

Oral Presentations

01 USING FUTILITY STUDY DESIGNS AND SAMPLE SIZE CALCULATIONS TO IMPROVE EARLY LABORATORY STUDIES

doi:10.1136/archdischild-2012-302724.0001

B Tilley. *Division of Biostatistics, University of Texas School of Public Health, Houston, TX, USA*

Futility designs have been used in Phase II human studies in cancer research for over thirty years. More recently the same designs have been applied in Phase II human studies in neurology. There has been little, if any application of these designs to laboratory studies. For initial laboratory experiments the sample size is often chosen as an n of 5, increasing the n a few more depending on observed results. Futility studies provide a more rigorous approach to determining the initial sample size for an experiment. To apply a futility design, investigators must have some knowledge of historical control rates in similar experiments in their laboratory, and must be able to specify the magnitude of an effect that would make an experiment worthwhile to pursue further. Using a futility approach to plan an initial laboratory study could reduce the chance of missing important effects that should be carried forward into more comprehensive experiments, and could reduce the chance of carrying forward experiments that have little likelihood of success. This session will present the concept of futility studies, provide laboratory-based examples, and discuss sample size calculation. At the end of the session participants should understand the concept of futility, be able to use standard software for sample size calculation, and be able to plan their own studies using a futility approach.

02 QUALITY IMPROVEMENT IN PEDIATRIC PRIMARY CARE

doi:10.1136/archdischild-2012-302724.0002

MR Massoud. *Quality and Performance Institute, University Research Co., LLC, Bethesda, MD, USA*

This session will address the issue of improving quality of pediatric care. It will emphasize pediatric primary care and draw on the experiences of the US Agency for International Development's Health Care Improvement Project in low and middle income economies. It will address the issue of quality in health care, the methodology for improving health care quality and use several examples to illustrate how improvements can be made and what results can be obtained. Following the session, participants will be able to:

1. Articulate what is meant by quality pediatric care.
2. Discuss the principles of improving health care quality.
3. Explain how to integrate discipline specific knowledge into the organization of care in order to improve quality of care.
4. Describe examples of quality improvement in pediatric primary care.

03 A DRAMATIC IMPROVEMENT OF THE QUALITY OF THE MEDICAL RECORD, USING THE INNOVATIVE COMPUTERIZED INFERENCE ALGORITHM TECHNOLOGY

doi:10.1136/archdischild-2012-302724.0003

¹N Yahagi, ²S Yokoya. ¹*Division of Advanced Clinical Research and Education; ²Department of Medical Subspecialties, National Center for Child Health and Development, Setagaya-ku, Japan*

Background and aims accurate knowledge of a Patient's medical problem is critical for clinical decision making, quality measurement, and clinical research. Common structured sources of problem information, include patient problem list and billing data; however, these sources are often inaccurate and incomplete. Innovative

computerized inference algorithm (ICIA) based decision support system was developed for Pediatric Primary Care in 2009. ICIA system will navigate Physicians; how to take patients' histories, what to write on physical examinations, and what to do for laboratory and medication. We evaluated the performance of ICIA technology by analyzing the quality of medical record data.

Methods We compared the quality of the manual chart (data used: before 2008) and the ICIA supported chart (data used: after 2010). The data used, were 1,000 randomly sampled from 100,000 patients' data, respectively. Each chart were scored by 3 physicians, who are highly trained and experienced in clinical research. The average score were used for analysis. Seven parameters (score) were defined as, clinical accuracy (0–10), legal accuracy (0–10), scientific accuracy (0–10), logical description (0–5), definition of terms (0–5), evidence based medicine (0–5), treatment plan (0–5) and total score (0–50).

Result The average of the total score was 38.0(±2.5) for the manual chart, and 43.0(±1.4) for the ICIA supported chart [P-value <0.001].

Conclusion The ICIA based decision support system improved the quality in medical record data, dramatically. The ICIA technology, from management sciences and engineering, will change the quality in patients' safety, clinical research and risk-management.

04 TRIALS OF IMPROVED PRACTICES - A PILOT STUDY EVALUATING THE ACCEPTABILITY AND PREFERENCES FOR A CHLORHEXIDINE CORD CARE INTERVENTION

doi:10.1136/archdischild-2012-302724.0004

¹S Sazawal, ²P Dhingra, ¹U Dhingra, ³A Dutta, ³SM Ali, ³S Ame, ²S Madhesiya, ³S Deb, ²S Gupta, ²A Ahmed, ¹RE Black. ¹*International Health, Johns Hopkins Bloomberg School of Public Health, Baltimore, Virgin Islands (U.S.); ²Center for Public Health Kinetics, New Delhi, India; ³Public Health Laboratory-IdC, Chake Chake Pemba, Zanzibar, Tanzania*

Background Chlorhexidine, a broad-spectrum topical antiseptic with strong residual activity, has a potential to reduce infections during the neonatal period. However, the challenge remains what would be the best mode to deliver the intervention. As a part of formative research, we evaluated three possible modes of chlorhexidine delivery i.e. 100ml bottle with cotton swab, 10ml single use dropper bottle and 3g single application squeeze tube containing gel, as an umbilical cord care intervention using Trials for Improved Practices (TIPS) methodology in preparation for a large double-blind randomized controlled trial evaluating the impact of chlorhexidine. in Pemba, Tanzania.

Methods 204 mother-newborn pairs were enrolled from hospital and community setting. Three different modes of application of intervention were tested (3 days for each preparation) in a cross over design. Mothers (on day 10), MCH, TBA and hospital staff was interviewed about their experience and feedback of their preference among the three delivery modes. Convenient and preference scores were calculated based on their feedback.

Results 97% mothers applied intervention for all 9 days. 10ml dropper bottle (49.7%) was rated as most convenient by the mothers, gel tube (32.2%) and 100ml bottle (19.8%). Mothers opted 10ml dropper bottle (44.6%) as their first choice over the 100ml bottle (21.5%) or gel tube (33.9%). MCH/hospital staff's choice was to use gel tube (84%) or 10ml dropper bottle (82%).

Conclusions Overall acceptability was high, in terms of convenience and preference 10ml dropper bottle was a winner. Based on their choice the 10ml dropper bottle was selected for RCT.

05 DIFFERENTIAL IN HEALTH-CARE SEEKING BEHAVIOR FOR MOTHERS VERSUS CHILDREN IN RURAL WESTERN INDIA

doi:10.1136/archdischild-2012-302724.0005