FISH and CHIPS Analysis plan

Background

Evaluation of the implementation of a health technology (Heartflow CT FFR) into the health system in NHS England. The FAC study encompasses all sites that were eligible and utilised the technology in its first year of roll out (2018). This represents a complex health intervention as it includes over 27 sites and 24 integrated care boards (ICB) across NHS England.

The aim of FAC is to determine the practical effectiveness of the complex health technology intervention on the system as a whole. Comparative analysis will differentiate between groups where the technology was not available (usual care) to times that the technology was available (new care) for clinical and cost effectiveness.

Primary Analysis

Primary Endpoints:

1. MI event rate, MI deaths and all-cause death.
2. Invasive coronary angiogram without revascularization
3. Downstream testing: numbers of non-invasive functional tests, and invasive coronary angiograms without revascularisation performed following the index FFRCT
4. Cost analysis: Total cost to the NHS of the index test and all downstream investigations, hospital outpatient visits and hospital admissions.

Event rates of the composite outcome of MI, MI death or all cause death over-time will be calculated using Kaplan-Meier methodology from the time of the CCTA at 12 and 24 months. A Cox proportional hazards model will be used to determine Hazard Ratio of 'usual care' versus 'new care'. The odds ratio (OR) of receiving angiography and revascularization post FFRCT compared to other tests will be determined.
Time to diagnosis will be compared using an 'intention to diagnose analysis' by analysing groups according to their investigative test (FFRCT vs CCTA alone).

Secondary Endpoints:

1. Time to diagnosis- Trust Referral to Treatment (RTT) time.
2. Qualitative assessment of the impact of the FFRCT health technology

The primary cost analysis will include total patient pathway costs at 12 months, with comparison between the two testing strategies. The mean cost difference with 95% confidence intervals and P value will be calculated. Sub-analysis will categorise the total costs breakdown as; Investigations, hospital stay, procedural costs.

Cost sensitivity analyses will be applied to the modelling, looking at different cost utilities in the UK and regional variability.

Secondary Analyses

Variations in health intervention effectiveness will be sub-analysed based on recipients of the technology:

- Indices of socioeconomic deprivation (IMD)
- Sex
- Age
- Site location
- Regional variation (ICB)
- Time effect (does utilisation over time impact outcomes)
- Learning curve effect (number of CT FFR performed over time)
- CT site quality (Determined by heart rate and rejection rates)