Critical pathway for developing and introducing a new type of oral contraceptive method

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A new type of oral contraceptive...

- Oral contraceptive (OC) taken around the time of sex instead of daily.
- Before or after sex.
- Also called “pericoital,” or “on-demand” OC.
- A dedicated product.
  - Proper labeling and use instructions.
  - Promotion and demand generation.
  - Regulatory approval confers legitimacy.
- No such dedicated product exists yet.
  - Levonorgestrel (LNG) is one possibility.
Why are we considering a new type of OC?

- It appeals to some women:
  - Connected to sex → intuitive?
  - Easier to remember → better compliance?
  - Woman-controlled.
  - Discreet.

- Some women have used/are using emergency contraception (EC) this way.
  - Old Postinor.
  - LNG EC.

- Unmet need for on-demand contraception:
  - Substantial proportion of women with unmet need cite “infrequent sex” as the reason.
Why develop a critical pathway?

- A dynamic planning tool to illustrate key decision points and issues in development and introduction of a health technology.
- Highlights connections between seemingly separate “tracks” of work.
- Coordination mechanism for diverse stakeholders.
- Demonstrates the significant level of effort to get a product out to users.
- Puts specific activities in the context of a longer-term process.
Product decision points

- What are key considerations for identifying potential commercial partners?
  - Clinical trial capacity.
  - Regulatory expertise.
  - Making method available to women in low-resource settings (price, quality, distribution network).

- How effective is the product?
  - Data needed from Phase III clinical trial results.

- How effective should it be?
  - Public health standards.
  - Regulatory requirements.
Regulatory decision points

- How can we determine which regulatory approach is feasible?
  - Manufacturing partner.
  - Requirements (e.g., effectiveness, trial design).
  - Timeline.
  - Cost.

- How can we determine which regulatory approach is strategic for product introduction and access?
  - Over the counter v. prescription.
  - Country registrations.
  - Priority distribution channels.
  - Likely user groups.
Procurement/distribution decision points

• What priority distribution channels will facilitate access?
  • Pharmacies.
  • Social marketing programs.
  • Public sector.

• What factors will influence procurement/distribution strategies?
  • Country capacity, infrastructure, regulatory context.
  • Likely user groups and preferences.
  • Experience with related family planning methods.
  • Counseling capacity.
  • Demand generation.
  • Profitability.
Policy/guidelines decision points

- What are key guidelines and norms?
- What are policymakers’ major concerns and expectations?
  - Effectiveness.
  - Safety.
  - Cost.
  - Potential impact on other methods (long-term methods, condoms).
  - Confusion regarding abortion.
  - Perceptions about impacts on sexual behavior.
Demand generation decision points

- Who will be likely to use the method?
  - Women who have sex relatively “infrequently”.
  - Young women, especially educated/professional women.
  - Older women who have tried other methods, have waning fertility.
  - Women who are not using other methods.
  - Women who have a low risk threshold for pregnancy.

- How many of these women are there, how much are they willing/able to pay, how will they use the method?
  - Qualitative and quantitative market research.
Education decision points

• What do women and providers need to know?
  • Effectiveness (Relative to other methods, actual risk of pregnancy).
  • Safety (It’s safe under X circumstances).
  • Side effects (What to expect, how to manage, preventing discontinuation, recognition of pregnancy given irregular bleeding).
  • Clear use instructions (Addressing frequency of sex).
  • Will not protect against sexually transmitted infections, including HIV/AIDS.
  • Women-led method (Role of women’s choice in contraceptive use and continuation).
Key conclusions: Pericoital oral contraception

- Much more information is needed from women/potential users.
  - Product name!
- Clinical trials would be needed for a dedicated product.
- Method of choice, empowerment, flexibility, responsibility for women.
- Critical pathway can support planning and coordination throughout product development and introduction.
Thank you

“The ‘right’ method for a woman is the one she will use.”

- Key stakeholder