UE 7.4 - Méthodologie **D'ANALYSE D'ARTICLES**

CM6 : Researcher integrity, Validity, and Qualitative research

Andrew Wakefield

Early report

Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children

A J Wakefield, S H Murch, A Anthony, J Linnell, D M Casson, M Malik, M Berelowitz, A P Dhillon, P Harvey, A Valentine, S E Davies, J A Walker-Smith

Summary

Background We investigated a consecutive series of children with chronic enterocolitis and regressive developmental disorder.

Methods 12 children (mean age 6 years [range 3-10], 11 boys) were referred to a paediatric gastroenterology unit with a history of normal development followed by loss of acquired skills, including language, together with diarrhoea and abdominal pain. Children underwent gastroenterological, neurological, and developmental assessment and review of developmental records. Ileocolonoscopy and biopsy sampling, magnetic resonance imaging (MRI), electroencephalography (EEG), and lumbar puncture were done under sedation. Barium follow-through radiography was done where possible. Biochemical, haematological, and immunological profiles were examined.

Findings Onset of behavioural symptoms was associ... by the parents, with measles, mumps, and rub... vaccination in eight of the 12 children, with measl... infection in one child, and otitis media in a... All 12 children had intestinal abnormalities ranging from lymphoid nodular hyperplasia to ... Histology showed patchy chronic infla... in 11 children and reactive ileal lymphoid hyperplasia in seven, but no granulomas. Behavioural disorders included autism (nine), disintegrative psychosis (one), a... possible postviral or vaccinal encephalitis (one). There were no focal neurological abnormalities and ... and EEG tests were normal. Abnormal laboratory results were significantly raised urinary ... acid compared with age-matched controls (p=0·003), low haemoglobin in four children, ... low serum IgA in four children.

Interpretation We ... associated gastrointestinal ... and developmental regression in a group of previously ... children, which was generally associated in time with ... possible environmental triggers.

Lancet 199...; 351: 637–41

See Commentary page

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Introduction

We saw several children who, after a ... of apparent normality, lost acquired skills, incl... communication. They all had gastrointestinal ... symptoms, including abdominal pain, diarrhoea, and ... and, in some cases, food intolerance. We ... clinical findings, and gastrointestinal features of these ch...

Patients and methods

12 children, ... referred to ... department ... paediatric gastroenterology ... a history of a pervasive developmental ... order with loss of acquired skills and intestinal symptoms ... abdominal pain, bloating and fo... intolerance, were investigated. All children were admitted to the ward ... week, accompanied by their parents.

Clinical investigations

... took history, including details of imm... exposure to infectious diseases, and assessed ... case history was obtained by the s... Neurological and psychiatric assessments ... done by consultant staff (PH, MB) with HMS-4 criteria.[4] Developm... included a review of prospective developmental ... from parents, health visitors, and general practitioners. ... children did not undergo psychiatric assessment in h... had been assessed professionally elsewhere, so these ... were used as the basis for their behavioural diagnosis.

After bowel preparation, ileocolonoscopy was ... SHM or MAT under sedation with midazolam ... Paired frozen and formalin-fixed mucosal bi... taken from the terminal ileum; a... descending, and sigmoid colons, and ... procedure was recorded by video ... compared with images of the ... paediatric colonoscopies (four ... on children with ulcerative ... reported normal appea... as the terminal ileum ... follow-through radiography was possible in some ca...

Also under sedation, cerebral magnetic ... (MRI), electroencephalography (EEG) ... stem auditory, and sensory evoked po... made these possible), and lumbar punctures w...

Laboratory investigations

Thyroid function, serum long-chain fatty ... cerebrospinal-fluid lactate were measured to ... causes of childhood neurodegenerative ... methylmalonic acid was measured in randomly ... eight of the 12 children and 14 age-matched ... normal controls, by a modification of ... previously.[5] Chromatograms were ... computer, to analyse the methyl... and controls. Urinary methyl... patients and controls were ... Urinary creatinine was ... assay.

Children were scree... boys were screened ...

The Lancet, 1998

Ileal-lymphoid-nodular Hyperplasia, Non-specific Colitis, and Pervasive Developmental Disorder in Children

12 enfants

Lien évoqué avec l'autisme

2000 : la ROUGEOLe eradiquée aux USA, mais...

Les medias en parlent

Les parents questionnent

Les cas se multiplient

"The Facts In The Case Of Dr. Andrew Wakefield." - Tall Guy Investigates. Web. 29 Feb. 2016

FLASHBACK : 1996

- Un avocat spécialisé recrute Wakefield
- Objectif, démontrer un lien
- £150 par heure – total ~ £500 000
- Puisé dans un fonds d’assistance juridique

VACCIN UNIQUE?

- Brevet depose auparavant
- Vaccin ROR néfaste = jackpot !

LES ENFANTS

Falsification des données

Tests non approuvés

2010

➔ Révocation de Wakefield

➔ Rétractation de l’article

Une nouvelle carriere

- Jim Carrey
- Cindy Crawford
- Jenny McCarthy
- De Niro
- Elle McPherson

ERRORS, FRAUD & ETHICS

retractionwatch.com

Retraction Watch

Tracking retractions as a window into the scientific process

PAGES

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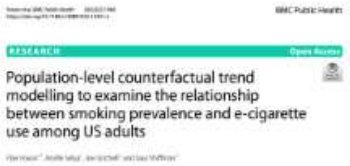
Authors file complaint with publisher as journal retracts vaping paper


BMC Public Health

RESEARCH

Population-level counterfactual trend modelling to examine the relationship between smoking prevalence and e-cigarette use among US adults

A paper that found smoking rates in the United States fell faster than expected as more people started using e-cigarettes has been retracted over the objections of its authors, who have filed a complaint with the journal's publisher.

As we reported in July, *BMC Public Health* informed the authors of "Population-level counterfactual trend modelling to examine the relationship between smoking prevalence and e-cigarette use among US adults" that the editors had decided to retract the article after receiving a critical letter. We reported:

> *The letter did not request retraction of the paper, but argued that its analyses "were flawed and therefore potentially*

Validité

Rappel :

Validité externe – conclusions peuvent être étendues à l'ensemble de la population

Validité interne – absence de biais

Evaluation de cet aspect

2 listes de points à vérifier

Menaces pour la validité interne

Maturation – Étude plus longue, changement des comportements ou attitudes des participants

Sélection – À l'inclusion, et à l'attribution

Histoire – Evénements socio-politiques

Instrumentation – calibration et contrôle

Régression – effet dû à un phénomène statistique

Attrition – données manquantes, différences fondamentales entre ceux qui perservèrent et les autres.

Menaces à la validité externe

Effet de test réactif – répondre à une enquête avant une intervention peut influer sur le comportement

Effet de sélection interactif – les participants ont des caractéristiques qu'on ne trouverait pas ailleurs

Effet **d'innovation** réactif – la nature artificielle de la situation change l'attitude des participants

Interférence externe – la participation à des activités en dehors de l'étude peut avoir une influence

L'IMPORTANCE de L'ÉCHANTILLON pour la validité

Un sous-groupe d'une population cible

- Objectif : pouvoir extrapoler les résultats

Obéit à des critères **d'inclusion** et **d'exclusion**

Méthodes d'attribution

- Aléatoire
- Systématique (tous les x)
- Stratification (tiré de sous-groupes)
- Communautés
- Convenance (biais quasi systématique)

L'ARTICLE de recherche qualitative

Questions humaines ou sociales dans leurs milieux naturels

Approche inductive

Raisons méthodologiques ou éthiques qui excluent une approche quantitative

- Sujets ne peuvent ou ne veulent pas participer dans une étude expérimentale traditionnelle
- Situations où il y a un groupe émergeant
- Supplément aux méthodes quantitatives – recherche d'hypothèses, d'explications
- Consentement impossible
- Etudes d'un individu, culture, société ou phénomène

4 approches possibles (non limitatif)

- Phenomenology
  - Souvent à partir d'entretiens
- Action research
  - Etude de son propre fonctionnement professionnel avec mise en application des améliorations, processus cyclique
- Grounded theory (Glaser & Strauss, 1967)
  - Développement d'une théorie à partir de données, comparaison et analyse répétées, recueil jusqu'à saturation
- Ethnography
  - Observation à long terme sur le terrain de comportements au sein d'un groupe

Des méthodes variées

Observation - participation

Immersion du chercheur dans le groupe

Observation directe

Le chercheur est effacé

Interview libre

Pas de structure fixe hormis quelques questions initiales

Etudes de cas

Faire ressortir des théories à partir des cas (entretiens et/ou observation)

Assurance qualité

Validité – reflet exact

- Triangulation – plusieurs approches
  - Méthodes
  - Sources
  - Analystes
  - Théories
- Observations contradictoires – identification et explication
- Validation par les sondés – vérification des interprétations
- Comparaisons répétées – vue d'ensemble, source d'idées

Fiabilité – reproductible?

Les plus et moins de L'APPROCHE qualitative

+

- Niveau de détail
- Questions évolutives en temps réel.
- Méthodologie adaptive pour tenir compte des nouveaux faits observés.
- Intérêt humain plus riche que des chiffres.
- Identification de nuances ou aspects compliqués.
- Conclusions peuvent être transférées à d'autres situations

-

- Qualité dépend de l'expérience et compétence du chercheur.
- Subjectivité peut mener à des biais.
- Méthodologie peut manquer de rigueur.
- Analyse des données prend du temps.
- Parfois vu comme inférieur à l'approche quantitative
- Réponses des participants peuvent être influées par la présence du chercheur.
- Problems d'anonymat et de confidentialité lors de la publication
- Difficultés de visualisation des observations.
- Conclusions ne peuvent pas être extrapolées à une population plus large

Méthodes mixtes – qualitative + quantitative

- Questionnaires
  - Échelles quantifiables
- Analyse de discours
  - Codification, traitement automatique
- Recueil de données des deux types
  - Séquentiel
  - Concomitant – deux études indépendantes ou recueil imbriqué

Eléments pour **L'ANALYSE**

Title	➢ Was the title a good one, suggesting the key phenomenon and the group or community under study?
Abstract	➢ Does the abstract clearly and concisely summarize the main features of the report?
Introduction Statement of the problem	➢ Is the problem stated unambiguously and is it easy to identify? ➢ Does the problem statement build a cogent and persuasive argument for the new study? ➢ Does the problem have significance for practice? ➢ Is there a good match between the research problem on the one hand and the paradigm, tradition, and methods on the other?

Source : Polit, Denise F., and Cheryl Tatano. Beck. Essentials of Nursing Research: Appraising Evidence for Nursing Practice. Philadelphia: Wolters Kluwer Health/Lippincott Williams & Wilkins, 2010. Print.

Research questions	➢ Are research questions explicitly stated? If not, is their absence justified? ➢ Are the questions consistent with the study's philosophical basis, underlying tradition, conceptual framework, or ideological orientation?
Literature review	➢ Does the report adequately summarize the existing body of knowledge related to the problem or phenomenon of interest? ➢ Does the literature review provide a solid basis for the new study?
Conceptual underpinnings	➢ Are key concepts adequately defined conceptually? ➢ Is the philosophical basis, underlying tradition, conceptual framework, or ideological orientation made explicit?

Source : Polit, Denise F., and Cheryl Tatano. Beck. Essentials of Nursing Research: Appraising Evidence for Nursing Practice. Philadelphia: Wolters Kluwer Health/Lippincott Williams & Wilkins, 2010. Print.

Method

Protection of participants' rights	➢ Were appropriate procedures used to safeguard the rights of study participants? Was the study subject to external review by an IRB/ethics review board? ➢ Was the study designed to minimize risks and maximize benefits to participants?
Research design and research tradition	➢ Is the identified research tradition (if any) congruent with the methods used to collect and analyze data? ➢ Was an adequate amount of time spent in the field or with study participants? ➢ Did the design unfold in the field, giving researchers opportunities to capitalize on early understandings? ➢ Was there an adequate number of contacts with study participants?

Source : Polit, Denise F., and Cheryl Tatano. Beck. Essentials of Nursing Research: Appraising Evidence for Nursing Practice. Philadelphia: Wolters Kluwer Health/Lippincott Williams & Wilkins, 2010. Print.

	➢ Was the number of data collection points appropriate? ➢ Did the design minimize biases and threats to the internal construct, and external validity of the study (e.g., was blinding used, was attrition minimized)?
Population and sample	➢ Was the population identified and described? Was the sample described in sufficient detail? ➢ Was the best possible sampling design used to enhance the sample's representativeness? Were sample biases minimized? ➢ Was the sample size adequate? Was a power analysis used to estimate sample size needs?

Source : Polit, Denise F., and Cheryl Tatano. Beck. Essentials of Nursing Research: Appraising Evidence for Nursing Practice. Philadelphia: Wolters Kluwer Health/Lippincott Williams & Wilkins, 2010. Print.

Data collection and measurement	➢ Are the operational and conceptual definitions congruent? ➢ Were key variables operationalized using the best possible method (e.g., interviews, observations, and so on) and with adequate justification? ➢ Are the specific instruments adequately described and were they good choices, given the study purpose and study population? ➢ Does the report provide evidence that the data collection methods yielded data that were high on reliability and validity?
Procedures	➢ If there was an intervention, is it adequately described, and was it properly implemented? Did most participants allocated to the intervention group actually receive the intervention? Was there evidence of intervention fidelity? ➢ Were data collected in a manner that minimized bias? Were the staff who collected data appropriately trained?

Source : Polit, Denise F., and Cheryl Tatano. Beck. Essentials of Nursing Research: Appraising Evidence for Nursing Practice. Philadelphia: Wolters Kluwer Health/Lippincott Williams & Wilkins, 2010. Print.

Results

Data analysis	➢ Were analyses undertaken to address each research question or test each hypothesis? ➢ Were appropriate statistical methods used, given the level of measurement of the variables, number of groups being compared, and so on? ➢ Was the most powerful analytic method used? (e.g., did the analysis help to control for confounding variables)? ➢ Were Type I and Type II errors avoided or minimized?
Findings	➢ Was information about statistical significance presented? Was information about effect size and precision of estimates (confidence intervals) presented? ➢ Are the findings adequately summarized, with good use of tables and figures? ➢ Are findings reported in a manner that facilitates a meta-analysis, and with sufficient information needed for EBP?

Source : Polit, Denise F., and Cheryl Tatano. Beck. Essentials of Nursing Research: Appraising Evidence for Nursing Practice. Philadelphia: Wolters Kluwer Health/Lippincott Williams & Wilkins, 2010. Print.

Discussion Interpretation of the findings	➢ Are all major findings interpreted and discussed within the context of prior research and/or the study's conceptual framework? ➢ Were causal inferences, if any, justified? ➢ Are the interpretations consistent with the results and with the study's limitations? ➢ Does the report address the issue of the generalizability of the findings?
Implications/ recommendations	➢ Do the researchers discuss the implications of the study for clinical practice or further research—and are those implications reasonable and complete?

Source : Polit, Denise F., and Cheryl Tatano. Beck. Essentials of Nursing Research: Appraising Evidence for Nursing Practice. Philadelphia: Wolters Kluwer Health/Lippincott Williams & Wilkins, 2010. Print.

Global Issues Presentation	➢ Is the report well written, well organized, and sufficiently detailed for critical analysis? ➢ In intervention studies, was a CONSORT flow chart provided to show the flow of participants in the study? ➢ Was the report written in a manner that makes the findings accessible to practitioners?
Researcher credibility	➢ Do the researchers' clinical, substantive, or methodologic qualifications and experience enhance confidence in the findings and their interpretation?
Summary assessment	➢ Despite any identified limitations, do the study findings appear to be valid—do you have confidence in the *truth* value of the results? ➢ Does the study contribute any meaningful evidence that can be used in practice?

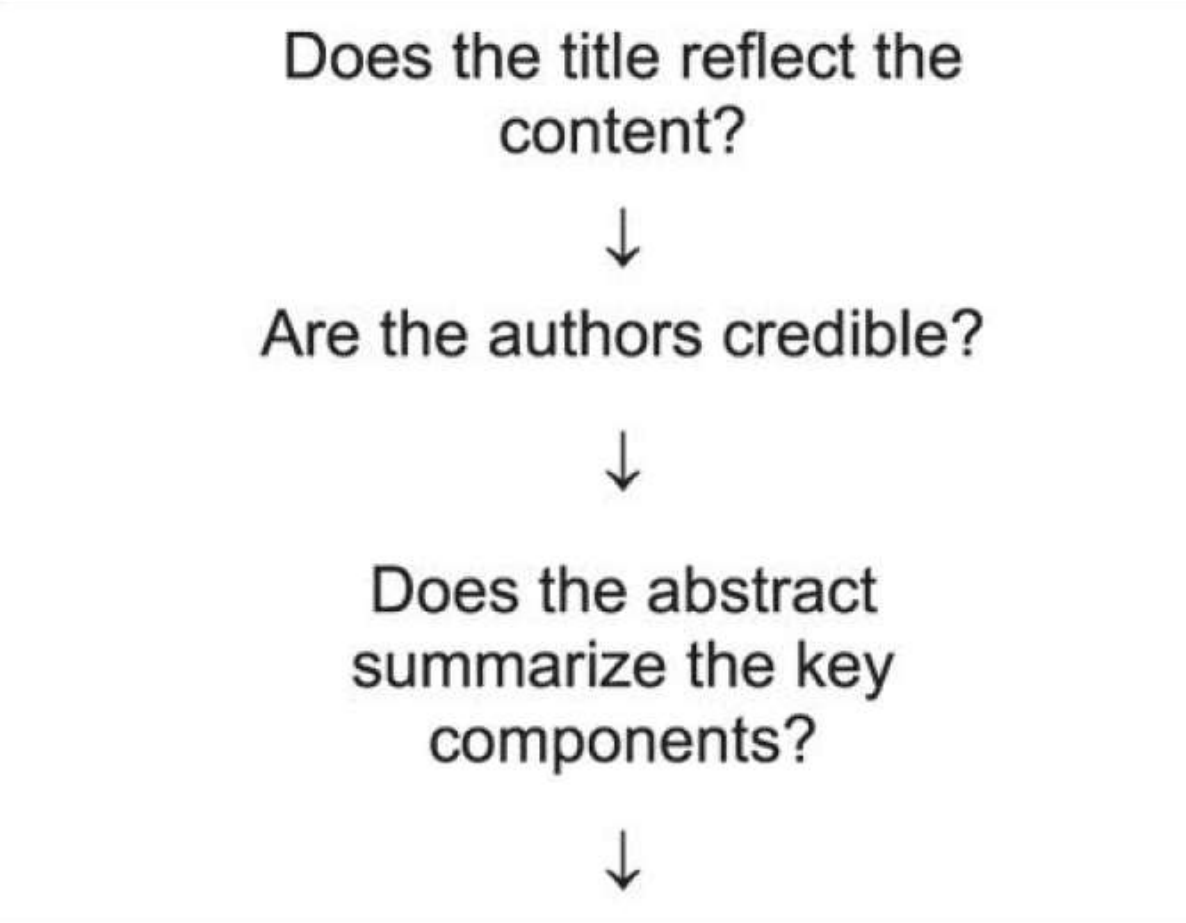
Source : Polit, Denise F., and Cheryl Tatano. Beck. Essentials of Nursing Research: Appraising Evidence for Nursing Practice. Philadelphia: Wolters Kluwer Health/Lippincott Williams & Wilkins, 2010. Print.

Un modèle **D'ANALYSE** : Caldwell *et al.* (2011)

Titre

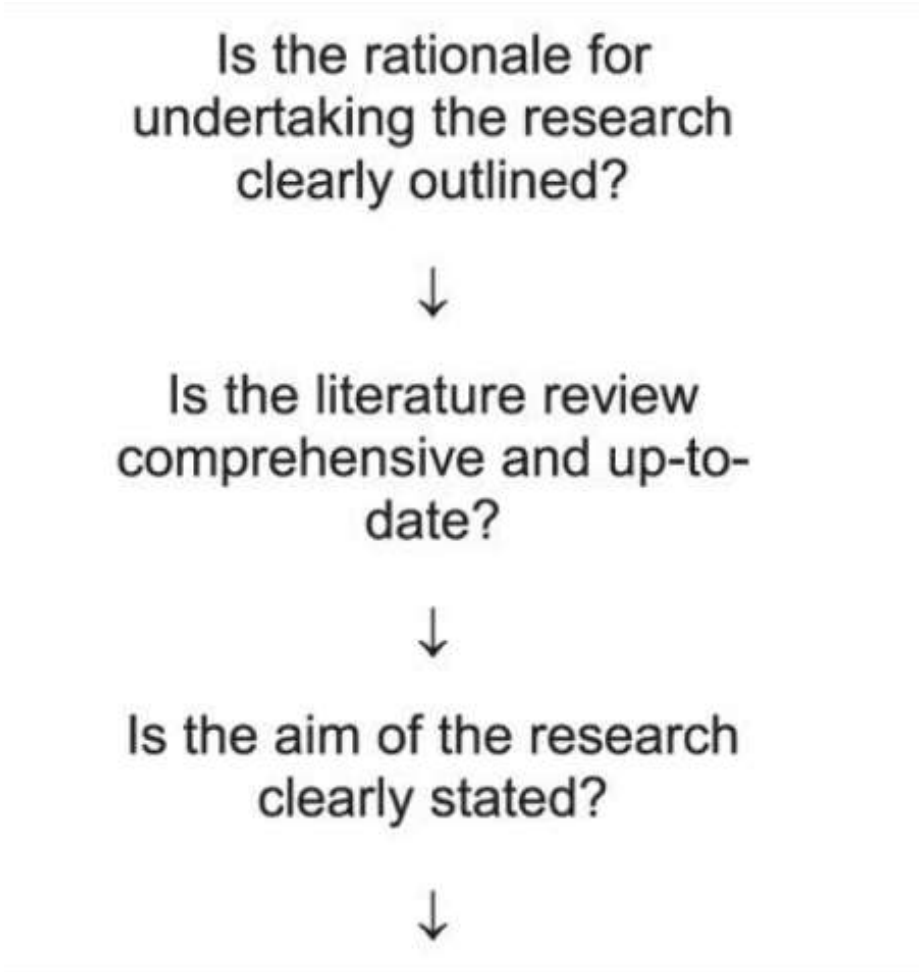
Auteurs

Abstract



Caldwell, Kay, Lynne Henshaw, and Georgina Taylor. "Developing a framework for critiquing health research: an early evaluation." Nurse education today 31.8 (2011): e1-e7.

Introduction



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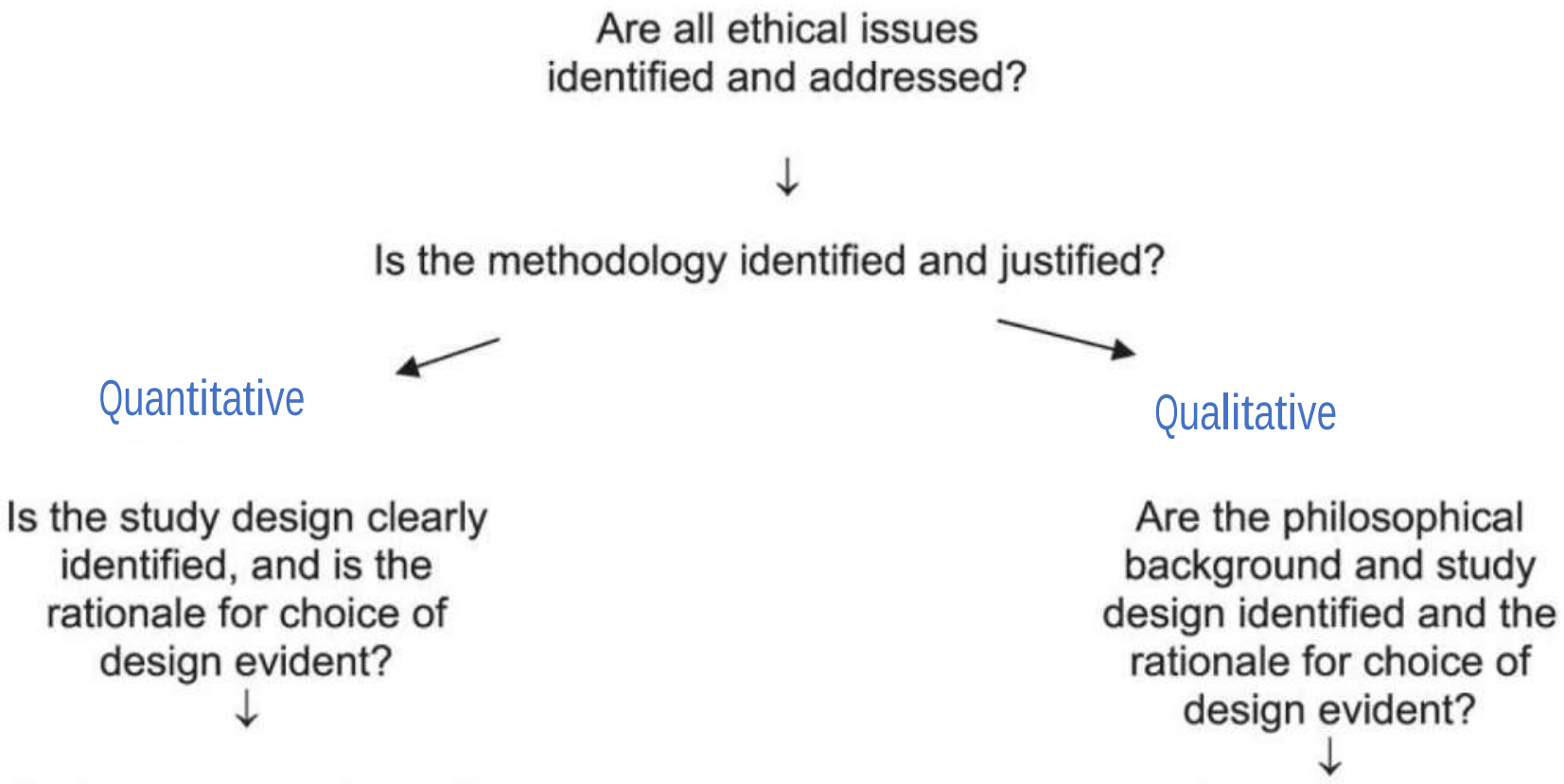
Méthodologie



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Méthodologie

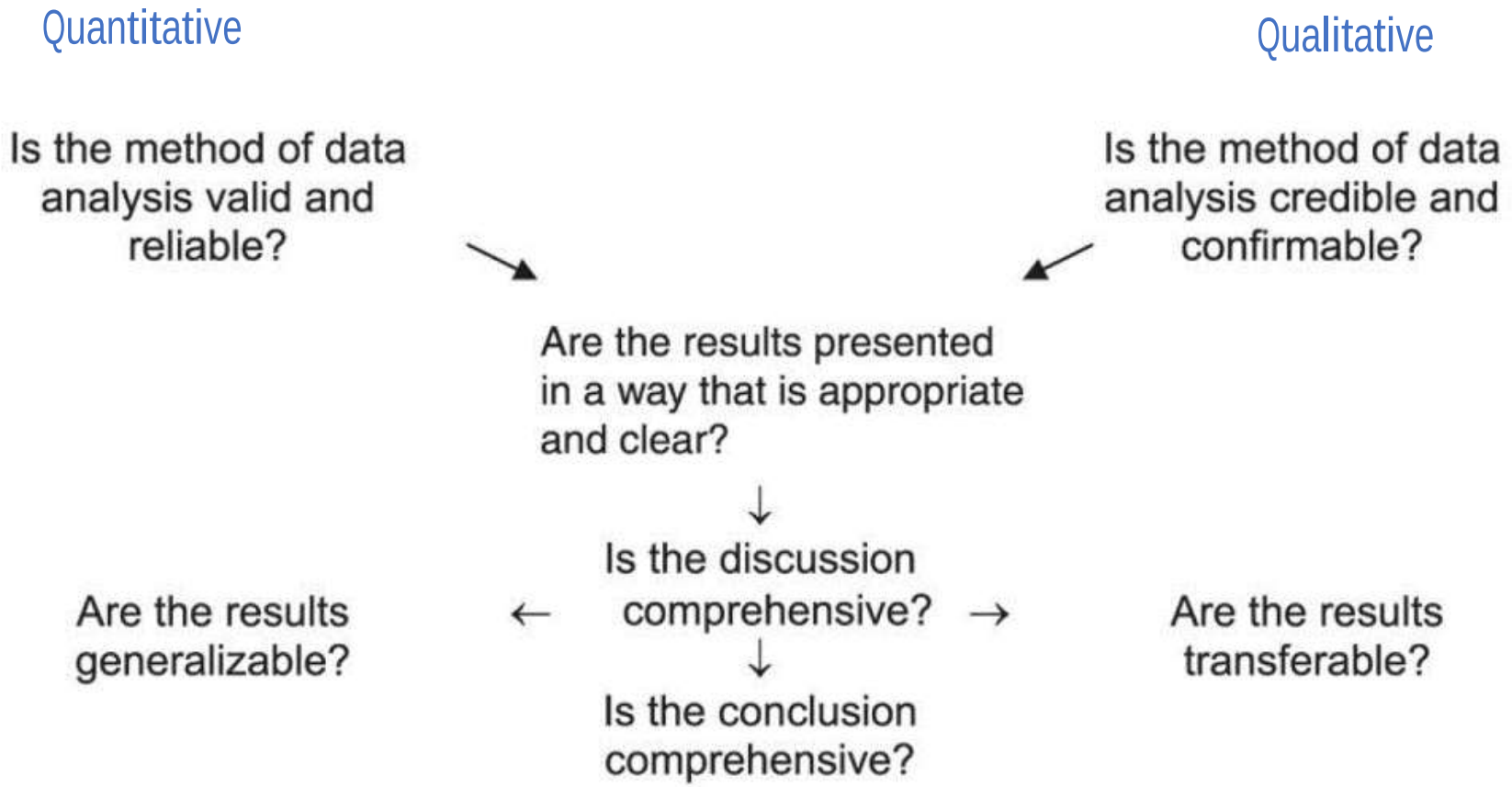
Quantitative

Is there an experimental hypothesis clearly stated?
Are the key variables clearly defined?
↓
Is the population identified?
↓
Is the sample adequately described and reflective of the population?
↓
Is the method of data collection valid and reliable?
↓

Qualitative

Are the major concepts identified?
↓
Is the context of the study outlined?
↓
Is the selection of participants described and the sampling method identified?
↓
Is the method of data collection auditable?
↓

Caldwell, Kay, Lynne Henshaw, and Georgina Taylor. "Developing a framework for critiquing health research: an early evaluation." Nurse education today 31.8 (2011): e1-e7.



Caldwell, Kay, Lynne Henshaw, and Georgina Taylor. "Developing a framework for critiquing health research: an early evaluation." Nurse education today 31.8 (2011): e1-e7.

Mise en application

Qualitative Research article :

Chau, W. M. W., & Furness, P. J. (2023). Happiness in Parents of Children with Autism Spectrum Disorder: A Qualitative Study. American Journal of Qualitative Research, 7(1), 168-190.