

# Process of and Problems in Changing a Birth Defects Registry Reporting System

CHARLOTTE DRUSCHEL,\* MONICA SHARPE-STIMAC AND PHILIP CROSS

*Congenital Malformations Registry, New York State Department of Health, Troy NY 12180–2216*

## ABSTRACT

**Background:** The New York State (NYS) Department of Health (DOH) Congenital Malformations Registry (CMR), which began operations in 1982, was developed after the Love Canal crisis. New York hospitals are mandated to report children under age 2 years in whom a congenital anomaly is diagnosed. The CMR has tried to maintain a quality birth defects registry by using identifiers; narrative for defects; and completeness and accuracy, balanced with timeliness. In recent years, the existence of the registry has been questioned, and the NYS DOH evaluated the CMR to streamline it and to reduce the reporting burden on the hospitals.

**Methods:** Because NYS hospitals were already required to submit hospital discharge data through the Statewide Planning and Research Cooperative System (SPARCS), the CMR used this system as an alternative method for reporting.

**Results:** The evaluation indicated that the CMR, SPARCS, and hospital systems needed to be modified. Modifications needed to maintain registry quality were the most difficult. CMR staff worked closely with hospital personnel on all modifications so they would understand the reasons for the modifications. The changes were more global than originally anticipated, involving large national software vendors.

**Conclusions:** The transition is ongoing. Additional work will be needed to verify data quality. Some of the modification will affect national software vendors and may be useful for other birth defects registries.

*Teratology* 64:S30–S36, 2001. © 2001 Wiley-Liss, Inc.

veillance Program by enactment of Part 22 of the New York Sanitary Code. This regulation mandated reporting by hospitals and physicians of all children under age 2 years in whom a birth defect is diagnosed in NYS. The CMR began operations in late 1982. After an evaluation resulting from decreasing resources, the CMR recently changed its reporting system to streamline operations and reduce costs, reduce the reporting burden on the hospitals, and take advantage of new technologies.

## EXISTING SYSTEMS

Two systems exist within the NYS DOH to collect information about congenital malformations—the CMR and the Statewide Planning and Research Cooperative System (SPARCS) (the hospital discharge database)—which operate in parallel (Figure 1). Hospitals are required to report to both systems. The systems only interact when SPARCS reports are used to monitor CMR reporting.

### The CMR reporting system

When a case is identified, hospitals and physicians are required to submit a report to the CMR within 10 days of the diagnosis by manually filling out the CMR reporting card. Over 95% of reports come from hospitals. From the beginning of reporting, most hospitals assigned the task of CMR reporting to their medical records departments. Medical records staff fill out the reporting cards when they routinely review and code the medical record. When the card reaches the CMR, it is reviewed and processed before it enters the CMR database. The CMR data processing system used batch processing and the database was maintained on an IBM mainframe. All changes, however minor, updates, and edits to the database had to be done through the batch processing system.

### The statewide planning and research cooperative system

SPARCS, a comprehensive patient data system, was established in 1979. SPARCS was originally used for reimbursement and is now a major management

## INTRODUCTION

During the 1970s, growing recognition of the problems associated with toxic waste dumps, such as Love Canal, led to the development of several birth defects registries. The New York State (NYS) Department of Health (DOH) Congenital Malformations Registry (CMR) was developed as the result of the Love Canal crisis. In 1978, the NYS DOH investigated whether adverse pregnancy outcomes increased in the Love Canal area. Birth certificates obtained and used for a study of low birth weight proved to be inadequate for the evaluation of birth defects. In 1981, the CMR was established as part of the Environmental Disease Sur-

\*Correspondence to: Charlotte Druschel, MD MPH, Congenital Malformations Registry, 547 River Street, Room 200, Troy NY 12180–2216. E-mail: cmd05@health.state.ny.us

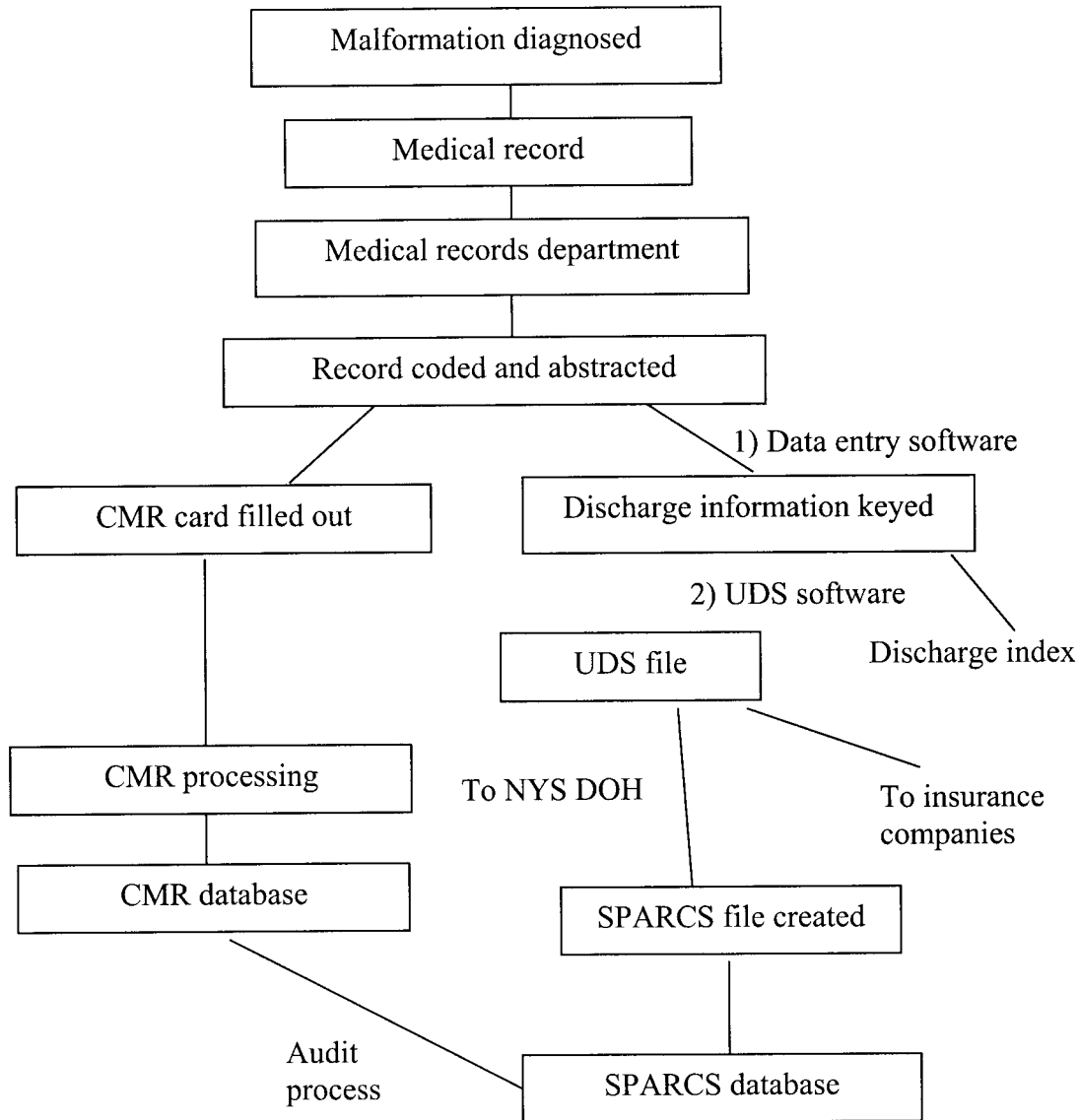


Fig. 1. Existing System

source of data for assisting hospitals, agencies, and health-care organizations with decision making regarding financial planning and monitoring of inpatient and ambulatory surgery services and costs. Data set specifications have been developed that blend the nationwide inpatient and outpatient billing requirements with the unique billing and discharge data reporting requirements of NYS—the Universal Data Set (UDS). Information from the medical record is entered into a database, and those data are processed to create the UDS file, which is used for insurance reimbursement and is sent to the NYS DOH. At NYS DOH, fields relevant to SPARCS are extracted. Hospitals insisted that patient identifiers not be included in SPARCS. SPARCS data is thought to be approximately 99% complete (NYS DOH 1999).

CMR reporting is not a priority among the many duties of medical records departments. A major prob-

lem, especially in recent years, is the lack of staff to do the reporting. Hospitals have regularly complained about the burdens of reporting and have asked for “electronic” reporting or that the CMR accept reports through SPARCS. In the past, CMR staff have rejected the use of SPARCS because no names were included and the diagnoses were given only as ICD-9 codes.

**PRINCIPLES FOR BIRTH DEFECTS REGISTRIES AND CMR APPLICATION**

From the beginning, CMR staff considered three principles vitally important and used them to guide changes in CMR procedures, especially when resources were reduced. These are: 1) each report should have personal identifiers; 2) each anomaly should have a narrative description; and 3) reporting should be complete and accurate while balanced with timeliness (Lynberg and Edmonds '92; Martin and Edmonds '91).

### Identifiers

Registries need to be able to locate enrollees for follow-up and to link them with other data sets (Cordero '92). Identifiers verify the individual's identity, assist in eliminating duplicates, and linking provides additional information about the infant and the mother, such as race/ethnicity, birthweight, and maternal residence.

Of course, having identifiers obligates the registry to maintain strict confidentiality. The CMR is covered by Public Health Law 206(1)(j), which holds the staff to the strictest confidentiality. However, the law inhibits our ability to fully communicate with service programs because we cannot release names to programs for the purpose of contacting families about services.

### Narrative diagnoses

To avoid unnecessary variability in coding, malformations are probably best coded by registry staff using a narrative diagnoses (Kallen '88). For greater consistency in coding, we ask that hospitals provide a narrative description of the malformation. CMR staff use this description to assign BPA codes; a computer look-up system then assigns the ICD-9 code.

### Completeness, accuracy and timeliness

Completeness and accuracy are important to a useful registry but are often in conflict with timeliness (Kallen '88). Because the CMR relies on passive reporting, we have long been concerned about the quality and completeness of reporting and have used various monitoring systems to attempt to evaluate completeness. However, over the years, the CMR staff has decreased and, at times, staff resources were diverted to studies and monitoring was not a priority. By the early 1990s, numbers of children reported had declined (this was responsible for an apparent decline in pyloric stenosis (Applegate and Druschel 1995)). This led to the development of a new monitoring system whereby every reporting hospital was audited using SPARCS. The development of this methodology was funded in part by the State-Based Birth Defects Surveillance Demonstration Project, a cooperative agreement with CDC.

This method of auditing hospital discharges improved the completeness of reporting. For birth years 1996 and 1997, the most recent years audited, approximately 33% of cases were ascertained through monitoring and the number of reports in those years was 110% of that expected on the basis of previous years' reports. Monitoring greatly assists in completeness, but unfortunately contributes to a decline in timeliness because several months are required to complete the process.

When we compared CMR prevalences of major malformations with those from other registries, especially those using active case-finding, most CMR prevalences were similar to those of the California Birth Defects Monitoring Program and the Metropolitan Atlanta Congenital Defects Program (New York State Congenital Malformations Registry '00). One paper has esti-

mated the CMR was about 86.4% complete for 1983 to 1986. (Honein and Paulozzi '99). However, because the CMR receives reports almost exclusively of live-born infants, CMR neural tube defect (NTD) prevalences, especially anencephaly, are low. (The CMR has a special regional NTD surveillance project that is funded by a CDC cooperative agreement.)

Because of resource limitations, no regular system had been in place to audit the accuracy of reports. Whenever CMR data are used for etiologic studies, medical records are obtained to verify the diagnoses. In the early 1990s, the CMR was used to ascertain over 800 cases of cardiovascular malformations for a case control study. Comparisons of CMR reports with the medical record information showed that the CMR diagnosis was confirmed by the medical record about 80% of the time (Charlotte Druschel, unpublished data, 1999). A regularly established system to audit the quality of reports would greatly enhance the usefulness of the CMR.

## THE RE-EVALUATION OF THE CMR

The federal Maternal and Child Health (MCH) Block grant funds many basic CMR activities. In 1996, MCH Block grant spending became over-extended, and extensive cutbacks were needed. Programs funded through the block grant, including the CMR, came under close scrutiny. In addition, the New York City Hospital Association, which represents many of our major reporting hospitals, petitioned the NYS DOH Commissioner to eliminate the requirement to fill out the CMR reporting cards, and thus reduce their reporting burden.

NYS DOH appointed a committee to assess the role and value of the components of the CMR. The committee evaluated the registry using four purposes as given in Edmonds et al ('81) and Holtzman and Khoury ('86): 1) to detect birth defects; 2) to investigate potential etiologic factors; 3) to plan and evaluate interventions and; 4) to ensure appropriate care for persons in need. In July 1996, the committee issued its report. The committee generally believed that the CMR had succeeded in the first three purposes; it provides information about birth defects to physicians and local communities, staff have analyzed various environmental factors and birth defects, and CMR data have been used in planning data by NYS DOH and various organizations. The fourth purpose is limited by the CMR's enabling legislation and history. CMR staff cannot release names of families to service programs that might then contact the families. To overcome this obstacle, CMR staff have worked with staff in maternal and child health programs to develop materials to inform families about available services. These materials have been sent out from the CMR directly since August, 1999.

The committee believed the CMR was important to the public health mission but that costs could be reduced; and one possibility was to use SPARCS/UDS to

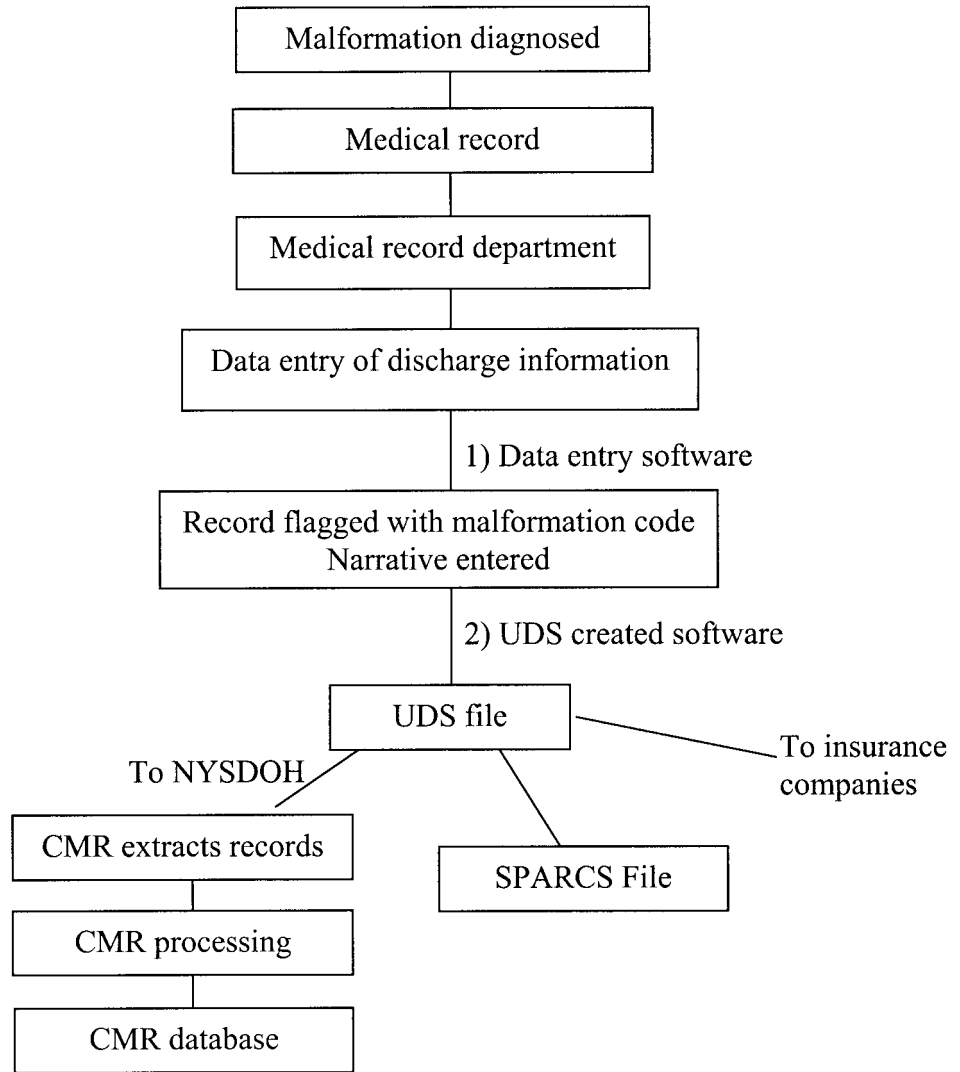


Fig. 2. New System Using SPARCS/UDS

ascertain cases for the CMR. This option was presented to the New York City Hospitals, which felt this would reduce their reporting burden. This added further impetus to developing case ascertainment using SPARCS/UDS.

**DEVELOPMENT OF A NEW SYSTEM**

Use of SPARCS/UDS reports combines the two reporting systems at the level of the medical records department so only one report is submitted to NYS DOH (Figure 2). Developing the new system required changes, some of them major, in case ascertainment, data processing, and verification from the CMR, SPARCS/UDS and the hospitals. In modifying the system and developing changes, CMR staff considered the three principles discussed above—identifiers, narrative description of each anomaly, and completeness and accuracy balanced with timeliness.

**CMR system changes**

Keeping the narrative was the major priority and presented the most difficulty. CMR staff solicited feed-

back from the major reporting hospitals about the importance of the narrative. The hospitals stated that retrieving medical records after filing the initial CMR report used much staff time and resources. They wanted to be able to give us the necessary information at the time of initial processing and to eliminate as much keying as possible. To make reporting the narrative easier, CMR staff determined the ICD-9 codes that indicate only one condition and thus would be acceptable without a narrative (e.g., 753.5 *Exstrophy of Urinary Bladder*) and the codes that needed more specificity (e.g., 756.79 *Other Congenital Anomalies of Abdominal Wall*, which includes both omphalocele and gastroschisis). If one of the first code group were entered, the ICD-9 code would be accepted and the narrative supplied using the ICD-9 code. However, if a code were entered from the second group, a screen would pop up offering choices. For example, for 756.79 the choices would be *omphalocele*, *gastroschisis*, and *other specified*. Choice of either *omphalocele* or *gastroschisis* would be accepted and used as the narrative, and a BPA code would be assigned based on this informa-



tion. If *other specified* were chosen, a blank field would pop up with a prompt to enter the exact diagnosis, which CMR staff would review and code. The development of this classification and choices for each code required considerable CMR staff time, but we believed it would best preserve the narrative diagnosis while making the system more acceptable to the hospitals.

Receiving reports from the SPARCS/UDS system would have required massive modification of the existing batch processing system. Rather than modify the current batch processing system, a new system would be created that would take advantage of new technologies and would be more interactive. The NYS DOH was moving several other databases including the vital records files to the new SYBASE system. Maintaining the CMR database on this system would allow for more timely matching to the birth records. In addition, we would like to have more CMR data on the Internet, with applications that would allow users to produce customized data outputs. The SYBASE server would allow for Internet access to CMR data. We created an interactive user menu system with numerous applications, and staff can now maintain and edit the database, enter and process new cases, review and code malformations, prepare routine reports and mailings to hospitals and parents, monitor and audit hospital reporting to the CMR, and perform routine backups. This new system allows for reporting congenital malformations using the existing reporting card or through the SPARCS/UDS reporting system. This interactive system has greatly improved the efficiency of the clerical staff in reviewing and in updating the files, even while using the current reporting cards.

#### **SPARCS/UDS system changes**

The SPARCS/UDS file structure already contains much of the information required for congenital malformation reports. However, to obtain the narrative and identifying information, some modifications would have to be made to the system. The first change created a new code for hospitals to use in the UDS record to indicate the record contains a congenital malformation code in a child under age 2 years. The second provided for new records for this subset of patients for the diagnostic narrative information describing the malformations.

The UDS file contains identifiers, but they are stripped off before coming to NYS DOH or are stripped off at NYS DOH before a record is included in SPARCS. Previously, removal of identifiers was considered essential by hospitals before they agreed to participate in SPARCS. However, because most hospitals want to participate in the electronic reporting system, they have allowed the CMR to have access to the UDS files with identifiers for the subset of patients with congenital malformations.

#### **Hospital system changes**

After meetings with hospital medical records departments and hospital information systems representa-

tives, CMR staff learned that what appeared to be two minor changes were in reality major changes for the hospitals. The information software environment of hospitals can be complex and varies widely between hospitals. Generally, two distinct applications require modification. First, the data entry software package used by the medical records department to enter discharge information needed to be modified to include the narrative information (Figure 2). Second, the software used by the hospital to construct the UDS file, which is then forwarded for both provider reimbursement and SPARCS reporting, also needed to be modified (Figure 2).

### **PROBLEMS ENCOUNTERED**

#### **Hospital software vendors**

For approximately one half of hospitals, the two applications described above are integrated. For ten percent of hospitals, the information systems staff run both applications and can make the needed modifications. For the remaining hospitals, the medical records data entry software will be in-house, and a vendor will handle the UDS files or two different vendors are involved. The software for the UDS system in NYS involves three or four major vendors who have contracts nationwide. The medical records software involves more. In addition, the medical records data entry software used by many hospitals incorporates diagnostic-related group (DRG) databases supplied under contract by national firms to either the hospital or the vendor. The hospitals cannot modify their medical records applications to include the list of CMR reportable ICD-9-CM codes, such modifications need to be made by the software vendor and in some cases incorporated into the DRG database.

Several vendors negotiate programming hours in their annual contracts with the hospitals to change or enhance their software products. However, for most hospitals, changes that result in increased revenue receive the highest priority—and medical records applications are not a priority. The hospitals are charged for changes that are not included in the contract. Medical records departments' concerns are only a small part of the total, and CMR electronic reporting an even smaller part. Most medical records departments are lacking in power within the hospital structure and have difficulty competing for the additional resources.

Convincing vendors to modify their software remains a major obstacle in implementing electronic reporting to the Registry. Contacting vendors, asking for invitations to information systems meetings, sending letters to medical records directors, inviting medical records and information systems personnel and vendors to meetings sponsored by the CMR are some of the methods used to draw attention to the possibility and benefit of electronic reporting. Timing was also a problem when the CMR first introduced these changes. During 1997–1999, hospital information systems departments

and computer vendors were not open to making changes for CMR reporting because they had dedicated resources to Y2K.

### **CMR system**

The problems CMR staff encountered in implementing the new reporting system were mainly limited to the programming difficulties and resources needed to create a new data processing system using new software with new hardware. In addition, all "routine" processing needed to be re-invented, resulting in delays in reports and data requests.

The potential exists for improvements in reporting timeliness because SPARCS/UDS data are generally complete and submitted shortly after discharge. However, a new methodology for checking completeness and accuracy must also be developed. The accuracy of SPARCS/UDS has not been systematically evaluated, although the same data used to examine CMR accuracy were also used to examine SPARCS/UDS, with similar results, about 80% (although with less specificity because only ICD-9 codes were available). As hospitals switch to the new system they will temporarily use both the old and the new systems, and we will compare the two systems during that time. We are also considering developing a system of on-site record reviews that will allow us to check both completeness and accuracy.

### **CONCLUSION, LESSONS LEARNED, AND POTENTIAL USEFULNESS**

Many birth defects registries have developed out of a crisis and as the crisis fades, resources may not be maintained and may even decrease. In times of scarce resources, birth defects registries may have to again prove their usefulness. The CMR has the advantage of strong legislation that mandates reporting of birth defects, but it needs hospital cooperation for timely, complete, and accurate data. As health care financing has changed, many hospitals have faced resource shortages and considered CMR reporting burdensome. Faced with these realities, the quality of CMR data could have declined or the CMR entirely shut down.

Several factors helped the CMR to survive and maintain its three major principles. The management of the Center for Environmental Health (CEH), the NYS DOH unit where the CMR is housed, understood the importance of the registry principles and supported CMR staff efforts to maintain them. That support also was essential in getting the resources to change the CMR system. Expertise and staff time from outside the CMR were necessary to accomplish this task. The changes needed for the system to function were simple in concept but difficult in execution.

The CMR offered hospitals a plan to change the reporting system, which would accommodate them and reduce their burden. This coincided with major changes within the NYS DOH for reporting and streamlining many systems. The SPARCS/UDS system was already being processed in the NYS DOH. The

support of the hospitals was also instrumental in getting the SPARCS/UDS system to make the necessary changes to their systems.

We gained much of the hospital cooperation by holding regional meetings with hospital staff and representatives from several of the major software vendors in NYS to discuss the implementation of the new SPARCS/UDS reporting system. These meetings proved to be informative and productive for all parties involved. We became aware of the diversity and complexity of the information systems used by medical records departments for data abstraction and creation of UDS files. The hospitals became aware of the importance of maintaining the integrity and usefulness of the CMR data.

At present, using the SPARCS/UDS electronic reporting remains a choice rather than a mandate. While, virtually all of the major hospitals who provide the majority of reports, want to use the new system, only about 10% of the smaller hospitals report using SPARCS/UDS. Many medical records directors believe that mandating SPARCS/UDS reporting is the most effective way to implement it for at least the larger hospitals in the State. Existing contacts cover changes mandated by regulation, and thus the vendors would be required to change their software to accommodate the new reporting elements without additional charge. The directors believe that without a mandate, the cost to many hospitals may be prohibitive. If cost continues to be a major obstacle, we will explore the possibility of requiring SPARCS/UDS reporting, at least for larger hospitals. Whether this change would increase the cost of the contracts in the future is not clear.

The story is not yet complete. Many hospitals are working with their vendors and have not yet started to use the new system. All CMR processing systems are not yet in place.

We must develop alternate methods to check on completeness and accuracy of reporting. However, the lessons learned and the work already done may be helpful to other registries. In the foreseeable future, most states will not receive adequate funding to perform in-hospital case ascertainment with their own staff and more hospitals may perceive that reporting is burdensome. Using a hospital discharge system with the modifications for identifiers and the narrative description might be an alternative. Some of the work has been done; CMR staff have created tables that assist the medical records data entry staff in supplying the narrative. These will have to be modified for ICD-10 but the basic structure has been developed. The UDS is based on national standards and is used in many states and the software vendors serve hospitals nationwide. It is possible that if more states wanted a narrative diagnosis software, the vendors might be more willing to make the software changes that would allow hospitals to report the narrative. This could perhaps become part of the UDS standard. Thus, while using the hospital discharge data system many more states could have

access to birth defects information with a narrative and better specificity without having to create their own reporting system.

#### LITERATURE CITED

- Applegate MS, Druschel CM. 1995. The epidemiology of infantile hypertrophic pyloric stenosis in New York State, 1983 to 1990. *Arch Pediatr Adolesc Med.* 149:1123-1129.
- British Paediatric Association. 1979. Classification of diseases. London: British Paediatric Association.
- Cordero JF. 1992. Registries of birth defects and genetic diseases. *Pediatr Clin North Amer* 39:65-77.
- Edmonds LD, Layde PM, James LM, Flynt JW, Erickson JD, Oakley GP. 1981. Congenital malformations surveillance: two American systems. *Inter J Epidemiol* 10:247-252.
- Holtzman NA, Khoury MJ. 1986. Monitoring for congenital malformations. *Ann Rev Public Health* 7:237-266.
- Honein M, Paulozzi L. 1999. Birth defects surveillance: assessing the "gold standard". *Am J Public Health* 89:1238-1240.
- International Classification of Diseases. 1998. International classification of diseases, 9th revision, clinical modification. 6th ed. Washington DC: National Center for Health Statistics and the Health Care Financing Agency.
- Kallen B. 1988. Epidemiology of human reproduction. Boca Raton: CRC Press.
- Lynberg MC, Edmonds LD. 1992. Surveillance of birth defects. In: Halperin W, Baker EL, Monson RR editors. *Public Health Surveillance*. New York: Van Nostrand Reinhold. pp 157-177.
- Martin ML, Edmonds LD. 1991. Use of birth defects monitoring programs for assessing the effects of maternal substance abuse on pregnancy outcomes. Methodological issues in controlled studies on effects of prenatal exposure to drug abuse. *Research Monograph* 114:66-82.
- New York State Congenital Malformations Registry. 2000. Congenital malformations registry annual report-statistical summary of children born in 1995 and diagnosed through 1997. New York State Department of Health.
- New York State Department of Health. 1999. SPARCS annual report, 1998 Volume 1. New York State Department of Health.