

Children's Persistence With Methylphenidate Therapy: A Population-Based Study

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Objective: To examine persistence with methylphenidate (MPH) therapy among children and youth in the general population.

Method: We conducted a retrospective analysis of longitudinally organized, individual-specific anonymous data from linked prescription and health databases covering the population of British Columbia for 1990 through 1996. No prescriptions being filled for 4 months indicated cessation of one bout of therapy.

Results: Among 16 945 identified MPH patients aged 19 years or under, overall duration of therapy was 584 days, and the average number of prescriptions received was 6.6. One-third of patients received 2 or fewer prescriptions, while 18% followed a chronic, continuous course. Among patients receiving more than 2 prescriptions, 50% of discrete therapy bouts lasted 4 months or less, and one-third of cases had multiple bouts of therapy (range 2 to 6 bouts). Younger age (that is, children aged 0 to 8 years, vs those aged 10 to 19 years), male sex, and receipt of initial prescription from a psychiatrist were associated with greater persistence.

Conclusions: Enormous variability in persistence with MPH therapy and often-occurring low rates of persistence raises questions about the diligence with which MPH patients are selected, prepared, and followed in the general population. Special attention to the needs of older children and to the needs of girls is required, and discontinuities during children's therapy courses require explication.

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Clinical Implications

- Persistence with methylphenidate (MPH) therapy is lower in a general population setting than in closely supported clinical or research cohorts; this supports the need for close follow-up and support of patients on stimulant therapy.
- Lack of persistence may be more of an issue among girls, who may therefore need even closer support and supervision.
- Discontinuities during a child's course of stimulant therapy are relatively frequent. Clinicians should enquire about these and try to understand the reasons for them.

Limitations

- Results reflect persistence with MPH, which was the main stimulant in use at the time of the study. The extent of persistence with stimulant drugs as a group may be somewhat higher than is reported here.
- The advent of new agents for treating attention-deficit hyperactivity disorder may affect persistence patterns.
- Use of administrative data does not allow us to understand persistence (or lack of persistence) at the individual patient level.

Key Words: methylphenidate, attention-deficit hyperactivity disorder, drug therapy, persistence, adherence, population-based research

The efficacy of stimulant drugs such as methylphenidate (MPH) and dextroamphetamine in reducing symptoms and normalizing function in children with attention-deficit hyperactivity disorder (ADHD) has been convincingly established (1). Between 70% and 80% of affected children show a positive response to the first drug tried, and up to 90% show a positive response if an alternative stimulant is used (2); however, ongoing benefit requires ongoing treatment (3). Remission of ADHD has been reported to occur in 20% to 30% of diagnosed children over periods of 2 to 3 years (4,5), while follow-up studies ranging across 3 to 8 years have found persistence of ADHD diagnosis and ADHD-related problems in between 40% and 80% of cases (5–10). Since stimulant drugs are therefore an effective treatment for a chronic disorder, we might expect that most children who are medically treated for ADHD remain on therapy more or less continuously for years. However, it is impossible to discern from the existing literature whether this is true. Estimates of children's persistence with stimulant therapy vary: one study found that only about one-half of a cohort of children who commenced MPH therapy were still taking MPH 10 months after commencement (11), while another study showed an average length of 7 to 8 years on stimulants (12). Differences in study settings and measures of persistence make it difficult to draw general conclusions, and it is often unclear how investigators have dealt with periods of time off therapy, which appear to occur quite frequently (13), when calculating overall duration of active therapy. To address these issues, we examined persistence with MPH therapy in a population-based cohort of children and youth aged under 19 years at the time of their first prescription. We conducted the study over a 7-year period in the 1990s, using multiple measures of persistence and predetermined strategies for dealing with discontinuities and potential censoring effects. At the time of the study, approximately 85% of stimulant prescriptions in British Columbia were for MPH (personal communication, D Rhodes, IMS Health, 2002), which is similar to data reported from the US (14). We describe persistence with and continuity of therapy in terms of overall duration, number of prescriptions received, occurrence of multiple bouts of therapy, and duration of such bouts. Further, we examine factors that might influence persistence with MPH therapy, specifically, age and sex of patients and the specialty type of the physician providing the initial prescription.

Methods

Study Design and Setting

This is a retrospective, longitudinal, database analytic study involving administrative health and prescription data from the entire population of British Columbia (population 3.7 million at the midpoint of the study period). General practitioners

(GPs) and family practitioners (FPs) provide for most of children's primary care needs, with pediatricians and psychiatrists providing mainly consultative services. The costs of medically necessary services for British Columbia residents are covered under the universal health insurance coverage plan known as medicare.

Data Sources

British Columbia's Triplicate Prescription Program database collects data from a statutory requirement in British Columbia, which requires that notification of all prescriptions of drugs with a potential for abuse must be sent to the provincial medical licensing authority, the College of Physicians and Surgeons of British Columbia. Prescription of MPH is regulated under this program, though dextroamphetamine and pemoline are not, perhaps owing to a historic view of each drug's relative degree of use or perceived potential for abuse. Routinely collected data include unique patient and physician identifiers, tablet type and strength, number of tablets, and date dispensed. Physicians are required to write a new prescription when a refill or renewal is needed, but there are no specific constraints on how many tablets may be prescribed or how long each prescription may last. We used the triplicate prescription database to identify children who received a prescription for MPH, physicians who prescribed MPH (prescribers), and dates of each prescription.

The British Columbia Linked Health Dataset (BCLHD) is a repository of administrative health records that are part of the provincial medicare program. The BCLHD is linked for individual residents of the province across files that cover basic demographic information, physician contacts, hospital separations, and vital events (15). We accessed BCLHD data for background demographic characteristics of patients and information on the prescriber's specialty type.

Overall Study Population and Subsidiary Cohorts

The overall study population (that is, persons aged 0 to 19 years in 1990 through 1996) was the principal cohort, providing data for most of the analyses. Patients' ages were taken at the time of their first MPH prescription. For analyses involving the prescriber's specialty type, we restricted the data set to January 1990 through September 1995, because audits of Triplicate Prescription Program data revealed instances of coding errors for prescriber identifiers following changes to recording practices in September 1995.

Measures

Persistence With Therapy

The overall length of time on medication was calculated as the number of days between a child's first and last prescription. For individuals who followed a noncontinuous course of therapy, with time off medications, this measure would overstate

the true duration of time that medications were actually taken. For this reason, we also calculated the duration of discrete bouts of active therapy.

The number of prescriptions received is a count of the total number of prescriptions of MPH dispensed to a child during the study period.

Continuity of Therapy

We calculated the proportion of patients who had multiple bouts of therapy within the study period. The criterion used to indicate the end of one bout of active therapy was a period of 4 months or longer with no prescription-filling activity. We adopted the criterion in light of 2 local observations: first, the average length of time between successive MPH prescriptions for children in British Columbia is 97 days, or approximately 3 months, and is even shorter for chronic, stable patients (16); and second, school summer vacation lasts just over 2 months. This criterion therefore appeared suitable for capturing unusually long periods with no prescription-filling activity, without overclassifying patients as having terminated therapy.

We calculated the duration of discrete bouts of active therapy as days from the first prescription to the last before a gap of 4 months or longer with no prescription-filling activity. For example, if prescriptions for MPH were dispensed to a patient in January, April, July, October, and December of one year, the duration of therapy would be about 11 months. Conversely, if prescriptions were received in January, April, October, and December, approximately 2 bouts of 3 months and 2 months, respectively, would be recorded.

Chronicity of Therapy Designation

Patients were designated as falling into 1 of 3 chronicity of therapy categories, based on the total number of prescriptions received and the continuity of therapy. Short-term patients received just 1 or 2 prescriptions in total during the study years, while chronic patients received at least 1 set of MPH prescriptions for at least 12 months, with no gaps between successive prescriptions of longer than 4 months. The remainder (that is, the intermediate group) did not conform to either of these criteria.

Data Organization, Management, and Analysis

We identified patients by their Personal Health Number (PHN), a unique identification issued to British Columbia residents by the Ministry of Health. Its use in both the prescription database and BCLHD allowed for the linkage of person-specific information across files. Patient anonymity was ensured by use of an encrypted version of each patient's PHN. The Ministry of Health granted access to data in this form under its access policy. The project was approved by the Research Ethics Review Board of the University of British

Columbia and by the College of Physicians and Surgeons of British Columbia.

In our large data set, some cases were excluded because of missing data; others were excluded because the available data appeared to represent highly exceptional situations, and we were unable to verify their accuracy. Instances of missing data, such as unknown patient sex, involved less than 1% of study cases and are not explicitly mentioned in the text. Two outlier situations recognized in our data set were very short intervals (that is, under 7 days) between successive prescriptions and apparent prescription of very high dosages of MPH (>100 mg daily). These cases collectively accounted for about 2.5% of our database cases, and their exclusion is specifically indicated in the text.

We present our data mainly as descriptive statistics. In comparing persistence among various groups of patients, we elected not to perform tests of statistical significance for 2 reasons. First, statistical inference is used to estimate population parameters from values obtained from sampling that population. The values we report are derived from the entire population; thus it would be inappropriate to apply inferential techniques. Second, tests of statistical probability may appear hugely significant when performed with the large number of cases employed in population-level research, and for this reason, results may be misinterpreted and misleading.

Results

Description of Population and Subsidiary Cohorts

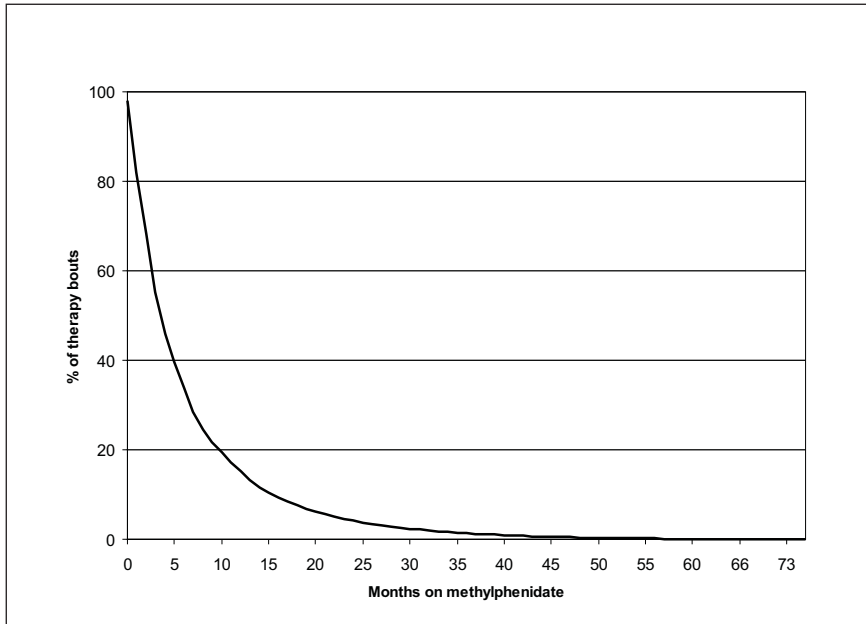
A total of 18 081 children received at least 1 prescription of MPH during the period from January 1, 1990, to December 31, 1996. A detailed description of patients and prescribing physicians forms the subject of another report (16), but key characteristics are summarized here. Average age at first prescription was 9.6 years. There was a marked preponderance of boys (male-to-female ratio 4.4:1) and of children in the group aged 5 to 9 years and 10 to 14 years (49% and 37% of the total patient population, respectively). GPs and FPs wrote 55.5% of all prescriptions to children, while pediatricians and psychiatrists accounted for 23% and 21%, respectively.

From this overall population, we worked primarily with data from 16 945 patients whose first recorded prescription of MPH was after the first 4 months of the study window. The restricted data set used for analyses involving prescriber specialty type comprised 13 289 patients.

Persistence and Continuity With Therapy

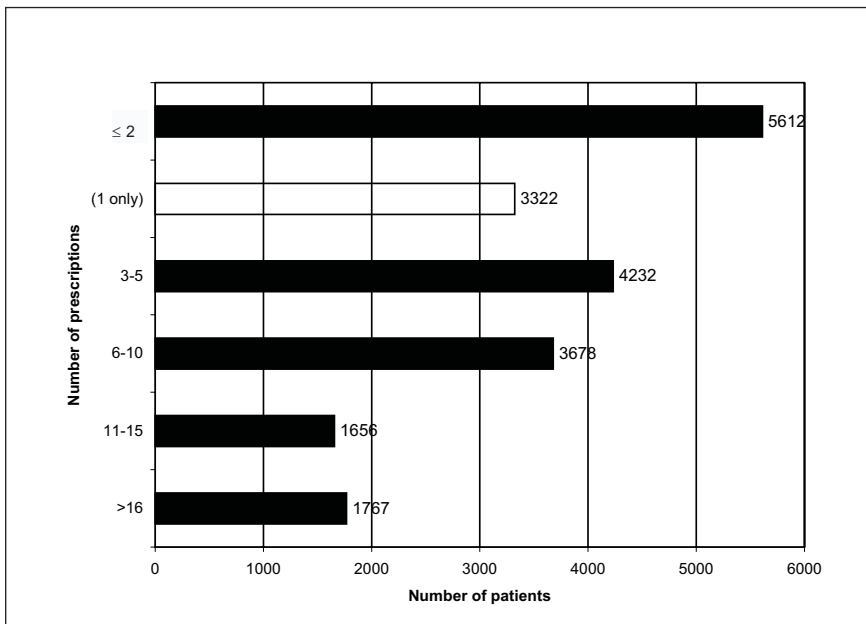
The average duration of therapy among all children was 584 days, or 19.2 months (after we excluded 3322 patients who received a single prescription only and 425 patients with a prescription duration of ≤ 7 days and [or] a prescribed daily dosage of >100 mg). Among the 13 449 patients who received

Figure 1 Persistence with MPH therapy by duration of therapy bouts



*Excludes children with single prescription only

Figure 2 Number of prescriptions received by child patients over a 7-year study period



more than a single prescription for MPH and who had less than 7 days between successive prescriptions, therapy bouts were mostly brief (Figure 1). One-half of the therapy periods continued for approximately 4 months, and about 15% lasted 1 year or more. Mean duration of bouts was 208 days, or roughly 6.8 months. The apparent dissociation between overall duration and bout length is partly attributable to the fact that 33% of patients (that is, 4444 of 13 449 patients) had more than one bout of MPH therapy, according to our criterion. Of

these patients, 3067 (69%) had 2 bouts of therapy, 1012 (23%) had 3 bouts, 280 (6%) had 4 bouts, 71 (1.6%) had 5 bouts, and 14 (0.3%) had 6 bouts.

Figure 2 depicts the distribution of the number of prescriptions to children over the 7-year study period. There is considerable skewing toward children receiving relatively few prescriptions (that is, 5 or fewer), but about one-fifth of patients received prescriptions over a longer term. The mean (SD) number of prescriptions received during the study period was 6.6 (7.9).

With respect to the number and continuity of prescriptions, one-third of all patients (33%) were categorized as short-term and about one-fifth (18%) as chronic. The remaining 49% fell into the intermediate group.

Influences on Persistence With Therapy

Therapy bout length decreased progressively with increasing patient age (Figure 3). Additional analyses showed that the average duration of therapy periods for children aged 0 to 9 years was 7.8 months, compared with 5.8 months for those aged 10 to 19 years. Age effects were also found in terms of the number of prescriptions received. Children aged 0 to 9 years received an average of 8.9 prescriptions, compared with 6.2 prescriptions for those aged 10 to 19 years. In addition to age effects, there were sex differences in the number of prescriptions received (Figure 4). The average number of prescriptions received by boys was higher than that for girls in all age groups except in the category aged 15 to 19 years. Across age groups, boys received an average of 7.6 prescriptions, while girls received an average of 6.6 prescriptions. Sex effects were

not detectable when examining the length of therapy bouts, suggesting that boys experience more bouts of therapy than girls.

Finally, the specialty type of the physician who provided the child's initial prescription for MPH was related to persistence on 2 measures. The mean (SD) number of prescriptions received by children whose initial prescription was from a psychiatrist was 7.9 (9.6), compared with 5.4 (5.5) and 6.3

(8.1) for first prescriptions from pediatricians, GPs, and FPs, respectively. Also, patients were more likely to be classified as chronic than short-term if their initial prescription was written by a psychiatrist rather than a pediatrician, GP, or FP (odds ratio 1.77; 95%CI, 1.55 to 2.02) (Table 1).

Discussion

This study shows the average therapy duration was 19 months, with a total receipt of fewer than 7 prescriptions in a 7-year period, indicating a lower degree of persistence with MPH therapy than usually reported. Various studies have found persistence to be at least 2 years in over 80% of children (17), with up to 4 years in 77% of boys and 50% of girls (18) and an average persistence of 3 years (9). The present study reports on persistence with MPH among children in a general population setting. The other studies are based on observations of cohorts that have been carefully selected, closely monitored, and intensively supported by clinicians or researchers. They only report the course of the subset of patients who were found to be positive responders to stimulant drugs, or they describe persistence with stimulants in general, not just MPH (9,18). Two community-based surveys that found an average length of time on stimulants to be 50 months (19) and patient age to be between 7 and 9 years (12), respectively, based their estimates on data from children who were actively on medication at the time of the survey. This would exclude a substantial number of stimulant-prescribed patients who might have taken medication for a shorter time period had they not discontinued treatment.

Studies involving the general population typically find lower rates of persistence than do studies from other settings, though variability is found even within the small group of population-based studies that exist. In contrast to our present findings, a study from Long Island county found that about 73% of children received just 1 or 2 prescriptions over a 1-year follow-up period (20), while in a prescription database study from the Netherlands, 50% of children had discontinued stimulant medications between 10 and 20 months after commencement (21). The Long Island study was conducted in

Figure 3 Methylphenidate therapy bout length by patient age

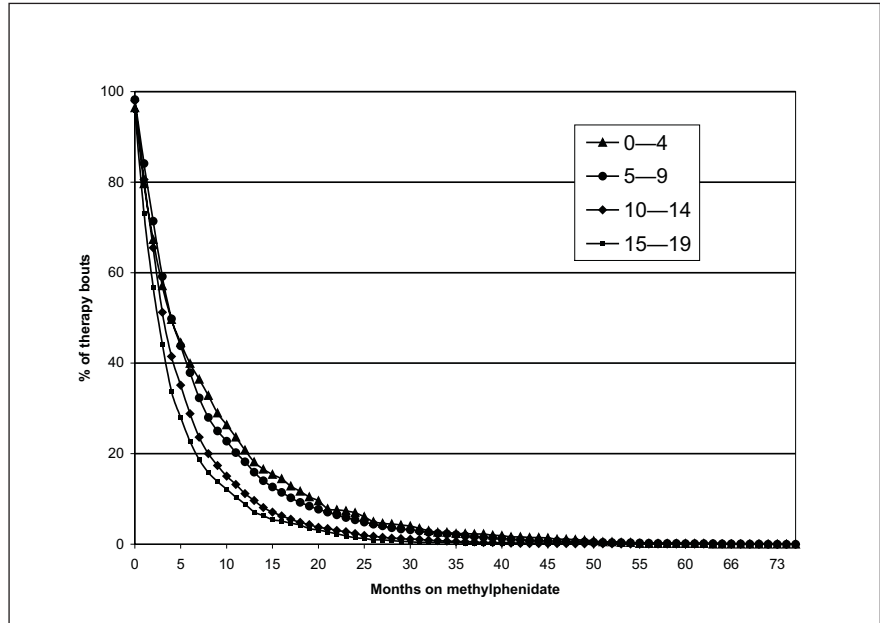
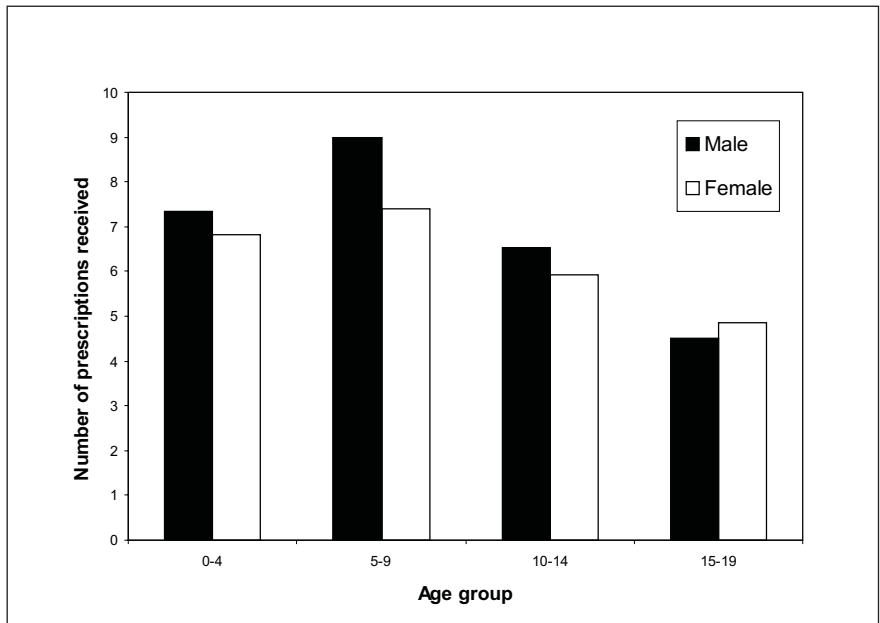


Figure 4 Average number of prescriptions received by age and sex



1986, while the present study and the Netherlands study were conducted in the 1990s. The possibility that period or era effects may explain these differences is supported by the fact that rates of persistence in the Netherlands were found to be higher later in the decade (21). This interpretation raises the question of whether contemporary patients are better educated, better prepared, or better supported by their physicians than those in the past.

Our estimates of overall persistence might have been somewhat lower had we been able to exclude periods when a patient might have discontinued (rather than temporarily

Table 1 Chronicity of methylphenidate therapy by prescriber type

Prescriber	Chronicity group	
	Short term	Chronic
Pediatrician, general practitioner, and (or) family physician	3696	1142
Psychiatrist	808	442

interrupted) his or her course of therapy. Continuity of MPH therapy has not received much research attention, though discontinuation followed by resumption of therapy was reported by parents to have occurred at least once in 40% of children during a 3-year follow-up study (13), a figure close to the 33% of children found to experience more than 1 bout of therapy in our 7-year study. Our finding that about one-third of subjects had more than 2 bouts of therapy shows that multiple discontinuities are not a rare occurrence among children on MPH in the general population. Our definition of discontinuation of therapy, namely, a 4-month period with no prescription filling activity, should have ensured that temporary but planned interruptions in a course of therapy, such as school vacation or a medication-free trial period, were not counted as discontinuations in therapy. It is not clear why patients should stop and restart medication during the course of treatment for a chronic condition. The frequency and brevity of discrete therapy bouts, averaging 6 to 7 months in this study, is a cause for some concern, because patients do not receive therapeutic benefit while off medication. It is possible that some of our subjects were incorrectly classified as having broken off active therapy when they had not. Some investigators have deemed a total of 14 weeks off medication in a year to indicate discontinuation (13), while others have taken 180 consecutive days without prescription activity as the threshold level (21). Employing a shorter period of time increases the risk of misclassifying patients as having terminated therapy when they have not, whereas the use of longer periods tends to miss those that did indeed stop medication therapy only to resume it later. Future research into how patients persist with stimulants and other drugs would be facilitated through some consensus on the definition of discontinuity.

An important contribution of the present study is the clear illustration that variability is an integral characteristic of persistence at the population level. Our chronicity of therapy measure, which incorporates 3 key dimensions of persistence, namely, duration, continuity, and number of prescriptions, provides a convenient and useful way to define subpopulations of patients taking medication. A substantial proportion of patients (one-third of the total) appear not to persist with MPH, while another one-fifth show high persistence and continuity. The remaining one-half of all children receiving a

prescription show intermediate degrees of persistence. The size of the short-term group in this study (that is, 33%) is consistent with a recent report from the US that about one-third of patients taking stimulants received only 1 or 2 prescriptions over a 1-year period (22); this is not out of keeping with expectations based on the proportion of children who fail to tolerate or respond to MPH (3). Conversely, a larger proportion of short-term cases would have raised concerns. The landmark Multimodal Treatment Study of ADHD showed that high degrees of persistence are possible with careful patient selection, drug titration, and follow-up (23). We suggest that the chronicity of therapy measure employed in the present study be considered a potentially useful indicator of the quality of medical care received by children and families in various settings, with a large proportion of short-term cases flagging possible shortcomings with patient selection, education, monitoring, or support.

The design of this study allowed us to examine a limited number of factors associated with persistence with therapy, and it was interesting to find fairly consistent age and sex effects across some measures. Findings of lower persistence among older children (that is, aged over 10 years) and youth are consistent with clinical experience and reports of poorer compliance among teenagers (24), though little has been published on this topic in relation to compliance with stimulant drugs (25). Lower persistence among girls has also been reported (11,13,18). The present findings therefore corroborate existing evidence and illustrate a further dimension of the problem of undertreatment and inadequate treatment of girls with ADHD (26).

Our findings of persistence in relation to physician factors are intriguing—a higher degree of persistence is associated with MPH therapy initiated by a psychiatrist. This could be attributed to differences in the way that different physician specialties manage children with ADHD (27), which is consistent with the notion that persistence may be related to aspects of clinical care provided. However, differences in the case mix among psychiatrists, pediatricians, and family practitioners may also be responsible.

Several study limitations need to be acknowledged. First, we derived our findings from analyses of administrative data, which are not primarily designed to address research questions and whose validity can be questioned (28). While there has been no comprehensive evaluation of the completeness and accuracy of British Columbia's Triplicate Prescription Program database, the legal requirement to report all prescriptions of MPH suggests that coverage of all cases would be close to complete. Also, the data captured are concrete, with no margin for ambiguities regarding coding of diagnoses and treatment, which can affect database analytic studies (29). Second, our study was restricted to persistence with MPH

therapy so that findings should not be construed as describing persistence with psychostimulants as a general class of medications. This aspect of our study design limits, but does not preclude, comparisons with studies describing persistence with all psychostimulants (9,12,13,18,19,21). As previously mentioned, MPH was certainly the main medication prescribed to children at the time of this study. In addition, recently acquired provincial prescription data suggest that, during the years 1996 and 1997, only about 7% of all stimulant patients received a prescription for more than one stimulant type (unpublished data). Switching from MPH to another stimulant would therefore have been an infrequent occurrence, with limited impact on overall persistence patterns. A third limitation is that a wider range of medications for treating children with ADHD has recently become available to Canadian physicians. Future research will have to examine the possible effects of newer once daily prescriptions on patients' patterns of persistence. Finally, because our findings are derived from records of the British Columbia population, there may be some limitations in generalizing these results to other provinces or health care systems.

Certain implications of our findings for medical practice, health policy, and research have already been mentioned, including the possibility of using persistence with therapy as a potentially useful, albeit indirect, indicator of the quality of care provided by physicians to patients with ADHD in community settings. The large group categorized as intermediate with respect to chronicity of therapy also requires further investigation. It is likely that the 20% to 30% of patients who are said to no longer require medications after 1 or 2 years of therapy (3–5) are found within this intermediate group. It would be helpful, however, to have additional information on the characteristics of patients and practitioners in this large group and to study the effects of interventions aimed at modifying persistence patterns within it. All the following are worthy of investigation as factors influencing persistence with stimulant medications: 1) type and severity of ADHD, presence of comorbid conditions, and child's attitude toward medication; 2) physician's specialty type and approach to assessment, patient and (or) parent's education, and management (that is, titration and follow-up visits) on the part of the physician initiating stimulant medication; 3) family stress and parent's attitudes toward medication; and 4) teacher and school attitudes. Apart from quality of care issues, our findings represent a benchmark for researchers who need to know whether a cohort they are following is representative of the general population in terms of persistence. In addition, the methodology used here can serve as a model for studying persistence with other chronic medication regimes.

Finally, knowledge of how children in the general population persist with stimulant therapy is important in the face of

expressed concerns about long-term effectiveness and safety of ADHD medications (30). Widespread failure to take medication properly and persistently has been suggested as a possible explanation for lack of evidence of long-term effectiveness of medication therapy (31). This study supports the legitimacy of that claim and underlines the need to improve understanding of nonadherence and of measures aimed at improving adherence, especially among girls. At the same time, the low prevalence of long-term users observed in our study allows us to conclude that relatively few children, perhaps only one-fifth of those exposed to stimulation medications, would be at potential risk were long-term adverse effects ever identified.

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Résumé : La persistance des enfants dans la thérapie au méthylphénidate : une étude de population

Objectif : Examiner la persistance dans la thérapie au méthylphénidate (MPH) chez les enfants et les adolescents de la population générale.

Méthode : Nous avons mené une analyse rétrospective de données anonymes propres à l'individu et organisées de façon longitudinale, tirées d'ordonnances connexes et de bases de données sur la santé de la population de la Colombie-Britannique, de 1990 à 1996. Aucune ordonnance remplie pendant 4 mois n'indiquait la cessation d'un épisode de thérapie.

Résultats : Parmi les 16 945 patients du MPH de 19 ans et moins identifiés, la durée globale de la thérapie était de 584 jours, et le nombre moyen d'ordonnances reçues était 6,6. Un tiers des patients avaient reçu 2 ordonnances ou moins tandis que chez 18 %, le cours de la thérapie était chronique et continu. Parmi les patients recevant plus de 2 ordonnances, 50 % des épisodes discontinus de thérapie duraient 4 mois ou moins, et un tiers des cas avaient de multiples épisodes de thérapie (de 2 à 6 épisodes). Le jeune âge (soit les enfants de 0 à 8 ans par rapport à ceux de 10 à 19 ans), le sexe masculin et le fait de recevoir la première ordonnance d'un psychiatre étaient associés à une plus grande persistance.

Conclusions : L'énorme variabilité de la persistance dans la thérapie au MPH et les faibles taux de persistance fréquents soulèvent des questions sur la diligence avec laquelle les patients du MPH sont sélectionnés, préparés et suivis dans la population générale. Il faut porter une attention particulière aux besoins des enfants plus âgés et à ceux des filles, et les interruptions du cours de la thérapie des enfants nécessitent une explication.