

# Should oral contraceptive pills be available without a prescription? A systematic review of over-the-counter and pharmacy access availability

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## ABSTRACT

**Introduction** Making oral contraceptives (OC) available over the counter (OTC) could reduce barriers to use. To inform WHO guidelines on self-care interventions, we conducted a systematic review of OTC availability of OCs.

**Methods** We reviewed data on both effectiveness and values and preferences surrounding OTC availability of OCs. For the effectiveness review, peer-reviewed articles were included if they compared either full OTC availability or pharmacist-prescribing (behind-the-counter availability) to prescription-only availability of OCs and measured an outcome of interest. For the values and preferences review, we included peer-reviewed articles that presented primary data (qualitative or quantitative) examining people's preferences regarding OTC access to OCs. We searched PubMed, CINAHL, LILACS and EMBASE through November 2018 and extracted data in duplicate.

**Results** The effectiveness review included four studies with 5197 total participants. Two studies from the 2000s compared women who obtained OCs OTC in Mexico to women who obtained OCs from providers in either Mexico or the USA. OTC users had higher OC continuation rates over 9 months of follow-up (adjusted HR: 1.58, 95% CI 1.11 to 2.26). One study found OTC users were more likely to report at least one WHO category 3 contraindication (13.4% vs 8.6%,  $p=0.006$ ), but not category 4 contraindications; the other study found no differences in contraindicated use. One study found lower side effects among OTC users and high patient satisfaction with both OTC and prescription access. Two cross-sectional studies from the 1970s in Colombia and Mexico found no major differences in OC continuation, but some indication of slightly higher side effects with OTC access. In 23 values and preference studies, women generally favoured OTC availability. Providers showed more modest support, with pharmacists expressing greater support than physicians. Support was generally higher for progestogen-only pills compared with combination OCs.

**Conclusion** A small evidence base suggests women who obtain OCs OTC may have higher continuation rates and limited contraindicated use. Patients and providers generally support OTC availability. OTC availability may increase access to this effective contraceptive option and reduce unintended pregnancies.

## Key questions

### What is already known?

- ▶ Making oral contraceptives (OC) available over the counter (OTC) may increase access.

### What are the new findings?

- ▶ A systematic review of the literature identified four studies using comparative designs to examine the effect of OTC availability of OCs and 23 studies examining values and preferences of patients and providers, mostly from the USA and Mexico.
- ▶ The more recent and rigorous studies suggested OTC users had higher rates of OC continuation over time; there was some indication that OTC users had lower rates of side effects but slightly higher rates of use of OCs despite contraindications.
- ▶ Values and preferences suggested general support for OTC availability or pharmacy access, with more support among women and pharmacists than among physicians.

### What do the new findings imply?

- ▶ Making OCs available OTC, perhaps with progestogen-only pills that have fewer contraindications to use, may be an approach to increasing access to and use of this effective contraceptive option.

**Systematic review (PROSPERO) registration number** CRD42019119406.

## INTRODUCTION

Ensuring access to contraceptive methods, including for vulnerable populations and young people, is essential for the well-being and autonomy of women and girls. Oral contraceptives (OC), both combined oral contraceptives (COC) and progestogen-only pills (POP), are widely used effective methods of birth control. However, access to OCs varies globally—in some countries, OCs are available over the counter (OTC), while other

countries restrict access to OCs either by requiring eligibility screening by trained pharmacy staff before dispensation (pharmacy access, or behind-the-counter availability), or by requiring a healthcare provider's prescription. A 2015 review of OC access across 147 countries found that 35 countries had OCs legally available OTC, 11 countries had OCs available without a prescription but only after eligibility screening by trained pharmacy staff, 56 countries had OCs available informally without a prescription and 45 countries required a prescription to obtain OCs.<sup>1</sup> Given the persistently high proportion of unintended pregnancies globally—44% according to some estimates<sup>2</sup>—making OCs available OTC in more settings has the potential to reduce barriers to access, thereby increasing use of this effective contraceptive option and reducing unintended pregnancies.

While different regulatory criteria are needed in different countries to make a specific medication available OTC or with eligibility screening by pharmacy staff, the WHO is responsible to provide overall guidance to critical questions of whether interventions should be recommended or not. We conducted this systematic review in the context of developing WHO normative guidance on self-care interventions for sexual and reproductive health and rights. We included both a review of effectiveness data and a review of data on values and preferences.

## METHODS

### Effectiveness review: PICO question and inclusion criteria

We sought to answer the following question: should contraceptive pill/oral contraceptives be made available over the counter without a prescription?

Our effectiveness review followed the PICO question format:

#### Population

Individuals using contraceptive pill/oral contraceptives.

#### Intervention

Availability of contraceptive pill/oral contraceptives OTC (without a prescription) or behind the counter (pharmacy access, including dispensing from trained pharmacy personnel and pharmacist prescribing of hormonal birth control).

#### Comparison

Availability of contraceptive pill/oral contraceptives by prescription only.

#### Outcomes

1. Uptake of OCs (initial use).
2. Continuation of OCs (or, conversely, discontinuation).
3. Adherence to OCs (correct use).
4. Comprehension of instructions (product label).
5. Health impacts (unintended pregnancy, side effects, adverse events or use of OCs despite contraindications).

6. Social harms (eg, coercion, violence (including intimate partner violence, violence from family members or community members, and so on), psychosocial harm, self-harm, and so on), and whether these harms were corrected/had redress available.

7. Client satisfaction.

To be included in the effectiveness review, a study had to meet the following criteria:

1. Employ a study design comparing OTC availability of OCs (with or without pharmacist dispensation) to prescription-only availability of OCs.
2. Measured one or more of the outcomes listed above.
3. Published in a peer-reviewed journal.

We focused on daily contraceptive pill/oral contraceptives for routine pregnancy prevention and did not include studies examining pills specifically for emergency contraception.

Where data were available, we stratified all analyses by the following subcategories:

- ▶ Behind-the-counter (pharmacy access) versus OTC availability without a prescription.
- ▶ COCs versus POPs.
- ▶ Point of access (eg, stores, pharmacies, and so on).
- ▶ Prior use of contraception.
- ▶ Age: adolescent girls and young women (aged 10–14, 15–19 and 15–24) and adult women (aged 25+).
- ▶ Vulnerabilities (ie, poverty, disability, religion).
- ▶ High-income versus low/middle-income countries.
- ▶ Literacy/educational level.

Study inclusion was not restricted by location of the intervention or language of the article. We planned to translate articles in languages other than English if identified. The complete protocol was registered and is available in PROSPERO (CRD42019119406).

### Values and preferences review: inclusion criteria

The same search strategy was used to search and screen for study inclusion in a complementary review of values and preferences related to OTC access to OCs (including pharmacy access). We included studies in the values and preferences review if they presented primary data (qualitative or quantitative) examining people's preferences regarding OTC access to OCs. We included studies examining the values and preferences of both people who have used or potentially would use OCs themselves as well as providers (including pharmacists) and other stakeholders, such as male partners, policymakers and insurance providers.

### Search strategy

The same search strategy was used for both the effectiveness review and the values and preferences review. We searched four electronic databases (PubMed, the Cumulative Index to Nursing and Allied Health Literature (CINAHL), Latin American and Caribbean Health Sciences Literature (LILACS) and Embase) through the search date of 30 November 2018. The following search strategy was developed for PubMed and adapted for entry into all computer databases; a full list of search terms for all databases is available from the authors on request.

(‘Contraceptives, Oral’ [Mesh] OR ‘oral contraceptive pill’ [tiab] OR ‘oral contraceptive pills’ [tiab] OR ‘birth control pill’ [tiab] OR ‘birth control pills’ [tiab] OR ‘oral contraceptives’ [tiab] OR ‘oral contraception’ [tiab] OR ‘hormonal birth control’ [tiab] OR ‘hormonal contraception’ [tiab] OR ‘the pill’ [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 ‘without prescription’ [tiab] OR ‘community pharmacy services’ [Mesh] OR ‘community center’ [tiab] OR ‘community centre’ [tiab] OR store [tiab] OR online [tiab] OR mobile [tiab] OR telehealth [tiab])

To identify articles that may have been missed through online database searching, we used several complementary approaches. We reviewed the resources section of the OCs OTC working group website,<sup>3</sup> which gathers scientific articles and reviews on this topic, and reviewed the citations included in several related recent reviews.<sup>1 4 5</sup> Secondary reference searching was also conducted on all studies included in the review. We searched for ongoing trials through ClinicalTrials.gov, the WHO International Clinical Trials Registry Platform, the Pan African Clinical Trials Registry, and the Australian New Zealand Clinical Trials Registry. Finally, selected experts in the field were presented with our list of included articles and asked to share any additional article we had missed.

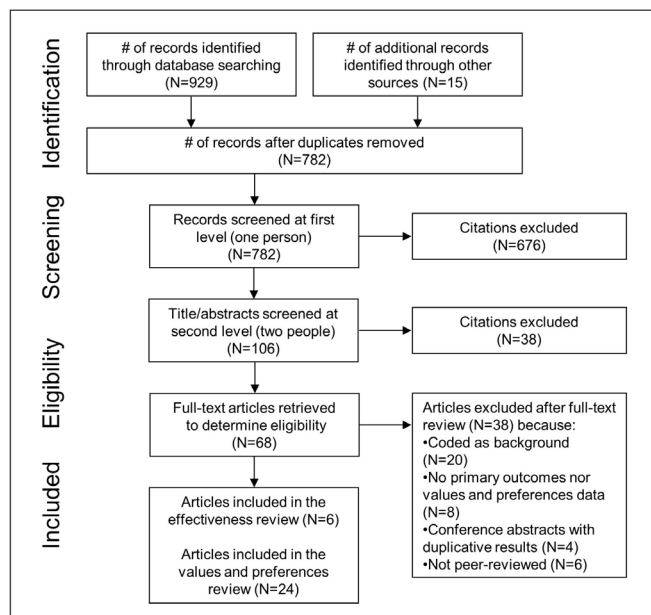
Titles, abstracts, citation information and descriptor terms of citations identified through the search strategy were initially screened by a member of the study staff. Remaining citations were then screened in duplicate by two reviewers (CEK and PTY) with differences resolved through consensus. Final inclusion was determined after full-text review.

### Data extraction and analysis

For each included article, data were extracted independently by two reviewers using standardised data extraction forms. Differences in data extraction were resolved through consensus.

For the effectiveness review, data extraction forms covered the following categories:

- ▶ Study identification: author(s); type of citation; year of publication, funding source.
- ▶ Study description: study objectives; location; population characteristics; type of oral contraceptives; description of OTC access; description of any additional intervention components (eg, any education, training, support provided); study design; sample size; follow-up periods and loss to follow-up.
- ▶ Outcomes: analytical approach; outcome measures; comparison groups; effect sizes; CIs; significance levels; conclusions; limitations.
- ▶ Risk of bias: assessed for randomised controlled trials with the Cochrane Collaboration’s tool for assessing risk of bias,<sup>6</sup> and for non-randomised trials but



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

comparative studies with the Evidence Project risk of bias tool.<sup>7</sup>

For the values and preferences review, data extraction forms included sections on study location, population, study design and key findings.

We did not conduct meta-analysis due to the small number and heterogeneous nature of included studies. Instead, we report findings based on the coding categories and outcomes.

### Patient and public involvement

Several of the authors are current or past OC users. HJ, chair of the advisory group for the WHO Patients for Patients Safety Program, was involved as a community representative starting with the phase of protocol development. He commented on the overall study design and protocol, including patient-relevant outcomes, interpretation of results and writing/editing the document for readability and accuracy. Patients were involved in a global survey of values and preferences and in focus group discussions with vulnerable communities conducted to inform the WHO guideline on self-care interventions<sup>8</sup>; they thus play a significant role in the overall recommendation informed by this review.

## RESULTS

### Search results

Figure 1 presents a flow chart showing study selection for both the effectiveness and values and preferences reviews. The initial database search yielded 929 records, with 15 records identified through other sources; 782 remained after removing duplicates. After the initial title/abstract review, 68 articles were retained for full-text screening. Ultimately, six articles reporting data from

**Table 1** Descriptions of studies included in the effectiveness review

Study	Location	Population	Sampling	Study design
2006–2008 Border Contraceptive Access Study <sup>10</sup> <small>12 13</small>	El Paso, Texas, USA	1046°C users aged 18–44 who obtained OCs either OTC from a Mexican pharmacy (n=532) or from a family planning clinic in El Paso (n=514)	Convenience sampling	Cohort study following both groups of women in four surveys over 9 months
2000 Mexican National Health Survey analysis <sup>14</sup>	Nationally representative sample from Mexico	1195°C users aged 20–49 who obtained OCs either OTC from a pharmacy (n=501) or from a health clinic of some sort (n=694)	Four-stage probability proportionate to size sampling	Cross-sectional study design
1979 Mexico National Fertility and Mortality Study <sup>9</sup>	Nationally representative sample from Mexico	2063°C users aged 15–49 who (when they first used contraception) obtained OCs either OTC from a pharmacy or store (39%) from a private physician or private clinic (17%), or from the national family planning programme (44%)	Stratified probability sample	Cross-sectional study design
1974 Colombian Fertility and Contraceptive Use Survey <sup>11</sup>	Bogotá, Colombia	893°C users aged 15–49 who (when they first used contraception) obtained OCs either OTC from a drugstore or similar commercial outlet without a medical prescription and without the advice of a physician or an organised family planning programme (n=298) or chose OCs as her first contraceptive method through a physician or family planning programme (n=595)	Three-stage probability sample	Cross-sectional study design

OC, oral contraceptive; OTC, over the counter.

four studies met the inclusion criteria and were included in the effectiveness review.<sup>9–14</sup> An additional 24 articles from 23 studies were included in the values and preferences review.<sup>13 15–37</sup>

One study was considered for the effectiveness review but ultimately judged to not meet the inclusion criteria.<sup>38</sup> In Kuwait, where OCs are available OTC, the study compared women who consulted with a physician and those who did not. We excluded the study because it was not clear whether women received OCs from these physicians or not. However, we note that the study found no difference across groups in OC continuation, duration of first OC use, method failure and reasons for discontinuation.

### Effectiveness review

**Table 1** shows the characteristics of the four studies included in the effectiveness review.<sup>9–14</sup> The first study, the Border Contraceptive Access Study, was a longitudinal cohort study conducted among women living in El Paso, Texas, USA, from 2006 to 2008 with results reported in a number of articles.<sup>10 12 13</sup> The study used convenience sampling to enrol 1046°C users who obtained OCs either OTC from a Mexican pharmacy (n=532) or from a family planning clinic in El Paso (n=514). These women were interviewed at baseline and then followed in three additional surveys over 9 months. The second study, an analysis of data from the 2000 Mexican National Health Survey<sup>14</sup> by an overlapping group of researchers, was

a cross-sectional comparison of women who reported obtaining OCs OTC to women who reported obtaining them from a healthcare provider. The third and fourth studies were significantly older, drawing on data from the 1970s. They presented cross-sectional comparisons of women whose initial contraceptive method was OCs, obtained OTC from a pharmacy/drugstore, from a private provider/clinician or the national family planning programme: one analysed data from the 1979 Mexico National Fertility and Mortality Study among 2063 women<sup>9</sup> and the other was a 1974 Fertility and Contraceptive Use survey in Bogotá, Colombia, among 893 women.<sup>11</sup> All studies included mainly women using COCs, rather than POPs, although pill formulations likely differed by time.

As all studies were observational, **table 2** shows the risk of bias assessments using the Evidence Project tool. The Border Contraceptive Access and Mexican National Health Survey studies found that women who obtained their OCs OTC were different in at least some sociodemographic characteristics than those who obtained them from clinics; however, both studies employed analyses that adjusted for confounders to address this discrepancy.<sup>10 12–14</sup> The Mexico National Fertility and Mortality Study and Colombian Fertility and Contraceptive Use Survey said there were only minor sociodemographic differences between groups but did not present actual statistics to support these statements; neither study

**Table 2** Evidence Project risk of bias assessment<sup>7</sup> for studies included in the effectiveness review

Study	Study design includes pre/post intervention data	Study design includes control or comparison group	Study design includes cohort	Comparison groups equivalent at baseline on sociodemographics	Comparison groups equivalent at baseline on outcome measures	Participants randomly selected for assessment	Participants randomly allocated to the intervention	Control for potential confounders	Follow-up rate ≥ 75%
2006–2008 The Border Contraceptive Access Study <sup>10,12,13</sup>	No	Yes	Yes	No	Yes	No	No	Yes	Yes
2000 Mexican National Health Survey analysis <sup>14</sup>	No	Yes	No	No	N/A	Yes*	No	Yes	N/A
1979 Mexico National Fertility and Mortality Study <sup>9</sup>	No	Yes	No	NR†	N/A	Yes	No	No	N/A
1974 Colombian Fertility and Contraceptive Use Survey <sup>11</sup>	No	Yes	No	NR†	N/A	Yes‡	No	No	N/A

\*Four-stage probability proportionate to size sampling.

†Authors state that the comparison groups were similar, but no comparative data provided to assess this.

‡Three-stage probability sampling.

N/A, not applicable; NR, not reported.

adjusted for confounders.<sup>9,11</sup> The Border Contraceptive Access Study relied on convenience sampling, but was strengthened by its longitudinal design.<sup>10,12,13</sup> Conversely, while the other three studies were cross sectional in nature, they were strengthened by their multistage sampling strategies.<sup>9,11,14</sup>

The included studies reported on three of the PICO outcomes: continuation of OCs, health impacts (specifically, use of OCs despite contraindications and side effects) and client satisfaction. For the other PICO outcomes, we found no studies. Results from each study are presented in table 3 and described below.

#### Continuation of OCs

The Border Contraceptive Access Study reported the proportion of women who continued OC use over the 9-month study period.<sup>12</sup> Overall, 25.1% of clinic users discontinued by the end of the study period compared with 20.8% of OTC users (p=0.12). In an unadjusted Cox proportional hazards model, OTC users were more likely to continue OC use than clinic users (unadjusted HR: 1.48, 95% CI 1.07 to 2.04); this estimate changed only slightly in the adjusted model and remained statistically significant (adjusted HR: 1.58, 95% CI 1.11 to 2.26).

The two studies from the 1970s also examined continuation. The Mexico National Fertility and Mortality Study presented continuation rates at 12 months per 100 women who accepted OCs as their first contraceptive method.<sup>9</sup> No difference by OC source was found: 59% of private physician or clinic users, 57% of government family planning programme users and 60% of OTC users remained on OCs after 12 months. The Colombian Fertility and Contraceptive Use Survey presented first contraceptive method continuation rates for women who chose OCs at 12 and 24 months.<sup>11</sup> Though a validation survey found that the continuation rates were overestimated by approximately 10%–15%, the study found that at both 12 and 24 months, OC continuation was approximately 5% higher for clinic users than OTC users.

#### Use of OCs despite contraindications

The two studies from the 2000s reported on the use of OCs despite contraindications.

The Border Contraceptive Access Study reported use of OCs despite contraindications using the WHO Medical Eligibility Criteria (MEC) (third edition) relative (category 3) and absolute (category 4) contraindications.<sup>10</sup> At the baseline survey, at least one category 3 or 4 contraindication was reported by 21.4% of OTC users and 13.8% of clinic users (p=0.002). OTC users were more likely to have any category 3 contraindication (13.4% vs 8.6%, p=0.006), but there was no difference in category 4 contraindications (7.4% vs 5.3%, p=0.162). The study also provided a list of specific contraindications. For most contraindications there was no significant difference for OTC and clinic users; however, OTC users were significantly more likely than clinic users to have category 3 hypertension (140–159/90–99) (8.4% vs 4.5%, p=0.036)

**Table 3** Outcomes of studies included in the effectiveness review

Citation	Results																																																																																																								
2006–2008 The Border Contraceptive Access Study <sup>10 12 13</sup>	<p><b>Continuation of OCs</b>                      Discontinuation of OCs over 9 months: OTC: 20.8% (97/466), clinic: 25.1% (119/474), p=0.12                      Unadjusted Cox proportional hazards model, clinic versus OTC: unadjusted HR: 1.48 (95% CI 1.07 to 2.04), adjusted HR: 1.58 (95% CI 1.11 to 2.26)                      Life table estimates of continuation at 9 months were 5% higher for OTC users than clinic users (p&lt;0.01).</p> <p><b>Health impacts: use of OCs despite contraindications</b>                      Unadjusted regression model for at least one category 3 or 4 contraindication, OTC versus clinic: unadjusted OR: 1.69 (95% CI 1.22 to 2.36), adjusted OR: 1.59 (95% CI 1.11 to 2.29), p=0.012</p> <table border="1"> <thead> <tr> <th></th> <th data-bbox="550 885 603 1023">Clinic users n (%)</th> <th data-bbox="550 597 603 736">OTC users n (%)</th> <th data-bbox="550 331 574 427">P value</th> </tr> </thead> <tbody> <tr> <td data-bbox="550 1481 574 1625">Hypertension</td> <td></td> <td></td> <td></td> </tr> <tr> <td data-bbox="579 1140 603 1604">Any hypertension (140/90 mm Hg or more)</td> <td data-bbox="579 938 603 1023">29 (5.6)</td> <td data-bbox="579 640 603 725">49 (9.8)</td> <td data-bbox="579 353 603 427">0.013</td> </tr> <tr> <td data-bbox="608 1193 632 1604">Hypertension 140–159/90–99 mm Hg</td> <td data-bbox="608 938 632 1023">23 (4.5)</td> <td data-bbox="608 640 632 725">42 (8.4)</td> <td data-bbox="608 353 632 427">0.036</td> </tr> <tr> <td data-bbox="638 1193 662 1604">Hypertension 160/100 mm Hg or more</td> <td data-bbox="638 938 662 1023">6 (1.2)</td> <td data-bbox="638 640 662 725">7 (1.4)</td> <td data-bbox="638 353 662 427">0.017</td> </tr> <tr> <td data-bbox="668 1225 692 1604">Smoking and age 35 years or older</td> <td data-bbox="668 938 692 1023">16 (3.1)</td> <td data-bbox="668 640 692 725">32 (6.4)</td> <td data-bbox="668 353 692 427">0.932</td> </tr> <tr> <td data-bbox="699 1183 722 1604">Smokes less than 15 cigarettes per day</td> <td data-bbox="699 938 722 1023">0 (0.0)</td> <td data-bbox="699 640 722 725">2 (0.4)</td> <td data-bbox="699 353 722 427">0.377</td> </tr> <tr> <td data-bbox="729 1193 753 1604">Smokes 15 or more cigarettes per day</td> <td data-bbox="729 938 753 1023">21 (4.1)</td> <td data-bbox="729 640 753 725">21 (4.2)</td> <td data-bbox="729 353 753 427">0.633</td> </tr> <tr> <td data-bbox="759 1278 783 1604">Migraine headaches with aura</td> <td data-bbox="759 938 783 1023">5 (1.0)</td> <td data-bbox="759 640 783 725">8 (1.6)</td> <td data-bbox="759 353 783 427">0.578</td> </tr> <tr> <td data-bbox="790 1289 813 1604">Current gall bladder disease</td> <td data-bbox="790 938 813 1023">2 (0.4)</td> <td data-bbox="790 640 813 725">3 (0.6)</td> <td data-bbox="790 353 813 427">0.986</td> </tr> <tr> <td data-bbox="820 1183 844 1604">High cholesterol and using medication</td> <td data-bbox="820 938 844 1023">2 (0.4)</td> <td data-bbox="820 640 844 725">1 (0.2)</td> <td data-bbox="820 353 844 427">0.152</td> </tr> <tr> <td data-bbox="850 1289 874 1604">Diabetes with complications</td> <td data-bbox="850 938 874 1023">0 (0.0)</td> <td data-bbox="850 640 874 725">3 (0.6)</td> <td data-bbox="850 353 874 427">0.986</td> </tr> <tr> <td data-bbox="880 1119 904 1604">Current liver disease or history of liver cancer</td> <td data-bbox="880 938 904 1023">1 (0.2)</td> <td data-bbox="880 640 904 725">1 (0.2)</td> <td data-bbox="880 353 904 427">0.986</td> </tr> <tr> <td data-bbox="911 1225 935 1604">History of or current heart disease</td> <td data-bbox="911 938 935 1023">0 (0.0)</td> <td data-bbox="911 640 935 725">2 (0.4)</td> <td data-bbox="911 353 935 427">0.311</td> </tr> <tr> <td data-bbox="941 1225 965 1604">Previous heart attack or stroke</td> <td data-bbox="941 938 965 1023">1 (0.2)</td> <td data-bbox="941 640 965 725">1 (0.2)</td> <td data-bbox="941 353 965 427">0.006</td> </tr> <tr> <td data-bbox="971 1108 995 1604">History of thrombosis or pulmonary embolism</td> <td data-bbox="971 938 995 1023">1 (0.2)</td> <td data-bbox="971 640 995 725">1 (0.2)</td> <td data-bbox="971 353 995 427">0.162</td> </tr> <tr> <td data-bbox="1002 1108 1038 1604">Current use of medications for tuberculosis or seizure</td> <td data-bbox="1002 938 1038 1023">0 (0.0)</td> <td data-bbox="1002 640 1038 725">1 (0.2)</td> <td data-bbox="1002 353 1038 427">0.002</td> </tr> <tr> <td data-bbox="1045 1225 1069 1604">History of or current breast cancer</td> <td data-bbox="1045 938 1069 1023">44 (8.6)</td> <td data-bbox="1045 619 1069 725">70 (13.4)</td> <td></td> </tr> <tr> <td data-bbox="1075 1129 1099 1604">Classification of assessed contraindications</td> <td data-bbox="1075 938 1099 1023">27 (5.3)</td> <td data-bbox="1075 619 1099 725">37 (7.4)</td> <td></td> </tr> <tr> <td data-bbox="1106 1257 1129 1604">Any category 3 contraindication</td> <td data-bbox="1106 938 1129 1023">71 (13.8)</td> <td data-bbox="1106 608 1129 725">107 (21.4)</td> <td></td> </tr> <tr> <td data-bbox="1136 1257 1160 1604">Any category 4 contraindication</td> <td></td> <td></td> <td></td> </tr> <tr> <td data-bbox="1166 1204 1190 1604">Any category 3 or 4 contraindication</td> <td></td> <td></td> <td></td> </tr> <tr> <td colspan="4" data-bbox="1197 1278 1220 1604"><b>Health impacts: side effects</b></td> </tr> <tr> <td colspan="4" data-bbox="1227 768 1251 1604">Reported side effects: OTC: 22.3% (104/466), clinic: 30.4% (144/474), p&lt;0.01</td> </tr> <tr> <td colspan="4" data-bbox="1257 1395 1281 1604"><b>Client satisfaction</b></td> </tr> <tr> <td colspan="4" data-bbox="1287 151 1337 1604">3/4 of clinic users and &gt;70% of pharmacy users said they were very satisfied with their source. Only about 4% of each group said they were either somewhat or very unsatisfied with their source.</td> </tr> </tbody> </table>		Clinic users n (%)	OTC users n (%)	P value	Hypertension				Any hypertension (140/90 mm Hg or more)	29 (5.6)	49 (9.8)	0.013	Hypertension 140–159/90–99 mm Hg	23 (4.5)	42 (8.4)	0.036	Hypertension 160/100 mm Hg or more	6 (1.2)	7 (1.4)	0.017	Smoking and age 35 years or older	16 (3.1)	32 (6.4)	0.932	Smokes less than 15 cigarettes per day	0 (0.0)	2 (0.4)	0.377	Smokes 15 or more cigarettes per day	21 (4.1)	21 (4.2)	0.633	Migraine headaches with aura	5 (1.0)	8 (1.6)	0.578	Current gall bladder disease	2 (0.4)	3 (0.6)	0.986	High cholesterol and using medication	2 (0.4)	1 (0.2)	0.152	Diabetes with complications	0 (0.0)	3 (0.6)	0.986	Current liver disease or history of liver cancer	1 (0.2)	1 (0.2)	0.986	History of or current heart disease	0 (0.0)	2 (0.4)	0.311	Previous heart attack or stroke	1 (0.2)	1 (0.2)	0.006	History of thrombosis or pulmonary embolism	1 (0.2)	1 (0.2)	0.162	Current use of medications for tuberculosis or seizure	0 (0.0)	1 (0.2)	0.002	History of or current breast cancer	44 (8.6)	70 (13.4)		Classification of assessed contraindications	27 (5.3)	37 (7.4)		Any category 3 contraindication	71 (13.8)	107 (21.4)		Any category 4 contraindication				Any category 3 or 4 contraindication				<b>Health impacts: side effects</b>				Reported side effects: OTC: 22.3% (104/466), clinic: 30.4% (144/474), p<0.01				<b>Client satisfaction</b>				3/4 of clinic users and >70% of pharmacy users said they were very satisfied with their source. 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Continued

Table 3 Continued

Citation	Results		
2000 Mexican National Health Survey analysis <sup>14</sup>	<b>Health impacts: use of OCs despite contraindications</b>		All p values non-significant
	Hypertension ( $\geq 160/100$ mm Hg)	<b>Clinic users (%)</b>	<b>OTC users (%)</b>
	Age $<35$	1.8	1.7
	Age $\geq 35$	1.1	1.2
	Smoking and age $\geq 35$	4.2	3.1
	Any contraindication	7.5	9.4
	Age $\geq 35$	3.6	4.5
Age $\geq 35$	1.1	1.2	
		11.6	12.8
1979 Mexico National Fertility and Mortality Study <sup>9</sup>	<b>Continuation of OCs</b>		
	First method continuation rates per 100 women who accepted OCs as their first method, by initial source of supply (1974–1979)	<b>Private physician/clinic users</b>	<b>Government programme users</b>
	Total at 12 months	59	57
	Age $<25$	57	56
	Age $\geq 25$	61	58
			<b>OTC users</b>
			60
			55
			66

Continued

**Table 3** Continued

Citation	Results	Clinic users (%) n=587	OTC users (%) n=295
1974 Colombian Fertility and Contraceptive Use Survey <sup>11</sup>	<p><b>Continuation of OCs</b></p> <p>First method continuation of OCs over 12 months: OTC: 79.2 per 100 women (unweighted number of users completing period n=191), clinic: 84.2 per 100 women (n=400)</p> <p>First method continuation of OCs over 24 months: OTC: 68.8 per 100 women (n=131), clinic: 74.3 per 100 women (n=269)</p> <p><i>Note: A January 1975 validation survey indicated that first-segment OC continuation rates were overestimated by approximately 10%–15%. Life table estimates of OC continuation at 12 and 24 months were approximately 5% higher for clinic users than OTC users.</i></p> <p><b>Health impacts: side effects</b></p>		
	Reported any side effects while using OCs	44.4	51
	Reported thrombophlebitis	0	0
	Reported thromboembolism	0	0
	Reported weight changes	7.2	4.9
	Reported varices	4.5	3.4
	Reported headache	27.4	25.1
	Reported nervousness	10.7	15.3
	Reported skin problems	6.2	14.7
	Reported pain	2.8	10.1
	Reported bleeding problems	3.7	5.2
	Reported various other side effects (not specified)	37.5	21.2

OC, oral contraceptive; OTC, over the counter.



or to both smoke (<15 cigarettes per day) and be 35 years or older (6.4% vs 3.1%,  $p=0.017$ ).

The 2000 Mexican National Health Survey analysis reported use of OCs despite category 3 contraindications using the WHO MEC Criteria from 1996 based on hypertension and smoking at or over age 35.<sup>14</sup> Overall, the study found no significant differences in contraindications between OC users who obtained their pills OTC versus those who obtained them at a clinic (table 3). This finding held true when comparing OTC to clinic users on contraindications related to hypertension ( $\geq 160/100$ ) (1.7% vs 1.8%), smoking and age 35 or older (9.4% vs 7.5%), and both contraindications combined (4.5% vs 3.6%).

### Side effects

Two studies reported on side effects related to OC use. The Border Contraceptive Access Study found that, at baseline, 22.3% (104/466) of OTC users reported side effects compared with 30.4% (144/474) of clinic users ( $p<0.01$ ).<sup>12</sup> The Colombian Fertility and Contraceptive Use Survey found that 51% of OTC users and 44.4% of clinic users reported any side effect from initial OC use.<sup>11</sup> Neither group reported the most important complications of OC use (thrombophlebitis and thromboembolism), and similar proportions reported the most common side effect (headache). OTC users were more likely to mention nervousness, skin problems, pain and bleeding problems, while clinic users were more likely to complain of weight changes, varices and other side effects (not specified).

### Satisfaction

One study—the Border Contraceptive Access Study—reported client satisfaction but did not present exact results. They stated, ‘three quarters of clinic users and more than 70% of pharmacy users said they were very satisfied with their source (results not shown). Only about 4% of each group said they were either somewhat or very unsatisfied with their source.’<sup>13</sup>

### Values and preferences review

We identified 24 articles from 23 studies that met the inclusion criteria for the values and preferences review. Of these, 13 articles focused on the perspectives of female OC users, potential users, or women in general,<sup>13 15 16 18 19 21–24 29–31 37</sup> 9 focused on the perspectives of healthcare providers (particularly physicians) and pharmacists,<sup>17 25 26 28 32–36 38 39</sup> and 1 focused on the general public;<sup>27</sup> one article included both women and healthcare providers.<sup>20</sup> Almost all studies were conducted in the USA, except for one each in Canada,<sup>32</sup> France<sup>17</sup> and Ireland<sup>15</sup>; one publication from the Border Contraceptive Access Study included in the values and preferences review included women residing in El Paso, Texas, who accessed OCs in both the USA and Mexico.<sup>13</sup> Studies used both quantitative and qualitative methodologies.

Studies covered both OTC and pharmacy access. While most studies of women asked about hypothetical values and preferences around OTC availability, a few studies reported the perspectives of women who had actually used OTC or pharmacy access services.<sup>13 20</sup> Most studies distinguished between pharmacy access and OTC availability, although a few were less clear about which approach they were studying, using terms such as ‘access to oral contraceptives without a prescription,’ which we assumed to be OTC availability. Using our best assessment of which model studies were examining, we present data for the values and preferences studies separated by true OTC access (table 4) and pharmacy access (table 5), and present results accordingly below. Two studies examined perspectives on both OTC and pharmacy access, so are presented in both tables 4 and 5. One cross-sectional survey among young women aged 14–17 in the USA found slightly higher support for dispensation in pharmacies compared with full OTC availability (79% vs 73%), but slightly higher potential use of full OTC availability compared with pharmacy access (61% vs 57%).<sup>30</sup> Another cross-sectional survey among healthcare providers in the USA found much higher rates of support for pharmacy access (74%) compared with full OTC access (28%), although this study combined the pill, patch and ring together in one question about hormonal contraceptives.<sup>35</sup>

### OTC access

Across studies using both quantitative and qualitative methods, women generally expressed high interest in hypothetical OTC availability of OCs. In quantitative studies, support for OTC availability of OCs ranged from a third of female students in two US colleges/universities<sup>19 31</sup> to 89% of current OC users aged 18–50 in Ireland.<sup>15</sup> However, most quantitative surveys of potential OC users found that a majority of participants supported OTC availability.<sup>15 18 21 24 30</sup> Slightly lower but still sizeable proportions of women said they would obtain OCs OTC if available.<sup>23 24 30</sup> Ease of access, convenience, privacy and time saved from clinician visits for prescriptions were the main benefits women anticipated from OTC availability.<sup>13 16 18 30</sup> However, across studies, participants noted concerns about cost, continued use of other preventive screening options (eg, for Pap smears, pelvic exams, clinical breast exams and sexually transmitted infections) and the safety of such access, particularly for young people, first-time pill users and women with medical conditions.<sup>13 16 18 19 23 30 31</sup>

Healthcare professionals from France and the USA, particularly medical doctors, voiced moderate to low support for OTC availability of OCs, often citing safety concerns, OC efficacy, concerns about correct OC use or missed examinations for medical contraindications.<sup>17 28 35</sup> Providers generally supported making POPs available OTC more than they supported making COCs available OTC.<sup>26</sup>

**Table 4** Study descriptions and key findings of studies included in the values and preferences review examining OTC access

Study authors and year	Country	Population	Study design	Key findings
Potential OC users				
Barlassina, 2015 <sup>15</sup>	Ireland	OC users aged 18–50	Cross-sectional survey (n=488)	88% (429/488) of participants were in favour of OTCs being available without prescription. 92% (448/488) said they were likely to obtain OTCs without prescription if available. Convenience and ease of access were the main advantages of OTC availability, while safety was the biggest concern.
Baum <i>et al</i> , 2016 <sup>16</sup>	USA	Women aged 13–45 who identified with at least one priority population: Black/African-American, Asian/Pacific Islander, Latina, and/or aged 13–24	Qualitative study using focus groups	Women reported potential benefits of OTC access, including convenience and privacy. Many believed OTC availability of OTCs would help reduce unintended pregnancy and help destigmatise birth control. Participants expressed concerns about OTC access, such as worry that first-time users and young adolescents would not have enough information to use the pill safely and effectively, as well as concerns about whether women would still obtain preventive screenings. Women were also worried that OTC OTCs would cost more if no longer covered by insurance.
Dennis and Grossman, 2012 <sup>8</sup>	USA	Low-income women	Qualitative study using focus groups and in-depth interviews	Most participants supported OTC access to OTCs. Participants expected that OTC availability would save women time in clinician visits for prescriptions and increase the convenience of the method. However, they raised concerns about cost, continued use of other preventive screening options and the safety of such access for minors, first-time users and women with medical conditions.
Forman <i>et al</i> , 1997 <sup>19</sup>	USA	Undergraduate students at an urban women's liberal arts college	Cross-sectional survey (n=290)	65% of all respondents felt OTCs should not be available without prescription. The two most commonly cited reasons for not wanting OTCs to be available OTC were: (1) side effect might occur that a healthcare provider could have prevented (59%) and (2) people would not go to their providers for regular check-ups (56%). The most commonly cited reason for wanting OTCs to be available OTC was there would be fewer unwanted pregnancies. Race, previous OC use, previous sexual activity and perceived risk of pregnancy were not significant predictors of believing OTCs should be available OTC. Having had a previous pregnancy was a significant predictor of believing OTCs should be available OTC (p=0.047). Those who believed OTCs should be available only with a prescription were willing to pay more for OCPs (p=0.033). Logistic regression controlling for race revealed that both younger age (p=0.030) and previous pregnancy (p=0.002) were independent predictors of believing OTCs should be available OTC.
Grindlay <i>et al</i> , 2014 <sup>21</sup>	USA	Women aged 15–46 seeking abortion services	Cross-sectional survey (n=651)	81% of respondents supported OTC access to OTCs. While 42% of women planned to use the pill after their abortion, 61% said they would likely use this method if it were available OTC. 33% of women who planned to use no contraceptive following their abortion said they would use an OTC pill, as did 38% who planned to use condoms afterward. In multivariable analysis, several subgroups had increased odds of likely OTC use: women older than 19 (OR: 1.8 for ages 20–29 and 1.6 for ages 30–46), uninsured (OR: 1.5), previous pill users (OR: 1.4), had difficulty obtaining a prescription refill for hormonal contraceptives (OR: 2.7) or planned postabortion pill use (OR: 13.0). Non-White women were less likely to say they would use OTC OTCs (ORs ranged from 0.4 to 0.7).

Continued

**Table 4** Continued

Study authors and year	Country	Population	Study design	Key findings
Grindlay and Grossman, 2018 <sup>23</sup>	USA	Sexually active adult women aged 18–44 not currently desiring pregnancy and female teens aged 15–17	Cross-sectional survey (n=2539: 2026 adult, 513 teens)	39% of adults and 29% of teens reported likely use of OTC POPs, with a greater likelihood if covered by insurance. Among adults, women who were never married or living alone (vs married), uninsured (vs privately insured), current pill or less effective method users (vs ring, patch, injectable or intrauterine device), tried to get a birth control prescription in the past year, or ever used a contraceptive pill/oral contraceptive or POP had higher odds of likely use. Among teens, Spanish speakers and those who ever had sex had higher odds of likely use; Black teens (vs White) had lower odds.
Grindlay and Grossman, 2015 <sup>22</sup>	USA	Women aged 18–44 at risk of unintended pregnancy	Cross-sectional survey (n=2046)	26% of respondents supported an age restriction for an OTC OC; 28% were against an age restriction; and 46% were unsure. In multivariable analysis, women were more likely to support an age restriction for an OTC OC if they had less than a high school degree (OR: 2.5), a high school degree (OR: 1.6) or some college (OR: 1.6) compared with a college degree; if they were married compared with never married (OR: 2.1); and if they lived in the Midwest (OR: 2.1) or South (OR: 2.1) compared with the West.
Grossman <i>et al</i> , 2013 <sup>24</sup>				62.2% of respondents were strongly (31.4%) or somewhat (30.9%) in favour of OTCs being available OTC. 37.1% reported being likely to use OTCs if available OTC, including 58.7% of current users, 28.0% using no method and 32.7% using a less effective method. Covariates associated with a higher odds of reporting interest in using OTC OCs were younger age; being divorced, being separated or living with a partner (vs married); being uninsured or having private insurance (vs public insurance); living in the South (vs North-East); and current use of OTCs or less effective methods, or non-use of contraception (vs use of another hormonal method or intrauterine device).
Landau <i>et al</i> , 2006 <sup>29</sup>	USA	Women aged 18–44 years at risk of unintended pregnancy	Cross-sectional survey (n=811)	Women were more likely to be potential OTC users of OTCs if they had problems with obtaining prescription contraception (OR: 2.55), were uninsured (OR: 2.31), were low income (OR: 1.53), had an unintended pregnancy or pregnancy scare (OR: 1.82), or were African-American (OR: 1.59) or Latina (OR: 1.90).
Manski and Kottke, 2015 <sup>30</sup>	USA	Young women aged 14–17	Cross-sectional survey (n=348)	73% of participants supported OTC access to OTCs, and 61% reported they would be likely to use OTCs available OTC. 79% of participants supported pharmacy access to OTCs, and 57% reported they would be likely to use OTCs available through pharmacy access. Few subgroup differences were noted, except that sexually experienced participants were more likely to both support OTC access and be likely to use it. Suburban teenagers were more likely to support pharmacy access than those from rural and urban areas. The most commonly cited advantage to OTC access was fewer teenage pregnancies (45%). Other common responses were that it would be easier for teenagers to get birth control (22%) and it would be more confidential (14%). Disadvantages cited included teenagers not using condoms to protect against STIs (22%), needing a doctor decide if OTCs are safe for them (19%), might have sex at a younger age (18%) and might use OTCs incorrectly (18%).

Continued

**Table 4** Continued

Study authors and year	Country	Population	Study design	Key findings
Nayak <i>et al</i> , 2005 <sup>31</sup>	USA	University women	Cross-sectional survey (n=500)	37% of participants favoured the acquisition of OCs without a prescription. Women associated OTC access to OCs with increased likelihood of adverse medical consequences and the prescription-only system with an increased likelihood of pregnancy avoidance. Women who preferred OTC availability reported more favourable attitudes towards OC use and stronger intentions to buy OCs without a prescription.
Potter <i>et al</i> , 2010 <sup>13</sup>	USA/Mexico	OC users aged 18–44	Cohort study following 1046°C users who obtained OCs either OTC from a Mexican pharmacy (n=514) or from a family planning clinic in El Paso (n=514)	Cost of pills was the main motivation for choosing their source for 40% of pharmacy users and 23% of clinic users. The main advantage cited by 49% of clinic users was availability of other health services. Bypassing the requirement to obtain a doctor's prescription was most important for 27% of pharmacy users.
<b>Providers</b>				
Billebeau <i>et al</i> , 2016 <sup>17</sup>	France	Health professionals concerned with contraception (internal medicine, obstetricians, medical gynaecologists and midwives)	Cross-sectional survey (n=956)	53.4% of respondents were in favour of OTC access to progestin-only contraceptive pill/oral contraceptives. Compared with other professional categories, medical gynaecologists were the least likely to be supportive (aOR: 0.63, 95% CI 0.46 to 0.87). 19.3% of respondents supported OTC access to combined oral contraceptives. Missed examination for medical contraindications was the main obstacle that respondents saw to free OC access.
Howard <i>et al</i> , 2013 <sup>26</sup>	USA	Physicians (primarily residents training in obstetrics and gynaecology and family practice)	Cross-sectional survey (n=638)	Most physicians (71%) were against a switch to OTC availability for combined oral contraceptives. Of those opposed, safety (92%) was cited as the primary concern. Respondents were fairly evenly divided on making progestin-only pills available OTC—52% were against and 48% were in favour. Of those opposed to POPs, 73% cited safety as their primary concern. Geographic location was not associated with attitude, but female physicians were more likely to favour OTC availability for POPs than their male counterparts.
Rafie <i>et al</i> , 2016 <sup>35</sup>	USA	Reproductive healthcare providers (physicians (mostly gynaecologists), nurse practitioners, certified nurse-midwives, physician assistants and registered nurses)	Cross-sectional survey (n=482)	Overall, 28% of providers supported complete OTC access to hormonal contraceptives (OCs, patch and ring). Physicians were somewhat more supportive of expanding contraceptive access than mid-level providers, but the differences were not significant.

OC, oral contraceptive; OCP, Oral Contraceptive Pill; OTC, over the counter; POP, progestogen-only pill; STI, sexually transmitted infection; aOR, adjusted OR.

**Table 5** Study descriptions and key findings of studies included in the values and preferences review examining pharmacy access

Study authors and year	Country	Population	Study design	Key findings
Potential OC users				
Gardner <i>et al</i> , 2008 <sup>20</sup>	USA	Women (and community pharmacists—see below)	Time series intervention study (n=214 women)	Both women and pharmacists were satisfied with the experience of pharmacist-led interventions for oral contraceptives, contraceptive patches or the contraceptive vaginal ring. Nearly all respondents expressed willingness to continue to see pharmacist prescribers and receive their services from them.
Landau <i>et al</i> , 2006 <sup>29</sup>	USA	Women aged 18–44 years at risk of unintended pregnancy	Cross-sectional survey (n=811)	68% of women said they would use pharmacy access for hormonal contraceptives if available. 41% of women who were not using any contraception said they would begin using a hormonal contraceptive if pharmacy access were available; this was 47% for uninsured women and 40% for low-income women. 66% of current hormonal contraceptive users said they would like to obtain their method through pharmacy access. 63% agreed that hormonal contraceptives should be available without a prescription if a pharmacist screens a woman first. Support declined to 43% when pharmacist screening was not mentioned. Among those not supporting pharmacy access, concerns focused on a potential lack of screening or information.
Manski <i>et al</i> , 2015 <sup>30</sup>	USA	Young women aged 14–17	Cross-sectional survey (n=348)	79% of participants supported pharmacy access to OCs, and 57% reported they would be likely to use OCs available through pharmacy access. Few subgroup differences were noted, except that sexually experienced participants were more likely to both support OTC access and be likely to use it. Suburban teenagers were more likely to support pharmacy access than those from rural and urban areas. The most commonly cited advantage to OTC access was fewer teenage pregnancies (45%). Other common responses were that it would be easier for teenagers to get birth control (22%) and it would be more confidential (14%). Disadvantages cited included teenagers not using condoms to protect against STIs (22%), needing a doctor decide if OCs are safe for them (19%), might have sex at a younger age (18%) and might use OCs incorrectly (18%).
Wilkinson <i>et al</i> , 2018 <sup>37</sup>	USA	Young women aged 18–19	Qualitative study using in-depth interviews	Nearly all participants were supportive of California's new law allowing pharmacists' prescription of contraception. While participants were satisfied with traditional service providers and valued those relationships, they appreciated the benefit of increased access and convenience of going directly to a pharmacy. Participants expected increased access to contraception in pharmacies would lead to both personal and societal benefits. They expressed concerns regarding parental involvement, as well as confidentiality in the pharmacy environment and with insurance disclosures.
Providers				
Gardner <i>et al</i> , 2008 <sup>20</sup>	USA	Community pharmacists (and women—see above)	Time series intervention study (n=26 pharmacists)	Both women and pharmacists were satisfied with the experience of pharmacist-led interventions for oral contraceptives, contraceptive patches or the contraceptive vaginal ring.
Hilverding <i>et al</i> , 2017 <sup>25</sup>	USA	Licensed pharmacists	Cross-sectional survey (n=138)	Most pharmacists indicated that oral and transdermal contraceptive methods should be pharmacist initiated (57% and 54%, respectively) through a collaborative practice agreement or state-wide protocol. Increased access to care and convenience for patients were the most frequently identified potential benefits. Time constraints and concerns about increased liability were identified as barriers. Pharmacists said they needed clinical guidelines, continuing professional education and patient education materials to successfully initiate contraceptive therapy regimens.

Continued

**Table 5** Continued

Study authors and year	Country	Population	Study design	Key findings
Landau <i>et al</i> , 2009 <sup>28</sup>	USA	Pharmacists	Cross-sectional survey (n=2725)	The majority of pharmacists were comfortable and interested in providing direct access to hormonal contraception in the pharmacy. Perceived barriers included lack of time, no mechanism of reimbursement for the service and possible resistance from physicians.
Norman <i>et al</i> , 2015 <sup>32</sup>	Canada	Pharmacists	Cross-sectional survey (n=146) followed by an optional qualitative interview	Over 80% of participating pharmacists indicated willingness to prescribe hormonal contraceptives. Factors associated with willingness to prescribe included comfort using a protocol to access sexual history, confidence about staff availability and public acceptability, and fewer years in practice. Pharmacists requested training in assessment protocols and liability issues prior to implementation.
Rafie <i>et al</i> , 2011 <sup>33</sup>	USA	Student pharmacists	Cross-sectional survey (n=502)	96% of student pharmacists were interested in providing hormonal contraception services to either both minors and adults (53%), adults (41%), or minors (6%). Students felt that patients would benefit from improved access and advice (94.0%). Inadequate pharmacist time was an important barrier in determining whether pharmacists could efficiently and effectively provide OC services, followed by lack of private counselling area in the pharmacy, inadequate patient health information and lack of appropriate incentive structure.
Rafie <i>et al</i> , 2012 <sup>34</sup>	USA	Reproductive healthcare providers, including physicians and advanced practice clinicians	Qualitative study using structured interviews	Most respondents considered the current prescription-only model of access to hormonal contraception to be too restrictive. Some reported a preference for a pharmacy access model where women could obtain contraceptives directly from a pharmacist, bypassing the clinic visit. Many providers believed that method continuation and compliance would improve with pharmacy access to contraception. The most common concern reported was pharmacist's refusal to provide services.
Rafie <i>et al</i> , 2016 <sup>35</sup>	USA	Reproductive healthcare providers (physicians (mostly gynaecologists), nurse practitioners, certified nurse-midwives, physician assistants and registered nurses)	Cross-sectional survey (n=482)	Overall, 74% of providers supported pharmacist-initiated access to hormonal contraceptives (OCs, patch and ring), while 45% supported behind-the-counter access (where any pharmacy personnel can ensure restrictions are met and provide contraceptives). Physicians were somewhat more supportive of expanding contraceptive access than mid-level providers, but the differences were not significant.
Vu <i>et al</i> , 2017 <sup>36</sup>	USA	Pharmacists	Cross-sectional survey (n=121)	Following a new law expanding pharmacists' scope of practice to include directly providing self-administered hormonal contraception to patients pursuant to a state-wide protocol, the majority (73%) of pharmacist respondents said they would likely provide this new service. Respondents reported being comfortable educating patients on short-acting (94%) and long-acting reversible contraception (82%), as well as identifying drug interactions with hormonal contraception (97%). Respondents indicated time constraints (74%), lack of reimbursement (64%) and liability concerns (62%) as barriers to prescribing hormonal contraception.
<b>Other stakeholders</b>				
Irwin <i>et al</i> , 2018 <sup>27</sup>	USA	General public commenting in online social discourse	Retrospective, cross-sectional, mixed methods analysis of public comments posted in response to articles published by major media outlets on OTC availability of OCs	Commenters were generally positive towards pharmacist-prescribed self-administered non-emergency hormonal contraception and cited several benefits, such as increasing access to healthcare, reducing unintended pregnancies and supporting individual autonomy. However, it was acknowledged that these benefits would need to be balanced with potential safety concerns and logistical issues associated with delivering clinical services in a community pharmacy setting.

OC, oral contraceptive; OTC, over the counter; STI, sexually transmitted infection.

## Pharmacy access

Among potential or current OC users, most women were in favour of pharmacy access, and substantial proportions said they would obtain OCs through pharmacy access if it were available.<sup>29 30 37</sup> Some women currently not using any contraception said they would begin using a hormonal contraceptive if pharmacy access were available.<sup>29</sup> One study found that women (and pharmacists) were satisfied with pharmacist-led OC use and expressed willingness to continue seeing pharmacist prescribers.<sup>20</sup> While young women appreciated their traditional healthcare providers, they liked the increased access and convenience of obtaining OCs directly from a pharmacy.<sup>37</sup>

In studies among healthcare providers, pharmacists were generally very supportive of pharmacy access to OCs, while physicians tended to be more moderately supportive.<sup>20 25 28 32–36</sup> Increased access to care, preventing unintended pregnancies and convenience for patients were the most frequently identified potential benefits.<sup>25 33–35</sup> Safety, time constraints, lack of private space in the pharmacy, increased liability and reimbursement were identified as potential barriers.<sup>25 28 33 36</sup> There was also concern from pharmacists about physician's resistance to making OCs available at pharmacies<sup>28</sup> and concern from physicians about pharmacist's refusal to provide services.<sup>34</sup>

Finally, in a study of digital comments on online media articles about pharmacy access to OCs in the USA, commentators were generally positive and cited benefits including increasing access to healthcare, reducing unintended pregnancies and supporting individual autonomy, but noted these must be balanced with potential safety and logistical concerns.<sup>27</sup>

## DISCUSSION

In this systematic review, we identified four studies using comparative designs to examine the impact of OTC availability of OCs. Two studies conducted in the 2000s examined women who obtained OCs OTC in Mexico and compared them with women who obtained OCs from providers in either Mexico or the USA. The other two studies were significantly older (from the 1970s) and compared first contraceptive method users who either obtained OCs OTC from a pharmacy or drugstore or through a provider or family planning programme; the OC formulations in these studies were likely different, and women 45 years ago potentially differ from women today in terms of desired fertility, decision-making around contraceptive methods and perception/tolerance of and tendency to report side effects. While the more recent studies suggested OTC users had higher rates of OC continuation over time and fewer side effects, there was some indication that OTC users had slightly higher rates of use of OCs despite contraindications. Contraindications are an important concern; however, research has indicated that women can self-screen for contraindications fairly well using a simple checklist.<sup>40 41</sup> Despite the

strengths of the studies included in the review, the small evidence base provides limited guidance for countries considering OTC availability of OCs.

We identified a much larger evidence base on the values and preferences of potential users, providers and the public. However, this evidence was also limited, since almost all studies were conducted in the USA. Women were generally in favour of OTC availability; healthcare providers were as well, with pharmacists expressing higher support than physicians for pharmacy access. Among both women and providers, support was generally higher for dispensation in pharmacies compared with full OTC availability, and for OTC access to POPs rather than COCs. Given the near-universal use of COCs at the times and locations where the studies included in the main review were conducted, we had no comparative effectiveness data on POPs. This is unfortunate, as POPs have been suggested as a good option for initial OTC availability, given that they have fewer contraindications to use.

An additional concern about OTC availability is that the concomitant reduced visits to clinicians may also translate to a reduction in routine preventive screening (including for Pap smears, pelvic exams, clinical breast exams and screening for sexually transmitted infections). This was not one of our prespecified PICO outcomes since such exams are not required to receive OCs per the WHO's Selected Practice Recommendations for Contraceptive Use.<sup>42</sup> However, the Border Contraceptive Access Study did report on preventive screening; while women who obtained their OCs from a clinic reported slightly higher rates of some screenings, both groups (OTC and clinic users) had high overall rates of reported screenings with relatively minimal differences between groups.<sup>43</sup> One values and preferences study also found that US women said they would continue to get screened if OCs were made available OTC,<sup>23</sup> although clinicians were afraid they would not.<sup>35</sup> These findings offer some indication that OTC access for OCs may not necessarily result in reduced use of other preventive services.

OTC availability is only one way to increase access to OCs. A previous systematic review found that increasing the number of OC pill packs dispensed or prescribed increased OC continuation, although it also resulted in increased pill wastage.<sup>44</sup> There are also internet-based platforms for ordering OCs, which comply with clinician prescriptions or pharmacist screening, but conduct all screenings online.<sup>45</sup> A modelling study found that making out-of-pocket pill pack costs low or free would increase OC use.<sup>46</sup> Finally, increased insurance coverage for OCs should also reduce access barriers to OC use, regardless of access point. Although moving OCs to OTC status should lead to fewer clinician visits for women, thus decreasing costs related to travel, time and other medical expenses associated with those visits, OTC access could potentially increase the cost of OCs if insurance does not cover OTC purchases, or if women are unaware that they can use insurance in OTC purchases. Insurance

considerations should be explicitly considered in policy discussions of OTC availability, as insurance coverage will be particularly important for some of the most vulnerable groups, such as low-income women and girls.

Our review has several strengths, including our broad search strategy and our inclusion of both effectiveness and values and preferences studies. However, conclusions from our review are limited by the small evidence base in this area. We identified four observational studies in our main effectiveness review, from the same global region, and there may have been residual confounding in comparing OTC and clinic OC users despite some analyses being adjusted. Although there were more studies in the values and preferences review, they were also geographically limited, and many relied on participants' responses to hypothetical questions about OTC availability. While it is challenging to conduct randomised trials of what is fundamentally a policy intervention, researchers should be encouraged to take advantage of natural experiments such as the Border Contraceptive Access Study or to study changes to policies such as those recently allowing pharmacy access to OCs in the US states of Oregon and California. Further, many countries already allow OTC availability of OCs, so policy decisions can also take into consideration the wide range of country experience in this area.

Despite the limitations of the evidence base, this review provides important information to guide policy decisions around OTC availability of OCs. This evidence has been used to inform the development of WHO recommendations for self-care interventions for sexual and reproductive health and rights in relation to OTC availability of OCs. The benefits and harms of OTC availability of OCs and the values and preferences of patients and providers found in the present review, along with a separate survey of community values and preferences and consideration of resource use, human rights and feasibility, will shape the recommendation. Additional research into outcomes critical to decision-makers where little comparative data currently exist should be done to address the gaps identified.

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