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Accreditation and Certification: Can They Work in Clinical Research?

Healthcare accreditation started in 1951 with hospitals.[1] It stemmed from the work of a Boston surgeon, who in 1910 proposed that surgeons assess the effectiveness of their interventions.[1,2,3] It has metamorphosed from a mechanism to ensure minimum working conditions in hospitals for surgeons to a general tool for healthcare quality improvement.[4,5] Worldwide since 1990, accreditation programs have doubled every five years,[6] which is evidence of the growing interest in external quality assessment (EQA).

Accreditation and certification are only two of many possible quality assurance and improvement mechanisms. Regulation (including licensure) is also a necessary adjunct to ensure compliance with minimum standards required to operate an institution or program or to practice a profession and has the advantage that it is, or at least should be, independent of the industry and institutions being regulated. Awards of excellence (such as that given by the Health Improvement Institute) may offer positive recognition.[7] Internal quality assessment (IQA) is essential as well.

This paper summarizes the characteristics of accreditation and certification, describes their application to clinical research, and speculates about future expectations.

Accreditation and Certification

Definitions

Accreditation is a formal process by which an authorized body assesses and recognizes as complying with established requirements (expressed as standards), a system (or network), an institution (or group), a (trans-institutional) program, or a component of an institution or facility, such as a blood bank. Because it is often conducted by an industry body, accreditation is sometimes referred to as "self-regulation." More over, accreditation should encourage creating and maintaining a culture of quality management, including safety, and demonstrating meaningful and continuous improvement in performance.

For institutions, certification may be synonymous with accreditation, but today the term is most commonly used in connection with individuals such as healthcare professionals. Certification involves an authorized body granting recognition to individuals who have demonstrated specialized competence, knowledge or skills, often through formal examination in relation to specified learning requirements. Certification and accreditation can work hand-in-

glove in that accreditation standards may require the employment of appropriately qualified individuals and needed qualifications may include appropriate certification.

As understood currently, accreditation has the following characteristics:

- Voluntary (although it may be mandatory); the institution wishing to be accredited pays a fee to the accrediting organization
- Principal goal is institutional development or improvement of its performance, preferably with a focus on patients (including research subjects)
- Authorized body (usually a non-government organization) that performs the accreditation process; authority stems from the legitimacy of the accrediting organization's founders or sponsors and/or its charter
- Written/published standards (preferably, available at no or nominal cost); transparent standard-setting process, including the opportunity for public comment
- Criteria/standards (requirements), which should encompass processes and their results, that are achievable by institutions to be accredited and are consistent with generally accepted notions of adequate performance and, preferably, are based on evidence or otherwise validated by and harmonized with applicable regulations; standards may exceed the minimum embodied in regulations, but generally fall short of the maximum possible, or ideal performance, but may be ratcheted up over time.
- Non-threatening peer review process (i.e., systematic assessment by qualified assessors, who may comprise a multi-disciplinary team, of compliance with published standards) that emphasizes education, consultation, and technical assistance, including disclosure of interests, especially those that may be perceived as a potential conflict between the accrediting organization or its assessors and the institution being accredited and/or procedures for minimizing the potential for occurrence of such conflict.
- Publication of accreditation status (and, preferably, assessors' detailed findings).

Accreditation Process

The process of accreditation generally involves the following:

- Application by the institution (applicant) that wants to be accredited
- Performance and submission by the applicant of a self-assessment
- Desk review of the applicant's submission, often including its self-assessment
- Site visit to the applicant (e.g., survey) by certified assessors (e.g., surveyors) in which assessors may inspect premises, documents, etc., interview staff, observe processes, review (samples of) records (and may conduct compliance tests); generally accrediting organizations train and certify their own assessors, who are mostly volunteers (and are often peers or colleagues of people in the institutions being accredited)
- Exit de-briefing in which assessors may provide initial feedback to the applicant's management team, in part to test the validity of conclusions and to ensure there are no surprises in the accreditation report
- Quality assurance of assessors' findings
- Formal notification of results to the applicant, including feedback on how well the institution is meeting standards, including any deficiencies and sometimes commendations on exceptional performance relative to some or all standards
- Publication of accreditation status (and perhaps details of accreditation results)
- Monitoring of the applicant's performance regarding compliance with requirements, such as conditions of accreditation and standards
- Periodic re-accreditation (repeats the above steps in the process, usually using revised published standards that account for changes in the operational environment and that are more stringent than those used in the previous cycle, which is intended to effect continuous improvement in performance)

Advantages of Accreditation

The claimed advantages of accreditation include the following.

For the accredited institution

Advantages include:

- Achievable standards against which to gauge performance
- Information on competitors' quality; benchmarking scores to show where the institution's performance ranks, absolutely and in comparison to peers, and what the best performers are achieving
- Supportive consultation to assist the institution to improve quality and to achieve standards (by assessors and firms owned or allied with, or themselves accredited by, the accrediting organization for this purpose).
- The right to participate in certain programs, receive payment, etc., including approved supplier status, higher payments, or in some instances, licensure
- Increased reputation among end-users (e.g., patients and research subjects)

- Reduced premiums for liability insurance when accreditation involves areas of high-risk

For the public

Advantages include the following:

- Publication of information on quality to which members of the public would otherwise not have access and cannot themselves make required assessments; competition can only work if there is reliable information on the quality of suppliers' performance
- If a sufficient percentage of institutions active in a field participate, accreditation provides some measure of quality assurance and promotes continuous improvement in that field (assuming that accreditation standards and processes are meaningful)

Disadvantages of Accreditation

Detractors often mention the following drawbacks of accreditation.

For the institution (to be) accredited

Disadvantages include the following:

- Additional work and stress for management and staff, both with respect to the accreditation process (for reasons given below) and their production jobs within the institution (because of engendered competition and the need to strive to improve performance)
- Changes to systems, processes, etc., needed to meet standards and to improve performance, including required additions to and (re)training of staff
- Increased strictures and more constraints on professionals, from explicit institutional processes and greater vigilance in their implementation
- Cost, which is often disproportionately large for smaller, poorer institutions
- Risk to morale, reputation, and/or revenue if not accredited (especially if this status is known widely)

For the public

Disadvantages include the following:

- Accreditation is not, and its precepts may conflict with, public accountability of institutions' and practitioners' performance
- Lack of evidence regarding its cost-effectiveness (or that of any type of EQA).[8] Few programs have been evaluated, and the few evaluations that have been completed often find fault with accreditation. There is ample evidence of increased compliance with published standards (at least in the period immediately prior to surveys)[9]; less evidence of a convincing link between accreditation and performance.[10] At best, there may be some improvement in a limited number of participating institutions.
- Its voluntary nature; institutions that participate are generally larger, wealthier, and cater to the best-off clients; those that need external quality review the most don't necessarily participate
- The accrediting organization is a captive of its industry
- Standards that are set low so that virtually all institutions can pass muster without meaningful improvement; at worst, standards that are tailored to an institution's capabilities or are "flexible," thereby resulting in the same end
- Process that may be without time limits so that no institution fails; accreditation is pending while the institution works on rectifying deficiencies or may never complete the process
- Lack of quality assurance and improvement on the part of the accrediting organization, resulting in variability (and hence lack of validity) of assessments and thus accreditation; including lack of sufficient ratcheting up of standards to ensure institutions' continuous improvement in performance
- Lack of transparency of the process and/or in not disclosing accreditation status or enough information about scores and deficiencies
- Lack of meaningful oversight of the accrediting organization and/or accreditation process, and, consequently, its failure to meet international standards, produce reliable assessments, and/or reveal serious deficiencies (as evidenced by constant scandals regarding their discovery at "accredited" institutions[11,12,13])
- Form over substance, including accredited institutions shining during the time of assessors' site visit, but not complying with standards at other times

Incentives for Accreditation

Before accreditation can gain widespread acceptance, it has to overcome a number of obstacles, including denial that there are any real problems (and the view that any reported incidents are merely the result of unstoppable evil people or "bad apples" in the institutional barrel), apathy, and cost. Incentives that might promote or accelerate accreditation include:

- Mandating it (in which it becomes a form of regulation except that the governing body may be somewhat independent of government, at least according to its charter)
- Permitting government funds to be dispersed only to accredited institutions
- Contracting only with accredited institutions (on the part of government or private entities)

- Paying a premium for services rendered by an accredited institution (either directly or through vouchers used by clients)
- Subsidizing the cost of accreditation, especially for smaller institutions
- Providing strong government support, e.g., in the form of public statements (and, possibly, public education campaigns by government regulators that they favor accreditation as a means of improving compliance with applicable regulations).
- Mandating that institutions disclose by whom they are accredited in all publications, advertisements, etc. (and, in the case of human research, in informed consent documents), including, if applicable, a statement that it is has chosen not to be accredited by the applicable accrediting organization
- Providing legal protection to quality improvement information, assessors' opinions, etc.

Human Research Protection Programs

History of Accreditation of HRPPs

The drive toward accreditation of human research protection programs (HRPPs), in the late 1990s, came from the following three principal sources:

- Highly publicized death of a research subject, Jesse Gelsinger, an 18-year-old participant in a gene transfer trial[14,15]
- External reviews of the IRB system by two government watchdog agencies that concluded that the overburdened and underresourced IRB system was paper driven and paid little attention to determining whether research institutions were actually fulfilling their responsibilities to protect human subjects,[16,17] which led to increased compliance oversight and, consequently, to a spate of institutions having their human research programs shut down[18]
- Commitment to accreditation by the Department of Veterans Affairs (VA) as a means of strengthening human research protection in response to discovered deficiencies[19,20]

At the request of the Secretary of Health and Human Services, the Institute of Medicine (IOM) of the National Academy of Sciences examined how to improve human research protection programs. As part of the study's first phase, in 2001 the IOM reviewed the standards of the two organizations developing them. In its report, the IOM endorsed accreditation and the concept of human research protection program as an institutional responsibility, with the IRB system as a component, cited the VA standards as a model, and recommended that accreditation should extend to all research programs.[18]

HRPP Accrediting Organizations

In 1999, Public Responsibility in Medicine and Research (PRIM&R), a nonprofit organization dedicated to education in the protection of human subjects, formed a working group to explore accreditation of HRPPs. This activity led in 2001, to the establishment of the Association for the Accreditation of Human Research Protections Programs (AAHRPP) which involved a consortium of other organizations.[21] In October 2001, AAHRPP issued its interim accreditation standards for public comment and, after a series of pilot tests, accredited it's first HRPP in 2003. To date, AAHRPP has accredited 33 institutions,[22] and although AAHRPP does not release this information, it is said that over 200 institutions have initiated the accreditation process.

In May 1999, the VA announced its intention to accredit VA HRPPs.[23] As the result of a competitive bid, in May 2000 the National Committee for Quality Assurance (NCQA) was awarded the contract. In 2001, NCQA released draft standards and began accrediting VA HRPPs. In 2002, NCQA released draft standards for accrediting nonVA institutions, and in January 2003, the Joint Commission on Accreditation of Health Care Organizations and NCAQ formed the Partnership for Human Research Protection (PHRP) to accredit nonVA institutions. In November 2005, PHRP was dissolved and is no longer conducting accreditation; it had accredited nine institutions.[24] As of the end of 2005, NCAQ had accredited 51 VA HRPPs with the accreditation of 18 additional VA HRPPs awaiting pending accreditation of their academic affiliate.[25] In December 2005, the VA awarded the contract for accrediting VA HRPPs to AAHRPP. Thus, now there is only one accrediting organization for HRPPs.

HRPP Accreditation Standards

Accreditation standards cover five domains (with a total of 20 specific standards in these domains and 75 elements within these standards).[22]

- *Domain 1, Organization*—covers responsibilities of the institution that is applying for accreditation; these include leadership, resources for the HRPP, oversight over the HRPP, and education in human research protections
- *Domain 2, Research review unit, including the IRB*—covers the responsibilities of the research review unit (administrative office), including the ethical review of research that complies with the regulatory criteria and appropriate documentation and recordkeeping
- *Domain 3, Investigator*—covers investigators' responsibilities in conducting research involving people; these include complying with IRB and regulatory requirements, as well

as the ethical recruitment and treatment of research subjects
- *Domain 4, Sponsored research*—covers the responsibilities of institutions when dealing with sponsors, including appropriate communication with sponsors and requiring in contracts that sponsors comply with ethical standards
- *Domain 5, Participant outreach*—covers the institution's responsibilities to the participants in research

HRPP Certification

With regard to HRPPs, certification takes two principal forms.

- Certification of investigators who have demonstrated that they have completed a training program
- Certification of IRB staff and clinical research personnel through competency testing

Although most institutions require investigators and others involved in human subjects research to participate in some sort of education program, not all require documentation that they have completed such training. Even fewer require some sort of testing on its subject matter. One program combines training with testing: Collaborative IRB Training Initiative (CITI).[26] This online training program in human research protections tests after each module. Each institution adopting CITI training establishes which modules are required and the passing grade for tests. Once an individual has passed the tests for all required modules, he receives a certificate documenting completion of training. About 600 institutions subscribe to CITI, and the number requiring training of investigators and others is increasing. Many institutions have developed their own program for certifying investigators.

The Council for Certification of IRB Professionals (CCIP), which operates under the auspices of PRIM&R/ARENA[27] and the National Association of IRB Managers (NAIM),[28] provide certification through competency testing for IRB administrators and staff. In both programs, individuals who meet eligibility criteria and pass an examination are certified and receive the designation of CIP or CIM, respectively. A number of other organizations offer a variety of research-related certification. For example, the Association of Clinical Research Professionals (ACRP) certified clinical research monitors and coordinators.[29] Starting in 2006, the Academy of Pharmaceutical Physicians and Investigators will offer an examination to certify physician researchers[30]; ACRP, one for nonphysician researchers.

Expectations

What can we expect accreditation and certification to achieve in the field of clinical research? Clearly, accreditation and certification are not panaceas for assuring that social and ethical goals for people who participate in research are, in fact, achieved. Such EQA mechanisms represent only one form of oversight, and they work best in concert with others, particularly government regulation. Moreover, meaningful IQA mechanisms hold the key to successful human research protection. Ultimately, the protection of research subjects is in the hand of the individual investigator and his or her staff. In this regard, IQA mechanisms can ensure that research complies with regulations; investigators and their staffs are properly trained; HRP policies and procedures are implemented effectively; results are monitored; and necessary improvements to the system made. In turn, EQA mechanisms can monitor the effectiveness of institutions' IQA mechanisms, encourage continuous improvement of performance, and hold institutional leaders accountable for failures. This chain works only to protect research subjects if accreditation standards (including any requirement to employ certified individuals) are sufficiently strict and are enforced rigorously.

With sufficient institutional funding for HRP programs (and incentives for accreditation), one could expect that institutions will comply with increasingly stringent standards and that such compliance should result in the improved protection of people who participate in research, at least at accredited institutions. Increasingly strict evidence-based standards will require an additional commitment to research to improve the technology of HRP and accreditation. Certification can be expected to professionalize the field, and lead to improved salary and career prospects. Will research subjects be better protected? Only if accreditation results in a true culture of safety and ethical conduct, and the public is educated to enroll only in clinical research being performed by an accredited institution. Will this state of affairs be achieved? Stay tuned for about the next 30 years.

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