Best Practice in Research:

Consensus Statement on Ethnopharmacological Field Studies – ConSEFS*

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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.

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

* - 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.

INTRODUCTION: THE NEED FOR A STANDARD OF BEST PRACTICE IN ETHNOPHARMACOLOGICAL FIELD STUDIES

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 international laws and agreements and their implementation in research	Ethnobiology, ethnomedicine, ethnopharmacology, pharmacognosy and bioprospecting	E.g. CBD 2001 and 2011; AAA 2012 as well as previous versions and updates; Cragg et al., 1997, 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.

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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.

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