Decoding the Signal from the Noise:

Building the Evidence Base to Prevent Pre-Hospital Diagnostic Delays

Summary

Preventing diagnostic delays—a "common, harmful, and costly" problem in U.S. health care[1]—offers real opportunities to improve patient experiences and outcomes. While research and quality improvement efforts have focused on delays once patients reach hospitals, less is known about delays along the diagnostic journey from onset of patient symptoms to primary care to emergency medical services (EMS).

On behalf of the Gordon and Betty Moore Foundation, AcademyHealth in late 2022 convened patients, clinical experts, researchers, and other stakeholders to inform a call for proposals to advance the evidence base for pre-hospital diagnostic delays related to cancer, sepsis, and acute cardiovascular conditions. Over two afternoons, participants identified and discussed myriad interacting factors that can stymy timely and accurate diagnoses—from economic, cultural/language, and other access barriers to implicit biases across gender, age, race, ethnicity, and other personal characteristics—all compounded by a health care system that lacks "systemness."

Given the interrelated complexities, using a framework like the Social-Ecological Model[2] that examines factors across individual, interpersonal, organizational, and societal levels could help ground research on pre-hospital diagnostic delay. Among the many unanswered questions about what influences pre-hospital diagnostic delay, participants identified the need to:

- Pinpoint what hinders clinicians from hearing and understanding the "complete story" of patients, including "their diseases, their new problem, their social situation, and their beliefs."[3] And on the other side of the dyad, identify how patients can tell their stories effectively—often in rushed clinical settings.
- Understand and address how implicit biases among clinicians and patients—across cascading dynamics of race, ethnicity, gender, age, income, health literacy, denial, fear, mistrust, and more—contribute to diagnostic delays.
- Identify how to help clinicians and patients alike separate the "signal from the noise," especially when faced with atypical or vague, nonspecific symptoms amid the relative rarity of the three targeted conditions across the entire population.
- Investigate how to transform potentially useful but vast health data from disconnected episodes of care into actionable intelligence to support clinicians and patients along a continuum of care over time.
- Quantify the personal and societal costs of pre-hospital diagnostic delays and where the greatest opportunities exist for improvement.

Moore Foundation Diagnostic Excellence Initiative

In the 2015 report *Improving Diagnosis in Health Care*, the National Academy of Medicine estimated "nearly every American will experience a diagnostic error in their lifetime, sometimes with devastating consequences." (National Academies of Sciences, Engineering, and Medicine 2015. Improving Diagnosis in Health Care. Washington, DC: The National Academies Press. https://doi.org/10.17226/21794). Since 2016, the Moore Foundation has awarded more than $60 million in research grants to strengthen accountability for diagnostic excellence, support growth and capacity of the field, and assess the potential for new technologies to improve diagnostic performance. The Foundation's Diagnostic Excellence Initiative focuses on three clinical categories—cancers, infections, and acute vascular events—because suboptimal diagnosis of these conditions drives a disproportionate share of serious harm and preventable death.

"We believe that diagnosis must be safe, accurate, cost efficient, timely, patient-centered, and equitable across populations," said Daniel Yang, M.D., of the Moore Foundation, citing the six dimensions of quality charted more than 20 years ago in *Crossing the Quality Chasm: A New Health System for the 21st Century.* (Institute of Medicine (US) Committee on Quality of Health Care in America. Crossing the Quality Chasm: A New Health System for the 21st Century. Washington (DC): National Academies Press (US); 2001. PMID: 25057539.)

Setting the stage for two patients and a caregiver to share their diagnostic stories, Yang said, "There's a false belief in the health care system that the doctor is the hero of the diagnostic journey, and we look up to master diagnosticians…but patient-centeredness means more than just having a good bedside manner. It means that patients are the protagonists of their own diagnostic journey."

This report summarizes the AcademyHealth meeting, *The Epidemiology of Pre-Hospital Diagnostic Delay: What is Needed to Build the Evidence Base?* Because the discussion was off the record, the report conveys general content without attribution to specific participants. The report's goal is to familiarize health services researchers and policymakers with fundamental issues related to diagnostic delays, particularly in pre-hospital settings, rather than an in-depth review of the topic. To inform the discussion and the call for proposals, AcademyHealth and the Moore Foundation commissioned six background papers to sketch the landscape of pre-hospital diagnostic delays in the context of cancer, sepsis, acute cardiovascular conditions, and the EMS system, as well as application of behavioral economics and real-world data to the problem (see http://academyhealth.org/dxdelay to download these papers or information about the call for proposals).

An 'Astonishing Dismissal of Patient Voices…'

The patient and caregiver stories—a Latina single mother living with metastatic breast cancer; a White mother of three trained as a nurse and paramedic who cares for her 4-year-old daughter with severe disabilities from sepsis as a newborn; and an older soft-spoken Black pastor who had to convince paramedics he'd had a stroke—all illustrated an "astonishing dismissal of patient voices and perspectives," as one expert said.

"How am I going to pay?" In 2015, Ana was 41, a single mom, and uninsured when she noticed a dimple on her right breast. She didn't give it much thought, attributing it to fluctuating weight. Ana mentioned the dimple to a family member who urged her to get it checked. "My first concern…was 'How am I going to pay for an exam?'…. I didn't know what to do, so I just kind of let it be for a few months," Ana said. She found a local nonprofit that helped her get a mammogram. She was diagnosed with breast cancer but still uninsured. Another nonprofit that assists Spanish speakers helped her navigate the insurance system and apply for and gain Medicaid coverage.

Ana had a mastectomy, learning her cancer was stage three with 13 involved lymph nodes. She underwent chemotherapy, radiation, and ongoing monthly hormone shots to suppress her ovaries. Tired of the monthly shots, Ana talked to her OB-GYN about removing her ovaries. He discouraged the procedure, saying she was young and might want more children. "I was like, 'No. I have one.' I just wanted them out," she said. She sought a second opinion from a female doctor in the same practice who agreed the procedure was warranted. "When I got them taken out, low and behold, there was a three-centimeter malignant tumor," Ana said. "So, now I've been living with metastatic breast cancer since then—thankfully, no evidence of active disease…. I still have in the back in my mind that things can change with insurance," she said. Now, Ana works to raise awareness about breast cancer and help people, especially Spanish speakers, understand their risks and symptoms, recalling, "Back then, I thought that breast cancer was hereditary, not something that can happen just to anyone."

"No one heard me." Born a few weeks early, Sheila weighed 6 lbs., 8 oz. and came home "healthy and happy," according to her mom, Kathleen. At two-and-a-half weeks, Sheila experienced intense gastrointestinal (GI) discomfort—projectile vomiting, diarrhea, difficulty rousing, and no appetite. Kathleen knew something was wrong and saw or spoke to her pediatrician or other clinicians every day for nearly a week. Because Sheila never had a fever, Kathleen was repeatedly dismissed as an inexperienced, overly concerned, and tired new mother.

"When I brought her in, they looked at her and said, 'Oh, she really doesn't look that bad. You know, it's really hard being a first-time mom.' I said, 'I'm not. This is my third… I work in health care….' The doctor was like, 'Oh, don't worry about it. She's not dehydrated, and she has no temperature,'" Kathleen said, recounting what happened on her first trip to the emergency room. Kathleen asked the doctor to check for a urinary tract infection (UTI), and a urine screen showed leukocytes and blood. Because Sheila was so young, the doctor didn't want to give her antibiotics, telling Kathleen that UTIs don't cause GI symptoms.

The following day Kathleen took Sheila back to her pediatrician, and the baby's weight had dropped from almost 7 lbs. to 5 in less than a week. "I just remember feeling so defeated. No one heard me," she recalled. Frustrated that her concerns were not taken seriously, Kathleen took Sheila back to the emergency room, where, after a three-hour wait, someone told Kathleen that the baby would need to be transported to a children's hospital. "They transported us non-emergent. So, we sat in that waiting room for hours before somebody saw us. When we finally got back, things kind of spiraled into a whirlwind. Before I knew it, Sheila was on life support," Kathleen remembered.

Kathleen asked repeatedly about the UTI results, but "they just kept pushing me off." Finally, a doctor found the results and "came running down the hall…and she said, 'She has a UTI. She has E. coli. She is in septic shock. I don't know if your baby is going to survive the night.'"

Sheila did survive, but "she's disabled because of sepsis…she has developmental delays, speech and language delays, and she can't eat any food. Unfortunately, sepsis caused the mucosal injury that destroyed her intestines…. It's not for any other reason but delayed diagnosis," Kathleen said.

"My body is off." For some time, James had a vague sense that something wasn't right. He had a regular doctor and made sure to get annual physicals. Other than occasional intense leg spasms, which he couldn't recall if he shared with his doctor, James had no symptoms other than a sense that "my body was not in sync."

James consulted with his doctor, who ordered blood work and looked for signs such as "slurred speech or twisted face or body movement—a change in my body movement. None of that was there, but I kept complaining. I kept saying, 'My body is off,'" James recalled. "So, I'd go back. He didn't prescribe anything. He just said, 'Maybe there's something else going on.' So, I'd leave. A few months later, I'd call. Come back again…. So, after a series of times coming to see him, I think he began to think maybe this is something psychological."

Meanwhile, James had his annual physical in May 2009, and he was in "great shape." That July, James awoke the morning after his wife's birthday and called to her, "You know, honey, I think I had a stroke." The two talked for a bit, and James, a pastor, asked his wife to pray for him and then call an ambulance. The ambulance arrived and the paramedics checked his vitals and asked if he could walk to the ambulance. James could, and as the examination continued in the ambulance, the paramedic said, "Sir, I don't think there's anything wrong with you."

"I said, 'Oh, something is wrong.' I can feel this strong, tingling sensation going down the left side of my body…. Mine was more intense. I could feel it all throughout my body, especially down the left side," he remembered. At the hospital, tests showed that James had indeed had a stroke, and he still wonders if there was something his doctor could have done to detect the coming stroke.

Common themes across the stories. "All three stories had this common thread of really emphasizing how the research and medical communities need to become better listeners," a physician researcher said. The stories also illustrated how complex interplaying factors can combine and cascade to thwart timely and accurate diagnoses, underscoring the importance of a coherent framework to ground research questions.

Applying a Social-Ecological Framework to Diagnostic Delays

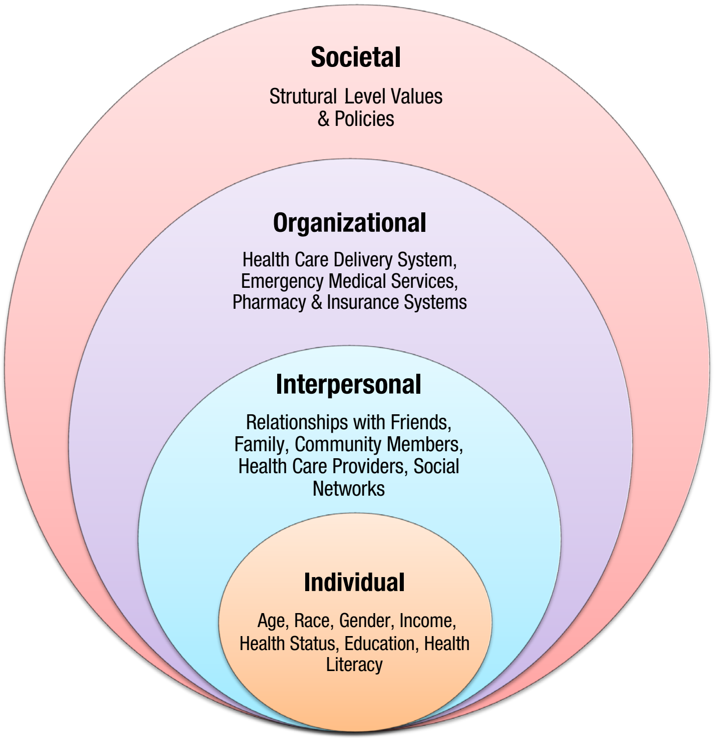
Most research on diagnostic delay focuses on individuals—patients and clinicians. One physician researcher recommended adopting a wider lens—using the Social-Ecological Model as an example (Exhibit 1)—to frame research on pre-hospital diagnostic delay across individual, interpersonal, organizational, and societal levels. "All of these things are really important when we're thinking about diagnostic delay…rather than focusing just on the individual level," the researcher said.

Individual

Who we are—our race, gender, ethnicity, age, income, health literacy, occupation, among other characteristics—coupled with economic and other barriers to care, as well as fear and denial, can all play roles in diagnostic delays. In Ana's case, her lack of health insurance and awareness of breast cancer risks and symptoms contributed to delays in her seeking care. But beyond cost, other social needs like childcare and transportation to get to a mammogram or colonoscopy, for example, as well as just being too busy, can lead to delays. "Whether it's being a parent, pastoring a congregation…where the decision to seek care may be delayed because of these external responsibilities, and what does that mean for us…to understand the context in which patients are living, working, and operating?" a participant observed.

Sometimes fear and denial of a diagnosis or mistrust of the health system might prevent people from seeking care, with a participant noting the importance of recognizing the "emotional, psychological, and mental toll" associated with seeking a diagnosis—"whether it's delaying to seek care because of the fear…what will happen after the diagnosis, whether to the patient or to their loved ones?"

Exhibit 1. Applying a Social-Ecological Model to Pre-Hospital Diagnostic Delays



Source: Adapted from the Centers for Disease Control and Prevention, The Social-Ecological Model: A Framework for Prevention, January 18, 2022, at https://www.cdc.gov/violenceprevention/about/social-ecologicalmodel.html; and a presentation at The Epidemiology of Pre-Hospital Diagnostic Delay: What is Needed to Build the Evidence Base?, AcademyHealth convening, Oct. 27 and 28, 2022.

Interpersonal

Our relationships—who we interact with and how we communicate with family, friends, and health care providers, for example—can influence our diagnostic path. At the same time, the implicit biases held by clinicians and patients alike can shape perceptions and alter decisions.

In the sepsis story, for example, clinicians' dismissal of Kathleen as an overly worried young mother and their reliance on Sheila's lack of fever—even though fever isn't present in a third of sepsis cases—and other "factors in their experience may have led them to dismiss the mother's concerns," a participant noted, adding, "So, thinking about how to address those biases within the decision trees that physicians have might be something that could be helpful."

Similarly, people's community and social networks matter, with one participant saying, "Patients don't make decisions in isolation about what to do to pursue medical care.…who they're interacting with that might suggest they go get care or not get care, and that can be a factor in the diagnostic delay."

Pointing to the patient stories, especially in the context of increased attention to health equity and the related "importance of building trust with patients," one participant observed that "in this case, there appears to be a lack of trust of providers or clinicians in patients, and what that means for the patient-provider relationship when it's the provider or the clinician not trusting the patient."

Examining ways for patients to share their histories and symptoms more effectively in clinical settings also might help keep important information from being overlooked, especially when "people don't present with classic, obvious symptoms." On the receiving end, rethinking who communicates with patients may be important as well, with a participant saying, "Sometimes the person who's got the M.D. degree is not the best person to be engaged in that conversation with patients. And we need to think about team-based care around this issue in a very, very different way and empower and give license to and help patients by having other members of the team be the communicators."

Organizational

Few, if any, would argue the U.S. health care system is seamless and easy to navigate—at its core it lacks "systemness," a word participants used repeatedly to describe what they believe is a major driver of missed diagnostic opportunities. As a participant said, "The circuitous pathways of being able to access care, even with the three patient stories that we heard today—all very articulate, advocating for what they needed or what their loved ones needed, but still had to keep repeating their complaints, their key complaints, their concerns to different health care team members, and it just didn't seem to go anywhere in terms of progress."

Likewise, participants stressed the importance of examining "process" issues in a health care system focused on isolated episodes of care rather than care along a continuum over time. One participant made a comparable point about how clinicians are trained to think, saying "Clinicians are maybe taught to think and look in snapshots, whereas diagnosis, evolution, delay, it's more of a video, it's over time, and that issue of snapshots versus continuity—video changes over time—is key." As a result, identifying "root causes of delays" and then fixing the underlying processes might be a fruitful research focus to advance the evidence base for pre-hospital diagnostic delays.

Primary care—so much complexity, so little time. One participant characterized primary care as a "maelstrom of complexity," citing a study[4] that looked at "clinics taking care of largely African-American populations with high prevalence of diabetes and heart disease, including hypertension and cholesterol-related disease. The visits in those primary care clinics, typically 25 different problems were addressed, ranging from 13 to 32 problems addressed in each visit. So, there's just such complexity in those visits."

Another participant observed that "having 15-minute visits for everybody is not a path to timely, accurate diagnosis. So, I think, how can primary care be supported? I mean, I think it just needs to be re-envisioned, right? And that goes from payment to actually how the day-to-day works—how nonphysicians on teams are empowered. All of those things are necessary for timely and accurate diagnosis."

Given the complexity of patients and limited time, primary care clinicians can't "really dig into the details, and especially into nonspecific symptoms that are so difficult to pinpoint," a participant said. "Everything is focused on the disease-specific symptoms rather than nonspecific things and quality of life and things like that. And, so I just want to echo that it really is going upstream and creating better structures for primary care to get to those diagnoses."

However, the nature of diagnostic delays in primary care are "so multi-factorial, even if you get providers more time, would it solve it?" a participant asked, adding, "I worked in the UK. We had six minutes per patient in general practice instead of 15, et cetera, et cetera. I think one thing that comes across in both the sepsis and cancer and others is uncertainty in primary care is the norm…. So how can we support with decision support that pre-test, post-test, the Bayesian thinking, which is not what doctors do numerically, but they do inside themselves. This is how doctors or clinicians think—less likely, more likely—they do that again and again, based on history, symptoms." The answer is unlikely to be found in endless EHR red alerts and instead may lie in examining and supporting "Bayesian reasoning in a practical real-life way," the participant said, adding, "I don't have the solution, but I think there could be."

You get what you pay for. Within the piecemeal fee-for-service payment system that still dominates U.S. health care, economic incentives for pressed-for-time clinicians typically are stronger to do something to patients—a test or a procedure—than listen to them.[6] One participant cited a study[6] examining Oregon's shift from fee-for-service to value-based payment that found significant savings because clinicians used much less diagnostic imaging. "Their interpretation of that was where you are able to just focus on the patient and what they need rather than counting all the beans, you diagnose smarter. And, so you were just kind of blindly ordering these tests that then led to more tests, but you're able to spend more time—15-minute visits became 20-minute visits and more of that communication and bidirectional listening can happen. And it actually saved costs and potentially improved things like diagnostic delays."

Another participant echoed that payment incentives matter, saying, "Our health system, and I hate to say this, in some ways, financially encourages late diagnosis, late presentation, costly care. We can all look out of our windows, probably, and look at massive cancer centers." In cancer screening and diagnosis, for example, the participant continued, health economic analysis of "potential overdiagnosis and over testing in primary care has really got to be very nuanced and holistic to consider the potential savings of lower stage, and just to follow up on something listed earlier, yes, for some cases, still need to show that detecting cancer earlier has got some health benefit."

Nonetheless, there may be other less tangible benefits of a definitive cancer diagnosis that matter to patients, the participant continued, saying, "I honestly think if you asked most patients, would you want to know or not? I truly do think nowhere in society do we want less information…. Our society has moved rapidly to more information, more of the time—kind of whether we like it or not. So yeah, there may not be a mortality outcome, but patient-centered outcomes, knowledge, comfort, don't have to keep chasing some other diagnosis and more tests. Those are things to consider as well as mortality."

Other systems fragmented and disconnected, too. Beyond the health care delivery system, other systems—health insurance, pharmacy, and the EMS system—offer fertile ground for better integration and connection that could ease barriers to care, help clinicians and patients put the pieces of the diagnostic puzzle together, and prevent delays. Both insurers and large employers in their respective payer and purchaser roles could explore how benefit designs encourage and discourage people from seeking care and the effect on diagnostic delays. Moreover, variation of what's covered and what's not from payer to payer and state to state in the case of Medicaid makes a complex system even more challenging for patients and clinicians to navigate. "We shouldn't forget that payers are in the room, even though that seems so immovable at times," a participant said.

Along with focusing on primary care and other upstream care settings, like nursing homes, the nation's overtaxed EMS system deserves researchers' attention, several participants stressed, with one saying, "I think there's a big opportunity, and one of our last papers of today's session really points out that improvement of EMS assessment and care is just critical, and some of that is access to appropriate EMS care as well, but there's such an important interface between community, primary care, nursing homes, and getting people assessed and into the appropriate vein of care quickly."

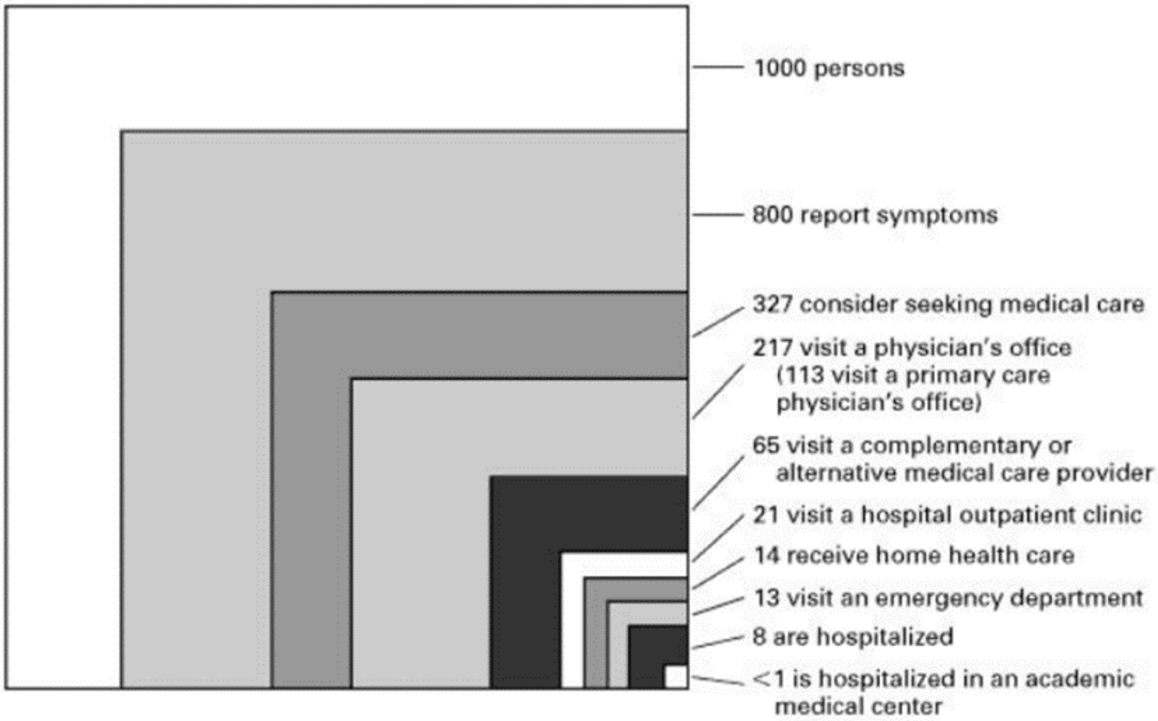
Societal

Examining the larger societal context and health care ecosystem, including factors like structural racism and health disparities, can help target research and interventions to prevent pre-hospital diagnostic delays. For example, in the case of many cancers, Black and Latinos people are more likely to be diagnosed later and at more advanced stages, so applying an equity lens to diagnostic delays can help inform research. Participants also urged researchers to begin quantifying the personal and societal costs of pre-hospital diagnostic delays and where the greatest opportunities for improvement exist.

Transforming data into intelligence. In 1961, Karl White and colleagues published, "The Ecology of Medical Care" in the New England Journal of Medicine,[7] finding that for every 1,000 people in the community, every month, about 750 would experience illness or injury and think about seeking care, about 250 would be seen in an outpatient setting—about half in primary care—nine would go to a hospital, and one would wind up in a university medical center. Sixty years later not much has changed despite major technological and other changes in the financing, delivery, and organization of health care. Updated versions of the White analysis in 2001[8] (Exhibit 2) and 2016[9] show "the consistency remains 60 years on—the patterns have not changed very much," a physician researcher said.

Exhibit 2. Results of a Reanalysis of the Monthly Prevalence of Illness in the Community and the Roles of Various Sources of Health Care

Note: Each box represents a subgroup of the largest box, which comprises 1000 persons. Data are for persons of all ages.



Source: Green, L. A., Fryer, G. E., Jr, Yawn, B. P., Lanier, D., & Dovey, S. M. (2001). The ecology of medical care revisited. *The New England journal of medicine*, *344*(26), 2021–2025. https://doi.org/10.1056/NEJM200106283442611.

"In terms of the biggest opportunities, both for improving care and for research, I think one of the biggest boxes is that 800 out of 1,000 people who have some symptoms or injury, but either for lack of access or awareness or fear, whatever it may be, how do we shift them into recognizing these important conditions and seeking care early?" the physician continued. Moreover, the "huge black box of outpatient care, a billion visits a year" is ripe with data "that have never been turned into information, never turned into risk assessment capacity, to early diagnosis, to disease progression/prevention, and it is just fallow. It is such an opportunity for both intervention and for research."

For example, about half of all patients with sepsis have an encounter with the health care system in the week before diagnosis, prompting a primary care physician to say, "In conversation with the providers that are in those visits that then spiral into something worse, there is information…if we want to help those upstream providers like me, right, who may be missing serious diagnoses, we need to engage them, and this work is not going to happen in a totally automated fashion."

Moreover, burgeoning data sources, especially real-world sources like wearable sensors or search engine results, may end up adding more noise than signal to the diagnostic journey without careful design of the choice architecture supporting clinician and patient decisions. As one participant observed, "Tech solutions are great, but putting a Fitbit on a patient and just monitoring their heart rate, and then sending that data to the doctor, telling me that you're tachycardic at 1:30 on a Tuesday without any clinical context, is quite meaningless. That clinical context, the transformation that must occur from data into intelligence that can be actionable for the clinician or the patient is a huge leap."

Scalability of interventions. Interventions to reduce diagnostic delay must both work and be scalable in the real world from economic and practical standpoints, with one physician saying, "We can get really excited about something that works really well, but when it's not scalable to broad populations, we're never going to truly move the needle." Looking to the COVID-19 public health emergency may offer useful models and lessons, with one researcher observing, "Can we run a massive population level, acute infection management program that incorporates prevention, diagnosis, risk stratification and treatment? And I would argue we've lived that over the past two years. That's called COVID."

Implementation and dissemination. Along with identifying new research questions, a participant noted, "Part of the conversation about pre-hospital diagnostic delay could and should include the opportunity to do better in areas where we already have a science base, and we're just not doing the implementation as well as we could." At the same time, there's a problem with "deimplementing" certain ingrained but unwarranted practices, such as cervical cancer screening for women aged 65 and older.

Next Steps in Solving a 'Wicked Problem'

Capping off two afternoons of concentrated conversation about the complex and interconnected layers of pre-hospital diagnostic delays—described by one as a "wicked problem" with no ready sweeping solutions—participants reflected on how to focus research priorities and questions "rather than boiling the ocean."

One suggested focusing on two distinct opportunities, saying, "Where are opportunities to make an immediate impact, where doing something in a couple of key areas is going to make a difference and fairly rapidly? The other option is to think about where are the communities and where the greatest harm has occurred, where we can think about targeting efforts in this realm? Because there are communities for whom the lack of diagnosis and these kinds of problems have the most extraordinary problems."

Again and again, participants cited the importance of listening and communication skills and how biases contribute to missed signals and clinicians not hearing the complete patient story. "It's the listening and the communication part, and who is listening, and who is communicating that are ripe opportunities," a researcher said, adding, "I'm going to make some connective tissue really to the cognitive biases, and we might call it choice architecture, but what struck me as so critical in all the conversations, is how biases about who has information, who knows what is happening, who should be listened to when we see these things is leading to a lot of our challenges and problems. Whatever solutions that we're considering, I think really thinking deeply about better listening and better listening of the people who are closest to the actual physical experience of the problem remains really critical in health care, and that has not changed."

About the Author

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Endnotes

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