

This measure was reviewed at 1.25.21 ASPIRE Quality Committee Meeting - the final vote for PUL 01 was 88% continue as is - and PUL 02 final vote was modify as recommended (50% vote) Further notes from this meeting found [here](#)



## PUL 01 and PUL 02 Review - January 2021

### **PUL 01 & PUL 02 Measure Specification**

PUL 01 - median TV less than 10 cc/kg PBW - measure specification [here](#)

PUL 02 - median TV less than 8 cc/kg PBW - measure specification [here](#)

### **Comments from Dr Tung**

I think Pul-01 is generally reasonable. Ventilator hawks may argue for a driving pressure standard but IMHO the OR is too dynamic to allow that without false signals.

Am working off the measure definition at

<https://spec.mpog.org/Spec/Public/4><https://spec.mpog.org/Spec/Public/4>

The 10 cc/kg threshold, even with IBW calculation, produces a TV threshold that would be accepted as reasonable. A 5'9" patient would be 175cm tall, have an IBW = 70 and meet the metric with TV = 700. Such a TV would be anachronistic today...I doubt anybody is ventilating a 5'9" patient with 700cc TV in 2020.

I agree that given current data including PMID 32870298 it is hard to identify an evidence based lower threshold than 10. 32870298 found no difference comparing 6 to 9...and in actuality the real median upper TVs in the study was 9.4 so the upper threshold of "no difference" is likely even higher than 9.

I see no exclusion for hypoxemic patients, which would be an argument to use higher TV. Even with PEEP low TV sometimes results in lower saturations. An unintended consequence of low TV ventilation is thus higher FiO2 (which is its own controversy). To exclude patients with gas exchange abnormalities that may drive a higher TV we could use P/F ratio < 250 (or whatever). Unfortunately low TV aficionados would howl that those patients are most likely to benefit from low TV. So probably best to just put a TV limit out there and ignore those who complain about hypoxemia.

If there is a methodological flaw to 32870298, it is that driving pressures (plateau -PEEP) were not compared between groups. The negative result has led investigators to whether the important intraoperative metric is driving pressure see PMID 26947624. If PEEP up titration decreases driving

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pressure then...good! If PEEP uptitration increases driving pressure then...bad. A variant on open lung theory.

But these data are in their infancy and only one paper so far. I think most anesthesiologists would accept that TV should not be too high...and 10cc/kg is enough. And, due to surgical intervention, kinked ETTs, laparoscopic insufflation, etc...driving pressure is probably not a good quality metric in the OR. Too dynamic.

I would reword the rationale to meet current data. Suggest "Current evidence suggests that low tidal volumes improve outcome in patients with ARDS and may reduce the incidence of postoperative pulmonary complications in patients undergoing surgery with general anesthesia & PPV. Although a cc/kg threshold and the magnitude of the benefit cannot be specified at this time, the detrimental effect of high tidal volumes, even for brief periods, is well-established in animal and human studies.

(e.g. the measure is intended to reduce dangerously high TV, not enforce low TV that may not have benefit)

If you use the current "several randomized trials" language you will have to explain why the largest of them (32870298) found no difference). And the 2015 meta 26120769 that found a mortality benefit in non ARDS patients GREATER than that in ARDS patients is mechanistically inconsistent. No current theory of LPV explains an effect in non ARDS patients greater than that in ARDS patients. And, you can't really say that PEEP is a key ingredient either as PROVHILO (PMID 24894577) found no difference between 12 and 2cm.

I would thus add the Karalapillai paper to references to show you are aware of the issues:

Effect of Intraoperative Low Tidal Volume vs Conventional Tidal Volume on Postoperative Pulmonary Complications in Patients Undergoing Major Surgery: A Randomized Clinical Trial.

Karalapillai D, Weinberg L, Peyton P, Ellard L, Hu R, Pearce B, Tan CO, Story D, O'Donnell M, Hamilton P, Oughton C, Galtieri J, Wilson A, Serpa Neto A, Eastwood G, Bellomo R, Jones DA.

JAMA. 2020 Sep 1;324(9):848-858.

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Due to the "no difference" Karalapillai paper (32870298), Pul-02 (TV<8cc/kg) is a harder sell. Karalapillai raises questions as to which part of the Futier "bundle" 23902482 (recruitment, low TV or PEEP) was the magic ingredient (assuming Futier's result is reproducible which many, including the late great Brian Kavanagh, thought unlikely). Setting TV to 8 cc/kg suggests that TV is the ingredient...but PEEP was the same in Karalapillai trial so maybe the ingredient is PEEP. But if so PROVHILO suggests no difference between 12 and 2 so no evidentiary standard there.

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I would delete Pul-02. Not supported by current evidence, and to specify a PEEP/TV/recruitment protocol is way beyond current evidence.

### **Addendum from Dr. Tung:**

For those looking up references...I misspoke...got my references wrong.

This 2012 meta 26181219 found a signal for mortality in non ARDS patients greater than in ARDS patients in the ICU. Mechanistically inconsistent as noted before.

Ref 4 in the measure spec, 26120769 is an Anesthesiology review in 2015 that claims no benefit from intraoperative TV alone...but meta-analyzed 4 studies (Futier (N=400) plus 3 others with Ns ~30 or less) to find a 0.27 OR for PPCs for a bundle of TV plus PEEP in the OR). That is scorchingly low...and has not been reproduced to date. Heavily dependent on Futier which (as noted) is increasingly an aberrant result.

I thought the ref in the measure spec was 25978326, which is an Anesthesiology meta also published in 2015 finding dose dependent effects of TV on PPCs with an OR ~0.5 for 6-8cc/kg Still very low, and incompatible with Karalapillai et al.

### **Comments from Dr. Colquhoun**

Agree that PUL-02 and 8ml/kg is becoming harder in light of Karalapillai and PREVENT (PMID: 30357256). Agree that does not take the onus off folks to keep tidal volumes somewhat reasonable... so 10ml/kg (PUL-01) seems about tolerable, although as you note this leads to some large and uncomfortable numbers. But when the facts change...

It would make me uncomfortable to tacitly endorse 10ml/kg + Zero-PEEP. While Futier is clearly becoming outside of the mainstream (especially given the all cause complication outcome used), single parameter interventions (PEEP, Tidal Volume and even RM's) generally lead to negative trials (RM: 24833726, Tidal Volume: 22661750, 32870298, PEEP: 24894577, 31157366, FiO2: 19826023).

I'd be a little happier if we brought PUL-03 into PUL-01 and say ZEEP and > 10ml/kg Tidal Volumes are probably detrimental and with little comment on what's actually good... It's two ideas together, but it's not a bundle! Promise!