

**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 qualitative 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.

**Funding:** National Institute for Health Research HS&DR (project number 12/64/118).

**Abstract #:** 02ITIS027

### 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.

**Funding:** National Institute for Health Research HS&DR (project number 12/64/118).

**Abstract #:** 02ITIS028

### 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