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## Review

## Lessons from reproductive health to inform multipurpose prevention technologies: Don't reinvent the wheel

Martha Brady <sup>a,\*</sup>, Judy Manning <sup>b,1</sup><sup>a</sup> Population Council, One Dag Hammarskjold Plaza, 9th Floor, New York, NY 10017, United States<sup>b</sup> USAID, 1300 Pennsylvania Avenue, NW Room 3.06-165, Washington, DC 20523, United States

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## ABSTRACT

This paper presents the public health rationale for multipurpose prevention technologies (MPTs) for sexual and reproductive health (SRH) based on regional trends in demographic and SRH indicators. It then distills important lessons gleaned from the introduction of contraceptive and reproductive health products over the past several decades in order to inform the development and future introduction of MPTs for SRH.

**Principal results:** A comparison of current demographic and public health regional data clearly revealed that the greatest confluence of women's SRH concerns occurs in sub-Saharan Africa and South/West Asia. These regional overlaps of SRH risks and outcomes present a strong rationale for developing MPTs designed to simultaneously protect against unintended pregnancy, HIV and other STIs. Information from acceptability, marketing, and operations research on the female condom, emergency contraception, pills and intravaginal rings identified key product characteristics and socio-behavioral issues to be considered in the development and introduction of MPTs. Product characteristics such as formulation, duration of action, presence and magnitude of side effects, prescription status (over-the-counter vs. prescribed), provider type and training and user perspectives, all contributed in varying degrees to both provider and user bias, and subsequent uptake of these family planning methods. Underlying socio-behavioral issues, including risk perception, ambivalence, and social costs also contributed to demand and use. Early identification of target populations will be critical to market shaping, demand creation and defining appropriate service delivery channels for MPTs. Ultimately, knowledge, attitudes, perceptions and practices of users (and their partners) will drive the success- or failure- of product introduction.

**Conclusions:** MPTs provide a compelling response to the multiple and reinforcing SRH risks faced by women in key regions of the world, but specific product characteristics and their socio-behavioral correlates must be taken into account early in the development process. Successful introduction of new MPTs will require solid understanding of socio-behavioral correlates, effective demand generation, appropriate integration into health service delivery systems, quality counseling for proper use and active engagement of both public and private sectors. This article is based on a presentation at the "Product Development Workshop 2013: HIV and Multipurpose Prevention Technologies," held in Arlington, Virginia on February 21–22, 2013. It forms part of a special supplement to *Antiviral Research*.

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\* Corresponding author. Tel.: +1 212 339 0618.

E-mail addresses: [mbrady@popcouncil.org](mailto:mbrady@popcouncil.org) (M. Brady), [jmanning@usaid.gov](mailto:jmanning@usaid.gov) (J. Manning).<sup>1</sup> Tel.: +1 202 712 1232.

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## 1. Introduction

The global reproductive health community has recognized the need for an integrated approach to women's sexual and reproductive health (SRH) in order to meet the needs of women. Clearly, 21st century SRH programs will require thoughtful design – engaging both public and private sectors – to meet the need for safe and effective multipurpose prevention technologies (MPTs).

The major challenge that SRH researchers and providers face is meeting the primary SRH concerns of all women: (1) healthy timing and spacing of intended pregnancies; (2) safe birth, for mother and child; and (3) protection against HIV, other sexually transmitted infections (STIs), and reproductive tract infections (RTIs). Prevention products that simultaneously address these primary SRH risks could contribute substantially to the health of women and girls, particularly in resource-poor settings.

The objectives of this paper are to: (1) present the public health rationale for MPTs for SRH by examining global summaries of recent epidemiological and demographic data, and (2) reviewing lessons learned from the introduction of different types of family planning (FP) methods in order to better inform the development and successful introduction of MPTs.

As scientific efforts to develop MPTs advance, the challenge is to ensure that women (and their partners) in developing countries will be able to access and use new technologies. Similar challenges have confronted the reproductive health field over the past four decades as new contraceptive technologies emerged from research and development (R&D) and were introduced into FP programs. Historically, technological innovations have had varying degrees of success in introduction; some have encountered obstacles along the way that might have been avoided with more careful planning and preparation.

Preparation for the introduction of any new MPT product will benefit from looking back at the introduction histories and experiences of a number of products (Brady and McGrory, 2007). Given that MPTs are a new combination product category, no single model exists for how best to integrate them into developing country health systems or into people's daily lives. And while each new health technology is unique, it is instructive to learn from the experience of other related products to inform the process and strategy for introduction of new products.

### 1.1. The public health rationale for MPTs

Current demographic and public health data maps from the Population Reference Bureau (PRB) (<http://www.prb.org/DataFinder.aspx>) and the World Health Organization (WHO) ([http://www.who.int/gho/map\\_gallery/en/index.html](http://www.who.int/gho/map_gallery/en/index.html)) were reviewed to identify current trends in SRH indicators and regional overlaps with mortality and morbidity due to unintended pregnancy, HIV and other STIs. These data maps show that birth rates, total fertility rates and unmet need for FP are all highest in sub-Saharan Africa and South/West Asia. While sub-Saharan Africa has the highest percent of unmet need for contraception (64%), the absolute number of women with unmet need is highest in

South and West Asia, at 88 million (Singh and Darroch, 2012). This unmet need contributes directly to 54 million unintended pregnancies and 26 million abortions every year (ibid.).

Unfortunately, unmet need for contraception contributes directly to high maternal mortality due to complications in pregnancy and childbirth (USAID, 2010). And too many pregnancies spaced closely together contributes to high rates of newborn death (WHO, 2013). The data maps from PRB and WHO show that sub-Saharan Africa and South/West Asia have high maternal, infant and under-five mortality rates. Sub-Saharan Africa and South Asia are also hit hard by HIV and human papillomavirus (HPV), the virus that causes cervical cancer. Each year, more than 2 million women die from these preventable diseases (WHO, 2012).

The comparison of current demographic and public health data from PRB and WHO clearly reveals that the greatest confluence of women's SRH concerns occurs in sub-Saharan Africa and South/West Asia. These regions have high unmet need for contraception which contributes directly to high maternal, infant and under-five mortality rates. There are also concentrated and generalized epidemics of HIV and HPV in many of the same countries in sub-Saharan Africa and South Asia. These regional overlaps of SRH risks and outcomes present a strong rationale for developing MPTs designed to simultaneously protect against unintended pregnancy, HIV and other STIs.

### 1.2. Lessons learned from the introduction of contraceptive and reproductive health products

#### 1.2.1. Many frameworks, common elements

If there is a singular lesson from the history of technology introduction, it is this: any new product will require a coherent strategy and program, along with political and financial support, in order to be successfully introduced and marketed. Numerous conceptual frameworks and critical pathways have been developed over the years for the introduction of reproductive health technologies (e.g., UNDP/UNFPA/WHO, 1994; Frost and Reich, 2008; Brady 2011). While these frameworks use different terminology and generally reflect the unique characteristics of the product being considered, most share common elements:

- Assess users' needs, understanding and perspectives.
- Determine service capacity to deliver.
- Build policy, financial and provider support.
- Obtain product registration and regulatory approval.
- Identify, train, and support product champions.
- Develop training program for providers.
- Build monitoring and evaluation into introduction efforts.
- Incorporate product into national norms and service guidelines.
- Conduct implementation science in tandem with introduction.

Several of these common elements are addressed below in regards to informing the MPT development and introduction process.

#### 1.2.2. Incorporating user perspectives into product development

Social science and acceptability research are needed to inform both product development (to guide new product designs) and

market shaping activities (to identify appropriate method mixes for particular populations). Moreover, attention to the explicit needs and interests of the intended “end user” is critical. In practical terms, this means embedding users’ perspectives strategically throughout the R&D process, including early clinical studies, and throughout product introduction. While there is some critique around how best to conceptualize and measure acceptability, most would agree that capturing users’ perspectives (and experience) about the product is critical and should be incorporated into product design and development pathways (Morrow and Ruiz, 2008; Mensch et al., 2012). Numerous acceptability studies across product categories (FP and HIV) have been conducted over the years. Gleaning key insights from that work and applying them to the evolving field of MPTs is underway, but is beyond the scope of this paper.

An understanding of the role that gender norms and power asymmetry play in women’s ability to access and use reproductive health technologies is paramount. This is particularly the case with user-controlled vaginal products that require acknowledgment (and discussion) of sexuality and sexual practices—issues that policy makers, providers and users can find difficult (Montgomery et al., 2008). Understanding reasons why women who wish to avoid getting pregnant do not adopt contraceptive methods can be instructive for MPT development. An analysis of reasons for non-use can help to identify which features are important, and which delivery and demand generation strategies would best address the various barriers to use. In addition, gaining a better understanding of the socio-behavioral determinants of demand and use would also be important.

In a recent DHS analysis (see Fig. 1) of more than 148 million women (Darroch et al., 2011), method-related reasons account for fully 70% of non-use of FP, primarily due to women’s concerns about: health risks and side effects (22%), low frequency of sex (21%), being postpartum or breastfeeding (17%) and opposition from partners (10%). These method-related factors suggest that new (and different) types of contraceptive technologies are needed to fill these gaps.

Recent evidence reinforces the fact that the major contribution to unmet need and unintended pregnancy is discontinuation and method failure or inconsistent/incorrect use of contraceptives (Singh and Darroch, 2012). The MPT field would benefit from social science research to inform interventions that can reduce some of the causative factors. Such evidence can also inform market

shaping to identify appropriate method mixes for particular populations, and product development to guide new product designs.

After decades of family planning product introduction across geographies with diverse groups of women, a few key themes emerge. Women need to know that the product is safe and effective, does not cause harm to themselves or their babies (if breastfeeding), does not disrupt sex, and importantly, does not jeopardize future fertility.

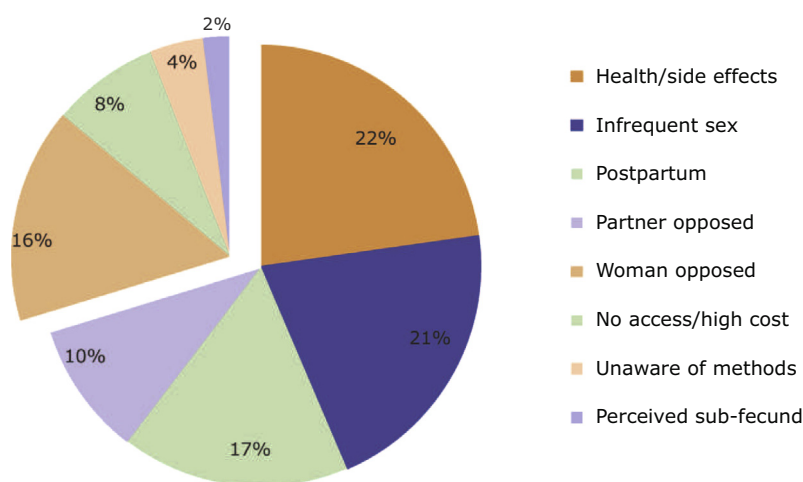
### 1.2.3. Case studies of existing contraceptive and reproductive health products

This paper draws upon operations research, acceptability studies, program reports, strategy documents and frameworks, as well as the primary author’s in-depth knowledge and experience with contraceptive introduction. This is not intended to be a systematic review of all research on the topic; rather, we highlight key lessons most relevant to the evolving MPT field. As evidence, we provide brief case studies of three different products: emergency contraception (EC), the female condom (FC), and the intravaginal ring (IVR). We also highlight key principles from the field of marketing.

Different product characteristics (e.g., formulation, duration of use, prescription status, provider-dependent vs. user-controlled, etc.) require different levels of provider and user effort (and behavior) to successfully use the product. At a minimum, the following product characteristics must be well understood in order to design appropriate service delivery and marketing strategies. Programs will want to know if the product:

- Is provided over-the-counter (OTC) vs. by prescription (Rx).
- Involves a skilled clinician vs. limited or none.
- Is user-controlled vs. user-independent.
- Is coitally dependent vs. coitally independent.
- Has local vs. systemic effects.
- Has different durations of action as a component of effectiveness.

Lessons from existing products that share similar features to potential on-demand MPTs – including EC, FCs, and IVRs – are especially relevant. While providers often serve as gatekeepers to “access” for many contraceptive methods, user-controlled products such as EC, FCs, and IVRs place the responsibility for use with the user.



**Fig. 1.** Shows a DHS analysis of over 148 million women living in sub-Saharan Africa, South Central Asia, Southeast Asia and reasons given for non-use of contraceptives. Method-related reasons account for fully 70% of non-use of family planning, suggesting that new and different types of contraceptive technologies are needed to fill these gaps (Darroch et al., 2011). Fig. 1. Reasons Women Give in DHS for Non-Use of Contraceptives. Source: Darroch et al., 2011. 148 million women living in sub-Saharan Africa, South Central Asia, Southeast Asia.



**1.2.3.1. Emergency contraception.** Emergency contraception (EC) has been in use for more than 30 years, is available in many countries, exists in multiple formulations and is offered through a range of service delivery points. EC is an effective and safe method of preventing pregnancy, and its provision of post-coital protection gives it a unique role in the contraceptive mix within family planning programs (FIGO/ICEC, 2012; WHO, 2010).

The dynamic and evolving story of EC illustrates several important issues. For example, because EC is considered politically sensitive in many settings (i.e., critics and skeptics confuse its use with medical abortion), intensive and continuous advocacy efforts have been required. Thus, it is critically important to identify and support local champions who can be called upon to address issues (scientific, political, etc.) that arise around a new product, particularly one that is politically sensitive and/or is a new type.

Because the effectiveness of EC is directly related to the timing of use, accurate information is critical for optimal use of the product. After a decade of EC programming, misunderstandings and misconceptions (on the part of both providers and users) still abound (Westley and Glasier, 2010). This is explained in part by the fact that, as the science and evidence evolves around a particular product, it takes time for updated information to reach provider populations in various settings (Williams, 2011).

EC was initially introduced as a prescription-only product. Over time and with mounting evidence of its safety along with considerable effort on the part of a consortium of agencies, EC gained OTC status in many countries (International Consortium for Emergency Contraception, <http://www.cecinfo.org/>). And, while acquiring OTC status has been very successful in terms of expanding access, it has also meant that the quality of provision and the ability to monitor use and impact has been limited. Little to no counseling occurs at the time of provision in pharmacies, which in many settings are the main channel for distribution. An unanticipated consequence, perhaps related to acquiring OTC status, has been the development of numerous brands of EC products entering the market. This may also be an indicator of high demand for post-coital contraceptive products. And while this has the potential to drive down price, having multiple products on the market can make it difficult for authorities to control drug quality. While challenges remain to ensure access to all women who need EC, enormous strides have been made, and scientific and programmatic progress continues.

**1.2.3.2. Female condoms.** The female condom (FC) is an effective, female-initiated method available now that can protect women from pregnancy and STIs (PATH/UNFPA, 2006; WHO, 1997). Although FCs have been introduced in many countries, their supply and uptake in countries hardest hit by the HIV/AIDS epidemic has been woefully inadequate.

The FC introduction experience reveals several important challenges. First, provider bias against FC, along with relatively high cost, has significantly hampered broad adoption and uptake, despite interest on the part of many women and advocates. Given that providers often serve as gatekeepers to access for women, tackling provider bias early on is critical for product introduction. For any new product to be distributed through health facilities, it is essential that the front line health workers who are tasked with delivery are trained and believe in the product's utility.

Another key lesson learned from the FC experience (as well as other contraceptive products) is that the notion of "acceptability" changes over time, and is tempered by actual experience and use (Warren and Philpott, 2003). For example, vaginal barrier products (e.g., FC, diaphragm) require practice for proper placement and thus a minimum comfort level with touching one's vagina (Bulut et al., 2001). Initially, some women find this difficult, but with practice become more comfortable with the product. There is a

definite learning curve with using such products, thus programs should support women as they transition through the learning period.

Finally, it is important to recognize that while consistent use is optimal, it is difficult to achieve. Research suggests that required repeated behaviors (e.g., oral pill taking) over an indefinite amount of time can be difficult to sustain, unless the behavior is relatively easy to do, is pleasurable, or there is extremely high motivation to continue the required behavior. Experience from family planning shows that "supportive counseling" can help women continue using their contraceptive method. It will be important for any future MPT introduction that adequate attention is given to appropriate women-centered and supportive counseling to help women use the product safely and effectively.

We have learned through numerous examples that if stock-outs are frequent and persistent, potential users lose confidence in the product and the service delivery system. Sustained donor (and government) commitment to ensuring product supply is critical to the success of any product introduction effort. In the case of the FC, a vicious cycle of high product cost, lack of donor commitment, imbalance in supply and demand, lack of provider adoption, and slow end user uptake, made FC introduction extremely challenging and limited its success (Pratt, 2008; Brady, 2011). New FC products have been developed, which offer a new opportunity to stimulate demand and increase access and availability.

**1.2.3.3. Intravaginal rings (IVRs).** A number of IVRs for contraception and/or dual indications are either already available or are currently under development. Three IVRs are currently approved and marketed for use: NuvaRing® (Merck) for contraception, and Estring® (Pfizer) and Femring® (Warner Chilcott) for hormonal therapy in post-menopausal women. A progesterone-only ring for use during lactation (Progering®) has also been studied (Nath and Sitruck Ware, 2010) and is approved in select markets in South America.

In general, IVRs provide slow, controlled release of drugs over extended periods of time. Although there are a number of different protocols for use of the various types of IVRs (e.g., 1 month, 3 months, 1 year), they share some commonalities. One of the key features of IVRs is that they do not require daily action (or coitally related action) on the part of the user. IVRs do, however, require some level of "user effort" in terms of learning how to insert; how, why and when to remove; and when and how to re-insert. Emerging evidence from a number of clinical studies with different types of IVRs suggests that it is relatively easy for women to learn how to use the IVR, and that their comfort level increases over time (Nel, 2011).

For IVR introduction and use, the extent to which slippage and/or partial expulsions occur is important to document. Toileting and hygiene practices, as well squatting behaviors (for work or otherwise), are important to understand in various contexts when introducing an IVR. Additionally, some women report that their partner can feel the IVR, which has in some cases led to discontinuation of the product. Understanding male partners' attitudes and behaviors around IVRs will also be critical (Woodson and Alleman, 2008). Analysis of existing vaginal ring data is underway (acceptability of NES/EE contraceptive vaginal ring data on file at Population Council, 2013).

### 1.3. Integrating MPTs into existing programs and structures

National health systems largely (but not solely) determine the institutional structures and processes through which new contraceptives (and potentially, future MPTs) are delivered and accessed. When considering a national health system from a "total market" perspective, we note that a product may be made available through

public, commercial, non-for-profit, and faith-based sectors (Barnes et al., 2012). Globally, the number and type of service delivery channels through which contraceptive products are delivered has increased dramatically over the past two decades, reflecting both expansion within the public sector and the growth of other sectors (Askew and Brady, 2013).

The most effective mix of program entry points and distribution channels for an MPT will vary, given regional and country contexts. While new channels and approaches may be needed in some countries – particularly to reach specific populations that are currently poorly served – incorporating a new product into existing services and better integration of SRH and HIV services will likely be the most efficient mode for MPT introduction. While there is some debate as to whether stand-alone, vertical programs have been more successful than integrated programs in terms of numbers served, it is likely that the long-term sustainability of MPTs will depend on supporting existing health structures and capitalizing on what is already in place.

Examples of the types of service delivery points through which MPTs may be provided could include some combination of existing reproductive health and maternal health services, given that these are the types of services that many women are able to access with some regularity. Different program models provide opportunities and challenges; thus it will be important to pilot and rigorously evaluate a number of service delivery approaches to determine what is most appropriate for any given product. Identifying necessary adjustments and inputs to the various service delivery approaches will be needed in order to determine the most effective ways to offer MPTs. Validated “total market” assessments will also be needed to determine the characteristics of existing and likely future markets, and to define the comparative advantage of commercial, social marketing, non-governmental organization (NGO) and public sector actors in terms of their competence and “value for money” in delivering future MPTs to various market segments (Barnes et al., 2012).

#### 1.4. Understanding the MPT regulatory pathway

MPT products for the simultaneous prevention of pregnancy, HIV and other STIs can be developed from various combinations of approved and/or experimental drugs and/or devices for different single indications. Such combination pharmaceutical products face development and regulatory complexity beyond what is involved with typical single-agent, single-indication products. The presence of more than one active pharmaceutical ingredient (API) increases the preclinical, CMC (chemistry, manufacture, control) and clinical development obligations. This is further compounded when a combination product targets more than one medical indication, such as in the case of MPTs and whether they are designed as drug + drug or drug + device combinations (Romano et al., 2012).

The MPT typology (Fig. 2) illustrates the possible permutations of MPTs in terms of indications, formulation/delivery vehicle, and status of API – all of which combine to make the regulatory pathway both complex and potentially lengthy. However, while each MPT product will have its own specific regulations, the three potential most important broad perspectives are likely: (1) whether the API is experimental or approved; (2) whether the product is a drug or device (biologics have their own pathway); and (3) whether the product is systemic or topical.

Both the US Food and Drug Administration (FDA) and the International Conference on Harmonization (ICH) have produced specific guidance documents that provide summary information on the preclinical and quality requirements for pharmaceutical product development. Although no specific guidance documents exist for the development of MPT products for SRH indications,

a number of relevant guidance documents do exist and have been summarized elsewhere (Brady and Park, 2011). Every pharmaceutical product will have its own specific requirements for development and regulatory approval and communication with regulatory agencies is a key component of a product development effort. Understanding the requirements at the different stages of product development is critical for efficient, cost-effective and successful product development. For MPT products with elevated development complexities and risks, a thorough understanding of the regulatory development requirements is all the more essential.

#### 1.5. Adoption, product positioning, marketing

Adoption and uptake of a new MPT will set the stage – in both positive and negative ways – for future products. Therefore, it is critical that initial introduction efforts are well conceived, supported and successful. Experience from the field of family planning suggests that it can take years to establish a market and a reliable system to deliver the product. Further, we have learned from Diffusion of Innovation (DOI) theory (Rogers, 1962), that behavior change communication can also play a critical role in the adoption and spread of new ideas and/or products.

Chief among the number of factors influencing product adoption is how much behavior change is required on the part of users, providers, and communities to safely and effectively use the product. If the product attributes or presentation represents a radical departure from other products or practices, the speed of uptake may be slow (Bass, 1969). In addition, issues of product cost, type of service delivery approach, and level of public awareness all shape the “adoption” of a new product (Feringa, 2007).

Typically, industry engages marketing early in the product development process; in many cases marketing is a driving force behind product development by helping to define product features and Target Product Profiles (TPPs). Marketing principles can also be applied to introduction efforts. For example, the introduction of an MPT might consider:

- **Product positioning:** Typically, a product is positioned based on one key characteristic, generally its primary benefit. Depending on type, an MPT might be positioned for its contraceptive effect first, which may be more acceptable in many settings. Decisions on product positioning will be critical for MPTs.
- **Market development:** Market development involves a variety of activities to prepare “the market” for a new product. Activities include educating health care professionals, forming partnerships with advocacy organizations, conducting public awareness campaigns and so forth. Market development is an upfront cost needed to help shape the market and help build demand for a product.
- **Market segmentation:** Prioritization of different market segments is key for long-term growth of any product. Segmentation also allows for client-specific focus and enables more effective communication strategies.
- **Social marketing:** Social marketing can play an important role in demand creation by using mass media and other techniques to increase understanding of and desire for a product. Depending on the MPT formulation, social marketing can also be an effective service delivery channel.

Planning for and implementing a market-shaping strategy for future MPTs will require attention to commodity production, pricing, forecasting procurement, efficient supply logistics and quality assurance, all of which have been identified as key barriers that restrict access and choice for women wishing to use family planning (Askew and Brady, 2013).

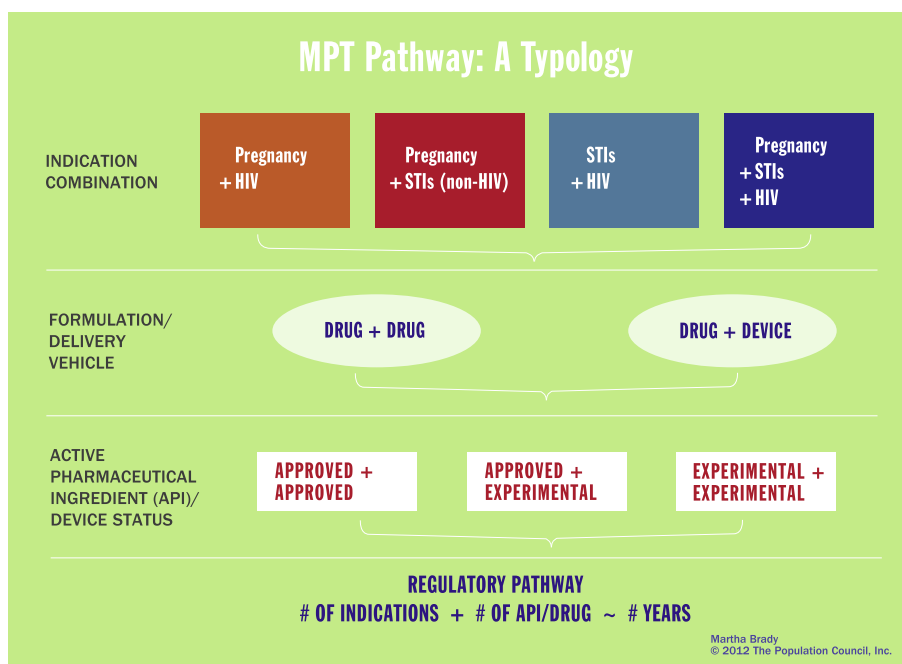


Fig. 2. The MPT typology illustrates the possible permutations of MPTs in terms of indications, formulation/delivery vehicle, and status of API—all of which combine to make the regulatory pathway both complex and potentially lengthy (Brady, 2011). Fig. 2. MPT Pathway: a typology.

## 2. Discussion

MPTs for SRH would have a dramatic impact on the health of women and girls in key regions of the world where unprotected sex provides a common platform of risk of unintended pregnancy, HIV and other STIs. Furthermore, the development of a suite of MPT options would enable women to address their perceived risks and fertility intentions as they change over time.

The history of the introduction of a number of SRH products offers valuable lessons for the introduction of MPTs, and highlights many common challenges with new SRH technologies. For example, unanticipated problems, such as stigma associated with product use, have either limited use of products in some countries and/or resulted in skewed utilization patterns across regions. Political, ethical, and religious opposition in some countries have often prevented widespread use of certain products, particularly abortifacients, EC, and other products under women’s control. On the other hand, there have been positive collateral effects of new technology introduction; in some instances it has helped to improve overall quality of care, and offered a strategic opportunity for improving provider training. The diversity of needs, populations and reproductive intentions of individuals and couples, along with the maturity of programs and the strength of national health systems, will influence the effectiveness and impact of any new MPT product.

Several key themes have emerged across the introduction of several SRH products (Brady and McGrory, 2007) that will be applicable to MPT introduction. These include:

- Regulatory processes are complex and in some instances, opaque. Engagement with regulatory authorities early on in MPT development will be critical.
- Drug regulatory authorities, including FDA, EMA, other SRAs and country drug regulatory authorities are responsible for the ultimate approval of any MPT product.
- Normative agencies, in particular WHO and ministries of health, play a critical role in developing policies and guidelines regarding the procurement, logistics and use of products.

- The positioning of an MPT product within the context of the mix of SRH technologies available will shape the market and its ultimate uptake.
- Effective global, regional and country-level financing mechanisms are needed, requiring donor commitment and links to both private and public commodity procurement.
- Given the differences in regulatory, health sector and market environments in different countries, the pace and coverage of roll-out of any MPT product will vary within and among countries.

Ultimately, the introduction, scale-up and adoption of any new technology will depend in large part on a country’s willingness to take responsibility for its introduction, a perceived need for the product on the part of donors, providers, and health systems and the financial and technical support to ensure quality and access.

## 3. Conclusions

As enthusiasm grows for the development of products to address critical SRH needs around the world, innovative development strategies are needed which are efficient, cost-effective and consistent with likely regulatory requirements for such products. As MPTs advance through clinical development, it is critical that we apply lessons learned from the development and introduction of other SRH products so as to anticipate challenges and solutions. For example, we have seen that the design and implementation of family planning services over the past four decades has benefited from substantial donor investments in demographic, social science and implementation research that has generated a body of evidence, some of which is context-specific but much of which can be generalized across social milieu and national health systems (Jacobstein et al., 2013).

Although MPTs provide a compelling response to the multiple and reinforcing SRH risks faced by women globally, specific product characteristics and their socio-behavioral correlates should be

taken into account early on in the development process. Successful introduction of new MPTs will require solid understanding of socio-behavioral correlates, effective demand generation, appropriate integration into health service delivery systems, quality counseling for proper use, and active engagement of both public and private sectors. To propel the MPT product development and introduction efforts forward will require political will, human and economic resources, technical expertise, vision and leadership.

### Disclosure statement

The authors confirm that they do not have any conflicts of interest.

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