Error Reporting Systems: New Directions

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Acknowledgments

- Charisse Johnson, David Brushwood, Adam Scheffler, Gordon Schiff, Jason Tan, Darren Toh, Swu-Jane Lin, Bob Wears, Paul Barach, and Stephen Landsman all contributed in some way to this presentation, and we thank them.

Learning Objectives

1. Compare and contrast a culture of safety and a culture of blame.
2. Identify the 5 (not 6) core principles of patient safety reporting systems.
3. Describe at least one recent innovation in state-based medication error reporting systems.
4. Identify three key obstacles to the widespread adoption of non-punitive error reporting systems.

Overview

- Brief Review of Existing Reporting Systems
- Culture of Blame/Culture of Safety
- Guiding Principles for Reporting Systems
- Limitations of Traditional Reporting Systems
- New Approaches to Reporting and Detecting Errors and Adverse Events
- Looking Toward the Future

Types of Reporting Systems

- Mandatory, external (e.g., state adverse event tracking, FDA serious incident reports from manufacturers)
- Voluntary, confidential, external (e.g., USP/ISMP MERP)
- Mandatory, internal, with possibility of external audit (e.g., OSHA)
- Error vs. adverse event reporting systems

Non-Medical Reporting Systems

- Non-medical reporting systems
  - Aviation Safety Reporting System (300,000+ reports since 1976)
    - http://asrs.arc.nasa.gov/
  - Nuclear power
  - Chemical/petroleum industry

Non-Medication Reporting Systems

- Transfusion errors (Medical Event Reporting System for Transfusion Medicine (MERS-TM)
  - www.mers-tm.net
- Anesthesia errors
  - www.gasnet.org/societies/apsf/index.php
- Device safety (ECRI)
  - www.mdsr.ecri.org

Med Error Reporting Systems

- USP/ISMP Medication Error Reporting Program (MERP)
- FDA MedWatch (more ADEs than errors)
- USP MedMaRX (hospitals only)
- Vaccine Adverse Event Reporting System (VAERS)
- Various state systems (e.g., Connecticut, Pennsylvania, New York, Massachussetts, Texas)

Culture of Blame or Safety

- Culture of Blame (still dominant)
  - Error is fault of individual
  - Error should be punished
  - Training, vigilance seen as solutions
- Culture of Safety (ascending?)
  - Errors due to system problems
  - Focus on learning and CQI
  - Non-punitive reactions to error
  - Tangible commitment to safety by leadership

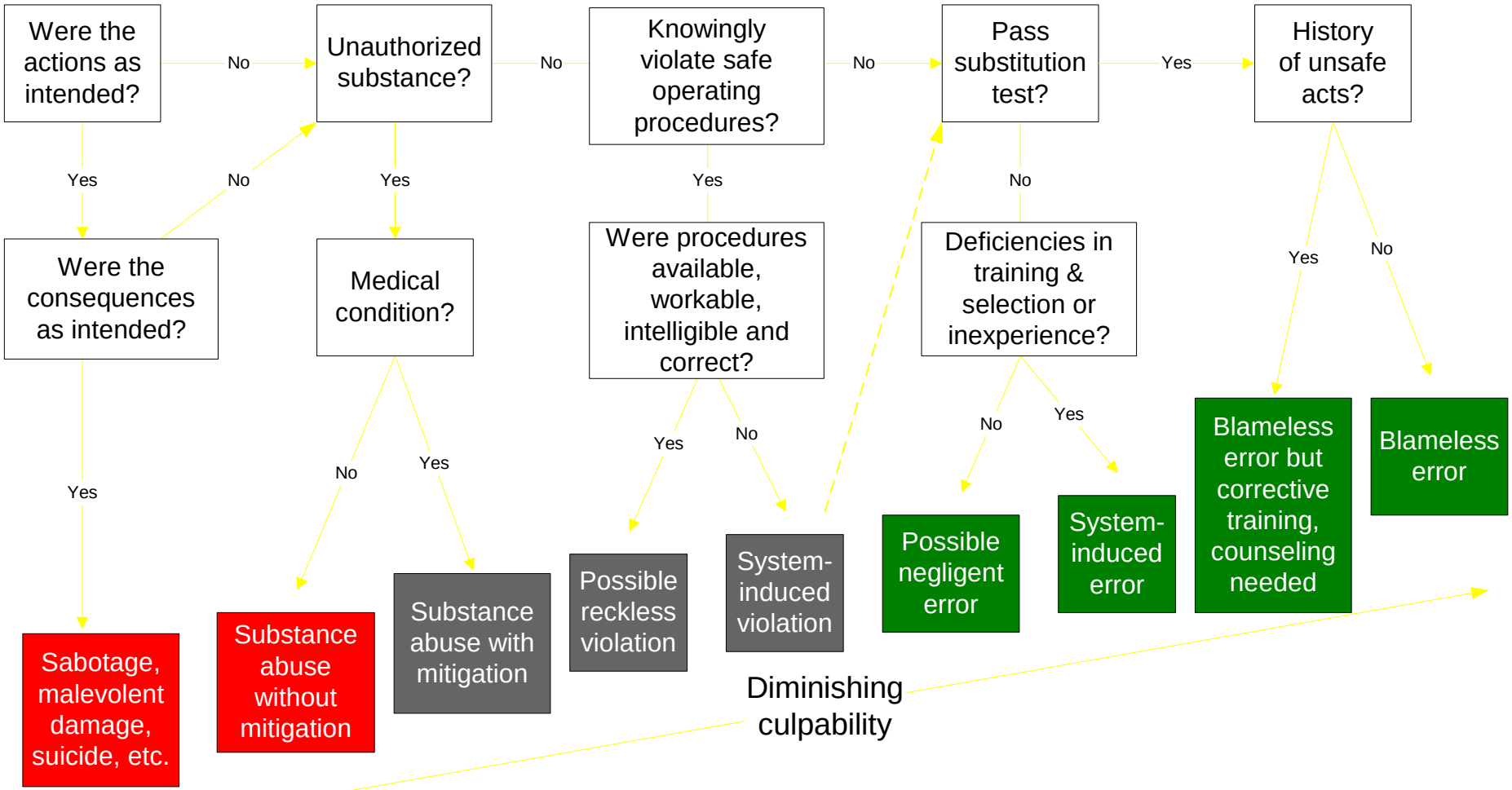
Culture of Safety

- Safety Climate Survey available (free!) from QualityHealthCare.org:

  “In a culture of safety, people are not merely encouraged to work toward change; they take action when it is needed. Inaction in the face of safety problems is taboo, and eventually the pressure comes from all directions — from peers as well as leaders. There is no room in a culture of safety for those who uselessly point fingers or say, "Safety is not my responsibility, so I’ll file a report and wash my hands of it."

Establish A Culture of Safety (from QualityHealthCare.Org)

1. Designate a Patient Safety Officer
2. Provide Feedback to Front-Line Staff
3. Conduct Safety Briefings
4. Conduct Patient Safety Leadership WalkRounds™
5. Appoint a Safety Champion for Every Unit
6. Involve Patients in Safety Initiatives
7. Create a Reporting System
8. Simulate Possible Adverse Events
9. Create an Adverse Event Response Team
10. Relay Safety Reports at Shift Changes
11. Reenact Real Adverse Events from Your Hospital



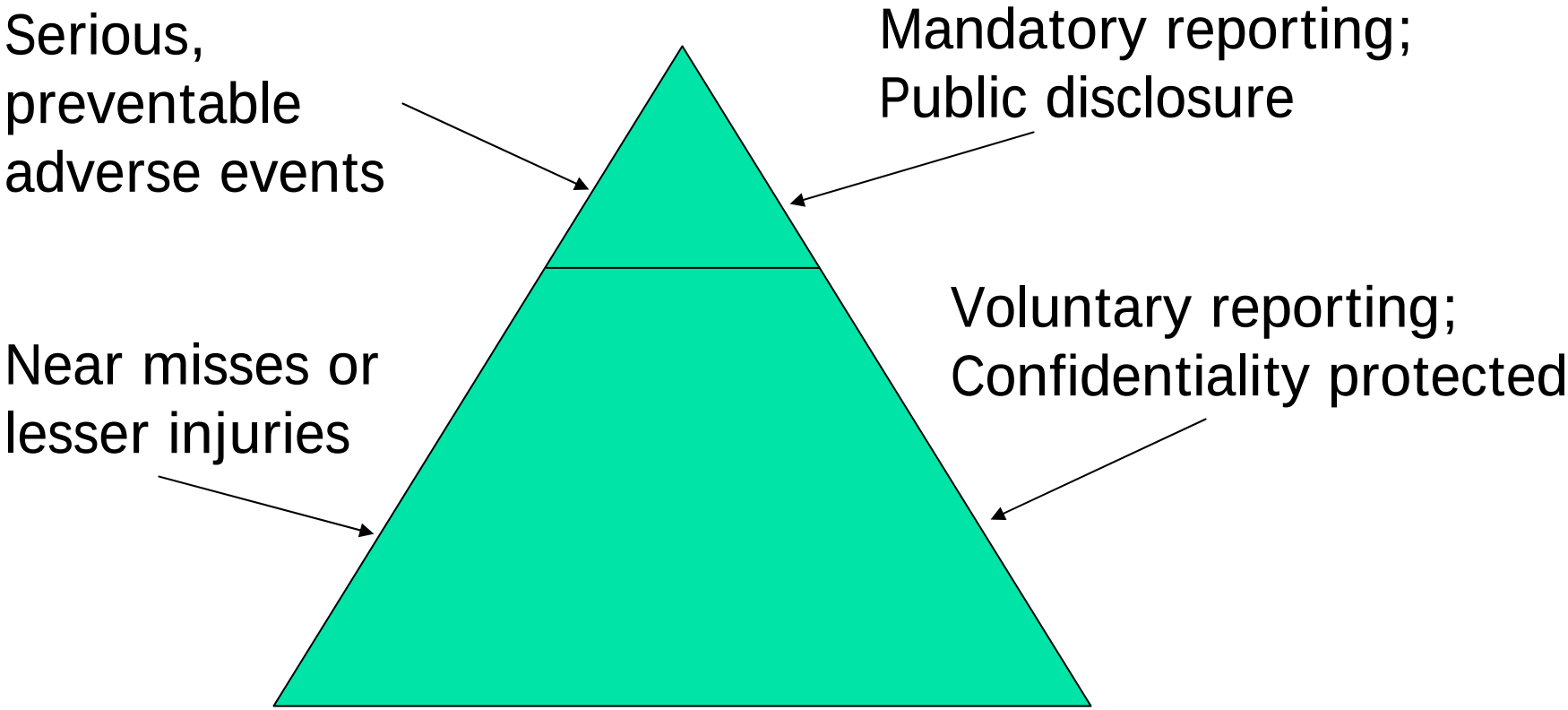
Decision Tree for Determining Culpability of Unsafe Acts

From Reason, J. Managing the risk of organizational accidents. 1997.

Obstacles to Adoption of Non-Punitive Culture/Systems

- Need for “accountability,” tension between accountability and learning
- Fear of litigation, reprisal
- Lack of trusted and time-tested state and federal statutory protection from discovery
- Lack of knowledge about structure, function, and purpose of non-punitive systems
- Generalized resistance to change

IOM Report: To Err is Human



IOM Reporting System Recommendations

- 5.1 A nationwide mandatory reporting system should be established that provides for the collection of standardized information by state governments about adverse events that result in death or serious harm.
  - Required initially for hospitals and eventually for all
  - Promulgate standard terminology, taxonomy, and format
  - Require standard reports on defined list of adverse events
  - Provide funds and expertise for states to collect, analyze and follow-up on reports
  - Convene states to share, evaluate, and assess impact
  - Receive and aggregate state reports and plan action

IOM Reporting System Recommendations

- 5.2 The development of voluntary reporting systems should be encouraged. The Center for Patient Safety should:
  - Describe and disseminate info about existing systems; track new systems
  - Convene sponsors/users of existing systems to see what works and what doesn't
  - Periodically assess information gaps and participation rates
  - Fund and evaluate pilot projects

NCC-MERP Principles for Patient Safety Reporting Systems

1. **Creating an Environment for Safety**.
2. **Data Analysis**.
3. **Confidentiality**.
4. **Information Sharing**.
5. **Legal Status of Reporting System Information.**

www.nccmerp.org/press/press2003-11-25.html

Limitations of Reporting Systems

- Not enough people report (voluntary systems)
- Data are incomplete and inconsistent
- Analysis is superficial or non-existent
- Feedback to reporters is weak or non-existent
- Systemic changes are slow or non-existent
- Too hospital-focused
- Too much focus on error reduction not enough on harm reduction

Underreporting: Name Confusions

- Flynn et al. (JAPhA, Vol. 43, No. 2, p. 191-200) recently reported that wrong-drug error rate in outpatient pharmacy was 0.13%
- With 3 billion scripts filled per year, this means 3.9 million wrong drug errors per year.
- Fewer than 10,000 reports in comprehensive search of literature on name confusion.
- 10,000/3.9 million=0.25%
- But this is an overestimate because the 3.9 million is per year, and the 10,000 is from the last 40 years.

Underreporting: USP/ISMP MERP

- USP/ISMP MERP received 3000 reports between 1993 and 1999, according to IOM report.
- Assume 2 billion prescriptions per year and a 1.7% error rate (from Flynn, Barker, & Carnahan, 2003) = 34 million errors per year.
- MERP received about 450 per year
- 450/34 million = 0.0013% of errors are reported or 1 in 75,555 errors

Underreporting: USP MedMaRX

- Rough “back of the napkin” calculation
- 197,000 reports in 2002 from 500 hospitals
- 5700 hospitals in US, 1 million beds
- Barker et. al 2002 report hospital med. error rate is 5% (excluding omission and wrong time errors)
- Assume (conservatively) 2 billion doses per year)

Underreporting: USP MedMaRX

- We expect 5% * 2 billion = 100 million errors/year
- MedMaRX has 500/5700 hospitals = 9%, so we'd expect 9% * 100 million errors in those hospitals = 900,000 errors.
- MedMaRX captured 197,000/9,000,000=2.2%
- Higher rate than most other systems

Underreporting: Central Arkansas VA

- Rolland, P. *Drug Safety*, 27(4), 271-282
- Based on a 2% error rate, Central Arkansas VA expects 105,059 errors annually (for 2001).
- Actual number of reports: 82
- 82/105,059=.08% or 1 out of every 1281 errors

Missing Information from Literature-Based Name Confusion Case Reports

Total literature review (1964~present)	1598 articles
Total	789 pairs (1578 names)
Missing Strength	1061
Missing Dosage Form	1262
Missing Route	1139
Missing Consequence	500 (cases)
Missing Direction	353 (of 789)

Missing Info from USP Name Confusion Dataset

Duration	1/1/1997~9/30/2003
Total number of cases	753 pairs
Missing Strength	633 (of 1506 drugs)
Missing Dosage Form	54 (of 1506)
Missing Route	39 (of 1506)
Missing Manufacturer	123 (of 1506)
Missing Direction	??

Improving Quality of Reports

- Establish standard template for reporting system
- Enforce data completeness
- Hire database expert to manage data
- Record consistently
- Publish descriptive statistics and recommendations periodically

States Requiring CQI Programs

- Arizona, California, Connecticut, Florida, Kentucky, Massachusetts, New Mexico, North Carolina, North Dakota, Oregon, Vermont, West Virginia
- Source: 2002-2003 NABP Survey of Pharmacy Law

Florida's CQI Rule

(see *CQI Compliance Guide for Florida Pharmacists, U. of FL COP*)

- Each pharmacy must have CQI program
  - "A system of standards and procedures to identify and evaluate quality related events and improve patient care"
  - Not errors but "quality related events"
    - Variation from prescriber order
    - Failure to identify and manage drug therapy issues
  - Events must be documented and kept 2 years
  - Documentation of events confidential and protected from discovery under Florida law.

Florida's CQI Rule

- Systems must show improvements in patient care
- CQI team must meet at least once per 3 months
- Must consider staffing, workflow and technology when examining contributing factors
- Documentation same day as error,
  - Done by pharmacist
  - Not same person who was involved in QRE
  - Detailed docs saved until CQI meeting
  - After meeting, only summary of remedial measures is saved, without names of those involved

Complying with Florida CQI Rule

- Select Quality Team Leader
- Define Quality Related Event
- Describe Practice Process
- Develop QRE Recording System
- Train Staff in CQI Principles
- Conduct CQI Meetings
- Implement Changes and Evaluate Results

Pennsylvania's Reporting System (PA-PSRS)

- Mandated by state law: Act 13 of 2002, the Medical Care Availability and Reduction of Error ("MCARE") Act
- Run under contract to ECRI, web-based
- Protected by statute from discovery
- Hospitals, birthing centers and ambulatory surgical facilities
- Mandatory reporting of "serious events" and "incidents"

New Directions in Reporting: ADE Triggers

- Based on work of Dr. David Classen
- Triggers are clinical events (med orders, lab values) that strongly suggest an adverse drug event (ADE) has occurred.
- Focus on ADEs not errors prioritizes harm reduction over error reduction
- Based on chart review or electronic analysis

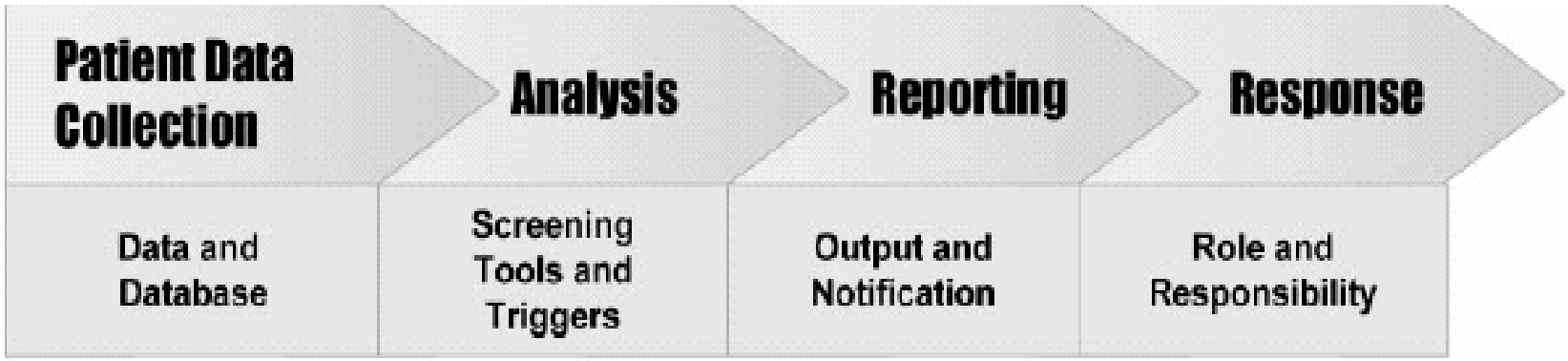
New Directions in Reporting: ADE Triggers

- Feasibility demonstrated recently (*Qual Saf Health Care* 2003;**12**:194-200)
- Training on trigger tool takes only 2-3 hours, can be done by any personnel with medical background
- Detects 50-60 times more ADEs than voluntary incident reporting

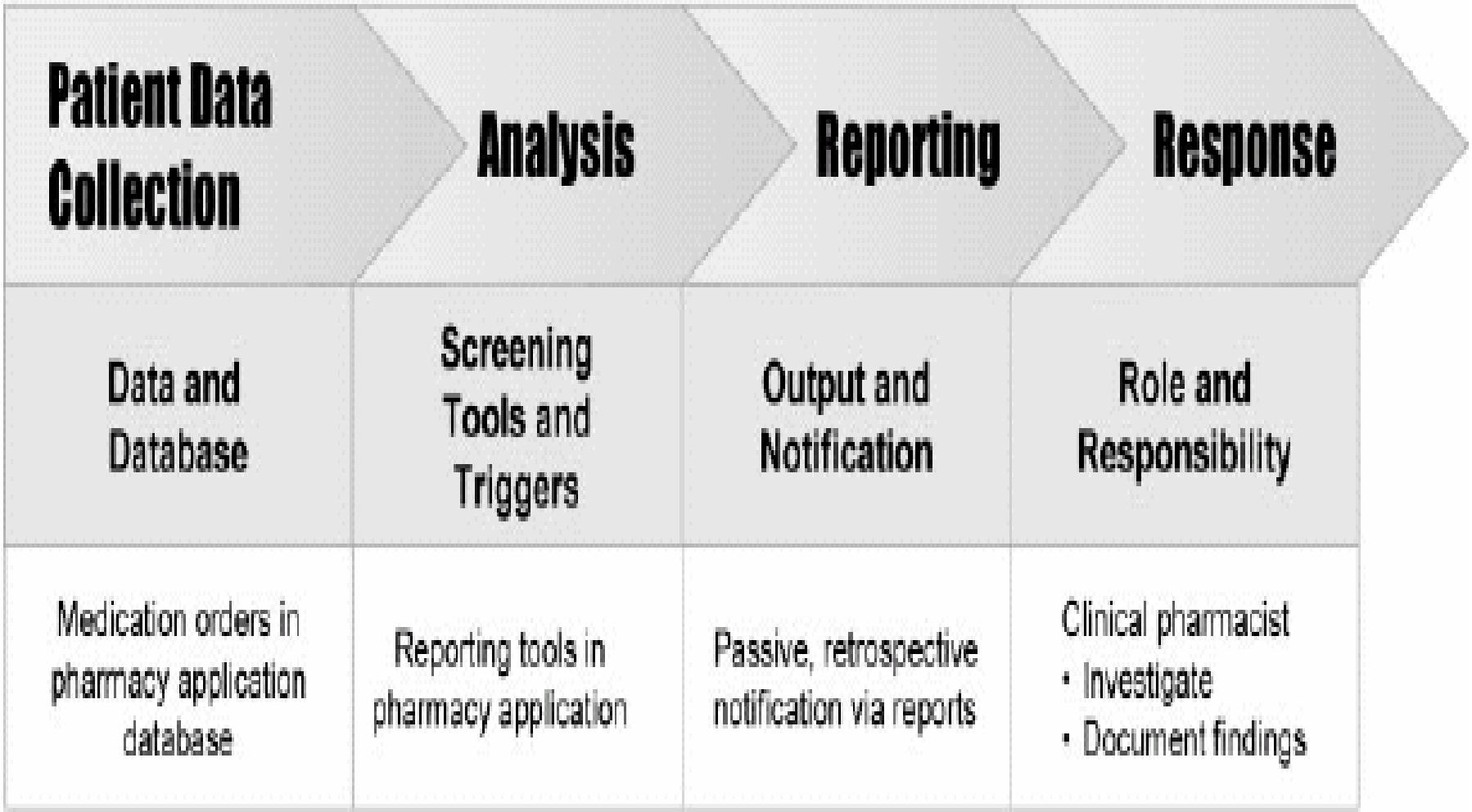
New Directions in Reporting: ADE Triggers

- Example Triggers (24 in all)
  - Diphenhydramine (allergy/hypersensitivity reaction)
  - Vitamin K (over anti-coagulation)
  - Flumazenil (over sedation by benzo)
  - Droperidol (nausea/vomiting related to drug use)
  - Naloxone (over sedation with narcotic)
  - PTT > 100 seconds (heparin overdose)
  - Serum glucose < 50 mg/dl (insulin overdose)

Computerized Measurement



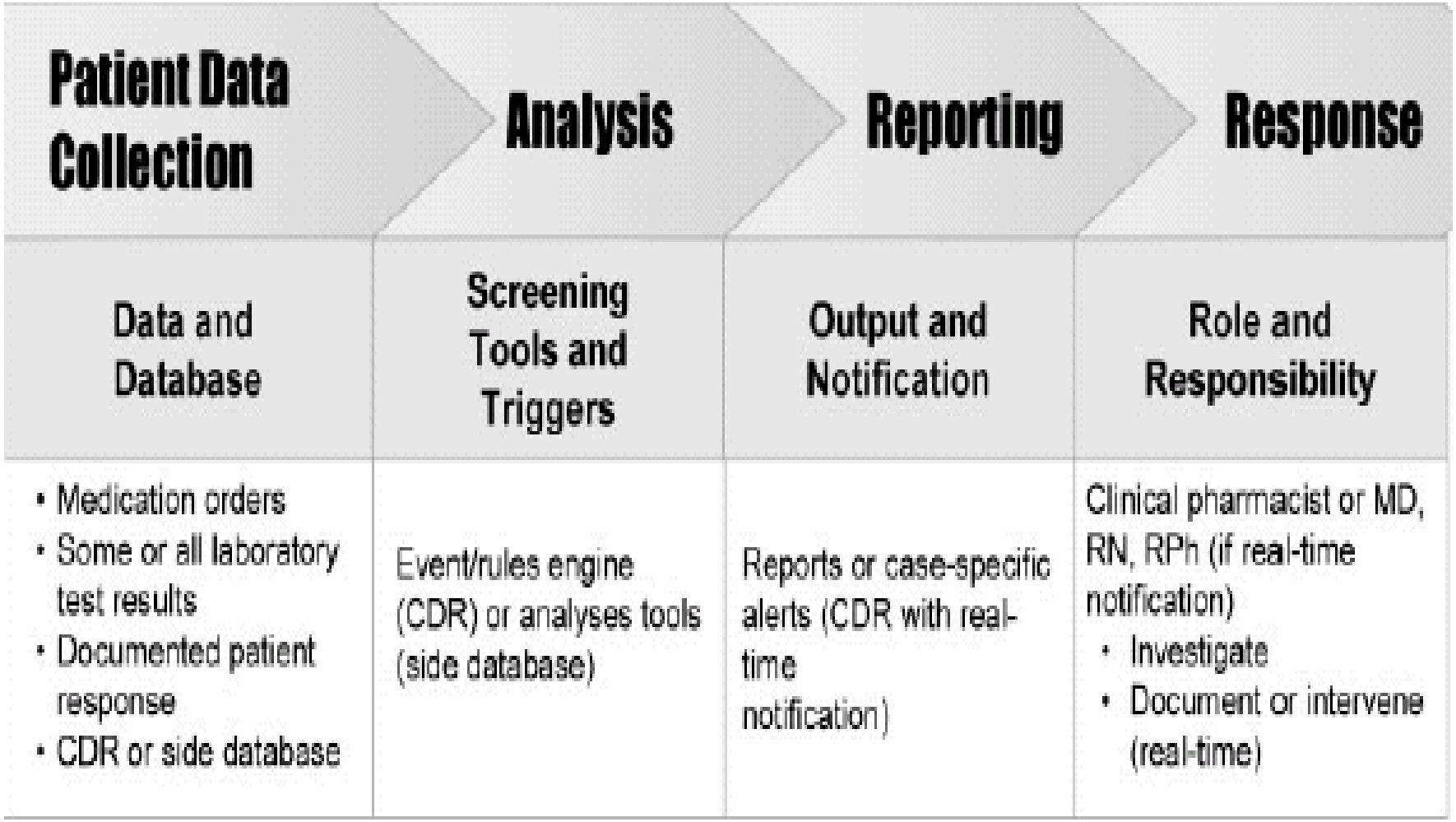
Components of computerized medication safety measurement. See Classen DC, Metzger J. *Int J Qual Health Care*, Vol. 15, Supp. 1, 141-147.



Components of computerized medication safety measurement: pharmacy data.

Patient Data Collection	Analysis	Reporting	Response
Data and Database	Screening Tools and Triggers	Output and Notification	Role and Responsibility
Medication orders and some or all laboratory test results in CDR or side database	Event/rules engine (CDR) or analyses tools (side database)	Reports or case-specific alerts (CDR with real-time notification)	Clinical pharmacist or MD, RN, RPh (if real-time notification) • Investigate • Document or intervene (real-time)

Components of computerized medication safety measurement: lab and pharmacy data.



Components of computerized medication safety measurement: lab, pharmacy, and medication administration record data.

New Directions in Reporting: USP MedMaRX

- Anonymous, Web-based, 650 hospitals
- Annual subscription fee (approx. $5000)
- Targeted at hospitals and health systems
- High volume of reports (> 500K total, 20K per month added)
- Standardization facilitates comparison
- Supports JCAHO patient safety goals
- Can be linked to risk management
- May lack detail needed for learning

New Directions in Reporting: Community Pharmacy

- Simple paper-based forms worked well in a recent UK pilot program (286 reports out of 51357 scripts dispensed = 0.56%).
- Using dictation to ease reporting burden did not increase reporting in Vermont pharmacies
- Corporate ownership's fear of liability pulls veil of secrecy over errors in retail pharmacy
- Getting reports from retail pharmacy is the greatest current challenge
- How can we apply trigger methods to retail?

Why Inpatient Solutions May Not Work for Retail Pharmacy

- Lack of Internet access surprisingly still an issue.
- Cost to participate (e.g., MedMaRX)
- Time and production pressures make reporting unlikely
- No electronic medical record
- Persistent culture of blame/fear of retribution
- Retail culture trumps healthcare culture
- Looser integration between MD, RN, PharmD

The Case Against Reporting

- More reports does not equal safer systems
- May be reaching point of diminishing returns where additional reports yield no new information
- We have not learned the lessons from many of the reports that have already been collected
- Even lessons learned have not been widely disseminated and adopted
- More important to measure and reduce harm than to measure and reduce errors

Final Thoughts

- Creating a culture of safety should be our goal
- Creating a culture of safety involves more than creating reporting systems
- Reporting systems have many serious flaws
- Limited active surveillance (e.g., triggers) may be much better/cheaper than new voluntary reporting systems
- Innovation is needed in getting reports from retail pharmacies
- Legal obstacles still exist, but can be overcome

Resources

- QualityHealthCare.org
  - www.qualityhealthcare.org/IHI/Topics/PatientSafety/
- Pennsylvania Patient Safety Authority
  - www.psa.state.pa.us/psa
- ISMP Reporting System Discussion Paper
  - www.ismp.org/Pages/concept.html
- Florida Reporting System Paper
  - umdas.med.miami.edu/MPSC/reports/Section%2036-1.pdf
  - All reports: http://umdas.med.miami.edu/MPSC/Reports.html
- Trigger tools: Qual Saf Health Care, 2003, 12: 194-200

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