

Elective Report

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1. Describe the pattern of disease/illness of interest in the population with which you will be working and discuss this in a global health context.

- I am doing an audit of patient satisfaction with their rheumatological clinical trials at a clinical research unit in Whipps Cross Hospital. Clinical trials are an integral part of developing new or breakthrough medicines and therapies.

- The Royal College of Physicians 2011 publication '*Consultant physicians working with patients: The duties, responsibilities and practice of physicians in medicine*' (available online) estimates the following prevalence of rheumatological conditions that rheumatologists are the lead physicians for:

Rheumatoid Arthritis: 580,000

Ankylosing Spondylitis: 200,000

Systemic Lupus Erythematosus: 10,000

Gout: 250,000

Fibromyalgia: 11.2% of the general adult population

Regional pain syndromes: 20% of adult population.

- The Whipps Cross Hospital Clinical Research Unit mainly sees patients with Rheumatoid Arthritis, Ankylosing Spondylitis and Psoriatic Arthritis.

- The field of rheumatology has been changed greatly by DMARDs (Disease Modifying Anti-Rheumatic Drugs), which include biological and non-biological therapies. A quick search in pubmed reveals that access to these gold standard drugs is variable globally, within Europe and within different parts of the same country. This is mainly due to the high cost associated with some of the medications.

2. Describe the pattern of health provision in relation to the country in which you will be working and contrast this with other countries, or with the UK

- Even though my elective was in the UK, patients in clinical trials do receive a different level of 'treatment' than a regular NHS patient. Clinical trial patients have many more appointments than a patient with their condition not in a clinical trial. Some trials require patients to come in every 3 weeks for monitoring and treatment. At each visit, every patient is seen by two different nurses (their trial nurse and an independent nurse to assess their joint function), and potentially a doctor as well. At each visit they will have a blood test, basic observations and potentially an ECG.

- Compared to a regular NHS patient, they have much more face time with medical staff and many more opportunities to ask questions about their condition. Conversely, the time commitment required from these patients is very significant.

3. Health related objective

To gain first hand experience developing and performing an audit in an area of medicine that I really enjoy.

Audits are an integral part of monitoring and improving health care services. To further develop myself as a doctor it's important that I gain skills in assessing my own practice and the health care services of the system I work in.

This is now my third placement in Rheumatology. As mentioned above the field of Rheumatology has had a dramatic change since the introduction of DMARDs. For me, this means I have really enjoyed seeing how much difference can be made to a patient's quality of life. I also really like that Rheumatology is more focussed on quality of life and what the patient wants to do and are able to do.

4. Personal/professional development goals. Must also include some reflective assessment of your activities and experience.

a) To complete an audit

My supervisor and I were interested to find out what our clinical trial patients thought about the clinical trial unit and their participation in the clinical trial. We felt this was an important audit to do, given how important clinical trials are to the development of new therapies. Ideally, you want to ensure that everyone involved in the clinical trial is satisfied with the trial as to ensure continued support and to promote a general positivity about clinical trials.

The development of the audit was a bit more complicated than I anticipated in that the literature on patient satisfaction within clinical trials is minimal, and there was no validated clinical trial patient satisfaction survey. After discussing with my supervisor and other rheumatologists we modified a survey used by Madsen *et al.* so that we would at least have something to compare too. This survey also had elements of the Net Promoter survey, which is a validated survey used by companies to establish 'loyalty' to a brand. We felt that clinical trials can be viewed as a brand, so it would be useful to establish how 'loyal' the users of our clinical trials are.

From this experience I have learnt that you can never have too much time to develop a survey. We developed the survey pretty quickly as I had significant time pressures of my own, but this meant that we overlooked some of the language barriers that present in East London and that the survey became a bit long and repetitive.

b) Learn more about clinical trials

In the general media this year there has been a lot of press about 'bad' pharmaceutical companies, stemming from the release of Ben Goldacre's book 'Bad Pharma'. I have read around a lot of the criticism, which mainly focuses on pharmaceutical companies hiding results and profiting hugely from drugs that have perhaps been discovered by tax payers money. From this, and my interest in DMARDs in rheumatology, I was keen to experience clinical trials first hand.

What I have learnt, can be summarized as follows: Clinical trials are A LOT of work.

While large pharmaceutical companies receive a lot of criticism, they should be commended for organizing and paying for clinical trials. I have since learnt that a lot of the research and development money spent by pharmaceutical companies is spent on the actual running of clinical trials. The amount of preparation and paperwork and organisation that is needed for each trial participant is mind-blowing. It is difficult to see how they could cut costs and be more efficient during this process when they are trying to prove their drugs are safe. However I am sure there is no evidence base for having 3 ECGs in a row instead of just 1 ECG.

At this time I don't know if I would choose to work in clinical trials or not, but I am glad that I got this experience.

c) Learn more about patient satisfaction.

Patient satisfaction with health services is a well established field of research, most hospitals will have a survey of sorts, and part of GPs pay is related to patient satisfaction. I assumed at the outset of this project there would be a lot of literature about patient satisfaction in clinical trials, because clinical trials rely on patients wanting to enter them. I assumed that pharma companies would want to know why patients decide to enter and stay with clinical trials in order to better them to keep patients enrolling. However, this was not the case and there is not much published research into patient satisfaction with clinical trials.

Throughout the course of the audit, a high degree of patient satisfaction was found. Patients were very satisfied with the clinical trial and more than 90% would recommend clinical trials to family members or friends. They found their questions were answered, enjoyed seeing the same staff at each visit and were made to feel valued and safe.

Anecdotally I had been told that the pharmaceutical companies who do clinical trials with the Whipps Cross Research Unit were always amazed at their recruitment and retainment rate, it seems likely that the way the unit has structured themselves and the competent staff they have is a significant reason for this.

I have learnt that taking time to be present and providing continuity of care is an important part of patient satisfaction.

Literature cited

1. Madsen SM, Holm S, Davidsen B, Munkholm P, Schlichting P, Riis P. Ethical aspects of clinical trials: the attitudes of participants in two non-cancer trials. *J Intern Med.* 2000 Dec;248(6):463-74.