Adverse Events in Hospitals: How Many and Why Not Reported

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Disclosure

- Currently full time employed at BD

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- Previously full time employee at IHI from 2002-2010

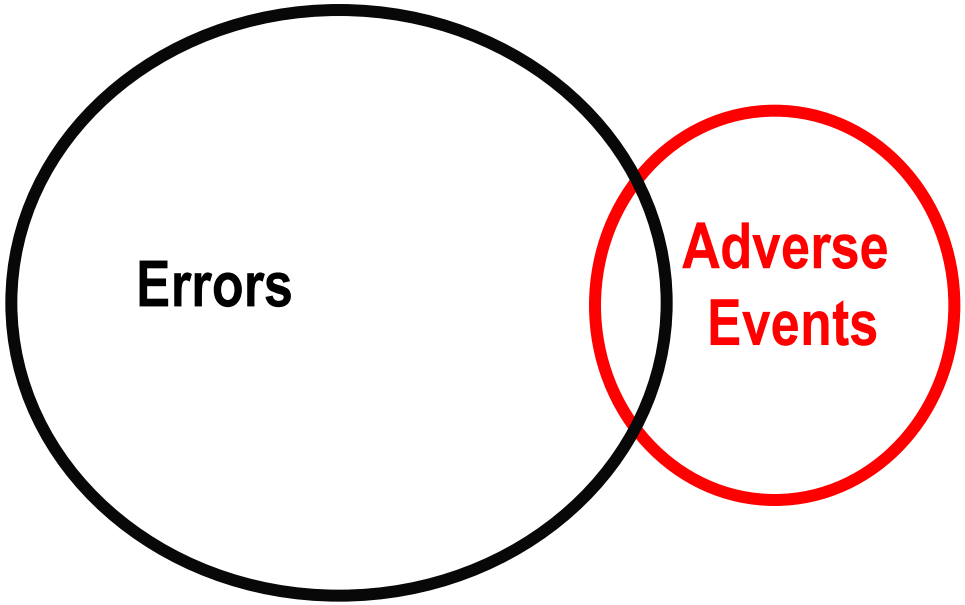
What is harm?

- Merriam Webster
  - physical or mental damage
- The Free Dictionary
  - physical or mental injury or damage
- Institute for Healthcare Improvement
  - unintended physical injury resulting from or contributed to by medical care that requires additional monitoring, treatment or hospitalization, or that results in death*

*Griffin FA, Resar RK. *IHI Global Trigger Tool for Measuring Adverse Events*. IHI Innovation Series white paper. Cambridge, Massachusetts: Institute for Healthcare Improvement; 2009.
(Available on www.IHI.org)

Error vs. Adverse Event (or harm)

- "Error": *process-focus*, preventability
- "Adverse event": *outcome focus*, harm experienced by patient

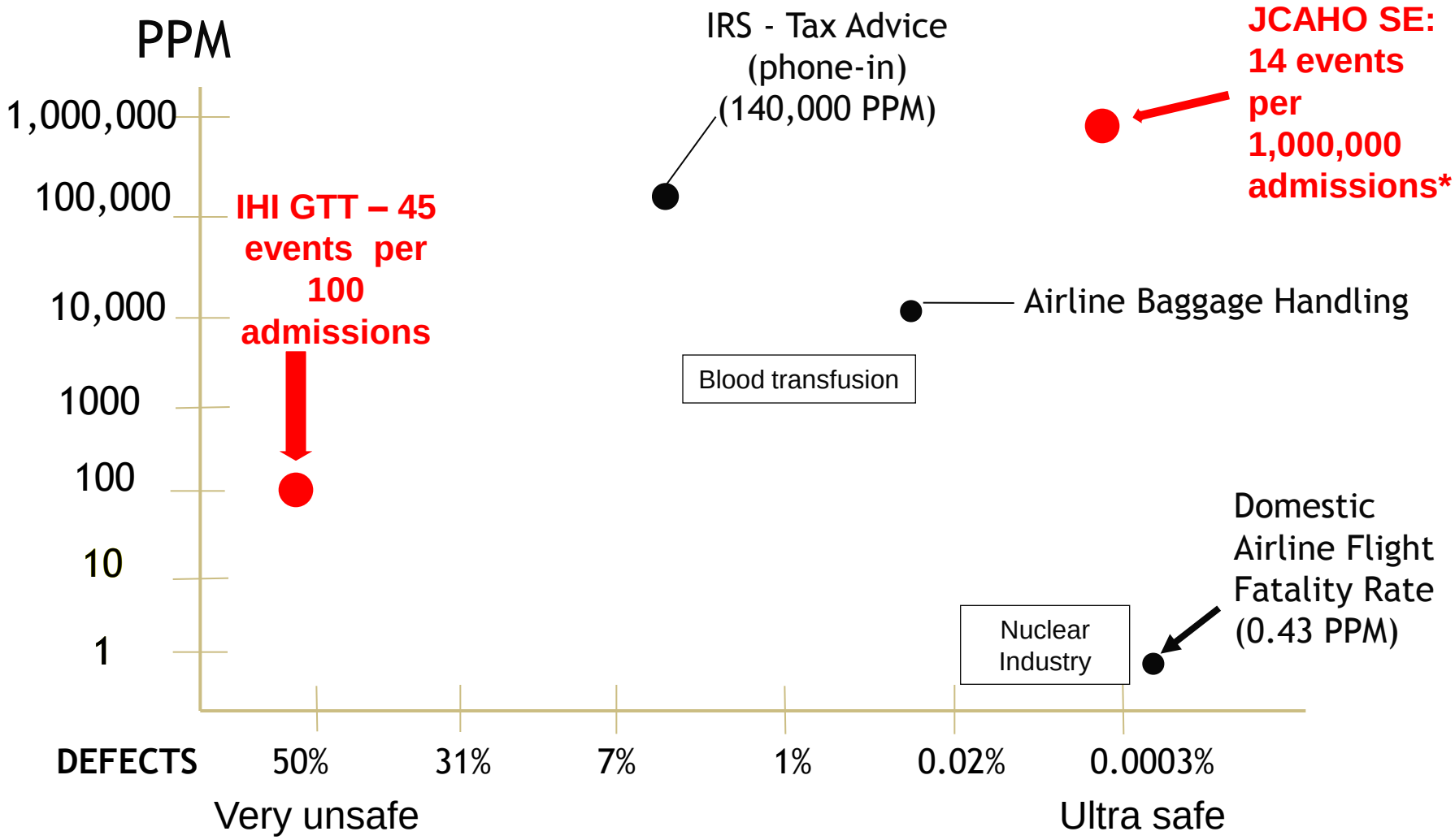


Measuring Harm

- Traditional Measurement Approaches
  - Voluntary reports
  - Safety indicators based on billing codes (AHRQ)
  - Complications
  - Morbidity & Mortality Reviews

How safe are we?

Comparison Between Industries



REFERENCE: René Amalberti

*JCAHO sentinel events statistics 2006
AHA : hospital admissions, 2006 survey

Institute for Healthcare Improvement (IHI) Trigger Tools

- Retrospective review of closed patient records
- Check for “triggers” or clues to harm
  - Examples: transfusions, Benadryl, Narcan
- Count all unintended consequences of medical care
- Focus on events of comission – not omission
- Faster than “reading” records
- Uses sampling for measure over time

Process

- Random selection of records
- Review using trigger tool process
  by 2 independent mid-level reviewers
  (clinical, non-physician)
- Consensus reviewed by physician
- Determine harm from patient's viewpoint without regard for preventability

  FOCUS: unintended
- Assign level of harm to each individual event

Categories of Harm
(adapted from NCC MERP Index)

E - Temporary harm, intervention required

F - Temporary harm, initial or prolonged hospitalization

G - Permanent patient harm

H - Life sustaining intervention required

I - Contributing to death

So…..

- How much harm?
- Are there differences in methods?

Multi-center ADE Data

- 2837 charts reviewed using trigger tool
- 86 institutions
- 720 ADE's found
- 268,796 medications doses administered
- ADE's/1000 doses = 2.67
- Admissions with ADE's = 24.9%

Rozich JD, Haraden CR, Resar RK The adverse drug event trigger tool: A practical methodology for measuring medication-related harm. Journal Quality and Safety in Health Care June 2003

ICU Trigger Tool Data

1294 patient records reviewed

- 1450 events detected in 55% of patients
  - 28% > 1 event
  - 18% medication related
  - 11% in E-codes
- LOS
  - 8.9 days with events
  - 4.3 day without events

Resar RK, Rozich JD, Classen D Methodology and rationale for the measurement of harm with trigger tools. Quality and Safety in Health Care. Vol 12. December 2003

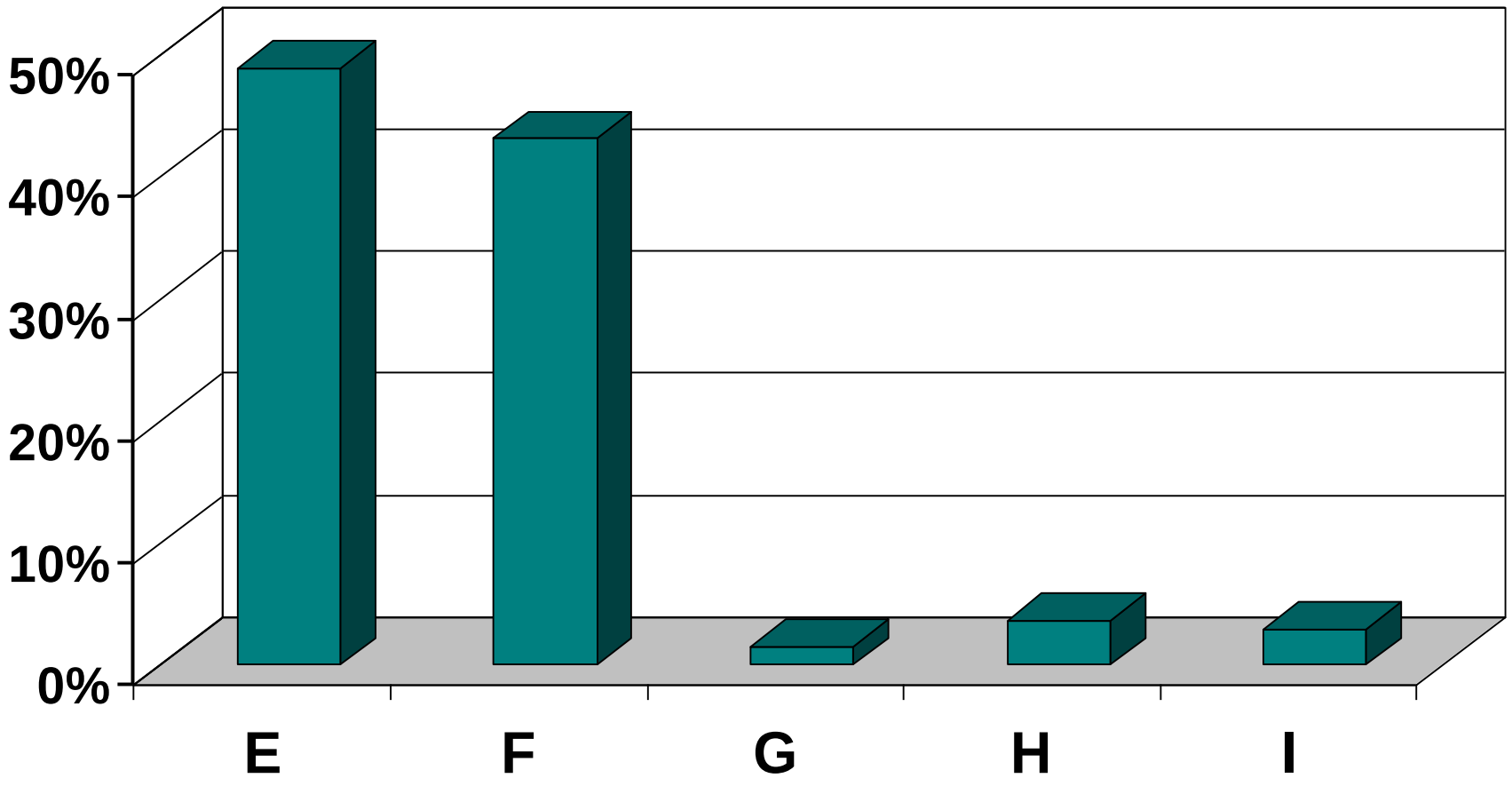
Surgical Trigger Tool
Data from IHI Collaborative

- 11 hospitals
  - Time period – over 1 year
  - Data submitted – 1-8 months (avg 4)
  - 854 charts reviewed

- 139 Adverse Events in 125 Patients
  - 14.6% of patients
  - 8% of events were G, H or I

Griffin FA, Classen DC. Detection of adverse events in surgical patients using the Trigger Tool approach. Qual. Saf. Health Care 2008 17: 253-258.

Perioperative Adverse Events:
Harm Categories



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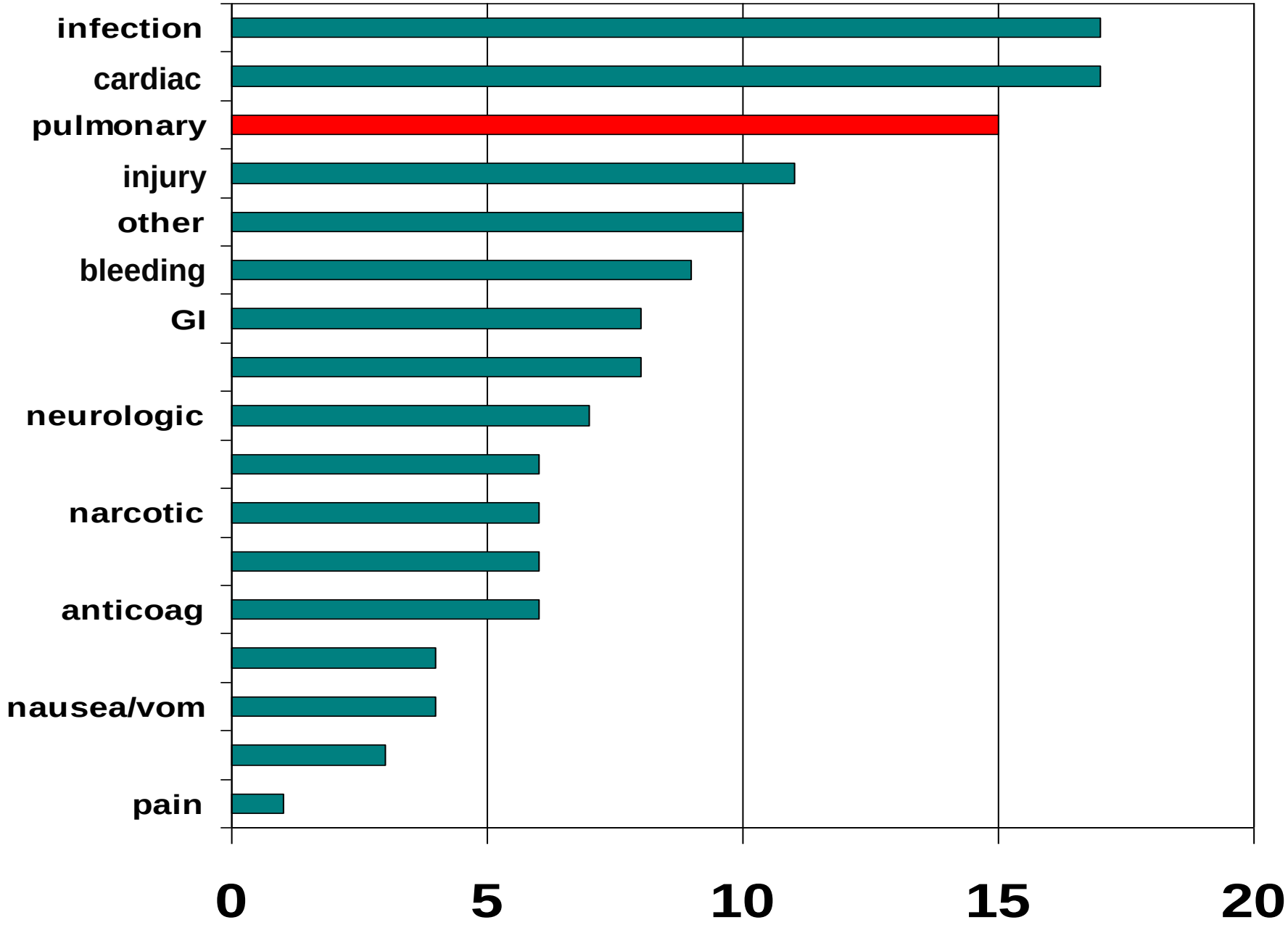

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Global Trigger Tool

- Extension from the topic & location focused trigger tools
- Uses multiple modules of triggers
  - Cares
  - Critical Care
  - Medication
  - Surgery
  - L&D
- Gathers events from the whole hospital
- Establishes a global harm measure for hospital
- Resource friendly - no dependency on high tech

Considerations

- 75% of all events will be picked up by both reviewers
  (these are the G,H,I harm levels)

- 25% of events will be picked up by one or the other reviewer (most often are E and F levels)

- Definitions of harm become more standard with 2 reviewers

Inter-Rater Reliability

- 4 primary reviewers + 2 physicians
- Structured process
  - 15 training records with 22 adverse events
  - 50 testing records with 49 adverse events
- Reliability measured

Classen DC, Lloyd RC, Provost L, Griffin FA, Resar RK. *Development and Evaluation of the Institute for Healthcare Improvement Global Trigger Tool*. J Patient Saf 2008; 4:169-177.

Process

1. All reviewers read GTT White Paper
2. Physicians thoroughly reviewed 15 records
3. Primary reviewers: independent GTT reviews with 20 minute limit
4. Discussion & consensus
5. 2 hour training session
6. All reviewers completed GTT review of 50 records

Development and Evaluation of the Institute for Healthcare Improvement Global Trigger Tool

David C. Classen, MD, MS, Robert C. Lloyd, PhD,† Lloyd Provost, PhD,†*
Frances A. Griffin, RRT, MPA,† and Roger Resar, MD†

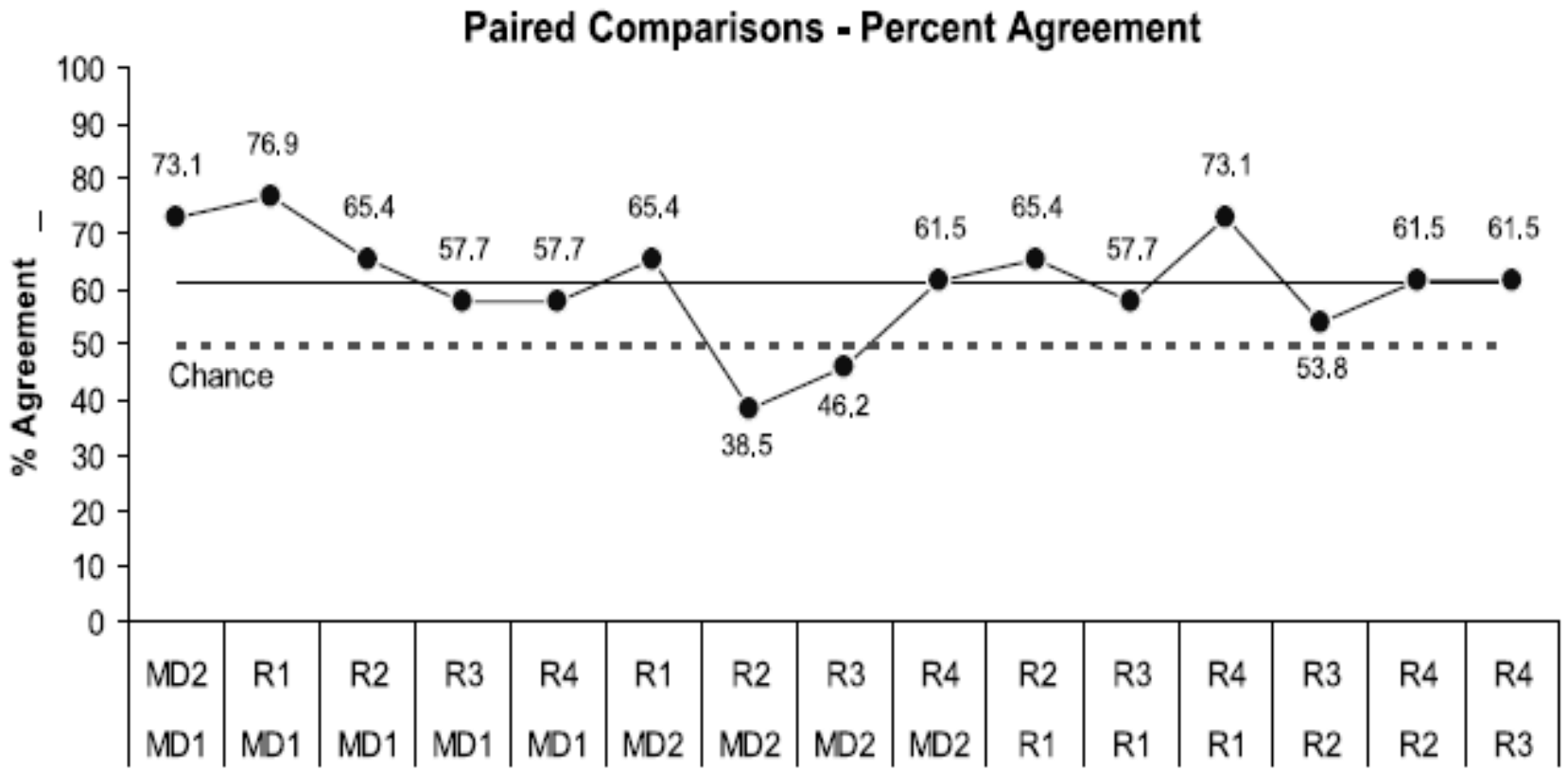


FIGURE 3. Percent agreement for reviewer paired comparisons using the 15 training records.

Classen DC, Lloyd RC, Provost L, Griffin FA, Resar RK. *Development and Evaluation of the Institute for Healthcare Improvement Global Trigger Tool*. J Patient Saf 2008; 4:169-177.

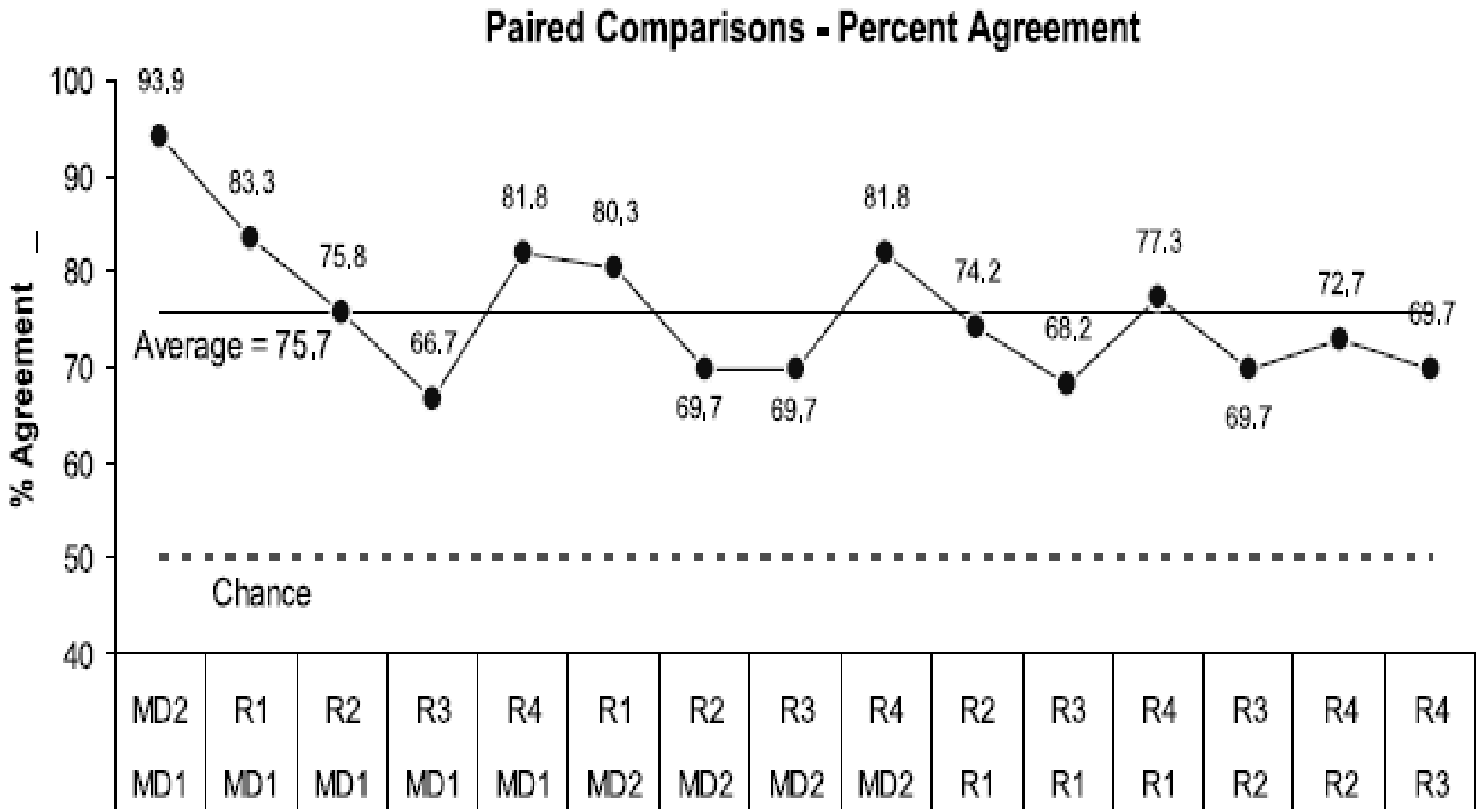


FIGURE 5. Percent agreement for reviewer paired comparisons using the 50 testing records.

Classen DC, Lloyd RC, Provost L, Griffin FA, Resar RK. *Development and Evaluation of the Institute for Healthcare Improvement Global Trigger Tool*. J Patient Saf 2008; 4:169-177.

Results & Conclusions

- High level inter-relater reliability can be achieved
  - Improved from training to testing phase
- Agreement increased with severity of events
- Greatest disagreement: category E events
- Process can be replicated

Classen DC, Lloyd RC, Provost L, Griffin FA, Resar RK. *Development and Evaluation of the Institute for Healthcare Improvement Global Trigger Tool*. J Patient Saf 2008; 4:169-177.

ERRORS & ADVERSE EVENTS

By David C. Classen, Roger Resar, Frances Griffin, Frank Federico, Terri Frankel, Nancy Kimmel, John C. Whittington, Allan Frankel, Andrew Seger, and Brent C. James

'Global Trigger Tool' Shows That Adverse Events In Hospitals May Be Ten Times Greater Than Previously Measured

Classen DC, Resar R, Griffin F, et al. *Global Trigger Tool shows that adverse events in hospitals may be ten times greater than previously measured.* Health Affairs. 2011 Apr;30(4):581-589.

Amount of Harm

- 3 tertiary care hospitals in US
- 795 records from Oct 2003 reviewed

- 393 adverse events total
  - 33% of admissions
  - 49 / 100 admissions
  - 91 adverse events / 1000 patient days

Classen DC, Resar R, Griffin F, et al. *Global Trigger Tool shows that adverse events in hospitals may be ten times greater than previously measured.* Health Affairs. 2011 Apr;30(4):581-589.

EXHIBIT 4

Adverse Event Detection, By Severity Level And Hospital

	IHI Global Trigger Tool	AHRQ Patient Safety Indicators	Hospital voluntary reporting system
SEVERITY LEVEL			
E	204	23	0
F	124	7	2
G	8	1	2
H	14	0	0
I	4	4	0
Total	354	35	4
HOSPITAL			
Hospital A	161	13	0
Hospital B	92	13	3
Hospital C	101	9	1
Total	354	35	4

Classen DC, Resar R, Griffin F, et al. *Global Trigger Tool shows that adverse events in hospitals may be ten times greater than previously measured.* Health Affairs. 2011 Apr;30(4):581-589.

US Government Study

ADVERSE EVENTS IN HOSPITALS: CASE STUDY OF INCIDENCE AMONG MEDICARE BENEFICIARIES IN TWO SELECTED COUNTIES

Daniel R. Levinson
Inspector General

December 2008
OEI-06-08-00220

OIG Study of Medicare Beneficiaries

- 780 patient records from October 2008

- 13.5% with adverse events
- 13.5% with temporary harm

28% with adverse event

- 44% preventable
- $234 million excess cost

Are we improving in the US?

The NEW ENGLAND JOURNAL of MEDICINE

SPECIAL ARTICLE

Temporal Trends in Rates of Patient Harm Resulting from Medical Care

Christopher P. Landrigan, M.D., M.P.H., Gareth J. Parry, Ph.D.,
Catherine B. Bones, M.S.W., Andrew D. Hackbarth, M.Phil.,
Donald A. Goldmann, M.D., and Paul J. Sharek, M.D., M.P.H.

Landrigan CP, Parry GJ, Bones CB, Hackbarth AD, Goldmann DA, Sharek PJ. Temporal trends in rates of patient harm resulting from medical care. New England Journal of Medicine. 2010 Nov; 363(22):2124-2134.

North Carolina Harm Study

- 10 hospitals
- 2341 patient records from 5 year period

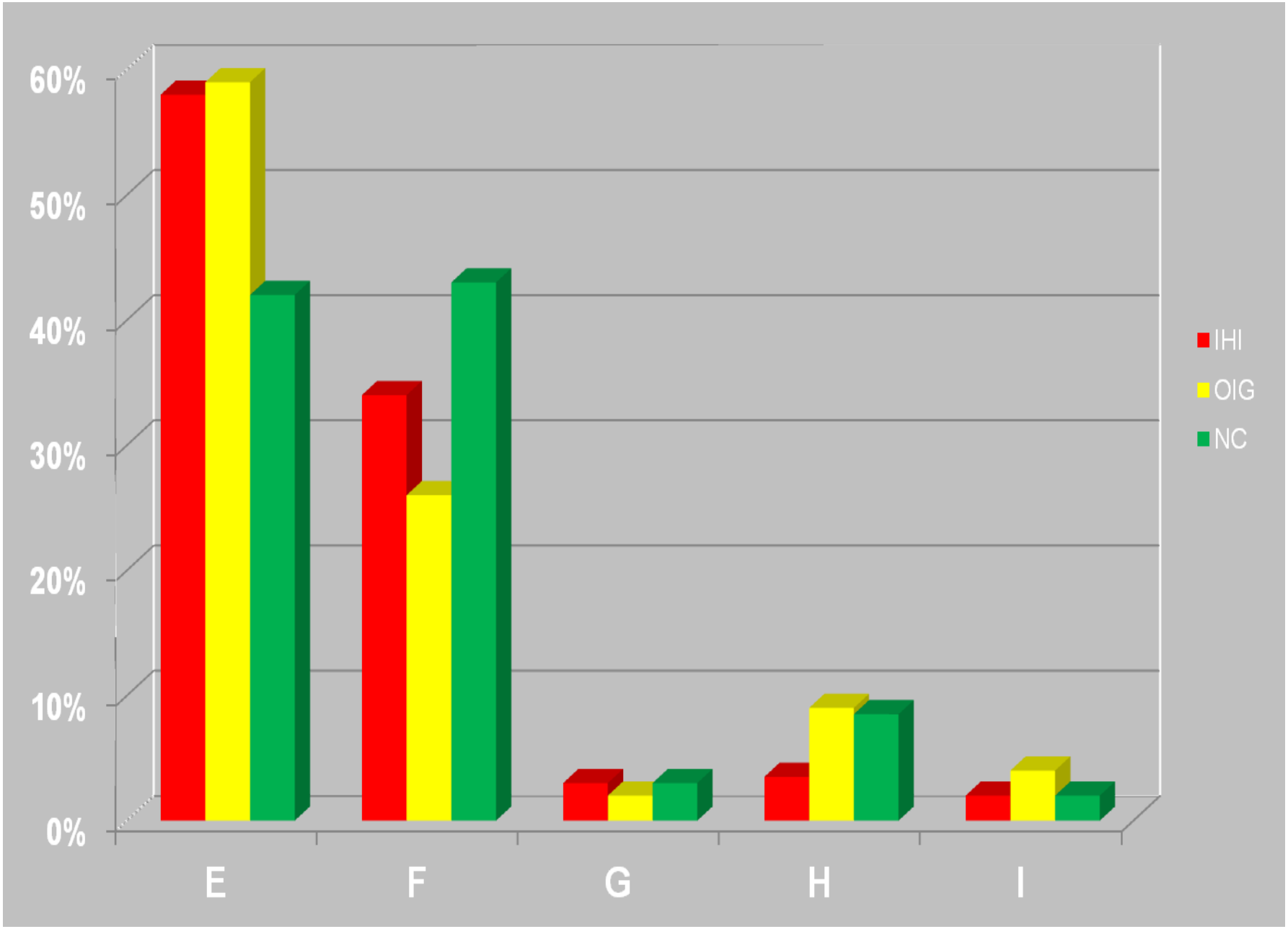
- 588 harms
  - 25 / 100 admissions

- Conclusions:
  - Harms remain common
  - Little evidence of improvement

Landrigan CP, Parry GJ, Bones CB, Hackbarth AD, Goldmann DA, Sharek PJ. Temporal trends in rates of patient harm resulting from medical care. New England Journal of Medicine. 2010 Nov; 363(22):2124-2134.

Results Across Studies

	IHI GTT	OIG	NC Harm
% Harm	33%	28%	18%
Per 100 admissions	49	36	25
Sample differences	• 795 patients • Ages 18+ • October 2003 • 3 Tertiary care hospitals – high case mix index	• 780 patients • Medicare only • October 2008 • Multiple hospitals & types (random sample of beneficiaries) • POA excluded	• 2341 patients • Ages 18+ • Jan 02 – Dec 07 • 10 hospitals, various types


60%
50%
40%
30%
20%
10%
0%
E
F
G
H
I
IHI
OIG
NC

Common Concerns & Limitations

- Lack of universal harm definition
- Subjectivity
- Preventability
- Resources
  - Collecting
  - Improving
  - Acting

Future Directions

- Elimination of Harm
  - CMS Partnership for Patients
- Value-based Purchasing
  - Score based on quality, improvement and outcome
- Conditions not Reimbursed