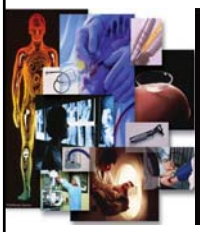

Educate Enable Enlist Explore
HoW to Improve the Health of Women

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U.S. Food and Drug Administration

CDRH HoW Program Launch
June 24-25, 2013

WORKSHOP FOCUS:
Educate, Enable, Enlist and Explore

The CDRH HoW program seeks to bring together clinicians, researchers, academia, government agencies, industry, and patient / advocacy groups in an effort to discuss "HoW" to improve the health of women and brainstorm effective success strategies to address clinical research needs.

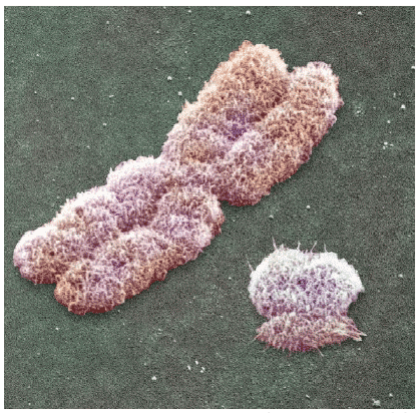
Why the "Health of Women (HoW)"?

Being a man or woman has a significant impact on health, as a result of both biological [sex] and psychosocial [gender] differences.

'Health of Women' encompasses health conditions that are specific to women; are more common or more serious in women; have distinct causes or manifestations in women; have different outcomes or treatment options in women; or have high morbidity or mortality in women

Sex or Gender

- **Sex:**



- **Gender**

Why are we here?

Uncertainty about utilization or outcomes of device use in women, due to underrepresentation and inconsistent analysis

Differences in outcomes or utilization due to biological sex differences

Potential difference in communication & healthcare decision making

Effects of hormones through life stages

Fertility, pregnancy & lactation

Unique Issues in the Regulation of Medical Devices Related to the Health of Women

Unique Women Specific Considerations: Pregnancy

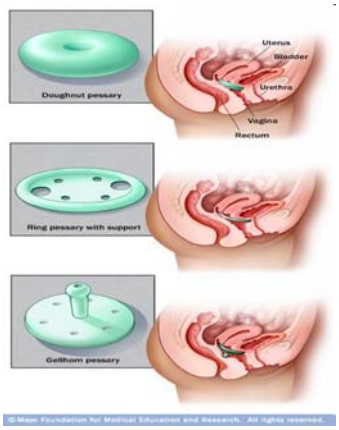
- Devices specifically indicated for use in pregnant women: *Fetal Monitor*
- Devices contraindicated for use in pregnant women: *Endometrial Ablation Devices*
- Devices dependent on pregnancy status of a woman: *Pessary*

Unique Considerations

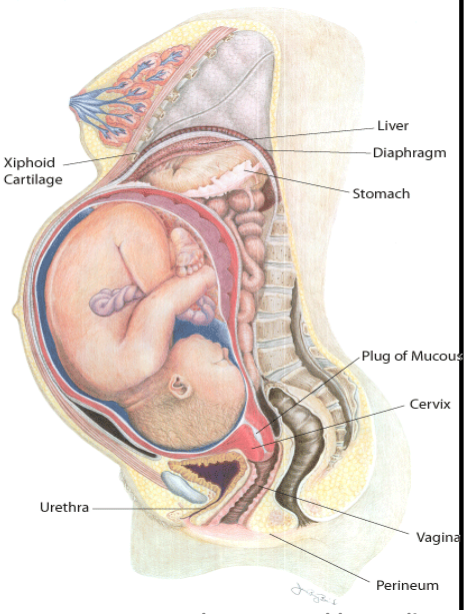
Different Indications: based on unique issues related to women pre menopause v during pregnancy v post menopause that determine the different uses /indications for the device:

1) Treat Prolapse: of uterus (pelvis) and/or bladder
2) Treat urinary incontinence

Unique considerations: anatomical and physiological changes that occur during pregnancy (hormonal changes are secondary)



Pregnant Uterus



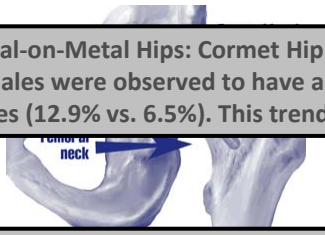
Pregnancy and Impact on Device Use (continued)

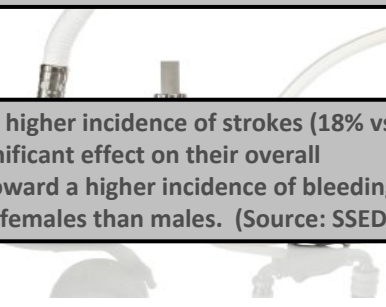
- Pap smear brush – contraindicated for use in pregnant women
- Pap smear brushes are routinely used in pregnant women to collect endocervical cells despite the contraindication in the labeling
- Unknown risks to mother and fetus

Difference in Safety: Sex or Covariates?

Hip Resurfacing System & Metal-on-Metal Hips

Ventricular Assist Devices (VAD)

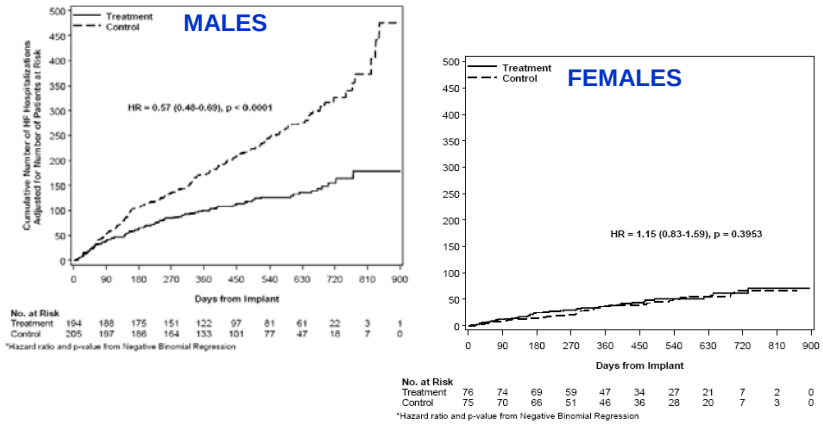




Metal-on-Metal Hips: Cormet Hip Resurfacing System SSED: Females were observed to have a higher revision rate when compared to males (12.9% vs. 6.5%). This trend has been seen in other systems as well.

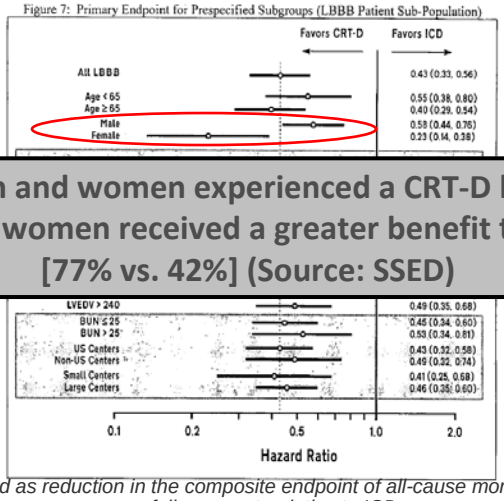
VAD: Women were observed to have a higher incidence of strokes (18% vs. 6%), but the strokes did not have a significant effect on their overall survival compared with men. Trends toward a higher incidence of bleeding and infection events were observed in females than males. (Source: SSED)

Difference in Treatment Effect?



Source: FDA presentation, Advisory Meeting for Champion HF Monitoring System, Dec 8, 2011

Difference in Treatment Effect?



Both men and women experienced a CRT-D benefit;* however, women received a greater benefit than men [77% vs. 42%] (Source: SSED)

** "benefit" defined as reduction in the composite endpoint of all-cause mortality or first heart failure event, relative to ICD*

HoW to Improve the Health of Women

MISSION—To improve the health of women by:

- **Improving the availability, consistency and communication of sex-specific information for the safe and effective use of medical devices in women**
- **Addressing identified gaps and unmet needs through targeted resources**
- **Fostering the development of innovative strategies, technology and clinical study paradigms**

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Early Steps

Draft Guidance for Industry and Food and Drug Administration Staff

Evaluation of Sex Differences in Medical Device Clinical Studies

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.
Document issued on: December 19, 2011

You should submit comments and suggestions regarding this draft document within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.regulations.gov. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this document, contact Kathryn O'Callaghan at 301-796-6349, or via email at kathryn.ocallaghan@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Recommendations:

- **Strategies to enhance participation**
- **Statistical analyses of trial data**
- **Transparent reporting of sex-specific findings to the public**

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Making Strides

- **Plenary 1: Recruitment & Retention**
- **Plenary 2: Analysis & Communication**
- **Breakout Sessions (Concurrent)**
  - Facilitated small group table discussions
  - Large group Action Plan development
- **Plenary 3: Research Sessions**
  - Moderated discussion

Refer throughout to the Participant Workbook

Recruitment & Retention

→Modernize medical research paradigms in the U.S. – patient-centered

- Enable collection of information related to device use in women through enhanced recruitment & retention
- Explore and test medical device-specific strategies
- Engage patients to actively participate in research important to health of women

Analysis & Communication

→ **Improve health of women through consistent analysis & communication of sex-specific findings**

→ **Communicate the right information to the right audience through the right vehicle**

- Partner with professional societies and advocacy groups to convey to women & providers the information they want to know
- Identify areas for meta-analysis or further research
- Foster the development of innovative technologies for female-typical conditions

Focus on Gap Analysis and Future Research

→ **Address identified gaps and unmet needs through targeted resources**

- Improve outcomes and minimize complications
- Maximize impact of regulatory science, research and policy efforts toward identified gaps through active collaboration

→ **Foster the development of innovative strategies, technology and clinical study paradigms**

VISION: Where are we going?

- Sex-specific device outcomes will be communicated in a way that is meaningful to healthcare practitioners and patients
- Device clinical studies will be designed to evaluate clinically meaningful sex differences in outcomes
- Research agendas will consistently take into account the unique differences in women
- Every medical device developed will account for the unique considerations of usability within women

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Laying the Groundwork for Tomorrow

Special Thanks!

The CDRH HoW Team:

- Dr. Renee Carter
- Joannie Adams-White
- Sophia Smith
- Joyce Raines

- **Office of Women's Health**