

**Institute for Safe Medication Practices**  
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**ISMP Points to Need for New Measures to  
Reduce *Dabigatran (PRADAXA)* Bleeding Risks**

**Horsham, Pa---**Based on two new published studies of the anticoagulant dabigatran (PRADAXA), the Institute for Safe Medication Practices (ISMP) is highlighting the need for U.S. healthcare practitioners to gain access to 1) a lower dose and capsule strength of dabigatran (110 mg), and 2) a blood test capable of identifying patients at highest risk for serious injury from bleeding. The lower dose and blood test are already currently available in Canada, Australia, Japan, New Zealand, and Europe but not in the U.S., and can substantially reduce high risk of hemorrhage in older patients.

Dabigatran was approved by the U.S. Food and Drug Administration (FDA) in October 2010 in a therapeutic dose of 150 mg BID for reducing the risk of stroke in patients with atrial fibrillation. Even if a patient appears at higher risk for bleeding, clinicians currently have no option for reducing the approved therapeutic dose. In most advanced countries, a 110 mg dose of dabigatran is recommended for patients age 80 and over and those with risk factors. In the U.S., a 75 mg dose has been approved for use only in patients with severe renal impairment.

ISMP's *QuarterWatch*<sup>™</sup> detected a strong signal of a safety problem with dabigatran while monitoring serious adverse drug events reported to the FDA in first months after the drug's approval; unexpectedly large numbers of serious and fatal bleeding reports, particularly in older patients, were occurring. *QuarterWatch* published an analysis, noting multiple severe and fatal bleeding events in patients with a median age of 80.

By the end of 2012, FDA had received 7,387 domestic reports serious injury associated with dabigatran, including 1,158 patient deaths. *QuarterWatch* ranked anticoagulants as the leading drug safety risks of both 2011 and 2012, and urged a 110 mg dose be reconsidered and monitoring be improved to identify high-risk older patients.

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Additional information and perspective on this safety problem recently emerged with two studies published in the *American Journal of Cardiology* and documents reported on by the media ([http://www.nytimes.com/interactive/2014/02/05/business/pradaxa-doc-viewer.html?\\_r=0](http://www.nytimes.com/interactive/2014/02/05/business/pradaxa-doc-viewer.html?_r=0)). These found that a lower 110 mg dose of dabigatran had similar efficacy to the higher dose, but potentially lower bleeding risk, and pointed out that there are 5-fold variations in plasma levels in 80% of patients receiving the same dose, increasing risks associated with a single dose strategy.

U.S. healthcare practitioners also do not have access to an assay test that can help determine a patient's plasma levels of dabigatran, which is currently in use in Europe and Canada. The test is called the Hemoclot thrombin inhibitor kit assay and measures thrombin clotting time, which is directly related to plasma concentrations. It is only available in the U.S. for research purposes. The test would be a valuable asset to healthcare practitioners because it can help identify the 10% of patients with extremely high blood levels of dabigatran that are greater than even the 5-fold variation range.

ISMP believes that this important additional information about dabigatran highlights the need to implement additional measures to reduce the risk of serious injury from one of highest risk outpatient drug treatments. For a copy of an article on this topic published in the February 13, 2014 issue of the *ISMP Medication Safety Alert!* newsletter, go to:

[www.ismp.org/newsletters/acute/acute/showarticle.aspx?id=71](http://www.ismp.org/newsletters/acute/acute/showarticle.aspx?id=71)

**About ISMP:** The Institute for Safe Medication Practices (ISMP) is an independent, nonprofit charitable organization that works closely with healthcare practitioners and institutions, regulatory agencies, consumers, and professional organizations to provide education about medication errors and their prevention. ISMP represents nearly 40 years of experience in helping healthcare practitioners keep patients safe, and continues to lead efforts to improve the medication use process. ISMP is a federally certified patient safety organization (PSO), providing healthcare practitioners and organizations with the highest level of legal protection and confidentiality for patient safety data and error reports they submit to the Institute. For more information on ISMP, or its medication safety alert newsletters and other tools for healthcare professionals and consumers, visit [www.ismp.org](http://www.ismp.org)