Autonomy and Privacy in Clinical Laboratory Science Policy and Practice

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LEARNING OBJECTIVES

1. Summarize the tension between the ethical principles of autonomy and privacy in the clinical laboratory services delivery.
2. Explain the characteristics of limited data sets and de-identified data sets.
3. Discuss the nexus among informed consent, shared decision-making, and clinical decision support for the medical laboratory practitioner.
4. Identify federal regulations prescribing controls on human subjects research, patient/consumer privacy, and protected health information.

ABSTRACT

Rapid advancements in diagnostic technologies coupled with growth in testing options and choices mandate the development of evidence-based testing algorithms linked to the care paths of the major chronic diseases and health challenges encountered most frequently. As care paths are evaluated, patient/consumers become partners in healthcare delivery. Clinical laboratory scientists find themselves firmly embedded in both quality improvement and clinical research with an urgent need to translate clinical laboratory information into knowledge required by practitioners and patient/consumers alike. To implement this patient-centered care approach in clinical laboratory science, practitioners must understand their roles in (1) protecting patient/consumer autonomy in the healthcare informed consent process and (2) assuring patient/consumer privacy and confidentiality while blending quality improvement study findings with protected health information. A literature review, describing the current ethical environment, supports a consultative role for clinical laboratory scientists in the clinical decision-making process and suggests guidance for policy and practice regarding the principle of autonomy and its associated operational characteristics: informed consent and privacy.

ABBREVIATIONS: CDC – U.S. Centers for Disease Control and Prevention CDS – clinical decision support, CLS – clinical laboratory scientist(s)/clinical laboratory science, CLIA – Clinical Laboratory Improvement Amendments of 1988, EBP - evidence-based practice, HHS – U.S. Department of Health and Human Services, IRB – institutional review board, LDS – limited data set(s), PHI – protected health information, QI – quality improvement, TQM – total quality management

INDEX TERMS: Clinical decision support, Clinical ethics, Clinical laboratory science, Evidence-based practice, Health policy, Patient-centered care, Patient safety, Quality improvement,

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"Education has to be re-energized periodically in order to keep the speed of the mind and technical know-how up to the speed and needs of the rapidly increasing demands of the times…it is apparent that the processes of education that worked 45 years ago, or last year for that matter, are likely to become more or less ineffective, as happened to the horse and buggy"

-Lall G Montgomery, MD (Chair of the Board of Registry from 1940-1964, a Founding Fellow of College of American Pathologists, and past President of the American Society of Clinical Pathologists) address given to medical technologists at University of Vermont, 1966 as quoted in Fruchtl, 1968[1]

INTRODUCTION

Through the years, four principles have emerged defining the foundation of medical ethics and providing the framework for reflection on moral considerations:

(1) autonomy, (2) beneficence, (3) nonmaleficence, and (4) justice[1,2] The Hippocratic Oath, summarized as "[I will] use my power to help the sick to the best of my ability and judgment," represents the first expression of strict ethical concepts in medicine.[3] More thoroughly developed considerations of medical applications emerged with the publication of the first physician code of ethics by Percival in the early 19th century.[4] In the 20th century, medical ethics developed duality, "bioethics" and "clinical ethics," in parallel with research innovations, technology, computerization, ethics committees, and institutional review boards.[1]

In the 21st century, the principle of autonomy is emerging as a priority in clinical ethics, that is, ethical considerations in all medical practice. In 2001, the Institute of Medicine (IOM) released aims for redesign of the U.S. healthcare system that focus on increasing the value of services for consumers.[5] These six aims frame a redesigned healthcare system that is safe, effective, patient-centered, timely, efficient, and equitable. For measurement of progress toward achievement of these aims, the U.S. Department of Health and Human Services (HHS) has established a quality improvement strategy, National Strategy for Quality Improvement in Health Care, required by the Patient Protection and Affordable Care Act of 2010.[6] Compliance with HHS National Strategy requires documentation, evaluation, and improvement in six priority domains: clinical care, patient experience/engagement, population and community health, safety, care coordination, and cost/efficiency.[7] In 2014 (effective April 7), HHS amended Clinical Laboratory Improvement Amendments of 1988 (CLIA) and HIPAA Privacy regulations to specify that, upon requests of patient/consumers (or their personal representatives), laboratories subject to CLIA and HIPAA may provide patient/consumers and authorized designees with copies of completed test reports. Even if CLIA does not apply to the conduct of certain types of laboratory tests, HIPAA may still apply if the laboratory is a HIPPA-covered entity and the information requested is protected health information. The intention of the 2014 rule is to remove barriers for consumer access to test reports maintained by laboratories subject to or exempt from CLIA.[8]

The nexus of these developmental forces suggests a prominent laboratorian responsibility in services delivery for two legally-interpreted aspects of autonomy: informed consent for medical care and privacy of health information. Providing direct access to test results increases value of laboratory services to patients/consumers by preparing them to share in medical decision-making leading to a more complete informed consent for their healthcare. In balance with value, privacy of consumer health information must be protected. Clinical laboratory scientists (CLS) find themselves firmly embedded in both research and clinical care with an urgent need to translate clinical laboratory information into knowledge required, even demanded, by other healthcare practitioners and patient/consumers alike. The ethics of value-based quality improvement and clinical research will be discussed relative to the role of CLS in preserving patient autonomy during informed consent and protecting privacy in electronic health information exchange.

Ethical Considerations in Informed Consent and Privacy

In the emerging patient-centered model at the nexus of participatory decision-making and more completely understood informed consent, patient/consumers must be involved in healthcare decisions along with payers and providers and feel ownership of the process. Patient/consumers are the focus of the healthcare delivery system and assume pivotal roles in healthcare decision-making and quality improvement. As potential care paths are discussed, patient/consumers become partners in healthcare delivery and require complete, evidenced-based presentations of associated risks and benefits. The information compiled for and generated from care should be kept private yet readily available to and analyzed for them and their healthcare providers.

Ethical standards of good laboratory practice have traditionally guided practice decisions in specimen analysis, i.e., issues arising as part of the analytic phase of testing.[9] Professional behavior is guided by the CLS Code of Ethics which identifies three preeminent responsibilities: duty to the patient, duty to colleagues and the Profession, and duty to society.[10] However, rapidly expanding capabilities in diagnostic technologies and informatics have created a gap in ethical guidance for the Profession in both practice and policy regarding the principle of autonomy and its two associated operational characteristics, informed consent and

privacy. Now, principles of timely access to best evidence for all providers and confidentiality of protected health information (PHI) compete in the healthcare delivery process.

CLS Contributions to Informed Consent

CLS Informed Consent Policy Development

At the same time healthcare costs are increasing dramatically, quality and value of healthcare services are being called into question. Clinical laboratory information should be assessed by the degree of correlation with patient outcomes, clinical decision-making, and cost. The concept of "value-based healthcare" is emerging in which this information regarding quality and value of services is made accessible to consumers, who generate demand for these products and services. Producers compete to increase the value of services which is defined as quality of patient outcomes relative to the cost.[11,12,13] In a value-based system, CLS services will be evaluated, not only on analytic validity, but on value, that is, correlation with positive health outcomes, informed clinical decisions, and favorable benefit/cost ratios as summarized by the six IOM aims.

Options for ordering and utilizing diagnostic laboratory testing are burgeoning. An estimated 4,000 diagnostic laboratory tests, ordered at a rate of 7 billion per year in the U.S., are available to providers to aid in diagnosis and treatment.[14] Further, spending for *in vitro* diagnostics represents 2-3% of the U.S. gross domestic product.[15] With the emergence of testing capability in the genome, and the promise of personalized, designer laboratory medicine, numbers of tests available, and their costs, are increasing daily. The gap between analytic accuracy (i.e., laboratorians' providing valid, actionable test results) and medical meaningfulness (i.e., providers' understanding of what to do with them) is growing larger, as well. These rapid advancements in diagnostic technologies coupled with similar growth in testing options mandate the development of evidence-based testing algorithms linked to the care paths of the major chronic diseases and health challenges encountered most frequently.[16] There is an equally compelling mandate to provide these evidence-based algorithms to providers and patient/consumers for their use in shared clinical decision-making for more completely understood, value-based, informed consent.[17,18,19]

In the U.S. healthcare system, healthcare providers traditionally order laboratory tests without benefit of evidence-based testing algorithms. This structure causes an inherent conflict of interest with significant ethical dimensions: practitioners are incentivized to order more frequent and often more expensive, higher profit margin tests in order to support healthcare decisions.[25,26,28] In the absence of outcomes data from evidence-based algorithms for use in clinical decision support (CDS), these expert-centric, discretionary ordering practices cannot be effectively described and audited. An emerging CLS role is to design and conduct clinical research to generate evidence for development of testing algorithms positively impacting patient safety and health outcomes.[13,18,24,30] The information thus generated could be tailored specifically to the needs of providers and patient/consumers and provided as best evidence for evaluation of treatment and other care options. Consultation is an existing CLS customer service.[16,18] Provision of diagnostic information in the context of best evidence and risk assessment tailored to particular patient/consumers' medical circumstances would expand this consultative role and significantly facilitate and substantiate the patient/consumer-provider shared decision making process.

From an ethical perspective, provision of best available evidence as the basis of shared treatment and planning decisions not only removes the informed consent process from conflict of interest bias but addresses directly the six IOM aims characteristic of improved healthcare delivery: safe, effective, patient-centered, timely, efficient, and equitable. The three elements considered essential in shared decision making are: recognizing and acknowledging that a decision is required, knowing and understanding the best available evidence, and incorporating patient/consumers' values and preferences into the decision.[31] The role described for CLS would address the second element, i.e., compiling and formatting the best available evidence for the particular patient/consumer's circumstances. (IOM aims addressed are effectiveness and efficiency.) The patient-centered information provided could include an informed consent questionnaire, as well, that would facilitate the discussion of treatment options and alternatives to them and serve to document the patient/consumer's values and preferences. (IOM aims addressed by these questionnaires are safety, patient-centeredness, timeliness, and equity.)

CLS Informed Consent Practice Development

Clinical Laboratory Context

Clinical laboratory information is foundational to any consideration of healthcare efficiency and effectiveness given that as much as 70% of the objective data in the clinical record is contributed by the laboratory, much of which impacts the clinical decision making process.[20, 21] Inefficiencies involving the generation of orders (pre-analytical processing) and dissemination of laboratory data (post-analytical processing) increase the possibility of inappropriate resource utilization. An estimated 50-60% of all laboratory orders may be inappropriate;[22] and most laboratory errors (68-87%), including inappropriate orders, are non-analytic.[23]

Despite this documentation, the ordering of diagnostic tests is rarely based on evidence of comparative effectiveness over the entire cycle of care.[12,24] In fact, the current payment structure of the U.S. healthcare system encourages overutilization of diagnostic services including those of the laboratory.[25,26] Though the federal Stark Laws prohibit patient referrals to facilities with which providers have financial relationships, the Stark rules and subsequent amendments (42 C.F.R. §411.350 through §411.389) do little to deter overutilization because, due to an exemption, providers can still self-refer if they have controlling interest in their own labs (Stark Law.org, 2013).[27] In the inpatient hospital setting, accounting for an estimated 60% of all laboratory testing, laboratories are vital profit centers. A recent report estimates that $70 billion will be spent in the U.S. on 7 billion lab tests in 2013.[28] Of this $70 billion, $25 billion (36%) is estimated to be overutilization through over-ordering or over-pricing. Medical liability concerns also contribute to diagnostic testing overutilization as providers, increasingly concerned about litigation, order diagnostic lab work to avoid malpractice suits.[28,29]

CLS Evidence-based Practice

CLS evidence-based practice (EBP) in health services delivery has historically surrounded the production of accurate and precise diagnostic test results with little evaluation of impact on measures of medical effectiveness and cost-efficiency. Consequently, quality measurements have been focused on the analytic phase of the testing cycle to include instruments, assay methods, and statistical control.[32,33] With growing recognition of the IOM value-based concepts, non-analytic events impacting analyses, e.g., inappropriate orders, failures in results communication, substandard specimen collection, inadequate results interpretation, are being included in quality investigations. Evidence-based QI methodologies, exemplified by the U.S. Centers for Disease Control and Prevention (CDC) Laboratory Medicine Best Practice Initiative's A6 Method and explained in detail elsewhere, provide the evidence-based clinical research strategies and structure to evaluate clinical effectiveness and cost efficiency of clinical laboratory services.[24] Also inherent in this methodology is the capability to determine the medical effectiveness of emerging technologies like pharmacogenomics and other molecular testing options.[12]

Figure 1 summarizes the relationship of evidence-based practice (EBP) to the total quality management (TQM) process.[34,35] Outside market pressures, e.g., competition, regulation, and benchmarking best practices, promote standardization and benchmarking within healthcare delivery systems. Implementing EBP, CLS practitioners then apply and evaluate those standards through quality improvement (QI) processes like the Plan-Do-Act-Check cycle for assessing laboratory analytics and the A6 method for measurement of non-analytic factor impact.[24,36,37] The summation of findings from these laboratory QI processes is evaluated for quality impact at the systems level as part of the institution-wide TQM program. Improvements to laboratory processes are made based on the evidence garnered from these QI assessments. Findings from well-designed, well-executed QI studies can be generalized to other (external) systems and thus modify the initiating outside market pressures in a quality feedback loop.

CLS Contributions to Patient/Consumer Privacy

CLS Privacy Policy Development

In CLS practice, the EBP quality improvement cycle combines clinical care and research for the purpose of improvement in patient safety and health outcomes. In EBP, the impact of laboratory information on patient outcomes is assessed and compared to existing clinical care guidelines. Variances from expected outcomes are investigated and processes involved targeted for QI

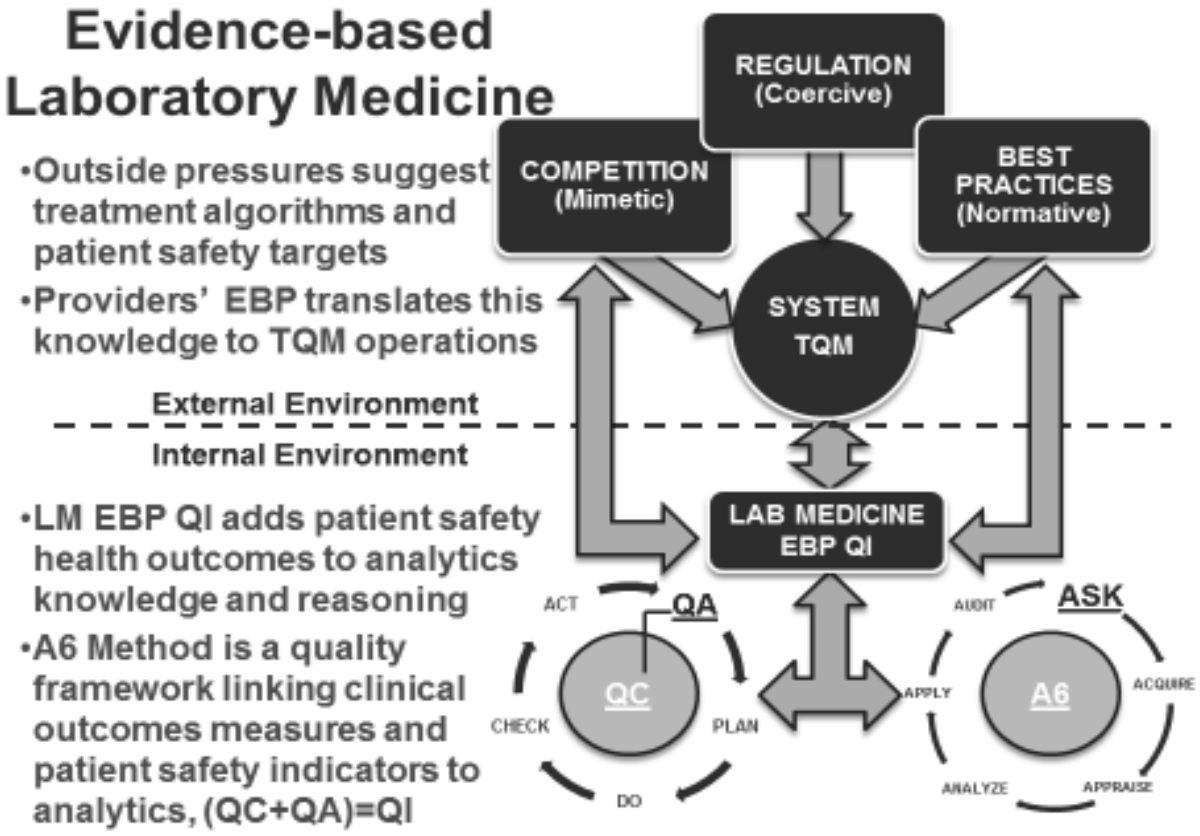

Figure 1. Clinical Laboratory Science Evidence-based Practice CLS evidence-based practice (EBP) is defined as, "the conscientious, explicit, and judicious use of the best evidence from clinical laboratory information in making decisions about the care of individual patients." EBP involves the systematic evaluation of existing evidence and incorporation of relevant conclusions from those evaluations into clinical practice.[24,34,35]

study if observed outcomes are judged to fall short of targeted quality thresholds. The iterative EBP process involves the analysis of individually identifiable health information ("protected health information," PHI) and, in some instances related to evaluation of alternative treatment interventions, patient participation in human subjects research.

The recommendation to incorporate IOM aims into practice, and the subsequent requirement to develop measures in each of the national quality strategy domains and document their uptake, obviates the debate regarding CLS responsibility for patient safety and health outcomes assessment. Regulatory pressure from the U.S. Department of Health and Human Services (HHS) is directing healthcare provider organizations to implement quality improvement initiatives related to IOM aims. Table 1 summarizes the relationship among the IOM aims and the quality measurement domains of the HHS. Also included in Table 1 are CLS examples of measures in each quality domain.

CLS Privacy Practice Development

HIPAA, HITECH, and Common Rule Regulations

In order to accomplish quality improvement in the domains recommended by HHS, CLS need to understand the ethical requirements of human subjects research as well as privacy and patient confidentiality as defined under the Health Insurance Portability and Accountability Act (HIPAA)[38] with subsequent amendments in the Health Information Technology for Economic and Clinical Health (HITECH) Act, enacted under Title XIII of the American Recovery and Reinvestment Act of 2009.[39] In addition to these federal laws regulating data collection and use, states generally have separate, sometime more stringent, laws governing these aspects of data protection, as well. Some private

certification bodies, such as The Joint Commission, have rules governing data collection and use in their subscribing facilities. HIPAA sets the "floor" for these data protections.

First, clinical activities, such as quality improvement interventions or informed consent and shared decision making consultation services, must be evaluated by an approved institutional review board (IRB) by criteria defining human subjects research. According to the Protection of Human Subjects "Common Rule" (2009), research is defined as "a systematic investigation including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."[40] The Rule further specifies that a human subject is a "living individual about whom an investigator (whether professional or student) conducting research obtains: (1) data through intervention or interaction with the individual, or (2) identifiable private information." Given that quality improvement studies can involve experimental interventions (e.g., comparing practices for blood drawing) and assessment of the impact on patient safety measures and health outcomes linked to specific patient/consumers, these activities can arguably be categorized as human subjects research. QI protocols should be submitted for IRB review, human subjects research evaluation, and protocol approval. If the study is categorized as human subjects research by the IRB, then the full measure of safeguards mandated in the Common Rule are required, beginning with an informed consent process for each research participant. In addition, investigators should comply with rules governing data storage and security.

Concurrent with the assessment of Common Rule applicability, the nature, source, and use of data generated by QI activities should be considered. HIPAA and HITECH rules are intended to assure the confidentiality, integrity, and availability of data for all types of healthcare, e.g., treatment, payment, health care operations, and research. Only data generated in "covered entities" are specifically regulated by the HIPAA and HITECH Acts. Covered entities include individual health providers, health provider organizations, health plans, and health information exchanges that engage in electronic health care transactions. If PHI is generated by a covered entity and used for research purposes, the collection of PHI, defined as containing any of 18 specified types of data identifiers potentially leading to positive patient/consumer identification, places the QI activity under regulation of not only the Common Rule but also the HIPAA and HITECH Acts. Collection and use of PHI usually require an authorization analogous to the informed consent required under the Common Rule. If the data use is deemed to be "non-research" by the appropriate review body, rules related to other uses of PHI apply in lieu of the research rules.

Table 1. Examples of Quality Domain Measures Providing Evidence of IOM Aims Operationalized in CLS Practice

IOM Aims[a] for Healthcare Delivery	U.S. HHS Quality Measurement Domains[b]	Example Measures[c]
Safe	Safety	Specimen collection; Patient identification
Effective	Clinical Care	Test ordering algorithm development
Patient-centered	Population and Community	Informed consent; Shared decision making
Timely	Care Coordination	Critical values reporting; Appropriate Ordering; Information interpretation
Efficient	Cost and Efficiency	Best practices reporting; Benchmarking value-based processes
Equitable	Patient Experience and Engagement	Consultations

a Institute of Medicine, 2001
b U.S. Department of Health and Human Services, 2012
c Measures developed for the informed consent and shared decision making processes would evaluate patient-centeredness of CLS services delivery. Also measured in the informed consent and shared decision making process would be effectiveness through patient-specific guidance development and services equity through feedback, from both patient/consumers and providers, on consultative services. The informed consent and shared decision making process would establish a platform for discussion of needs related to safety and cost efficiency because of the opportunity for patient/consumers to document their values and preferences as process requisites.

Ethical and Regulatory Decision Points in CLS Privacy Practice

Many CLS QI studies do not collect and use PHI. Rather, data collected are "de-identified" by removal of all 18 defined identifiers and reported only in the aggregate. De-identifying data means that the possibility of re-identification is highly improbable or eliminated altogether. De-identified data are no longer considered human subjects research under the Common Rule or

PHI under HIPAA and HITECH rules. Therefore authorization for collection and use is not required. HIPAA and HITECH Acts also allow for the collection and use of "limited data sets" (LDS). These data sets allow the retention of 2 of 18 types of identifiers: (1) town, city, state, and zipcodes and (2) dates, e.g., birth dates, service date, discharge dates, etc. Easing of restrictions on LDS comes with an additional safeguard: the covered entity generating the LDS must require a data use agreement, to be signed by all users, delineating the permitted uses and disclosures of information (consistent with the purposes of research) and limiting the persons that can use or receive data. Lastly, the data use agreement requires the recipient to agree not to re-identify the data or contact individuals linked to the data. If in fact, no individually identified data, or PHI, linked to specific patient/consumers is exchanged or transmitted, then only regulations protecting human subjects apply. Figure 2 summarizes the major decision points in the research categorization process. However, complexities exist in every determination and decisions at these major junctures open a cascade of additional questions all of which will be addressed in IRB applications. In designing QI protocols, consult early in the process with an IRB official for Common Rule advice or a Privacy Board or Privacy Officer designated to adjudicate HIPAA and HITECH questions.

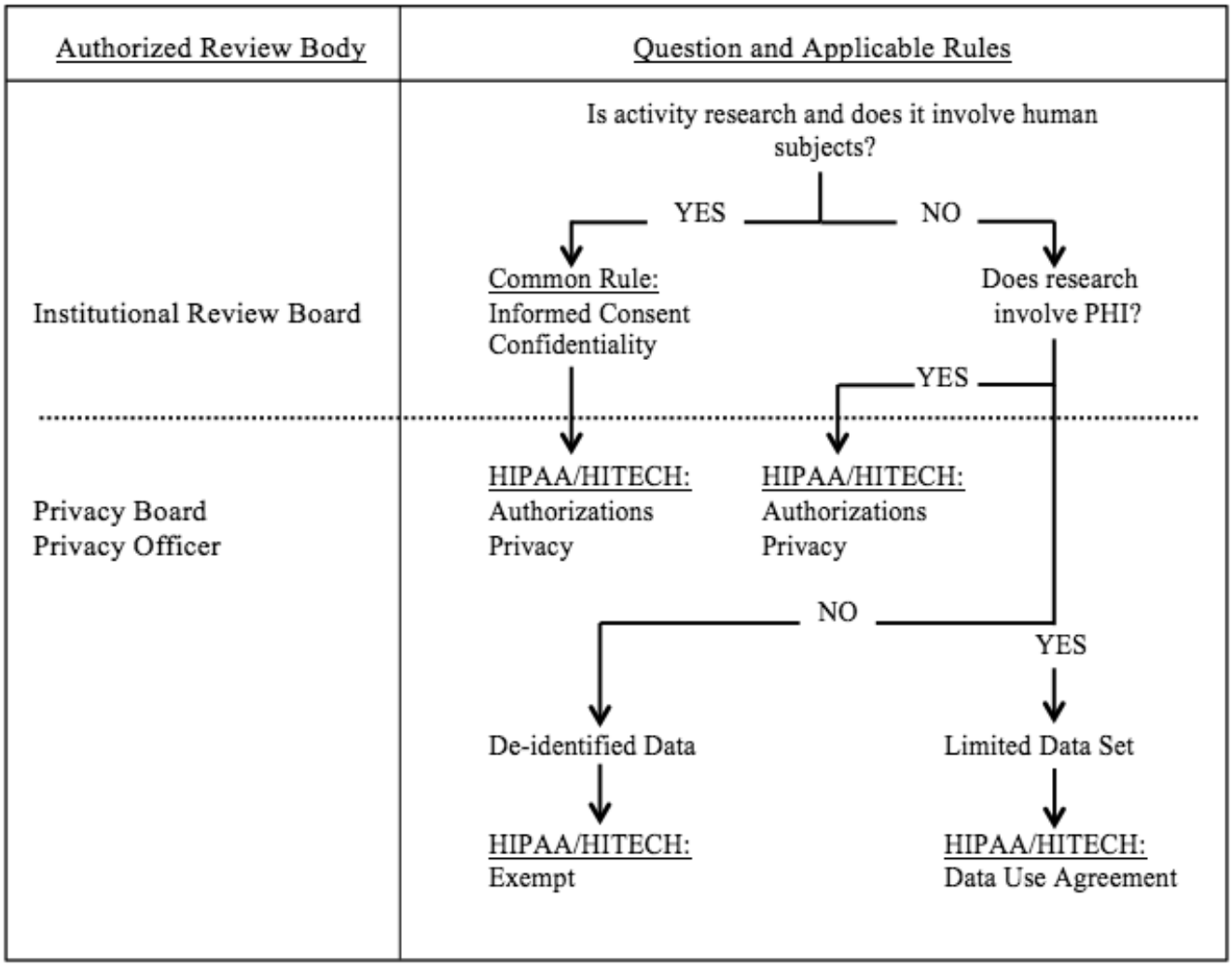

Figure 2. Summary of Major Decision Points in the Research Categorization Process Institutional Review Boards (IRB) are authorized under the Common Rule to adjudicate questions related to human subjects research and associated confidentiality of subjects and their data. Also, the IRB reviews and evaluates data storage and security plans related to human subjects research. Privacy Boards and/or Privacy Officers are authorized to adjudicate questions related to HIPAA and HITECH rules protecting PHI collected and/or used by covered entities.

CONCLUSION

Evidence-based practice in CLS has (1) provided the methodology for evaluating the impact of laboratory information on patient safety and other health outcomes and (2) supplied the measures for calculating medical effectiveness and cost efficiency of laboratory information in clinical decision support. Algorithms to guide the behavior of practitioners ordering diagnostic tests can be developed from the evaluation of evidence-based quality improvement studies. Providing practitioners, who order diagnostic tests, with evidence-based ordering algorithms in an individualized diagnostic care plan would remove conflict of interest bias from this portion of the care path. Provider and patient/consumer dyads could then use these evidence-based materials in the shared decision making process to arrive at a thoroughly informed consent for next steps in patient/consumer care. For CLS, this consultative process dictates that the highest clinical research standards be incorporated into each individual patient/onsumer diagnostic care plan generated. The knowledge created from evaluation of each care path implementation can be generalized to refine algorithms in an iterative quality improvement cycle that will foster better value (quality outcomes per dollar spent) in healthcare services delivery.

This consultation model mandates paramount trust in the knowledge, objectivity, and ethics of the CLS practitioner. Particularly significant in the ethical evaluation is protection of patient/consumer autonomy, confidentiality, and privacy throughout the entire blended TQM-clinical research process. This significant ethical mandate, involving evaluation of each of these ethical principles, should be acknowledged, debated, and documented in every QI study and consultation undertaken.

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