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#Could not attend the consultation meeting.

Protocol Driven Extubation in Neonates- A Quality Improvement Initiative

We read with interest the study on a quality improvement (QI) initiative for extubation in newborns [1]. Failed extubation is a common problem faced by healthcare workers across all neonatal intensive care units [2,3] and a QI initiative designed to improve this is a welcome step. We have two observations regarding this reasonably well-conducted study.

Authors have stated that ethical approval was not obtained as this study was a quality improvement initiative. Multiple articles have questioned this approach of not obtaining ethics approval for QI studies [4,5]. We feel ethics committee approval should be sought for all QI studies when it directly impacts patient care.

Secondly, authors have not specified if they have calculated sample size, as primary objective was to reduce extubation failure rates by 25% from baseline.

In Table I of the article, extubation failure in PDCA-1 is mentioned as 23.8% (5/21) while in figure 2 it is mentioned as 10/21. The other two categories *ie*, baseline and PDCA-2 figures are appropriate.

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AUTHOR'S REPLY

We thank the readers for their queries - their concern is justifiable. Quality improvement (QI) projects are being widely used to improve quality of care in patient management. In fact several government-supported QI projects are underway *eg*, LaQshya program. These projects do not need any ethical approval as they intend to implement already established evidence-based recommendations in clinical practice. We also implemented evidence-based practices and recommendations modified to our needs and available resources in this project. As long as no new intervention of questionable efficacy is introduced, QI projects do not need any ethical approval. Taking ethical approval in such cases would just hamper rapid progress in delivering quality care.

We did not calculate sample size for the study. The targets in QI projects are usually not based on sample size. There are many ways to set targets *eg*, benchmarks, percentiles, best achieved elsewhere etc. In our project, there is no benchmark or we can say that there should be theoretically zero extubation failures. Setting zero extubation failures as target would be unrealistic. So, a realistic target is set depending on our current performance and feasibility.

We did not find any discrepancy in Fig. 2 and table I of the article.

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