COMMENT ON STEMPNIEWICZ ET AL.

# Chronic Kidney Disease Testing Among Primary Care Patients With Type 2 Diabetes Across 24 U.S. Health Care Organizations. Diabetes Care 2021;44:2000–2009

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Stempniewicz et al. (1) highlight the variability and significant gaps in adherence to guideline-recommended urine albumin-to-creatinine ratio (uACR) testing in primary care. Innovation could close these gaps, as demonstrated by a home-based uACR testing program in the U.K. that combines service design and new technology to improve population health.

The disparity between rates of uACR and estimated glomerular filtration rate testing across organizations, as highlighted in the article, is not a uniquely American problem. A recent National Health Service diabetes audit reported 53% adherence to uACR testing (2), and, considering the coronavirus disease 2019 (COVID-19) crisis and threat of worsening chronic disease management, in October 2020 the National Health Service implemented a broad, patient-centric screening campaign in the U.K. Using the Healthy.io Minuteful Kidney test system, an in vitro diagnostic, home-use device for the qualitative and semi-quantitative detection of albumin, creatinine, and the ACR, 635,000 people with diabetes who have not undergone ACR testing within a year were identified.

To date, among at-risk previously untested patients, 51% responded to a request for at-home screening, leading to 45,500 completed tests. Ongoing usability studies for Minuteful Kidney across highly diverse patient populations show that nearly 100% of users who begin successfully complete a test, with an overall ease of use rating of 92%. This implementation highlights that well-designed, clinically valid solutions can improve adherence to guideline-recommended testing of uACR while shifting the burden of screening away from primary care. As the prevalence of such conditions rises, patient self-management presents opportunities to improve clinical efficiencies, increase the accessibility of health care, and ultimately deliver better health outcomes in the time of COVID-19 and beyond.

The system comprises a test kit with accompanying smartphone application and image recognition algorithm and uses the more accurate uACR dipsticks. Specifically, it uses the YD URiSCAN stick (as opposed to general proteinuria dipsticks), which accurately risk-stratify kidney disease and are supported by the UK National Institute for Health and Care Excellence (2). Further accuracy validation through this rollout has compared favorably to results obtained by the reference standard quantitative laboratory spot uACR test (AU5800; Beckman Coulter Inc., CA). The AU5800 is a fully automated instrument for the analysis of general and urine chemistries, protein, and serological assays and is the reference standard platform for ACR analysis due to its high performance in studies of imprecision, linearity, and comparison. In a recent paired study in Israel, 194 random urine samples (93 of which with ACR >30 mg/g), the Minuteful Kidney test demonstrated high degrees of both specificity (87.1%) and sensitivity (92.5%). The positive and negative predictive values were high, at 86.8% and 92.6%, respectively.

Health technologies provide many opportunities to engage and work with previously hard-to-reach communities and address health inequalities. Technologies such as Minuteful Kidney enable a new paradigm of home-based, patient-driven care that increases remote monitoring of chronic conditions to close the care gap for those with the greatest need and overcome access barriers imposed by COVID-19.

**Duality of Interest.** All authors have a financial affiliation with Healthy.io. No other potential conflicts of interest relevant to this article were reported.

## References

1. Stempniewicz N, Vassalotti JA, Cuddeback JK, et al. Chronic kidney disease testing among primary care patients with type 2 diabetes across

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24 U.S. health care organizations. Diabetes Care 2021;44:2000–2009
2. NHS Digital. National diabetes audit, 2019-20. Report 1: care processes and treatment targets. England and Wales, 2021. Accessed 9 September 2021. Available from https://files.digital.nhs.uk/42/B253B1/National%20Diabetes%20Audit%202019-20%20Full%20Report%201.pdf
3. Lippi G, Dipalo M, Musa R, et al. Evaluation of the analytical performances of the novel Beckman Coulter AU5800. Clin Biochem 2012; 45:502–504