



***Determining the feasibility of randomising children and young people to invasive and non-invasive urine sampling techniques (FROG)***

**Health Economic Analysis Plan (HEAP)**

Protocol /Study number:	B24/28
Trial registration number:	ISRCTN 84676764 <a href="https://www.isrctn.com/ISRCTN84676764">https://www.isrctn.com/ISRCTN84676764</a>
Funder and number	National Institute for Health and Care Research Health Technology Assessment Programme; NIHR156005 <a href="http://www.fundingawards.nihr.ac.uk/award/NIHR156005">www.fundingawards.nihr.ac.uk/award/NIHR156005</a>
Sponsor:	Queen's University Belfast 63 University Road Belfast, BT7 1NN
REC and number:	North East - Newcastle & North Tyneside 1 Research Ethics Committee 24/NE/0222
Protocol version:	V3.0 24/04/2025
HEAP version:	Final 1.0 29/01/2026
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# 1. Main study: background and design

FROG is a pragmatic multi centred randomised controlled feasibility trial and a mixed methods feasibility perspectives study.

**Aim:** To conduct a study of feasibility to assess which participants and interventions should be included in a subsequent randomised controlled trial, explore potential barriers to recruitment and determine the feasibility of randomisation to invasive versus non-invasive urine testing.

## Objectives

1. To determine the number of potential participants with suspected UTI presenting to a range of clinical settings, including emergency care, inpatients, and outpatients.
2. To conduct a quantitative assessment of the ability to screen, recruit and randomise children and young people to one of three interventions : clean catch urine (CCU), transurethral bladder catheterisation (TUBC) and suprapubic aspiration (SPA).
3. To explore the views of parents, children, young people, and clinicians on the acceptability of different collection methods, and the appropriate population for inclusion in a future study.
4. To identify potential barriers to recruitment and consent.
5. To establish the most appropriate design, including important patient centred outcomes, for use in a future study.
6. To perform a cost analysis of the three urine collection methods to inform the resource planning and design of a future cost-effectiveness study.

# 2. Health economic study: design and objective

Health economic objectives:

1. A detailed costing analysis will be performed of three methods of urine sampling in children (CCU, SPA and TUBC).
2. To pilot methods for collecting primary and secondary care resource use for a future cost-effectiveness analysis.

## 2.1 Methods

### *Measurement of resource use and costs.*

A cost analysis will be performed from the perspective of the hospital to estimate the resources and costs involved in the urine sampling process up to the point of obtaining a definitive urinary tract infection (UTI) diagnosis. We will collect participant-level data on the case-report form (CRF) relating to which urine sampling method was used (CCU, SPA or TUBC), any repeat sampling, follow up investigations, imaging and length of stay. We will collect information on the equipment used and the amount of staff time required to collect urine samples via a questionnaire sent to all sites. Section one of the questionnaire asks for a description of the clinical materials and equipment typically required for each sampling method using a checklist. The description can be completed at any time over the study period. Sites have also been asked to set up a mock trolley of all the equipment they typically use for each sampling method and to send a photograph of it to the clinical trials unit. Section two of the questionnaire asks sites to record the staff (role and banding level) and time involved in two real samples collected via CCU, TUBC, and SPA as soon as possible after collecting the sample to ensure the information is accurate. If a sampling method is not available at the site or not used during the FROG study there is no requirement to complete a description of the equipment or provide information on staff time input.

To fully capture the longer-term impact on economic and health outcomes, it is essential that a definitive cost-effectiveness analysis incorporates an extended follow-up period. A version of the Modular Resource-Use Measure (ModRUM) [1] adapted for completion by a parent/guardian will be used to collect primary and secondary care resource use after the participants have left the hospital setting up to a maximum of 6 months post-randomisation. This questionnaire has adaptable sections in it to suit the needs of a study, and so by pilot testing it in FROG study we can assess what would be appropriate for a future cost-effectiveness analysis. We will obtain feedback on the questions from parents/guardians at the end of the questionnaire. Questionnaires will be posted to parent/guardians by sites along with a pre-paid envelope to facilitate returns. We will collect as much health service use data as we can for each participant during the 10 month data collection window up to a maximum of 6 months post-

randomisation, so for some participants the recall period for the ModRUM will be less than 6 months.

### *Analysis of resource use costs*

We will apply unit costs from publicly available sources (e.g. NHS Reference Costs, Unit Costs of Health and Social Care) to the recorded resource use where possible. Where these are unavailable, alternative sources such as hospital costing departments and published literature will be used. All costs will be presented in Great British Pounds (GBP£). As the time horizon for the analysis is less than one year, discounting of costs is not required. Standard reporting guidelines will be followed [2]. Using data collected via the case report form (CRF) and site questionnaire, we will estimate the site resource required to undertake each urine sampling method and the mean cost per definitive UTI diagnosis, with 95% confidence intervals (CI). Sensitivity analyses will be conducted to assess the impact of variations in key parameters (e.g. time estimates, staff grade) on cost estimates.

Using MoDRUM data, we will identify the types of health resources used by participants post-discharge and the key cost drivers. We will use this information to refine the MoDRUM questionnaire. We will examine return rates and levels of missing data across different follow-up durations. To enable comparison across participants with varying follow-up periods (e.g. 3 vs. 6 months), total resource use will be normalised by time, calculated as mean monthly use with 95% CI. This approach allows us to assess cumulative resource use patterns and determine whether shorter follow-up durations capture sufficient data for robust economic analysis. We will use our findings to select the most appropriate follow up duration in a future cost-effectiveness analysis.

## **3. References**

1. Garfield KM, Thorn JC, Noble SM, Husbands SK, Hollingworth W. Development of a brief, generic, modular resource-use measure (ModRUM): piloting with patients. *BMC Health Services Research*. 2023 Sept 15;23(994):994
2. Husereau D, Drummond M, Augustovski F, de Bekker-Grob E, Briggs AH, Carswell C, Caulley L, Chaiyakunapruk N, Greenberg D, Loder E, Mauskopf J, Mullins CD, Petrou S, Pwu RF, Staniszezwska S; CHEERS 2022 ISPOR Good

Research Practices Task Force. Consolidated Health Economic Evaluation Reporting Standards 2022 (CHEERS 2022) Statement: Updated Reporting Guidance for Health Economic Evaluations. Value Health. 2022 Jan;25(1):3-9.

## 4. Appendix

### Example Draft Summary Tables

Table XX Unit costs of urine sampling equipment

Material Description		Unit Cost (£)	Source and details
Dressing pack			
Antiseptic solution (e.g. Betadine)			
Apron			
Aqueous lubricant			
Biological waste bag			
Boric acid urine container			
Catheter (urinary/urethral)	plastic		
	latex		
	silicone		
Catheter (nasogastric feeding tube)			
Cotton balls			
Disinfectant wipes (for equipment)			
Drape			
Face mask			
Forceps			
Gauze			
Gloves (pair)- Non-sterile			
Gloves (pair)-Sterile			
Gown			
Hat/hair net			
Instillagel			
Labels			
Needle for suprapubic aspirate			
Skin cleansing wipes 'Clinel' 2% chlorhexidine			
Skin cleansing wipes 'Clinel' alcohol			
Sterile water (10ml)			
Syringe for aspiration of urine			
Trolley for equipment			
Ultrasound probe covers			
Ultrasound/bladder scanner			
Universal urine container			
Urine collection gallipot/dish			
Other (specify) _____			
Other (specify) _____			

Table XX Units costs of health and social care [Price year TBC] Great British pounds (GBP, £)

Resource item	Unit Cost (£)	Source and details
GP appointment (face-to-face)		Unit Costs of Health and Social Care
GP appointment (online/telephone)		Unit Costs of Health and Social Care
GP appointment (home)		Unit Costs of Health and Social Care
Other health care professionals		Unit Costs of Health and Social Care
Accident and Emergency department visit		NHS Reference Costs
Outpatient appointment (face-to-face)		Unit Costs of Health and Social Care
Outpatient appointment (online/telephone)		Unit Costs of Health and Social Care
Hospital day case		Unit Costs of Health and Social Care
Hospital admission		NHS Reference Costs

Table XX Cost of equipment use for the urine sampling methods

Material Description	CCU	TUBC	SPA
	Mean (95% CI)	Mean (95% CI)	Mean (95% CI)
Dressing pack			
Antiseptic solution (e.g. Betadine)			
Apron			
Aqueous lubricant			
Biological waste bag			
Boric acid urine container			
Catheter (urinary/urethral)	plastic		
	latex		
	silicone		
Catheter (nasogastric feeding tube)			
Cotton balls			
Disinfectant wipes (for equipment)			
Drape			
Face mask			
Forceps			
Gauze			
Gloves (pair)- Non-sterile			
Gloves (pair)-Sterile			

Gown			
Hat/hair net			
Instillagel			
Labels			
Needle for suprapubic aspirate			
Skin cleansing wipes 'Clinel' 2% chlorhexidine			
Skin cleansing wipes 'Clinel' alcohol			
Sterile water (10ml)			
Syringe for aspiration of urine			
Trolley for equipment			
Ultrasound probe covers			
Ultrasound/bladder scanner			
Universal urine container			
Urine collection gallipot/dish			
Other (specify)			
Other (specify)			

Table XX Staff resource use and costs by urine sampling

Staff role	CCU		TUBC		SPA	
	Time in minutes (Mean, 95%)	Cost (Mean, 95%)	Time in minutes (Mean, 95%)	Cost (Mean, 95%)	Time in minutes (Mean, 95%)	Cost (Mean, 95%)
Nurse						
Doctor						
Play therapist						
Other						
Other						

Table XX Health service use over the study period. Values are number (percentages) of patients using the service, mean (95% CI) use and mean (95% CI) costs (£).

	Intervention (n=)		
	Number (%)	Mean (95% CI)	Mean Cost (95% CI)
GP appointment (face-to-face)			
GP appointment (online/telephone)			
GP appointment (home)			
Other health care professionals			
Accident and Emergency department visit			

Outpatient appointment (face-to-face)			
Outpatient appointment (online/telephone)			
Hospital day case			
Hospital admission			

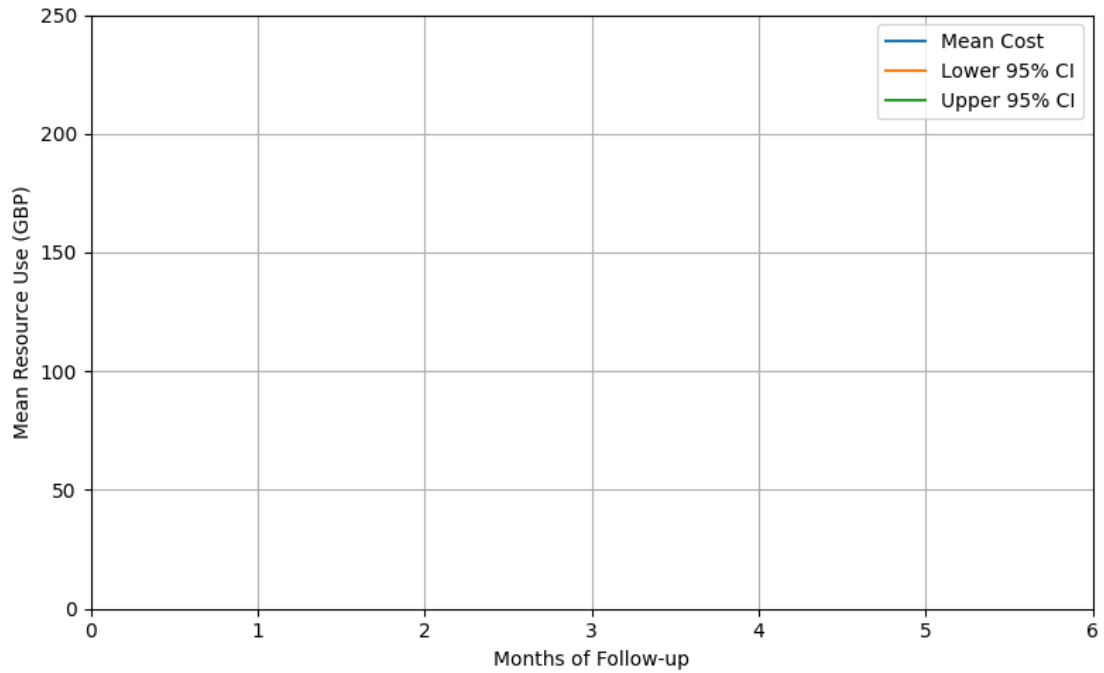


Figure X Cumulative mean monthly resource use