## Short Term Outcomes of Prostate Biopsy in Men Tested for Cancer by Prostate Specific Antigen: Prospective Evaluation within ProtecT and ProBE Studies

Introduction and Objective: The impact and acceptability of transrectal ultrasound guided biopsy (TRUS-Bx) of the prostate has rarely been investigated systematically. We aimed to establish the short term outcomes of TRUS-Bx in asymptomatic men undergoing prostate specific antigen testing. Materials and Methods: Between February 2006 and May 2009, 1147 men aged between 50-69 years with a PSA result of 3-19.9 ng/ml ng/ml were recruited to the ProBE study (65% of those offered) prior to 10-core TRUS guided prostate biopsies in the ProtecT (Prostate cancer testing and Treatment) trial (ISRCTN 2014129769). Participant questionnaires at 7 and 35 days post-biopsy, measured patient symptoms and acceptability of the procedure. Healthcare resource utilisation was collected by nurses from medical records. Participants were also interviewed to assess men's experiences of the procedure.

Results: Pain was reported by 429/984 (43.6%), fever by 172/985 (17.5%), haematuria by 642/976 (65.8%), haematochezia by 356/967 (36.8%), and haemoejaculate by 605/653 (92.6%) men during the 35 days after biopsy. Fewer men rated these symptoms as a major/moderate problem: 71/977 (7.3%) for pain, 54/981 (5.5%) for fever, 59/958 (6.2%) for haematuria, 24/951 (2.5%) for haematochezia, and 172/646 (26.6%) for haemoejaculate. Immediately after biopsy, 124/1142 (10.9%, 95% confidence interval 9.2 to 12.8) men reported that a further biopsy would be a major or moderate problem: seven days later this had increased to 213/1085 (19.6%, 17.4% to 22.1%). 119 (10.4%, 8.7% to 12.3%) men reported consultation with a healthcare professional (usually their family doctor), most commonly for infective symptoms. Interview data revealed that most men found biopsies unpleasant but tolerable although for a few men they caused significant distress.

Conclusions: Prostate biopsy is generally well tolerated but is associated with significant symptoms in a minority of men and influences attitudes to repeat biopsy and primary care resource use. These findings should inform men who seek PSA testing and assist their physicians during counselling about the potential risks and effect of biopsy.