**Development of a Pediatric Adverse Events Terminology**

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**Abstract**

In 2009, the Eunice Kennedy Shriver National Institute of Child Health and Human   
Development (NICHD) established the Pediatric Terminology Harmonization Initiative to create a core library of terms to facilitate the acquisition and sharing of knowledge between pediatric clinical research, practice, and safety reporting. The goal of this effort is a better understanding of the factors that influence health throughout the stages of childhood by addressing the significant gaps among terminologies within their respective pediatric adverse event terms and by facilitating harmonization between established biomedical vocabularies. The Pediatric Terminology Adverse Event Working Group (AEWG) was established to develop a terminology relevant to international pediatric adverse event reporting. Sixty-two pediatric specialists with backgrounds in clinical care, research, safety reporting, and/or informatics participated in the AEWG. Supported by biomedical terminology experts from the National Cancer Institute’s Enterprise Vocabulary Services (NCI EVS), the multinational working group reviewed concepts (terms, synonyms, and definitions) from sixteen pediatric clinical domains. The Adverse Event (AE) Terminology contains over 1000 pediatric diseases, disorders, and/or clinical findings that meet the definitional criteria of an adverse event, adapted from the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). Advantages of the AE Terminology include ease of adoption due to integration with well-established and internationally accepted biomedical terminologies, a uniquely temporal focus on pediatric health and disease from conception through adolescence, and terms that are fit for use in both well- and under-resourced environments. The AE Terminology is available for use without restriction through NICHD and NCI EVS (http://evs.nci.nih.gov/ftp1/NICHD/About.html), and, as of 2015, is fully compatible with, and represented in, the Medical Dictionary for Regulatory Activities (MedDRA). It is expected that the terminology will mature with use, user feedback, and optimization.

**Introduction:**

Until recently, there was no unified, semantic authority to promote the development, use, and maintenance of terminologies specific to pediatric research and practice (Kahn 2014).In 2009, the Eunice Kennedy Shriver National Institute of Child Health and Human   
Development (NICHD) established the Pediatric Terminology Harmonization Initiative to assemble a core library of terms to address current terminology gaps, to facilitate harmonization between established biomedical vocabularies, and to ease the electronic transfer of data between systems.

Unique challenges are present in pediatric clinical research: patient populations are generally limited in size, long-term outcomes are difficult to evaluate as subjects grow into adulthood, and disease pathophysiology often varies at different stages of development (Forrest 2014, Field 2004). Children are particularly vulnerable to experiencing harm associated with medical intervention because developmental, stage-dependent variability in disease progression and response to therapy are significant risk factors for precipitating adverse events (Carleton 2006, Stephenson 2005, Matlow 2012). In addition, rates of potential adverse drug events are higher in pediatric patients than in adult populations for many reasons, including the added complexity of dosing medications based on weight (Kaushal, Bates, et al 2001, McPhillips, Stille 2005).

Until recently, there have been limited pediatric clinical safety research data for a multitude of reasons: few therapies have been tested and approved for specific use in children, difficulty in accessing outcome measures in pediatric populations, and a disproportionately high level of underreporting of adverse events in children versus adults (Kahn 2014, FDA Guidance, Stephenson 2005, and Carleton 2006). Though the National Cancer Institute’s Common Terminology Criteria for Adverse Events (CTCAE) is a widely utilized and comprehensive adverse event terminology, it does not have a pediatric-specific version, and is specifically focused on the particular toxicities associated with oncology and cancer treatments. (http://ctep.cancer.gov/protocolDevelopment/electronic\_applications/ctc.htm)

Initiatives, including the Best Pharmaceuticals for Children Act of 2002, and organizations, including the World Health Organization, the Gates Foundation, the European Medicines Evaluation Agency, and the International Conference on Harmonization, have recently brought new focus to the knowledge deficit concerning the safe and effective use of therapeutics in children, and have provided incentives for new studies (Spielberg 2010, http://bpca.nichd.nih.gov). However, data in pediatric clinical research and practice is often collected using project-specific methodologies, terms, and definitions. The result is the absence of a common terminology dedicated to pediatric adverse events, which is a major impediment to data exchange, reuse, and comparative analysis, potentially limiting the return on significant research investments (Kahn 2014, Padula 2012, http://www.research.chop.edu/blog/researchers-must-talk-talk-advance-science/).

In September 2012, the NICHD and the Pediatric Electronic Health Record Data Sharing Network (PEDSNet) co-sponsored a symposium entitled *Bridging the Terminology Gap in Pediatrics: Developing an Action Plan to Support the Continuum from Clinic to Research*. Over one hundred key stakeholders from government, academia, industry, and professional organizations participated in discussions focused on developing a framework for both a governance structure and a method for prioritizing the alignment of multiple pediatric terminology development projects across various clinical research domains (Kahn 2014). The NICHD Pediatric Terminology Harmonization Initiative Governance Model and Terminology Development Process was subsequently adopted by the NICHD governance committee, which was specifically created to identify opportunities for pediatric terminology development, to recruit and select clinical domain leaders, and to provide oversight, coordination, and evaluation of terminology development efforts. The goal of this effort was to improve the health of children globally by enabling clinical investigators to more readily compare and aggregate data across clinical research portfolios, to facilitate the acquisition and sharing of knowledge between pediatric clinical research studies and clinical practices, and to improve quality and safety reporting on an international level.

**Methods**

As an initial step in the terminology development process, the governance committee selected Pediatric Adverse Events, one of several child health domains of interest, to be the focus of one of several working groups. The governance committee decided to select a pediatric specialist to serve as the leader of each working group (working group lead or WGL), and based their selection on the specialist’s knowledge of the clinical domain of interest and their leadership ability. The WGL was responsible for recruiting individuals with clinical and/or informatics expertise in the domain of interest to participate in the working group (WG), either as a full member or as a subject matter expert (SME). The National Cancer Institute’s Enterprise Vocabulary Services (NCI EVS) terminology experts also participated in the WG to ensure adherence to best practices for terminology development and to facilitate communication and consistency between working groups.

The Adverse Event Working Group (AEWG) was formed to develop terminology that is applicable to international pediatric adverse event (AE) reporting in research, quality, and safety contexts. This diverse working group consisted of 62 subject matter experts from Australia, Canada, Germany, Italy, New Zealand, Great Britain, and the United States, with backgrounds in clinical care, research, safety reporting, and/or informatics. Subject matter experts were invited to participate in sub-domain specific review or for review of the entire terminology set, depending on their area of expertise.

The starter set of terms for the Pediatric AE Terminology WG was derived from multiple sources: the non-pediatric specific National Cancer Institute Common Terminology Criteria for Adverse Events (v4.0); NCIt NICHD Terminology; the FDA Adverse Event Reporting System (FAERS) Q12Q2-Q13Q1 and Vaccine Adverse Event Reporting System (VAERS) components of MedWatch; the Systematized Nomenclature of Medicine (SNOMED) and Medical Dictionary for Regulatory Activities (MedDRA) components of the 2013 AB release of the Unified Medical Language System (UMLS); and the International Classification of Diseases (ICD9, ICD10 and ICPD2P). Additionally, WG participants provided material for discussion from their clinical research, from the Vermont Oxford Network (VON), from the Pediatric Heart Network, and from the Global Research in Pediatrics Network (GRiP). The final terminology comprises pediatric diseases, disorders, and clinical findings that meet the definitional criteria of an adverse event as adapted from the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. (http://www.ich.org/fileadmin/Public\_Web\_Site/ICH\_Products/Guidelines/Efficacy/E2A/Step4/E2A\_Guideline.pdf)

The AEWG defined an AE as any untoward medical occurrence in a patient or clinical investigation subject that occurs in association with medical management, but which does not necessarily have a causal relationship with said management. Therefore, an AE can be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with medical management, regardless of whether said adverse event is causally related to the medical management. Medical management includes diagnostic, therapeutic, or preventive procedures, as well as the use of medicinal products, medical supplies, and/or medical equipment. An AE may or may not be preventable. Adverse events occurring in the perinatal and/or pediatric population, as well as maternal adverse events that directly affect the fetus or newborn were included in the terminology subset; AEs occurring exclusively in adult populations, as well as pregnancy related AEs that do not directly affect the fetus or newborn were excluded. Concept modifiers related to AE outcome status, relatedness, severity, and toxicity grade were also considered out of scope due to the absence of consistent, objective criteria that were broadly applicable. The terminology, developed in partnership with NCI EVS, is based on a developmental stage framework that follows the various child life stages from conception through adolescence (https://www.nichd.nih.gov/health/clinicalresearch/clinical-researchers/terminology/Pages/current.aspx).

Prior to the first AEWG meeting, draft lists of terms and associated synonyms related to the clinical domain of interest were compiled by the EVS terminology experts using data mining of primary sources (e.g. Case Report Forms, clinical trial data collection instruments, proceedings from standards organizations, published scientific literature, and existing biomedical terminologies), and draft definitions were created. The WG members and SMEs were asked to review the terminology set, to draft definitions, and to identify and submit any additional, relevant primary resource materials that could be used to eliminate gaps in the terminology.

WG meetings were conducted via web conference, generally on a weekly basis, to review the draft terms, synonyms, and definitions, all of which were accepted, deleted, or modified as necessary. As a result, highly specific definitions, which are flexible enough to be used internationally and in both high- and low-resource environments, were created. The WGL was responsible for management of the workflow, as well as asking the governance committee to adjudicate any unresolved issues.

Following completion of the initial draft AE terminology set, testing of the set was conducted using two existing, de-identified data sets. Data sets were provided from a single children’s hospital readmission file and from a single randomized clinical trial. Terms and concepts from these data files were mapped to the AE terminology set. Gaps in the terminology set were identified, and new terms were developed and added accordingly.

**Results**

After review by the AEWG members and SMEs, 1,338 terms and definitions were adopted. These terms were classified into clinical sub-domains for the purpose of organizing SME consultation. Those sub-domains include Cardiology, Constitutional, Dermatology, Endocrinology, Gastroenterology, Hematology/Oncology, Immunology/Rheumatology, Infectious disease, Metabolic, Miscellaneous, Nephrology/Urology, Neurology, Ophthalmology, Psychiatry, Pulmonary, and Surgical/Orthopedic. The domain information was not kept as part of the resulting terminology structure. Terms that fit multiple clinical domains were reviewed by SMEs from all relevant domains and were modified as necessary.

The AE Terminology underwent its first test case with a quality data set from a single children’s hospital. Using the electronic medical record, signs and symptoms leading to a patient’s readmission were abstracted, and the terms were compared to the AE terminology database. There were 1,889 unique admissions, comprising 3,335 terms, 811 of which were unique. When compared to the terminology database, there was a 66% match. To fill the gaps in the term set identified by this test case, new terms were generated for the AE terminology database, which added 150 new terms and 44 synonyms (Figure 1). Additionally, three new codelists from Clinical Data Interchange Standards (CDISC) were added to the Pediatric Terminology: Anatomical Locations, Directionality, and Laterality. The 811 unique terms were then compared to the revised AE terminology database (AEv2), producing a 94% match. Six percent of the quality data set terms were excluded because they were either too vague (e.g., “abnormal lab”) or anatomically inaccurate.

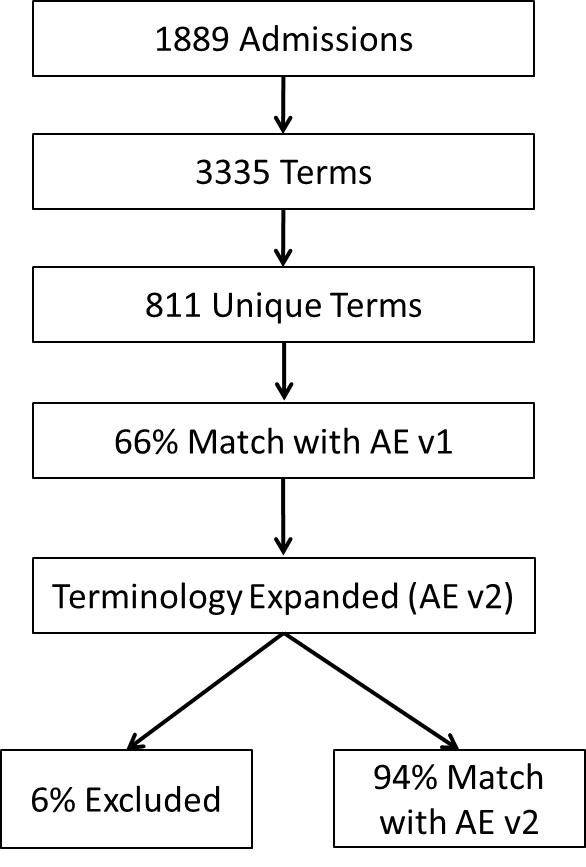
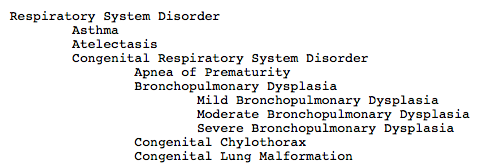


Fig.1 Terminology Mapping

The second test dataset was provided by NCT01941745, Efficacy of Recombinant Human Clara Cell 10 Protein (rhCC10) Administered to Premature Neonates With Respiratory Distress Syndrome. This was submitted by the Floating Hospital for Children at Tufts Medical Center. There were 226 terms in total, 68 of which were deemed unique. Eighty-one percent of the trial adverse events were matched to the Pediatric AE Terminology v1. The AE Terminology was then expanded to add 21 new terms/findings, which were included in AE Terminology version 2.0.

At the completion of the WG term review, the newly developed terminology underwent a rigorous quality control process, and the terms were integrated into an overarching NICHD Pediatric Terminology Harmonization Initiative hierarchical structure. The hierarchy was developed to reflect logical relationships between broader and narrower terms, to facilitate visualization of the terminology, and to assist with the identification of areas of incompleteness (Figure 2). Fig. 2 Pediatric Terminology Hierarchy

Descending levels of the hierarchy represent narrower or more specific subconcepts. Unlike ontologies without definitions, which rely on large poly-hierarchies, parent terms were assigned sparingly, as definitions provide a clearer picture of the concept intent. Following the creation of the hierarchy, the Working Group Lead asked select stakeholders to perform a review of the terminology subset. Subsequent to the external review, the terminology was published in the NCI Thesaurus (Sioutos 2007). The terminology is currently available for public access through the NCI Term Browser (https://nciterms.nci.nih.gov/) and the NCI ftp site (http://evs.nci.nih.gov/ftp1/NICHD/About.html). The Pediatric Adverse Events Terminology is provided in Excel and text formats. The entire NCI Thesaurus is available in Web Ontology Language (OWL) format, which can be loaded into Protégé, a public source ontology editor and framework product of Stanford University (protégé.stanford.edu). Documentation, including a summary of the contents of the terminology, information about the terminology development, information about terminology application in support of research studies, and details regarding the process for updating the terminology, is provided on the NCI Enterprise Vocabulary Services (EVS) homepage (http://evs.nci.nih.gov). Information specific to the Pediatric Terminology can be found on the Pediatric Terminology About page (https://evs.nci.nih.gov/ftp1/NICHD/About.html).

Finally, the participation of MedDRA representation throughout the process facilitated rapid incorporation of the terminology into MedDRA. To accurately represent the MedDRA terminology in the NCI Thesaurus, EVS added a feature to the NCI Thesaurus to represent mappings between terminologies at the concept level. This feature permits the addition of a relationship type between the terminologies, e.g. Maps To , as not all ontologies are developed with the same objective or possess a common level of granularity. This new property in the NCI Thesaurus will provide specific target terminology data and metadata, while also providing a relationship that indicates synonymy, the direction of granularity, or a concept note indicating that there is no appropriate match between identified concepts.

**Discussion**

Clinicians, researchers and regulators have been challenged by the lack of robust terminology resources designed specifically for children. The Pediatric Adverse Events Terminology is the result of international collaboration with a common goal to address this need by creating a universal working vocabulary for pediatric safety events. This freely available resource is intended for use in pediatric clinical research, quality and safety initiatives to foster data collection, aggregation, analysis and reporting.

The Pediatric Adverse Events Terminology is easily adoptable due to its compatibility with other well-established terminologies, such as MedDRA and SNOMED and alignment of concepts and terms. The Pediatric Terminology AE subset, which contains 1,388 unique concepts, has been harmonized with MedDRA. Implementation of the terminology for individual clinical studies, for registry development, and for incorporation into medical records is readily performed through the resources of the NCI Enterprise Vocabulary Services. The Pediatric Terminology is published as a freely available subset of the NCI Thesaurus, and is utilized in the creation of pediatric common data elements in the NCI Cancer Data Standards Registry and Repository (caDSR).

The initial testing of the Adverse Events terminology, which was set against existing safety and research data sets, generated important information. Of the concepts determined to be of sufficient specificity to be included in a terminology set, 76% were included in version one of the draft terminology set. Approximately nineteen percent were considered to be gaps in this initial terminology set, and new terms were developed and added into the currently published set to eliminate those gaps. A process of review and expansion of the adverse event terminology set has been established to facilitate continuous improvement; it is published on the following website: https://ncitermform.nci.nih.gov/ncitermform/?dictionary=NCI%20Thesaurus.

**Conclusion**

Terminology harmonization enhances communication between researchers and practitioners, ensuring that data meet established standards. This is a fundamental step toward enabling interoperability, which, based on the mapping and linkage between concepts, terms, and variables, allows for accurate information exchange between systems (Mead, 2006; Ohman and Kuchinke, 2009, Richesson and Nadkami, 2011, Padula 2012). It is this accurate exchange of information that facilitates data reuse, increases the value of the initial investment, and allows for new analyses, including meta-analyses, epidemiological analyses, and assessment of secular effects of general advances in healthcare. This form of enhanced collaboration provides significant opportunities for broadened scientific understanding through a common terminology for pediatric safety surveillance. Additionally, data mapping to established, widely used, existing terminologies can lead to further increases in research scale.

The Pediatric Terminology is dynamic, and updates are expected as additional use cases are identified and scientific knowledge increases. A framework for maintaining and tracking change requests, and for labeling successive versions of the terminology, has been established. A Listserv supported by the NIH is available for public subscription; it will notify members to both newly published material and to changes to existing terminology. See https://list.nih.gov to subscribe for updates to the NICHD listserv, which is titled: evs-nichd-terms-l.

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**Appendix**

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