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Can Point-of-Care Testing Outside the Hospital Improve Chronic Disease Management?

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Abstract

Objectives: To outline a paradigm shift in blood testing for monitoring chronic diseases from a hospital or central laboratory setting to a point-of-care setting. We sought to determine if this paradigm would align with the Institute for Healthcare Improvement's (IHI) "Triple Aim": the experience of care, population health, and cost.

Methods: We undertook a literature review of scientific articles which addressed the issues of feasibility, population health, patient satisfaction, provider satisfaction, and economic impact of implementing point-of-care testing (POCT) for chronic disease management.

Results/Conclusions: There are numerous examples of POCT being used for chronic disease management, including for kidney disease, cardiovascular disease, and diabetes, among others. POCT appears to satisfy the triple aim of the IHI in most situations. More widespread implementation of POCT should improve patient satisfaction, population health, and overall cost of care, in addition to improving provider satisfaction.

Introduction

There are increasing needs to shift routine testing for chronic disease management from traditional sites such as hospitals or stand-alone laboratories to locations such as clinics, pharmacies, and physician's offices. Benefits include lowering costs (without sacrificing quality) and improving patient access, thus improving compliance, patient satisfaction, and outcomes. Ample evidence now exists that point-of-care testing (POCT) using simple fingerstick capillary technology can be successfully utilized in both developed countries (e.g., USA, Spain, Netherlands, South Africa), and low- and middleincome countries (e.g., Nepal, Malawi, Bolivia), in outpatient settings such as pharmacies, clinics, and dental offices [1-7]. These studies show improved outcomes and/or lowered costs for patients with chronic diseases, especially chronic kidney disease and diabetes. They also help to provide access to testing in previously underserved communities and populations. Studies using POCT for chronic disease management are currently ongoing in pharmacies and clinics in the United Kingdom, Italy, Bermuda, and Egypt using the same fingerstick capillary blood technology [unpublished communications]. The concept of using POCT in pharmacies has been endorsed and encouraged by The National Community Pharmacists Association in the USA, International Pharmaceutical Federation (FIP) and the National Health Service in the United Kingdom [8-10]. The current paradigm of laboratory testing fosters a cycle of decreased compliance, ultimately leading to increased costs and morbidity. The use of POCT encourages improved compliance and therefore should lead to improved outcomes and decreased costs. In a cost-conscious healthcare environment, a new technology which decreases costs and improves outcomes for patients with chronic diseases is an ideal and increasingly rare scenario.

In 2007, the Institute for Healthcare Improvement (IHI) developed the "Triple Aim" as a framework to gauge healthcare system performance in both macro- and micro-environments and to better quantify new

interventions, such as a new drug, medical device, or treatment. They distilled this complex metric into 3 basic tenets:

- The experience of care—make sure patients are satisfied.
- Population health—keep the people in the system as healthy as possible.
- Per capita cost—keep it affordable.

Some have advocated for a fourth goal of provider satisfaction as well, the so called "Quadruple Aim", but this is not currently a formal position by the IHI. Although in an environment of increased provider workload and burnout, this additional goal certainly makes logical sense.

An alternative way of framing the statements above would be as questions to ask when evaluating a change in medical care, such as introducing a new device or drug, implementing a new payment scheme or screening program, etc.:

- Does it provide increased patient satisfaction?
- Does it improve the overall health of the community?
- Is it affordable?
- Is it acceptable to providers?

POCT for chronic disease management answers "yes" to all these questions.

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Chronic diseases such as diabetes, atherosclerotic cardiovascular disease (ASCVD), chronic kidney disease (CKD), and hypertension account for a significant number of physician visits and healthcare expenditure, in addition to considerable patient morbidity and mortality. ASCVD is by far the leading cause of mortality in the USA [11]. Diabetes and CKD are in the top 10 causes of mortality in the USA [11], and also cause significant morbidity and deterioration in quality of life. All 3 of these diseases are also prevalent throughout the world, and account for a large percentage of healthcare expenditure. These chronic diseases also have hidden costs due to decreases in productivity and time off from work that are difficult to quantify but nonetheless significant [12]. Although POCT is also being used for infectious diseases, this paper will focus mainly on non-communicable chronic diseases (NCD). In many countries with limited resources, NCD's are given less attention because of a focus on preventing and treating the more prevalent infectious diseases, and a low-cost, portable option could improve the care of these patients.

Barriers to Testing Outside Traditional Settings

Why doesn't something like this exist already? There are several likely reasons.

The biggest factor is that until relatively recently, technology has not existed to test capillary blood and provide simple to use tests for essential analytes in chronic disease management. At least one company has an extensive portfolio and experience with numerous analytes, which require just a fingerstick (capillary blood). The test menu of POC assays using a single drop of capillary blood includes HbA1c, lipids, creatinine, PT/INR, estimated glomerular filtration rate (eGFR), glucose, C-reactive protein (CRP), urine albumin, and electrolytes. This depth of expertise was initially focused on hospital testing and is being transitioned to outpatient testing for chronic diseases. Devices of this nature go through the same rigorous validation and accuracy studies that core laboratory analyzers do, thus the medical consumer (patients and providers) can be assured of a reliable and accurate result.

Another barrier is cost. Previously, if a provider wanted to set up laboratory testing in an outpatient setting, it would require expensive hospital analyzers, with trained laboratory staff to run the equipment and phlebotomists to draw blood, as well as infrastructure changes such as plumbing and hazardous waste disposal protocols. This is simply too cost-prohibitive for most clinics, pharmacies, or practices. The development of a Clinical Laboratory Improvement Amendments (CLIA)-waived, self-contained device which can be operated by someone without formal laboratory training is essential to bring testing outside traditional laboratory settings. Although some individual, single-test devices are available, no device with a broad test panel exists in the market today.

Regulatory hurdles such as College of American Pathologists (CAP) inspections, Quality Control (QC) and validation studies are another barrier. These processes are cumbersome, time consuming, and expensive. A putative POCT device should be able to perform QC validation simply.

Patient Satisfaction

Several studies show that patient satisfaction is improved with POCT [13-15]. Fast turnaround times, convenience, and a capillary blood sample likely contribute to this. Patient satisfaction and convenience go hand in hand with compliance, and better compliance leads to improved outcomes. In a study from Saudi Arabia after implementing POCT HbA1c testing in an endocrinology clinic at a major medical center,

patients responding to a standardized questionnaire had an overall satisfaction of 86.7%, with a median score of 9 out of 10 with the testing [13]. Additionally, compliance with testing increased and HbA1c levels decreased compared to before introduction of POCT [13]. A prospective study from Australia comparing POCT in general practitioners' offices in urban, rural, and remote areas compared with standard laboratory testing for anticoagulation, diabetes, and hyperlipidemia found that those in the POCT arm had higher satisfaction with the collection process and had increased confidence in the process [14]. They also found improved patient motivation in terms of being more engaged in their care and patients had an improved perception of their relationship with their provider [14]. In a US study performed in an urban medical center, it was found that after implementing POCT for electrolytes, HbA1c, and lipids, patient satisfaction averaged 3.96 out of 4 when asked "Compared with your past experiences of physician office visits that did not have on-site testing please rank your overall level of satisfaction with today's office visit" [15].

Thus, across a wide variety of settings—urban, rural, remote—and in clinics, hospital-based practices, and in provider's offices, POCT improves patient satisfaction. This also extends to in-home POCT [16], with increased exposure to POCT leading to increased support by patients. The authors of this survey found that use of in-home POCT "empowers patients and home caregivers to diagnose, manage, enhance their adherence to medical treatments, and more efficiently engage their physicians" [17].

Population Health

Population health is the area where POCT has the biggest potential to impact meaningful change. This can be influenced both by screening for common conditions (e.g., diabetes, hypercholesterolemia, CKD, etc.), chronic disease management, and monitoring of patients with known chronic disease (e.g., diabetes, CKD, cardiovascular disease). Patients with diabetes, CKD, ASCVD, and hypertension will especially benefit from this technology. This is particularly true for patients in remote areas where blood testing is costly or impractical and the increased availability of testing could lead to improved outcomes. A cost-modeling study from South Africa using real world data looked at POCT to monitor HIV patients receiving anti-retroviral treatment, testing for viral load, CD4 count, and creatinine. This intervention was projected to reduce HIV infection by 4.5% and deaths from HIV by 3.9% [17], in large part due to improved compliance with testing. It was also projected to be cost effective (more below).

1. Diabetes

In a cohort of diabetic patients, HbA1c levels improved after the initiation of POCT in an endocrinology clinic [13]. In this study, compliance with HbA1c testing recommendations increased from 24% prior to POCT to 85% after initiation of on-site POCT for HbA1c. Increased compliance and increased testing is also associated with reduction in HbA1c levels, as patients and providers get immediate feedback and can quickly see the results of healthy or unhealthy lifestyle choices, and providers can give immediate, face-to-face counseling. Improvement in HbA1c levels has also been seen in other studies looking at POCT in various settings [18,19]. It is well known that reduction in HbA1c reduces healthcare costs [20] by decreasing the risk of diabetic complications. In a large UK study following nearly 4000 type-2 diabetics for over 10 years, for every 1% reduction in HbA1c, the relative risk for diabetes-related deaths decreased by 21%, myocardial infarction and heart failure by 14%, and amputation or death due to peripheral vascular disease by 43% [21].

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2. Chronic Kidney Disease

Approximately 90% of people with kidney disease are undiagnosed [22]. Kidney disease is often termed the "silent killer" because it shows no symptoms until its very late stages when there are few options other than renal replacement therapy (RRT). Even with RRT, mortality of patients with end-stage kidney disease (ESKD) is as high as 50% at 5 years [23]. The American Diabetes Association (ADA) recommends yearly screening for CKD in people with diabetes [24]. Despite this, the current screening rate for CKD in these patients is as low as 35% [25,26]. A primary reason for this is underutilization of screening by health care professionals [25], potentially due to lack of availability of POCT, and patient-related factors such as the inconvenience of having to travel to another site or fear of having to undergo a venous blood draw. Readily available POCT to screen for CKD would allow for improved screening rates. Early identification of CKD is critically important now more than ever because of the availability of new medications which can slow its progression [27]. The burden of CKD in the US was recognized in a 2019 Executive Order, Advancing American Kidney Health, which aims to decrease the incidence of kidney failure using a multifaceted approach [23]. One important aspect is identifying and managing kidney disease in outpatient settings such as pharmacies [28].

Another important use for POCT in CKD is for medication management. Many medications are nephrotoxic, or are cleared by the kidneys, and require dose adjustment or discontinuation in patients with CKD. In one study using capillary creatinine testing in a group of Spanish pharmacies, roughly 20% of patients required a dosing change or discontinuation of a drug when they had their kidney function checked at the pharmacy [29]. A study in 351 community pharmacies in the Netherlands showed lower hospitalization rates and cost savings by screening for renal function in patients over 65 who were prescribed antibiotics [3].

In addition to blood testing for creatinine and estimated glomerular filtration rate (eGFR), screening for CKD should also include testing for the urine albumin: creatinine ratio (UACR). UACR is recommended by the Kidney Disease, Improving Global Outcomes (KDIGO) group in conjunction with eGFR in screening for CKD [1,30]. This component of CKD screening is often neglected but is a key component in CKD diagnosis.

3. Dyslipidemia

Dyslipidemia is the most important risk factor for ASCVD, along with family history. It causes no symptoms until ASCVD becomes apparent, which can take several decades. It is recommended that individuals be screened as children, both before and after puberty [31], as there can be inherited or congenital causes for increased lipid profiles. Screening and follow-up for dyslipidemia is recommended in adults every one to five years [31,32], and sometimes more frequently depending on severity and treatment. As with HbA1c in diabetes, both dietary and lifestyle changes as well as medication are used to treat dyslipidemia, and feedback may improve compliance leading to better outcomes. Although guidelines continue to evolve, in general "lower is better" in terms of total cholesterol and triglyceride levels, and the risk of a cardiac event increases by 1% with every 1% increase in cholesterol levels [32]. Testing for dyslipidemia remains a mainstay of assessing cardiovascular risk, and a real-time POCT lipid profile would allow for the provider and patient to have a real-time face-toface discussion about the results and initiate a treatment plan if there are abnormalities. It also allows for immediate feedback for patients with known dyslipidemia, so that the treatment plan can be modified as needed. This is more convenient for both the provider and the patient and is likely to lead to improved compliance and outcomes.

4. Other Conditions

In addition to the testing described above the ability also exists to measure PT/INR using POCT, which allows for anticoagulation monitoring. Measuring ketones is also feasible and can be useful for diabetics or those on ketogenic diets. Hemoglobin and hematocrit testing can be useful in several scenarios, as would be electrolyte testing. Uric acid testing for patients with gout, especially in patients on some of the newer agents can save multiple laboratory visits and facilitate treatment. Additional tests can be anticipated to be developed and added to the POCT platforms as time goes on.

5. Acute Care

In the acute care setting, C-reactive protein (CRP), an acute phase reactant, has been identified as a useful marker for inflammation and infection, and has been shown to be effective in clinical decision making in a variety of settings [33]. It seems to be particularly useful as a negative marker to rule out bacterial infections as there is a relatively low rate of false-negative results [33,34]. In a randomized study from the United Kingdom evaluating COPD patients presenting with an exacerbation to a primary care provider, the group that underwent POCT CRP testing had fewer prescriptions for antibiotics (57%) than the group that did not undergo CRP testing (77%) [35]. It has also been shown to be useful in the pediatric population in distinguishing serious bacterial infections from viral infection and other sources of inflammation [33,34,36]. As more experience is gained in outpatient POCT for CRP, it will likely allow for fewer hospital visits, decreased antibiotic use, and lower rates of ancillary testing.

Is It Cost Effective?

There have been numerous studies evaluating cost effectiveness of POCT in terms of overall healthcare savings. One recent systematic review [37] evaluated 44 studies worldwide where the majority of POCT (70%) were in primary care settings. Over 60% of the testing was for diagnostic purposes, with the remaining testing being evenly split between screening and monitoring. The study found POCT to have health economic benefits including early diagnosis, a decrease in the number of hospitalizations and referrals to specialized care, reduced antibiotic prescriptions, and a decrease in the burden and costs associated with referrals and additional testing. Those studies which incorporated a longer time horizon found that costs continued to decrease over time [37]. This is generally true in all settings: urban centers, rural centers, and in both wealthy and low- and middle-income countries [25-27]. Very few studies recommended against primary care practices adopting POCT, and cost-effectiveness was linked to following established guidelines [37].

A cost-modelling study looking at patients followed using POCT to monitor HIV treatment in South Africa found lower overall costs than those undergoing standard laboratory testing [18]. This study estimated that in a population of 175,000, POCT to monitor HIV treatment would save \$40-44 million over a 5-year period [18]. Although there are upfront capital costs, POCT can also be expected to be cost-effective on a smaller scale, such as an individual practice, because of the potential to bill for testing and capture revenue that would otherwise go elsewhere.

Chronic kidney disease accounts for a disproportionate financial burden to the healthcare system. Although in the US patients with ESKD make up fewer than 1% of the total Medicare population, they

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represent 7% of total Medicare spending, or over \$35 billion in 2016 [24,38]. This is in part due to the high costs associated with RRT and costs are expected to increase as CKD prevalence increases. Identifying and treating individuals at an earlier stage and preventing progression to ESKD would undoubtedly decrease these costs. As noted above, a study in 351 community pharmacies in the Netherlands showed overall cost savings by screening for renal function in patients over 65 who were prescribed antibiotics [3]. If this were expanded to testing for all nephrotoxic medications further savings could be expected.

Studies which have examined cost benefits for patients have shown that implementing POCT also lowered out of pocket costs for patients when considering co-pays and travel time [39].

Provider Satisfaction

Physician burnout is becoming an increasing reality and was recognized well before the COVID pandemic [40], which exacerbated the issue. POCT can streamline workflow and lessen the burdens on providers' time. Many of the strategies used to alleviate burnout and improve satisfaction revolve around workflow improvement [40], which is improved using POCT. It makes logical sense that provider satisfaction will improve with fewer impositions on a provider's time and being able to "close the loop" on a patient encounter in one sitting, rather than having pending lab results when a patient leaves the clinic.

Office or clinic-based testing can save providers and their staff significant time. Although this is a cost savings that is difficult to quantify, saving time and making care more efficient are obvious benefits for providers. One study which evaluated POCT in the emergency department found that POCT was able to achieve a 20% reduction in treatment time, or approximately 20-30 minutes per patient [41]. This timesaving can be translated to a primary care or specialty practice, when a provider may need to retrieve and review outside lab results, and then contact the patient to review them and discuss treatment plans. In a large urban academic medical center, implementation of POCT in the outpatient clinic resulted in an 89% decrease in follow-up phone calls, an 85% decrease in letters and emails sent to patients regarding test results, and a 62% decrease in follow-up visits for abnormal lab results [42]. This resulted in an estimated savings of roughly \$25 per patient visit [42]. Time and efficiency are also appreciated by patients, and not having to travel to a separate site for laboratory testing can be a significant benefit that cannot be understated.

In addition to increasing efficiency and saving time, providers may also benefit from a revenue stream by billing for POCT. Over time this would offset any capital cost associated with POCT.

Where can POCT be used?

Pharmacies

According to Sherif Guorgui, co-chair of FIP's Policy Committee on Point-of-Care Testing, "Providing health screening services through point-of-care tests has increased in importance with improved technologies, greater acceptance, and current global agendas such as the World Health Organization Declaration of Astana on Primary Health Care steering changes in practice. Moreover, we now have clear evidence for the benefits of pharmacy-based testing" [43]. Most patients with chronic diseases are frequent visitors to pharmacies. In addition, pharmacists are trained to counsel patients about medication, and to communicate with physicians about medications and other patient needs. Thus, a pharmacy is an ideal place where POCT can impact outcomes, which is borne out by data in patients with CKD. National

and international pharmacy organizations have endorsed POCT in community pharmacies and established guidelines for pharmacists who wish to perform these tests [9-11,29].

A program known as the Personalized-Medication Adherence and Persistence Program (P-MAPP) is a US based initiative which is the first all pharmacy-based program supported by representatives from multiple stakeholder groups including the FDA, prescribers, pharmacists, pharmaceutical companies, health insurers, professional organizations, medical device companies and academia [44,45]. This program is using POCT devices in pharmacies to monitor HbA1c, lipids, and renal function in patients with Type 2 diabetes. This large-scale study is in progress and results are not yet available.

Primary Care Clinics, Physicians' Offices

POCT has many aspects which can lead to increased patient and provider satisfaction: it is fast, with results typically being obtained in seconds or minutes; it can be performed on-site, without the need for a patient to go to a separate location; it can be performed using a capillary (fingerstick) sample, eliminating the need for venipuncture, and since the results are available immediately, patient-provider discussions can happen right on the spot. It can offer a comprehensive panel of tests, making phlebotomy or trips to the lab potentially unnecessary, leading to fewer follow-up visits or phone calls to review results, saving time and inconvenience [42]. Even in a large academic medical center with an on-site laboratory, patient satisfaction increased with the introduction of POCT [16]. These benefits would also particularly apply to remote or rural areas, where traveling to a lab might require a significant trip and time commitment.

Walk-In Clinics, Urgent Care Centers

These sites are, by their nature, ideally meant for minor illnesses or trauma and are less expensive than other alternatives such as emergency departments (ED). However, the lack of diagnostic testing such as POCT or x-ray sometimes makes transfers unavoidable, thereby increasing the cost of care and inconveniencing the patient [46]. A study from a large urban ED validates this, determining that most such transfers are unnecessary and some of these would have been avoidable with POCT [47].

Another benefit of a more robust walk-in clinic is shifting of care to less expensive locations. With better-equipped centers, the burden of unnecessary ED visits could be alleviated, and care could be given at more appropriate, and more cost-effective sites [46,48]. Thus, more widespread POCT adoption could ultimately lead to a reduction in overall health care costs.

Remote or Low-resource Settings

Patients who live in remote or rural areas face extra burdens to access than those who live in more populous, high-resource settings [49]. Even in developed countries, these remote areas exist, and many patients live hours away from laboratory facilities or hospitals, making routine testing extremely cumbersome. Infrastructure challenges also create obstacles for lab testing, with standard analyzers requiring significant support and trained technicians. POCT offers an ideal solution especially if it is CLIA-waived and therefore can be operated by an individual without formal laboratory training. Improving access, and by extension outcomes, will offer a significant benefit to these underserved areas. A pilot study conducted in conjunction with the International Society of Nephrology in Nepal, Bolivia, and Malawi found that POCT for kidney disease in these settings is feasible and

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increases detection rates [7]. Many of these remote areas have accessible health centers or have regular outreach programs which could perform POCT.

Ideal POCT device

The ideal POCT device would feature:

- Wi-Fi and/or Bluetooth connectivity with appropriate encryption to allow for data transfer to smart phone applications and electronic health records
- · A panel of tests for managing chronic diseases
- Expandability to allow for incorporation of future tests
- CLIA-waived testing and/or self-testing clearance
- Lower or equivalent cost to existing laboratory testing
- Comparable accuracy and precision compared to existing laboratory testing
- · Ability to carry out testing with a finger stick
- Minimal maintenance and calibration requirements, or automatic calibration
- The ability to work in austere environments
- Compact size

Self-Testing

A special case for POCT is self-testing. Capillary blood (fingerstick) testing lends itself to this by individuals at home. This is not a novel concept. Diabetics have used hand-held capillary blood testing devices for measuring glucose levels for the past 40 years. There is no reason, therefore, that other POC devices cannot be utilized for remote patient monitoring for both acute and chronic conditions. With proper education, a patient can reliably use these devices for other biomarkers such as creatinine, PT/INR, uric acid, hemoglobin, and hematocrit, amongst others which are now available. Self-testing offers many advantages over traditional hospital and laboratory testing:

- Flexibility of when and where to test at home, at work or while on vacation
- No travel time saving patients time, money, and inconvenience
- Privacy
- · Avoidance of contagious diseases at healthcare facilities
- Patient empowerment leading to improved compliance
- Patient ownership of their disease management
- Immediate feedback in unwell patients leading to earlier diagnosis (e.g., ketone measurement in diabetics)

A good example is management following kidney transplantation. Patients who receive a transplant are typically tested 1-3 times per week to monitor serum creatinine. Most of these testing visits can be replaced by a simple home creatinine test with real time results done at home [50,51]. These results can be immediately transmitted to the physician taking care of the patient. Capillary blood testing in this setting has already been shown to be accurate for daily trending of kidney function.

Furthermore, it is known that clinic nonattendance in the first year of kidney transplant results in worse outcomes in terms of eGFR and twice the risk of graft loss [52] whereas self-monitoring leads to a high

level of adherence [50,51]. Patients also report high levels of satisfaction with at home creatinine and blood pressure monitoring [53].

A similar case can be made for other diseases. Patients with gout can monitor their uric acid levels at home to determine if therapies are effective or need to be modified. Patients who are at risk from electrolyte imbalance whether from medications or hemodialysis, can monitor their potassium, sodium, calcium, etc. Appropriate modifications can be made while the patient is home averting the risk of an imbalance resulting in an ER visit. A diabetic patient can check for ketosis and potentially avoid a hospital visit or begin treatment earlier.

Conclusion

POCT satisfies all the principles of the IHI triple aim: it improves patient satisfaction and population health in a cost-effective manner. It also improves provider satisfaction by making care more efficient. Wider adoption of POCT should be encouraged by making implementation easier, and by regulatory and funding groups. It has the potential to improve management of chronic diseases and improve access to care in remote or austere environments. Technology which can accomplish improved outcomes at a lower cost without sacrificing quality should be facilitated and encouraged on a broad scale, and it is likely that doing so will shift care to less expensive, more user-friendly environments.

The COVID-19 pandemic has shown that moving testing and care to outside traditional settings is safe and effective, and generally acceptable to both patients and physicians. This is true across a wide spectrum of conditions and locations [54-59]. This momentum in shifting care to more convenient, less expensive locations should be encouraged and built upon.

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