Facilitating the Process of Medication Re-evaluation and Withdrawal in the Long-Term Institutionalized Population: The Example of Cisapride

Barbara Farrell, Lorna Hughes, Ineke Neutel, and Kelly Babcock

INTRODUCTION

It is well documented that many patients in long-term or complex continuing care* facilities receive medications that are considered inappropriate, are not indicated, or are not utilized optimally, and that these problems occur at a higher rate than among their counterparts living at home.[1-3] The prevalence of inappropriate prescribing is reportedly as high as 40% in nursing homes.[4-6] For many medications prescribed to patients living in nursing homes, the indications are often not documented, which makes it difficult to evaluate the effectiveness of drug therapy.[7]

The occurrence of avoidable adverse drug reactions is the most serious consequence of suboptimal medication use. Drugs identified as particularly hazardous in this population include antipsychotics, antidepressants, sedatives, digoxin, diuretics, and nonsteroidal anti-inflammatory drugs.[8-11] It is challenging to recognize treatment-emergent symptoms as adverse effects because they may not present in the standard way in frail elderly or chronically ill patients and may be misinterpreted as part of the normal aging process.

The economic burden of the cost of medications, the cost of medication administration time, and the cost (although difficult to measure) of the negative pharmacotherapeutic outcomes associated with suboptimal medication use are also of concern.[12] Such concerns regarding cost often create the impetus for facilities to take on the challenge of reducing inappropriate or suboptimal medication use.

Attempts to decrease inappropriate medication use and corresponding costs have been successful to varying degrees. Mechanisms include consultant pharmacists providing medication reviews, interdisciplinary medication review, face-to-face educational interventions for physicians and nurses, academic detailing, pharmacy and therapeutics committee policies on formulary management, application of criteria to identify inappropriate prescribing, and drug utilization review of specific drugs or categories of drugs.[13-26]

Studies examining the outcome of medication withdrawal in elderly patients have shown that a high percentage of medications can be discontinued without adverse consequences.[27] The nursing home or long-term care setting is believed to be a good environment in which to attempt drug withdrawal because patients can be monitored closely for adverse drug withdrawal events.[28]

The SCO Health Service provides long-term care, complex continuing care, palliative care, and rehabilitation services through 3 main sites in Ottawa: Elisabeth Bruyère Health Centre, St. Vincent Hospital, and Résidence St. Louis (the abbreviation SCO refers to the founding Soeurs de la charité d'Ottawa or Sisters of Charity of Ottawa). In addition to an ongoing patient-

*Patients receiving complex continuing care are those who need an interdisciplinary team larger than those available in nursing homes. They either require specialized care (e.g., renal dialysis, ventilator dependence, or care for advanced Parkinson's disease) or have multiple comorbidities that complicate therapy. Most patients live in the institution until death, but an increasing few get sufficiently better and require less care, which allows discharge to home or to a nursing home. At the authors' institution, each full-time pharmacist cares for 80 to 100 patients requiring complex continuing care.

Table 1. Protocol Development and Approval Process

Date	Activity
April 2000	Tapering withdrawal protocol, monitoring protocol, and forms developed (by pharmacists, with input from dietitians and Director of Complex Continuing Care)
April/May 2000	Physicians and pharmacists started withdrawal process in patients in whom drug efficacy was questioned and those thought to be at risk for adverse effects (in anticipation of impending market withdrawal)
May 2000	P&T Committee approval of standard withdrawal protocol and monitoring form Decision made to proceed as a P&T initiative rather than a research project
June 27, 2000	Received notice that cisapride was to be withdrawn from Canadian market by August 7, 2000 Withdrawal process started in remaining patients taking cisapride

P&T = Pharmacy and Therapeutics.

specific interdisciplinary medication review conducted every 4 months at this institution, it was decided, in 1999, to explore the possibility of a targeted medication withdrawal program. In this program a drug or group of drugs would be identified for withdrawal, and the withdrawal process would be applied to all 437 patients in the institution's complex continuing care program at the same time, rather than waiting for individual medication reviews (during which numerous issues may have to be addressed).

The first drug identified for withdrawal was cisapride. A number of patients were receiving it, it accounted for a substantial portion of the institution's drug budget, and its potential side effects are significant. A random chart audit revealed that cisapride had usually been initiated upon insertion of a feeding tube to prevent symptoms of gastroesophageal reflux disease (GERD) or aspiration pneumonia.

This article describes how a carefully planned and monitored medication withdrawal program for one drug was successful in decreasing medication use and costs in a complex continuing care facility and in identifying patients who required alternative or continued medication for their condition. This example illustrates the need for continuous re-evaluation of medication treatment in long-term institutionalized patients. The process described here is one method of ensuring that medication therapy does get re-evaluated in patients for whom pharmacists and physicians may have difficulty making medication therapy changes.

METHODS

A literature search was conducted to determine whether there was any evidence supporting the use of cisapride as prophylaxis for aspiration pneumonia or GERD in tube-fed patients. The MEDLINE and Healthstar databases were searched for the period 1994 to 1999 using the term cisapride combined with each of the following terms: feed* tube, tube feed*, PEG, j-tube, j tube, g-tube, g tube, ng-tube, ng tube, enteral feed* (where the asterisk indicates "wild card"). The Cochrane database was also searched.

No randomized, controlled trials were found to clearly support this practice in the complex continuing care population. Two gastroenterologists in the Ottawa area were also questioned regarding this practice, and both concurred that there was no evidence to support cisapride in this role.†

The original plan was to initiate a research project in which tube-fed patients would be randomly assigned to continue cisapride treatment or to have treatment withdrawn. Within days, however, a decision to withdraw cisapride from the US market by July 2000 was announced, and it was believed that Canada would follow suit. Therefore, a randomized trial of cisapride withdrawal no longer seemed appropriate. On the basis of the literature search and consultations, automatic substitution to domperidone did not seem appropriate either. It was decided to proceed with the withdrawal and monitoring arm of the original randomized controlled trial. This appeared to be a good opportunity to observe and summarize the effects of withdrawing cisapride from a large group of patients. The plan was to have an established withdrawal protocol ready for the time when Canada decided to withdraw cisapride from the market.

The steps in developing and implementing the cisapride withdrawal and monitoring protocol are outlined in Table 1.

The hypothesis during development of the withdrawal process and monitoring tools was that cisapride could be withdrawn from patients' medication

†S. Gregoire, consultant gastroenterologist, SCO Health Service, personal communication, Apr. 13, 2000; L. Rochon, consultant gastroenterologist, SCO Health Service, personal communication, Apr. 27, 2000.

regimens without significant exacerbation of symptoms. The primary outcomes were the recurrence or worsening of symptoms of the primary indication for use (including the ability to tolerate oral or tube feeding) and the need to start another drug or increase the dose of another drug to treat these symptoms. The need to adjust doses or types of other drugs because of a drug interaction was considered a secondary outcome.

The withdrawal protocol and monitoring form are included here as Appendices 1 and 2. The protocol involved a gradual reduction in the dosage of cisapride over several days with no automatic substitution to another drug. The gradual reduction in dose was designed to minimize the impact of emergent symptoms. The parameters and frequency of monitoring were dependent on the indication for cisapride. Monitoring was to be continued for at least 2 weeks after final discontinuation of cisapride. Suggestions for alternative therapy were included in the protocol for patients whose symptoms worsened or recurred. Pharmacists were also given reference lists of medications that could exacerbate or cause GERD symptoms or constipation. The investigators believed that it was important to assess such medications to ensure that patients were not being treated for a drug-induced symptom. Suggestions for handling potential drug interactions were also included. For patients who needed to begin therapy with domperidone or metoclopramide, monitoring parameters were included.

A chart review was conducted 1 year after the withdrawal had taken place to determine whether the 2-week follow-up period was long enough to identify patients whose symptoms recurred. Given the pattern of symptom occurrence and prescription of other medications, it was concluded that the follow-up period should have been at least 4 months.

Patients were divided into 2 groups for the analysis: those in whom cisapride withdrawal was successful (i.e., no significant exacerbation of symptoms) during the 4-month period and those for whom it was unsuccessful. Variables such as age, sex, cisapride dose, indication, and number of indications were examined by χ^2 analysis (when numbers were adequate for the analysis) to determine whether there were any predictors of successful withdrawal.

RESULTS

By July 2000, cisapride had been withdrawn from the medication regimens of all 41 complex continuing care patients (21 female, 20 male, out of a total patient population of 437) who had been receiving the drug before implementation of the withdrawal protocol. This number included 18 (24%) of the 75 patients who were receiving tube feeding at that time. The patients ranged in age from 29 to 93 years (median 72 years). For 6 patients, domperidone was automatically substituted for cisapride by the attending physician. For the remaining 35 patients (including 15 tube-fed patients), the withdrawal protocol was followed correctly, and data were available for statistical analysis as described in the Methods.

The 2-week, 4-month, and 1-year outcomes of the withdrawal process are depicted in Figure 1.

Most patients tolerated the cisapride withdrawal protocol with no recurrence or worsening of symptoms and did not require additional medication or dose changes. At the 2-week follow-up, 29 (83%) of the 35 patients, including 10 tube-fed patients, had completed the protocol without any adverse outcome. Two of the patients noticed improvement in their symptoms after cisapride withdrawal. Even at the 1-year follow-up, 20 (57%) of the 35 patients had experienced no symptom recurrence requiring medication changes.

Some patients required further symptom management as cisapride was withdrawn: 6 during the 2-week follow-up and 9 more over the remainder of the year (6 within the first few months and 3 almost 1 year later). The symptoms were primarily mild, were detected quickly through close monitoring, and were easily treated with small adjustments to other medications and feeding procedures. Of the 9 patients whose symptoms recurred or worsened over the 1-year period after cisapride withdrawal, all were eventually treated with domperidone. Two patients who had experienced symptoms and required medication changes in the first 2 weeks after cisapride withdrawal went on to receive domperidone over the next few months.

A chart review for the 9 patients whose symptoms recurred or worsened over the remainder of the 1-year period (after the 2-week post-withdrawal observation period) indicated that the 6 patients whose symptoms recurred within a few months had other challenges related to symptom management after withdrawal of cisapride. The other 3 patients had been well for some time, and their symptoms developed much later. Given that the 2-week cutoff for follow-up was chosen arbitrarily, it was decided to extend the follow-up period to 4 months; the 6 patients whose symptoms worsened or recurred early after cisapride withdrawal were thus captured in the analysis.

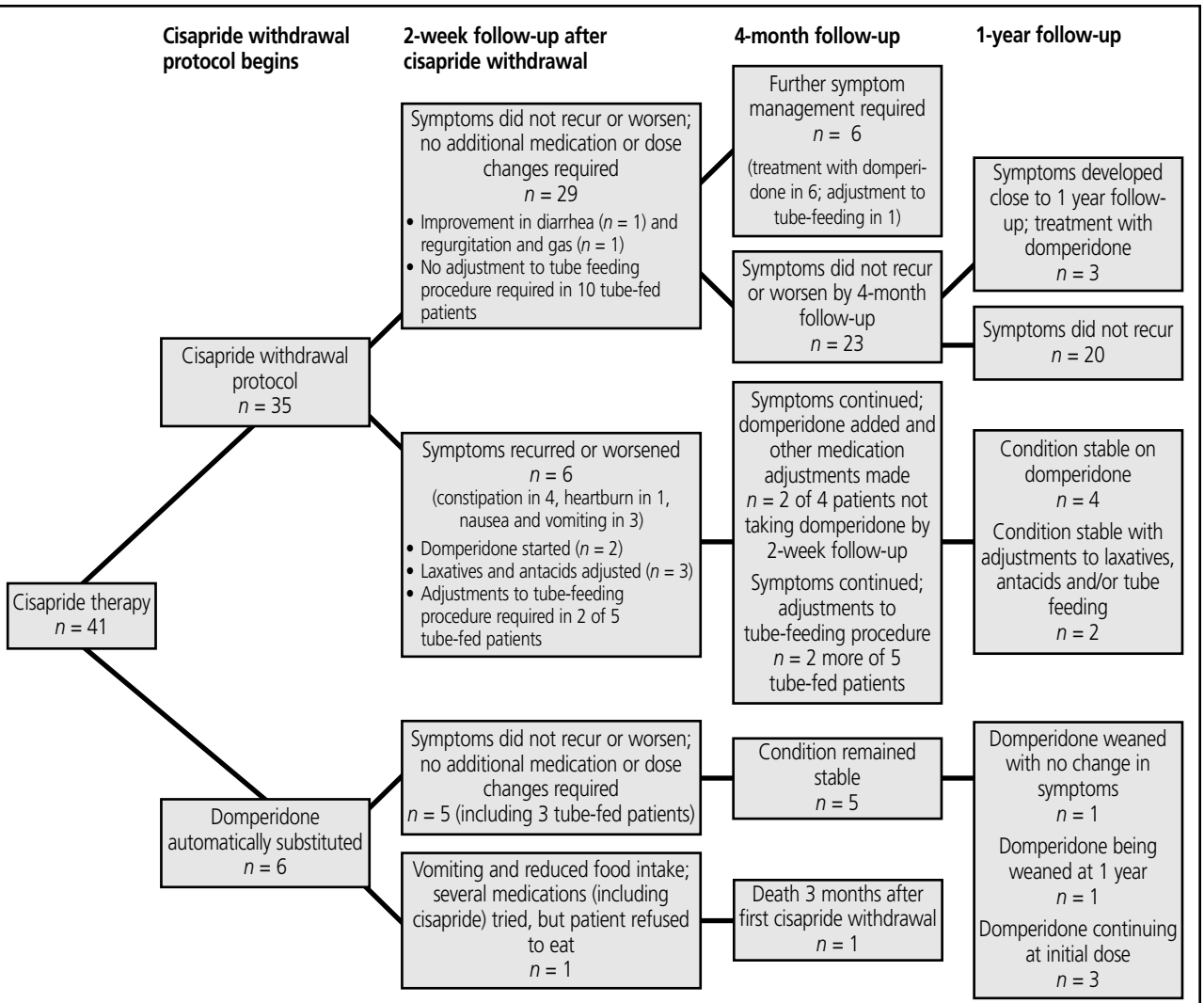

Figure 1: Flow chart showing outcomes of cisapride withdrawal.

Table 2 presents the demographic characteristics of the 35 patients who underwent the cisapride withdrawal protocol. No variables were found, by χ^2 analysis, to be predictive of successful withdrawal.

Despite lack of literature evidence and pharmacy and therapeutics committee-approved guidelines to the contrary, automatic substitution to domperidone was instituted for 6 patients. In 2 of these cases, the same attending physician felt strongly that such substitution was necessary; the regular attending pharmacist was on holidays that week, and the covering pharmacist did not know the patients well enough to provide sufficient evidence to change the physician's decision. In a third case, another attending physician also thought that the patient needed the substitution and therefore did not want to observe a drug-free period. The reasons given by the pharmacist and the physician for automatic substitution in the fourth and fifth patients were that both had a history of vomiting and significant gastrointestinal distress, both were doing well on the medication with no apparent side effects, and the family of one patient was very anxious about changes in medications, particularly when the patient appeared to be doing well. For these 5 patients, symptoms did not recur or worsen, and no additional medication (beyond the domperidone) or dose changes were required. In the sixth case, all parties believed that the patient needed the substitution. Even with domperidone use, however, this patient's symptoms of nausea and vomiting worsened. Despite several interventions, including restarting cisapride, adding other antiemetics, and initiating psychiatric treatment, the patient began refusing to eat and died several months later. A direct relationship between the death and the withdrawal

Table 2. Demographic Characteristics of 35 Patients Undergoing Cisapride Withdrawal

Characteristic	No. (and %) of Patients*	
Sex		
Male	19	(54)
Female	16	(46)
Age (yr)		
<60	10	(29)
≥60	25	(71)
Mean (and SD)	68.1	(14.9)
Range	29–92	
Cisapride daily dose (mg)		
≤40	31	(89)
>40	4	(11)
Indication		
Tube feeding	15	(43)
Nausea or vomiting	21	(60)
Gastroparesis	9	(26)
GERD	7	(20)
Aspiration	2	(6)
Irritable bowel syndrome	1	(3)
Constipation	1	(3)
None identified	3	(9)
No. of indications		
None	3	(9)
1	15	(43)
2	13	(37)
3	2	(6)
4	1	(3)
5	1	(3)
Mean (and SD)	1.6	(1.0)
Range	0–5	

GERD = gastroesophageal reflux disease, SD = standard deviation.
*Except where indicated otherwise.

of cisapride is difficult to ascertain, as reinstitution of the drug for 1 week had no effect and there was a history of psychological issues, including refusal to eat.

Before implementation of the cisapride withdrawal protocol, the hospital spent approximately $50 000 on cisapride annually and negligible amounts on domperidone. After implementation of the protocol, expenditures were reduced to $4200 for domperidone. There was no noticeable change in the amount of other related agents used (e.g., laxatives, antiemetics, or antacids).

DISCUSSION

This targeted medication withdrawal process clearly identified patients who required ongoing treatment with cisapride-like drugs and those who did not. The high rate of successful withdrawal (66% at 4 months after withdrawal) indicates that there was significant and costly use of an unnecessary drug. These outcomes support the continued use of the targeted medication withdrawal approach. However, they also raise a question as to why such unnecessary use of cisapride continued in these patients, despite periodic individualized interdisciplinary medication reviews and other mechanisms designed to minimize suboptimal drug use. This result has prompted the institution to conduct an internal evaluation of its medication review procedure and to examine the literature further to determine how to improve this process.

Some important lessons were learned in conducting this first targeted medication withdrawal.

The follow-up period after drug withdrawal should be longer. The initial plan was to follow the patients for 2 weeks only, but a chart review 1 year later revealed several patients whose symptoms had worsened or recurred shortly after this period. A follow-up period of 4 months appears more appropriate to ensure identification of all those who experience problems after withdrawal of a drug.

One patient died after cisapride withdrawal. Although the relationship between the death and drug withdrawal is uncertain, all caregivers indicated that if they had had a choice, this patient would not have been considered for drug withdrawal. This situation highlights the importance of obtaining the informed consent of all parties (both patients and caregivers) for such processes. In future targeted medication withdrawal programs, the issue of consent will be explored.

It is difficult to predict who will do well and who will not after medication withdrawal. The numbers in this study were too small and the indications too varied to provide predictors of success. It is recommended that future targeted medication withdrawal approaches be assessed in multicentre studies. Increasing the numbers of patients may also provide an opportunity to use a randomized design.

In conclusion, the authors' institution plans to continue using the targeted medication withdrawal approach. The institution's staff believe that it helps pharmacists, physicians, and nurses to safely "rock the boat" by providing a formal structure for withdrawal, detailing the monitoring parameters to be used, ensuring follow-up, and, most important of all, affording institutional support in decision making regarding drug therapy.

Addendum

The Pharmacy Department of SCO Health Services received a 2002 CSHP Research and Education Foundation grant in support of a research project involving a similar approach to withdrawing baclofen and dantrolene in complex continuing care patients with spasticity. This project involves informed consent

from patients or substitute decision makers. It also uses patient and physician questionnaires to collect qualitative information to help determine factors that play a role in medication decision making for long-term institutionalized patients. The baclofen and dantrolene withdrawal process is currently in progress. It is hoped that follow-up and analysis will be completed by fall 2003, with publication of results by spring 2004.

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Barbara Farrell, PharmD, is Clinical/Research Coordinator in the Pharmacy Department, SCO Health Service, Ottawa, Ontario.

Lorna Hughes, BScPharm, was, at the time of this study, a Staff Pharmacist in the Pharmacy Department, SCO Health Service, Ottawa, Ontario.

Ineke Neutel, PhD, FACE, is a Pharmacoepidemiologist in the Research Department, SCO Health Service, Ottawa, Ontario

Kelly Babcock, BSP, is Director of the Pharmacy Department, SCO Health Service, Ottawa, Ontario.

Address correspondence to:
Dr Barbara Farrell
Pharmacy Department
SCO Health Service
43 Bruyère Street
Ottawa ON
K1N 5C8

e-mail: bfarrell@scohs.on.ca

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Appendices on pages 38–41

Appendix 1. Cisapride Withdrawal Protocol at Authors' Institution (May 2000)

Dosing: Decrease cisapride dose to 50%, then 25% of original dose every 3 days until dose has remained at less than or equal to 20 mg/day, then discontinue.

e.g., from 20 mg qid to 10 mg qid x 3 days to 5 mg qid x 3 days, then discontinue
e.g., from 10 mg qid to 5 mg qid x 3 days, then discontinue
e.g., from 10 mg tid to 5 mg tid x 3 days, then discontinue

Monitoring Plan: Inform dietitian prior to starting withdrawal.

Reason for Cisapride Use	Monitoring Parameter	Frequency of Monitoring	Alternatives if Significant Symptoms Recur
GERD	Reflux symptoms: • Heartburn • Nocturnal cough • Asthma (SOB) • Bile/acid regurgitation • Dysphagia	• Start first day following dose decrease and continue daily until 3 days following complete discontinuation, then twice per week for 2 more weeks	Consider: • contributing medications • non-drug measures If medication required, consider: • Diovol or Gaviscon • ranitidine • lansoprazole
Gastroparesis	• Postprandial discomfort • Nausea • Vomiting • Anorexia	• Start first day following dose decrease and continue daily until 3 days following complete discontinuation, then twice per week for 2 more weeks	If medication required, consider: • domperidone • metoclopramide
Dyspepsia, nausea	• Dyspepsia • Nausea	• Start first day following dose decrease and continue daily until 3 days following complete discontinuation, then twice per week for 2 more weeks	Consider: • contributing medications If medication required, consider: • Diovol or Gaviscon • ranitidine • prochlorperazine
Refractory constipation	• Decreased frequency of bowel movements • Hard stools • Gastrointestinal discomfort • Bloating • Nausea	• Start first day following dose decrease and continue daily until 3 days following complete discontinuation, then twice per week for 2 more weeks	Consider: • contributing medications If medication required, consider: • laxatives (patient specific) • motility agents (domperidone, metoclopramide)
Tube feeding (with or without other indications as above)	• Gastric residual >150 mL • Nausea • Vomiting • Change in PO intake • Plus above parameters as needed for individual patients	• Nurse to check gastric residuals just prior to change in cisapride dose then every feed as follows until 1 week following complete discontinuation (nurse to call dietitian if residual > 150 mL found) • Start first day of dose decrease and continue daily until 3 days following complete discontinuation, then twice per week for 2 more weeks	• If residual >150 mL, delay feed by 30 min, check residual again, slow rate down if in doubt and contact dietitian Dietitian may: • change feeding rate • change feed volume • change feed type If medication required, consider: • ranitidine • lansoprazole • metoclopramide • domperidone

GERD = gastroesophageal reflux disease, SOB = shortness of breath, PO = by mouth, Diovol = aluminum hydroxide–magnesium hydroxide, Gaviscon = alginic acid compound.

Appendix 1. continued

Drug interaction management plan: Most drug interactions with cisapride result in its decreased metabolism, elevated levels of cisapride, and subsequent cardiotoxicity. These interactions are not dealt with here because withdrawing cisapride will not have an effect on the metabolism of these drugs.

Since cisapride accelerates gastric emptying, its discontinuation may increase the absorption from the stomach of other concomitantly administered drugs, whereas absorption of drugs from the small bowel may be decreased. Therefore, be aware that any drug may possibly be affected.

The following interactions are those for which we have some documentation. As with many drug interactions, these are theoretical and may not necessarily occur.

Drug Affected by Cisapride	Expected Outcome of Cisapride Withdrawal	How to Manage
Warfarin	INR may decrease; may need to increase warfarin dose	Check INR every 2–3 days after each dose change, then 1 week after complete discontinuation; adjust dose of warfarin as needed
Levodopa	May decrease levodopa levels which could affect Parkinson's symptoms	Monitor for signs and symptoms of parkinsonism and adjust dose of levodopa as needed
Digoxin	May increase effect of digoxin	Monitor for signs and symptoms of digoxin toxicity and adjust dose of digoxin as needed (not necessary to do digoxin levels unless symptoms occur and you want to confirm)

INR = international normalized ratio.

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Appendix 2. Patient Data Collection and Monitoring Tool for Use by Pharmacist and Dietitian

Service de santé *des Soeurs de la Charité d'Ottawa inc.*
Sisters of Charity of Ottawa HEALTH SERVICES INC.
Care of the Elderly and Rehabilitation

CISAPRIDE WITHDRAWAL DATA COLLECTION FORM

Attach copies of patient medication profiles from Day 1 of cisapride withdrawal and from the last day of monitoring (2 weeks after complete discontinuation of cisapride).

Patient: _____ **Day 1 of withdrawal:** _____/ _____/ _____

Permanent Unit # (U#): _____ **Retrospectively completed:** ☐
Prospectively completed: ☐

Complete this section prior to starting cisapride withdrawal

Reason for cisapride use:

☐ **GERD** ☐ **Refractory Constipation** ☐ **Dyspepsia/Nausea**

☐ **Gastroparesis** ☐ **Tube Feeding (check below)** ☐ **Other** _____

Baseline tube feeding information:
Rate : _____ **Type of tube:** _____ **Pump?:** _____

Volume: _____ **Type of feed:** _____

Complete this section 2 weeks following complete cisapride withdrawal:

What was the patient outcome after the discontinuation? Include specifics.

☐ **no change**

☐ **worsening of initial symptoms** _____

☐ **addition of medication to treat worsened symptoms** _____

☐ **increased dose of medication to treat worsened symptoms** _____

☐ **alteration of feeding rate/volume/type** _____

☐ **other** _____

Were there any other medications that required dose adjustment secondary to the discontinuation of cisapride? If so, which medications and what was done? _____

_____

_____

_____

_____

Appendix 2. continued.

Complete this section daily, then twice weekly according to the cisapride withdrawal protocol. Begin with a baseline assessment on the day prior to beginning cisapride withdrawal (Day 0). Attach details or photocopies of chart notes if necessary.

Adverse Event		First Dose Decrease			Second Dose Decrease or Discontinuation			Third Dose Decrease or Discontinuation			Follow-up Week 1			Follow-up Week 2	
	day 0	day 1	day 2	day 3	day 1	day 2	day 3	day 1	day 2	day 3	day 1	day 3	day 5	day 2	day 6
Heartburn															
Nocturnal cough															
Asthma (SOB)															
Bile/acid regurgitation															
Dysphagia															
Postprandial discomfort															
Nausea															
Vomiting															
Anorexia															
Dyspepsia															
↓ frequency of bowel movements															
Hard stools															
Gastrointestinal discomfort															
Bloating															
Change: PO intake*															
Gastric residuals >150 mL															
Change: feeding rate, volume, type*															
Other															

*Ask dietitian to complete:

PO intake changes: _____

_____

Tube feeding changes: _____