Received: 26 November 2021 | Revised: 19 May 2022 | Accepted: 22 May 2022

DOI: 10.1111/nicc.12810

SERVICE EVALUATION

BACCN Nursing in Critical Care WILEY

Using the TIDieR checklist to describe the intervention of the Sedation and Weaning in Children (SANDWICH) trial

Lyvonne N. Tume RN, PhD, Reader (Associate Professor) in Child Health[1,2] | **Bronagh Blackwood RN, PhD, Professor of Critical Care**[3] | **Daniel F. McAuley MD, Professor of Intensive Care Medicine**[3] | **Kevin Morris MD, Professor of Paediatric Intensive Care Medicine**[4,5] | **Mark J. Peters MD, PhD, Professor of Paediatric Intensive Care**[6,7] | **Joanne Jordan DPhil, Research fellow**[8] | **Timothy Simon Walsh MD**[9] | **Lisa McIlmurray RN, MPhil, Senior PICU Nurse, Clinical Research Fellow**[3,10]

[1]School of Health and Society, University of Salford, Manchester, UK

[2]Paedaitric Intensive Care Unit, Alder Hey Children's NHS FT, Liverpool, UK

[3]Wellcome-Wolfson Institute for Experimental Medicine, Queen's University, Belfast, UK

[4]PICU, Birmingham Women's and Children's NHS Foundation Trust, Birmingham, England, UK

[5]PICU, Institute of Applied Health Research, University of Birmingham, Birmingham, England, UK

[6]Great Ormond Street Hospital NHS Foundation Trust, London, England, UK

[7]Great Ormond Street Institute of Child Health, NIHR Biomedical Research Centre, University College London, London, England, UK

[8]PICU, Faculty of Wellbeing, Education and Language Studies, School of Health, Wellbeing and Social Care, The Open University, Milton Keynes, UK

[9]Department of Anaesthesia, Critical Care and Pain Medicine, Usher Institute, University of Edinburgh, Edinburgh, UK

[10]Children's Health Ireland at Temple Street Hospital, Dublin, Republic of Ireland

Correspondence
Lyvonne N. Tume, School of Health and Society, University of Salford, Manchester UK.
Email: l.n.tume@salford.ac.uk

Funding information
UK Paediatric Critical Care Society Study Group; NIHR HTA, Grant/Award Number: 15/104/01

Abstract

Background: Published reports of complex interventions in randomized controlled trials often lack sufficient detail to allow trial replication and adoption into practice.

Aim: The aim of this paper is to describe our experience of using the Template for Intervention Description and Replication (TIDieR) checklist in reporting a recent trial of sedation and ventilation weaning in critically ill children (the Sedation and Weaning in Children [SANDWICH] trial).

Methods: The TIDieR 12-point checklist has been used to detail and describe the specific SANDWICH trial intervention and methods of implementation.

Results/Discussion: Overall, we found the checklist a useful tool to direct and ensure consistency of reporting of our complex intervention used in a multi-centre clinical trial. We experienced some minor limitations in classifying training materials and delivery mode into one item because of the overlapping nature of this component.

Conclusion: Using the TIDieR checklist to report complex interventions tested in trials provides a structured, systematic way of describing necessary detail. This allows

clinicians to understand the theory behind the intervention, how it should be delivered, and the resources required.

Relevance to Clinical Practice: The SANDWICH intervention had a significant beneficial effect on reducing time on ventilation for children. The detailed description of the team-based intervention will aid replication, implementation and monitoring of fidelity in other paediatric intensive care units.

KEYWORDS
child, complex intervention, intensive care, mechanical ventilation, paediatric, neonate

1 | INTRODUCTION

The Sedation and Weaning in Children (SANDWICH) trial was the largest recruiting trial in critically ill children ever undertaken, with over 10 000 children enrolled.[1] The stepped wedge cluster trial and process evaluation (PE) evaluated a team-based approach, with greater involvement of nurses in assessing and weaning children from sedation and mechanical ventilation, with the aim of reducing the duration of invasive ventilation.[2] The trial, conducted between 2017 and 2019 in 18 UK paediatric intensive care units (PICUs), reported a significantly reduced time to successful extubation for all children by around 7 h (6 h in a prolonged ventilation cohort) with no significant increase in adverse events.[1] This paper describes the SANDWICH intervention using a recognized framework (Template for Intervention Description and Replication [TIDieR]) for detailing complex health care interventions,[3,4] allowing critical care nurses to gain a greater understanding of the intervention applied in this trial. The TIDieR provides a 12-point checklist and guide and was developed as an extension to the Consolidated Standards of Reporting Trials (CONSORT) 2010 reporting guidance to improve intervention reporting in clinical trials.[3,5]

The SANDWICH trial was complex in that it incorporated multiple components and involved a change in practice for health care professionals in paediatric intensive care. The key elements of this intervention were: patient-relevant sedation plans linked to regular assessment using the validated COMFORT sedation assessment tool (a tool that quantifies clinical parameters indicating a critically ill child's level of distress[6]); regular assessment of ventilation parameters with a higher than usual trigger for undertaking an extubation readiness test; and progression to a spontaneous breathing trial (SBT) on low levels of respiratory support to test extubation readiness. The comparison was 'usual' PICU care in the United Kingdom: this was primarily medically led by PICU intensivists with little involvement of junior medical or nursing staff.[7] During the 20-month stepped wedge cluster randomized trial, PICUs were sequentially randomized at 4-week intervals to cross over from usual care to the SANDWICH intervention (Figure 1). Prior to cross over, there was an 8-week training period on the trial intervention to facilitate practice change for all PICU clinical staff. This paper reports the detail around the trial intervention using the TIDieR in a way that will allow both replication of the study and effective implementation of the intervention into PICUs.

What is Known About the Topic

- Weaning from mechanical ventilation is a highly complex process
- Complex behaviour change interventions are not well described, and this hampers reproduction and subsequent implementation of successful interventions
- The TIDieR checklist enables more precise reporting of complex interventions used in trials

What this Paper Adds

- A detailed and explicit description of the behaviour change intervention used in the SANDWICH trial of weaning children from mechanical ventilation
- An example of how to use the TIDieR checklist to provide greater clarity in describing functional components of a complex intervention

2 | DESCRIPTION OF SANDWICH INTERVENTION ACCORDING TO THE TIDieR CHECKLIST

2.1 | Item 1: Brief name

SANDWICH intervention.

2.2 | Item 2: rationale, theory or goal of the elements essential to the intervention

Weaning from invasive mechanical ventilation (IMV) is a complex process involving several stages: recognition that the child is ready to begin the weaning process; steps to reduce ventilation while optimizing sedation in order not to induce distress; and removing the endotracheal tube.[8] Delay at any stage can prolong the duration of IMV, therefore an intervention targeted at assisting clinicians to safely expedite this process will minimize the risks associated with IMV.[8]

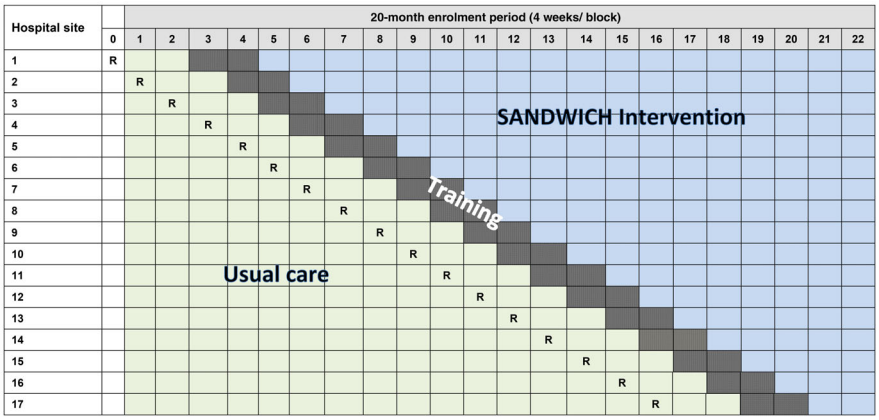

FIGURE 1 Schematic for the SANDWICH stepped wedge, cluster randomized trial. Twenty-month trial delivered in 22 4-week blocks. One hospital site sequentially randomized [R] from block 0 to 16. One hospital site had two PICUs. Following training, each PICU transitioned to delivering the SANDWICH intervention. PICU, paediatric intensive care unit; SANDWICH, Sedation and Weaning in Children

The judgement and experience of clinicians are critical in guiding weaning from ventilation; however, as data from a feasibility study on paediatric usual practice showed, there was wide variation both in sedation and ventilator weaning practices and junior staff were rarely involved in the process.[7]

Despite strong evidence that coordinated care improves quality and saves money in health care, it depends on the approach used, how well it is implemented and in a particular environment.[9] Within PICU, the dynamic, complex and time-pressured environment necessitates a team approach to care delivery that requires effective communication and collaboration.[10] Various intensive care unit (ICU) studies have reported associations between rates of high inter-professional collaboration and patient mortality[10–12]; and improved clinician-to-clinician communication with reductions in ICU length of stay.[12,13] A team-led approach that maximizes engagement of all staff in early recognition of readiness and preparation for weaning ventilation could potentially reduce the duration of IMV and PICU length of stay. This in turn would allow maximum utilization of PICU beds, frequently a scarce resource in the United Kingdom. As 67% of nurses employed in UK PICUs are staff nurses (many junior) (in the United Kingdom, a Band 5), this would greatly maximize nursing contribution to the weaning process.[14] Qualitative research indicates that inter-professional collaboration and communication are major factors that influence weaning and adoption of weaning protocols.[15]

In ventilator weaning, there is strong evidence that mechanically ventilated patients should have their readiness to wean assessed daily and weaning should be initiated on the basis of objective clinical criteria, rather than the clinician's subjective impression.[16] Weaning generally involves either a period of spontaneous breathing (SBT), or a gradual reduction in the amount of ventilator support. The SBT was developed to identify patients who are ready to discontinue ventilation.[16] The test aims at monitoring signs of respiratory muscle fatigue while the patient is still intubated. Adult studies have shown that most patients do not need gradual weaning; when assessed with a daily evaluation and SBT, approximately 75% of patients are ready to be extubated.[17] Early paediatric studies have shown similar results.[18,19] However, although the introduction of weaning protocols has resulted in decreased ventilation times in adult patients,[20] at the time of designing the SANDWICH trial, only one study ($n = 260$) had shown that a protocol of daily screening with SBT benefited the paediatric population.[21]

In randomized trials of sedation weaning, a Cochrane systematic review in adults (2 single-centre studies, 633 participants)[20] and a subsequent multi-centre paediatric cluster randomized trial in 31 PICUs (2449 children) showed no clear evidence that protocol-directed sedation is more effective than non-protocolised care.[22] However, a systematic review of observational studies (6 studies, 2011 children) reported a beneficial association between the use of sedation guidelines and reduced PICU length of stay, frequency of unplanned extubation, prevalence of patients experiencing drug withdrawal, total doses delivered and duration of sedation.[23]

The weaning of sedative drugs and the ability to wean from mechanical ventilation are interconnected concepts: the child cannot wean from ventilation if they are too sedated and fail to 'breathe' spontaneously. Nurses are the only constant presence at the child's bedside and are in control of sedation level assessment and the titration of these drugs, thus they are in an ideal position to assess the child's readiness to wean from the ventilator. In the SANDWICH intervention, these components were bundled together, which was unique in comparison to other study interventions. The model outlined in Figure 2 shows each component of this complex intervention and the proposed mechanisms of action to achieve the intervention goal.

2.3 | Item 3: Materials used in the intervention (those provided to participants or used in intervention delivery or training of providers)

The 8-week training period involved a multi-faceted approach to education for all clinical staff involved in patient care. A purposively developed SANDWICH course (developed by the implementation manager and clinical experts within the trial team) delivered training and assessment of intervention components and the underpinning clinical evidence supporting protocolised weaning.

The courses consisted of six short online learning modules (four modules focusing on the core components of the intervention and two additional sedation and pharmacology modules) hosted by

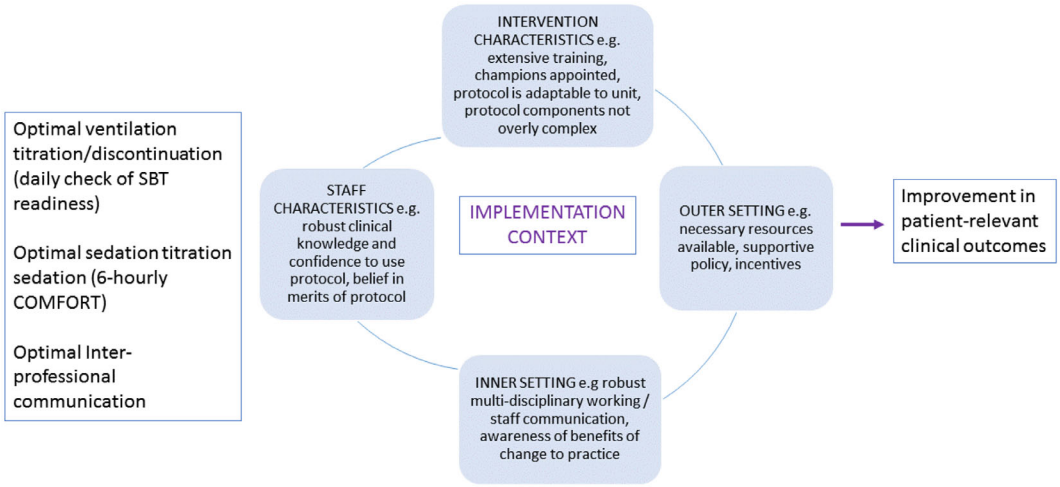

FIGURE 2 Theoretical model of the proposed mechanism of action of the SANDWICH intervention components. SANDWICH, Sedation and Weaning in Children

LearnPro (https://learnpro.co.uk/products/lms/learning-management-system),[24] a learning management system used across the UK National Health Service (NHS) that incorporates compliance monitoring. This learning system records delivery, course uptake by staff member by unit and the participants' assessment and mark. A score of 80% was required by staff to pass and receive a certificate. Compliance measures for course completion were fed back to individual PICU trainers during the training period for monitoring purposes. The online SANDWICH course was supplemented by a 136-page Trainer's Manual with PowerPoint slides, video and online and written educational material providing detail around the components of the intervention. Additional resources were produced to provide reminders and facilitate adoption of the intervention, and these included flyers, posters, screensavers, lanyards, badges and banner message pens. All training materials, including the SANDWICH course, are freely available on the SANDWICH website at https://www.qub.ac.uk/sites/sandwich/.[25]

2.4 | Item 4: Procedures, activities and/or processes used in the intervention

The SANDWICH intervention comprised four key components:

1. Greater inter-professional collaboration was enabled by multidisciplinary ward rounds and other ad hoc rounds in reviewing sedation management including COMFORT scores (a validated sedation scale), sedative regimen and setting targets. In addition, regular review (minimum twice daily) of the child's ventilation status and setting ventilation goals. A ward round checklist was used to capture adherence to goal setting and goals were fed back to the bedside nurse.
2. Minimum 6-hourly assessment of sedation using the COMFORT score by bedside nurses. Nurses titrated sedatives according to unit policy to attain the child's COMFORT score within the agreed target range.
3. Twice-daily assessment of criteria for readiness to perform an SBT by bedside nurses. The criteria were as follows:
   a. FiO_2 ≤0.45
   b. SpO_2 ≥95% (or as appropriate to underlying condition)
   c. PEEP ≤8 cmH_2O
   d. PIP ≤22 cmH_2O
   e. Cough present
4. When readiness for SBT criteria was met, nurses stopped or reduced sedation and informed an appropriately trained nurse or doctor who initiated an SBT with a positive end expiratory pressure (PEEP) of 5 cmH_2O and a pressure support of 5 cmH_2O (above PEEP). During the SBT, the child was monitored for signs of respiratory distress indicated by a 20% increase in heart or respiratory rate (above pre-SBT rates), signs of increased work of breathing, or a SpO_2 <92% or increase in FiO_2 requirement. The SBT duration was a maximum of 2 h, but if the child was breathing spontaneously with no distress at any time during this period, the medical team could decide to stop and extubate.

2.5 | Item 5: Description of the expertise, background and specific training given to intervention providers

A trial implementation manager (LM) was employed during the trial to develop the training materials and resources. The implementation manager was a senior paediatric nurse with a BSc, MSc in Nursing and 11 years experience in practice and education in PICU. LM was a trial team member and worked closely with the trial investigators in developing the intervention. Her responsibilities were to visit each PICU and train additional local PICU trainers and provide training and implementation support and guidance for each participating PICU.

Each participating PICU nominated a SANDWICH nurse with two-fold responsibility: liaising with the implementation manager and training clinical staff on the intervention during the 8-week training; and liaising with the research team and collecting trial data in the usual care and intervention periods. Payment for the SANDWICH nurses' time was reimbursed to the hospital from the trial grant. Each PICU also nominated multidisciplinary SANDWICH trainers who were responsible for planning, organizing and rolling out intervention training to all clinical staff during the 8-week training period. The number of trainers varied according to the size of the PICU and included nursing and medical clinical staff of varying grades including medical consultants, advanced nurse practitioners, nursing managers and clinical nurses. Additionally, the PICUs nominated SANDWICH 'champions' to promote implementation, assist with training queries and provide local support when necessary. Champions included varying grades of medical and nursing staff in addition to pharmacists and physiotherapists.

When the PICU was randomized and informed of their cross over date, the implementation manager liaised with the SANDWICH nurse to organize training dates at the start of the training period. LM visited each PICU and provided between two and four face-to-face sessions, depending on the size of the unit, to all SANDWICH trainers and champions. The PICU designated responsibility for conducting specific intervention components to relevant staff. The bedside nurse was responsible for conducting COMFORT assessments, titration of sedation and assessment of criteria for readiness to perform an SBT. Staff responsibility for the decision to proceed to an SBT when criteria were met and the conduct of an SBT varied among PICUs depending upon their local scope of practice policy. In all PICUs, the decision to extubate consistently remained with the doctor. All clinical staff involved in the delivery of the intervention had to successfully complete the online assessment. The target for achieving staff training was 80% within the 8-week training period.

2.6 | Item 6: Mode of delivery

The mode of delivery included both online and face-to-face engagement. Online education was delivered using an established NHS online education provider (LearnPro NHS: http://sdwhtraining.learnprouk.com). Face-to-face training using the SANDWICH manual was delivered by the implementation manager to each SANDWICH training team. Training for all staff included a mix of online and face-to-face training either in seminar rooms and/or at the bedside as necessary.

2.7 | Item 7: Type(s) of location(s) where the intervention occurred, including any necessary infrastructure

The intervention was delivered in 18 UK PICUs, and these comprised general, mixed general and cardiac surgical, and standalone cardiac surgical PICUs. In UK PICUs, there are no respiratory therapists, so the three professional groups involved in weaning ventilation are nurses, doctors and sometimes respiratory physiotherapists. On average, around half of nurses working in PICUs had a specialist critical care qualification, and many units employed newly qualified nurses directly into intensive care. Medical staff generally comprise consultant intensivists, PICU trainees and various trainees from other specialty areas (paediatricians, anaesthetists, emergency department and surgical trainees). In UK PICUs, the nurse-to-patient ratio is typically 1:1 for invasively ventilated children. Table 1 provides more detail around the context in which this trial took place. This facilitated bedside nurses to be integral to the co-ordination of all aspects of the SANDWICH bundle in the clinical environment.

TABLE 1 Participating PICUs

Participating UK PICUs	*N* 18 (%)
Unit type	
General	11 (61%)
Cardiac	2 (11%)
Mixed general-cardiac	5 (28%)
Number of beds	
<8	4 (22%)
8–11	5 (28%)
12–15	2 (11%)
≥16	7 (39%)
Annual PICU admissions	
<500	4 (22%)
500–749	9 (50%)
750–999	4 (22%)
≥1000	1 (6%)
Units with a sedation assessment tool prior to trial	13 (72%)
Units with a sedation protocol prior to trial	4 (22%)
Units with a ventilation weaning policy prior to trial	3 (17%)
1:1 RN:Patient ratio for invasively ventilated children	18 (100%)

Abbreviations: PICU, paediatric intensive care unit; RN, registered nurse.

2.8 | Item 8: Number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose

The intervention was delivered daily for all invasively mechanically ventilated children over the trial intervention period.

2.9 | Item 9: Tailoring of the intervention

This was a pragmatic trial and therefore tailoring and flexibility of certain intervention components were permitted. There was flexibility in intervention delivery related to: the location of the ward round; the

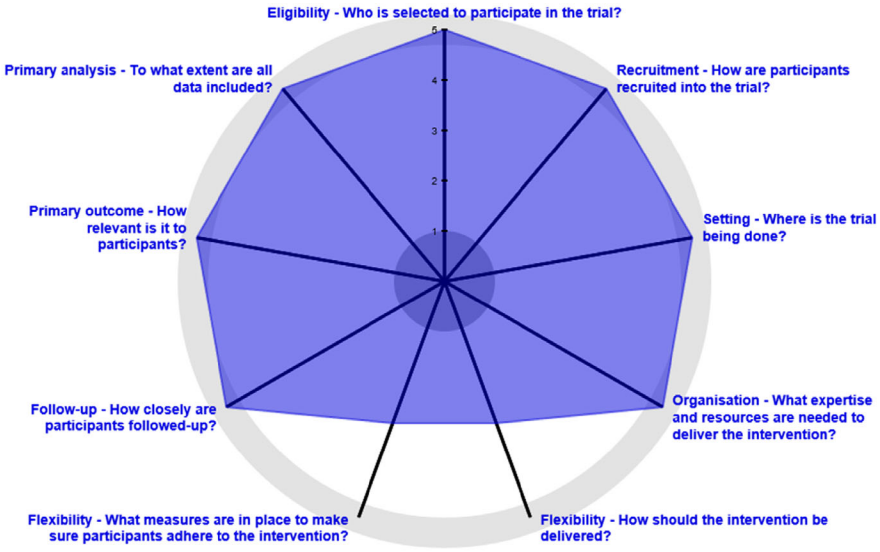

FIGURE 3 The pragmatic nature of the SANDWICH trial as shown by the PRagmatic-Explanatory Continuum Indicator Summary (PRECIS-2). SANDWICH, Sedation and Weaning in Children

number and proportion of multidisciplinary staff involved in the ward round; and assessment times for COMFORT scoring and the daily screen for SBT readiness. The intervention slotted into the usual organization of care, requiring no additional or specialist staff. Figure 3 shows the highly pragmatic nature of the trial as assessed using the PRagmatic-Explanatory Continuum Indicator Summary (PRECIS-2).[26] The nine domains of PRECIS-2 are scored from 5 (very pragmatic) to 1 (very restricted) and show that the SANDWICH intervention's scores ranged from 4 to 5. This indicates that the SANDWICH intervention can be delivered in the 'real world' and alongside usual care.

2.10 | Item 10: Modifications of the intervention during the study

No amendments were made to the intervention during the study.

2.11 | Item 11: How adherence or fidelity was assessed

The planned procedures for monitoring fidelity were as follows. Data were collected by the SANDWICH nurses daily and entered into an electronic case report form. These data included: completion of the ward round checklist on setting targets; completing a COMFORT score at least every 6 h; daily screening for readiness for SBT; time and duration of SBT (if undertaken); and reasons for non-progression to an SBT when criteria were met and non-progression to extubation when the child passed an SBT. Adherence was measured by the proportion of intervention components performed, staff trained and intervention reach (admissions screened divided by admissions of children on IMV). We fed back the intervention adherence proportions on three occasions during the trial to the SANDWICH nurse to disseminate within the PICU and promote adherence. The feedback included the unit's own adherence values alongside an anonymized unit's high adherence values for comparison. This process was used to maintain/improve fidelity. We collected feasibility and acceptably from the PE, for example, interviews with key staff during the trial and approximately 2 months following the training period.

2.12 | Item 12: Actual adherence or fidelity

Before the trial, adherence targets were set at 80% for staff trained and 75% for intervention components completed. Across all 18 PICUs, 1865 of 2247 staff were trained (median 85%, interquartile range, [IQR] 80%, 90%) and the intervention reached a high proportion of patient admissions (median 82%, IQR 77%, 89%). Adherence to the intervention components was high for sedation assessment (median 83%, IQR 82%, 91%), setting targets at ward round for sedation level (median 85%, IQR 63%, 89%) and ventilation support (median 90%, IQR 81%, 96%). Adherence was moderate for daily screening of readiness for an SBT (median 74%, IQR 66%, 83%) and lower for undertaking an SBT when criteria were met (median 40%, IQR 31%, 51%). Full details of the PE data will be reported in a separate paper.

3 | DISCUSSION

The TIDieR checklist provided a structured method for reporting all specific details of the SANDWICH intervention sufficient to allow replication. This is important because to accumulate evidence of effectiveness and the processes of practice change, it is necessary to have accurate replication. The TIDieR checklist facilitated a clear description of the intervention, how and when it was delivered; how staff were trained and detail about the training and the expertise of who was involved. Such complex interventions like SANDWICH are multi-faceted with several components and it is not always possible to know which components provide the 'active ingredient(s)'. Moreover, both the effectiveness and the replicability of such interventions are

reliant not only on how they were provided but by whom. These are important points that are frequently inadequately unreported.[27] TIDieR builds upon the 2008 extension to the CONSORT (Consolidated Standards of Reporting Trials) Statement for trials of non-pharmacological treatments to accommodate items that were frequently not reported in these interventions[28]: namely complexity of the intervention and expertise of the care provider. Thus, the more clearly the intervention components are detailed, the easier it will be to implement change successfully. Furthermore, knowing what the SANDWICH intervention components are, and how they were delivered, may allow more efficient and cost-effective implementation and lead to better decisions about the non-core components that can be adapted to suit other PICUs. The culture and context of PICUs are also important factors to consider when implementing any change in behaviour practice. It is beyond the scope of this paper to prescribe what will work best, for whom and in what circumstances. However, a Cochrane systematic review of factors that impact on the use of ventilator weaning protocols has detailed this.[15]

For us, the real value of using the TIDieR checklist was as a framework to really articulate individual components of this complex trial than are often poorly described in trial reporting. In this paper, we wanted to really demonstrate to readers and researchers how to use this checklist by describing it in the context of a recently published large multi-centre RCT.

A limitation of the checklist is that some items may be open to interpretation. For example, in our case, items 3 (materials) and 6 (delivery mode) overlapped as the materials included method of delivery (online educational course). On the other hand, the process of using TIDieR initiated discussions about how the intervention components were described. This enabled the team to capture a clear picture of the reality of implementation into practice. Thus, describing an intervention using TIDieR can be useful for facilitating clinicians to reflect on what they are doing and see what part they play in delivering the intervention.

Difficulties in reporting the checklist within or alongside the main trial paper concern available word count and inclusion of supplemental material. Typically, mainstream journals in which clinical trial results are reported impose strict limits on word count, meaning that information that is not immediately required may be lost. In addition, the size and number of permitted online-only supplements are typically restricted to additional tables and figures supporting the trial results and trial protocol and amendments.

4 | CONCLUSIONS

Weaning mechanical ventilation is a complex process, dependant on many patient and organizational factors; thus, implementing behavioural change in clinical practice is a major challenge. The SANDWICH intervention tackled this challenge by providing a pragmatic team-based approach to optimizing sedation and assessing a child's readiness for liberation from mechanical ventilation. Overall, we found the TIDieR tool beneficial as it enabled a detailed description of the intervention to improve understanding and usability across multiple research sites. Such full description is important in enabling the SANDWICH intervention to be adopted in other PICUs that were not involved in the trial.

ETHICS APPROVAL

The National East Midlands research ethics committee approved the protocol (17/EM/0301) on September 12, 2017. An opt-out consent approach was used with distribution of study leaflets to parents. There was no requirement for written or oral informed consent. Trial registration: isrctn.org Identifier ISRCTN16998143.

AUTHOR CONTRIBUTIONS

All authors were involved in the development and conduct of this trial and the intervention development. All authors have read and contributed to this manuscript.

ACKNOWLEDGEMENTS

The authors acknowledge all the staff and PICUs who participated in the trial and all the families and children involved across the 18 UK PICUs.

The principal investigator and research nurses for each of the 18 sites: Nazima Pathan, MD; Deborah White, RN; Esther Daubney, RN; Ben Lakin, MD; Laura Rad, RN; Dawn Jones, RN; Laura O'Malley, RN; Sean Cuddihy, RN; Alex Taylor, RN; Jaspreet Sodhi, RN; Katie Price, RN; Rachel Loughead, RN; Helen Winmill, RN; Mireia Garcia Cusco, MD; Sarah Mogan, RN; Kate Baptiste, RN; Helen Marley, RN; Hope Lacy, RN; Chris MacKerness, RN; Rachel Agbecko, MD; Angela Woodhall, RN; Lindsay Cooper, RN; Dawn Metcalfe, Ms; Suzan Kakat, MD; Lauran O'Neill, RN; Holly Belfield, RN; Ana Luisa Tomas, RN; Francesca Standing, RN; Yvonne Leonard, RN; Helen Vander-Johnson, RN; Deirdre O'Shea, MD; Kirsten Beadon, RN; Nicola Howell, RN; Pam D'Silva, MD; Sam Archer, RN; Stacey Bedford, RN; Jo Lumsden, MD; Louise Turner, RN; Heather Rostron, RN; Donna Ellis, RN; Sarah Hanson, RN; Emily Scriven, RN; Julie Armstrong, RN; Siva Oruganti, MD; Iona Buchanan, RN; Claire Speirs, RN; Julie Richardson, MD; Caroline McCluskey, RN; Becky Simpson, RN; Carolyn Green, RN; Rachel Anderson, RN; Angela Aramburo, MD; Helena Sampaio, RN; Laura Alcantara, RN; Laura Tous, RN; John Alexander, MD; Penny Percical, RN; Claire Sidley, RN; Rum Thomas, MD; Amy Pickard, RN; Jade Bryant, RN; Samanatha Burns, RN; John Pappachan, MD; Christie Mellish, RN; Soumendu Manna, MD; Elena Maccacari, RN; Joana Queiroz, RN; Sian Butler, RN; David Inwald, MD; Thomas Bycroft, MD; Sarah Darnell, RN.

FUNDING INFORMATION

The SANDWICH trial was funded by the NIHR HTA (Ref: 15/104/01) and supported by the UK Paediatric Critical Care Society Study Group. The views expressed in this article are those of the authors and do not necessarily represent the National Health Service, the National Institute for Health Research, or the Department of Health.

CONFLICT OF INTEREST

None of the authors have any conflicts of interest to declare. McAuley reports a grant from the NIHR HTA programme for the conduct of the study.

ORCID

Lyvonne N. Tume https://orcid.org/0000-0002-2547-8209
Bronagh Blackwood https://orcid.org/0000-0002-4583-5381
Daniel F. McAuley https://orcid.org/0000-0002-3283-1947
Mark J. Peters https://orcid.org/0000-0003-3653-4808
Timothy Simon Walsh https://orcid.org/0000-0002-3590-8540
Lisa McIlmurray https://orcid.org/0000-0001-6376-468X

REFERENCES

1. Blackwood B, Tume LN, Morris K, et al. McAuley D for the SANDWICH investigators*sedation and ventilator weaning in children: a stepped-wedge cluster trial. *JAMA*. 2021;5:401-410.
2. Blackwood B, Agus A, Boyle R, et al. Sedation AND weaning in CHildren (SANDWICH): protocol for a cluster randomised stepped wedge trial. *BMJ Open*. 2019. doi:10.1136/bmjopen-2019-031630
3. Hoffman TC, Glasziou PP, Milne R, et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. *BMJ*. 2014;348:g1687. doi:10.1136/bmj.g1687
4. Skivington K, Matthews L, Simpson SA, et al. A new framework for developing and evaluating complex interventions: update of the Medical Research Council guidance. *BMJ*. 2021;374:2061.
5. Schulz KF, Altman DG, Moher D. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. *BMC Med*. 2010;8:18. doi:10.1186/1741-7015-8-18
6. Boerlage A, Ista E, Duivenvoorden H, Wildt S, Tibboel D, van Dijk M. The COMFORT behavior scale detects clinically meaningful effects of analgesic and sedative treatment. *Eur J Pain*. 2014;19:473-479. doi:10.1002/ejp.569
7. Blackwood B, Tume L. The implausibility of 'usual care' in an open system: sedation and weaning practices in paediatric intensive care units (PICUs) in the United Kingdom (UK). *Trials*. 2015;16:325.
8. Blackwood B, Murray M, Chisakuta A, Cardwell CR, O'Halloran P. Protocolized versus non-protocolized weaning for reducing the duration of invasive mechanical ventilation in critically ill paediatric patients. *Cochrane Database Syst Rev*. 2013;Issue 7:CD009082. doi:10.1002/14651858.CD009082.pub
9. Øvretveit J. *Does Clinical Coordination Improve Quality and Save Money? A Review of the Evidence*. The Health Foundation; 2011. http://www.health.org.uk/publication/does-clinical-coordination-improve-quality-and-save-money#sthash.dPaZWWdG.dpuf
10. Rose L. Interprofessional collaboration in the ICU: how to define? *Nurs Crit Care*. 2011;16:5-10.
11. Knaus WA, Draper EA, Wagner DP, Zimmerman JE. An evaluation of outcome from intensive care in major medical centres. *Ann Intern Med*. 1986;104:410-418.
12. Wheelan S, Burchill C, Tilin F. The link between teamwork and patients' outcomes in intensive care units. *Am J Crit Care*. 2003;12:527-534.
13. Pronovost P, Needham D, Berenholtz S, et al. An intervention to decrease catheter-related bloodstream infections in the ICU. *N Engl J Med*. 2006;355:2725-2732.
14. PICANet. 2015 Annual report. Accessed January 24, 2016.http://www.picanet.org.uk/Audit/Annual-Reporting/PICANet_2015_Annual_Report_Summary.pdf. 2015.
15. Jordan J, Rose L, Dainty KN, Noyes J, Blackwood B. Factors that impact on the use of mechanical ventilation weaning protocols in critically ill adults and children: a qualitative evidence-synthesis. *Cochrane Database Syst Rev*. 2013;10(10):CD011812.
16. Hess DR, MacIntyre NR. Ventilator discontinuation: why are we still weaning? *Am J Respir Crit Care Med*. 2011;184:392-394.
17. Frutos-Vivar F, Esteban A. Our paper 20 years later: how has withdrawal from mechanical ventilation changed? *Intensive Care Med*. 2014;40:1449-1459.
18. Farias JA, Alia I, Esteban A, Golubicki AN, Olazarri FA. Weaning from mechanical ventilation in pediatric intensive care patients. *Intensive Care Med*. 1998;24:1070-1075.
19. Farias JA, Retta A, Alia I, et al. A comparison of two methods to perform a breathing trial before extubation in pediatric intensive care patients. *Intensive Care Med*. 2001;27:1649-1654.
20. Blackwood B, Burns KE, Cardwell CR, O'Halloran P. Protocolized versus non-protocolized weaning for reducing the duration of mechanical ventilation in critically ill adult patients. *Cochrane Database Syst Rev*. 2014;11:Cd006904.
21. Foronda FK, Troster EJ, Farias JA, et al. The impact of daily evaluation and spontaneous breathing test on the duration of pediatric mechanical ventilation: a randomized controlled trial. *Crit Care Med*. 2011;39:2526-2533.
22. Curley MA, Wypij D, Watson RS, et al. Protocolized sedation vs usual care in pediatric patients mechanically ventilated for acute respiratory failure: a randomized clinical trial. *JAMA*. 2015;313:379-389.
23. Poh YN, Poh PF, Buang SN, Lee JH. Sedation guidelines, protocols, and algorithms in PICUs: a systematic review. *Pediatr Crit Care Med*. 2014;15:885-892.
24. LMS. The NHS & social care e-learning management system for compliance and auditing. Accessed November 2021. https://learnpro.co.uk/products/lms/learning-management-system.
25. QUB. The SANDWICH trial webiste, hosted by Queens University Belfats. Accessed November 2022. https://www.qub.ac.uk/sites/sandwich/.
26. Loudon K, Treweek S, Sullivan F, Donnan P, Thorpe KE, Zwarenstein M. The PRECIS-2 tool: designing trials that are fit for purpose. *BMJ*. 2015;350:h2147. doi:10.1136/bmj.h2147
27. Moher D, Schulz KF, Altman DG. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomised trials. *Lancet*. 2001;357:1191-1194.
28. Boutron I, Moher D, Altman D, Schulz KF, Ravaud P, CONSORT Group*. Methods and processes of the CONSORT group: example of an extension for trials assessing nonpharmacologic treatments. *Ann Int Med*. 2008;148(4):W-60. doi:10.7326/0003-4819-148-4-200802190-00008-w1

How to cite this article: Tume LN, Blackwood B, McAuley DF, et al. Using the TIDieR checklist to describe the intervention of the Sedation and Weaning in Children (SANDWICH) trial. *Nurs Crit Care*. 2022;1-8. doi:10.1111/nicc.12810