Common Drug Review
Patient Group Input Submissions

Apixaban (Eliquis VTE) for Thromboembolic events (venous), treatment and prevention of recurrence

Patient group input submissions were received from the following patient groups. Those with permission to post are included in this document.
Heart and Stroke Foundation — permission granted to post.

CADTH received patient group input for this review on or before October 9, 2014.

CADTH posts all patient input submissions to the Common Drug Review received on or after February 1, 2014 for which permission has been given by the submitter.

The views expressed in each submission are those of the submitting organization or individual; not necessarily the views of CADTH or of other organizations. While CADTH formats the patient input submissions for posting, it does not edit the content of the submissions.

CADTH does use reasonable care to prevent disclosure of personal information in posted material; however, it is ultimately the submitter's responsibility to ensure no personal information is included in the submission. The name of the submitting patient group and all conflict of interest information are included in the posted patient group submission; however, the name of the author, including the name of an individual patient or caregiver submitting the patient input, are not posted.

Heart and Stroke Foundation

Section 1 — General Information

Name of the drug CADTH is reviewing and indication(s) of interest		Apixaban
Name of the patient group		Heart and Stroke Foundation
Name of the primary contact for this submission:		[redacted]
Position or title with patient group		[redacted]
Email		[redacted]
Telephone number(s)		[redacted]
Name of author (if different)		[redacted]
Patient group's contact information:	Email	cadth@hsf.ca
	Telephone	(613)691-4062
	Address	1402-222 Queen Street, Ottawa, ON
	Website	www.heartandstroke.ca
Permission is granted to post this submission		Yes

1.1 Submitting Organization

The Heart and Stroke Foundation of Canada (HSF), a volunteer-based health charity, leads in eliminating heart disease and stroke and reducing their impact. Its mission is to prevent disease, save lives, and promote recovery.

The Heart and Stroke Foundation is one of Canada's largest and most effective health charities. Over the last 60 years we have invested more than $1.39 billion in heart and stroke research, making us the largest contributor in Canada after the federal government. In that time, the death rate from heart disease and stroke has declined by more than 75 per cent.

The Foundation's health promotion and advocacy programs across the country are saving lives every day. Working together, our employees, volunteers, donors and world-class researchers have made the Heart and Stroke Foundation what we are today: Canada's most widely recognized and trusted authority on cardiovascular health. Our vision is healthy lives free of heart disease and stroke. Together, we will make it happen.

The Heart and Stroke Foundation is a national organization led and supported by a force of about 140,000 volunteers.

1.2 Conflict of Interest Declarations

a) We have the following declaration(s) of conflict of interest in respect of corporate members and joint working, sponsorship, or funding arrangements:

In the last 5 years, HSF has received unrestricted financial support from Bristol-Myers Squibb

Canada and/or Pfizer Canada Inc. for the development of educational materials, education and awareness activities, and funding of research awards across the country.

b) We have the following declaration(s) of conflict of interest in respect of those playing a significant role in compiling this submission:

There is no conflict of interest.

Section 2 — Condition and Current Therapy Information

2.1 Information Gathering

The information on condition impact to patients and caregivers was gathered by HSF through an online survey using the 'Survey Monkey' tool. Access and links to the survey were advertised using targeted, promoted posts through HSF's public Facebook page (www.facebook.com/heartandstroke) and pop-ups on our public website (www.heartandstroke.ca). Individuals were also provided the survey link directly through email using existing lists of potential patients and caregivers. The survey was made available to the public for two weeks (September 18 – October 2, 2014).

In total, 152 individuals participated in the online survey. Participants were not obligated to complete all questions in the survey. Participants were asked whether they have ever been told by a healthcare professional that they have a blood clot. Of the 152 individuals who responded, 45 participants indicated that they have had a blood clot. Participants were also asked whether they are a caregiver for someone who has experienced a blood clot. Of the 132 individuals who responded, 11 participants indicated that they were a caregiver for someone with this condition. Responses from participants that answered yes to either (or both) of these questions were used to inform this submission.

Information was also generated through literature searches from peer reviewed publications, Heart and Stroke Foundation health information and guidelines and policies from credible organizations such as the Canadian Cardiovascular Society. The Heart and Stroke Foundation develops guidelines, policies and position statements that are based on scientific evidence. These guidelines, policies and position statements form the basis of health information provided to the public, health professionals and the media in various formats (print, web, CPR training materials, media releases, etc).

Limitations: This survey was not a population based survey. This submission reflects the views and/or experiences of survey respondents and not the views of all patients with blood clots or their caregivers living in Canada.

2.2 Impact of Condition on Patients

Deep vein thrombosis occurs in about 200,000 Canadians every year with up to 60,000 patients being hospitalized each year.[1]

Survey participants were asked if they had ever been told by a healthcare professional that they have a blood clot. A total of 45 survey participants identified as having had a blood clot. Responses from these individuals are reported below.

[1] Trepanier, N. (2014, March 1). *March is DVT Awareness Month.* Retrieved from: http://www.ohri.ca/newsroom/03152004.asp

As a result of this condition, 14 patients said that it has affected their day-to-day life because they have to take medication at specific times. Another 13 noted that they have to take medication multiple times per day. A further 10 patients reported that they have to visit a healthcare provider frequently as a result of this condition. Having to take time off work (n=4) and managing the condition with other forms of therapy (n=4) were also noted. Patients also mentioned that they had to change their diet (n=1) as a result of the blood clot. One patient mentioned that it is scary to be told that you have a blood clot. Patients also felt that communication surrounding the condition (including dosage and medication) from their healthcare provider was not acceptable (n=3).

Nineteen patients of a possible 32 indicated that having a blood clot has not affected their ability to do activities. Thirteen individuals answered that there are activities that they are unable to do as a result of this condition. The most common responses were loss of ability to exercise/lift items (n=7) and feeling tired more quickly (n=2). Two individuals also noted that they were unable to return to work as a result of this condition.

When asked about symptoms related to this condition, 23 of a possible 33 respondents indicated that they have experienced symptoms as a result of this condition. The most common symptoms experienced were fatigue (n=15) followed by general swelling and swelling in the legs/ankles (n=9). Other reported symptoms include pain/leg cramps (n=6), shortness of breath (n=2), depression (n=2) and bruising (n=1).

2.3 Patients' Experiences With Current Therapy

Thirty-three patients (of a possible 35) reported that they have been prescribed medication to control or prevent a blood clot. Of those, 8 patients had been prescribed Apixaban by their healthcare provider or as part of a clinical trial. Six patients prescribed Apixaban identified as having Atrial Fibrillation (AFib), four patients identified as having heart disease, and three patients identified as having had a stroke. Seven of these patients are actively taking Apixaban (having last taken this medication 'today'). All patients actively taking this medication reported that Apixaban has helped to control their condition. The respondent that took Apixaban more than one month ago noted that they were unsure whether Apixaban helped to control the condition. Four Apixaban users have to take medication in addition to Apixaban to help control the condition. Only one Apixaban user noted problems in obtaining this medication as their pharmacy has to order it specifically for them.

Five of the 8 Apixaban users experienced unwanted side effects as a result of taking Apixaban. The unwanted side effects included allergic reactions (n=1), bruising and swelling (n=1), bleeding (n=1) and nausea (n=1). One person noted that they would feel better if there was some way to reverse [the effects of Eliquis] as they didn't think there is a way currently.

Of the remaining 25 patients prescribed medication to control or prevent a blood clot, the most common medications taken were Warfarin (n=12), NSAIDS (including ASA n=4 and Celebrex, n=1), Plavix (n=4) Xarelto (n=3), and Pradaxa (n=3). Eighteen respondents are actively taking medication to control this condition (having last taken this medication 'today' or 'yesterday'). Sixteen respondents noted that these medications have helped to control this condition with the remaining seven indicating that they were unsure whether these medications helped to control this condition. Eleven of 23 responders have to take more than one medication to control this condition. There were no concerns regarding access of these medications.

Six of the 24 patients prescribed medication to control or prevent a blood clot experienced unwanted side effects as a result of taking this medication. The unwanted side effects included bruising and swelling (n=3), bleeding (n=2), dizziness (n=1), drowsiness (n=1), tingling in the hands and feet (n=1) and joint pain (n=1).

2.4 Impact on Caregivers

Eleven individuals identified themselves as a caregiver for someone who has experienced a blood clot. While 4 of 7 respondents have not faced any challenges as caregivers, other have faced challenges including having to provide medication multiple times per day (n=2), providing medication at specific times (n=3), providing additional care because of side effects from treatment (n=3), having to frequently transport someone to their healthcare provider (n=2), and having to take time off work (n=3). Caring for someone with this condition impacted five of seven caregiver's daily routine. Specifically, individuals are often more anxious or stressed (n=4), are busier than they used to be (n=3), have had their own health suffer (n=3), often feel more overwhelmed (n=3), do not have as much freedom (n=2), and have experienced significant financial costs (n=1). One caregiver reported feeling scared all the time while another noted that they are "always awaiting the next [doctor's] appointment, tests, specialist appointment..." in an emergency or hospital setting.

Section 3 — Information about the Drug Being Reviewed

3.1 Information Gathering

Information to complete Section 3 was gathered in the same way as Section 2. Please refer to section 2.1 for further information on this process.

3.2 What Are the Expectations for the New Drug or What Experiences Have Patients Had With the New Drug?

a) Based on no experience using the drug:

- Is it expected that the lives of patients will be improved by this new drug, and how?
- Is there a particular gap or unmet patient need in current therapy that this drug will help alleviate?
- Would patients be willing to experience serious adverse effects with the new therapy if they experienced other benefits from the drug?
- How much improvement in the condition would be considered adequate? What other benefits might this drug have — for example, fewer hospital visits or less time off work?

Through the survey, patients were not asked to compare Apixaban with other forms of therapy. As such, we are not able to provide information on this section of the submission.

b) Based on patients' experiences with the new drug as part of a clinical trial or through a manufacturer's compassionate supply:

- What positive and negative effects does the new drug have on the condition?
- Which symptoms does the new drug manage better than the existing therapy and which ones does it manage less effectively?
- Does the new drug cause adverse effects?
- Which adverse effects are acceptable and which ones are not?
- Is the new drug easier to use?
- How is the new drug expected to change a patient's long-term health and well-being?

All patients actively taking this medication reported that Apixaban has helped to control their condition. In terms of accessibility, only one Apixaban user noted problems in obtaining this medication.

Five of the 8 Apixaban users experienced unwanted side effects as a result of taking Apixaban. Adverse effects as a result of taking this medication included allergic reactions (n=1), bruising and swelling (n=1), bleeding (n=1) and nausea (n=1). Four Apixaban users have to take medication in addition to Apixaban to help control the condition.