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Which Point-of-Care Tests Would Be Most Beneficial to Add to Clinical Practice?

Findings From a Survey of 3 Family Medicine Clinics in the United States

Victoria Hardy, MSc,* William Alto, MD,† Gina A. Keppel, MPH,*‡
 Laura-Mae Baldwin, MD,*‡ and Matthew Thompson, MBChB*

Background: Point-of-care tests (POCTs) are increasingly used in family medicine to facilitate screening, diagnosis, monitoring, treatment, and referral decisions for a variety of conditions. Point-of-care tests that clinicians believe might be beneficial to add to clinical practice and the conditions for which they would be most useful in family medicine remain poorly understood in the United States.

Methods: Forty-two clinicians at 3 family medicine residency clinics completed a brief survey asking which POCTs they believed would be beneficial to add to their clinical practice and the conditions POCTs would be most useful for. We calculated frequencies of reported POCTs and conditions using descriptive statistics.

Results: Clinicians identified 34 POCTs that would be beneficial to add to family medicine, of which hemoglobin A_{1c}, chemistry panels, and human immunodeficiency virus and gonococcal and/or chlamydia were most frequently reported and anticipated would be used weekly. Clinicians reported 30 conditions for which they considered POCTs would be useful. Diabetes mellitus, sexually transmitted infections, and respiratory tract infections were the most often reported and were identified as benefiting diagnosis, monitoring, and treatment decisions.

Conclusions: Clinicians identified a number of POCTs they viewed as being beneficial to add to their routine clinical practice, mostly to inform diagnosis and treatment planning. Some POCTs identified are available in the United States; thus, understanding barriers to implementation of these POCTs in primary care settings is necessary to optimize adoption.

Key Words: CLIA waived, family medicine, point-of-care testing, primary care

(*Point of Care* 2017;16: 168–172)

From the *Department of Family Medicine, University of Washington; †Seattle Indian Health Board; and ‡Institute of Translational Health Sciences, Seattle, WA.

Reprints: Victoria Hardy, MSc, Department of Family Medicine Research Section, University of Washington, 4225 Roosevelt Way NE, Suite 308, Seattle, WA 98195-4696. E-mail: vhardy4@uw.edu.

This research was funded by the National Center for Advancing Translational Sciences of the National Institutes of Health under award UL1TR000423.

The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

M.T. has received funding from Alere Inc to conduct research on C-reactive protein point-of-care testing and has received funding from Roche Molecular Diagnostics for consultancy work. He is cofounder of Phoresa Inc, which is developing point-of-care tests. The other authors declare no conflict of interest.

This study was approved by the University of Washington Human Subjects Division (48541).

Data supporting the conclusions of this article are stored at the Department of Family Medicine, University of Washington, on the secure institutional server. Ethics restrictions prevent public sharing of the data.

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ISSN: 1533-029X

Point-of-care tests (POCTs) are currently used in family medicine settings for a number of reasons, including screening,¹ diagnosis,² monitoring disease,³ and guiding treatment decisions. Because the results of many POCTs are available within minutes (eg, hemoglobin A_{1c}, group A streptococcal antigen),⁴ clinicians are able to use them to make informed treatment decisions during the patient visit. Furthermore, obtaining test results in real time enables potentially serious conditions or deterioration of illnesses to be promptly identified in a “one-stop-shop” approach, averting adverse outcomes.⁵

The global market for POCTs is estimated to reach \$16.7 billion by 2018.⁶ Escalating market demand for POCTs reflects pressures exerted by rising prevalence of chronic diseases such as diabetes and an aging population (among others).⁷ Consequently, there is a need for more efficient alternatives to disease management, especially in primary care settings, which are constrained by increasing patient bottlenecks. Yet, despite commercial availability of a variety of POCTs, comparatively few have been adopted into routine clinical practice in most countries, including the United States.⁸ Research conducted in primary care settings in the United States suggests clinicians may not always be aware of existing POCTs for some conditions,⁹ contributing to slow adoption into clinical practice.

Clinical need is a powerful driver of innovation and also of decisions to adopt technology into practice.¹⁰ However, there is limited understanding regarding end-users' perceptions of the POCTs that would be most beneficial to add to clinical practice and the associated conditions for which they would be useful. Identifying the POCTs clinicians believe align with clinical priorities may accelerate translation of accredited POCTs into clinical practice. As part of a qualitative study exploring the barriers and facilitators to use of POCTs in family medicine, we conducted a survey to determine which existing or novel (ie, not yet developed) POCTs clinicians believed would be most beneficial to add to family medicine and the conditions for which they would be most useful. We report the findings from this survey.

MATERIALS AND METHODS

This anonymous survey was conducted at 3 family medicine residency clinics from 2 states; the methods are described in full elsewhere.¹¹ Clinicians (ie, family physicians, resident family physicians, nurse practitioners) participating in qualitative interviews at 3 clinics that are part of the Washington, Wyoming, Alaska, Montana, and Idaho Region Practice and Research Network were asked to complete a brief survey.

The survey asked respondents for demographic data (ie, job title, age, sex, year of completion of education/training for current job role, and years worked at the participating clinic) and to indicate up to 5 POCTs (that may or may not currently exist) they considered would be most beneficial to add to family medicine clinics, and how frequently they estimated they would use each POCT stated (ie, daily, weekly, monthly, yearly, or less). In addition, they were asked to indicate up to 5 conditions/illnesses for which POCTs

would be most useful for supporting clinical practice, along with the purpose(s) for which they were desired (ie, diagnosis, treatment, referral, monitoring, and other).

A total of 20 physicians, 20 resident physicians, and 3 nurse practitioners completed the survey; 1 physician did not complete the POCT “needs assessment” component of the survey and so was excluded from this analysis. The remaining 42 respondents were predominantly female (53%), had a mean age of 40 years, and had worked at their clinic for a mean of 5.5 years. Survey data were entered, coded, and analyzed in MS Excel, Microsoft Office Professional Plus 2013. Respondents were asked to check only 1 box for estimated frequency of use; where multiple selections were made, we used the more conservative frequency (eg, monthly, if both weekly and monthly were checked). Respondents could indicate multiple purposes for POCTs that would be useful for specific conditions/illnesses. Descriptive statistics were used to calculate the frequencies of POCTs reported, their estimated frequency of use, and the conditions for which POCTs would be beneficial (and their intended purpose/s).

This study was approved by the University of Washington Human Subjects Division (48541). Verbal informed consent was obtained from all participants who presented to scheduled focus groups/interviews after they had read the participant information sheet. Consent was obtained by the interviewer prior to commencement of any of the described study procedures.

RESULTS

POCTs That Clinicians Considered to Be Most Beneficial to Add to Family Medicine

The 42 respondents reported a total of 34 different POCTs that they believed would be most beneficial to add to clinical practice (Table 1). Of a total of 148 responses, the 5 most frequently reported POCTs were hemoglobin A_{1c} (16.9%), electrolytes or basic metabolic panels (10.1%), human immunodeficiency virus (HIV) and gonococcal and/or chlamydia infection (GC/chlamydia) (9.4%), albumin-creatinine ratio (6.1%), and urine drug testing (5.4%). Overall, most respondents anticipated they would use the listed POCTs on a weekly basis (34.5%), followed by daily (30.4%), monthly (23.6%), or yearly or less (4.7%). Of the top 5 POCTs reported, respondents anticipated that they would predominantly use them daily. Respondents reported 3 POCTs that are currently not commercially available (to the authors' knowledge), including tests for pain levels, attention-deficit/hyperactivity disorder, depression, and one (ultrasound) that is not a POCT in the way the question was asked.

Types of Conditions for Which Clinicians Reported POCTs Would Be Most Useful in Family Medicine

Respondents identified 30 different conditions for which they believed POCTs would be most useful. Of a total of 348 responses, the 5 most frequently reported conditions were diabetes (18.4%), upper and lower respiratory tract infections (RTIs) (12.6%), sexually transmitted infections (STIs) (7.2%), heart failure (6.9%), and anemia (5.5%) (Table 2). Overall, respondents most wanted POCTs to facilitate diagnosis (41.1%), followed by informing treatment (31.9%), monitoring (19.3%), and making referral decisions (5.2%). For some conditions, most notably diabetes, RTIs, and STIs, POCTs were identified as being beneficial for a mixture of purposes, namely, to direct diagnosis, monitoring, and treatment for diabetes and to facilitate diagnosis and treatment decisions for RTIs and STIs.

DISCUSSION

Clinicians identified a wide range of POCTs that they believed would be beneficial to add to family medicine. Although some of the POCTs clinicians reported have market approval for use in primary care, not all have been Clinical Laboratory Improvement Amendments (CLIA) waived by the US Food and Drug Administration (eg, GC/chlamydia, C-reactive protein [CRP], procalcitonin), and so patients in the United States are currently sent for testing in on-site clinic laboratories or at hospital or commercial laboratories (depending on clinic facilities). Hemoglobin A_{1c} was the most frequently reported POCT, which corresponded with diabetes being the most frequently reported condition for which a POCT would be useful. Clinicians reported wanting to add a POCT for the purposes of diagnosis, monitoring, and treatment of diabetes and also estimated that they would use the HbA_{1c} POCT on a daily basis. These findings suggest that diabetes (and its associated conditions) may be a priority area for improved diagnostic initiatives in family medicine. The rising prevalence of diabetes is a growing concern nationally (as well as globally) and is estimated to increase in the United States among adults between 20 and 79 years old from 26,814 in 2010 to 35,958 by 2030,¹² with most of the burden of clinical management likely placed on primary care services. Furthermore, the initial assessment of diabetes often requires at least 2 office visits¹³; a blood sample is typically taken during the first visit not only for diagnostic confirmation but also to identify related conditions such as abnormal lipid profiles or renal impairment. Confirmatory tests and results are then discussed in a follow-up appointment. Therefore, having tests that could decrease the number of required clinician-patient visits without compromising therapeutic management could be beneficial to patients and primary care clinicians.

As POCTs for hemoglobin A_{1c} have been readily available for use as a CLIA-waived test in US primary care settings for about a decade,^{14,15} the fact that this test was most frequently reported as being beneficial to add to practice is surprising. This finding could imply variability in adoption or use of this test at the point of care, but given that we did not ask clinicians to list the POCTs that were available or in use at their clinic we are unable to draw conclusions. An international cross-sectional survey of clinicians' current use of POCTs revealed that hemoglobin A_{1c} was used as a POCT by only 40% of a representative sample of US primary care clinicians.¹⁶ The fact that POCTs for HbA_{1c} are not widely used in family medicine might reflect clinician uncertainty regarding the accuracy of HbA_{1c} for diagnosing diabetes compared with standard methods (ie, fasting blood glucose) or lack of confidence in the accuracy of hemoglobin A_{1c} POCTs compared with laboratory-based hemoglobin A_{1c} tests. Indeed, concerns about the variability of POCT hemoglobin A_{1c} results compared with laboratory measurements have been reported in both qualitative¹¹ and diagnostic accuracy studies.¹³

Clinicians identified RTIs as a condition for which POCTs would be useful, but did not report as beneficial the existing POCTs for RTIs, such as the biomarkers CRP and procalcitonin. This mismatch suggests lack of awareness of these tests as implied in previous research⁹ and/or poor confidence in their usefulness, which in addition could be compounded by the fact that neither POCT for CRP nor that for procalcitonin is CLIA waived,¹⁷ necessitating the somewhat inconvenient process of having patients leave the doctors' office to visit on-site/external laboratories and then check back in with the clinician either immediately afterward or at a later visit.^{9,18} It is possible that clinicians were aware of some of the limitations of CRP and procalcitonin for the work-up of RTIs. For example, procalcitonin is reported as more specific for bacterial infections,¹⁹ whereas CRP has better sensitivity but is less specific

TABLE 1. POCTs Considered Beneficial to Add to Family Medicine Clinics

POCTs	Frequency of Reported POCTs, n (%)	Frequency of Anticipated Use of POCTs				
		Daily, n	Weekly, n	Monthly, n	Yearly or Less Frequent, n	Not Specified, n
Hemoglobin A _{1c}	25 (16.9)	11	10	2	1	1
Chemistry panels (5- or 8-test panel)	15 (10.1)	7	7	—	—	1
HIV and GC/chlamydia	14 (9.4)	3	3	3	3	2
Albumin-creatinine ratio	9 (6.1)	3	2	3	—	1
Urine drug screen	8 (5.4)	—	5	3	—	—
Lipids	6 (4.1)	3	1	1	—	1
Thyroid-stimulating hormone	6 (4.1)	2	3	—	1	—
Brain natriuretic peptide	6 (4.1)	1	2	3	—	—
Troponin and MI/ACS	6 (4.1)	—	2	4	—	—
CRP	5 (3.4)	—	3	2	—	—
Pathogen panel	5 (3.4)	2	2	—	—	1
Complete blood count	5 (3.4)	3	1	1	—	—
Lactate	4 (2.7)	—	3	1	—	—
Group A streptococcal antigen	3 (2)	—	1	1	—	1
Respiratory syncytial virus	3 (2)	2	—	1	—	—
Bilirubin	3 (2)	—	1	2	—	—
Hemoglobin	2 (1.4)	1	1	—	—	—
Prothrombin time/international normalized ratio	2 (1.4)	1	1	—	—	—
More comprehensive chemistry panel, including LFTs	2 (1.4)	2	—	—	—	—
Test for pain levels*	2 (1.4)	2	—	—	—	—
Uric acid	2 (1.4)	1	1	—	—	—
D-Dimer	1 (0.7)	—	—	—	—	1
Venous blood gas	1 (0.7)	—	—	1	—	—
Blood cultures	1 (0.7)	—	—	1	—	—
Procalcitonin	1 (0.7)	—	—	1	—	—
Rapid influenza	1 (0.7)	—	—	1	—	—
Pertussis	1 (0.7)	—	1	—	—	—
Rhinovirus	1 (0.7)	—	—	1	—	—
Test for depression*	1 (0.7)	—	—	—	—	1
Test for ultrasound*	1 (0.7)	1	—	—	—	—
Anticyclic citrullinated peptide	1 (0.7)	—	—	1	—	—
AmniSure Rupture of Membrane Test (2017 QIAGEN Sciences, LLC, Germantown, MD)	1 (0.7)	—	—	—	1	—
Fetal fibronectin	1 (0.7)	—	—	—	1	—
Test for attention-deficit/hyperactivity disorder*	1 (0.7)	—	—	1	—	—
Total responses	148	45	51	35	7	10

*Tests may not currently be available as point-of-care technology.

ACS indicates acute coronary syndrome; LFTs, liver function tests; MI, myocardial infarction.

and may yield false-positive results in some patient populations (eg, those with inflammatory comorbidities). Respiratory tract infections are among the most frequently encountered conditions in US primary care,²⁰ but effective management remains constrained by the inability to determine viral or bacterial etiology with sufficient certainty²¹ using clinical signs and is only moderately enhanced with available POCTs.²² This has challenged clinicians, researchers, and innovators alike globally for decades and represents one of the primary areas for innovation, as reflected in the recently announced \$10 million Longitude Prize to fund a diagnostic test that can be used globally, to improve the targeting of antibiotics for RTIs.²³

Interest in POCTs for STIs may reflect a need to fulfill not only routine screening recommendations (eg, chlamydia), but also the frequent need to test for diagnostic purposes or reassurance.

Almost all STIs require samples to be sent from family practice offices to laboratories, as none of the current POCTs for STIs are accurate enough for routine use. Furthermore, POCTs for STIs might facilitate immediate treatment of a population who can often be difficult to contact and may be unwilling to return to clinic for treatment of an asymptomatic condition.

Although most POCTs that respondents reported would be beneficial to primary care are commercially available within the United States, POCTs to diagnose or monitor pain, attention-deficit/hyperactivity disorder, and depression, to the authors' knowledge, currently do not exist. Although POCTs for these conditions were infrequently reported in this study, the fact that they were mentioned may reflect the pressures of managing complex biopsychosocial conditions (often requiring multidisciplinary

TABLE 2. Type of Conditions for Which POCTs Would Be Most Useful in Family Medicine

Types of Condition(s)	Frequency of Responses, n (%)	Frequency of Reported Purpose(s) of POCTs					
		Diagnosis, n	Monitoring, n	Referral, n	Treatment, n	Other, n	Not Reported, n
Diabetes mellitus	64 (18.4)	23	22	1	18	—	—
RTIs	44 (12.6)	23	2	1	18	—	—
STIs (including GC/chlamydia, HIV)	25 (7.2)	13	—	—	11	—	1
Heart failure	24 (6.9)	8	8	1	7	—	—
Anemia	19 (5.5)	6	6	1	5	1	—
Kidney function/failure/disease	17 (4.9)	5	4	2	5	—	1
Pregnancy	16 (4.6)	10	2	—	3	1	—
Nonspecific infections	16 (4.6)	9	1	—	5	—	1
Depression/mood disorders	11 (3.7)	3	2	3	3	—	—
Ischemia (myocardial infarction, stroke)	10 (2.9)	7	—	1	2	—	—
Electrolyte imbalances	10 (2.9)	5	1	—	4	—	—
Lipids	10 (2.9)	3	2	—	3	—	2
Serum drug levels	9 (2.6)	2	4	1	2	—	—
Hypothyroidism	8 (2.3)	2	4	—	2	—	—
Methicillin-resistant <i>Staphylococcus aureus</i>	8 (2.3)	4	—	—	4	—	—
Sepsis	7 (2)	3	—	2	2	—	—
Coagulation disorders	7 (2)	—	3	—	4	—	—
Nonspecific pain	7 (2)	1	2	2	2	—	—
Attention-deficit/hyperactivity disorder	5 (1.4)	3	—	1	1	—	—
Abdominal pain	5 (1.4)	2	1	1	1	—	—
Headache	4 (1.1)	1	1	1	1	—	—
Liver disease	3 (0.9)	2	—	—	1	—	—
Vitamin D deficiency	3 (0.9)	1	1	—	1	—	—
Deep vein thrombosis	2 (0.6)	1	—	—	1	—	—
Skin cancer	2 (0.6)	1	—	—	1	—	—
Rheumatoid arthritis, lupus	2 (0.6)	1	—	—	1	—	—
Urinary tract infection	2 (0.6)	1	—	—	—	—	1
Malaria	1 (0.3)	1	—	—	—	—	—
Vaginal discharge	1 (0.3)	1	—	—	—	—	—
Obesity	1 (0.3)	—	—	—	1	—	—
Total responses	348	143	67	18	111	2	7

input) in primary care.²⁴ In addition, because the medications used to manage these conditions can be associated with significant adverse patient outcomes (eg, addiction, overdose, and diversion),²⁵ it is not surprising that some respondents reported that objective tests for diagnosing and monitoring these conditions would be beneficial.

STRENGTHS AND WEAKNESSES

Our survey asked clinicians to report on both the types of POCTs they would like to include in clinical practice and the target conditions, which allowed responses to be compared for consistency. Capturing how frequently clinicians anticipate using POCTs along with the purposes for which tests were desired provides some indication for researchers, industry, regulators, and policy makers of the potential value of specified POCTs to clinical practice and indicates priority areas that may benefit from future technological innovation. A weakness of this study is its small sample size, which reduces generalizability of results, including to other primary care settings (eg, urgent care, pharmacy-based clinics) in the United States and limits our ability to draw firm conclusions. Although we collected clinicians' opinions related to implementing POCTs in family medicine in the qualitative aspect of

the study, we did not explore the barriers and facilitators to use of each POCT mentioned, which might otherwise have contextualized clinicians' beliefs regarding the POCTs/conditions they reported.

CONCLUSIONS

Agreement between clinicians' responses for POCTs they believed would be beneficial to add to practice and conditions for which POCTs would be useful identified hemoglobin A_{1c} for diabetes and HIV and GC/chlamydia for STIs as the most desired POCTs. Diabetes, STIs, and RTIs were highlighted as potential priority areas for POCTs. Understanding reasons for the variability in implementation of available tests (eg, HbA_{1c}) and inconsistencies in POCT adoption within primary care in different countries (eg, CRP) would be valuable in order to optimize adoption.

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