

Error and Near-Miss Reporting in Radiotherapy

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Outline

- **Introduction**
- **Reporting infrastructure**
- **Organizational culture**
- **Errors and near-misses**
- **Reporting systems**
- **Feedback mechanisms**
- **Lessons learned**

Errors in Radiation Therapy

- **Staff and public exposures**
- **Misadministrations**
 - Underdose
 - Overdose
 - Anatomical misses
- **Magnitude**
 - From few percent to lethal doses
 - From couple of millimeters to complete misses
- **Regulatory**
 - Nuclear Regulatory Commission
 - Errors that do not necessarily affect patients but have regulatory/legal consequences
- **Sources**
 - Staff
 - Software
 - Hardware
- **Random**
 - Affect one to few patients
- **Systematic**
 - Affect hundreds of patients
 - Potentially in a short period

Background Global Problem

- “...it calls into question the integrity of hospital systems and their ability to pick up errors and the capability to make sustainable changes.”

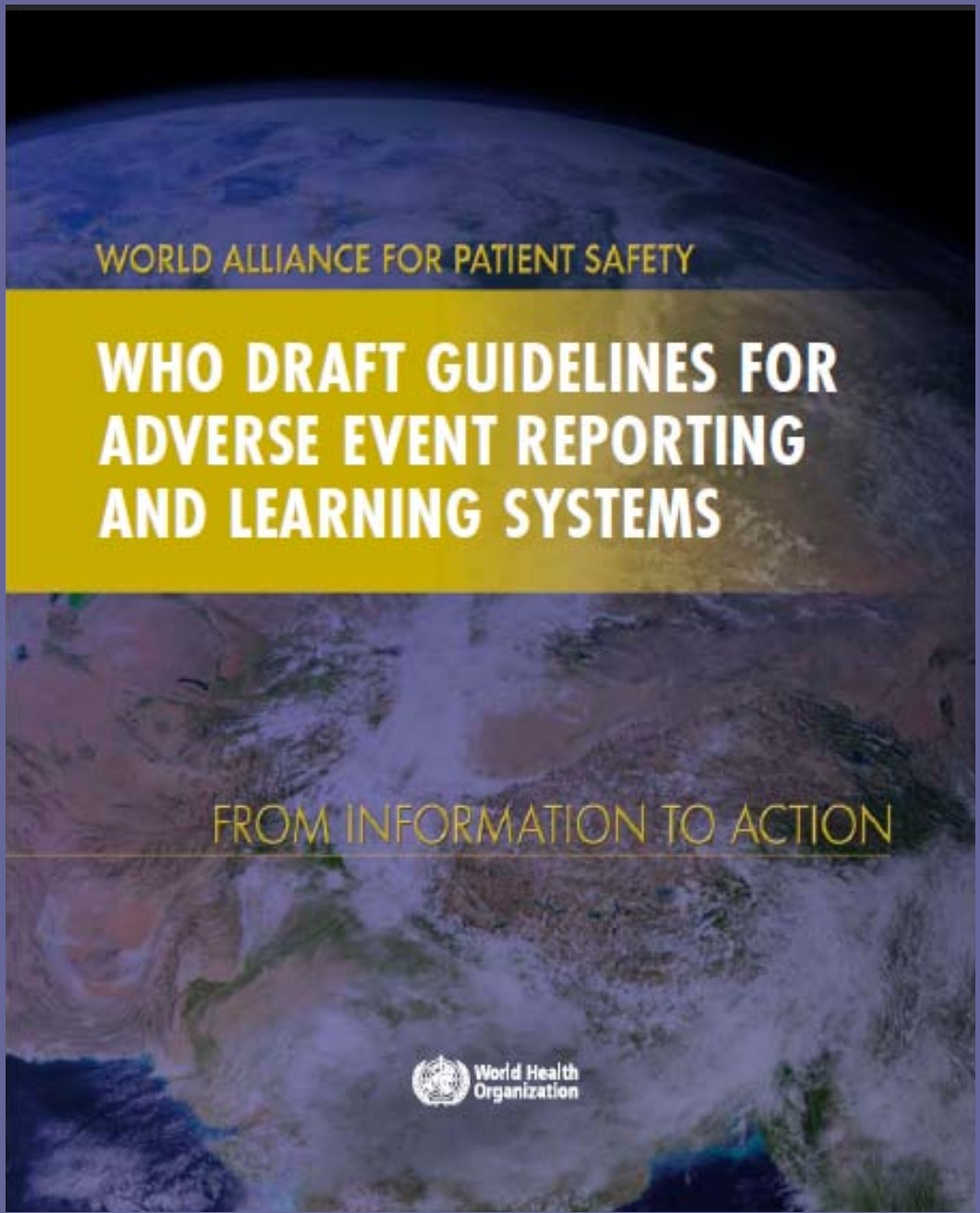
- Sir Liam Donaldson, Chief Medical Officer, Department of Health**



Towards Safer Radiotherapy. London: The Royal College of Radiologists, 2008.



Radiotherapy Risk Profile, Geneva: World Health Organization, 2009.



WORLD ALLIANCE FOR PATIENT SAFETY

WHO DRAFT GUIDELINES FOR ADVERSE EVENT REPORTING AND LEARNING SYSTEMS

FROM INFORMATION TO ACTION



 Washington
University in St. Louis
SCHOOL OF MEDICINE

 MIR Mallinckrodt Institute
of Radiology

Error Reporting

- **We are not airline industry nor nuclear power**
- **Perfection in complex systems across hundreds of diverse clinics is impossible**
- **Reporting systems for sake of reporting alone are a great way to squander resources and demoralize staff**
- **Error reporting as a part of broader process improvement efforts can be very valuable**

Event Reporting

- **Mandatory (statutory)**
 - Reporting required by law
 - NRC in U.S.
 - State requirements
 - Mainly concentrated on well defined *treatment delivery errors*
 - Guidelines for near-miss reporting typically not provided
- **Voluntary**
 - Mainly at institutional level
 - Some states in the U.S. have voluntary reporting systems – utility for radiation therapy not clear
 - Errors and near misses tracked

Voluntary Reporting Dependent on Many Factors

- **Culture**
- **Reporting guidelines**
- **Reporting system**
- **Competence to interpret reported data**
- **Willingness to implement, when necessary, significant changes based on collected data and subsequent analyses**
- **Ability to share the collected data and provide feedback**

Lessons Learned I

Naming a Voluntary Reporting System

- We often name our homegrown software by what it does
- Our brand new web-based system, back in 2007, was named “Process Improvement Logs”
- Our staff provided a nickname

“E-Snitch”

Organizational Culture

- ***“Shared values (what is important) and beliefs (how things work) that interact with an organization’s structures and control systems to produce behavioural norms (the way we do things around here).”*** *Uttal, B., Fortune. 17 October 1983.*
- **Safety culture**
 - Reporting culture
 - Just culture



Organizational Cultures

Pathological Culture	Bureaucratic Culture	Generative Culture
Do not want to know	May not find out	Actively seek it
Messengers (whistle blowers) are “shot”	Messengers are listened to if they arrive	Messengers are trained and rewarded
Responsibility is shirked	Responsibility is compartmentalized	Responsibility is shared
Failure is punished or concealed	Failures lead to local repairs	Failures lead to far reaching reforms
New ideas are actively discouraged	New ideas often present problems	New ideas are welcomed

Reporting Culture

- **Indemnity against disciplinarily proceedings and retribution**
- **Confidentiality**
- **To the extent practical, separation of those collecting the event data from those with the authority to impose disciplinary actions**
- **An efficient method for event submission**
- **A rapid, intelligent, and broadly available method for feedback to the reporting community**

Just Culture

Acceptable and Unacceptable Actions

- **Vast majority of errors is due to factors and actions where attribution of blame is not appropriate nor useful**
- **Rarely events are due to unacceptable actions:**
 - **Recklessness**
 - **Negligent or malevolent behavior**
- **The line between these can be thin and the tendency is to attribute errors to acceptable actions**
- **It is operationally impossible to give a blanket immunity which would include unacceptable actions**

Errors and Near Misses

- **Error**
 - “The failure of planned action to be completed as intended (i.e., error of execution) or the use of a wrong plan to achieve an aim (i.e., error of planning).”

Institute of Medicine. To Err is Human: Building a Safer Health System, 2000.



Errors and Near Misses

- **Near Misses**
 - Near Hits
 - Free Lessons
 - Close Calls
 - Near Collisions



Small to Sentinel Events

- ***“We know that single events are rare, but we do not know how small events can become chained together so that they result in a disastrous outcome. In the absence of this understanding, people must wait until some crisis actually occurs before they can diagnose a problem, rather than be in a position to detect a potential problem before it emerges. To anticipate and forestall disasters is to understand regulations in the ways small events can combine to have disproportionately large effects.”***

K.E. Weick, “The vulnerable system: an analysis of the Tenerife air disaster” in P.J. Forst et al Reframing Organizational Culture



Error Process

- Errors are product of a chain of causes



What to Report/Track

- **Explicit events – frequent events**
- **Random events**
- **Actual errors**
- **Potential errors (near misses)**

Reporting process

- **Statutory reporting**
 - Which agencies should receive reports
 - Which errors are subject to reporting
 - Do near misses have reporting mandates
 - Reporting process
- **Voluntary reporting**
 - Which errors/near misses to report
 - Reporting process
 - What should be provided in the report
 - Feedback mechanism

Taxonomy and Event Classification

- **Event reporting should enable process improvement**
- **This requires efficient processing and analysis of data**
- **Submitted events must be classified and organized**
- **Enables efficient processing, analysis, and communication of data and trends**

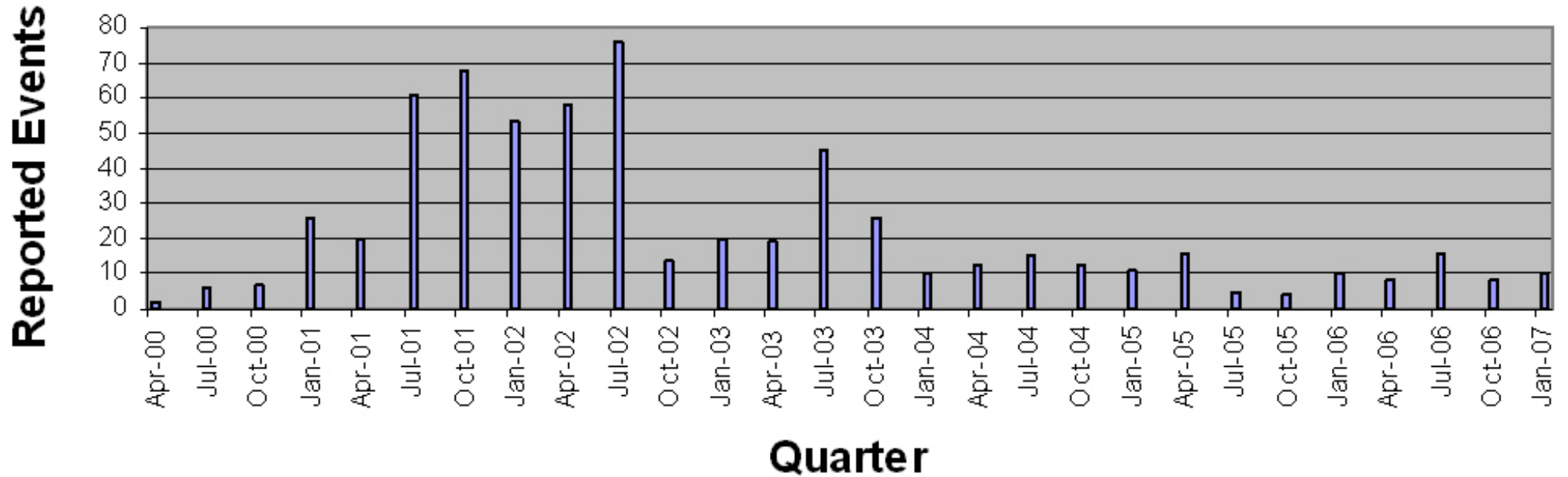
Taxonomy and Event Classification

- **Organized data can provide insight in system weaknesses and opportunities for improvement**
- **Submitted number of events alone are not an indicator as it is difficult to differentiate between increased problems and improved reporting culture**

Reporting Systems

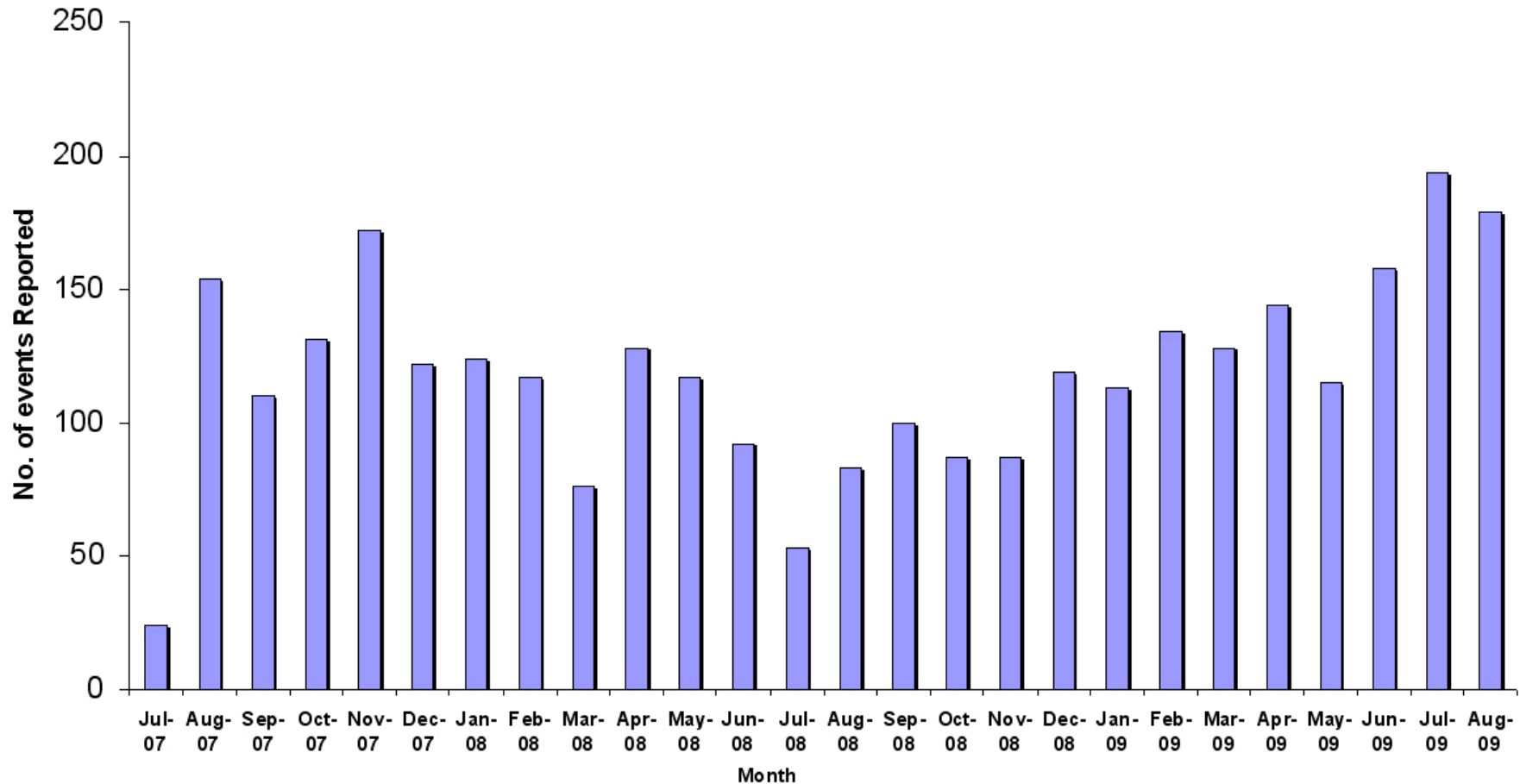
- **Paper**
 - Single form or set of multiple forms
 - Well defined submission and routing process
 - Manual processing and data extraction
- **Electronic**
 - Desktop or web-based applications
 - Commercial and home grown (rad-onc specific)
 - Automatic processing and data mining
 - ROSIS - <http://www.clin.radfys.lu.se/default.asp>

System Acceptance Paper



System Acceptance *Voluntary Web-based*

Events Reported

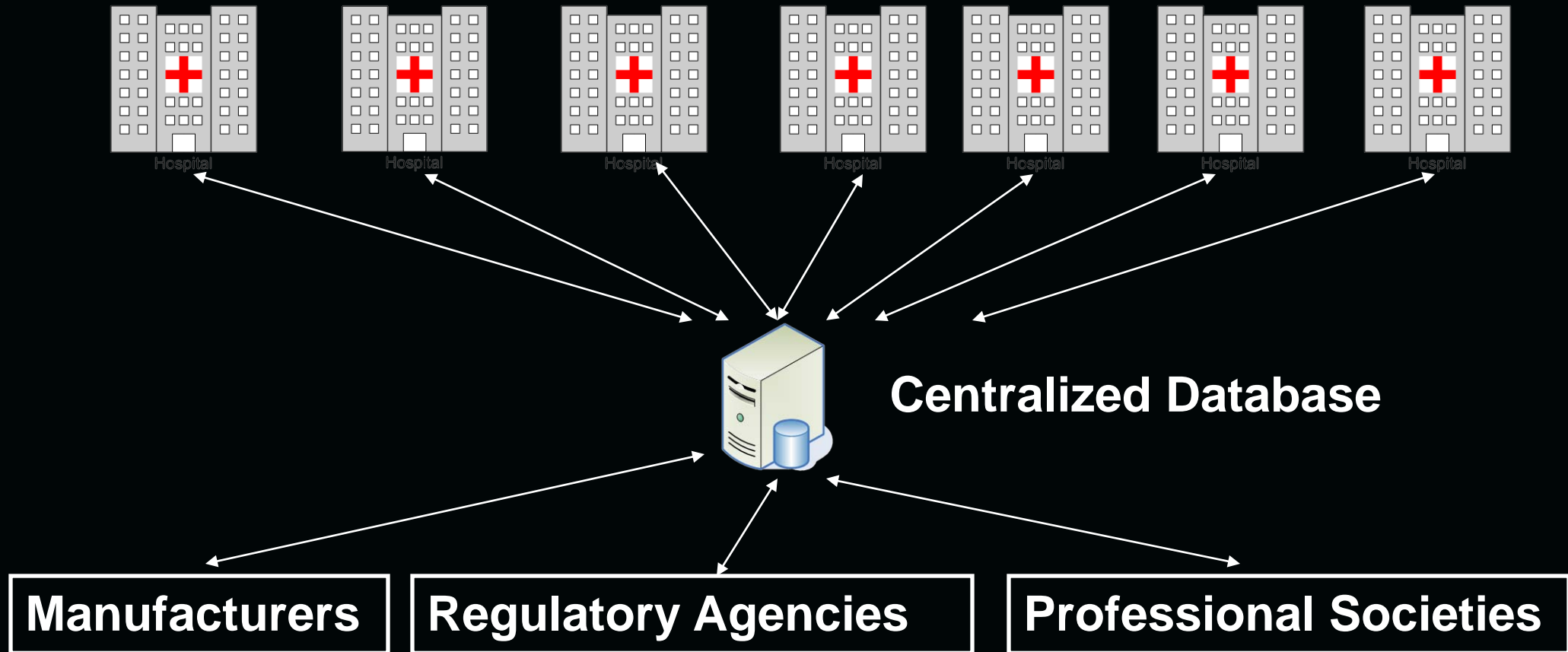


Feedback Mechanisms

- **Feedback process often stated as a prerequisite**
- **Feedback can be provided as individual correspondence or by demonstrating sustainable changes**
- **A combination of the above two methods is likely the best solution**
- **Need a method to deal with anonymous submissions**

Data Collection, Standardization, and Benchmarking

Each clinic with its own independent database and varied software



Conclusions

- **Sustainable data collection possible**
- **Need to collect broader parameters to determine failure triggers**
- **Need resources to process events and follow up on effects of implemented changes**
- **Electronic reporting and standardized classification could facilitate benchmarking among institutions**

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