Science For A Better Life

Clinical Study Synopsis

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Title	Evaluation of Physician and Patient Knowledge of Safety and Safe Use Information for Aflibercept in Europe: An Observational Postauthorisation Study
Keywords	Eylea (aflibercept); postauthorisation safety study; evaluation of risk minimisation measures; physician survey; patient survey
Rationale and background	As part of the risk management plan for aflibercept, Bayer developed materials to educate both physicians and patients on the key safety information and safe use for aflibercept and distributed these materials to increase awareness and understanding about risks associated with aflibercept. The current study was conducted to evaluate the understanding and use of these materials.
Research question and objectives	The primary objectives were to measure whether physicians and patients received and used the educational materials and to evaluate their awareness and understanding of the key safety messages.
Study Design	The study was an observational, cross-sectional study among physicians and patients with recent aflibercept experience. Eligible physicians and patients were invited to complete a brief questionnaire regarding their knowledge of key safety in the aflibercept educational materials.
Setting	The UK, Germany, France, Spain, and Italy
Subjects and Study Size, including dropouts	Physicians were eligible to participate if they had prescribed or administered aflibercept in the past 6 months for one of the indications of interest. A total of 8,424 physicians were invited to participate and 798 completed the screener. Of these, 14 did not consent, 339 were ineligible, and 17 did not meet the definition for a completed questionnaire. The target sample size was 300 to 500 physicians overall, and the study achieved 428 completed physician questionnaires, for a response rate of 5.1%. Patients were eligible if they had been administered an aflibercept injection within the last 6 months for one of the indications of interest. Of the 874 patients approached to participate, 23 were ineligible. Of the 851 patients who were eligible, 75 declined, 2 did not consent, and 1did not meet the definition for a completed questionnaire. The target sample size was 750 patients overall, and the study achieved 773 completed patients questionnaires, for a response rate of 91%.
Variables and Data sources	Data were obtained through questionnaire responses.
Results	In general, physicians' knowledge of questions related to aflibercept storage and preparation and injection procedures was high. Physician knowledge on dosing requirements was higher for wAMD and lower for newer or less commonly prescribed indications. Some physicians responded that monitoring is required during the first 12 months for the treatment of wAMD and the

	treatment of DME even though there is no requirement for monitoring between injections during the first 12 months. Most physicians knew the recommended dose for aflibercept, and knowledge on questions related to excess volume of aflibercept varied. Overall, physicians' knowledge of actions to prepare patients for treatment with aflibercept was high, and most physicians knew the contraindications for aflibercept use. Knowledge was also high for recognising signs and symptoms of possible side effects. Most physicians reported that they received the SmPC and the prescriber guide. Approximately half of physicians reported that they received the intravitreal injection procedure video and the patient booklet. Likewise, half of physicians reported providing the patient booklet to most or all of their patients. Patients' knowledge of the health conditions to discuss with a doctor prior to injection was high for 8 out of 9 individual items. Approximately half of patients correctly responded to the question related to pregnancy and breastfeeding, likely because this condition is less salient in the aflibercept patient population given the patients' ages (99% of the patients in the study were 46 years or older). Patient knowledge about possible side effects with aflibercept varied by item. Most patients knew that they should speak to their ophthalmologist (or someone in his or her office) immediately if they think they might be having a side effect from their aflibercept injection. The levels of reported receipt of the aflibercept patient booklet and the audio CD were relatively low, and there was considerable variation across countries.
Discussion	Physicians' knowledge of most important topics was high (e.g., side effects). Knowledge was lower for topics that are less frequently encountered (e.g., use in women of childbearing potential) and for more complex aspects of safe use (e.g., dosing and monitoring) for which we assume that physicians would consult the label and/or prescriber guide rather than relying on recall. The reported receipt of the SmPC and prescriber guide was high, and the high level of knowledge among treating physicians also suggests that the key safety information is available to the treating physicians. Levels of patient knowledge were as expected – with highest knowledge on less complex concepts (e.g., health conditions to discuss with the physician and easily identified side effects) and lower knowledge on more complex concepts and issues less salient to the patient population (e.g., more complex side effects and issues pertaining to women of childbearing potential).

Marketing Authorisation Holder(s)	Bayer AG
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