An assessment of the scientific status of anthroposophic medicine, applying criteria from the philosophy of science

Erik W. Baars\textsuperscript{a,b,c,*}, Helmut Kienle\textsuperscript{d}, Gunver S. Kienle\textsuperscript{a,d,e}, Peter Heusser\textsuperscript{b,f}, Harald J. Hamre\textsuperscript{a,d}

\textsuperscript{a} ESCAMP, Zechenweg 6, D-79111 Freiburg, Germany
\textsuperscript{b} Louis Bolk Institute, Kosterrijnlaan 3-5, 3981 AJ Bunnik, The Netherlands
\textsuperscript{c} University of Applied Sciences Leiden, Zernikedreef 11, 2333 CK Leiden, The Netherlands
\textsuperscript{d} Institute for Applied Epistemology and Medical Methodology at the Witten/Herdecke University, Zechenweg 6, D-79111 Freiburg, Germany
\textsuperscript{e} Center for Complementary Medicine, Institute for Infection Prevention and Hospital Epidemiology, Faculty of Medicine, University of Freiburg, Freiburg, Germany
\textsuperscript{f} Witten/Herdecke University, Gerhard-Kienle-Weg 4, D-58313 Herdecke, Germany

\textbf{ARTICLE INFO}

\textbf{Keywords:}
Anthroposophic medicine
Demarcation criteria
Philosophy of science
Scientific research field

\textbf{ABSTRACT}

\textbf{Objectives:} The objective was to evaluate the scientific status of anthroposophic medicine (AM) according to demarcation criteria proposed in contemporary philosophy of science.

\textbf{Design:} Criteria for what is science were retrieved from eight publications in the philosophy of science, focusing either on science in medicine or on the demarcation between science and pseudoscience or non-science. Criteria were combined, redundancies were excluded, and the final set of criteria was ordered in a logical sequence. The analysis yielded 11 demarcation criteria (community, domain, problems, goals, axiomatic basis, conceptual basis, quality of concepts, methodology, deontic basis, research products, tradition).

\textbf{Results:} Assessing the scientific status of AM according to the 11 criteria, all criteria were fulfilled by AM.

\textbf{Discussion:} AM is grounded on the notion that specific non-atomistic holistic formative forces exist and can be empirically and rationally assessed. From a position claiming that such holistic forces cannot possibly exist or cannot be empirically and rationally assessed, the axiomatic and conceptual basis of AM can be contested. However, such an a priori rejection is problematic in the presence of empirical evidence supporting the validity of holistic concepts, as discussed in the paper. Future research should therefore focus on the tenability of the ontological reductionist position in science and on the further validation of AM non-atomistic holistic concepts, methods and practices.

\textbf{Conclusion:} In this analysis, using criteria from philosophy of science, AM fulfilled all 11 criteria for what is science.

1. Introduction

Anthroposophic medicine (AM) is an integrative medical system, founded in Central Europe in the early 1920s. AM is provided by physicians, therapists and nurses and integrates conventional medicine with the concepts, methods and therapies derived from anthroposophy.\textsuperscript{1,2} The anthroposophic concept of man claims the human organism to be not only formed by physical (cellular, molecular) forces but by altogether four classes of formative forces: (1) formative physical forces; (2) formative vegetative forces which interact with physical forces and bring about and maintain the living form, as in plants; (3) a further class of formative forces (\textit{anima}, soul) which interact with the vegetative and physical forces, creating the duality of internal-external and the sensory, motor, nervous and circulatory systems, as in animals; (4) and an additional class of formative forces (\textit{Geist}, spirit) which interact with the three others and enables the manifestation of individual mind with the capacity for reflective thinking, as in humans.\textsuperscript{3,4} The interactions of these forces are understood to vary between different regions and organs in the human body, resulting in a complex equilibrium. This equilibrium can be distorted in various forms of human disease, and is sought to be regulated by anthroposophic therapies.\textsuperscript{5-7} Since its initiation by Rudolf Steiner (1861–1925) and Ita Wegman (1876–1943), AM has developed worldwide,\textsuperscript{5} its scientific status however has been repeatedly questioned.\textsuperscript{5,9}

In this paper we assess the scientific status of AM, checking its
concepts, methods and practice against criteria from the philosophy of science. This discipline conceives science as “a cognitive activity that is uniquely capable of yielding justified beliefs about the world”\textsuperscript{10,p. ixx} and that is capable “to determine which beliefs are epistemically warranted”\textsuperscript{11} p. 331. Theoretical and practical criteria in order to demarcate science from pseudoscience or non-science have been developed\textsuperscript{12} with a focus on methods rather than on contents or doctrine,\textsuperscript{13} assuming that adequate methods will result in valid knowledge. Since the 1930s, various demarcation criteria have been proposed: verification of statements\textsuperscript{14}; falsification of theory\textsuperscript{15,16}; development of research programs\textsuperscript{17}; capability for puzzle-solving\textsuperscript{18}; presence of an epistemic field, i.e. groups of people with conjoint cognitive aims and practices.\textsuperscript{19,20} Criteria have referred to practice,\textsuperscript{21,22} problems,\textsuperscript{23} the intention for inquiry\textsuperscript{18,24} and normative aspects\textsuperscript{25} such as universalism, communism (sharing all produced knowledge), disin- terestedness, and organized skepticism.\textsuperscript{13} A one-criterion demarcation has been proposed,\textsuperscript{12} but multi-criteria approaches are more often used.\textsuperscript{12,19,26} Various sets of criteria, however, turned out as too narrow or too wide,\textsuperscript{27} and altogether there is no consensus on the content or number of criteria, nor on their hierarchy and logical structure.\textsuperscript{11,27} Consequently, a plurality of methods, systems, explanatory models, and evidence theories has been advocated.\textsuperscript{28,29}

2. Methods

In order to test the scientific status of AM, a set of demarcation criteria was needed. As in the philosophy of science there is no consensus on which criteria to use, and to our knowledge no comparable testing of a medical system had been undertaken so far, we decided to establish a set of criteria for our analysis. Taking an inclusive and broad approach, criteria were retrieved from eight publications, thereof two with focus on science in medicine\textsuperscript{10,31} and six on the demarcation between science and non- or pseudoscience.\textsuperscript{12,13,22-25} Publications were chosen based on the following inclusion criteria: (1) year of publication > 2005, (2) publication includes a thorough discussion on demarcation between science and non- or pseudoscience; (3) publication is within the field of the philosophy of science or the philosophy of medicine. We stopped adding new publications after saturation was reached and no new information was provided. We combined these criteria, excluded redundancies, and ordered the criteria in a logical sequence. The final set of criteria (Table 1) was then applied to AM.

3. Results

In the following we describe the results of our criteria-based analysis of the scientific status of AM. For each criterion (Table 1) the corresponding AM features are outlined, in order to assess the degree of criterion fulfillment.

3.1. Community

AM is based in the conceptual and empirical work of Rudolf Steiner.\textsuperscript{36,37} A first medical research community with physicians and pharmacists was established in the early 1920ies in Arlesheim, Switzerland, and in Stuttgart, Germany. Since then, research has been a major issue of national and international AM organizations. Today, university chairs for AM (three in Germany, one each in The Netherlands and Switzerland) and research institutes around the world examine AM. Scientists are trained in natural sciences and evidence-based medicine as well as in AM concepts and methodologies.\textsuperscript{38,39} They use a well-structured and transparent language, as laid out in AM textbooks in different languages,\textsuperscript{16-4} they communicate and cooperate among another and with other scientists; they publish in peer reviewed journals of conventional medicine, CAM or AM\textsuperscript{11} and participate in research conferences on conventional medicine, CAM and AM worldwide. A large number of publications in peer-reviewed journals and presentations in conventional scientific conferences demonstrate the exchange of results and ideas with other scientific communities.\textsuperscript{45}

3.2. Domain

AM regards itself as an extension of modern medicine.\textsuperscript{46-48} AM physicians, therapists, and nurses are fully trained in conventional medicine, and additionally go through structured AM training.\textsuperscript{49} AM covers more or less all areas of medicine including emergency and intensive care services in AM hospitals. Specific issues of the AM domain include the epistemological foundation, development, description and validation of the concepts of AM, its working principles and medical and non-pharmacological treatments, and its diagnostic procedures; the evaluation of safety, quality, efficacy, effectiveness, and costs of AM; the integration of AM with conventional medicine; and the development, description and validation of specific AM healthcare practice-oriented evaluation methodologies.\textsuperscript{4,40-43,50}

3.3-3.4 Problems and challenges

Major problems and challenges for the scientific AM community are\textsuperscript{49,50,51}:

- the need to produce a broader range of high quality evidence on AM concepts (e.g., health, disease, treatment) and AM practice (e.g., effectiveness), and of more specific AM methods for diagnostics and therapeutic decisions;
- the paucity of financial and personnel resources compared to the
multitude of research issues relating to the large number of therapeutic AM procedures and their individualized and often complex application to a broad range of indications;
- the necessity of strategies for AM evaluation, in order to achieve optimal cohesion, maximize synergy effects and increase the impact.

3.5. Axiomatic basis

For AM, main axiomatic positions include 1,4,36,37,52–54:
- AM is a medical system that integrates the specific anthroposophic insights, diagnostics and therapies into the diagnostics, therapies and preventive strategies of conventional medicine.
- AM is founded in an epistemology that refers to an empirical and rational cognition of holistic formative forces.
- In order to explore these levels of formative forces and according organizational and functional levels of the organisms, specific methods are applied.
- AM acknowledges the level of causative factors that are investigated by conventional physics, chemistry, physiology, etc., as well as the causative levels of formative forces, and integrates both.
- The observation and recognition of relationships between the formative forces in humans and other realms of nature (minerals, plants and animals) are used to develop and apply anthroposophic medicinal products.
- Concerning health and disease, AM intends to understand salutogenetic and pathogenetic effects on specific organs, organ systems and the whole organism by exploring the abovementioned levels of formative forces, hereby differing from the conventional biomedical paradigm that ultimately attempts to explain health and disease by physico-chemical interactions of molecules.
- AM therapies are systems-oriented, aiming at: (1) influencing the relevant organizing system level in health and disease concurrently or sequentially (multi-modal, poly-target-treatment); (2) restoring balance and wholeness within the system by stimulating the higher organization levels to regulate the lower levels (health promotion).

3.6. Conceptual basis

AM concepts and treatments are derived from general anthroposophic concepts, and have led to new forms of therapy (e.g., eurythmy therapy) and new modalities of existing therapies. The concepts and treatments evolve through inter- and intra-subjectivistic knowledge development, as described in textbooks, applied in clinical practice, and tested in clinical research.7,40–43,45,51

The conceptual systems used by the AM scientific community in dealing with the AM research domains include: the non-atomistic holistic concepts of life, soul, and spirit; the relationship between the realms of nature and man; the origins of health and disease; possible spiritual-existential aspects of disease in the patient’s biography; diagnosing and treating the different levels of organization in organisms with regard to health and disease; the specific pharmaceutical procedures used in AM; the modes of actions of different artistic mediums such as drawing, painting, sculpturing, music, and recitation; the modes of action of different substances and techniques used in nursing and AM-derived physiotherapy; the understanding of concepts and treatments used in conventional medicine from the perspective of AM; and the integration of different conventional and AM therapy forms into a whole therapy system treatment.55

3.7. Quality of concepts

Since the inception of AM 90 years ago, its concepts have been consistently and transparently used across different fields of medicine (anatomy, biochemistry, cardiology, dermatology, embryology, gynecology, internal medicine, neurological rehabilitation, obstetrics, oncology, pediatrics, primary care, psychiatry, pulmonary medicine, rheumatology) 7,56 and among AM researchers, pharmacists, physicians, and therapists. Although the concepts are relatively stable, they have been further elaborated and diversified through research. Like in other scientific areas, the concepts are not always easily accessible when specific AM training is lacking.

The concepts have been operationalized and tested in a broad array of preclinical research, for example on mistletoe extracts,57–59 and in more than 300 clinical studies ranging from case series and qualitative studies to double-blind randomized trials.4,45,51 Due to limited resources, however, only a part of the full range of concepts has been validated empirically while others await their investigation or are subject to ongoing work.

The AM research community is striving for further theoretical and empirical testing of its concepts. Results have led to adaptation of AM concepts,40 to integration of AM concepts with relevant non-AM scientific concepts, and to changes of AM clinical practice.51,62

The AM concepts are in line with a general epistemological trend in the life sciences: from a mechanistic, reductionist worldview towards a more holistic approach in developing theories of living organisms.47,64 This trend is manifest in systems biology, epigenetics and emergence.4 Moreover, regarding the empirical observations in these research fields, AM concepts can have a bearing on conceptualization and explanation, thus demonstrating their original and enriching quality and their explanatory power, without having an overloaded ontology.4,41.

Nevertheless we acknowledge that for many scientists who accept and are interested in the fields of systems biology, epigenetics and emergence, the concept of non-atomistic holistic formative forces might be a step too far, and will be regarded as ‘overloaded ontology’ (= demarcation criterion 71). Although going into this topic is beyond the scope of this article, we refer to the references in Section 8, where methods have been described that lead to observations of these higher order, non-atomistic holistic formative forces. Based on such observations, conceptualization of non-atomistic holistic formative forces can be performed.

3.8. Methodological basis

Standard quantitative and qualitative clinical research methods are applied in AM. As, however, AM is often tailored to the individual patient48 and group-based methods can be inadequate or fail for this purpose65 individualized research methods have been developed.66

Double-blind randomized controlled trials (RCTs) often cannot be applied, since only a small number of AM treatments (e.g., Citrus/ Cydonia for hay fever67,68) fit the ‘one-identification one-treatment’ approach, and treatments often are difficult to blind because of specific physiological reactions to medication treatment and due to therapist-patient interactions during art or movement therapy sessions. AM physicians and their patients often reject randomization because it can disturb the physician-patient relationship and because of strong therapy preferences.51 Randomization refusal and other obstacles have led to recruitment problems and premature termination of a number of AM-RCTs.69 Therefore, in line with developments in complementary medicine systems70,71 and in complex interventions of conventional medicine,72,73 other methodologies are used (e.g., mixed methods approaches, pragmatic trials) and new methodologies, including single case causality assessment,74 have been developed.75,76

Specific methods for the assessment of the organism’s higher organization levels and their relationship to the lower physical and physiological levels have been and are being developed and investigated.4,38,52,54,77–82

Research networks have been built to perform multicenter studies on AM use, safety and effectiveness in naturalistic in- and outpatient settings, for example in oncology.83

In today’s EBM context, AM is increasingly challenged to provide high quality evidence of its diagnostic procedures and treatments, with
an increasing number of publications appearing in peer-reviewed journals, with the peer review serving as “organized skepticism”.

3.9. Deontic basis

Since AM is a system of medicine that integrates diagnostics and therapies from conventional medicine with anthroposophic insights, diagnostics and therapies, the deontic rules in conventional medical research largely also apply for AM research. Due to the holistic ontological and epistemological position of AM, additional rules are used, guiding some of the research for the holistic approach to diagnostic, preventive and treatment procedures.41,62,77–79,87–89

3.10. Research products

Different types of research products come from AM: study results, healthcare programs, methods for healthcare practice, measurement instruments and research methodologies.

A Health-Technology Assessment (HTA) report identified 265 clinical studies on the efficacy and effectiveness of AM, covering a broad spectrum of disorders and showing predominantly good results, with few, mostly mild to moderate side effects, a high measure of client satisfaction and favorable cost-effectiveness compared to conventional treatment.45,51 AM healthcare programs encompassing multidisciplinary diagnostic and therapeutic procedures for specific indications were developed and validated,46,90 as well as new diagnostic and therapeutic methods,54 questionnaires91, and research methodologies2,50,74–76. Standard methods and these new methods complement each other in the overall strategy of AM research.29,93

3.11. Tradition

The AM research frame relates to several tradition lines.

The tradition of the natural sciences and of conventional medicine is a general basis for AM practice and research. AM is compatible with the scientific facts of this tradition line, except for positions that categorically exclude the possibility of formative forces and their accessibility through observation and cognition. Empirical research is equally valued in AM as in conventional medicine, and is used as source material for acquiring knowledge of higher organization levels in nature and man.38,51,54,55

The epistemological foundation of AM36,37 can be described as an objective and empirical ontological idealism,55 which has also been called universalism and, in the sense of Goethe, phenomenalism.27,81,94 Universalism has been a major conceptual framework in Western thought from classical Greece to present times, e.g. Plato (427-347 BCE), Aristotle (384-324 BCE), Anselm von Canterbury (1033–1109), Albertus Magnus (1206–1280), Thomas Aquinas (1225–1274), Niklaus von Kues (1441–1464), Spinoza (1632–1677), Schelling (1775–1854), Hegel (1770–1831), Goethe (1749–1832), Schiller (1759–1805), Hartmann (1882–1950), Whitehead (1861–1947), Heisenberg (1901–1976), Heitler (1904–1981), Wandsdchneider (1938–), and Hötle (1960–).55 Phenomenalism in the sense of Goethe and Steiner27,77,94 stands in a tradition of holistic thinking in science86, which is important in contemporary research fields such as ecology and quantum mechanics,46 in methodologies such as phenomenology92 and in the evaluation of whole medical systems71 and complex interventions.72,73

AM also stands in a historical tradition of preventive and curative health promotion. Dating back to ancient cultures throughout the world, this tradition was part of Greek and Medieval medicine,36 is part of different CAM systems in the 20th and 21st centuries, and has received renewed attention in the last decades.24,99 Health promotion of holistic forms of healthcare are presently studied and taught in 73 academic centers for integrative medicine in the US102 and in academic centers in the fields of the social sciences and public health.

Finally, AM stands in a tradition of diagnostic and therapeutic orientation on the individual. This approach was common medical practice until the arrival of epidemiology in the 20th century. The dominance of epidemiological results over clinical expertise has led to professional protocols and guidelines focusing on group characteristics.105 However, both in conventional medicine and in CAM there is renewed interest in the development of methodologically sound approaches to the individual patient.102–106

4. Discussion

One limitation of the study regards the chosen set of the criteria. Not only is there no consensus about these criteria in contemporary philosophy of science, but also our set of criteria could be subject to criticism or (e.g. redundancy, need to differentiate between essential and accessory criteria). A further limitation is a potential “conflict of interest” as the study has been conducted by experienced AM researchers and may be considered an “inside perspective”. However, for the application of the criteria, sufficient knowledge of and insight into AM is mandatory, just as only quantum physicists may be able to judge specific issues of quantum mechanics.

Withstanding such potential criticism, our application of the criteria reveals the very crucial point of the whole issue which could eventually outweigh all other issues: Do formative forces, as assumed in AM, exist and if so, can they be empirically and rationally assessed – or not? Ultimate clarification of this question is beyond the scope of this paper. It may be fair, however, to point out that the holism-reductionism debate has provided strong arguments pro holism,107,108 and current conceptualizations of the organization of living organisms are shifting towards holistic views, e.g. in epigenetics92 and emergence.110,111 In several research fields, emergent phenomena are characterized as irreducible and in need of new holistic conceptualizations.112 Furthermore, some holistic conceptions of AM have been validated to a considerable extent. A first example is mistletoe. From the anthroposophic view, it had been predicted as effective in cancer treatment. Meanwhile, a considerable number of mistletoe ingredients have been shown to have anti-cancer effects, covering a broad array of oncological working principles; and clinical mistletoe studies demonstrated effectiveness, for example in advanced pancreatic cancer.107,58,84,113–119 Another example are recent experiment series on ultra-high dilutions providing replicable effects far beyond Avogadro’s number.120,121 These examples clearly support the validity of the respective AM concepts.

Considering the dynamics of the scientific and medical communities, further and more diverse validations may be needed. Future research should therefore focus on the tenability of the ontological reductionist position in science and on the further validation of AM non-atomistic holistic concepts, methods and practices. In particular the identification and assessment of the above-mentioned formative forces will require more specific explanations. As the concept of non-reductionist formative forces is also present in other complementary and traditional whole medical systems,7 this study may be seen as a contribution to the international debate on the ontological, methodological and practical status of traditional & complementary medicine.122

5. Summary and conclusion

We have assessed the scientific status of AM according to 11 demarcation criteria proposed in contemporary philosophy of science (community, domain, problems, goals, axiomatic basis, conceptual basis, quality of concepts, methodology, deontic basis, research products, tradition). AM fulfilled all 11 criteria – but their application reveals a controversial topic: AM is grounded on the notion that specific holistic formative forces exist and can be empirically and rationally assessed. From a position claiming that such holistic forces cannot possibly exist or cannot be empirically and rationally assessed, the axiomatic and conceptual basis of AM can be contested. However, such
an a priori rejection is problematic in the presence of empirical evidence supporting the validity of holistic concepts, as discussed above.

To conclude: In this analysis, using criteria from philosophy of science, AM fulfilled all 11 criteria for what is science.

Funding sources

ESCAMP aims to receive financial support preferentially from non-profit organizations and public funds, if necessary also from manufacturers of anthroposophic medicinal products (AMPs). Financial support from AMP manufacturers requires that the funding is not subject to conditions that could affect the independence of ESCAMP.

To date ESCAMP has received financial support from the following non-profit organizations:

- Software AG – Stiftung (Germany), Mahle-Stiftung (Germany), Christophorus Stiftung (Germany), Ekhasstiftelsen (Sweden), Vidarstiftelsen (Sweden), Iona Stichting (The Netherlands); and from the following industrial sponsors: European Association of Manufacturers of Medicines for Anthroposophic Therapy (AEFMTUA, France), WALA-Heilmittel GmbH (Germany), Weleda AG (Switzerland).

The sponsors had no influence on the study design; in the collection, analysis and interpretation of data; in the writing of the report; and in the decision to submit the article for publication.

References

