A Critical Look Down the Critical Path to MPT Development

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Population Council

MPT Product Development Workshop
February 20-21, 2013
CONRAD
Who Needs MPTs?
Diverse groups of women across geographies, ages, cultures
Constructing a Critical Path from Product Development to Introduction

Brady, M., Critical Path Framework © 2011 Population Council
Critical Activities

• Clarify regulatory pathway(s) for MPTs

• Engage regulatory bodies at global and local levels

• Work with product developers and/or manufacturers to submit dossiers
MPT Pathway: A Typology

**INDICATION COMBINATION**
- Pregnancy + HIV
- Pregnancy + STIs (non-HIV)
- STIs + HIV
- Pregnancy + STIs + HIV

**FORMULATION/DELIVERY VEHICLE**
- Drug + Drug
- Drug + Device

**ACTIVE PHARMACEUTICAL INGREDIENT (API)/DEVICE STATUS**
- Approved + Approved
- Approved + Experimental
- Experimental + Experimental

**REGULATORY PATHWAY**
# of Indications + # of API/Drug ~ # Years

Martha Brady
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MPT Regulatory Puzzle

Specific regulations will vary with each MPT, however the following perspectives provide a basis:

- Experimental versus approved
- Drug versus device
- Systemic versus topical delivery
Tailored MPT Guidance and Policy Could Help to:

- Clarify pathways for regulatory review and licensure of MPTs within key regulatory authorities
- Set overall regulatory and development strategy
- Determine resource requirements and research approaches (assessments, algorithms)
- Inform intellectual property arrangements
- Define options for pricing, manufacturing, and ultimately availability of future MPT
Where Should Users’ and Providers’ Input Fit Along the Pathway?
Weighing and Balancing

Product attributes, efficacy, safety, “ease” of use, locus of control, effects on fertility, social cost, perception, pleasure, price

Brady, M. Population Council, 2008
MPTs and the End User: Shaping a Research Agenda

- Understanding women’s motivations to use MPTs (what indication trumps, why, and in what contexts?)
- Marketing and product positioning (how should a specific MPT be pitched; what is the USP)?
- Financing mechanisms (funded via FP or HIV?; in US issue of reimbursement)
- Access and Acceptability (AA) Working Group
Access and Acceptability Working Group

- Newly forming; soft launch 2013
- Inter-agency effort, chaired by Martha Brady
- Virtual meetings; work towards consultation in late 2013
- Will adapt *access frameworks* and modify for MPTs
- Learn from the past to inform the future

More to follow……..
Too early? Too late?
Time to get started!!
"Sure, St. Luke's has a heart-lung machine, but we have a heart-lung-kidney-liver-spleen machine."
Aligning Goals

- Individual Rights & Choice
- Public Health Impact
- Commercialization

Brady, M., Population Council, 2009
Building an Investment Case
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<td>Demonstrating Medical and/or Public Health Utility</td>
<td>Create awareness among policymakers, providers, users. Engage civil society. Build champions. Train providers. Identify advertising and pricing strategies.</td>
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<td>Demand Creation Market Development</td>
<td>Develop introduction plan with key stakeholders. Integrate product into service delivery norms and guidelines. Conduct implementation research.</td>
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<td>Enabling Policy</td>
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Brady, M. Population Council 2011
Population Council’s “Bench to Bedroom” Research

Biomedical

Basic Research  Product Development  Clinical Trials  Product Introduction  Health Delivery Systems  Operations Research

Social Science