

Managing for Ethical Health Care Delivery

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A range of patient interactions

3

Health
Professions
Training

1

Health Care Operations

2

Epidemiologic Research

(Observational; population-level)

Non-identifiable
patient data

Identifiable
patient data
(usually for
record linkage)

Direct patient
contact

Experimental Research

Randomized
treatments

Experimental
treatments

Core ethical principles of

- ◆ *Autonomy*
- ◆ *Beneficence*
- ◆ *Non-maleficence*
- ◆ *Justice*

*cross all categories of activities and
apply equally within each*

Care delivery organizations

are required, by

- ◆ ***professional standards***
- ◆ ***explicit regulatory requirements***
(e.g., JCAHO, CMS)

to oversee and manage ethical practice in all areas, through

- ◆ ***quality assurance*** *and*
- ◆ ***quality improvement***

Quality assurance

*uses implicit or explicit criteria to assess ethical conduct and outcome performance **one case at a time***

(case-by-case peer review)

Examples include:

- ◆ **credentialing and privileging of health professionals**
- ◆ **surgical case review**
- ◆ **mortality and morbidity conferences**
- ◆ **infection control**
- ◆ **informed consent** *(patient autonomy) on clinic or hospital admission for care delivery in general, with treatment-specific informed consent for high risk surgical procedures or medical interventions*

Quality improvement

tracks empiric care delivery performance (*intermediate and final outcomes*) **across groups of similar cases** (*process-level peer review*).

- ◆ **Traditional belief that an ethical clinician-patient relationship guarantees "best care" is scientifically untenable in today's complex care delivery environment** (*implications for ethical review*).
- ◆ **Often called "clinical epidemiology"** -- *uses epidemiologic measurement methods.*
- ◆ **Attempts to systematically implement evidence-based best practice** (*Level I, II, or III evidence*).
- ◆ **Works at the level of open-loop systems** (*doesn't step between a clinician and a patient*) -- *the care delivery physical and information environment, combined with the complex social structures made up of self-aware, choice making, health professionals.*
- ◆ **defined in HIPAA as part of "health care operations"** (§164.501)

Care delivery falls short of potential

- 1. Well-documented, massive, variation in practices** (beyond the level where it is even remotely possible that all patients are receiving good care)
- 2. High rates of inappropriate care** (2 - 32% of all care delivered, depending on specific condition examined)
- 3. Unacceptable rates of preventable care-associated patient injury and death**
- 4. A striking inability to "do what we know works"**
- 5. Huge amounts of waste** (>45%, by best recent measures), **spiraling prices, and limited access** (46.6 million uninsured Americans, increasing rates of under-insured, employers exiting the insurance market, medical tourism)

Evidence-based best practice

I. At least one randomized controlled trial

II-1. Controlled trials without randomization
(quasi-experimental designs)

II-2. Cohort or case-control studies

II-3. Multiple time series *(observational studies)* **or dramatic results**

III. Agreement among a group of respected authorities using formal consensus methods

IV. Personal anecdote *("in my experience")*

HIPAA: §164.501 - Definitions

Health care operations means any of the following activities of the covered entity to the extent that the activities are related to covered functions:

(1) Conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines, provided that the obtaining of generalizable knowledge is not the primary purpose of any studies resulting from such activities; population-based activities relating to improving health or reducing health care costs, protocol development, case management and care coordination, contacting of health care providers and patients with information about treatment alternatives; and related functions that do not include treatment;

(2) Reviewing the competence or qualifications of health care professionals, evaluating practitioner and provider performance, health plan performance, conducting training programs in which students, trainees, or practitioners in areas of health care learn under supervision to practice or improve their skills as health care providers, training of non-health care professionals, accreditation, certification, licensing, or credentialing activities; ...

QI: Part of health care operations

3

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Health Care Operations

Direct patient care

QA (individual level)
- surgical case review
- infection control
- M&M conference
- credentialing/privileging
- etc.

QI (process mgmt; population level)
- planning
- evaluation

Population-level care delivery

Billing

System planning

- location, level, and organization of health services

2

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Experimental treatments

Two oversight tools

- ◆ **Prevent controls** (*e.g., IRBs, some financial controls*)
- ◆ **Detect controls** (*enforceable policy*)

Prevent controls

- ◆ *Independent review of proposed actions before those actions are executed.*
- ◆ *Only approved actions may proceed.*
- ◆ *Oversight group also monitors execution, to assure that all agreed actions are followed.*
- ◆ *Requires large time and effort investment by both the oversight group and by those applying for approval.*
- ◆ *Tends to suppress the activity* ("the process is the punishment").
- ◆ *Generally reserved for very high risk, low volume activities that are not time critical.*

Detect controls

- ◆ **Train everyone regarding ethical conduct** *(including a responsibility to report any potential unethical conduct) -- retrain regularly*
- ◆ **Commit everyone in writing** *-- and re-commit regularly*
- ◆ **Monitor for potential violations**
- ◆ **Investigate and confirm actual violations**
- ◆ **Take appropriate action** *(against individuals, to tighten detect control systems, and to improve care delivery systems)*
- ◆ **Work best in high volume, time-sensitive areas** *(much lower real-time burden)*
- ◆ **Very effective** *(in Intermountain, about 40 investigations and 2 - 4 actions per month)*
- ◆ **The mainstay of care delivery oversight**
(the main method used by OHRP to execute its regulatory mission)

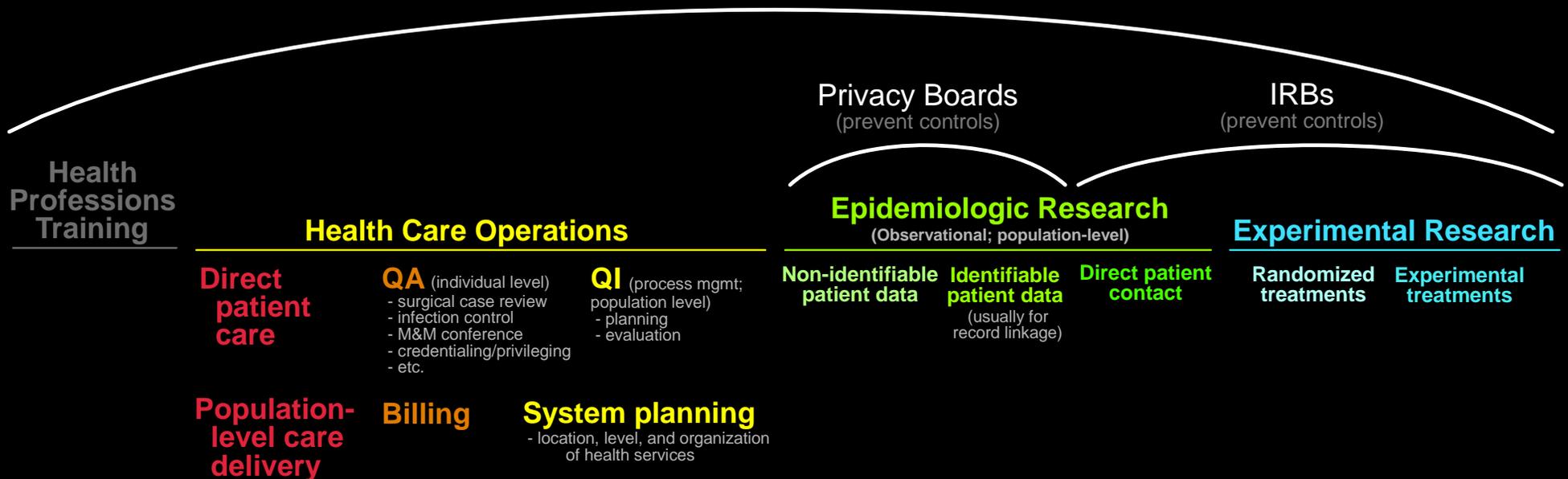
Oversight with enforceable policy

Ethical Principles

Autonomy
Beneficence
Non-maleficence
Justice



Enforceable policy
(detect controls)



Summary

Quality improvement is primarily about care delivery management, not the creation of new scientific knowledge. Both must be done ethically, and both tend to produce generalizable knowledge, but ethical management is done in ways profoundly different than ethical research because the need to decide, innovate, and improve is so constant and imperative in management.