Description of the immunization information database: a tool for investigating allegations made against childhood immunizations

Benjamin H. Levi[a,*], Georgia Brown[b,1]

[a] Departments of Pediatrics and Humanities, Penn State College of Medicine, 500 University Drive, Room C1743, Hershey, PA 17033, USA
[b] Health Evaluation Sciences Department, Penn State College of Medicine, 500 University Drive, Room C1743, Hershey, PA 17033, USA

Abstract

This paper describes the Immunization Information Database (IID). The IID is designed for cataloguing and systematically analyzing allegations that give rise to public concern regarding the safety, efficacy, and appropriateness of routine childhood immunizations. We describe the IID's eight data tables (*Immunization Type*; *Claim*; *Claim Basis*; *Claimant*; *Source Documentation*; *Source Type*; *Claim Analysis*; and *Claim Analysis Type)*, and explain how these tables function to create a conceptual map of existing allegations.
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1. Introduction

This paper describes the Immunization Information Database (IID), developed as part of the Penn State Immunization Project. The IID is designed for cataloguing and systematically analyzing allegations that give rise to public concern regarding the safety, efficacy, and appropriateness of routine childhood immunizations. (Note: throughout the IID as well as this paper, the term "claim" is used to refer to any documented allegation made *against* a routine childhood immunization.)

Established in 2000, the Penn State Immunization Project (PSIP) is an independent research project funded by the Children's Miracle Network and the Robert Wood Johnson Foundation, with no support from either the Federal government or any aspect of the pharmaceutical industry. The PSIP involves two components: (i) the Immunization Information Database and (ii) a CD-ROM tutorial, *Addressing Parents' Concerns about Childhood Immunizations*. Together, they are intended to help address parents' concerns regarding routine childhood immunizations.

Despite routine childhood immunizations' history of success in preventing serious infectious disease, [1,2] a growing segment of parents is resisting having their children immunized [3–6]. This resistance arises from several quarters, including alternative health beliefs [7–11], skepticism over the efficacy of vaccines [12], different risk assessments regarding the epidemiology and likelihood of contracting vaccine preventable illnesses [13], various religious and political convictions [14–16], and perhaps most prominently, concern about possible adverse events associated with vaccination [3,5,17–20].

In response to parents' concerns, the medical profession has stepped up efforts to provide reassurance regarding the safety and efficacy of routine childhood immunizations. These efforts have come primarily in the form of large epidemiologic studies and outcomes research, [21–25] buttressed by an independent review process (through the Institute of Medicine) of specific vaccines and/or allegations against them [26–30].

* Corresponding author. Tel.: +1 717 531 8778; fax: +1 717 531 3894.
E-mail addresses: bhlevi@psu.edu (B.H. Levi), gbrown@psu.edu (G. Brown).
[1] Tel.: +1 717 531 6849; fax: +1 717 531 3894.

Confounding these efforts, however, is the pace at which allegations proliferate. Books, newspaper and magazine articles, and electronic sources continually eclipse the slow, methodical response of scientific inquiry, and its publication through professional forums. Moreover, the fervent nature of many allegations concerning childhood immunizations often makes it difficult to conduct constructive dialogue about the benefits and risks associated with vaccination.

In an attempt to respond with greater agility to the wide scope of concerns, various organizations—notably, the National Network for Immunization Information (www.immunizationinfo.org/) and New Zealand's *Immunisation Advisory Centre* (www.imac.auckland.ac.nz/)—have created innovative websites that address frequently voiced concerns. But even these efforts are ill-equipped to redress the scores of allegations that, weekly, spring forth from a broad array of sources, including the Internet.

As one begins to examine the many concerns raised over routine childhood vaccinations, it becomes readily apparent that their pedigrees are quite variable, and that discerning the etiology of a given claim is often not at all straightforward.

We conjectured that a database that catalogued individual concerns and traced their origins could identify linkages between allegations and the published material cited to support various claims, and in doing so create a conceptual map of the universe of concerns being voiced. The Immunization Information Database (IID) has been built through exhaustive investigative library research, tracking down all source materials associated with individual claims against childhood immunizations. The IID is not a collection of previously developed databases.

The overarching goal of the Penn State Immunization Project is to help healthcare providers better understand the nature and origins of parents' resistance to routine childhood immunizations, as well as, develop effective and respectful ways of addressing parents' concerns. The IID contributes to this goal by placing these concerns in context and identifying their foundations.

2. Database design overview and description of supporting user application

The IID contains eight data tables: *Immunization Type*; *Claim*; *Claim Basis*; *Claimant*; *Source Documentation*; *Source Type*; *Claim Analysis*; and *Claim Analysis Type*. Table 1 details and summarizes their properties and their relationships to one another are represented in Fig. 1.

The IID is accessed through a browser-based intranet application developed with programming assistance from the Penn State College of Medicine Health Evaluation Sciences department. It is password protected so as to (i) allow viewing access only to pre-authorized individuals and (ii) require separate security authorization for actual data entry. The application is comprised of three distinct data management modules: Claim, Administration, and Claim Analysis.

2.1. Claim Module

The Claim Module is where all claims (after being identified in published material) are initially entered into the IID. This module catalogs the following five attributes of a claim (corresponding to data tables A–E in Table 1):

1. The type of immunization cited in the claim (identified from a pre-defined pick-list housed in the *Immunization Type* data table).
2. An abbreviated and full text description of the claim.
3. A claim basis type (a quick summary of the rationale(s) underlying the claim, selected from a pick-list of values housed in the *Claim Basis* type data table).
4. Who authored the allegation and their affiliation.
5. Citation information identifying where a claim was found.

If a new claim "fits" an existing abbreviated claim description (e.g., "DPT causes sudden infant death syndrome"), this text can be selected; if not, a new abbreviated claim is created, which then is added to the pick-list available for subsequent claims. With this construction, the IID can be searched along categories of abbreviated claims—for example, looking at all claims that share the abbreviated claim "DPT causes sudden infant death syndrome."

2.2. Administration Module

This component maintains the pre-defined values for various tables and forms used throughout the application.

2.3. Claim Analysis Module

Once a claim is entered into the database, it acquires an "open" status, and the investigation begins to find the "ultimate root source" from which it emanates. The Claim Analysis Module is the tool we use to catalogue and trace the path that leads from a primary claim to the ultimate root source. Usually, there are two or more references between a primary claim (as entered in the database) and the ultimate root source. These intermediary references are referred to as "root sources."

Typically, it is not until the ultimate root source is reached that substantive analysis of the underlying evidence for an allegation is actually possible. Prior to that, the investigative analysis will simply describe the data within a given root source as referencing a further root source, whereupon the next step is to investigate that subsequent root source. As before, this involves identifying the author of that next source, where it is located (*Source Documentation*), and its root level (*Source Type*), then examining the published material itself for evidence of the primary claim (or allegation). Clearly, the number of intervening root sources between the primary source and the ultimate root source determines how many such cycles of investigation (Fig. 1) will occur before the substantive, final claim analysis transpires.