Editorial

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Biographical notes: Anthony Crabbe was a reader in design at the Nottingham Trent University until his retirement in December 2015. He has been involved in numerous contract research and knowledge transfer projects with manufacturing companies, including a secondment as a project manager to develop a patient-operated microwave disinfecting system, which was the first ever to be given medical device approval by the CE for use with contact lenses. He has also long been interested in the representation of temporal relationships, and is an associate editor of the journal *Kronoscope*.

Medical device technology involves levels of complexity rarely found in other fields. Medical technology is, like aerospace technology, highly regulated by both national agencies, e.g., the US Food and Drugs Agency (FDA), and international standards treaties. The latter may involve a whole network of agencies, as is found in the Communauté Européenne (CE) system of device accreditation – a system which is itself connected by further treaties to many other non-CE agencies, including the International Standards Organisation (ISO).

Numerous human factors are also fundamental to the design and development of medical devices, right down to the text and images used for their packaging and marketing, which are subject to rigorous pre-market approval in most countries. And perhaps the most striking contrast with an engineering field such as aerospace is that the design engineer is not the arbiter of what is considered the most efficacious design, because that is, of course, the role of the clinician.

The design and development of medical devices is then most often a cross-disciplinary enterprise, which can be led either by clinicians who have limited engineering knowledge, or engineers not qualified to make clinical judgements. This team of collaborators must also answer to the directors of the commercial organisation that is capable of undertaking the kind of research-intensive, high-cost, high-risk manufacturing that is needed to produce most medical devices.

However, a cursory review of the different risk categories for medical devices soon reveals that not all medical devices are complicated – they can be as simple as an acupuncture needle, which is classed as a medical device by the FDA, even though the same agency questions the scientific status and clinical efficacy of acupuncture treatment. At the other end of the spectrum lie devices like dialysis machines, which are shown in the paper by Andrè Lupi, Athanasios Kolios, and Konstantinos Salonitis to involve advanced engineering knowledge and skills that are unlikely to be possessed by the very clinicians who have identified the possibility of such devices and set the parameters for their performance.

Fortunately, dialysis machines are operated by highly trained clinical staff, which lessens some of the risks that can be presented by far simpler devices such as contact

lenses. However, contact lenses are operated by patients who are assumed by good design practice to be ignorant and potentially idiotic people who must still be well-cared for. The design of patient-operated devices then requires great concentration on making the compliance requirements of the device sufficiently easy to follow to warrant the risk of marketing it. The periodic press scares about serious contact lens related eye infections may then be seen to be one of the many drivers of innovation in such device sectors, e.g., the development of the daily disposable lens, which is the result of a massive investment in state of the art polymer moulding equipment and processes.

The patient's well-being is then the primary objective of medical device design at any technological level. And as emerges from the paper by Clara B. Aranda-Jan, Heather Cruickshank and James Moultrie, patient consultation is a key requirement of the medical design process. Their work parallels some of that presented in general design under the umbrella of 'co-design', and demonstrates the particular value of such approaches where development and marketing resources are limited, as found in developing nations. But this approach is not confined to such contexts, because as found in the aerospace industry, the development of an aeroplane that breaks new ground in aviation is impossible without the collaboration of pilots who have to personally test whether the design prototype fulfils its promise, or return it to the drawing board if it cannot.

The advent of new technologies is opening up further opportunities for smaller companies to contribute to medical device engineering, as well as for clinicians to setup their own small design workshops. Rapid manufacturing technologies are a good case in point, since they allow for novel and bespoke items to be manufactured in onsite environments, with less red tape, because much of the work done can be described as necessary to an experimental surgical process that is usually covered by the patient giving his or her informed consent. However, as discussed in the paper by Manak L. Jain, Sanjay G. Dhande and Nalinaksh S. Vyas, the setting up and calibration of rapid manufacturing processes usually requires knowledge and skills that can only be provided by specialist engineers, who may themselves choose to take a lead in the production of such devices.

As rigorous as the regulatory framework may appear, the approaches of different national agencies show some striking differences that reflect different national attitudes to law. The most obvious opposition is between the legal tradition that people have the right to do anything that is not specifically forbidden by law, and the tradition that people can only do things that are already pre-specified in a published legal code. The code compliant approach is often named after Napoleon, following his attempt to foresee every possible legal contingency in his new empire by drafting for it a single legal code that could be distributed as a definitive reference book to be used in every provincial courthouse.

Curiously, given the similarity of US to British law, the FDA operates far more in this Napoleonic way than does the CE, since applicants for FDA approval have to find the type and classification of their device from a pre-defined list that may not actually contain the new device that the applicant wishes to be approved (in which case he or she has to find the nearest equivalent). Every such product on the FDA list then has its own pre-market guidance document, often hundreds of pages of long, which also contains a specific set of testing protocols that applicants must follow to the letter in order to gain approval.

By contrast, the CE process gives far more scope for applicants to identify novel devices, as well as the risks that they themselves might identify, and to then suggest the kinds of testing and post production protocols which they think would properly address not only the commonly identified risks, but also the ones that they have identified. The final examination process is then conducted by a 'notified body', a company approved by the CE, whose job is to examine and interrogate the efficacy of the proposed device in a way that would be familiar to academics – except that the examination typically involves a three day onsite series of inspections and interviews!

Each approval system brings its own advantages and disadvantages. The principal benefit of the FDA system is that the design and testing objectives are clearly identified from the outset, and cannot drift in the way that the CE process sometimes does. The main disadvantage of the FDA approach is that it does not promote the same level of thoughtfulness about the design challenges, and research teams can be seduced into concentrating only upon jumping the pre-defined testing hurdles. Between these two regulatory approaches, gaps may then open up, some of which are explored by Tom Page's paper which examines the extent to which tolerance analysis procedures commonly used in engineering practice are either recognised or implemented in the design and manufacture of medical devices, which is so dominated by the kind of clinical regulatory framework cursorily described above.

The design and development of medical devices is then a very rich area for further examination by both clinicians and design engineers. The four papers presented in this special issue indicate something of the huge scope for members of each discipline to contribute to the knowledge and working practices of the other. Each paper looks at an area or issues that may not be immediately obvious when thinking about the interface between engineers and clinicians.

For example, Clara B. Aranda-Jan, Heather Cruickshank and James Moultrie highlight the necessity for engineers to understand the context in which the design and development of medical devices takes place, especially for low income populations. Their work then attempts a systematic review of the medical device provision for such populations as step towards building a richer reference base for future researchers and developers. Tom Page likewise observes a lack of information and understanding about how to conduct tolerance analysis, which is crucial in assessing the efficacy of medical device designs – and he too considers ways in which that gap might be closed by a more systematic review of how tolerance analysis is presently understood and the steps that may be taken to improve it.

Andrè Lupi, Athanasios Kolios, and Konstantinos Salonitis introduce not only clinicians, but also many engineers to the kind of sophisticated mathematical techniques that can be used to assess the reliability and safety of medical fluid management devices. Their paper is then a worked example of how good modelling practice can help manufacturers to assist clinicians in developing the most robust means of improving the safety factor of some of the most sophisticated and highest-risk medical devices. Manak L. Jain, Sanjay G. Dhande and Nalinaksh S. Vyas are also concerned about how best to improve the kind of resolution necessary to make best use of the promising new technologies of rapid prototyping and manufacture. In observing the currently low resolution (by clinical standards) of current 3D printers, they consider techniques for making higher resolution ones that can properly simulate the functioning of the skeletal structure of the foot of any particular patient seeking treatment.

The range of these papers then illustrates how the interaction between engineers and clinicians is one richly deserving of far more attention that it presently receives. For that to happen, a formal dialogue is necessary and this special issue is a small step on the way to building that dialogue. Hopefully, it will be among the first of many such steps.