Ophthalmic Medical Devices and Risk Communications Joint Panel Meeting:

Medical Device Report (MDR) On Misuse of Hydrogen Peroxide-Based Contact Lens Care System Products

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Medical Device Reports (MDRs)

Limitations of MDRs

- Under-reporting
- Data quality issues
- Biased information
- Inability to determine rate
- Cannot definitively determine causality/relationship to device

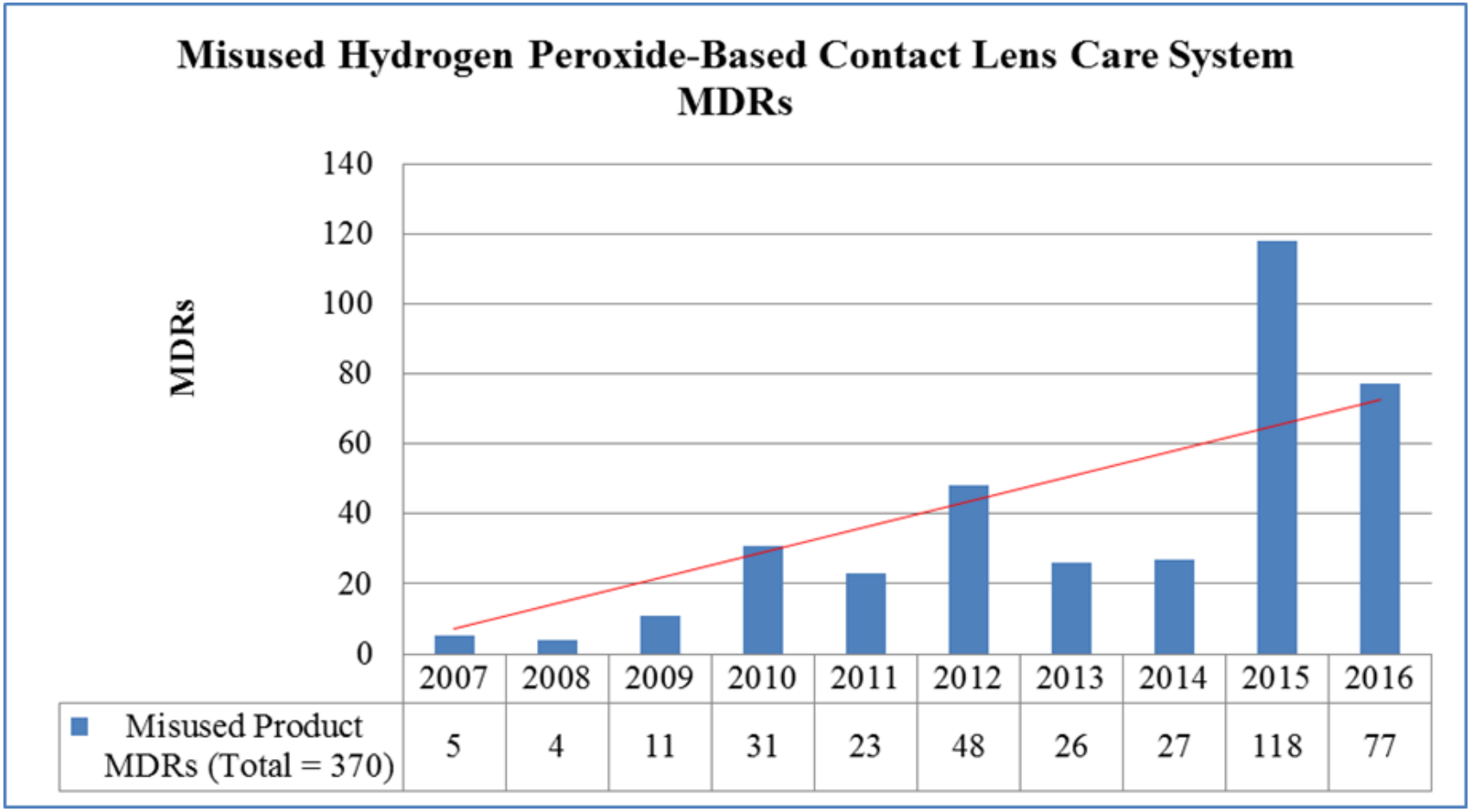
Methods

FDA Medical Device Adverse Event Reporting System

- **Medical Device Reports (MDRs) Search Criteria:**
  - ✓ Date Entered: December 14, 2006 to December 14, 2016
  - ✓ Misuse: Hydrogen peroxide-based contact lens care system product instructions for use were not followed

- **Search Result: 370 pertinent MDRs**

Overview of Pertinent Medical Device Reports (MDRs) Entered Dec. 16, 2006 – Dec. 16, 2016



Overview of Pertinent Medical Device Reports (MDRs) Entered Dec. 16, 2006 – Dec. 16, 2016

- **Report Source**

Report Source	Count of MDRs	%
Voluntary	216	58.38%
Manufacturer	154	41.62%
Total	**370**	**100%**

- **Event Type**

Event Type	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	Total	%
Injury	5	4	6	23	23	48	26	27	118	77	**357**	**96.49%**
Malfunction			5	8							**13**	**3.51%**
MDRs Total	**5**	**4**	**11**	**31**	**23**	**48**	**26**	**27**	**118**	**77**	**370**	**100%**

Overview of Pertinent Medical Device Reports (MDRs) Entered Dec. 16, 2006 – Dec. 16, 2016

- **Demographic Data**

Reporter Country		
	Unknown:	179
	United States:	161
	Outside United States:	30
		370
Report on Gender (reported in 289 MDRs)		
	Female:	228
	Male:	61
Report on Age (reported in 110 MDRs)		
	Median:	42.5 years

Outcomes of Clinical Interest

A. Misuse - hydrogen peroxide-based contact lens care system product instructions for use were not followed.

B. Reported eye problems - clinical outcomes

B.1. Serious eye injuries (not including infection or inflammation) – any serious injury to the eye region

B.2. Visual issues - complaints of effects on vision or visual acuity

B.3. Eye infection/inflammation – an eye condition that is caused by a pathogenic microorganism and/or localized eye protective response elicited by an injurious agent

B.4. Ocular signs and symptoms – reports received on clinical signs and patient reported symptoms

C. Personal burden – qualitative measures of personally experienced burden outcomes

Overview of Pertinent Medical Device Reports (MDRs) Entered Dec. 16, 2006 – Dec. 16, 2016

A. Reports by Type of **Misuse** - Hydrogen peroxide-based contact lens care system product instructions for use were not followed

Types of Misuse	Count of MDRs**	%
Accidental use	168	**45.41%**
Failure to follow neutralization method	107	**28.92%**
Erroneous purchase	40	**10.81%**
Unspecified detail of misuse	19	**5.14%**
Use of expired product	15	**4.05%**
Improper care of lens case	12	**3.24%**
Healthcare provider error	9	**2.43%**
Total	**370**	**100%**

** Misuse associated MDRs were categorized based on the type of misuse which primarily reflects the manner in which the product was misused.

Overview of Pertinent Medical Device Reports (MDRs) Entered Dec. 16, 2006 – Dec. 16, 2016

B. Reported eye problems - clinical outcomes

B.1. Serious eye injuries – serious injury to the eye region

Serious Eye Injuries	Count**
Corneal ulcer	11
Corneal damage - nonspecific	9
Vision loss/blindness	2

**The total number of serious eye injury events does not equal the total number of Medical Device Reports. Each Medical Device Report may have multiple serious eye injuries.

Overview of Pertinent Medical Device Reports (MDRs) Entered Dec. 16, 2006 – Dec. 16, 2016

B. Reported eye problems - clinical outcomes

B.2. *Visual issues* – subjective complaints of effects on vision or visual acuity

Visual Issues	Count**
Blurred vision	41
Temporary vision loss	7
Partial vision loss	2

**The total number of visual issue events does not equal the total number of Medical Device Reports. Each Medical Device Report may have multiple visual issues.

Overview of Pertinent Medical Device Reports (MDRs) Entered Dec. 16, 2006 – Dec. 16, 2016

B. Reported eye problems - clinical outcomes

B.3. *Eye infection/inflammation* – caused by a pathogenic microorganism and/or localized eye protective response elicited by an injurious agent

Eye Infection/Inflammation	Count**
Chemical conjunctivitis	12
Chemical keratitis	9
Eye inflammation – nonspecific	8
Eye infection – nonspecific	7
Bacterial eye infection	3
Conjunctival inflammation	3
Keratoconjunctivitis	2
Blepharoconjunctivitis	1
Fungal keratitis	1

**The total number of eye infection/inflammation events does not equal the total number of Medical Device Reports. Each Medical Device Report may have multiple eye infections/inflammation.

Overview of Pertinent Medical Device Reports (MDRs) Entered Dec. 16, 2006 – Dec. 16, 2016

B. Reported eye problems - clinical outcomes

B.4. *Ocular Signs and Symptoms* – reports received concerning clinical signs and patient reported symptoms

Ocular Signs and Symptoms	Count**
Burning sensation	210
Chemical eye burn	186
Corneal abrasion	33
Conjunctival hyperemia	18
Superficial punctate keratitis	11
Ocular injection	9
Corneal epithelial erosion	7
Conjunctival hemorrhage	6
Epithelial defect – nonspecific	2
Superficial punctate epitheliopathy	1
Superficial punctate keratopathy	1

**The total number of ocular sign and symptom events does not equal the total number of Medical Device Reports. Each Medical Device Report may have multiple ocular signs and symptoms and the same sign or symptom may have been reported using multiple different terms.

Overview of Pertinent Medical Device Reports (MDRs) Entered Dec. 16, 2006 – Dec. 16, 2016

C. Reports by **Personal Burden Outcome** - qualitative measures of personally experienced burden outcomes

Burden Outcome**	MDR Count	%
Medical practitioner consult	193	**52.16%**
Did not contain personal burden information	162	**43.78%**
Missing work/school	8	**2.16%**
Difficulty driving	4	**1.08%**
Difficulty in providing family care	3	**0.81%**
Total	**370**	**100%***

*Rounded from 99.99%

**Burden outcome associated MDRs were categorized based on the type of burden outcome which primarily reflects the personal burden experienced by the consumer as reported in the MDRs.

Overview of Pertinent Medical Device Reports (MDRs) Entered Dec. 16, 2006 – Dec. 16, 2016

- **Reports of Recovery** - outcome reports of recovery

Recovery Status**	MDR Count	%
Did not contain information on recovery status	243	**65.68%**
Recovered from eye injury	83	**22.43%**
Continuing eye issues	30	**8.11%**
No eye injury	14	**3.78%**
Total	**370**	**100%**

**Recovery status associated MDRs were categorized based on the type of recovery status outcome which primarily reflects recovery from the the reported eye problem experienced by the consumer.

Summary of Medical Device Report (MDR) Review

- 370 MDRs identified misuse of hydrogen peroxide-based contact lens care system products over a ten-year period.
- 58% of the MDRs were submitted by voluntary reporters.
- Burning sensation and chemical eye burn were the most frequently reported patient problems and symptoms described.
- Two reports describe loss of vision/blindness. Due to limited information, it cannot be determined if these were permanent or if they were caused by misuse.

Summary of Medical Device Report (MDR) Review (continuation)

- It appears that some consumers assume that all contact lens care solutions are the same and safe to use.
- Based on the narrative event description, some suggestions from the MDR reporters to prevent misuse are:
  - ✓Make the product appear less similar to saline/multi-purpose solution.
  - ✓Have the product dispensed by a pharmacist.
  - ✓Create separate areas on store shelves for the different types of solution.
  - ✓Improve labeling.

Thank you!

Back Up Slides

What Are MDRs Best Used For?

- **Qualitative snapshot of adverse events for a device or device type**
  - Types of malfunctions and/or clinical events
  - Severity of events
  - Clinical sequelae
  - Treatments required to address issue

- **Monitor device performance**
  - Ensure within expectations

- **Signal detection**
  - Unexpected events for that device or device type
  - Change in severity of expected events
  - User error/human factors issues

Limitations of MDR Data

- **Under-reporting**
  - Users unfamiliar with reporting or fear of unintended consequences if they report
  - Confusion about HIPAA privacy and reporting
  - Malfunction or injury may not be clinically apparent

- **Limitations of MDR regulation**: Certain device malfunctions may not meet MDR reporting requirements
  - Therefore, **lack of MDRs ≠ lack of problems**

- **Insufficient/Inadequate information in report**
  - Information not obtainable from end user
  - Devices not returned or made available for manufacturer evaluation

- **Inability to Establish Causality**
  - Cannot determine link/causality between the use/malfunction of the device and the negative clinical adverse event or outcome in that report.

MDR Reporting Requirements

REPORTER	WHAT TO REPORT	WHERE	WHEN
Manufacturer (Mfr) (Domestic and Foreign)	Deaths, Serious Injuries, Malfunction	FDA	Within 30 calendar days of becoming aware
User Facility	Deaths	FDA and Mfr	Within 10 working days of event
	Serious Injury	Mfr (FDA if unknown)	Within 10 working days of event
Importer	Deaths and Serious Injuries	FDA and Mfr	Within 30 calendar days
	Malfunctions	Mfr	Within 30 calendar days
Voluntary	Any type of event	FDA	Any time

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