Standardization in Action: A Critical Path for Translational STEM Education at Drexel University

Sharon Tsai-hsuan Ku

Standards in Action: a Missing Link in Translational Research/Education

In 2015, the author got involved in a discussion initiated by the former Dean of the School of Biomedical Engineering and Health Systems (BME) in Drexel, about a course design that could better educate biomedical undergraduates/graduate students on the topic of standardization and innovation. The discussion was initiated by two reasons. First, the evaluation result from the Accreditation Board for Engineering and Technology (ABET) suggested the need to incorporate “standards” into the current BME curriculum. Second, and perhaps the most influential factor that made the Dean fully aware of the importance of standard education, came from her own experience in dealing with the US Food and Drug Administration (FDA) for an in-vitro medical device targeted at brain injury detection. The research success turned out not be enough to guarantee regulatory approval. Their device was categorized as “de novo”, a new innovative medical device that needs proper reasoning, citation of references, and the use of “standards” to pass FDA’s risk evaluation process. However, for pioneering technologies, there is often no existing rules to follow. Thus, innovators have to work with FDA by writing their own standard protocol for future regulatory reference. Because of the lack of knowledge and experience in standardization, the whole team spent more than two years producing such a document, along with the struggles of regulators’ principles, language use, classification, and decision-making based on “standards”.

The translational obstacle in moving academic research from the bench to the market has created the incentive of learning about standards/standardization. Yet, what to teach, and how to motivate faculty and students to actively participate in such a course, is still a challenge. The unfamiliarity, and sometimes resistance to engage in standardization, is not unique to Drexel biomedical engineers. Academic innovators often express less interest and a reluctance to think about and utilize standards during the research design and development process. Unlike the factors of novelty and intellectual property, little attention has been given to standardization; it is normally viewed as “boring, repetitive efforts” that do not fit into the spirit of innovation. As a consequence, such a narrow view on standardization and a lack of awareness of standards have made the biomedical innovation a field full of competing and contradictory interests, including diverse definitions, incompatible experimental data, and user-unfriendly designs which could lead to detrimental and unethical outcomes. According to FDA, standardization is a life-death issue—98,000 deaths and $29 billion in added costs in US medical device development is due to nonstandardized human factors engineering, and inappropriate designs that sometimes failed to guide users to properly follow the instructions.

Standardization in Action: a Translational Curriculum Development at Drexel

The discussion later was turned into an educational grant award, sponsored by the National Institute of Standards and Technology (NIST) Standards Services Curricula Development Cooperative Agreement Program. The idea was to add standardization—as a product and process—to BME education, addressing translational gaps and communication barriers between research, regulation, and societal concerns. Instead of creating a standing alone course taught by one discipline, we designed an interdisciplinary curriculum that combines one newly created humanities course, Standardization in Action: A

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Global Perspective, informed by four existing biomed courses (Medical Device Development, Design Thinking, Biomedical Ethics, and Senior Design) to address life science standardization and its application (Figure 1). This new course was created as a historical elective for all undergraduates, with a focus on BME majors who can choose this one as a substitute for their humanities requirement. We particularly encouraged students who have taken or are planning to take the four BME courses to register, as we believe that this curriculum can offer a continuous and integrated knowledge base to bridge engineering and humanities. In addition, we believe that understanding and participating in standardization is crucial for Drexel, a co-op university where students receive six-month periods of full-time industrial employment where standardization is considered a must-learn. The sociological examination helps students develop critical thinking toward those biomedical standards they used or heard of in their professional training. Students then acquire the knowledge and sensitivity of evaluating different standards; their technical assumptions, their socio-political origins, and their embedded powers and limitations.

Designing such a curriculum requires interdisciplinary and international scope, and intense collaboration between humanities and engineering faculty. Drexel, like many other universities, values interdisciplinary education. However, the actual given courses are still based on one department or school without further integration to help students see beyond disciplinary silos. The design and implementation of this curriculum offers the catalyst to cultivate teaching collaboration across colleges. The Principal Investigators (PIs) and the guest lecturers from history, biomed and design schools conducted regular meetings to align with each other’s interests, expectations, course contents, and schedule coordination. In addition, we also participate in each other’s class as “students” to learn how standards-related topics were taught in different disciplinary settings, in order to create the connectivity and integration within the curriculum. These mutual visits not only helped us plan a truly interdisciplinary standards education, but also inspired students to see the healthy tensions, fun (how professors argued with each other in defending their disciplinary perspectives), and the benefit of interdisciplinary communication.

By leveraging Drexel’s co-op network, expertise in history and sociology of science, biomedical engineering, product design, and global studies, the curriculum emphasizes the following unique features:

• bringing social science/humanistic components to the center of standards education, highlighting the social construction of standardization;

• utilizing standardization as a platform for translational STEM education, through which to develop constant and close communication among academia, standard development organizations (SDOs), industry, NGOs and government; and

• working with SDOs to turn standardization from concept to action, encouraging students to participate in standards production for emerging technologies. Our goal of teaching is to use standardization as an integration platform for students to learn the entanglement of technology, history, law, cultures, and global politics, connecting technical training with broader social, economic, ethical, and legal impacts.

Nine themes were selected to facilitate the socio-technical investigation of standardization in eleven weeks. They included naming and classification; the human body; risk; regulation; innovation; globalization; infrastructure; ethics and justice; and design. The themes were not randomly chosen but informed by existing BME courses, as the purpose of this course is to offer the sociological, historical, and philosophical angles to re-examine the topics students have been familiar with from their technical training. By juxtaposing how these concepts are treated by different disciplines in different cultures, the course invited students to question not just how to follow standards, but why standards have the power they do in technology and trade governance: Who does standardization, for whom, and what motivate them to join the process? What kind of knowledge claims are chosen to be standards, based on what criteria? Why are there so many standards organizations claiming similar standards? Who are benefited/harmed by standardization? How do social, political, cultural, and economic factors influence standardization? Given the heavy participation from industries, why can standards be used as a regulatory tool? For example, in the week of naming and classification, we use international disease categories and drug labeling as cases to engage the class discussion about the social origin of these standards, examining the interests embedded in the seemingly neutral systems, and how they have fundamentally shaped the way we understand life/health.

**Standardization in Life Science:**

**An translational Curriculum**

<table>
<thead>
<tr>
<th>Course Description</th>
<th>Fall 2016</th>
<th>Winter 2017</th>
<th>Spring 2017</th>
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</thead>
<tbody>
<tr>
<td>HIST 280: Standardization in Action -- A Global Perspective</td>
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<td>BMES 488: Medical Device Development</td>
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<td>BMES534/535: Design Thinking for Biomedical Engineers</td>
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<td>BMES 338: Biomedical Ethics and Laws</td>
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<td>Students senior design thesis</td>
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Figure 1: Standardization-in Action Curriculum at Drexel University
This curriculum also aims to prepare students’ active participation in standardization at an early stage of engineering education. Rather than viewing standards as neutral technical artifacts, or ready-made static rules waiting to be followed, the curriculum emphasizes “the coming-into-being” of standards, in order to cultivate students’ critical thinking to examine the assumptions, interests, as well as the power and limitations embedded in the construction of standards. We expect this dynamic portrait of standards/standardization can raise the awareness of “standardization in action,” through which students no longer think standards as a set of ready-made rigid rules, but state-of-the-art processes and an opportunity of shaping the future.

**Methodology**

We believe that the rule-of-thumb of teaching standardization is to prevent students getting bored and not being able to see the extremely vital but hidden social and political life associated with standards. In addition, to teach a subject that involves multiple actors and their dynamic relationships, layers of infrastructures, and social and cultural values, we need pedagogical approaches that enable students to read texts differently as objects of interrogation rather than slavishly through a culture of pedagogical conformity that teaches unquestioning reverence. Twenty-two students from three departments—BME, Business Management, and Media Studies—who are interested in entrepreneurship, innovation, product design, and international studies enrolled in the *Standardization in Action* course. The wide backgrounds and the proper class size allow the instructors to experiment with various interactive teaching and team projects to stimulate and monitor students’ performance.

The weekly teaching schedule of this four-credit course was divided into three parts. The first ninety minutes had time for students to present and discuss reading materials, followed by a ninety minute meeting with guest speakers who brought in their real-world experiences to extend the theoretical discussion into practical actions. A bi-weekly online meeting was also hosted for students to share their learning and term projects progress. In addition, we designed a wide range of interactive in-class and out-class activities that allowed students to directly witness and engage with the experts, organizations, and procedures of standardization, summarized as follows.

**Meet the Experts**

Standardization cannot be simply taught as textbook knowledge, since it requires intense know-how to deal with “uncertainties” coming from both the technical and the social sides. Meeting the experts therefore constitutes a key learning process for students to understand different stakeholders’ interests and approaches to standardization. According to the weekly theme, we invited twelve guest speakers from academia, industry, government, and SDOs (see Table 1) to share their real-world experiences, helping students comprehend the complex interaction among science, market, regulations, and public trust that can be shaped by stakeholders’ participation in standardization. For example, in the “Body” section, we encouraged students to challenge the taken-for-granted assumption that the body is a universal biological entity. In addition to reading materials from medical anthropology that gives cross-cultural perceptions and representations of “body,” we also invited a transgender professor who works in the field of bioinformatics and modeling, to share her personal and professional experience of how the assumed gender and body norms impact her social, medical and legal identity, as well as her work on medical modeling and device design. Figure 2 shows the visit of Liu Fei, ASTM’s chief representative in China, who discussed not only different technical concerns, but also the cultural and political distinctions underneath the US and Chinese standardization systems. The comparison provided an intense cultural shock that challenged students to rethink their assumptions about standards as universally objective rules, and about the role of international politics in framing “international standardization” and “globalization.”

Our survey shows that the selected topics, cases, and experts have turned the complex socio-political and technical process of standardization into engaging personal stories and professional experiences, successfully firing up students’ interest in learning about and participating in standardization.

![Figure 2: Guest speaker Mr. Liu Fei’s visit from ASTM China (Source: ASTM Facebook)](Image)

(Continued on page 14)

| Table 1: Expert list of the Standardization-in-Action course |
|-------------------|-----------------|-----------------|-----------------|
| **Academia**      | **Industry**    | **Government**  | **SDOs**        |
| History           | Infrascan Inc.  | CDRH/FDA        | ASTM International |
| English           | Exponent        |                 | IEEE-SA         |
| BME               | Pennsylvania BioNano Systems, LLC |
| Library           |                  |                 |                 |
| Mechanical Engineering |              |                 |                 |
| Design            |                  |                 |                 |
| Computer Science  |                  |                 |                 |
ASTM International Field Trip

A half-day field trip to ASTM International in Conshohocken, Pennsylvania was organized during the term for students to participate in a mock committee meeting on toy standardization, directly witnessing the operation of an international standard organization and the procedures it uses for standardization (Figure 3). ASTM staff played the script constructed by the meeting minutes from the actual toy standards committees—manufacturers from China, competitors from Canada, designers, users, and regulators in the US—to explore issues regarding the existence of scientific evidence, language use, public trust, and different regulatory concerns in standardizing toy safety testing. Short discussions were hosted between scenarios to guide students in connecting these lively debates to the in-class lectures. Witnessing the bargaining, strategic actions, writing, and verbal communication among international stakeholders, students quickly understood the level of complexity involved in standardizing a simple toy testing standard and how ASTM project managers mobilized organizational management and voting rules to resolve conflicts and facilitate consensus. The mock meeting turned the abstract social theories and case studies read in class into concrete practices and engaging dialogs that resonated with students’ daily experiences and technical training, illustrating vividly the intimate connections between technology, society, and global politics.

Stakeholders’ Conference

Our grant allowed us to support the attendance of three students at a two-day Standards Engineering and Sustainability Workshop, co-organized by NIST and Michigan State University in May of 2016. We met industrial stakeholders, EPA staff, and faculty and students from other standards education programs to explore how standardization can be developed to achieve sustainable development. We were also able to compare notes on different teaching and learning experiences. On the second day, students were teamed up with industrial and government standardizers to participate in a standards simulation game that mimics the actual standardization process taking place in international standard organizations (Figure 4). Through a guided role-play, each group received a script indicating the role they were assigned: a standards developer with a large market share; standards competitors with high technical capacity; manufacturers who produce the products that require using the standard; a government agency in charge of regulation and trade issues; and NGOs who act as gatekeepers to oppose standards that could harm public interests. Students enjoyed the standard simulation game; they learned the state-of-the-art of voluntary consensus standardization—that it is not only a technical competition, but also a political process, where standardizers need to cultivate their sensitivity and awareness of science, language, local interests, and global power in order to defend their proposal and conduct successful bargaining.

Whitepapers

Students were required to produce a whitepaper to discuss the standardization of a new/emerging technology, examining the current status, problems, and societal concerns associated with the technology development; and whether standardization could help resolve the issues. Each group was offered a small research grant to support their investigation, such as a field trip and interviews to collect research data. Through the assistance of several SDOs, students were able to reach out to standardizers in the US, UK, Korea and China to develop comparative studies. By leveraging what they’ve learned in this class, we expected the final paper to contain:

1. a social analysis that reveals different stakeholders’ interests, power, and knowledge claims in standardization;
2. an epistemic awareness that includes a reflection on different scientific methods and reasons in standard making; and
3. suggested practices to engage broader participation and conflict resolution in the production of standards. At the end of term, we invited three reviewers from BME, the School of Design,
and the History Department to evaluate students’ presentation of their research finding and proposed solutions.

Ranging from AI-facilitated therapies, Uber, and safety standards for smart phones, to alternative medicine, all the papers revealed multiple stakeholders’ perspectives regarding why and how standardization should be considered at the early stage of technology development when the technical and socio-political uncertainties are huge. One common finding is that standardization plays an important role in shaping the design, the intended use, and the social trajectories of new technologies. For example, the medical device group found that the available standards for skin testing materials are mostly light colored; this triggered new experimental issues in machine training designed for diagnosing non-white people. The smart phone group discovered that the notions of “safety” and “risks” associated with new technical products not only possess different meanings across nations, but also have distinct perceptions among innovators, regulators, and users. However, it is important to note that the general public normally is not aware of the existence of standards or standards developing organizations as tools that can be utilized to address public interests. Through writing and defending the whitepapers, students gained the experience of identifying and interviewing global stakeholders, listening to their voices, and mobilizing their research findings to make suggestions for future standard development.

Individual Research Projects

Our grant also supported students who were interested in incorporating standards in their engineering design projects. One of the outcomes is a Virtual-Reality Assisted Surgical Simulation Training Program, a software application designed to help third-world medical students to conduct remote anatomy training. The student documented the whole design process, and showed how taking standards into account has completely changed the simulation modeling and forced her to re-evaluate the goal of the design: if the intent of this software is to help medical students in Africa who do not have resources to run gross anatomy on-site, what standard skin reference material should be used for simulating the scalpel-skin interaction of the African body, which has different skin tones and fat layers? Are the existing surgical protocols designed for the operation run in western hospitals a suitable standard in the African environment, which might have different spatial layout and manpower deployed in the operative room? If the purpose of this software is to help train doctors from less resourceful areas, is it a good strategy to patent the product and claim the intellectual property—the action suggested by the tech transfer office? In other words, standards helped to channel her innovative ideas into practical real-world scenarios and stimulated a set of new technical, social, and ethical challenges for her design. This project won the ASTM International student essay competition and changed the students’ career goal from a pre-med applicant to a medical-VR designer; the student now hopes to make a contribution at the interface of AI, cultural diversity, and future medicine.

Summary of Students’ Learning Result

We designed a self-evaluation survey to understand students’ learning outcome. The quantitative data shows a big difference of students’ overall confidence in understanding standardization before and after the course (Figure 5a, b). In particular, students reported that this course filled the knowledge gap between their theoretical education and the hands-on training in their co-op work. As one student noted,

In junior design, which I am taking right now, the instructor mentioned that we should use standards to justify all of our verification procedures and specifications. Other than that, the biomed department NEVER mentioned standards...it would be beneficial to make this class required. Being the only class where I discussed standards,
if I had missed it I would have been at a huge disadvantage both in school and in the field.

More importantly, students saw the benefit of this course beyond simply learning practical skills or being fed information by some useful information/social networks. Instead, they acknowledge the critical thinking approach which did not offer them convenient answers, but constantly challenged the taken-for-granted neutrality of engineering standards by revealing the social construction of rules:

This course expands students’ ability to use critical thinking and reflection when evaluating standards and technology...even for those who aren’t engineers, because it shows them how to navigate an arcane set of rules. Hearing from regulation makers, regulation followers, and everyone in between helps with other Drexel courses such as the senior design sequence and for a career where most things are based on standards. Once completed, the course gives students access to a powerful new language as well as knowledge about important aspects of the process.

The majority of students also reported that this course has had an impact on their career choice (see Figure 5c): Three out of the twenty-two students joined the ASTM International as student members; one PhD student joined the ANSI/ISO nanotechnologies committee; one student applied for a co-op position in China; and one student won the ASTM International student essay competition. A short video clip of students’ comments can be found at https://youtu.be/H8MDUNG81TU.

Conclusion and Future Steps

Our teaching experiment proved that standard education can be fun, creative, and highly interactive. It will help students to connect their engineering training with broader societal issues, at the same time putting their innovative designs in proper social contexts to reduce the translational gaps. After planting the seeds of standardization at Drexel, we are glad to see that the awareness of standards is growing; which enables several ongoing activities/projects to continue the efforts. BME is integrating standardization as a topic in their seminar/junior/senior design courses and faculty from the neuroengineering research center are involved in the IEEE Standards Association and show interest in incorporating standards into their research. Our students continue to pursue their career in academia and industry, occasionally sending us emails reporting how their current work reminds them of those cold Monday evenings we spent in the winter of 2016 to discuss one of the most interesting subjects in the STEM curriculum—standardization.

Acknowledgement

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About the Author

Dr. Sharon Tsai-hsuan Ku was a research assistant professor at Drexel University. She has been participating in international standardization as a researcher, reviewer, and instructor, with a focus on nanotechnology. Recently she has been involved in AI-related standardization in the US and China; she is keen to bring cross-cultural perspectives into international standard education. She is currently an assistant professor in the Department of Engineering & Society at the University of Virginia. She can be reached at tk9na@virginia.edu.

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