AN INTERVIEW WITH DR. GREG SIMON

Principal Investigator, Suicide Prevention Outreach Trial (SPOT)

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Dr. Simon provided an update on the Suicide Prevention Outreach Trial (SPOT) at the April 2015 Collaboratory Steering Committee Meeting (view slides). A focus was on sharing lessons learned in overcoming barriers to trial implementation in health systems. SPOT transitioned to a UH3 project in late 2014. Recruitment began at the first site, Group Health, on March 3, 2015. The other two sites are expected to begin recruiting patients in May 2015.

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Dr. Simon described that each site goes through a ramp-up phase over a period of about 2 months to make sure the systems are working and staff feel confident delivering the interventions. During this time, an increasing number of eligible patients is enrolled each week. For example, at Group Health, about 70 people are eligible for the trial every week. The first week, they recruited only 10, and then increased to 15, 20, and so on in the following weeks.

Once the trial is fully underway at all sites, they plan to enroll 165 patients per week across all three sites. Enrollment will continue over 30 months for a planned sample size of 19,500. Dr. Simon explained that recruitment is essentially a fixed quantity in this trial, because it includes everyone in all of the participating healthcare systems who becomes eligible every week. The team has been monitoring these numbers and is confident that enrollment will meet expectations unless something dramatic changes.

Rather, Dr. Simon explained, "a key marker of success is what level we are able to engage people." This refers to whether people respond to the messages as part of the trial's outreach interventions. These are outgoing messages sent through the patient portal in the electronic health record. For example, "You told your doctor you were having thoughts about harming yourself, and we'd like to help you."

Multiple rounds of pilot testing were done to refine the outreach programs in order to maximize engagement. They sought to find a balance between being assertive while not being overly intrusive. The team included individuals with experience of self harm or suicidal ideation in the process of developing and refining the outreach messages. Based on the pilot testing, they have an expectation of what the level of engagement should be. However, the pilot was conducted at only one site. It is hoped that engagement will be about the same or better at the other sites, but this remains to be seen.

Dr. Simon noted that issues related to engaging patients are not expected to vary widely among sites. However, they may run into some technical or health system issues, because all of the sites have different customized versions of the Epic electronic health record system. The trial relies on embedded tools in Epic to make its processes

work. “Writing all that code and translating it to another Epic instance is not simple. It’s not like a Microsoft Word document that any version of Microsoft Word can open,” said Dr. Simon.

Challenges in Implementation

In the process of transitioning to a UH3 project, Dr. Simon described that “the biggest issues for us were ethical and regulatory issues.” The institutional review board (IRB) process took an additional 9 to 10 months from what was expected. He explained that people have strong opinions about suicide risk, and often the same individual can have contradictory opinions, making negotiation difficult. For example, a single person might say, “You can’t possibly bother these people by reaching out to them, and you can’t possibly leave them alone, because we know they’re at risk for suicide.” It is the classic conflict of autonomy versus beneficence experienced by a clinician. This made navigating the IRB process very difficult in terms of defining appropriate ways to reach out to people and appropriate consent procedures. A fundamental question was whether one can conduct minimal risk studies in high-risk populations. Agreement was eventually reached that minimal risk refers to incremental risk to participants. However, gaining IRB consensus that the research could not be practicably carried out without a waiver or alteration of informed consent was even harder to achieve than the minimal risk determination.

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Overall, the ethical/regulatory review was a “long, laborious, and sometimes contentious process,” according to Dr. Simon. On the positive side, they found that once the major issues were worked out with the pilot site’s IRB, it made subsequent reviews by the other sites’ IRBs much faster. This was due to involving all IRBs in the conversations during the pilot work. The other sites essentially watched as the major issues were ironed out with the first IRB, so only minor issues were encountered in the subsequent IRB reviews.

Looking ahead, a challenge Dr. Simon sees as not completely resolved is the data and safety monitoring process. They are finding that the automatic response from the data and safety monitoring board (DSMB) is to do things the way they have always done it, which does not work for this type of trial. For example, in a traditional study of a mental health intervention, if someone attempts suicide, it requires stopping the trial, completing a full investigation, and waiting for the DSMB to review. Based on sample size projections in this trial, suicide attempt is expected to happen about 870 times, so the traditional process would not work.

Furthermore, the DSMB typically wants immediate reporting of all deaths for anyone enrolled in the trial. In SPOT, deaths are determined from state mortality data, which are delayed about 16 months. Dr. Simon explained that while a 48-hour reporting and review cycle for a death that happened 16 months ago does not seem to make sense, it was a very difficult and contentious negotiation.

While enough of these issues were worked out to get the project into the field, Dr. Simon still expects some difficulties if the DSMB tries to apply its usual processes to this trial. As another example, the DSMB has an expectation for immediate reporting of suicide attempts that the study team is aware of. In SPOT, the study team has contact with the people in the intervention groups but not those in the usual care group. This means it is certain that more suicide attempts will be identified in the intervention groups early in the trial. The study team will need to negotiate with the DSMB regarding safety monitoring procedures and interim analyses appropriate to the design of this trial and the nature of data available for monitoring.

For more information on the Suicide Prevention Outreach Trial, visit the Collaboratory website.