The Impact of Sex and Gender on Disease and Medication

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I have nothing to disclose.
Objectives

1. Define sex and gender based medicine terminology.
2. Explain sex differences in disease presentation.
3. Identify and select medication(s) considering sex and gender.
4. Recognize opportunities for pharmacists to practice sex and gender based medicine

Terminology
Sex and Gender

Sex
- Biological differences
  - Sex organs
  - Hormones
  - Chromosomes

Gender
- Characteristics that a society or culture attributes to masculine or feminine

Intersex
- Identity associated with having a disorder or difference of sex development

There’s More to Gender…

Gender Identity
- An individual's intrinsic sense of self and how they fit into the world, from the perspective of gender

Gender Expression
- Outward manner one uses to present their gender

Gender Nonconforming
- Person whose gender identity, role, or expression is different from what is assigned at birth or what is considered normative for their assigned sex in a given culture or historical period

Sex and Gender. NIH. https://orwh.od.nih.gov/sex-gender

### And More…!

#### Transgender
- An umbrella term for people whose gender identity and expression differs from the sex assigned at birth

#### Cisgender
- A word used to describe those whose sex assigned at birth matches gender identity and expression

#### Nonbinary
- Transgender or gender-nonconforming person who does not identify either with sex

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### So what is Sex and Gender Based Medicine (SGBM)?

> “With continuous interaction between sex and gender, health is determined by both biology and the expression of gender.”

*National Institutes of Health Office of Research on Women’s Health*

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Sex and Gender. NIH. https://orwh.od.nih.gov/sex-gender
What is Gender Based Medicine? https://www.laurabushinstitute.org/gender/default.aspx
SGBM Implications

- Research
- Education
- Practice
- Outreach

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Differences in Disease Presentation
Does Sex Really Matter?

“There are multiple, ubiquitous differences in the basic cellular biochemistry of males and females that can affect an individual’s health.”

“Every cell has a sex”

IOM Report, 2001

Wizeman et al, Nat Academy Press (2001)

True or False

Depression is twice as common in women.

True or False

Men and women experience the same heart attack symptoms.

What is Gender Based Medicine? https://www.laurabushinstitute.org/gender/default.aspx
Heart Disease in Women. NHBLI. https://www.nhlbi.nih.gov/health-topics/heart-disease-women

True or False

Men are twice as likely to die after an osteoporotic hip fracture compared to women.

True or False

Low-dose aspirin reduces the risk of heart attacks in women.


True or False

Nicotine replacement therapy has the same efficacy in smoking-cessation for men and women.

True or False

Men are more severely affected by autoimmune disorders, such as lupus and multiple sclerosis.


Implications on Medications
Sex Differences

- Pharmacokinetics
- Pharmacodynamics
- Adverse Drug Effects

Pharmacokinetics

**Absorption**
- Dependent on route of administration
- Oral
  - Gastric motility
  - GI enzymes in drug metabolism

**Distribution**
- Body composition
  - Weight
  - Fat
- Plasma volume
- Plasma protein binding

Pharmacokinetics

Metabolism

- Phase I
  - CYP 1A2
  - CYP 3A4
  - CYP 2D6

- Phase 2
  - COMT

Excretion

- eGFR

Pharmacodynamics

- Central Nervous System Medications
  - Depression
  - Pain

- Cardiovascular Medications
  - Aspirin
  - Statins

Adverse Effects

- Occur more in women
- QTc prolongation
- Other ADEs

- 10 prescription medications withdrawn from U.S. Market
  - 8 associated with more adverse events in women


History

1977- FDA Clinical Evaluation of Drugs
1993- FDA Guidance Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs
1998- FDA Demographic Rule and Investigational New Drug Application

Understanding Sex Differences at FDA. https://www.fda.gov/scienceresearch/specialtopics/womenshealthresearch/ucm131182.htm
Opportunities for Pharmacists

Education

- Recognize SGBM as an integral part of the patient care process
- Educate yourself, trainees, and patients!
  - Online course series
    - The Science of Sex & Gender in Human Health
      - https://sexandgendercourse.od.nih.gov
- Stay abreast of SGBM updates
Practice and Promote

• Consider SGBM during clinical encounters

• Pharmacist Patient Care Process
  – Collect
  – Assess
  – Plan
  – Implement
  – Follow-up: Monitor and Evaluate

• Advocate for advancing and integrating SGBM

SGBM and Patient Communication

A
Ask open-ended questions
Acceptance
Avoid Assumptions

B
Be respectful

C
Create a welcoming and inclusive environment
Case Application

Casey, 60 years old, presents for your first MTM session. You collect the following information:

**PMH:**
Depression  
H/o opioid abuse  
Lower back pain with sciatica  
Hypertension  
h/o MI (2 years ago)

**SH:**
Tobacco: Current (1ppd x 40 years)  
Illicit Drugs:

**FH:**
Father- deceased (MI @ 50yo)  
Mother- alive (79yo); h/o breast cancer

**Medications:**
Metoprolol succinate 50 mg PO daily  
Sertraline 100mg PO daily  
Gabapentin 300 mg PO TID  
Lisinopril 10mg PO daily  
Rosuvastatin 20mg PO daily  
Aspirin 81mg PO daily

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**Question 1**

What is the patient’s sex?

A. Male  
B. Female
Question 2

What medications have sex and gender implications?

1. Metoprolol succinate
2. Lisinopril
3. Sertraline
4. Rosuvastatin

A. 1 and 2
B. 1 and 3
C. 1, 2, and 3
D. 1, 3, and 4

Question 3

What opportunities as a pharmacist do you have to practice sex and gender-based medicine (SGBM) for this patient?

A. There is no need to practice SGBM.
B. Educate the patient about SGBM.
C. Encourage medication adherence.
D. Call prescribers to modify the medication regimen.
And then….

During your session, Casey inquires about the use of zolpidem for sleep.

What sex and gender-based medicine (SGBM) considerations might be on your radar?
   A. Zolpidem has different maximum doses for men and women.
   B. Zolpidem has the same maximum doses for men and women.
   C. Zolpidem is not effective in women.
   D. Zolpidem is not effective in men.

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Thank you!

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