EXPOSURE OF CAREGIVERS TO ANTINEOPLASTIC DRUGS IN THE HOME ENVIRONMENT.

by

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CHAPTER I
INTRODUCTION

The toxicity of antineoplastic drugs used in the treatment of cancer patients has been well documented. The known toxic side effects include alopecia, bone marrow depression, diarrhea, stomatitis, vomiting, esophagitis and cardiac arrest (Rogers, 1986). In addition, some treated cancer patients go on to develop secondary malignancies believed to be caused by the drug treatment itself (Sieber, & Adamson,1975).

The toxicity of these drugs may present a health hazard for cancer patients' caregivers as well. Strong evidence exists that antineoplastic drugs are absorbed by health professionals when they mix and administer the drugs and care for patients treated with the agents (Chrysostomou, Morley & Seshadri, 1984; Falck, Grohn, Sorsa, Vainio, Heinonen & Holsti, 1979; Kolmodin-Hedman, Hartvig, Sorsa & Falck, 1983; Nikula, Kiviniitty, Leisti & Taskinen, 1984; Norppa, H., Sorsa, M., Vainio, H., Grohn, P., Heinonen, E., Holsti, L, & Nordman, E., 1980); Rogers, 1987; Sorsa, Hemminki & Vainio, 1985; Staiano, Galleli, Adamson, & Thorgeirsson, 1981; Strueker, Hirsch, Doloy, Bastie-Sigeac & Hemon, 1986; Venitt, Crofton-Sleigh, Hunt, Speechley & Briggs, 1984; Waksvik, Klepp &

Brogger, 1981; Wilson & Solimando, 1981). Exposure to antineoplastic drugs is also known to cause illness in health workers such as skin irritation, headaches, skin discoloration, hair loss, nasal problems, nail disorders, nausea, and vomiting (Crudi, Stephens & Maier, 1982; Ladik, Stohr, & Maurer, 1980; Sotaniemi, E., Sutinen, S., Arranto, A., Sutinen, S., Sotaniemi, K. A., Lehtola, J., & Pelkonen, O. R., 1983; Valanis & Shortridge, 1988). Furthermore, there is growing evidence that the use of precautionary measures while handling the drugs substantially reduces the incidence of absorption and side effects. Yet, researchers have not addressed the issue of whether home caregivers face potential health hazards through the absorption of antineoplastic drugs.

The nature of the biotransformation and excretion of drugs explains why they might potentially pose a health hazard to caregivers, both within the health care setting and in the home. Although the mode of action and excretion of a wide variety of antineoplastic drugs are not well understood as yet, basic drug pharmacology suggests drug clearance of high levels occurs within the first 48 hours after administration. Furthermore, most of the cancer treatment-related side effects such as vomiting and diarrhea which expose caregivers

to body fluids occur within the first 48 hours (Valanis & Shortridge,1988).

As the treatment of cancer patients shifts increasingly from the hospital to an outpatient setting, cancer patients are at home during the crucial first 48 hours after therapy. This means that home caregivers, as well as home health nurses, will be increasingly at risk of exposure to toxic antineoplastic drugs through contact with body fluids. The present investigation addresses the question of the extent to which home caregivers are in fact exposed to potentially hazardous antineoplastic drugs.

Theoretical Framework

The theoretical framework chosen for this study focuses on the epidemiological triad. Epidemiology is the "study of the distribution of states of health and determinants of deviations from health in populations" (Valanis, 1984, p 146), and it is the basis science of community health.

The triad consists of, host, agent and environment. The health of an individual, the family, and the community depend upon the state of equilibrium within the triad. In this conceptualization the agents are antineoplastic drugs suspended in perspiration, saliva, vomitus, stool and urine of cancer clients. These agents may pose a potential health

hazard to the hosts. The environment (i.e. skin, clothing and bedsheets of the patients) then provides the reservoir and mode of transmission of the agent to the host (i.e. family caregivers of the treated cancer patient). Routes of exposure to the antineoplastic drugs include oral ingestion due to hand-to-mouth contact, skin absorption, and conjunctival contact when caring for patients (Valanis, 1986).

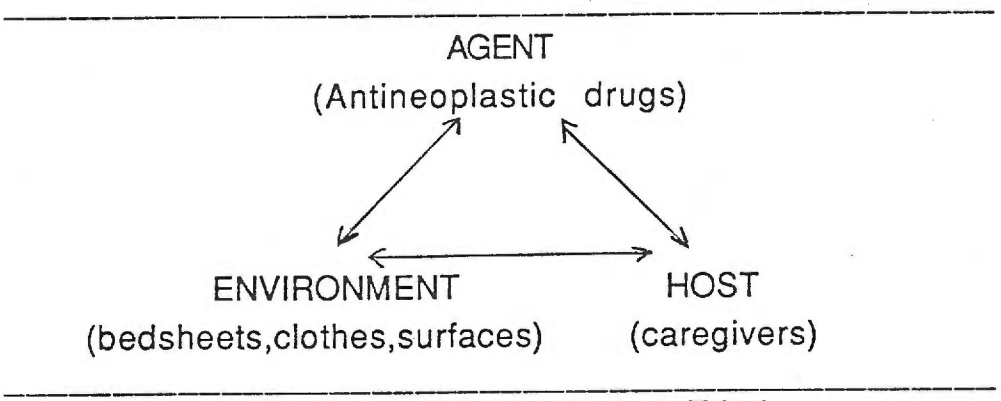

Figure 1: Epidemiological Triad

This study will attempt to determine the extent of the hosts' (caregivers') direct exposure to the agents (antineoplastic drugs) as a result of contact with contaminated body fluids in the environment (bedsheets, clothes, surfaces) while caring for outpatient cancer patients after their chemotherapy treatment.

It is assumed that many cancer patients treated as outpatients require bedside care when suffering from medication side effects such as vomiting, urinary incontinence, diarrhea and heavy sweats. It is assumed that very few caregivers in the home setting take precautions when coming in contact with body fluids. Furthermore, some antineoplastic drugs, adriamycin, for example, are slow to break down in the environment and require bleach for removal from skin and clothes (Van Raalte, 1986). Failing to take precautions could result in an accumulation of the drug on skin and surfaces and prolong drug exposure.

Review of the Literature

In this review, first the literature regarding the physiology of biotransformation and excretion of antineoplastic drugs will be covered. Next, studies will be described which concern the absorption by health care workers of antineoplastic drugs from various sources in the environment. Thirdly, the evidence regarding the use and effectiveness of protective measures will be summarized.

Biotransformation and excretion of antineoplastic drugs

Cancer drugs are divided into five groups: alkylating agents, antimetabolites, antibiotics, steroid hormones and miscellaneous drugs. Each of these categories include many

different drugs (see classification of antineoplastic agents and their toxic effects in Appendix A, Tables A and B). Because of unique functions in each category, three to four types of drugs are often given in combination depending on the type of tumor, stage of the disease, response of the patient to the drugs, and the functions of vital organs. (There are numerous treatment protocols) The rationale for using combinations of drugs is based on the fact that different drugs affect cell growth at different stages of cell division. Alkylating drugs are classified as cell-cycle nonspecific, whereas other drugs such as antibiotics and antimetabolites are specific to one particular phase of the cycle (DiPalma, 1982).

The biotransportation of all drugs varies. For example, methotrexate (antimetabolite) and its metabolite are rapidly excreted in the urine and the blood concentration falls to negligible levels 3 to 7 hours after administration of the drug. Lomustine (alkylating agent) has a serum half-life ranging from 16 to 48 hours. The mode of excretion is not yet understood. Platinol, a heavy metal complex drug, has an initial half-life of 25 to 49 minutes and a postdistribution plasma half-life of 25 to 73 hours. Platinol is excreted primarily in the urine within the first 5 days (Medical Economics Company Inc., 1987).

Adriamycin (antibiotic) is metabolized in three different half-lives of 11 minutes, 3 hours and 25 to 28 hours (DiMarco, 1982; DiPalma, 1982; Facts and Comparisons, 1987). DiMarco (1982) reports that studies on mice and rats show that after a single intravenous (IV) dose of adriamycin, initial high levels following a rapid decrease in most tissues are seen. In lymph nodes, spleen, and bone marrow the drug level increases slowly and remains for long periods of time. Four to five percent of the drug given will be excreted in the urine over five days. Forty to fifty percent will be found in the bile or feces over seven days. However, most of the unmetabolized drug and its by-products will have left the body in the first 48 hours. There is a wide variety of antineoplastic drugs in which the mode of action and excretion are not yet understood. However, it is believed that for most drugs, clearance of high levels occurs within the first 48 hours.

Absorption of antineoplastic drugs by health workers

The concept of the epidemiological triad has been used in research exploring the absorption and side effects of the antineoplastic drugs by health care workers (hosts) from various sources in the environment. The agents are introduced into the environment when antineoplastic drugs are mixed and

administered and when they are excreted through body fluids of treated cancer patients.

The most frequently used tests for absorption of the drugs by the host from various environmental sources are lymphocyte tests and urinary mutagen assay. Lymphocyte tests are classified as the sister chromatid exchange analysis (SCE) and chromosomal aberration analysis (CA). Lymphocyte tests of sister chromatid exchanges and chromosomal aberrations detect accumulated, unrepaired damage in the lymphocytes over 30 days and imply a health hazard (Sorsa et al., 1985). Urinary mutagen assays serve as short term exposure indicators. A positive test indicates that antineoplastic drugs are absorbed, showing that the urine contains some of the drug passing through the body. It does not establish the amount of damage caused to the body. However, evidence of long-term health risk from occupational exposure is still being disputed (Levy, 1986).

Two less common tests measure urinary platinum levels (Venitt et al., 1984) and urinary cyclophosphamide excretion (Hirst, Mills, Tse, & Levin, 1984). These tests are of limited value in that they do not detect mutagen changes but test for the excretion of the drugs themselves.

Evidence of antineoplastic drug absorption through contact with the drug in the environment was first reported by Falck et al. (1979). They showed that the urine of nurses who handled antineoplastic drugs was more mutagenic than the urine of office clerks. All test subjects were non-smokers, so the mutagens in the urine could not be attributed to smoking (Bos, R. P., Leenaars, A. O, Theuws, J. L. G., & Henderson, P. Th., 1982). Evidence of antineoplastic drug absorption was also reported by Rogers (1987) who found that 59 oncology nurses who prepared or administered antineoplastic drugs had significantly more mutagenic activity than 64 community nurses who did not come in contact with the drugs. She established evidence of absorption of the drugs through urine analysis.

Duration of exposure is linked to elevated mutagenic urine levels. Chrysostomou et al. (1984) concluded from their study that mutation frequency in the urine of nurses and pharmacists working with antineoplastic drugs was significantly elevated and seemed to be related to duration of exposure. Theiss (as cited in an editorial on Hazards of Cancer Chemotherapy in Lancet, 1982) linked duration of exposure to increased mutagenicity in pharmacists reconstituting antineoplastic agents. When drug exposure was stopped, the

mutagenic activity fell within two days to the level of the control group.

Additional evidence of antineoplastic drug absorption from the environment from performing sister chromatid exchange analyses arouses concern among staff handling chemotherapy agents. Waksvik et al. (1981) found that 10 nurses working with antineoplastic drugs (at an average exposure of 2150 hours) had slightly more sister chromatid exchanges than the control group. Norppa et al. (1980) and Nikula et al. (1984) reported significantly more sister chromatid exchanges and chromosomal aberrations in nurses handling antineoplastic drugs than in a control group. However, Strueker et al. (1986), reported no difference in frequency of sister chromatid exchanges and chromosomal aberrations between 17 nurses who handled antineoplastic drugs and a control group of 25 nurses.

Absorption of antineoplastic drugs from the environment leads to adverse health effects in health professionals. Sotaniemi et al. (1983) reported that three nurses showed liver damage after years of handling antineoplastic drugs. Selevan, Lindbohm, Polsci, Hornung, & Hemminki (1985) published results from a case control study on the relationship between fetal loss and occupational exposure of nurses to

antineoplastic drugs in 17 Finnish hospitals over a 7-year period. Analyses show a significant association between fetal loss and a history of handling antineoplastic drugs. Ladik et al. (1980) reported that several pharmacists complained of lightheadedness, dizziness and facial flushing while preparing antineoplastic drugs.

Adverse health effects were also reported by Crudi et al. (1982). A survey of 547 oncology nurses assessed occupational hazards associated with the preparation and administration of antineoplastic drugs. From 15% to 33% of the nurses, depending on the amount of exposure, complained of symptoms such as skin irritation, headaches, skin discoloration, hair loss, nasal pathology, nail disorders, nausea, or vomiting.

A yet unpublished study by Valanis and Shortridge (1988), lends support to the view that home caregivers coming in direct contact with body fluids of treated cancer patients are at risk. These authors report that nurses who do not mix or administer antineoplastic drugs, but who do handle patient's excreta, experience significantly more symptoms reflective of early drug side effects than the control group. These symptoms are nausea and vomiting, headache, eye irritation

and decreased libido. Similar symptoms are reported by nurses mixing or administering drugs.

Protection against absorption of antineoplastic drugs

There is strong evidence that creating a barrier between environment and host through the use of protective gear such as gloves, gowns and goggles, has resulted in reduced to non-detectable levels of absorption. Kolmodin-Hedman et al. (1983) evaluated the exposure of different groups of hospital personnel to antineoplastic drugs. The mutagen activity in the urine of health workers after a weekend off duty was minimal, but rose to high levels later in the work week if they failed to take adequate safety precautions. Staiano et al. (1981) examined urine of pharmacists who routinely handled antineoplastic drugs. No mutagens were found and this was attributed to the use of vertical laminar hoods and protective clothing. Wilson and Solimando (1981), tested mutagen activity in the urine of their staff. Again no mutagen activity was found. This was thought to be the result of careful handling of the drugs. Valanis and Browne (1985), surveyed 67 nurses handling antineoplastic drugs with and without gloves. Symptoms were significantly greater among those who mixed more than 50 doses per week and who did not wear gloves. Symptoms included increased nausea and vomiting, diarrhea,

eye irritation, chronic cough, chronic throat infection, viral or other infections and headache. Significantly more of the nurses handling drugs without gloves experienced these symptoms than did nurses who handled the equivalent number of doses but wore gloves. These symptoms were also significantly greater among exposed nurses not wearing gloves than among members of a control group.

Barriers chosen for protection when in contact with antineoplastic drugs depend to some degree on the risk involved. For example, many pharmacists reconstituting antineoplastic drugs use vertical laminar hoods, gloves, gowns, and goggles. The OSHA (1986) guidelines recommend that nurses caring for cancer patients and coming in contact with their body fluids during the first 48 hours should wear latex gloves and disposable gowns. Ethene acrylate gloves were found to be the best barrier to prevent absorption of antineoplastic drugs (Kolmodin-Hedman et al., 1983).

While there is a need for studies with more controls, e.g. type and dosage of antineoplastic drugs administered, years in contact with the agents, difference in procedures for specimen collection and exposure to other mutagens such as cigarette smoke, alcohol, hair dyes etc. (Venitt et al., 1984), this literature review documents the absorption of antineoplastic

drugs and the potential health hazard to health care professionals who do not take precautions when exposed to the drugs.

Statement of the Problem

The purpose of this study is to determine the extent to which caregivers are exposed to antineoplastic drugs through direct contact with body fluids (urine, vomit, stool, heavy perspiration) while caring for outpatient cancer patients after their chemotherapy treatment.

From the literature review it is clear that health professionals in contact with antineoplastic drugs absorb the drugs. Furthermore, health professionals in contact with these drugs show side effects such as skin irritation, headaches, skin discoloration, hair loss, nasal problems, nail problems, nausea, and vomiting. It would seem logical that caregivers in the home environment would also come in contact with these drugs, and be at risk particularly since cancer patients may be treated for years with potent drugs. Hence a survey of caregivers' exposure to antineoplastic drugs would appear justified.

Caregivers in the home are at risk to exposure of significant levels of these drugs during the first 48 hours after chemotherapy treatment when coming in contact with

body fluids while changing diapers, cleaning vomitus, or washing sheets soiled by urine and feces (Valanis, 1986). The risk of exposure is particularly high for mothers of toddlers in diapers and caregivers of elderly persons suffering from incontinence and other chronic disabilities requiring around the clock assistance. Probably those at greatest risk once exposure occurs are pregnant mothers for whom fetal exposure is a concern, and elderly individuals suffering from multiple chronic conditions where drug exposure could cause additional health problems. According to Valanis (personal communication, February 17, 1988) oncology nurses across the country have reported suspicions of an increased incidence of upper respiratory infection among siblings of children on chemotherapy, and among elderly caregivers of treated cancer patients. However, no systematic study of the issue has been made to date. The purpose of the present study is to begin to fill in this gap in our knowledge.

The specific questions addressed by this research were:

1. What percentage of patients have a primary caregiver who has had contact with the patient's body fluids during the first 48 hours after the most recent chemotherapy treatment?

2. What was the type and frequency of contact of primary caregivers with patients' body fluids during the first 48 hours after the most recent treatment cycle?

3. What was the estimated frequency of contact of the primary caregiver with the patient's body fluids across the patient's treatment cycles?

4. Did selected patient characteristics such as age, sex, and cancer site, influence the amount of caregiver contact with body fluids of patients experiencing symptoms?

5. Who were the primary caregivers?

6. What percentage of primary caregivers took precautions when coming in contact with body fluids?

Importance of the Problem

Statistics by the American Cancer Society suggest that the number of patients treated as outpatients will continue to increase. The incidence of cancer is high and on the rise. Nationally one out of four people will be afflicted by the disease in their lifetime (Shimkin, 1980). The estimated number of new cancer cases of all sites nationally increased from 930,000 in 1986 to 965,000 for 1987 (American Cancer Society, 1987).

As the treatment of cancer patients shifts increasingly from the hospital to the community, more and more caregivers

and home health nurses will be at risk of exposure to antineoplastic drugs. Already many individuals with cancer are treated with antineoplastic drugs as outpatients, with treatments being administered every three to five weeks depending on the malignancy and its protocol. Some patients are treated for years with combinations of potent intravenous drugs. Therefore, it is important to establish the extent to which caregivers are at potential health risk through contact with body fluids.

CHAPTER II

METHOD

Sample and Setting

The sample for this study included all outpatient cancer patients on an active chemotherapy treatment program as of April, 1988 at a Kaiser Permanente Health Center in Oregon. Names were obtained from an in-house printout. Only patients currently receiving treatment were included, in order to achieve better recall concerning symptoms experienced following the last treatment and assistance required. Type of treatment and frequency of treatment were not controlled through the sample selection.

One hundred forty questionnaires were send out to 116 adult patients and 24 caregivers of pediatric cancer patients. Questionnaires to two adult and to two pediatric patients were returned because of wrong addresses and another four because the adult patients had died. Of the remaining 132 questionnaires, 78 (71%) concerning adult and 13 (59%) concerning pediatric patients were returned. Four adult respondents returned blank questionnaires since they did not wish to participate. Thus, data regarding 87 patients (66%), 74 adult and 13 children, were available for analysis.

This sample should be fairly representative of patients receiving outpatient chemotherapy. Kaiser-Permanente serves a broad range of people of all ages and socio-economic statuses, including individuals on Medicaid and Medicare. This particular oncology clinic receives patients from other Kaiser-Permanente health centers located at various sites both in Oregon and Washington.

As may be seen in Table 1, the total sample (N=87) consisted of 14% more females than males. Patients ranged in age from 2 to 78 years. Over half of all adult patients were 65 years of age or above, 31% were from 45 to 64 years old, and 16.2% were from 19 to 44 years old. Pediatric patients were evenly divided in terms of sex. Their distribution by age was fairly even across all the age groups 1 to 5, 6 to 10, and 11 to 18. Almost 37% of all reported cancers were breast cancer or lymphoma. Bone cancer or leukemia were responsible for an additional 28% of all cancers. Over half of the pediatric patients reported leukemia as their diagnosis. Ovarian cancer was reported by 11% of the adult sample and colon or stomach cancer by an additional 10%. The mean number of treatment cycles for the adults was 11 (SD=16), with a range of 1 to 85. The mean number of treatment cycles received by the pediatric patients was 63 (SD=68), with a range of 10 to 200+.

Table 1

Sex, Age, Site of Primary Cancer and Treatment Cycles of Cancer Patients

Characteristic	Adult Patients		Pediatric Patients		Total	
	Number	Percent	Number	Percent	Number	Percent
Sex						
M	30	41.0%	7	53.8%	37	43.0%
F	44	59.0	6	46.2	50	55.0
Age Group						
1-5			4	30.7	4	4.6
6-10			4	30.7	4	4.6
11-15			5	38.6	5	5.7
19-44	12	16.2			12	13.8
45-64	23	31.1			23	26.5
65-78	39	52.7			39	44.8
Type of Cancer						
Breast	16	21.6	0	0	16	18.4
Leukemia	5	6.7	7	53.8	12	13.8
Ovary	8	10.8	0	0	8	9.2
Colon	4	5.4	0	0	4	4.6
Lymphoma	15	18.9	1	7.8	16	18.4
Stomach	3	4.0	0	0	3	3.4
Lung	5	6.7	0	0	5	5.7
Bones	10	13.5	2	15.4	12	13.8
Intestine	2	2.7	0	0	2	2.3
Others	6	8.1	3	23.0	11	10.4
Number of Treatments						
1-10	55	76.3	1	8.3	56	66.7
11-20	11	15.3	4	33.4	15	17.9
21-50	3	4.2	3	25.0	6	7.o
51-85	3	4.2	1	8.3	4	4.8
86-150	0	0	1	8.3	1	1.2
151-200	0	0	2	16.7	2	2.4

Note: 2 Missing Values for Adults , 1 Missing Value for Pediatric

Design and Procedure

This descriptive study took the form of a survey, and relied on reports of patients or of their caregivers. Two forms of the questionnaires were designed. One was designed for completion by adult patients. The other was designed for completion by the caregiver on behalf of patients under 18 years of age (see questionnaires, Appendix B). Permission to use the clinical records for the identification of subjects for the survey was given by the Oncology Clinic Director of the Health Center of Kaiser Permanente, and by the Human Subjects Committee of Kaiser Permanente. A cover letter to the adult patient, and a similar one to the care provider of each pediatric patient, explained the purpose of the study and what would be done with the information (see cover letters, Appendix C). It further assured the patients that they might refuse to participate in the study without affecting their relationship with or treatment at Kaiser-Permanente health center and/or the Oregon Health Science University. Brief instructions were given on the questionnaire itself concerning procedural matters.

Informed consent was inferred from the return of the questionnaire. Confidentiality was assured. Respondents were identified by code number, not names. After the completion of

the data collection and analysis the list of cancer patients was destroyed and patients were not identified by name in the reports of the study.

Questionnaires were mailed simultaneously to all patients. They were asked to return the survey within one week. Fifty one percent of patients responded to the first mailing. After two weeks a follow-up letter with a second copy of the questionnaire was mailed to non- respondents, encouraging a reply. Seventeen percent of non-respondents responded and at this point survey collection was discontinued.

Data Collection Instrument

Data were gathered by means of a self-administered mail questionnaire addressed either to the patient or to the parent/responsible party if the patient was under the age of 18 years. Variables included: (1) Presence or absence of a primary caregiver; (2) contact or lack of contact of the caregiver with body fluids; (3) type of contact; (4) frequency of contact (within 48 hours of last treatment and total number over all treatment cycles); (5) estimated frequency of contact across all treatment cycles; (6) characteristics of patients; (7) characteristics of primary caregivers; and (8) precautions or lack of precautions taken by caregivers. Definitions of these variables with their measurement follow:

1. Presence or absence of a primary caregiver. The presence or absence was determined by a "yes" or "no" response to item # 46 (See Appendix C). The primary caregiver is the caregiver who was identified as generally providing most of the care for the cancer patient.

2. Contact or lack of contact with body fluids. Contact was defined as occurring if the caregiver provided at least one type of care for the patient, and as lacking if the caregiver provided none. The types of care were bathing the patient, changing sheets and clothing, rinsing soiled laundry by hand in preparation for laundering and washing surfaces where the patient had spilt body fluids by vomiting, diarrhea, involuntary urine loss and drenching sweats (item # 20-39).

3. Type of contact within the last 48 hours. There were five categories of contact, corresponding to items # 20-39, as listed above. These were considered the most common forms of contact by which caregivers might be exposed to antineoplastic drugs.

4. Frequency of contact. One measure of frequency of contact was the total number of contacts that a caregiver had with the patient's body fluids during the first 48 hours after the most recent treatment cycle. This value was obtained by summing the number of contacts indicated across items # 20-39.

5. Estimated frequency of contact across all treatment cycles. A second measure of frequency of contact was an estimate of the number of contacts made by the caregiver across all treatment cycles. This measure was calculated for only those caregivers whose contacts during the first 48 hours of the last treatment cycle were described as typical contacts during previous cycles. The calculation proceeded through three steps. First, the number of treatment cycles during which a given patient had experienced side effects was estimated for each symptom category. In the second step, the estimated number of treatment cycles during which a patient experienced side effects for a given symptom category was multiplied by the total frequency of primary caregiver contact for the corresponding symptom during the first 48 hours after the most recent treatment cycle. These calculations provided an estimate of the number of contacts across the treatment cycle for each symptom category. In the third step the number of estimated contacts for each symptom category were added together, to obtain a total estimate of the frequency of primary caregivers contact for the patient's entire program of treatment (see Appendix F for a computational example).

6. Characteristics of patients. Three patient characteristics were noted: site of cancer, age, and sex. From the open ended item # 3, sites were categorized by organs, e.g.

breast, lung. There was a possibility that certain cancer sites might be associated with greater contact by caregivers, due in part to the specific drugs used for that type of cancer. Adriamycin for example, is often used in the treatment of breast cancer and is known to produce more severe side effects that require caregivers' assistance.

Four age categories were distinguished - under the age of 18 years, 19 to 44, 45 to 64, and 65 + years. It was reasonable to assume that the patient's age might be a factor in determining amount of contact to caregivers. Small children in diapers for example, depend on total care. The elderly also tend to require more care. Age of the patient was determined from birth date (item # 1). A third characteristic was the sex of the patient (item # 2). There was a possibility that sex of the patient is associated with the amount of contact of caregivers.

7. Characteristics of primary caregivers. Three characteristics were noted - age, sex, and relationship to patient (items # 41 to 43). The relationship of primary caregivers to patients was categorized as spouse, mother, father, children, relative, friend and others. Age of the primary caregiver was classified into one of three categories, 19 to 44, 45 to 64, and 65 + years. These age groups seemed important because women from 19 to 44 are of child bearing age, and if exposed may themselves present a risk to their unborn children.

Those over 65 are also at special risk since many suffer from multiple chronic conditions which might be exacerbated by exposure to antineoplastic drugs.

8. Precautions or lack of precautions taken by caregivers. Precaution was defined as the use of gloves when in contact with patient body fluids. Primary caregivers identified as wearing gloves ("yes" on item # 45) were considered to have taken precautions. Research has established that creating a barrier between the environment and the caregiver reduces drug absorption and symptoms in the caregiver.

Data Analysis

Descriptive statistics (percentages, means, and standard deviations) were used to answer all research questions. Data from adult and pediatric patients were analyzed separately. Caregivers of pediatric patients were believed to have more contacts. Initially a chi-square test was planned to analyze the difference between primary caregiver contact and sex, age and cancer site of patients. However, due to the small expected frequencies in cells it could not be used.

CHAPTER III
RESULTS

Data regarding the caregivers of 74 adult and 13 pediatric patients, were used for this analysis. A total of 41 adult patients (55%) reported experiencing side effects of vomiting, diarrhea, loss of urine and/or drenching sweats during their treatment cycles, whereas 33 patients (45%) did not. A much higher proportion (85%) of pediatric patients experienced side effects. Only 2 of the 13 children were symptom free. Potentially, then, 52 patients with symptoms posed a risk to their intimates and caregivers. The findings from this survey about direct contact with patients' body fluids by caregivers are presented in this section as they relate to each of the study's six research questions.

Research Question 1: What percentage of patients have a primary caregiver who has had contact with the patient's body fluids during the first 48 hours after the most recent chemotherapy treatment?

In this sample 7 (9.5%) of the 74 adult cancer patients and 3 (23%) of the 13 pediatric patients had primary caregivers during the first 48 hours after the most recent chemotherapy treatments. Therefore, few caregivers were at

risk for antineoplastic absorption and side effects due to contact with body fluids. An additional two patients, one adult and one pediatric, reported having multiple caregivers who had contact with body fluids: hence, data regarding those caregivers were not usable.

Research Question 2: What was the type and frequency of contact of primary caregivers with patients' body fluids during the first 48 hours after the most recent treatment cycle?

The frequency of contact for all symptoms during the first 48 hours after the most recent treatment ranged from 1 to 25 with a mean of 6 contacts (SD=8.4) per primary caregiver for the 7 adult patients. Contacts of the caregivers of the three pediatric patients numbered 4, 5 and 14.

As shown in Table 2, the type of contacts for primary caregivers has been totaled for the different care activities and by symptom category. By far the most frequent type of contact for the caregivers of the adult patients was associated with vomiting, almost 90%. There were few contacts as a result of diarrhea and drenching sweats and none for loss of urine. Almost half of the contacts reported by care activity was associated with washing surfaces where body fluids were spilled. The other contacts were fairly evenly distributed across the care activities.

Table 2

Frequency and Type of Contacts of Primary Caregivers of Adult and Pediatric Patients

Caregiver Activity	Patient Symptom: Vomiting	Diarrhea	Loss of Urine	Drenching Sweats	Total
Adult Patients (N=7)					
Bathing patient	6	1	0	0	7(16%)
Change sheets	3	1	0	0	4 (9%)
Change clothes	5	0	0	1	6(14%)
Do laundry	5	0	0	1	6(14%)
Wash surfaces	20	0	0	1	21(46%)
Total	39(89%)	2(5%)	0	3 (6%)	44(100%
Pediatric Patients (N=3)					
Bathing patient	4	1	0	1	6(26%)
Change sheets	1	1	0	2	4(17%)
Change clothes	1	1	0	1	3(14%)
Do laundry	2	1	0	1	4(17%)
Wash surfaces	4	1	0	1	6(26%)
Total	12(52%)	5 (22%)	0	6(26%)	23(100%

Slightly more than one half of the caregivers of pediatric patients reported contact with vomitus as the most frequent type. The remaining contacts were fairly equally distributed between those associated with the symptoms of diarrhea and drenching sweats. As with the adult group, no contact was reported for care activities associated with loss of urine. Unlike the adult, group contacts were similar for all types of activities.

Research Question 3: What was the estimated frequency of contact of the primary caregiver with the patient's body fluids across the patient's treatment cycles?

One adult patients reported that their caregivers' contact during the first 48 hours after the most recent treatment cycle as atypical of all other treatment cycles and was therefore omitted from analysis for this question. Using the frequency of contact during the most recent 48 hours as an estimate of caregiver contact during previous cycles, the estimated frequency of contact across all treatment cycles for caregivers of the remaining six adult patients ranged from 4 to 30 contacts per caregiver with a mean of 15 (SD=11, see Table 5).

All three of the primary caregivers of the pediatric cancer patients who reported contact during the first 48 hours indicated that the care provided during the most recent

treatment cycle was typical of all other treatments. For them the number of caregiver contacts across the treatment cycles was estimated to be 24+, 250+ and 398+.

Research Question 4: Did selected patient characteristics such as age, sex and cancer site, influence the amount of caregiver contact with body fluids of patients experiencing symptoms?

All patients with symptoms were included in this analysis (adults, n=41, pediatric patients, n=11). Those with caregiver contact and those without caregiver contact where compared. It should be noted that one adult and one pediatric patient with multiple caregivers were also included in this analysis. This question was addressed descriptively because the small number of expected cases per cell did not permit use of the chi-square test.

As illustrated in Table 3, in adult patients gender did not appear to be related to caregiver contact. However, both age and cancer site may influence contact. As might be expected, a higher proportion of patients in the 65+ age group, reported caregiver contact. The difference was marked between patients 65 and over and patients 45 to 64 years old (30% versus 0%). However, the difference was not so great between the proportions of patients in the 65+ age group and in the 19 to 44 age group (30% versus 20%), suggesting the influence of

Table 3

Characteristics of 41 Adult Patients with Symptoms as Related to Caregiver Contact with Body Fluids

Patient Characteristics	Caregiver Contact with Patient Body Fluids			
	No Contact		Contact	
	No.	%	No.	%
Age				
19-44	8	80%	2	20%
45-64	11	100	0	0
65-78	14	70	6	30
Sex				
M	13	87	2	13
F	20	77	6	23
CA Site				
Breast	7	100	0	0
Ovary	6	75	2	25
Lymphoma	6	75	2	25
Bones	3	100	0	0
Colon	3	100	0	0
Stomach	2	100	0	0
Intestine	2	100	0	0
Leukemia	1	100	0	0
Lung	1	33	2	67
Others	2	50	2	50

other factors. Cancer site perhaps also seemed to influence contact for caregivers of patients with symptoms. Two of the 3 adult patients reporting lung cancer, 2 of the 8 patients with ovarian cancer, and 2 of the 8 patients with lymphoma required care. By contrast, none of the 17 patients with breast, bone, stomach, colon and intestinal cancers received care.

With pediatric patients, gender did not seem to be related to caregiver contact. However, age and site may each be related to contact (see Table 4). Both pediatric patients with symptoms in the 1 to 5 year age group required care. In contrast, 7 of the 9 children with symptoms in the two older age groups required no caregiver contact but cared for themselves. With regard to site, the caregiver of one child with lymphoma and caregivers of three of the six patients with leukemia reported contact with body fluids. By comparison, caregivers had no contacts with body fluids for the patients listed as "other", a category which included cancer of the eye, chest muscles and bladder. It must be noted that the numbers of patients in these categories are very small and therefore, the percentages are unstable.

Research Question 5: Who were the primary caregivers?

Ages of the 10 primary caregivers ranged from 28 to 83, with 5 in the 19 to 44 year age range, and 4 over the age of 65+. All except one caregiver lived in the household. The ratio

Table 4

Characteristics of 11 Pediatric Patients with Symptoms as Related to Caregiver Contact with Body Fluids

Patient Characteristics	Caregiver Contact with Patient Body Fluids: No Contact No.	No Contact %	Contact No.	Contact %
Age				
1-5	0	0%	2	100%
6-10	3	75	1	25
11-15	4	80	1	20
16-18	0	0	0	0
Sex				
M	4	67	2	33
F	3	60	2	40
CA Site				
Leukemia	3	50	3	50
Bones	1	100	0	0
Lymphoma	0	0	1	100
Others	3	100	0	0

of male to female caregivers was 1:1.5 (4 males and 6 females). Parents were the primary caregivers for their children, and spouses and relatives cared for the adult cancer patients (see Table 5).

Research Question 6: What percentage of primary caregivers took precautions when coming in contact with body fluids?

Six (86%) out of the seven adult patients with caregivers reported that their caregivers took no precautions. One patient reported that the caregiver did occasionally wear gloves. This question was omitted in the questionnaire for the pediatric caregivers on request of the pediatric oncologist.

Table 5

Estimated Frequency of Contact for Primary Caregivers Across the Treatment Cycles, and Caregivers' Characteristics

Age of Care giver	Sex	Relationship to Patient	Living in House	Number of Treatment Cycles	Estimated Frequency of Contact
			Adult Patients		
28	F	Relative	no	5	30
40	F	Spouse	yes	15	15
52	F	Relative	yes	1	25
69	M	Spouse	yes	4	4
73	F	Spouse	yes	4	4
78	M	missing	yes	4	-[a]
83	M	Spouse	yes	5	10
			Pediatric Patients		
28	F	Mother	yes	20+	24+
35	F	Mother	yes	200+	250+
41	M	Father	yes	80+	398+

[a] Contact across cycles was not estimated for this patient because it was not typical for other cycles.

Chapter IV

DISCUSSION, RECOMMENDATIONS AND IMPLICATIONS

The purpose of this study was to describe the amount and type of the caregivers' direct exposure to antineoplastic drugs through contact with contaminated body fluids while caring for outpatient cancer patients after their chemotherapy treatment. From the literature review, it is clear that health professionals in contact with antineoplastic drugs have experienced absorption and side effects such as skin irritation, headaches, skin discoloration, hair loss, nasal problems, nail problems, nausea, and vomiting. While absorption and site effects for home caregivers had not been previously studied, it was reasonable to assume that they would be at similar risk if they had contact.

Prior to this study it was known that a large number of patients receive cancer treatment as outpatients. However, it was not known how many of the outpatient experience symptoms and require bedside care while suffering from side effects such as vomiting, diarrhea, involuntary urine loss and heavy sweats. To the extent that patients need care, it was believed that caregivers might be exposed to chemotherapy

drugs during the first 48 hours after treatment when coming in contact with body fluids while changing diapers, cleaning vomitus, or washing sheets soiled by urine and feces (Valanis, 1988).

The data analysis, based on reports of caregivers of 74 adult and 13 pediatric patients, indicated that 55% of adult patients experienced side effects of vomiting, diarrhea, loss of urine and/or drenching sweats during their treatment cycles, as did 85% of pediatric patients. The others were symptom free. Only 8 adult and 4 pediatric patients with symptoms required care, therefore, 12 caregivers were at risk for antineoplastic absorption and side effects due to contact with body fluids.

The exposure of the caregivers of the adult patients taken as a group did not appear to be extensive. As indicated in Table 1, 76.3% of all adult patients had 10 or fewer treatments. As a consequence of the small number of treatments, the total estimated number of contacts per caregiver was limited, with a mean of 15 contacts and a range of from 4 to 30 contacts. However, it should be noted that this study did not address the issue of projected treatments. If, for example, the total number of projected cycles was large even a small amount of contact per cycle could have a cumulative effect on the caregiver.

While the amount of caregiver contact does not suggest that caregivers of adult patients generally are a high risk group, elderly caregivers may be an exception. The elderly are known to have compromised body systems as a result of aging and therefore, the absorption of even small amounts of the drugs might have a more serious effect on their health than on the health of younger caregivers. Additionally, many elderly suffer from chronic diseases. It is possible that the exposure of antineoplastic drugs aggravates the symptoms associated with chronic diseases. In this study 40 % of all caregivers were 65 years and older. If this number represents the general population it suggests the need for further research on the relationship between age and drug absorption and its associated side effects.

The results of the study suggest a relationship and the presence or absence of caregiver contact and both age and cancer site in adult patients. Overall a larger proportion of patients over 65 had caregivers, suggesting that the debilitation associated with increased age influences the extent to which patients with symptoms need caregiver assistance. This explanation is supported by the fact that the proportions of patients with symptoms were similar in the 45 to 64 and 65 to 78 age groups (approximately 50% each), but the proportion of those patients needing caregiver's assistance

was substantially larger for the 65+ age group (30% versus 0%).

Age does not appear to be the only explanatory factor identified in this study. Cancer site in general also appears to be a factor in the amount of side effects experienced and therefore, caregiver contact. However, caution must be used in the interpretation of the relationship between caregiver contact and the patients characteristics of age and cancer site.

Other factors such as staging of the cancer, liver and kidney functions of the patients, overall physical condition and drug protocol represent potential explanations of the findings and were not controlled in this study. It may be, for example, that the relationship between age and symptoms found in the older and younger age adults is really due to cancer site and the staging of the disease. It is also possible that drugs such as cisplatin and adriamycin are responsible for severe side effects which seem to be associated with cancer site. For example, all eight patients in this survey with ovarian cancer, for which cisplatin is generally used, reported side effects and two required care. (The majority of patients with ovarian cancer were 65+ years old). In contrast, the women in this study treated for breast cancer reported fewer side effects. From a total of 16 patients treated for breast cancer, nine

experienced no symptoms, and those with symptoms required no caregivers. In this sample, most women with breast cancer were in the 45 to 64 age group. Although the drug protocol for these women is not known, breast cancer is frequently detected in the earlier stages and treated with drugs that tend to be less toxic. In summary, the results of this study suggest a relationship between age and cancer site and caregiver contact. However, one can not rule out the influence of other factors or the possibility of interrelatienships between these factors and caregivers contact.

The need for care among the pediatric patients was much greater than for the adult patients. Eighty five percent of all pediatric patients had symptoms, 30% required care, and 23% required care and had a primary caregiver. Although the number of exposed pediatric caregivers with contact was very small (n=3) caregivers of the pediatric patients appear to be at considerable risk of exposure to antineoplastic drugs with 24+, 250+, and 398+ contacts. This is a matter for concern, in that magnitude of risk depends on the extent of exposure (Chrysostomou et al., 1984). The exposure appears to be greater than the number indicates. Parents tended to be conservative in estimating the number of reported treatment cycles. Each caregiver, while specifying the number of treatments, also qualified that number with a plus sign.

Furthermore, parents tended to simply checked off having provided the activity rather than giving the number of times the activity was performed. Therefore, each check mark was counted as only one contact when potentially the number of contacts could have been higher for the symptoms and their care activities. The under estimation is likely to be very great for caregivers of children under two or three years, who are still in diapers.

Although exposure to drugs is a matter of concern for caregivers of any age, it is of particular concern for women of child bearing age. Selevan et al. (1985) detected a relationship between fetal loss and occupational exposure of nurses to antineoplastic drugs. In the present study all primary caregivers for the pediatric patients were 19 to 44 years old and the amount of contact was high although conservatively estimated. Although the caregivers for this group of patients were not asked about precautionary measures taken, the oncologist in charge of these patients asserted that caregivers did not use gloves when coming in contact with body fluids. If that assertion is correct, which is likely because 6 out of the 7 adult patients with caregivers reported that their caregivers took no precautions, this caregiver group should be the focus of studies on absorption and side effects of antineoplastic

drugs, as well as the target for educational sessions on precautionary measures.

As with the adult patients, gender did not seem to be related to caregiver contact for pediatric patients. However, age and cancer site appear to have an effect, with younger patients requiring more care. Furthermore, the patient with lymphoma and one of the two patients with leukemia reported caregiver contact in contrast to none of the three patients with cancer of the eye, chest muscles and bladder. Again, caution must be used in the interpretation of the relationship between caregiver contact and the patients characteristics of age, sex and site because other variables represent potential confounders. It must also be noted that the numbers of patients in the pediatric age categories were very small and therefore the percentages are most unstable. As with the adult patients, additional studies are needed to clarify and to explore the impact of other factors as well as the interrelationships of those factors.

The results and conclusions of this study must be considered as tentative only. The very small numbers on which the answers to the research question were based limit the generalizability of the results. More confidence may be expressed in the results about the percentage of patients that experience symptoms and the proportion that require care by

others because of the larger numbers on which those results were based.

In addition to the small sample there are two limitations which should be noted. The first is posed by the response rate itself (66% of sample reported with usable data), which introduces the possibility of a selection bias. Were some patients not replying because they received treatments for years and experienced symptoms but found it too difficult to remember specifics? Or were nonrespondents persons who had not experienced symptoms and were coping adequately without care?

The second limitation of this study is the non-numeric response mode used by some caregivers and patients when reporting contacts for the first 48 hours after the most recent treatment cycle. Many simply checked off having provided the activity rather than giving the number of times the activity was performed. Therefore, each check mark was counted as only one contact when potentially the number of contacts could have been higher for the symptoms and their care activities. However, this limitation underestimates the frequency of contact and only serves to strengthen the recommendations.

Recommendations for Further Study

Most exposed caregivers in this study were either elderly spouses or parents of child bearing age, groups which may be

at relatively high risk for potential adverse health effects when exposed to antineoplastic drugs. Therefore, it is very important at this point to determine how much contact may be tolerated before side effects are experienced by caregivers. A carefully designed mutagen assay study should be conducted with caregivers identified as having a substantial amount of contact. Second, those caregivers should be questioned about their experience of side effects to the exposure of antineoplastic drugs.

Further, it is recommended that a survey be conducted with a larger samples of elderly adults and pediatric patients to explore the relationships of age and cancer site to amount of contact with body fluids. These age groups appear to experience more symptoms which result in caregiver contact than do patients 19 to 64 years of age. While it appears that cancer site and age may also influence the amount of contact, it is possible that other factors such as the types of drugs and combinations of drugs used influence the extent of the side effects suffered, and consequently for the extent of caregiver contacts. Therefore, these and other variables such as staging of the cancer, liver and kidney functions, the patients over all physical condition, and the interrelationship of those factors should be examined in future research. If for example, drugs can provide some clue as to the severity of patients' symptoms

and potential caregiver contact, one might look at the drugs as a means of identifying likely candidates for side effects and caregiver contacts before the treatment is commenced and single out those persons for educational sessions on precautionary measures.

Implications for Practice

Until such studies have been completed it is reasonable to recommend precautionary measures to be used by home caregivers based on recommendations of OSHA's guidelines (1986) for the health professional caring for treated chemotherapy patients. These guidelines suggest that all personnel dealing with vomitus, or excreta from patients who have received chemotherapy treatment in the last 48 hours should wear surgical latex gloves and disposable gowns, to be discarded after each use. (No protective equipment is recommended for ordinary patient contact not dealing with bodily secretions.) Hands should be washed after removal of gloves or after contact with the above substances.

Furthermore, family caregivers should be advised to separately wash soiled linens twice in a bleach solution. Additionally, disposable items such as diapers, gloves and gowns should be disposed separately from other garbage in a special plastic bag marked "contaminated with toxic waste" provided by the clinic. This bag should periodically be dropped

off at the clinic which provides the treatment or at the nearest hospital.

The literature review documents the absorption of antineoplastic drugs and the potential health hazard to health care professionals not taking precautions when exposed. Wearing gloves has been shown to create a barrier to the absorption of drugs (Kolmodin-Hedman et al., 1983, Staiano et al., 1981, Valanis & Browne,1985). One might argue that the amount of exposure is much higher for nurses in the hospital. However, Valanis and Shortridge's (1988) study lends support to the view that home caregivers coming in direct contact with body fluids of treated cancer patients are at risk of experiencing side effects.

The use of gloves by caregivers for example should be acceptable. A high proportion of reported contacts with body fluids of caregivers for both the adult and pediatric groups was not associated with body contact such as bathing the patient, but with washing sheets and cleaning surfaces where body fluid spilled. It is easier to convince a caregiver to use gloves when washing surfaces then when bathing a person.

Health professionals should routinely ask patients whether they experience symptoms after their treatment and inquire about the frequency of caregiver contact with body fluids. Caregivers of those patients with symptoms should be

warned and educated about the potential implications concerning caregiver contact with body fluids.

The results of this study and of further studies as they are conducted should be disseminated through general publication, through workshops, in-services and newsletters to alert the profession about the population at risk of antineoplastic drug exposure and the extent of caregivers' contact with these drugs. It is hoped that if more evidence of danger to caregivers is gathered in future research, OSHA (1986) will establish guidelines for home caregivers, both for the adults and pediatric patients.

Educational services should be conducted by the Oncology Nursing Society and OSHA to inform health professionals about the purpose of the policy and guidelines. Additionally, teaching strategies should be developed to effectively convince family caregivers of the importance of using protective clothing for a given time frame. For example, family caregivers should be taught the rationale behind the proposed guidelines. It would be advisable for health professionals to provide a certain number of disposable gloves to patients suffering from side effects.

Chapter V

SUMMARY

The literature has established that health workers in contact with antineoplastic drugs absorb the agents and are at risk of ill health effects. The magnitude of risk appears to depend on the extent of exposure. As the treatment of cancer patients shifts increasingly from the hospital to the community, more and more caregivers and home health nurses will be at risk of exposure to antineoplastic drugs. Already many individuals with cancer are treated with antineoplastic drugs as outpatients. Some patients are treated for years with combinations of potent intravenous drugs, with treatments being administered every three to five weeks depending on the malignancy and its protocol.

The purpose of this study was to describe the extent of the caregivers' direct exposure to antineoplastic drugs with contaminated body fluids while caring for outpatient cancer patients after their chemotherapy treatment. It was not known how many cancer patients treated as outpatients experience symptoms and require bedside care while suffering from side effects such as vomiting, diarrhea, involuntary urine loss and heavy sweats.

The theoretical framework for this study focused on the epidemiological triad, the agent, antineoplastic drugs, the host the caregivers, and the environment, skin, clothing and bedsheets of the patients. Routes of exposure to the antineoplastic drugs include oral ingestion due to hand-to-mouth contact, skin absorption, and conjunctival contact when caring for patients (Valanis, 1986).

This descriptive study took the form of a survey, and relied on the reports of patients or of their caregivers. The sample included all cancer patients on an active chemotherapy treatment program at the Kaiser Permanente health center in Oregon. Data from 87 questionnaires (66%), concerning 74 adult and 13 pediatric patients served as the basis for the analysis.

Only 9.5 % of the adult cancer patients on outpatient treatment reported having caregivers. A higher proportion of patients over 65 reported caregiver contact with body fluids than younger patients. The difference in reported caregiver contact was especially marked between patients aged 65+ and patients aged 45 to 64 (30% versus 0%). However, the difference in the proportion of patients 65+ and patients aged 19 to 44 reporting caregiver contact was not that large (30% versus 20%).

The amount of contact per caregiver for the adult patients was small across all treatment cycles (4-30 contacts, $\bar{X}$=15). The number of treatment cycles were few (1-5, $\bar{X}$=3). The most frequent symptom requiring caregiver contacts was vomiting (88%). The activity involving most contacts was washing surfaces where body fluids had spilt (52%). Sixty seven percent of all caregivers providing care for the adult patients were over 65 years of age, and spouses of the patients. Except for one caregiver, who was reported to take precautions occasionally when coming in contact with body fluids, none of the others did.

With respect to patient characteristics, there appears to be no relationship between gender of patient and caregiver contact. However, both age and cancer site might influence contact.

The need for care among the pediatric patients was much greater than for the adult patients. Eleven of the 13 pediatric patients had symptoms, 4 required care, and 3 received care from a primary caregiver. The primary caregivers of the three pediatric patients appear to be at considerable risk of exposure to antineoplastic drugs with 24+, 250+ and 398 contacts. These three children received many treatments, 20+, 80+ and 200+. The most frequent type of contact by symptom

was associated with vomiting. The number of contacts by care activity were similar across all activities.

Parents were the caregivers for the pediatric patients. They ranged in age from 28 to 41 years old. Gender of patients did not appear to be related to caregiver contact. However, both patient's age and cancer site might influence contact. The question pertaining to precautionary measures was omitted for the pediatric caregivers on request of the pediatric oncologist

The results and conclusions of the findings must be considered as tentative only. The very small number on which the answers to the research question were based limit generalization of the results. More confidence may be expressed with the results about the percentage of patients that experience symptoms and the proportion that require care by others, because of the larger numbers involved. An additional limitation of this study includes the response rate itself (66% of subjects with usable data) which introduces the possibility of a selection bias.

It is very important at this point to determine the amount of contact tolerated by caregivers before symptoms appear. A carefully designed mutagen assay study should be conducted with caregivers identified to have a substantial amount of contact. In addition, caregivers should be

questioned about side effects associated with the exposure of antineoplastic drugs.

Research is also needed to explicate the relationship of patient's age and cancer site with caregiver contact. In particular the caregivers of the elderly and of the very young should be followed. Patients in these age groups appear to experience more symptoms which result in caregiver contact than do patients 19 to 64 years of age. It may be that cancer site and types of drugs and possibly combinations of drugs used, are responsible for the amount of the side effects suffered and consequently caregiver contacts. Other variables such as staging of the cancer, liver and kidney functions of the patients, over all physical condition etc., represent potential confounders and should be controlled in future research.

Until such studies have been completed it is reasonable to recommend that health professionals adopt OSHA'S (1986) guidelines to teach caregivers safe methods of caring for clients on chemotherapy treatment during the first 48 hours. Health professionals should routinely ask patients whether they experience symptoms after their treatment and inquire about caregiver contact with body fluids and its frequency. Those patients with symptoms and caregivers should be warned and educated about the potential implications concerning caregiver contact with body fluids.

Findings of this study and studies as they are conducted should be published in journals, through workshops, in-services and newsletters to alert the profession about the population at risk of antineoplastic drug exposure and the extent of the caregivers' contact. It is hoped, that if more evidence of caregiver contact is gathered in future research, that OSHA (1986) will establish guidelines for home caregivers, both for the adults and pediatric patients.

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APPENDIX A

CLASSIFICATION OF ANTINEOPLASTIC AGENTS AND THEIR TOXIC EFFECTS (Rogers, 1986)

Table A

CLASSIFICATION OF ANTINEOPLASTIC AGENTS AND THEIR TOXIC EFFECTS

Class of Agent	Type of Agent	Name(synonym)	Toxicity	Principle Route of Adm
ALKYLATING	Nitrogen Mustards	Mechlorethamine (HN Mustargen)	GI, Hematologic, Dermatitis, Amenorrhea, Teratogenic	I.V.
		Chlorambucil (Leukeran)	GI, Hematologic, Dermatitis	Oral
		Cyclophosphamide (Cytoxan, Endoxan)	GI, Dizziness, Hematologic, Alopecia, Cystitis Teratogenic	I.V. Oral
	Ethylerimine Derivatives	Thiotepa	GI, Hematologic	Oral
	Alkyl Sulfonates	Busulfan (Myleran)	Hematologic Amenorrhea, Persistent Cough, Skin Hyperpigmentation	I.V.
	Nitrosureas	BCNU (Carmustine)	GI, Esophagitis, Hematologic	I.V.
		CCNU (Lomustine)	GI, Hematologic, Alopecia	Oral
		Methyl-CCNU (Semustine)	GI, Hematologic, Alopecia	Oral
		Streptozotocin	GI, Hematologic Renal	I.V.
	Methyl Hydrazine Derivative	Procarbazine (Matulane, Natulan)	GI, Hematologic Peripheral Neuropathy, Dizziness, Lethargy, Dermatitis Hyperpigmentations	I.V.
	Nitrogen Mustards	Melphan (Alkeran, L-Pam)	GI, Hematologic	Oral

	Triazones	Dacarbazine (DTIC, DIC)	GI, Hematologic, Alopecia, Flu-like Syndrome Teratogenic	I.V.
ANTIMETABOLITES				
	Folic Acid	Methotrexate (Amethopterin)	GI, Hepatic Alopecia, Tubular necrosis, Dermatitis Teratogenesis	I.V. I.M.
	Pyrimidine Analogs	Fluorouracil (5 FU)	GI, Hematologic, Dermatitis, Skin Hyperpigment	I.V.
		Cytosine Arabinoside (Ara-C, Cytosar, Cytarabine)	GI, Hematologic, Dermatitis, Fever	I.V.
	Purine Analogs	6-Mercaptopurine (6-MP, Purinethol)	GI, Hepatic, Hematologic	Oral
NATURAL PRODUCTS	Vinca Alkaloids	Vinblastine (Velban)	GI, Hematologic Alopecia, Local irritant	I.V.
		Vincristine (Oncovin)	Hematologic, Sensory impairment, Severe paresthesia, Constipation, Cranial nerve palsies, Alopecia, Local irritant	I.V
		Vindesine	Same as Vincristine plus GI	
	Antibiotics	Actinomycin D (Dactinomycin, Cosmegan)	GI, Hematologic, Local irritant, Alopecia, Acne, Skin Hyperpigment.	I.V.
		Adriamycin	GI, Hematologic,	I.V.

		(Doxorubicin)	Cardiac, Alopecia, Local irritant	
		Daunorubicin (Daunomycin, Rubidomycin)	Same as Adriamycin	
		Bleomycin (Blenoxane)	GI, Fever, Chills, Hypotension, Nail ridging, Alopecia, Hyperpigment, Pruritic, Erythema	I.V. I.M
		Mithramycin	GI, Hematologic, Renal, Headache, Lethargy, Irritability, Skin rash, Facial flush	I.V.
		Mitomycin C (Mutomycin)	GI, Hematologic, Alopecia, Local irritant	I.V.
	Enzymes	L-Asparaginase	GI, Chills, Urticaria, Fever, Hematologic, Lethargy, Sensory impairment	I.V.
MISCELLANEOUS OR SYNTHETIC	Platinum	Cis-platinum (Cisplatin, CPDD, DDP)	GI, Hematologic, Peripheral neuropath	I.V.
		Carboplatin	Same as Cis-Platinum	I.V.
	Antimetabolite	Hexamethylmelamine	GI, Hematologic	Oral
	Substituted Urea	Hydroxyurea (Hydrea)	GI, Hematologic, Rash, Alopecia	Oral
	Antiviral Agent	Interferons	Hematologic, Fever, Malaise	I.M.
	Interferon Inducer	Poly I:C (Polyriboinosinic Acid)	GI, Fever Hematologic	I.V.
	Vinca Alkaloid Analog	VP 16-213-Epipodophyllotoxin (Etoposide)	GI, Hematologic, Alopecia, Orthostatic hypotension	Oral I.V.

	VM26- Epipodophyllotoxin	GI, Hematologic Immunosuppression	I.V.
Aklylating Analog	Spirohydanotoin Mustard (Spiromustine)	Same as Alkylating Agents	I.V.
	Spirogermanium (Spiro-32)	None reported	I.V.
	AZQ (Aziridinylbeno-quinone)	Myelosuppression, Anaphylactic reaction	I.V.
Adrenocortico-steroids	Prednisone (Prednisolone)	GI, Weight gain, Hematologic, Metabolic, Euphoria, Osteoporosis, Paper thin skin	Oral
	Dexamethasone (Decadron)		
Progestins	Medropogesterone (Provera)	GI	I.M.
Estrogens	Diethystilbesterol (DES)	GI	Oral, I.M.
	Estradiol		I.M.
Androgens	Testosterone (Oreton)	Fluid retention Masculinization, Hypertension	I.M.
	Decadurabolin (Nandrolone)		I.M.

Rogers, 1986

Table B

CLASSIFICATION OF CHEMOTHERAPEUTIC TOXICITY
COMMON TO MANY AGENTS

I. IMMEDIATE (onset in hours to days)	Nausea/vomiting
	Local tissue necrosis
	Phlebitis
	Hyperuricemia
	Renal failure
	Anaphylaxis
	Skin rash
II. Early (onset in days to weeks)	Leukopenia
	Thrombocytopenia
	Diarrhea
	Megaloblastosis
III. Delayed (onset in weeks to months)	Anemia
	Aspermia
	Hepatocellular damage
	Hyperpigmentation
	Pulmonary fibrosis
IV. Late (onset in months to years)	Sterility
	Hypogonadism
	Acute Leukemia
	Lymphoma
	Solid tumors
	Other second malignancy.

Rogers, 1986

APPENDIX B

QUESTIONNAIRES

DIRECT CONTACT WITH BODY FLUIDS OF CAREGIVERS

ADULT QUESTIONNAIRE

Instructions: Please enter the information requested on the lines provided, or, where indicated, check the appropriate response. Your participation in this study is greatly appreciated. Your answers to the questionnaire are essential to the success of the survey. After completion of the questionnaire please fold and staple the pages so that the address and the stamp is on the outside and mail. Please complete and return within one week.

1. Birth date:_____year_____month_____day

2. Sex: __ M __ F

3. Site of primary cancer (circle): Lung, Breast, Bones, Glands, Stomach, Intestine, Uterus, Blood, Others:_____

4. How many chemotherapy treatments have you been given as an outpatient?
   Total number:_____

5. As far as you can remember, did you experience vomiting, diarrhea, accidental loss of urine or drenching sweats during any treatments? ___yes ___no

IF NO GO TO QUESTION NUMBER 8.

6. If yes, please indicate the treatment in which it first showed up: (1st, 2nd, 3rd)

   a) vomiting: _____
   b) diarrhea: _____
   c) loss of urine: _____
   d) drenching sweats: _____

7. How often in subsequent treatments did you experience:
   (Please check the appropriate boxes)

	none of the treatments	1/4 of the treatments	1/2 of the treatments	3/4 of the treatments	all of the treatments
a) vomiting:					
b) diarrhea:					
c) loss of urine:					
d) drenching sweats:					

8. Thinking now of your most recent treatment, did you have any of these symptoms within the first 48 hours? ___yes ___no

9. If yes, how many times did you experience each symptom:

	none	one	two	three	four	five	more than five
a) vomiting:							
b) diarrhea:							
c) loss of urine:							
d) drenching sweats:							

10. If you experienced any of these symptoms within the first 48 hours during your most recent treatment, did anyone help you wash yourself, change sheets and clothes, rinse clothes by hand or wipe surfaces where body fluids were spilt? ___yes ___no

IF NO GO TO QUESTION NUMBER 13.

11. If yes, how many times did some one other than yourself:

	wash you	change sheets	change your clothes	rinse laundry by hand,preparing for laundering	wash surfaces where body fluids were spilled
a) vomiting:					
b) diarrhea:					
c) loss of urine:					
d) drenching sweats:					

12. Was the amount and type of the help for this treatment typical of the previous treatments? ___yes ___no

13. Who is the main person assisting in your care after you experience these symptoms? Relationship:_____
Sex: __M __F Age:_____
Living in household?__yes __no

14. Does the main person assisting you in the clean-up wear gloves for these activities? ___yes ___ no

15. Is it generally the same person assisting after you experience these symptoms? ___yes ___no

16. If not, how many caregivers do assist you (count all) during treatments after experiencing symptoms? Total number:_____
(circle all that apply) Relationship: spouse, child, other relative, friend, others, specify:__

17. If you have several caregivers, do they wear gloves for the clean-up activities? (circle the most appropriate response) __yes __no __some of them?

Thank you for taking the time to complete this questionnaire.

DIRECT CONTACT WITH BODY FLUIDS OF CAREGIVERS

PEDIATRIC QUESTIONNAIRE

Instructions: Please enter the information requested on the lines provided, or, where indicated, check the appropriate response. Your participation in this study is greatly appreciated. Your answers to the questionnaire are essential to the success of the survey. After completion of the questionnaire please fold and staple the pages so that the address and the stamp is on the outside and mail. Please complete and return within one week.

1. Birth date of child:_____year_____month_____day

2. Sex: __M __F

3. Site of primary cancer (circle): Bone, Blood(Leukemia), Lymphnodes, Brain, Eye, Kidney, Others:_____

4. How many injectable chemotherapy treatments has your child been given as an outpatient? Total number:_____

5. As far as you can remember, did your child experience vomiting, diarrhea, accidental loss of urine or drenching sweats during any treatments?___yes _no

IF NO GO TO QUESTION NUMBER 8.

6. If yes, please indicate the treatment in which it first showed up: (1st, 2nd, 3rd)
   a) vomiting: _____
   b) diarrhea: _____
   c) loss of urine:_____
   d) drenching sweats: _____

7. How often in subsequent injectable treatments did your child experience: (Please check the appropriate boxes)

	none of the treatments	1/4 of the treatments	1/2 of the treatments	3/4 of the treatments	all of the treatments
a) vomiting:					
b) diarrhea:					
c) loss of urine:					
d) drenching sweats:					

8. Thinking now of your child's most recent treatment, did your child have any of these symptoms within the first 48 hours? ___yes ___no

9. If yes, how many times did your child experience each symptom (roughly):

	none	one	two	three	four	five	more than five
a) vomiting:							
b) diarrhea:							
c) loss of urine:							
d) drenching sweats:							

10. If your child experienced any of these symptoms within the first 48 hours during her/his most recent injectable treatment, did anyone help him/her wash them, change sheets and clothes, rinse clothes by hand or wipe surfaces where body fluids were spilled? ___yes ___no

IF NO GO TO QUESTION NUMBER 13.

11. If yes, how many times did he/she need help in relationship to each symptom?

	wash body	change sheets	change clothes	rinse laundry by hand,preparing for laundering	wash surfaces where body fluids were spilled
a) vomiting:					
b) diarrhea:					
c) loss of urine:					
d) drenching sweats:					

12. Was the amount and type of the help for this treatment typical of the previous treatments? ___yes ___no

13. Who is the main person assisting in your child's care after he/she experiences these symptoms? Is it you? __yes ___no Relationship:_____ Sex: __M __F Age:_____ Living in household? __yes __no

14. Is it generally the same person assisting your child after he/she experiences these symptoms? ___yes ___no

15. If not, how many caregivers do assist your child (count all) during treatments after experiencing symptoms? Total number:_____ Relationship: specify:__

APPENDIX C

CODED QUESTIONNAIRE

DIRECT CONTACT WITH BODY FLUIDS OF CAREGIVERS

ADULT QUESTIONNAIRE

Instructions: Please enter the information requested on the lines provided, or, where indicated, check the appropriate response. Your participation in this study is greatly appreciated. Your answers to the questionnaire are essential to the success of the survey. After completion of the questionnaire please fold and staple the pages so that the address and the stamp is on the outside and mail. Please complete and return within one week.

1) Birth date:_____year_____month_____day

2) Sex: __1 M __2 F

3) Site of primary cancer (circle): Lung, Breast, Bones, Glands, Stomach, Intestine, Uterus, Blood, Others:_____

4) How many chemotherapy treatments have you been given as an outpatient? Total number:_____

5) As far as you can remember, did you experience vomiting, diarrhea, accidental loss of urine or drenching sweats during any treatments? 1___yes 2___no

IF NO GO TO QUESTION NUMBER

If yes, please indicate the treatment in which it first showed up: (1st, 2nd, 3rd)

6) vomiting:_____
7) diarrhea: _____
8) loss of urine:_____
9) drenching sweats: _____

How often in subsequent treatments did you experience:
(Please check the appropriate boxes)

	0 none of the treatments	1 1/4 of the treatments	2 1/2 of the treatments	3 3/4 of the treatments	4 all of the treatments
10) vomiting:					
11) diarrhea:					
12) loss of urine:					
13) drenching sweats:					

14) Thinking now of your most recent treatment, did you have any of these symptoms within the first 48 hours? 1 ___yes 2___no

If yes, how many times did you experience each symptom:

	0 none	1 one	2 two	3 three	4 four	5 five	6 more than five
15) vomiting:							
16) diarrhea:							
17) loss of urine:							
18) drenching sweats:							

19) If you experienced any of these symptoms within the first 48 hours during your most recent treatment, did anyone help you wash yourself, change sheets and clothes, rinse clothes by hand or wipe surfaces where body fluids were spilt?

1___yes 2___no

IF NO GO TO QUESTION NUMBER

If yes, how many times did some one other than yourself:

	wash you	change sheets	change your clothes	rinse laundry by hand,preparing for laundering	wash surfaces where body fluids were spilled
a) vomiting:	20	21	22	23	24
b) diarrhea:	25	26	27	28	29
c) loss of urine:	30	31	32	33	34
d) drenching sweats:	35	36	37	38	39

40) Was the amount and type of the help for this treatment typical of the previous trea

1___yes 2___no

Who is the main person assisting in your care after you experience these symptoms?

41) Relationship:_____

42) Sex: 1__M 2__F 43) Age:__

44) Living in household? 1yes 2no

45) Does the main person assisting you in the clean-up wear gloves for these activities? 1___yes 2___ no

46) Is it generally the same person assisting after you experience these symptoms? 1___yes 2___no

If not, how many caregivers do assist you (count all) during treatments after experiencing symptoms? 47) Total number:_____

(circle all that apply) 48) Relationship: spouse, child, other relative, friend, others, specify:__

49) If you have several caregivers, do they wear gloves for the clean-up activities? (circle the most appropriate response) 1__yes 2__no 3__some of the times

APPENDIX D

COVER LETTERS

OREGON HEALTH SCIENCE UNIVERSITY
SCHOOL OF NURSING
3181 S.W. SAM JACKSON PARK ROAD
PORTLAND, OREGON 97201

156 Country Club Lane
Albany, Oregon 97321

Dear

My name is Heinke Bonnlander. I am a graduate student in nursing at the Oregon Health Science University, Portland, Oregon. For my Master's Thesis I am conducting a survey to identify some of the drug side effects cancer patients experience following their chemotherapy treatment. Furthermore, I would like to know how much direct contact with body fluids caregivers have when assisting cancer patients at home after their treatment.

Recent studies in hospitals have indicated that some body fluids (vomit, diarrhea, and perspiration) from cancer patients treated with chemotherapy drugs may contain small amounts of the drugs. These drugs could pose a hazard to those coming in contact with them. Furthermore, results of the research may indicate the need for patient teaching programs to be developed by health personnel. By completing the enclosed questionnaire you will contribute important information. There is no risk or cost involved for you in participating in this survey.

Confidentiality is assured as the questionnaire itself is kept anonymous. On the outside of the questionnaire is a return address, a stamp, and an assigned number to allow the follow-up with nonrespondents. The number will be destroyed as soon as the questionnaire has been received, so that persons completing the questionnaire cannot be identified. You may refuse to participate in the study without affecting your relationship with or treatment at Kaiser-Permanente health center and/or Oregon Health Science University.

I would be very grateful if you could take ten minutes now to fill out the questionnaire describing your symptoms and the care given to you by the main caregiver. Please return the questionnaire within one week. If you have any questions concerning this survey call me collect in the evenings (503) 926-9698 after 7 pm or call Dr. Darlene McKenzie, advisor and co-investigator, at 279-7709 during the day between 10 am and 4 pm. Thank you very much.

Heinke Bonnlander
Principal Investigator

OREGON HEALTH SCIENCE UNIVERSITY
SCHOOL OF NURSING
3181 S.W. SAM JACKSON PARK ROAD
PORTLAND, OREGON 97201

156 Country Club Lane
Albany, Oregon 97321

Dear

My name is Heinke Bonnlander. I am a graduate student in nursing at the Oregon Health Science University, Portland, Oregon. For my Master's Thesis I am conducting a survey to identify some of the drug side effects cancer patients experience following their chemotherapy treatment. Furthermore, I would like to know how much direct contact with body fluids mothers, fathers or other caregivers have when assisting your cancer patient at home after treatments.

Recent studies in hospitals have indicated that some body fluids (vomit, diarrhea, and perspiration) from cancer patients treated with chemotherapy drugs may contain small amounts of the drugs. These drugs could pose a hazard to those coming in contact with them. Furthermore, results of the research may indicate the need for patient teaching programs to be developed by health personnel. By completing the enclosed questionnaire you will contribute important information. There is no risk or cost involved for you in participating in this survey.

Confidentiality is assured as the questionnaire itself is kept anonymous. On the outside of the questionnaire is a return address, a stamp, and an assigned number to allow the follow-up with nonrespondents. The number will be destroyed as soon as the questionnaire has been received, so that persons completing the questionnaire cannot be identified. You may refuse to participate in the study without affecting your relationship with or treatment at Kaiser-Permanente health center and/or Oregon Health Science University.

I would be very grateful if you could take ten minutes now to fill out the questionnaire describing your child's symptoms and the care given to your child by the primary caregiver. Please return the questionnaire within one week. If you have any questions concerning this survey call me collect in the evenings (503) 926-9698 after 7 pm or call Dr. Darlene McKenzie, advisor and co-investigator, at 279-7709 during the day between 10 am and 4 pm. Thank you very much.

Heinke Bonnlander
Principal Investigator

APPENDIX E

FOLLOW-UP LETTER

OREGON HEALTH SCIENCE UNIVERSITY
SCHOOL OF NURSING
3181 S.W. SAM JACKSON PARK ROAD
PORTLAND, OREGON 97201

156 Country Club Lane
Albany, Oregon 97321

Two weeks ago I sent out a questionnaire to identify some of the drug side effects cancer patients experience following their chemotherapy treatment.

I would very much appreciate if you could take a few minutes to fill out the enclosed questionnaire. Your information is very important to our understanding of cancer treatment and essential to the success of the survey.

Please fill out the questionnaire even if you do not have a lot of side effects and do not require care. We need to know this too. You might ask for some help if you are not able to fill it out yourself. I am grateful to you.

Thank you very much.

Heinke Bonnlander
Principal Investigator

APPENDIX F

ESTIMATION OF CONTACTS ACROSS THE TREATMENT CYCLES

CALCULATION

The following is an example of the method in which the frequency of contact of all treatment cycles was estimated for one patient using data from the attached adult questionnaire numbered for data entry. Note that steps One and Two are completed for each symptom category. In step Three, these estimations are then added together.

Step One and Two: Estimating contact for each symptom category. (#'s correspond with questionnaire for data entry)

Estimation of contacts for vomiting:

4 (total treatments received) is 10.

6 (treatment cycle in which vomiting first showed up) is 3rd cycle.

Total cycles in which contact possible (10 - 2) is 8.

Next identify the proportions of those cycles in which vomiting occurred.

10 (vomiting) is 1/2 of the time.

Therefore, total cycles in which symptoms occurred for vomiting is 8 x .50 = 4.

Now go to # 20 through 24, and total contacts during the last treatment cycle for vomiting which is 9 (2 + 1 + 2 + 4).

Then take total cycles in which symptoms occurred for vomiting x contacts for the last treatment cycle which is 4 x 9 = 36 contacts for vomiting across the treatment cycles.

Estimation of contacts for diarrhea:

4 (total treatments received) is 10.

7 (treatment cycle in which diarrhea first showed up) is 3rd cycle.

Total cycles in which contact possible (10 - 2) is 8.

Next identify the proportions of those cycles in which diarrhea occurred.

11 (diarrhea) is 1/4 of the time.

Therefore, total cycles in which symptoms occurred for diarrhea is 8 x .25 = 2.

Now go to # 25 through 29, and total contacts during the last treatment cycle for diarrhea which is 3 (1 + 2).

Then take total cycles in which symptoms occurred for diarrhea x contacts for the last treatment cycle which is 2 x 3 = 6 contacts for diarrhea across the treatment cycles.

Estimation of contacts for loss of urine and drenching sweats:

4 (total treatments received) is 10.

8 + 9 (treatment cycle loss of urine and drenching sweats first showed up) is none.

Therefore, total estimated contacts across treatment cycles is 0.

Step Three: Estimated contact for the entire program across all treatment cycles.

Estimation of contacts for vomiting =	36
Estimation of contacts for diarrhea =	6
Estimation of contacts for loss of urine =	0
Estimation of contacts for drenching sweats =	0
Total	42

DIRECT CONTACT WITH BODY FLUIDS OF CAREGIVERS

ADULT QUESTIONNAIRE

Instructions: Please enter the information requested on the lines provided, or, where indicated, check the appropriate response. Your participation in this study is greatly appreciated. Your answers to the questionnaire are essential to the success of the survey. After completion of the questionnaire please fold and staple the pages so that the address and the stamp is on the outside and mail. Please complete and return within one week.

1) Birth date:_____year_____month_____day

2) Sex: __1 M __2 F

3) Site of primary cancer (circle): Lung, Breast, Bones, Glands, Stomach, Intestine, Uterus, Blood, Others:_____

4) How many chemotherapy treatments have you been given as an outpatient? Total number: 10

5) As far as you can remember, did you experience vomiting, diarrhea, accidental loss of urine or drenching sweats during any treatments? 1 ✓ yes 2___no

IF NO GO TO QUESTION NUMBER

If yes, please indicate the treatment in which it first showed up: (1st, 2nd, 3rd)

6) vomiting: 3rd
7) diarrhea: 3rd
8) loss of urine: 0
9) drenching sweats: 0

How often in subsequent treatments did you experience:
(Please check the appropriate boxes)

	0 none of the treatments	1 1/4 of the treatments	2 1/2 of the treatments	3 3/4 of the treatments	4 all of the treatments
10) vomiting:			✓		
11) diarrhea:		✓			
12) loss of urine:	✓				
13) drenching sweats:	✓				

14) Thinking now of your most recent treatment, did you have any of these symptoms within the first 48 hours? 1 ___yes 2___no

If yes, how many times did you experience each symptom:

	0 none	1 one	2 two	3 three	4 four	5 five	6 more than five
15) vomiting:							
16) diarrhea:							
17) loss of urine:							
18) drenching sweats:							

19) If you experienced any of these symptoms within the first 48 hours during your most recent treatment, did anyone help you wash yourself, change sheets and clothes, rinse clothes by hand or wipe surfaces where body fluids were spilt?

1___yes 2___no

IF NO GO TO QUESTION NUMBER

If yes, how many times did some one other than yourself:

	wash you	change sheets	change your clothes	rinse laundry by hand,preparing for laundering	wash surfaces where body fluids were spilled	
a) vomiting:	20 (2)	21 (1)	22 (0)	23 (2)	24 (4)	=9
b) diarrhea:	25 (0)	26 (0)	27 (1)	28 (2)	29 (0)	=3
c) loss of urine:	30 (0)	31 (0)	32 (0)	33 (0)	34 (0)	=0
d) drenching sweats:	35 (0)	36 (0)	37 (0)	38 (0)	39 (0)	=0

40) Was the amount and type of the help for this treatment typical of the previous trea

1___yes 2___no

Who is the main person assisting in your care after you experience these symptoms?

41) Relationship:_____

42) Sex: 1__M 2__F 43) Age:__

44) Living in household? 1yes 2no

45) Does the main person assisting you in the clean-up wear gloves for these activities? 1___yes 2___ no

46) Is it generally the same person assisting after you experience these symptoms? 1___yes 2___no

If not, how many caregivers do assist you (count all) during treatments after experiencing symptoms? 47) Total number:_____

(circle all that apply) 48) Relationship: spouse, child, other relative, friend, others, specify:__

49) If you have several caregivers, do they wear gloves for the clean-up activities? (circle the most appropriate response) 1__yes 2__no 3__some of them?

APPENDIX G

APPROVAL TO CONDUCT STUDY

KAISER PERMANENTE

FILE COPY

May 04, 1988

Heinke Bonnlander
156 Country Club Lane
Albany, OR 97321

The Committee for the Protection of Human Subjects reviewed and contingently approved your study entitled, "Exposure of Caregiver to Antineoplastic Drugs in the Home Environment", at their meeting on April 20, 1988.

As you are aware, the approval contingencies included revision of the questionnaire to delete references to treatment "cycles" and revision of the letter to soften the language. I have received the revised adult cover letter, and both questionnaires. I understand the revised pediatric cover letter has not been received yet.

This approval becomes final when you have completed the attached assurance and returned it to your Kaiser Permanente (KP) sponsor for signature. Your KP Sponsor will send it to us.

[redacted]
Sharon Patterson
Administrator
Committee for the Protection of Human Subjects

encl: assurance form

cc: B. Valanis, Dr.P.H.
C. Pope, Ph.D.
M. Greenlick, Ph.D.
A. Glass, M.D.

Further information may be obtained from Sharon Patterson, Human Subjects Committee Administrator, Kaiser Permanente Center for Health Research, 4610 S.E. Belmont, Portland, Oregon 97215 Telephone 233-5631 or (760) x 222.

THE OREGON
HEALTH SCIENCES UNIVERSITY
3181 S.W. Sam Jackson Park Road, L106, Portland, Oregon 97201 (503) 279-7784/7887
Research Services

DATE: April 15, 1988

TO: Heinke Bonnlander, B.S.N. and Darlene McKenzie, RN, Ph.D. (Advisor)

FROM: Donna Buker, Administrative Assistant
Committee on Human Research

SUBJECT: "Exposure of Caregivers to Antineoplastic Drugs in the Home Environment"

The above entitled study falls under category # 3 and is considered to be exempt from review by the Committee on Human Research. Therefore, I have put your study into our exempt files and you will receive no further communication from the Committee concerning this study.

If the involvement of human subjects in this study changes you should contact the Committee on Human Research to find out whether or not these changes should be reviewed.

If you have any questions regarding the status of this study, please contact Donna Buker at X7887.

[redacted]

AN ABSTRACT OF THE THESIS OF

HEINKE BONNLANDER

For the degree of MASTER OF SCIENCE

Date of Receiving this Degree: June, 1989

Title: EXPOSURE OF CAREGIVERS TO ANTINEOPLASTIC DRUGS IN THE HOME ENVIRONMENT

Approved: [redacted]

Darlene A. McKenzie, R.N., Ph.D.,
Assistant Professor, Thesis Advisor

The purpose of this study was to determine the extent to which caregivers are exposed to antineoplastic drugs through direct contact with body fluids (urine, vomit, stool, heavy perspiration) while caring for outpatient cancer clients after their chemotherapy treatment.

This descriptive study took the form of a survey, and relied on the reports by patients or of their caregivers. The sample included all cancer patients on an active chemotherapy treatment program at a Kaiser Permanente health center in Oregon. Data from 87 questionnaires (66%), concerning 74

adult and 13 pediatric patients served as the basis for the analysis.

Results show that 55% of adult patients (n=41) experienced side effects of vomiting, diarrhea, loss of urine and/or drenching sweats during their treatment cycles. Forty five percent (n=33) reported no side effects. A substantially higher proportion of pediatric patients experienced side effects, 85% (n=11) and the remaining 15% (n=2) were symptom free.

Only 9.5 % of the adult cancer patients on outpatient treatment reported having caregivers. A higher proportion of patients over 65 reported caregiver contact with body fluids than younger patients. The difference between the age group of 65+ and the 45 to 64 age group was marked (30% versus 0%). However, the difference in the proportion of 65+ and 19 to 44 age group was not that large (30% versus 20%).

The amount of contact per caregiver was small across all treatment cycles (4-30 contacts, $\bar{X}$=15). The number of treatment cycles were few (1-5, $\bar{X}$=3). The most frequent symptom requiring caregiver contacts was vomiting (88%). The activity involving most contacts was washing surfaces where body fluids had spilt (52%). Sixty seven percent of all caregivers providing care for the adult patients were over 65 years of age and spouses of the patients. Except for one

caregiver, who was reported to take precautions occasionally when coming in contact with body fluids, none of the others did. Based on the survey, there appears to be no relationship between gender of patient and caregiver contact. However, both age and cancer site appear to influence contact.

The need for care among the pediatric patients was much greater than for the adult patients with 85% experiencing symptoms, 30% requiring care, and 23% receiving care from a primary caregiver. Caregivers of the pediatric patients appear to be at considerable risk of exposure to antineoplastic drugs with larger numbers of contacts (24+, 250+, 397+). The number of treatment cycles were much greater than for the adult patients (20+, 80+, 200+). The most frequent type of contact by symptom was associated with vomiting. Contact by care activity were similar for all activities. Gender of patients did not appear to be related to caregiver contact. However, both age and cancer site of patients may possibly influence contact. Parents were the caregivers for the pediatric patients. They ranged in age from 28 to 41 years old. The question pertaining to precautionary measures was omitted for the pediatric caregivers on request of the pediatric oncologist

The results and conclusions of the findings must be considered as tentative only. The very small numbers on which

answers to the research question were based, limit the generalization of the results. Because of a larger sample size, more confidence may be expressed with the results about the percentage of patients that experience symptoms and the proportion that require care by others.