Health Effects of Urea Formaldehyde Foam Insulation

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ABSTRACT

This thesis investigated the health effects of urea formaldehyde foam insulation (UFFI) as assessed by utilization of medical care by a sample of Montreal residents before and after their homes were insulated with UFFI. At the ecological level of analysis, a statistically significant trend over time of increasing visits to a physician coincided with the average time of initial exposure to UFFI for this sample. However, a time series analysis, based on each subject's exposure and response periods, revealed no statistically significant changes in number of visits to a physician in three months, six months, or yearly intervals following exposure. The banning of UFFI in Canada on December 18, 1980 also had no apparent effect on the number of visits to a physician. Of the 94% of the sample who completed an interview or questionnaire (323/351), 70 residents (22% of 323) were still exposed to UFFI in their homes as of March 1, 1984. These results suggest that possible health problems which occur as an effect of exposure to UFFI, are not problems for which a physician's care is sought, at least within one year following initial exposure.

The discussion centers on methodological issues such as the the validity of the medical care data base, and possible bias issues. Also discussed are the potential use of the time series design for investigating environmental hazards and some implications of the results.

RÉSUMÉ

Cette thèse étudie les effets de la mousse isolante d'urée formaldéhyde (MIUF) sur la santé, en rapport avec la consommation de soins médicaux par un échantillon de population de Montréal, avant et après l'isolation de leurs domiciles avec MIUF. Au niveau écologique de l'analyse, le temps ou apparaît une tendance, significative statiquement, à l'augmentation de la fréquence des visites chez le médecin coïncide avec le temps moyen d'exposition initiale au produit pour cet échantillon. Cependant, une analyse en séries temporelles, basée sur les périodes d'exposition et de réaction de chaque sujet, ne révèle aucun changement significatif statistiquement en ce qui concerne le nombre de visites chez le médecin liées à des périodes d'exposition allant de 3 à 12 mois. L'interdiction de la MIUF le 18 décembre 1980 n'a pas eu d'effet apparent sur le nombre de visites chez le médecin. Parmi les 94% de personnes (323/351) ayant participé a l'enquête, 70 (22% de 323) étaient encore exposées au produit chez elles, le 1er mars 1984. Ces résultats semblent indiquer que les problèmes potentiels de santé suivant une exposition au produit ne requièrent pas de soins médicaux, du moins pendant la première année d'exposition.

La discussion portera sur des questione méthodologiques, telles que la validité des données de base concernant les soins médicaux, et sur d'éventuelles questions d'objectivité. Sera aussi disuté le recours éventuel au procédé des séries temporelles pour l'étude des risques dont l'environnement est l'objet, ainsi que quelques implications issues des résultats.

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PREFACE

It must be noted that chapter two, a literature review of the thesis subject, is an updated version of a paper by the author and her advisor, Dr. John Hoey, which has been published in Environmental Research. The text of the review article is not submitted as part of this thesis, but is included as an appendix in illustrating the development of this thesis.

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ABBREVIATIONS

UFFI = urea-formaldehyde foam insulation

ppm = parts per million

CHIP = Canadian Home Insulation Program

FEV1 = one-second forced expiratory volume,

FVC = forced vital capacity

BCME = bis (chloromethyl) ether

DEN = diethylnitrosamine

SMR = standard mortality ratio

PMR = proportional mortality ratio

ICD = International Classification of Diseases, 9th revision.

CHAPTER ONE

INTRODUCTION

This thesis investigated the health effects of urea formaldehyde foam insulation (UFFI). The possibility that exposure to UFFI might be detrimental to good health was raised after publication of preliminary results of a study which reported development of nasal carcinoma in rats exposed to high concentrations of formaldehyde. Following this, residents of UFFI insulated homes began to complain to physicians and to local departments of community and public health about symptoms which they attributed to exposure. Within a short time, reports of illnesses, supposedly related to UFFI, were disseminated through the media, and state and national governments held court hearings which reviewed the sparse evidence available at the time. Acting on the side of caution, several court rulings banned the use of UFFI, at least temporarily, and recommendations were made that studies should investigate alleged health effects.

In Canada, the federal government had previously approved UFFI as one type of home insulation which qualified for homeowner subsidies. The government's subsequent decision to ban UFFI identified an urgent need for studies to define possible health risks caused by exposure to UFFI, the results of which would have broad public policy and financial implications. At this time, Canada is the only country in which UFFI is still banned.

In response to public and governmental concern, the Department of Community Health of the Montréal General Hospital decided to investigate the acute health effects of UFFI. Several challenges soon became apparent, such as improvement in study design over previous studies, use of an objective measurement of health effects, and the choice of a study design which would adequately investigate the effects of a known environmental exposure amidst a plethora of possible exposures.

This thesis begins with a review of published literature relating to the health effects of urea-formaldehyde and other products, with concentration on study methodology. This leads to a discussion of possible study designs, and finally to the objectives of this study. Chapter three covers study methodology, chapter four details results, and chapter five contains a discussion of methods, results, and potentials for future research. For ease of reading, tables, figures and references are presented at the end of each chapter. Supporting documents are contained in the appendices.

CHAPTER TWO

LITERATURE REVIEW

The intent of this chapter is to summarize and to critically review the scientific literature published on the health effects of urea-formaldehyde foam insulation. Discussion centers on the strengths and weaknesses of study methodology which leads to the development and purpose of this thesis.

2.1 - INTRODUCTION

Epidemiologic studies give the most direct evidence of the potentially detrimental health effects of UFFI, and several studies have now been conducted. Indirect evidence can be provided by epidemiologic studies on occupational exposure to urea-formaldehyde and formaldehyde manufacturing processes. Laboratory studies on the toxicity, mutagenicity, and potential carcinogenicity of urea-formaldehyde and related products provide further essential indirect evidence for human health effects. Although epidemiologic investigations are more likely than laboratory studies

to reflect the complexity of real life situations, such as the interactions of variables in the home environment, several studies of both types are necessary to arrive at definitive statements on the health effects of UFFI.

This review begins with a description of UFFI, the method of measurement of formaldehyde concentrations and the results of available household surveys. Subsequently, the putative health effects of formaldehyde and UFFI are reviewed with attention given to study methodology. A discussion follows of the potential mutagenicity, carcinogenicity, and teratogenicity of formaldehyde and UFFI. Throughout, the concentration is on the health effects of UFFI and the reader is referred to the extensive literature available on formaldehyde.

2.2 - UFFI: PROPERTIES

UFFI is made from a resin of water, urea, and formaldehyde which is mixed on site of installation with an acid catalyst and a propellant, usually

compressed air, to form a foam which is pumped into residential and commercial buildings through small holes (21). The exact formulation of UFFI can differ between commercial products since many different chemicals can be used as catalysts, deodorizers, and fire-retardants (80). Desirable because of its resistance to heat loss (high R value) and the low cost of formaldehyde, UFFI has been extensively applied in northern Europe and North America, with an acceleration in use corresponding to the worldwide "energy crisis" of the mid-1970's. Estimates of the number of homes insulated with UFFI are 500,000 in the United States and 100,000 in Canada.

Although formaldehyde exposure is ubiquitous, additional concern over potential health hazards has arisen because of the widespread use of UFFI for home insulation. Questions of the extent of possible toxicity of UFFI have been raised as a public health issue, with the notion that gaseous formaldehyde emanation from UFFI was causing health problems. Even under ideal conditions, small amounts of formaldehyde emanate from UFFI in the hardening (curing) process which usually lasts about a week after installation.

The concentration and duration depend on several factors, including the quality of the installation process, the quality and age of the foam ingredients and building construction materials, and the air temperature and relative humidity at the time during and after installation (5,14). In conventional homes where formaldehyde is detected, UFFI is probably the primary source; whereas in mobile homes and in many new conventional homes, the extensive use of particle board contributes most to these concentrations (16-18). Of the estimated 3 billion kilograms of formaldehyde produced in the United States in 1978 (111), half was used in synthetic resin production (84). These urea-formaldehyde, phenol-formaldehyde, and acetal resins are used primarily as adhesives in plywood and particle board. Other commercial products containing minimal amounts of formaldehyde include permanent press clothing, paper products, shampoos, cosmetics, cigarettes, some medications and fuels (13,35,112).

2.3 - UFFI: CURRENT STATUS

Recommendations for the reduction in the occupational standard for formaldehyde exposure from 10 parts per million (ppm) to 1 ppm in any 30 - minute sampling period were made in the United States in 1976, based on the irritant effects of formaldehyde (84). Following preliminary reports during the 16th month of a 24-month study on formaldehyde-exposed rats which revealed carcinogenic potential (20), UFFI as a source of formaldehyde was implicated and temporarily banned on December 18, 1980 in Canada (54). Following extensive review of UFFI, the ban was extended in April, 1981 and again in October, 1982 and December, 1982 (52,95). Consumer aid was established, such as the "UFFI Information and Co-Ordination Centre" in Ottawa, and remedial measures for the reduction of formaldehyde concentrations in the home were suggested (110). In the summer of 1983, a consensus conference held in Quebec to assess potential health effects concluded that "although there is no good evidence that systemic symptoms and respiratory illnesses are directly attributable to exposure to UFFI, such attribution is consistent with experience

with other toxic gases" (58).

On January 13, 1981, the United States Consumer Product Safety Commission issued a prospective ban where enactment was under state jurisdiction (24), but this ban was reversed in April, 1983 (34). UFFI has not been banned in Britain, where it has been used for over 20 years under strictly controlled standards (47). It is not permitted in timber and other lightweight buildings, and materials, installation techniques and workmanship must be registered. Very few health complaints have been reported, although a decrease in sales followed the bans in North America.

2.4 - MEASUREMENTS

Formaldehyde concentrations in the air are usually measured by the chromotropic acid method, or a modification of this method, which uses impingers for formaldehyde absorption from a known volume of air (84). This method produces repeated measurement levels within 5% at 0.8 ppm formaldehyde in air (7), and has a detection limit of about 0.01 ppm (94).

House preparation which controls for variations in emanation of formaldehyde, ventilation, temperature, and humidity has been utilized for improved precision in measurement (7,96).

Surveys which used the standardized chromotropic acid method give an indication of levels of formaldehyde in dwellings. Concentrations of 0.064 to 1.8 ppm, with an average of 0.5 ppm, were measured in 23 dwellings in Denmark, where particle board with urea-formaldehyde glue was the major source of emanation (7). In Finland, 186 measurements in 65 dwellings were recorded, with an arithmetic mean of 0.29 ppm, and a range of 0.01-0.93 pm: main sources were particle board in 61 homes, UFFI in 3 homes, and glue in the wall panel of 1 home (86) (see table 1). These levels can be compared to reported atmospheric levels ranging from 0.005 ppm to 0.06 ppm, the latter near industrial sites and in heavy smog (13).

In the largest study to date, indoor and ambient formaldehyde concentrations were measured in and adjacent to 2,400 homes in Canada (96). The survey involved 100 houses selected from among those whose

occupants complained of serious health effects to the federal UFFI Information Coordination Centre (52,96,117). From this source and from provincial records, an additional 700 homes insulated with UFFI were selected. Lastly, from Canadian Home Insulation Program (CHIP) files, two groups were selected: 1,200 homes insulated with UFFI, and 400 with other types of insulation, the latter group comprising the "control" homes used for comparison. Measurements made in 125 homes were judged to be of poor quality, and these homes were excluded from the analysis. Table 2.1 shows the results of this survey and summarizes formaldehyde concentrations reported in other studies.

In the Canadian survey, concentrations of formaldehyde were slightly lower in control homes than in homes with UFFI, and highest levels were found in homes of residents who complained. The time of the measurements since installation of UFFI in these homes was not reported. Formaldehyde concentrations were probably highest directly after installation, although a laboratory study simulating the home environment showed potential for significant formaldehyde release

from UFFI even at 16 months after installation (53).

The use of a consistent measurement technique, house preparation, quality control, and a group of measurements for comparison taken in homes without UFFI minimize potential bias in the Canadian study. However, the method of house selection was not random, and the technicians taking the measurements were not blinded to the type of insulation. The issue of health effects of UFFI was not addressed in this study.

2.5 - FORMALDEHYDE: EFFECTS ON SKIN, MUCOUS MEMBRANES AND AIRWAYS

It is clear that acute exposure to high concentrations of formaldehyde, for example 14 ppm (103), results in mucous membrane irritation of the eyes, and upper respiratory tract. Odor from formaldehyde can be detected by most people at or below 1 pm (15), and the lowest detectable odor has been reported at 0.04 ppm (88). Studies relating to exposures above .1 ppm have been summarized and reviewed (64). Here, studies are reviewed of the irritation, tolerance, and sensitization following

exposure to low concentrations of formaldehyde. Predicted irritation responses of humans to exposure to formaldehyde is seen in Table 2.2. Evidence related to carcinogenicity, mutagenicity, and teratogenicity is reviewed in a later section.

2.5.1 - Laboratory Studies

The mechanism by which airborne formaldehyde causes irritation may be similar to that of sulphur dioxide which stimulates bronchial irritant receptors (23). Other mechanisms, such as an immunological reaction, have also been postulated (11,73). Mechanical stimulation of nerve endings by formaldehyde has been reported in animal studies; it is difficult to know, however, if this is a result of direct stimulation by formaldehyde, or the result of interactions with other irritants in the environment, such as ozone or amyl alcohol.

Repeated exposures of small groups of mice to formaldehyde caused reactions in the upper respiratory tract (64). A linear dose-response relation was shown between the logarithm of the concentration of

formaldehyde and the net decrease in respiratory frequency, the latter being a characteristic measure of sensory irritation. When mice inhaled formaldehyde, maximal response was reached within a few minutes, and after this, short-term tolerance to exposures below 1 ppm developed. This accomodation was lost, however, after 1-2 hour interruption of exposure. The minimal detectable irritant effect occurred around 0.5 ppm of formaldehyde, and repeated exposures produced no pathologic effect. Through quantitative models, the authors relate these results from animals to humans and suggest that the threshold limit value for occupational formaldehyde exposure should be reduced to 0.1 - 0.3 ppm. The then current level of 3 ppm in 8 hours had been established following observations on a working population who may have developed tolerance to the irritant effects of formaldehyde exposure.

2.5.2 - Case Reports

A 32-year-old pathology resident was described as having acute symptoms, such as eye and nose irritation, headaches, and sore throat, following exposure to formalin (37% solution of formaldehyde) (69). Another

case was reported to develop hypersensitivity pneumomitis after formaldehyde exposure (91). Allergic dermatitis has also been reported (44). Two cases of asthma and rhinitis were documented in carpenters exposed to cedar urea-formaldehyde particle board (22). This exposure provoked no response in a previously unexposed asthmatic, suggesting that perhaps sensitization to a component of the particle board exposure is responsible. Specific IgE antibody testing could not demonstrate a relationship with formaldehyde.

2.5.3 - Controlled Human Studies

Studies on the irritating effects of low concentrations of formaldehyde have shown that onset and severity of irritation to the eyes, nose, and throat were directly proportional to formaldehyde concentration and continuity of exposure (12,90,115). In one study, although continuous exposure was more irritating to the eyes than discontinuous exposure, the opposite was true for nose irritation (115). During a five hour exposure to formaldehyde concentrations of 0.24 ppm in another study, irritation was evident for 3 of 16 subjects (6,8). As concentrations increased to

1.6 ppm, number of subjects affected likewise increased, but 6 of 16 subjects had no complaints. For all 16 subjects, ability to perform mathematical tests was not affected by formaldehyde exposure. The author proposes a standard of 0.12 ppm or lower for continuous exposure which would protect all but sensitized subjects. These studies suggest that tolerance to odor (88) and adaptation to formaldehyde (115) may develop during prolonged exposure, while illustrating variability in individual susceptibility (6,8).

All subjects and controls exposed to formaldehyde concentrations of 0.9 to 1.8 ppm for 30 minutes in an experimental chamber experienced nasal and ocular irritation, while no increased lower respiratory tract reactivity was noted at 6, 24, 48, or 72 hours following testing (28). Subjects for this study were residents of homes with UFFI who had complained of upper and lower respiratory tract illnesses which they attributed to UFFI.

In Norway, children with bronchial asthma were exposed to formaldehyde emission from particle board at levels around 0.25 ppm for one or two nights (98). No

increase in bronchial obstruction was noted.

A double-blind study using closed patch testing with three concentrations of formaldehyde applied to formaldehyde-sensitive patients for one week was conducted (62). An independent interpreter determined that, after 168 hours, 6 of 9 subjects had allergic reactions at either 30, 60, or 100 ppm. No reactions were apparent for the control exposures of 0 ppm. Subsequent testing of 13 subjects to sprayed on 30 ppm formaldehyde solution for two weeks suggested that most sensitive subjects could tolerate exposures below this level.

Contact dermatitis is common in industrial settings using formaldehyde, and sensitization after prolonged exposure can result in eczema (50), which can also result from contact with formaldehyde releasing agents in cosmetics and medicaments (37). In skin sensitization experiments, diluted formalin (37% aqueous formaldehyde) was found to be a potentially strong sensitizer which showed a dose-response relationship (77). The prevalence of positive reactions to skin patch testing with formaldehyde

increased with increased exposure duration (36). In Japan, a decrease in the incidence of contact hypersensitivity to formaldehyde in workers coincided with a regulation limiting the permissible levels of formaldehyde in underclothes to 75 ppm for adults and to 15 ppm for babies (105).

2.5.4 - Epidemiologic Studies

Epidemiologic studies cited as evidence for the health effects of UFFI have focused on a wide range of exposures to formaldehyde and related products. Conjunctival irritation, eye tearing, and lower respiratory tract symptoms were reported following exposure to phenolic resin (phenol-formaldehyde) fumes in a small sample of production line workers in an acrylic-wool filter manufacturing plant (100). Forty-eight employees with past or present exposure to the production line (formaldehyde concentration estimates of 0.40 to 0.80 ppm) were compared to workers who had never worked on the production line. Subjects responded to symptom questionnaires and underwent sets of five pulmonary function tests at the beginning and end of the work week. Associations with exposure were

found for symptoms of excessive cough and/or phlegm and decreased FEV_1/FVC ratio after adjustment for smoking, statistically significant only when comparing the presently exposed more than five years exposure group (n=15) to the never exposed control group (n=15). This result suggested chronic airways obstruction as an effect of prolonged exposure. Despite the high proportion of acute effects reported, no significant decreases in pulmonary function were apparent over the workday or workweek. Study limitations which the authors acknowledge include small exposure groups, the use of formaldehyde estimates, occasional exposure of almost everyone in the plant and the use of a cross-sectional design in attempting to assess a chronic disease.

On the presumption that visual tests may be a more sensitive parameter of the effects of formaldehyde exposure than respiratory measures, 83 workers in a wood production plant (average formaldehyde concentrations of 0.6-0.9 ppm) were studied (114). Although workers with chronic exposure attributed their eye symptoms to their work, the frequency of these symptoms was not greater compared to those less

exposed, according to work histories. Also, exposure to formaldehyde had no noticable effect on visual tasks, tested before and after an 8-hour workshift.

In a tire manufacturing plant, 52 of 68 workers known to be directly exposed to phenol-formaldehyde resins were compared to one group of 50 workers matched individually by sex, race, age, and shift job who were exposed to rubber stock but not to the resin in question, and to a second group of 55 control workers selected at random from the total worker population (42). Symptom questionnaires and baseline lung function tests were administered, and 19 resin exposed, 16 rubber exposed, and 19 control workers underwent lung function tests before and after work. Of the measured pollutants, particulate levels were high; mean formaldehyde concentrations were 0.05 ppm for the resin exposed group, and 0.02 and 0.04 ppm for the rubber exposed and control groups respectively. Although excessive symptom reports and decreased expiratory flow rates for those with low lung volumes were statistically significant for the resin-exposed group, results could not be associated with formaldehyde. Indeed, the differences in mean

concentrations of formaldehyde to which the groups were exposed were not statistically significant.

Exposure to formaldehyde fumes from the use of aqueous formaldehyde has been the focus of three studies of embalmers. In a study of 6 Detroit area funeral homes, formaldehyde concentrations ranged from 0.09 to 5.26 ppm, with the majority below the recommended ceiling concentration of 2 ppm (66). This study did not measure health effects. A mail survey of 80 Los Angeles embalmers asked about symptoms related to formaldehyde exposure on the job (89). Of the 57 individuals responding, 31 were classed as asymptomatic, 9 as having acute bronchitis related to their work, and 17 as having chronic bronchitis. Interpretation is not possible because of the absence of a comparison group and of information on exposure levels or work practices.

A questionnaire was administered to 105 of 112 licensed white male embalmers in West Virginia, and pulmonary function tests were taken by a volunteer sample of 99 (71). The prevalence of chronic bronchitis and decreased pulmonary function was similar

to that observed in an age and sex matched population sample of residents of Oregon (79,81) and Michigan (78). When time spent embalming and years of work were used as indices of exposure to formaldehyde and its polymers, no difference in prevalence of chronic bronchitis or reduced pulmonary function was detected.

The use of occupational histories to compile exposure indices, comparison of respiratory measurements, and the control of possible confounding factors such as smoking and age represent improvements in study design. However, limitations of this study include the use of a cross-sectional design to assess chronic effects, and the fact that a relatively healthy worker population was compared to the general population.

A cross-sectional survey of all 28 staff members of a haemodialysis unit using formalin (10-25% formaldehyde in water) to sterilize artificial kidney machines reported that 8 (29%) had developed symptoms of recurrent wheezing and cough, since they began employment on the unit (55). All had normal pulmonary

function tests. Five symptomatic women volunteered for bronchial provocation tests. Exposure to formalin resulted in wheezing and productive cough in two staff members but not in the other three study subjects. This suggested an immunologic mechanism of a specific, non-irritative type. After five years, the two nurses who had formaldehyde asthma were retested (56). Specific late asthmatic reactions after an exposure of 3 ppm formaldehyde for five minutes were noted for one nurse who had continued to work with formaldehyde. For the nurse who had avoided exposure to formaldehyde, no asthmatic responsiveness was provoked.

In a study designed to investigate the relationship between exposure to woodstoves and upper respiratory infections in elementary school children, no association was noted (109). However, a control variable, formaldehyde, was related to these infections with a risk ratio of 2.4. Sources of formaldehyde such as remodeling and new upholstered furniture had additive effects on the risk of upper respiratory infections.

The toxicity of formaldehyde, revealed by

laboratory and expidemiologic studies, suggests that formaldehyde is a mild sensory, upper respiratory, and mucous membrane irritant for some people at concentrations commonly occurring in occupational settings. Subjectivity of symptom reports, unrepresentativeness of study populations, lack of comparison groups, small sample sizes, and the difficulty of attributing results to formaldehyde alone pose limitations to decisive conclusions and to postulating causal relationships. It is especially difficult to extrapolate results to the effects of lower concentrations encountered in individual dwellings.

2.6 - UFFI: EFFECTS ON SKIN, MUCOUS MEMBRANES AND AIRWAYS

The issue of health effects is extended from formaldehyde to UFFI by laboratory and epidemiologic investigations, and by case-reports. Several studies have investigated complaints from residents of homes with UFFI, reporting formaldehyde concentrations and symptom frequencies. However, formaldehyde in the home

may represent only part of the issue of health problems potentially associated with indoor air pollutants.

For example, increased humidity resulting from improper installation conditions and from leakage of water may result in fungal growth within the walls of dwellings with UFFI. Agriculture Canada has isolated Aspergillus spp., Cladosporium resinae, and Penicillium spp. from samples taken from walls in homes (14). These samples were not representative, and only the worst building problems were studied (R.P. Bowen, personal communication). Although formaldehyde is a fungicide, not all fungi are susceptible. It is postulated that fungal spores or breakdown products of fungi may be drawn through the walls and released in the ambient air. Reactions to fungi isolated from UFFI can often be similar to reactions caused by formaldehyde, but presently very little is known about the prevalence of this problem and its health implications.

Possible chemicals affecting health in the home environment include ozone from electrostatic cleaners, and carbon monoxide, sulfur and nitrogen oxides, and

oily aerosols from home heating and cooking. Tobacco smoking may also contribute formaldehyde and carbon monoxide, creating complex interactions. Also, irritant effects attributed to formaldehyde alone are not specific to this pollutant. Since pollutant concentrations increase as ventilation decreases (7), and with heavy insulation and reduced building construction permeability (118), several pollutants may reach potentially harmful concentrations as homes become "tighter" in response to energy conservation.

In controlled measurements in an energy efficient home without UFFI, when new furniture was added to the empty home, formaldehyde concentrations doubled to almost 0.1 ppm (59). A further increase occurred when the house was inhabited, mostly due to gas cooking. When the windows were opened, formaldehyde levels decreased substantially.

2.6.1 - Laboratory Study

Formaldehyde emanation of 5 ppm to 65 ppm from burning UFFI resulted in potent sensory irritation in mice with considerable recovery at termination of

exposure (9). Acute mortality of mice was attributed to hydrogen cyanide produced when UFFI was subjected to very high temperatures (>500°C). Histopathological evaluation revealed changes in the myocardium, the most severe lesion occurring in the ventricle with myofibril structure loss and infiltration of macrophages, not attributed to formaldehyde or hydrogen cyanide exposure. It has been suggested that cardiotoxicity may result from exposure to presently unknown chemicals in UFFI.

2.6.2 - Case Reports

A 45-year old woman who did not smoke developed steroid resistant asthma shortly after her home, in which she had lived for 26 years, had been insulated with UFFI (40). Although this woman had asthma as a child, she had been asymptomatic since the age of 2. Bronchial challenge tests showed that exposure to "fine buoyant dust" brought from the woman's home resulted in severe bronchospasm, whereas exposure to aluminium oxide dust, gaseous formaldehyde at 3 ppm, and dust from urea-formaldehyde resin produced no bronchial reactions. A methodological weakness was that this

women was not challenged with histamine or lightweight dust (85).

The authors reporting this case continued to test subjects referred to them because low level formaldehyde exposure was suspected as a cause of asthma. Thirteen selected asthmatic subjects were evaluated through bronchial challenge testing, single-blind, with formaldehyde at 0.1, 1, and 3 ppm (41). Five subjects lived in homes with UFFI, 5 had occupational exposure, and 3 lived in mobile homes and/or had wood paneling. All tests were negative; in no case was it apparent that formaldehyde either caused or aggravated asthmatic symptoms.

2.6.3 - Epidemiologic Studies

Requests for assistance by persons who experienced health problems felt to be related to their mobile or conventional dwellings prompted one of the first published series of surveys of formaldehyde concentrations and symptom experiences (16-18). Formaldehyde concentrations ranged from 0.03 ppm to 1.77 ppm in 608 samples from 334 mobile homes; 66%

ranged between 0.1 to 0.49 ppm while 21% measured >0.5 ppm. For 523 persons who experienced symptoms and lived in mobile homes, eye irritation (58%) and upper respiratory irritation (55%) were most frequently reported by adults (n=424). For 99 children, frequency of eye (41%) and respiratory irritation (62%) were also highest, while chronic cough or colds were reported by 33%. Results from conventional homes with UFFI showed lower formaldehyde levels and similar symptomatology in residents, with eye (53%) and respiratory tract irritation (56%) most frequently reported by adults (n=32); for children (n=12), nose irritation (33%) and allergies (33%) were most frequently reported. Table 2.3 summarizes these results and those from other epidemiologic studies reviewed here.

In the only published study with a comparison group, responses to a symptom questionnaire administered by telephone to residents of 395 homes insulated with UFFI in New Jersey in 1979 were compared to responses of residents of 400 control homes (108). The sample of UFFI insulated homes was obtained from manufacturers. A total of 77% of these homes were subsequently excluded from the study for a variety of

reasons; 63% of neighbourhood controls were likewise excluded. No evidence of excess morbidity was noted among UFFI exposed residents except for the symptoms of "wheezing or difficulty breathing" and "skin burning". A subgroup of residents of 33 UFFI homes reporting persistent odor ($\geq$ 7 days post-insulation) had an increased rate of self-reported symptom acquisition, physician visits, and medications taken after UFFI was installed. Although this study used a much stronger research design than previously reported studies, no formaldehyde measurements were taken, a large number of case and control homes were excluded, and the authors state that because of many potential biases including response bias, ambiquity remains in the interpretation of the results from the subgroup.

Following complaints by 245 Minnesota residents concerned with possible formaldehyde exposure from UFFI in their homes, 168 were interviewed for symptom reports (43). Of the adults, 78% reported symptoms of eye, nose, and throat irritation. In children, 63% reported cough and wheezing. Of 25 respondents asked to state where and when their worst symptoms occurred, 20 indicated that the home setting was responsible for

their worst symptoms. Formaldehyde concentrations ranged from 0.24 ppm to 1.0 ppm, with the lowest level in April and the highest in June. No data were reported to show the relationship between symptoms and concentrations of formaldehyde, although the majority of respondents reported more symptoms during summer.

Using symptom questionnaires, responses were obtained from 48 of 100 Denver residents who had complained about deleterious health effects and whose homes were insulated with UFFI (51). One or more symptoms were recorded for an occupant if he/she claimed that symptoms were related to the time of UFFI installation and if they had persisted for more than one month. Dyspnea (46%), headache (44%), rhinitis (44%), eye irritation (40%), and cough (40%) were most frequently reported. No measurements of formaldehyde or any other potential irritant were taken in homes.

In a similar manner, symptoms were elicited from 196 Connecticut residents living in 68 households in which at least one member of the household had complained of health problems believed related to UFFI (97). Of the 196 persons interviewed, 167

described symptoms. Follow-up of individuals in 173 UFFI homes by the Connecticut State Department of Health showed that, after an average of 2.3 years following UFFI installation, individuals in 65% of homes still experienced symptoms (82).

In response to complaints of health problems, the Wisconsin division of health investigated 261 occupants of 14 conventionnl homes with UFFI, 65 mobile homes, 13 conventional homes and 8 other structures with potential formaldehyde emitting wood products (27). Most frequently reported symptoms were eye irritation (68%), burning eyes (60%) and dry or sore throat (57%). Mean formaldehyde concentrations for all structures ranged from below the detection limit to 3.68 ppm, and in homes with UFFI (n=14) ranged from 0.10 to 1.09 ppm. Age of building materials was found to be inversely related to median formaldehyde concentrations in the structures (older building, lower concentrations).

Symptom questionnaires were administered to staff of seven mobile day care centers where urea-formaldehyde glued particle board was used for indoor paneling (87). For this group, response rate

was 94% (n=66), while 76% (n=26) of control staff responded from day care centers without particle board. Unnatural thirst, eyes, nose, and throat irritation, unnatural drowsiness, headache, and menstrual irregularities were reported significantly ($p<0.05$) more by the staff in the mobile day care centers, where the median formaldehyde concentration was 0.344 ppm. In control centers, the concentration was 0.064 ppm.

An occupational and environmental health center conducted a cross-sectional study of 24 self-referred consecutive patients (18 adults and 6 children) from six homes with UFFI (99). All results of standarized skin allergy and respiratory tests were normal. 14 adults underwent psychological testing which showed abnormally short attention spans for 11 subjects, but no memory storage deficits were documented, even though memory difficulty was a frequently reported symptom (39%). In addition, prevalence of self-reported eye (52%) and lower respiratory symptoms of cough (46%), wheeze (21%) and phlegm (25%) were high. Formaldehyde sampling done 7 to 34 months following UFFI installation in 4 homes of these subjects revealed concentratons of 0.02 ppm to 0.23 ppm. Small sample

size, sample selection, and low statistical power limits the inferences which can be drawn from this study.

In Quebec, preliminary analysis revealed no correlation between the severity of residents' symptoms related to exposure to UFFI, as judged by a physician in a medical examination, and formaldehyde concentrations in the dwellings of these residents (83). Imprecision in health measures and lack of repeated formaldehyde measurements under various conditions may,however, account for no recognized correlation.

These studies, although limited because of the unrepresentativeness of the samples, show that a substantial proportion of people exposed to urea-formaldehyde report upper respiratory and eye symptoms. However, the methodology of these studies does not permit statements on causality or attributability of symptom reports to UFFI. More studies are needed to evaluate the possibility of an association between UFFI and adverse health effects.

2.7 - POTENTIAL MUTAGENICITY - CARCINOGENICITY

Formaldehyde has been repeatedly implicated as a mutagenic agent for animal test systems, but not for mammals and man. Recent animal studies have suggested that this chemical is carcinogenic. At this time epidemiologic evidence is not sufficient to evaluate carcinogenic risk to humans, and further studies are urgently needed. An extensive review of this subject was published in 1982 (94).

2.7.1 - Formaldehyde and Cancer: Laboratory Studies

Laboratory studies of the mutagenicity of formaldehyde have been carefully reviewed (10), and summarized and updated (25). In brief, the conclusion reached from the compilation of several types of animal studies is that formaldehyde is a weak mutagen, although dose-response relationships are difficult to determine. Interaction of formaldehyde with other mutagens such as ultraviolet radiation appears to increase the frequency of mutations. The action of formaldehyde on bacterial DNA is not exerted directly, but through amino-containing compounds. Dose-dependent

single-strand breaks in DNA in *E. coli* and yeast occur when formaldehyde combines with amino acids and proteins (74,92). However, the understanding of these mechanisms and their application to different organisms remains unclear.

Concern over formaldehyde as a possible carcinogen was sparked in 1979 with the release of preliminary research findings in the 16th month of a 24-month inhalation study (20). Groups of 120 male and female (B_6 C_3 F_1) mice and of 120 male and female Fisher 344 rats were exposed for 6 hours a day, five days per week, to mean formaldehyde concentrations in air of 0.0, 2.1, 5.6, and 14.3 ppm. Histopathological results showed squamous cell carcinomas of the nasal turbinates in 103 of 240 rats (51 male and 52 female) from the highest exposure group, in 2 of 240 rats (1 male and 1 female) in the 5.6 ppm group, and in 2 of 120 male mice in the 14.3 ppm exposure group (106). No female mice developed nasal carcinomas. No carcinomas were reported in unexposed animals.

Mice experienced mainly irritant effects and only at 14.3 ppm. The frequency and severity of squamous

metaplasia in the epithelium of anterior nasal cavities in rats were exposure-related in all groups after 24 months of inhalation. Because of this finding, the study was extended after exposure had been stopped. Regression of metaplasia became apparent at 27 months (3 months post-exposure) in the 2.0 and 5.6 ppm exposed groups of rats. A weak association was found between formaldehyde exposure and increase in the frequency of polypoid adenomas in the nasal cavity of male rats (65).

Sialodacryoadenitis virus, found at the scheduled 12-month necropsy, may have played a role in promotion of carcinogenesis in formaldehyde-exposed animals (107). However, this possibility is unlikely because mice without this infection developed nasal cancer, and many nasal cancers had probably already started developing at the time of infection.

Under similar 14 ppm formaldehyde exposure conditions, another strain of rats developed nasal cancer (8 out of 100 rats) after 19 months (4). The virus mentioned above was not found in this study, and thus provided confirmation that the virus probably did

not promote carcinogenesis. The authors state that their results neither disprove nor support the hypothesis that carcinogenicity is a nonspecific response to irritation following exposure to formaldehyde (4).

In the same study, rats exposed to bis (chloromethyl) ether (BCME), a product of the reaction of formaldehyde and hydrochloric acid (39,63), developed nasal cancer, attributed mainly to formaldehyde (4). Exposure to hydrochloric acid alone produced no carcinogenic response. Since rats exposed to BCME developed nasal cancers (4,68,101), whereas chemical plant workers also exposed appeared to have an excessive risk of lung cancer (116), direct application of results from animal studies to humans is unwarranted. Different breathing mechanisms and vastly different exposure levels necessitate the use of epidemiologic data in addition to animal studies.

Hamsters exposed to 10 ppm formaldehyde for 5 hours a day for lifetime developed no respiratory tract tumors, and only a slight increase in hyperplastic and metaplastic areas in the nasal epithelium, when

compared to unexposed animals (26). In another experiment, combined exposures of formaldehyde prior to diethylnitrosamine (DEN) injections produced more tracheal tumors than DEN exposure alone, thus suggesting that formaldehyde may act as a cofactor in tumors induced by DEN (26).

By several established criterion used to judge immune function and host resistance, studies with mice revealed no evidence of immuno-suppression following short term exposure to 15 ppm of formaldehyde (29).

2.7.2 - Formaldehyde and Cancer: Case Report

One case has been reported of squamous cell carcinoma of the nasal cavity in a 57 year old man with 25 years of occupational exposure to low levels of formaldehyde (46). This man worked in the textile finishing industry and he described development of symptoms 21 years after initial exposure. The patient smoked, and was also exposed to metal fumes, quenching and cutting oils, nickel, chromium, and to fabric dycing.

2.7.3 - Formaldehyde and Cancer: Epidemiologic Studies

Cytogenetic analyses of blood lymphocytes of 15 workers exposed to formaldehyde manufacturing and processing for an average of 28 years showed no increased chromosome aberration rates when compared to 15 unexposed workers matched for age and sex (38). Mean formaldehyde exposure did not exceed concentrations of 5 ppm before 1971, and 1 ppm since 1971. No correlation was found between formaldehyde exposure and frequency of aberrant metaphases.

A few epidemiologic studies have investigated the possibility of excess risks for nasal or lung cancer in groups occupationally exposed to formaldehyde. In the largest study to date, 98% of a cohort of 7680 men exposed to formaldehyde and employed in the British chemical or plastics industry were traced to the end of 1981 (3). 21% had died, and excess mortality was apparent only for lung cancer when England and Wales mortality rates were used as the standard, and not when comparison was made with local rates. There were no nasal cancer deaths, and no associations with exposure were found for pancreatic, skin, kidney, and brain cancers.

Professional membership lists were used in Britain to locate 2,079 pathologists and 12,944 laboratory technicians (49). Of the pathologists, failure to trace was limited to 0.6%, and of the 156 who died between 1955 and 1973, copies of the cause of death entry were obtained for 97%. Failure to trace technicians amounted to 1.5% and cause of death entries were obtained for all 154 who died during the study period. The standard mortality ratio (SMR) for all causes combined was lower and statistically significant for pathologists (156 observed, 259 expected) and technicians (154 observed, 231 expected) than that of the general population of Britain. For pathologists, 4 observed versus 19 expected deaths were attributed to bronchitis, asthma, and emphysema, and 11 observed versus 28 expected deaths were attributed to cancers of the lung, bronchus and trachea. These results were not statistically significant. The SMR for pathologists was statistically significantly higher for the causes of suicide (10 observed, 4 expected), and for lymphohematopoetic neoplasms, excluding Hodgkin's disease and leukaemia, (8 observed, 4 expected) for males only. For technicians, the SMR was elevated and statistically significant only for suicide (17

observed, 7 expected). This study has been extended for the period 1973 to 1980 with an additional 139 deaths among pathologists (48). Although the findings for suicide and other violent deaths were again noted, no excess deaths from lymphohematopoetic neoplasms were found.

A recent cohort study of 2239 male anatomists reported an increased standardized mortality rate for brain cancer (10 observed deaths; SMR=2.71) after 99% of the cohort were traced (104). Deaths from lung cancer were low (SMR=28), and no specific exposure could be linked with brain cancer.

Preliminary findings from a cohort study of white male Ontario undertakers show no nasal cancer deaths, and fewer than expected deaths from cancer of the respiratory system (70). The only excessive risk was recorded for cirrhosis of the liver (SMR=172) after 85% of the cohort had been traced.

A proportional mortality study of 1132 white male embalmers who died between 1925 and 1980 indicated significantly (p 0.05) elevated proportional mortality

(PMR) for cancers of the skin (PMR=221) and colon (PMR=143) and for arteriosclerotic heart disease (PMR=112) (113). No nasal cancer deaths were reported, and mortality from respiratory diseases including cancer was unremarkable. A subgroup of those licensed only as embalmers (546 men), without the additional license as funeral directors, indicated significantly elevated mortality from skin cancer (PMR=326), kidney cancer (PMR=247) and cancers of the brain and central nervous system (PMR=234), while less respiratory system cancers were observed (27 deaths) than were expected (28.6 deaths) from the age, race, and calendar year specific U.S. male mortality rates.

Another proportional mortality study of a group of male workers exposed to formaldehyde in a chemical plant reported no nasal cancer deaths and no elevated mortality for any type of cancer (76). An extension of this study reported that of 24 known deaths, age- sex- and race-specific proportional mortality ratios were significantly elevated ($p<0.05$) for cancer of the colon (4 observed deaths; PMR=702*, 424**, and 333***) and buccal and pharyngeal cancer (2 observed deaths;

* U.S. comparison: all mortality
** County comparison: all mortality
*** County comparison: cancer mortality.

PMR=870*, 952**, and 833***) (72). These authors also mention one worker who died of sinus cancer but who was not included in the study. With this study design, it is not clear if the elevated ratios reflect real increases in mortality rates, or proportional decreases in other causes of death. Further limitations include a small number of observed deaths, mixed exposures, and lack of quantitative exposure histories.

A case-control study of 481 DuPont workers who died of respiratory cancers showed no association with potential formaldehyde exposure (33). There were no nasal cancer deaths, and analyses of lung cancer deaths were adjusted for cigarette smoking, and analyzed for tumour site, latent period, duration and level of exposure, and age of first exposure and age of death.

Formaldehyde exposure of 84 Danish physicians (79 male, 5 female) who died of lung cancer was compared with the exposure history of 252 physician controls, matched to the cases for age, sex, and survival at least to the time of cases' lung cancer diagnoses (60). The relative risk was 1.0. No deaths from nasal cancer

* U.S. comparison: all mortality
** County comparison: all mortality
*** County comparison: cancer mortality.

were found among formaldehyde-exposed physicians in the Danish Cancer Registry data for the period 1943-76 (61). Similarly, since the late 1960's when occupation was coded in the Ontario cancer registry, no deaths from nasal cancer have been recorded for the following occupational groups: physicians, dentists, morticians, and non-MD anatomists and pathologists (67). Nasal cancer has been associated with exposure to nickel dust (30,32), chromates (19,31) with exposure to hardwood dusts in work in the furniture (2,57), boot, and shoe manufacturing industries (2), and, for women, with exposure to dusts in the textile industry (19).

These studies do not substantiate a carcinogenic association between formaldehyde exposure and nasal, lung, or any type of cancer for humans. Since cohort mortality studies have limited statistical power in studying a relatively rare disease such as nasal cancer, a case-control design may lead to a better understanding of any potential association with formaldehyde exposure.

2.7.4 - UFFI and Cancer: Laboratory Studies and Case Reports

Two aqueous ingredients of UFFI, the catalyst and resin, evaluated by in-vitro reactions revealed that both ingredients reacted with purified E. coli DNA (80), the catalyst reacted directly, and the resin after metabolic transformation by enzymes of the rat liver extract. These reactions with cellular macro-molecules occur with other tumor-producing chemicals and raise the tenuous possibility that some ingredients of UFFI may have genetic and carcinogenetic potential.

There have been no animal studies with UFFI exposure testing carcinogenicity reported to date. Regarding UFFI, no reports of cancer have been published in the scientific literature, even in Europe, where this product has been used for over fifty years. There are no reports of detailed clinical studies of the immune system, such as immunoglobulin measurements, descriptions of cellular immunity, and studies of sub-populations of lymphocytes. Because of the long latency period between exposure and the occurence of cancer, many long-term studies must be conducted, and

the potential carcinogenicity and mutagenicity of UFFI cannot be assessed at this time.

2.8 - POTENTIAL TERATOGENICITY OF FORMALDEHYDE

2.8.1 - Laboratory Studies

The effects of formaldehyde concentrations of 0.0, 0.001, and 0.8 ppm, on the embryonic development of the offspring of three separate groups of twelve female rats showed that mean duration of pregnancy was prolonged by 14-15% by formaldehyde exposure in comparison to the unexposed group (45). The number of offspring was lower in the group not exposed to formaldehyde compared to the number of offspring for exposed groups. This apparent paradox was not commented on by the authors.

Oral intubation of pregnant mice for 10 days during gestation with 1% aqueous formaldehyde caused toxicity, but did not result in teratogenicity (75).

2.8.2 - Epidemiologic Study

Menstrual and reproductive functions of 446 women exposed to formaldehyde in the fabric industry were compared to those of 200 relatively unexposed fabric saleswomen (102). Formaldehyde concentrations ranged from 0.04 to 3.6 ppm in areas where exposed women worked. Medical examinations revealed menstrual disorders in 47.5% of exposed workers, compared to 18.6% of the saleswomen. Self-reported menstrual irregularities were also significantly higher ($p \leq 0.05$) for staff of mobile day care centers where the median formaldehyde concentration was 0.344 ppm (87), as reported here in an earlier section.

Several other laboratory and epidemiologic studies are inadequate for evaluation of teratogenicity. Studies reported here do not provide enough evidence for a conclusion as to whether or not formaldehyde exposure presents a teratogenic risk. No studies were found of the potential teratogenicity of UFFI.

2.9 - SUMMARY

It is clear that formaldehyde is a mild sensory irritant, affecting some people more than others, at concentrations encountered in many occupational settings. Formaldehyde concentrations in homes with UFFI are generally too low to cause sensory irritation, but levels in some homes may be high enough to affect a limited number of people who may, for unknown reasons, be particularly sensitive to this pollutant. Formaldehyde may not be solely responsible for reported health effects, suggesting that unknown factors or complex chemical interactions in the home or general indoor environment may cause health problems.

Although many case reports and epidemiologic studies have reported acute effects, a direct association with UFFI exposure has not been established. One comparative study of a random sample of residents of UFFI insulated homes and of residents of non-UFFI insulated homes was found, and results were inconclusive. No cohort studies of occupants of UFFI and non-UFFI insulated homes were found. At this time, nothing is known about possible chronic effects.

High concentrations of formaldehyde may be carcinogenic to animals, but epidemiologic studies do not support a causal link between formaldehyde and human cancers. It may be necessary to conduct case-control studies and to identify representative cohorts of exposed and non-exposed individuals for more indepth inquiry into the suggestion from animal studies that formaldehyde exposure can cause respiratory cancers.

2.10- INCENTIVES FOR RESEARCH

The limited extent of present knowledge regarding the health effects of UFFI affords an incentive for research with improved methodology. In the studies concerned with the acute effects of UFFI, the most apparent weakness in methodology is the bias in sample selection: in all but one study, the subjects were complainers. At least three problems arise. The first is that no idea is available of the overall prevalence of alleged health effects. It is likely that complainers experience the most severe health effects, or they express themselves more than non-complainers

for a variety of unknown reasons. Secondly, a study sample of a potentially biased group of respondents may not represent all complainers, and will certainly not represent the population of residents of UFFI dwellings as a whole. Thirdly, the nature of complaints is that they occur after a perceived exposure and are attributed to that exposure. Only retrospective study designs have been used, and the perceived exposure is often taken for granted as the cause of health problems.

The indices used to measure health effects in the studies reviewed here are invariably subjective, thus constituting the second major weakness of the study designs. Prevalence of self-reported symptoms, occurrence in time of these symptoms, and odor detection with regard to self-reported time of UFFI installation are the measures used. Consequently, results could be biased towards rejecting the null hypothesis of no effect of exposure to UFFI. As for prevalence of symptoms, the proportion of the population reporting at least one health problem at any one time was 50% for males, and 58,6% for females, according to the Canada Health Survey(1). With such a

high "background" prevalence, a study would have to discern between background problems and possible health effects of UFFI. Also, with self-reported information, recall bias a major drawback to the use of these indices.

Small sample size and limited statistical power are also weaknesses in these studies. High random variability in exposure levels and low expected frequency in real health effects of UFFI require a relatively larger sample size than has been used in these studies.

A further possible limitation in study design has to do with the lack of an exposure measurement in most of these studies. Even when formaldehyde concentration is measured, the applicability of this cross-sectional result is questionable for many reasons. Variability in measurement by season, time of day, humidity, lack of repeated measurements, and the validity of this exposure as the true exposure of interest arise as issues. Also, the studies do not consider additive or synergistic effects of indoor pollutants, and other factors such as tobacco smoking, building construction,

gas cooking, and other relevant factors. People spend a considerable amount of time indoors, especially the very young, elderly, and infirm, and epidemiologic studies should consider indoor exposures as well as occupational and outdoor exposures. These are difficult questions to address, however, especially in preliminary epidemiologic studies, and several controlled laboratory studies, modelling of relationships, and costly and lengthy epidemiologic studies are required.

For improvements in study design, a population based sample would provide an estimate of the prevalence of health effects, a suitable control group to control for biases, and a basis for generalizing to the sampling frame. Cohort studies could be facilitated by drawing a sample from a registry, available in some countries, which contains information on construction materials, heating methods, room sizes, and other characteristics of buildings (93). In Canada, a type of registry was developed by the Canada Home Insulation Program (CHIP) which provided federal grants for any approved type of home insulation, including UFFI.

To combat the problems of small sample size, low statistical power, and attributability of effects to particular low level exposures, a World Health Organization meeting recommended a "staged design" for epidemiologic studies of the health effects of indoor air pollutants (93). With this design, estimates of exposures are made initially by simplified modelling of many dwellings in a representative sample (from a registry, for example). The sample is then characterized by demographics, pollution sources, and a health profile for each dwelling. Small cohorts of people with particular exposures, and appropriate controls, are studied in a prospective or cross-sectional manner. In this way, random variation in exposure and vulnerability are reduced.

For a case-referent study of the health effects of UFFI, it is difficult to imagine how a comparable set of cases and controls could be drawn. The health profiles from the registry mentioned above could be reviewed, blind to exposure status, for cases and controls. The problem would be in the definition of a case, for a well-defined health status is required. This type of registry with health profiles does not

exist presently.

A more objective measure of health status is available in Canada, Britain, and in prepaid health insurance plans, for example, where health care utilization patterns can be used as an index. For studying the health effects of UFFI, this data base affords the opportunity of conducting a historical cohort study of a sample of residents of UFFI homes drawn from a registry, comparing utilization of physician services before and after installation of homes with UFFI. Residents would therefore be their own controls, and an additional control group of residents of non-UFFI homes drawn from the same registry would enhance the study design. In this way, the time series approach is particularly suitable for studying the health effects of UFFI or of any such environmental exposure.

2.11- DEVELOPMENT OF THIS STUDY

Following a review of the literature in 1982 (appendix 1), a study of the health effects of UFFI was

planned with the design outlined above in mind to fulfill the following objectives:

1. to determine overall utilization of physician services for an average of 4 years before and 4 years after installation of insulation for residents of single family detached homes with UFFI and residents of single family detached homes with other types of insulation;
2. to describe the symptomatology of these groups;
3. to assess the lung function of these groups; and
4. to assess the immunological function of adults in these groups.

As a test of the major study design, a pilot study with a sample of 60 residents from dwellings with UFFI and 60 residents from dwellings with other types of insulation was to be randomly selected from CHIP files. Data on utilization of physician services was to be obtained from the Régie de l'assurance maladie du Québec (hereafter referred to as Régie). Home interviews were planned to obtain information on symptomatology. Lung function tests were to be performed in the resident's home for a cross-sectional assessment. Adults were to be asked to volunteer a blood sample.

Since access to the CHIP files has been denied, and since no other registry source is available for sampling, a revised protocol was developed and is the basis for this thesis.

2.12- PURPOSE OF THIS STUDY

The purpose of this study is to determine the health effects of urea-formaldehyde foam insulation. Specific objectives are:

1) to compare utilization of medical services by residents of Montréal homes with UFFI, before and after exposure to UFFI,

2) to determine the impact, if any, of the banning of UFFI on December 18, 1980 on the utilization of medical services by residents of Montréal homes with UFFI,

3) to determine the frequency of the following selected medical diagnoses for these residents:

SYSTEM	DIAGNOSIS	ICD CODE
Nervous and sense organs	migraine, visual disturbances, and conjunctivitis	346 368 372
Respiratory	acute and chronic nasopharyngitis and pharyngitis, sinusitis, allergic rhinitis asthma, and respiratory conditions due to chemical fumes and vapours	460 462 472 477 493 506
Skin and subcutaneous tissue	pruritus and related conditions	698
All	symptoms, signs, and ill-defined conditions	780 782 784 786 799

4) to determine the proportion of residents exposed to UFFI before it was banned on December 18, 1980, were still exposed to UFFI on March 1, 1984.

TABLE 2.1:

FORMALDEHYDE CONCENTRATIONS IN HOMES

			Concentrations of Formaldehyde (ppm)		
		No. of dwellings	Arithmetic $\bar{X}$	$\bar{X}$ of maximum of readings	Range
UFFI:					
Residents "complained"	Canada	100	0.139	0.174	<0.01->0.2[3]
	Washington	39	[2]	[2]	<0.1 -≥1.0
Residents did not "complain"					
1. UFFI Information & provincial records	Canada	651	0.04	0.048	<0.01->0.2[3]
2. CHIP[1] files	Canada	1146	0.054	0.067	<0.01->0.2[3]
NO UFFI:					
CHIP files	Canada	378	0.034	0.042	<0.01- 0.2
OTHER:					
Particle board	Denmark	23	0.5	[2]	0.064-1.8
Mainly particle board	Finland	65	0.29	[2]	0.01-0.93
Residents "complained" (Mainly mobile homes)	Minnesota	[2]	[2]	[2]	0.24-1.0 (mean values range)
Residents "complained" (mobile homes)	Washington	334	[2]	[2]	0.03-1.77

[1] CHIP: Canadian Home Insulation Program

[2] not reported

[3] Values below .01 could not be determined and the upper limit of the range was reported only as >0.2

Table 2.2:

PREDICTED IRRITATION RESPONSES OF HUMANS EXPOSED TO AIRBORNE FORMALDEHYDE[a]

Concentration (ppm)	Percentage of population giving indicated response	Degree of irritation[b]
1.5-3.0	20	7-10
	>30	5-7
0.5-1.5	10-20	5-7
	>30	3-5
0.25-0.5	20	3-5
<0.25	<20	1-3

a From the report "Formaldehyde-An Assessment of Its Health Effects," prepared for the Consumer Product Safety Commission by the Committee on Toxicology, National Academy of Sciences, March 1980, p. 29.

b Irritation index

10-Strong eye, nose, and throat irritation; great discomfort; strong odor.
7-Moderate eye, nose, and throat irritation; discomfort.
5-Mild eye, nose, and throat irritation; mild discomfort.
3-Slight eye, nose, and throat irritation; minimal discomfort.
1-Minimal eye, nose, and throat irritation; minimal discomfort.
0- No effects.

Table 2.3:

Epidemiologic studies of self-reported symptoms and formaldehyde concentrations.

# of residents interviewed that had "complained"	Place	Formaldehyde concentration range (ppm)	% of sample reporting indicated symptoms	Reported symptoms
1- 168	Minnesota	0.24-1.0	78% of adults	eye, nose and throat irritation
		(1)	63% of children	cough and wheezing
2- 48	Denver	(1)	46%	dyspnea
			44%	headache
			44%	rhinitis
			40%	eye irritation
			40%	cough
3- 24	Massachusetts	0.02-0.23	52%	eye symptoms
			46%	lower respiratory symptoms and cough
			39%	memory difficulty
			25%	phlegm
			21%	wheeze
4-	Wisconsin	<0.01-3.68	68%	eye irritation
			60%	burning eye
			60%	runny nose
			57%	dry or sore throat
5-	Connecticut	(1)	65%	experienced various symptoms after an average of 2.3 years following UFFI installation
6- 99 children	Washington (mobile homes)	0.03-1.77	62%	respiratory tract irritation
			41%	eye irritation
			33%	chronic cough or colds
7- 32 adults	Washington	(1)	56%	respiratory tract irritation
			53%	eye irritation
8- 12 children	Washington	(1)	33%	nose irritation
			33%	allergies
9- 424 adults	Washington (mobile homes)	0.03-1.77	58%	eye irritation
			55%	upper respiratory irritation

(1) not reported

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CHAPTER THREE

METHODS

This section describes the sampling frame, sample selection, data collection, and medical services data base, defines the variables used in this thesis, and outlines the analytic procedures.

3.1. Sampling Frame

Residents who applied for the "Assistance program for victims of urea-formaldehyde foam" offered by the Québec government Ministry of Social Affairs between November, 1981 and September, 1983 formed the sampling frame. This program provided financial assistance for relocation and/or removal of UFFI from homes. Potential applicants telephoned the Bureau de dépannage des victimes de la MIUF (hereafter refered to as Bureau) and received an identification number and information about the requirements for the assistance program. These requirements included ownership of the home with UFFI, proof and date of UFFI installation from the installer's receipt, and completion of a questionnaire by the applicant and by a physician of their choice.

The application procedure stressed that only one person per home needed to have a medical examination (part of the questionnaire), and that examinations should at least begin with

the person in the household who was most severely affected. Using the examination data and following criteria established by the Centre de toxicologie du Québec (hereafter referred to as Centre), physicians ranked "the extent of damage to health following exposure to UFFI" as "serious", "moderate", or "slight". For eligibility to the assistance program, a physician was required to certify that at least one person in the home exhibited health problems compatible with exposure to UFFI.

Potential applicants obtained questionnaires from local Departments of Community Health (D.S.C.) which returned completed questionnaires to the Centre. In Montréal, all eight D.S.C.s participated. Included in the 29-page questionnaire was a section asking the resident taking the medical examination (or a parent if a child was examined) for demographic information, including Régie de l'assurance maladie du Québec number (hereafter referred to as medicare number). The resident was also asked to sign an authorization form permitting use of the information for research purposes. See appendix 2 for details of the assistance program, the questionnaire, and the consent form.

Between November, 1981 and September, 1983, the Centre received 9059 completed questionnaires. For further study, the Centre chose to code only information from Gaspesie and Montreal because of high proportion of use of UFFI in the former case, and high density of population in the latter case (personal communication, Dr. A. Nantel). Data placed on disks by the Centre included identification number, postal code, social

insurance number, date of birth, sex, D.S.C. region, and severity of health problems. Because of limited resources, the Centre was able to code 4453 questionnaires. Of the 2393 residents who lived in Montréal, 453 residents (18.9%), the last group of residents, were not coded and therefore were not included in the listing that was received for this study. The computer listing of 4453 residents from Montréal and Gaspésie became the sampling frame (fig.3.1).

3.2 Sample Selection

Residents in the sampling frame were stratified by birth date (10-year age groups) and sex; those born before 1900 and after 1979 were excluded because of small numbers and since those born after 1979 had little or no pre-exposure time. Of the 4453 residents in the sampling frame, 1940 lived in metropolitain Montréal, as identified by postal code and by D.S.C. region. Within each stratum records were ordered by identification number which reflected the time sequence of the inquiries to the Bureau for assistance, thereby stratifying by time.

For systematic sampling, sampling ratios for each stratum were calculated to obtain an equal number of residents per stratum for an approximate sample size of 350 (per pre and post exposure group). At alpha=0.01, this sample size would yield a power of 95% to detect a difference (two-tailed) of 10% between utilization before and after exposure (2) (see table 3.1 for power at differing sample sizes and alpha levels). Systematic

sampling with differing sampling intervals (every fifth, for example, starting from a randomly chosen first identification number) of those within metropolitan Montréal was done, blind to the severity of health problems, which yielded 20 to 25 residents per stratum for a total sample of 351 residents of UFFI homes. The flow chart in figure 3.2 illustrates the selection procedure and table 3.2 shows details of sample stratification.

3.3 Data Collection

The original questionnaires for residents in the sample were obtained from the Centre. The following information was abstracted for use in this study:

1) name of resident and address of the UFFI home;

2) date the resident moved to that address;

3) telephone number;

4) medicare number;

5) date of medical examination for the assistance program; and

6) address, relationship, and telephone number of a person to contact if the resident could not be contacted. In addition, postal code, social insurance number, date of birth, and sex of the resident were abstracted to verify information from the computer listing. The date of UFFI installation was recorded from a copy of the installer's receipt kept by the Bureau.

Following development of a questionnaire and training of an

interviewer, residents were contacted by telephone for a short interview (appendix 3). The purpose of the interview was to establish the length of exposure following UFFI installation (end of exposure date), and to ask for any missing information. For those who were contacted by telephone but who refused to give their medicare number, the reason for this was asked, and a letter (appendix 4) was sent explaining the intent of the research and asking for medicare number by mail. For those not contacted by telephone, a complete questionnaire (appendix 5) in French and English was sent to the resident at the address of the UFFI home.

Once the follow-up was completed, all known medicare numbers were sent to the Régie. For each number corresponding to its files, a "fiche historique medicine" for January, 1977 to January, 1984 was returned to the investigator on computer printouts, as detailed below (section 3.4).

3.4 Medical services data base

The Régie de l'assurance maladie du Québec is a health insurance system with universal coverage of physician services. All who legally reside in Québec are registered. Each resident has an enduring, unique alphanumeric code (medicare number) comprised of the first three letters of the surname, first letter of the given name, birth date, and registration number. This number does not change for any reason, as long as a person maintains residency in Québec. The medicare number must be presented at each physician encounter.

The data base used in this study was organized for the administration of the fee-for-service payment scheme for physicians. Claims are submitted by physicians on a temporal basis for reimbursement for services rendered.

Annually, the Régie compiles and publishes data, including utilization of medical services. Reports detail methods of reliability and quality of the data, as seen in figure 3.3. All reliability checks are made for monetary purposes. For example, physician practice files are routinely audited for analysis of outlier practice patterns to correct for overbilling. A one percent random sample of billing claims are validated by contacting the patients who reportedly received the services. Also, number and type of services, which determine the amount paid to the physician, are checked for internal agreement with the stated diagnosis. Physicians submit a diagnosis in written or

coded form (ICD, ninth revision) for approximately 60% of claimed medical services rendered:

Le taux de presence de cette donnee est d'environ 50 a 60%; 10% étant code par le médicin ou son personnel; le reste etant codifie par la Regie selon un choix aléatoire (personal communication, P. Bossé: appendix 6).

The date and type of medical service are 100% complete on Régie records. Indepedent checks of reliability with written records were beyond the scope of this project.

Data from medical records can be compiled according to several types of information. For this study, data from medical claims were compiled for individuals for all instances of care received from November, 1976 (when this particular type of data storage began) to January, 1984. The "fiche historique medicine" dossiers contained information on utilization of medical care, including speciality of physician, diagnosis, date of service, and type of service for each resident with a correct medicare number.

3.5 Data Coding

Information from the data sources, excluding that from the Régie, was coded and stored on disks with a software program, "Knowledgeman", for use with the IBM personal computer. Data from the Régie were keyed, verified, and transferred to magnetic tape by A&C Data Entry, Inc. of Montréal. Several files were merged and analysis was undertaken on the McGill OS system with Statistical Analysis Systems.

To maintain confidentiality, demographic records were kept seperately from medical care utilization records where the only identification was the medicare number. Name and address are never specified on Régie data. All linking of the files was done through medicare numbers. After the research was completed, personal identification data were stricken from all records.

3.6 Variables

The variables used in this thesis and defined below include:

A. Identifying Variables
- Birth date
- Sex
- Medicare number

B. Exposure Variables
- Occupancy date
- Date of UFFI installation
- End of exposure date
- Pre-exposure period
- Post-exposure period
- Banning date

C. Response Variables
- Examination date
- Medical service
- Visit to a physician
- Utilization of medical care
- Diagnosis

3.6.1 Identifying Variables

Date of birth and sex are self-explanatory. They are used for stratification when comparing utilization of medical services for various age and sex groups of the sample.

Medicare number is assigned by the Régie to each person living in Québec, as discussed in section 3.4.

3.6.2 Exposure Variables

Occupancy date is the date when the resident moved to the home that was at some time insulated with UFFI, marking the beginning of the period before exposure if the occupancy date preceded the date of UFFI installation.

Date of UFFI installation is the date when the home was insulated with UFFI, as recorded on the insulator's receipt. If this information was missing from the Bureau's records, the resident was asked by interview for the date.

End of exposure date is the date when exposure to UFFI ended. Exposure to UFFI was considered to have ended if any of the following occurred: moving away from the UFFI home, partial or complete removal of the UFFI, changes made to the home in order to reduce exposure (blocking off the UFFI, or installing a ventilation system), or death of the resident. This date was obtained through telephone interview or by letter.

Pre-exposure period refers to the time a resident lived in the UFFI home before it was insulated with UFFI, from the occupancy date to the date of UFFI installation. In an attempt to reduce possible confounding effects on exposure and response variables due to variable housing characteristics, for this study the resident must have lived in the same dwelling for the pre and post exposure periods. There is no pre-exposure period for the residents who were born or who moved in to the UFFI home at the time of UFFI installation or after.

Post-exposure period refers to the time a resident lived in the UFFI home following UFFI installation, until the end of exposure date, as detailed above. The post-exposure period can be divided in to the period before and after the banning date of UFFI on December 18, 1980.

3.6.3 Response Variables

Examination date is the date when a resident was medically examined as required for application to the assistance program, which will be treated seperately from other response variables. This date was available from assistance program questionnaires and from Régie data.

A medical service (referred to as "act") for a resident is an examination, consultation, diagnostic act, radiologic act, therapeutic act, psychiatric treatment, surgical act, surgical assistance, act of anaesthesia, or other medical act for which a

physician asked for payment from the Régie. This information was available from Régie records.

One visit to a physician is defined by a date on which a resident saw a physician (or physicians) for a service (or services) as defined above which was claimed by the physician. More than one encounter with a physician or more than one service received in one day is counted as one visit to a physician, ie. dates are counted. The date corresponds to when the service was rendered, and not to when it was paid.

Utilization of medical care is a concept which summarizes, by averages or totals, the number of visits to a physician for a resident or group of residents in a specified period of time. In this study, the definition for counting a medical service, a visit to a physician, and total utilization of medical care is the same for the pre and post-exposure periods.

A diagnosis refers to the recording of a diagnosis on Régie data, as explained in section 3.4. Coding was done according to the International Classification of Diseases (ninth revision).

3.7 Missing Information

If occupancy date (2 missing values), date of UFFI installation (14 missing values), end of exposure date (26 missing values), or examination date (2 missing values) was unknown, the mean of the known values was used in place of the missing value.

3.8 Data Analysis

The data analysis was in accordance with the time series design of the study: "the essence of the time-series design is the presence of a periodic measurement process on some group or individual and the introduction of an experimental change into this time series of measurements, the results of which are indicated by a discontinuity in the measurements recorded in the time series" (1).

In this study, the periodic measurement process was the continuous recording of all instances of medical care for each individual, at least from the beginning of the pre-exposure period to the end of the post-exposure period. The measurement process was completely independent of any change in exposure. The discontinuity in the outcome measure was seen through analysis of the changes in frequency of visits to a physician in a given time period. The first analysis investigated any possible trends over time, looking at frequency of visits to a physician by calendar three-month periods and year from 1977 to 1982, regardless of time of UFFI installation and pre and post-exposure periods which varied between individuals in the sample. This can be seen as an ecological or group analysis.

The effect of the "natural experimental" change (the installation of UFFI in the homes of these people), was investigated through comparison of the frequency of visits to a physician in pre and post-exposure periods. Since UFFI was

installed in different homes at different times, pre and post exposure periods were different for each resident, and were calculated as such to create an exposure index based on individual level information. An example of how this analysis would work for each study subject is seen in figure 3.4. Three month periods of measurement of utilization of medical care were chosen as the shortest duration of interest: if exposure and response were associated, the effect would be apparent within a short time following UFFI installation, as suggested by the literature review. Also, the plausibility of inferring an acute effect of exposure is greatest immediately following the exposure. Analysis was also carried out on frequency of visits to a physician in groupings of three month intervals in to six months before and after exposure. The physician visit for the examination required by the assistance program was subtracted from the post-exposure period for each resident.

For the second objective, the analysis was similar to the initial ecological analysis, this time looking at pre and post-banning periods since the time of banning of UFFI on December 18, 1980 was the same for the total sample. The ecological analysis of visits to a physician by season and year was also used to compare utilization of medical care by this sample to utilization by the general population of Québec for 1977 to 1982, and to utilization by the population of Montréal for 1982 (the only year for which regional data was published by the Régie).

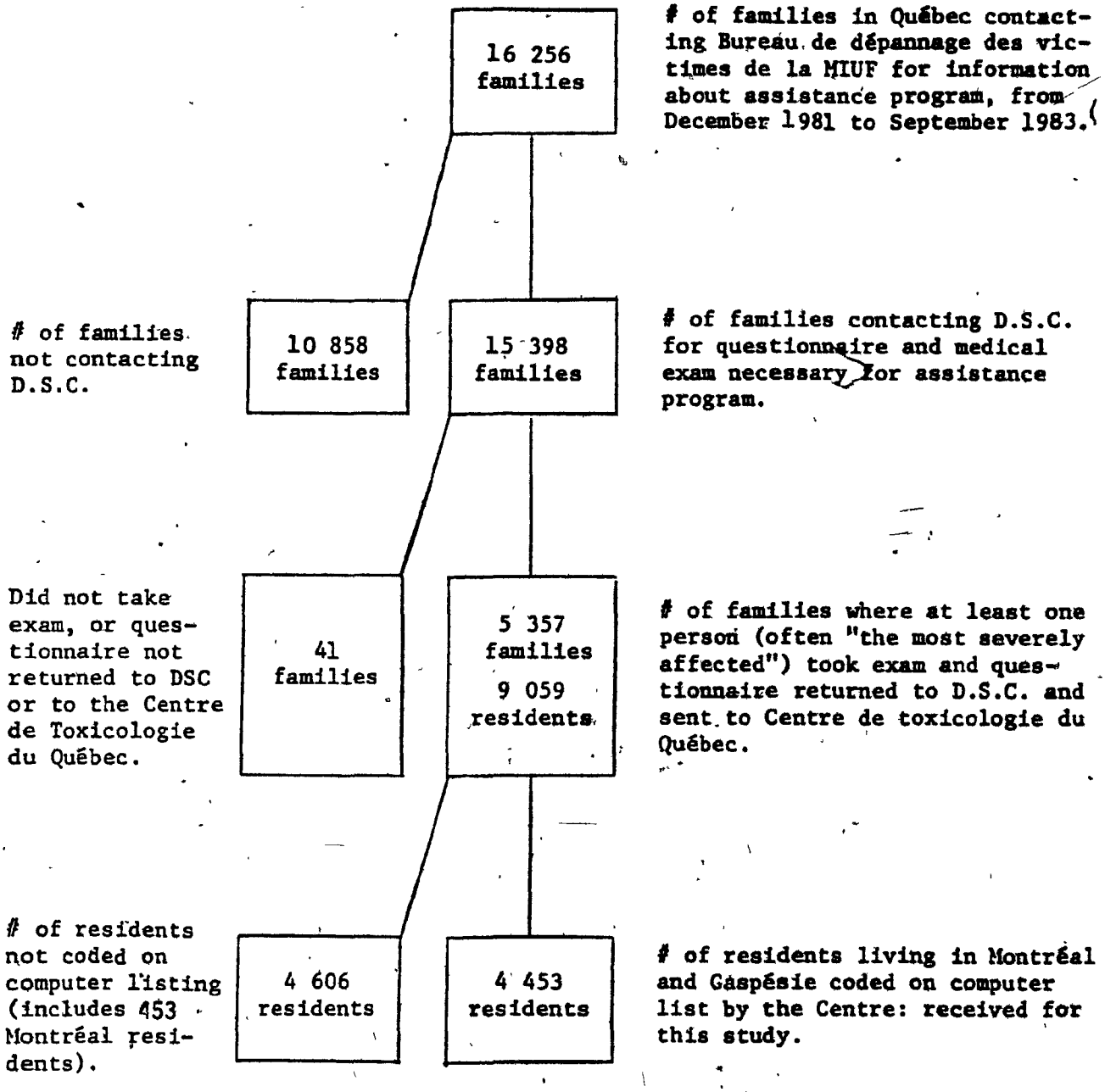
To control for differential utilization of medical care according to season, all pre and post exposure comparisons were made at the corresponding time of year. Another threat to internal validity in this study is the possibility of differential recording of medical care over time, especially if changes in the measurement process occurred coincident with the change in exposure. A sudden change in recording of medical care coincident with variable times of initial exposure is unlikely, however; a gradual change over time may be more likely. Where this was apparent, the trend was quantified in an attempt to differentiate between the effect of changes in the measurement process and the effect of the natural "experimental" change.

Descriptive statistics were used to compare the frequency of selected diagnoses in the pre and post exposure periods (objective 3), and to assess the proportion of residents who remained exposed to UFFI as of March, 1984.

For each objective, analysis of utilization of medical care for the total sample, for females alone, and for males alone was undertaken. Analysis by age groups was initiated but highly variable results emerged. It was judged that these results had very little meaning due to the lack of statistical power because of small numbers; therefore, few age-specific results are presented.

All statistical tests were two-tailed self-paired t-tests on mean differences, allowing for either an increase or decrease in frequency of visits to a physician. The null hypothesis was that of no effect, i.e., no difference in the outcome measure between the pre and post-exposure periods and between pre and post-banning periods. A probability of 0.01 or less of obtaining a difference at least as large as that observed if chance alone were operating was taken as statistically significant, although caution was noted because of the multiple comparisons being made. The sensitivity and public health (or clinical) significance of the results was evaluated through calculation of 99% confidence intervals for the mean differences.

Figure 3.1: Evolution of sampling frame.



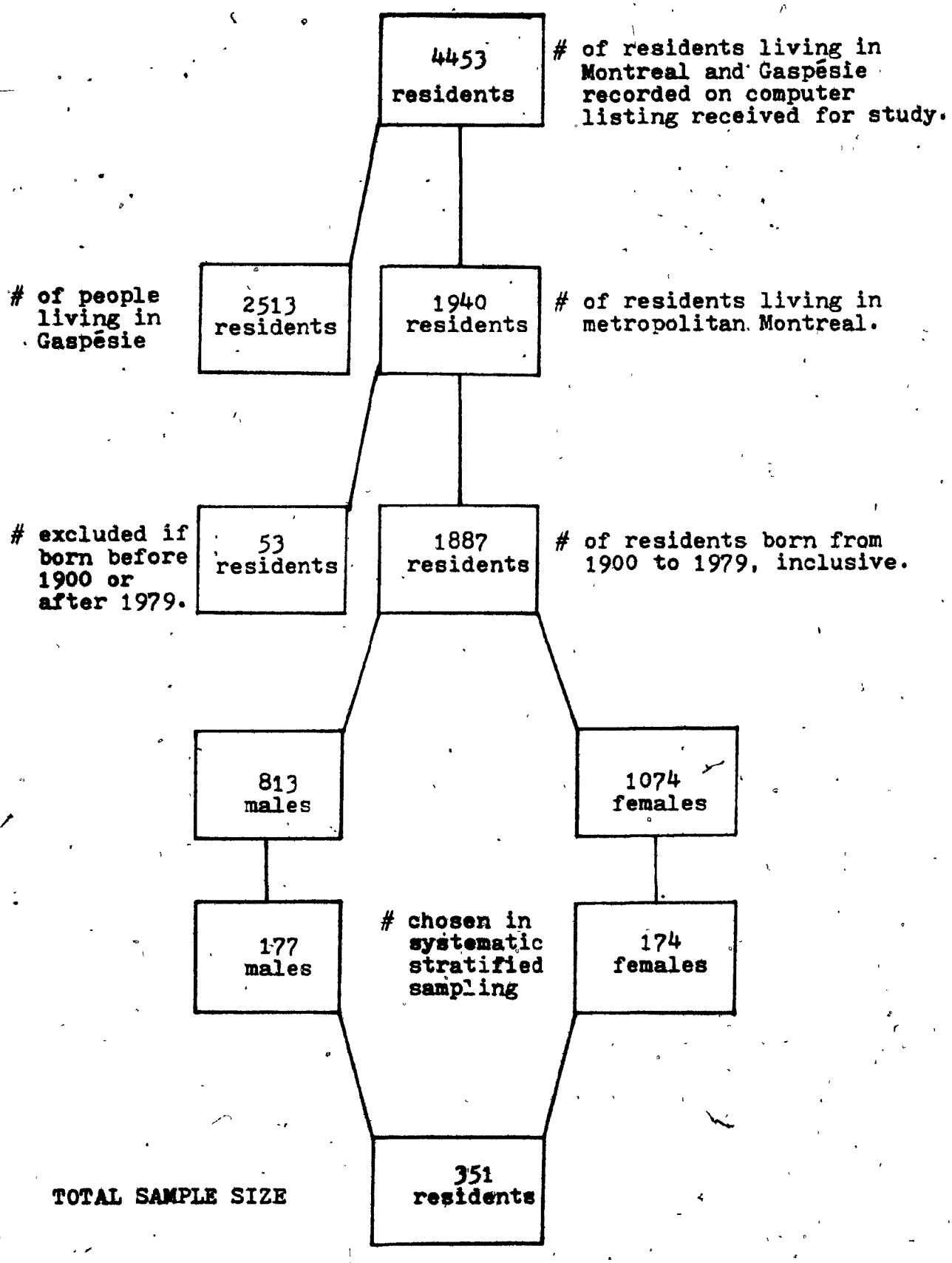
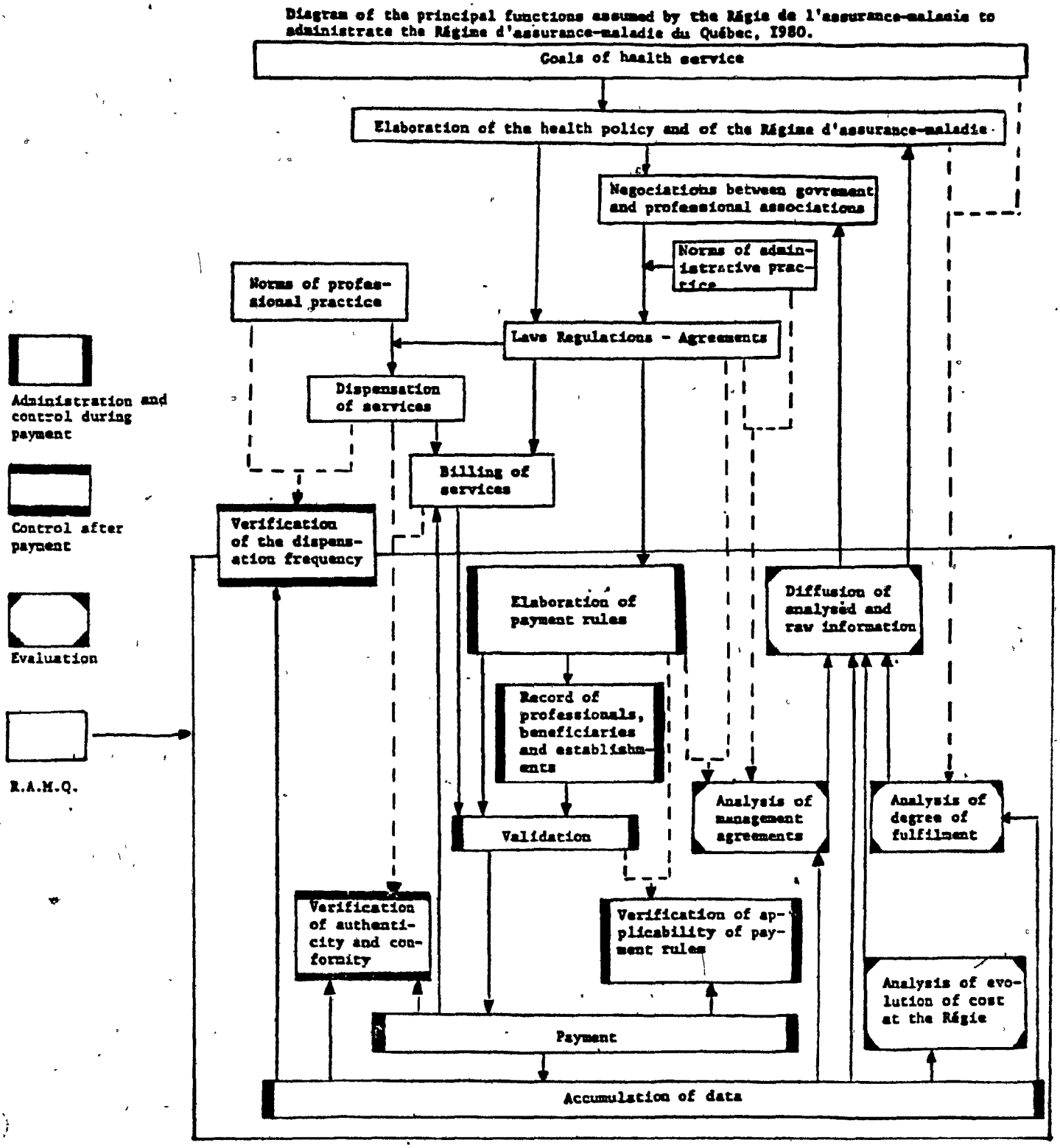


Figure 3.2: Evolution of sample selection.

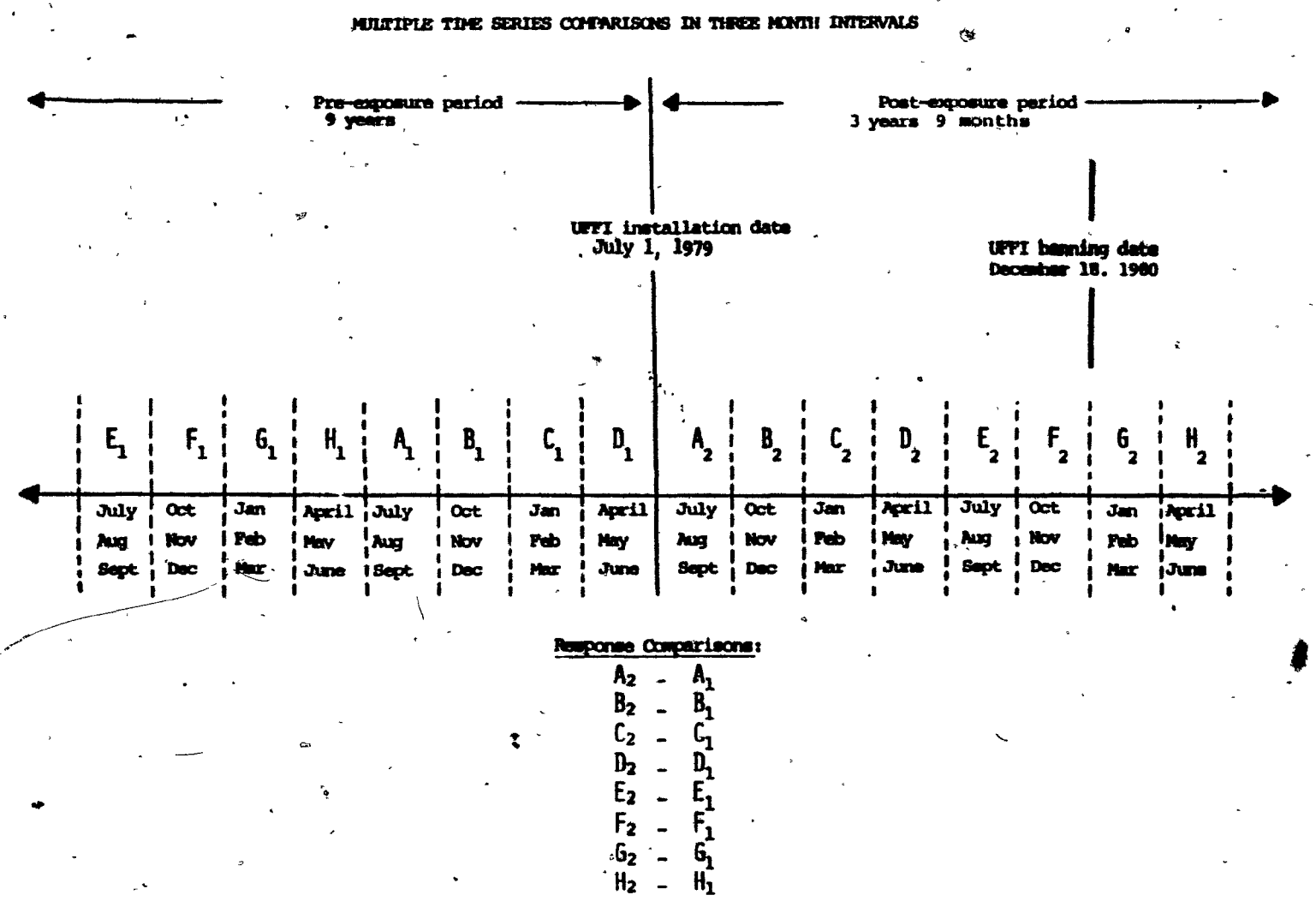
Figure 3.3:

Diagram of principal functions assumed by the Régie de l'assurance-maladie to administer the Régime d'assurance-maladie du Québec, 1980.



Source: Translated from Statistiques annuelles 1979, RAMQ, p.17. used with permission.

Figure 3.4: Example of analysis for one subject



Response Comparisons:

$A_2 - A_1$
$B_2 - B_1$
$C_2 - C_1$
$D_2 - D_1$
$E_2 - E_1$
$F_2 - F_1$
$G_2 - G_1$
$H_2 - H_1$

Table 3.1:

Sample sizes per group for a two-tailed test on proportions. $P_1 = 0.05$

		POWER			
P_2	Alpha	0.99	0.95	0.90	0.85
0.10	0.20	-	-	-	336
0.15	0.01	-	337	285	-
0.15	0.02	-	300	252	-
0.15	0.05	345	251	-	-
0.15	0.10	299	-	-	-
0.15	0.20	250	-	-	-

P_1= proportion of members of the first group, (pre-exposure group), who experience the outcome being studied.

P_2= proportion of members of the second group, (post-exposure group), who experience the outcome being studied.

Source: Fleiss, JL (1981). Statistical Methods for Rates and Proportions, second edition. New York: John Wiley and Sons, pp.35 and 260.

Table 3.2: Sampling frame, sampling intervals, and numbers of residents chosen in systematic sampling, by age (10 year groups) and sex.

MALES					FEMALES			
# chosen in sampling	sampling interval	# living in Montréal	# in sampling frame	Year of birth	# in sampling frame	# living in Montréal	sampling interval	# chosen in sampling
-	excluded	28	69	1980-1983	54	21	excluded	-
20	5	102	325	1970-1979	284	101	5	20
23	4	92	215	1960-1969	244	96	4	24
25	4	76	196	1950-1959	292	124	6	20
23	5	111	275	1940-1949	374	163	7	23
22	6	136	272	1930-1939	384	191	9	22
21	7	151	336	1920-1929	436	221	10	22
22	5	113	213	1910-1919	264	136	6	22
21	2	32	95	1900-1909	109	42	2	21
-	excluded	2	6	1890-1899	10	2	excluded	-
177		843	2002		2451	1097		174

Total # of residents in sampling frame= 4453
# of residents living in Montréal= 1940
# of residents chosen in systematic sampling= 351

REFERENCES FOR CHAPTER THREE

1- Campbell DT and Stanley JC (1963). Quasi experimental and experimental designs. Chicago: Rand-McNally & Co.

2- Fleiss JL (1981). Statistical Methods for Rates and Proportions, second edition. NY: John Wiley and Sons.

CHAPTER FOUR

RESULTS

In this chapter the completeness of the data collection is reviewed, the sample is described through summary statistics, and results of the analysis in order of the objectives are detailed. Discussion, conclusions, and implications for further research follow in the final chapter.

4.1 Completeness of data collection

337 residents from the total sample of 351 (96%) were included in the analysis (figure 4.1). This number was reached by including all those for whom their medicare number was known and correct, and by excluding coding errors and those from non-UFFI homes, as detailed below. Completion of the questionnaire designed for this study was not necessary for inclusion in the analysis, since the mean of known values was used for a total of 44 out of 1348 possible values (3%) in place of any missing values remaining from interviews and questionnaires not completed.

Of the total sample of 351 residents, 5 were excluded because of coding errors on the list received for sampling. Identification codes did not correspond to any files kept for the assistance program at the Centre de Toxicologie du Québec. Follow-up by telephone was attempted for the remaining 346

residents. Of these, 3 refused to participate, 21 were not contacted, and 320 residents and 5 relatives of deceased residents were contacted. Two residents were excluded from further analysis at this stage since they reported that the adjacent home and not their own dwelling was insulated with UFFI. The study questionnaire was sent to 21 residents not interviewed by telephone, and 5 of these returned completed questionnaires. Time to complete the interview or questionnaire was estimated at 3 minutes. In total, 323 questionnaires for this study were completed for a follow-up of 93.5% (323/346)* (figure 4.2).

4.2 Description of the sample

4.2.1. Identifying variables

For the 337 residents included in the analysis, final groupings by sex and birth date, known for every resident, are seen in table 4.1. Unexpected errors (6 persons) for birth date on the original list received for sampling were corrected by the residents themselves in completing the interview or

* Of the 323 residents who completed questionnaires, 301 (93.2%) gave their medicare number, while 14 (4.3%) refused, and 8 (2.5%) had lost their card or did not respond with the complete number (see figure 4.3). For the 14 who refused, 12 residents were hesitant about quoting their number over the telephone, and 2 residents declined for personal reasons. Since medicare numbers were available from the original assistance program questionnaire, asking for medicare numbers by telephone simply gave an idea of response, information for future studies. Those who refused to give their number but whose number was previously known were nevertheless included in the analysis since the resident had signed a consent form for use of this information for research. Letters were sent to residents whose medicare was not known, and I returned this number by mail.

questionnaire. This caused some slight shifting of residents from one age group to another.

In summary, following 7 exclusions for reasons detailed above, 344 residents remained for potential inclusion in the analysis. Of these, however, medicare numbers, necessary for inclusion, were unknown for 3 and were incorrect for 4 residents, as identified by the Régie. Thus, these residents were excluded, leaving 337 residents for inclusion in the analysis.

4.2.2. Exposure variables

The range, mean, and standard deviation of the exposure variables for the total sample are seen in table 4.2. The mean occupancy date for 335 residents (2 missing value) was July 1, 1970, with a standard deviation of about 9 and a half years. The range was from Jan. 1, 1922 to June, 1982.

July 3, 1979 was the mean date of UFFI installation for 323 residents (14 missing values). Standard deviation was 1 year and 3 months, and the range was from July 1, 1971 to December 11, 1980, seven days before UFFI was initially banned in Canada.

The mean end-of-exposure date for 311 residents (26 missing values) was April 27, 1983 with a standard deviation of just over 9 months and a range of July 1, 1980 to April 1, 1984, when the final interview was completed.

Values for exposure variables for males and females in the sample were similar, and are seen in tables 4.3 and 4.4, respectively.

For each of the 337 residents used in the analysis, individual pre and post exposure periods were calculated, with the UFFI installation date as the division. The mean pre exposure period for the sample (N=337) was 9 years while the mean post exposure period was 3 years and 9 months. The mean time period from the mean date of UFFI installation to the banning of UFFI on December 18, 1980 was 1 year and 5 months (five three month intervals), and the mean time period from UFFI installation to the examination for the assistance program was 2 years and 7 and a half months.

4.2.3. Response variables

For 335 residents (2 missing values), the mean examination date was March 17, 1982 (SD= 2 months, 25 days). The range was from Febuary 3, 1981 to April 4, 1983.

4.3. Results of Analysis: Objective 1

Over 33,000 records of instances of medical care were received from the Régie. In the first analysis, the number of visits to a physician were arranged chronologically, and divided for analysis into three month calendar periods, regardless of the date of UFFI installation for each resident. All comparisons were seasonal; that is, months of one year were compared to the same months in the previous year. A trend over time of increasing frequency of visits to a physician became apparent in all months of 1979 in comparison with 1978, at varying levels of statistical significance (table 4.5). Most notably, self-paired comparisons of mean number of visits were statistically significant at $p \leq 0.01$ for the two periods of January, February, and March, and of July, August, and September, 1979 as compared to the same months in 1978. At this ecological level of analysis, the increases coincided with the majority of the distribution of dates of UFFI installation for the sample (n=337) (figure 4.4). An analysis at the ecological level for males (N=169) and females (N=168) in the sample produced similar results, as seen in tables 4.6 and 4.7, respectively. This data is graphically represented in figures 4.5 for males and 4.6 for females.

Quantified, the trend over time from 1977 to 1982, and the notable increase from 1978 to 1979, in terms of the difference in mean number of visits to a physician (with reference to table 4.5) can be seen as:

1977 to 1978=(1978A + 1978B + 1978C + 1978D) - (1977A + 1977B + 1977C + 1977D)= 0.1 increase in mean visits to a physician from

1977 to 1978; 1978 to 1979=6.09-4.7=1.39; and 1979 to 1980=6.24-6.09=0.15. To investigate in particular the increase for 1979, the above equations reduce to: (1979A + 1979B + 1979C + 1979D) - 2(1978A + 1978B +1978C + 1978D) + (1977A + 1977B + 1977C + 1977D), which quantify a particular effect in 1979 by subtracting from it the overall trend in the data. The result was: 6.09-2(4.7) + 4.6= 1.29 mean visits to a physician for 1979 above and beyond any apparent trend, representing an average increase per three month period for 1979 of 1.29/4= 0.3225 visits.

A further analysis for objective one incorporated individual exposure information. For the sample of 337 residents, self-paired analysis of visits to a physician before and after date of UFFI installation, seasonally compared, showed no statistically significant changes in the four 3month periods (1 year) after initial exposure to UFFI, as seen in table 4.8. This was in comparison with the same periods in the year prior to exposure to UFFI. All but one difference (post minus pre) in mean frequency of visits were positive, representing very slight increases following initial exposure to UFFI.

More than a year after initial exposure to UFFI, at 13 to 15 months, the mean number of visits was 1.46 (SD=2.06), which was represented by a statistically significant (p=0.0001) self-paired increase over the corresponding 3-month period at 22 to 24 months before exposure. For three of the four 3-month periods in the second year following UFFI installation, mean differences in visits to a physician were positive and statistically

significant, compared with the same 3-month periods in greater than one year before UFFI exposure. These results were replicated in the analysis of males alone (table 4.9) and females alone (table 4.10).

In analyzing the possibility of a type II error, 95% confidence intervals were calculated on observed mean self-paired differences in frequency of visits for medical care. Relatively high standard deviations resulted in wide confidence intervals, but the upper limits for increases in frequency were below what was considered of clinical or public health significance.

The concern arose that the statistically significant increases in mean number of visits to a physician in periods greater than one year post exposure may have been an artifact of the comparison of time periods further and further apart in time. This was especially possible given the results of the ecological analysis. To address this concern, a further analysis was undertaken comparing all 3-month periods beyond one year post exposure to the same periods in the year just prior to UFFI installation. Results revealed no significant changes in the response variable for any of the 3-month periods 2 years post exposure, compared to the four 3-month periods 1 year pre exposure (table 4.11).

This type of analysis for males alone (table 4.12) yielded identical results. For females, however, a marginal increase was still apparent at 19 to 21 months post exposure seasonally compared to 4 to 6 months pre exposure (table 4.13). The level

of probability for this result was 0.0143.

A comparison with the population of Régie beneficiares in Québec in terms of utilization of medical services shows that a mean increase occurred for each year from 1977 to 1980, as seen in table 4.14 for males and table 4.15 for females. The largest increase was seen from 1979 to 1980, while a slight decrease was recorded for each year after 1980. Number of visits per se was not readily available from annually published statistics: instead, the Régie counted number of services (acts, as defined in the methods section). For crude comparability, since the number of services per visit was approximately 1.55 (personal communication, P. Bossé), a simple calculation showed that the approximate number of visits per resident per year was 4.6 for beneficiares in Quebec (table 4.16). The highest number of visits was seen for 1980. A simplified version of table 4.5 is seen in table 4.17 to show that the average number of visits per year for this sample of over 5.5, with the highest amount per year also occurring in 1980, while the greatest increase occurred from 1978 to 1979 for this sample. The pattern of utilization of services in 1979 by age and sex groups for residents of Quebec is seen in figure 4.7. Although these variables are important in the consideration of possible confounding effects, it was judged that age and sex groups in this sample had too few subjects to permit comparison, crude or standardized. The highly variable results of the attempt to show utilization by age and sex groups for this sample are seen in figure 4.8.

4.4 Results of Analysis: Objective 2

The arrangement of visits to a physician by calendar three-month periods and year, regardless of the various times of UFFI installation for the residents in the sample, was used to test the null hypothesis that the banning of UFFI on December 18, 1980 had no effect on utilization of medical care. The data from tables 4.5, 4.6, and 4.7 are seeen again in tables 4.18, 4.19, and 4.20 with the date of banning of UFFI, and are graphically shown in figures 4.9 (sample), 4.10 (males), and 4.11 (females) to illustrate the pre and post banning months and years. The first post banning period of January, February, and March, 1981 was compared to the same months from the previous year, 1980, in the pre banning period, and analysis proceeded in this manner, comparing all post exposure periods to the same pre exposure period to a limit of one year before the period when the ban was announced. No mean self-paired differences in number of visits to a physician were statistically significant in this analysis of 337 residents. Mean differences (post minus pre) ranged from -0.069 to 0.312, while the lowest p-value was 0.20.

4.5 Results of Analysis: Objective 3

As detailed in the methods section, the Régie receives complete diagnostic information from physicians for about 60% of claimed services. This could result in severe bias as a result of differential recording of diagnoses at different times or by different physicians. This consideration and the fact that the null hypothesis of no effect of exposure was not rejected for

objectives 1 and 2, led to the judgement that analysis of diagnostic distribution of visits for this sample before and after exposure would be meaningless. Therefore, objective 3 was not fulfilled by this study.

4.6 Results of Analysis: Objective 4

As of March 1, 1984, 79.3% (256/323; 2/323 no response to this question) of the residents who completed an interview or questionnaire were still living in the home in which UFFI was installed. However, 178 (69.5% of 256) removed the UFFI and continued to live in the same dwelling, while 8 reported making changes to reduce exposure to UFFI. These changes included partial removal, blocking off of the UFFI, and installation of air exchange and ventilation systems. The remaining 70 residents (27.3% of 256) reported having made no changes to their home or to the UFFI in an attempt to reduce exposure. This represented 22% (70/323) of the sample with complete follow-up who were still exposed to UFFI in their homes as of March 1, 1984.

By contrast, of the 323 residents who completed follow-up, 65 (20.1%) moved away from the UFFI home as of March 1, 1984. Of these, 41 (63.1% of 65) reported removing the UFFI before moving away, while 22 (33.8% of 65) reported moving away without removing the UFFI. All results above for this objective are seen in figure 4.12.

The residents who moved away from the home where UFFI was originally installed, regardless of whether or not they removed or kept the UFFI before moving, were asked directly (the second to last question in the questionnaire) if the move was because of UFFI. 36 residents (55.4% of 65) answered affirmatively, while 27 (41.5% of 65) moved for other reasons (figure 4.13).

Finally, as the last question of the questionnaire, all 323 residents were asked if they thought that UFFI effected their health or the health of anyone in their family. 211 residents (65.3%) answered affirmatively, 78 (24.1%) said that they had no health problems associated with UFFI, 28 (8.7%) were uncertain if health problems were related to UFFI, and 6 residents did not respond to this question (figure 4.14).

Figure 4.1: Sample exclusions

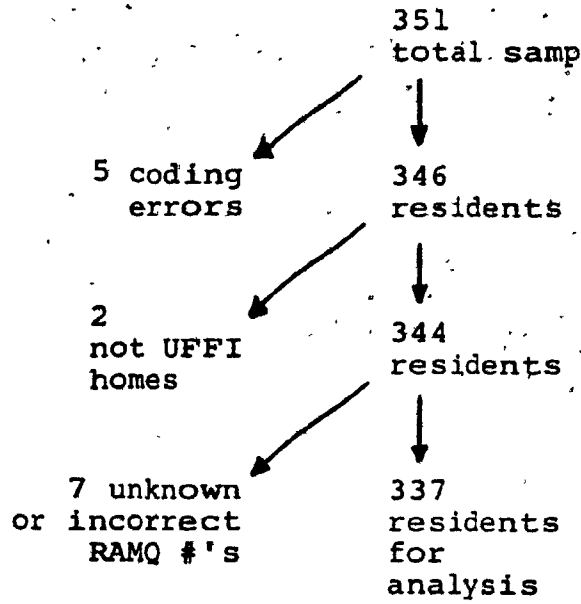


Figure 4.2:
Flow chart of sample, exclusions, and questionnaire response

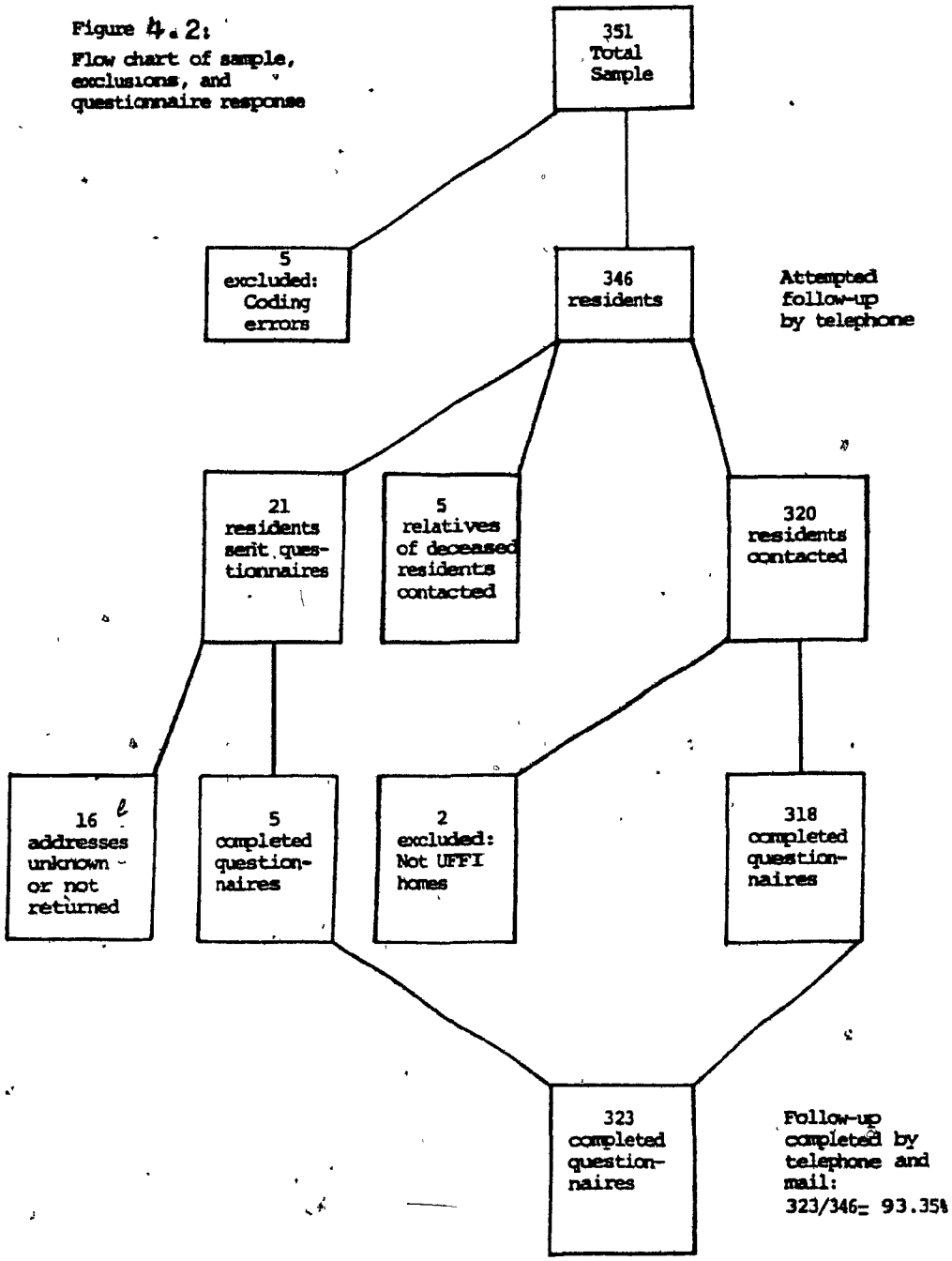
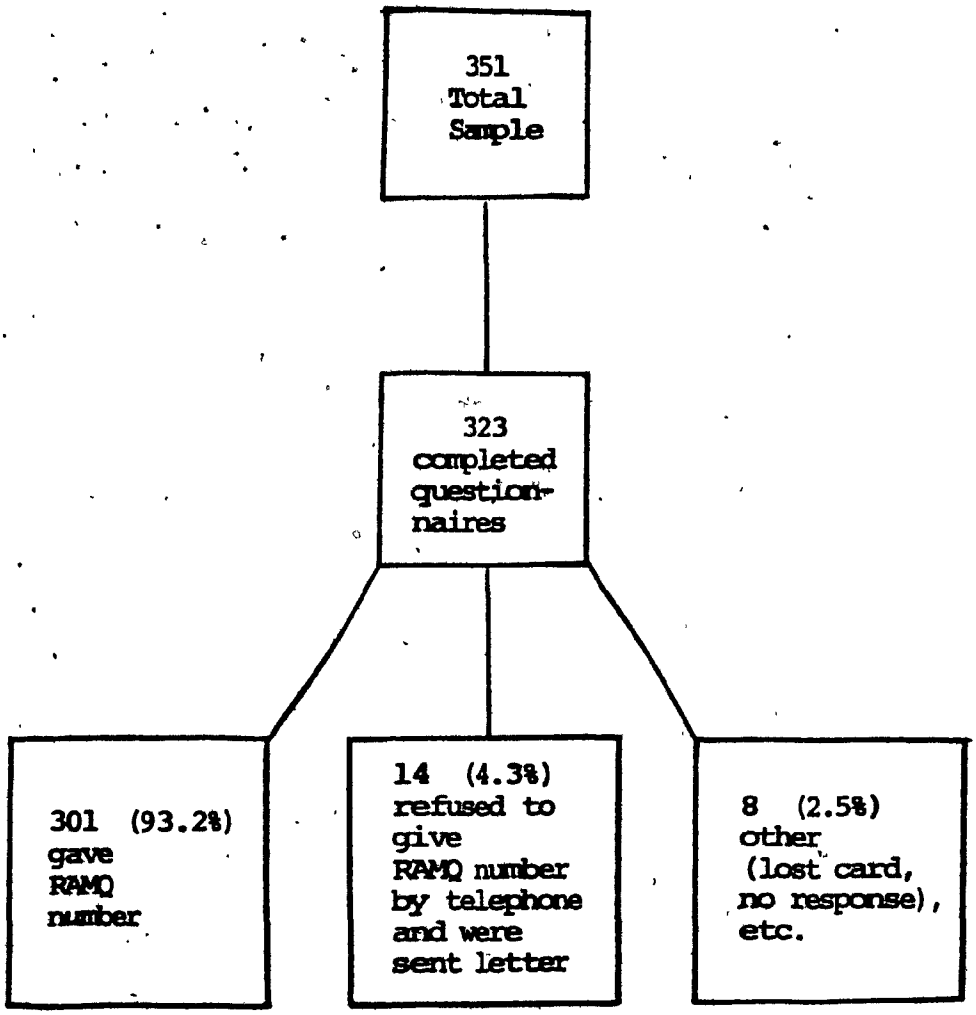


Figure 4.3: Response to asking for RAMQ number by telephone



Question: May I ask you your medicare number?

Quel est votre numéro d'assurance-maladie (la carte soleil)?

Figure 4.4:
Mean number of visits by season and year, 1977-1982

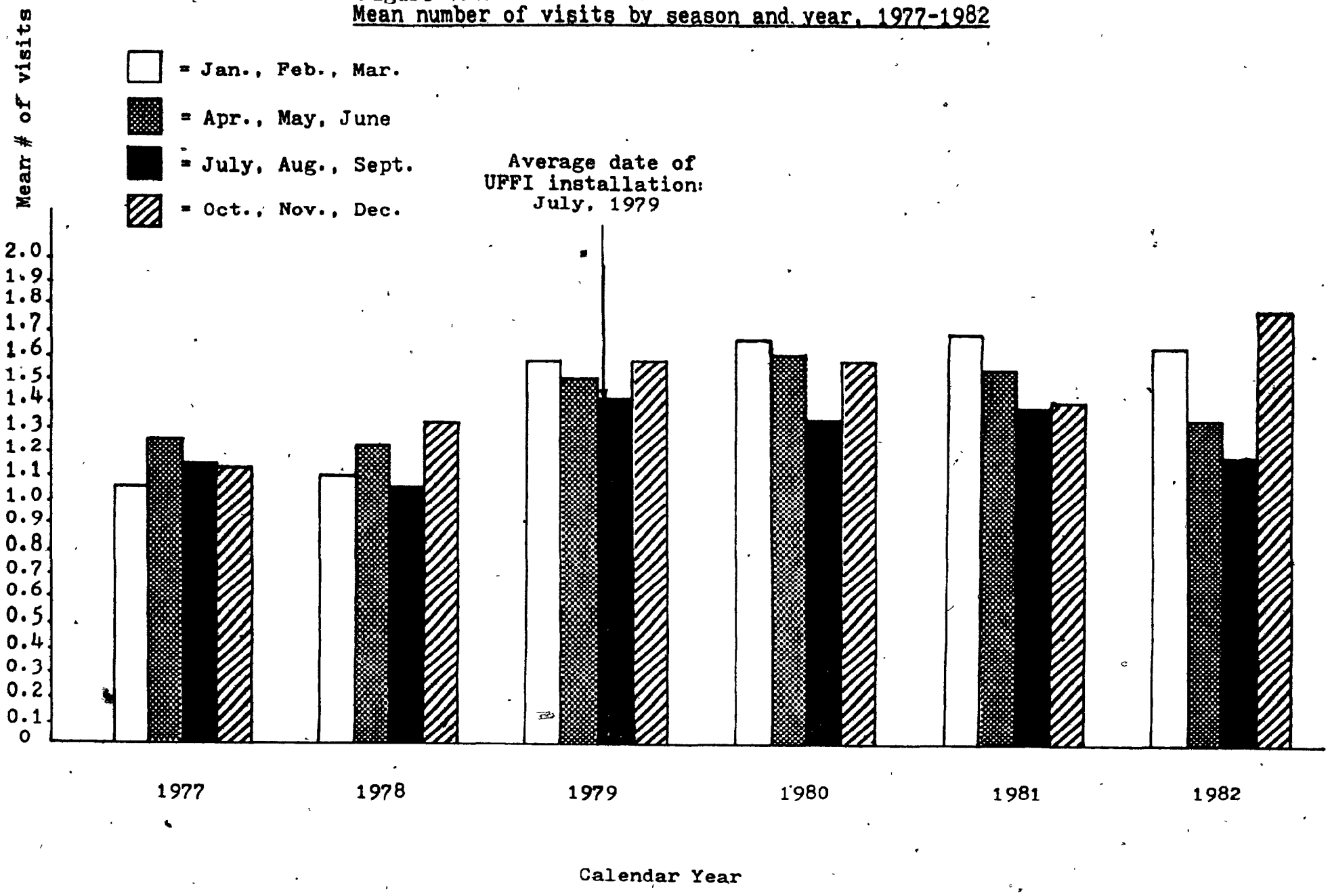


Figure 4.5:
Mean number of visits by season and year, males (N=169), 1977-1982

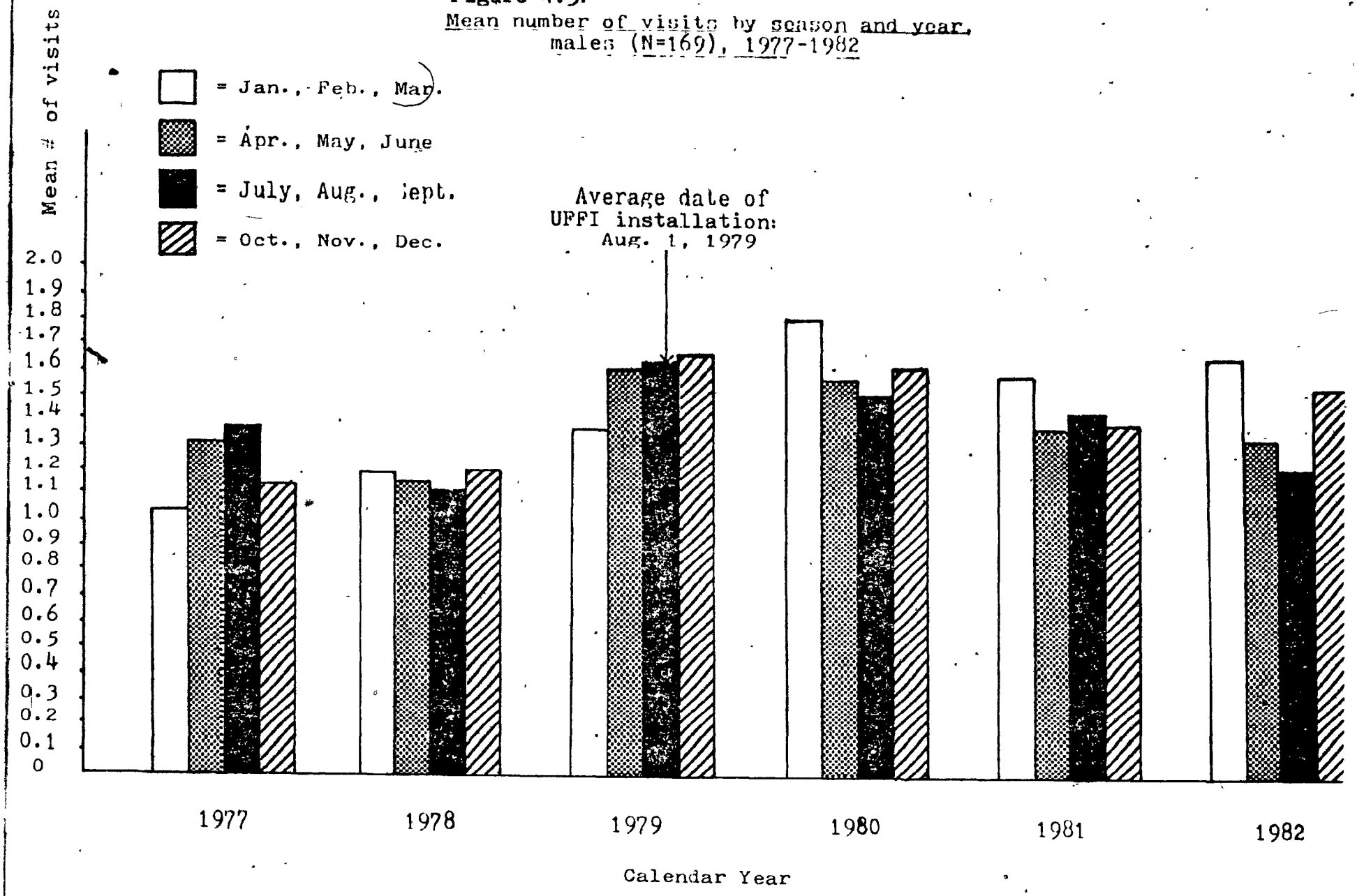


Figure 4.6:
Mean number of visits by season and year, females (N=168), 1977-1982

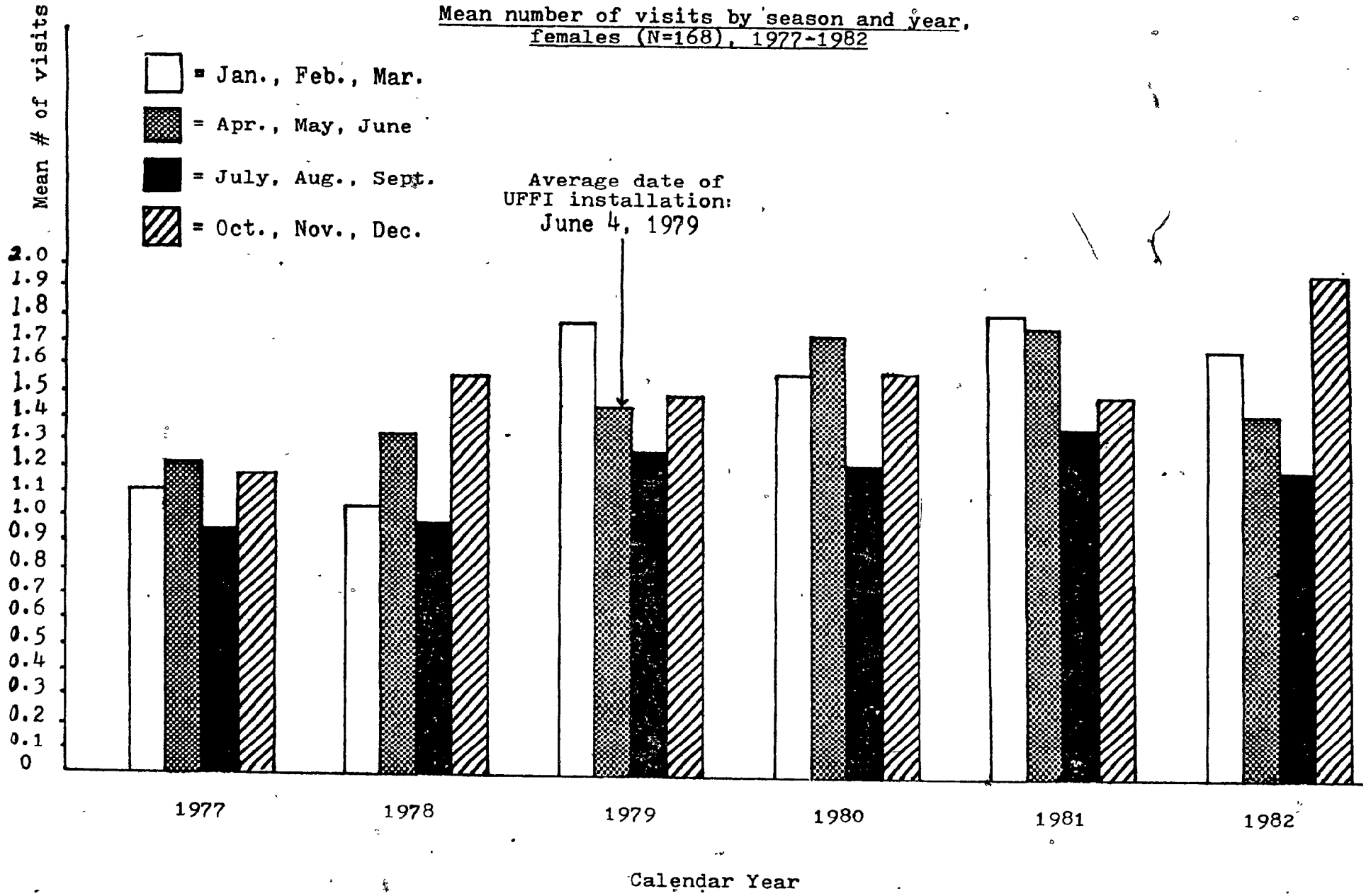
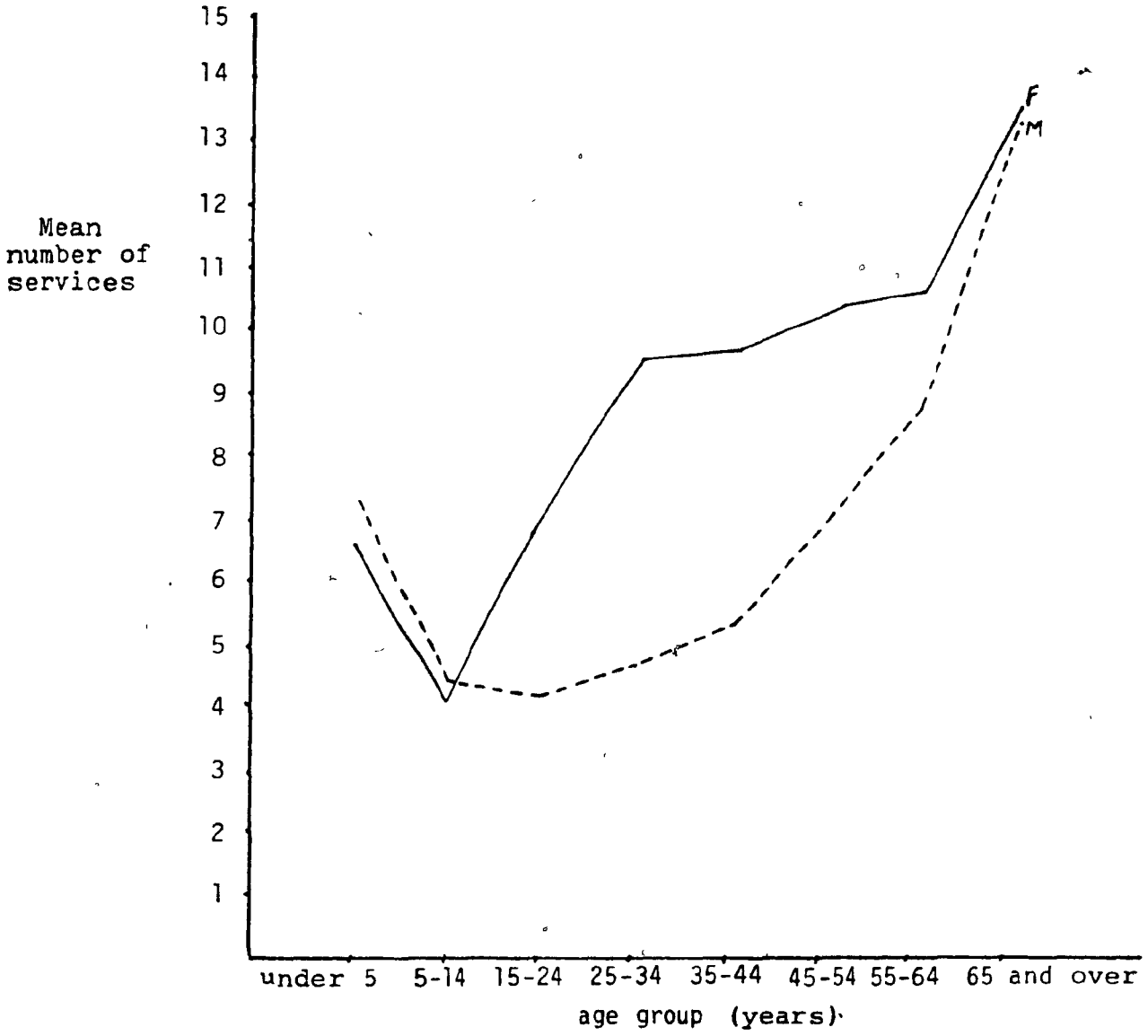


Figure 4.7:

Mean number of medical services received by age and sex of all beneficiaries in Quebec, 1979

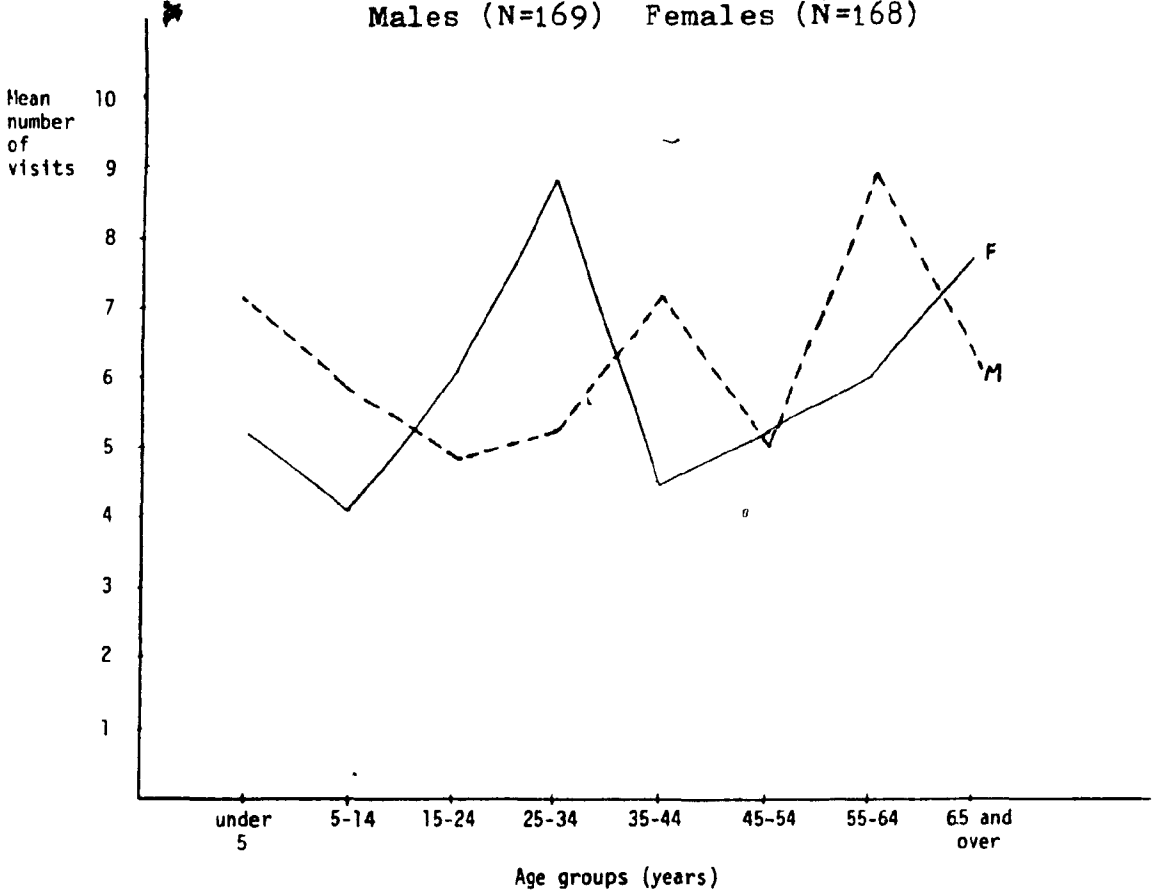


	MALE (---)	FEMALE (——)
under 5 years old	7.27	6.52
5-14	4.33	3.92
15-24	4.09	6.90
25-34	4.63	9.49
35-44	5.25	9.56
45-54	6.59	10.27
55-64	8.67	10.30
65 and up	13.04	13.31

Figure 4.8:

Mean number of visits, by age and sex, for 1979

Males (N=169) Females (N=168)



	MALES(--)	FEMALES(——)
under 5	7.00	5.23
5-14	5.69	4.41
15-24	4.90	5.99
25-34	5.39	8.70
35-44	7.36	4.61
45-54	5.33	5.32
55-64	8.91	6.04
65 and over	6.17	7.74

Figure 4.9:

Mean number of visits by season and year, 1977-1982

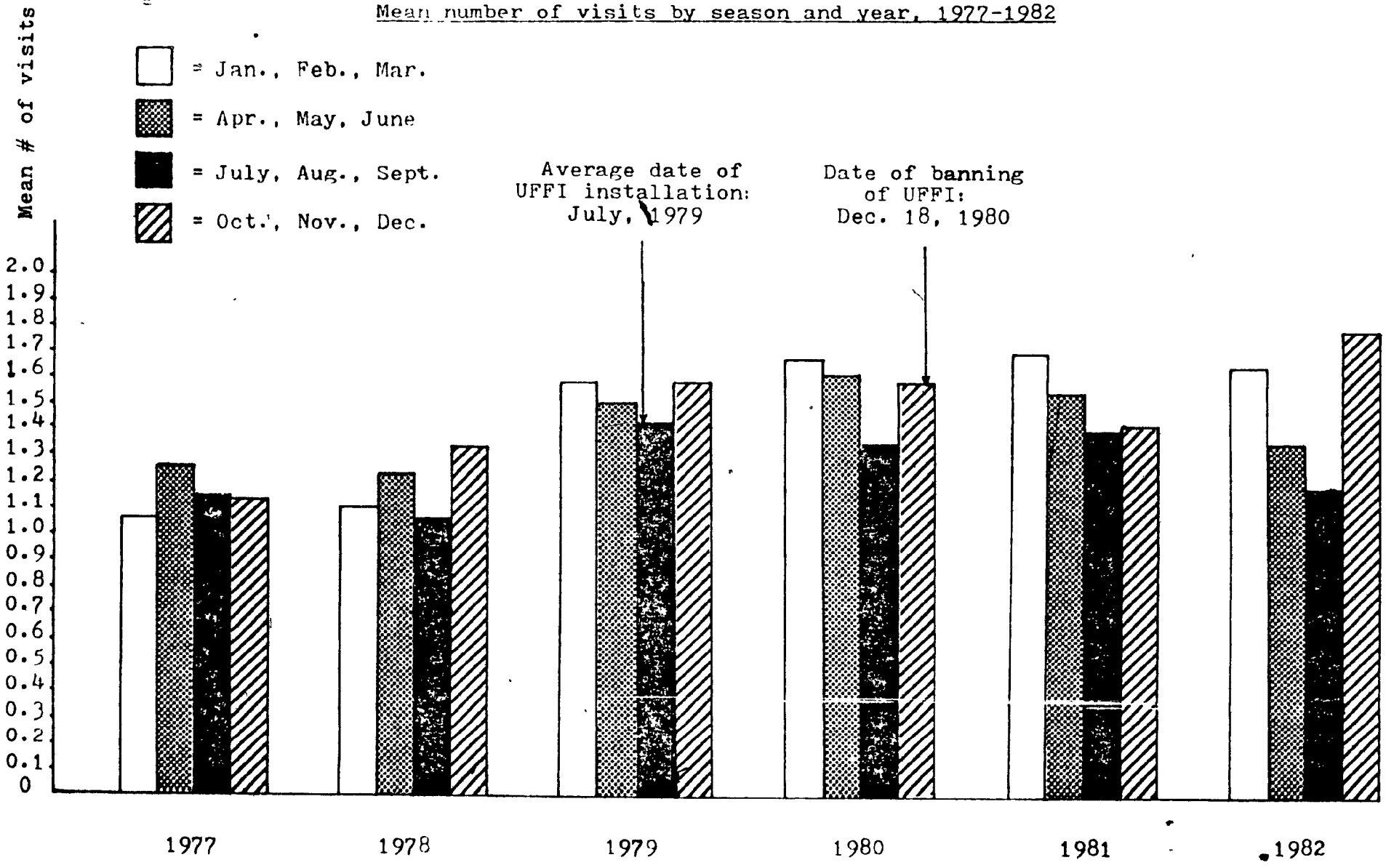


Figure 4.10:

Mean number of visits by season and year, males (N=169), 1977-1982

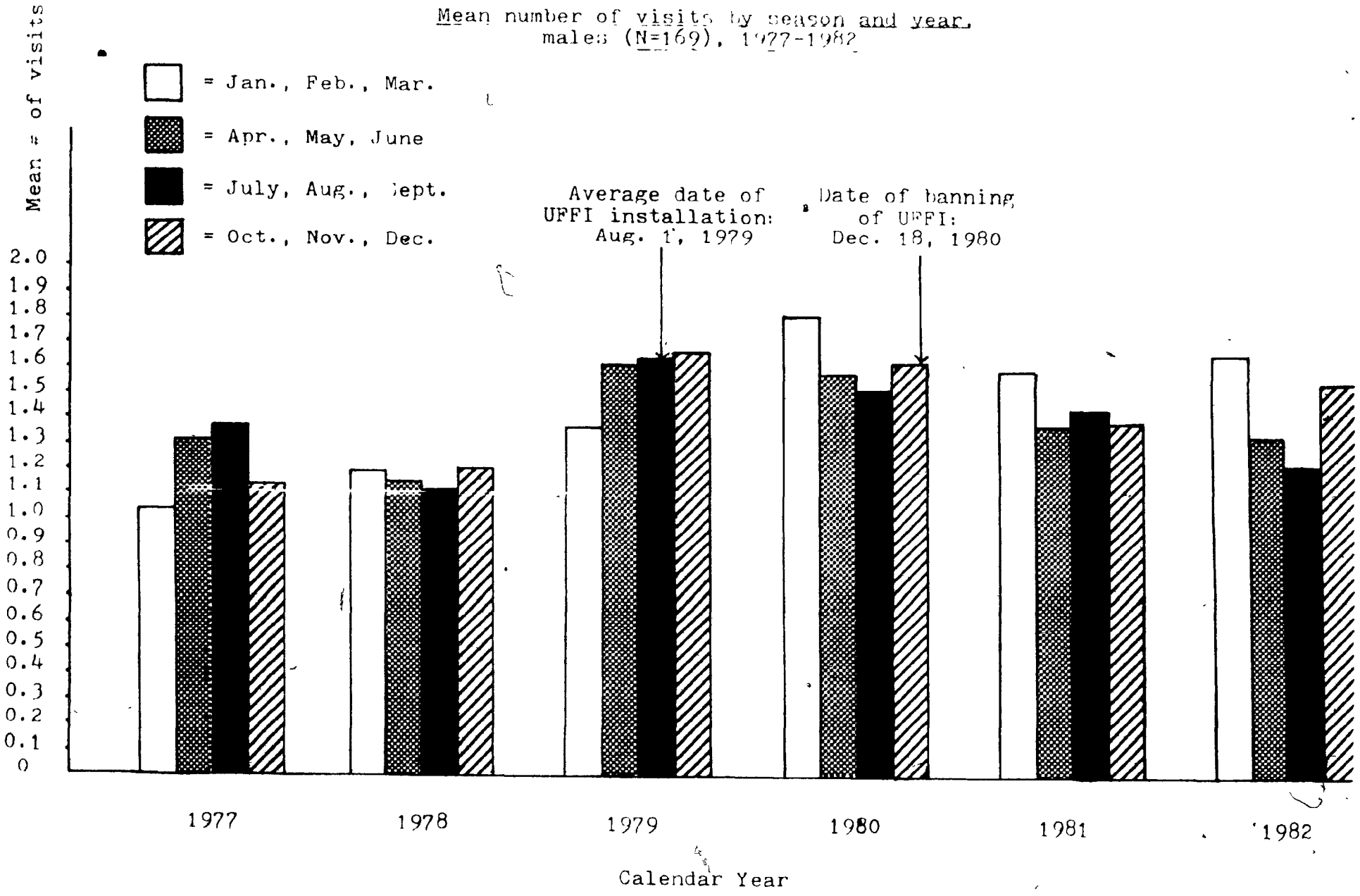


Figure 4.11:
Mean number of visits by season and year, females (N=168), 1977-1982

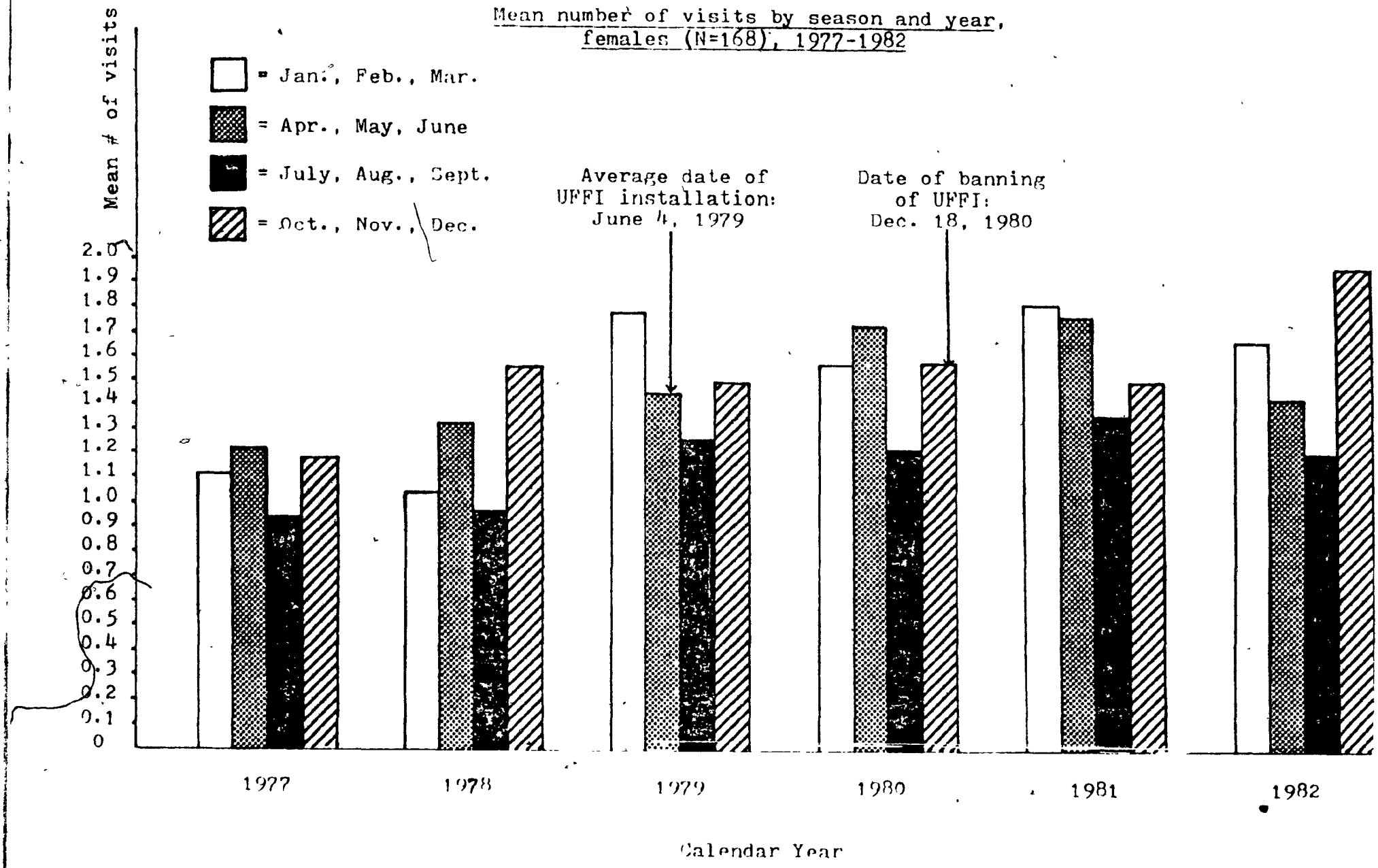
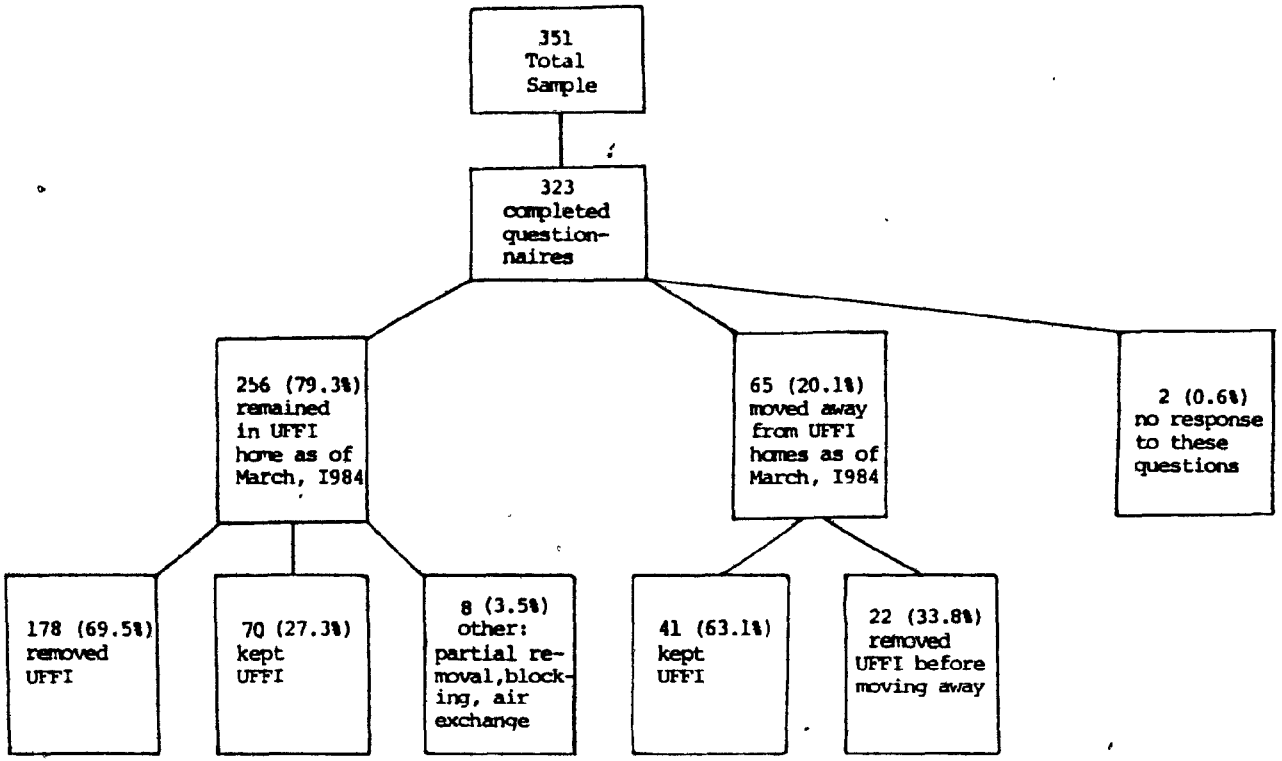


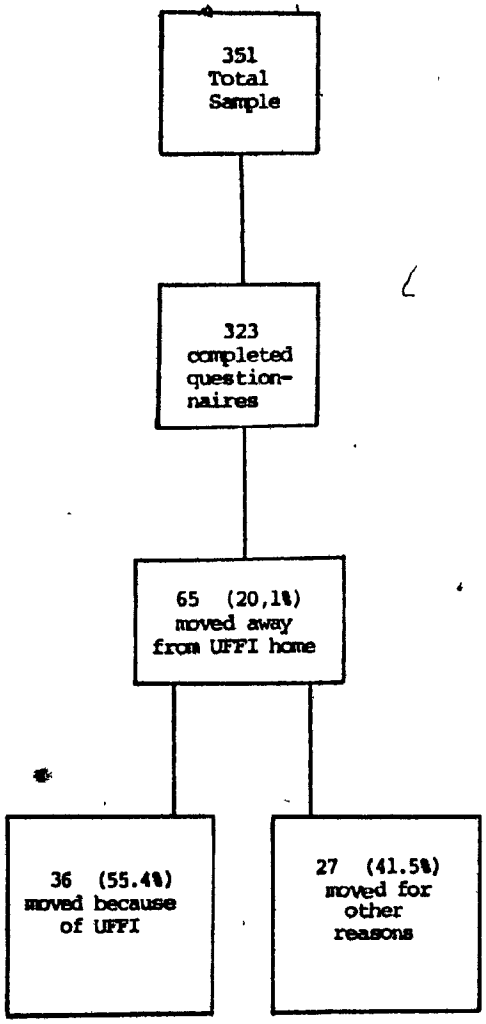
Figure 4.12: Questionnaire response for exposure status



Questions: If you do not live in the UFFI home, when did you move?
Did you or your family make any changes to your home after UFFI was installed?
For example, did you remove the UFFI, keep the UFFI, block off the UFFI, or other _____?
If you made changes, what was the date the changes were made?

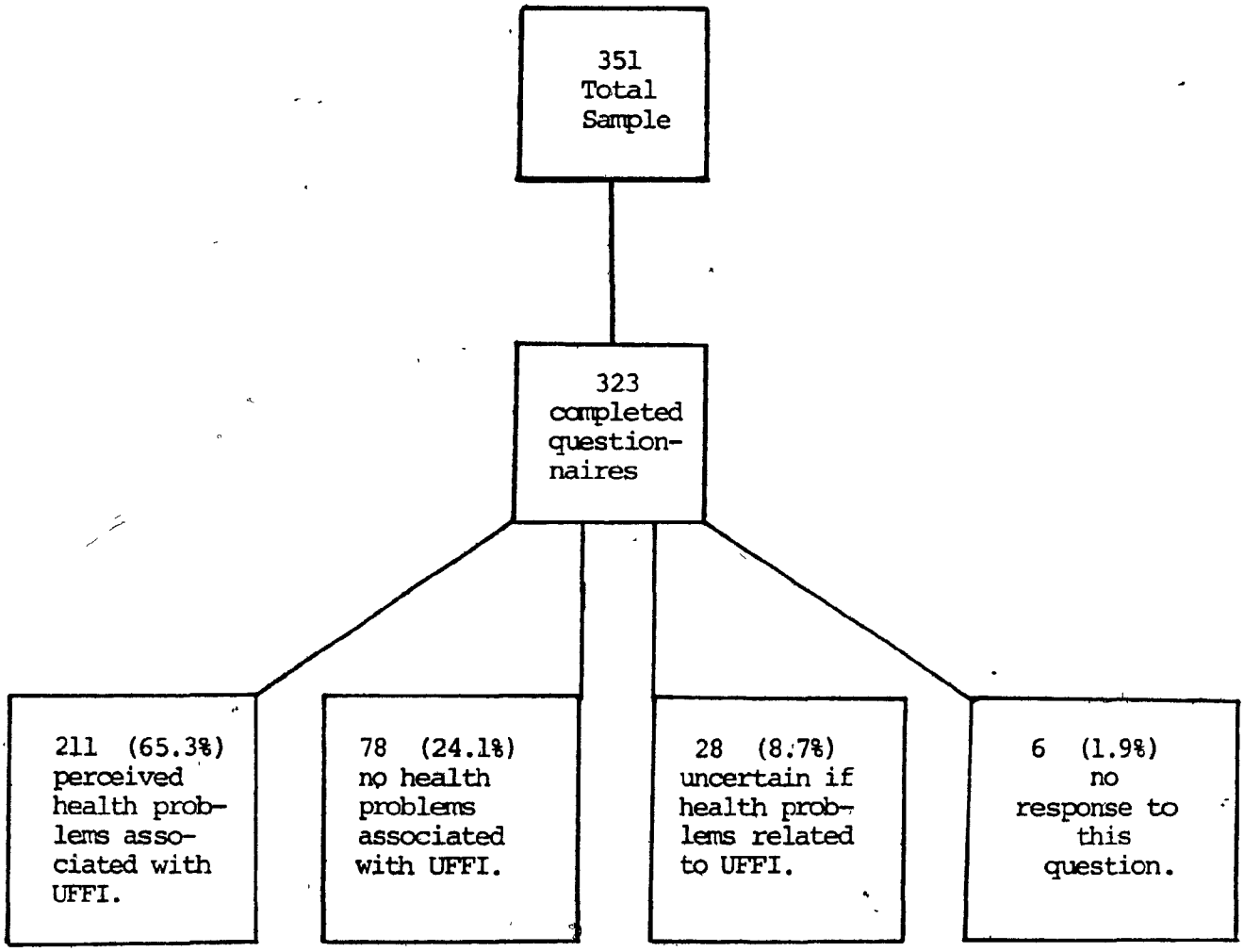
Si vous n'habitez plus la maison isolée à la MIUF, à quelle date êtes-vous déménagé?
Avez-vous fait des changements à votre maison après que la MIUF ait été installé?
Par exemple, avez-vous fait enlever la MIUF, gardé la MIUF, recouvert les murs et plafonds afin d'enrayer les émanations de la MIUF, ou autre _____?
Si vous avez fait des changements, à quelle date ont-ils été fait?

Figure 4.13:
Questionnaire response to reasons for moving



Question: If you moved, was the move because of UFFI? Yes or no.
Si vous êtes déménagé, est-ce à cause de la MIUF? Oui ou non.

Figure 4.14:
Questionnaire response to attribution of health problems



Question: Do you think that UFFI affected your health or the health of anyone in your family?

Croyez-vous que la MIUF ait affecté votre santé ou la santé d'un membre de votre famille?

Table 4.1:
Description of 337 residents included in the analysis, by age (10 year groups) and sex.

MALES			FEMALES	
# included in analysis	# chosen in sampling	Year of birth	# chosen in sampling	# included in analysis
16	20	1970-1979	20	21*
23	23	1960-1969	24	23
24	25	1950-1959	20	20
23	23	1940-1949	23	20
24*	22	1930-1939	22	21
23*	21	1920-1929	22	20
17	22	1910-1919	22	21
19	21	1900-1909	21	22*
169	177		174	168

Total # of residents chosen in systematic sampling = 351
Total # of residents excluded from analysis = 14
Total # of residents included in analysis = 337 (96%)

* increase in number in statum due to corrections of birth dates: errors on original sampling list.

Table 4.2:

Values of exposure variables for total sample (N=337)

VARIABLE	# of KNOWN VALUES (TOTAL for analysis: 337)	RANGE (yr)	MEAN (yr)
OCCUPANCY DATE	335	1922 1982	1970
DATE OF UFFI installation	323	1971 1980	1979
END-of-EXPOSURE date	311	1980 1984	1983

Table 4.3:

Values of exposure variables for males (N=169)

VARIABLE	# of KNOWN VALUES (TOTAL for analysis: 169)	RANGE (yr/m/d)	MEAN (yr/m/d)	STANDARD DEVIATION (yr/m/d)
OCCUPANCY DATE	167	1922/01/01 1982/05/01	1970/04/01	09/10/20
DATE of UFFI installation	163	1975/03/01 1980/12/11	1979/08/01	01/01/24
END-of-EXPOSURE DATE	153	1981/01/01 1984/03/01	1983/04/13	00/08/15

Table 4.4:

Values of exposure variables for females (N= 168)

VARIABLE	# of KNOWN VALUES (TOTAL for analysis: 168)	RANGE (yr/m/d)	MEAN (yr/m/d)	STANDARD DEVIATION (yr/m/d)
OCCUPANCY DATE	168	1934/01/01 1981/11/05	1970/09/28	09/00/22
DATE of UFFI installation	160	1971/06/01 1980/12/11	1979/06/04	01/04/11
END-of-EXPOSURE DATE	158	1980/06/01 1984/03/01	1983/04/11	00/09/28

Table 4.5:

Visits to a physician (1) by season and year, 1977-1983, and seasonal comparisons to previous year, total sample (N=337)

		Mean number of visits	Standard Deviation	Number
1977				
A		1.06	1.77	229
B		1.25	2.73	234
C		1.15	1.86	248
D		1.14	1.80	251
1978				
A		1.11	1.83	251
B		1.22	1.61	252
C		1.04	1.76	254
D		1.33	2.64	269
1979				
A		1.58**	2.18	271
B	Average date of	1.51*	2.05	277
C	UFFI installation	1.42**	2.16	281
D		1.58*	2.53	292
1980				
A		1.69	2.91	296
B		1.62	2.54	298
C		1.35	1.99	302
D	Date of banning: Dec. 18, 1980	1.58	2.41	315
1981				
A		1.70	2.60	316
B		1.55	2.19	317
C		1.40	2.44	322
D		1.43	2.21	322
1982				
A		1.65	2.33	321
B		1.36	1.86	317
C		1.19	1.88	296
D		1.69	3.42	263
1983				
A		1.45	2.32	247
B		1.52	2.48	238
C		1.11	1.99	158
D		1.14	2.68	104

A= January, February, March
B= April, May, June
C= July, August, September
D= October, November, December

(1) As defined by visits to a physician for any of the following services: consultations, exams, diagnostic acts, radiologic acts, psychiatric treatments, surgical acts, surgical assistance, aneasthesia-reanimation.

* $p \leq 0.05$
** $p \leq 0.01$
*** $p \leq 0.001$
} in comparison with same season in previous year only.

Table 4.6:

Visits to a physician (1) by season and year, 1977-1983, and seasonal comparisons to previous year, males (N=169)

		Mean number of visits	Standard Deviation	Number
1977				
	A	1.04	1.71	114
	B	1.32	2.46	116
	C	1.37	2.07	126
	D	1.13	1.61	127
1978				
	A	1.20	1.83	127
	B	1.16	1.78	127
	C	1.12	1.96	127
	D	1.21	1.66	136
1979				
	A	1.38	2.27	138
	B Average date of	1.61*	2.35	139
	C UFFI installation	1.64	2.58	139
	D	1.67**	2.30	144
1980				
	A	1.81	3.57	145
	B	1.60	2.31	146
	C	1.53	2.23	150
	D	1.65	2.60	156
1981				
	A	1.61	2.36	156
	B	1.37	1.92	158
	C	1.46	2.93	161
	D	1.39	2.22	166
1982				
	A	1.67	2.36	164
	B	1.36	1.84	163
	C	1.23	1.92	152
	D	1.55	3.86	134
1983				
	A	1.42	2.18	125
	B	1.48	2.60	121
	C	0.73	1.26	80
	D	0.79	1.54	52

A= January, February, March
B= April, May, June
C= July, August, September
D= October, November, December

(1) As defined by visits to a physician for any of the following services: consultations, exams, diagnostic acts, radiologic acts, psychiatric treatments, surgical acts, surgical assistance, aneasthesia-reanimation.

* $p \leq 0.05$
** $p \leq 0.01$
*** $p \leq 0.001$
} in comparison with same season in previous year only.

Table 4.7:

Visits to a physician (1) by season and year, 1977-1983, and seasonal comparisons to previous year, Females (N=168)

		Mean number of visits	Standard Deviation	Number
1977				
A		1.11	1.83	114
B		1.21	2.99	117
C		0.95	1.59	121
D		1.18	1.99	123
1978				
A		1.06	1.85	123
B		1.33	1.42	124
C		0 99	1.55	126
D		1 55	3.43	132
1979				
A		1.79**	2.06	132
B	Average date of	1.45	1.70	137
C	UFFI installation	2.24**	1.63	141
D		1.51	2.75	147
1980				
A		1.59	2.10	150
B		1.72	2.76	151
C		1.22	1.72	151
D		1.58	2.20	158
1981				
A		1.81	2.82	159
B		1.78	2.42	158
C		1.39	1.84	160
D		1.51	2.20	155
1982				
A		1.67	2.31	156
B		1.43	1.92	153
C		1.20	1.84	143
D		1.91	2.90	128
1983				
A		1.55	2.47	121
B		1.59	2.36	116
C		1.51	2.47	78
D		1.50	3.44	52

A= January, February, March
B= April, May, June
C= July, August, September
D= October, November, December

(1) As defined by visits to a physician for any of the following services: consultations, exams, diagnostic acts, radiologic acts, psychiatric treatments, surgical acts, surgical assistance, aneasthesia-reanimation.

* p ≤0.05
** p ≤0.01
*** p ≤0.001
} in comparison with same season in previous year only.

Table 4.8:

Visits to a physician (1) before and after date of UFFI installation, in 3 month intervals, seasonally compared.

Time interval (inclusive) 0 = date of UFFI installation	Comparison visits (post-pre)	Mean number of visits (S.D.)	Mean of self-paired differences in number of visits (S.D.)	Number
22-24 months before	E(pre)	0.93 (1.67)***	*	285
19-21 months before	F	0.94 (2.52)*		291
16-18 months before	G	1.10 (1.87)		293
13-15 months before	H	1.02 (1.73)**		298
10-12 months before	A(pre)	1.26 (2.80)		305
7-9 months before	B	1.44 (2.68)		309
4-6 months before	C	1.19 (1.88)		317
1-3 months before	D	1.28 (2.18)		333
1-3 months after	A(post)	1.28 (2.19)	0.07 (2.89)	337
4-6 months after	B	1.35 (2.07)	-0.03 (2.70)	337
7-9 months after	C	1.41 (2.27)	0.25 (2.38)	334
10-12 months after	D	1.35 (2.41)	0.09 (2.43)	334
13-15 months after	E(post)	1.46 (2.06)***	0.55 (2.14)***	333
16-18 months after	F	1.35 (2.06)*	0.37 (2.89)*	332
19-21 months after	G	1.36 (1.95)	0.26 (2.37)	329
22-24 months after	H	1.42 (2.05)**	0.39 (2.18)**	319

* $p \leq 0.05$
** $p \leq 0.01$
*** $p \leq 0.001$
} as compared with same months for corresponding comparison visits (post minus pre)

(1) As defined by visits to a physician for any of the following services: consultations, exams, diagnostic acts, radiologic acts, psychiatric treatments, surgical acts, surgical assistance, anesthesia-reanimation.

(S.D.) Standard deviation.

Table 4.9:

Visits to a physician (1) before and after date of UFFI installation in 3 month intervals, seasonally adjusted. Men (N=169)

Time interval (inclusive) 0= date of UFFI installation	Comparison visits (post-pre)	Mean number of services (S.D.)	Mean of self-paired differences in number of services (S.D.)	Number men
22-24 months before	E_{pre}	1.04 (1 73)**		143
19 21 months before	F	0 82 (1.72)*		147
16-18 months before	G	1 09 (1 81)		147
13-15 months before	H	1.08 (1.85)*		151
10-12 months before	A_{pre}	1 36 (3 45)		155
7-9 months before	B	1.34 (2.39)		157
4-6 months before	C	1 36 (2.14)		160
1-3 months before	D	1.37 (2.30)		167
1-3 months after	A_{post}	1.34 (2.38)	0.077 (3 50)	169
4-6 months after	B	1.46 (2 25)	0 210 (2 78)	169
7-9 months after	C	1 48 (2.25)	0 175 (2 28)	168
10-12 months after	D	1.49 (2 84)	0 139 (2 50)	168
13-15 months after	E_{post}	1.55 (2.20)**	0 573 (2 38)	168
16-18 months after	F	1 36 (2 20)*	0 408 (2 22)	168
19-21 months after	G	1.33 (1 89)	0 240 (2 40)	166
22-24 months after	H	1.51 (2 20)*	0 459 (2 41)	160

* p≤ 0 05
** p≤ 0 01
*** p≤ 0 001

(1) As defined by visits to a physician for any of the following services. consultations, exams, diagnostic acts, radiologic acts, psychiatric treatments, surgical acts, surgical assistance, aneasthesia-reanimation
(S D) Standard deviation

Table 4.10:

Visits to a physician (1) before and after date of UFFI installation in 3 month intervals, seasonally adjusted Women (N=168)

Time interval (inclusive) 0= date of UFFI installation	Comparison visits (post-pre)	Mean number of visits (S D.)	Mean of self-paired differences in number of visits (S D)	Number women
22-24 months before	E_{pre}	0 89 (1 64) **		142
19 21 months before	F	1 15 (3 17)		144
16-18 months before	G	1 14 (1 93)		146
13-15 months before	H	1 00 (1.64)*		147
10-12 months before	A_{pre}	1 22 (1 92)		150
7-9 months before	B	1 55 (2 96)		152
4-6 months before	C	1.01 (1.56)		157
1-3 months before	D	1.23 (2 08)		166
1-3 months after	A_{post}	1 25 (1.97)	0 027 (2 13)	168
4-6 months after	B	1.30 (1.89)	-0 224 (2 62)	168
7-9 months after	C	1.34 (2 29)	0 327 (2 47)	166
10-12 months after	D	1 23 (1 89)	0 037 (2 39)	166
13-15 months after	E_{post}	1.36 (1 86)**	0 479 (1 96)	165
16-18 months after	F	1.38 (1 94)	0 275 (3 45)	164
19-21 months after	G	1.44 (2 02)	0.294 (2 43)	163
22-24 months after	H	1 44 (1 96)*	0 379 (1 95)	159

* $p \leq 0.05$
** $p \leq 0.01$
*** $p \leq 0.001$

(1) As defined by visits to a physician for any of the following services consultations, exams, diagnostic acts, radiologic acts, psychiatric treatments, surgical acts, surgical assistance, aneasthesia-reanimation.
(S D) Standard deviation

Table 4.11:

Visits to a physician (1) before and after date of UFFI installation, seasonally compared in 3 month intervals to limit of one year pre-exposure (N=337)

Time interval (inclusive) 0= date of UFFI installation	Comparison visits (post-pre)	Mean number of visits (S.D.)	Mean of self-paired differences in number of visits (S.D.)	Number
10-12 months before	A(pre)	1.26 (2.80)		305
7-9 months before	B	1.44 (2.68)		309
4-6 months before	C	1.19 (1.88)		317
1-3 months before	D	1.28 (2.18)		333
1-3 months after	A(post)	1.28 (2.19)	0.07 (2.89)	337
4-6 months after	B	1.35 (2.07)	-0.03 (2.70)	337
7-9 months after	C	1.41 (2.27)	0.25 (2.38)	334
10-12 months after	D	1.35 (2.41)	0.09 (2.43)	334
13-15 months after	E(post)	1.46 (2.06)	0.24 (3.03)	333
16-18 months after	F	1.35 (2.06)	-0.09 (2.95)	332
19-21 months after	G	1.36 (1.95)	0.19 (2.22)	329
22-24 months after	H	1.42 (2.05)	0.13 (2.48)	319

(1) As defined by visits to a physician for any of the following services: consultations, exams, diagnostic acts, radiologic acts, psychiatric treatments, surgical acts, surgical assistance, anesthesia-reanimation.

(S.D.) Standard deviation.

Table 4.12:
Visits to a physician (1) before and after date of UFFI installation, seasonally compared to one year pre exposure. Males (N=169)

Time interval (inclusive) 0= date of UFFI installation	Comparison visits (post-pre)	Mean number of visits (S.D.)	Mean of self-paired differences in number of visits (S.D.)	Number
10-12 months before	A_{pre}	1.36 (3.45)		155
7-9 months before	B	1.34 (2.39)		157
4-6 months before	C	1.36 (2.14)		160
1-3 months before	D	1.37 (2.30)		167
1-3 months after	A_{post}	1.34 (2.38)	0.077 (3.50)	169
4-6 months after	B	1.46 (2.25)	0.210 (2.78)	169
7-9 months after	C	1.48 (2.25)	0.175 (2.28)	168
10-12 months after	D	1.49 (2.84)	0.139 (2.50)	168
13-15 months after	E_{post}	1.55 (2.20)	0.239 (3.67)	168
16-18 months after	F	1.36 (2.20)	0.0191 (2.60)	166
19-21 months after	G	1.33 (1.89)	0.00 (2.30)	166
22-24 months after	H	1.51 (2.20)	0.108 (2.39)	160

(1) As defined by visits to a physician for any of the following services: consultations, exams, diagnostic acts radiologic acts, psychiatric treatments, surgical acts, surgical assistance, aneasthesia-reanimation.

(S.D.) Standard deviation

Table 4.13:

Visits to a physician (1) before and after date of UFFI installation, seasonally compared to one year pre exposure. Females (N=168)

Time interval (inclusive) 0= date of UFFI installation	Comparison visits (post-pre)	Mean number of visits (S.D.)	Mean of self-paired differences in number of visits (S.D.)	Number
10-12 months before	A_{pre}	1.22 (1.92)		150
7-9 months before	B	1.55 (2.96)		152
4-6 months before	C	1.01 (1.56)*		157
1-3 months before	D	1.23 (2.08)		166
1-3 months after	A_{post}	1.25 (1.97)	0.027 (2.13)	168
4-6 months after	B	1.30 (1.89)	-0.224 (2.62)	168
7-9 months after	C	1.34 (2.29)	0.327 (2.47)	166
10-12 months after	D	1.23 (1.89)	0.037 (2.39)	166
13-15 months after	E_{post}	1.36 (1.86)	0.196 (2.18)	165
16-18 months after	F	1.38 (1.94)	-0.187 (3.32)	164
19-21 months after	G	1.44 (2.02)*	0.422 (2.11)*	163
22-24 months after	H	1.44 (1.96)	0.217 (2.66)	159

* $p \leq 0.05$: in comparison with same months in year before exposure

(1) As defined by visits to a physician for any of the following services: consultations, exams, diagnostic acts radiologic acts, psychiatric treatments, surgical acts, surgical assistance, aneasthesia-reanimation.

(S.D.) Standard deviation

Table 4.14:

Change in the number of medical services by male inhabitants, (according to age). 1977-1982. Québec.

	AGE GROUP (years)									
YEARS	under 5	5-14	15-24	25-34	35-44	45-54	55-64	65 and over	Total	Mean Δ
Δ 1977-78	.24	.13	.13	.17	.15	.23	.32	.68	2.05	.256
Δ 1978-79	-.05	.20	.15	.01	.03	-.03	-.09	.69	0.91	.114
Δ 1979-80	.36	.15	.17	.19	.22	.32	.60	1.43	3.44	.430
Δ 1980-81	-.51	-.06	-.06	-.06	-.10	-.14	-.09	-.60	-1.62	-.203
Δ 1981-82	.24	-.34	-.04	-.14	-.04	-.09	-.06	.08	-0.39	-.049
Δ 1977-82	.28	.08	.34	.16	.26	.30	.67	2.37	4.46	.558

Source: Statistiques annuelles 1977, RAMQ, pp. 17 and 48.
Statistiques annuelles 1978, RAMQ, pp. 19 and 55.
Statistiques annuelles 1979, RAMQ, pp. 31 and 81
Statistiques annuelles 1980, RAMQ, pp. 31 and 75
Statistiques annuelles 1981, RAMQ, pp. 33 and 84
Statistiques annuelles 1982, RAMQ, pp. 30 and 86

Table 4.15:

Change in the number of medical services by Female inhabitants, (according to age). 1977-1982. Québec.

YEARS	AGE GROUP (years) under 5	5-14	15-24	25-34	35-44	45-54	55-64	65 and over	Total	Mean Δ
Δ 1977-78	.20	.14	.21	.29	.23	.45	.35	.73	2.60	.325
Δ 1978-79	.13	.38	.21	.25	.07	-.15	-.07	.39	1.21	.151
Δ 1979-80	.36	.21	.31	.31	.36	.44	.54	.94	3.47	.434
Δ 1980-81	-.51	-.01	.02	-.16	-.12	-.08	-.06	-.14	-1.06	-.133
Δ 1981-82	.17	-.03	-.06	-.34	-.13	00	.02	-.02	-0.39	-.049
Δ 1977-82	.35	.71	.68	.36	.44	.66	.78	1.90	5.88	.735

Source: Statistiques annuelles 1977, RAMQ, pp. 17 and 48.
Statistiques annuelles 1978, RAMQ, pp. 19 and 55.
Statistiques annuelles 1979, RAMQ, pp. 31 and 81
Statistiques annuelles 1980, RAMQ, pp. 31 and 75
Statistiques annuelles 1981, RAMQ, pp. 33 and 84
Statistiques annuelles 1982, RAMQ, pp. 30 and 86

Table 4.16:

Approximate* number of visits per resident per year 1977-1981 for Quebec

1977	1978	1979	1980	1981	Δ1977-81
4.30	4.50	4.65	4.90	4.85	0.55

* number of medical services / $\frac{(1.4 + 1.7)}{2}$ = approximate number of visits

Source: Statistiques annuelles 1981, RAMQ, p. 57

Table 4.17:

Visits to a physician by season and year, and change in visits by year, 1977-1982.

		Mean number of visits (1)	
1977			
	A	1.06	
	B	1.25	
	C	1.15	
	D	1.14	
		4.60	
1978			
	A	1.11	
	B	1.22	
	C	1.04	
	D	1.33	
	Total	4.70	Δ1977-78 = 0.10
1979			
	A	1.58**	
	B Average date of	1.51*	
	C UFFI installation	1.42**	
	D	1.58*	
	Total	6.09	Δ1978-79 = 1.39
1980			
	A	1.69	
	B	1.62	
	C	1.35	
	D	1.58	
	Total	6.24	Δ1979-80 = 0.15
1981			
	A	1.70	
	B	1.55	
	C	1.40	
	D	1.43	
	Total	6.08	Δ1980-81 = 0.16
1982			
	A	1.65	
	B	1.36	
	C	1.19	
	D	1.69	
	Total	5.89	Δ1981-82 = -0.19

A = January, February, March
B = April, May, June
C = July, August, September
D = October, November, December

(1) As defined by visits to a physician for any of the following services: consultations, exams, diagnostic acts, radiologic acts, psychiatric treatments, surgical acts, surgical assistance, anesthesia-reanimation.

* $p \leq 0.05$
** $p \leq 0.01$
} in comparison with same months

Table 4.18:

Visits to a physician (1) by season and year, 1977-1983, and seasonal comparisons to previous year (N=337)

		Mean number of visits	Standard Deviation	Number
1977				
A		1.06	1.77	229
B		1.25	2.73	234
C		1.15	1.86	248
D		1.14	1.80	251
1978				
A		1.11	1.83	251
B		1.22	1.61	252
C		1.04	1.76	254
D		1.33	2.64	269
1979				
A		1.58**	2.18	271
B	Average date of	1.51*	2.05	277
C	UFFI installation	1.42**	2.16	281
D		1.58*	2.53	292
1980				
A		1.69	2.91	296
B		1.62	2.54	298
C		1.35	1.99	302
D	Date of banning: Dec. 18, 1980	1.58	2.41	315
1981				
A		1.70	2.60	316
B		1.55	2.19	317
C		1.40	2.44	322
D		1.43	2.21	322
1982				
A		1.65	2.33	321
B		1.36	1.86	317
C		1.19	1.88	296
D		1.69	3.42	263
1983				
A		1.45	2.32	247
B		1.52	2.48	238
C		1.11	1.99	158
D		1.14	2.68	104

A= January, February, March
B= April, May, June
C= July, August, September
D= October, November, December

(1) As defined by visits to a physician for any of the following services: consultations, exams, diagnostic acts, radiologic acts, psychiatric treatments, surgical acts, surgical assistance, aneasthesia-reanimation.

* p ≤0.05
** p ≤0.01
*** p ≤0.001
} in comparison with same season in previous year only.

Table 4.19:

Visits to a physician (1) by season and year, 1977-1983, and seasonal comparisons to previous year, males (N=169)

		Mean number of visits	Standard Deviation	Number
1977				
	A	1.04	1.71	114
	B	1.32	2.46	116
	C	1.37	2.07	126
	D	1.13	1.61	127
1978				
	A	1.20	1.83	127
	B	1.16	1.78	127
	C	1.12	1.96	127
	D	1.21	1.66	136
1979				
	A	1.38	2.27	138
	B Average date of	1.61*	2.35	139
	C UFFI installation	1.64	2.58	139
	D	1.67**	2.30	144
1980				
	A	1.81	3.57	145
	B	1.60	2.31	146
	C	1.53	2.23	150
	D Date of banning: Dec. 18, 1980	1.65	2.60	156
1981				
	A	1.61	2.36	156
	B	1.37	1.92	158
	C	1.46	2.93	161
	D	1.39	2.22	166
1982				
	A	1.67	2.36	164
	B	1.36	1.84	163
	C	1.23	1.92	152
	D	1.55	3.86	134
1983				
	A	1.42	2.18	125
	B	1.48	2.60	121
	C	0.73	1.26	80
	D	0.79	1.54	52

A= January, February, March
B= April, May, June
C= July, August, September
D= October, November, December

(1) As defined by visits to a physician for any of the following services: consultations, exams, diagnostic acts, radiologic acts, psychiatric treatments, surgical acts, surgical assistance, aneasthesia-reanimation.

* $p \leq 0.05$
** $p \leq 0.01$
*** $p \leq 0.001$
} in comparison with same season in previous year only.

Table 4.20:

Visits to a physician (1) by season and year, 1977-1983, and seasonal comparisons to previous year, Females (N=168)

		Mean number of visits	Standard Deviation	Number
1977				
A		1.11	1.83	114
B		1.21	2.99	117
C		0.95	1.59	121
D		1.18	1.99	123
1978				
A		1.06	1.85	123
B		1.33	1.42	124
C		0.99	1.55	126
D		1.55	3.43	132
1979				
A		1.79**	2.06	132
B	Average date of	1.45	1.70	137
C	UFFI installation	2.24*	1.63	141
D		1.51	2.75	147
1980				
A		1.59	2.10	150
B		1.72	2.76	151
C		1.22	1.72	151
D	Date of banning: Dec. 18, 1980	1.58	2.20	158
1981				
A		1.81	2.82	159
B		1.78	2.42	158
C		1.39	1.84	160
D		1.51	2.20	155
1982				
A		1.67	2.31	156
B		1.43	1.92	153
C		1.20	1.84	143
D		1.91	2.90	128
1983				
A		1.55	2.47	121
B		1.59	2.36	116
C		1.51	2.47	78
D		1.50	3.44	52

A= January, February, March
B= April, May, June
C= July, August, September
D= October, November, December

(1) As defined by visits to a physician for any of the following services: consultations, exams, diagnostic acts, radiologic acts, psychiatric treatments, surgical acts, surgical assistance, aneasthesia-reanimation.

* p ≤0.05
** p ≤0.01
*** p ≤0.001
} in comparison with same season in previous year only.

CHAPTER FIVE

DISCUSSION

In this chapter, results are reviewed while discussing methodological issues such as the validity of the medical care data base and possible bias issues. Also discussed are the usefulness of medical care data bases, the potential for the time series design in investigating environmental hazards, and some implications of the results.

This study showed an increase in utilization of medical services following the average date of UFFI installation. with no further analysis, if an inference was drawn of an association between exposure to UFFI and increased use of medical services, the investigator would have fallen into the trap of an ecological fallacy. The apparent correlation between variables at the total sample level was not reproduced between variables at the individual level, based on each resident's exposure and response periods. Analysis using individual exposure times showed that the pattern of utilization of medical services before and after exposure to UFFI remained virtually stable. No statistically significant increases or decreases were apparent in visits to a physician for males or females within the first year following UFFI exposure, seasonally compared. The reason why there is an increase in medical services over time from 1978 to 1979 and not from any other year to the next remains open to speculation. For the general population of Quebec, a similar increase is seen from 1979 to 1980, and not from 1978 to 1979.

The banning of UFFI on December 18, 1980 also had no apparent effect on utilization of medical services, as might be expected if utilization patterns of the exposed population were influenced by media coverage and governmental action. A National Cancer Institute survey revealed that "most frequently reported sources of information about cancer were magazines, newspapers, and television" (6). This is probably also true for sources of acute health effect information. Studies done following the Three Mile Island crisis revealed slight increases in utilization rates during the year following the crisis (2). These increases were attributed to distress and not to any measurable physical health impact. At Three Mile Island, people who were upset during the crisis tended to be high utilizers both before and after the crisis. In the present study, although the majority of residents perceived health problems which they attributed to UFFI, they either did so in retrospect, or these perceptions did not lead to an increase in utilization of medical services. Also, for many people who applied to the assistance program, the motivation may have been financial since almost 25% of this sample said that they did not attribute any health effects to UFFI.

In analyzing the possibility of a type II error, upper limits of 95% confidence intervals were not judged as significant, from a clinical or public health point of view. However, the sensitivity of the analysis would have been improved by looking at office visits while excluding hospital visits, and by an analysis of the frequency of diagnoses for this sample, before and after exposure, if adequate diagnostic records had existed.

One unique aspect of this study was the use of a health care data bank, allowing for assessment of utilization of medical care before and after a known environmental exposure. This represents an improvement over published studies where health effects were measured invariably through retrospective self-reported symptoms. The use of the medical care data base eliminated any possible bias in subjects' reporting behavior and provided investigators with a more objective health measure. However, it is possible that these records may themselves have their own biases, and the issues of reliability and validity must be addressed. The Regie publishes annual reports, but they do not deal extensively with these issues. No independent studies were found on Quebec's system, and since checks of the validity and reliability of Regie records were beyond the scope of this project, evidence was sought from similar pre-paid health insurance plans. Some excellent research on the Manitoba Health Services Commission data bank, a similar system to the Regie's, has shown that the fee-for-service administrative scheme provides valid data on total patient-physician contact (3,4). Similar research on

Quebec's medicare system is needed.

Several advantages are apparent when using a health care data base. The flexibility of the records permits the investigation of outcome measures which vary in time for each study subject, a design which may not be possible without the use of a data base. Benefits are also derived from the ability to look at relatively long periods of follow-up, the wide range of applicability of utilization data including for cost analysis, and from the availability of population based health care information. Other important utilization concepts, such as an "episode of illness" (5), are more easily approached in a data base than from private medical records for example. There is a need to explore the possibilities for longitudinal research implicit in data base information.

Selection bias in the context of this study becomes a problem when attempting to generalize the results to the entire population of Montreal residents who were exposed to UFFI in their homes. Among those excluded from our sample were residents who ended their exposure (by whatever means) before the assistance program was offered. It is possible that these residents were a more severly affected group, and that their utilization of medical services may have increased following exposure. Use of a random sample of all exposed residents would have answered this question, but this sample proved impossible to obtain. Excepting this group, we would expect that our results of no evidence of a short term effect of public health significance would apply to the majority of Montrealers exposed

to UFFI. However, as with previous studies, it is impossible to estimate the incidence or prevelance of health problems among the entire population exposed to UFFI. If this question is deemed relevant, more studies with large sample sizes and objective health outcomes are needed to verify these findings.

One final issue warrants discussion, and that is the design of this study. Time series comparisons of the incidence of visits to a physician characterize this design as a longitudinal cohort study. The literature review of UFFI suggested that an acute health effect would be apparent within weeks of initial exposure. For this type of design, statistical inferences of attributing an effect to a particular exposure are most convincing during the period directly following the exposure. A graph in Campbell and Stanley (1) shows the strength of association which can be inferred between exposure "x" and various patterns of response using this type of study design (figure 5.1). Also, the fact that exposure periods differed for each resident obviate the main threat to the internal validity of this study. That is, if an effect of exposure was apparent, a causal inference rests on the exclusion of coincident exposures and all alternative hypotheses external to the study design which may account for the apparent health effect. Through comparison of pre and post exposure periods that vary in calendar time between study subjects, an apparent effect could be more strongly attributed to the particular exposure being investigated. In the case of our study, outcome was measured independently of any changes in exposure, which helped to strengthen design and

inferences.

The strengthening of the time series design brings me to the more general contention that this uncommonly used design with time series comparisons is particularly suited to the investigation of newly introduced environmental agents. This design has been used extensively in the social sciences, and more recently in looking at utilization rates before and after hysterectomy. Cursory discussion of this design is found in educational research texts such as in Campbell and Stanley (1), but it is not well recognized for epidemiologic research. Among its attributes are that it is relatively simple, inexpensive, and quickly conducted. Exposure periods may not always be known and may not vary for study subjects, but there are other as yet unexplored ways to improve this design. The ideal study of this type would compare a random sample of exposed and unexposed groups drawn from a population type registry. The ever increasing array of environmental contaminants both inside and outside the home presents epidemiology with the challenge of improving the design and analysis of time series studies, and adding it to the roster of research design possibilities.

An important responsibility of the epidemiologist is to realize that research may have political or regulatory implications. One political question which remains to be answered is that of recommending, in the light of these results, if the ban on UFFI should be maintained or rescinded. It is the opinion of this investigator (only) that the ban on use of UFFI

in Canada should continue until the time when strict regulations for its proper use can be enforced at the provincial level. Possible regulations could include registration of installers, conditions of UFFI application, and prohibiting the use of UFFI in inner wall cavities and in wood frame buildings. In fact, many other home insulation products of high quality and relatively low cost are readily available. Although any short term health effects seem negligable, long term effects are not known, and interactions with other chemicals may be important especially in "tight" homes and offices which are sealed for supposed energy conservation. Uncertainty is everpresent as a condition under which regulatory bodies must make decisions; and, if an error is to be made, it should be made on the side of caution.

To summarize, we can conclude that utilization of medical services was apparently not influenced by exposure to UFFI, or to the banning of UFFI, for this group of Montreal residents of UFFI homes. It is clear, however, that the majority of residents, at least in retrospect, associate some health problems with their exposure to UFFI. These reported health problems are not reflected in visits to a physician, and we can only speculate from a public health point of view that perhaps the alleged problems are not serious enough to warrant the utilization of medical services. Since obtaining a sample of all Montreal residents exposed to UFFI was not possible, inference to this population must be made with caution.

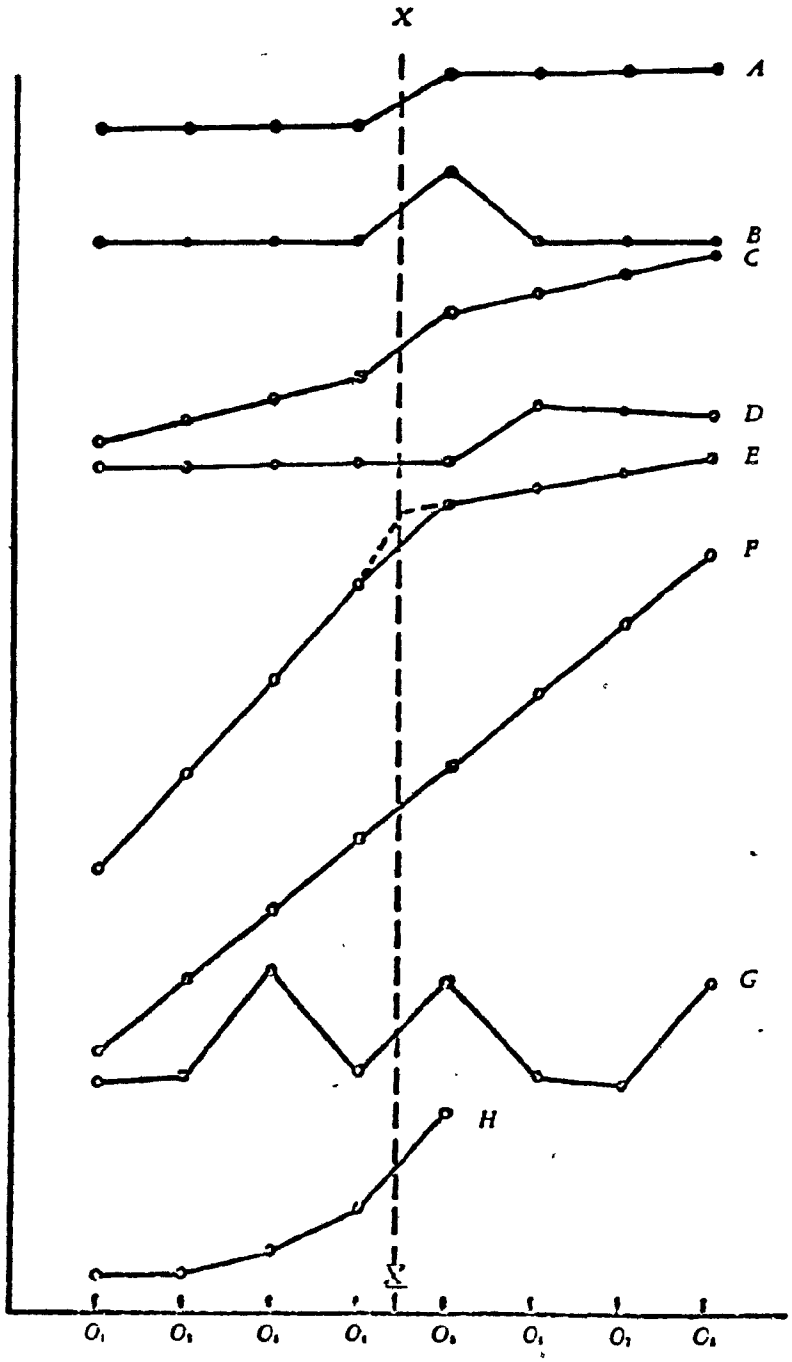


Figure 5.1:
Some Possible Outcome Patterns from the Introduction of an Experimental Variable at Point X into a Time Series of Measurements, O_1–O_3. Except for D, the O_4–O_5 gain is the same for all time series, while the legitimacy of inferring an effect varies widely, being strongest in A and B, and totally unjustified in F, G, and H.

Source: Campbell, DT and Stanley, JC (1963). Experimental and Quasi-Experimental Designs for Research. Chicago: Rand McNally and Co., p.38.

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Appendix 1

ENVIRONMENTAL RESEARCH 35, 246–263 (1984)

Review of the Health Effects of Urea–Formaldehyde Foam Insulation

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INTRODUCTION

Much controversy exists over the health effects of urea–formaldehyde foam insulation (UFFI),[2] and in many instances, the information reaching the public has very little scientific basis. The extent to which symptoms felt in the home can be attributed to the presence of UFFI is a major point of contention. Several investigators have suggested that formaldehyde emanation from UFFI and, consequently, formaldehyde concentrations in the air of dwellings may be the main cause of the alleged health problems. Some studies indicate, however, that formaldehyde may not be responsible, and that other presently unknown ingredients or some undefined interactions of chemicals in the home may be the cause of these putative health effects. A review of the pertinent literature will serve to dispel misinformation and to establish a framework for future research.

Epidemiologic studies give the most direct evidence of the potentially detrimental health effects of UFFI, and several studies have now been conducted. Indirect evidence can be provided by epidemiologic studies on occupational exposure to urea–formaldehyde and formaldehyde-containing manufacturing processes. Laboratory studies on the toxicity, mutagenicity, and potential carcinogenicity of urea–formaldehyde and related products provide further essential indirect evidence for human health effects. Although epidemiologic investigations are more likely than laboratory studies to reflect the complexity of real life situations, such as the interactions of variables in the home environment, several

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[2] Abbreviations used: UFFI, urea–formaldehyde foam insulation; CHIP, Canadian Home Insulation Program; FEV_1, 1-sec forced expiratory volume; FVC, forced vital capacity; SMR, standard mortality ratio; BCME, bis(chloromethyl) ether; DEN, diethylnitrosamine.

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studies of both types are necessary to arrive at definitive statements on the health effects of UFFI.

UFFI PROPERTIES

UFFI is made from a resin of water, urea, and formaldehyde which is mixed on site of installation with an acid catalyst and a propellant, usually compressed air, to form a foam which is pumped into residential and commercial buildings through small holes (18, 35) The exact formulation of UFFI can differ between commercial products since many different chemicals can be used as catalysts, deodorizers, and fire-retardants (54). Desirable because of its resistance to heat loss (high R value) and the low cost of formaldehyde, UFFI has been extensively applied in northern Europe and North America, with an acceleration in use corresponding to the worldwide "energy crisis" of the mid-1970s Estimates of the number of homes insulated with UFFI are 500,000 in the United States and 100,000 in Canada.

Questions of the extent of possible toxicity of UFFI have been raised as a public health issue, with the notion that gaseous formaldehyde emanation from UFFI was causing health problems Even under ideal conditions, small amounts of formaldehyde emanate from UFFI in the hardening (curing) process which usually lasts about a week after installation The concentration and duration depend on several factors, including the quality of the installation process, the quality and age of the foam ingredients and building construction materials, and the air temperature and relative humidity at the time during and after installation (2, 12, 35). In conventional homes where formaldehyde is detected, UFFI is probably the primary source, whereas in mobile homes and in many new conventional homes, the extensive use of particle board contributes most to these concentrations (14–16) Of the estimated 3 billion kilograms of formaldehyde produced in the United States in 1978 (76), half was used in synthetic resin production (57). These urea–formaldehyde, phenol–formaldehyde, and acetal resins are used primarily as adhesives in plywood and particle board Other commercial products containing minimal amounts of formaldehyde include permanent press clothing, paper products, shampoos, cosmetics, cigarettes, some medications, and fuels (11, 23, 77).

Although formaldehyde exposure is ubiquitous, additional concern over potential health hazards has arisen because of the widespread use of UFFI for home insulation. If formaldehyde or other as yet unidentified agents resulting from UFFI are health hazards then many people will be affected

UFFI CURRENT STATUS

Recommendations for the reduction in the occupational standard for formaldehyde exposure from 10 to 1 ppm in any 30-min sampling period were made in the United States in 1976, based on the irritant effects of formaldehyde (57) Following preliminary reports during the 16th month of a 24-month study on formaldehyde-exposed rats which revealed carcinogenic potential (17), UFFI as a source of formaldehyde was implicated and temporarily banned on December 17, 1980 in Canada (36). Following extensive review of UFFI, the ban was ex-

tended in October, 1982 (65). On January 13, 1981, the U.S. Consumer Product Safety Commission issued a prospective ban where enactment was under state jurisdiction (20).[1] Consumer aid was established, such as the "UFFI Information and Coordination Centre" in Ottawa, and remedial measures for the reduction of formaldehyde concentrations in the home were suggested (75). In Canada and the United States several local and federal government bodies undertook formaldehyde measurements in homes of concerned occupants.

This review begins with a description of the method of measurement of formaldehyde concentrations and the results of available household surveys. Subsequently, the putative health effects of formaldehyde and UFFI are reviewed with attention given to study methodology Lastly, we discuss the potential mutagenicity, carcinogenicity, and teratogenicity of formaldehyde and UFFI Throughout, we concentrate on the health effects of UFFI and refer the reader to the extensive literature available on formaldehyde

MEASUREMENTS

Formaldehyde concentrations in the air are usually measured by the chromotropic acid method, or a modification of this method, which uses impingers for formaldehyde absorption from a known volume of air (57) This method produces repeated measurement levels within ±5% at 0 8 formaldehyde in air (3), and has a detection limit of about 0.01 ppm (64) House preparation which controls for variations in emanation of formaldehyde, ventilation, temperature, and humidity has been utilized for improved precision in measurement (3, 66)

Two surveys using the chromotropic acid method give an indication of levels of formaldehyde in dwellings. Concentrations of 0 064 to 1.8 ppm, with an average of 0 5 ppm, were measured in 23 dwellings in Denmark, where particle board with urea–formaldehyde glue was the major source of emanation (3) In Finland, 186 measurements in 65 dwellings were recorded, with an arithmetic mean of 0 29 ppm, and a range of 0 01–0.93 ppm. main sources were particle board in 61 homes, UFFI in 3 homes, and glue in the wall panel of 1 home (58) These levels can be compared to reported atmospheric levels ranging from <0 005 ppm to 0.06 ppm, the latter near industrial sites and in heavy smog (11).

In the largest study to date, indoor and ambient formaldehyde concentrations were measured in and adjacent to 2400 homes in Canada (66) The survey involved 100 houses selected from among those whose occupants complained of serious health effects to the federal UFFI Information Coordination Centre (66, 81). From this source and from provincial records, an additional 700 homes insulated with UFFI were selected. Lastly, from Canadian Home Insulation Program (CHIP) files, two groups were selected: 1200 homes insulated with UFFI, and 400 with other types of insulation, the latter group comprising the "control" homes used for comparison. Measurements made in 125 homes were judged to be of poor quality, and these homes were excluded from the analysis. Table 1 shows the results of this survey and summarizes formaldehyde concentrations reported in other studies

In the Canadian survey, concentrations of formaldehyde were slightly lower in control homes than in homes with UFFI, and highest levels were found in homes

[1] See Notes Added in Proof, No 1.

TABLE 1
FORMALDEHYDE CONCENTRATIONS IN HOMES

		Concentration of formaldehyde (ppm)				
		No of dwellings	Arithmetic $\bar{X}$	$\bar{X}$ of maximum of readings	Range	Reference no
UFFI						
Residents "complained"	Canada	100	0 139	0 174	<0.01 – >0.2[c]	66, 81
	Washington	39	—[b]	—[b]	<0.1 – ≧1.0	14–16
Residents did not "complain"						
UFFI information & provincial records	Canada	651	0 04	0 048	<0 01 – >0.2[c]	66
CHIP[a] files	Canada	1146	0 054	0.067	<0 01 – >0.2[c]	66
No UFFI						
CHIP files	Canada	378	0 034	0.042	<0.01 – 0.2	66
Other						
Particle board	Denmark	23	0.5	—[b]	0.064 – 1.8	3
Mainly particle board	Finland	65	0 29	—[b]	0 01 – 0 93	58
Residents "complained" (mainly mobile homes)	Minnesota	—[b]	[b]	—[b]	0.24 – 1 0 (mean values range)	29
Residents "complained" (mobile homes)	Washington	334	[b]	—[b]	0.03 – 1 77	14–16

[a] CHIP Canadian Hôme Insulation Program
[b] Not reported.
[c] Values below 0.01 could not be determined and the upper limit of the range was reported only as >0.2.

of residents who complained Age of UFFI (time since installation) in these homes is assumed to be at least 1 year, and formaldehyde concentrations were probably highest directly after installation Age of home, also negatively correlated with formaldehyde concentrations, was not reported

The use of a consistent measurement technique, house preparation, quality control, and a group of measurements for comparison taken in homes without UFFI minimize potential bias However, the method of house selection was not random, reasons for exclusions were unclear, the technicians taking the measurements were not blinded to the type of insulation, and the report does not include results of statistical tests for an indication of the significance of the mean differences The issue of health effects of UFFI was not addressed in this study

FORMALDEHYDE EFFECTS ON SKIN, MUCOUS MEMBRANES, AND AIRWAYS

It is clear that acute exposure to high concentrations of formaldehyde, for example 14 ppm (71), results in mucous membrane irritation of the eyes and upper respiratory tract. Odor from formaldehyde can be detected by most people at or below 1 pm (13), and the lowest detectable odor has been reported at 0.04 ppm (60) Studies relating to exposures above 1 ppm have been summarized and reviewed (42) We here review studies of the irritation, tolerance, and sensitization following exposure to low concentrations of formaldehyde Evidence related to carcinogenicity, mutagenicity, and teratogenicity is reviewed in a later section

Laboratory Studies

The mechanism by which airborne formaldehyde causes irritation may be similar to that of sulfur dioxide which stimulates bronchial irritant receptors (19) Other mechanisms, such as an immunological reaction, have also been postulated (9, 48). Mechanical stimulation of nerve endings by formaldehyde has been reported in animal studies, it is difficult to know, however, if this is a result of direct stimulation by formaldehyde, or the result of interactions with other irritants in the environment, such as ozone or amyl alcohol

Repeated exposures of small groups of mice to formaldehyde caused reactions in the upper respiratory tract (42) A linear dose–response relation was shown between the logarithm of the concentration of formaldehyde and the net decrease in respiratory frequency, the latter being a characteristic measure of sensory irritation When mice inhaled formaldehyde, maximal response was reached within a few minutes, and after this, short-term tolerance to exposures below 1 ppm developed This accomodation was lost, however, after a 1- to 2-hr interruption of exposure. The minimal detectable irritant effect occurred around 0 5 ppm of formaldehyde, and repeated exposures produced no pathologic effect Through quantitative models, the authors relate these results from animals to humans and suggest that the threshold limit value for occupational formaldehyde exposure should be reduced to 0.1–0.3 ppm. The then current level of 3 ppm in 8 hr had been established following observations on a working population who may have developed tolerance to the irritant effects of formaldehyde exposure

Controlled Human Studies

Studies on the irritating effects of low concentrations of formaldehyde have shown that onset and severity of irritation to the eyes and nose were a function of formaldehyde concentration and continuity of exposure. Eye, nose, and throat irritation was found to be directly proportional to formaldehyde concentrations (10, 79). In one study, although continuous exposure was more irritating to the eyes than discontinuous exposure, the opposite was true for nose irritation (79). During a 5-hr exposure to formaldehyde concentrations of 0.24 ppm, irritation was reported by 3 of 16 subjects (4). As concentrations increased to 1.6 ppm, number of subjects affected likewise increased, but 6 of 16 subjects had no complaints. For all 16 subjects, ability to perform mathematical tests was not affected by formaldehyde exposure. These studies suggest that tolerance to odor (60) and adaptation to formaldehyde (79) may develop during prolonged exposure, while illustrating variability in individual susceptibility (4).

Contact dermatitis is common in industrial settings using formaldehyde, and sensitization after prolonged exposure can result in eczema (34). Allergic dermatitis has been reported after exposure to formaldehyde (30). In skin sensitization experiments, diluted formalin (37% aqueous formaldehyde) was found to be a potentially strong sensitizer which showed a dose–response relationship (51). The prevalence of positive reactions to skin patch testing with formaldehyde increased with increased exposure duration (24).

Case Reports

A 32-year-old pathology resident was described as having acute symptoms, such as eye and nose irritation, headaches, and sore throat, following exposure to formalin (37% solution of formaldehyde) (46). Another case was reported to develop hypersensitivity pneumonitis after formaldehyde exposure (62).

Epidemiologic Studies

Epidemiologic studies cited as evidence for the health effects of UFFI have focused on a wide range of exposures to formaldehyde and related products. Conjunctival irritation, eye tearing, and lower respiratory tract symptoms were reported following exposure to phenolic resin (phenol–formaldehyde) fumes in a small sample of production line workers in an acrylic-wool filter manufacturing plant (68). Forty-eight employees with past or present exposure to the production line (formaldehyde concentration estimates of 0.40 to 0.80 ppm) were compared to workers who had never worked on the production line. Subjects responded to symptom questionnaires and underwent sets of five pulmonary function tests at the beginning and end of the work week. Associations with exposure were found for symptoms of excessive cough and/or phlegm and decreased FEV_1/FVC ratio after adjustment for smoking, statistically significant only when comparing the presently exposed more than 5 years exposure group ($n = 15$) to the never-exposed control group ($n = 15$). This result suggested chronic airways obstruction as an effect of prolonged exposure. Despite the high proportion of acute effects reported, no significant decreases in pulmonary function were apparent over the

workday or workweek Study limitations which the authors acknowledge include small exposure groups, the use of formaldehyde estimates, occasional exposure of almost everyone in the plant and the use of a cross-sectional design in attempting to assess chronic lung disease

On the presumption that visual tests may be a more sensitive parameter of the effects of formaldehyde exposure than respiratory measures, 83 workers in a wood production plant (average formaldehyde concentrations of 0 6–0 9 ppm) were studied (78) Although workers with chronic exposure attributed their eye symptoms to their work, the frequency of these symptoms was not greater compared to those less exposed, according to work histories Also, exposure to formaldehyde had no noticeable effect on visual tasks, tested before and after an 8-hr workshift

In a tire manufacturing plant, 52 of 68 workers known to be directly exposed to phenol–formaldehyde resins were compared to one group of 50 workers matched individually by sex, race, age, and shift job who were exposed to rubber stock but not to the resin in question, and to a second group of 55 control workers selected at random from the total worker population (28) Symptom questionnaires and baseline lung function tests were administered, and 19 resin-exposed, 16 rubber-exposed, and 19 control workers underwent lung function tests before and after work Of the measured pollutants, particulate levels were high, mean formaldehyde concentrations were 0 05 ppm for the resin-exposed group, and 0.02 and 0 04 ppm for the rubber-exposed and control groups respectively Although excessive symptom reports and decreased expiratory flow rates for those with low lung volumes were statistically significant for the resin-exposed group, results could not be associated with formaldehyde Indeed, the differences in mean concentrations of formaldehyde to which the groups were exposed were not statistically significant.

Exposure to formaldehyde fumes from the use of aqueous formaldehyde has been the focus of three studies of embalmers. In a study of six Detroit area funeral homes, formaldehyde concentrations ranged from 0 09 to 5 26 ppm, with the majority below the recommended ceiling concentration of 2 ppm (44) This study did not measure health effects. A mail survey of 80 Los Angeles embalmers asked about symptoms related to formaldehyde exposure on the job (61) Of the 57 individuals responding, 31 were classed as asymptomatic, 9 as having acute bronchitis related to their work, and 17 as having chronic bronchitis. Interpretation is not possible because of the absence of a comparison group and information on exposure levels or work practices

A questionnaire was administered to 105 of 112 licensed white male embalmers in West Virginia, and pulmonary function tests were taken by a volunteer sample of 99 (47). The prevalence of chronic bronchitis and decreased pulmonary function was similar to that observed in an age- and sex-matched population sample of residents of Oregon (53, 55) and Michigan (52). When time spent embalming and years of work were used as indices of exposure to formaldehyde and its polymers, no difference in prevalence of chronic bronchitis or reduced pulmonary function was detected.

The use of occupational histories to compile exposure indices, comparison of

respiratory measurements, and the control of possible confounding factors such as smoking and age represent improvements in study design However, limitations of this study include the use of a cross-sectional design to assess chronic effects, and the fact that a relatively healthy worker population was compared to the general population

A cross-sectional survey of all 28 staff members of a haemodialysis unit using formalin (10–25% formaldehyde in water) to sterilize artificial kidney machines reported that 8 (29%) had developed symptoms of recurrent wheezing and cough, since they began employment on the unit (37) All had normal pulmonary function tests Five symptomatic women volunteered for bronchial provocation tests Exposure to formalin resulted in wheezing and productive cough in two staff members but not in the other three study subjects This suggested an immunologic mechanism of a specific, nonirritative type After 5 years, the two nurses who had formaldehyde asthma were retested (38) Specific rate asthmatic reactions after an exposure of 3 ppm formaldehyde for 5 min were noted for one nurse who had continued to work with formaldehyde For the nurse who had avoided exposure to formaldehyde, no asthmatic responsiveness was noted

The toxicity of formaldehyde, revealed by laboratory and epidemiologic studies, suggests that formaldehyde is a mild sensory, upper respiratory, and mucous membrane irritant for some people at concentrations commonly occurring in occupational settings Subjectivity of symptom reports, unrepresentativeness of study populations, lack of comparison groups, small sample sizes, and the difficulty of attributing results to formaldehyde alone pose limitations to decisive conclusions and to postulating causal relationships It is especially difficult to extrapolate results to the effects of lower concentrations encountered in individual dwellings

UFFI EFFECTS ON SKIN, MUCOUS MEMBRANES, AND AIRWAYS

The issue of health effects is extended from formaldehyde to UFFI by laboratory and epidemiologic investigations, and by a case report Several studies have investigated complaints from residents of homes with UFFI, reporting formaldehyde concentrations and symptom frequencies. However, formaldehyde levels in the home may represent only part of the issue of domestic health problems.

For example, increased humidity resulting from improper installation conditions and from leakage of water may result in fungal growth within the walls of dwellings with UFFI. Agriculture Canada has isolated *Aspergillus* spp., *Cladosporium resinae*, and *Penicillium* spp from samples taken from walls in homes (12). These samples were not representative, and only the worst building problems were studied (R. P. Bowen, personal communication). Although formaldehyde is a fungicide, not all fungi are susceptible. It is postulated that fungal spores, or breakdown products of fungi, may be drawn through the walls and released in the ambient air. Reactions to fungi isolated from UFFI can often be similar to reactions caused by formaldehyde, but presently very little is known about the prevalence of this problem and its health implications.

Possible chemicals affecting health in the home environment include ozone

from electrostatic cleaners, carbon monoxide, sulfur, and nitrogen oxides, and oily aerosols from home heating and cooking Tobacco smoking may also contribute formaldehyde and carbon monoxide, creating complex interactions Also, irritant effects attributed to formaldehyde alone are not specific to this pollutant Since pollutant concentrations increase as ventilation decreases (3), and with heavy insulation and reduced building construction permeability (82), several pollutants may reach potentially harmful concentrations as homes become "tighter" in response to energy conservation

Laboratory Study

Formaldehyde emanation of 5 to 65 ppm from burning UFFI resulted in potent sensory irritation in mice with considerable recovery at termination of exposure (5) Acute mortality of mice was attributed to hydrogen cyanide produced when UFFI was subjected to very high temperatures (>500°C) Histopathological evaluation revealed changes in the myocardium, the most severe lesion occurring in the ventricle with myofibril structure loss and infiltration of macrophages, not attributed to formaldehyde or hydrogen cyanide exposure It has been suggested that cardiotoxicity may result from exposure to presently unknown chemicals in UFFI

Case Report

A 45-year-old woman who did not smoke developed steroid-resistant asthma shortly after her home, in which she had lived for 26 years, had been insulated with UFFI (27) Although this woman had asthma as a child, she had been asymptomatic since the age of 2. Bronchial challenge tests showed that exposure to "fine buoyant dust" brought from the woman's home resulted in severe bronchospasm, whereas exposure to aluminium oxide dust, gaseous formaldehyde at 3 ppm, and dust from urea–formaldehyde resin produced no bronchial reactions. This report and others reported earlier in this review suggest that some people exposed to UFFI or formaldehyde may develop an allergic reversible bronchial constriction upon exposure. Controlled human studies are needed to confirm or deny this possibility

Epidemiologic Studies

Following complaints by 245 Minnesota residents concerned with possible formaldehyde exposure in their homes, 168 were interviewed for symptom reports (29). Of the adults, 78% reported symptoms of eye, nose, and throat irritation. In children, 63% reported cough and wheezing Of 25 respondents asked to state where and when their worst symptoms occurred, 20 indicated that the home setting was responsible for their worst symptoms. Formaldehyde concentrations ranged from 0.24 to 1.0 ppm, with the lowest level in April and the highest in June. No data were reported to show the relationship between symptoms and concentrations of formaldehyde, although the majority of respondents reported more symptoms during summer.

Using symptom questionnaires, responses were obtained from 48 of 100 Denver residents who had complained about deleterious health effects and whose homes

were insulated with UFFI (35). One or more symptoms were recorded for an occupant if he/she claimed that symptoms were related to the time of UFFI installation and if they had persisted for more than 1 month Dyspnea (46%), headache (44%), rhinitis (44%), eye irritation (40%), and cough (40%) were most frequently reported No measurements of formaldehyde or any other potential irritant were taken in homes

In a similar manner, symptoms were elicited from 196 Connecticut residents living in 68 households in which at least one member of the household had complained of health problems believed related to UFFI. Of the 196 persons interviewed, 167 described symptoms (67). Follow-up of individuals in 173 UFFI homes by the Connecticut State Department of Health showed that, after an average of 2 3 years following UFFI installation, individuals in 65% of homes still experienced symptoms (56)

Symptom questionnaires were administered to staff of seven mobile day care centers where urea–formaldehyde-glued particle board was used for indoor paneling (59) For this group, response rate was 94% (n = 66), while only 76% (n = 26) of control staff responded from day care centers without particle board Menstrual irregularities, unnatural thirst, eyes, nose, and throat irritation, unnatural drowsiness, and headache were reported significantly ($P < 0.05$) more by the staff in the mobile day care centers, where the median formaldehyde concentration was 0.344 ppm In control centers, the median concentration was 0.064 ppm

Requests for assistance by persons who experienced health problems felt to be related to their mobile or conventional dwellings prompted a survey of formaldehyde concentrations and symptom experiences (14–16). Formaldehyde concentrations ranged from 0.03 to 1.77 ppm in 608 samples from 334 mobile homes, 66% ranged between 0.1 to 0.49 ppm, while 21% measured >0.5 ppm (Table 1) For 523 persons who experienced symptoms and lived in mobile homes, eye irritation (58%) and upper respiratory irritation (55%) were most frequently reported by adults (n = 424). For 99 children frequency of eye (41%) and respiratory irritation (62%) were also highest, while chronic cough or colds were reported by 33%. Results from conventional homes with UFFI showed lower formaldehyde levels and similar symptomatology in residents, with eye (53%) and respiratory tract irritation (56%) most frequently reported by adults (n = 32); for children (n = 12), nose irritation (33%) and allergies (33%) were most frequently reported.

Responses to a symptom questionnaire administered by telephone to residents of 395 homes insulated with UFFI in New Jersey in 1979 were compared to responses of residents of 400 control homes (74). The sample of UFFI-insulated homes was obtained from manufacturers. A total of 77% of these homes were subsequently excluded from the study for a variety of reasons; 63% of neighborhood controls were likewise excluded. No evidence of excess morbidity was noted among UFFI-exposed residents except for the symptoms of "wheezing or difficulty breathing" and "skin burning." A subgroup of residents of 33 UFFI homes reporting persistent odor (≥7 days postinsulation) had an increased rate of postinsulation symptom acquisition, physician visits, and medications taken. Although this study used a much stronger research design than previously reported studies, no formaldehyde measurements were taken, a large number of

case and control homes were excluded, and the authors state that because of many potential biases, ambiquity remains in the interpretation of the results from the subgroup

These studies, although limited because of the unrepresentativeness of the samples, show that substantial proportion of people exposed to urea–formaldehyde report upper respiratory and eye symptoms The methodology of these studies does not permit statements on causality or attributability of symptoms reports to UFFI. More studies are needed to evaluate the possibility of an association between UFFI and adverse health effects.

POTENTIAL MUTAGENICITY—CARCINOGENICITY

Formaldehyde has been repeatedly implicated as a mutagenic agent for animal test systems, but not for mammals and man. Recent animal studies have suggested that this chemical is carcinogenic. At this time epidèmiologic evidence is not sufficient to evaluate carcinogenic risk to humans, and further studies are urgently needed. An extensive review of this subject was published in 1982 (64).

Formaldehyde and Cancer: Laboratory Studies

Laboratory studies of the mutagenicity of formaldehyde have been carefully reviewed (8), and summarized and updated (21). In brief, the conclusion reached from the compilation of several types of animal studies is that formaldehyde is a weak mutagen, although dose–response relationships are difficult to determine Interaction of formaldehyde with other mutagens such as ultraviolet radiation appears to increase the frequency of mutations. The action of formaldehyde on bacterial DNA is not exerted directly, but through amino-containing compounds Dose-dependent single-strand breaks in DNA in *E. coli* and yeast occur when formaldehyde combines with amino acids and proteins (49, 63). However, the understanding of these mechanisms and their application to different organisms remains unclear.

Concern over formaldehyde as a possible carcinogen was sparked in 1979 with the release of preliminary research findings in the 16th month of a 24-month inhalation study (17). Groups of 120 male and female ($B_6C_3F_1$) mice and of 120 male and female Fisher 344 rats were exposed for 6 hr per day, 5 days per week to mean formaldehyde concentrations in air of 0.0, 2 1, 5.6, and 14.3 ppm Histopathological results showed squamous cell carcinomas of the nasal turbinates in 103 of 240 rats (51 male and 52 female) from the highest exposure group, in 2 of 240 rats (1 male and 1 female) in the 5.6-ppm group, and in 2 of 120 male mice in the 14.3-ppm exposure group (72). No female mice developed nasal carcinomas. No carcinomas were reported in unexposed animals.

Mice experienced mainly irritant effects and only at 14.3 ppm. The frequency and severity of squamous metaplasia in the epithelium of anterior nasal cavities in rats were exposure-related in all groups after 24 months of inhalation. Because of this finding, the study was extended after exposure had been stopped. Regression of metaplasia became apparent at 27 months (3 months postexposure) in the 2.0- and 5.6-ppm groups of rats. A weak association was found between formal-

dehyde exposure and increase in the frequency of polypoid adenomas in the nasal cavity of male rats (43)

Sialodacryoadenitis virus, found at the scheduled 12-month necropsy, may have played a role in promotion of carcinogenesis in formaldehyde-exposed animals (56) However, this possibility is unlikely because mice without this infection developed nasal cancer, and many nasal cancers had probably already started developing at the time of infection.

Under similar 14-ppm formaldehyde exposure conditions, another strain of rats developed nasal cancer (8 out of 100 rats) after 19 months (1) The virus mentioned above was not found in this study, and thus provided confirmation that the virus probably did not promote carcinogenesis. The New York University group state that these results neither disprove nor support the hypothesis that carcinogenicity is a nonspecific response to irritation following exposure to formaldehyde (1).

In the same study, rats exposed to bis(chloromethyl) ether (BCME), a product of the reaction of formaldehyde and hydrochloric acid (26, 41), developed nasal cancer, attributed mainly to formaldehyde (1). Exposure to hydrochloric acid alone produced no carcinogenic response (1) Since rats exposed to BCME developed nasal cancers (1, 45, 69), whereas chemical plant workers also exposed appeared to have an excessive risk of lung cancer (80), direct application of results from animal studies to humans is unwarranted Different breathing mechanisms and vastly different exposure levels necessitate the use of epidemiologic data in addition to animal studies.

Hamsters exposed to 10 ppm formaldehyde for 5 hr per day for lifetime developed no respiratory tract tumors, and only a slight increase in hyperplastic and metaplastic areas in the nasal epithelium, when compared to unexposed animals (22) In another experiment, combined exposures of formaldehyde prior to diethylnitrosamine (DEN) injections produced more tracheal tumors than DEN exposure alone, thus suggesting that formaldehyde may act as a cofactor in tumors induced by DEN (22)

Formaldehyde and Cancer: Epidemiologic Studies

Cytogenetic analyses of blood lymphocytes of 15 workers exposed to formaldehyde manufacturing and processing for an average of 28 years showed no increased chromosome aberration rates when compared to 15 unexposed workers matched for age and sex (25). Mean formaldehyde exposure did not exceed concentrations of 5 ppm before 1971, and 1 ppm since 1971. No correlation was found between formaldehyde exposure and frequency of aberrant metaphases.

A few epidemiologic studies have investigated the possibility of excessive risks for nasal or lung cancer in groups occupationally exposed to formaldehyde. In Britain, professional membership lists were used to locate 2079 pathologists and 12,944 laboratory technicians (33). Of the pathologists, failure to trace was limited to 0.6%, and of the 156 who died between 1955 and 1973, copies of the cause of death entry were obtained for 97%. Failure to trace technicians amounted to 1.5% and cause of death entries were obtained for all 154 who died during the study period. The standard mortality ratio (SMR) for all causes combined was lower

and statistically significant for pathologists (156 observed, 259 expected) and technicians (154 observed, 231 expected) than that of the general population of Britain For pathologists, 4 observed versus 19 expected deaths were attributed to the causes of bronchitis, asthma, and emphysema, and 11 observed versus 28 expected deaths were attributed to cancers of the lung, bronchus, and trachea These results were not statistically significant The SMR for pathologists was statistically significantly higher for the causes of suicide (10 observed, 4 expected), and for lymphohaematopoetic neoplasms, excluding Hodgkin's disease and leukemia (8 observed, 4 expected) for males only. For technicians, the SMR was elevated and statistically significant only for suicide (17 observed, 7 expected), and for lymphohematopoetic neoplasms, excluding Hodgkin's disease tional 139 deaths among pathologists (32). Although the findings for suicide and other violent deaths were again noted, no excess deaths from lymphohematopoetic neoplasms were found.

Formaldehyde exposure of 84 Danish physicians (79 male, 5 female) who died of lung cancer was compared with the exposure history of 252 physician controls, matched to the cases for age, sex, and survival at least to the time of cases' lung cancer diagnoses (39). The relative risk was 1.0 No deaths from nasal cancer were found among formaldehyde-exposed doctors in the Danish Cancer Registry data for the period 1943–76 (40).

In the largest study to date (7776 men), industrial workers exposed to formaldehyde did not have an increased risk of any type of cancer (6) There were no nasal cancer deaths, and no association with exposure was found for pancreatic, skin, kidney, and brain cancers

The National Institute for Occupational Safety and Health has initiated a "Case–control study of formaldehyde-exposed workers," with special attention to cases of nasal cancer (7). Since cohort mortality studies have limited statistical power in study a relatively rare disease such as nasal cancer, the case–control design may lead to a better definition of this potential risk factor

UFFI and Cancer. Laboratory Studies and Case Reports

Two aqueous ingredients of UFFI, the catalyst and resin, evaluated by *in vitro* reactions, revealed that both ingredients reacted with purified *E. coli* DNA (54): the catalyst reacted directly, and the resin after metabolic transformation by enzymes of the rat liver extract. These reactions with cellular macromolecules occur with other tumor-producing chemicals and raise the possibility that some ingredients of UFFI may have genetic and carcinogenetic potential.

There have been no animal exposure studies reported to date. Regarding UFFI, reports have yet to be published in the scientific literature, and there are no reports of detailed clinical studies of the immune system, such as immunoglobulin measurements, descriptions of cellular immunity, and studies of subpopulations of lymphocytes.

The potential carcinogenicity and mutagenicity of UFFI can not be assessed at this time. Case reports carried in the media and the few laboratory studies published to date indicate only the urgent need for more evidence

POTENTIAL TERATOGENICITY OF FORMALDEHYDE

Laboratory Studies

The effects of formaldehyde concentrations of 0 0, 0 001, and 0.8 ppm on the embryonic development of the offspring of three separate groups of 12 female rats showed that mean duration of pregnancy was prolonged by 14–15% by formaldehyde exposure in comparison to the unexposed group (31) The number of offspring was lower in the group not exposed to formaldehyde compared to the number of offspring for exposed groups This apparent paradox was not commented on by the authors

Oral intubation of pregnant mice for 10 days during gestation with 1% aqueous formaldehyde caused toxicity, but did not result in teratogenicity (50).

Epidemiologic Study

Menstrual and reproductive functions of 446 women exposed to formaldehyde in the fabric industry were compared to those of 200 relatively unexposed fabric saleswomen (70). Formaldehyde concentrations ranged from 0.04 to 3.6 ppm in areas where exposed women worked. Medical examinations revealed menstrual disorders in 47 5% of exposed workers, compared to 18.6% of the saleswomen. Several other laboratory and epidemiologic studies are inadequate for evaluation of teratogenicity. Studies reported here do not provide enough evidence for a conclusion as to whether or not formaldehyde exposure presents a teratogenic risk.

No studies were found of the potential teratogenicity of UFFI

CONCLUSION

It is clear that formaldehyde is a mild sensory irritant, affecting some people more than others, at concentrations encountered in many occupational settings. Formaldehyde concentrations in homes with UFFI are generally too low to cause sensory irritation, but levels in some homes may be high enough to affect a limited number of people who may, for unknown reasons, be particularly sensitive to this pollutant.

One comparative study of a random sample of occupants of UFFI insulated homes and of residents of non-UFFI insulated homes was found In addition, we found no cohort studies of occupants of UFFI and non-UFFI insulated homes. In Canada, for example, and in prepaid health insurance plans, it should be relatively easy to examine health care utilization patterns of residents before and after insulation of their homes. Such historical cohort studies would be able to indicate relative symptom severity leading to physician visits and to allow for comparative analysis for the periods prior to and following the development of awareness of the potential problem by the general population. Because of the genuine concern of residents of UFFI-insulated dwellings, such studies are urgently needed.

Although high concentrations of formaldehyde may be carcinogenic to animals, epidemiologic studies show no consistent findings to evaluate the risk of cancer for humans. Cross-sectional comparative studies of the immunologic surveillance

systems of residents of UFFI- and non-UFFI-insulated homes could be done to examine the hypothesis that UFFI has a depressive effect In addition, it may be necessary to identify representative cohorts of exposed and nonexposed individuals for long term prospective studies.

Epidemiologic studies have not established causation or an association between UFFI exposure and health effects Formaldehyde alone may not be responsible for alleged health effects, suggesting that unknown factors or complex chemical interactions in the domestic environment may cause health problems The limited extent of present knowledge regarding the health effects of UFFI affords an incentive for research which will provide evidence and definite answers for presently unanswered questions.

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Notes added in proof (1) Since submission of this manuscript, the U S Consumer Product Safety Commission banned the use of UFFI on August 10, 1982 The ban is being contested

(2) The study of the association between formaldehyde exposure and cancer, referred to in Ref (6), has been published since this manuscript was submitted A cohort of 98% of 7680 men exposed to formaldehyde and employed in the British chemical or plastics industry were traced to the end of 1981 Twenty-one percent had died, and excess mortality was apparent only for lung cancer when mortality rates from England and Wales were used as the standard, and not when comparison was made with local rates Other results are as previously noted [E D Acheson, H R Barnes, M J Gardner, C Osmond, B Bannett, and C P Taylor, (1984) Formaldehyde in the British Chemical Industry *Lancet* 1, 611–616]

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Ministère des Communications
Direction de la traduction

Appendix 2

Votre référence	Ministère ou organisme
	Affaires sociales

Notre référence	Langue	Traducteur(s)	Date
GA-3457-MAS	Fr-ang	RCM/MP	1982 01 13

CENTRE DE TOXICOLOGIE DU QUÉBEC

ASSISTANCE PROGRAM FOR VICTIMS OF UREA-FORMALDEHYDE FOAM

ASSISTANCE PROGRAM FOR VICTIMS OF UREA-FORMALDEHYDE FOAM

Assessment of effects on health

Centre de Toxicologie du Québec

Section I

Information for the examining physician.

Section II

General information on residents of the house. Must be completed by one of them.

Section III

Information on the person examined, and his medical and occupational history. Must be completed by the person examined or, if that person is a child, by one of his parents.

Section IV

Assessment of symptoms. Must be completed by the physician or the nurse.

Section V

Physical examination. Must be done by the physician.

Section VI

Authorization to transmit medical information, and physician's attestation.

SECTION I

Information for the Examining Physician

When houses are insulated with urea-formaldehyde foam insulation (UFFI), varying concentrations of formaldehyde, and probably other toxic gases, are released into the air in the rooms of the house. The amount of formaldehyde released depends on a number of factors: the architecture, the surface insulated, the technique used to inject the foam, the degree of humidity, the quality of the product, and so on. Furthermore, concentration in the atmosphere will vary by reason of climatic conditions, the degree of heating and ventilation in the house, the degree of instability of the product, and so on. The extent to which residents are exposed, then, can fluctuate according to what room they are in and at what time. The persons most exposed are those who spend the entire day in the house.

Formaldehyde is an allergenic primary irritant. The degree of irritation it produces varies according to its concentration. Where concentration is slight, it affects primarily the eyes and the upper respiratory tract. If concentration increases, the skin becomes irritated, as does the lower respiratory tract. If exposure is not prolonged, the symptoms disappear quickly. On the

other hand, when exposure is repeated or continuous, irritation can provoke persistent inflammatory phenomena, superinfection and hemorrhaging, especially in the mucosa.

Formaldehyde is readily water soluble, so it dilutes in the saliva which carries it into the digestive system, provoking gastro-intestinal symptoms (nausea, anorexia, vomiting, diarrhea). In the nose, it can disturb the sense of smell.

If absorbed into the circulatory system, formaldehyde provokes systemic effects especially in the nervous system (headaches, somnolence, a tendency to fatigue, irritability, disturbed sleep, and so on). After a while the exposed person's entire general condition is affected. Persons with lower physical resistance will be affected the most quickly and severely (children, elderly persons, sick persons).

Other products which may be released into the air from UFFI have not yet been identified and, consequently, we know nothing of their toxic potential. However we believe such emanations exist for the following reasons:

1. There seems to be no correlation between the level of formaldehyde in the air and the degree to which health is affected.

2. The pathological symptoms observed in persons exposed to UFFI do not always correspond to what we know of the toxic effects of formaldehyde.

3. The composition of UFFI has varied from time to time, and we do not yet know the toxic effects of the other substances added or of the products of reaction or degradation.

Chronic exposure can bring about a certain sensitivity and consequent allergic reactions either local (rhinitis, sinusitis, dermatitis) or pulmonary (asthma). Persons with a history of allergy are more likely to develop such reactions. Once an individual has become sensitive to the product, he will react to even very weak concentrations.

The mutagenic effects of formaldehyde have been shown up in experiments in vitro. Nose cancers have been induced in rats and mice, in laboratory conditions, although there is as yet no evidence that urea-formaldehyde is carcinogenic in man.

Little is known of the risks to pregnant women; therefore we consider that, where at all possible, they should avoid exposure to this substance.

Objectives

1. Immediate. The immediate objective here is to enable the physician to determine whether the symptoms reported and the signs observed are compatible with abnormal exposure to formaldehyde.

Since there are no laboratory examinations to confirm such a cause-and-effect relationship, the physician's judgment must be based on clinical observation. For that reason, this examination formula is directive, and particular stress is placed on the characteristic symptoms of over-exposure to formaldehyde. The time at which the medical problems appeared, and the fact that they become less marked or disappear outside the home may aid in making a diagnosis.

If, on concluding his examination, the physician believes that one or more persons living in a particular house have health problems related to exposure to UFFI, he must submit a written attestation to that effect.

The attestation will permit the residents in that house to have access to the relocation assistance program (assessment of the level or formaldehyde in the house, establishment of specifications for the work required to rectify the situation, and financial assistance toward temporary relocation).

2. Secondary The second objective is to attempt to establish whether there is a correlation between the clinical picture observed and toxic emanations from UFFI.

Note

(a) In order to qualify for a relocation program, it is not necessary that several residents of the house affected show health problems compatible with exposure to UFFI. Only one need do so. If the situation requires it, then, you need not examine all the residents immediately before you issue a written attestation. Begin by examining the person who seems the most affected.

(b) In your examination, pay particular attention to the most exposed tissues and organs (eyes, nose, throat, lungs, skin) which are identified by an asterisk.

(c) You must send this form, and the signed attestation, to your regional community health department (D.S.C.) immediately. It will advise the Bureau de dépannage by telephone of the nature of your attestation, in order that the other steps in the procedure can be put into operation immediately. It will then forward the file, as soon as possible, to

Dr. Albert J. Nantel, Director,
Centre de toxicologie du Québec
2705, boul. Laurier
Sainte-Foy, (Québec) G1V 4G2

The severity of the health problems may be determined on the basis of the criteria described at the end of this document, which are intended only as a guide in reaching your decision. As you will note, they are of two kinds:

1. Severity of the pathology observed (e.g. asthma).
2. Severity of symptoms (e.g. cough).

Thank you for helping with this program to assist UFFI victims. Your participation will make it possible to ease the suffering and the serious problems now plaguing thousands of Quebecers.

SECTION II

TO BE FILLED OUT BY ONE OF THE RESIDENTS

General information on the Residents

A. Personal information

1. Father _____ Age _____
2. Mother _____ Age _____
3. Children _____ Age _____
   _____ Age _____
   _____ Age _____
   _____ Age _____
   _____ Age _____
   _____ Age _____

4. Address of house insulated with UFFI

Street and Number _____

City or Town: _____ Postal Code _____

Telephone (____) _____

When did you move to the premises? _____

5. Others living in the house — Relationship — Tenant

Name _____ Age ____ _____ _____

Name _____ Age ____ _____ _____

Name _____ Age ____ _____ _____

Name _____ Age ____ _____ _____

Section II (cont'd)

6. Present address of family, or name and address of person to contact if the family cannot be reached

Telephone ( ) _____

Address _____

Relationship _____

B. Family history (parents, children and maternal and paternal grand parents)

Diabetes ____ Arterial hypertension ____

Tuberculosis ____ Heart disease ____

Cancer ____ If known, which?

_____

_____

Chronic bronchitis ____ Emphysema ____

Asthma ____ Hay fever ____

Rash ____ Eczemas. ____

Other allergies YES _____ NO _____

If yes, to: animals _____ food _____ plants _____

medication _____ other _____

Specify _____

_____

SECTION III

TO BE COMPLETED BY THE PERSON EXAMINED, OR BY EITHER PARENT OF A CHILD EXAMINED

Information on the Person Examined: medical and occupational history

1. Identification

Name _____ Given names _____

Father's name _____ Mother's name _____

Social Insurance No. _____

Health Insurance No. _____

Date of birth _____ Sex M _____ F _____

2. Level of contact with insulation

- Pre-schooler _____
- Child attending school: part time _____
  all day _____
- Working child _____
- Working adult _____
- Adult continually at home _____

Section III (cont'd)

3. Personal history

Have you visited a physician during the past five years?

YES _____ NO _____

If yes:

Date	Name of physician	Reason

Have you ever been hospitalized? YES _____ NO _____

If yes:

Date	Name of hospital	Reason

Section III (cont'd)

Do you suffer, or have you ever suffered, from:

Asthma _____

Rash _____

Eczema _____

Allergy: _____

to animals _____

to food _____

to medication(s) _____

to other products _____

Specify _____

_____

If applicable

Have you been pregnant since your home was insulated with urea-formaldehyde foam? YES _____ NO _____

If yes:

Was your pregnancy normal?

YES _____ NO _____

If no:

Did you experience any particular symptoms? YES _____ NO _____

If yes, which ones? _____

_____

_____

Section III (cont'd)

Did you suffer any of these complications?

Bleeding _____

Phlebitis _____

Risk of abortion _____

Spontaneous abortion _____ At what stage of pregnancy? _____

Premature delivery _____ After how many weeks? _____

Was your labour normal? YES _____ NO _____

If not, why? _____

_____

Was the child normal at birth? YES _____ NO _____

Weight _____

If not, what anomalies were there? _____

_____

4. Way of life

Are you taking medication at present? YES _____ NO _____

If yes:

Name of medication Reason For how long?

_____

_____

_____

_____

_____

Have you ever smoked? YES _____ NO _____

If yes, did you stop? YES _____ NO _____

If yes, when? _____

If no:

- Do you smoke cigarettes? YES _____ NO _____

  If yes,

  How many per day _____

  Since when? _____

  Do you inhale the smoke? YES _____ NO _____

- Do you smoke a pipe? YES _____ NO _____

  If yes,

  How many pipefuls a day? _____

  How many pouches of tobacco a week? _____

  Do you inhale the smoke? YES _____ NO _____

- Do you smoke cigars? YES _____ NO _____

  If yes, how many a day _____/ a week? _____

  Do you inhale the smoke? YES _____ NO _____

Section III (cont'd.)

Occupational history (Person working outside)

1. Present occupation

Company	Position held	Since
_____	_____	_____
_____	_____	_____

2. Previous occupations

Date	Companies	Positions held
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

3. Are you suffering or have you suffered from an occupational disease? YES _____ NO _____

If yes, which one? _____

How long? From _____ to _____

Are you still suffering from it? YES _____ NO _____

4. Does your work expose you to:

- Dust? YES _____ NO _____

If yes, what kind? _____

- Smoke? YES _____ NO _____

If yes, what kind? _____

- Irritating gases? YES _____ NO _____

If yes, what kind? _____

Section III (cont'd)

- Solvents: YES _____ NO _____

If yes, what kind? _____

- Any other irritating substances or agents? YES _____ NO _____

If yes, what kind? _____

5. Do you work in a sector where any of the following are manufactured or processed?

- Plywood YES _____ NO _____
- Chipboard YES _____ NO _____
- Glue YES _____ NO _____
- Paint YES _____ NO _____
- Plastics YES _____ NO _____
- Leather YES _____ NO _____
- Synthetic textiles YES _____ NO _____

(b) In a pathology laboratory? YES _____ NO _____

On a farm? YES _____ NO _____

With an embalmer? YES _____ NO _____

SECTION IV

TO BE FILLED OUT BY THE PHYSICIEN OR THE NURSE

Assessment of Symptoms	Severity			Do these disappear outside the home?		Date of appearance
Eyes	+	++	+++	YES	NO	
Irritation	___	___	___	___	___	_____
Redness	___	___	___	___	___	_____
Watering	___	___	___	___	___	_____
Dryness	___	___	___	___	___	_____
Blurred vision	___	___	___	___	___	_____
Double vision	___	___	___	___	___	_____
Failing vision	___	___	___	___	___	_____
Scotoma	___	___	___	___	___	_____

Does patient wear contact lenses? YES ___ NO ___

EARS

Irritation of pavilions: YES ___ NO ___

Irritation of exterior auditory canals: YES ___ NO ___

Discharge: YES ___ NO ___

Pain: YES ___ NO ___

Hearing normal: YES ___ NO ___

If no, localization at left _____ at right _____

Since _____

Section IV (cont'd)

	Severity			Do these disappear outside the home?		Date of appearance
Nose	+	++	+++	YES	NO	
Irritation	___	___	___	___	___	_____
Dryness	___	___	___	___	___	_____
Running	___	___	___	___	___	_____
Pain	___	___	___	___	___	_____
Bleeding	___	___	___	___	___	_____
Crusted lesions	___	___	___	___	___	_____

Smell: normal _____ abnormal _____

If abnormal: odours less perceptible _____ abnormal odours _____

total loss of sense of smell _____

Does the problem completely or partly correct itself outside the home? YES _____ NO _____

	Severity			Do these disappear outside the home?		Date of appearance
Throat	+	++	+++	YES	NO	
Irritation	___	___	___	___	___	_____
Pain	___	___	___	___	___	_____
Dryness	___	___	___	___	___	_____
Secretions	___	___	___	___	___	_____

Voice: normal _____

abnormal _____

Section IV (cont'd.)

Pulmonary system

Cough: YES__ NO__ If yes, date of appearance: _____

If yes, dry: YES __ NO __ in fits: YES __ NO __

with expectorations: YES __ NO __

If yes, abundant: YES ___ NO ___ whitish ____

yellowish ___ greenish ____ reddish ____

Plain hemoptysis: YES ____ NO ____

These symptoms occur mainly:

in the morning ___ in the forenoon ____ in the afternoon ____

in the evening ____ at night ____ all day ____ at various times ____

Dyspnoea: YES ___ NO ___

Wheezing : YES ___ NO ___

Chest pains: YES ___ NO ___

If yes, when inhaling: YES ___ NO ___

when coughing : YES ___ NO ___

Cardio-vascular system

Dyspnoea with effort: YES ___ NO ___

If yes, specify _____

Orthopnea: YES ___ NO ___

Nocturnal paroxysmic dyspnoea: YES ___ NO ___

Edema: YES ___ NO ___

If yes, malleolar _____ M.I. _____ diffuse _____

Section IV (cont'd.)

Retro-sternal pain: YES _____ NO _____

If yes, specify: _____

_____

Palpitations: YES _____ NO _____

Digestive system

Nausea: YES _____ NO _____ If yes, date of appearance _____

Vomiting: YES _____ NO _____

If yes, accompanying coughing fits: YES _____ NO _____

Constipation: YES _____ NO _____

Diarrhea: YES _____ NO _____ If yes, date of appearance _____

Abdominal pain: YES _____ NO _____

If yes, where? _____

Heaviness _____ Intermittent _____

Ponderosity _____ Constant _____

Colic _____

Burning _____

related to meals: YES _____ NO _____

related to foods: YES _____ NO _____

Hepatemesis: YES _____ NO _____

Melena: YES _____ NO _____

Section IV (cont'd.)

Neuro-psychic system

	Severity			Do these disappear outside the home?		Date of appear
	+	++	+++	YES	NO	
Headaches	___	___	___	___	___	___
Dizziness	___	___	___	___	___	___
Vertigo	___	___	___	___	___	___
Somnolence	___	___	___	___	___	___
Tendency to fatique	___	___	___	___	___	___
Disturbed sleep	___	___	___	___	___	___
Irritability	___	___	___	___	___	___

Headaches: throbbing: YES _____ NO _____

localized: _____

spreading _____

Fainting: YES _____ NO _____

If yes, specify: _____

Convulsions: YES _____ NO _____

If yes, specify: _____

Sensitivity: normal _____ abnormal _____

hyperesthenia _____ localization _____

hypoesthenia _____ localization _____

Section IV (cont'd)

Muscle strength: normal _____ abnormal _____

If reduced, where: _____

Recall of recent events: normal _____ abnormal _____

Recall of past events: normal _____ abnormal _____

Concentration capacity: normal _____ abnormal _____

Cutaneous system

	Severity			Do these disappear outside the home?		Date of appearance
	+	++	+++	YES	NO	
Irritation	___	___	___	___	___	_____
Redness	___	___	___	___	___	_____
Pruritus	___	___	___	___	___	_____
Dryness	___	___	___	___	___	_____
Edema	___	___	___	___	___	_____

Endocrine system

_____

_____

_____

_____

Genito-urinary system

Locomotor system

General observations

Infections YES _____ NO _____

If yes, what kind _____

General remarks

Section V

TO BE FILLED OUT BY THE PHYSICIAN

CENTRE DE TOXICOLOGIE DU QUÉBEC

PHYSICAL EXAMINATION I

Please concentrate on areas indicated by an asterisk.*

SUMMARY - ELEMENTS OF PROBLEMS TO BE REMEMBERED

1 _____ 2 _____

3 _____ 4 _____

5 _____ 6 _____

7 _____ 8 _____

GENERAL APPEARANCE (describe) _____

VITAL SIGNS Arterial tension: Right arm Left arm

lying _____ _____

seated _____ _____

Pulse: Frequency _____ rhythm _____

Respiration: Frequency _____ rhythm _____

	NORM	ABNORM	NOT EXAM	ANOMALIES
*Epidermis:				
Eruptions	___	___	___	
Texture	___	___	___	
Hair	___	___	___	
Local lesions	___	___	___	
Pigmentation	___	___	___	
Scars	___	___	___	
Other	___	___	___	
Head:				
*Eyes:				
Lids	___	___	___	
Conjunctiva	___	___	___	
Cornea	___	___	___	
Sclerotica	___	___	___	
Eye mvmts	___	___	___	
Fundus	___	___	___	

	NORM	ABNORM	NOT EXAM	ANOMALIES
Arteries	/			
Veins				
Retina				
Papilla				
Lens				
Field of vision				
*Ears:				
Hearing				
Canals				
Drums				
Weber Rhinne				
*Nose:				
Septum				
Sphenoids				
Sinus				
*Mouth:				
Lips				
Teeth				
Gums				
Tongue				

	NORM	ABNORM	NOT EXAM	ANOMALIES
Mucosa	____	____	____	
Pharynx	____	____	____	
Tonsils	____	____	____	

Neck:

Tranchea	____	____	____	
Thyroid	____	____	____	
Mobility	____	____	____	

Ganglions:

Cervical	____	____	____	
Supraclavicular	____	____	____	
Axillary	____	____	____	
Epitrochlean	____	____	____	
Inguinal	____	____	____	

Breasts:	LR	LR		
Nipple	____	____	____	
Mass	____	____	____	
Discharge	____	____	____	
Symmetry	____	____	____	

	NORM	ABNORM	NOT EXAM	ANOMALIES
Thorax:				
Shape	____	____	____	
Expansion	____	____	____	
*Lungs:				
Palpation	____	____	____	
Percussion	____	____	____	
Auscultation	____	____	____	
*Heart:				
Movements:	____	____	____	
Apex tap:	____	____	____	
Auscultation:	____	____	____	
rhythm:	____	____	____	
B 1				
B 2 (intensity and doubling)	____	____	____	
Other sounds	____	____	____	
Murmurs	____	____	____	
Grade out of VI	____	____	____	
and describe	____	____	____	
Neck veins	____	____	____	
Vein waves	____	____	____	
Hep.-jug. ref.	____	____	____	

	NORM	ABNORM	NOT EXAM	ANOMALIES
Peripheral pulsations:				
Temporal	____	____	____	
Carotid	____	____	____	
Cubital	____	____	____	
Radial	____	____	____	
Aortic	____	____	____	
Femoral	____	____	____	
Posterior	____	____	____	
Tibial	____	____	____	
Popliteal	____	____	____	
Pedal	____	____	____	

PHYSICAL EXAMINATION I

CENTRE DE TOXICOLOGIE DU QUÉBEC

PHYSICAL EXAMINATION II

	NORM	ABNORM	NOT EX	ANOMALIES
Peripheral veins				
Abdomen:				
Shape				
Defence				
Reflex				
Percussion				
Sensibility				
*Spleen				
Hypertrophy				
Masses				
Murmurs				
Hernias				
Scars				
Intestinal sounds				
Male genital organs:				
Penis				
Testicles				
Discharge				

	NORM	ABNORM	NOT EX	ANOMALIES
Rectum:				
Anus	____	____	____	
Sphincter	____	____	____	
Prostate	____	____	____	
Masses, etc.	____	____	____	
Stools-blood	____	____	____	
Female genital organs:				
Vulva	____	____	____	
Ureter	____	____	____	
Vagina/discharge	____	____	____	
Uterine cervix	____	____	____	
Uterine body	____	____	____	
Adnexa	____	____	____	
Perineum	____	____	____	
Smear	____	____	____	
Culture/Trich	____	____	____	
Column: Shape and movements				
Extremities:	____	____	____	
Articulations:				
(Structure-movement)	L R	L R	____	

	NORM	ABNORM	NOT EX	ANOMALIES
Fingers	___	___	___	
Wrists	___	___	___	
Elbows	___	___	___	
Shoulders	___	___	___	
Hips	___	___	___	
Knees	___	___	___	
Ankles	___	___	___	
Toes	___	___	___	
Others	___	___	___	

PHYSICAL EXAMINATION II

Neurological examination				
Mental state:	___	___	___	
Collaboration	___	___	___	
Orientation	___	___	___	
Humour	___	___	___	
Behaviour	___	___	___	
Appearance	___	___	___	
Verbal content ("thought")	___	___	___	
Memory/ concentration	___	___	___	
Intelligence	___	___	___	
Language	___	___	___	
Reading/ writing	___	___	___	

	NORM	ABNORM	NOT EX	ANOMALIES
Motor functions:				
Gait	____	____	____	
Strength	____	____	____	
Musculature	____	____	____	
Abnormal movements	____	____	____	
Coordination	____	____	____	

Cranial nerves:

I	____	____	____	VII
II	____	____	____	VIII
III	____	____	____	IX
IV	____	____	____	X
V	____	____	____	XI
VI	____	____	____	XII

Sensitivity:			
Pain	____	____	____
Touch	____	____	____
Attitude	____	____	____
Vibration	____	____	____

Reflexes: **Other reflexes**

0 - absent 1 - diminished

2 - normal 3 - accentuated

4 - very accentuated

Name of Physician _____

Signature _____

Date: D.S.C. or C.L.S.C.

Medical Clinic _____

AUTHORIZATION

I authorize one copy of this file to be sent to the D.S.C. of C.H. and to the Centre de toxicologie du Québec, solely for purposes related to Québec's assistance program and to research.

Date _____

Name of person examined _____

Signature of person examined, or of a representative of that person

_____

To be returned to:

Doctor Albert J. Nantel,

Director

Centre de Toxicologie du Québec

2705, boul. Laurier

SAINTE-FOY (Québec)

G1V 4G2

CRITERIA FOR DETERMINING THE EXTENT OF DAMAGE TO HEALTH FOLLOWING EXPOSURE TO UFFI

I Serious

R.S. Chronic bronchitis, bronchopneumonia, pneumonia, asthma, pulmonary edema, epiglottitis, tumerous lesion, recurrent nosebleeds, chronic uncontrollable cough, recurrent tracheolaryngitis.

Blood Anemia, blood dyscrasia, adenosplenomegaly, mononucleosis.

D.T. Esophagitis, gastritis, colitis, persistent diarrhea, recurrent vomiting, anorexia with weight loss.

Eyes Recurrent keratoconjunctivitis.

N.S. Loss of consciousness, incapacitating headache or insomnia, vertigo, noticeable behaviour disturbances.

II Moderate

R.S. Irritating cough, occasional nosebleeds, rhinopharyngitis, sinusitis.

D.S. Occasional vomiting, occasional diarrhea, frequent nausea.

N.S. Frequent headaches, sleeping problems, irritability, dizziness, fatigue.

Eyes Conjunctivitis, blepharitis.

Skin Simple dermatitis.

III Slight

R.S. Dryness of the nose, dryness of the throat, sneezing, rhinorrhea, occasional cough, perception of disagreeable odours.

D.T. Nausea, decreased appetite, changes in taste of food, dyspepsia.

N.S. Occasional headaches, slight somnolence, somewhat disturbed sleep.

Skin Irritation, pruritis, dryness.

Eyes Irritation, tearing.

MEDICAL CERTIFICATE

Please fill out a certificate for each family member examined and enter it in the file.

This is to confirm that I have examined _____ _____(name), who is _____ years of age, and resides at _____;

I have observed health problems compatible with exposure to urea-formaldehyde foam insulation.

The extent to which his health is affected is

Serious

Moderate

Slight

Date _____

Name of Physician _____

Signature of Physician _____

Appendix 3

Identification _____

___ francais
___ english

Date/hour _____
_____
_____

No answer _____
Comments _____
Telephone # where reached: _____

Name: _____ _____
last first

Address of home with UFFI:

_____

_____
postal code

Interviewer>> Introduction:

Hello. I would like to speak to _____. My name is _____. I work for the Department of Community Health, Montreal General Hospital. We are doing a study on urea-formaldehyde foam insulation for the home. I would like to ask you a few questions. All information is strictly confidential.

(additional info: concerned with health in the home: information to improve D.S.C. services)

Interviewer>> to all:

-- What is your present address? _____ same as above

_____

_____
postal code

Interviewer>> if applicable:

-- When did you move in to (address of home with UFFI)?

Date ____ ____ ____
yr m day

-- If you do not know the exact month and year, since about what year did you live at (address of UFFI home)?

Since _____

Interviewer>> for all:

-- When was this home insulated with UFFI?

Date ____ ____ ____
yr m day

-- If you do not know the exact date, can you remember what time of year it was? What season?

Season: fall (09)____ spring (05)____
winter (12)____ summer (07)____

Interviewer>> if present address different from UFFI home:

-- When did you move from (address of UFFI home)?

Date ____ ____ ____
yr m day

Interviewer>> for all:
May I ask you your medicare number? _____-_____-_____

This information was (incomplete) on your application for the assistance program for the Bureau des victimes de la MIUF. We would like to use this information for confidential research.

Interviewer>> If respondent willing to cooperate:
-- I have just a few additional questions:

— Did you or your family make any changes to your home after UFFI was installed? For example, did you

____ remove the UFFI or ____ keep the UFFI Date changes made:
____ block off the UFFI or _____ (open)? ____ ____ ____
____ no changes made yr m day

-- May I ask why you moved? _____

-- Was the move because of UFFI?

____ yes ____ no

-- Do you think that UFFI affected your health or the health of anyone in your family?

_____

_____

That's all, and thank you for answering these questions.

Interviewer's comments:

Appendix 4

QUESTIONNAIRE Dossier no _____

Nom _____

- Quelle est votre présente adresse? ☐ même que celle indiquée sur la lettre

_____

_____

code postal _____ # téléphone _____

- À quelle date avez-vous emménagé dans la maison isolée à la MIUF?

Date ____ ____ ____
an *mois* *jour*

- Si vous ne connaissez pas la date exacte, depuis quelle année habitez-vous la maison isolée à la MIUF?

Depuis _____

- À quelle date cette maison a-t-elle été isolée à la MIUF?

Date ____ ____ ____
an *mois* *jour*

- Si vous ne connaissez pas la date exacte, pouvez-vous vous souvenir du moment de l'année, de la saison?

☐ automne (09) ☐ hiver (12) ☐ printemps (05) ☐ été (07)

- Si vous n'habitez plus la maison isolée à la MIUF, à quelle date avez-vous déménagé?

Date ____ ____ ____
an *mois* *jour*

- Si vous avez déménagé, est-ce à cause de la MIUF? ☐ oui ☐ non

- Avez-vous fait des changements à votre maison après que la MIUF ait été installée? Par exemple, avez-vous:

☐ fait enlever la MIUF
☐ recouvert murs et plafonds afin d'enrayer les émanations de la MIUF
☐ gardé la MIUF
☐ autre (S.V.P., spécifiez) _____

_____

.../

HÔPITAL GÉNÉRAL DE MONTRÉAL
THE MONTREAL GENERAL HOSPITAL

Montréal, le

Cher

Cette lettre a pour but de confirmer que le Département de santé communautaire de l'Hôpital général de Montréal fait présentement une étude sur la mousse isolante d'urée-formaldéhyde. Nous avons communiqué avec vous par téléphone, et nous aimerions que vous nous donniez votre numéro d'Assurance-Maladie en complétant l'espace réservé à cet effet plus bas. Cette information est utilisée à des fins de recherche et est strictement confidentielle. Si vous avez des questions, vous pouvez communiquer avec Kristan L'Abbé au 932-9231, poste 26. Votre coopération est grandement appréciée.

d'Assurance-Maladie: _____-_____-_____

Veuillez s'il-vous-plaît nous retourner cette lettre dans l'enveloppe affranchie ci-incluse. Nous vous ferons parvenir les résultats de notre étude dans quelques mois.

Merci.

Kristan A. L'Abbé
Agent de recherche

KAL/md
p.j.

DSC Département de santé communautaire 1597 avenue des Pins ouest Montréal H3G 1B3 937-9231

Appendix 5

HÔPITAL GÉNÉRAL DE MONTRÉAL
THE MONTREAL GENERAL HOSPITAL

Montreal,

Dear

We are writing this letter to confirm that the Department of Community Health is doing a study on urea-formaldehyde foam insulation. We have contacted you by telephone, and now we would like you to give us your medicare number by completing this form and returning it to us. This information is used in research and is strictly confidential. If you have any questions, please contact Kristan L'Abbé at 937-9231, ext. 26. Your cooperation is greatly appreciated.

Medicare # __ __ __ __ - __ __ __ __ - __ __ __ __

Please return this form to us in the enclosed stamped envelope. We will send you the results of our study in several months from now.

Thank you.

Sincerely,

Kristan A. L'Abbé
Research Associate

KAL/md
encl.

DSC
Département de santé communautaire 1597 avenue des Pins ouest Montréal H3G 1B3 937-9231

Appendix 6

Régie de
l'assurance-maladie
du Québec

Case postale 6600
Québec (Québec)
G1K 7T3

Québec, le 29 juin 1984.

Hôpital Général de Montréal,
Département de santé communautaire,
1597 avenue des Pins ouest,
Montréal,
H3C-1B3.

Madame,

La présente fait suite à notre conversation téléphonique du 28 juin.

Je vous confirme la distinction à établir entre le code de l' acte et le code du diagnostic.

Le code de l'acte réfère à la codification du service professionnel rendu par le dispensateur v.g. examen, injection, réparation de plaie, etc... Le taux de présence de cette donnée sur la demande de paiement est de 100%. Le code de diagnostic réfère plutôt au motif de consultation ou à la pathologie. Cette information sommaire est contenue dans la case: "Diagnostic principal et renseignements complémentaires". Le taux de présence de cette donnée est d'environ 50 à 60%; 10% étant codé par le médecin ou son personnel; le reste étant codifié par la Régie selon un choix aléatoire.

Espérant ces précisions utiles, je vous prie d'agréer, Madame, l'expression de mes sentiments les meilleurs.

Pascal Bossé

Pascal Bossé.

PB/dbd