Impact of chemotherapy-associated nausea and vomiting on patients' functional status and on costs: survey of five Canadian centres

Bernie J. O'Brien,* PhD; James Rusthoven,† MD; Angela Rocchi,‡ MSc; Jean Latreille,§ MD; Sheldon Fine,¶ MD; Ted Vandenberg, MD; Francis Laberge, MD**

Objective: To estimate the effect of chemotherapy-associated nausea and emesis on patients' functional status and on costs to the health care system, the patients and society before antagonists to the serotonin (5-hydroxytryptamine) receptor subtype 5-HT_3 became available.
Design: A 5-day prospective survey between February and May 1991 of patients receiving chemotherapy for cancer. Data were obtained from questionnaires completed by nurses and patients.
Setting: Five Canadian cancer treatment centres in Ontario (three) and Quebec (two).
Patients: Outpatients and inpatients 18 years of age and older who were scheduled to receive chemotherapy with a moderate to high potential for emesis as defined by standardized criteria. Patients were excluded if they were scheduled to receive an investigational antiemetic or had received chemotherapy within the previous 7 days. Of the 128 who were eligible, 112 agreed to participate; 107 returned the completed questionnaire, but the data for 15 were excluded because the patients received multiple-day chemotherapy.
Main outcome measures: The degree of nausea (on a seven-point scale) and the frequency of emesis (vomiting or retching) were recorded for each day of the survey. Functional status was assessed before and after chemotherapy by means of the Functional Living Index–Emesis (FLIE). The direct health care costs and the indirect costs (e.g., of time off work) associated with nausea and emesis were estimated from the survey responses and secondary data sources.
Results: On the day of chemotherapy 38 of the 92 patients (41%) experienced emesis with or without nausea, and over the 5 days of the survey 72 patients (78%) reported at least one episode of nausea or emesis. The absolute risk of either problem decreased over time, but the risk of nausea relative to emesis increased over time. The FLIE scores indicated significant worsening of functional status after chemotherapy. On the day after treatment the main impact was from emesis, particularly with regard to leisure activities, household tasks and hardship to the family. Nausea had a significantly greater impact than emesis on overall functioning. The additional direct health care cost for managing emesis was estimated to be $63 and the indirect cost $121.
Conclusions: Despite prophylaxis with antiemetic drugs, nausea and emesis were significant problems in this population receiving chemotherapy. The management of emesis consumed relatively small amounts of health care resources, but there were costs outside the hospital for patients and others.

Objectif : Estimer l'effet des nausées et des vomissements liés à la chimiothérapie sur l'état fonctionnel des patients et sur les coûts pour le réseau de soins de santé, les patients et la société avant la commercialisation des antagonistes des récepteurs de la sérotonine (5-hydroxytryptamine) du sous-type 5-HT_3.

*From *the Department of Clinical Epidemiology and Biostatistics, McMaster University, Hamilton, Ont., †the Hamilton Regional Cancer Centre, Ontario Cancer Foundation, Hamilton, Ont., ‡Innovus Inc., Hamilton, Ont., §the Department of Haematology–Oncology, Hôpital Hôtel-Dieu de Montréal, Montreal, Que., ¶the Department of Oncology, Credit Valley Hospital, Mississauga, Ont., the Department of Hematology/Oncology, St. Joseph's Health Centre, London, Ont., and **the Department of Pneumologie, Hôpital Laval, Sainte-Foy, Que.*

Reprint requests to: Dr. Bernie J. O'Brien, Department of Clinical Epidemiology and Biostatistics, Faculty of Health Sciences, HSC-3H25, McMaster University, 1200 Main St. W, Hamilton, ON L8N 3Z5

Conception : Une enquête prospective de 5 jours, entre février et mai 1991, chez des patients qui ont subi une chimiothérapie anticancéreuse. Les données sont extraites de questionnaires remplis par les infirmières et les patients.
Contexte : Cinq centres canadiens de traitement du cancer situés en Ontario (trois) et au Québec (deux).
Patients : Patients externes et hospitalisés de 18 ans et plus qui devaient recevoir une chimiothérapie comportant une possibilité modérée à élevée de vomissements, tels que définis par des critères standardisés. On a exclu les patients qui devaient recevoir un antiémétique expérimental ou qui ont subi une chimiothérapie dans les 7 jours précédents. Des 128 patients admissibles, 112 ont accepté de participer; 107 ont renvoyé le questionnaire dûment rempli, mais on a exclu les données de 15 patients parce qu'ils avaient subi la chimiothérapie pendant plus d'une journée.
Principales mesures des résultats : Le degré des nausées (sur une échelle de sept points) et la fréquence des vomissements (ou haut-le-coeur) ont été notés à chaque jour de l'étude. Au moyen du Functional Living Index–Emesis (FLIE), on a évalué l'état fonctionnel avant et après la chimiothérapie. À partir des réponses au questionnaire et de sources de données secondaires, on a estimé les coûts directs en soins de santé et les coûts indirects (p. ex., les absences du travail) liés aux nausées et aux vomissements.
Résultats : Pendant la journée de chimiothérapie 38 patients sur 92 (41 %) ont vomi avec ou sans nausées, et pendant les 5 jours d'enquête 72 patients (78 %) ont signalé au moins une crise de nausées ou de vomissements. Le risque absolu d'un problème ou de l'autre a diminué en fonction du temps, mais le risque de nausées par rapport à celui des vomissements a augmenté en fonction du temps. Les résultats du FLIE témoignent d'une aggravation significative de l'état fonctionnel après la chimiothérapie. Le lendemain du traitement, la principale incidence était attribuable aux vomissements, en particulier à l'égard des loisirs, des tâches ménagères et des difficultés pour la famille. Les nausées ont eu une incidence significativement plus importante que les vomissements sur le fonctionnement global. Pour traiter les vomissements, on a estimé le coût direct en soins de santé supplémentaires à 63 $ et le coût indirect à 121 $.
Conclusions : Malgré la prophylaxie au moyen d'antiémétiques, les nausées et les vomissements ont constitué des problèmes significatifs dans la population qui a subi la chimiothérapie. Le traitement des vomissements a exigé un nombre relativement modeste de ressources en soins de santé, mais les patients et d'autres personnes ont dû assumer des coûts à l'extérieur de l'hôpital.

Nausea and emesis (vomiting or retching) are common adverse effects of chemotherapy for cancer and are primary concerns of patients receiving chemotherapy. [1] Although a number of drugs have been tested for their ability to prevent these effects, some 25% to 50% of patients still experience various degrees of nausea and emesis.[2,3] Lindley, Bernard and Fields[4] studied the incidence and duration of nausea and emesis in outpatients treated with various combinations of chemotherapy and antiemetic regimens, but there is little information on the patients' quality of life and on health care costs.

The consequences of nausea and emesis can be quantified in various ways. First, the patient's quality of life may be reduced, perhaps so severely as to threaten compliance with future treatment.[5,6] Second, there may be costs for the cancer therapy centre, both for antiemetic prophylaxis and for the management of nausea and emesis. Finally, to the extent that these adverse effects impair a person's normal functioning and productive capacity there may be costs to society more generally in the form of time lost from work.

The advent of a new class of antiemetic drugs — antagonists to the serotonin (5-hydroxytryptamine) receptor subtype 5-HT_3, such as ondansetron — may significantly reduce the incidence of nausea and emesis, particularly for patients receiving highly emetogenic cisplatin-containing chemotherapy regimens.[7] However, the relatively high cost of these new drugs has generated debate about their use.[8] Although such issues are open to standard methods of economic enquiry, such as cost-effectiveness analysis,[9] no studies have yet been published, probably because of an absence of data on the consequences and costs to patients of nausea and emesis with currently available treatment regimens.

To address this situation we conducted a prospective survey of patients receiving chemotherapy at five Canadian cancer treatment centres to quantify the functional and cost consequences of chemotherapy-associated nausea and emesis.

Methods

Survey subjects and design

The aim of the study was to document the consequences of emesis rather than to estimate its incidence. Between February and May 1991, survey subjects were

recruited from five Canadian cancer treatment centres: St. Joseph's Health Centre, London, Ont.; the Hamilton Regional Cancer Centre, Hamilton, Ont.; Credit Valley Hospital, Mississauga, Ont.; Hôpital Hôtel-Dieu de Montréal, Montreal, Que.; and Hôpital Laval, Sainte-Foy, Que. The study was not restricted to a particular cancer type, chemotherapy regimen or antiemetic drug; it recruited patients who were due to receive, as outpatients or inpatients, chemotherapy considered to be moderately or highly emetogenic by criteria established by the National Cancer Institute of Canada Clinical Trials Group.[10] In addition, patients had to be 18 years of age or older and fluent in English or French. Patients were excluded from the study if they were scheduled to receive an investigational antiemetic drug as part of a different clinical study or if they had received chemotherapy within the previous 7 days.

The survey was conducted in two phases over a 5-day period. In the first phase, study nurses at each centre recruited eligible patients attending routine scheduled appointments for chemotherapy and recorded basic demographic and clinical data. Before receiving chemotherapy the patients completed an emesis-specific instrument for the assessment of functional status — the Functional Living Index–Emesis[11] (FLIE, described later). While the patient was at the treatment facility the nurse monitored and recorded episodes of emesis, defined as vomiting or retching. Such an episode was considered anticipatory if it occurred on the same day as but before the chemotherapy. The study nurse also recorded any resources used for the prophylaxis or management of emesis; categories included nursing time, physician time, drugs and other materials.

In the second phase of the survey, patients were asked to complete questionnaires at the end of each of the 5 days of the survey, including the day of chemotherapy (day 1). The patients recorded the number of emetic episodes and the degree of nausea experienced (on a seven-point scale). They were also asked to judge whether nausea or emesis during the day had required them to (a) consult a health care professional, (b) take any prescribed or over-the-counter medication or special foods, (c) take time off work or usual activities or (d) be cared for by a friend or relative who had to take time away from work or other daily activities. In addition, on days 2 and 5 the patients completed another FLIE questionnaire.

The FLIE

Lindley and associates[11] developed the FLIE, a self-administered patient questionnaire to quantify the impact of nausea and emesis on various aspects of functional status. The FLIE is closely modelled on the Functional Living Index–Cancer (FLIC),[12] which has been used as a disease-specific instrument for assessing quality of life in oncology studies. Preliminary data have suggested that the FLIE provides a valid and reliable indication of the impact of nausea and emesis on functional status.[11] Patients are asked to rate on a seven-point scale the impact that vomiting had on nine items of functioning (see Appendix 1); the questions are then repeated for nausea.

A mean score for the entire study group between 1 and 7 for each FLIE item was calculated for nausea and emesis separately. To assess the impact of nausea and emesis individually on overall functional status for each patient we summed the scores and standardized them to lie in the range 0 ("not at all affected") to 100 ("affected a great deal"). Then separate mean standardized scores for nausea and emesis were calculated for the entire study group. Using the same approach over all 18 emesis and nausea items we constructed an overall standardized FLIE score. To determine to what extent chemotherapy-induced nausea or emesis had an impact on functional status we compared FLIE scores before and after chemotherapy. To determine what differential impacts nausea and emesis had on functional status we compared, for each patient, FLIE scores for nausea and emesis on day 2.

Costs of nausea and emesis

To quantify direct health care costs arising out of the prophylaxis or treatment of emesis, survey data on the volume and type of resources used to manage emesis were combined with estimates of unit prices. Various secondary data sources were used to put a cost on resources. For example, nursing time was valued at the gross cost of employment (the midpoint of the provincial salary plus the employer's contributions) per unit time with an allowance for relevant hospital overhead (estimated from a cost model for Chedoke–McMaster Hospitals in Hamilton, which is based on Management Information Service guidelines[13]). Provincial fee schedules were used to determine costs for physician services.[14] The cost of drugs prescribed in hospital was the purchase price for the hospital pharmacy plus a dispensing cost; the cost of outpatient medication was determined from the Ontario Drug Benefit Formulary.[15] We used published per-diem rates for each centre[16] to estimate the cost of any inpatient stay due to emesis. All costs are reported in 1991 Canadian dollars.

Indirect costs included estimates of patients' out-of-pocket expenses for the purchase of nonprescription medicines and any travel costs (e.g., to visit a physician) associated with nausea or emesis. Patient or caregiver time diverted from paid or unpaid employment to managing the consequences of emesis was valued according to the average provincial industrial wage rate[17] and the provincial minimum wage rate respectively.

Statistical methods

We compared FLIE scores over time using a

method for analysis of variance (repeated measures) that allows for unequal numbers of observations per subject owing to missing values.[18] Patients' subscale scores for nausea and emesis on day 2 were compared by means of a paired *t*-test for within-subject differences.

Results

Description of patients surveyed

Of the 128 patients who were approached for the survey, 112 agreed to participate and were enrolled; 107 completed and returned the questionnaire. We excluded the data for 15 patients from the analysis because they had multiple-day chemotherapy regimens. The patients were aged 23 to 75 (mean 56) years; 65% were women. Other characteristics are given in Table 1. All the patients received antiemetics prophylactically. The regimen used most commonly (for 55% of the patients) was dexamethasone plus metoclopramide in various doses; other antiemetic agents such as prochlorperazine, lorazepam and diphenhydramine were occasionally added. No patient received a 5-HT_3-receptor antagonist, because no drug from this group had been approved for use in standard practice at the time of the survey.

Frequency of nausea and emesis

During the 5-day survey period 72 of the 92 patients (78%) reported at least one episode of nausea or emesis. Anticipatory emesis was reported by 15 (16%) of the patients. Over the 5 survey days the proportion of patients experiencing no nausea or emesis after chemotherapy or only nausea increased, and the proportion experiencing nausea and emesis or only emesis decreased (Table 2).

Functional status

The mean FLIE scores for the study group are presented in Table 3. Before chemotherapy the scores for nausea and emesis were markedly different (6.5 and 15.2 respectively, $p < 0.01$), which suggests that anticipatory emesis was more prevalent and had a greater impact on functional status than anticipatory nausea. The subscale and overall scores showed significant ($p < 0.01$) worsening of functional status associated with chemotherapy but an improvement after the first 24 hours following chemotherapy, an improvement that was greater for emesis than for nausea.

Fig. 1 shows that nausea and emesis had some impact on all the areas of functioning assessed. The main effects were from emesis and were hardship on the family, reduced leisure time and reduced performance of household tasks. However, nausea had a greater impact than emesis on overall functioning ($p = 0.05$), enjoyment of eating ($p < 0.05$) and hardship on the patient ($p < 0.05$).

Costs

In Table 4 the direct and indirect costs associated with emesis are given as means for two different groups, the 72 patients who experienced nausea or emesis and all 92 patients, to show that patients not experiencing these problems still incurred the costs of prophylaxis.

The two main direct health care costs were for an additional 42 hours of nursing time ($17.80 per patient

Table 1: Characteristics of 92 patients undergoing chemotherapy

Characteristic	No. (and %) of patients
Cancer type	
Breast	27 (29)
Lung	15 (16)
Lymphoma	21 (23)
Ovarian	20 (22)
Other	9 (10)
Previous chemotherapy	
Yes	87 (95)
No	4 (4)
Not reported	1 (1)
Chemotherapy received as	
Inpatient	30 (33)
Outpatient	62 (67)
Emetogenic potential of chemotherapy	
High	27 (29)
Moderate	65 (71)
Antiemetic regimen*	
Dexamethasone, 10–20 mg IV, plus metoclopramide, ≥ 0.5 mg/kg IV	18 (20)
Dexamethasone, 10–20 mg IV, plus metoclopramide, ≥ 0.5 mg/kg IV, plus other antiemetics	15 (16)
Dexamethasone, 10–20 mg IV, plus metoclopramide, < 0.5 mg/kg IV	14 (15)
Dexamethasone, 10–20 mg IV, plus metoclopramide, < 0.5 mg/kg IV, plus other antiemetics	4 (4)
Dexamethasone, 10–20 mg IV, plus prochlorperazine, 10 mg PO, plus lorazepam, 1–2 mg SL	17 (18)
Other combinations	17 (18)
Single entity	7 (8)
Potency of antiemetic therapy	
High	21 (23)
Moderate	61 (66)
Low	10 (11)
Performance status†	
0. Fully active	58 (63)
1. Ambulatory	29 (32)
2. In bed < 50% of time	1 (1)
3. In bed > 50% of time	1 (1)
4. Completely bedridden	0 (0)
Not reported	3 (3)

*IV = intravenously, PO = by mouth, SL = sublingually.
†Graded according to the scale of the Eastern Clinical Oncology Group.[19]

with emesis) and three hospital admissions, totalling nine hospital days ($31.90 per patient with emesis). The use of out-of-hospital health care resources for emesis was low (i.e., only two visits to physicians and one housecall). Hence the average additional direct cost per patient experiencing emesis ($63) was borne mainly by the chemotherapy treatment centres.

Among the 72 patients experiencing nausea or emesis there were total losses of 198 hours of paid employment and 409 hours of unpaid employment and among the caregivers a further 186 hours of time. Adding the approximate value of this lost production and the patients' out-of-pocket expenses to the direct costs, the average total additional cost per patient with nausea or emesis was estimated to be $184.

Discussion

This survey was undertaken before 5-HT_3-receptor antagonists were available outside clinical trials but with a growing awareness that these new antiemetic drugs, although more effective, would also be more expensive than existing drugs. Our aim was to estimate the impact of chemotherapy-associated nausea and emesis on patients' functional status and on costs so as to provide information against which data from future studies of new antiemetic regimens could be compared.

It is difficult to assess the validity and reliability of our survey findings by comparison with the results of other studies, because so little information on this problem has been published. The main comparable study was an outpatient chemotherapy survey by Lindley and colleagues.[4] That study included patients whose regimens had a weak potential for emesis, however; thus, the overall rate of emesis (27% of patients on day 1) was lower than ours. But the temporal trends in nausea and emesis were consistent: the absolute risk of either problem declined over time, and the risk of nausea was greater over time than that of emesis.

The FLIE data demonstrated a significant decline in functional status with nausea and emesis after chemotherapy, particularly in the first 24 hours. Nausea had a significantly greater impact than emesis on overall functioning, the FLIE scores reflecting the persistence and magnitude of this problem between days 2 and 5. The continuing problem of nausea even when emesis has been controlled by therapy suggests that such therapy does not adequately control nausea. This may be an important hypothesis to explore further with new antiemetic regimens, which may offer differential control of emesis and nausea.

The main costs to the health care system were those of increased nursing time for managing emesis and hospital admissions for severe cases. Although admission was rare the cost was high, and it is therefore an important factor in the cost per patient. Although 78% of the patients experienced at least one episode of nausea or emesis over the 5-day period, the expected additional cost per chemotherapy patient was relatively small ($53), and most of it was for management rather than prophylaxis.

It is important to consider the indirect societal costs of nausea and emesis — that is, the cost of time lost from work. However, our estimates of indirect costs

Table 2: Numbers of patients experiencing nausea and emesis after chemotherapy over the 5 days of the survey (n = 92)

	No. (and %) of patients				
Experience	Day 1	Day 2	Day 3	Day 4	Day 5
Nausea or emesis	41 (45)	44 (48)	46 (50)	47 (51)	54 (59)
Nausea only	10 (11)	15 (16)	25 (27)	26 (28)	18 (20)
Emesis only	13 (14)	8 (9)	2 (2)	2 (2)	0 (0)
Nausea and emesis	25 (27)	21 (23)	16 (17)	13 (14)	13 (14)
Missing data	3 (3)	4 (4)	3 (3)	4 (4)	7 (8)

Table 3: Scores for nausea and emesis on the Functional Living Index–Emesis (FLIE)[11] before chemotherapy (day 1) and afterwards

	Mean score*			
Adverse effects	Day 1 (n = 90)	Day 2 (n = 77)	Day 5 (n = 75)	*p* value
Nausea	6.5	23.5	22.3	< 0.01
Emesis	15.2	25.3	20.2	< 0.01
Overall	10.8	24.3	21.5	< 0.01

*On a scale of 0 (not at all affected) to 100 (affected a great deal).

should be considered separately from those of direct costs because their validity rests on a number of assumptions (e.g., that absence from work actually results in lost production). In addition, there are a number of problems associated with establishing a monetary value for lost productive time that is not marketed labour (e.g., that of homemakers).[9]

In summary, this study indicates that antiemetic use in the era just before 5-HT_3-receptor antagonists became available was often suboptimal, in that emesis was not well controlled and nausea was a persistent and distinct problem that adversely affected patients' functional status. We believe that these data may serve as useful baselines against which to assess the costs and effectiveness of new drugs to reduce the incidence of nausea and emesis after chemotherapy.

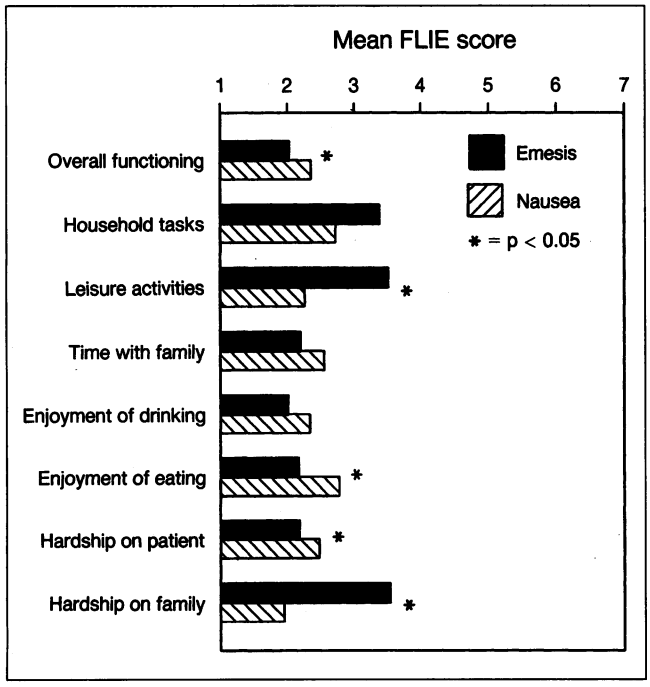

Fig. 1: Mean scores on the Functional Living Index–Emesis[11] (FLIE) for emesis and nausea the day after chemotherapy (1 = not at all affected, 7 = affected a great deal).

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Table 4: Additional costs associated with nausea and emesis (1991 Canadian dollars)

Costs	Mean cost per patient, $	
	Patients with nausea or emesis (n = 72)	All patients (n = 92)
Direct health care costs		
In treatment facility		
Nursing	17.80	16.50
Drugs to prevent emesis	5.00	5.00
Drugs to treat emesis	0.40	0.30
Hospital admissions	31.90	24.90
Contact with health care professionals	1.70	1.30
Materials	0.80	0.60
Outside of treatment facility		
Drugs	2.10	1.60
Medical services	3.30	2.50
Subtotal	63.00	52.70
Indirect costs		
Patients' out-of-pocket expenses	2.60	2.00
Value of lost production	118.70	93.10
Direct plus indirect costs	184.30	147.80

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Appendix 1: Functional Living Index–Emesis (FLIE)[11]

Item*
How much nausea (vomiting) have you had in the past 3 days?
Has nausea (vomiting) affected your ability to maintain usual recreation or leisure activities in the past 3 days?
Has nausea (vomiting) affected your ability to complete your usual household tasks during the past 3 days?
How much has nausea (vomiting) affected your ability to enjoy a meal in the past 3 days?
How much has nausea (vomiting) affected your ability to enjoy liquid refreshment in the past 3 days?
How much has nausea (vomiting) affected your willingness to see and spend time with family and friends in the past 3 days?
Has nausea (vomiting) affected your daily functioning in the past 3 days?
Rate the degree to which nausea (vomiting) has imposed a hardship on you (personally) in the past 3 days.
Rate the degree to which nausea (vomiting) has imposed a hardship on those closest to you in the past 3 days.

*Subjects respond according to a seven-point scale, 1 indicating "none" or "not at all" and 7 "a great deal." The phrase "in the past 3 days" can be adjusted.

Conferences
continued from page 293

Oct. 6–8, 1993: Canadian Waste Management Conference — Innovative Waste Management Solutions: an Outlook for the Future
Saint John, NB
Susan Clarke, technical seminar coordinator, Technology Development Branch, Environment Canada, Unit 100, Asticou Centre, 241 Cité des Jeunes Blvd., Hull, PQ K1A 0H3; tel (819) 953-5227, fax (819) 953-9029

Du 6 au 8 oct. 1993 : Conférence canadienne sur la gestion des déchets — Solutions innovatrices en matière de gestion des déchets : Perspectives d'avenir
Saint-Jean, N-B
Susan Clarke, coordonnatrice des séminaires techniques, Direction du Développement Technologique, Environnement Canada, Unité 100, Centre Asticou, 241, Cité des Jeunes, Hull, QC K1A 0H3; tél (819) 953-5227, fax (819) 953-9029

Oct. 7–10, 1993: 3rd Congress of the Asian Pacific Society of Respirology (organized by the Singapore Thoracic Society)
Singapore
Secretariat, 3rd Congress of the Asian Pacific Society of Respirology, 336 Smith St. 06-302, New Bridge Centre, Singapore 0105; tel 011-65-227-9811, fax 011-65-227-0257

Oct. 9–13, 1993: Medical Oncology Board Review Course
Pentagon City, Va.
John F. Vargo, Office of Continuing Medical Education, George Washington University Medical Center, 2300 K St. NW, Washington, DC 20037; tel (202) 994-1791, fax (202) 994-1791

Oct. 10–15, 1993: 4th International Conference on Noninvasive Cardiology
Limassol, Cyprus
Ambassador Chevy Chase Travel, 2 Wisconsin Circle, Chevy Chase, MD 20815, tel (800) 424-8282, fax (301) 907-4787; or Secretariat, 4th International Conference on Noninvasive Cardiology, PO Box 50006, Tel Aviv 61500, Israel, tel 011-972-3-517-4571, fax 011-972-3-660-325

Oct. 14, 1993: Support for Families of Women and Children with HIV (sponsored jointly by the Royal Postgraduate Medical School [RPMS] Institute of Obstetrics and Gynaecology and the Terence Higgins Trust)
London, England
Symposium Secretary, RPMS Institute of Obstetrics and Gynaecology, Queen Charlotte's and Chelsea Hospital, Goldhawk Road, London, England W6 0XG; tel 011-44-81-740-3904, fax 011-44-81-741-1838

continued on page 316