Best practice in research: consensus statement on ethnopharmacological field studies – ConSEFS

Heinrich, Michael ; Lardos, Andreas ; Leonti, Marco ; Weckerle, Caroline S ; Willcox, Merlin ; ConSEFS

DOI: https://doi.org/10.1016/j.jep.2017.08.015

Originally published at:
Heinrich, Michael; Lardos, Andreas; Leonti, Marco; Weckerle, Caroline S; Willcox, Merlin; ConSEFS (2018). Best practice in research: consensus statement on ethnopharmacological field studies – ConSEFS. Journal of Ethnopharmacology, 211:329-339.
DOI: https://doi.org/10.1016/j.jep.2017.08.015

Best Practice in Research: Consensus Statement on Ethnopharmacological Field Studies – ConSEFS

Michael Heinrich, Andreas Lardos, Marco Leonti, Caroline Weckerle, Merlin Willcox

www.elsevier.com/locate/jep

PII: S0378-8741(17)32403-0
DOI: http://dx.doi.org/10.1016/j.jep.2017.08.015
Reference: JEP10985

To appear in: *Journal of Ethnopharmacology*

Received date: 26 June 2017
Revised date: 27 July 2017
Accepted date: 9 August 2017

Cite this article as: Michael Heinrich, Andreas Lardos, Marco Leonti, Caroline Weckerle and Merlin Willcox, Best Practice in Research: Consensus Statement on Ethnopharmacological Field Studies – ConSEFS, *Journal of Ethnopharmacology,* http://dx.doi.org/10.1016/j.jep.2017.08.015

Best Practice in Research: Consensus Statement on Ethnopharmacological Field Studies – ConSEFS[1]

Michael Heinrich[1]; Andreas Lardos[2]; Marco Leonti[3]; Caroline Weckerle[4]; Merlin Willcox[5] with the ConSEFS advisory group[2]

[1]Research Cluster 'Biodiversity and Medicines' / Research Group 'Pharmacognosy and Phytotherapy', UCL School of Pharmacy, Univ. London, 29 - 39 Brunswick Sq., London WC1N 1AX, UK

[2]Vorhaldenstrasse 8, 8049 Zurich, Switzerland;

[3]Department of Biomedical Sciences, University of Cagliari, Via Ospedale 72, 09124 Cagliari (CA), Italy

[4]Institute of Systematic Botany, University of Zürich, Zollikerstrasse107,CH-8008Zürich, Switzerland;

[5]Department of Primary Care and Population Sciences, University of Southampton, UK;

[6]Missouri Botanical Garden, P.O. Box 299, St. Louis, MO 63166-0299, USA;

[7]Laboratorio Ecotono, INIBIOMA, CONICET-Universidad Nacional del Comahue. Argentina;

[8]College of Life and Environmental Sciences, Minzu University of China. Beijing 100081, China

[9]School of Natural Product Studies, Department of Pharmaceutical Technology, Jadavpur University, Kolkata, India

[10]Department of Botany and Zoology, Stellenbosch University, 7601, Stellenbosch, South Africa

m.heinrich@ucl.ac.uk

andreas.lardos@nilufar.ch

marcoleonti@netscape.net

caroline.weckerle@systbot.uzh.ch

M.L.Willcox@soton.ac.uk

wendy.applequist@mobot.org

[1] We dedicate this paper to the memory of Prof. Bernardo Ortiz de Montellano (formerly Wayne State University; 1938 -2016), who was one of the early advocates of transdisciplinary research in ethnopharmacology.

[2] based on a consultative process of researchers active in ethnopharmacology and with particular input by the ConSEFS Advisory group: Wendy Applequist[6] (including feedback from members of the Society for Economic Botany), Ana Ladio[7] (Argentina), Chun Lin Long[8], Pulok Mukherjee[9] (on behalf of the Society for Ethnopharmacology, India), Gary Stafford[10] (South Africa),

ladioah@comahue-conicet.gob.ar

long@mail.kib.ac.cn <long.chunlin@muc.edu.cn>

pulokm@gmail.com

garyistafford@gmail.com

Abstract

BACKGROUND

Ethnopharmacological research aims at gathering information on local and traditional uses of plants and other natural substances. However, the approaches used and the methods employed vary, and while such a variability is desirable in terms of scientific diversity, research must adhere to well defined quality standards and reproducible methods

OBJECTIVES

With ConSEFS (the Consensus Statement on Ethnopharmacological Field Studies) we want to define best-practice in developing, conducting and reporting field studies focusing on local and traditional uses of medicinal and food plants, including studies using a historical approach.

METHODS

After first developing an initial draft the core group invited community-wide feedback from researchers both through a web-based consultation and a series of workshops at conferences during 2017.

OUTCOMES

The consultation resulted in a large number of responses. Feedback was received via a weblink on the Journal of Ethnopharmacology's website (ca. 100 responses), other oral and written responses (ca. 50) and discussions with stakeholders at four conferences. The main outcome is a checklist, covering best practice for designing, implementing and recording ethnopharmacological field studies and historical studies.

CONCLUSIONS

Prior to starting ethnopharmacological field research, it is essential that the authors are fully aware of the best practice in the field. For the first time in the field of ethnopharmacology a community-wide document defines guidelines for best practice on how to conduct and report such studies. It will need to be updated and further developed. While the feedback has been

based on responses by many experienced researchers, there is a need to test it in practice by using it both in implementing and reporting field studies (or historical studies), and peer-review.

Graphical abstract

Keywords: Traditional medicine, ethnopharmacological field studies, historical studies, Consort (adaption), medicinal plants.

A large number of reports on peoples' local and traditional uses of plants as medicines and (health) foods are now published every year. The intention very often is to document such information and to make it accessible for future research most commonly in drug discovery (see Table 1 for references). The scientific goals of research on peoples' uses of plants differ widely. Even before the creation of the term 'ethnobotany' in 1896, a large number of studies looked at the use of plants, for example as a part of the North American expansion westwards

(see the analysis of these sources by D. Moerman, 1998) and as pointed out throughout this paper, this is in general recording knowledge and not practice.

In the context of much wider sociocultural studies or botanical explorations and research, such plant uses were documented and studied. The term “ethnopharmacology” was first coined in 1967 (Efron et al., 1970). A symposium entitled ‘Ethnopharmacologic search for psychoactive drugs’ gave the name to a discipline which today is much more broadly defined, dealing with local and traditional medicines, their biological activities and chemistry. Globalisation has resulted in a world-wide commodification of many traditional medicines and psycho-actives, and today it is a flourishing field driven by a wide range of research interests (Heinrich and Jaeger, 2015). An essential basis for laboratory-based studies are field-studies, i.e. studies documenting and investigating the local and traditional use of medicinal and food plants (and other preparations) on all continents. Such field studies generally claim – in a broad sense – to contribute to a more evidence based use of such resources or to their documentation for posterity (Heinrich et al., 2009).

One problem which has ‘haunted’ ethnopharmacology is the lack of clearly defined standards on how to conduct and report ethnopharmacological field studies [c.f. Cotton, 1996; Cunningham, 2001; Elizabetsky, 1991; Heinrich et al. 1998; Lipp, 1989; Martin, 1998 or the "recommended standards for conducting and reporting ethnopharmacological field studies by Weckerle et al.,2017 (which provides guidelines specifically tailored to the J. Ethnopharmacol.) and others]. A considerable share of the manuscripts containing original data collected in field studies that are submitted to journals have no clear research question, hypothesis or objectives. In many of these cases the methods used in the field study are inadequate for attaining the research goal or there is a lack of compliance with ethical requirements and existing biodiversity regulations. Very often analysis are conducted that produce data which is at best doubtful and often non-existent. To give a simple example, discussing how many species are used based on the level of botanical families is not meaningful if it is not properly contextualised. From the perspective of the culture (the emic perspective), botanical families are not relevant. From a botanical perspective (one of many etic ones) it will only be relevant if such data could be compared to the total number of species in the region. This would allow the identification of commonly or rarely used families. From a pharmaceutical or chemical perspective, there is no need to know this and one would not be able to use it in research based on such a field study. One could cite other examples of ambiguous or poorly relevant aspects of such reports, but this example must

suffice. This ambiguity regarding appropriate approaches and methods and how to analyse data has resulted in a lack of clear and well-communicated outcomes. The focus of this consensus document is about *best practice and how to achieve it*.

With this approach we want to develop a well-defined, community-wide consensus on what constitutes meaningful objectives and aims of ethnopharmacological field studies and how to achieve this. This *community-wide consensus defines best practice for developing, conducting and reporting ethnopharmacological field studies*. While it cannot define specifics of a project, it will help all researchers to ascertain that the data are reported in a transparent way, that they are meaningful and can be applied in future research (and development).

Written evidence from the past continues to be an important topic in ethnopharmacology. Either evidence from the past is compared with modern uses, or research is entirely based on historical sources focusing on occurrences or changes in the ethnoflora or its uses over a certain period of time (Lardos, 2015). Therefore, the perspective of the consensus document has been expanded to include ethnopharmacological studies with a historical approach. These can make use of a wide range of resources including historical manuscripts, any kind of ethnographic literature or information on plant use preserved in herbarium collections (all of them both in original or edited form) but also compilations of such information in electronic databases.

Table 1 Selection of topics treated in previous examples of papers covering best practise, in methods manuals, specific approaches and international standards

Topics covered	**Field of research**	**References**
Best practice on the basis of a researcher's personal experience and knowledge	Ethnobotany, ethnomedicine, ethnopharmacology	E.g. Browner et al., 1988; Cotton, 1996; Cunningham, 2001; Elizabetsky 1991; Lipp, 1989; Martin, 1995; Weckerle et al., 2017
Field-specific methods manuals	Cultural anthropology	E.g. Bernard (1988; 2000a,b)
	Botany, especially herbaria	E.g. Bridson and Forman (1992)
Specific approaches or steps to be considered from the perspective of one field of research	Anthropology, environmental anthropology	E.g. Browner et al., 1988; Etkin, 1993; Johnson, 1992.
	Ethnopharmacology, especially drug discovery	E.g. Andrade-Cetto and Heinrich, 2011.
Associated ethical and biodiversity standards based on national and	Ethnobiology, ethnomedicine, ethnopharmacology,	E.g. CBD 2001 and 2011; AAA 2012 as well as previous versions and updates; Cragg et al., 1997,

international laws and agreements and their implementation in research	pharmacognosy and bioprospecting	Edwards et al., 2005, Soejarto et al., 2005, http://ethnobiology.net/code-of-ethics/

It has been argued that, instead of studies on the *knowledge* about traditional medicines, more focus needs to be put on understanding the outcomes of such treatments, e.g. retrospective treatment outcome studies (Graz et al. 2007). In such studies it is essential that authors specify how a plant use is associated with a reported health outcome for a definite ailment in order to produce indices of safety and effectiveness. (cf. online tutorial: https://globalhealthtrainingcentre.tghn.org/elearning/the-retrospective-treatment-outcome-study/). While we recognise the importance of the above research, the focus in this consensus document is not on treatment outcomes, but on the investigation of local and traditional *knowledge* about medical substances and their use.

With this document we follow the basic idea of a CONSORT statement, which is an evidence-based set of recommendations for best practice in reporting randomized clinical trials (www.consort-statement.org/). In medicine efforts to improve the reporting of randomised controlled trials dates back to the mid-1990s (Begg et al., 1996; for the most recent version see Schulz et al. 2010). These initiatives have been driven by concern about the quality, reproducibility and ultimately the usefulness of clinical studies, and the need to synthesise their results in systematic reviews and meta-analyses. The guidelines have been modified and adapted for a wide range of studies related to the use of treatments, including clinical trials of herbal medicines (Gagnier et al. 2005). CONSORT has become an important tool to overcome poor reporting of trials. The CONSORT statement offers a standard way for authors to report the findings of randomised controlled trials, aiding their critical appraisal, interpretation and meta-analysis.

Here we propose a similar strategy for reporting studies on local and traditional uses of plants and other natural substances both in current cultures and in studies using historical documentary evidence, which is intended for ethnopharmacological field studies irrespective in which journal they are published.

OBJECTIVES

Ethnopharmacological fieldwork is different from clinical studies, but it is also focused on understanding the medical use of substances. In a very general sense, it centres around humans' strategies to overcome illnesses and on the identification of substances used

therapeutically. With the **Consensus Statement on Ethnopharmacological Field Studies** (ConSEFS), we offer a guideline defining best practice for those studies investigating local and traditional medicinal substances (esp. medicinal plants and fungi) aiming at documenting this knowledge, contributing to better healthcare at a community level or/ and to identifying plants for future developments into medicines or botanicals (supplements, nutraceuticals, cosmetics and the like).

THE PROCESS ('METHODS')

During 2016 the core group (the main authors of this paper) developed a first draft of the consensus statement. From November 2016 until May 2017, the draft document was open for consultation via the website (https://www.journals.elsevier.com/journal-of-ethnopharmacology/) of the Journal of Ethnopharmacology. The information about it was distributed via a range of social media (like via blogs of forntiersin.org), networks of academics/ learned societies and through the personal networks of the core group.
It was discussed and refined at a series of user group meetings at international conferences covering key areas relevant in ethnopharmacology during the year 2017:

- The Int. Soc. Ethnopharmacology mtg. in Beirut, Lebanon (24. – 27.04.; www.ethnopharmacology.org and http://webapp.usek.edu.lb/forms/WS/ise/)
- The Society for Economic Botany meeting in Bragança, Portugal (05. – 09.06.)
- The Soc. for Ethnopharmacology meeting in Surat, Gujarat, India (22. – 25.02.; http://www.ethnopharmacology.in/files/4th_SFEC_2017_Brochure.pdf)
- The World Congress of Integrative Medicine in Berlin, Germany (03. – 05. 05. https://www.ecim-iccmr.org/2017/)

A group of colleagues was invited to discuss the document within their respective networks in Africa, the Americas and Asia and to send their feedback. Feedback was recorded and was – after discussions among the core group – included in the final document. Members of the core group also met at these meetings (and others). This advisory group and the core group then agreed on the final version as published in this paper (Tables 2a and 2b).

RESULTS AND DISCUSSION

Core recommendations

The core recommendations as outlined in this document including **Tables 2a and 2b**, which serve as a checklist for assessing a study, focus on the conducting and reporting of

ethnopharmacological field studies and studies with a historical approach. The two parts of the table are designed in such a way that it can be used as a guide covering all steps from the initial design to the reporting of an ethnopharmacological field study.

The specific situations in a country or culture will always differ and the document will need to be adapted to these needs generally. These tables cover this through defining best practice in all areas relevant in an ethnopharmacological field study and can be used as a checklist, which should help researchers, editors, and reviewers to assess a study both during the development of the project and during publication. Here we do not wish to repeat these recommendations of the table, but to flag important elements.

It is a guide to facilitate best practice and, of course, is not intended to add another barrier to developing, implementing and reporting such studies. Very often many if not all recommendations of the statement are largely covered, but far too often manuscripts received by learned journals fall far short of these standards (and are often not published), calling for such guidelines for best practice.

Of course, national and international laws and agreements including the Convention on Biological Diversity (CBD) and subsequent agreements must be complied with fully. In the consultation process the importance of complying with these laws and regulations has been stressed frequently, and there is a general consensus that this is an essential prerequisite for any ethnopharmacological field study. For each study this must be assessed individually, since the international treaties have been translated into individual laws and regulations at national level and, of course, these must be followed. The obligations of these treatise focus on access, benefit sharing and ascertaining compliance with the regulations. Since the international treaties have been translated into individual laws and regulations at national level, the requirements concerning the compliance with existing regulations must be assessed individually for each study prior to the start of the field work and in respect of the country of research as well as the researcher's legal domicile (for the purpose of the research). For the example of the Nagoya Protocol of the CBD, the appropriate platform for access to this kind of information is the Access and Benefit-sharing Clearing-house (ABSCH) which has been developed for exchanging information on access and benefit sharing and for facilitating the implementation of the protocol (https://absch.cbd.int/).

During the consultation numerous colleagues highlighted the risk of unsustainable use and associated threats to the conservation of resources as exemplified in the following: 'If natural resources used in local medical systems is the subject being dealt with, it is necessary to make an effort, where possible, to pay attention to the state of conservation of the species in

question; species are often brought to the notice of the market through scientific publications, and this may indirectly contribute to the risk of over exploitation. I therefore suggest that this aspect be described in reports, so that sustainable use is promoted. Even if the work does not deal specifically with any of these aspects, I consider that a truly multidisciplinary approach like ethnopharmacology should contain information (even if brief) on the conservation status of the resources in question, for one reason alone: all the relationships and practices associated with the animals and plants used for medicinal and/or alimentary purposes, which we study and value so much, depend directly on the availability, access and renewal of these resources' (Ana Ladio pers. Comm. 17.01.17).

This is included in several parts of the checklist (esp. Table 2a) and an essential basis for this is that researchers build up a detailed understanding of the specific situation in a certain region or country.

An important requirement and an overarching requirement is the need for well-described primary data – these must be reported in the manuscript or an appendix. Journal requirements on the content will vary. For example, some journals will prefer reports on specific disease groups while others expect a more monographic treatment of a region.

Introduction

The relevant conceptual and theoretical basis of the paper must be included and it must be embedded in the respective literature. An important part is a section providing the ethnographic and geographical background to the study.

The **methods** must be described clearly and must cover all aspects from design (including permits and approvals) to the execution of the field study and to the way the data were analysed. These methods are equally relevant if they are used in community-based research, where direct interviews or surveys are conducted, as they are in studies using web-based methods and strategies (currently much less common in ethnopharmacology).

As indicated in Table 2a, primary data need to report the frequency of use, or knowledge about a species or similar quantitative data. Usually primary data is presented in the form of frequency of use-reports (individual citations) of a plant taxon or organs/ parts thereof for a specific use or a category of use including the mode of application and the product's preparation. Often, percentage values can reasonably be used for comparisons.

Indices are commonly used for transforming primary data, but need to be meaningful, provide additional insights and be statistically correct. Major concerns have been raised about their usefulness, relevance and robustness (e.g. Weckerle et al. 2017; Dudney et al. 2015). Here we do not endorse any specific indices.

Results and discussion

(as a combined or separate sections) should focus on what the core novel findings are and how they are linked to the previous knowledge. Many of the data will generally be reported in a quantitative or semi-quantitative way and this may again be influenced by a specific journal's editorial policy. Explicitly, we want to encourage researchers to report and discuss problems encountered during the research, and how they were overcome. The data need to be compared to previous research on the topic. This can be other studies in the same region, with the same linguistic family, in a similar ecological or political context or studies which used a similar approach. Authors should discuss priorities for future research steps and what new challenges this research is pointing to.

Conclusions

Should critically assess the implications of the study and its findings, and highlight future research needs.

The majority of the points relevant for field studies are also, at least to a certain extent, of direct relevance for studies relying on documented evidence from the past (see **Table 2a**, column "Relevant for historical studies"). There are, of course, certain points, which are specific for historical studies, and these are detailed in **Table 2b**. Of particular importance in this context are the description of the resource and how it was accessed, the method used to extract the relevant ethnopharmacological information, the identification of the plants or other natural products and the interpretation of the (medicinal) uses mentioned in it.

Limitations

Importantly, the focus here is on ethnopharmacological field studies or historical studies which address questions on the use of medicinal and (health) food plants, if it is the goal of the authors to document such local and traditional medical *knowledge*, to contribute to better healthcare at a community level or/ and to identify plants for future developments into

medicines or botanicals (like supplements, nutraceuticals, cosmetics). Of course, it cannot be all-inclusive. For example, it is not intended for other studies in the ethnosciences, like cognitive or ethnolinguistic research.

While research is by definition focusing on some aspects of a culture, medical practice in a culture is always a part of a complex and integrated network of knowledge and practice. We recognise that local and traditional knowledge cannot be represented in an integrated and all-encompassing way. However, in the studies we focus on here, such an integrated perspective is generally neither the goal nor would it be realistic to expect it.

Again, concerns about the environmental context were a common theme in the consultation and were highlighted by participants in the four workshops at the conferences and in numerous responses by researchers.

IMPLICATIONS AND CONCLUSIONS

Foremost, ConSEFS is intended to help researchers to develop and report research on the use of local and traditional medicines. Planning for the final outcomes of a research project, most commonly a publication, starts when developing a research question and the project itself. Prior to starting ethnopharmacological field research, it is essential that the authors are fully aware of the best practice in the field including the guidelines in this paper. We trust that these guidelines will also be accepted by the relevant journals where ethnopharmacological field studies are published and that they are used in the evaluation of manuscripts.

In the consultations concerns were raised that it is an additional bureaucratic barrier, but clearly it is not. It simply defines the current best practice in this field of research. Similarly, it provides editors and peer reviewers with a tool to review manuscripts prior to publication, and helping readers in understanding best practice in published articles reporting such studies.

This paper does not provide a ready-made recipe for conducting and reporting research (but see Collins et al. (2017)) and instead highlights how to avoid potential pitfalls and how to achieve the scientific goals of ethnopharmacological research. It is a next step in an ongoing debate and development and will help in further improving best practice in research.

Acknowledgements

We are very grateful to the many colleagues who have sent us feedback, on all aspects of this statement. While we will not have done justice to all, nor has it been possible to incorporate

the often contradictory views, the consensus statement and this article have greatly benefitted from everyone's input. We are grateful to all who helped to disseminate the information about earlier drafts of this document, most importantly Anne Marie Pordon (Elsevier) and Brian Boyle (Frontiers) and well as to the many colleagues who disseminated the information in their networks.

This project received no external funding.

Authors' contributions

MH. designed the overall strategy for the consensus process and the manuscript. In consultation with the other authors (AL, ML, CW, MW) he drafted the initial version of the best practice checklist (now included as Table 2a and b in the paper). The advisory group facilitated discussions in specific regions and provided feedback on various aspects of this checklist as well as commented on earlier drafts of the MS.

References

AAA (American Anthropological Association), 2012. Statement on Ethics. Principles of Professional Responsibility. First approved 1971, as amended, http://ethics.americananthro.org/category/statement/ (last accessed 10.05.2017).

Andrade-Cetto, A., Heinrich, M., 2011. From the field into the lab: Useful approaches to selecting species based on local knowledge. Fr. Pharmacol. (Ethnopharmacol.) **2,** 20. doi: 10.3389/fphar.2011.00020

Begg, C., Cho, M., Eastwood, S., Horton, R., Moher, D., Olkin, I., et al., 1996. Improving the quality of reporting of randomized clinical trials: the CONSORT statement. JAMA 276: 637-339.

Bernard, H.R., 1988. Research Methods in Cultural Anthropology. Sage Publ., New York, USA.

Bernard, H.R., 2000a. Social Research Methods, Qualitative and Quantitative Approaches. Sage Publications, Thousand Oaks.

Bernard, H.R., 2000b. Handbook of Methods in Cultural Anthropology. Alta Mira Press, Walnut Creek, Lanham, New York, USA and Oxford, UK.

Bernard, H.R., 2011. Research Methods in Anthropology – Qualitative and Quantitative Approaches, 3rd edition, Altamira Press, New York, USA.

Bridson, D., Forman, L., 1992. The Herbarium Handbook. Revised ed. (first publ. in 1989)], Kew, Royal Botanic Gardens, Richmond, UK.

Browner, C.H., Ortiz de Montellano, B.R., Rubel, A.J., 1988. A methodology for cross-cultural ethnomedicinal research. Curr. Anthr. 29:681-702.

CBD, 2001. Handbook of the Convention on Biological Diversity. Secretariat of the Convention on Biological Diversity. Earthscan Publ., London.

CBD, 2011. Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity. Convention on Biological Diversity. United Nations, Montreal, Canada.

CITES: https://cites.org/eng/app/appendices.php (accessed 20.06.2017)

Collins, S., Gemayel, R., Chenette, E.J., 2017. Avoiding common pitfalls of manuscript and figure preparation. FEBS J. 284, 1262–1266.

CONSORT: www.consort-statement.org/ (accessed: 20.06.2017)

Cotton, C.M., 1996. Ethnobotany: Principles and Applications. Wiley and Sons, Chichester. UK.

Cragg, G.M., et al., 1997. Interactions with Source Countries. Guidelines for Members of the American Society of Pharmacognosy. J. Nat. Prod. **60**, 654-655.

Cunningham, A.B., 2001, Applied Ethnobotany: People, Wild Plant Use and Conservation, (People and Plants Conservation Manual) Earthscan Publications Ltd. London, UK and Sterling, VA, USA.

Dauncey, E.A.; Irving, J., Allkin, R., Robinson, N., 2016. Common mistakes when using plant names and how to avoid them. Eur. J. Integrat. Med. 8, 597–601.

Descola, P., 2005. Par-delà nature et culture. Gallimard, Paris.

Dudney, K., Warren, S., Sills, E., Jacka, J., 2015. How study design influences the ranking of medicinal plant importance: a case study from Ghana, West Africa. Econ. Bot. 69, 306–317.

Edwards, S., Nebel, S., Heinrich, M., 2005. Methodological and epidemistiological considerations on the use of questionaires in ethnopharmacology. J. Ethnopharmacol. 100, 30–36.

Efron, D., Farber, S.M., Holmstedt, B. et al., 1970. Ethnopharmacologic search for psychoactive drugs. Reprint, orig. 1967. Public Health Service Publications no. 1645. Government Printing Office, Washington, DC.

Elisabetsky, E., 1991. Sociopolitical, economical, and ethical issues in medicinal plant research. J. Ethnopharmacol. 32, 235–239.

Ember, C.R., Ember, M., 2001. Cross-Cultural Research Methods, AltaMira Press, Lanham, MD.

Etkin, N.L., 1993. Anthropological methods in ethnopharmacology. J. Ethnopharmacol. 38, 93–104.

Gagnier, J.J., Boon, H., Rochon, P., Moher, D., Barnes, J., Bombardier, C.(for the CONSORT Group), 2005. Reporting Randomized, Controlled Trials of Herbal Interventions: An Elaborated CONSORT Statement. Ann. Int Med. 144, 363–367

Global Health Training Centre: https://globalhealthtrainingcentre.tghn.org/elearning/the-retrospective-treatment-outcome-study/ (accessed: 20.06.2017)

Graz, B., Elisabetsky, E., Falquet, J., 2007. Beyond the myth of expensive clinical study: Assessment of traditional medicines. J. Ethnopharmacol.113, 382–386.

Heinrich, M., Jaeger, A.K. (Eds.), 2015. Ethnopharmacology. Wiley, Chichester.

Heinrich, M., Ankli, A., Frei, B., Weimann, C., Sticher, O., 1998. Medicinal plants in Mexico: healers' consensus and culturalmportance. Soc. Sc. Med. 47, 1863–1875.

Heinrich, M., Edwards, S., Moerman, D.E., Leonti, M., 2009. Ethnopharmacological Field Studies: A Critical Assessment of their Conceptual Basis and Methods. J. Ethnopharmacol. 124, 1–17.

Johnson, M. (Ed.), 1992. LORE, Capturing Traditional Environmental Knowledge. Dene Cultural Institute and IDRC, Ottawa.

Lardos, A., 2015. Historical Approaches in Ethnopharmacology. In: Heinrich, M. and A.K. Jaeger (Eds.), Ethnopharmacology. Wiley, Chichester.

Lipp, F.J., 1989. Methods for ethnopharmacological fieldwork. J. Ethnopharmacol. 25:139-150.

Martin, G.M., 1995. Ethnobotany. Chapman and Hall, London, UK (on a little island off the coast of Eurasia).

Medicinal Plant Names Services. Kew, Royal Botanical Gardens. http://mpns.kew.org/mpns-portal/ (accessed 20.06.2017)

Moerman, D. E., 1998. Native American Ethnobotany. Timber Press, Portland, OR, USA.

Ortiz de Montellano, B., 1975. Empirical Aztec medicine. Science 188, 215–220.

Rivera, D., Allkin, R., Obón, C., Alcaraz, F., Verpoorte, R., Heinrich, M., 2014. What is in a name? The need for accurate scientific nomenclature for plants. J. Ethnopharmacol. 152, 393–402.

Schulz, K.F., Altman, D.G., Moher, D. (for the CONSORT Group), 2010. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. Br. Med. J. 340: c332

Soejarto, D.D., Fong, H.H.S., Tan, G.T., et al., 2005. Ethnobotany/ethnopharmacology and mass bioprospecting, issues on intellectual property and benefit-sharing. J. Ethnopharmacol. 100, 15–22.

The ISE Code of Ethics: http://www.ethnobiology.net/what-we-do/core-programs/ise-ethics-program/code-of-ethics/ (accessed 20.06.2017)

The Plant List: http://www.theplantlist.org/ (accessed 20.06.2017)

Weckerle et al., 2017 Recommended standards for conducting and reporting ethnopharmacological field studies. MS under review.

Table 2a: Best practice in ethnopharmacological field studies in the context of research on bioactive natural products

Section, Item (this will vary according to the requirements of the journal)	**Topic** (a short overview on the main aspects to be covered)	**Design** (information for best practice in designing each aspect of an ethnopharmacological field study?	**Reporting** (information for best reporting for each of these points)	**Notes** and (if available) references	Relevant for historical studies, see Table 1.b
Title	Title	N/A	Clear definition or headline outcomes of the overall project and its context		Yes
Abstract	Structured summary of the	N/A	Structured summary of objectives or hypothesis,		Yes

	field study		background, study design and methods, results, and conclusions. An overview of the main findings must be included, as well as concluding critical appraisal	
Introduction	**Overview on rationale for the study, and clearly defined objectives for this study (or a working hypothesis) including the following:**			
	Ethnomedical tradition	Critical literature review (incl. historical sources if available) highlighting state of the art and gaps in knowledge.	A short contextualization of the (regional) philosophical and medical foundation (e.g. American indigenous or African medical traditions of a specific region, Ayurveda, Arabic medicine, TCM). How is traditional medicine contextualized by the population within the whole spectrum of health care possibilities?	Yes (excluding information on health care and population)
	Theoretical and conceptual	Assess the relevant theoretical literature in	Clear description of the conceptual basis for the study and the theoretical	Yes

	framework of the study	relation to your project and its conceptual basis. What research question will be tested?	rationale. Define the gap of knowledge this study is designed to fill.	
	Previous research on the topic	Review of the literature relevant to the topic and region of study	Overviews on previous studies in the region of study, or in linguistically or otherwise related groups and / or of studies which conceptually lead to this study	Yes
	Objectives or hypothesis to be tested	Develop the objectives and / or hypothesis and define the (statistical) requirements	Specific and clearly defined aims and objectives/hypothesis to be tested. While a study may well be descriptive, the exclusive documentation of knowledge will only provide the baseline data of such a paper and cannot be a sole objective of the project.	Yes
Ethnopharmacological	Detailed description of the	Search in local archives,	Short review of the area and relevant indigenous or other	No

background	sociocultural background	government agencies and other sources for qualitative data as well as quantitative epidemiological data (mostly addressing a larger geographical area).	ethnic groups studied. This should include cultural, demographic, wherever possible medical / epidemiological and basic geographical data (possibly in tabular form) or at least references to these. What kind of health care choices and facilities are available to the population of the study site (including biomedical services)?	
	Literature review	Database searches incl., for example, Scopus, Pubmed. Include also relevant books or book chapters, incl. those written in local language. Generally look also for	Summarise previous studies directly relevant to the project	Yes

		relevant locally published literature.			
Methods	General methodological information	The methods used should be in accordance with your focus and research questions. If applicable, discuss with a statistician beforehand for adequate sampling strategy.	Including sampling period, duration of fieldwork, number of fieldworkers, their expertise (i.e. training, language used in the interviews) and their contribution, use of interpreters; tools used and how they were developed.	For a general overview see Heinrich et al 2009)	See Table 2b
	Botanical / Biological	Plan and undertake field trips with participants where you collect specimens and parts thereof (for a later recalling and writing down information in field notes).	Full description of methods of collection, processing and storage of plants, collectors and specimen numbers, information on the taxonomic validation of the species, repositories used for voucher specimens. If applicable, regional floras should also be used	http://mpns.kew.org/mpns-portal/ or http://www.theplantlist.org/ Dauncey et al 2016; Rivera et al 2014,	No

	Select local and international herbaria where to deposit the specimens	and must be cited.		
Anthropological / sociological	Define and implement anthropological method and selection of adequate methods for research goal. Interview local health care professionals and general population about use of medicinal plants and associated outcomes.	Description of approach and methods; validation of the survey methods used (e.g. through piloting); recruitment strategy and sample size, eligibility criteria for participants; settings and locations where the data were collected (incl. use of translators). If applicable, selection of a comparator group and criteria for their selection; methodological innovations / changes to previous protocols	Bernard (1988, 2000a,b, 2011); Ember. and Ember (2001)	No
Sample size and sampling strategy	Define and implement sampling method. General or	Details about sample size and how participants were selected and contacted. If		No

		specialist knowledge. Entire medicinal flora (*materia medica*) of a region or specific elements of the flora (eg. Groups of diseases).	possible, details about the professional background of each participant (proof of consent for publishing this data as part of the appendix).		
	Ethnomedical	If possible involve a qualified medical doctor in the design and development of the study. Define appropriate methods like pile sorting for classifying ethnomedical uses. Collect information on outcomes associated with use of the plants.	Criteria used to define the uses reported or observed and how these criteria were defined (e.g. based on participant's statements, medical diagnosis, or a combination of both)		No
	Clinical or interventi	Enlist the support of local health	Information on whether the information is	Schulz et al 2010 and updates)	No

on or observational studies (if applicable)	care providers for medical examinations and diagnosis provided. While currently not common, in the future it will be desirable to design more outcome ortiented and especially observational studies.	strictly based on interviews with stakeholders (e.g. healers and patients), and if applicable, how the diseases or condition was diagnosed about the validation of any clinical tools used and of the establishment of an adequate sample size. For randomised controlled clinical trials, the CONSORT statement (current version), esp. the one for herbal medicines needs to be followed.	
Data collection	Develop a strategy for collecting the data, design the necessary tools (e.g. interview forms, questionnaires).	Types of interviews and other tools used for data collection should be specified. If applicable, copy of the questionnaire in the appendix.	
Data analysis	Primary (quantitative)	In general terms, all information	Yes

	data must be included unaltered as possible (see results). Explain on which grounds and significance level a hypothesis is being refuted (or accepted)	necessary for reproducibility need to be included. Strategy and statistics, tools used and how they were selected, if applicable, (semi-) quantitative analysis of the data		
Additional analysis	Consider variance of data and interval of confidence. Venn diagrams can be useful in showing amount of overlap between different groups of data.	Methods for additional analyses including description how the data were analysed (e.g. FIC – Factor of Informant Consensus, comparison with other groups, historical analysis)		Yes
Ethical considerations	Ethical approval and national governmental permits as required by the authorities	Incl. compliance with international botanical and social science standards and agreements / protocols, approval by an institutional or national review	See also Cragg et al. (1997).	No

			board, prior informed consent for research and publishing of the data.		
	Intellectual property rights and CBD and subsequent treaties and regulations including the Nagoya Protocol	Full compliance with international conventions and the national legislation including collection permits, for specimens and bioprospecting samples (if applicable)	Compliance with all relevant agreements and protocols (i.e the CBD, subsequent agreements, most recently the Nagoya Protocol)se the Access and Benefit-sharing Clearing-house (ABSCH) (https://absch.cbd.int/).Information on any agreement on access and benefit-sharing, compliance with the relevant agreements and whether the code of ethics of the International Society of Ethnobiology was followed.	http://ethnobiology.net/code-of-ethics/ For example, in the European Union this is implemented through Regulation (EU) No. 511/2014 in order to assure compliance with the protocol.	No
Results (depending on the journal policy, this is	Baseline data on findings	Systematic coverage of all data relevant to the topic.	In general journals will expect a substantial set of data, small samples both in terms of		Yes

often combined with discussion)	Coverage of general or specialist knowledge. The focus may be on an entire medicinal flora of a region or on *materia medica* for a certain (group of) disease(s) (often depending on journal policies, see Weckerle et al 2017). Descriptive (ethnographic) data may be useful and relevant in order to present the current situation and should be incorporated into the design, if applicable	numbers of participants and numbers of species would only be acceptable in exceptional circumstances. Often a journal will expect the coverage of the entire medicinal flora (*materia medica)* of a region or, for example, of a specific therapeutic category. . This needs to be defined on the basis of a journal's specific guide to authors. The triangulation of the data gathered is essential.
	Full confidentialit	

	y must be guaranteed, wherever applicable.			
Main data	See previous point	There needs to be a focus on what were the main outcomes of the study based on the objectives defined above.		Yes
Data presentation	Ascertain what analyses are meaningful, relevant in the context of you research questions and can be achieved	A table (or more) listing the main plants or preparations recorded, the scientific name of the plant, the plant part used, the method of preparation, the dosage, route of administration, whether it is combined with other plants, how many participants mentioned this preparation for this condition, how many reported perceived efficacy (i.e. that they themselves or their patients improved after taking it), any		Yes (excluding data referring to informants)

		contraindications or concerns about safety. Taxonomically fully valid names must be included		
Conservation status	Define which species may have to be excluded due to CITES or national regulations	If applicable, information on endangered species should be presented, esp. if these are marketable species.	CITES Appendices https://cites.org/eng/app/appendices.php	Normally no
Quantitative parameters determined	Determine which quantitative parameters can be used to analyse the data in a meaningful way	Data on medical uses need to contribute to the scientific understanding of the medicinal species in the region. The quantification should be made by reporting the frequency of individual citation (use reports; absolute, primary data) of the mode of application and use of a specific drug, (not % or relative data).		Yes

Discussion (depending on the journal policy, this is often combined with results)	Critical assessment of the relevance of the study	In the design phase it is essential to assess whether the methods can actually yield the desired data Work out similarities/dissimilarities with other groups/region/country Was gap in knowledge closed?	Relevance of the study in the context of the cultural group, region, country.	Yes
	Methodological limitations	Were the methods adequate for answering the research questions?	An assessment of the methodological limitations must be included. Also included must be external and internal factors, which may have affected the study. Factors and changes to the initial study protocol, which will have affected the study. Bias caused due to sampling strategy or other factors.	Yes

		A discussion of any problems (e.g. lack of willingness to collaborate) encountered during the field study	
Interpretation and analysis of the data consistent with results	N/A	Have the research questions (as outlined in the aims and objectives) been answered or not?	Yes
Comparability to other studies	Assessment of approaches and outcomes of previous studies as a basis for a comprehensive comparison to regional studies and to nationally relevant textbooks about herbal medicine, pharmacopoeias and prescription books	Comparability to other studies in the region or which have used similar approaches An evaluation of the existing evidence on the most frequently cited plants. Are these "new" or "unusual", or are they already well-known and well-documented? Consider also literature on mainstream herbal medicine and phytotherapy.	Yes
Implications in a	Ideally connect with	External validity, applicability. An	Yes

	wider scientific context	national health care service in order to ascertain the use of the data generated in the study	assessment of how this information will be of scientific relevance	
	Implications of the study for the *local population(s)* and the country or region	Design of feedback for local population in form of brochure or medicinal plant book	Assessment of how this study impacts on the study population.	No
	Next steps for developing research on the topic	N/A	Based on the new information collected, and existing literature on these plants, which plant(s) should be prioritised for further research, and why? E.g. plant(s) with good perceived efficacy for important disease(s) which have also been cited in other studies, but insufficient	Yes

			preclinical / clinical studies have been done to test their safety, pharmacological effects and efficacy.	
Conclusions	Critical appraisal of the overall findings in a wider context	N/A	Generalizability and short generalised assessment of the implications of the study and its findings, including an assessment of its limitations	Yes
Other information	Supplementary information	N/A	Inclusion of research tools and other materials like questionnaire/ interview guide used (optional).	see Table 1b
	Funding	N/A	Financial support received. Any commercial or other interests that need to be declared	Yes
	Acknowledgement	N/A, but of course permits need to be obtained, see above	The support of all involved needs to be included (as is the standard in scientific practice) local peoples. If images of persons are included, in the	Yes

		paper, permissions need to be obtained in advance.		

N/A – not applicable

Table 2b. Additional points referring specifically to historical studies (especially to the analysis of historical texts)

Many of the more general points listed in the above table on the field studies (Table 2a) are also applicable for historical studies.

Section, Item (this will vary according to the requirements of the journal)	**Topic** (a short overview on the main aspects to be covered)	**Design** (information for best practice in designing for each of these points)	**Reporting** (information for best reporting for each of these points)	**Notes**
Title				See Table 2a
Abstract				See Table 2a
Introduction	Scientific relevance	Assessment of the context and importance of the text within the tradition concerned (e.g. through comparison with culturally or historically related texts) and its significance as a	Validity of the text in context of ethnopharmacological research	Additional points, see Table 2a

		resource for ethnopharmacological research.		
Ethnophar-macological background	Detailed description of the cultural-historical context	Review of the literature to understand how the text is embedded in the relevant cultural-historical environment and, if applicable, how it is linked to other written traditions.	Short review of the cultural and historical setting concerned and details about the relevant indigenous, ethnic or cultural group. Impact, if any, of the text on today's herbal medicine of the respective culture.	Additional points, see Table 2a
Methods	General methodological information	See Table 2a In case of an unedited or non-translated text it is often useful to involve researchers from different disciplines.	Details about the general procedure used to access and analyse the text, including specific tools used and how they were developed; Contribution and expertise of the study team members.	Additional points, see Table 2a
	Description of the text, access and data extraction	Locate the relevant copy or edition of the text (physical or digital archive) and establish access to it. Develop a protocol for analysing the text that is specific to your focus and research question.	Description of the text investigated including type, format, language, date and place of origin and where it is stored today; The method used to extract relevant information from the text (e.g. manual line by line reading or computer assisted reading of	

		text).		
	Identification of plants or other natural products	The identification of plants or other natural substances mentioned in the text should involve a broadly based body of literature (e.g. pharmacognostic reference texts, dictionaries of *materia medica* and other useful literature) and take into consideration cultural historical and geographical aspects; Plant illustrations contained in the text can be valuable in this context but should be used in combination with other information available; Pharmacognostic samples of the relevant culture or tradition that are held in collections can contribute to the identification procedure.	Plant names cited in the text should be listed and the references used to identify them cited for each case; Scientific names stated in the references used need to be verified based on information in up-to-date databases on plant nomenclature.	Specifically refers to unedited texts.
Results				See Table 2a
Discussion	Problems encountered in the analysis of	N/A	A discussion about the major problems encountered (e.g.	Additional points, see Table 2a

	historical texts		difficulties in accessing the resources, legibility of original manuscripts, uncertainties in the plant identifications and the interpretations of symptoms and diseases).	
Conclusions				See Table 2a
Other information	Supplementary information	N/A	Complete list of the plant names mentioned in the text and their cross-referencing with scientific names; If applicable, scans of the plant illustrations or photographs of pharmacognostic samples involved in the identification procedure.	Specifically refers to unedited texts.