

# Factors Associated with the Use of Over-the-Counter Medications in Cases of Acute Gastroenteritis in Hamilton, Ontario

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## ABSTRACT

**Background:** Monitoring over-the-counter (OTC) medication sales may provide an accurate, reliable way to observe trends and detect aberrations in community health status. This study assessed demographic and symptomatic factors associated with the use of OTC anti-nauseants (AN), anti-diarrheals (AD), and rehydration therapies (RT) in cases of acute gastroenteritis (GE).

**Methods:** Data on 351 cases of self-reported, acute GE obtained from a population-based telephone survey were analyzed. The four outcomes of interest were use of an OTC 1) AD, 2) AN, 3) RT, and 4) use of at least one of the three. The association between each factor of interest and the use of OTC treatments was assessed.

**Results:** Of the 351 cases, 110 (31%) used at least one OTC AD, AN, or RT for their illness. The most significantly associated factor was primary symptom group: cases with both vomiting and diarrhea were 3.6 times more likely to use at least one of the three OTC medications than cases with either vomiting or diarrhea only. Other factors associated with the use of at least one OTC were being female (OR=1.97), being 10-14 years of age (OR=11.22), and use of antacids in the 28 days prior to illness (OR=2.31).

**Conclusion:** This study provides the first published assessment of factors associated with the use of OTC medications by community cases of GE. Those who use OTC medications for their illness appear to differ from those who do not. This information can inform health officials, and aid development of pharmacy-based syndromic surveillance.

**MeSH terms:** Gastroenteritis; antidiarrheals; fluid therapy; signs and symptoms; drugs, non-prescription

*La traduction du résumé se trouve à la fin de l'article.*

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Gastroenteritis (GE) is a significant cause of morbidity in Canada.<sup>1-3</sup> Traditionally, clinical surveillance data have been the main source of information for estimating the incidence of GE. However, due to under-reporting, these data only represent a small proportion of cases actually occurring in the community.<sup>1</sup> In addition, a significant lag time exists between onset of illness and notification of health officials via these clinical health surveillance systems.<sup>4</sup>

Other health surveillance strategies may reduce the time between onset of illness and public health notification, enabling faster response. For example, monitoring over-the-counter (OTC) sales of pharmaceuticals may provide an accurate, reliable way to observe trends and detect aberrations in community health status.<sup>4,7</sup> OTC medication sales have been related to epidemic curves<sup>4</sup> and clinical health data,<sup>5</sup> and they provide an earlier indication of the development of public health conditions than that which is provided by physician consultation and hospitalization records.<sup>4,7</sup> One drawback is that OTC medication sales information does not necessarily indicate the buyer's location, their demographic status, or the reason for the purchase. As well, it is possible that those who purchase OTC medications for their illness may not be representative of the sick population as a whole.

From February 2001 to February 2002, the Public Health Agency of Canada (formerly Health Canada) performed a population-based survey to describe self-reported, acute GE in the population of Hamilton, Ontario.<sup>2</sup> This was a retrospective, telephone survey with a response rate of 36.6%. Of the 3,496 respondents, 351 (10.04%) reported acute GE (diarrhea or vomiting) in the 28-day period prior to the interview. Using data from this survey, the purpose of this study was to identify the demographic and symptomatic factors associated with OTC medication use, specifically anti-diarrheals (AD), anti-nauseants (AN), and rehydration therapies (RT), in individuals reporting acute GE.

## METHODS

### Data

The survey from which the data were obtained has been described in detail elsewhere.<sup>2</sup> We analyzed data from the 351

respondents who reported acute GE in the 28 days prior to interview. The outcomes of interest were whether or not the respondent used an OTC AD, AN, or RT because of their illness. Independent factors included demographics, primary symptoms (vomiting only, diarrhea only, or both vomiting and diarrhea), other symptoms of illness, and measures of severity.

### Analysis

Data were summarized and analyzed using Microsoft® Excel 2003 (Microsoft Corporation, Redmond, WA, USA) and SAS version 9.1 (SAS Institute Inc., Cary, NC, USA). A severity score, modified from those presented in the literature,<sup>8,9</sup> was used to represent individual case severity (see Appendix). Cases with scores of 0-8, 9-16, and 17-24 were considered to be 'mild', 'moderate', and 'severe', respectively. Severity scores were compared to the severity as self-reported by respondents.

Fisher's two-tailed exact test was used to test for differences in prevalence of OTC use for all independent factors of interest. The chi-square test was used to test for an overall association between each of the factors of interest and four outcomes: use of an OTC 1) AD, 2) AN, 3) RT, and 4) use of at least one of the three. Univariate logistic regression was used to explore the presence and strength of association between all factors of interest and use of at least one OTC product. Factors significant at the  $p < 0.2$  level, as well as potential confounders, were then included in the multivariate model. Multivariate analysis was done by backward elimination.

### RESULTS

Of the 351 individuals with self-reported GE, 110 (31%) used at least one OTC AD, AN, or RT because of their illness: 65 (19%) used an AD, 57 (16%) used an AN, and 10 (3%) used a RT. Specifically, 48 (44%) used only an AD, 38 (34%) used only an AN, 3 (3%) used only a RT, 14 (13%) used both an AD and an AN, 4 (3%) used both an AN and RT, 2 (2%) used both an AD and RT, and 1 (1%) individual used all three treatments. The prevalence of OTC medication use by demographics, symptoms, measures of severity, and duration of illness, is shown

**TABLE I**

**Among Cases of Acute, Self-reported Gastroenteritis, the Percent Who Used Over-the-counter Medications [anti-nauseants (AN), anti-diarrheals (AD), rehydration therapies (RT), or at least one of the three], Shown for Each Level of the Independent Factors Assessed in this Study**

Independent Factor Assessed		AN (%)	AD (%)	RT (%)	At Least One of the Three (%)
Sex	Male	7*	17	3	23*
	Female	22*	20	3	37*
Age (years)	0-9	17	7	12*	26
	10-14	30	40	10	70*
	15-59	18	18	2	31
	60+	8	24	0	30
Cultural group	North American	16	19	3	32
	Other	17	19	2	29
Total household income	<\$20,000	14	16	4	30
	\$20,000-\$39,999	26*	21	4	38
	\$40,000-\$59,999	19	14	5	35
	\$60,000-\$79,999	6*	21	2	25
Highest level of education	≥\$80,000	17	17	2	30
	Some high school	11	13	0	22
	High school diploma	15	22	2	34
	College/trade	19	19	2	32
Location	University degree(s)	14	61*	2	26
	Urban	16	19	3	31
Season of interview	Rural	21	17	2	38
	Spring	17	19	0*	31
Primary symptom group	Summer	19	19	8*	36
	Fall	12	18	3	28
	Winter	18	20	2	34
	Vomiting only	20	6*	0	24
Maximum number of vomiting episodes in 24-hour period	Diarrhea only	11*	18	1	26*
	Vomiting and diarrhea	33*	31*	10	56*
	1	16	16	0	21
	2-3	26	21	3	41
Maximum number of loose stools in 24-hour period	4-6	37	19	11	48
	7+	42	26	17	58
	1	9	27	0	23
	2-3	8*	17	3	24*
Self-reported severity	4-6	14	16*	1	29
	7-12	30	26	9	48
	13-23	0	0	0	0
	24+	22	41*	5	42*
Nausea†	25*	20	4*	40*	
Abdominal cramps†	18	21	3	34	
Fever†	23*	18	5	36	
Chills†	23*	15	4	32	
Joint pain/stiffness†	18	16	3	30	
Headache†	20*	19	3	34	
Excessive thirst†	21	20	3	34	
Lethargy†	18	19	4	32	
Runny nose/sore throat†	23*	15	2	32	
Coughing/sneezing†	21	19	3	34	
Bloody stool†	17	17	0	33	
Prior antibiotic use†,‡	23	10	7	33	
Prior laxative use†,‡	0	10	0	10	
Prior antacid use†,‡	19	32*	0	46*	
Severity score	Mild	9*	18	1*	25*
	Moderate	21	19	4	39
	Severe	36*	21	11*	46*
	Mild	8*	16	1*	24*
Health care provider telephoned†	Moderate	22*	21	2	37
	Severe	55*	32	23*	68*
Health care provider visited†	25*	15	9*	35	
Travel outside of Canada in prior 28 days†	26*	15	9*	36	
Duration of illness (days)	1-2	24	14	0	33
	3-4	13	17	1*	26*
	5-6	23	18	3	38
	7+	17	26	13*	39
		20	22	9*	38

\* Percent of over-the-counter medication use per factor level significantly different ( $p < 0.05$ ) than all other factor levels combined

† Percent in those without the factor is not shown

‡ Use of the medication in the 28 days prior to illness

in Table I. Cause of illness as reported by respondents was compared to OTC medication use for all cases. For each of the

four outcome variables, the most frequent ( $\geq 50\%$ ) perceived cause of illness was "caught a flu or virus".

**TABLE II**  
**Overall Chi-square Results for Factors Significantly Associated† with Over-the-counter Medication Use in Cases of Acute Gastroenteritis**

Factor	AN (n=57)	AD (n=65)	RT (n=10)	At Least One of the Three (n=110)
Sex	0.0002	–	–	0.0080
Age	–	–	0.0011	–
Primary symptom group	<0.0001	0.0016	0.0004	<0.0001
Maximum number of vomiting episodes in 24-hour period	–	–	0.0498	–
Maximum number of loose stools in 24-hour period	0.0473	0.0051	–	0.0081
Nausea	<0.0001	–	–	0.0005
Fever	0.0183	–	–	–
Chills	0.0137	–	–	–
Headache	0.0364	–	–	–
Runny nose/sore throat	0.0202	–	–	–
Prior antacid use*	–	0.0093	–	0.0127
Self-reported severity	<0.0001	–	0.0003	0.0035
Severity score	<0.0001	–	<0.0001	<0.0001
Health care provider telephoned	0.0424	–	0.0052	–
Health care provider visited	0.0230	–	0.0033	–
Duration of illness (days)	–	–	0.0004	–

\* Use of medication in 28 days prior to illness

† p<0.05

AN = antinauseants, AD = antidiarrheals, RT = rehydration therapies

travel outside of Canada in 28 days prior to illness. All factors listed in Table I were included in the univariate logistic regression analysis for individuals who used at least one of the three OTC medications of interest; significant results are shown (Table III).

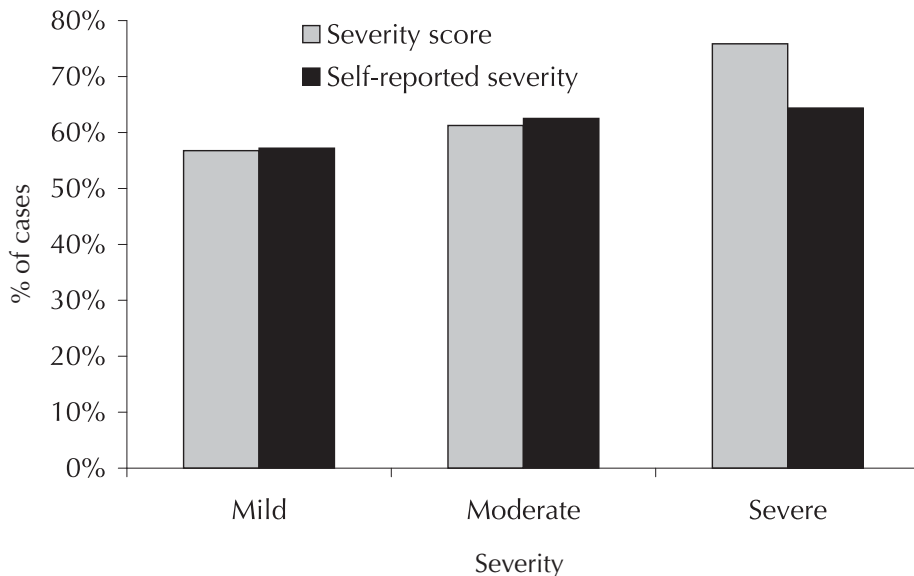
Variables included in the multivariate analysis were sex, age, primary symptom group, maximum number of loose stools in 24 hours, nausea, abdominal cramps, use of laxatives in 28 days prior to illness, use of antacids in 28 days prior to illness, self-reported severity, and severity score. The final model included age, primary symptom group, sex, and maximum number of loose stools in a 24-hour period. Results of the multivariate analysis are shown (Table III).

## DISCUSSION

This study used the results from a population-based survey of acute gastroenteritis to identify demographic and symptomatic factors associated with the use of over-the-counter anti-diarrheals, anti-nauseants and rehydration therapies. To the authors' knowledge, this is the first such study of its kind. The results presented here suggest that, among community cases of GE, those who use OTC medications for their illness differ from those who do not.

The initial chi-square analysis showed different associations for each outcome of interest. Factors associated with OTC medication use for three of the four outcomes were maximum number of loose stools in 24 hours, self-reported severity, and severity score. Primary symptom group was associated with OTC medication use for all four outcomes. Season of interview was not significant across all four outcomes indicating that, in those who have GE, season does not appear to impact use of OTC medication.

From the univariate analysis, individuals who reported both vomiting and diarrhea were four times more likely to use at least one of the OTC medications than individuals reporting vomiting alone. Additionally, females were twice as likely as males to use at least one of the three OTC medications of interest, and adolescents aged 10-14 were 6.6 times more likely to use at least one OTC medication than those aged 0-9. Cases who reported 24 or



**Figure 1.** Percent of cases of acute gastroenteritis who used at least one over-the-counter anti-diarrheal, anti-nauseant, or rehydration therapy, by severity score and self-reported severity

The overall mean and median severity scores for all 351 cases were 8.6 and 8, respectively (range: 2 to 22). For those cases that took at least one of the three OTC medications of interest, the mean and median severity scores were 10.4 and 10, respectively (range: 2 to 22). Mean and median severity scores for individuals who used AD, AN, or RT were 9.8 and 9 (range: 3 to 20), 11.5 and 11 (range: 2 to 22), and 15.1 and 15 (range: 6 to 22), respectively. The proportion of individuals who used at least one of the three OTC

medications is shown by both self-reported severity and severity score (Figure 1).

Significant results of the overall chi-square analysis are shown in Table II. The following variables were not significant across all four outcome variables: cultural group, total household income, highest level of education, urban/rural location, season of interview, abdominal cramps, joint pain/stiffness, excessive thirst, lethargy, coughing/sneezing, bloody stool, antibiotic use in 28 days prior to illness, laxative use in 28 days prior to illness, and

TABLE III

Factors Significantly Associated† with Use of One or More of Over-the-counter (OTC) Anti-diarrheals, Anti-nauseants, or Rehydration Therapies in Cases of Acute Gastroenteritis via the Univariate and Multivariate Analyses

Factor (n <sub>OTC+</sub> /n <sub>OTC-</sub> )	Univariate				Multivariate			
	Odds Ratio	95% CI		p-value	Odds ratio	95% CI		p-value
		Upper	Lower			Upper	Lower	
Sex								
Male (28/95)	1.00	–	–	–	1.00	–	–	–
Female (82/142)	1.959	1.187	3.235	0.009	1.97	–1.228	–0.131	0.0152
Age (years)								
0-9 (11/31)	1.00	–	–	–	1.00	–	–	–
10-14 (7/3)	6.576	1.442	29.987	0.014	11.22	0.819	4.017	0.003
15-59 (74/164)	1.272	0.606	2.667	0.148	1.258	–0.567	1.026	0.573
60+ (15/35)	1.208	0.483	3.019	0.200	1.207	–0.814	1.191	0.713
Primary symptom group								
Vomiting only (12/38)	1.00	–	–	–	1.00	–	–	–
Diarrhea only (59/168)	1.112	0.545	2.270	0.022	0.99	–0.788	0.759	0.971
Both V and D (39/31)	3.984	1.786	8.386	<0.001	3.60	0.435	2.129	0.003
Maximum number of loose stools in 24-hour period								
1 (3/8)	1.00	–	–	–				
2-3 (16/50)	0.853	0.202	3.607	0.063				
4-6 (27/65)	1.108	0.273	4.495	0.280				
7-12 (11/12)	2.444	0.514	11.619	0.165				
13-23 (0/0)	N.D.*	N.D.*	N.D.*	N.D.*				
24+ (30/28)	2.857	0.688	11.860	0.014				
Nausea (75/113)	2.323	1.437	3.754	0.001				
Prior antacid use (25/29)	2.100	1.162	3.793	0.014	2.31	0.190	1.487	0.011
Self-reported severity								
Mild (51/152)	1.00	–	–	–				
Moderate (33/52)	1.928	1.123	3.311	0.466				
Severe (26/30)	2.500	1.358	4.601	0.049				
Severity score								
Mild (45/144)	1.00	–	–	–				
Moderate (50/86)	1.860	1.147	3.016	0.258				
Severe (15/7)	6.857	2.632	17.865	0.001				

\* N.D. = No Data

† p<0.05

more loose stools in a 24-hour period were three times more likely than cases with one loose stool to use at least one OTC medication, and those who experienced nausea were approximately two times more likely to use at least one OTC medication. These results are expected, since the OTC medication examined here provide treatment specifically for nausea, diarrhea, and dehydration.

The highest mean and median severity scores were observed in individuals who took OTC RT, while the lowest severity scores were observed in those who took AD. In the univariate analyses, both the self-reported severity and severity score were significantly associated with the use of at least one of the three OTC medications. Individuals with self-reported 'severe' GE were 2.5 times more likely to use at least one OTC medication than those with self-reported 'mild' illness. Comparatively, 'severe' cases as classified by the severity score were 6.9 times more likely to use at least one OTC medication than cases defined as 'mild'. This magnitude of difference between self-reported severity and severity score is likely due to the fact that

the severity score was a composite measure that captured not only subjective self-reported severity, but also more objective factors such as the presence of specific symptoms. As well, several factors which contributed to the severity score were individually associated with the use of at least one of the three OTC medications, thus contributing to a stronger association with OTC use when combined in the form of the severity score.

Interestingly, more cases used at least one of the three OTC medications of those who were categorized as 'severe' by the severity score, than of those who classified themselves as 'severe'. This suggests that those who used OTC medications may have had the tendency to underestimate the severity of their illnesses when compared to those who did not use OTC medications. It is possible that use of OTC medications modified symptoms, resulting in a lower perceived level of illness. Although we know cases took these medications for their GE illness, we do not know if the medications were taken before or after onset of severe symptoms, and thus, the reason for this disparity remains unclear.

Consistent with the univariate analysis, the factor most significantly associated with the use of at least one of the three OTC medications via the multivariate analysis was primary symptom group, with those with both vomiting and diarrhea 3.6 times more likely to use OTC medication. This may reflect an increase in OTC medication use as perceived severity increases. As well, women were two times more likely than men to use at least one OTC medication. Cases aged 10-14 were 11.2 times more likely to use at least one of the three OTC medications than those aged 0-9. Interestingly, those aged 15 and older were no more likely to use OTC medications than those aged 0-9. Cases who reported having used antacids in the 28 days prior to their illness were twice as likely to use at least one OTC medication of interest than those who did not use antacids. The association between prior antacid use and OTC medication use during the GE episode may reflect the tendency of some individuals to self-medicate using more than one symptom-alleviating therapy.

The major limitation of this study was the low sample size. For this reason, we

were unable to assess factors associated specifically with each of AN, AD, and RT. Further studies should attempt to assess this, since it is likely that different OTC medications are used by different subsets of the population, as indicated in the univariate analysis presented here.

This study is the first published assessment of the association between various case characteristics and use of OTC AD, AN, and RT in cases of GE. Females, cases aged 10-14, cases with both vomiting and diarrhea, and cases who used antacids in the 28 days prior to illness were more likely to use OTC medications for their GE than their counterparts. As syndromic surveillance systems which use OTC medication sales are being investigated for potential use, the results of this study provide valuable information on factors that drive those with GE to use such products. Additionally, these results can be used by health care providers and public health officials to gain insight as to whether or not there is appropriate use of OTC medications in response to symptoms of GE.

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## Appendix

### Severity Scores Used for Cases of Self-reported Acute Gastroenteritis

Factor	Severity Score
Duration of illness (days)	
1-4	1
5-6	2
7+	3
Primary symptom group	
Vomiting only	0
Diarrhea only	0
Both vomiting and diarrhea	2
Maximum number of vomiting episodes in 24-hour period	
1	1
2-4	2
5+	3
Maximum number of loose stools in 24-hour period	
1-3	1
4-5	2
6+	3
Self-reported severity*	
Mild	1
Moderate	2
Severe	3
Health care use†	
Health care provider phoned	1
Health care provider visited	2
Hospitalized	3
Nausea	1
Cramps/abdominal pain	1
Fever	2
Headache	1
Excessive thirst	1
Blood in stool	2
Total possible score	24

\* Mild – feeling slightly unwell but able to do all or most of normal activities

Moderate – having to stay at home but able to get out of bed for limited activities

Severe – confined to home and unable to do any usual activities, or hospitalized

† For individuals who replied 'yes' to more than one option, the score for the highest option was used

## RÉSUMÉ

**Contexte :** La surveillance des ventes de médicaments en vente libre pourrait être un moyen précis et fiable d'observer les tendances et de déceler les aberrations dans l'état de santé au palier communautaire. Notre étude porte sur les facteurs démographiques et symptomatiques liés à l'utilisation des antinauséux (AN), des anti-diarrhéiques (AD) et des traitements de réhydratation (TR) en vente libre pour soigner les gastro-entérites (GE) aiguës.

**Méthode :** Nous avons analysé les données concernant 351 cas de GE aiguës déclarées par les intéressés, obtenues grâce à une enquête téléphonique représentative. Les quatre résultats qui nous intéressaient étaient l'utilisation 1) d'un AD, 2) d'un AN ou 3) d'un TR en vente libre, et 4) l'utilisation d'au moins un de ces trois médicaments. Nous avons examiné l'association entre chacun de ces facteurs et l'utilisation de médicaments en vente libre.

**Résultats :** Sur les 351 cas, 110 (31 %) avaient utilisé au moins un AD, AN ou TR en vente libre pour traiter leur maladie. Le facteur connexe le plus significatif était celui des symptômes primaires : les personnes ayant eu à la fois des vomissements et une diarrhée étaient 3,6 fois plus susceptibles d'avoir utilisé au moins un des trois médicaments en vente libre que les personnes n'ayant eu que des vomissements ou qu'une diarrhée. Les autres facteurs associés à l'utilisation d'au moins un médicament en vente libre étaient le fait d'être une femme (RC=1,97), le fait d'avoir entre 10 et 14 ans (RC=11,22) et la consommation d'antiacides au cours des 28 jours ayant précédé la maladie (RC=2,31).

**Conclusion :** Cette étude est la première évaluation publiée des facteurs associés à l'utilisation de médicaments en vente libre par des personnes atteintes de GE dans la collectivité. Les personnes qui utilisent des médicaments en vente libre pour traiter leurs symptômes semblent différentes de celles qui ne le font pas. Ces données peuvent être utiles aux autorités sanitaires et aider à la mise en place d'une surveillance syndromique en pharmacie.

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