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Hormonal contraception without a prescription: opinions of pharmacists, general practitioners and gynaecologists in Flanders, Belgium

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ABSTRACT

Objective: The accessibility of contraceptives varies greatly from country to country. Because unintended pregnancies have a considerable impact, programmes have been initiated in some countries to make certain contraceptives available without a prescription. We therefore investigated whether or not Flanders, the Dutch-speaking part of Belgium, is ready for such an initiative.

Method: We used a mixed-methods approach with a mainly qualitative methodology. The opinions of pharmacists, general practitioners (GPs) and gynaecologists, the three types of health care provider most closely involved in the prescription and delivery of contraception, were examined.

Results: A majority of pharmacists supported the idea. Moreover, a large majority occasionally dispensed hormonal contraception without a prescription. Pharmacists expected negative responses from physicians. Among GPs and gynaecologists, a small majority supported the idea conditionally. A minority either fully supported the idea or found it completely unacceptable.

Conclusion: Economic aspects were clearly important in forming an opinion on the topic, although medical arguments were often used when they happened to point in the same direction. Flemish pharmacists were willing to train for and implement a new service that would provide contraceptives without a prescription. The majority of GPs and gynaecologists expressed reservations about such a service and doubted that it would reduce unintended pregnancies. If this service were to be implemented, caution would be needed to avoid giving contraceptive users conflicting information.

KEYWORDS

Contraceptives, general practitioners, gynaecologists, health knowledge, health service accessibility, pharmaceutical services/legislation and jurisprudence, pharmacists/legislation and jurisprudence

Introduction

Enovid was approved by the US Food and Drug Administration in 1960 and signalled the start of oral hormonal contraception for women [1,2]. A lot of knowledge has been gained since then and the risk/benefit ratio of oral contraceptives has improved considerably [3]. General acceptance of contraception in society has also increased dramatically and it is agreed by the international community that the right to health includes the right to control one's reproduction [4]. The health benefits of family planning and contraception are well documented [5,6] and as such were among the millennium development goals [7]. Further investment in family planning should be instrumental in reaching the sustainable development goals of the United Nations [8]. There is, however, still room for improvement, as a very large number of pregnancies in developed and developing countries are unintended [9]. The total cost of unintended pregnancies is high [10], both for the individual [11,12] and for the community at large [13]. Consequently, there are still a considerable number of abortions [14] and globally the serious problem of unsafe abortions continues, although there has been evident progress [15].

Barriers to contraceptive services are to some extent responsible for the large number of unintended pregnancies [16–21]. In this context, a number of initiatives have tried to address the problem of availability of hormonal contraception [22,23]. In the USA, this research motivated the American College of Obstetricians and Gynecologists to recommend switching to over-the-counter (OTC) status [24] for certain forms of hormonal contraception, as suggested more than two decades ago by Trussell et al. [25]. This OTC status is uncommon in the developed world but, globally, a prescription was found to be necessary in only 31% of the 147 countries assessed [26].

In an attempt to reduce the number of unintended pregnancies, a new initiative was started in January 2016 in the US state of Oregon: trained pharmacists were allowed to dispense certain hormonal contraceptives without a doctor's prescription [27]. Currently, women must be older than 18 and a questionnaire-based screening process is necessary to reduce inappropriate use. These initiatives are not limited to the USA; in the UK, a recent report from the London School of Economics [28] urged broader implementation of the knowledge gained from successful pilot schemes [29,30].

The percentage of unintended pregnancies in Belgium [31,32] is smaller than the high, but declining, number in the USA [33]. As there is a lack of good data, however, the prevalence of unintended pregnancies can only be evaluated indirectly through abortion statistics. In Belgium, the prevalence of abortion is among the lowest but has not decreased in the last decade [14,31,32], in contrast to other European countries. The recently noted increased prevalence of certain sexually transmitted infections in Belgium [34] might also have had an influence on health care providers' opinions about changing access to contraception. A European Union report about access to contraception [35], published after completion of the present study, ranked Belgium among the top performers in Europe. The same report notes that, in those countries that have them, there is room to improve prescription requirements: 'to ensure that they are clear and concise and are implemented effectively'. In this way the report avoids taking a stance on the need for these requirements.

The aim of this study was to determine the responses of health care providers (pharmacists, general practitioners [GPs] and gynaecologists) to a potential change in the legal status of contraception, i.e. making it available without prescription, as a strategy for reducing unintended pregnancies [36]. It is important to gain a detailed insight into the opinions of a diverse population of health care providers and any opposition that a change may encounter.

Methods

A qualitative research approach was used to study the possible removal of the need for a prescription to obtain hormonal contraception. The aim was to document the range and diversity of opinions and suggestions or objections to the proposal. Pharmacists, GPs and gynaecologists were interviewed, as they are currently involved in the prescribing and dispensing of these products in Flanders, the Dutch-speaking part of Belgium. Initially, a prototype questionnaire was developed that was subsequently adapted for the three different health care provider groups to be interviewed, but the questionnaires of the GPs and gynaecologists ultimately turned out to be very similar. Great care was taken to formulate the questions in an unbiased manner, in order to allow the interviewees to express their opinions freely, enabling a grounded theory-based analysis. The interviews were tested on two recently graduated pharmacists, two GPs and two gynaecologists in residency. Practice location and the years of experience of the interviewees

were also recorded. The questionnaires are included in the Appendix. As they are easily accessible, pharmacists were visited directly. By contrast, more effort was needed to find physicians willing to participate. There was no prior relationship with the interviewees and transcripts of the interviews were not shared with them. During the interviews no other people were present who might have influenced the process.

Answers to the questionnaires were entered either by the health care worker into the online form generated by Qualtrics software [37] or by a researcher using an audio-recording of the interview. Responses illustrating the diversity of opinions encountered are discussed in the results section below.

Results

Tables 1–3 summarise the most important results of the questionnaires.

Pharmacists' responses

Pharmacists were approached first; 64 pharmacies were visited and 59 agreed to participate. There was a wide range of professional experience in the sample (<5 years, 31%; 5-10 years, 21%; 10-20 years, 19%; >20 years, 29%).

Emergency contraception was dispensed on a regular basis, but the frequency was markedly higher in urban areas compared with rural settings, confirming previous internal research. Eighty percent of pharmacists reported more frequent demand for contraceptives out of hours.

A small majority (53%) of the pharmacists surveyed, mostly working in urban or suburban areas, said that they had been asked questions about unintended pregnancy. Questions most often asked were:

- I forgot to take my pill and had intercourse, can I be pregnant now?
- When should I take the emergency pill and does it work properly?
- How late can you get an abortion?
- What steps do I need to take now that I have an unintended pregnancy?

Ninety percent of respondents confirmed that they had dispensed contraception without a prescription. Most said they had done this only for individuals they already knew or who were on the pharmacy's computer system and had promised to provide a prescription. Some reported they had dispensed contraceptives after telephone contact with the attending physician. Other pharmacists dispensed only a 1 month strip out of a multi-strip box, paid in full and to be dispensed only on receipt of the prescription. A few pharmacists admitted that they gave contraception to regular customers even if no prescription was provided later. No difference between pharmacists was noted in terms of their years of experience.

Eighty percent of the pharmacists interviewed thought that a visit to the doctor was one of the biggest obstacles to obtaining contraception:

When young girls inquire about or buy emergency contraception, my advice to consult a physician often deters them (Urban area, >20 years' experience)

Other barriers cited were cost, restrictions by parents or fear of side effects. In addition, nonchalance or ignorance was reported, especially by more experienced pharmacists.

After being informed about the Oregon approach, 75% of pharmacists were willing to take a training course in order to be licensed to deliver the service. Those not willing were mostly pharmacists with 10-20 years of experience:

The number of tasks a pharmacist has to perform is already large enough; this is something doctors need to do (Rural setting, 10-20 years' experience)

A 14% minority stated that this was simply part of their job, whether or not there was separate remuneration for the task. A similar minority, however, stated that they did not have sufficient time to deliver this type of service. Approximately 73% said that they were able and willing to do so, provided there was extra remuneration:

What will the pharmacist gain from this? We already carry out a large number of tasks and do not have much time to take on extra responsibilities (Rural setting, >20 years' experience)

A large majority of pharmacists (70%) thought that the introduction of this service would affect the relationship between pharmacists and physicians. The majority of pharmacists who thought

otherwise had less than 5 years of experience:

It depends on the particular physician, as there can be big disparities between them. Some do not mind that you call them, while others do not even want to hear that some of their prescriptions are indecipherable. Some already have too much work. Especially the younger generation would not mind us performing this task, if it is done in a well-structured manner (Urban area, >20 years' experience)

I think that some conservative physicians will not be willing to take part in this. They are used to being in control, as they decide which medications to start and continue. If they no longer control this process, then they would also lose the income from the consultation. On the other hand, many physicians are extremely busy and they would probably prefer to be relieved of the administrative burden if no start-up or switch of contraception is involved (Rural area, <5 years' experience)

I don't think that physicians will agree with this. If problems arise with a particular patient, their response could be: 'The pharmacist may have said so, but he is acting beyond his professional competencies' (Rural area, 5-10 years' experience)

Many doctors still feel superior to other health professionals and they will especially fear losing income (Rural area, 10-20 years' experience)

For the important question of whether the newly proposed service would result in fewer unintended pregnancies and consequently fewer abortions, 33% of pharmacists responded that it would not make a difference:

I think that mainly young girls would be better off talking about this with a female health care provider, although nowadays there are lots of female physicians, both GPs and gynaecologists (Urban area, >20 years' experience)

In order to reduce these numbers, I think efforts should be focused on providing extensive information, especially to very young girls (11-18 years) and to women approaching the menopause. In carrying out this task, both the doctor and the pharmacist can play a role (Rural area, <5 years' experience)

I don't have the impression that not taking the pill is caused by not daring to go to the doctor. Those who have religious objections or are pressured at home will not suddenly change their mind and go to the pharmacy (Rural area, 5-10 years' experience)

The 66% majority assumed that the number of unintended pregnancies would fall:

The patient will be spared the effort to obtain a timely appointment with the GP or gynaecologist (Rural area, <5 years' experience)

I expect a limited decrease. The question remains whether that contraception will then be reimbursed without a prescription (Rural area, >20 years' experience)

The purpose of the last question was to get a more detailed view of the pharmacists' opinions on the proposed new service. Approximately 80% indicated their support if certain conditions and rules were met. Many pharmacists found themselves not properly trained to perform the task. A minority (20%) unequivocally rejected the idea:

This would make it more difficult for physicians to keep on top of things, as contraception would then no longer be contained in their medical files (Urban area, <5 years' experience)

There is so much more than just that piece of paper to get the pill: STDs, breast examinations, Pap smears and so on are also very important (Urban area, >20 years' experience)

I wonder how gynaecologists themselves determine which pill they would prescribe, because I cannot discern any consistency in their prescribing habits (Urban area, 5-10 years' experience)

What if the patient has an adverse reaction? Who would be held responsible? (Urban area, >20 years' experience)

'A cobbler should stick to his last', and that says it all (Rural area, 10-20 years' experience)

A number of pharmacists reported some practical problems that would need to be considered:

This basically means we'll have to reserve a block of time for consultations. That's going too far (Urban area, 10-20 years' experience)

If I am alone here in the pharmacy, reserving 15 min to talk privately with a patient is hardly possible. A physician is much better equipped for that (Urban area, >20 years' experience)

How will this practically be implemented? Either everyone follows the extra training or no one does; otherwise, it will not work (Rural area, 5-10 years' experience)

A lot of time needs to be reserved for this contact with the patient and that is not straightforward in daily practice (Rural area, > 20 years' experience)

Furthermore, some pharmacists expressed doubts about the patient questionnaire:

Having a good relationship with the patient seems to be essential because she has to be able to answer the questions honestly (Urban area, 5-10 years' experience)

Do all patients want to sit down and answer such an extensive questionnaire in a pharmacy where there is no privacy? (Rural area, 10-20 years' experience)

I wonder whether patients will be capable of filling in the questionnaire and whether they will do it in an honest manner (Urban area, >20 years' experience)

I hope that the questionnaire does not come with extra 'red tape'. In itself for me this questionnaire is clear enough, but I expect precise directives (Urban area, > 20 years' experience)

A fourth concern from the pharmacists was reimbursement; 13% indicated this as a possible problem:

Lots of things change these days. New tasks appear and then disappear just as fast, including the attached financial compensations. We need to think about long-term projects (Urban area, >20 years' experience)

What is in it for us? Many such tasks are forthcoming, but they all require lots of time, so there must be something in return. After all, a physician is also paid for a consultation (Urban area, >20 years' experience)

I would like more clarity about reimbursement for seeing the patient (Rural area, >20 years' experience)

In addition, more than 27% of pharmacists questioned whether the proposal would negatively affect preventive services by physicians:

The visit to a doctor can ensure that a gynaecological exam takes place on a regular basis, which, for several women I know, meant early detection of certain medical conditions and/or cancer (Urban area, 10-20 years' experience)

It also seems important to occasionally measure the blood pressure of the patient. In principle, a pharmacist could also do this, but where does it stop? Can we interpret the data correctly? (Urban area, > 20 years' experience)

I fear that if there is no longer the need for a prescription, people will simply skip gynaecological examinations. We should instead think about extending the validity of a contraceptive prescription, for example, to 3 years (Rural area, >20 years' experience)

Finally, below are some opinions from pharmacists (34%) who thought that current regulations and procedures provided adequate availability of contraception and that the proposal would not reduce unintended pregnancies:

I don't think that this will lead to fewer unintended pregnancies, as many women simply do not take the pill correctly. In addition, I think that this will lead to more sexual contacts with increased STD risks, as many do not realise the pill does not offer any protection for STDs (Urban area, 10-20 years' experience)

I wonder if this is necessary, because with 13 cycle packages you only need to go to the doctor once a year. I doubt whether this will prevent many unintended pregnancies, because the morning-after pill is already available without a prescription (Urban area, 10-20 years' experience)

Many people take the pill without realising that they are using hormones. It would be better to focus more on informing women about the use of contraception and what that entails. With this proposal, there would be a lot of unnecessary use (Rural area, <5 years' experience)

A lot of positive comments were also recorded and many pharmacists were in favour if certain prerequisites were met:

For me, this is workable on condition there is some kind of prescription from a physician that applies to all types of contraceptives and is valid for a period of, for example, 3 years. In addition, I expect sufficient training and remuneration for the pharmacist (Urban area, >20 years' experience)

Only if there is adequate training and a handy, efficient 'tool' is developed to process the questionnaire (Rural area, 10-20 years' experience)

I conditionally agree, either with a standardised list and a fee for the pharmacist or after a doctor starts it up. Controls must be built in to make sure that the necessary medical examinations are not skipped and additionally patient registration at one pharmacy must be done to avoid 'shopping' or overconsumption (Rural area, 10-20 years' experience)

I can support this if adequate screening is done by a type of 'family pharmacist' who has a therapeutic relationship with the patient (Rural area, >20 years' experience)

Many pharmacists made remarks about the usefulness of the proposal:

For people who are long-time users of certain contraceptives, I do not see the added value of a doctor's visit. My doctor has never measured my blood pressure while renewing my prescription (Rural area, <5 years' experience)

I support the proposal because many young girls never go to the doctor as they rarely get sick. It is quite a burden for them to go to the GP with the sole aim of obtaining a prescription. I am therefore convinced that more girls would take the pill if it were facilitated in this way (Rural area, <5 years' experience)

I do not think that women have any apprehensions about going to their gynaecologist, but if you make an appointment you need to wait for another 4 months before it takes place. That is too long for starting the pill. You could just enter a pharmacy and be helped on the same day (Rural area, 5-10 years' experience)

There were also some unequivocally positive opinions:

I think it is long overdue to abandon the prescription requirement for contraception (Urban area, >20 years' experience)

I definitely want to do this. We dispense the pill very often, so that could certainly be an added value (Urban area, >20 years' experience)

I do not need an extra fee for this, as I welcome the licence to do this (Urban area, 5-10 years' experience)

We are still a first point of contact for patients. We are evolving towards a system where we will (have to) make more time available for patients and this is completely in line with that (Urban area, 10-20 years' experience)

This could catalyse a reappraisal of the role of pharmacists, something patients will appreciate and would abate their 'shopkeeper' image (Rural area, <5 years' experience)

GPs' responses

The opinions of 26 GPs were obtained (experience distribution: <5 years, 27%; 5-10 years, 19%; 10-20 years, 12%; >20 years, 42%). Before proceeding to the questions, a brief introduction to the Oregon programme was provided. About one-third of the GPs surveyed opposed the ideas behind the Oregon proposal. A larger group conditionally supported the proposal, although they wanted it to be thoroughly amended. GPs with between 5 and 10 years of work experience were the least disapproving.

A large proportion (38%) of GPs feared that women would be less likely to have preventive health care carried out by a physician:

I always use a consultation for a pill prescription to remind young women that they should have a Pap smear test. It is a population that we do not see very frequently, so I fear that the absence of these consultations will influence cervical cancer screening (Urban area, 5-10 years' experience)

I find it useful to see young girls on a yearly basis to build some kind of rapport. During the consultations, often other questions emerge (not just pill-related) (Urban area, <5 years' experience)

Doubts about the practical implementation of this service were expressed by 42% of the GPs, who questioned how privacy could be guaranteed. The screening questionnaire itself and its administration also raised doubts:

I think that many people often do not know the answers to the questions. Actually, there should be an additional box to respond 'I don't know' (Urban area > 20 years' experience)

When I see patients for a pill prescription, it really takes a full consultation. Can the pharmacist perform this task in 15 min, while not even going through all the possibilities? (Rural area, <5 years' experience)

The pharmacies in Belgium are not prepared for this initiative, as there is a huge lack of privacy. If space needs to be created where the patient can consult with the pharmacist privately, then this can just as well be done in the doctor's surgery (Rural area, >20 years' experience)

Approximately 64% of the GPs provided a negative response to the question whether the proposal would reduce unintended pregnancies and consequently result in fewer abortions:

The morning-after pill is available in this way. And even though there is access to the pill, there are also risks of the incorrect use of contraception or when the patient receives incorrect information (Urban area, 10-20 years' experience)

In order to really have an impact, the age limit should be lower than 18 years of age (Urban area, >20 years' experience)

I do not expect a reduced incidence. Unexpected sexual relations will still happen. (Urban area, >20 years' experience)

I do not think that the obstacle for consulting us is that high. Going to the pharmacy and discussing everything 'in plain sight' is also a barrier (Rural area, 10-20 years' experience)

Half of all GPs were of the opinion that implementing the proposal would change their relationship with pharmacists:

I think older colleagues will no doubt say: 'shoemaker, stick to your last' (Urban area, >20 years' experience)

Are we somehow not overstepping the mark here? Typically, a patient sees a doctor to be treated and then goes to the pharmacist to obtain the medication, which is accompanied with the appropriate advice. I am having great difficulty getting to grips with this idea (Rural area, <5 years' experience)

There will be GPs who will be very angry about this, but some are already angry now. But, if the government decides to implement this, then the pharmacists cannot be blamed (Rural area, 10-20 years' experience)

They will become competitors (Rural area, >20 years' experience)

I think you will get opposition from all the gynaecologists; they are still acting out of a notion of superiority and always seek a reason to have a special relationship with a patient (Rural area, >20 years' experience)

Twenty percent of GPs pointed out that the health care system in the USA cannot be compared to the system in Belgium. A few additional, disapproving opinions were expressed as follows:

In my view, pharmacists sometimes fail to even explain the use of contraception and can be described more accurately as retailers (Urban area, 10-20 years' experience)

As a woman, the faster you can obtain the pill, the better. A more appropriate step here would be a shift from gynaecologists to GPs (Urban area, 10-20 years' experience)

I think there would be an increase in STDs (Urban area, >20 years' experience)

In any case, the opportunity to talk about sexuality and relationships will be lost (Rural area, <5 years' experience)

After contraception, what will be next? Will there be a shift to consultations with the pharmacist? We can of course choose to work together, but everybody has to stick to their own tasks (Rural area, 5-10 years' experience)

I cannot help but feel that pharmacists want to take over a number of essential tasks from GPs. But it requires more than pure pharmaceutical science (Rural area, >20 years' experience)

More than 60% of the interviewees, however, supported the idea if certain conditions were met. The majority of GPs wanted the initiation of contraception to be done by a physician:

The pharmacist should explain the medication. It should not become an OTC product (Urban area, >20 years' experience)

I support this if the patient goes to a permanent pharmacist and the initiation of contraception is registered so that the GP can monitor what has been given (Urban area, >20 years' experience)

Initiation by a pharmacist must be communicated to the GP. The follow-up must be done by a doctor (Urban area, >20 years' experience)

What I miss here is a blood pressure measurement. This can conceivably be done by pharmacists and then they can refer the patient to the GP if a certain value is exceeded. In the checklist, an additional question could be included inquiring when the last smear was done (Rural area, <5 years' experience)

Pharmacists have to be adequately trained and should fully support this effort. Responsibility lies with them, and as a result I would then not want to be bothered with phone calls about it (Rural area, >20 years' experience)

Some GPs clearly observed a number of advantages both for themselves and for hormonal contraceptive users, and 23% explicitly expressed the need for closer collaboration with pharmacists:

The goal should be a much better exchange of information about the medications used by the patient and this should be in two directions (Urban area, <5 years' experience)

I think there are more interesting topics to collaborate on instead of squabbling about this. It would be better if we could cooperate to optimise the information provided to patients, instead of allowing polarisation to take place (Urban area, 10-20 years' experience)

In my opinion, a regular home pharmacy would be ideal for this (Urban area, >20 years' experience)

If the rules are clear and a short checklist with precise instructions is used, I do not think it will cause problems. In that way, pharmacists will know exactly what to do (Rural area, <5 years' experience)

The GP already has such a heavy workload and should not have to deal with trivial matters. Task delegation is important. Perhaps pharmacists can perform a number of tasks better (Rural area, >20 years' experience)

A number of GPs felt the Oregon proposal should be expanded:

After all options have been discussed during an initial consultation with a doctor, contraceptive prescription could be passed to the pharmacist. It should also be extended to women under the age of 18 (Urban area, >20 years' experience)

When passed to a pharmacist, it should of course not be limited to oral contraception and the patch (Urban area, 10-20 years' experience)

Finally, some additional positive comments were expressed as follows:

I am open to this. For us it often becomes routine and we can forget how important it is (Urban area, >20 years' experience)

I sometimes find it frustrating to get phone calls from women just to write a prescription. This could solve the problem immediately (Urban area, >20 years' experience)

This is an excellent plan. Contraception is known to be very safe. The risks involved with not providing birth control and women first having to visit a doctor are probably greater (Rural area, >20 years' experience)

I support it for the following reasons. The regular Belgian reimbursement system implies that every patient must be seen. In the system where I work, as a salaried GP, this is not a problem. Secondly, I wonder what the added value of a doctor's consultation is. I think it is hard to prove (Rural area, >20 years' experience)

When asked whether their process of prescribing contraceptives was comparable to the structure of the Oregon questionnaire, 38% of GPs responded that they always measured blood pressure. Some pointed to other factors that they routinely incorporated into the process of prescribing contraception.

I do not work with questionnaires, but I tailor my questions to the individual I am seeing at the time (Urban area, >20 years' experience)

If I had to go through that list every time, I would be a 'very' good doctor (Urban area, >20 years' experience)

The first time that I provide a prescription of the pill, I restrict it to 3 months, after which I ask if they like it and if they have any questions. If they are OK then they get a prescription for a longer time (Urban area, 10-20 years' experience)

I review all the different options, some of which they may not know about. I inquire about their expectations and their family history. I also measure their starting weight because women often think that they will gain weight (Rural area, 5-10 years' experience)

I carry out very few additional tests myself. According to the Flemish recommendations, lots of them should be done, while the Dutch guidelines do not require them at all. I inquire about family history and whether the patient is aware of potential side effects. In addition, I always inform the patient about the deleterious health effects of smoking (Rural, >20 years' experience)

Gynaecologists' responses

After contacting, in many different ways, 121 gynaecologists, 19 indicated they were willing to participate in the survey (experience distribution: <5 years, 32%; 10-20 years, 47%; >20 years, 21%). The Oregon programme was first explained before proceeding to the questionnaire. Approximately 44% of the gynaecologists surveyed categorically opposed the proposal and 31% feared that fewer women would forgo preventive investigations. Half of the interviewees, however, approved, if certain conditions were met. A single gynaecologist thought it was a very good idea and suggested extending the scope of the proposal even further. In this group it was clear that the more recent graduates and those working in a hospital setting were more in favour of the Oregon proposal.

Conducting a clinical exam before starting contraception is very important. There are patients who, for example, develop kidney failure when contraception is started without prior examination or a blood pressure measurement. I think you're doing a bad job if you leave this to the pharmacist (Urban area, >20 years' experience, hospital)

We already see lots of problems with pharmacists. They often dispense therapies that do not fit together. I think that they must first learn to work on the tasks already assigned to them before they add other things (Urban area, >20 years' experience, hospital)

Contraception would be more easily accessible to the patient, but on the other hand there are also clear advantages if the patients first need to visit a doctor to obtain a prescription. During that initial doctor's

consultation, not only can contraception be discussed but a gynaecological examination and screening for cervical cancer and other STDs can also be performed (Urban area, <5 years' experience, hospital)

Without a visit to a doctor, women who want to become pregnant will stop contraception without knowing that they should start taking folic acid and stop taking other medications (Urban area, <5 years' experience, hospital)

This will endanger the doctor–patient relationship. People often come to the doctor so that they also know who to contact when future problems may arise or which obstetrician to select (Rural area, 10-20 years' experience, hospital and private practice)

The gynaecologists were also concerned about the extensive range of existing contraceptives:

Today there are many different contraceptives on the market with additional benefits that only we as medical doctors are especially qualified in. You will not change that with just 5 h of training (Urban area, 10-20 years' experience, hospital and private practice)

Gynaecologists must develop the guidelines for GPs and pharmacists on the use of oral contraceptives and contraceptive patches, to avoid a bidding war between these three professional groups, and also to forestall any promotional activities of the pharmaceutical industry (Urban area, >20 years' experience, hospital)

Is it not the case that the pharmacist will dispense something more readily if that product makes them more profit? (Rural area, 10-20 years' experience, hospital)

Approximately 40% of gynaecologists questioned whether pharmacists were really willing to take on this extra task and also expressed doubts about how it would work in practice. The patient questionnaire also raised doubts:

The checklist requires some health literacy, which is probably missing in some Flemish youth – perhaps especially so among those who would opt for OTC contraception. There are also some medico-legal issues: for example, are pharmacists willing to see their liability premiums increase? There are also challenges with costs and administration (Urban area, >20 years' experience, hospital)

Almost 70% of the interviewees answered negatively about whether the Oregon proposal would decrease unintended pregnancies and lead to fewer abortions:

If you really want to lower the threshold, I think you have to offer OTC contraception from the age of 13. It is precisely young women who are hesitant to contact a doctor about it (Urban area, <5 years' experience, hospital and private practice)

In my experience, unintended pregnancies are not so much the result of not having access to contraception, but simply from non-use or failure of a particular contraceptive method (Urban area, 10-20 years' experience, private practice.)

The OTC availability of emergency contraceptives and the decreased cost of contraception have had no effect on the abortion rate (Urban area, >20 years' experience, hospital)

What is needed is better information in schools. This topic should ideally be taught by a doctor and/or pharmacist as a guest teacher (Urban area, >20 years' experience, hospital)

There will always be situations where things go wrong. I still meet people who think that they have to take a pill before they have sex (Rural area, 10-20 years' experience, hospital and private practice)

Half of the gynaecologists predicted problems between doctors and pharmacists as a result of such a proposal:

There will more than likely be a tsunami on telephone advice (Rural area, 10-20 years' experience, hospital and private practice)

Difficult communication between doctors and pharmacists could cause misunderstandings and could therefore harm the patient (Rural area, <5 years' experience, hospital)

- Anyhow, this will not change **a relationship that is already burdened with problems**
–(Rural area, 10-20 years' experience, hospital and private practice)

It's one or the other, but not both (Rural area, >20 years' experience, private practice)

Similarly to GPs, approximately 30% indicated that health care in America could not be compared to health care in Flanders.

With regard to the financial barriers for accessing medical care provided by a physician, the situation in Flanders is not comparable to that of the USA. Here, the maximum co-payment is €16, while in the USA it is about a €100 (Urban area, <5 years' experience, hospital and private practice)

The crux of the matter is not whether Belgium is ready for this initiative; it is simply not necessary. A good medical system like ours should not follow the example of a bad medical system, such as that in the USA (Rural area, 10-20 years' experience, hospital and practice)

Some gynaecologists, however, would certainly support the idea if certain conditions were met. Almost 40% confirmed that an initial consultation with a doctor was important:

The offer must be limited to one or two different pills. At the same time as the checklist, a leaflet must be included with brief information about the correct use, referral to websites and advice to consult a doctor in case of poor tolerance, doubts about STDs, etc. (Urban area, >20 years' experience, hospital)

More so than for adults, it seems to be important for those under 18 years of age. Patients over the age of 18 can take the initiative themselves, while minors depend on their parents for a visit to the doctor and for which medications they can take (Urban area, >20 years' experience, hospital)

Pharmacists should receive a fee for this advice/consultation. After all, this type of consultation takes time. Pharmacists would admittedly encroach on the territory of GPs, but in one way or another a *modus vivendi* must be possible between the various health care providers (Urban area, >20 years' experience, hospital)

Some supported an effort to better allocate the tasks between doctors and pharmacists:

I hope that doctors and pharmacists, in one way or another, will learn to cooperate on this more closely by developing a strategy to guarantee optimal health of young women on the one hand, while making access to contraception as easy as possible (Urban area, >20 years' experience, hospital)

Every scientifically grounded intervention that makes contraception more accessible and, in this way, reduces the number of unintended pregnancies gets my support if the safety of the patient is not compromised. If the pharmacist succeeds in prescribing the best product for 'this specific patient', without allowing any business or other interests to interfere, then it all seems feasible to me (Rural area, 10-20 years' experience, hospital and private practice)

Only a 30% minority of the gynaecologists were of the opinion that introducing such a proposal would reduce unintended pregnancies:

The 'shame' of contacting a doctor is eliminated (Rural area, <5 years' experience, hospital)

Patients will visit pharmacists sooner if a pill strip is finished. To see a doctor you typically first need to make an appointment (Rural area, <5 years' experience, hospital)

A large majority of gynaecologists thought such a proposal could be discussed with the Flemish Association for Obstetrics and Gynaecology (VVOG), or a similar association, but it was difficult to prefigure their possible response:

Just try. First list arguments in favour, then consider to what extent it is a threat to a medical practice, then find arguments so that doctors do not feel threatened. It is best to work with them to draw up a type of decision tree, a clinical pathway to be followed and whose conditions should be met (Urban area, >20 years' experience, hospital)

These proposals have already been discussed and defended by some at VVOG meetings, but at present there is resistance among the majority of practising gynaecologists because they fear a loss of income. Once a good system has been worked out, however, most people will change their mind (Urban area, >20 years' experience, hospital)

I think it will be very tough. There are hundreds of gynaecologists in Belgium and for some these consultations are an important source of income. By doing this, you would trivialise the medical profession (Urban area, >20 years' experience, hospital)

Discussion

Findings and interpretation

In this study a mixed-methods approach with mainly qualitative research was used to efficiently explore the prevailing opinions of health care workers about the availability of OTC contraception, as recently implemented in certain US states. These changes were first introduced in January 2016 in the state of Oregon [27], but other states, such as California, are following suit. For health authorities, and all other stakeholders, knowledge and understanding of the gathered opinions are valuable while deciding, designing or implementing potential reforms. A very broad spectrum of opinions was obtained, reaching an acceptable degree of data saturation notwithstanding the smaller sample size of physicians.

An initial finding was the high prevalence of pharmacists who currently dispensed hormonal contraception without a prescription on a timely basis to women who were already using it. This practice anticipates what a large proportion of all health care providers suggested, or could agree with: namely, extending a prescription to the pharmacist. Although a prescription is valid for 1

year in Belgium, the need to help out appeared to be a phenomenon that occurs quite frequently. The majority of pharmacists and physicians clearly feel that this practice has a beneficial risk/benefit ratio. Indeed, legalising the practice would provide certainty for users and could further secure the elimination of an important barrier. Reimbursing this service would incrementally diminish cost, a barrier shown to be important for hormonal contraception use [13,36,38].

Initiation of oral contraception by a pharmacist using an Oregon-style questionnaire was, however, controversial and elicited broad opposition among all physicians, but it was not a universal finding [39]. Often-cited practical objections were the lack of privacy in the pharmacy and time constraints for the pharmacist. Although an area in the pharmacy where a private consultation with a patient can take place is legally required, implementation is certainly uneven in reality. Furthermore, in the many small pharmacies in Belgium with limited staff it is difficult for the pharmacist to free up the necessary time. The need for extra training of pharmacists seemed to be universally acknowledged and accepted by pharmacists, but there remained some doubt as to what amount of training was required.

Moreover, all groups had some medical objections to the Oregon questionnaire: medical illiteracy and missing blood pressure measurements and cervical cancer screening were frequently mentioned. We note, however, that guidelines do not uniformly show that blood pressure measurement is an important issue: Dutch guidelines do not require it [40], in contrast to Flemish guidelines [41], and blood pressure can indeed be measured outside a doctor's surgery. That some women may be incapable of responding to an Oregon-style questionnaire is conceivable, but previous research shows that women can self-detect the major contraindications to oral contraceptives [42]. As for missing out on cervical cancer screening, for example, we note that good screening should not depend on women wanting or needing prescription-requiring contraception; good screening practices should be organised independently of contraception need or use [43].

Economic motives pervaded the arguments for and against the Oregon initiative, although financial details were not mentioned. Economic motives were nearly universally attributed to health care providers from another profession or another subgroup within the profession. The

remarks were probably indicative of the inherently strained relationships between different health care providers. Losing the exclusivity of prescribing rights or the evolution towards sharing of responsibilities is frequently seen as a threat to one's income, although this was nearly always reformulated as the opinion of another subgroup within the profession. A similar pattern emerged when barriers to use were discussed. If they were perceived to be present in one group, then they were always present in other groups: access and waiting times before consulting a physician, and privacy in the pharmacy.

What was most surprising was that the arguments previously used in debates about emergency contraception, and refuted by research [44,45], resurfaced in this context, i.e. that these policy changes would increase hazardous sexual activity, with its associated transmissible disease risk. There is, however, no evidence that withholding oral contraceptives results in a beneficial risk/benefit ratio for the women involved [44,45].

Several interviewees in all categories noted the special needs of those younger than 18 years and criticised the Oregon proposal for not including them, a position that has also been expressed in the literature [46,47].

Strengths and weaknesses of the study

A weakness of this study is that it included a relatively small number of GPs and gynaecologists, which precludes straightforward numerical generalisations. As pointed out by several interviewees, the situation in Flanders has its own characteristics and is different from that in the USA. Other options for increasing the accessibility of contraception, such as telemedicine [47,48] or distribution through family planning centres [49] and schools [50], were outside the scope of the study. It is noteworthy that these options were also not mentioned by the interviewees, although in the south of Belgium (Wallonia) there was much debate about this matter a couple of years ago [51].

A strength of the study is the availability of a clearly worked-out protocol, which avoided discussions about details and allowed us to probe and directly compare the opinions and motives of the different stakeholders. A mainly qualitative research methodology enabled efficient acquisition of a broad spectrum of opinions.

Similarities and differences in relation to other studies

There is a paucity of literature about this specific topic. To the best of our knowledge, we found no published literature combining the opinions of different health care workers before a possible change from prescription to OTC status. This observation may be explained in part by the wide global diversity in the way oral contraceptives are distributed [26], as mentioned in the introduction. A number of organisations have, however, clearly expressed their opinion [24,52]. The point of view of pharmacists after a switch has been documented [53] and in the USA an anonymous internet-based electronic survey of physician trainees has been carried out [54].

Open questions and future research

We did not study the opinions of the authorities involved or the perspectives prevalent in industry. The opinion of users and potential users of contraception, including adolescents, are certainly also worth investigating. In this way, current and future research can inform accompanying measures that anticipate reactions to policy changes including those expressed in the media known to have a real impact on patients [55].

Relevance of the findings: implications for policy-makers and health care providers

As recently described by Flanigan in her book *Pharmaceutical freedom* [56], condoms with their high failure rate and associated latex allergies may not compare favourably with oral contraceptives but are nevertheless regulated in a completely different way and do not require a prescription. This comparison is easily faulted in certain aspects but it is a powerful reminder that the ultimate beneficiary of the regulation should primarily be the women in question and not the different health care providers or the structures in which they operate.

Nevertheless, implementing an important change in a health care system without considering, discussing or determining its impact on the livelihood of the health care providers who are part of the system would not be very productive. This is clearly discernible from the questionnaire responses and it may hamper the introduction of any potentially beneficial changes for women by antagonising certain health care provider groups. It may be safely assumed that closer collaboration between health care providers is required and any change to the health care system

should likely include the necessary incentives to catalyse and support that collaboration, something a fair number of providers want to see implemented.

Conclusion

In the present study, using a mainly qualitative approach, the opinions were documented of GPs, gynaecologists and pharmacists about the possibility of a protocol-guided dispensing of certain hormonal contraceptives without a prescription. Although our study did not quantify these opinions, we may conclude that an Oregon-type proposal would encounter significant resistance from GPs and even greater opposition from gynaecologists if implemented in Belgium. Income security is very important to everybody, but it is clear that medical arguments are willingly used by health care providers if they concur with their economic interests. It may be concluded that regulatory changes without thoroughly considering these factors would result in mixed messages reaching the women involved, as different health care providers will emphasise different medical aspects. Changes should therefore involve the necessary incentives to strengthen collaborations among health care providers, with the ultimate goal of giving women their right to health, including their right to control their reproduction [4]. As Belgium has a single-payer health care system, it is the singular responsibility of the health policy decision-makers to organise and promote these important collaborations. For the different health care providers, there should be the possibility to propose initiatives to the health authorities that establish and augment these collaborations, but this is currently an option that is lacking, which is to patients' detriment.

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Table 1. Summary data of the pharmacist questionnaire ($n=59$).

1.	How often you dispense emergency contraception in the pharmacy on a regular weekday? Only pharmacies in a city environment dispense this medication on a regular semi-daily basis
2.	Do you dispense emergency contraception more often during out-of-hours service? 80% Yes
3.	Do you receive questions about unintended pregnancies? 53% Yes, I have already had questions about this
4.	Do you ever dispense contraception to a patient without a prescription? 90% Yes
5.	What is the biggest barrier to the use of contraception for a patient? 80% Physician appointment <5% All other answers
6.	Would you be willing to take a course so that you can provide this service? 75% Yes
7.	Would you have time to go through the questionnaire with a patient in combination with your other work in the pharmacy? 73% Yes, with compensation 14% Yes, with or without compensation 13% No
8.	Do you think that providing this service would affect the relationship between pharmacists and physicians? 70% Yes
9.	Do you think that providing this service would result in fewer unintended pregnancies and consequently fewer abortions? 66% Yes
10.	Do you support the proposal? 80% Yes

Table 2. Summary data of the GP questionnaire ($n=26$).

1.	What do you think of this proposal? 35% Completely opposed
2.	What measures must be taken or what conditions must the proposal meet to enable you to support it? 62% Initiation of contraception needs to be prescription-only 42% There will be privacy problems and complications filling in the questionnaire
3.	Do you prescribe contraception similarly to what is done in Oregon, following a questionnaire? 38% No (blood pressure is always measured)
4.	Do you think that providing this service would affect the relationship between pharmacists and physicians? 50% Yes
5.	Do you think that by introducing this service fewer unintended pregnancies and consequently fewer abortions will occur? 64% No

Table 3. Summary data of the gynaecologist questionnaire ($n=19$).

1.	What do you think of this proposal?
	44% Completely opposed
	31% Reduced possibility of preventive investigation is problematic
	31% The Flemish and American systems are not comparable
2.	What measures must be taken or what conditions must the proposal meet to enable you to support it?
	40% Initiation needs to be prescription-only
	40% Big practical implementation barriers are present
3.	Do you think such a proposal can be discussed within the VVOG or another similar organisation?
	90% Yes
4.	Do you think that providing this service would affect the relationship between pharmacists and physicians?
	50% Yes
5.	Do you think that by introducing this service fewer unintended pregnancies and consequently fewer abortions will occur?
	70% No

Appendix

Before proceeding to the questionnaire, it was made clear this was part of a master's degree research project of a final year pharmacy student (SN) at the University of Antwerp and that the time needed to complete it would be less than 10 min.

Pharmacist questionnaire

1. How often do you dispense emergency contraception in the pharmacy on a regular weekday?
 - Several times a day
 - Daily
 - Weekly
 - Monthly
 - Other:
2. Do you dispense emergency contraception more often during out-of-hours service?
 - No
 - Yes, in the following way:
3. Do you receive questions about unintended pregnancies?
 - No, I have not experienced this yet
 - Yes, I have already had questions about this. For example:
4. Do you ever dispense contraception to a patient without a prescription?
 - No, I do not.
 - Yes, this has already happened. Possibly on condition that:
5. What is the biggest barrier to the use of contraception for a patient? (multiple answers allowed)
 - Physician appointment
 - Cost
 - Not allowed by parents
 - Religious objections
 - Lack of communication within a relationship
 - Fear of side effects
 - Compliance
 - Other:

In the US state of Oregon, since 1 January 2016, patients have no longer needed a prescription from a doctor to obtain contraception from a pharmacist. Of course, some conditions and restrictions apply: only oral contraception and a patch may be dispensed and the patient must be at least 18 years old. The pharmacist must obtain consent after the patient has answered a questionnaire. (This questionnaire is shown/displayed.) The patient is referred to a physician if the eligibility criteria are not met. Pharmacists who want to provide this service must complete a

total of 5 h of specific training.

6. Would you be willing to take a course so that you can provide this service?
 - Yes
 - No, because:
7. Do you have time to go through the questionnaire with a patient in combination with your other work in the pharmacy?
 - Yes, it is part of our job
 - Yes, if the service is reimbursed
 - No
8. Do you think that providing this service would affect the relationship between pharmacists and physicians?
 - No
 - Yes. Please specify:
9. Do you think that providing this service would result in fewer unintended pregnancies and consequently fewer abortions?
 - No, because:
 - Yes, because:
10. You do/do not support the proposal (delete as appropriate)
 - For what reason? Under what conditions would you participate?

Finally, two questions to better categorise the results:

11. Postal code of the pharmacy where you work:
12. How many years of experience do you have?
 - <5 years
 - 5-10 years
 - 10-20 years
 - >20 years

This concludes the questionnaire. Thank you for your cooperation.

GP questionnaire

This survey will take about 10 min and all data will be processed anonymously.

In the US state of Oregon, since 1 January 2016, patients have no longer needed a prescription from a doctor to obtain contraception from a pharmacist. Of course, some conditions and restrictions apply: only oral contraception and a patch may be dispensed and the patient must be at least 18 years old. The pharmacist must obtain consent after the patient has answered a

questionnaire. (This questionnaire is shown/displayed.) The patient is referred to a physician if the eligibility criteria are not met. Pharmacists who want to provide this service must complete a total of 5 h of specific training.

1. What do you think of this proposal? Please provide the reasons for your opinion:
2. What measures must be taken or what conditions must the proposal meet to enable you to support it?
 - I fully support the proposal as applied in Oregon
 - I support the proposal, but the following limitations/conditions should be included:
.....
 - I support the proposal, but for me it could be applied even more broadly, namely in the following way:
 - I do not support the proposal because:
3. Do you prescribe contraception similarly to what is done in Oregon, following a questionnaire?
 - Yes, it is similar. Please elaborate:
 - No, my approach is very different, namely in the following way:
4. Do you think that providing this service would affect the relationship between pharmacists and physicians?
 - No
 - Yes, in the following way:
5. Do you think that by introducing this service fewer unintended pregnancies and consequently fewer abortions will occur?
 - No, because:
 - Yes, because:
6. Do you have any other comments or opinions about this proposal? :

Finally, two questions to better categorise the results:

7. Postal code where you practise:
8. How many years of experience do you have?
 - <5 years
 - 5-10 years
 - 10-20 years
 - >20 years

Gynaecologist questionnaire

This survey will take about 10 min and all data will be processed anonymously.

In the US state of Oregon, since 1 January 2016, patients have no longer needed a prescription from a doctor to obtain contraception from a pharmacist. Of course, some conditions and restrictions apply: only oral contraception and a patch may be dispensed and the patient must be at least 18 years old. The pharmacist must obtain consent after the patient has answered the questionnaire. (This questionnaire is shown/displayed.) The patient is referred to a physician if the eligibility criteria are not met. Pharmacists who want to provide this service must complete a total of 5 h of specific training.

1. What do you think of this proposal? Please provide the reasons for your position:
2. What measures must be taken or what conditions must the proposal meet to enable you to support it?
 - I fully support the proposal as applied in Oregon
 - I support the proposal, but the following limitations/conditions should be included:
.....
 - I support the proposal, but for me it could be applied even more broadly, namely in the following way:
 - I do not support the proposal because:
3. Do you think such a proposal can be discussed within the VVOG or another similar organisation?
4. Do you think that providing this service would affect the relationship between pharmacists and physicians?
 - No
 - Yes, in the following way:
5. Do you think that by introducing this service fewer unintended pregnancies and consequently fewer abortions will occur?
 - No, because:
 - Yes, because:
6. Do you have any other comments or opinions about this proposal?

Finally, two questions to better categorise the results:

7. Where do you work?
 - In a hospital
 - In private practice
 - Both
8. Postal code where you practice:
9. How many years of experience do you have?
 - <5 years
 - 5-10 years

- 10-20 years
- >20 years