INTRODUCTION

Australian paediatricians commonly see children with a diverse range of sometimes complex health conditions. Clinical practice guidelines (CPGs) are available to help healthcare providers deliver appropriate care (care in line with evidence-based or consensus-based guidelines). However, it is not always easy for healthcare providers to navigate their way through CPGs due to factors such as: lack of timely access, multiple CPG sources and hence a lack of consensus, and lengthy recommendations that may not be specific or practical for point-of-care decision-making. Definitions of objective or measurable compliance with processes and outcomes are often lacking.

Research was undertaken in the USA between 1998 and 2000 to develop recommendations for a range of paediatric conditions, and to benchmark the quality of ambulatory care against these recommendations. However, no such study has been conducted in Australia or elsewhere. The overall objective of CareTrack Kids (CTK) is to determine the appropriateness and safety of healthcare for common conditions delivered to children in Australia. In order to achieve this, a set of measurable clinical indicators is required.

The CTK project involves a suite of three separate but related studies: part 1 (this study)—developing a set of clinical ‘appropriateness’ indicators for common paediatric conditions; part 2—measuring the appropriateness of paediatric care in Australia against these clinical indicators (using an onsite
METHODS AND ANALYSIS

There are three key components for this study protocol: to identify candidate paediatric conditions, to develop clinical indicators for these conditions and to evaluate the wiki methodology. The methods for the other CTK studies will be presented in separate protocol papers.12 15

Component 1: identify candidate paediatric conditions

A scoping exercise was undertaken to identify common candidate conditions from published research,1 17 18 burden of disease (BOD),17 prevalence (Children’s and General Hospital 2011–12 New South Wales. SNOMED-CT Emergency departments, personal correspondence; Bettering the Evaluation and Care of Health. Top 100 most frequently managed problems 2011–12 weighted data: Age 0–17 years, personal correspondence, 2012),19 frequency of presentation (Children’s and General Hospital 2011–12 New South Wales, personal correspondence)19 and quality of care priority lists (table 1).20 Using these data, the CTK research team identified an initial list of 28 conditions common across a range of healthcare practice facilities, including primary care provided by general practitioners, secondary care provided by outpatient paediatricians and tertiary care in hospitals.

The CTK research team further refined the list of candidate conditions by evaluating them against three criteria to determine their eligibility for inclusion: high prevalence (Bettering the Evaluation and Care of Health, personal correspondence),1 high clinical impact20 21 and BOD.17 Two additional conditions were recognised by the research team as having significant clinical importance and were therefore recommended for inclusion: obesity (high prevalence, impact and BOD)20 21 and urinary tract infection (high impact).23 24 Using these criteria, a list of 20 paediatric conditions (table 2) has been selected for inclusion.

Component 2: develop clinical indicators

Clinical indicators for this study will be developed using a three-stage process: (1) search and source relevant CPGs; (2) select, draft and format proposed clinical indicators; and (3) subject the indicators to several rounds of internal and external review using a modified Delphi approach.

Stage 1: search and source relevant CPGs

All clinical indicators will be derived from published CPGs relevant for the years 2012 and 2013. A systematic search will be undertaken sequentially in order of priority for national-level CPGs from Australia (eg, for the National Health and Medical Research Council (NHMRC)),2 and internationally (eg, for the National Institute for Health and Care Excellence (NICE) in England,3 Scottish Intercollegiate Guidelines Network (SIGN)4 and the Agency for Healthcare Research and Quality’s (AHRQ’s) National Guideline Clearinghouse in the USA).5 In the absence of Australian national and international CPGs, the CPGs of relevant professional medical colleges and associations will also be searched, as well as state or professional level (eg, the New South Wales (NSW) Clinical Practice Guidelines for Paediatrics).6 Three research team members (LKM, TDH and PDH) will be primarily responsible for conducting the CPG searches and developing the proposed clinical indicators. Full details of the search strategy are provided in online supplementary appendix A.7 27 28

Stage 2: select, draft and format proposed indicators

Recommendations from each CPG will be collated and used to inform the content and format of the proposed clinical indicators. For the purposes of this study, a clinical indicator is defined as a “measurable component of a standard or guideline, with explicit criteria for inclusion, exclusion, time frame and setting.”5 Not all recommendations published in CPGs will become indicators for the CTK study. Recommendations will be excluded based on the following criteria (table 3):

- Strength of the wording of the recommendation (ie, “may” and “could” statements would be excluded; ‘should’ and ‘must’ statements would be included);
- Low likelihood of information being documented in the medical record;
- Guiding statements without recommended actions.

All clinical indicators will be written in a structured and standardised format (ie, starting with the inclusion criteria followed by the action). For example, the inclusion criteria will define the age (infant, child, adolescent), condition and the phase of care (at diagnosis/presentation or ‘with’, indicating the diagnosis is existing). Indicators will be arranged chronologically according to phases of care (ie, screening, diagnosis, treatment, ongoing management). Table 4 provides examples.

Stage 3: subject the indicators to several rounds of internal and external review

There are two stages involved in the indicator review. The proposed clinical indicators will initially undergo an internal review (stage 3a), followed by an external wiki-style
| Condition | Paediatric outpatients/community | General practitioners (Bettering the Evaluation and Care of Health, personal correspondence) | Hospital inpatients (>400 NSW cases pa) | ED cases (Children’s and General Hospital 2011–12 New South Wales, personal correspondence) |
|-----------|---------------------------------|---------------------------------------------|-----------------------------------|------------------------------------------------|
| ADHD† | • | • | | |
| Learning difficulty/disability/behaviour/language delay† | • | | | |
| Eczema and dermatological/skin problems† | • | • | | |
| Asthma*†‡ | • | | | |
| Allergy (food other than cows’ milk)* | • | | | |
| Newborn/neonatal care* | • | | | |
| Anxiety*†‡ | • | | | |
| General check-up/preventive care | • | | | |
| GORD | | • | | |
| Autism* | • | | | |
| Intellectual disability | • | | | |
| URTI | | • | • | |
| Fever | | • | | |
| Acute gastroenteritis | | • | | |
| Croup | | • | | |
| Head injury | | • | | |
| Acute bronchiolitis | | • | | |
| Sore ear—otitis media* | | • | | |
| Acute abdominal pain | | • | | |
| Renal dialysis | | • | | |
| Leukaemia | | • | | |
| Poisoning‡ | | • | | |
| Red blood cell disorders | | • | | |
| Surgical repair cleft palate/lip | | • | | |
| Tonsillitis/adenoids | | • | | |
| Cerebral palsy | | • | | |
| Diabetes‡ | | • | | |
| Viral illness | | • | | |

*Leading cause of DALYs in 0–14-year olds by sex, Australia 2003.17†Most frequently reported long-term conditions on children aged 0–14 years, 2007–08.18‡NHPA.20

ADHD, attention deficit hyperactivity disorder; DALYs, disability adjusted life years; ED, emergency department; GORD, gastro-oesophageal reflux disease; NHPA, National health priority area; NSW, New South Wales; URTI, upper respiratory tract infection.
review using a modified Delphi process (stage 3b). This approach has been chosen to enhance methodological rigour and optimise the content and face validity of the final set of clinical indicators.

**Stage 3a: internal review processes**

Internal reviews will be conducted by paediatricians and general practitioners sourced from within the CTK research team and their professional networks. It is envisaged that these reviewers will be employed as the head or director of a relevant paediatric department in a large hospital, hold at least an adjunct academic appointment or be directly involved in clinical care (eg, clinical psychologist). The clinical indicators for each condition will be reviewed by a panel of at least three different reviewers who, depending on their self-reported scope of practice and expertise, are able to participate in review panels for more than one condition. The total number of invitations will therefore depend on the skill-mix of invited reviewers and overall recruitment rate. This selection strategy is well supported within the Delphi process literature.

The internal review will consist of three rounds. In the first round, drafts of proposed clinical indicators for each condition, and the recommendations on which they are based, will be sent via email to a panel of at least three internal reviewers. The review criteria to be used are based on the methods from the previous US and Australian studies. Internal reviewers will be asked to: score each indicator against three key criteria: acceptability, feasibility and impact (online supplementary appendix B); to recommend the indicators for inclusion or exclusion; and provide any additional comments. In this round, reviewers will complete their assignments independently from one another to minimise bias from ‘group-think’. Three team members (LKM, TDH and PDH) will collate the feedback and revise the content, structure and format of each indicator. The refined set of indicators (including the original indicator and de-identified feedback) will be sent to the same internal reviewers for a second round of scoring. The same approach will be used in this round, with a request for more information and identification of indicators to be included or excluded. In the final round, the proposed set of indicators will be sent to one of the three existing reviewers to review and approve the indicators for the external wiki-based review process.

**Stage 3b: external wiki-based review**

External reviews will be conducted by invited paediatricians and general practitioners. Relevant medical colleges, professional associations and networks, such as the...
Royal Australasian College of Physicians, Australian Paediatric Research Network (APRN), Children’s Healthcare Australasia (CHA), Australian Research Alliance for Children and Youth (ARACY), Bettering the Evaluation and Care of Health (BEACH) programme, New South Wales (NSW) Kids and Families, Sydney Children’s Hospitals Network, Children’s Health Queensland (QLD), Women’s and Children’s Health Network (South Australia), will be contacted, requesting assistance with the recruitment of clinical experts to register as external reviewers. Invitations will comprise email notifications to members, media releases and articles within newsletters. Clinical experts will self-nominate as reviewers for one or more of the CTK conditions based on their interest, scope of practice and clinical experience.33 34

The external review will involve a wiki-based process whereby indicators for each condition (from round 3 of the internal review) will be posted to an online wiki site. The wiki ‘live’ time will depend on the recruitment rate of experts and the progress of their reviews, but is anticipated to be no longer than 3 months. The aim is for each condition to be independently reviewed by a minimum of nine experts. In addition to the scoring criteria used in the internal review process, indicators will be scored on a nine-point Likert scale as representative of appropriate care delivered to children during 2012 and 2013.11 15 37 A clinical champion for each condition will follow-up and manage external reviewers’ responses, and to make final recommendations regarding the inclusion, content, structure and format of indicators. For most conditions, this role will be undertaken by one of the stage 3a internal reviewers as previously identified by the CTK research team. The final sets of clinical indicators for care during 2012 and 2013 will be considered representative of appropriate care for Australian children for the candidate conditions and will form the suite of indicators for the second (part 2) CTK study.12

### Table 3 Example recommendations mapped against indicator eligibility criteria

| Indicator eligibility criteria | Example exclusions | Rationale for exclusion |
|--------------------------------|--------------------|-------------------------|
| Strength of wording            | Following multidisciplinary review, if moderate to severe depression in a child (5–11 years) is unresponsive to a specific psychological therapy after four to six sessions, the addition of fluoxetine should be cautiously considered, although the evidence for its effectiveness in this age group is not established29 | Use of wording: ‘cautiously considered’ and ‘evidence for its effectiveness in this age group is not established’ |
| Likelihood of documentation    | In children aged 4 weeks to 5 years, healthcare professionals should measure body temperature by one of the following methods: ▶ Electronic thermometer in the axilla ▶ Chemical dot thermometer in the axilla ▶ Infrared tympanic thermometer30 | The method used to measure body temperature is unlikely to be documented in a medical record |
| Guiding statement without recommended action | Observation of infants and young children (ie, aged under 5 years) is a difficult exercise and therefore should only be performed by units with staff experienced in the observation of infants and young children with a head injury. Infants and young children may be observed in normal paediatric observation settings, as long as staff have the appropriate experience31 | Guiding statement with no specific actions/criteria able to be used to determine compliance |

### Table 4 Examples of possible condition indicators

| Condition | Classification | Indicator |
|-----------|----------------|-----------|
| Obesity   | Screening/diagnosis | Children aged between 2–16 years have their BMI measured and diagnosed (using a BMI percentile chart) as follows according to the result: ▶ BMI for age and sex in 85th–94th centile are diagnosed as overweight OR ▶ BMI for age and sex >95th centile are diagnosed as obese |
| URTI      | Treatment       | Children with URTI are NOT to be prescribed antibiotics |
| Diabetes  | Ongoing management | Children and young people with type 1 diabetes and their families are informed that the target for long-term glycaemic control is an HbA1c of less than 7.5% |

BMI, body mass index; HbA1c, glycated haemoglobin; URTI, upper respiratory tract infection.
and measurable compliance points to assist with point-of-care decision-making.

Component 3: evaluate the ‘wiki’ methodology
A multimethods evaluation of the wiki’s methodology will be undertaken, with the aim of assessing utilisation, accessibility and ease of use. Three data sources will be used to inform the evaluation: (A) utilisation statistics sourced from the wiki logs—these will include demographics of users and rates and times of use; (B) the nature and content of reviewers’ and clinical champion’s comments (eg, the format and rationale of proposed changes to indicators, level of agreement between reviewers, and resulting changes to the indicators); and (C) user perspectives. Following completion of their clinical indicator reviews, external reviewers will be invited to participate in an online survey of their experiences and perspectives. Both quantitative and qualitative analyses of these three data sources will be undertaken including: descriptive statistics for the characteristics of wiki users, their patterns of use and scores for clinical indicators; and frequency counts and content analyses of ratings and free-text responses from the user perspectives survey. Using these data, recommendations will be developed regarding the overall feasibility of the wiki process for future indicator developments and potential changes for improvement.

ETHICS AND DISSEMINATION

Ethical approval
Applications are under review with the Royal Australian College of General Practitioners.

To minimise the risk of bias, all reviewers will be required to complete a Conflict of Interest (COI) declaration. The COI declarations will be recorded for each reviewer and managed according to the NHMRC protocol for conflict.

Dissemination
We will submit the results of the study to relevant national and international journals with the intention of publishing the results widely. As well, we will make national and international oral presentations to stakeholder groups including those involving patients, researchers, clinicians, managers and policymakers.

DISCUSSION

We recognise several potential limitations to our study. The approaches used to identify candidate paediatric conditions and develop clinical indicators are specific to the Australian healthcare setting for the years 2012 and 2013. Findings can therefore not be generalised beyond these contexts. Experts will be invited to participate and self-nominate to review conditions that are within their scope of practice and for which they have current clinical experience. This may introduce a selection bias, as reviews will be representative of the participating sample rather than the general population of Australian paediatricians and general practitioners. There is potential for the final sets of clinical indicators to be a function of the scope of practice, clinical experience, level of research participation and degree of literacy with information technology of a subset of healthcare practitioners.

The CTK part 1 study will use and evaluate a novel method for ratifying indicators of ‘appropriate care’ for 20 paediatric conditions. These indicators will form the criteria against which the CTK part 2 study can, for the first time in Australia, measure appropriateness of paediatric care in 2012 and 2013. This study will help to establish the feasibility of using wiki-based technology for the purposes of developing clinical indicators. This information can be used to inform the design of future studies using Delphi processes to establish consensus on recommended healthcare, and will be relevant for national and international researchers, policymakers, healthcare practitioners and patients.

Author affiliations
1Division of Education, Arts and Social Sciences, Centre for Sleep Research, School of Psychology, Social Work and Social Policy, University of South Australia, Adelaide, South Australia, Australia
2Faculty of Medicine and Health Sciences, Australian Institute of Health Innovation, Macquarie University, Sydney, New South Wales, Australia
3Discipline of Paediatrics, School of Women’s and Children’s Health, University of New South Wales, Sydney, New South Wales, Australia
4Sydney Children’s Hospital, Sydney Children’s Hospitals Network, Randwick, New South Wales, Australia
5New South Wales Health, NSW Kids and Families, North Sydney, New South Wales, Australia
6Department of Respiratory Medicine, Sydney Children’s Hospital, Sydney Children’s Hospitals Network, Randwick, New South Wales, Australia
7Sydney Medical School, University of Sydney, Sydney, New South Wales, Australia
8Institute of Endocrinology and Diabetes, Children’s Hospital at Westmead, Sydney Children’s Hospitals Network, Westmead, New South Wales, Australia
9Faculty of Medicine, Centre for Primary Health Care and Equity, University of New South Wales, Sydney, New South Wales, Australia
10Australian Patient Safety Foundation, Adelaide, South Australia, Australia
11BUPA Health Foundation Australia, Sydney, New South Wales, Australia
12Patient Safety and Quality Unit, Children’s Health Queensland Hospital and Health Service, Herston, Queensland, Australia
13Division of Paediatric Medicine, Women’s and Children’s Health Network, South Australia, Australia
14Russell Clinic, Blackwood, South Australia, Australia
15Clinical Excellence Commission, Sydney South, New South Wales, Australia

Contributors JB and PDH initiated the project and led the National Health and Medical Research Council (NHMRC) grant proposal. JB, AJ, LKW, CTC and MFH are chief investigators on the project, led the design of the grant and shared in the development of the protocol and the initial drafting of the grant application and protocol. TDH, PDH, NM and LKW are project team members and did the first drafting of the protocol manuscript. WBR, SG, ARH, JGW, EM, AL, GW, HMW and CH are associate investigators or industry partners and helped write the grant proposal, protocol and manuscript.

Funding This work is supported by NHMRC Partnership Grant APP1065898. It is led by the Australian Institute of Health Innovation, Macquarie University. The partners in the research are BUPA Health Foundation, Sydney Children’s Hospitals Network, NSW Kids and Families, Children’s Health Queensland, the South Australian Department of Health, the University of South Australia (UNISA) and the NSW Clinical Excellence Commission.

Competing interests None.
REFERENCES

1. Hiscock H, Roberts G, Efron D, et al. Children attending paediatricians' clinics: a national prospective audit of outpatient practice from the Australian Paediatric Research Network. Med J Aust 2011;194:392–7.

2. National Health and Medical Research Council. 2013. http://www. nhmrc.gov.au/guidelines-publications (1 April 2013).

3. National Institute for Health and Care Excellence. 2013. http://guidance.nice.org.uk/CG/Published (1 April 2013).

4. Scottish Intercollegiate Guidelines Network. Guidelines by topic. 2014. http://www.sign.ac.uk/guidelines/published/index.html

5. Runciman WB, Colier EW, Day RO, et al. Towards the delivery of appropriate health care in Australia. Med J Aust 2012;197:78–81.

6. National Health & Medical Research Council (NHMRC). Clinical Practice Guidelines portal. 2011. http://www.clinicalguidelines.gov.au/.

7. National Stroke Foundation. Clinical guidelines for acute stroke management. National Health and Medical Research Council, 2007.

8. National Asthma Council Australia. Asthma management handbook. National Asthma Council, 2006.

9. Bastian H, Glasziou P, Chalmers I. Seventy-five trials and eleven systematic reviews a day: how will we ever keep up? PLoS Med 2010;7:e1000326.

10. National Health and Medical Research Council. 2007. http://www.health.nsw.gov.au/lhd/pages/chn-guidelines.aspx

11. Begg S, Vos T, Barker B, et al. The burden of disease and injury in Australia 2003. PHE 82. Canberra: AIHW, 2007.

12. Australian Institute of Health and Welfare. A picture of Australia’s children 2012. Canberra: AIHW, 2012.

13. Australian Institute of Health and Welfare. National health priority areas. Canberra: AIHW, 2013.

14. McGlynn EA, Asch SM, Adams J, et al. The quality of care delivered to adults in the United States. N Engl J Med 2003;348:2635–45.

15. Runciman WB, Hunt TD, Hannaford NA, et al. CareTrack Kids—part 2 assessing the appropriateness of healthcare delivered to Australian children: a study protocol for a retrospective medical record review. BMJ Open 2015. In press; doi:10.1136/bmjopen-2015-007749.

16. Hunt TD, Ramanathan SA, Hannaford NA, et al. CareTrack Australia: part 3 adverse events in children’s healthcare in Australia: study protocol for a retrospective medical record review. BMJ Open 2015. In press; doi:10.1136/bmjopen-2015-007750.

17. Begg S, Vos T, Barker B, et al. The burden of disease and injury in Australia 2003. PHE 82. Canberra: AIHW, 2007.

18. Australian Institute of Health and Welfare. A picture of Australia’s children 2012. Canberra: AIHW, 2012.

19. NSW Health. Children’s and General Hospital 2011–12 New South Wales. Diagnostic Related Group Data. Sydney: NSW Health, 2013.

20. Australian Institute of Health and Welfare. National health priority areas. Canberra: AIHW, 2013.

21. Olds TS, Tomkinson GR, Ferrar KE, et al. Trends in the prevalence of childhood overweight and obesity in Australia between 1985 and 2008. Int J Obes (Lond) 2010;34:57–66. http://dx.doi.org/10.1038/ijo.2008.21.

22. Campbell M, Bryson HE, Price AMH, et al. Obesity in childhood: a national prospective audit of Australian pediatric practice. Acad Pediatr 2013;13:168–76.

23. Fitzgerald AMR, Mori R, Lakanapaul M, et al. Antibiotics for treating boils, abscesses and urinal tract infection in children. Cochrane Database Syst Rev 2012;8:CD006857.

24. Smellie JM, Poulton A, Prescod NP. Retrospective study of children with renal scarring associated with reflux and urinary infection. BMJ 1994;308:1193–6.

25. Agency for Healthcare Research and Quality (AHRQ) National Guideline Clearinghouse. Guidelines by topic 2014. http://www.guideline.gov/browse/by-topic.aspx

26. New South Wales (NSW) Health Paediatric Clinical Practice Guidelines. NSW Health Paediatric Clinical Practice Guidelines. 2014. http://www.health.nsw.gov.au/ltb/pages/chn-guidelines.aspx

27. Alonso-Coello IA, Irfan A, Sola I, et al. The quality of clinical practice guidelines over the last two decades: a systematic review of guideline appraisal studies. Qual Saf Health Care 2010;19:e58.

28. Hayen JA, Altmann R, Haynes K, et al. A systematic review of appraisal tools for clinical practice guidelines: multiple similarities and one common deficit. Int J Qual Health Care 2005;17:235–42.

29. National Institute for Health and Care Excellence (NICE). Depression in children and young people: identification and management in primary, community and secondary care. 2005.

30. National Institute for Health and Care Excellence. Feverish illness in children: assessment and initial management in children younger than 5 years. 2013.

31. National Institute for Health and Care Excellence. Head injury: triage, assessment, investigation and early management of head injury in children, young people and adults. 2014.

32. Geist MR. Using the Delphi method to engage stakeholders: a comparison of two studies. Eval Program Plann 2010;33:147–54.

33. Boukiedd RAH, Loustau M, Sibony O, et al. Using and reporting the Delphi method for selecting healthcare quality indicators: a systematic review. PLoS ONE 2011;6:e20476.

34. Hasson F, Keeney S. Enhancing rigour in the Delphi technique research. Technol Forecasting Soc Change 2011;78:1695–704.

35. Franklin K, Hart JK. Idea generation and exploration: benefits and limitations of the policy Delphi research method. Innovative Higher Educ 2007;31:237–46.

36. Raine S, Sanderson C, Black N. Developing clinical guidelines: a challenge to current methods. BMJ 2005;331:631–3.

37. Hermann RC, Matiske S, Somekh D, et al. Quality indicators for international benchmarking of mental health care. Int J Qual Health Care 2006;18(Suppl 1):S1–8.

38. Archambault PM, van de Bell TH, Grajales F, et al. Wikis and collaborative writing applications in health care: a scoping review. J Med Internet Res 2013;15:e210.

39. den Breejen EM, Nelen WL, Knijnenburg JM, et al. Feasibility of a wiki as a participatory tool for patients in clinical guidelines development. J Med Internet Res 2012;14:e138.

40. National Health and Medical Research Council. NHMRC Guideline development and conflict of interest: identifying and managing conflicts of interest of prospective member and members of NHMRC committees and working groups developing guidelines. 2012.