Trial Issues Survey Results

PICU

Sixteen PICU outcomes were scored in round 1. These were:

1. GI Morbidity: Diarrhoea
2. Incidence of GI Morbidity: Vomiting
3. Incidence of Ventilator Acquired Pneumonia (VAP)
4. Length of Stay: Hospital
5. Length of Stay: PICU
6. Length of Time Invasive Ventilation
7. Long Term Feeding Issues
8. Long Term Outcomes (After Hospital Discharge)*
9. Looking and/or Behaving Like Their Normal Self*
10. Mortality
11. Nursing Time Spent Measuring GRV
12. Time Feed Stopped per 24h
13. Time to Achievement of Predicted Energy Goals (Full Feeds)
14. Total Length of Time Respiratory Support (IV + NIV)
15. Change in Weight (Growth) Between PICU Admission and Discharge
16. Change in Length (Growth) Between PICU Admission and Discharge

Six outcomes were added in R2:

1. Administration of Parenteral Nutrition Secondary to Feed intolerance
2. Post-Pyloric Feeding (Placing An Pp Tube) Secondary to Feed intolerance
3. Parental Satisfaction
4. Change to Feed Formula Type Secondary to Feed intolerance
5. Administration of Prokinetic Drugs Secondary to Feed intolerance
6. Incidence of Necrotising Enterocolitis

Table 1 Free-text responses from PICU respondents regarding inclusion and exclusion criteria

	Stakeholder group
Other suggested inclusion criteria	
I think you have some problems with the design of the survey since you have 'only' in some questions which means the answers can be internally inconsistent	PICU Doctor/Paediatric Surgeon
I would exclude all patients with unrepaired hyperplastic left heart syndrome or coarctation and for the first 48hrs post repair	PICU Nurse
Include all children on PICU and HDU	PICU Doctor/Paediatric Surgeon
There is overlap here and I'm not sure	PICU Doctor/Paediatric Surgeon
This may depend on outcome measures that you plan to look at.	PICU Nurse
We need to include all children currently receiving GRV measurements. Selectively excluding them biases the results	PICU Dietitian
Other suggested exclusion criteria	
Children – nil by mouth on PN	PICU Dietitian
Children with hyperplastic left heart syndrome (unrepaired) or coarctation (unrepaired) and for both for first 48hrs post-surgery	PICU Nurse
Exclude only children with gut pathology whether medically or surgically managed e.g. NEC. Exclude also children in whom vomiting dangerous e.g. acute TBI	PICU Doctor/Paediatric Surgeon
If any child commenced on enteral feeding routinely receives GRV monitoring then they need to be included in this study	PICU Dietitian
It will depend on outcome measures i.e. of you want to look at achievement of goal feeding or VAP you may wish to exclude those in PICU <24hrs or those not receiving invasive ventilation. May be worth excluding GI surgery patients as these are often managed by the surgeons and not directly by PICU and therefore adherence to a study protocol may be challenging.	PICU Nurse
NJ fed	PICU Doctor/Paediatric Surgeon

Table 2: Line-listing of feedback offered during R1 regarding potential outcomes (text exactly as input by respondents)

Outcome	Stakeholder Group	Score	Feedback
GI morbidity: diarrhoea	PICU nurses	6	*May be confounded by other factors such as antibiotics*
	PICU dietitians	1	*diarrhoea may be present for many reasons. Not relating to the measurement of GRV or not.*
Incidence of GI morbidity: vomiting	PICU nurses	6	*May be confounded by bolus versus continuous feeds - is the study going to correct for this?*
Incidence of ventilator acquired pneumonia (VAP)	PICU nurses	6	*Again other factors may be involved i.e. VAP Care bundles (Head of bed elevation; dependent ventilator tubing) so although important I'm not sure it is the critical study outcome measure*
Length of stay PICU	PICU dietitians	6	*Better establishment of nutrition could result in significant reduction in LOS*
Length of time invasive ventilation	PICU dietitians	7	*Especially if relating to vomiting / reflux aspiration of feed / feed suctioning from nose / mouth where GRV not measured.*
Long term feeding issues	PICU nurses	6	*Again other factors influence this other than GRVs*
	PICU dietitians	7	*Failure to establish feeding on PICU would affect outcomes and therefore an important outcome for this study. Long term issues out of PICU is a major issue; but not an outcome for this study ...; I don't think.*
Long term outcomes (after hospital discharge)	PICU nurses	9	*Time to rehabilitate in relation to functional outcomes*
	PICU dietitians	4	*V important issues - not something I had though of as an outcome measure in this study.*
Looking and/or behaving like their normal self	PICU dietitians	4	*V important issues - not something I had though of as an outcome measure in this study.*
Mortality	PICU nurses	6	*Important but with PICU mortality so low morbidity may be a more important outcome measure*
	PICU dietitians	7	*If it relates to vomit / aspiration / VAP*
Time feed stopped per 24h	PICU nurses	9	*An important putcome measure regardign GRV versus no GRV measurement and impacts on patient outcome due to nutritional deficits*
Time to achievement of predicted energy goals (full feeds)	PICU nurses	9	*Important outcome measure regarding GRV monitoring and feed advancement that is known to impact on patient outcomes*
Total length of time respiratory support (IV + NIV)	PICU dietitians	9	*Particularly if prolonged as a result of vomits / presumed aspiration / reflux episodes causing desats.*
Change in weight (growth) between PICU admission and discharge	PICU dietitians	4	*Don't trust weight on PICU - crude measure. Vast majority of children lose weight - muscle wastage; critical illness - it would be amazing if this study could show that this was not inevitable.*
Change in length (growth) between PICU admission and discharge	PICU dietitians	4	*Again - growth would be ideal but often in this population - especially those with long LOS; growth is not the child's top priority.*

Figure 1 Histograms comparing the distribution of mean Round 1 (R1) scores of outcomes in the PICU Delphi in those that did and did not complete Round 2 (R2)

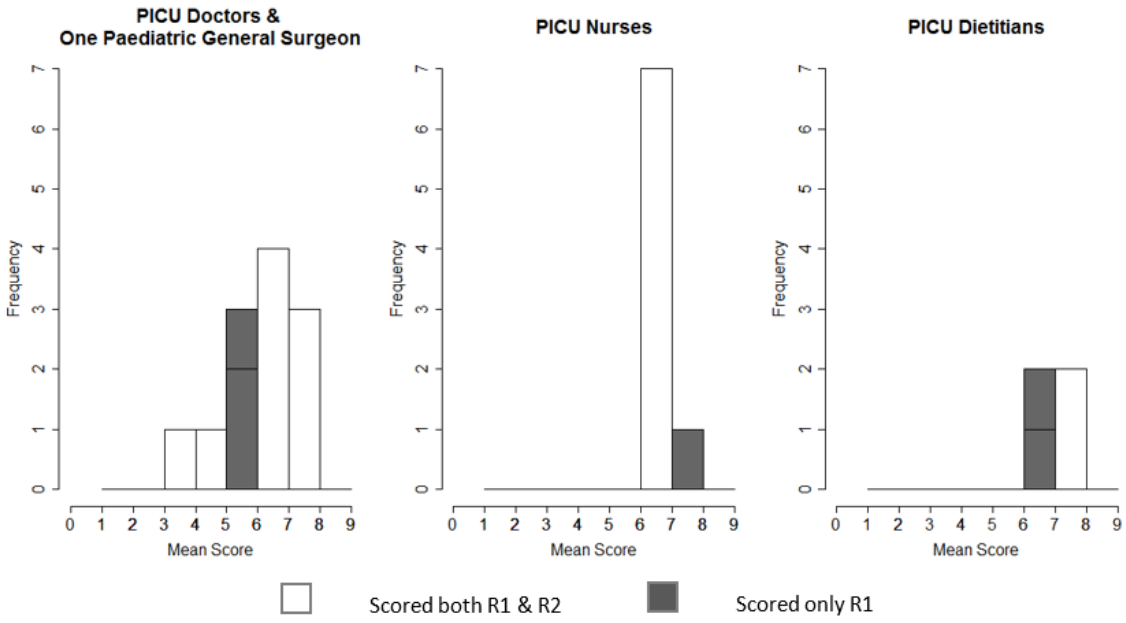

Figure 2 Histogram showing the number of outcomes where the score changed between rounds 1 and 2 (n=22 participants that scored outcomes in both rounds). [E.g. 36% of participants changed their score on only 0, 1 or 2 outcomes]

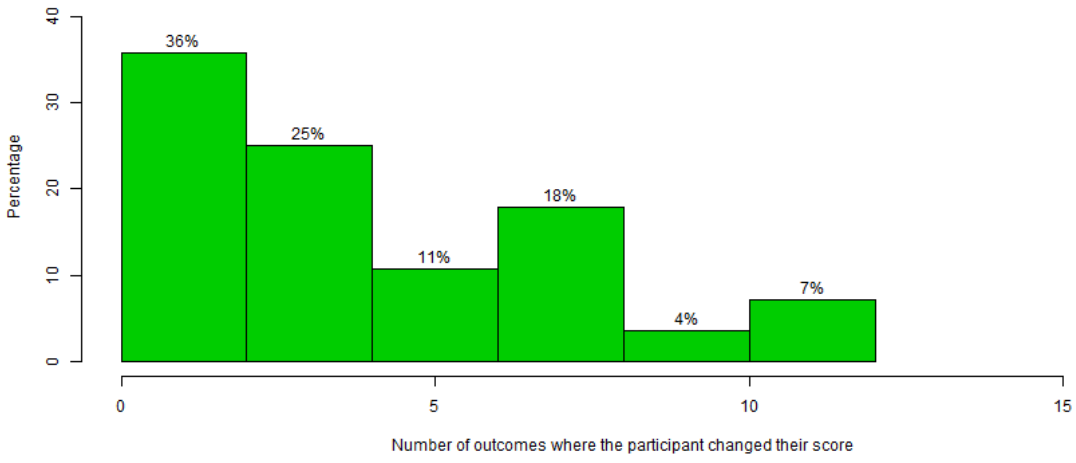

Table 3 PICU Round 2 score summary statistics: median score within stakeholder group and median (inter-quartile range) score overall

Outcome	PICU Doctors & 1 Paediatric general surgeon (n=11)	PICU Nurses (n=8)	PICU Dietitians (n=3)	All (n=22)
GI morbidity: Diarrhoea	5	6	7	6 (4.3,6.8)
Incidence of GI morbidity: Vomiting	7	7.5	9	7 (7,8.8)
Incidence of ventilator acquired pneumonia (VAP)	7	8	9	8 (7,9)
Length of stay: Hospital	7	5	7	7 (5,7)
Length of stay: PICU	7	7	7	7 (6,7)
Length of time invasive ventilation	7	7.5	8	7 (5.5,8)
Long term feeding Issues	6	5.5	6	6 (5,7)
Long term outcomes (After hospital discharge)	5	4.5	6	5 (4,6.8)
Looking and/or behaving like their normal self	5	4	6	5 (3,6)
Mortality	7	7.5	8	7 (5.3,8)
Nursing time spent measuring GRV	7	6.5	7	7 (5.3,7)
Time feed stopped per 24h	7	8	9	8 (7,9)
Time to achievement of predicted energy goals (Full feeds)	8	8	9	8 (8,9)
Total length of time respiratory support (IV + NIV)	7	6.5	8	7 (6,7.8)
Change in weight (Growth) between PICU admission and discharge	6	6.5	8	6 (6,7.8)
Change in length (Growth) between PICU admission and discharge	5	5	6	5 (4,6)
Administration of parenteral nutrition secondary to feed intolerance*	6	5.5	7	6 (6,7)
Post-pyloric feeding (Placing an Pp tube) secondary to feed intolerance*	6	6.5	7	6 (5.3,7.8)
Parental satisfaction*	5	5	5	5 (4,5.8)
Change to feed formula type secondary to feed intolerance*	5	5	7	5 (4,5.8)
Administration of prokinetic drugs secondary to feed intolerance*	5	5	7	5 (4.3,6)
Incidence of necrotising enterocolitis (NEC)*	8	8.5	8	8 (7,9)

**Outcomes added in Round 2*

NNU

Twenty-two NNU outcomes were scored in round 1. These were:

1. Days of central venous line access
2. Days on parenteral nutrition
3. GI morbidity: Diarrhoea
4. GI morbidity: Vomiting
5. Incidence of necrotising enterocolitis
6. Length of stay hospital
7. Length of stay neonatal unit
8. Length of time invasive ventilation
9. Mortality
10. Nursing time spent measuring GRV
11. Time feed stopped per 24h
12. Time from start of enteral feeding to achieve full (150ml/kg/day) enteral feeds
13. Time to nasogastric tube removal
14. Total length of time respiratory support (IV + NIV)
15. Change in weight (growth) between birth and neonatal unit discharge
16. Change in length (growth) between birth and neonatal unit discharge
17. Long term outcomes: Hearing loss
18. Long term outcomes: Problems with eye sight
19. Long term outcomes: Problems with cognition
20. Long term outcomes: Brain injury on imaging
21. Long term outcomes: Problems with mobility like cerebral palsy
22. Healthcare associated infections

Four outcomes were added in R2:

1. Change in head circumference between birth and neonatal unit discharge
2. Incidence of pneumonia due to milk aspiration
3. Incidence of catheter-associated blood stream infection
4. Time to oral feeding

Table 4 Free-text responses from NNU respondents regarding inclusion and exclusion criteria

Stakeholder group	Suggestions
Other suggested inclusion criteria	
N/P Doctors & Paediatric Surgeons	*>1000g* *Depends upon the surgery; why have you referred to infants in this question*
N/P Nurses	*All infants less than 36 weeks requiring enteral feeding.* *Answer depends on the type of surgery* *Babies on CPAP or Vapotherm/ Optiflow as well as stable long-term ventilated babies should be included* *Needs to include those IUGR babies <1500grams regardless of gestation as they are also included in the high risk feeding group.* *Only babies with no gut surgical issues* *Small for dates infants* *What about infants with gastrostomy / PEG?*

Other suggested exclusion criteria	
N/P Doctors & Paediatric Surgeons	*?GI anomalies* *<1000g* *absent end diastolic flow* *Ambiguous - is this yes exclude or yes include* *Babies with gastroschisis* *Exclude post GI surgery* *Exclude those with known surgical problem* *If babies had suspected NEC they wouldn't be receiving feeds* *In infants of diabetic mothers who have high amylin levels and may have increased gastric residual volumes (ADC papers on AMYLIN and FI in preterm and IDM)* *Neurology conditions* *Post GI surgery* *Potentially could make inclusion criteria very broad* *surgical infants* *to consider analysing some of the groups (only) separately if included; G) depends on the non-trial treatment protocol; j) not necessarily all abnormalities; (K) does not make sense in that place)*
N/P Nurses	*If babies are on 2 hourly feeds* *Not likely to survive* *unstable sick ventilated babies* *Babies less than 28 wks because if being fed measuring gastric content regularly could have a detrimental effect when measuring gastric content on their stomachs* *Babies who have other co-morbidities apart from being premature such as patients with gut problems or surgical cases babies.*

Abbreviations: N/P Neonatal/Paediatric

Table 5 Line-listing of feedback offered regarding potential outcomes during Round 1 of the NNU Delphi

Outcome	Stakeholder Group	Score	Feedback
Days of central venous line access	Nurses	9	*It will potentially reduce infection risk by removing early an reduce hospitalisation time*
Days on parenteral nutrition	Nurses	9	*It will potentially reduce infection risk by removing early an reduce hospitalisation time*
GI morbidity: vomiting	Nurses	7	*increased risk of aspiration and therefore complications*
Incidence of necrotising enterocolitis	Doctors/Surgeons	9	*Probably most important*
	Nurse	9	*This can have significant lifelong implications and so is very important in terms of trying to prevent occurrence*
Length of stay hospital	Doctors/Surgeons	4	*Could be influenced by many confounding variables*
Mortality	Doctors/Surgeons	7	*if related to feeding*
	Doctors/Surgeons	8	*Mortality due to NEC*
	Nurse	10	*Not as an outcome measure; but obviously important to know.*
Nursing time spent measuring GRV	Nurse	1	*Minimal amount of time spent; even if you add them all up together.*
Time feed stopped per 24h	Nurse	9	*this could have a significant impact on motility and developing normal gut function*
Time to nasogastric tube removal	Nurse	10	*Not sure why this would be relevant unless it is expected non measurement of GRV leads to earlier oral feed establishment*

Figure 3 Histograms comparing the distribution of mean Round 1 (R1) scores of outcomes in the NNU Delphi in those that did and did not complete Round 2 (R2)

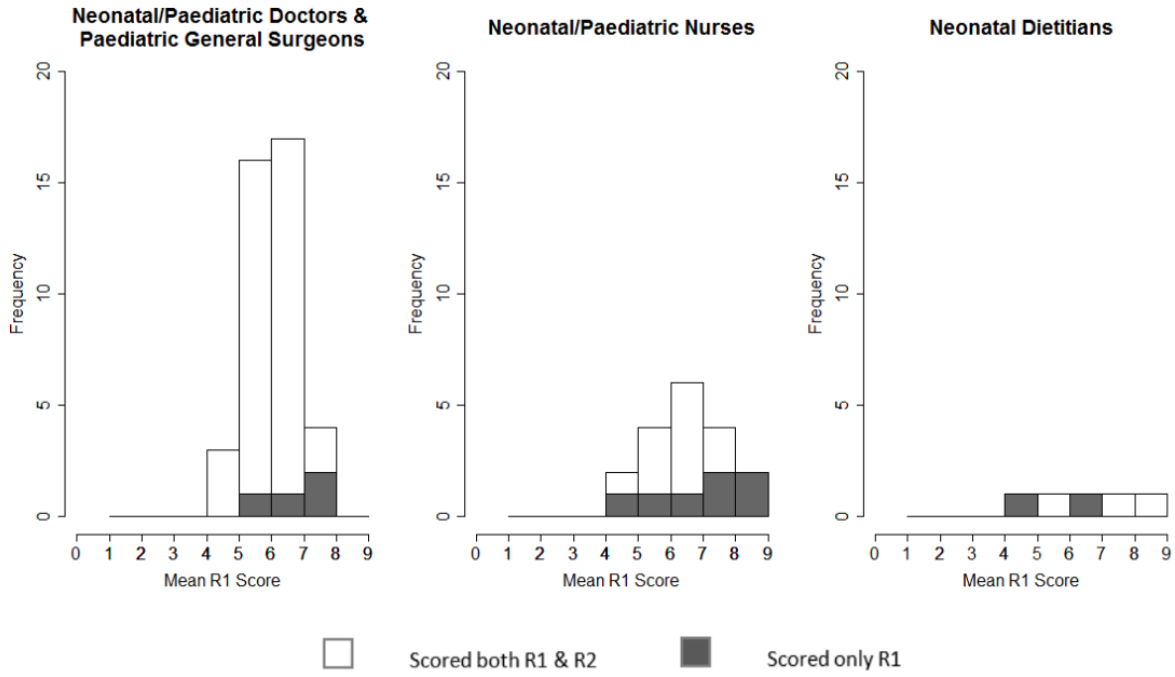

Figure 4 Histogram showing the number of outcomes where the score changed between rounds 1 and 2 (n=61 participants that scored outcomes in both rounds). [E.g. 24% of participants changed their score on only 0, 1 or 2 outcomes]

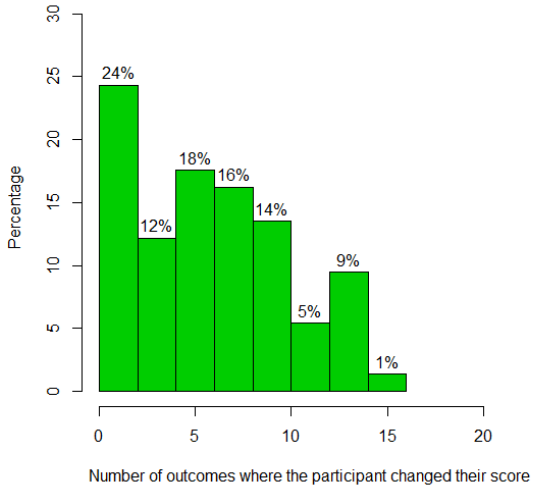

Table 6: NNU Round 2 score summary statistics: median score within stakeholder group and median (inter-quartile range) score overall.

Outcome	N/P Doctors /Paediatric Surgeon (n=40)	N/P Nurses (n=18)	Neonatal Dietitians (n=3)	All (n=61)
Days of central venous line access	7	7.5	8	7 (6,8)
Days on parenteral nutrition	8	8	9	8 (7,9)
GI morbidity: Diarrhoea	5	5.5	6	5 (4,6)
GI morbidity: Vomiting	6	7	7	6 (6,7)
Incidence of necrotising enterocolitis	9	9	9	9 (9,9)
Length of stay hospital	6	7	8	7 (6,7)
Length of stay neonatal unit	6	7	8	6 (6,7)
Length of time invasive ventilation	6	6.5	7	6 (5,7)
Mortality	9	9	9	9 (9,9)
Nursing time spent measuring GRV	4.5	4.5	7	5 (3,6)
Time feed stopped per 24h	7	7.5	7	7 (7,8)
Time from start of enteral feeding to achieve full (150ml/kg/day) enteral feeds	8	8	9	8 (7,9)
Time to nasogastric tube removal	5	5.5	5	5 (4,6)
Total length of time respiratory support (IV + NIV)	5	6	5	5 (5,6)
Change in weight (growth) between birth and neonatal unit discharge	7	7	7	7 (7,7)
Change in length (growth) between birth and neonatal unit discharge	6	6	7	6 (5,7)
Long term outcomes: Hearing loss	6	6	6	6 (4,6)
Long term outcomes: Problems with eye sight	6	6	5	6 (5,6)
Long term outcomes: Problems with cognition	6	6	6	6 (6,7)
Long term outcomes: Brain injury on imaging	6	6	6	6 (5,7)
Long term outcomes: Problems with mobility like cerebral palsy	6	6.5	6	6 (5,7)
Healthcare associated infections	7	8	7	8 (7,8)
Change in head circumference between birth and neonatal unit discharge*	8	7	6	6 (5,7)
Incidence of pneumonia due to milk aspiration*	7	6	6	7 (5,8)
Incidence of catheter-associated blood stream infection*	6	6	7	8 (7,8)
Time to oral feeding*	6	7	6	6 (5,7)

*Outcomes added in round 2