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Toward an Electronic Pregnancy Registry in The Gambia:

Linking up Maternal and Newborn Health Data Using the Smart Paper Technology

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Abstract

Smart Paper Technology, an innovative paper-to-digital system implemented at Bundung Maternal and Child Health Hospital in The Gambia links maternal and newborn health information with immunization records. In 9 months, Smart Paper Technology facilitated over 3500 mother–child connections, replacing traditional paper-based registers and ensuring DHIS2 interoperability. This pilot enhances reporting and data availability, advancing maternal vaccine safety surveillance in resource-limited settings.

Keywords

Smart Paper Technology; pregnancy registry; maternal and neonatal outcomes; electronic health information system; maternal vaccine safety surveillance

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The safety assessment of novel maternal vaccines, including the respiratory syncytial virus vaccine, approved for use in pregnancy by the U.S. Food and Drug Administration and European Medicines Agency, as well as those targeting Group B Streptococcus, will require a robust surveillance system to collect and assess adverse pregnancy outcomes and newborn events.¹ In low- and middle-income countries (LMICs), post-licensure safety data is typically obtained from spontaneous reports or through active surveillance, including prospective and retrospective cohort studies, pregnancy registries and other types of epidemiological study designs.^{2–5} Despite their significance in the post-marketing assessment of adverse events, these systems remain limited in the presence, scope and effectiveness.^{2,3,5,6} It is timely to strengthen data management within the context of routine clinical care to facilitate the appropriate collection and linkage of maternal and child health data. Traditional paper-based health management information systems (HMIS) in LMICs do collect routine facility-based information but may not be sufficient for maternal vaccine safety monitoring, as important maternal and neonatal variables are reported separately and only as aggregate data.² To address the need for high-quality, individual-level maternal and child health information in a linked manner, the Medical Research Council Unit The Gambia at the London School of Hygiene and Tropical Medicine (MRCG@LSHTM), in collaboration with the Ministry of Health The Gambia (MoH) and the Shifo Foundation,⁷ launched a project to pilot an electronic pregnancy registry in an antenatal care setting in The Gambia. Initiated in 2023, the project was rolled out at Bundung Maternal and Child Health (BMCH) Hospital, an urban secondary-level public health facility in the Western Region of the country. The registry development was built upon an innovative paper-to-digital technology called Smart Paper Technology (SPT), which had already been introduced into the Expanded Program for Immunization (EPI) as a replacement for the paper-based HMIS to digitize immunization information.⁸ This hybrid solution, developed by the Shifo Foundation,⁷ allows for paper-based individual-level data (e.g., vaccination records) to be scanned, automatically digitized, and uploaded onto an electronic data management system. The technology has gained international recognition, being adopted at varying scopes in countries like Afghanistan, Honduras, Haiti and Uganda, where it supports diverse health services, including primary healthcare, logistics management and results-based financing.⁹ This demonstrates SPT's versatility and scalability across different health system needs. In The Gambia, the solution was first introduced in 2016 into the EPI program and was initially piloted in 4 fixed and 14 outreach health service delivery points in the Western Regions.¹⁰ Following an external evaluation¹⁰ of data quality, administrative time efficiency, operating costs and user experience, the SPT system was scaled up nationally in all EPI clinics.¹¹ It is timely to expand this solution into the Reproductive, Maternal, Newborn and Child Health (RMNCH) program to link immunization records with maternal and child health information. This record linkage is essential for routinely collecting vaccine exposures along with important outcome information for pregnant women and infants, which is highly relevant to maternal vaccine safety surveillance. To identify safety-related events in The Gambia, a set of key maternal and neonatal outcomes (i.e., low birth weight, preterm birth, congenital malformation, neonatal death, maternal death and stillbirth) are prioritized in line with World Health Organization interest and Global Alignment of Immunization Safety Assessment in Pregnancy (GAIA) guidance.¹²

METHODOLOGY

The development of an electronic pregnancy registry at BMCH hospital builds upon the SPT solution already in use for immunization services. At the point-of-care, this novel hybrid technology continues to rely on the use of paper forms to collect information and is therefore not affected by electricity or internet connectivity issues. This enables countries to benefit from electronic HMIS despite their limited infrastructure. The SPT forms are data collection tools modeled after existing HMIS registers to capture essential health information. They are specifically designed to allow recognition of handwritten information. After data collection, the digitization process begins with scanning. Healthcare workers use either a dedicated scanning station, consisting of a scanner and laptop, or the SPT mobile application called MyShifo app, which uses smartphones as efficient scanning tools. On completion of the scanning process, the synchronization component of the solution ensures accurate routing of scanned forms, which then enter the digitization pipeline. During the pivotal phase, information written on the SPT forms is recognized using an intelligent handwriting recognition engine. The recognized information undergoes validation, serving as a quality control measure by assessing the data against predefined criteria to minimize errors and ensure data integrity. The system then uses machine learning for automatic corrections. The robust validation and autocorrection mechanism ensures that only valid data is passed to Clarity, a central repository for storing and managing SPT data. This guarantees the accuracy and reliability of healthcare data used for decision-making. Invalid information is presented to health workers or other authorized individuals for verification using a verification feature directly on their smartphones. All digitization stages result in detailed digital profiles with a person's biodata and healthcare history. The system works based on unique personal identifiers, linking collected data to individual records. In settings where national identification numbers have limited coverage and usability, the system generates unique SPT IDs, which are assigned to individuals at their first contact with a health facility using the SPT system. These IDs are copied onto client cards and used at any future health facility visit. Moreover, the SPT system offers compatibility for integration with other national systems, such as the District Health Information Software (DHIS2). The Clarity component of the SPT solution includes an interface to generate customized reports tailored to user requirements. This report builder allows MoH to generate monthly reports and connect each indicator with the corresponding DHIS2 dataset, enabling automatic monthly integration without additional manual steps. When new data variables are introduced, SPT forms can be customized or newly designed using the embedded form builder function with automatic setup for recognition, validation and autocorrection, eliminating the need for developer involvement. In addition, the SPT includes administrative functions to manage users and access rights. Authorized health workers can access data and view reports using the MyShifo app, a user-friendly SPT interface that can also be used for direct digital data entry.

RESULTS

The expansion of SPT into maternal and newborn health services at BMCH hospital began in July 2023. For a successful roll-out, it was crucial for all parties to be actively involved from the start and engaged in all aspects of the implementation, including planning,

development monitoring and evaluation. The involved parties included key representatives from MoH, MRCG@LSHTM, Shifo Foundation and CDC, as well as the CEO and staff members from the implementing facility. Bi-weekly meetings were held to discuss progress, challenges and the next steps. A Technical Working Group was formed at MoH, comprising members from the RMNCH, EPI, Directorate of Planning, HMIS, Information and Communication Technology, Monitoring & Evaluation, Quality Assurance and Health Financing departments. This group focused specifically on the technical aspects of the SPT implementation, including integration with DHIS2, and on continuously building capacity for all components of the SPT solution.

To adapt the SPT solution for maternal and newborn health services, the Shifo Foundation team joined BMCH staff in their daily activities to observe existing data flow and data collection processes, including the use of HMIS registers. Based on these observations, several approaches to designing SPT forms were considered to ensure easy adoption. All data variables required to capture antenatal, delivery, postnatal and maternal immunization information were retrieved from MoH and reviewed with senior epidemiologists from MRC@LSHTM and CDC to standardize terminology and ensure the capture of key variables for monitoring pregnancy outcomes and newborn events of interest. These variables include gestational age at birth, maternal and newborn complications, newborn sex, birth weight, newborn outcome (i.e., live birth, intrapartum stillbirth, antepartum stillbirth) and others. Drafts of the SPT forms were reviewed with BMCH staff during Clinical Unit Heads meetings, and practical sessions were held to practice filling out the forms and optimize them for usage. Based on the feedback received, final adjustments were made and approved by MoH, and the forms, as presented in Table, Supplemental Digital Content 1, <http://links.lww.com/INF/F987>, were printed (see Form, Supplemental Digital Content 2, <http://links.lww.com/INF/F988>).

To link maternal and infant records, the backend of the SPT solution was adjusted by Shifo Foundation developers to enable client-to-client connections. Using the SPT Registration Form, newborns are registered and issued an SPT ID as soon as they receive a health service, such as their first immunization or postnatal visit. The mother's SPT ID and contact information are also captured on the form, allowing the newborn's record to be linked with the mother's record within the client database (Clarity). This unique mother-child linkage facilitates the assessment of maternal and newborn outcomes and enables follow-up over time.

Before piloting at BMCH, the Technical Working Group set all EPI and RMNCH indicators required for monthly reporting within Clarity and connected them with relevant datasets in DHIS2 to enable automatic calculation and integration. Comprehensive training for BMCH staff introduced all aspects of the SPT solution, and a practical session was held to train on filling out the SPT forms. A scanning station was installed at the Medical Records office, and relevant staff members were trained on scanning and synchronizing SPT forms. Starting October 1, 2023, the HMIS registers for antenatal, delivery, postnatal and immunization services were replaced with SPT forms, and the use of the SPT solution was rolled out.

Within the first 9 months of the SPT implementation at BMCH (from October 1, 2023, to June 30, 2024), 3583 mother–child connections were established, linking EPI and RMNCH records. A total of 11,151 antenatal visits, 3785 delivery visits and 7770 postnatal visits for both mothers and newborns were captured using the SPT forms. Only 16 COVID-19 vaccinations were recorded in the system among pregnant women, of whom 4 delivered, and 1323 TD vaccinations among pregnant women, of whom 752 delivered. An additional report was created in Clarity to automatically generate data on prespecified key maternal and neonatal outcomes (Table, Supplemental Digital Content 3, <http://links.lww.com/INF/F989>).

DISCUSSION

The SPT system shows great promise for capturing and linking health information of pregnant women and their offspring following its pilot phase in The Gambia. By assigning a unique personal identifier, the system links collected data to individual records, allowing for the continuous building of medical history. Following its introduction to maternal and newborn health services, the BMCH hospital expanded the use of SPT to cover the entirety of primary health care, replacing over 30 existing HMIS registers. This system can therefore generate essential numerator and denominator information needed to calculate background rates, which can be used to monitor the safety of vaccines administered during pregnancy. Its interoperability with DHIS2 eliminates the need for manual reporting and ensures the availability of health facility data at the central level. Through its built-in reporting feature, SPT can identify multiple maternal and neonatal outcomes, including low birth weight, preterm birth, congenital malformations, neonatal death, maternal death and stillbirth. Essential data variables, such as gestational age, neonatal complications and vaccination status, can be directly extracted from the SPT central repository for further safety analysis and in-depth assessment, thereby reducing the burden of staff to collect similar data for additional surveillance systems.

The SPT pilot has been successfully rolled out in BMCH hospital, an urban secondary-level public health facility with well-established antenatal care settings. Before a national scale-up, it is desirable to evaluate the feasibility of extending SPT to more remote and resource-limited settings. The MoH and key stakeholders have decided to expand the use of SPT for maternal and child health services to a second designated public healthcare facility. This will be followed by a comprehensive qualitative and quantitative external evaluation to assess the uptake of the technology, gather user-feedback and review data quality. The findings will provide robust evidence to inform the potential nationwide roll-out of SPT into RMNCH services, with the prospect of eventually encompassing all primary healthcare services.

This decision must, however, be accompanied by consideration of other key technical and operational factors to determine the long-term sustainability of the solution. Previous studies^{13–15} in countries such as Uganda, Afghanistan, as well as The Gambia have assessed factors like cost-effectiveness, administrative time efficiency and the transition of work processes compared with conventional HMIS. These studies provide valuable insights into the feasibility of adopting SPT in resource-limited settings, suggesting that SPT is operationally more effective than traditional paper-based HMIS. In addition, the

standardization of SPT data collection tools and processes ensures that functionalities, such as the unique mother–infant record linkage developed during this pilot, can be easily replicated in other settings. This enables data comparability and strengthens the case for its potential application in other LMICs. However, the successful implementation of an electronic pregnancy registry requires context-specific considerations to address the specific needs of each country. Examining other existing pregnancy registry demonstration projects could provide valuable comparative insights. For example, the ScanForm¹⁶ technology used in Kenya as part of the Malaria in Mothers and Babies¹⁷ project generates robust safety data on antimalarials for treating acute malaria during pregnancy. Lessons from such initiatives could complement the findings of the SPT pilot and guide its broader application for safety monitoring.

The forthcoming introduction of novel vaccines in pregnancy will require additional efforts to generate appropriate data for safety monitoring within the context of routine clinical care. Revision of case definitions and the degree of diagnostic certainty needs to be considered to allow comparability of maternal and child health outcomes through standardize case definitions, for example, GAIA, MedDRA and ICD.^{1,6} The collection of vaccine-specific information, including manufacturer, batch number and expiry date was not a common practice for routinely administered vaccines before the introduction of SPT forms. Data collection guidelines will need to be reviewed, and health workers may require retraining as necessary.

In conclusion, the initial phase of the pregnancy registry demonstration project has shown promising results in implementing SPT within maternal and newborn health services in The Gambia. With a successful roll-out at BMCH hospital and the expansion to a second site underway, this project lays the foundation for a robust electronic pregnancy registry that links antenatal care with immunization data. Moving forward, continued collaboration and capacity building among MoH, MRCG@LSHTM, Shifo Foundation and other stakeholders will be crucial for scaling this innovative solution nationally, aiming to enhance the monitoring of key maternal and neonatal health outcomes through improved data management.

Limitations

This article focuses on describing the pilot initiative to expand the use of SPT into RMNCH services following its nationwide adoption for routine immunization in The Gambia. As such, it does not include detailed results on the performance of the established records linkage, or an in-depth assessment of the data quality produced by the technology. A comprehensive evaluation is currently underway to address the challenges and limitations faced during the initial pilot at BMCH hospital as well as at the second implementation site, Faji Kunda Major Health Centre, where SPT was introduced in July 2024. This evaluation consists of 2 components: (i) a qualitative component aimed at exploring the introduction, adaptation and uptake of SPT in maternal and infant services, and (ii) a quantitative component aimed at evaluating the quality of maternal and neonatal health data generated by the SPT system. This includes assessing the accuracy of digitized information, the completeness of key indicators for priority pregnancy outcomes, the timeliness and

completeness of reporting and the linkage of maternal and infant records. The findings from this evaluation will provide essential evidence to inform decisions on the potential wider roll-out of SPT.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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