Appendix 2

Issues leading to lower than expected recruitment and efforts to alleviate these

The feasibility of the original sample size was based on numbers provided in 2010 by surgeons at each NHS and private site in Scotland. These formed part of the original NIHR application along with a declaration of their willingness to recruit patients for the study. Generally, these numbers were based on the numbers of surgeries that were funded at each health board each year and they were believed to be correct by co-investigators who had expert knowledge of bariatric surgery in the UK, and a further increase in numbers was anticipated by surgeons at each site (although that was not necessary to reach recruitment targets). These numbers were not realised and there were a number of reasons for this:

1. Reduction of volume of bariatric surgery performed at each NHS board versus number reported by NHS teams prior to study start-up:

Unlike England, bariatric surgery in Scotland is not centrally-funded. The costs for bariatric surgery generally come from the upper gastrointestinal (GI) surgery budget and therefore compete with upper GI malignancy surgery for resource. In 2010, the Scottish Government produced Best Practice Guidance for Bariatric Surgery. A number of the SCOTS co-applicants were involved in the development of this guidance. The purpose was to develop a uniform approach to patient selection for bariatric surgery (ending the 'postcode lottery') and standardise pre- and postoperative care.

In order to facilitate a managed increase in surgery volume, specific patient groups were to be targeted as priority, namely patients with newly diagnosed type 2 diabetes who were under the age of 50 years. This was not intended to be the only group offered surgery and there were plans for regular meetings to identify future priority groups. These meetings were never convened. In a number of health boards, the guidance was misinterpreted and only the very small pool of young patients with newly diagnosed type 2 were allowed surgery, a group that are seldom seeking this treatment. As a consequence, surgery numbers have decreased rather than increased.

The SCOTS Chief Investigator met with civil servants involved in health service planning twice about this and also wrote to the Scottish Health Minister. There was promise of a further review of bariatric surgery in autumn 2015 but, to date, this has not commenced.

2. Rapid decrease in patients seeking bariatric surgery in the private sector:

This has been a combination of the downturn in the economy, a number of surgeons with established private practice retiring, and patients, as consumers, choosing to have their surgery outside Scotland (and the UK) where it is far cheaper. This includes a number of clinics in England where the patient attends the clinic for all pre- and postoperative care but the actual surgery is performed overseas; this is a far cheaper option.

Consequently, we engaged with the surgeons working in the private sector and made the procedures for recruiting patients from the private sector as simple as possible by making the private hospital a participant identification site only. However, the numbers of surgeries at each site were very low and the patients were often having revisional rather than primary surgery, making them ineligible for SCOTS.

3. Local issues at sites resulting in long periods with no bariatric surgery:

At a number of sites there were local changes which resulted in there being no bariatric surgery for many months. These included surgeons leaving jobs (moves and retirement) with considerable delay in replacement. This generally meant that no patients were even placed on the long pathway for surgery from the point the surgeon's intention to leave was known, leaving gaps of over a year until a new surgeon was in place and patients had made it through the extensive presurgery programme.

At other sites, there were decisions to clear waiting lists of revisional cases, again taking up to a year. Some sites decided to establish formal medical weight management services to select patients for bariatric surgery, with no surgery carried out until those services were established and patients attended the programmes for many months, again leaving gaps of up to a year with no surgery.

All three of these factors meant that the numbers of likely participants estimated at each site by local principle investigators was not realised.