CNNAR, APRIL 2007

Regulating in the Regulatory Society

Frances Picherack

Petrine Consulting Inc.

The Regulatory Society

- Regulation is main form of governance
- Broad regulatory model, includes economic, political and social arenas
- Increased number, complexity and players
- Self-regulation just one part of larger integrated policy arena
- Regulatory focus on accountability, transparency and trust

Braithwaite, Jordanna, Levi-Fahr

Meta-Regulation

- Self- regulation part of a multi-sector regulatory regime of several layers and player

- Government *steers* regulatory policy *boat*

- Integrating oversight agencies; (procedural fairness, privacy, competition) that regulate the regulators

- Self-regulating industries and professionals *row* the regulatory *oars* through various instruments

Osborne and Gaebler

Meta-regulation cont'd

- Increased regulation not just for economic reasons, or policy expertise reasons, but primarily to nurture an eroding public trust of social institutions and regulators *(Baldwin, Scott, Hood)*

- Focus on accountability and trust demands new attention to monitoring, compliance and enforcement for self-regulators *(Downie et al, Parker, Canadian Patient Safety Institute)*

Meta-regulation cont'd

- Intersection of two trends, legalization of politics, non-judicial methods of accountability
- "Hard law and soft law"
- Regulatory Oversight embedded
- Non-exclusivity, competition
- Stakeholder Consultation; Collaboration
- Regulating the regulated (Parker)

Today's Regulatory Environment

- Increasingly competitive and collaborative regulatory and legal environment that enables competition and innovation

- Interdependence; jurisdictions, players

- Privacy principles and compliance embedded; an example of meta-regulation

- Trade and Mobility Agreements:TILMA

- Competition Act, Bureau, Compliance

Privacy Regulation Embedded

"From Trust us to Show Us"

Oversight and Procedural Rules

- PERSONAL INTEGRITY
- PERSONAL DIGNITY

"Any time you are talking accountability or transparency with respect to information, you must discuss privacy" Enright, 2006

Privacy Principles

- **Accountability, identifying purpose, consent**
- **Limiting collection**
- **Limiting use, disclosure, retention**
- Accuracy
- Safeguards, openness, individual access
- **Challenging Compliance**

Privacy Builds Trust

To build and maintain trust, Privacy should be viewed as a **governance** issue, not just a *compliance* issue

A. Cavoukian, Ont. Privacy Commissioner, 2003

Competition

- Federal statute
- All sectors of the economy
- "To maintain and encourage competition to promote the efficiency of the Canadian economy and to provide consumers with competitive prices and product choices."

Competition Bureau Website

Competition Bureau

- "Competition is the best way to ensure resources are allocated efficiently, innovation is rewarded, and consumers are offered the widest choice of high quality goods and services at competitive prices."

  Competition Bureau

- Enforcement: judicial and quasijudicial

- Promote competition

Health Professions Regulation

- Regime broader than self-regulation
- Current focus is on safety and trust
- Laws for patient safety regulation "siloed"
- Adverse events and patterns show need for better monitoring and prevention
- Patient safety law needs reform to facilitate better patient safety regulation

Downie et al, Canadian Patient Safety Insititue

Public Health Legislation

Charter of Rights and Freedoms

Health Professions Legislation

Privacy Legislation

Trade and Immigration Law

Health Services Legislation

Administrative Law

Insurance / Contract Law

Registration, Permits

Standards

Compliance Monitoring

Complaints Resolution or Hearings Tribunals

Minister's Office, Legislature

Ombudsman, Competition Bureau

Privacy , Fairness Commissioner

The Courts

Health Professions Regulatory Regime

Patient Safety Focus

- Emerging area of meta-regulation and increased oversight
- Accountability and transparency focusing on tracking, disclosure of patterns of error, in adverse events or new prevalence such as system-acquired infections
- Provincial disclosure laws changing
- Root Cause Analysis: systems approach
- Professional regulation only one factor

Patient Safety Law: From Silos to Systems

Final Report

Jocelyn Downie
William Lahey
Don Ford
Elaine Gibson
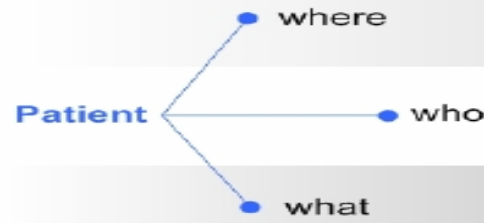Mary Thomson
Tom Ward
Fiona McDonald
Alison Shea

March 31, 2006

Patient Safety Law Matrix

Preventing
- Patient
  - where
  - who
  - what

Event(s)

Knowing About
- Discovery
  - complaints
  - disclosure
  - data gathering & analysis
- Inquiry
  - public inquiries
  - regulatory agencies
  - coroner
  - court
    - civil
    - criminal
  - institutional mechanisms
  - independent complaints body

Outcome(s)

Responding
- Individual
  - provider
    - institution/organization
    - individual
  - patient
- Systemic

Health Canada. Patient Safety Law: From Silos to Systems March 2006
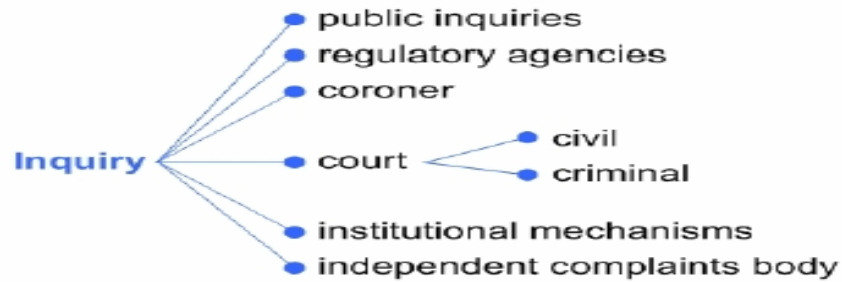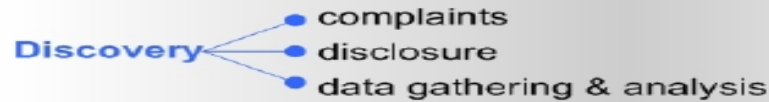
Patient Safety Law Matrix Applied

	Canadian legal framework	Sample Gaps & Weaknesses	Sample Possible Solutions
Preventing	**Patient** — where	underregulated contexts	national standards and certification
	who	unregulated health care professionals	Health and Disability Commissioner
	what	underregulated drugs and devices	clinical trial quality oversight

Event(s)

	Canadian legal framework	Sample Gaps & Weaknesses	Sample Possible Solutions
Knowing About	**Discovery** — complaints / disclosure / data gathering & analysis	underreporting of adverse events	mandatory adverse event reporting systems
	Inquiry — public inquiries / regulatory agencies / coroner / court — civil, criminal / institutional mechanisms / independent complaints body	information sharing across inquiry processes	harmonization of fatality legislation

Outcome(s)

	Canadian legal framework	Sample Gaps & Weaknesses	Sample Possible Solutions
Responding	**Individual** — provider — institution/organization, individual / patient	need for outcomes with a systems perspective to drive improvements in system while maintaining individual accountability where appropriate	coordinated model for organizing compensation system, adverse event reporting system and complaints/disciplinary system
	Systemic		

Adverse Event Reporting

- Tied to facilities, teams, practitioners
- If unregulated facility, may go unreported
- New normative arrangements for facilities or practice setting monitoring and enforcement required
- Recent provincial legislative changes to facilitate prevention, disclosure and resolution
- Monitoring "sharp" and "blunt" end of system

Canadian Patient Safety Institute

March 2006

CANADIAN ROOT CAUSE ANALYSIS FRAMEWORK

A tool for identifying and addressing the root causes of critical incidents in healthcare

Canadian
Patient
Safety
Institute

Institut
canadien
pour la sécurité
des patients

cpsi·icsp

Saskatchewan
Health

ismp
CANADA

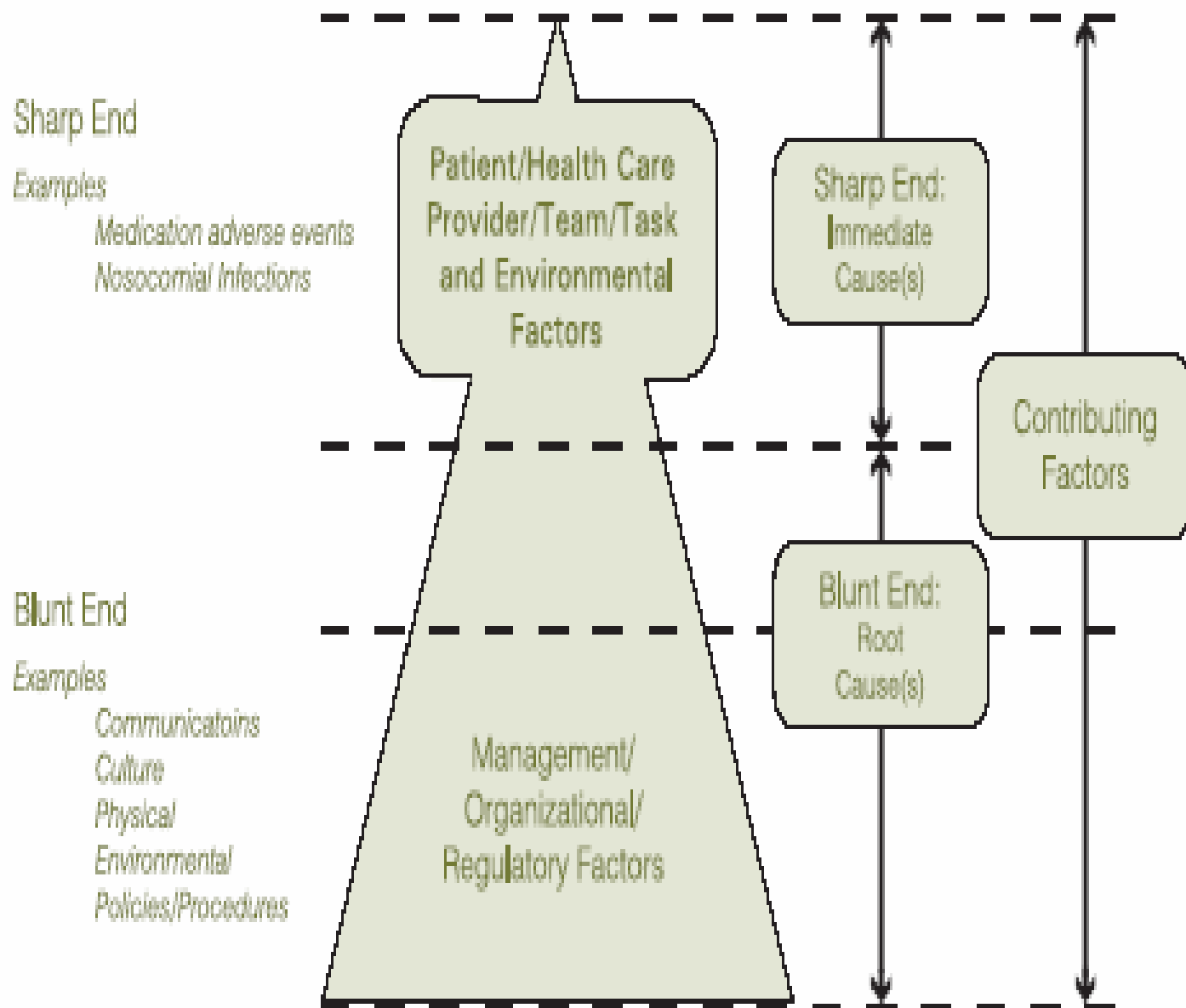# Figure 1: Adapted from the NHS Report - Doing Less Harm, 2001[15]

Sharp End

Examples

    Medication adverse events

    Nosocomial Infections

Blunt End

Examples

    Communicatoins

    Culture

    Physical

    Environmental

    Policies/Procedures

Patient/Health Care Provider/Team/Task and Environmental Factors

Management/ Organizational/ Regulatory Factors

Sharp End: Immediate Cause(s)

Blunt End: Root Cause(s)

Contributing Factors

Figure 3: Conceptual Model of Effective System Change Strategy

Measurement

Reliable, Valid, Cost Effective &
Accepted Timely

Culture

Non-blaming, To err is human,
Learning, Leadership

**System Tools &
Change Strategies**

Improvement, System Thinking,
Redesign Processes, Rapid Cycle,
Near Miss

Source: Baker, G.R. & Norton, P.
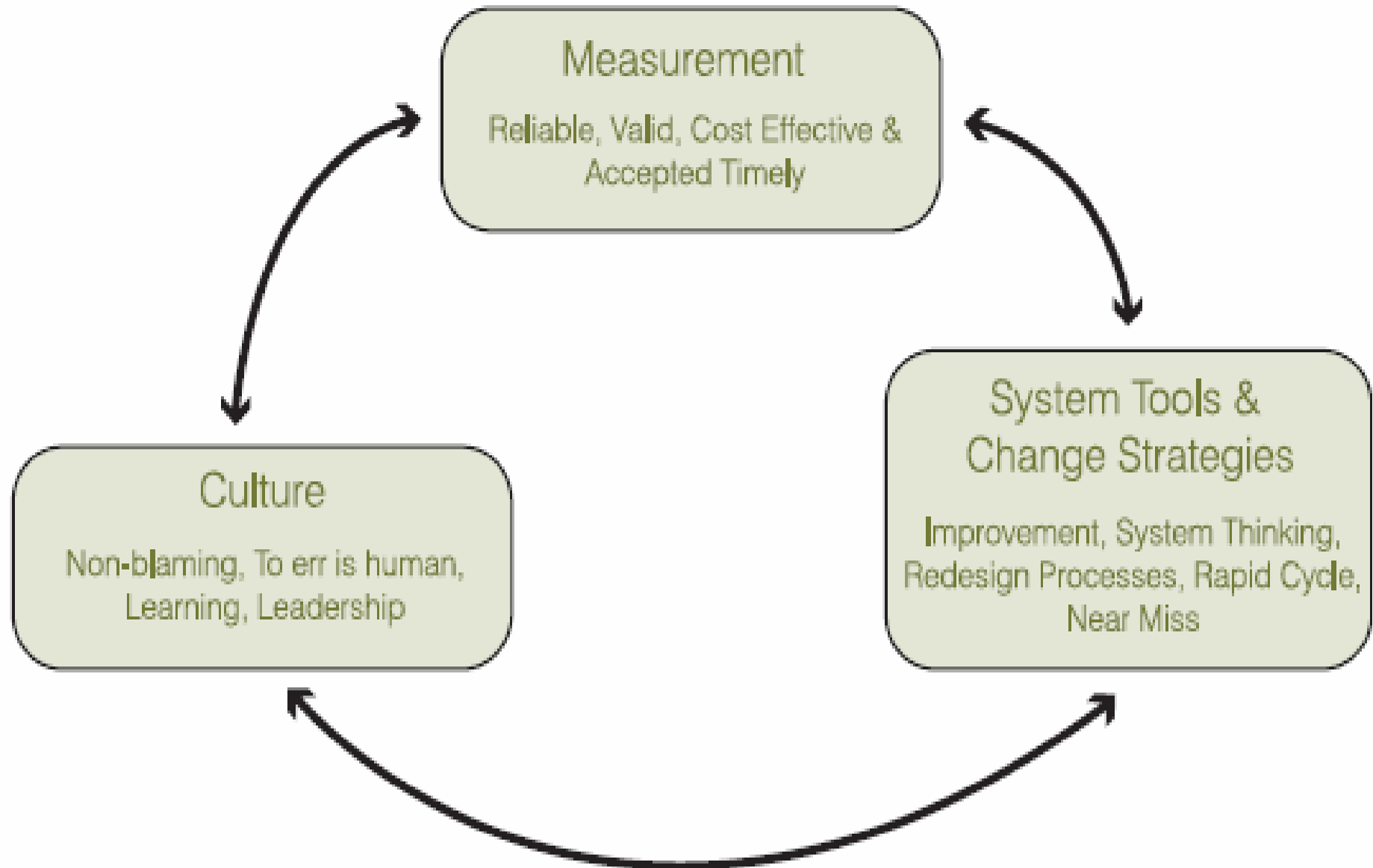
The Next Wave (embedding)

- Fundamental and Distributive Justice

- Meta-regulation of SAFETY

- Adverse Event Reporting: Disclosure

- Root Cause Analysis Framework

- Beyond individual: teams, facilities

- Ongoing embedding of oversight requirements into self-regulation (e.g. infection control)

- Role of regulators in best practices for safety

Best Practices

Searchvb.com

A BEST PRACTICE IS A TECHNIQUE OR TECHNOLOGY, THAT THROUGH EXPERIENCE AND RESEARCH, HAS PROVEN TO RELIABLY LEAD TO A DESIREABLE RESULT.

Shawna Mireau, Law Now; March 2007 (Field LLP)

Summary: Insight

- Regulation a principal form of governance
- Integrated regulatory regime, vertically and horizontally; "Meta-regulation"
- "Regulation of the regulators" embedded
- Several oversight agencies: privacy ombudsman, competition, fairness, the "new" public health
- Transparency, Accountability: TRUST

Summary: Foresight

- Safety across all regulators, sectors
- Primacy of *public* safety: *public* health
- Compliance Monitoring and Enforcement
- Enforceable standards (not just principles)
- Oversight scrutiny of competition and fairness in registration, mobility and trade
- Focus on regulator competencies
- Best practices for regulatory purposes

Thank you

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