Report Writing and Causation Analysis

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Financial Disclosure

I do not have any relationships to report with ACCME defined ineligible companies.

I will not be discussing unlabeled/investigational uses of medical devices or pharmaceuticals during this presentation.

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Disclosure/Disclaimer

The views expressed in this presentation are those of the presenter and do not reflect the official policy or position of the Transportation Security Agency, the Department of Homeland Security, or the U.S. government.

NIOSH: A Guide to the Work-Relatedness of Disease

Definition of a six step method to determine the "work-relatedness of a disease"

- 1. Consideration of evidence of disease
- 2. Consideration of epidemiologic data
- 3. Consideration of evidence of exposure
- 4. Consideration of validity of testimony
- 5. Consideration of other relevant factors
- 6. Evaluation and conclusion

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Introduction

Six steps of work-relatedness determination

- Defined by the National Institute of Occupational Safety and Health (NIOSH), a branch of the Centers for Disease Control and Prevention (Kusnetz S, 1979) and by the American College of Occupational and Environmental Medicine (Greaves WW, 2018)
- Adopted by the American Medical Association Guides to the Evaluation of Disease and Injury Causation (Melhorn JM, 2014)

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Step 1: Evidence of disease

- State the diagnosis
- Source
- Date of diagnosis
- Confirmation
- Diagnostic criteria

Step 1: Cancer

- The pathology report dated January 1, 1990, of a XXX biopsy shows invasive carcinoma. A YYY biopsy also found metastatic carcinoma.
- The evidence of the disease [*state diagnosis*] is established by these pathology reports and confirmed by multiple imaging studies.

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Step 1: COVID-19

• Positive PCR test for COVID-19 on January 1, 2021

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Step 2: Epidemiological data

- State inclusion/exclusion and search criteria
- Cannot be one-sided
- Be cautious with meta-analyses and systematic reviews

Step 2: No epidemiological data

- Biomechanics
- Expert consensus
- Your explanation
 - Hill's criteria applied to the individual case

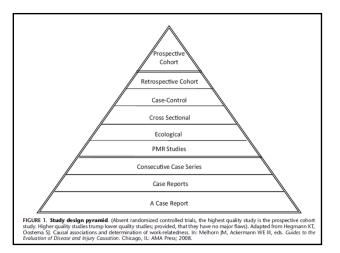
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Step 2

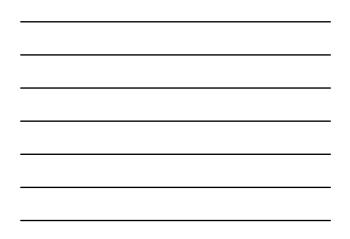
- National Library of Medicine database, search terms "(firefighters) AND (cancer)" 280 publications
- Inclusion: Cohort studies of at least 1,000 firefighters that addressed XXX cancer incidence
- Exclusion: Studies that only included volunteer firefighters
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Study (lead author and year of publication)	Population (number of firefighters)	Total number of cancer cases / number of NHL cases	Risk for NHL and 95% <u>confidence interval</u> (CI)	Comment
Ahn 2012	29,438	446 / 18	Standardized incidence ratio (SIR) 1.69 (1.01 to 2.67)	Statistically significant increase
Bigert 2020	8,136	1,483 / 42	SIR 1.05 (0.75 to 1.41)	Non-statistically significant difference
Daniels 2014	29,992	4,461 / 170	SIR 0.99 (0.85 to 1.15)	Non-statistically significant difference
Demers 1994	2,447	242 / 7	SIR 0.9 (0.4 to 1.9)	Non-statistically significant difference
Glass 2016	30,057	1,693 / 66	SIR 0.97 (0.75 to 1.24); SIR 2.12 (0.71 to 6.34) for full-time firefighters with 10 to 20 years of employment; SIR 3.67 (1.24 to 10.54) for full-time firefighters more than 20 years of employment	Non-statistically significant difference except in subgroup with more than 20 years of employment
Harris 2018	4,535	505 / 30	Hazard ratio 1.00 (0.71 to 1.42)	Non-statistically significant difference
Kullberg 2018	1,080	265 / 6	SIR 0.68 (0.25 to 1.48)	Non-statistically significant difference
Ma 2006	36,813	1,022 / 15	SIR 1.09 (0.61 to 1.80) in male firefighters	Non-statistically significant difference
Pukkala 2014	16,422	2,653 / 82	SIR 1.04 (0.83 to 1.29)	Non-statistically significant difference



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	Studies included	Number of studies related to NHL	Risk for NHL and 95% confidence interval (CI)	Comment
Casjens 2020	25 cohort studies related to cancer risk and freighting presented with standardized incidence ratios (SIRs) or standardized mortality ratios (SMRs)	6 studies related to incidence; 4 studies related to mortality	Meta-rohive standardized miscience ratio 105 (0.83 to 1.28); meta-rohiviry standardized motality ratio 1.31 (0.92 to 1.70)	Non-statistically significant difference
Jahlian 2019	48 studies related to freefighting occupation and cancer incidence and mortality	14 studies related to incidence; 8 studies related to mortality	Summary incidence risk estimate.107 (0.96 to 1.20); summary mortality risk estimate 1.42 (1.05 to 1.90)	Non-statistically significant difference for incidence risk; statistically significant increase for mortality risk
LeMasters 2006 (included for historical reasons)	28 studies related to cancer risk and firefighters	8 studies	Summary risk estimate 1.51 (1.31 to 1.73)	Statistically significant increase

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Step 2: Hill's criteria

Temporality: This criterion is met. The exposure (i.e., working as a firefighter) preceded the outcome (i.e., NHL diagnosis) in the above-mentioned studies.

Step 2: Hill's criteria

Strength of association: The best evidence is represented by cohort studies. Every relevant cohort study (with at least 1,000 firefighters), except one, showed a non-statistically significant difference in NHL incidence between firefighters and the reference population. The strength of association is none to minimal.

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Step 2: Hill's criteria

- Dose-response: The largest study looking at dose-response showed "no evidence of an association between any quantitative exposure measure and NHL" (Pinkerton L, 2020).
- Consistency of the association: Most highquality incidence studies did not show an association.

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Step 2: Individual epidemiologic causation

Even if we accept an SIR of 1.69 (Anh YS, 2012) – this is the highest risk found in the studies mentioned above – as the true (and generalizable) risk of NHL for firefighters, this increased risk does not allow to establish a "more likely than not" causal association in individual firefighters. If we accept an increased risk of 69% (i.e., an SIR of 1.69), 69 additional firefighters will have NHL due to occupational exposure for each group of 100 firefighters with NHL due to non-occupational exposure. Each of the 169 firefighters with NHL then has a 41% likelihood (69/(100+69) as a percentage) of having their cancer because of occupational exposure, which does not meet the "more likely than not" threshold to determine causal association.

Step 2: COVID-19

The incubation period for COVID-19 is 14 days or less in the vast majority of the cases, with a median time of 4 to 5 days from exposure to symptoms onset, according to the CDC (<u>https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-guidance-managementpatients.html</u>).

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Step 3: Evidence of exposure

- Exposure = occupation?
- Exposure to a specific agent?
- Level of the exposure?

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Step 3: Cancer

The exposure in this analysis is defined as working as a firefighter. There is evidence of exposure since Examinee was employed as a firefighter by Employer from 1980 until 1995.

Step 3: COVID-19

Examinee was exposed on the following dates to patients and coworkers who were infected with COVID-19.

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Step 4: Other relevant factors

Other jobs (current and past) Nonoccupational factors:

- Aggravation of preexisting conditions
- Personal factors (obesity, age, smoking...)
- Other sources of exposure (hobbies...)

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Step 4: Cancer

- Family history: SIR 1.71 with first-degree relative with lymphoma
- Mitigating factors:
 - Exact occupation
 - Personal protective equipment
 - Estimated duration of exposure

Step 4: COVID-19

- Exposures outside of the workplace
- Personal protective equipment during patient care and at the workplace

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Step 5: Validity of testimony

Reliability of the sources

- "This is not an issue in this case"
- "I assume that the records provided and Examinee's statements made to me are true and accurate with correct recall"
- Inconsistencies in the records and in the statements
- Unavailability of records
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Step 6: Conclusions

- It is my opinion that, more likely than not, Examinee's condition was/was not caused by his occupation.
- Use jurisdiction-specific language
- Answer the questions with specific language

Appendices

- Review of records
- Definitions (epidemiology terms)
- References

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References

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