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Evaluation of current health advisory letters to identify optimal characteristics and improve regulatory policy.

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Introduction

- Health advisory letters are used by many regulatory health agencies, as well as by the pharmaceutical industry to communicate with clinicians.
- The letters regularly contain information about changing indications, potential safety hazards or newly identified adverse reactions to particular medications
- Many health advisory letters do not communicate relevant information to health care providers effectively, and many health care providers are unlikely to change their practice after receiving them.

Objectives

- To explore the use of specific characteristics in health advisory letters
- Describe the characteristics of recently released health advisory letters
- Make recommendations to health regulatory agencies with respect to aspects of structure and design, format, and content of letters that best address the information needs of health professionals.

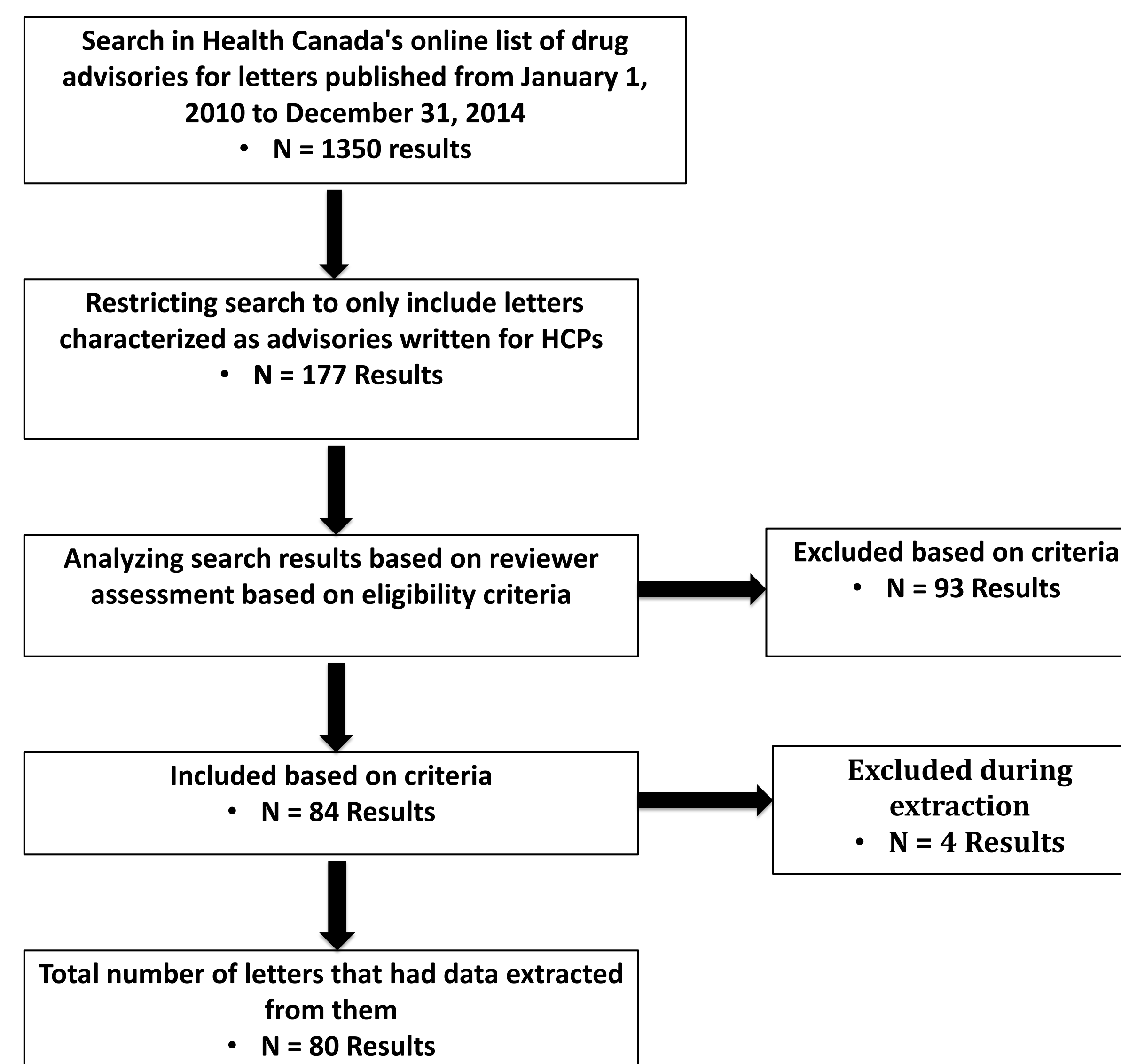
Methods

We began by searching online lists of active health advisory letters in Canada using Health Canada's online database; and the United States of America (USA), using the Food and Drug Administration (FDA) online database. Eligibility criteria required the letters to be 1) an advisory letter (as opposed to a letter of recall for something like a manufacturing issue); and 2) specifically written because of adverse effects that the medication may have.

The advisory letters were screened by reviewers in order to determine whether or not they met inclusion criteria. The drug referenced in each included Health Canada letters was searched on the FDA website to identify matching advisories. FDA letters were included if they: 1) matched the adverse event and warning for the same drug, and 2) had the closest release date to the Canadian letter where multiple letters for the same drug and same adverse event were found on the FDA website.

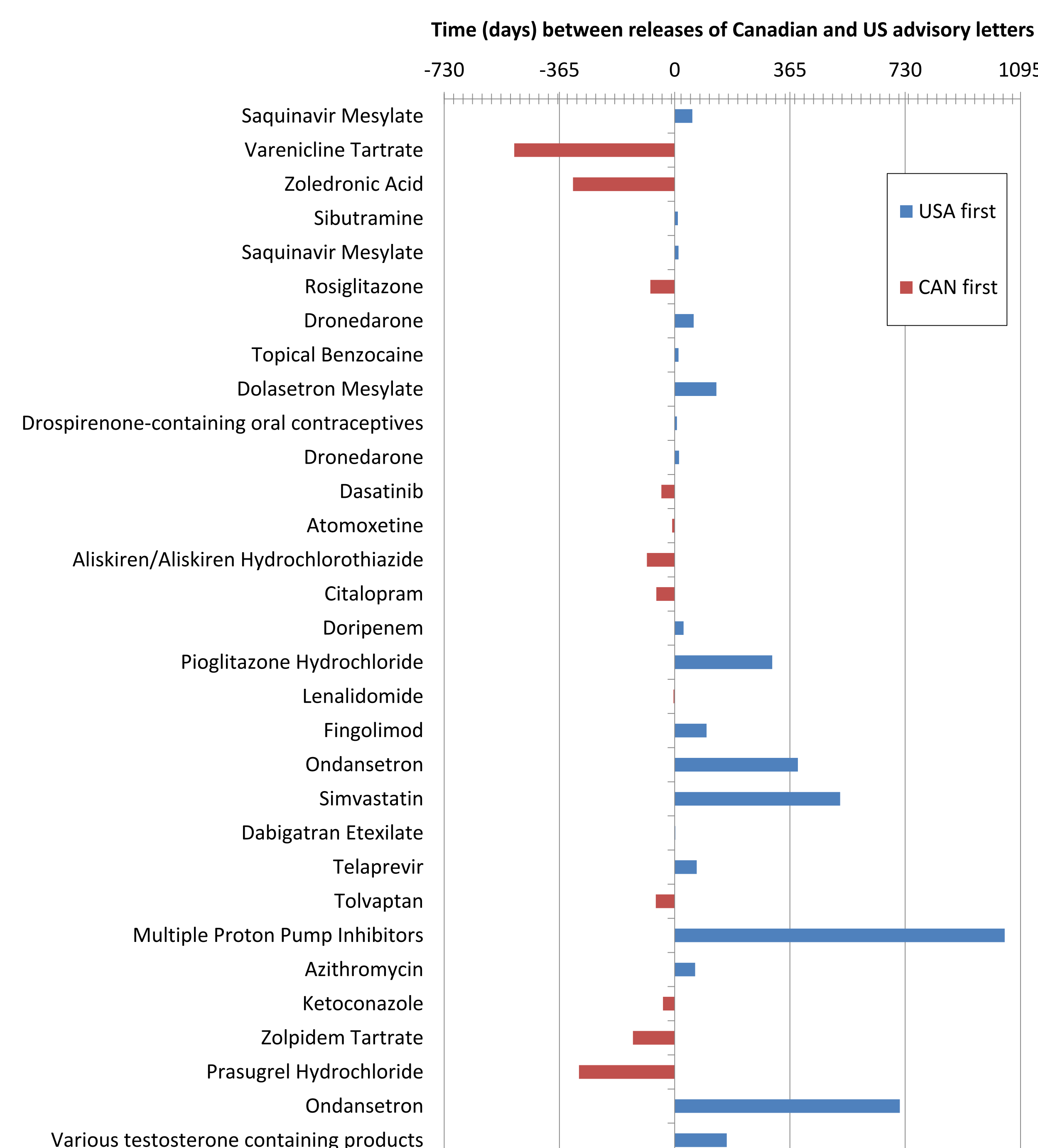
A list of qualities considered essential for advisory letters to contain was then drafted and shared with team members for input. Using these characteristics, a tool was created with Microsoft Excel that gave abstractors the ability to clearly identify the qualities that each advisory letter possessed. Each letter was then extracted using this tool.

Figure 1: Search Strategies to Identify Letters in Health Canada Database



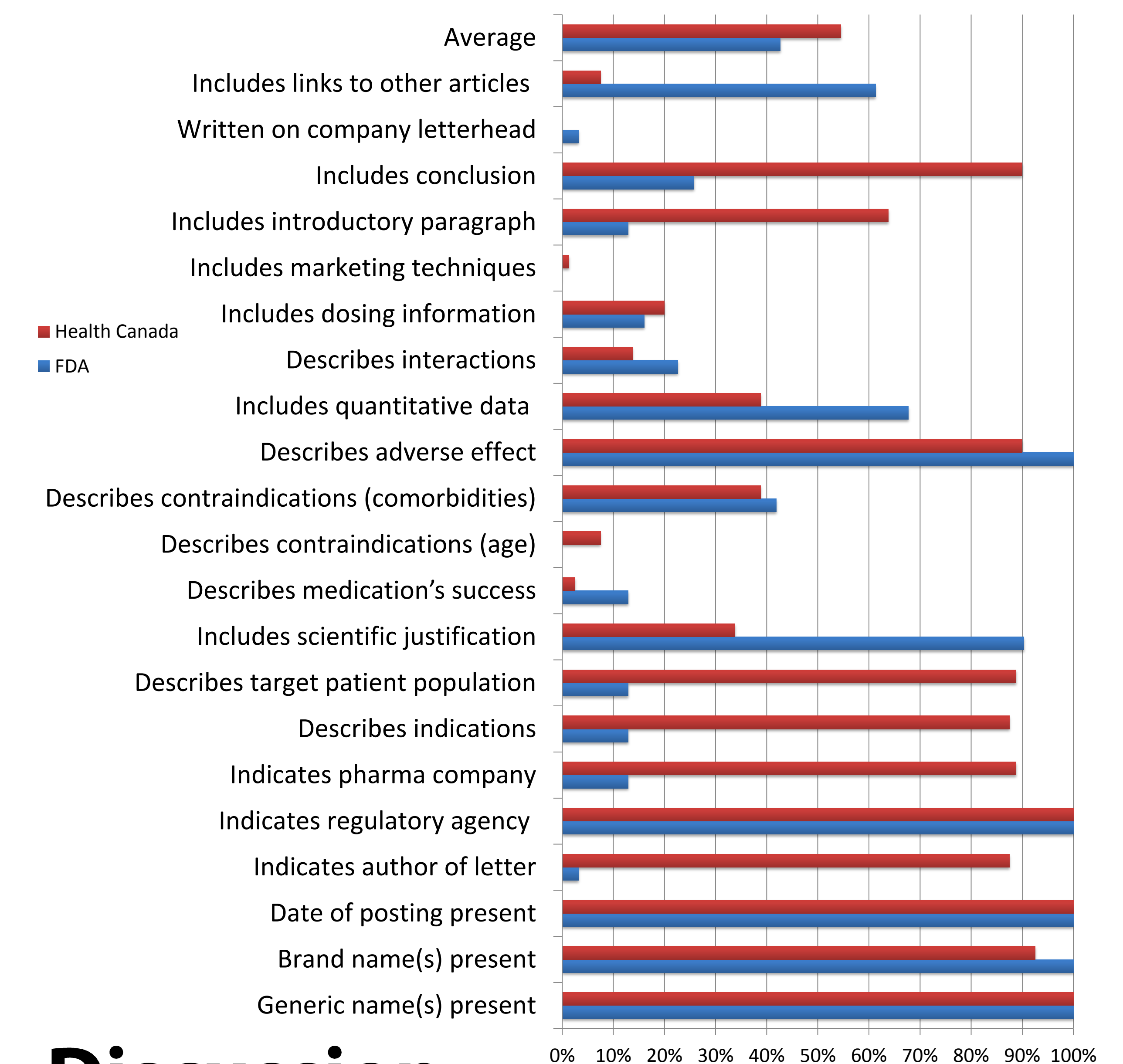
Results

Figure 1: Variation between Health Canada and FDA in date of publication of letters



- We extracted information from 80 Health Canada letters, and of these 31/80 matched in the FDA database.
- Across all quality characteristics, the average prevalence in Health Canada letters was 54.9% and the average prevalence in FDA letters was 42.7%. Across all of our chosen Health Canada letters, the average number of quality characteristics found was 11.4 (out of a maximum 21), and across all of our chosen FDA letters, the average number of characteristics found was 10.5.
- Health Canada letters are more likely to describe the pharmaceutical company involved, provide indications for the drug and include an introductory paragraph. Letters endorsed by the FDA are more likely to include scientific justification, give quantitative data for adverse effects, and include links to additional articles.

Figure 2: Percentage of Letters From Each Jurisdiction That Had Listed Quality Characteristics



Discussion

Health Canada generally includes more information about the drug itself and describes less scientific data and reasoning for the advisory, excluding long descriptions of studies resulting in shorter letters. This could appeal to physicians who might not have time to read a long letter and instead want a shorter version, trusting in the scientific basis for the advisory. The FDA letters usually contain more data. The letters are longer, and generally appeal to physicians who have time to read detailed advisories, and who want to know quantitative data in order to guide their practice and communicate with patients more effectively. Both regulatory sources could be presented to Canadian health care professionals, and the FDA database could be considered as an alternate data source for those that may want more information.

Notable reference:
Mazor, K. M., Andrade, S. E., Auger, J., Fish, L., & Gurwitz, J. H. (2005). Communicating safety information to physicians: An examination of dear doctor letters. *Pharmacoepidemiology and Drug Safety*, 14(12), 869-875.