Welcome!

The PCIS Webinar
June 24, 2009

“An Update on Neurotoxins”
An in-depth look at what injectors need to know about BoNTA

Julius W. Few, MD, Moderator
Clinical Associate, Division of Plastic Surgery, University of Chicago
Board-certified Plastic Surgeon
Chicago, IL
Tonight’s Faculty

Ira D. Papel, MD
Associate Professor, Johns Hopkins University Medical School
Board-certified Facial Plastic Surgeon and Otolaryngologist
Baltimore, Maryland

Neal R. Reisman, MD, JD
Board-certified Plastic Surgeon
Practicing Attorney
Houston, Texas

Roger A. Dailey, MD
Lester T. Jones Chair, Oregon Health and Sciences University
Board-Certified Ophthalmologist
Portland, Oregon

Mark L. Jewell, MD
Chair, Physicians Coalition for Injectable Safety
Board-certified Plastic Surgeon
Eugene, Oregon
Disclosures
Julius W. Few MD FACS

Allergan-Consultant
J&J (Ethicon/Colbar)- Consultant
Mentor-Advisory Board
Medicis- Consultant, Investigator
Bioform- Consultant
• PCIS is an international coalition of core-trained, board-certified specialists members of:
  – ASDS
  – AAFPRS & INTERNATIONAL FACIAL PLASTIC SOCIETY
  – ASAPS-ASPS-CSAPS-ISAPS
  – ASOPRS
Mission Statement

The mission of the Physicians Coalition for Injectable Safety is to provide the public with unbiased and necessary information on injectable cosmetic treatments, appropriate injectors and where to safely access cosmetic medical procedures.

Our goal is to eradicate the practice of unqualified persons providing injections, to promote treatment supervised by properly qualified and trained, board-certified doctors and to promote only the use of U.S. FDA-approved, appropriately administered products.
www.injectablesafety.org
WEBINAR AGENDA

• June 2009: Two BoNTA toxins-PCIS Update
• Labeling, Reconstitution, “Single Use Vial” Issues
• Informed Consent
• Safety of Concomitant Use of Neurotoxins and Fillers
• Safety Engineering with Neurotoxins
• Safety With Injectables Workbook
STATISTICS

• Botox® Cosmetic - #1 Cosmetic Procedure
• Hyaluronic Acid - #3 Cosmetic Procedure
• Injectables – almost 4 million injections of fillers or neurotoxins in US last year

*ASAPS 2008 Statistics
Risk / Benefit Profile BoNTA

• Since 1989 22 million vials Botox®, 17 million injections worldwide
• FDA review April 2009 did not identify serious adverse events associated with Botox® when used to treat wrinkles at labeled dosing
• Serious adverse events, including death reported from high-unit injections to treat functional disorders
Changes in BoNTA Labeling

- FDA requires label update to characterize safety profile and risk factors for toxin to spread
- FDA requires a boxed warning and risk evaluation management strategy- a medication guide to assure safe use
FDA Recommends

• Healthcare professional who use Botulina toxin products should:
  – Dosage strength (units) are different between approved products and not interchangeable
  – Be alert to and educate patients regarding the potential for adverse events caused by spread of toxin
  – Advise patients to seek medical attention if these occur
Labeling, Reconstitution, “Single Use Vial” Issues

Ira D. Papel, MD
Facial Plastic Surgicenter
The Johns Hopkins University
Baltimore, Maryland, USA
Disclosures

No relevant affiliations to disclose
<table>
<thead>
<tr>
<th><strong>Botox® Cosmetic</strong></th>
<th><strong>Dysport®</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Botulinum Toxin A</td>
<td>Abotulinumtoxin A</td>
</tr>
<tr>
<td>Single Use Vial</td>
<td>Single Use Vial</td>
</tr>
<tr>
<td>FDA Boxed Warning: Distant Spread</td>
<td>FDA Boxed Warning: Distant Spread</td>
</tr>
<tr>
<td>100 Units</td>
<td>300 Units</td>
</tr>
</tbody>
</table>
Dysport.
axdabotulinumtoxinA
HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use DYSPORT® for injection safely and effectively. See full prescribing information for DYSPORT® for injection.
DYSPORT® for injection
(abobotulinumtoxinA),
Initial U.S. Approval: April 2009
Distant Spread of Toxin Effect
The effects of DYSPORT® and all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. These symptoms have been reported hours to weeks after injection. Swallowing and breathing difficulties can be life threatening and there have been reports of death. The risk of symptoms is probably greatest in children treated for spasticity but symptoms can also occur in adults, particularly in those patients who have underlying conditions that would predispose them to these symptoms.
INDICATIONS AND Usage
DYSPORT® is an acetylcholine release inhibitor and a neuromuscular blocking agent indicated for:
The treatment of adults with cervical dystonia to reduce the severity of abnormal head position and neck pain in both lonot- and previously treated patients (1.1)
The temporary improvement in the appearance of moderate to severe glabellar lines associated with procerus and corrugator muscle activity in adult patients <65 years of age (1.2)
Once reconstituted, DYSPORT® should be stored in the original container in a refrigerator 2°-8°C and used within four hours (1.2)
Do not freeze after reconstitution (2.16)
Protect from light (1.16)
Reconstitution instructions are specific for the 300 Unit and 500 Unit vials
Cervical Dystonia (1.1)
Initial dose of DYSPORT® is 50 Units given intramuscularly as a divided dose among the affected muscles
Re-treatment every 12 to 16 weeks or longer, as necessary, based on return of clinical symptoms with doses administered between 250 and 1900 Units to optimize clinical benefit
Re-treatment should not occur in intervals less than 12 weeks
Titratin should occur in 250 Unit steps according to the patient’s response
Glabellar Lines (2.2)
A total dose of 50 Units of DYSPORT®, divided in five equal aliquots of 10 Units each, should be administered to affected muscles to achieve clinical effect
Re-treatment with DYSPOINT® should be administered no more frequently than every 3 months
DOSE FORMS AND STRENGTHS
Cervical dystonia: Single use vials of 500 Unit

BOTOX® Cosmetic
(Botulinum Toxin Type A)
Purified Neurotoxin Complex
Manufactured by Allergan Pharmaceuticals Int'l
A subsidiary of Allergan, Inc.
1900 Spy Pond Dr.
Parsippany, NJ 07054

DESCRIPTION
BOTOX® Cosmetic (Botulinum Toxin Type A) Purified Neurotoxin Complex is a sterile, vacuum-dried purified botulinum type A toxin, produced from fermentations of strain Clostridium botulinum type A grown in a medium containing soybean hydrolysate, glucose, and propyl gallat. It is purified from the culture broth by a series of adsorption and desorption steps to produce a complex consisting of the neurotoxin, and several accessory proteins. The complex is dissolved in sterile sodium chloride solution containing Allantoin Human and is sterile filtered (0.2 microns) prior to filling into vials.

One unit of BOTOX® Cosmetic corresponds to the calculated median international unit (MIU) in mice. The method utilized for determining the potency is specific to Allergan’s product BOTOX® Cosmetic. Due to specific details of this assay such as the vehicle, dilution scheme and animal protocols for the various mouse LD₅₀, assays of biological activity of BOTOX® Cosmetic cannot be compared to other reported units of botulinum toxins.

DESCRIPTION
BOTOX® Cosmetic (Botulinum Toxin Type A) Purified Neurotoxin Complex is a sterile, vacuum-dried purified botulinum type A toxin, produced from fermentations of strain Clostridium botulinum type A grown in a medium containing soybean hydrolysate, glucose, and propyl gallat. It is purified from the culture broth by a series of adsorption and desorption steps to produce a complex consisting of the neurotoxin, and several accessory proteins. The complex is dissolved in sterile sodium chloride solution containing Allantoin Human and is sterile filtered (0.2 microns) prior to filling into vials.

Each vial of BOTOX® Cosmetic contains either 100 Units of Clostridium botulinum type A neurotoxin complex, 0.5 mg of Alumina-Human, and 0.9 mg of sodium chloride, or 50 Units of Clostridium botulinum type A neurotoxin complex, 0.25 mg of Alumina-Human, and 0.9 mg of sodium chloride in a sterile, vacuum-dried form without a preservative.

CLINICAL PHARMACOLOGY
BOTOX® Cosmetic contains a preservative (bromine tocinose dimethylethanolamine) to prevent bacterial proliferation in the vial at room temperature. The formulation is sterile and not sterile filtered. This formulation is not intended for intravenous administration.

CLINICAL PHARMACOLOGY
BOTOX® Cosmetic contains a preservative (bromine tocinose dimethylethanolamine) to prevent bacterial proliferation in the vial at room temperature. The formulation is sterile and not sterile filtered. This formulation is not intended for intravenous administration.

CLINICAL PHARMACOLOGY
BOTOX® Cosmetic contains a preservative (bromine tocinose dimethylethanolamine) to prevent bacterial proliferation in the vial at room temperature. The formulation is sterile and not sterile filtered. This formulation is not intended for intravenous administration.

CLINICAL PHARMACOLOGY
BOTOX® Cosmetic contains a preservative (bromine tocinose dimethylethanolamine) to prevent bacterial proliferation in the vial at room temperature. The formulation is sterile and not sterile filtered. This formulation is not intended for intravenous administration.

CLINICAL PHARMACOLOGY
BOTOX® Cosmetic contains a preservative (bromine tocinose dimethylethanolamine) to prevent bacterial proliferation in the vial at room temperature. The formulation is sterile and not sterile filtered. This formulation is not intended for intravenous administration.

CLINICAL PHARMACOLOGY
BOTOX® Cosmetic contains a preservative (bromine tocinose dimethylethanolamine) to prevent bacterial proliferation in the vial at room temperature. The formulation is sterile and not sterile filtered. This formulation is not intended for intravenous administration.

CLINICAL PHARMACOLOGY
BOTOX® Cosmetic contains a preservative (bromine tocinose dimethylethanolamine) to prevent bacterial proliferation in the vial at room temperature. The formulation is sterile and not sterile filtered. This formulation is not intended for intravenous administration.

CLINICAL PHARMACOLOGY
BOTOX® Cosmetic contains a preservative (bromine tocinose dimethylethanolamine) to prevent bacterial proliferation in the vial at room temperature. The formulation is sterile and not sterile filtered. This formulation is not intended for intravenous administration.

CLINICAL PHARMACOLOGY
BOTOX® Cosmetic contains a preservative (bromine tocinose dimethylethanolamine) to prevent bacterial proliferation in the vial at room temperature. The formulation is sterile and not sterile filtered. This formulation is not intended for intravenous administration.

CLINICAL PHARMACOLOGY
BOTOX® Cosmetic contains a preservative (bromine tocinose dimethylethanolamine) to prevent bacterial proliferation in the vial at room temperature. The formulation is sterile and not sterile filtered. This formulation is not intended for intravenous administration.

CLINICAL PHARMACOLOGY
BOTOX® Cosmetic contains a preservative (bromine tocinose dimethylethanolamine) to prevent bacterial proliferation in the vial at room temperature. The formulation is sterile and not sterile filtered. This formulation is not intended for intravenous administration.

CLINICAL PHARMACOLOGY
BOTOX® Cosmetic contains a preservative (bromine tocinose dimethylethanolamine) to prevent bacterial proliferation in the vial at room temperature. The formulation is sterile and not sterile filtered. This formulation is not intended for intravenous administration.

CLINICAL PHARMACOLOGY
BOTOX® Cosmetic contains a preservative (bromine tocinose dimethylethanolamine) to prevent bacterial proliferation in the vial at room temperature. The formulation is sterile and not sterile filtered. This formulation is not intended for intravenous administration.

CLINICAL PHARMACOLOGY
BOTOX® Cosmetic contains a preservative (bromine tocinose dimethylethanolamine) to prevent bacterial proliferation in the vial at room temperature. The formulation is sterile and not sterile filtered. This formulation is not intended for intravenous administration.

CLINICAL PHARMACOLOGY
BOTOX® Cosmetic contains a preservative (bromine tocinose dimethylethanolamine) to prevent bacterial proliferation in the vial at room temperature. The formulation is sterile and not sterile filtered. This formulation is not intended for intravenous administration.

CLINICAL PHARMACOLOGY
BOTOX® Cosmetic contains a preservative (bromine tocinose dimethylethanolamine) to prevent bacterial proliferation in the vial at room temperature. The formulation is sterile and not sterile filtered. This formulation is not intended for intravenous administration.

CLINICAL PHARMACOLOGY
BOTOX® Cosmetic contains a preservative (bromine tocinose dimethylethanolamine) to prevent bacterial proliferation in the vial at room temperature. The formulation is sterile and not sterile filtered. This formulation is not intended for intravenous administration.

CLINICAL PHARMACOLOGY
BOTOX® Cosmetic contains a preservative (bromine tocinose dimethylethanolamine) to prevent bacterial proliferation in the vial at room temperature. The formulation is sterile and not sterile filtered. This formulation is not intended for intravenous administration.

CLINICAL PHARMACOLOGY
BOTOX® Cosmetic contains a preservative (bromine tocinose dimethylethanolamine) to prevent bacterial proliferation in the vial at room temperature. The formulation is sterile and not sterile filtered. This formulation is not intended for intravenous administration.

CLINICAL PHARMACOLOGY
BOTOX® Cosmetic contains a preservative (bromine tocinose dimethylethanolamine) to prevent bacterial proliferation in the vial at room temperature. The formulation is sterile and not sterile filtered. This formulation is not intended for intravenous administration.

CLINICAL PHARMACOLOGY
BOTOX® Cosmetic contains a preservative (bromine tocinose dimethylethanolamine) to prevent bacterial proliferation in the vial at room temperature. The formulation is sterile and not sterile filtered. This formulation is not intended for intravenous administration.

CLINICAL PHARMACOLOGY
BOTOX® Cosmetic contains a preservative (bromine tocinose dimethylethanolamine) to prevent bacterial proliferation in the vial at room temperature. The formulation is sterile and not sterile filtered. This formulation is not intended for intravenous administration.

CLINICAL PHARMACOLOGY
BOTOX® Cosmetic contains a preservative (bromine tocinose dimethylethanolamine) to preven
Reconstitution of BoNTA

- Aseptic Technique
- 0.9% Preservative Free Saline
- Insert Needle at 45 Degrees and Allow Saline to Be Pulled Slowly Into Vial
- Gently Rotate Vial: Do Not Shake
Reconstitution/Preparation

- Draw Patient Dose Into Syringe
- Eliminate Bubbles
- Attach #30/32 Needle
- Storage/Use Per Label
  - 36-46 Degrees F
  - Protect From Light
  - Do Not Freeze
  - Use Within 4 Hours
## Dilutions

<table>
<thead>
<tr>
<th>Diluent</th>
<th>Units Yields</th>
<th>Volume Yields</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dysport (300 Units)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.5 mL</td>
<td>10 Units</td>
<td>.05 mL</td>
</tr>
<tr>
<td>2.5 mL</td>
<td>10 Units</td>
<td>.08 mL</td>
</tr>
<tr>
<td><strong>Botox Cosmetic (100 Units)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.0 mL</td>
<td>10 Units</td>
<td>.1 mL</td>
</tr>
<tr>
<td>2.0 mL</td>
<td>5 Units</td>
<td>.1 mL</td>
</tr>
<tr>
<td>4.0 mL</td>
<td>2.5 Units</td>
<td>.1 mL</td>
</tr>
</tbody>
</table>
Single Use Vial Issues

- Usual Cosmetic Dose is 20-25 Units for Botox Cosmetic/30-60 Units for Dysport
- Impractical to Discard Unused Portion Due to Cost Factors
- Proper Sterile Technique Will Prevent Spread of Diseases
Multiple Use Precautions

- Sterile Technique in Reconstitution
- Never Use Syringe That Has Contact With Patient in Bottle Again
- Proper Storage in Refrigerator Between Uses
- Never Recap and Store a Partially Used Syringe for Later Use on Patient
- Many Injectors Use a Multi-Dose Method
Multiple Use Precautions

• Do Not Leave Needles Inserted Into Vials
• Discard Medications Upon Expiration Or If Sterility is Questionable
• Never Pool Medications For Later Use
• Use Gloves and Universal Precautions for all Patient Procedures
• Common Sense
Thank you!

Ira D. Papel, MD
Facial Plastic Surgicenter
The Johns Hopkins University
Baltimore, Maryland, USA
Informed Consent

Neal R Reisman MD JD

Plastic Surgery Specialists
Practicing Attorney
Houston, Texas
Disclosure

No relevant affiliations to disclose
INFORMED CONSENT

• Informed Consent is a Process, Not a Piece of Paper

• Include All Information a *Reasonable Patient* Needs To Know To Make An Informed Decision

• Alternatives, Risks, Hazards, Inherent Risks, General Risks, No Treatment, And *Foreseeable Risks* ....
Foreseeable Risks

• Any and All Risks That “More Likely Than Not” May Occur

• It is Not Any Risk That Could Occur, BUT Those Risks That Probably, with Over 50% Likelihood, May Occur

• So...Anticipate Foreseeable Risks and Discuss and Document
Inherent Risks

• Incomplete effect of injection
• Asymmetry
• Droopy Eyelid or Other Muscle Effects
• Migration & Bruising
• Length of Effect Variable
General Risks

• Sun Exposure – Tanning
• Medications – Herbal Supplements
• Bleeding – Bruising & Sun Exposure
• Travel Plans
• Expectations - Warranty
FDA CLASSIFICATIONS

• APPROVED

• Non-FDA Approved Products
  • Do Not Use Anything but FDA approved Toxins

• OFF-LABEL Consent
  • Full Disclosure -
  • Document Non-Experimental
  • Include : Areas, Single Vial Issues

• Note- these topics are covered in the Safety With Injectables Workbook that Dr. Jewell will cover in this webinar
FDA ISSUES

- Off-Label Disclosure
  - Cosmetic Areas Approved – Glabellar
    - All Others Off-Label
  - Dispensing Bottle
    - System for Safe Individual Use other than 1 Vial per Patient
OBTAINING CONSENTS

• Informed Consent Is A Process
• Each & Every Time
• Who Should Do?
  • MD
  • Nurse
  • Assistant
  • A combination
• How is this all documented?
SUMMARY

• Documentation Required Each Treatment

• Off-Label Documentation Important

• Full Disclosure – Not Only Toxin Related
  ➢ But General Risks & Inherent Risks

• Caution about “BOTOX® Parties”, Absent Disclosures...

• Use Consents as Achieving a Higher Level of Care.
Thank you!

Neal R. Reisman, MD, JD
Plastic Surgery Specialists
Practicing Attorney
Houston, Texas
Safety of Concomitant Use of Neurotoxins and Fillers

Periocular AEs – Avoidance & Management
Disclosures

• Unrestricted Educational Grant from Allergan, Inc.
Safety of Concomitant Use of Neurotoxins and Fillers
Botox           Botulinum toxin type A
              Allergan, Inc, Irvine CA

Myobloc         Botulinum type B
                Solstice Pharmaceuticals, Inc, San Francisco, CA

Dysport         Botulinum type A
                Medicis
                Scottsdale, Arizona
Standard Aesthetic Uses
BoNTA and Fillers

- Restrict movement (BoNTA)
  - Glabella
  - Horizontal forehead lines*
  - Crow’s feet*
  - Bunny lines*
  - “Chemical” brow lift*

- Filling lines and folds (Filler)
  - Nasolabial folds
  - Lips (border and volume)

* = Off-label use

Adapted from Facial Aesthetics Consensus Group
Plastic and Reconstructive Surgery • May Supplement 2008
BoNTA and Hyaluronic Acid Fillers
Facial Treatment Examples

• Brow lifting and shaping (Both)
• Periorbital rhytids
  – Volumizing (Filler)
  – Restore malar projection (Filler)
  – Diminish wrinkle formation (BoNTA)*
• Perioral rhytids
  – Restrict movement of the DAO (BoNTA)*
  – NLF and melolabial fold filling (Filler)

* = Off-label use

Adapted from Facial Aesthetics Consensus Group
Plastic and Reconstructive Surgery • May Supplement 2008
BoNTA and Hyaluronic Acid Fillers

Facial Treatment Examples

• Shape jaw line
  – Masseter reduction (BoNTA)*
  – Prejowl sulcus filling (Filler)

* = Off-label use

Adapted from Facial Aesthetics Consensus Group
Plastic and Reconstructive Surgery • May Supplement 2008
Our experience the past few years would indicate that the use of neurotoxins in conjunction with fillers has become a widely accepted technique without evidence of significant safety concerns.
Periocular AEs – Avoidance & Management

Roger A. Dailey, M.D., FACS
Charter member, Injectable Safety Coalition
Professor and Endowed Chair
Division of Oculofacial Plastic Surgery
Casey Aesthetic Facial Surgery Center
OHSU, Portland, OR
Periocular Side Effects of BoNTA Injections

- Ptosis
- Ectropion
- Brow ptosis
- Diplopia
BoNTA Induced Ptosis

Photo provided by Jill Foster, MD
Eyelid Ptosis in Allergan/FDA Studies

Both: 3.2% (7 of 30 centers)

Conclusion: *Eyelid ptosis is technique-dependent.*
BoNTA Induced Ptosis Management

• This is a TEMPORARY problem.

• An alpha adrenergic agonist can be used to stimulate muller’s muscle
Apraclonidine Hydrochloride (an α adrenergic agonist) Ophthalmic Solution (IOPIDINE® 0.5%) was surreptitiously discovered to lower IOP when being used for hemostasis with YAG laser iridotomy.

It can be instilled into the conjunctival sac which then stimulates the contraction of Müller’s muscle lifting the lid 1 to 2 mm. This compensates for the toxin-induced loss of levator palpabrawe superioris activity.
Post injection ptosis
Better to AVOID!!

Iopidine 0.5% one drop BID
Approximately $100.00/bottle
Periocular side effects of BoNTA injections

- Ptosis
- Ectropion
- Brow ptosis
Ectropion

Monitor until ectropion resolves
Artificial tears
Artificial tear ointment
Tape (steri strips)
Surgical repair as necessary
Examination prior to neurotoxin injection into lower eyelid

Better to AVOID!!
Periocular side effects of BoNTA injections

- Ptosis
- Ectropion
- Brow ptosis
Brow Ptosis / “Mr. Spock” Deformity

Photos provided by Jill Foster, MD
Brow Ptosis
Avoidance and Management

- Evaluate extent of brow ptosis pre injection with the patient’s frontalis muscle at rest
- Titrate amounts and distribution of injections accordingly
- Fully inform the patient about this possibility before injection

- Monitor
- Tape (steri strips)
- Endoscopic forehead lift
- Better to recognize early and AVOID
Thank you!

Roger A. Dailey, M.D., FACS
Founding member, Injectable Safety Coalition
Professor and Endowed Chair
Division of Oculofacial Plastic Surgery
Casey Aesthetic Facial Surgery Center
OHSU, Portland, OR
Mark Jewell, M.D.
Chair, Injectable Safety Coalition
Assistant Clinical Professor Plastic Surgery, OHSU, Portland, OR

Safety Engineering with Neurotoxins
Safety With Injectables Workbook™
Disclosures

Advisor to Allergan, Medicis, Sound Surgical, Coapt, AorTech, and New Beauty Magazine

Approved Clinical Researcher for Allergan, Mentor, and Medicis
Patient Safety with Injectables: Guiding Principles

“A safe injection does not harm the recipient, does not expose the provider to any avoidable risks and does not result in waste that is dangerous for the community”

The SIGN Alliance, World Health Organization
Center for Disease Control (CDC)  
“Never Events”

1. **Unsafe Injection Practices**
   - Accessing a shared medication vial with a syringe that has already been used to administer medication to a patient
   - Reuse of needles / syringes that have had patient contact

2. **Pathogen Transmission by Contaminated Product**
   - Hepatitis C, HIV, Microbial

3. **Medication Errors and Mistakes**
   - Wrong drug
     - Insulin mistaken for saline
     - Sodium bicarb. mistaken for lidocaine
   - Wrong concentration
     - Concentrated heparin IV flush
   - Wrong site of administration
     - CAHA filler in lips

**Summary:**
- Aseptic technique
- Non-reuse of syringes and needles
- Safety engineering
- Policies, procedures, protocols
Patient Safety with Neurotoxins Summary

- Aseptic technique for withdrawal of product from vial
- Protection from blood-borne pathogens with gloves
- Disposal of used needles, syringes, and gel cooling packs as medical waste
- Never reuse a syringe, needle, or gel cooling pack that had patient contact
- Never reinsert a needle into a vial that has had patient contact
- Do not pool injectables
- Do not leave needles/syringes inserted into vials
- Disclose off-label use and practices
Unsafe Injection Practices:

- Accessing a shared medication vial with a syringe that has already been used to administer medication to a patient
- Reuse of needles / syringes that have had patient contact

Blood reflux in neurotoxin syringe
32 gauge needle
Dispose of gel cooling packs as medical waste after injections

They have had contact with blood and cannot be safely reused or decontaminated
Safety Engineering with Injectables

• Take active measures to prevent medication mistakes with 2 different BoNTA product
• Office policies, procedures that identify what BoNTA is being used and its concentration
  – Utilize reference sheets for reconstitution and dosing
  – Label syringe to prevent medication errors
Office policy and procedures for safe use of neurotoxin

- Order from approved distributor
- Store according to labeling
- Safety engineering: separate storage for product to avoid mistakes in use
- Protocol for reconstitution of specific neurotoxins
  - Sterile technique
  - Defined dilution of “XX” units / mL
- Protocol for storage and use of reconstituted neurotoxin
  - According to labeling and DFU
  - Off-label storage (defined time of storage) and use (vial splitting)
Medication Errors and Mistakes

Wrong Drug:
Mistake Botox®
Cosmetic and
Dysport®

Wrong Concentration:
Botox® Cosmetic and Dysport® units of potency are different and not interchangeable

Safety Engineering prevents medication errors and mistakes
Syringe labeling
(use address labels)
Order Product from Approved Distributors

- Each injectable has approved distributors
  - Allergan sells directly and fulfills orders from its distribution centers
  - Medicis uses McKesson for order fulfillment

- Legal Issues: reimportation, counterfeit, non-approved product, misbranded product
  - All have serious consequences: prosecution, fines, litigation, and possible loss of license
Why a workbook?
- Use of injectables has become more complex
  - On and off-label usage
  - Regulatory issues
  - Infection control
- Patient safety
- Quality of outcomes

Resource for injectors and their staff
- Not meant to be a standard of care
What’s Inside

• Injectables: Policies and Procedures
  – Patient treatment
  – Reconstitution reference
  – Dosing range
• Treatment Templates
  – Patient treatment
  – Reconstitution reference
  – Dosing range
• Informed Consents
  – Neurotoxin / Others (fillers)
  – Risk Mitigation and “boxed” warning
• Infection Control
• Adverse Event (AE) Template
  – AE treatment bibliography
• Quality Improvement Template
• Safety Engineering
Thank you!

Mark Jewell, M.D.
Chair, Injectable Safety Coalition
Assistant Clinical Professor Plastic Surgery, OHSU, Portland, OR
Discussion

Julius Few, M.D.
Faculty