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Introducing and embedding innovation practices in a UK medical engineering degree course

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***Abstract*— Exposing medical engineering students to innovation and entrepreneurial practices and training them in concepts and models encountered in industry in a simulated start-up company environment allowed students to explore whether this career route was of interest to them and is expected to enhance the employability of all participants. A module, MedTech BEST (Business and Entrepreneurial Skills Training), was developed to focus on the needs of the medical technology industry sector and piloted at the University of Leeds in 2016/2017. Students acquired the skills and knowledge to be able to pitch a hypothetical medical device product together with its supporting business case, developed over the course of the module, to a panel of experienced judges.**

Keywords*— innovation; entrepreneurship; medical technology; medical engineering; biomedical engineering.

I. Introduction

The OECD defines innovation as "the implementation of a new or significantly improved product (good or service) or process, a new marketing method, or a new organisational method in business practices, workplace organisation or external relations" [1]. Technological innovations can result in the introduction of new products and processes and significant technological changes to existing products and processes [2] and Lettl *et al* [3] conclude from a review of the literature that innovativeness may be understood as a multidimensional phenomenon that relates to technology, market, and organisational change. It was our aim to provide a concise means of introducing students to these concepts with a view to embedding key traits.

There can be no doubt that effective innovation requires multidisciplinary or interdisciplinary team working. The latter goes beyond collaboration in that it uses expertise from different disciplines (e.g. engineering, biological sciences, chemistry, business) to create new approaches or concepts that would not arise if team members stayed within their discipline boundaries [4]. Within medical technology, integration is needed in order to generate new ideas and solutions to address unmet or poorly-met clinical needs and continued interdisciplinary working is likely to be required to progress these solutions through the new product development process.

The UK Royal Academy of Engineering (RAEng) emphasises that innovation is about successful exploitation – in other words it has to create value (economic, social, environmental; [5]). Innovation must therefore occupy a central place in the strategic plans for economic growth and development of all nations. In the case of the UK, approximately half of the productivity growth during 2000 – 2008 (i.e. immediately pre-financial crash of 2008) can be attributed to innovation [6]. According to McKinsey, "without innovation, economies and firms stagnate and become increasingly unable to compete with those that do invest in, deliver and adopt innovation" (McKinsey & Company 2013, cited in [6]).

This paper describes the work undertaken at the University of Leeds, UK under the RAEng Visiting Professors scheme from 2015 – 2017 to introduce training in innovation practices and translation (the process of "moving knowledge and technology from "bench to bedside""; [7]) to a group of medical engineering students. This is consistent with one of the RAEng's stated aims to embed innovation practices in industry and academia [5].

II. Methods

At the University of Leeds, all engineering students study a common set of compulsory modules in Years 1 and 2 of their degree course giving them a grounding in areas such as engineering materials and design and manufacture. In Years 3 and 4 students take modules in their specialism of medical engineering with further compulsory modules and optional modules such as magnetic resonance imaging in Year 3 for the 3 year BEng and functional joint replacement technology and biomaterials in Year 4 for the MEng degree. Although the students can take the optional Managing for Innovation module in Year 4 this is one of eight modules from which they must choose three. It is thus possible for medical engineering students to have very little exposure to or training in innovation and translation processes and practices during their degree course.

We assessed the interest in acquiring skills in these areas as well as in concepts relating to entrepreneurship through Medical Engineering Evenings lasting 2 hours to which engineering students of all levels and subject entry points were invited. Students were given a scenario relating to a disease outbreak in a hypothetical humanitarian crisis requiring the rapid distribution of a novel therapy for which the optimal route of administration had yet to be determined. Working in small teams, students were required to use brainstorming for idea generation, and idea grouping, ranking and selection (i.e. activities providing input into the wide part of the innovation funnel, Wheelwright and Clark [8], Fig 1). Teams reported back to the other teams after a fixed time to receive feedback from tutors and peer-to-peer scoring. There was a modest prize for the team presenting the highest scoring solution.

We used the experience gained from the Medical Engineering Evenings to design a "full-line", medical technology (MedTech)-specific innovation and translation module which was piloted in the following academic year (2016/2017). This became the MedTech BEST (Business and Entrepreneurial Skills Training) module. MedTech BEST provides training on what might be required to take research into the marketplace (translation) using the Technology Readiness Level (TRL) model (Fig 2) for the stages of the new product development process. Participants on the course learnt about the skills, evidence, and regulations needed and the challenges likely to be encountered along this pathway. Students were given the task to develop a MedTech product concept to solve a verified clinical need. This concept could be hypothetical but had to be plausible and grounded in real science to address a real market. Teams first needed to generate ideas for a technology and select their lead idea(s) to take forward. They also needed to "build" a company formed to commercialise this product concept.

Teams received training in building a business and technology case around their idea – elements of this were delivered by external MedTech sector specialists from industry and the supply/support chain. Eight sessions were developed covering the topics listed in Table I. Sessions were 2 hours in duration in which around 30 minutes were taught and 90 minutes devoted to working within teams. Exceptions to this were Session 4 and Session 8 which were extended to accommodate talks from visiting sector specialists and the pitch final respectively.

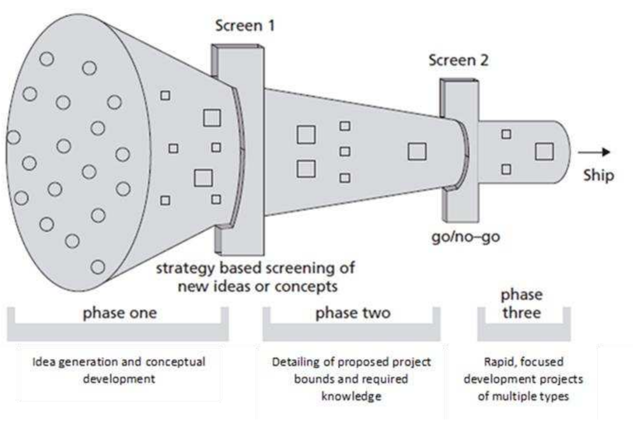

Fig. 1. Idealised innovation funnel based on Wheelwright & Clark [8]; (source: Maj Engineering Publishing and Koos Slagter, http://innovationcenter.nl/innovation-resources/innovation-models) and on Barbieri & Álvares [9].

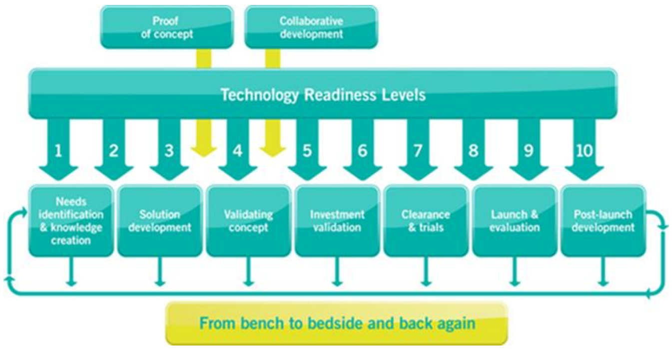

Fig. 2. Pathway for medical technology translation to the clinic and the market. Flow is from ideas generation and concept formulation to commercialisation by moving projects on to progressively higher technology readiness levels (TRLs). Source: http://medical-technologies.leeds.ac.uk

TABLE I. MEDTECH BEST MODULE CONTENT

Session	Taught component	Focus of group work
1	New product development process; innovation funnel	Team formation, idea generation (clinical need)
2	Stages of translation and the translation gaps; drivers for innovation; the customer	Idea generation (product concept), idea selection process
3	Business Plan and value proposition; requirements for translation of idea to product concept/prototype; IP; stages of start-up company development	Product concept refinement; company mission, vision and strategy
4 (longer duration)	MedTech sector markets and trends; understanding customer need; medical device regulations; (from industry and sector specialists)	Q&A to sector specialists; outline Business Plan assembled
5	Project personnel and management; Stage Gate Process; routes to market	Mock Stage Gate (team and external mentors); adjustments to Business Plan
6	Resources and Financial requirements and sources of funding; operational plan; Opportunity Note	Opportunity Note preparation; Business Plan gap identification and resolution; cashflow forecast
7	Investor's view (sector specialist) – including exit strategy	Business Plan and Opportunity Note completion; presentation preparation. Opportunity Note submission 1 week before Session 8
8 (longer duration)	Pitch final Judges feedback and decisions MedTech BEST winning product and team announced.	Team pitch presentation (15 min); Judges Q & A (30 min) for each team

III. Results and Discussion

A. *Medical Engineering Evening exercise*

Participants in these sessions gained experience in the following: teamwork, communication skills, assessment of customer need, brainstorming, generation of early stage ideas, generation of screening criteria, assessment of technological options, generation of a design brief, and building a compelling case. This event was shown to be a good primer and recruitment exercise for MedTech BEST.

B. *MedTech BEST*

Nearly 30 students were involved in MedTech BEST in 2016/2017. Four "business case" teams were initially formed, each with an assigned post-doctoral-level mentor (see Fig 3). Twelve industry and support chain experts were involved in delivering the course. We found that from the start of Semester 2 participant numbers began to decline and led to an action to consolidate participants into two teams. These teams continued to the conclusion of the module.

In addition to the experience and skills listed in (a) above, participants gained a thorough understanding of the new product development process, value proposition and the role of innovation, addressing market and customer needs and had the opportunity to build a compelling business case and "sell" this to experienced reviewers assessing the potential for clinical, product and financial success (Table II).

For MedTech BEST we sought to create an environment in which students "owned" the idea, product concept and company in which they adopted corporate, board-level roles. Although there was a component of formal teaching in each session, students were encouraged to deploy this immediately within their teams and apply this to their innovation so that it developed through the necessary translational stages.

Fig. 3. Students engaged in generating ideas for medical technology product concepts around which a supporting business plan could be developed.

TABLE II. MedTech BEST teaching and assessment methods

Teaching	Feedback
Early stage innovation activities	Generation of ideas, selection and ranking within teams; in-class discussion - formative
Project management and control	Development of proposals within teams; presentation to external assessors with feedback following questions to teams - formative
Market and customer analysis	Delegated role to specific team members, who then report to their team. Opportunity to modify and refine - formative
Business Plan generation	Whole team responsibility with specific roles assigned to individual members – formative
Making a compelling pitch	Culmination of all learning – teams pitch their product ideas and supporting business plan to external judges to test suitability for investment. Detailed formative feedback received; one team will win MedTech BEST competition.

Teams worked with mentors throughout and so received feedback at all stages. Teams were also encouraged to make contact with the external sector specialists contributing to the course and seek their advice and input on specific points.

All assessment of progress was formative (Table II). In contrast to more formal teaching methods (eg lectures, short courses or project-based assignments) there was no summative assessment (marked individual or group assignments). Students were encouraged to seek and respond to feedback (peers, experienced mentors, course leaders, external sector experts) to improve their final proposal. Teams pitched against each other to win the award for the development of the best MedTech product and investment opportunity (supported by a business plan) for that year's competition.

Participant feedback was requested and received and has been used to plan and refine the programme for 2017-2018. The comments received included, "MedTech BEST pushed us to explore the realities of business and innovation and apply that knowledge to medical devices. It was important to first understand the industry, and this was aided by real-world scientists, CEOs, investors and regulators".

Exposure and acquisition of the skills outlined will be of direct value to students considering entry into the world of medical device start-ups. Furthermore, students that, having explored, conclude that this career path is not right for them, gain new understanding and skills that will enhance their employability after graduation. The innovation practices and their application will also be of benefit in roles with more mature companies as well as those in academic and clinical settings.

IV. Conclusions

MedTech BEST and its predecessor event were demonstrated to be effective means of introducing innovation practices and an awareness of the challenges in identifying, developing and introducing new product opportunities into the medical technology sector to medical engineering students. We encountered challenges in the engagement of significant numbers of students and may need to run the module as part of the formal curriculum (rather than the present extra-curricular status) in the future to address this. Firmly embedding these skills and practices will require additional exposure of the students to opportunities such as acting as mentors to others taking the module, undertaking secondments into industry and other innovative and entrepreneurial environments and establishing a mentee-mentor arrangement with a senior industrialist. The impact and influence on employability of MedTech BEST will be monitored through the destinations of graduates that have completed the course.

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