Data Access Improvements

In August 2013, Eric Johnson, PhD (University of Arkansas) submitted a proposal for permission to obtain data from the Massachusetts Cancer Registry to study excess cancers among Poultry Workers. It was a multi-state analytic project with a complex design that proposed the use of biological specimens. In addition to requiring someone with background in the specific content area of cancer, it also required a broader expertise related to the use of biologic specimens and complex study designs.

The application was initially assessed for clarity and completeness. After several rounds of communication with Dr. Johnson, a revised application was submitted in February, 2014. A full review was completed in June, 2014, but there was no further progress until October 2014 when the project was discussed by the full DPH Data Access Oversight Committee. As one might expect, the length of time between the submission and final approval can make it difficult to remember details. The need for a better process was clear.

At the time, the delay seen for Dr. Johnson's project was not unusual. The process used to move Dr. Johnson's project forward (and others like it) embodied a quality improvement approach undertaken in 2014 to improve the review process. The approach included identifying the issue to be addressed, trying small tests of change, reviewing data to determine if the change achieved the desired result and, as needed, continuing to test new approaches until the desired results were achieved.

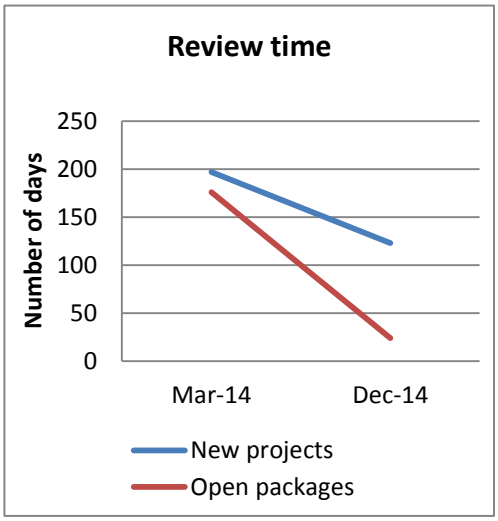
System improvements have been integrated into the overall process. Also, the lessons learned have led DPH to craft a pilot project to simplify the review process while maintaining the integrity of the review process and remaining excellent stewards of confidential Massachusetts data. We could not have arrived at this point nor designed a pilot project without the diligent efforts of all parties both inside and outside DPH.

Among the approaches and ideas tested were:

- Scheduling full days meetings to deal with long-delayed projects
- Using standardized metrics to measure progress
- Integrating the initial review into the Overall review process to minimize the gap between review and approval
- Delegating work so specific individuals would handle fewer specific tasks and existing resources were optimized
- Meeting regularly to measure progress and ensure that projects did not "stall"
- Delegating review of approved studies which were requesting staffing changes and continuations to a single person to streamline review

Some of our efforts were clear successes. For example, regular meetings of key personnel were essential. Other efforts, such as full day meetings to try to address the backlog were not. The team continued with small tests of change with the goal of an efficient and transparent review process.

While this process improvement is ongoing, a review of data between March 2014 and December 2014 shows clear successes in two major areas. First, the number of projects awaiting initial approval or approval of modifications has decreased. In March, 2014, there were 54 new projects and 63 open packages* awaiting approval. In December, 2014, these numbers had dropped to 33 and 39 respectively. Second, the median review time for both new projects and open packages has decreased. In March, 2014 the median days for review of a new project was 197; in December it had dropped to 123 days. For open packages, the change has been even more dramatic, with the median review time decreasing from 176 days to 24 days.



*Note: New projects are those projects that have not yet received DPH approval. Open packages are those projects that have already received approval, but for which the researcher is now submitting an amendment or continuation. We measure packages rather than projects given that one project can have multiple packages (i.e. an amendment and a continuation or multiple amendments)

The Privacy and Data Access Office (PDAO) and the Office of Data Management and Outcomes Assessment (ODMOA) are now embarking on a pilot project to test the model learned over the last 15 months, with a specific emphasis on new projects. The goals are to: 1) help facilitate more timely access to public health data for both internal staff and external researchers, and 2) create a more transparent review process. The increased timeliness and transparency will enable those who interact with the Data Access process to more effectively manage project timelines, resources and collaborations.

The revised process for new projects includes:

1) Development of a "Smart Form" to integrate the application process for all DPH data, for both internal and external use. This Smart Form will consist of a series of yes/no questions that are critical decision points to make a preliminary determination about the required level of review for the project. This will bring greater objectivity, uniformity, transparency to the application and review process;
2) Engagement of bureau directors and epidemiologists early in the approval process. This increased bureau engagement enables the bureau staff, who are most familiar with the data, to have a dialog with the potential recipient about the data and related methodological and scientific issues, early on in the process. Then, once all the possible options regarding data and methodology have been thoroughly explored and plans are finalized, the project is eligible for IRB and/or data access review and approval; and
3) Training and availability of on-going technical assistance on use of this smart form and application process.

This new process will be introduced as a pilot involving two bureaus. PDAO and ODMOA will ensure that all forms, concepts, and decision flowcharts are thoroughly tested before rolling out any changes to the full Department. In general, projects that can benefit the health of the citizens of Massachusetts as well as the nation should move forward quickly but not at the risk of endangering the confidence of the public and the confidentiality of the data we have been charged to oversee. Progress on this pilot will be measured in much the same way as progress has been measured over the last 15 months. We will look at projects reviewed and approved, average review time, and the number of times we need to communicate with applicants.

Dr. Johnson's project was approved on 12/5/2014.