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Over-the-counter provision of emergency contraceptive pills: A systematic review

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Abstract

Introduction: Improving access to emergency contraception (EC) can reduce unintended pregnancy and improve sexual and reproductive health and rights. We examined the evidence for availability of over-the-counter (OTC) EC in order to expand the evidence base of the World Health Organization's Guideline on Self-care Interventions to include EC.

Methods: We systematically reviewed the literature to evaluate the effectiveness of OTC EC. We searched for publications that compared OTC or pharmacy-access EC with prescription-only EC. We included studies measuring EC uptake, correct use, unintended pregnancy, abortion, sexual practices or behavior, self-efficacy, and side effects or harms. After abstract screening and full-text review, we summarized data in GRADE Evidence Profile tables. We also reviewed studies assessing values/preferences and costs of OTC EC.

Results: We included 19 studies (reported in 21 articles) evaluating the effectiveness of OTC EC; 56 studies related to values/preferences for OTC EC; and three studies on costs of OTC EC. All studies except one were from high- and middle-income settings. Overall, there were no differences in EC use, pregnancy, or sexual behavior when comparing OTC or pharmacy EC and prescription-only EC groups. Studies showed similar or lower abortion rates in areas with pharmacy availability of EC. There was a wide range of user and provider support for OTC EC, and decisions to use OTC EC were influenced by privacy/confidentiality, convenience, and cost. Three modeling studies found pharmacy-access EC would lower health sector costs.

Conclusion: Offering OTC EC is feasible, acceptable, and may increase access to effective contraception. Improving contraceptive choice remains important towards reducing the continued unmet need for underserved populations. Existing evidence suggests OTC EC does not substantively change reproductive health outcomes, but evidence gaps remain due to limited studies in low-resource settings.

Keywords: emergency contraceptives, contraceptives, pregnancy, pharmaceutical services

Systematic review registration number: PROSPERO CRD42021231625

Strengths and limitations of this study

- Emergency contraception is recommended by the World Health Organization and can prevent up to 95% of pregnancies when taken within five days of intercourse. Expanding access to over-the-counter emergency contraception without prescription can promote people's autonomy in health decision-making and could increase contraception coverage and uptake.
- Evidence from 19 studies suggests that providing emergency contraception over-the-counter or at pharmacies results in no substantial changes in EC use or sexual practices and behavior, and may reduce abortion rates.
- User and provider support for over-the-counter emergency contraception is motivated by convenience, privacy, comfort, control, cost, and effectiveness amidst concerns about increased risk behavior, repeat use, and less clinician support.
- Evidence from three studies suggests that providing emergency contraception in pharmacies may lower health sector costs.
- Providing emergency contraception over-the-counter or in pharmacies does not negatively impact sexual and reproductive health outcomes, and may be a preferred option for many users.

Introduction

The World Health Organization (WHO) recommends the use of several forms of emergency contraception (EC), which can substantially reduce unintended pregnancy when used correctly [1, 2]. Reducing barriers to EC may increase access to effective contraceptive options, reduce unintended pregnancies, and overall improve sexual and reproductive health and rights (SRHR) outcomes.

In many settings, EC is delivered through one or more modalities [3]: (1) prescription-only, wherein physicians or other medical providers prescribe EC 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) OTC, wherein medication is available on store shelves without a prescription. While both pharmacy access and OTC may reduce barriers to access by no longer requiring a visit to a physician or other health care 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 [4], the WHO is responsible to provide overall guidance to critical questions of intervention recommendations. The 2019 WHO normative guidance on self-care interventions [5] included a recommendation on OTC oral contraception (contraceptive pills). This was informed by a previous systematic review [6], in which we found that OTC oral contraception may result in higher continuation and limited contraindications among users, and was generally supported by patients and providers. This earlier review and the 2019 WHO guidance did not include OTC delivery of EC. 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 [7]. WHO has prioritized self-care interventions in response to maintaining essential sexual and reproductive health 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 [7-10]. 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 [11], which may lead more women and girls to need and/or use OTC EC. 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 EC.

Methods

This review addressed the following question: Should emergency contraceptive pills 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. The review followed Preferred Reporting Items for Systematic Review and Meta-Analyses (PRISMA) guidelines [12], and the protocol was published on PROSPERO (registration number CRD42021231625). Ethical approval was not required for this systematic review, since all data came from information freely available in the public domain (i.e. published articles).

Effectiveness review inclusion criteria

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

- **Population**: Individuals using emergency contraceptive pills
- **Intervention**: Availability of EC OTC (without a prescription or screening) or from a pharmacist (behind-the-counter or pharmacy access)
- **Comparison**: Availability of EC by prescription only (by a clinician other than a pharmacist)
- **Outcomes**: (1) Uptake of EC (initial use); (2) Correct use of EC, including comprehension of product label instructions; (3) Unintended pregnancy; (4) Abortion (medical or unsafe); (5) Changes in sexual and reproductive health (SRH) practices or behavior; (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 EC to prescription-only access (including randomized controlled trials (RCTs), non-randomized 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 IUD insertion can also be a form of EC, it requires insertion by a provider and thus cannot be made available OTC. This review thus focuses on emergency contraceptive pills. Studies that examined the provision of EC 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 (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 December 2, 2020, using consistent search strings including a list of oral and emergency contraceptives, plus terms associated with medication provision without a prescription (see Appendix).

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 standardized 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:

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

For RCTs, we assessed risk of bias using the Cochrane Collaboration's tool for assessing risk of bias [13]. For studies that were non-randomized trials comparative, we assessed study rigor using the Evidence Project eight-item risk of bias tool [14].

Data analysis

We analyzed 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 with the Comprehensive Meta-Analysis program.

For each outcome assessed in the review, we summarized data in GRADE Evidence Profile tables using GRADEPro [15]. 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 vs true OTC; (2) point of access (e.g. stores, pharmacies, telehealth, etc.); (3) type of EC pills (progestin-only vs ulipristal acetate vs combined vs mifepristone); (4) prior use of contraception; (5) age group; (6) vulnerabilities (e.g. poverty, disability, religion, literacy); (7) high-income vs low- or middle-income setting.

Additional reviews

We conducted additional reviews examining values and preferences and costs of OTC provision of EC. 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 summarized 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 emergency contraceptive pill. 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 emergency contraceptive pills 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 organized 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 [16-36], 56 values and preferences studies [37-91], and three cost studies [92-94].

Figure 1. PRISMA flow chart showing disposition of citations through the search and screening process.

Effectiveness review

Overall, 19 studies from eight countries (published in 21 articles) met the inclusion criteria for the effectiveness review [16-36] (Table 1). This included one 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 EC uptake, changes in SRH practices and behavior, or abortion. Only one study [25, 33, 34] assessed

side effects, adverse events, or social harms. There was no comparative data on correct use of emergency contraceptive pills or self-efficacy, self-determination, autonomy, or empowerment. Effect sizes are reported by outcome in Table 2.

EC uptake

Nine studies reported on the impacts of OTC and pharmacy-access EC on EC use, prescribing, and uptake. Evidence from one RCT [33] showed no difference in use of EC with pharmacy access (RR 1.15, 95% CI: 0.90-1.48). In the same trial, there were no differences in EC use by age [25]. Three serial cross-sectional studies similarly found no changes in overall EC use over time with implementation of OTC access in Finland [23], the UK [27], and Australia [30]. 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 EC within 24 hours of sex increased with pharmacy access in the UK (18% increase; p=0.03) [26] and the USA (aOR 2.17, 95% CI: 1.06-4.44) [35]. 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 assessing rates of pharmacy distribution in a safety-net hospital showed that EC distribution increased by 800% over a 1.5-year period, while EC prescribing increased by 50% over the same period [32]. 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 EC use increased from 15.3% before EC was available OTC to 21.5% in the year after OTC EC became available (X^2=1.54, p=0.24), before decreasing 8.5% another year following OTC availability (X^2=7.11, p=0.01) [27]. Potential bias in this study was from having no comparison group (pre/post only).

Unintended pregnancy

Three studies assessed pregnancy as an outcome, which does not explicitly consider whether the pregnancy was intended but is an indirect proxy measure. The one RCT found no significant change in pregnancy among women who did not wish to become pregnant (RR 0.82, 95% CI: 0.53-1.27) [33]; this did not differ by age [25]. 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) [31]. This finding was determined to have risk of bias based on having no comparator or control for confounders. Finally, an ecological study assessing changes in conception rate over time in the UK 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) [24]. 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 EC on abortion rates per 1,000 women, all with risk of bias related to lack of comparison groups or pre/post data [20-22, 29]. These studies found no difference in overall abortion rates with pharmacy-access EC. Evidence from one study among 18- to 19-year-olds showed a decrease of 1.6 abortions per 1,000 women after pharmacy-access EC became available in the USA (p<0.05) [21]. Another study among 15- to 19-year-olds found a decrease of 1.97 abortions per 1,000 (p<0.01).

Finally, evidence from one serial cross-sectional study showed that reporting ever having an abortion declined from 17.0% before OTC EC access to 15.6% after OTC EC access (p=0.04) [28]. Bias in this study was related to lack of a comparison group (pre/post only).

Sexual health-related practices and behavior

Seven studies assessed outcomes related to SRH practices and behavior. 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: 0.95-1.61), condom use at last sex (RR 0.92, 95% CI: 0.81-1.05), consistent condom use (RR 1.07, 95% CI 0.76-1.51), change in contraceptive method (RR 1.16, 95% CI: 0.92-1.47) or missed contraceptive pills (among pill users; RR 0.92, 95% CI: 0.80-1.06) [33]. The same RCT found decreases in unprotected intercourse with increased access to OTC EC (RR 0.82, 95% CI: 0.70-0.97). These findings did not vary by age [25].

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 EC in German-speaking Switzerland [16]. 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 EC had no effect on sexual activity or contraceptive use over time [17, 18], though it reduced condom use among adolescents by 5.2% to 7.2% ($p<0.01$) [18]. 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 EC was associated with reduced reporting of five or more sexual partners (30.6% without OTC access vs 9.6% with OTC access; $p<0.001$) [19]. Bias in this study were 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 EC and found that there was no difference in reporting being pressured into sex (RR 0.82, 95% CI: 0.43-1.56) [33]. For this outcome, there was no difference in age subgroup analyses [25].

Table 1. Description of included studies.

Study	Study Design	Location	Population	Intervention*	Outcomes
Arnet et al. 2009	Pre/Post	Switzerland: Basel, Bern, Zurich	Women aged 15-49 accessing EC at pharmacies; 2003, 2006 N=729	Pharmacy access	5. SRH practices or behavior
Atkins & Bradford 2015	Serial Cross-Sectional	USA: ME, NH, VT, RI	Public school students who responded to sexual activity questions in Youth Risk Behavior Survey; 2003-2009 N=49,454	Pharmacy access	5. SRH practices or behavior
Atkins 2014	Serial Cross-Sectional	USA: national	Non-pregnant women of aged 18-45 who responded to NHANES; 2001-2004, 2007-2010 N=NR	Pharmacy access	5. SRH practices or behavior
Bumbul et al. 2013	Cross-Sectional	Poland: Warsaw Lithuania: Vilnius	Female students and high school pupils N=1,366	OTC access	1. EC uptake 5. SRH practices or behavior
Cintina & Johansen 2015	Ecological	USA: national (states except AK, DC, DE, HI, IA, MA, ME, NJ, NM, VT, WA)	Women aged 15-19 years; 2000-2010 N=NR	Pharmacy access	4. Abortion
Cintina 2017	Ecological	USA: WA, OR, ID	Women aged 15-44 N=1,747	Pharmacy access	4. Abortion
Durrance 2013 †	Ecological	USA: WA	Women aged 15-24 years; 1993-2005 N=507	Pharmacy access	4. Abortion
Falah-Hassani,et al. 2007	Serial Cross-Sectional	Finland: national	Adolescents aged 12-18; 1991, 2001, 2003 N=12,121	OTC access	1. EC uptake
Girma & Paton 2011	Ecological	UK: national	Women aged 13-44; 1998-2004 N=NR	OTC access	3. Unintended pregnancy
Harper et al. 2005; Raine et al. 2005; Rocca et al. 2007	RCT	USA: California: San Francisco	Women aged 15-24 attending clinics providing family planning; not desiring pregnancy, using long-term hormonal contraception or requesting EC; 2001-2003 N=2,117	Pharmacy access	1. EC uptake 3. Unintended pregnancy 5. SRH practices or behavior 7. Side effects, adverse events, social harms
Killick & Irving 2004	Cross-Sectional	UK: national	Women accessing EC at pharmacies N=419	Pharmacy access	1. EC uptake

Marston et al. 2005	Serial Cross-Sectional	UK: national	Women aged 16-49 who responded to Omnibus survey; 2000-2002 N=5,984	OTC access	1. EC uptake 5. SRH practices or behavior
Moreau et al. 2006	Serial Cross-Sectional	France: national	Women aged 15-44 years responding to national health surveys; 1999, 2004 N=11,656 (1999: 4,146; 2004: 7,490)	OTC access	4. Abortion
Mulligan 2016	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; 1997-2009 N=4385 for 1997 NLSY; otherwise NR	Pharmacy access	4. Abortion
Novikova et al. 2009	Serial Cross-Sectional	Australia: Sydney	Women attending abortion clinics N=718	OTC access	1. EC uptake
Payaka-chat et al. 2010	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 behavior
Pentel et al. 2004	Ecological	USA: MN: Minneapolis	Female patients at a safety-net hospital N=NR	Pharmacy access	1. EC uptake
Rubin et al. 2011	Cross-Sectional	USA	Females aged 14-19 who had engaged in unprotected sex while aware of EC N=531	Pharmacy access	1. EC uptake
Soon et al. 2005	Retrospective Cohort	Canada: British Columbia	Women aged 10-59 who received EC prescriptions from 1996-2002 N=1,172	Pharmacy access	1. EC uptake

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

Table 2. Summary of results.

No. and type of studies	Specific Outcome	N (%) or Mean (SD)		Effect
		OTC/pharmacy access	Prescription-only availability	
PICO Outcome 1: EC Uptake				
1 RCT **[33]**	EC use	197/814 (24.2%)	65/310 (21.0%)	**RR 1.15** (0.90-1.48)
1 Retrospective cohort **[36]**	Physician prescribing of EC	2001: 9,447 2002: 10,669	1996-2000: 8,805/year (95% CI: 7,823-9,787)	NR
3 serial cross-sectional **[23, 27, 30]**; 3 cross-sectional **[19, 26, 35]**	EC use	**Summary:** All studies found no difference in EC use overall or by age subgroups with increased OTC EC access. Two studies found increased use of EC within 24 hours (X^2: 17.08; p=0.03 [26]; aOR 2.17; 95% CI: 1.06-4.44 [35]).		
1 ecological **[32]**	EC distribution from pharmacies	**Summary:** EC distribution from a hospital pharmacy increased by 800% over 1.5 years, while prescription use of EC increased by 50%.		
PICO Outcome 3: Unintended Pregnancy				
1 RCT **[33]**	Unintended pregnancy	58/814 (7.1%)	27/310 (8.7%)	**RR 0.82** (0.53-1.27)
1 cross-sectional **[31]**	Unintended pregnancy	88 (90.7%)	24 (72.7%)	p=0.02
1 ecological **[24]**	Conception rate	**Summary:** Among women aged 13-15, 15-17, and 15-19, there was no change in EC use with increased access to OTC EC. Among women aged 25-44, increased access was associated with increased use (p<0.05).		
PICO Outcome 4: Abortion				
4 ecological **[20-22, 29]**	Abortion rate per 1000 women	**Summary:** Most studies found no difference in abortion rates with increased access to OTC EC. Two studies identified significant decreases among younger age groups: a decrease of 1.6 abortions per 1,000 18-19 year old women (p<0.05) [21], and a decrease of 1.97 per 1,000 among women aged 15-19 (p<0.01) [29].		
1 serial cross-sectional **[28]**	Abortion (ever)	1168/7490 (15.6%)	708/4166 (17.0%)	p=0.04
PICO Outcome 5: Sexual health-related practices and behavior				
1 RCT **[33]**	Unprotected sex	274/814 (33.7%)	127/310 (41.0%)	**RR 0.82** (0.70-0.97)
	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 **[16]**	Condom use	220/333 (66.0%)	232/350 (66.3%)	NS
	Oral contraceptive use	69/333 (20.7%)	90/350 (25.7%)	NS
	OC + condoms	10/333 (3.0%)	7/350 (2.0%)	NS
	Unprotected sex	17/340 (5.0%)	25/361 (6.9%)	NS
	Missed pills	53/79 (67.1%)	47/97 (48.5%)	NS
3 serial cross-sectional**[17, 18, 27]**; 2 cross-sectional **[19, 31]**	Multiple partners	**Summary:** Increased access to OTC EC had mixed effects. One study [17] identified a 5.2% increase in reporting multiple partners (p<0.01); another study [19] identified a decrease from 30.6% to 9.6% reporting multiple partners (p<0.004).		
	Contraceptive use	**Summary:** Overall, studies found no difference in oral contraceptive use with increased access to OTC EC. One study [17] found a 7.6% decrease in injectable contraceptive use (p<0.05).		
	Condom use	**Summary:** One study [27] identified no difference in condom use with increased access to OTC EC. Another study [18] found it decreased condom use among public school students by between 5.2% and 7.2% (p<0.01).		
PICO Outcome 7: Side effects, adverse events, and social harms				
1 RCT **[33]**	Pressured into sex	28/814 (3.4%)	13/310 (4.2%)	**RR 0.82** (0.43 -1.56)
NS = not significant at p<0.05 NR = not reported				

Values and preferences review

Overall, 56 studies from 33 countries were included in the values and preferences review (Figure 2) [26, 37-91]. There were 39 quantitative studies (all cross-sectional surveys), 11 qualitative studies, and six mixed-methods studies. Twenty-two studies included end-users, 33 studies included pharmacists or other health care providers or professional stakeholders, and one study included both groups. One study [26] 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.

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

Of the values and preferences studies among end-users, support for OTC EC varied widely within and across countries, ranging from 12% among college students in India [65] to 100% among women who used OTC EC in Sweden [37]. In one study, where women could choose whether to obtain EC from a pharmacist or a physician [26], satisfaction with information received was 91% among those receiving EC in pharmacies, compared to 58% among those receiving prescription-only EC (p=0.006). Broadly, end-users supported OTC EC 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 EC 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 behavior. One study noted this concern was for others; the individuals participating in the study, all of whom were EC users, did not believe their own behavior would be shaped by EC use [70].

Of the values and preferences studies among pharmacists and other health care providers and professionals, support for OTC EC ranged widely. In quantitative surveys, pharmacist support ranged from 16% in South Dakota, USA [58] to 97% in San Francisco, USA [48]. Among doctors, support was generally lower, ranging from 6.1% in South Korea [76] to 68.9% in Canada [74]. Broadly, providers supported OTC EC 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 [38] and concerns about long-term impacts of repeat EC use [79]. In contrast, one study found that providers supported OTC delivery as they saw EC as having relatively few side effects [76]

Providers were also found to have concerns about increased risk behavior, misuse/repeat use of EC, and communication. Specifically regarding communication, providers felt concerned about discouraging other contraceptives [47, 62, 74, 77, 82], and felt that OTC delivery might preclude delivery of necessary education and counseling. In some studies, providers had religious/moral concerns about OTC delivery [41, 45, 54, 62, 82]. One study found that these concerns were more common among providers who believed EC was an abortifacient [54].

Cost review

Three studies met inclusion criteria for the cost review (Table 3) [92-94]. All were modelling studies, two from the USA [92, 93] and one from Canada [94]. All examined the impact of pharmacy-access EC (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.

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

Study	Location	Study design	Impact of pharmacy access
Marciante et al., 2001	USA	Decision model	Among private payers (private insurance): $158 (95% CI=$76, $269) reduction in cost per woman having unprotected intercourse Among public payers: $48 (95% CI=$16, $93) reduction in cost per woman having unprotected intercourse
Soon et al., 2007	Canada	Three decision model	One-year cost saving to the Ministry of Health (MOH) of $0.64 million (95% CI: $0.24 million, $1.28 million). In sensitivity analyses, there were no set of assumptions that would lead to pharmacy access increasing costs to the MOH.
Foster et al., 2010	USA	Markov model	For Medicare: Compared to no EC 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 to 2.49 For prescription-only access: range 1.00 to 1.56

Discussion

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

For most outcomes, our review did not identify any substantial or concerning differences in subgroup analyses by age. Observational evidence included in our review showed that abortion rates decreased significantly among younger age groups with increased access to OTC EC [21, 29], while there was no significant difference in the overall population of women. Given the unique barriers faced by younger women accessing prescription-only EC in many settings, it may be that increased access to OTC EC has unique benefits for younger women. Given that 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 [11, 95], access to contraceptive choice for these younger women is particularly important. This should be explored further.

Due to lack of data, we were not able to compare outcomes by other subgroups (e.g. point of access, type of EC pills, or vulnerabilities). This is an important area for further exploration, given self-care interventions may present unique opportunities and challenges for different populations and in different settings [5]. Equitable implementation of OTC EC 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 SRHR and key factors affecting delivery, uptake, and impact of OTC EC [96].

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

While many studies found that women valued the privacy and control offered by OTC EC, two studies found that women were concerned about having limited interaction with providers in true OTC delivery [37, 75]. In both studies, while there was widespread support for OTC availability of EC (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 EC is offered as one of an array of options including receiving EC 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 EC in a pharmacy or from a physician [26], EC use and knowledge was similar between groups, but pharmacy-access EC resulted in higher use and

satisfaction. Given this and our findings about OTC EC's effectiveness, blended delivery modalities wherein users can choose where and how to access EC may be most responsive to user preferences.

Providers also expressed concern that OTC EC might not allow for sufficient education or counseling, including about how to use OTC EC correctly and counseling about other routine SRH services (including use of other contraceptives and screenings for cervical and breast cancers and sexually transmitted infections [STIs]). In our effectiveness review, we did not identify any studies assessing correct use of OC in OTC vs prescription-only delivery modalities. While knowledge of ECs was not one of our PICO outcomes, one study from the UK found no significant difference in correct knowledge of EC between women receiving EC from a physician vs OTC, with correct knowledge >90% for both groups [26], and another found no significant difference between OTC and prescription delivery in reporting adequate information received about EC [30]. Future research should assess whether correct knowledge of EC translates to correct use in OTC modalities.

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 [6]. We did not assess 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 EC [19, 25, 29, 33], while others identified increases in STI acquisition among younger age groups [22, 24]. Because this evidence is primarily from observational studies, it is unclear through what mechanisms OTC EC may impact STI acquisition, and if routine preventive SRH care plays a role. This should be investigated further, particularly in light of the finding that these phenomena may differ for younger vs. older women.

Results from OTC EC cost studies are promising, though limited. In our three included studies from the US 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 EC access expands. Indeed, several included values and preferences studies noted increased cost as a concern [37, 61, 74, 79]. On the other hand, some studies have shown that increased cost was perceived as a benefit, as it may deter repeat or overuse of EC [49, 61].

Finally, though OTC EC is 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 EC's 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 (DRC) was represented in a lone study [59]. Meaningful efforts are needed to recognize, invest in, and promote future research on the effects of increased OTC EC in low- and middle-income countries, including from user and cost perspectives.

Conclusion

Increasing OTC contraceptive choice and availability is an urgent need for many women and girls. OTC EC is 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 SRHR outcomes.

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Contributions

MN conceptualized the study. CEK and PTY designed the protocol with feedback from MN. PTY ran the database search and oversaw search, screening, full text review, and data extraction processes. CEK and PTY performed data analysis. KA and PTY assessed quality and risk of bias. CEK and KA drafted the manuscript. PTY and MN reviewed the draft, provided critical review, and read and approved the final manuscript. The corresponding author, as guarantor, accepts full responsibility for the finished article has access to any data and controlled the decision to publish. The corresponding author attests that all listed authors meet the authorship criteria and that no others meeting the criteria have been omitted.

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Competing interests

None declared.

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Not required.

Provenance and peer review

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Ethical approval was not required for this systematic review, since all data came from published articles.

Data availability statement

Extracted data are available on request to the corresponding author.

Transparency declaration

The corresponding author, as guarantor, affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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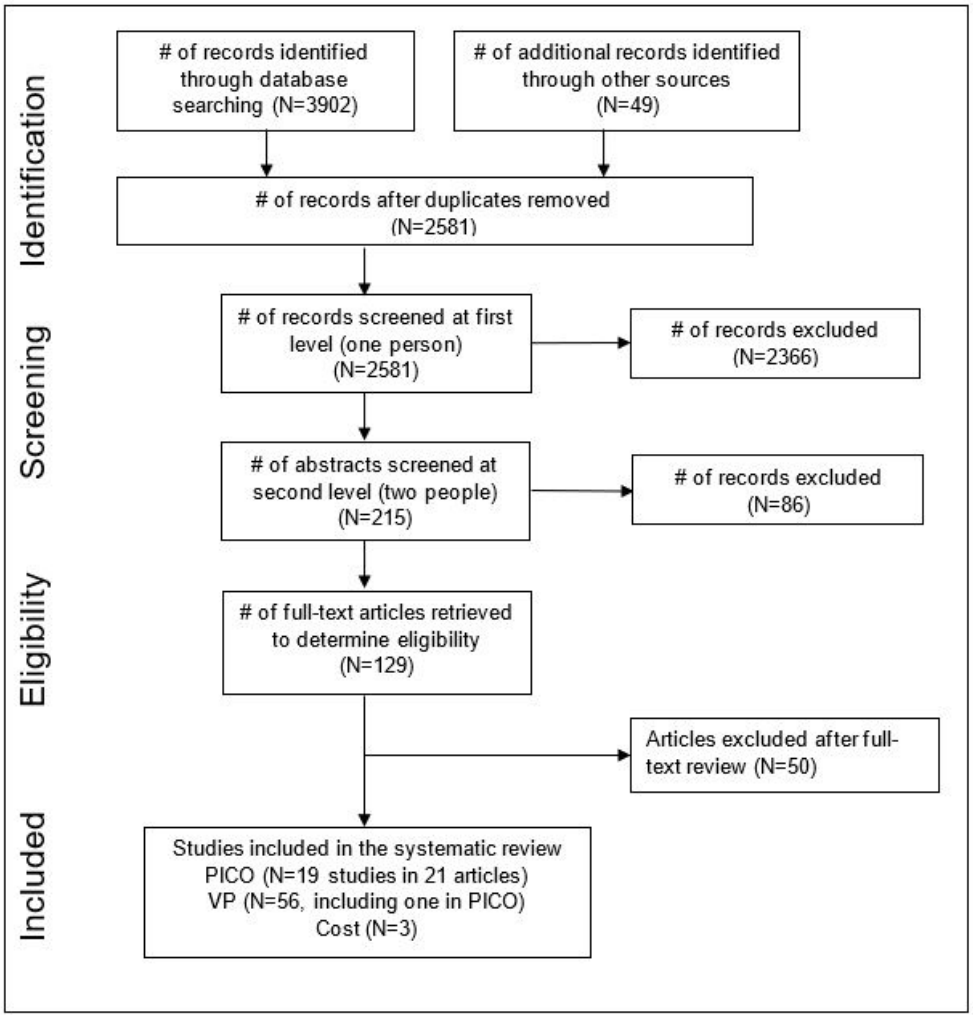

Figure 1. PRISMA flow chart showing disposition of citations through the search and screening process.

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

273x157mm (120 x 120 DPI)

APPENDIX: Search Strategy

The following search strategy was adapted for entry into all computer databases. These search terms were used both for the main systematic review (PICO question) and for the values and preferences and cost reviews.

("Contraceptives, Oral" [Mesh] OR "Contraceptives, Postcoital" [Mesh] OR "emergency contraceptive pill" [tiab] OR "emergency contraceptive pills" [tiab] OR "morning-after pill" [tiab] OR "Plan B One-Step" [tiab] OR "Take Action" [tiab] OR "Next Choice One-Dose" [tiab] OR "My Way" [tiab] OR "AfterPill" [tiab] OR "Preventeza" [tiab] OR "My Choice" [tiab] OR "Aftera" [tiab] OR "Athentia Next" [tiab] OR "EContra Ez" [tiab] OR "Fallback Solo" [tiab] OR "Opcicon One-Step" [tiab] OR "Option 2" [tiab] OR "Afirmelle" [tiab] OR "Altavera" [tiab] OR "Amethia" [tiab] OR "Amethia Lo" [tiab] OR "Amethyst" [tiab] OR "Aubra" [tiab] OR "Ayuna" [tiab] OR "Aviane" [tiab] OR "Camrese" [tiab] OR "CamreseLo" [tiab] OR "Chateal" [tiab] OR "Cryselle" [tiab] OR "Elinest" [tiab] OR "Enpresse" [tiab] OR "Falmina" [tiab] OR "Introvale" [tiab] OR "Jolessa" [tiab] OR "Kurvelo" [tiab] OR "Lessina" [tiab] OR "Lenovest" [tiab] OR "Levora" [tiab] OR "LoSeasonique" [tiab] OR "Low-Ogestrel" [tiab] OR "Lutera" [tiab] OR "Marlissa" [tiab] OR "Myzilra" [tiab] OR "Nordette" [tiab] OR "Orsythia" [tiab] OR "Portia" [tiab] OR "Quasense" [tiab] OR "Seasonale" [tiab] OR "Seasonique" [tiab] OR "Setlakin" [tiab] OR "Sronyx" [tiab] OR "Triphasil" [tiab] OR "Trivora" [tiab] OR "Vienva" [tiab] OR "After-1" [tiab] OR "Agesta" [tiab] OR "Ai Wu You" [tiab] OR "Aleze EC" [tiab] OR "Alterna" [tiab] OR "Amor" [tiab] OR "An Ting" [tiab] OR "Anlitin" [tiab] OR "Anthia" [tiab] OR "Auxxil" [tiab] OR "Bao Shi Ting" [tiab] OR "Bi Yun" [tiab] OR "Ciel EC" [tiab] OR "Contragest" [tiab] OR "Contraplan II" [tiab] OR "Control NF" [tiab] OR "Control Uno" [tiab] OR "Copill" [tiab] OR "Curesinor" [tiab] OR "D-Sigyent" [tiab] OR "Dan Mei" [tiab] OR "Dia S MP" [tiab] OR "Diad" [tiab] OR "Dreams" [tiab] OR "Duet" [tiab] OR "Duprisal 30" [tiab] OR "Dvella" [tiab] OR "E Pills" [tiab] OR "E-72" [tiab] OR "e-con" [tiab] OR "ECee2" [tiab] OR "ECP" [tiab] OR "ella" [tiab] OR "ellaOne" [tiab] OR "Emcon" [tiab] OR "Emergyn" [tiab] OR "Emkit" [tiab] OR "Emkit Plus" [tiab] OR "Escapel" [tiab] OR "Escapel-1" [tiab] OR "Escapel-2" [tiab] OR "Escapelle" [tiab] OR "Escinor" [tiab] OR "Estinor" [tiab] OR "Evadir 2" [tiab] OR "Evital" [tiab] OR "Evitarem" [tiab] OR "Fermerleve Sagiram" [tiab] OR "Feminor" [tiab] OR "Fertilan" [tiab] OR "Fu Nai Er" [tiab] OR "G-Nancy" [tiab] OR "Glanique" [tiab] OR "Glanix" [tiab] OR "Glostinor 2" [tiab] OR "Gynepriston" [tiab] OR "Gynotrel 2" [tiab] OR "Hispratel" [tiab] OR "Hou Ding Nuo" [tiab] OR "Hua Dian" [tiab] OR "Hui Ting" [tiab] OR "i-pill" [tiab] OR "Imediat" [tiab] OR "Imediat N" [tiab] OR "Impreviat" [tiab] OR "Jin Xiao" [tiab] OR "Jin Yu Ting" [tiab] OR "Ka Rui Ding" [tiab] OR "L Novafem" [tiab] OR "Laliades" [tiab] OR "Le Ting" [tiab] OR "Lenor 72" [tiab] OR "Levo-72" [tiab] OR "Levodonna" [tiab] OR "Levogest" [tiab] OR "Levogynon 1500" [tiab] OR "Levonelle" [tiab] OR "Levonelle-1" [tiab] OR "Levonia" [tiab] OR "Levonorgestrol Biogaran 1500" [tiab] OR "Levonorgestrel Richter" [tiab] OR "Levonormin" [tiab] OR "Lonel" [tiab] OR "Longil" [tiab] OR "Lydia 1Safe Pill" [tiab] OR "Lydia Post Pill" [tiab] OR "Madonna" [tiab] OR "Max-72" [tiab] OR "Me Tablet" [tiab] OR "Mergynex" [tiab] OR "Mifepristone 72" [tiab] OR "Mifestad 10" [tiab] OR "Minipil 2" [tiab] OR "Morning After" [tiab] OR "MS Pill" [tiab] OR "Negele" [tiab] OR "Nerostinor" [tiab] OR "Next Choice" [tiab] OR "Nicpostinew" [tiab] OR "Nogestrol" [tiab] OR "Nogravide" [tiab] OR "Norgestrel Max Unidosis" [tiab] OR "Norgestrel-Max" [tiab] OR "NorLevo" [tiab] OR "Nortrel 2" [tiab] OR "Novalen" [tiab] OR "Oportuna" [tiab] OR "Optinor" [tiab] OR "Ovocease" [tiab] OR "Ovulol" [tiab] OR "P2" [tiab] OR "PiDaNa" [tiab] OR "Pilem" [tiab] OR "Pill 72" [tiab] OR "Pillanor 2" [tiab] OR "Pillex" [tiab] OR "Pilule S" [tiab] OR "Planfam" [tiab] OR "Poslov" [tiab] OR "PostDay" [tiab] OR "Poster Tablets" [tiab] OR "Postiga 4" [tiab] OR "Postinor" [tiab] OR "Postinor 1" [tiab] OR "Postinor 1.5" [tiab] OR "Postinor 1500" [tiab] OR "Postinor 2 SD" [tiab] OR "Postinor Duo" [tiab] OR "Postinor Life" [tiab] OR "Postinor PI" [tiab] OR "Postinor Uno" [tiab] OR "Postinor-2" [tiab] OR "Postinor-2 Unidosis" [tiab] OR "Postpill" [tiab] OR "Pozato" [tiab] OR "Pozato Uni" [tiab] OR "PPMS" [tiab] OR "Pregnon" [tiab] OR "Pregnon 1" [tiab] OR "Pregnon 1.5" [tiab] OR "Prevemb" [tiab] OR "Preventol" [tiab] OR "Previdez 2" [tiab] OR "Previfem" [tiab] OR "Prevyol" [tiab] OR "Prikul" [tiab] OR "Pronta" [tiab] OR "Prudence for Her" [tiab] OR "Rely-X" [tiab] OR "Revoke 1.5" [tiab] OR "Revoke 72" [tiab] OR "Rigesoft" [tiab] OR "Rogotinor" [tiab] OR "Secufem" [tiab] OR "Seguidet" [tiab] OR "Segurit" [tiab] OR "Segurite UD" [tiab] OR "SEKURE" [tiab] OR "Sendinor 2" [tiab] OR "Sexcon One&One" [tiab] OR "Si Mi An" [tiab] OR "Silogin" [tiab] OR "Smart Lady (Pregnon)" [tiab] OR "So-Ezzy" [tiab] OR "Tace" [tiab] OR "Tibex" [tiab] OR "Truston-2" [tiab] OR "Ulipristal 30" [tiab] OR "Unlevo 1500" [tiab] OR "Unofem" [tiab] OR "Unwanted 72" [tiab] OR "Upostelle" [tiab] OR "UPRIS" [tiab] OR "Vermagest" [tiab] OR "Vika" [tiab] OR "Vikela" [tiab] OR "Vonstrel" [tiab] OR "Xian Ju" [tiab] OR "Yi Ting" [tiab] OR "Yu Ting" [tiab] OR "Zimtemore" [tiab])

AND

(“Nonprescription Drugs” [Mesh] OR nonprescription [tiab] OR “over the counter” [tiab] OR “over-the-counter” [tiab] OR “without a prescription” [tiab] OR “pharmacist-prescribed” [tiab] OR “pharmacy access” [tiab] OR "clinician-prescribed" [tiab] OR "physician-prescribed" [tiab] OR "GP-prescribed" [tiab] OR "general practitioner prescribed" [tiab] OR “without prescription” [tiab] OR "community pharmacy services" [Mesh] OR "community center" [tiab] OR "community centre" [tiab] OR store [tiab] OR shop [tiab] OR online [tiab] OR mobile [tiab] OR telehealth [tiab])

PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	4
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	4
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	2
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	4-5
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	5
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	25
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	5
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	5
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	4-5
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	5
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	NA
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	NA

PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	NA
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	6
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	6
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	6-10
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	6-10
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	6-8, 11-12
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	NA
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	NA
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	7-8
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	14
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	15-16
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	15-16
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	17

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

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Over-the-counter provision of emergency contraceptive pills: A systematic review

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Abstract

Objective: To synthesize 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/behavior, 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 December 2, 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 summarized data in duplicate using GRADE Evidence Profile tables, reporting findings by study design and outcome. We qualitatively synthesized values/preferences and cost data.

Results: We included 19 studies evaluating effectiveness of OTC ECP, 56 on values/preferences, and three on costs. All studies except one were from high- and middle-income settings. Broadly, there were no differences in overall ECP use, pregnancy, or sexual behavior, 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 modeling 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.

Keywords: emergency contraceptives, contraceptives, pregnancy, pharmaceutical services, self-care

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 generalizable, as the majority of studies were conducted in high- and middle-income countries.

Introduction

The World Health Organization (WHO) recommends the use of several forms of emergency contraception, which can substantially reduce unintended pregnancy when used correctly [1, 2]. 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 and rights [3].

In many settings, ECPs are delivered through one or more modalities [4]: (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) 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 [5]. While both pharmacy access and OTC may reduce barriers to access by no longer requiring a visit to a physician or other health care 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 [6], the WHO is responsible to provide overall guidance to critical questions of intervention recommendations. The 2019 WHO normative guidance on self-care interventions [7] included a recommendation on OTC oral contraception (contraceptive pills). This was informed by a previous systematic review [8], 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 [9, 10]. WHO has prioritized self-care interventions in response to maintaining essential sexual and reproductive health 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 [9, 11-13]. 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 [14], 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 [10, 15-17].

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 [18]. The review followed Preferred Reporting Items for Systematic Review and Meta-Analyses (PRISMA) guidelines (see Appendix 1) [19], and the protocol was published on PROSPERO (registration number CRD42021231625). Ethical approval was not required for this systematic review, since all data came from information freely available in the public domain (i.e. published articles).

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 sexual and reproductive health (SRH) practices or behavior; (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 randomized controlled trials (RCTs), non-randomized 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 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 (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 December 2, 2020, using consistent search strings including a list of oral and emergency contraceptives, plus terms associated with medication provision without a prescription (see 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 standardized 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:

- Study identification: Author(s); type of citation; year of publication
- Study description: Study objectives; location; population characteristics; type of ECP; description of OTC access; description of any additional intervention components (e.g. any education, training, support provided); study design; sample size; follow-up periods and loss to follow-up

- Outcomes: Analytic approach; outcome measures; comparison groups; effect sizes; confidence intervals; significance levels; conclusions; limitations

For RCTs, we assessed risk of bias using the Cochrane Collaboration's tool for assessing risk of bias [20]. For studies that were non-randomized comparative trials, we assessed study rigor using the Evidence Project eight-item risk of bias tool (see Appendix 3) [21].

Data analysis

We analyzed 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 with the Comprehensive Meta-Analysis program.

For each outcome assessed in the review, we summarized data in GRADE Evidence Profile tables using GRADEPro [22]. 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 vs true OTC; (2) point of access (e.g. 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 (e.g. poverty, disability, religion, literacy); (7) high-income vs low- 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 summarized 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 organized 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 [23-43], 56 values and preferences studies [44-98], and three cost studies [99-101].

Figure 1. PRISMA flow chart showing disposition of citations through the search and screening process.

Effectiveness review

Overall, 19 studies from eight countries (published in 21 articles) met the inclusion criteria for the effectiveness review [23-43] (Table 1). This included one 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 behavior, or abortion. Only one study [32, 40, 41] assessed side effects, 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.

ECP uptake

Nine studies reported on the impacts of OTC and pharmacy-access ECP on ECP use, prescribing, and uptake. Evidence from one RCT [40] showed no difference in use of ECPs with pharmacy access (RR 1.15, 95% CI: 0.90-1.48). In the same trial, there were no differences in ECP use by age [32]. Three serial cross-sectional studies similarly found no changes in overall ECP use over time with implementation of OTC access in Finland [30], the UK [34], and Australia [37]. 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) [33] and the USA (aOR 2.17, 95% CI: 1.06-4.44) [42]. 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 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 [39]. 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 (X^2=1.54, p=0.24), before decreasing 8.5% another year following OTC availability (X^2=7.11, p=0.01) [34]. 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: 0.53-1.27) [40]; this did not differ by age [32]. 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) [38]. 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 [31], 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) [31]. 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 1,000 women, all with risk of bias related to lack of comparison groups or pre/post data [27-29, 36]. 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 1,000 women after pharmacy-access ECPs became available in the USA (p<0.05) [28]. Another study among 15- to 19-year-olds found a decrease of 1.97 abortions per 1,000 (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) [35]. Bias in this study was related to lack of a comparison group (pre/post only).

Sexual health-related practices and behavior

Seven studies assessed outcomes related to SRH practices and behavior. 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: 0.95-1.61), condom use at last sex (RR 0.92, 95% CI: 0.81-1.05), consistent condom use (RR 1.07, 95% CI 0.76-1.51), change in contraceptive method (RR 1.16, 95% CI: 0.92-1.47) or missed contraceptive pills (among pill users; RR 0.92, 95% CI: 0.80-1.06) [40]. The same RCT found decreases in unprotected intercourse with increased access to OTC ECPs (RR 0.82, 95% CI: 0.70-0.97). These findings did not vary by age [32].

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 [23]. 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 [24, 25], though it reduced condom use among adolescents by 5.2% to 7.2% (p<0.01) [25]. 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; p<0.001) [26]. Bias in this study were 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: 0.43-1.56) [40]. For this outcome, there was no difference in age subgroup analyses [32].

Table 1. Description of included studies.

Study	Study Design	Location	Population	Intervention*	Outcomes
Arnet et al. 2009 **[23]**	Pre/Post	Switzerland: Basel, Bern, Zurich	Women aged 15-49 accessing ECPs at pharmacies; 2003, 2006 N=729	Pharmacy access	5. SRH practices or behavior
Atkins & Bradford 2015 **[25]**	Serial Cross-Sectional	USA: ME, NH, VT, RI	Public school students who responded to sexual activity questions in Youth Risk Behavior Survey; 2003-2009 N=49,454	Pharmacy access	5. SRH practices or behavior
Atkins 2014 **[24]**	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 behavior
Bumbul et al. 2013 **[26]**	Cross-Sectional	Poland: Warsaw Lithuania: Vilnius	Female students and high school pupils N=1,366	OTC access	1. ECP uptake 5. SRH practices or behavior
Cintina & Johansen 2015 **[28]**	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 **[27]**	Ecological	USA: WA, OR, ID	Women aged 15-44 N=1,747	Pharmacy access	4. Abortion
Durrance 2013 **[29]**	Ecological	USA: WA	Women aged 15-24 years; 1993-2005 N=507	Pharmacy access	4. Abortion
Falah-Hassani,et al. 2007 **[30]**	Serial Cross-Sectional	Finland: national	Adolescents aged 12-18; 1991, 2001, 2003 N=12,121	OTC access	1. ECP uptake
Girma & Paton 2011**[31]**	Ecological	UK: national	Women aged 13-44; 1998-2004 N: Not reported	OTC access	3. Unintended pregnancy†
Harper et al. 2005 **[32]**; Raine et al. 2005 **[40]**; Rocca et al. 2007 **[41]**	RCT	USA: California: 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=2,117	Pharmacy access	1. ECP uptake 3. Unintended pregnancy 5. SRH practices or behavior 7. Side effects, adverse events, social harms
Killick & Irving 2004 **[33]**	Cross-Sectional	UK: national	Women accessing ECPs at pharmacies N=419	Pharmacy access	1. ECP uptake
Marston et al. 2005 **[34]**	Serial Cross-Sectional	UK: national	Women aged 16-49 who responded to Omnibus survey; 2000-2002 N=5,984	OTC access	1. ECP uptake 5. SRH practices or behavior

Moreau et al. 2006 **[35]**	Serial Cross-Sectional	France: national	Women aged 15-44 years responding to national health surveys; 1999, 2004 N=11,656 (1999: 4,146; 2004: 7,490)	OTC access	4. Abortion
Mulligan 2016 **[36]**	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; 1997-2009 N=4385 for 1997 NLSY; otherwise not reported	Pharmacy access	4. Abortion
Novikova et al. 2009 **[37]**	Serial Cross-Sectional	Australia: Sydney	Women attending abortion clinics N=718	OTC access	1. ECP uptake
Payaka-chat et al. 2010 **[38]**	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 behavior
Pentel et al. 2004 **[39]**	Ecological	USA: MN: Minneapolis	Female patients at a safety-net hospital N: Not reported	Pharmacy access	1. ECP uptake
Rubin et al. 2011 **[42]**	Cross-Sectional	USA	Females aged 14-19 who had engaged in unprotected sex while aware of ECPs N=531	Pharmacy access	1. ECP uptake
Soon et al. 2005 **[43]**	Retrospective Cohort	Canada: British Columbia	Women aged 10-59 who received ECP prescriptions from 1996-2002 N=1,172	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.

Table 2. Summary of results.

No. and type of studies	Specific Outcome	N (%) or Mean (SD)		Effect	Risk of Bias
		OTC/pharmacy access	Prescription-only availability		
PICO Outcome 1: ECP Uptake					
1 RCT **[40]**	ECP use	197/814 (24.2%)	65/310 (21.0%)	**RR 1.15** (0.90-1.48)	Low
1 Retrospective cohort **[43]**	Physician prescribing of ECPs	2001: 9,447 2002: 10,669	1996-2000: 8,805/year (95% CI: 7,823-9,787)	Not reported	Lack of comparison; no control for confounding
3 serial cross-sectional **[30, 34, 37]**; 3 cross-sectional **[26, 33, 42]**	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 (X^2: 17.08; p=0.03 [33]; aOR 2.17; 95% CI: 1.06-4.44 [42]).			Lack of comparison [30, 34, 37]; No control for confounding [26, 30, 33, 37]; No pre/post [26, 33, 42]
1 ecological **[39]**	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
PICO Outcome 3: Unintended Pregnancy					
1 RCT **[40]**	Unintended pregnancy	58/814 (7.1%)	27/310 (8.7%)	**RR 0.82** (0.53-1.27)	Low
1 cross-sectional **[38]**	Unintended pregnancy	88 (90.7%)	24 (72.7%)	p=0.02	Lack of comparison; no control for confounding
1 ecological **[31]**	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
PICO Outcome 4: Abortion					
4 ecological **[27-29, 36]**	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 1,000 18-19 year old women (p<0.05) [28], and a decrease of 1.97 per 1,000 among women aged 15-19 (p<0.01) [36].			No pre/post [28]; Lack of comparison [27, 29, 36]
1 serial cross-sectional **[35]**	Abortion (ever)	1168/7490 (15.6%)	708/4166 (17.0%)	p=0.04	Lack of comparison
PICO Outcome 5: Sexual health-related practices and behavior					
1 RCT **[40]**	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 **[23]**	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 **[24, 25, 34]**; 2 cross-sectional **[26, 38]**	Multiple partners	**Summary:** Increased access to OTC ECPs had mixed effects. One study [24] identified a 5.2% increase in reporting multiple partners (p<0.01); another study [26] identified a decrease from 30.6% to 9.6% reporting multiple partners (p<0.001).			Lack of comparison [24, 25, 34, 38]; No pre/post [26]; No control for confounding [26, 38]
	Contraceptive use	**Summary:** Overall, studies found no difference in oral contraceptive use with increased access to OTC ECPs. One study [24] found a 7.6% decrease in injectable contraceptive use (p<0.05).			
	Condom use	**Summary:** One study [34] identified no difference in condom use with increased access to OTC ECPs. Another study [25] found it decreased condom use among public school students by between 5.2% and 7.2% (p<0.01).			
PICO Outcome 7: Side effects, adverse events, and social harms					
1 RCT **[40]**	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.					

Values and preferences review

Overall, 56 studies from 33 countries were included in the values and preferences review (Figure 2) [33, 44-98]. There were 39 quantitative studies (all cross-sectional surveys), 11 qualitative studies, and six mixed-methods studies. Twenty-two studies included end-users, 33 studies included pharmacists or other health care providers or professional stakeholders, and one study included both groups. One study [33] 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.

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

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 [72] to 100% among women who used OTC ECPs in Sweden [44]. In one study, where women could choose whether to obtain ECPs from a pharmacist or a physician [33], satisfaction with information received was 91% among those receiving ECPs in pharmacies, compared to 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 behavior. 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 behavior would be shaped by ECP use [77].

Of the values and preferences studies among pharmacists and other health care providers and professionals, support for OTC ECPs ranged widely. In quantitative surveys, pharmacist support ranged from 16% in South Dakota, USA [65] to 97% in San Francisco, USA [55]. Among doctors, support was generally lower, ranging from 6.1% in South Korea [83] to 68.9% in Canada [81]. 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 [45] and concerns about long-term impacts of repeat ECP use [86]. In contrast, one study found that providers supported OTC delivery as they saw ECPs as having relatively few side effects [83].

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

Cost review

Three studies met inclusion criteria for the cost review (Table 3) [99-101]. All were modelling studies, two from the USA [99, 100] and one from Canada [101]. 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.

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

Study	Location	Study design	Impact of pharmacy access
Marciante et al., 2001 **[100]**	USA	Decision model	Among private payers (private insurance): $158 (95% CI=$76, $269) reduction in cost per woman having unprotected intercourse Among public payers: $48 (95% CI=$16, $93) reduction in cost per woman having unprotected intercourse
Soon et al., 2007 **[101]**	Canada	Three decision model	One-year cost saving to the Ministry of Health (MOH) of $0.64 million (95% CI: $0.24 million, $1.28 million). In sensitivity analyses, there were no set of assumptions that would lead to pharmacy access increasing costs to the MOH.
Foster et al., 2010 **[99]**	USA	Markov model	For Medicare: Compared to 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 to 2.49 For prescription-only access: range 1.00 to 1.56

Discussion

OTC ECP effectiveness

We identified 19 studies from eight countries assessing how OTC ECPs influence uptake of ECPs, unintended pregnancy, abortion, and other sexual practices and behavior. Broadly, we found no differences in overall ECP use, pregnancy, or sexual risk behavior 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.

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 [33, 42]. 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 [28, 36], 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 [14, 102], 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 [103, 104]. However, there is some evidence that even with increased access and uptake, ECPs may have minimal impacts on unintended pregnancy or abortion

[105]. 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 [106], 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 [103].

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 [8]. We did not assess 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 [26, 32, 36, 40], while others identified increases in STI acquisition among younger age groups [29, 31]. 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 behavior. However, our effectiveness review found that there were no differences in sexual practices and behavior 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 [44, 82]. 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 [33], 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 counseling, including about how to use OTC ECPs correctly and counseling about other routine SRH services (including use of other contraceptives and screenings for cervical and breast cancers and sexually transmitted infections [107]). In our effectiveness review, we did not identify any studies assessing correct use of OC in OTC vs 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 vs OTC, with correct knowledge >90% for both groups [33], and another found no significant difference between OTC and prescription delivery in reporting adequate information received about ECPs [37].

Cost

Results from OTC ECP cost studies are promising, though limited. In our three included studies from the US 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 [44, 68, 81, 86]. 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 [56, 68].

Areas for future research

Our review highlights some critical areas for future research on OTC ECPs. 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 the impact of OTC ECPs among key subgroups, including younger women. This is important as self-care interventions may present unique opportunities and challenges for different populations and in different settings [7]. 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 sexual and reproductive health and rights and key factors affecting delivery, uptake, and impact of OTC ECPs [108].

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 [66]. Meaningful efforts are needed to recognize, invest in, and promote future research on the effects of increased OTC ECPs in low- 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 did not include grey literature and conference abstracts, which may have provided valuable information given the evolving nature of this field. We also did not include studies of expanded access to ECPs that did not specifically assess OTC availability, such as trials of advance provision of ECPs direct to potential users. Conclusions of this review are also limited by the quality and diversity of included studies. Many observational studies lacked 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 summarized findings qualitatively. Our conclusions are also limited by the concentration of articles in high- 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 sexual and reproductive health and rights outcomes.

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Contributions

MN conceptualized the study. CEK and PTY designed the protocol with feedback from MN. PTY ran the database search and oversaw search, screening, full text review, and data extraction processes. CEK and PTY performed data analysis. KA and PTY assessed quality and risk of bias. CEK and KA drafted the manuscript. PTY and MN reviewed the draft, provided critical review, and read and approved the final manuscript. The corresponding author, as guarantor, accepts full responsibility for the finished article has access to any data and controlled the decision to publish. The corresponding author attests that all listed authors meet the authorship criteria and that no others meeting the criteria have been omitted.

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Competing interests

None declared.

Patient consent for publication

Not required.

Provenance and peer review

Not commissioned; externally peer reviewed.

Ethics statement

Ethical approval was not required for this systematic review, since all data came from published articles.

Data availability statement

All data relevant to the study are included in the article or uploaded as supplementary information. Extracted data are available on request to the corresponding author.

Transparency declaration

The corresponding author, as guarantor, affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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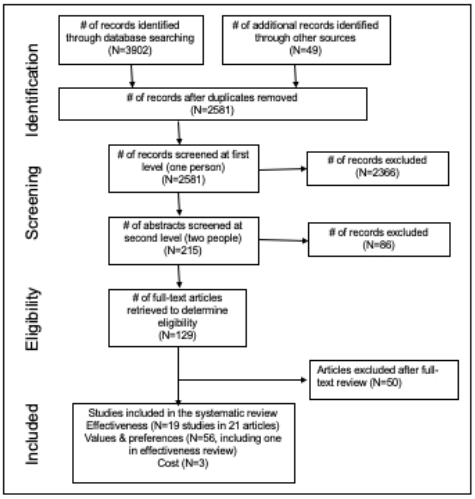

Figure 1. PRISMA flow chart showing disposition of citations through the search and screening process.

338x190mm (54 x 54 DPI)

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

273x157mm (120 x 120 DPI)

PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	4
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	4
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	2
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	4-5
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	5
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	25
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	5
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	5
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	4-5
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	5
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	NA
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	NA

PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	NA
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	6
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	6
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	6-10
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	6-10
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	6-8, 11-12
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	NA
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	NA
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	7-8
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	14
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	15-16
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	15-16
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	17

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

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WHO self-care v2 (2020)
Over the counter emergency contraception
Search strategy documentation

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[tiab] OR "Postinor 1.5" [tiab] OR "Postinor 1500" [tiab] OR "Postinor 2 SD" [tiab] OR "Postinor Duo" [tiab] OR "Postinor Life" [tiab] OR "Postinor PI" [tiab] OR "Postinor Uno" [tiab] OR "Postinor-2" [tiab] OR "Postinor-2 Unidosis" [tiab] OR "Postpill" [tiab] OR "Pozato" [tiab] OR "Pozato Uni" [tiab] OR "PPMS" [tiab] OR "Pregnon" [tiab] OR "Pregnon 1" [tiab] OR "Pregnon 1.5" [tiab] OR "Prevemb" [tiab] OR "Preventol" [tiab] OR "Previdez 2" [tiab] OR "Previfem" [tiab] OR "Prevyol" [tiab] OR "Prikul" [tiab] OR "Pronta" [tiab] OR "Prudence for Her" [tiab] OR "Rely-X" [tiab] OR "Revoke 1.5" [tiab] OR "Revoke 72" [tiab] OR "Rigesoft" [tiab] OR "Rogotinor" [tiab] OR "Secufem" [tiab] OR "Seguidet" [tiab] OR "Segurit" [tiab] OR "Segurite UD" [tiab] OR "SEKURE" [tiab] OR "Sendinor 2" [tiab] OR "Sexcon One&One" [tiab] OR "Si Mi An" [tiab] OR "Silogin" [tiab] OR "Smart Lady (Pregnon)" [tiab] OR "So-Ezzy" [tiab] OR "Tace" [tiab] OR "Tibex" [tiab] OR "Truston-2" [tiab] OR "Ulipristal 30" [tiab] OR "Unlevo 1500" [tiab] OR "Unofem" [tiab] OR "Unwanted 72" [tiab] OR "Upostelle" [tiab] OR "UPRIS" [tiab] OR "Vermagest" [tiab] OR "Vika" [tiab] OR "Vikela" [tiab] OR "Vonstrel" [tiab] OR "Xian Ju" [tiab] OR "Yi Ting" [tiab] OR "Yu Ting" [tiab] OR "Zimtemore" [tiab])

AND

("Nonprescription Drugs" [Mesh] OR nonprescription [tiab] OR "over the counter" [tiab] OR "over-the-counter" [tiab] OR "without a prescription" [tiab] OR "pharmacist-prescribed" [tiab] OR "pharmacy access" [tiab] OR "clinician-prescribed" [tiab] OR "physician-prescribed" [tiab] OR "GP-prescribed" [tiab] OR "general practitioner prescribed" [tiab] OR "without prescription" [tiab] OR "community pharmacy services" [Mesh] OR "community center" [tiab] OR "community centre" [tiab] OR store [tiab] OR shop [tiab] OR online [tiab] OR mobile [tiab] OR telehealth [tiab])

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Appendix 3: Risk of Bias Assessments

Non-Randomized Trials (n=18): Evidence Project Risk of Bias Tool

Citation ID	Pre/Post	Comp. group	Cohort	Baseline Equivalence		Random selection	Random allocation	Control for confounders	Follow-up >=75%	Specific Concerns
				Demos	Outcome					
Arnet et al. 2009 [23]	Yes	No	No	NA	NA	No	No	No	NA	Lack of comparison group, no control for confounding
Atkins & Bradford 2015 [25]	Yes	No	No	NA	NA	No	No	Yes	NA	Lack of comparison
Atkins 2014 [24]	Yes	No	No	NA	NA	No	No	Yes	NA	Lack of comparison
Bumbul et al. 2013 [26]	No	Yes	No	No	NA	NR	No	No	NA	No pre/post, no control for confounding
Cintina & Johansen 2015 [28]	No	Yes	No	NR	NA	No	No	Yes	NA	No pre/post
Cintina 2017 [27]	Yes	No	No	NA	NA	No	No	Yes	NA	Lack of comparison
Durrance 2013 [29]	Yes	No	No	NA	NA	No	No	Yes	NA	Lack of comparison
Falah-Hassani,et al. 2007 [30]	Yes	No	No	NA	NA	Yes	NA	No	NA	Lack of comparison, no control for confounding

										(though random selection)
Girma & Paton 2011[31]	No	Yes	No	No	NA	No	No	Yes	NA	No pre/post
Killick & Irving 2004 [33]	No	Yes	No	NR	NR	No	No	No	NA	No pre/post, no control for confounding
Marston et al. 2005 [34]	Yes	No	No	NA	NA	Yes	No	Yes	NA	Lack of comparison
Moreau et al. 2006 [35]	Yes	No	No	NA	NA	Yes	No	Yes	NA	Lack of comparison
Mulligan 2016 [36]	Yes	No	Yes	NA	NA	NR	No	Yes	NR	Lack of comparison
Novikova et al. 2009 [37]	Yes	No	No	NA	NA	No	No	No	NA	Lack of comparison group, no control for confounding
Payakachat et al. 2010 [38]	Yes	No	No	NA	NA	No	No	No	NA	Lack of comparison group, no control for confounding
Pentel et al. 2004 [39]	Yes	No	No	NA	NA	No	No	No	NA	Lack of comparison group, no control for confounding
Rubin et al. 2011 [42]	No	Yes	No	NA	NA	No	No	Yes	NA	No pre/post
Soon et al. 2005 [43]	Yes	No	No	NA	NA	No	No	No	NA	Lack of comparison group, no control for confounding

Randomized Controlled Trials (n=3 papers reporting 1 RCT): Cochrane Collaboration Tool

Study ID : Harper et al. 2005 [32]; Raine et al. 2005 [40]; Rocca et al. 2007 [41]

Domain 1: Risk of bias arising from the randomization process

Signalling questions	EC use	Pregnancy	Unprotected sex	Consistent condom use	Condom use last sex	Multiple partners	Contraceptive method change	Missed pills	Comments
1.1 Was the allocation sequence random?	Y	Y	Y	Y	Y	Y	Y	Y	
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?	Y	Y	Y	Y	Y	Y	Y	Y	
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	N	N	N	N	N	N	N	N	There was also a slightly higher proportion of blacks in the clinic access group (P=.045), but no other notable differences
Risk-of-bias judgement	Low	Low	Low	Low	Low	Low	Low	Low	
Optional: What is the predicted direction of bias	NA	NA	NA	NA	NA	NA	NA	NA	

arising from the randomization process?									

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	EC use	Pregnancy	Unprotected sex	Consistent condom use	Condom use last sex	Multiple partners	Contraceptive method change	Missed pills	Comments
2.1. Were participants aware of their assigned intervention during the trial?	Y	Y	Y	Y	Y	Y	Y	Y	Blinding not possible given the intervention
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?	Y	Y	Y	Y	Y	Y	Y	Y	
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?	N	N	N	N	N	N	N	N	California legalized pharmacy access six months into the trial, but this is not related to trial context
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?	NA	NA	NA	NA	NA	NA	NA	NA	
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?	NA	NA	NA	NA	NA	NA	NA	NA	
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	Y	Y	Y	Y	Y	Y	Y	Y	Modified ITT used

2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?	NA	NA	NA	NA	NA	NA	NA	NA	
Risk-of-bias judgement	Low	Low	Low	Low	Low	Low	Low	Low	
Optional: What is the predicted direction of bias due to deviations from intended interventions?	NA	NA	NA	NA	NA	NA	NA	NA	

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of adhering to intervention*)

Signalling questions	EC use	Pregnancy	Unprotected sex	Consistent condom use	Condom use last sex	Multiple partners	Contraceptive method change	Missed pills	Comments
2.1. Were participants aware of their assigned intervention during the trial?	Y	Y	Y	Y	Y	Y	Y	Y	Blinding not possible given the intervention
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?	Y	Y	Y	Y	Y	Y	Y	Y	
2.3. [If applicable:] If Y/PY/NI to 2.1 or 2.2: Were important non-protocol interventions balanced across intervention groups?	NA	NA	NA	NA	NA	NA	NA	NA	
2.4. [If applicable:] Were there failures in implementing the intervention that could have affected the outcome?	Y	Y	Y	Y	Y	Y	Y	Y	Yes, deviations because of change in CA law but rerandomized
2.5. [If applicable:] Was there non-adherence to the assigned intervention regimen that could have affected participants' outcomes?	PY	PY	PY	PY	PY	PY	PY	PY	Contamination between groups due to change in law

2.6. If N/PN/NI to 2.3, or Y/PY/NI to 2.4 or 2.5: Was an appropriate analysis used to estimate the effect of adhering to the intervention?	Y	Y	Y	Y	Y	Y	Y	Y	
Risk-of-bias judgement	Some concerns	Some concerns	Some concerns	Some concerns	Some concerns	Some concerns	Some concerns	Some concerns	
Optional: What is the predicted direction of bias due to deviations from intended interventions?	Favors experimental	Favors experimental	Favors experimental	Favors experimental	Favors experimental	Favors experimental	Favors experimental	Favors experimental	

Domain 3: Missing outcome data

Signalling questions	EC use	Pregnancy	Unprotected sex	Consistent condom use	Condom use last sex	Multiple partners	Contraceptive method change	Missed pills	Comments
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	PY	PY	PY	PY	PY	PY	PY	PY	814/889 pharmacy access; 826/884 advance provision; 310/344 clinic access
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?	NA	NA	NA	NA	NA	NA	NA	NA	
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?	NA	NA	NA	NA	NA	NA	NA	NA	
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?	NA	NA	NA	NA	NA	NA	NA	NA	
Risk-of-bias judgement	Low	Low	Low	Low	Low	Low	Low	Low	
Optional: What is the predicted direction of bias due to missing outcome data?	NA	NA	NA	NA	NA	NA	NA	NA	

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	EC use	Pregnancy	Unprotected sex	Consistent condom use	Condom use last sex	Multiple partners	Contraceptive method change	Missed pills	Comments
4.1 Was the method of measuring the outcome inappropriate?	N	N	N	N	N	N	N	N	
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?	N	N	N	N	N	N	N	N	
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?	Y	Y	Y	Y	Y	Y	Y	Y	
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?	PN	PN	PN	PN	PN	PN	PN	PN	
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?	PN	PN	PN	PN	PN	PN	PN	PN	

Risk-of-bias judgement	Low	Low	Low	Low	Low	Low	Low	Low	
Optional: What is the predicted direction of bias in measurement of the outcome?	NA	NA	NA	NA	NA	NA	NA	NA	

Domain 5: Risk of bias in selection of the reported result

Signalling questions	EC use	Pregnancy	Unprotected sex	Consistent condom use	Condom use last sex	Multiple partners	Contraceptive method change	Missed pills	Comments
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?									
	Y	Y	Y	Y	Y	Y	Y	Y	
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...									
5.2. ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	N	N	N	N	N	N	N	N	
5.3 ... multiple eligible analyses of the data?	N	N	N	N	N	N	N	N	
Risk-of-bias judgement	Low	Low	Low	Low	Low	Low	Low	Low	
Optional: What is the predicted direction of bias due to selection of the reported result?	NA	NA	NA	NA	NA	NA	NA	NA	

Overall risk of bias

Overall assessment	EC use	Pregnancy	Unprotected sex	Consistent condom use	Condom use last sex	Multiple partners	Contraceptive method change	Missed pills	Comments
Risk-of-bias judgement	Low	Low	Low	Low	Low	Low	Low	Low	
Optional: What is the overall predicted direction of bias for this outcome?	NA	NA	NA	NA	NA	NA	NA	NA	

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Over-the-counter provision of emergency contraceptive pills: A systematic review

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Over-the-counter provision of emergency contraceptive pills: A systematic review

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Abstract

Objective: To synthesize 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/behavior, 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 December 2, 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 summarized data in duplicate using GRADE Evidence Profile tables, reporting findings by study design and outcome. We qualitatively synthesized values/preferences and cost data.

Results: We included 19 studies evaluating effectiveness of OTC ECP, 56 on values/preferences, and three on costs. All studies except one were from high- and middle-income settings. Broadly, there were no differences in overall ECP use, pregnancy, or sexual behavior, 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 modeling 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.

Keywords: emergency contraceptives, contraceptives, pregnancy, pharmaceutical services, self-care

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 generalizable, as the majority of studies were conducted in high- and middle-income countries.

Introduction

The World Health Organization (WHO) recommends the use of several forms of emergency contraception, which can substantially reduce unintended pregnancy when used correctly [1, 2]. 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 and rights [3].

In many settings, ECPs are delivered through one or more modalities [4]: (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) 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 [5]. While both pharmacy access and OTC may reduce barriers to access by no longer requiring a visit to a physician or other health care 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 [6], the WHO is responsible to provide overall guidance to critical questions of intervention recommendations. The 2019 WHO normative guidance on self-care interventions [7] included a recommendation on OTC oral contraception (contraceptive pills). This was informed by a previous systematic review [8], 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 [9, 10]. WHO has prioritized self-care interventions in response to maintaining essential sexual and reproductive health 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 [9, 11-13]. 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 [14], 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 [10, 15-17].

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 [18]. The review followed Preferred Reporting Items for Systematic Review and Meta-Analyses (PRISMA) guidelines (see Appendix 1) [19], and the protocol was published on PROSPERO (registration number CRD42021231625). Ethical approval was not required for this systematic review, since all data came from information freely available in the public domain (i.e. published articles).

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 sexual and reproductive health (SRH) practices or behavior; (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 randomized controlled trials (RCTs), non-randomized 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 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 (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 December 2, 2020, using consistent search strings including a list of oral and emergency contraceptives, plus terms associated with medication provision without a prescription (see 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 standardized 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:

- Study identification: Author(s); type of citation; year of publication
- Study description: Study objectives; location; population characteristics; type of ECP; description of OTC access; description of any additional intervention components (e.g. any education, training, support provided); study design; sample size; follow-up periods and loss to follow-up

- Outcomes: Analytic approach; outcome measures; comparison groups; effect sizes; confidence intervals; significance levels; conclusions; limitations

For RCTs, we assessed risk of bias using the Cochrane Collaboration's tool for assessing risk of bias [20]. For studies that were non-randomized comparative trials, we assessed study rigor using the Evidence Project eight-item risk of bias tool, which has been shown to have moderate to substantial reliability [21]. 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 analyzed 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 with the Comprehensive Meta-Analysis program.

For each outcome assessed in the review, we summarized data in GRADE Evidence Profile tables using GRADEPro [22]. 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 vs true OTC; (2) point of access (e.g. 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 (e.g. poverty, disability, religion, literacy); (7) high-income vs low- 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 summarized 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 organized 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 [23-43], 56 values and preferences studies [44-98], and three cost studies [99-101].

Figure 1. PRISMA flow chart showing disposition of citations through the search and screening process.

Effectiveness review

Overall, 19 studies from eight countries (published in 21 articles) met the inclusion criteria for the effectiveness review [23-43] (Table 1). This included one 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 behavior, or abortion. Only one study [32, 40, 41] assessed side effects, 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 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 [40] showed no difference in use of ECPs with pharmacy access (RR 1.15, 95% CI: 0.90-1.48). In the same trial, there were no differences in ECP use by age [32]. Three serial cross-sectional studies similarly found no changes in overall ECP use over time with implementation of OTC access in Finland [30], the UK [34], and Australia [37]. 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) [33] and the USA (aOR 2.17, 95% CI: 1.06-4.44) [42]. 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 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 [39]. 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 (X^2=1.54, p=0.24), before decreasing 8.5% another year following OTC availability (X^2=7.11, p=0.01) [34]. 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: 0.53-1.27) [40]; this did not differ by age [32]. 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) [38]. 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 [31], 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 ($p<0.05$) [31]. 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 1,000 women, all with risk of bias related to lack of comparison groups or pre/post data [27-29, 36]. 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 1,000 women after pharmacy-access ECPs became available in the USA ($p<0.05$) [28]. Another study among 15- to 19-year-olds found a decrease of 1.97 abortions per 1,000 ($p<0.01$).

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 ($p=0.04$) [35]. Bias in this study was related to lack of a comparison group (pre/post only).

Sexual health-related practices and behavior

Seven studies assessed outcomes related to SRH practices and behavior. 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: 0.95-1.61), condom use at last sex (RR 0.92, 95% CI: 0.81-1.05), consistent condom use (RR 1.07, 95% CI 0.76-1.51), change in contraceptive method (RR 1.16, 95% CI: 0.92-1.47) or missed contraceptive pills (among pill users; RR 0.92, 95% CI: 0.80-1.06) [40]. The same RCT found decreases in unprotected intercourse with increased access to OTC ECPs (RR 0.82, 95% CI: 0.70-0.97). These findings did not vary by age [32].

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 [23]. 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 [24, 25], though it reduced condom use among adolescents by 5.2% to 7.2% ($p<0.01$) [25]. 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; $p<0.001$) [26]. Bias in this study were 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: 0.43-1.56) [40]. For this outcome, there was no difference in age subgroup analyses [32].

Table 1. Description of included studies.

Study	Study Design	Location	Population	Intervention*	Outcomes
Arnet et al. 2009 **[23]**	Pre/Post	Switzerland: Basel, Bern, Zurich	Women aged 15-49 accessing ECPs at pharmacies; 2003, 2006 N=729	Pharmacy access	5. SRH practices or behavior
Atkins & Bradford 2015 **[25]**	Serial Cross-Sectional	USA: ME, NH, VT, RI	Public school students who responded to sexual activity questions in Youth Risk Behavior Survey; 2003-2009 N=49,454	Pharmacy access	5. SRH practices or behavior
Atkins 2014 **[24]**	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 behavior
Bumbul et al. 2013 **[26]**	Cross-Sectional	Poland: Warsaw Lithuania: Vilnius	Female students and high school pupils N=1,366	OTC access	1. ECP uptake 5. SRH practices or behavior
Cintina & Johansen 2015 **[28]**	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 **[27]**	Ecological	USA: WA, OR, ID	Women aged 15-44 N=1,747	Pharmacy access	4. Abortion
Durrance 2013 **[29]**	Ecological	USA: WA	Women aged 15-24 years; 1993-2005 N=507	Pharmacy access	4. Abortion

Falah-Hassani,et al. 2007 **[30]**	Serial Cross-Sectional	Finland: national	Adolescents aged 12-18; 1991, 2001, 2003 N=12,121	OTC access	1. LCP uptake
Girma & Paton 2011**[31]**	Ecological	UK: national	Women aged 13-44; 1998-2004 N: Not reported	OTC access	3. Unintended pregnancy†
Harper et al. 2005 **[32]**; Raine et al. 2005 **[40]**; Rocca et al. 2007 **[41]**	RCT	USA: California: 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=2,117	Pharmacy access	1. LCP uptake 3. Unintended pregnancy 5. SRH practices or behavior 7. Side effects, adverse events, social harms
Killick & Irving 2004 **[33]**	Cross-Sectional	UK: national	Women accessing ECPs at pharmacies N=419	Pharmacy access	1. LCP uptake
Marston et al. 2005 **[34]**	Serial Cross-Sectional	UK: national	Women aged 16-49 who responded to Omnibus survey; 2000-2002 N=5,984	OTC access	1. LCP uptake 5. SRH practices or behavior
Moreau et al. 2006 **[35]**	Serial Cross-Sectional	France: national	Women aged 15-44 years responding to national health surveys; 1999, 2004 N=11,656 (1999: 4,146; 2004: 7,490)	OTC access	4. Abortion
Mulligan 2016 **[36]**	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; 1997-2009 N=4385 for 1997 NLSY; otherwise not reported	Pharmacy access	4. Abortion

Novikova et al. 2009 **[37]**	Serial Cross-Sectional	Australia: Sydney	Women attending abortion clinics N=718	OTC access	1. ECP uptake
Payaka-chat et al. 2010 **[38]**	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 behavior
Pentel et al. 2004 **[39]**	Ecological	USA: MN: Minneapolis	Female patients at a safety-net hospital N: Not reported	Pharmacy access	1. ECP uptake
Rubin et al. 2011 **[42]**	Cross-Sectional	USA	Females aged 14-19 who had engaged in unprotected sex while aware of ECPs N=531	Pharmacy access	1. ECP uptake
Soon et al. 2005 **[43]**	Retrospective Cohort	Canada: British Columbia	Women aged 10-59 who received ECP prescriptions from 1996-2002 N=1,172	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.

Table 2. Summary of results.

No. and type of studies	Specific Outcome	N (%) or Mean (SD)		Effect	Risk of Bias
		OTC/pharmacy access	Prescription-only availability		
PICO Outcome 1: ECP Uptake					
1 RCT **[40]**	ECP use	197/814 (24.2%)	65/310 (21.0%)	**RR 1.15** (0.90-1.48)	Low
1 Retrospective cohort **[43]**	Physician prescribing of ECPs	2001: 9,447 2002: 10,669	1996-2000: 8,805/year (95% CI: 7,823-9,787)	Not reported	Lack of comparison; no control for confounding
3 serial cross-sectional **[30, 34, 37]**; 3 cross-sectional **[26, 33, 42]**	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 (X^2: 17.08; p=0.03 [33]; aOR 2.17; 95% CI: 1.06-4.44 [42]).			Lack of comparison [30, 34, 37]; No control for confounding [26, 30, 33, 37]; No pre/post [26, 33, 42]
1 ecological **[39]**	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
PICO Outcome 3: Unintended Pregnancy					
1 RCT **[40]**	Unintended pregnancy	58/814 (7.1%)	27/310 (8.7%)	**RR 0.82** (0.53-1.27)	Low
1 cross-sectional **[38]**	Unintended pregnancy	88 (90.7%)	24 (72.7%)	p=0.02	Lack of comparison; no control for confounding
1 ecological **[31]**	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
PICO Outcome 4: Abortion					

4 ecological **[27-29, 36]**	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 1,000 18-19 year old women (p<0.05) [28], and a decrease of 1.97 per 1,000 among women aged 15-19 (p<0.01) [36].			No pre/post [28]; Lack of comparison [27, 29, 36]
1 serial cross-sectional **[35]**	Abortion (ever)	1168/7490 (15.6%)	708/4166 (17.0%)	p=0.04	Lack of comparison
PICO Outcome 5: Sexual health-related practices and behavior					
1 RCT **[40]**	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 **[23]**	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 **[24, 25, 34]**; 2 cross-sectional **[26, 38]**	Multiple partners	**Summary:** Increased access to OTC ECPs had mixed effects. One study [24] identified a 5.2% increase in reporting multiple partners (p<0.01); another study [26] identified a decrease from 30.6% to 9.6% reporting multiple partners (p<0.001).			Lack of comparison [24, 25, 34, 38]; No pre/post [26]; No control for confounding [26, 38]
	Contraceptive use	**Summary:** Overall, studies found no difference in oral contraceptive use with increased access to OTC ECPs. One study [24] found a 7.6% decrease in injectable contraceptive use (p<0.05).			
	Condom use	**Summary:** One study [34] identified no difference in condom use with increased access to OTC ECPs. Another study [25] found it decreased condom use among public school students by between 5.2% and 7.2% (p<0.01).			
PICO Outcome 7: Side effects, adverse events, and social harms					
1 RCT **[40]**	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.					

Values and preferences review

Overall, 56 studies from 33 countries were included in the values and preferences review (Figure 2) [33, 44-98]. There were 39 quantitative studies (all cross-sectional surveys), 11 qualitative studies, and six mixed-methods studies. Twenty-two studies included end-users, 33 studies included pharmacists or other health care providers or professional stakeholders, and one study included both groups. One study [33] 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.

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

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 [72] to 100% among women who used OTC ECPs in Sweden [44]. In one study, where women could choose whether to obtain ECPs from a pharmacist or a physician [33], satisfaction with information received was 91% among those receiving ECPs in pharmacies, compared to 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 behavior. 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 behavior would be shaped by ECP use [77].

Of the values and preferences studies among pharmacists and other health care providers and professionals, support for OTC ECPs ranged widely. In quantitative surveys, pharmacist support ranged from 16% in South Dakota, USA [65] to 97% in San Francisco, USA [55]. Among doctors, support was generally lower, ranging from 6.1% in South Korea [83] to 68.9% in Canada [81]. 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 [45] and concerns about long-term impacts of repeat ECP use [86]. In contrast, one study found that providers supported OTC delivery as they saw ECPs as having relatively few side effects [83].

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

Cost review

Three studies met inclusion criteria for the cost review (Table 3) [99-101]. All were modelling studies, two from the USA [99, 100] and one from Canada [101]. 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.

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

Study	Location	Study design	Impact of pharmacy access
Marciante et al., 2001 **[100]**	USA	Decision model	Among private payers (private insurance): $158 (95% CI=$76, $269) reduction in cost per woman having unprotected intercourse Among public payers: $48 (95% CI=$16, $93) reduction in cost per woman having unprotected intercourse
Soon et al., 2007 **[101]**	Canada	Three decision model	One-year cost saving to the Ministry of Health (MOH) of $0.64 million (95% CI: $0.24 million, $1.28 million). In sensitivity analyses, there were no set of assumptions that would lead to pharmacy access increasing costs to the MOH.
Foster et al., 2010 **[99]**	USA	Markov model	For Medicare: Compared to 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 to 2.49 For prescription-only access: range 1.00 to 1.56

Discussion

We identified 19 studies from eight countries assessing how OTC ECPs influence uptake of ECPs, unintended pregnancy, abortion, and other sexual practices and behavior. Broadly, we found no differences in overall ECP use, pregnancy, or sexual risk behavior 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.

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 [33, 42]. 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 [28, 36], 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 [14, 102], 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 [103, 104]. However, there is some evidence that even with increased access and uptake, ECPs may have minimal impacts on unintended pregnancy or abortion

[105]. 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 [106], 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 [103].

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 [8]. We did not assess 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 [26, 32, 36, 40], while others identified increases in STI acquisition among younger age groups [29, 31]. 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 behavior. However, our effectiveness review found that there were no differences in sexual practices and behavior 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 [44, 82]. 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 [33], 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 counseling, including about how to use OTC ECPs correctly and counseling about other routine SRH services (including use of other contraceptives and screenings for cervical and breast cancers and sexually transmitted infections [107]). In our effectiveness review, we did not identify any studies assessing correct use of OC in OTC vs 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 vs OTC, with correct knowledge >90% for both groups [33], and another found no significant difference between OTC and prescription delivery in reporting adequate information received about ECPs [37].

Cost

Results from OTC ECP cost studies are promising, though limited. In our three included studies from the US 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 [44, 68, 81, 86]. 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 [56, 68].

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 [7]. 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 sexual and reproductive health and rights and key factors affecting delivery, uptake, and impact of OTC ECPs [108].

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 [66]. Meaningful efforts are needed to recognize, invest in, and promote future research on the effects of increased OTC ECPs in low- 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 summarized findings qualitatively. Our conclusions are also limited by the concentration of articles in high- 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 sexual and reproductive health and rights outcomes.

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Contributions

MN conceptualized the study. CEK and PTY designed the protocol with feedback from MN. PTY ran the database search and oversaw search, screening, full text review, and data extraction processes. CEK and PTY performed data analysis. KA and PTY assessed quality and risk of bias. CEK and KA drafted the manuscript. PTY and MN reviewed the draft, provided critical review, and read and approved the final manuscript. The corresponding author, as guarantor, accepts full responsibility for the finished article has access to any data and controlled the decision to publish. The corresponding author attests that all listed authors meet the authorship criteria and that no others meeting the criteria have been omitted.

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Competing interests

None declared.

Patient consent for publication

Not required.

Provenance and peer review

Not commissioned; externally peer reviewed.

Ethics statement

Ethical approval was not required for this systematic review, since all data came from published articles.

Data availability statement

Extracted data are available on request to the corresponding author.

Transparency declaration

The corresponding author, as guarantor, affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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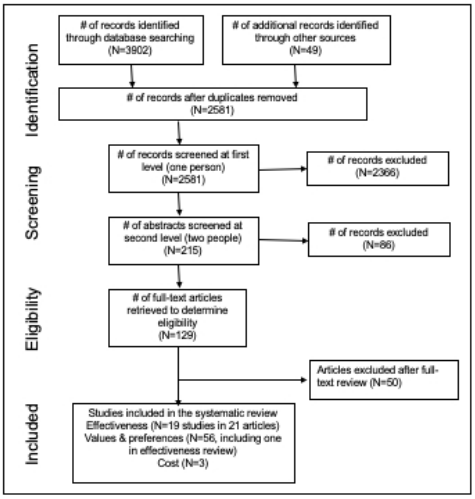

Figure 1. PRISMA flow chart showing disposition of citations through the search and screening process.

60x34mm (300 x 300 DPI)

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

109x63mm (300 x 300 DPI)

PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	4
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	4
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	2
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	4-5
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	5
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	25
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	5
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	5
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	4-5
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	5
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	NA
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	NA

PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	NA
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	6
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	6
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	6-10
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	6-10
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	6-8, 11-12
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	NA
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	NA
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	7-8
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	14
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	15-16
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	15-16
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	17

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit: www.prisma-statement.org.

WHO self-care v2 (2020)
Over the counter emergency contraception
Search strategy documentation

Search date: 27 April 2020 / updated 02 Dec 2020
Total hits: 3902
After removing duplicates: 2581
Assigned for primary screening: 2581

Pubmed: 1492 hits

("Contraceptives, Oral" [Mesh] OR "Contraceptives, Postcoital" [Mesh] OR "emergency contraceptive pill" [tiab] OR "emergency contraceptive pills" [tiab] OR "morning-after pill" [tiab] OR "Plan B One-Step" [tiab] OR "Take Action" [tiab] OR "Next Choice One-Dose" [tiab] OR "My Way" [tiab] OR "AfterPill" [tiab] OR "Preventeza" [tiab] OR "My Choice" [tiab] OR "Aftera" [tiab] OR "Athentia Next" [tiab] OR "EContra Ez" [tiab] OR "Fallback Solo" [tiab] OR "Opcicon One-Step" [tiab] OR "Option 2" [tiab] OR "Afirmelle" [tiab] OR "Altavera" [tiab] OR "Amethia" [tiab] OR "Amethia Lo" [tiab] OR "Amethyst" [tiab] OR "Aubra" [tiab] OR "Ayuna" [tiab] OR "Aviane" [tiab] OR "Camrese" [tiab] OR "CamreseLo" [tiab] OR "Chateal" [tiab] OR "Cryselle" [tiab] OR "Elinest" [tiab] OR "Enpresse" [tiab] OR "Falmina" [tiab] OR "Introvale" [tiab] OR "Jolessa" [tiab] OR "Kurvelo" [tiab] OR "Lessina" [tiab] OR "Lenovest" [tiab] OR "Levora" [tiab] OR "LoSeasonique" [tiab] OR "Low-Ogestrel" [tiab] OR "Lutera" [tiab] OR "Marlissa" [tiab] OR "Myzilra" [tiab] OR "Nordette" [tiab] OR "Orsythia" [tiab] OR "Portia" [tiab] OR "Quasense" [tiab] OR "Seasonale" [tiab] OR "Seasonique" [tiab] OR "Setlakin" [tiab] OR "Sronyx" [tiab] OR "Triphasil" [tiab] OR "Trivora" [tiab] OR "Vienva" [tiab] OR "After-1" [tiab] OR "Agesta" [tiab] OR "Ai Wu You" [tiab] OR "Aleze EC" [tiab] OR "Alterna" [tiab] OR "Amor" [tiab] OR "An Ting" [tiab] OR "Anlitin" [tiab] OR "Anthia" [tiab] OR "Auxxil" [tiab] OR "Bao Shi Ting" [tiab] OR "Bi Yun" [tiab] OR "Ciel EC" [tiab] OR "Contragest" [tiab] OR "Contraplan II" [tiab] OR "Control NF" [tiab] OR "Control Uno" [tiab] OR "Copill" [tiab] OR "Curesinor" [tiab] OR "D-Sigyent" [tiab] OR "Dan Mei" [tiab] OR "Dia S MP" [tiab] OR "Diad" [tiab] OR "Dreams" [tiab] OR "Duet" [tiab] OR "Duprisal 30" [tiab] OR "Dvella" [tiab] OR "E Pills" [tiab] OR "E-72" [tiab] OR "e-con" [tiab] OR "ECee2" [tiab] OR "ECP" [tiab] OR "ella" [tiab] OR "ellaOne" [tiab] OR "Emcon" [tiab] OR "Emergyn" [tiab] OR "Emkit" [tiab] OR "Emkit Plus" [tiab] OR "Escapel" [tiab] OR "Escapel-1" [tiab] OR "Escapel-2" [tiab] OR "Escapelle" [tiab] OR "Escinor" [tiab] OR "Estinor" [tiab] OR "Evadir 2" [tiab] OR "Evital" [tiab] OR "Evitarem" [tiab] OR "Fermerleve Sagiram" [tiab] OR "Feminor" [tiab] OR "Fertilan" [tiab] OR "Fu Nai Er" [tiab] OR "G-Nancy" [tiab] OR "Glanique" [tiab] OR "Glanix" [tiab] OR "Glostinor 2" [tiab] OR "Gynepriston" [tiab] OR "Gynotrel 2" [tiab] OR "Hispratel" [tiab] OR "Hou Ding Nuo" [tiab] OR "Hua Dian" [tiab] OR "Hui Ting" [tiab] OR "i-pill" [tiab] OR "Imediat" [tiab] OR "Imediat N" [tiab] OR "Impreviat" [tiab] OR "Jin Xiao" [tiab] OR "Jin Yu Ting" [tiab] OR "Ka Rui Ding" [tiab] OR "L Novafem" [tiab] OR "Laliades" [tiab] OR "Le Ting" [tiab] OR "Lenor 72" [tiab] OR "Levo-72" [tiab] OR "Levodonna" [tiab] OR "Levogest" [tiab] OR "Levogynon 1500" [tiab] OR "Levonelle" [tiab] OR "Levonelle-1" [tiab] OR "Levonia" [tiab] OR "Levonorgestrol Biogaran 1500" [tiab] OR "Levonorgestrel Richter" [tiab] OR "Levonormin" [tiab] OR "Lonel" [tiab] OR "Longil" [tiab] OR "Lydia 1Safe Pill" [tiab] OR "Lydia Post Pill" [tiab] OR "Madonna" [tiab] OR "Max-72" [tiab] OR "Me Tablet" [tiab] OR "Mergynex" [tiab] OR "Mifepristone 72" [tiab] OR "Mifestad 10" [tiab] OR "Minipil 2" [tiab] OR "Morning After" [tiab] OR "MS Pill" [tiab] OR "Negele" [tiab] OR "Nerostinor" [tiab] OR "Next Choice" [tiab] OR "Nicpostinew" [tiab] OR "Nogestrol" [tiab] OR "Nogravide" [tiab] OR "Norgestrel Max Unidosis" [tiab] OR "Norgestrel-Max" [tiab] OR "NorLevo" [tiab] OR "Nortrel 2" [tiab] OR "Novalen" [tiab] OR "Oportuna" [tiab] OR "Optinor" [tiab] OR "Ovocease" [tiab] OR "Ovulol" [tiab] OR "P2" [tiab] OR "PiDaNa" [tiab] OR "Pilem" [tiab] OR "Pill 72" [tiab] OR "Pillanor 2" [tiab] OR "Pillex" [tiab] OR "Pilule S" [tiab] OR "Planfam" [tiab] OR "Poslov" [tiab] OR "PostDay" [tiab] OR "Poster Tablets" [tiab] OR "Postiga 4" [tiab] OR "Postinor" [tiab] OR "Postinor 1"

[tiab] OR "Postinor 1.5" [tiab] OR "Postinor 1500" [tiab] OR "Postinor 2 SD" [tiab] OR "Postinor Duo" [tiab] OR "Postinor Life" [tiab] OR "Postinor PI" [tiab] OR "Postinor Uno" [tiab] OR "Postinor-2" [tiab] OR "Postinor-2 Unidosis" [tiab] OR "Postpill" [tiab] OR "Pozato" [tiab] OR "Pozato Uni" [tiab] OR "PPMS" [tiab] OR "Pregnon" [tiab] OR "Pregnon 1" [tiab] OR "Pregnon 1.5" [tiab] OR "Prevemb" [tiab] OR "Preventol" [tiab] OR "Previdez 2" [tiab] OR "Previfem" [tiab] OR "Prevyol" [tiab] OR "Prikul" [tiab] OR "Pronta" [tiab] OR "Prudence for Her" [tiab] OR "Rely-X" [tiab] OR "Revoke 1.5" [tiab] OR "Revoke 72" [tiab] OR "Rigesoft" [tiab] OR "Rogotinor" [tiab] OR "Secufem" [tiab] OR "Seguidet" [tiab] OR "Segurit" [tiab] OR "Segurite UD" [tiab] OR "SEKURE" [tiab] OR "Sendinor 2" [tiab] OR "Sexcon One&One" [tiab] OR "Si Mi An" [tiab] OR "Silogin" [tiab] OR "Smart Lady (Pregnon)" [tiab] OR "So-Ezzy" [tiab] OR "Tace" [tiab] OR "Tibex" [tiab] OR "Truston-2" [tiab] OR "Ulipristal 30" [tiab] OR "Unlevo 1500" [tiab] OR "Unofem" [tiab] OR "Unwanted 72" [tiab] OR "Upostelle" [tiab] OR "UPRIS" [tiab] OR "Vermagest" [tiab] OR "Vika" [tiab] OR "Vikela" [tiab] OR "Vonstrel" [tiab] OR "Xian Ju" [tiab] OR "Yi Ting" [tiab] OR "Yu Ting" [tiab] OR "Zimtemore" [tiab])

AND

("Nonprescription Drugs" [Mesh] OR nonprescription [tiab] OR "over the counter" [tiab] OR "over-the-counter" [tiab] OR "without a prescription" [tiab] OR "pharmacist-prescribed" [tiab] OR "pharmacy access" [tiab] OR "clinician-prescribed" [tiab] OR "physician-prescribed" [tiab] OR "GP-prescribed" [tiab] OR "general practitioner prescribed" [tiab] OR "without prescription" [tiab] OR "community pharmacy services" [Mesh] OR "community center" [tiab] OR "community centre" [tiab] OR store [tiab] OR shop [tiab] OR online [tiab] OR mobile [tiab] OR telehealth [tiab])

CINAHL: 184 hits

AB ("Contraceptives postcoital" OR "emergency contraception" OR "emergency contraceptive" OR "emergency contraceptives" OR "morning after pill" OR "plan b") AND AB ("Nonprescription Drugs" OR nonprescription OR "over the counter" OR "over-the-counter" OR "without a prescription" OR "pharmacist-prescribed" OR "pharmacy access" OR "clinician-prescribed" OR "physician-prescribed" OR "GP-prescribed" OR "general practitioner prescribed" OR "without prescription" OR "community center" OR "community centre" OR store OR shop OR online OR mobile OR telehealth)

LILACS: 204 hits

Title/abstract/subject: ("Contraceptives postcoital" OR "emergency contraception" OR "emergency contraceptive" OR "emergency contraceptives" OR "morning after pill" OR "plan b")

EMBASE: 494 hits

AB,TI ('Contraceptives postcoital' OR 'emergency contraception' OR 'emergency contraceptive' OR 'emergency contraceptives' OR 'morning after pill' OR 'plan b') AND AB,TI ('Nonprescription Drugs' OR nonprescription OR 'over the counter' OR 'over-the-counter' OR 'without a prescription' OR 'pharmacist-prescribed' OR 'pharmacy access' OR 'clinician-prescribed' OR 'physician-prescribed' OR 'GP-prescribed' OR 'general practitioner prescribed' OR 'without prescription' OR 'community center' OR 'community centre' OR store OR shop OR online OR mobile OR telehealth)

Appendix 3: Risk of Bias Assessments

Non-Randomized Trials (n=18): Evidence Project Risk of Bias Tool

Citation ID	Pre/Post	Comp. group	Cohort	Baseline Equivalence		Random selection	Random allocation	Control for confounders	Follow-up >=75%	Specific Concerns
				Demos	Outcome					
Arnet et al. 2009 [23]	Yes	No	No	NA	NA	No	No	No	NA	Lack of comparison group, no control for confounding
Atkins & Bradford 2015 [25]	Yes	No	No	NA	NA	No	No	Yes	NA	Lack of comparison
Atkins 2014 [24]	Yes	No	No	NA	NA	No	No	Yes	NA	Lack of comparison
Bumbul et al. 2013 [26]	No	Yes	No	No	NA	NR	No	No	NA	No pre/post, no control for confounding
Cintina & Johansen 2015 [28]	No	Yes	No	NR	NA	No	No	Yes	NA	No pre/post
Cintina 2017 [27]	Yes	No	No	NA	NA	No	No	Yes	NA	Lack of comparison
Durrance 2013 [29]	Yes	No	No	NA	NA	No	No	Yes	NA	Lack of comparison
Falah-Hassani,et al. 2007 [30]	Yes	No	No	NA	NA	Yes	NA	No	NA	Lack of comparison, no control for confounding

										(though random selection)
Girma & Paton 2011[31]	No	Yes	No	No	NA	No	No	Yes	NA	No pre/post
Killick & Irving 2004 [33]	No	Yes	No	NR	NR	No	No	No	NA	No pre/post, no control for confounding
Marston et al. 2005 [34]	Yes	No	No	NA	NA	Yes	No	Yes	NA	Lack of comparison
Moreau et al. 2006 [35]	Yes	No	No	NA	NA	Yes	No	Yes	NA	Lack of comparison
Mulligan 2016 [36]	Yes	No	Yes	NA	NA	NR	No	Yes	NR	Lack of comparison
Novikova et al. 2009 [37]	Yes	No	No	NA	NA	No	No	No	NA	Lack of comparison group, no control for confounding
Payakachat et al. 2010 [38]	Yes	No	No	NA	NA	No	No	No	NA	Lack of comparison group, no control for confounding
Pentel et al. 2004 [39]	Yes	No	No	NA	NA	No	No	No	NA	Lack of comparison group, no control for confounding
Rubin et al. 2011 [42]	No	Yes	No	NA	NA	No	No	Yes	NA	No pre/post
Soon et al. 2005 [43]	Yes	No	No	NA	NA	No	No	No	NA	Lack of comparison group, no control for confounding

Randomized Controlled Trials (n=3 papers reporting 1 RCT): Cochrane Collaboration Tool

Study ID : Harper et al. 2005 [32]; Raine et al. 2005 [40]; Rocca et al. 2007 [41]

Domain 1: Risk of bias arising from the randomization process

Signalling questions	EC use	Pregnancy	Unprotected sex	Consistent condom use	Condom use last sex	Multiple partners	Contraceptive method change	Missed pills	Comments
1.1 Was the allocation sequence random?	Y	Y	Y	Y	Y	Y	Y	Y	
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?	Y	Y	Y	Y	Y	Y	Y	Y	
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	N	N	N	N	N	N	N	N	There was also a slightly higher proportion of blacks in the clinic access group (P=.045), but no other notable differences
Risk-of-bias judgement	Low	Low	Low	Low	Low	Low	Low	Low	
Optional: What is the predicted direction of bias	NA	NA	NA	NA	NA	NA	NA	NA	

arising from the randomization process?									

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	EC use	Pregnancy	Unprotected sex	Consistent condom use	Condom use last sex	Multiple partners	Contraceptive method change	Missed pills	Comments
2.1. Were participants aware of their assigned intervention during the trial?	Y	Y	Y	Y	Y	Y	Y	Y	Blinding not possible given the intervention
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?	Y	Y	Y	Y	Y	Y	Y	Y	
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?	N	N	N	N	N	N	N	N	California legalized pharmacy access six months into the trial, but this is not related to trial context
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?	NA	NA	NA	NA	NA	NA	NA	NA	
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?	NA	NA	NA	NA	NA	NA	NA	NA	
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	Y	Y	Y	Y	Y	Y	Y	Y	Modified ITT used

2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?	NA	NA	NA	NA	NA	NA	NA	NA	
Risk-of-bias judgement	Low	Low	Low	Low	Low	Low	Low	Low	
Optional: What is the predicted direction of bias due to deviations from intended interventions?	NA	NA	NA	NA	NA	NA	NA	NA	

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of adhering to intervention*)

Signalling questions	EC use	Pregnancy	Unprotected sex	Consistent condom use	Condom use last sex	Multiple partners	Contraceptive method change	Missed pills	Comments
2.1. Were participants aware of their assigned intervention during the trial?	Y	Y	Y	Y	Y	Y	Y	Y	Blinding not possible given the intervention
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?	Y	Y	Y	Y	Y	Y	Y	Y	
2.3. [If applicable:] If Y/PY/NI to 2.1 or 2.2: Were important non-protocol interventions balanced across intervention groups?	NA	NA	NA	NA	NA	NA	NA	NA	
2.4. [If applicable:] Were there failures in implementing the intervention that could have affected the outcome?	Y	Y	Y	Y	Y	Y	Y	Y	Yes, deviations because of change in CA law but rerandomized
2.5. [If applicable:] Was there non-adherence to the assigned intervention regimen that could have affected participants' outcomes?	PY	PY	PY	PY	PY	PY	PY	PY	Contamination between groups due to change in law

2.6. If N/PN/NI to 2.3, or Y/PY/NI to 2.4 or 2.5: Was an appropriate analysis used to estimate the effect of adhering to the intervention?	Y	Y	Y	Y	Y	Y	Y	Y	
Risk-of-bias judgement	Some concerns	Some concerns	Some concerns	Some concerns	Some concerns	Some concerns	Some concerns	Some concerns	
Optional: What is the predicted direction of bias due to deviations from intended interventions?	Favors experimental	Favors experimental	Favors experimental	Favors experimental	Favors experimental	Favors experimental	Favors experimental	Favors experimental	

Domain 3: Missing outcome data

Signalling questions	EC use	Pregnancy	Unprotected sex	Consistent condom use	Condom use last sex	Multiple partners	Contraceptive method change	Missed pills	Comments
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	PY	PY	PY	PY	PY	PY	PY	PY	814/889 pharmacy access; 826/884 advance provision; 310/344 clinic access
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?	NA	NA	NA	NA	NA	NA	NA	NA	
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?	NA	NA	NA	NA	NA	NA	NA	NA	
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?	NA	NA	NA	NA	NA	NA	NA	NA	
Risk-of-bias judgement	Low	Low	Low	Low	Low	Low	Low	Low	
Optional: What is the predicted direction of bias due to missing outcome data?	NA	NA	NA	NA	NA	NA	NA	NA	

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	EC use	Pregnancy	Unprotected sex	Consistent condom use	Condom use last sex	Multiple partners	Contraceptive method change	Missed pills	Comments
4.1 Was the method of measuring the outcome inappropriate?	N	N	N	N	N	N	N	N	
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?	N	N	N	N	N	N	N	N	
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?	Y	Y	Y	Y	Y	Y	Y	Y	
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?	PN	PN	PN	PN	PN	PN	PN	PN	
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?	PN	PN	PN	PN	PN	PN	PN	PN	

Risk-of-bias judgement	Low	Low	Low	Low	Low	Low	Low	Low	
Optional: What is the predicted direction of bias in measurement of the outcome?	NA	NA	NA	NA	NA	NA	NA	NA	

Domain 5: Risk of bias in selection of the reported result

Signalling questions	EC use	Pregnancy	Unprotected sex	Consistent condom use	Condom use last sex	Multiple partners	Contraceptive method change	Missed pills	Comments
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?									
	Y	Y	Y	Y	Y	Y	Y	Y	
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...									
5.2. ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	N	N	N	N	N	N	N	N	
5.3 ... multiple eligible analyses of the data?	N	N	N	N	N	N	N	N	
Risk-of-bias judgement	Low	Low	Low	Low	Low	Low	Low	Low	
Optional: What is the predicted direction of bias due to selection of the reported result?	NA	NA	NA	NA	NA	NA	NA	NA	

Overall risk of bias

Overall assessment	EC use	Pregnancy	Unprotected sex	Consistent condom use	Condom use last sex	Multiple partners	Contraceptive method change	Missed pills	Comments
Risk-of-bias judgement	Low	Low	Low	Low	Low	Low	Low	Low	
Optional: What is the overall predicted direction of bias for this outcome?	NA	NA	NA	NA	NA	NA	NA	NA	