

Food and Drug Administration (FDA)
Center for Drug Evaluation and Research (CDER)
FDA Public Virtual Scientific Workshop
Morphine Milligram Equivalents: Current Applications and
Knowledge Gaps, Research Opportunities, and Future Directions
June 7-8, 2021

Agenda

Day 1: June 7, 2021

- | | |
|---|---|
| 9:00 am - Welcome and Panelists Introductions | Grace Chai, PharmD
Associate Director for Special Initiatives
Office of Surveillance and Epidemiology (OSE)
CDER, FDA |
| 9:15 am - Opening Remarks | Patrizia Cavazzoni, MD
Director
Center for Drug Evaluation and Research
FDA |
| 9:30 am - Introduction: Morphine Milligram
Equivalents (MMEs)
Current Applications and Knowledge
Gaps, Research Opportunities, and Future
Directions | Grace Chai, PharmD
Associate Director for Special Initiatives
OSE, CDER, FDA |
| 9:40 am - Impact of Science on Real Life
Experiences | Penney Cowan
Founder, CEO American Chronic Pain
Association |
| 10:00 am - Overview of Current Applications and
Uses of MMEs | Corinne Woods, RPh, MPH
Team Lead, Drug Utilization Team
OSE, CDER, FDA |
| 10:15 am - Calculating Conversations in Opioid
Conversions | Mary Lynn McPherson, PharmD, MA, MDE,
BCPS
Professor and Executive Director, Advanced
Post-Graduate Education in Palliative Care
Executive Program Director, Online Master of
Science and Graduate Certificate Program in
Palliative Care
Department of Pharmacy Practice and Science
University of Maryland School of Pharmacy |
| 11:00 am - Break | |

- 11:10 am** - Individual Patient & Medication Factors that Invalidate Morphine Milligram Equivalents
- Jeffrey Fudin, PharmD, FCCP, FASHP, FFSMB**
Albany College of Pharmacy and Health Sciences; Albany, NY
Western New England University College of Pharmacy; Springfield, MA
Stratton VA Medical Center; Albany, NY
Remitigate Therapeutics; Delmar, NY
- 11:40 am** - Opioid Prescribing and the Opioid Safety Initiative in the Veterans Health Administration
- Friedhelm Sandbrink MD**
National Program Director for Pain Management,
Opioid Safety and PDMP (PMOP), Specialty Care Services, Veterans Health Administration
Director Pain Management, Department of Neurology, Washington DC VA Medical Center.
- Thomas Emmendorfer, PharmD**
Department of Veterans Affairs
- Francesca Cunningham, PharmD**
Department of Veterans Affairs
- 12:10 pm** - Clarifying Questions to Speakers
- Moderator: Grace Chai, PharmD**
- 12:25 pm** - Lunch
- 1:20 pm** - Overview of the Opioid NDC and MME Analytical File Compiled by CDC
- Kun Zhang, PhD**
Health Scientist, Division of Overdose Prevention, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention (CDC)
- 2:05 pm** - MHRA-UK Work in Development of MME Tables
- Justin Pittaway-Hay, PhD**
Medicine and Healthcare Products Regulatory Agency (MHRA)
- 2:20 pm** - Improving Information for Opioids Prescribers on the Safest Possible Effective Dose of Morphine or Equivalent: A UK Perspective
- Maria Luisa Molinari, MD**
Senior Clinical Assessor at the MHRA
PGDip in Drug Development Science from King's College London
- 2:35 pm** - Clarifying Questions to Speakers
- Moderator: Grace Chai, PharmD**
- 2:50 pm** - Break

3:00 pm - Public Comment Session

Moderator: Tamra Meyer, PhD, MPH
Team Lead, Nonmedical Use Team #1
Division of Epidemiology II
OSE, CDER, FDA

5:00 pm Closing Remarks

Grace Chai, PharmD

Day 2: June 8, 2021

9:00 am - Welcome
Introductions, Speakers and Panelist
Recap of Day 1 and Introduction to Day 2

Grace Chai, PharmD
Associate Director for Special Initiatives
OSE, CDER, FDA

9:15 am - Opioid Conversion Information in
Approved Labeling

Mary Therese O'Donnell MD, MPH
Medical Reviewer in the Division of
Anesthesiology,
Addiction Medicine and Pain Medicine
(DAAP)
Office of Neuroscience (ON)
Office of New Drugs (OND)
CDER, FDA

9:30 am - Nonclinical Pharmacology and Toxicology
Considerations Regarding Opioid
Comparisons and Risk Assessments (Basic
Opioid Pharmacology 101)

R. Daniel Mellon, PhD
Division of Pharmacology/Toxicology for
Neuroscience
ON, OND, CDER, FDA

Donna A. Volpe, PhD
Division of Applied Regulatory Science
Office of Clinical Pharmacology
CDER, FDA

10:15 am - MME Calculations and Abuse Liability
Considerations

Chad J. Reissig, PhD
Behavioral Pharmacologist
Controlled Substance Staff
CDER, FDA

10:45 am - Clarifying Questions to Speakers

Moderator: Grace Chai, PharmD

11:00 am - Break

- 11:10 am** - Oral and Intravenous Oxymorphone: Relative Potency Compared to Other μ Opioid Agonists in Humans
- Shanna Babalonis, PhD**
Assistant Professor in the Center on Drug and Alcohol Research and the College of Medicine at the University of Kentucky
- 11:35 am** - Opioid Potency: Pharmacological and Non-pharmacological Factors
- Sandra Comer, PhD**
Professor of Neurobiology in the Department of Psychiatry at Columbia University, Research Scientist VI, New York State Psychiatric Institute
- 11:45 am** - Inches, Centimeters, and Yards: Overlooked Definition Choices Inhibit Interpretation of Morphine Equivalence
- Nabarun Dasgupta, MPH, PhD**
University of North Carolina at Chapel Hill
Departmental Affiliation: Gillings School of Global Public Health and Injury Prevention Research Center
- 12:15 pm** - Clarifying Questions to Speakers
- Moderator: Grace Chai, PharmD**
- 12:30 pm** - Lunch
- 1:30 pm** - Panel Discussion
- Moderators:**
- Judy A. Staffa, PhD, RPh**
Associate Director for Public Health Initiatives
OSE, CDER, FDA
- Jennifer Nadel, MD**
Medical Officer
DAAP, ON, OND, CDER, FDA
- 3:30 pm** - Break
- 3:40 pm** - Panel Discussion
- Moderators:**
Judy A. Staffa, PhD, RPh
Jennifer Nadel, MD
- 4:55 pm** - Closing Comments
- Grace Chai, PharmD**