Welcome

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WebEx Housekeeping Tips

In order to ask questions or make comments during this WebEx meeting, you must be connected to both the WebEx and audio portions.

- First, sign into the WebEx and accept an “ATTENDEE I.D.” (pop-up box)
- Then, call in to teleconference and enter your “ATTENDEE I.D.” at prompt

During the meeting, you may ask questions or make comments by posting through the WebEx chat feature. Access this feature through the **Chat** tab at the top of the right hand column of your WebEx view page

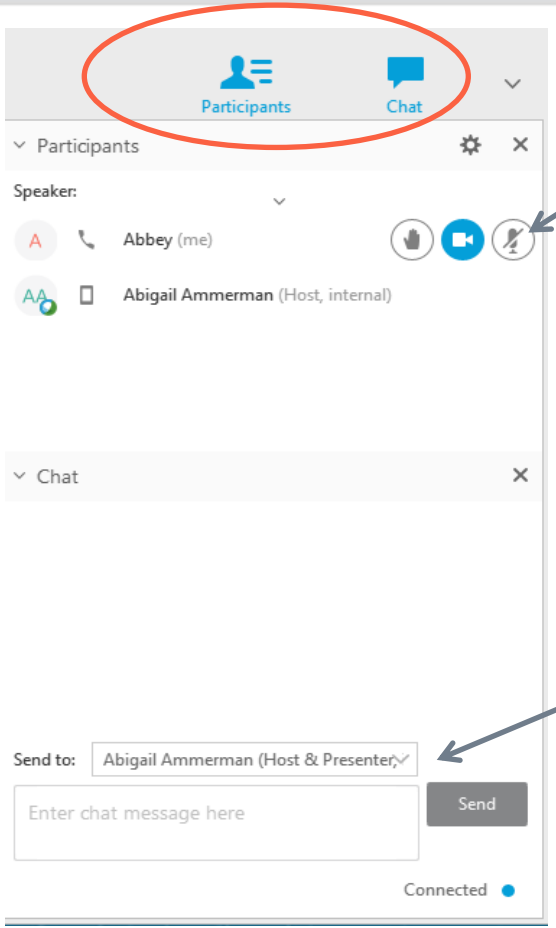
Use the text box at the bottom of the right hand column to enter your question or comment

- In the “Sent To” dropdown, select “Abigail Ammerman, Host”

Questions and comments will be collated for the Q&A portion of the WebEx, and will be addressed in order. If you would like to be called upon for a verbal statement or question, please indicate in your “chat” message.

If possible, USP will provide an opportunity for all the phone lines to be open for verbal comments, depending on the number of participants on the call.

WebEx Housekeeping Tips



Please mute yourself

Use the chat feature to submit a question or comment.

USP Drug Classification 2019

Open Microphone Meeting #1
Health plans/PBMs + Providers/Healthcare Associations
November 6, 2018
12:00pm to 2:00pm

Agenda

- Welcome & Introductions
- Overview of the USP
  - How we work
- USP Drug Classification 2019
  - Orientation to the draft
  - EP review processes
  - Preliminary summary of additions and revisions

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Overview of the USP

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Diana Kwan PharmD
USP Associate Scientific Liaison
Healthcare Quality and Safety

Mission

To improve global health through public standards and related programs that help ensure the quality, safety and benefit of medicines and foods

- Beyond standard-setting
- Making an impact on public health and patient safety

usp
200
years building quality
foundations for a
healthier world

Advocating for quality

Founding of USP

- In the early 1800s, medicine quality was inconsistent create public health risk.
- In response, 11 physicians (3 US senators) drafted book of formulas to help ensure consistent drug preparation.
- This was the first US Pharmacopeial Convention and led to the first U.S. Pharmacopeia.

USP is cited in law…

- **1848:** Drug Import Act
- **1906:** 1906 Pure Food and Drugs Act
- **1938:** Food, Drug, and Cosmetic Act (FDCA)
- **1994:** Dietary Supplement Health Education Act (DSHEA)
- **2003:** Medicare Modernization Act

Section 1860D-4(b)(3)(c) defines role of USP

"(ii) MODEL GUIDELINES- The secretary shall request the United States Pharmacopeia to develop, in consultation with pharmaceutical benefit managers and other interested parties, a list of categories and classes that may be used by prescription drug plans under this paragraph and to revise such classification from time to time to reflect changes in therapeutic uses of covered part D drugs and the additions of new covered part D drugs."

How we work

Healthcare Quality & Safety Standard-Setting Process

Stakeholders

USP actively seeks engagement with stakeholders throughout the standard-setting process through stakeholder meetings, advisory roundtables, and open-microphone webinars.

- Healthcare Practitioners
- Patients
- Academicians
- Healthcare Industry
- Regulatory Authorities
- Manufacturers

USP Process

1. Public Health Need
- Need identified by any stakeholder or USP
- Need evaluated for possible standard development

2. Draft Standard
- Best practices and scientific information collected

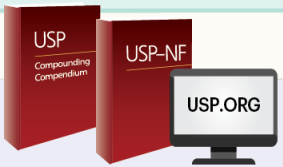
3. Public Comment Period
- Draft standard published for stakeholder input

4. Review & Approval
- Comments evaluated and addressed <or>
- Comments evaluated and further revision and comment needed

Revision Continues

Approved

5. Publication
- Final standard published



USP Expert Committee

USP convenes a committee of independent experts that are knowledgeable on the public health issue to develop the standard.

- Healthcare Practitioners
- Academicians
- Healthcare Industry
- Regulatory Authorities (Non-voting Liaisons)
- Manufacturers

Stakeholder Implementation

Regulatory Authorities, State Practice Boards, Healthcare Industry, Healthcare Practitioners and other stakeholders utilize USP Healthcare Quality & Safety standards within their specific authority to help ensure public health.

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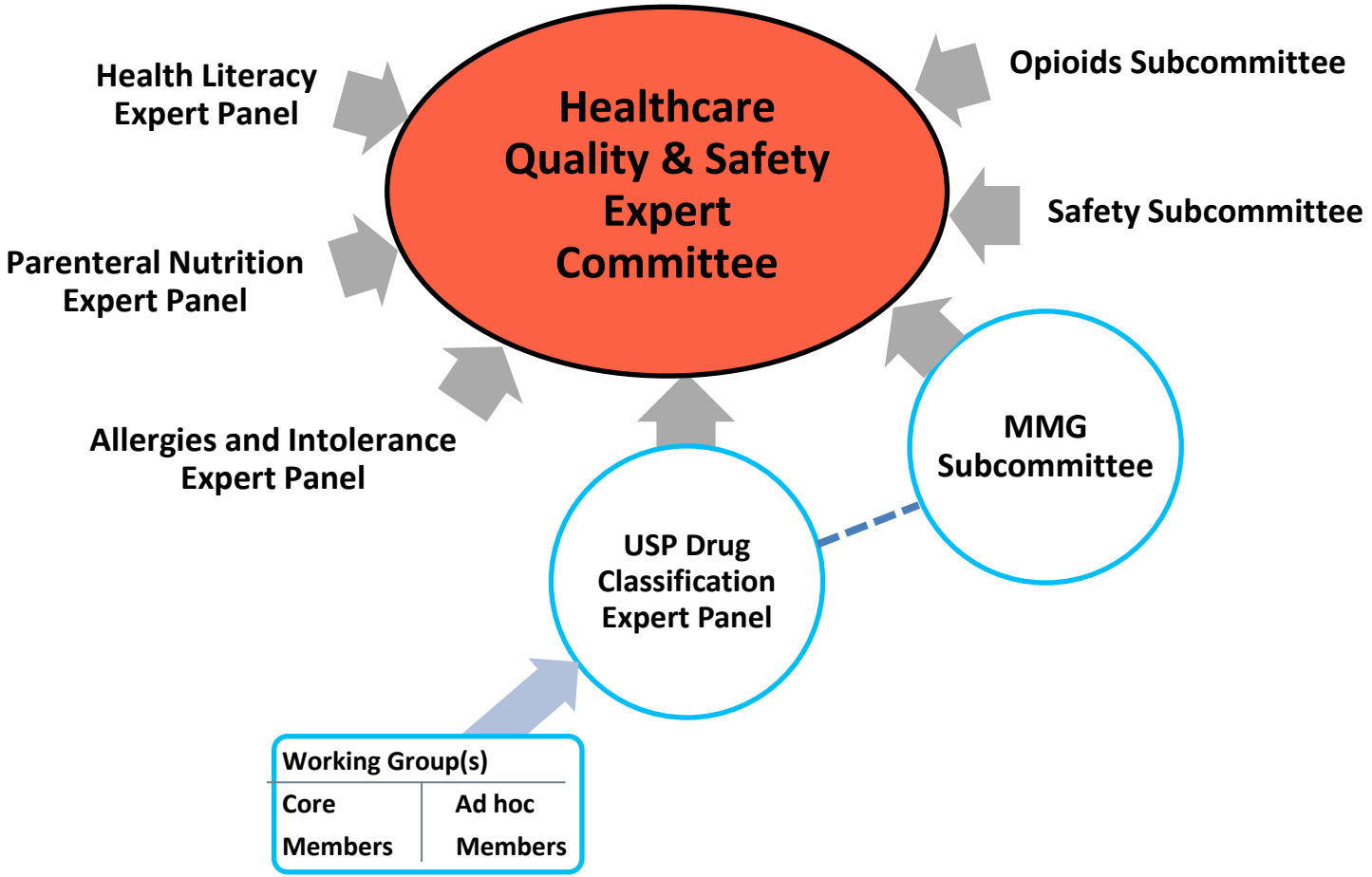
Healthcare Quality and Safety Expert Committee Members



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Healthcare Quality and Safety Expert Committee Members

Expert Committee members	
Dennis Doherty MD (chair)	Peter Glassman MD
Duane Kirking PharmD, PhD	Roy Guharoy PharmD, MBA
Mark Decerbo PharmD	Joanne G. Schwartzberg MD
Melody Ryan PharmD, MPH	Shonna Yin MD, MS
Jeanne Tuttle BS Pharm	Patricia Sokol JD
Phil Ayers PharmD	Terri Warholak PhD
Danial Baker PharmD	Timothy Albertson MD, MPH, PhD
Raymond J. Hohl MD, PhD	Russell Teagarden,BS Pharm, MA

USP Expert Committee

- **Ballots on standards for official status**
- **5 year commitment (2015-2020)**
- **HQS EC also ballots on Medicare Model Guidelines (MMG)**

USP DC Expert Panel Members

Expert Panel Members	Government Liaisons	Consultant
Duane Kirking PharmD, PhD (chair)	Coco Tsai PharmD	Mike Heath
Danial Baker PharmD	William Hess BS Pharm	
Lauren Hoffman PharmD, MPH		
Melody Ryan PharmD, MPH		
Jeanne Tuttle BS Pharm		
Dennis West PhD		
Gerry McEvoy Pharm D		
Lee Rucker MSPH		
Russell Teagarden BS Pharm, MA		
Seth Powsner MD		

USP Expert Panel

- **Non-voting members**
- **Time commitment is “as needed”**
- **The USP DC EP started developing USP DC in March 2016 and has met 1-2x a month since then**

USP DC 2019

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Duane M Kirking PharmD, PhD
Chair of the USP DC Expert Panel
Healthcare Quality and Safety Expert Committee

USP DC: What it is

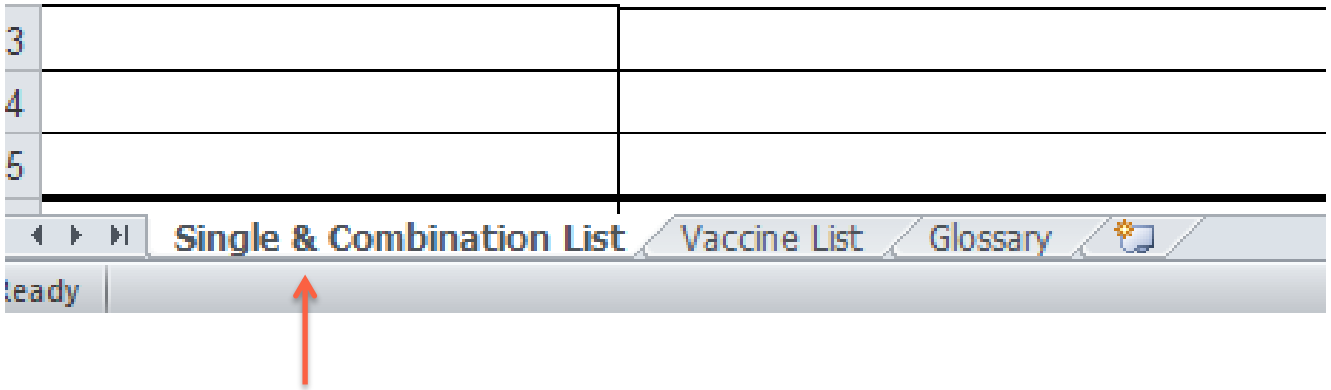
The USP Drug Classification system (USP DC) is an independent drug classification system developed by the USP Healthcare Quality & Safety Expert Committee. The Healthcare Quality Expert Committee's goal is to create a comprehensive classification system for use in formulary development or review. Potential uses include:

- Building and Mapping Formularies
- Reviewing Formularies for a Minimum Baseline of Drugs
- Identifying drugs included in a particular Pharmacological Grouping

Orientation to the Draft

Combining Single Entity and Combination List

Rationale: Improve readability due to stakeholder feedback



Orientation to the Draft

Adding a Combination Drug Product Column

Rationale: Lets viewers filter/ select view on these data elements:

- Category (Cat)
- Class (Class)
- Single Entity Drug Product (no)
- Combination Drug Product (yes)

	USP Category	USP Class	Example Drugs	Salt/Ester	Pharmacotherapeutic Group (Informational)	Combination Drug Product
2	Analgesics					Cat
3		Nonsteroidal Anti-inflammatory				Class
4			Celecoxib			no
5			Diclofenac	Potassium		no
6			Diflunisal			no
7			Etodolac			no
8			Fenoprofen	Calcium		no
9			Flurbiprofen			no
10			Ibuprofen			no
11			Indomethacin			no
12			Ketoprofen			no
13			Ketorolac	Tromethamin		no
14			Meclofenamate	Sodium		no

Filter Icon

Expert Panel Review Processes

Review Drugs

- Drugs are identified from various sources:
  - Drugs@FDA
  - RxNorm
  - Purple book
  - Stakeholder feedback
- Included drugs are used in outpatient settings including:
  - Pharmacies
  - Specialty pharmacies
  - Skilled nursing facilities
  - Infusion centers
- Excluded drugs
  - Acute-care drugs
  - Over-the-counter (OTC)
  - Unapproved Drugs

Review Topics

- Topics are reviewed to add, rename, or remove drugs in the classification structure.
  - Anticonvulsants
  - Blood Products/ Modifiers/ Volume Expanders
  - Combination Drugs

Potential Future Topics

- Topics are identified through public comment and internal review.
  - Antineoplastics
  - Immunological Agents
  - Cardiovascular Drugs
  - Electrolytes/ Minerals/ Metals/ Vitamins
  - Analgesics
  - Dosage forms
  - OTC drugs

Review Drugs

46 New FDA approved drugs

+

8 Previously approved drugs

54 Drugs reviewed

247 Combination Drug Products reviewed

~301 Drugs Added

Approach to Placing Combination Drug Products

- Prefer placing combination drugs in existing category or class
- Second preference is placing combination drugs in “other” class
- Option to also create new classes
- Multiple placements
  - based on pharmacology is discouraged
  - based on indication are recommended
- In combinations with augmenters, the primary drug (drug that contributes to therapy) is the determinant for placement
- The combination column will be retained to distinguish single-entity and combination drug products
- Order of active ingredients harmonized with Nomenclature and Labeling EC monograph document and drug label

Preliminary Summary of Changes from first USP DC

USP Categories	USP Classes	Drugs
1 Renamed	7 New	46 New FDA-approved drugs added
	3 Renamed	8 Previously approved drugs
	4 Removed	247 Combination drug products added

Summary of Differences- Renamed Category

Previous Name	New Name	Rationale
Blood Products/ Modifiers/ Volume Expanders	**Blood Products and Modifiers**	Renamed category to remove, "Volume Expanders" since drugs that are volume expanders also modify blood products.

Summary of Differences- New Classes

USP Category	USP Class	Rationale
Analgesics	**Analgesics, Other**	New class to add analgesic combination drug products
Blood Glucose Regulator	**Antidiabetic Agents, Other**	New class to add antidiabetic combination drug products
Blood Products and Modifiers	**Blood Component Deficiency/ Replacement**	New USP Class to add drugs used for hemophilia and blood replacement products, usually covered under specialty pharmacies
Hormonal Agents, Stimulant/ Replacement/ Modifying (Sex Hormones/ Modifiers)	**Hormonal Agents, Stimulant/ Replacement/ Modifying (Sex Hormones/ Modifiers), Other**	New class to add combination drug products
Otic Agents	**Otic Agents, Other**	New class to add otic combination drug products
Respiratory Tract/ Pulmonary Agents	**Bronchodilators, Other**	New class to add combination drug products
Respiratory Tract/ Pulmonary Agents	**Cold-Cough**	New class to add cold and cough combination drug products

Summary of Differences- Renamed Classes

USP Category	Previous Name	New Name	Rationale
Anti-Addiction/ Substance Abuse Treatment Agents	Opioid Dependence Treatments	**Opioid Dependence**	Renamed class to "Opioid Dependence" to avoid redundancy in category name, since the concept of "treatment agents" is already included
Blood Formation Modifiers	Blood Formation Modifiers	**Blood Products and Modifiers, Other**	Renamed class to "Blood Products and Modifiers, Other" to encompass additional drugs
Contraceptives	Oral Estrogens	**Oral Contraceptive Combinations**	Renamed class to "Oral Contraceptives Combinations" to encompass additional drugs

Summary of Differences- Removed Class

USP Category	USP Class	Rationale
Anticonvulsants	**Glutamate Reducing Agents**	Removed class due to multiple mechanism of actions of example drugs. Example drugs with multiple mechanism of actions moved to USP Class, "Anticonvulsants, Other.“
Hormonal Agents, Stimulant/ Replacement/ Modifying (Sex Hormones/ Modifiers)	**Progesterone Agonists/ Antagonists**	Removed class since has only one example drug, Ulipristal, which has placement in Contraceptives, Other Class
Respiratory Tract/ Pulmonary Agents	**Antitussive**	Removed class, drugs moved to new class, “Cold-Cough”
Respiratory Tract/ Pulmonary Agents	**Decongestant**	Removed class, drugs moved to new class, “Cold-Cough”

Next Steps

Oct 2018-Nov 2018	• Public Comment Period 10/15-11/15 • Engage and Participate!
Nov 2018-Dec 2018	• Revisions by the USP Drug Classification Expert Panel • Ballot by Healthcare Quality and Safety Expert Committee
Dec 2018-Jan 2019	• Alignment file creation
Jan 31, 2019	• Post USP DC 2019 on USP website • Post USP DC alignment file on USP website

Questions

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Thank You

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