

Neonatal Abstinence Syndrome: A Tale of Two Studies (Part 2)

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Investigators at Yale University wanted to improve care of newborn infants with neonatal abstinence syndrome via a QI initiative. They used standard QI procedures to institute a series of 8 tweaks to the care of such infants, implemented in a sequential manner over a 5+ year period.

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As promised, here is the second of 2 well-designed studies to improve care of newborns with opiate withdrawal. One was published in the *New England Journal of Medicine*, this one in *Pediatrics*.

Source: Grossman MR , Berkwitz AK, Osborn RR, et al. An initiative to improve the quality of care of infants with neonatal abstinence syndrome. *Pediatrics*. 2017;**39(6): e2 0163360**; doi:10.1542/ peds. 2016- 3360. See **AAP Grand Rounds**

commentary by Dr. Jeffrey Winer (subscription required).

The current study is a poster child for how to perform and report a **quality improvement (QI) study**. The juxtaposition of a randomized controlled trial (RCT) and a QI study on the same topic in this month's AAP Grand Rounds gives us an opportunity to compare strengths and weaknesses of both approaches, as well as to think about which ultimately is the more significant study.

Investigators at Yale University wanted to improve care of newborn infants with neonatal abstinence syndrome via a QI initiative. They used standard QI procedures to institute a series of 8 tweaks to the care of such infants, implemented in a sequential manner over a 5+ year period. Their results are impressive: length of stay decreased from about 3 weeks to 5 days, morphine use decreased from 98% to 14%, they saw cost savings of over \$30,000 per infant, and saw no increase in adverse events or readmissions. Importantly, they did most of this through concerted efforts to implement nonpharmacologic treatments, empowering and enabling families to participate in the care of their infants.

Everyone should at least browse this article. The **key driver diagram**, a cornerstone of QI project planning, is depicted, as are the 8 tweaks, that included such interventions as changing the manner in which such infants are assessed, a more rapid morphine weaning schedule, and use of prenatal counseling and empowering messaging to parents.

In my opinion, these sequential interventions are the most important differentiation of a QI study from an RCT. Planning an RCT is almost identical to planning a QI study, with 1 crucial difference: in an RCT, there is 1 hypothesis proposed at the start of the study, and it remains the same throughout, to be either supported or refuted by the data collected. In a QI study, the hypothesis changes over time. Study of 1 intervention leads to generation of a new hypothesis, which is then subject to new data collection and analysis, etc, an iterative process commonly known as a Plan, Do, Study, Act (PDSA) cycle.

Let's compare the key findings of the NEJM (RCT) study to the *Pediatrics* (QI) report. They both studied interventions to improve care for neonatal abstinence syndrome patients at single institutions, the first involving 63 subjects versus 287 in the second. The RCT demonstrated a decrease in length of stay from 33 to 21 days, not as dramatic as the QI intervention. The RCT was focused on pharmacologic interventions (buprenorphine versus morphine), while the QI focused on nonpharmacologic interventions and family involvement. The studies had minor differences in the patient populations and in assessment methods, but overall represent a good opportunity for comparison. Both studies explained their respective limitations, including the fact that they were performed at single institutions and may have limited generalizability. Of course, a QI study is really a roadmap that likely will differ at different institutions as the hypotheses evolve in the PDSA cycle.

I've probably tipped my hand as to which study I think is most important; it's the QI study. With apologies to the NEJM, the QI study has a much greater potential for sustainability at that institution, and their methods can be adapted for use in other hospitals. Kudos to both groups of investigators for excellent studies, but QI wins the day.

- [Neonatal Abstinence Syndrome: A Tale of Two Studies \(Part 1\)](#)
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