

Background principles

- Intermountain Healthcare's (IH) employees and associated **health professionals interact with patients through 3 general classes of activities** (Figure 1): **direct patient care, health professions training, and research.**

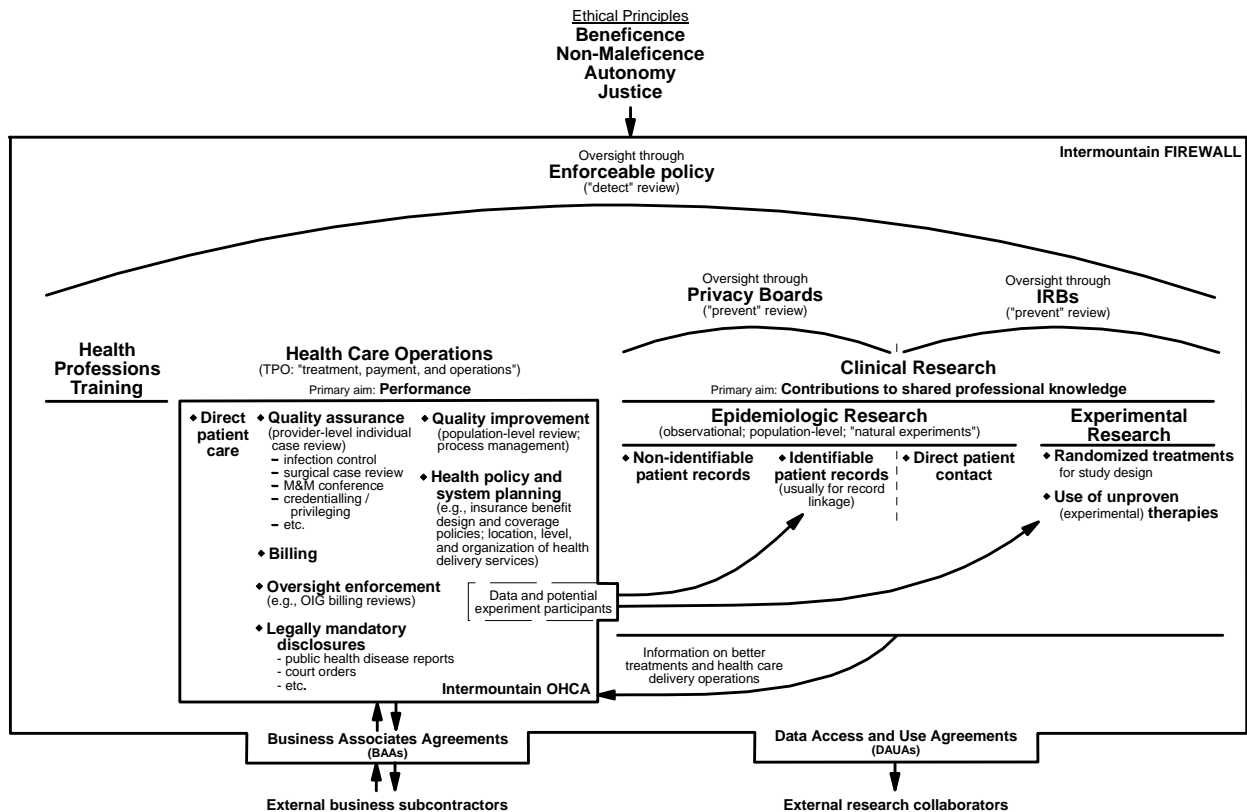


Figure 1. Classes of activities under which care delivery groups interact with patients. The same ethical principles govern patient interactions across the entire continuum.

- The IH team's **ethical obligations to patients cross all classes of activities, and apply equally within each.** Those ethical obligations include (AMA Code of Medical Ethics):
 - a. patients' health needs come before any other end or goal (fiduciary trust)
 - b. knowledge:
 - (1) knowledge application (practice) and maintenance (e.g., CME, journals, etc., so each clinician is prepared to offer "best knowledge" to each patient);
 - (2) extending the professions' knowledge ahead in time, so that future generations can benefit (teaching); and
 - (3) improving the professions' shared knowledge base (research)
 - c. professional autonomy (a social contract between the healing professions, as groups, and society): health professionals cross-evaluate to insure that any patient, approaching any duly licensed and recognized health professional, can be assured of very high level of fiduciary trust and knowledge competence.

A set of ethical principles summarizes and extends health professionals' obligations toward each patient (Hastings report):

1. autonomy
2. beneficence
3. non-maleficence
4. justice

- Risks associated with ethical failures fall into 2 broad categories:
 1. risks to privacy and confidentiality
 2. risks to mental or physical health
- An extensive body of research demonstrates that (1) **in terms of health benefits to patients and care-associated harms, health care delivery falls far short of its theoretic potential (the quality chasm)**; that (2) it is possible to close that gap; and (3) that the largest opportunities for improvement comes at the level of systems, built on a foundation of personal professional excellence (IOM Chasm report). Closing the quality gap resides far more in the consistent application of existing biomedical knowledge, than in the generation of new generalizable knowledge.

Under the principles of beneficence and non-maleficence, **health care delivery organizations have an ethical obligation to close the performance gap**. From the patient perspective, risks arising from the performance gap often outweigh other potential risks (Hastings report).

(In other words: The belief that an ethically-founded clinician-patient relationship guarantees best care is not scientifically tenable in today's complex care delivery environment (Eddy). Ethical analysis therefore requires careful evaluation of all alternatives, not just the isolated ethics of a proposed project. The current controversy over the Michigan Hospital Association central line infection control effort is a good example of this.)

- In line with the ethical requirement outlined above, **health care delivery organizations have explicit legal and regulatory requirements to monitor and manage care delivery systems to maximize performance**:
 1. 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

2. **Quality improvement practice (as opposed to quality improvement research) tracks empiric care delivery performance across groups of similar cases (process-level peer review).** It is sometimes called “clinical epidemiology,” because it uses epidemiologic measurement tools for that purpose.

Epistemology (the theory of knowledge) distinguishes “knowledge that” (e.g., the tensile strength and load bearing capacity of steel girders) from “knowledge how” (e.g., to use steel girders to build a bridge). Traditional medical research and its attendant methods (the biomedical model) focus on “knowledge that.” Quality improvement concentrates on “knowledge how.” It functions at the level of systems – the care delivery physical and information environment, as well as the complex social structures, made up of self-aware, choice making, health professionals, by which care delivery takes place (Davidoff). It attempts to implement evidence-based best treatment,^{*} rather than to test the relative efficacy of alternative treatments. In some instances, evidence of best practice is so strong that organizations can reasonably demand compliance with specific care delivery practices (e.g., sterile technique during surgical procedures). Most quality improvement activities, however, are “open loop” – they explicitly encourage practitioners to vary based upon individual patient needs (ref: “shared baselines,” Practice-Based Learning and Improvement, Chapter 7). **Quality improvement’s system-level interventions thus do not interrupt the individual clinician’s ethical obligations to a particular patient.**

An engineer must address local “knowledge how” constraints when applying “knowledge that” to build a bridge. As a result, individual bridges differ from one another, even though the same scientific “knowledge that” applies across all bridges. Similarly, quality improvement must address a series of system-level, unique local constraints, including resources and culture. Reflecting those unique local circumstances, quality improvement efforts addressing a common topic usually show local variation. What works in one place usually will not work in another place without modification (Rogers – Diffusion of Innovation).

Successful implementation of best practice thus requires careful performance measurement, analysis, feedback, and systems-level correction. Without such quality management systems in place, patients have no assurance of high quality care delivery.

Both quality assurance and quality improvement are direct extensions of the concept of “practice” – clinical professionals’ ethical commitment to track the care they deliver to individual patients, and the outcomes that result, with the aim to improve care to future patients. To that end, clinicians working in a shared environment (e.g.,

^{*} Identification of “best practice” accepts 3 general levels of evidence: (I) studies using randomized controlled trial designs; (2) observational designs, including (II-1) prospective non-randomized controlled trials (quasi-experiments), (II-2) cohort and case-control designs, and (II-3) multiple time series studies, or a single time series study with very dramatic results; (3) agreement among a group of respected authorities using formal consensus methods (Lawrence & Mickalide; Natl Q Forum SFB report)

within a specialty department in a hospital) routinely share patient care experiences (“over the back fence” consultations). Many care groups recognize that subjective recall is not a reliable foundation to assess their own treatment experience, and so move toward explicit measurement. In other words, quality improvement practice should happen on a very broad scale at the level of individual physicians and nurses monitoring and improving their own personal practices; extending up to practice groups working together; and to health care delivery organizations creating a “shared learning” environment, focused on execution, within their walls. **Quality improvement practice is a high volume, time sensitive undertaking directly tied to routine patient care.**

HIPAA regulations identify both quality assurance and quality improvement activities as part of “health care operations” (a.k.a. “treatment, payment, and operations,” or TPO) (§164.501).

Health care delivery oversight agencies (e.g., CMS and the Joint Commission) require that care delivery groups put in place both quality assurance and quality improvement (process-level performance measurement and management) systems. Beyond care delivery oversight, many collaborative professional efforts track care delivery performance for specific subsystems, with the aim to implement effective care (e.g., the American College of Surgeons NSQIP program; Cystic Fibrosis Foundation activities; the Society for Thoracic Surgery’s national cardiac surgery data base; the international Vermont-Oxford newborn ICU tracking system).

When defects in care are found using either quality assurance or quality improvement methods, care delivery organizations are required to act to correct those defects. Appropriate corrections may include actions regarding individual health professionals (e.g., additional training; better oversight; decertification), and changes to care delivery systems (e.g., changes to policy; changes to physical layout; changes to data systems).

- **Participation in the ethical oversight of care delivery (quality assurance and quality improvement) is not optional, either for care delivery organizations or for those organizations’ staff and allied health professionals.**
- Organizations have 2 general mechanisms to oversee and manage ethical patient interactions:
 1. Prevent controls involve independent review of proposed actions before those actions are executed (e.g., IRBs). Only approved actions may proceed. The oversight group also monitors execution, to assure that all agreed actions are followed.

Prevent controls require a large investment in time and effort by both the oversight group and by those applying for approval. Execution of prevent controls often introduces significant time delays. **Prevent controls (IRBs) are**

therefore generally reserved for very high risk, low volume, activities that are not time critical.

2. Detect controls (enforceable policy) establish a standard for ethical behavior (including reporting of potential unethical behavior); train and regularly retrain all employees and associated health professionals in the standard; commit and regularly recommit, in writing, all employees and associated health professionals to follow the standard; monitor for potential ethical violations (through electronic case review, structured manual case review, and alerts from professionals or patients); review all potential violations, to confirm actual violations; then respond appropriately to violators, and modify the detect controls and other care delivery environment factors to increase future effectiveness (apply sanctions grid to the individual employees / health professionals involved; regularly review and appropriately modify detect control policies, based on violations; update system of care delivery)

Detect controls work best in high volume, time sensitive areas. They impose a much lower real-time burden than do prevent controls.

(Interesting fact: OHRP's oversight of IRBs is itself a detect control system)

Detect control systems are the mainstay of care delivery oversight in the U.S. health system. For example, health care organizations implement informed consent (the ethical principle of patient autonomy) through detect controls: They implement policies whereby each patient must sign a general consent upon entry into a hospital or clinic. High-risk medical or surgical treatments require additional, specific, signed and witnessed informed consents. The care delivery organization routinely monitors to confirm that informed consent policies are followed for every patient. The Joint Commission (or some other oversight agency) regularly reviews the care delivery organization's informed consent system. The malpractice tort system assesses claims of egregious violations, taking action at both the level of individual practitioners and care delivery organizations for actions judged to be ethically inappropriate.

Detect control systems are effective. For example, IH averages about 40 investigations and 2 – 4 corrective actions per month arising from detect control systems (most in the area patient privacy and confidentiality). Over the past 20 years, essentially all actions responding to potential ethical breaches inside IH have arisen from detect control systems.

Comprehensive management systems use prevent controls and detect controls together, as an interlocking whole.

- A Hastings Ethics Center analysis determined that it is not possible to consistently identify “research” based on a project's stated intent, the measurement and analytic tools used within the project, funding sources, or whether or not the project's results were published. The key rule for ethical oversight is a potential or actual conflict of

interest that might cause a health professional or care delivery organization to place some other value above an individual patient's health care needs (e.g., academic production for career advancement, in terms of publications or grants; or, in other settings, direct or indirect financial payment). This approach applies across the full continuum of health care delivery activities shown in Figure 1 (Hastings report).

- Useful “knowledge how” often arises from careful observation of operations. For example, while there is no single correct way to build a bridge, an engineer can learn a very great deal by examining well-built bridges. Failed designs sometimes give even deeper insights. Within health care, observational studies (e.g., case series) have made many significant contributions to clinical knowledge while informing the focus and direction of experimental research. Such follow-on observational studies differ from experimental research in that there are no associated risks to physical or mental health.

Care delivery organizations functionally separate ethical oversight of the care itself from the ethical oversight of data compilation and analysis in subsequent observational assessments. Ethical oversight of observational analysis focuses on risks to privacy and confidentiality, often through the application of standard policies (“expedited review”). Sharing the results of quality assurance or quality improvement practice typically falls into this observational category.

(draft) Policy Framework

- IH oversees the ethical conduct of general quality assurance and quality improvement practice through a system of robust detect controls.
 - Legitimate quality improvement practice activities attempt to implement best practice, based on Level I, II, or III evidence (in other words, to qualify as quality improvement, a change initiative must offer “best care” to each patient managed under the initiative).
 - Any project that involves either unproven therapies (no existing Level I, II, or III evidence base), or that compares competing therapeutic approaches (for example, randomizes among treatments) is by definition research, not quality improvement.
 - Except in some limited circumstances where the evidence and medical consensus support mandatory care delivery requirements, quality improvement practice leaves clinicians free to vary based on individual patient needs (open loop, shared baseline, care, which doesn't interrupt clinicians' ethical obligations to each patient).
 - Quality improvement activities should not add substantial direct or indirect burden to patients (e.g., data collection or other expense beyond the cost of routine best care)
- Projects that compare alternative evidence-based best practice implementation strategies constitute a special class of “quality improvement comparative research.” Such projects should go through IH's prevent controls (IRB), but with special rules as to their appropriate ethical conduct based on the principles outlined above.

- IH should carefully distinguish care delivery management and improvement, from the publication of successful projects with an aim to share learning broadly, within the health professions.