Developing Web Applications for Expedited Risk Assessment at the FDA

Hong Yang (FDA/CBER), Yin Huang (FDA/CBER), Rebecca Kahn (SAIC) Jason Claeys (FDA/CBER), Mark Walderhaug (FDA/CBER), Wei Wang (SAIC), Richard Forshee (FDA/CBER)

Abstract

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

Methods
CBER's Office of Biostatistics and Pharmacovigilance (OBPV) created two decision support tools: GIS-based Risk Evaluation and Assessment Tool (GREAT) web application, which provides geographic risk information, and Blood Risk (BRisk) Tool, which performs risk assessment using probabilistic algorithms in predetermined models. These tools were developed as web applications on the FDA OIMT Innovation Lab Sandbox and have been deployed to the FDA's Amazon Web Services (AWS) GovCloud West organization.

Results
GREAT integrates and visualizes disease-related geographic information, generates geographic risk ranking maps, estimates geographic risk contribution and ranks geographic risks. Once the potential regions of interest are identified, BRisk can be used to update models for running simulations of how potential interventions would impact the risk of disease transmission through blood transfusions and the potential donor loss.

Conclusions/Implications
The AWS-based tools provide decision-makers with information concerning identified threats and possible mitigations and assist in the development and evaluation of emerging donor deferral and blood screening policies. These applications utilize AWS to take advantage of the flexibility and scalability the cloud provides.

Introduction

The BRisk and GREAT applications were developed to expedite the process of evaluating potential policy responses to emerging or resurging infectious diseases that may spread through the blood supply.

First, GREAT aggregates geographic data that is spread across a variety of sources and displays this information on a map. GREAT provides quick estimates of the impact of potential mitigation policies. Once the regions that contribute the most risk have been identified, BRisk can be used to conduct a more detailed analysis of the impact of potential mitigation policies, which could include conducting blood testing or deferring at-risk donors from donating blood.

GREAT

GREAT assists modelers and decision-makers in evaluating the latest public health data from the perspective of geographic risk. The tool provides a rapid overview of changes in emerging infectious diseases using data from a variety of sources and identifies the regions with the most risk (e.g. ranked by risk contribution that takes into account the potential number of U.S. donors exposed in the region) for further analysis.

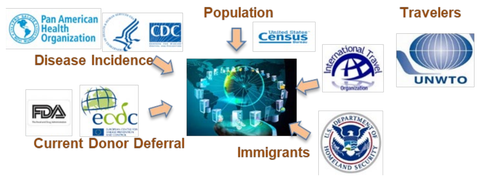

Figure 1: GREAT incorporates data from a variety of online sources

GREAT's homepage includes an interactive map. Users can select which data attributes should be displayed on this map, including disease, traveler, population, and immigration data as well as risk contribution and donor loss calculations. These risk contribution and donor loss calculations take into account any mitigation policies configured by the user with GREAT. GREAT also generates charts of disease trends over time.

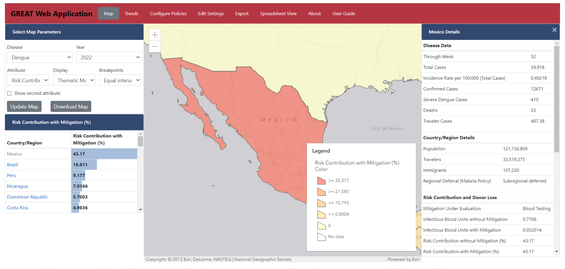

Figure 2: GREAT's homepage features an interactive map

Figure 3: GREAT provides a chart of disease trends over time

BRisk

Once GREAT has been used to identify regions of interest and potential intervention policies, BRisk is used to conduct more detailed risk assessment using probabilistic algorithms in predetermined models. Three model templates, which model different exposure mechanisms (travel, behavior, or residence), are used to create models for emerging infectious diseases using Lumina's Analytica. These templates are designed to be modular to be easily modified by users. They contain thousands of interconnected nodes but only a small subset of these nodes need to be changed to model a new disease.

The model templates consist of three modules:

Module 1: Disease prevalence estimates the number of cases of the disease in the population.

Module 2: Infectious blood units calculates the number of infectious blood units, taking into account existing and alternative risk mitigation strategies, such as donor deferral and/or blood testing.

Module 3: Transfusion-transmitted risk determines the number of infections using dose-response information.

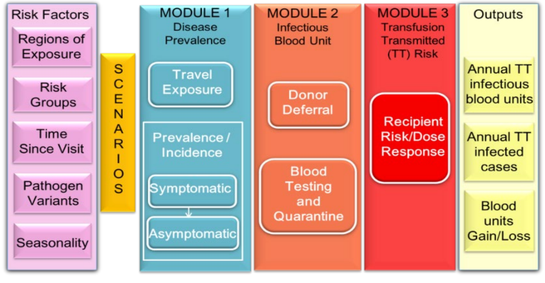

Figure 4: BRisk Model Structure

BRisk assists users in updating these templates so that they model an emerging disease by only exposing the nodes that need to be updated within an easy-to-use web user interface.

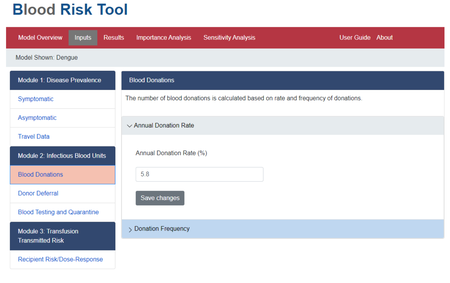

Figure 5: Modifying model inputs in BRisk

Once a model has been updated for a selected disease, BRisk can be used to share the model with other users. Each user can revise the model's inputs and run the model to see the results.

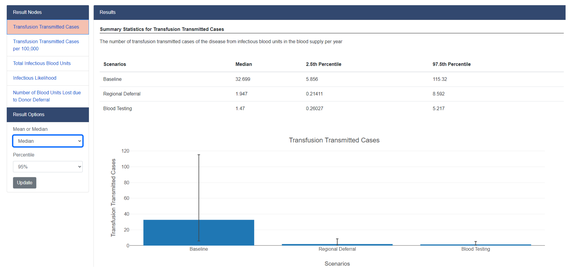

Figure 6: Results calculated in BRisk

Development and Deployment

Technologies Utilized

CBER along with SAIC developed BRisk and GREAT initially on the Office of Information Management and Technology Innovation Lab sandbox, which allows for experimentation with technologies not currently on the FDA Master Approved Technology List. The applications use Angular JavaScript, Plot.ly, ArcGIS JavaScript, Analytica Decision Engine, C# and Java.

AWS Deployment

On AWS, the applications use Lambda serverless functions combined with API Gateway to keep costs down. Additional AWS resources utilized include EC2 virtual servers and Aurora Relational Database Service. Overall the applications are architected to take advantage of the flexibility and scalability provided by AWS.

Conclusion

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. Both tools are currently available to selected internal FDA users on the development enclave on AWS at the FDA.

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