

Rapid Geographic Risk Assessment and Model Development using GREAT and BRisk Applications

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Introduction

A major challenge for the FDA Center for Biologics Evaluation and Research (CBER) Office of Biostatistics and Epidemiology (OBE) is evaluating and responding quickly to emerging diseases that may impact the blood supply. When a new transfusion transmitted disease emerges, detailed information and knowledge about the disease is often limited, scattered across myriad sources, which complicates risk assessment for regulatory decision-making.

This interactive poster steps through the process of responding to an emerging disease using tools OBE developed, GIS-based Risk Evaluation and Assessment Tool (GREAT) and BRisk (Blood Risk), to expedite risk assessment and risk management, helping to assess potential policy options (blood testing or donor deferral) to protect the blood supply.

Interactive Experience: Use the Tools

A new transfusion-transmitted disease, Crimson fake disease, has emerged, and poses a risk to the U.S. blood supply. CBER needs to use BRisk and GREAT to evaluate potential responses.

Step 1: Use GREAT to identify regions of interest

Decision-makers would use GREAT to identify the regions that require deferral policies and/or blood testing.

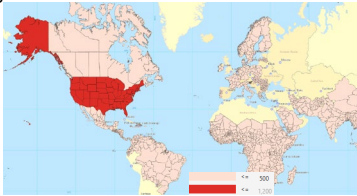


Figure 1: Map of incidence of Crimson fake disease

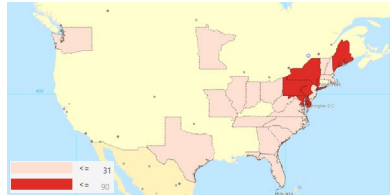


Figure 2: Map of incidence of Crimson fake disease within U.S.

Step 2: Use BRisk to compare policy options

Once the regions of interest have been identified, BRisk can be used to compute the transfusion transmitted cases for various policy options under consideration, in the example below, **reducing transfusion transmitted cases by more than 90% in the United States.**

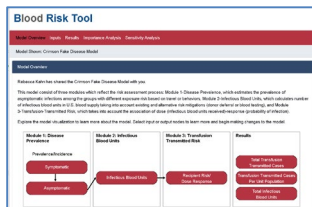


Figure 3: BRisk-Web homepage, featuring model structure visualization

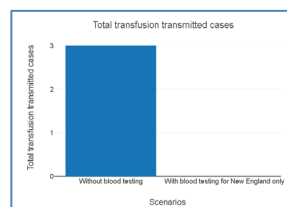


Figure 4: BRisk-Web total transfusion transmitted cases data visualization

BRisk and GREAT

Modeling and simulation tools for risk assessment and policy evaluation to assist CBER in responding to emerging infectious diseases that may impact the safety of U.S. blood supply



Scan the QR code to access additional information online

GREAT and BRisk Overview

GREAT

GREAT assists risk modelers and decision-makers in evaluating the latest public health data from the perspective of geographic risk. The tool is designed to provide a rapid overview of changes in emerging infectious diseases using data from the U.S. Centers for Disease Control and Prevention (CDC) and the World Health Organization.

BRisk-Desktop

Three model templates are used to create models for emerging infectious diseases using Lumina's Analytica, including:

- A travel-based risk model template to assess risks for diseases that spread through travel, e.g. Malaria, Dengue and Chikungunya
- A behavior-based risk model template to perform risk assessment for diseases that spread through risky behaviors, e.g. HIV, HBV, HCV, HTLV
- A residents model template to perform risk assessment for residents of U.S. states

These models contain thousands of interconnected nodes but only a small subset of these nodes need to be changed to model a new disease. BRisk-Desktop assists users in modifying a template to model an emerging disease by only exposing the nodes that need to be updated for editing in a user interface.

BRisk-Web

BRisk-Web allows users without any background in modeling or Analytica to easily make changes to and run models and simulations. BRisk-Web also makes it easy for users to share interactive models with others.

Conclusions

The tools provide decision-makers with important information concerning identified threats and possible mitigations and assist in the development and evaluation of emerging donor deferral and blood screening policies.

Next steps include integrating BRisk and GREAT as well as migrating GREAT to the web.

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