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3M

An Epidemiologic Analysis of the Inpatient and Outpatient Claims Event and Episode Experience of 3M Decatur Employees, 1993-1998

The purpose of this research protocol is to examine the Corporate Health Strategies Ingenix (CHS) inpatient and outpatient claims databases from January 1, 1993 through December 31, 1998 of Decatur chemical and film plant employees. Claims data are not available from CHS prior to 1993. The observed claims events (individual claims) and episodes (multiple related claims grouped according to the episode they form) will be compared to an expected number calculated by indirect standardization methods to adjust for age and gender. Corrected for their different age structures, we will examine the ratio of the observed to expected chemical plant to the observed to expected film plant. The many limitations of the analysis of claims data are detailed in the study protocol. This study design was originally proposed in 1998 but was placed "on hold" to allow for the completion of the random sample assessment of serum fluorochemical measurements of Decatur chemical and film plant employees as well as the completion of the abstraction, data input and quality assurance of the Decatur work history record project. Both of these projects were required to be completed prior to the claims analysis in order to provide the necessary supporting information regarding employee serum fluorochemical levels and work history experience. Estimated date of the final report for this study is September 15, 2000.

ADDENDUM
EPIDEMIOLOGY PROTOCOL

Epidemiology, 220-3W-05
Medical Department
3M Company
St. Paul, MN 55144

Date: February 27, 2000

Title: An Epidemiologic Analysis of the Inpatient and Outpatient Claims Event and Episode Experience of 3M Decatur Employees, 1993-1998

Addendum Study
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Sponsor: 3M Medical Department, 220-3W-05, St. Paul, MN

INTRODUCTION

This epidemiology study protocol (Epi-0004) was placed "on hold" in 1998 while two supplemental research activities clarified the potential differences in fluorochemical exposure among employees at the Decatur chemical and film plants. These two research endeavors were the "Fluorochemical Exposure Assessment of Decatur Chemical and Film Plant Employees (EPI-0006)" and the abstraction, data input and quality assurance of the Decatur work history record project. As a result of these two research activities, this study's methods have been modified and improved. Therefore, this Addendum supplants the original study protocol. The purpose of this revised research protocol is to examine the Corporate Health Strategies Ingenix (CHS) inpatient and outpatient claims databases from January 1, 1993 through December 31, 1998 of Decatur chemical and film plant employees. The observed claims events and episodes (as described below) will be compared to an expected number calculated by indirect standardization methods to adjust for age and gender. Provided below is a detailed description of the study methods.

METHODS

Description of CHS

CHS is located in New Haven, Connecticut. CHS creates and updates health claims and related databases for 3M and many other companies. CHS uses Parallax® software for its analytical interface. CHS also provides analytic consulting services to its member companies which will be used in this study. CHS will serve as the only claims data resource to 3M for this research study.

Description of CHS inpatient and outpatient databases

There are several CHS databases. These include: 1) the monthly cost and utilization database; 2) the focused MSR database (allows detailed investigation of trends found in monthly cost and utilization; 3) the eligibility data base; 4) the prescription drug database; 5) the inpatient database; and 6) the outpatient database. CHS can only provide claims data for Decatur employees who have chosen the 3M Medical Plan or BlueCross/Blue Shield of Alabama. Beginning in 1996, 3M Decatur employees had the option of choosing an HMO; to the best of our knowledge, few (< 50) have done so. It appears that equal percentages of chemical and film plant employees choose HMO coverage although we suspect a greater percentage of younger employees choose HMO coverage than older employees.

The formation of a complete inpatient record includes the hospital record and the physician record. There are 27 Major Diagnosis Categories (MDCs) [CHS, 1993]. There are approximately 500 DRGs which are subcategories of the 27 MDCs. DRGs were developed at Yale University and group similar patients. Diagnosis codes (ICD-9) can also be obtained from the hospital record. The MDCs that are of particular interest in this study are the following:

MDC 1	Nervous System
MDC 4	Respiratory System
MDC 5	Circulatory System
MDC 6	Digestive System
MDC 7	Hepatobiliary System and Pancreas
MDC 10	Endocrine, Nutritional and Metabolic
MDC 11	Kidney & Urinary Tract
MDC 12	Male Reproductive
MDC 13	Female Reproductive

MDC 14	Pregnancy, Childbirth & Puerperium
MDC 15	Newborns and Other Neonates
MDC 16	Blood and Immunological
MDC 17	Myeloproliferative and other neoplasms

From these MDCs more specific DRGs and even more specific ICD-9 codes can be selected for comparative analysis with the normative databases. The inpatient claims database can be analyzed for all claims from January 1, 1993 (CHS's contract with 3M began at this time) through December 31, 1998. A single hospitalization results in only one DRG and MDC code despite the possibility there could be one or more diagnoses made during hospitalization. It is also important to recognize that multiple inpatient claims of a single DRG may represent one employee or more than one employee with the same DRG. Thus, each inpatient claim cannot necessarily be considered an incident (i.e., new) or prevalence diagnosis during the study time period. Rather, this analysis should be viewed as an evaluation of the existence of inpatient claim events from January 1993 through December 31 1998. It will be possible, when necessary, to determine how many individuals contributed to the number of claim events for a MDC or a DRG. This will be helpful in data interpretation when an excess of observed claims is reported

Most physician-diagnosed illnesses do not require hospitalization. Therefore, we will also examine, for the same time period (1/1/93 - 12/31/98), the CHS outpatient claims database. As with the inpatient records, an employee may have one or more outpatient records of the same ICD-9 code. Furthermore, a claim may not represent a physician diagnosis as outpatient ICD-9 codes may be used as a suspected diagnosis code in the ordering of medical diagnostic procedures for which a claim is filed. Thus, each outpatient claim, like inpatient claims cannot necessarily be considered an incident (i.e.,

new) or prevalence diagnosis during the study time period. Rather, this analysis should be viewed as an evaluation of the existence of outpatient claim events from January 1993 through December 31 1998. It will be possible, if necessary, to identify the number of employees per each ICD-9 code. Finally, it should be noted that the same person could have several claims for the same diagnosis in both the inpatient and outpatient databases.

The three digit ICD-9 codes that will be examined for outpatient claims are the following:

ICD-9 Code	Description
140-239	Neoplasms
240-279	Endocrine, Nutritional, Metabolic, Immunity
280-289	Blood and Blood-Forming Organs
320-389	Nervous System and Sense Organs
390-459	Circulatory System
460-519	Respiratory System
520-579	Digestive System
580-629	Genitourinary System
630-676	Pregnancy, Childbirth and the Puerperium
710-739	Musculoskeletal System and Connective Tissue
740-759	Congenital Anomalies
760-779	Conditions in the Perinatal Period
780-799	Symptoms, Signs, and Ill-Defined Conditions

Should it be necessary, an analysis of the fourth digit of the ICD-9 code is feasible.

Inpatient claim events regarding newborns are assigned to the employee. Neonates (less than 30 days of age) generally, but not always, have their inpatient and outpatient claims assigned directly to the employee's record. By 30 days of age, most infants have their own separate records and are then defined as an employee dependent. Employee dependent records will not be examined.

Description of Clinical Care Groups™ (CCG) Methodology

Claims event data by itself, as described above, are not an ideal representation of clinical events when directly used. To better understand the treatment of diseases, individual services with their respective diagnosis codes should be linked together according to logic that combines clinical expertise and detailed knowledge of administrative data. When claims records are linked, they can form disease episodes, which represent all the services provided for the diagnosis, treatment, and management of a disease or condition. Thus, where individual claims data represent an "event", claims data that is grouped by diagnosis, treatment and management of a disease can represent an "episode."

Because of CHS's recent merge with Ingenix, Inc., CHS now has access to CCG software. This software groups all visits, procedures, ancillary services, and prescription drugs used in the diagnosis, treatment, and management of more than 400 diseases or conditions. An episode can be considered a constellation of one or more claims data records representing an occurrence of a disease or condition for a particular individual. An episode is assigned to a CCG Class. A CCG Class have several important qualities. It is: 1) clinically homogenous; 2) exhaustive; 3) belong to a disease hierarchy; and 4) is classified as a chronic or acute condition. Several CCG Classes constitute a CCG Category. Several CCG Categories constitute a Specialty Category. Altogether, there are 442 CCG Classes that fall into 103 CCG Categories and 20 Specialty Categories. The CCG software provides a summary output file with one record per episode. The methodology on how the CCG software works is described elsewhere [Valdivia and Van

Vorst, 2000]. For the purpose of this study, the CCG software will be utilized to describe the episode experience of the study cohorts (described below).

Decatur Study Population

The initial study population consists of all full-time and inactive employees at the Decatur plant as identified in the 3M epidemiology's Decatur work history database as of January 1, 1993. Employees hired, transferred to a non-Decatur site or terminated during the interval of time from 1/1/93 through 12/31/98 will have their claim event analyses limited to their time of employment. Full-time active employees who retired or went on long-term disability (LTD) within the six year interval of time (1993 - 1998) will be followed through 12/31/98. However, it should be recognized that employees placed on LTD are eligible for Medicare after 18 months; thereafter 3M becomes the secondary provider. Employees who retire prior to age 65 may have 3M as the primary insurance provider. Medicare becomes the employee's primary provider upon reaching the employee's 65^{th} birthday.

Cohort Size

Based on a review of the recently computerized epidemiology Decatur work history database, the number of employees eligible for this study are the following (percents in parentheses):

Category	Chemical	Film
All Employees	652	659
Gender		
Male	530 (81)	558 (85)
Female	122 (19)	101 (15)
Age		
<30	59 (9)	36 (6)
30-39	124 (19)	82 (12)
40-49	238 (37)	194 (29)
50-59	182 (28)	267 (41)
>=60	49 (7)	80 (12)
Average age	45 years	49 years
"High" exposure job#	498 (76)	490 (77)*
Only worked in chemical (film) plant#	388 (60)	424 (64)
Worked only in chemical (or film) plant and, at least, from 1983-1998	176 (27)	269 (41)

*refers to comparable non-exposed jobs in film (i.e., operators, maintenance and supervisors) similar to those jobs in chemical which were considered "high" exposure (see text for definition of "high").
#refers to chemical employees with no work experience in film after 1/1/83 and film employees with no work experience in chemical after 1/1/83.

Data Analysis

Claims Events

For each year from 1993-1998, the chemical and film plant cohorts will be identified in order to calculate the observed and expected inpatient (MDC, DRG) and outpatient (ICD-9) claims experience. The overall claim events experience, for each MDC, DRG and ICD-9 code, is the sum of the individual six years of observed and

expected experience. Employees who chose an HMO in 1996, 1997 and 1998 will be excluded from the analyses for the year(s) they have HMO coverage.

Analysis of the claim events experience will be examined by whether the employee is considered a chemical plant or film plant employee. Each employee's work history record has been examined by the investigators (JMB, GWO, MMB) to determine whether the employee: 1) ever worked in chemical, film or both; 2) worked in chemical, film or both during the claims analysis time period of January 1, 1993 through December 31, 1998; and 3) worked continuously in chemical or film for the entire 10 years prior to the beginning of the claims analysis time period. For employees who have worked in both plants, their records were reviewed to identify which plant each employee primarily worked at in his/her career at Decatur. Both chemical and film plant employees will be subdivided in the analyses (see below) as to whether they have, or have not, worked in the other plant. The majority of film plant employees with prior work experience in the chemical plant worked at the chemical plant for a short period of time (1 to 3 months) and this usually occurred during the first year of their employment. Film plant workers were employed, on average, 25 years. Like film plant employees, many chemical plant employees have worked at the film plant at the beginning of their career. In addition, employees who have site-wide responsibilities (those who may work in both chemical and film such as environmental health and safety specialists) were assigned to the chemical plant.

Each employee was assigned a job title which described the person's usual job activity while a Decatur employee. These job titles were: boiler operator, environmental health and safety specialist, engineer, mill operator, maintenance, office worker, operator,

quality control worker, shipping clerk and supervisor. Based on the findings from the Decatur exposure assessment study (Olsen et al., 1999), maintenance workers, operators (includes cell, chemical, mill and waste) and supervisors in the chemical plant had significantly higher serum fluorochemical levels [e.g., approximate geometric mean of 1 to 2 ppm of PFOS (perfluorooctanesulfonate) and/or PFOA (perfluorooctanoic acid)] than the other job categories (approximate geometric mean levels of 0.2 to 0.5 ppm for PFOS and/or PFOA). Therefore, these two job groups will be the high and low fluorochemical exposure categories in the chemical plant analyses. All chemical plant workers, regardless of job title, were found to have, on average, significantly higher serum fluorochemical levels than employees assigned to the film plant. The geometric mean for film plant employees approximated 0.1 ppm PFOS and less than 0.1 ppm for PFOA. Thus, the film plant workers are considered to be the least exposed and will be considered the comparison population.

The observed number of claims based on MDC's, DRG's and ICD-9 codes will be compared to an expected value using indirect standardization methods [Tsai and Wen, 1986] to adjust for age (<40, 40-49 and >=50) and gender (male, female). Two normative databases will be used to calculate the expected number of claims: 1) the entire U.S. 3M population excluding the Cottage Grove (location code = 064) and Cordova (location code = 034) sites due to their fluorochemical production activities; and 2) the U.S. 3M population excluding employees at the St. Paul (location code = 089), Woodbury (location code = 343), Cottage Grove (location code = 064) and Cordova (location code = 034) sites. The latter database, hereafter called the 3M manufacturing plant normative database, will be developed to provide a normative database that would likely be more representative of 3M manufacturing

plant employees as it excludes the St. Paul 3M Center (corporate and research employees). It also excludes the downtown St. Paul manufacturing plant as the 3M St. Paul sites use the same location code (089). A third normative database, which consists of other companies that belong to the CHS aggregate database, was not considered appropriate to use by CHS staff because the different health insurance plans that these other companies use may greatly influence the likelihood of hospitalization. This is especially true when studying small populations such as those identified in this Decatur study.

Standardized Claims Ratios (SCR) for MDCs (inpatient), DRGs (inpatient) and ICD-9 codes (outpatient) will be calculated. The $SCR_{chemical}$ is the ratio of the observed to expected claims experience for the chemical plant. The SCR_{film} is the ratio of the observed to expected claims experience for the film plant. Ninety-five percent Confidence Intervals (95% CI) of the $SCR_{chemical}$ and SCR_{film} will be calculated using methods described by Rothman and Boice [1979]. However, the estimate that is most important is the ratio of these two indirect standardized ratios which we will define as the Claims Event Ratio:

$$CER = SCR_{chemical} / SCR_{film}$$

The direct comparison of two indirect standardized ratios (e.g., Standardized Mortality Ratios) can be made only if the age structures are similar or age-specific mortality ratios are homogeneous. Because the chemical and film plant populations have somewhat different age structures used for indirect standardization (see cohort size above which shows chemical plant employees are somewhat younger than film plant employees), the SCRs for the chemical and film plant populations are not necessarily directly comparable. We will use the methods by Tsai and Wen (1986) to compare whether the ratio of two indirect standardized ratios, corrected for their age structure, is similar to an unadjusted ratio. The ratio of two

indirect standardized ratios, upon correction for their age structure differences, can be considered an unbiased estimator of a risk ratio [Tsai and Wen, 1986].

$$CER_{corrected} = SCR_{chemical\text{-}corrected} / SCR_{film\text{-}corrected}$$

Each age corrected SCR is not meaningful by itself, only the ratio, $CER_{corrected}$, of two corrected SCRs. Although Tsai and Wen suggest that the confidence interval of $CER_{corrected}$ can be calculated using the procedures developed by Ederer and Mantel (1974) for the ratio of two Poisson variables, such methods, in fact, cannot be used. Unlike CER which is a Poisson variable (sum $Obs_{chem\text{-}3\ age\ groups}$ /sum $Obs_{film\text{-}3\ age\ groups}$) multiplied by a constant (sum $Exp_{film\text{-}3\ age\ groups}$ /sum $Exp_{chem\text{-}3\ age\ groups}$), the calculation of a confidence interval for $CER_{corrected}$ is not readily apparent as each $Obs_{corrected\text{-}chem}/Obs_{corrected\text{-}film}$ subgroup (n = 3 age groups) is not a Poisson variable and neither is the sum (personal communication, Dr. Tim Church, biostatistician, University of Minnesota). Therefore, our analysis strategy will be to calculate both CER and a $CER_{corrected}$. If the two ratios are relatively similar, which we suspect they will be given the fact that their age structures are not substantially different, then we will only calculate the confidence limit of CER ($SCR_{chemical}/SCR_{film}$) using the methods proposed by Ederer and Mantel (197). We will calculate CER and $CER_{corrected}$ for those inpatient (MDC and DRG) and outpatient (ICD-9) claim categories where there are two or more observed claims in either the chemical or film plant populations.

Because of confidentiality concerns regarding employee medical information, the identification of the inpatient and outpatient claims experience is known only by CHS. Therefore, the cohorts must be established by 3M prior to the determination of the claims data. Record linkage with the CHS claims data will include the employee's name, gender, social security number, employee number and date of birth.

The observed and expected inpatient and outpatient claims experience (and their SCRs, CERs and $CERs_{corrected}$) will be determined for several cohorts (excluding those individuals who have HMO coverage). These will include the following comparisons:

1) all chemical plant workers (n = 652) compared to all film plant workers (n = 659);

2) all chemical plant workers who never worked in film (n = 388) versus all film plant workers who never worked in chemical (n = 424);

3) all 'high' (defined above) exposure chemical plant workers who have not worked in film for at least since January 1, 1983, if ever (n = 498), compared to their job counterparts (considered 'least exposed') in the film plant who have not worked in chemical for at least since January 1, 1983, if ever (n = 490, this would include operators, supervisors and maintenance workers in the film plant); and

4) all long-term 'high' exposure chemical plant workers who have not worked in film since at least January 1, 1983, if ever (n = 211), compared to their job counterparts of 'least exposed' workers in the film plant who have not worked in chemical since at least January 1, 1983, if ever (n = 345);

Claims Episodes

Comparable indirect standardization techniques, as described above for the claims events data, will be used to analyze the claims episode data derived from the CCG software. We will utilize the same two 3M normative populations for calculation of expected values. Basically, instead of calculating an observed to expected ratio of claim 'events', we will calculate an observed to expected ratio of episodes based on the CCG software. In other words: $CEpR = SC_{EpR_{chemical}}/SC_{EpR_{film}}$) where CE_pR = Claims Episodes Ratio; $SC_{EpR_{chemical}}$ = Standardized Episode Claims Ratio for chemical; and $SC_{EpR_{film}}$ = Standardized Episode

Claims Ratio for film. The CE_pR will include the CCG Class, CCG Category and Specialty Category episodes.

Additional Study Logistics

Jennifer Bilodeau and Doug Bates will coordinate the CHS aspects of this project. Geary Olsen will serve as the 3M principal investigator. Jean Burris, Michele Burlew and Jeff Mandel will serve as 3M co-investigators. For each cohort that 3M provides, CHS will determine the observed and calculate the expected number of claims by MDC (inpatient), DRG (inpatient), ICD-9 (outpatient) codes as well as the CCG Classes, CCG Categories and CCG Specialty Categories (as discussed above) per each age group and gender. Calculation of the SCR_{chem}, SCR_{film} and CER (and their associated 95% confidence intervals) will be performed by 3M investigators as well as the calculation of the $SCR_{chem\text{-}corrected}$, $SCR_{film\text{-}corrected}$ and $CER_{corrected}$. The title of the revised study protocol is changed (from the original protocol) to include outpatient claims, claim episodes and extend the study time period one additional year (through 1998).

Quality Assurance

This study protocol, any addenda to the protocol, data analyses, and a copy of the final report will undergo a Quality Assurance audit. Permanent records of all other data generated during the course of this study are subject to privacy and confidentiality considerations. All data gathered or generated including protocol addendum and the final report will be archived by the Medical Department, 3M Company, St. Paul,

Minnesota. Upon review and approval of the final report, study results will be communicated to the Decatur employees.

DISCUSSION

The purpose of this study is to examine the inpatient and outpatient medical claim event experience of Decatur chemical and film employees from January 1, 1993 through December 31, 1998. Since the writing of the original study protocol, software became available to also analyze claims data into episodes. The overall hypothesis is that the inpatient and outpatient claims event experience as well as the episode experience is comparable between employees of the 3M Decatur chemical and film plants who differ in their serum fluorochemical measurements by, on average, one order of magnitude, but do not differ in their access to the same medical care delivery system (i.e., the Decatur medical practices available to them). With the computerization of the Decatur work history database, we can also restrict the claims analysis to those chemical plant employees who have worked solely in the chemical plant for at least 10 years prior (starting 1/1/83) to the claims analysis time period in jobs that are considered to have the highest potential of exposure.

This claim event analysis can provide a much broader perspective of possible employee health outcomes than a retrospective cohort mortality study, especially in instances, such as this, where employees' serum fluorochemical exposure levels, based on findings from toxicology studies, would not suggest an increased risk for mortality. We can also address some questions of female chemical employees about the potential effect, if any, of placental transfer of their occupational-derived fluorochemical serum levels.

The CHS claims event data will allow for an evaluation of the claim events related to childbirth and the neonatal period. We are not certain whether the CCG episodes data will provide data regarding the neonatal period. The analysis of claims data is less subjective than direct employee interviews that would lack the extremely time-consuming validation of self-reports through a medical record review. The study design also maintains the confidentiality of employees' medical claims data.

There are several limitations that must be understood. First and foremost, an analysis of claims data should not be considered a study of risk (i.e., the probability of disease in an 'exposed' group compared to the probability of disease in an 'unexposed' group). Claims data should not be considered incidence or prevalence data. Rather, the study should be viewed as an analysis of the comparison of medical claim events between two populations (chemical and film). A claim does not mean that it represents an accurate diagnostic description of the reason for the hospitalization or the outpatient visit. As previously discussed, ICD-9 codes for outpatient claims may be related to the reason why a procedure was done, not because the diagnosis was made as the result of the procedure. The claims episodes data also does not provide information regarding incident risk. It may, however, provide a reasonable prevalence description during the six year time period. The employees' claim event and episode experience will only be examined for a recent 6 year time period at a chemical plant that began fluorochemical production in the early 1960's. It is not possible to conduct a comprehensive longitudinal analysis of claim events and episodes data. The study is also limited within the 6 year time frame as we can examine only for the existence of claims data for individuals who remain full-time active employees or are inactive employees between 1/1/93 and

12/31/98. The claim event and episode experience of employees who subsequently quit, terminated or transferred during the six years are not considered. Employees who are placed on LTD will likely only have claim events reported by CHS for the first 18 months as Medicare would then take over as the primary provider. Likewise claim event and episode experience of those individuals who retire and reach the age of 65 will likely not be observed as these individuals are primarily covered by Medicare. Part-time and summer employees as well as contractors' employees are not included in the analysis. Another limitation is the small size of the study population (total of 652 chemical and 659 film plant employees). The person-years will be further reduced by the exclusion of those employees who have chosen HMO coverage.

Despite the above shortcomings, this claim event and episode analysis can provide 3M Decatur employees a better perspective as to whether the health experience of chemical plant employees, as measured by the existence of CHS claims information, is significantly different than the claims experience of film plant employees. Additional investigations can be designed should there be significantly more observed than expected claims events and/or episodes for chemical than film plant employees for specific MDC, DRG, ICD-9 and CCG codes.

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