HMCS CHICOUTIMI Health Surveillance Study

Executive Summary

The fire onboard Her Majesty's Canadian Ship (HMCS) CHICOUTIMI on 5 October 2004 resulted in one death as well as smoke-related lung injuries in a number of the 56 surviving crewmembers. Initial medical assessments and care of the crew, as well as an environmental health and safety investigation of the submarine after the fire, was provided by Canadian Forces Health Services. Crewmembers received extra medical follow-up during the year after the fire, as well as additional post-deployment mental health screenings in early 2005. After that, the crew received regular care from their military and civilian primary health care providers.

This study identifies a number of health effects that were recorded in the military medical records of HMCS CHICOUTIMI crewmembers (CC) in the five years before the fire to the five years after the fire. These findings were then compared to those of a random group of unexposed Royal Canadian Navy submariners (Controls) for the same time periods. Similarly, the health of the Faslane Care & Custody Team (CCT) was included in the study as a second group of personnel who had possible exposure to the interior of the boat after the fire. Both the CCT and Controls received regular standard medical care during the study period with no additional medical screening.

Healthcare professionals, who were trained and monitored, conducted the medical records review. The data collection process by individual reviewers and between reviewers was checked for consistency and accuracy.

Results indicate that the short to medium term post-fire medical outcomes of the CC were different from the other two submariner groups. The significant findings included a number of health effects. For example, the CC had more blocks of sick leave of at least three days in length (SL) and were more likely to be limited in their ability to do their work (have medical employment limitations(s) or (MEL(s)). Indeed, the CC were medically unfit to go to sea on about 26% of their post-fire service days (due to either SL or MELs), compared to around 5% of the days for Controls.

Although low to begin with, the CCT had a higher rate of days in the “sick leave or any type of MEL” category than Controls, but there was no significant difference between the two in the number of days in the “lost to sick leave or Unfit Sub/Unfit Along-side MEL” category after the fire.

The medical cause most often associated with SL and MELs was psychiatric, both in terms of the percentage of the CC and the proportion of work days affected. Post Traumatic Stress Disorder (PTSD) was the most common new medical condition diagnosed. It was found in 60% of the CC and occurred at approximately 45 times greater rate than that found in unexposed Controls. New cases of depression were reported to have occurred after the fire in 15% of the CC, compared to 2% of the Controls.

The second most common medical condition among the CC after the fire was new onset breathing problems (asthma/reactive airways disease), occurring in 21%. This represented a 10 times greater rate than in Controls. Slight increases in muscle and joint/spine conditions were noted in the CC group but the numbers were not statistically different when compared to the Controls or the CCT.

There were no observed differences in the numbers of the above major health outcomes between the CCT and Controls.

As of 31 December 2009, over one third (35%) of the CC had been released from the CAF, which was similar to the number released in the Controls (34%). A larger number of the CC released medically, 12.5%, as compared with only 5.3% of the Controls. The 4.8% of the CCT who released was not statistically different from the Controls.

No cancers were reported in the CC or the CCT during the study period. As detailed in a previous report, it was felt unlikely that the CC exposure would increase their chances of developing cancer above that of Canadian general population background levels.[1]

Together the data and results identify, document, and provide insights into the short to medium term health effects associated with the HMCS CHICOUTIMI fire. The major medical conditions noted above were evident clinically and statistically, given the large proportion of members affected (effect size). Ongoing medical support and medical care of these submariners will occur through the usual health care systems (CF H Svcs clinics for CAF members and the provincial health care systems for those who have released), and the Veterans Affairs claims process.

As for further stages of the study, as outlined in two calculations[2,3] used to plan the study (statistical power calculations), making sound statistical conclusions about medical conditions that occur infrequently is limited by the small number of crew members. As more study subjects leave the military and transition to civilian medical care it will be more challenging, for a variety of reasons, to accurately count health outcomes from community medical records. This would make subsequent stages of the study less effective in providing follow-up to the CC or CCT. It is recommended that the medical monitoring of key outcomes would be more effectively done through the now established Canadian Forces Cancer and Mortality Study II[4], which is based on the most complete data sources for this information.

[1] Tsekrekos, S., Lalonde, J.D., HMCS CHICOUTIMI Fire Incident of 5 October 2004 Potential Chemical Exposures and Health Consequences, 16 June 2008.
[2] Tsekrekos, S., Power Calculations for Health Outcomes of Interest in the HMCS CHICOUTIMI Cohort, Directorate of Force Health Protection (DHFP)-CF Health Services Group, March 2009.
[3] Whitehead, J., Feasibility of Mortality Surveillance of the Chicoutimi Crew, DFHP, CF Health Services Group, October 2008.
[4] Conducted in collaboration with Veterans Affairs and Statistics Canada.

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1.0 Introduction

The 5 October 2004, fire on the HMCS CHICOUTIMI resulted in one fatality and several smoke inhalation injuries among the 56 surviving crewmembers. Following the fire, Canadian Forces Health Services supported the initial medical care of the crew, as well as an environmental health and safety investigation of the submarine at port in Faslane, Scotland.

Upon returning to Canada, the HMCS CHICOUTIMI crew (CC) was subject to extensive medical follow-up as a cohort, until approximately one-year post-fire. Additionally, they received enhanced post-deployment mental health screening in early 2005. After that the CC was supported medically through their military and civilian primary health care providers.

The investigation of the fire involved experimental re-creation of the fire scene by the National Research Council of Canada to help better understand the exposures involved. During this time, concern built among the crew about the health consequences of the incident. In 2008, with the support of the Surgeon General and the Clinical Council, the Canadian Forces Health Services Group (CF H Svcs Gp) committed to this research study which included a health status report of the crew.

Following an ethics board review and the approval of the Directorate of Access to Information & Privacy, the HMCS CHICOUTIMI Health Surveillance Study commenced in 2010.

This study compares health indicators extracted from the military health files of the 56 affected CC in the five years preceding the fire to the five years after the event, to that of a randomly selected group of unexposed Royal Canadian Navy submariners (Controls) for the same time periods. Similarly, the health of the Faslane Care & Custody Team (CCT), who used personal protective equipment and tended the submarine after the incident, were included in the study as a second group of potentially exposed personnel. The CCT and Controls did not receive enhanced medical screening (as did the CC group) after the fire.

The resulting data were analyzed to provide insights into the health effects associated with the fire. In addition to the identification, documentation, and analysis of the early and medium-term health effects to guide care, this report provides a foundation to guide decisions regarding future studies on the potential health effects of the fire.

2.0 Methods

2.1 Study Design

The HMCS CHICOUTIMI Health Surveillance Study was a retrospective cohort study that used existing Canadian Armed Forces (CAF) medical records to develop subject-specific data. Medical and ancillary data included for consideration in the study covered the time period from a subject's enrolment in the CAF through to 31 December 2009 or the subject's release date if earlier.

2.2 Subjects

The 250 subjects enrolled in the study were active serving male members on the date 5 October 2004. There were three cohorts in the study:

- the HMCS CHICOUTIMI crew (CC, n = 56);
- the Faslane Care & Custody Team (CCT, n = 42); and
- the unexposed control submariners (Controls, n = 152).

Subject selection is summarized in Figure 1.

2.2.1 HMCS CHICOUTIMI Crew

There were 56 surviving CC on board the HMCS CHICOUTIMI after the fire, and all were included in the study.

2.2.2 Faslane Care & Custody Team

While the study was being planned, a request was made to include the 42 members of the CCT as a population of interest. Members of this team worked in the smoke-damaged HMCS CHICOUTIMI after it returned to port in Faslane, Scotland. While aboard the submarine, they wore a personal protective ensemble. The list of these individuals was provided to the Occupational Medicine Specialist (OHS) by the leadership of the CCT.

2.2.3 Control Submariners

The Controls were selected as a non-exposed comparison group. To identify individuals for possible inclusion, DND Human Resources Information Centre (HRIC) provided a list of submariners who satisfied the following inclusion criteria:

- male;
- completed the CAF Submarine Basic Qualification Course (AILS) prior to 5 October 2004; and
- were actively serving as a Regular Member in the CAF as of 5 October 2004.

Personnel in the CC and CCT were then removed from this list. There were 287 remaining eligible participants, of which 168 were randomly selected to achieve a 3:1 ratio with the CC.

The Personnel Access Support System Verification of Former Service (PASS-VFS) detailed report was reviewed for each selected submariner to confirm that they were actively serving as of 5 October 2004. Twenty-two were not and were removed from this cohort, to be replaced by 22 individuals randomly selected from the remaining 119 eligible subjects. All of these members were serving as of 5 October 2004.

Upon completion of the data collection, the data fields related to sick leave (SL) and medical employment limitation(s) (MEL(s)) were reviewed. Fifteen of the 168 Controls were either on SL or had a MEL that included "unfit sub" or "unfit sea". The intent was for the Controls to be comprised of submariners who could have been on HMCS CHICOUTIMI at the time of the fire, but were not posted to that boat. Being on SL or having a MEL that precluded service on submarines would have made these 15 submariners dissimilar to the CC in this regard (all of whom were fit to go to sea as of 5 October 2004). Hence, it was decided to exclude these individuals from further analyses. Additionally, one Control subject was subsequently found to have a 2003 release date, and was excluded from the analyses, leaving a final number of 152 Controls.

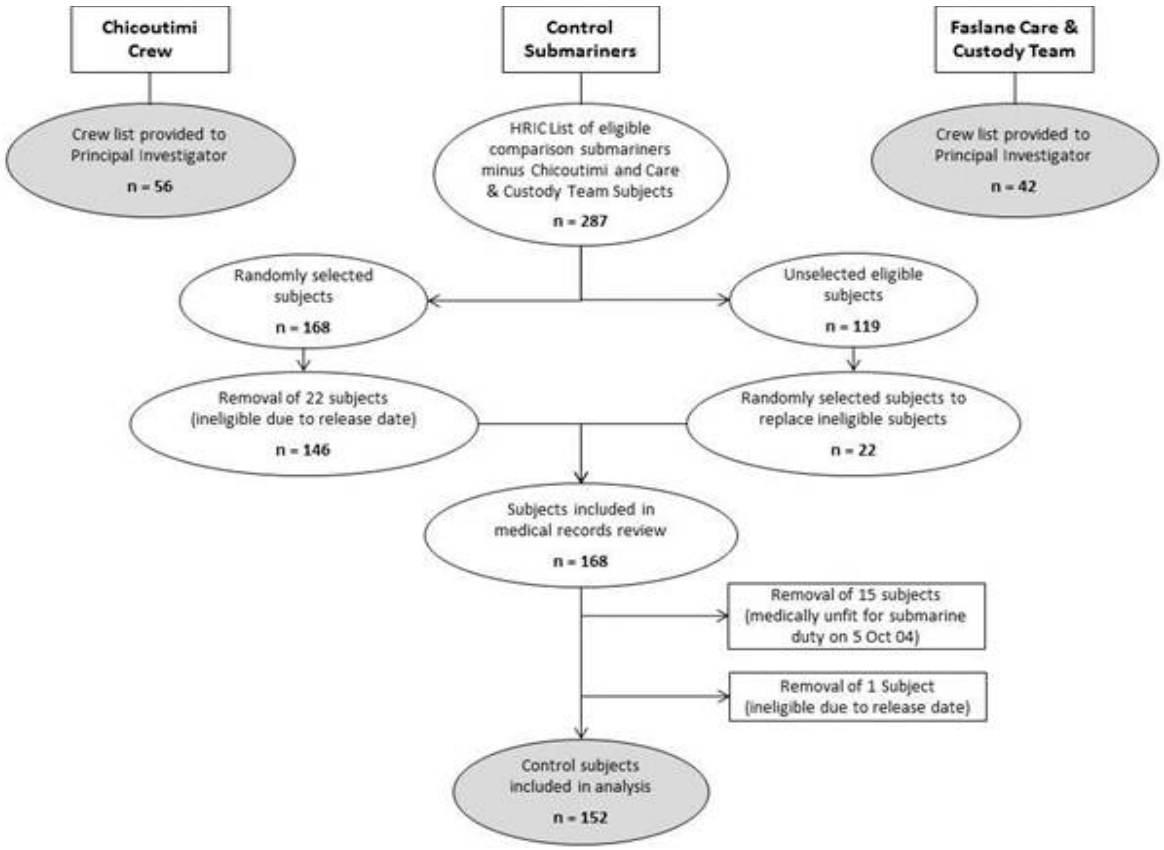


Figure 1: Control submariners' selection process. A total of 250 subjects made up the study groups. HRIC = Human Resources Information Centre.

2.3 Data sources

2.3.1 Medical Records

During the period of data collection, up to 31 December 2009, the CAF was transitioning to an electronic medical record, Canadian Forces Health Information System (CFHIS). However, as the CFHIS did not, at this time, contain information in addition to what was available in paper records, it was not used. Thus, the primary source of medical information was the paper-based medical record (CF2034) for each member. The information found in the CF2034 was supplemented by additional sources as described below.

2.3.2 PASS-VFS

For each subject, a PASS-VFS detailed report was generated via online access to the DND PASS-VFS database. This report was used to extract and enter into the study data collection form:

- Date of birth;
- CAF enrolment date;
- CAF release date (if released);
- Release item (if released);
- Rank; and
- Posting history.

2.3.3 Pharmacy Profile

A pharmacy profile was generated for each subject by D Med Pol personnel. It summarized all medications dispensed from CAF pharmacies to the subject, and included the ATC Level 1 (categorical information for the medication, e.g., cardiovascular system, respiratory system, etc.), medication name, and medication dosage. Dispensed medications were cross-referenced against date dispensed, with results divided into a pre-fire time period (the year preceding 5 October 2004) and a post-fire time period (one-year intervals from 5 October 2004 through to 31 December 2009).

2.3.4 HMCS CHICOUTIMI Fire Board of Inquiry

The HMCS CHICOUTIMI Fire Board of Inquiry report provided crewmember locations at the time of the onset of the fire (Annex F: Location of crew when fire erupts, in the Board of Inquiry report). This information was summarized into a spreadsheet with the following information for each of the CC: deck level (i.e., 1-deck, 2-deck), fore/aft location (i.e., aft of bulkhead 56, between bulkhead 56 and bulkhead 35), and specific compartment (i.e., control room, bunk space).

2.3.5 Faslane Care & Custody Team Arrival and Departure dates

The CCT list also included the dates that team members arrived in and departed from Faslane. These data were included in the study data collection form (discussed below).

2.4 Data Collection Form

Data from the above-listed sources were entered into an interactive PDF form. The form contained various types of data fields: date, numeric, text, drop-down lists, and radio buttons. See Annex A for a complete list of the data fields in the form. All completed forms were provided to the OHS, who extracted data into a spreadsheet for analysis.

The form was divided into three main sections:

- Baseline: demographic and medical information for all subjects from enrolment in the Regular Force until the date of the HMCS CHICOUTIMI fire (5 October 2004);

- CC, immediate fire aftermath: information related to the fire on board HMCS CHICOUTIMI up until the end of crewmembers' initial medical assessment in Faslane, Scotland; and

- Post-fire: demographic and medical information for all subjects from 5 October 2004 until 31 December 2009 (or the date of release from the CAF).

2.5 File Review process

2.5.1 Overview

Medical records and ancillary information (described in section 2.3) were reviewed and extracted by nurses who entered data into the collection forms. Three nurses served as file reviewers over the course of the data collection phase.

2.5.2 File Reviewer Training

Each file reviewer received training on the use of the data collection form, including the type of information to be collected and how it was to be entered into the form. They were also provided with an instruction manual, which they read before commencing reviews. The manual provided instructions on how to complete the data fields, inclusion and exclusion criteria, decision rules, and examples.

Reviewers started reviewing files under the direct oversight of the OHS. Once the reviewers developed sufficient competency, they reviewed files without direct oversight. The initial forms that were completed "unsupervised" were reviewed separately by the OHS, who compared the form contents to the source documentation in order to verify accuracy and completeness. Any errors or omissions in the file reviewer's data collection form were corrected by the OHS. Feedback was provided to the reviewers as necessary.

Once satisfied with the reviewer's performance, the OHS ceased performing the thorough "double-check" of the file reviewer's work. At this point, they were considered "trained" and would continue with the data collection work independently. To reach the "trained" status, file reviewers needed to complete approximately ten data collection forms (i.e., the review of medical and ancillary documentation of ten subjects).

Throughout the course of the data collection phase, the work of the research staff was reviewed by the OHS in order to verify accuracy and completeness. This was accomplished through the use of "validation files", which are described in more detail in section 2.5.4.

2.5.3 Medical Records Review Procedure

Before commencing data collection, the OHS prepared the following documentation for use by the file reviewers:

- PASS-VFS detailed report for each subject;
- pharmacy profile for each subject;
- CC location spreadsheet;
- CCT list with arrival and departure dates; and
- a master list, containing subject name, Service Number, and a unique six-digit subject study identification number.

Medical records were ordered in small batches from their source locations and delivered to CF H Svcs Gp HQ, where the review work was done. Subjects were distinguished on the data collection form by their unique six-digit subject study identification number. Data collection forms did not contain subject name or Service Number and were therefore "anonymized".

Due to the nature of the contents of the medical records and the need to abstract specific information regarding the HMCS CHICOUTIMI fire events, file reviewers could not be blinded to subject status (i.e., CC, Controls, or CCT).

2.5.4 Validation Files

To assess inter-reviewer agreement and to monitor file reviewer performance, 5% of subject files (13 subjects in total) were used as validation files.

Each validation file was reviewed by all three file reviewers and the OHS. After the first file reviewer had completed the review of the subject file, it would then be identified as a validation file (the initial reviewer was unaware that the file they were reviewing was going to be used for validation purposes). The same file would then be reviewed by the remaining two reviewers as per any other subject file, with completed data collection forms sent to the OHS. Although the

first reviewer was blinded to the fact that the data collection form they were completing would be evaluated, the second and third reviewers were not blinded.

After all three reviewers had processed the validation file, the OHS reviewed the validation subject's medical records, any ancillary information, and then completed a data collection form. The OHS's form served as the standard for comparison to the data collection forms completed by the three file reviewers for the same subject. The performance of the three file reviewers, as compared to each other and the standard was evaluated by the OHS. Identified inaccuracies or omissions were cross-referenced against source documents to verify the assessment. The OHS provided feedback to individual reviewers regarding their performance after the completion of each validation file.

Validation files were randomly selected over the course of the data collection phase and included five CC, six Controls, and two CCT. Two file reviewers were the initial reviewer on four occasions, and one file reviewer was the initial reviewer on five occasions.

With all reviewers and all validation files considered, the average file reviewer accuracy was 93.3% (range: 87.1% to 98.8%). With respect to inter-reviewer agreement: complete agreement (for a particular data field, all three file reviewers entered the same information) occurred 73.1% (range: 58.3% to 86.1%) of the time; two-thirds agreement (for a particular data field, two file reviewers entered the same information while the third file reviewer entered different information) occurred 26.1% (range: 14.0% to 41.4%) of the time; and no agreement (for a particular data field, all three file reviewers entered different information) occurred 0.8% (range: 0% to 2.3%) of the time. Further details regarding the methods and results of the validation file analysis can be found in Annex B.

2.5.5 Data Collection Timelines

Medical and ancillary record review and data abstraction started 25 August 2010 and was completed on 9 January 2012.

Reviewer 1 worked from 25 August 2010 to 16 December 2011 and completed data collection forms for 101 subjects (not including validation files).

Reviewer 2 worked from 25 January 2011 to 22 December 2011 and completed data collection forms for 67 subjects (not including validation files).

Reviewer 3 worked from 4 April 2011 to 9 January 2012 and completed data collection forms for 58 subjects (not including validation files).

The OHS completed data collection forms on 24 subjects including those used for validation purposes.

When all work days are considered, and work absences due to vacation or illness are included, file reviewers completed an average of 1.5 to 1.8 subject data collection forms per week (including validation files).

2.6 Data Processing and Analysis

2.6.1 Demographic Information

Enrolment and release dates were based on CAF Regular Force service. Reserve service before enrolment in the Regular Force was not included in calculations of years of service. The vast majority of subjects who released from the Regular Force transferred to the Reserve Force or the Supplementary Reserve. For most subjects, medical records were only available up until the date of release from the Regular Force. Three Controls, however, had continued postings and medical records post Regular Force release while serving as Reservists. For these three subjects, post-release service was counted towards their total Regular Force service duration. These subjects were classified as "currently serving" despite their Regular Force release.

Subjects actively serving as of 31 December 2009 in the Regular Force were classified as "currently serving". Subjects, who had released from the Regular Force (with the exception of the three Controls described above), were classified as "released".

For comparison between groups, dates (e.g., date of birth, enrolment date, etc.) were expressed as the year with a two-digit decimal, with the numbers to the right of the decimal representing the proportion of a complete year. Rank was categorized as either Junior NCO (Able Seaman/Private to Master Seaman/Master Corporal), Senior NCO (Petty Officer 2nd Class/Sergeant to Chief Petty Officer 1st Class/Chief Warrant Officer), or officer (Naval Cadet/Officer Cadet to Captain(N)/Colonel).

Subject posting history was categorized as either "submarine," "ship", or "other" by the OHS. The amount of time spent at sea could not be determined from the available data. Submarine postings included Victoria and Oberon-class submarines.

Release items were categorized as "medical release" (Release item 3A or 3B) or "other" (the only non-medical release designations were: 4A, 4B, 4C, 5A, and 5C).

Body Mass Index (BMI) was calculated by dividing a subject's weight in kilograms by the square of their height in metres. BMI was categorized as follows: normal weight (BMI = 18.5 to 24.9), overweight (BMI = 25.0 to 29.9), and obese (BMI = 30.0 or greater).

2.6.2 Sick Leave and Medical Employment Limitations

SL variables captured included: the SL reason (i.e., diagnosis or medical procedure), diagnostic category (selected from a drop-down list), SL start date, and SL duration in days. Temporary (Temp) MEL variables included: limitation description (e.g., "light-duties," "unfit sea," "no heavy lifting", etc.) and reason for limitation (i.e., diagnosis or medical procedure), start date of TempMEL, and TempMEL duration in days. Permanent (Perm) MEL variables included: limitation description (e.g., "light-duties", "unfit sea", "no heavy lifting", etc.) and reason for limitation (i.e., diagnosis or medical procedure) and start date of PermMEL.

Medical record documentation for SL and MELs differed with respect to how diagnosis/reason was recorded. For SL, the clinician would identify the diagnostic category that necessitated the SL. In the data collection form, the file reviewer simply had to select the corresponding SL diagnostic category from the drop-down list. For MELs, however, the clinician would often document all current active diagnoses, and not necessarily identify the specific diagnosis that necessitated the MEL. In the data collection form, file reviewers abstracted the diagnoses listed in the medical records for the MEL into a text field. During the analysis, the OHS reviewed the MEL text fields and chose a diagnostic category, often relying on supporting information (e.g., medical history text fields) to make this determination. The same diagnostic categories were used for both SL and MELs: cardiovascular; ear, nose, and throat (ENT); endocrine; gastrointestinal; malignancy; musculoskeletal (MSK); neurological; psychiatric; respiratory; urological; other; and, unknown.

Only SL or MELs lasting at least three days were included in the data collection form. SL and MEL durations were based on calendar days. SL and MEL information was captured in either the Baseline or Post-Fire sections of the data collection form, depending on the start date of the SL or MEL; start dates that preceded 5 October 2004 were captured in the Baseline section, and start dates of 5 October 2004 or later were captured in the Post-Fire section.

The raw SL and MEL data were processed to create a database. Baseline information was divided into two time periods: within five years of the fire date (5 October 1999 to 4 October 2004) and greater than five years before the fire date (earlier than 5 October 1999). Analyses focused on the baseline "within five years" and post-fire time periods, so that time periods of similar duration pre- and post-fire were compared. SL or MEL entries that overlapped time periods due to a combination of the start date and duration were split so that the duration was allocated appropriately between time periods and truncated if they went beyond the observation period. For example:

- a 30-day SL that started on 30 September 1999 would be recorded in the analysis database as "baseline greater than five years before the fire date, start date 30 September 1999, duration five days", and "baseline within five years of the fire date, start date 5 October 1999, duration 25 days"; and,

- a 180-day TempMEL that started on 15 November 2009 would be recorded in the analysis database as "post-fire, start date 15 November 2009, duration 47 days" (duration truncated to the end of the study period, 31 December 2009).

Often, two dates were associated with PermMELs: the date that the treating clinician sent the subject's medical records to D Med Pol for review; and the date that D Med Pol officially assigned the PermMEL. In this circumstance, the earliest possible date was used. Almost all PermMELs were preceded by at least one TempMEL. If the TempMEL overlapped with the start date of the PermMEL, then the TempMEL was truncated as if it had ended on the day before the start date of the PermMEL.

For analyses, PermMELs were treated similarly to TempMELs, except that a duration value had to be assigned to the PermMEL. For post-fire PermMELs, the duration was calculated starting

from the start of the PermMEL and ending on the subject's release date. Four subjects (two Controls and two CCT) had PermMELs that started before the fire date, and all four had released by 31 December 2009. These baseline PermMELs were treated similarly to baseline TempMELs that overlapped with the post-fire time period. For example:

- a baseline PermMEL with a start date of 24 February 2004 and a subject release date of 22 September 2005, would be recorded in the analysis database as "baseline within five years of fire date, start date 24 February 2004, duration 224 days" (i.e., ending on 4 October 2004), and "post-fire, start date 5 October 2004, duration 352 days" (i.e., ending on the release date).

MELs were classified as follows:

- Unfit sea or submarine, and unfit alongside (UFS/UFA): the MEL description had to state explicitly "unfit alongside" or "unfit work in military environment";

- Unfit sea or unfit submarine (UFS): the MEL description had to state "unfit sea" (with either a statement of fit alongside or no mention of alongside fitness), "unfit submarine," "no deployment", "unfit operational environment", "unfit combat", "unfit field", or "draft ashore";

- Activity restrictions: essentially anything else that could have potentially limited day-to-day work activities in some way, such as "light duties", "unfit dive", "no drill or PT", "avoid heavy lifting", etc., but the subject was still "fit sea" or "fit sub";

- Other restrictions: these included noted limitations that likely would not have directly limited day-to-day work activities, such as "requires medical follow-up every two weeks";

- Unknown restrictions: no information on the type of restriction was provided in the data collection form; and

- TempMEL descriptions that were unlikely to have an operational impact (e.g., "avoid dehydration", "requires medical follow-up every 6 months", "requires maximum hearing protection", etc.) were not included in the database.

There were instances where SL overlapped with a MEL or a MEL of one type would overlap with another MEL type. A work restriction hierarchy was developed to avoid double counting days. It was, in order of severity, SL> UFS/UFA> UFS> activity restrictions> other restrictions. Where there was overlap, the higher severity work restriction took precedence. For example:

- if a subject had an UFS/UFA Temp MEL starting 5 July 2006 for a duration of 90 days and they also had a SL episode starting 1 August 2006 for 30 days, then this would be captured in the database as "SL, start date 1 August 2006, duration 30 days," and "TempMEL, UFS/UFA, start date 5 July 2006, duration 60 days" (i.e., the SL duration has been subtracted out of the MEL duration); and

- if a subject had an UFS TempMEL starting 1 January 2007 for 180 days, and also had two activity restriction TempMELs (one starting 30 March 2007 for ten days and another starting 15 June 2007 for 30 days), then this would be captured in the analysis database as "TempMEL, UFS, start date 1 January 2007, duration 180 days", and "TempMEL, activity restriction, start date 30 June 2007, duration 15 days".

In some cases, subjects had multiple contiguous TempMELs for the same medical condition. Frequently, these TempMEL time periods (as recorded in the medical records) would overlap or would not be exactly contiguous (i.e., the first 180-day UFS TempMEL would end five days before the second 180-day UFS TempMEL started). Instances of TempMEL overlap were treated as described previously. For instances where long duration TempMELs were not quite contiguous, the duration gap between the TempMELs was assumed to be also affected by a TempMEL (i.e., it was presumed that the MEL gap was an administrative one as opposed to the subject being unfit sea for six months, suddenly completely well for five days, and then unfit sea again for six months). Examples of how multiple contiguous TempMELs were entered into the analysis database are provided below:

- if a subject had an UFS/UFA TempMEL starting 1 January 2007 for 180 days and then a subsequent UFS/UFA TempMEL starting 5 July 2007 for 180 days for the same condition, this would be captured in the analysis database as "TempMEL, UFS/UFA, start date 1 January 2007, duration 365 days"; or

- if a subject had an UFS TempMEL starting 1 March 2006 for 90 days and then a subsequent UFS TempMEL starting 1 May 2006 for 90 days for the same condition, this would be captured in the analysis database as "TempMEL, UFS, start date 1 March 2006, duration 151 days" (i.e., the duration is 1 March 2006 to 30 April 2006 + 90 days).

The variable of interest for the SL and MEL analyses was duration in days. Duration was divided into diagnostic categories, and also by the type of work restriction (i.e., SL, UFS/UFA, UFS). For example, a subject who had a 30-day respiratory SL, a 14-day ENT activity restriction MEL, a 60-day respiratory UFS MEL, and a 90-day ENT UFS/UFA MEL could be summarized as follows:

- total restricted days (SL plus MEL) for respiratory and ENT was 90 days and 104 days, respectively, for an all diagnosis total of 194 days;

- the total SL days was 30 and total MEL days was 164; and

- the total days SL or UFS/UFA or UFS was 180.

To account for different lengths of service in the different time periods[6], the number of restricted days was divided by the total number of days that the subject served in the CAF during that time period. In this respect, for the baseline period (5 October 1999 to 4 October 2004) the total

[6]This was particularly important for the post-fire period because > one third of subjects released from the CAF before the end of the observation period.

possible number of days was 1827; while for the post-fire time period (5 October 2004 to 31 December 2009), it was 1913 days.

Only two subjects had enrolment dates that occurred after 5 October 1999 and their days served was based on enrolment date. For the post-fire period, the number of days served ranged from 23 days to 1871 days for the 89 subjects who released. Fourteen subjects released within one year of the fire date (i.e., released prior to 5 October 2005): three CC, four CCT, and seven Controls. Using this method, a subject with a specific number of restricted duty days could have a different estimate of proportional loss based on time served. For example, using 194 as the total restricted days (assuming that this was the post-fire time period), a subject would be restricted for:

- 53.2% of the time if released on 4 October 2005 (194 / 365 * 100 = 53.2%); and
- 10.1% of the time if still serving as of 31 December 2009 (194 / 1913 * 100 = 10.1%).

As mentioned above, the OHS reviewed the MEL text fields and assigned an appropriate diagnostic category, often relying on supporting information (e.g., medical history text fields) to determine the primary diagnostic category that necessitated the MEL. MELs were typically assigned a single diagnostic category, except where a dual diagnosis category was warranted because both conditions were active concurrently. In this case, the total number of MEL days was divided equally between the two diagnostic categories.

2.6.3 Medical History Text Field Diagnoses

The data form contained text fields that were used for the abstraction of medical history details. For the baseline and post-fire time periods, separate text fields were used to enter details of any respiratory, ear, nose and throat, cardiovascular, gastrointestinal, psychiatric, neurological, and "other" conditions. With the exception of the "other" text field, reviewers were instructed to capture information related to any condition that fell within the text field's diagnostic category. These included details such as diagnosis, pertinent dates, and additional relevant details related to treatment and condition severity. This information was found in and extracted from clinic notes (CF2016), consultation letters, and periodic medical evaluation notes.

For conditions other than respiratory, ear, nose and throat, cardiovascular, gastrointestinal, psychiatric, or neurological, the reviewer would judge whether to include information under "other" in the form. In this respect, the instruction was to exclude minor or self-limited one-time conditions; and to include conditions that were chronic or that occurred frequently, or were a significant isolated event (e.g., surgery, hospitalization, etc.).

The OHS compiled all of the subject medical history text fields across the different diagnostic categories and reviewed the captured information. The total number of words included in the baseline and post-fire medical history text fields was 113,015 and 80,862, respectively. Any misclassified diagnoses (e.g., "headaches" documented in the psychiatric text field instead of the neurological text field, or "pneumonia" documented in the "other" text field instead of the respiratory text field, etc.) were assigned to the correct diagnostic category by the OHS.

The OHS extracted information from the compiled post-fire medical history text fields into a database, which included diagnostic category (mirroring the diagnostic list used for SL and MELs), specific diagnosis, and whether or not the diagnosis was present in the baseline time period. With respect to the latter variable, for each post-fire diagnosis identified, the OHS cross-referenced the subject's corresponding baseline medical history information (from the date of enrolment to the date of the fire). If the post-fire diagnosis had not been documented in the baseline time period, then it was coded as a "new" post-fire diagnosis. If the post-fire diagnosis had been documented in the baseline time period, then it was coded as a pre-existing condition.

The OHS used judgment as to which diagnoses to include in the database. The intent was to include medical conditions that were significant or chronic/recurrent and to exclude minor self-limited conditions. For example, if a subject had a single documented headache, this would not be included in the database, but if a subject had recurrent migraine or cluster headaches, then this would be included in the database. Similarly, one or several self-limited upper respiratory tract infections (i.e., common cold) would not be included in the database, but asthma would be included.

Analysis of the medical history text fields does not necessarily provide a complete picture of all medical conditions present. Some chronic conditions, such as hyperlipidemia or hypertension, might not have been documented (for various reasons) by clinicians. Similarly, conditions identified in laboratory reports (e.g., micro-hematuria or proteinuria, etc.) might not have been included in written clinical notes.

2.7 Statistics

Statistical analyses were restricted to demographic variables and selected health outcomes. Pair-wise comparisons for continuous variables were done using an independent sample T-test, and categorical variables were compared using a Chi square test. The threshold for statistical significance was a P value of 0.05. SPSS software was used for the majority of analyses. Stata version 11 was used to compute incidence rates and their corresponding confidence intervals as well as the incidence rate ratios (IRR), which were estimated using Poisson's regression models.

3.0 Results

3.1 Demographics

Table 1 shows demographic data for the three groups (CC, CCT, and Controls). Although not statistically significant, CC tended to be: younger, with fewer years of service (as of 5 October 2004), were more likely to be junior NCOs, were more likely to be currently smoking, and had a lower BMI rate of obesity.

With respect to postings, CC had served for significantly more time on submarines than Controls ($p=<0.01$), and these postings made up a significantly greater proportion of their total posting time (compared to Controls and CCT; $p=0.002$ and $p=0.04$, respectively).

Table 1: Demographic comparison between subject groups

	CC	Controls	CCT
n	56	152	42
Age as of Fire Date (s.d.)	37.0 (5.5)	38.0 (5.6)	38.8 (6.0)
Age at Enrolment (s.d.)	20.3 (2.3)	20.2 (2.3)	20.9 (3.1)
Years of Service as of Fire Date	16.8 (5.5)	17.8 (5.7)	18.0 (6.0)
Rank as of Fire Date			
Jr NCO, n (% of total n)	33 (58.9%)	66 (43.4%)	18 (42.9%)
Sr NCO, n (% of total n)	15 (26.8%)	55 (36.2%	15 (35.7%)
Officer, n (% of total n)	8 (14.3%)	31 (20.4%)	9 (21.4%)
Smoking status as of Fire Date			
Never Smoker, n (% of total n)	24 (42.9%)	60 (39.5%)	18 (42.9%)
Current Smoker, n (% of total n)	21 (37.5%)	48 (31.6%)	12 (28.6%)
Ex-Smoker, n (% of total n)	11 (19.6%)	44 (28.9%)	12 (28.6%)
BMI as of Fire Date			
BMI (s.d.)	28.2 (4.3)	28.8 (4.0)	30.3 (4.5)
Normal Weight, n (% of total n)	14 (25.0%)	23 (15.1%)	5 (11.9%)
Overweight, n (% of total n)	25 (44.6%)	72 (47.4%)	13 (31.0%)
Obese, n (% of total n)	17 (30.4%)	57 (37.5%)	24 (57.1%)
Postings*			
Total Career Posting Time, years (s.d.)	21.2 (5.2)	22.1 (5.3)	22.0 (5.3)
Total Sub Postings, years (s.d.)	**8.6 (4.8)****	**6.9 (3.9)****	7.5 (5.0)
Total Ship Postings, years (s.d.)	3.8 (3.5)	4.9 (4.1)	3.8 (3.4)
Total "Other" Postings, years (s.d.)	8.8 (4.3)	10.3 (4.5)	10.7 (4.9)
Sub Postings, % of Total Posting Time (s.d.)	**40.2 (20.8)****	**31.7 (17.1)****	32.8 (18.9)
Ship Postings, % of Total Posting Time (s.d.)	18.6 (16.4)	21.7 (16.5)	18.9 (17.1)
"Other" Postings, % of Total Posting Time (s.d.)	41.3 (16.4)	46.7 (16.2)	48.2 (16.2)
Service Status as of 31 December 2009			
Currently Serving, n (% of total n)	36 (64.3%)	101 (66.4%)	24 (57.1%)
Released, n (% of total n)	20 (35.7%)	51 (33.6%)	18 (42.9%)

Notes: s.d. = standard deviation. Fire Date = 5 October 2004

* Average posting time expressed in years and as a percentage of total posting time, including all subjects.

** CC vs. Controls, p< 0.01

Table 2 shows that as of 31 December 2009, over one third (35%) of the CC had been released from the CAF, which was similar to the number released in the Controls (34%). A significantly larger number of the CC released medically, 12.5% (95% CI: 5.2, 24.1), as compared with only 5.3% (95% CI: 2.3, 10.1) of the Controls (p=0.04). The percentage of the CCT who released medically, 4.8% (95% CI: 0.6,16.1) was not statistically significantly different than the Controls (p=0.90).

Table 2: Comparison of currently serving and released subjects as of 31 December 2009

	CC	Controls	CCT
Currently Serving	36	101	24
Years of Service (s.d.)	20.1 (4.4)	21.4 (5.5)	20.3 (5.7)
Total in Each Cohort	56	152	42
Released (% of Total)	20(36%)	51(34%)	18(43%)
Years of Service (s.d.)	23.3 (6.0)	23.7 (4.7)	24.3 (3.8)
Date of Release (s.d.)	2007.9 (1.5)	2007.6 (1.4)	2007.2 (1.1)
Age at Release (s.d.)	43.1 (6.2)	43.9 (4.9)	45.3 (5.0)
Medical Release (% of Total)	7 (12.5%)*	8 (5.3%)*	2 (4.8%)
Non-Medical Release (% of Total)	13 (23.2%)	43 (28.3%)	16 (38.1%)

*p= 0.04 CC vs Controls

3.2 Sick Leave and Medical Employment Limitations

Table 3a summarizes the frequency of SL or MELs (all types included versus UFS or UFA only), all diagnostic categories combined, by group, and time period, with baseline referring to the pre-fire period. Roughly 45% of members in all three subject groups had no documented SL over the study periods. Post-fire, the CC had 37.5% of its members recorded as having new SL, as compared to the 18.4% for Controls; 28.6% of the CCT had new SL during this time. The number of subjects in each group with new post-fire MEL's, all types included, was the same as that of SL, except the CCT who had three fewer members affected post-fire. Post-fire, 50% of the CC had new MELs UFS or UFA only, as compared to 17.8% of the Controls; the CCT had 16.7% of their members in this category.

Table 3a: Subjects with Sick Leave and Medical Employment Limitations at baseline and in the five years post-fire, all diagnostic categories combined

Condition	Baseline	Post-Fire	CC (n = 56)	Controls (n = 152)	CCT (n = 42)
Sick Leave	No	No	25 (44.6%)	70 (46.1%)	19 (45.2%)
	No	Yes	21 (37.5%)	28 (18.4%)	12 (28.6%)
	Yes	No	3 (5.4%)	30 (19.7%)	9 (21.4%)
	Yes	Yes	7 (12.5%)	24 (15.8%)	2 (4.8%)
MELs (all types included)	No	No	5 (8.9%)	38 (25.0%)	9 (21.4%)
	No	Yes	21 (37.5%)	28 (18.4%)	9 (21.4%)
	Yes	No	4 (7.1%)	25 (16.4%)	7 (16.7%)
	Yes	Yes	26 (46.4%)	61 (40.1%)	17 (40.5%)
MELs (UFS or UFA only)	No	No	18 (32.1%)	93 (61.2%)	24 (57.1%)
	No	Yes	28 (50.0%)	27 (17.8%)	7 (16.7%)
	Yes	No	1 (1.8%)	12 (7.9%)	5 (11.9%)
	Yes	Yes	9 (16.1%)	20 (13.2%)	6 (14.3%)

In Table 3b, composite baseline is defined as a member who had a condition in the baseline period, plus those who had the conditions in both the baseline and post-fire periods. Composite post-fire was defined as those who had a condition post-fire, plus those who had the condition of interest both in the baseline and post-fire periods. The number of Controls with composite post-fire SL (34.2%) was very similar to the number of them who had composite baseline SL (35.5%). The number of CCT subjects with composite SL in the post-fire period (33.4%) was slightly greater than the number of them who had composite baseline SL (26.2%). In contrast, 50.0% of CC subjects had composite post-fire SL (50.0%) as compared to composite baseline SL (17.9%) and the 32.2% difference was significant (CI: 15.7, 48.7, $p < 0.001$). Similar to SL, the CC had 30.4% more composite post-fire MELs, all types included, as compared to 2.0% for the Controls; the CCT had 4.7% more. Finally, the CC had 48.2% more composite post-fire MELs UFS or UFA only, as compared to 10% for the Controls; the CCT had 4.8% more members who had post-fire MELs UFS or UFA only.

Table 3b: Subjects with Composite Sick Leave and Medical Employment Limitations at baseline* and in the five years post-fire, all diagnostic categories combined**

Condition	Study Period	CC (n = 56)	Controls (n = 152)	CCT (n = 42)
Sick Leave	Baseline	10 (17.9%)	54 (35.5%)	11 (26.2%)
	Post-Fire	28 (50.0%)	52 (34.2%)	14 (33.4%)
MELs (all types included)	Baseline	30 (53.5%)	86 (56.5%)	24 (57.2%)
	Post-Fire	47 (83.9%)	89 (58.5%)	26 (61.9%)
MELs (UFS or UFA only)	Baseline	10 (17.9%)	32 (21.1%)	11 (26.2%)
	Post-Fire	37 (66.1%)	47 (31.0%)	13 (31.0%)

*Composite Baseline = condition baseline, plus condition baseline and post-fire
** Composite Post-fire = condition post-fire, plus condition baseline and post-fire

SL and MELs for all diagnostic categories were combined in Figure 2 (all MEL types) and Figure 3 (UFS or UFS/UFA). The proportion of subjects with either SL or MELs was roughly similar in the baseline and post-fire time periods when looking at the Controls or CCT subjects. However, for CC, there is a marked difference between the proportions of subjects with SL or MELs in the post-fire time period only (black bars) as compared to the baseline time period only (white bars).

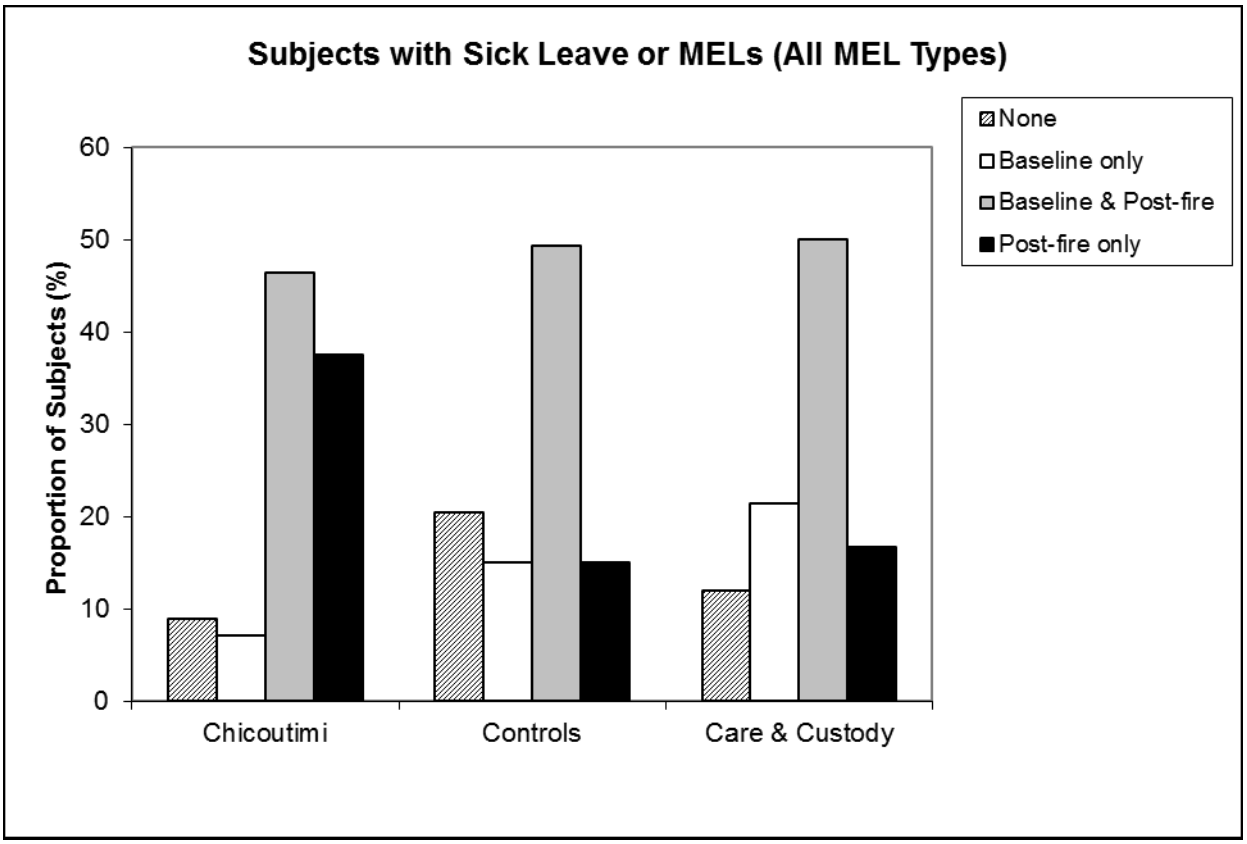


Figure 2: Subjects with either Sick Leave and Medical Employment Limitations, all types. The striped bars ("None") represent the proportion of subjects in a subject group that had no SL or MELs in both the baseline and post-fire time periods. The white bars ("Baseline only") represent the proportion of subjects in a subject group that either had SL, MELs, or both in the baseline time period, but not in the post-fire time period. The gray bars ("Baseline & Post-fire") represent the proportion of subjects in a subject group that were either on SL, MELs, or both in the baseline time period and the post-fire time period. The black bars ("Post-fire only") represent the proportion of subjects in a subject group that were either on SL, MELs, or both in the post-fire time period but not in the baseline time period.

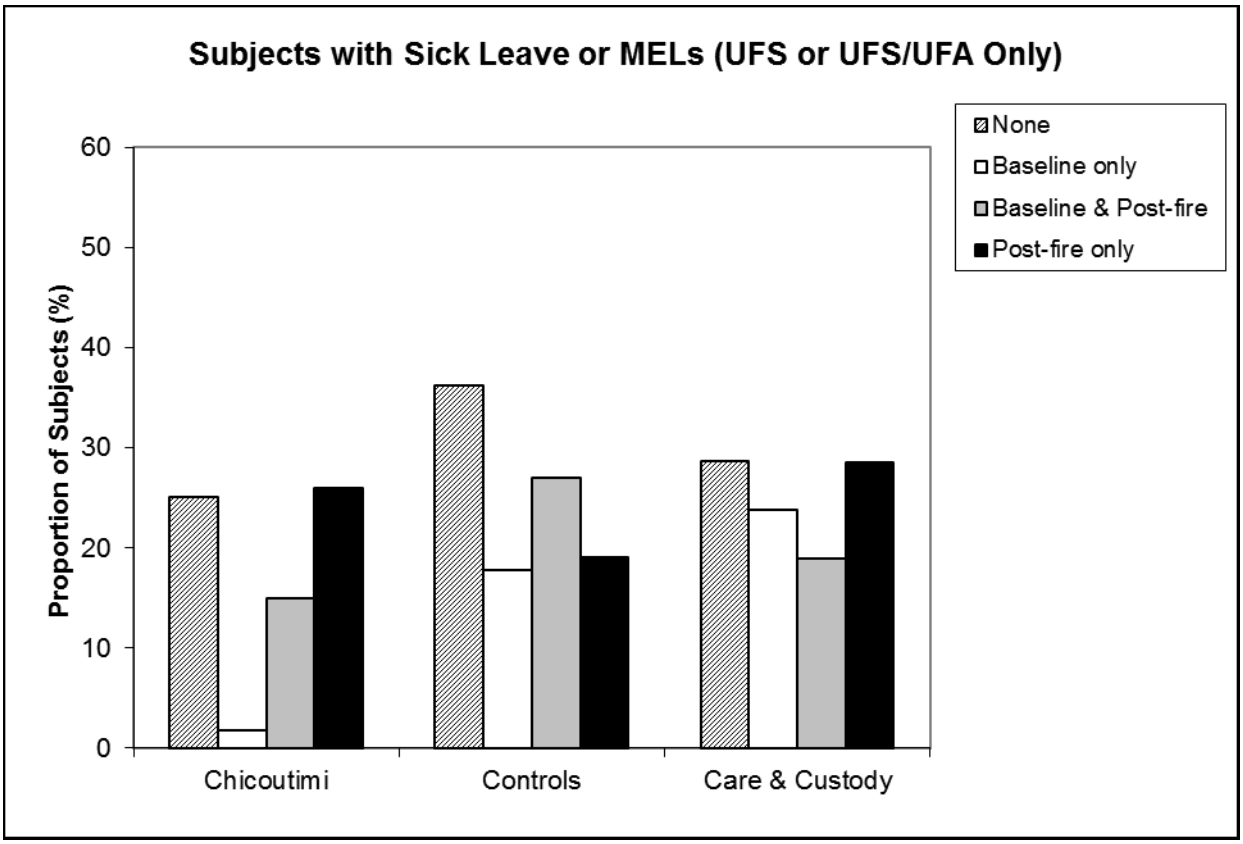
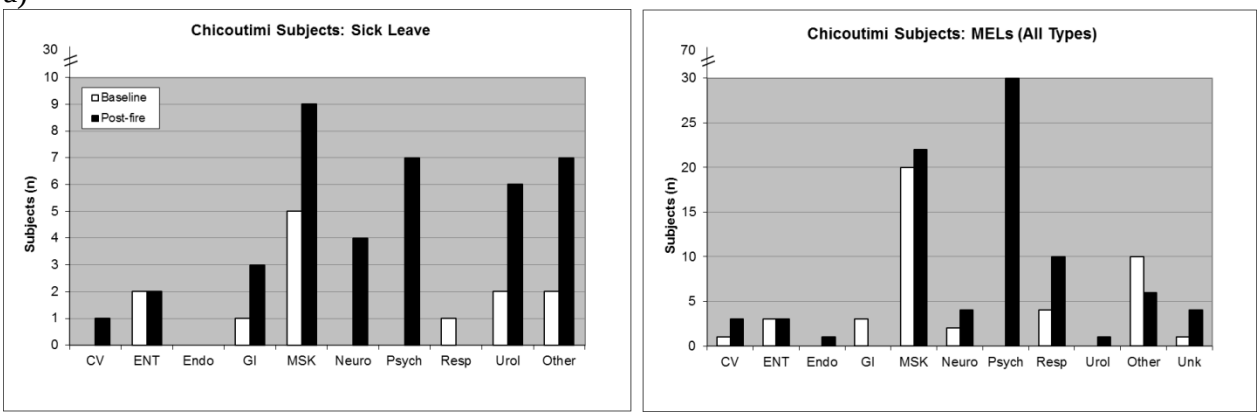


Figure 3: Subjects with either Sick Leave or Medical Employment Limitations, UFS or UFS/UFA only. See Figure 2 caption for an explanation of the different bars.

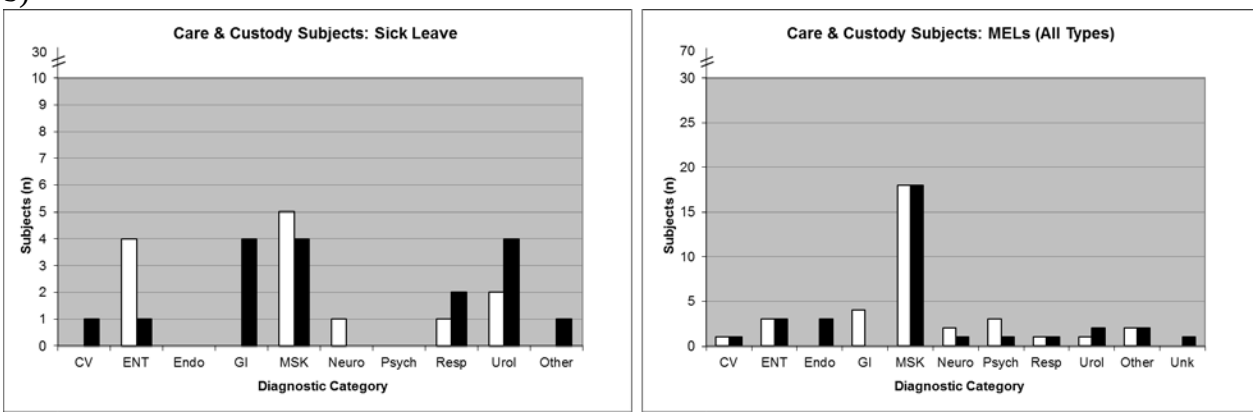
Figure 4 illustrates SL and MELs (all types) by diagnostic categories. In the baseline and post-fire time period musculoskeletal was the most common diagnostic category for the CCT. For Controls, there were more subjects with psychiatric MELs in the post-fire time period compared to the baseline time period (14 subjects versus three subjects). Among CC, there were substantial differences in baseline and post-fire SL results with the incidence of gastrointestinal, musculoskeletal, neurological, psychiatric, urological, and "other" diagnostic categories being higher in the latter period. For subjects with MELs, the most striking difference between the baseline and post-fire time periods for CC is for the psychiatric diagnostic category: no subjects in baseline versus 30 subjects post-fire. Musculoskeletal was the most common diagnostic category across all subject groups and time periods with the notable exception of the CC in the post-fire time period, where the most common diagnostic category was psychiatric. Among the CCT, there was an increase in SL for gastrointestinal diagnoses post-fire that accounted for 36% of sick days versus only 10.4% for Controls.

To simplify Figure 4, one Control subject with MELs in the post-fire period due to malignancy was not included.

a)



b)



c)

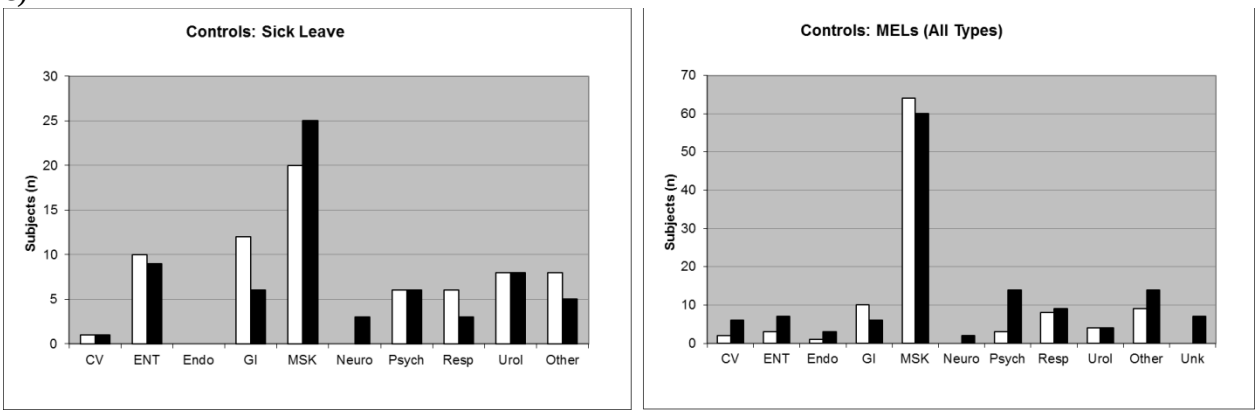


Figure 4: Number of Subjects with sick leave and medical employment limitations for a) CC, b) Controls, and c) CCT. White bars represent subjects with SL or MELs in the baseline time period and black bars represent subjects with SL or MELs in the post-fire time period. Individual subjects may have had SL or MELs for more than one type of diagnostic category in a given time period.

Table 4 shows SL and MELs as a percentage of total lost days in service. For cumulative SL in days (among all subjects in the group) for baseline and post-fire periods, the Controls had 908 days and 912 days, respectively, and the CCT had 146 days and 200 days, respectively. In contrast, the CC post-fire SL exceeded baseline SL by a factor of approximately ten (1953 days versus 175 days). Excluding the CC post-fire time period, the diagnostic category with the highest proportion of total SL days was musculoskeletal (42.7%). For the CC and during the post-fire period, the psychiatric diagnostic category accounted for 64.6% of total SL days.

Table 4: Total duration of sick leave and medical employment limitations by diagnostic categories, number of lost days and percentage of total lost days*

a) Sick Leave

	Baseline						Post-fire					
	CC n = 10		Controls n = 54		CCT n = 11		CC n = 28		Controls n = 52		CCT n = 14	
Diagnostic Category	Days	%	Days	%	Days	%	Days	%	Days	%	Days	%
All Diagnoses	175	100	908	100	146	100	1953	100	912	100	200	100
Cardiovascular	0	0	7	0.8	0	0	29	1.5	3	0.3	10	5.0
ENT	9	5.1	97	10.7	14	9.6	17	0.9	20	2.2	15	7.5
Endocrine	0	0	0	0	0	0	0	0	0	0	0	0
Gastrointestinal	14	8.0	205	22.6	0	0	38	1.9	95	10.4	72	36.0
MSK	113	64.6	357	39.3	52	35.6	240	12.3	400	43.9	75	37.5
Neurological	0	0	0	0	10	6.8	234	12.0	24	2.6	0	0
Psychiatric	0	0	82	9.0	0	0	1262	64.6	106	11.6	0	0
Respiratory	10	5.7	41	4.5	30	20.5	0	0	33	3.6	7	3.5
Urological	8	4.6	30	3.3	6	4.1	19	1.0	37	4.1	14	7.0
Other	21	12.0	89	9.8	0	0	114	5.8	125	13.7	7	3.5

b) MELs (All Types)

	Baseline						Post-fire					
	CC n = 30		Controls n = 86		CCT n = 24		CC n = 47		Controls n = 89		CCT n = 26	
Diagnostic Category	Days	%	Days	%	Days	%	Days	%	Days	%	Days	%
All Diagnoses	1851	100	6715	100	2857	100	25853	100	19945	100	5415	100
Cardiovascular	11	0.6	521	7.8	78	2.7	998	3.9	2255	11.3	1167	21.6
ENT	50	2.7	25	0.4	223	7.8	33	0.1	418	2.1	125	2.3
Endocrine	0	0	237	3.5	0	0	90	0.3	595	3.0	480	8.9
Gastrointestinal	24	1.3	232	3.5	132	4.6	0	0	302	1.5	0	0
Malignancy	0	0.0	0	0	0	0	0	0	570	2.9	0	0
MSK	957	51.7	4015	59.8	1396	48.9	3256	12.6	7921	39.7	3005	55.5
Neurological	141	7.6	0	0	295	10.3	1851	7.2	585	2.9	90	1.7
Psychiatric	0	0	420	6.3	450	15.8	14839	57.4	2893	14.5	30	0.6
Respiratory	187	10.1	805	12.0	36	1.3	4105	15.9	3741	18.8	106	2.0
Urological	0	0	91	1.4	180	6.3	451	1.7	176	0.9	262	4.8
Other	426	23.0	369	5.5	67	2.3	87	0.3	264	1.3	120	2.2
Unspecified	55	3.0	0	0	0	0	144	0.6	225	1.1	30	0.6

* The "n" values correspond to the number of subjects with the outcome of interest (SL or MELs) for each particular subject group and time period.

All groups had more MELs in the post-fire time period. This effect was most striking for the CC, with 25,853 MEL days post-fire compared to 1851 during baseline. The CC accounted for 29% of all subjects with post-fire MELs, and approximately 50% of post-fire MEL days. For the CC, more than 57% of CC post-fire MEL days were in the psychiatric diagnostic category. Other categories with increases in MEL's post-fire in the CC were cardiovascular, musculoskeletal, neurological, respiratory, and urological diagnostic categories.

SL and MEL (all types) days combined, expressed as a percentage of total service time in a given time period, are shown in Table 5a.

Table 5: Incidence of days lost to sick leave and medical employment limitations, per 100 service days (95% CI)

a) Sick Leave and MELs (all types)

Diagnostic category	Five years pre-fire						Five years post-fire					
	CC		Controls		CCT		CC		Controls		CCT	
All Diagnoses	2.0	(1.9, 2.1)	2.8	(2.7, 2.8)	3.9	(3.8, 4.1)	30.4	(30.1, 30.7)	8.5	(8.4, 8.6)	9.1	(8.9, 9.3)
Cardiovascular	0.01	(0.01, 0.02)	0.19	(0.17, 0.21)	0.10	(0.08, 0.12)	1.0	(1.0, 1.1)	0.81	(0.78, 0.85)	1.5	(1.5, 1.6)
ENT	0.06	(0.04, 0.07)	0.04	(0.04, 0.05)	0.35	(0.31, 0.40)	0.05	(0.04, 0.06)	0.18	(0.17, 0.20)	0.18	(0.15, 0.22)
Endocrine	- -	- -	0.09	(0.07, 0.10)	- -	- -	0.09	(0.07, 0.11)	0.21	(0.20, 0.23)	0.63	(0.57, 0.68)
Gastrointestinal	0.04	(0.03, 0.05)	0.16	(0.14, 0.17)	0.17	(0.14, 0.20)	0.04	(0.03, 0.05)	0.14	(0.13, 0.16)	0.09	(0.07, 0.12)
Malignancy	- -	- -	- -	- -	- -	- -	- -	- -	0.21	(0.19, 0.22)	- -	- -
MSK	1.1	(1.0, 1.1)	1.6	(1.5, 1.6)	1.9	(1.8, 2.0)	3.4	(3.3, 3.5)	3.0	(2.9, 3.1)	4.0	(3.9, 4.1)
Neurological	0.14	(0.12, 0.16)	- -	- -	0.40	(0.35, 0.44)	2.0	(2.0, 2.1)	0.22	(0.21, 0.24)	0.12	(0.09, 0.14)
Psychiatric	- -	- -	0.18	(0.17, 0.20)	0.59	(0.53, 0.64)	15.8	(15.6, 16.0)	1.1	(1.0, 1.1)	0.04	(0.03, 0.06)
Respiratory	0.19	(0.17, 0.22)	0.31	(0.29, 0.33)	0.09	(0.07, 0.11)	4.0	(3.9, 4.2)	1.4	(1.3, 1.4)	0.15	(0.12, 0.18)
Urological	0.01	(0.00, 0.02)	0.04	(0.04, 0.05)	0.25	(0.21, 0.28)	0.46	(0.42, 0.50)	0.08	(0.07, 0.09)	0.36	(0.32, 0.40)
Unspecified	0.05	(0.04, 0.07)	- -	- -	- -	- -	0.14	(0.12, 0.17)	0.08	(0.07, 0.09)	0.04	(0.03, 0.06)
Other	0.44	(0.40, 0.48)	0.17	(0.15, 0.18)	0.09	(0.07, 0.11)	0.20	(0.17, 0.23)	0.14	(0.13, 0.16)	0.17	(0.14, 0.20)

b) Sick Leave and MELs (UFS and UFS/UFA Only)

Diagnostic category	Five years pre-fire						Five years post-fire					
	CC		Controls		CCT		CC		Controls		CCT	
All Diagnoses	0.78	(0.72, 0.83)	1.4	(1.4, 1.5)	2.2	(2.1, 2.2)	25.9	(25.6, 26.2)	5.4	(5.3, 5.5)	5.5	(5.3, 5.6)
Cardiovascular	- -	- -	0.10	(0.09, 0.12)	- -	- -	1.0	(0.95, 1.1)	0.08	(0.07, 0.10)	0.01	(0.01, 0.02)
ENT	0.01	(0.00, 0.02)	0.04	(0.03, 0.05)	0.30	(0.26, 0.34)	0.02	(0.01, 0.03)	0.14	(0.12, 0.15)	0.07	(0.05, 0.09)
Endocrine	- -	- -	0.09	(0.07, 0.10)	- -	- -	- -	- -	0.09	(0.08, 0.11)	0.59	(0.53, 0.64)
Gastrointestinal	0.03	(0.02, 0.05)	0.10	(0.08, 0.11)	0.03	(0.02, 0.04)	0.04	(0.03, 0.05)	0.12	(0.10, 0.13)	0.09	(0.07, 0.12)
Malignancy	- -	- -	- -	- -	- -	- -	- -	- -	0.21	(0.19, 0.22)	- -	- -
MSK	0.36	(0.32, 0.39)	0.71	(0.68, 0.74)	0.95	(0.9, 1.0)	1.8	(1.8, 1.9)	1.9	(1.8, 1.9)	3.2	(3.1, 3.3)
Neurological	0.03	(0.02, 0.04)	- -	- -	0.05	(0.04, 0.07)	2.0	(1.9, 2.1)	0.22	(0.20, 0.24)	0.11	(0.09, 0.14)
Psychiatric	- -	- -	0.18	(0.17, 0.20)	0.59	(0.53, 0.64)	15.3	(15.1, 15.5)	1.0	(0.97, 1.1)	0.04	(0.03, 0.06)
Respiratory	0.12	(0.10, 0.15)	0.05	(0.04, 0.06)	0.04	(0.03, 0.06)	2.4	(2.4, 2.5)	0.87	(0.84, 0.91)	0.01	(0.00, 0.02)
Urological	0.01	(0.00, 0.02)	0.03	(0.03, 0.04)	0.25	(0.21, 0.28)	0.46	(0.42, 0.50)	0.07	(0.06, 0.08)	0.25	(0.22, 0.29)
Unspecified	0.05	(0.04, 0.07)	- -	- -	- -	- -	0.02	(0.01, 0.03)	- -	- -	- -	- -
Other	0.22	(0.19, 0.25)	0.14	(0.13, 0.15)	- -	- -	0.12	(0.10, 0.14)	0.11	(0.10, 0.13)	0.02	(0.01, 0.03)

During the five years preceding the fire, the CC spent 2.0% of all their service days on either SL or any type of MEL. Over the same time period, the Controls and CCT respectively spent 2.8% and 3.9% of their service days on either SL or any type of MEL (Table 5a). The incidence rate of days lost to SL or any type of MEL in the five years preceding the fire was 38% greater in Controls (IRR: 1.38; 95% CI: 1.32, 1.45) and 97% greater in the CCT (IRR: 1.97; 95% CI: 1.86, 2.08) compared to the CC. It should also be noted that the incidence rate of days lost to SL or any type of MEL in the five years preceding the fire was 42% greater in the CCT than in Controls (IRR: 1.42; 95% CI: 1.36, 1.48). All three of these differences were statistically significant at the 95% confidence level.

During the five years following the fire, the CC spent 30.4% of all their service days on either SL or any type of MEL. Over the same post-fire time period, the Controls and the CCT respectively

spent 8.5% and 9.1% of their service days on either SL or any type of MEL (Table 5a). The post-fire incidence rate of days lost to SL or any type of MEL was 258% greater in the CC than in Controls (IRR: 3.58; 95% CI: 3.52, 3.65). It should also be noted that the post-fire incidence rate of days lost to SL or any type of MEL was 7% greater in the CCT than in the Controls (IRR: 1.07; 95% CI: 1.04, 1.11). These two differences were statistically significant at the 95% confidence level.

Post-fire the primary diagnostic category for the CC was psychiatric with 15.8% of service days on either SL or a MEL (all types). Post-fire the CC had increases as compared to baseline in the percent of service days spent on SL and MEL (all types) in other diagnostic categories: cardiovascular (from 0.01 to 1.0), musculoskeletal (from 1.1 to 3.4), neurological (from 0.14 to 2.0), respiratory (from 0.19 to 4.0), and urological (from 0.01 to 0.46). Compared to the Controls, the post-fire percent of service days affected by SL or MEL (all types) for the CC were substantially greater for neurological (2.0 vs. 0.22), psychological (15.8 vs. 1.1), respiratory (4.0 vs. 1.4), and urological (0.46 vs. 0.08) categories.

Analyses were repeated using only MELs that specified "unfit sea" or "unfit sub" (UFS), or "unfit alongside" (UFS/UFA). These types of MELs are more significant than other types of MELs, such as activity restriction and are presented in Table 5b.

During the five years preceding the fire, the CC spent 0.78% of all their service days on either SL or UFS/UFA MELs. Over the same time period, the Controls and CCT respectively spent 1.4% and 2.2% of their service days on either SL or UFS/UFA MEL (Table 5b). The incidence rate of days lost to SL of UFS/UFA MEL in the five years preceding the fire was 85% greater in Controls (IRR: 1.85; 95% CI: 1.71, 1.99) and 183% greater in the CCT (IRR: 2.83; 95% CI: 2.60, 3.08) compared to the CC. It should also be noted that the incidence rate of days lost to SL or UFS/UFA MEL in the five years preceding the fire was 53% greater in the CCT than in the Controls (IRR: 1.53; 95% CI: 1.45, 1.62). All three of these differences were statistically significant at the 95% confidence level.

Indeed, the CC were medically unfit to go to sea on 25.9% of their post-fire service days (due to either SL or MELs), as compared to 5.4% of the days for Controls. Over the same time period, the CCT spent 5.5% of their service days on either SL or UFS/UFA MEL. The post-fire incidence rate of days lost to SL or UFS/UFA MEL was 379% greater in the CC than in Controls (IRR: 4.79; 95% CI: 4.69, 4.89). It should be noted that the incidence rate of days lost to SL or UFS/UFA MEL in the five years post-fire was not significantly different between the CCT and Controls (IRR: 1.01; 95% CI: 0.97, 1.05).

3.3 Medical History Text Field Diagnoses

Table 6 provides a summary of all post-fire medical conditions. It includes newly diagnosed and pre-existing conditions. Table 7 summarizes new diagnoses documented in the post-fire period.

For medical conditions newly diagnosed in the post-fire time period (i.e., "new" diagnoses; Table 7) PTSD stands out among the CC, i.e., 31/52 (60%) persons received this diagnosis, compared to 2/151 (1.3%) Controls (diff: 58.3%; CI: 44.8, 71.8). Similarly, 8/55 of the CC

were diagnosed with depression[7] in the post-fire period, compared to 3/151 Controls (diff: 12.5%; CI: 2.9, 22.1). Asthma or Reactive Airways Disease (RAD) was newly diagnosed in 21% (11/52) of the CC and 2.0% (3/148) of Controls (diff: 19.2%; CI: 7.9, 30.5). There were no new cases of malignancy in the CC or the CCT in the five year post-fire period, but there were two cases in the Controls.

Table 6: Medical history text field diagnostic summary for all post-fire diagnoses (including baseline pre-existing diagnoses)*

Diagnostic Category	CC (n = 56)		Controls (n = 152)		CCT (n = 42)	
	d	Most Common Diagnoses (D)	d	Most Common Diagnoses (D)	d	Most Common Diagnoses (D)
Cardiovascular	12	Hypertension (9)	21	Hypertension (16)	4	Hypertension (2)
ENT	27	Hearing loss (8) Tinnitus (7)	38	Hearing loss (10) Obstructive sleep apnea (8)	12	Hearing loss (4) Obstructive sleep apnea (4)
Endocrine	9	Hyperlipidemia (9)	34	Hyperlipidemia (27) Diabetes (6)	11	Hyperlipidemia (8) Diabetes (3)
Gastrointestinal	7	GERD (5)	29	GERD (16)	5	Inguinal hernia (2)
Malignancy	0		2		0	
MSK	24	Fracture, sprain, or tear (9) Mechanical low back pain (6)	71	Mechanical low back pain (25) Fracture, sprain, or tear (16)	19	Mechanical low back pain (7), fracture, sprain, or tear (5)
Neurological	10	Headaches, recurrent (4)	5	Headaches, recurrent (3)	3	Headaches, recurrent (2)
Psychiatric	60	PTSD (35) Depression (9) Alcohol dependence or abuse (5) Adjustment disorder (4) Anxiety disorder (4)	32	Adjustment disorder (7) Depression (4) Alcohol dependence (4) PTSD (3)	8	Panic or anxiety disorder (2)
Respiratory	24	Asthma or RAD (15) COPD or bronchitis (3)	10	Asthma or RAD (7)	4	Asthma or RAD (2)
Urology	5	Hematuria or proteinuria (4)	10	Nephrolithiasis (4) Hematuria (2) Prostatitis (2)	2	
Other	9	Skin conditions (5) Blood conditions (3)	17	Blood conditions (5) Skin conditions (4) Eye conditions (3)	2	

* Each subject group has two columns, "d" and "most common diagnoses (D)". The "d" column refers to the number of diagnoses identified in a corresponding diagnostic category, not to subject numbers, since subjects could have had more than one diagnosis (for example, a subject with hearing loss and tinnitus would count as two diagnoses in the ENT diagnostic category). The "most common diagnoses (D)" column provides a short list of the most frequent diagnoses within a diagnostic category, with the number in brackets providing the number of times that the diagnosis occurred. Specific diagnoses that only occurred once were not documented in the table. GERD = gastro-esophageal reflux disease; PTSD = Post traumatic stress disorder; RAD = Reactive airways disease; COPD = Chronic obstructive pulmonary disease.

[7]Diagnoses were not mutually exclusive, e.g., a person could be diagnosed with PTSD, depression and other conditions.

Table 7: Medical history text field diagnostic summary for all post-fire diagnoses that were NOT documented in medical records prior to the date of the HMCS CHICOUTIMI fire*

Diagnostic Category	CC (n = 56)		Controls (n = 152)		CCT (n = 42)	
	d	Most Common Diagnoses (D)	d	Most Common Diagnoses (D)	d	Most Common Diagnoses (D)
Cardiovascular	6	Hypertension (4)	10	Hypertension (7)	3	Hypertension (2)
ENT	18	Hearing loss (6) Tinnitus (6)	22	Obstructive sleep apnea (7) Hearing loss (6)	5	Obstructive sleep apnea (3)
Endocrine	4	Hyperlipidemia (4)	12	Hyperlipidemia (7) Diabetes (5)	4	Diabetes (3)
Gastrointestinal	5	GERD (3)	15	GERD (6)	3	Inguinal hernia (2)
Malignancy	0		2		0	
MSK	20	Fracture, sprain, or tear (9) Mechanical low back pain (4)	39	Fracture, sprain, or tear (14) Mechanical low back pain (6)	12	Mechanical low back pain (3), fracture, sprain, or tear (3)
Neurological	6	Headaches, recurrent (2)	3		1	
Psychiatric	52	PTSD (31) Depression (8) Alcohol dependence or abuse (4) Anxiety disorder (4) Adjustment disorder (3)	22	Adjustment disorder (6) Depression (3) Alcohol dependence (2) PTSD (2)	4	
Respiratory	18	Asthma or RAD (11) COPD or bronchitis (2)	4	Asthma or RAD (3)	2	
Urology	3	Hematuria or proteinuria (3)	7	Nephrolithiasis (3) Prostatitis (2)	2	
Other	9	Skin conditions (3) Blood conditions (2)	17	Blood conditions (3) Skin conditions (3) Eye conditions (2)	2	

* Each subject group has two columns, "d" and "most common diagnoses (D)". The "d" column refers to the number of diagnoses identified in a corresponding diagnostic category, not to subject numbers, since subjects could have had more than one diagnosis (for example, a subject with hearing loss and tinnitus would count as two diagnoses in the ENT diagnostic category). The "most common diagnoses (D)" column provides a short list of the most frequent diagnoses within a diagnostic category, with the number in brackets providing the number of times that the diagnosis occurred. Specific diagnoses that only occurred once were not documented in the table. GERD = gastro-esophageal reflux disease; PTSD = Post traumatic stress disorder; RAD = Reactive airways disease; COPD = Chronic obstructive pulmonary disease.

The Relative risk (RR) and 95% confidence intervals for the three leading CC post-fire new diagnoses (PTSD, Asthma/RAD, and Depression) as compared to Controls, is presented in Table 8. Estimates are of a 45 times increase in the RR for PTSD, a tenfold increase in Asthma/RAD, and a 7.3 times increase in depression.

Table 8: Relative Risk calculations and 95 % Confidence Intervals for newly diagnosed PTSD, Asthma/Reactive Airways Disease (RAD), and Depression

PTSD	CC	Control
New diagnosis	31(60%)	2(1.3%)
Pre-existing diagnosis	4	1
No diagnosis	21	149
Total	56	152
Total at risk at time of fire	52	151

RR = (31/52) / (2/151) = 45 (95% CI: 11, 190)

Asthma/RAD	CC	Control
New diagnosis	11(21%)	3(2%)
Pre-existing diagnosis	4	4
No diagnosis	41	145
Total	56	152
Total at risk at time of fire	52	148

RR = (11/52) / (3/148) = 10 (95% CI: 2.9, 37)

Depression	CC	Control
New diagnosis	8(15%)	3(2%)
Pre-existing diagnosis	1	1
No diagnosis	47	148
Total	56	152
Total at risk at time of fire	55	151

RR = (8/55) / (3/151) = 7.3 (95% CI: 1.9, 28)

Slight increases in musculoskeletal diagnoses were noted in the CC group but did not reach statistical significance when compared to Controls or CCT. Other diagnostic categories that showed increases post-fire compared to baseline for the CC were: cardiovascular, neurological, and urological. However, making sound statistical inferences of diagnoses which occurred with a low incidence was hampered by the small sample size of the CC.

4.0 Discussion

4.1 Interpretation

The HMCS CHICOUTIMI Health Surveillance Study baseline data shows that before the fire, the CC had only 2.0% of their baseline service days on SL or MELs, as compared to 2.8% for Controls and 3.9% for the CCT. Following the fire, however, the CC experienced substantially more SL and MEL days, compared to their baseline rates or that of the Controls. Indeed, the CC were medically unfit to go to sea on 25.9% of their post-fire service days (due to either SL or MELs), as compared to 5.4% of the days for Controls and 5.5% of the days for CCT.

The diagnostic category with the greatest impact on the CC (number affected or number of SL or MEL days) was psychiatric, accounting for almost two thirds of total SL days. The predominant diagnosis was PTSD, which was newly diagnosed in 60% of CC after the fire. The relative risk for this diagnosis in the CC was 45 (95% CI: 11, 190) compared to Controls. Depression as a new diagnosis occurred in 15% of CC, a relative risk of 7.3 (95% CI: 1.9, 28) as compared to the Controls.

The second most common post-fire newly diagnosed condition among CC was asthma/reactive airways disease, with a 21% incidence and a RR of 10 (95% CI: 2.9, 37) compared to Controls.

Post-fire the CCT had 7% more days in the "sick leave or any type of MEL" category than Controls, and although both groups had a low baseline rate, the CCT's rate was 42% greater. However, this effect was not great enough to cause a statistically significant difference between the CCT's total number of days in the "lost to sick leave or Unfit Sub/Unfit Along-side MEL" category post-fire, as compared to the Controls.

No cancers were reported in the CC or the CCT during the study period. As detailed in a previous report, it was felt unlikely that the CC exposure would increase their incidence of cancer above that of Canadian general population background levels.[8]

The HMCS CHICOUTIMI Health Surveillance Study's completion helps to fulfill the undertaking between the CF H Svcs Gp and the Clinical Council to provide answers to the HMCS CHICOUTIMI crew about the status of their health post-fire. It also complements an earlier peer reviewed document, HMCS CHICOUTIMI Fire Incident of 5 October 2004 Potential Chemical Exposures and Health Consequences (dated 16 June 2008).

4.2 Study Limitations

4.2.1 Bias and Blinding

The CC received enhanced medical care for the first year with additional mental health screening in early 2005, whereas the CCT and Controls received usual care. There is potential for bias due to the additional mental health surveillance of the CC (i.e., the CC might have had higher rates of

[8] Tsekrekos, S., Lalonde, J.D., HMCS CHICOUTIMI Fire Incident of 5 October 2004 Potential Chemical Exposures and Health Consequences, 16 June 2008.

case ascertainment). The medical practitioners providing medical care were not blinded when making diagnoses, or prescribing SL or MELs to the CC (or the other groups). The reviewers and the OHS were not blinded during the data extraction.

4.2.2 Inter-Observer Diagnostic Variability

The reviewers and OHS relied on the accuracy of the medical service providers to document all medical diagnoses present, the standard and application of which, could vary between caregivers. For example, the criteria that practitioners used to diagnose asthma/RAD might have been made subjectively as opposed to an objective diagnosis through the use of spirometry or methacholine challenge test standards.

The validation process indicated an average file reviewer accuracy of 93.3% (range 87.1% to 98.8%). Judgment was required by the reviewers and the OHS in abstracting the data from the medical records.

4.2.3 Controlling for Subject Demographics and Study Design

Demographically, despite randomization, there were some differences between the CC and the other two groups. With respect to postings, CC had served for significantly more time on submarines than Controls ($p=<0.01$), and these postings made up a significantly greater proportion of their total posting time (compared to Controls; $p=0.002$). This has to be taken into consideration when interpreting the results of the study.

Smoking was analyzed categorically as smoker, previous smoker, and non-smoker. The development of the data to use the metric pack-years, as a measure of smoking experience, would represent a more robust method of comparing smoking exposure. It would be needed if consideration were given to the further development of the respiratory data.

The loss of subjects to follow-up after their release prior to 31 December 2009 limited the health information available to the OHS for the full five-year post-fire period.

SL was not recorded unless the duration was at least three days. Total days missed for all reasons per year could provide further insights into the health experience of the subjects.

4.2.4 Statistical Power Calculations

The fixed small size of the CC limited the statistical power of the study. Large effect sizes for common diagnoses were therefore needed to show that the incidence of a condition was different between the Controls and the CC. In contrast, the study was not powered to make sound statistical inferences of low incident uncommon diagnoses. Such diagnoses, which could occur by chance alone, as could happen in the general population, would require analysis by comparison to other reference populations. Similar limitations would apply to the CCT group.

4.3 Possible Development and Application of Remaining Data

Data collected from before and after a fire in a submarine is rare in the world literature. Although further analysis of the existing data at this time will not provide significant improvement in the medical care and surveillance of the CC, it may provide guidance for similar incidents in the future (e.g., pulmonary function data).

4.4 Conclusion

Together the data and results identify, document, and provide insights into the short to medium term health effects associated with the HMCS CHICOUTIMI fire. The high incidence of major post-fire diagnoses that were evident clinically were confirmed statistically, despite the small size of the CC cohort. No cancers were reported in the CC or the CCT.

As outlined in the post hoc statistical power calculations referred to in the executive summary, making sound statistical inferences of diagnoses which occurred with a low incidence was hampered by the small number of crew members. This limitation will be compounded progressively as more study subjects leave the military and transition to civilian medical care. This would make subsequent stages of the study impractical and ineffective in providing a follow-up to the crew of HCMS CHICOUTIMI. Therefore, future monitoring of this group should occur through normal standard medical care of individuals, the Veterans Affairs claims process, and the ongoing Canadian Forces Cancer and Mortality Study II[9]. This approach would provide a more effective follow-up mechanism to identify and address long-term health concerns or outcomes.

[9] Conducted in collaboration with Veterans Affairs and Statistics Canada

Annex A: Data Fields in the Data Collection Form

A1.0 Data Fields applicable to HMCS Chicoutimi Subjects Only

- Subject location at the onset of the fire;
- Respiratory protection used during the fire (type used, time to don, use details);
- Firefighting activities;
- Symptoms experienced from time of fire until arrival in Faslane on 10 October 2004;
- Medical assessment or treatment received from time of fire until arrival in Faslane;
- Symptoms reported by subject at initial medical assessment in Faslane;
- Clinical findings noted by clinician at initial medical assessment in Faslane;
- Spirometry results from Faslane (FVC, FEV_1, FEV_1/FVC, PEF);
- Laboratory results from Faslane (hemoglobin, hematocrit, MCV, platelets, WBC, neutrophils, lymphocytes, ALT, AST, GGT, Alk Phos, BUN, creatinine); and
- Additional comments related to subject's medical condition from time of fire to completion of Faslane medical assessment that was not already captured.

A2.0 Data Fields applicable to All Subjects

a. Date of Birth and CAF Service History

- Subject study identification number;
- Subject Status (Chicoutimi, Control, Care & Custody);
- For Care & Custody team only: start and end date in Faslane;
- Date of Birth;
- CAF Enrolment Date;
- Posting history (Unit/location, start date, end date);
- Service Status (Currently serving or released as of 31 December 2009);
- If released:
    - Release date;
    - Release type (e.g., 3B, 4A, etc.);
    - Medical conditions present at release (as documented in release medical);
    - Release medical conditions believed to be attributable to CAF service; and
    - Release medical conditions believed to be attributable to HMCS Chicoutimi fire.
- Rank as of 5 October 2004; and
- MOC / MOSID as of 5 October 2004.

b. Health Status as of 5 October 2004 (most recent information available prior to 5 October 2004)

- Height and date recorded;
- Weight and date recorded;
- Blood pressure and date recorded;
- Smoking status and source information date;
- Alcohol intake and source information date;
- Exercise (yes/no, hours per day/week, express test results) and source information date;
- Audiogram (date and results for the most recent audiogram just prior to 5 October 2004 plus earliest audiogram in CAF medical record);
- Family history (text field);
- Medications prescribed between 5 October 2003 and 4 October 2004 (medication name, dosage, ATC Level 1, start date, amount prescribed if single prescription);

- Chest x-ray (date, report comments);
- Pulmonary function test (date, report comments, FVC, FEV_1, FEV_1/FVC, $FEF_{25-75\%}$, $FEF_{50\%}$, $FEF_{75\%}$, PEF, post-bronchodilator FVC and FEV_1, TLC, DLCO, DLCO/VA);
- Methacholine challenge test (date, report comments, PC_{20});
- Electrocardiogram (date, report comments);
- Additional investigations (for each: date, investigation type, indication and report comments);
- Complete blood count (date, hemoglobin, hematocrit, MCV, platelets, WBC, neutrophils, lymphocytes);
- Liver function tests (date, ALT, AST, GGT, alk phos);
- Fasting blood glucose (date, value);
- Renal function (date, BUN, creatinine);
- Lipid profile (date, total cholesterol, HDL, LDL, triglycerides);
- Urinalysis (date, result comments if abnormal); and
- Additional laboratory tests (for each: date, test name, test results, indication and additional comments).

c. Past Medical History (complete data from enrolment date until 5 October 2004)

- Sick leave (reason, diagnostic category, start date, number of days);
- Temporary medical employment limitations (limitation description, reason for MEL, start date, number of days);
- Temporary medical "G" or "O" categories with a value of three or greater (G category, O category, reason for TCat, start date, number of days);
- Permanent medical employment limitations (limitation description, reason for MEL, start date);
- Permanent medical "G" or "O" categories with a value of three or greater (G category, O category, reason for TCat, start date);
- Past medical history of respiratory conditions (textual narrative to include date, diagnosis, treatment, and any additional pertinent details);
- Past medical history of ear, nose, and throat conditions (textual narrative to include date, diagnosis, treatment, and any additional pertinent details);
- Past medical history of cardiovascular conditions (textual narrative to include date, diagnosis, treatment, and any additional pertinent details);
- Past medical history of gastrointestinal conditions (textual narrative to include date, diagnosis, treatment, and any additional pertinent details);
- Past medical history of mental health conditions (textual narrative to include date, diagnosis, treatment, and any additional pertinent details)
- Past medical history of neurological conditions (textual narrative to include date, diagnosis, treatment, and any additional pertinent details);
- Past medical history of other significant conditions (textual narrative to include date, diagnosis, treatment, and any additional pertinent details for conditions not previously described in other preceding past medical history textual narratives that either frequently occurred, were chronic in nature, or were significant events such as surgery or hospitalization); and
- Past history of unusual hazardous exposures (textual narrative to include date, description of event and exposure, clinical effects).

d. Post-Fire Information (most recent information available just prior to 31 December 2009 or date of release)

- Rank;
- MOC / MOSID;
- Height and date recorded;
- Weight and date recorded;
- Blood pressure and date recorded;
- Smoking status and source information date;
- Alcohol intake and source information date;

- Exercise (yes/no, hours per day/week, express test results) and source information date; and
- Audiogram (date and results).

e. Post-Fire Medical History (complete data from 5 October 2004 to 31 December 2009 or date of release)

- Medications prescribed (medication name, dosage, ATC Level 1, start date, end date);
- Sick leave (reason, diagnostic category, start date, number of days);
- Temporary medical employment limitations (limitation description, reason for MEL, start date, number of days);
- Temporary medical "G" or "O" categories with a value of three or greater (G category, O category, reason for TCat, start date, number of days);
- Permanent medical employment limitations (limitation description, reason for MEL, start date);
- Permanent medical "G" or "O" categories with a value of three or greater (G category, O category, reason for TCat, start date);
- Medical history of respiratory conditions (textual narrative to include date, diagnosis, treatment, and any additional pertinent details);
- Medical history of ear, nose, and throat conditions (textual narrative to include date, diagnosis, treatment, and any additional pertinent details);
- Medical history of cardiovascular conditions (textual narrative to include date, diagnosis, treatment, and any additional pertinent details);
- Medical history of gastrointestinal conditions (textual narrative to include date, diagnosis, treatment, and any additional pertinent details);
- Medical history of mental health conditions (textual narrative to include date, diagnosis, treatment, and any additional pertinent details);
- Medical history of neurological conditions (textual narrative to include date, diagnosis, treatment, and any additional pertinent details);
- Medical history of other significant conditions (textual narrative to include date, diagnosis, treatment, and any additional pertinent details for conditions not previously described in other preceding post-fire medical history textual narratives that either frequently occurred, were chronic in nature, or were significant events such as surgery or hospitalization);
- History of unusual hazardous exposures (textual narrative to include date, description of event and exposure, clinical effects);
- Chest x-rays (for each: date, report comments);
- Pulmonary function tests (for each: date, report comments, FVC, FEV_1, FEV_1/FVC, $FEF_{25-75\%}$, $FEF_{50\%}$, $FEF_{75\%}$, PEF, post-bronchodilator FVC and FEV_1, TLC, DLCO, DLCO/VA);
- Methacholine challenge tests (for each: date, report comments, PC_{20});
- Electrocardiograms (for each: date, report comments);
- Additional investigations (for each: date, investigation type, indication and report comments);
- Complete blood count (for each: date, hemoglobin, hematocrit, MCV, platelets, WBC, neutrophils, lymphocytes);
- Liver function tests (for each: date, ALT, AST, GGT, alk phos);
- Fasting blood glucose (for each: date, value);
- Renal function (for each: date, BUN, creatinine);
- Lipid profile (for each: date, total cholesterol, HDL, LDL, triglycerides);
- Urinalysis (for each: date, result comments if abnormal); and
- Additional laboratory tests (for each: date, test name, test results, indication and additional comments).

Annex B: Validation File Analysis

B1.0 Introduction

In order to assess file reviewer performance and inter-reviewer agreement, the medical records and ancillary data of 13 randomly selected subjects were used as validation files. Validation files were reviewed by all three file reviewers, which generated three data collection forms for each validation file (one for each reviewer). A fourth data collection form for each validation file was generated by the OHS, and this form served as the standard for comparison purposes.

B2.0 Methods

B2.1 Procedures

For each validation file, a spreadsheet was created that summarized each file reviewer's performance in relation to the standard for each data field in the data collection form. The file reviewer data collection forms were reviewed by the OHS and individual data fields for each file reviewer was coded with one of five possible "response scores" in the spreadsheet:

- **"Correct"**: the information entered in the data field by the file reviewer matches the information entered in the corresponding data field in the standard;

- **"Data Error"**: the information entered in the data field by the file reviewer does not match the information entered in the corresponding data field in the standard;

- **"Created Data"**: information was entered in a data field by the file reviewer, but the corresponding data field in the standard is blank;

- **"Omitted Data"**: the file reviewer's data field is blank but the corresponding data field in the standard has information entered in it; and

- **"Not Counted**": the file reviewer's data field is linked in some way to a related data field for which the file reviewer's entry was incorrect. For example, the results of the most recent pulmonary function test (PFT) just prior to 5 October 2004 were to be entered in the data form. In addition to the date data field, the pre-fire PFT section of the form had 26 separate data fields to capture the different PFT parameters. If the file reviewer selected the wrong pre-fire PFT (e.g., selected a PFT dated January 2002 instead of one dated June 2004), then even if the file reviewer abstracted the PFT parameter fields correctly, they would be coded as "data error" since they would not match the PFT parameter fields in the standard. In these situations, the selection of the wrong item by the file reviewer was only counted as one error: the date data field was coded as "data error" and the 26 PFT parameter data fields were coded as "not counted". In this manner, the file reviewer's error was captured as a single error and not as 27 errors.

All identified errors (i.e., "data error," "created data," and "omitted data"), were further coded as either "minor" or "major." This coding was dependent on the judgment of the OHS and was meant to distinguish inconsequential errors (errors that would not significantly impact any future analyses) from errors that could potentially affect future analyses. The following are examples of distinctions between minor and major errors:

- A missed diagnosis of a significant medical condition (e.g., Asthma, PTSD, etc.) would count as a major error. A missed diagnosis of a minor self-limited condition (e.g., self-limited upper respiratory tract infection) would count as a minor error;

- Any error with respect to the labelling of a result as normal or abnormal was considered a major error (e.g., a complete blood count value that is outside the normal reference range that the file reviewer coded as "normal");

- A measured pulmonary function test parameter value that was greater than 1% higher or 1% lower than the corresponding standard value was considered a major error;

- Adding or omitting a significant MEL or SL (i.e., greater than two weeks in length) was considered a major error. Omitting a three-day SL, for example, was considered a minor error. Regardless of MEL duration, if "unfit sub" or "unfit sea" was incorrectly added or omitted to the MEL text field, this counted as a major error; and

- If the error was obvious and the correct value could easily be deduced by neighbouring fields, then it was counted as a minor error. For example, a situation where a SL reason (text field) is "laryngoscopy" but the corresponding SL diagnostic category (selected from a drop-down menu) was "cardiovascular," would be counted as a minor error. In this situation, "cardiovascular" is adjacent to "ENT" (a more appropriate selection for a laryngoscopy) in the drop-down menu. Since it was far more likely for the drop-down menu selection to have been made incorrectly (as opposed to typing in "laryngoscopy" when one meant to type in a cardiovascular-related reason for SL), the error is obvious and the correct value can easily be deduced.

Each data fields in the data collection form was also assigned with a "variable type" code in the validation file spreadsheet that was created by the Principal Investigator. The different variable types and the criteria for determining when a file reviewer's data field entry was "correct" or "data error" are described below:

- **"Date"**: all date variables, whether a specific date data field in the data collection form, or if a date was entered into a text field as part of a medical history description. If the date entered by the file reviewer was within two days of the corresponding date entry in the standard, then the file reviewer's entry was coded as "correct". Otherwise, the file reviewer's entry was coded as "data error";

- **"Numeric"**: this variable type was assigned to all data fields that required the direct copying of a numeric value from a subject's medical records into the data collection form. Examples of numeric variables include values for laboratory results or pulmonary

function test parameters. File reviewer entries had to match the standard exactly to be coded as "correct";

- **"Numeric – judgment"**: this variable type was assigned specifically to data fields that represented duration for SL, MELs, and medical categories. In many cases, these specific values were not copied directly from a lab report, for example (as was the case for simple "numeric" data fields), but were from hand-written notes. As well, the data collection form required that duration be entered in units of days, whereas duration for SL, MELs, and medical categories were frequently reported in medical records in units of weeks or months. Because these numeric values required more thought and interpretation on the part of the file reviewer (as opposed to simply copying a value directly), they were coded as "numeric – judgment" in the validation file spreadsheet. The file reviewer's entry for a "numeric – judgment" variable had to be within one day of the corresponding standard entry to be coded as "correct";

- **"Categorical"**: this variable type was assigned to all data fields that required the file reviewer to select a value from a fixed set of choices that existed in the data collection form. Example data fields were drop-down lists and radio buttons. The file reviewer's entry had to match the standard exactly to be coded as "correct";

- **"Free text – copy"**: this variable type was assigned to all data fields that required the file reviewer to copy the textual information found in a data source by typing it directly into a text data field in the data collection form. Examples of these types of fields include posting location, medication name, investigation name, etc. The file reviewer's entry in a "free text – copy" field was coded as "correct" if one could reasonably determine that the file reviewer's entry was equivalent to the corresponding standard entry. In other words, differences between the file reviewer's entry and the standard due to the use of abbreviations, spelling errors, or other nuances were taken into account and there did not need to be an "exact" match to be coded as "correct"; and

- **"Free text – judgment"**: this variable type was assigned to all text data fields that required the file reviewer to interpret information contained within a medical record and then summarize this information in the data collection form. For example, medical history text fields required the file reviewer to provide a textual summary of the subject's medical history. From the medical history narrative, the Principal Investigator identified specific medical events, and each event would then be divided into three distinct variables: the date of the event was coded as a "date" variable, the diagnosis was coded as a "free text – judgment" variable and one more "free text – judgment" variable for additional information, such as treatment. Additionally, if the standard description of the event was "16 July 2003, pneumonia, Rx erythromycin" and the file reviewer's entry was "July 16, 2003: cough, shortness of breath, abnormal x-ray, dx: pneumonia", then that event would be coded as "correct" for the date variable, "correct" for the diagnosis free text – judgment variable, and "omitted data" for the additional information "free text – judgment" variable. Similarly to the "free text – copy" variables, abbreviations, spelling errors, and other nuances were taken into account when evaluating the file reviewer's

entries. Other examples of "free text – judgment" variables were the reasons or descriptions for SL, MELs, and medical categories.

B2.2 Analyzes

Each validation file spreadsheet created by the Principal Investigator, Dr. S. Tsekrekos, listed all data fields that were in the data collection form, and had the following columns with coding for each data field:

- Variable type (e.g., date, numeric, etc.);
- Present in standard (a binary code indicating if the data field was completed in the standard); and
- Two columns for each of the three file reviewers: "Response" (e.g., correct, data error, created data, etc.) and "Error severity" (i.e., minor, major).

In order to derive an accuracy score, the data fields that were scored as "correct" for a file reviewer served as that file reviewer's numerator. The denominator was the number of data fields that were present in the standard minus the number of data fields that were "not counted" (see discussion above) for that file reviewer. To illustrate, a hypothetical standard for a validation file had 500 completed data fields. A file reviewer's data collection form for the same validation file had 430 "correct" data fields. Expanding on the example from the above "not counted" discussion, one of the errors made was on a pulmonary function test (PFT) entry: the wrong PFT was selected from the medical record, and so the date and all the PFT parameter values did not match the standard. The PFT date field was coded as "data error" but the 26 PFT parameter fields on the file reviewer's data collection form were coded as "not counted" (so that the file reviewer's single error in selecting the wrong PFT was not scored as 27 errors). Assuming that there were no more "not counted" data fields for this file reviewer, their accuracy score would be 430 / (500 – 26) = 0.907 or 90.7%.

In situations where a file reviewer's data field was scored as "created data", the number of "created data" errors were subtracted from the "correct" data fields, with no change to the denominator. Continuing with the preceding example, if the file reviewer also made five "created data" errors, then the accuracy calculation would be: (430 – 5) / (500 – 26) = 0.897 or 89.7%.

In order to determine inter-reviewer agreement, response scores (e.g., “correct,” “data error”, etc.) were compared across file reviewers and a file agreement code assigned:

- All reviewers agree (all had the same response score);
- Reviewer 1 and reviewer 2 agree only (reviewer 3 had a different response score);
- Reviewer 1 and reviewer 3 agree only (reviewer 2 had a different response score);
- Reviewer 2 and reviewer 3 agree only (reviewer 1 had a different response score); and
- No reviewers agree (all three reviewer’s response scores differed).

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Note that agreement scores were not necessarily directly related to accuracy (in comparison to the standard). For example, if all three file reviewers had “omitted data” for a data field that was in the standard, then this would be coded as “all reviewers agree”. In the vast majority of cases, however, all three reviewers were in agreement or two reviewers were in agreement because their data fields were “correct” in relation to the standard.

B3.0 Results

B3.1 File Reviewer Accuracy

Table B1 summarizes the spreadsheet coding for each validation file. Unless indicated otherwise, the numbers in Table B2 represent the number of data fields. Accuracy is expressed as a percentage and is simply the "correct" responses divided by the denominator. Note that the denominators differ from the number of data fields in the standard, which is due to the presence of "not counted" data fields, as discussed above. The number of major errors is also provided in the table, which ranged from 0 to 9 across all reviewers and all validation files. When expressed as a percentage of total errors (i.e., total errors equals the denominator minus the "correct" responses value), the proportion of errors that were "major" ranged from 0% to 17.2% of total errors for a given validation file.

With respect to average accuracy, when all validation files were equally weighted (i.e., the simple average of the 13 validation files accuracies), the average accuracies for Reviewers 1, 2, and 3 were 97.0%, 92.6%, and 90.9%, respectively. Because the validation files had different numbers of completed data fields in the standard (from a low of 347 to a high of 872), a more appropriate measure of "total accuracy" is the total correct responses divided by the total denominators when all validation file results were added together. With this approach, the average accuracies was 96.8%, 92.5%, and 90.7%, respectively. When all three reviewers were combined using this "total accuracy", the total average accuracy was 93.3%. Considering the substantial time required to review a subject's medical record (up to two to three days in some cases), and the number of pieces of information that the file reviewer was required to abstract into the data collection forms, this level of accuracy was considered acceptable.

Table B1: File Reviewer performance for all 13 validation files*

Validation File Number	Standard Data Fields	Performance	Reviewer 1	Reviewer 2	Reviewer 3
1	573	Correct	536	449	451
		Denominator	554	504	508
		Accuracy (%)	**96.8%**	**89.1%**	**88.8%**
		Major Errors	0	4	1
2	416	Correct	410	388	377
		Denominator	415	407	400
		Accuracy (%)	**98.8%**	**95.3%**	**94.3%**
		Major Errors	0	1	1
3	848	Correct	807	661	653
		Denominator	829	737	739
		Accuracy (%)	**97.3%**	**89.7%**	**88.4%**
		Major Errors	0	2	2
4	794	Correct	716	687	648
		Denominator	756	735	716
		Accuracy (%)	**94.7%**	**93.5%**	**90.5%**
		Major Errors	0	3	5
5	842	Correct	756	626	635
		Denominator	799	719	723
		Accuracy (%)	**94.6%**	**87.1%**	**87.8%**
		Major Errors	0	5	3
6	411	Correct	371	319	312
		Denominator	380	353	357
		Accuracy (%)	**97.6**	**90.4**	**87.4**
		Major Errors	0	2	0
7	362	Correct	356	321	285
		Denominator	362	341	310
		Accuracy (%)	**98.3**	**94.1**	**91.9**
		Major Errors	0	1	1
8	821	Correct	765	722	697
		Denominator	794	776	760
		Accuracy (%)	**96.3%**	**93.0%**	**91.7%**
		Major Errors	5	1	3
9	872	Correct	799	769	709
		Denominator	829	821	797
		Accuracy (%)	**96.4%**	**93.7%**	**89.0%**
		Major Errors	2	5	9
10	837	Correct	800	756	736
		Denominator	819	795	786
		Accuracy (%)	**97.7%**	**95.1%**	**93.6%**
		Major Errors	0	0	0
11	347	Correct	334	302	293
		Denominator	342	317	313
		Accuracy (%)	**97.7%**	**95.3%**	**93.6%**
		Major Errors	0	1	1
12	472	Correct	432	383	402
		Denominator	448	420	438
		Accuracy (%)	**96.4%**	**91.2%**	**91.8%**
		Major Errors	0	0	0
13	565	Correct	539	518	514
		Denominator	547	539	553
		Accuracy (%)	**98.5%**	**96.1%**	**92.9%**
		Major Errors	0	0	1

* Unless otherwise noted, the numbers in the table represent the number of data fields

As mentioned in section 2.5.4, if file reviewers were second or third in line to review the validation file, they would be aware that their work would be evaluated. This may have resulted in the second and third file reviewers completing the form with more care and precision than they normally would. If such an effect were present, the validation file assessment of the file reviewer accuracy would overestimate the true accuracy of the file reviewers.

In order to assess for this "accuracy bias", the performance of the file reviewer when they were a first ("blinded") reviewer of a validation file was compared to their performance when they were a second or third reviewer on a validation file ("unblinded"). The results are summarized in Table B2. If an accuracy bias was present, it seems to have had only a minimal effect and was largely restricted to Reviewer 2, who had a 3% higher average accuracy when "unblinded", as compared to a 0.6% higher average accuracy for Reviewer 1 and a 1.9% lower average accuracy for Reviewer 3. When the performance of all three file reviewers was considered together, the average accuracy differed by only 0.2% between the "blinded" first review (93.3%) and the "unblinded" second or third review (93.5%). These results suggest that the validation file accuracy scores were a reasonable reflection of the accuracy of the file reviewers over the course of the entire study when reviewing non-validation files.

Table B2: Comparison of File Reviewer performance as a function of the order in which they reviewed the file: files where a reviewer was the first to review versus files that the reviewer was a second or third reviewer

	Reviewer 1		Reviewer 2		Reviewer 3	
	1st ("blinded")	2nd or 3rd ("unblinded")	1st ("blinded")	2nd or 3rd ("unblinded")	1st ("blinded")	2nd or 3rd ("unblinded")
Validation File Numbers	1,2,4,9,12	3,5,6,7,8,10,11,13	3,5,7,11	1,2,4,6,8,9,10,12,13	6,8,10,13	1,2,3,4,5,7,9,11,12
Total Correct	2893	4728	1910	4991	2259	4453
Total Denominator	3002	4872	2114	5350	2456	4944
Accuracy Score (%)	**96.4%**	**97.0%**	**90.4%**	**93.3%**	**92.0%**	**90.1%**

Similar to the effect of validation file review order, the effect of file complexity was also assessed. A marker of validation file complexity was the number of data fields that were completed in the standard. The greater the number of data fields, then the greater the amount of information that had to be abstracted from subject medical records and ancillary information. This would have increased the time required to complete the data collection form, and fatigue or decreased concentration over time may have had a negative impact on file reviewer accuracy.

In order to assess the effect of file complexity, reviewer performance was compared between the three validation files with the fewest standard data fields and the three validation files with the most standard data fields. The results are shown in Table B3. As predicted, the average accuracy score for the files with the highest number of standard data fields was slightly less (1.8 to 2.9%) than the average accuracy score for the files with the lowest number of standard data fields, and this was a consistent finding for all three file reviewers. When the performance of all three file reviewers was considered together, the average accuracy was 94.1% for the three validation files with the fewest standard data fields, which was 2.4% greater than the average accuracy of 91.7% for the three validation files with the most standard data fields.

Table B3: Comparison of File Reviewer performance as a function of the length/complexity of the validation file, based on the number of data fields

	Reviewer 1		Reviewer 2		Reviewer 3	
	Fewest Data Fields	Most Data Fields	Fewest Data Fields	Most Data Fields	Fewest Data Fields	Most Data Fields
Validation File Numbers	6,7,11	3,5,9	6,7,11	3,5,9	6,7,11	3,5,9
Total Correct	1061	2362	942	2056	890	1997
Total Denominator	1084	2457	1011	2277	980	2259
Accuracy Score (%)	**97.9%**	**96.1%**	**93.2%**	**90.3%**	**90.8%**	**88.4%**

The possibility of learning effects on the file reviewer accuracy was also assessed. The average accuracy of the first three validation files that a file reviewer completed was compared to the last three files that a file reviewer completed. Depending on the file reviewer, there was a seven to twelve-month separation between the first and last validation files reviewed.

The results are shown in Table B4 and suggest a slight learning effect across for all three file reviewers, most pronounced in Reviewer 2. When the performance of all three file reviewers was considered together, the average accuracy was 92.2% for the first three validation files reviewed and 93.1% for the last three validation files reviewed.

Table B4: Comparison of File Reviewer performance over time: first three validation files reviewed versus the last three validation files reviewed

	Reviewer 1		Reviewer 2		Reviewer 3	
	First Files	Last Files	First Files	Last Files	First Files	Last Files
Validation File Numbers	1,2,4	11,12,13	1,2,3	11,12,13	5,6,7	1,3,4
Total Correct	1662	1305	1498	1203	1232	1752
Total Denominator	1725	1337	1648	1276	1390	1963
Accuracy Score (%)	**96.3%**	**97.6%**	**90.9%**	**94.3%**	**88.6%**	**89.3%**

File reviewer accuracy was also influenced by the type of variable (e.g., “date,” “numeric”, etc.). This is summarized in Table B5. Not unexpectedly, data fields that required more thought or interpretation on the part of the file reviewer (i.e., “Numeric – judgment,” Text – judgment”) were somewhat more prone to error than data fields that required direct copying or selection

from a fixed set of choices (i.e., “Numeric,” “Categorical,” “Text – copy”), as indicated by the accuracy scores for the different variable types.

“Date” variables had the lowest accuracy scores, but this is not simply a reflection of inaccuracy on the part of the file reviewers with respect to copying date information. This accuracy score also takes into account omitted and created data errors that involved multiple related data fields (e.g., lab results such as complete blood counts or investigations such as pulmonary function tests, etc.); if the wrong laboratory or investigation result was entered into the data collection form, then that error would be scored towards the date variable.

Table B5: Overall File Reviewer performance for different variable types

	Average Accuracy Score (%)			
Variable Type	**Reviewer 1**	**Reviewer 2**	**Reviewer 3**	**All Reviewers Combined**
Date	93.02	83.56	81.93	**86.17**
Numeric	99.24	98.22	93.79	**97.08**
Numeric - judgment	92.14	90.32	91.91	**91.46**
Categorical	97.39	95.76	95.14	**96.10**
Text - copy	98.87	93.18	93.25	**95.10**
Text - judgment	96.83	91.04	90.44	**92.77**

B3.1 File Reviewer Agreement

File reviewer response score agreement for each of the validation files is summarized in Table B6. On average, for just over 73% of data fields, all three file reviewers had the same response score. For the vast majority of validation file data fields, this 100% agreement occurred because all three file reviewers had the correct data field entry as compared to the standard. On rare occasion, 100% agreement occurred because all three file reviewers had the same type of error for a particular data field (e.g., “omitted data”).

Less than 1% of the total data fields for all validation files combined had no agreement between the three file reviewers (such as situation when the three reviewer response scores for a particular data field were “correct,” “data error”, and “omitted data”, for example).

The results of the agreement analyses suggest that, overall, the three file reviewers abstracted information from medical files and ancillary information in a similar manner.

Table B6: Summary of the File Reviewer agreement for all 13 validation files

	File Reviewer Response Score Agreement (% of data fields)*		
Validation File Number	**100% Agreement (3/3 with same response score)**	**67% Agreement (2/3 with same response score)**	**No Agreement (different response score for all 3)**
1	62.1%	36.7%	1.2%
2	86.1%	14.0%	0%
3	70.6%	28.5%	0.8%
4	71.8%	27.9%	0.3%
5	69.0%	28.7%	2.3%
6	58.3%	41.4%	0.2%
7	75.4%	24.6%	0%
8	76.7%	22.3%	1.0%
9	71.3%	28.0%	0.7%
10	81.5%	18.0%	0.6%
11	72.1%	26.7%	1.1%
12	71.7%	26.6%	1.7%
13	81.9%	18.1%	0%
All Combined	**73.1%**	**26.1%**	**0.8%**

* Rows might not total to exactly 100% due to rounding