

Survey Evaluating the Practice of Children's Hospitals Having Pharmacist Collaborative Drug Therapy Management Protocols

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OBJECTIVES: The purpose of this study is to determine how frequently children's hospitals in the United States are using pharmacist-physician collaborative drug therapy management (CDTM), and to characterize their use in this population.

METHODS: A phone survey was created to collect data regarding the use of pharmacist-physician CDTM at children's hospitals. Children's hospitals were called between February 2014 and April 2014. Data were collected from either a clinical pharmacist or pharmacy director. Pharmacists were asked to answer questions regarding hospital demographics as well as to what extent and for which medications they use CDTM. Differences between types of hospitals were evaluated using Fisher exact test.

RESULTS: A total of 171 children's hospitals were identified; 51.5% hospitals (n = 88) completed the survey. Of the 88 hospitals that completed the survey, 32 (31.7%) had some level of CDTM in place. Of the 28 children's hospitals with CDTM in place that completed the survey, all allowed pharmacists to modify doses and monitor therapy, and 75% provided pharmacists with the ability to initiate the first dose. The specific medications that were included in the CDTM protocols in children's hospitals included vancomycin (n = 23), aminoglycosides (n = 22), anticoagulation medications (n = 7), and total parenteral nutrition (n = 3). Training was required for pharmacists to participate in CDTM protocols at most hospitals (n = 26). Lack of support from medical staff was the most common perceived barrier. No differences were identified between types of children's hospitals.

CONCLUSION: CDTM protocols are practiced in about one third of the children's hospitals. Pharmacists commonly initiate, monitor, and modify therapies as part of these protocols. The most frequently included medications were vancomycin and aminoglycosides.

INDEX TERMS: children's hospitals, collaborative drug therapy management, pediatrics

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INTRODUCTION

Collaborative drug therapy management (CDTM) is an interdisciplinary approach to health care delivery and gives pharmacists the opportunity to manage patients' therapeutic care. CDTM allows pharmacists and prescribers to establish written protocols that legally authorize pharmacists to manage a patient's medication therapy. Activities may include initiating, modifying, and monitoring drug therapy; ordering laboratory tests; and monitoring serum concentrations.¹

The health care reforms of the last several years at both the federal and state levels have created the increased need for patient-centered care with an interdisciplinary approach. Both the U.S.

Surgeon General and Centers for Disease Control and Prevention (CDC) have independently noted that pharmacists are vital members of the interprofessional team.^{2,3} Acknowledgment of the clinical pharmacist's role has contributed to an increase in CDTM legislation across the United States. As of 2015, 48 states (94%), plus the District of Columbia have legislative provisions allowing for CDTM,⁴ up from just 38 states (75%) in 2002.⁵ This recent expansion highlights role for clinical pharmacists as integral members of the interprofessional team.

Although most states now allow for pharmacist-physician CDTM, the roles and responsibilities of pharmacists vary by state legislation. Data collection completed by the CDC concluded that, as of 2012, pharmacists were allowed to initiate

therapy in 21 states, and modify drug therapy in 38 states.⁶ Other features of state regulations governing CDTM include types of collaborative practice agreements, levels of review or approval required (e.g., Board of Pharmacy, physician approval), and types of medications included (e.g., all medications, all medications except narcotics).⁵

The roles and responsibilities of pharmacists are defined in state laws; however, the extent to which CDTM is used in the acute care setting is not fully known. Lack of this information occurs because few states provide public listings of providers participating in CDTM agreements.⁶ Some surveys have attempted to determine this information.^{7,8} Among those surveys was one conducted in 1996, which included results obtained from 713 hospital pharmacy directors.⁷ This study found that 56% of hospital pharmacists participated in some form of CDTM at their institution. The report did not, however, specify differences between use in adult vs. pediatric settings. Another survey published in 2006 evaluated the use of CDTM in the acute care setting. This study included results from 318 hospitals, with 49.7% indicating that at least some of their pharmacists were engaged in CDTM, but this study also did not distinguish between adult and pediatric institutions.⁸ Thus, data with the use of such protocols in children's hospitals at this time are still lacking. This study aims to evaluate how frequently CDTM is being used for pediatric patients in children's hospitals, when allowed by state law.

MATERIALS AND METHODS

U.S. children's hospitals located in states that allow for CDTM were identified using the Children's Hospital Directory at <https://www.childrenshospitals.org>. A data collection tool (Table 1) was used to ensure the consistency of questions being asked. A phone survey was chosen to guarantee the survey went to the appropriate personnel within the pharmacy department. The survey was reviewed by the hospital Institutional Review Board, which determined that approval was not required.

Departments of pharmacy at identified children's hospitals were contacted via phone at least twice between February and April 2014. Clinical pharmacists or pharmacy directors were identi-

fied and questioned to determine: 1) the type of children's hospital (i.e., freestanding, within an adult institution); 2) the size of the institution; the use of any pharmacist-physician CDTM protocols, and if so, the medications involved; 3) the responsibilities (e.g., initiating, monitoring, modifying) of the pharmacist; 4) the training required of pharmacists to participate in CDTM; and 5) how supportive other pharmacist staff members were of the CDTM protocols. Fisher exact test was used to determine whether any differences existed between the types of children's hospitals that used CDTM and medications that pharmacists were permitted to use in CDTM.

RESULTS

Of the 171 children's hospitals that were called, 88 (51%) provided responses to the survey. As shown in Table 2, 41% (n = 36) were freestanding and 59% (n = 52) were located within adult institutions. Children's hospitals within adult institutions tended to be smaller (<200 beds), with 82% located within an adult institution compared to 47% in freestanding children hospitals.

Of the 88 children's hospitals contacted, 32 (36%) had pharmacist-prescriber CDTM. All hospitals with CDTM were able to provide basic hospital demographics, but because of time restrictions, 4 hospitals did not complete the full survey and results were calculated with the remaining 28 hospitals. Of the children's hospitals using CDTM, 21 (75%) allowed pharmacists to initiate the first dose, whereas 100% of the hospitals using CDTM allowed pharmacists to modify doses and monitor (i.e., order laboratories) therapy. A total of 71% of children's hospitals (n = 20) used CDTM protocols for all pediatric patients, 14% (n = 4) only included general pediatrics and the pediatric intensive care units (ICUs), 11% (n = 3) only included general pediatrics units, and 4% (n = 1) only used CDTM protocols for their ICUs. Two hospitals excluded neonatal ICU patients, and 1 hospital excluded ICU patients.

All 28 children's hospitals using CDTM provided the service 24 hours per day, 7 days per week. Ninety-six percent of children's hospitals reported that 75% to 99% of pharmacists at their institution were involved in CDTM practices. Seventy-one percent of hospitals reported that in the prior 12 months, 100% of eligible patients were included in their CDTM practices, whereas

Table 1. CDTM Survey Questions (Via Phone Call)**Hospital Demographics**

Number of beds: ☐ ≤ 99 ☐ 100-199 ☐ 200-299 ☐ ≥300

Institution Classification: ☐ Free standing ☐ within an adult institution

Do you have a pharmacist-physician CDTM protocol at your hospital? ☐ Yes ☐ No

What drugs do you have in your hospital that fall under the pharmacist-physician CDTM?

☐ Aminoglycosides ☐ Vancomycin ☐ Antiepileptics ☐ Zosyn

☐ Antifungals ☐ Anticoagulation ☐ Renal Drugs

☐ Transplant: Tacrolimus & Cyclosporine ☐ Other: _____

Which patient populations do you provide these services for?

☐ NICU ☐ CF ☐ General pediatrics ☐ PICU ☐ Other _____

Follow up: Why are other patients excluded from the group? _____

In the past 12 months, what percentage of patients that received these medications were included in the collaborative practice agreements?

☐ ≤ 24% ☐ 25% ☐ 50%- 74% ☐ 75% ☐ 100%

How many hours of the day is this service provided?

☐ Only during weekdays ☐ 24hr service ☐ Emergency on call services

What percentage of pharmacists are involved in this practice?

☐ ≤ 24% ☐ 25% ☐ 50%- 74% ☐ ≥ 75%

What system do pharmacists use to look at orders and adjust the system? _____

Responsibilities:

Who are the facilitators of the CDTM? ☐ physician ☐ pharmacists ☐ nurse or other staff

What type of pharmacist training is required to participate into CDTM? _____

What are the roles of the pharmacist?

☐ Initiation

☐ Modification which? ☐ Adjust drug strength ☐ Order lab or related tests

☐ Change a drug's frequency of administration ☐ based on drug interactions

☐ Monitoring of a patient's drug therapy

In what situations, does the pharmacist need to contact the physician? _____

How is that notification done: ☐ Phone ☐ Note

What steps does the pharmacist need to carry out in order to change the current order in the system?

☐ Note to MD ☐ Reauthorization from MD ☐ Others

When changes are performed does the pharmacist? ☐ Call the physician ☐ Write a note

What are the roles of a physician?

☐ Initiation of order per pharmacy ☐ Initiates order and asks pharmacy to follow and adjust as needed

Table 1. CDTM Survey Questions (Via Phone Call) (*cont.*)

Does the prescriber choose:

Does prescriber choose dosing for aminoglycoside, such once daily, TID, or synergy

☐ Yes ☐ No

For vancomycin would the physician or indication trigger the appropriate trough?

☐ Physician ☐ Indication

Challenges:

What are some pitfalls that you have encountered while introducing this practice?

- ☐ Shortage of pharmacists ☐ Lack of support from physicians and medical staff
- ☐ Pharmacist time constraint ☐ Financial or reimbursement issues
- ☐ Pharmacist competencies ☐ Lack of upper administration support
- ☐ State legislation support ☐ Pharmacist unwillingness
- ☐ Lack of appropriate protocols

What steps were taken to solve these issues? _____

Education:

Who required training to while this new agreement was being implemented?

☐ Pharmacist ☐ Physician ☐ Nurses ☐ Lab/chemistry

How do you train pharmacists? ☐ Modeling ☐ Online ☐ Test

How do you evaluate pharmacists' performance?

☐ Annual validation ☐ Intermediate checks/verifications?

How do you train MD, Nurses, etc? ☐ In person ☐ Online ☐ none

Outcomes:

What benefits have you seen with CDTM in place?

- ☐ Enhanced patient care ☐ Decreased drug related problems ☐ Reduced costs
- ☐ Decrease physician visits ☐ Improve patient satisfaction

How supportive are the other healthcare providers and administrators about this practice?

Are you reimbursed for your services?

Does this take more or less pharmacist time than before?

29% reported that only 75% to 99% of eligible patients were included.

The breakdown of CDTM by type of children's hospitals and the types of medications most commonly included in the CDTM protocols are depicted in Table 2. The vast majority of hospitals where CDTM occurred had vancomycin (82%) and aminoglycoside (79%) monitoring programs.

Relatively few children's hospitals had anticoagulation (25%) or total parenteral nutrition (11%) CDTM protocols. Additional CDTM protocols that were reported were: total parenteral nutrition (n = 3), insulin (n = 2), opioids (n = 2), asthma medications (n = 2), over-the-counter medications (n = 1), antiepileptic therapies (n = 1), and statin therapies (n = 1). No differences were seen

Table 2. Respondent Characteristics

Characteristics	Freestanding, n (%)	Not freestanding,* n (%)
No. of respondents	36 (41)	52 (59)
No. of beds		
≤ 99	9 (25)	21 (40)
100-199	8 (22)	22 (42)
200-299	10 (28)	6 (12)
> 300	9 (25)	3 (6)

*Children's hospital located within an adult hospital

between type of hospital (i.e., freestanding and within an adult institution) in the use of CDTM or the types of CDTM (Table 3).

Training is an essential component of any protocol. As such, the vast majority of the children's hospitals with CDTM protocols required pharmacist training (89%; n = 25). At the hospitals that use training, the most common training method employed was in-person/case-based training (n = 12), followed by online modules (n = 7), testing (n = 5), and continuing education-based methods (n = 1). Unfortunately, although most programs had training in place for pharmacists, only 2 had training required for their physician partners.

Supportiveness and barriers encountered were also assessed. Eighty-four percent of the pharmacists contacted indicated that other health care providers were supportive of the pharmacist-prescriber CDTMs. Further, 64% (n = 18) of pharmacists noted that they did not feel there were any major barriers to their programs. The remainder of the pharmacists did report some barriers, which are noted in Table 4.

DISCUSSION

This was the first study to evaluate CDTM frequency specifically in children's hospitals. The results from this survey indicate that pharmacist-prescriber CDTM protocols are authorized at about one third of the children's hospitals that responded to the survey, with no significant difference between freestanding children's hospitals and those within adult institutions. These results were particularly surprising because a previously published survey concluded that CDTM was used at about 50% of hospitals in the United States, not distinguishing between adult hospitals and children's hospitals.⁷ It appears that CDTM occurs less often in the care of children,

regardless of the type of children's hospital. Therefore, some adult hospitals may limit the CDTM to adult patients only and not provide it for their pediatric patients. This combined with the results of our study suggests there is significant room for growth.

The responsibilities of the pharmacist differed by institution. Seventy-five percent of pharmacists in our study were authorized to initiate a first dose of select medications. This is higher than that previously reported, with pharmacists participating in the initiation of a dose ranging from 46% to 56%.^{6,7} Although this could be due to a change of practice over time, it may be a finding unique to children's hospitals. In this study, at all institutions providing CDTM, pharmacists were able to monitor and modify a patient's therapy per protocol, highlighting the important role for pharmacists in these specific areas. In contrast, a similar survey evaluating the use of CDTM protocols in hospitals not distinguishing between adult and children, reported that pharmacists were authorized to adjust a medication's strength in only 87% of hospitals and change a drug's frequency of administration in 82% of hospitals surveyed.⁷

Based on the results of our survey, when CDTM is performed in children's hospitals it generally involves antibiotic and anticoagulation therapy. Although previous reports did not differentiate between adult and children's hospitals,⁶⁻⁹ pharmacists are generally managing the same types of medications in children and adult hospitals.

Most respondents reported no barriers to implementation of CDTM; however, when barriers were reported, respondents often noted similar findings: lack of support from physicians and other medical staff, shortage of pharmacists, and time constraints. The most frequent barrier for pharmacists participating in CDTM was lack of

Table 3. Medications Included in CDTM Protocols

Criteria	Total, n (%) [*]	Type of Hospital, n (%)		p Value [†]
		Freestanding	Non-Freestanding [‡]	
CDTM used	28§	12 (43)	16 (57)	0.82
Type of CDTM used				
Vancomycin	23 (82)	8 (67)	15 (93)	0.133
Aminoglycosides	22 (79)	8 (67)	14 (88)	0.354
Anticoagulation	7 (25)	3 (25)	4 (25)	1
Other¶	12 (43)	5 (42)	7 (44)	1

CDTM, collaborative drug therapy management

^{*} Percent is >100% because some institutions cited more than one barrier[†] Freestanding vs. non-freestanding[‡] Children's hospital located within an adult hospital[§] Included the 28 hospitals with CDTM that completed the full survey[¶] Total parenteral nutrition (n = 3), insulin (n = 2), opioids (n = 2), asthma (n = 2), antiepileptics (n = 1), statin (n = 1) medications

support from other health care providers. Only 2 hospitals included physician training for CDTM. It is interesting to note that these hospitals did not list lack of physician and other medical staff support as a barrier. Because most CDTM is facilitated by physicians and focuses on a team-based interprofessional approach, it is imperative that pharmacists obtain support from physicians and other health care providers on the team. Important factors for improving relationships between physicians and pharmacists include respect, pharmacist presence, and visibility.¹⁰

It is important to note that interprofessional training is becoming a standard for many health professionals' education and training programs, which could lessen the prevalence of such barriers. The Institute of Medicine recently released reports noting the need for changes in our health care system to improve medication safety and patient outcomes, and one change noted was the need for working in interprofessional teams.¹¹ This recent report has triggered accreditation bodies, such as the American Council for Pharmacy Education and the Liaison Committee on Medical Education, to require interprofessional training as part of their education standards.^{12,13} These new education standards may have an impact on these perceived barriers. It is important to note that despite these barriers, most respondents indicated that other health care providers and administrators were generally supportive of the CDTM practice (84%).

There were limitations to this study, one of which had to do with the survey response rate. Of the 171 hospitals identified as eligible to par-

ticipate in this survey, only 88 hospitals (51%) responded. This response rate is comparable to that reported in other phone surveys, but it is lower than the response rate for other methods, such as email and in-person surveys.¹³ Our response rate was higher than the average response rate achieved for any type of survey for data collected from organizations (51% vs. 35.7%).¹³ Studies similar to this study used mail surveys with response rates ranging from 32.7% to 51%.^{6,7,9} Although the amount of responses may not have been as robust as those obtained using some other methods, it was similar or better than the response rates seen in similar studies and determined to be the most appropriate method for this survey, considering the detailed nature of some of these questions.

Another limitation to this study was the use of individuals' self-reports for data collection. All of the data collected on the use of CDTM were based on self-reports from one clinical pharmacist or director at each institution. This could have introduced some bias on the questions regarding perceptions and barriers of the service; however, the clinical pharmacists or director of pharmacy should be a reliable source to estimate the extent of use of which pharmacists are employing CDTM. Other studies looking for similar data have strictly used pharmacy directors to answer the questions regarding CDTM.^{6,7,9} However, it was determined for this survey that allowing a clinical pharmacist or a pharmacy director to answer questions regarding CDTM use may improve response rates, especially in those hospitals where some pharmacists were unable to take the time to complete the survey.

Table 4. Common Barriers to CDTM Implementation and Use

Perceived Barrier	% (n)*
Lack of support from medical staff	18 (5)
Shortage of pharmacists	11 (3)
Pharmacist time constraints	11 (3)
Issues adjusting to the process	4 (1)
No major barriers	65 (18)

CDTM, collaborative drug therapy management

*Included the 28 hospitals with CDTM that completed the full survey

†Number is >100% because some institutions cited more than one barrier

Future studies should be completed to determine the clinical impact of CDTM protocols on the clinical outcomes, quality scores, and resulting quality of patient care in children's hospitals. Other studies have concluded that there are positive impacts on clinical care when pharmacists are responsible for managing therapies. The first evidence of the positive impact of the clinical pharmacist on mortality was noted in a study of adult heart failure patients in 1999.¹⁵ Clinical pharmacists evaluated medication therapies, made therapeutic recommendations, and provided the attending physician and patient education.¹⁵ The results highlighted the positive impact pharmacists managing medication therapy can have on patient outcomes, including a statistically significant decrease in all-cause mortality.¹⁵ Data are still lacking with regard to the clinical impact on patient outcomes and use of CDTM in pediatric patients.

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Abbreviations CDC, Centers for Disease Control and Prevention; CDTM, collaborative drug therapy management

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