



Examining the regulatory and standardization challenges of connected and intelligent medical devices

BSI Student Research Programme Case Study



“We want our students to understand how science, technology and policy interface”

Dr Irina Brass,
UCL Associate Professor in Regulation,
Innovation and Public Policy



Plotting a research path

In February 2020, with the UK on the cusp of its first COVID-19 lockdown, five postgraduate students from University College London (UCL) met (safely) with four BSI staff members at BSI's headquarters building in Chiswick, west London.

This was the kick-off meeting for the students' final assignment – an eight-month-long dissertation project to produce a research report, as part of BSI's 2020 Student Research Programme (SRP).

The SRP exists to match postgraduate students who're conducting research with a BSI information need. On this occasion, we wanted to increase our understanding of the regulatory and standardization gaps and misalignments that have arisen from the growing use of connected and intelligent medical devices, such as smart wearables and wellness apps.

Digital healthcare is a big growth area – but one that increasingly blurs the line between medical devices and consumer technology, disrupting the established regulatory and standardization frameworks. We wanted to know where and how standards-making bodies and regulators should be intervening to ensure that new medical devices are safe, secure and developed with transparency and accountability.

This is a hugely important area because people's health and lives are at stake. We required novel thinking about the complex socio-technical opportunities and challenges that

digital healthcare technologies present. We also wanted recommendations on where standards should play a role in providing stability and predictability in a dynamic market where, frankly, regulators and policy-makers are struggling to catch up.

Taking up the challenge were five Master of Public Administration (MPA) STEaPP (Department of Science, Technology, Engineering and Public Policy) postgraduates: Natalia Maj, Gabriella Ezeani, Malla Tedroff, Jiehui Song and Jan Sassenberg.

Throughout the project, they benefited from the academic supervision of Dr Irina Brass, UCL Associate Professor in Regulation, Innovation and Public Policy; and mentoring from BSI's Rob Turpin (Head of Sector, Healthcare), Paul Sim (Medical Devices Knowledge Manager), Dr Matthew Chiles (BSI Education) and Gill Jackson (Research Manager).



Jans Sassenberg
Master of Public Administration (MPA) STEaPP
(Department of Science, Technology, Engineering and
Public Policy) postgraduate

About BSI and standards

BSI - the British Standards Institution - is the UK's national standards body. We represent UK economic and social interests across all European and international standards organizations and in the development of information solutions for British organizations of all sizes and sectors.

Standards are simply documents that set out precise criteria for an agreed best way to do or make something. As unspectacular as that sounds, standards can nevertheless be extraordinarily powerful. They gain authority by being developed through a rigorous consultation process that builds an expert consensus. Thereafter, the use of standards boosts productivity and performance; improves confidence, transparency and resilience; and enables innovation to flourish by widely disseminating the proven knowledge on which innovations are built.



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Jiehui Song
Master of Public Administration (MPA)
STePP (Department of Science, Technology,
Engineering and Public Policy) postgraduate

The project

The group’s dissertation topic was initially suggested by Irina. She teaches on the MPA programme at UCL, which covers technology policy and regulations and the role standards play in supporting policy objectives and regulation.

She also chairs BSI’s Internet of Things technical committee and has worked with BSI before on the SRP. “We want our students to understand how science, technology and policy interface,” says Irina. “Digital technology policy is an incredibly exciting area of study, but the focus is too often on governments or the tech giants. Standards play a fundamental role in digital technologies and systems, but this role is often misunderstood and obscured. We want our students to get a more complete picture of what happens in digital technology policy beyond the “state v big tech” dichotomy.”

BSI agreed that the challenges of digital healthcare was an important area for research. The brief was further developed in collaboration with Rob and Paul, then presented as an option to the MPA postgraduates.

Each had their own reasons for choosing this topic. “On the face of it, standards and regulation can look like pretty dry stuff,” says Malla, “but actually it’s playing such an important

role, it decides the rules of the game, so I think that’s cool and interesting, and I also wanted to look at how the healthcare industry is developing.”

“I studied law,” adds Natalia, “so was interested in the regulation of technology in different regulatory mechanisms, including self-regulation and standards. Also because technology has the potential to change so much in healthcare, I was interested to see how these issues come together.”

Song was also drawn to the topic because of BSI’s involvement. “BSI is known and quite reputable in Asia,” she says. “I also wanted to see how standardization was done across different regions, so decided to give this topic a go.”

Delivering the report

The postgraduates began by studying the client brief and preparing questions to ask at the kick-off meeting. They also started thinking about possible research methods and questions. It was found very useful that the brief included the questions that BSI wanted answered. Says Song: "This really helped us scope the project and the different areas that we wanted to explore and the different research methods that we would potentially use."

At the February meeting BSI covered the issues that are presented by a changing medical device market with evolving regulations. The postgraduates asked questions about the angle BSI would like to see and who to target during the research. Because of COVID-19 this turned out to be the only face-to-face meeting held during the course of the project.

Thereafter the students agreed a timeline with BSI, set up a system of sending BSI fortnightly update emails and held monthly Zoom calls. In addition they were encouraged to get in touch any time to ask questions. "We could always sound them out," says Song, "even though they were also very busy. It was extremely helpful for us."

Conducting the research

The group adopted a mixed-method research approach using primary and secondary data sources. A literature review was conducted, followed by a horizon scanning exercise: a technique of looking into the near-future to spot upcoming challenges.

The group then conducted 19 semi-structured interviews of representative individuals from industry, academia and public authorities to gain detailed insights. For this process, Rob and Paul provided introductions to key contacts in industry and the NHS. Natalia notes: "In fact they linked us up with some very senior people who would have been very hard for us to get access to in other circumstances. That was very helpful for the quality of our research."

We also helped with questions and hosted the group's online survey on the BSI website. This asked 19 qualitative and quantitative questions on the challenges encountered by medical device manufacturers. The group promoted the survey, as did we to our stakeholders, enabling the target number of 50 respondents to be reached within six weeks.

Facilitated by BSI, the group also attended online industry events (the only possibility because of COVID-19). One opportunity was to present at BSI's annual standards' conference where group members presented on their project at a breakout session. It gave them the chance to engage further with stakeholders, understand what they think and get some initial feedback. Finally, Paul and Rob looked at three drafts of the research report as it was being developed, and gave detailed comments on each.

Entrepreneurs' Guide

As their research got underway, it became ever-clearer to the group that start-ups, entrepreneurs and SMEs lacked simple guidance on how to navigate the regulatory and standardization landscape for connected and intelligent medical devices; and that this was a major problem for them.

BSI had also told the group that we'd value any mechanism that would help us engage with medical device manufacturers earlier in a product's lifecycle, so innovators are thinking about working with standards and regulations from day one, and not too late in the process.

The UCL research team therefore decided to produce an extra deliverable for their client in the form of an Entrepreneurs' Guide. This would supply clear, practical guidance for manufacturers of connected and intelligent medical devices, taking them through the key considerations they should bear in mind at each step of developing their device, from concept, planning and design, to validation and launch, and then post-market obligations and product retirement.

The Guide was duly delivered at the end of the project. "A lot of standards are aimed at people who understand them already," explains Rob Turpin. "A new strategic direction for BSI is to develop documents that help people who aren't yet experienced with standards. The Entrepreneurs' Guide fits very neatly into that space."



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Rob Turpin
Head of Sector, Healthcare
BSI Group

The results

The project produced a comprehensive 191-page research report that is international in scope, and which contributed to all five postgraduates passing their MPA degrees with what Irina calls “flying colours”. She notes: “The standard of the research goes beyond a student project.”

The research involved a wide range of stakeholders from SMEs, to regulators and clinicians. It’s grounded in real-world needs and challenges. BSI has gained a fresh, objective perspective on the issues, but also on how our work is understood by external parties. The research also uncovered the technical and regulatory barriers faced by small companies seeking to develop innovative medical devices. It will feed into BSI’s five-year healthcare strategy and contribute to our goal of growing our presence even further in the huge international medical devices market.

The postgraduates themselves gained a lot of important knowledge of where and how standards work. They developed teamwork skills, and learned how to manage responsibilities across roles. They learned about managing client expectations and timelines, and about how to conduct stakeholder engagement and thorough research. Also how to act as communication brokers between expert technical people and expert policy-makers. They also learned about group dynamics and the value of diversity. “Among our group,” says Song, “we decided to be accountable to each other, and to have honest, open and respectful communication about the things that could be improved. I think this was something very valuable for the group, especially because we’re from different parts of the world and I think the way you communicate varies between different cultures.”

Natalia agrees, adding, “It was also interesting that we all had slightly different background experiences and interests. Each of us brought a different perspective and understanding and we were able to combine all those different interests together.”

Professional path

What’s most striking is how the skills and experience gained have fed into the professional path that some of the postgraduates has subsequently followed. Malla, for instance, has now started working for a global social media platform in policy and regulation. “What I found most helpful,” she says, “was that before the masters and the project, I’d only worked with private companies who wanted to avoid regulation and saw it as a cost and inhibitor of growth. It was really helpful to get the standardization and regulatory perspective.”

Natalia now works as a Competition Policy Manager at the UK’s communications’ regulator, Ofcom. She says that as the group’s Project Manager she definitely gained useful skills. “It was also interesting to see how standards can set the rules of how things work in practice, and how BSI engages with its stakeholders – that was the most interesting thing for me.”

Gabriella now works for an organization that aims to transition research into innovations that have a sustainable impact. “Basically,” she says, “I’m creating a standardization culture within the company which focuses on how we’re ensuring that the deliverables we create within different projects can have a bigger impact through standards. So for instance, how can we standardize crisis management or the way we use augmented and virtual reality? I provide input and insights based on the knowledge gained in the project and also a general understanding of standards and the process.” Through this role, she’s also become involved in developing AI and cyber security standards, and is currently sitting on three national mirror committees and an ISO working group on AI governance.



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Natalia Maj
Master of Public Administration (MPA) STEaPP
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In summary

All the postgraduates are hugely appreciative of the time and effort Irina gave them to make sure the project was a success, and of BSI's unstinting support. All would recommend participating in BSI's SRP. Meanwhile, Rob and Paul use words like "motivated", "phenomenal" and "brilliant" to describe the postgraduates. "They were a joy to work with," says Rob.

In turn, Song notes: "BSI was really an incredibly supportive partner. I think it was particularly helpful, especially during the pandemic, that even when we didn't have a scheduled call, the BSI team would make time for us. Also I think in terms of the exposure that we gained from working with such a reputable client, this is something that would be hard to find elsewhere."

Gabriella found the topic fascinating and the focus on standards very illuminating. "Despite the fact that standards are a niche area," she says, "the opportunities in this space are becoming much larger. For instance, standardization can define the state-of-the-art in emerging technologies. It can change the way you see different technologies and understand them."

Natalia agrees that it was fantastic to work with such a reputable institution on quite a cutting-edge topic. "I also think it allowed us to put into practice some of the frameworks that we've been studying on the MPA," she says, "so was a great conclusion to the course."

Malla would choose to work with BSI regardless of the industry and scope of the project, "Just because of their engagement and support, the network that they have and the help they can give. The entire approach from their side was amazing."

The postgraduates were also highly motivated by the knowledge that their research will contribute to shaping future standardization in the medical devices industry. Notes Natalia: "I think we always felt that our project mattered to BSI and they were very interested in it. We were providing research that can shape real world outcomes. I found that quite important."



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