



Roadmap to 2030 for New Drug Evaluation for Older Adults: The Problem Statement

Patricia Slattum, PharmD, PhD, Virginia Center on Aging

I have no disclosures related to this workshop. The views presented in this presentation represent the personal opinion of the speaker and do not reflect the official positions of the United States Food and Drug Administration (FDA).

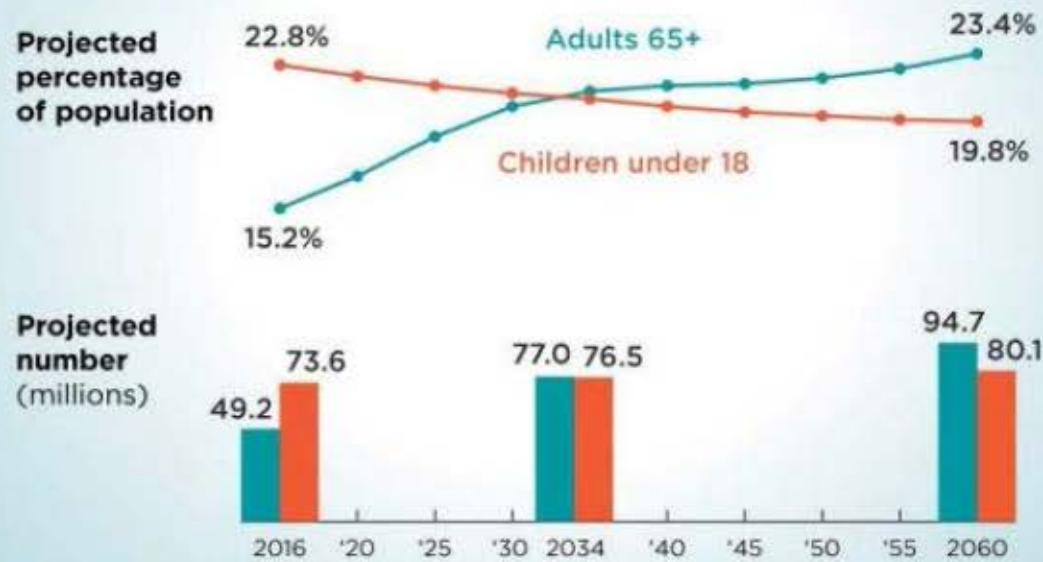




An Aging Nation

Projected Number of Children
and Older Adults

For the First Time in U.S. History Older Adults Are
Projected to Outnumber Children by 2034



Note: 2016 data are estimates not projections.

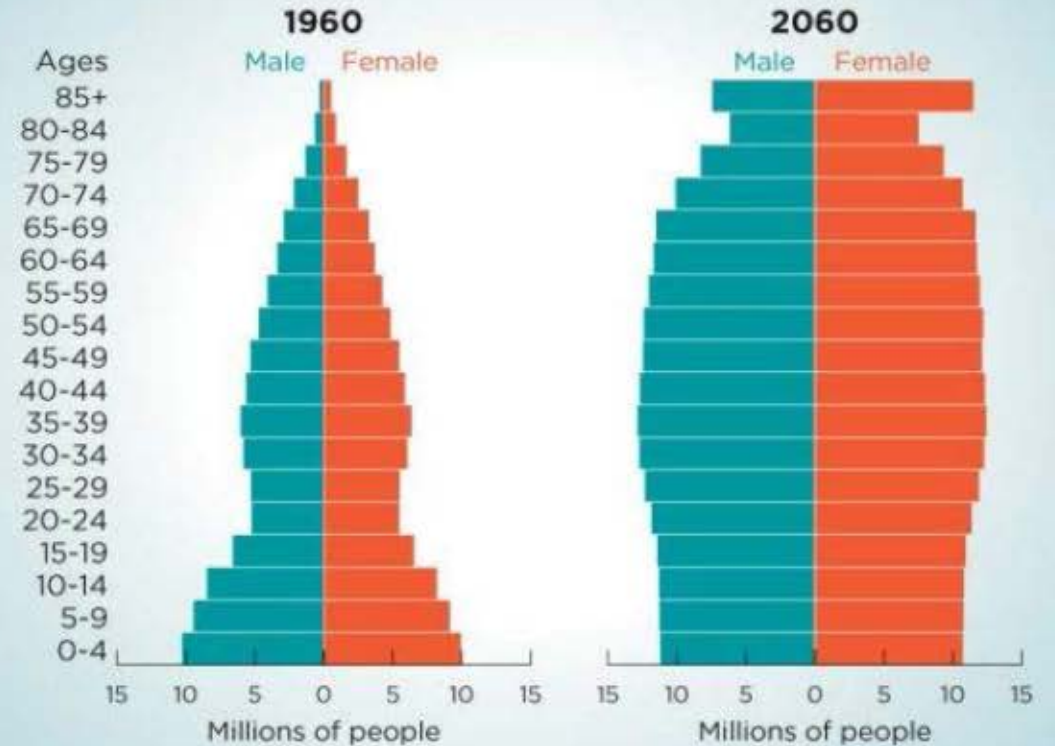
United States[®]
Census
Bureau

U.S. Department of Commerce
U.S. CENSUS BUREAU
census.gov

Source: National Population
Projections, 2017
www.census.gov/programs-surveys/popproj.html

From Pyramid to Pillar: A Century of Change

Population of the United States



United States[®]
Census
Bureau

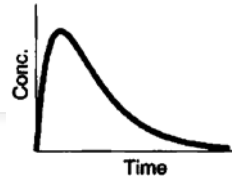
U.S. Department of Commerce
U.S. CENSUS BUREAU
census.gov

Source: National Population
Projections, 2017
www.census.gov/programs-surveys/popproj.html

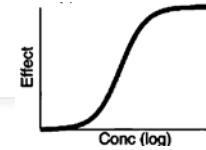


Physiologic Changes with Age Alter Pharmacokinetics and Pharmacodynamics

Pharmacokinetics



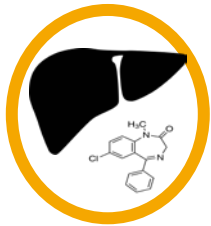
Pharmacodynamics



Dose

Concentration

Response



Metabolism



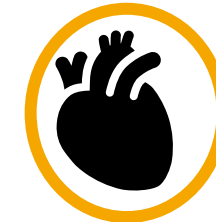
Distribution



Excretion



Nervous System



Cardiovascular System



Musculo-skeletal System



Immune System



Chronic Health Conditions and Multimorbidity increase with Age

10 Common Chronic Conditions for Adults 65+

Quick Facts



80% have at least 1 chronic condition



68% have 2 or more chronic conditions



Hypertension
(High Blood Pressure)
58%



High Cholesterol
47%



Arthritis
31%



Ischemic Heart Disease
(or Coronary Heart Disease)
29%



Diabetes
27%



Chronic Kidney Disease
18%



Heart Failure
14%



Depression
14%



Alzheimer's Disease and Dementia
11%



Chronic Obstructive Pulmonary Disease
11%

Source: Centers for Medicare & Medicaid Services, Chronic Conditions Prevalence State/County Table: All Fee-for-Service Beneficiaries, 2015

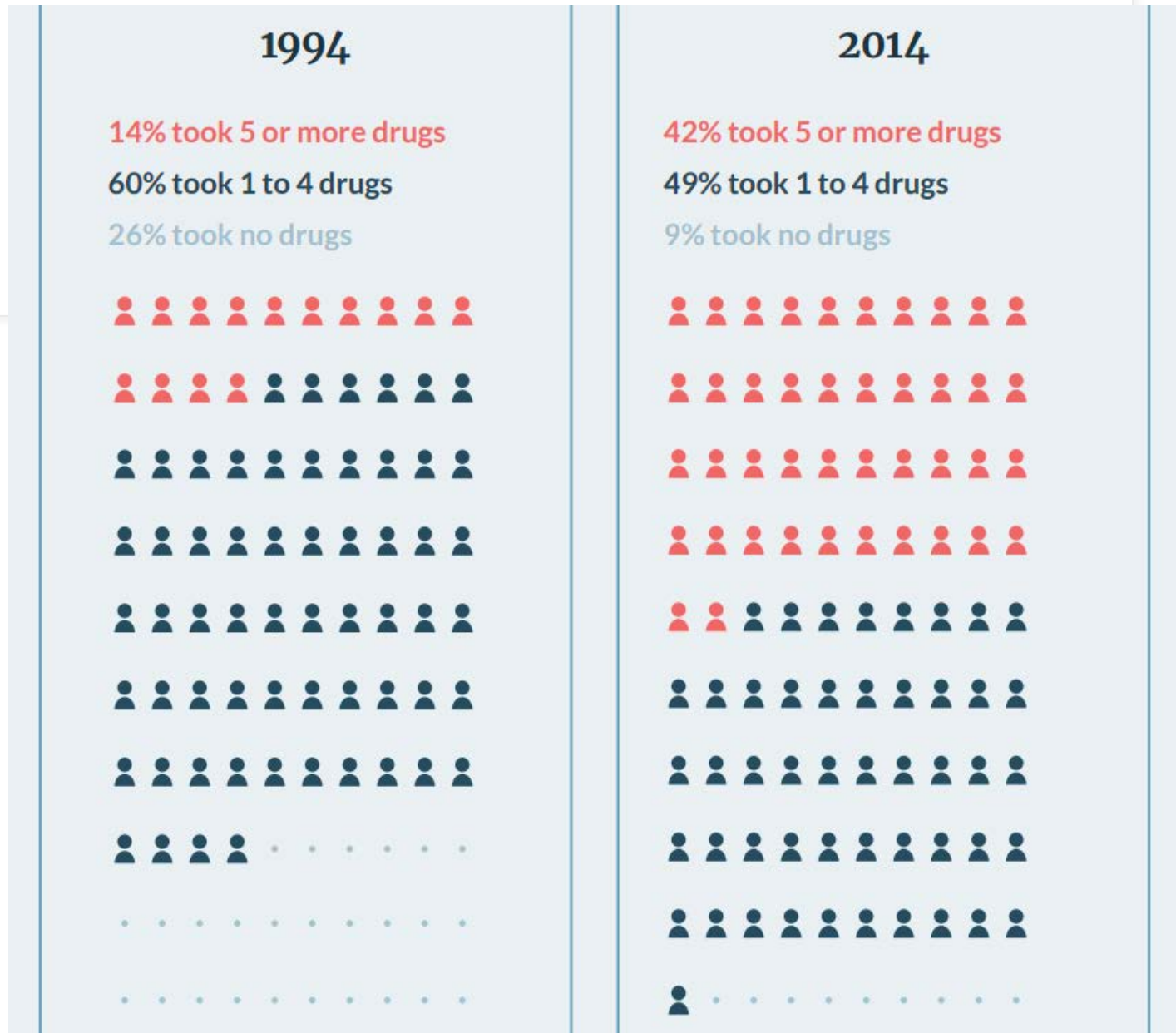


Polypharmacy is increasing

From 1994 to 2014, the proportion of older adults taking five or more drugs tripled, from 13.8 percent to 42.4 percent.



[This Photo](#) by Unknown Author is licensed under [CC BY-SA-NC](#)



Frailty increases with age



Table 1.

Prevalence of Frail Status by Demographic Subgroups: National Health and Aging Trends Study, 2011; $n = 7,439$

Characteristic	Subgroup Prevalence (%)	Frail Status Prevalence Within Subgroup (%)		
		Robust	Prefrail	Frail
Age***	28.1	51.6	39.5	8.9
65-69	25.0	44.2	45.1	10.7
70-74	19.1	37.2	49.3	13.5
75-79	14.6	29.3	50.6	20.1
80-84	9.0	19.3	47.4	33.3
85-89	4.2	13.4	48.7	37.9
90+				



Medications: The Right Balance

"Medications are probably the single most important health care technology in preventing illness and disability in the older population."



"Any symptom in an elderly patient should be considered a drug side effect until proven otherwise."



Improving medication therapy for older persons is complex

- Physiology changes
- Multimorbidity
- Polypharmacy
- Frailty
- Vulnerable functional and cognitive status
- Healthcare provider training
- Uncoordinated healthcare delivery
- Patient and caregiver expectations
- Many other factors!

Our Evidence Base is Insufficient



Who are the stakeholders in improving medication therapy for older persons?

- Older persons and their caregivers
- Health care providers and health care delivery organizations
- Academic institutions
- NIH, PCORI, AHRQ and others
- CMS, Department of Veterans Affairs and other payers
- Pharmaceutical industry
- Professional societies
- Advocacy organizations
- Providers of tertiary medical databases
- FDA

What more can FDA do to address this challenge?



Session I--Objectives

- Review the history and current guidances for older adults in evaluation of new drugs
- Review the current enrollment of older adults in clinical trials of new drugs in the U.S.
- Review international perspectives on enrollment of older adults in evaluation of medications
- Define the problems/gaps

