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PREPARING FOR VANESSA'S LAW: COLLABORATION BETWEEN THE MEDICAL RECORDS AND PHARMACY DEPARTMENTS AT A CANADIAN HOSPITAL CENTER

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ABSTRACT

Background and objective

In the context of Vanessa's Law, the medical records department and the pharmacy team of a mother–child hospital collaborated to create a system for coding adverse drug reactions (ADRs). This study was conducted to validate the coding of ADRs by the medical records team.

Material and methods

This retrospective descriptive study covered 12 months of coding of hospitalization data by the medical records team (November 1, 2017, to October 31, 2018). The pharmacy team performed twice-monthly analysis to validate the ADR data, based on coded information for drugs and associated clinical manifestations.

Results

Over the 12-month study period, a total of 755 ADRs were coded by the medical records department (i.e., 2.1 ADRs per day, corresponding to 7.1% of admissions). For 34 (4.5%) of these ADRs, the pharmacy team made a change to the code originally assigned by the medical records department. Eighty-five (11.5%) of the coded ADRs were deemed serious, as defined by Health Canada, but only 13 (15%) of these serious ADRs were reported to the regulatory authority. The new process allowed clinical manifestation codes to be associated with individual drugs in the pharmacy's Med-Echo-Plus® software, which facilitated interpretation of the data. Following this study, coding practices were reviewed, a coding algorithm was developed, and the codes for 18 drugs were clarified.

Conclusion

This study highlights the feasibility of establishing a link between the medical records and pharmacy departments to validate the coding of ADRs. At the study hospital, this linkage has identified serious ADRs, for which reporting will soon be required by Health Canada.

Keywords: *Adverse drug reaction reporting systems; Clinical coding; Drug-related side effects and adverse reactions; Forms and records control; Medical records*

INTRODUCTION

In Canada, recent legislative changes mean that health facilities will soon be required to report serious adverse drug reactions (ADRs) within 30 days of their documentation (1–3). In light of this regulatory requirement, practices within health facilities must be reviewed to identify effective ways of identifying and reporting serious ADRs within the prescribed timeframe.

In our health facility, a collaborative process involving the medical records and pharmacy departments was set up in 2017 (4). When a patient is discharged, a medical records technician reviews the entire file, including the hospitalization summary sheet, and codes all diagnoses and medical procedures performed during the stay (5). The diagnoses are coded according to the International Statistical Classification of Diseases and Related Health Problems, 10th Revision, Canada (ICD-10-CA), and interventions are coded according to the Canadian Classification of Health Interventions (6). Coding of the summary sheet makes it possible to identify ADRs on the basis of their clinical manifestations and to associate these manifestations with a particular drug or class of drugs (7). Previous work has highlighted the need to reconcile coding data for patients' hospital stays, as generated by medical records technicians, to improve the detection and reporting of ADRs (4).

The main objective of this study was to identify and describe ADRs on the basis of coding of the summary sheet by the medical records technicians. The secondary objective was to identify avenues for improvement in the coding of ADRs that occur during hospital stays.

METHODS

Study setting

This retrospective descriptive study was based on hospitalization data from a 500-bed mother-and-child university hospital located in Montréal, Quebec, Canada. The research protocol was approved by the ethics committee of CHU Sainte-Justine.

Period of analysis

The study covered 12 months of coded pediatric hospitalization data (November 1, 2017, to October 31, 2018). Data from mother-and-child and nursery hospitalizations were excluded.

Data sources

In health establishments in the Quebec Province, medical records are coded using

Med-Écho-Plus® software (version 7.15.0.0, Logibec, Montréal, Quebec, Canada). For the purposes of this study, the medical records were analyzed using the ChartMaxx® integrated chart system (Quest Diagnostics, Secaucus, New Jersey, USA).

Extraction and analysis of data by medical records department

To extract all coded ADRs in the medical records, we sought retrieval codes corresponding to pairs consisting of an "offending drug code" and a "clinical manifestation code." External codes cause Y40 to Y59 of ICD-10-CA were used to identify offending drugs, and ICD-10-CA diagnostic codes were used to identify clinical manifestations (7). Data were extracted twice monthly from the Med-Écho-Plus® software database in a 20-column spreadsheet (Excel, Microsoft Corporation, Seattle, WA, USA). The first 13 columns corresponded to the administrative data for each patient: file number, admission number, date of admission, date of discharge, age, sex, code and description of the major diagnostic category, code and description of the homogeneous group, severity index, mortality index, and relative intensity level of resources used. The remaining seven columns corresponded to the description of the ADR, including the numeric code, the relevant diagnosis, and the date.

Analysis and reconciliation of data by pharmacy department

Twice a month, the pharmacy team analyzed the data to validate the extracted drug–clinical manifestation pairs (8). The work file for this analysis was augmented with 14 columns for a description of the ADR, the presence of severity criteria, elements of declarations to competent authorities, comments, and any coding modifications that were made, as well as the date of the extraction and the operator. The pharmacy team then validated the ADRs using the patient record and communication with the medical records technicians if required (for the more complicated files).

Statistical analysis

Only descriptive statistics were calculated, with the unit of analysis being the individual ADRs.

RESULTS

Identification and description of ADRs

A total of 1722 rows of coded data were extracted for analysis. Of these, 755 represented unique ADRs experienced by patients admitted between November 1, 2017, and October 31, 2018 (a 364-day period), which were coded by the medical records team and subsequently analyzed by the pharmacy department team. On average, 2.1 ADRs were coded per calendar day, corresponding to 7.1% of the 10,601 pediatric admissions during the study period and 0.9% of the resulting 78,771 patient-days. Eighty-five (11.5%) of the coded ADRs were deemed serious, as defined by Health Canada, but only 13 (15%) of these serious ADRs were reported to the regulatory authority. Table 1 presents a profile of the ADRs analyzed over a 12-month period.

Of the ADRs analyzed, 23.4% (177/755) were associated with the Y43 class (primarily systemic agents), 19.7% (149/755) with the Y40 class (systemic antibiotics), 13.2% (100/755) with the Y42 class (hormones and their synthetic substitutes and antagonists, not elsewhere classified), 9.3% (70/755) with the Y45 class (analgesics, antipyretics, and anti-inflammatory drugs) and 34.4% (259/755) with all other drug classes combined. Figure 1 presents the profile of all ADRs analyzed by classes.

The 85 serious ADRs had a roughly even distribution across three main categories: 38.8%

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TABLE 1. Profile of adverse drug reactions (ADRs) extracted and analyzed over a 12-month period.

Variable	Number (Percentage of ADRs analyzed)
Rows of ADR data extracted and supplied for analysis	1722
Rows of ADR data analyzed[a]	755
ADRs coded as occurring before hospitalization	278/755 (36.8)
ADRs coded as occurring during hospitalization	477/755 (63.2)
Change made to ADR coding	34/755 (4.5)
Addition of ADR to patient's chart	10/755 (1.3)
Modification of ADR code(s)	14/755 (1.9)
Removal of ADR from patient's chart	10/755 (1.3)
Serious ADRs	85/755 (11.3)
Serious ADRs causing hospitalization	40/755 (5.3)
ADRs reported to Health Canada following reconciliation by pharmacy team	72/755 (9.5)

[a]*After elimination of duplicate dates for the same ADR and additional diagnostic lines unrelated to the ADR for some patients.*

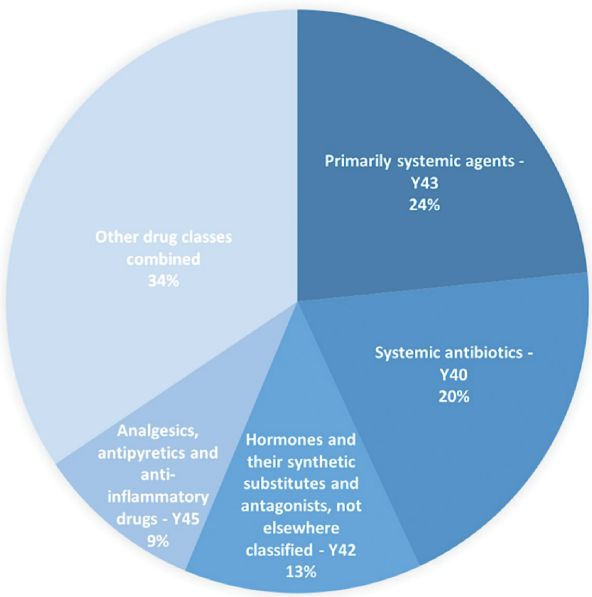

FIG 1. Profile of all ADRs analyzed by classes (n=755).

(33/85) were associated with the Y43 class (primarily systemic agents), 18.8% (16/85) with the Y40 class (systemic antibiotics), and 42.4% (36/85) with all other drug classes combined. A more detailed analysis of the serious ADRs by subclass showed that 20% (17/85) were associated with the Y43.3 subclass (other antineoplastic drugs), 11.8% (10/85) with the Y43.1 subclass (antineoplastic antimetabolites), 4.7% (4/85) with the Y40.0 subclass (penicillins), 4.7% (4/85) with the Y42.0 subclass (glucocorticoids and synthetic analogues), 4.7% (4/85) with the Y43.4 subclass (immunosuppressive agents), 4.7% (4/85) with the Y40.4 subclass (tetracyclines), and 49.4% (42/85) with all other drug subclasses combined.

Improvements to the system for tracking ADRs

The collaboration between the medical records team and the pharmacy department including twice-monthly reconciliation of ADR coding allowed staff members to identify ways to improve ADR coding.

As a first step, the algorithm for coding ADRs was revised to extract only rows about ADRs (i.e., clinical manifestation associated with the offending drug). Without this selective step, the interpretation of data is more difficult for the pharmacy department team. Figure 2 presents the revised algorithm for coding ADRs.

As a second step, specific codes associated with coding difficulties were identified, and a

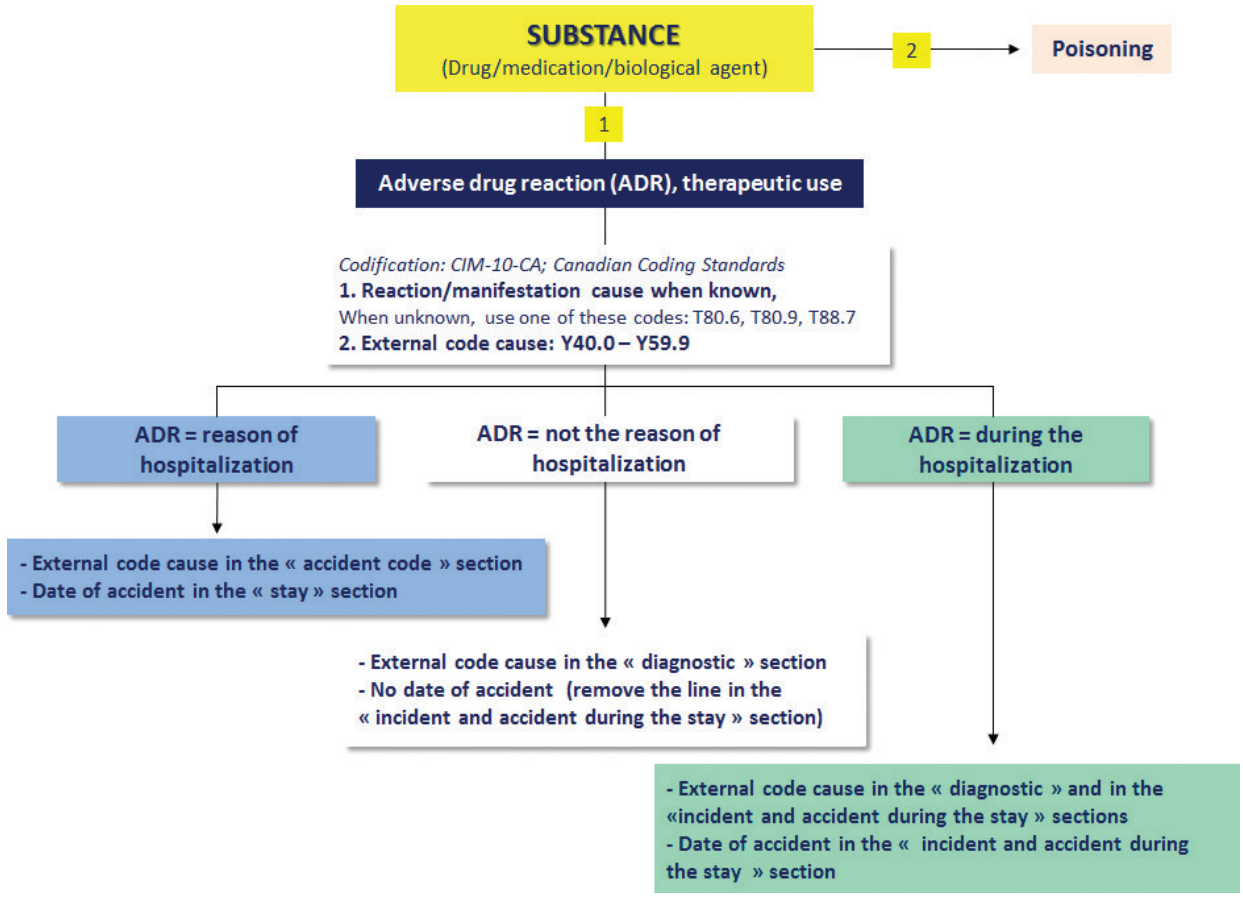

FIG 2. Algorithm for coding adverse drug reactions (ADRs).

table of problem codes was developed to support consistent coding of ADRs by medical records technicians. As background, the ICD-10-CA provides a drug nomenclature that does not include all drugs currently marketed in Canada (given that a new drug is marketed every 10 days, on average) and differs from the classification typically used by Canadian hospital pharmacists (the Classification of American Hospital Formulary Service) (9, 10). For example, some drugs combine two active ingredients but ADR coding was based on only one of the ingredients. As such, in the study hospital, the combination of ibuprofen and pseudoephedrine is no longer coded with the ibuprofen Y45.2 code but rather with a dual code for the combination (Y45.2 + Y51.9). Some drugs used in the study hospital were not marketed in Canada (e.g., zoledronic acid, dexmedetomidine, quetiapine, tacrolimus, and venlafaxine). For example, no specific code was available for tacrolimus, so the code Y43.4 (immunosuppressive agents) was used. Finally, some of the codes used by the medical records technicians were incorrect because of the search method applied. For example, prednisone was sometimes coded as Y54.0 (mineralocorticoid) or Y56.0 (topical agents mainly affecting skin and mucous membrane and ophthalmological, otorhi-nolaryngological, and dental drugs) because only the steroid suffix was used to search for and select the drug code. Now, the code Y.42 (glucocorticoids and synthetic analogues) is used for prednisone.

TABLE 2. Examples of changes to coding of certain drugs during the study.

Drug name	Code used before study	Modified code
5-Aminosalicylic acid	Y43.1	Y53.8
Chlorhexidine	Y56.4	Y56.0
Dexmedetomidine	No code was used	Y47.8
Diachylon dressings	Y56.3	Y56.4
G-CSF[a]	Y44.1 or Y43.8	Y44.9
Glucocorticoid	Y56.0 or Y54.0	Y42.0
Guanfacine	Y51.6	Y52.5
Ibuprofen + pseudoephedrine	Y45.2	Y45.2 and Y51.9
Infliximab	Y43.8 or Y43.1	Y43.4
Meropenem	Y40.8	Y40.1
Piperacillin + tazobactam	Y40.0	Y40.0 and Y40.1
Pregabalin	Y45.09	Y46.6
Quetiapine	No code was used	Y49.5
Tacrolimus	No code was used	Y43.4
Trimethoprim + sulfamethoxazole	Y41.8	Y40.8
Venlafaxine	No code was used	Y49.2
Voriconazole	Y40.7	Y41.8
Zoledronic acid	No code was used	Y54.7

[a]*G-CSF, granulocyte colony-stimulating factor.*

TABLE 3 List of codes created for the "M" characteristic.

Code[a]	Meaning
M1	Drug 1
M1A	Drug 1 – external cause causing trauma
M1P	Drug 1 – probable cause
M1X	Drug 1 – complication
M1PA	Drug 1 – probable or external cause causing trauma
M1PX	Drug 1 – probable cause or complication

[a]*When an adverse drug reaction is induced by multiple drugs, the other drugs are represented by codes with incremental numerals.*

Table 2 lists examples of changes made to the coding of certain drugs during the course of this study.

As a third step, we explored the possibility of adding a characteristic to the offending drug and the associated clinical manifestation to facilitate the pairing of these two elements during analysis of the extracted data. Although the Med-Écho-Plus® software does not have a dedicated field for matching a clinical manifestation to a drug, it is possible to add a characteristic to an existing field to ensure the desired pairing. Thus, for each ADR, an "M" (matching) characteristic was added to both the drug and the clinical manifestation when the medical records technicians coded the hospital stay in the Med-Echo-Plus® software. Table 3 lists the various codes created for the "M" characteristic.

Finally, a change was made to the method of entering ADRs into the software. Before the study, when an ADR was coded as being responsible for the hospitalization (i.e., external cause), the offending medication was automatically

added to the "incident and accident during stay" section of the patient's medical record. However, this designation is not necessarily relevant for the coding of all ADRs. Therefore, one parameter of the software was modified so that an alert is now displayed to the medical records technician during coding, which forces registration of the start date for use of the offending drug, when relevant.

DISCUSSION

This study describes an original approach to identifying, coding, reconciling, and analyzing the management of ADRs by the medical records and pharmacy departments at a Canadian university hospital center.

Over the 12-month study period, a total of 755 ADRs were identified and coded (i.e., about two ADRs per calendar day), and 7.1% of admitted patients had at least one ADR associated with their hospital stay. These data are similar to those reported by Kongkaew et al. (11), who observed at least one ADR in 5.3% of hospitalized patients, and Pirmohamed et al. (12), who observed at least one ADR in 6.5% of admitted patients. Underreporting of ADRs is well recognized in the literature (13, 14). However, where ADRs are based on data coded in the patient record, it is reasonable to assume that the number of ADRs identified is closer to reality, given that those performing the coding have access to additional administrative procedures that are not available to clinicians for documenting professional activity and the clinical evolution of the patient.

In this study, the prevalence of serious ADRs after analysis and reconciliation by the pharmacy team was 11.3% (85/755) or a rate of 0.17 ADR per bed (n = 85/500). This proportion was similar to the rate of serious ADRs found by Impicciatore et al. (15) in their systematic review of ADRs in patients admitted to pediatric hospitals. In that study, serious ADRs represented 12.3% of all adverse reactions (95% confidence interval, 8.43–16.17). In addition, given the absolute number of serious ADRs identified, our study indicates that it is realistic for a health facility to meet the new regulatory requirement to report serious ADRs to Health Canada.

Following reconciliation by the pharmacy department team, ADR coding was modified for a total of 34 patients: for 10 patients, an ADR code was added; for another 10 patients, an ADR code was deleted; and for the remaining 14 patients, the ADR code was modified. The proposed code changes corresponded to either a change in the subclass of drug involved, a change in the clinical manifestation code or a change in the timing of the ADR.

This study follows an initial exploratory study by our research team over a period of 7 months (April 1, 2017 to October 31, 2017) (6). The ADR data collected in the exploratory and current studies were similar (i.e., 1.5 vs. 2.1 ADRs/calendar day, 8.7% vs. 11.3% severe ADRs). However, there was a decrease in the number of changes resulting from pharmacy reconciliation (11.9% vs. 4.5%). We attribute this reduction to the collaboration between the medical records and pharmacy departments, the development of a table of drug codes and the continuous training that is now provided within the medical records department.

Before the establishment of this collaboration between the medical records and pharmacy departments, ADRs detected by physicians, pharmacists, and nurses at the bedside were reported to the pharmacy team by telephone, and a few dozen ADRs were reported to Health Canada each year. Since this collaboration began, the number of serious ADRs identified has surged, and all serious ADRs are now reported to Health Canada.

Our study highlights various avenues for concrete improvements in the management of ADR coding, including development of a table of problematic codes, matching by adding "M" characteristic to the data entry of offending

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drugs and applicable clinical manifestations to facilitate interpretation of ADRs during the reconciliation process, addition of an alert to the data entry software to systematically identify the start date for a drug that was being used before admission, exchanges of information between the pharmacy and the medical records department, and continuing education for medical records technicians.

The collaboration between the medical records and pharmacy departments required additional human resources during the study period. About 16 hours per month were required for medical records technicians to extract the ADR data (2 hours) and analyze problematic files (14 hours). Similarly, about 16 hours per month were required for the pharmacy team to analyze and reconcile the coding data (13 hours), conduct information exchanges with the medical records technicians (1 hour), and report serious ADRs to Health Canada (2 hours). It is reasonable to assume that this workload will eventually decline, with experience and the use of suitable coding tools. In addition, complementary approaches can be considered to identify ADRs more quickly (e.g., machine learning, which has been used in the detection of ADRs and the analysis of ADR coding in Australia (16)).

A lasting collaboration has now been established between the medical records department and the pharmacy department at the study hospital. Beyond publication of these results in the medical literature, this work was shared with members of the pharmacovigilance community in Quebec and at the annual meeting of the Association of Health Information Managers of Quebec in May 2019 (17).

Limitations

This descriptive study had some limitations. It is based on data from a single health facility and involved collaboration between two separate teams within that facility. Other health facilities may not necessarily have any pre-established collaboration between the medical records and pharmacy departments. Such a collaboration may be more or less easy to establish depending on the people in place and the priority given to ADR coding. The upcoming legislative changes represent a great opportunity to develop such collaborations.

CONCLUSION

This study highlights the feasibility of establishing a formal link between the medical records and pharmacy departments in a health facility to validate the coding of ADRs. The collaboration described here led to accuracy in identifying ADRs, especially serious ADRs, the reporting of which will soon be required by Health Canada.

CONFLICTS OF INTEREST

None.

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