THE HELICOBACTER ERADICATION ASPIRIN TRIAL (HEAT):
DEMOGRAPHIC DATA FOR RANDOMISED (H. pylori POSITIVE) PATIENTS

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1. Introduction
The Helicobacter Eradication Aspirin Trial (HEAT) is a multicentre, double blind, randomised controlled trial investigating whether Helicobacter pylori eradication reduces the incidence of hospitalisation for peptic ulcer bleeding [1].

2. Background
• HEAT is being conducted in GP practices across the whole of the UK
• HEAT is important medically because aspirin is so widely used, and methodologically as, if successful, it will demonstrate that large-scale studies of important clinical outcomes can be conducted at a fraction of the cost of those conducted by industry
• The primary endpoint of the study is the rate of hospitalisation due to definite or probable peptic ulcer bleeding
• The study will end when 87 adjudicated events have occurred

3. Methods
• Participants are aged over 60, taking low dose aspirin for at least four months at the time of recruitment; all participants were recruited from primary care.
• Participants testing positive for H. pylori were randomised to receive one week active trial treatment (lansoprazole 30mg, clarithromycin 500mg and metronidazole 400mg twice daily) or placebo
• Participants are followed up using a bespoke web-based trial management system that communicates directly with HEAT Toolkit software downloaded at contributing GP practices, which issues electronic queries searching follow-up criteria
• Events are tracked by accumulating information from electronic searches of GP databases via the HEAT toolkit, patient contact, review of national Hospital Episode Statistics secondary care admission and ONS mortality data

4. Results
• Recruitment to the trial started in 2012 and completed in 2017; follow-up is endpoint driven and is ongoing
• HEAT is the largest CRN CTIMP trial, with 188,428 invitation letters sent from 1,208 practices
• A total of 37,247 positive responses were received, representing a 20% response rate
• 30,025 participants were consented to the study of whom 5,356 H. pylori positive participants were randomised.
• The mean age at randomisation for the H pylori-positive parents was 73.6 ± 7.0 (SD) years, and 73.8% of participants were male. Only 7.2% of participants were smokers although 52.9% were ex-smokers
• Recruitment figures for English participants were analysed with respect to Multiple Deprivation Indices (MDI) [4] of the GP practices. MDI=1 represents the 10% most deprived and MDI=10 is the 10% least deprived

5. Conclusion
The trial methodology has shown that recruitment of large numbers of participants from primary care is attainable, with the assistance of the NIHR Clinical Research Network, and could be applied to other outcomes studies at relatively low cost.

Last year, there were almost 17,000 hospital admissions for gastric ulcers [2] and more than 1,850 recorded deaths [3] for gastric and duodenal ulcers. If successful, the study will help to reduce NHS costs and improve health outcomes by reducing hospital admissions, increasing patient safety and preventing premature deaths.

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Department of Health Disclaimer: The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the HTA programme, NIHR, NHS or the Department of Health.

**Figure 1: Participant recruitment by CRN region**
Figures show the mean ± SD of percentages calculated for each contributing GP practice in the respective CRN regions

**Figure 2: Participant recruitment in England with respect to the Multiple Deprivation Index of their respective GP practices**
Figures show the mean ± SD of percentages calculated for each contributing GP practice in the respective MDI category

**Figure 2a:** Multiple Deprivation Index
**Figure 2b:** Multiple Deprivation Index

2. NHS Digital, Hospital Admitted Patient Care Activity, 2016-17