Medical Device Epidemiology – Introduction

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Mary E Ritchey, PhD

Pre-Conference Educational Session
International Conference on Pharmacoepidemiology

Course Overview

Topic	Time
Welcome and Introduction	8:30
Data Sources for Medical Device Epidemiology	8:40
Surveillance and Medical Devices	9:10
Break	9:40
Methods for Scaling Medical Device Analyses to Large Data	9:50
Advanced Topics in Medical Device Epidemiology Methods	10:20
Advancing Regulatory Decision Making through Translational Epidemiology: The Case of Arthroplasty Devices	10:50
Break	11:05
Comparative Effectiveness Research and Medical Devices in the Healthcare Environment	11:15
Case Study	11:45
Wrap-up & Evaluation	12:20

Introduction of Faculty

Maria Inacio

Nicole Pratt

Michael Matheny

Theodore Lystig

Danica Marinac-Dabic

Jessica Jalbert

Irene Murimi

Mary E Ritchey

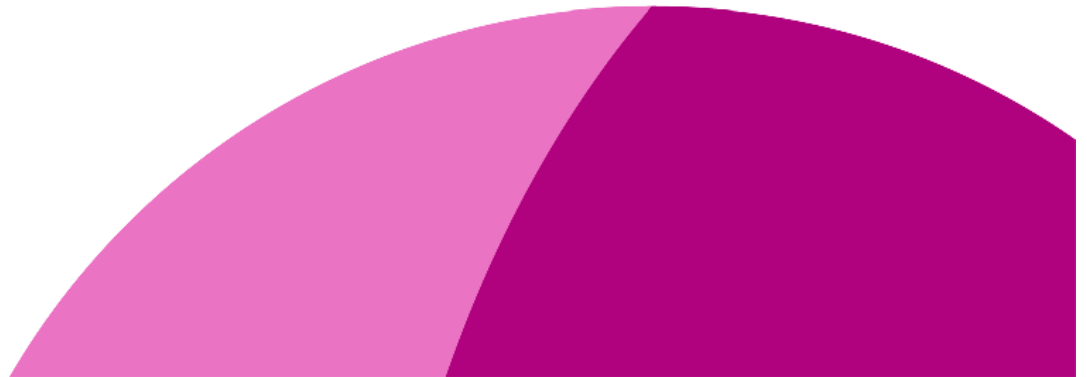
Disclosures - Ritchey

- The following personal or financial relationships relevant to this presentation existed during the past 12 months/during the conduct of the study:
  - Current employee and stockholder at Procter & Gamble
  - Also employed at Merck & Co for part of past year

- The content of this presentation is the opinion of the presenter and does not necessarily represent the position of P&G, Merck, or any other entity

Multiple Choice Questions

- Throughout the course, at least one per presentation – on concept within presentation
- 5 possible answers, 1 correct answer
- Goals: check understanding, generate discussion, available for those viewing later



Housekeeping

Facilities

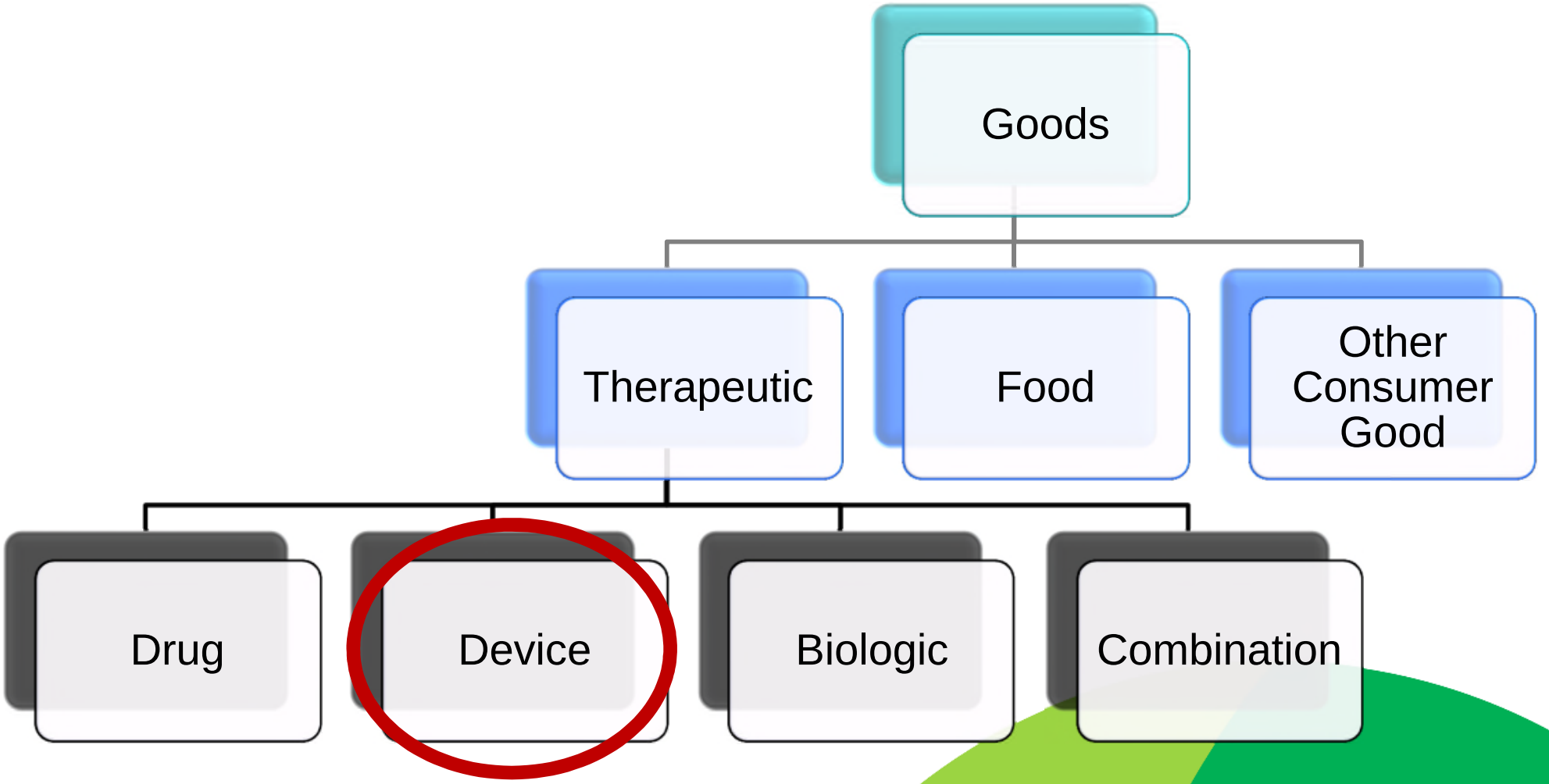
Handouts

Timing

Questions

Feedback

Therapeutic Goods



What is a Medical Device?

A medical device is:

- any instrument, apparatus, appliance, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended, by the person under whose name it is or is to be supplied, to be used for human beings for the purpose of one or more of the following:
  - diagnosis, prevention, monitoring, treatment or alleviation of disease;
  - diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;
  - investigation, replacement or modification of the anatomy or of a physiological process;
  - control of conception;
- and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means; or
- an accessory to such an instrument, apparatus, appliance, material or other article.

Ref: 1989 TGA 41BD

Definition Nuances

- Australia – definition on previous slide
- US
  - Includes non-humans
  - Specifies chemical action in or on body in regards to metabolism
- EU
  - Not for a toiletry or cosmetic purpose
  - Not necessarily articles compensating for handicap
- China
  - Clinical evaluation must be conducted prior to marketing any class II or III device
- Elsewhere – other nuances

Ref: MEDDEV 2.1/1; CN-001 Reg for Supervision and Admin of Med Dev; 21 USC 201(h)

Classification

Class	EU	US	Australia	China
General Info	Classified according to 18 rules	Classified based on understanding and reasonable assurance of S/E	Classified by level of risk according to 5 rules (multiple parts)	Classified based on ensuring S/E
Class I	Low level of vulnerability	General controls sufficient to provide reasonable assurance of S/E	Low	Ensure S/E through routine administration
Class IIa	Review needed at production stage	II: Special controls needed for S/E	Low-medium	II: Further control required to ensure S/E
Class IIb	High risk potential	n/a	Medium-high	n/a
Class III	Critical devices, require explicit prior authorization	Insufficient information exists regarding S/E or potential unreasonable risk of illness/injury	High	Implanted, used for life support, or post potential risk and thus must be strictly controlled in respect to S/E
AIMD	n/a	n/a	High	

Ref: Directive 93/42/EEC; 21 CFR 860.3; ARGMD Part 1; CN-001 Reg for Supervision and Admin of Med Dev

Is this a medical device?

Ref: http://www.aseptix.com/aseptix-brand/healthcare/medical-devices/; http://www.interface-analysis.com/IAA/images/site/medicaldevice.jpg; http://www.exova.com/sectors/pharmaceuticals/medical-device-testing-and-development/; http://www.pharmaceutical-int.com/upload/image_files/Pre-Filled-Syringes-3b.jpg; http://badbooksgoodtimes.files.wordpress.com/2012/06/toothbrush.jpg

Epidemiological Considerations for Medical Products

- Confounding by indication
- Reduce bias from healthy initiator, healthy adherer, healthy user effects
- Heterogeneity of treatment effects
- Validation of outcomes
- Etc
- Etc

Specific Additional Considerations for Medical Devices

- Device identification
- Exposure to device
- Provider characteristics
- Procedure effects

- Data sources
- Surveillance
- Comparator selection
- Etc…

Question: Introduction

Which of the following is NOT part of the definition of a medical device?

A. Must be metabolized by the body
B. Must be implanted in the body
C. Must be used to treat or prevent disease
D. All of the above (i.e. all of these are NOT part of the definition)
E. None of the above (i.e. all of these ARE included in the definition)