

Methods: We undertook a mixed methods study combining a detailed data coding process of reports, a descriptive statistical analysis, and a thematic analysis of a theoretical and special-case sample of reports. An inductive, grounded approach was used to apply codes to each incident report from a codebook containing two distinct multi-axial coding frameworks to describe the type of safety incident (administration, medication, etc.) and contributory factors (patient, staff, environmental, etc.), as well as harm severity. Cross-tabulations identified relationships between incident types and contributory factors. New ideas and hypotheses emerged throughout each step of analysis for later corroboration. All reports of moderate harm, severe harm, or death were qualitatively analysed. Thematic analysis of reports provided in-depth contextual insights. Subject matter experts discussed findings and identified primary and secondary drivers for improvement and to raise recommendations for practice.

Findings: 1788 reports were identified with 765 (42.8%) describing harm to children. Priority areas (most harmful incidents) and common contributory factors were identified. Vaccine-delivery errors such as administering the wrong vaccine resulted from failures and discrepancies in documentation. Errors of medication provision such as prescribing were frequently the result of inadequate double-checking. Delays or failures to refer to hospitals were commonly underpinned by poor understanding of referral protocols. Treatment and procedure failures such as not providing lifesaving care identified further training needs of practitioners. Knowledge issues also underpinned diagnosis and assessment errors, for example diabetic emergencies. Qualitative analysis identified poor referral and treatment decisions in severely unwell or vulnerable children (e.g. under care of social services) as well as system several system failures contributing to a delayed diagnosis and assessment of such children; these featured prominently in incidents with severe harm outcomes.

Interpretation: The most frequent and severe sources of reported iatrogenic harm were identified. Priority areas to mitigate harm to children have been identified; in addition recommendations for improvement, include: improving processes relating to vaccine documentation; mandatory pediatric training for all family physicians; and utilizing human factors awareness to minimize mistakes in error-prone areas of practice. These recommendations for improvement can form the basis of improvement projects or initiatives, and collectively contribute to the design of logic models for further development and testing using improvement methods in clinical practice.

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Identifying drivers for improvement using a mixed methods analysis of pediatric vaccine-related safety incidents from England and Wales (2003-2013)

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Background: Immunization has saved millions of lives from vaccine-preventable disease worldwide. Around 14 million vaccines are administered to children annually in the UK alone. Benefits of immunization for the individual and the public are clear, and whilst

adverse reactions following vaccination are rare, little is known about the safety of their delivery. The aim of this study was to characterize immunization error-related incidents involving children in family practice reported to a national reporting system. The objective was to identify concepts and content of a change model for safer, effective, timely and equitable vaccine delivery to children.

Methods: A multi-axial coding (incident descriptors, contributory factors, harm outcomes) was applied to safety incident reports from family practice in England and Wales. Frequency distribution, cross-tabulation, discriminatory and cluster analyses explored the relationship between incident types and respective contributory factors. New ideas and hypotheses emerged throughout each step of analysis for later corroboration. 'Hunches' during the coding process were documented. A theoretical sample reports supporting and disconfirming these 'hunches' were selected for thematic analysis to provide in-depth contextual insights. Subject matter experts identified key primary and secondary drivers for improvement.

Findings: Most reports described harm (n=1070; 59.8%) including 3 deaths, 68 reports of moderate harm and 1009 reports of low harm. Failure of timely vaccination was the potential cause of three child deaths from meningitis and pneumonia, and described by a further 113 reports. Vaccine administration errors included the wrong number of doses (n=479), wrong vaccine (n=317), and wrong timing (n=177). Discrepancies between documents such as personal held records and child health records frequently contributed to these incidents. An empirical, grounded model summarizes opportunities to improve vaccine-delivery. Key components include process failures at the staff level such as making mistakes during vaccine delivery (e.g. confusing siblings for each other or selecting the wrong vaccine); the parent level such as failing to bring personal held vaccine records; and, the system level such as sending appointments for the wrong vaccine.

Interpretation: Recommendations for improvement are targeted at education, policy, manufacture and practice. Example recommendations include: creating a unified documentation system to prevent record discrepancies; encouraging a renewed commitment from vaccine manufacturers not to produce vaccines with similar packaging; and utilizing human factors awareness in practice to reduce administration mistakes. This is the largest analysis of vaccine-related pediatric safety incidents to date and demonstrates the value of utilizing incident reports to generate ideas for improvement. These recommendations can form the basis of improvement projects, and collectively contribute to the design of logic models for further development and testing using improvement methods. Important lessons for improvement and recommendations have been generated to mitigate harm to children.

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Mobile solutions for public health supply Chains

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Program/Project Purpose: In many countries, cumbersome paper-based information systems provide late or incomplete information about stock levels of health commodities at health facilities, making it difficult for program managers to make informed decisions about stock positioning and resupply. From 2010-2014, JSI has worked across several projects in Sub-Saharan Africa to develop and scale mobile technology to improve visibility of stock levels nationwide.

Structure/Method/Design: JSI has deployed three mobile supply chain solutions to improve visibility into stock availability at health facilities. The ILSGateway, operating on an open-source platform in all

public health facilities in Tanzania, is used by staff to report stock levels and receipts of essential medicines via SMS using their own phones. This information is analyzed and displayed on a web-based dashboard, where decision makers at higher levels of the supply chain access reports and monitor the functioning of the supply chain. In Malawi, under the cStock system, community health workers (CHWs) report stock on hand every month via SMS, after which the system calculates the amount that each CHW should be resupplied and sends this information to resupply points via SMS. In 9 countries, the End-Use Verification (EUV) activity is conducted under the President's Malaria Initiative (PMI), where survey teams from the Ministry of Health and other national programs use mobile phones on a quarterly basis to visit health facilities and collect patient and supply chain data that is used to provide actionable findings to decision makers.

Outcomes & Evaluation: All three mobile supply chain programs have achieved scale, with the ILSGateway in Tanzania now functioning in all 4600+ public health facilities, and cStock in Malawi scaled to all 3000+ CHWs. A mixed-methods midline evaluation in 2013 found that cStock notably improved community logistics data visibility and reduced stock outs. End Use Verification continues to be conducted every quarter in the countries listed, and has collected data from 10000+ site visits since 2009. The data collected in each system is routinely used to make better informed supply chain decisions, leading to better targeted use of scarce resources, and increased availability of vital health commodities.

Going Forward: As with all information systems in resource-challenged countries, ongoing sustainability is a challenge. High turnover rates among health facility staff require plans for ongoing refresher trainings. National budgets must be revised to include system main **Funding:** cStock was funded through a grant from the Bill and Melinda Gates Foundation, and is being maintained by WHO, Save the Children, UN Foundation, and USAID. The ILSGateway is funded by USAID, and the EUV is funded through USAID under PMI.

Abstract #: 02ITIS029

AfyaJamii: Introducing a group prenatal and postnatal care model in Kenya

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Program/Project Purpose: Focused Antenatal Care (ANC) is a pillar of Safe Motherhood strategies worldwide. Endorsed by the WHO in 2002, its focus on 4 ANC visits was introduced in Kenya as a strategy to improve the uptake and quality of health services in pregnancy. Although 92% of women report receiving skilled ANC in their pregnancy, fewer than half attend the 4 recommended visits (47%), deliver in a facility (43%), and just 35% receive any kind of postnatal checkup in the first 48 hours after birth. Community health workers see 0.3% of all women postnatally. The very unfocused way in which focused ANC is delivered, without attention to the contextual needs of pregnant women and the challenges faced by health centers, became the focus for change in 2013 for a large Primary Health Care program. The Academic Model Providing Access to Healthcare (AMPATH), in partnership with the Government of Kenya designed and implemented a Group Prenatal and Postnatal Care Model called AfyaJamii (Community Health) in 5 facilities in Busia County.

Structure/Method/Design: Each woman attending her first ANC appointment is registered into a group based on her expected date of delivery, and then, provided monthly appointment dates until her infant's

fourth month of life. To provide care jointly to 15-20 women, providers partner with local CHWs to ensure that women and infants receive comprehensive antenatal, postnatal, as well-childcare per guidelines during their 2-hour appointments. By task-shifting measurement of vitals and health education to CHWs and grouping women based on their EDD, over-extended providers in high volume and understaffed clinics are now able to ensure that all women receive enhanced care while capitalizing on the collective energy gained through the group meeting.

Outcomes & Evaluation: To date, 1158 mother-child pairs have participated in this new model of care. To evaluate the impact, acceptability and sustainability of AfyaJamii, we are using a mixed-methods evaluation strategy comparing data from 5 intervention sites and 10 control sites. We have found that uptake of 4 ANC visits, facility delivery, postnatal care and family planning has improved (final analysis to follow). Furthermore, providers and CHWs have expressed greater job satisfaction and less congestion in the clinic the rest of the week.

Going Forward: Harmonizing the postnatal visit schedule with immunization schedule has been the source of poor attendance postnatally. As a result, we have restructured the visits to 3 prenatal visits and 1 postnatal visit. We currently aim to scale this model of care a **Funding:** We received funding from Saving Lives at Birth and USAID PEPFAR.

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Detecting substandard pharmaceuticals through spectral finger-printing

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Background: Estimates suggest 30% to 50% of pharmaceuticals sold in global markets are falsified or substandard with low active ingredients or contaminants. Substandard pharmaceuticals lead to healthcare failures including, antibiotic resistance, increased morbidity and mortality, and loss of confidence in healthcare systems as individuals equate healthcare systems with negative outcomes of low-quality medications. This subsequently compounds existing challenges to improve global health. Pharmaceutical quality testing methodologies previously developed are aggregated in three categories: Supply-Chain Security (SCS), Laboratory Testing (LT), and Point-of-Care Testing (PoCT). SCS and LT have limited effectiveness in moderating proliferation of substandard pharmaceuticals due to inadequate government oversight of drug stock (SCS), or high marginal cost of testing (LT). PoCT methodologies are attractive alternatives as they empowerment local healthcare providers to assess local drug stocks. These are, however, not widely implemented, as witnessed in field visits, or yield low sensitive and specificity, limiting effectiveness. Western New England University's (WNE) Department of Industrial Engineering, in cooperation with the College of Pharmacy is developing a PoCT methodology intended to: 1) be transferable to frontiers of global health, 2) have minimal skill-based barriers to implementation, and 3) have near zero marginal cost of testing.

Methods: Proof of Concept The methodology leverages intrinsic absorbance profiles of pharmaceutical compounds across the visible light spectrum to determine if suspected samples contain anticipated compounds at labeled concentrations, and are free of unexpected substances (impurities). For this, a discrete set of wavelengths are