

Impact of Point-of-Care Diagnostics on Clinical Decision-making in Low- and Middle-Income Countries

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Background: Rapid tests have transformed the landscape of available tools for clinicians caring for patients who are critically ill. Their emergence as part of routine care increases the capacity for similar devices to reverse or minimize major epidemics and assist healthcare providers in their clinical decision-making. To assess how a point-of-care complete blood count (CBC) could change patterns in clinical decision-making, we presented low and middle income (LMIC) healthcare providers with hypothetical clinical scenarios to understand how such a device could impact the way they treat and refer patients.

Methods: Our survey asked about current use of CBC results, and then presented three separate scenarios that occur in LMICs. Survey respondents were queried about how they might change hospitalization plans and/or mediations based on point-of-care CBC results.

Results: In all three scenarios, a majority of clinicians were likely to modify the way they triage patients based on real-time results.

Conclusion: Our survey demonstrates that a point-of-care CBC diagnostic could change the way providers in resource-limited settings treat and refer critically ill patients. All hypothetical clinical scenarios describe common, urgent case presentations that can occur at any level of a health system in resource-limited settings. Rapid, simple and accessible technology for basic lab tests like CBC could impact patient care in low and middle-income countries by providing health care workers with actionable data with the potential to affect patient-centered outcomes.

IMPACT STATEMENT

Access to high quality diagnostics tests can reduce disease transmission and death. We surveyed health-care providers with hypothetical clinical scenarios to understand how a novel diagnostic could change how they evaluate patients. Results indicate that a point-of-care blood test could help triage patients and potentially reduce antibiotic use for viral infections.

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⁴ **Nonstandard abbreviations:** CBC, complete blood count; WBC, white blood cell; LMIC, low- and middle-income countries.

Rapid tests have transformed the landscape of available tools for clinicians caring for patients with infectious diseases such as malaria, syphilis, and tuberculosis (1, 2). Their emergence as part of routine care increases the capacity for similar devices to reverse or minimize major epidemics and assist healthcare providers in their clinical decision-making. In support of such advances, which are disease- or pathogen-specific, basic laboratory tests are also undergoing accessible innovation. The recent CLIA-waived approval of the Sysmex XW-100 allows for the rapid enumeration of a complete blood count (CBC)⁴ without a laboratory or qualified technician. The current Food and Drug Administration approval allows the XW-100 to be used in healthcare settings in the US for diagnosing and monitoring patients who are >2 years of age and are not oncology patients or chronically or critically ill (3). The HemoCue™ is an even more rapid point-of-care device that provides real-time hemoglobin and white blood cell (WBC) counts. Both tests facilitate a care continuum through which results are made available during patient-provider interactions (4). Additionally, a review of preliminary studies on host biomarkers, like C-reactive protein for acute febrile illness, concluded that research funding should focus on point-of-care diagnostics that can be deployed at the “lowest level of the healthcare system” (5, 6). To assess how a point-of-care CBC could change patterns in clinical decision-making, we presented healthcare providers in low- and middle-income countries (LMICs) with hypothetical clinical scenarios to understand how such a device could change the way they treat and refer patients.

Our survey asked about current use of CBC results in their practices, presented 3 separate scenarios that occur in LMICs, and then queried the survey respondents about how they might change hospitalization and/or mediations based on point-of-care CBC results. The Johns Hopkins Institutional Review Board acknowledged this survey as nonhuman subject research. We distributed the

survey to e-mail networks of Asian and African healthcare professionals who were affiliated with our Fogarty International Center capacity-building programs, and out of approximately 200 contact e-mails, 110 clinicians from Uganda, Malawi, Kenya, South Africa, Mozambique, Nigeria, Ghana, the Gambia, India, and Nepal responded. Ninety-three completed the survey, and only those results are described (responses were not required for every question, so denominators vary).

All respondents were from LMICs, were primarily public physicians or clinicians (78%; n = 75), and have a heavy patient load, with 51% (n = 50) seeing >50 patients per day. Forty-seven respondents could identify the current CBC analyzer used in their hospital or clinic, and reported that CBC results are most often ordered for patients suspected to have anemia (25%; n = 88), fever (24%; n = 83), and myelosuppression (16%; n = 57), out of 305 check-all-that-apply responses. Nearly identical conditions were checked by care providers for situations critical for CBC results [anemia (25%; n = 88), fever (24%; n = 83), and myelosuppression (16%; n = 57)]. In addition to these conditions, CBCs were noted to be important for pregnancy (15%; n = 46) and trauma (13%; n = 38) cases.

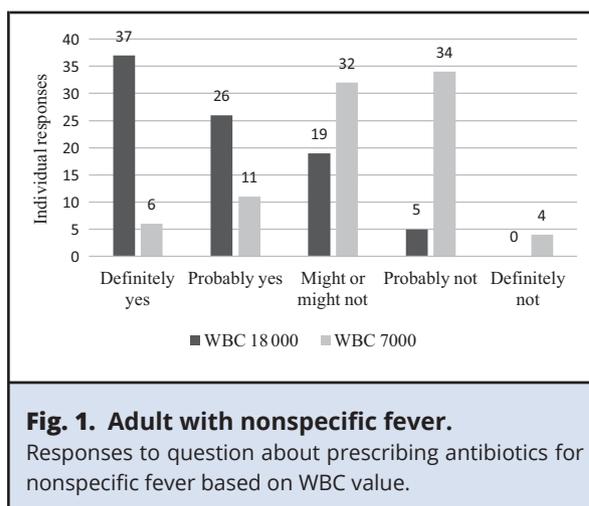
Scenario A presented a 22-year-old pregnant woman with fatigue and weakness at 37 weeks of gestation. Further 89% (n = 78) of care providers said they would definitely or probably order a CBC if the patient had reported without CBC results. We then asked whether a point-of-care device providing a real-time hemoglobin result of 9.5 g/dL would change their treatment plans. In total, 73% (n = 58) said “definitely yes” or “probably yes.”

Scenario B presented a 4-year-old child with malaria who appears to be stable. In total, 75% (n = 56) of care providers said they would definitely or probably order a CBC after consultation. Without any CBC results, 30% (n = 26) of care providers said they would definitely or probably refer the patient to the hospital for care. However, when real-time hemoglobin results of 7.0 g/dL were made available, 91%

(n = 80) said this would definitely or probably change their plan for hospitalization—a result that was statistically significant ($P = 0.00$) using Wilcoxon Signed Rank testing.

Finally, to evaluate how real-time CBC results could change prescription of antibiotics, scenario C presented an adult with nonspecific fever. With clinical examination not indicating focal signs or a specific diagnosis, 95% (n = 83) said they would definitely or probably order a CBC after consultation. We asked whether a real-time WBC count of 18000 cells/mL would cause the providers to prescribe antibiotics on the basis of that result, with 72% (n = 63) answering definitely or probably yes. We then asked whether a real-time result of 7000 cells/mL would cause the providers to prescribe antibiotics based on that result; in this situation, only 20% (n = 17) said definitely or probably yes, a significant difference ($P = 0.00$) (Fig. 1).

CBCs are a fundamental component of clinical care in LMICs. The results of our survey demonstrate that a point-of-care CBC diagnostic tool could change the way providers in resource-limited settings treat and refer critically ill patients. All 3 hypothetical clinical scenarios describe common, urgent case presentations that can occur at any level of a health system in resource-limited settings. Although these survey results are meant to represent the impact of point-of-care CBCs on clinical care, our findings may not be generalizable to low-burden, private-care settings. We also framed our questions to provide starkly



different scenarios with polarized results, whereas real-life situations may present a more complicated clinical picture. The extreme CBC values detailed in the clinical scenarios may have led our survey respondents to quantify what could be assumed as obvious changes in treatment and referral plans. However, documenting the potential impact of a point-of-care CBC in settings that largely rely on tertiary laboratories for results can be used as evidence to further advocate for research funding and access at the “lowest level” of care. In conclusion, rapid, simple, and accessible technology for basic laboratory tests like CBCs could impact patient care in LMICs by providing healthcare workers with actionable data with the potential to affect patient-centered outcomes.

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