



SYSTEMATIC REVIEW

What do we know about ancillary care practices in East and Southern Africa? A systematic review and meta-synthesis

[version 1; peer review: awaiting peer review]

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V1 First published: 29 Jun 2021, 6:164
<https://doi.org/10.12688/wellcomeopenres.16858.1>

Latest published: 29 Jun 2021, 6:164
<https://doi.org/10.12688/wellcomeopenres.16858.1>

Abstract

Background: Despite growing calls for the provision of ancillary care to study participants during medical research, there remains a noticeable gap in ethical guidelines for medical researchers in resource-constrained settings (RCS). We reviewed recent studies to determine the extent to which ancillary care is provided in East and Southern Africa and to examine the ethical justifications researchers provide to support their views on ancillary care obligations.

Methods: A systematic search for qualitative and mixed methods studies on ancillary care was conducted across MEDLINE, Embase, African Wide Information, PubMed, CINAHL Plus, and Scopus. The National Institutes of Health (NIH) Department of Bioethics and H3 Africa websites and Google Scholar were further searched. Studies conducted in East and Southern Africa between 2004 and 2020, as well as those that reported on ancillary care provided to study participants were included. All studies included in this review were evaluated for methodological quality as well as bias risk. NVivo version 12 was used for thematic analysis.

Results: Overall, 4,710 articles were identified by the initial search. After the data extraction and quality assessment, 24 articles were included. Key areas presented include ancillary care approaches and the themes of researcher motivation for providing ancillary care and expectations of participants in medical research. The review shows that while some international researchers do provide ancillary care to their study participants, approaches are not standardised without consistent guidelines for ethical practice for ancillary care. We found limited empirical studies in RCS that report on ancillary care, hence findings in this review are based on single studies rather than a collection of multiple studies.

Conclusions: This paper emphasizes the value of establishing ethics guidelines for medical researchers in RCS who consider provision of

Open Peer Review

Reviewer Status *AWAITING PEER REVIEW*

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ancillary care to their participants, and the need to account for these ethical guidelines in medical research.

Keywords

Ancillary Care Practices, Medical Research, Meta-Synthesis, Research Participants, Resource Constrained Settings, East and Southern Africa

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Author roles: **Kapumba BM:** Conceptualization, Data Curation, Formal Analysis, Methodology, Resources, Writing – Original Draft Preparation, Writing – Review & Editing; **Desmond N:** Conceptualization, Methodology, Resources, Supervision, Validation, Writing – Review & Editing; **Seeley J:** Conceptualization, Funding Acquisition, Methodology, Resources, Supervision, Validation, Writing – Review & Editing

Competing interests: No competing interests were disclosed.

Grant information: This work was supported by the Wellcome Trust [096527, <https://doi.org/10.35802/096527>; a Strategic Award to the Global Health Bioethics Network, administered by the London School of Hygiene and Tropical Medicine]. The funding body had no role in the design of the study and collection, analysis, and interpretation of data and in writing of the manuscript.

The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

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How to cite this article: Kapumba BM, Desmond N and Seeley J. **What do we know about ancillary care practices in East and Southern Africa? A systematic review and meta-synthesis [version 1; peer review: awaiting peer review]** Wellcome Open Research 2021, 6:164 <https://doi.org/10.12688/wellcomeopenres.16858.1>

First published: 29 Jun 2021, 6:164 <https://doi.org/10.12688/wellcomeopenres.16858.1>

Abbreviations

RCS: Resource-constrained settings; LMICs: Low-and-Middle-Income Countries; PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses; JBI-QARI: Joanna Briggs Institute Qualitative Assessment and Review Instrument; AMSTAR: A Measurement Tool to Assess Systematic Reviews

Introduction

Providing care and support to study participants during medical research that is not in pursuit of the research scientific objectives, to prevent study-related harms, or address study-related injuries presents ethical challenges worldwide¹. There remains a noticeable gap in research guidelines addressing medical researchers' obligations to provide additional or ancillary care in resource-constrained settings (RCS). Without clear guidance, how can and do researchers navigate and respond to the broader needs of ancillary care in RCS? The ethical imperative for provision of ancillary care during medical research has been documented and recommendations for the provision of such care are incorporated in ethical guidance such as the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO) and the Nuffield Council on Bioethics. These respectively state:

“when participants’ health needs during and after research cannot be met by local health infrastructure or the participant’s pre-existing health insurance, the researcher and sponsor must make prior arrangement for adequate care for participants with local health authorities, members of the communities from which persons are drawn, or nongovernmental organisations such as health advocacy groups”².

“...during research, participants may develop an entirely unrelated condition. In some circumstances, it may be relatively easy for researchers to treat the condition or refer participants to a local health centre where treatment can be provided”³.

Despite the existence of such guidance and extensive discussion in the ethics literature⁴, how this care can be achieved in practice, particularly across populations that vary politically, socially, and culturally is a matter for debate. This debate is heightened in RCS, where individuals who volunteer to participate in research may have several unmet health needs. Participants in low- and middle-income countries (LMICs) often live in poverty, suffer disproportionately from high disease burdens, such as HIV, tuberculosis, and malaria, and are often limited to sub-standard health care systems⁵. Even while health care services can be available within the local health care system, people are concerned about such services because of quality and costs^{6,7}. Existing limitations in accessibility and affordability of health care services are compounded by ongoing structural inequalities in health access, education, and socioeconomic status, leading to poor health outcomes. These underlying and overlapping structural issues may influence research participation amongst those most in need in order for them to access effective health care provided as a component of research. Recognising these structural concerns in RCS, researchers encounter a variety of unmet health needs among

their research participants, many of whom will require medical care ancillary to the study⁸. For example, a study on malaria may uncover other comorbidities like HIV or other infectious disease other than the condition under study. Despite recognition that additional health needs commonly arise amongst research participants, there is a lack of evidence as to how researchers actually respond when conducting research in RCS as well as questions as to their obligations to provide such care.

There is some evidence regarding the ethics of ancillary care in research conducted in developing countries^{4,9,10}. Some recent studies have reported on the obligations of medical researchers to provide ancillary care to their participants^{11–13}. While recognising these ethical obligations of ancillary care in medical research, researchers have argued that provision of ancillary care could unduly influence^{4,14,15} or could be a form of structural coercion to participants^{16–18} and also as one way of exploitation of vulnerable populations^{19–21}. The challenge, however, is that while much research has been conducted on the ethics of ancillary care in the context of medical research, there is a lack of clarity of what ancillary care means and the concept remains insufficiently unpacked to guide medical research in RCS. Our focus in this paper is on this paucity of information on approaches to and applications of ancillary care provision in East and Southern Africa.

Using a mixed methods approach, including systematic review and meta-synthesis, we looked for evidence of information on ancillary care provision or provision of care to study participants during research. We carried out a review of studies conducted in East and Southern Africa, where structural inequalities are particularly salient, that reported some ancillary care or the need to provide ancillary care to study participants. We seek to answer the question: “what are the current practices of and factors that influence the provision of ancillary care during medical research in east and southern Africa?” Specifically, we aimed to ascertain the current evidence on the extent of provision of ancillary care in East and Southern Africa and to explore the ethical justifications researchers provide to support their views on ancillary care obligations.

Methods

A systematic search was conducted to synthesise published articles and researchers that have recently worked on medical research that involved the provision of care and support to study participants in East and Southern Africa were contacted in an attempt to obtain their published articles if not available online. This review included qualitative empirical studies, systematic reviews, and theoretical articles describing the ethics of ancillary care. The Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA)^{22,23} guidelines were followed. Since this study utilised a secondary synthesis of data, which is already in the public domain, ethical approvals, and consent to participate were not necessary.

Search strategy

A comprehensive electronic search strategy was conducted to identify all relevant published studies where the primary focus was to highlight the provision of care to study participants by medical researchers, the variety of forms of care provided,

and the ethical basis justifying care provision. The search covered the period between June 2004 and November 2020 to ensure that the studies' findings reflected the role of ancillary care in medical research established in 2004¹ and reflect key information pertaining to current practices of ancillary care in RCS. Six databases were searched in November 2020. The initial search was conducted using a combination of index terms and text-based queries in [Ovid MEDLINE](#). We used this as a primary search strategy to identify text words contained in the title and abstract as well as classify the appropriate MeSH terms to be used ([Table 1](#)).

The next step used identified keywords and index terms in five electronic databases: [Embase](#) via Ovid® host, [African Wide Information](#) via EBSCO host, [PubMed](#), [CINAHL Plus](#), and [Scopus](#), [Table 2](#). A search string involving relevant key words and possible variations was constructed based on the domain (medical and behavioural research in RCS) and practices (provision of ancillary care to study participants). The search strategy was readjusted several times for comprehensive and updated retrieval. The National Institutes of Health (NIH) Department of Bioethics, Human Heredity and Health in Africa (H3 Africa) and Google Scholar websites were added to the search. The

reference lists of all studies potentially eligible for inclusion were screened to elicit additional relevant articles. If the full-text article was not available online, one attempt was made to contact the author, and if no response was received the article was excluded.

Study selection and eligibility criteria

The database search was initially conducted against a broad inclusion criterion by the first reviewer (BK) and was focused on the title and abstract of the articles. All articles identified to be potentially eligible for inclusion in this study were obtained in full texts. BK then conducted full-text article screening to identify studies that met the following inclusion criteria:

- Qualitative empirical study, systematic review or theoretical article
- *Published between June 2004 and November 2020*
- *Related to the domain of medical research involving human subjects conducted in East and Southern Africa*
- *Providing narratives on the ethics of ancillary care provision and experiences in RCS*

Table 1. Systematic review MEDLINE full search strategy.

Database: Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Daily and Versions(R) <1946 to November 23, 2020>	
Ancillary care	
1	ancillary.mp.
2	additional.mp.
3	practice*.mp.
4	care.mp.
5	service*.mp.
6	exp "Delivery of Health Care"/
7	(additional adj5 care).mp.
8	(additional adj5 service*).mp.
9	(additional adj5 practice*).mp.
10	Ancillary Care, Research/
Forms of ancillary care	
1	treat*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
2	(referral* or refer or referred).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
3	"Referral and Consultation"/
4	(consulted or consultation* or consult?).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
5	insurance. mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

Ethics of ancillary care	
1	ethic*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
2	exp Ethics/
3	moral*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
4	social.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
5	obligation*.mp [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
6	responsib*.mp [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
7	dut*.mp [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
Behavioral and medical research	
1	(medical or health-related or biomedical).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
2	(behavioral or social).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
3	researche*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
4	(clinical trials or observation* studies or cohort studies).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
East and Southern Africa	
1	LMIC/
2	south africa*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
3	South Africa/
4	malawi*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
5	Malawi/
6	east* africa*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
7	exp Africa, Eastern/
8	exp Africa, Southern/
9	southern africa*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

Table 2. Summary of the search strategy used for the review.

1.	Type of literature	Source
a	Published materials	MEDLINE
		EMBASE
		African Wide Information
		PubMed
		CINAHL Plus
		Scopus
b	Grey Literature	Google Scholar
		NIH – the department of Bioethics
		H3 Africa
2.	Search Terms	
		ancillary OR additional AND care OR treatment OR services
		obligation OR responsibilities OR duties AND researcher
		behavioural OR medical OR health related AND research OR studies
		LMIC OR sub-Saharan Africa OR southern Africa OR east Africa OR Malawi
		ethics

- *Reporting ancillary care practices, including the provision of standard of care to research participants additional to study related care. Clinical trials, observational studies, and prospective cohort studies that report on provision of ancillary care as part of the trial, either formally or informally were eligible.*

Studies were excluded if they were published prior to 2004 and not in English; if they documented or reported provision of care or support to study participants as part of the study; if conducted in high-resource settings; if they were opinion or commentary papers and workshop or meeting reports; and if there was no clear statement on the study setting.

Quality appraisal

Methodological rigor was achieved through three independent reviewers (BK, ND and JS) critically appraising the methodological quality of the included studies. All potentially eligible studies were appraised and scored for methodological quality according to the Joanna Briggs Institute critical appraisal checklist for qualitative studies (JBI-QARI)^{24,25}. Compared to other commonly used tools, the domains examined in this tool have been found to be more coherent and sensitive to assessment of quality, Table 3. The quality assessment was used not as a basis to exclude studies but rather to: (1) ascertain the relative contribution of each study to the overall synthesis and (2) assess the methodological rigour of each study as part of a process of assessing confidence in the review findings as well as to assess risk of bias^{26,27}.

The JBI-QARI 10 questions were applied to each individual paper and an aggregate score was calculated (Table 4). For systematic reviews and theoretical studies, we applied the AMSTAR 2 (a measurement tool to assess systematic reviews)²⁸ checklist based on the 16 items (Table 5 and Table 6).

Any disagreements that arose between reviewers were resolved through discussion with at least one other member of the research team. Team meetings were used to achieve a shared and consistent approach in operationalising the domains in the tools and inclusion of studies.

Data extraction

Details of each of the included papers were imported into a 2016 Microsoft Excel® (Microsoft Corporation, Redmond, WA, USA) file and duplicate articles were removed. Data extraction of study characteristics was primarily undertaken by one reviewer (BK); however, a second and third reviewer (ND and JS) randomly selected papers and double-checked the extractions for accuracy. In addition, the team had regular meetings to discuss any uncertainties, to ensure consistency of the approach and to agree definitions.

Portable Document Format files of all the included papers were then imported into NVivo 12 (QSR International, Warrington, UK) software and the “methods and results” sections were coded and analysed. If relevant information was located in other parts of the papers (for example, the background or discussion sections), these were also coded. Each relevant full-text

Table 3. Critical appraisal checklist for qualitative studies. Y=yes, N=no, U=unclear/unsure, P=partially.

Question	Y	N	U	P
1. Is there congruity between the stated philosophical perspective and the research methodology?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Is there congruity between the research methodology and the research question or objectives?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Is there congruity between the research methodology and the methods used to collect data?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Is there congruity between the research methodology and the representation and analysis of data?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Is there congruity between the research methodology and the interpretation of results?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Is there a statement locating the researcher culturally or theoretically?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Is the influence of the researcher on the research, and vice-versa, addressed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Are participants, and their voices, adequately represented?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Is the research ethical according to current criteria or, for recent studies, and is there evidence of ethical approval by an appropriate body?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Do the conclusions drawn in the research report flow from the analysis, or interpretation, of the data?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Table 4. JBI-QARI quality assessment score.

Study	Question										Score	Quality band	Richness: thick or thin	Publication type	Relevance: high, medium or low
	1	2	3	4	5	6	7	8	9	10					
Barsdorf <i>et al.</i> , 2010	Y	Y	Y	Y	Y	N	P	Y	Y	Y	8.5	high	thick	journal	high
Chou <i>et al.</i> , 2007	Y	Y	Y	Y	Y	P	Y	U	U	P	8	high	thick	journal	high
Devries <i>et al.</i> , 2015	Y	U	Y	U	Y	N	Y	U	Y	N	7	high	thick	journal	high
Essack <i>et al.</i> , 2010	Y	P	Y	N	U	P	U	U	Y	N	5.5	low	thin	journal	low
Gooding <i>et al.</i> , 2018	Y	Y	P	U	U	Y	N	Y	P	N	6	medium	thick	journal	medium
Kamuya <i>et al.</i> , 2013	Y	P	Y	Y	Y	P	Y	U	Y	P	8	high	thick	journal	high
Kamuya <i>et al.</i> , 2014	Y	N	Y	P	P	Y	P	Y	Y	U	7	high	thick	journal	high
Lairumbi <i>et al.</i> , 2012	Y	Y	Y	N	Y	N	Y	N	Y	N	6	medium	thick	journal	medium
Mfutso-Bengo <i>et al.</i> , 2008	Y	Y	Y	U	Y	P	P	U	Y	N	7	high	thick	journal	high
Mfutso-Bengo <i>et al.</i> , 2015	Y	Y	Y	Y	P	U	U	U	Y	N	7.5	high	thick	journal	medium
Mtunthama <i>et al.</i> , 2008	Y	P	Y	Y	Y	P	Y	U	Y	P	8	high	thick	journal	high
Nkosi <i>et al.</i> , 2020	Y	Y	Y	Y	Y	Y	U	U	Y	P	8.5	high	thick	journal	high
Pratt and Hyder, 2018	Y	Y	Y	P	P	Y	P	U	N	N	6	medium	thin	journal	low
Ramjee <i>et al.</i> , 2010	Y	U	Y	U	Y	N	Y	U	Y	U	7.5	high	thick	journal	high
Sullivan <i>et al.</i> , 2020	Y	Y	Y	Y	Y	U	U	U	Y	Y	8.5	high	thick	journal	high
Vreeman <i>et al.</i> , 2012	Y	Y	Y	N	U	P	Y	Y	Y	Y	8	High	thick	journal	high
Ward <i>et al.</i> , 2018	Y	U	Y	U	Y	Y	N	Y	Y	N	7	high	thick	journal	medium

Key: Y=yes, N=no, U=unclear/unsure, P=partial

Note: The questions refer to those in the JBI-QARI, [Table 3](#)

Table 5. AMSTAR 2 - a critical appraisal tool for systematic reviews. Y=yes, P=partially, N=no, NA=not applicable, PICO=population, intervention, comparator group, outcome.

Question	Y	P	N	NA
1 Did the research questions and inclusion criteria for the review include the components of PICO?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2 Did the report of the review contain an explicit statement that the review methods were established prior to the conduct of the review and did the report justify any significant deviations from the protocol?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3 Did the review authors explain their selection of the study designs for inclusion in the review?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4 Did the review authors use a comprehensive literature search strategy?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5 Did the review authors perform study selection in duplicate?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6 Did the review authors perform data extraction in duplicate?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7 Did the review authors provide a list of excluded studies and justify the exclusions?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8 Did the review authors describe the included studies in adequate detail?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9 Did the review authors use a satisfactory technique for assessing the risk of bias (RoB) in individual studies that were included in the review?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10 Did the review authors report on the sources of funding for the studies included in the review?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11 If meta-analysis was performed did the review authors use appropriate methods for statistical combination of results?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12 If meta-analysis was performed, did the review authors assess the potential impact of RoB in individual studies on the results of the meta-analysis or other evidence synthesis?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13 Did the review authors account for RoB in individual studies when interpreting/ discussing the results of the review?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14 Did the review authors provide a satisfactory explanation for, and discussion of, any heterogeneity observed in the results of the review?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15 If they performed quantitative synthesis did the review authors carry out an adequate investigation of publication bias (small study bias) and discuss its likely impact on the results of the review?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16 Did the review authors report any potential sources of conflict of interest, including any funding they received for conducting the review?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Table 6. AMSTAR 2 quality assessment score. P=partially.

Study	Question & inclusion	Protocol	Study design	Search strategy	Study selection	Data extraction	Exclusion reasons	Inclusion details	Assess risk of bias	Funding source	Analysis method	Risk of bias on analysis	Risk of bias	Discuss heterogeneity	Publication bias	Conflict of interest
Chilengi, 2009	P	P	Yes	No	No	No	No	No	No	No	No	N/A	N/A	Yes	Yes	Yes
Cohen et al., 2009	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	N/A	N/A	Yes	Yes	Yes
Embleton et al., 2015	P	P	Yes	No	No	No	No	No	No	Yes	No	N/A	N/A	Yes	Yes	Yes
Ngongo et al., 2012	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	N/A	N/A	Yes	Yes	Yes
Oduwo and Edwards, 2014	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	N/A	N/A	Yes	Yes	Yes
Richards and Helmchen, 2013	P	P	Yes	No	No	No	No	No	No	No	No	N/A	N/A	Yes	Yes	Yes
Stunkel and Grady, 2011	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	N/A	N/A	Yes	Yes	Yes

paper was analysed, and key details were recorded including year of publication, country in which the study was conducted, methods used, the phenomenon of interest, and target population. Furthermore, note was made of funding sources and any potential conflict of interest. Only qualitative data were extracted, whatever the type of research method used (qualitative or systematic reviews).

Data synthesis

The review followed the principles of a thematic synthesis approach as described by Thomas *et al.*^{29,30}. This process involved the aggregation of findings and categories to generate a set of synthesised statements that represented aggregation through categorisation of findings related in meaning by all the three reviewers (BK, ND, and JS). We followed the three stages outlined in thematic synthesis theory: (i) coding text from the methods, findings, and discussion sections of the included studies line-by-line; (ii) organising free codes into related

areas to structure descriptive themes to capture meaning; and (iii) developing analytical themes³¹. The themes for synthesis were predefined from the research questions that guided the coding, and then additional themes emerged as the data was examined. The outcome of coding was verified and discussed by BK with ND and JS to check for clarity, consistency and understanding. Each study was read several times to ensure that all texts relating to provision of care or support to study participants were integrated. The concepts were examined for similarities and differences and grouped together based on shared meanings to create new codes, and then organised into a set of descriptive themes³².

Results

The electronic search across all databases yielded a total of 4,710 references of which 3,469 unique articles remained after removal of duplicates, [Figure 1](#). All 3,469 were screened by title and abstract. A total of 3,379 articles that did not meet the

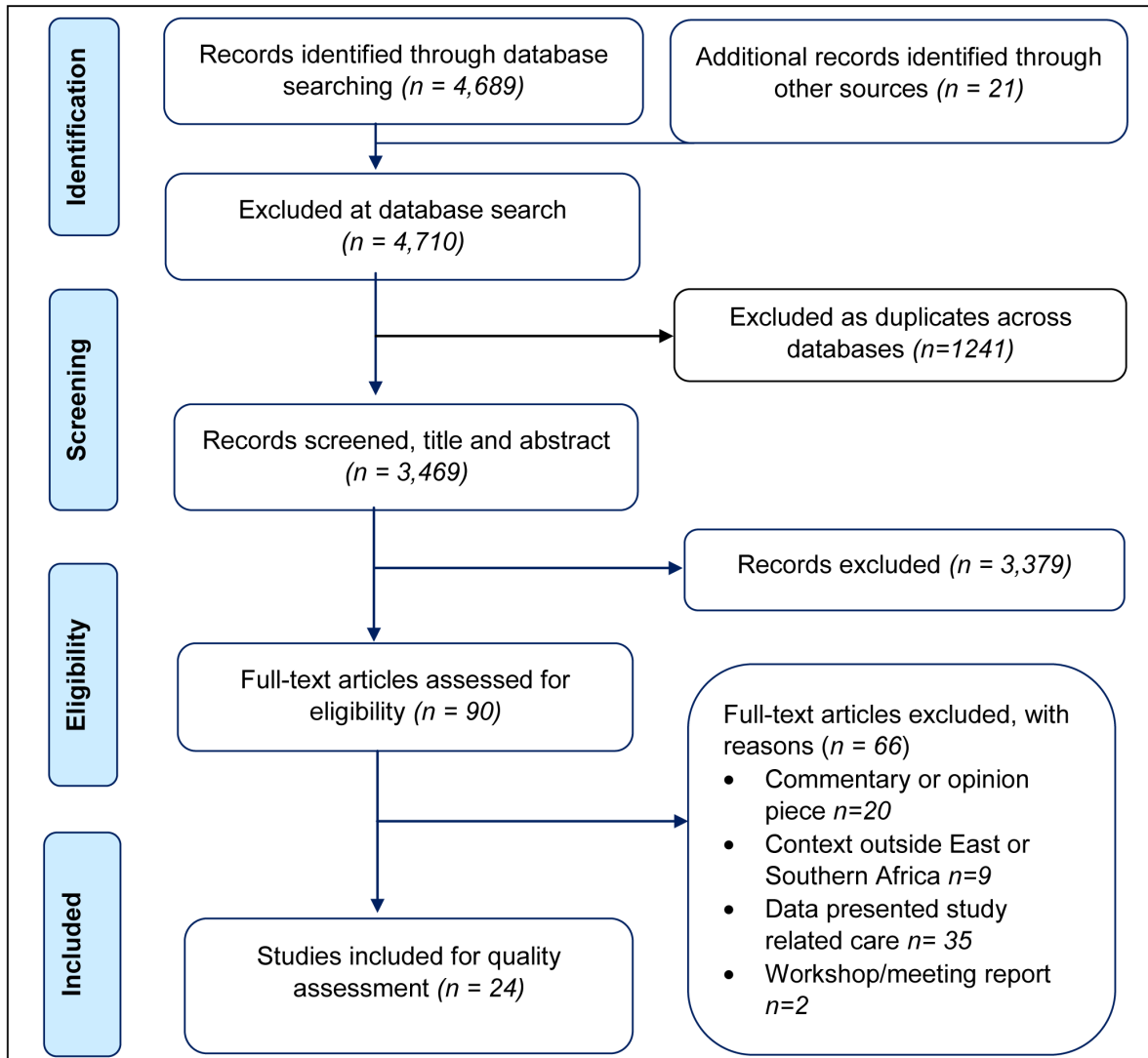


Figure 1. Prisma flow diagram – identification of relevant studies.

inclusion criteria were removed during screening. Of the 90 full-text articles screened, 66 were excluded: 20 were opinion or commentary papers, 9 were conducted outside East and Southern Africa, 35 reported provision of care that was related to the study (not ancillary), and 2 were workshop or meeting reports. The remaining 24 articles met the inclusion criteria and were included in the quality assessment.

Characteristics of included studies

All of the studies reported in the review were conducted in East and Southern African settings: Kenya ($n=6$)^{33–38}, Uganda ($n=2$)^{39,40}, Malawi ($n=5$)^{41–45}, South Africa ($n=4$)^{46–49}, Tanzania ($n=1$)⁵⁰, one study ($n=1$)⁵¹ was conducted at multiple research centres of East and Southern Africa and those that focused on RCS in general ($n=5$)^{52–56}. In total, 16 studies were qualitative, four were systematic reviews, three were theoretical and one quantitative. Only qualitative data was extracted from the quantitative study and used in the analysis. Although the search criteria focused on studies published from June 2004 to November 2020, 85% of the studies were published since 2010, reflecting a more contemporary context. This was expected given the fact that the concept of ancillary care in medical research has been increasingly recognised as a complex ethical challenge particularly where medical research is conducted in RCS. The included studies are summarised in [Table 7](#).

Key themes

The studies focused on different approaches to ancillary care provision (direct medical care, referral, non-medical support); researcher motivation for providing ancillary care (inadequate health care options, lack of available and accessible basic medical services, constraints in resources, vulnerability due to socio-economic inequalities); and participation for purpose (gaining access to medical care and support, ancillary care alternative for standard care offered by the local health care system, better medical care). A theme matrix of the included studies is summarised in [Table 8](#).

Approaches to ancillary care provision

In total, 14 studies conducted in Kenya ($n=5$)^{33,34,36–38}, Malawi ($n=3$)^{41,44,45}, South Africa ($n=3$)^{46–48}, Uganda ($n=2$)^{39,40}, and East and Southern Africa research centres ($n=1$)⁵¹ were explicit in mentioning the care and support provided to study participants additional to the study related care. Three main approaches are reported in the included studies that researchers use to address health needs of their participants identified during the conduct of research. The type of ancillary care reported in these studies ranged from provision of medical care by the research team or partners to assisting with referral services for participants to access additional care ([Table 9](#)).

Direct medical care. Studies that reported researchers provided health care according to the needs of participants made available access to free medical treatment, screening and diagnostic services and other services such as counselling.

Some studies reported that participants felt that they get better medical services when they join to participate in medical research.

Two studies reported the provision of ancillary care being extended to non-research participating individuals including partners of volunteers, ineligible to participate volunteers following screening, and former volunteers^{47,51}.

Referral. Referral was common for those participating in medical research to access healthcare services from partners or local health care service providers if not provided for by researchers. Referral was described to support participating individual access to specialised services or services not provided locally such as diagnostic and screening services or met the healthcare costs incurred by participants only during the study^{33,38,40,46,51}.

Non-medical support. While most of the studies reported the provision of health or medical care to meet participants' needs, there was a range of studies that mentioned non-health related support, and some studies provided both including for example provision for the tuition for children of parents participating in a study or the provision of water and sanitation in households and communities where research was conducted^{34,36,39,42}.

Researcher's motivation for providing ancillary care

Researcher motivations for providing ancillary care referred to researchers' justifications for meeting a particular additional need requiring either health care or support services. Ten studies explicitly mentioned the reasons researchers took a decision to consider providing care and support for their participants' ancillary health needs^{33,35,36,40,46,47,50–52,54}.

Increased vulnerabilities due to the lower socio-economic status of most participants in RCS was a frequently cited reason for ancillary care provision^{33,36,54}, justified because individuals failed to afford the costs for access to routine or basic medical care and treatment such as antiretroviral treatment³⁵. Other studies reported poor and resource-constrained health care demanding for additional mechanisms to address participants needs^{36,40,50,51}.

Participation for purpose

Evidence that individuals volunteer to participate in medical research to accrue benefits was reported in ten studies^{34,35,39,40,42,44,46–48,52}. Although participation is voluntary in medical research, participants expect researchers to be clear about the benefits whether directly or indirectly adding to their study responsibilities. Participants expectations on benefits from participating in medical research were reported across the majority of the studies. Perceived benefits expected by participants were dominated by the opportunity to access better quality care unavailable in the local health care system^{38,42,44,45,50,55}.

Table 7. Characteristics of included studies.

Author & year	Study aim	Methods	Description of participants	Funding
Barsdorf et al., 2010 South Africa	To explore a South African community's perceptions of who should provide what to HVT participants and explore respondents' perceptions of how and why this should be done	Qualitative (interviews)	29 respondents - adult men and women working at or attending five primary health care clinics in two rural areas in KwaZulu-Natal where HVT preparation activities have been carried out	International AIDS Vaccine Initiative (IAVI); US NIH funded HIV Vaccine Trials Network (HVTN) and FIT Biotech.
Embleton et al., 2015 Kenya	To describe the processes of adapting ethical guidelines for SCCY's specific vulnerabilities in LMIC	Theoretical study	446 SCCY included across the three studies based in Eldoret.	Eunice Kennedy Shriver National Institute of Child Health and Human Development
Richards and Helmchen, 2013 RCS	To highlight two previously underappreciated facets of ancillary care adoption and develop plausible solutions to reduce the unintended and overlooked adverse consequences from mandating the provision of ancillary care in developing countries	Theoretical study		Details not available
Chou et al., 2007 Uganda	To estimate the cost of identification, reporting, treatment, and follow-up of AEs in a perinatal HIV clinical trial in a developing country setting and to establish the relative cost for components of the AE reporting and management system	Quantitative – (cost evaluation)		HIV Prevention Trials Network and sponsored by the NIH, and US Department of Health and Human Services, under Cooperative Agreement
Pratt and Hyder, 2018 RCS	To identify how HSR funding schemes are designed to incentivise research that contributes to better health systems for the worst-off	Qualitative – (Semi-structured in-depth interviews)	- Grants officers working for 11 funders and organisations that support HSR in LMICs regarding their largest HSR funding scheme - 10 women and six men were interviewed about nine HSR funding schemes	Australian NHMRC Early Career Sidney Sax Public Health Overseas Fellowship
Ngongo et al., 2012 East and Southern Africa	To determine what services are currently provided by IAVI-sponsored RCs, identify gaps and challenges in service provision, and whether sponsors and RCs can agree on standards of care despite the differences in national and regional contexts	Systematic review		USAID
Ward et al., 2018 Tanzania & Ghana	To address the ethical issues raised by the provision of health care during the conduct of a long-standing PMVT in resource constrained settings	Qualitative – (key informant, semi-structured interview)	- clinical and research team members from four separate research centres in Ghana and Tanzania - wider partners of the PMVT were also included as respondents: respective government bodies, ethics review committees, health care system representatives, and international partners	GlaxoSmithKline Biologicals SA (GSK) and the PATH/MVI in partnership with Malawi Clinical Trials Alliance (MCTA)
Chilengi, 2009 RCS	To address from an ethical perspective, the moral obligations that the various stakeholders in biomedical research inevitably inherit by virtue of being in their state either as research participants themselves, researchers and their institutions, sponsors of the research, data safety monitoring boards, community advisory boards, regulatory authorities or committees that review and approve the research	Theoretical study		Details not available

Author & year	Study aim	Methods	Description of participants	Funding
Kamuya et al., 2013 Kenya	To explore how social relations between one group of fieldworkers and participants, and associated practical and ethical dilemmas, evolved and shifted over the course of the study	Qualitative (interviews and observations)	Fieldworkers	KEMRI-Wellcome Trust (Strategic Award and fellowship to SM)
Ramjee et al., 2010 South Africa	To describe the methods used to conduct HIV prevention trials in KwaZulu Natal, South Africa, with a focus on strategies developed to ensure good data quality, completion of the trial within an ethical framework, and partnerships developed with participants, the broader community and other health care providers	Qualitative approaches	Consultation and information sessions held with community stakeholders and political and traditional leaders as part of the community-entry process, prior to development of the CRS	The Bill and Melinda Gates Foundation, USAID, UK DfID and the MRC, the US NIH
Lairumbi et al., 2012 Kenya	To explore the views of stakeholders involved in health-related research regarding these forms of benefit sharing in a developing world context	Qualitative (in-depth interviews)	52 respondents drawn from institutions involved in global health research in Kenya	Wellcome Trust Biomedical Ethics PhD Studentship awarded to Lairumbi
Devries et al., 2015 Uganda	To describe how current research guidelines and best practice for conducting research with children may be applied to survey research, and to explore tensions between recommended best practices and real-life challenges encountered during data collection.	Qualitative (interviews with trial participants)	- 23 children who had been referred and who had received some sort of help from a protection agent, another 7 children who had been referred and who also had requested counselling after the survey, and a further 10 who had been referred for violence but did not request counselling and did not receive any support from a community agency. -The children attended different schools in Luwero. -22 were girls and 18 were boys, and most were aged 12-14 years.	Hewlett Foundation, UK-MRC, DfID and the Wellcome Trust, and Unicef Uganda.
Mtunthama et al., 2008 Malawi	To determine the usefulness of our subject recruitment information, the reasons for subject's participation in the research and the complication rates of our programme	Qualitative (interviews with trial volunteers)	A total of 100 volunteers (36 women; 64 men) participated in the audit in 2004. Nine subjects had been patients in the hospital, while the others were either employees, relatives of patients. Volunteers ranged from 20 to 57 years of age (mean 33.9 yrs).	Wellcome Trust of Great Britain
Nkosi et al., 2020 South Africa	To describe how research staff and intervention implementing partners responded to these needs, the challenges they faced in responding and the insights they shared for improving ancillary care planning in LMICs	Qualitative (interviews)	- 77 participants 1) participants from the research case study 2) ethics committee, PE officers and CAB members 3) community stakeholders	Wellcome Centre award - Wellcome Trust & MRC Newton Fund Collaborative Award
Stunkel and Grady, 2011 RCS	To examine, classify and compare empirical studies which measure self-reported motivations, reasons for participation, and/or decision-making processes for healthy volunteers participating in drug studies and other clinical research not intended to offer direct health benefits	Systematic review		NIH Clinical Center Department of Bioethics
Mfutsso-Bengo et al., 2015 Malawi	To fill a gap in the literature by contributing to the understanding of factors that motivate research participants to give their consent to participate in biomedical research in Malawi	Qualitative – (focus group discussion)	One hundred eighty-two research participants took part in 18 FGDs. Most of the participants were women and had attended at least primary school.	The Wellcome Trust

Author & year	Study aim	Methods	Description of participants	Funding
Vreeman et al., 2012 Kenya	To evaluate the community's perspectives on research, informed consent, and use of the baraza within the research process to engage families in western Kenya	Qualitative using mabaraza (similar to focus groups)	- 108 total participants - male and female Orphaned and separated children (vulnerable), chiefs, caregivers and members of the general public from selected communities	Multiple international funding organisation including NICHD, NIMH and USAID-AMPATH Partnership as part of the President's Emergency Plan for AIDS Relief (PEPFAR)
Cohen et al., 2009 RCS	To determine the extent to which recently registered clinical trials report the use of standard of care and post-trial obligations in trial registries, and whether trial characteristics vary according to setting	Systematic review		Details not available
Gooding et al., 2018 Malawi	To deepen understanding of the acceptability of research to potential participants, and to suggest directions for future assessment of acceptable trial design	Qualitative – (interviews)	- Parents in 41 households invited to enrol their children, including parents who enrolled their child (21), who withdrew (9), and who did not participate (11). - Most interviews involved the main carer (usually the mother), but in some cases a wife and husband were interviewed together because both wanted to be interviewed.	Research Project Cooperation Agreement between the University of Liverpool and the Centre for Disease Control: Epidemiology, Prevention and Treatment of Influenza and Other Respiratory Infections
Essack et al., 2010 South Africa	To identify and explore the ethical concerns of various stakeholders through an open-ended, in-depth interview approach	Qualitative – (open-ended, in-depth interview approach)	Stakeholder groups involved were Community Advisory Boards (CABs) at sites; site staff (including site principal investigators, medical officers and vaccine educators); media personnel that have reported on HVTs; civil society representatives (including human rights, gender and child groups); government representatives; Research Ethics Committee (REC) members who had reviewed HVT protocols; and HVT sponsors.	South African AIDS Vaccine Initiative
Oduwo and Edwards, 2014 Kenya	To determine whether cluster trials in Kenya are used artificially to delay or limit children's access to treatment, or designed and implemented to avoid obligations for children's right to health	Systematic reviews	Focused on clinical trials conducted in Kenya between 2003 and 2014	Wellcome Trust
Kamuya et al., 2014 Kenya	To explore nature of interactions between fieldworkers and research participants in community-based studies, the challenges that fieldworkers faced, and if and how these challenges were resolved	Qualitative – (in-depth interviews)	42 fieldworkers, 4 researchers, and 40 study participants	Wellcome Trust strategic award
Mfutso-Bengo et al., 2008 Malawi	To understand participants' perceptions, understanding and attitudes towards health research	Qualitative – (focus group discussion)	- 18 focus group discussions - 23 male and 159 female - 30 rural and 11 from urban	The Wellcome Trust, UK
Sullivan et al., 2020 Malawi	To elicit the views of Malawian women on factors influencing women's interest in participating in a HIV prevention clinical trial that involves initiating PrEP while pregnant.	Qualitative – (semi-structured interviews)	35 reproductive-aged women at risk for HIV in but HIV-negative	National Institute of Allergy and Infectious Diseases of the NIH

Table 8. Theme matrix of the included studies.

Author & year	Themes								
	Approaches to ancillary care			Researcher motivation for providing ancillary care			Participation for purpose		
	1	2	3	1	2	3	1	2	3
Barsdorf <i>et al.</i>, 2010		x		x					
Embleton <i>et al.</i>, 2015		x				x			
Richards and Helmchen, 2013						x			
Chou <i>et al.</i>, 2007	x		x				x	x	
Pratt and Hyder, 2018					x				
Ngongo <i>et al.</i>, 2012	x	x		x					
Ward <i>et al.</i>, 2018				x	x			x	
Chilengi, 2009						x			
Kamuya <i>et al.</i>, 2013	x		x						
Ramjee <i>et al.</i>, 2010	x	x		x					
Lairumbi <i>et al.</i>, 2012						x	x	x	x
Devries <i>et al.</i>, 2015	x	x		x	x	x			
Mtunthama <i>et al.</i>, 2008	x							x	x
Nkosi <i>et al.</i>, 2020		x			x	x			
Stunkel and Grady, 2011							x		
Mfutso-Bengo <i>et al.</i>, 2015				x	x				x
Vreeman <i>et al.</i>, 2012	x		x	x		x			
Cohen <i>et al.</i>, 2009					x				
Gooding <i>et al.</i>, 2018							x		
Essack <i>et al.</i>, 2010					x			x	
Oduwo and Edwards, 2014	x			x					
Kamuya <i>et al.</i>, 2014	x								x
Mfutso-Bengo <i>et al.</i>, 2008	x						x		x
Sullivan <i>et al.</i>, 2020	x							x	x
Key	1 = direct medical care 2 = referral 3 = non-medical support			1 = inadequate health care options 2 = constrained resources 3 = vulnerability due to socio-economic inequalities			1 = gain access to care and support 2 = alternative for standard care 3 = better medical care		

Gaining access to better medical care and support was reported as one of the direct benefits that most participants expected. Additional direct benefits included researchers providing direct health care for any problem presented or found in their participants, but not as a direct result of participation^{39,40,42,44,46,52}. Some studies reported participants expectations beyond direct

medical care provided by the study, such as for food items, cell phone airtime, and baby clothes^{34,36,47,48}. Others thought that participants considered provision of ancillary care as an alternative for standard care offered by the local health care system³⁹, for example, participants thinking that effective drugs are always available in medical research clinics⁴² and that any researcher

Table 9. Approaches to ancillary care provided to study participants.

Author	Context	Study-purpose	Form of ancillary care
Vreeman <i>et al.</i> , 2012	Kenya - Uasin Gishu county of western Kenya	To evaluate the community's perspectives on research, informed consent, and use of the baraza within the research process to engage families in western Kenya	<p>Health related care</p> <ul style="list-style-type: none"> - Primary health care services - Access to free treatment (ART) - Nutrition support services - Psychosocial support <p>Social support</p> <ul style="list-style-type: none"> - support with tuition for children - provide water sources - economic development training
Oduwo and Edwards, 2014	Kenya - Only trials conducted in Kenya were eligible for review.	To determine whether cluster trials in Kenya are used artificially to delay or limit children's access to treatment, or designed and implemented to avoid obligations for children's right to health	<p>Health related care</p> <ul style="list-style-type: none"> - any needed care equivalent to the local standard of care
Barsdorf <i>et al.</i> , 2010	South Africa - primary health care clinics in rural areas in KwaZulu-Natal	To explore a South African community's perceptions of who should provide what to HIV participants and explore respondents' perceptions of how and why this should be done	<p>Health related care</p> <ul style="list-style-type: none"> - Assisting with referral to access ART
Embleton <i>et al.</i> , 2015	Kenya	To describe the processes of adapting ethical guidelines for SCCY's specific vulnerabilities in LMIC.	<p>Health related care</p> <ul style="list-style-type: none"> - Assisting study participants with referral for specialised health care services
Ngongo <i>et al.</i> , 2012	East and Southern Africa - Research centres within the IAVI collaborative network in sub-Saharan Africa - Eastern and Southern Africa	To determine what services are currently provided by IAVI-sponsored RCs, identify gaps and challenges in service provision, and whether sponsors and RCs can agree on standards of care despite the differences in national and regional contexts	<p>Health related care</p> <ul style="list-style-type: none"> - Provided counselling - Provided CD4 count services to volunteers - Assisting study participants with referral for ART - Management or treatment of STIs - Provided male condoms, FP services, information, education and counselling on Adult male Circumcision - paying service costs for volunteers - Ancillary care extended to non-trial volunteers (STIs and CD4 count) including partners of volunteers, screen outs, and former volunteers
Kamuya <i>et al.</i> , 2013	Kenya	To explore how social relations between one group of fieldworkers and participants, and associated practical and ethical dilemmas, evolved and shifted over the course of the study	<p>Health related care</p> <ul style="list-style-type: none"> - Free medical care for all common illnesses during study period <p>Social support</p> <ul style="list-style-type: none"> - two chairs for each participating household, - sweets for children and minors, - educational materials to school going children, - in-kind token to each household at end of study

Author	Context	Study-purpose	Form of ancillary care
Ramjee <i>et al.</i> , 2010	South Africa - The HPRU set up clinical research sites (CRS) in several communities in the greater Durban area and one site in a rural area	To describe the methods used to conduct HIV prevention trials in KwaZulu Natal, South Africa, with a focus on strategies developed to ensure good data quality, completion of the trial within an ethical framework, and partnerships developed with participants, the broader community and other health care providers	Health related care <ul style="list-style-type: none"> - Provided HIV prevention, treatment, and care education to communities where Clinical Research Sites (CRSS) are based - Provided Pap smears to women of 18-50 years old - Referral of participants to health care partners - Provided STI screening with support from partners - Provided oral and injectable hormonal contraception at clinic sites
Devries <i>et al.</i> , 2015	Uganda - Luwero in Uganda	To describe how current research guidelines and best practice for conducting research with children may be applied to survey research, and to explore tensions between recommended best practices and real-life challenges encountered during data collection.	Health related care <ul style="list-style-type: none"> - Offered counselling to children (participants) - referral of participants urgently if they required immediate intervention - attending to children's health and emotional needs
Mtunthama <i>et al.</i> , 2008	Malawi - Queen Elizabeth Central Hospital, Blantyre, Malawi	To determine the usefulness of our subject recruitment information, the reasons for subject's participation in the research and the complication rates of our programme.	Health related care <ul style="list-style-type: none"> - provided free medical care to study participants for all their health problems
Nkosi <i>et al.</i> , 2020	South Africa - PIPSA of the Africa Health Research Institute (AHRI), KwaZulu-Natal, South Africa.	To describe how research staff and intervention implementing partners responded to these needs, the challenges they faced in responding and the insights they shared for improving ancillary care planning in LMICs	Social support <ul style="list-style-type: none"> - Referral for social and welfare services - Facilitate access to social grants
Chou <i>et al.</i> , 2007	Uganda, Kampala. The Makerere University-Johns Hopkins University Research Collaboration (MU-JHU)	To estimate the cost of identification, reporting, treatment, and follow-up of AEs in a perinatal HIV clinical trial in a developing country setting and to establish the relative cost for components of the AE reporting and management system	Health related care <ul style="list-style-type: none"> - provide prescribed medications without charge to study participants - paying expenses billed to the study by pharmacies Social support <ul style="list-style-type: none"> - paying expenses for meals for participants visiting the research clinic - financial assistance for hospitalised patients
Kamuya <i>et al.</i> , 2014	Kenya - The KEMRI-Wellcome Trust Research Programme (KEMRI-WT) in Kilifi on the Kenyan Coast.	To explore nature of interactions between fieldworkers and research participants in community-based studies, the challenges that fieldworkers faced, and if and how these challenges were resolved	Health related care <ul style="list-style-type: none"> - provided all needed health care to study participants and household members - assisting with referral costs of participants for other common illnesses - free medical care for all common illnesses during the study
Mfutso-Bengo <i>et al.</i> , 2008	Malawi - in the rural and urban health centre setting within Blantyre.	To understand participants' perceptions, understanding and attitudes towards health research	Health related care <ul style="list-style-type: none"> - free medical treatment for conditions unrelated to the study
Sullivan <i>et al.</i> , 2020	Malawi - Lilongwe	To elicit the views of Malawian women on factors influencing women's interest in participating in a HIV prevention clinical trial that involves initiating PrEP while pregnant.	Health related care <ul style="list-style-type: none"> - access to high quality care including treatment unavailable in the local healthcare system - access to diagnostic services

is mistakenly considered as a doctor who would provide care for any health problem³⁴.

Discussion

This study describes the practices of ancillary care provision to study participants in medical research in East and Southern Africa. The results show that reporting on care and support provided for the ancillary health needs of study participants in RCS remains low, despite growing calls for its implementation in medical research^{9,57–59}. For researchers conducting medical research in RCS to consider planning for ancillary care, as recommended in international ethical guidelines, the existing evidence-base is currently insufficient to guide best practice. For example, in the commentary to guideline 6 of the CIOMS it states that “*while sponsors are generally not obliged to provide healthcare services beyond what is required for their research, it is morally admirable to do so*”², but as universal guidelines how relevant are they to contexts with underlying poverty or structural inequalities in health care access? Should ancillary care be considered as unethical when it is really a need among participants and communities in RCS? Because it is difficult to establish whether medical researchers care about participants’ ancillary care needs, it was hard to explore the rationale for decisions on provision of ancillary care, particularly in clinical trials and observational studies. According to Haire⁶⁰, it could be that the possible reasons why medical researchers fail to provide ancillary care to their participants include funders’ or sponsors’ stringent rules over research funds. The systematic review and meta-synthesis undertaken here points toward some key considerations in relation to optimising the evidence on the ethics of ancillary care in research especially where it is conducted in RCS.

The findings of this study, consistent with the findings of other studies conducted in RCS, reveal that given the numerous health challenges faced by individual volunteers who participate in medical research, it may be obvious that researchers bear some responsibilities (not all) for the well-being of their participants⁶¹. The evidence has shown that participants in research conducted in RCS are likely to be socioeconomically vulnerable and face particular barriers to access healthcare services⁶². This inequality in health care access presents medical researchers in RCS with a need to provide or consider ancillary care for their participants as a direct benefit. The possible levels of ancillary care reported in the findings of this review are similar to what Dickert and Wandler⁵⁸ suggested which include: providing diagnostic information, making referrals for care, providing treatment, or paying for treatment. Ancillary needs of participants were documented in at least some of the included studies in this review, and researchers’ responsiveness to them was reported as justification for the provision of additional care. A cross-cutting theme in our synthesis was the tension between what researchers can provide as ancillary care for participants’ unmet health needs and the obligations linked to ethics of conducting medical research. However, it has proven difficult to establish strict rules as to what levels of ancillary care is universally required of researchers working in RCS^{13,58}.

While some contend that the provision of ancillary care can be perceived as either structural coercion or undue inducement for study participants or communities because of the health-care disparities in RCS^{16,18,63}, we argue that applying ethical guidelines makes this a requirement. Applying the concepts of coercion and undue influence are inadequate in determining whether or not ancillary care is unethical in medical research. We agree with JA Fisher¹⁶ in asserting that these terms (coercion and undue influence) only serve as a rational approach to ethics, one that ignores the social and economic contexts of research and instead places those domains outside the needs of participants. When considering the arguments advanced by others on medical researchers’ obligations, we contend that it is ethical for researchers to demonstrate responsiveness to the ancillary needs of individual participants or communities by offering care or support if they have the capacity to do so¹³. Both L Belsky and HS Richardson¹ and MW Merritt¹¹ have also suggested that the duty to address the health needs of study participants must be well anticipated and planned for during the planning of research studies, and funds specifically budgeted to provide ancillary care. In this review, however, it is unclear to what extent authors of the included studies included plans to provide for the ancillary health needs. That said, there are key questions concerning the impact this has on ethical research practice in RCS.

Notwithstanding the concerns that different authors raise about ancillary care, the findings support the theory that the ancillary care model has the potential to promote individual’s participation in medical research¹. Careful consideration of what participants expect from participating in medical research, as reported in the included studies, ancillary care can only be regarded as a benefit for individual volunteers to participate^{35,42,47,50}. Although most of the included studies that reported ancillary care provision to study participants did not mention any ethical conflicts encountered, Lairumbi and colleagues³⁵ suggested that since ancillary care conflates the benefits in research participation to those of clinical care – it may lead to errors in ethical judgement. While identifying variations in ancillary care practices across studies can indicate ways to strengthen medical research design, there is a debate over how much ancillary care is needed to be ethical⁴⁸, and how to make standardised research design responsive when approaches from different studies vary.

In order to develop and maintain trust and commitment of participants to the research, findings in this review revealed that researchers felt the need to demonstrate an understanding of participant health needs and be responsive to them^{46,51,52,54}. Special consideration on strategies that can improve conceptualisation of ancillary care are recommended to balance study related demands with ethical conduct of research and ancillary care obligations. Furthermore, medical research should be conducted with proper clinical and ethical oversight, and participants should be treated in a way that minimizes risks and maximises (feasible) benefits to their well-being.

Additionally, our findings highlight the importance of researchers seeking a balance between taking into consideration the

immense health burdens their participants face, while also ensuring that study regulations are upheld. Providing ancillary care in medical research is a critical issue to consider in RCS, but whereas provision of any care unrelated to the study may appear to be in question, this study reveals that such care is often critical. It must be noted that if additional care is given to participants through the study, would it qualify as reciprocity? In that specific case, who defines what benefit is in the context of RCS? If the community defines school fees as a benefit to them and researchers give it to them, should that be considered unethical?

This review is not without limitations. As discussed above, the provision of ancillary care is inconsistently reported in most of the biomedical research studies (observational or clinical trials). Moreover, due to limited reporting of ancillary care in biomedical research in RCS, we were unable to relate provision of ancillary care with guidelines from funding institutions. Also, because of the limited research in this area, some of the results presented within this review are based on single studies rather than the compilation of several studies. To aid clarity when presenting a description of the results of this review, we have summarised the volume of evidence supporting key themes drawn, [Table 8](#).

Conclusion

This systematic review and meta-synthesis aimed to understand the current practices of ancillary care provision by researchers conducting medical research in East and Southern Africa. While several studies have documented ancillary care being an ethical obligation for researchers conducting medical research in RCS, this, to our knowledge, is the first systematic review and meta-synthesis to assess the reporting of practices in East and Southern Africa. Understanding these current practices could help steer guidelines in the direction that meets the broader needs of ancillary care ethics in medical research. This review has shown that, factors influencing ancillary care decisions, participants expectation from participating in medical

research, and the ethical basis of conducting medical research in settings coupled with competing health challenges may explain the current practices of ancillary care in RCS. While the specifics of the issues that researchers face are likely to vary depending on the type of research and the context in which that research is being conducted, we recommend that appropriate ancillary care is also a key requirement to strengthen research practice and for the long-term sustainability of research programmes in RCS. The ethical challenges that must be addressed in medical research in RCS, such as those related to making provisions for ancillary care to study participants during research, are rarely clearly described. We highlight the importance of developing adaptable ethics guidelines for medical researchers in RCS to consider provision of ancillary care to their participants, and the need for these ethical guidelines to be accounted for in the conduct of medical research that aim to enhance quality of life in this population.

Data availability

All data underlying the results are available as part of the article and no additional source data are required.

Reporting guidelines

Figshare: PRISMA Checklist for “What do we know about ancillary care practices in East and Southern Africa? A systematic review and meta-synthesis.” <https://doi.org/10.6084/m9.figshare.14703426.v1>²³.

Data are available under the terms of the [Creative Commons Zero “No rights reserved” data waiver](#) (CC0 1.0 Public domain dedication).

Acknowledgements

We thank Deborah Nyirenda (Malawi-Liverpool Wellcome Trust Clinical Research Programme) for her help with additional articles included in this review and for reviewing the draft manuscript.

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