Prescribers’ perception of the pregnancy and lactation labeling rule (PLLR) when making clinical decisions for patients with chronic respiratory conditions

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Background

In June 2015, Food and Drug Administration (FDA) released its final Guidance for Industry: Pregnancy, Lactation, and Reproductive Potential: Labeling for Human Prescription Drug and Biological Products - Content and Format referred to as the “Pregnancy and Lactation Labeling Rule” or PLLR. This rule revises the content and format of the Physician Labeling Rule (PLR) for subsections 8.1, 8.2, and 8.3 of section 8 “Use in Specific Populations” in the full prescribing information. These required changes were intended to help healthcare providers prescribe and counsel women of childbearing potential on their medications. In March 2018, FDA called a Risk Communication Advisory Committee meeting asking for feedback on how the PLLR changes were being perceived by healthcare providers. While no formal vote was taken, the committee discussed several factors including the many definitions of risk, information uncertainty in pregnancy, frustration with lack of lactation data, and simplicity of the lettered categories that played a role in how the PLLR was received. Overall, it was agreed that transparency, as well as clear and consistent language, is instrumental to communicate the risks and benefits of drugs in women of childbearing potential.

Objective

To evaluate the prescribers’ perception of the pregnancy and lactation labeling rule (PLLR) when making clinical decisions for patients with chronic respiratory conditions.

Method

The study is an observational, prospective, anonymous questionnaire comprised of 19 survey questions for prescribers who make clinical decisions for patients with chronic respiratory conditions. The survey population of prescribers was taken from an internal distribution list comprised of 10,000 key opinion leaders within the respiratory and therapeutic area. Survey responses from prescribers were collected through the Qualtrics® online survey platform from February 12, 2019 to May 13, 2019. The survey was designed to capture prescriber demographics, patient population demographics, and qualitative data regarding their perception on the pregnancy and lactation labeling rule. No identifying information of the prescribers was collected. Upon completion of the survey, descriptive analyses were used to analyze the data.

Results

Of the 10,000 healthcare providers surveyed, 84 responses were collected from licensed prescribers who make clinical decisions for patients with chronic respiratory conditions, leaving a total of 50 completed survey responses. Of the 94 responses, 59.6% of prescribers have been practicing for at least 20 years and 73.4% primarily practice in the ambulatory care setting. Thirty-seven percent (USP90) of prescribers reported that more than a quarter of their patients are women of childbearing potential. When asked if awareness of the PLLR changes to the United States Prescribing Information (USPI), 36.7% (22/60) said yes.

Figure 1. How useful is the PLLR when prescribing for patients with chronic respiratory conditions? (n=50)

- Neither useful nor useless
- Moderately useful
- Extremely useful
- Moderately useless
- Extremely useless

Of the following choices, which change would you most like to see as it relates to pregnancy and lactation?

- Additional of “Clinical Considerations” subheading
- Additional of Pregnancy Registry subheading
- Additional of “Risk Summary” subheading
- Additional of Pregnancy Exposure Registry (if available)
- Removal of risk summary in categories B, D, and X
- Removal of Pregnancy Registry subheading

Figure 3. Of the following PLLR changes, rank in order of positive impact when making clinical decisions for patients with chronic respiratory conditions (> most positive impact, < least positive impact)

- Recording of the current pregnancy and lactation subsection (8.1 Pregnancy, 8.2 Lactation, 8.3 Females and Males of Reproductive potential)
- Addition of information regarding discontinuation of therapy during pregnancy
- Addition of Pregnancy Registry initiation date
- Include information regarding non-active metabolites in breast milk within the “Risk Summary” subheading (in addition to active metabolites)
- Other:

Figure 4. Of the following changes, which change would you most like to see to the USPI as it relates to pregnancy and lactation?

- Neither useful nor useless
- Moderately useful
- Extremely useful
- Moderately useless
- Extremely useless

Discussion

Of the completed survey responses, 66.8% and 64% of individuals reported that they found the PLLR to be neither useful nor useless when prescribing and counseling patients with chronic respiratory conditions (Figure 1 and 2). This study shows that prescribers are open to the restructuring and renaming of section 8 of the USPI as it had the most positive impact; however, the removal of the pregnancy letter categories (A, B, C, D, X) had the least positive impact (Figure 3).

Figure 2. How useful is the PLLR when counseling patients with chronic respiratory conditions? (n=50)

Limitations

The study lacks external validity due to the sample population of only respiratory focused healthcare providers and the small sample size. Additionally, the majority of prescribers had a neutral response and thus the overall usefulness of the PLLR was difficult to pinpoint.

Conclusions

After analyzing the prescribers’ perception of the PLLR when making clinical decisions for patients with chronic respiratory conditions, it was found that some prescribers feel there is a lack of information surrounding recommendations for women of childbearing potential. Although the goal of the PLLR was to provide more clarity and information regarding pregnancy and lactation, this change is not always helpful, as it is integral to it’s usefulness when prescribing and counseling patients. In addition, only 36.7% of prescribers were aware of the PLLR. This study recognizes that additional measures for improving and educating prescribers about the PLLR are recommended if the USPI is to be used effectively when making clinical decisions for patients.

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Authors have nothing to disclose.