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Reducing Unnecessary High Flow Nasal Cannula Oxygen Usage in Mild to Moderate Bronchiolitis --Manuscript Draft--

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Abstract:	<p>Background: Heated high flow nasal cannula (HHFNC) therapy for bronchiolitis has become increasingly popular without evidence that this costly therapy impacts patient outcomes. Lack of criteria for appropriate may lead to overutilization, resulting in increased costs without patient benefit.</p> <p>Objective: Our primary aim was to decrease use of HHFNC in mild to moderate bronchiolitis over one bronchiolitis season.</p> <p>Design/Methods: Patients with Bronchiolitis < 2 years of age admitted to Hospital Medicine Service were included in this study. Using the model for improvement framework, we identified key drivers for HHFNC overuse and revised our bronchiolitis protocol to include LFNC trials prior to HHFNC initiation. We compared pre-intervention HHFNC utilization (December 2018 - April 2019) with post-intervention HFNC utilization (December 2019 to March 2020).</p> <p>Results: One hundred ninety patients met inclusion criteria, 98 of them in the pre-intervention cohort and 92 in the post-intervention cohort. Overall, the median age was 9.1 months and 65% of patients were male. Our HHFNC utilization rate decreased from 62% (61/98) to 43% (40/92) in the post-intervention period. Our SPC analysis suggested special cause variation based on 8 points below the pre-intervention mean. Incremental cost per case declined from \$84.15 pre-intervention to \$59.20 post-intervention.</p> <p>Conclusions: Our QI intervention implementing a specified LFNC trial prior to the initiation of HHFNC shows promise in reducing overall HHFNC use. Future studies should focus on clear initiation and discontinuation criteria for HHFNC use in bronchiolitis.</p>
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Reducing Unnecessary High Flow Nasal Cannula Oxygen Usage in Mild to Moderate Bronchiolitis

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Dr. Siraj conceptualized and designed the study, drafted the research protocol, participated in manuscript drafting, and approved the final manuscript as submitted.

Dr. Compton assisted with data collection and multidisciplinary hospital-wide education.

Dr. Russell assisted with data collection and multidisciplinary hospital-wide education.

Dr. Ralston conceptualized and designed the study, drafted the research protocol, participated in data extraction / quality review, performed statistical analyses, assisted with manuscript drafting, provided scientific mentorship, and approved the final manuscript as submitted.

Abbreviations: HHFNC- Heated High Flow Nasal Cannula, LFNC- Low Flow Nasal Cannula; LOS – length of stay; PICU – pediatric intensive care unit

Keywords: bronchiolitis; high flow nasal cannula; low flow nasal cannula

1 ABSTRACT

2 Background: Heated high flow nasal cannula (HHFNC) therapy for bronchiolitis has become increasingly
3 popular without evidence that this costly therapy impacts patient outcomes. Lack of criteria for
4 appropriate may lead to overutilization, resulting in increased costs without patient benefit.

5 Objective: Our primary aim was to decrease use of HHFNC in mild to moderate bronchiolitis over one
6 bronchiolitis season.

7 Design/Methods: Patients with Bronchiolitis < 2 years of age admitted to Hospital Medicine Service were
8 included in this study. Using the model for improvement framework, we identified key drivers for
9 HHFNC overuse and revised our bronchiolitis protocol to include LFNC trials prior to HHFNC
10 initiation. We compared pre-intervention HHFNC utilization (December 2018 - April 2019) with post-
11 intervention HFNC utilization (December 2019 to March 2020).

12 Results: One hundred ninety patients met inclusion criteria, 98 of them in the pre-intervention cohort and
13 92 in the post-intervention cohort. Overall, the median age was 9.1 months and 65% of patients were
14 male. Our HHFNC utilization rate decreased from 62% (61/98) to 43% (40/92) in the post-intervention
15 period. Our SPC analysis suggested special cause variation based on 8 points below the pre-intervention
16 mean. Incremental cost per case declined from \$84.15 pre-intervention to \$59.20 post-intervention.

17 Conclusions: Our QI intervention implementing a specified LFNC trial prior to the initiation of HHFNC
18 shows promise in reducing overall HHFNC use. Future studies should focus on clear initiation and
19 discontinuation criteria for HHFNC use in bronchiolitis.

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28 INTRODUCTION

29 Bronchiolitis is a leading cause of inpatient hospitalizations among children less than two years of
30 age and is associated with estimated direct annual costs of over US \$700 million.¹ As such, a multitude of
31 efforts have emerged to address quality of care for bronchiolitis, stressing the importance of adhering to
32 evidence-based guidelines for the diagnosis and management of patients diagnosed with acute
33 bronchiolitis.² Application of this framework has reduced the usage of some non-evidence-based
34 interventions such as chest radiography, corticosteroids, and bronchodilators.^{3,4}

35 Heated high flow nasal cannula (HHFNC) oxygen has gained popularity in the care of patients
36 with bronchiolitis but was not addressed in the latest guidelines. Despite promising initial observational
37 evidence on this intervention,^{5,6} the two randomized trials in hospitalized patients with moderate
38 bronchiolitis provide clear evidence that early use of HHFNC does not impact outcomes.^{7,8} Kepreotes et
39 al randomized 202 children with moderate bronchiolitis to either HHFNC or standard low flow oxygen
40 therapy upon admission.⁷ There were no differences in duration of oxygen therapy, or in the overall
41 length of stay (LOS) or pediatric intensive care unit (PICU) transfer rate. Franklin et al performed a
42 similar randomized controlled trial including 1472 patients, also finding no differences in duration of
43 oxygen therapy, length of hospital stay or intubation rates.⁸ These findings have been echoed in recent
44 larger observational studies in the US and Canada, demonstrating no beneficial outcome effect in
45 hospitals adopting wider use of HHFNC.^{9,10} Thus, the question of overutilization of this therapy has been
46 raised.^{11,12}

47 Based on the most recent literature, we began to perceive that the rate of HHFNC usage in
48 patients admitted to our children's hospital's general inpatient units with bronchiolitis as inordinately
49 high. Thus, our specific aim in this quality improvement study was to decrease use of HHFNC in mild to
50 moderate bronchiolitis in patients admitted to our ward over one bronchiolitis season.

51

52 METHODS

53 *Context*

54 We conducted this quality improvement initiative in a 200 bed, free-standing children's hospital
55 in Saint Petersburg, Florida between December 2019 and March 2020. We admit approximately ~300
56 patients with acute viral bronchiolitis annually and had an established institutional bronchiolitis pathway
57 in place for 2 years at the time of project initiation. Our pathway includes a respiratory distress scoring
58 system adapted from published work.¹³ The scoring tool served as a guide to categorize patients as mild,
59 moderate and severe bronchiolitis with interventions suggested by disease severity category. Patients
60 admitted to the general pediatrics floor with bronchiolitis are managed by the pediatric hospital medicine

61 group as well as one of two different residency programs rotating in our hospital. Our pathway allows for
62 use of HHFNC on the general pediatrics wards in previously healthy children with acute viral
63 bronchiolitis at flow rates up to 12 liters and FiO₂ up to 50%, but criteria for initiation were non-specific
64 and there was no requirement that a patient be hypoxic prior to initiation of HHFNC.

65 *Population*

66 We included patients aged 1 month to 24 months admitted to the hospital with mild to moderate
67 acute viral bronchiolitis from Dec 2019 through March 2020. Every 2 weeks, we manually chart reviewed
68 all patients receiving ICD-10 billing codes for acute viral bronchiolitis (J21.0, J21.1, J21.8, J21.9) and/or
69 acute respiratory failure (J96.00) to find patients that were initially admitted to the general pediatric floor
70 and to ensure that they met clinical history and physical examination consistent with bronchiolitis, such as
71 increased work of breathing, cough, feeding difficulties, congestion, tachypnea, and wheeze. Patients
72 initially admitted to the PICU were excluded from this study. Using the same ICD-10 codes and
73 inclusion/exclusion criteria, we obtained baseline data by performing a retrospective chart review of cases
74 admitted initially to the general pediatrics floor from Dec 2018-April 2019 at our institution.

75 *Intervention*

76 We utilized the model for improvement framework for our quality improvement initiative.¹⁴ We
77 performed a literature review and shared findings with key stakeholders in hospital medicine, emergency
78 medicine, critical care and the residency program. We solicited their feedback on key drivers of HHFNC
79 use and knowledge, attitudes, beliefs about the therapy. Key drivers of overuse of HHFNC we chose for
80 focus included (1) lack of available guidance on initiation criteria for use of HHFNC (2) knowledge gap
81 on current literature on efficacy of HHFNC and (3) concerns surrounding patient experience.

82 We then attempted to standardize formal initiation criteria but struggled to reach consensus
83 without existing published guidance on the topic. We ultimately proposed a single change to the existing
84 emergency department and inpatient bronchiolitis algorithms for which we could easily achieve
85 consensus. We added a trial of LFNC for at least 30 min with subsequent reassessment prior to the
86 initiation of HHFNC. Our updated pathways are presented as Supplemental Figure 1 (ED) and
87 Supplemental Figure 2 (Inpatient) with the specific change we made annotated. If there was no
88 improvement in respiratory rate, tachycardia or hypoxia (oxygen saturation <90%), patients were then
89 placed on HHFNC. Improvement was determined by subjective consensus among team members.

90 We presented our rationale and subsequent modified algorithm to all stakeholders in multiple
91 venues in November 2019. We also met with the nursing and respiratory therapy leadership and attended

92 their group meetings to discuss the changes. Education for resident physicians was performed at academic
93 lectures and orientation to the wards service.

94 *Study of the Intervention*

95 We provided feedback on the primary and secondary outcomes to stakeholders in two-weekly
96 intervals using simple run charts. Throughout the project, team leaders discussed cases that did not adhere
97 to the new algorithm to encourage feedback and familiarity with the change. We chose to track a process
98 measure, protocol compliance with the LFNC trial, as well as our primary outcome of HHFNC usage
99 with the hypothesis that protocol compliance should track along with any change in the primary outcome
100 if there was a cause and effect relationship between the two.

101 *Measures*

102 The primary outcome in this study was rate of HHFNC use in patients admitted to the general
103 ward with viral bronchiolitis between December 2019-March 2020, defined as the number of patients
104 placed on any amount of HHFNC over the total number of patients admitted to the general pediatrics
105 floor. Our secondary outcome was protocol compliance, defined as the number of patients who received
106 the recommended LFNC trial prior to HHFNC initiation over the total number of patients on HHFNC.
107 Our balancing measure was rate of unplanned transfers to the PICU within 24 hours of admission to
108 assess for the possibility of unintentional harm due to the protocol change. Other secondary outcomes
109 were LOS and estimated direct costs of HHFNC usage. Direct costs were calculated using only the cost of
110 the HHFNC setup used at our institution, not including labor costs.

111 *Analysis*

112 We analyzed the data using statistical process control methods. Western Electric rules for
113 establishing special cause were pre-specified¹⁵. Baseline values were calculated by using the 5 months of
114 the preceding bronchiolitis season December 2018 – April 2019. Postintervention data are reported for 4
115 months from Dec 2019–Mar 2020 as the project was stopped early due to the COVID-19 pandemic which
116 terminated the bronchiolitis season early due to school closures and social distancing measures, resulting
117 in dramatic decline in census.

118 *Ethics*

119 This QI project was deemed exempt by the Johns Hopkins All Children’s Hospital Institutional
120 Review Board.

121 **RESULTS**

122 In this study 190 patients admitted to the general pediatrics ward with bronchiolitis were
123 included. There was a total of 98 patients in the preintervention cohort and 92 in the postintervention
124 cohort. Patient characteristics in each cohort are presented in Table 1. Overall, the median age was 9.1
125 months and 65% of patients were male. Our HHFNC utilization rate decreased from 62% (61/98) to 43%
126 (40/92) in the post-intervention period. Our SPC analysis suggested special cause variation based on 8
127 points below the pre-intervention mean (Figure 1). Of the patients placed on HHFNC, 39% (24/61) were
128 initially trialed on standard low flow nasal cannula (LFNC) prior to the initiation of HHFNC in the pre-
129 intervention period compared to 73% (29/40) in the post-intervention period (Figure 2). Our SPC analysis
130 suggested special cause based on 2 out of 3 consecutive points above 2 sigma in the post-intervention
131 period.

132 Our system direct cost for the HHFNC setup alone were between \$98 and \$198 depending on
133 flow rate. Total direct costs of the HHFNC cartridges were \$8878 preseason and \$5720 postintervention.
134 Incremental cost per case declined from \$84.55 pre-intervention to \$58.60 post-intervention (Figure 3),
135 though special cause was likely due to the COVID-19 pandemic.

136 Overall mean length of stay in our study population did not change, with an average of 2.7 days pre-
137 intervention and 2.6 days post-intervention. Our balancing measure appeared unchanged, with 6 (6.1%)
138 unplanned PICU transfers in the bronchiolitis population in the pre-intervention period and 7 (7.6%) in
139 the post-intervention period. Time between transfers demonstrated a similar pattern pre and post
140 intervention (Figure 4), with time between transfers increasing toward the end of each winter season.

141

142 **DISCUSSION**

143 In this QI intervention, we saw a reduction in HHFNC usage in patients admitted to a general
144 pediatric ward with acute viral bronchiolitis from 62% to 43% after a relatively simple intervention. This
145 change to our pathway guided providers to attempt a LFNC trial prior to the initiation of HHFNC for
146 patients with mild to moderate disease severity which we hypothesized would be sufficient intervention
147 for many patients. We tracked both compliance with this recommendation as well as overall HHFNC use
148 in order to more clearly establish that this specific change resulted in the desired outcome and found that
149 protocol compliance indeed tracked with decreased HHFNC usage. Furthermore, we noted that
150 noncompliance with the new protocol (occurring in 11 patients) occurred primarily in patients under the
151 care of per diem providers (8 of 11) who would not have received our interventions or been as aware of
152 our pathways.

153 Unfortunately, we had to prematurely terminate our project at the end of March 2020 due to the COVID-
154 19 pandemic which dramatically decreased our hospitalization rate and likely impacted our results. Our

155 data point for the last two weeks of March indicating zero HHFNC usage is an outlier and was certainly
156 impacted by the pandemic in terms of likelihood that a patient would receive HHFNC given concern that
157 it may be an aerosolizing procedure. While all of our prior datapoints had been below the pre-intervention
158 mean up until that time, we believe the zero use that occurred during that timeframe was due to external
159 events and not directly linked to our intervention. Thus, our evidence must be considered preliminary and
160 potentially confounded.

161 We hypothesized that lack of criteria for initiation and/or discontinuation of HHFNC created an
162 environment of potential overuse of this costly therapy. In fact, the increasingly widespread use of
163 HHFNC for other conditions including asthma and pneumonia without proven data on efficacy suggests
164 the potential for indication creep. As noted previously, HHFNC has not been shown to improve clinical
165 outcomes in patients with bronchiolitis and therefore indiscriminate use of this costly therapy has been
166 questioned. A recent analysis evaluating the cost of providing high flow therapy as first line therapy
167 compared to rescue therapy after failure of standard oxygen revealed that the mean cost of bronchiolitis
168 treatment (including intervention costs and costs associated with LOS) was AU\$420 higher in the early
169 HHFNC group compared to the rescue HHFNC group¹⁶. We did not attempt to calculate labor costs as
170 that may overestimate cost savings unless total number of employees can truly be reduced due to a single
171 project, thus our conservative estimate of cost savings at \$3158 is modest. Nevertheless, we would
172 suggest that a parsimonious approach to the use of HHFNC will save a significant amount of money for a
173 health system over time without significant risk.

174 Our study has limitations, the most important being that we had to terminate prematurely due to a
175 dramatic decline in volume of hospitalizations due to the COVID-19 pandemic. It is possible that
176 HHFNC use will revert to the mean with decreased scrutiny, and that the proposed association of our
177 intervention with the outcome of interest was due to the Hawthorne effect. Furthermore, our study only
178 includes one season of bronchiolitis data and therefore conclusions surrounding long term implications
179 are limited. We did not collect data on oxygen saturation values at the time of initiation of LFNC or
180 HHFNC since our institutional practice was to focus on respiratory effort and not a prespecified oxygen
181 saturation limit. Given that individual provider definitions of hypoxia may vary greatly, we may have
182 substituted one unnecessary therapy for another by replacing HHFNC with LFNC, although such a
183 substitution would not negate the cost savings noted in our project.

184

185 **CONCLUSIONS**

186 HHFNC has not been proven to alter patient-centered outcomes in mild to moderate acute viral
187 bronchiolitis. Our QI intervention implementing a trial of standard LFNC prior to the initiation of

188 HHFNC shows promise in reducing the overuse of this therapy. Future studies should focus on clear
189 initiation and discontinuation criteria for HHFNC use in bronchiolitis.

190

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Figure 1

Figure 1. Proportion of Bronchiolitis Patients Receiving High Flow Nasal Cannula Over Total Number of Bronchiolitis Patients Admitted to the Hospital Medicine Service (p Chart)

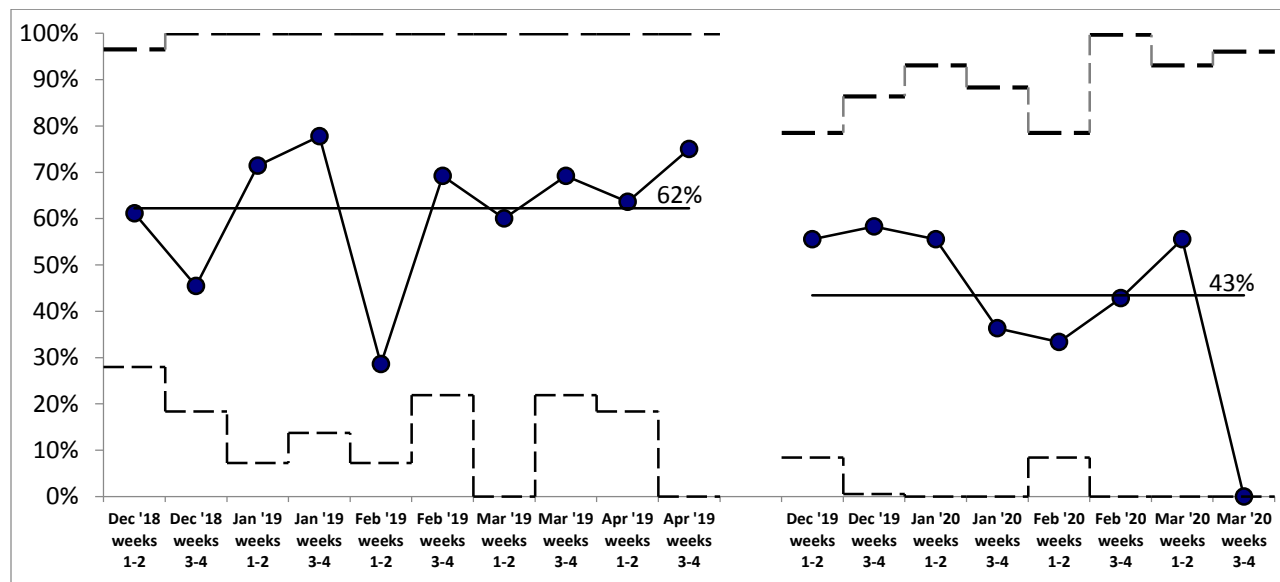


Figure 2

Figure 2. Proportion of Bronchiolitis Patients Receiving a Trial of Low Flow Oxygen Prior to High Flow Nasal Cannula Initiation (p Chart)

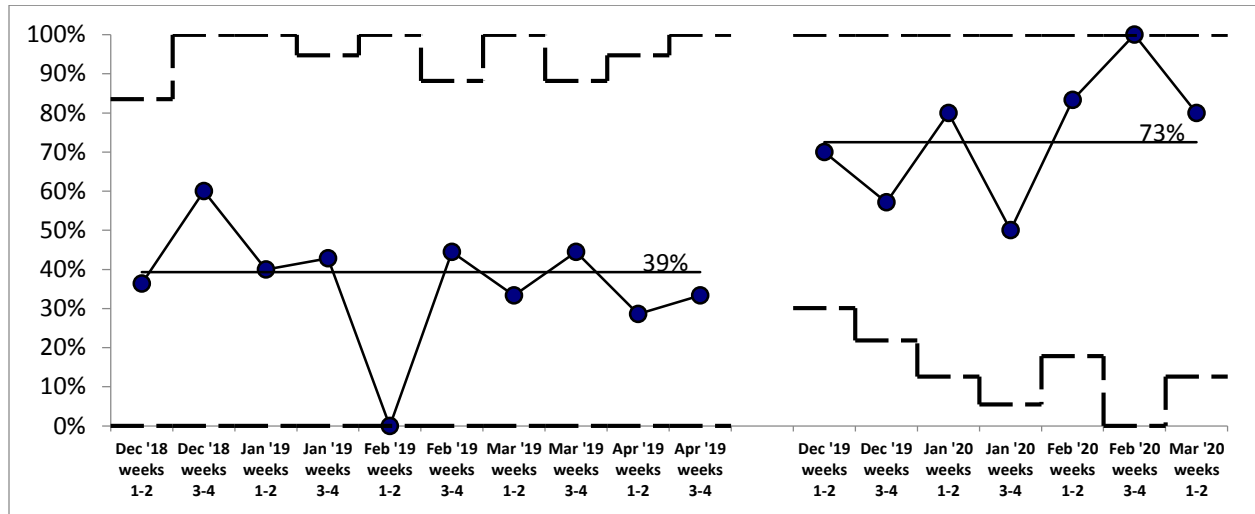


Figure 3. Incremental Cost per Case Attributed to the Use of High Flow Nasal Cannula (X-chart)

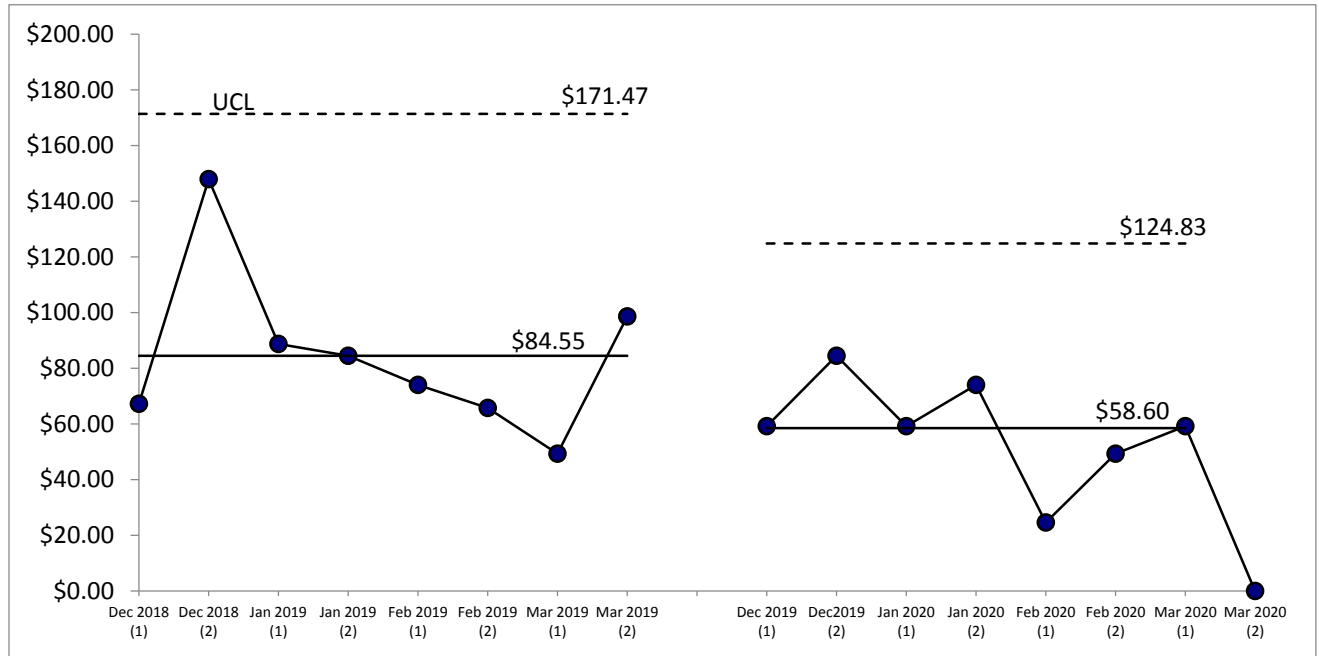


Figure 4

Figure 4. Number of Days Between Unplanned Transfer to Higher Level of Care in Study Population (g Chart). The graph on the left represents the immediate pre-intervention seasonal data. The graph on the right represents data during the intervention season.

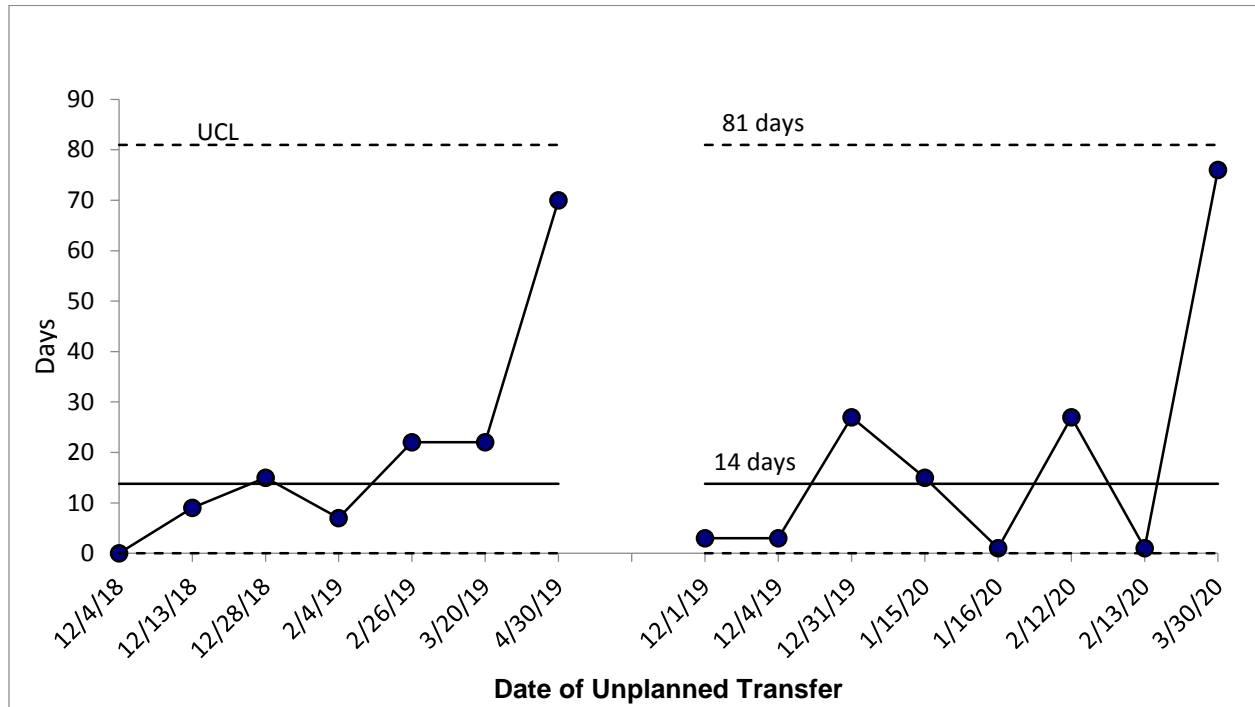


Table 1: Demographics for Study Population

Patient Characteristics	All Patients (n=190)	Preintervention (n=98)	Postintervention (n=92)
Mean age, months	9.1 ± 7.1	9.9 ± 7.9	8.3 ± 6.2
Male	64.7% (123/190)	61.2% (60/98)	68.4% (63/92)
Length of Stay, Days	2.6 ± 2.1	2.7 ± 2.5	2.6 ± 1.5
HHFNC	3.3 ± 2.5	3.3 ± 2.9	3.3 ± 1.5
LFNC trial	3.4 ± 2.1	3.4 ± 2.6	3.4 ± 1.7
LFNC only	1.9 ± 0.99	1.8 ± 0.67	1.9 ± 0.88



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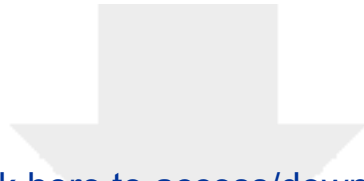
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