Evaluation of the HITSystem to improve early infant diagnosis outcomes in Kenya

While great advances have been made in treatments for HIV and AIDS, the virus remains one of the leading killers in sub-Saharan Africa. In Kenya alone, approximately 6,000 babies each year become infected with the virus. For HIV-exposed infants, early diagnosis is critical to identify those who are HIV-positive so that they can receive lifesaving antiretroviral therapy (ART). Dr Sarah Finocchario Kessler, from the University of Kansas Medical Center focuses her research on mHealth interventions like the HIV Infant Tracking System (HITSystem) to improve early infant diagnosis (EID) of HIV and prevent perinatal HIV transmission among pregnant women in Kenya.

The effectiveness and efficiency of early infant diagnosis services in Kenya and other low resource settings are hampered by system and structural barriers. These include late presentation for care, long turnaround times for results to be returned to the hospital and communicated to mothers, poor retention of infants and delayed ART initiation for HIV-positive infants. In response to these issues, Brad Gautney, President of Global Health Innovations explored the potential of technology to mitigate many of the barriers to early infant diagnosis experienced in Kenya and other low resource countries. As former classmates at Hopkins, Gautney and Sarah Kessler teamed up to pilot a system-level intervention utilising internet and text messaging to improve infant outcomes. Their theory was that by strengthening channels of communication and accountability, standards of care could be raised to meet national guidelines. This, in turn, would prevent people from falling through the cracks in the system and thus save lives.

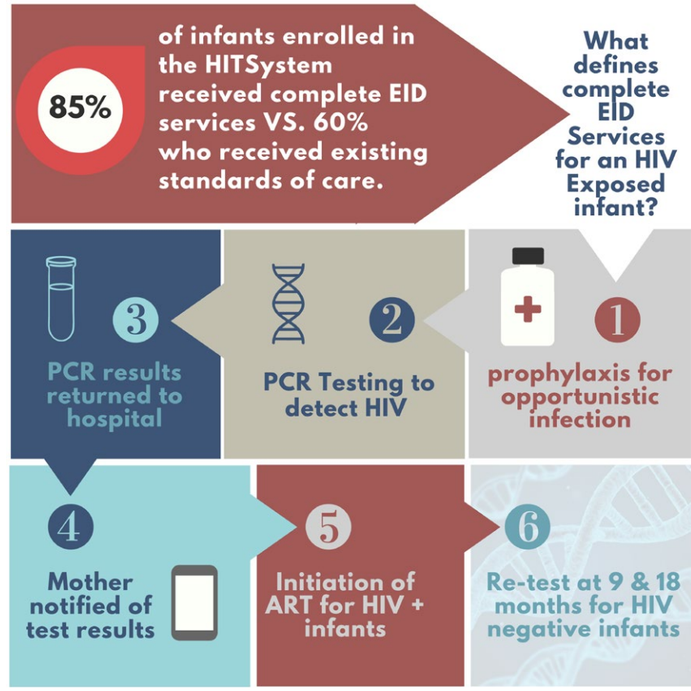
EVALUATING THE HITSYSTEM

Kessler and collaborators developed the idea for the study in 2012. At this time, the rate of mobile phone usage in Kenya was estimated at 75%. Evidence for mobile health (mHealth) interventions in the scientific literature were promising but scant. Findings from previous research had shown that HIV treatment outcomes could be improved with weekly text messages sent to adult patients. Early attempts to apply mHealth strategies to improve early infant diagnosis focused solely on reducing turnaround time for infant *polymerase chain reaction* (PCR) test results. At the time, an innovation commonly referred to as SMS printers could provide one-way communication from the laboratory to the health centre to expedite PCR results. However, no research had been published on interventions targeting clinical or patient outcomes for early infant diagnosis.

In order to address this gap in the literature, Kessler and colleagues designed a cluster-randomised trial to assess the efficacy of the HITSystem to improve key measures of early infant diagnosis quality and efficiency in Kenya. In cluster-randomised trials, groups (rather than individuals) are randomly assigned to receive an intervention or control condition. The HITSystem targets multiple clinical, laboratory, and participant engagement outcomes throughout the early infant diagnosis cascade of services. Evaluating the impact of this intervention requires determining if, and how quickly, all eligible services have been completed.

Kessler's team conducted their study at six government hospitals in Kenya. At three hospitals, they used the HITSystem to track participants. At the same time, participants from the three other hospitals were tracked using traditional methods. The HITSystem prompts immediate antiretroviral therapy for infants testing HIV-positive, to maximize the chance of survival. Alerts on the programme's dashboard allow health care providers to quickly identify infants who are overdue for testing or follow-up services. Events in the early infant diagnosis (EID) service sequence automatically trigger text messages to mothers, supporting timely clinic attendance with their infants. These communications help keep infants in the system until they are 18 months old, an age when they typically can be declared HIV-free.

The figure depicts the series of services indicated for HIV-exposed infants. The primary outcome for the study was receipt of complete EID services. This was an aggregate measure, meaning only infants who received each service in the cascade could be counted as receiving complete EID care. Missing one or more service would be categorised as incomplete EID.



In the study, the HITSystem group showed significant improvement in the proportion of infants completing the EID cascade (a range of HIV tests and possible treatments) throughout the 18-month time period compared to the control group (85% vs 60%). Furthermore, the study found that 100% of the HIV-positive infants in the HITSystem group were started on antiretroviral therapy (ART) compared to 72% in the control group. Testing turnaround times were also greatly improved, which resulted in earlier treatment for HIV-positive infants (17 vs 25 weeks of age).

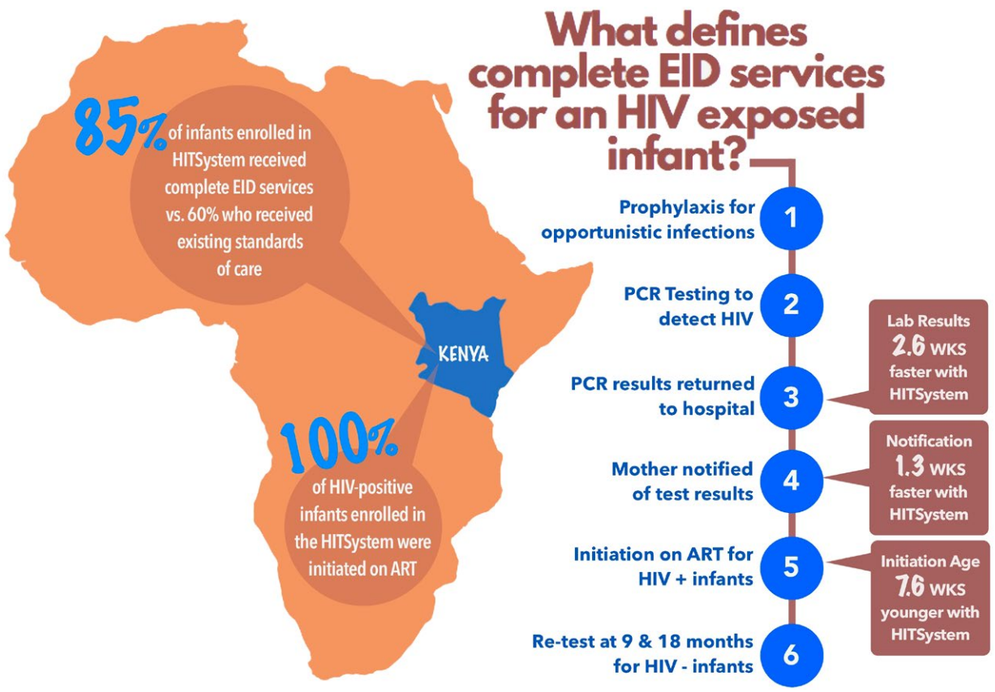
In addition to improving health outcomes, the programme is also able to help save money. By optimizing early diagnosis, retention for re-testing, and treatment when indicated, the intervention is highly cost-effective, based on World Health Organization standards. Currently, the system is in use in more than 40 hospitals across Kenya and nearly 250 facilities in Africa, including Tanzania, Malawi and Nigeria. Over 120,000 patients have been enrolled, and unlike routine data monitoring strategies, the HITSystem tracks linked data for mother and infant pairs to facilitate more integrated analysis of service uptake.

PILOTING AT-BIRTH POINT OF CARE HIV TESTING STRATEGIES

HIV-positive infants who do not start receiving ART by 12 weeks of age are at distinctly higher risk of dying. Under standard EID services built around lab-based PCR testing at 6 weeks, most HIV+ infants are older than 12 weeks when they first receive ART. Kenya's 2016 national EID guidelines provisionally recommended accelerating the process by engaging mothers and infants with PCR testing at birth. Kessler's team are among the first in the country actively piloting the implementation of PCR testing for newborns, a crucial step to facilitate countrywide scale-up. The study is also pilot testing the implementation of newly approved point-of-care (POC) HIV testing platforms in the clinic. The POC test technologies are aimed at further expediting diagnosis by bypassing the time-consuming steps of PCR testing at off-site laboratories, ideally enabling mothers to be notified of their infants' results before discharge from Maternity.

Kessler's pilot study, ongoing at four Kenyan hospitals, is designed to evaluate the acceptability of these very early HIV testing interventions for mothers and healthcare providers, and also gauge the feasibility and costs of incorporating the new practices and technology into the facilities' existing patient flow and infrastructure. Preliminary outcomes of birth PCR implementation are promising, showing that 55% of infants are engaged with PCR testing before 2 weeks of age. Turnaround times for birth PCR test results

It has been incredibly rewarding to be part of this team effort, partnering with so many passionate and committed people to improve maternal and pediatric HIV services in Kenya and beyond.



are similar to tests in the standard 6-week time point, so that median infant age at the return of results is about 3 weeks younger and over 90% of birth PCR results are available for mothers upon return for infant 6-week appointment. The preliminary data suggest birth PCR testing is feasible in Kenyan government hospitals. Furthermore, POC testing platforms for newborn and 6-week infants have demonstrated feasibility in the same contexts – approximately half of the infants received a POC test within the birth window. Adoption of these innovations requires collaboration and accountability among departments and cadres of personnel. Acceptability and implementation data from Kessler's study are highlighting key barriers and facilitators of uptake that will shape future efforts to expedite infant diagnosis and treatment across Kenya.

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ADAPTING THE HITSYSTEM TO SUPPORT PMTCT OUTCOMES

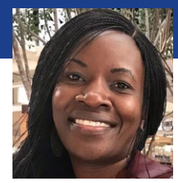
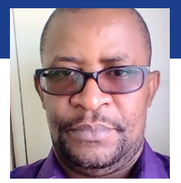
Kessler and her team have also modified the HITSystem to support prevention of mother to child transmission of HIV (PMTCT). This 2.0 version of the program enrols HIV positive pregnant women, tracks them through their pregnancy and then automatically links their HIV-exposed infants to EID services. Text messages are sent to mothers to support ART adherence, appointment attendance and hospital deliveries. Electronic alerts are sent to providers who can identify patients that need additional follow up. This programme is currently being piloted at two hospitals in Kenya. Key outcomes include PMTCT appointment attendance, ART adherence, hospital delivery and infant status at 6-weeks of age. So far, researchers have enrolled approximately 113 HIV positive pregnant women in the study. Kessler and colleagues have also applied for grant renewals that would allow them to introduce the HITSystem in several additional counties in Kenya. In addition, Gautney is leading the team in the development of a 3.0 version of the system which will track guideline-adherent treatment of HIV-positive children from infancy through adolescence to maximize clinical retention, health, and survival.

THE FUTURE

Kessler and her team make a valuable contribution not only to the research literature but also to improving maternal and paediatric services for thousands of families in Kenya and in several other countries in Africa. Their research has demonstrated that even in remote settings, Internet-based interventions are feasible, allowing for improved health outcomes and substantial cost savings. The work paves the way for greater implementation of health interventions in Kenya as well as in other countries with limited resources.

Behind the Research

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Research Objectives

Dr Kessler's research focuses on how to strengthen healthcare delivery in low resource settings to empower providers to deliver guideline-adherent care and to engage patients to improve retention and timely utilisation of services. While much of the science to prevent HIV is known, our team focuses on leveraging simple technology to facilitate the implementation of clinical best practices to optimize HIV outcomes.

Detail

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Bio

Finocchario-Kessler completed her International Public Health training at the Johns Hopkins Bloomberg School of Public Health. Her work focuses on the intersection of reproductive health and HIV prevention, including safer conception strategies for couples affected by HIV, preventing perinatal HIV transmission and improving early infant diagnosis of HIV-exposed infants.

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Personal Response

How has the HITSystem been received by both patients and health care providers?

"Many mothers shared their appreciation for better communication with the clinicians and a greater sense of engagement. They often commented that text message prompts to return to the clinic for test results helped relieve the anxiety of waiting weeks to find out their infant's HIV status. The providers also widely appreciated the HITSystem's capacity to simplify patient management and enhance communications with patients and testing laboratories. Achieving these critical services in a more efficient manner worked to everyone's advantage."