

## A Brief History of the Regulation of Medical Practice: Hammurabi to the National Board of Medical Examiners

Claudio Violato, PhD, Wake Forest School of Medicine

### Abstract

Physicians' practices have been regulated since time immemorial. In antiquity a set of laws known as the Code of Hammurabi (circa BC 1740) governed nearly all aspects of social, political, economic and professional life including those pertaining to physicians, surgeons, veterinarians, midwives and wet nurses. Hippocrates (circa BC 460-360) of Greek antiquity, and Galen (AD 130-200), also established clinical guidelines and regulations for practice, many of which endure today. During the medieval period physician guilds and university faculty increased their power and control of the medical marketplace in places like Paris and Milan.

The modern rules, policies and regulations governing the practice of medicine today are well established. In the United States, for example, a number of organizations such as the American Board of Internal Medicine (ABIM), and American Medical Association (AMA), are involved in governing the assessment, licensing, and behavior of physicians. Since the mid-20th century, psychometric testing has dominated the entry into the profession (Medical College Admissions Test) and the licensing of physicians (National Board of Medical Examiners). Testing and assessments are likely to play an even larger role in the licensure and regulation of medical practice in the future. The future focus will be on competency-based testing of, among other things, entrustable professional activities.

Another future direction for licensure and regulation will be lifelong assessment for maintaining competency. Physicians will be required to undergo a regular (e.g., every five years) assessment such as multi-source feedback. The standards for accreditation of medical schools in the United States and Canada have become more rigorous in the past decade and this will have implications on assessment of medical competence as all levels.

### Licensing Physicians throughout the Ages

Physicians' practices have been regulated since time immemorial. Control of the medical market place through licensing, prosecutions and penalties has a long history and is not unique to modern society. Prior to systematic testing in modern times, various methods have been employed to regulate medical practice. In the United States, some of the earliest regulation began in New York with colonial law in 1684 that prohibited the practice of medicine "without the advice and consent of such as are skillful in the said Arts."<sup>1</sup> But regulation of physicians began at least 4,000 years ago. Homer, for example, praised Egyptian physicians and their practice "with knowledge beyond all men" as a specialized profession.<sup>2</sup> There are many references throughout the Old Testament of the Bible as well on whom and how medicine should be practiced.<sup>3</sup> Regulation in modern times is accomplished largely through psychometric testing. The major purpose of the present paper is to provide a brief history of the regulation of medical practice from antiquity to the present day, including the development of testing. Several instances illustrate the practices in the past several thousand years.

### Medical Practice in Antiquity

A set of laws known as the Code of Hammurabi (circa 1740 BC) have come down to us from the Babylonians after its namesake, the founder of the Babylonian empire.<sup>4</sup> These 282 statutes or common laws governed nearly all aspects of social, political, economic and professional life including those pertaining to physicians, surgeons, veterinarians, midwives and wet nurses. Carefully conscribed details were devoted to specifying the relationship between patients and practitioners, including fees and penalties. Problems of "internal medicine" were dealt with by physicians of

the priestly class who saw to internal disorders caused by supernatural factors. These healers were not generally accountable for the efficacy of their ministrations as there was no metrics on which to assess them.

The surgeon who dealt with physical problems, however, was accountable for both remuneration and liability to earthly courts. If a healer performed surgery, generally with a bronze knife, and saved the life or eyesight of an upper class citizen, he was to be paid 10 shekels of silver.<sup>4</sup> A similar outcome for a commoner was worth 5 shekels and only 2 shekels for a slave. If the outcome for the upper class citizen was bad (blindness or death), the physician's hand was amputated. If a slave died because of the surgery, the physician had to provide a replacement, but had to pay only half the value in silver if the slave was blinded.<sup>4</sup> The Code provided further detail for many procedures including those of the "doctor of an ox or ass" (veterinarians).

Hippocrates (circa 460-360 B.C.E.) of Greek antiquity, the putative author of the *Corpus Hippocraticum*, set out standards for physician behavior. Upon graduation from medical school, many modern physicians continue to take some variant of the Hippocratic Oath, the model of the ideal physician. Many historians question whether Hippocrates actually wrote this Oath or even the essays attributed to him. Some even question whether Hippocrates was a real person or was a composite created later by Greek and Roman scholars. Nonetheless, even in antiquity there were rules, policies, and regulations on how to behave as a physician.

Galen, probably the next most famous physician in history, also established clinical guidelines and regulations for practice. His works and texts continued to be studied by medical students and scholars for hundreds of years after his death. When he went to Rome in 161 A.D., Galen was met with hostility by the medical establishment. He was able to remain to practice medicine, lecture and conduct public discussions under the protection of the powerful Emperor Marcus Aurelius who named him the "first of physicians and philosophers."<sup>5</sup> Eventually, Galen left to return to Greece complaining that he had been driven out

of Rome by the medical establishment who saw him as an unwelcome foreigner. Galen did subsequently return to Rome honoring a request from Marcus Aurelius. He remained for the rest of his life.

### **The Medieval Period and the Case of Jacoba Felicie**

The case of Jacoba Felicie illustrates regulation during the "dark ages". This was Paris in 1322 and the physician guilds and university faculty had increased in power and control of the medical marketplace. They were seeking to consolidate their regulation of medical practice. They decided that Jacoba was a particularly good case to prosecute as she was a woman practicing medicine. The Dean and Faculty of Medicine were determined to put a stop to the illegal practice of medicine.

Jacoba glanced through her notes a final time before setting out for the court house.<sup>6</sup> Powerful forces including the Dean and Faculty of Medicine at the University of Paris were allied against her. For some time now they wanted to gain stronger control over various practitioners of medicine such as surgeons, barbers and empirics whether male or female. Jacoba had been charged with illegally visiting the sick, examining their limbs, bodies, urine and pulse, prescribing drugs and collecting fees. Her most egregious fault?: She actually cured some patients, frequently after conventional physicians had failed to do so.<sup>7</sup>

The Dean and Faculty of Medicine who prosecuted her did not deny her skill or even that she cured patients. They argued that Jacoba had not read the proper texts; medicine was a science to be acquired through proper reading of texts such as Galen and lectures and discourse based on the written word. Medicine was not a craft to be learned empirically.

Jacoba argued in court that the intent of the law was to forbid the practice of medicine by ignorant and dangerous quacks and charlatans but that this did not apply to her as she was both knowledgeable and skillful.<sup>8</sup> She also argued that she was fulfilling a particular need with female illnesses because conventional modesty precluded male practitioners from dealing with these. Many of Jacoba's patients came to court that day to testify to her skill, knowledge and caring. Jacoba

must have been crushed when the court ruled in favor of the Dean and Faculty of Medicine that she was not legally constituted to practice medicine in Paris. She was therefore prohibited from practicing medicine in the future on penalty of imprisonment.<sup>8</sup> The court acknowledged her patients' positive testimonies, but this was not deemed relevant to her legal status as a medical practitioner. Thus, the case of Jacoba ended and we have no further historical record of her.<sup>7</sup> Perhaps she left Paris to practice medicine.

### The Renaissance and the Case of Leonardo Fioravanti

Fioravanti felt that the Milanese physicians had been plotting against him since his arrival from Venice in 1572. He had been arrested and imprisoned by officers of the Public Health Board in Milan on the sketchy charge of not medicating in the accepted way. After eight days in prison Fioravanti was becoming increasingly outraged by the indignity he was suffering. The Milan medical establishment considered him an outsider, an alien and an unwelcome intruder. They finally were able to have him incarcerated.<sup>9</sup>

Fioravanti was not a conventional medical charlatan hawking his nostrums in the piazza and then moving on. Nor was he an ordinary barber-surgeon. He had practiced medicine for years in Bologna, Rome, Sicily, Venice and Spain.<sup>9</sup> He had an MD from the University of Bologna, had published several medical texts, had developed many medicines, but was a severe critic of much of conventional medical practice. The Milan physicians were not welcoming and considered him a foreign doctor.<sup>10</sup>

A prison guard provided pen-and-paper for Fioravanti, and in his most elegant and formal language, he addressed it to Milan's public health minister from "Leonardo Fioravanti

of Bologna, Doctor of Arts and Medicine, and Knight". He asked to be released from prison and to "medicate freely as a legitimate doctor". A paid messenger delivered the letter to the Health Office located in the Piazza del Duomo<sup>11</sup>.

The health minister, Niccolo Boldoni, was responsible for overseeing every aspect of medical practice in Milan, from examining midwives, barber-surgeons, and physicians, to collecting fees, imposing fines, inspecting apothecaries, and ruling on appeals. The letter from the Doctor and Knight claimed that the Milan physicians were in a plot to stop him from providing care and cures to the sick of Milan.<sup>10</sup> Moreover, he claimed that the Milan physicians were a menace to their patients and did more harm than good with quack treatments, poisonous medicines, and careless and arrogant behaviors. Fioravanti challenged the minister to provide 25 of the sickest patients to him and an equal number to Milan doctors that the minister selected; he - Fioravanti - would cure his patients quicker and better than the other doctors.<sup>11</sup> There is no historical record of this early clinical trial that probably never occurred, but Boldoni and the Milan court set Fioravanti free.<sup>11</sup>



Leonardo Fioravanti

Adapted from: Santoni-Rugiu P, Mazzola R10

### Modern Regulations and Procedures for Licensing Physicians

The modern rules, policies and regulations governing the practice of medicine today are well established. In most jurisdictions — the United States, Canada, Europe — like the Code of Hammurabi, regulations govern nearly every aspect of the patient — physician relationship, clinical guidelines, best practices, evidence based medicine, fees, collegiality, and so forth. In the United States, for example, a number of organizations such as the American Board of Internal Medicine (ABIM), American Board of Medical Specialties (ABMS), and the state licensing authorities (e.g. Medical Board of California), as well as doctor organizations such as the American Medical Association (AMA), are all involved in governing the assessment, licensing, and behavior of physicians in the United States.

Nearly all jurisdictions in the world nowadays require physicians to be university educated and earn an MD (medical doctor degree) or other approved degree (e.g.,

MBBS, MBChB). In many jurisdictions students who have earned a medical degree are required to undergo further postgraduate supervised clinical training. In the United States and Canada this is called residency, also called a house officer or senior house officer in the United Kingdom and several Commonwealth countries. Depending on the medical specialty and jurisdiction, residency can be 1 to 6 years in duration. Once a doctor has passed all relevant examinations and qualifying procedures, the physician may be granted a license in a specified jurisdiction to practice medicine without direct supervision.

### The Flexner Report

In 1910, Abraham Flexner produced the now famous Flexner Report, *Medical Education in the United States and Canada: A Report to the Carnegie Foundation for the Advancement of Teaching* that was commissioned by the Carnegie Foundation.<sup>12</sup> At that time there were approximately 157 medical schools that were loosely affiliated with educational institutions and the education of physicians was primarily a for-profit business. The knowledge and skills of the graduating physicians was highly variable, resulting in an over-production of poorly educated medical practitioners.

Flexner provided a review of medical education and medical institutions and reviewed the economic and social factors that had an impact on the delivery of medicine of that era. He concluded that the situation was untenable and that medical education needed to be radically transformed. Today, with a few rare exceptions, medical school organization in the United States and Canada consist of 4 years, the first two pre-clinical or laboratory sciences consisting of foundational knowledge in anatomy, physiology, pharmacology, and pathology, followed by two years of clinical sciences experiences. The Flexner Report also contained arguments for evidence-based and scientific-based medicine. It has had an impact on the medical school admissions process, the learning environment, the qualifications and expectations of medical teachers and the need for standardized licensure exams. The Flexner Report has been pivotal to most of modern medical education including the development of standardized testing and assessment in medicine.

### Methods of Testing

In the United States written tests to assess students were not generally used until Horace Mann introduced them in 1845. This was seen as a radical and controversial innovation when American educators adopted them in the late 1800s. Testing quickly became an important element in America's modern public school system as well as in postsecondary education including medical schools.

Developments in large scale standardized testing took place in Europe and the United States largely as a consequence of World War I. Large scale testing in Germany for army inductees had been in progress since 1905. Alfred Binet and Theodore Simon had discussed the application intelligence testing for the French army in 1910. In the United States Lewis Terman had completed the revision and standardization of the Binet scales in 1917 and these principles of mass testing were soon applied to the American military effort resulting in the Army Alpha and Beta Tests of intelligence. Nearly two million recruits were tested with these instruments before the end of WWI.<sup>13</sup> This psychometric testing (scientific application of reliability and validity theories) was seen as so successful, that after the war large scale standardized testing swept the American school systems, including universities and medical schools. The major types of tests used throughout the 20th century were pencil-and-paper multiple choice questions (MCQ).

The advent of computers has played a large role in the expansion and evolution of testing in the last 60 or so years. Many of the complex statistical techniques that have been applied to testing, such as correlational and factor analysis and test theories such as Item Response Theory have only been possible with the use of computers. As large main frame computers became commonplace in universities and some other institutions during the 1960s, large data bases from testing programs could be stored and the data analyzed with software programs. At the same time, software programs that could be installed into the computers also became available. Prior to this, users had to write their own software from scratch. Data could be entered into the computers (e.g., with punch cards, optical scanning sheets, bubble sheets,

keyboards) and analyzed and reports generated for individual test takers. By the 1980s, optical reading scanning machines (reading bubble sheets marked with pencils) had been more-or-less perfected and matched to desktop computers. Large numbers of bubble sheets (e.g., thousands) can be quickly and efficiently entered into a desktop computer where sophisticated software can quickly analyze the test results and produce individual reports, and psychometric results of the test.

The next evolutionary step that began in the 1990s was the elimination of pencil-and-paper (i.e., bubble sheets) so that students could take a test directly on a computer. This is called computer based testing (CBT). The main advantage of CBT historically has been for report generation and quick feedback. With the advent of the personal computer, CBT functions primarily for the computer-administered versions of paper-and-pencil tests. These provided some advantages over paper-and-pencil in test administration, and item innovation. Some disadvantages include the need for latest hardware and software and large test centers to accommodate large group testing.

CBT can be innovative allowing flexible scoring of items. Test items can use sound or video to create multi-media items. An item may contain a 40 second video and audio sequence of a doctor performing a focused physical exam on the left lower quadrant of the abdomen for example. This can be followed by series of MCQ questions to the student. Content innovation also relates to the use of dynamic item types such as drag-and-drop, point-and-click, or hovering over hot-spots. Future developments in CBT are likely to focus on item innovation that measure complex cognitive outcomes such as clinical judgment and professionalism.

### Online testing

Online testing refers to the delivery of tests via the internet. This approach also provides a new medium for distribution of test materials, reports and practice manuals, and for the automated collection of data. Even traditional paper-and-pencil materials can be delivered online as PDF format files using e-book publishing technologies. Theoretically, anyone

with an internet connection could take a test at anytime from anywhere in the world. Such an approach provides much more flexibility in testing than has been possible in the past. Online testing highlights a whole set of issues: confidentiality, cheating, test taker identification, hacking, breaching the test bank, and so on.

### Current Status of Testing

The current status of testing is paradoxical. On the one hand, rapid advances in computer technology, statistics and test theory have brought impressive new capabilities to assessment of learning and performance. On the other hand, most classroom testing is still very primitive. For those that teach in post-secondary institutions and medical schools (i.e., instructors, professors) have no education in testing and assessment, and they have no instruction of basic pedagogical principles or learning theories. The situation is similar throughout most of the world.<sup>14</sup>

There is a further irony to the situation. While as we have seen testing is on the increase and instructors and professors as well as university administrators know little about it, the general public is very much in favor of increased testing and assessment<sup>15</sup> including post-secondary institutions. To sum up the current situation in the educational institutions, then, the public overwhelmingly supports testing, as does the current political climate, but most medical teachers who are the primary constructors and administrators of tests, know little about appropriate testing practices and standards. Testing and assessment is likely to increase in the future, but most instructors and professors know little about appropriate testing practice and standards.

The demands of assessment are currently rigorous and are likely to become even more so. Professors and instructors may spend as much as 20% or 30% of their professional educational time in assessment related activities. These include designing, developing, selecting, administering, scoring, recording, evaluating and revising tests, and assignments. Healthcare instructors, professors and medical education leaders such as Holmboe, Ward, Reznick and others<sup>16</sup> are very concerned about the quality of tests and measurements, and lack confidence in them.

Currently medical education is under pressure to adopt competency-based approaches that emphasize outcomes. This shift in emphasis requires more effective evaluation and feedback by professors and instructors than is currently the case. The existing faculty is not fully prepared for this task for traditional competencies of medical knowledge, clinical skills, and professionalism, never mind for the newer competencies of interdisciplinary teamwork, quality improvement, evidence-based practice, and systems. Medical and healthcare faculty welcomes relevant and useful training or assistance in measurement and assessment but they feel frustrated by their lack of training and support.<sup>16</sup>

### Medical Licensure, Testing and the National Board of Medical Examiners

State board exams for medical licensure ended in 1978 in the United States (Table 1). The Federation Licensing Exam or the National Boards became the standard. The United States Medical Licensing Exam (USMLE) under the auspices of the NBME was administered for the first time in 1992 (Table 1). There are three assessments called step exams which reflect emerging competence over time in the physician's development. Step 1 assesses understanding and application of important concepts of the sciences basic to the practice of medicine, Step 2 the application of medical knowledge, skills, and understanding of clinical science essential for the provision of patient care under supervision, and Step 3 the application of medical knowledge and understanding of biomedical and clinical science essential for the unsupervised, independent practice of medicine, with emphasis on patient management in ambulatory settings.

Step 1 is generally taken at the end of second year of medical school, Step 2 sometime in the second year, and Step 3 usually by the end of the first year of residency. Through these various measures and stages of basic science knowledge and clinical knowledge development, the USMLE is intended to assess the physician's competence in diagnostic reasoning, clinical competency and patient care.

**Table 1:** History of Medical Licensure and Regulation in the United States\*

Date	Event
1649	Physicians and Surgeons are prohibited from treating "without the advice and consent of such as are skillful in the same art" by the Massachusetts Bay Code
1772	New Jersey institutes examination requirements for physicians
1830s	Antebellum licensing laws are repealed, in part due to the rise of alternative medicines
1870s	State medical boards begin to emerge
1903	Practice rights are extended to osteopathic physicians in Michigan
1912	Federation of State Medical Boards (FSMB) is established
1920s	Many states adopt basic science exams and citizenship requirements for licensure
1956	The Essentials of a Modern Medical Practice Act sets national uniformity for practitioners
1960s	State boards emphasize their disciplinary roles
1961	The Medical Board of California is the first state to appoint a public member
1970	New Mexico was the first board to require continuing medical education
1978	State board exams end. The Federation Licensing Exam or the National Boards become the standard
1992	The United States Medical Licensing Exam was administered for the first time
2010	FSMB adopted a resolution for ensuring physicians' continuing competency to maintain licensure

\* Adapted from: Johnson DA, Chaudhry HA<sup>17</sup>

### The Future of Licensure and Regulation of Medical Practice

Testing and assessments are likely to play an even larger role in the licensure and regulation of medical practice in the future. The future focus will be on competency-based testing of, among other things, entrustable professional activities (EPAs).<sup>18</sup>

Competency refers to an area of performance that can be described, operationalized and measured. These are performance areas in patient care, medical knowledge, professionalism, practice-based learning and

improvement, systems-based practice, and interpersonal and communication skills. An EPA is a clinical activity that requires the use and integration of several competencies such as delivering a baby. Each EPA is based on a number of competencies. To assess the competency of physicians to deliver a baby, for example, requires complex and comprehensive tests of this EPA. Such assessment can direct the learner in a specified number of selected, representative, and important daily activities. Although EPA based assessment is gaining momentum, challenges of feasibility of implementation remain. It is an assessment strategy where the main goal is of patient safety and optimal patient care. This is an opportunity to improve training and assessment by increasing focus on appropriate supervision and regulation of students, residents and physicians to assess competence.

Another future direction for licensure and regulation will be lifelong assessment for maintaining competency. In some jurisdictions such in Alberta, for example, the licensing and regulatory body (College of Physicians and Surgeons of Alberta – CPSA) has mandated that all physicians will undergo a regular (every five years) assessment using multi-source feedback (MSF).<sup>19</sup> MSF, also referred to as a 360-degree assessment, uses various assessor groups (e.g., peers, patients, coworkers) to rate doctors' clinical and nonclinical performance. This is a unique form of evaluation that provides more valuable information than any single feedback source, useful for both formative and summative assessment of professionals. Professionalism, communication, interpersonal relationships, and clinical and procedural skills competence MSF can assess.<sup>20</sup> One of the main benefits of MSF is that it provides physicians and surgeons with information about their clinical practice that may help them in improving and monitoring their performance.<sup>21</sup> A recent meta-analysis has concluded that the validity of the MSF system is supported by large effect sizes for physician and surgeon performance across different clinical and nonclinical domain measures.<sup>22</sup>

The standards for accreditation of medical schools in the United States and Canada have become more rigorous in the past decade<sup>23</sup> and this will have implications on assessment

of medical competence at all levels. A recent study was conducted by the Liaison Committee on Medical Education (LCME), the medical school accreditation body for American and Canadian medical schools of schools that were reviewed between October 2004 and June 2012.<sup>24</sup> The study focused on severe action decisions, an LCME decision to grant an established medical education program an unspecified or shortened term of accreditation instead of the full eight-year term, place a program on warning status, place a program on probation status, or withdraw accreditation. Severe action decisions can be very serious for the medical school because that information becomes public (newspapers, television, etc.) leading to embarrassment and other consequences such as student anxiety, reduction of future applicants, possible loss of funding opportunities, and the ultimate possible catastrophe, the loss of accreditation as a medical school.

During the nine year period, the LCME issued 40 severe action decisions that were significantly associated with 1) an insufficient response in the data collection instrument/self-study, 2) chronic noncompliance with one or more accrediting standards, 3) noncompliance with standards related to the educational program for the MD degree, and 4) noncompliance with a large number of standards. The two most common violations that that resulted in severe action decisions were 1) a lack of evidence of comparability across instructional sites, and 2) the absence of a strong central management of the curriculum (by a curriculum committee)<sup>24</sup>. These findings and the recent actions of the LCME will increase the rigor of the regulation of the efficacy of medical schools themselves.

## Summary and Conclusion

Although as we have seen the regulation of medical licensure and practice is not new, the current and future methods are based on rigorous scientific testing methods and rigorous review of the educational institutions themselves. This is likely to continue and intensify in the future.

The cases of Jacoba Felicie and Leonardo Fioravanti illustrate the difficulty — until modern times — which women have had in gaining legitimacy as physicians. They also show the

reticence of medical regulatory bodies of allowing foreign medical practitioners into their jurisdictions. With increasing regulation using psychometric testing for licensure, a focus on competency-based testing of EPAs, and workplace-based assessment such as MSF for continued licensure, regulation of physicians is becoming increasingly rigorous. Finally, the recent actions of the LCME and its published intentions will also increase the rigor of medical education of the medical schools themselves.

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