Project scope: Minuteful Kidney

21st October 2021

Name of technology and potential application

Minuteful Kidney uses smartphone-based urinalysis to shift testing from the clinic to home based self-testing.

Scotland do not have a regular urine test reported leaving many cases of Chronic Kidney Disease (CKD) undetected.

Innovative aspect

The innovative aspects of Minuteful Kidney are that it allows non-clinical users to do semi-quantitative albumin to creatinine ratio (ACR) testing with a smartphone in their own home. Results can be shared with a clinician through Electronic Medical Record (EMR). This allows real-time results to be reviewed and followed up.

Inclusion criteria

The selection of studies for inclusion will be based on the following criteria:

Population	Adults at risk of CKD ; people with diabetes, hypertension and other risk factors including acute kidney injury, cardiovascular disease, structural renal tract disease, recurrent renal calculi or prostatic hypertrophy, multisystem diseases with potential kidney involvement, family history of end-stage kidney disease, opportunistic detection of haematuria, and prescribed drugs that have an effect on kidney function.
Intervention	Minuteful Kidney uses computer vision and user centric design to enable smartphone-based urinalysis. Built around existing semi-quantitative urinalysis dipsticks, it complements established clinical efforts by empowering patients to test themselves at home with no quality compromise, and securely share results with a clinician. The patient receives a postal test kit and downloads the app, which provides step-by-step instructions to complete the test.

	Synonyms:
Comparator	Standard current practice of care for urine ACR testing involves asking the patient to collect a urine sample at home which they bring back to the healthcare provider for lab analysis
Outcomes	ACR screening in at-risk populations Microalbuminuria in urine Chronic Kidney Disease *Quality of life/PROMS Safety/adverse effects/complications Patient uptake Economic and cost considerations (value for money) Equality of access/impact on inequalities Patient experience
National Priorities	Scottish Government Policy document on illnesses-and-long-term-conditions Scottish Government public health priorities Strategic priorities mentioned in A Fairer Healthier Scotland 2017-22

Planned activities

SHTG have agreed on the following activities to support the development of the Minuteful Kidney IMTO focusing on:

1. Evidence review of the published literature on clinical effectiveness, cost effectiveness, safety and patient aspects

2. Patient organisation input (to be confirmed)

3. Engagement of clinical experts through professional commentary

4. Engagement of manufacturer/developer through fact check

Exceptions to be noted

Please note that if and when the technology is very specific, the team will allow industry engagement on the topic/tech, as there may not be sufficient real world data to develop an IMTO.

End products

At the end of the project SHTG will produce an

- IMTO - Please specify if this will be:
    - An analysis of performance data of a technology that is ready for clinical use in NHSScotland (this will be published as a report and disseminated to relevant stakeholders)
    - An analysis of interim data of a technology which is still in development for clinical use in NHSScotland (this will be published as a report and disseminated to relevant stakeholders)
    - A report for the developers providing bespoke analysis and advice related to the technology and their methodology in relation to HTA and NHSScotland (this will be a unpublished report and only submitted to the relevant project team)

- PLS IMTO

Timescales (approximate)

Work on the project is estimated to begin in early Dec 2021 and will aim to be completed by early Feb 2022.