



## Re: Request for Information National Test Collaborative 75D301-19-Q-69537

### Section 1. Administrative Information

- a. Patricia L. Hale, MD, FACP, Chair of the Medical Informatics Committee

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- b. On behalf of the American College of Physicians, a professional membership organization composed of internal medicine physicians and medical students.

### Section 2. Requested Information

The American College of Physicians (ACP) is grateful for the opportunity to share comments and feedback on the Centers for Disease Control and Prevention (CDC) Request for Information (RFI) Regarding a National Test Collaborative (NTC). The College is the largest medical specialty organization and the second-largest physician group in the United States. ACP members include 154,000 internal medicine physicians (internists), related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness.

As electronic health records (EHRs) become more integral in providing patients high-quality care, ACP appreciates the Agency's attention to this issue. In the RFI, CDC sought information regarding approaches for developing a NTC that would allow for the field testing of health information technology (HIT) in a live clinical setting. The College certainly sees the value in facilitating the real-world application of HIT in production environments as part of the testing process. Production testing more accurately replicates clinical environments and patient interactions that may not occur in a controlled, non-production testing environment, ensuring HIT operates as its designers intended it to. Errors can be identified before roll out and implementation by an institution that otherwise may have gone unnoticed until years later. The literature has identified numerous cases where HIT errors were discovered in a live production environment.<sup>1,2,3</sup> For example, in production testing the computerized provider order-entry system between a lab and radiology department, it was found that a misalignment in data fields resulted in test results being misrouted.<sup>4</sup> Additionally, testing in a clinical setting gives insight into its usability by observing how the HIT performance and response time impacts workflow in its day-to-day use. While live testing is important and deserving of urgency, a project of this scale is a massive and difficult undertaking and CDC must adequately plan for and thoroughly consider the challenges prior to

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<sup>1</sup> Yackel TR, Embi PJ. Unintended errors with EHR-based result management: a case series. *JAMIA*. 2010;17(1):104–107.

<sup>2</sup> Wright A, Hickman TT, McEvoy D, et al. Analysis of clinical decision support system malfunctions: a case series and survey. *JAMIA*. 2016 (in press).

<sup>3</sup> Meeks DW, Smith MW, Taylor L, et al. An analysis of electronic health record- related patient safety concerns. *JAMIA*. 2014;21(6):1053–1059.

<sup>4</sup> Kaner C, Bach J, Pettichord B. *Lessons Learned in Software Testing: a Context-driven Approach*. New York: Wiley Computer Publishing; 2002.

proceeding. Based on the College's direct participation in a similar effort in the past, we hope to offer the following insight for consideration should the Agency pursue the development of an NTC.

In early 2015, the Office of the National Coordinator for Health Information Technology (ONC) recruited and assembled a workgroup of volunteers to design and run an HIT field-testing pilot. Included in the Surveillance Post Continuous Quality Improvement Workgroup were representatives from ACP, Surescripts, International Computer Security Association (ICSA) Labs, Meditech, and Medhost. The group identified potential test sites to implement a surveillance testing program in order to evaluate the utility of HIT field testing. After months of effort and pursuing implementation at two different sites, the group was unsuccessful in executing an agreement, let alone conducting a test. In attempting this project, the Workgroup identified three main challenges which the Agency may find useful as they consider a field testing initiative of their own.

**1. Communicating the importance of surveillance testing and the benefit to the organization.**

The Workgroup observed that it was conceptually difficult for individuals at the field location to understand the purpose of the project. Explaining the project numerous times to test site stakeholders consumed much more time and resources than was initially anticipated. A large gap in testing requirements knowledge and understanding was identified between the vendors/developers and the end users. When identifying potential test sites, the Workgroup was often working from scratch with those involved. Furthermore, information did not flow laterally and the concept would have to be re-explained every time the Workgroup had to work with a new staff member. For many, it was unclear what the benefit was to the host organization that would make the project worthwhile.

**2. Identifying and working with test locations.**

In identifying sites, the Workgroup found that leadership would be generally supportive of the project. However, that enthusiasm and support did not necessarily flow down to the rank-and-file staff. Due to the voluntary nature, the project lacked a "driver" at the host institution, which resulted in a loss of momentum and prevented the project from being seen to completion. The project ended up becoming a low priority for the organization, which would make scheduling and coordination complicated and drawn out. Responsibility for the execution of the project would shift and, along the way, the project, goals, and next steps would have to be re-explained each time it was transitioned to a new staff member. These shifts in responsibility resulted in significant delays in communication as well as lack of buy-in from the test sites – and ONC inevitably decided to end the program before any tests were scheduled.

**3. Administrative and legal issues.**

Without an incentive or penalty to participate, the program was a low priority for the identified test sites and resulted in months of scheduling, coordinating, and planning with a site before they decided not to proceed, wasting valuable time and resources. Additionally, given that testing with patient records presented a liability risk, numerous legal documents had to be produced by the host site to proceed with the project. Procuring the legal agreements resulted in an enormous time strain for the Workgroup, preventing them from moving forward with implementation of the project.

In issuing its final report to the ONC National Coordinator, the Workgroup offered the following suggestions for future field testing pilot efforts:

- **Start with proper preplanning.** Rather than initially discussing internally how the NTC would work, start by identifying sites and resources and directly involve them in the planning of the testing. Identify legal and contracting issues from the start to ensure there is enough time to draft and execute agreements.
- **Get adequate buy-in and support.** The benefit of and need for live testing must be clearly conveyed to garner sufficient support and participation for the project to be successful. Including candidate participants from the earliest planning stages will more likely facilitate buy-in by participants. Additional industry support, such as a vendor representative, could also be beneficial in the design and execution of the NTC.
- **External communication and promotion.** In order to successfully recruit volunteers and potential sites, the NTC program must be widely known and understood.
- **Institutional familiarity.** Ensure there is institutional knowledge within the Agency about the NTC project to increase general awareness and be able to address skeptical or uncertain candidate sites.
- **Provide appropriate incentives.** Offer an incentive to make the project worthwhile to participate in given the immense, time, monetary, and other resources an organization would need to expend to participate in such a complex effort.

CDC could furthermore gain insight from Wright, Aaron, and Sittig's guidance on developing a production testing program.<sup>5</sup> The ONC Workgroup took guidance from these guidelines in developing their pilot program and it could be a helpful reference article for the Agency.

### Section 3. Conclusion and Recommendations

In summary, ACP is concerned that building an entirely new testing network will be prohibitively difficult and execution could go wrong unless it is carefully designed, piloted, and tested. Emailing and conference calling with every level of every organization is labor intensive and getting participants engaged in this process will be an enormous effort. Shifting priorities may cause delays and the external nature of the project may make maintaining engagement difficult. This is compounded by the fact that the lack of direct benefit to the testing site may make participants indifferent to the success of the project. If CDC is to proceed they must address these barriers by figuring out a way to pilot the production testing to show it works and has value and by identifying a sponsor and champion within the organization to maintain momentum.

Should CDC attempt to create a network of live clinical settings, they will have to address the patient privacy issues associated with production settings. These privacy issues may cause concern amongst hospitals and may prevent them from wanting to participate unless addressed. Additionally, smaller, ambulatory practices may lack the financial or infrastructure capability to participate in a field-testing program. CDC will also have to consider how they may seek participation of these smaller practices, as they may be reluctant to purchase another interface from their EHR vendor.

Prior attempts at executing a project similar to the NTC were unable to get a single hospital to agree to test. As evidenced by the 2015 ONC pilot program in which ACP was involved, organizational and workflow issues are widespread when implementing a complex network of testing sites from the ground

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<sup>5</sup> Wright, Adam, Skye Aaron, and Dean F. Sittig. "Testing electronic health records in the "production" environment: an essential step in the journey to a safe and effective health care system." JAMIA 24, no. 1 (2016): 188-192.

up and are often unsuccessful. It will be difficult to get buy-in and bring healthcare businesses on board without any sort of regulatory mandate or incentive. **Alternatively, The College recommends CDC consider building a CDC-Vendor-End User communication methodology that may be a more manageable undertaking utilizing existing infrastructures. Such a system could allow for CDC to notify EHR vendors who would notify product users when they receive an alert or guidance from CDC, using a process similar to how software updates are released. This approach does not require the sharing of protected health information nor does it require direct access into the production system.** Again, the College appreciates the opportunity to comment and provide insight for the CDC on this important undertaking. If we can be of any further assistance as the development of the NTC proceeds, please feel free to reach out to Brooke Rockwern, MPH, Associate, Health IT Policy, at [brockwern@acponline.org](mailto:brockwern@acponline.org).