SPHERE
NHMRC Centre of Research Excellence in Sexual and Reproductive Health for Women in Primary Care

RESPONSE TO SENATE COMMITTEE HEARING

28 April 2023

QUESTIONS ON NOTICE

1. **Assessment of what extra funding will be required to address inequities**

   Ensuring equitable access to effective contraception and abortion services

   What are the problems?

   - Women are often not aware of the range of contraceptive options available to them, and there is also misinformation and misperceptions about different methods
   - Women are unaware of the availability of medical abortion
   - There are financial barriers to obtaining effective contraception in Australia
     - Cost of repeat prescriptions
     - Some contraceptive methods are not listed on the Pharmaceutical Benefits Scheme and are, therefore, not subsidised
     - Costs associated with insertion of long-acting reversible contraceptive (LARC) methods (upfront costs and multiple appointments) despite their long-term cost-effectiveness
   - There are financial barriers to accessing medical abortion services in Australia
     - Out-of-pocket costs for the procedure are considerable and many women rely on financial assistance
     - Women living in rural and regional areas often need to travel to access the services
   - Lack of financial incentives for GPs and other health practitioners to undergo the necessary contraception and medical abortion training, particularly when they have to bear the costs of training themselves
   - Inadequate remuneration for GPs to prescribe or provide LARC
   - Lack of training and support opportunities for primary care providers to provide LARCs and medical abortion services
   - Lack of remuneration for registered nurses, nurse practitioners, and registered midwives who are well-placed to provide LARC insertion and removal services, as occurs in many other countries and in some community settings in Australia

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Solutions

A. Improving consumer health literacy about sexual reproductive health: *A collaborative digital hub that is focused on increasing young women's health literacy in relation to their sexual and reproductive health and assisting them to navigate the health system to access services*

Leveraging off the success of the SPHERE NHMRC Centre of Research Excellence and its Coalition in women's sexual and reproductive health in primary care and building on and engaging with other initiatives such as the Jean Hailes National Communication Network, the Periods, Pain, Endometriosis Program (PPEP Talk), the "Your Fertility" website and 1800 MyOptions, the hub would work in partnership with key stakeholders, clinical experts, consumers and researchers to co-design, co-create, disseminate and evaluate a suite of educational and health promotion materials and implement a nationwide contraception and abortion provider directory and information service for young women.

The focus would be on periods, fertility, pregnancy planning, contraception and abortion. Creation of the hub would involve:

- A prioritisation and codesign process with relevant stakeholders and consumers
- Creation of a suite of engaging multilingual stand-alone videos and TikTok videos, animations, low literacy decision aids and social media resources
- Promotion of these materials on a dedicated website, through our partners, and through a targeted and tailored social media campaign
- A national contraception and abortion provider directory and information service for young women
- A rigorous evaluation of outcomes
- Development of a national sustainability plan

In undertaking this work, the expertise of health literacy and health promotion experts, IT and marketing and media experts is necessary. Collaboration would also occur with Healthdirect Australia to optimise outcomes.

How much would it cost?
This five-year program of work is estimated to cost $6.5 million dollars. Key deliverables include:

1. Partnership process to delineate priorities for materials and resources ($250K)
2. Codesign of materials and dissemination plan with relevant stakeholders and consumers ($600K)
3. Process and outcome evaluation protocol completion ($50K)
4. Filming and design and development of resources ($2.0 Million)
5. Website development and maintenance over course of project ($300K)
6. National contraception and abortion provider directory and information service ($2.0 million)

7. Dissemination through partners, advertising and social media campaign ($1.0 million)
8. Outcome evaluation ($250K)
9. Development of a national sustainability plan ($50K)

B. *A community of practice to support primary care providers to provide contraception and abortion services:* *ongoing support for the online Australian Contraception and Abortion Primary Care Practitioner Support Network*

AusCAPPS (The Australian Contraception and Abortion Primary Care Practitioner Support Network) is a NHMRC partnership grant-funded online community of practice designed to support primary care practitioners (GPs, practice nurses and pharmacists to deliver LARC and early medical abortion.

AusCAPPS has brought together key stakeholders, professional, government and non-government organisations involved in women's health care including the Royal Australian College of General Practitioners, the Royal Australian and New Zealand College of Obstetrics and Gynaecology, the Australian Practice Nurse Association, the Pharmaceutical Society of Australia, Marie Stopes, Family Planning Organisations and the Department of Health.

AusCAPPS offers peer networking, support for clinical issues from clinical experts, a resource library of guidelines, checklists and patient information, links through to training in LARC and early medical abortion, webinars, podcasts, case discussions and a database of local providers to build local networks. It has a growing number of participants (1690 members as of 02/05/23) but is currently only funded till early 2024. New funding is needed to continue this valuable initiative that has become an important source of information and support for Australian primary care practitioners.

How much would it cost?

Continued support for the operations of AusCAPPS, including staffing, content delivery, hosting and marketing over three years, is estimated at $1,050,000 ($350k/year).

C. *Targeted incentives for training in LARC insertion and abortion care in areas of need*

A lack of financial incentives for GPs and other health practitioners to undergo necessary training is a barrier to providing LARC services, particularly when GPs and other practitioners usually bear the costs of the training themselves. Current IUD insertion training can cost GPs approximately $2,000, excluding travel, loss of income and other associated costs.

Additionally, there are relatively few abortion providers in the primary care setting and hospital system in Australia and even fewer who can manage complex medical and gynaecological cases. Only 3,885 out of approximately 34,132 registered GPs are active prescribers of medical abortion drugs. About 30% of women in Australia live in regions where there is no local GP provision of medical abortion including about 50% of women living in remote Australia ("abortion deserts"). Whilst there is scope for task-sharing of this service between nurses and doctors in primary care, legislative barriers currently prevent nurses from becoming medical abortion prescribers. This is a considerable barrier to provision of abortion care and is out of step with globally accepted normative standards.

One solution to address these barriers is to incentivise and fund GPs and other health practitioners working in areas of need to undertake LARC insertion/removal training. Areas of need would be identified according to regional reporting.

How much would it cost?

Training grants of $5000 per GP could be made available with several allocated to each PHN to administer. If 10 grants were available in each PHN, then the cost would be $5000 x 10 x 31= $1.55 million

D. *Establishment and implementation of a leadership program in women's sexual and reproductive health*

Ensuring we have future clinical leaders in contraception and abortion should be a priority to guarantee sustainability of the workforce. Special fellowships of up to two years' duration that encompasses training in clinical service delivery, education, research and leadership and advocacy should be established for GPs and gynaecologists. The US has already successfully implemented these schemes (RHEDI, RHAP, SFP, Complex Family Planning) to support trainee GPs and gynaecologists. These fellowships provide salary support for one to two years, which might incorporate a Master of Public Health where these trainees can learn the core skills of clinical care, advocacy and leadership, and education and research skills that can help make them be leaders in sexual reproductive health in the future. This model could be implemented in the Australian setting at relatively low cost.

How much would it cost?

Each Fellowship would cost approximately $300,000 in salary for a two-year program. If two were offered in each state/territory each year, then the salary cost over a two-year period and administration of the program will amount to $300,000 per year. The total cost would be = $300,000 x 14 (for trainees) + $300,000 x 2 (for administration) = $4.8 million over two years.

E. Commissioning services in areas of need

The long distances women often must travel for an abortion poses a significant barrier to access. 'Abortion deserts', defined as areas where there are no GP prescribers and no surgical options and women must travel more than 160km to access services, are common in rural and remote parts of Australia. Women must rely on hospitals and private clinics in metropolitan areas, which can pose financial and logistical challenges and delays to care. More than one in ten women require an overnight stay when accessing an abortion due to the long distance they are required to travel, and 4% must travel outside their state of residence.

Additionally, there is currently no regional accountability for service provision. Primary Health Networks provide a mechanism to address this just as they do for mental health and drug and alcohol services.

As part of their mandate, PHNs should develop an integrated regional approach to LARC and abortion care that involves:

- Identifying gaps in service provision at a local level (including remote, rural, and regional areas)
- Commissioning one or more services to provide abortion (surgical and/or medical) and LARC insertion to fill those gaps. Services should:
    - In the case of abortion be delivered by suitably trained practitioners in accredited surgical facilities including day procedure centres and local hospitals (supported by larger tertiary hospital to deliver integrated care)
    - Provide abortion care training for primary care health professionals to build capacity and support sustainable service provision (including GPs, nurses, midwives, and pharmacists)
    - Mapping the availability of services

How much would it cost?

Appropriate costing of the implementation of this recommendation would require the establishment of an advisory committee that would comprise health economists, PHNs, GPs and consumers. This committee would provide advice on the elements required for implementation along with the costs associated.

F. Free contraception and abortion for all Australian women

Financial barriers to accessing effective contraception and abortion services can be overcome by making these free for all Australian women.

Contraception should be free to access (including costs of consultations and costs of LARC insertion and removal) to ensure women can choose from all available options

and not be hampered by cost. Internationally, England, Ireland, Scotland, France and Sweden are all countries that offer free contraception to women.

All contraceptive options available overseas should also be made available in Australia. Government should facilitate mechanisms to register and make available contraceptive options that pharmaceutical companies may not seek to register due to Australia's small market.

Across Australia, there is also a lack of affordable or no-cost abortion services. Access to low-cost surgical procedures outside of public hospitals is difficult in most jurisdictions, especially in rural areas where there are very few providers. Additional expenses may also include travel costs, overnight accommodation, taking time off work and childcare if required. Two-thirds of women must obtain financial assistance from one or more sources (e.g., partner, family members) to pay for their abortion. Women not eligible for Medicare, including international students and women on temporary visas, must also pay for the procedure and other associated costs in full. While Medicare rebates are available for consultations concerned with medical abortion (including, since July 2021, those consultations delivered by telehealth), considerable out of pocket costs and gap payments still apply.

How much would it cost?

A formal costing would need to be undertaken to estimate the cost of offering free contraception and medical abortion services to all women in Australia. Apart from the cost of the medication and devices, consideration should also be given to the costs associated with follow-up consultations and procedures. In Ireland, GPs are paid €300 to provide medical abortion for up to 12 weeks' gestation, which is separate to the medication (available for free) and any required ultrasounds and low-sensitivity urine pregnancy tests for follow-up. In the Canadian province of British Columbia, where contraception has been made available for free for all residents, it is estimated that the policy will cost around $119 million over three years.

G. *Increasing the uptake of effective contraception by offering effectiveness-based counselling in general practice and establishing a fast-track referral pathway to LARC insertion*

Attachment 1
Increasing long-acting reversible contraceptives: the Australian Contraceptive ChOice pRoject (ACCORd) cluster randomized trial.
Mazza D, Watson CJ, Taft A, Lucke J, McGeechan K, Haas M, McNamee K, Peipert JF, Black KI.
Am J Obstet Gynecol. 2020 Apr;222(4S):S921.e1-S921.e13. doi: 10.1016/j.ajog.2019.11.1267.

Attachment 2
Cost-effectiveness of a complex intervention in general practice to increase uptake of long-acting reversible contraceptives in Australia.
Lewandowska M, De Abreu Lourenco R, Haas M, Watson CJ, Black KI, Taft A, Lucke J, McGeechan K, McNamee K, Peipert JF, Mazza D.
Aust Health Rev. 2021 Dec;45(6):728-734. doi: 10.1071/AH20282.

The Australian Contraceptive ChOice pRoject (ACCORd), undertaken by SPHERE, tested whether a complex intervention involving online education for GPs on effectiveness-based contraceptive counselling together with the availability of a fast-track referral process to a LARC insertion clinic could increase the uptake of LARC in general practice. This intervention resulted in a significant uptake of LARC among women attending general practices compared to usual care.

Further analysis of the ACCORd intervention was conducted to determine its cost-effectiveness. This analysis showed that the ACCORd intervention has the potential to be highly cost-effective in terms of both increasing the number of women using LARC and the longer-term quality of life outcomes. Evaluation over a 10-year period indicates that the ACCORd intervention is more effective than usual care in preventing unintended pregnancies resulting in birth and abortions, but it is more expensive. However, our assessment also showed that the value to both the healthcare system and society of the ACCORd intervention is enhanced if more women access it (reducing the impact of start-up costs).

How much will this cost?

Appropriate costing of the implementation of this model of care still needs to be conducted. This would require the establishment of an advisory committee comprising health economists, GPs and consumers.

2. Research on "abortion deserts" in Australia (publication attached)

Attachment 3
Early medical abortion services provided in Australian primary care.
Subasinghe AK, McGeechan K, Moulton JE, Grzeskowiak LE, Mazza D.
Med J Aust. 2021 Oct 18;215(8):366-370. doi: 10.5694/mja2.51275

This study assessed the variability in the availability and uptake of medical abortion in Australia, with particular focus on primary care.

Data available for analysis:

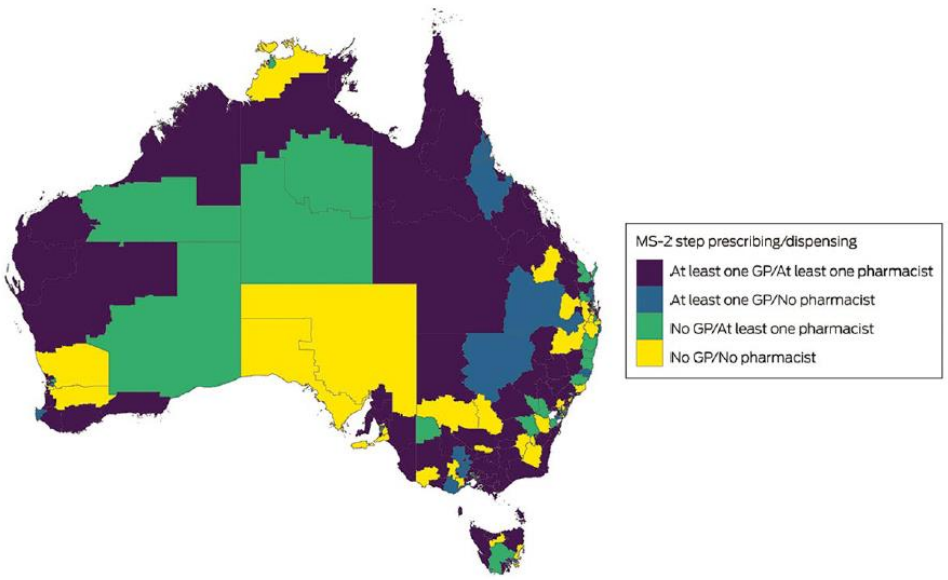
- Analysed aggregated data for all PBS claims for MS-2 Step dispensing

- Services Australia provided the number of MS-2 Step prescriptions dispensed to women aged 15-54 years in each ABS level 3 statistical area (SA3) during 2015-2019, irrespective of prescriber type or location
- Services Australia also supplied numbers of MS-2 Step prescriptions written by GPs and dispensed by pharmacists by SA3
- SA3s provide a regional breakdown of Australia into areas that usually include populations of between 30 000 and 130 000 people. In urban centres, they are often closely aligned with local government areas while for outside urban centres, they include areas recognised as sharing a distinct identity and socio-economic characteristics

Findings:

- During 2015-2019, the PBS subsidised 91,643 MS-2 Step prescriptions. The national age-standardised rate increased from 1.63 prescriptions per 1000 women aged 15–54 years in 2015 to 3.79 prescriptions per 1000 in 2019.
- In 2019, the age-standardised dispensing rate was highest in the Northern Territory (7.16 MS-2 Step prescriptions per 1000 women aged 15–54 years) and lowest in the Australian Capital Territory (3.15 per 1000) and New South Wales (3.23 per 1000).
- On a national basis, MS-2 Step prescription rates were higher in outer regional Australia (6.53 prescriptions per 1000 women aged 15-54 years) and remote Australia (6.02 per 1000) than in major cities (3.30 per 1000).
- Prescribing of MS-2 Step
    - Nationwide, about 30% of women aged 15–54 years lived in SA3s where MS-2 Step had not been prescribed by a GP during 2019.
        - The proportion was highest in South Australia (64%) and New South Wales (40%)
    - In terms of remoteness, about 50% of women aged 15–54 years living in remote Australia lived in SA3s where MS-2 Step had not been prescribed by a GP during 2019
- Dispensing of MS-2 Step
    - Nationwide, about 25% of women aged 15–54 years lived in SA3s where MS-2 Step had not been dispensed by a community pharmacist during 2019
        - The proportion was highest in South Australia (46%) and the Australian Capital Territory (36%)
- **In 74 of 338 SA3s (22%) in Australia, MS-2 Step was neither prescribed by a GP nor dispensed by a community pharmacist during 2019 (“abortion deserts”)**

6 MS-2 Step prescribing and dispensing during 2019, by level 3 statistical area (SA3)



This figure shows areas in Australia where there were no GPs or pharmacists who prescribed MS-2 Step in 2019 (yellow). These areas represent 74 of the 338 SA3s in Australia. Note that the lack of MS-2 Step prescribing and dispensing in South Australia in 2019 is likely due to legislation requiring abortions to be performed in hospitals. This legislation was changed in July 2022.

Implications:

- Rates of early medical abortion are higher among women in outer regional, remote and inner regional Australia than in major cities, however, MS-2 Step had not been prescribed by GPs or dispensed by community pharmacists in a large proportion of SA3s in these geographic areas during 2019. Consequently, women living in these areas who needed access to early medical abortion may have travelled long distances or received it using telehealth services.
- Higher rates of early medical abortion in rural and remote areas could be due to:
    - Difficulty accessing surgical abortion, as many public hospitals do not provide it at all or only in cases of foetal abnormality and private clinics that provide surgical abortion are predominantly located in major cities
    - Many women choose telehealth early medical abortion services for a range of geographic, financial, and social reasons. This mode of early medical abortion delivery is highly acceptable and convenient for women because they can remain at home and manage their personal responsibilities. It also satisfies their privacy needs

- Lower rates of prescribing and dispensing of MS-2 Step in some rural and remote SA3s could be due to barriers such as:
    - Restrictive laws during 2015-2019 – abortion was only decriminalised in the Northern Territory in 2017, in Queensland in 2018, and in New South Wales in 2019 (South Australia decriminalised abortion in 2021). Inconsistencies in knowledge of the law pertaining to abortion would have discouraged some GPs from providing the service.
    - Doctors in rural and regional areas having concerns about support services, including after-hours emergency and surgical care in case of complications, and about access to ultrasound services (for gestation dating and excluding ectopic pregnancy). They might also have been concerned about their capacity to provide anti-D, which was a recommendation at the time for medical terminations before ten weeks' gestation.
    - Doctors conscientiously objecting to performing abortions and/or refusing to refer patients for this procedure despite legally obliged to do so.
    - Many GPs not having the training or knowledge required to confidently provide early medical abortion.
    - Women choosing to not use local GP providers for abortion services
- These barriers are also compounded by the shortage of GPs in rural and remote areas. Solutions include:
    - Increasing the use of collaborative task-sharing arrangements and models involving nurses, whereby they undertake most of the counselling administration and follow-up health care.
    - Improved access to telehealth services, which was achieved as part of the federal government's COVID-19 pandemic response.
    - Supporting GPs in the local delivery of early medical abortion services through more local training and opportunities to educate doctors about early medical abortion and referral pathways. An example would be peer support networks that include other prescribing GPs, pharmacists, sonographer and MS-2 Step 24-hour nurse hotline

GYNECOLOGY

Increasing long-acting reversible contraceptives: the Australian Contraceptive ChOice pRoject (ACCORd) cluster randomized trial

Danielle Mazza, MD; Cathy J. Watson, PhD; Angela Taft, PhD; Jayne Lucke, PhD; Kevin McGeechan, PhD; Marion Haas, PhD; Kathleen McNamee, MBBS, M Epi; Jeffrey F. Peipert, PhD; Kirsten I. Black, MD

BACKGROUND: Long-active reversible contraceptives reduce unintended pregnancy and abortions, but uptake is low. Interventions to increase uptake in family medicine settings are untested.

OBJECTIVE: The Australian Contraceptive ChOice pRoject, which was adapted from the successful US Contraceptive CHOICE study, aimed to evaluate whether a complex intervention in family medicine practices resulted in increased long-active reversible contraceptive uptake.

STUDY DESIGN: This cluster randomized controlled trial was set in family practices in metropolitan Melbourne, Australia. From April 2016 to January 2017, we recruited 57 family physicians by mail invitation. Each family physician aimed to recruit at least 14 female patients. Eligible family physicians worked ≥3 sessions per week in computerized practices. Eligible women were English-speaking, sexually active, not pregnant, not planning a pregnancy in the next year, 16–45 years old, and interested in discussing contraception or in starting a new, reversible method. With the use of a randomization sequence with permuted blocks that were stratified by whether the family physician performed long-active reversible contraceptive insertion or not, family physicians were assigned randomly to a complex intervention that involved training to provide structured effectiveness-based contraceptive counselling and access to rapid referral to long-active reversible contraceptive insertion clinics. The 6-hour, online educational intervention was based on the US Contraceptive CHOICE Project and adapted for the Australian context. The control family physicians received neither the educational intervention nor access to the long-active reversible contraceptive rapid referral clinics and conducted their usual contraception counselling. We used the chi-square test, which was adjusted for clustering and stratification by whether the family physician inserted long-active reversible contraceptives, and binary regression models with generalized estimating equations and robust standard errors to compare, between the intervention and control groups, the proportions of women who had a long-active reversible contraceptive inserted. The primary outcome was the proportion of women with long-active reversible contraceptives that were inserted at 4 weeks. Secondary outcomes included women's choice of contraceptive method, quality of life, and long-active reversible contraceptive use at 6 and 12 months. Analyses were performed according to intention-to-treat.

RESULTS: A total of 25 intervention and 32 control family physicians recruited 307 and 433 women, respectively (N=740). Within 4 weeks, 19.3% of women in the intervention group and 12.9% of women in the control group had long-active reversible contraceptive inserted (relative risk, 2.0; 95% confidence interval, 1.1–3.9; *P*=.033). By 6 months, this number had risen to 44.4% and 29.3%, respectively (relative risk, 1.6; 95% confidence interval, 1.2–2.17; *P*=.001); by 12 months, it had risen to 46.6% and 32.8%, respectively (relative risk, 1.5; 95% confidence interval, 1.2–2.0; *P*=.0015). The levonorgestrel intrauterine system was the most commonly chosen long-active reversible contraceptive by women in the intervention group at all time points. Differences between intervention and control groups in mean quality-of-life scores across all domains at 6 and 12 months were small.

CONCLUSION: A complex intervention combination of family physician training on contraceptive effectiveness counselling and rapid access to long-active reversible contraceptive insertion clinics resulted in greater long-active reversible contraceptive uptake and has the potential to reduce unintended pregnancies.

Key words: contraception, education, effectiveness, family physician, implant, intrauterine device, IUD, LARC, referral

International evidence shows that the increased use of long-acting reversible contraceptives (LARCs), defined as intrauterine devices (IUDs) and contraceptive implants, can reduce unintended pregnancy and abortion rates across all stages of a woman's reproductive life.[1–4] LARCs are the most effective reversible methods of contraception; with typical use, failure rates are 0.05–0.8% in the first-year of use compared with 9% with the oral contraceptive pill and 18% with male condoms.[5] LARCs are highly acceptable to women and also have higher continuation rates than other less effective forms of contraception.[6,7] Despite this evidence, the prescription and use of LARCs remains low. In the United Kingdom, LARC prescription by family physicians (FPs) fell by 6% from 2014–2016.[8] In the United States, LARC uptake is increasing, but is approximately 14%.[9] Australia has similarly low rates, with national data from 2012–2013 reporting that only 11% of women were using a LARC (6.1% for IUDs and 4.9% for implants).[10]

In the US-based Contraceptive CHOICE Project (CHOICE), a prospective cohort study of 9526 women 14–45 years old,[11] the provision of evidence-based information about all reversible contraceptive options through structured counselling and free provision of implants and IUDs led to a

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0002-9378/$36.00

https://doi.org/10.1016/j.ajog.2019.11.1267

AJOG at a Glance

Why was this study conducted?

Long-acting reversible contraceptives are the most effective form of reversible contraception; however, the uptake of long-acting reversible contraceptives remains low. The Australian Contraceptive ChOice pRoject cluster randomized controlled trial investigated the impact of a complex family physician intervention on the uptake of long-acting reversible contraceptives.

Key findings

Training family physicians in effectiveness-based contraception counselling and providing rapid long-acting reversible contraceptive insertion clinics increased long-acting reversible contraceptive uptake in the intervention group compared with the control group.

What does this add to what is known?

Training family physicians in effectiveness-based contraceptive counselling and providing rapid-referral long-acting reversible contraceptive insertion clinics increases long-acting reversible contraceptives uptake and may reduce unplanned pregnancies. The Australian Contraceptive ChOice pRoject is the first trial to extend efficacy that was demonstrated by providing long-acting reversible contraceptive education to doctors in reproductive health/family planning clinics to family practice, where most contraceptives are prescribed.

significant increase in the uptake of LARC compared with national averages. This resulted in a 20-fold reduction in unplanned pregnancy rates at 3 years of follow up compared with contraceptive pill, patch, or ring users[3] and a significant reduction in abortion rates compared with the regional and national rates.[12] A subsequent randomized controlled trial, also undertaken in reproductive health clinics in the United States, trained healthcare providers in LARC counselling and insertion but maintained normal costs to replicate real-life conditions. This study resulted in increased rates of counselling and LARC uptake in the intervention group and reduced pregnancy rates in women seeking family planning consultations.[13]

These 2 studies, both undertaken in specialized clinic settings, demonstrated that improving healthcare provider knowledge and skills and addressing some of the financial and service access barriers[14] can impact women's uptake of LARC. However, in many countries, including Australia, specialized reproductive health services are not widely available, and women rely on their FP for contraceptive counselling and provision. Although the barriers to primary care provision of LARC have been well-documented,[4,14] to our knowledge, no studies have tested interventions in this setting. Consequently, this study sought to compare a complex intervention on the uptake of LARC in the family medicine practice setting.

Materials and Methods

Trial design and oversight

The Australian Contraceptive ChOice pRoject (ACCORd) trial was set in metropolitan Melbourne, Australia, with the FP as the unit of randomization. Approved by the Monash University Human Research Ethics Committee (CF 14/3990-2014002066 and CF 16/188-2016000080) and conforming to CONSORT guidelines,[15] the study was conducted and reported with fidelity to the protocol described elsewhere.[16] The conduct of the trial was reviewed periodically by an independent data safety monitoring committee that comprised a statistician and 2 academic researchers (independent from the ACCORd study) who monitored recruitment, trial outcomes, and adverse events. The authors vouch for the accuracy and completeness of the data presented.

Trial Population and Recruitment Procedures

FPs were eligible if they worked ≥3 sessions (half days) per week, were based at a computerized practice, and had reception staff who could assist with recruiting. FP recruitment took place between May 2016 and January 2017, and all FPs who participated in the study gave written consent at enrolment. To avoid contamination because of cross-over effects, only 1 FP was included per practice. Participating FPs were accredited with Continuing Professional Development points necessary to maintain professional FP qualifications and received $500 (Australian dollars) as reimbursement for time spent on completion of the study.

Reception staff from ACCORd FPs invited women to complete an online eligibility survey that included contact details, with the use of an iPad (Apple, Cupertino, CA) in the waiting room. Women were eligible to participate if they were 16−45 years old, had been sexually active with a male partner in the previous 6 months or anticipated sexual activity in the subsequent 6 months, had not undergone tubal ligation or hysterectomy, had sexual partners who had not undergone a vasectomy, were neither pregnant nor anticipating a pregnancy in the next 12 months, spoke proficient English, and were interested in discussing contraception or in starting a new reversible contraceptive method.

All eligible women were contacted by telephone by an ACCORd researcher to obtain consent and complete baseline questionnaires. After enrolment, women were asked to return to their ACCORd FP within 1 week for a contraceptive counselling appointment. Any additional charges for this visit were covered by ACCORd to ensure that the women did not bear out-of-pocket costs for this additional visit. ACCORd did not provide coverage for the cost of individual contraceptive products.

Randomization and masking

The trial statistician generated a randomization sequence with permuted

blocks (block sizes of 4, 6, and 8), stratified by whether the FP performed LARC insertion (IUDs/implants).[17] This sequence was then held by a research assistant who was not involved in the ACCORD trial. When a FP was recruited, ACCORd staff contacted the research assistant to assign the FP to the next allocation in the sequence.

Interventions

FPs in the intervention group were trained to deliver structured contraceptive counselling and given access to rapid referral to LARC insertion clinics through an online booking system. Materials from the "LARC first" (contraceptive effectiveness) online training site of the Contraceptive CHOICE project[3] were adapted to the Australian context with input from an advisory group comprising the project investigators, FPs, and consumers. Training was delivered online through a 6-hour training package with additional practice visits, email messages, and telephone support, where required. Structured contraceptive counselling[18] that consisted of nonbiased, scripted descriptions of all available contraceptive methods, with particular reference to the safety and efficacy of each method, was then delivered to the participating women by the intervention-trained FPs. FPs also collected clinical information from the women to identify any contraindications or conditions that may influence the choice of contraception. Women were able to choose their contraception method, provided that it was not medically contraindicated. The FP was then advised to screen the woman for pregnancy (history and urine pregnancy test) and chlamydia (according to clinical practice guidelines published by the Royal Australian College of General Practitioners).[19] The online training recommended ruling out pregnancy before (1) providing a prescription for the method of choice, (2) offering "same day" insertion of the LARC method or at a subsequent time at the FP clinic, or (3) providing an appointment for insertion of the LARC method at 1 of the insertion clinics. Emergency contraception was advised for women who had recent unprotected intercourse, although "quick start" contraception (ie, commencing contraception at any time rather than at the start of the next menstrual cycle) was recommended for women in cases in which pregnancy could be ruled out (as per the Faculty of Sexual and Reproductive Healthcare guidelines).[20] In both of these cases, a return appointment in 3−4 weeks for a LARC insertion (and a repeat pregnancy test) was also recommended.

A rapid referral pathway to a LARC insertion clinic with 2 local private gynecologists was implemented through an online booking system for intervention FPs who did not or chose not to perform insertions in their own rooms. Gynecologists who provided these LARC insertion clinics received payment of $300 (Australian dollars) per 3.5-hour clinic use and were free to charge patients their usual fees at these clinics.

FPs in the control group provided usual contraceptive care to women who were recruited to this group and did not have access to the rapid referral LARC insertion clinics. At the conclusion of the trial, the control group of FPs were invited to undertake the online contraceptive effectiveness training.

Fidelity checking

To ensure fidelity of the counselling, a researcher (blinded to the allocation of the FP to intervention group or control group) visited FPs in both groups. During this visit, the researcher observed a single consultation and completed a checklist regarding the content of the contraceptive counselling that was provided to ascertain whether the counselling was structured with an emphasis on effectiveness.

Trial measures

At baseline, eligible women undertook an initial telephone-based questionnaire that was drawn from the CHOICE Project[3] and included the Health Literacy Questionnaire[21] and Medical Outcomes Survey.[22] Further surveys were conducted online at 6 months (including the Medical Outcomes Survey) and at 12 months (including the Health Literacy Questionnaire and Medical Outcomes Survey). After completing each survey, women were given an entry into a monthly prize draw for a $150 gift voucher.

Participating FPs and gynecologists working in the LARC insertion clinics were asked to complete a standardized data collection form at every consultation that involved an ACCORd participant.

Primary and secondary outcomes

The primary outcome was the proportion of women who had a LARC inserted within 4 weeks of the initial contraceptive consultation with their FP. Secondary outcomes included women's choice of contraceptive method, quality of life, and LARC use at 6 and 12 months. These outcomes were measured with the use of data that were sourced from the standardized data collection forms and from the 6- and 12-month surveys.

Statistical analysis

Current LARC use increased from 2.3−11% of all contraceptives used in Australia over a 13-year time frame.[10,23] A British study estimated that, if 5% of British women who used oral contraceptives used LARC instead, the decrease in contraceptive failure would result in 7500 annual unplanned pregnancies.[24] Therefore, we chose an effect size of 10%. We estimated that we would require 24 FPs and 24 women per FP in each of the 2 study groups (intervention and control) to detect a 10% increase in the LARC insertion rate, with 80% power and a significance level of 5% that allowed for stratification according to whether FPs inserted LARCs and a clustering effect (intracluster correlation) of 0.05. This corresponds to the maximum intracluster correlation for variables that are associated with FP−patient encounters in a recent cluster randomized control trial[25] and other FP-specific studies.[26] We aimed to recruit 27 FPs and 27 women per FP in each of the 2 study groups to allow for up to a 10% drop-out rate among FPs and a 10% drop-out among participants.

We calculated counts and proportions for descriptive characteristics of FPs and

women at baseline. We used the χ^2 test, adjusted for clustering and stratification by whether the FP inserted LARCs, and binary regression models with generalized estimating equations and robust standard errors to compare the proportions of women who had a LARC inserted (the primary outcome) between the intervention and control groups for women who had outcome data available. The outcomes for women were analyzed according to their randomized group (intention-to-treat analysis). This method was also applied to the secondary outcomes of LARC use at 6 and 12 months. Linear regression models, which were also adjusted for study design, were used to compare mean quality-of-life scores between groups. We conducted sensitivity analyses by adjusting for the following variables: FP sex, FP age group, women's age group, parity, and use of LARC at baseline. Additional sensitivity analyses were carried out assuming that women with missing outcome data were not missing at random. For these analyses, we used multiple imputation under plausible missing data scenarios; women with missing outcome data had (1) the same probability of the outcome as those from the same group, (2) the same probability of the outcome as those from the control group, (3) the same probability of the outcome as those from the intervention group, and (4) no LARC inserted. Twenty imputation datasets were created in each analysis, and the results were combined with the use of Rubin's rules. In the binary regression models and the use of interaction terms, we investigated whether the effect of the intervention varied across subgroups that were defined by age, parity, use of LARC at baseline, marital status, socioeconomic status, education, previous unintended pregnancy, and previous abortion. All analyses were carried out with SAS software (version 9.4; SAS Institute Inc, Cary, NC).

Stakeholder involvement

Before commencement of recruitment and before final ethics submission, the study tools (FP surveys) were piloted among 5 FPs who provided suggestions for amendment. FPs were also asked to assess the burden of intervention and the time required to participate in the study.

Results

Trial sites and participants

From April 2016 to May 2017, 43 FPs were allocated randomly to the intervention group (with 25 subsequent withdrawals), and 44 FPs were allocated to the control group (with 23 subsequent withdrawals). A total of 25 intervention FPs recruited at least 1 participant, as did 32 control FPs (Figure). The characteristics of the FPs were well-balanced between the intervention and control groups (Table 1). Most of the FPs, who were women who were 35−54 years old, inserted implants but not IUDs. Most FPs (81%) had ≥10 years of experience. Recognized training in contraception had been undertaken by 25% of FPs; 40% of intervention FPs and 34% of control FPs also had specific training in IUD insertion (Table 1).

Between June 2016 and July 2017, intervention FPs recruited 410 women (103 women initially expressed an interest in the study but did not consent) and control FPs recruited 622 women (189 women initially expressed an interest in the study but did not consent) that resulted in 307 and 433 women in the intervention and control groups, respectively (N=740). The characteristics of the women were also well-balanced between the 2 groups (Table 1). This balance was retained among women with available data from the Standardized Data Collection Forms and from the 6- and 12-month survey. Most women were <35 years old, had no children, and were not currently using a LARC. The rate of cohort retention was 71% in both groups.

Primary and secondary outcomes

Within 4 weeks of the contraceptive counselling consultation, 8% more women in the intervention group than in the control group had had a LARC inserted (95% confidence interval, 1.5−15.4; P=.018; Table 2), with intracluster correlation of 0.13.

LARC uptake continued to rise with time at 6 and 12 months, with a greater proportion of women in the intervention group (44% and 47%, respectively) currently using a LARC compared with the control group (29% and 33%, respectively; Table 2).

The levonorgestrel intrauterine system was the most commonly chosen LARC in the intervention group; the etonogestrel implant was most commonly chosen in the control group at the 4-week, 6-month, and 12-month time points. (Table 3). None of the interaction tests indicated a differential effect of the intervention across subgroups defined by age, parity, use of LARC at baseline, marital status, socioeconomic status, education, previous unintended pregnancy or previous abortion (Supplemental Table 1).

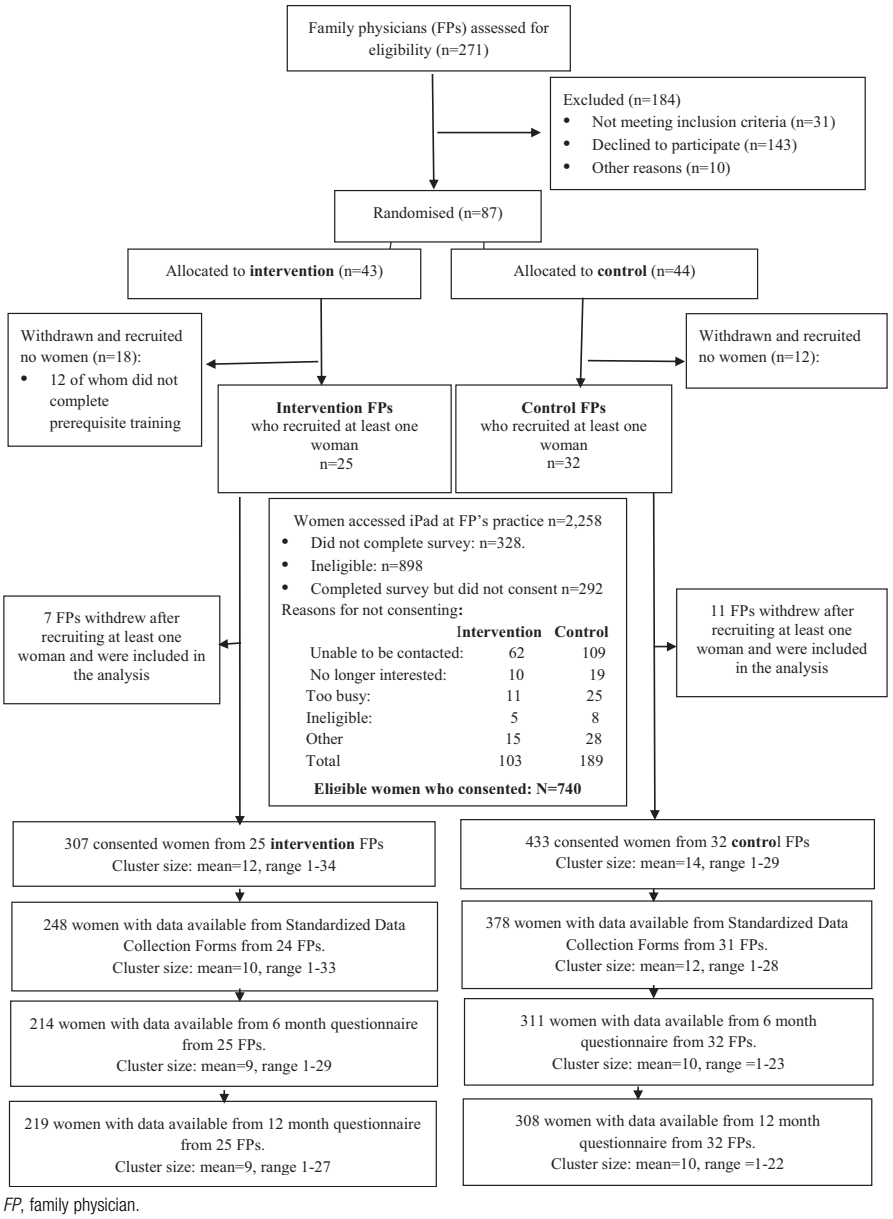
The results of the primary outcome analysis were similar, although the effects were smaller, when covariates were adjusted for or when missing data were imputed under various assumptions. The probability values for the comparison of binary outcomes were similar when calculated with the χ^2 test, with adjustment for clustering and stratification, or with the use of binary regression with generalized estimating equation for all outcomes, except for insertion at 4 weeks where the probability values were .20 and .03, respectively (Supplemental Table 2).

The differences between intervention and control groups in mean quality-of-life scores across all domains at 6 and 12 months were small and unlikely to be of practical importance or clinical significance, despite 2 of the comparisons being statistically significant. The statistically significant differences did not persist at 12 months (Table 4).

Process data

Fidelity checks were completed for 9 intervention FPs and 12 control FPs. Initiation of structured efficacy-based contraceptive counselling was observed for 44% of the intervention FPs (n=4) compared with 8% of the control FPs (n=1). Also, the data monitoring committee met every 3 months during the recruitment and data collection phases of the study. No unexpected complications or adverse effects were noted in either group.

FIGURE
Trial flow chart



FP, family physician.

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Comment

Principal findings

The ACCORd trial data demonstrated that a family medicine practice–based intervention that consists of online training in structured effectiveness-based contraceptive counselling and the provision of a rapid referral pathway to LARC insertion clinics results in an increased LARC uptake. Participants of FPs who had received these interventions were significantly more likely to have had a LARC inserted 4 weeks from the receipt of contraceptive counselling by their FP. This number increased by 6 months and increased further at 12 months.

Results (in context of what is known)

Although ACCORd was modelled on the successful CHOICE study in the United States,[11] our intervention differed from CHOICE in that it did not focus on reducing the cost of contraceptive methods, which suggests that, in contexts such as Australia, where LARC uptake is poor despite universal health coverage and subsidized contraception, the cost of contraception for an individual woman may not impact on contraceptive decision-making as much as receiving structured effectiveness-based contraceptive counselling and the availability of a timely pathway to LARC insertion. Indeed, the effect of the intervention did not differ by socioeconomic status.

Lack of FP training in LARCs and LARC insertion has been identified as a barrier to increasing LARC uptake.[14] Even with training, FPs often face difficulties sustaining practice in LARC insertion; 1 study found that only approximately 30% of those FPs who were trained in LARC insertions continued to insert ≥12 devices per year, which is the minimum suggested by experts to maintain skill levels.[27] The ACCORd intervention did not train FPs to insert LARCs. Despite this, it still achieved increased rates of LARC uptake, which may be because the ACCORD intervention addressed other barriers that have been well-described in the literature, such as tackling the myths and misconceptions concerning LARCs held by both FPs (through the training) and women (through structured effectiveness focused counselling) ,and by making LARC insertion more accessible through rapid referral pathways to insertion clinics.

Clinical implications

Our findings are important because ACCORd is the first trial to extend the efficacy demonstrated by providing LARC education to doctors in reproductive health and family planning clinics[9] to a new and important site: family practice. Extending LARC education to primary care can assist the large number of women who access general practice for their health care. In many countries internationally, there is a paucity of specialized contraceptive clinics, and general practice is the main provider of women's sexual and reproductive health services, particularly contraception.

TABLE 1
Characteristics of family physicians and women participants

Characteristic	Intervention group, n (%)	Control group, n (%)	Total, n
Family physicians			
N	25	32	57
Gender			
Male	2 (8.0)	4 (12.5)	6
Female	23 (92.0)	28 (87.5)	51
Age group			
25–34	3 (12.0)	2 (6.3)	5
35–54	17 (68.0)	24 (75.0)	41
≥55	5 (20.0)	6 (18.8)	11
Inserts intrauterine devices			
No	22 (88.0)	27 (84.4)	47
Yes	3 (12.0)	5 (15.6)	8
Inserts implants			
No	7 (28.0)	10 (31.3)	17
Yes	18 (72.0)	22 (68.8)	40
Implants inserted each month, n			
1–4	3 (12.0)	3 (9.4)	6
5–9	1 (4.0)	4 (12.5)	5
≥10	21 (84.0)	25 (78.1)	46
Specific training in contraception			
No	19 (76.0)	24 (75.0)	43
Yes	6 (24.0)	8 (25.0)	14
Trained—insert intrauterine devices			
No	15 (60.0)	21 (65.6)	36
Yes	10 (40.0)	11 (34.4)	21
Women participants			
N	307	433	740
Age, y			
16–24	104 (33.9)	163 (37.6)	267
25–34	111 (36.2)	173 (40.0)	284
35–45	92 (30.0)	97 (22.4)	189
Parity			
0	207 (67.4)	313 (72.3)	520
1	24 (7.8)	32 (7.4)	56
2	53 (17.3)	71 (16.4)	124
≥3	23 (7.5)	17 (3.9)	40
Long-acting reversible contraceptives use at baseline			
No	266 (87.2)	379 (87.5)	645
Yes	39 (12.8)	54 (12.5)	93

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Research implications

Although the trial demonstrated that a complex intervention that involved training FPs to deliver structured effectiveness-based contraceptive counselling and making available timely access to LARC insertion clinics is effective at increasing LARC uptake, we cannot identify which aspect of the intervention mattered the most. Although LARC uptake increased in both the intervention and control groups, the intervention group had higher uptake of the hormonal intrauterine system, which may indicate the importance of timely access to insertion clinics, especially because only 44% of intervention fidelity checks witnessed the delivery of structured efficacy based contraceptive counselling.

Strengths and limitations

The strengths of this study include the evaluation of intervention in routine general practices and the examination of the sustainability of the effects after the availability of the intervention has ceased. We undertook randomization of doctors rather than women in our cluster randomized controlled trial, which reduced contamination that would have occurred if women had been randomly assigned individually, because individual women in the same practice may have been in different groups of the study.

The intervention effect and the high cohort retention rate are also strengths that provided us with the opportunity to demonstrate the longevity of the effect of the ACCORd intervention. Although the use of LARCs in our population of participants was lower at baseline (13%) than a recently reported population-based survey that involved a younger population (19%),[28] it was similar to another Australian study that reported 11% LARC use.[10] At 6 months, 44% of our intervention group and 29% of our control group were using LARCs, which reflects an increase in LARC use over both groups (but significantly higher in the intervention group) and a higher proportion of current LARC users than recently reported. At 12 months, the increase was sustained with 47% of women in the intervention group and 33% in the control group. Longer follow

TABLE 1
Characteristics of family physicians and women participants *(continued)*

Characteristic	Intervention group, n (%)	Control group, n (%)	Total, n
Marital status[a]			
Married/de facto	133 (43.5)	184 (42.5)	317
Single	173 (56.5)	249 (57.5)	422
Household income[a]			
≤$600 per week	75 (30.4)	126 (35.3)	201
>$600 per week	172 (69.6)	231 (64.7)	403
Education			
Completed <12 y	99 (32.2)	144 (33.3)	243
Completed ≥12 y	208 (67.8)	289 (66.7)	497
Previous unintended pregnancy			
No	249 (81.1)	363 (83.8)	612
Yes	58 (18.9)	70 (16.2)	128
Previous abortion			
No	267 (87.0)	390 (90.1)	657
Yes	40 (13.0)	43 (9.9)	83

[a] Data are missing for some women.

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up would have allowed us to determine whether this rise in LARC uptake persisted beyond 1 year.

Our trial had several limitations. Masking of doctors and women during implementation was not feasible; because women's outcomes were self-reported, there may have been some bias responding to the survey questions.

Withdrawal of both FPs (58% in the intervention group and 52% in the control group) and participants (29% across both groups) from the study was higher than the 10% anticipated, which may reflect the difficulty some FPs had completing a 6-hour online learning module, an inability of participants to spend the required time to complete the study, and/or poor incentives for both FPs and participants. Future research should focus on determining whether other approaches to the training of FPs that are less time consuming, such as academic detailing or involvement in an online community of practice to achieve the same outcomes.

TABLE 2
Outcomes at 4 weeks, 6 months, and 12 months[a]

Outcomes	Women with information available, n		Women with outcome, n (%)		Prevalence ratio (95% confidence interval)	*P* value	Difference (95% confidence interval)	*P* value[b]
	Intervention group	Control group	Intervention group	Control group				
At 4 wks								
Long-acting reversible contraceptive insertions	248	378	48 (19.3)	45 (12.9)	2.0 (1.1— 3.9)	0.033	8.4 (1.5—15.4)	.018
At 6 mos								
Long-acting reversible contraceptive use at any time in 6 months	214	311	106 (49.5)	99 (31.8)	1.7 (1.3—2.2)	<0.001	21.8 (13.3—30.2)	<.001
Currently using a long-acting reversible contraceptive	214	311	95 (44.4)	91 (29.3)	1.6 (1.2— 2.2)	<0.001	18.9 (10.2—27.7)	<.001
At 12 mos								
Long-acting reversible contraceptive use at any time in 12 mo	219	308	113 (51.6)	108 (35.1)	1.6 (1.2—2.0)	<0.001	20.0 (10.6—29.5)	<.001
Currently using a long-acting reversible contraceptive	219	308	102 (46.6)	101 (32.8)	1.5 (1.2—2.0)	0.0015	16.7 (7.4—26.0)	<0.001

[a] Adjusted for clustering by the family physician and stratified by whether the family physician inserted long-acting reversible contraceptives; [b] The statistical test in the tables is the Wald chi-square test from the fitted binary regression models with generalized estimating equation.

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TABLE 3
Choice of contraceptive method

Variable	Hormone intrauterine system, n (%)	Copper intrauterine device, n (%)	Implant, n (%)	Injection, n (%)	Oral contraceptive pill (combined or progestogen only), n (%)	Ring, n (%)	Condoms n (%)	Withdrawal, n (%)	Nothing, n (%)	Other, n (%)	Not answered, n (%)
Contraception recorded at baseline for women with data available from standardized data collection forms[a]											
Intervention (n=248)	16 (6.5)		13 (5.2)	3 (1.2)	114 (46.0)	4 (1.6)	61 (24.6)	14 (5.6)	34 (13.7)	9 (3.6)	
Control (n=378)	16 (4.2)		29 (7.7)	5 (1.3)	173 (45.8)	1 (0.3)	87 (23.0)	9 (2.4)	65 (17.2)	7 (1.9)	
Contraception method recorded within 4 wks of initial contraceptive counseling consultation[b]											
Intervention (n=248)	39 (15.7)	2 (0.8)	28 (11.3)	3 (1.2)	94 (37.9)	3 (1.2)	30 (12.1)	2 (0.8)	33 (13.3)	5 (2.0)	9 (3.6)
Control (n=378)	28 (7.4)	4 (1.1)	45 (11.9)	4 (1.1)	162 (42.3)	2 (0.5)	64 (16.9)	2 (0.5)	58 (15.3)	2 (0.5)	7 (1.9)
Current contraceptive method used at 6 mos[c]											
Intervention (n=214)	65 (30.4)	5 (2.3)	25 (11.7)	3 (1.4)	54 (25.2)	1 (0.5)	74 (34.6)	31 (14.5)	4 (1.9)	5 (2.3)	
Control (n=311)	36 (11.6)	8 (2.6)	47 (15.1)	3 (1.0)	122 (39.2)	3 (1.0)	101 (32.5)	46 (14.8)	7 (2.3)	3 (1.0)	
Current contraceptive methods used at 12 mos[a,d]											
Intervention (n=219)	63 (28.8)	6 (2.7)	26 (11.9)	4 (1.8)	68 (31.1)	0 (0)	67 (30.6)	—	4 (1.8)	4 (1.8)	
Control (n=308)	39 (12.7)	11 (3.6)	49 (15.9)	2 (0.7)	106 (34.4)	2 (0.7)	98 (31.8)	—	15 (4.9)	3 (1.0)	

[a] Of the women, 78% had the baseline survey completed after the initial family physician visit (For these women, baseline contraception information was derived from the data collected at this initial visit. Only 1 form of contraception was recorded at these visits; however, the baseline questionnaire allowed for multiple forms. To reconcile the 2 data sources, women were been assigned the most effective method if they recorded use of multiple methods. The baseline questionnaire also did not differentiate between hormonal and copper intrauterine devices); [b] Note only 1 form of contraception recorded at family physician visits; [c] Women could record multiple methods; [d] Women were not asked whether they were currently using withdrawal.

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TABLE 4
Participant quality-of-life scales at baseline and 6 and 12 months

Scale	Baseline	6 Mos			12 Mos		
	Mean (standard deviation)	Mean (standard deviation)	Difference (95% confidence interval)[a]	*P* value	Mean (standard deviation)	Difference (95% confidence interval)[a]	*P* value
Physical functioning							
Intervention group	93 (11.7)	94 (10.7)	2.4 (0.04–4.7)	.05	93 (12)	1.3 (−1.4–4.1)	.34
Control group	93 (14.9)	91 (16.9)			91 (17.6)		
Role limitations because of physical health							
Intervention group	73 (38.9)	87 (27.7)	5.4 (−0.2–1.1)	.06	87 (29.5)	2.2 (−2.7–7.2)	.37
Control group	76 (35.3)	83 (31.6)			84 (32.4)		
Role limitations because of emotional problems							
Intervention group	73 (36.6)	74 (37.8)	1.3 (−5.2–7.8)	.70	75 (36)	0.6 (−4.7–5.9)	.83
Control group	75 (36.4)	73 (39.0)			74 (38.5)		
Energy/fatigue							
Intervention group	55 (19.3)	51 (19.9)	0.4 (−2.6–3.3)	.81	51 (21.1)	−0.5 (−4.1–3.2)	.80
Control group	52 (20.8)	50 (19.8)			50 (20.6)		
Emotional well-being							
Intervention group	76 (15.1)	71 (17.2)	2.3 (−0.2–4.8)	.07	72 (16.7)	0.8 (−1.9–3.5)	.56
Control group	75 (16.6)	69 (19.1)			70 (18.3)		
Social functioning							
Intervention group	82 (18.7)	84 (18.1)	2.3 (−1.6–6.1)	.24	82 (19.9)	−0.1 (−3.0–2.8)	.94
Control group	82 (19.6)	82 (20.3)			82 (20.2)		
Pain							
Intervention group	74 (21.5)	81 (18.4)	2.2 (−0.6–5.0)	.13	78 (21.9)	−0.3 (−3.1–2.4)	.81
Control group	76 (21.7)	79 (20.7)			79 (21.0)		
General health							
Intervention group	71 (19.1)	68 (18.4)	2.2 (1.2–3.2)	<.0001	67 (19.4)	0.7 (−2.9–3.3)	.62
Control group	70 (19.8)	66 (19.6)			66 (19.5)		

Note: Question 23 of SF-36, which contributes to the energy/fatigue scale, was not included in the survey. Results were similar when missing data were imputed, with the assumption that women with missing outcome data have similar outcomes as (1) those from same group or (2) those in the control group.

[a] Adjusted for clustering by family physician, stratification (whether family physician inserts long-acting reversible contraceptives and baseline values.

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We originally designed the study with 24 FPs in each group and each FP recruiting 24 women. However, once recruitment began, it was apparent that some FPs would not reach the target of 24 women in the required time. For some FPs, this was because their patient population did not include many women of reproductive age. This was particularly the case for male FPs and female FPs who were themselves >45 years old. To compensate, we decided to recruit more FPs, and we allowed FPs (who were able) to recruit >24 women.

Setting 1 of the primary outcomes as LARC insertion at 4 weeks was problematic for some women because there was a delay in returning to the FP for a contraceptive consultation and a further delay if LARC referral/insertion was instigated. A more clinically meaningful outcome may have been LARC use at 6 or 12 months, to reflect LARC insertion and retention over time.

Our sample of FPs and their patients were highly educated. We anticipated that FPs who were interested in contraception would be over-represented in our study, and indeed 25% of ACCORd FPs had undertaken additional training in contraception. This rate, however, was well-balanced across both intervention and control groups, making the effect of our intervention even more compelling. Noninclusion of women who spoke limited English may affect the generalizability of our findings to women of non−English-speaking backgrounds. Additionally, our sample of women was from the metropolitan area, and rural women may face greater challenges with access to LARC insertion. The small number of male FPs in our study may impact on the generalizability of the ACCORd intervention in general practice settings where there are larger proportions of male practitioners.

The probability value for the outcome insertion at 4 weeks differed when calculated by the χ^2 test, adjusted for clustering and stratification, and binary regression model with generalized estimating equations. However, the χ^2 test can be less powerful than binary regression and may not detect a difference if it exists; the binary regression model will provide an unbiased estimate with appropriate confidence interval coverage. Hence, we consider the results from the binary regression model to be more informative.[29,30]

Conclusion

In conclusion, the provision of training to FPs in structured efficacy-focused contraceptive counselling together with providing FPs with a rapid referral pathway to LARC insertion clinics results in increased LARC uptake. Implementation of this approach more broadly in family medicine practice settings, particularly in contexts in which free contraception is not feasible and in which specific sexual and reproductive health services are either not available or accessible, could lead to reductions in unplanned pregnancies and abortion. ■

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SUPPLEMENTAL TABLE 1

Subgroup analyses: insertion of long-acting reversible contraceptives at 4 weeks

Subgroup and variable	Women with information available, n	Intervention group, n (%)		Control group, n (%)			*P* value for interaction between intervention and subgroup variable
		Yes	No	Women with information available	Yes n (%)	No n (%)	
Age group, y							
16–24	87	20 (23.0)	67 (77.0)	142	17 (12.0)	125 (88.0)	.61
25–34	84	17 (20.2)	67 (79.8)	153	23 (15.0)	130 (85.0)	
35–45	77	11 (14.3)	66 (85.7)	83	5 (6.0)	78 (94.0)	
Parity							
No children	164	33 (20.1)	131 (79.9)	275	36 (13.1)	239 (86.9)	.08
1 Child	19	2 (10.5)	17 (89.5)	24	4 (16.7)	20 (83.3)	
2 Children	44	7 (15.9)	37 (84.1)	63	5 (7.9)	58 (92.1)	
≥3 Children	21	6 (28.6)	15 (71.4)	16	0	16 (100.0)	
Marital status							
Married/de facto	103	18 (17.5)	85 (82.5)	160	14 (8.8)	146 (91.3)	.23
Single	144	30 (20.8)	114 (79.2)	218	31 (14.2)	187 (85.8)	
Household income							
≤$600 per week	59	10 (16.9)	49 (83.1)	110	18 (16.4)	92 (83.6)	.31
>$600 per week	140	29 (20.7)	111 (79.3)	201	21 (10.4)	180 (89.6)	
Highest level of education							
Year 12 or below	84	18 (21.4)	66 (78.6)	127	18 (14.2)	109 (85.8)	.64
Beyond Year 12	164	30 (18.3)	134 (81.7)	251	27 (10.8)	224 (89.2)	
Previous unintended pregnancy							
No	200	38 (19.0)	162 (81.0)	319	33 (10.3)	286 (89.7)	.18
Yes	48	10 (20.8)	38 (79.2)	59	12 (20.3)	47 (79.7)	
Previous abortion							
No	214	40 (18.7)	174 (81.3)	340	36 (10.6)	304 (89.4)	.22
Yes	34	8 (23.5)	26 (76.5)	38	9 (23.7)	29 (76.3)	
Using long-lasting reversible contraceptives at baseline							
No	219	179 (81.7)	40 (18.3)	333	33 (9.9)	300 (90.1)	.82
Yes	29	8 (27.6)	21 (72.4)	45	12 (26.7)	33 (73.3)	

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SUPPLEMENTAL TABLE 2

Probability values from chi-squared Mantel-Haenszel analysis and binary regression models with generalized estimating equations for outcomes

Outcomes	*P* value	
	Generalized estimating equation	Mantel-Haenszel analysis
At 4 wks after initial consult		
Referred for long-acting reversible contraceptives insertion	.0001	.0002
Long-acting reversible contraceptives insertion	.033	.20
At 6 mos		
Long-acting reversible contraceptive use at any time in 6 mos	<.0001	.00053
Currently using a long-acting reversible contraceptives	.0007	.003
At 12 mos		
Long-acting reversible contraceptive use at any time in 12 mos	.0002	.0011
Currently using a long-acting reversible contraceptives	.0015	.0086

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Cost-effectiveness of a complex intervention in general practice to increase uptake of long-acting reversible contraceptives in Australia†

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Abstract.

Objective. The aim of this study was to evaluate the cost-effectiveness of the Australian Contraceptive ChOice pRoject (ACCORd) intervention.

Methods. An economic evaluation compared the costs and outcomes of the ACCORd intervention with usual care (UC). Data from the ACCORd trial were used to estimate costs and efficacy in terms of contraceptive uptake and quality of life. Rates of contraceptive failure and pregnancy were sourced from the literature. Using a Markov model, within-trial results were extrapolated over 10 years and subjected to univariate sensitivity analyses. Model outputs were expressed as the cost per quality-adjusted life years (QALY) gained and cost per unintended pregnancy resulting in birth (UPB) avoided.

Results. Over 10 years, compared with UC, initiating contraception through the ACCORd intervention resulted in 0.02 fewer UPB and higher total costs (A$2505 vs A$1179) per woman. The incremental cost-effectiveness of the ACCORd intervention versus UC was A$1172 per QALY gained and A$7385 per UPB averted. If the start-up cost of the ACCORd intervention was removed, the incremental cost-effectiveness ratio was A$81 per QALY gained and A$511 per

†This trial has been registered with the Australian and New Zealand Clinical Trial Registry (ANZCTR ID 12615001346561, 10 December 2015).

UPB averted. The results were most sensitive to the probability of contraceptive failure, the probability of pregnancy-related healthcare service utilisation or the inclusion of the costs of implementing the ACCORd intervention.

Conclusions. From a health system perspective, if implemented appropriately in terms of uptake and reach, and assuming an implicit willingness to pay threshold of A$50 000 the ACCORd intervention is cost-effective.

What is known about the topic? The uptake of long-active reversible contraceptives (LARC) in Australia is low. The ACCORd trial assessed the efficacy of providing structured training to general practitioners (GPs) on LARC counselling, together with access to rapid referral to insertion clinics.

What does this paper add? This study is the first to assess the cost-effectiveness of a complex intervention in the general practice setting aimed at increasing the uptake of LARC in Australia.

What are the implications for practitioners? The results show that implementing a complex intervention in general practice involving GP education and the availability of rapid referral to LARC insertion clinics is a cost-effective approach to increase LARC use and its attending efficacy. If the majority of Australian GPs were able to deliver effectiveness-based contraceptive counselling and either insert LARC or use a rapid referral process to a LARC insertion clinic, the additional cost associated with the purchase of LARC products and their insertion would be offset by reductions to health system costs as a result of fewer UPB and abortions. Moreover, the benefits to women's physical and psychological health of avoiding such events is substantial.

Keywords: ACCORd, contraceptive counselling, economic evaluation, general practice, health economics, health services, long-acting reversible contraceptives, quality of life.

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Introduction

In Australia and other high-income countries, unintended pregnancies (UPs) are relatively common, and many result in abortion.[1,2] In a survey of Australian women conducted in 2010–11, 30% of women reported a UP; one in four pregnancies were terminated.[3]

International evidence suggests that long-acting reversible contraception (LARC) products such as subdermal hormone implants (etonorgestrel subdermal implant (Implanon NXT)) and hormone intrauterine devices (IUD; levonorgestrel (Mirena) and the copper IUD (Cu IUD)) can reduce the rate of UPs.[4–6] Compared with short-acting reversible contraception (SARC), including the oral contraception pill (OC), LARC methods are not dependent on user compliance and therefore have a very low failure rate.[6] Thus, increasing the uptake of LARC in Australia is likely to reduce the rate of UPs, the associated negative effect a UP has on a woman's quality of life and health service costs.[7]

LARC methods have been shown to be cost-effective[8–10] compared with other contraceptive methods, despite increased health care utilisation and up-front costs associated with their insertion. However, the uptake of LARC in Australia is low.[11] Important barriers to increasing LARC uptake include a lack of familiarity with their use at the primary care level and misconceptions among both general practitioners (GPs) and women about LARC.[12] Therefore, training to provide structured effectiveness-based contraceptive counselling and access to rapid referral to LARC insertion clinics provided by gynaecologists are potential strategies for increasing their utilisation.

Australian Contraceptive ChOice pRoject (ACCORd), an adaptation of the US Contraceptive Choice Project (CHOICE),[13] was designed as a cluster randomised controlled trial.[14] The aim of the ACCORd study was to test whether a complex intervention based in general practice consisting of online education for GPs on effectiveness-based contraceptive counselling, together with the availability of a fast-track referral process to a LARC insertion clinic, is a cost-effective means of increasing the uptake of LARC compared with usual care (UC) among Australian women (an overview of the baseline characteristics of the women included in the ACCORd trial is presented in Supplementary Table S1).

Methods

The economic evaluation of the ACCORd trial was undertaken in two parts: (1) a within-trial cost-effectiveness analysis restricted to the period of the ACCORd study; and (2) a longer-term modelled evaluation.

The within-trial analysis focused on the short-term costs and outcomes of the ACCORd intervention (the proportion of women using LARC). A quasi-societal perspective was used to calculate costs, including the cost of the intervention and the cost associated with use of healthcare services. Contraception-specific health service utilisation was measured largely using Australian Medicare data (Medical Benefits Schedule (MBS) and Pharmaceutical Benefits Scheme (PBS)) for women participating in the ACCORd study; costs were calculated as the sum of observed out-patient service use. Hospital costs associated with pregnancy (as observed in ACCORd) and costs associated with the purchase and insertion of IUDs funded outside the public healthcare system were included based on reported Australian-Refined Diagnosis-Related Groups (for pregnancy) and private sector costs (for the copper IUD). Direct non-medical costs (e.g. transportation) and indirect costs (productivity losses) were not included in the analysis.

Total costs per group (intervention or UC group) are reported for the within-trial period (12 months) and disaggregated by service component: the cost of the contraceptive product; insertion and removal of the device; and management of contraceptive failure. Because the outcome of interest was the proportion of women using LARC at 12 months, the incremental

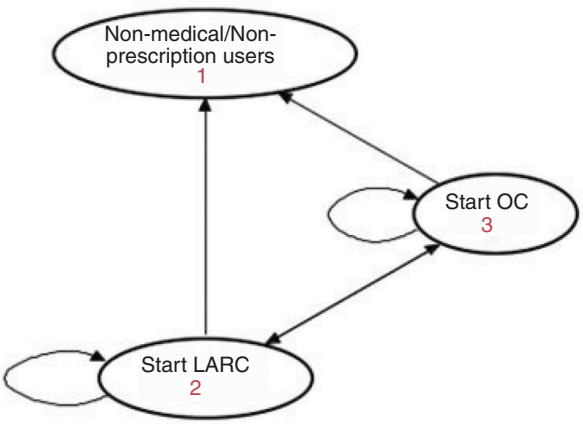

Fig. 1. Economic model structure.

analysis is expressed as the cost per additional woman using LARC at 12 months.

A Markov model was constructed to extrapolate the costs and outcomes observed in the ACCORd study over 10 years, allowing us to estimate the cost per quality-adjusted life years (QALY) gained. The model structure is shown in Fig. 1.

The model consisted of three health states: (1) discontinuation of the contraceptive method (non-medical contraceptive (NMC)); (2) commencement of a contraceptive method ('start LARC', 'start OC'); or (3) continuing use of a method. The NMC alternative included women who stopped using a contraceptive method due to adverse events or personal choice. The proportion and direction of method switch was estimated using information from the within-trial analysis and is provided in Table 1. The key assumptions underpinning the transitions applied in the model are as follows:

- women could switch between contraceptive methods once per cycle (each cycle = 6 months), but a switch independent of contraceptive failure could only occur once in the overall duration of the model
- all switches were from OC to LARC and NMC; there were no switches from LARC and NMC
- contraceptive failures were assumed to occur at the end of each cycle
- method failure resulted in termination of pregnancy (TOP) or unplanned pregnancy resulting in birth (UPB). Women who experienced a method failure were assumed to switch to a new method. Those whose method was effective continued to use the same method. We assumed that UPB and TOP could occur once per year for an individual woman.

Costs included are as described for the within-trial analysis. The costs of side-effects, such as infections and adverse events related to method use, were not included in the analysis because the occurrence of such events reported by ACCORd Trial Data Monitoring Committee was very low.[15]

Health state transitions and treatment use were based on data observed in the ACCORd trial (see Table 1). The probability of method failure and pregnancy outcomes was sourced from the literature.[8] The number of QALYs gained was calculated using the results of the 36-Item Short Form Health Survey (SF-36) surveys completed by women participants in ACCORd for which quality of life weights were estimated using the Short Form Health Survey Six-Dimension (SF-6D) algorithm with Australian weights.[16,17] The number of UPB avoided was expressed as the cumulative number of UPB resulting from contraceptive failure over the time horizon of the analysis.

Table 1. Probabilities and utility weights applied in the Markov model
LARC, long-acting reversible contraception; OC, oral contraception; NMC, non-medical contraception; TOP, termination of pregnancy; UPB, unintended pregnancies resulting in birth

Method type	ACCORd intervention	Usual care	Source
Initial health states probabilities			
LARC	0.51	0.33	ACCORd
OC	0.28	0.43	ACCORd
NMC	0.21	0.24	ACCORd
Within-health state outcomes probabilities			
TOP LARC	0.0014	0.0014	Trussell *et al.*[8]
TOP OC	0.0378	0.0378	Trussell *et al.*[8]
UPB LARC	0.0019	0.0019	Trussell *et al.*[8]
UPB OC	0.0492	0.0492	Trussell *et al.*[8]
Transition probabilities			
Probability of continuing OC	0.57	0.75	ACCORd
Probability of switch from OC to LARC	0.28	0.12	ACCORd
Probability of switch from OC to NMC	0.15	0.13	ACCORd
Probability of continuing LARC	1.00	1.00	ACCORd
Probability of switch from LARC to OC	0.00	0.00	ACCORd
Probability of switch from LARC to NMC	0.00	0.00	ACCORd
Utility weights			
TOP	0.59	0.59	ACCORd
LARC	0.60	0.60	ACCORd
OC	0.60	0.60	ACCORd
UPB	0.62	0.62	ACCORd

All costs were discounted at a rate of 5% per year. The within-trial data analysis was performed in STATA version 15.1 (StataCorp LLC, College Station, TX, USA) and the modelled analysis was performed in Tree Age Pro 2019 (TreeAge Software, Williamstown, MA, USA). Differences in mean costs between groups were estimated by bootstrapping.

One-way sensitivity analyses were conducted, rather than probabilistic sensitivity analyses, because this is consistent with Australian and international health technology assessment guidelines[18] and avoids potential uncertainties associated with determining parameter ranges and distributions for probabilistic analyses.[18] Sensitivity analyses were used to test the effects on the incremental cost-effectiveness ratio (ICER) of varying the failure rates of the methods, assuming switching from the LARC method to OC and NMC (in 5% of women) after the initial replacement period for LARC (i.e. 5 years for Mirena[19] and the copper IUD;[20] 3 years for Implanon NXT[21]), and the costs of contraceptive products, UPB and TOP.

We also conducted two scenario analyses: (1) we tested the effect on the ICER of removing the start-up costs of the ACCORd intervention; and (2) we applied standard MBS fees for healthcare

services rather than mean costs per service obtained from the within-trial-based costs. This second analysis served as a robustness check on the sensitivity of the results to the estimation of the costs from the observed administrative data. Australian funding authorities have no explicit willingness to pay (WTP) threshold. However, we have assumed an implicit WTP of A$50 000 as the benchmark for determining cost-effectiveness.[22]

Results

Within-trial analysis

The results from the ACCORd trial showed that 13.8% more women in the intervention group used LARC compared with the UC group (46.6% vs 32.8%; $P = 0.0015$).[14] Cost data related to medical services (MBS data) were available for 212 women (69%) in the ACCORd intervention group and for 306 women (71%; $P = 0.56$) in the UC group; data on the use of contraceptive products (PBS data) were available for 206 women (67%) in the intervention group and for 297 women (69%, $P = 0.11$) in the UC group. An analysis of these data showed a difference in LARC use that was consistent with the primary analysis from ACCORd: 6% more women in the intervention group used LARC compared with the UC group (45% vs 39%; $P = 0.17$).

Markov model analysis

The results of the within-trial analysis comparing the total costs and mean cost per woman are presented in Table 2. It is assumed

Table 2. Estimated annual costs: within-trial analysis

GP, general practitioner; IUD, intrauterine device; LARC, long-acting reversible contraceptive; MBS, Medicare Benefits Schedule; OC, oral contraception; PBS, Pharmaceutical Benefits Scheme; TOP, termination of pregnancy; UPB, unplanned pregnancy resulting in birth

Cost type	Cost (A$)		Difference in mean costs (*P*-value)[C]	Source
	ACCORd intervention	Usual care		
Copper IUD				
Total	440	807	NA	Chemist Warehouse[23]
Mean	73	73	NA	Chemist Warehouse/ACCORd
Levonorgestrel IUD (Mirena)				
Total	7708	7503		PBS data
Mean	79	49	15.56 (0.03)	PBS data
Etonorgestrel subdermal implant (Implanon NXT)				
Total	3372	6249		PBS data
Mean	25	48	–6.90 (0.17)	PBS data
OC				
Total	3426	5406		PBS data
Mean	38	39	–2.65 (0.42)	PBS data
Medical TOP (mifepristone)				
Total	623	311		PBS Data
Mean	156	156	2.62 (0.25)	PBS data
PBS total[A]				
Total	61 999	200 767		PBS data
Mean	301	676	–750.03 (0.11)	PBS data
GP consultations				
Total	2791	2528		MBS data
Mean	52	32	6.51 (0.13)	MBS data
Specialist consultations				
Total	22 884	32 222		MBS data
Mean	197	195	0.25 (0.99)	MBS data
LARC insertion				
Total	2205	3603		MBS data
Mean	30	33	–2.28 (0.38)	MBS data
LARC removal				
Total	738	1352		MBS data
Mean	35	33	–1.44 (0.32)	MBS data
UPB				
Total	6732	5139		
Mean	449	302	20.12 (0.37)	MBS data
TOP				
Total	508	1301		
Mean	73	145	–2.70 (0.32)	MBS data
MBS total[B]				
Total	368 374	489 550		MBS data
Mean	1738	1600	138.63 (0.56)	MBS data

[A]Total PBS mean calculated for all costs incurred per woman in the intervention or usual care group during the 12-month period.
[B]Total MBS mean calculated for all costs incurred per woman in intervention or usual care group during the 12-month period.
[C]The estimates around the differences in mean costs between the groups were estimated by bootstrapping.

that the patterns of care among women consenting to the use of their Medicare data are not different to those who did not consent and that the mean costs per women are therefore representative of all women in the trial.

Overall, compared with UC, women in the intervention group had both a lower annual mean Medicare cost per woman and lower total Medicare costs over the trial period. The mean cost of OC was lower than LARC in both groups (Table 2). Although the total cost of health care utilisation was lower in the intervention than UC group, the total cost associated with UPB was higher for the intervention group due to the higher proportion of unintended pregnancies in this group (0.05 vs 0.04). However, this difference was not statistically significant ($P = 0.37$).

When the start-up costs of the intervention were included, the cost per additional woman using LARC at 12 months was A$11 149. However, the intervention was more effective and less costly when start-up costs were removed; that is, compared with UC, the intervention resulted in both an increase of 14 percentage points in the proportion of women using LARC and a reduction in the mean cost per woman of A$226.The results of the modelled analysis are presented in Table 3. The key difference between this and the within-trial analysis is the addition of the quality of life effects. The results of the SF-6D survey showed no differences between the groups in terms of quality of life (0.63 vs 0.65 on a scale 0–1; $P = 0.14$). Although the number of specific pregnancy-related events (e.g. obstetric care) varied between the groups, the frequency of these events was very low, resulting in no statistically significant difference between the groups in terms of quality of life. Accordingly, the same quality of life weights were applied to events within the analysis, regardless of the treatment group, namely an overall quality of life weight of 0.60 for women without a pregnancy event, a weight of 0.59 for TOP events and a weight of 0.62 for UPB events.

The base case analysis resulted in a cost per QALY gained of A$1172 for the intervention compared with UC. After excluding start-up costs (A$1234 per woman), the ICER was A$81 per QALY gained for the intervention compared with UC group. This shows that the ICER is most sensitive to variations in the probability of method failure resulting in UPB or TOP. However, the results are relatively robust to variations in costs related to method failure and variation in probability of switching from LARCs to OC or NMC (see results of the sensitivity analyses provided as a tornado plot in Figure S1).

The results of the scenario analysis in which mean MBS and PBS item fees related to gynaecological services were used instead of mean costs based on the results of the within-trial analysis are presented in Table 3. These results were consistent with those of the base case.

Discussion

LARC methods have been shown to be a highly cost-effective means of reducing the rate of unplanned pregnancies.[24,25] Our analysis shows that the ACCORd intervention has the potential to be highly cost-effective, assuming an implicit WTP of A$50 000,[22] in terms of both increasing the number of women using LARC and the longer-term quality of life outcomes. Importantly, we show that the cost-effectiveness of the ACCORd intervention is influenced by both the efficacy of outcomes and the ability to defray start-up costs.

Our evaluation of the cost-effectiveness of the ACCORd intervention over a 10- year period indicates that, from a healthcare perspective, the ACCORd intervention is more effective than UC in preventing UPB and abortions but is more expensive. However, our assessment has also shown that the value to both the healthcare system and society of the ACCORd intervention is enhanced if more women access it (reducing the impact of start-up costs).

Table 3. Results of economic evaluation

ICER, incremental cost-effectiveness ratio; LARC, long-acting reversible contraceptive; NMC, non-medical contraceptive; OC, oral contraceptive; MBS, Medicare Benefits Schedule; PBS, Pharmaceutical Benefits Scheme; QALY, quality adjusted life year; UPB, unplanned pregnancy resulting in birth

	Intervention			Usual care			Cost (A$)/QALY	Cost (A$)/UPB	Outcome
	Cost (A$)	QALYs	UPBs	Cost (A$)	QALY	UPBs			
Base case[A]	2505	16.77	0.09	1179	15.64	0.25	1172	7385	Intervention more effective and more expensive
LARC	1609	13.07	0.05	433	9.59	0.06	337.93	117 600	Intervention more effective and more expensive
OC	534	0.76	0.04	602	1.92	0.19	59.48	453	Usual care more effective and more expensive
NMC	362	2.94	0.00	145	4.13	0.00	182.35	NA	Usual care more effective and less expensive
Scenario analyses									
Excluding start-up cost	1271	16.77	0.09	1179	15.64	0.25	81	511	Intervention more effective and more expensive
Applying MBS and PBS fees									
Including start-up cost	3482	16.77	0.09	1638	15.64	0.25	1631	10 276	Intervention more effective and more expensive
Excluding start-up cost	2248	16.77	0.09	1638	15.64	0.25	540	3402	Intervention more effective and more expensive

[A]Including start-up cost.

To the best of our knowledge, this study is the first to assess the cost-effectiveness of a complex intervention in the general practice setting aimed at increasing the uptake of LARC in Australia. The results are similar to studies of the cost-effectiveness of GP educational initiatives in other areas, such as diabetes[26] and the management of lower back pain,[27,28] which have shown that adding advice, education and behavioural counselling to usual GP care is efficient at the primary care level and has a positive financial effect on the health system.

This study has several strengths. The within-trial analysis is based on the results of a rigorous pragmatic randomized control trial. Most women participants consented to the use of their Medicare data for the analysis of medical service and pharmaceutical utilisation and costs, increasing the accuracy of the results and hence the relevance in the Australian context of the cost inputs to the model. The information about quality of life was collected from women participants and Australian weights were used to estimate the utilities for the QALY outcome measure.

The study also has some limitations. Because GPs who agreed to participate in ACCORd may have been more interested in contraception and LARC uptake than the average GP, the overall uptake of LARC, and therefore the benefits accruing to the wider population, are uncertain. The time span of the trial may not have adequately captured resource utilisation for women in the intervention and control groups. Therefore, we did not restrict the analysis based on study start date. Although the Markov model includes a pathway for non-prescribed contraceptive methods, we did not include the effect on the costs and effectiveness of these types of contraception, because we assumed the use of these methods would be similar in both groups. The use of private prescriptions was not included in the analysis because it was likely to be very low and not different across the groups. Our sensitivity analyses showed that the model results were robust to variations in the cost of care.

In this analysis we applied the same quality of life scores to women in both the intervention and UC groups. This is reasonable because it is unlikely that consulting a GP who participated in the ACCORd study would alter a woman's quality of life. Finally, the start-up cost of the ACCORd intervention may be overestimated. Because ACCORd involved an educational intervention, it is likely to have had a spin-off effect on women who were not directly included in the trial; we did not seek to capture the benefits to women who attended intervention GPs but did not participate in ACCORd, but note that this is likely to have enhanced the cost-effectiveness of the intervention.

Our results show that implementing a complex intervention in general practice involving GP education and the availability of rapid referral to LARC insertion clinics is a cost-effective approach to increase LARC use and its attending efficacy. Such uptake is likely to have benefits beyond those included in our analysis. Although the quality of life weights applied assumed no difference between the groups in terms of the impact of pregnancy events on women, LARC use may benefit women in ways not captured by standard quality of life measures (e.g. increased convenience, lower rates of heavy menstrual bleeding, improved fertility control, improved spacing of pregnancies and enhanced productivity). Further research should explore how such benefits may be valued.

If the majority of Australian GPs were able to deliver effectiveness-based contraceptive counselling and either insert LARC or use a rapid referral process to a LARC insertion clinic, the additional cost associated with the purchase of LARC products and their insertion would be offset by reductions to health system costs as a result of fewer UP and abortions. Moreover, the benefits to women's physical and psychological health of avoiding such events is substantial.[7]

Competing interests

The authors declare that they have no competing interests.

Declaration of funding

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Early medical abortion services provided in Australian primary care

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The known: Access to early medical abortion can be difficult, particularly for women in rural and regional Australia. Providing it through primary care would be ideal, but the distribution of medical practitioners who provide early medical abortion services is unclear.

The new: We found that rates of early medical abortion are highest outside metropolitan centres, but about 30% of women live in areas in which it had not been prescribed by a local general practitioner during 2019.

The implications: General practitioners should be supported to enable them to provide early medical abortion services.

Abstract

Objectives: To examine primary care provision of early medical abortion services in Australia.

Design: Cross-sectional study; analysis of Pharmaceutical Benefits Scheme (PBS) dispensing data.

Setting, participants: Women of child-bearing age (15–54 years), Australia, 2015–2019.

Main outcome measures: Age-standardised rates of MS-2 Step prescriptions dispensed by year for 2015–2019, and age-standardised rates by state, remoteness area, and level 3 statistical areas (SA3s) for 2019. Numbers and proportions of SA3s in which MS-2 Step was not prescribed by a GP or dispensed by a community pharmacy during 2019 (unweighted and weighted by number of women of reproductive age), by state and remoteness area.

Results: During 2015–2019, 91 643 PBS prescriptions for MS-2 Step were dispensed; the national age-standardised rate increased from 1.63 in 2015 to 3.79 prescriptions per 1000 women aged 15–54 years in 2019. In 2019, rates were higher in outer regional Australia (6.53 prescriptions per 1000 women aged 15–54 years) and remote Australia (6.02 per 1000) than in major cities (3.30 per 1000). However, about 30% of women in Australia lived in SA3s in which MS-2 Step had not been prescribed by a GP during 2019, including about 50% of those in remote Australia.

Conclusions: The rate of early medical abortion is greater among women in remote, outer regional, and inner regional Australia than in major cities, but a considerable proportion of women live in areas in which MS-2 Step was not locally prescribed or dispensed during 2019. Supporting GPs in the delivery of early medical abortion services locally should be a focus of health policy.

Abortion, both surgical and medical, is an essential healthcare service. Early medical abortion — using mifepristone and misoprostol to terminate a pregnancy — has been endorsed as safe and effective during early pregnancy by Australian and overseas peak medical bodies.[1] In Australia, early medical abortion can be provided by telehealth or in person in primary care.[2]

Medical practitioners can register to provide early medical abortion services after undertaking online training delivered without cost by Marie Stopes Australia.[3] If a practitioner holds a Fellowship or Advanced Diploma from the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG), they can register as prescribers without this training.[1] Doctors in private practice or working with family planning organisations or Marie Stopes Australia can also provide early medical abortion. The locations of family planning and Marie Stopes clinics are publicly available, but national information on where general practitioners prescribe early medical abortion or pharmacists dispense the required drug has not been published.

Although the Therapeutic Goods Administration (TGA) approved mifepristone for use as a medical abortifacient during early pregnancy in 2012[1] and MS-2 Step (composite regimen of mifepristone and misoprostol) has been subsidised by the Pharmaceutical Benefits Scheme since 2015,[1] integration of early medical abortion into primary health care has been slow.[4] In December 2020, only 2841 of 29 017 registered GPs were active prescribers of MS-2 Step, and 5347 of 32 393 registered pharmacists were active dispensers.[5]

Several system, provider and patient factors have limited the integration of early medical abortion into general practice. Legislative differences have contributed to variations between Australian states and territories in its availability.[1] Some GPs believe early medical abortion is not within their area of responsibility,[4] while others lack training and awareness of how to provide it.[6,7] Further, those who do provide the service can feel stigmatised and isolated, and speak of the need for peer support and supportive referral pathways.[4,8] Fear of criminal prosecution for performing abortion and of potential complications have also been noted as barriers to GPs providing early medical abortion.[4] Finally, many women are unaware that it is available or of the 63 days' gestation eligibility limit; other barriers include needing to travel, take time off work, and to find childcare to access early medical abortion services, and many require financial support to pay for it.[9]

Access to abortion services can be difficult for women in rural and regional areas. Women in rural areas are 1.4 times as likely to experience an unintended pregnancy than women living in metropolitan areas, with contributory factors including geographic isolation, limited access to contraception services, and not knowing where these services are available.[10] The cost is also a major barrier to access to early medical abortion, with a median out-of-pocket cost of $560.[9]

Understanding demographic differences in the provision of early medical abortion is crucial for tailoring interventions to improve access. We therefore assessed variability in early medical abortion availability and uptake in Australia, focusing on its provision in primary care.

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asvini.subasinghe@monash.edu • doi: 10.5694/mja2.51275 • See Editorial (de Costa).

Methods

We analysed aggregated data for all Pharmaceutical Benefits Scheme (PBS) claims for MS-2 Step dispensing. The PBS is a federal government-funded program that subsidises listed medicines dispensed by community pharmacies and private hospitals for all Australian citizens, permanent residents, and eligible foreign visitors (from countries with reciprocal health-care agreements with Australia) medicines.[11] In addition, the PBS subsidises medicines dispensed to public hospital outpatients and non-admitted patients, as well as for inpatients on their discharge from hospital (in most, but not all, states after public hospital pharmaceutical reforms).[11]

Services Australia provided the number of MS-2 Step prescriptions (PBS item 10211K) dispensed to women aged 15–54 years resident in each Australian Bureau of Statistics (ABS) level 3 statistical area (SA3) during the calendar years 2015–2019, irrespective of prescriber type or location, aggregated by ten-year age group and year. MS-2 Step is listed on the PBS for terminating intrauterine pregnancies of up to 63 days' gestation. Services Australia also supplied the numbers by SA3 of MS-2 Step prescriptions written by GPs and dispensed by pharmacists. Population data for each SA3 were derived from ABS data.[12] SA3s provide a regional breakdown of Australia into areas that usually include populations of between 30 000 and 130 000 people. In urban centres, they are often closely aligned with local government areas; outside urban centres, they include areas recognised as sharing a distinct identity and socio-economic characteristics.[13]

We calculated age-standardised rates of MS-2 Step dispensing to women of reproductive age in each SA3 for each year by applying the ABS 2001 standard population.[14] We defined the magnitude of variation in dispensing for a given year as the ratio of the highest and lowest age-standardised rates by SA3; we also calculated variation after excluding the 10% of SA3s with the lowest and the 10% with the highest age-standardised rates. For these calculations, we excluded SA3s in which fewer than twenty prescriptions had been dispensed, those that included fewer than 1000 women of reproductive age, and SA3s in which any ten-year age group (for women aged 15–54 years) included fewer than thirty women.

In the dataset provided by Services Australia, counts were suppressed if one to six prescriptions had been dispensed for a combination of SA3, age group, and year. In our analysis, we replaced the suppressed counts with a value of five prescriptions.

In a separate analysis, we included data from all SA3s to calculate age-standardised rates for the 2019 calendar year by state and ABS remoteness area.[15] We also calculated the numbers and proportions of SA3s in which MS-2 Step had not been prescribed by a GP or dispensed by a community pharmacy during 2019, both unweighted and weighted by the number of women aged 15–54 years resident in the SA3. As population data by SA3 were not available for 2019, we used population data for 2018.[12]

Ethics approval

Formal ethics approval was not required for our analysis of de-identified Services Australia data.

1 Pharmaceutical Benefits Scheme-subsidised MS-2 Step dispensing rates (per 1000 women aged 15–54 years), 2015–2019, by year

	2015	2016	2017	2018	2019
Number of dispensed prescriptions	9373	15 092	19 236	18 735	29 207
Age-standardised rate	1.63	2.39	2.93	3.46	3.79
Highest rate for an SA3	7.3	8.5	9.8	13.6	11.1
Lowest rate for an SA3	0.4	0.6	0.6	1.0	1.1
Magnitude of variation (ratio of highest to lowest SA3 rate)	19	14	16	13	9.8
Age-standardised rate, excluding SA3s in highest and lowest rate deciles					
Highest rate for an SA3	3.1	4.1	5.2	6.5	7.0
Lowest rate for an SA3	0.9	1.4	1.8	2.1	2.3
Magnitude of variation (ratio of highest to lowest SA3 rate)	3.4	3.0	2.9	3.1	3.0

SA3 = statistical area level 3. ◆

2 Age-standardised MS-2 Step dispensing per 1000 women aged 15–54 years, 2019, by state and remoteness area[14]

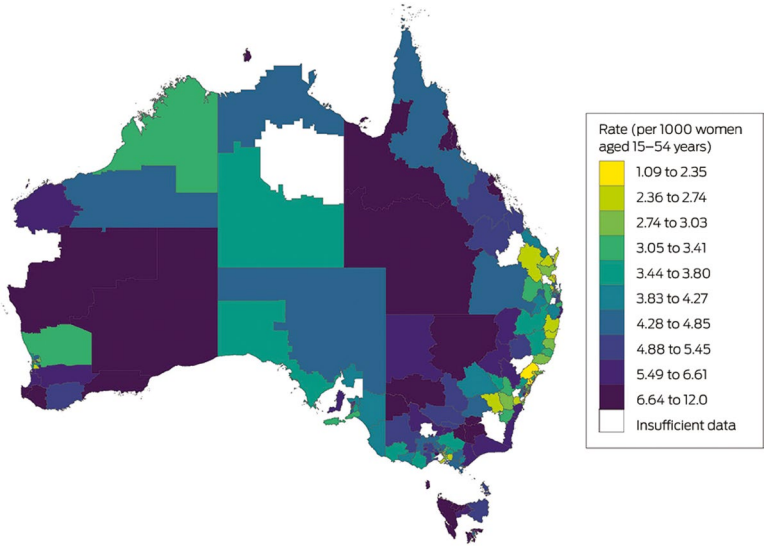
	Remoteness area					
State	Major cities	Inner regional	Outer regional	Remote	Very remote	All regions
Australia	3.30	4.94	6.53	6.02	5.02	3.79
Australian Capital Territory	3.16	0.00	—	—	—	3.15
New South Wales	2.94	4.31	5.12	8.19	0.00	3.23
Northern Territory	—	—	9.75	4.30	4.31	7.16
Queensland	3.51	4.55	6.21	8.04	6.01	4.06
South Australia	4.70	4.73	4.57	4.36	—	4.60
Tasmania	—	6.03	8.43	—	—	6.69
Victoria	3.26	5.63	6.83	—	—	3.79
Western Australia	3.35	6.45	7.24	7.44	5.05	3.90

Results

During 2015–2019, the PBS subsidised 91 643 MS-2 Step prescriptions. The national age-standardised rate increased from 1.63 prescriptions per 1000 women aged 15–54 years in 2015 to 3.79 prescriptions per 1000 in 2019. The magnitude of variation in age-standardised dispensing rates declined from 19 in 2015 to 9.8 in 2019, but was fairly steady if the SA3s in the highest and lowest rate deciles were excluded (2015, 3.4; 2019, 3.0) (Box 1).

In 2019, the age-standardised dispensing rate was highest in the Northern Territory (7.16 MS-2 Step prescriptions per 1000 women aged 15–54 years) and lowest in the Australian Capital Territory (3.15 per 1000) and New South Wales (3.23 per 1000). On a national basis, rates were higher in outer regional

3 Age-standardised MS-2 Step dispensing per 1000 women aged 15–54 years, 2019, by level 3 statistical area (SA3)



Australia (6.53 prescriptions per 1000 women aged 15-54 years) and remote Australia (6.02 per 1000) than in major cities (3.30 per 1000) (Box 2, Box 3).

About 30% of women aged 15–54 years — and about 50% of those in remote Australia — lived in SA3s in which MS-2 Step had not been prescribed by a GP during 2019; the proportion was highest in South Australia (64%) and New South Wales (40%) (Box 4). About 25% of women aged 15–54 years lived in areas in SA3s in which MS-2 Step had not been dispensed by a community pharmacist; the proportion was highest in South Australia (46%) and the Australian Capital Territory (36%) (Box 5). In 74 of 338 SA3s (22%), MS-2 Step was neither prescribed by a GP nor dispensed by a community pharmacist during 2019 (Box 6).

Discussion

We found that rates of early medical abortion are higher among women in outer regional, remote, and inner regional Australia than in major cities; however, MS-2 Step had not been prescribed by GPs or dispensed by community pharmacists in a large proportion of SA3s in these geographic areas during 2019. Women may have travelled long distances to access early medical abortion, or received it using telehealth services. The reduction in the range of dispensing rates by SA3 between 2015 and 2019 suggests, however, that equitable provision of early medical abortion improved during this period.

Higher rates of early medical abortion in rural and remote areas could be explained by several factors. Women in these areas may have difficulty accessing surgical abortion, as many public hospitals do not provide it at all or only in cases of fetal abnormality,[16] and private clinics providing surgical abortion are predominantly located in major cities.[2] Further, many women choose telehealth early medical abortion services for a range of geographic, financial, and social reasons.[17] During the study period, telehealth was available across Australia (except in South Australia) from private providers.[17] Early medical abortion delivered by telehealth is highly acceptable and convenient for women because they can remain at home and manage their personal responsibilities, and because it satisfies their privacy needs.[17,18] Concerns about privacy and confidentiality, and perceived stigmatisation by health professionals, may diminish the acceptability of obtaining early medical abortion from local providers.[19]

As the number of early medical abortions increased during 2015–2019, that of surgical abortions declined; claims for Medicare Benefits Schedule (MBS) item number 35643 (evacuation of the contents of the gravid uterus by curettage or suction curettage) declined from about 50 000 in 2015 to 40 000 in 2019.[20] However, these numbers do not provide a complete account of surgical abortion in Australia, as the delivery of surgical abortion services differs between states.[21]

Restrictive laws have also limited access to early medical abortion in Australia, especially in rural and remote areas.[2] Abortion was decriminalised in the Northern Territory in 2017, in Queensland in 2018, and in New South Wales in 2019.[22] South Australia decriminalised abortion in 2021, permitting service delivery in primary care settings.[22] Inconsistencies in knowledge of the law pertaining to abortion also discourage GPs from providing the service.[2]

We used the lack of MS-2 Step prescribing by GPs in an SA3 as a surrogate marker of GPs not providing early medical abortion. However, that GPs had not prescribed and pharmacists had not dispensed MS-2 Step in some rural and remote SA3s could have a number of explanations. Firstly, rural and regional doctors may have concerns about support services, including after-hours emergency and surgical care in case of complications, and about access to ultrasound services (recommended for gestation dating and to exclude ectopic pregnancy[8,23]). They might also have been concerned about their capacity to provide anti-D, but recently updated guidelines no longer recommend the routine use of RhD immunoglobulin in medical terminations before ten weeks' gestation.[1] Early medical abortion can proceed without ultrasound assessment after careful screening for risk factors for ectopic pregnancy and when the gestational age can be accurately estimated on the basis of the woman's history.[24] Secondly, many doctors conscientiously object to performing abortions, and some refuse to refer patients for such procedures, despite a legal obligation to do so.[25] Thirdly, many GPs do not have the training or knowledge required to confidently provide early medical abortion.[25] Finally, women may choose not to use local GP providers for abortion services.

These barriers to providing early medical abortion are compounded by the shortage of GPs in rural and remote areas.[26] While financial incentives are frequently used to recruit and retain GPs in rural and remote areas, recent research suggests they play only a limited role in improving access to primary care.[26] Other strategies are therefore required. Options include increasing the use of collaborative task-sharing arrangements and models in which nurses undertake most of the counselling, administration and follow-up tasks of healthcare provision.[8] While clinical trials have found nurse-led models to be safe and effective,[27] only medical practitioners are authorised to prescribe MS-2 Step in Australia. An alternative approach has been facilitated by improved access to telehealth services. The introduction of MBS telehealth item numbers as part of the federal response to the coronavirus disease 2019 (COVID-19) pandemic has meant

4 Level 3 statistical areas (SA3s) in which MS-2 Step had not been prescribed by a general practitioner during 2019, by state and remoteness area

Location of SA3	SA3s	SA3s with no MS-2 Step prescriptions by GPs		
		Number	Proportion (raw)	Proportion (weighted*)
Australia†	338	128	38%	30%
State				
Australian Capital Territory	10	4	40%	25%
New South Wales	90	43	48%	40%
Northern Territory	9	4	44%	34%
Queensland	82	29	35%	31%
South Australia	28	17	61%	64%
Tasmania	15	3	20%	7%
Victoria	66	12	18%	10%
Western Australia	34	12	35%	29%
Remoteness area[14]				
Major cities	190	76	40%	31%
Inner regional	82	28	34%	25%
Outer regional	47	15	32%	21%
Remote	8	3	38%	50%
Very remote	11	6	55%	21%

* By number of women in SA3 aged 15–54 years. † Includes SA3s not assigned to any state; eg, SA3 99999 = no usual address. ◆

5 Level 3 statistical areas (SA3s) in which MS-2 Step had not been dispensed by a community pharmacist during 2019, by state and remoteness area

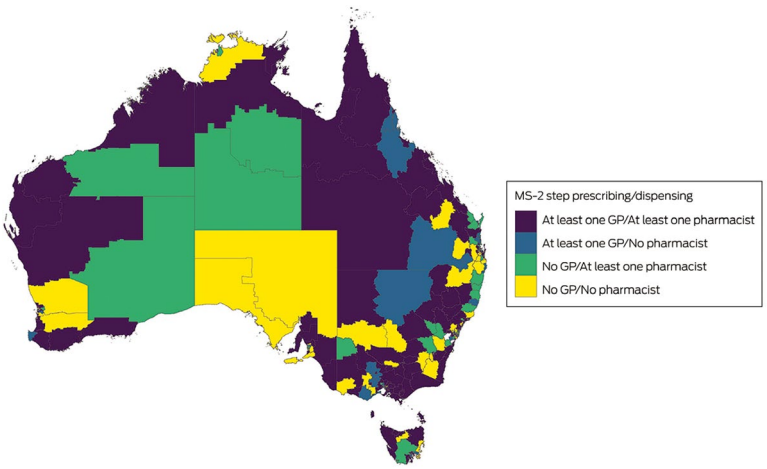
Location of SA3	SA3s	SA3s with no MS-2 Step dispensing by community pharmacists		
		Number	Proportion (raw)	Proportion (weighted*)
Australia†	338	112	33%	25%
State	334	108		
Australian Capital Territory	10	3	30%	36%
New South Wales	90	34	38%	29%
Northern Territory	9	1	11%	7%
Queensland	82	27	33%	26%
South Australia	28	14	50%	46%
Tasmania	15	4	27%	15%
Victoria	66	15	23%	12%
Western Australia	34	10	29%	27%
Remoteness area[14]				
Major cities	190	60	32%	24%
Inner regional	82	31	38%	27%
Outer regional	47	14	30%	20%
Remote	8	2	25%	30%
Very remote	11	5	45%	16%

* By number of women in SA3 aged 15–54 years. † Includes SA3s not assigned to any state; eg, SA3 99999 = no usual address. ◆

that telehealth early medical abortion services are now covered by Medicare for eligible patients.[28] One services provider reported a 30% increase in the number of early medical abortions provided via telehealth, an 8% increase in the number of regional clients, and a 20% increase in the number of remote clients during 2020.[5]

In addition to resolving workforce problems, supporting GPs in the local delivery of early medical abortion services should be a focus. Increased local training and opportunities for educating doctors about early medical abortion and referral pathways are required to ensure that women have access to abortion services. Peer support networks has been cited by GPs as crucial for delivering early medical abortion in primary care,[8] and may include other prescribing GPs, as well as a pharmacist, sonographer, and the MS-2 Step 24-hour nurse hotline.

6 MS-2 Step prescribing and dispensing during 2019, by level 3 statistical area (SA3)



Limitations

In the dataset provided by Services Australia, counts were suppressed if one to six prescriptions had been dispensed for a combination of SA3, age group, and year; our replacing suppressed counts with a standard value (five) probably reduced the estimated variability in dispensing rates across SA3s. Allocation of dispensed scripts to SA3s was based on the location of the provider GP recorded by Services Australia; this may have been inaccurate if a GP practised in multiple locations.

Conclusion

Our analysis of aggregated PBS MS-2 Step dispensing data indicated that early medical abortion rates are higher in outer regional, remote, and inner regional Australia than in major cities,

but it had not been prescribed by GPs or dispensed by local pharmacists in many SA3s in these geographic regions during 2019. State and federal governments have a duty of care to ensure that essential health services, including early medical abortion and abortion services in general, are available, affordable, and accessible to all Australian women, in public hospitals and in primary care. Local provision of early medical abortion services by GPs should be supported, and delivery via telehealth should be included in Medicare.

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