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Received: 31 August 2022 | Revised: 12 September 2023 | Accepted: 23 October 2023

DOI: 10.1111/bioe.13240

SPECIAL ISSUE: TRANSLATIONAL BIOETHICS

From book to bedside? A critical perspective on the debate about "translational bioethics"

Alexander Kremling[1] | Jan Schildmann[1] | Marcel Mertz[2]

[1]Institute for History and Ethics of Medicine, Interdisciplinary Center for Health Sciences, Martin Luther University Halle-Wittenberg, Halle, Germany

[2]Institute for Ethics, History and Philosophy of Medicine, Hannover Medical School, Hannover, Germany

Correspondence
Alexander Kremling, Institute for History and Ethics of Medicine, Martin Luther University Halle-Wittenberg, Halle, Germany.
Email: alexander.kremling@medizin.uni-halle.de

Abstract

The concept of "translational bioethics" has received considerable attention in recent years. Most publications draw an analogy to translational medicine and describe bioethical research that aims at implementing and evaluating ethical interventions. However, current accounts of translational bioethics are often rather vague and seem to differ with regard to conceptual and methodological assumptions. It is not clear and scarcely analyzed what exactly "translation" in the field of bioethics means, in particular regarding goals and processes so that it is justified to appeal to translational medicine. In this article, we thus explore possible analogies and disanalogies between translational medicine and translational bioethics to establish whether the often occurring reference to concepts of translational medicine in the field of bioethics can be justified by substantial analogies. We will first provide an account of different models of translational medicine. In a second step, we will propose an analytic definition that explicitly articulates the essential characteristics of "translational research" irrespective of the research field (i.e., biomedicine, bioethics). Subsequently, we will explore whether and in how far general characteristics and phases of translational research in medicine can be applied to translational research in bioethics. Based on our analyses, we will come to the skeptical conclusion that at present there are considerable conceptual disanalogies and unsolved conceptual problems that disallow using "translational bioethics" in a meaningful analogy to respective accounts in biomedicine. Nevertheless, we will demonstrate that some insights gained by the conceptual accounts of translational medicine can contribute to advance current research activities in bioethics.

KEYWORDS

definition, empirical ethics, translational bioethics, translational medicine

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1 | BACKGROUND

The term "translational bioethics" has received considerable attention in recent years in the debate about research in bioethics that is oriented toward biomedical practice. Most commonly, the term is used in two rather different ways. First, it refers to research on ethical aspects of translational biomedical research ("translational medicine" for short), also concerning the influence of public interests.[1] Second, it can refer to bioethical research that aims at implementing and evaluating ethical interventions or tools (e.g., recommendations, guidelines, decision aids, etc.) in the "real world," more or less explicitly analogous to translational research in biomedicine.[2] Next to the aforementioned two meanings of the term, there exists a further usage of the term that is neither referring to biomedical research nor bioethics: it can refer to ethical aspects of translation in linguistics.[3] Moreover, since terms do not have a "natural" meaning, it is conceivable that the term "translational" is used in completely different ways, without any borrowing from the established understanding of biomedicine.

However, the fact that terms are not naturally "fixed" does not mean that they are completely arbitrary. They have a history and, in one way or another, refer back to existing meanings and usages. This is especially true when the extension of the term under discussion ("translational bioethics") refers to a similar context as already established terms with similar words ("translational medicine"). The assumption that in such cases the intension of the (new) term is entirely different from the known and established terms therefore has—we would argue—to bear the greater burden of proof than the counter-thesis that there are at least borrowings of meaning from the medical context. That there may be a tendency in bioethics to adopt or adapt existing concepts from biomedicine is indicated by the history and the discourses of older, equally not always uncontroversial terms, for example, "evidence-based ethics" in relation to evidence-based medicine or "systematic review of ethics literature" in relation to systematic review methodology in medicine.[4]

In addition, the current debate uses, to the best of our knowledge, "translation" in ethics with implicit or explicit reference to the understanding of translation coined in the biomedical research setting. An analogy to translational medicine is not an assumption of this article but part of the literature that tries to conceptualize translational bioethics. For example, Cribb explicitly refers to the importance of "translational research […] in academic medicine" before discussing ways of "bringing ethical scholarship into the sphere of personal and public action."[5] Bærøe discusses the "parallel track" of ethics to translational medicine in "[translating] theoretical conclusions into adequate practice."[6] Schwietering et al. identify a bioethics "subfield […] in line with similar subfields in biomedicine or psychology where the evaluation of how effectively, efficiently or valid certain practice-oriented (treatment or prevention) recommendations are translated or implemented into practice is a field in its own."[7] Buchbinder et al. discuss translational bioethics about ethics issues of the COVID-19 pandemic, "[b]orrowing from the concept of translational science in medicine."[8] In addition to such explicit references,[9] we think it has to be acknowledged that "translation" in the field of bioethics is implicitly and intuitively linked to translational medicine and would not be the designated term for a new field of research, where it not for the successes and reasonableness of translational medicine. Moreover, a word like "translational" can be misunderstood by those who follow an already established usage of the word; that is, here, medical researchers will most likely think of "their" understanding of "translational" when they hear of "translational bioethics." Due to the proximity of the fields of bioethics and biomedicine, sometimes also interdisciplinary collaborations, it makes sense not to use "translational" completely detached from the established usage in biomedical research.

Against this background, we therefore limit our analysis to an understanding of translational bioethics that refers back to translational medicine. On the other hand, we do not claim that any possible meaning one might want to give to "translational bioethics" is limited to this analogy. We particularly address the question whether and in how far the more or less implicit analogy to translational medicine does hold when the research activities in both fields are compared. Furthermore, in order to be consistent with the debate to date, we use the term "translational bioethics," though "translational medical ethics" might be more precise. "Translational bioethics" would be the more general term, encompassing—next to ethical issues in medicine—also further topics such as animal rights or climate engineering.

Thus, we assume from now on that existing accounts for translational bioethics are explicitly or recognizably oriented to some characteristics that have been established for translational

[1]Hostiuc, S., Moldoveanu, A., Dascălu, M.-I., Unnthorsson, R., Jóhannesson, Ó. I., & Marcus, I. (2016). Translational research—The need of a new bioethics approach. *Journal of Translational Medicine*, *14*(1), 16. https://oi.org/10.1186/s12967-016-0773-4; Rothstein, M.A. (2023), Translational Bioethics and Health Privacy. *Ethics & Human Research*, *45*, 40–44. https://doi.org/10.1002/eahr.500167; Evans, J. H. (2023), Translational Bioethics and Public Input. *Ethics & Human Research*, *45*, 35–39. https://doi.org/10.1002/eahr.500175

[2]Bærøe, K. (2014). Translational ethics: An analytical framework of translational movements between theory and practice and a sketch of a comprehensive approach. *BMC Medical Ethics*, *15*(1), Article number: 71. https://doi.org/10.1186/1472-6939-15-71; Cribb, A. (2010). Translational ethics? The theory-practice gap in medical ethics. *Journal of Medical Ethics*, *36*(4), 207–210. https://doi.org/10.1136/jme.2009.029785

[3]See, for example, Chou, I. C., Lei, V. L. C., Li, D., & He, Y. (2016). Translational ethics from a cognitive perspective: a corpus-assisted study on multiple English-Chinese translations. In T. Seruya & J. Justo (Eds), Rereading Schleiermacher: Translation, Cognition and culture. New frontiers in translation studies (pp. 159–173). Springer. https://doi.org/10.1007/978-3-662-47949-0_14.

[4]For critical discussions see Birchley, G., & Ives, J. (2022). Fallacious, misleading and unhelpful: The case for removing 'systematic review' from bioethics nomenclature. *Bioethics*, *36*, 635–647. https://doi.org/10.1111/bioe.13024; Sulmasy, D. P. (2019). Ethics and evidence. *The Journal of Clinical Ethics 30*, 56–66. https://doi.org/10.1086/JCE2019301056

[5]Cribb, op. cit. note 2.

[6]Bærøe, op. cit. note 2.

[7]Schwietering, J., Langhof, H., & Strech, D. (2023). Empirical studies on how ethical recommendations are translated into practice: A cross-section study on scope and study objectives. *BMC Medical Ethics 24*, 2. https://doi.org/10.1186/s12910-022-00873-x

[8]Buchbinder, M., Berlinger, N., & Jenkins, T. M. (2022). Protecting practitioners in stressed systems: Translational bioethics and the COVID-19 pandemic. *Perspectives in Biology and Medicine*, Project MUSE *65*, 637–645. https://doi.org/10.1353/pbm.2022.0055

[9]See also Parsons, J. A., Johal, H. K., Parker, J., & Romanis, E. C. (2023). Translational or translationable? A call for ethno-immersion in (empirical) bioethics research. *Bioethics*, 1–10. https://doi.org/10.1111/bioe.13184, page 7.

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medicine.[10] At the same time, these accounts are often rather vague and seem to differ with regard to conceptual and methodological assumptions. In particular, it is not clear what exactly is meant by "translation" regarding goals and processes in the field of bioethics. A reference to translational medicine should, at best, provide meaningful insights to be substantial and that go beyond a mere heuristic use, for example concerning goals and characteristics of translational bioethics.[11] In particular, there should be more than a mere reference to the goal to become more relevant in practice, if the term "translational bioethics" is not just used as buzz word and with reference to already valued concepts to legitimize one's work. Given that translational medicine refers to defined processes of research and interactions with the aim to implement and improve healthcare, one would expect that authors subscribing to the project of translational bioethics are able to provide ideas about shared goals and process elements. However, there is currently a scarcity of reflections and analyses on what exactly "translational" could mean in "translational bioethics," in a way that it is justified to appeal to translational medicine.

In this article, we thus explore possible analogies and disanalogies between translational medicine and translational bioethics. It should be noted that our aim is not to argue about the semantics of the term but to explore whether the term "translational," if used as an analogy to the established use in biomedical research, can be substantiated in bioethics research, for example, with regards to possible goals or procedural steps. The aim is to contribute to a less vague concept of translational bioethics or at least to establish whether current references to concepts of translational medicine in the field of bioethics can be justified by substantial analogies. The latter question leads to a decision about whether the term—if at all—should be rather used in a heuristic sense.

We will first provide an account of different models of translational medicine with a focus on shared characteristics of translational phases, associated types of research methods as well as translational gaps that need to be overcome. In a second step, we will propose an analytic definition that explicitly articulates the essential characteristics of "translational research" irrespective of the research field (i.e., biomedicine, bioethics). Subsequently, we will explore whether and in how far general characteristics and phases of translational research in medicine can be applied to translational research in bioethics. Based on our analyses, we will come to the skeptical conclusion that at present there are considerable conceptual disanalogies and unsolved conceptual problems that disallow using "translational bioethics" in a meaningful analogy to respective accounts in biomedicine. Nevertheless, we will demonstrate that some insights gained by the conceptual accounts of translational medicine can contribute to advance current research activities in bioethics.

2 | MODELS OF TRANSLATIONAL MEDICINE

In a first step and prior to exploring the analogy in more depth, it is necessary to clarify what "translational medicine" means. While there have been proposed various models during the last years[12] it comes at some surprise that an actual explicit definition can hardly be discerned. It seems rather that a "definition in use" is employed, whose descriptions result from the (basal) common features in the proposed models. Ultimately, all models characterize translational research as a *temporal process that leads the further development and especially implementation of scientific ideas at least from basic (and preclinical) research to clinical research and, beyond that, even to post-clinical research, and may finally result in an impact on public health*.[13] This characterization must also be seen against the background of research that aims to improve, that is, shorten, the long time lag between basic research and implementation in practice (up to 30 years) without risking a loss of quality or generating (excessive) additional costs.[14] "From bench to bedside" has become the typical phrase to refer to this research approach.

However, while there are shared characteristics, the published models of translational medicine differ in whether they locate the translation of scientific ideas in (i) certain *gaps* between two research areas (which pursue different sub-goals and sometimes use different methods/types of studies) or (ii) in individual, separable phases in a research process, which, however, is to be understood as a *continuum*, or (iii) as both. The *gap definitions* are older than the *continuum definitions*[15] and originally referred mainly to the gap between laboratory or basic research ("bench") and clinical research ("bedside"). While gap definitions usually describe only a few phases of (translational) research—for example, two, namely "basic research" (T1) and "clinical research" (T2)—continuum definitions distinguish up to six different phases (T0–T5).[16]

Table 1 provides a summary of the different phases of translational medicine and selected publications referring to these phases. In accordance with this summary, T0 refers to identifying relevant biological targets for further translational research. T1 refers to the translation of results gained by intervening into nonhuman

[10]Mathews, D. J., Hester, D. M., Kahn, J., McGuire, A., McKinney, R., Meador, K., Philpott-Jones, S., Youngner, S., & Wilfond, B. S. (2016). A conceptual model for the translation of bioethics research and scholarship. *Hastings Center Report*, *46*(5), 34–39. https://doi.org/10.1002/hast.615; Bærøe, op. cit. note 2; Cribb, op. cit. note 2; Sisk, B. A., Mozersky, J., Antes, A. L., & DuBois, J. M. (2020). The "ought-is" problem: An implementation science framework for translating ethical norms into practice. *The American Journal of Bioethics*, *20*(4), 62–70. https://doi.org/10.1080/15265161.2020.1730483

[11]Fort, D. G., Herr, T. M., Shaw, P. L., Gutzman, K. E., & Starren, J. B. (2017). Mapping the evolving definitions of translational research. *Journal of Clinical and Translational Science*, *1*(1), 60–66. https://doi.org/10.1017/cts.2016.10, Callard, F., Rose, D., & Wykes, T. (2011). Close to the bench as well as at the bedside: Involving service users in all phases of translational research. *Health Expectations*, *15*(4), 389–400. https://doi.org/10.1111/j.1369-7625.2011.00681.x

[12]See Fort et al., op. cit. note 4.

[13]Following Trochim, W., Kane, C., Graham, M. J., & Pincus, H. A. (2011). Evaluating translational research: A process marker model. *Clinical and Translational Science*, *4*(3), 153–162. https://doi.org/10.1111/j.1752-8062.2011.00291.x

[14]Ibid.

[15]Fort et al., op. cit. note 4.

[16]For example, Hostiuc et al., op. cit. note 1.

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TABLE 1 Phases of translational biomedical research.

Phase	Description	Type of research; disciplines, methods, study types…
T0	Hostiuc et al. (2016): "Valley of death" between fundamental research and developing a medical product	Biomarkers, Genes, Biochemistry, Molecular mechanisms (if applicable, also findings from clinical practice that are significant for this phase)
T1	Khoury et al. (2007): Discovery to candidate health application	Phases I and II clinical trials; observational studies
	Westfall et al. (2007): Translation to humans	Basic science research, preclinical studies, animal research; case series, Phase 1 and 2 clinical trials
	Dougherty et al. (2008): Activity to test what care works	Clinical efficacy research
	Santen et al. (2012): From bench research into clinical research	Clinical efficacy research: move basic science to clinical (patient); basic biomedical science
	Seals (2013): –	Basic laboratory research (preclinical models); human subjects research (clinical research setting)
	Rubio et al. (2014): discoveries from the basic science phase are applied to human condition; can include animal models of human disease	–
	Hostiuc et al. (2016): Gap between developing a medical product and making it ready for the clinic (Hostiuc 2016)	Proof of concept, phase I clinical trials, phase II clinical trials
T2	Khoury et al. (2007): Health application to evidence-based practice guidelines	Phase III clinical trials, observational studies, evidence synthesis, and guidelines development
	Westfall et al. (2007): Translation to patients	Human clinical research, practice-based research; (controlled) observational Studies, phase 3 and 4 clinical trials, guideline development, meta-analyses, systematic reviews, survey research
	Dougherty et al. (2008): Activities to test who benefits from promising care	Outcomes research, comparative effectiveness research, health services research
	Santen et al. (2012): From individual patient care into systematic acceptance and widespread use	Implementation research: activity provides effective care to communities, proliferation of evidence-based practice; (improved education practices in the community)
	Seals (2013): Clinical guidelines/practice (medical office/ centers)	–
	Rubio et al. (2014): Results from clinical research are applied in clinical practice; results of this research provide evidence for best practices	–
	Hostiuc et al. (2016): Gap between making a medical product ready for the clinic and its routine application in clinical practice	Phase III clinical trials, clinical efficacy, clinical guidelines
T3	Khoury et al. (2007): Practice guidelines to health practice	Dissemination research, implementation research, diffusion research; phase IV clinical trials
	Westfall et al. (2007): Translation to practice	Dissemination research, implementation research
	Dougherty et al. (2008): Activities to test how to deliver high-quality care reliably and in all settings	Measurement and accountability of health care quality and cost, implementation of interventions and health care system redesign, scaling and spread of effective interventions, research in the above domains
	Santen et al. (2012): From clinical research into evidence-based guidelines for patient care	Outcomes & comparative effectiveness research: activities produce evidence of effectiveness at the level of the patient; effectiveness studies/comparative effectiveness studies
	Seals (2013): Public health policy	Population health outcomes (community settings)
	Hostiuc et al. (2016): Gap between the routine application in clinical practice and population-wide effects	Dissemination, phase IV clinical trials, community engagement

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TABLE 1 (Continued)

Phase	Description	Type of research; disciplines, methods, study types…
T4	Khoury et al. (2007): Practice to population health impact	Outcomes research (includes many disciplines); population monitoring of morbidity, mortality, benefits, and risks
	Hostiuc et al. (2016): Gap between population-wide effects and policies derived from them	Public health, prevention, behavioral and lifestyle changes
T5	Hostiuc et al. (2016): –	Social health care, macroeconomics, Political measures (access to health care and education)

Note: Phases of translational research and according to descriptions from exemplary models.

systems (e.g., molecules, cells in vitro or animal models in vivo) to humans. While some models only include "proof of concept" studies others also include early clinical studies in this phase. T2 describes the translation of these results to larger clinical studies up to the development of clinical guidelines. T3, which similarly to T1 and T2 has been described widely in the literature, refers to translating the results of T2 to practice by implementation and dissemination. T4 and T5 are used more seldom and describe research on outcomes and effectiveness in larger populations and the translation to the macro level of the health system (e.g., health policies).

Comparing the different models of translational medicine it can be observed that (at least implicitly) all models distinguish between research or research phases that take place *before* and ones that take place *after* the development of *syntheses* from human clinical experiments (*cross-study synthetic knowledge*). Accordingly, there seems to be a distinction between knowledge gained "from individual clinical studies (before) to more synthesized general knowledge that cuts across studies (after)."[17] The increasing expansion and more nuanced differentiation from initially only T1 and T2 to T0 up to T5 also reflects that the understanding of "translation" depends on the involved disciplines and institutions. While from a basic science perspective translation from T1 to T2 (e.g., taking new discoveries from the laboratory to develop, for example, new drugs) is crucial, public health agencies tend to view translational research as something covering also later stages, from building clinical evidence up to demonstrating health impact at the population level.[18]

The proposed models differ in their degree of linearity. While all models actually describe bidirectionality between phases of translational research (so that findings in later phases can influence studies in earlier phases), some models assume a more cyclical or dynamic model than others.[19] However, this does not change the fact that the intention or goal is always to move research "from left to right."[20] Furthermore and as indicated in Table 1, the authors of different models explicitly tie the translational research phases to certain *methods* or *types of studies*, even if it is admitted that there may also be overlap.[21] This points to different demands on the (methodological) skills of the researchers and the necessary infrastructure: While, for example, "basic to clinical science skills and laboratory facilities" are still sufficient at T1 and T2, T3 requires skills "in epidemiology, behavioral science, public policy, and other fields to be able to synthesize relevant knowledge (via systematic reviews, meta-analyses, and medical guidelines development)."[22] Beyond this, and relevant for T4 and T5, there is also a need for knowledge about "disseminating and implementing observations made at the clinical research level to population health outcomes in settings of clinical practice and the community."[23] Depending on the respective phase, it is also possible to identify different obstacles to translation ("translation blocks"), which, in turn, can also be tied back to the different methods or study types. Examples of such "blocks" are regulatory burdens, career disincentives, high research costs, and lack of funding.[24]

This admittedly brief and not comprehensive overview of accounts of translational medicine indicates shared but also differing elements with implications for the goals of translational research, methods, and involved professions. This already raises the question of which model (or common aspects of the models) translational bioethics might borrow its name in a justified way. However, it is first necessary to examine whether overarching elements of translational research—which can be applied to different fields (e.g., biomedicine, bioethics)—can possibly be identified via an analytical definition that is informed by the models of translational medicine.

3 | TRANSLATIONAL RESEARCH. PROPOSAL FOR AN ANALYTIC DEFINITION

In order to reach a better understanding of both—translational medicine and translational bioethics—a reflection on the core aspect of translational research and the development of an analytical definition is useful.

[17]Trochim et al., op. cit. note 6, p. 156.

[18]Khoury, M. J., Gwinn, M., Yoon, P. W., Dowling, N., Moore, C. A., & Bradley, L. (2007). The continuum of translation research in genomic medicine: How can we accelerate the appropriate integration of human genome discoveries into health care and disease prevention? *Genetics in Medicine*, *9*(10), 665–674. https://doi.org/10.1097/gim.0b013e31815699d0

[19]Trochim et al., op. cit. note 6.

[20]Ibid.

[21]For example, Khoury et al., op. cit. note 10.

[22]Seals, D. R. (2013). Translational physiology: From molecules to public health. *The Journal of Physiology*, *591*(14), 3457–3469. https://doi.org/10.1113/jphysiol.2013.253195, p. 3458.

[23]Ibid: p. 3459.

[24]Sung, N. S., Crowley, W. F., Genel, M., Salber, P., Sandy, L., Sherwood, L. M., Johnson, S. B., Catanese, V., Tilson, H., Getz, K., Larson, E. L., Scheinberg, D., Reece, E. A., Slavkin, H., Dobs, A., Grebb, J., Martinez, R. A., Korn, A., & Rimoin, D. (2003). Central challenges facing the national clinical research enterprise. *JAMA*, *289*(10), 1278. https://doi.org/10.1001/jama.289.10.1278

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At the center of translational medicine seems to be an epistemic problem that is not specific to medicine: The *target system*—the system we want to achieve effects in or gain knowledge about—might be difficult to study from an epistemological, methodological, or ethical perspective. The target system might be too small/large/hot/far away to study and manipulate it directly. It might be a complex system that has to be broken down into subsystems first. It also might be unethical to experiment with it directly (e.g., global climate because there is no second system in case of adverse effects, or humans because the health of every single human is valuable).

In these cases, there is a need for *model systems* that might be easier to access epistemically, methodically, or ethically and that allow for deriving promising hypotheses about the target system. For medicine, these are, for example, cell lines in basic laboratory work, animal models, and sometimes even representations of biomolecular processes in computer programs (in silico experimentation).

Working with model systems allows for systematic variation, isolation from possibly interfering background conditions and—important for medicine—testing of hypotheses in ways that would be ethically impossible when carried out in the target system. For medicine, the target system would be the human patient. Doing "trial and error" science directly with patients would be often harmful and would be, as a consequence, unethical. Therefore, one tries to approach the target system by model systems step by step.

Gaining reliable knowledge without damaging the human target system comes with a cost: The model might not scale up. "Promising effects" in the model system might not be found in the target system. Several steps have to be taken to safeguard that what is true in a model system is actually true in the target system. "Translational," referring to the latin verb "transferre"—to transfer, bring across, cross over—in "translational medicine" (or "translational biomedical research") expresses these steps. They can, from the perspective of theory of science, be conceptualized as *steps to secure the validity of a series of analogies*.[25]

Therefore, "translational research" *in general* can be defined explicitly in the following way:

[1] *Translational research is a scientific process in which researchers try to gain knowledge about a target system by transferring knowledge from a system that is easier to access, in a time- and cost-effective way, sticking to predefined steps.*

"Translational biomedical research"can be defined by integrating the specific practical goals and the target system of medical research:

[2] *Translational biomedical research is a scientific process in which researchers try to achieve the promotion of health, cure, or prevention of diseases of humans by transferring knowledge from laboratory and/or animal model research in a time- and cost-effective way, sticking to predefined steps.*

The exact sequence of steps might vary depending on whether the medical goal is defined narrowly (effects for single patients) or more broadly (society-wide or global effects).

For exploring the possible meanings of "translational bioethics," though, the possible analogies to this core concept of translational medicine have to be discussed.

An attempt to apply [1] to the field of bioethics, that is, to try an analytic definition of "translational bioethics" or rather "translational bioethics research" (of which "translational bioethics" is again an abbreviated way of speaking), leads to several questions.[26] Nevertheless, one *possible* definition could be:

[3] *Translational bioethics research is a scientific process in which researchers (ethicists?) try to establish morally right (or prevent morally wrong) actions concerning the promotion of health, cure, or prevention of diseases of humans by implementing theoretical insights (mainly of ethics?), in a time- and cost-effective way, sticking to predefined steps.*

There are alternatives to this definition depending on decisions about the following questions:

- *Object of translation*: Is there something that is transferred and thereby transformed "from left to right"? What could this be? *Moral obligations* for actions, as in the proposed definition, "from well justified in the books to established at the bed"? Or *concepts*, used theoretically in the books, now used to defend moral obligations for actions (e.g. from Kant's use of "autonomy" to obligations concerning vaccination[27]).
- *Goal of translation*: What could be the goal of translational bioethics? A morally right practice? Obligations that are concrete enough to be put into practice, maybe justified in light of available empirical data?[28] Guidelines for ethical practice?
- *Research economics of translation*: Are time- and cost-effectiveness declared goals? How could the time and cost of research in ethics be measured and optimized in the first place?
- *Structure of translation*: Is it possible to define a sequence of research phases with recognizable gaps between them, which have to be bridged by means of specific translation?

The latter two sets of questions touch the core of what is typical for translational research in general and for translational medicine in particular. Based on our description of the phases of translational medicine and the analytic definitions, we can now take a closer look

[25]Hesse, M. B. (2001). Models and analogies. In W. H. Newton-Smith (Ed.), *A companion to the philosophy of science* (pp. 299–307). Blackwell; Kremling, A. (2018). *Eingreifen und Schließen: Interventionistische Kritik kausaler Erkenntnis*. Karl Alber.

[26]We think that it is not problematic though in general to talk about a "scientific process" in the field of bioethics. Ethics is a scientific discipline—in the general meaning of the term "science," not to be confused with "natural science." Matters of translation can also be found in other scientific disciplines like psychology, politics, or economics.

[27]Schröder-Bäck, P., Van Duin, C., Brall, C., Scholtes, B., Tahzib, F., & Maeckelberghe, E. (2019). Norms in and between the philosophical ivory tower and public health practice: A heuristic model of translational ethics. *South Eastern European Journal of Public Health (SEEJPH), XI*, 2019. https://doi.org/10.4119/SEEJPH-1882

[28]Kühlmeyer, K., Mertz, M., Haltaufderheide, J., Kremling, A., Schleidgen, S., & Inthorn, J. (2022). Empirical research and recommendations for moral action: A plea for the transparent reporting of bridge principles in public health research. *Public Health Ethics*, *15*(2), 147–159. https://doi.org/10.1093/phe/phac002

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at possible analogies in search of a meaningful concept of translational bioethics. Are there corresponding elements between translational biomedical and bioethical research?

4 | "TRANSLATION" IN MEDICINE AND BIOETHICS. A COMPARATIVE ANALYSIS

For our comparative analysis of translational medicine and translational bioethics, we will use T1, T2, and T3 in biomedical research as starting points. The rationale is that these phases are, as indicated above, shared across the multiple accounts of translational medicine and therefore may be conceived as core elements.

T1: In biomedicine, this phase covers the fundamental steps from basic and preclinical research to clinical research. Accordingly, the obvious candidate for a functional equivalent of translation in bioethics is the step from general philosophical (or theological) theories to theoretical approaches to medical ethics ("medium-range theories"), that is, approaches that have a certain application reference. This would imply agreement that "general ethical theories" are sufficiently similar to "basic research" in biomedicine, for example, that normative questions are easier to access than the targets further down the continuum of translation. Idealized examples might even look like they have been cleaned from "possibly intervening background factors." However, it is questionable whether we may accept philosophical research as fundamental to bioethics comparable to natural science to biomedicine. Firstly, it seems obvious that there is no isolated "model system" for which normative claims hold that have been developed in general ethical theories. As a consequence, normative judgments might change when more realistic situations are considered—while results of earlier phase studies in translational medicine stand as they are, even if they fail to "scale up" in the next study, and the hypothesis about the human population of, for example, real patients has to be changed. Second, it can be objected that in bioethics, being an interdisciplinary field, there is often little recourse to the "grand theories" or in-depth philosophical analyses. Some proponents of common morality approaches may even deny that general philosophical theories are of particular importance for bioethics.

Even if we would buy into the idea, there is a second obvious limitation to compare T1 of translational medicine to translational bioethics. In the latter, there seems to be no equivalent to *translation to humans*. This in turn is considered a decisive step in T1 in biomedicine. Of course, it is conceivable that we test an ethical guideline or an ethical intervention with humans. However, such translation into practice much more resembles later stages (e.g., T3, possibly also T2), as we will show. In summary, it seems that there are no or at most few uncontroversial functional elements in bioethics for what has been described in biomedicine concerning the early phase of translation.

T2: In biomedicine, this phase refers to clinical research (especially phase III studies) and proof of effectiveness being translated into clinical guidance. Similarly to T1, there are challenges to identify corresponding elements in bioethics. However, one may say that on the level of study design, there is research in bioethics that investigates the "effectiveness" of ethical interventions, such as the effectiveness of ethics consultation or advance care planning.[29] Still, there seems to be a crucial difference concerning the actual translation from knowledge of effectiveness toward guidance. This is because in medicine such translation takes place when data on the effectiveness of the health technology has already been generated. In bioethics, however, the guideline whose effectiveness would be tested in T2 would already have to exist—that is, the validity of the content for a possible clinical guideline is only just being tested in T2 in medicine, while bioethics must already presuppose the validity of the content for an ethical guideline. There is no "translation to patients." This is a clear disanalogy, which could only be reduced, but not eliminated, if research into the "clinical effectiveness" of a health technology were *not* to be understood as part of T2 (but only the step toward the development of guidelines etc. were to be regarded as T2).

This disanalogy may weigh heavily in that perhaps some proponents of translational bioethics regard precisely the step of developing guidelines or decision aids as an important (perhaps even the most important) step of translation in bioethics. Critically, it can be said that—at best!—the aspect of guideline development (or similar) in T2 is transferable to bioethics, and this is only by omitting the step that is the decisive basis for the *legitimate* development of guidelines for translational research in biomedicine (namely the proof of effectiveness of a health technology). The challenge is maybe somewhat alleviated when it is not so much a question of developing genuine ethical guidelines and decision-making aids, but rather of integrating "ethical knowledge" into clinical guidelines, decision-making aids or, for example, HTA reports.[30] Otherwise, only rather *metaphorical* transmissions remain, for example, "translation to patients" to be understood as checking how (proposed) ethical norms or recommendations are perceived by those concerned (patients), for example, whether they agree with them or think that they would improve their situation if they were followed, and so on.

T3: As laid out in our distinction of different models of translational medicine, this translation phase encompasses translating guidance into implemented practice. This phase may be the one in which functional equivalents or analogies can be found most easily. This is because—independent of the content—the nature of the research and the associated challenges of dissemination and implementation are quite similar once a guideline or decision aid has been developed and is now to be (broadly) introduced "into

[29]Detering, K. M., Hancock, A. D., Reade, M. C., & Silvester, W. (2010). The impact of advance care planning on end of life care in elderly patients: Randomised controlled trial. *BMJ*, *340*(1), c1345–c1345. https://doi.org/10.1136/bmj.c1345; Schneiderman, L. J., Gilmer, T., Teetzel, H. D., Dugan, D. O., Blustein, J., Cranford, R., Briggs, K. B., Komatsu, G. I., Goodman-Crews, P., Cohn, F., & Young, E. W. D. (2003). Effect of ethics consultations on nonbeneficial life-sustaining treatments in the intensive care setting. *JAMA*, *290*(9), 1166. https://doi.org/10.1001/jama.290.9.1166

[30]Mertz, M., & Strech, D. (2014). Systematic and transparent inclusion of ethical issues and recommendations in clinical practice guidelines: A six-step approach. *Implementation Science*, *9*(1). Article number: 184. https://doi.org/10.1186/s13012-014-0184-y

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practice" (and here it is assumed that the contents of such guidelines etc. are "valid").

It seems that at least implicitly much of the translational bioethics debate to date refers to these challenges in particular, and some approaches address them even more explicitly, for example, by proposing to apply the findings of "implementation science" to bioethics.[31] However, if we include comparative effectiveness studies and phase IV studies in T3, there is again no direct functional equivalent to these types of studies and associated goals in the currently widely established bioethics. It is conceivable (and it cannot be ruled out that it has in fact already been carried out) to evaluate various ethical guidelines and the like comparatively with regard to their "effectiveness" or other characteristics. Still, here, too, the same basic disanalogy occurs that has already been mentioned in T2: While certain *effects* of specific health technology are examined in medicine (as a basis for formulating recommendations or guidelines), in bioethics, an already existing guideline etc. would be examined. In summary, while T3 seems most promising concerning the actual translational processes, our analysis shows that there are fewer equivalents concerning what is needed to be able to test effectiveness. This is also true for T4 and T5, which provide more nuanced accounts of T3 and therefore add little new insight for our purpose.

5 | IS "TRANSLATIONAL BIOETHICS" A MEANINGFUL ANALOGY? CRITICAL REMARKS AND POSSIBLE LESSONS TO LEARN FOR RESEARCH IN BIOETHICS

The comparison with concepts of translational medicine as well as our attempt to gain more clarity about the understanding of translational research via an analytical definition suggest that there are major challenges when making a case for translational bioethics beyond a mere heuristic similarity to translational medicine. Nevertheless, our analysis does not show that it is not possible in principle to use "translational" as a concept that could be meaningful for bioethics. It also does not claim that the validity of "translational bioethics" hinges on the comparison with "translational biomedicine." However, given the lack of work on alternative understandings of "translational" on the one hand and the increasing number of publications referring explicitly or implicitly to "translational medicine" on the other hand, we believe that our focus on such an understanding of translational remains warranted.

We see one fundamental characteristic that undeniably belongs to translational research in biomedicine, but cannot be assumed in the same way in bioethics—a difference that cannot be passed over easily by just elaborating phases more precisely. This difference refers to the *goal* of translational medicine. Translational phases, no matter how they are conceived, always presuppose one thing: a clear goal of moving forward in a continuum of research "from left to right," that is, in translational medicine from early research phases (basic research) to the development and implementation of health technology. There is likely little doubt about this objective in biomedicine. Why should we do research in medicine at all if not to be able to improve health at some point? But there is, as we indicated in the discussion of the analytic definition, likely less consensus that bioethics needs or should be pursued toward a particular, especially *practical* goal. This seems even more true for the *motivation* behind translational processes in biomedicine, namely to make those processes faster and more cost-effective that have "always existed" in modern medicine anyway. It seems hard to conceive that such economic consideration could or should underlie the work in translational bioethics.

So it seems that there is probably no continuum from "left to right," from so to speak theoretical ethics ("book") to the implementation of "ethical knowledge" (whatever that may be exactly) in medical practice ("bedside") in the research of bioethics at all. Those who regard bioethics as the *always* theoretical analysis and testing of the validity of arguments will probably find little to like about the idea of incorporating any "ethical knowledge" into "guidelines" or other types of interventions. At least, from such a position, this will have nothing more to do with "ethics" and its (academic) tasks—and ethicists who are eager to bring ("their"?) moral insights into an existing practice may rather cause alienation and may raise the concern that academic research is no longer being conducted here, thus a "translation" is possibly unethical itself as it blurs the line between being a researcher and being an "activist."[32] Such concerns must be taken seriously in "translational bioethics," and it must be made clear how they could be dispelled. Even if it were accepted that bioethics research is or should at least also be concerned with an influence on practice, presumably no consensus could be found on the goal either; nor on the question of whether it can or should be the *task of bioethics itself* to carry out or support, for example, something like *implementation of knowledge* (or *practices*).

Still, one may reasonably object to the view that "translational bioethics" needs to have the same phases as they have been described for translational medicine. While this is true, it does not change the fact that our comparative analysis indicates that much more precise thought would have to be given to distinguish and elaborate phases of translational bioethics, that is, which object of translation (ethical norms, concepts, etc.?), which steps, methods or study types and skills they require, and so on.[33]

So to sum up, it seems that the term "translational bioethics" joins other terms, such as in former times the already mentioned

[31]See, for example, Sisk et al., op. cit. note 3—who do not use the term translational bioethics—and respective commentaries on their article.

[32]Cf. Rogers, W. (2019). Bioethics and activism: A natural fit? *Bioethics*, *33*(8), 881–889. https://doi.org/10.1111/bioe.12558

[33]Kuehlmeyer, K., Jansky, B., Mertz, M., & Marckmann, G. (2023). Transformative medical ethics: A framework for changing practice according to normative–ethical requirements. *Bioethics*, 1–11. https://doi.org/10.1111/bioe.13185

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"evidence-based ethics,"[34] that have been adopted from medicine (probably) because of their positive connotations, but which, on closer inspection, require at least considerably more theoretical clarification than is currently often available to justify a *substantial* analogy. Despite our skeptical results concerning more substantial analogies between translational medicine and translational bioethics, we nevertheless argue that studying the conceptual accounts of translation in biomedicine bears some fruits for such an enterprise, and for interdisciplinary research in bioethics, which focuses on biomedicine as a practice in general. In this respect, we consider (i) insights into methodological knowledge needed for such research and (ii) consideration of the so-called "translation blocks" as two possible lessons learnt.

With regard to the first issue, we would argue that even if there are only a few functional equivalents for the different translational phases, one can also assume that, as in translational medicine, the requirements for knowledge and skills are probably different when one distinguishes phases—still to be determined more precisely—also in translational bioethics. This is because different types of research must be conducted (e.g., philosophical/theoretical vs. socio-empirical studies) and different methods should be used (concept analysis, philosophical-ethical analysis, qualitative and quantitative approaches to empirical research, implementation and evaluation research, participatory research, community-engagement etc.). Just as in translational medicine one does not expect that someone who is active in basic research in the laboratory must also be able to conduct clinical studies (or even engage in public health research), in "translational bioethics" it should not be assumed that every bioethicist is able to work in or contribute to the different tasks associated with implementing or evaluating ethical concepts in the "real world." In fact, we might even want to move away from thinking that it always has to be "ethicists" who carry out just the later stages of translation into practice and subsequent evaluation of the implementation, etc. Nevertheless, little would be gained by any idea of "translational bioethics" if a corresponding process was not understood as such and (increasingly) coordinated. As in translational medicine, more attempts would be necessary to bring together the more theoretically working researchers with those—also from entirely different disciplines, even without reference to ethics as a field—who have the skills, for example, to conduct implementation research.

With regard to the second issue of "translation blocks," at least some of the challenges described within the context of translational medicine are also relevant to many types of research in bioethics. For example, it may also be difficult to find participants for an evaluation study of an "ethics tool"; publications of implementation studies may find only little interest in the journals (and thus act as a career disincentive), and so on. Similarly, qualification problems of researchers can also occur. Conversely, high research costs, regulatory burdens, or difficulties in exchanging data among each other are probably rather minor translation blocks for bioethics. Thus, the discussion about translation blocks in biomedicine may stimulate the field to examine more closely whether there are *specific* blocks for the phases of "translational bioethics" (that are yet to be defined in more detail) that do not occur or occur less in biomedicine. For at least this lesson can be drawn from translational medicine: In order to better identify the gaps between translational phases and, above all, to find solutions, a precise, empirical investigation of those circumstances that impede or even block translation is necessary. It is possible that, for example, the lack of acceptance of a moral norm among practitioners might play a role as a translation block, just as different moral views in general, or a widely accepted value pluralism in democratic Western states, but perhaps also the theory pluralism in ethics as a discipline. Also, the fact that there is probably not a shared long-range goal in bioethics (see above) could be aggravating for a translational process, since neither individual actors see themselves (nor *want* to see themselves) as part of a knowledge cascade with translational steps, nor are provisions made institutionally and structurally in a discipline with theological and philosophical roots to support translation into ultimately "the practice."

Aside from the aforementioned possible lessons, our conclusion concerning the term "translational bioethics" remains rather skeptical. It is tempting for ethicists to appeal to a research discipline that has a (widely) unquestioned desirable goal and pursues it in a structured way, especially when they navigate between medical and life science researchers. The term "translational bioethics" implies the same desirability and at least a similarly structured way to achieve a comparable unquestioned goal of the discipline. However, as shown in our analysis, we seem to have either too limited a substantial analogy to translational medicine, or too weak an independent conceptualization of "translational bioethics," which goes beyond an often still rather vague concern to make bioethics more relevant in practice or policy. While there are admittedly approaches that aim to elaborate more substantial analogies or an independent conceptualization of translational bioethics,[35] we argue that for the moment we should be cautious to talk about "translational bioethics" with the self-assurance that is currently sometimes displayed in the debate.

There may be ways to develop translational bioethics into a comprehensible field of research or movement but the allusion of an analogy to translational medicine alone or the work done so far does not clarify the concept sufficiently. Some authors might embrace the idea that there is no substantial analogy. The cost then is that it is even more an open question whether it is possible to unify and systematize the efforts of ethicists to be relevant enough to justify a comprehensible field or movement in bioethics—and whether "translational" is a proper name for it.

[34]For example, critically, Strech, D. (2008). Evidence-based ethics—what it should be and what it shouldn't. *BMC Medical Ethics*, *9*(1), Article number: 16. https://doi.org/10.1186/1472-6939-9-16

[35]For example, Sisk et al., op. cit. note 3; Schröder-Bäck et al., op. cit. note 18; Kühlmeyer et al., op. cit. note 23.

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ACKNOWLEDGMENTS

Open Access funding enabled and organized by Projekt DEAL.

ORCID

Alexander Kremling http://orcid.org/0000-0002-2674-2497
Jan Schildmann https://orcid.org/0000-0002-5755-7630
Marcel Mertz https://orcid.org/0000-0002-4871-4219

AUTHOR BIOGRAPHIES

Alexander Kremling studied Philosophy of Science and is working at the Institute for History and Ethics of Medicine at the Martin Luther University Halle-Wittenberg, mostly on sedation in palliative care, complementary and alternative medicine, and methodological questions of medical ethics.

Jan Schildmann is a specialist in internal medicine and director of the Institute for History and Ethics of Medicine at the Martin Luther University Halle-Wittenberg. In his research, he combines normative and empirical methods to explore ethical challenges in clinical practice and medical research.

Marcel Mertz is head of the working group Research/Public Health Ethics and Methodology at the Institute for Ethics, History and Philosophy of Medicine, Hannover Medical School, Germany. With a background in philosophy and sociology, he works primarily on topics of empirical ethics, methods of medical ethics, and health technology assessment.

How to cite this article: Kremling, A., Schildmann, J., & Mertz, M. (2024). From book to bedside? A critical perspective on the debate about "translational bioethics". *Bioethics*, *38*, 177–186. https://doi.org/10.1111/bioe.13240

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