Evaluation of Patient Knowledge of Safety and Safe Use Information for Aflibercept in Europe

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DISCLOSURES

- EA, BC, ED, DW, and LZ are full-time employees of RTI Health Solutions, which received funding from Bayer AG to conduct this study. The contract between RTI Health Solutions and the sponsor includes independent publication rights. RTI conducts work for government, public, and private organizations, including pharmaceutical companies. ZV is a full-time employee of Bayer, the funder of this study.

BACKGROUND

- Aflibercept (Eylea), administered via intravitreal injection, is approved in Europe for the treatment of neovascular (wet) age-related macular degeneration (wAMD), visual impairment due to macular edema secondary to central retinal vein occlusion (CRVO), visual impairment due to macular edema secondary to branch retinal vein occlusion (BRVO), diabetic macular edema (DME), and visual impairment due to myopic choroidal neovascularization (myopic CNV).
- Risk minimization measures for aflibercept in Europe included:
  - A prescriber guide and injection procedure video
  - A patient booklet and audio CD

OBJECTIVE

- To measure whether patients received the educational materials and to evaluate their knowledge of the key safety and safe use information.

METHODS

Overview of Study Design

- The study was an observational, cross-sectional survey of knowledge and understanding among a sample of physicians and patients with recent aflibercept experience in France, Germany, Italy, Spain, and the United Kingdom (UK). The information in this poster focuses on the patient survey.
- Figure 1 provides an overview of study start-up activities, and Figure 2 provides an overview of study implementation.

Survey Design and Administration

- The questionnaire included 12 primarily closed-ended items on: (1) patient characteristics, (2) patient knowledge, (3) patient preinjection instructions and receipt of aflibercept educational materials, and (4) patient use of aflibercept education materials.
- The questionnaire was developed using best practices for instrument development and was tested through cognitive interviews with patients in each country.
  - As a result of initial interviews highlighting patients' serious visual impairment and the high cognitive burden of the questionnaire, the decision was made to administer the questionnaire by an in-person interviewer.
- The target sample size was 150 per country for a total of up to 750 patients overall.
- Data collection ran from 7 December 2015 to 29 September 2016.

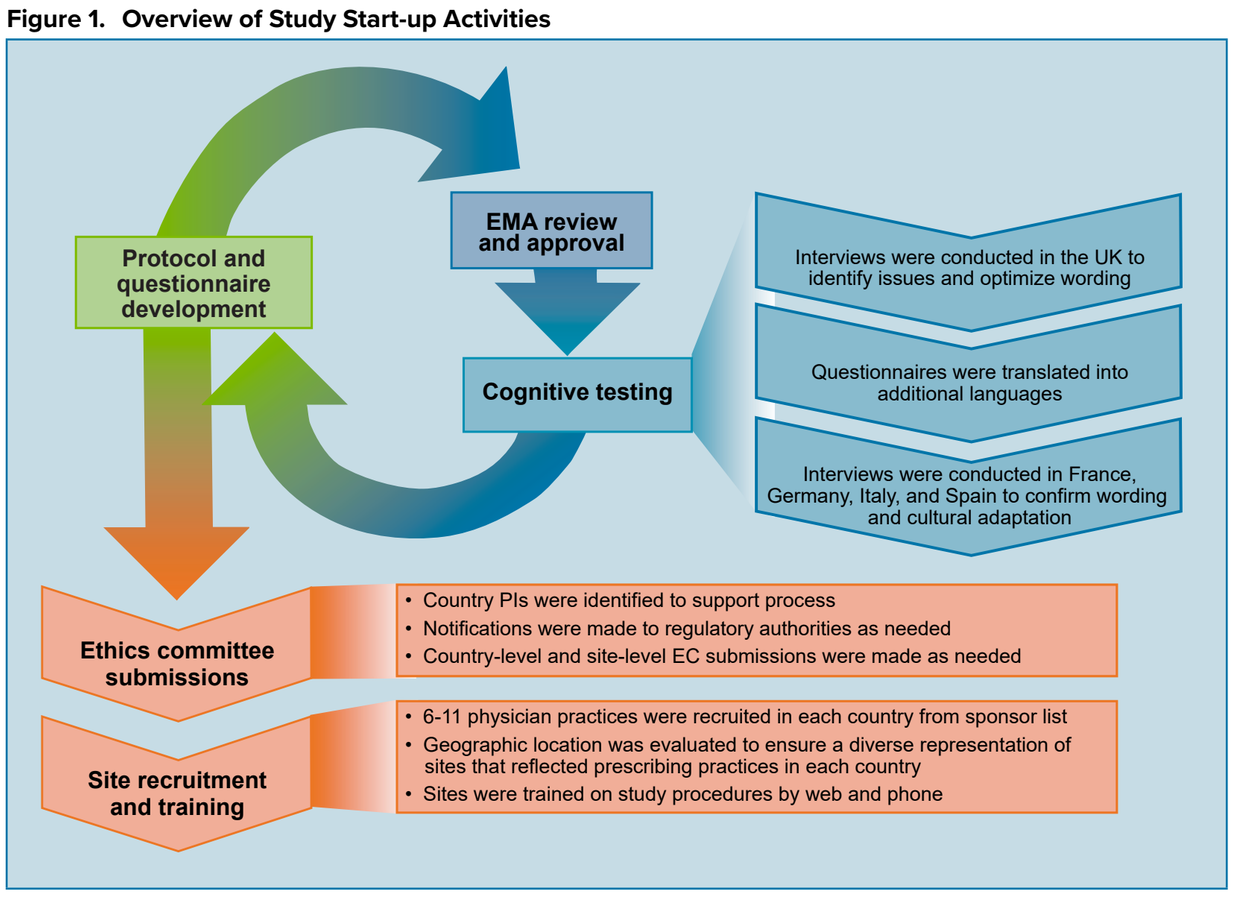
To minimize the possibility of a study intervention effect:

- Sites were trained not to discuss the study with patients in advance of their visit so as not to allow patients to prepare for the survey beforehand.
- Sites were asked not to deviate from their customary patient counseling practices and were asked to administer the questionnaire to patients during the visit prior to any patient counseling.
- Site personnel were trained on the importance of and processes for conducting an objective interview.
- The questionnaire was administered without the aid of a patient booklet for referral, thus relying on patients' recall of the key messages for completion.

Analysis

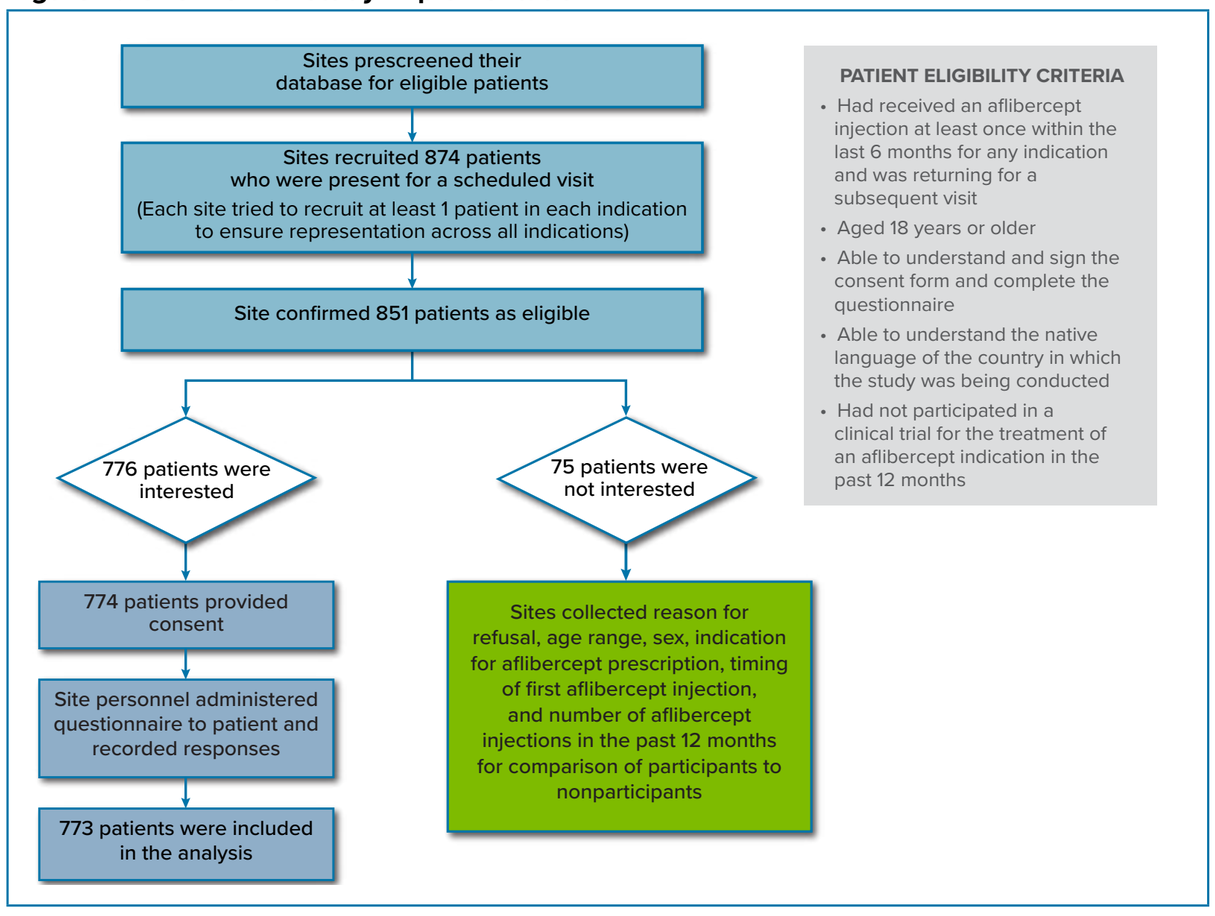
- Data analyses were descriptive and focused on summarizing the questionnaire responses by country and overall.
- The results for knowledge questions were reviewed individually and overall to assess the effectiveness of the educational materials and to identify any knowledge gaps.

Figure 1. Overview of Study Start-up Activities



EC = ethics committee; EMA = European Medicines Agency; PI = principal investigator.

Figure 2. Overview of Study Implementation



RESULTS

Participants

- Of the 773 patients included in the analysis, most patients were aged 66 years or older (81%) and reported having no college-level education (82%); 54% were female.
- The most common indication for which aflibercept was prescribed was wAMD (71%) followed by DME (19%). More than half of the patients (60%) had received their first injection of aflibercept within the past year. Most patients (74%) had received 1 to 6 aflibercept injections in the past year.

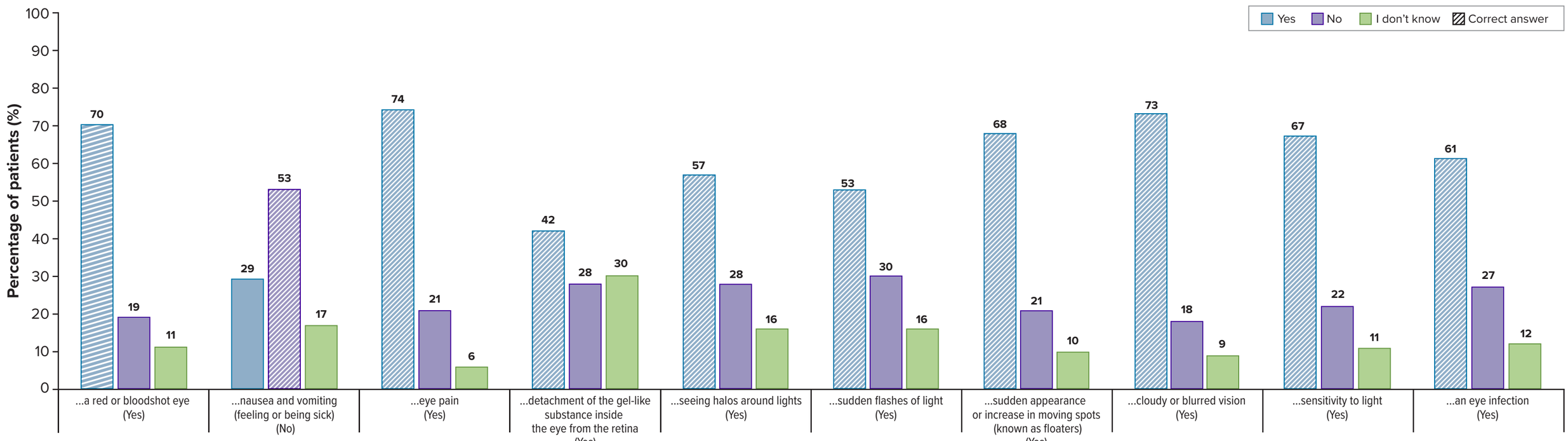
Receipt and Review of Materials

- Thirty-eight percent of patients reported receipt of the aflibercept patient booklet, 23% the aflibercept audio CD, and 35% the aflibercept patient information leaflet. There was considerable variation in the proportions of patients reporting receipt of each item across countries.

Knowledge Questions

- Point estimates (exact 95% confidence intervals [CIs]) for patients' knowledge of health conditions to discuss with a doctor before an aflibercept injection were high, from 85% (82%-87%) to 92% (90%-94%) on 8 of 9 individual items. Knowledge was lower, 52% (48%-55%), on the one item about discussing pregnancy or breastfeeding with a doctor.
- Knowledge about possible side effects varied by item, with the highest correct response proportion (74% [70%-77%]) for "eye pain" and the lowest (42% [39%-46%]) for "detachment of the gel-like substance inside the eye from the retina" (Figure 3).
- Most patients (78% [75%-81%]) knew that they should speak to their health care provider immediately if they thought they might be having a side effect from their aflibercept injection.

Figure 3. Is [...side effect] a possible side effect of Eylea? (N = 773)



DISCUSSION

- The relatively low level of reported receipt of materials may reflect poor recall if the materials had indeed been received or could reflect various reasons for not receiving the educational material.
  - For example, in some countries (e.g., France and Spain), physicians are required to have patients sign an informed consent form with relevant safety information prior to treatment. Therefore, it is possible that physicians could prioritize providing competing information sources that are legally required over the patient booklet.
- Patient knowledge was high for health conditions that they should tell their ophthalmologist about before receiving an aflibercept injection.
- Patient knowledge was high for side effects that are easier to identify (e.g., "red or bloodshot eye," "eye pain," and "cloudy or blurred vision") and lower for side effects that may be more complex to identify (e.g., "detachment of the gel-like substance inside the eye from the retina").
- Most patients knew that they should speak to their ophthalmologist (or someone else in his or her office) immediately if they think they might be experiencing a side effect, which suggests that the patients would take appropriate action if there were any question of a side effect.

CONCLUSIONS

- Levels of patient knowledge were as expected, with the highest knowledge on less complex concepts (e.g., health conditions to discuss with a 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).
- The fact that patient knowledge was relatively high despite the low reported receipt of the educational materials suggests that patients were receiving the information from other sources. Determining the most effective formats and distribution channels for communicating safe use information to physicians and patients was beyond the scope of this study but remains an important question in risk management.

REFERENCES

1. European Medicines Agency. Eylea summary of product characteristics. October 26, 2017. Available at: https://www.medicines.org.uk/emc/medicine/27224. Accessed June 12, 2018.

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