

ORIGINAL ARTICLE

Test Result Management in Global Health Settings

全球健康机构的测试结果管理

Gestión de resultados de las pruebas en el marco de la salud mundial

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Citation

Global Adv Health Med.
2012;1(4):42-46.

Key Words

Electronic medical records, test results, short messaging service, integrated voice response, text messages, mobile devices, community health workers, global health

OVERVIEW

Across the globe, the ways in which patients' test results are managed are as varied as the many different types of healthcare systems that manage these data. The outcomes, however, are often not too dissimilar: too many clinically significant test results fall through the cracks. The consequences of not following up test results in a timely manner are serious and often devastating to patients: diagnoses are delayed, treatments are not initiated or altered in time, and diseases progress. In resource-poor settings, test results too commonly get filed away within the paper chart in ways that isolate them and prevent passage to future providers caring for a patient. To make matters worse, the onus to act upon these test results often rests on patients who need to return to the clinic within a specified timeframe in order to obtain their results but who may not have the means or are too ill to do so. Even in more developed healthcare settings that use electronic records, clinical data residing in the electronic medical record (EMR) are often stubbornly "static"—key pieces of clinical information are frequently not recognized, retrieved, or shared easily. In this way, EMRs are not unlike paper record systems, and therefore, EMRs alone will not solve this problem. To illustrate this problem, consider the case of a patient newly diagnosed with HIV in 3 different healthcare delivery settings.

摘要

在全球，正如存在许多不同类型管理患者测试结果数据的医疗护理系统一样，管理这些数据的方式也多种多样。但是，结果通常都大同小异：大量临床重要测试结果都被疏忽。如未能及时跟进测试结果，会造成严重后果，并且通常会对患者造成巨大伤害：延误诊断、未及时开始或更改治疗及病情恶化。在资源贫乏的机构中，测试结果通常存档于纸图中，并将其隔离，以致这些信息不能传到将来为患者提供护理的人士手中。使情况更糟的是，获取测试结果的责任往往会落在患者身上，患者若要获得其测试结果，则需在指定的时间内返回诊所，但他们可能没有方法或因病得太重而无法做到。即使在较为发达的使用电子记录的医疗护理机构，存于电子病历（EMR）中的临床数据经常顽固地保持“静止”——关键的临床信息往往不易被识别、检索或分享。因此，在某种程度上，EMR 和纸质记录系统是一样的，因此单靠 EMR 并不能解决这个问题。为阐明这个问题，想想在 3 个不同的医疗护理交付机构新确诊为 HIV 患者的案例。

SINOPSIS

En todo el mundo, las maneras en las cuales se gestionan los resultados de las pruebas de los pacientes son tan variadas como lo son los diferentes tipos de sistemas de atención sanitaria que gestionan dichos datos. Sin embargo, con frecuencia los resultados no son muy diferentes: demasiadas pruebas significativas a nivel clínico quedan perdidas. Las consecuencias de no seguir los resultados de las pruebas de modo oportuno son graves y, a menudo, devastadoras para los pacientes: los diagnósticos se retrasan, los tratamientos no se inician o se alteran en el tiempo y la enfermedad progresa. En ámbitos de pocos recursos, es muy común que los resultados de las pruebas queden archivados entre papeles de tal modo que quedan aislados y no llegan a los futuros profesionales que atenderán al paciente. Para empeorar aún más las cosas, la responsabilidad de actuar en función de estos resultados muchas veces recae sobre los pacientes que necesitan volver a la clínica en un marco de tiempo específico para obtener sus resultados, pero que no tienen los medios o están demasiado enfermos para hacerlo. Incluso en ámbitos sanitarios más desarrollados que utilizan expedientes electrónicos, los datos clínicos que residen en el expediente clínico electrónico (Electronic Medical Record, EMR) a menudo son tenazmente "estáticos"; con frecuencia piezas clave de la información clínica no se reconocen, no se recuperan ni se comparten fácilmente. De este modo, los EMR no son muy diferentes de los sistemas de expediente en papel y, por lo tanto, los EMR por sí solos no resolverán el problema. Para ilustrar este problema, considere el caso de un paciente que acaba de ser diagnosticado con VIH en tres entornos diferentes de prestación de atención sanitaria.

AN IMPOVERISHED DEVELOPING COUNTRY, A PUBLIC HOSPITAL, A STATIC PAPER, OR ELECTRONIC RECORD SYSTEM

In this setting, an impoverished developing country (eg, some of the more impoverished countries in Sub-Saharan Africa, Asia, or Latin America), the patient obtains diagnostic tests at a public hospital with a specific budget for a human immunodeficiency virus (HIV)–screening campaign. The HIV test returns positive, but the CD4⁺ count has not dropped to levels that would prompt initiation of antiretroviral therapy (ART). After the visit, the patient's test results remain in the onsite chart, kept in storage and rarely shared with other providers until the patient initiates the next clinical interaction. Additionally, in such resource-limited settings, patients do not typically have healthcare providers (beyond those assigned in the hospital) to receive and act upon their test results. The concept of a dedicated primary care doctor is increasingly a luxury for these patients. The more common model is either the “fee for service” urgent care private physician who generally has no incentive or mechanism by which to share information beyond the fee-generating urgent care visit or the public hospital doctor who, if unaided, is too busy to manage the patient's care at this level of detail. The loss to follow-up of such patients is notoriously high, and unfortunately, these patients often return to the hospital setting after developing symptoms of advanced AIDS. In one systematic review, Rosen et al estimated that fewer than one third of patients testing positive for HIV but not yet eligible for ART were retained in pre-ART care continuously. Timely follow-up of test results was one of several problems contributing to this statistic.¹ The problem in this setting is not only the lack of dedicated ambulatory care providers but also how inefficiently clinically important test results are shared outside the setting in which they were ordered. With the responsibility of follow-up resting on impoverished patients, and without the availability of a responsible provider in the ambulatory setting, the likelihood of timely follow-up and initiation of appropriate medical therapy is significantly reduced.

A MIDDLE-INCOME DEVELOPING COUNTRY, A PUBLIC HOSPITAL, OR A NON-GOVERNMENT ORGANIZATION—MINISTRY OF HEALTH PUBLIC-PRIVATE PARTNERSHIP, A STATIC PAPER, OR ELECTRONIC RECORD SYSTEM

In this second setting (eg, some countries in Latin America, Asia, or Africa where innovation is encouraged and piloted), a middle-income country that has a higher-functioning healthcare system than the first, a patient may receive a diagnosis of HIV during an “active case finding” campaign. In this setting, because a team of care providers travel to the community to screen and potentially treat at-risk patients, the diagnosis of HIV may be made earlier in a patient's clinical course. This healthcare system then may use one of

many well-defined processes for maintaining direct contact with patients (eg, a robust network of community health workers [CHWs]) or it may finance one or more programs known to assist with patient retention (eg, food support, travel stipends, the provision of quality primary care in addition to specialized HIV care). These investments increase the likelihood that providers will follow up with a patient and initiate appropriate ART therapy when a test result returns positive. Rich et al showed how such a robust system of communication and support contributed to improved adherence and excellent clinical outcomes 2 years after the initiation of ART.² Nevertheless, because these programs depend largely on the availability, commitment, and initiative of patients, providers, and CHWs, they are not foolproof. If information does not flow efficiently through this system (albeit more robust and patient-centered), missed treatment opportunities and losses to follow-up will persist at unacceptable levels.

A DEVELOPED COUNTRY WITH A VARIETY OF CLINICAL PROVIDERS AND ELECTRONIC CLINICAL INFORMATION SYSTEMS

In this third setting (eg, the United States, many rapidly developing middle-income countries such as Mexico), a disenfranchised intravenous drug user presents to an emergency department with an injection-site cellulitis and is admitted to the hospital. Because of risk factors, the inpatient medical team orders a diagnostic HIV test. The result does not return until after the patient is discharged, and unfortunately, it returns positive. There is a strong possibility that the inpatient doctor who ordered the test will not be aware of the result. In fact, Roy et al determined that 72% of physicians were unaware of such potentially actionable test results that were pending at the time of hospital discharge.³ Interestingly, this often occurs even when test results are available to all providers (both inpatient and ambulatory) within the electronic medical record (EMR). In these settings, lack of awareness of test results is a common cause of delays in diagnosis (particularly when multiple providers are involved) and often leads to subsequent patient harm.⁴ In the United States, the “systems” issues that plague test result management are multi-fold, including different providers caring for patients in different settings, poor delineation of responsibility, and lack of systems to flag and alert responsible providers when finalized results become available. The consequence is a faulty system in which an inadvertent error propagates, often resulting in a suboptimal or poor outcome. Even if providers are aware of the test result, it is often difficult to track homeless or migratory patients until they present to the acute-care setting with signs of advanced AIDS. Unfortunately, this may be true for patients who are aware of important pending tests and motivated to follow up. Finally, even after patients initiate appropriate ART, similar

problems typically arise in the ambulatory setting with regard to following CD4+ counts and viral loads and assuring adherence to the ART regimen.⁵

In all of these settings, the main challenges are not limited to a lack of resources or “caring” by the individual providers; the central issue is the lack of coordination and timely communication among the various providers involved in the care of the patient across different settings, perpetuated by a system (either paper or electronic) not set up to reliably ensure timely acknowledgment and follow-up on these test results. From the most impoverished to the richest healthcare delivery systems, a central theme is apparent: poor awareness of test results at the time that vital decisions need to be made leads to delays in diagnosis and the subsequent failure to institute appropriate treatments. What is particularly striking is that developed healthcare systems with the most advanced EMRs still struggle with this problem. In the United States, failure to follow up on test results is an increasingly recognized problem (estimated at 15%-40%), often leading to clinically important treatment delays and unfortunately, malpractice claims.^{3,4,6,7} Despite the associated morbidity and mortality, healthcare delivery systems have not developed effective solutions to address the problem. In general, there is a lack of consensus with regard to what constitutes “best practices” in managing test results across the continuum of care. As a result, individual providers typically have their own systems of managing test results. Additionally, despite efficiency gains realized by near instantaneous availability of clinical data from EMRs, test result tracking systems are either nonexistent or poorly designed. The high degree of variability in individual clinician practices and the murky delineation of responsibility for specific test results make it mandatory to establish clear lines of responsibility prior to implementation of any electronic test result management system. It is not just the availability of information that is necessary to improve the system, but more importantly, the ability to foster improved awareness of that information to the providers responsible for overseeing the care of the patient. This can be achieved only by seamless integration into clinical workflow.

Ideally, any test result management system, whether paper or electronic, should include a few basic features: it should flag important tests results, clearly assign responsibility, and facilitate acknowledgment. Without these basic features, providers caring for a patient across a variety of clinical settings will be ineffectual at receiving and acting upon clinically relevant information in a timely manner. There are few examples of successful electronic strategies to manage test results. At Partners HealthCare in Boston, Massachusetts, Poon et al developed a results management application to help ambulatory clinicians review and act upon test results reliably and efficiently.⁸ Dalal et al developed an automated notification system to prompt the responsible inpatient and ambulatory phy-

sicians of the results of tests pending at the time of hospital discharge.⁹ The success of these systems is based on not only the fundamental features mentioned above but also thoughtful consideration of the electronic clinical workflow of the patients’ responsible providers. Automated notifications are useful but only when the identities of the responsible providers have been clearly established and notifications are sent via messaging systems in widespread use by these clinicians. Alphanumeric pagers are an excellent option in many settings as the first choice, but clinical messaging systems (within EMRs) and secure, network email are being used as well. With the rapid growth and spread of wireless telecommunication networks, advanced mobile devices that access clinical messaging systems and network email using push-notification services are an increasingly attractive option.

The advent of global health as a field focused on, among other objectives, strengthening the systems of healthcare delivery around the world presents an opportunity to determine how best to develop and implement systems of managing test results in a variety of resource-limited settings. The World Health Organization (WHO) has delineated essential building blocks that contribute to a high-functioning healthcare system. According to WHO, a well-functioning health information system is one that “ensures the production, analysis, dissemination and use of reliable and timely information on health determinants, health system performance and health status.” Similarly, good health services are those that “deliver effective, safe, quality personal and non-personal health interventions to those that need them, when and where needed, with minimum waste of resources.”¹⁰ Therefore, a number of essential components are required in order for medical information to flow efficiently so that health services can be delivered effectively. With regard to test result management, developing healthcare systems might benefit from adapting successful strategies and principles from more developed healthcare systems. Specifically, these include (1) identification of responsible providers, (2) seamless clinical workflow integration, (3) a mechanism to acknowledge test results, and (4) a fail-safe escalation hierarchy for unacknowledged test results.

One area in which developing healthcare systems are perhaps ahead of more developed systems is the use of mobile telecommunication networks. Such networks, when used by health workers and their patients, can meaningfully affect the determinants of health outcomes. For example, the use of mobile technology by health workers has been shown to improve adherence to medication regimens. In Kenya, text-message reminders (using short messaging service [SMS] protocol) sent to health workers’ mobile phones resulted in a 23% improvement in adherence to malaria treatment guidelines for outpatient pediatric malaria.¹¹ In Tanzania, text message reminders sent to CHWs reduced the average number of days that clients were

overdue for community-based HIV case management by 86%.¹² In Ghana, pregnant women can register to receive weekly educational messages and appointment reminders via text message or integrated voice response (IVR) systems.¹³ In a randomized trial, Lester et al demonstrated significant improvement in ART adherence and rates of viral suppression among HIV patients through weekly interactive SMS communication with a clinic nurse.¹⁴ Though there are few published examples of the use of mobile technology for directly notifying providers or clients of test results, qualitative studies in both low- and high-income settings have shown high acceptability among patients.¹⁵⁻¹⁷ Finally, in places such as Zambia, laboratories use text-messaging systems to reduce the time between collection of a blood sample and delivery of results back to the health facility where the sample was obtained.¹⁸ In this way, the widespread use of mobile technology by health workers, clients, and health facilities offers a unique opportunity to tackle the test result management conundrum in developing healthcare settings. And, if implemented wisely, the use of automated text-messaging services may positively influence the determinants of health outcomes, particularly when used for test results with a high potential to result in meaningful actions taken by providers (eg, HIV tests, viral loads, CD4+ counts).

How would such a mobile test-result management system function in developing healthcare settings? The overarching goal of any system is to positively influence clinical outcomes by initiating, altering, or discontinuing treatments in a timely manner. Ideally, such a system would draw upon the key principles of test-result management from developed settings: reliable identification of responsible providers, real-time notification of test results, timely acknowledgment and follow-up, and an escalation mechanism such that supervising clinicians or public health authorities can intervene when timely acknowledgment and follow-up do not occur. For example, when actionable test results (eg, a positive HIV result associated with a low CD4+ count) become available, the responsible CHW would receive an automated text-message alert prompting a visit to the patient. Patients who register to receive SMS or IVR messages (at the time the tests are drawn) would receive an alert prompting them that the CHW will visit shortly. (If no CHWs are identified, the system would provide patients with information about how to seek out a nearby health worker.) If the CHW does not acknowledge the actionable test result after a predefined time interval, the CHW's overseeing clinician then would receive an automated text-message alert. Ultimately, if still left unacknowledged, the automated alert would escalate to more centralized public health authorities. Once acknowledged, mobile healthcare teams (where they exist) can coordinate with CHWs to ensure appropriate follow-up in the patient's community.

There are many barriers and challenges that need

to be addressed for such a mobile test-result notification system to be realized in developing settings. Although an estimated 90% of the world's population is within coverage of a cellular network, more investment is needed to extend the network's reach to the most marginalized populations (these are likely to have a higher burden of treatable diseases and therefore, would serve to gain the most).¹⁹ Yet even simple measures such as charging phones remain an obstacle in impoverished areas—solar chargers could alleviate this problem, but they are typically cost prohibitive (although the use of “hand crank” chargers are one possible lower-cost solution). Also, governments and healthcare providers typically lack experience in and capacity for deploying mobile programs. There is little guidance available to health systems in low- and middle-income countries to support the scale-up of mobile health programs, including issues around patient privacy, confidentiality, security, interoperability with existing health information systems, and sustainable sources of financing. Finally, contextually appropriate messaging and notification strategies would need to be developed given the sensitivity of certain test results and the likelihood that many households and communities commonly share mobile phones.

Mobile health is a nascent industry but one that holds much promise in countries with developing healthcare systems. Mobile test result management systems capable of leveraging automated SMS and IVR notifications are promising, but rigorous studies demonstrating the effectiveness of these systems are necessary to advocate for their widespread adoption. Key to success will be integrating strategies and lessons learned from more developed healthcare settings with some of the innovative approaches that have proven effective in developing health systems. These principles include identification of responsible providers, seamless workflow integration, a mechanism to acknowledge test results, and a fail-safe escalation mechanism for unacknowledged test results. When such a system is in place, patients and providers alike could feel reassured that important test results will no longer fall through the cracks.

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