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Transformative medical ethics: A framework for changing practice according to normative–ethical requirements

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Abstract

We propose a step-by-step methodological framework of translational bioethics that aims at changing medical practice according to normative–ethical requirements, which we will thus call "transformative medical ethics." The framework becomes especially important when there is a gap between widely acknowledged, ethically justified normative claims and their realization in the practice of biomedicine and technology (ought–is gap). Building on prior work on translational bioethics, the framework maps a process with six different phases and 12 distinct translational steps. The steps involve various research activities including conceptual philosophical inquiry and (socio-) empirical research. On the one hand, the framework can be used as a heuristic tool to identify barriers to the transformation process. On the other hand, it can provide guidance for researchers and practitioners to develop appropriate (conceptual action and practice) models, which are then implemented and evaluated in specific practice contexts. We use the example of realizing the norm of respect for autonomy in the practice of medical decision-making to illustrate the framework. Further research is required, for example, to theoretically underpin the framework, to apply it to other ought–is gaps, and to evaluate its feasibility and effectiveness in various practice areas. Overall, the framework of transformative medical ethics suggests a strategic process to investigate and promote practice change that is ethically informed in all phases.

KEYWORDS

ethical reasoning, implementation science, medical decision-making, policy-making, theory–practice gap, translational bioethics

1 | INTRODUCTION

Translational bioethics[1] is an aspiring subfield of bioethics, which is itself a subfield of applied ethics.[2] The term was proposed in analogy to translational medicine where translation "requires researchers to identify the steps to transfer basic scientific discoveries from laboratory benches to bedside decision-making and eventually into clinical practice."[3] The purpose of *applied ethics* is that "principles or standards with substantial philosophical justification, in particular ethical and political principles with such justification, are applied to particular cases and guide action."[4] Keeping this overarching goal in mind, translational bioethics should be concerned with identifying strategic activities that shall guide researchers and practitioners in narrowing the "theory–practice gap" in bioethics.[5] This gap can be understood in at least two ways: (a) Theory and practice can be seen as "epistemologically distinct areas involving different kinds of training and competence,"[6] requiring activities to promote knowledge translation, or (b) theoretical ethical reasoning justifies certain normative requirements[7] (e.g., of norms or virtues) but we can identify everyday practices, practice contexts, or actors that do not meet these requirements. In this article, we are concerned with b), to which we refer—in accordance with Sisk et al.—as the "ought–is problem" or the "ought–is gap," that is, a gap between what *should* be done from an ethical perspective ("ought") and what *is* actually done in practice ("is").[8]

The term alludes to the more familiar is–ought problem, that is, the problem that one cannot logically derive a normative prescription ("ought") from a pure description ("is"). The is–ought problem is a *logical* or *meta-ethical* problem that, depending on the philosophical position, is unsolvable, or its "gap" can only be circumvented with suitable bridge principles.[9] The ought–is problem, on the other hand, denotes a *practical* problem that is in principle solvable: An ought–is gap can be narrowed or even closed by suitable activities that promote "value translation" between abstract theoretical and practical ethical scholarship. We rely on cultural change as a process that can stipulate value translation on a large scale, especially when dealing with aspirational (not mandatory) norms. In health care, such kind of change is often difficult to implement because professional action takes place in highly structured systems like health care organizations, which respond slowly to changes.

There are at least two elaborated frameworks for *doing* translational bioethics: the frameworks by Sisk et al. and by Bærøe.[10] In the following, we present a new framework that draws on the work of Bærøe and Sisk et al, but goes beyond it.[11] In addition to prior frameworks, the goal of this framework is not only to provide (general) guidance for activities of *transference of knowledge*, that is, bringing ethical insights into practice or policy discussions. Such an approach of transference may suggest actions to practitioners but leave open whether and how normative insights will be implemented.[12] We explicitly propose steps aiming at ultimately *transforming* practice according to ethical requirements. We assume that a sustainable transformation of practice will require cultural change. We thus chose the term "transformative medical ethics" for our specific approach of translational bioethics to highlight its focus on narrowing ought–is gaps, to ensure that practitioners will more likely act in accordance with the normative requirements for a practice area.

We propose this framework with its concrete, step-by-step guidance to bioethicists as well as other researchers who should be part of such a transformative process, for example, social scientists, clinicians, or other stakeholders. They can use it in different professional fields like health care, health promotion, health research, or health policy-making. The proposed activities may have different relevance to researchers with different professional backgrounds. At the core, our proposed framework highlights inter- and transdisciplinarity in translational and transformative activities. What unites such a diverse group of actors is the shared goal to gather knowledge about and promote the normative (re-)orientation of practice.

[1]The term *translational ethics* has also been used in two other ways to address the *ethics of language translation* and the *ethics of translational medical research*, which are not relevant to this article. For a brief overview of the ethics of translational research, see, for example, Mandal, J., Ponnambath, D. K., & Parija, S. C. (2017). Ethics of translational medical research. *Trop Parasitol*, *7*(2), 62–64; The ethics of language translation is discussed outside of health-related disciplines, for example, Greenall, A. K. (2019). The discursive (re-) construction of translational ethics. *Perspectives*, *27*(5), 648–663. Hence, we refer to "translational bioethics" to reduce the risk of confusion.

[2]Researchers who have been concerned with translational bioethics and who shaped our understanding of the term include, for example, Kagarise, M. J., & Sheldon, G. F. (2000). Translational ethics: A perspective for the new millennium. *The Archives of Surgery*, *135*(1), 39–45; Cribb, A. (2010). Translational ethics? The theory-practice gap in medical ethics. *Journal Medical of Ethics*, *36*, 207–210; 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*(71), 1–7; 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*, *11*(1), 1–13; Little, M., Edenberg, E., Luken, S., & Healey, J. (2020). Ethics lab. Harnessing design methodologies for translational ethics. In E. Brister, & R. Frodeman (Eds.), *A guide to field philosophy: Case studies and practical strategies* (pp. 63–77). Routledge; Wexler, A., & Sullivan, L. S. (2021). Translational neuroethics: A vision for a more integrated, inclusive, and impactful field. *AJOB Neuroscience*. https://doi.org/10.1080/21507740.2021.2001078.

[3]Bærøe, op. cit. note 2. It is debatable how far the analogy between translational research in biomedicine and translational ethics actually holds; see Kremling A., Schildmann J., & Mertz M. (2022). From book to bedside? A critical perspective on the debate about "translational bioethics". *Bioethics*, under review.

[4]O'Neill, O. (2009). Applied ethics: Naturalism, normativity and public policy. *Journal of Applied Philosophy*, *26*(3), 219–230, p. 219.

[5]Cribb, op. cit. note 2, p. 208; Bærøe, op. cit. note 2, p. 2; Schröder-Bäck, P., et. al., op. cit. note 2, p. 3.

[6]Bærøe, op. cit. note 2, p. 3.

[7]We will only use the term to refer to ethically justified normative requirements and do not mean other forms of normative requirements (e.g., laws).

[8]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. *American Journal of Bioethics*, *20*(4), 62–70.

[9]Kuehlmeyer, 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.

[10]Bærøe, op. cit. note 2; Sisk, B. A., et al., op. cit. note 8.

[11]We developed a first version of the framework by reading and discussing original research articles on the background of our heterogeneous research experiences in a paper club (K. K., B. J., G. M., and Niels Nijsingh). We chose exemplary articles that were concerned with either the theory or practice of medical decision-making (MDM). Only articles that referred to (the realization of) normative requirements were included. Some of these publications now serve as examples for the illustration of steps and phases of our framework, while others have been left out or newly brought in during the further refinement of the framework and the writing of the article with M. M.

[12]The implementation of one bioethicist in a committee or board that has been entrusted with the ethical deliberation and decision-making in a practice area, like, for example, an institutional research ethics board, can be an example of transference of knowledge but can have no impact on the (culture of the) review practice of other group members.

In the following, we elaborate the framework with exemplary scholarly work on realizing the ethical principle of respect for autonomy in MDM with competent adult patients.[13] There has been extensive work in bioethics on specifying respect for autonomy with regard to the doctrine of informed consent.[14] Despite these efforts, there are still ought–is gaps between the normative requirement of informed consent in MDM and current medical practice in various contexts.[15] For example, empirical studies show that a considerable number of patients do not sufficiently understand the disclosed information about different treatment options,[16] that the uncertainty of a prognosis is poorly communicated,[17] and that patients' wishes are not sufficiently taken into account.[18] With reference to the doctrine of informed consent, some authors propose shared decision-making (SDM) as a paradigm for MDM and investigate ought–is gaps between this model and current (mal-)practice, while others question its relationship with the principle of respect for autonomy.[19]

We propose the framework for transformative medical ethics as (1) a tool for the analysis of ought–is gaps with regard to *ethical* normative requirements and (2) as a process to promote the realization of these normative requirements in medical practice. We will conclude our proposal with considerations about the usability and transferability of our framework and suggestions for future research.

2 | FRAMEWORK FOR TRANSFORMATIVE MEDICAL ETHICS

Transformative medical ethics describes a complex process with the aim of increasing the probability that normative requirements are realized in practice. We use "normative requirement" as a broader term that can include norms, virtues, values, normative concepts (e.g., "autonomy"), and morally relevant conceptual distinctions (e.g., between "killing" and "letting die").

The framework is based on two normative assumptions. We assume that (1) if there is an ought–is gap between a normative requirement and a certain practice and (2) if the normative requirement is sufficiently ethically justified, implementable and—at least in principle—acceptable by practitioners, transformative action is required.[20] Consequently, rational and morally serious actors in the health care system should aim at changing the current practice according to that requirement. Subsequently, if there are barriers to the implementation of an ethically justified normative requirement, relevant actors in policy and practice should find ways to overcome these barriers. This change can either be self-directed or externally managed through a systematic approach of additional measures.[21]

There are multiple ways to act morally in accordance to a justified ethical requirement. Even though there may be legitimate variability, paradigmatic models for good practice can give actors direction in realizing normative requirements. In terms of such models, one should distinguish conceptual *action models* from implementable *practice models*. Action models are concepts of actions. They integrate aims, content, and means for a certain type of action in a meaningful way. Yet, they are not directly implementable. Practice models, on the other hand, build on action models, but are more contextualized, concrete, and closer to the real world. They can play an important role for the communication of ethical insights to health practitioners. Furthermore, practice models can be used for educational purposes and are important for the design and evaluation of complex interventions. They can provide orientation for actors in balancing and consequently prioritizing certain values over others, and still, actors have some leeway to deviate from paradigmatic practices in certain cases where it is justified. We can increase the probability of *ethical actions*,[22] if *ethically informed practice models* are implemented. The implementation of practice models in certain practice fields requires not only a change of actions, for example, by appropriate training, but also a change of contextual (e.g., organizational) conditions (e.g., by providing organizational resources for certain practices).[23]

The outlined framework is supposed to guide the process of *translating* normative–ethical research into practice to promote practice *transformation*. It entails prescriptions of strategic activities (e.g., aims and tasks in the different phases of the process). Realizing this process entails

[13]Authors of these examples do not relate their work to translational bioethics. The examples might only illustrate the results of translational steps, not the translation itself. Furthermore, we did not choose the examples to position ourselves normatively nor could we ensure coherence between the examples.

[14]For example, see Beauchamp, T. L., & Childress, J. F. (2019). *Principles of biomedical ethics* (8th ed.). Oxford University Press. for one of the most influential elaborations.

[15]With the term "context," we either refer to areas of medical practice (e.g., medical disciplines, interdisciplinary practice fields), practice settings (e.g., hospitals, hospital units), or regional areas (e.g., districts, countries).

[16]Rothberg, M. B., Sivalingam, S. K., Ashraf, J., Visintainer, P., Joelson, J., Kleppel, R., Vallurupalli, N., & Schweiger, M. J. (2010). Patients' and cardiologists' perceptions of the benefits of percutaneous coronary intervention for stable coronary disease. *Annals of Internal Medicine, 153*(5), 307–313; Lin, Y. K., Liu, K. T., Chen, C. W., Lee, W. C., Lin, C. J., Shi, L., & Tien, Y. C. (2019). How to effectively obtain informed consent in trauma patients: A systematic review. *BMC Medical Ethics*, *20*(1).

[17]See, for example, Krawczyk, M., & Gallagher, R. (2016). Communicating prognostic uncertainty in potential end-of-life contexts: Experiences of family members. *BMC Palliative Care, 15*(59), 2–8; Cox, C. L., Miller, B. M., Kuhn, I., & Fritz, Z. (2021). Diagnostic uncertainty in primary care: What is known about its communication, and what are the associated ethical issues? *Family Practice, 38*(5), 654–668.

[18]A lack of informed consent is a prevalent reason for legal malpractice suits; see, for example, Shlobin, N. A., Sheldon, M., & Lam, S. (2020). Informed consent in neurosurgery: A systematic review. *Neurosurgical Focus*, *49*(5), E6.

[19]Ubel, P. A., Scherr, K. A., & Fagerlin, A. (2017). Empowerment failure: How shortcomings in physician communication unwittingly undermine patient autonomy. *The American Journal of Bioethics, 17*(11), 31–39; Childress J. F. (2017). Needed: A more rigorous analysis of models of decision making and a richer account of respect for autonomy. *The American Journal of Bioethics*, *17*(11), 52–54; Ubel, P. A., Scherr, K. A., & Fagerlin, A. (2018). Autonomy: What's shared decision making have to do with it? *The American Journal of Bioethics*, *18*(2), W11–W12.

[20]The claim that normative requirements must be justified, implementable, and acceptable leads to the exclusion of *controversial* requirements. In return, the framework is most significant for issues where normative–ethical debates are (currently) largely settled. This functions as a safeguard that a practice is not (yet) transformed on the basis of partial, problematic, or controversial normative requirements.

[21]This distinction is further explained by Nijsingh, N., Jansky, B., Marckmann, G. & Kuehlmeyer, K. (2020). Mind the gap: How should we translate specific ethical norms into interventions? *The American Journal of Bioethics, 20*(4), 89–90; p. 90.

[22]With the term ethical actions, we refer to actions in accordance to the relevant normative–ethical requirements.

[23]See De Silva, M. J., Breuer, E., Lee, L., Asher, L., Chowdhary, N., Lund, C., & Patel, V. (2014). Theory of change: A theory-driven approach to enhance the Medical Research Council's framework for complex interventions. *Trials*, *15*, 267. for an approach to outline the mechanisms of change when implementing a complex intervention.

highly inter- or transdisciplinary collaborative activities instead of a division of labor between the involved disciplines. The idea is not to hand over a task or a responsibility to the next discipline but to act in an interdisciplinary community with shared responsibility.

The initial decision to start a transformative medical ethics process can in principle be made by any researcher. For the realization of the whole framework, an inter- or transdisciplinary group of researchers and stakeholders have to commit themselves to a set of strategic activities. They collaboratively decide which action or practice models they deem appropriate to implement, based on their joint moral deliberation and judgment. Throughout this process, the members of the research program stay the same while the lead of a sub-project usually will shift between persons with different expertise. For example, the specification of the normative requirements may be led by a philosopher and the evaluation of a complex intervention may be led by a social scientist. Various interconnected and interdependent studies function as vehicles to facilitate, monitor, and reflect the change process with its intended and non-intended outcomes. The framework of transformative medical ethics can also be used as a heuristic instrument to further investigate a presumed ought–is gap, for example, to identify reasons for its persistence, to reconsider proposed actions, or to analyze the design of interventions that could promote value translation and cultural change.

The systematic process includes six different *phases* that include various research activities on different levels of abstraction, from conceptual ideas to actual practice (and back). Along these phases, we propose 12 translational steps that are based on different research questions and methodologies.

The six phases are:

Phase A: Concretiziation of normative requirements
Phase B: Identification of conceptual action models
Phase C: Transfer of conceptual action models to practice models
Phase D: Contextualization of practice models
Phase E: Multiplication of practice models
Phase F: Endorsement of practice change

We distinguish phases of vertical translation (A–D) moving from more abstract to more concrete levels of action and horizontal translation moving on the same level of abstraction between different action contexts (E-F). The framework and its application to the example of MDM are shown in Table 1.

2.1 | Phase A: Concretization of a general normative requirement (steps 0–2)

The process of transformative medical ethics starts when a *general* normative requirement has been identified and sufficiently justified.[24] Therefore, the starting point (which we refer to as step 0 as it acts as the cornerstone of the translational process) is an elaboration of general normative concepts to determine what they mean, what they relate to, and how they are characterized. In the example of MDM, this activity requires developing a general account of personal autonomy. An example for a possible result is the account of autonomy as individual self-determination proposed by Roessler: "In principle, a person is autonomous if she reflects upon how she wishes to live, upon the person she wants to be, and then both lives and is allowed to live in that self-chosen way, such that she as an individual is able authentically to identify with her own goals and projects, as well as being actually able to pursue them; if, generally speaking, she lives in conditions that make it possible for her to learn and to accustom herself to being autonomous, and to develop the structures of desire and need proper to an autonomous individuality."[25]

In the first step of vertical translation, the research task is to further elaborate the general normative concept. It entails making the concept more concrete and defining the resulting normative requirements for a certain area of practice. Beauchamp and Childress, for example, elaborate normative requirements of an autonomous decision based on a more general concept of personal autonomy.[26] They start with an account of an autonomous person as a "normal chooser" and propose a three-condition theory of autonomous choice (intentionality, understanding, and noncontrol). Based on this account, they define the more concrete normative requirements of respecting patient autonomy with considerations on how to ensure and promote autonomous choice.

In the second translational step, the domains of responsibility of concrete actors involved in a particular type of action are determined based on the normative requirements defined in the prior step. Beauchamp and Childress, for example, determine physicians' obligations to obtain informed consent of patients in MDM based on the predefined normative requirements.[27] They consider informed consent as a prerequisite for the legitimacy of a medical procedure that "occurs if and only if a patient (…) with substantial understanding and in absence of substantial control by others intentionally authorizes a professional to do something (…)."[28] This normative standard is justified based on the concept of respect for autonomy and further specified in terms of five conditions that must be fulfilled to account for informed consent: (1) competence, (2) disclosure, (3) understanding, (4) voluntariness, and (5) consent.[29]

At the end of phase one, the normative requirements are sufficiently concrete so that all involved actors can be made aware of their domain of professional responsibility and of what the normative requirements specifically entail. At this point, we do not know which

[24]This is due to the prerequisite that an ought–is gap has to be identified prior to the decision of whether transformative medical ethics is a suitable approach to translation. Identifying an ought–is gap involves the determination of a normative requirement as well as an empirical description of a practice that does not adhere to this normative requirement.

[25]Rössler, B. (2002). Problems with autonomy. *Hypatia*, *17*(4), 143–162, pp. 146–147.
[26]Beauchamp & Childress, op. cit. note 14, pp. 104–113.
[27]Ibid: 118–142.
[28]Ibid: 124.
[29]Ibid: 104–123. They further elaborate the nuances of these requirements with examples from empirical research in the rest of the chapter (pp. 123–142), which are also important for the understanding of the components of informed consent. Yet, in these sections, they sometimes take further translational steps that we only explain in the next phase of our framework.

TABLE 1 Framework for transformative medical ethics with the example of realizing respect for autonomy through practice models for MDM.

Phases	Steps	Research tasks	Example for a result
A	*Concretize normative requirements*		
	0	Elaborate a general normative concept	Autonomy as (a specific form of) self-determination (Roessler, 2002)
	1	Define normative requirement(s) for a certain area of practice based on the concept	Respect for autonomy in health care based on the concept of a normal chooser (Beauchamp & Childress, 2019, pp. 104–113)
	2	Determine the domain of responsibility of actors in concrete situations based on the requirement(s)	Doctors' responsibilities in ensuring patients' informed consent in medical treatment (Beauchamp & Childress, 2019, pp. 118–123)
B	*Identify conceptual action models*		
	3	Examine types of actions that do justice to the requirement (s) in the central domain of responsibility	Preferable model of informed consent built on trust: Negatively informed consent (Kihlbom, 2007)
	4	Identify paradigmatic normative action models with great potential to realize the normative requirement(s)	Preferable model for MDM: the deliberative model (Emanuel & Emanuel, 1992)
	5	Refine the paradigmatic normative action models	Preferable versions of the deliberative model of MDM (Sandman & Munthe, 2009)
C	*Transfer conceptual action models to practice models*		
	6	Define core elements of practice based on the refined normative action model	Specific professional actions required to realize shared deliberation (Stigglebout et al., 2015)
	7	Develop a transferable practice model with clearly defined roles and tasks based on the core elements of practice	Design of professional role (decision coach) and support interventions (decision aid) to promote SDM (Elwyn et al., 2010)
D	*Contextualize practice models*		
	8	Adapt and refine the practice model to the specific context of the practice setting, together with stakeholders involved	Development of a nurse-led ISDM DCIS program (Berger-Höger et al., 2017)
	9	Implement the adapted context-specific practice model and evaluate direct effects	Pilot test of the nurse-led ISDM DCIS program (Berger-Höger et al., 2017)
E	*Multiply practice models*		
	10	Adapt, refine, and implement the practice model in multiple contexts and evaluate direct effects	Randomized-controlled multicenter study of the nurse-led DCIS program for the evaluation of direct effects (Berger-Höger et al., 2019)
	11	Review direct and indirect effects of multiple implemented practice models	Review of cost savings of patient decision aids (Scalia et al., 2020)
F	*Advocate practice change*		
	12	Endorse and promote a practice change in comparison with status quo based on empirical evidence	Argumentation for SDM based on the evidence against claims about the negative sides of SDM (Coulter, 1997)

Note: The table shows the phases and steps of the transformative medical ethics framework. We start with step 0 as a starting point. It has the number 0 because it does not involve the vertical or horizontal *translation of knowledge or values*.

Abbreviations: DCIS, ductal carcinoma in situ; ISDM, informed shared decision-making; MDM, medical decision-making; SDM, shared decision-making.

types of actions are necessary to meet these requirements in the different domains of responsibility.

2.2 | Phase B: Identification of conceptual action models (steps 3–5)

To delineate the types of actions that are best suited to fulfill the normative requirements in a domain of responsibility, conceptual action models have to be identified and further developed.

In the first step of phase B (step 3), we propose to examine types of actions that have the potential to fulfill the normative requirements. Kilbohm, for example, addresses the question of whether informed consent can only be sufficiently realized if the patient is informed about the methods and means of a certain medical treatment, its risks, and associated potential difficulties.[30] He argues that patients could give valid informed consent without a full

[30]Kihlbom, U. (2008). Autonomy and negatively informed consent. *Journal of Medical Ethics*, *34*(3), pp. 146–149.

disclosure of such information: "To exercise your autonomy, you do not need to know how your ends are realized, given that you have good grounds to believe that they will be realized. You might, instead, have a number of well-founded negative beliefs, beliefs about what will not happen to you."[31] He calls this form of action *negatively informed* consent and deems it suitable in relationships between physicians and patients that are characterized by confidence and trust.

In step four, different paradigmatic action models for the physician–patient interaction are identified and comparatively assessed regarding their potential to realize the defined normative requirements. They have to build upon the prior analysis, but they are also enriched with general approaches to professional action. Emanuel and Emanuel, for example, illustrate that several conceptual action models can be reconstructed for the field of MDM.[32] The authors distinguish paternalistic, interpretive, deliberative, and informative models of MDM that elaborate "different visions of essential features of the physician-patient interaction."[33] These models are still rather abstract, but with more concrete guidance for MDM, and, importantly, with different normative implications (e.g., regarding a physician's moral obligations in the concrete patient–physician encounter) when further specified. While different models may be appropriate in different clinical situations, the authors identify the deliberative model as the conceptual action model that fits best to realize the norm of respect for autonomy under ideal circumstances for MDM. So, in this step, they narrow down the possibilities to one preferable, but still abstract conceptual action model.

In the next step (step 5), action models are further refined to give even more concrete guidance for specific actions. An example of such work is found in the different versions of SDM described by Sandman & Munthe.[34] They are concerned with the question of which version of SDM fits best to realize the norm of respect for patient autonomy, a model "without abandoning the patient or giving up the possibility of influencing how the patient is benefited."[35] As a result of their analysis, they identify two preferred versions of a deliberative SDM model, which can be distinguished by the distribution of roles in the final treatment decision: In the "shared rational deliberative patient choice" model, the patient decides herself about the treatment, while in the "shared rational deliberative joint decision" model, both parties consensually agree on the treatment decision. Both models are still rather abstract, but they narrow down the possibilities of interaction. Now, the question arises as to how these conceptual action models can be realized in relevant practice contexts.

[31]Ibid: 147.
[32]Emanuel, E. J., & Emanuel L. L. (1992). Four models of the physician-patient relationship. *JAMA*, *267*(16), 2221–2226.
[33]Ibid: 2221.
[34]Sandman, L., & Munthe, C. (2009). Shared decision-making and patient autonomy. *Theoretical Medicine and Bioethics*, *30*(4), 289–310. In fact, in their article, they take translational steps that we described prior to step 5.
[35]Ibid: 289.

2.3 | Phase C: Transfer of conceptual action models to practice models (steps 6–7)

This phase is concerned with the transfer of a conceptual action model into a practice model for a specific type of practice and/or specific groups of practitioners. The aim is to identify the means of transformation (e.g., the necessary courses of action, the required competencies of relevant actors, and the necessary modifications of the general conditions) in practice contexts to get closer to the ethical ideal under real-world conditions. More specifically, researchers need to develop approaches for complex interventions.[36] The result of this step are practice models (or if they have proven themselves "best practice models") that provide practical guidance for all actors involved, but are still adaptable to a particular care context.

A large proportion of the research on SDM corresponds with this and the following phases. For example, conceptual models have been proposed for SDM for preference-sensitive decisions with great prognostic uncertainty, for example, the choice between breast conservation surgery or mastectomy in (malformations that could lead to) early breast cancer. We will follow this example through phases C–E.

In line with, but without reference to the shared rational deliberative approach to decision-making by Sandman and Munthe (2009), Stigglebout et al. (2015) present an example of the first step in this phase (step 6) by defining core elements of the practice of SDM: "(1) The professional informs the patient that a decision is to be made and that the patient's opinion is important; (2) The professional explains the options and the pros and cons of each relevant option; (3) The professional and the patient discuss the patient's preferences and the professional supports the patient in deliberation; (4) The professional and patient discuss the patient's wish to make the decision; they make or defer the decision and discuss follow-up."[37]

The definition of such observable elements of practice is very important for the later evaluation of the practice. The determination of key elements of practice here can, for example, help to distinguish this proposed version of SDM from other models for MDM.

The next step (step 7) entails the identification of appropriate tools and measures by which these elements can be implemented. The goal is to develop an operational practice model, which can be transferred to specific practice contexts in the following phase. At this stage, other normative requirements may have to be integrated into such a practice model, to prevent value conflicts or to create common interests with other actors in the field. Such a practice model of SDM is envisaged by Elwyn and colleagues, who aim at implementing SDM on a large scale into the British National Health Service (NHS).[38] Their model for SDM is not only based on the norm of respect for autonomy but also incorporates other normative

[36]Complex interventions entail multiple components; see: Nijsingh, N., et al., op. cit. note 21, p.90 for another example of an *ethical* complex intervention.
[37]Stiggelbout, A. M., Pieterrse, A. H., & De Haes, J. C. J. M. (2015). Shared decision making: Concepts, evidence, and practice. *Patient Education Counseling*, *98*(10), 1172–1179, p. 1173.
[38]Elwyn, G., Laitner, S., Coulter, A., Walker, E., Watson, P., & Thomson, R. (2010). Implementing shared decision making in the NHS. *BMJ*, 314 (c5146), 1–6.

requirements related to health care, for example, that of evidence-based medicine: SDM "is an approach where clinicians and patients make decisions together using the best available evidence."[39] They describe "decision support interventions designed for patients (which) ensure that the ethical imperative of informed patient choice and consent is met (…)."[40]

Above all, they suggest the provision of evidence-based decision support (e.g., decision aids, written and appealingly visualized material to inform the decision-making process) and "decision coaching" for patients with professional "guidance on how to weigh up the pros and cons of different options."[41] Furthermore, they propose a change in organizational culture to support SDM, for example, by social marketing through public support of the implementation of a practice model by leaders for this type of practice.

2.4 | Phase D: Contextualization of practice models (steps 8–9)

The next step is to transform a general practice model into a context-specific practice model. In this phase, the model has to be adapted and refined to fit into a specific care context. More precisely, a specific care setting has to be altered by incorporating the new practice model and (possibly) actors start to perform actions for the first time. Implementation research can be helpful in identifying and addressing the barriers that have impeded the realization of a normative requirement so far. Stakeholders who are affected by the practice need to be involved in the process of shaping locally implemented practices. They should be considered equal partners whose routines, preferences, and intuitions are of great importance in order to successfully put a practice model to a practice test under real-world conditions. They should be invited to voice concerns early on, and to have those concerns discussed and appropriately addressed. Through this step in the process, the core elements of practice are further adapted to the specific features of a certain context of health care practice (e.g., historically shaped professional roles, resources, other and potentially conflicting normative requirements). It has to be clarified who exactly should do what and when, by which means, and to what ends. Furthermore, an appropriate evaluation of the means of implementation as well as their ends has to be designed. We assume that this entails a complex intervention, in which professionals are either additionally integrated into an existing care setting or trained to change their professional role to enable the required changes of actions.

The example that illustrates such type of work is concerned with SDM in a specific care setting for adult competent patients (oncology) for a specific care case (DCIS, ductal carcinoma in situ). Berger-Höger et al. have developed a complex intervention for oncology care that is designed for MDM when a patient is diagnosed with DCIS, a malformation that can develop into a malignant tumor.[42] Through their practice model of informed SDM (ISDM), combined with evidence-based patient information (EBPI), the researchers intended to increase patient participation in MDM in such cases.

The authors did not explicitly refer to the practice model by Elwyn et al., but the components of their ISDM model are very much in line with it.[43] They described the development of an evidence-based decision aid, they trained nurses to act as discussion coaches, and prepared physicians for the new division of labor and their part in the process (through a structured treatment discussion) by conducting a two-hour workshop. The reason for re-allocating tasks from physicians to nurses was to overcome a common barrier to the implementation of SDM: physicians had mentioned time restraints as a reason for not implementing SDM. Therefore, specialized nurses were trained as decision coaches. The decision aid was developed with stakeholder participation. Whether the coaching fulfilled the required elements of the practice was evaluated with the MAPPIN' SDM tool.[44] This inventory allows one to analyze whether the conversations are in accordance with Kasper et al.'s set of SDM indicators.[45]

2.5 | Phase E: Multiplication of practice models (steps 10–11)

If the context-specific practice model has proven to be feasible in the pilot testing, we should aim at multiplying the approach into other contexts. Hereby, the differentiation between core and adaptable elements of practice becomes essential. Even though it is important to adapt practice models when implementing them in different contexts, the core elements should remain the same to allow for comparability and to maintain normative consistency throughout the phases. The goal is to implement a practice model under the conditions of routine care by testing it in multiple contexts to establish a meta-methodology for achieving change in various care contexts. In this phase, we move from vertical to horizontal translation. When it comes to horizontal translation, the need for agreement with specified normative requirements among stakeholders in an organization is particularly important. Otherwise, it could happen that the practice model is rejected or that the core elements of practice are modified instead of the adaptable elements. Such modifications could lead to inconsistencies with the normative requirements that the practice model is built on as well as

[39]Ibid: 1.
[40]Ibid: 1.
[41]Ibid: 1.

[42]Berger-Höger, B., Liethmann, K., Mühlhauser, I., & Steckelberg, A. (2017). Implementation of shared decision-making in oncology: Development and pilot study of a nurse-led decision-coaching programme for women with ductal carcinoma in situ. *BMC Medical Informatics and Decision Making*, *17*(160), 1–14; Berger-Höger, B., Liethmann, K., Mühlhauser, I., Haastert, B., & Steckelberg, A. (2019). Nurse-led coaching of shared decision-making for women with ductal carcinoma in situ in breast care centers: A cluster randomized controlled trial. *International Journal of Nursing Studies*, *93*, 141–152.
[43]Elwyn, G., et al., op. cit. note 38.
[44]Kasper, J., Hoffmann, F., Heesen, C., Köpke, S., & Geiger, F. (2012). MAPPIN'SDM: The multifocal approach to sharing in shared decision making. *PLoS One*, *7*(4), 1–9.
[45]Ibid.

inconsistencies in the empirical research. In this phase, implementation research plays a crucial role in identifying key facilitators and barriers across different contexts. In categorically different care settings, the determination of the suitable model could entail to start a new process of elaborating differentiations on higher levels of abstraction.

For the first step in this phase (step 10), we can take up another example of Berger-Höger, in which the initial pilot project was expanded into a randomized-controlled multicenter study.[46] The researchers attempted to implement the practice model in eight breast care centers through roughly the same means as that described in the pilot study. After the recruitment of 36 patients, the project was stopped due to implementation difficulties, for example, related to the moral beliefs of the involved physicians.[47]

The last step requires an active research field with multiple activities to measure and describe not only the direct but also the indirect consequences of implemented practice models in concrete care contexts. The selection of adequate measures requires a self-reflective discourse, which is, for example, stipulated by the proposal of Elwyn et al.[48] To evaluate practice models across a wide variety of contexts, systematic reviews seem to be the preferable research method. Scalia et al., for example, have systematically reviewed the potential cost savings of decision aids.[49]

2.6 | Phase F: Endorsement of practice change (step 12)

The last phase is concerned with the endorsement of a certain practice change that effectively increases the probability that certain normative requirements are met. Policy-makers and key decision-makers should be committed to promote the large-scale implementation of a practice model (e.g., through public or institutional policies) to ensure that, for example, the necessary financial, structural, and personal preconditions for a wider implementation of the intended practice change are met. This phase is only justified if the results of prior research activities in phase D are sufficient to assume that the proposed practice model fulfills its aspirations and is preferable compared to the current status-quo. An example for the type of academic work we have in mind is presented by Coulter, who examines the evidence for claims against the promotion of SDM.[50] She examines assertions such as that "most patients do not want to participate in decisions; that revealing the uncertainties inherent in medical care could be harmful; that it is not feasible to provide information about the potential and benefits of all treatment options; and that increasing patient involvement in decision-making will lead to greater demand for unnecessary, costly or harmful procedures which could undermine the equitable allocation of health care resources" and discusses whether they can be confirmed by current evidence from socio-empirical research.[51] She concludes that evidence from the USA had suggested that patients wanted more involvement, and yet, more research was needed at that time.[52] It is important in this phase that researchers avoid motivated reasoning, the tendency to look selectively for arguments—and corresponding study results—that support their preferred conclusions and neglect counterarguments.

3 | DISCUSSION

3.1 | Added value of the framework

We propose a framework for transformative medical ethics that builds on, but goes beyond prior frameworks for translational bioethics.[53] This framework enables (1) a strategic approach to develop practice change that is ethically and empirically informed in all phases, (2) a clarification of areas of controversy when dealing with conflicting views, and (3) the development of a comprehensive normative requirement that spans across different levels of abstraction, which is an important prerequisite for effective implementation of ethically justified practice models and their evaluation under real-world conditions.

The framework is based on the assumption that translational bioethics should be concerned with strategic activities that support the implementation of ethically justified practices in various practice areas of bioethics. Through our framework for transformative medical ethics, we aim to narrow ought–is gaps: gaps between normative requirements and everyday practice. For example, the framework delineates different levels of considerations of how respect for patient autonomy can be implemented effectively in MDM through appropriate practice models. The differentiation of scholarly activities through our framework has the potential to reveal gaps between elaborated normative requirements and their incorporation in practice models and policies. In our example, this gap is tangible between research on conceptual action models for the realization of respect for autonomy (phase A–B) and research on practice models for the implementation of SDM (phase C–F). We noted some inconsistencies between these two clusters of research phases that could either relate to a problem of our framework or of the example by

[46]Berger-Höger, B., et al. (2019), op. cit. note 42.

[47]We speculate that in the case of Berger-Höger, B., et al. (2019), op. cit. note 42, translational failure can be explained by a lack of recognition of physicians' moral concerns based on their conceptualizations of beneficence. A stronger recognition of their concerns could have led to a different foundation of the practice model, including ethical requirements that are specified from the norm of beneficence and non-maleficence in the concretization of a DM model.

[48]Elwyn, G., Frosch, D. L., & Kobrin, S. (2016). Implementing shared decision-making: Consider all the consequences. *Implementation Science*, *11*(114), 1–10.

[49]Scalia, P., Barr, P. J., O'Neill, C., Crealey, G. E., Bagley, P. J., Blunt, H. B., & Elwyn, G. (2020). Does the use of patient decision aids lead to cost savings? A systematic review. *BMJ Open*, *10*(11).

[50]Coulter, A. (1997). Partnerships with patients: The pros and cons of shared clinical decision-making. *Journal of Health Services Research & Policy*, *2*(2), 112–121.

[51]Ibid: 112.

[52]Ibid: 118.

[53]Sisk, B. A., et al., op. cit. note 8, Bærøe, op. cit. note 2.

which we developed it.[54] For a successful transformation of clinical practice, it would be valuable to examine whether a better connection between the conceptual and practical phases has an added value.

Our framework explicitly serves the goal to change practice effectively according to normative requirements. If this turns out to be unfeasible in certain cases, our research approach can be used to systematically investigate barriers that make practice change impossible under the given circumstances (e.g., in a certain way, with certain resources, with certain actors, etc.). Such research results could be relevant for normative–ethical research.[55] Furthermore, it suggests a strategic step-by-step approach to developing practice change that is ethically informed in all phases, a structured pathway between theory and practice. It involves empirical research and especially research strategies developed for the promotion of evidence-based health care and implementation science, but goes beyond these approaches.[56] Here, our framework has great potential in promoting a more reliable translation on each of the different steps of the process. It can be used to identify and resolve controversies in the concretization of normative actions. For example, the question of whether a patient who delegates a decision to a physician can act autonomously is a rather abstract issue in one of the first phases; yet, the answer has consequences for what we consider as acting ethically—in accordance with the norm to respect patient autonomy.[57]

3.2 | Challenges and limitations of this framework

The transformative medical ethics framework prescribes an idealized process. We reconstructed the different phases and steps based on exemplary articles in research on MDM. To our knowledge, research programs that entail projects along all the different phases of the proposed complex, interdisciplinary transformative process have not been realized in the real world so far. By explicating our considerations, our framework at least can be compared with other frameworks, criticized, and revised. It is hard to determine who should coordinate such a complex process. At least some persons have to have an overview to ensure that the process remains coherent and that there is no "handing-over" of tasks without sufficient *knowledge and value translation*. We propose building a group of researchers with diverse disciplinary backgrounds and experiences, who shift the primary lead (and consequently the weight of the shared responsibility) in the different phases.

One of the challenges that we faced while developing this framework included the differentiation of the different phases and the designation of the translational steps. There are sometimes rather subtle differences between these steps. Some exemplarily mentioned articles about MDM span across multiple steps and do not necessarily take all of the steps that we suggest, nor do they take them in the order that we propose. It needs to be examined further whether the steps and phases of transformative ethics are too broad or too fine-grained in order to demarcate an effective chain of translational research activities. It can also be questioned whether the six phases that we propose *should* be taken in a particular order. Jumping between scholarly activities in different phases and leaving out some of the steps could also lead to valuable insights.

Since we focus on an overview of all necessary phases and steps of transformative medical ethics, there is a lack of guidance for each task. Further work should focus on single phases and provide more insights into effective strategies for their realization. Specific guidance for phases D and E, for example, should reflect experiences with (un)successful implementation strategies to promote a change of the moral actions of professional actors in certain practice contexts. Such guidance will help researchers to decide on the uptake, design, and optimization of specific implementation strategies, based on research on their appropriateness and effectiveness. Transformative medical ethics projects can, for example, demand an *attitude* to be willing to change current practices in view of ethical requirements. In general, it might become necessary to convince actors to prioritize their ethical values and norms over other (legal, economical, bureaucratic, etc.) claims. Furthermore, it might be necessary to change priorities among different ethical requirements. Such an aim cannot be achieved by an information intervention through instruction. It demands good ethical deliberation in discourses that encourage stakeholders to share their lived experiences and moral concerns.[58] If adequate, researchers should hence create occasions for ethical deliberation and if necessary, try to convince actors to adopt a different opinion based on compelling arguments. If not successful, this is an important insight into the possible acceptability or actual acceptance of ethical requirements.

Lastly, we have not tested, yet, as to how far our framework is transferable to other research areas and how far a transfer would result in similar or different steps. MDM may be conceived as a relatively simple problem compared to more wicked or more contested problems in bioethics. It remains to be tested in which cases the framework can (not) be used effectively. We assume that many research areas could benefit from an analysis with the

[54]One explanation for this friction could also be that SDM is in fact based on a different conceptual model of autonomy than informed consent, namely, relational autonomy, as suggested by Ubel, P. A., et al. (2018), op. cit. note 19. SDM could be grounded in the normative concept of relational autonomy rather than individual autonomy.

[55]An example for an obvious refutation of an argument based on the assumption of insurmountable implementation barriers without a practice test but based on an educated guess gives Ardagh, M. (2017). Triage, terrorism and translational ethics. *Journal of Medical Ethics*, *43*, 301–302.

[56]See, for example, Greenhalgh, T. (Ed.). *How to implement evidence-based healthcare*. Willey-Blackwell, for a comprehensive introduction to the implementation of evidence-based health care, the field of research for which implementation science was initially developed.

[57]Kihlbom, op. cit. note 30.

[58]Senghor, A. S., & Racine, E. (2022). How to evaluate the quality of an ethical deliberation? A pragmatist proposal for evaluation criteria and collaborative research. *Medicine, Health Care and Philosophy*, *25*(8), 309–326.

framework for transformative medical ethics. For example, we suggest its application to the ought–is gap between the normative requirement of respect for autonomy and the current practice of surrogate decision-making for patients who have lost decision-making capacity. This gap can be narrowed through practice models of advance care planning (ACP).[59] To point to a research area outside of health care, we suggest use of this framework to analyze the ought–is gap between the normative requirement of justice in the access to and handling of health measures and current practices in the usage of digital health technologies for health promotion. With our article, we hope to inspire researchers to apply our framework to other ought–is gaps to participate in a test of its applicability and robustness.

A more fundamental philosophical question is *when* it is epistemologically and above all ethically justified to initiate such a transformation process. For this purpose, it must be clarified as to what constitutes "sufficient justification" and "acceptability" of a normative requirement. Furthermore, it has to be determined why such an ethical justification can be relevant in the field of policy-making in case of insufficient approval by practitioners. These issues go far beyond what can be discussed in this paper. As a tentative short answer, we assume that a (wide) reflective equilibrium[60] that takes into account theoretical arguments as well as intuitions and current beliefs from practice could serve as a basis for such a justification. Although there may be plausible justifications for different, even mutually exclusive normative requirements, the state of academic debate can inform how well justified a specific normative requirement is considered to be. We would suggest to start transformative processes with those normative requirements that are well established in academic discourses and widely accepted—at least in principle—in society, sometimes even supported by the law.

4 | CONCLUSION

With our framework of transformative medical ethics, we propose a step-by-step methodological approach that aims at promoting practice change to increase the probability that ethically justified normative requirements are met in practice areas of biomedicine. With the outline of this framework, we hope to stimulate a methodological discourse as well as to promote research that aims at testing its different phases and steps. Further research is required, for example, to theoretically underpin this framework, to apply it to other ought–is gaps, and to evaluate its feasibility and effectiveness in various practice areas.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

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