

New decision model seeks to avert flu vaccine mismatch of 2007-2008 season

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To avoid producing vaccines that treat the wrong strains during flu season, the FDA should consider deferring some of its selections as well as other changes to the vaccine composition, according to a study by two decision analysts published in a journal of the Institute for Operations Research and the Management Sciences (INFORMS).

"Repeated Commit-or-Defer Decisions with a Deadline: The Influenza Vaccine Composition" is by Laura J. Kornish of the University of Colorado and Ralph L. Keeney of Duke University. It appears in the current issue of Operations Research.

The researchers seek to help reduce the chances of problems like those seen in the 2007-2008 flu season, when two of the three vaccines prepared early in the year for millions of Americans failed to treat the flu strains that actually emerged at the height of flu season.

"There are two key takeaways from this research," says Prof. Kornish. "First, that the FDA should be willing to consider deferring a decision about which strains to include if early, conclusive evidence isn't available. This would mean accepting the proposition that identifying the right strain is worth waiting for, even if the supply produced won't be sufficient. It may be better to have some of the right vaccine than a lot of the wrong vaccine.

"Second, the FDA should reexamine its commitment to the rigid structure of the vaccine, with exactly one strain from each of three

categories. For example, if there's agreement on choosing two of the strains and disagreement about which strain to pick for the third, why not include four?"

A key problem addressed by the researchers is how to deal with uncertainty in the process of choosing the flu strains for the vaccine. In February of every year, the FDA examines early evidence about flu strains circulating and selects three strains so that manufacture can begin and sufficient flu vaccine is available in the fall. By the time that production normally begins, though, it may not yet be clear which flu strain will be most menacing in October. This bind leaves officials to trade off between picking early, which may mean that there are sufficient supplies of vaccines whose effectiveness is limited; and picking late, leading to vaccine supplies that are insufficient to treat the needed population.

The decision to defer production on one or more of the strains makes sense, says Prof. Kornish, when there's current uncertainty but confidence that more time will lead to more useful information.

For public officials, the authors acknowledge, deferring a decision brings pressure that may increase if additional information doesn't arrive and they stick with an early proposal after sacrificing time that might have gone to vaccine production.

The authors developed their mathematical model to describe the repeated nature of the decision over time. It allows decision makers to make what-if analyses of vaccine production rates, severity of the flu, and effectiveness of the vaccines. Numerous sensitivity analyses of assumptions and parameters in the model provide insights for improved communication among those responsible for selecting the vaccines.

The problem resembles one faced by companies that market perishable

products and products with limited seasons: when new products are developed specifically for an upcoming retail season, producers balance time spent deliberating about the best product with time spent producing the inventory.

Source: Institute for Operations Research and the Management Sciences

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