E-learning tools to enhance decision-making skills in safe medicine development

Project Summary

New medicines undergo extensive safety testing both in animals and in clinical trials so that side-effects can be minimised prior to a medicine being licensed. Evaluation of a medicine’s safety requires integration of complex scientific knowledge within the context of regulatory guidelines and financial considerations; with decisions regarding safety being made at all stages of the process from target identification to use of the medicine in the clinic. Advanced decision-making skills are therefore essential for anyone involved in this assessment of risk to benefit, including: biomedical researchers, clinical trial personnel, doctors, nurses, pharmacists and regulators.

A major objective in the training of our biomedical and medical students, therefore, is to develop competence in decision-making skills and apply these to safe medicines development. Expert decision making skills are a necessary task for all management functions, and critical decisions demand a degree of intellectualisation, extending beyond that of a routine nature. (Reeves & Jauch, 1978; Zane et al, 1982; Uhl, 1983, Babbie,1990). Credible and reliable results can be obtained through professional judgement and group decision making processes. With this in mind, we have developed and implemented an integrated workshop group exercise as part of the Drug Safety and Toxicology module (6BBM0310). This workshop culminates in student groups making and defending their decision to progress a particular drug into clinical development, based on available drug safety data sets. This workshop is undertaken in conjunciton with pharmaceutical industry experts who provide tutorials and instant feedback relating to data driven decision making, and further form a ‘Dragon’s Den’ panel, in front of whom students present their conclusions. However, to compliment this summative workshop, and to further exemplify decision making skills, we have now produced a series of formative E-learning tools/objects.

Grant CTF13/22 funded the development of a King’s College London branded suite of interactive, extensible, future-proofed, e-learning objects. The tools were designed for formative learning, and specifically aimed at facilitating understanding of the pivotal role of decision-making in the analysis and evaluation of complex drug safety data. The initial aims of the proposal were to develop, two e-learning objects incorporating audio explanations and feedback. We have enhanced the original usability and value of the tools by using video in addition to audio, and have developed an extra rapid response Quickfire revision quiz tool to complete the suite of learning objects. In addition to these tools, we have developed and filmed a student’s perspective of the module and workshop exercise which will be accessible by current undergraduates through KEATS.

The suite of tools and Student’s Perspective video are available from this semester (Autumn 2014) on KEATS for use initially by the 2014 intake of the final year BSc Drug Safety and Toxicology in Drug Development module, 6BBM0310 (70 biomedical sciences/ intercalating medical students). See pages 3-7 for further information and http links.

After reviewing student feedback (December 2014) and further refining, we will look into publishing the tools in mobile formats, and extending and further developing the tools for other courses at King’s and externally (funding permitting). Details of the tools have been presented at the 8th Excellence in Teaching Conference (June 2014); and in collaboration with Dr Gabriel Reedy, we will look to publish details of the tools in appropriate discipline specific peer reviewed journals.
Contributors and project management
The lead applicant is Dr Manasi Nandi, Lecturer in the Faculty of Life Sciences & Medicine, King’s College London. The project was directed and managed by an independent consultant Dr Jude Hall (6BBM0310 co-organiser) who developed the scientific content/scenarios; audio and video scripts; and sourced and liaised with subject experts and contributors. The tools interface was designed and developed by Vanessa Skiadelli (King’s Centre for Technology Enhanced Learning) who also had responsibility for uploading content and audio for the instant feedback Revision Exercises. KEATS enabling was aided by Andrew Cavers (Virtual Campus and Technology Enhanced Learning).
Dr Gabriel Reedy (King’s Learning Institute) advised on learning and teaching methodology and Angela Frisby (recipient of 2013 Teaching Fund grant) advised on various aspects of the project, particularly student participation and media content. Numerous King’s academic and clinical staff (Mike Curtis, John Posner, David Phillips, Aileen King, David Mountford, Phillip Morgan, Volker Arlt) and external regulatory and industry colleagues (including: Pfizer, Novartis, GSK, AstraZeneca, UCB, Xenogesis, Janssen, MHRA, Quintiles) contributed as advisors and content verifiers. Senior industry safety pharmacologists and toxicologists, Dr Gareth Waldron and Liz Mortimer (Pfizer) and Dr Nick Buss (AstraZeneca) were central to the development and filming of the decision scenarios.
Filming and editing was carried out by independent filmmaker, Miggle Ltd, with stills photography carried out by Jessica Cheeseman (AudioVisual KCL). Concept design and content development was undertaken by Drs Hall and Nandi.

The project was highly student focused. Final year King’s BSc and intercalated medical students (2012; 2013; and projected-2014 intakes) contributed in the following ways:

- Focus groups: design, evaluating and refining the tools
- Beta-testing the prototype tools
- Development and appearance in the Student’s Perspective video
- Narrators in the audio of the instant feedback tool
- Testing the completed tools and feedback (projected Autumn 2014)

Future-proofing-Software and media used
Scientific knowledge constantly changes and regulatory safety guidelines are from time to time updated. Software and media formats were therefore chosen in order that (a) the tools are future-proofed should existing content need to be changed; (b) additional content and/or tools can be added to the existing suite of tools; and (c) the tools are in a format supported by devices in addition to the KCL intranet such as mobile phones and tablets. Articulate Storyline® was chosen as the tool interface and for the Revision Exercise Instant Feedback Tool; iSpring Quizmaker® software was chosen for the QuickFire questions quiz; and audios and videos were provided in appropriate transferrable formats.
**Project Outcomes-The Learning Objects**

The three tools are packaged into a suite using Articulate Storyline® interface, which is accessible on KEATS as shown below:
(a) Revision Exercises-Instant Feedback Audio.
This tool has 30 short safety scenarios, each with 3 evaluative statements for students to consider. Students make decisions on these 90 statements based on the information presented and then hear an instant (1-2 min) audio (and written) feedback expert opinion (ArticulateStoryline®).
(b) Decision Making Exercises - Decision Scenario Videos. These are 10-15 min video recordings of experts discussing ‘real-life’ safety decision-making scenarios, with associated framework questions. Students read the questions and then watch the videos, identifying key issues that informed the scientists decision-making process.
(c) Quick-fire Questions-Instant Answer Revision. This is a revision quiz incorporating audio/video and picture links, over multiple question types and allowing randomised and categorised testing with scoring and written explanations of answers on review (iSpring Quizmaker®).
Summary of video tools and http links.

Student perspective video – student narrated video describing course and decision making group workshop:

![Image of student perspective video]

Expert decision making scenarios – two industry expert led scenarios, discussing data integration, ethics, cost, company policy to aid decision making relating to drug progression.

![Image of expert decision making scenarios]
Project Outcomes – students’ learning

These tools introduce a flexible e-learning component to the Drug Safety and Toxicology module, thus making this a truly blended learning course. The tools complement the small group interactive workshops and lectures and further provide aids for self directed learning, consolidation of key concepts and preparation for the online and written examinations.

The immediate outcome for students will be an enhanced understanding of the strategies behind the integrated nature of decision making, in all areas of medicines safety. Students will gain an appreciation and understanding of ‘expertness’ and that expert opinions may differ; how decision-making is a balance of risk:benefit; appreciation of relevance of cost in decision making; that the consequences of poor decision-making can have significant economic and ethical implications. Finally, the importance of having a strong knowledge base in the subject and mathematical competence is emphasised and tested throughout.

Each tool can be used stand-alone, serving a different but linked purpose.

Specific outcomes from each tool

Revision Exercises-Instant Feedback audio tool: this tool encourages students to spend time in formulating a decision about whether they agree or disagree with specific statements. There are 3 statements which are associated with a single scenario and 30 scenarios in total – giving a total of 90 ‘questions’ spanning all core topics of the module.

Once students click on their decision (thumbs up – agree; thumbs down – disagree) an audio and written feedback of an expert’s opinion immediately, providing instant feedback to the students.

This will add instant value to revision, and to comprehension of course content. All key areas of Safety Pharmacology and Toxicology on drug development are covered (categorised as: General Concepts; Mechanisms of Toxicity; Pharmacokinetics; Non-clinical testing; Clinical safety Evaluation). Each of the 30, expert-verified, scenarios was developed in order to highlight that there are no ‘right or wrong’ answers to the questions asked, and the instant feedback response explains why this is the case, for each. The audio clips are 1-2 min long in order to provide time to discuss the scenario statements. The instant feedback explains the expert’s evaluation and how he/she came to a decision, including formative learning content on the particular topic. At the end of sections, there is a scoring option where students can find out in how many instances their answer concurred with the expert.

Decision-making Exercise-Decision Scenario videos tool: by watching videos of real scientists discussing safety data and formulating ‘go; no-go’ decisions, students will appreciate how expert decision making is undertaken in industry, and gain an appreciation of the various considerations (economic, ethical, timing) in addition to the detailed science, that have to be considered when making decisions regarding progression of candidate drugs. Ethical issues relating animal research and studies in humans are highlighted, as are the roles of regulatory bodies, economics and individual company policies. They will also appreciate that decision-making requires input from many members of a team. The framework questions which accompany the videos can be used in tutorials and interactive workshops, and this will be used as a mechanism to encourage students to engage fully with the videos.

Quickfire Questions Instant Answer tool: The tool is intended to develop students’ knowledge base of key terms and concepts relating to the core topics and skills (including mathematical), essential for making
informed complex evaluative and analytic decisions. The quiz is scored, so students can evaluate their progress. We believe this quiz will be a useful revision aid for the on-line and final written exams.

**The Students Perspective video:** this 6 minute video is narrated by a former student on the Drug Safety and Toxicology module. The video is intended to serve two purposes. Firstly it provides a mechanism for students to familiarise themselves with the workshop which they are about to undertake, as the narrator takes the viewer through each of the stages of the 3-week workshop (introduction, data handling, industry led tutorials, presentations and written reports). It further provides a personalised student view of the workshop in its entirety, explaining which sections were deemed challenging, enjoyable, helpful etc. Secondly, the tool emphasizes the key intended learning outcomes of the workshop exercise - stressing the importance of selecting and integrating pertinent data sets (rather than using everything), and taking into consideration the intended patient population, to make a clear, evidence based decision.

**Specific Outcomes – industry collaborations**
Voluntary input from an extensive network of industry collaborations was key to this project, and as a result, we have established strong links with senior scientists in the all major pharmaceutical companies; many of which will additionally be lecturing and acting as workshop tutors on the module. This relatively new area of safety pharmacology is emerging as a major source of employment within the pharmaceutical industry, and our colleagues have indicated that decision-making skills and subject knowledge in this area is lacking in UK graduates. The feedback that we have received from our safety pharmacology collaborators for the development of these tools has been entirely positive; with several voluntarily giving up large amounts of time to develop and appear in the videos. King’s has the potential to be at the forefront of training and has opportunity to excel in undergraduate teaching and thus employability of our graduates in this emerging area.

**Future development and outcomes**

These can be summarised as follows:

- **Students** - the project was highly student-focused, evident in the audios and videos. The Student’s Perspective video in particular can be viewed by putative home and overseas students, and thus aid student recruitment. Furthermore, this video can provide an example of the interactive teaching that takes place within the Pharmacology department at KCL (and beyond), providing an exemplar video to facilitate undergraduate recruitment.

- **External audiences** - we presented the outcome of the grant at the 2014 Excellence in Teaching Conference, and in collaboration with Gabriel Reedy (King’s Learning Institute) we will seek to publish details of the tools in appropriate peer-reviewed journals.

- **Other KCL courses** - the tools were designed so that he template format can be adapted to areas in drug discovery and development in addition to safety, thus increasing appeal to additional audiences. We have had interest from additional module organisers at KCL (Susan Duty/Lawrence Moon and Julie Keeble) and with time with present these tools to other departments to facilitate the development of future e-learning tools throughout the college. The potential users include pharmacy (450), medicine (2000), nursing (500), MSc. (Pharmacology; Biomed Sci; Drug Discovery Skills; Pharmaceutical Medicine) (~50-100 students).

- **KCL branded resource** - following student feedback and review, we will look into using the tools as a KCL branded OER for other universities and not-for-profit institutions. We have had initial
discussions with Professor Shirly Price (University of Surrey, Dean of Teaching and Learning) and the Education Committee of the British Pharmacological Society in relation to this.

- **Distance Learning** - there is potential to use the resource as part of distance learning modules within the college. Summative assessment can be easily incorporated into the existing tool interface.

- **Graduate Employability** - Safety assessment is a major source of employment within the pharmaceutical industry and research institutions. As far as we are aware, there are no other dedicated Drug Safety undergraduate modules in the UK, so King’s is at the forefront of training and has opportunity to excel in undergraduate teaching in this area.

- **Business** - Given the emphasis on critical decision making within these tools (i.e. those decisions which can positively or negatively impact on the functioning of an organisation), we may consider incorporating more on how business decisions are formulated within the context of new medicines by inviting industry leaders to lecture on the course.

**How we will assess the enhanced learning**

The initial target group is final year King’s BSc (pharmacology/biomedical sciences) and intercalated medical students taking the Safety Pharmacology and Toxicology module 6BBM0310 from 2014; 70 students/year. These students will have access to the tools throughout the module via KEATS.

We will obtain feedback from these students in the following ways:

**Formative feedback**

a. We will ask students to complete a specific tools-feedback questionnaire asking them to indicate the usefulness of the tools and videos and suggest improvements.

b. We will hold a focus group during the first 2014 semester to discuss the tools.

c. In the Autumn 2014, we are trialling the use of one video in a scheduled interactive teaching session and the instant feedback scenario tool as an optional tutor-led revision session. In both cases, we will obtain instant feedback from the students after the session on how useful they thought the session was.

d. We have a post-module survey that will allow comparison of student satisfaction with the previous 2 years the module has run prior to the tools being available.

e. We will encourage students to post on our KEATS forum to give ‘live’ feedback.

f. We will obtain informal feedback from King’s staff and industry personnel.

g. Via KEATS (Moodle) analytics we will determine extent and type of on-line presence of students.

**Summative feedback**

a. We will compare scores from the end of module on-line exam with previous years and the final exam (particularly mathematical skills).

b. We will compare student performance at decision-making workshops pre and post access to the tools.