

*NIH Clinical Center:
Patient Safety, Clinical Quality,
and Employee Safety Update*



Report to the NIH Clinical Center Research Hospital Board

October 21, 2016

Agenda

- NIH CC Overview and Recent Accomplishments
 - John I. Gallin, MD
- Patient Safety and Quality Performance Metrics
 - Laura M. Lee, RN, MS
- Employee Safety Overview and Performance Metrics
 - Michele Evans, DrPH
 - James Schmitt, MD

Overview and Recent Accomplishments

John I. Gallin, MD

Director, NIH Clinical Center

NIH Associate Director for Clinical Research Chief Scientific Officer, Clinical Center

New Position:

- Report directly to NIH Director
- Extensive interactions with ICs and Intramural Research Program
- Major role developing a systematic approach to distribute scarce CC resources
- Close partnership with CC CEO and NIH Deputy Director for Intramural Research (DDIR)

NIH Associate Director for Clinical Research

Chief Scientific Officer, Clinical Center

Duties:

1. Scientific review of clinical protocols
2. Setting priorities for use of scarce CC resources
3. Review IC Directors oversight of Clinical Directors
4. Scientific Director for independent research of CC investigators
5. Strategic planning for intramural clinical research (with DDIR)
6. Strategic partnerships
7. Clinical research training

Improving Clinical Studies in the IRP

Strategic Planning Clinical Research

**NIH Associate Director
for Clinical Research and
Chief Scientific Officer, CC**

**Priority Setting for Scarce Resources
Scientific Review of Clinical Protocols**



**Deputy Director for
Intramural Research**

**OHSRP
ORSC**

CC CEO

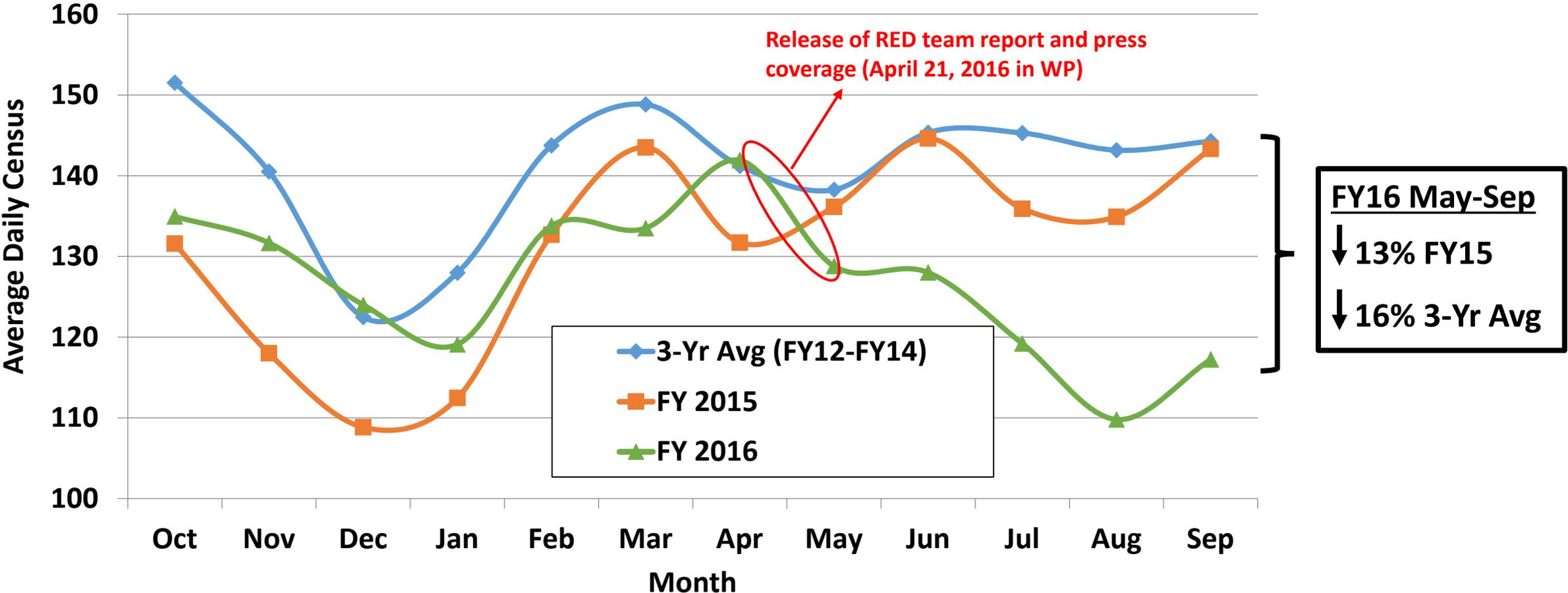
Patient Care

NIH CC Patient Activity

Year End Activity

	Year End 2015	Year-End 2016	% Change FY15-16
Inpatient Admissions	5,448	5,275	-3%
Average Length of Stay	8.9	8.7	-2%
Inpatient Days	47,847	46,394	-3%
Average Daily Census (7-Day)	131.1	126.8	-3%
Outpatient Total Visits	100,507	100,141	0%
<i>Clinic Visits</i>	81,471	81,210	0%
<i>Day Hospital Visits</i>	19,036	18,931	-1%
New Patients	10,761	10,498	-2%

Average Daily Census (ADC) by Month



ADC Stats

- 3-Year Average (FY 2012-2014) = 141.0
- Year End FY 2015: 131.1
- Year End FY 2016: 126.8

Recent Accomplishments

Patient Safety and Clinical Quality

Patient Safety and Quality Initiatives

- New Patient Safety Event Reporting System (ORS)
- Anonymous Reporting System
- Morbidity and Mortality Rounds
- Institute-based Patient Safety/Quality Liaisons
- Cascading Patient Safety Element in Personnel Reviews (PMAPs)
- New Recruits
 - New Chief of Pediatric Anesthesia and Critical Care (recruiting)
 - Staff for New Pediatrics Observation Unit
 - New Chief of Pharmacy
- Physical Infrastructure Upgrades for Sterile Manufacturing
- Visits to Academic Medical Centers

Environmental Scan: Site Visits

Johns Hopkins Medicine – Peter Pronovost, MD



- Armstrong Institute infrastructure
- Approach to identifying and managing risk
- Data dashboard

Sibley Hospital – Chip Davis, PhD



- Innovation Center
- Similar scale/size as the NIH CC

Environmental Scan: Site Visits

Brigham & Women's – Allen Kachalia, MD



- Public display of data and transparency
- Death reviews
- Team members had multiple roles

Future Visits

- New York Presbyterian
- University of Virginia
- Massachusetts General Hospital

Communicating Performance

Patient Safety and Clinical Quality Dashboard

Performance Metrics Dashboard

- What we measure:
 - Regulatory (Joint Commission, FDA, OSHA)
 - Protocol-related (SAEs, UPs)
 - High-Risk Processes (Medications, Infection Control, Blood Use)
 - Patient Perceptions

Performance Metrics Dashboard

Best options to present data?

How to capture centrally clinical research metrics?

Discussion

Patient Safety and Quality Performance Metrics

Laura M. Lee, RN MS

Director, Office of Patient Safety and Clinical Quality, NIH Clinical Center

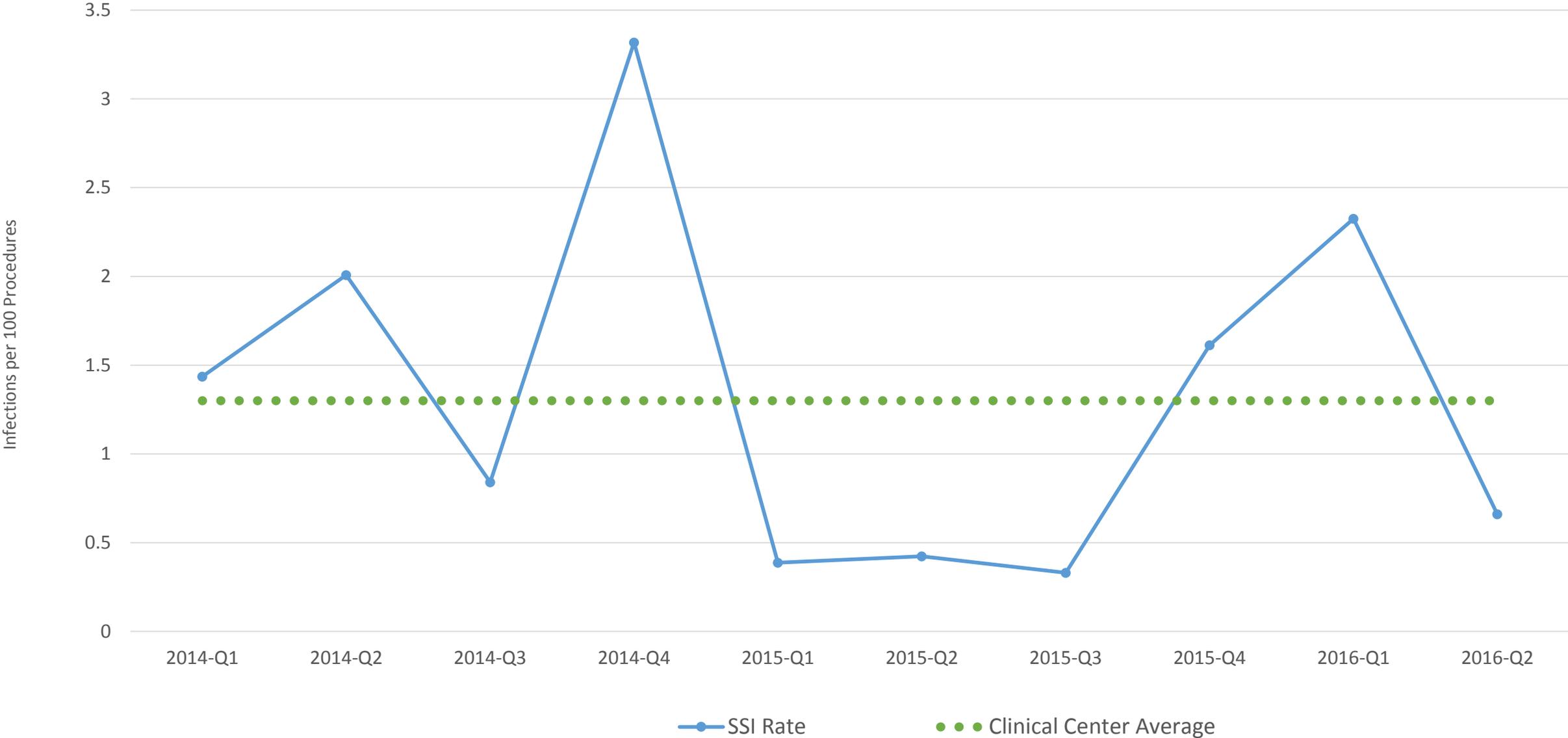
Patient Safety and Quality Metrics

- Measurement Challenges/Opportunities
 - Operative Environment
 - Small 'n'
- Anonymous Reporting Hotline
- New Patient Safety Event Reporting System

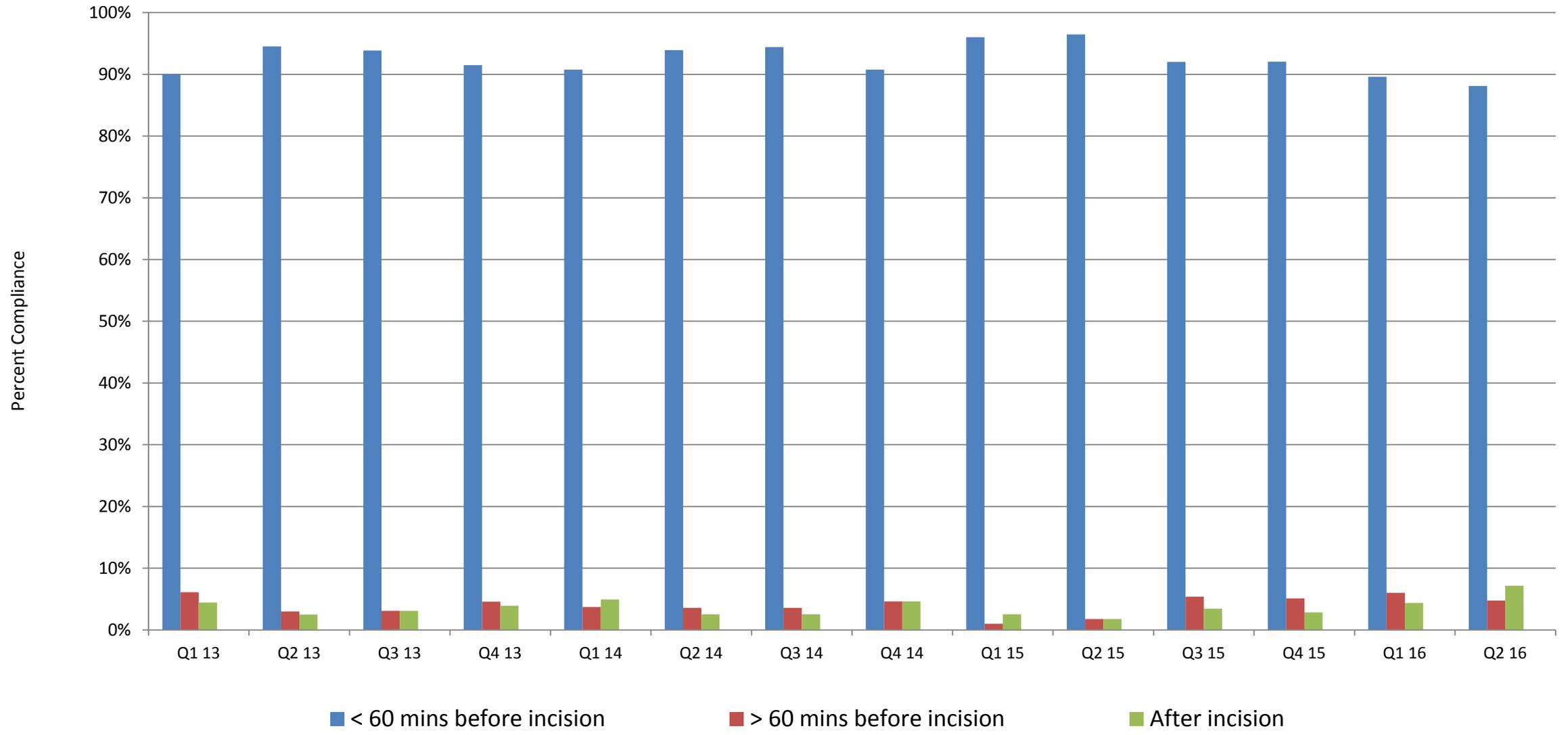
Metrics Challenges/Opportunities

The Operative Environment

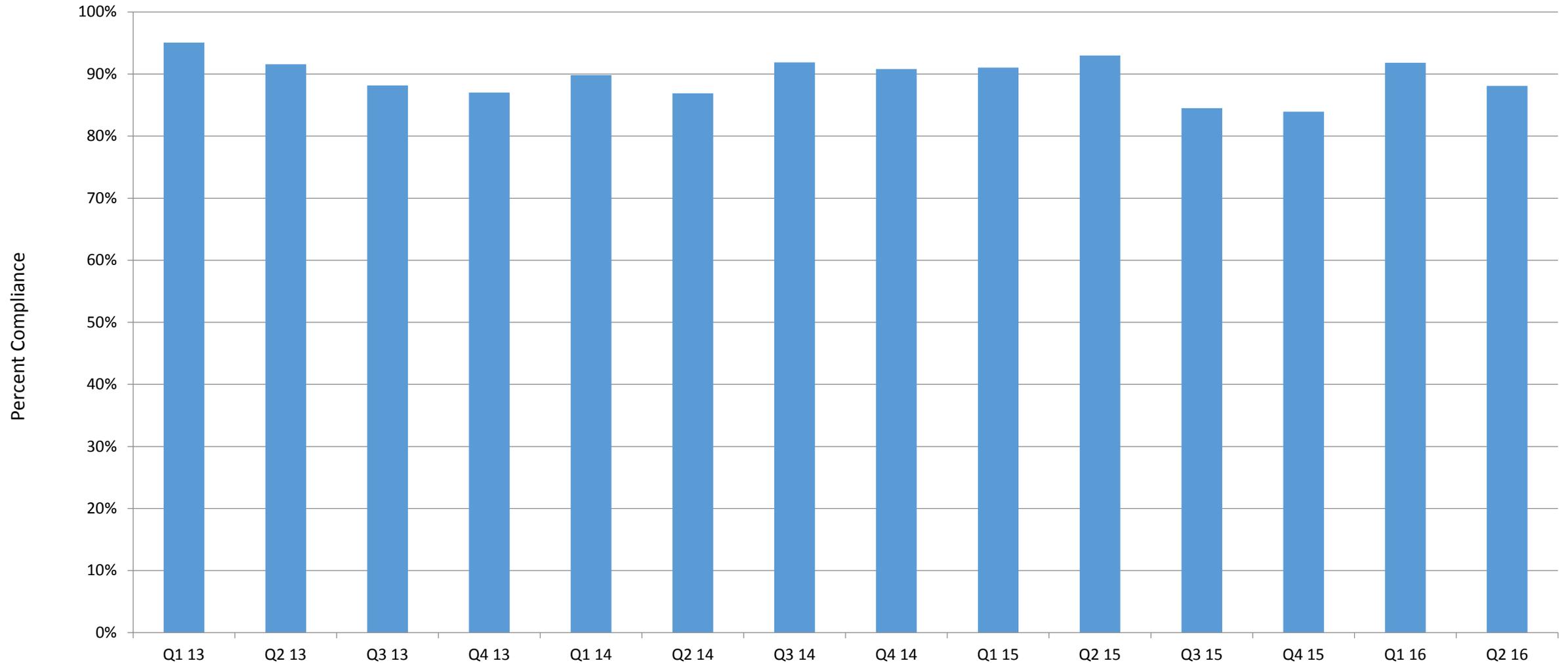
Surgical Site Infections



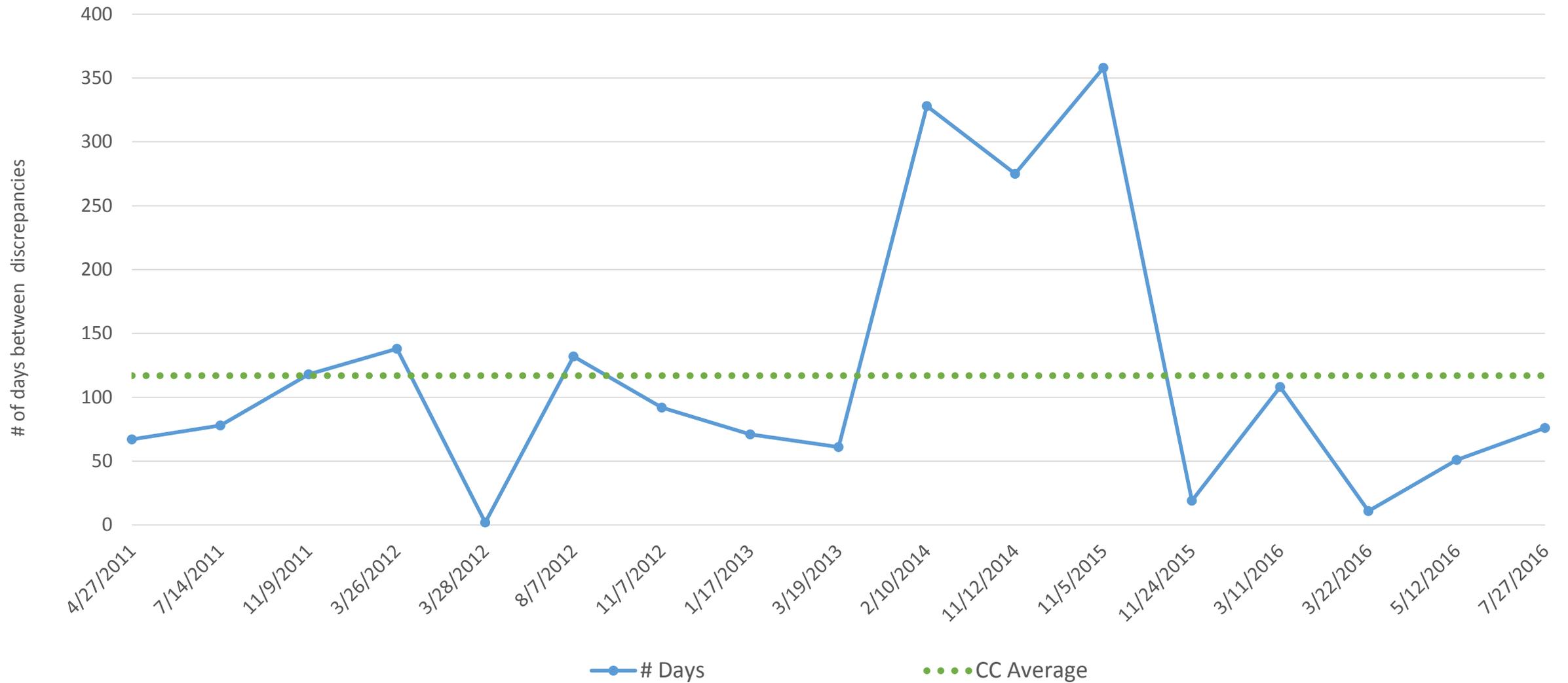
Peri-Operative Antibiotic Delivery



Post-Operative Antibiotics Discontinued within 24 Hours



Days Between Count Discrepancies



Other Operative Measures.....

- Complications
- Duration of cases
- Returns to the OR
- Blood use
- Others?

The Conundrum of Small 'n'.....

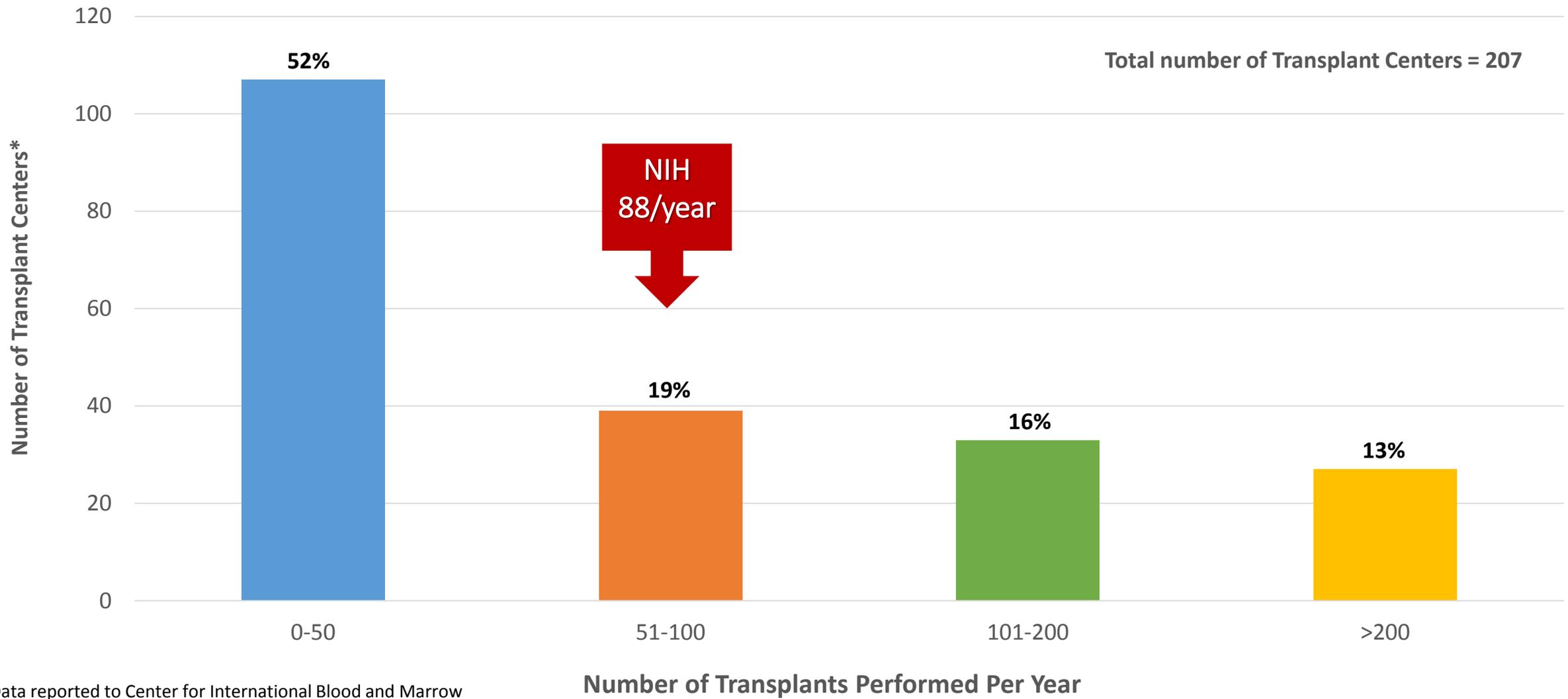
Programs and Procedures

Programs

NIH Transplant Program

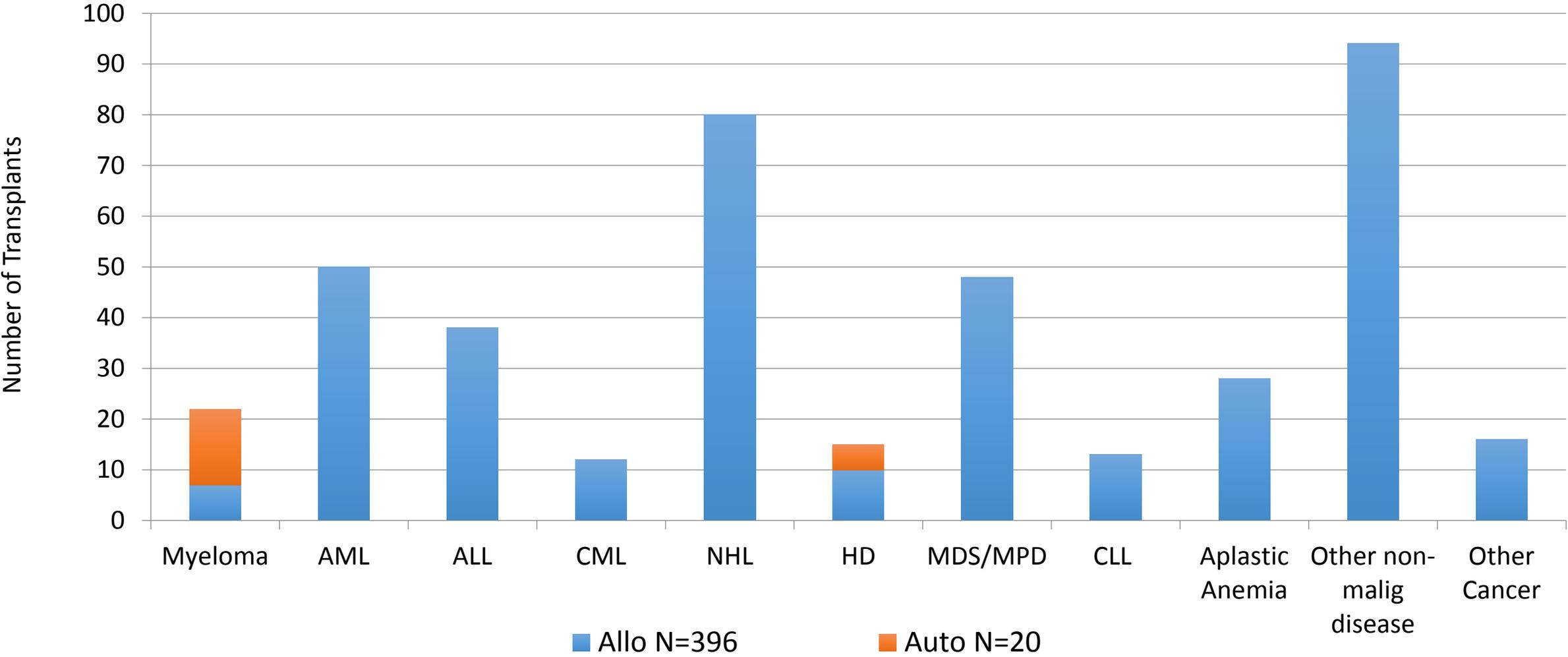
- Multi-Institute Consortium (NCI, NHLBI, NIAID)
- Malignant and Non-Malignant Disease
- High acuity population; novel therapies
- Focus on use of innovative therapies for reducing Graft Versus Host Disease, transplant mortality, and minimizing relapse

Relative Size of NIH CC Transplant Program: 2012-2013



* Data reported to Center for International Blood and Marrow Transplant Research (CIBMTR)

Indications for Stem Cell Transplantation: 2010-2015



Acute myeloid leukemia (AML) - 1st Complete Remission

Transplants performed 2010-2014

Survival

Source	Donor type	#	F/U	Day 100	1 year	3 year	Overall
NHLBI (7) NCI (2)	Sibs	9	31 mo (8-47)	100%	77.8%	66.7%	66.7%
National Benchmark ¹	Sibs	2297		93.3% (92.1-94.2%)	72.5% (70.6-74.2%)	55.0% (52.7-57.3%)	

¹ Center for International Blood and Marrow Transplant Research (CIBMTR)

Severe Aplastic Anemia – Unrelated Donors

Transplants performed 2010-2014

Survival

Source	Cell source	# pts	F/U	Day 100	1 year	3 year	Overall
08-H-0046	cord + haplo CD34	14	35 mo (3-59)	100%	92.9%	85.7%	85.7%
National Benchmark ¹	cord	62		75.8% (63.1-84.6%)	59.7% (46.4-70.7%)	52.4% (39.1-64.1)	
European Benchmark ²	cord	71	35 mo (8-83)			38% (32-44%)	

¹ Center for International Blood and Marrow Transplant Research (CIBMTR)

² European Society for Blood and Marrow Transplantation (EBMT)

Sickle Cell Anemia

Transplants performed 2010-2014

Survival

Source	Donor type	# pts	F/U	Day 100 Survival	1 year Survival	3 year Survival	Overall Survival	Reject
03-H-0170 14-H-0077	Matched related	27	31mo (5-62)	100%	96.3%	96.3%	96.3%	11.1%
09-H-0225	Haplo PBSC	18	32mo (6-60)	94.4%	94.4%	94.4%	94.4%	50%
National Benchmark ¹	Matched related	228		98.7% (96.0-99.6%)	96.9% (93.6-98.5%)	95.0% (90.9-97.3%)		
Hopkins ²	Haplo marrow	14	21mo (13-35)	100%	100%		100%	43%

¹ Center for International Blood and Marrow Transplant Research (CIBMTR)

² Bolaños-Meade J, Fuchs EJ, Luznik L, et al. HLA-haploidentical bone marrow transplantation with posttransplant cyclophosphamide expands the donor pool for patients with sickle cell disease. *Blood*. 2012 Nov 22;120(22):4285-91

Procedures

The Conundrum of Small 'n'....

- Protocol-driven (and dependent)
 - Phase I/II
 - Rare diseases
- Consultative cases
- Incidental cases

Complex cases (“redux”; court of last resort)

Operative Procedures: Small 'n'...

- Number of surgical procedures
- Appendectomy
- Cholecystectomy

Operative Procedures: Small 'n'....

- How do you measure competence?
 - Volume
 - Complications
 - Other?

- How do you maintain competence?
 - Simulation
 - Outside cases (legal issues; competition)
 - Other?

Operative Procedures: Small 'n'.....

- What is the trigger for changing privileges?
- How do you sustain clinical investigators participation in clinical care?



SPEAK **UP**
FOR
SAFETY



The safety of NIH Clinical Center patients, visitors and staff is our highest priority.

If you have concerns about your care or see an unsafe condition, please tell us.

Dial the NIH Clinical Center
Anonymous Safety Hotline
1-866-444-8811



For more information, please contact the NIH CC Office of Patient Safety and Clinical Quality at 301-496-8025 or ccpscq@mail.nih.gov

Anonymous Reporting Hotline

<i>Week</i>	<i>Occurrence Reporting System</i>	<i>Anonymous Reporting</i>
June 12	90	2
June 19	96	0
June 26	132	3
July 3	62	1
July 10	81	3
July 17	101	3
July 24	118	3
August 7	91	2
August 14	73	0
August 21	124	1
August 28	57	0
Sept 4	56	0
Sept 11	62	2
Sept 18	70	0
Sept 25	52	2
TOTAL	1,265	22

Summary of Anonymous Reports

<i>Total Reports</i>	22
<i>Reports with Identifiers</i>	5
<i>Mean Follow-Up Time</i>	6 days
<i>Median Follow-Up Time</i>	6.5 days
<i>Range of Follow-up Time</i>	1-23 days
<i>Direct Follow-Up Possible</i>	20
<i>No Direct Follow-Up Possible</i>	2

Anonymous Reporting Hotline

Clinical Care

- Practitioner competence/technique
- Obtaining consultative services
- Staff fatigue
- Capacity to provide pediatric cardiac monitoring
- Staffing
- Orders in CRIS after practitioners have departed NIH

Communication

- Contacting appropriate practitioners with test results
- Information re: MRI safety training

Leadership/Culture

- Supervisor response to event reporting

Ethics/Human Subjects Protection

- Capacity to give informed consent
- Treatment of research participants
- Clinical research data collection practices

Facilities/Security

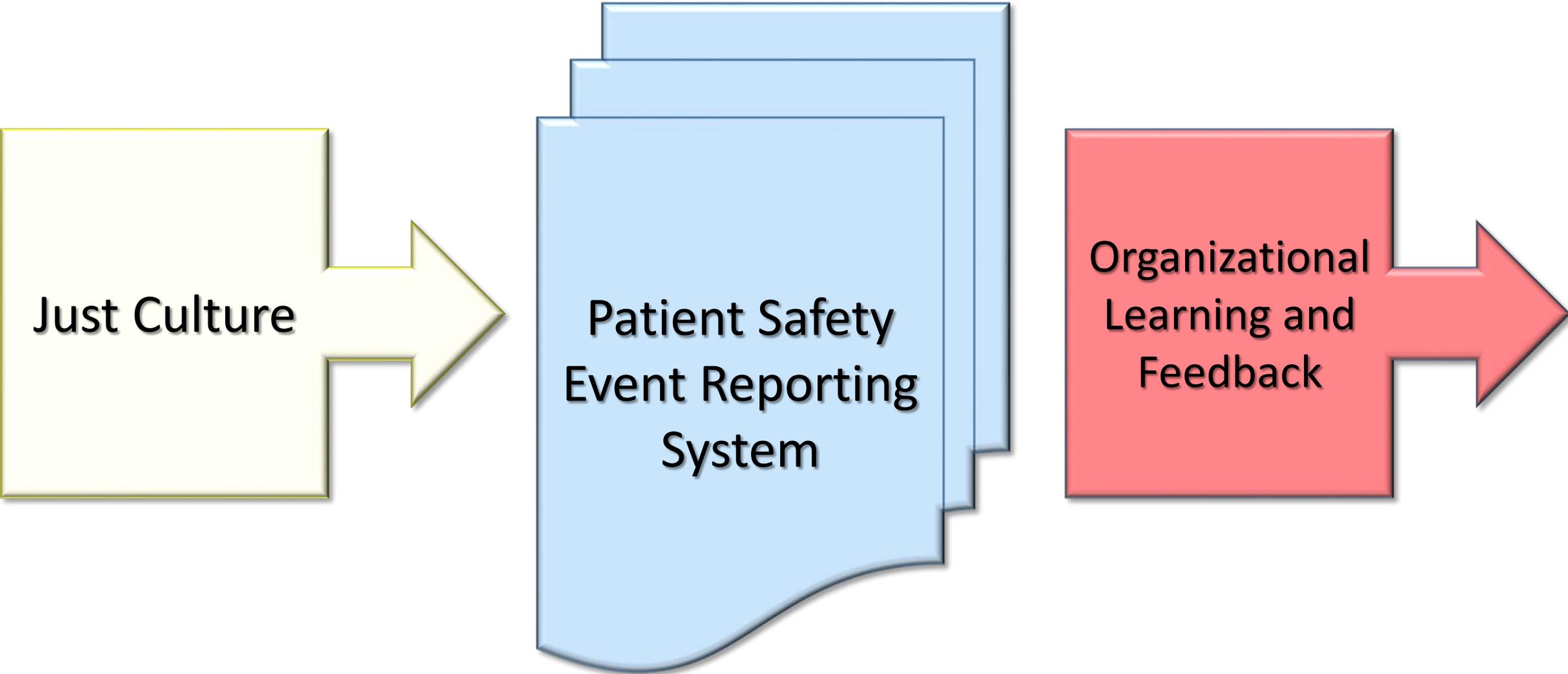
- Leaking tiles
- Room temperature
- Use of security cameras in pediatric areas
- Handicap accessibility of NIH hotel shuttles
- Pedestrian safety

Other

- Policies related to specimen transport
- Lag time in electronic health record changes
- Co-worker “etiquette”

Patient Safety Event Reporting

Patient Safety Event Reporting Framework



Existing Occurrence Reporting System

- “Custom-built” web-based system since mid 1980’s
- 4000 reports submitted per year
 - Errors
 - Near misses
 - Process issues
 - Kudos
- Exceedingly limited data analytics capacity
- Data analytics and reporting is time consuming and limited

Future State?

What does the ideal state look like?

What are the significant challenges to use/success?

What are the significant drivers to use/success?

Discussion

Occupational Illness and Injury

Michele Evans, DrPH

Environmental Safety Officer, NIH Clinical Center

James Schmitt, MD

Medical Director, Occupational Medical Service, NIH Division of Safety

NIH Occupation Medicine Service (OMS)

- Occupational exposures to blood and body fluids and management of post-exposure prophylaxis for blood-borne pathogens
- Emergency services
- Routine occupational health issues
- Health education and promotion
- Preplacement examinations
- Management of occupational injuries
- Workers' compensation filing
- Return to work/"fitness for duty" exams
- Immunization, physical therapy, acupuncture
- Fit testing for respirators
- Targeted medical surveillance program



OSHA Criteria For **Recordable** Occupational Illness or Injury

- An occupational illness or injury is recordable if it results in:
 - death,
 - days away from work,
 - restricted work or transfer to another job,
 - medical treatment beyond first aid, or
 - loss of consciousness.

Also, an employer must consider a case to meet the general recording criteria if it involves a significant injury or illness diagnosed by a licensed health professional, even if it does not result in any of the above events.

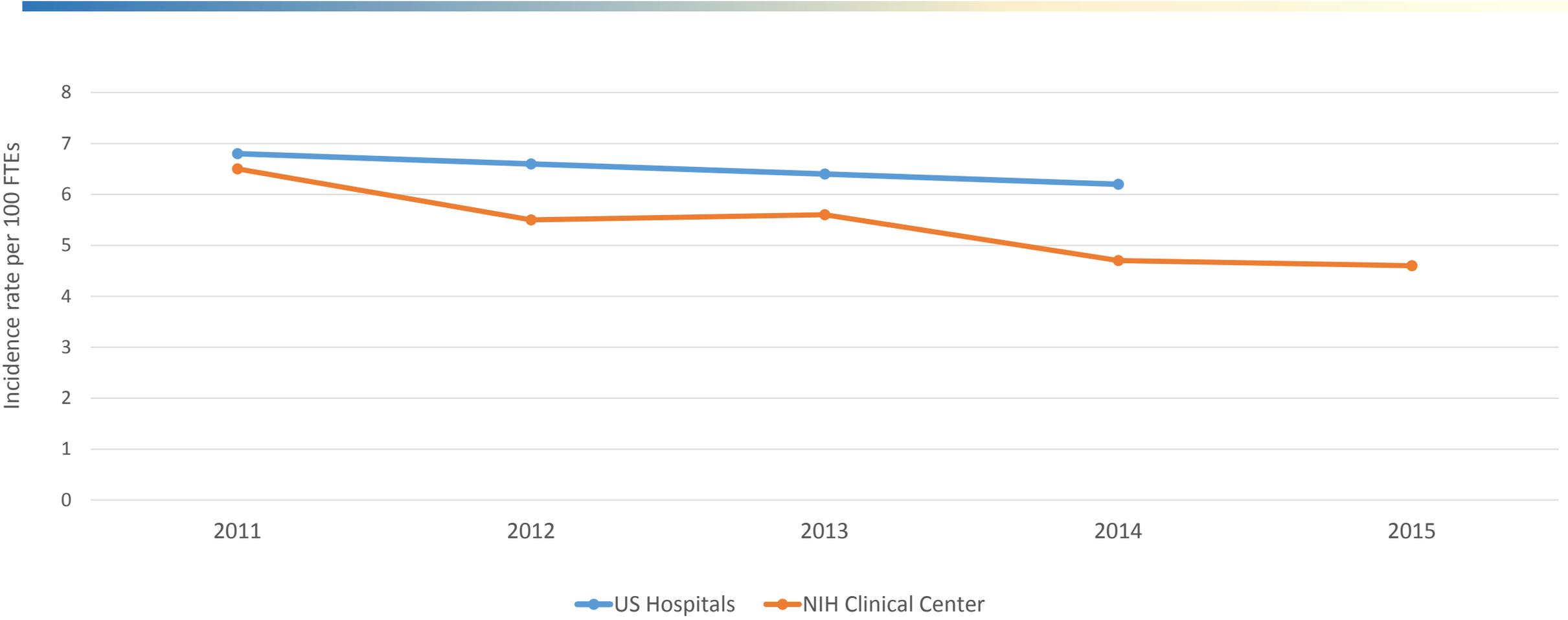
OSHA Reportable Occupational Illness or Injury?

As of January 1, 2015, all employers must report:

- All work-related fatalities within 8 hours.
- All work-related inpatient hospitalizations, all amputations and all losses of an eye within 24 hours.

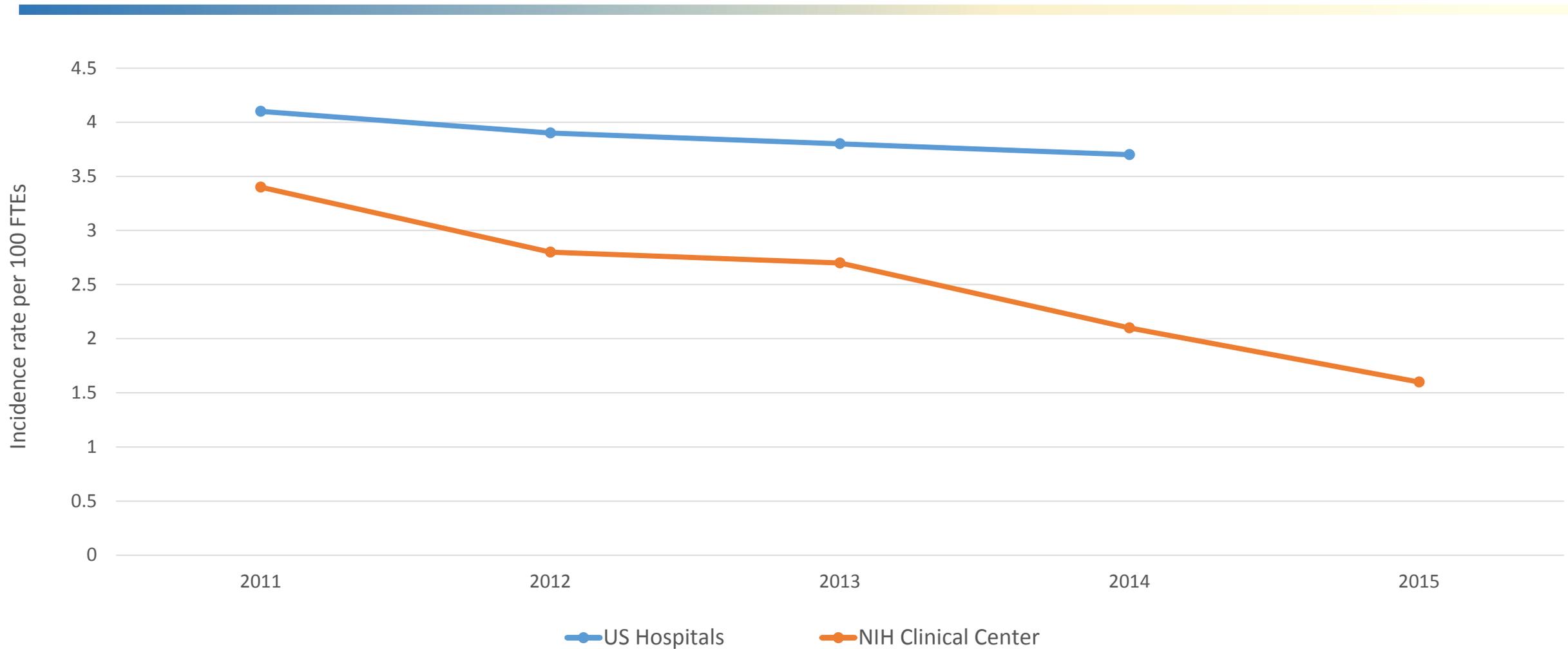
Comparison of the NIH CC's Recordable Nonfatal Occupational Injuries and Illnesses To U.S. Hospitals

(North American Industry Classification System, 622- as reported by Bureau of Labor Statistics)



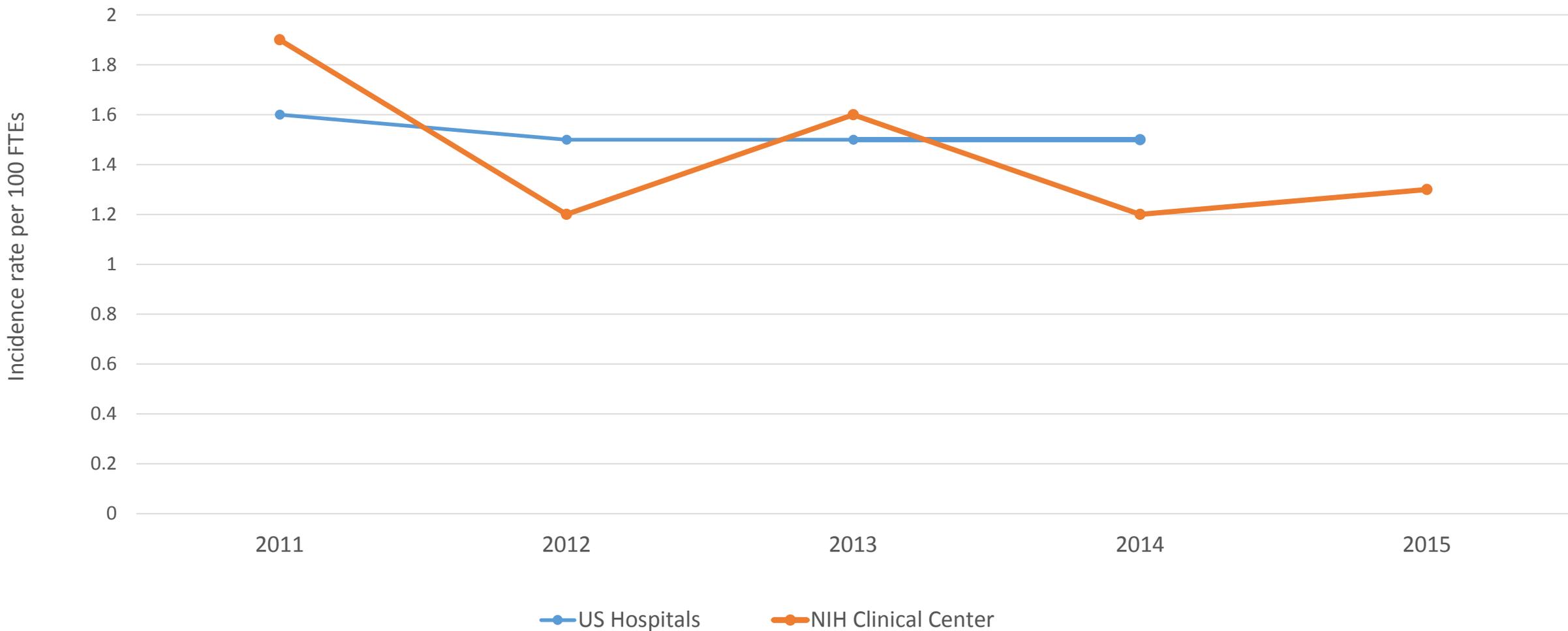
Since 2011, the total number of recordable OI in the NIH CC fell by 31.4% compared to a decline of 8.8% for hospitals nationwide.

Comparison of Other Recordable Case (ORC) Incidence for the NIH CC to that of U.S. Hospitals

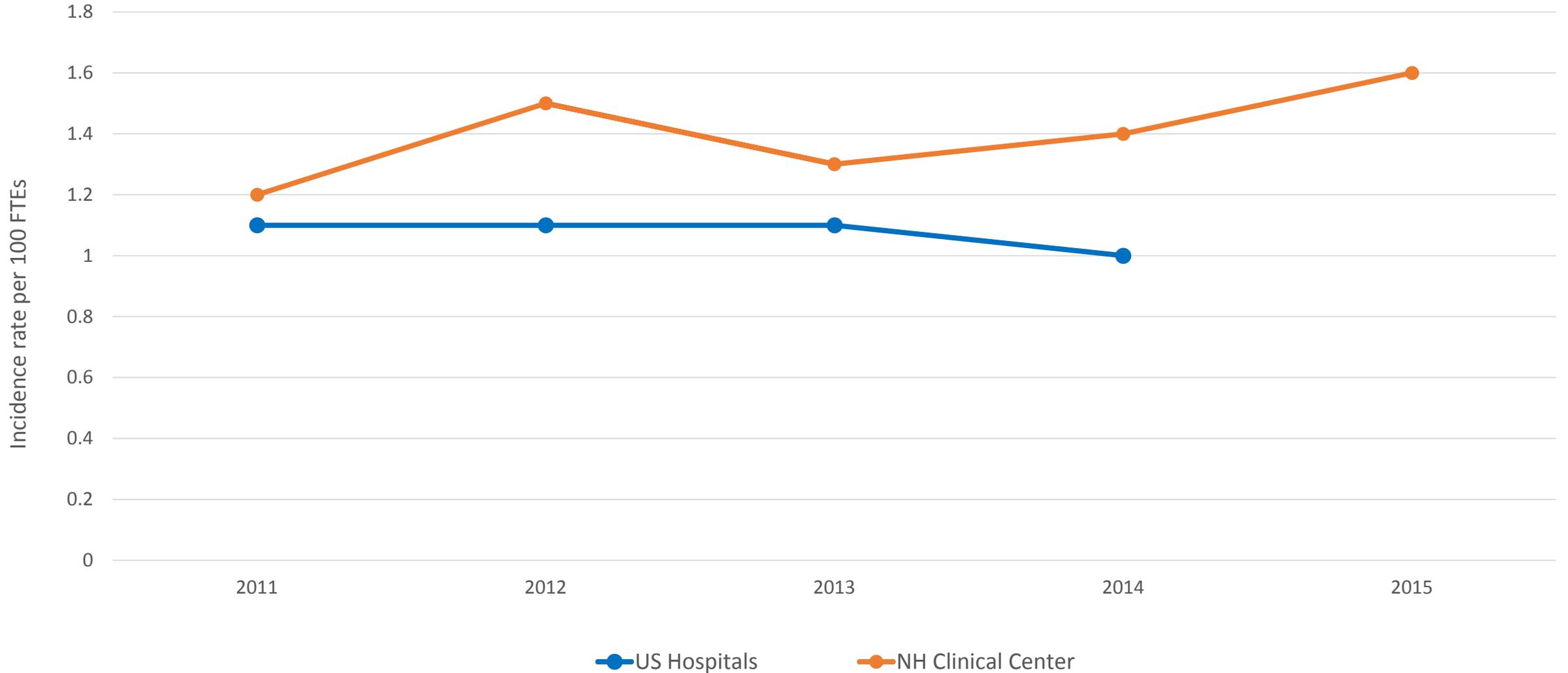


The dramatic reduction in TRC at the NIH CC is attributed to a significant drop in the number of OI that required more than first aid but did not require significant accommodations or lost time, i.e., ORC.

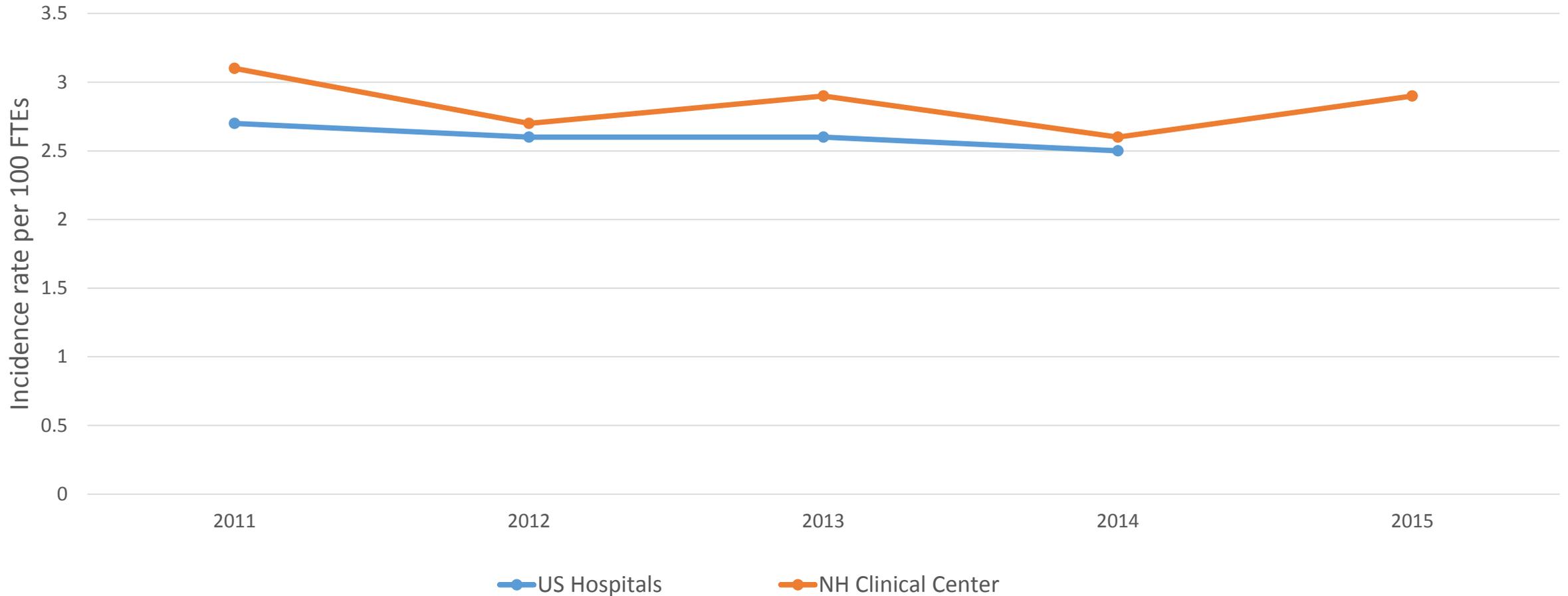
Comparison of the NIH CC's Days Away From Work (DAFW) incidence to that of U.S. Hospitals



Comparison of the NIH CC's Days of Job Transfer or Restriction (DJTR) incidence to that of U.S. Hospitals

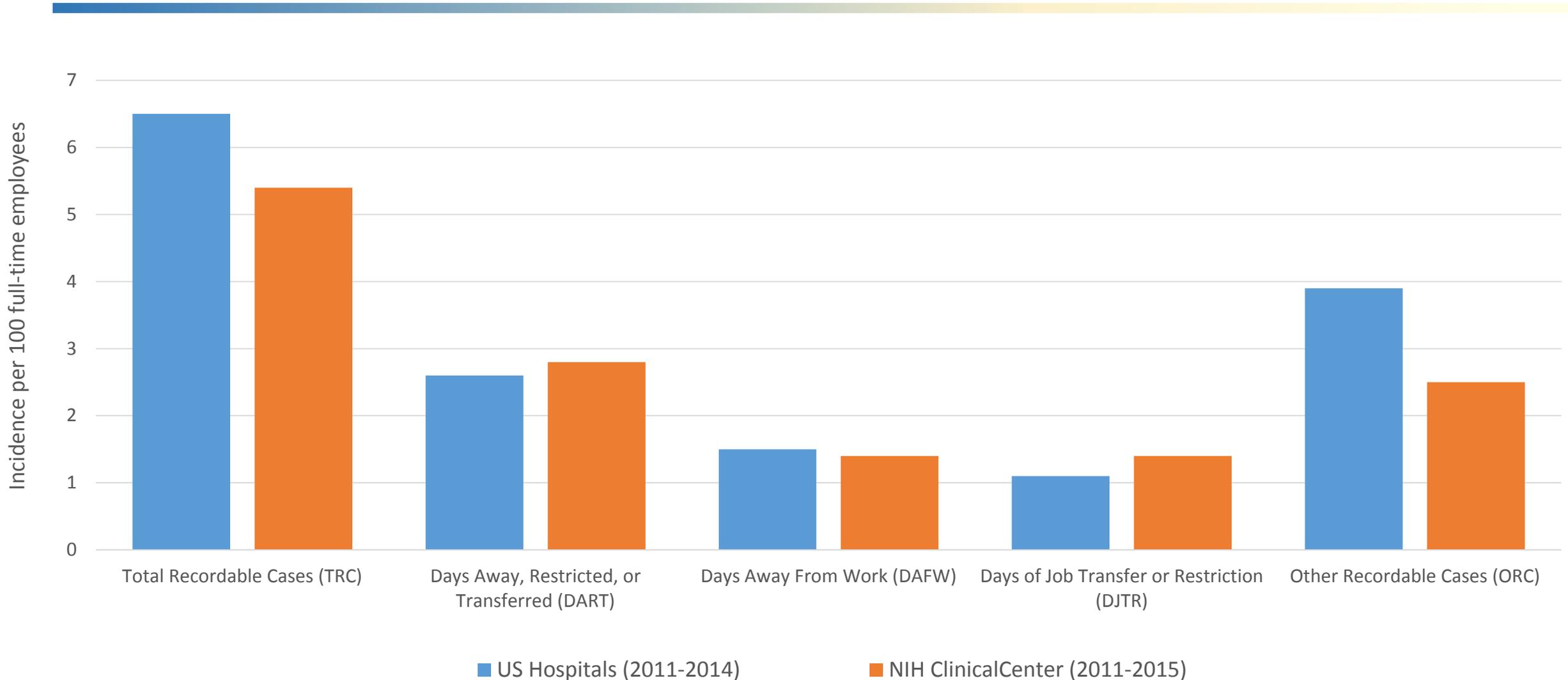


Comparison of the NIH CC's Days Away, Restricted or Transfer (DART) incidence to that of U.S. Hospitals



Nationally, the incidence of DART cases in hospitals averaged 2.6 cases per 100 FTE/year. The NIH CC's DART incidence was 2.8 cases per 100 FTE/year with a range of 3.1 to 2.6.

Comparison of Incidence of Nonfatal Occupational Illness and Injuries



The NIHCC averaged 5.4 Total Recordable Cases per 100 FTE/year over the past five years.

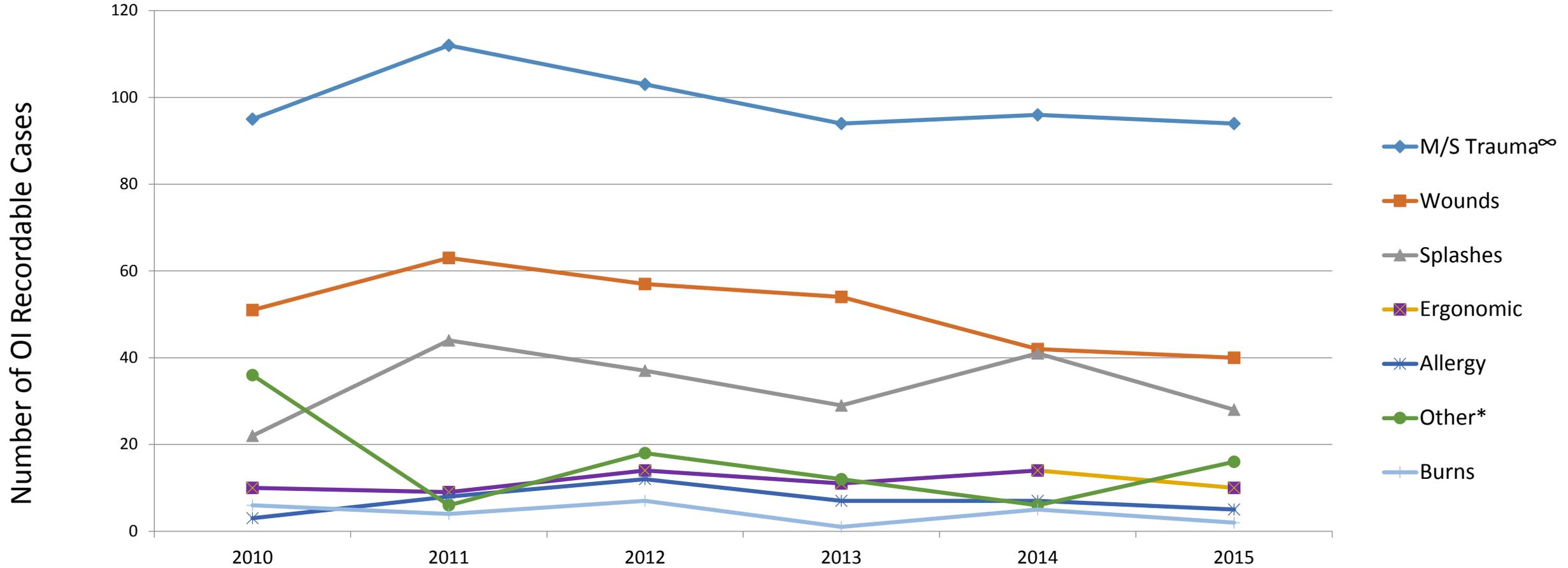
The national average for hospitals was 6.4 per 100 FTE/year.

Caveats and Summary

- Total Recordable Case (TRC) incidence for the CC declined by 31.4% from 2011 to 2015.
- This reduction resulted from a significant drop in ‘Other Recordable Cases’
 - Our ORC incidence was 2.5 cases per 100 FTE/year versus the national average of 3.9 cases per 100 FTE/year.
- No work-related fatalities occurred at the CC in decades. Nationwide, approximately 25 fatalities occur among health care personnel in hospitals.

How Do We Use These Data to Reduce Occupational Illness and Injuries (OI) in the Hospital?

Comparison of the number and types of all OI reported by CC employees (2010 – 2015)

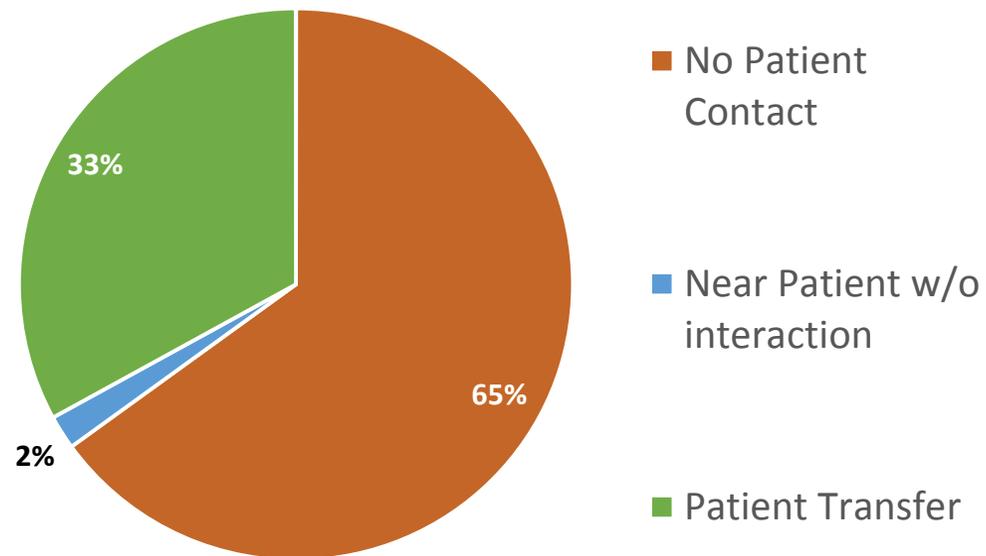


[∞] M/S Trauma: Musculoskeletal Trauma

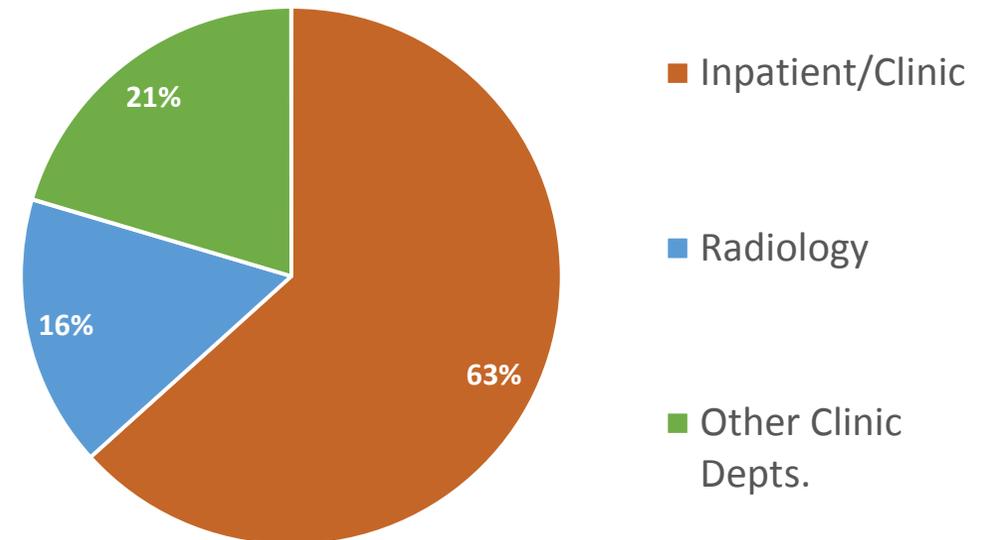
* Other cases includes inhalation, infectious exposures, and mental health concerns

Musculoskeletal Trauma Events In Clinical Areas in 2015 (N=49)

Activity at Time of Event



Location at Time of Event



Musculoskeletal Trauma

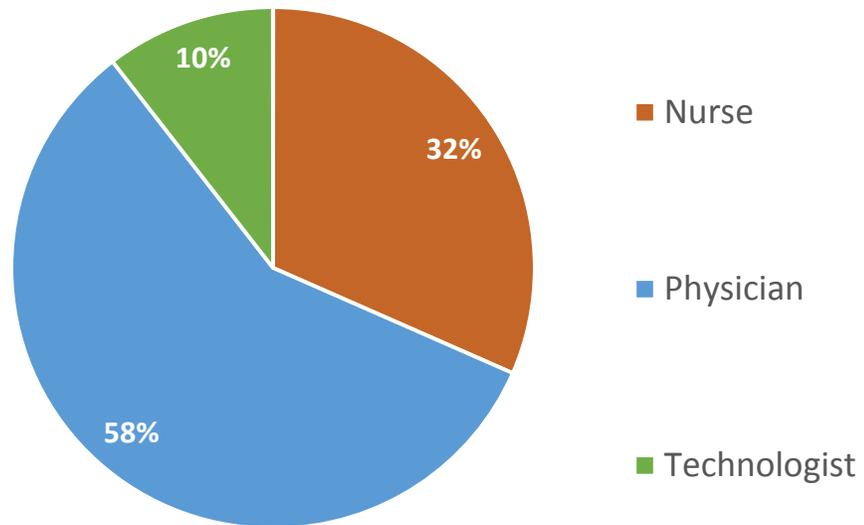
Examples of Interventions and Control Measures

- Individualized consultations with an occupational therapist
- Improvements to the Grounds and Walkways
- Availability and use of powered and manual lifts and transfer devices for patients
- Standards of practice to safely manage patients at risk of falls
- Orientation and retraining on ergonomically safe techniques and practices
- Specially designed devices to reduce repetitive motion disorders
- Workplace assessments for ergonomic friendly furnishings

Human Blood & Body Fluid Wounds Among Health Care Personnel in 2015

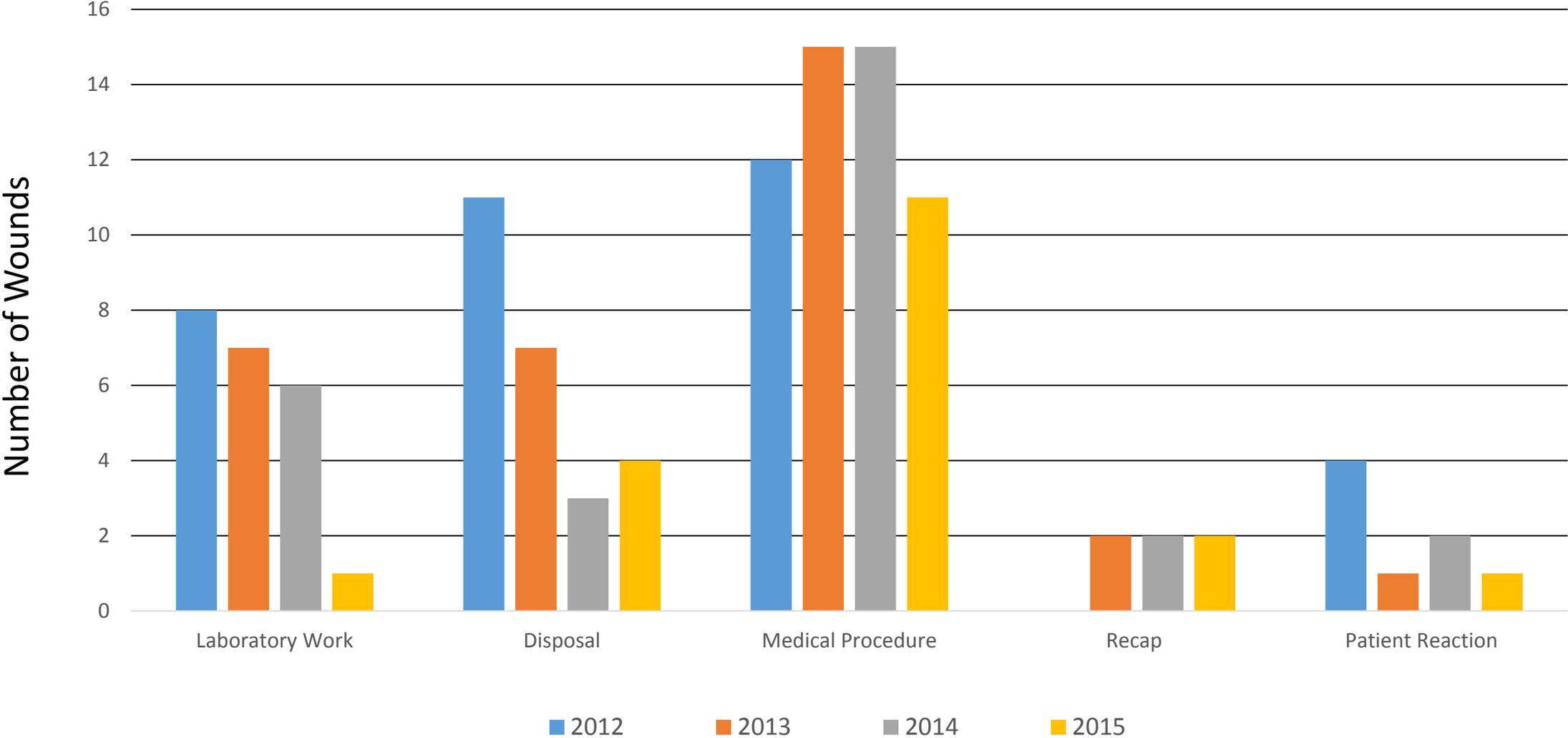
N=19

Job Titles

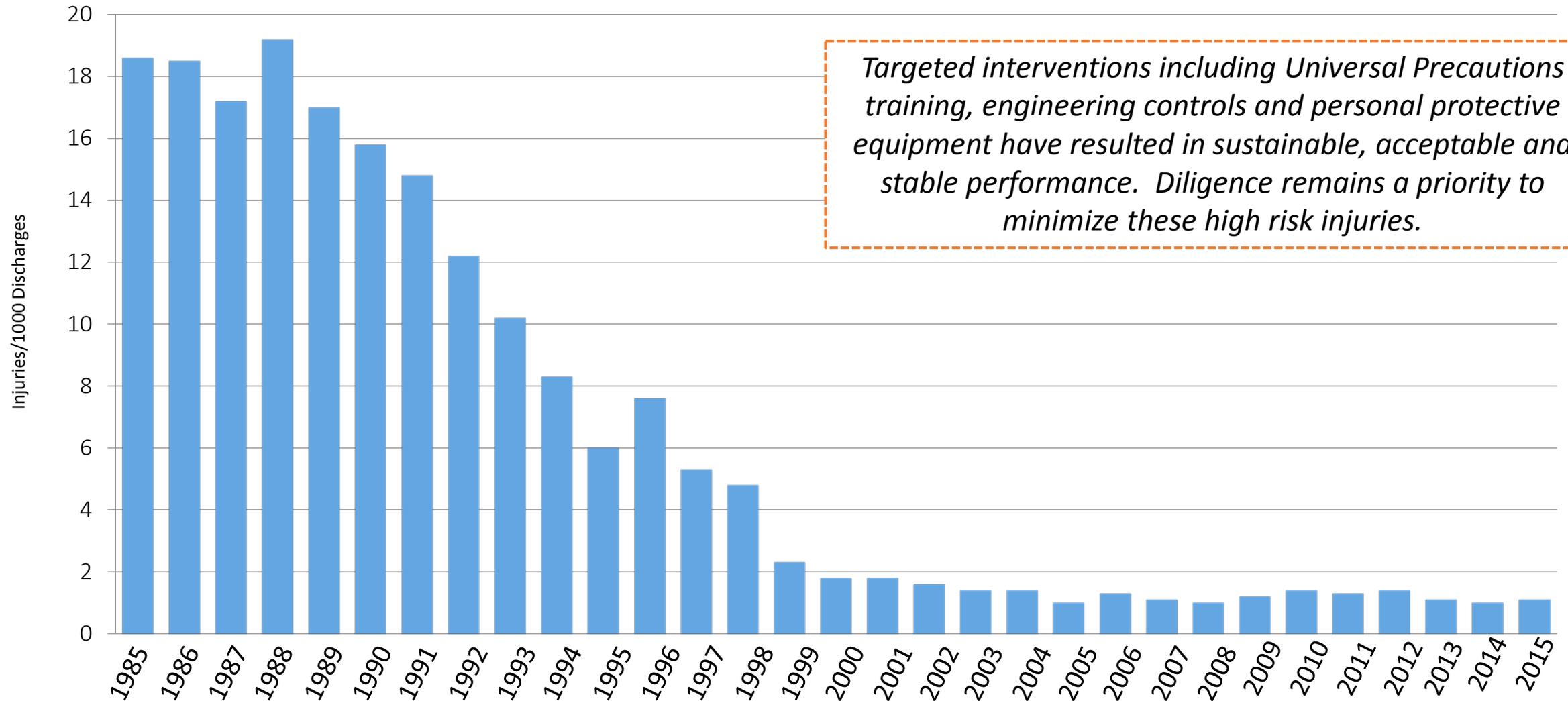


- Includes all HBBF in the hospital regardless of IC affiliation.
- Majority (13) classified as mild risk with remaining (6) as moderate risk. No high risk exposures.
- Factors associated with wounds reported by physicians discussed with the Medical Executive Committee & the Hospital Epidemiologist.
- Two injuries involved recapping a needle during medical procedure.

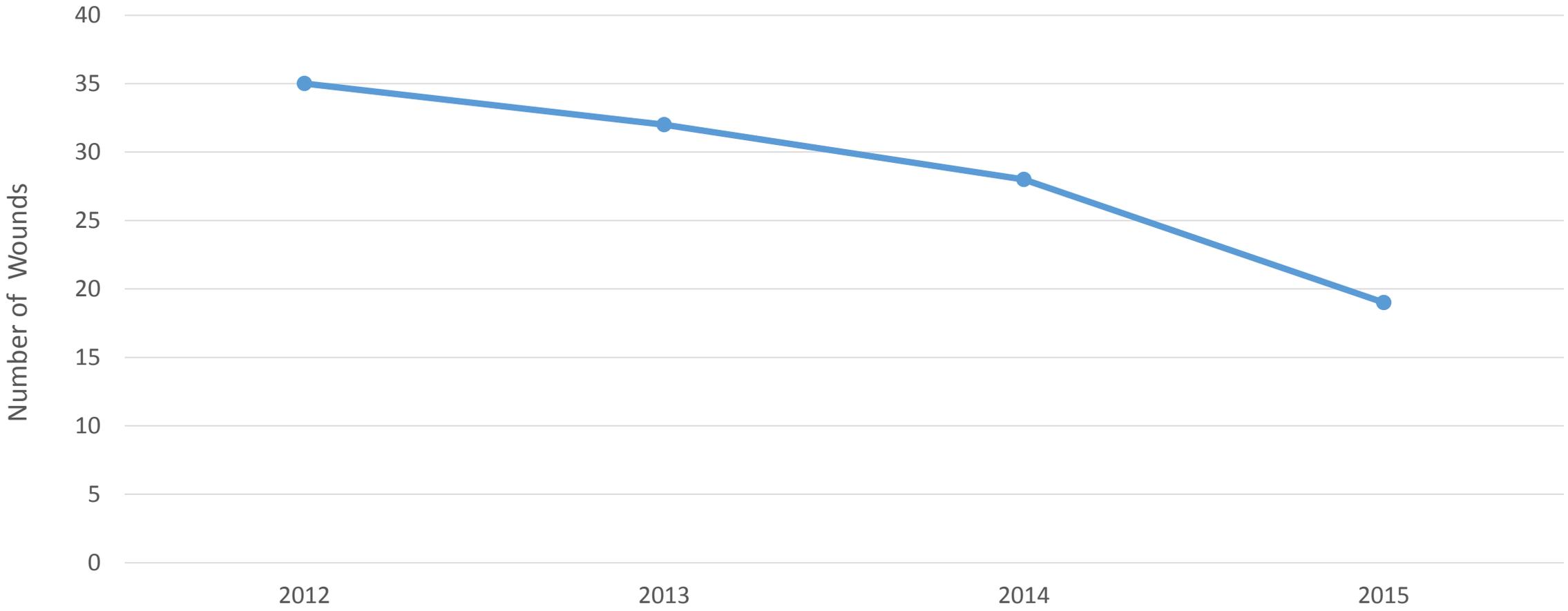
Factors associated with HBBF wounds reported in 2012-2015



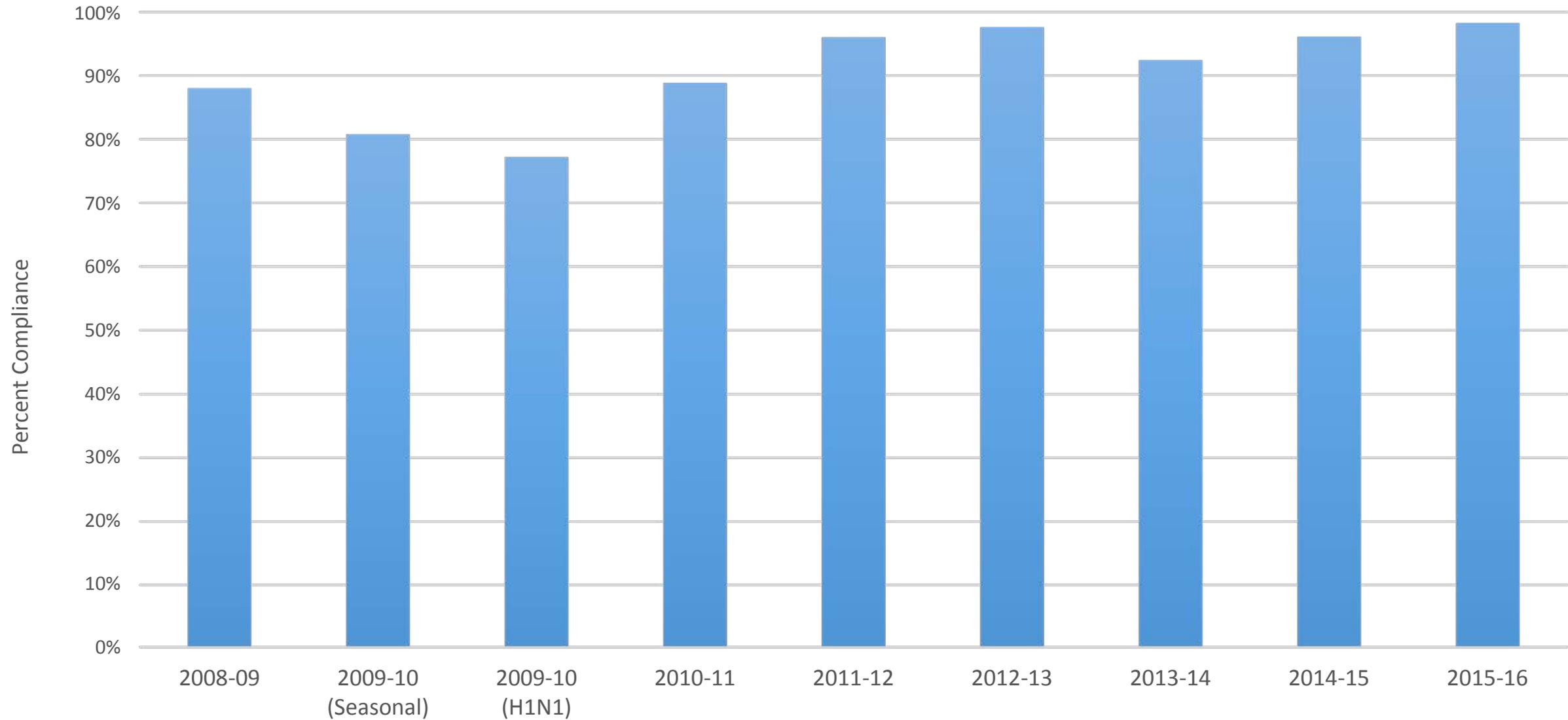
Parenteral Injuries per 1000 Discharges: 1985-2014



Human Blood & Body Fluid Wounds Reported by Health Care Personnel 2012-2015



Influenza Immunization Rates Among Staff with Patient Contact



Discussion
