



Topic Exploration Report

Topic explorations are designed to provide a high-level briefing on new topics submitted for consideration by Health Technology Wales. The main objectives of this report are to:

1. Determine the quantity and quality of evidence available for a technology of interest.
2. Identify any gaps in the evidence/ongoing evidence collection.
3. Inform decisions on topics that warrant fuller assessment by Health Technology Wales.

Topic:	Smartphone urinalysis for people at home
Topic exploration report number:	TER124

Introduction and aims

People are currently required to attend a GP or clinic when they need to take a urine-based diagnostic test (urinalysis).

Smartphone-based urinalysis allows users to self-test at home, using a test kit and mobile app. The kit is based around a 10-parameter dipstick, The app guides the user through the testing process, and send the results to the clinician.

Health Technology Wales researchers searched for evidence on smartphone-based urine analysis for the following populations:

- People with diabetes (who are at increased risk of chronic kidney disease)
- People with hypertension (who are at increased risk of chronic kidney disease)
- Women receiving antenatal care
- People with urinary tract infections
- People with acute or chronic renal conditions (such as chronic kidney disease, nephrotic syndrome, glomerulonephritis, dialysis, renal transplant)

Evidence

We did not identify any systematic reviews on the use of smartphone urinalysis.

We identified one primary study that assessed whether using smartphone urinalysis could improve adherence to proteinuria screening for previously-unscreened people with hypertension. Proteinuria is associated with increased risk of chronic kidney diseases. The study concluded that home urinalysis increased adherence to proteinuria screening in people who normally went unscreened (28.9% versus 18/0%; $p < 0.001$).

Several relevant guidelines were identified. NICE are also assessing this technology as part of a Medtech Innovation Briefing, which is due to be published in April 2020.

NICE guidelines for the assessment and management of chronic kidney disease (CG182) in adults states that reagent strips should not be used to identify proteinuria unless they are capable of specifically measuring albumin at low concentrations and presenting the results as an albumin:creatinine ratio. Strips should be used to test for haematuria (rather than urine microscopy). NICE NG136 recommends that all people with hypertension should test for protein in the urine by sending a sample for albumin:creatinine ratio testing, and use a reagent strip to test for haematuria. NICE NG17 for type 1 diabetes recommends that 'first urine sample of the day' should be sent for albumin:creatinine ratio testing; urine albumin concentration alone is a poor alternative.

Regarding UTI, dipstick (or reagent strip) testing was only recommended for UTI management in women <65 years old who presented ≤ 2 symptoms of UTI (SIGN 88). Dipstick was not recommended for catheterised patients nor for antenatal screenings (SIGN 88). It may be used for long-term care residents who are symptomatic (HTAG). NICE guidelines on antenatal care (CG62) states that women should be offered urine tests to screen for proteinuria and asymptomatic bacteriuria at first appointment, and proteinuria screening at subsequent meetings.

The manufacturer highlighted several projects with planned evidence generation for smartphone urinalysis:

- An Innovate UK funded pilot to assess home urinalysis combined with home blood pressure measurement for antenatal care in 100 women in NHS England (Royal United Hospitals Bath NHS Foundation Trust). Expected start date was July 2019.
- The THOMAS study in the Netherlands, where home testing will be offered to 15,000 people in the Netherlands (Breda region). Expected start date was September 2019.
- NHS Care City Test Beds, which is using carers to extend the reach of digital urinalysis in the older population. Project ongoing.
- Boots Cystitis Test and Treat, where Boots UK Ltd (a health and beauty retailer, and pharmacy chain in the UK) are evaluating the impact and effectiveness of smartphone urinalysis for the urinary tract infections service, to determine the feasibility of a nationwide roll out in the pharmacy setting. Project ongoing.
- Evaluation of the benefits of giving renal patients home tests for patients in the South Tees area.

Using the NICE Digital Evidence Standards, this technology may be classified as tier 3b. However, further refinement of the research question is required to more accurately classify this technology.

Areas of uncertainty

The manufacturer has identified multiple potential populations that may benefit from smartphone urinalysis. Further rationalisation of which area demonstrates most benefit would be beneficial, but this is limited by the lack of published evidence at this time. There may also need to be further subgrouping to identify who would be eligible for this test within each population; for example, due to the acute, transient nature of UTIs, not all women may foresee the need for a test.

More clarity is required on what is included in the test, and whether there are different test kits available. For example, the company describes that the test is based on the 'standard' 10-

parameter dipstick. However, the company also describes a kit to test for albumin:creatinine ratio; this is not usually included on a standard 10-parameter dipstick test.

Conclusions

Limited evidence was identified for smartphone urinalysis, with the exception of one study in people with hypertension. Further evidence would be required in order to proceed with an appraisal of this technology. Identifying a specific population of interest would help to refine a research question for rapid review.

Brief literature search results

Resource	Results
HTA organisations	
Healthcare Improvement Scotland	We did not identify any relevant evidence from this source.
Health Technology Assessment Group	Diagnosis & Management of Urinary Tract Infection (UTI) in Long Term Care Residents > 65 years https://www.hse.ie/eng/about/who/healthwellbeing/infectcont/sth/gl/app-12-1-1.pdf
Health Information and Quality Authority	We did not identify any relevant evidence from this source.
UK guidelines and guidance	
SIGN	Sign 88: Management of suspected bacterial urinary tract infection in adults https://www.sign.ac.uk/sign-88-management-of-suspected-bacterial-urinary-tract-infection-in-adults.html
NICE	<p>NG136 Hypertension in adults: diagnosis and management https://www.nice.org.uk/guidance/ng136</p> <p>CG182 Chronic kidney disease in adults: assessment and management http://nice.org.uk/guidance/cg182</p> <p>NG17 Type 1 diabetes in adults: diagnosis and management https://www.nice.org.uk/guidance/ng17</p> <p>NG28 Type 2 diabetes in adults: management https://www.nice.org.uk/guidance/ng28</p> <p>CG62 Antenatal care for uncomplicated pregnancies https://www.nice.org.uk/guidance/cg62</p>
Secondary literature and economic evaluations	
ECRI	We did not identify any relevant evidence from this source.
Cochrane library	We did not identify any relevant evidence from this source.
Medline	We did not identify any relevant evidence from this source.
Primary studies	
Medline	We did not identify any relevant evidence from this source.
Cochrane library	Improving proteinuria screening with mailed smartphone urinalysis testing in previously unscreened patients with hypertension: a randomized controlled trial BMC nephrology, 2019, 20(1) added to CENTRAL: 30 June 2019 2019 Issue 06 https://doi.org/10.1186/s12882-019-1324-z

Date of search:	October 2019
Concepts used:	Smartphone urinalysis, home urine analysis, home urine test (combine with concepts chronic kidney disease, urinary tract infection, pregnancy/antenatal care, hypertension, renal)