



Reinvention Centre – Academic Fellowship Final Report – June 2009

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1. Project Title

Groupwork clinical science research projects in undergraduate teaching

2. Keywords

Student-led research
Good Clinical Practice (GCP)
Biomedical science

3. Summary

U14640 Neuromuscular Physiology and the Control of Human Movement (NPCHM) is an advanced double module where the subject matter is taught from a clinical science viewpoint and half the coursework assessment (20% of a double module) is a groupwork research project on clinical biomechanics/physiology..

The aim of the project was to provide the students with direct and structured participation in the research programme of the Movement Science Group incorporating elements such as research ethics and Good Clinical Practice (GCP) in line with the recent EU Directive on GCP in clinical research.

Outcome measures from the first cohort indicated mixed success with the project; whilst overall student evaluation was enthusiastic about this part of the module, the individual topics mentioned above received less positive feedback, even though they were seen as essential to the quality of the finished product. This finding was repeated to some extent with the second cohort, although they did perform noticeably better in terms of enthusiasm and willingness to accept the extra demands made on their time.

Unfortunately the unexpected low recruitment on the module in the first run of the scheme (22 instead of the 40-45 students registered in previous years) precluded valid statistical analysis, as the large variations found together with

the small sample size rendered the analysis underpowered. The second cohort of 42 students was also found to be underpowered for meaningful analysis.

The outcomes of this exercise have been positive for both staff and students, though the main beneficiaries have been the students who stay with the Movement Science Group and undertake experimental Honours Projects with us in their third year (usually to help with graduate applications to medical school), and those who seek careers in the pharmaceutical industry, where firsthand experience of clinical trials procedures must confer some advantage to their applications.

4. Activities

(a) Background:-

(i) module and students

U14640 NPCHM is a Year 2/3 module which has had four runs since its inception. Usually 80% of the students are second years. The module is acceptable for the Human Biology and Exercise/Sports science degrees, and is the only prerequisite for a double Honours module in Neuroscience. Past cohorts have been mainly (>70%) Human Biology students, and the module evaluations have given interest in medical subject areas as a prime reason for inclusion of this module in their Stage 2 programs. A substantial proportion of Human Biology students are interested in doing graduate medicine; our first year careers talk in this area last summer attracted over 50 first year students. Although many of our Human Biology modules of necessity include medical subject matter, U14640 is probably the most clinically based.

The main reason for this is that the module leader and S2 lecturer are respectively Manager and Director of the Movement Science Group (MSG), which is the largest research group in this area of the School. Since its inception in 2003-4, we have made student participation in our research one of the Group's priorities. Our success with Honours project students was probably the initial stimulus for moving in this direction, and our first cohort of project students in 2003 helped generate at least one publication each, as well as student presentations at the BASES Summer student conference. At the last BASES conference, four of our students presented posters of their project work. Such inclusion does have considerable resource implications, in that students working with patients need Criminal Records Bureau checks (which cost £60 each), ethical permission and Honorary Contracts with the relevant Hospital Trusts. This must be set against the value of such student work in helping their applications for medical school/postgraduate work and in enhancing OBU's profile in the local clinical community.

This impetus carried us through to the final design of the module, and the decision to go for a groupwork project as a substantial part of the coursework. At the time, the University was going through one of its periodic transferable skills crises and wanted to incorporate groupwork assessment

wherever it would go (not to mention a few places where it wouldn't) so we had School blessing for this initiative. We did not need to draw upon any paedagogic research to justify the decision, and just used student evaluation of the previous module in this area, which had a smaller groupwork project as part of the assessment.

(ii) U14640 – first cohort; semesterisation and groupwork issues

For the first two runs of the module we were limited in the number of research staff available for supervision, and this necessarily restricted the scope and diversity of the topics available to the students. We also became aware of three other possible limiting factors, none specific to this module but nevertheless possibly putting brakes on student achievement.

The first was a result of course planning for semesterisation. Like many Schools, we adopted a Stage 2 (Years 2-3) program with many double modules (the direct result of fatuous University pressures to cut the administrative costs of examination assessment). For a majority of our students, this means a program of four double modules in their second year. We are still coping with the results of this; despite careful planning by module leaders, student perception is still that Semester 2 over-works them too much, and that the amount and level of S2 coursework is excessive. This is plainly shown by the module evaluations for these four core double modules, where the Learning Outcome scores and positivity of student comments are often disappointingly low. Informal scoring of the modules just before the Christmas break reveals much more positive feedback. This 'double module fatigue' is a serious handicap to our efforts and there are no more palliatives we can introduce to amend the situation.

The second factor was that of groupwork administration. Introduction of groupwork in Year 1 led the School to adopt a rigorous procedure for ensuring that inequalities in student effort can be quantified so as to reward hard workers and penalise non-participation. The necessary paperwork to document this is absolute anathema to most of our students, who would rather the slackers got away with it than fill in all the forms (and the paperwork required for this is excessive in the extreme) and also 'inform' on their fellow students. Although the students' work in 14640 was usually carried out in the presence of research staff (for safety reasons) and so repeated absence (rare but it did happen) was noticed, we did not find a satisfactory time-efficient methodology for dealing with this problem.

The third potential problem concerned the consequences of failing the assessment work and getting a Resit Coursework (RC) grade. Given that the learning outcomes specifically refer to the groupwork, an RC grade has to mean exactly that, so the student must return to Brookes in the summer and retake that part of the module, including the groupwork assignment. As this is obviously not feasible, students on the module are warned in Week 1 that failure in this part of the module will result in an overall Fail grade. Although this was ratified by the Modular Management Office, informal advice was that a student appeal against such a ruling might succeed. We have since amended the module rules so that such fails will entail a resit examination, but obviously such students will still not have attained the Learning Outcomes for the module. Five students have since gone down this route.

On a happier note, student evaluation was unanimously positive on the academic and transferable skill benefits of working in a research laboratory in 'real-life' situations as opposed to carrying out set-piece laboratory exercises in practical classes. The direct relevance of the work to clinical rehabilitation and practice provided a real spur to student enthusiasm, even in the normally less-motivated students. Some of the students were less enthusiastic about direct participation (ie hard and sustained work) in experimental planning and data analysis, but in the main we felt the potential advantages more than outweighed the above negative factors.

(iii) Research governance and good clinical practice (GCP)

One of the main spurs to changing the module to give a more true to life experience of clinical research was the recent introduction of research governance legislature. This sets out the procedures to be followed in all clinical experimentation such that the rights of patients and other subjects are protected, and full documentation is available to support such work (and will be kept as a permanent record).

The original policy on these matters was set out in the World Medical Association Declaration of Helsinki (1964). In the UK, ethical guidance on student-conducted research was further examined by the Doyal Report in 2005 and the Warner Report on clinical research ethics in 2006. These were further refined by the Medical Research Council in its policy statement on research governance and ethics in 2007.

The legal requirements were set out in the UK Clinical Trials Regulations of 2004, which implemented the EU Clinical Trials Directive of 2001. Current legislation is that of EU Directive 2005/28/EC and its recent amendments. The executive summary neatly encapsulates what this directive sets out:-

“Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety and well-being of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible.”

This means that consistent standards must range across the following stages of clinical experimentation:-

- Ethical applications and procedures
- Investigator's qualifications and training, dealings with trial subjects, safety assessment, reporting and auditing
- Sponsor's responsibilities (NHS)
- Trial protocol
- Subject monitoring
- Data handling and record keeping
- Auditing

In practice this means all of the above plus Standard Operating Procedures (SOPs) for all experimental techniques must be adhered to, and paper records kept for a minimum of 20 years. The laboratory/clinic is open to audit at any time, and unsatisfactory performance could shut down all our experiments for an indefinite time. This is our 'real world', and students dealing with this area of biomedical science should surely have to be conversant with and perhaps have competence in these areas. All of our postgraduate and postdoctoral staff have to take and pass the online ICH MHR GCP Training Course before they are allowed to conduct clinical investigations. At £35.00 each it would not be feasible for undergraduates to jump this hurdle, but we do ask them to go through the website course demo. *Student feasibility issues.* For this module, it is simply not feasible for all students to have direct dealings with NHS patients who take part in our clinical trials; the financial and administrative burden would be overwhelming. The experimentation that the students carry out is thus restricted to normal 'control' subjects, and in most cases this means the students themselves plus their friends. We use this experimentation to quantify accuracy of measurement, problems with techniques (experimentation with human subjects always raises problems with measurements) and generation of sample sizes using power laws.

This does not deny the use of *hypothetical* patients in these exercises, and from the start of the module we have used such simulations to question student beliefs and assumptions. For the proposed plan, much more use will be made of these.

For Ethics Committee permission, this type of human experimentation can be dealt with at School level, and, more importantly, can be completed and approved before the start of the module.

(b) Implementation

(i) Changes to module timetable and teaching

Timetabling. The groupwork project runs in Semester 2. In the original timetable, Semester 1 was essentially the theory part of the module, detailing the nerve:muscle physiology knowledge base needed for safe and accurate experimentation in the projects, and the groupwork element more or less stood alone as the practical component in S2. For the new run of the module, the ethics, research governance, experimental design and data analysis would run as a longitudinal strand in S1 alongside the theoretical material. Given the vagaries of student attendance at lectures, this element of the course would have to be formative coursework, so participation is compulsory for passing the module but this element of the module is not formally assessed.

This never goes down well with students, and there were the expected long faces when this was explained to them at the start of the course, but lecture attendance has always been fairly good on this module, and the mode of delivery, as open tutorial/discussion sessions rather than didactic lecturing, helped to generate and maintain student interest. As expected, there were absentees, and these were dealt with promptly. For most students, emphasis of the material as a skill set which could be used to enhance their CV further improved participation. It was emphasised that this material could

significantly improve their Personal Development Plans (PDPs - reflective diaries of transferable skill acquisition and aspiration) – a laudable aim, but somewhat negated by the very low numbers of students who actually participate in drawing up PDPs.

Group and project selection. The students were allowed to self-select into their groups, the unexpectedly low recruitment on to the module (23) giving five groups. The normal recruitment is @ 35-45 (2006-07, n=37, 2008-09, n=45), so teaching resources (in terms of part-time hours) for this cohort were restrained by the low numbers. The range of putative projects was demonstrated by MSG post-graduates (including last year's efforts), and a short practical session showed the techniques available and 'hands-on' experience. Each student would be a subject for all the other groups, so every student sampled every project. Selected reference lists for each project area were taken from the MSG literature database and made available to the students to help them finalise decisions on which project area to pursue, and time was made available at the end of the lecture sessions each week for discussion. Student groups and provisional projects were defined by Week 5 of S1, and targets were then set for hypothesis generation, experimental planning, protocol generation and ethics/GCP submissions.

Project monitoring. It was originally intended for the whole of this project to be driven by an Access database detailing individual/group progress and relevant paperwork for ethics/GCP. A beta test version was set up using our laboratory version as a guide, but after two weeks of student input it became unworkable; we didn't realise how fragile Access can be at the hands of 23 students. The groups' work had thus to be paper-driven, and each group filled two box files before Christmas, a fitting tribute to GCP requirements. This probably taught them more about the real world than anything else in S1. It also reminded us of the value of student testing!

Copyright issues. We have since realised that there are also security and copyright issues with using research material for undergraduate teaching. Under Brookes' Staff Conditions of Service, the copyright for all teaching materials devolves automatically to the University. Our GCP arrangements are currently the only body of such knowledge/expertise/procedure in the University. They represent the culmination of a lot of hard work by the Movement Science Group, and have a definite commercial value, a view independently confirmed (albeit unofficially) by the Research and Business Development Office. Regretfully, we thus cannot publicise the GCP material in its entirety into the student domain, so the all-seeing, all-doing Access database will remain wishful thinking.

Student evaluation of S1. Given the small cohort size, we decided to use Focus Group methodology to gather feedback during this part of the course. We use this methodology routinely with our patient groups. This encourages active participation and is in itself groupwork, particularly in evaluating priorities at the end of the session.

Contrary to popular belief, it is not difficult to encourage students to engage in active discussion; students will tell you time and again that as long as the lecturer can hold his/her tongue long enough for them to get into their stride, a group of students can easily go on talking for hours.

Three limitations quickly became apparent during the course of the exercise. Our research is primarily on populations with long-term neurological disorders

(multiple sclerosis, Parkinson's disease, stroke). The relative (in some cases absolute) immaturity of the students does make it hard for them to empathise with these (usually) intractable problems faced by (mainly) elderly people. This appeared to extend to some extent to all elderly people; students were more or less completely unaware of the physiological changes which accompany normal ageing. To give an example, people with multiple sclerosis are intolerant of exercise programs because they have problems with temperature regulation. Further discussion elicited the real reason for their avoidance of exercise, which is exacerbation of an already dehydrated state. Continence issues are a real problem for very many MS sufferers and, quite understandably, they will avoid situations that force them to drink. To a lesser extent, many (25% in the UK) normal females also have continence issues. Sadly, some students even exhibited visible distaste when asked to consider such issues. Fortunately they were a minority, and over time their repugnance appeared to lessen. It does make one wonder how medical schools deal with such immaturity. This gives measurable credence to the Ecclestone/Hayes hypothesis of 'infantilised' students produced by so-called therapeutic education, where they cannot cope with everyday challenges. Our final project students (obviously, an elective population) do interact very well with the patients, and it was suggested that members of our User-led Steering Group (MSG patients who help us form group policy and research) could come and run question:answer sessions in the Focus Groups. Surprisingly the class elected not to do this on the grounds that it might prove too stressful for the volunteers! Again their immaturity showed through, confusing physical frailty with lack of strength of mind/purpose. Granted that the physical environment of Oxford Brookes in mid-semester is not a haven of tranquility, their mis-placed concern did show some consideration.

Secondly, and this and the following issue occur throughout the Modular Program, some students began to adopt the "why should I do this when there are no marks for it" attitude. This has become more and more pronounced in recent years, no doubt due to the overwhelming influence of SATS on school syllabus content. Finally, the appearance of an evaluation questionnaire in Week 10 produced a universal groan. These students were only half way through their degree and already had evaluation fatigue. In addition they were faced with a shortened version of the Manchester EBL (evidence based learning) Evaluation Survey, which adapted well to the learning methodology employed on the focus groups.

(ii) Semester 2 – groupwork project execution

Timetabling. At the start of S2 the students had all completed the rest of the coursework for the module, and had the marks for this work. In previous cohorts some of the other coursework was not handed in until half way through S2, and students complained about too much work in S2. For this cohort, there was thus a clear run through with no distractions. The type of teaching on the module changed also, from the more orthodox lecture:practical class format to seminar-based material in the lecture slots. The groupwork projects could be timetabled throughout the week, not just in the module slots, thus drawing the students away from 'if it's Wednesday, it must be U14640' attitudes.

Execution. The first few weeks of S2 were taken up with gaining experimental expertise, organising testing and the groups learning to work as a team. For this exercise, we did not assign team roles; this has been tried elsewhere in the School and has not worked too well. The research staff supervising the projects reported that in general the groups multitasked well, and that everyone participated in all the activities (each student had to act as a subject in all the experiments) with two exceptions, one hopelessly disorganised student and one persistent non-attender (who failed the module). Obviously, this was made easier with the small cohort size. All the projects were completed on time, and informal feedback from the students at this stage was very favourable. The second Evaluation Survey was filled in when the posters were handed in (students anonymised but numbered).

(iii) Second cohort: 2008-09

For the second run of the module, we had 42 students enrolled. This gave us surprisingly few extra problems apart from the volume of paperwork produced to satisfy GCP requirements and a few difficulties in ensuring adequate supervision of experimental work. Nine groups of “free-running” students requires a large research laboratory (both in space and manpower) for the process to work satisfactorily; fortunately we had both. As is usual in such cases, this run of the module seemed to go much more smoothly and the students seemed more positive, but the evaluation again revealed non-significant changes.

5. Outcomes

Student evaluation. The standard module evaluation form was used, in order to compare students’ responses with previous cohorts. As previously mentioned, 70% of these students are doing four double modules in their second year, and the revision load at the end of Semester 2 does generate a negative loading to their perceived experience during the year. This year was no exception, and the comments and Learning Outcomes scores were similar to last year’s results. As with previous years, the consolation factor was that the other Life science Year 2 double modules received similar relatively ‘disappointing’ scorings.

Manchester Evaluation Survey. This produced more positive reports, but no significant improvements from the end of S1 to the completion of the project in S2. Given the spread of answers received, a sample size of @50 may give the sample size needed for statistical evaluation; this will certainly be carried out if enrolment increases. Informal feedback revealed that students were appreciative of the effort put in to give them a more ‘real-life’ experience, and that they found working in a research laboratory more conducive to generating high quality work; as one student succinctly put it, “it beats the hell out of 3 hours of test-tubes and white coats”.

Staff Evaluation The teaching staff and participating research staff were unanimous in declaring a significant improvement in the quality of the module. It also proved very useful in ensuring all staff acquired a good grounding in this subject area; with most things, having to teach it does depend on mastery of the subject matter... Would we have implemented this initiative without Reinvention Centre resourcing? Again, a unanimous answer – no. The extra work involved in setting up the material could not have been carried out without the time we were able to buy.

Dissemination The work produced, whilst of fairly high quality, did not really merit inclusion in the BASES Summer Conference. Unfortunately, dissemination of best practice is not yet a forte within the School of Life Sciences. The School's Learning and Teaching Committee has not yet established pathways within School procedures for this. Within our Section, we will certainly advise and help colleagues interested in such initiatives. As for wider dissemination, on reflection we feel that our work is probably too specialised and not of high enough quality to warrant blowing of trumpets....

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