Prospective Tracking of Drug Information Resource Updates Following FDA Approved Labeling Changes

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INTRODUCTION

- Bristol-Myers Squibb has implemented a "Medical Information Resource Update Initiative" to notify major drug information resources of new and updated product labeling and safety information for Bristol-Myers Squibb marketed products.
- Through this process, we hope to provide the most up-to-date medical information for our products and to expedite the provision of important safety information to all major medical information resources.
- The FDA provides product label updates and specifies the date and type of update.
- The feedback provided identified valuable insights for future enhancements.

OBJECTIVE

- The primary objective of this project was to determine if there is a difference in the time it takes to update content based on the compendia or the type of labeling change on the FDA website.

METHODS

- The FDA website was monitored for drug prescribing information updates for a period of six weeks. These updates along with the date of the FDA approval were noted.
  - A total of 12 drug products and 18 updates were collected.
- Five different drug information compendia were selected and checked daily for the inclusion of the update in the respective resource.
  - **AHFS**- updates occur monthly
  - **Lexicomp online**- updates occur daily
  - **Epocrates**- updates occur daily
  - **Drugs.com**- updates occur quarterly, monthly, and daily depending on the origin of the resource
  - **Mayo Clinic**- updates vary
- Compendia drug information updates were tracked daily for a six week period (November 25, 2013 to January 31, 2014).
- The drug information in each compendia was compared to the associated updates daily in order to calculate the time needed for each drug information source to update the information.

RESULTS

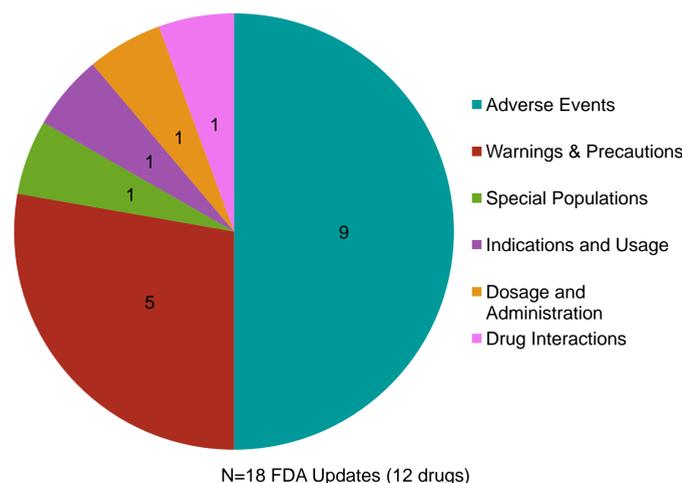**Figure 1.** Type of FDA Approved Label Updates

N=18 FDA Updates (12 drugs)

Figure 2. Type of FDA Label Updates Observed in the Studied Drug Information Compendium Through 6 Weeks
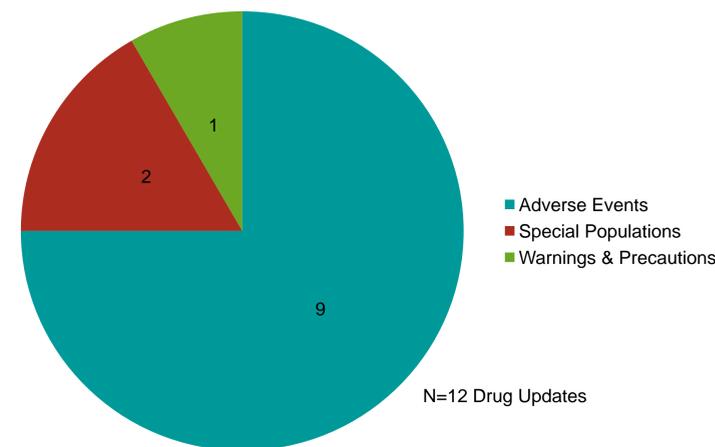

N=12 Drug Updates

Figure 3. Average Days for Drug Information Compendia Update Following FDA Label Updates
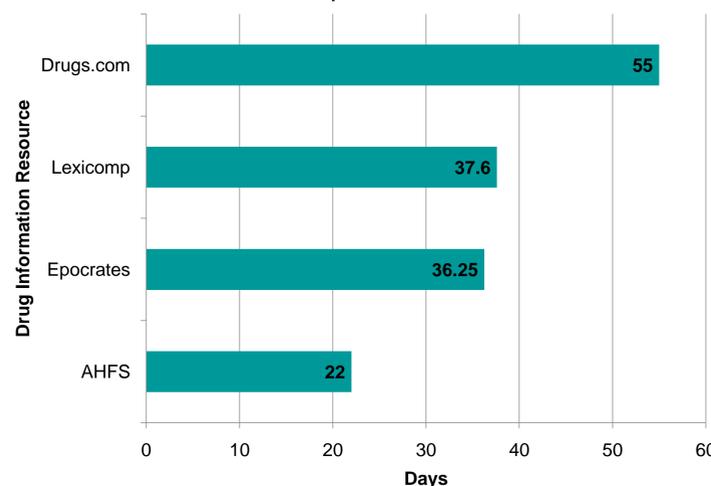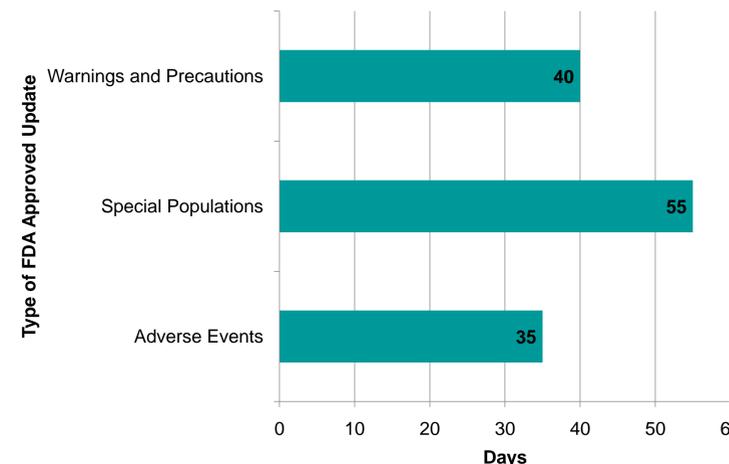

Figure 4. Average Days for Drug Information Compendia Update Categorized by Type of Label Update

RESULTS (CONTINUED)

- 50% of the FDA approved updates included in this study were related to adverse events. (Fig. 1)
- Of the 12 updates that were reflected in drug information compendia, 75% were related to adverse events. (Fig. 2)
- Of the drug resources surveyed; Drugs.com, Lexicomp, Epocrates, and AHFS, the average number of days it took to update the resource was 55, 37.6, 36.3, and 22 days respectively, while MayoClinic.com made no updates during the study period. (Fig. 3)
- For updates involving adverse events, it took an average of 35 days for the resources to updates these drugs. (Fig. 4)

LIMITATIONS

- The timeframe for checking updates was during the holidays, which may impact the speed at which updates are added to the resource.
- Difficulty in identifying the updates in the resources when the language used for patients does not include the medical language used in the label update.

CONCLUSIONS

- Out of the 18 FDA approved drug updates collected; the majority (n=9) included adverse events, with warnings and precautions (n=5), special populations (n=1), indications and usage (n=1), and dosage and administration (n=1) accounting for the remaining updates. Only the adverse events (n=9), special populations (n=2), and warnings and precautions (n=1) were updated within the drug information resources.
- One of the five drug information resources did not incorporate the update within the time frame that this data was collected (MayoClinic). The other references updated the drug information within 22 to 57 days of the FDA approved update notification.
- This research was conducted without bias. Limitations may include the time period in which this research was conducted, since many companies are not open according to normal business hours during the holidays.
- The data indicates that during the six week study period, drug information compendia took an average of 38 days to reflect FDA approved updates. Further research is needed to determine the consistency of updates and the potential methods to improve the speed that updates are applied within each drug information resource.

DISCLOSURE

- No authors of this presentation have conflicts of interest to disclose.