Pediatric Endoscopy: New Information from the PEDS-CORI Project

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Introduction
Gastrointestinal endoscopy is a common diagnostic and therapeutic procedure in the United States [1•]. Until recently, little was known about why physicians performed endoscopy. In 1995, the Clinical Outcomes Research Initiative (CORI) began under the leadership of David Lieberman [1•]. The goal of the CORI project was to develop a national repository (ie, database or registry) of endoscopic procedures. This database could then be queried to determine the need, effectiveness, cost, and outcome of gastrointestinal endoscopy for the diagnosis and management of the spectrum of digestive diseases. Beginning with data collected on 200 endoscopies in 1996, the CORI database has grown to include over 800,000 procedures performed at 115 centers in 35 states in the United States and Canada.

However, what was missing in the CORI project was data on endoscopy in the pediatric population (ie, <18 years of age). Because the majority of third-party payers consider “lives” from birth to the grave, and the natural history of many common adult gastrointestinal diseases begins in childhood, a pediatric contribution (ie, specific component) to the database was critically needed.

Recognizing the need for a pediatric component of CORI, the Children’s Digestive Health and Nutrition Foundation (CDHNF) and the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition (NASPGHAN) developed a proposal with input from a scientific advisory board, comprised of pediatric gastroenterologists, epidemiologists, and outcomes researchers. This led to the creation of the Pediatric Endoscopy Database System–Clinical Outcomes Research Initiative (PEDS-CORI) in December 1999.

The specific aims of PEDS-CORI are twofold: 1) to develop and maintain a database of pediatric endoscopy procedures, and 2) to promote scientific inquiry into the need, efficacy, costs, and outcomes of pediatric endoscopy in North America. The purpose of the analysis reported here is to describe the breadth and character of pediatric endoscopy in North America using the PEDS-CORI database and to determine why endoscopy is performed in children.

Methods
The Pediatric Endoscopy Database System–Clinical Outcomes Research Initiative, accessible at http://www.peds-cori.org, uses software that is designed to capture key elements of every endoscopic procedure [2–4]. After a 1-year period of development and field testing, the database began to enroll pediatric gastroenterologists across North America, who agreed to obtain local investigational review board approval for the project at their respective institutions. All physicians enrolled agreed to use the database for endoscopy reports and to transmit the data to a central repository in Portland, OR and Houston, TX. Participating PEDS-CORI physicians also capture clinical information associated with each endoscopic procedure.

Practice sites are selected on the basis of interest in participation in endoscopic research, ability to obtain local institutional investigational review board approval,
practice type, and geographic location. The sites represent academic centers and private practices with both large (17 physicians) and small (two physicians) groups. A predominance of sites in the eastern United States mirrors physician distribution.

How PEDS-CORI Data Are Transmitted

Endoscopic reporting software

The endoscopist enters data into the program in the endoscopy office or suite. Procedure reports are created and can be printed as soon as the data entry is completed. The local site’s database is populated as the physician fills out the report in what is referred to as “real time” processing. This means that the CORI software records and saves information as the user enters it. The CORI software uses a different series of “Tables” to partition or separate portions of the data. Those considered identifiable, or private data (the “List” and “User” tables) are recorded and are separate from data that are void of any personal information (the “Data” tables); only the latter are sent to the national repository. Each week, a transmission file is automatically prepared by batching portions of the “Data” tables that have newly recorded information from procedures performed since the previous data transmission. Subsequently, the de-identified data are compressed or “zipped” (to make the overall size of the transmission file smaller) and then are “secured” (password-encrypted) using a 128-byte encryption method. This 128-byte code is equivalent to the level of encryption used by major banks, secure websites, and the US Department of Defense. This 128-byte code is considered the standard and is virtually impossible to decode or break. Once the encrypted data package is prepared electronically, it is ready to be sent to the CORI Central Repository (Oregon Health Sciences Center, Portland, OR), where it is decompressed and decoded, and combined with data already in the repository. As an additional measure to maintain data integrity and safety, the Gastrointestinal Procedures Suite at Texas Children’s Hospital (Houston, TX) also stores all pediatric data.

Central data repository

The transmission file is sent using a modem, or over the Internet using “FTP” (file transfer protocol), to secure host servers at CORI central. The data are backed up and stored in duplicate to ensure safe and durable storage. The transmitted file is unpacked and automatically screened for obvious problems in completeness or quality, using predetermined screening processes developed by the CORI Research Committee (www.cori.org).

Data and research services

CORI’s team of data analysts performs bimonthly monitoring of the data. Many of the screening procedures validate the data by checking for completeness and accuracy and by deleting any procedures that do not meet the very stringent requirements. A complete procedure report for entry into the central repository includes the following minimal data set: unidentifiable patient information such as age, race, and gender and the type of specific procedure performed; the indications leading to the procedure; the findings of the procedure; and whether any unplanned interventions or complications occurred during the procedure. These critical elements must be in each report for it to be considered “complete.” Complete reports are saved in a new table and eventually forwarded to the end user. The CORI research staff can create and build data collection forms for ongoing, current clinical trials (which require individual patient consent for that study and institutional review board protocol submission at each participating site). The data transmitted from ongoing clinical trials are encrypted and sent in the same manner described previously.

Data and research requests

PEDS-CORI participants and other researchers are encouraged to conduct research using the shared CORI and PEDS-CORI data repository. Each request is reviewed by the PEDS-CORI Research Committee to ensure that the question being asked can be answered, has merit and quality, and has not been previously queried. Once the request is approved by the Research and Steering Committee, the data are queried, collected from the repository, and prepared as requested by the investigator.

Patient and Practitioner Confidentiality and Health Insurance Portability and Privacy Act (HIPAA) compliance

Patient and practitioner information is protected in the following ways: Any personal information is scrubbed or removed and made unidentifiable before being loaded for shipping (ie, electronic transmission) to the CORI repository. All information, as specified by HIPAA requirements, that can identify a patient and/or practitioner, including name, address, phone or fax numbers, date of birth, medical record number, and so forth are completely removed from the patient record. Only a special encrypted number identifies each patient. This number is designed to allow patients and practitioners to be uniquely identified across sites, while preserving anonymity. To do this, social security numbers (SSN) are used as a starting “seed” for the encryption process. For pediatric patients, a random number is generated to replace the SSN seed. When used locally at each site, the actual SSN is scrubbed from the record as part of the de-identification process described previously. For practitioners, the SSN seed is used to create the CORI staff number, and once this is accomplished, the SSN is discarded. The end user, or third-party receiver of any data, once approved after submission of data request, never receives any of these coding numbers or materials. Any and all staff members at