

information with VARIZIG in pregnancy, our objective was to describe the safety and varicella outcomes in pregnant women who were enrolled across 2 studies of VARIZIG.<sup>3,4</sup>

**STUDY DESIGN:** The first study, a randomized, controlled trial (RCT), compared intravenous vs intramuscular administered VARIZIG (625 IU).<sup>3</sup> The second study was an open-label, expanded-access program (EAP) in which participants received 625 IU of intramuscular VARIZIG in a real-world setting (NCT00338442).<sup>4</sup> Patient safety (adverse events) and varicella outcomes were analyzed with the use of descriptive statistics. Both studies followed institutional review board guidelines, and all patients provided written informed consent.

**RESULTS:** The RCT included 60 VZV-seronegative pregnant women, of whom 38 received VARIZIG intramuscularly (n=17) or intravenously (n=21). Of 166 pregnant women in the EAP, full safety data were available for 147 participants, and 137 participants had varicella outcome data. At least one-half of VZV exposures occurred in a household setting (RCT, 68%; EAP, 47%). In the EAP, the following VZV exposures occurred: 58% varicella zoster, 14% herpes zoster, 19% unspecified, and 8% unknown; VZV type was not specified in the RCT. Most participants (RCT, 61%; EAP, 81%) received VARIZIG within 96 hours of VZV exposure. Varicella incidence was 29% in the RCT and 7.3% in the EAP (Figure). Incidence of varicella was not impacted by duration of time between VARIZIG administration and VZV exposure nor the trimester of pregnancy. No cases of varicella-related pneumonia occurred in either study.

Common related adverse events were injection site pain (RCT, 19%; EAP, 3%) and headache (RCT, 7%; EAP, 1%). No maternal deaths occurred in either study. Serious adverse events occurred in 2 participants (5%) in the RCT (worsening of asthma and spontaneous abortion) and 5 participants (3%) in the EAP (spontaneous abortion, premature separation of the placenta, congenital anomaly, and fetal growth restriction); none of these serious adverse events were considered related to VARIZIG or varicella.

**CONCLUSION:** In the 2 available studies of pregnant women who received postexposure prophylaxis with VARIZIG,<sup>3,4</sup> the incidence of varicella was low, especially compared with findings from a 20-year retrospective study of postexposure

prophylaxis with varicella zoster immune globulin (VZIG, discontinued in 2006) that reported varicella incidence of 42% vs 72% among those who did not receive postexposure prophylaxis.<sup>5</sup> In each study, there was a similar varicella incidence, regardless of the timing of the administration after VZV exposure. No cases of varicella-related pneumonia occurred in either study. Both studies had a similar safety profile, and VARIZIG was well-tolerated. Based on Centers for Disease Control and Prevention recommendations for the administration of VARIZIG to this high-risk population,<sup>2</sup> clinicians should use VARIZIG when their pregnant patients are exposed to VZV. ■

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## QI Bootcamp: feasibility and acceptability of a novel approach to training residents in process improvement



**OBJECTIVE:** The Accreditation Council for Graduate Medical Education (ACGME) requires that residents receive training and experience in quality improvement (QI),

specifically that “Residents must have the opportunity to participate in interprofessional quality improvement activities,” yet many obstetrics/gynecology training programs

**TABLE**  
**Resident experience of an intensive quality improvement course**

| Variable                                     |                                                                                                                     | Strongly agree, % | Agree, % | Uncertain, % | Disagree, % | Strongly disagree, % |
|----------------------------------------------|---------------------------------------------------------------------------------------------------------------------|-------------------|----------|--------------|-------------|----------------------|
| Before the quality improvement course (n=29) | I feel qualified to carry out a quality improvement project.                                                        | 3                 | 34       | 45           | 14          | 3                    |
| After the quality improvement course (n=26)  | I feel qualified to carry out a quality improvement project.                                                        | 15                | 84       | 0            | 0           | 0                    |
|                                              | I would feel confident applying the techniques I learned during this course to future quality improvement projects. | 58                | 42       | 0            | 0           | 0                    |
|                                              | This quality improvement course format was acceptable to me.                                                        | 69                | 19       | 0            | 12          | 0                    |
|                                              | I recommend this workshop for future obstetrics/gynecology residents in our program.                                | 69                | 27       | 0            | 4           | 0                    |

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struggle with meeting that directive. The limited literature suggests that project-based learning is effective in teaching QI to medical trainees but in practice can be difficult to implement.<sup>1–3</sup> We aimed to develop an innovative training program for obstetrics/gynecology residents that was feasible, acceptable, and successful in meeting the needs of our trainees and the ACGME QI mandates.

**STUDY DESIGN:** The Obstetrics/Gynecology Residency Process Improvement Course was designed to condense a locally taught, 4-month course that is directed at faculty and staff into a 5-week intensive program. Two 2-hour long sessions were divided into didactic and project work. Teams of 3–5 residents applied newly learned techniques to a project of their own design, in their work area, reaching out to stakeholders to create problem and aim statements, to process maps, to perform root cause analysis, to brainstorm solutions, and to collect baseline measures. They considered Institute of Medicine and ACGME/American Board of Medical Specialties focus areas when developing interventions and tests of change and learned to analyze data over time to understand the impact of change. Each team was tasked with completing 1 plan-do-study-act cycle during the course and, in week 5, with presenting their projects using a standardized template slide set at department conferences, including qualitative and quantitative data.

The course prioritized team learning over absolute outcomes, and all residents participated except those on night shifts. Residents work primarily at 2 teaching hospitals; to optimize participation, the workshops were run concurrently at both sites. The 2 faculty instructors were obstetrics/gynecology physicians who had completed formal QI education

courses. Faculty met with team representatives once between sessions.

We surveyed participating residents before and after the course to assess knowledge of common QI techniques, confidence in quality improvement, and feasibility and acceptability of the course. This educational project was undertaken as a Quality Improvement Initiative and, as such, was exempt from Institutional Review Board review.

**RESULTS:** The Obstetrics/Gynecology Process Improvement Course was implemented in October 2018 with 35 participating postgraduate year 1, 2, 3, and 4 residents in 8 teams. For most participants (27/29; 93%), this was the first QI training they had received in residency. Ten percent of the residents (3/29) had participated previously in a QI project during residency.

Thirty-seven percent of participants felt qualified to carry out a QI project before the course, while 100% felt qualified after. All of them felt confident that they could apply techniques that they had learned to future projects. Thirty-four percent of residents were able to list any process improvement techniques before the course (mean, 1.2); all of them could list 2–5 (mean, 3.4) after. All 8 teams implemented 1 test of change, and 6 teams completed a plan-do-study-act cycle. Five participants commented that it was difficult to complete a test of change in 5 weeks.

This intensive program required faculty who were trained in process improvement techniques, dedicated didactic time, and engaged trainees. Eighty-eight percent of them felt that the format was acceptable, and 96% of them recommended that it be made available for future residents (Table).

**CONCLUSION:** These data demonstrate the feasibility of an intensive QI course in providing ACGME recommended training and experience to obstetrics/gynecology residents in a format acceptable to trainees. ■

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