

# BMJ Open Over-the-counter provision of emergency contraceptive pills: a systematic review

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## ABSTRACT

**Objective** To synthesise evidence around over-the-counter (OTC) emergency contraceptive pills (ECPs) to expand the evidence base on self-care interventions.

**Design** Systematic review (PROSPERO# CRD42021231625).

**Eligibility criteria** We included publications comparing OTC or pharmacy-access ECP with prescription-only ECPs and measuring ECP uptake, correct use, unintended pregnancy, abortion, sexual practices/behaviour, self-efficacy and side-effects/harms. We also reviewed studies assessing values/preferences and costs of OTC ECPs.

**Data sources** We searched PubMed, CINAL, LILACS, EMBASE, clinicaltrials.gov, WHO International Clinical Trials Registry Platform, Pan African Clinical Trials Registry, Australian New Zealand Clinical Trials Registry, Cochrane Fertility Regulation and International Consortium for Emergency Contraception through 2 December 2020.

**Risk of bias** For trials, we used Cochrane Collaboration's tool for assessing risk of bias; for other studies, we used the Evidence Project risk of bias tool.

**Data extraction and synthesis** We summarised data in duplicate using Grading of Recommendations Assessment, Development and Evaluation (GRADE) Evidence Profile tables, reporting findings by study design and outcome. We qualitatively synthesised values/preferences and cost data.

**Results** We included 19 studies evaluating effectiveness of OTC ECP, 56 on values/preferences and 3 on costs. All studies except one were from high-income and middle-income settings. Broadly, there were no differences in overall ECP use, pregnancy or sexual behaviour, but an increase in timely ECP use, when comparing OTC or pharmacy ECP to prescription-only ECP groups. Studies showed similar/lower abortion rates in areas with pharmacy availability of ECPs. Users and providers generally supported OTC ECPs; decisions for use were influenced by privacy/confidentiality, convenience, and cost. Three modelling studies found pharmacy-access ECPs would lower health sector costs.

**Conclusion** OTC ECPs are feasible and acceptable. They may increase access to and timely use of effective contraception. Existing evidence suggests OTC ECPs do not substantively change reproductive health outcomes. Future studies should examine OTC ECP's impacts on user costs, among key subgroups and in low-resource settings.

## INTRODUCTION

The World Health Organisation (WHO) recommends the use of several forms of

## Strengths and limitations of this study

- We comprehensively searched the literature on effectiveness, costs, and values and preferences of over-the-counter emergency contraception.
- We searched four major databases and four clinical trial registries, with no restrictions on language or geography.
- Given our focus on over-the-counter delivery modalities, we may have excluded studies that assessed relevant outcomes of expanded access to emergency contraception through advance provision or other modalities.
- The findings of this review may not be generalisable, as the majority of studies were conducted in high- and middle-income countries.

emergency contraception, which can substantially reduce unintended pregnancy when used correctly.<sup>1 2</sup> Reducing barriers to emergency contraceptive pills (ECPs) may increase access to effective contraceptive options, reduce unintended pregnancies, and overall improve outcomes related to sexual and reproductive health (SRH) and rights.<sup>3</sup>

In many settings, ECPs are delivered through one or more modalities:<sup>4</sup> (1) prescription-only, wherein physicians or other medical providers prescribe ECPs based on individual need; (2) pharmacy access (also called behind-the-counter), wherein the medication is available via screening or prescription from a pharmacist; and (3) over-the-counter (OTC), wherein medication is available on store shelves without a prescription. As of December 2021, ECPs are available via pharmacy access in 76 countries and OTC in 19 countries.<sup>5</sup> While both pharmacy access and OTC may reduce barriers to access by no longer requiring a visit to a physician or other healthcare provider, pharmacy access still requires the presence of a pharmacist, while truly OTC availability means an individual can purchase medication in the absence of a medical or pharmacy provider.

While countries have varying regulatory criteria involved in making a specific medication available OTC or with eligibility screening by pharmacy staff,<sup>6</sup> the WHO is responsible to provide overall guidance to critical questions of intervention recommendations. The 2019 WHO normative guidance on self-care interventions<sup>7</sup> included a recommendation on OTC oral contraception (contraceptive pills). This was informed by a previous systematic review,<sup>8</sup> in which we found that OTC oral contraception may result in higher continuation with limited contraindicated use among users, and was generally supported by patients and providers. This earlier review and the 2019 WHO guidance did not include OTC delivery of ECPs. We therefore conducted this systematic review as part of expanding the evidence base of the guideline.

This review was also conducted in response to the COVID-19 pandemic that has seen overstretched health systems and disruptions of health services globally.<sup>9–10</sup> WHO has prioritised self-care interventions in response to maintaining essential SRH services during the pandemic as people fail to access care and services, highlighting the need to improve availability of options that people can use outside of formal health facilities.<sup>9–11–13</sup> Further, WHO has warned that the COVID-19 pandemic has further increased women's exposure to intimate partner violence, as a result of measures such as lockdowns and disruptions to vital support services,<sup>14</sup> which may lead more women and girls to need and/or use OTC ECPs. In addition, supply-side constraints and other barriers related to COVID-19 may reduce access and availability of condoms and other forms of medically prescribed contraceptive options, thus increasing the need for and importance of OTC ECPs.<sup>10–15–17</sup>

## METHODS

This review addressed the following question: Should ECPs be made available without a clinician's prescription? We reviewed the extant literature in three areas relevant to this question: effectiveness of the intervention, values and preferences of end-users and providers and cost information. These three areas are all required information in the WHO guideline development process.<sup>18</sup> The review followed Preferred Reporting Items for Systematic Review and Meta-Analyses guidelines (see online supplemental appendix 1),<sup>19</sup> and the protocol was published on PROSPERO (registration number CRD42021231625).

### Effectiveness review inclusion criteria

The effectiveness review was designed according to the PICO format as follows:

- ▶ Population: Individuals using ECPs.
- ▶ Intervention: Availability of ECPs OTC (without a prescription or screening) or from a pharmacist (behind-the-counter or pharmacy access).
- ▶ Comparison: Availability of ECPs by prescription only (by a clinician other than a pharmacist).

- ▶ Outcomes: (1) uptake of ECPs (initial use); (2) correct use of ECPs, including comprehension of product label instructions; (3) unintended pregnancy; (4) abortion (medical or unsafe); (5) changes in SRH practices or behaviour; (6) self-efficacy, self-determination, autonomy, empowerment; (7) side effects, adverse events or social harms and whether harms were corrected/had redress available.

To be included in the effectiveness review, an article must have: (1) had a study design comparing OTC or behind-the-counter (pharmacy) access of ECPs to prescription-only access (including randomised controlled trials (RCTs), non-randomised trials and comparative observational studies); (2) measured one or more of the outcomes listed above; and (3) been published in a peer-reviewed journal. We did not restrict inclusion on the basis of language or intervention location. Articles in English, French, Spanish and Chinese were coded directly; articles in other languages were translated before coding.

For the purposes of this review, we considered both behind-the-counter (pharmacy access) and true OTC availability as 'over-the-counter' in our intervention definition. Our definition also includes availability through a range of locations other than pharmacies, including drug shops, vending machines and online or telehealth services. Although intrauterine device (IUD) insertion can also be a form of emergency contraception, it requires insertion by a provider and thus cannot be made available OTC. This review thus focuses on ECPs. Studies that examined the provision of ECPs for clients to keep at home versus OTC or prescription-only access were not included.

### Search strategy and screening

We searched four electronic databases (PubMed, CINAL, LILACS and EMBASE) and four clinical trial registries (clinicaltrials.gov, WHO International Clinical Trials Registry Platform, Pan African Clinical Trials Registry and Australian New Zealand Clinical Trials Registry). We also searched the website of the Cochrane Fertility Regulation Group (<https://fertility-regulation.cochrane.org/>) and its COVID-19 specific page (<https://cgf.cochrane.org/news/covid-19-coronavirus-disease-fertility-and-pregnancy>), as well as the International Consortium for Emergency Contraception (<https://cecinfo.org>) and its regional consortia. Electronic databases were searched through 2 December 2020, using consistent search strings including a list of oral and emergency contraceptives, plus terms associated with medication provision without a prescription (see online supplemental appendix 2).

Secondary reference searching was conducted on all studies included in the review. Further, selected experts in the field were contacted to identify additional articles not identified through other search methods.

Titles, abstracts, citation information and descriptor terms of citations identified through the search strategy were screened by a member of the study staff. Full-text articles were obtained of all selected abstracts and two

independent reviewers assessed all full-text articles for eligibility to determine final study selection. Differences were resolved through consensus.

### Data extraction and management

Two reviewers independently extracted data using standardised forms. Differences in data extraction were resolved through consensus and referral to a senior study team member from WHO when necessary. The following information was gathered from each included study:

1. Study identification: Author(s); type of citation; year of publication.
2. Study description: study objectives; location; population characteristics; type of ECP; description of OTC access; description of any additional intervention components (eg, any education, training, support provided); study design; sample size; follow-up periods and loss to follow-up.
3. Outcomes: analytic approach; outcome measures; comparison groups; effect sizes; CIs; significance levels; conclusions; limitations.

For RCTs, we assessed risk of bias using the Cochrane Collaboration's tool for assessing risk of bias.<sup>20</sup> For studies that were non-randomised comparative trials, we assessed study rigour using the Evidence Project eight-item risk of bias tool, which has been shown to have moderate to substantial reliability.<sup>21</sup> We selected the Evidence Project tool given its applicability to a wide range of study designs, ease of use and interpretation, and consistency in assessing bias for individual studies rather than outcomes, which may vary across studies and topics.

### Data analysis

We analysed data according to coding categories and outcomes. If multiple studies reported the same outcome, we conducted meta-analysis using random-effects models to combine risk ratios (RR) with the Comprehensive Meta-Analysis programme.

For each outcome assessed in the review, we summarised data in GRADE Evidence Profile tables using GRADEPro.<sup>22</sup> We used RCT data where they were available; if RCT data were not available for an outcome, we pulled data from observational studies.

Where possible, we stratified analyses by the following subgroups: (1) behind-the-counter versus true OTC; (2) point of access (eg, stores, pharmacies, telehealth, etc); (3) type of ECPs (progestin-only vs ulipristal acetate vs combined vs mifepristone); (4) prior use of contraception; (5) age group; (6) vulnerabilities (eg, poverty, disability, religion, literacy); (7) high-income versus low-income or middle-income setting.

### Additional reviews

We conducted additional reviews examining values and preferences and costs of OTC provision of ECPs. We used the same search strategy and terms to identify studies for these reviews. Studies were included in these reviews if they presented results from primary data

collection; opinion pieces and reviews were excluded. We summarised this literature qualitatively and presented it with consideration of study design, methodology, location, and population.

### Values and preferences review

We included studies in this review if they presented primary data examining preferences of women and girls regarding OTC access to ECPs. We focused on studies examining the values and preferences of women and girls who have used or potentially would use emergency contraceptives themselves, but we also included studies examining the values and preferences of healthcare providers, including in particular pharmacists and other providers. We considered issues around OTC access to ECPs as they relate to age of availability and marital status (both in law and in practice), broader social/structural factors that affect values and preferences, informed decision-making, coercion and seeking redress in this section.

### Cost review

We included studies in this review if they presented primary data comparing costing, cost-effectiveness, cost-utility or cost-benefit of the intervention and comparison listed in the PICO above, or if they presented cost-effectiveness of the intervention as it relates to the PICO outcomes listed above. We classified cost literature into four categories (health sector costs, other sector costs, patient/family costs and productivity impacts) and within each category organised results by study design/methodology, location, and population.

### Patient and public involvement

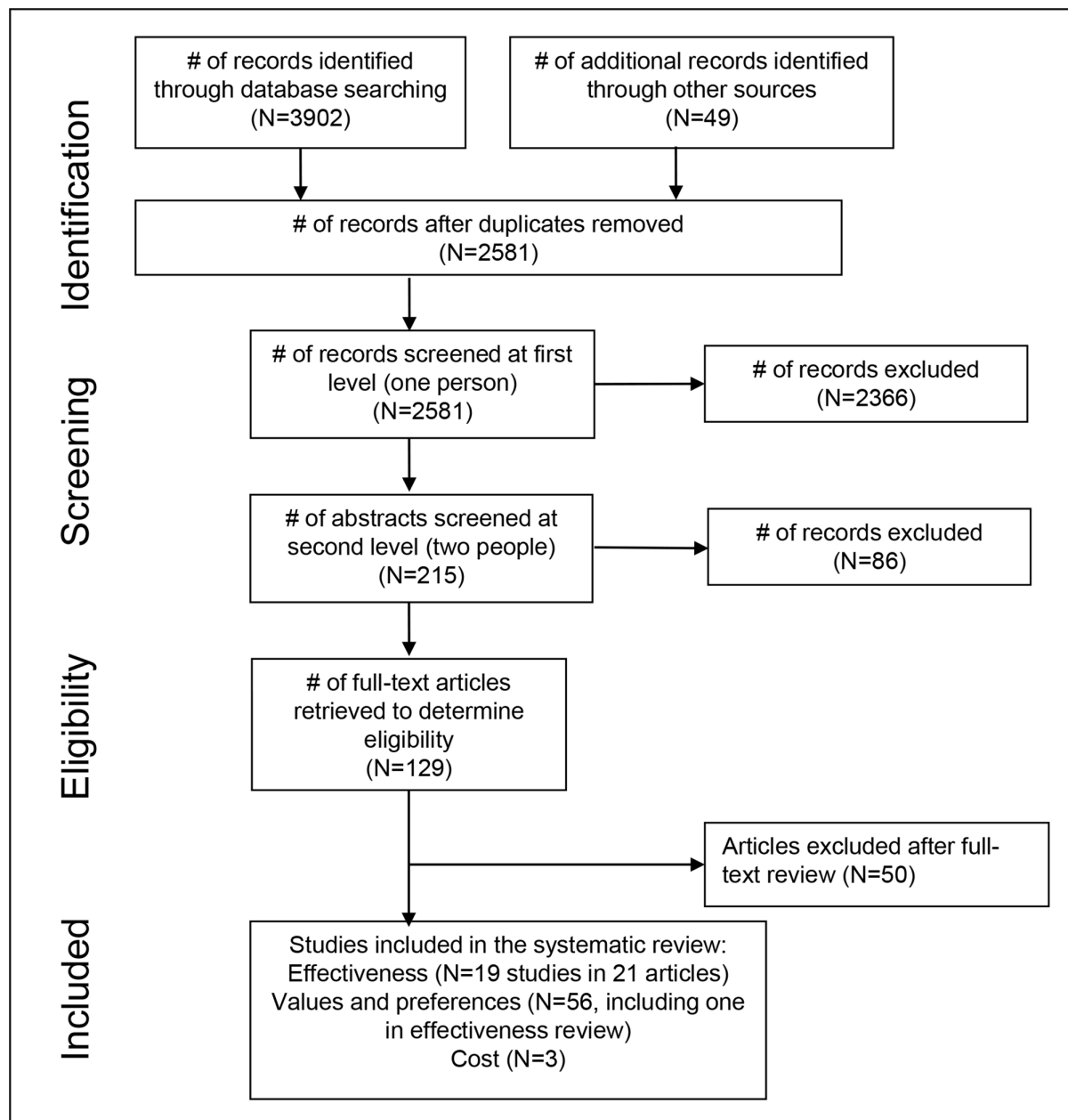
Feedback on the review protocol and analysis was received from the WHO patient safety working group. Patients were involved in a global survey of values and preferences conducted to inform the WHO guideline on self-care interventions; they thus play a significant role in the overall recommendation informed by this review.

## RESULTS

Our search yielded 2581 unique references, of which 129 were retained for full-text review (figure 1). Ultimately, we identified 19 studies (reported in 21 articles) that met the inclusion criteria for the effectiveness review,<sup>23–43</sup> 56 values and preferences studies,<sup>44–98</sup> and 3 cost studies.<sup>99–101</sup>

### Effectiveness review

Overall, 19 studies from eight countries (published in 21 articles) met the inclusion criteria for the effectiveness review<sup>23–43</sup> (table 1). This included 1 RCT (published in three articles), which was shown to have generally low risk of bias, and 18 observational studies, with risk of bias related to the presence of comparison groups, controls for confounding, and/or pre/post data. All studies were from high-income countries, and most presented data on ECP uptake, changes in SRH practices and behaviour or abortion. Only one study<sup>32 40 41</sup> assessed side effects,



**Figure 1** Preferred Reporting Items for Systematic Review and Meta-Analyses flow chart showing disposition of citations through the search and screening process.

adverse events or social harms. There was no comparative data on correct use of ECPs or self-efficacy, self-determination, autonomy or empowerment. Effect sizes are reported by outcome in [table 2](#), and risk of bias assessments are presented in online supplemental appendix 3.

#### ECP uptake

Nine studies reported on the impacts of OTC and pharmacy-access ECP on ECP use, prescribing and uptake. Evidence from one RCT<sup>40</sup> showed no difference in use of ECPs with pharmacy access (RR: 1.15, 95% CI: 0.90 to 1.48). In the same trial, there were no differences in ECP use by age.<sup>32</sup> Three serial cross-sectional studies similarly found no changes in overall ECP use over time with implementation of OTC access in Finland,<sup>30</sup> the United

Kingdom (UK)<sup>34</sup> and Australia.<sup>37</sup> The studies in Finland and the UK were found to have risk of bias due to lack of comparison groups in either study (both were pre/post only); biases in the study in Australia were related to the absence of a comparison group (pre/post only) and lack of control for confounding in the analysis.

Two cross-sectional studies found that use of ECPs within 24 hours of sex increased with pharmacy access in the UK (18% increase;  $p=0.03$ )<sup>33</sup> and the United States of America (USA) (adjusted odds ratio: 2.17, 95% CI: 1.06 to 4.44).<sup>42</sup> The study in the UK was found to have risk of bias, having no pre/post data and no control for confounding. The study from the USA was found to have risk of bias due to lack of pre/post data. Finally, a study

**Table 1** Description of included studies

Study	Study design	Location	Population	Intervention*	Outcomes
Arnet <i>et al</i> 2009 <sup>23</sup>	Pre/post	Switzerland: Basel, Bern, Zurich	Women aged 15–49 accessing ECPs at pharmacies; 2003, 2006 n=729	Pharmacy access	5. SRH practices or behaviour
Atkins and Bradford 2015 <sup>25</sup>	Serial cross-sectional	USA: ME, NH, VT, RI	Public school students who responded to sexual activity questions in Youth Risk Behaviour Survey; 2003–2009 n=49454	Pharmacy access	5. SRH practices or behaviour
Atkins 2014 <sup>24</sup>	Serial cross-sectional	USA: national	Non-pregnant women of aged 18–45 who responded to National Health and Nutrition Examination Survey; 2001–2004, 2007–2010 N: Not reported	Pharmacy access	5. SRH practices or behaviour
Bumbul <i>et al</i> 2013 <sup>26</sup>	Cross-sectional	Poland: Warsaw Lithuania: Vilnius	Female students and high school pupils n=1366	OTC access	1. ECP uptake 5. SRH practices or behaviour
Cintina and Johansen 2015 <sup>28</sup>	Ecological	USA: national (states except AK, DC, DE, HI, IA, MA, ME, NJ, NM, VT, WA)	Women aged 15–19 years; 2000–2010 N: Not reported	Pharmacy access	4. Abortion
Cintina 2017 <sup>27</sup>	Ecological	USA: WA, OR, ID	Women aged 15–44 n=1747	Pharmacy access	4. Abortion
Durrance 2013 <sup>29</sup>	Ecological	USA: WA	Women aged 15–24 years; 1993–2005 n=507	Pharmacy access	4. Abortion
Falah-Hassani <i>et al</i> 2007 <sup>30</sup>	Serial cross-sectional	Finland: national	Adolescents aged 12–18; 1991, 2001, 2003 n=12121	OTC access	1. ECP uptake
Girma and Paton 2011 <sup>31</sup>	Ecological	UK: national	Women aged 13–44; 1998–2004 N: Not reported	OTC access	3. Unintended pregnancy†
Harper <i>et al</i> 2005 <sup>32</sup> ; Raine <i>et al</i> 2005 <sup>40</sup> ; Rocca <i>et al</i> 2007 <sup>41</sup>	RCT	USA: CA: San Francisco	Women aged 15–24 attending clinics providing family planning; not desiring pregnancy, using long-term hormonal contraception or requesting ECPs; 2001–2003 n=2117	Pharmacy access	1. ECP uptake 3. Unintended pregnancy 5. SRH practices or behaviour 7. Side effects, adverse events, social harms
Killick and Irving 2004 <sup>33</sup>	Cross-sectional	UK: national	Women accessing ECPs at pharmacies n=419	Pharmacy access	1. ECP uptake
Marston <i>et al</i> 2005 <sup>34</sup>	Serial cross-sectional	UK: national	Women aged 16–49 who responded to Omnibus survey; 2000–2002 n=5984	OTC access	1. ECP uptake 5. SRH practices or behaviour
Moreau <i>et al</i> 2006 <sup>35</sup>	Serial cross-sectional	France: national	Women aged 15–44 years responding to national health surveys; 1999, 2004 n=11 656 (1999: 4146; 2004: 7490)	OTC access	4. Abortion
Mulligan 2016 <sup>36</sup>	Cross-sectional	USA: national (all states except CA, NH (post-1997), MD (post-2006))	Women aged 15–44 in the USA, 1993–2011; female respondents to the National Longitudinal Survey of Youth (NLSY); 1997–2009 n=4385 for 1997 NLSY; otherwise not reported	Pharmacy access	4. Abortion
Novikova <i>et al</i> 2009 <sup>37</sup>	Serial cross-sectional	Australia: Sydney	Women attending abortion clinics n=718	OTC access	1. ECP uptake
Payaka-chat <i>et al</i> 2010 <sup>38</sup>	Cross-sectional	USA: AR: Little Rock	Pregnant women receiving prenatal care at a large urban community women's clinic; 2003–2008 n=272	Pharmacy access	3. Unintended pregnancy 5. SRH practices or behaviour
Pentel <i>et al</i> 2004 <sup>39</sup>	Ecological	USA: MN: Minneapolis	Female patients at a safety-net hospital N: Not reported	Pharmacy access	1. ECP uptake
Rubin <i>et al</i> 2011 <sup>42</sup>	Cross-sectional	USA	Females aged 14–19 who had engaged in unprotected sex while aware of ECPs n=531	Pharmacy access	1. ECP uptake

Continued

Table 1 Continued

Study	Study design	Location	Population	Intervention*	Outcomes
Soon <i>et al</i> 2005 <sup>43</sup>	Retrospective cohort	Canada: British Columbia	Women aged 10–59 who received ECP prescriptions from 1996 to 2002 n=1172	Pharmacy access	1. ECP uptake

\*For all included studies, the comparator was prescription-only access to ECPs.

†This study assessed changes in conception rate, which does not explicitly consider whether the pregnancy was intended but is considered an indirect proxy measure.

ECPs, emergency contraceptive pills; NLSY, National Longitudinal Survey of Youth; OTC, over-the-counter; RCT, randomised controlled trial; SRH, sexual and reproductive health.

assessing rates of pharmacy distribution in a safety-net hospital showed that ECP distribution increased by 800% over a 1.5-year period, while ECP prescribing increased by 50% over the same period.<sup>39</sup> This study was found to have risk of bias related to having no comparison group (pre/post only) or control for confounders.

When assessing impacts among the subgroup of adolescents and young adults, one study among women aged 16–19 in the UK found that ECP use increased from 15.3% before ECPs were available OTC to 21.5% in the year after OTC ECPs became available ( $\chi^2=1.54$ ,  $p=0.24$ ), before decreasing 8.5% another year following OTC availability ( $\chi^2=7.11$ ,  $p=0.01$ ).<sup>34</sup> Potential bias in this study was from having no comparison group (pre/post only).

#### Unintended pregnancy

Two studies assessed unintended pregnancy as an outcome. The one RCT found no significant change in pregnancy among women who did not wish to become pregnant (RR 0.82, 95% CI: 0.53 to 1.27)<sup>40</sup>; this did not differ by age.<sup>32</sup> A small cross-sectional study among pregnant women receiving prenatal care in the USA found that the proportion of women who reported their pregnancy as unintended increased from 72.7% before pharmacy access to 90.7% after pharmacy access ( $p=0.02$ ).<sup>38</sup> This finding was determined to have risk of bias based on having no comparator or control for confounders.

Additionally, one ecological study assessed changes in conception rate over time in the UK,<sup>31</sup> which does not explicitly consider whether the pregnancy was intended but is an indirect proxy measure. The study found no differences before or after OTC access among individuals aged 13–19, but was associated with an increase in conception of about 0.9% among women aged 25–44 ( $p<0.05$ ).<sup>31</sup> Lack of pre/post data in this study was identified as a potential source of bias.

#### Abortion

Four ecological studies from the USA assessed the impact of pharmacy-access ECPs on abortion rates per 1000 women, all with risk of bias related to lack of comparison groups or pre/post data.<sup>27–29 36</sup> These studies found no difference in overall abortion rates with pharmacy-access ECPs. Evidence from one study among 18-to-19-year-olds showed a decrease of 1.6 abortions per 1000 women after pharmacy-access ECPs became

available in the USA ( $p<0.05$ ).<sup>28</sup> Another study among 15-to-19-year-olds found a decrease of 1.97 abortions per 1000 ( $p<0.01$ ).

Finally, evidence from one serial cross-sectional study from France showed that reporting ever having an abortion declined from 17.0% before OTC ECP access to 15.6% after OTC ECP access ( $p=0.04$ ).<sup>35</sup> Bias in this study was related to lack of a comparison group (pre/post only).

#### Sexual health-related practices and behaviour

Seven studies assessed outcomes related to SRH practices and behaviour. Specific outcomes assessed included condom use (three studies), unprotected sex (two studies), reporting multiple partners (three studies), contraceptive method use (four studies) and missing contraceptive pills (two studies).

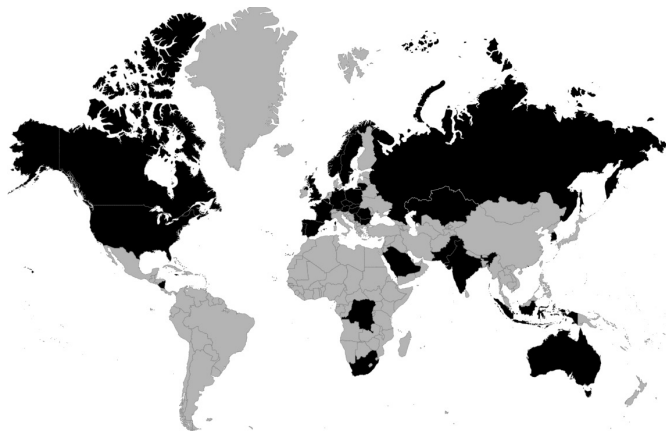
Evidence from one RCT showed no difference in number of sexual partners (RR: 1.24, 95% CI: 0.95 to 1.61), condom use at last sex (RR: 0.92, 95% CI: 0.81 to 1.05), consistent condom use (RR: 1.07, 95% CI: 0.76 to 1.51), change in contraceptive method (RR: 1.16, 95% CI: 0.92 to 1.47) or missed contraceptive pills (among pill users; RR: 0.92, 95% CI: 0.80 to 1.06).<sup>40</sup> The same RCT found decreases in unprotected intercourse with increased access to OTC ECPs (RR: 0.82, 95% CI: 0.70 to 0.97). These findings did not vary by age.<sup>32</sup>

An observational study found no significant changes in condom use, contraceptive use (including multimethod use), unprotected intercourse or missed contraceptive pills (among pill users), when comparing outcomes before and after pharmacy-access ECPs in German-speaking Switzerland.<sup>23</sup> This finding may have been influenced by bias from having no comparator (pre/post only) and no control for confounders. In the USA, evidence from two serial cross-sectional studies showed that increased access to OTC ECPs had no effect on sexual activity or contraceptive use over time,<sup>24 25</sup> though it reduced condom use among adolescents by 5.2%–7.2% ( $p<0.01$ ).<sup>25</sup> Both serial cross-sectional studies were found to have risk of bias due to lack of comparison groups (pre/post only). Finally, cross-sectional evidence from Lithuania and Poland showed that increased access to OTC ECPs was associated with reduced reporting of five or more sexual partners (30.6% without OTC access vs 9.6% with OTC access;

**Table 2** Summary of results

Number and type of studies	Specific outcome	n (%) or Mean (SD)			Effect	Risk of bias
		OTC/pharmacy access	Prescription-only availability			
<b>PICO outcome 1: ECP uptake</b>						
1 RCT <sup>40</sup>	ECP use	197/814 (24.2%)	65/310 (21.0%)	RR: 1.15 (0.90–1.48)	Low	
1 Retrospective cohort <sup>43</sup>	Physician prescribing of ECPs	2001: 9447 2002: 10 669	1996–2000: 8805/year (95% CI: 7823 to 9787)	Not reported	Lack of comparison; no control for confounding	
3 serial cross-sectional <sup>30 34 37</sup> ; 3 cross-sectional <sup>26 33 42</sup>	ECP use	Summary: all studies found no difference in ECP use overall or by age subgroups with increased OTC ECP access. Two studies found increased use of ECPs within 24 hours ( $\chi^2$ : 17.08; p=0.03 <sup>33</sup> ; aOR: 2.17; 95% CI: 1.06 to 4.44 <sup>42</sup> ).			Lack of comparison <sup>30 34 37</sup> ; No control for confounding <sup>26 30 33 37</sup> ; No pre/post <sup>26 33 42</sup>	
1 ecological <sup>39</sup>	ECP distribution from pharmacies	Summary: ECP distribution from a hospital pharmacy increased by 800% over 1.5 years, while prescription use of ECPs increased by 50%.			Lack of comparison; no control for confounding	
<b>PICO outcome 3: unintended pregnancy</b>						
1 RCT <sup>40</sup>	Unintended pregnancy	58/814 (7.1%)	27/310 (8.7%)	RR: 0.82 (0.53–1.27)	Low	
1 cross-sectional <sup>38</sup>	Unintended pregnancy	88 (90.7%)	24 (72.7%)	p=0.02	Lack of comparison; no control for confounding	
1 ecological <sup>31</sup>	Conception rate*	Summary: among women aged 13–15, 15–17 and 15–19, there was no change in conception rate with increased access to OTC ECPs. Among women aged 25–44, increased access was associated with increased use (p<0.05).			No pre/post	
<b>PICO outcome 4: abortion</b>						
4 ecological <sup>27–29 36</sup>	Abortion rate per 1000 women	Summary: most studies found no difference in abortion rates with increased access to OTC ECPs. Two studies identified significant decreases among younger age groups: a decrease of 1.6 abortions per 1000 18–19 year old women (p<0.05), <sup>29</sup> and a decrease of 1.97 per 1000 among women aged 15–19 (p<0.01). <sup>36</sup>			No pre/post <sup>28</sup> ; Lack of comparison <sup>27 29 36</sup>	
1 serial cross-sectional <sup>35</sup>	Abortion (ever)	1168/7490 (15.6%)	708/4166 (17.0%)	p=0.04	Lack of comparison	
<b>PICO outcome 5: sexual health-related practices and behaviour</b>						
1 RCT <sup>40</sup>	Unprotected sex	274/814 (33.7%)	127/310 (41.0%)	RR: 0.82 (0.70–0.97)	Low	
	Consistent condom use	110/814 (13.5%)	39/310 (12.6%)	RR: 1.07 (0.76–1.51)		
	Condom use last sex	383/814 (47.1%)	158/310 (51.0%)	RR: 0.92 (0.81–1.05)		
	Multiple partners	192/814 (23.6%)	59/310 (19.0%)	RR: 1.24 (0.95–1.61)		
	Contraceptive method change	220/814 (27.0%)	72/310 (23.2%)	RR: 1.16 (0.92–1.47)		
	Missed pills (among subgroup of reported contraceptive pill users)	245/391 (62.7%)	84/123 (68.3%)	RR: 0.92 (0.80–1.06)		
1 pre/post study <sup>23</sup>	Condom use	220/333 (66.0%)	232/350 (66.3%)	Not significant at p<0.05	Lack of comparison; no control for confounding	
	Oral contraceptive use	69/333 (20.7%)	90/350 (25.7%)	Not significant at p<0.05		
	Oral contraceptives + condoms	10/333 (3.0%)	7/350 (2.0%)	Not significant at p<0.05		
	Unprotected sex	17/340 (5.0%)	25/361 (6.9%)	Not significant at p<0.05		
	Missed pills	53/79 (67.1%)	47/97 (48.5%)	Not significant at p<0.05		
3 serial cross-sectional <sup>24 25 34</sup> ; 2 cross-sectional <sup>26 38</sup>	Multiple partners	Summary: increased access to OTC ECPs had mixed effects. One study <sup>24</sup> identified a 5.2% increase in reporting multiple partners (p<0.01); another study <sup>26</sup> identified a decrease from 30.6% to 9.6% reporting multiple partners (p<0.001).			Lack of comparison <sup>24 25 34 38</sup> ; No pre/post <sup>26</sup> ; No control for confounding <sup>26 38</sup>	
	Contraceptive use	Summary: overall, studies found no difference in oral contraceptive use with increased access to OTC ECPs. One study <sup>24</sup> found a 7.6% decrease in injectable contraceptive use (p<0.05).				
	Condom use	Summary: one study <sup>34</sup> identified no difference in condom use with increased access to OTC ECPs. Another study <sup>25</sup> found it decreased condom use among public school students by between 5.2% and 7.2% (p<0.01).				
<b>PICO outcome 7: side effects, adverse events and social harms</b>						
1 RCT <sup>40</sup>	Pressured into sex	28/814 (3.4%)	13/310 (4.2%)	RR: 0.82 (0.43–1.56)	Low	

\*This study assessed changes in conception rate, which does not explicitly consider whether the pregnancy was intended but is considered an indirect proxy measure. aOR, adjusted odds ratio; ECPs, emergency contraceptive pills; OTC, over-the-counter; RCT, randomised controlled trial.



**Figure 2** Map showing distribution of studies included in the values and preferences review.

$p < 0.001$ ).<sup>26</sup> Bias in this study was related to lack of pre/post evidence and no control for confounders.

#### Side effects, adverse events, and social harms

One RCT assessed potential social harms resulting from pharmacy-access ECPs and found that there was no difference in reporting being pressured into sex (RR: 0.82, 95% CI: 0.43 to 1.56).<sup>40</sup> For this outcome, there was no difference in age subgroup analyses.<sup>32</sup>

#### Values and preferences review

Overall, 56 studies from 33 countries were included in the values and preferences review (figure 2).<sup>33 44–98</sup> There were 39 quantitative studies (all cross-sectional surveys), 11 qualitative studies and 6 mixed-methods studies. Twenty-two studies included end-users, 33 studies included pharmacists or other healthcare providers or professional stakeholders and 1 study included both groups. One study<sup>33</sup> was also included in the effectiveness review.

Of the included studies, most were in the USA (n=19) and UK (n=9), followed by Sweden (n=5), Canada (n=4), Australia (n=3), India (n=3), South Africa (n=2) and South Korea (n=2). One study each was conducted in Austria, Barbados, Belgium, Bulgaria, Czech Republic, Democratic Republic of Congo, France, Germany, Hong Kong, Hungary, Indonesia, Jamaica, Kazakhstan, Lithuania, Nicaragua, Norway, Pakistan, Poland, Portugal, Romania, Russia, Saudi Arabia, Serbia, Slovakia, and Spain.

Of the values and preferences studies among end-users, support for OTC ECPs varied widely within and across countries, ranging from 12% among college students in India<sup>72</sup> to 100% among women who used OTC ECPs in Sweden.<sup>44</sup> In one study, where women could choose whether to obtain ECPs from a pharmacist or a physician,<sup>33</sup> satisfaction with information received was 91% among those receiving ECPs in pharmacies, compared with 58% among those receiving prescription-only ECPs ( $p=0.006$ ). Broadly, end-users supported OTC ECPs because they felt it offered improved access/availability, convenience, more flexible hours (particularly weekend

hours), confidentiality/privacy/anonymity and reduced cost. End-users also anticipated that OTC delivery would offer less opportunity for judgement from providers and greater control for women.

End-users who did not support OTC ECPs expressed concern about potential lack of privacy or increased cost, in addition to having a preference for more personal contact with providers for support and information. They also expressed some concerns about increased risk behaviour. One study noted this concern was for others; the individuals participating in the study, all of whom were ECP users, did not believe their own behaviour would be shaped by ECP use.<sup>77</sup>

Of the values and preferences studies among pharmacists and other healthcare providers and professionals, support for OTC ECPs ranged widely. In quantitative surveys, pharmacist support ranged from 16% in South Dakota, USA<sup>65</sup> to 97% in San Francisco, USA.<sup>55</sup> Among doctors, support was generally lower, ranging from 6.1% in South Korea<sup>83</sup> to 68.9% in Canada.<sup>81</sup> Broadly, providers supported OTC ECPs for similar reasons as end-users. Some studies found that providers had concerns about side effects, including the inability to communicate about side effects in OTC delivery modalities<sup>45</sup> and concerns about long-term impacts of repeat ECP use.<sup>86</sup> In contrast, one study found that providers supported OTC delivery as they saw ECPs as having relatively few side effects.<sup>83</sup>

Providers were also found to have concerns about increased risk behaviour, misuse/repeat use of ECPs and communication. Specifically regarding communication, providers felt concerned about discouraging other contraceptives,<sup>54 69 81 84 89</sup> and felt that OTC delivery might preclude delivery of necessary education and counselling. In some studies, providers had religious/moral concerns about OTC delivery.<sup>48 52 61 69 89</sup> One study found that these concerns were more common among providers who believed ECPs were an abortifacient.<sup>61</sup>

#### Cost review

Three studies met inclusion criteria for the cost review (table 3).<sup>99–101</sup> All were modelling studies, two from the USA<sup>99 100</sup> and one from Canada.<sup>101</sup> All examined the impact of pharmacy-access ECPs (not true OTC) and found that pharmacy access was expected to lead to lower health sector costs. No studies examined other sector costs, patient/family costs or productivity impacts.

## DISCUSSION

We identified 19 studies from 8 countries assessing how OTC ECPs influence uptake of ECPs, unintended pregnancy, abortion and other sexual practices and behaviour. Broadly, we found no differences in overall ECP use, pregnancy or sexual risk behaviour when comparing pharmacy access or true OTC availability to prescription-only ECP access. We found no comparative data on correct use of ECPs or self-efficacy, self-determination, autonomy or empowerment.



**Table 3** Description of studies included in the cost review

Study	Location	Study design	Impact of pharmacy access
Marciante <i>et al</i> 2001 <sup>100</sup>	USA	Decision model	Among private payers (private insurance): US\$158 (95% CI=US\$76 to US\$269) reduction in cost per woman having unprotected intercourse. Among public payers: US\$48 (95% CI=US\$16 to US\$93) reduction in cost per woman having unprotected intercourse.
Soon <i>et al</i> 2007 <sup>101</sup>	Canada	Three decision models	One-year cost saving to the MOH of US\$0.64 million (95% CI: US\$0.24 million to US\$1.28 million). In sensitivity analyses, there were no set of assumptions that would lead to pharmacy access increasing costs to the MOH.
Foster <i>et al</i> 2010 <sup>99</sup>	USA	Markov model	For Medicare: compared with no ECP use, pharmacy access was more cost-effective than prescription access across all assumptions of amount and frequency of use. Cost savings ratios for pharmacy access: range 1.61–2.49. For prescription-only access: range 1.00–1.56.

ECP, emergency contraceptive pill; MOH, Ministry of Health.

### OTC ECP effectiveness

Though we found minimal changes in overall ECP use in OTC models, two studies included in the review found that after OTC provision, use of ECPs within 24 hours of sex increased.<sup>33 42</sup> This is promising, given ECPs are more effective when used promptly.

For most outcomes, our review did not identify any substantial or concerning differences by age. However, there is promising evidence regarding OTC ECPs among younger women. Observational evidence included in our review showed that abortion rates decreased significantly among younger age groups with increased access to OTC ECPs,<sup>28 36</sup> while there was no significant difference in the overall population of women. Given the unique barriers faced by younger women accessing prescription-only ECPs in many settings, it may be that increased access to OTC ECPs has unique benefits for younger women. Since one in four young women who have been in a relationship will have already experienced intimate partner violence by the time they reach their mid-twenties,<sup>14 102</sup> access to contraceptive choice for these younger women is particularly important.

Our finding that OTC ECPs had minimal impacts on unintended pregnancy and abortion may be explained in part by overall low use of ECPs, regardless of conception intention.<sup>103 104</sup> However, there is some evidence that even with increased access and uptake, ECPs may have minimal impacts on unintended pregnancy or abortion.<sup>105</sup> Most studies in our review did not report on both pregnancy or abortion and ECP use. In the sole study reporting both unintended pregnancy and ECP uptake,<sup>40</sup> the authors found no change in either ECP uptake or unintended pregnancy with expanded access. This suggests that additional efforts may be required to ensure that increased ECP access reaches those most at risk of unintended pregnancy.<sup>103</sup>

In terms of routine preventive screenings and other SRH services, we did not assess this as a PICO outcome. Findings from our previous review of OTC oral contraceptives suggested that OTC oral contraceptive access

might not reduce use of other preventive services.<sup>8</sup> We did not assess sexually transmitted infection (STI) screenings, though there was mixed evidence around STI acquisition. Several included studies found no differences or lower rates of STI acquisition with increased access to OTC ECPs,<sup>26 32 36 40</sup> while others identified increases in STI acquisition among younger age groups.<sup>29 31</sup> Because this evidence is primarily from observational studies, the mechanisms of OTC ECPs' impacts in this area remain unclear.

### Values and preferences

In terms of values and preferences, we found that OTC ECPs were supported for their perceived convenience, privacy, comfort, control, cost and effectiveness. Some end-users and providers expressed concerns that OTC ECPs might increase sexual risk behaviour. However, our effectiveness review found that there were no differences in sexual practices and behaviour when comparing OTC or pharmacy ECPs with prescription-only ECPs.

While many studies found that women valued the privacy and control offered by OTC ECPs, two studies found that women were concerned about having limited interaction with providers in true OTC delivery.<sup>44 82</sup> In both studies, while there was widespread support for OTC availability of ECPs (between 78% and 100%), a large proportion of women expressed a preference for behind-the-counter modalities which allowed for interaction with a pharmacist. Indeed, in many settings, OTC ECPs are offered as one of an array of options including receiving ECPs from a pharmacist (behind-the-counter), from a physician (prescription OTC) or on store shelves (true OTC). We found that, in a study where women could choose whether to obtain ECPs in a pharmacy or from a physician,<sup>33</sup> ECP use and knowledge was similar between groups, but pharmacy-access ECPs resulted in higher use and satisfaction. Given this and our findings about OTC ECPs' effectiveness, blended delivery modalities wherein users can choose where and how to access ECPs may be most responsive to user preferences.



Providers also expressed concern that OTC ECPs might not allow for sufficient education or counselling, including about how to use OTC ECPs correctly and counselling about other routine SRH services (including use of other contraceptives and screenings for cervical and breast cancers and sexually transmitted infections<sup>106</sup>). In our effectiveness review, we did not identify any studies assessing correct use of ECPs in OTC versus prescription-only delivery modalities. While knowledge of ECPs was not one of our PICO outcomes, one study from the UK found no significant difference in correct knowledge of ECPs between women receiving ECPs from a physician versus OTC, with correct knowledge >90% for both groups,<sup>33</sup> and another found no significant difference between OTC and prescription delivery in reporting adequate information received about ECPs.<sup>37</sup>

### Cost

Results from OTC ECP cost studies are promising, though limited. In our three included studies from the USA and Canada, pharmacy access was anticipated to yield lower health sector costs. However, we identified no data on cost impacts for patients and families, which will be important to consider as OTC ECP access expands. Indeed, several included values and preferences studies noted increased cost as a concern.<sup>44 68 81 86</sup> On the other hand, some studies have shown that increased cost was perceived as a benefit, as it may deter repeat or overuse of ECPs.<sup>56 68</sup>

### Areas for future research

Our review highlights some critical areas for future research on OTC ECPs and its impacts. First, given provider concerns identified in our review, future research should also assess whether correct knowledge of ECPs translates to correct use in OTC modalities.

Second, future research should more closely examine OTC ECPs' impacts among key subgroups, including younger women. This is important given self-care interventions may present unique opportunities and challenges for different populations and in different settings.<sup>7</sup> For example, it is unclear through what mechanisms OTC ECPs may differentially impact outcomes such as abortion or STI acquisition among younger age groups, and if routine preventive SRH care plays a role. Equitable implementation of OTC ECPs as a self-care intervention should consider the intersecting roles of race/ethnicity/culture/language, occupation, gender/sex, religion, education, health literacy, socioeconomic status and social capital as determinants of SRH and rights and key factors affecting delivery, uptake and impact of OTC ECPs.<sup>107</sup>

Finally, though OTC ECPs are an important contraceptive option for individuals, communities and health systems worldwide, the evidence base identified through our effectiveness, cost and values and preferences reviews was concentrated in high-income settings. Specifically, we only found evidence of OTC ECPs' effectiveness and costs from high-income countries. In our values and preferences review, 80% of identified studies were from

high-income settings, and a low-income setting (Democratic Republic of Congo) was represented in a single study.<sup>66</sup> Meaningful efforts are needed to recognise, invest in and promote future research on the effects of increased OTC ECPs in low-income and middle-income countries. Future research should particularly consider impacts on user cost in these settings, given concerns identified in this review.

### Strengths and limitations

Our review has several strengths and limitations. Our search was comprehensive and included not only literature on the effectiveness of OTC ECPs, but on their costs and the values and preferences of providers and end users. However, we may have been limited by our exclusion of grey literature and conference abstracts, which may have provided valuable information given the evolving nature of this field. As OTC ECPs have expanded, communities and health systems may observe its impacts without rigorous or published evaluations. It is also possible that we excluded relevant findings from studies of expanded access to ECPs that did not specifically assess OTC modalities, such as trials of advance provision of ECPs.

We were also limited by the quality and diversity of included studies. Many observational studies in the review were limited by lack of comparison groups or pre/post data, and several did not control for confounding. Further, given the wide range of included study designs and outcomes, we were unable to perform meta-analysis but instead summarised findings qualitatively. Our conclusions are also limited by the concentration of articles in high-income and middle-income settings; future research should examine the impacts of OTC ECPs in resource-limited settings.

### Conclusion

Increasing OTC contraceptive choice and availability is an urgent need for many women and girls. OTC ECPs are available in many settings worldwide, suggesting its feasibility as an additional delivery option. This review of existing evidence suggests that providing emergency contraception OTC may be cost saving and responsive to user preferences, while introducing no negative SRH and rights outcomes.

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