The Evolution of a Fast Fit Test Protocol

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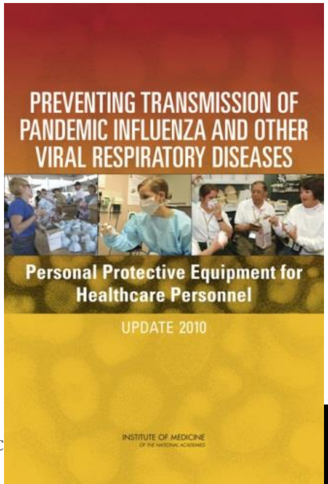
TSI UNDERSTANDING, ACCELERATED

Why Faster Fit Testing is Needed

+ In the US, 5 million workers in 1.3 million workplaces are required to wear respirators
  - Require annual fit testing
+ Faster fit test protocols would make it easier to comply with regulations
  - QLFT ~ 10 minutes/person (Bitrex/Saccharin/Etc….)
  - QNFT ~ 7 minutes/person (CNC Ambient Aerosol)
+ IOM study (2010) recommended faster method of fit testing to reduce burden on Healthcare



TSI 2006 Fast Fit Protocol Submission

- TSI submitted two new protocols for consideration by OSHA

What we learned from this submission

- Compare two protocols (OSHA vs. new) using the ANSI Z88.10-2010 Respirator Fit Test Methods, Annex A2 criteria
- Conduct separate studies for each mask type
- Not be constrained by the current fit test exercises

ANSI Z88.10-2010 Annex A2

	Failed Reference Test	Passed Reference Test
Passed New Fast Fit Test	A	B
Failed New Fast Fit Test	C	D

Statistic	Equation	Criterion
Test Sensitivity	C / (A+C)	≥ 0.95
Predictive Value of a Pass	B / (A +B)	≥ 0.95
Test Specificity	B / (B + D)	≥ 0.50
Predictive Value of a Fail	C / (C + D)	≥ 0.50
Kappa Statistic[a, b]	$(P_o - P_e) / (1 - P_e)$	>0.70

[a] $P_o = (B + C) / (A + B + C + D)$
[b] $P_e = [(A + B)(B + D) + (C + D)(A + C)] / (A + B + C + D)^2$

- ***Number of Fit Test Pairs:*** 100 (ANSI minimum requirement)
- ***Number of Participants:*** 25 (ANSI minimum requirement)
- ***Number of Fit Test Pairs Below Pass/Fail Criterion:*** ≥ 50 measured Reference fit factors between 5% of the pass/fail and the lower bound of the exclusion zone (ANSI requirement)

Pilot Study

+ Pilot study was conducted in 2012-2013
  - To determine if a shortened fit test protocol could pass the ANSI criteria
  - To develop a test methodology for the formal studies
  - To determine which fit test exercises are most useful to identify poor-fitting respirators

Pilot Study Design

+ Part A – determine variability of current OSHA method using sequential fit tests during same respirator donning
+ Part B – compare OSHA method to new method using sequential fit tests during the same respirator donning
+ Conducted for 3 types of respirators
    - Full-face Elastomeric Respirators (FF), with Model 8030 PortaCount ® Pro
    - Half-face Elastomeric Respirators (HF), with Model 8030 PortaCount ® Pro
    - Filtering-facepiece Respirators (FFR), with Model 8038 PortaCount® Pro+

Pilot Study Design

- ANSI requires a minimum of 50 failed fit test for the analysis
  - If respirators are properly sized and donned, a large number of tests is required to achieve enough failures
  - To achieve more failures some test subjects were given incorrect size respirators or were intentionally donned improperly
  - No user seal checks permitted

Pilot Study Lessons Learned

+ Cannot intentionally don mask poorly
  - Causes mask slippage during tests greatly varying fit factors
+ To pass the ANSI criteria a new method must be more conservative than existing method
  - Select exercises that are more likely to identify a poor-fitting respirator
+ By modifying test procedure taking into account lessons learned, a shorter fit test method can pass the ANSI Criteria

Selection of Exercises

+ Used data from OSHA vs. OSHA test pairs
  - Paired t-test of log transformed overall fit factors for fit test pairs showed no significant difference between first and second fit factors (p-value >0.005), indicating that fit test pairs could be separated as individual fit tests
+ Initial analysis supported conclusions made by Zhuang (2004)
  - 3 exercises were the most rigorous overall
  - Head Up and Down……Talking……Bending
+ Focus is which exercises are most likely to identify poor fitting respirators (fit test fails)
  - Not necessarily the same as which exercises measure lowest average fit

Selection of Exercises

+ Data was separated into 3 groups
  - All respirators
  - Poor-fitting respirators where at least one exercise fit factor failed
  - Good-fitting respirators where no exercises failed
+ Data group for poor-fitting respirators of primary interest
  - Identify the exercises that best challenge the face seal
+ Good-fitting respirators were analyzed separately
  - Show that exercises affecting good-fitting respirators are not necessarily the exercises that affect poor-fitting respirators
+ Talking exercise often had the lowest fit factor among good-fitting respirators, but was rarely the lowest for poor-fitting respirators

Full-face Elastomeric Respirators

- 71 Fit Test pairs = 142 OSHA fit tests

Percentage of Times Exercise was Lowest for Full-face Respirators							
Exercise:	NB1	DB	SS	UD	T	B	NB2
All Fit Tests (n=142)	**1**	**11**	**17**	**11**	**28**	**24**	**8**
Poor-fitting only (n=32)	**0**	**0**	**19**	**16**	**3**	**44**	**19**
Good-fitting only (n=110)	**2**	**14**	**16**	**10**	**35**	**18**	**5**

- For all full-face respirators, the talking exercise was the lowest for 28% of the fit tests
- For poor-fitting respirators, number was reduced to only 3%

Full-face Elastomeric Respirators

Mean Ratio of Log Transformed Exercise Fit Factor to Log Transformed Highest Fit Factor of Fit Test (Full-face Respirators)						
	All Tests		Poor-fitting		Good-fitting	
Exercise	Mean Ratio	Std Dev	Mean Ratio	Std Dev	Mean Ratio	Std Dev
NB1	**0.94**	**0.06**	**0.92**	**0.10**	**0.95**	**0.05**
DB	**0.90**	**0.08**	**0.90**	**0.11**	**0.90**	**0.06**
SS	**0.88**	**0.13**	**0.78**	**0.22**	**0.91**	**0.08**
UD	**0.85**	**0.16**	**0.66**	**0.21**	**0.91**	**0.08**
T	**0.88**	**0.11**	**0.82**	**0.16**	**0.89**	**0.09**
B	**0.82**	**0.19**	**0.62**	**0.28**	**0.88**	**0.08**
NB2	**0.92**	**0.11**	**0.81**	**0.19**	**0.94**	**0.05**

NB=normal breathing, DB=deep breathing, SS=head side-to-side, UD=head up-and-down, T=talking, B=bending

- Mean ratios for all fit tests indicate that SS, UD, T, and B were the lowest
- When only poor-fitting respirators are examined SS, UD and B ratios dropped significantly while T shows little change
- This indicates that the talking exercise does not contribute significantly towards the identification of poor-fitting full-face elastomeric respirators

Half-face Elastomeric Respirators

+ 42 Fit Test pairs = 84 OSHA fit tests

Percentage of Times Exercise was Lowest for Half-face Respirators							
Exercise:	NB1	DB	SS	UD	T	B	NB2
All Fit Tests (n=84)	**7**	**5**	**13**	**10**	**44**	**14**	**7**
Poor-fitting (n=21)	**14**	**14**	**14**	**14**	**10**	**19**	**14**
Good-fitting only (n=63)	**5**	**2**	**13**	**10**	**56**	**13**	**5**

+ For all half-face respirators, the talking exercise was the lowest for 44% of the fit tests
+ When poor-fitting respirators were isolated, that number was reduced to only 10%

Half-face Elastomeric Respirators

Mean Ratio of Log Transformed Exercise Fit Factor to Log Transformed Highest Fit Factor of Fit Test (Half-face Respirators)						
	All Tests		Poor-fitting		Good-fitting	
Exercise	Mean Ratio	Std Dev	Mean Ratio	Std Dev	Mean Ratio	Std Dev
NB1	**0.88**	**0.15**	**0.71**	**0.19**	**0.94**	**0.09**
DB	**0.87**	**0.12**	**0.78**	**0.18**	**0.90**	**0.08**
SS	**0.87**	**0.14**	**0.73**	**0.16**	**0.91**	**0.09**
UD	**0.85**	**0.15**	**0.69**	**0.19**	**0.90**	**0.09**
T	**0.84**	**0.14**	**0.89**	**0.18**	**0.82**	**0.12**
B	**0.82**	**0.17**	**0.69**	**0.26**	**0.87**	**0.09**
NB2	**0.87**	**0.14**	**0.72**	**0.16**	**0.92**	**0.10**

+ Mean ratios for all fit tests indicate that UD, T and B were the lowest
+ When only poor-fitting respirators are examined UD and B were lowest and T increased
+ Talking exercise does not contribute significantly to identify poor-fitting half-face elastomeric respirators

Filtering-facepiece Respirators

+ 38 Fit Test pairs = 76 OSHA fit tests

Percentage of Times Exercise was Lowest for Filtering-Facepiece Respirators							
Exercise:	NB1	DB	SS	UD	T	B	NB2
All fit tests (n=76)	**4**	**1**	**17**	**14**	**22**	**33**	**8**
Poor-fitting (n=43)	**7**	**2**	**19**	**19**	**2**	**37**	**14**
Good-fitting only (n=33)	**0**	**0**	**15**	**9**	**48**	**27**	**0**

+ For all filtering-facepiece respirators, the talking exercise was the lowest for 22% of the fit tests
+ When poor-fitting respirators were isolated, that number was reduced to only 2%

Filtering-facepiece Respirators

Mean Ratio of Log Transformed Exercise Fit Factor to Log Transformed Highest Fit Factor of Fit Test (FFR Respirators)						
	All Tests		Poor-fitting		Good-fitting	
Exercise	Mean Ratio	Std Dev	Mean Ratio	Std Dev	Mean Ratio	Std Dev
NB1	**0.897**	**0.130**	**0.85**	**0.15**	**0.95**	**0.05**
DB	**0.887**	**0.126**	**0.87**	**0.16**	**0.91**	**0.06**
SS	**0.861**	**0.146**	**0.85**	**0.16**	**0.88**	**0.12**
UD	**0.843**	**0.134**	**0.80**	**0.15**	**0.90**	**0.07**
T	**0.868**	**0.123**	**0.92**	**0.08**	**0.80**	**0.13**
B	**0.818**	**0.135**	**0.80**	**0.16**	**0.84**	**0.08**
NB2	**0.891**	**0.141**	**0.85**	**0.16**	**0.95**	**0.07**

+ Mean ratios for all fit tests indicate that SS,UD, T and B were the lowest
+ When only poor-fitting FFR respirators are examined, UD and B were lowest and T increased
+ As with full-face and half-face respirators, this shows that the talking exercise does not contribute significantly towards the identification of poor-fitting FFR's

Selection of Fast Fit Test Protocols

CNC 4-Exercise Protocol for Full- and Half-facepiece Elastomeric Respirators – Pass/Fail = 500 or 100, respectively; 2:29 mm:ss

1. Bending Over – 50 seconds
2. Jogging In-place – 30 seconds
3. Head Side to Side – 30 seconds
4. Head Up and Down – 39 seconds

CNC 4-Exercise Protocol for Filtering Facepiece Respirators – Pass/Fail = 100; 2:29 mm:ss

1. Bending Over – 50 seconds
2. Talking – 30 seconds
3. Head Side to Side – 30 seconds
4. Head Up and Down – 39 seconds

Conclusions

+ To pass the ANSI criteria, new method must be more conservative than existing method
  - Select exercises that are more likely to identify a poor-fitting respirator
+ Overall the talking exercise resulted in the lowest fit factor within each fit test
+ When only poor-fitting respirator data was analyzed, the talking exercise was rarely the lowest
  - Effect of exhaled particles is minimal on poor fits
+ Pilot studies indicate a shorter fit test method can pass the ANSI criteria if more conservative exercises are used

Bibliography

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Questions?

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