

Medicines in pregnancy: Building a Scottish surveillance system

Authors: Marion Bennie,^{1,2} Amanj Kurdi,^{1,2,3} Stuart McTaggart,¹ Tanja Mueller,^{1,2} Euan Proud,¹ Rachael Wood^{1,4}

¹Public Health Scotland, Edinburgh, Scotland, UK; ²Strathclyde Institute of Pharmacy and Biomedical Sciences, University of Strathclyde, Glasgow, Scotland, UK; ³Department of Clinical Pharmacy, College of Pharmacy, Hawler Medical University, Erbil, Iraq; ⁴Usher Institute, University of Edinburgh, Edinburgh, Scotland, UK

Background

Some medicines have the potential to cause harm to the developing child if taken during pregnancy.¹ In July 2020, the Cumberlege Report, 'First do no harm', included examination of the harms of sodium valproate, an anti-seizure medication, during pregnancy.² In March 2021, the Scottish Government published its delivery plan.³

Aim and objectives

Establish a 'Medicines in pregnancy' programme to allow investigation of potentially harmful medicines among those who are, or could become, pregnant.

- Development of a harmonised Scottish Combined Medicines Dataset (SCoMeD).
- Development of a Scottish Linked Pregnancy and Baby Dataset (SLiPBD).
- Linkage of the datasets to quantify the use of defined medicines during pregnancy.

Methods

Data: identify and link relevant data sources on medication use and pregnancies.

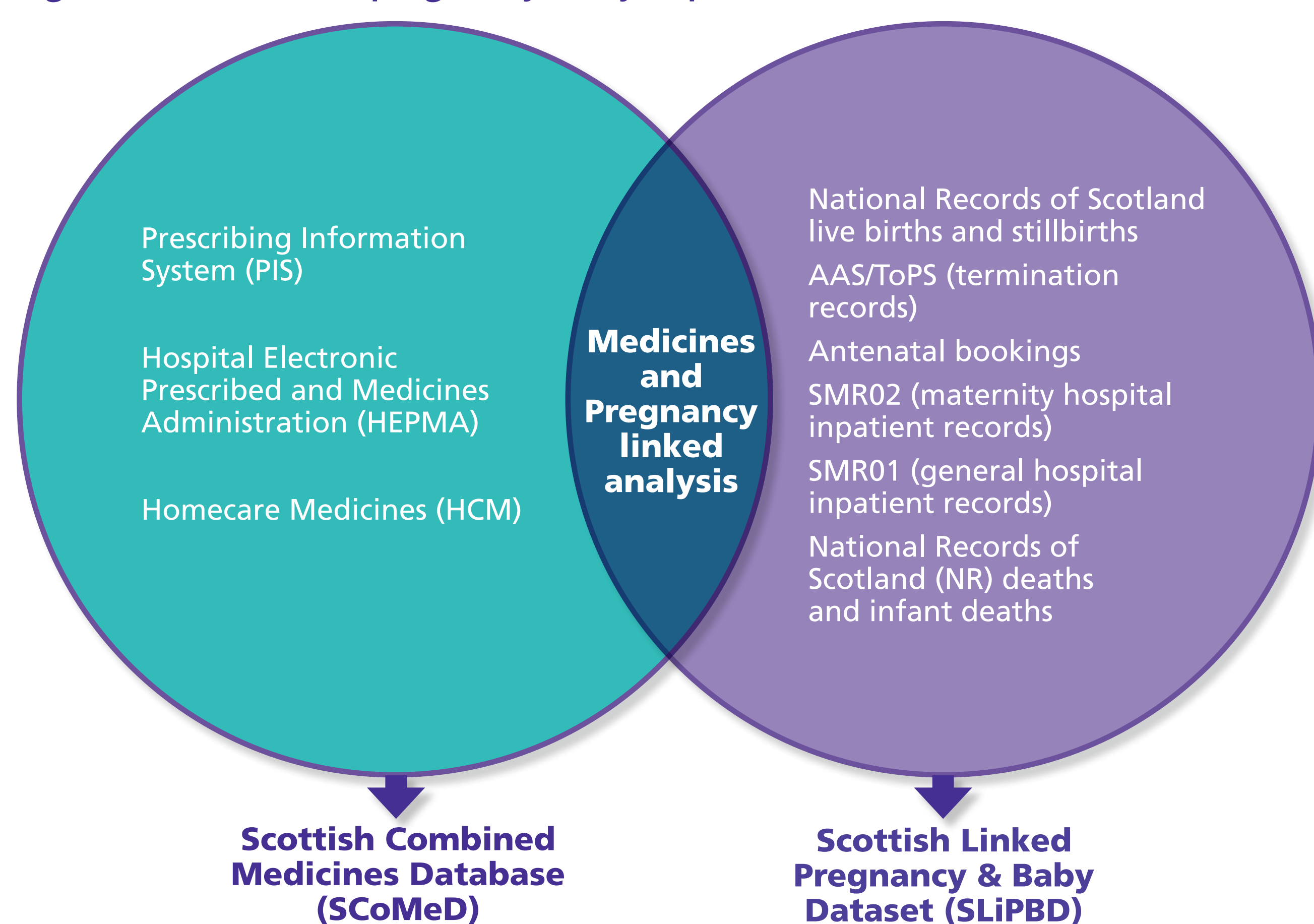
Cohort: all females aged 0–54 years prescribed anti-seizure medicines between January 2017 and September 2023 – all pregnancies conceived between April 2018 and September 2023.

Exposure: valproate or topiramate.

Results

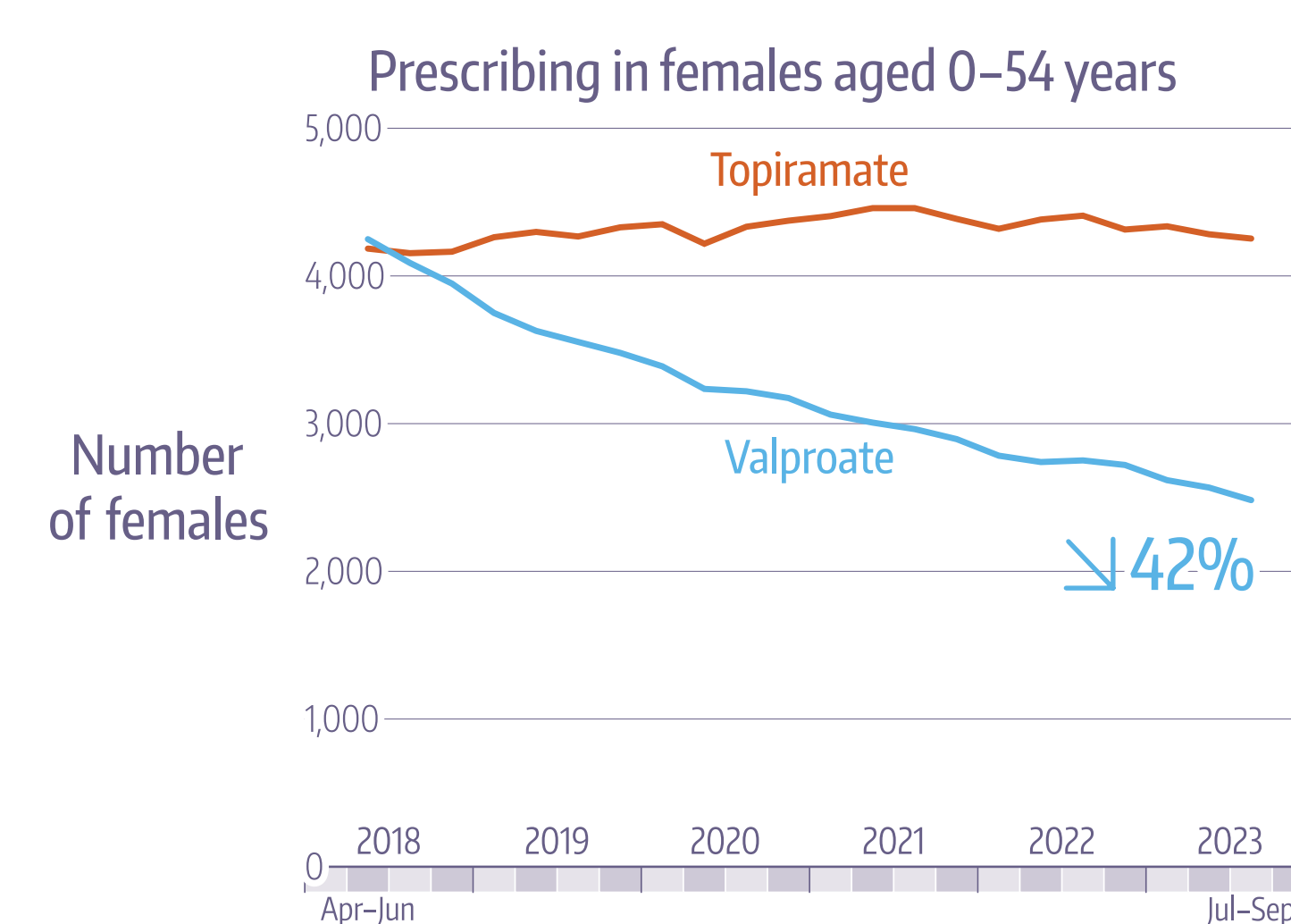
Information on anti-seizure medicines dispensed in community pharmacies and dispensing doctors, administered in hospital, and supplied through home care services was combined with pregnancy and births data (Figure 1).

Figure 1: Medicines in pregnancy analysis platform



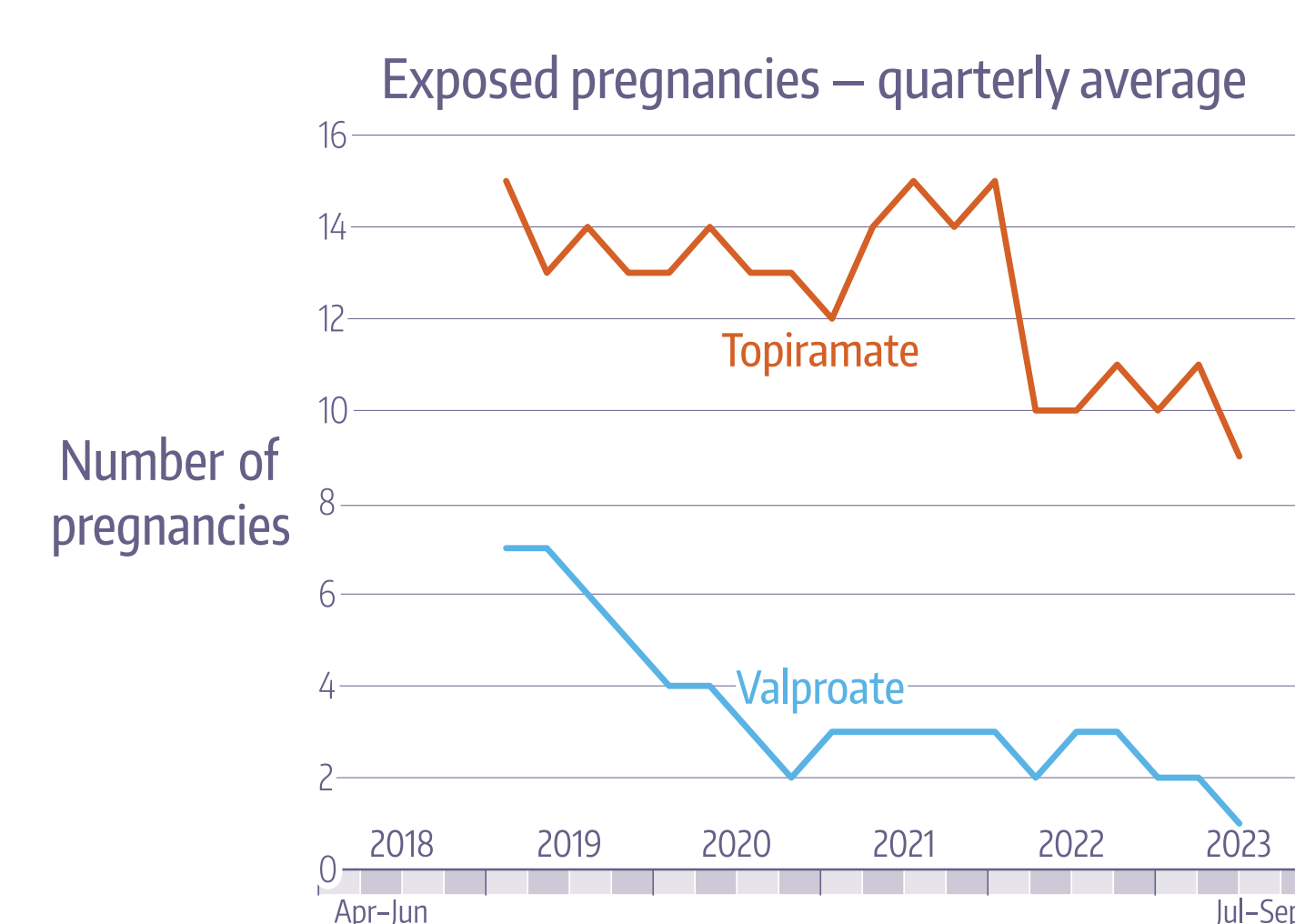
In the most recent quarter (July–September 2023), 2,482 females were prescribed valproate and 4,253 were prescribed topiramate. While valproate prescribing has steadily decreased over the study period, topiramate prescribing has remained level (Figure 2).

Figure 2: Prescribing of valproate and topiramate in females aged 0–54 years in Scotland, April 2018 to September 2023, by quarter



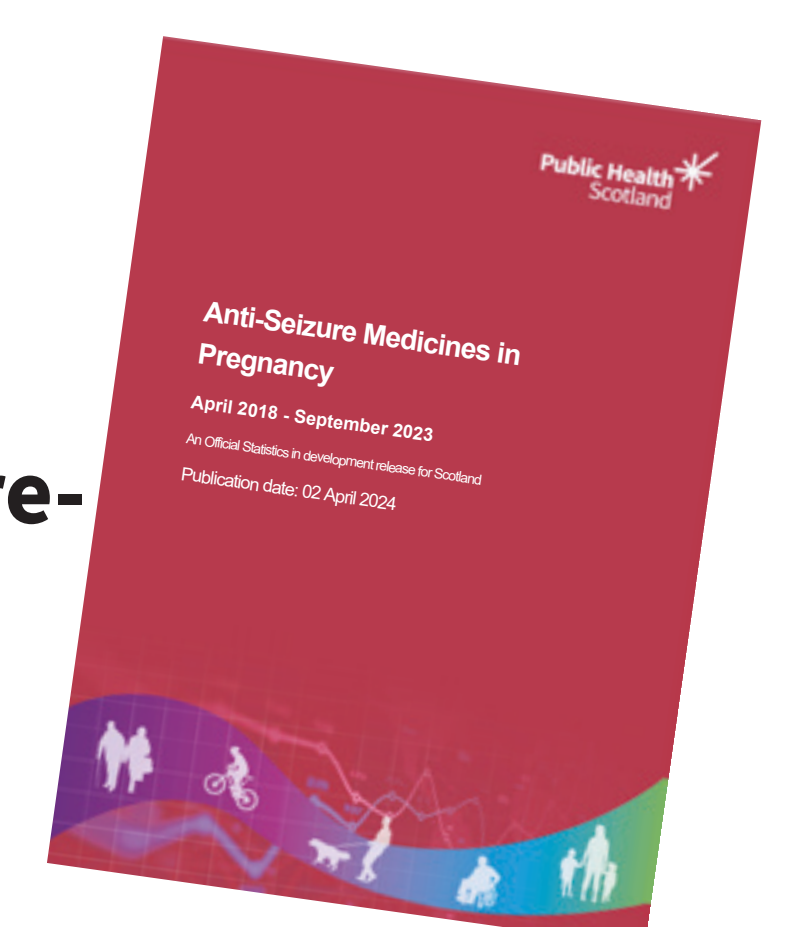
A total of 75 pregnancies conceived between April 2018 and September 2023 were exposed to valproate, and 268 pregnancies to topiramate. Exposure to both medicines has decreased over the study period (Figure 3).

Figure 3: Pregnancies exposed to valproate or topiramate in Scotland, April 2018 to September 2023, by quarter



The first national report (see Figure 4) was published in April 2024 and is available at: <https://publichealthscotland.scot/publications/anti-seizure-medicines-in-pregnancy/anti-seizure-medicines-in-pregnancy/>

Figure 4: Medicines in pregnancy programme first national report



Conclusions

Scottish national datasets stemming from routine clinical care can be used as part of an evolving national surveillance capability. Generating new evidence on the use and impact of medicines in pregnancy is an important step in augmenting current harm minimisation systems.

References

1. McTaggart et al (2022). Impact of regulatory safety notices on valproate prescribing and pregnancy outcome among women of child-bearing potential in Scotland. *BMJ Open*, 12:e058312
2. Department of Health and Social Care (2020). First do no harm: the report of the Independent Medicines and Medical Devices Safety Review. www.immndsreview.org.uk/downloads/IMMDSReview_Web.pdf
3. Scottish Government (2021). Delivery plan to implement the recommendations of the Independent Medicines and Medical Devices Safety Review. www.gov.scot/publications/independent-medicines-and-medical-devices-safety-review-first-do-no-harm-scottish-government-delivery-plan/