

# Doctors debate use of blood thinners to prevent clots in women after C-sections

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Nearly all women who deliver babies through cesarean section at Columbia University Irving Medical Center in New York City receive injections of the blood thinner heparin for weeks after the procedure, to

prevent potentially life-threatening blood clots.

Obstetric leaders there say that's good medical practice because the formation of those clots, called venous thromboembolism or VTE, though uncommon, is a leading cause of maternal death after delivery, particularly C-section delivery. Broad use of heparin has been shown to be effective and safe in the United Kingdom in reducing that risk and should be adopted in the U.S., they argue.

But there's sharp debate among physicians about whether wide use of heparin is effective, worth the cost and safe, since it carries the risk of bleeding. Last year, the American College of Obstetricians and Gynecologists and the Society for Maternal-Fetal Medicine recommended heparin only for [women](#) at elevated risk of VTE, citing a lack of evidence supporting near-universal use.

The controversy illustrates a classic dilemma for physicians: whether and how to adopt promising new treatments before studies have proven their safety and effectiveness. There also are questions about keeping drug company funding from influencing clinical recommendations around the drug.

The Columbia doctors were lead authors of 2016 guidelines from the National Partnership for Maternal Safety—a multidisciplinary group of medical experts—encouraging doctors to give heparin shots to all women after C-sections, except patients with specific risks. Previously, only a small percentage of mothers received them. Nearly 1.2 million U.S. women deliver via C-section each year.

Other U.S. physician groups generally promote heparin use only for women with a personal or family history of deep vein thrombosis or blood clots in the lungs, called pulmonary embolism, or other high-risk factors. They are estimated to make up less than 5% of pregnant or

postpartum women.

Despite gaps in evidence, experts said, the use of heparin has increased across the U.S. since the 2016 guidelines came out, though practices vary widely among doctors and hospitals. One reason for the rise is that more women giving birth have risk factors for VTE, such as obesity and older age.

"We have to make sure we're doing everything possible to reduce preventable maternal death," said Dr. Mary D'Alton, chairperson of obstetrics and gynecology at Columbia University and lead author of the 2016 guidelines. She called heparin treatment "very reasonable" after a cesarean delivery.

One of her co-authors has had second thoughts, however.

"I'd have to agree with some of the critics that there isn't solid evidence we should be giving heparin to as many patients as we do here at Columbia," said Dr. Richard Smiley, an anesthesiologist. "I'd probably want to take a step back. But physicians are willing to be a little more aggressive on this because maternal death is so traumatizing."

The deputy editor of *BJOG: An International Journal of Obstetrics and Gynaecology* scathingly compared widespread use of heparin for post-delivery patients to debunked obstetric practices of the past like enemas and pubic hair shaving. In a 2018 editorial, he suggested that obstetricians deserved a "booby prize" for adopting this practice without adequate scientific evidence.

One big reason for the lack of evidence is that it's a difficult issue to study, because VTE is relatively rare in women during pregnancy and after delivery, with an estimated incidence of 1 in 1,500 patients. A 2014 study found that out of 466,000 women who delivered through C-

section and received the standard nondrug therapy of pneumatic compression devices applied to the legs to reduce clotting risk, just one woman died from [pulmonary embolism](#).

"If those data are valid, and heparin were 50% effective in preventing fatal embolism, we'd have to treat almost 1 million women with heparin to prevent a single maternal death from embolism," said Dr. Dwight Rouse, a professor at Brown University and editor-in-chief of *Obstetrics & Gynecology*, ACOG's journal.

The cost of preventing that one death? A 2016 editorial he co-authored estimated the minimum national cost associated with widespread use of heparin after C-sections would be \$52 million to \$130 million annually, not counting the cost of treating serious bleeding complications caused by the drug.

Rouse and other critics say there have been no solid studies either of how effective heparin is at preventing clots or of how many women suffer adverse effects from heparin such as hemorrhage or problems in wound healing. Without those numbers, it's impossible to determine how effective and safe heparin is, they argue. There's also a lack of research on how to best calculate patients' clotting risk based on various individual factors.

While D'Alton and her co-authors claim U.K. data show that maternal deaths from VTE have dropped since British obstetricians recommended broad use of heparin in 2004, critics note that deaths actually have ticked up slightly in recent years to the same level as in the 1980s and '90s.

From 2007 to 2017, the death rate in Britain increased from less than 1 per 100,000 births to about 1.5, according to an analysis by Dr. Andrew Kotaska, an adjunct professor of epidemiology at the University of British Columbia who wrote a 2018 BJOG article arguing that broad

heparin use may cause more harm than good.

"The basic rule in evidence-based medicine is you don't implement large-scale interventions that have side effects without first demonstrating net benefit over harm," Kotaska said in an interview. "And this is being done to women without discussing it with them and getting their informed consent."

Obstetricians followed other medical specialties in using heparin after surgical procedures. But the American College of Chest Physicians, whose previous guidelines had strongly advocated giving heparin to post-surgical patients, softened its support in 2012 by saying the evidence for net benefit over harm wasn't clear.

The ACCP also acknowledged that the authors of its previous guidelines promoting heparin use had "highly problematic" financial and intellectual conflicts of interest, including financial relationships with major drug companies that produce anti-clotting drugs. To eliminate such conflicts, the ACCP sharply revised its process for choosing the experts who write its guidelines.

A controversy over drug company funding also arose in connection with the 2016 National Partnership for Maternal Safety guidelines on VTE prevention. In 2019, the editors of *Obstetrics & Gynecology*, which published the guidelines, disclosed that the National Partnership's guidelines effort received funding from industry groups, including three companies that produce anticoagulant drugs—though the journal said none of the authors received any of those funds.

"We didn't disclose the funding originally because we had no knowledge of it," D'Alton said.

Some critics say funding from drugmakers and other health industry

players casts doubt on the credibility of this and other guidelines from physician groups.

"It's a toxic problem for medicine and the care of women," said Dr. Adam Urato, chief of maternal and fetal medicine at MetroWest Medical Center in Framingham, Massachusetts, who pressed Obstetrics & Gynecology to disclose the partnership's drug company funding. "Corporate cash will push guidelines toward things that are good for corporate profits, not for patients."

Meanwhile, Canadian researchers are planning to test an alternative drug that may be equally effective, safer and cheaper in preventing VTE in women after delivery—aspirin.

Orthopedic surgeons have reported that aspirin is as effective as injectable blood thinners at preventing clots.

"I'm not against [heparin](#), but we don't know the best way to prevent clots," said Dr. Leslie Skeith, an assistant professor of hematology at the University of Calgary who launched a five-nation study. "We just need better evidence.

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