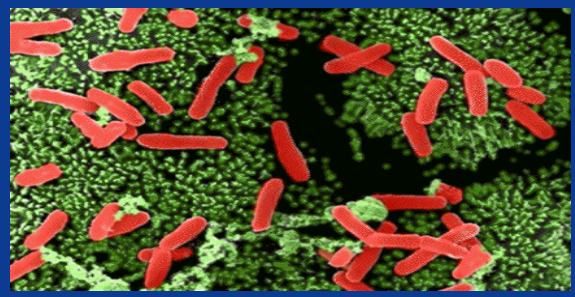
Laboratory Positive *Clostridium difficile*: BioSense 2007-2008



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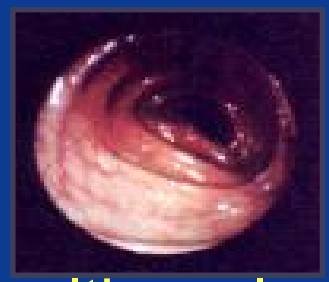
The findings and conclusions in this presentation are those of the author and do not necessarily represent the views of the Centers for Disease Control and Prevention

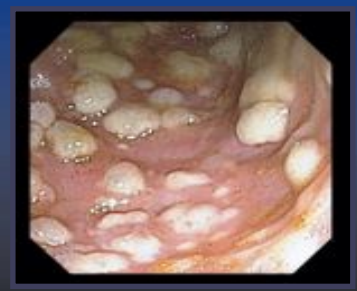
Clostridium difficile Infection (CDI)

- Anaerobic, spore-forming bacillus
- Wide spectrum of disease
  - Simple diarrhea
  - → Pseudomembranous colitis
  - → Toxic megacolon
  - → Sepsis and death
- Transmission through contaminated environment & hands of healthcare personnel
- Risk factor: recent antimicrobial exposure

C. difficile



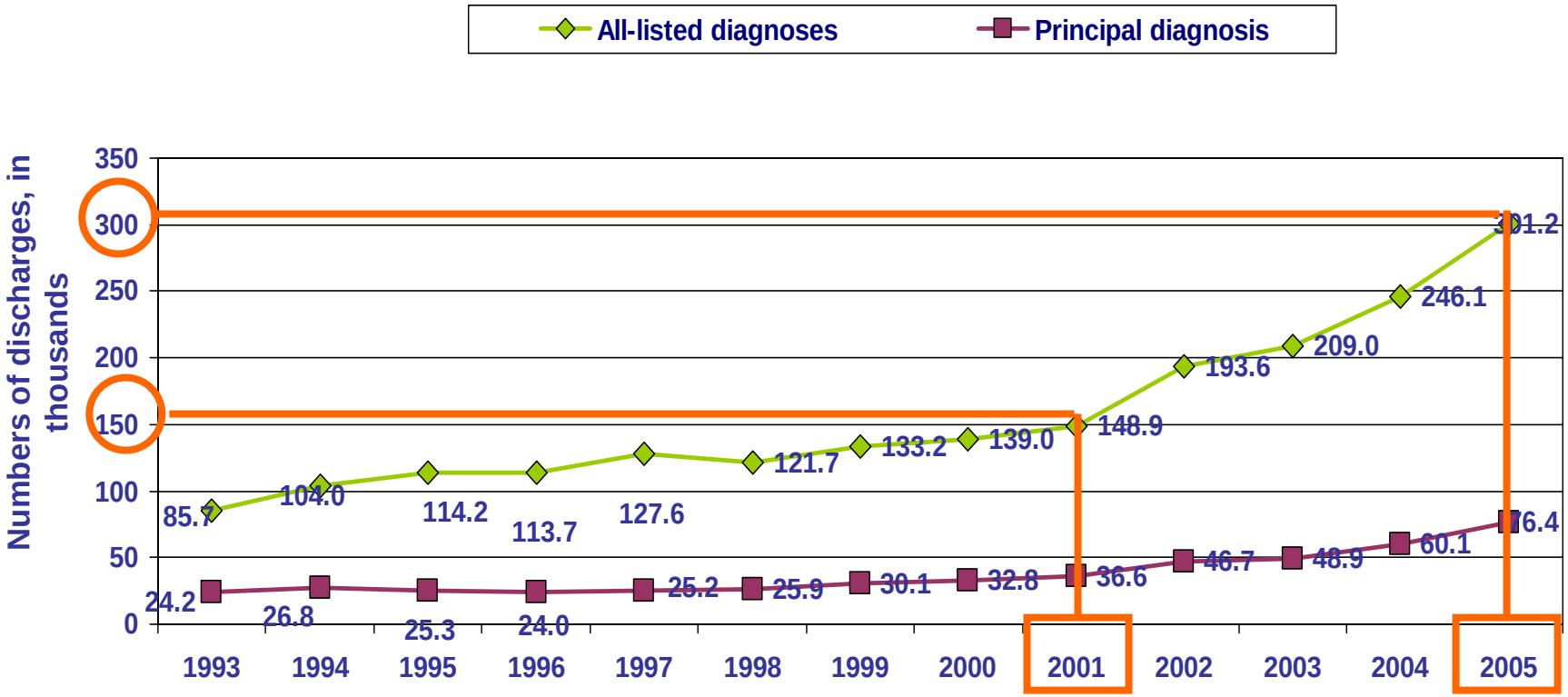
Healthy colon



Pseudo-membranous colitis

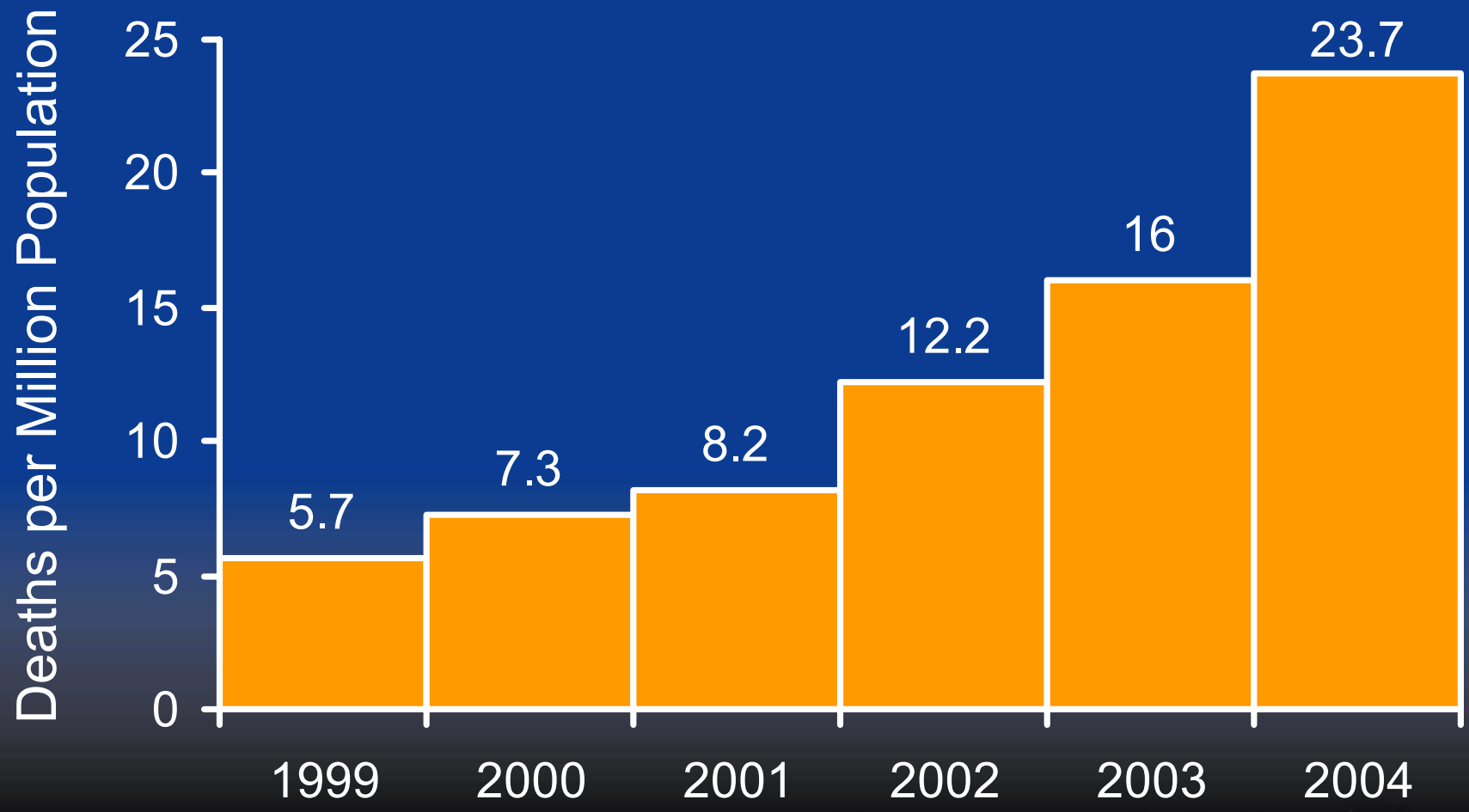
Changing Epidemiology of *Clostridium difficile*

Figure 1. Trends in hospital stays associated with Clostridium difficile-associated disease, 1993-2005



From Elixhauser A, *Clostridium difficile*-associated disease in U.S. Hospitals, 1993–2005. HCUP Statistical Brief #50. April 2008.

Clostridium difficile–related Mortality by Listing on Death Certificates, United States—1999-2004



Adapted from Redelings MD, *et al*. Emerg Infect Dis. 2007

C.difficile in Previously Low-Risk Populations

MMWR™

Morbidity and Mortality Weekly Report

Weekly December 2, 2005 / Vol. 54 / No. 47

Severe *Clostridium difficile*–Associated Disease in Populations Previously at Low Risk — Four States, 2005

- 10 pregnant women
- 23 generally healthy persons in the community
- Cases *without* precedent antimicrobial use

Centers for Disease Control and Prevention. *MMWR Morbid Mortal Wkly Rep*. 2005

Recommendations from Ad Hoc *C. difficile* Surveillance Working Group

- Hospitals should conduct surveillance for CDI
  - Track positive laboratory results (e.g., toxin assays)
  - Consider measures to track outcomes
  - Determine Healthcare vs. Community-associated disease if possible

INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY FEBRUARY 2007, VOL. 28, NO. 2

ORIGINAL ARTICLE

Recommendations for Surveillance of *Clostridium difficile*–Associated Disease

L. Clifford McDonald, MD; Bruno Coignard, MD, MSc; Erik Dubberke, MD; Xiaoyan Song, MD, MS; Teresa Horan, MPH; Preeta K. Kutty, MD, MPH; the Ad Hoc *Clostridium difficile* Surveillance Working Group

BioSense

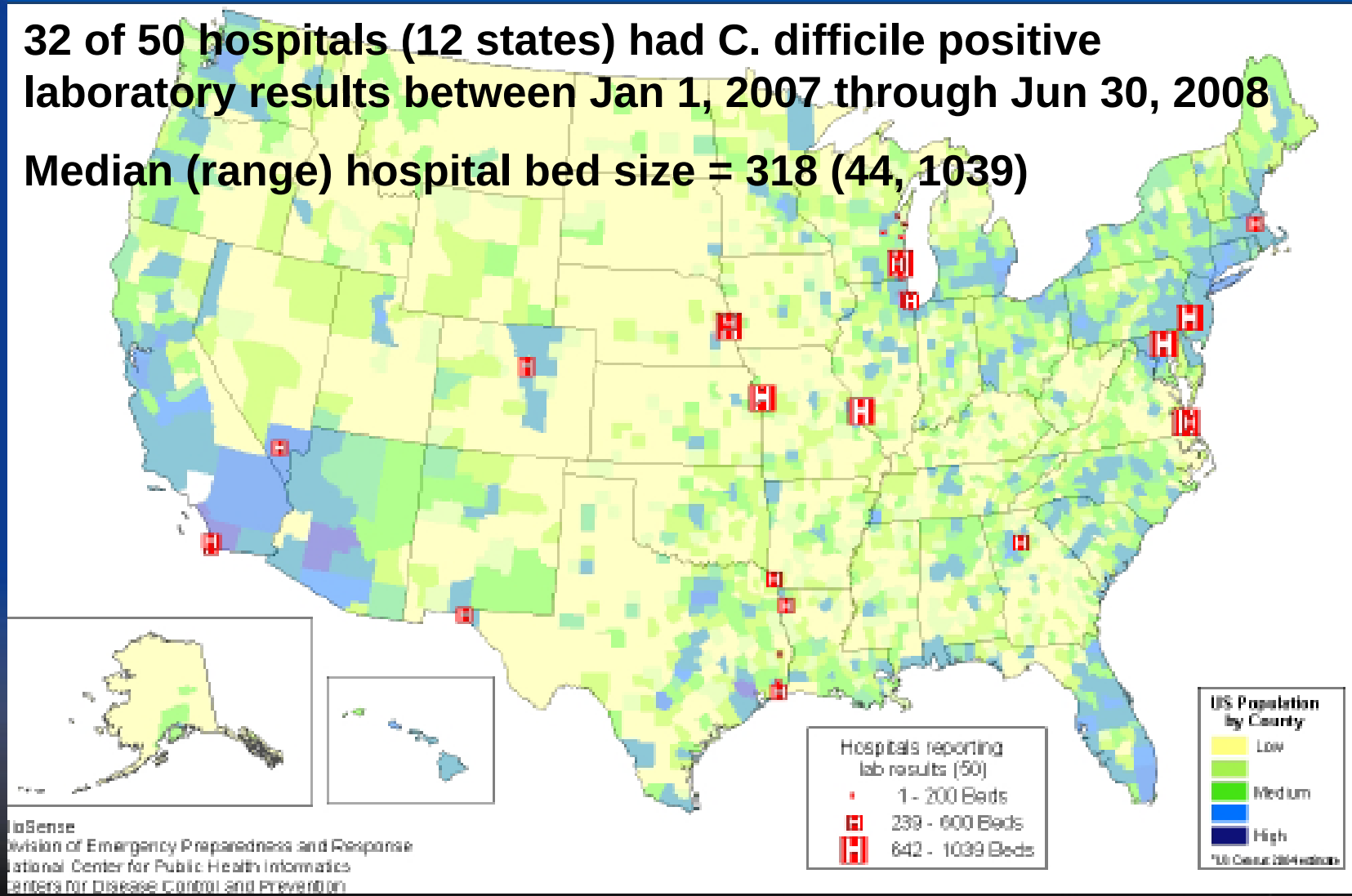
- Surveillance system designed for:
  - Disease detection
  - Monitoring
  - Real-time health situational awareness
- Data sources:
  - Non-federal hospitals: 569
  - Veteran's Administration facilities: 833
  - Department of Defense facilities: 355
- Data types:
  - Chief complaints, working and final diagnoses
  - Subset of hospitals: laboratory*, radiology, pharmacy data

* Focus of this study

BioSense Facilities reporting Laboratory Results - August 2008 -

32 of 50 hospitals (12 states) had C. difficile positive laboratory results between Jan 1, 2007 through Jun 30, 2008

Median (range) hospital bed size = 318 (44, 1039)



Objectives

- Determine the feasibility of using BioSense laboratory data for surveillance on a disease of public health importance
- Apply surveillance definitions and calculate overall and facility rates of disease based on definitions created by the *C. difficile* Surveillance Working Group

C. difficile Definitions

	Laboratory collection	Healthcare facility (HCF) exposure from time of laboratory collection
Healthcare-onset	≥3 days after hospital admission	
Community-onset, HCF-associated	<3 days or in outpatient setting	≤30 days
Community-associated	<3 days or in outpatient setting	no HCF admission or ≥90 days
Indeterminate	<3 days or in outpatient setting	≤90 but >30 days

Methods

- Identified positive *C. difficile* toxin assays and cultures in laboratory data sent to BioSense from January 1, 2007 through June 30, 2008
- Searched for *C. difficile* in SNOMED-CT*-coded and text-based reports
- Merged laboratory data with Admission, Discharge, Transfer (ADT) data to determine healthcare setting, patient demographics, and previous healthcare exposures
- De-duplicated data; earliest report kept for each unique patient

*Systematized Nomenclature of Medicine

SNOMED-CT[1] Codes from PHIN VADS[2]

SNOMED-CT	CodeName
120953000	Clostridium difficile antibody
423590009	Clostridium difficile colitis
96001009	Clostridium difficile toxin B
404907009	Toxic megacolon due to Clostridium difficile
186431008	Clostridium difficile infection
121963002	Clostridium difficile antibody assay
121897008	Clostridium difficile detection
5933001	Clostridium difficile
255823007	Clostridium difficile enterotoxin A
310541005	Clostridium difficile toxin A detected
122209009	Clostridium difficile culture
72415005	Clostridium difficile assay
118114008	Clostridium difficile antigen assay
122174009	Clostridium difficile toxin A assay
75332002	Clostridium difficile toxin assay
413047002	Clostridium difficile toxin detection
12671002	Clostridium difficile toxin
117963005	Clostridium difficile toxin A AND B assay
121964008	Clostridium difficile toxin B assay

ObsResult	ObsResu	ObsResultText	ObsRes
StdCode=5933001,	5933001	Clostridium difficile	SNOMED
StdCode=5933001,	5933001	Clostridium difficile	SNOMED
StdCode=5933001,	5933001	Clostridium difficile	SNOMED
StdCode=5933001,	5933001	Clostridium difficile	SNOMED
StdCode=5933001,	5933001	Clostridium difficile	SNOMED
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StdCode=5933001,	5933001	Clostridium difficile	SNOMED
StdCode=5933001	5933001	Clostridium difficile	SNOMED

[1]Systematized Nomenclature of Medicine; [2]Vocabulary Access and Distribution System

LOINC[1] Codes from PHIN VADS[2]

Loinc Code	Name
20761-3	C dif Stl Ql Aggl
20762-1	C dif Stl Ql Aerobe Cul
34712-0	C dif Stl Ql
563-7	C dif XXX Ql Cult
562-9	C dif Stl Ql Cult
31308-0	C dif Ab Ser-aCnc
9365-8	C dif Ab Titr Ser
26697-3	C dif IgA Ser-aCnc
26702-1	C dif IgG Ser-aCnc
26694-0	C dif IgM Ser-aCnc
13957-6	C dif Tox A Stl Ql EIA
6359-4	C dif Tox A Stl EIA-aCnc
6360-2	C dif Tox A XXX EIA-aCnc

Loinc Code	Name
34468-9	C dif Tox A+B Stl Ql EIA
34713-8	C dif Tox A+B Stl Ql
6361-0	C dif Tox A+B Ser EIA-aCnc
6362-8	C dif Tox A+B Stl Ql CT Tiss Cult
6363-6	C dif Tox A+B Stl EIA-aCnc
6364-4	C dif Tox A+B XXX EIA-aCnc
33947-3	C dif Tox Ab Titr Ser Nt
43055-3	C dif Tox Ab Titr Ser
10895-1	C dif Tox B Stl Ql
46131-9	C dif Tox B Stl Ql CT Tiss Cult
6365-1	C dif Tox B Stl EIA-aCnc
6366-9	C dif Tox B XXX EIA-aCnc

[1]Logical Observation Identifiers Names and Codes; [2]Vocabulary Access and Distribution System

Text Reports

EIA positive for **C.difficile** toxin

POSITIVE FOR **C.DIFFICILE** TOXINS A AND/OR B CALLED TO, READ BACK AND CONFIRMED BY KM 03/07/08 1330 BY CAM FINAL 03/07/2008

C. diff Toxin B SPECIMEN DESCRIPTION STOOL COMMENTS NONE TEST RESULT POSITIVE FOR CLOSTRIDIUM DIFFICILE TOXIN B REPORT STATUS FINAL 03192007

Soft stool:Positive for **Clostridium difficile** toxin

******* MICROBIOLOGY ******* C. DIFFICILE TOXIN A & B EIA @ ACC#: COLL D/T:12/31/07 1800 ---------- FINAL REPORT ---------- 02JAN08 **CLOSTRIDIUM DIFFICILE** TOXIN A & B POSITIVE .END OF REPORT

SP 2020 01 RAPID MICROBIOLOGY TESTS ---------- PROCEDURE: **CLOSTRIDIUM DIFF** TOXIN A/B @ COLLECTED: 03/18/08 0945 SOURCE: STOOL RECEIVED: 03/18/08 1552 STARTED: 03/18/08 1603 ----FINAL REPORT---------- FINAL REPORT 03/18/08 1954 POSITIVE for **C. difficile** Toxin A and/or Toxin B @ = CLOS DIFF TXN A

Text Reports - Negations

C.difficile toxins are **absent** or below the limit of detection

---

NEGATIVE FOR C.DIFFICILE TOXINS A AND/OR B FINAL 05/24/2008

******* MICROBIOLOGY ******* C. DIFFICILE TOXIN A & B EIA @ ACC#:02-xxxxx COLL D/T:06/18/08 0630 ---------- FINAL REPORT ---------- 18JUN08 CLOSTRIDIUM DIFFICILE TOXIN A & B **NOT DETECTED**

Clostridium difficile toxin A and/or B **not present**.

No Clostridium difficile toxin detected.

C. diff Toxin EIA SPECIMEN DESCRIPTION STOOL COMMENTS NONE TEST RESULT **CANCELLED** REQUEST CANCELLED. THIS TEST EXCEEDED REPLICA LIMIT. SPECIMEN WILL BE HELD 24 HOURS. CALL LAB AT xxx-xxx-xxxx IF NECESSARY. REPORT STATUS FINAL

******* MICROBIOLOGY ******* C. DIFFICILE TOXIN A & B EIA @ ACC#:xx-xxxxxx COLL D/T:01/05/07 1040 ---------- FINAL REPORT ---------- 06JAN07 **SPECIMEN REJECTED**. Testing for C. difficile toxins will only be performed on one specimen within a 24 hour timeframe. Patient account has been credited for this test.

Results: Characteristics of Patients with *C. difficile* Laboratory Positive Tests (Jan 1, 2007 – Jun 30, 2008)

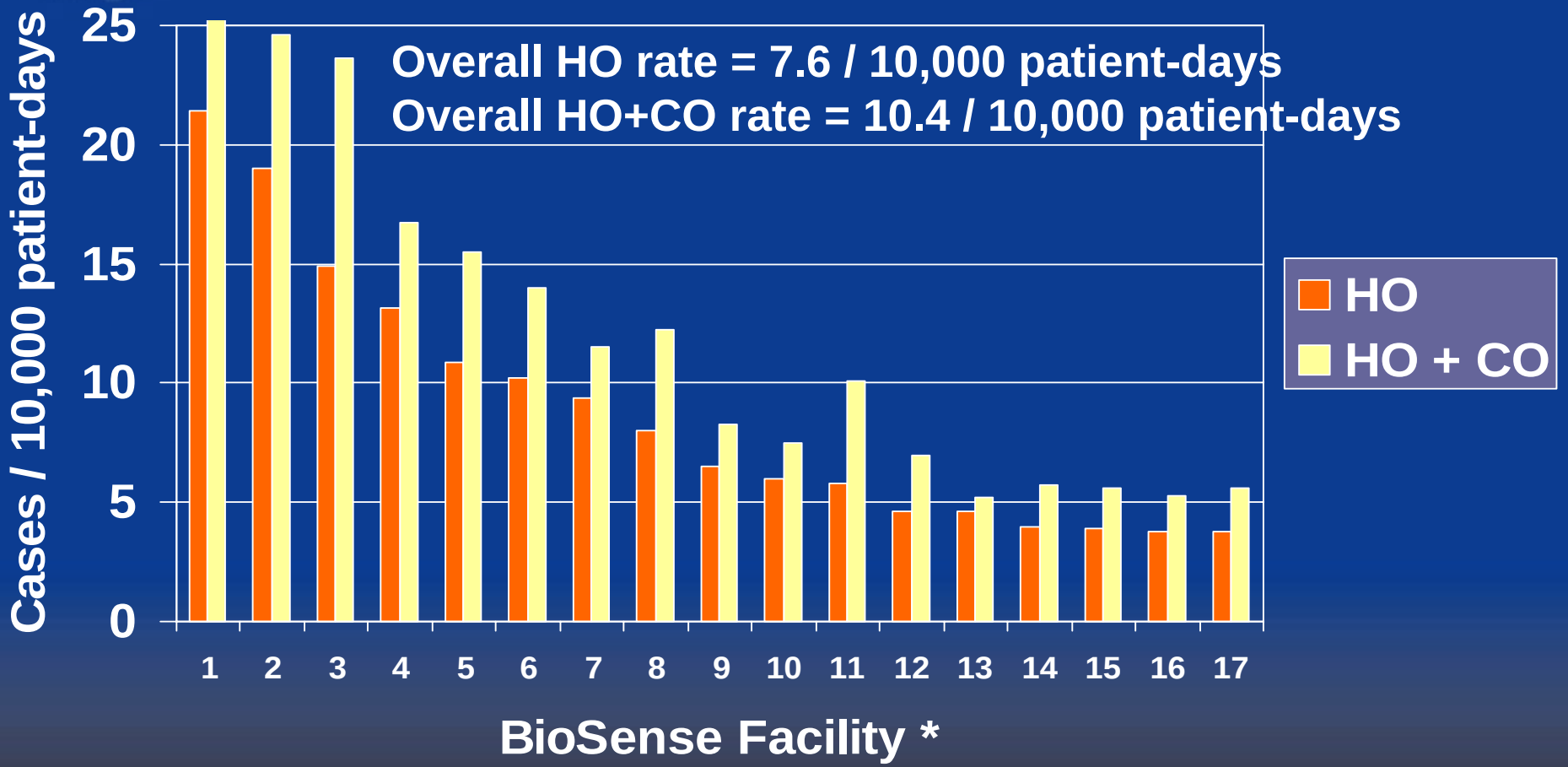
Unique patients with laboratory positive tests	N = 4,203
Median (range) age in years	67 (<1, 101)
Females	54%
Laboratory collection setting	
Inpatient	88%
Outpatient	8%
Emergency department	4%

C. difficile Types (N = 4,203)

	n (%)
Healthcare-onset	1,905 (45%)
Community-onset, HCF-associated	704 (17%)
Community-associated*	1,242 (30%)
Indeterminate	286 (7%)
Community-onset, unknown exposure	66 (1%)

* Likely an overestimate since healthcare exposures in other facilities are not captured

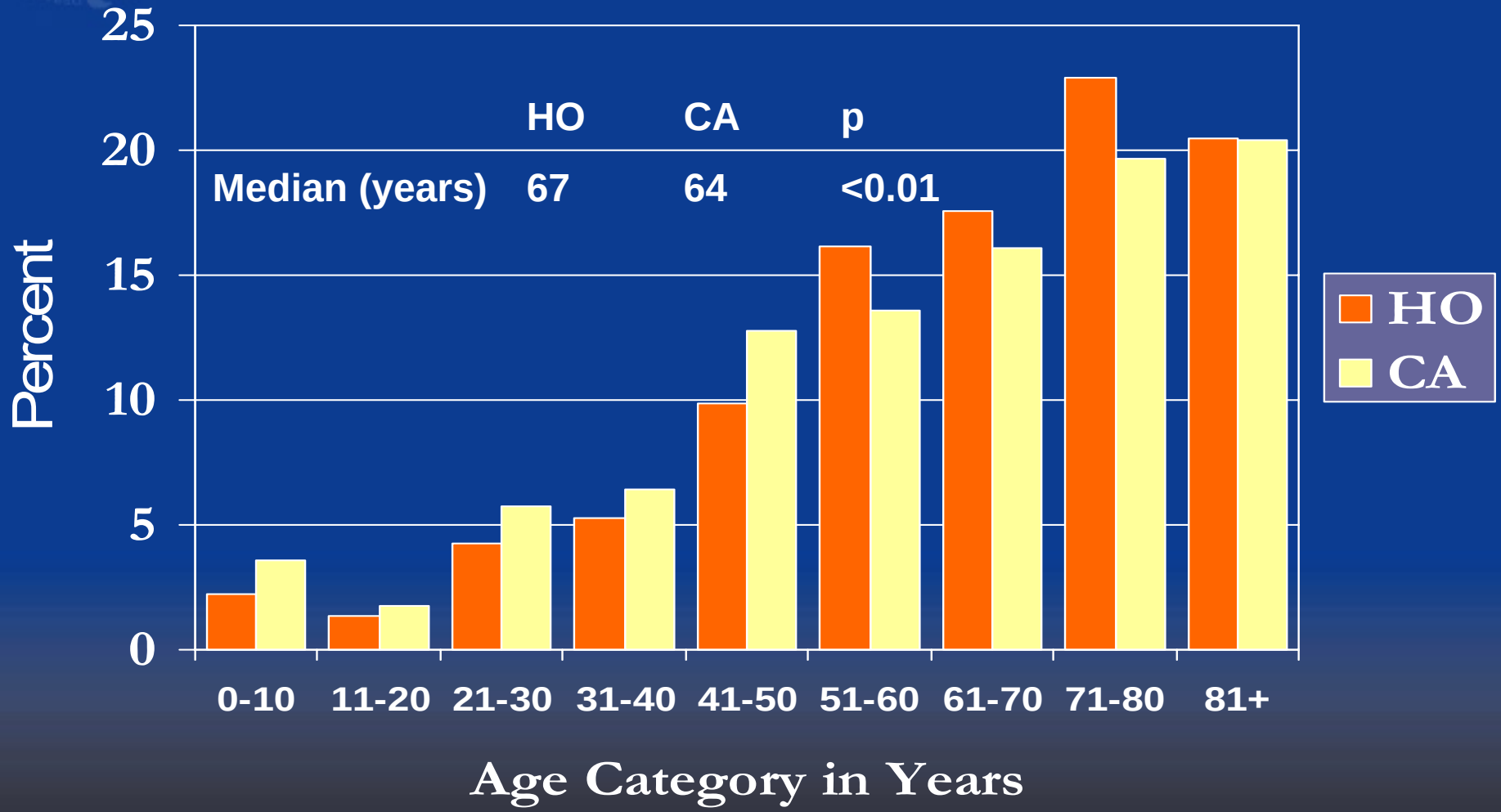
C.difficile Rates by Facility



HO = Healthcare-onset: laboratory collection date ≥3 days after hospital admission
CO = Community-onset, HCF-associated: laboratory collection date <3 days after hospital admission or in outpatient setting AND hospital admission ≤30 days from time of laboratory collection

* 17 facilities with ≥20 laboratory positive *C. difficile* reports

Age Distribution of Healthcare-onset and Community-associated *C. difficile* Disease



HO = Healthcare-onset: laboratory collection date ≥3 days after hospital admission

CO = Community-associated: laboratory collection date <3 days after hospital admission or collection in outpatient setting AND no HCF admission within 90 days from time of laboratory collection

Comparing BioSense to Other Studies

	BioSense	Kutty et al. 6 hospitals in N.C.	Dubberke et al 5 hospitals nationwide
Healthcare-onset			
Proportion	45%	42%	60%
Rate/10,000 pt-days	7.6		11.4
Facility rate range	3.8 – 21.4	1.4 – 16.8	4.1 – 16.8
Community-associated			
Proportion	30%	20%	

Kutty et al, *Infect Control Hosp Epidemiol* 2007
Dubberke et al, SHEA 2008, Abstract #377

Limitations

- Assumed previous healthcare exposures were at the same facility
- No formal validation of the data
- 4% of BioSense visits were missing admission/discharge dates which affects rate calculations

Discussion

- Identified 4,203 laboratory positive *Clostridium difficile* records from 32 laboratories in 12 states
- Proportion of healthcare-onset cases and overall rates and facility rate ranges were similar to other studies
- Automated data from BioSense appears to be a useful tool in tracking *C. difficile* infections

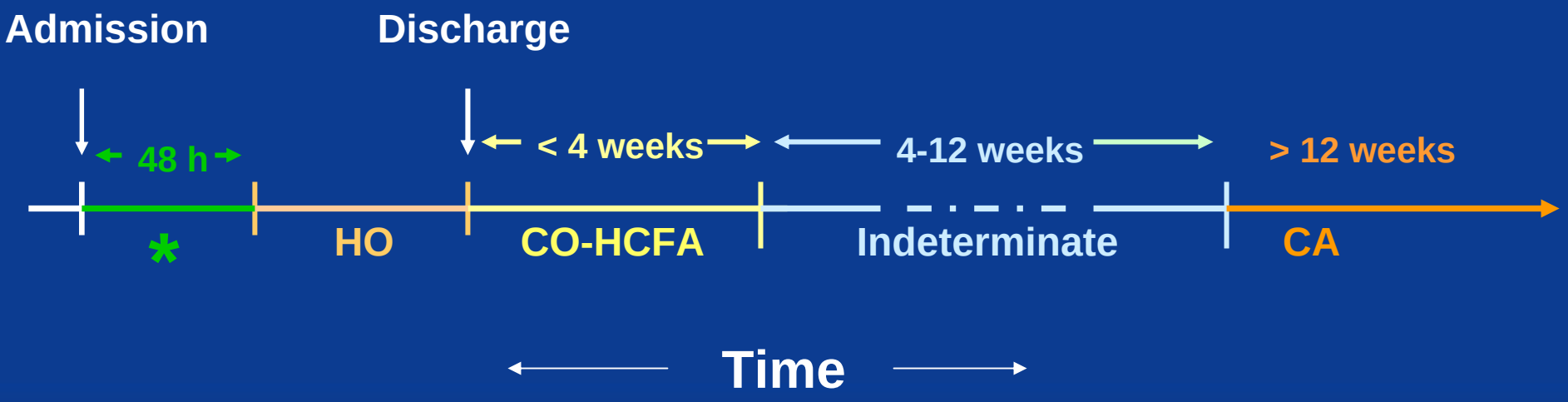
Next Steps

- Incorporate other data types in the analysis (e.g., pharmacy data)
- Verify data with sample chart review
- Continue to work with subject matter experts and hospital infection control practitioners to maximize utility of data

Acknowledgements

- L. Clifford McDonald, MD
- Peter Hicks

Recommendations for Surveillance of *Clostridium difficile* Infection



HO: Healthcare-onset

CO-HCFA: Community-Onset Healthcare facility-associated

CA: Community-Associated

*Depending on whether patient was discharged within previous 4 weeks, CO-HCFA vs. CA

CDAD Surveillance Working Group. *Infect Control Hosp Epidemiol* 2007; 28:140-145