


1 Abstract

Title: Evaluation of the Physician Education Component of the Ozurdex Risk Management Plan

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Keywords: Ozurdex (dexamethasone), PASS, physician survey

Rationale and background: As part of the risk management plan for Ozurdex, Allergan revised the educational materials for Ozurdex and distributed these materials to physicians beginning in 2014. The current study was conducted to evaluate physicians' understanding and use of these materials.

Research question and objectives: The primary objective of this survey was to assess the effectiveness of the educational material provided to physicians treating patients with Ozurdex by evaluating the physicians' knowledge and understanding of the key information in the Ozurdex Injector's Guide and the summary of product characteristics (SmPC).

Study design: The study was an observational, cross-sectional study of physicians who had recently administered Ozurdex. Eligible physicians were invited to complete a survey regarding their knowledge of key safety information in the Ozurdex Injector's Guide and SmPC.

Setting: France, Germany, Spain, and the United Kingdom

Subjects and study size, including dropouts: Physicians were eligible to participate if they had administered an Ozurdex injection to at least one patient in the past 6 months. A total of 4,162 physicians were invited to participate, and 455 physicians completed the screener. Of these, 3 physicians did not consent, 37 were ineligible, 14 were not included in the analysis, and 401 physicians completed the questionnaire, for a response rate of 9.6%.

Variables and data sources: The data source was self-reported data collected using a standard questionnaire with closed-ended response choices. The questionnaire included items in the following six knowledge areas: contraindications for Ozurdex injection, patient preparation for Ozurdex injection, proper injection technique, important risks associated with Ozurdex injection, patient monitoring after injection, and importance of counselling patients on symptom reporting. Some knowledge areas had multiple questions assessing comprehension of the knowledge area.

Results: Physician knowledge was highest for proper injection technique (knowledge ranged from 58% to 99% correct for 7 items). Most physicians (76%) answered at least 80% of the items in this knowledge area correctly.

In general, knowledge was also high with some exceptions for Ozurdex contraindications, important risks associated with Ozurdex, and the importance of counselling patients on symptom reporting. Knowledge of contraindications ranged from 45% to 92% for six items;

61% of physicians answered at least 80% of the items in this knowledge area correctly. Knowledge of the risks associated with Ozurdex ranged from 32% to 100% for 12 items; more than two-thirds of physicians (68%) answered at least 80% of the items in this knowledge area correctly. Knowledge of the importance of counselling patients on symptom reporting ranged from 61% to 96% for the five items representing actual symptoms; nearly two-thirds of physicians (65%) answered at least 80% of the items in this knowledge area correctly.

Overall, physician knowledge of preparing patients for injection for Ozurdex and patient monitoring after injection was lower. Knowledge of the steps to prepare the patient for injection ranged from 21% to 98% for five items; 31% of physicians answered at least 80% of the items in this knowledge area correctly. Knowledge of patient monitoring after injection ranged from 22% to 75% for four items; 3% of physicians answered at least 80% of the items in this knowledge area correctly.

Overall, 31% of physicians reported receiving the Ozurdex Injector's Guide, and of those, 82% reviewed/read it.

Discussion: Knowledge varied across categories of information, with highest knowledge associated with proper injection technique. In general, knowledge was also high, with some exceptions, for Ozurdex contraindications, important risks associated with Ozurdex, and the importance of counselling patients on symptom reporting. Overall, physician knowledge of preparing patients for an Ozurdex injection and monitoring a patient after an injection was lower.

The levels of reported receipt of the injector's guide was low. Because the guide was distributed as early as 2014, these data may be subject to poor recall.

Marketing Authorisation Holder(s): Allergan Pharmaceuticals Ireland

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