



Modular Program Report

The following report(s) provides findings from an FDA-initiated query using its Mini-Sentinel pilot. While Mini-Sentinel queries may be undertaken to assess potential medical product safety risks, they may also be initiated for various other reasons. Some examples include determining a rate or count of an identified health outcome of interest, examining medical product use, exploring the feasibility of future, more detailed analyses within Mini-Sentinel, and seeking to better understand the capabilities of the Mini-Sentinel pilot.

Data obtained through Mini-Sentinel are intended to complement other types of evidence such as preclinical studies, clinical trials, postmarket studies, and adverse event reports, all of which are used by FDA to inform regulatory decisions regarding medical product safety. The information contained in this report is provided as part of FDA's commitment to place knowledge acquired from the Mini-Sentinel pilot in the public domain as soon as possible. Any public health actions taken by FDA regarding products involved in Mini-Sentinel queries will continue to be communicated through existing channels.

FDA wants to emphasize that the fact that FDA has initiated a query involving a medical product and is reporting findings related to that query does not mean that FDA is suggesting health care practitioners should change their prescribing practices for the medical product or that patients taking the medical product should stop using it. Patients who have questions about the use of an identified medical product should contact their health care practitioners.

The following report contains a description of the request, request specifications, and results from the modular program run(s).

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Overview

Request Description FDA requested use of Modular Program 1 (MP1) to investigate prevalent and incident use of Selegiline, a monoamine oxidase inhibitor used to treat depression. The query was run against the **Mini-Sentinel Distributed Database** and distributed on **March 30, 2012**.

Results presented in this report provide counts of prevalent and incident users, dispensings, and days supplied of Selegiline. Incident Selegiline use was established using drug washout periods of 183 and 365 days. The program was run from January 1, 2006 to December 31, 2010.

Please review the Notes below and refer to the specifications page for request details.

Request ID msy3_mpr8

Specifications Program parameter inputs and scenarios

Table 1 Table of the number of prevalent users, dispensings, and days supplied of Selegiline as well as the number of days supplied per user, dispensings per user, and days supplied per dispensing by age group and sex

Figure 1 Six figures depicting the number of prevalent users, dispensings, and days supplied for Selegiline use as well as the number of days supplied per user, dispensings per user, and days supplied per dispensing by age group and sex

Table 2 Table of prevalence rates of Selegiline use (number of users per 100,000 enrollees) by year - 2006-2010

Figure 2 Figure of prevalence rates of Selegiline use (number of users per 100,000 enrollees) by year - 2006-2011

Table 3 Two tables of the number of incident users, dispensings, and days supplied of Selegiline as well as the number of days supplied per user, dispensings per user, and days supplied per dispensing by age group, sex, and washout period

Figure 3 Six figures depicting the number of incident users, dispensings, and days supplied for Selegiline use as well as the number of days supplied per user, dispensings per user, and days supplied per dispensing by age group, sex, and washout period

Table 4 Table of incidence rates of Selegiline use (number of users per 100,000 enrollees) by washout period and year - 2006-2010

Figure 4 Figure of incidence rates of Selegiline use (number of users per 100,000 enrollees) by washout period and year - 2006-2011

Notes: Please contact the Mini-Sentinel Operations Center (MSOC_Requests@harvardpilgrim.org) for questions and to provide comments/suggestions for future enhancements to this document.

Modular Program Specifications

Modular Program #1 was used to investigate the number of prevalent and incident users of selegiline. The query period was from January 1, 2006 to December 31, 2010. This request examined 4 age groups, split as follows: 00-21, 22-44, 45-64, 65+ years. A total of 2 different scenarios were examined in this report with differing washout periods. See below for a description of each of these scenarios.

Scenario	Drug/Exposure Criteria		
	Incident exposure	Incident w/ respect to (incidence criteria):	Washout (days)
1	Selegiline	Selegiline	183
2	Selegiline	Selegiline	365

Table 1. Number of Prevalent Users, Dispensings, and Days Supplied, Dispensings per User, Days Supplied per User, and Days Supplied per Dispensings of Selegiline by Age Group and Sex - 2006-2010

		Users	Dispensings	Days Supplied	Dispensings/User	Days Supplied/ User	Days Supplied/ Dispensing
Overall		4,705	25,925	790,194	5.5	167.9	30.5
Age Group	0 to 21	191	861	24,548	4.5	128.5	28.5
	22 to 44	1,706	8,999	270,909	5.3	158.8	30.1
	45 to 64	2,241	13,360	413,215	6.0	184.4	30.9
	65+	567	2,705	81,522	4.8	143.8	30.1
Sex	Female	2,939	15,942	489,649	5.4	166.6	30.7
	Male	1,762	9,979	300,395	5.7	170.5	30.1
	Unknown	4	4	150	1.0	37.5	37.5

Figure 1a. Number of Prevalent Selegiline Users by Age Group, and Sex - 2006-2010

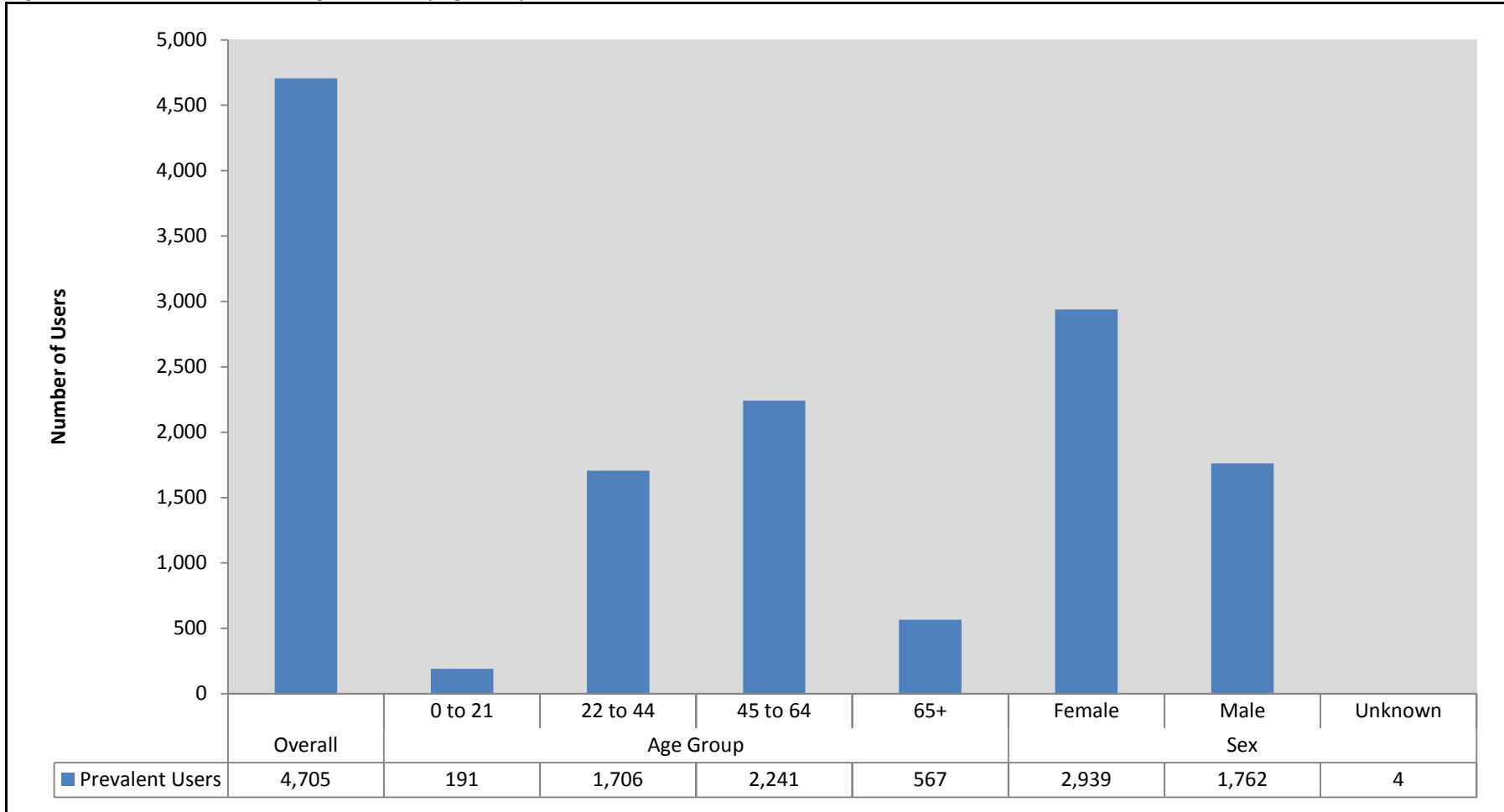


Figure 1b. Number of Dispensings for Prevalent Selegiline Users by Age Group and Sex - 2006-2010

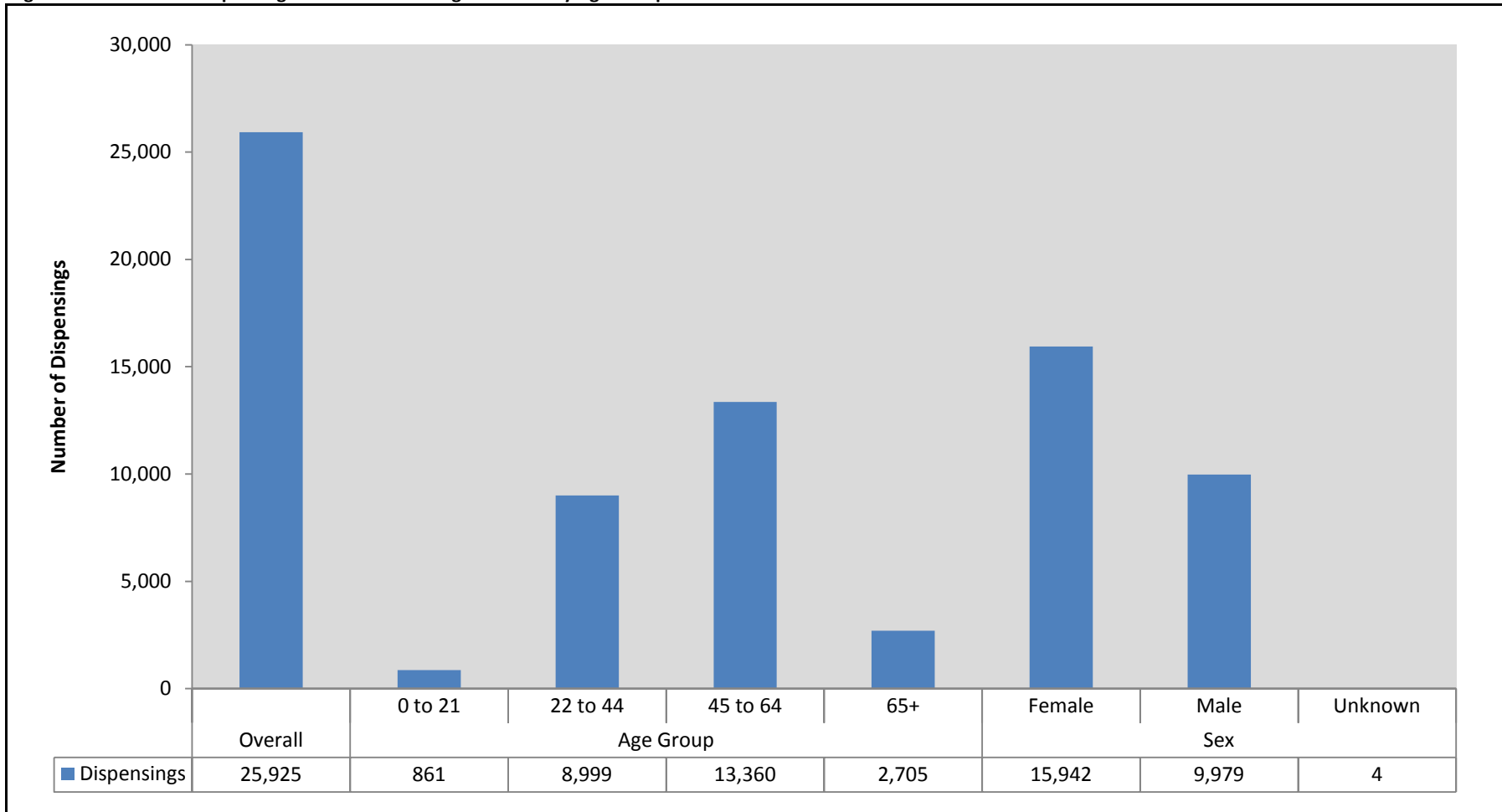


Figure 1c. Number of Days Supplied for Prevalent Selegiline Users by Age Group and Sex - 2006-2010

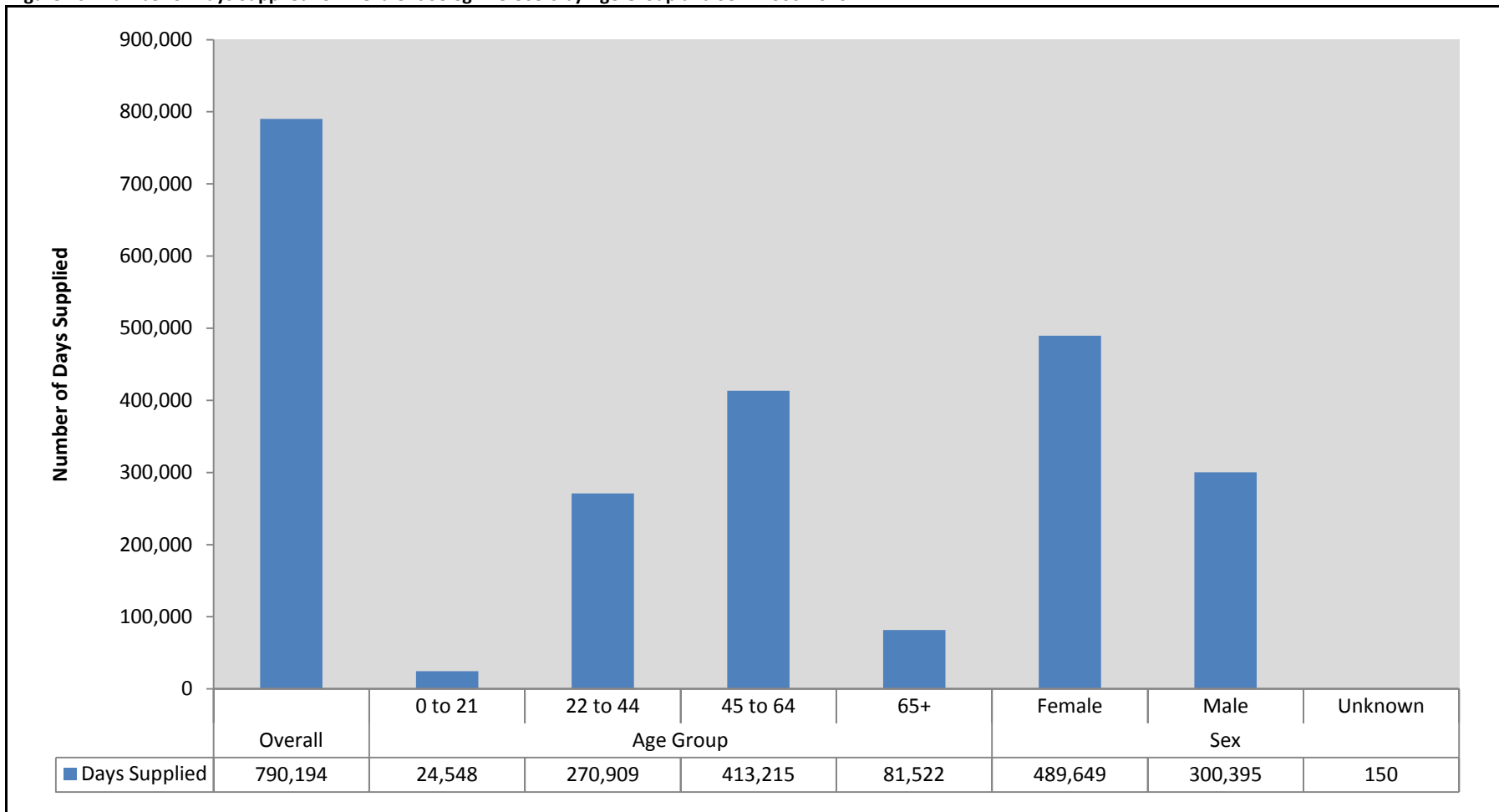


Figure 1d. Number of Dispensings per Prevalent Selegiline User by Age Group and Sex - 2006-2010

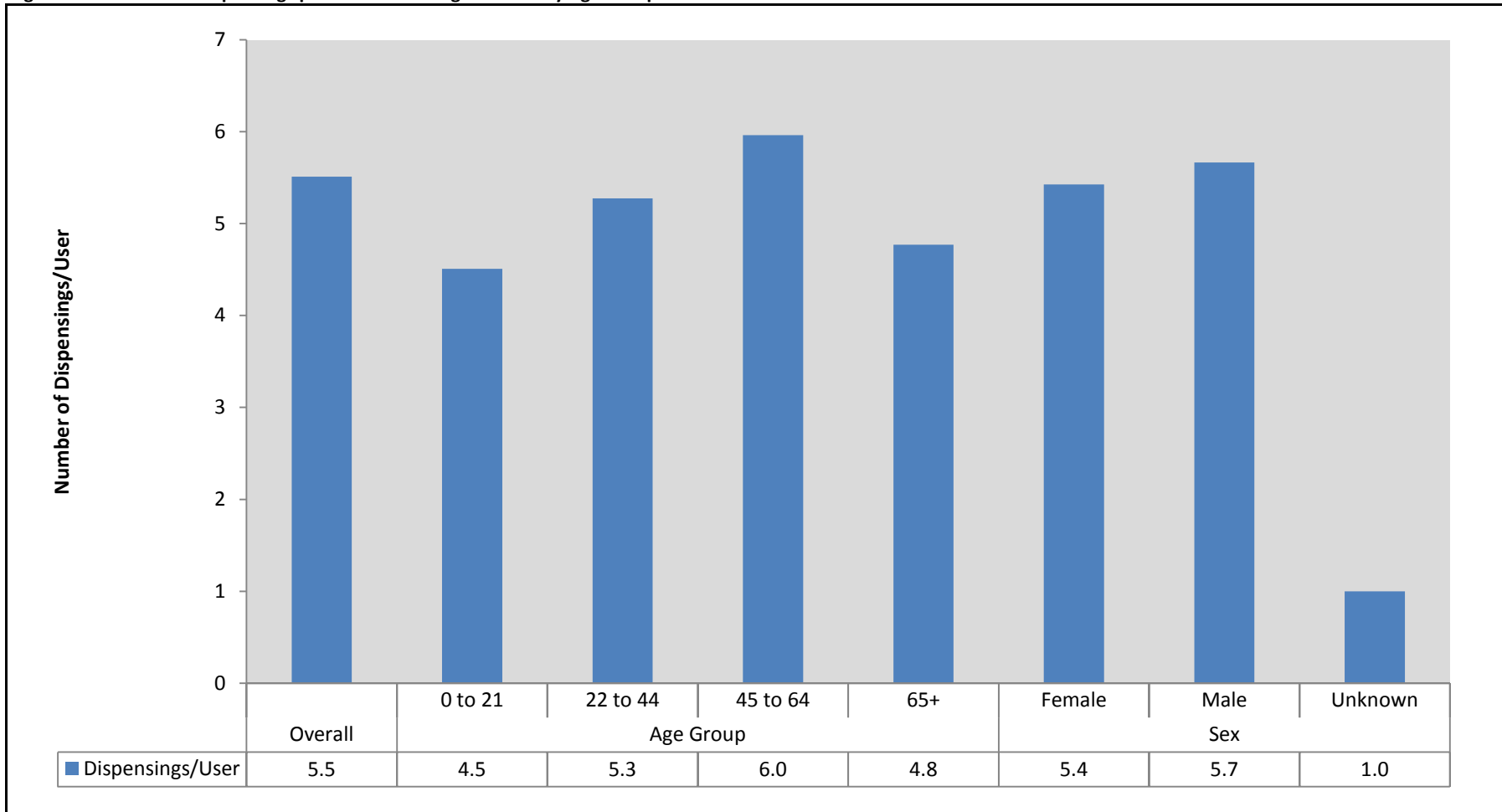


Figure 1e. Number of Days Supplied per Prevalent Selegiline User by Age Group and Sex - 2006-2010

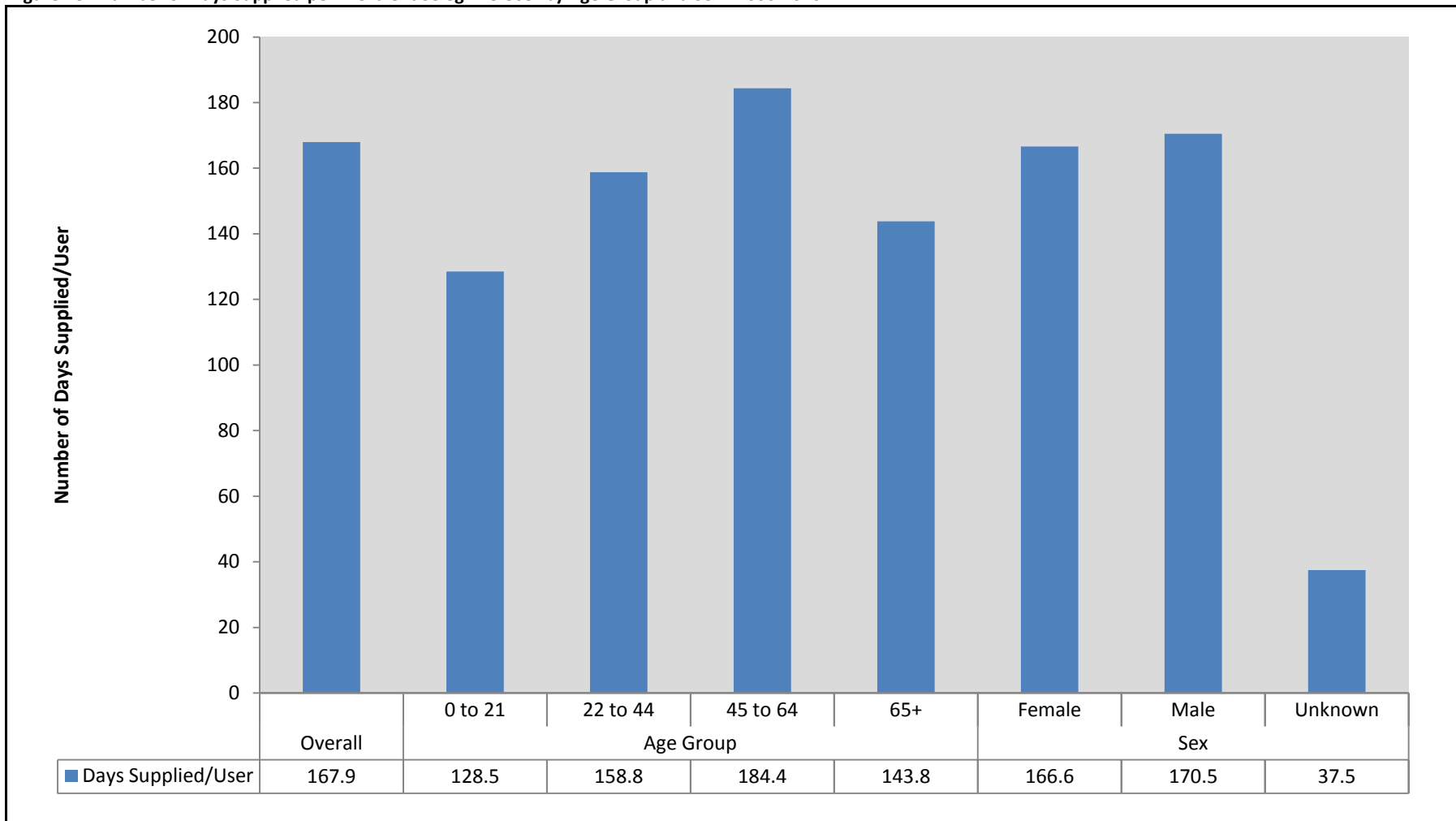


Figure 1f. Number of Days Supplied per Dispensing for Prevalent Selegiline Users by Age Group and Sex - 2006-2010

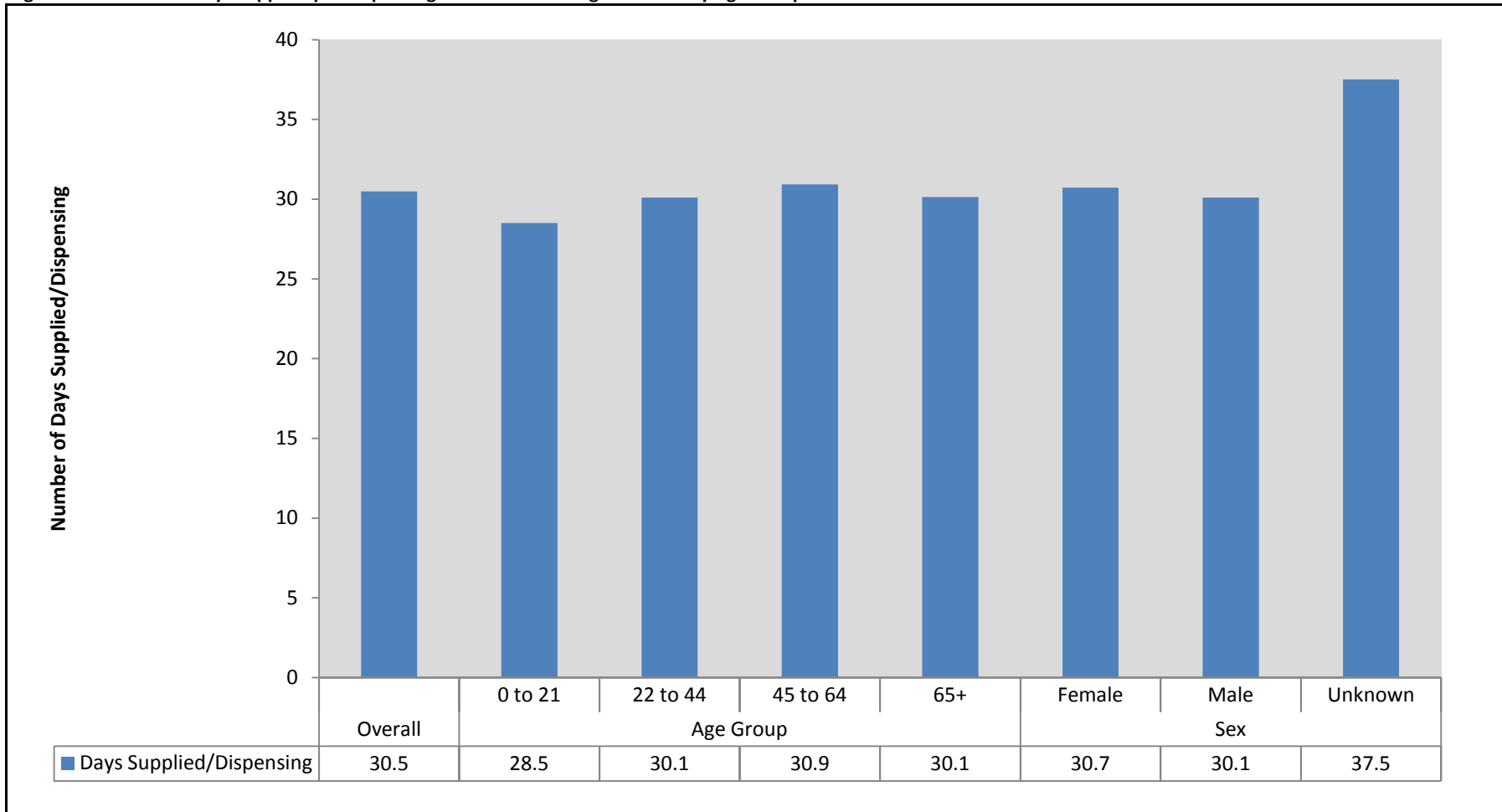


Table 2. Prevalence of Selegiline Use (Number of Users per 100,000 Enrollees) by Year - 2006-2010

	Users	Enrollees	Rate
2006	958	30,811,115	3.1
2007	1,739	34,303,646	5.1
2008	1,396	47,086,296	3.0
2009	1,363	45,103,516	3.0
2010	1,158	43,790,907	2.6

Figure 2. Rate of Prevalent Selegiline Use (Number of Users per 100,000 Enrollees) by Year - 2006-2010

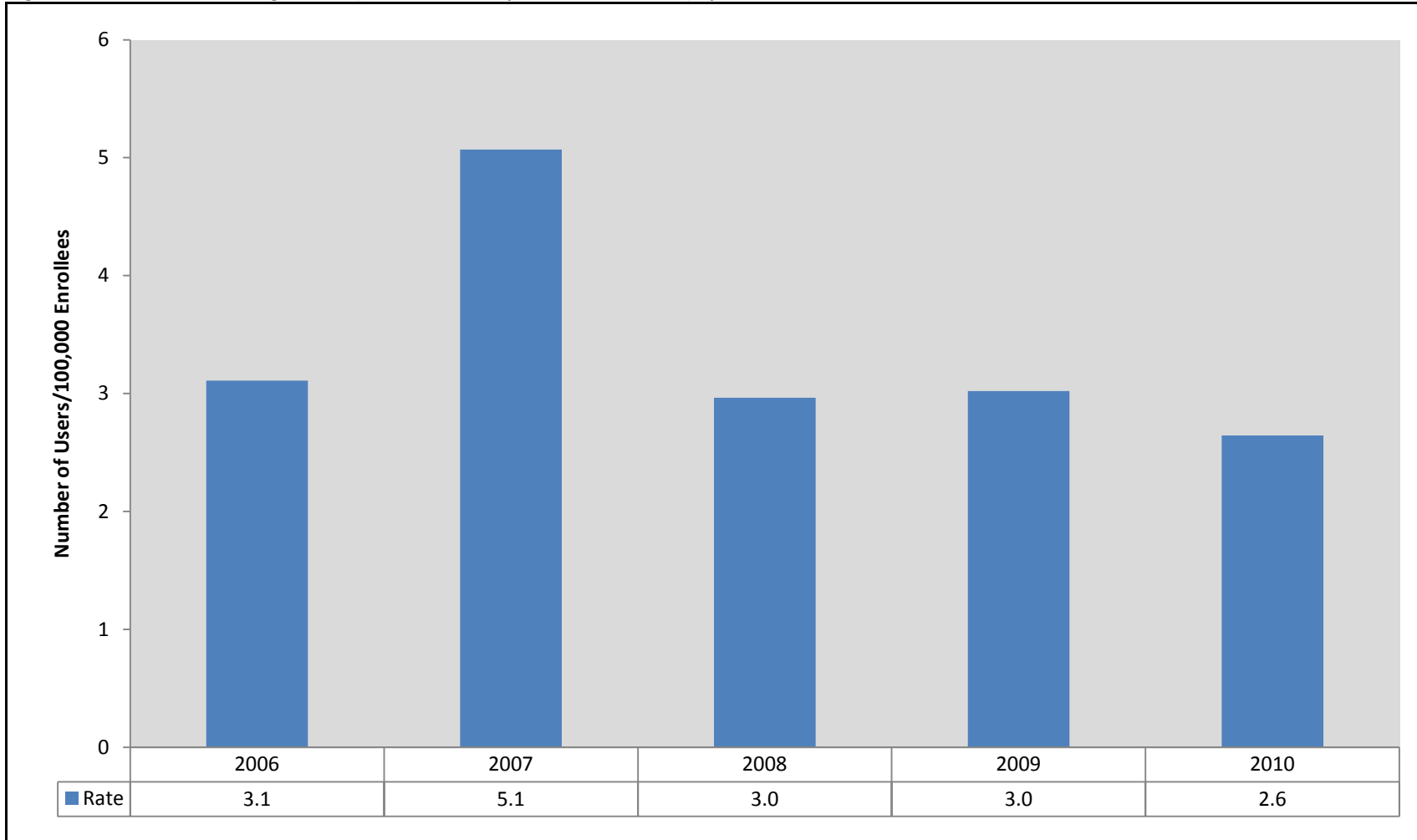


Table 3a. Number of Incident Users, Dispensings, Days Supplied, Dispensings per User, Days Supplied per User, and Days Supplied per Dispensings of Selegiline for 183-Day Washout by Age Group and Sex, 2006-2010

		183-Day Washout					
		Users	Dispensings	Days Supplied	Dispensings/User	Days Supplied/ User	Days Supplied/ Dispensing
Overall		3,229	16,939	500,315	5.2	154.9	29.5
Age Group	0 to 21	137	596	16,100	4.4	117.5	27.0
	22 to 44	1,124	5,572	161,119	5.0	143.3	28.9
	45 to 64	1,616	9,282	279,160	5.7	172.7	30.1
	65+	352	1,489	43,936	4.2	124.8	29.5
Sex	Female	2,008	10,177	301,696	5.1	150.2	29.6
	Male	1,217	6,758	198,469	5.6	163.1	29.4
	Unknown	4	4	150	1.0	37.5	37.5

Table 3b. Number of Incident Users, Dispensings, Days Supplied, Dispensings per User, Days Supplied per User, and Days Supplied per Dispensings of Selegiline for 365-Day Washout by Age Group and Sex, 2006-2010

		365-Day Washout					
		Users	Dispensings	Days Supplied	Dispensings/User	Days Supplied/ User	Days Supplied/ Dispensing
Overall		2,624	14,217	418,125	5.4	159.3	29.4
Age Group	0 to 21	117	532	14,390	4.5	123.0	27.0
	22 to 44	869	4,426	126,668	5.1	145.8	28.6
	45 to 64	1,379	8,233	246,654	6.0	178.9	30.0
	65+	259	1,026	30,413	4.0	117.4	29.6
Sex	Female	1,609	8,474	250,931	5.3	156.0	29.6
	Male	1,012	5,740	167,044	5.7	165.1	29.1
	Unknown	3	3	150	1.0	50.0	50.0

Figure 3a. Number of Incident Selegiline Users by Washout Period, Age Group, and Sex - 2006-2010

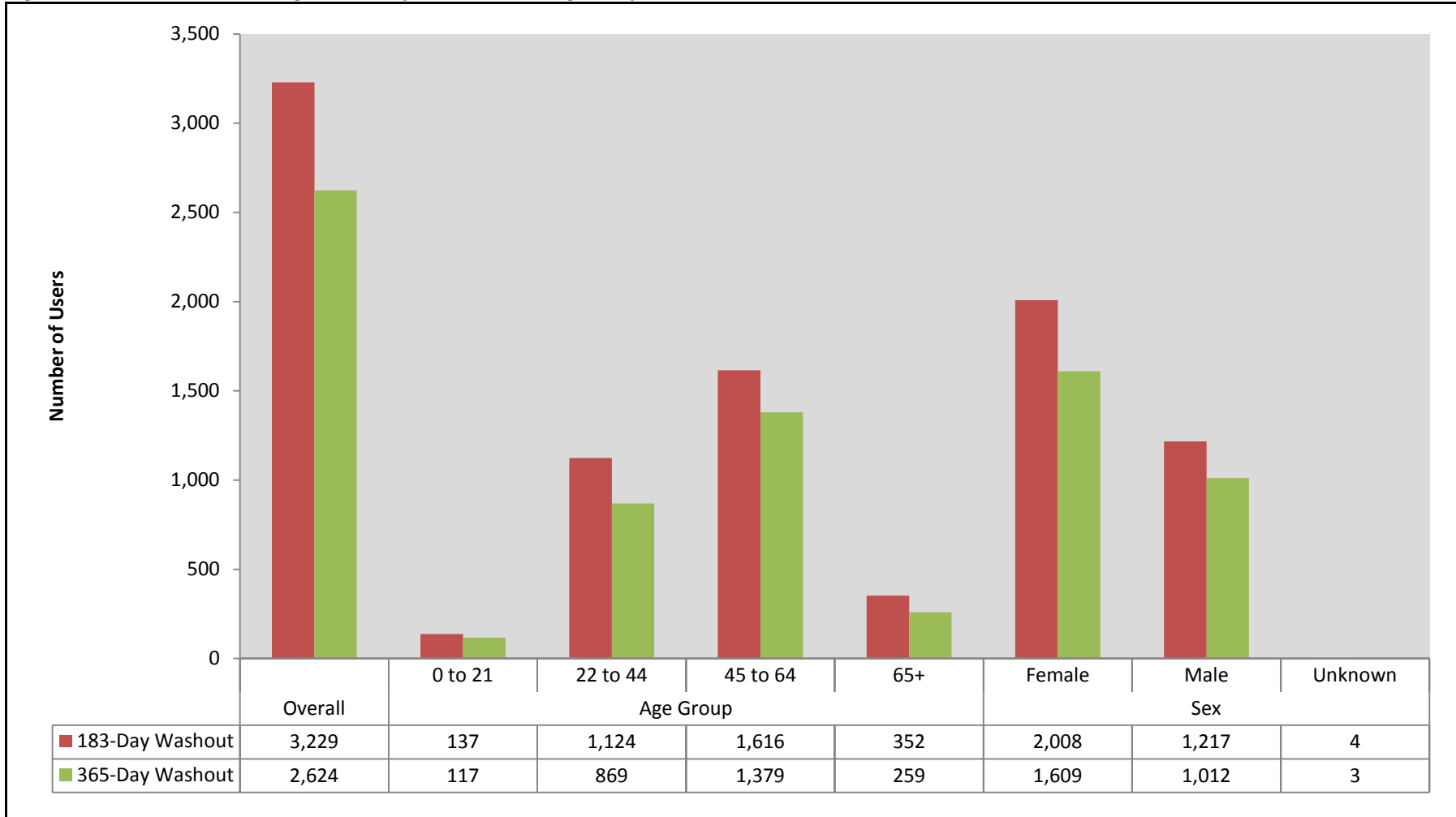


Figure 3b. Number of Dispensings among Incident Selegiline Users by Washout Period, Age Group, and Sex - 2006-2010

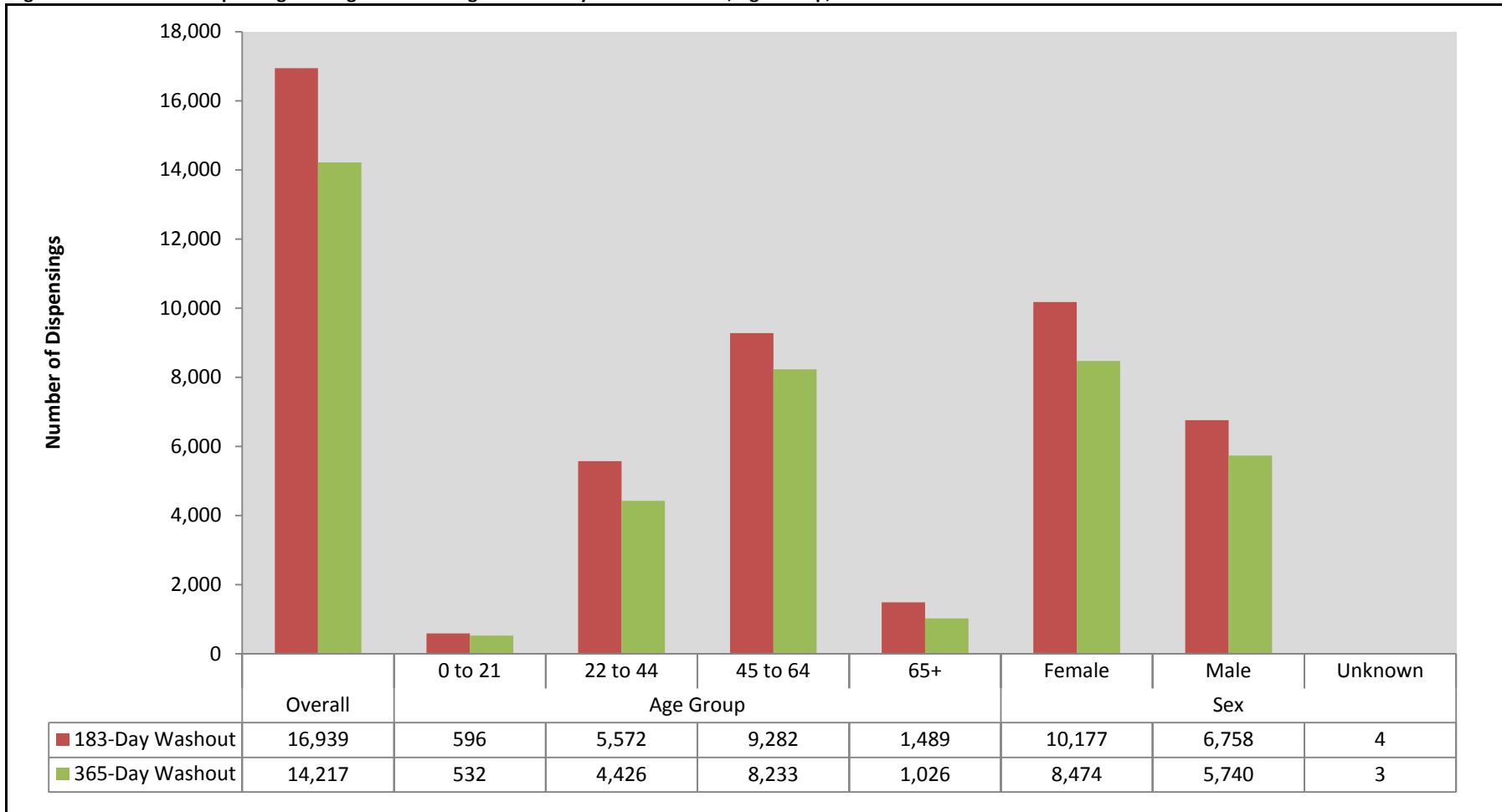


Figure 3c. Number of Days Supplied among Incident Selegiline Users by Washout Period, Age Group, and Sex - 2006-2010

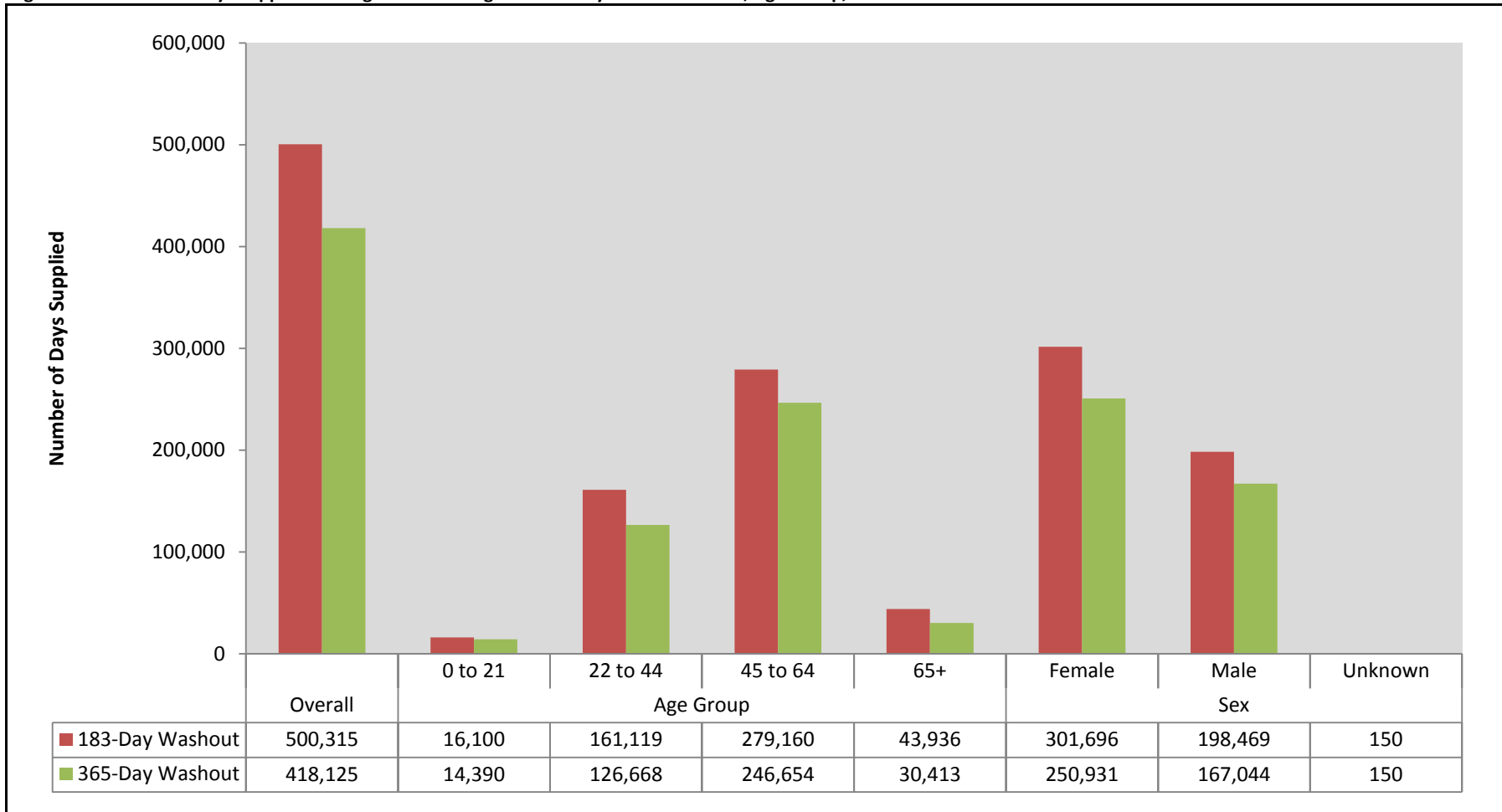


Figure 3d. Number of Dispensings per Incident Selegiline User by Washout Period, Age Group, and Sex - 2006-2010

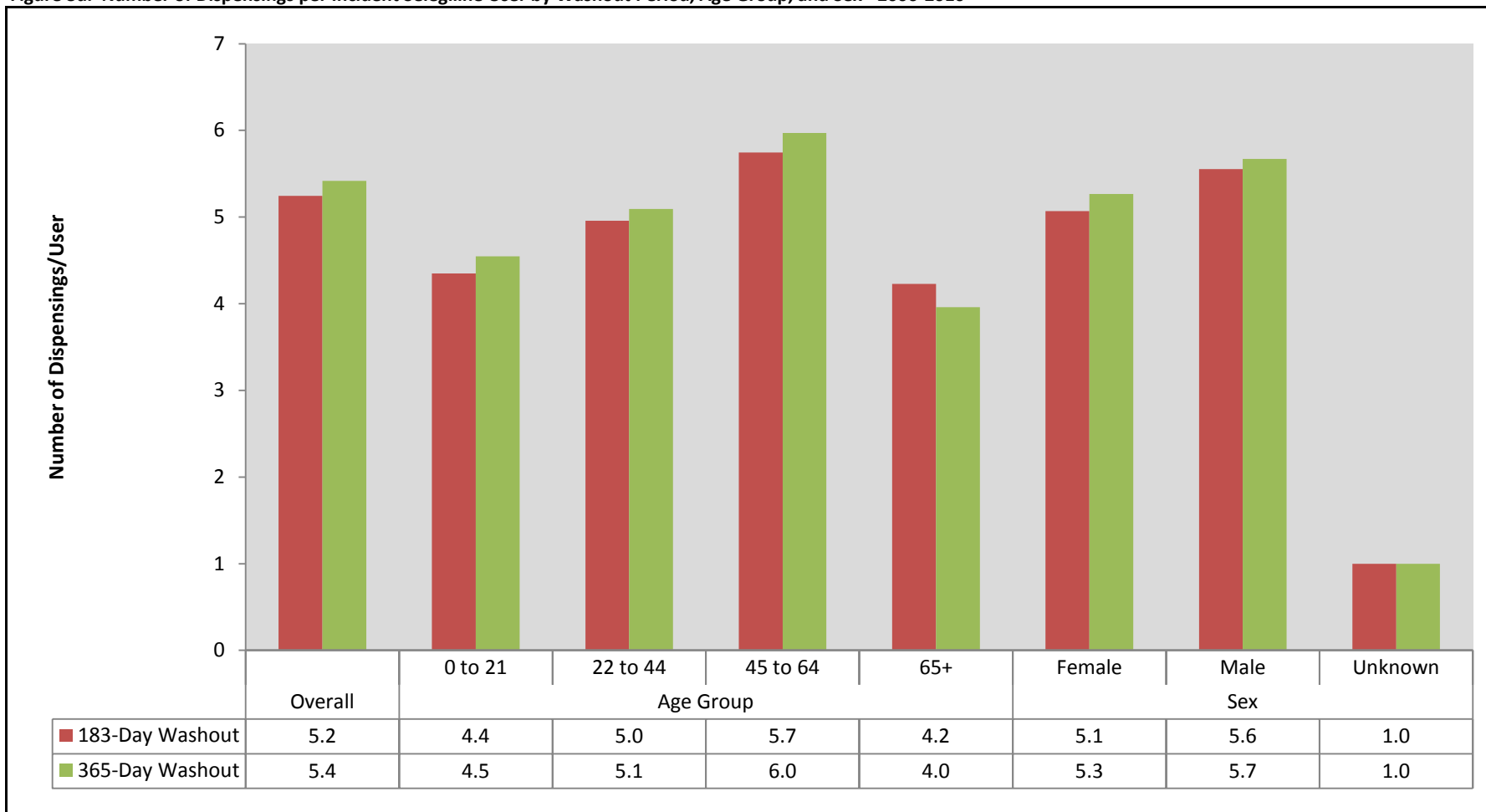


Figure 3e. Number of Days Supplied per Incident Selegiline User by Washout Period, Age Group, and Sex - 2006-2010

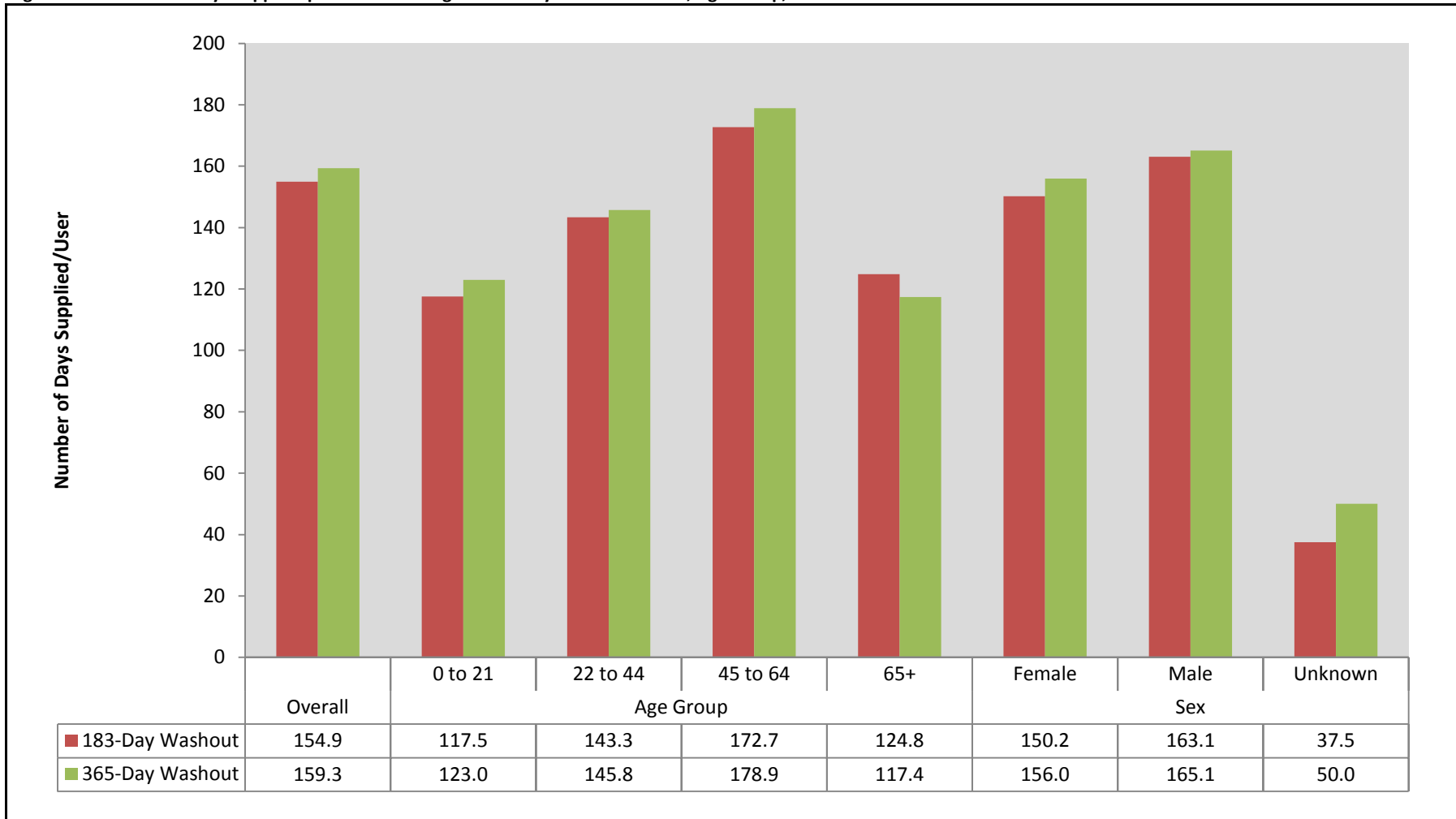


Figure 3f. Number of Days Supplied per Dispensing for Incident Selegiline Users by Washout Period, Age Group, and Sex - 2006-2010

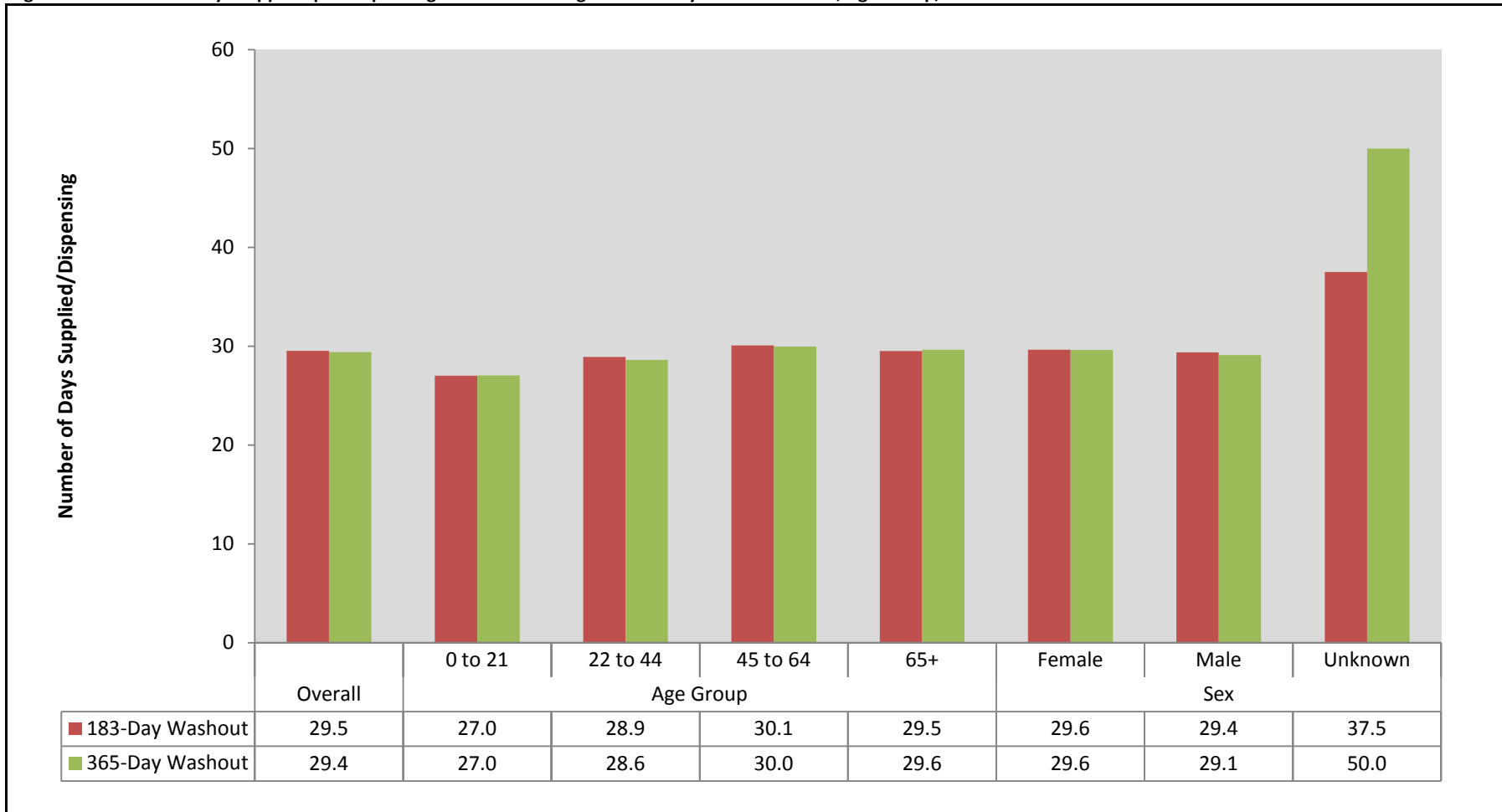


Table 4. Rate of Incidence Selegiline Use (Number of Users per 100,000 Enrollees) by Washout Period and Year - 2006-2010

	183-Days Washout			365-Days Washout		
	Users	Enrollees	Rate	Users	Enrollees	Rate
2006	816	30,811,115	2.6	660	30,811,115	2.1
2007	1,182	34,303,646	3.4	1,020	34,303,646	3.0
2008	984	47,086,296	2.1	789	47,086,296	1.7
2009	773	45,103,516	1.7	606	45,103,516	1.3
2010	748	43,790,907	1.7	616	43,790,907	1.4

Figure 4. Rate of Incident Selegiline Use (Number of Users per 100,000 Enrollees) by Washout Period and Year - 2006-2010

