

# The opportunities and obstacles in developing a vascular birthmark database for clinical and research use

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VK Sharma, FOG Fraulin, AR Harrop, DF McPhalen. The opportunities and obstacles in developing a vascular birthmark database for clinical and research use. *Can J Plast Surg* 2011;19(4):122-124.

**INTRODUCTION:** Databases are useful tools in clinical settings. The authors review the benefits and challenges associated with the development and implementation of an efficient electronic database for the multidisciplinary Vascular Birthmark Clinic at the Alberta Children's Hospital, Calgary, Alberta.

**METHODS:** The content and structure of the database were designed using the technical expertise of a data analyst from the Calgary Health Region. Relevant clinical and demographic data fields were included with the goal of documenting ongoing care of individual patients, and facilitating future epidemiological studies of this patient population. After completion of this database, 10 challenges encountered during development were retrospectively identified. Practical solutions for these challenges are presented.

**RESULTS:** The challenges identified during the database development process included: identification of relevant data fields; balancing simplicity and user-friendliness with complexity and comprehensive data storage; database expertise versus clinical expertise; software platform selection; linkage of data from the previous spreadsheet to a new data management system; ethics approval for the development of the database and its utilization for research studies; ensuring privacy and limited access to the database; integration of digital photographs into the database; adoption of the database by support staff in the clinic; and maintaining up-to-date entries in the database.

**CONCLUSIONS:** There are several challenges involved in the development of a useful and efficient clinical database. Awareness of these potential obstacles, in advance, may simplify the development of clinical databases by others in various surgical settings.

**Key Words:** Database; Development; Epidemiological studies; Vascular birthmark

Vascular birthmarks are common pediatric conditions, and include hemangiomas and vascular malformations. The Vascular Birthmark Clinic at the Alberta Children's Hospital (Calgary, Alberta) was established in 1997 as Canada's first comprehensive vascular birthmark clinic (1).

With the ever-increasing clinical caseload, the multidisciplinary team became interested in developing a well-designed, centralized database. The aim of the database was to accurately record clinical information related to these patients specifically. The goals were to facilitate accurate electronic patient records; clinical decision making; quality assurance; continuity of care between multidisciplinary team members; improved clinic efficiency; and answering of clinical research questions.

A database for the collection and storage of information is an asset to a large health care centre. It permits retrospective epidemiological analysis of a variety of parameters in an organized and methodical fashion. There has been significant progress in the development and use of health care databases, and there are several strengths with respect to their applications (2). They enable the study of rare events as a result of their large sizes. Additionally, databases provide up-to-date information

## Les possibilités et les obstacles dans l'élaboration d'une base de données des angiomes vasculaires pour des besoins cliniques et de recherche

**INTRODUCTION :** Les bases de données sont des outils utiles en milieu clinique. Les auteurs passent en revue les avantages et les problèmes associés à l'élaboration et à l'adoption d'une base de données électronique efficace à l'intention de la clinique multidisciplinaire des angiomes vasculaires de l'Alberta Children's Hospital de Calgary, en Alberta.

**MÉTHODOLOGIE :** Le contenu et la structure de la base de données ont été conçus grâce aux compétences techniques d'un analyste de données de la région régionale de la santé de la région de Calgary. Les champs de données cliniques et démographiques pertinents ont été inclus afin d'étayer les soins continus de chaque patient et de faciliter les futures études épidémiologiques de cette population de patients. Une fois la base de données montée, on a déterminé rétrospectivement dix problèmes affrontés pendant son élaboration. Des solutions pratiques pour les vaincre sont présentées.

**RÉSULTATS :** Les problèmes relevés pendant le processus d'élaboration de la base de données s'établissaient comme suit : détermination des champs de données pertinents; équilibre entre, d'une part, la simplicité et la convivialité et, d'autre part, l'entreposage complet des données; compétences à l'égard des bases de données par rapport aux compétences cliniques; sélection de la plateforme logicielle; lien entre les données tirées du tableur antérieur et un nouveau système de gestion des données; approbation éthique pour l'élaboration de la base de données et son utilisation dans le cadre de recherches; garantie du respect de la vie privée et de l'accès limité à la base de données; intégration de photographies numériques à la base de données; adoption de la base de données par le personnel de soutien de la clinique et tenue à jour des saisies dans la base de données.

**CONCLUSIONS :** Plusieurs problèmes sont liés à l'élaboration d'une base de données cliniques utile et efficace. La sensibilisation préalable à ces obstacles potentiels peut simplifier l'élaboration de bases de données par d'autres intervenants de divers milieux chirurgicaux.

about the current clinical care offered and demonstrate real-world effectiveness of therapies. Because of their relatively low cost and easy access, clinical epidemiologists can ask a plethora of research questions, with rapid return of answers in a cost-effective manner.

The purpose of the present study was to identify the challenges associated with the development and implementation of an efficient electronic database for the Vascular Birthmark Clinic at the Alberta Children's Hospital.

## METHODS

The database was designed with the goal of developing a tool to catalogue information related to the vascular birthmark, including details of diagnosis and management, in a centralized, user-friendly system. A data analyst, employed by the department of surgery, assisted with construction and maintenance of the database. The clinic surgeons facilitated its design, content and structure based on clinical utility. The analyst then translated this information into a functional database entity accessible on the Calgary Health Region's intranet webpage. Relevant clinical and demographic fields were included and multiple revisions were required during the evolution of the database.

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Ideal components of the user interface in this database included the following:

- a reliable input system to record data in a secure, limited-access fashion;
- accessibility from any computer within the Calgary Health Region;
- unique username and password logins to maintain security and track data entry progress;
- user-friendliness with drop-down boxes, item selections and checkboxes;
- the ability to generate summary sheets for entered data;
- the ability to edit previously entered data;
- the ability to make changes in the database infrastructure in a user-friendly manner (by an appropriate administrator);
- the ability to perform queries on data entries using whole or part of a patient name or identification numbers;
- the ability to attach digital photographs of patients' birthmarks to database records;
- the ability to obtain data reports based on specific search criteria; and
- the implementation of the database into practical use relying on the currently available clinic staff and resources.

The completed database has now been in use for eight months. A retrospective identification of the challenges involved in its development and the solutions to overcome these challenges was subsequently performed on completion.

## RESULTS

Ten challenges were identified in the development of the database.

### 1. Identification of relevant data fields to be included in the database

One of the first challenges encountered was the identification of relevant information to be included in the database. It was simple enough to propose that all aspects of a patient's history and physical examination findings be recorded electronically, without any consideration of the utility of this information or the practicality of inputting and managing such a large amount of data. It was, therefore, essential that the group of plastic surgeons involved in the Vascular Birthmark Clinic discussed which factors were important to record for the purposes of patient care and future data analyses. Initially, tracking the lesion sizes and considering their evolution at each clinical visit was believed to be important. It was soon discovered that in many cases, it was quite difficult to assess the lesion size accurately. Often, there were little new clinical data from visit to visit. Instead, it was decided that important changes in patient management should be summarized rather than detailing each visit.

### 2. Balancing simplicity and user-friendliness with complexity and comprehensive data storage

It became apparent that balance needed to be reached between keeping the database simple, efficient, user-friendly and manageable while still considering other factors such as comprehensiveness, dynamicity, sophistication and breadth of data. The establishment of the database, therefore, required multiple revisions of data input strategies and attempts to consolidate information in a reasonable fashion. It is important to ensure that relevant variables were recorded, without measuring superfluous parameters.

### 3. Database expertise versus clinical expertise

In developing this database, it became evident that both clinical expertise and database expertise were necessary to the success of the setup. The data analyst who helped with the actual programming of the database did not have much insight into the medical jargon and clinical context for which the system was being designed. Similarly, the clinicians had little understanding of the time-consuming effort required to design the system in an appropriate computer language, and to test its functioning for errors and glitches. Clear and frequent

communication was, therefore, necessary between those with clinical expertise and those with database expertise.

### 4. Software platform selection

Before database development, much of the clinical and clerical data were stored in a very basic Excel (Microsoft Corporation, USA) spreadsheet that was accessible at only one computer, and whose data were entered and retrieved by only one person. Although such a system is simple to build and use, it lacks much of the more sophisticated features that a professionally developed database may offer. At the same time, establishing an Oracle (Oracle Corporation, USA)-based database required the skills of a database expert, and the need for frequent modifications and glitch-testing. Even minor alterations required direct input from the database expert. Other software platforms considered included Access (Microsoft Corporation, USA), which was simpler to use and maintain; however, it lacked some of the more complex features of being shared on a network, having unique login usernames and tracking of data entries. It was also less amenable to specific design for a Vascular Birthmark Clinic.

### 5. Linkage of data from the previous administrative Excel spreadsheet to the new Oracle system

The next challenge involved the mass transfer of data from the Excel spreadsheet to the new database to populate the new resource with data from previous patient encounters. The Oracle-based database contained many new data fields that were not present in the older system. The database consultant helped with this importation by linking old parameters to new fields. Additionally, the clinicians had to monitor for any errors in the data transfer, and enter clinical information into the missing fields contained in the new database.

### 6. Ethics approval for the development of the database and its utilization for research studies

Ethics approval was required and obtained for the design and implementation of the database for the Vascular Birthmark Clinic. Additional ethics approval is required to use the information for clinical research studies. Because obtaining ethics approval can be lengthy, it is advised that this process be started early to avoid unnecessary delays in project design.

### 7. Ensuring privacy and limited access to the database

Because the database contains large volumes of confidential patient information, including patient demographics, photographs and treatment plans, it was crucial that such information be heavily protected from unapproved access. Developing methods to ensure data privacy was also essential for ethics approval. To access the database to enter or retrieve data, a user must have a preauthorized username and password before access can be granted. Each time a user logs into the database, his or her individual username, the date and time are all recorded at the bottom of each patient record. Additionally, any changes to patient records are noted when the user saves his or her modifications. These efforts were designed to ensure that patient data were being accessed and modified only by approved individuals. As a final measure of privacy, the database is hosted on the Calgary Health Region's internal website, which is accessible with appropriate usernames and passwords for internal website access. Together, these measures ensure patient privacy within the database.

### 8. Integration of digital photographs into the database

From the beginning of the development of the Vascular Birthmark Database, it was deemed essential that digital photographs of patients' birthmarks be linked to their records. Before the outset of this database development project, digital photographs were taken by a professional photographer employed by the Calgary Health Region, and the images were stored on a secure computer server. These digital photographs were then printed and attached to the patients' charts to follow lesion progression. The database has implemented a feature to enable uploading of these digital photographs to the patient's electronic data record. This allows for

birthmark progress to be viewed via the database, without the need for printing hard copy photographs to include in the patient charts.

### 9. Adoption of the database by support staff in the clinic

Perhaps the greatest challenge encountered in the database project was adoption of the database by all clinic staff. Change can be difficult to implement in the organization of a clinic, especially when there are multiple disciplines and support staff involved in its operation. It is essential that all members of the clinic understand how to use the database and recognize its value for it to be fully utilized. Furthermore, it was critical that data could be entered using existing resources and infrastructure, without the need to seek additional staff or significantly increase the workload of the existing staff members.

### 10. Maintaining accurate, up-to-date entries into the database and using it each clinic day

The final challenge in developing the Vascular Birthmark Database was ensuring that data entries are regularly entered into the system. The utility of the database is limited by the data it contains. Querying the database for research purposes relies on accurate and up-to-date information stored within the patient records. On the other hand, the database offers the potential advantage of improving clinic efficiency if used regularly. Hard-copy forms were created for the plastic surgeons to use during clinic visits to record patient progress. These data can then be entered into the database by an administrative assistant who works in the clinic. Following the initial patient visit and entry of the pertinent information into the database, subsequent clinic visits often require only minor additions to the patient's electronic record. This process is further simplified with the use of checkboxes and drop-down menus wherever possible in the graphical user interface.

## DISCUSSION

Databases offer numerous opportunities with respect to accurately tracking important clinical information for future analysis. In the United Kingdom, a research database exists as a medical resource designed for epidemiological research primarily addressing drug safety issues. Hundreds of scientific articles have been published using this database, and evaluations have confirmed its quality, completeness and validity, establishing this valuable resource as an important research tool (3). A review of various administrative databases in the United States, Canada and Europe has shown that observational database studies are powerful modern tools for providing crucial data (4). It has also been noted that the data can be more representative of a whole population and that studies can be conducted more quickly, are less expensive and are less prone to selection bias as a result of database collection systems. A number of other authors have used modern database technology to assist with clinical studies and note that the use of such a database can facilitate research and quality assurance (5,6).

Even as early as 1994, databases were recognized as being important tools in the realm of plastic surgery (7). A retrospective observational study examining the surgical treatment and outcomes of malignant melanoma by dermatologists, general surgeons, plastic surgeons and general practitioners was conducted with the help of a modern database that records information including clinicopathological features, surgical treatment and follow up information (8). This study represents an efficient method of assessing the management of skin lesions by various specialists through the use of database technology. With the recent establishment of the Vascular Birthmark Database, a similar type of research study may be conducted in the near future, enabling us to closely study the behaviour and treatment of vascular birthmarks.

While the benefits of such an electronic tool have been established, it is equally important to recognize the obstacles involved in developing such a resource. It can be challenging to choose relevant data fields to include in a database designed on an appropriate software platform that maintains practicality without compromising the inclusion of detail. There are challenges involved in transferring data from

old data tracking systems to new ones that require database expertise and the cooperation of clinic staff. Obtaining ethics approval, ensuring patient privacy and incorporating digital photographs are all further important considerations that should be anticipated in the establishment of a quality database. Finally, once constructed, the utility of such a database is largely dependent on its regular use and input of current and accurate data as it becomes available through clinical encounters.

Ultimately, a database for a multidisciplinary facility, such as the Vascular Birthmark Clinic, represents an invaluable technological tool with potential for improving patient data organization, integrating digital photographs with text data fields, developing future clinical studies and improving clinic efficiency. Ten important challenges in the development of such a clinical database are identified herein. An awareness of these obstacles in advance can facilitate the establishment of a comprehensive, yet user-friendly, clinical database that is well worth the effort.

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**ACKNOWLEDGEMENTS:** This project was supported by a grant from the Calgary Surgical Research Development Fund. The authors also acknowledge Huijin Yu, the data analyst employed by the Department of Surgery, University of Calgary who was instrumental in helping to create this database.

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**DISCLOSURES:** None of the authors have any financial interest in this project or in the production of this article. The Oracle database platform produced by Oracle Corporation is the only product used in this article. The authors have no commercial associations or financial disclosures that pose any conflict of interest with information presented in this article.

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This article was presented at the following meetings: The 63rd Annual Meeting of the Canadian Society of Plastic Surgery in Kelowna, British Columbia, on June 20, 2009; The 27th Annual Surgeons' Day Research Symposium in Calgary, Alberta, on June 26, 2009; and The 1<sup>st</sup> Annual Leaders in Medicine Research Symposium in Calgary, Alberta, on November 20, 2009.

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**CONFLICTS OF INTEREST:** None of the authors has any commercial associations or other arrangements (financial compensation received, patient-licensing arrangements, potential to profit, consultancy, stock ownership, etc) that pose a conflict of interest in connection with this article.

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