

# Harmonizing Terminology for Child Health Research

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## **Standard terminology is a fundamental step toward enabling interoperability among systems associated with pediatric clinical research**

- ▶ Child health research has evolved over the past 50 years into an accepted culture that is supported and taught in all parts of the world
- ▶ The current status is a robust but a highly fragmented enterprise that must compete for limited resources with other worthy endeavors
- ▶ A major goal is to transform the infrastructure into one with interoperable components to leverage the expertise but eliminate redundancies and improve efficiency

# The NICHD is involved in activities that support or influence data sharing for pediatric research

- ▶ Genome Wide Association Studies policy development with NIH
- ▶ Trans NIH Biomedical Informatics Committee with National Library of Medicine (NLM) and other Institutes and Centers (ICs)
- ▶ Trans NIH Information Technology Standards Subcommittee with NLM and other ICs
- ▶ Trans NIH Data Sharing Workgroup
- ▶ ClinicalTrials.gov with NLM and others
- ▶ Neonatal examination terminology prototype project with NCI and others
- ▶ Newborn Examination Data Harmonization and Use Case with HHS and others
- ▶ Value case for bridging research standards and health care delivery standards with HHS and others
- ▶ Methods of integrated analysis for pediatric research with CDISC, FDA and others
- ▶ Clinical Data Acquisition Standards Harmonization Collaborative Group with NIH, FDA and others

## The research community should focus efforts on harmonizing terminology rather than standardizing

- ▶ Words matter, and can only be understood with sufficient precision when referenced out of context
- ▶ The general framework for harmonization is to identify a concept, describe concept with a term, and then use the term to develop the concept in a context
- ▶ There are not enough words to capture all concepts - there will always be degeneracy
- ▶ Concepts continue to evolve
- ▶ Harmonization efforts should be based on established Use Cases

# Identifying and curating terminology is a systematic process that involves tools and workflows

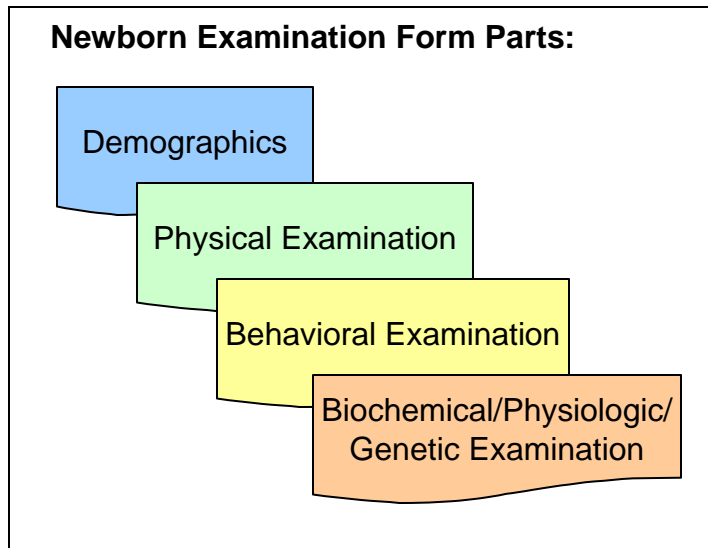
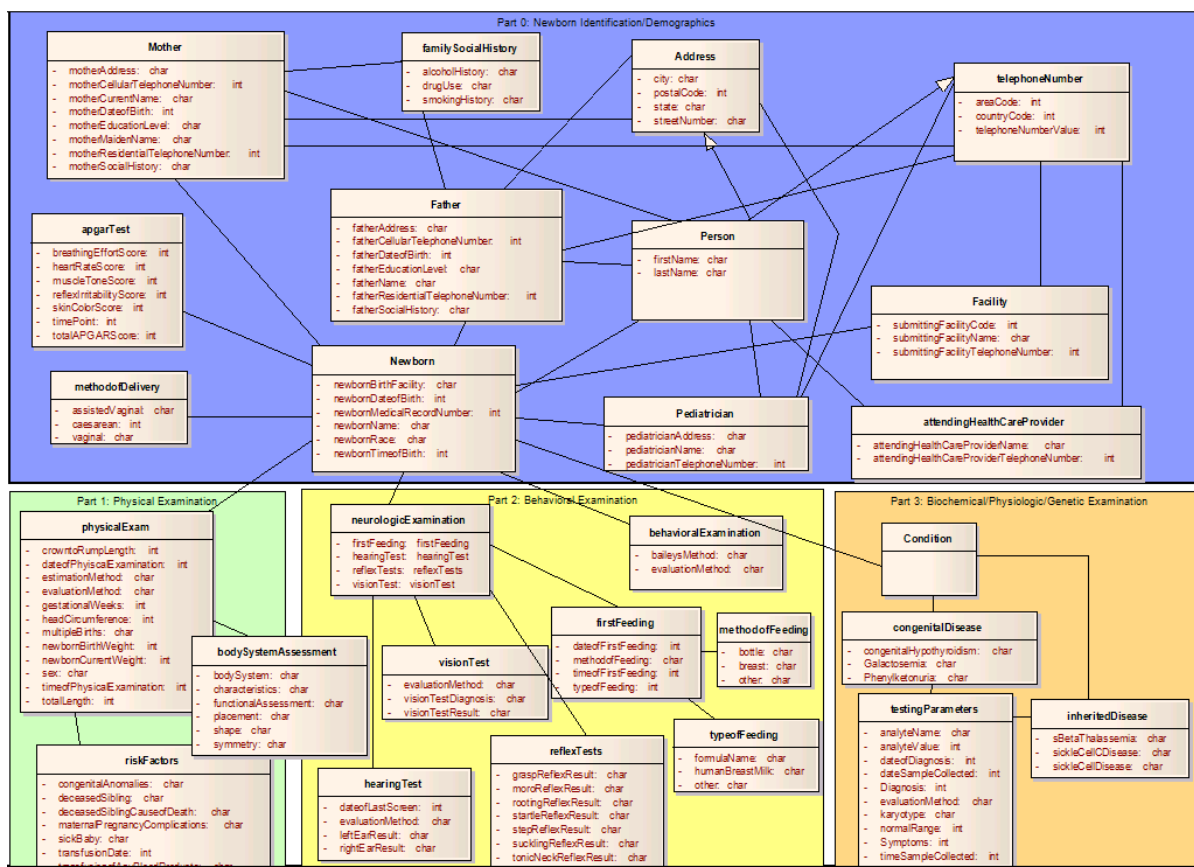


- ▶ Determine the terms that will require harmonization
- ▶ Identify which of the terms are unique concepts
- ▶ Reference terminology resources to find matching concepts
- ▶ Develop a model for concepts as a terminology that depicts concepts and their attributes and the relationships between concepts
- ▶ Prepare terminology to be incorporated into a reference terminology, such as the National Cancer Institute (NCI) Thesaurus
- ▶ Use terminology curation tools such as the NCI's Semantic Integration Workbench (SIW) to annotate the model with the reference terminology
- ▶ Load metadata from the Annotated Model to a metadata repository, such as the NCI's cancer Data Standards Repository (caDSR)
- ▶ Leverage open source clinical research tools to extract metadata to generate Standardized Lab Test Forms

# To facilitate data sharing and collaborative research, the NICHD initiated a prototype pediatric terminology project

- ▶ In January 2009, the NICHD charged a small team with beginning the process of developing a newborn examination form outline
- ▶ This form will help set a framework and process for developing standard terminology for research in newborns, and also in pediatrics
- ▶ The process for harmonization of the newborn examination form concepts includes:
  - Standardization and vetting of form concepts by the stakeholder community
  - Development of standard terminology to be used by the research community

# A model developed in the Unified Modeling Language (UML) can be used to map the concepts of interest and can be leveraged by modeling tools to efficiently and extensibly harmonize terminology



# The NICHD identified potential partners for the Newborn Examination Prototype Project as well as users of the terminology

- ▶ American Academy of Pediatrics (AAP)
- ▶ The Society for Pediatric Radiology (SPR)
- ▶ American Pediatric Society (APS)
- ▶ Society for Pediatric Research (SPR)
- ▶ American College of Medical Genetics (ACMG)
- ▶ American College of Obstetricians and Gynecologists (ACOG)
- ▶ American College of Cardiology (ACC)
- ▶ Centers for Disease Control and Prevention (CDC)
- ▶ U.S. Food and Drug Administration (FDA)
- ▶ The Association of Public Health Laboratories (APHL)
- ▶ American Academy of Family Physicians (AAFP)
- ▶ American Society of Human Genetics
- ▶ Society for Inherited Metabolic Disorders
- ▶ March of Dimes
- ▶ National Heart, Lung, and Blood Institute (NHLBI)
- ▶ National Institute of Neurological Disorders and Stroke (NINDS Common Data Elements Project)
- ▶ NCI Cancer Therapy Evaluation Program/Clinical Investigations Branch (CIB/CTEP)
- ▶ National Cancer Institute, Pediatric Oncology Branch
- ▶ Pediatric specialists involved in the Common Terminology Criteria for Adverse Events (CTCAE) Revision 3.0
- ▶ *Eunice Kennedy Shriver* National Institute of Child Health & Human Development (NICHD)
  - Center for Developmental Biology & Perinatal Medicine (CDBPM)
  - Newborn Screening Translational Research Network
  - Center for Research for Mothers & Children (CRMC), Obstetric & Pediatric Pharmacology (OPP) Branch
  - Division of Intramural Research (DIR), Program in Perinatal Research & Obstetrics

## Current Status and Future Directions

- ▶ An initial newborn examination prototype form and an associated model have been developed for community review and input, to be followed by terminology curation
- ▶ Multiple ethical, technical and process issues must be addressed
- ▶ Please contact Dr. Steven Hirschfeld, Associate Director for Clinical Research, NICHD, with any questions about or interest in providing input into the Newborn Examination Prototype effort