

BACKGROUND

- In 2008, Bayer Healthcare Pharmaceuticals (Bayer) was notified by the United States (US) Food and Drug Administration (FDA) that a Risk Evaluation and Mitigation Strategy (REMS) was requested for all fluoroquinolones, including Moxi (marketed as Avelox by Merck in the US) and Cipro because of the frequency of tendon-related adverse events reported.
- Cipro and Avelox, like other quinolones, are covered by a medication guide-only REMS. The goal of the medication guides (MGs) is to inform patients of serious risks associated with the use of fluoroquinolones, particularly tendonitis and tendon rupture.
- To support the evaluation of these REMS, Bayer sponsored a survey of patients prescribed Cipro (tablets, oral suspension, or intravenous [IV] infusion) or Avelox (tablets or IV infusion) to measure patient awareness of the risks associated with these medications and comprehension of the key messages outlined in the respective MGs.
- MGs are distributed to patients at the pharmacy when they pick up their prescription.

OBJECTIVES

- To assess whether patients receive and read the MG.
- To evaluate patient awareness of the risks associated with Cipro and Avelox.
- To examine patient understanding of actions they should take if adverse symptoms are experienced.

METHODS

- A cross-sectional study was conducted with 204 patients prescribed Cipro and 215 patients prescribed Avelox in the US.
- Patients were identified either through a clinical or pharmacy database.
- Two questionnaires (one each for Cipro and Avelox) were developed and cognitively tested prior to data collection.
- Participants were limited to adult patients who had filled a prescription in the previous 30 days.
- Participating patients were asked a series of questions addressing the following topics
 - Awareness of the key risks associated with fluoroquinolones as described in the MG
 - Awareness of which patient groups should not receive Cipro or Avelox
 - Knowledge of actions patient should take if adverse symptoms are experienced
 - Receipt and review of the MG.
- Data were collected between August 31, 2010, and October 20, 2010.

RESULTS

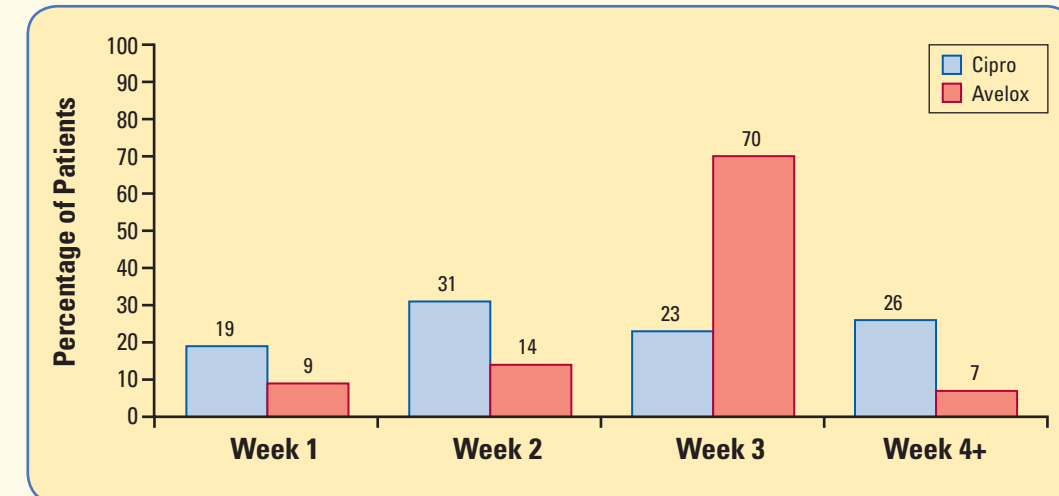
Response Rates

- Of the patients invited through the clinical data repository, 38% of the patients prescribed Cipro and 51% of the patients prescribed Avelox completed the questionnaire.
- 2,000 patients from the pharmacy network were invited, and 150 (7.5%) completed the questionnaire before data collection was closed.
- The distribution of the patients who completed the Cipro and Avelox questionnaires were generally similar to those of the nonrespondents and the overall list of participants invited.

Respondent Demographics and Background

- Cipro respondents were predominantly white (86%), female (73%), and the majority had some education beyond high school: either some college/technical training (35%) or a college degree or more (39%).
- Similar to the Cipro respondents, the majority of Avelox respondents were white (85%), female (68%), and had some education beyond high school: either some college/technical training (29%) or a college degree or more (44%).
- The distribution of respondents by week between prescription fill/IV infusion and questionnaire completion across four time categories is displayed in Figure 1.

Figure 1. Weeks Between Prescription Fill/IV Infusion and Questionnaire Completion



Disease and Treatment History

- Figures 2 and 3 display the distribution of respondents' self-report indication for treatment.

Figure 2. Why Were You Prescribed Cipro?

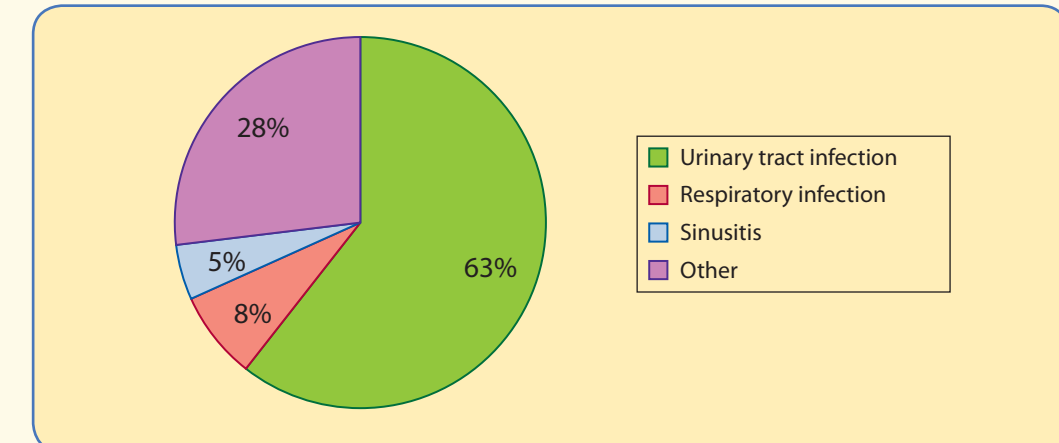
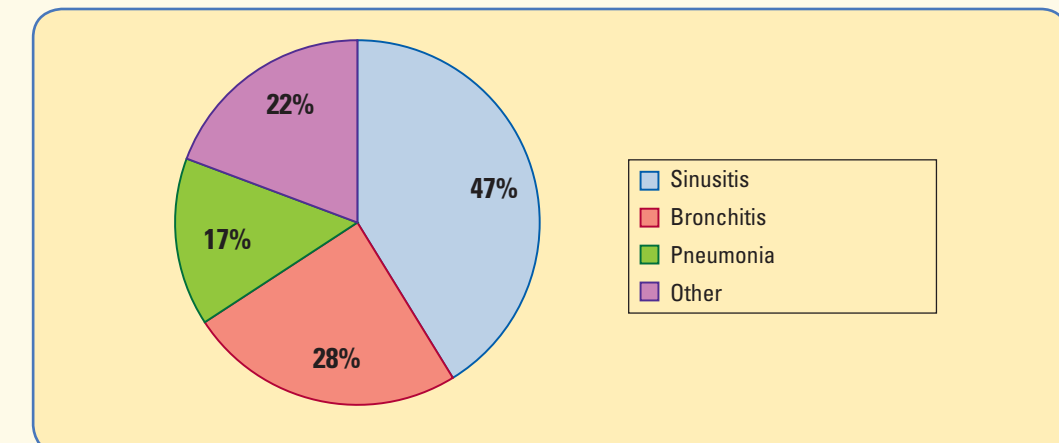


Figure 3. Why Were You Prescribed Avelox?

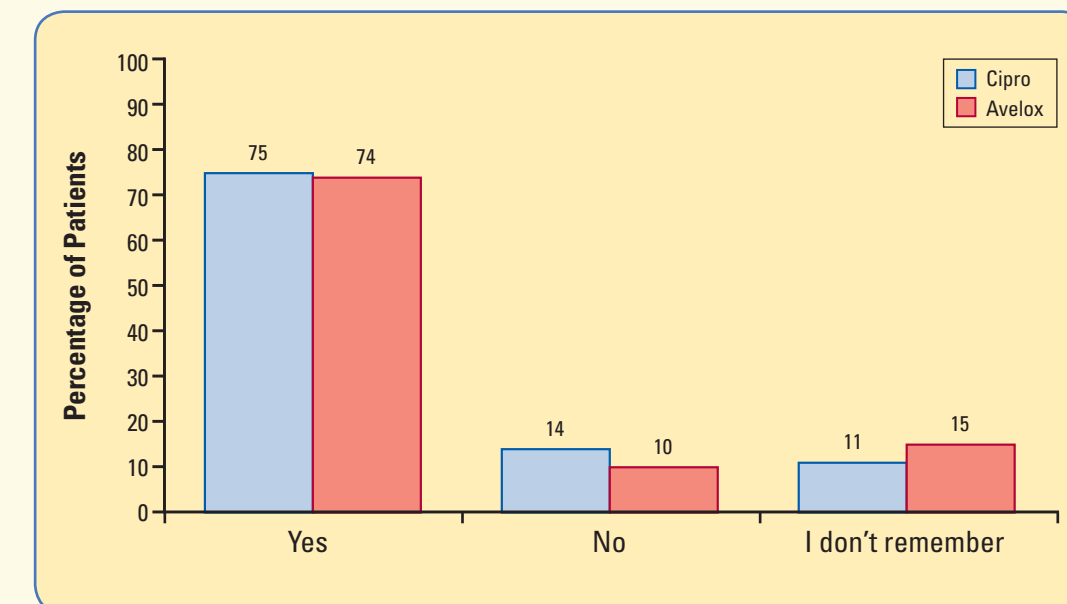


- Almost all Cipro and Avelox respondents (93% and 94%, respectively) reported receiving a written prescription from a healthcare provider and filling it at a pharmacy or online.
- Most Cipro and Avelox respondents (95% and 98%, respectively) who filled their prescriptions indicated that they had already begun taking their prescription, with the majority of these respondents indicating that they had already finished taking it.

Medication Guide Receipt and Review

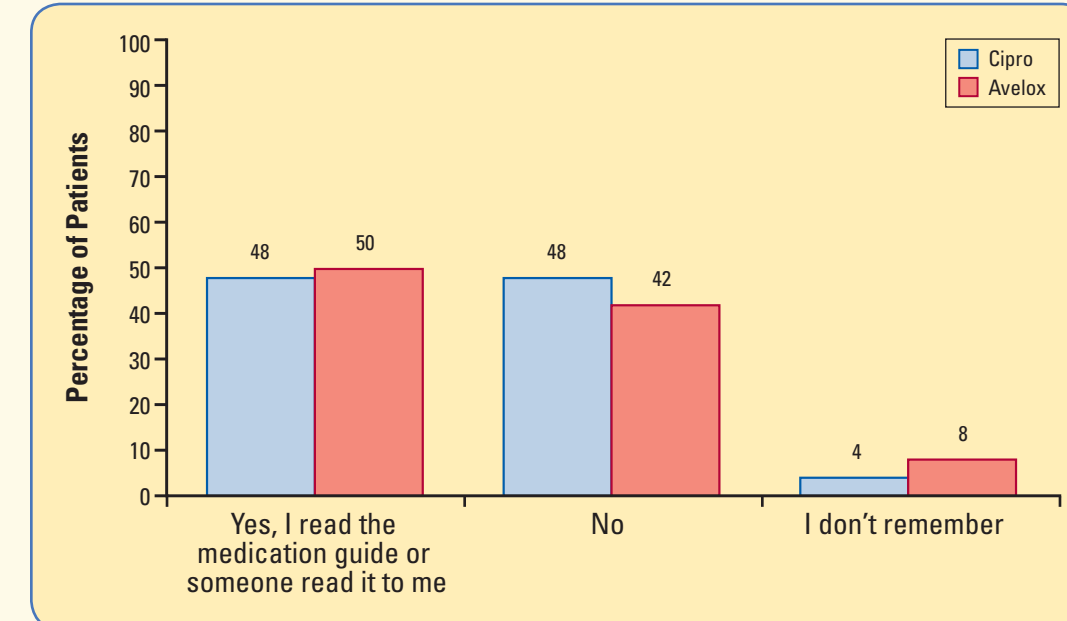
- Most Cipro and Avelox respondents indicated that they had received the MG with their prescription (Figure 4).

Figure 4. Did You Receive a Copy of the Cipro Medication Guide With Your Prescription?



- If respondents had not received the MG with a prescription, 14% and 11% of Cipro and Avelox respondents (respectively) indicated they had received it somewhere else.
- Most Cipro and Avelox respondents read the MG (Figure 5).

Figure 5. Did You Read the Avelox Medication Guide or Did Someone Read It to You?



- 29% and 28% of respondents indicated that someone had discussed with them the potential risks associated with Cipro and Avelox, respectively.
- Respondents who reported reading or being read the MG were much more likely to report having been told of the potential risks of Cipro/Avelox at the time they received their prescription/treatment compared with those who did not.

Knowledge Results

- Respondents were asked a series of questions designed to assess their knowledge about information provided in the MG. Responses are summarized in the following tables with frequencies, percentages, and 95% exact confidence intervals (CIs).
- Four of the questions evaluated respondent knowledge of the key risks associated with Cipro and Avelox (Table 1).

Table 1. Knowledge of Key Risks

Question and Responses	Cipro		Avelox	
	n (%)	95% CI	n (%)	95% CI
Knowledge of Serious Side Effects	n = 196		n = 210	
Respondents who selected all four of the correct responses	6 (3)	1-7	13 (6)	3-10
Respondents who selected at least three out of the four correct responses	22 (11)	7-16	27 (13)	9-18
Respondents who selected at least two out of the four correct responses	51 (26)	20-33	57 (27)	21-34
Respondents who selected at least one out of the four correct responses	81 (41)	34-49	96 (46)	39-53
Knowledge of Tendon Problems	n = 203		n = 213	
Respondents who selected all three of the correct responses	20 (10)	6-15	26 (12)	8-17
Respondents who selected at least two out of the three correct responses	43 (21)	16-27	48 (23)	17-29
Respondents who selected at least one out of the three correct responses	89 (44)	37-51	97 (46)	39-52
Knowledge of Contraindications	n = 199		n = 211	
Respondents who selected all three of the Cipro correct responses	20 (10)	6-15		
Respondents who selected at least two out of the three Cipro correct responses	53 (27)	21-33		
Respondents who selected at least one out of the three Cipro correct responses	124 (62)	55-69		
Respondents who selected both Avelox correct responses			61 (29)	23-36
Respondents who selected at least one out of the two correct Avelox responses			144 (68)	62-74

* Correct response; ^b Cipro response only.

- Three questions evaluated respondent knowledge of actions to take if they experienced symptoms of the risks associated with Cipro and Avelox.
- Generally, the results indicated that respondents had greater knowledge of actions to take than of the key risks associated with Cipro and Avelox, suggesting that even if the specific risks were not well acknowledged, respondents generally knew the right course of action if they experienced a symptom.
- Seventy-eight percent of Cipro respondents and 80% of Avelox respondents indicated awareness of the correct action to take should a serious event occur while taking the medication.
- Higher percentages of respondents who read the MG for Cipro or Avelox indicated someone had discussed the potential risks with them (Figure 6 and Figure 7).

Figure 6. At the Time You Received Your Prescription/Treatment for Cipro, Did Anyone Discuss The Potential Risks (Serious Side Effects) of Taking Cipro With You?

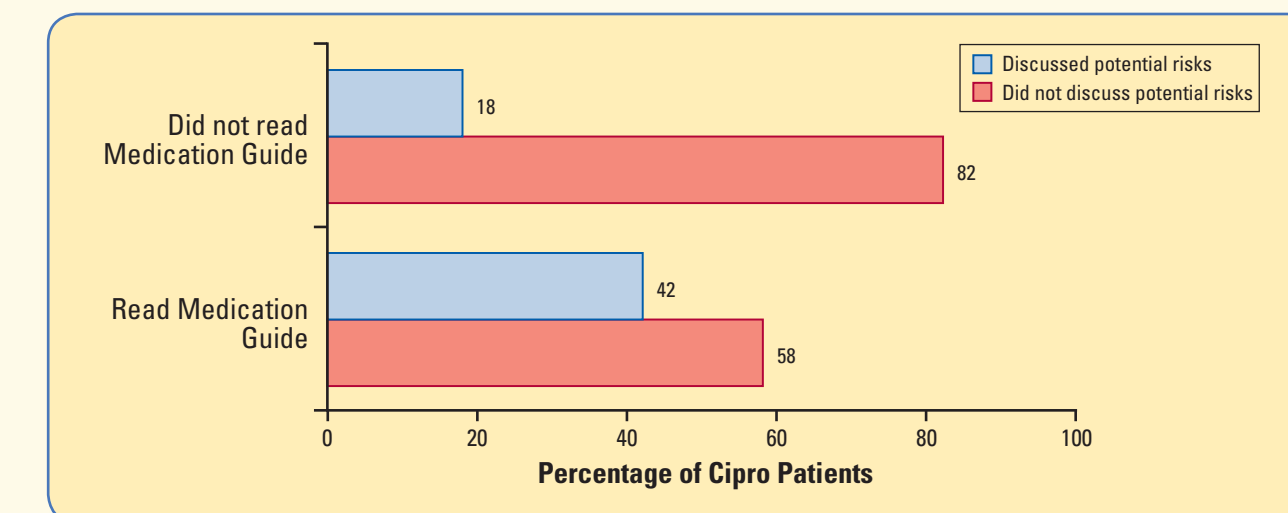
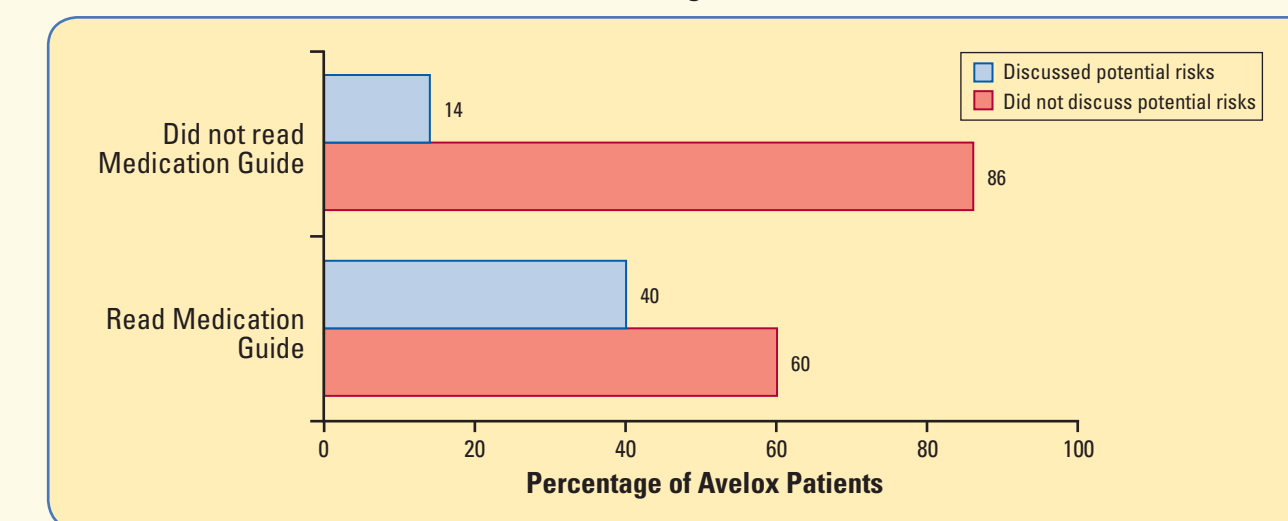


Figure 7. At the Time You Received Your Prescription/Treatment for Avelox, Did Anyone Discuss the Potential Risks (Serious Side Effects) of Taking Avelox With You?



Stratified Results

- In general, respondents showed a very similar response distribution on the knowledge questions regardless of the category by which they were assessed: number of weeks between filling prescription and completing questionnaire, read MG, or age.
- Respondents who completed the questionnaire closer to filling their prescription did not show a clear trend of selecting more correct responses as might be expected, suggesting that recall period was not a major factor in patient knowledge, at least up to 30 days from prescription.
- As expected, respondents who indicated that they read or were read the MG had substantially higher percentages of correct responses on the knowledge questions than those who reported not reading it or not remembering if they read it.
 - This finding suggests that if patients do read the MG, the key messages are communicated.
 - In particular, respondent knowledge of the serious side effects associated with Cipro and Avelox was higher among those who indicated that they read the MG.
- Knowledge of key risks was somewhat greater among respondents over the age of 60 for Cipro respondents, but generally very similar across age groups for Avelox respondents.

CONCLUSIONS

- The results suggest that the Cipro and Avelox REMS programs are having a positive impact by improving patient awareness of the key messages included in the MG.
- Higher awareness of key risks emerged among individuals who read the MG compared with those who did not.
- Respondents who had been counseled by a healthcare professional were more likely to have read the medication guide, demonstrating the impact of healthcare professions.
- Knowledge of key risks was highest among respondents aged 60 and older (the category with the highest risks). This finding indicates that knowledge may depend on the perceived relevance of the information to the patient.

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