Original Manuscript

Nursing Ethics
1–19

10.1177/0969733018795207
journals.sagepub.com/home/nej

The development of a clinical policy ethics assessment tool

Diego José Garcia-Capilla
University of Murcia, Spain

Alfonso Rubio-Navarro
University Hospitals of Leicester NHS Trust, UK

Maria José Torralba-Madrid
University of Murcia, Spain

Jane Rutty
De Montfort University, UK

Abstract

Introduction: Clinical policies control several aspects of clinical practice, including individual treatment and care, resource management and healthcare professionals' etiquette. This article presents Clinical Policy Ethics Assessment Tool, an ethical assessment tool for clinical policies that could be used not only by clinical ethics committees but also by policy committees or other relevant groups.

Aim: The aim of this study was to find or create a tool to identify ethical issues and/or confirm ethical validity in nursing practice policies, protocols and guidelines.

Methodology: The development of Clinical Policy Ethics Assessment Tool involved first a literature review, followed by modification of the Research Protocol Ethics Assessment Tool, which was created to identify research protocols' ethical issues, and finally, a trial of Clinical Policy Ethics Assessment Tool to ensure its reliability and validity.

Ethical consideration: The policies analysed trialling Clinical Policy Ethics Assessment Tool were in the public domain and did not contain any confidential information. Despite that, Clinical Policy Ethics Assessment Tool also had the approval of a research ethics committee.

Results: Research Protocol Ethics Assessment Tool was chosen as the template for a Clinical Policy Ethics Assessment Tool, to which several modifications were added to adapt it to work within a nursing practice context. Clinical Policy Ethics Assessment Tool was tested twice, which resulted in a general test–retest reliability coefficient = 0.86, $r = 0.84$, $\alpha_1 = 0.817$, $\alpha_2 = 0.824$ and interclass correlation coefficient = 0.874.

Discussion: Contemporary nursing practice in a developed country is often ruled by clinical policies. The use of Clinical Policy Ethics Assessment Tool could confirm the ethical validity of those clinical practice policies, impacting on nurses' education, values and quality of care.

Conclusion: Clinical Policy Ethics Assessment Tool has the potential to detect ethical issues and facilitate the correction and improvement of clinical policies and guidelines in a structured way. This is especially so as it has shown reliability in detecting issues in clinical policies involving human participants and in encouraging policymakers to consider common ethical dilemmas in nursing practice.

Corresponding author: Alfonso Rubio-Navarro, Emergency Department, University Hospitals of Leicester NHS Trust, Leicester LE1 5WW, UK.
Email: alfonso.rubio.navarro@gmail.com

Keywords
Assessment, ethics, guideline, policy, practice, tool

Introduction

From administering inadequate medication to ignoring patients' decisions in regards to their own health, ethical issues that are not tackled can have a significant impact on the public's well-being. However, despite the impact that this could have, there are differences between how ethical issues are handled in clinical practice[1] and in research studies.[2,3]

To be able to offer treatment or care as part of a research trial in England, the Chief Investigator needs to comply with strict guidelines and policies from the National Health Service (NHS) Health Research Authority,[4] the Medicines and Healthcare Products Regulatory Agency[5] and/or the sponsor's research ethics committee (REC). To comply with these guidelines, the research documentation must include an adequate informed consent for each participant, every adverse event or reaction documented and an explanation for any suspicion against the transparency of the research trial or the researchers' credibility. This documentation must be stored under specific conditions to avoid confidentiality breaches and must only be accessible to the researchers of that specific study and inspectors for different institutions.[6]

The procedure necessary to run a research project could be considered tedious, but it has several fundamental benefits. It does not only hold malicious or persuaded researchers accountable but also ensures adequate research standards, promotion in the search of knowledge and truth and help to build public support, guaranteeing that it should be beneficial to the English population as a whole, not only to the participants. However, despite the potential benefits of a strict and national monitoring structure, clinical policies do not follow these standards.[7]

In England, clinical policies and guidelines are produced and monitored by NHS Trusts that apply them to ensure a safe clinical practice, which results in the creation of one or more policies per clinical issue per Trust, possibly obstructing a standardised national practice.[8] Moreover, if a policy has internal ethical issues or conflicts with applicable regulations deriving in an ethical dilemma, the nurse has to choose between being held accountable for breaching the policy or the applicable regulation, which can cause errors, legal problems and moral distress.[9]

The systematic review of Schildmann et al.[10] exemplified the need for ethical case interventions in clinical practice, since it indicated the lack of strong research and training around it. However, it analysed individual case interventions instead of wider policy implications, so there is no guidance to create a clinical policy ethical assessment tool.

Furthermore, individuals who create and update these policies need to be experts in the policy's relevant field, but they do not need to have any knowledge about ethics or how ethical issues could arise or be managed.[11] Furthermore, policies and guidelines are not always approved by a clinical ethics committee (CEC)[12] but by another committee that is not bound to perform an ethical assessment.[13] This context facilitates ignoring some ethical-based concepts like informed consent, confidentiality or fair resource allocation, which could affect the service user negatively.[14]

To facilitate a structured ethical assessment of the clinical decision-making process, CECs apply the Ethox structured approach, a tool that divides ethical decision-making into five distinguishable steps. However, this is only useful in a specific situation and when there is time to analyse it.[15] In the vast majority of clinical practice situations, policies and guidelines are followed as the gold standard, so assessing and fixing policies before they regulate practice is essential to ensure safe and ethically sound nursing clinical practice.[16] To prevent ethical inconsistencies in clinical policies and the problems they cause in nursing practice, this article presents the Clinical Policy Ethics Assessment Tool (CliPEAT; see Appendix 1). This

ethical assessment tool designed for clinical policies and guidelines could be used not only by CECs but also by policy and guideline committees or other relevant groups.

CliPEAT was created as part of a doctorate research study, since an ethical assessment tool that was able to analyse clinical policies was necessary to progress that research forward, as no suitable tools were found after a literature review. This article will show the potential use as of CliPEAT a tool by CECs, and other committees could be beneficial beyond its academic use.

Aim

The aim of this study was to find or create a tool to identify ethical issues and/or confirm ethical validity in nursing practice policies, protocols and guidelines.

Ethical considerations

The policies analysed trialling CliPEAT were in the public domain. There were official policies and guidelines from an NHS Trust and did not contain any confidential information. In addition to that, CliPEAT only assessed policies and guidelines, so it was not related to animal or human research. Due to this, the creation and trial of CliPEAT did not have any major ethical aspects that needed to be addressed.

Nevertheless, CliPEAT was part of a bigger project that included reflections on practice and semi-structured interviews with nurses, which was considered human research and doubts about data protection therefore was understandable. Hence, the creation and trial of CliPEAT had the approval of De Montfort University Faculty of Health and Life Sciences REC, the Health Research Authority and University Hospitals of Leicester Research and Innovation Department.

Methodology

The development of CliPEAT involved (1) a literature review, (2) the analysis of the assessment tools found and their potential for clinical policy ethical analysis, (3) the creation of an ethical assessment tool able to analyse clinical practice policies based on the modification of the Roberts Research Protocol Ethics Assessment Tool (RePEAT; a checklist of common ethical issues in research protocols) and (4) a trial of the modified tool following the methods as described by Giesen et al.[17]

The conceptual framework for this project was based on a working hypothesis linked to participant observation during personal nursing practice, which indicated that several ethical issues in nursing practice could be avoided if the policies that regulate it were ethically scrutinised, as it has happened in the research field since the 1970s. Since no adequate tools were found to aid that scrutiny, the team involved in this study used their theoretical and practical knowledge to modify a validated tool, by asking for expert opinion on their results and then trialled it with policies that regulate nursing practice.

Literature review

PubMed, SciELO, CUIDEN and the Cochrane Library were searched to identify healthcare sciences published journal articles in English and Spanish from January 1995 to June 2018. The keywords used were clinical, Ethics, protocol, tool, clinical, policy, assessment and guideline.

The search terms included were: [1] clinical [All Fields] AND Ethics [All Fields] AND protocol [All Fields] AND tool [All Fields], [2] clinical [All Fields] AND policy [All Fields] AND Ethics [All Fields] AND assessment [All Fields] and [3] clinical [All Fields] AND guideline [All Fields] AND Ethics [All Fields] AND assessment, both in English and Spanish.

The inclusion criteria were journal articles that included an ethical assessment tool to analyse clinical practice policies or information related to the creation of one. The exclusion criteria were articles that did not consider ethical assessment as the main theme, articles that included assessment tools that did not assess ethical issues or articles which full text could not be recovered.

This literature review, which followed the O'Gorman et al.'s[18] definition, was not a systematic review, since it did not consider grey literature and focus on the ability of the tool of guiding ethical policy analysis, even though the quality of the articles was also considered. It was performed by one PhD student supported by two professors.

RePEAT modification

A working model of an ethical assessment tool for clinical practice guidelines was found in the literature review, AGREE-Ethics.[19] However, its implementation in relation to nursing practice could be considered inadequate on its own due to the lack of some fundamental ethical questions. Even if it included important items like scope and purpose, stakeholder involvement and applicability, it did not directly tackle recurrent ethical issues in nursing practice (e.g. confidentiality breaches, misuse or lack of informed consent, and accountability dilemmas). Consequently, the next available option to be able to analyse the ethical validity of clinical practice policies was the modification of a validated tool for research protocols: Roberts RePEAT.

To adapt a research protocol assessment tool into a clinical policy assessment tool, all items within RePEAT needed to be either modified or eliminated to adjust it to the context of clinical practice. Moreover, additional items were generated using an inductive approach based on nursing practice experience to allow the assessor to include not only ethical issues but also legal and professional issues that are connected with the ethical validity of a policy. This modification was undertaken using a qualitative method in which a panel of five experts and a clinically active nurse modified 18 RePEAT's items and generated seven new ones so they can be used to assess common ethical issues in nursing practice. Successively, six items that were not applicable were eliminated.

The modification of RePEAT to create CliPEAT was performed mainly by a clinically active nurse who was also the PhD student who performed the literature review, a Nursing Professor and a Philosophy Professor. Further individual consultations with another three experts in nursing sciences were made to refine the tool regarding its items and its structure.

CliPEAT trial

To ensure the reliability and validity of CliPEAT, it was trialled on 54 policies and guidelines applicable to nursing practice at the Leicester Royal Infirmary Emergency Department (see Appendix 2). These policies and guidelines were chosen using purposeful sampling based on their regular application in nursing practice and their possible ethical implications in practice, since policies that directly or indirectly affect patient care can arise to a number of different ethical issues if they are not constructed appropriately.

After choosing the policies, they were divided into three groups: (1) clinical techniques and competencies, (2) general clinical practice and (3) nursing resources management. This division was designed to structure the testing process and establish the scope that CliPEAT could attain.

These three groups of policies were assessed separately with CliPEAT by the same researcher twice in an interval of 14 days between assessments, allowing the verification of its reliability when comparing both results. Furthermore, expert review and analysis of the qualitative survey material were employed to strengthen CliPEAT's validity and reliability.

Results

Literature review findings

Using the keywords listed before, 1427 articles were found in the literature review. However, after reading their content, only one of them contained an ethical assessment tool applicable to clinical policies. Unfortunately, it did not consider current ethical issues in nursing practice. Nevertheless, 25 articles that have ethical elements of clinical policies or research protocols as part of their purpose and/or content were found. These 25 articles had the potential of supporting the creation of a clinical policy ethical assessment tool, even though only three of them included research policy assessment tools (see Figure 1).

The focus on policies' ethical validity at institutional level with the boom of health technology assessment research shows the lack of research on policies' ethical validity at individual level.[20–27] In regards to conflicts of interests, several articles explain that sometimes not only researchers have them but also policymakers can act maliciously or negligently in regards to them.[28–32]

Informed consent is a topic that is closely related to both research and clinical practice, since articles focusing on informed consent quality[33–36] and decisional capacity[37–39] can be applied to both research and clinical practice. Moreover, Knüppel et al.[40] and Landau[41] reinforce the dangers of coercive or incomplete clinical guidelines, in which ethical issues are ignored or misused.

Finally, three research protocol ethical assessment tools were found: the Public Health Ontario (PHO) Risk Screening Tool,[42] the Ethics Tool Kit[43] and RePEAT.[44] To choose one that would be the best base structure for the creation of a CliPEAT, all of them were compared in relation to their purpose, their item structure and their items' applicability to clinical policies that regulate aspects of nursing practice such as patient care or nursing techniques (see Table 1).

The PHO Risk Screening Tool was created as a guide to establish the level of ethics scrutiny required for a specific protocol. Its items have a variable number of closed-ended responses, hindering quantitative analysis of them. In regards to how its items could be applicable to clinical policies, 35% of them needed major modifications and 60% of them were not applicable, so modifying it to analyse clinical policies would leave 5% of its original items, reducing its original validity.

The Ethics Tool Kit was focussed on addressing a wide range of ethical issues in the design of research protocols, offering a standardised format to document them. It used open-ended questions, encouraging complex answers, but with its high number of questions it is time-consuming and requires qualitative analysis. In addition, 72% of its items cannot be used to analyse clinical policies, while only 9% of them can be serviceable without major modifications.

RePEAT's initial purpose was to facilitate researchers with a tool to assess important ethical elements in their research protocols. Its closed-ended questions have four pre-established answers, the same for every item. RePEAT's items cover many of the ethical topics commonly present in clinical practice, since 67% of its items could be applied to clinical policies with minor nomenclature changes, adding a further 9% if two of the items had major modifications. Furthermore, Li et al.,[43] the creators of the Ethics Tool Kit, indicated in their article that RePEAT was a relevant tool that provided guidance for drafting and/or reviewing the ethical elements of a clinical trial protocol.

Due to the evidence gathered, RePEAT was chosen to be the base of a new tool to analyse clinical policies. This decision was made considering its consistent responses, its possible use by both researchers and policymakers and its high applicability to clinical policies compared to the other two options. Even if the Ethics Tool Kit was a more complete and complex tool to analyse research protocols, its high specialisation impede its use as the backbone of a new tool aimed at clinical policies.

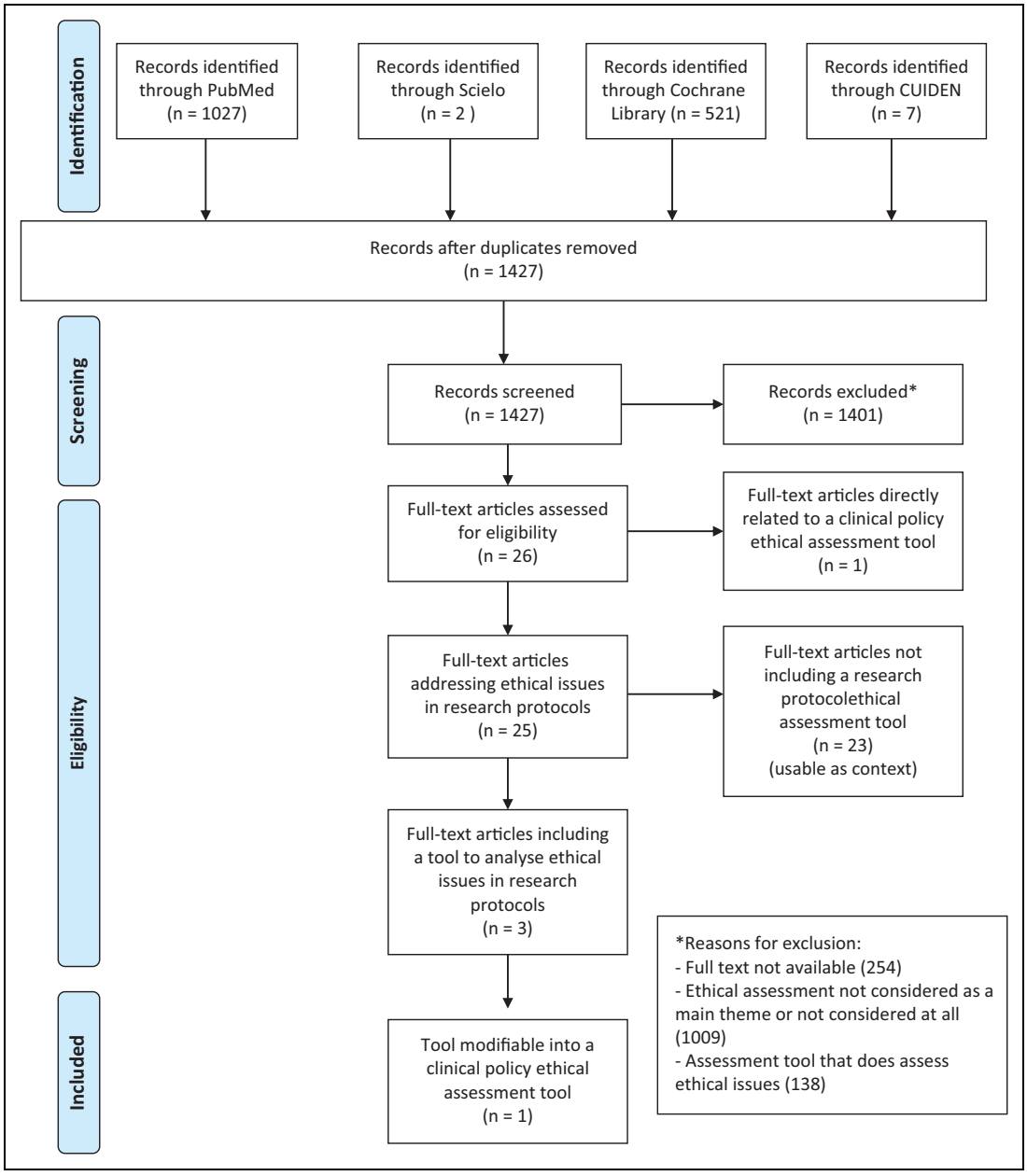

Figure 1. Literature review's flow diagram.

Moreover, the different English professional ethical frameworks and codes of conduct (e.g. The Code for Nurses and Midwives by the Nursing and Midwifery Council or The General Medical Council Code of Conduct) were considered to avoid ethical dilemmas and enrich the content of RePEAT's modification.

Table 1. Research protocol ethical assessment tools' comparison table.

	PHO Risk Screening Tool	Ethics Tool Kit	RePEAT
Tool purpose	Establish the required level of ethics scrutiny and the next steps for ethics review	Encourage protocol authors to address ethical issues in the design of studies and document their rationale	Assure that ethically important elements are self-assessed and explicitly addressed by investigators in their work with protocols
Number of items	20	11	24
Number of questions	20	89	41
Item structure	– Closed-ended questions – Variable number of pre-established responses depending on the item – Open comments section at the end	– Open-ended questions – No pre-established responses – No comments section	– Closed-ended questions – 4 different pre-established responses – Open comments section at the end
Items applicable to clinical policies with minor modifications	– Additional notes (item 7.1)	– Potential benefits and harms (item 5)	– Scientific merit (item 1) – Protocol design (item 2) – Team expertise (item 3) – Commitment, resources and support (item 4) – Knowledgeable and respectable team (item 5) – Evidence of past misconduct (item 6) – Integrity threats (item 7) – Risk control (item 8) – Excessive risks (item 9) – Emerging symptoms (item 10) – Benefits optimization (item 11) – Confidentiality (item 12) – Documentation practices (item 20) – Other ethical problems (item 22) – Other issues (item 23) – Additional review (item 24)
Items applicable to clinical policies with major modifications	– Harm as a result of reporting results (item 2.2) – Information disclosure (item 2.4) – Use of informed consent (item 3.2)	– Informed consent (item 6) – Study-related injury (item 11)	– Informed consent (item 17) – Diminished decisional capacity (item 18)

(continued)

Table 1. (continued)

	PHO Risk Screening Tool	Ethics Tool Kit	RePEAT
	– Access to non-publicly available data (item 4.2) – Analysis of non-publicly available documents (item 4.6) – Use of personal information (item 5.1) – Collection of personal information (item 5.2)		
Items not applicable to clinical policies	– Research Ethics Review Board review (item 1.1) – Report of vulnerable groups data (item 2.1) – Results that subject want to know (item 2.3) – Recruitment (item 3.1) – Subject deception during consent (item 3.3) – Data collection (item 4.1) – Human tissue research (item 4.3) – Direct observation research (item 4.4) – Access to private property (item 4.5) – Group-identifiable data (item 5.3) – Linkage of two or more data sources (item 5.4) – Commercial interests (item 6.1)	– Addressing relevant question (item 1) – Choice of control and standard of care (item 2) – Choice of study design (item 3) – Choice of subject population (item 4) – Community engagement (item 7) – Return of research results and management of incidental findings (item 8) – Post-trial access (item 9) – Payment for participation (item 10)	– Recruitment of vulnerable population (item 13) – Understudied populations (item 14) – Non-coercive recruitment process (item 15) – Research benefits (item 16) – Incentives (item 19) – Subject debriefing (item 21)

RePEAT: Research Protocol Ethics Assessment Tool.

CliPEAT as a modification of RePEAT

CliPEAT is a 25-item tool based on the structure of RePEAT, but even with a favourable tool that already covered some clinical practice ethical issues several item modifications were necessary to ensure that CliPEAT could analyse all ethically sensitive aspects of a clinical policy. Every item had minor nomenclature but some of them needed more extensive changes to accommodate them into the context of clinical practice while others had to be created specifically for CliPEAT:

- Design issues (items 1 and 2): Minor changes were applied because both research protocols and clinical policies needed to be designed around a specific subject. These items were focussed on identifying the scope of the policy in clinical practice;
- Expertise, commitment and integrity issues (items 3–7): Minor changes were applied because policymaker teams had to be scrutinised similarly when they created research protocols and clinical policies. These items established the qualities expected of an adequate team of policymakers to ensure a non-biased evidence-based clinical policy;
- Risks and benefits (items 8–11): Minors changes were applied because risk assessment and benefit boosting were concepts used in both research protocols and clinical policies. These items facilitated risk management and side-effect controls of practice that a clinical policy regulates;
- Confidentiality (item 12): Minors changes were applied because management of confidential data is a well-known issue in both research and clinical practice. This item assured the confidential handling of data related to a clinical policy or its application in practice;
- Informed consent and decisional capacity (items 13–14): Major modifications were needed to ensure that an appropriate informed consent process was linked to the relevant clinical policies. These major modifications were as follows:
  - 13a: Some policy design questions were erased, since they were not applicable to clinical policies;
  - 13d: The concept of oral informed consent was introduced as an alternative to written informed consent in clinical practice;
  - 13e: A new item was added to acknowledge the limited resources present in clinical practice and the exceptional circumstances of an emergency when considering the option of an implied consent;
  - 14c: The examples for possible temporal diminished decisional capacity were changed, since clinical practice and research trials lessen decisional capacity in different ways;
- Professional accountability (items 15–17): A new set of items were created for CliPEAT. The purpose of which was to ensure that clinical practice regulated by a policy was performed by an adequately trained professional who followed best evidence in their practice and their applicable codes of conduct;
- Legal accountability (items 18–19): Another new set of items were created for CliPEAT. Despite being legal issues, its consequences can be ethical because conflicts between ethical values, codes of conduct, clinical policies and legal regulations can create ethical dilemmas that promote defensive practice, negligence and malpractice on professionals working under those policies;
- Other issues (items 20–25): Major modifications were necessary to ensure that clinical policies stayed updated and relevant. Therefore, an item related to the monitoring of future revisions was added. Also, the 'debriefing' item was erased, since no research findings should be produced during routine clinical practice.

Furthermore, two sections of items were erased: 'participant selection and recruitment' and 'incentives'. These items did not fit into a clinical practice context because every willing individual that has a treatable

illness in a public healthcare system needs to be treated, nullifying any selection process, and patients do not need to be convinced to be cared for, invalidating any need for incentives.

CliPEAT's items have four different qualitative scores: yes, not applicable, requires clarification and no. These were divided into two groups, acceptable (yes and not applicable) and unacceptable (requires clarification and no). All evaluative criteria (items 1–25) must receive an acceptable response for the policy to be minimally acceptable on legal and ethical grounds. Problems, as indicated by an item scoring unacceptable, should be addressed formally and should undergo re-review prior to policy approval.

CliPEAT trial results

After applying CliPEAT to 54 policies twice in an interval of 14 days between them, several psychometric measures were calculated using SPSS statistical package version 22 and Microsoft Excel 2011. Comparing both tests, the general test–retest reliability coefficient was 0.86 and Pearson's correlation coefficient was $r = 0.84$. Considering the internal consistency of the test itself, Cronbach's alpha was measured in both trial tests, giving a result of $\alpha_1 = 0.817$ for the first test and $\alpha_2 = 0.824$ on the second test.

Moreover, test–retest reliability coefficient for each group of policies was varied: 0.91 for clinical techniques and competencies policies, 0.87 for general clinical practice policies and 0.80 for nursing resources management policies.

Nonetheless, when measuring the use of the term 'not applicable' to estimate the applicability of CliPEAT to different types of policies, 100% of nursing resources management policies scored 'not applicable' in four items or more, and 90% of those policies scored 'not applicable in six items or more'. In comparison, 63% of general clinical practice policies scored 'not applicable' in four items or more, and 7.1% of clinical techniques and competencies policies scored 'not applicable' in two items.

The interclass correlation coefficient (ICC) was 0.874, with a 95% interval of 0.869–0.877. Following the flowchart from Koo and Li,[45] ICC estimates and their 95% confidence intervals were calculated based on a mean-measurement ($k = 2$), absolute-agreement, two-way mixed-effects model.

Discussion

CliPEAT's creation and trialling was a process aimed to find a tool that allows different groups and organisations to avoid several ethical issues caused by clinical policies through a structured assessment. However, since we did not find a well-established clinical policy ethical assessment corpus, to ensure its validity and reliability trial data, item modifications, limitations and implications for clinical practice have to be discussed in more depth.

Data analysis

To ensure that the modifications that allow CliPEAT to assess clinical practice policies did not alter the quality of the tool itself we needed to consider its reliability and viability using psychometrics measures, questionnaire testing and evaluation methods as described by Giesen et al.[17]

When considering test–retest reliability, both the general test–retest reliability coefficient and the Pearson's correlation coefficient were at acceptable levels, showing CliPEAT's consistent reliability with the same policies. In regards to CliPEAT's internal consistency, Cronbach's alpha was satisfactory in both tests. Furthermore, the ICC was showing a great stability level, which further supported CliPEAT's reliability. In addition to these psychometric measures, Giesen et al. indicated other techniques to develop, test and evaluate questionnaires, which increased their validity. The methods used in this case were expert review and analysis of qualitative survey material.

Item addition, subtraction and modification

Even before starting the literature review, several ethical dilemmas were identified during the 3 years of participant observation in an English emergency department, which were triggered or not prevented by different clinical policies (e.g. confidentiality breaches, accountability issues, and inadequate consent for invasive interventions). When RePEAT was chosen as a base to create CliPEAT, we had to consider how we could avoid these dilemmas without restricting efficient clinical practice, considering the differences between a controlled research environment and a dynamic clinical setting.

The first step was to specify which items needed to be adapted or expanded to be able to capture the ethical dilemmas identified in nursing clinical practice. After that items that were not applicable in a clinical setting were eliminated (e.g. participant recruitment and incentives). The remaining items were modified slightly to allow them to be applied in the analysis of clinical policies without changing the purpose of the item (e.g. changing study to policy). However, even after two revisions of the tool, we were not able to capture all the ethical aspects of nursing practice that could derive into an ethical issue.

In this stage, we asked three different experts for advice on how to perfect the tool and give it the scope needed. Considering the expert reviews and the ethical dilemmas identified in nursing practice, on the last revision we decided to add several items to CliPEAT to include limit resource distribution (item 13e), professional scope of practice (item 15), evidence-based practice (item 16), discrepancies with the applicable codes of conduct (item 17), inconsistencies with relevant legislation (item 18), vicarious accountability (item 19) and policy updates (item 21).

Strengths and limitations

CliPEAT has shown great reliability across different statistical tests, and it is applicable to different policies involving human participants. Since an inductive approach based on nursing practice has been used to create or modify the items, its straightforward structure can guide policymakers to avoid missing important issues in nursing practice that could be ignored with more generalised tools like AGREE-Ethics. It also considered concepts that have commonly been ignored in the tested policies like oral consent, emergency situations and conflicts with regulations and codes of conduct.

On the other hand, no assessment tool that can evaluate the ethical validity of nursing practice in clinical policies in depth was found during the literature review. It is complicated therefore to set a standard of how CliPEAT should work and which policies could be assessed with it.

It is considered that CliPEAT's trial would be more authoritative if there had been more than one researcher trialling the tool to allow inter-rater reliability to be measured. However, the lack of funding did not allow more than one researcher to be actively involved in developing and trialling this tool. Therefore, CliPEAT should be trialled by different people with other policies to ensure its reliability across different policies and users. Moreover, due to the sample size being 54, we could not apply conformity factor analysis reliably to check CliPEAT's validity, since more than 200 samples are recommended.[46]

CliPEAT is flexible and can be adapted to a large range of clinical policies, but its trial showed that it could not adequately analyse nursing resources management policies due to the large use of the response 'not applicable' and the fact that no ethical concerns were identified in any of these specific policies. That does not mean that the use of the response 'not applicable' is inadequate, but its overuse could indicate that the results from CliPEAT for that specific group of policies were not accurate.

Implications for nursing clinical practice

Nurses' education and experience gives nurses a set of values that allow them to provide compassionate, fair and non-maleficent care, but if they are forced to follow a set of policies that could be considered ethically poor they have two main options: deliver the care they deem appropriate and face professional and legal sanctions or follow those policies and be bound to ethically poor standards of care. Putting the livelihood of an individual at risk could push them to make questionable decisions, which would affect their patients and themselves.

In complete contrast, if clinical policies are ethically solid, they will encourage nurses to base their practice within the same values as their employer, allowing them to care for their patients safely, compassionately and fairly without any professional or legal repercussions. At the same time, those policies will discourage nurses to provide ethically poor care or selfish malpractice, since sanctions could be more important for the nurse than following their challenging values.

The use of CliPEAT could confirm the ethical validity of those clinical policies, impacting on the nurses' education, values and quality of care. Also, it will ensure that adequate nursing values do not have to compete with hospital values, boosting their confidence and diminishing their frustration and stress, which consequently could increase nurse retention. Furthermore, CliPEAT also considers and detect problems that other authors have considered to impact nursing practice greatly, such as conflict of interests,[28–32] informed consent[33–39] and incomplete guidelines.[40,41]

Conclusion

The lack of ethical oversight of clinical practice policies compared to research protocols affects both nurses and patients, greatly limiting the quality of care. CliPEAT could be used as a safety check for policymakers and healthcare professionals alike that could spot ethical issues in clinical policies, since it was created modifying RePEAT in three steps maximising its validity and reliability.

CliPEAT has the potential to detect ethical issues and facilitate the correction and improvement of clinical policies and guidelines in a structured way, since it has shown great reliability in detecting issues in clinical policies involving human participants through a straightforward layout encouraging policymakers to consider common ethical dilemmas in nursing practice. In addition, it could be used in combination with AGREE-Ethics to cover a larger spectrum of policies.

Even if further research considers CliPEAT ineffective in assessing the ethical validity of clinical policies in other hospitals, the creation of a CliPEAT does underline the concept of ethical issues in clinical policies and how it could affect nursing practice, patient safety and professional integrity. As healthcare policy research moves towards macro-level concepts like health technology assessment, we have to consider the effects of clinical practice policies at individual level to avoid both healthcare institutions and nurses basing their decisions in ethically poor policies, which could have far-reaching consequences.

Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

References

1. Shaneyfelt TM and Centor RM. Reassessment of clinical practice guidelines: go gently into that good night. *JAMA* 2009; 301: 868–869.
2. Royal College of Nursing. Research ethics: RCN guidance for nurses, https://www.rcn.org.uk/professional-development/publications/pub-003138 (2011, accessed 4 July 2018).
3. Medical Research Council. MRC ethics series – good research practice: principles and guidelines, https://mrc.ukri.org/publications/browse/good-research-practice-principles-and-guidelines/ (2012, accessed 4 July 2018).
4. NHS Health Research Authority. HRA approval, https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/hra-approval/ (2016, accessed 1 July 2018).
5. Medicines and Healthcare Products Regulatory Agency. Clinical trials for medicines: apply for authorisation in the UK, https://www.gov.uk/guidance/clinical-trials-for-medicines-apply-for-authorisation-in-the-uk (2017, accessed 1 July 2018).
6. Maloney C. Research support office SOP S-1015 UHL V7 February 2017, 2017, http://www.leicestersresearch.nhs.uk/wp-content/uploads/2017/03/SOP-S-1015-UHL-V7-Feb-17-fully-signed.pdf
7. Resnik DB. *What is ethics in research & why is it important?* National Institute of Environmental Health Sciences, https://www.niehs.nih.gov/research/resources/bioethics/whatis/index.cfm?links=false (2015, accessed 4 July 2018).
8. Som C. Sense making of clinical governance at different levels in NHS hospital trusts. *Clin Gov: Int J* 2009; 14: 98–112.
9. Kälvemark S, Höglund AT, Hansson MG, et al. Living with conflicts-ethical dilemmas and moral distress in the health care system. *Soc Sci Med* 2004; 58: 1075–1084.
10. Schildmann J, Nadolny S, Haltaufderheide J, et al. Ethical case interventions for adult patients. *Cochrane Database Syst Rev.* Epub ahead of print 19 April 2017. DOI: 10.1002/14651858.CD012636.
11. Corporate Assurance Manager. *Policy on the production and control of policies, procedures, protocols and guidelines*. SWBCCG Pol01, https://sandwellandwestbhamccg.nhs.uk/freedom-of-information/our-policies-and-procedures/146-policy-on-policy-development/file (2012, accessed 4 July 2018).
12. United Kingdom Clinical Ethics Network. A brief introduction to CECs and clinical ethics support, http://www.ukcen.net/committees/introduction#Raising (2011, accessed 1 July 2018).
13. Newcastle Upon Tyne Hospitals NHS Foundation Trust. Clinical practice guidelines and protocols policy, http://www.newcastle-hospitals.org.uk/downloads/policies/Operational/ClinicalGuidelinesProtocols201702.pdf (2017, accessed 4 July 2018).
14. UK Clinical Ethics Network. UKCEN: ethical issues, http://www.ukcen.net/ethical_issues (2015, accessed 4 July 2018).
15. UK Clinical Ethics Network. A collection of educational resources for clinical ethics committee, http://www.ukcen.net/education_resources (2011, accessed 1 July 2018).
16. Melnyk BM. Important information about clinical practice guidelines: key tools for improving quality of care and patient outcomes. *Worldviews Evid Based Nurs* 2015; 12: 1–2.
17. Giesen D, Meertens V, Vis-Visschers R, et al. Questionnaire development, https://www.cbs.nl/nr/rdonlyres/99b7482f-e09e-4d86-90a1-666dc42745bd/0/2012questionairedevelopmentart.pdf (2012, accessed 1 July 2018).
18. O'Gorman CS, Macken AP, Cullen W, et al. What are the differences between a literature search, a literature review, a systematic review and a meta-analysis? And why is a systematic review considered to be so good? *Ir Med J* 2013; 106: 8–10.
19. Strech D and Schildmann J. Quality of ethical guidelines and ethical content in clinical guidelines: the example of end-of-life decision-making. *J Med Ethics* 2011; 37: 390–396.
20. Scott AM, Bond K, Gutiérrez-Ibarluzea I, et al. Qualitative assessment of ethics analyses for health technology assessment. *Int J Technol Assess Health Care* 2016; 32: 362–369.

21. Assasi N, Tarride J-E, O'Reilly D, et al. Steps toward improving ethical evaluation in health technology assessment: a proposed framework. *BMC Med Ethics* 2016; 17: 34.
22. Rosén M and Werkö S. Does health technology assessment affect policy-making and clinical practice in Sweden? *Int J Technol Assess Health Care* 2014; 30: 265–272.
23. Tantivess S. Social and ethical analysis in health technology assessment. *J Med Assoc Thai* 2014; 97(Suppl. 5): S81–S86.
24. Giacomini M. One of these things is not like the others: the idea of precedence in health technology assessment and coverage decisions. *Milbank Q* 2005; 83: 193–223.
25. Ten Have H. Ethical perspectives on health technology assessment. *Int J Technol Assess Health Care* 2004; 20: 71–76.
26. Oliver A, Mossialos E and Robinson R. Health technology assessment and its influence on health-care priority setting. *Int J Technol Assess Health Care* 2004; 20: 1–10.
27. Papatheofanis FJ. Health technology assessment. *Q J Nucl Med* 2000; 44: 105–111.
28. Elwyn G, Dannenberg M, Blaine A, et al. Trustworthy patient decision aids: a qualitative analysis addressing the risk of competing interests. *BMJ Open* 2016; 6: e012562.
29. Jones DJ, Barkun AN, Lu Y, et al. Conflicts of interest ethics: silencing expertise in the development of international clinical practice guidelines. *Ann Intern Med* 2012; 156: 809.
30. Höschl C, Fialová L and European Psychiatric Association. European Psychiatric Association guidance on the conflicts of interest. *Eur Psychiatry* 2012; 27: 142–146.
31. Adibi S and Bebermeyer RD. Conflicts of interest in research: is clinical decision-making compromised? An opinion paper. *Tex Dent J* 2010; 127: 735–741.
32. Kirch DG. Conflict-of-interest management: efforts and insights from the Association of American Medical Colleges. *Cleve Clin J Med* 2007; 74(Suppl. 2): S23–S25; discussion S32–S37.
33. Chohda E, Doddi S, Sundaramoorthy S, et al. An audit of consenting practices in a district general hospital. *Can we improve? G Chir* 2015; 36: 263–266.
34. Ossorio PN. The ethics of translating high-throughput science into clinical practice. *Hastings Cent Rep* 2014; 44: 8–9.
35. Festinger DS, Dugosh KL, Marlowe DB, et al. Achieving new levels of recall in consent to research by combining remedial and motivational techniques. *J Med Ethics* 2014; 40: 264–268.
36. Fisher JA. Procedural misconceptions and informed consent: insights from empirical research on the clinical trials industry. *Kennedy Inst Ethic J* 2006; 16: 251–268.
37. Swedish Council on Health Technology Assessment. *Dementia – caring, ethics, ethnical and economical aspects: a systematic review*. Stockholm: Statens beredning för medicinsk utvärdering (SBU), 2008.
38. Siegel AM, Barnwell AS and Sisti DA. Assessing decision-making capacity: a primer for the development of hospital practice guidelines. *HEC Forum* 2014; 26: 159–168.
39. Wendler D and Prasad K. Core safeguards for clinical research with adults who are unable to consent. *Ann Intern Med* 2001; 135: 514–523.
40. Knüppel H, Mertz M, Schmidhuber M, et al. Inclusion of ethical issues in dementia guidelines: a thematic text analysis. *PLoS Med* 2013; 10: e1001498.
41. Landau WM. Pertinacious prescription of practice paradigms: the ethical burden of coercive clinical guidelines. *Curr Neurol Neurosci Rep* 2007; 7: 355–358.
42. Ondrusek NK, Willison DJ, Haroun V, et al. A risk screening tool for ethical appraisal of evidence-generating initiatives. *BMC Med Ethics* 2015; 16: 47.
43. Li RH, Wacholtz MC, Barnes M, et al. Incorporating ethical principles into clinical research protocols: a tool for protocol writers and ethics committees. *J Med Ethics* 2016; 42: 229–234.
44. Roberts LW. Ethical dimensions of psychiatric research: a constructive, criterion-based approach to protocol preparation. *The Research Protocol Ethics Assessment Tool (Repeat). Biol Psychiatry* 1999; 46: 1106–1119.

45. Koo TK and Li MY. A guideline of selecting and reporting intraclass correlation coefficients for reliability research. *J Chiropr Med* 2016; 15: 155–163.
46. Myers ND, Ahn S and Jin Y. Sample size and power estimates for a confirmatory factor analytic model in exercise and sport: a Monte Carlo approach. *Res Q Exerc Sport* 2011; 82: 412–423.

Appendix 1

CliPEAT

Clinical Policy Ethics Assessment Tool (CliPEAT)[a]

		Acceptable	Unacceptable	
Design issues				
1. Does the policy content manages a clinical field or is connected to an aspect of clinical practice?	Yes	Not applicable	Requires clarification	No
2. Does the policy design appropriately describe the clinical practice that it represents?	Yes	Not applicable	Requires clarification	No
Expertise, commitment and integrity issues				
3. Does the team that created the policy have sufficient expertise to successfully create and update the policy?	Yes	Not applicable	Requires clarification	No
4. Does the team that created the policy have sufficient commitment, resources and support from the institution to successfully create and update the policy?	Yes	Not applicable	Requires clarification	No
5. Are the members of the team that created the policy experts in regards to the relevant clinical field and in good standing within the professional communities?	Yes	Not applicable	Requires clarification	No
6. Does evidence exist of past misconduct by members of the team that created the policy, individually or collectively?	No	Not applicable	Requires clarification	Yes
7. Do the financial, institutional, or other arrangements related to the policy pose any threat to the integrity of members of the team that created the policy, individually or collectively (e.g. significant 'conflicts of interests')?	No	Not applicable	Requires clarification	Yes
Risks and benefits				
8. Are risks associated with the relevant clinical practice minimised by the policy design?	Yes	Not applicable	Requires clarification	No
9. Does the policy pose excessive risk or other burdens to individual patients, the community or society?	No	Not applicable	Requires clarification	Yes
10. If patients are likely to have emerging symptoms (e.g. new symptoms or worsening existing symptoms) as a result of or during relevant clinical practice:				
a. Has an appropriate mechanism for identifying and following symptom progression been built into the policy?	Yes	Not applicable	Requires clarification	No

(continued)

Appendix 1. (continued)

Clinical Policy Ethics Assessment Tool (CliPEAT)[a]				
		Acceptable	Unacceptable	
b. Has an appropriate mechanism for identifying when to discontinue the relevant clinical practice in order to begin standard treatment for emerging symptoms that pose safety risks or enduring distress been built into the policy?	Yes	Not applicable	Requires clarification	No
c. Has an appropriate referral mechanism to provide patients with standard treatment for emerging symptoms that pose safety risks or enduring distress been built into the policy?	Yes	Not applicable	Requires clarification	No
11. Are benefits in association with the relevant clinical practice optimised by the policy design for individuals and society?	Yes	Not applicable	Requires clarification	No
Confidentiality				
12. Do the policy design and plans for data use adequately protect patient confidentiality?	Yes	Not applicable	Requires clarification	No
Informed consent and decisional capacity				
13. Does the policy design define an appropriate informed consent process including: – The policy's purpose? – Who is responsible for the relevant clinical practice?	Yes	Not applicable	Requires clarification	No
a. Disclosure of information regarding: – Why may the individual be eligible as a receptor of the relevant clinical practice? – The nature of the illness (or the relevant phenomenon)? – The proposed intervention? – The associated risks and benefits associated and their relative likelihood? – Alternatives to participation?	Yes	Not applicable	Requires clarification	No
b. Reasonable assurance of adequate decisional capacity of patients with respect to the ability to understand, rationally analyse and appreciate the meaning of their decision in regards to relevant clinical practice, OR reasonable assurance of adequately meeting all criteria under item 14 below?	Yes	Not applicable	Requires clarification	No
c. Reasonable assurance that individuals will not experience coercive pressure to be receptors of the relevant clinical practice (e.g. enough time obtaining the consent so all individuals can consider in detail their decision and seek the advice of other people, explicit recognition that participation is voluntary and that individuals can reject or withdraw their decision to be part of the relevant clinical practice without adverse consequences, provision of the right to refuse to	Yes	Not applicable	Requires clarification	No

(continued)

Appendix 1. (continued)

Clinical Policy Ethics Assessment Tool (CliPEAT)[a]				
		Acceptable	Unacceptable	
be the receptor of the relevant clinical practice to individuals unable to give an informed consent)?				
d. A concise, readable, accurate and understandable consent form, adapted to the relevant population OR an oral informed consent obtained in a conversation that includes all the criteria listed previously under items 13, 13a, 13b and 13c?	Yes	Not applicable	Requires clarification	No
e. The context, if there are any, in which the lack of time and/or resources (emergency, crowding, major incident, etc.) allow the healthcare professional to obtain a presumed consent and/or to not obtain an informed consent for the benefit of the clinical practice receptor, the community and/or society?	Yes	Not applicable	Requires clarification	No
14. If individuals are likely to experience diminished decisional capacity during relevant clinical practice (including when they give their informed consent):				
a. Has an appropriate mechanism for identifying, following and documenting the level of diminished decisional capacity of the clinical practice receptor been built into the policy?	Yes	Not applicable	Requires clarification	No
b. When possible, has an appropriate mechanism for enhancing or restoring the decisional capacity of the clinical practice receptor been built into the policy?	Yes	Not applicable	Requires clarification	No
c. If a period of diminished decisional capacity may be necessary because of the nature of the relevant clinical practice (e.g. surgery under general anaesthesia, medication with neurological side effects, etc.), does the policy include:				
1) An appropriate mechanism for advance decision-making by the clinical practice receptor or for identifying an alternative decision-maker for the clinical practice receptor?	Yes	Not applicable	Requires clarification	No
2) An appropriate mechanism for implementing advance decisions or for preparing and utilising the alternative decision-maker when necessary?	Yes	Not applicable	Requires clarification	No
Professional accountability				
15. Do the professionals authorised by the policy to perform the relevant clinical practice have enough training and/or experience to perform it, supervise it and/or evaluate it?	Yes	Not applicable	Requires clarification	No
16. Is the policy updated in accordance with the latest evidence-based practice?	Yes	Not applicable	Requires clarification	No

(continued)

Appendix 1. (continued)

Clinical Policy Ethics Assessment Tool (CliPEAT)[a]				
		Acceptable	Unacceptable	
17. Does the policy follow the codes of conduct of the regulatory bodies of the healthcare professional involved in the relevant clinical practice (GMC, NMC, etc.)?	Yes	Not applicable	Requires clarification	No
Legal accountability				
18. Does the policy follow the applicable legislation without any discrepancies?	Yes	Not applicable	Requires clarification	No
19. Does the policy specify in which situations, if there are any, healthcare professionals are not covered by the vicarious liability of the institution for which they practice?	Yes	Not applicable	Requires clarification	No
Other issues				
20. Are documentation practices adequate to monitor policy procedures and healthcare professionals' accountability?	Yes	Not applicable	Requires clarification	No
21. Are future revisions of the policy programmed?	Yes	Not applicable	Requires clarification	No
22. Are other ethical problems apparent in this policy? If 'yes', describe:	No	Not applicable	Requires clarification	Yes
23. Are other legal problems apparent in this policy? If 'yes', describe:	No	Not applicable	Requires clarification	Yes
24. Are there other issues that interfere with policy approval? If 'yes', describe:	No	Not applicable	Requires clarification	Yes
25. Prior to its approval, does the policy require additional review by others with more specialised expertise or by others with especially relevant interest and experience to assess its ethical or legal validity?	No	Not applicable	Requires clarification	Yes
Does the policy, in its present form, meet minimal criteria for being ethically sound[b]?	Yes		No	
Does the policy, in its present form, require a more rigorous level of monitoring than is customary?	No		Yes	
Comments:				

[a] For use in the assessment of ethical aspects of clinical policies involving human participants.

[b] All evaluative criteria (items 1–25) must receive an acceptable response for the policy to be minimally acceptable on legal and ethical grounds. Problems, as indicated by responses in either of the second two columns, should be addressed formally and should undergo re-review prior to policy approval.

Appendix 2

CliPEAT's trial policies and guidelines	
Clinical techniques and competencies	
Blood transfusion policy B16/2003 V4.0	CPR UHL / LPT / LLR policy E4/2015 V2
Oxygen therapy policy B27/2010 V2	Urethral catheterisation policy B29/2007
Administration of medicines to adult patients who cannot swallow tablets Guidelines for practice B31/2008	Guideline for the insertion, care of and removal of a peripheral cannula in adults B33/2010
IV UHL Policy B25/2010 V3	Leicestershire medicines code policy B60/2011 V6
Policy for the documentation of medication allergies B2/2013 V3	Self administration of medicines by adult patients or their relatives/carers [policy] B13/2004 V4
Patient group directions policy B43/2005 V5.0	Management of medication errors policy B45/2008 V2
Procedure for obtaining venous blood samples from an adult [guideline] B16/2010	Venous access in adults and children policy and procedures B13/2010 V3
General clinical practice	
Adult patient transfer and escort policy and guidelines B30/2004 V3	Healthcare environment cleaning policy and procedures B36/2010
Aggressive parents in ED SOP C207/2016	Policy for clinical handover B18/2013 V2
Guidelines for the supervision and management of adult patients with agitated/challenging behaviours B6/2012	Management of violence, aggression and disruptive behaviour policy B11/2005 V4
Bed rail policy E2/2015 V7	Aseptic non-touch techniques guidelines B20/2013
Policy for delegated consent B10/2013 V2	Policy for consent to examination or treatment A16/2002 V10
Fall management policy for adult-in-patients B15/2014 V2	Good practice for patient-side nursing handover [guideline]
UHL policy for assessment and care management of patients at risk of wandering in hospital B25/2008 V4	Guideline for the completion and escalation of Early Warning Scoring (EWS) monitoring system in adult patients B25/2011
Policy for managing fluid balance and hydration in adult patients B38/2016 V1	Mentorship policy for nursing and midwifery staff B24/2010 V2
Hand hygiene policy and procedures B32/2003	Infection prevention policy B4/2005 V3
Hospital linen infection prevention principles [policy] B14/2012	Guidance for the care of patients in the last days of life [guidelines] B1/2014
Mental Capacity Act policy B23/2007 V4	Missing patients policy – adults B15/2005 V3.1
Policy for documenting in patients' health records B30/2006 V2	Prevention and management of pressure ulcers in adults and children policy and guidance B23/2014 V2
Patient identification band policy B43/2007 V3	Managing pre-alert calls SOP C176/2016 V1.0
Safeguarding adults – alerting and referring SOP C181/2016 V7	UHL policy on safety standards for invasive procedures B31/2016 V1
Sharps management policy B8/2013 V2	Uniform and dress code policy B30/2010 V2
Nursing resources management	
Cohorting of ambulance patients within the ED SOP V1.0	Managing assessment bay at full capacity SOP V2.0
Assessment bay operations and escalation SOP V3.0	Majors standard operating procedures manual SOP V1
The assessment of administration of medicines by nurses and midwives policy and procedures B13/2009 V2	Policy for the support of staff involved in incidents, inquests, complaints and claims B28/2007 V3.0
Work experience policy E4/2010 V2	Initial assessment & dynamic priority scoring C174/2016 V3
Temporary staffing policy and procedure B58/2011 V5.0	Temporary nurse staffing operational policy B35/2016 V1.0