Online participation assignment

by ALINA HADJIKYPRI

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MSc CT Introduction to Clinical Trials

Edinburgh University Semester 1 2013/2014

Online participation

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MSc CT Introduction to Clinical Trials

Edinburgh University Semester 1 (2013/14)

Online participation assignment template

Note to course participant:

- If possible please use the table below for ease of marking the self-assessment part of the assignment. The table is expandable.
- Remember to save this template as a new file once you begin editing-include your UUN number in the filename/NOT your name.
- If you are submitting more than one posting per criteria please clearly number and date (date of posting) each one separately-use of a smaller font (8/9pt) is fine for the copy-pasted postings.

Part I. Self-assessment

Criteria	Unit origin of post (s)	Your selected posts (font 8/9 pt fine) inserted here (~1200 W in total)	Marks & self-assessment (75-100 W each)
Timeliness Postings are well written and usually made in a timely fashion (ie, in good time for others to read and respond to before the discussion closes).	Unit 1 Q3, Unit 1 Q1	Unit 1 Q3, 11/10/13 The HOPE (Heart Outcomes Preventions Evaluation) trial is an example of a success story. The idea was to look into a group of patients with evidence of vascular disease or diabetes mellitus and one more cardiovascular risk factor but with no heart failure. Treatment with the antihypertensive drug **ramipril**, an AMEA (angiotensin converting enzyme inhibitor) was given in the test arm against placebo, to investigate if there was any benefit in prevention of new cardiovascular morbidity non-connected to a change in BP levels. The study was stopped early due to important benefit in the active arm, where significant risk reduction rates were already evident for stroke, myocardial infarction and even for all-causes mortality. Almost fifteen years later, AMEA have changed the therapy of cardiovascular diseases by helping doctors to fight atherosclerosis and opening new ways for other renin-	I think I should award myself 9/10 pts for I have always posted my opinions early during the discussion allocated time. It allowed me both the time to study the course materials, and so to have a structured opinion about the question, and the time to receive feedback from my peers or from

		angiotensin drugs. References 1. The HOT Study Investigators. N Eng J Med 2000; 342:145-153. 2. Cifkova R. The optimal BP goal for brain, heart and kidney.04/05/2012 EuroPRevent 2012. Unit 1 Q3, 11/10/13 Hello Ben, HOPE trial was stopped three years after, while the estimated duration was five years. So, is it a good idea to stop early a clearly-benefit trial? -Yes, because the study results can be published earlier and messages applied to clinical practice and help many patients. Also, the placebo group could benefit too from the same therapy. -No, if it means to stop follow-up (at least in the active group). Certainly, there is more information out there! However, many other studies came after the HOPE trial. (I could mention the EUROPA, with perindopril).Favorable effects have been confirmed in more cardiovascular indications and groups of patients and so have stimulated research in RAS (Renin Angiotensin System) drugs. Unit 1 Q3, 15/10/13 Hello Ben, This is certainly an interesting paper. In truncated trials, authors identify an overestimation of effects that can be misleading. The probability of this to happen depends on the number of participants in trial. Small trials may even lead to conclusions able to harm when stopped early, while large trials are less probable to have significant overestimates. I had a look at some other papers on the subject, and I found that other authors too consider that the risk of overestimating treatment effects decreases markedly when the number of events is very large. One study suggest that considering in advance the possibility of early-stopping for efficacy and pre-plan an open labeled extension are important. Also, that medical journals should require authors to report details that would allow readers to carefully evaluate the early stopping reasons and procedures. -Zannad F, Experience from trials that stopped early. ESC (European Society of Cardiology) Congress 2012 -Montori V, Devereaux P, et al. Randomized trials stopped early for benefit. JAMA 2005;294(17)2203-2209	tutors and to engage in debates based on my colleagues posts. This was the case in Unit 1 Q1, Unit 1 Q3, Unit III Q 1, Unit IV Q2. Q3. 11/10/13
			Mark out of 10: 9
Engagement	Unit 4 Q3	Unit 4 Q3 25/11/13 I would like to add to the commentaries by answering to both Paula and Tze Shin, as I	I would award myself 8/10 pts for my participation in the online

Postings draw on other course participants' responses in a constructive way (ie, not simply confirming a similarity or difference in views, but elaborating and explaining similarities or differences.)		think that both of you are right from different points of view; regulatory criteria are tight enough, maybe more than that will "strangle" research, but on the other hand, it seems that changes are required in certain directions. I found of concern the high percent of comparator bias presented by Mann and Djulbegovic. Maybe one main reason for that is that many trials aim not to address the "uncertainty principle" but to show in a favorable light a new drug, often a so-called "me-too" one. Last year I have attended the Advanced Hypertension course and I've heard Prof. Peter Sleight, from Oxford University, to lecture about "How to read papers critically". One of the aspects he stressed was the importance of "reading between the lines" for clinicians so they always should use the clinic common sense, knowledge and experience when reading papers and decide to implement study conclusions in practice.	debates, as I have actively engaged in dialogues with my peers in all the units. I will give as an example Q3 in Unit 1 (already presented above) where my posting has prompted an interesting dialogue with Ben and expanded a new approach of the subject. I could also add Unit 3 Q1, Unit 4 Q2 and Q3.
			Mark out of 10:8
Relevance Postings are relevant to the general themes of the Thought questions.	Unit 2, Q4	Unit 2, Q4, 28/10/13 Searching for "cluster randomized trial" on UK Clinical trials gateway I came across the PREVENTION study. This is an ongoing trial currently conducted in Leicester County, who examine people at high-risk of Diabetes Mellitus (DM) to identify those with Pre-Diabetes (PDM). Consecutively, the patients are cluster randomized, according to the GP practice they are attending, in two groups: -the first group (active arm) will attend educational sessions as a part of a low-cost prevention program concerning mainly dietary and lifestyle advice. -the second group (control) receive the current employed medical advice in this situation. The investigators plan to enroll 748 patients from 44 GP practices. Both groups will be re-examined once a year for three years, aiming to see whether the intervention can improve the rates of development of DM and cardiovascular disease. Cluster randomized trials are often the choice of an investigation group looking to find how an educational intervention work in a population in a specific disease, as this study type have better chances to avoid the contact between the two groups and so to limit bias. I think that another option could be a "zelen" study.	I feel that I could award myself 9/10 for relevance as defined by the grading criteria, as my comments referred to and developed the question directly and while elaborating the discussions.
			Mark out of 10:9
Critical thinking Postings demonstrate evidence of critical analysis and exploration of concepts and ideas	Unit 3 Q3 Unit 1 Q1	Unit 3 Q3, 24/11/13 The stratified medicine is a concept of personalizing the treatment of a severe disease to a group of patients, based on their genetic or other biochemical characteristics, identifiable by tests. It is a "precision medicine", which aims to tailor the therapy for a specific patient, thus improving prognostic, reducing time delays, side effects and toxicity, at the same time as being cost-effective. For the time we are speaking, applications of the stratified medicine can be identified mainly in cancer therapy.	I believe I should award myself 9/10 for the critical thinking as reflected in the postings through the study units. My answers draw from the course lectures but also critically develop the

relevant to the general themes of the Thought questions, or other themes that have emerged in the discussion.		The concept represents an immense challenge for the future development in all medical fields, both in treatment and in prevention of diseases. I was impressed by the how many postgraduate programs someone could identify scheduled to start in 2014 at different UK Universities for training in stratified medicine. At the same time, various programs are organized in US and EU, to inform and to stimulate interest for further development. In my opinion, a long time will pass until stratified medicine will develop in an extent that will change the daily clinical practice in the different medicine fields .New directions of studies are at the horizon, but the road is long and difficult, involving economic, technologic ,research, regulatory and educational issues, and time. The randomised clinical trials will probably have a different design for those purposes, but it is about the future. http://blogs.bmj.com/bmj/2012/10/15/richard-smith-stratified-personalised-or-precision-medicine/ http://ec.europa.eu/research/health/pdf/biomarkers-for-patient-stratification_en.pdf Unit 1 Q1. 09/10/13 A randomized clinical trial, even if it is not a perfect solution, is the most efficient way to test the efficacy and the safety of a therapy or a procedure. Randomization removes in great extent bias and aim to equalize variables in the compared groups. I think these are the most important aspects -more objectivity, bias limitation, a better control and results closer to real-life. I think that finding out what trials have misleading results is not so easy. One should probably analyze first the robustness of the research hypothesis, the trial design and the sample-size which is connected to the study power. Maybe the study details are a catch too, as they are easy to misinterpret. To try to answer to Ben, I could only agree with Sally about high therapy cost as being an impediment in implementation of research results in clinical practice. An example is the NOACs (Novel Oral Anticoagulants) therapy in patients with non-valvular atrial fibrillation. There is an increasing evidence about the superiority of NOACs compared to classic vitamin K antagonists for those patients, and European Society of Cardiology recommends this therapy. However, these drugs are prescribed mostly to selected patients with certain co-morbidities, as we could only think what this would mean for the health systems around the world, since it is estimated that atrial fibrillation affects cca 1% of population at some point in lifetime and the therapy cost would rise more than eight times. Also, most physicians do need a time to make sure that adopting new concepts in real-life would be in the advantage of their patients and would not harm. As I live in Greece, I could add one more' barrier': some therapies imply specialized follow-up, which is not available in small islands and other remote areas.	concepts where appropriate.
			Mark out of 10:9
Evidence base	Unit 1 Q3 Unit 3 Q3	See Unit 1 Q3 from the Timeliness section. See Unit 3 Q3 from the Critical Thinking section.	I feel I can award myself 9/10 for evidence base as I included in

Where relevant, key points in postings are supported by good use of current literature, from the Unit readings and elsewhere.	many postings and where applicable the consulted bibliography. I give as examples the above mentioned postings, Unit 1 Q3 11/10/13. Unit 1 Q3 15/10/13. Unit 3 Q3 24/11/13.
	Mark out of 10:9
TOTAL MARKS	**Mark out of 50:44**

Part II. Reflections

Contributing to the thought discussion panels through the different stages of the Semester I courses has been a novel and interesting experience to me, and, in a numbers of different ways, a challenge. It was a challenge to handle the computer issues (I am not so skilled with technology, but getting better!), to manage to be in time with the theory and bibliography study, so I can shape an opinion on the question and to contribute to discussions, and to use my English!

The online thoughts helped to debate important issues of the courses and to think about them in a practice-based approach, while sharing from our own experience and listening from the others.

I believe that one of most essential subjects examined was 'Why a RCT?", in Unit 1 as it helped to throw light on the importance of randomization in trials and correct sample size and it was a background for a good conversation, with comments from Professor Ralston, Ben and Andrew that clarified point issues. Other key debates focused on bias, from involuntary ones to fraud. This was analyzed in depth, in more than one module, and some of the colleagues, who are currently working in the field of clinical trials, shared interesting experiences. A stimulating conversation developed about patients' enrollment and trials ethics, focusing on rules and GCP, again with interesting practical comments from those engaged in trials. Future direction for CTs has been presented in Unit 3 with lights on the stratified medicine, a huge challenge for medicine. Unit 4 was, probably, the most animated, even if we were more busy with the projects, in part because of the interesting themes but also because we probably have gotten into the pace of the debates. I found very interesting the Karen McIntyre's commentaries about her participations in WOSCOPS, Sally's and Paula's about their unit's trials and the TOPS system,

Riette's about CT in children in South Africa, Karen McCutchon's description of her own experience as a volunteer in a CT, Tze Shin's opinions about regulatory laws in CTs which have prompted a debate that I took part too, and this is to mention only a few.

Overall, my participation in online though discussions has been a rewarding and enjoyable experience. After the first contact and the adaptation within the Course, I've found my pace with the modules. I think that it helped me to improve my language skills, and in this context my confidence. Thought discussions contributed in consolidating knowledge, developing subjects in more depth, in exchanging views, sharing experiences and personal opinions. They have stimulated a critical study of the core readings, with focus on practice, which I consider to be an advantage of this course. Last, but also important, it helped to establish a relation between students, which I believe it is valuable. As further learning areas, I certainly should read in more extent medical statistics, CT design, regulatory issues, but a good first approach has been done.

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GRADEMARK REPORT

FINAL GRADE

80/100

GENERAL COMMENTS

Instructor

Dear Alina,

Thank you for your assignment submission. Please find below the tutor's marks and comments as laid out in the assignment specifications folder for the Online participation assignment Parts I & II:

Part I:
Timeliness
Agreed. Your postings are close to the start of a Unit discussion which elicits suitable engagement from others and ensures that your original ideas are posted. 9/10 pts

Engagement
Agreed. These are informative and thoughtful posts underpinned by relevant course readings and direct engagement with the contributions by peers as well as your own experiences. 9/10 pts

Relevance
Your post is linked to the topic at hand and you draw from relevant readings and resources consulted for support. 9/10 pts

Critical thinking
You evaluate and challenge concepts critically which you explore further drawing also from the literature and your own experience in support of/or against your ideas presented while positioning the ideas of your peers/tutor as well. Ask yourself further what else might stand in the way of stratified medicine, for example-what does the lit say? What is your experience (from practice or further readings) and can stratified medicine really be taught for practice already ? Is there a practice that is common today that took huge change and restructuring to implement in comparison. 8/10 pts

Evidence base
Agreed. You have drawn from the course readings, and you make links to results from external literature and current practice which you have referenced. 9/10 pts

Total tutor mark: 44/50 pts

Participant mark: 44/50 pts
Average: 44/50 pts

Part II
Section 1: Subjective account of new and challenging experience and initial excitement including how this feeling eventually changed over time. Other areas for reflection might have included online learning/communicating in general compared to conventional modes of communication. Was it easier/hard/daunting/tedious to logon than you had envisioned? To scroll through reems of posts? etc. 8/10 pts

Section 2: You describe selected topics discussed but only briefly how this online communication experience contributed to your learning and improved your understanding. You do well to underpin your accounts with examples directly from the discussions, but further areas for personal reflection could have included thoughts around anything that surprised/angered/scared you about the online discussion? Based on this experience, how does the online discussion compare to face to face live discussions? To the synchronous lectures? 20/30 pts

Section 3: This is a more subjective reflection about the online discussion experience. You share your own learning from the posts of others and how the online postings complemented the written lessons and fostered student-student relationships-a very important point, indeed. Clearly, you feel that the online discussions assisted your understanding in a number of ways including your English language proficiency. 8/10 pts

Total Tutor mark:36/50 pts
+ Part I average: 44/50 pts

Final mark: 80/100 pts (A2)

This is an excellent result! You are on your way to becoming a truly reflective practitioner.

The Tutor Team

General note about reflection:

On the MSc CT we regard reflection as the opportunity to learn from the learning experience itself (here participating in online discussions) rather than from the learning material. In addition to the valid points you have already made when reflecting in the future try asking yourself even more about

the (here) discussion experience - for example, what is familiar/unfamiliar compared to other forms of communication? How have your feelings changed about the online discussion experience compared to the very first post? How has this impacted on your learning-if at all? What are the questions your experience raises about your approach to learning/communicating in general? Is there anything you would do differently the next time?