

Nonprescription Medications: MinuteClinic Strategies to Improve Safe Use

- Convenient access to care, point-of-care testing
- Technology, Telemedicine
- Assessment of Preferred Learning Style
- Methods to increase self-management awareness and skills:
behavioral and motivational interviewing
- Written and verbal communication of information
- Patient Centered Medical Home colleague communications
 - PCPs, Pharmacy, screening/monitoring retail sites
- National Patient Safety Foundation: “Ask Me 3” Program
- Patient call-backs, Follow-up strategies



Expert Workshop: Nonprescription Medication with Conditions of Safe Use as a Novel Solution for Undertreated Diseases or Conditions

Session II: Strategies and Applicable Methods – Pharmacists

The Brookings Institution • Washington, DC

November 8, 2012

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American Pharmacists Association**



American Pharmacists Association[®]
Improving medication use. Advancing patient care.

APhA

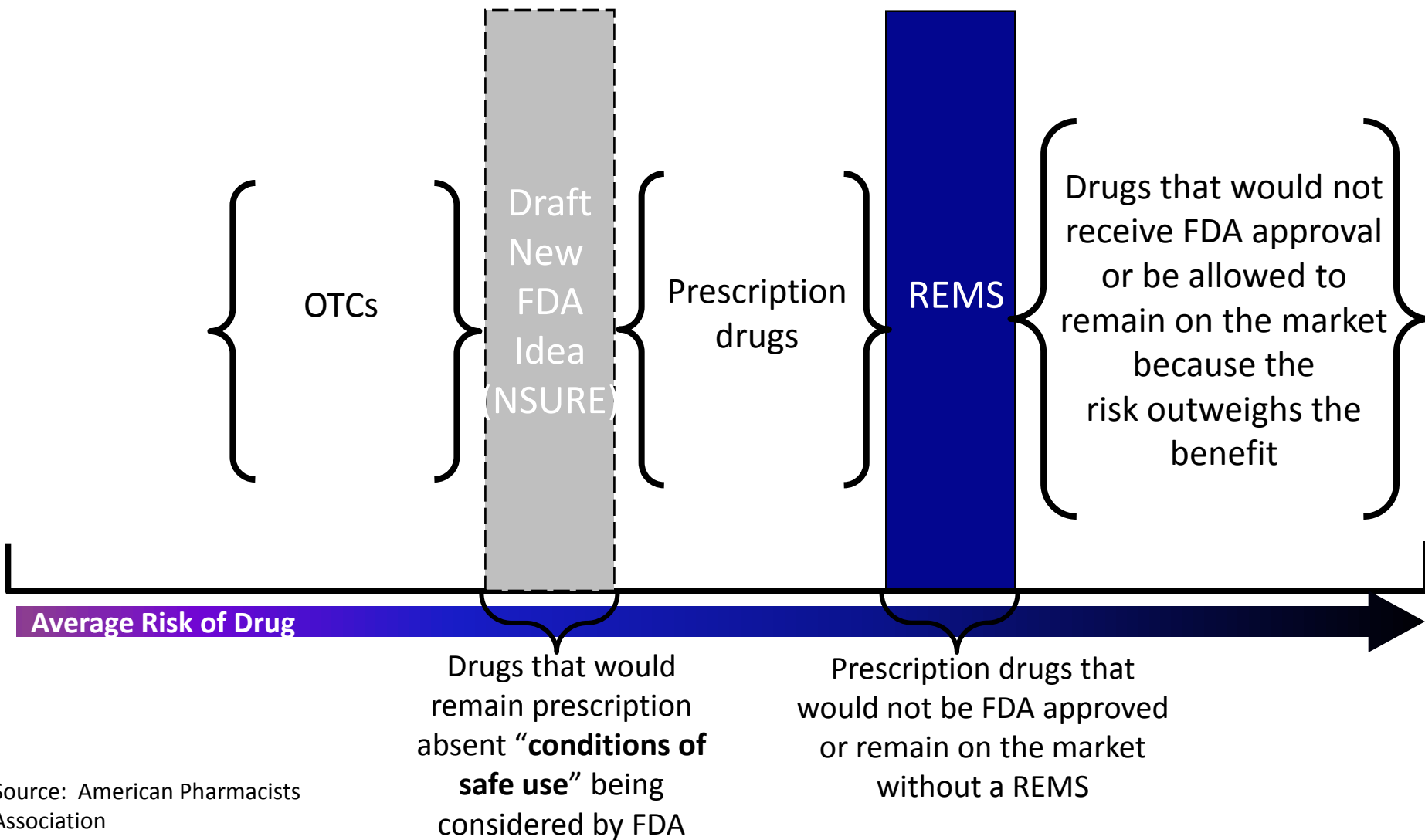
American Pharmacists Association (APhA)

- Largest and oldest national professional society for pharmacists
- Represents over 62,000 pharmacists, student pharmacists, pharmaceutical scientists and pharmacy technicians
- APhA members provide care in all practice settings, including: community pharmacies, hospitals, long-term care facilities, community health centers, managed care organizations, hospice settings and the uniformed services

Key Points

- APhA supports using conditions of safe use to improve access and public health
- APhA aims to be a resource for and work with FDA, manufacturers, and other stakeholders to ensure that the Nonprescription Safe Use Regulatory Expansion (NSURE) initiative becomes a reality
- A more flexible drug approval process also requires communication and collaboration of the health care team
- Many logistics, awareness, payment, challenges, and other uncertainties about any potential new paradigm can we worked out in the future
 - Challenges not significant enough to stop this initiative from moving forward
- Conditions of safe use fits in to the drug paradigm much like risk evaluation and mitigation strategy (REMS) programs

Figure 1. Potential New Drug Paradigm Being Considered by FDA: Creating More Flexibility on the Drug Safety Continuum to Benefit Patients and Public Health



Source: American Pharmacists Association

Conditions of Safe: Opportunities for Pharmacists

- Leverage **patients' access** to pharmacists to safely increase the availability of certain medications as pursued by manufacturers
- **Reconnect and refer** patients back into the health care system
 - Much like pharmacists do today for OTCs and prescriptions
- **Communicate and collaborate** with the medical community to improve team-based care
- Pharmacists are **well qualified** to perform interventions as required through conditions of safe use



Conditions of Safe: Opportunities for Pharmacists

- **Build upon the success of existing pharmacist-provided patient care services provided through:**
 - Immunizations
 - Collaborative practice agreements
 - Successful models used by the U.S. Public Health Service and others
 - Chronic disease state management programs
 - Medication adherence programs
 - OTC self-care programs



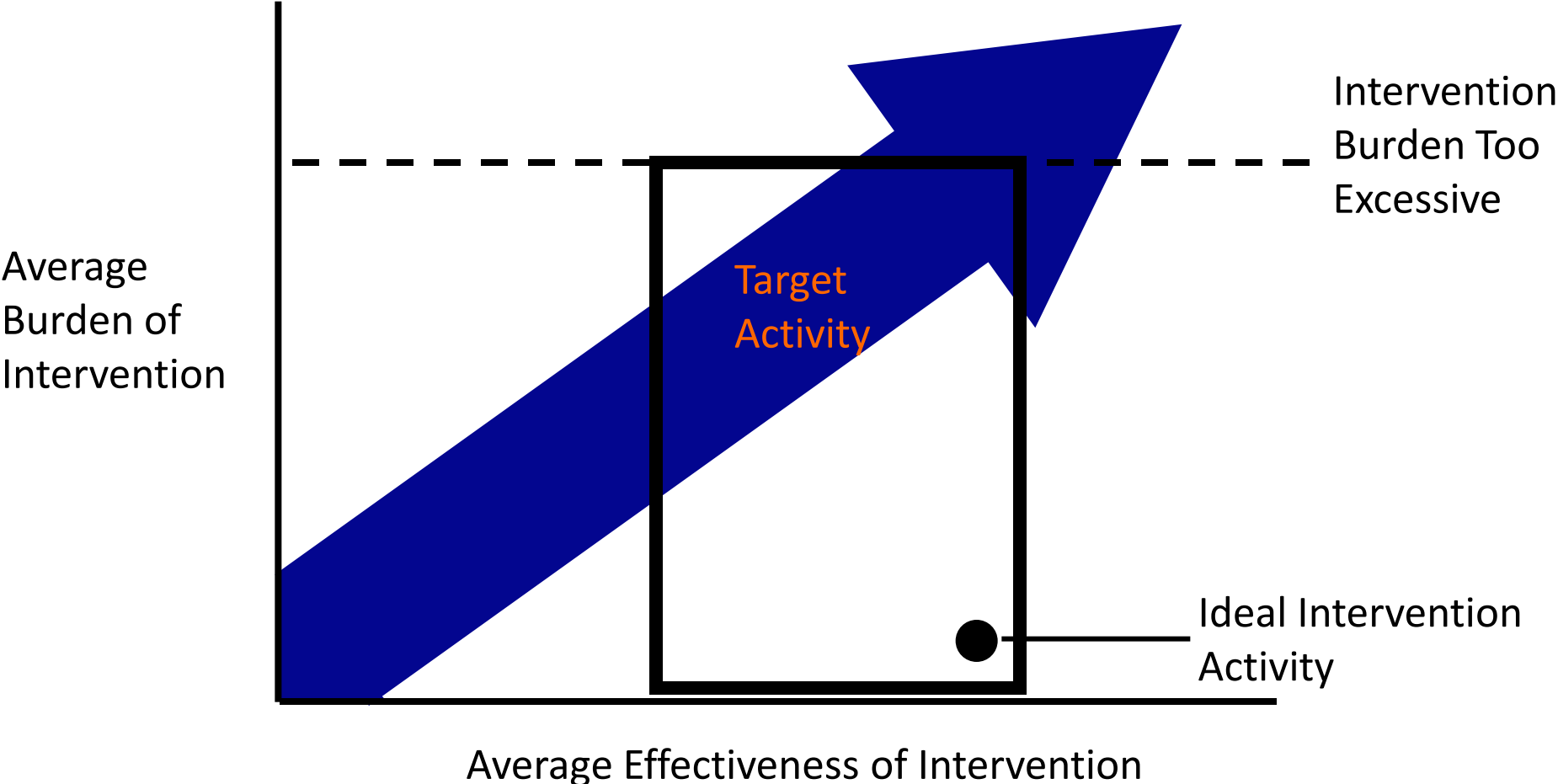
Conditions of Safe Use:

Key Provisions for a Pharmacist Intervention

- Uniform and standardized processes
- Integration into workflow
- Based on consensus-driven, best-practice algorithms
- Efficient and effective documentation and communication using health information technology infrastructure
- Billing mechanisms must be standardized and in place for a viable business model
- Process driven by science and manufacturer interest/application
- Opportunity for public input when conditions of safe use applications being considered



Conditions of Safe Use: Effective Provider Interventions



Source: American
Pharmacists
Association

Thank You

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Nonprescription Medications with Conditions of Safe Use

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November 8, 2012

American Academy of Physician Assistants (AAPA)

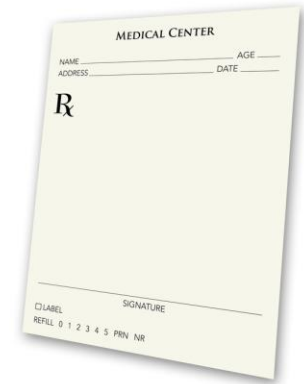
- Founded in 1968, the AAPA is the only national professional society to represent all physician assistants (PAs) in every area of medicine.
- The Academy has a federated structure of 57 chartered chapters representing PAs in all 50 states, the District of Columbia, Guam, and the federal services.

AAPA's Vision and Mission

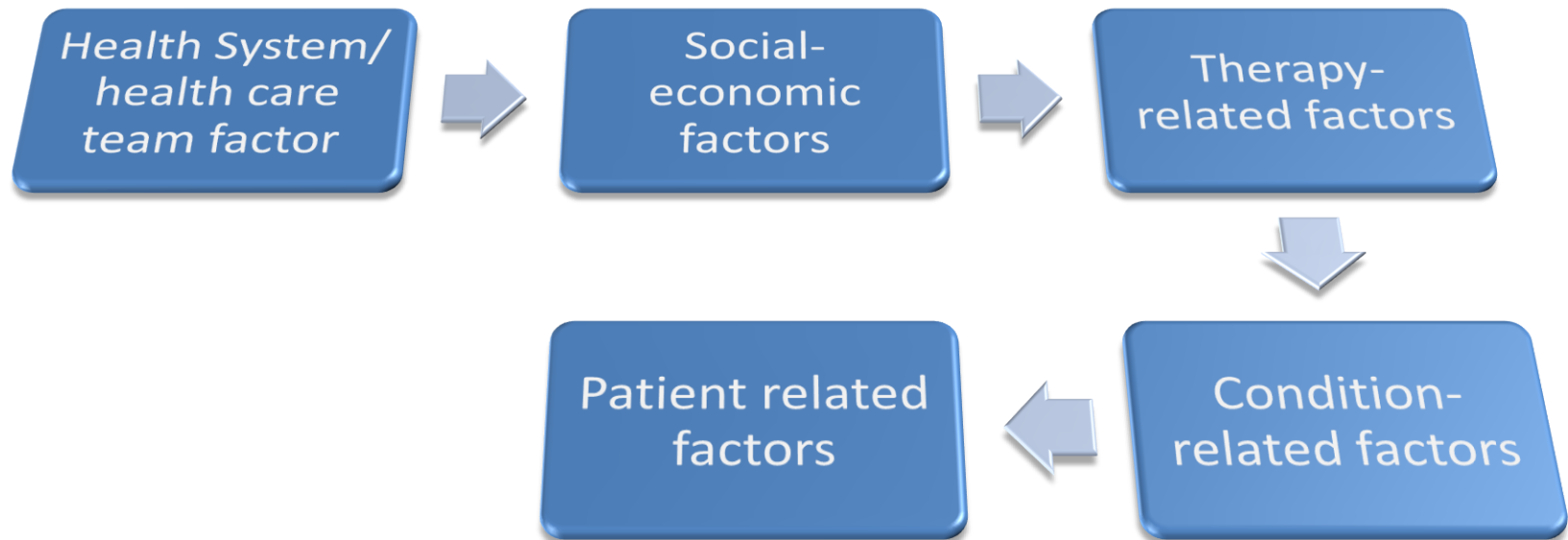
- Our Vision for the Profession
 - PAs transforming health through patient-centered, team-based care
- The Mission of our Academy
 - AAPA provides innovative solutions that empower our members to connect, enhance their careers and improve patient health

PAs Prescriptive Privileges

- Training
 - PA educational training
 - Post graduate training
- Delegated prescribing authority in all states
 - Kentucky and Florida do not include controlled substance authority
- DEA Registration
 - registration category authorized by state law
 - Some states require a state registration in addition to DEA registration

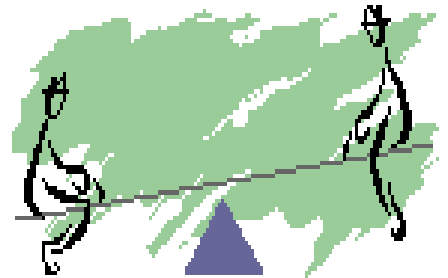


Dimension of Adherence



Conditions of Safe Use for Undertreated Diseases

- Tailored to the individual patient
- Well managed chronic disease
- Established therapeutic relationship
 - Rapport
 - Trust
- Adherence to long-term therapies
 - Care coordination



Conditions of Safe Use for Undertreated Diseases

- Components of successful program
 - Patient centered care
 - Self management
 - Medical team (interdisciplinary/multidisciplinary)
 - Treatment goals
 - Patient involvement
 - Effective communication (bidirectional)
 - Medical technology for monitoring
 - Reassessment of treatment



Asthma Example

- Asthma treatment plan
 - Pattern of use of therapy
 - Fully adherent
 - Under-use
 - Non use
 - Understanding the type/purpose of medicine medicine used
 - quick relief (prn)
 - Long term control (daily)



Asthma

Asthma	Factors Affecting Adherence	Intervention to Improve Adherence
Socioeconomic factors	cultural or lay beliefs; denial of the severity of the disease; poly-pharmacy	Clear instruction of treatment plan
Health care team/system factors	short consultation time	Management of disease and treatment in conjunction with patient ; multidisciplinary care
Condition related factors	Inadequate understanding of the disease	Patient education beginning at the time of diagnosis and integrated at every step of care
Therapy related factors	Complex treatment regimen; long duration of therapy	Education on use of meds continuous monitoring reassessment of therapy
Patient related factors	Misunderstanding of instructions, side effects	Self management programs to include educational and behavioral components

Recommendations for Conditions of Safe Use

- One size does not fit all
- Partnership
 - Patient centered care
 - Team based care
- Communications
 - Multidisciplinary
 - Interdisciplinary
- Ensuring patient safety



Questions

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Undertreatment of Common Diseases and Conditions within the United States

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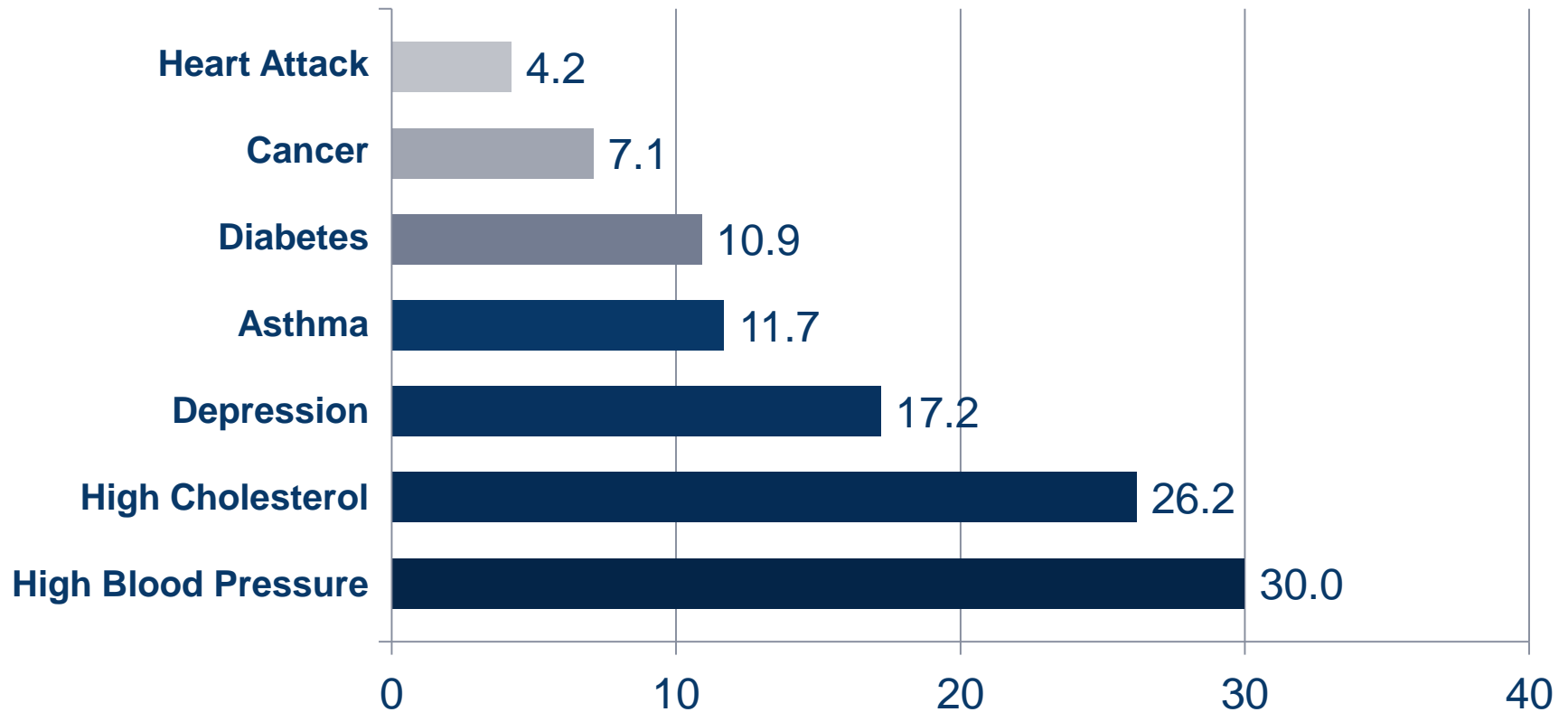
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Topics

- Common Diseases and Conditions within the United States
- Concerns with Access and Quality of Health Services
- Recent Findings of Common Undertreated Diseases and Conditions

Common Diseases and Conditions within the United States

Percentage of U.S. Adults Diagnosed with Selected Diseases and Conditions



Impact of Chronic Illness within the United States

- In 2005, **133 million** Americans had at least one chronic illness
 - Chronic illnesses are the cause of **7 in 10** deaths in the U.S. annually
- More than **1 in 4** have concurrent multiple chronic conditions
 - Includes arthritis, asthma, chronic respiratory conditions, diabetes, heart disease, HIV infection, and hypertension
- The medical care costs of people with chronic illness represents **75%** of the **\$2 trillion** spent on health care in the US annually

Access and Quality of Health Services

Percentage of Adults				Regression-adjusted difference, 2000–10	
Type	2000	2010	Unadjusted difference, 2000–10	Without controls for coverage	With controls for coverage
Unmet medical need	12.4%	20.6%	8.2%	6.8%	6.1%
Delay in care because of cost	8.8%	13.7%	4.9%	3.8%	3.4%
Delay in care for noncost reasons	9.1%	11.8%	2.7%	1.9%	1.9%

Years: 2000 to 2010

Source: Kenney G M et al. Health Aff 2012;31:899-908

Access to Quality Care	Percentage of Quality Standards Failed (95% CI)
Underuse	46.3% (45.8-46.8)
Overuse	11.3% (10.2-12.4)

Recommended Care Received, by Disease and Condition

Recommended Care Received	
Condition	Recommended Care Received (95% CI)
Coronary Artery Disease	68.0% (64.2-71.8)
Hypertension	64.7% (62.6-66.7)
Congestive Heart Failure	63.9% (55.4-72.4)
Chronic Obstructive Pulmonary Disease	58.0% (51.7-64.4)
Asthma	53.5% (50.0-57.0)
Hyperlipidemia	48.6% (44.1-53.2)
Diabetes Mellitus	45.4% (42.7-48.3)
Urinary Tract Infection	40.7% (37.3-44.1)
Hip Fracture	22.8% (6.2-39.5)

List not comprehensive

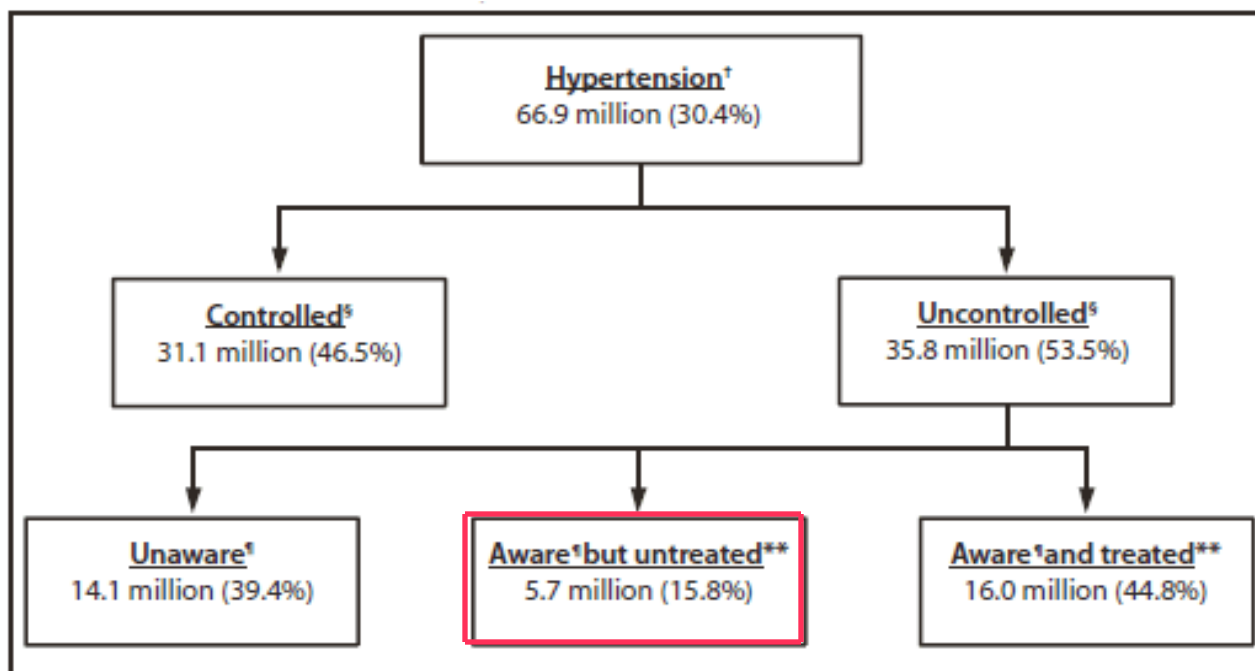
Quality of Pharmacologic Care for Adults in the United States

Pharmacologic Quality	Percentage of Recommended Care Received
Total (aggregate)	61.9% (60.3-63.5)
Underuse of appropriate medications	62.6% (60.7-64.6)
Overuse of inappropriate medication	83.5% (81.1-85.9)
Medication monitoring	54.7% (49.7-59.7)
Education and documentation	46.2% (42.9-49.5)

Scores represent percentage of appropriate care received for each category (e.g. higher scores always suggest higher quality care in each of the categories represented)

Examples of Common Undertreated Diseases & Conditions

- Hypertension among U.S. adults, 2003–2010
 - Prevalence of hypertension was an estimated **66.9 million** (30.4%)
 - Among those with hypertension, **35.8 million** (53.5%) did not have their hypertension controlled
 - **5.7 million** (15.8%) were aware of their hypertension but were not receiving pharmacologic treatment



Examples of Common Undertreated Diseases & Conditions

- Diabetes among U.S. adults
 - Among diagnosed adults, **2.4%** were not treating their condition and **10.6%** were using diet but not medications to treat their diabetes
 - **13%** of adults with diagnosed diabetes do not use recommended medications
 - **5.5%** of those uninsured for a full-year were untreated
 - **7.9%** of those lacking a usual source of care were untreated

Appropriate Use of Medications

- Multiple factors influencing medication utilization
 - Lack of knowledge
 - Complexity
 - Side effects
 - Quality of life
 - Demographics
 - Access to care
 - Insurance coverage
 - Cost
 - Accessibility
 - Convenience

Workshop Objectives

- Identify strategies to:
 - Reduce undertreatment by increasing access to pharmacologic care
 - Ensure the safe and effective use of medications