The Value of Clinical Laboratory Sciences Research

ELIZABETH KENIMER LEIBACH

Clin Lab Sci 2014;27(4):220

Elizabeth Leibach, Ed.D., MLS^{CM}, SBB^{CM}, *Principal Officer, Healthcare Management and Education Services, Augusta, GA*

Address for Correspondence: Elizabeth Kenimer Leibach, Ed.D., M.S., MLS(ASCP)^{CM}SBB^{CM}, *706 Summergate Court, Augusta, Georgia 30909, 706-925-0810, eleibach@comcast.net,*

Consumer demand for increased value in clinical laboratory services delivery has intensified. On the heels of the Health Insurance Portability and Accountability Act (HIPAA) of 1996,[1] Protection of Human Subjects, "Common Rule,"[2] and Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009,[3] the U.S. Department of Health and Human Services, effective April 7, 2014, amended Clinical Laboratory Improvement Amendments of 1988 (CLIA) and HIPAA Privacy regulations to allow patients/consumers direct access to their laboratory reports.[4]

The nexus of these regulatory forces, along with unprecedented health information access and exchange characterizing our society, suggests a prominent consultative role in services delivery for clinical laboratory practitioners. However, the interpretation of duty to patients, society, and other healthcare professionals, as codified in the clinical laboratory science Code of Ethics,[5] becomes critical to ethical practice as issues of societal duty and "good" are viewed through the lens of patient/consumer autonomy. Our responsibility broadens and deepens if we accept the challenge to transform laboratory information into actionable knowledge for patients/consumers and providers alike.

With these recent environmental changes, principles of access to meaningfully interpreted best evidence for providers' clinical decision support and patients/consumers' shared decision making compete with confidentiality concerns in everyday services delivery. We must internalize not only the laws and regulations governing protected health information, but we must also operationalize decision-making grounded in fundamental ethical principles guiding thorough informed consent. Patients/consumers expect to gain knowledge from us that will equip them to share in decisions regarding their medical care; they want personalized healthcare addressing quality of life.

Providing best evidence for personalized healthcare increases value for patients/consumers and providers alike.[6,7] Discerning relevant, appropriate, cost-effective (i.e., best) evidence to illuminate the care path of particular patients/consumers requires evaluation and synthesis of research, formulation of individualized care plans, and accomplishment of succinct and clear communication exchange. Underlying the ability to fulfil this mandate is significant familiarity with the relevant bodies of diagnostic and treatment evidence. While much applicable best evidence is garnered from clinical trials and systematic literature reviews of treatment guidelines, other more behavior-oriented, arguably more patient-centered evidence, comes from disparate areas of research related to healthcare access, education, social theory, economic theory, and organizational systems. We must become critical consumers of both basic science and clinical healthcare research who understand bias and limitations to generalizability of conclusions. Then we must be able to transform general information into specific and unique knowledge for both patients/consumers and providers.[7]

Educators face daunting challenges in this time of accelerated scientific and technological advancement: how to remain relevant and patient-centered while preserving and transferring the fundamentals of the body of knowledge, how to sequence concepts through the multiple curricula defining clinical laboratory sciences practice levels and professions, how to incorporate the expanded body of knowledge and scope

of practice necessitated by greater professional autonomy. There is increasing pressure to educate practitioners who can think critically, judge ethically, perform reliably, analyze thoroughly, summarize succinctly, and communicate clearly. These Focus articles summarize fundamental concepts and principles that undergird these competencies characteristic of value-based healthcare delivery. Hopefully, you will find them useful in development of instructional materials as well as in design, implementation, and evaluation of your own research agenda.

REFERENCES

1. Health Insurance Portability and Accountability Act (HIPAA) of 1996 [cited 2014 Aug 31] Pub.L. 104–191, 110 Stat. 1936. Available from http://www.gpo.gov/fdsys/pkg/PLAW104publ191/html/PLAW-104publ191.htm.
2. Protection of Human Subjects, "Common Rule"; 2009 [cited 2014 Aug 31] 45 CFR part 46. Available from http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html.
3. Health Information Technology for Economic and Clinical Health (HITECH) Act enacted under Title XIII of the American Recovery and Reinvestment Act of 2009 [cited 2014 Aug 31] Pub.L. 111–5. Available from http://www.gpo.gov/fdsys/pkg/BILLS-111hr1enr/pdf/BILLS-111hr1enr.pdf.
4. CLIA Program and HIPAA Privacy Rule; Patients' Access to Test Reports (CMS-2319-F), Federal Register February 6, 2014 [cited 2014 Aug 31] 75(25): 7290-7316. Applicable Code: 42 C.F.R. Sect. 493, 45 C.F.R. Sect. 164. Available from https://www.federalregister.gov/articles/2014/02/06/2014-02280/clia-program-and-hipaa-privacy-rule-patients-access-to-test-reports.
5. American Society for Clinical Laboratory Science, ASCLS. Code of Ethics. McLean, VA: ASCLS; 2013 [cited 2014 Aug 31] Available from: http://www.ascls.org/about-us/code-of-ethics.
6. Porter ME. What is value in health care? N Engl J Med 2010; 363(26):2477-81.
7. Légaré F, Witteman H. Shared decision making: Examining key elements and barriers to adoption into routine clinical practice. Health Affairs 2013;32(2):276-84.