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CKJ Review

CKJ REVIEW

Point-of-care testing technologies for the home in chronic kidney disease: a narrative review

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ABSTRACT

Point-of-care testing (POCT) performed by the patient at home, paired with eHealth technologies, offers a wealth of opportunities to develop individualized, empowering clinical pathways. The non-dialysis-dependent chronic kidney disease (CKD) patient who is at risk of or may already be suffering from a number of the associated complications of CKD represents an ideal patient group for the development of such initiatives. The current coronavirus disease 2019 pandemic and drive towards shielding vulnerable individuals have further highlighted the need for home testing pathways. In this narrative review we outline the evidence supporting remote patient management and the various technologies in use in the POCT setting. We then review the devices currently available for use in the home by patients in five key areas of renal medicine: anaemia, biochemical, blood pressure (BP), anticoagulation and diabetes monitoring. Currently there are few devices and little evidence to support the use of home POCT in CKD. While home testing in BP, anticoagulation and diabetes monitoring is relatively well developed, the fields of anaemia and biochemical POCT are still in their infancy. However, patients' attitudes towards eHealth and home POCT are consistently positive and physicians also find this care highly acceptable. The regulatory and translational challenges involved in the development of new home-based care pathways are significant. Pragmatic and adaptable trials of a hybrid effectiveness–implementation design, as well as continued technological POCT device advancement, are required to deliver these innovative new pathways that our patients desire and deserve.

Keywords: chronic kidney disease, delivery of healthcare, eHealth, home-based care, point-of-care systems, point-of-care testing

INTRODUCTION

Point-of-care testing (POCT) in healthcare refers to the analysis of patient samples beside or close to the patient. POCT can be used in three settings: by a healthcare professional (HCP) in a healthcare setting, by an HCP in the patient's home or by the patient in their own home. The reason for POCT in the former two settings is to reduce the time between test and decision (primarily in emergency/acute medicine, the time from admission to a decision on disposition) [1]. To this end, POCT has been shown to be effective, at least in the emergency department and ambulatory care clinic [1]. However, improvements in healthcare processes do not reliably translate into meaningful changes for patients; the effects of introducing POCT to a clinical process can be complex and are often not properly evaluated subsequently [2].

The outcome focus when POCT is used at home by the patient is different. The National Health Service (NHS) England makes it clear in their 'long-term plan' that health innovation

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and development of new models of care must be accelerated to give patients greater control over their care [3, 4]. There is increasing acknowledgement of patients as 'experts by experience'; allowing them a role in the management of their conditions is likely to lead to better concordance and improve health outcomes. POCT performed by the patient at home offers a wealth of opportunities to develop individualized, empowering clinical pathways. The non-dialysis-dependent chronic kidney disease (NDD-CKD) patient who is at risk of or may already be suffering from a number of associated complications of CKD represents an ideal patient group for the development of such initiatives. Renal medicine physicians have a track record of early adoption of such technologies, as exemplified by widespread use of the 'PatientView' web portal [5].

Remote patient management presents a potential opportunity in renal medicine to improve clinical outcomes and patient quality of life (QoL) while boosting patient engagement with their disease management [6]. This has been demonstrated in studies in peritoneal dialysis (PD) and home haemodialysis (HD); patients on these programmes report improved satisfaction and comfort, with the suggestion of improved outcomes in terms of treatment concordance and access dysfunction [7–9]. The recent coronavirus disease 2019 (COVID-19) pandemic has made such programmes highly topical, with efforts made to limit travel and hospital visits by integrating home management into existing healthcare programmes [10, 11]. In order for improved home-based healthcare to be delivered, interplay between telehealth solutions and POCT needs to exist. eHealth, where healthcare provision and related processes take place through the cost-effective and secure use of information and communication technologies (ICTs), consists of the electronic patient record (EPR), telemedicine, mobile health applications (mHealth) and associated POCT devices [12]. The World Health Organization (WHO) has previously set the development of eHealth solutions among its top priorities [12].

eHealth solutions have been shown to be attractive to patients; a randomised controlled trial (RCT) of 601 patients receiving care at home through the LifeView (AmericanTeleCare) system, making use of devices such as blood pressure (BP) monitors and glucometers, demonstrated high acceptance and engagement with the intervention (91% completion of 1-year follow-up) [13]. The eHealth-based TAKE-IT trial, involving 189 adolescent and young adult kidney transplant patients, utilizing eHealth to deliver coaching, problem-solving skill sessions and reminders, led to a significant improvement in medication adherence in these patients [14]. A Cochrane review and meta-analysis including 43 studies (RCTs and quasi-RCTs, $N = 6617$) found that eHealth can aid in dietary sodium intake and fluid management [15]. Similarly, the use of mHealth in HD patients was recently systematically reviewed (22 studies: 4 RCTs, 16 cohort studies and 2 mixed methods studies), highlighting potential positive outcomes with regards to QoL, patient satisfaction and user acceptance with possible cost-saving implications. However, as in the Cochrane review, the authors emphasized the absence of evidence with regards to cost-effectiveness and safety [16].

Such results underline the benefit of remote patient monitoring and the rationale behind the movement towards chronic disease home-based management. The majority of eHealth technology already exists and could be readily applied to the care of patients; the exception is the POCT technologies themselves [12]. POCT devices can be incorporated into eHealth solutions, and patients managing their conditions with a POCT device have greater motivation to be involved in the management of their condition and greater confidence in their doctors. Additionally, in the field of diabetes, significant improvement in clinical outcomes such as glycaemic control has been demonstrated by patients who use a home POCT device [2]. However, devices and their associated pathways need to demonstrate accuracy, validity and non-inferiority to traditional care [2]. eHealth and home POCT introduce a number of potential safety concerns over traditional care, such as data security and patient and staff training; extreme care should be taken when any eHealth and POCT intervention is used in place of traditional care without full validation [17]. Consequently, the WHO has issued their ASSURED guidance to aid in the development of POCT devices and their pathways (Table 1) [18].

POCT, as with laboratory testing, is subject to several international standards to ensure quality. It is paramount that quality assurance is maintained alongside efficient record keeping and results interpretation [19]. Continuous and ideally bidirectional flow of data between potentially hundreds of POCT devices, the laboratory information system and the EPR should be engineered to make this possible [19, 20]. A number of programmes, such as POCcelerator (Siemens Healthineers, Erlangen, Germany) and RALS Web 3 (Alere Informatics, Charlottesville, VA, USA), have been designed to fulfil these roles of data collection and review, internal quality control (IQC), external quality assurance (EQA) and, via intelligent dashboards, data-driven decision making. Systems can be further enhanced through the use of 'machine learning' and programmable alerts, as currently seen in the analysis of implantable loop recorders in cardiology [21]. The vast amount of data analysed by such systems, assessing the regular testing of hundreds of patients, presents an ideal opportunity for the discovery of new insights via the use of machine learning/artificial intelligence [22]. However, ICT alone is inadequate to ensure the quality of such pathways. Appropriately trained staff need to be vigilant in reviewing results and communicating concerns regarding device and patient factors, while ensuring sufficient patient training on the use of their devices. Hence the work involved in the implementation of a new POCT pathway can appear monumental and involves a transformation of diagnostic services and care provision [23]. The UK Medicines and Healthcare Products Regulatory Agency has recently published guidance on the implementation of POCT solutions [24]. Advice includes the creation of a specialist POCT committee composed of laboratory staff, clinicians, specialist nurses, nursing staff, information technology specialists, pharmacists and finance specialists responsible for the overall service, IQC and EQA. Identifying all stakeholders early in the implementation of a POCT pathway will allow topics such as record keeping, accreditation and maintenance to be addressed while troubleshooting logistic and equipment problems [24]. Integration of POCT pathways into existing systems is often expensive and difficult and

Table 1. WHO ASSURED criteria for evaluating POC devices in resource limited environments

Affordable
Sensitive
Specific
User-friendly
Rapid and robust
Equipment-free
Deliverable to end users

Adapted from Kosack *et al.*, 2015 [48]

many initiatives suffer from a lack of dedicated support [19]. Without specialist support, POCT pathways lack quality control, become isolated and are liable to become unsafe and ineffective [19].

Thousands of POCT devices have been developed in academic labs, but only a minority are able to analyse untreated samples and involve processes that make them suitable for home use [12]. A small percentage of these devices have been commercialized and only a few of these have been successfully evaluated and integrated into clinical practice [12]. Devices that are suitable and licensed for home monitoring make up an even smaller proportion [12]. Additionally, large healthcare organizations are slow to change routine clinical practice and care pathways must be optimized to gain the maximum benefit from a POCT device [2]. Despite this, the global POCT market is worth >US$28 billion, with an estimated 5-year compound growth rate of ∼9% [18].

Home POCT has been integral to diabetes care for years and other fields, namely that of anticoagulation, have established the use of home testing pathways [25]. CKD is a common and long-term condition with high associated healthcare costs. Innovative pathways including home POCT have the potential to improve patients' health status and allow them to understand and take greater control of their health [26]. The POCT devices themselves are the weak link in the development of such pathways and their review in the field of renal medicine has been neglected. This article outlines the technologies present for POCT at home and reviews the currently available devices relevant to renal medicine and the evidence supporting their use.

OUTLINE OF POCT TECHNOLOGIES

A great amount has been written about the design and function of the multitude of POCT devices that have been developed; these have been the subject of numerous detailed reviews and are beyond the scope of this article [2, 12, 27]. Table 2 briefly summarizes the technologies used in POCT to add context to the later discussion [25, 28–35].

CLINICAL APPLICATIONS

A number of the markers of interest in CKD are challenging to measure via POCT; for example, the complexity of creatinine's specimen matrix makes it prone to many confounders and the haemolysis associated with finger-pricking makes potassium measurement almost impossible via this method [36]. Additionally, CKD poses a number of additional challenges to the developers of POCT devices over and above those experienced in the general population. Fluctuations in volume status, and therefore in haematocrit (Hct), are common in CKD due to dialysis or the use of diuretics; POCT devices that use finger-prick samples are especially prone to this confounder due to the contribution of interstitial fluid. Variations in Hct affect haemoglobin (Hb) calculations in applicable POCT devices but have also been shown to affect the calculation of other parameters such as glucose concentration and international normalized ratio (INR) [37, 38]. Readings from POC devices measuring glucose and creatinine have also been shown to be confounded by fluctuations in potassium, calcium, albumin, urea and uric acid, all of which are frequently seen in CKD [39, 40].

In this section we will discuss the small number of devices that are available and appropriate for patient use in home monitoring and the evidence surrounding their use. Popular and adaptable POC devices such as the iSTAT (Abbott Point of Care, Princeton, NJ, USA) will not be discussed, as they are too bulky and expensive for widespread home use. Devices in development that have not yet achieved authorization for either professional or home use fall outside the scope of this current review and will not be discussed. Furthermore, interesting POCT devices for home use, such as the PERiPLEX device (Mologic, Thurleigh, UK) for the diagnosis of PD peritonitis and those for the monitoring of immunosuppressive therapy in renal transplant patients, fall outside the scope of this current review and will also not be discussed. The analytical performance and clinical utility of key devices discussed are summarized in Table 3 and illustrated in Figure 1.

Anaemia management

It is well established that appropriate management of renal anaemia by the use of iron supplementation and erythropoietin-stimulating agents (ESAs) improves CKD patients' QoL, lessens symptom burden and improves aspects of prognosis [70–72]. Enabling this care to take place in the home is attractive to physicians and patients.

Luma (Entia, London, UK) is a 78 × 83 × 52 mm device weighing 96 g with a Conformité Européen mark for home use in the measurement of Hb [73]. The device uses a microcentrifuge on 4–8 μL capillary blood in a reagent-free cuvette for a measure of Hct followed by photometric absorptiometry to calculate Hb. A smartphone app is available to use with the device for data storage, symptom tracking, reminders and the display and transmission of Hb results. In preliminary studies of 376 paired capillary and venous blood samples, the device has been compared to lab-based Hb measurement (LH750, Beckman Coulter, Brea, CA, USA). The Entia device measurements showed a high degree of correlation with the LH750 ($r = 0.99$), with a coefficient of variation (CV) of 7.1% (unpublished data, Entia) (Table 3). The device has been used successfully in the iron-deficiency anaemia population and currently Luma is undergoing deployment at a number of NHS trusts to assess the utility of the device in the ESA-prescribed NDD-CKD population, with studies yet to report. The fact that this device is the only haematology POCT device on the market for home use makes it a promising candidate for wider use within healthcare services once service evaluations are complete. The company is also developing a similar device for monitoring the full blood count (FBC) aimed at the oncology market.

Hemocue (Radiometer Medical, Copenhagen, Denmark) has been making Hb monitoring devices for >35 years. The HemoCue Hb 801 System represents their most recent device iteration. The device measures 143 × 87 × 45 mm and weighs <250 g. The device measures Hb concentration by absorptiometry in <1 s in 10 μL of capillary blood. Earlier iterations of the HemoCue Hb System have shown good correlation with central laboratory testing and have subsequently been considered suitable for monitoring Hb levels in selected patient groups, such as obstetric and paediatric surgery patients, in the professional setting [47, 74] (Table 3). The authors are unaware of any use of this device by patients. However, the HemoCue WBC DIFF System, a similar if slightly larger and prohibitively expensive device (>£4000) using macroscopically similar microcuvettes, has been used by patients in their own homes [25, 45]. In a trial of 14 breast cancer patients undergoing chemotherapy, 42 HemoCue results were compared with lab measurements within 3 h [45]. The mean difference (MD) between methods for white cell count (WCC) was 0.36×10^9/L [standard deviation (SD)

Table 2. A summary of the various technologies employed in POCT

Technology	Technical summary	Advantages	Disadvantages	Application examples
Dipsticks	Paper-backed device supporting one or several porous reagent pads; reflectance technology gives a colour change allowing qualitative/semi-quantitative estimation of the analyte. Analyte applied directly to pad (cf. LFA) Can be paired with automated dipstick readers allowing more objective measure of analyte presence and a level of quantification. Readers vary from bench-top devices (negate some of the simplicity and economy of dipstick testing), to colorimetric smartphone-based detector apps (hold greater opportunities in terms of home use and ease of deployment) [25, 26]	Simple in design, use and manufacture; therefore, cheap and well suited to use in resource-limited settings [18]. Portable and easily disposable. Can detect >10 analytes simultaneously	Subjective nature of reagent colour change prone to interpretation error. Multi-reagent strips can be misread due to misalignment with the key. Excessively dilute or concentrated urine may lead to errors in interpretation	Siemens Multistix (10 parameter urinalysis) Bayer Ketostix (single parameter ketone urinalysis)
LFA	Composed of a number of abutted pads mounted on backing card. Sample applied to sample pad and drawn by capillary action through several pads and into contact with reagents and a label to produce a visible marker of detection. Most read after 5–15 min; display a control line (as proof of assay validity) and one or more test lines allowing qualitative or semi-quantitative estimation of analyte/s. Multiplexing possible by the use of multiple test strips or multiple test lines on the same strip. Colorimetric, fluorescent, electrochemical or enzymatic detection systems designed [26]. Can be read by eye or via a reader tool which may improve accuracy of quantification [18]	As per dipsticks can be multiplexed to detect >10 analytes simultaneously. Simple, portable, easily disposable and low cost	Label in LFA should be detectable over a large and clinically useful range, have low non-specific binding, be stable in storage, low-cost and be easily conjugated with its biological compound without losing activity [18]. Sensitivity an issue	Clearblue pregnancy test (urine human chorionic gonadotropin) SD Biosensor Lateral Flow Test (saliva severe acute respiratory syndrome coronavirus 2)
Paper-based analytical devices (μPAD)	Microfluidic channels are created by printing hydrophobic or hydrophilic material onto paper. Screen printing is widely used. A μPAD made from a few stacked layers of patterned paper is able to	Paper's 3D fibrous structure facilitates pump-free wicking, and is fluid permeable so allows creation of multi-layered devices with vertical as well as horizontal flow [12].	As with LFA sensitivity an issue, a problem particularly predominant in microbiological assays. Enzyme-, silver- or gold-based amplification schemes can be used to increase the	Beginning to transition from research to commercial applications: no devices in widespread commercial use PTS Diagnostics CardioChek Home Use Analyser (serum

Table 2. (continued)

Technology	Technical summary	Advantages	Disadvantages	Application examples
	store reagents and allow the controlled wicking of fluids to create a multiplexed device and allow multistep analysis or quantification of analytes [12]. The analyte is labelled and read, by colorimetric or fluorescent methods as per the LFA [18] Can be paired with electrochemical or potentiostat readers. These can be bought for USD $90 and provide high sensitivity for the reading of multiplexed μPADs [26]	Paper can act as a microcuvette for the storage of reagents and can be machined, by printing or other methods, in similar ways to silicone for a fraction of the cost [23]. Screen printing technique and is inexpensive and readily reproducible [18]	sensitivity of a μPAD or LFA but these only recently practical without additional user steps [12]	glucose, high-density lipoprotein, total cholesterol and triglyceride)
Chip-based microfluidics (lab-on-a-chip)	Microfluidic devices that use pressure, centrifugal, electrokinetic or acoustic, in addition to capillary, driving forces [26]. Based on silicone, glass or polymer base and requiring pumps, valves, microfilters and containers of regent, which have proven expensive and challenging to miniaturize [12, 23]	Innovation continually reducing the price and need for user input into such devices. Potentially able to overcome some of the limitations of LFA and μPAD	Components formally expensive, challenging to miniaturize and required additional user steps (thereby reducing usability and introducing error)	Abbott Point of Care iSTAT (multi-cassette device allowing analysis of various serum parameters, e.g. creatinine)
Microcell-based devices	Analyse $<100\mu$L of untreated samples inside a microcuvette or electrochemical microcell with the reagents required for analysis stored in dry form within the microcell [18]. For example, upon the addition of untreated blood to a microcell, the reagents facilitate the lysis of undesired cells and staining of target cells. The sample is subsequently imaged and differential cell counts made via image recognition technologies [12, 19]	Does not rely on the use of appropriate labels. Able to perform high-quality analyses not currently possible in other devices (e.g. five-part FBC differentiation and quantification)	Limited by the ability of the reagents to be stored effectively within the cell and also by the need for electricity, increasing complexity and expense	Radiometer Medical HemoCue WBC DIFF (serum FBC and five-part differential) Entia Luma (serum Hb)
Wearable devices	Design depending on use. Devices should require minimal input from the user and be fabricated as to be almost unnoticeable to the wearer. Continuous glucose metres consist of a microneedle inserted into the subcutaneous tissue connected to a wearable electrochemical potentiostat which allows monitoring of	Potentially enable continuous and unnoticeable monitoring of parameters. Can be made from low cost, flexible, waterproof substrates such as thin silicone layers. pH sensing decals have been fabricated for USD $0.08 making single-use application possible [28]	Colorimetric devices, while economical do not allow continuous monitoring and have limited resolution; potentiometric or amperometric sensors have traditionally been expensive [28]. Many devices affected by temperature, pH and humidity and require advanced calibration so	With the exception of wearable glucose meters, wearable POCT devices remain in the early stages of development, interest primarily focussed on military and sports science applications. Abbott Diabetes Care Freestyle Libre (interstitial fluid glucose)

Table 2. (continued)

Technology	Technical summary	Advantages	Disadvantages	Application examples
	glucose in the interstitial fluid [12]. Sweat analysing devices have been developed using microfluidic microchips and printed electrodes to measure analytes by potentiometry, chronoamperometry and voltammetry [1]. Sweating is induced by an iontophoresis interface using heaters or pilocarpine-based hydrogels [1]. Devices can be read and analysed using a smartphone camera and app [1]		are not currently suitable for clinical use [12]	SWEATCH platform (sweat sodium and potassium)
Smartphone-based systems	Smartphones contain processing, data acquisition, display and transmitting technologies that can integrate with and supplement home POCT devices; apps may allow the smartphone to act as a POCT device alone. There are three levels of smartphone involvement with POCT: 1. Self-contained POC devices receive, process and analyse a sample, the smartphone then acts to receive, store and send the data produced [29] 2. Use of hardware that supplements the abilities of a smartphone. E.g. an optics system that illuminates a test strip with the smartphone acting as sensor (via the camera) and analyser [29] 3. Use of systems and sensors available on the smartphone alone; the phone becomes the POC device	Increasing smartphone integration has benefits in terms of ease of deployment, use and low cost [13]. The ICT in smartphones is robust and well developed. May allow better integration into user's life	Concerns regarding data security. Issues of integration with varying smartphone models	HemaApp (application estimates Hb via the phone's flash, infra-red emitter and camera alone) Holomic rapid diagnostics reader (HRDR-200) (opto-mechanical attachment and smartphone app that allows the phone to act as a LFA reader)

LFA, lateral flow assay.

1.01, correlation (r) 0.86, limits of agreement (LOA) -1.61×10^9/L–2.34×10^9/L (7.1% of measurement pairs outside of the LOA)] [45]. The LOA was wider than is considered clinically acceptable and the device was not considered suitable for use at home [45]. In another oncology study, 60 outpatients and 22 inpatients on active treatment were asked to test themselves using the same device, this time in the hospital only, with results compared with lab FBCs [25]. Fifty-seven percent of the patients were able to conduct a self-test on this machine after a single demonstration with no further help needed; after follow-up guidance, 96% were judged able to test in their own homes [25]. Ninety percent of the patients were successful in filling and placing the cuvette on their first try, with no difference in success observed between younger and older individuals [25]. All results were within the predefined acceptable range of $\pm 1 \times 10^9$/L for WCC [25]. The device was considered to be reliable and clinically

Table 3. Summary of key devices licensed or suitable for home use in anaemia management, biochemical analysis and anticoagulation monitoring with selected devices for hypertension and diabetes care.

Device	Design (test)	Analytical performance	Approved for home use (evidence supporting home use)
Anaemia management			
Entia	Centrifugation and photometric detection with reagent-free cuvette (Hb)	Unpublished data, Entia (2020): Precision analysis using fixed control blood (103 repeats) at low (Hb 75 g/L), normal (Hb 125 g/L), high (Hb 175 g/L) Hb values: CV 5.2, 3.1, 2.6, respectively. Paired capillary and venous blood samples ($n = 376$) Luma versus lab-based Hb measurement (Beckman Coulter LH750) showed high correlation between devices ($r = 0.99$, CV 7.1%)	Yes (Unpublished data: Service evaluations currently on going in three NHS trusts with CKD patients)
Luma			
EKF Diagnostics	Photometric azide methemoglobin method (Hb and estimated Hct)	Singh *et al.* (2015) [41]: In detecting Hb <125 g/L in 485 prospective blood donors: Sensitivity 86.8%, intra-class correlation 0.77 CV 2.2%. Max. tolerance 3 g/L at 150 g/L.	No (No)
HemoControl			
DiaSpect	Photometric detection with reagent free cuvettes (Hb)	Singh (2015) [41]: In detecting Hb <125 g/L in 485 prospective blood donors: Sensitivity 98.1%, intra-class correlation 0.78, CV 2.19%	No (No)
Hemocue	RBC lysed and WBC nuclei stained, sample imaged. Concentration calculations via automated image recognition technology (total WBC, neutrophils, lymphocytes, eosinophils, basophils, monocytes)	Bui (2016) [42]: $n = 60$; WBC DIFF versus lab Cell-Dyn Sapphire; $r > 0.95$ for leucocyte, neutrophil and lymphocyte counts. $r = 0.772$ leucocytes, 0.817 neutrophils and 0.798 lymphocytes. Intra-assay reproducibility was insufficient for lymphocytes Karawajczyk (2017) [43]: $n = 158$; WBC DIFF versus lab Cell Dyn Sapphire, median CV 2.22% WCC, 2.44% neutrophils, 8.56% lymphocytes and 15.2% monocytes. Deviation >15% between methods in 9% WCC, 28.7% neutrophil counts and 48% lymphocyte counts. Utility is limited to WCC and neutrophil counts only. Dunwoodie (2018) [44]: The imprecision (SD) values between the duplicate samples for neutrophils were 0.18 in the low range ($<2 \times 10^9$/L $n = 54$), 0.43 in the normal range and 0.56 in the high range ($>7 \times 10^9$/L, $n = 47$). Lymphocyte counts are less well correlated but still clinically acceptable	No [Yes, Lohman *et al.* (2018) [45]: $n = 14$, WBC DIFF versus lab: MD WCC 0.36×10^9/L, SD: 1.01, $r = 0.86$, 7.1% of measurement pairs outside LOA. LOA outside those considered acceptable for clinical use at home. Otto Mattsson *et al.* (2020) [25]: $n = 82$; All results recorded as a result of self-testing were within pre-defined acceptable range. Fifty-seven percentage able to conduct a test after single demonstration, 96% judged able to test in own homes. Dunwoodie (2018) [44]: $n = 50$; high correlation between measurement pairs (HCP test versus patient test, $R^2 = 0.921$, $P < 0.001$)]
Hemocue WBC DIFF			
HemoCue Hb System	Absorptiometry (Hb)	Back (2004) [46]: $n = 497$. Imprecision from duplicate	No (No)

Table 3. (continued)

Device	Design (test)	Analytical performance	Approved for home use (evidence supporting home use)
		samples 0.5– 1.1%. Correlation against the ICSH reference method >0.99, with mean bias of 0.10 g/dL. Imprecision calculated from duplicate samples on the HemoCue Hb system was 0.75%. Akhtar *et al.* (2008) [47]: $n = 540$: For detection of Hb <125 g/L sensitivity 94.1%, specificity 95.2%, versus ICSH reference method $r = 0.99$. Other studies have reported sensitivity 56–94.7%; specificity 80.1–100% for capillary blood	
Biochemical analysis **Nova biomedical** StatSensor and StatSensor Xpress Creatinine	Amperometry [creatinine and calculation of eGFR (StatSensor only)]	StatSensor Xpress: Kosack *et al.* (2015) [48]: $n = 60$, acceptable to good utility in terms of repeatability, inter-device reproducibility and between-run reproducibility over time using quality control reagents; sufficient accuracy in detecting pathological samples based on the CV for repeatability and between-run reproducibility (2.3–5.9% and 4.2–9.0%, respectively). Some underestimation of higher values was seen based on the Bland and Altman technique StatSensor Creatinine: van der Heijden *et al.* (2019) [49]: $n = 120$, exceeded pre-defined analytical error limits of 8.87% for creatinine and 10% for eGFR (creatinine: 15%, eGFR: 13%), with greater variation in results compared to i-STAT and epoc Blood Analysis System	No (No)
Hemocue Hemocue Albumin 201	Photometry via immunoturbidometric reaction (urinary albumin)	Heerspink (2008) [50]: $n = 259$: HemoCue Albumin 201 versus laboratory technique: no sig. difference between the median urinary albumin concentration in the first morning void ($P = 0.082$), intra-individual variability in patients excreting >30 mg/day ($P = 0.459$) and the prediction of microalbuminuria in 24-h collections ($P = 0.103$) between the two methods Sarafidis (2008) [51]: $n = 165$; diagnosis of microalbuminuria using laboratory urinary albumin excretion as reference (HemoCue versus conventional dipsticks versus laboratory ACR). Sensitivity and specificity 92% and 98%	No (No)

Table 3. (continued)

Device	Design (test)	Analytical performance	Approved for home use (evidence supporting home use)
		for HemoCue, 73% and 96% for ACR and 70% and 83% for Chemstrip Micral dipstick	
Anticoagulation monitoring **Roche Diagnostics** CoaguChek XS	Amperometry (prothrombin time and INR)	Sobieraj-Teague (2009) [52]: Hospital setting: 98-paired INR results; 93.5% Coaguchek XS results within 0.5 of laboratory INR. CV < 5%. Bereznicki (2006) [53]: Community setting: 59-paired results; high correlation between methods ($r = 0.91$). About 94.6% of results within 15% of the lab value. No INR results varied by >20% or >0.5 from lab values	Yes [Yes: Many studies including: McCahon (2007) [54]: TTR: PSM 70% versus controls 64%. 45% patients performing IQC, 82% performing EQA on a regular basis. da Silva Saraiva (2016) [55]: $n = 31$, no sig. change in QoL throughout course of use as assessed using DASS score. Chapman (1999) [56]: $n = 45$, usability was high (error messages 6.3%)]
Siemens Healthcare Diagnostics Xprecia Stride	Amperometry (prothrombin time and INR)	McCahon *et al.* (2018) [57]: Xprecia Stride versus laboratory versus CoaguChek INR results ($n = 102$ laboratory, 205 parallel coaguglometer tests) showed good correlation: Xprecia Stride versus laboratory $r = 0.83$, Xprecia Stride versus Coaguchek $r = 0.92$. CV < 5%. Piacenza *et al.* (2017) [58]: $n = 163$ compared Xprecia Stride versus laboratory; high precision with a CV < 3%. Analytical accuracy within acceptable range (Lin's concordance = 0.962). Results tally with Siemens' in house testing	No (No)
Hypertension **HealthSTATS International** BPro	Non-inflating cuff; modified applanation tonometry (BP, pulse)	Needs regular calibration against a standard oscillometric device. Nair (2008) [59]: $n = 89$, BPro versus MC3000 standard oscillometric device, sitting standing and lying, readings within ±5 (SD < 8) mmHg. Komori (2013) [60]: $n = 15$ BPro versus standard ABPM device; values in arms-raised position higher in BPro (SBP: 129 ± 14 versus 108 ± 14 mmHg, P < 0.01; DBP: 83 ± 13 versus 64 ± 11 mmHg, P < 0.01). No sig. difference in other arm positions. Harju (2018) [61]: $n = 28$, BPro versus arterial line postoperatively; BPro inaccurate, Bland–Altman plot 19.8 ± 16.7 mmHg, LOA −20.1–59.6 mmHg, Spearman's $r = 0.61$. Movement sig. increased failure rate (P < 0.001)	Yes: AAMI and ESH validated. [Yes: Komori (2013) [60]: $n = 50$, BPro versus standard ABPM device, no sig. difference in awake mean DBP or sleep mean SBP, however, sig. difference in awake mean SBP and mean sleep DBP (BPro 122 ± 13 versus standard 127 ± 11 mmHg, P < 0.01 and BPro 71 ± 8 versus standard 64 ± 8 mmHg, P < 0.01, respectively). Correlation between devices: 0.54 for 24-h SBP and 0.52 for awake SBP; moderate agreement, considered acceptable for ABPM use]
Maisense Freescan	Cuff-less; calculation of pulse transit time via embedded electrodes and force sensor (BP, pulse)	Needs regular calibration against a standard oscillometric device. Boubouchairopoulou (2017) [64]: $n = 85$, Freescan versus mercury sphygmomanometer, MD in paired	No: AAMI validated in the non-ambulatory setting (No)

Table 3. (continued)

Device	Design (test)	Analytical performance	Approved for home use (evidence supporting home use)
		measurements: SBP (SD) 3.2 (6.7) mmHg, DBP 2.6 (4.6) mmHg; therefore, AAMI validated. Wu (2016) [65]: $n = 100$, Freescan versus mercury sphygmomanometer, MD (SD) SBP: −1.39 (4.2) mmHg. MD (SD) DBP: 0.32 (2.5) mmHg	
Diabetes care **Abbott Laboratories** FreeStyle Libre	Glucose-oxidase enzyme-based sensor and wireless recorder (FGM)	Bailey (2015) [64]: $n = 72$, Libre versus BG finger-prick; % results in consensus group A (no effect on clinical action) on Days 2, 7 and 14 was 88.4, 89.2 and 85.2%, respectively. The overall mean ARD 11.4%. Sensor accuracy not affected by factors such as BMI, age, type of diabetes, clinical site, insulin administration or HbA1c. CV 8.6%. Fokkert (2017) [65]: $n = 20$, Libre versus Statstrip; 85.5% of results within consensus group A. Accuracy only demonstrated for readings from upper arm, data obtained from abdomen placement was not reliable (62.9% of readings in zone A). 20% relative difference when BG $\leq$ 70 mg/dL; therefore, may be inaccurate in this range	Yes [Yes: multiple, including Olafsdottir (2017) [66]: $n = 58$, Libre versus Hemocue; mean ARD was 13.6% (95% CI 12.1–15.4%) Week 1 and 12.7% (95% CI 11.5–13.9%) Week 2. Overall $r = 0.96$. High patient satisfaction 10-item VAS (mean value range: 8.22–9.8). In keeping with two previous similar studies. Thirty-two percentage had a visible skin reaction after sensor removal]
Dexcom Dexcom G4 Platinum	Glucose-oxidase enzyme-based sensor and wireless recorder (FGM)	Nakamura (2015) [67]: $n = 72$, DG4P versus YSI reference measurement; overall mean ARD: 13%, median 10%. Precision ARD 9 ± 4% between 2 sensors with CV 7%. Ninety-four percentage sensors lasted 7 days and systems displayed 97% of expected glucose readings. Peyser (2015) [68]: $n = 51$, DG4P versus YSI reference in hypoglycaemia; 96% CGM values were within 20 mg/dL of YSI between 40 and 80 mg/dL, an area of weakness in other CGM devices	Yes Yes: multiple, including Nakamura (2015) [67], $n = 72$: night-time hypoglycaemia decreased from first night to sixth night ($P < 0.001$) with small improvement in mean glucose (147 ± 40 to 166 ± 62 mg/dL). Boscari (2018) [69]: $n = 22$, DG4P versus Libre finger-prick; mean ARD 12.9 ± 2.5%. Other studies show high usability and patient satisfaction]

Hb: haemoglobin, Hct: Haematocrit, CV: coefficient of variation, FBC: full blood count, MD: mean difference, SD: standard deviation, RBC: red blood cells, WCC: white cell count, Plt: Platelets, LOA: limits of agreement, INR: international normalised ratio, DASS: Duke Anticoagulation Satisfaction Scale, VAS: Visual analogue scale, QoL: Quality of life. ICSH: International Committee for Standardization in Hematology. TTR: time in therapeutic range. PSM: Patient self management. IQC: Internal quality control. EQA: External quality assurance. AAMI: Association for the Advancement of Medical Instrumentation. ESH: European Society of Hypertension. ARD: Absolute relative difference. CGM: continuous glucose monitoring.

$P < 0.001$), but 18% of patients were unable to achieve a result with the device, most commonly due to air in the cuvette [44] (Table 3). It is important to specify that although the cuvettes and sampling techniques are superficially similar, it cannot be assumed that the results for this device can be applied to the HemoCue Hb systems or are applicable to CKD patients. No device is authorized for home use.

While a number of other devices for professional use are small and simple enough for potential use at home, such as DiaSpect (EKF Diagnostics, Cardiff, UK), none have been evaluated for patient use (Table 3) [44]. Furthermore, even for the Luma and WBC DIFF devices, the integration of home POCT haematology devices into clinical care has yet to be demonstrated and there are significant regulatory and economic hurdles to

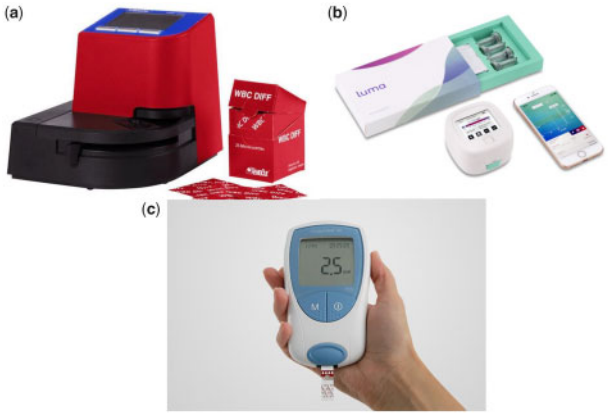

FIGURE 1: A selection of POCT devices either specifically designed for home use or with evidence supporting their use in the home: (**A**) HemoCue WBC DIFF (RadioMeter) (not approved for home use), (**B**) Luma (Entia) (approved for home use) and (**C**) CoaguChek XS (Roche) (approved for home use).

overcome before this can be done, in addition to issues about the transfer of results onto hospital EPR systems.

Hypertension

Good BP control is one of the key interventions that can slow renal decline [75]. Thus it follows that home BP monitoring is one of the most important aspects in nephrology; devices that can aid effective BP control have a great potential to improve renal outcomes in NDD-CKD patients. Ambulatory BP monitoring (ABPM) is the preferred method for diagnosing hypertension [76]. However, the principle advantage of ABPM, multiple readings, especially at night, is the main reason that the devices may not be acceptable to patients; they are uncomfortable and disturb sleep [76]. ABPM also has costs in terms of time and money associated with travel to and from hospitals for fitting and device drop-off [76]. Home BP monitoring (HBPM) is a more acceptable alternative to ABPM, with similar benefits over clinic monitoring, and consequently it is also endorsed in guidelines for both confirmation of diagnosis and in the monitoring of hypertension [77].

BP monitors can be defined as cuff and non-cuff devices; cuffed devices can be designed to be fitted to the upper arm, wrist or finger [27]. Few studies have rigorously assessed BP monitoring devices against each other despite significant differences between commercially available models [78]. No significant differences in mean BP were noted when several fully automated oscillometric upper arm devices meeting American National Standards Institute (ANSI) standards were compared with a standard manual mercury sphygmomanometer or a manual aneroid sphygmomanometer in a review of the literature [78]. However, a significantly higher mean BP was noted with a fully automated cuffed wrist device compared with the mercury sphygmomanometer ($153 \pm 28/87 \pm 18$ versus $137 \pm 20/80 \pm 11$ mmHg; $P < 0.001$) [78]. Meanwhile, a finger BP cuff device was noted to give significantly lower readings than a mercury sphygmomanometer (114/69 versus 129/78 mmHg; $P < 0.05$) [78].

Non-inflating wristwatch-like devices, such as BPro (HealthSTATS International, Singapore), utilizing a pulse wave acquisition system via modified applanation tonometry to acquire arterial radial pulse waves and calculate BP, have been shown in several studies to correlate well with upper arm BP measurement but remain prohibitively expensive (>£2000) (Table 3) [27, 79, 80]. Fully cuff-less BP monitoring devices able to calculate BP based on pulse transit time currently have limited validation data, in addition to a high calibration failure rate and frequent need for recalibration, although the Freescan (Maisense, Zhubei, Taiwan) device has achieved ANSI validation for non-ambulatory use (Table 3) [17, 27, 81]. Bard *et al.* [60] have comprehensively reviewed these technologies, their advancement and limitations [82].

In patients suffering hypertension alone, remote BP monitoring has been shown to improve BP control and treatment adherence [83]. The evidence is less clear in those with CKD and hypertension. A systematic review on the subject of remote home management in dialysis-dependent or transplanted CKD patients assessed three randomized studies that focussed on BP control [26]. No significant difference in systolic BP (SBP) or diastolic BP (DBP) was noted in the patients who used remote monitoring of their BP versus standard care [26]. However, in dialysis-dependent patients, remote monitoring did allow optimization of weight gain and reduced ultrafiltration volumes, albeit in a small sample size ($N = 120$) [26]. Despite this apparent lack of effectiveness, patients and nephrologists consistently showed a positive attitude towards remote monitoring, with 96% of patients in one study stating that they would like to continue using their BP monitor [26, 84]. Similarly, in another study, 91% of 601 CKD patients assigned to home monitoring completed a year of monitoring with an average of 14.2 completed virtual clinics per year and 14.9 BP readings per month [85].

The use of BP devices at home is well established but the associated eHealth technologies are only just emerging. HBPM is effective in hypertensive patients and shows a lack of efficacy in dialysis-dependent patients; however, there is a lack of evidence in NDD-CKD patients. Currently a fully automated oscillometric upper arm BP monitor with wireless connectivity to a mobile app for the storage and transmission of results appears to be the most reliable, acceptable and cost-effective method of monitoring. However, with ongoing development, wristwatch devices and completely cuff-less devices are likely to become increasingly prominent in hypertension monitoring [82].

Biochemical analysis

Monitoring of electrolytes, urea and creatinine is important in the routine care of CKD patients and the benefits of home monitoring of these parameters are easy to imagine. However, in this field there are currently very few devices available that are potentially suitable and none that are currently authorized for home use.

The small and user-friendly StatSensor Xpress Creatinine (Nova Biomedical, Waltham, MA, USA) is $91 \times 58 \times 23$ mm and weighs 75 g, making it potentially suitable for home use, with acceptable concordance to lab-based systems at creatinine values $<600\ \mu$mol/L (Table 3) [48]. However, other investigators have found the sister device, StatSensor Creatinine, substantially exceeded predefined analytical error limits of 8.87% for creatinine and 10% for estimated glomerular filtration rate (eGFR; creatinine 15%, eGFR 13%), with greater variation in results compared with other POC devices such as the i-STAT (Table 3) [49].

A number of other companies and universities (Kalium Health, Cambridge, UK; University of Cambridge, University of California, etc.) are currently developing paper-based analytical devices and microcell devices for the sensing of potassium, phosphate, urea and creatinine, with great promise for use in the home setting, but they currently lack any significant real-world data for their use [86, 87]. The effect of haemolysis in finger-prick blood samples has proven very difficult to overcome

in microcell devices. The use of wearables in this area is promising, with the SWEATCH sweat potassium sensor as an example, but it similarly lacks data to support its home use [34].

Diabetes mellitus care

Diabetes mellitus is the most common aetiology of CKD and good glycaemic control is an important factor in renal disease progression [88]. POCT has long been part of the care of patients with diabetes; glucose meters have the largest share of the POCT market and dominate the home testing market [28]. There are a large number of commercially available glucose meters that are small, light and simple-to-use and are licensed for use at home; evidence supporting their use exists in the general diabetes and CKD-diabetes populations [89–91].

Continuous and flash continuous glucose monitoring (CGM and FGM, respectively), which measure interstitial glucose concentrations either continuously (CGM) or on patient demand (FGM), have been shown to be effective in CKD patients. The DIALYDIAB pilot study used the iPro2 (Medtronic, Minneapolis, MN, USA) to monitor glycaemic control in 15 HD-dependent diabetic patients. Patients were followed up for 12 weeks, with CGM taking place in Weeks 6 and 12 after the device was fitted by a nurse specialist. The study concluded that CGM led to more frequent changes in the treatment regimen, resulting in improved glycaemic control and decreased frequency of hypoglycaemia [92]. Despite performance of QoL assessments, the impact of such a regimen on QoL was not commented on in the study [92]. A further pilot study assessed the same patient group ($n = 28$ type 2 diabetes patients using the Navigator device; Abbott Laboratories, Abbott Park, IL, USA). CGM-facilitated change in insulin management at the beginning of the trial led to a significant decrease in HbA1c at 3 months (8.4 ± 1.0% to 7.6 ± 1.0%; $P < 0.001$) and a significant decrease in hyperglycaemia [93]. A randomized trial comparing CGM with self-monitoring of blood glucose ($n = 30$; CKD G3) indicated that the proportion of time CGM patients were hyperglycaemic decreased from baseline to Week 6 (65.4 ± 22.4% to 54.6 ± 23.6%; $P = 0.033$) with no significant change in hypoglycaemic time. Both self-monitoring and CGM were successful in improving glycaemic control [HbA1c baseline 9.9 ± 1.2; end of trial 9.0 ± 1.5% ($P < 0.001$)], with no difference between the two modalities ($P = 0.869$) [94]. Within the caveats of the small and short-term studies presented CGM appears to afford the same benefits to diabetic CKD patients as to the general diabetic population [93, 95]. The analytical performance of two popular CGM devices for home use is summarized in Table 3.

The integration of smartphones with BP and glucose monitoring devices is particularly key in diabetes care. DiaFit is a smartphone app that allows integration and storage of diabetic patients' dietary intake, physical activity (via integration with a Fitbit; San Francisco, CA, USA), medication use, blood glucose values (via Bluetooth upload or manual entry) and general wellbeing [96]. The physician can view this information and communicate with the patient via the app. Although such an app represents no technological innovation, increased usability and effective integration of data can deliver significant benefits for patients. Similar innovative apps may prove vital to realizing the greatest gain from home testing pathways.

Anticoagulation monitoring

Anticoagulation is commonly required in CKD patients and anticoagulants are among the most prescribed drugs in this patient group [97]. However, despite the standard use of direct oral anticoagulants in the general population, the pharmacodynamic properties of these drugs limit their use in advanced CKD, with multiple guidelines suggesting warfarin to be the safest choice in patients with creatinine clearance <15 mL/min/1.73 m^2 [98]. As CKD and declining eGFR represent a paradoxical state of hypercoagulability with increased haemorrhagic risk, INR home monitoring with POCT devices represents an attractive prospect [99].

Compared with the other POCT device applications mentioned in this review, there is a relative wealth of data surrounding the use of home POCT in anticoagulation. There are a small number of INR monitors available for home use; however, the majority of the studies supporting use at home have been conducted with the CoaguCheck XS (Roche Diagnostics, Rotkreuz, Switzerland) (Table 3). The CoaguCheck XS (dimensions 138 × 78 × 28 mm; weight 127 g) provides amperometric determination of prothrombin time and INR using capillary blood in <1 min, with an INR measurement range of 0.8–8.0. Initial studies using CoaguCheck technology indicated excellent correlation with laboratory measures ($r = 0.95$, 85% consistency with laboratory method) (Table 3) [100] and a potential reduction in bleeding rates ($n = 128$; home monitoring versus usual care: incidence of bleeding at 3 months with home monitoring 15%, with usual care 36%; $P < 0.01$) [101]. A later RCT ($N = 2922$) suggested that there was no difference in the time to first event (stroke, major bleeding episode or death) between participants using home devices and those being monitored traditionally {hazard ratio 0.88 [95% confidence interval (CI) 0.75–1.04]; $P = 0.14$} [102]. It did, however, demonstrate a significant improvement in satisfaction with care and QoL in patients in the home monitoring group ($P = 0.002$ and $P < 0.001$, respectively), with these results ratified more recently [102, 103]. The Xprecia Stride (Siemens Healthineers; dimensions: 40 × 170 × 70 mm) is a pocket-sized device that functions in a similar fashion as the CoaguCheck XS, with an INR measurement range of 0.8–4.5. Studies have compared this device with both laboratory equipment (ACL TOP 700, Werfen, Milan, Italy) and the CoaguCheck XS and have demonstrated strong linear correlation between the device and laboratory and CoaguCheck systems ($r = 0.83$ and $r = 0.92$, respectively) (Table 3); however, device usability data and patient-related outcomes were not reported [57, 58].

The positive impact of coagulation home monitoring has been highlighted in a recent Cochrane review (28 RCTs, $N = 8950$); despite the low quality of evidence, improved QoL and a reduced rate of thromboembolic events was seen with home monitoring [104]. Sharma *et al.* [105] also performed a systematic review and economic evaluation on the use of these devices (26 RCTs, $N = 8763$), which despite clinical heterogeneity among the trials, indicated an improved time in therapeutic range (TTR) with self-testing [weighted MD 4.4% (95% CI 1.71–7.18); $P = 0.02$] and cost-effectiveness given the positive effect on thromboembolic event incidence [105]. Self-monitoring was also deemed to be cost-saving, with a reported net savings of £112 million in the NHS if 10% of the current 950 000 patients on vitamin K antagonists were to switch to home POC coagulation monitoring [106]. No studies specific to CKD have been carried out with the Xprecia Stride or CoaguCheck. The positive trends exhibited with home monitoring of anticoagulation via the use of POCT could reasonably be transferrable to the CKD population, but this remains to be proven.

CONCLUSION

CKD is a common and increasing health problem with high associated healthcare costs [26]. Remote home management,

made possible through eHealth pathways and suitable POCT devices, has great potential to improve health outcomes for these patients and help them understand their condition and engage more with their care [26]. Such pathways are highly in keeping with numerous steering committees' forward plans [3, 4]. Patient motivation is a key part of CKD management and eHealth has already shown itself to be an effective tool in CKD patients; however, the development of the POCT devices themselves has been the weak link in this innovation and has held back the development of increasingly integrated pathways [14]. Home self-testing using a POCT device is still in its infancy in all fields other than diabetes care, hypertension and anticoagulation monitoring; in haematology and electrolyte measurement few devices suitable for home use exist and evidence supporting their use is absent. However, where the devices are well-developed, evidence shows the benefits of their use both in terms of clinical and patient-centred outcomes. Patients' attitudes towards eHealth and home POCT are consistently positive and physicians also find this care highly acceptable [14, 26, 107]. POCT devices need to be valid, operate with minimal user involvement and be cost-effective [12]. New care pathways need to be created, utilizing eHealth, to maximize the benefit of such devices; these pathways must be safe, non-inferior and effectively integrated within the wider healthcare system. It seems prudent to incorporate patient smartphones into these care pathways due to the wealth of ICT they contain that can supplement, or even allow the phone to become, a POCT device. Such integration enables interventions to become scalable across socio-economic groups [96].

Currently there are few devices and little evidence to support the use of home POCT in CKD; regulatory and translational challenges loom large. Evidencing the benefits of these care pathways and the subsequent calculation of financial reimbursement is challenging. Pragmatic and adaptable trials of a hybrid effectiveness–implementation design, as well as continued technological POCT device advancement, are required to deliver these innovative new pathways that our patients desire and deserve [17, 25]. The need for this change has been greatly enhanced by the current COVID-19 pandemic.

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