Streamlining the Use of Mifepristone for Early Pregnancy Loss Across a Large Health Care System Sets the Stage for Rapid Expansion of Medication Abortion Access in a Post-Roe Environment

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THE INNOVATION

Based on safety and efficacy, mifepristone and misoprostol together remain the standard for medical management of early pregnancy loss (EPL) and first trimester abortion.[1,2] While misoprostol is readily available, distribution of mifepristone has been restricted, regardless of indication for use. Despite its documented safety, mifepristone is regulated by a Risk Evaluation and Mitigation Strategy (REMS) program—a barrier for both labeled and off-label use.[3-5] This regulation burdens individual prescribers and has significantly limited integration into primary care.[6] We created a process facilitating access to mifepristone across a large health care system for medication management of EPL. This allowed for rapid expansion to medication abortion access post-Roe.

WHO & WHERE

Initiated by a pharmacist/family physician dyad, this interprofessional process was supported and developed with several system stakeholders. MHealth Fairview is a large academic health care system affiliated with the University of Minnesota and includes 10 hospitals and 60 primary care and multispecialty clinics across the Twin Cities and greater Minnesota. Before this process, mifepristone was only available in 2 system clinics.

HOW

We partnered locally with our compliance department to create standard processes for ordering and documenting mifepristone administration that adhered to the REMS requirements. The manufacturers (Danco Laboratories LLC and GenBioPro Inc) are also equipped to provide guidance. Mifepristone is accessible only after setting up an account with a manufacturer and their drug wholesale company—a process initiated by prescribers signing and submitting the Prescriber Agreement Form.[7] The REMS requirements imply that every prescriber complete this step; however, we learned we could establish a single account and have a single prescriber sign to represent all system prescribers who met the outlined requirements, allowing our pharmacy purchasing team to centralize the ordering and distribution process as used for other inventory.

We partnered with clinic management to ensure the process was scalable across sites (**Supplemental Appendixes**). They supervised site medication management, including setting a periodic automatic replenishment (PAR) level for medication stock, ordering through centralized purchasing, and storing mifepristone (together with required documents) according to local standards. These partners also connected staff and prescribers to training materials that reviewed mifepristone, the REMS program, and electronic health record (EHR) tools. We collaborated with our education team who provided a centralized location for these materials, which were required for all clinicians interested in prescribing mifepristone for EPL.

To ensure standardized processes we embedded tools in the EHR through partnership with information technology (IT). This included a best practice alert programmed to open the tools (built as an Epic SmartSet, Epic Systems Corp) whenever mifepristone is ordered. Key elements included note templates, reminders to complete the required Patient Agreement Form,[8] patient instructions, and associated orders like misoprostol and ibuprofen. Finally, to ensure administration documentation met REMS requirements, a retrievable field was created within the medication administration record for documentation of the unique serial number.

We gained buy-in from leadership by focusing first on mifepristone's less controversial off-label indication, EPL, to demystify its use in routine reproductive health care. After the Dobbs decision, as it became clear that Minnesota would be a haven state for abortion access in the upper Midwest, these processes for EPL served as the scaffolding to broaden medication abortion access across the system. The additional regulatory requirements involved in abortion care fit into this established structure. Current work is fine tuning EHR tools and education available to prescribers. What took 3 years to build for EPL rapidly expanded to medical abortion within 3 months.

LEARNING

Establishing processes for mifepristone for EPL accelerated integration of its use for medical abortion. As the barriers to mifepristone use are similar, regardless of indication, our process made it easier for our system to scale up and provide greater access to abortion care at a time when access has become limited throughout the Midwest.

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Key words: early pregnancy loss; miscarriage; abortion; access to health care

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Supplemental materials, including appendixes, affiliations, acknowledgments, references, etc.

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