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Face Masks Reduce the Release of Pseudomonas aeruginosa Cough Aerosols when Worn for Clinically-Relevant Time Periods

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1 **Face masks reduce the release of *Pseudomonas aeruginosa* cough aerosols when worn for**
2 **clinically-relevant time periods**

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42 **Author contributions:** G.R.J., L.D.K., T.J.K., R.E.S., L.J.S., L.M. and S.C.B. conceived and
43 designed the experiment. S.C.B., T.J.K. and L.M. led the funding applications with other
44 members of the CF cough aerosol group (C.E.W and P.D.S.). M.E.W. and S.C.B. recruited
45 the study participants. R.E.S. and C.H. conducted the cough studies. G.R.J. acquired the
46 aerosol data. R.E.S. performed microbiological analysis. E.L.B. led the data analysis. R.E.S.
47 and S.C.B. provide overall responsibility for the data and wrote the manuscript, with input
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61

62 **Abstract**

63 **Introduction:** The cystic fibrosis (CF) infection control guidelines recommend that people with
64 CF wear face-masks when in communal areas of hospitals. Recently, we reported short-term
65 wear of face-masks (~10-minutes) reduced the release of *Pseudomonas aeruginosa* aerosols
66 during coughing. However, there is limited evidence to determine if face-masks continue to be
67 effective at reducing the release of infectious cough aerosols after longer wear times. **Methods:**
68 We recruited 25 people with CF and chronic *P. aeruginosa* infection and 10 healthy volunteers.
69 All participants underwent up to 5 cough tests in a validated cough rig: 1) uncovered cough; 2)
70 coughing with surgical mask worn for 10-minutes; 3) coughing with surgical mask worn for
71 20-minutes; 4) coughing with a surgical mask worn for 40-minutes; 5) coughing with an N95
72 respirator worn for 20-minutes (optional). The wear time of the mask included a 5-minute cough
73 period in the aerosol collection rig. Sputum samples and cough aerosols were collected from
74 participants with CF as previously described. All participants rated their level of comfort post-
75 test. **Results:** Surgical masks and N95 respirators were effective at reducing the release of *P.*
76 *aeruginosa* aerosols during coughing after 40-minutes total wear and 20-minutes total wear
77 respectively. Both participants with CF and healthy volunteers rated the surgical masks as more
78 comfortable compared to N95 respirators. **Conclusions:** Surgical masks were the preferred
79 interface to wear as source control and were effective at reducing the release of *P. aeruginosa*
80 aerosols during coughing after 40-minutes of total wear.

81 **Introduction**

82 Aerosol dissemination of respiratory pathogens may contribute to person-to-person
83 transmission in people with cystic fibrosis (CF) [1]. This evolving knowledge of transmission
84 modes has led to an update of the CF Foundation Infection and Prevention Control Guidelines
85 recommending people with CF wear surgical masks in communal hospital areas to prevent the
86 spread of CF respiratory pathogens [2]. These guidelines recommended the use of surgical
87 masks as source control despite limited evidence for this application.

88

89 We recently demonstrated that short-term wear of face-masks (10-minutes total wear)
90 significantly reduces the release of *Pseudomonas aeruginosa* aerosols during coughing in
91 people with CF [3]. These findings are consistent with an earlier study of people with CF that
92 reached the same conclusion after very short-term wear of surgical masks (worn for 21 coughs)
93 [4]. These results and a recent editorial to our short-term mask wear study [5] support our
94 current aim to investigate the effectiveness, tolerability and functionality of face-masks as
95 source control after extended wear.

96

97 **Methods**

98 We recruited 25 people with CF and chronic *P. aeruginosa* infection [6] from the Adult Cystic
99 Fibrosis Centre, The Prince Charles Hospital, Brisbane, Australia. Ten healthy volunteers were
100 recruited from hospital and research staff to assess mask comfort and mask weight change. All
101 participants performed up to five randomly ordered tests in a validated cough system [7]: 1)
102 uncovered cough; 2) coughing with surgical mask worn for 10-minutes); 3) coughing with
103 surgical mask worn for 20-minutes; 4) coughing with surgical mask worn for 40-minutes; 5)
104 coughing with N95 mask worn for 20-minutes [3, 7]. The N95 test was an optional test based
105 on the poor comfort ratings observed in our earlier mask study [3].

106

107 The duration of the mask wear tests were selected based on observation of patients moving
108 around communal areas of the hospital described here. Two types of masks were tested:
109 “surgical mask” [Catalogue # 47107; Halyard FLUIDSHIELD Level 3 Fog-Free Procedure
110 Mask ($\Delta P < 2.5$), Georgia, USA] and “N95 mask” [Catalogue # 46827 (small) or 46727
111 (regular), Halyard FLUIDSHIELD N95 Particulate Filter Respirator and Surgical Mask,
112 Georgia, USA]. New masks were used for each test. The total wear time of the masks included
113 1-minute positioning of the participant into the rig, 2-minutes of tidal breathing with HEPA-
114 filtered air, a 5-minute cough period, followed by another 2-minutes of tidal breathing. Cough
115 aerosol collection, sputum processing and *P. aeruginosa* genotyping were performed as
116 previously described [1, 3, 8]. All participants rated their comfort levels after each test [3, 9].
117 All masks were weighed before and following each test.

118

119 SPSS version 25 was used for statistical analysis. Participants with CF were stratified by the
120 amount of aerosol colony forming units (CFU) produced during the uncovered cough test: high
121 producer (total CFU was ≥ 10) or no/low producer (total CFU was < 10) [3]. Categorical
122 variables were examined using Pearson Chi-squared test or Fisher’s Exact test. Continuous
123 variables were examined using a Student t-test or Mann-Whitney U test. CFU were log
124 transformed and the paired t-test examined changes over time. The McNemar-Bowker test was
125 used to examine comfort scores over time. The Wilcoxon Signed Rank Test was used to
126 examine the change in mask weight over time.

127

128 **Results**

129 *P. aeruginosa* was cultured from the sputum of 25/25 participants with CF and was cultured in
130 cough aerosols during the uncovered cough test of 20/25 participants (Table 1). *P. aeruginosa*

131 was cultured from cough aerosols of 9/20 participants during any of the surgical mask tests (10-
132 minutes, 20-minutes and 40-minutes total wear time) and 4/20 participants during the N95 mask
133 test of 20-minutes total wear. The CFU were significantly reduced for the surgical mask tests
134 compared with the uncovered cough test ($p < 0.001$). Between mask tests, the CFU count
135 remained similar as the duration of surgical mask wear increased as well as between mask types
136 (Table 1). The *P. aeruginosa* strain types found in the cough aerosols were genetically
137 indistinguishable from the paired sputum sample of each participant.

138
139 Participants with CF rated surgical masks less comfortable than healthy volunteers for all test
140 durations (surgical mask: 10-minutes, $p = 0.001$; 20-minutes, $p = 0.007$; 40-minutes, $p = 0.023$;
141 N95: 20-minutes, $p = 0.018$) (Table 2). Participants with CF were more tolerant of surgical mask
142 wear (good comfort) after 10- and 20-minutes total wear time if they had higher lung function,
143 yet this difference was lost after 40-minutes of surgical mask wear. N95 masks were rated less
144 comfortable in both participants with CF and healthy volunteers (Table 2).

145
146 The change in mask weight for each test ranged from no weight change to a maximum weight
147 change of 0.02g and was comparable between participants with CF and healthy volunteers
148 (Table 2). There was a minor increase in surgical mask weight (median change, 0.01g) after 40-
149 minutes compared with 10-minutes wear ($p = 0.031$) (Table 2). No statistical differences in mask
150 weight change were seen in other time or mask type comparisons (Table 2).

151 152 **Discussion**

153 Our study demonstrates that face masks worn for clinically-relevant time periods are effective
154 at reducing the release of potentially infectious aerosols during coughing in people with CF.
155 These results extend upon our earlier observations that demonstrated surgical masks and N95

156 masks were both effective at reducing the release of infectious cough aerosols when the mask
157 wear was of shorter duration [3]. The outcomes of our studies demonstrate that surgical masks
158 are effective and tolerable as source control [3] and support the CF Foundation (USA)
159 recommendations for surgical mask wear to reduce the risk of CF pathogen transmission in the
160 hospital setting [2].

161
162 Surgical masks were the preferred mask type for source control in terms of comfort, which is
163 similar to our short-term wear mask study findings [3]. Healthy volunteers tolerated the surgical
164 masks better than those with CF and participants with CF who had higher lung function
165 tolerated surgical masks better. When the comfort of surgical masks was assessed after extended
166 wear in this cohort, a major finding was that the comfort ratings remained unchanged regardless
167 of wear time for both people with and without CF. Therefore, surgical masks are not only
168 effective but are also well tolerated by participants after 40-minutes total wear.

169
170 An accompanying editorial of our recent mask study [3] questioned if mask dampness may
171 affect the ability of the mask to function as source control after prolonged wear times [5]. The
172 CF infection control guidelines indicate that masks being used as source control should be
173 replaced when damp [2] and excessive moisture accumulation was a common reason for
174 surgical mask replacement in people with tuberculosis using surgical masks as source control
175 [10]. Our data indicates that although there was evidence of surgical mask moisture
176 accumulation after 40-minutes total wear (estimated by increased weight), the surgical mask
177 continued to function effectively as source control mitigating this concern.

178
179 There are several limitations to this study: 1) The infectious dose of *P. aeruginosa* is unknown
180 and therefore the infection risk cannot be determined; 2) Participants remained in view of staff

181 while wearing the masks and this may have modified the extent to which participants interfered
182 with the mask leading to an incorrect estimation on the masks protective effects; 3) Participants
183 were seated during the cough testing and this may have impacted on the participant's ability to
184 cough freely; 4) While some participants experienced episodes of spontaneous cough during
185 testing, we were unable to differentiate between spontaneous and voluntary cough. Therefore,
186 the protective effects of the masks may be overestimated; 5) The effectiveness and tolerability
187 of masks is reported in adults only and these characteristics need to be studied in children; 6)
188 Our study had a maximum wear time of 40-minutes and the effectiveness of masks worn for
189 longer periods is unknown; 7) We did not assess inward protection provided by masks but this
190 has been highlighted as an understudied field of research [11].

191

192 Our study confirms the effectiveness of surgical masks at reducing the release of *P. aeruginosa*
193 cough aerosols in people with CF and provides evidence of patient tolerability and functionality
194 of these masks as source control after 40-minutes of total wear.

195

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200 the study for supporting the work.

201

202 Table 1: Demographic and clinical characteristics of the study participants

	Group			Production level in CF participants		
	Healthy (n = 10)	CF (n = 25)	p-value	No/low (<10 CFU) (n = 14)	High (≥ 10 CFU) (n = 11)	p-value
Participant characteristics						
Age, years, mean (SD)	37.3 (12.3)	33.3 (9.0)	0.29	36.7 (9.3)	28.9 (6.9)	0.029
Sex, male, n (%)	6 (60.0)	15 (60.0)	1.00	9 (64.3)	6 (54.5)	0.70
Body mass index (BMI), kg/m ² , mean (SD)	24.6 (3.5)	22.8 (3.2)	0.14	22.5 (3.7)	23.1 (2.6)	0.63
FEV ₁ % predicted, mean (SD)	92.6 (9.2)	53.8 (20.8)	<0.001	54.2 (23.2)	53.3 (18.2)	0.91
Mean <i>P. aeruginosa</i> sputum concentration, x 10 ⁷ CFU/mL (95% CI) ^a	n/a	5.2 (2.1 – 12.9)	-	1.9 (0.7 – 5.7)	18.3 (4.7 – 70.9)	0.008
Participants with <i>P. aeruginosa</i> detected in cough aerosols						
Uncovered cough test						
n (%)	n/a	20 (80.0)	-	9 (64.3)	11 (100.0)	
Mean CFU (95% CI) ^a		17 (7 - 43)		2 (1 – 4)	75 (34 – 165)	<0.001 ^d
Surgical mask tests						
10-minutes total wear						
n (%)	n/a	9 (36.0)	-	1 (7.1)	8 (72.7)	
Mean CFU (95% CI) ^a		4 (1 – 10)		1	5 (1 – 13)	
20-minutes total wear						
n (%)	n/a	9 (36.0)	-	1 (7.1)	8 (72.7)	
Mean CFU (95% CI) ^a		4 (1 – 10)		1	4 (1 – 11)	0.99 ^e
40-minutes total wear						
n (%)	n/a	9 (36.0)	-	1 (7.1)	8 (72.7)	
Mean CFU (95% CI) ^a		3 (1 – 7)		1	4 (1 – 9)	0.56 ^f , 0.64 ^g
N95 mask test[~]						
20-minutes total wear (n=23)						
n (%)	n/a	4 (17.4)	-	0 (0.0) ^b	4 (40.0) ^c	
Mean CFU (95% CI) ^a		2 (0 – 6)		n/a	2 (0 – 6)	0.19 ^h

203 *Definitions:* FEV₁, forced expiratory volume in 1 second; CFU, colony forming unit; CFU/mL, CFU per millilitre of sputum; SD, standard deviation;
204 CI, confidence interval, n/a, not applicable ~ Optional test

205

206 ^ageometric mean

207 ^bparticipant number (n) = 13

208 ^cparticipant number (n) = 10

209 ^dUncovered cough (geometric mean CFU) compared to each surgical mask test (geometric mean CFU)

210 ^eSurgical masks (geometric mean CFU): 10-minutes *versus* 20-minutes total wear

211 ^fSurgical masks (geometric mean CFU): 10-minutes *versus* 40-minutes total wear

212 ^gSurgical masks (geometric mean CFU): 20-minutes *versus* 40-minutes total wear

213 ^hMean CFU surgical mask 20-minutes total wear *versus* mean CFU N95 mask 20-minutes total wear

214 Table 2: Summary of mask properties

Mask properties	Mask comfort			Mask weight change	
	Healthy n (%)	CF n (%)	p-value	All participants Median (IQR)	p-value
Uncovered cough comfort level			1.00	n/a	n/a
Poor	0 (0.0 %)	0 (0.0 %)			
Sufficient	1 (10.0 %)	2 (8.0 %)			
Good	9 (90.0 %)	23 (92.0 %)			
Coughing wearing a surgical mask – 10-minutes total wear			0.001	0.01g (0.00g – 0.02g)	n/a
Poor	1 (10.0 %)	0 (0.0 %)			
Sufficient	0 (0.0 %)	15 (60.0 %)			
Good	9 (90.0 %)	10 (40.0 %)			
Coughing wearing a surgical mask – 20-minutes total wear			0.007	0.01g (0.00g – 0.02g)	0.73 ^a
Poor	1 (10.0 %)	1 (4.0 %)			
Sufficient	0 (0.0 %)	13 (52.0 %)			
Good	9 (90.0 %)	11 (44.0 %)			
Coughing wearing a surgical mask – 40-minutes total wear			0.023	0.02g (0.01g – 0.03g)	0.25 ^b , 0.031 ^c
Poor	1 (10.0 %)	2 (8.0 %)			
Sufficient	1 (10.0 %)	15 (60.0 %)			
Good	8 (80.0 %)	8 (32.0 %)			
Coughing wearing N95 mask -20-minutes total wear			0.018	0.02g (0.00g – 0.04g)	0.21 ^d
Poor	0 (0.0 %)	11 (47.8 %)			
Sufficient	7 (77.8 %)	8 (34.8 %)			
Good	2 (22.2 %)	4 (17.4 %)			

215

216 ^aSurgical mask weight change: 10-minutes *versus* 20-minutes total wear

217 ^bSurgical mask weight change: 20-minutes *versus* 40-minutes total wear

218 ^cSurgical mask weight change: 10-minutes *versus* 40-minutes total wear

219 ^dMask weight change after 20-minutes wear: surgical mask *versus* N95 mask

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