Ogden, J (2001) From protocol into practice: who needs the research? The Lancet [letter] 357, 482.

From protocol into practice -

who needs the research?

Jane Ogden

Department of General Practice, Guys Kings and St Thomas' Medical Schools, Kings College
London, UK

Address for correspondence
Jane Ogden PhD
Reader in Health Psychology
Department of General Practice
GKT
Kings College London
5 Lambeth Walk
London SE 11 6SP

email: Jane.Ogden@kcl.ac.uk
Tel: 020-7735-8881 X417
Fax: 020-7793-7232

It is well known to researchers that the best way to cure any clinical problem is to study it. Set up a project to examine the obese and all patients seeing their GP suddenly become thin. Establish a recruitment goal of 20 teenagers per week wanting contraception and teenagers avoid family planning clinics like the plague. Negotiate with dermatologists to select 50 patients a month with a common skin condition and it suddenly becomes rare. The Hawthorne effect describes how the world changes when it is studied (1). This includes even the most apparently intractable medical conditions. My recent experience suggests however, that it is not only medical complaints which are apt to change, but the most intractable problem of all - clinical practice. Further, it is not only studying this phenomena which brings about change; the intention to study is equally effective. For arguments sake, I will call this the Ogden effect.

Three years ago I decided to evaluate the best way to manage first trimester spontaneous miscarriage. I spoke to several clinicians and wrote to several hospitals and it appeared that miscarriage was being managed in an idiosyncratic way and was not in any shape or form being guided by an acceptable evidence base. Some hospitals offered surgical management only and could not believe that there was any other viable option. Some offered only expectant management whilst others offered both. How a woman was treated depended upon the personal preference of the consultants involved. I designed a randomised control trial and sent it to several consultants to find myself a clinical collaborator. All agreed it was interesting area. One, coming from a surgically orientated hospital said that they wouldn't be able to get women to agree to expectant management. One coming from a hospital with the opposite policy said that they couldn't justify subjecting their women to surgery. One enthusiastically agreed to collaborate. This hospital had a policy of offering both expectant and surgical management and the consultant recognised a need for an evidence base to justify

this approach. The grant application was completed, sent off to the funding body, reviewed by independent experts, the funding body was re organised, the committee was dismantled and three years after the original idea the money came through. Now ready to start the project I was told that the clinical practice at the hospital had changed. They no longer offered surgical management only expectant management. To my knowledge, the data on miscarriage management remains inconclusive and the evidence base is as sparse as it was three years ago. Yet although researchers have written endlessly on how difficult clinical practice is to change (2,3); it had happened, with very little effort and not by research, education or evidence, just by writing a protocol and recruiting a collaborator. This may just reflect the whims of one hospital. Or does it tell us something about clinical practice? And does it also inform our understanding of the research process?

Psychologists use the stages of change model to describe changes in behaviour such as smoking, eating and exercise (4,5). From this perspective, individuals about to change their behaviour are described as contemplators which is followed by a stage of preparation and then one of action. When I searched around for a collaborator most were reluctant as the proposed experimental clinical behaviour was too far removed from their current practice. These could be considered precontemplators. My collaborator however reported current practice which was similar to the proposed experimental behaviour and collaboration would therefore not involve much reorganisation of his current thinking. He could be considered a contemplator and agreed to take part in the study, not because he was a disinterested party who needed an evidence base, but because his behaviour was already moving away from conventional practice. He then focused on the protocol, considered the issues, decided to collaborate and waited for the money to come through. Then he shifted through the preparation stage into one of action. Patients change their behaviour when they are studied (6). This hospital changed

its behaviour when it was going to be studied. Research is supposed to drive practice. But can research happen without changes in practice preceding it? Evidence is supposed to provide the basis for deciding on best practice. But can evidence be gathered without glimpses of best practices already being known? And trials are supposed to occur from a state of equipoise. But can there ever be equipoise if the clinicians who agree to collaborate are the very ones who are already shifting their positions? And even if the unwilling ones were made to take part, then surely their reluctance reflects their own perspectives on the likely outcome? If the contemplators take part in studies then the new experimental practice is favoured. If the precontemplators are enticed into participating then the situation is simply reversed. We know that those patients who agree to enter trials are different to those who refuse (7) and we take steps to minimise the effect of this by keeping our response rates high, analysing on an intention to treat versus explanatory basis and collecting baseline data. Doctors who agree to collaborate, however, are also different to those who don't. They are not neutral participants and are the ones who are more likely to change their clinical practice. Steps are also needed to minimise, or at least acknowledge this 'Ogden effect'.

Clinical behaviour is notoriously difficult to change but my experience indicates that, like intractable clinical problems it can be changed through study. Further, it can be changed through the intention to study. With a research protocol who needs the research? But best practice is supposed to follow evidence, and evidence is supposed to be gathered from a position of equipoise. My experience suggests that this rhetoric does not reflect the reality.

1. Argyle, M (1963). The relay assembly test room in retrospect. *Occupational Psychology*, 27, 98-103.

2.

3.

4.