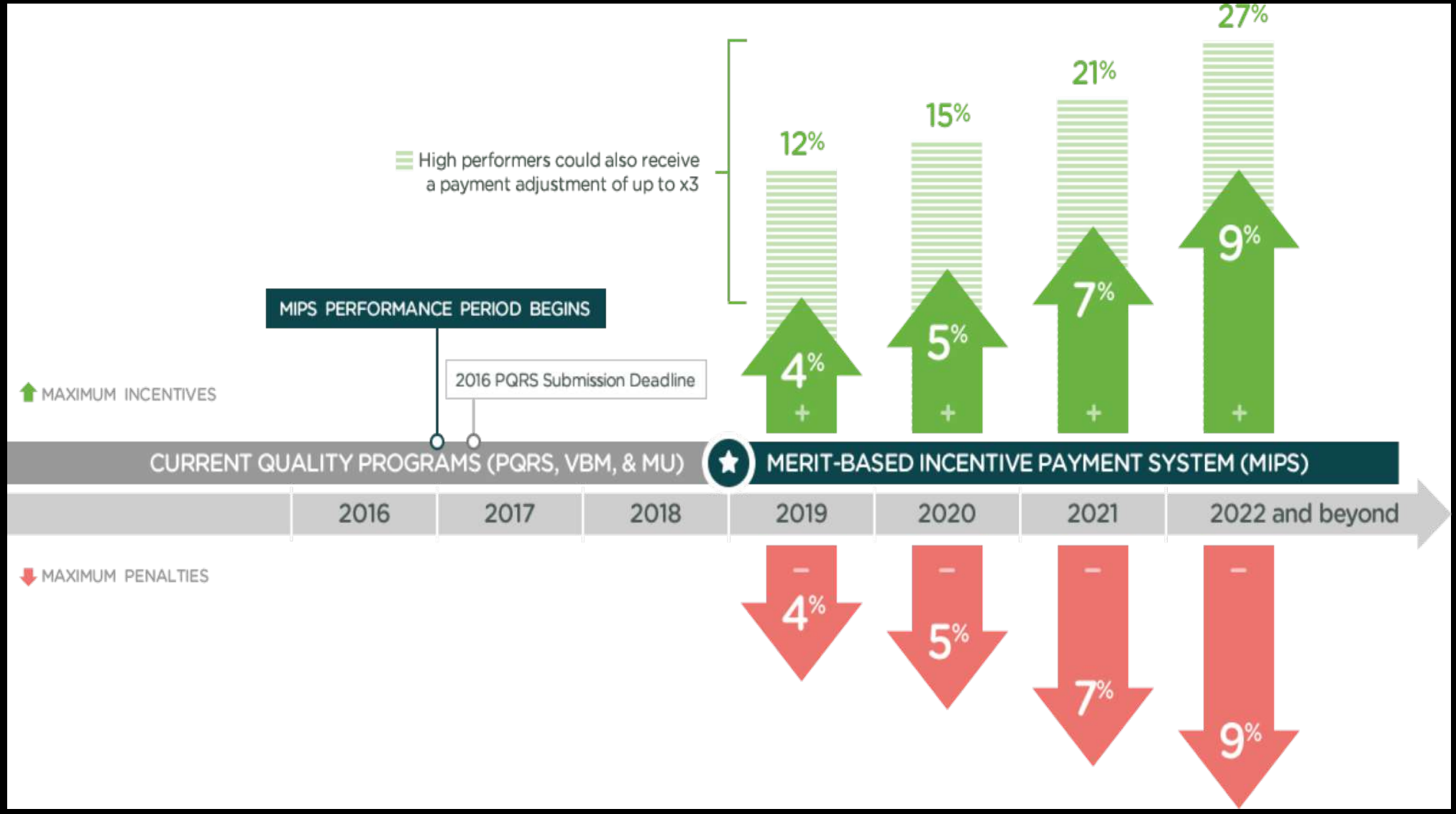


Institute of Medicine, 2006

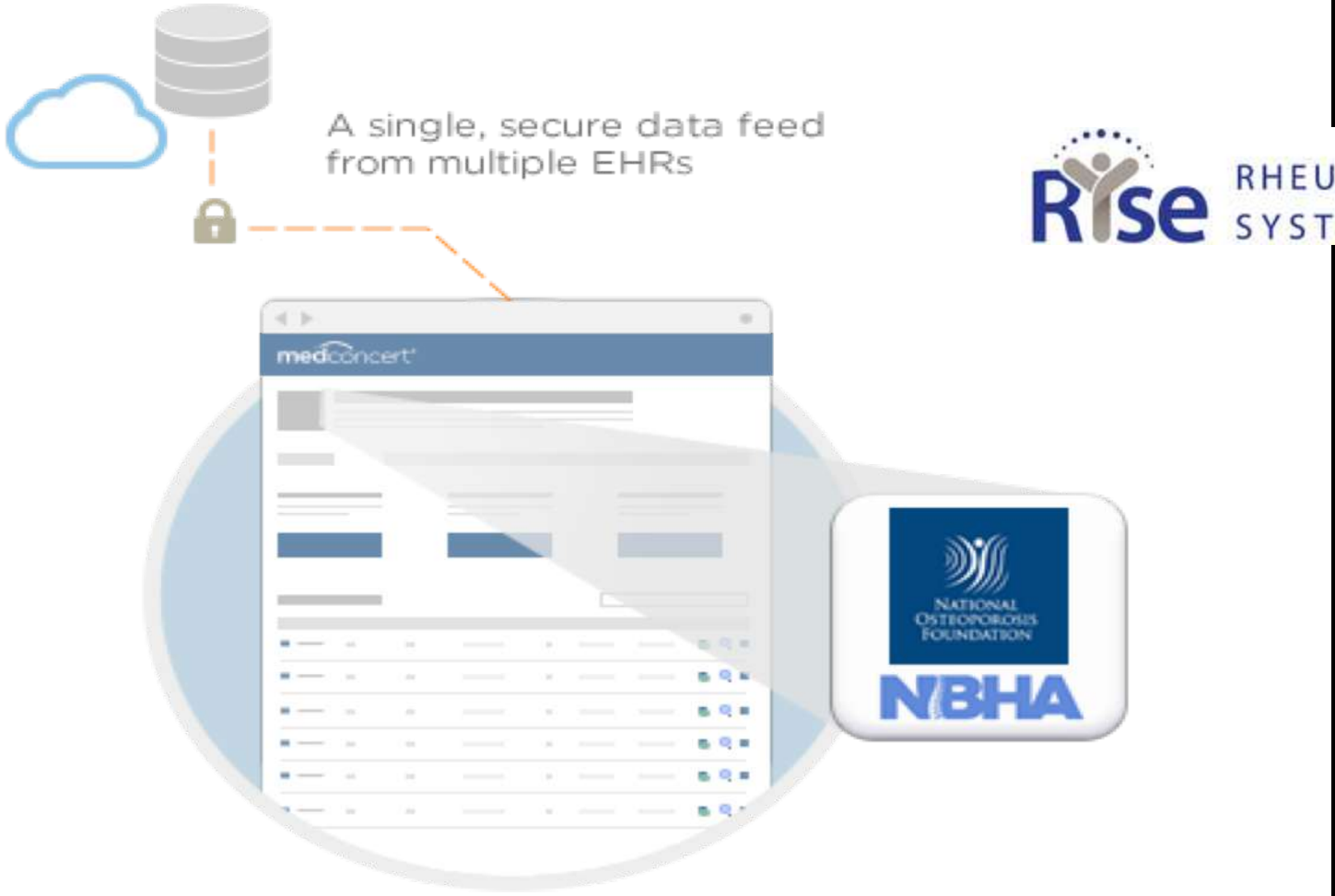
Standforquality.org

Building a Foundation for High Quality, Affordable Health Care: Linking Performance Measurement to Health Reform

CMS MIPS Program



Qualified Clinical Data Registries (QCDR)



RISE RHEUMATOLOGY INFORMATICS SYSTEM for EFFECTIVENESS

NOF/NBHA QCDR

QCDR (Custom) Measures

- Hip Fracture Mortality Rate (IQI 19) (NOF6) (Group Reporting)
- Osteoporosis: percentage of patients, any age, with a diagnosis of osteoporosis who are either receiving both calcium & vitamin D intake, & exercise at least once within 12 months. (NOF7)
- Median Time to Pain Management for Long Bone Fracture (NOF 12)
- Osteoporosis: Management Following Fracture of Hip, Spine or Distal Radius for Men and Women Aged 50 Years and Older (NOF 13)

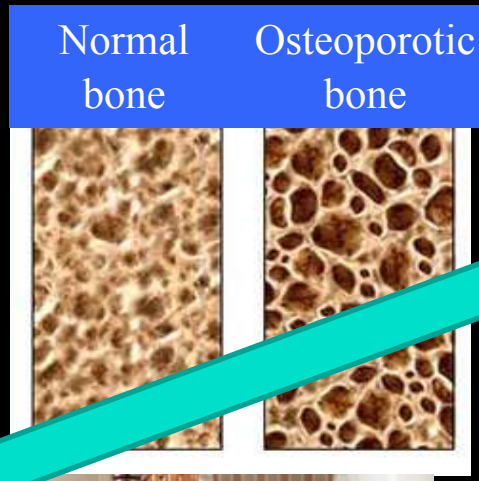
MIPS Quality and Electronic Clinical Quality Measures (eCQMs)

- Screening for Osteoporosis for Women Aged 65–85 Years of Age Q#039, NQF 0046
- Medication Reconciliation Post-Discharge Q#046, NQF 0097
- Care Plan Q#047, NQF 0326
- Osteoarthritis (OA): Function and Pain Assessment Q#109
- Preventive Care and Screening: Influenza Immunization Q#110, NQF 0041
- Osteoporosis Management in Women Who Had a Fracture Q#418, NQF 0053
- Functional Status assessment for Total Hip Replacement Q#376
- Falls: Screening for Future Fall Risk Q#318, NQF 0101

The Quality Problem In Osteoporosis

Radiology

PCP/IM/Rheum/Endo



Emergency Department

Orthopaedic Surgery

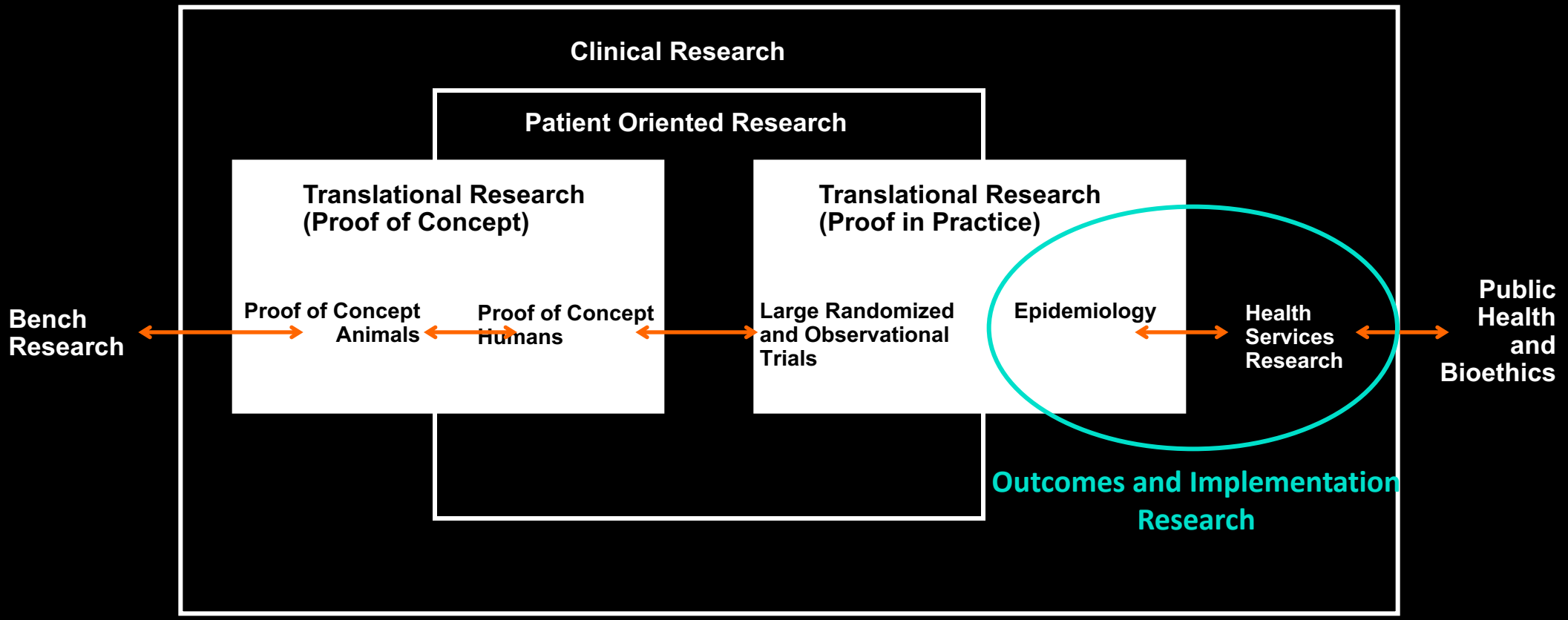
Why Most Clinicians Don't Recognize High Risk patients and Provide Osteoporosis Management?

- Primary prevenion (no prior fractures)
  - BMD testing confusion and (increasing) scarcity
  - FRAX or other risk prediction tools not routinely used/understood
  - Uncertainty regarding treatment (risks vs benefits)

- Secondary prevention (prior fracture)
  - Orthopaedic surgeons reluctance to treat osteoporosis
  - Osteoporosis prescribers not alerted to fracture occurrence
  - Uncertainty regarding treatment (risk vs benefits)

Spectrum of Clinical Research

The diagram below is designed to demonstrate visually the different approaches available in clinical research, relationships among the different approaches, and the relationships among clinical research approaches, bench research, and public health.



This diagram is based on the report written by members of the Clinical Research Roundtable of the Institute of Medicine and published in the March 12, 2003 issue of *JAMA*.

What Is Outcomes Research? Basic Tenets

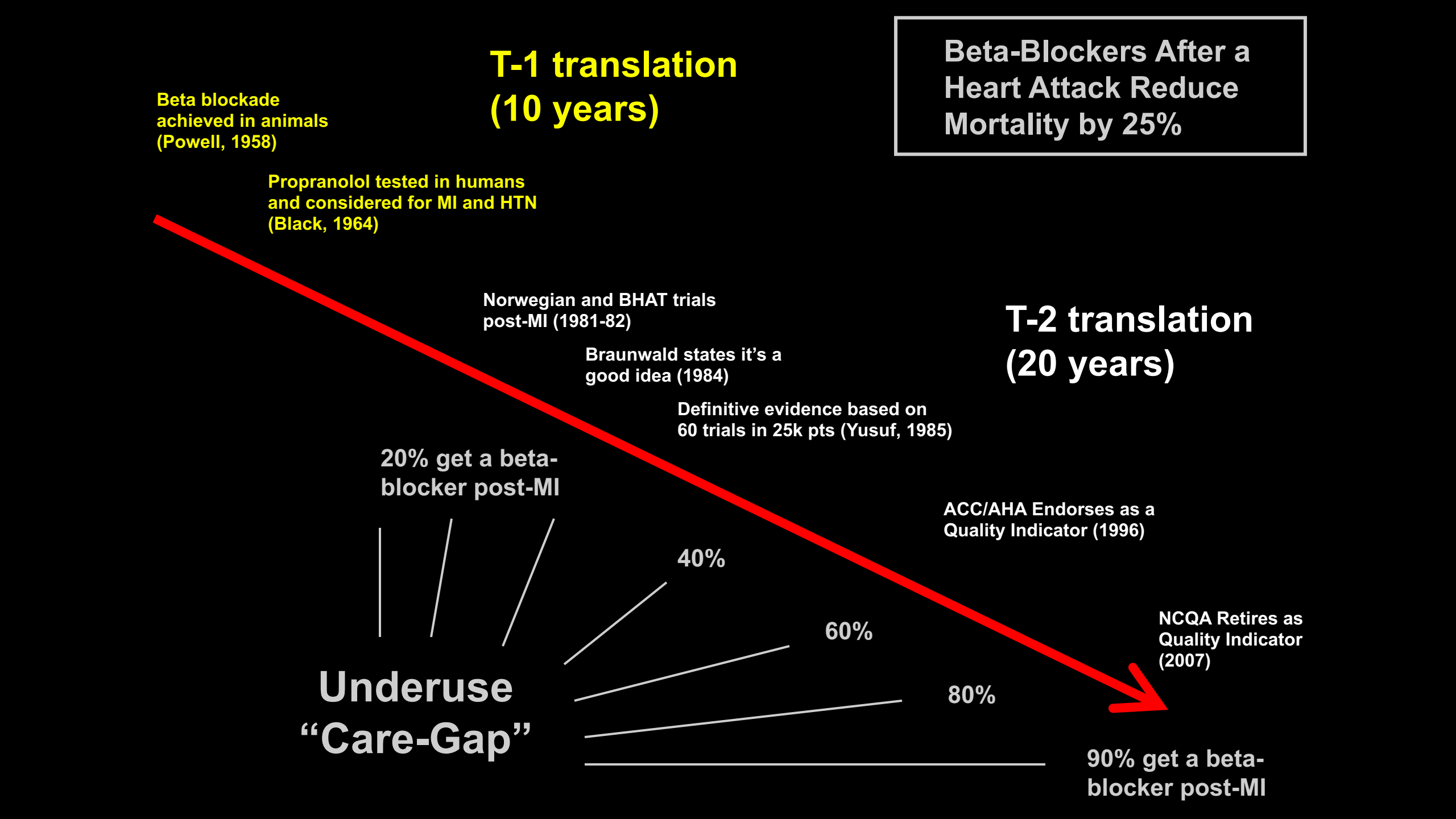
- Outcomes, not geography or ethnicity, should determine which treatment a patient receives
- Variations in practice are associated with differences in patient outcomes
- Patient values and preferences should be incorporated into clinical decision making

Implementation Research

- At the intersection between research and quality improvement (QI)
- Uses methods from health services research (HSR) and qualitative methods
- Translation science that goes beyond the bedside

Implementation Research

The scientific study of methods to promote the rapid uptake of research findings, and hence to reduce inappropriate care and improve the health of individuals and populations


Beta-Blockers After a Heart Attack Reduce Mortality by 25%
T-1 translation (10 years)
Beta blockade achieved in animals (Powell, 1958)
Propranolol tested in humans and considered for MI and HTN (Black, 1964)
Norwegian and BHAT trials post-MI (1981-82)
Braunwald states it's a good idea (1984)
Definitive evidence based on 60 trials in 25k pts (Yusuf, 1985)
T-2 translation (20 years)
ACC/AHA Endorses as a Quality Indicator (1996)
NCQA Retires as Quality Indicator (2007)
20% get a beta-blocker post-MI
40%
60%
80%
90% get a beta-blocker post-MI
Underuse "Care-Gap"

Approaches to Evidence Implementation Research

Model for Quality Improvement

AIM STATEMENT

- What are we trying to accomplish?

MEASURE

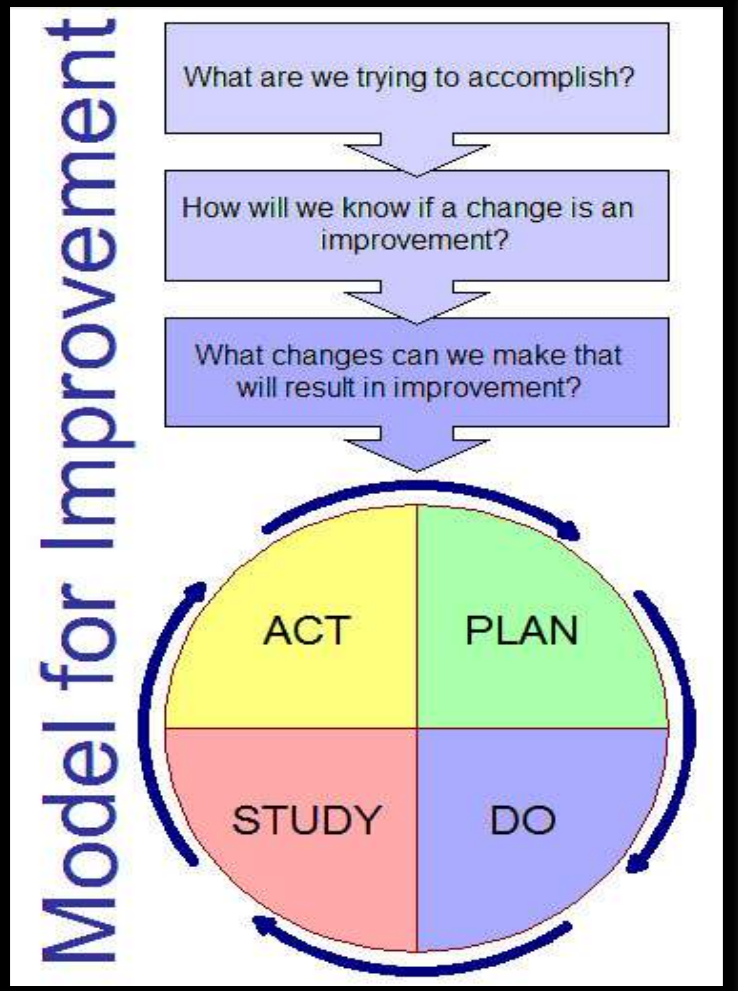
- How will we know if a change is an improvement?

PI TOOLS

- What changes can we make that will result in an improvement?

PDSA

- Tests of change



ORIGINAL CONTRIBUTION

Effects of Care Coordination on Hospitalization, Quality of Care, and Health Care Expenditures Among Medicare Beneficiaries

15 Randomized Trials

Deborah Peikes, PhD
Arnold Chen, MD, MSc
Jennifer Schore, MS, MSW
Randall Brown, PhD

Context Medicare expenditures of patients with chronic illnesses might be reduced through improvements in care, patient adherence, and communication.

Objective To determine whether care coordination programs reduced hospitalizations and Medicare expenditures and improved quality of care for chronically ill Medicare beneficiaries.

Design, Setting, and Patients Eligible fee-for-service Medicare patients (primarily with congestive heart failure, coronary artery disease, and diabetes) who volunteered to participate between April 2002 and June 2005 in 15 care coordination programs (each received a negotiated monthly fee per patient from Medicare) were randomly assigned to treatment or control (usual care) status. Hospitalizations, costs, and some quality-of-care outcomes were measured with claims data for 18 309 patients (n=178 to 2657 per program) from patients' enrollment through June 2006. A patient survey 7 to 12 months after enrollment provided additional quality-of-care measures.

Interventions Nurses provided patient education and monitoring (mostly via telephone) to improve adherence and ability to communicate with physicians. Patients were contacted twice per month on average, frequency varied widely.

Main Outcome Measures Hospitalizations, monthly Medicare expenditures, patient-reported and care process indicators.

Results Thirteen of the 15 programs showed no significant ($P<.05$) differences in hospitalizations; however, Mercy had 0.168 fewer hospitalizations per person per year (90% confidence interval [CI], −0.283 to −0.054; 17% less than the control group mean, $P=.02$) and Charlestown had 0.118 more hospitalizations per person per year (90% CI, 0.025-0.210; 19% more than the control group mean, $P=.04$). None of the 15 programs generated net savings. Treatment group members in 3 programs (Health Quality Partners [HQP], Georgetown, Mercy) had monthly Medicare expenditures less than the control group by 9% to 14% (−$84; 90% CI, −$171 to $4; $P=.12$; −$358; 90% CI, −$934 to $218; $P=.31$; and −$112; 90% CI, −$231 to $8; $P=.12$; respectively). Savings offset fees for HQP and Georgetown but not for Mercy; Georgetown was too small to be sustainable. These programs had favorable effects on none of the adherence measures and only a few of many quality of care indicators examined.

Conclusions Viable care coordination programs without a strong transitional care component are unlikely to yield net Medicare savings. Programs with substantial in-person contact that target moderate to severe patients can be cost-neutral and improve some aspects of care.

Trial Registration clinicaltrials.gov Identifier: NCT00627029

JAMA. 2009;301(6):603-618 www.jama.com

CHRONIC ILLNESSES POSE A SIGnificant expense to the Medicare program and a major detriment to beneficiaries' quality of life. The cost and complexity of care are greater for those patients with multiple chronic illnesses. In 2002, for example, half of Medicare beneficiaries had been treated for 5 or more conditions but accounted for a disproportionately large 75% of Medicare spending.[1]

The high Medicare expenditures generated by these beneficiaries are driven primarily by hospital admissions and readmissions.[2] Several factors appear to contribute to the high rate of hospitalizations. Chronically ill patients may have received inadequate counseling on diet, medication, and self-care, or may find it hard to adhere to such regimens,[3-9] leading to acute exacerbations of their conditions.[10-15] Patients may lack the knowledge to recognize early warning signs of decompensation or the skills to respond to such signs, or they may not have ready access to medical help other than the emergency department.[13,16] Physicians may be unaware of patients' deficits in knowledge and skills, or of patients' barriers to adherence.[17-19]

Chronically ill patients often see multiple physicians (1 study[20] found a median of 7 different physicians per year) who may be incompletely aware of each

For editorial comment see p 668.

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Corresponding Author: Randall Brown, PhD, Mathematica Policy Research Inc, 600 Alexander Pk, Princeton, NJ 08550 (rbrown@mathematica-mpr.com).

Potential sequelae of the "NIKE approach" ?

- Widespread adoption of ineffective programs

- Unintended harms

- Opportunity costs

- Loss of MD and RN goodwill (i.e., social capital)

- etc.

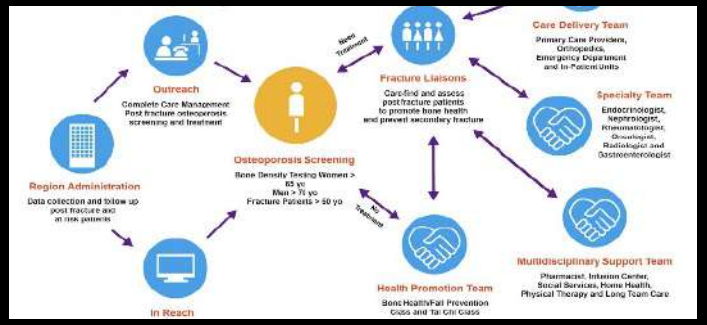
Implementation Research vs. QI

- Generalizablity is a consideration (so is “All quality is local”)
- Context is frequently health care system and policy, not just local
- Theory-driven vs. “Shot-gun”
- Emphasis is on knowledge and action, not just results

Strategies for Overcoming Barriers to Improve Quality

4 Levels

- Individual clinicians
- Patients
- Health care system interventions
- Health care financing reform



Implementation Science
Levels of Targets

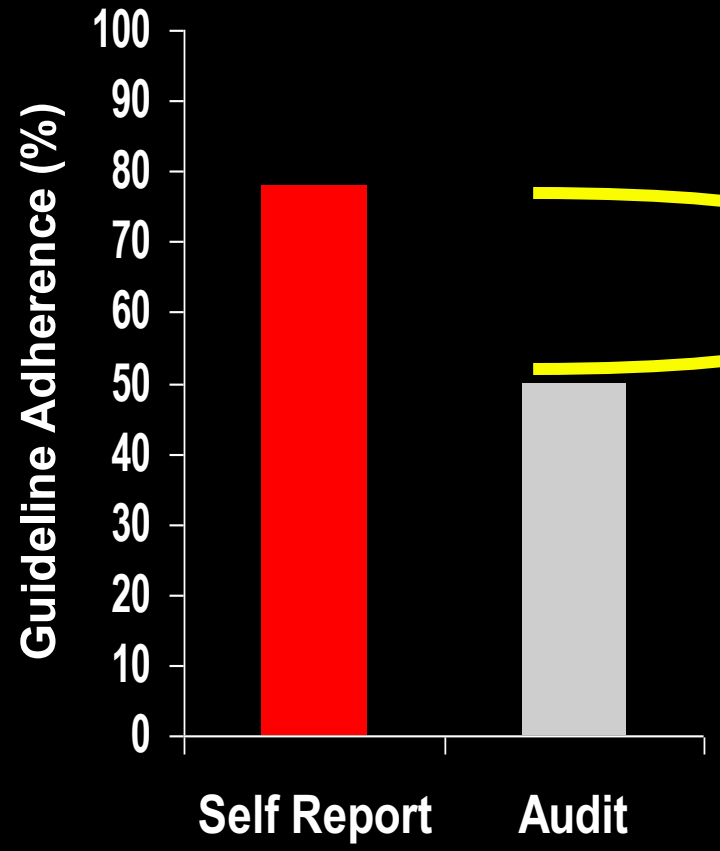
Levels of Targets	Pro's	Con's
Individual Clinicians and Patients		
Health Care System		
Health Care Financing		

Heterogeneity in Osteoporosis Implementation Studies

- Rigor of study design
- Targets: providers, patients, health systems, health care financing, and mixed
- Primary vs. Secondary prevention
- Timing to fracture event
- Initiating vs. sustaining testing/therapy
- Osteoporosis sub-types
- Type of health care coverage/systems

Provider Interventions

Pervasive Care-Gap Between What Doctors Know and What They Do



- Reviewed studies with both self-report and practice audits:
  - Median difference (care-gap) = 28%
  - MDs overestimate own guideline adherence 88% of time

Adams A. *Int J Qual Healthcare.* 1999;11:187

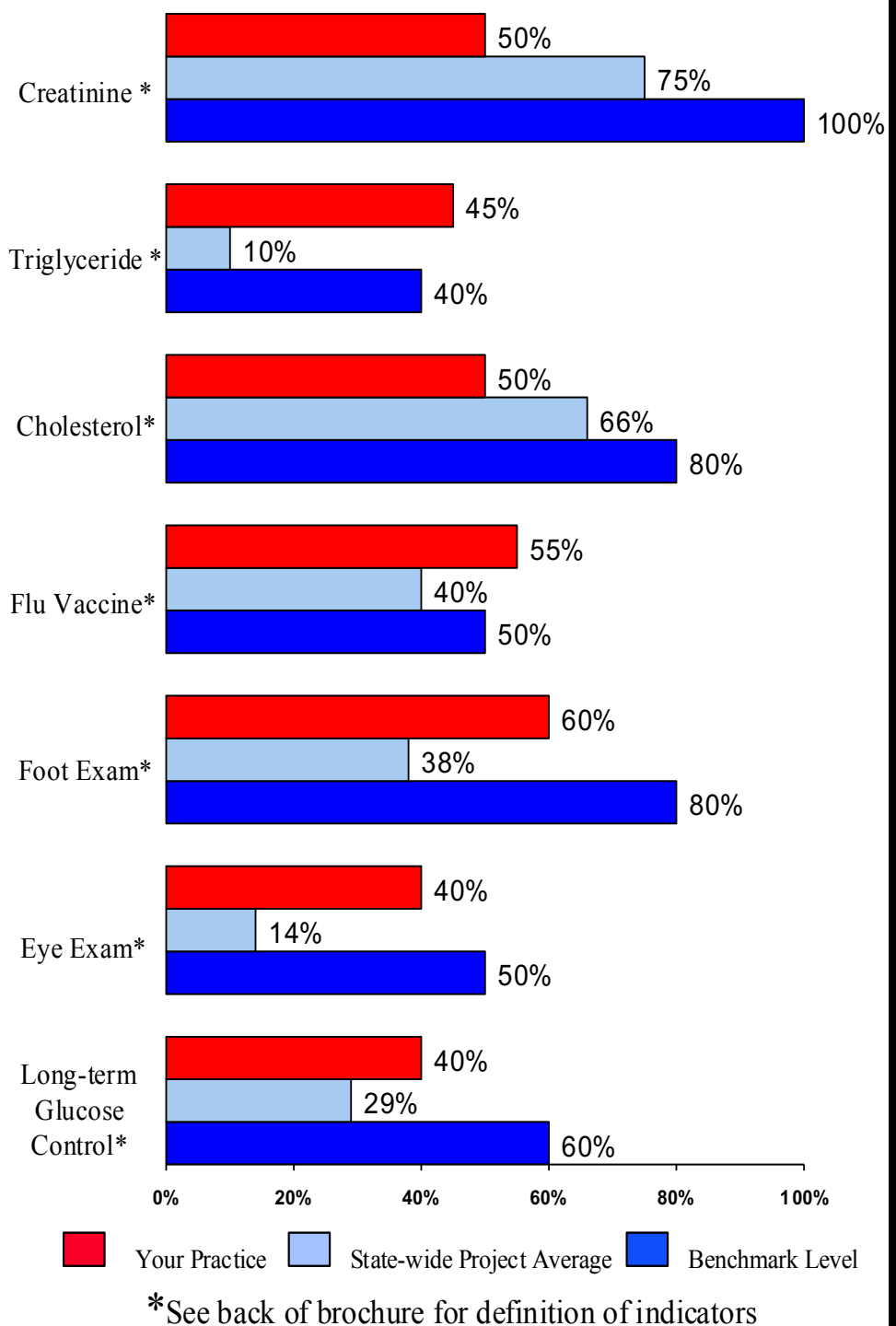
Designing Evidence-Based Interventions to Overcome Barriers to Best Practice

- Physician level
  - Lack of knowledge; lack of time ; clinical inertia
- Patient level
  - Lack of information; symptomatic vs preventive care bias; preferences, demands, expectations; non-adherence
- System level
  - Lack of information systems (i.e., registries with real time reminders); access; reimbursement

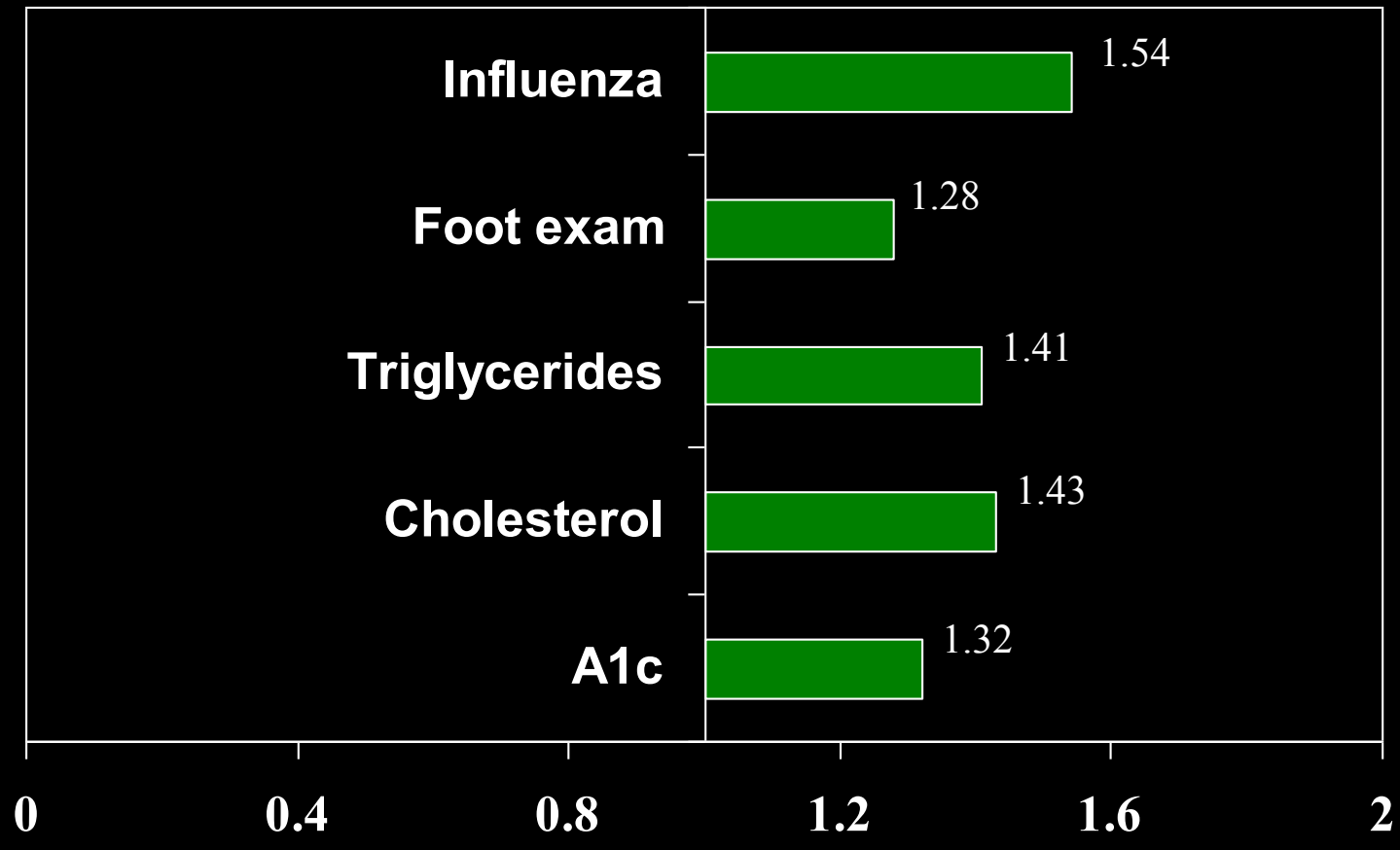
Majumdar S. *CMAJ* 2003;169:30
Majumdar S. *JACC* 2004;43:1738

Doctor Data Feedback DM Example

Thank you for your participation in AQAF's *quality improvement efforts*. In this report, we are pleased to provide you with feedback that includes benchmarks (dark blue bars). They are intended to provide you with practical goals. You may be above the benchmark in some aspects of care and below in others.



Achievable Benchmarks Improve Process of Care Over Conventional Feedback

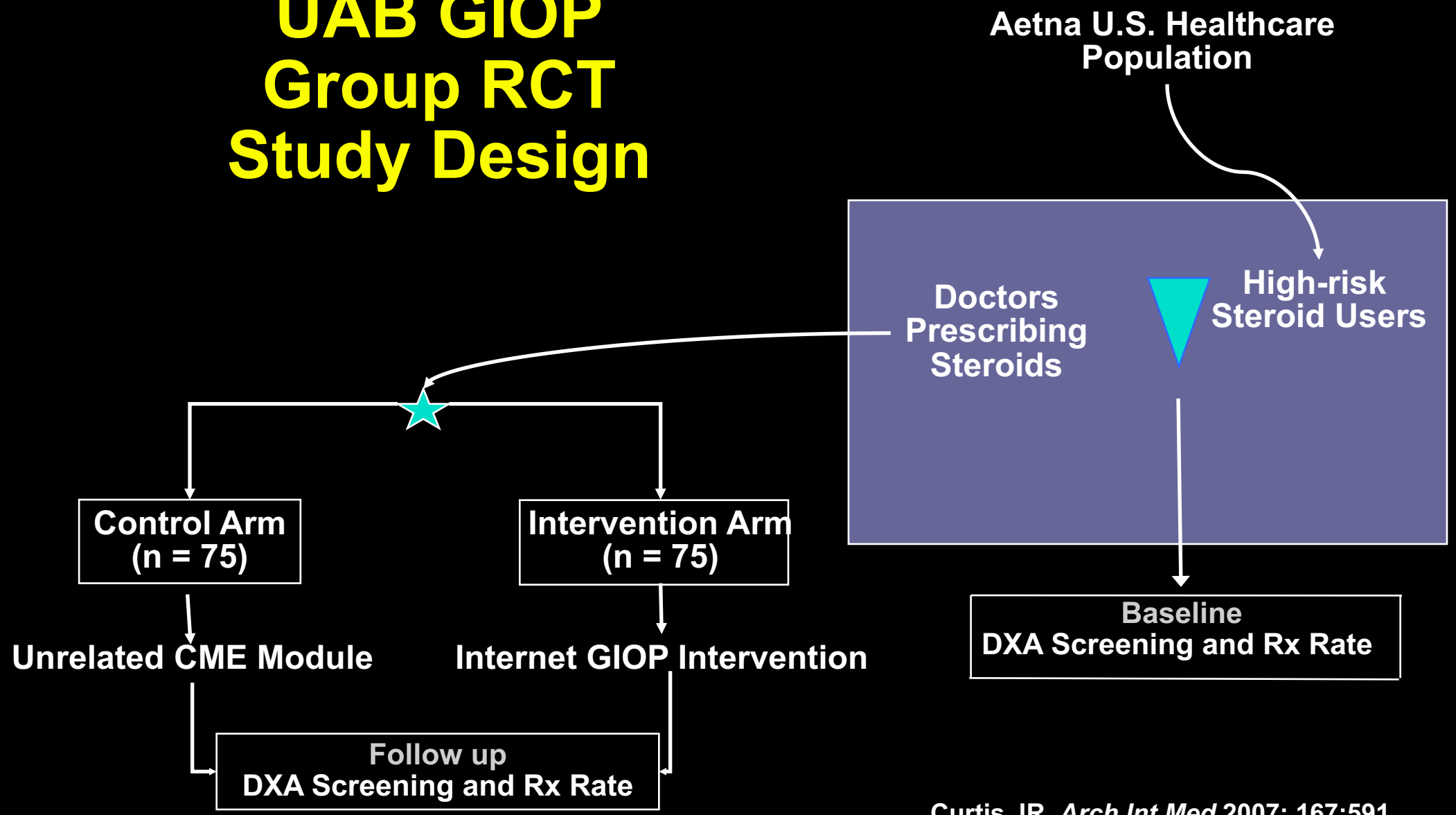


Odds Ratios: Intervention vs. Control*

*Receipt of therapy at follow up for intervention vs control physicians after adjusting for (1) baseline performance (2) nesting of pts within MDs and (3) MD characteristics

Kiefe C. *JAMA* 2001;285:2871

UAB GIOP Group RCT Study Design



Curtis JR. *Arch Int Med* 2007; 167:591

GIOP Internet Intervention

- Access via e-mail
- Tailored presentation
- Case-based interactive learning
- Personal data feedback using Achievable Benchmark of Care (ABC™)
- Improvement “toolbox”
- Printable CME certificate
- Continued exposure to combat “decay”

Kiefe C. *JAMA* 2001;285:2871

GIOP Group RCT Results

	% Receipt		
Intent-To-Treat	**Intervention (n = 76 docs)**	**Control (n = 73 docs)**	**p-value**
BMD	19	21	NS
Prescription Rx	26	24	NS
Per Protocol*	**(n = 27 docs)**	**(n = 18 docs)**	**p-value**
BMD	26	16	0.04
Bisphos Rx	24	17	0.09
BMD or Rx	54	44	0.07

Curtis JR. *Arch Int Med* 2007; 167:591

* Completed all 3 modules

Review of Glucocorticoid-Induced Osteoporosis (GIOP) Interventions (n = 7 Studies)

- Education-based interventions (n = 5)
  - RCTs (n= 2) focused on physicians- NS
  - Non-randomized educational interventions (n = 2) - NS
  - RCT focused on pharmacists and patients - increased calcium supplementation in the intervention vs. control arm (55.7% vs. 31.6%, $p < 0.05$)

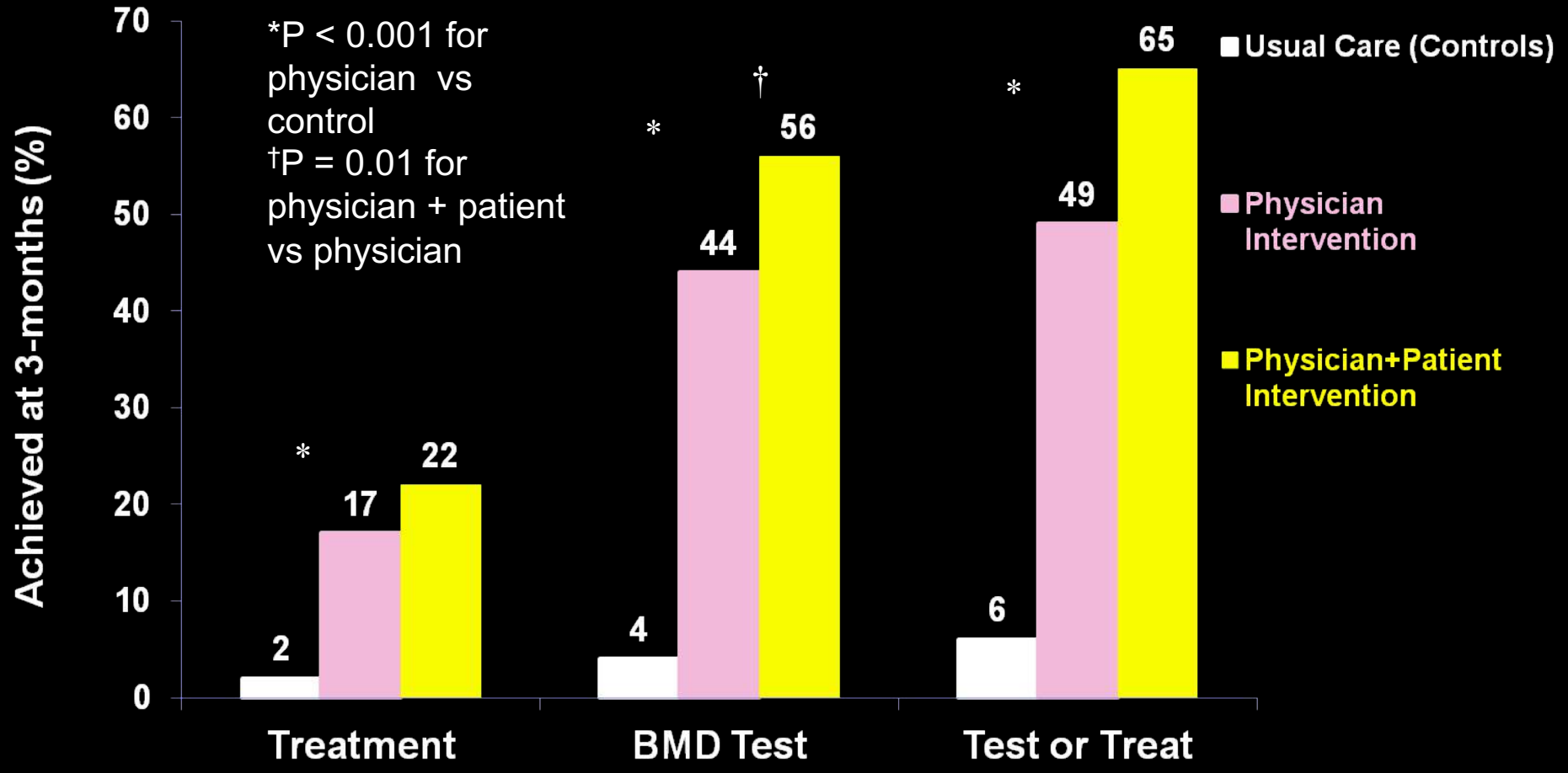
Tory HO. *Semin Arthritis Rheum* 2015;44:483

Tasmanian GIOP Intervention

- Non-randomized, pre-/post with controls
- Intervention in Northern Tasmania
  - Educational Material/Guidelines and Academic Detailing
  - GPs (n = 200), Pharmacists (n = 81)
  - 113 pts
- Southern Tasmania “control”
- Changes in GIOP Prevention in Hospitalized Patients
  - Any GIOP Rx: ↑ 31 to 57%
  - Bisphosphonates: ↑ 6 to 24%

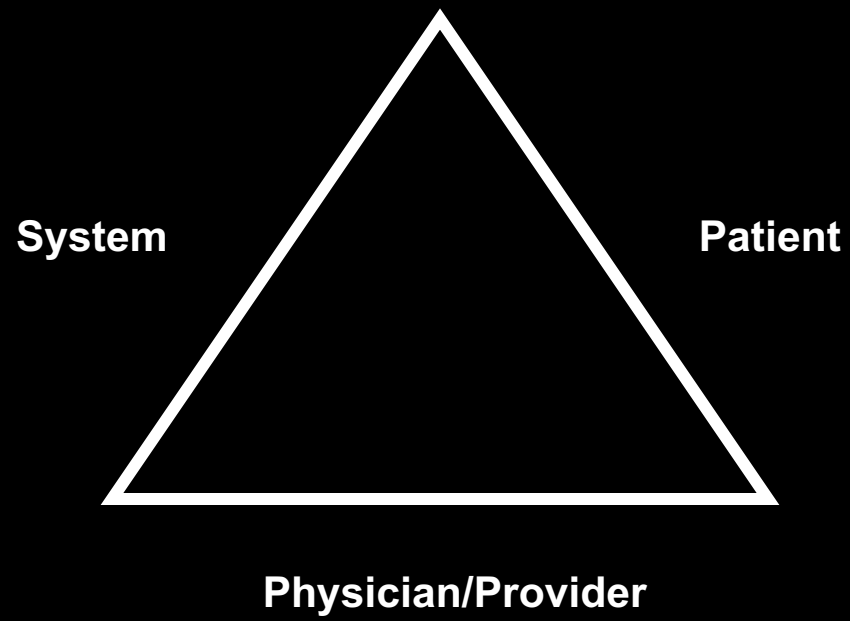
Naughton M. *J Rheumatol* 2004;31:550

Effect of 2 Interventions on Osteoporosis Testing and Treatment After Vertebral Compression Fracture Reported on CXR



Majumdar S. *Am J Med* 2012;125:929

Alternate Evidence Implementation Approaches in Osteoporosis



Patient Interventions

Patient Activation after DXA Result Notification (PAADRN) Study Design

- Pragmatic Randomized controlled trial
- Unit of randomization and analysis: Study Participants and Providers
- Two Arms
  - Usual Care
  - Tailored letter containing DXA test information and educational brochure
- Power based on n = 7500 participants (7,749 randomized)

Cram P. *Osteoporos Int* 2016; 27: 3513

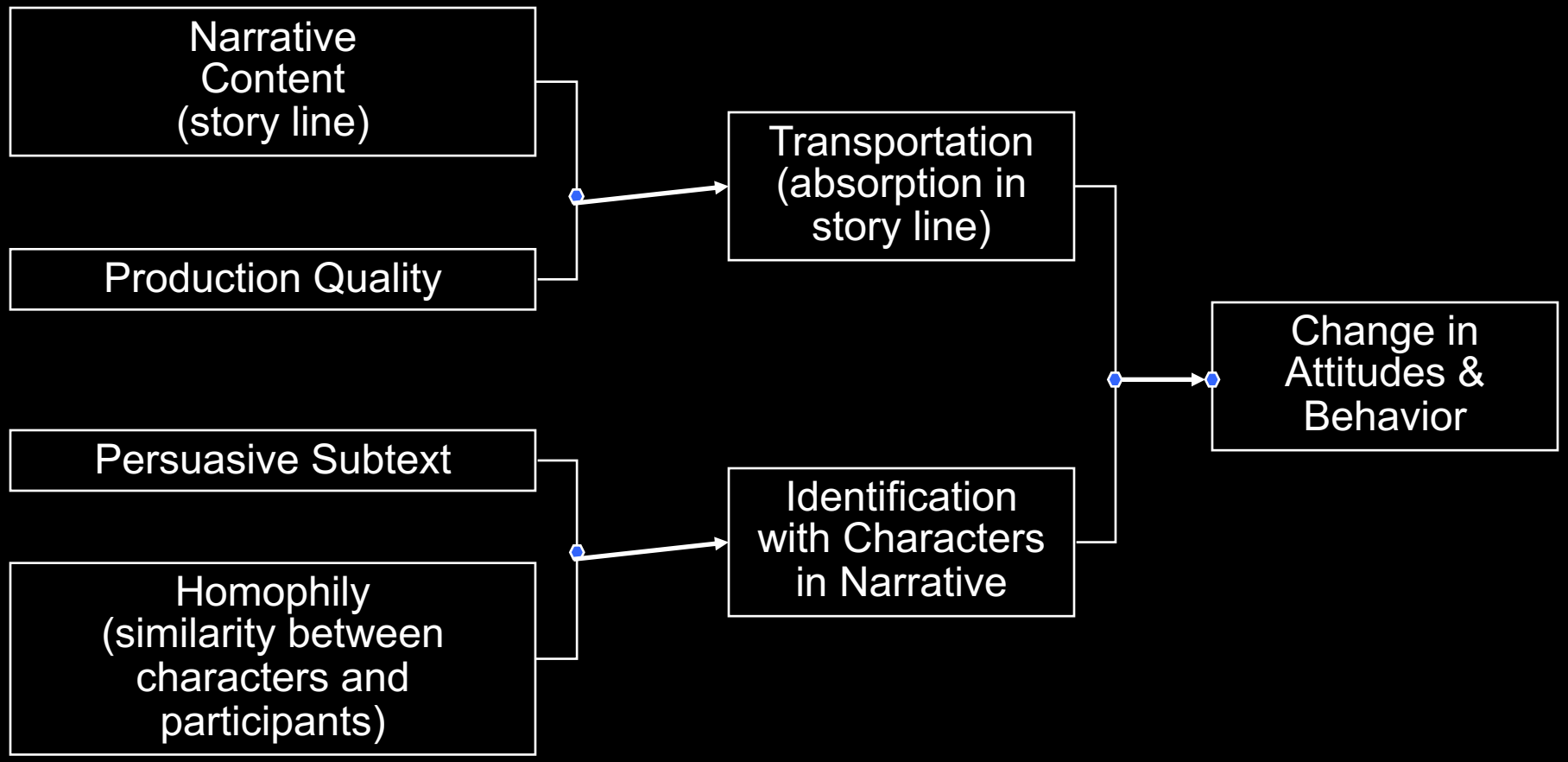
PAADRN- Results

- 6,728 (86.8%) completed 12-week follow-up.
  - 84% women
  - 77% White
  - Mean age 66.5 years
- At follow-up: 65.4% of intervention and 64.4% of control patients on guideline concordant therapy (P=0.41)*
- Intervention patients more likely to know DXA results (69.7% vs 56.8%; p<0.001)
- Intervention patients more likely to speak to their physician about DXA results (61% vs 57.3%; p=0.02)

*signifiant effect at one of three study sites (p<0.05).

Cram P. *Osteoporos Int* 2016; 27: 3513

Narrative Communication
Why Give Stories to Patients?



Slater M. *Communication Theory.* 2002;12 :173

“The power of narratives to change belief has never been doubted and has always been feared.”

Green MC. J Personality Social Psychology 2000; 79 :701

Improving Blood Pressure Medication Adherence

Culturally Sensitive Intervention (CSI)

Cooper Green Jefferson County Hospital

	Baseline systolic BP	3-Month Follow-up systolic BP*
Intervention	132.5 mmHg	127.5 mmHg
Control	131.1 mmHg	132.2 mmHg

Benefit greatest among those with uncontrolled BP at baseline
(-17 mmHg intervention, -7 mmHg control, p = 0.03)

* p = 0.04, intervention vs. control

Houston T. *Ann Int Med* 2011;154:77

Steroids and Fractures

Improving GIOP Treatment Rates

Internet-based Video Intervention In Chronic Steroid Users from MEDCO

("Light Touch, Low Cost")

	Total N	% Osteoporosis Rx at 180 days
Intervention		
Intent-to-treat	3018	2.9%
Per protocol*	1780	2.9%
"Self-click"**	87	5.7%
Usual care (control)	1641	2.7%

* Per protocol indicates a measurable exposure to the online intervention video
**Self-click indicates that person self-clicked on web link to watch video

Warriner A. *J Rheumatol* 2015;42:1478

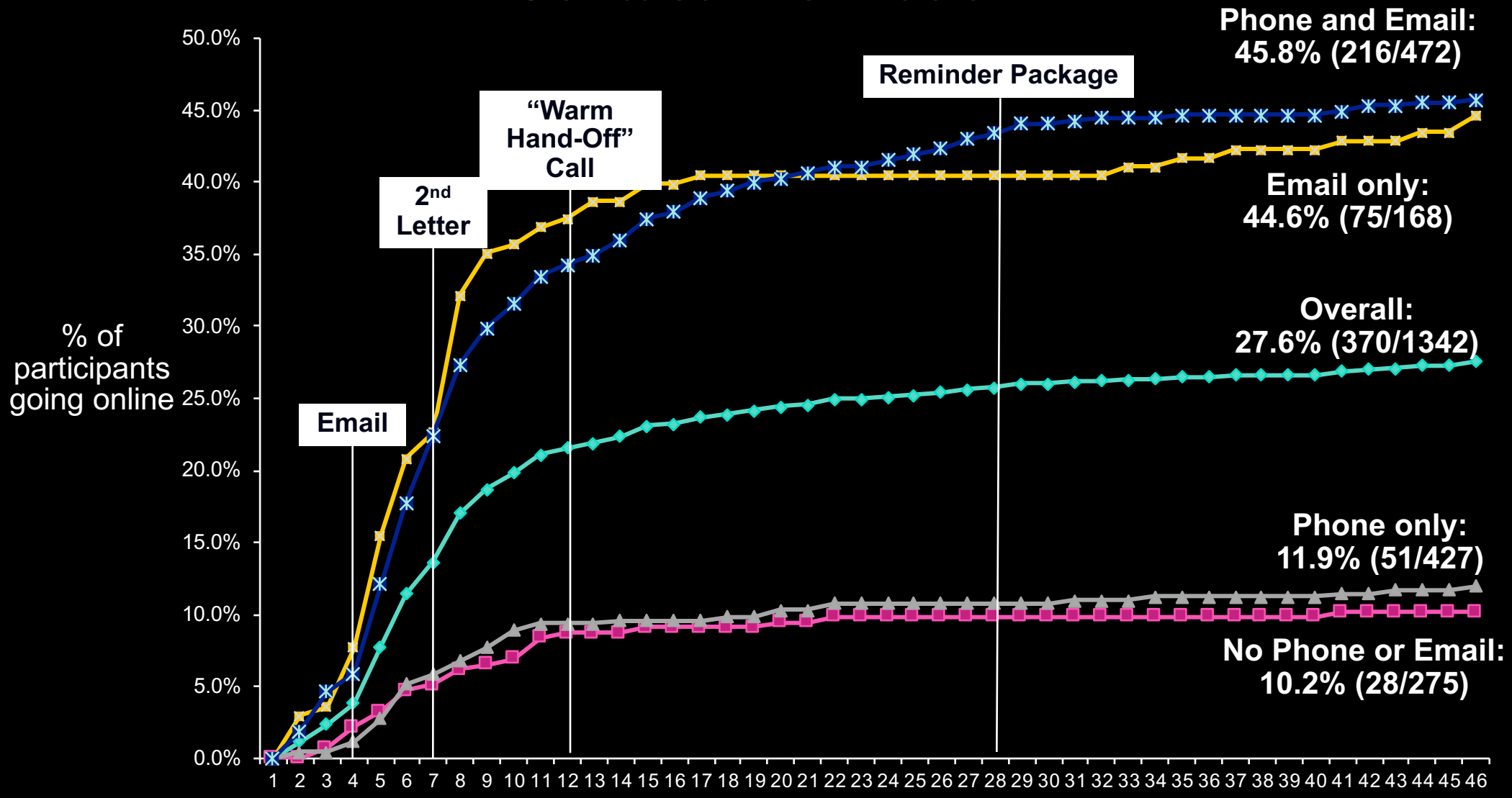
Activating Patients to Reduce OsteoPorOsiS (APROPOS)

- Subset of Global Longitudinal Registry of Osteoporosis in Women (GLOW) study population
  - US women 55+ yrs
  - Self-report of fracture on any GLOW survey
  - No current osteoporosis Rx
- Randomized Controlled Trial of patient activation approach
  - Usual Care (n = 1342)
  - Online/DVD tailored educational intervention (n = 1342)
  - Power 80%, alpha = 0.05, min detectable difference = 4%
    - N_{adj} per treatment group = 850

NIH National Institute of Arthritis and Musculoskeletal and Skin Diseases R01AG18947

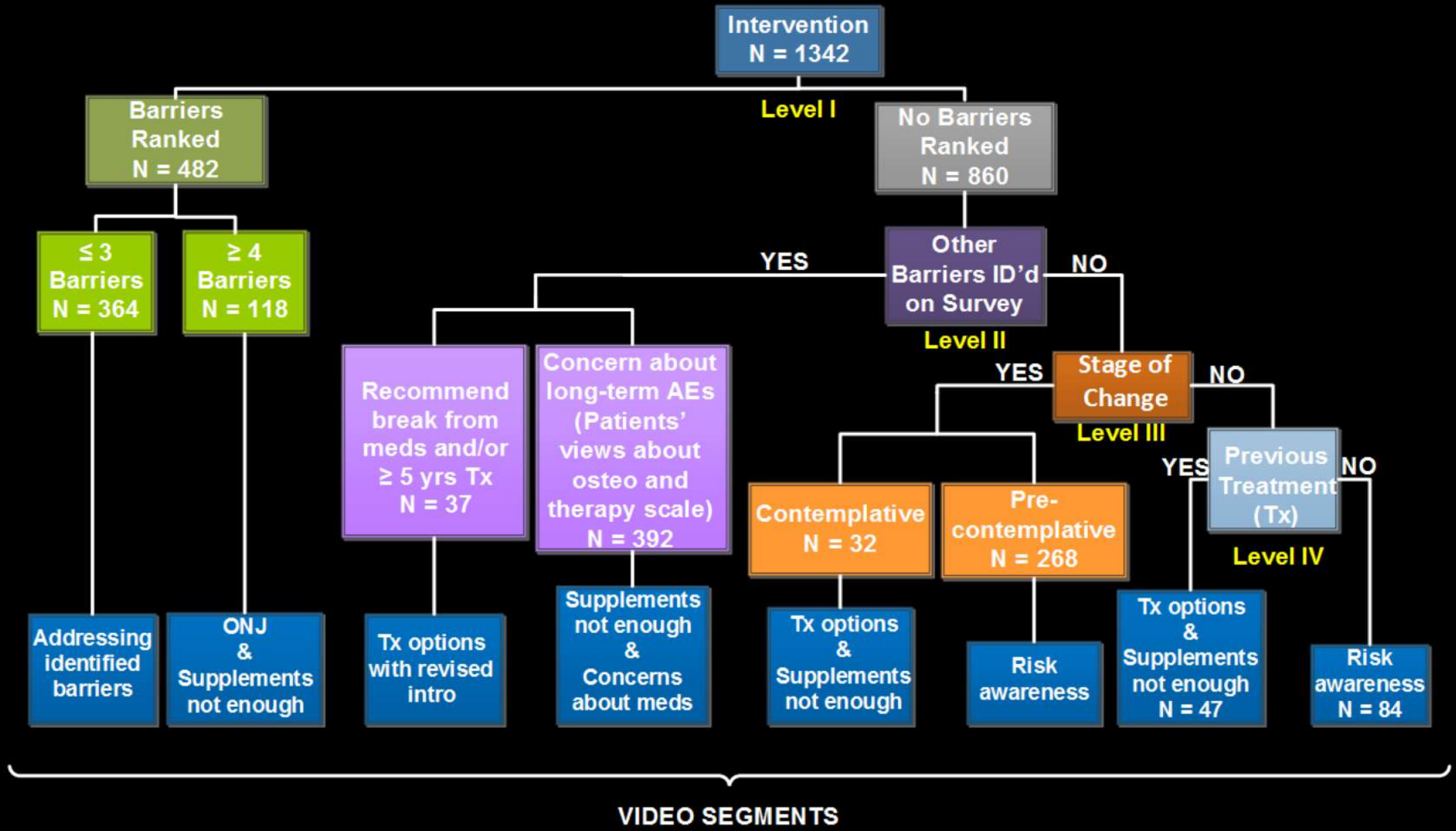
Danila M. *Contemp Clinical Trials Com* 2016; 4:14
Danila M. *JBMR* 2018;33:763

Percentage of Participants Interacting with APROPOS Intervention Website by Contact Information



Danila M. ASBMR, 2015

UAB APPROPOS Tailored Intervention



Appropos Tailored Video Osteonecrosis of the Jaw

APROPOS Results

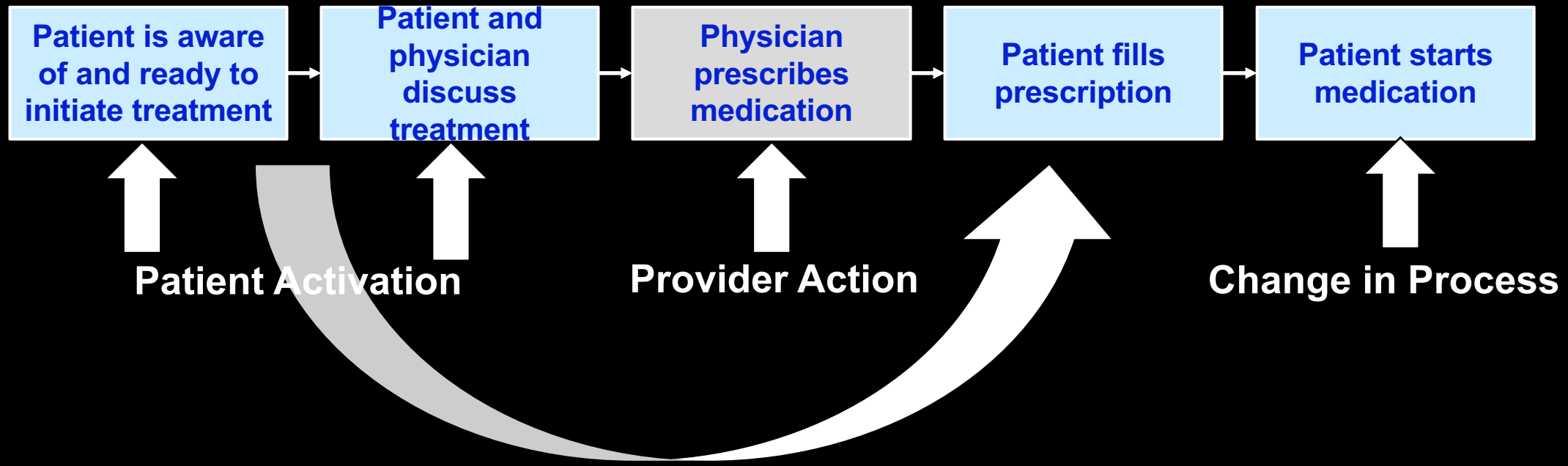
- No differences in treatment rates between intervention and control arms in ITT population
- More individuals in the intervention arm shifted from pre-contemplative to contemplative stage of behavior change relative to usual care
- Increased reports of treatment-related barriers including ONJ, difficulty taking medication, and GI/stomach in intervention group
- Subgroup and per protocol analyses showed increased DXA testing in intervention arm
  - No prior DXA
  - Providing an email address
  - Measurable exposure to intervention

Danila M. *Contemp Clinical Trials Com* 2016; 4:14
Danila M. *JBMR* 2018;33:763

Patient Interventions for Primary Osteoporosis Prevention

Reference	Intervention	Sample size	Results
Tüzün et al. 2013	Telephone calls, interactive education	Intervention (N = 226) Control (N = 222)	Intervention: Self-reported persistence and compliance = 152 (50.5) Control: Self-reported persistence and compliance = 149 (49.5) (p = 0.862)
Solomon et al. 2012	Telephone-based counseling/motivational interviews by health educator	Intervention (N = 1046) Control (N = 1041)	Intervention: MPR = 49% (IQR 7, 88) Control: MPR = 41% (IQR 1.5, 86.0) (p = 0.074)
Bianchi et al. 2015	Educational booklets, calendar alarms (Grp 2) Added Phone call reminders (Grp 3)	Group 2 (N = 110) Group 3 (N = 111) Control (N = 113)	Group 2: 90.1% persistent Group 3: 84.6% persistent Control: 92.0% persistent (p=0.288)
Cizmic et al. 2015	Interactive voice response followed by reminder letter	Intervention (N = 126) Control (N = 118)	Intervention: 48.8% bisphosphonates Control: 30.5% bisphosphonate OR = 2.17, 95% CI 1.29-3.67

"Activating Patients" to Increase Osteoporosis Treatment Initiation



- Multi-stage, complex pathway to change process
- Involves patient and clinician
- Success may depend in part on how far down pathway you start

System Interventions

Improving Care of Osteoporosis: Multi-Modal Intervention to Increase Testing and Treatment (ICOMMIITT)

Interventions at the Patient and System Level

UAB: K Saag, A Warriner, R Outman, J Curtis, J Bodon, J Allison, M Safford, T Houston

KPGA: D Roblin, J Calvi, J Ren

KPNW: A Feldstein, M Rix, A Rosales

hmo research network

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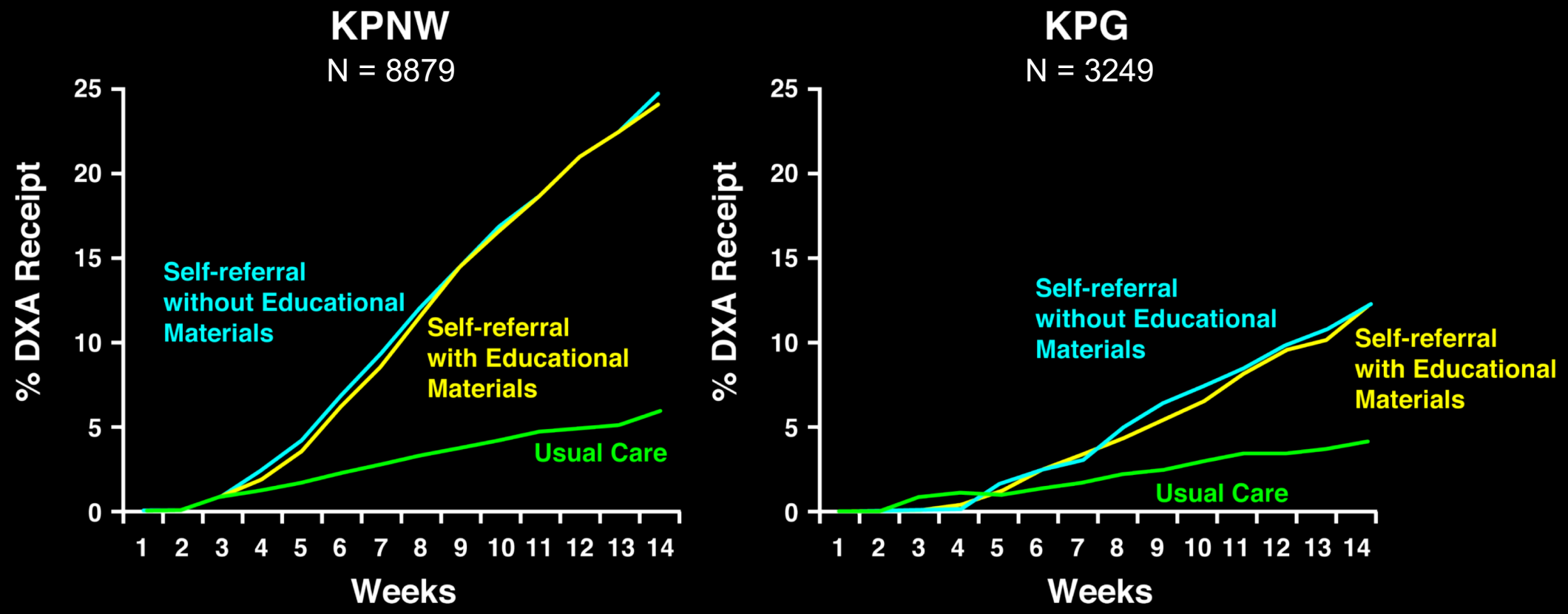
Improving Care of Osteoporosis: Multi-Modal Intervention to Increase Testing and Treatment (ICOMMIITT)

- Partnership with Kaiser Permanente of Georgia and Kaiser Northwest
- Multi-Modal Intervention
  - System (practice redesign strategy, BMD testing alert)
  - Patient (education and activation, improve patient-provider communication)
  - Provider (web-based CME) (control)

DXA Self-Referral Significantly Increased Testing Rates

(Kaiser Permanente Health Systems)



Warriner AH. *Medical Care,* 2014;52:743
Warriner AH. *JBMR*, 2012.;27:2603

Recent System Interventions for Adherence

Reference	Population	Intervention	Sample size	Results
Stuurman-Bieze et al. 2014	1° prevention	Pharmacist-delivered medication monitoring and counseling	Intervention (N = 495) Historical control (N = 442)	Intervention: 19.0% discontinued medications or non-adherent Control: 32.8% discontinued medications or non-adherent (p< 0.001)
Majumdar et al. 2017	2° prevention	Catch-a-Break: "Type C" FLS program	Intervention (N = 4633) Simulated control (N = 2690)	Intervention: 17.5% (95% CI 15.6–19.4) bisphosphonates Rx Simulated Control: 13.2% (95% CI 12.4–14.0) bisphosphonate Rx (p < 0.001)
Ganda et al. 2014	2° prevention	"Type A" FLS program in Group A Intervention (6 visits with FLS);	Intervention (N = 49) Control (N = 53)	Intervention: MPR = 0.78 (IQR, 0.50–0.93) Control: MPR = 0.79 (IQR, 0.48– 0.96) (p=0.68)

Review of GIOP Interventions (n = 7 Studies)

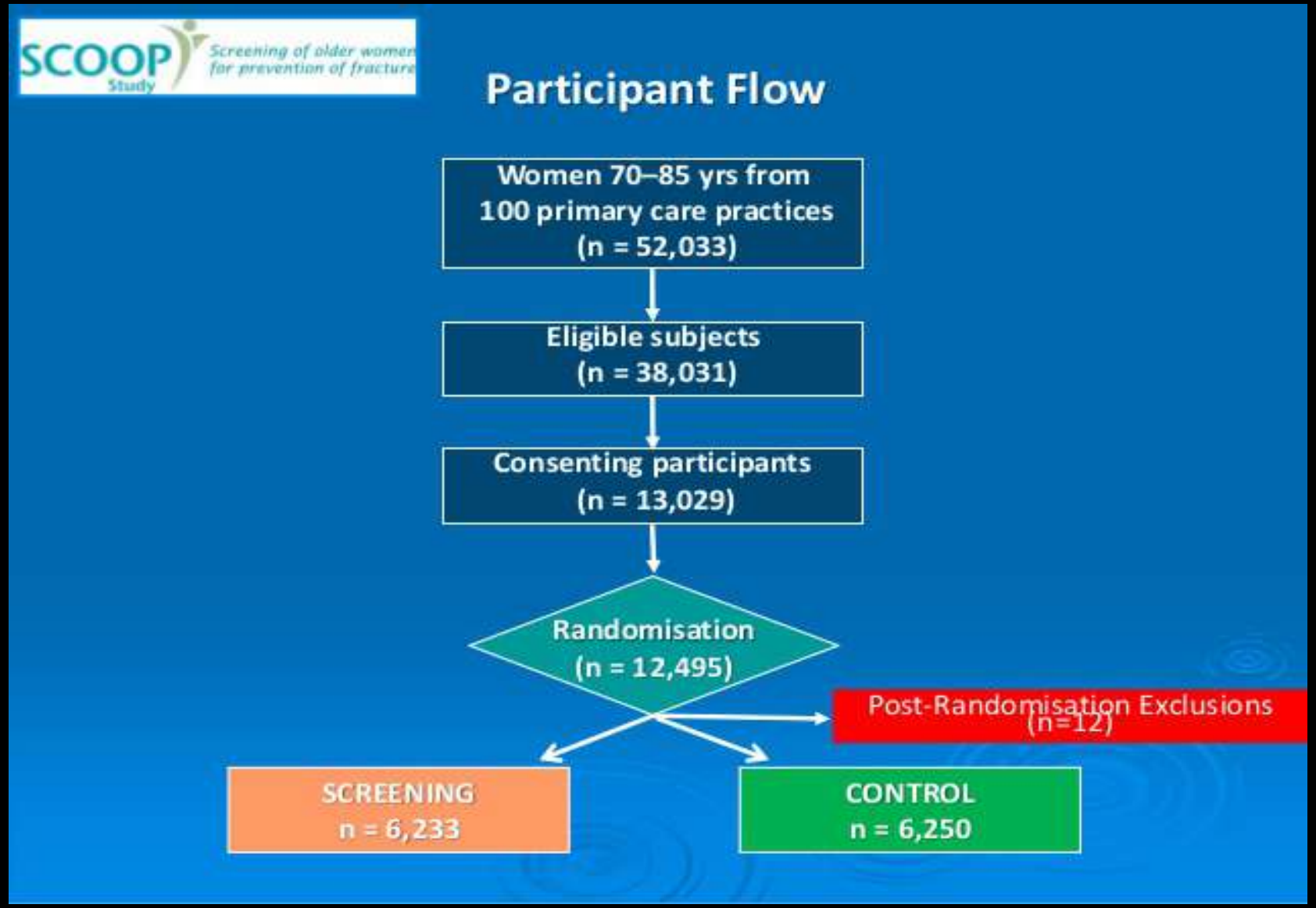
- Education-based interventions (n = 5)
  - RCTs (n= 2) focused on physicians- NS
  - RCT focused on pharmacists and patients - increased calcium supplementation in the intervention vs. control arm (55.7% vs. 31.6%, $p < 0.05$)
  - Non-randomized educational interventions (n = 2) - NS
- Non-randomized, uncontrolled studies of system changes (n = 2)
  - Increased concomitant prescriptions of glucocorticoids and calcium (37- 49%, $p < 0.0001$) and vitamin D (38-53%, $p < 0.0001$) using computerized order entry system
  - Dedicated clinical team - increased vitamin D levels from 19.5 to 29.4 ($p = 0.001$) and improved GIOP-related habits

Tory HO. *Semin Arthritis Rheum* 2015;44:483

Screening in the Community to reduce fractures in Older women with OP (SCOOP) Trial

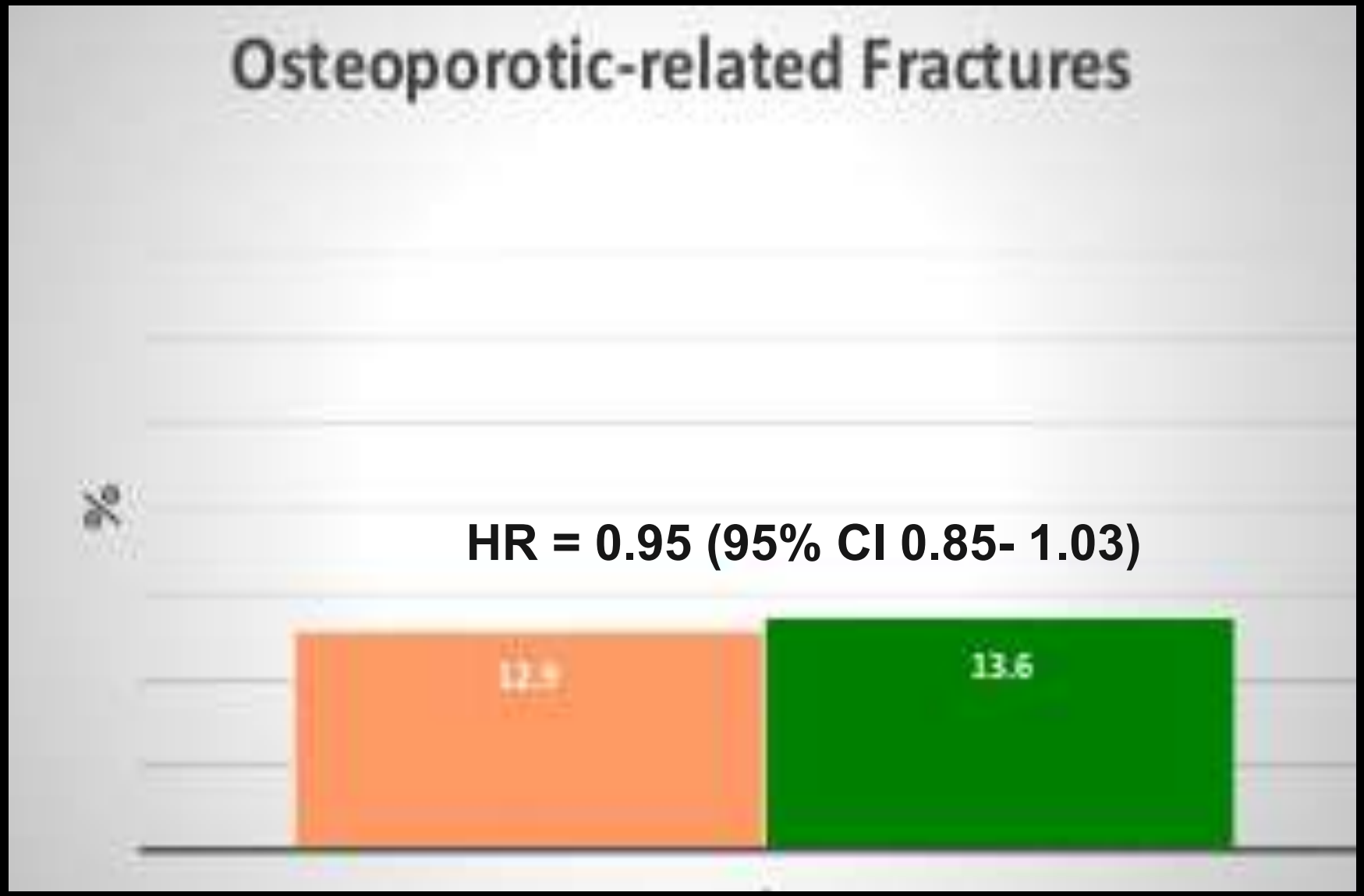
- Two-arm randomised controlled Trial
  - Compared a screening programme using the Fracture Risk Assessment Tool (FRAX) vs. Usual management
  - In screening group, treatment recommended in women identified to be at high risk of hip fracture, according to FRAX 10-year hip fracture probability
  - Letter to patient and to GP with FRAX results
- Primary outcome
  - Proportion of individuals who had one or more osteoporosis-related fractures over a 5-year period
- Pre-specified secondary outcomes
  - Proportions of participants who had at least one hip fracture, any clinical fracture, or mortality
  - Effect of screening on anxiety and health-related quality of life

SCOOP Study



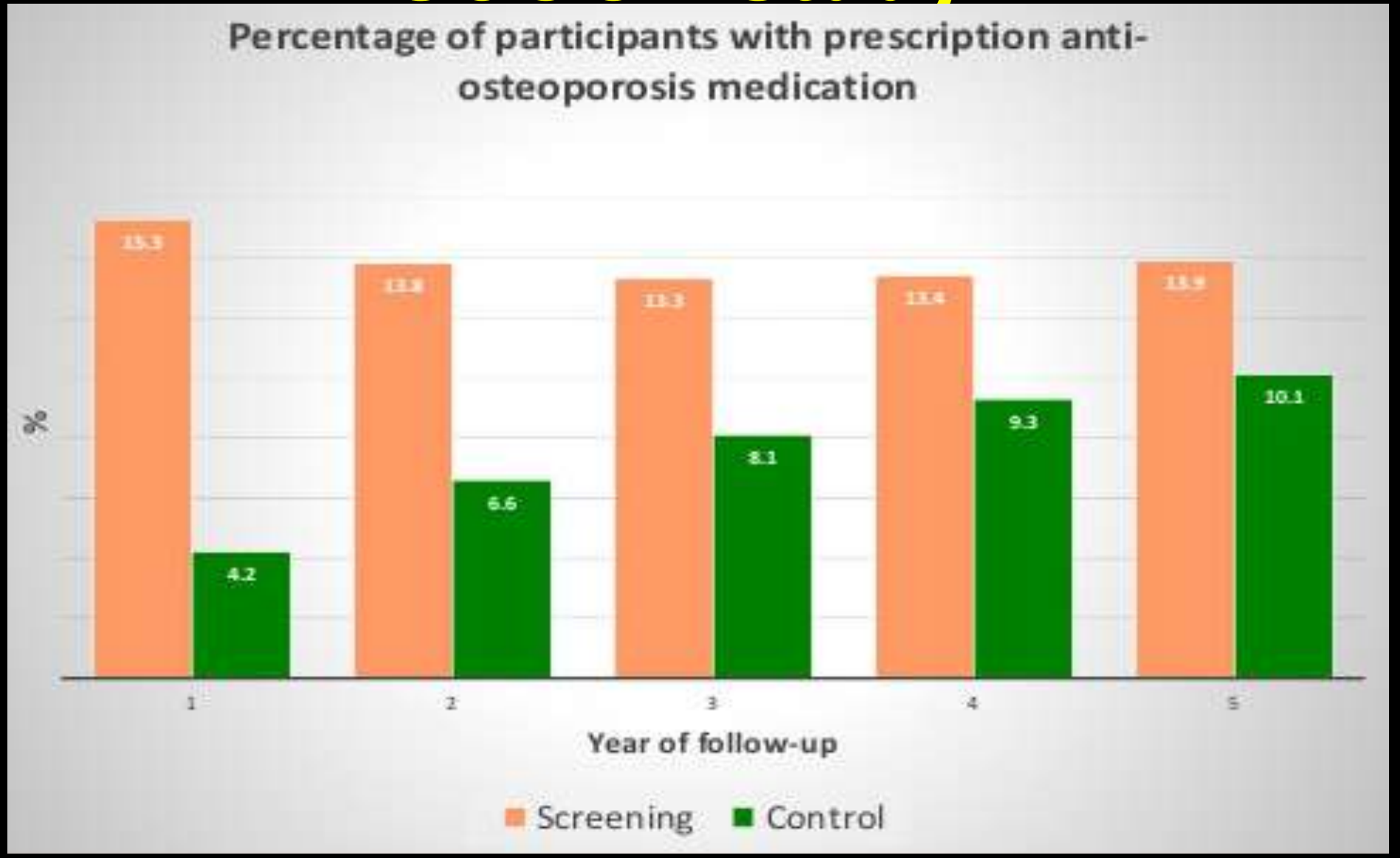
Shepstone L. *Lancet* 2018; 391: 741

SCOOP Study



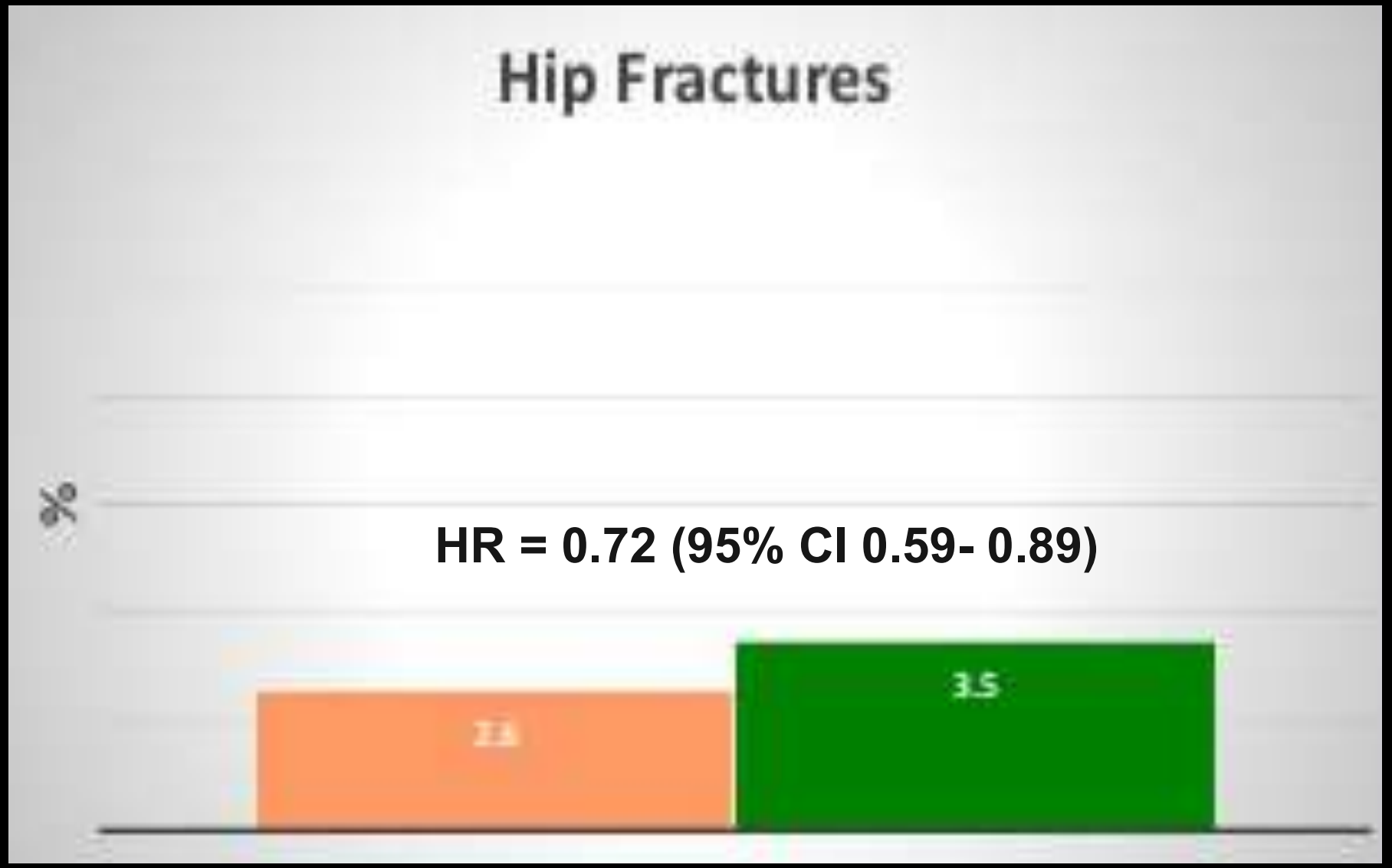
Shepstone L. *Lancet* 2018; 391: 741

SCOOP Study



Shepstone L. *Lancet* 2018; 391: 741

SCOOP Study



Shepstone L. *Lancet* 2018; 391: 741

SCOOP Conclusion

- Community based UK screening program was feasible, generally well received
- No evidence of overall fracture risk reduction, mortality, or quality of life
- Evidence that medication prescribing increased and hip fractures could be reduced

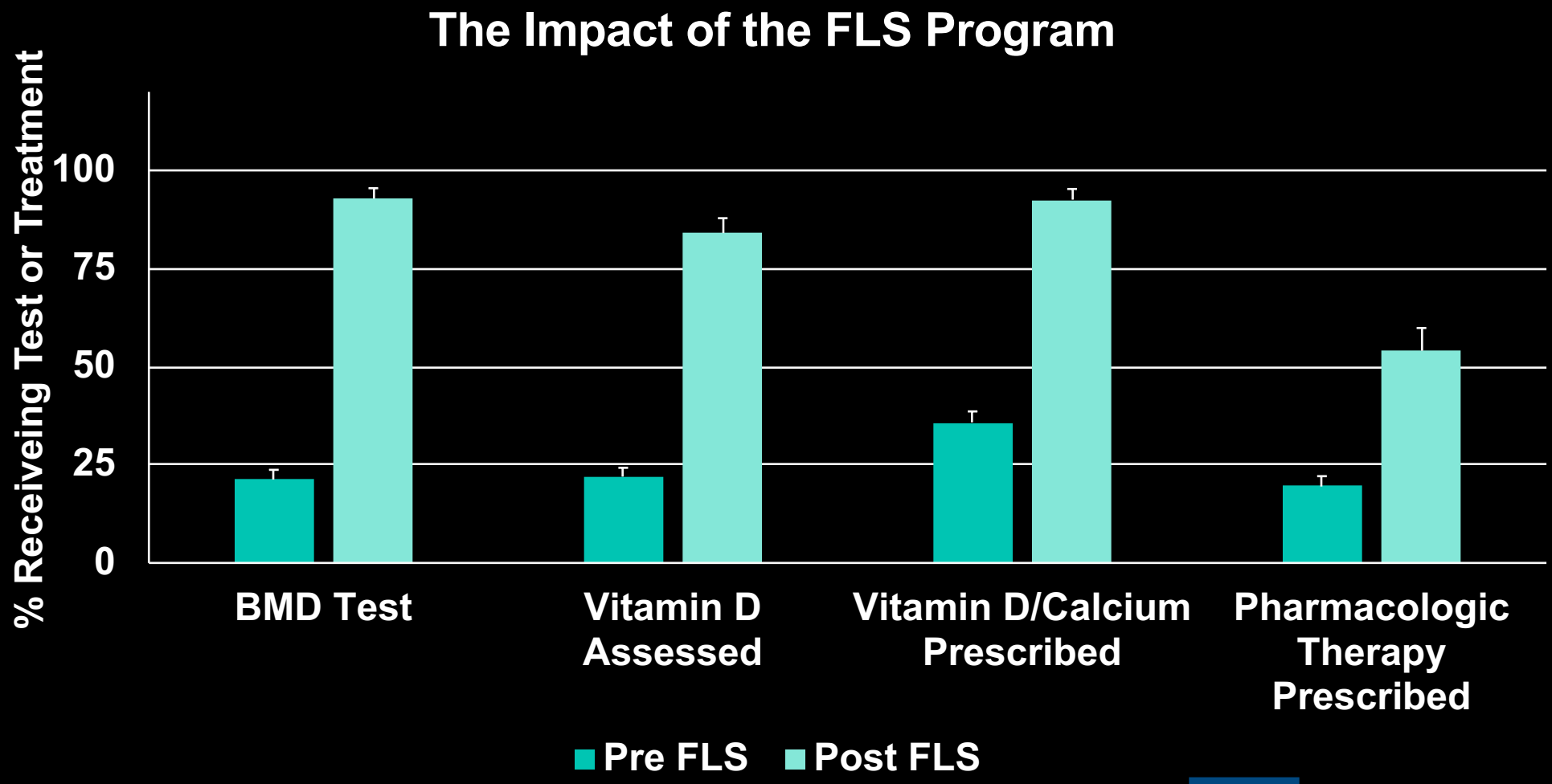
Shepstone L. *Lancet* 2018; 391: 741

Fracture Liason Services (FLS) in an "Open" System

- Study design: Pre-post comparison of fracture care before and after FLS program
- Pre-FLS: Retrospective chart review for 6 months after fracture (N=344)
- Post-FLS: Prospective assessment for 6 months after fracture (N=148)
- Facilities: 3 independent health care systems
  - A, B, C that serve 450-600 adults hospitalized with low-trauma fractures
  - Open System: payers, hospitals, patients and physicians *not* closely aligned

Greenspan S. *Osteo Int*. 2018;29:953

Fracture Liaison Service (FLS) Results in a "Open" System



Greenspan S. *Osteo Int*. 2018;29:953

ORIGINAL ARTICLE

JBMR®

The Potential Economic Benefits of Improved Postfracture Care: A Cost-Effectiveness Analysis of a Fracture Liaison Service in the US Health-Care System

Daniel H Solomon,[1,2] Amanda R Patrick,[2] John Schousboe,[4] and Elena Losina[1,3]

[1]Division of Rheumatology, Brigham and Women's Hospital, Boston, MA, USA
[2]Division of Pharmacoepidemiology, Brigham and Women's Hospital, Boston, MA, USA
[3]Department of Orthopaedic Surgery, Brigham and Women's Hospital, Boston, MA, USA
[4]HealthPartners, Minneapolis, MN, USA

- To evaluate cost-effectiveness of Fracture Liaison Service (FLS)
- To test cost-effectiveness under a universal vs targeted (based on DXA) approach
- Examine sensitivity of findings to:
  - Target population (prior hip fracture only; hip, vertebral, or wrist fracture)
  - Cost of FLS
  - Efficacy in increasing bisphosphonate use
  - Cost of medications (IV Zol)

Solomon D. *JBMR* 2014;29:1667

FLS Economic Results

Scenarios	Delta Cost	Delta QALY	ICER ($/QALY)
Base case	-7	0.004	Cost saving
One Way Sensitivity Analyses			
FLS cost at $205	93	0.004	24,933
OP med costs at $250	54	0.004	14,513
2nd fx rates reduced by 10%	17	0.005	4,072
BIS disutility included	11	0.003	3,971
FLS treatment rates 66%	-145	0.008	Cost saving
Multi Way Sensitivity Analyses			
FLS $205, OP med $250	141	0.004	37,729
Worst case analysis 1	207	0.003	68,124
Worse case analysis 2	226	0.002	112,877

Solomon D. *JBMR* 2014;29:1667

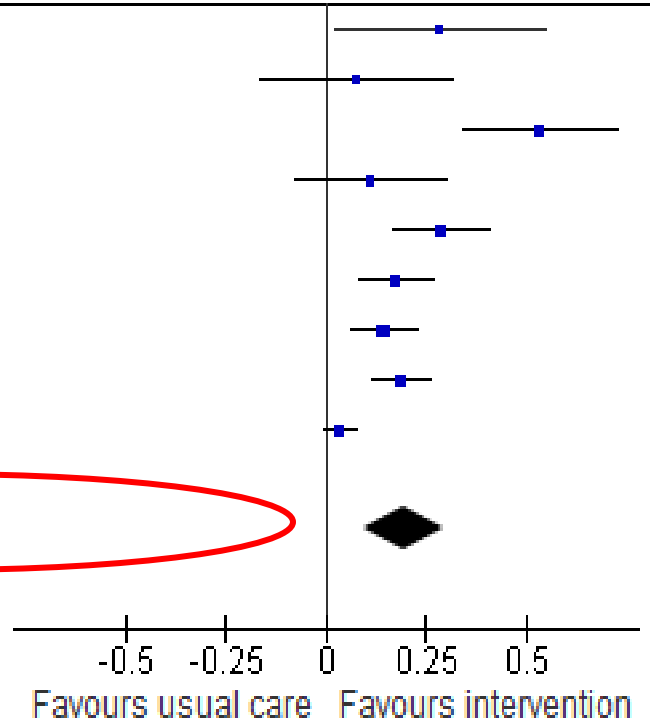
Pooled Absolute Effects (risk difference) on Osteoporosis Rx From 9 Secondary Prevention RCTs (intervention vs usual care)

Study or Subgroup	Intervention Events	Intervention Total	Usual care Events	Usual care Total	Weight	Risk Difference M-H, Random, 95% CI
Miki 2008	15	26	7	24	7.3%	0.29 [0.02, 0.55]
Rozental 2008	8	27	5	23	7.9%	0.08 [-0.16, 0.32]
Davis 2007	15	28	0	20	9.4%	0.54 [0.34, 0.73]
Gardner 2005	10	36	6	36	9.5%	0.11 [-0.08, 0.30]
Majumdar 2007	56	110	24	110	12.0%	0.29 [0.17, 0.41]
Cranney 2008	35	125	15	145	12.9%	0.18 [0.08, 0.27]
Majumder 2008	30	137	10	135	13.2%	0.14 [0.06, 0.23]
Feldstein 2006 (1)	50	210	5	101	13.5%	0.19 [0.12, 0.26]
Solomon 2007	6	134	1	95	14.2%	0.03 [-0.01, 0.07]
Total (95% CI)		**833**		**689**	**100.0%**	**20% (10-30%)**
Total events	225		73			

Heterogeneity: Tau² = 0.02; Chi² = 66.69, df = 8 (P < 0.00001); I² = 88%

Test for overall effect: Z = 3.83 (P = 0.0001)

(1) Intervention groups combined

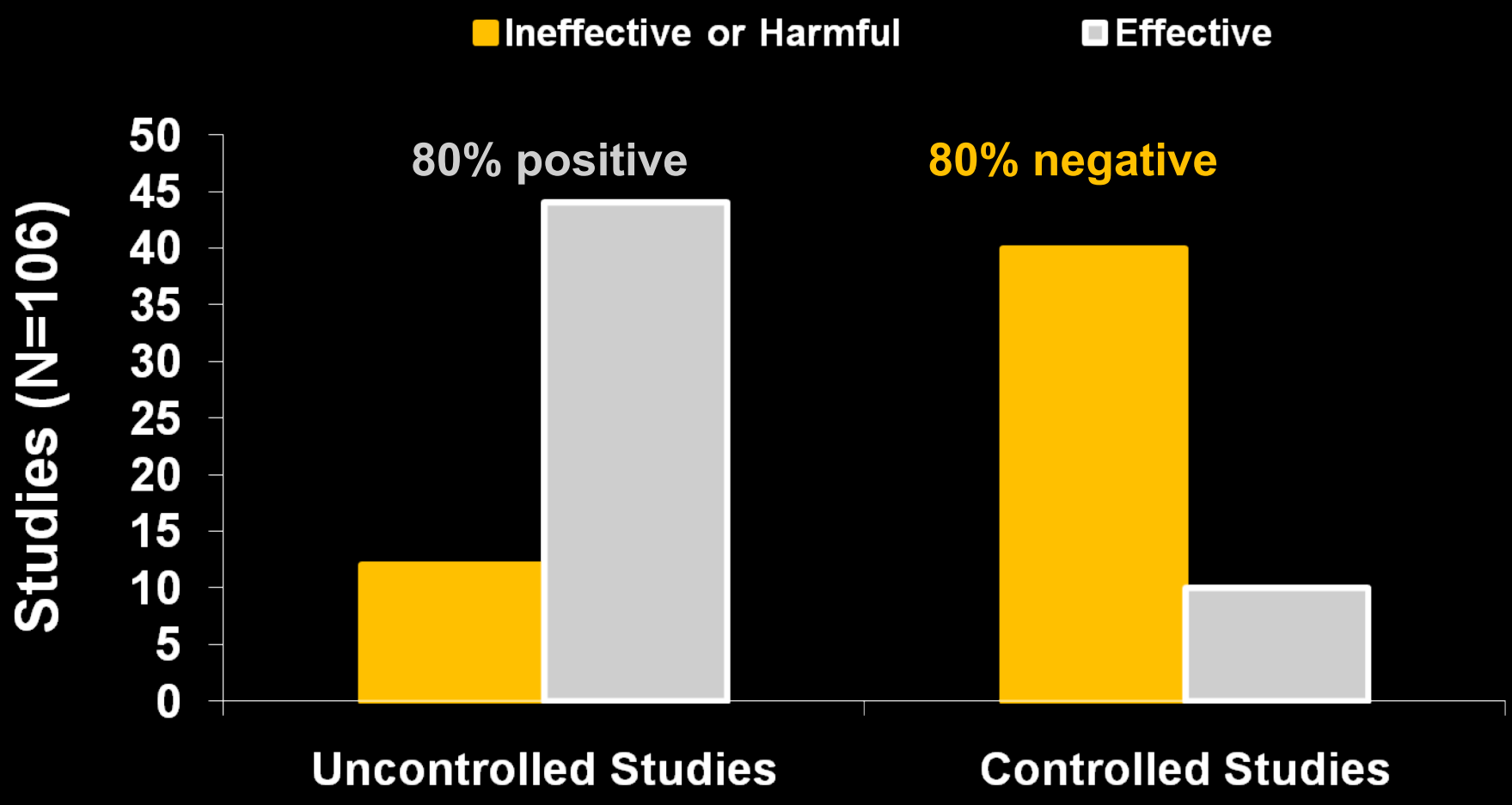


Little EA. *Implement Sci* 2010;5:80

Summary of Evidence Implementation Research in Osteoporosis

- Defining quality is necessary first step
- Increasing armamentarium of evidence implementation interventions
- System approaches largely superior to approaches targeting patients or providers alone
- Implementing evidence at community level is not easy
  - Technology offers promises, context and engagement are key
  - “Teachable moment” is optimal (secondary prevention)
  - Multi-modal approaches often work better, but one size fits none
  - Approaches SHOULD BE tested

Adopting Ineffective Programs
Be Skeptical About Uncontrolled Studies



Sacks, Chalmers, Smith. *Am J Med* 1982;72:233

Acknowledgements

- Stephanie Biggers, RN
- Jeffrey Curtis, MD, MPH, MS
- Peter Cram, MD, MBA
- Gary Cutter, PhD
- Maria Danila, MD, MSPH
- Stefanie Edmonds, MS
- Jeffrey Foster, MPH
- Meredith Kilgore, PhD
- C. Beth Lewis, MD, MSPH
- Peng Li, PhD
- Josh Melnick, MPH
- Sarah Morgan RD, MD
- Amy Mudano, MPH
- Elizabeth Rahn PhD
- David Redden, PhD
- Douglas Roblin , PhD
- Amy Warriner, MD
- Nicole Wright, PhD
- Huifeng Yun, BS

NIAMS
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Supported by a grant from the National Institutes of Health

R01AR060240

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U18HS10389

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5UL1 RR025777