BMJ Open

CareTrack Kids – Part 2 Assessing the appropriateness of the healthcare delivered to Australian children: a study protocol for a retrospective medical record review

Journal:	*BMJ Open*
Manuscript ID:	bmjopen-2015-007749
Article Type:	Protocol
Date Submitted by the Author:	22-Jan-2015

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Primary Subject Heading:	Evidence based practice
Secondary Subject Heading:	Paediatrics, Health services research, Research methods
Keywords:	Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Clinical audit < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

CareTrack Kids – Part 2 Assessing the appropriateness of the healthcare delivered to Australian children: a study protocol for a retrospective medical record review

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Keywords: Quality of Health Care, Paediatrics, Patient Safety, Medical Record Review, Guideline Adherence

Word count: 3,272

ABSTRACT

Introduction

Australian and international clinical practice guidelines are available for common paediatric conditions. Yet there is evidence that there are substantial variations between the guidelines, recommendations ("appropriate care") and the care delivered. This paper describes a study protocol to determine the appropriateness of the healthcare delivered to Australian children for 16 common paediatric conditions in acute and primary healthcare settings.

Methods and analysis

A random sample of 6,000-8,000 medical records representing a cross-section of the Australian paediatric population will be reviewed for appropriateness of care against a set of indicators within three Australian states (New South Wales, Queensland and South Australia) using multi-stage, stratified sampling. Medical records will be reviewed of children aged <16 years who presented with at least one of the study conditions during 2012 and 2013.

Ethics and dissemination

Human Research Ethics Committee approvals have been received from the Sydney Children's Hospital Network, Children's Health Queensland Hospital and Health Service and Women's and Children's Hospital Network (South Australia). An application is under review for the Royal Australian College of General Practitioners. The authors will submit the results of the study to relevant journals and offer oral presentations to researchers, clinicians, and policy-makers at national and international conferences.

Strengths and limitations of this study

- Obtain population level information regarding the appropriateness of healthcare delivered for Australian children for a range of conditions.
- Provide baseline condition and indicator data for ongoing monitoring in Australia overall, state and regional areas.
- The potential attrition rate of healthcare practices may introduce selection bias.

INTRODUCTION

Widespread variation in the healthcare delivered to patients persists despite the availability of clinical practice guidelines (CPGs) for the last 20 years.(1) CPGs emerged to promote the uptake of evidence into routine practice and standardise care. However healthcare professionals do not always follow them.(2-7) Further, there are many examples of variation in healthcare delivery which can impact on health outcomes as well as generate financial waste.(8, 9) For example, childhood asthma is estimated to affect more than 10% of Australian children, and, over a 12 month period, be associated with 15% of children missing school and 4% of all hospital admissions.(10) On the other hand inappropriate prescribing of combination pharmaceuticals containing inhaled steroids and long acting beta agonists for asthma can lead to unnecessary costs for consumers and the healthcare system resulting in adverse events and contributing to poor asthma control.(11, 12)

The measurement of how often appropriate care is delivered (care in line with evidence-or consensus based guidelines) can identify variations and gaps in care. Our adult study, CareTrack Australia,(3, 13, 14) undertaken by a number of the current authors, demonstrated that there are large gaps in the provision of appropriate care to patients, which is delivered on average only 57% of the time.(14) There is also considerable variation by type of healthcare practice [range 32% to 80%] and condition [13% to 90%].(14) These results are similar to the only other system-wide study of appropriateness of healthcare which showed that adults in the United States (US) received "recommended care" only 55% of the time.(15) In paediatrics there is only one comprehensive international study. This examined care in the US during 1998 and 2000 and was published in 2007.(16) This showed that children received appropriate care 68% of the time for acute medical problems, 53% for chronic medical conditions and 41% for preventive healthcare, yielding an average of 47%.(16) Clearly there is a need for strategies to reduce such deficits in order to deliver appropriate healthcare more effectively and efficiently.(14-16) Information at a population level regarding the appropriateness of healthcare delivered for children for a range of conditions is not available in Australia.

CareTrack Kids (CTK) aims to measure the appropriateness and safety of the healthcare delivered to children in Australia, and to establish a baseline for the variation and gaps in care identified. The CTK project involves a suite of three related studies: Part 1 - developing a set of clinical "appropriateness" indicators for common paediatric conditions; Part 2 - *this study* - measuring the appropriateness of paediatric care in Australia against these clinical indicators (using an on-site retrospective review of medical records during 2012 and 2013); and Part 3 collecting information regarding the prevalence and characteristics of adverse events in paediatric healthcare encounters during 2012 and 2013.

This protocol paper describes the methodology for Part 2 of the CTK project. The primary aim is to measure the appropriateness of healthcare delivered to Australian children for 16 common conditions during 2012 and 2013 in acute, primary, community and hospital healthcare settings. The study will identify areas with poor compliance for selected conditions to enable targeted healthcare improvements and provide baseline condition and indicator data for the ongoing monitoring of care for these conditions in Australia and at national, state, district/network and facility levels.

Box 1 Definitions used (13)

- *Condition* refers to acute (e.g. abdominal pain, gastroenteritis) and chronic (e.g. asthma, diabetes) conditions or being eligible for screening or preventive care (e.g. immunisations).
- *Evidence-based care (EBC)* is the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients. The practice of EBC means integrating individual clinical expertise with the best available external clinical evidence from systematic research.
- *Appropriate care* for this study is clinical care for a condition considered to be evidence based or consensus based by a panel of clinical experts in Australia in the context in which it was delivered in the years 2012 and 2013.
- *Indicator* is a condition-specific process measurement of healthcare management, appropriate for Australian practice during 2012 and 2013. Each indicator is scored as to whether eligible processes for prevention (e.g. immunisation), monitoring (e.g. asthma inhaler technique, HBA1C annual check) or treatment (e.g. antibiotics, prednisolone) have been carried out by answering 'yes' or 'no'.
- *Healthcare provider* refers to doctors, nurses, medical specialists and clinical psychologists.
- *Healthcare practices (HCP)* refers to hospitals, general practices, facilities, clinics, community centres.
- *Encounter* means any consultation with a healthcare provider or attendance at a healthcare practice for an activity relevant to one of the selected conditions for which there is an eligible indicator.
- *Compliance* with indicators is expressed as the percentage of eligible healthcare encounters at which appropriate care was received. Eligibility or scoring will be determined by the criteria listed under Component 9 of the Methods section.
- *Surveyor* is a person with appropriate clinical and audit experience who has been trained and accredited for this study to review medical records in relation to the care indicators.

METHODS AND ANALYSIS

This protocol is based on the methods used in the US(16) and CareTrack Australia(14) studies. We will develop a set of indicators for common paediatric conditions, recruit healthcare practices (HCPs), and collect information on-site from the HCP medical records. Medical records will be reviewed of children aged <16 years who presented with at least one of the 16 study conditions during 2012 and 2013. Our study will be a retrospective review of medical records, assessed against indicators of appropriate care. There are 10 components to this protocol (Figure 1).

INSERT FIGURE 1 ABOUT HERE

Component 1: Develop a list of candidate conditions

We identified 20 conditions amenable to population-level appropriateness of care research, based in published research,(17, 18) burden of disease(19) and quality of care priority lists.(20) We also included

other high prevalence conditions which are not well captured by these data sources (e.g. obesity(21) and urinary tract infection(22)). The CTK study will include 16 conditions, with the final list confirmed after the pilot stage (Component 5).

Component 2: Develop indicators

Candidate indicators will be extracted from national and international CPGs. These will be collated, reviewed internally by CTK investigators, and then posted on a wiki site for open, transparent review of their feasibility, acceptability and clinical impact by national clinical experts. This process has been described in detail elsewhere.(23)

Component 3: Determine the sampling strategy

Sampling method

A multi-stage, randomised, stratified sampling plan will be used to obtain a representative, national estimate of the percentage of healthcare encounters at which Australian children receive appropriate care. This sampling plan describes: the total number of medical records to be reviewed, the allocation of condition sampling per HCP type, the selection of geographical areas per state, the desired number and type of hospitals, the number and type of HCPs and the number of medical records per HCP. Geographical areas within the three states are defined by South Australian (SA) Local Health Networks, New South Wales (NSW) Local Health Districts and Queensland (QLD) Hospital and Health Services. The sampling plan will first select geographical areas within participating states, then HCPs within geographical areas after stratifying by metropolitan and regional locations. Medical records will be selected for review by sampling the databases of these nominated HCPs. Estimates of compliance with indicator at condition, state and national level and stage of care (screening, diagnosis, treatment, ongoing management) will also be reported (secondary outcomes).

Number of medical records to be reviewed per condition

Assuming a 95% confidence interval and an infinite population, at least 384 medical record reviews (MRRs) are required to estimate the true proportion of medical records that document appropriate care for 5% precision, and 97 records for 10% precision.(24) A conservative prevalence estimate of 50% was used in these sample size calculations, since *a priori* data do not exist for appropriate care delivered in Australian children as a national estimate. These calculations were determined at medical record level, since HCP encounters are nested within medical records and are challenging to compile into a sampling frame.

A minimum of 400 records per condition will be reviewed to report national estimates at condition level with 5% precision. A minimum of 100 records per condition will be reviewed in each state for state-

based reporting at 10% precision, and with allocation to metropolitan and regional locations according to population size. This study will not be powered for indicator reporting by stage of care.

Based on this, 100 MRR per condition will be allocated to SA and 300 MRR per condition to each of NSW and QLD (approximately proportional to the size of the state and location) (Table 1). With 16 conditions being assessed, at least 6,400 records will be reviewed to achieve the primary study aim—a national estimate with precision under 5%.

Table 1: Allocation of sample to the participating states per condition and stratified by geographical location

State	Geographical Location	Population count (0-16 year olds)[+]	Proportion (%)	Number of medical record reviews(25)
NSW	State	-	-	183*
	Metropolitan	1,098,745	39.6	134
	Regional	401,868	15.4	49
QLD	State	-	-	118*
	Metropolitan	593,910	21.4	73
	Regional	366,202	13.2	45
SA	State	-	-	100*
	Metropolitan	232,974	8.4	74
	Regional	81,719	2.9	26

[+]Population counts according to the 2011 Population Census(25)
[*]Allocate 100 to SA and 300 to Qld and NSW proportionally (based on size of the state & geographical area)

There will be a design effect, since records will be clustered by HCP facilities, and non-responses. A pilot study (component 5) will be used to obtain an estimate of the proportion of appropriate care delivered for some conditions, HCP response rates and the intraclass correlation by HCP type. Sample size estimates will be adjusted as necessary based on the results of the pilot study. It is expected that between 6,000 and 8,000 records will be reviewed.

Condition sampling

Each condition can be managed by more than one HCP type. Since CTK will recruit HCPs and sample from their databases, the proportion of management by each HCP for each condition needs to be specified. All available prevalence data (with gaps for some conditions) and input from expert clinicians were used to estimate the proportion of frequency of attendance by HCP type for each condition (Table 2). All percentages were rounded to the nearest multiple of five, to highlight that these are approximate. Preventive Care is not a standard condition and the data collected for this condition will be opportunistic (and hence not included in the sample size calculation). All hospital, emergency department (ED) and general practice (GP) records reviewed for the other conditions will also be assessed for preventive care.

Table 2 Proposed frequency of attendance to HCP types and condition

		Weighting by HCP type (%)				
#	Condition	Hospital	Emergency Department	General Practice	Specialist	Clinical Psychologists
1	Abdominal pain	5	50	45	0	0
2	ADHD	0	0	20	50	50
3	AGE	5	10	85	0	0
4	Anxiety/Depression	5	5	40	30	20
5	Asthma	5	10	80	5	0
6	Autism	0	0	20	50	30
7	Bronchiolitis, acute	10	10	80	0	0
8	Croup	5	25	70	0	0
9	Diabetes	20	35	10	35	0
10	Eczema	5	5	75	15	0
11	Fever, unspecified	5	60	30	5	0
12	GORD	20	5	65	10	0
13	Head Injury	5	70	25	0	0
14	Obesity	5	0	85	10	0
15	Otitis Media	0	10	80	10	0
16	Status Epilepticus	15	55	20	10	0
17	Tonsillitis	10	10	75	5	0
18	UTI	5	15	75	5	0
19	URTI	5	15	80	0	0
20	Preventive Care	all	all	all	0	0

All percentages have been rounded to the nearest multiple of 5.

The allocations in Table 2 reflect estimated frequency of attendance but not the amount of time spent on care or severity of conditions. In order to obtain sufficient records across HCP types when stratified by geographical location and state, we will over-sample some HCP types and under-sample others. At the end of the study, sample weights according to Table 2 will be applied when analysing the data (component 10).

Regional sampling

The Australian States of NSW, QLD and SA account for 51% of the Australian population of children under 14 years old(25) and were selected based on relationships with CTK partners. In each of these States all hospitals dedicated to the care of children will be included. Geographical areas will be eligible for inclusion if there is at least one non-children's hospital receiving at least 2,000 ED presentations and at least 500 paediatric inpatient admissions per annum. A sampling frame of geographical areas will be constructed stratified by state and location (metropolitan, regional). In total, eleven geographical areas will be involved in this study as listed in Table 3 (two metropolitan and two regional per state). SA had only three eligible areas (two metropolitan and one regional), so all were selected. Within the remaining four stratum per state (NSW and QLD), two areas each were selected for each location using simple

random sampling. SAS version 9.1.3 [SAS Institute, Cary, NC, USA] was used to perform the randomisation. The same number of records will be reviewed in each of the metropolitan and regional areas selected within a stratum.

Table 3 NSW and QLD stratum

	State	Geographical Location	Geographical Area Name*
1	NSW	Metropolitan	Central Coast
2	NSW	Metropolitan	Illawarra Shoalhaven
3	NSW	Metropolitan	Nepean Blue Mountains
4	NSW	Metropolitan	Northern Sydney
5	NSW	Metropolitan	South Eastern Sydney
6	NSW	Metropolitan	South Western Sydney
7	NSW	Metropolitan	Western Sydney
1	NSW	Regional	Hunter New England
2	NSW	Regional	Mid North Coast
3	NSW	Regional	Murrumbidgee
4	NSW	Regional	Northern NSW
5	NSW	Regional	Western NSW
1	QLD	Metropolitan	Gold Coast
2	QLD	Metropolitan	Metro North
3	QLD	Metropolitan	Metro South
4	QLD	Metropolitan	West Moreton
1	QLD	Regional	Cairns and Hinterland
2	QLD	Regional	Central Queensland
3	QLD	Regional	Darling Downs
4	QLD	Regional	Mackay
5	QLD	Regional	Sunshine Coast
6	QLD	Regional	Townsville
7	QLD	Regional	Wide Bay

* Only eligible geographical areas are included

Healthcare Practice (HCP) sampling

The hospitals in Table 4 will be invited to participate: all six major/tertiary children's hospitals in NSW, QLD and SA; and hospitals within each of the areas that provide substantive (as defined previously) emergency and inpatient services. An invitation to participate will be sent to a random selection of the practices and facilities inclusive of GPs, specialists, paediatricians and clinical psychologists who are geographically located within the selected state areas. Across all conditions and areas combined, a total of 555 HCPs are required. The number needed to recruit by HCP type across all conditions and areas is:

hospitals n-23, Emergency Departments (ED) n-23, GPs n-155, specialists n-258 and clinical psychologists n-96.

Table 4 Hospitals selected for invitation to participate in CTK

State	Areas	Hospitals
NSW	Sydney Children's Hospitals Network	Sydney Children's Hospital* Children's Hospital at Westmead*
	Hunter New England Network	John Hunter Children's*
	Illawarra Shoalhaven Local Health District	Wollongong
	South Western Sydney Local Health District	Bankstown Bowral Campbelltown Fairfield Liverpool
	Northern NSW Local Health District	Grafton Lismore The Tweed
	Western NSW Local Health District	Bathurst Dubbo Orange
QLD	Children's Health Queensland Hospital and Health Service	Royal Children's* Mater Misericodiae*
	Gold Coast Health Service District	Gold Coast University Robina
	Metro North Health Service District	Caboolture The Prince Charles Redcliff
	Central QLD Health Service District	Gladstone Rockhampton
	Wide Bay Health Service District	Bundaberg Hervey Bay Maryborough
SA	Women's and Children's Health Network	Women's and Children's*
	Southern Adelaide Local Health Network	Flinders Medical Centre Noarlunga Health Service
	Northern Adelaide Local Health Network	Lyell McEwin Modbury
	Country Health SA Local Health Network (SA Regional)	Whyalla Port Augusta Mt Gambier

*major/tertiary children's hospitals

Medical record sampling per HCP

HCPs that agree to participate will be asked to provide de-identified lists of children who meet the criteria for inclusion i.e. those aged <16 years who presented with one of the 16 conditions during 2012 and 2013. A random sample of records stratified according to condition will be drawn from each HCP. The number of records collected per HCP will be:

1. 25 records per GP (five records from five conditions)
2. Five records per specialist/clinical psychologist practice (five records from one condition)

3. A maximum of 100 records from each hospital (all conditions)

Component 4: Resolve data management requirements and structure

A web-based tool developed for the CareTrack Australia study(14) to enter data during MRR and subsequent data analysis, will be modified to include the CTK paediatric conditions and indicators. The tool will support secure data access, data encryption, off-line data collection and subsequent database synchronisation (in order to mitigate against the problems of fire-walls and poor internet connectivity in various healthcare settings).

Given the complexity of the indicator set, the tool will generate a set of indicators relevant to a particular condition, based upon participant demographic information, such as age. For example, the database will automatically filter out children without asthma aged < 5 years and > 12 years if the indicator is "*Children aged 5-12 years with mild frequent intermittent asthma are prescribed inhaled short acting beta2 agonists".* Algorithms will also filter indicators by the type of healthcare facility or practice. For example, the indicator for children diagnosed with mild or moderate croup presenting to an ED will not appear in the list of indicators to be reviewed in the GP setting. This will significantly reduce the workload on surveyors as only relevant indicators need to be reviewed.

Component 5: Undertake pilot study

Given the scale and complexity of the full study, a pilot study will be undertaken. This will help determine the types of problems that may be encountered and will inform the final selection of conditions, their indicators, and the logistical and practical aspects of recruiting participants and healthcare practices, of accessing records, and of extracting, recording, storing, and analysing the data. It will also inform the adjustments required to the sample size calculations in relation to non-response and design effects.

Component 6: Recruit healthcare practices

Recruitment of HCPs will follow the sampling procedures described in component 3.5. Invitations will be sent to Chief Executives (geographical areas and /or hospitals), General Managers, Specialists and Practice Managers requesting participation in the study. Due to the large number of GPs within each geographical area a random sample of practices will be generated, creating a list of practices to invite initially. GPs that decline participation will be replaced by the next GP on the list until the required number of practices is reached.

Component 7: Recruit surveyors

Experienced nurses will be employed to act as surveyors to collect the data. A key selection criterion will be experience in clinical audit and MRR. Eight full-time equivalent staff will be required. During the

employment process, prospective surveyors will participate in a test which involves the review of a mock medical record by coding indicators for each condition under time constraints (inclusion and exclusion criteria are provided for each indicator). Those applicants who score 90% or greater against a gold standard (the score achieved by TDH) will be considered for appointment.

Component 8: Train and quality check surveyors, measure inter-rater reliability

Training

Surveyors will participate in a training week which will include further mock MRRs; education on condition level information such as the evidence in the literature and CPGs; indicator inclusion and exclusion criteria; assessment and management procedures; inter-rater reliability testing against the gold standard; and database orientation and training.

Inter-rater reliability (IRR)

Each surveyor must achieve a kappa score of 0.8 against the 'gold standard' before collecting data. After the first two weeks of data collection another IRR test will assess progress against the 'gold standard' involving a random dual review of records. IRR results of 0.8 are acceptable for the surveyor to continue. Surveyors scoring less than 0.8 will be provided with training and re-evaluated against the gold standard. Surveyors unable to achieve this target will be redeployed within the project.

Other quality assurance activities

A comprehensive instruction manual will be developed prospectively which provides condition level information, indicator inclusion and exclusion criteria, and directions for use of the database, as used in the CareTrack adult study. Weekly teleconferences will be conducted to share expertise and address problems. Questions and scenarios provided in this forum will be collated and the responses forwarded to each surveyor.

Component 9: Undertake medical record reviews

Surveyors will undertake criterion-based(26) MRR using the data tool (see component 4). MRRs will be conducted for each participant-healthcare practice encounter (therefore more than one MMR may be undertaken for a participant). Surveyors will assess the record for evidence that the participant presented for treatment for the condition. The surveyor will respond to each indicator as 'Yes' (care provided during the encounter was consistent with the indicator), 'No', or 'Not Applicable' (N/A) (the indicator was not relevant to the encounter). For example, N/A will be assigned to those indicators that relate to a new diagnosis if the participant was already documented to have that condition. For all indicators, a text field is available for surveyors to explain the reason for their answer.

Component 10: Analyse data

The final sample will be weighted to the general population using pre-specified survey weights for state, geographical location, geographical area and HCP type (as per Table 2). The primary outcome is to report the percentage of eligible healthcare encounters at which appropriate care was received, analysed by aggregating percentage compliance for all conditions. Secondary outcomes are the percentage of appropriate care stratified by state, geographical location (metropolitan vs regional), and stages of care (screening, diagnosis, treatment, ongoing management). These will be analysed and reported by aggregating all conditions. The corresponding 95% exact binomial confidence interval will be calculated.

ETHICS AND DISSEMINATION

Ethical approval

Relevant Human Research Ethics Committee (HREC) approvals have been secured and Site Specific Approvals will be sought and received prior to participant and healthcare practice recruitment and MRRs in all jurisdictions, authorities, and health services. Single ethical review approval has been provided from a lead HREC in each state in order to provide ethical approval for the hospitals within that state. The lead HRECs include: Sydney Children's Hospitals Network (15 NSW hospitals), Queensland Royal Children's Hospital (12 QLD hospitals) and Women's and Children's Health Network (eight SA hospitals). The Royal College of General Practitioners National Research and Ethics Evaluation Committee application is under review. Site specific approvals will be sought from each hospital.

As part of the HREC application we are proposing that patient and individual HCP consent be waived as the project complies with the NHMRC "Guidelines approved under Section 95A of the Privacy Act 1988(27) and the NHMRC Chapter 2.3.10 "Qualifying or waiving conditions for consent".(28) In summary the study involves: minimal risk (to healthcare practices and participants) and cannot be achieved without access to records; with dispersed geographic areas across three states, the large number of HCPs and records (6,000-8,000) is logistically difficult to obtain consent; information is retrospective and there is no likely reason patients would not consent; data are entered directly onto a database which does not contain personal information; and only aggregated data are disseminated.

Statutory immunity

Statutory immunity protects participants from disclosure of any identifying information obtained through an approved quality assurance activity(29). CTK has applied to the Federal (Commonwealth) Minister for Health for statutory immunity under Section VC of the Commonwealth Health Insurance Act 1973.

Dissemination

The results of the study will be submitted to relevant national and international journals with the intention of publishing the results widely. The authors will offer oral presentations to stakeholder groups including those involving patients, researchers, clinicians, managers and policy-makers at national and international conferences.

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AUTHORS' CONTRIBUTIONS

JB and PDH initiated the project and led the NHMRC grant proposal. JB, AJ, LW, 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, AH, JW, EM, AL, GW, HMW, and CFH are Associate Investigators or Industry Partners and helped write the grant proposal, protocol and manuscript.

FUNDING STATEMENT

This work is supported by National Health and Medical Research Council (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 Australia (senior partner), 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 STATEMENT

Authors are salaried academics, clinicians, project staff or industry partners. They declare they have no competing interests.

FIGURE LEGENDS

Figure 1 Components of the CTK study

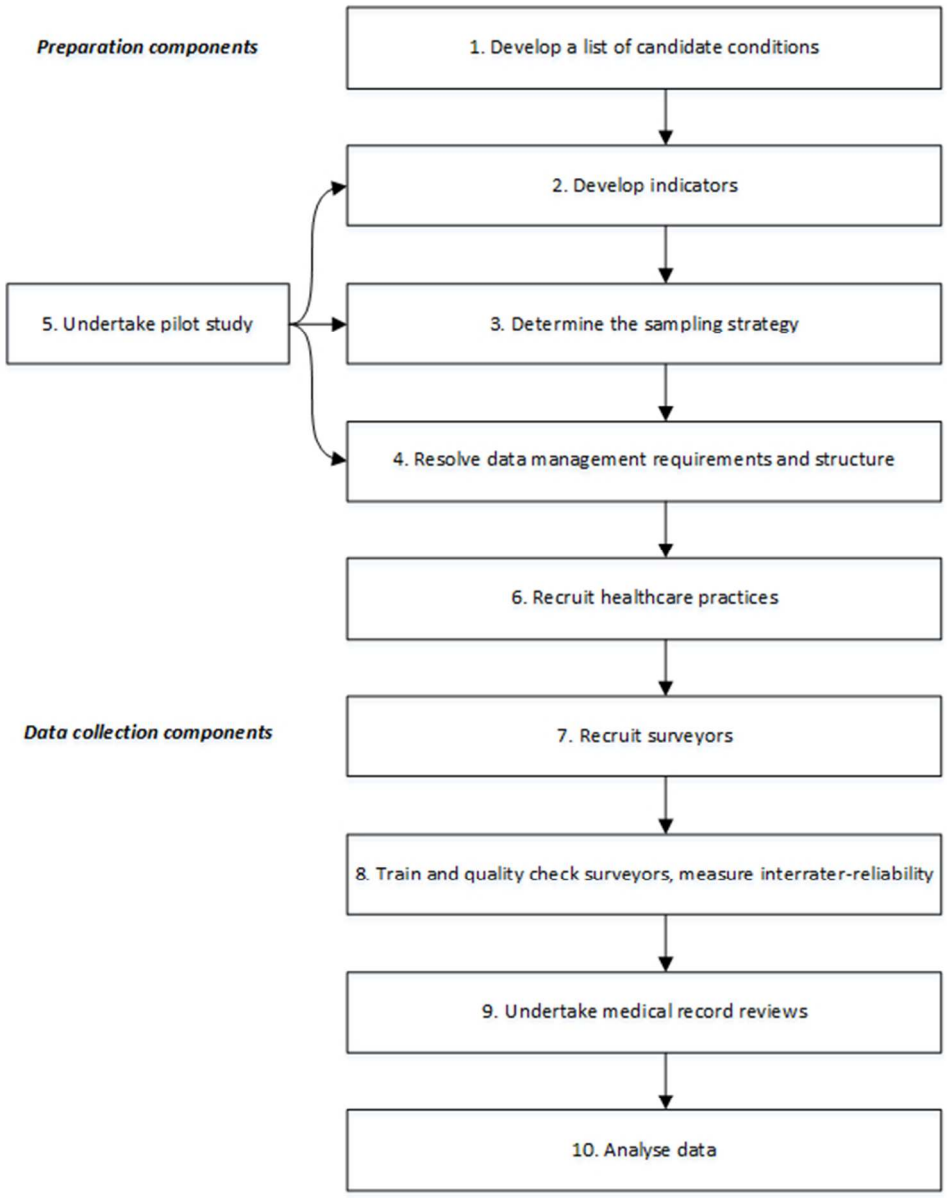

Figure 1 Components of the CTK study
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BMJ Open

CareTrack Kids – Part 2 Assessing the appropriateness of the healthcare delivered to Australian children: a study protocol for a retrospective medical record review

Journal:	*BMJ Open*
Manuscript ID:	bmjopen-2015-007749.R1
Article Type:	Protocol
Date Submitted by the Author:	17-Feb-2015

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Primary Subject Heading:	Evidence based practice
Secondary Subject Heading:	Paediatrics, Health services research, Research methods
Keywords:	Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Clinical audit < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

CareTrack Kids – Part 2 Assessing the appropriateness of the healthcare delivered to Australian children: a study protocol for a retrospective medical record review

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Keywords: Quality of Health Care, Paediatrics, Patient Safety, Medical Record Review, Guideline Adherence

Word count: 3,374

ABSTRACT

Introduction

Australian and international clinical practice guidelines are available for common paediatric conditions. Yet there is evidence that there are substantial variations between the guidelines, recommendations ("appropriate care") and the care delivered. This paper describes a study protocol to determine the appropriateness of the healthcare delivered to Australian children for 16 common paediatric conditions in acute and primary healthcare settings.

Methods and analysis

A random sample of 6,000-8,000 medical records representing a cross-section of the Australian paediatric population will be reviewed for appropriateness of care against a set of indicators within three Australian states (New South Wales, Queensland and South Australia) using multi-stage, stratified sampling. Medical records will be reviewed of children aged <16 years who presented with at least one of the study conditions during 2012 and 2013.

Ethics and dissemination

Human Research Ethics Committee approvals have been received from the Sydney Children's Hospital Network, Children's Health Queensland Hospital and Health Service and Women's and Children's Hospital Network (South Australia). An application is under review for the Royal Australian College of General Practitioners. The authors will submit the results of the study to relevant journals and offer oral presentations to researchers, clinicians, and policy-makers at national and international conferences.

Strengths and limitations of this study

- Obtain population level information regarding the appropriateness of healthcare delivered for Australian children for a range of conditions.
- Provide baseline condition and indicator data for ongoing monitoring in Australia overall, state and regional areas.
- The potential attrition rate of healthcare practices may introduce selection bias.

INTRODUCTION

Widespread variation in the healthcare delivered to patients persists despite the availability of clinical practice guidelines (CPGs) for the last 20 years.(1) CPGs emerged to promote the uptake of evidence into routine practice and standardise care. However healthcare professionals do not always follow them.(2-7) Further, there are many examples of variation in healthcare delivery which can impact on health outcomes as well as generate financial waste.(8, 9) For example, childhood asthma is estimated to affect more than 10% of Australian children, and, over a 12 month period, be associated with 15% of children missing school and 4% of all hospital admissions.(10) On the other hand inappropriate prescribing of combination pharmaceuticals containing inhaled steroids and long acting beta agonists for asthma can lead to unnecessary costs for consumers and the healthcare system resulting in adverse events and contributing to poor asthma control.(11, 12)

The measurement of how often appropriate care is delivered (care in line with evidence-or consensus based guidelines) can identify variations and gaps in care. Our adult study, CareTrack Australia,(3, 13, 14) undertaken by a number of the current authors, demonstrated that there are large gaps in the provision of appropriate care to patients, which is delivered on average only 57% of the time.(14) There is also considerable variation by type of healthcare practice [range 32% to 80%] and condition [13% to 90%].(14) These results are similar to the only other system-wide study of appropriateness of healthcare which showed that adults in the United States (US) received "recommended care" only 55% of the time.(15) In paediatrics there is only one comprehensive international study. This examined care in the US during 1998 and 2000 and was published in 2007.(16) This showed that children received appropriate care 68% of the time for acute medical problems, 53% for chronic medical conditions and 41% for preventive healthcare, yielding an average of 47%.(16) Clearly there is a need for strategies to reduce such deficits in order to deliver appropriate healthcare more effectively and efficiently.(14-16) Information at a population level regarding the appropriateness of healthcare delivered for children for a range of conditions is not available in Australia.

CareTrack Kids (CTK) aims to measure the appropriateness and safety of the healthcare delivered to children in Australia, and to establish a baseline for the variation and gaps in care identified. The CTK project involves a suite of three related studies: Part 1 - developing a set of clinical "appropriateness" indicators for common paediatric conditions(17); Part 2 - *this study* - measuring the appropriateness of paediatric care in Australia against these clinical indicators (using an on-site retrospective review of medical records during 2012 and 2013); and Part 3 collecting information regarding the prevalence and characteristics of adverse events in paediatric healthcare encounters during 2012 and 2013(18).

This protocol paper describes the methodology for Part 2 of the CTK project. The primary aim is to measure the appropriateness of healthcare delivered to Australian children for 16 common conditions during 2012 and 2013 in acute, primary, community and hospital healthcare settings. The study will identify areas with poor compliance for selected conditions to enable targeted healthcare improvements and provide baseline condition and indicator data for the ongoing monitoring of care for these conditions in Australia and at national, state, district/network and facility levels.

Box 1 Definitions used (13)

- *Condition* refers to acute (e.g. abdominal pain, gastroenteritis) and chronic (e.g. asthma, diabetes) conditions or being eligible for screening or preventive care (e.g. immunisations).
- *Evidence-based care (EBC)* is the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients. The practice of EBC means integrating individual clinical expertise with the best available external clinical evidence from systematic research.
- *Appropriate care* for this study is clinical care for a condition considered to be evidence based or consensus based by a panel of clinical experts in Australia in the context in which it was delivered in the years 2012 and 2013.
- *Indicator* is a condition-specific process measurement of healthcare management, appropriate for Australian practice during 2012 and 2013. Each indicator is scored as to whether eligible processes for prevention (e.g. immunisation), monitoring (e.g. asthma inhaler technique, HBA1C annual check) or treatment (e.g. antibiotics, prednisolone) have been carried out by answering 'yes' or 'no'.
- *Healthcare provider* refers to doctors, nurses, medical specialists and clinical psychologists.
- *Healthcare practices (HCP)* refers to hospitals, general practices, facilities, clinics, community centres.
- *Encounter* means any consultation with a healthcare provider or attendance at a healthcare practice for an activity relevant to one of the selected conditions for which there is an eligible indicator.
- *Compliance* with indicators is expressed as the percentage of eligible healthcare encounters at which appropriate care was received. Eligibility or scoring will be determined by the criteria listed under Component 9 of the Methods section.
- *Surveyor* is a person with appropriate clinical and audit experience who has been trained and accredited for this study to review medical records in relation to the care indicators.

METHODS AND ANALYSIS

This protocol is based on the methods used in the US(16) and CareTrack Australia(14) studies. We will develop a set of indicators for common paediatric conditions, recruit healthcare practices (HCPs), and collect information on-site from the HCP medical records. Medical records will be reviewed of children aged <16 years who presented with at least one of the 16 study conditions during 2012 and 2013. Our study will be a retrospective review of medical records, assessed against indicators of appropriate care. There are 10 components to this protocol (Figure 1).

INSERT FIGURE 1 ABOUT HERE

Component 1: Develop a list of candidate conditions

We identified 20 conditions amenable to population-level appropriateness of care research, based in published research,(19, 20) burden of disease(21) and quality of care priority lists.(22) We also included

other high prevalence conditions which are not well captured by these data sources (e.g. obesity(23) and urinary tract infection(24)). Following the pilot stage (Component 5) the CTK research team will assess each condition for feasibility (level of documentation in the medical record AND/OR the indicator is applicable to sufficient patients), impact (effect on patient health outcomes and/or healthcare system costs) and prevalence in order to confirm the final list of 16 conditions.

Component 2: Develop indicators

Candidate indicators will be extracted from national and international CPGs. These will be collated, reviewed internally by CTK research team, and then posted on a wiki site for open, transparent review of their feasibility, acceptability and clinical impact by national clinical experts. This process has been described in detail elsewhere.(17)

Component 3: Determine the sampling strategy

Sampling method

A multi-stage, randomised, stratified sampling plan will be used to obtain a representative, national estimate of the percentage of healthcare encounters at which Australian children receive appropriate care. This sampling plan describes: the total number of medical records to be reviewed, the allocation of condition sampling per HCP type, the selection of geographical areas per state, the desired number and type of hospitals, the number and type of HCPs and the number of medical records per HCP. Geographical areas within the three states are defined by South Australian (SA) Local Health Networks, New South Wales (NSW) Local Health Districts and Queensland (QLD) Hospital and Health Services. The sampling plan will first select geographical areas within participating states, then HCPs within geographical areas after stratifying by metropolitan and regional locations. Medical records will be selected for review by sampling the databases of these nominated HCPs. Estimates of compliance with indicator at condition, state and national level and stage of care (screening, diagnosis, treatment, ongoing management) will also be reported (secondary outcomes).

Number of medical records to be reviewed per condition

Assuming a 95% confidence interval and an infinite population, at least 384 medical record reviews (MRRs) are required to estimate the true proportion of medical records that document appropriate care for 5% precision, and 97 records for 10% precision.(25) A conservative prevalence estimate of 50% was used in these sample size calculations, since *a priori* data do not exist for appropriate care delivered in Australian children as a national estimate. These calculations were determined at medical record level, since HCP encounters are nested within medical records and are challenging to compile into a sampling frame.

A minimum of 400 records per condition will be reviewed to report national estimates at condition level with 5% precision. A minimum of 100 records per condition will be reviewed in each state for state-based reporting at 10% precision, and with allocation to metropolitan and regional locations according to population size. This study will not be powered for indicator reporting by stage of care.

Based on this, 100 MRR per condition will be allocated to SA and 300 MRR per condition to each of NSW and QLD (approximately proportional to the size of the state and location) (Table 1). With 16 conditions being assessed, at least 6,400 records will be reviewed to achieve the primary study aim—a national estimate with precision under 5%.

Table 1: Allocation of sample to the participating states per condition and stratified by geographical location

State	Geographical Location	Population count (0-16 year olds)[+]	Proportion (%)	Number of medical record reviews(26)
NSW	State	-	-	183*
	Metropolitan	1,098,745	39.6	134
	Regional	401,868	15.4	49
QLD	State	-	-	118*
	Metropolitan	593,910	21.4	73
	Regional	366,202	13.2	45
SA	State	-	-	100*
	Metropolitan	232,974	8.4	74
	Regional	81,719	2.9	26

[+]Population counts according to the 2011 Population Census(26)
*Allocate 100 to SA and 300 to Qld and NSW proportionally (based on size of the state & geographical area)

There will be a design effect, since records will be clustered by HCP facilities, and non-responses. A pilot study (component 5) will be used to obtain an estimate of the proportion of appropriate care delivered for some conditions, HCP response rates and the intraclass correlation by HCP type. Sample size estimates will be adjusted as necessary based on the results of the pilot study. It is expected that between 6,000 and 8,000 records will be reviewed.

Condition sampling

Each condition can be managed by more than one HCP type. Since CTK will recruit HCPs and sample from their databases, the proportion of management by each HCP for each condition needs to be specified. All available prevalence data (with gaps for some conditions) and input from expert clinicians were used to estimate the proportion of frequency of attendance by HCP type for each condition (Table 2). All percentages were rounded to the nearest multiple of five, to highlight that these are approximate. Preventive Care is not a standard condition and the data collected for this condition will be opportunistic (and hence not included in the sample size calculation). All hospital, emergency department (ED) and general practice (GP) records reviewed for the other conditions will also be assessed for preventive care.

Table 2 Proposed frequency of attendance to HCP types and condition

		Weighting by HCP type (%)				
#	Condition	Hospital	Emergency Department	General Practice	Specialist	Clinical Psychologists
1	Abdominal pain	5	50	45	0	0
2	ADHD	0	0	20	50	50
3	AGE	5	10	85	0	0
4	Anxiety/Depression	5	5	40	30	20
5	Asthma	5	10	80	5	0
6	Autism	0	0	20	50	30
7	Bronchiolitis, acute	10	10	80	0	0
8	Croup	5	25	70	0	0
9	Diabetes	20	35	10	35	0
10	Eczema	5	5	75	15	0
11	Fever, unspecified	5	60	30	5	0
12	GORD	20	5	65	10	0
13	Head Injury	5	70	25	0	0
14	Obesity	5	0	85	10	0
15	Otitis Media	0	10	80	10	0
16	Status Epilepticus	15	55	20	10	0
17	Tonsillitis	10	10	75	5	0
18	UTI	5	15	75	5	0
19	URTI	5	15	80	0	0
20	Preventive Care	all	all	all	0	0

All percentages have been rounded to the nearest multiple of 5.

The allocations in Table 2 reflect estimated frequency of attendance but not the amount of time spent on care or severity of conditions. In order to obtain sufficient records across HCP types when stratified by geographical location and state, we will over-sample some HCP types and under-sample others. At the end of the study, sample weights according to Table 2 will be applied when analysing the data (component 10).

Regional sampling

The Australian States of NSW, QLD and SA account for 51% of the Australian population of children under 14 years old(26) and were selected based on relationships with CTK partners. In each of these States all hospitals dedicated to the care of children will be included. Geographical areas will be eligible for inclusion if there is at least one non-children's hospital receiving at least 2,000 ED presentations and at least 500 paediatric inpatient admissions per annum. A sampling frame of geographical areas will be constructed stratified by state and location (metropolitan, regional). In total, eleven geographical areas will be involved in this study as listed in Table 3 (two metropolitan and two regional per state). SA had

only three eligible areas (two metropolitan and one regional), so all were selected. Within the remaining four stratum per state (NSW and QLD), two areas each were selected for each location using SAS version 9.1.3 [SAS Institute, Cary, NC, USA] to perform the randomisation. The same number of records will be reviewed in each of the metropolitan and regional areas selected within a stratum.

Table 3 NSW and QLD stratum

	State	Geographical Location	Geographical Area Name*
1	NSW	Metropolitan	Central Coast
2	NSW	Metropolitan	Illawarra Shoalhaven
3	NSW	Metropolitan	Nepean Blue Mountains
4	NSW	Metropolitan	Northern Sydney
5	NSW	Metropolitan	South Eastern Sydney
6	NSW	Metropolitan	South Western Sydney
7	NSW	Metropolitan	Western Sydney
1	NSW	Regional	Hunter New England
2	NSW	Regional	Mid North Coast
3	NSW	Regional	Murrumbidgee
4	NSW	Regional	Northern NSW
5	NSW	Regional	Western NSW
1	QLD	Metropolitan	Gold Coast
2	QLD	Metropolitan	Metro North
3	QLD	Metropolitan	Metro South
4	QLD	Metropolitan	West Moreton
1	QLD	Regional	Cairns and Hinterland
2	QLD	Regional	Central Queensland
3	QLD	Regional	Darling Downs
4	QLD	Regional	Mackay
5	QLD	Regional	Sunshine Coast
6	QLD	Regional	Townsville
7	QLD	Regional	Wide Bay

* Only eligible geographical areas are included

Healthcare Practice (HCP) sampling

The hospitals in Table 4 will be invited to participate: all six major/tertiary children's hospitals in NSW, QLD and SA; and hospitals within each of the areas that provide substantive (as defined previously) emergency and inpatient services. Once the sampling frame containing all the GPs, specialists, paediatricians and clinical psychologists who are geographically located within the selected state areas has been compiled a simple random sample of practices will be selected using a SAS randomisation

script. An invitation to participate will be sent to a practices selected, if a practice declines the next practice on the list will be approached. Across all conditions and areas combined, a total of 555 HCPs are required. The number needed to recruit by HCP type across all conditions and areas is: hospitals n-23, Emergency Departments (ED) n-23, GPs n-155, specialists n-258 and clinical psychologists n-96.

Table 4 Hospitals selected for invitation to participate in CTK

State	Areas	Hospitals
NSW	Sydney Children's Hospitals Network	Sydney Children's Hospital* Children's Hospital at Westmead*
	Hunter New England Network	John Hunter Children's*
	Illawarra Shoalhaven Local Health District	Wollongong
	South Western Sydney Local Health District	Bankstown Bowral Campbelltown Fairfield Liverpool
	Northern NSW Local Health District	Grafton Lismore The Tweed
	Western NSW Local Health District	Bathurst Dubbo Orange
QLD	Children's Health Queensland Hospital and Health Service	Royal Children's* Mater Misericodiae*
	Gold Coast Health Service District	Gold Coast University Robina
	Metro North Health Service District	Caboolture The Prince Charles Redcliff
	Central QLD Health Service District	Gladstone Rockhampton
	Wide Bay Health Service District	Bundaberg Hervey Bay Maryborough
SA	Women's and Children's Health Network	Women's and Children's*
	Southern Adelaide Local Health Network	Flinders Medical Centre Noarlunga Health Service
	Northern Adelaide Local Health Network	Lyell McEwin Modbury
	Country Health SA Local Health Network (SA Regional)	Whyalla Port Augusta Mt Gambier

*major/tertiary children's hospitals

Medical record sampling per HCP

HCPs that agree to participate will be asked to provide de-identified lists of children who meet the criteria for inclusion i.e. those aged <16 years who presented with one of the 16 conditions during 2012 and 2013. The records of each HCP will be stratified and a random selection of records will be selected from each strata using a SAS randomisation script.

The number of records collected per HCP will be:

1. 25 records per GP (five records from five conditions)
2. Five records per specialist/clinical psychologist practice (five records from one condition)
3. A maximum of 100 records from each hospital (all conditions)

Component 4: Resolve data management requirements and structure

A web-based tool developed for the CareTrack Australia study(14) to enter data during MRR and subsequent data analysis, will be modified to include the CTK paediatric conditions and indicators. The tool will support secure data access, data encryption, off-line data collection and subsequent database synchronisation (in order to mitigate against the problems of fire-walls and poor internet connectivity in various healthcare settings).

Given the complexity of the indicator set, the tool will generate a set of indicators relevant to a particular condition, based upon participant demographic information, such as age. For example, the database will automatically filter out children without asthma aged < 5 years and > 12 years if the indicator is "*Children aged 5-12 years with mild frequent intermittent asthma are prescribed inhaled short acting beta2 agonists".* Algorithms will also filter indicators by the type of healthcare facility or practice. For example, the indicator for children diagnosed with mild or moderate croup presenting to an ED will not appear in the list of indicators to be reviewed in the GP setting. This will significantly reduce the workload on surveyors as only relevant indicators need to be reviewed.

Component 5: Undertake pilot study

Given the scale and complexity of the full study, a pilot study involving a review of 200 medical records across all healthcare practice types will be undertaken. This will help determine the types of problems that may be encountered and will inform the final selection (as described in component 1) of conditions, their indicators, and the logistical and practical aspects of recruiting participants and healthcare practices, of accessing records, and of extracting, recording, storing, and analysing the data. It will also inform the adjustments required to the sample size calculations in relation to non-response and design effects. The data obtained from the pilot will not be included in the main results.

Component 6: Recruit healthcare practices

Recruitment of HCPs will follow the sampling procedures described in component 3. Invitations will be sent to Chief Executives (geographical areas and /or hospitals), General Managers, Specialists and Practice Managers requesting participation in the study. Due to the large number of GPs within each geographical area a random sample (as described in component 3) of practices will be generated, creating a list of practices to invite initially. GPs that decline participation will be replaced by the next GP on the list until the required number of practices is reached.

Component 7: Recruit surveyors

Registered nurses with a broad range of clinical knowledge, computer literacy and previous experience in MMR and clinical audit will be employed to act as surveyors to collect the data. Eight full-time equivalent staff will be required. During the employment process, prospective surveyors will participate in a test which involves the review of a mock medical record by coding indicators for each condition under time constraints (inclusion and exclusion criteria are provided for each indicator). Those applicants who score 90% or greater against one of the CTK researchers (a clinician who is involved in the condition clinical practice guideline searches, recommendation extraction, rewording of proposed indicators and will supervise the writing of the indicator inclusion/exclusion criteria) will be considered for appointment.

Component 8: Train and quality check surveyors, measure inter-rater reliability

Training

Surveyors will participate in a training week which will include further mock MRRs; education on condition level information such as the evidence in the literature and CPGs; indicator inclusion and exclusion criteria; assessment and management procedures; inter-rater reliability testing database orientation and training.

Inter-rater reliability (IRR)

Kappa scores will be calculated to test the level of agreement between each surveyor and one of the CTK researchers. Each surveyor must achieve a kappa score of 0.8 before collecting data. After the first two weeks of data collection another IRR test will be undertaken to assess progress. IRR results of 0.8 are acceptable for the surveyor to continue. Surveyors scoring less than 0.8 will be provided with training and re-evaluated. Surveyors unable to achieve this target will be redeployed within the project.

Other quality assurance activities

A comprehensive instruction manual will be developed prospectively which provides condition level information, indicator inclusion and exclusion criteria, and directions for use of the database, as used in the CareTrack adult study. Weekly teleconferences will be conducted to share expertise and address problems. Questions and scenarios provided in this forum will be collated and the responses forwarded to each surveyor.

Component 9: Undertake medical record reviews

Surveyors will undertake criterion-based(27) MRR using the data tool (see component 4). MRRs will be conducted for each participant-healthcare practice encounter (therefore more than one MMR may be undertaken for a participant). Surveyors will assess the record for evidence that the participant presented for treatment for the condition. The surveyor will respond to each indicator as 'Yes' (care

provided during the encounter was consistent with the indicator), 'No', or 'Not Applicable' (N/A) (the indicator was not relevant to the encounter). For example, N/A will be assigned to those indicators that relate to a new diagnosis if the participant was already documented to have that condition. For all indicators, a text field is available for surveyors to explain the reason for their answer.

Component 10: Analyse data

The final sample will be weighted to the general population using pre-specified survey weights for state, geographical location, geographical area and HCP type (as per Table 2). The primary outcome is to report the percentage of eligible healthcare encounters at which appropriate care was received, analysed by aggregating percentage compliance for all conditions. Secondary outcomes are the percentage of appropriate care stratified by state, geographical location (metropolitan vs regional), and stages of care (screening, diagnosis, treatment, ongoing management). These will be analysed and reported by aggregating all conditions. The corresponding 95% exact binomial confidence interval will be calculated.

ETHICS AND DISSEMINATION

Ethical approval

Relevant Human Research Ethics Committee (HREC) approvals have been secured and Site Specific Approvals will be sought and received prior to participant and healthcare practice recruitment and MRRs in all jurisdictions, authorities, and health services. Single ethical review approval has been provided from a lead HREC in each state in order to provide ethical approval for the hospitals within that state. The lead HRECs include: Sydney Children's Hospitals Network (15 NSW hospitals), Queensland Royal Children's Hospital (12 QLD hospitals) and Women's and Children's Health Network (eight SA hospitals). The Royal College of General Practitioners National Research and Ethics Evaluation Committee application is under review. Site specific approvals will be sought from each hospital.

In all HREC applications (as named above) we proposed that patient and individual HCP consent be waived as the project complies with the NHMRC "Guidelines approved under Section 95A of the Privacy Act 1988(28) and the NHMRC Chapter 2.3.10 "Qualifying or waiving conditions for consent".(29) In summary the study involves: minimal risk (to healthcare practices and participants) and cannot be achieved without access to records; with dispersed geographic areas across three states, the large number of HCPs and records (6,000-8,000) is logistically difficult to obtain consent; information is retrospective and there is no likely reason patients would not consent; data are entered directly onto a database which does not contain personal information; and only aggregated data are disseminated.

Statutory immunity

Statutory immunity protects participants from disclosure of any identifying information obtained through an approved quality assurance activity(30). CTK has applied to the Federal (Commonwealth) Minister for Health for statutory immunity under Section VC of the Commonwealth Health Insurance Act 1973.

Dissemination

The results of the study will be submitted to relevant national and international journals with the intention of publishing the results widely. The authors will offer oral presentations to stakeholder groups including those involving patients, researchers, clinicians, managers and policy-makers at national and international conferences.

DISCUSSION

We recognise several potential limitations to our study. HCPs will be invited to participate. Practices which agree may introduce a selection bias as they may have a higher rate of participation in research, proactive audit and existing feedback processes and hence a higher level of compliance. We consider this bias to be low as recognised in our CTA results where compliance ranged from 32-86%.(14) Retrospective MRRs done retrospectively does not capture the exact compliance of care which is received but not documented, thought to be generally about 5%. (15, 31)

In summary, CTK will, for the first time in Australia, provide information at a population-level information regarding the appropriateness of healthcare delivered for children for a range of conditions. Furthermore, baseline appropriateness data will be available which could provide the basis for ongoing monitoring processes in Australia overall, state and regional areas which may be of value to national and international researchers, policymakers, patient groups and practitioners.

AUTHORS' CONTRIBUTIONS

JB and PDH initiated the project and led the NHMRC grant proposal. JB, AJ, LW, 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 research team members and did the first drafting of the protocol manuscript. WBR, SG, AH, JW, EM, AL, GW, HMW, and CFH are Associate Investigators or Industry Partners and helped write the grant proposal, protocol and manuscript.

FUNDING STATEMENT

This work is supported by National Health and Medical Research Council (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 Australia (senior partner), 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 STATEMENT

Authors are salaried academics, clinicians, project staff or industry partners. They declare they have no competing interests.

FIGURE LEGENDS

Figure 1 Components of the CTK study

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CareTrack Kids – Part 2 Assessing the appropriateness of the healthcare delivered to Australian children: a study protocol for a retrospective medical record review

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Keywords: Quality of Health Care, Paediatrics, Patient Safety, Medical Record Review, Guideline Adherence

Word count: 3,374

ABSTRACT

Introduction

Australian and international clinical practice guidelines are available for common paediatric conditions. Yet there is evidence that there are substantial variations between the guidelines, recommendations ("appropriate care") and the care delivered. This paper describes a study protocol to determine the appropriateness of the healthcare delivered to Australian children for 16 common paediatric conditions in acute and primary healthcare settings.

Methods and analysis

A random sample of 6,000-8,000 medical records representing a cross-section of the Australian paediatric population will be reviewed for appropriateness of care against a set of indicators within three Australian states (New South Wales, Queensland and South Australia) using multi-stage, stratified sampling. Medical records will be reviewed of children aged <16 years who presented with at least one of the study conditions during 2012 and 2013.

Ethics and dissemination

Human Research Ethics Committee approvals have been received from the Sydney Children's Hospital Network, Children's Health Queensland Hospital and Health Service and Women's and Children's Hospital Network (South Australia). An application is under review for the Royal Australian College of General Practitioners. The authors will submit the results of the study to relevant journals and offer oral presentations to researchers, clinicians, and policy-makers at national and international conferences.

Strengths and limitations of this study

- Obtain population level information regarding the appropriateness of healthcare delivered for Australian children for a range of conditions.
- Provide baseline condition and indicator data for ongoing monitoring in Australia overall, state and regional areas.
- The potential attrition rate of healthcare practices may introduce selection bias.

INTRODUCTION

Widespread variation in the healthcare delivered to patients persists despite the availability of clinical practice guidelines (CPGs) for the last 20 years.(1) CPGs emerged to promote the uptake of evidence into routine practice and standardise care. However healthcare professionals do not always follow them.(2-7) Further, there are many examples of variation in healthcare delivery which can impact on health outcomes as well as generate financial waste.(8, 9) For example, childhood asthma is estimated to affect more than 10% of Australian children, and, over a 12 month period, be associated with 15% of children missing school and 4% of all hospital admissions.(10) On the other hand inappropriate prescribing of combination pharmaceuticals containing inhaled steroids and long acting beta agonists for asthma can lead to unnecessary costs for consumers and the healthcare system resulting in adverse events and contributing to poor asthma control.(11, 12)

The measurement of how often appropriate care is delivered (care in line with evidence-or consensus based guidelines) can identify variations and gaps in care. Our adult study, CareTrack Australia,(3, 13, 14) undertaken by a number of the current authors, demonstrated that there are large gaps in the provision of appropriate care to patients, which is delivered on average only 57% of the time.(14) There is also considerable variation by type of healthcare practice [range 32% to 80%] and condition [13% to 90%].(14) These results are similar to the only other system-wide study of appropriateness of healthcare which showed that adults in the United States (US) received "recommended care" only 55% of the time.(15) In paediatrics there is only one comprehensive international study. This examined care in the US during 1998 and 2000 and was published in 2007.(16) This showed that children received appropriate care 68% of the time for acute medical problems, 53% for chronic medical conditions and 41% for preventive healthcare, yielding an average of 47%.(16) Clearly there is a need for strategies to reduce such deficits in order to deliver appropriate healthcare more effectively and efficiently.(14-16) Information at a population level regarding the appropriateness of healthcare delivered for children for a range of conditions is not available in Australia.

CareTrack Kids (CTK) aims to measure the appropriateness and safety of the healthcare delivered to children in Australia, and to establish a baseline for the variation and gaps in care identified. The CTK project involves a suite of three related studies: Part 1 - developing a set of clinical "appropriateness" indicators for common paediatric conditions(17); Part 2 - *this study* - measuring the appropriateness of paediatric care in Australia against these clinical indicators (using an on-site retrospective review of medical records during 2012 and 2013); and Part 3 collecting information regarding the prevalence and characteristics of adverse events in paediatric healthcare encounters during 2012 and 2013(18).

This protocol paper describes the methodology for Part 2 of the CTK project. The primary aim is to measure the appropriateness of healthcare delivered to Australian children for 16 common conditions during 2012 and 2013 in acute, primary, community and hospital healthcare settings. The study will identify areas with poor compliance for selected conditions to enable targeted healthcare improvements and provide baseline condition and indicator data for the ongoing monitoring of care for these conditions in Australia and at national, state, district/network and facility levels.

Box 1 Definitions used (13)

- *Condition* refers to acute (e.g. abdominal pain, gastroenteritis) and chronic (e.g. asthma, diabetes) conditions or being eligible for screening or preventive care (e.g. immunisations).
- *Evidence-based care (EBC)* is the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients. The practice of EBC means integrating individual clinical expertise with the best available external clinical evidence from systematic research.
- *Appropriate care* for this study is clinical care for a condition considered to be evidence based or consensus based by a panel of clinical experts in Australia in the context in which it was delivered in the years 2012 and 2013.
- *Indicator* is a condition-specific process measurement of healthcare management, appropriate for Australian practice during 2012 and 2013. Each indicator is scored as to whether eligible processes for prevention (e.g. immunisation), monitoring (e.g. asthma inhaler technique, HBA1C annual check) or treatment (e.g. antibiotics, prednisolone) have been carried out by answering 'yes' or 'no'.
- *Healthcare provider* refers to doctors, nurses, medical specialists and clinical psychologists.
- *Healthcare practices (HCP)* refers to hospitals, general practices, facilities, clinics, community centres.
- *Encounter* means any consultation with a healthcare provider or attendance at a healthcare practice for an activity relevant to one of the selected conditions for which there is an eligible indicator.
- *Compliance* with indicators is expressed as the percentage of eligible healthcare encounters at which appropriate care was received. Eligibility or scoring will be determined by the criteria listed under Component 9 of the Methods section.
- *Surveyor* is a person with appropriate clinical and audit experience who has been trained and accredited for this study to review medical records in relation to the care indicators.

METHODS AND ANALYSIS

This protocol is based on the methods used in the US(16) and CareTrack Australia(14) studies. We will develop a set of indicators for common paediatric conditions, recruit healthcare practices (HCPs), and collect information on-site from the HCP medical records. Medical records will be reviewed of children aged <16 years who presented with at least one of the 16 study conditions during 2012 and 2013. Our study will be a retrospective review of medical records, assessed against indicators of appropriate care. There are 10 components to this protocol (Figure 1).

INSERT FIGURE 1 ABOUT HERE

Component 1: Develop a list of candidate conditions

We identified 20 conditions amenable to population-level appropriateness of care research, based in published research,(19, 20) burden of disease(21) and quality of care priority lists.(22) We also included

other high prevalence conditions which are not well captured by these data sources (e.g. obesity(23) and urinary tract infection(24)). Following the pilot stage (Component 5) ~~T~~the CTK research team ~~study~~ will assess each condition for feasibility (level of documentation in the medical record AND/OR the indicator is applicable to sufficient patients), impact (effect on patient health outcomes and/or healthcare system costs) and prevalence in order to confirm the final list of~~include~~ 16 conditions.~~, with the final list confirmed after the pilot stage (Component 5).~~

Component 2: Develop indicators

Candidate indicators will be extracted from national and international CPGs. These will be collated, reviewed internally by CTK ~~investigators~~research team, and then posted on a wiki site for open, transparent review of their feasibility, acceptability and clinical impact by national clinical experts. This process has been described in detail elsewhere.(17)

Component 3: Determine the sampling strategy

Sampling method

A multi-stage, randomised, stratified sampling plan will be used to obtain a representative, national estimate of the percentage of healthcare encounters at which Australian children receive appropriate care. This sampling plan describes: the total number of medical records to be reviewed, the allocation of condition sampling per HCP type, the selection of geographical areas per state, the desired number and type of hospitals, the number and type of HCPs and the number of medical records per HCP. Geographical areas within the three states are defined by South Australian (SA) Local Health Networks, New South Wales (NSW) Local Health Districts and Queensland (QLD) Hospital and Health Services. The sampling plan will first select geographical areas within participating states, then HCPs within geographical areas after stratifying by metropolitan and regional locations. Medical records will be selected for review by sampling the databases of these nominated HCPs. Estimates of compliance with indicator at condition, state and national level and stage of care (screening, diagnosis, treatment, ongoing management) will also be reported (secondary outcomes).

Number of medical records to be reviewed per condition

Assuming a 95% confidence interval and an infinite population, at least 384 medical record reviews (MRRs) are required to estimate the true proportion of medical records that document appropriate care for 5% precision, and 97 records for 10% precision.(25) A conservative prevalence estimate of 50% was used in these sample size calculations, since *a priori* data do not exist for appropriate care delivered in Australian children as a national estimate. These calculations were determined at medical record level, since HCP encounters are nested within medical records and are challenging to compile into a sampling frame.

A minimum of 400 records per condition will be reviewed to report national estimates at condition level with 5% precision. A minimum of 100 records per condition will be reviewed in each state for state-based reporting at 10% precision, and with allocation to metropolitan and regional locations according to population size. This study will not be powered for indicator reporting by stage of care.

Based on this, 100 MRR per condition will be allocated to SA and 300 MRR per condition to each of NSW and QLD (approximately proportional to the size of the state and location) (Table 1). With 16 conditions being assessed, at least 6,400 records will be reviewed to achieve the primary study aim—a national estimate with precision under 5%.

Table 1: Allocation of sample to the participating states per condition and stratified by geographical location

State	Geographical Location	Population count (0-16 year olds)[+]	Proportion (%)	Number of medical record reviews(26)
NSW	State	-	-	183*
	Metropolitan	1,098,745	39.6	134
	Regional	401,868	15.4	49
QLD	State	-	-	118*
	Metropolitan	593,910	21.4	73
	Regional	366,202	13.2	45
SA	State	-	-	100*
	Metropolitan	232,974	8.4	74
	Regional	81,719	2.9	26

[+]Population counts according to the 2011 Population Census(26)
*Allocate 100 to SA and 300 to Qld and NSW proportionally (based on size of the state & geographical area)

There will be a design effect, since records will be clustered by HCP facilities, and non-responses. A pilot study (component 5) will be used to obtain an estimate of the proportion of appropriate care delivered for some conditions, HCP response rates and the intraclass correlation by HCP type. Sample size estimates will be adjusted as necessary based on the results of the pilot study. It is expected that between 6,000 and 8,000 records will be reviewed.

Condition sampling

Each condition can be managed by more than one HCP type. Since CTK will recruit HCPs and sample from their databases, the proportion of management by each HCP for each condition needs to be specified. All available prevalence data (with gaps for some conditions) and input from expert clinicians were used to estimate the proportion of frequency of attendance by HCP type for each condition (Table 2). All percentages were rounded to the nearest multiple of five, to highlight that these are approximate. Preventive Care is not a standard condition and the data collected for this condition will be opportunistic (and hence not included in the sample size calculation). All hospital, emergency department (ED) and general practice (GP) records reviewed for the other conditions will also be assessed for preventive care.

Table 2 Proposed frequency of attendance to HCP types and condition

		Weighting by HCP type (%)				
#	Condition	Hospital	Emergency Department	General Practice	Specialist	Clinical Psychologists
1	Abdominal pain	5	50	45	0	0
2	ADHD	0	0	20	50	50
3	AGE	5	10	85	0	0
4	Anxiety/Depression	5	5	40	30	20
5	Asthma	5	10	80	5	0
6	Autism	0	0	20	50	30
7	Bronchiolitis, acute	10	10	80	0	0
8	Croup	5	25	70	0	0
9	Diabetes	20	35	10	35	0
10	Eczema	5	5	75	15	0
11	Fever, unspecified	5	60	30	5	0
12	GORD	20	5	65	10	0
13	Head Injury	5	70	25	0	0
14	Obesity	5	0	85	10	0
15	Otitis Media	0	10	80	10	0
16	Status Epilepticus	15	55	20	10	0
17	Tonsillitis	10	10	75	5	0
18	UTI	5	15	75	5	0
19	URTI	5	15	80	0	0
20	Preventive Care	all	all	all	0	0

All percentages have been rounded to the nearest multiple of 5.

The allocations in Table 2 reflect estimated frequency of attendance but not the amount of time spent on care or severity of conditions. In order to obtain sufficient records across HCP types when stratified by geographical location and state, we will over-sample some HCP types and under-sample others. At the end of the study, sample weights according to Table 2 will be applied when analysing the data (component 10).

Regional sampling

The Australian States of NSW, QLD and SA account for 51% of the Australian population of children under 14 years old(26) and were selected based on relationships with CTK partners. In each of these States all hospitals dedicated to the care of children will be included. Geographical areas will be eligible for inclusion if there is at least one non-children's hospital receiving at least 2,000 ED presentations and at least 500 paediatric inpatient admissions per annum. A sampling frame of geographical areas will be constructed stratified by state and location (metropolitan, regional). In total, eleven geographical areas will be involved in this study as listed in Table 3 (two metropolitan and two regional per state). SA had

only three eligible areas (two metropolitan and one regional), so all were selected. Within the remaining four stratum per state (NSW and QLD), two areas each were selected for each location using ~~simple random sampling.~~ SAS version 9.1.3 [SAS Institute, Cary, NC, USA] ~~was used~~ to perform the randomisation. The same number of records will be reviewed in each of the metropolitan and regional areas selected within a stratum.

Table 3 NSW and QLD stratum

	State	Geographical Location	Geographical Area Name*
1	NSW	Metropolitan	Central Coast
2	NSW	Metropolitan	Illawarra Shoalhaven
3	NSW	Metropolitan	Nepean Blue Mountains
4	NSW	Metropolitan	Northern Sydney
5	NSW	Metropolitan	South Eastern Sydney
6	NSW	Metropolitan	South Western Sydney
7	NSW	Metropolitan	Western Sydney
1	NSW	Regional	Hunter New England
2	NSW	Regional	Mid North Coast
3	NSW	Regional	Murrumbidgee
4	NSW	Regional	Northern NSW
5	NSW	Regional	Western NSW
1	QLD	Metropolitan	Gold Coast
2	QLD	Metropolitan	Metro North
3	QLD	Metropolitan	Metro South
4	QLD	Metropolitan	West Moreton
1	QLD	Regional	Cairns and Hinterland
2	QLD	Regional	Central Queensland
3	QLD	Regional	Darling Downs
4	QLD	Regional	Mackay
5	QLD	Regional	Sunshine Coast
6	QLD	Regional	Townsville
7	QLD	Regional	Wide Bay

* Only eligible geographical areas are included

Healthcare Practice (HCP) sampling

The hospitals in Table 4 will be invited to participate: all six major/tertiary children's hospitals in NSW, QLD and SA; and hospitals within each of the areas that provide substantive (as defined previously) emergency and inpatient services. Once the sampling frame containing all the GPs, specialists, paediatricians and clinical psychologists who are geographically located within the selected state areas

has been compiled a simple random sample of practices will be selected using a SAS randomisation script. An invitation to participate will be sent to a practices~~random~~ selected, if a practice declines the next practice on the list will be approached. ~~ion of the practices and facilities inclusive of GPs, specialists, paediatricians and clinical psychologists who are geographically located within the selected state areas.~~ Across all conditions and areas combined, a total of 555 HCPs are required. The number needed to recruit by HCP type across all conditions and areas is: hospitals n-23, Emergency Departments (ED) n-23, GPs n-155, specialists n-258 and clinical psychologists n-96.

Table 4 Hospitals selected for invitation to participate in CTK

State	Areas	Hospitals
NSW	Sydney Children's Hospitals Network	Sydney Children's Hospital* Children's Hospital at Westmead*
	Hunter New England Network	John Hunter Children's*
	Illawarra Shoalhaven Local Health District	Wollongong
	South Western Sydney Local Health District	Bankstown Bowral Campbelltown Fairfield Liverpool
	Northern NSW Local Health District	Grafton Lismore The Tweed
	Western NSW Local Health District	Bathurst Dubbo Orange
QLD	Children's Health Queensland Hospital and Health Service	Royal Children's* Mater Misericodiae*
	Gold Coast Health Service District	Gold Coast University Robina
	Metro North Health Service District	Caboolture The Prince Charles Redcliff
	Central QLD Health Service District	Gladstone Rockhampton
	Wide Bay Health Service District	Bundaberg Hervey Bay Maryborough
SA	Women's and Children's Health Network	Women's and Children's*
	Southern Adelaide Local Health Network	Flinders Medical Centre Noarlunga Health Service
	Northern Adelaide Local Health Network	Lyell McEwin Modbury
	Country Health SA Local Health Network (SA Regional)	Whyalla Port Augusta Mt Gambier

*major/tertiary children's hospitals

Medical record sampling per HCP

HCPs that agree to participate will be asked to provide de-identified lists of children who meet the criteria for inclusion i.e. those aged <16 years who presented with one of the 16 conditions during 2012 and 2013. The records of each HCP will be stratified and a random selection of records will be selected from each strata using a SAS randomisation script. ~~A random sample of records stratified according to condition will be drawn from each HCP.~~

The number of records collected per HCP will be:

1. 25 records per GP (five records from five conditions)
2. Five records per specialist/clinical psychologist practice (five records from one condition)
3. A maximum of 100 records from each hospital (all conditions)

Component 4: Resolve data management requirements and structure

A web-based tool developed for the CareTrack Australia study(14) to enter data during MRR and subsequent data analysis, will be modified to include the CTK paediatric conditions and indicators. The tool will support secure data access, data encryption, off-line data collection and subsequent database synchronisation (in order to mitigate against the problems of fire-walls and poor internet connectivity in various healthcare settings).

Given the complexity of the indicator set, the tool will generate a set of indicators relevant to a particular condition, based upon participant demographic information, such as age. For example, the database will automatically filter out children without asthma aged < 5 years and > 12 years if the indicator is "*Children aged 5-12 years with mild frequent intermittent asthma are prescribed inhaled short acting beta2 agonists".* Algorithms will also filter indicators by the type of healthcare facility or practice. For example, the indicator for children diagnosed with mild or moderate croup presenting to an ED will not appear in the list of indicators to be reviewed in the GP setting. This will significantly reduce the workload on surveyors as only relevant indicators need to be reviewed.

Component 5: Undertake pilot study

Given the scale and complexity of the full study, a pilot study involving a review of 200 medical records across all healthcare practice types will be undertaken. This will help determine the types of problems that may be encountered and will inform the final selection (as described in component 1) of conditions, their indicators, and the logistical and practical aspects of recruiting participants and healthcare practices, of accessing records, and of extracting, recording, storing, and analysing the data. It will also inform the adjustments required to the sample size calculations in relation to non-response and design effects. The data obtained from the pilot will not be included in the main results.

Component 6: Recruit healthcare practices

Recruitment of HCPs will follow the sampling procedures described in component 3.~~5.~~ Invitations will be sent to Chief Executives (geographical areas and /or hospitals), General Managers, Specialists and Practice Managers requesting participation in the study. Due to the large number of GPs within each geographical area a random sample (as described in component 3) of practices will be generated, creating a list of practices to invite initially. GPs that decline participation will be replaced by the next GP on the list until the required number of practices is reached.

Component 7: Recruit surveyors

~~Experienced nurses~~Registered nurses with a broad range of clinical knowledge, computer literacy and previous experience in MMR and clinical audit will be employed to act as surveyors to collect the data. ~~A key selection criterion will be experience in clinical audit and MRR.~~ Eight full-time equivalent staff will be required. During the employment process, prospective surveyors will participate in a test which involves the review of a mock medical record by coding indicators for each condition under time constraints (inclusion and exclusion criteria are provided for each indicator). Those applicants who score 90% or greater against ~~a~~one of the CTK researchers (a clinician who is involved in the condition clinical practice guideline searches, recommendation extraction, rewording of proposed indicators and will supervise the writing of the indicator inclusion/exclusion criteria) ~~gold standard (the score achieved by TDH)~~ will be considered for appointment.

Component 8: Train and quality check surveyors, measure inter-rater reliability

Training

Surveyors will participate in a training week which will include further mock MRRs; education on condition level information such as the evidence in the literature and CPGs; indicator inclusion and exclusion criteria; assessment and management procedures; inter-rater reliability testing ~~against the gold standard; and~~ database orientation and training.

Inter-rater reliability (IRR)

Kappa scores will be calculated to test the level of agreement between each surveyor and one of the CTK researchers. Each surveyor must achieve a kappa score of 0.8 ~~against the 'gold standard'~~ before collecting data. After the first two weeks of data collection another IRR test will be undertaken to assess progress. ~~against the 'gold standard' involving a dual review of records.~~ IRR results of 0.8 are acceptable for the surveyor to continue. Surveyors scoring less than 0.8 will be provided with training and re-evaluated. ~~against the gold standard.~~ Surveyors unable to achieve this target will be redeployed within the project.

Other quality assurance activities

A comprehensive instruction manual will be developed prospectively which provides condition level information, indicator inclusion and exclusion criteria, and directions for use of the database, as used in the CareTrack adult study. Weekly teleconferences will be conducted to share expertise and address problems. Questions and scenarios provided in this forum will be collated and the responses forwarded to each surveyor.

Component 9: Undertake medical record reviews

Surveyors will undertake criterion-based(27) MRR using the data tool (see component 4). MRRs will be conducted for each participant-healthcare practice encounter (therefore more than one MMR may be undertaken for a participant). Surveyors will assess the record for evidence that the participant presented for treatment for the condition. The surveyor will respond to each indicator as 'Yes' (care provided during the encounter was consistent with the indicator), 'No', or 'Not Applicable' (N/A) (the indicator was not relevant to the encounter). For example, N/A will be assigned to those indicators that relate to a new diagnosis if the participant was already documented to have that condition. For all indicators, a text field is available for surveyors to explain the reason for their answer.

Component 10: Analyse data

The final sample will be weighted to the general population using pre-specified survey weights for state, geographical location, geographical area and HCP type (as per Table 2). The primary outcome is to report the percentage of eligible healthcare encounters at which appropriate care was received, analysed by aggregating percentage compliance for all conditions. Secondary outcomes are the percentage of appropriate care stratified by state, geographical location (metropolitan vs regional), and stages of care (screening, diagnosis, treatment, ongoing management). These will be analysed and reported by aggregating all conditions. The corresponding 95% exact binomial confidence interval will be calculated.

ETHICS AND DISSEMINATION

Ethical approval

Relevant Human Research Ethics Committee (HREC) approvals have been secured and Site Specific Approvals will be sought and received prior to participant and healthcare practice recruitment and MRRs in all jurisdictions, authorities, and health services. Single ethical review approval has been provided from a lead HREC in each state in order to provide ethical approval for the hospitals within that state. The lead HRECs include: Sydney Children's Hospitals Network (15 NSW hospitals), Queensland Royal Children's Hospital (12 QLD hospitals) and Women's and Children's Health Network (eight SA hospitals). The Royal College of General Practitioners National Research and Ethics Evaluation Committee application is under review. Site specific approvals will be sought from each hospital.

~~As part of the~~ In all HREC applications (as named above) we ~~are~~ proposed~~ing~~ that patient and individual HCP consent be waived as the project complies with the NHMRC "Guidelines approved under Section 95A of the Privacy Act 1988(28) and the NHMRC Chapter 2.3.10 "Qualifying or waiving conditions for consent".(29) In summary the study involves: minimal risk (to healthcare practices and participants) and cannot be achieved without access to records; with dispersed geographic areas across three states, the large number of HCPs and records (6,000-8,000) is logistically difficult to obtain consent; information is retrospective and there is no likely reason patients would not consent; data are entered directly onto a database which does not contain personal information; and only aggregated data are disseminated.

Statutory immunity

Statutory immunity protects participants from disclosure of any identifying information obtained through an approved quality assurance activity(30). CTK has applied to the Federal (Commonwealth) Minister for Health for statutory immunity under Section VC of the Commonwealth Health Insurance Act 1973.

Dissemination

The results of the study will be submitted to relevant national and international journals with the intention of publishing the results widely. The authors will offer oral presentations to stakeholder groups including those involving patients, researchers, clinicians, managers and policy-makers at national and international conferences.

DISCUSSION

We recognise several potential limitations to our study. HCPs will be invited to participate. Practices which agree may introduce a selection bias as they may have a higher rate of participation in research, proactive audit and existing feedback processes and hence a higher level of compliance. We consider this bias to be low as recognised in our CTA results where compliance ranged from 32-86%.(14) Retrospective MRRs done retrospectively does not capture the exact compliance of care which is received but not documented, thought to be generally about 5%. (15, 31)

In summary, CTK will, for the first time in Australia, provide information at a population-level information regarding the appropriateness of healthcare delivered for children for a range of conditions. Furthermore, baseline appropriateness data will be available which could provide the basis for ongoing monitoring processes in Australia overall, state and regional areas which may be of value to national and international researchers, policymakers, patient groups and practitioners.

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AUTHORS' CONTRIBUTIONS

JB and PDH initiated the project and led the NHMRC grant proposal. JB, AJ, LW, 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~~ research team members and did the first drafting of the protocol manuscript. WBR, SG, AH, JW, EM, AL, GW, HMW, and CFH are Associate Investigators or Industry Partners and helped write the grant proposal, protocol and manuscript.

FUNDING STATEMENT

This work is supported by National Health and Medical Research Council (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 Australia (senior partner), 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 STATEMENT

Authors are salaried academics, clinicians, project staff or industry partners. They declare they have no competing interests.

FIGURE LEGENDS

Figure 1 Components of the CTK study

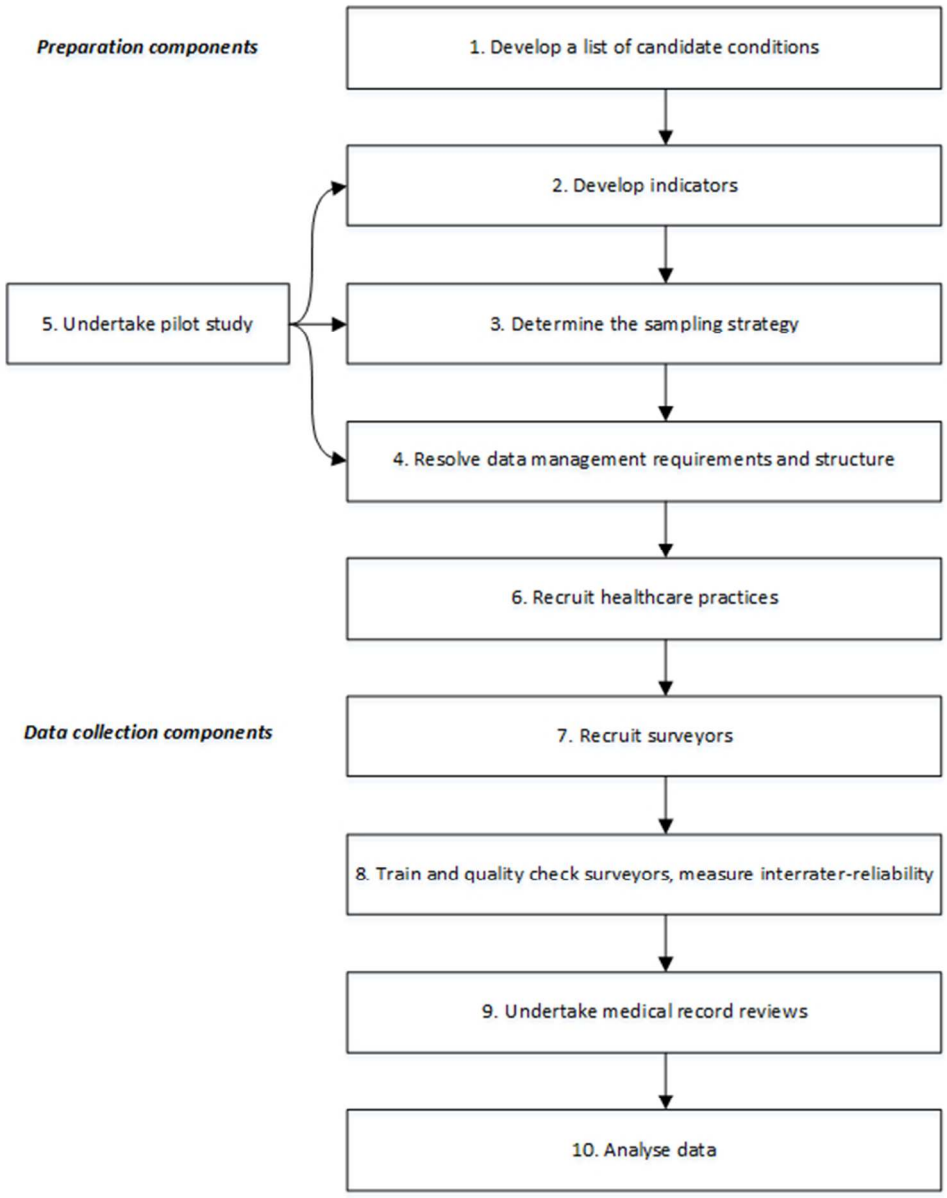

Figure 1 Components of the CTK study
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