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**Telecontraception – A Way to Address A Health Care Disparity
A Preliminary Literature Review**

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ABSTRACT: Unintended pregnancy continues to be a significant personal and public health concern in all countries. In 2015-2019 there were 121 million unintended pregnancies annually, corresponding to a global rate of 64 unintended pregnancies per 1000 women aged 15-49 years. While there are multiple contraception options available in general, access to them can be limited by a myriad of factors. Over the past two decades there has been an increase in mail order services for contraception that bypasses the traditional clinician office visit-examination-pharmacy model, thus increasing access for many women (and men). These companies have been proven to provide safe, convenient and economical contraception, thereby decreasing access burden for women throughout the world. This paper reviews the literature on evolution of mail order contraception, safety concerns, and technological advances that facilitate provision of these services.

INTRODUCTION: I am a Board-Certified Obstetrician-Gynecologist with twenty-one years of experience. For the past two years I have worked as a provider filling contraception requests via an on-line platform. This is a direct-to-consumer service. At the outset, I vaguely knew companies existed that provided mail order contraception, but I had no idea the extent of their services, or details about how they worked. When I mentioned this service to colleagues and patients, the vast majority indicated they had never heard of this as an option for contraception and what a great idea it was. While the need for improved contraceptive services has existed for decades, access was more severely limited with the arrival of COVID-19. Individuals requiring contraception who would normally have access did not feel safe going into a clinic or pharmacy. The number of daily requests to my telecontraception service skyrocketed. This paper intends to present historical background of online ordering of contraception and changes to date. I wanted to explore how long contraception has been available via mail order, and how these services have evolved since their inception. I wanted to learn how these pharmaceutical companies are able to safely provide contraception. I was also intrigued as to whether these services could address the myriad reasons why women cannot or do not access contraceptive methods. This historical review produced sixty-four publications that addressed the topic of telecontraception. The search parameters were limited to [Reproductive Age Women], [Adolescents] and [English language].

BACKGROUND: The history of telemedicine dates back to the 1950's and was first mentioned in a scientific article in 1974 (Lee & Hitt 2020). Many medical specialties have utilized some form of telemedicine when information needed to be conveyed from a distant site. There are three methods of accomplishing this: (1) Store-and-Forward (asynchronous interactions) where medical information is stored and then sent to a specialist for interpretation at a later time. There is a limit to the information that can be gathered at this type of interaction. (2) Real Time

Telemedicine (synchronous interactions) which are real-time interactions between patients and clinicians. The format can be videoconference, telephone or online communications. Histories can be obtained and limited physical examinations are possible. Both parties must be present at the same time for this type of interaction. Diagnosis and treatment can be offered. Finally (3) Remote Patient Monitoring can be utilized for patients with chronic diseases such as hypertension or diabetes. Numerical values for blood pressures and blood sugars can be transmitted and adjustments can be made. The utility of this type of medical interaction for contraceptive purposes is highlighted in the 2010 U.S. County Census File for adult women of reproductive age and women 15 years of age and older. The survey revealed 2.65 OB-Gyn doctors for every 10,000 women and 5.39 OB-Gyns for every 10,000 reproductive-age women in the United States. Approximately 49% of all the U.S. counties did not have a single OB-Gyn doctor and 8.2% of all American women lived in those predominantly rural counties (Rayburn et al 2012; Lee, Hitt 2020). These locations were labeled “contraceptive deserts” due to the scarcity of medical providers and pharmacies. The study did not obtain statistics for other clinicians such as family medicine, internal medicine, and pediatrics. The bottom line was limited access to contraception exists and could be addressed by telemedicine services. For women’s health alone, telemedicine was found to be beneficial in accomplishing well-woman visits, preconception counseling, preventive care, fertility advice, family planning and mental health interventions. Even women who reside in resource poor areas have access to cell phones and Wi-Fi connections for such interactions. De Nicola and Marko (2020) noted mobile applications (apps) are increasingly relevant in women’s health. They observed apps exist for everything from menstrual tracking to menopause. Their study revealed more than 30% of cell phone users look up health information on their devices and one out of five users have downloaded a health-related mobile app. Even more amazing is, among the 100,000 health-related mobile apps offered in the Apple store, more than 1800 are related to obstetrics and gynecology. While De Nicola and Marco acknowledged such apps can be useful tools for diagnosis, management and education, and can bridge gaps for the underserved, not all apps were useful and many of them were inaccurate. They proposed further work on identifying and improving these apps for women who cannot or will not connect with a clinician in person.

Access to Contraception

The evolution of hormonal contraception is a fascinating story complete with divergent attitudes, myths and safety concerns. Access to contraception has been a universal problem for decades. Grindlay and Grossman (2016) quantified 29% of women in the USA have had some type of problem either starting or refilling contraception. As early as 1972 Farley and Harvey described a plan to market contraceptives by mail to address the problem of access. They were anxious to expand family planning activities beyond the traditional physician-clinic-pharmacy sphere. The factors motivating them included “high illegitimacy rates, growing problems of venereal disease, sluggish progress of traditional programs, and increasing population pressures”. The authors ran ads in 51 college newspapers asking one of 7 headline questions including: “Do you want contraception privately?” “Who causes pregnancy?” “Too embarrassed to ask for contraceptives?” My favorite headline was: “If you want to have a baby, that’s your business. If you don’t, that’s ours.” The authors were proposing mail order availability of condoms and foam in their study. They found the majority of respondents were very interested

in such availability. A study from 1980 (Barnes & Maxwell) discussed reasons why individuals of variable ages failed to access contraception and included concerns like embarrassment or guilt, negative attitude by their physician, and fear of criticism or judging from the individual providing the contraception such as clerks, doctors, and pharmacists.

In 2001 Miller and Nielsen visited 200 on-line sites that advertised contraception supplies including condoms, foam, pills, diaphragms, cervical caps, vaginal sponges and IUDs. The following findings are relevant to consider as no standardization had been implemented. For the majority of the sites no health history was taken. The prescriber was not a medically qualified individual – not a licensed physician, midwife, nurse or pharmacist. Prices varied widely. For example, a copper IUD only cost \$50.00 but a single packet of emergency contraception cost \$141.00 due to prescription and shipping fees. Some products were from overseas. According to the United States Food and Drug Administration (USFDA), it is illegal for anyone including a foreign pharmacy to import non-FDA-approved medications with few exceptions. In addition, they found products coming in from overseas could be held up at the whim of Customs Agents. Miller and Nielsen noted anecdotally that one particular agent held up a hormonal IUD and asked the buyer why she didn't just use Tri-Phasil instead - Customs agents practicing medicine! Mail order contraception was available in the early 2000's, but there were no regulations or safeguards in place. Phillips, Stotland et al (2004) noted cost as a significant barrier to continuous use of contraception. The cost of contraceptive pills was so prohibitive that women could only afford to get one packet at a time. This resulted in the need for repeat visits to the prescriber, a separate copay each time and increased chance of running out before a refill could be obtained.

Prior to 1998 providers in the United States had to prescribe "regular" oral contraceptives in off-label use for emergency contraception. In 1997 the USFDA determined that birth control pills were safe and effective for emergency contraceptive use. In 1999 the FDA approved Plan B. O'Callaghan and Andrist (2001) explored the availability of emergency contraception and found providers did not routinely prescribe or even discuss this option. This study recommended Plan B should be made available over the counter in order to reduce the barrier of provider reluctance to prescribe and patient inability to obtain emergency contraception in a timely manner. Wu et al (2007) expanded on the reasons why women sought emergency contraception via the internet. The study profiled the women who chose to get emergency contraception on line. Some of the reasons included (1) Being "fired" by their health care provider after asking for emergency contraception; (2) Discomfort and frustration with the health care providers; (3) Answering services that were not helpful, thus increasing the time from request to possibly obtaining emergency contraception; and (4) Self-blame for being in a situation requiring emergency contraception. Of interest, although women requested emergency contraception, some women perceived it to be inferior to "regular" contraception.

Scholarly work on expanded access to hormonal contraception really blossomed around the year 2006 despite the existence of data that attested to the safety of these medications having been available decades earlier. In 1973 the International Planned Parenthood Federations Central (IPPF) Medical Committee declared "limiting oral contraceptives to doctors'

prescriptions makes the method geographically, economically and sometimes culturally inaccessible to many women. Death and sickness of women and children, which might be avoided by voluntary limitation of fertility, continues". This landmark statement guided the spread of over-the-counter and community-based distribution programs, more so in countries other than the United States. Thanks to the IPPFC declaration, family planning specialists at multiple levels began to encourage on-line and even over-the-counter access to contraception.

Over-The Counter Availability and Patient Safety

One of the biggest barriers to promoting over-the-counter (OTC) availability was safety. For any medication to be eligible for OTC status, the USFDA requires it to pass two safety criteria: (1) It cannot be habit-forming. (2) It can be used safely without supervision of a licensed health care practitioner (Grindley, Burns and Grossman 2013). Unfortunately, the process of transitioning from prescription-only to over-the-counter status can take years. Many studies reviewed for this project focused on the issue of safety, and how women are capable of properly self-screening for contraindicated conditions (Zavala et al 1987; O'Callaghan & Andrist 2001; Memmel, Miller, Gardner 2006; Shotorbani, Miller, Blough, Gardner 2006; Yeatmen, Potter, Grossman 2006; Kaskowitz et al 2007; Grossman, Fernandez et al 2008; Singh, Frost, Jordan 2009; Averbach et al 2010; Grossman, White et al 2011; Nguyen and Jamieson 2011; Liang, Mackey, Lovett 2012; Grindlay, Burns, Grossman 2013; Yu and Hu 2013; Gawron and Tyrok 2015; Grindlay and Grossman 2016; Hariton and Tracy 2019; Jain 2019; Stifani et al 2020; Zuniga et al. 2020).

The World Health Organization (WHO) developed a list of contraindications to hormonal contraception in 2000 which has since been expanded by the Centers for Disease Control (CDC) in the United States. This screening information was available to all medical providers. While there were multiple medical contraindications against the use of estrogen-containing hormonal contraception, most of these contraindications did not occur in the population of women seeking birth control at that time. This is not as true today where the epidemics of obesity and smoking have increased risks for many more young women. Hypertension, migraine with aura, and smoking (particularly in women over age 34) were three major contraindications. Prior to the WHO statement, Zavala et al in 1987 designed a study to determine whether distribution of combined hormonal contraception to women through a community-based distribution program exposed those women to more health risks than if the program didn't exist. Their premise was the level of medical supervision needed to ensure safe and effective distribution of oral contraceptives was debatable. Physical examinations and screening tests should not be tied to the provision of contraception. This was a seminal study that is referenced in many subsequent research projects. Zavala's outcomes revealed: (1) Many contraceptive users already self-screen for conditions that might make hormonal use unsafe. (2) There are myths about perceived dangers of hormonal contraception that need to be dispelled. Many women believed birth control pills were more dangerous than childbirth. (3) Other than identifying women with previously unknown hypertension, screening does nothing but add expense to distribution programs. Zavala's study suggests that resources should go toward promoting more contraception and education for women rather than building elaborate screening processes designed to keep women from using contraception. In 2006 Memmel,

Miller and Gardner devised a project wherein they presented different health scenarios to on-line providers. They attempted to get hormonal contraception over-the-counter posing as (1) a healthy 25-year-old; (2) a 35-year-old who was obese and smoked heavily; and (3) a 35-year-old smoker taking medication for hypertension. Despite the known WHO contraindications, they were able to get combined hormonal contraception even though the risks were clearly presented. Further evaluation of these companies revealed the prescriptions were coming from out of the United States and were not written by physicians who were licensed. The data from this study reinforced previously voiced concerns about safety of prescribing via such on-line platforms.

In contrast, Shotorbani et al (2006) determined that women could self-screen for contraindicated conditions if given an appropriate screening questionnaire. Their study involved having women at family planning clinics complete a health history questionnaire. This was then followed by a similar questionnaire that was completed by these same women's providers at the family planning clinic. There was a 96% overall concurrence about risk factors that were present. Yeatman, Potter and Grossman (2006) reiterated a common theme: Oral contraceptives were introduced in the 1960's and have been proven safe, effective and popular around the world. But multiple barriers prevent women from accessing and properly utilizing this resource. Yeatman et al found that in addition to medical screening for appropriateness for oral contraceptive use, many providers were insisting patients undergo examinations (pap test, pelvic and breast examination) before receiving a prescription, even though these examinations are unrelated to proving suitability for hormonal contraception use.

Stewart et al (2001) raised ethical considerations as a access barrier to consider. The study explains the perpetuation of medically unnecessary requirements for examinations and testing, and coercing women to get this testing if they want contraception involves "unexamined premises or assumptions": (1) that policy makers rather than women are the appropriate decision makers. (2) the health impact of missed screening for these women is more significant than the health impact of delayed or less effective contraception. The study also states that requiring breast and pelvic examinations is likely to reinforce the incorrect belief that hormonal contraceptive methods are dangerous or that these exams are actually capable of finding occult disease such as breast or ovarian cancer in asymptomatic women. Multiple sources including the USFDA (1994), Planned Parenthood (1999), WHO (2000) and American College of Obstetrics and Gynecology (ACOG 2018) have reiterated prescribing birth control should not be linked with the need for pelvic examinations. Several researchers recommended educating providers who still believe such examinations are key to providing safe hormonal contraception. In 2007 Kaskowitz et al compared two programs designed for providing contraception in and around Portland Oregon: Pills Without a Pelvic (PWOP) which was a clinic program and Hormones Without a Pelvic Exam (HOPE) which was an online program. Both programs provided hormonal contraception without requiring a pelvic examination. The women either completed an online questionnaire about their health, or were asked about health history in person at the clinic. They found women who went in person had the same knowledge of contraindications to hormonal contraception and warning signs as did those who prefer online services.

Demographics, however, revealed women who preferred the online platform were more affluent, educated, older and better insured than the clinic population.

Popularity of telecontraception increased from 2015 on, in part as public figures promoted and joined the boards of directors for these companies – Chelsea Clinton (Nurx) and former U.S. Surgeon General Dr. Regina Benjamin (The Pill Club). By 2019 telecontraceptive providers appeared to be much more discriminating when it came to medical contraindications. Jain et al (2019) devised a “secret shopper” survey to assess the process and safety of telecontraception for patients. Utilizing seven standardized patient scenarios that included DVT, migraine with aura, 15 days postpartum and breast feeding, unresected hepatocellular adenoma, smoker over age 35, and no medical contraindications but history of poor adherence to pills, Jain’s group visited nine online vendors and attempted to get contraception. Unlike the companies described by Memmel, Miller and Gardner (2006), these nine services followed the MEC guidelines completely. The only true criticism the researchers had was none of these companies provided information about long-acting reversible contraception (LARC) choices. Since these companies did not provide LARC, they did not offer information about these options. A second concern in the Jain study was lack of screening for compliance in daily pill takers. With the advent of COVID-19, racial and ethnic disparities in health care were exacerbated - both because these groups are at higher risk for worse health outcomes and they already have decreased access to services. In addition to more telecontraception companies developing, consideration for extending use for LARC was proposed beyond the approved duration: Paragard for twelve instead of ten years, Mirena for seven years rather than five, and Nexplanon for five rather than three years. Data already existed proving efficacy beyond the approved duration found on these products websites. There was also encouragement for approving adequate refills to established patients – yearly instead of monthly for pills, patches and vaginal rings.

Current Access to Telecontraception

As of March 2021, there are seventeen companies in the USA and eight overseas that provide telecontraception (**Table 1**). They differ in many ways: education and training background of providers; whether they provide synchronous (telephone or video chat) versus asynchronous (information collected on line and providers review then respond on line) interactions with clients; products that are available; refillability (how many refills are approved); complexity of screening for contraindications; requirement for real time data (BP, height, weight); allowable age of clients (mandated by states); company-specific guidelines for prescribing (e.g. BMI > 30 and smoker gets POP) and so forth. Needs of the clientele vary, but according to Thompson et al (2020) asynchronous delivery is the most suitable for women who have time constraints that would keep them from talking to a provider in person, or going to a clinic/pharmacy during open hours. She points out that benefits of family planning remain limited by the number of people who can access services. Telecontraception companies are one solution. In addition, efforts to address access problems globally include campaigns such as Family Planning 2020 – a global partnership meant to empower women and girls by investing in rights-based family planning and allowing individual countries to determine what will work best for its citizens.

SUMMARY STATEMENT

It seems intuitive that women who do not have access to contraception will likely have unprotected intercourse and are at risk for more unintended pregnancies. It has been the traditional practice to “blame” the woman. But her ability to successfully initiate, continue and consistently use contraception is influenced by manifold and diverse factors. Health care systems, society, culture and personal attitudes can all create barriers that prevent women from achieving their pregnancy goals. Failure to succeed should be shared by health care providers, societal and health system barriers (Singh, Frost, Jordan 2009).

The reasons for lack of access are many and complex:

- 1) Contraceptive deserts: no clinicians or pharmacies; lack of confidentiality in small towns; recent move without a local provider
- 2) Financial: high cost of contraceptives and co-pays; lack of insurance or poor insurance coverage; loss of wages when appointments are during work hours; child care costs; lack of transportation;
- 3) Psychosocial: religious barriers; age limits (state mandates/office mandates); embarrassment; fear of painful procedures; forgetfulness for refills; partner unwillingness or coercion; reluctance to visit clinics like Planned Parenthood due to protesters; adverse outcome from previous contraception;
- 4) Lack of Knowledge: understanding the need for contraception, how it works; physiology of menstrual period and pregnancy; importance of consistent proper use of contraception; holding onto myths and incorrect information about contraception from family and friends; fear of future infertility; unsure which contraceptive would suit them best and where to get it;
- 5) Professional Roadblocks: providers insist on office visits, pelvic exams, pap testing; annual visits; insufficient refills to last a year; inconvenient office or pharmacy hours; LARC denial to nulliparous women; firing patients if they request emergency contraception; discomfort with clinic staff or providers (religious-based practice; transgender individuals);
- 6) COVID-19: even women with financial means declined office visits due to fear of becoming infected at an in-person visit; less appointments were available and many offices shut down during the peak of the pandemic
- 7) Legal: age limits for contraception and emergency contraception; requiring parental consent; USFDA preventing granting over-the-counter status to contraception; limited access in conservative states; lack of Medicaid expansion in conservative states; policies prohibiting/discouraging sexual activity (especially in the Armed Services - Grindlay and Grossman 2012); limited Medicaid eligibility for family planning services; Congressional and Presidential dictates;
- 8) Adolescents in addition have unique barriers including fear of disclosing sexual activity; stigma associated with teen pregnancy; fear parents will find out; peer pressure; embarrassment; lack of transportation; lack of independent financial resources; and even their age depending in which state they reside.

Discussion

Actual contraindications to use for underlying medical problems are far fewer than the barriers that many women face attempting to secure contraception for themselves. A root cause analysis would be an enormous undertaking, but would undoubtedly point out at least four patient-centered strategies to eliminate unnecessary barriers to contraception: (1) Provide opportunities to discuss pregnancy planning and changing contraceptive needs at every visit. Ask about barriers she may be experiencing. (2) Acknowledge challenges of using methods effectively: forgetting to take a pill daily, difficulty in use (condoms, vaginal rings), actual or anticipated side effects (decreased libido, irregular bleeding, weight gain, mood changes), worry about efficacy. These become less of a taboo once they are discussed openly and transparently. (3) Update clinicians' knowledge and skills. In-person visits and pap testing are not necessary to initiate or continue contraception. LARC contraindications are few and should not be related to age or gravidity. IUDs can be inserted any time of the menstrual cycle as long as pregnancy is not likely. The black box warning about bone health and DMPA is theoretical not actual. Patients can be taught to self-administer DMPA. (4) Help patients navigate the complexities that create barriers: prescribe less expensive contraception if possible; price-reducing coupons; mail order for 3 months of supplies with refills for a year; find out who locally supplies emergency contraception; Vending machines with emergency contraception at colleges, and possibly high schools; Explore state and federal resources like Health Texas Women's coverage (Singh, Frost, Jordan 2009).

Further Consideration

While telecontraception is not the solution for all of the access barriers listed in this paper, it has already proven to be an effective means of bringing contraceptive supplies to many women in the USA and abroad during the COVID crisis. Ultimately granting over-the-counter status to hormonal contraception will advance the cause of reducing access barriers. It has been available for decades in countries other than the United States with no ill effects to users. Until that time comes, telecontraception is an easy, safe and effective alternative to providing contraception and education to women across all walks of life.

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TABLE 1
TELECONTRACEPTION PLATFORMS*

PLATFORM	AGE LIMITATIONS**	LOCATION LIMITATIONS
Alpha Medical	18+	31 States USA
Amazon Pharmacy	13+	44 States USA
Blink Health	18-49	22 States USA
HERS	18-50	All States + D.C.
Hey Doctor	18-50	49 States USA
Lemonaid	18-49	All States + D.C.
Maven	13+	All States + D.C.
Nurx	13+	30 States USA
Pandia Health	Varies	5 States USA
Planned Parenthood Direct	12+	40 States USA
PlushCare	18+	All States + D.C.
PRJKT RUBY	18+	49 States USA
The Pill Club	12-44	43 States USA
Simple Health	13+	23 States USA
Twentyeight Health	16-49	6 States USA
Virtuwell	18-39	13 States USA
Wisp	13+	All States
121docOnline Clinic	18+	Brazil, Switzerland, UK
Ease	16+	Singapore
euroClinix	18+	Brazil, Switzerland, UK
Lloyds Pharmacy	18+	UK only
PharmaDoctor	17+	UK only
Women Help Women	N/A	Multiple countries
Women on Web	N/A	Countries without safe access to abortion
Zava	18+	Germany only

***Free the Pill** online list of telecontraception platforms is the source of this Figure;
updated 10/16/2020

**State laws determine age limits for many of these platforms

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