

Elective report

Introduction

Being based here in the UK, my elective has principally focused on some areas of interest I have cultivated over my time at medical school: that of functional pain, its impact on the individual and society, along with the formal organisation and administration of scientific research. With these aims in mind, the principal focus has been around a feasibility study involving the neuroimaging of painful stimuli, the full title of which is: 'mapping the pain matrix with a functional pain paradigm – a feasibility study'.

My main aim for the elective period was irrespective of the study's hypothesis and related more to developing a practical and meaningful understanding of research techniques and what it takes to get research off the ground. I have tried to gain research experience with an emphasis on good clinical practice and research governance, ethics committees, recruitment and exclusion as well as the pathological basis of functional pain.

So why is functional pain important?

Functional pain, which may be thought of as one of the more debilitating types of medically unexplained symptoms (MUS), is undoubtedly a drain on medical resources in both the developed and developing worlds. Dealing with individuals with MUS is challenging and these patients are more likely to consume a disproportionate amount of healthcare resources¹.

Research suggests that patients who suffer discomfort or pain from medically unexplainable or functional origins, have as poor a quality of life as those who have similar symptoms caused by conventional 'explainable' disease².

One of the concepts still harbored by unenlightened physicians, whether general practitioners, psychiatrists or neurologists, in this country or abroad, is that patients with a physical (or 'organic') disorder are the victim and absolved of responsibility, while those with functional symptoms are in some way responsible for their own problems. This group of patients may be perceived by themselves and by the people responsible for their healthcare, as having a 'weakness', which is in some way a detrimental reflection on their character.

The term 'functional' can still be used pejoratively in the developed world but is this a problem restricted to places where western medicine has been subscribed to for several hundred years, or does it exist in the developing world too? The complexities of attitudes to health and disease, along with the stigmas and mysteries that surround them, are incredibly difficult to pull apart even in the UK. In less developed areas of the world, where even basic sanitation and the simplest of medical interventions are hard to attain, the suffering caused by functional pain is impossible to quantify. Cultural differences, together with religious and societal diversity, mean that pain is perceived and managed with huge

¹ Salmon P, Humphries GM, Ring A, Davies JC, Dowrick CF. (2007) Somatic interventions for unexplained symptoms. *Psychosomatic Medicine* 69:571–577

² Stanley IM, Peters S, Salmon P. A primary care perspective on prevailing assumptions about persistent medically unexplained physical symptoms. *Int J Psychiatry Med* 2002;32:125–40.

variability across the globe. The one area of certainty when dealing with functional pain, is that every patient must be treated as an individual.

Having stressed the multifactorial and personal nature of functional pain, it is now time to describe how this study aims to reduce some of the complexities by observing functional brain changes during different modalities of pain: If one can scientifically and objectively observe the changes in brain metabolism that occur when an individual is subjected to somatic and visceral pains, hopefully one can start to demystify one of the most subjective unpleasant sensations a patient can suffer.

The organisation of modern medical research in the UK

In response to the process of setting up a research study becoming more and more clogged up with paperwork³ and bureaucracy⁴ there is now a slightly more stream-lined online system called the Integrated Research Application System (IRAS).

<https://www.myresearchproject.org.uk/SignIn.aspx>

This should allow researchers to fill in a single electronic form that will act as an application to multiple agencies (such as NHS research and development offices and ethics committees).

Headings on the form include:

- Purpose and design - requiring details on methodology, primary and secondary research questions and scientific justification.
- Risks and ethical issues - requiring details such as whether the study is the first of its kind in humans, the inclusion and exclusion criteria, potential risks and benefits, together with how the subjects will be recruited, confidentiality and specifics of their participation.
- Science - requiring scientific critique and statistical management information.
- Management of the research - requiring details on collaborators, sponsors, funding, host organisations, insurance and indemnity.

The full details of the process are too lengthy and convoluted to detail in full here, but this very fact gives some indication of the difficulties of going about research and consequently, the myriad of stumbling blocks which can crop up along the way. A good guide, which explains things as succinctly and simply as is possible, was published in the BMJ in 2009 entitled, "Applying for ethical approval for research in the United Kingdom" and this provides a good overview and glossary of the processes involved⁵.

³ Hallowell N, Cooke S, Crawford G, Parker M, Lucassen A. Ethics and research governance: the views of researchers, health-care professionals and other stakeholders. Clin Ethics 2008;3:85-90.

⁴ Hackshaw A, Farrant H, Bulley S, Seckl M, Ledermann J. Setting up non-commercial clinical trials takes too long in the UK: findings from a prospective study. J R Soc Med 2008;101:299-304.

⁵ Smajdor A, Wilkinson M. Applying for ethical approval for research in the United Kingdom. BMJ 2009; 339:b4013

Conclusion

In summary, this elective has given me a valuable insight into the difficulties, stresses and strains of getting a research study 'off the ground'. I now have a very real understanding of the administrative challenges which can plague an application and in particular, the finer points of gaining ethical approval.

On top of this generalised knowledge about research organisation, I have been able to respond to my interest in functional disease and the physiology of different modalities of pain. I have also increased the detail in my understanding of brain anatomy and gained some insight into the benefits and limitations of fMRI.

My hope is that in the future, when I come to designing research myself, this elective will have given me the experience I need to get the answers I will be searching for. This opportunity has certainly given me an insight into the hard work and persistence necessary to get modern clinical research started. As the findings unfold, I hope to continue to gain clinical experience which benefits my future practice and increases my understanding of complicated pathology.