Original Article

Preparation Method for Protocols of Case Studies in Apitherapy – The Common Language of Integrative Medicine ◆

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ABSTRACT

The integration of apitherapy into modern medicine requires robust documentation and communication of its clinical efficacy. This paper addresses the need for standardized protocols to guide case studies in apitherapy, ensuring credibility and comparability across treatments. By outlining essential parameters for case documentation—including patient history, experimental conditions, product characterization, and evaluation criteria—this framework aims to enhance the quality and acceptance of alternative treatments. The proposed methodology aligns with established guidelines from organizations like the Joanna Briggs Institute and Cochrane, facilitating the adoption of a common language in integrative medicine. Standardized protocols will support practitioners in demonstrating the efficacy of apitherapy while adhering to ethical and regulatory standards. Ultimately, these measures aim to bridge the gap between anecdotal evidence and scientific validation, fostering greater trust and integration of apitherapy within conventional medical practice.

Keywords: Apitherapy, Case studies, Integrative medicine, Protocol development, Medical documentation, Standardization, Complementary treatments

INRTODUCTION

The primary goal of healthcare is to heal and, at the very least, alleviate the suffering of the patient. No other objective should override this fundamental principle. However, for healing to have a broader societal impact, effective communication is essential. This makes the success of treatments a matter of public interest, extending beyond individual recoveries.

It is challenging to inspire trust in patients, societies, policymakers, and legislators without a clear explanation of the treatment's nature. In certain countries, apitherapy has historically relied on anecdotal evidence, leading to its perception as a form of holistic medicine. Miraculous stories of recovery in distant regions, attributed to unknown healers, often prompt scepticism. Such cases raise important questions: Did the patient's belief in the treatment trigger natural healing mechanisms? Was it merely a placebo effect, or was the entire narrative exaggerated?

In countries like Italy, France and Poland etc. every scientific study must adhere to the language and rules of conventional Western medicine. Research that falls outside of these strict parameters is typically dismissed. Similarly, in the Netherlands, clinical studies are subject to rigorous regulation by ethical commissions, ensuring both safety and high quality. However, collecting retrospective data—after a treatment has been completed based on the physician's deci-

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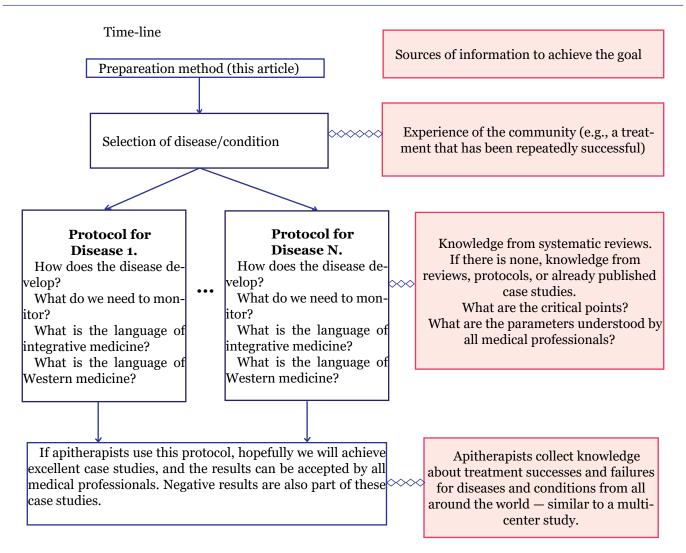


Figure 1. Graphical abstract

sion, even in off-label cases—does not require ethical approval.

Nevertheless, adherence to the Declaration of Helsinki and the General Data Protection Regulation (GDPR) is mandatory, and obtaining informed consent is highly recommended.

THE ROLE OF CASE STUDIES IN MEDICAL RESEARCH

In addition to clinical trials, case studies can provide invaluable insights for the medical community, especially in fields like apitherapy. However, this practice is not widespread in some countries, such as France. Only a few university hospital doctors occasionally undertake such studies, and even then, only in cases where no conventional treatment proves effective or when the patient refuses standard care. These case studies often address rare or poorly understood pathologies.

To ensure that case studies are credible and their results are valuable, it is essential to define certain parameters before beginning the study. Key information must be established and reported, such as:

- The patient's anthropometric characteristics,
- Their medical history,
- The reasons for not following the conventional treatment recommended by medical associations (e.g., treatment failure).
- The experimental conditions under which the treatment was administered,
- A precise physico-biochemical characterization of the product used,
- The evaluation criteria applied to measure results, whether through biological markers or validated assessment scales.

Thorough examination and evaluation of case studies are crucial to provide reliable and accurate information to both patients and physicians who are searching for effective and credible treatments. Properly designed and documented case studies can play a significant role in demonstrating the efficacy of alternative treatments, including apitherapy, and contribute to the body of evidence needed for broader acceptance.

THE ROLE OF APITHERAPY IN MODERN MEDICINE

Apitherapy represents a treatment that is officially accepted in some countries, tolerated in others, and outright banned elsewhere. This disparity underscores the need for precise and well-documented studies to ensure that those with experience in apitherapy can share their knowledge reliably with others. It is important that competing interests do not impede the application of proven treatments.

One of the most critical requirements for effective communication is a shared language between those delivering and those receiving medical information. This includes using consistent terminology, employing the same validated methods to track disease progression or regression, and documenting the healing process in a standardized way.

In medical literature, systematic reviews, such as those produced by the Cochrane Review [2], represent one of the highest standard. These are followed by traditional reviews, clinical trials, and case studies. To establish a common language within integrative medicine, especially in the field of apitherapy, the following steps are essential (see figure 1):

- 1. If an apitherapist or physician achieves positive results in treating a specific disease, the first step is to focus on that particular condition. The next step is to determine whether a systematic review exists on the treatment of that disease, regardless of the treatment method used. A systematic review will highlight the critical factors of the studies and identify any gaps that could render the case study invalid.
- 2. If no systematic review is available, the practitioner should look for reviews, clinical trials, and case studies. Paying close attention to their methodologies and the language used will reveal the common terminology and frameworks doctors and patients use to measure healing and outcomes with other treatments.

In cases where neither a systematic review nor a traditional review is available for the specific disease, the general rules must be applied and adapted to create a protocol for that disease.

The Joanna Briggs Institute [1] has developed several simplified checklists for case reports, case series, and other study types. These checklists provide a structured approach to ensure that key elements of the research are adequately addressed. Cochrane also offers widely accepted checklists, such as the Risk of Bias tool II for randomized controlled trials and ROBINS-I [3] for cohort studies. For animal studies, the ARRIVE guidelines [4] are available.

ESTABLISHING A FRAMEWORK FOR FUTURE CASE STUDIES

A comprehensive article detailing the processes for assessing, monitoring, and documenting recovery for a given disease could serve as a guide for future case studies. Such a guide would need to remain independent of any individual case reports to ensure that its methodology is unbiased by specific treatment outcomes.

The common language of integrative medicine will not remain static. As new knowledge emerges and our understanding of diseases evolves, so too will the language and standards we use.

Particular attention must be given to obtaining informed consent from patients, enabling their cases to be communicated. Additionally, it is important to report cases where treatments did not yield positive results, as this enhances the reliability of the information and helps identify the limitations of certain products or potential interactions with medications.

CONCLUSION

The development of protocols for each specific disease, aimed at gaining wide acceptance among healthcare professionals, is a crucial first step. These protocols will enable practitioners, both medical doctors and naturopaths, to create "perfect" case studies in the future. To achieve this, it is essential to synthesize the insights gathered from existing systematic reviews, general checklists, and the established measures commonly used in traditional medical case reports for tracking disease progression.

Once the scientific groundwork is laid through these protocols, healthcare professionals can apply them in practice, ensuring consistent, high-quality documentation of treatments and outcomes. This structured approach will not only strengthen the credibility of case studies but also contribute to the integration of apitherapy and other complementary treatments into broader medical practice, fostering a common language in integrative medicine.

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