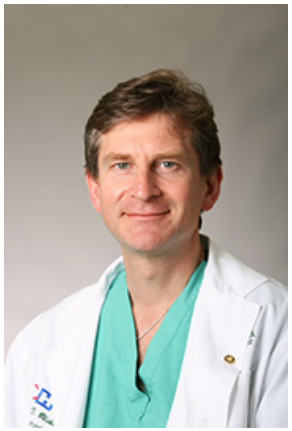
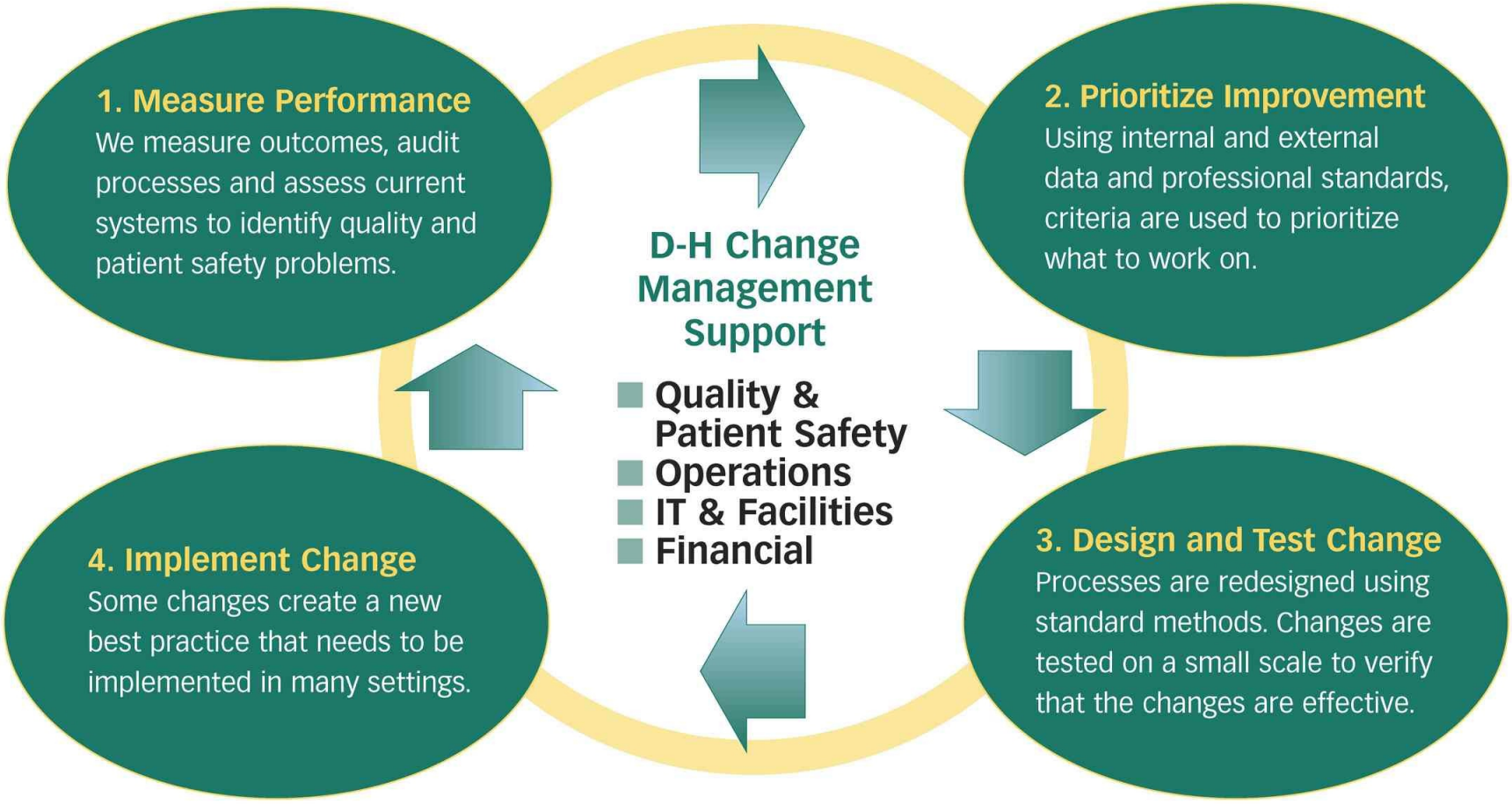


Safety Technology in Drug Delivery

George Blike MD
Professor of Anesthesiology
Quality and Patient Safety Officer
Medical Director Patient Safety Training Center

- Academic (~700 physicians in training) Tertiary Care Medical Center (~450 beds and 5,200 total staff)
- ~20,000 surgeries and procedures per year
- ~150,000 in-patient care days per year

Dartmouth-Hitchcock Uses a Systems Approach That Forms a Quality Improvement Loop



Dartmouth-Hitchcock

Definitions

- **Safety:** is the state of being "safe" (from French *sauf*), the condition of being protected against physical, social, spiritual, financial, political, emotional, occupational, psychological, educational or other types or consequences of failure, damage, error, accidents, harm or any other event which could be considered non-desirable. ***Safety can also be defined to be the control of recognized hazards to achieve an acceptable level of risk.*** This can take the form of being protected from the event or from exposure to something that causes health or economical losses.

Definitions

- Medication Error: ***any preventable event that may cause or lead to inappropriate medication use or patient harm*** while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use

Definitions

- **Drug Delivery:** method or process of administering a pharmaceutical compound to achieve a therapeutic effect in humans or animals.[1][2] Drug delivery technologies are patent protected ***formulation technologies that modify drug release profile, absorption, distribution and elimination*** for the benefit of improving product efficacy and safety, as well as patient convenience and compliance.[3]

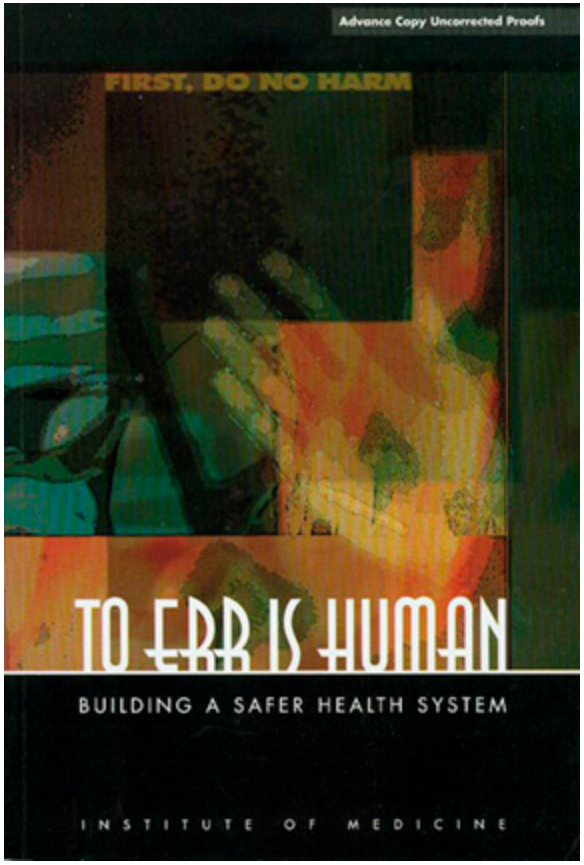
Agenda

- **Define Problem**
  - Safety, Medication Errors, Anesthesia/Peri-op
- **Current State-of-the-Art**
  - Focus on key enabling technologies
- **Example/Case Study**
  - Smart IV Pumps
- **Conclusion**

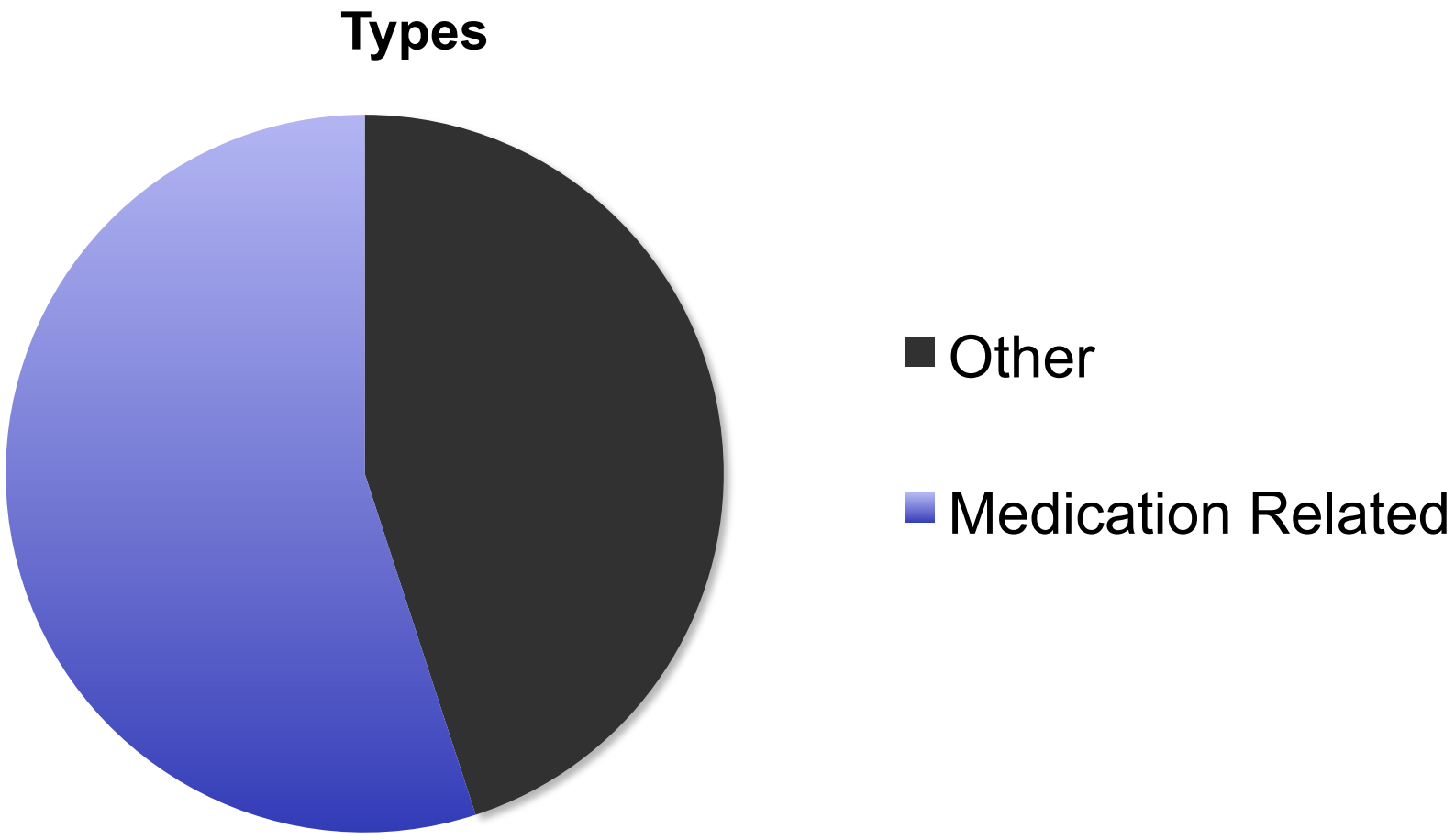
To Err is Human…

- 7% of hospitalized patients experience a serious medical error. **More recent studies ~10%**

- 44,000-98,000 Americans die in hospitals each year from care injuries.



All Error in Healthcare



Gawande A., Thomas E., et. al. "Incidence and Nature of Surgical Adverse Events in Colorado and Utah in 1992." *Surgery Vol 126(1), 1999.*

- *Methods/Results:*
  - Sampled 15,000 randomly selected admissions
  - Screened with "trigger" tool, 18 markers for Adverse Events AND Secondary review of hospitalization by two trained physicians
    - 402 Surgical Adverse Events
  - Preventable AE—54% Percent of Total
    - 4% of total

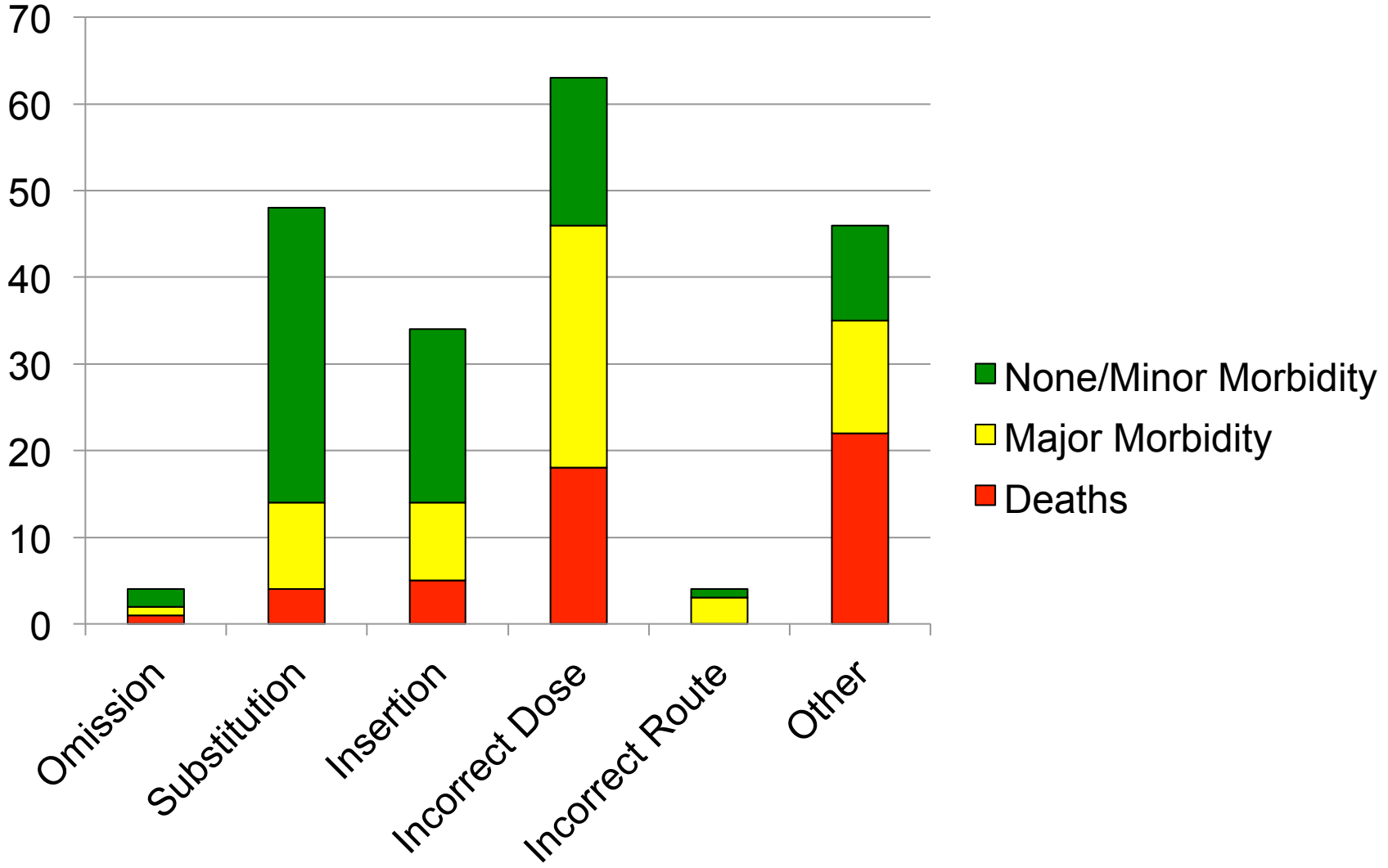
* For every 10,000 surgeries ~800 AEs ~400 PAEs

Nature of Surgical Adverse Events (402 events)

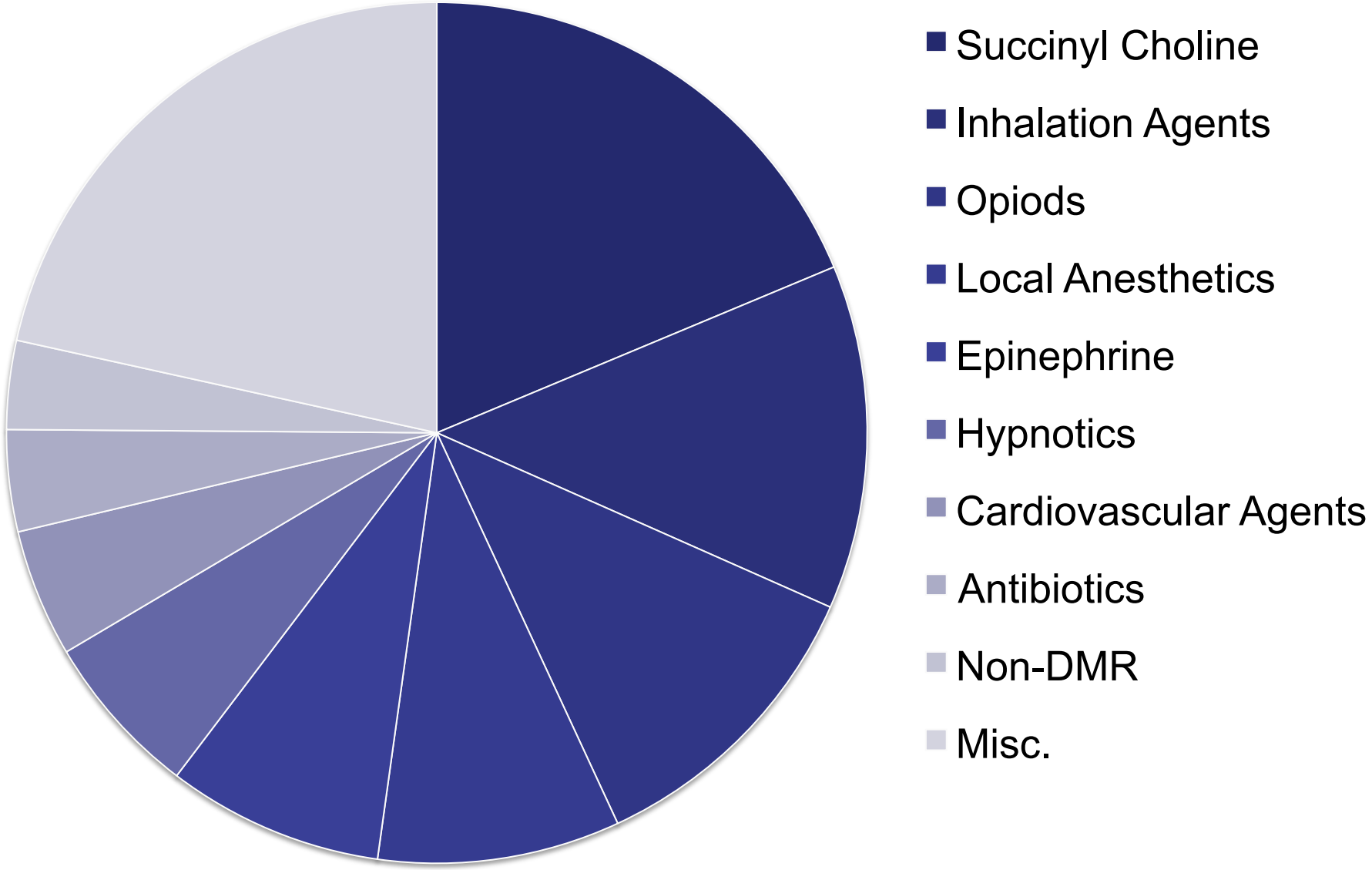
Type of Event	*% of Surgical AE*	*% Preventable*
Technique related complication	24	68
Wound infection	11	23
Post-operative bleeding	11	85
Post-partuum/Neonatal related	8	67
Other infection	7	29
Pulmonary embolus	2	14
Acute Myocardial infarction	2	0
Inappropriate therapy	2	100
Anesthesia Injury	2	45
Congestive heart failure	1	33
Stroke	1	0
Pneumonia	1	65
Fall	.5	50

~30 % of Surgical Adverse Events are Potentially Medication Related

Closed Claims: Anesthesia Medication Errors



Closed Claims: Anesthesia Medication Errors

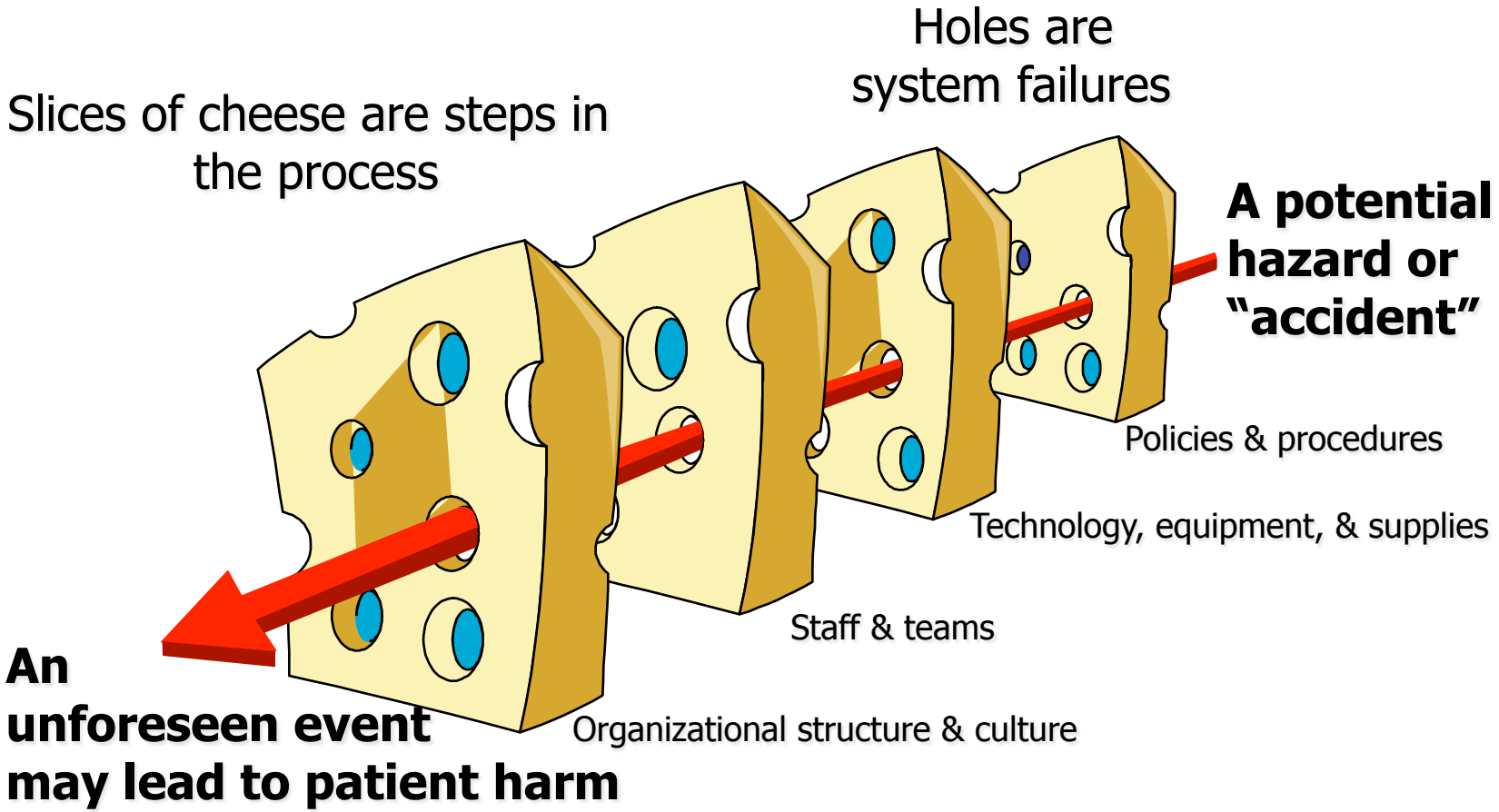


ISMP-High Alert Medications

- adrenergic agonists
- adrenergic antagonists
- anesthetic agents
- antiarrhythmics
- antithrombotics
- cardioplegia
- chemotherapeutics
- dextrose
- hypertonic >20%
- dialysis solutions
- epidural or intrathecal
- hypoglycemics, oral
- inotropic meds liposomal forms of drugs
- moderate sedation agents
- moderate sedation peds
- narcotic/opiates
- neuromuscular blockers
- radiocontrast
- TPN
- Misc Individual Drugs:
  - colchinine inj
  - epoprosteniol IV
  - Insulin, SQ and IV
  - Magnesium Sulfate IV
  - methotrexate, oral, non onc
  - opium tincture
  - oxytoxcin
  - nitroprusside
  - IV potassium chloride
  - IV potassium phosphate
  - IV promethazine
  - IV sodium chloride
  - hypertonic sterile water vials <100ml

Human Factors Engineering of Safety

"Swiss Cheese" Model

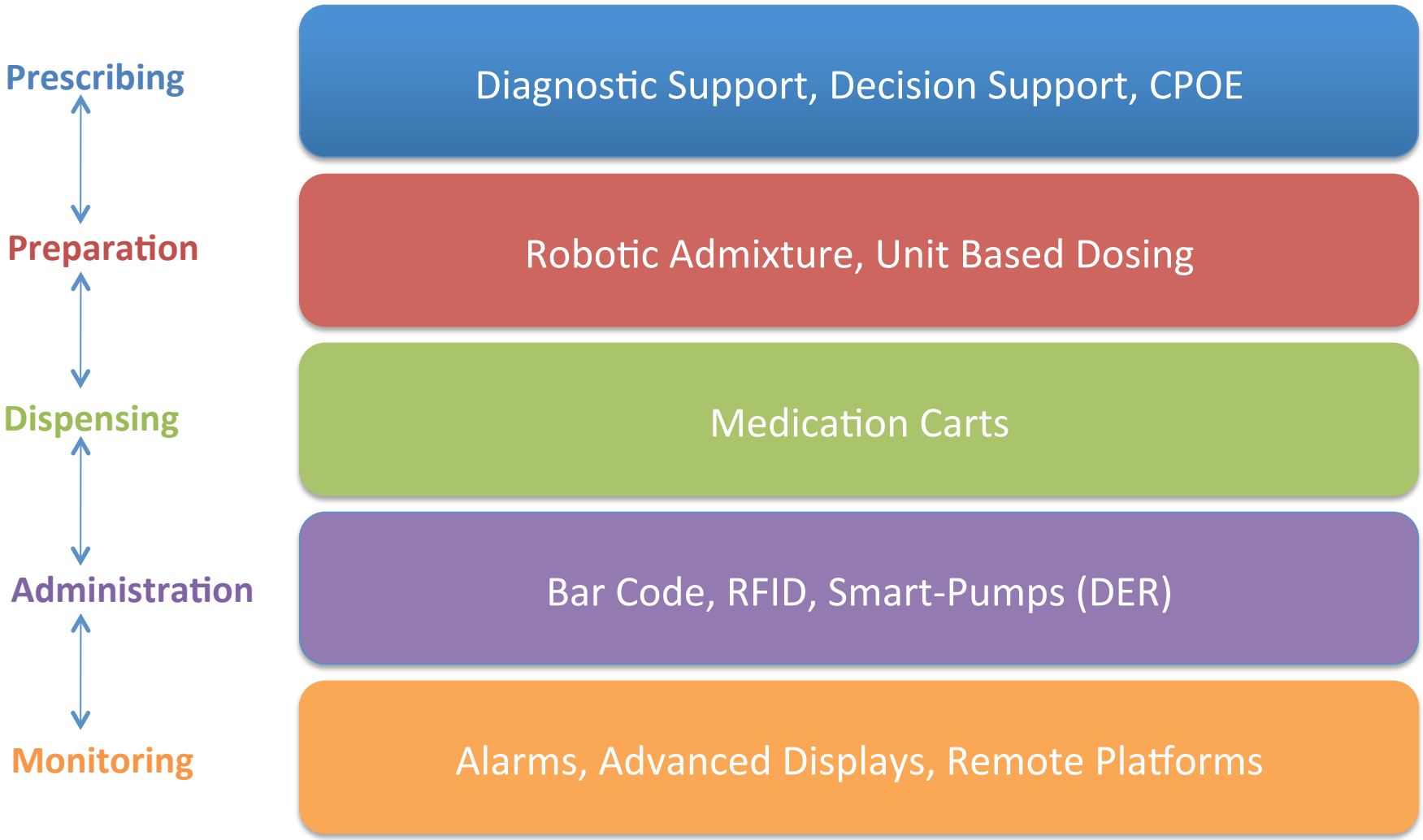


Every process has successive layers of defenses, barriers, & safeguards

Anesthesia Closed Claims Conclusions: Drug-related Injury

- Patient Safety Measures Recommended
  - Knowledge (BPA)
  - Allergy list reliability (Verification)
  - Cross-checks (High Alert Med Double Check)
  - Single concentration (Formulary, Stocking)
  - Labeling (Tall Man Lettering)
  - Packaging for safety (Robot Ready, Bar Code Ready)
  - IV infusion safety software (DER)
  - Forcing functions (Connectors for Drugs)
  - Recovery strategy (Monitoring Patients on Opiods)

Chemotherapy High Level Process Map



"Smart Infusion Pumps"

- Software to alert users to potential errors
  - Library of medications
    - Dosing Guidelines (Standard Concentrations, Dose limits, Clinical Advisories)
  - Alerts
    - Clinical Advisories "just in time information"
    - Soft Stops-Out of dose range, ABLE to override
    - Hard Stops-Out of dose range, UNABLE to override

Institute for Safe Medication Practices: Proceedings from the ISMP Summit on the use of Smart Infusion Pumps: guidelines for safe implementation and use (2007)

Desirable Functionality

- Wireless enabled-I/O capable while in use
- Compatible with CPOE, Barcode, EMR
- Hard-stops for selected medications
- Soft-stops with default rates
- Rate settings default to zero at end of infusion
- Libraries inclusive of all meds used with pump
- Automated navigation to library

Institute for Safe Medication Practices: Proceedings from the ISMP Summit on the use of Smart Infusion Pumps: guidelines for safe implementation and use (2007)

Benefits

- Reduced Administration Errors (Dose Calc)
- Actual drug concentration checked by some pumps (Bar Code)
- Decision-Support (Clinical Advisories)
- Mitigate Risk of High Hazard Medications
  - Sedative/Analgesics; Anticoagulants; Hypoglycemics; Pediatric; Chemotherapeutics
- Organizational QI data

Institute for Safe Medication Practices: Proceedings from the ISMP Summit on the use of Smart Infusion Pumps: guidelines for safe implementation and use (2007)

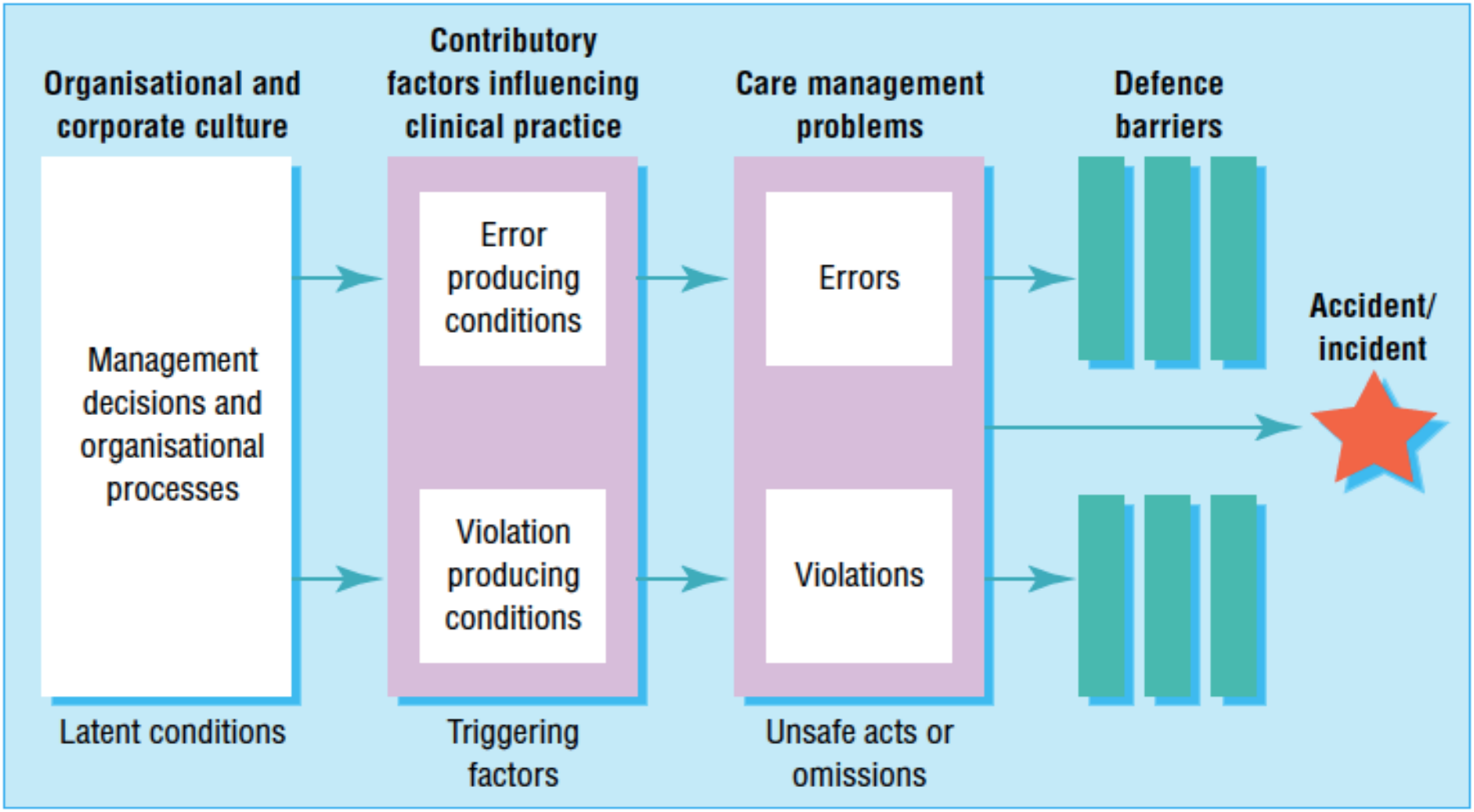
Limits

- Organizational culture to use
- Does not replace independent double checks
- Still requires accurate data entry
- Correct sensitivity and specificity of soft and hard alerts requires analysis and adjustment
- Requires significant organizational infrastructure

**Only one hole in the "Swiss Cheese"*

Institute for Safe Medication Practices: Proceedings from the ISMP Summit on the use of Smart Infusion Pumps: guidelines for safe implementation and use (2007)

Accident Causation



Model of organisational causes of accidents (adapted from Reason[9])

Case Example: D-H Infusion Pump

- Supply Chain Black Belt
- System wide review and selection
- Smart Pump Deployment
- CQI Data
- Challenges in OR/Critical Care

- ECR
- ISM
- D-H
- D-H

Evaluation at a Glance

General-Purpose Infusion Pumps (Page 1 of 2)

	B. Braun Outlook 300	Baxter Colleague CXE and 3CXE	Cardinal Health Alaris SE	Cardinal Health Alaris System
Rating	NOT RECOMMENDED Limited DERS functionality, only one-way wireless capability	NOT RECOMMENDED Limited DERS functionality, no wireless capability, but accepts Baxter standard sets	NOT RECOMMENDED A fine pump overall, but with somewhat restricted limit functionality and no wireless capability	PREFERRED One of the better pumps we tested, with an extensive implementation history
Number of channels	1	1 (CXE), 3 (3CXE)	1 or 2	Up to 4
SIGNIFICANT TEST RESULTS				
Infusion pump capabilities and features	● Good	● Good	● Good	✪ Excellent—large dedicated DERS log
Performance	● Good	● Good	● Good	✪ Excellent—facilitates detection of alerts/alarms
Dose error reduction system	◐ Fair—no wireless networking, limited functionality, small drug library	✘ Poor—no wireless networking, control design could lead to medication errors, limited functionality	● Good overall, but lack of wireless networking is a major disadvantage	✪ Excellent—wireless capability, comprehensive log analysis, easy access to drug library
Human factors	◐ Fair—menu navigation difficult	◐ Fair—menu navigation difficult	● Good	● Good
COMPLIANCE WITH ECRI INSTITUTE MINIMUM SPECIFICATIONS FOR DOSE ERROR REDUCTION SYSTEMS				
DERS on primary and secondary (piggyback) infusions	▼ Primary only	▼ Primary only	▼ Primary only	▲ Both primary and secondary
Drug library capacity: 100 entities per location/therapy	▼ Up to 70	▲ Up to 500 (64 prepopulated)	▲ Up to 100	▲ Up to 1,500
10 locations/therapies	▼ 6 (names cannot be modified)	▼ Up to 8	▲ Up to 12	▲ Up to 15
1,000 drug entities total	▼ 70	▼ 500 (64 prepopulated)	▲ 1,200	▲ 1,500
Limits available for bolus delivery	▼ No	▼ No	▼ No	▲ Yes
Event/alarm log covers at least a few months (usually 1,000 entries)	▼ 256 entries	▲ 1,000 entries (log not specific to DERS)	▲ 1,500 entries	▲ 10,000+ entries
Comprehensive log-analysis software	▼ No, limited	▼ No, limited	▲ Yes	▲ Yes
Bidirectional wireless communication	▼ No, outbound only (two-way available on Outlook 400)	▼ No (planned for 2008)	▼ No	▲ Yes, and mobile server for non-wireless hospitals
Bar-code scanner	▲ Integrated	▼ No	▼ No	▲ Integrated
Additional pump types or capabilities	None specified	None specified	None specified	▲ PCA, syringe, $ETCO_2$, SpO_2

▲ = Meets our minimum criterion ▼ = Does not meet our minimum criterion

DERS = dose error reduction system **$ETCO_2$** = end-tidal carbon dioxide **PCA** = patient-controlled analgesia **SpO_2** = pulse oximetry

Smart Pump Deployment

- Executive leadership of the process
  - Set policy and procedures for use, consequence
  - Interdisciplinary team
    - Org readiness, Drug library development, implementation plan, Use model
- Technological Readiness
- Physical Environment and Equipment
- Staff Education
- Specialized Patient Care Areas
- Vendor Support
- Roll-out

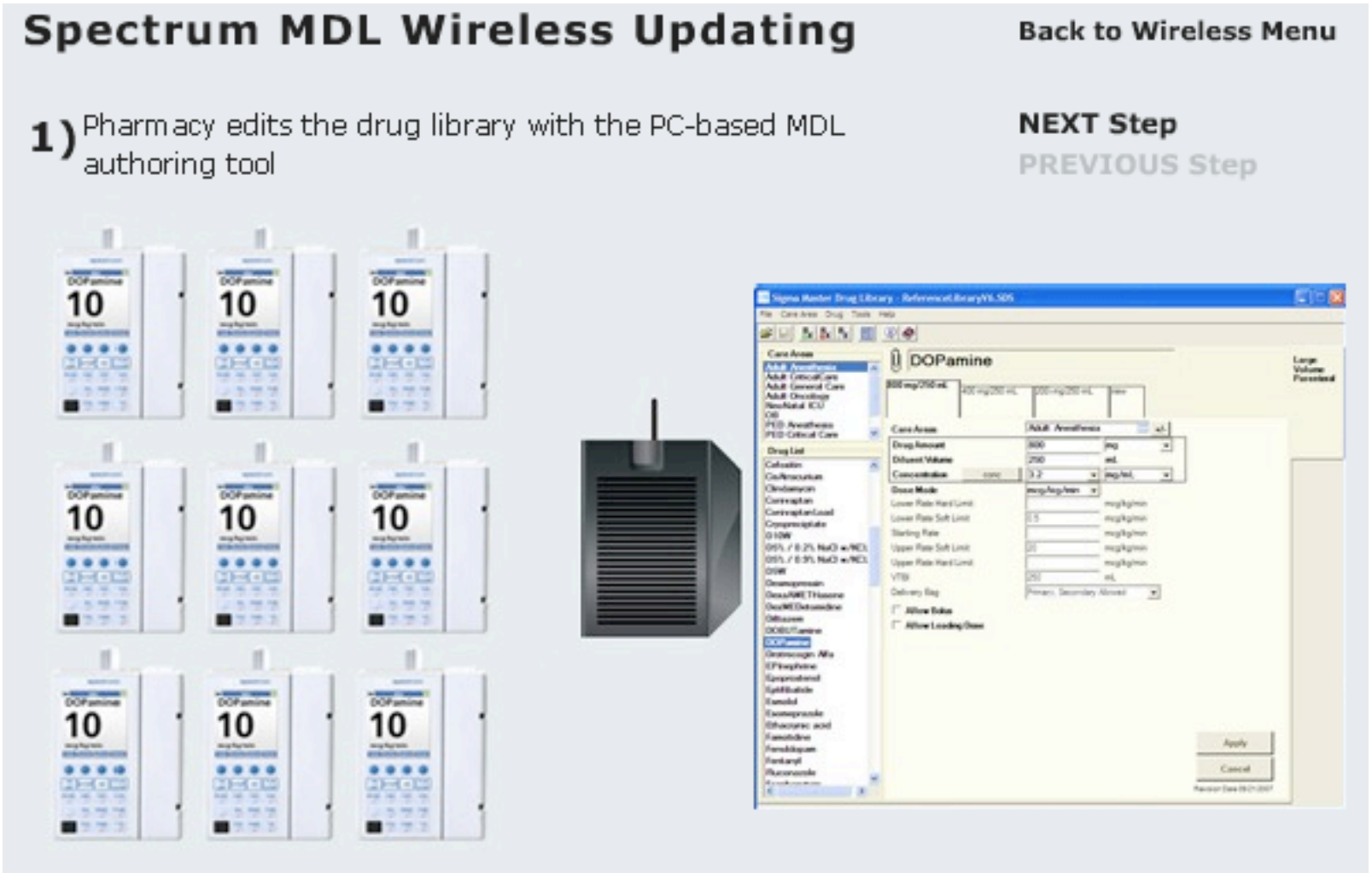
Timeline

- Implemented Phase I
  - ~400 pumps to critical care locations
- Implemented Phase II
  - ~500 pumps to rest of inpatient and outpatient
  - Revised drug library 8/26/2009


0.75
mcg/kg/hr
NOREpinephrine
10
mcg/min
EPINEPHrine
2.5
mcg/min
DOPamine
21


sigmaspectrum
Adult General Care
cefAZOLIN
200
mL/hr
review
options
titrate
ON OFF
SETUP
OK
RUN STOP
BASIC 0
ABC 1
DEF 2
GHI 3
JKL 4
MNO 5
PQR 6
STU 7
VWX 8
YZ 9

Wireless Network



Continuous Quality Improvement

Spectrum Wireless - CQI

Back to Wireless Menu

1. Clinician action (programming change, start or stop, etc.)
2. If the network or server is unavailable the pump will store the data, in non-volatile memory for at least 1 week, and send the data to the server the next time it connects
3. Pump sends data about each event to server in real-time
4. Server stores all pump data in a database for ready access to data from all the pumps
5. User queries database to create CQI report

Soft Limits Alerts

- **Double confirmation =** a number exceeding a soft limit is selected. The programmer receives an alert and rather than changing the entry, continues with the original programming – confirms the selected number a second time.

- **Revised programming =** When an alert is received by the programmer that a soft limit has been exceeded and the programmer "pulls back" and reprograms the pump – likely a near miss

Hard Limits Alerts

- **Revised programming =** When an alert is received by the programmer that a hard limit has been exceeded and the programmer reprograms the pump – likely a near miss

Pump Fleet Utilization

- % of pumps that have been in use at any point during the month
  - Jan 85% (Phase I)
  - Feb 90%
  - Mar 90%
  - Apr 90%
  - May 91%
  - Jun 90%
  - Jul 96% (Phase II)
  - Aug 97%
  - Sept 95%

Use of Drug Error Prevention Mode

- Jan 92% (Phase I)
- Feb 95%
- Mar 96%
- Apr 96%
- May 97%
- Jun 97%
- Jul 96% (Phase II)
- Aug 95%
- Sep 95%

Soft and Hard Limit Alerts

- One Month reviewed 12,274 uses
- 1,154 total soft limit alerts
  - 1,027 double confirmations:
    - where the clinician proceeded with original programming
  - 80 “pull backs”:
    - revised programming where the clinician changed the original entry based on the alert
- 588 hard stops:
    - revised programming mandates the clinician change the original entry based on the alert

Drugs Involved in Soft Limit Pullbacks

- Maintenance IV – 18 (23%)
- Propofol – 10 (13%)
- Midazolam – 6 (8%)
- TPN – 5 (6%)
- Hydromorphone – 4 (5%)
- Phenylephrine – 4 (5%)
- Cefazolin – 4 (5%)
- Insulin – 3 (4%)
- Phenylephrine – 3 (4%)
- Norepinephrine – 3 (4%)

Drugs Involved in Hard Limit Alerts

- fentanyl (77) 13%
- maintenance IV (46) 8%
- heparin (40) 7%
- Insulin (36) 6%
- vancomycin (31) 5%
- furosemide (27) 5%
- pip/tazobactam (23) 4%
- dexmedetomidine (21) 4%
- magnesium sulfate (20) 3%
- hydromorphone (19) 3%
- propofol (19) 3%
- midazolam (15) 3%
- potassium chloride (15) 3%
- ondansetron (14) 2%
- oxytocin (12) 2%
- pot phosphate (9) 2%
- TPN (9) 2%
- azithromycin (8) 1%
- cefazolin (7) 1%

Fentanyl Error

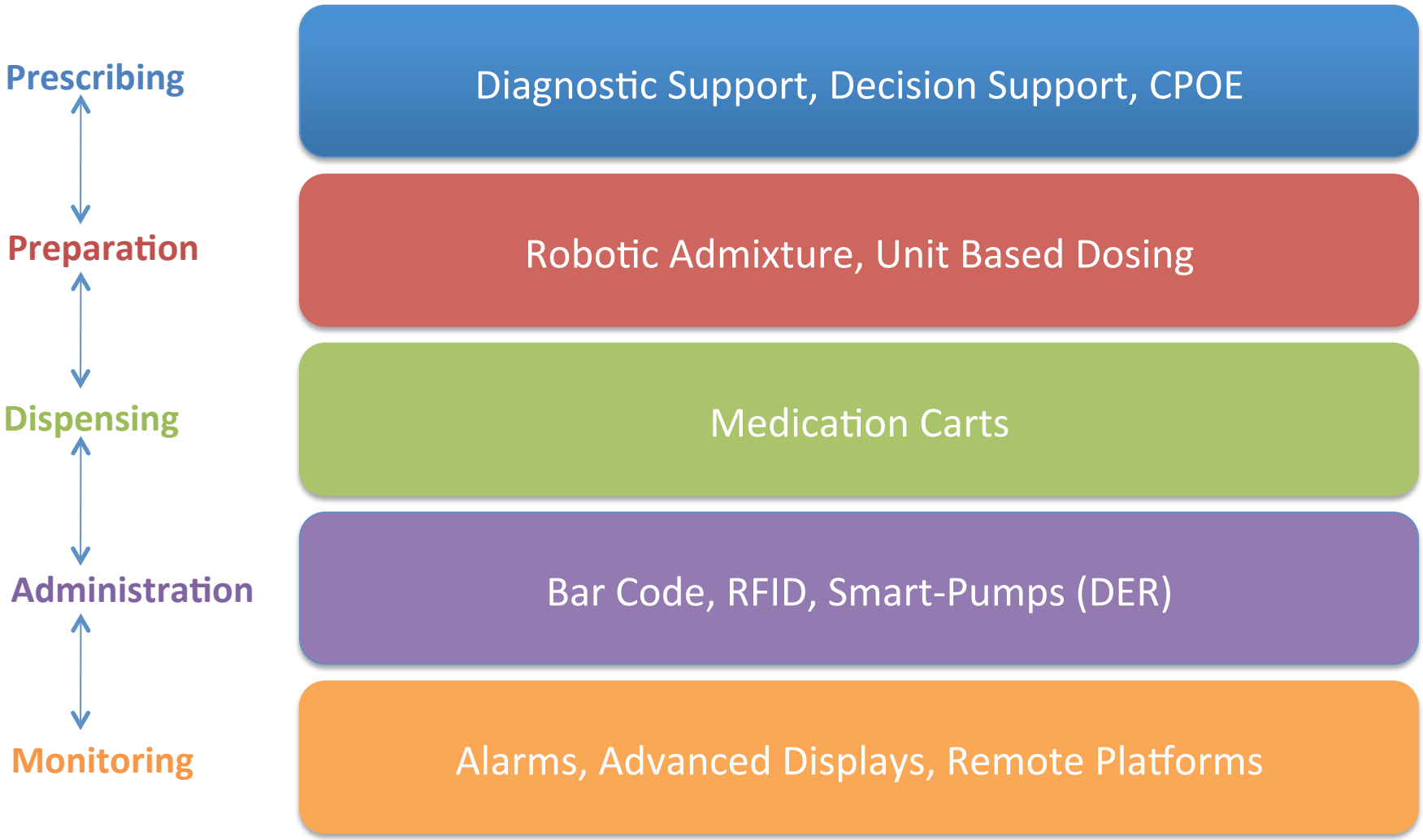
S: 2500 mcg (50mL) Fentanyl administered over 30 minutes

B: Patient ordered to receive 300 mcg/hr Fentanyl infusion (2500mcg/50mL) . Infusion completed requiring a new bag to be hung a the same time an antibiotic was to be administered.

A: The antibiotic was connected appropriately to the correct tubing/device, but the RN programmed the antibiotic to be administered as a secondary infusion into the device infusing Fentanyl.

R: Change Fentanyl (and all other dose sensitive high risk drugs) allowing the infusion to be administered as either a primary or secondary infusion to primary only.

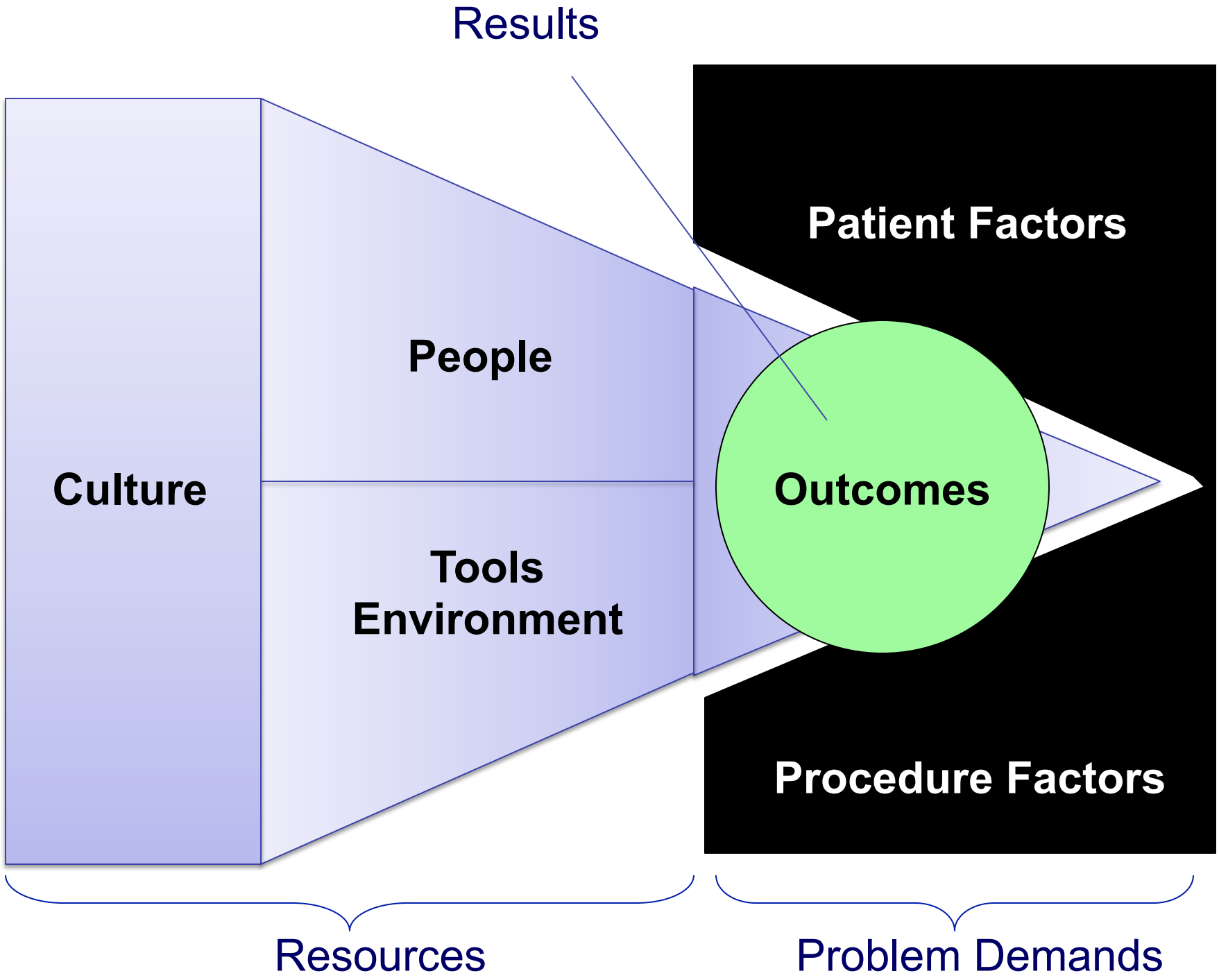
Summary: Safe Medication Processes



Conclusion

- Medications represent major source of risk and preventable harm for patients in healthcare AND in peri-operative setting
- Practice of Anesthesiology carries special risks due to tempo, consequence and lagging instrumentation
- Technology is not enough, safety requires

People + Systems + Org Culture


Results
Patient Factors
People
Culture
Outcomes
Tools
Environment
Procedure Factors
Resources
Problem Demands

Culture of Quality and Patient Safety

"A just culture and transparent culture, where no one person is punished for making or reporting errors, while at the same time everyone is held accountable. A culture of mindfulness and vigilance where every individual feels personally responsible for practicing safely and for reducing hazards. A culture where everyone feels valued and respected, but processes are standardized and simplified, teamwork trumps autonomy, and quality & safety takes precedence over productivity."

–Adapted from Lucian Leape 2008

Anesthesia Patient Safety

"Anesthesia is the only system in healthcare that begins to approach the vaunted "six sigma" level of perfection that other industries strive for."

Lucian Leape MD

What practices will most improve safety?

JAMA, July 2002