



Drug Safety in Ambulatory Care

Where is the Patient?

Changing Prescription Medication Use Instructions
Roundtable on Health Literacy
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Outline

- Use the “public health” approach to describe the ambulatory drug safety problem
- Highlight the key role of patients in ambulatory drug safety
- Review considerations for patient-centered drug safety measures



Disclaimer

“The findings and conclusions in this presentation have not been formally disseminated by the Centers for Disease Control and Prevention and should not be construed to represent any agency determination or policy.”

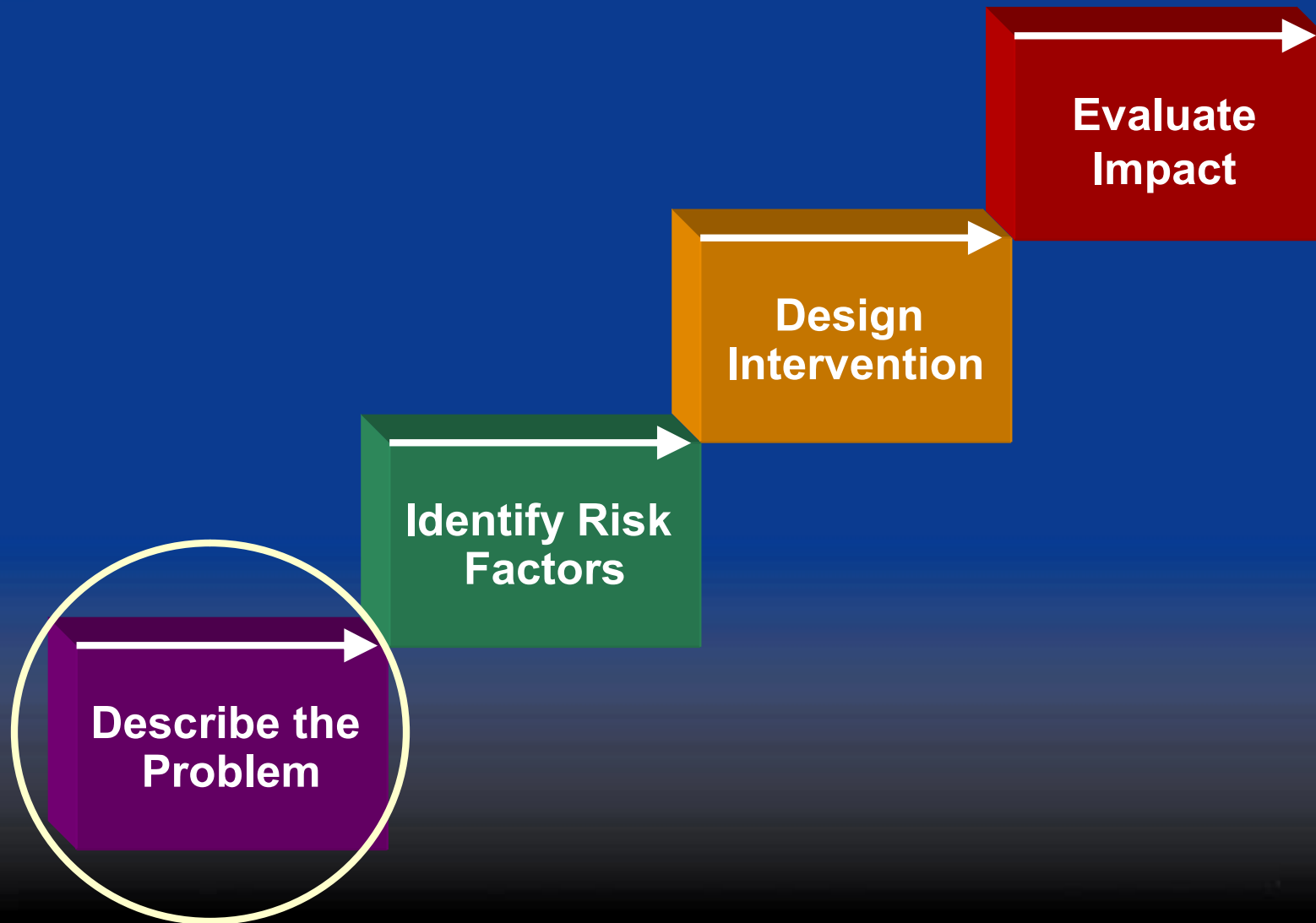


“If you don’t know where you’re going,
any road will get you there”

The Cheshire Cat
Alice in Wonderland
Lewis Carroll



The Public Health Approach



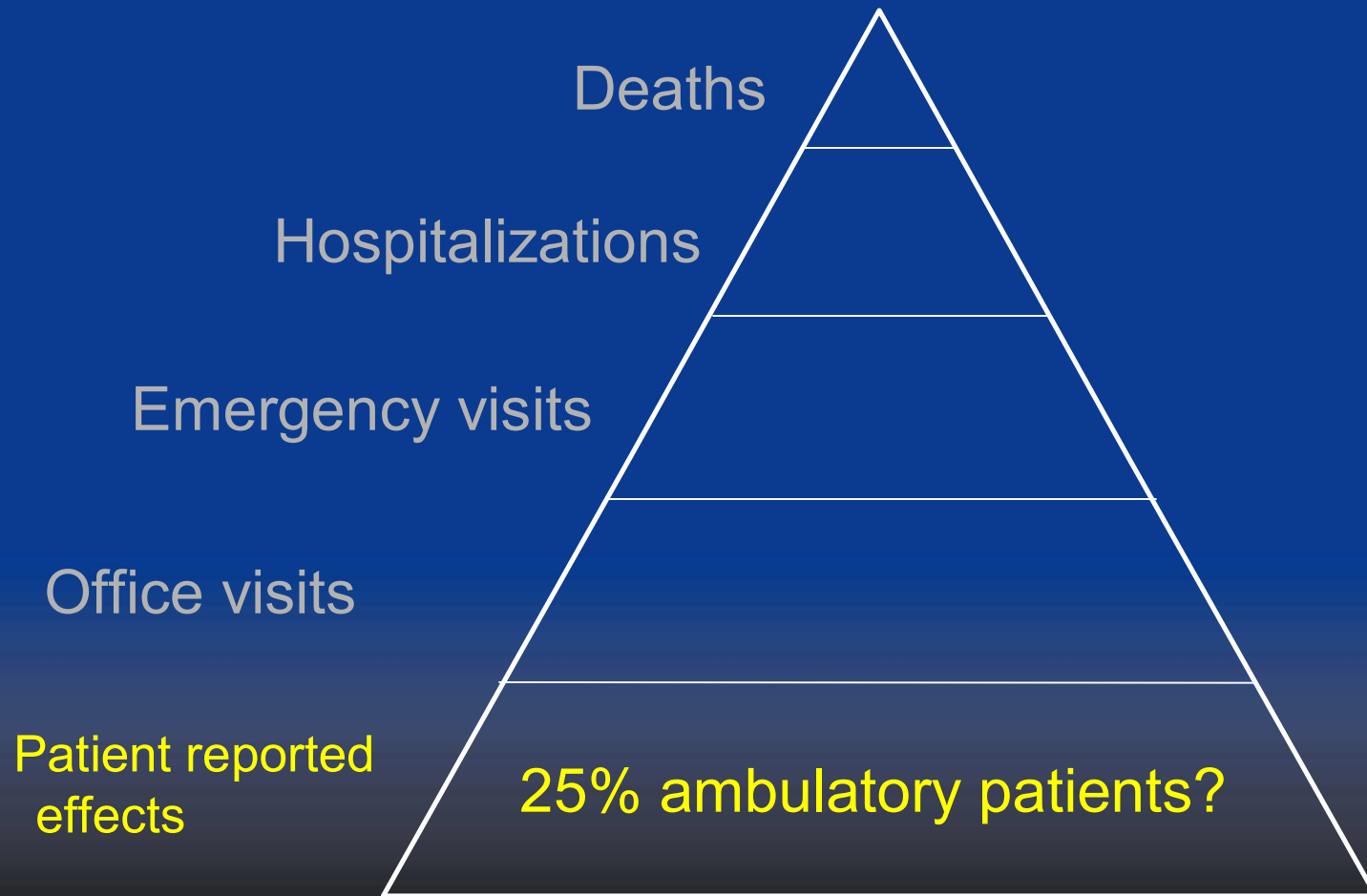


The Adverse Drug Event (ADE) Definition

- Harm (injury) from medication use
- Excludes:
 - Abuse
 - Self-harm (suicide attempts)
 - Illicit substances

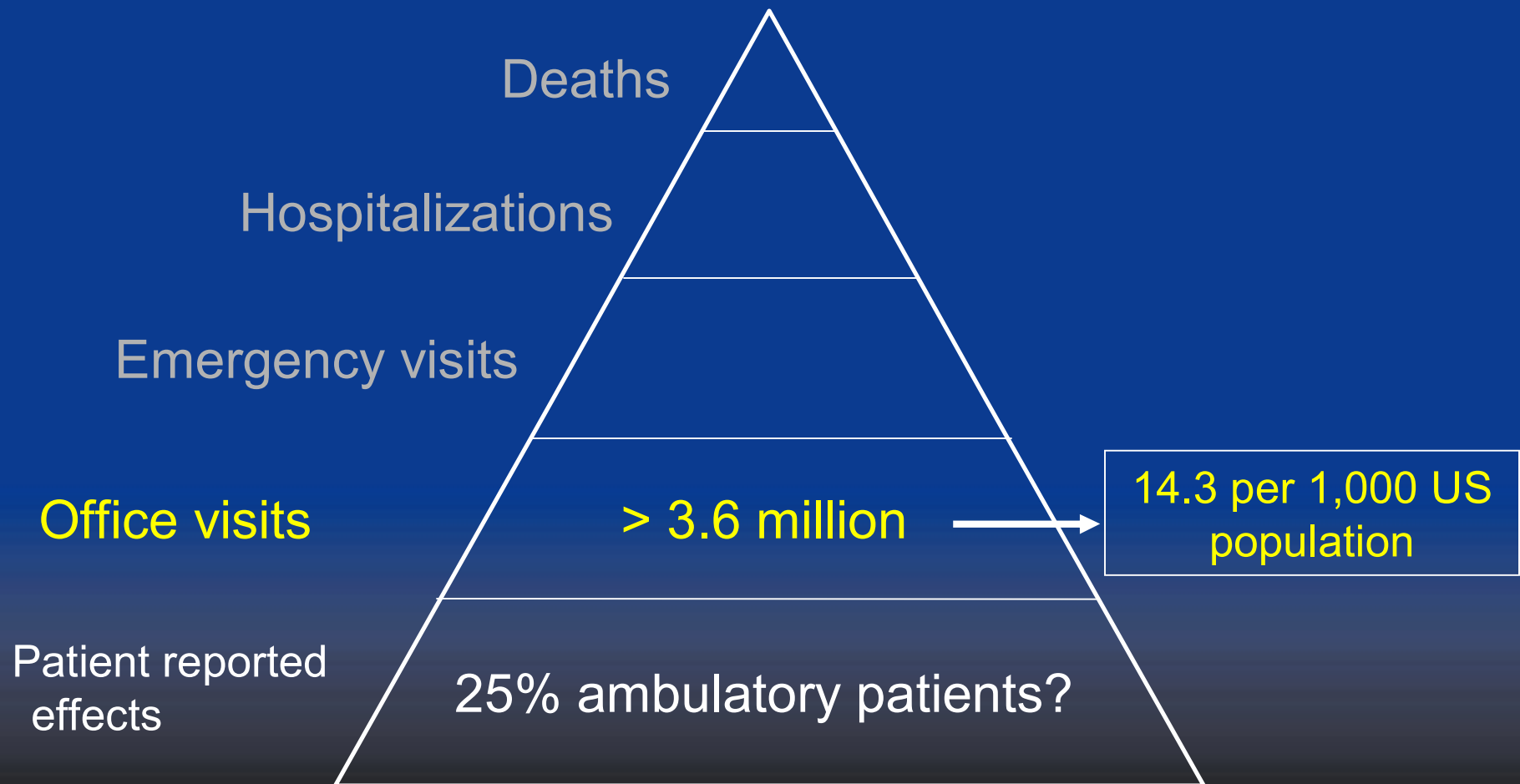


Estimated Annual Impact of Ambulatory ADEs



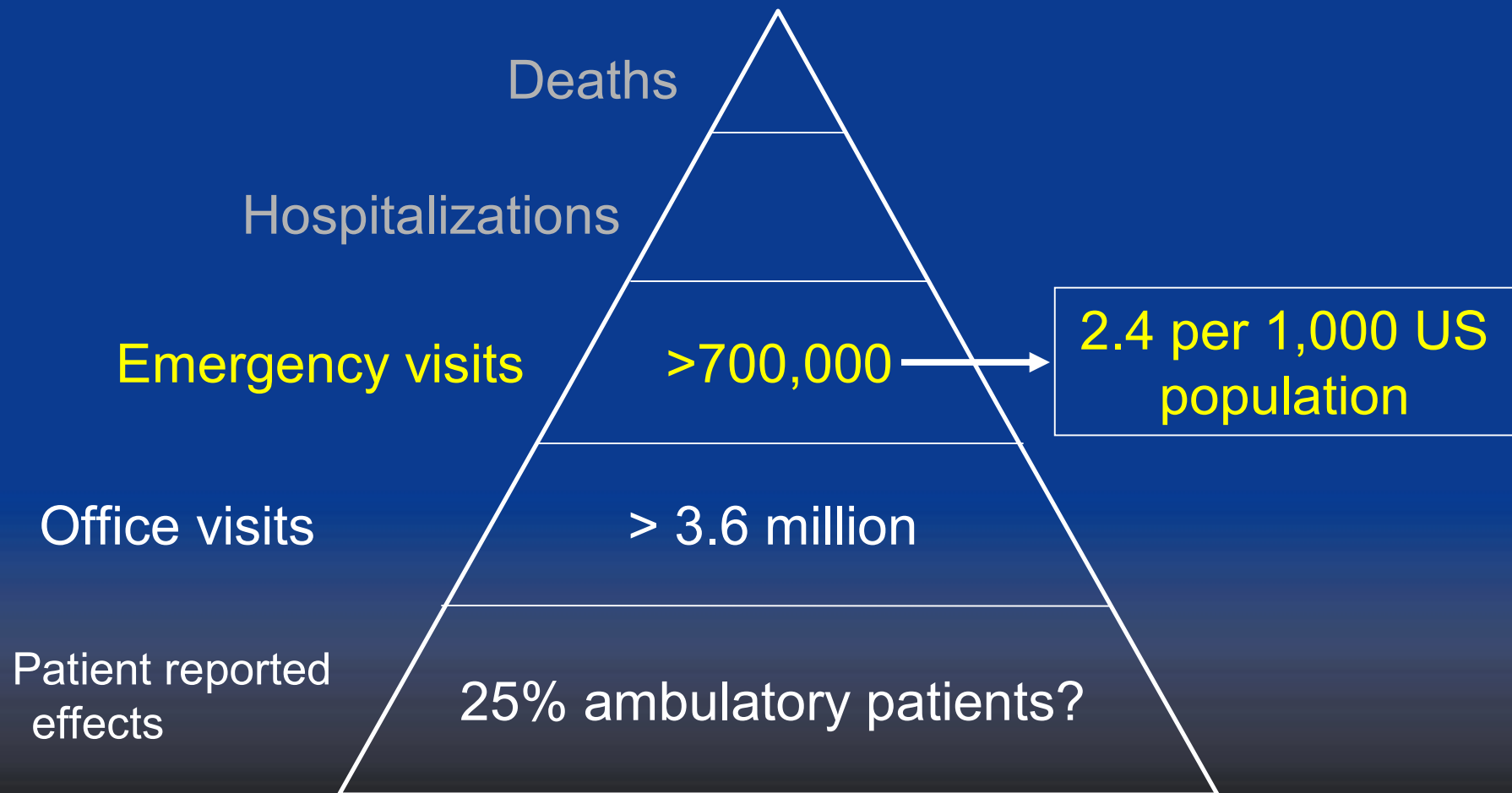


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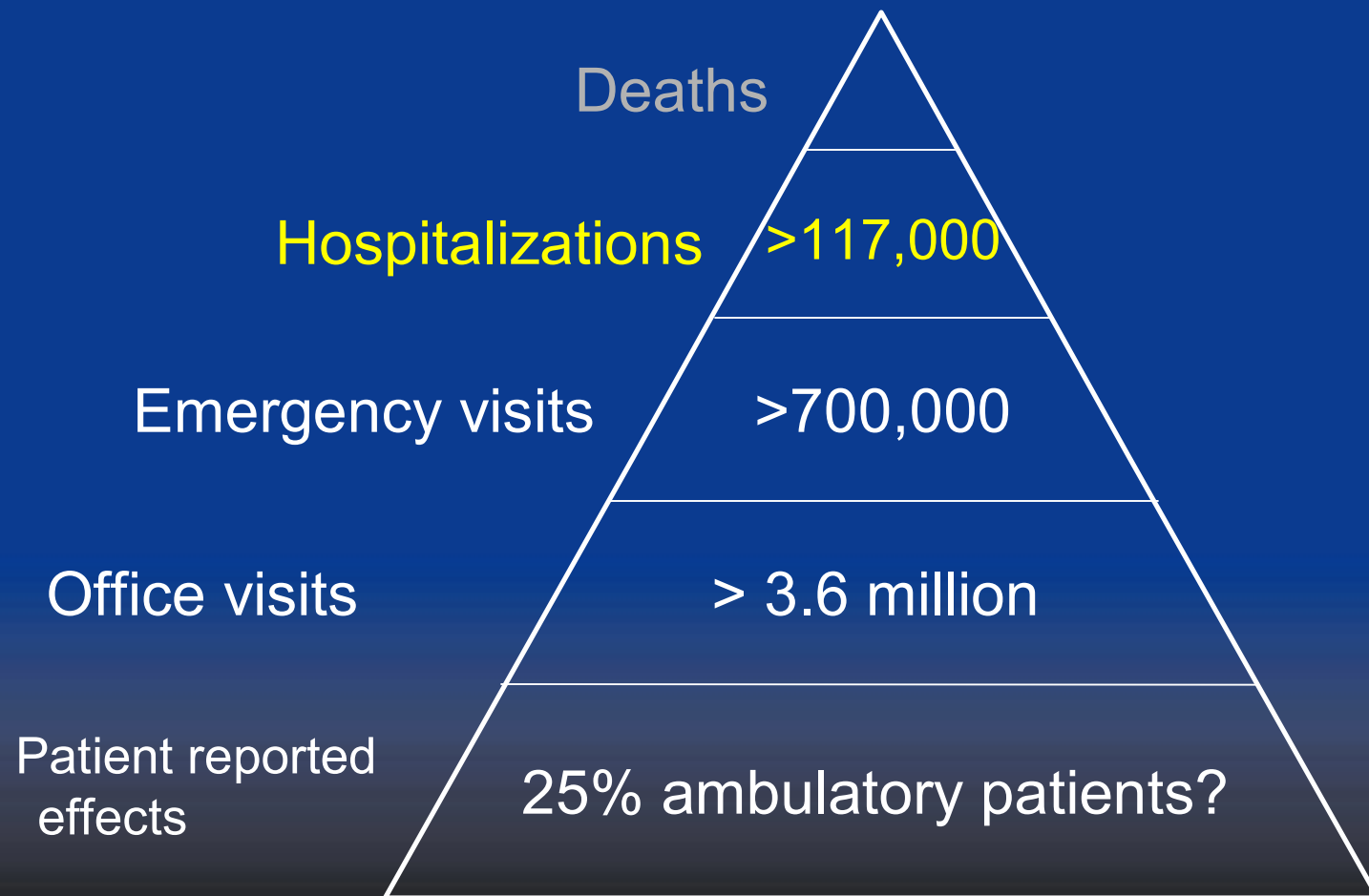


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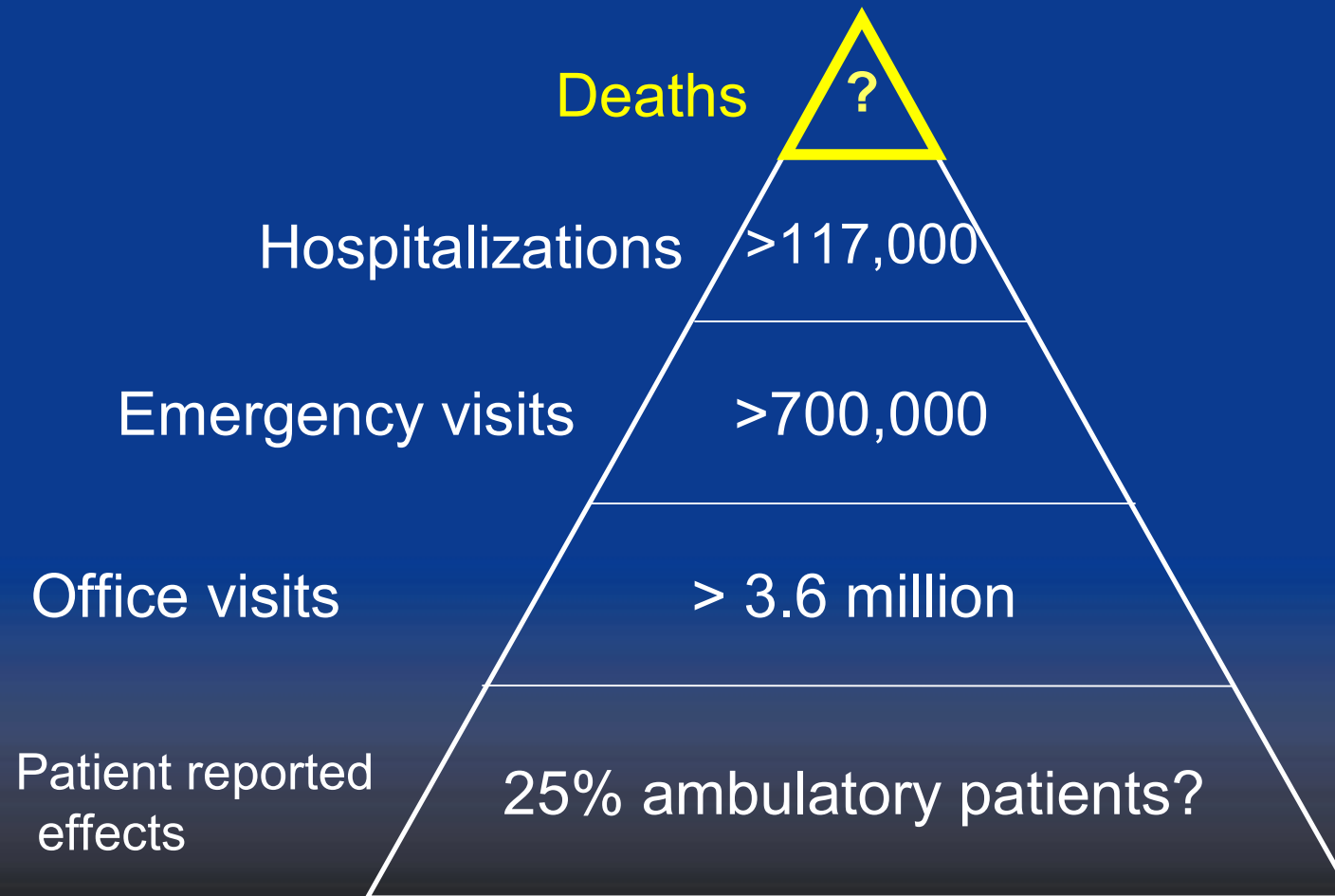


Estimated Annual Impact of Ambulatory ADEs





Estimated Annual Impact of Ambulatory ADEs





The Public Health Approach Applied to Ambulatory ADEs



Describe the Problem

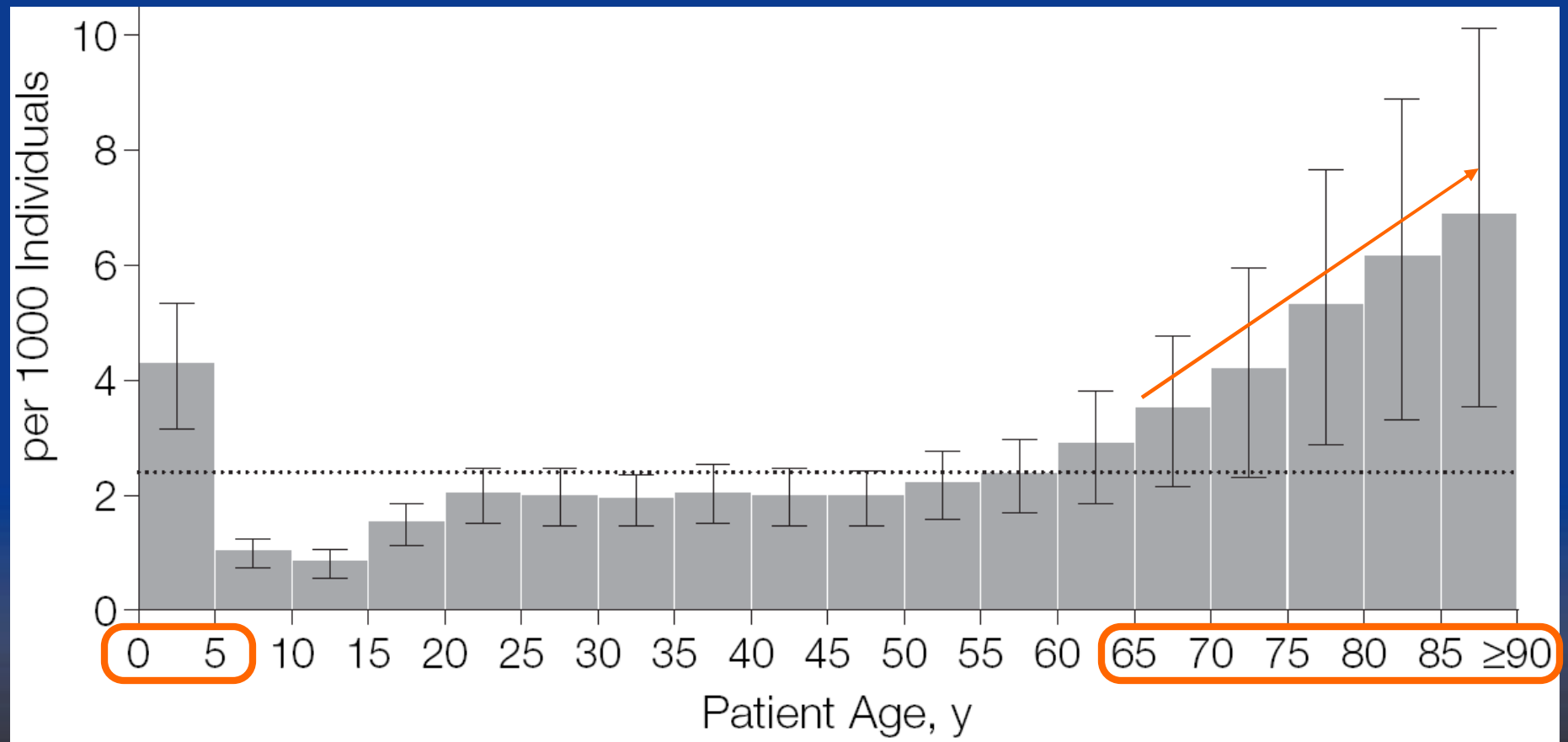
- Ambulatory ADEs harm many people
- Range of severity



The Public Health Approach



Emergency Visits for ADEs by Patient Age, 2004-2005, Estimated



Number of Cases and Annual Estimate of Individuals with Adverse Drug Events Treated in Emergency Departments by Event Type--United States, 2004-2005

Adverse Drug Event†	Overall		Hospitalizations*		
	Cases, No.	Annual Estimate, No. (%)	Cases, No.	Annual Estimate, No. (%)	Hospitalized, %
Allergic reactions	6890	235 202 (33.5)	375	13 232 (11.3)	5.6
Unintentional overdoses	7249	225 298 (32.1)	1919	62 607 (53.4)	27.8
Adverse effects	5846	200 887 (28.6)	1069	36 397 (31.0)	18.1
Secondary effects	669	24 371 (3.5)	102	4333 (3.7)	15.6
Vaccine reactions	644	15 790 (2.3)	22	751 (0.6)‡	4.8

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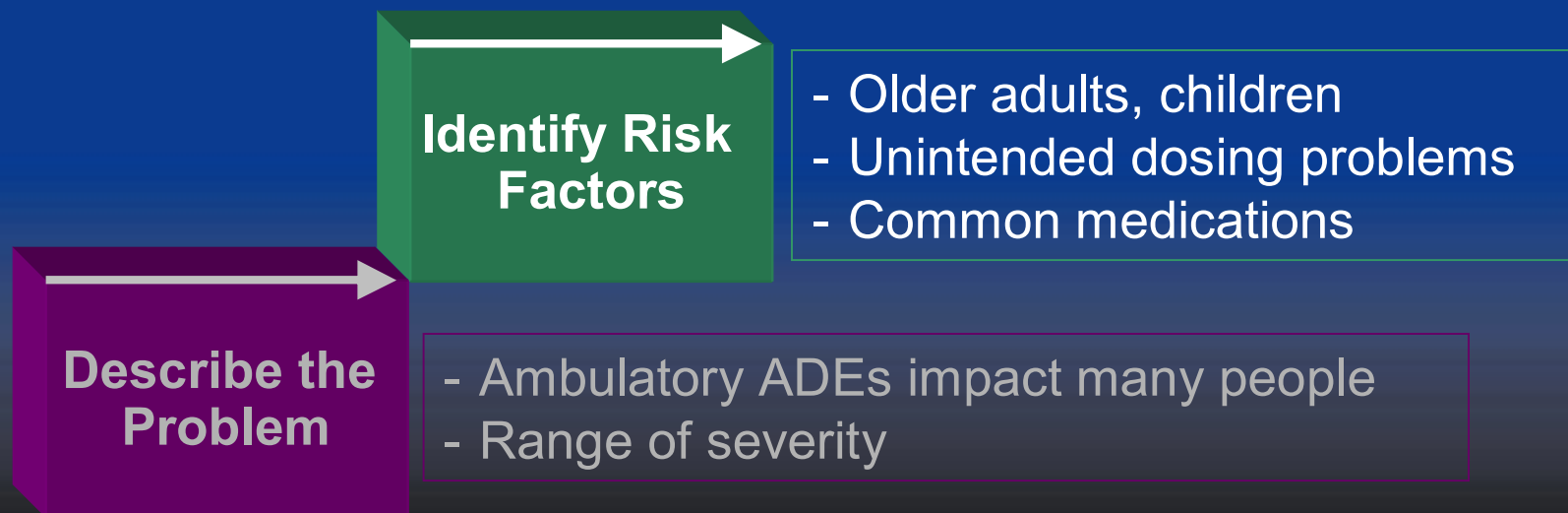
Over half of hospitalizations from unintended overdoses or supra-therapeutic drug levels

Number of Cases and Annual Estimate of Drugs Most Commonly Implicated in Adverse Events Treated in Emergency Departments--United States, 2004-2005

Drug	Cases, No.	Annual Estimate, No. (%)
● Insulins	1577	55 819 (8.0)
● Warfarin	1234	43 401 (6.2)†
Amoxicillin	1022	30 135 (4.3)
Aspirin	473	17 734 (2.5)
Trimethoprim-sulfamethoxazole	447	15 291 (2.2)
Hydrocodone-acetaminophen	420	15 512 (2.2)
Ibuprofen	526	14 852 (2.1)
Acetaminophen	497	12 832 (1.8)
Clopidogrel	241	10 931 (1.6)†
Cephalexin	293	10 628 (1.5)
Penicillin	270	9 275 (1.3)
Amoxicillin-clavulanate	274	8 959 (1.3)
Azithromycin	255	8 794 (1.3)
Levofloxacin	230	8 682 (1.2)
Naproxen	245	8 634 (1.2)
Phenytoin	238	7 937 (1.1)
Oxycodone-acetaminophen	227	7 328 (1.0)
Metformin	179	6 678 (1.0)



The Public Health Approach Applied to Ambulatory ADEs

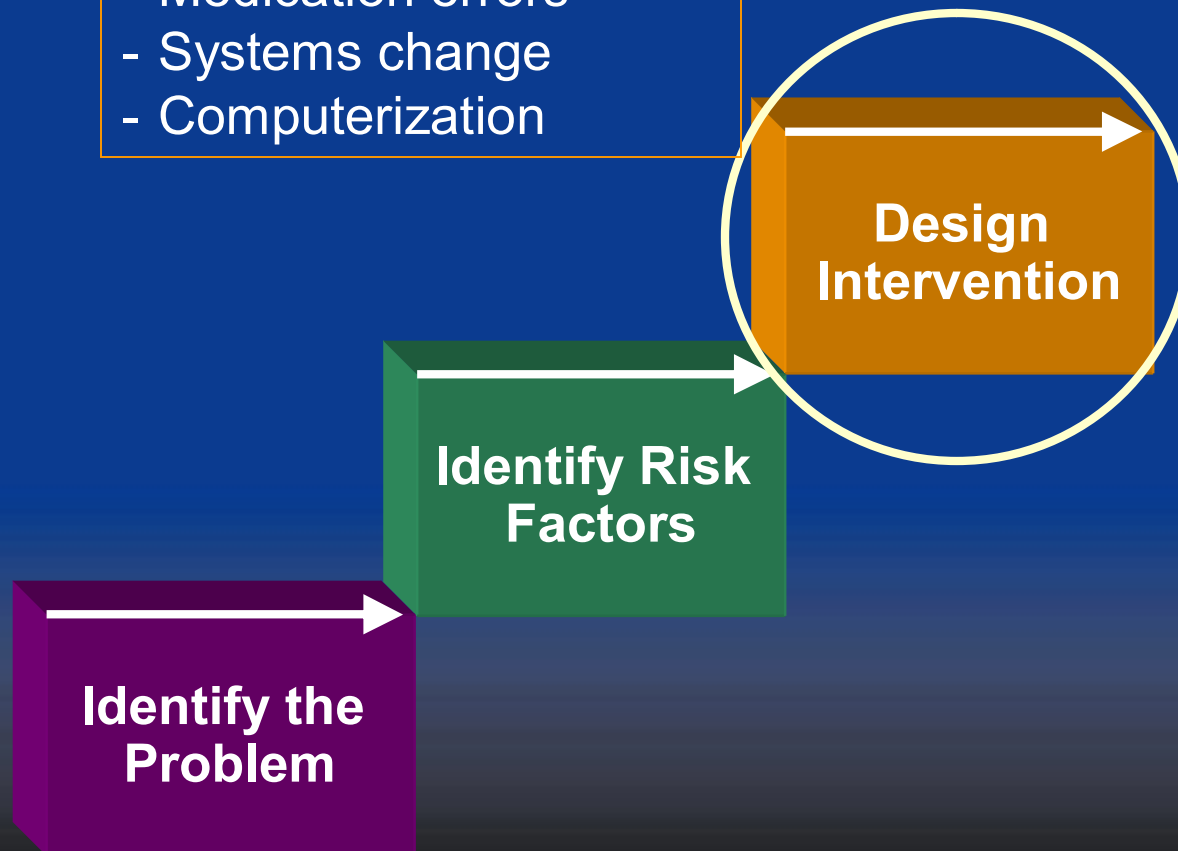




The Public Health Approach

Interventions in Hospitals

- Medication errors
- Systems change
- Computerization





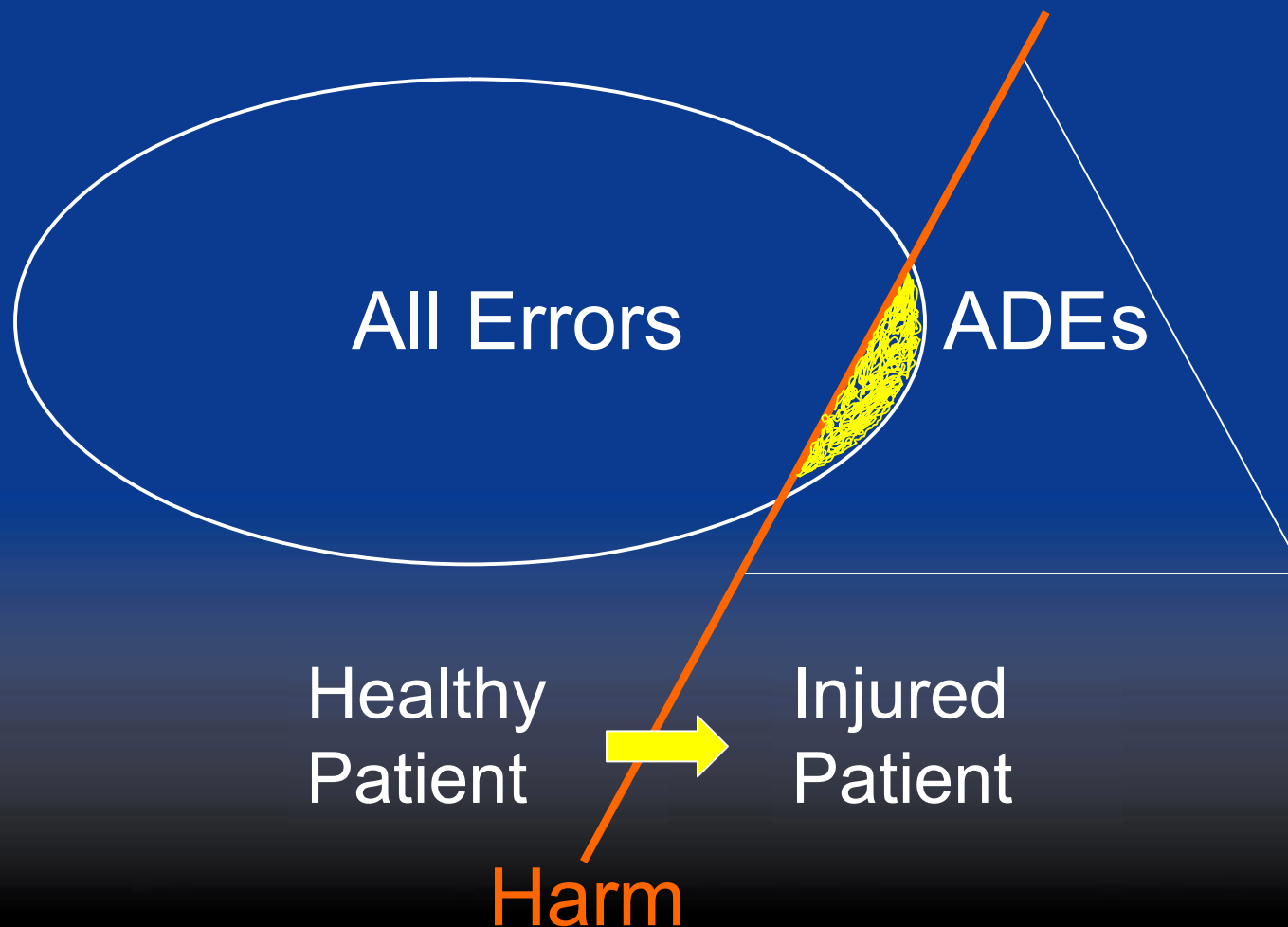
Medication Errors

All Errors

Preventable events that may lead to inappropriate medication use or patient harm

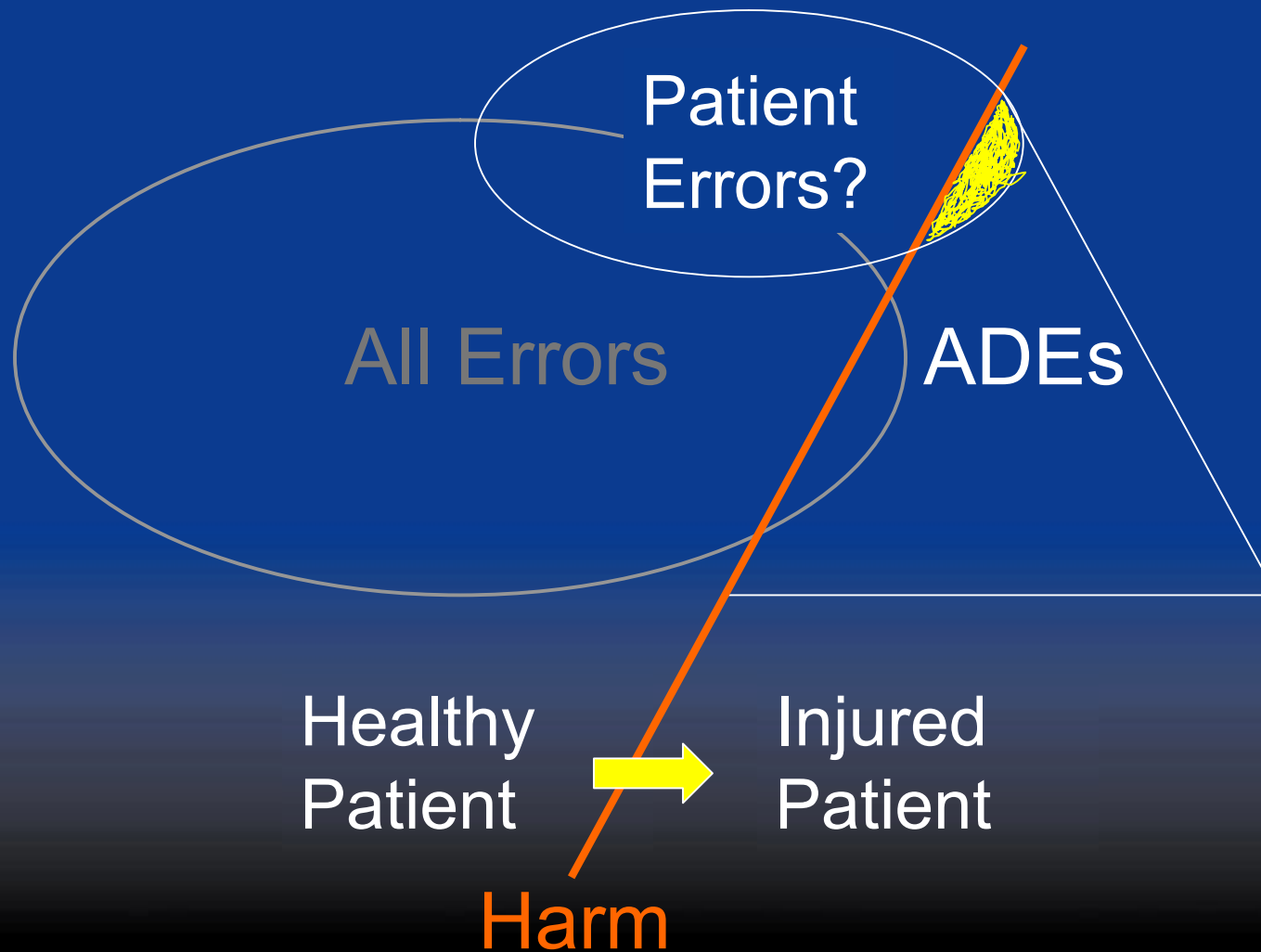


Medication Errors and Adverse Drug Events





Contribution of Patient Errors?





Drug Management by Setting



	Hospital	Ambulatory
Who prescribes?	Professionals	
Who administers?	Professionals	
Who stores?	Professionals	
Who monitors?	Professionals	
Support systems?	Extensive	
Basis for safety interventions?	Systems engineering Industrial quality control	



Drug Management by Setting



	Hospital	Ambulatory
Who prescribes?	Professionals	Physicians & Laypersons
Who administers?	Professionals	Laypersons
Who stores?	Professionals	Laypersons
Who monitors?	Professionals	Laypersons & Physicians
Support systems?	Extensive	Minimal (Medication Label)
Basis for safety interventions?	Systems engineering Industrial quality control	Population-based Injury Prevention



“To eliminate an injury, one need only find
a controllable necessary condition
... and control that condition”

Leon S. Robertson

Injury Epidemiology: Research and Control Strategies
2nd ed. New York, NY: Oxford University Press; 1998



Techniques of Population-based Injury Prevention

- A. Identify plausible interventions
 - Haddon's phase-factor matrix

- B. Consider 3 types of strategies
 - Education, Engineering, Enforcement

- C. Consider 2 types of approaches
 - Active vs. Passive



A. Identify Plausible Interventions

Phase-Factor Matrix

Factor \ Phase	Host (Patient)	Agent (Drug)	Environment
Pre-event			
Event			
Post-event			

Preventing Adverse Events from Warfarin

Phases Factors	Host (patient)	Agent (drug)	Environment (outpatient setting)
Pre-event (before over-anticoagulation occurs)	<ul style="list-style-type: none"> Exclude certain patients based on risk factors (e.g., age, history of medication non-adherence, cognitive impairment, genetic factors) Educate patients about proper anticoagulation management (e.g., need for monitoring, food-drug and drug-drug interactions) 	<ul style="list-style-type: none"> Substitute drugs with different adverse effect profile (e.g., anti-platelet agents) Develop new anticoagulant drugs with wider therapeutic index 	<ul style="list-style-type: none"> Standardize drug naming conventions, dosages, and appearance of doseforms to help reduce patient administration errors (e.g., include both brand and generic names on labels) Improve package labeling (e.g., write labeling to be read and understood by patients rather than healthcare professionals, increase font size of package inserts) Implement reminder systems for physicians to monitor anticoagulation (e.g., computerized decision support) Require evidence of recent anticoagulation monitoring prior to dispensing warfarin prescription refills
Event (over-anticoagulation occurs)	<ul style="list-style-type: none"> Develop technology to automatically monitor anticoagulation and immediately signal the patient of anticoagulation outside the indicated range (e.g., a device to be worn by the patient or implanted) 	<ul style="list-style-type: none"> Simplify dosing algorithms to reduce unintentional over-anticoagulation due to drug administration errors 	<ul style="list-style-type: none"> Improve and increase availability of drug dispensing technologies for accurate home administration, especially for high-risk patients (e.g., pill dispensers which remind patients to take drugs and record dispensing history) Improve accessibility of outpatient anticoagulation testing and result reporting (e.g., on-site testing in medical offices, self-monitoring devices for use in patients' homes)
Post-event (signs or symptoms of over-anticoagulation begin)	<ul style="list-style-type: none"> Educate patients and caregivers to recognize over-anticoagulation and respond appropriately 	<ul style="list-style-type: none"> Ensure availability of safe and effective therapies for over-anticoagulation (e.g., antidotes) 	<ul style="list-style-type: none"> Ensure timely access to professional advice and care if over-anticoagulation suspected Develop emergency medical services protocols for anticoagulation testing in high-risk patients (e.g., trauma patients 65 years or older) Improve access to medication lists to help identify patients taking warfarin and at risk for over-anticoagulation (e.g., interoperable electronic health records)
Results	<ul style="list-style-type: none"> For patients: Acute injury. Permanent injury and disability, death For healthcare systems: Telephone consultation, outpatient or emergency evaluation, hospitalization For society: Direct costs of healthcare, indirect costs including productivity loss 		



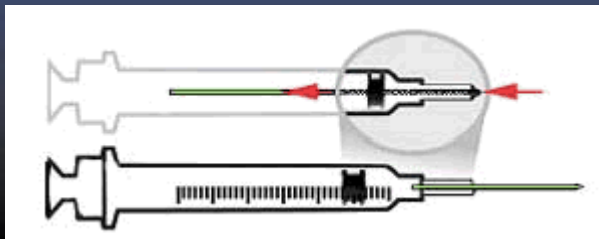
Consider Implementation Strategies



Education



Engineering



Enforcement

Needlestick Safety and Prevention Act, 2000



Insert Part 2

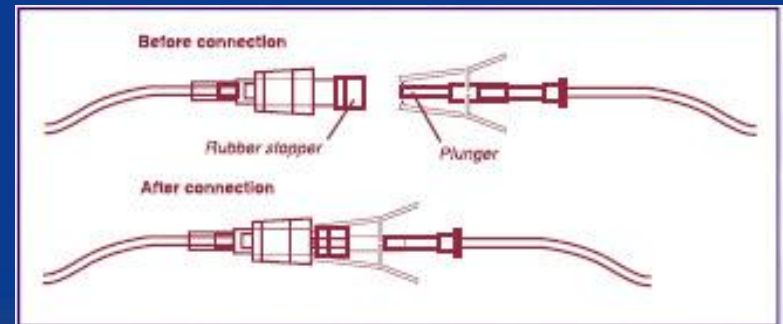
C. Consider Preferred Approach

Active



DISPOSE WITH CARE. Be responsible for the sharps you use. Activate safety features. Dispose in sharps containers.

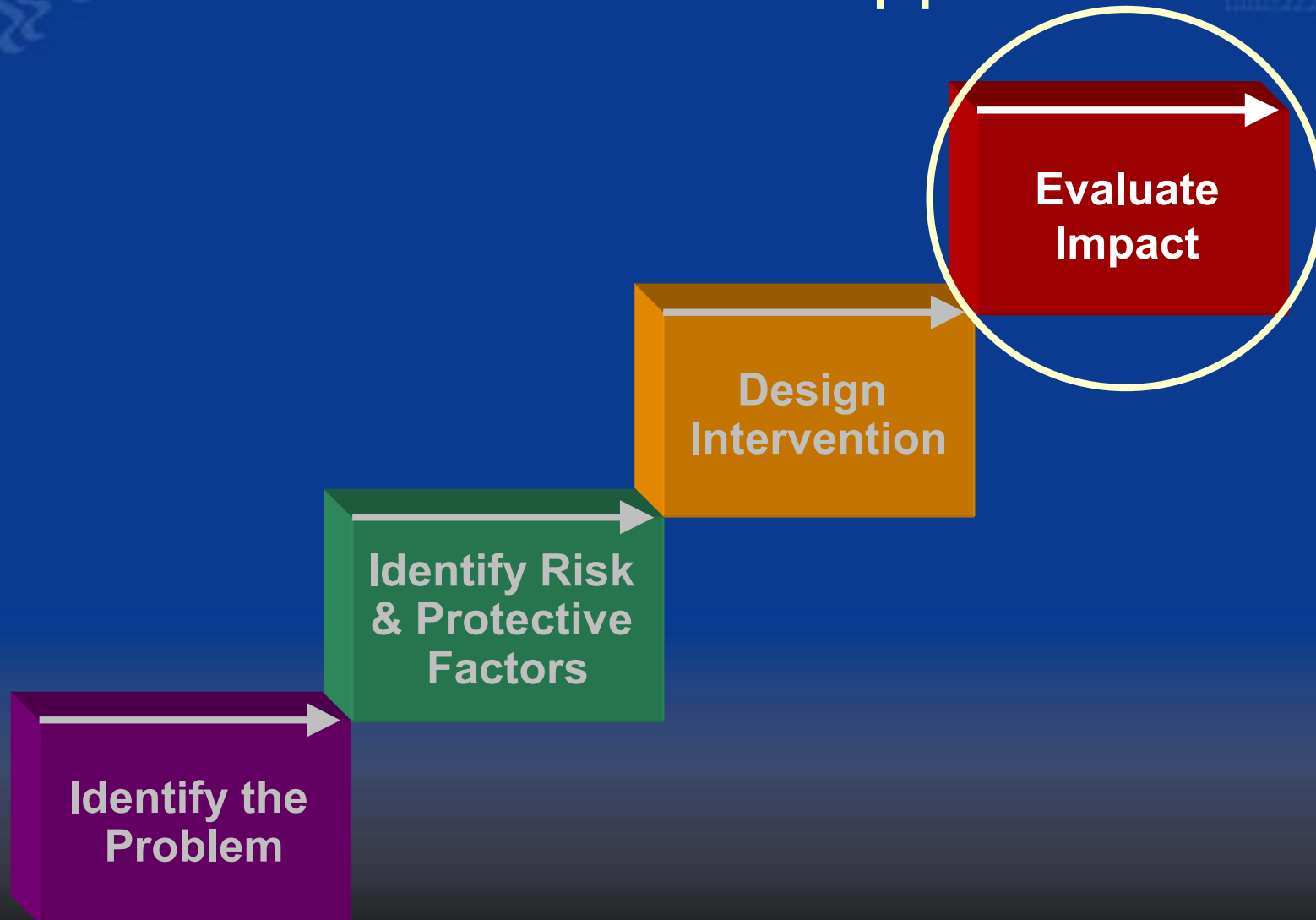
Passive



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The Public Health Approach





Summary

- Drug safety for ambulatory patients is an important public health problem
- Patients play the central role in ambulatory drug safety
- Opportunity for patient-centered ambulatory drug safety measures



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