Diagnostic Safety Worldwide

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Diagnostic error is a global issue. Recognized as a problem in different cultures around the world,\(^1\)\(^4\) it is a concern in settings that vary dramatically in terms of economic, physical, and workforce resources.\(^5\)\(^8\) Despite that variety, diagnostic error (like medical error in general) is most often studied and addressed in settings that enjoy good healthcare resources, stable economies, and modern technologies. Researchers, government agencies, non-profit groups, international aid organizations, and digital communities are beginning to explore diagnostic error and apply both traditional and innovative solutions to the problem in all settings.

The first challenge is to identify and understand diagnostic error in low-resource or challenging settings. Some studies that appear to examine patient safety in low- and middle-income countries (LMIC) don’t reflect typical conditions in those communities. For example, the World Health Organization (WHO) examined patient safety in LMIC in 2 separate studies. One measured preventable harm in hospitals in “developing and transitional economies” across 8 countries in Africa and the Eastern Mediterranean\(^1\) and the other, in 5 countries in Latin America.\(^4\) The research, which was based on chart review, is useful and relevant to patient safety but, as observed by Médecins San Frontières (MSF; Doctors Without Borders), the results may not actually reveal much about medical error in delivery settings that authentically represent the range of conditions in those countries:

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New Initiative Launched: ACT for Better Diagnosis\(^\text{TM}\)

On September 13, 2018, ACT for Better Diagnosis was launched at an event at the National Press Club in Washington, DC. ACT for Better Diagnosis is an initiative of the Society to Improve Diagnosis in Medicine (SIDM) and the Coalition to Improve Diagnosis. It aims to improve the diagnostic process by calling on organizations to identify and spread practical steps to better ensure diagnoses are Accurate, Communicated, and Timely.

The name, ACT for Better Diagnosis, was built out of the National Academy of Medicine’s (formerly the Institute of Medicine) definition of diagnostic error as the failure:

- to establish an accurate and timely explanation of the patient’s health problem(s) or
- to communicate that explanation to the patient.

Representatives from the Coalition, representing more than 40 healthcare and patient advocacy organizations, attended the event. Paul Epner, chief executive officer and co-founder of SIDM, made opening remarks, which were followed by a heartbreaking story from Michael Night about his son’s stroke misdiagnosis. Representing the Agency for Healthcare Research and Quality (AHRQ), Gopal Khanna spoke about the importance of working together to achieve more accurate and timely diagnoses.

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The samples in both studies include mainly large teaching and urban hospitals and therefore are not likely representative of hospitals in low resourced… or humanitarian settings.5(10)

A few studies of patient safety, including diagnostic error, have been performed in settings where care is provided to citizens during wartime, political upheaval, humanitarian crisis, or in areas where natural disasters have occurred.5,7 Other studies have examined safety and quality across broad demographics and also found that addressing diagnostic error should be a priority.2,6 In a drive to encourage universal health coverage, WHO, World Bank, and the Organisation for Economic Co-operation and Development point out that all people deserve not only access to healthcare, but access to high-quality care, including diagnosis.5 A report published recently by the National Academy of Sciences, Engineering, and Medicine agrees.9

WHO has initiated or been involved in many of the studies that include low-, middle-, and high-income countries. In 2012, WHO convened a panel of experts in patient safety to study the extent of iatrogenic harm in primary care across LMICs.6 Formation of this panel demonstrated the challenge of assembling a truly representative group. Despite making broad representation a priority, high-income countries were over-represented. Nevertheless, some of the findings were reported by income group, with awareness that experience and priorities vary according to demographics. In results reported by income level, diagnostic error is more prominent in the high-income group. Counterfeit drugs and lack of clinical training and skills were named as the top causes of harm in the low-income group. Wrong or missed diagnoses appear as important causes of harm in the overall results.1

Many conditions that countries, organizations, and providers face in difficult settings complicate the process of diagnosis and make safe care harder to deliver. In addition to population-wide problems related to clean water, nutritious food, adequate supplies, and reliable housing, challenges can include access to care, shortage of trained caregivers, severity/complexity of injuries, language barriers, and lack of appropriate facilities.1,8

How do these circumstances contribute to diagnostic error in developing countries? Diagnostic safety work originated and is chiefly pursued in high-resource communities. Can the same research and improvement methods be applied to less developed, less resourced communities? How can care providers working in under-resourced communities best address diagnostic safety? Which tools will be most helpful?

Applying safety practices in challenging settings: A case study

In a study published in 2015, Medecins San Frontieres shows how patient safety tools and principles can be applied in challenging settings, with differences and similarities to safety work in more stable circumstances. In 2010, an MSF operational center in Amsterdam established an incident reporting system for its medical programs, motivated by two factors: a general desire to improve quality by applying safety science to ongoing initiatives and a pattern of complaints from patients who had suffered harm.5 According to a freelance journalist writing in June 2018, this study distinguishes MSF as the only international aid organization to have published results from an error reporting system.7

MSF developed its reporting system to be consistent with those used in healthcare settings that do not face the kinds of challenges MSF faces. It used the National Academy of Medicine’s definition of medical error and typology for error classification.10 Reports, which were sent to headquarters by email, did not identify involved parties by name but did request information about their role, ie, physician, pharmacist, etc. Follow up was done as necessary to clarify what had happened and why. Medical coordinators in the field were trained to perform root cause analysis. After reports were analyzed, field teams were sent feedback and suggestions for remedial action. Implementation of the program included disseminating tools and information drawn from the WHO’s patient safety program (http://www.who.int/patientsafety/en/), including guidance for disclosing errors to patients and families. New staff members were trained in the reporting system, and standard management training included modules on patient safety and error reporting. MSF further supported the program through its newsletters.
Stories and lessons learned were shared regularly and directly with staff members in the field.5

MSF implemented the error-reporting program in crisis points throughout the world, disseminating it to all field programs active between June 2010 and May 2013, an average of 20 concurrent programs at any one time, operational in 19-23 countries, with a diverse mix of settings and circumstances. During the 3-year study period, 179 errors were reported from 38 projects in 18 countries. Dispensing errors were most prevalent (34.6%), followed next by errors or delay in diagnosis (13.4%). Errors caused harm or death in 62.6% of the reported cases. MSF acknowledges that these reports do not represent accurate error rates, probably to an even larger degree than is true for error reporting in high-resource settings.5

The program faced many challenges, including some related to the difficult circumstances in which these programs deliver care, as well as barriers encountered in safer, highly resourced settings. In addition to concern that reporting errors may increase exposure to legal liability, management and field staff members feared that host countries would retaliate against programs that admitted to making mistakes, which had happened to at least one program prior to the study.5

MSF was also aware it needed to support staff members who experienced emotional fallout following medical errors and anxiety related to reporting. The desire to help people, which motivates most healthcare workers, had an additional dimension for some MSF caregivers, who felt increased responsibility caring for people who were already in crisis.5

Next steps

If awareness is the first step toward improvement, there are hopeful signs for patient safety and diagnostic improvement becoming priorities in LMICs and areas under siege from conflict or natural disasters. The following actions, tools and programs represent progress and demonstrate the breadth of problems that need to be addressed.

To improve patient safety in crisis response, the WHO has developed minimum standards for foreign medical teams deployed to low-and middle-income countries in response to “sudden onset disasters.”11 Launched in 2015, the program had certified 15 programs and has 80 more under review, as of June 2018. Among other requirements, the teams must report unexpected deaths and adverse events to local authorities and the WHO.

Recognizing the crucial role of testing in diagnosis across all settings, WHO issued a list of “essential” in vitro diagnostics in May 2018.12 The list includes recommendations that entities may apply according to each community’s needs and abilities and is divided into different tiers. The recommendations are described in detail for 2 levels of service: primary care settings without little or no access to laboratory services and laboratory-based facilities.

Clinical decision support for diagnosis, such as symptom checkers and tools for building differential diagnoses, are available to clinicians and patients regardless of setting or level of resources. Increasingly, access to the internet represents the beginning of access to care.

A virtual community for diagnosis

With a vision of being available “to every person on earth,”13(np) the non-profit Human Diagnosis Project (Human Dx) has been developing a virtual community of physicians and other experts in diagnosis and treatment. Beginning with human intelligence in the form of responses to clinical cases and adding machine learning and data, Human Dx offers educational activities to medical students and consultation to practicing physicians across the globe. Anyone can join Human Dx for free and solve cases online. The Human Dx system analyzes the quality of the reasoning and results of each participant, case by case. It develops a personal score for everyone over time to determine each person’s level of expertise. Most but not all contributors are physicians. Shantanu Nundy, MD, director of Human Dx, explains:

We understand where you have strengths and weaknesses,… We can have people in other countries where there aren’t board scores and certifications, and we could even have patients – particularly around elements of their conditions that they understand best, like self-management of IBD (inflammatory bowel disease).13(np)

Human Dx is meant to be helpful regardless of the user’s resources. The 2-year-old project is currently used most often in medical education, but Nundy and his colleagues anticipate Human Dx will provide consultation for primary care physicians practicing in communities where resources are constrained, including
The Society to Improve Diagnosis in Medicine recognizes corporate members and organizations that support the society and its mission of attaining better outcomes through better diagnosis.

Corporate Members

**Gold**
- Teladoc Health
- Coverys

**Bronze**
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- CRICO
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- ProAssurance

**Silver**
- Isabel Healthcare
- Medical Interactive Community
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- MCIC Vermont
- Press Ganey
- SYSMEX America

Health Institution/Nonprofit Organization

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- Permanente Medicine—The Permanente Federation, Kaiser Permanente

**Supporter**
- AcademyHealth

**Member**
- University of Florida College of Medicine

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Many settings in the United States. Nundy, for example, when not working on Human Dx, practices primary care at a federally qualified health center for low-income and uninsured individuals in Washington, DC.

Human Dx’s approach – with members in more than 70 countries – is a reminder that pockets of excellence and expertise can be found anywhere, regardless of resources.

The movement referred to as “reverse innovation” is consistent with Human Dx’s open-minded, democratic approach. Reverse innovation recognizes high-value contributions from LMIC and observes that high-income communities do not have a monopoly on innovation and learning. High-income, industrialized communities may, in fact, stand to learn from groups that have to be creative to provide high-quality care in difficult circumstances.

Diagnostic error is nondiscriminatory, occurring in diverse settings across the globe, wherever healthcare is delivered. Fully understanding factors that contribute to diagnostic error and actions that improve diagnostic safety will take individuals, organizations, and countries of all kinds, everywhere. As the movement toward high-quality healthcare as a right for all people develops, high-quality diagnosis will receive attention as an important priority.

References


The event also featured a panel discussion among a variety of voices in the field of diagnostic quality and safety: P. Jeffrey Brady, MD, MPH, director of the Center for Quality Improvement and Patient Safety at AHRQ; Helen Burstin, MD, MPH, FACP, executive vice president and CEO of the Council of Medical Specialty Societies; Amy Friedrich-Karnik, MPP, director of Public Policy at WomenHeart; David Mayer, MD, vice president of Quality and Safety at MedStar Health; and Reynold Salerno, PhD, director of the Division of Laboratory Systems at the Center for Disease Control and Prevention. The panel discussion was moderated by New York Times columnist and Yale professor Lisa Sanders, MD, FACP. The discussion was followed by a Q&A session that gave attendees the opportunity to ask questions about the effort. The full event is available via webcast and can be viewed at www.improvediagnosis.org.

Researchers estimate that 40,000-80,000 deaths a year in U.S. hospitals can be attributed to inaccurate or delayed diagnoses. Each year, diagnostic errors affect 12 million adults in outpatient settings and are the most common cause of medical errors reported by patients. “Providing an accurate medical diagnosis is complex and involves uncertainty, but it’s obviously essential to effective and timely treatment,” said Epner. “Nearly everyone will receive an inaccurate diagnosis at some point in their life, and for some the consequences will be grave. Major improvement is needed to systematically identify how to improve diagnostic quality and reduce harm to patients.”

Working in collaboration over several months, members of the SIDM-led Coalition identified initial obstacles they believe impede diagnostic accuracy, including:

- **Incomplete communication during care transitions.** When patients are transferred between facilities, physicians or departments, there is potential for important information to slip through the cracks.

- **Lack of measures and feedback.** Unlike many other patient safety issues, there are no standardized measures for hospitals, health systems, or physicians to understand their performance in the diagnostic process.
to guide improvement efforts or to report
diagnostic errors. Providers rarely get feedback
that a diagnosis was incorrect or changed.

- **Limited support to help with clinical reasoning.** With hundreds of potential explanations for any one symptom, clinicians need timely, efficient access to tools and resources to assist in making diagnoses.

- **Limited time.** Patients and their care providers overwhelmingly report feeling rushed by limited appointment times. That poses real risks to gathering a complete history, which is essential to formulating a working diagnosis, and allows scant opportunity to thoroughly discuss any further steps in the diagnostic process and set appropriate expectations.

- **The diagnostic process is complicated.** There is limited information available to patients about the questions to ask, whom to notify when changes in their condition occur or what constitutes serious symptoms. It’s also unclear who is responsible for closing the loop on test results and referrals and how to communicate follow-up.

- **Lack of funding for research.** The impact of inaccurate or delayed diagnoses on healthcare costs and patient harm has not been clearly articulated, and there is a limited amount of published evidence to identify what improves the diagnostic process.

The organizations behind the effort, which represent clinicians, patients, health systems, researchers and testing professionals, acknowledge that improvement will require sustained work over several years with all stakeholders engaged. To see the actions that Coalition member organizations are taking for better diagnosis, visit www.BetterDiagnosis.org.

ACT for Better Diagnosis is supported by the Gordon & Betty Moore Foundation and The Mont Fund. If your organization is interested in joining the Coalition to Improve Diagnosis and the ACT for Better Diagnosis initiative, please email: coalition@improvediagnosis.org.