



Next Steps in the Integration of FDA and NIOSH Processes Used to Evaluate Respiratory Protective Devices for Health Care Workers: A Workshop – August 1, 2016

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Overview

- Inpatient
 - 13 Patient Care Units
 - 62 Reporting (work) Units
- Surgery
- Outpatient
- Miscellaneous (Laboratory, Autopsy, etc.)

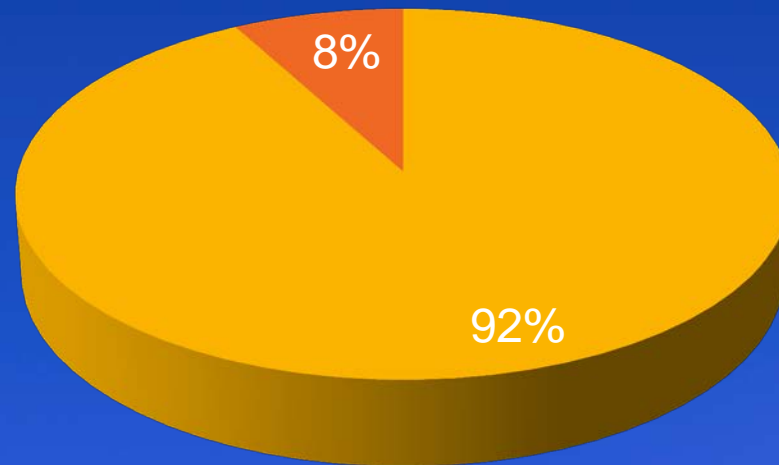
Overview – Filtering Facepiece (N95)

- 3 Manufacturers
 - 8 Models
 - 1 Manufacturer FDA approved surgical
 - 1 Manufacturer not FDA approved
 - 1 Manufacturer not FDA approved but passed fluid resistance performance¹
- Approximately 1700 Fit Tested Staff

Fit Test Pass Rate - 2015

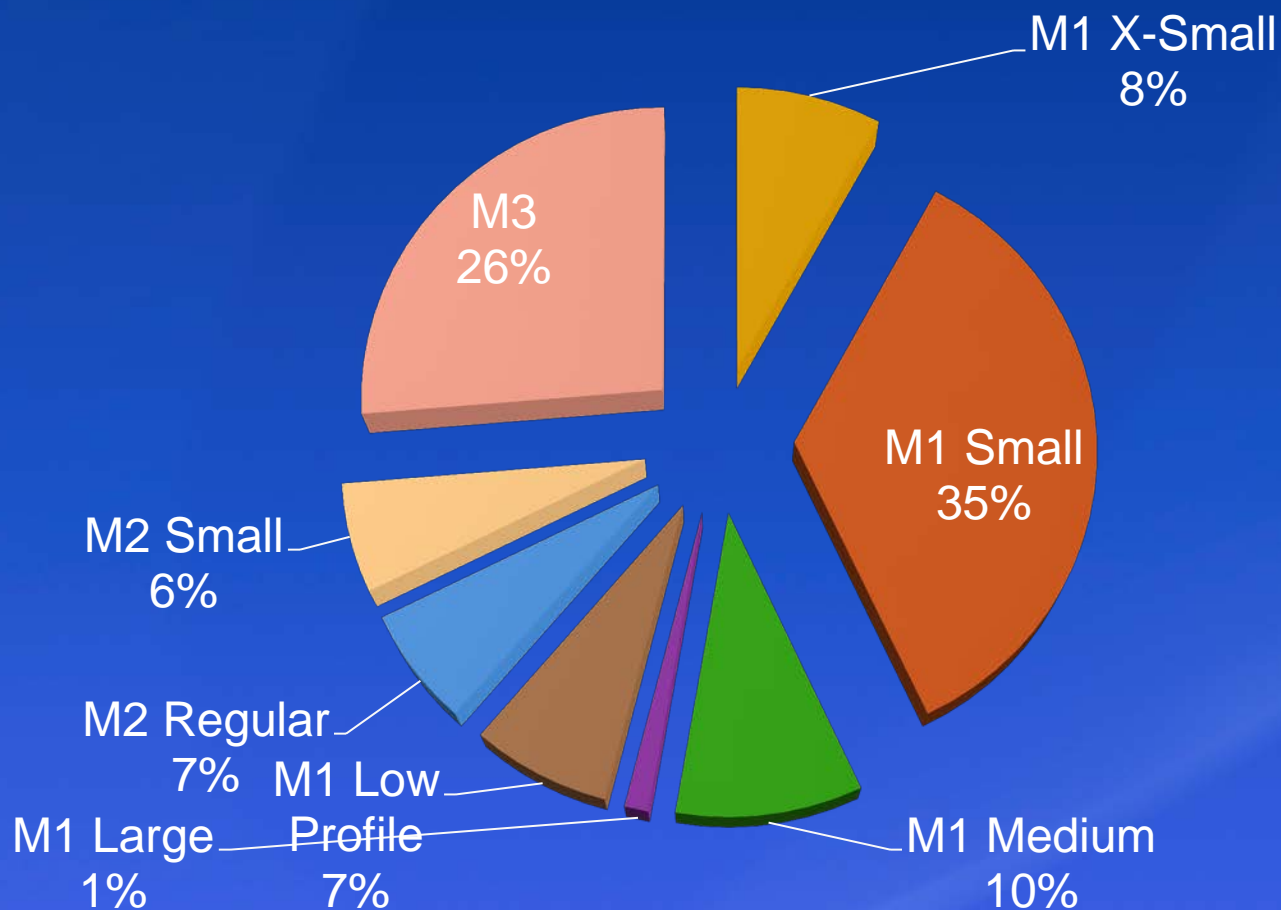
3 Manufacturers – 8 sizes

■ % Pass ■ % Fail



Respirator Selection Data

- M1 X-Small
- M1 Small
- M1 Medium
- M1 Large
- M1 Low Profile
- M2 Regular
- M2 Small
- M3



Inefficiencies

- Several manufactures take up significant warehousing space
- Stockpile – Pandemic Planning vs Operational
- Cost
- Waste
- Fit tests

Issues for Presentations and Discussion

- What N95 respirator attributes need to be tested to assure worker safety and health in health care settings (e.g., filtration, flammability, fluid resistance, biocompatibility, others)?
Performance and comfort
- What, if any, are the current issues being faced with having two types of N95 respirators (surgical N95s and standard N95s)?
Default to any N95 with the assumption that fluid resistance is adequate.
- In your opinion, what are the priorities for research, testing, and post market surveillance to improve N95s for health care workers' safety and health? What are the priorities to be considered in integrating FDA and NIOSH evaluation processes for N95s? Fit, Performance, Comfort, Re-use guidance

References

1. **Resistance to synthetic blood penetration of National Institute for Occupational Safety and Health-approved N95 filtering facepiece respirators and surgical N95 respirators**
[American Journal of Infection Control Volume 43, Issue 11, 1](#)
November 2015, Pages 1190–1196
2. **Challenge of N95 Filtering Facepiece Respirators with Viable H1N1 Influenza Aerosols**
Infection Control Hospital Epidemiology
May 2013

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