

Clinical ethics support services (CESS) as complex intervention. Preliminary findings of a conceptual analysis and possible implications for outcomes research

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Evaluating outcome quality of clinical ethics support services

The assessment of the quality of ethics consultation and other forms of clinical ethics support services (CESS) is a topic of ongoing and in parts controversial discussions with participants from normative and empirical disciplines [1–9]. One focus of the debate is the evaluation of outcomes which, next to structural aspects and processes, is one of three domains of empirical evaluation research [3]. Advocates of outcomes evaluation have argued that such research is necessary for the transparency with regards to any intervention in healthcare and in particular important to generate viable information about the possible benefit harm of CESS [10]. On the other hand critical views have been aired with regards to the possibility of defining outcomes within the context of CESS evaluation which are empirically robust and normatively justifiable at the same time [2].

While there have been several evaluation studies on a range of types of CESS using different methods of evaluation and outcome criteria, there is to our knowledge no comprehensive review on the effectiveness of “ethical case interventions” which we understand as a structured process as part of which an individual ethicist or a team with ethics expertise analyzes ethical issues involved in a defined clinical case with the aim to support further clinical practice related to this case [11]. Against this background the authors in collaboration with the Cochrane Collaboration are currently conducting a systematic review on the effectiveness of ethical case interventions on patients in the last year of life. The review forms part of a larger project synthesizing available quantitative and qualitative evaluation data and is accompanied by methodological analyses on normative and empirical challenges relevant to the evaluation of CESS.¹

In this viewpoint article we present preliminary findings of the ongoing work with a focus on the possible contribution of conceptualizing ethical case interventions as “complex interventions” to outcomes research. We will briefly introduce the concept of a “complex intervention” and distinguish two types of “conceptual frameworks” designed to provide insight into complex interventions and their interactions. Subsequently we will apply the concept of complex interventions to ethical case intervention. In this context we provide a first sketch of how we may use conceptual frameworks to illustrate elements and processes of ethical case interventions. In the concluding part we provide two examples for implications for outcome research gained by our approach.

Ethical case interventions as complex intervention. Two conceptual frameworks

The Medical Research Council [12] characterizes a complex intervention as follows: “The greater the difficulty in defining precisely what exactly are the ‘active ingredients’ of an intervention and how they relate to each other, the greater the likelihood that you are dealing with a complex intervention.”

The complexity is defined via the following characteristics:

- Degree of flexibility or tailoring of the intervention permitted
- Number of groups or organizational levels targeted by the intervention
- Number and difficulty of behaviors required by those delivering or receiving the intervention
- Number of and interactions between components within the experimental and control interventions
- Number and variability of outcomes [13].

Looking at the debate about the evaluation of ethical case interventions it seems plausible to frame ethical case interventions as complex interventions. Interestingly, there is up to now little research which explores

1 For further information please check www.ruhr-uni-bochum.de/malakow/bmbf/bmbf.html (accessed 01/25/2016).

Figure 1: Process-orientated logic model of ethical case interventions

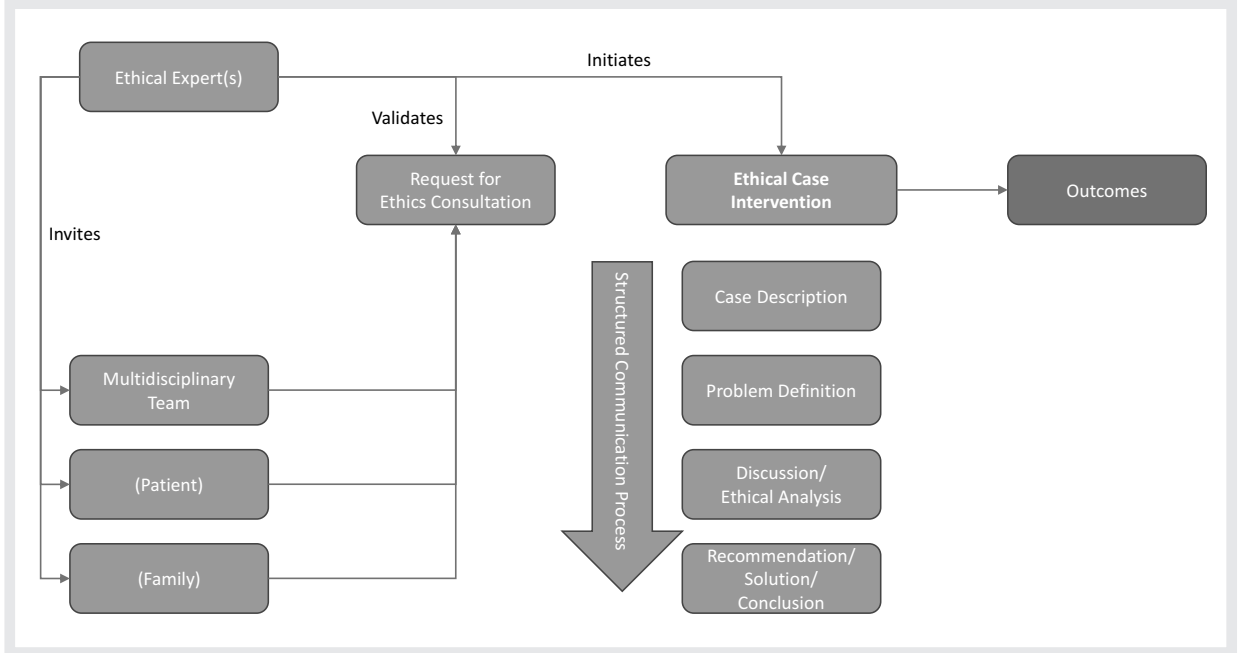
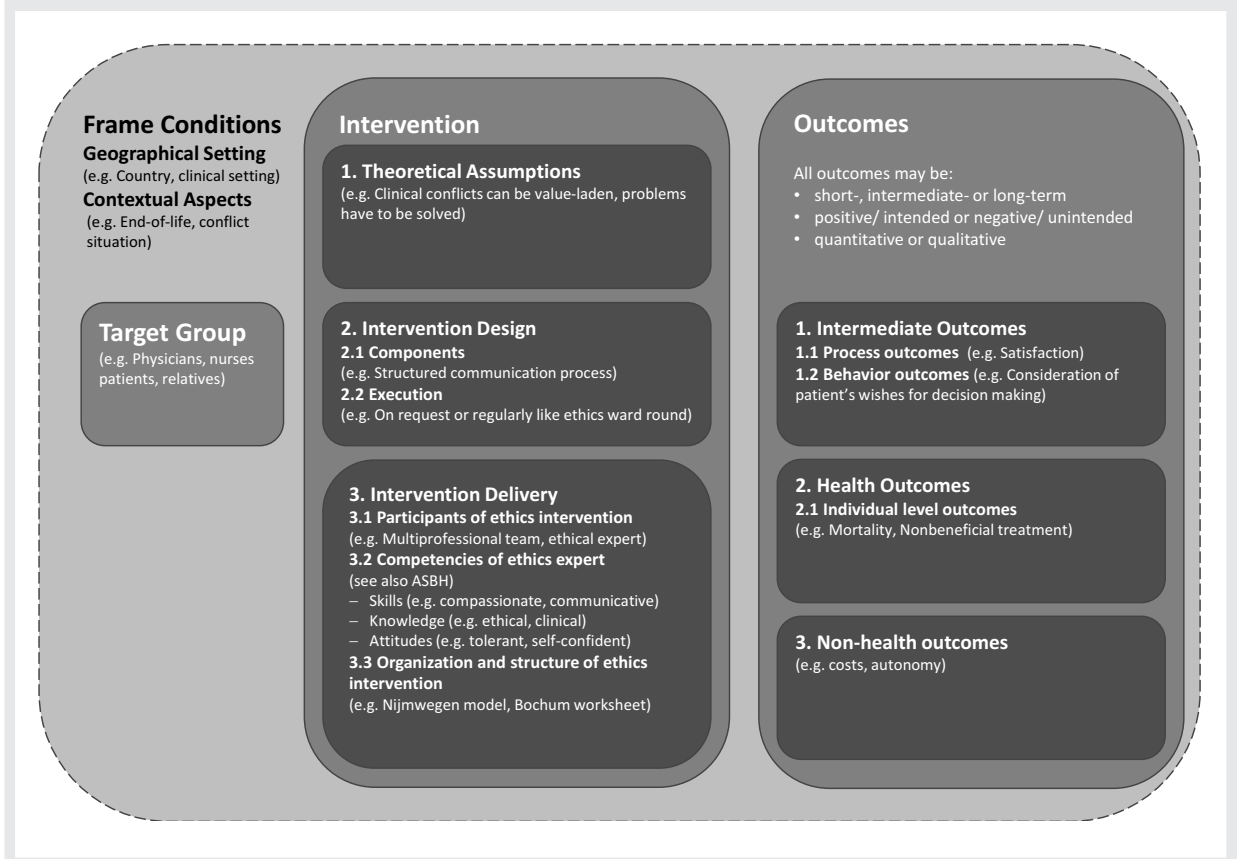


Figure 2: System-based framework (using a template by Rohwer and Rehfuess 2013) adapted for ethical case interventions



in more detail what ethical case interventions exactly do, what outcomes they specifically aim for and how they bring about change to clinical practice. Furthermore, we do have several models of ethical case interventions but the theoretical concepts underlying the intervention, its elements and procedures are rarely spelt out. However, as outlined for example in the Medical Research Council Framework for complex interventions it is exactly this kind of work which is necessary to be able to conduct evaluation research [13].

To understand the ethical case interventions and possible implications for outcomes in more detail we have searched for methods to identify elements, processes and interactions of ethical case interventions. As part of this search we have identified “conceptual frameworks” as one possible way to advance our knowledge in this respect. “Conceptual frameworks” or synonymously “logic models” can be described as graphic descriptions of a system. They are designed to identify important elements and relationships within that system [14]. In our research we identified two different kinds of conceptual framework templates as useful to describe ethical case interventions [15]: system-based and process-based frameworks. The latter focus on causal relationships and active components, while the former have a more comprehensive approach and give an overview of the different elements of the intervention and interactions with the environment.

Figure 1 summarizes the preliminary findings with regards to applying the process-orientated logic model to ethical case interventions. Here, the starting point is the request which depending on the realized model can come from different sides (e.g., healthcare professionals, patient, relatives). In case the request is deemed appropriate for an ethical case intervention by a single clinical ethicist or a group, a structured communication process is initiated with different participants. The ethical case intervention ends with a decision, recommendation or other type of results of this communication process.

Figure 2 summarizes first findings of applying the system-based logic model to ethical case interventions. Different from the first model there is no pre-defined starting point for the model. This model shows that the intervention is taking place within an environment and contextual factors possibly influencing the way the intervention is working. Furthermore, the model distinguishes different elements of the interventions such as theoretical assumptions, interventions design and mode of delivery. Finally, the model illustrates possible interactions between different elements for example with regards to theoretical assumptions underlying ethical case interventions and different domains of outcomes.

Ethical case interventions as complex interventions and possible implications for outcome research

Both conceptual frameworks applied to ethical case interventions are not meant as a fully developed model but rather as a first insight into ongoing work in which we have asked ourselves whether such work can be helpful for our thinking about outcomes evaluation of CESS. From our research experience we can confirm that looking at ethical case interventions from a perspective of complex interventions at least furthered our understanding of possibly relevant details regarding the intervention. In addition and while acknowledging that more research is necessary for a full account of both models, we believe that such an approach is also valuable to identify issues relevant to future outcomes research of ethical case interventions. We would like to illustrate this with two examples based on the above sketches of conceptual frameworks:

1. The system-based framework suggests that theoretical assumptions underlying the ethical case intervention are relevant for determining the outcomes. While it seems not necessary to develop a whole theory of ethics consultation or other forms of CESS it seems important to have a coherent account of theoretical assumptions underlying the intervention and the outcomes which shall be reached. To evaluate an ethics intervention for example which is designed primarily to support patient autonomy with tools on aggregated quality of life or satisfaction of healthcare professionals begs questions in this respect. Conceptual frameworks can help to identify such potential incoherence within outcome research of ethical case interventions.
2. The process-orientated logic model shows that there is much leeway for variation in the conduct of ethical case intervention. Even if the process elements are the same there may be rather large differences simply due to the personal characteristics of those involved in the process. In this sense the model increases our awareness for the issue of standardization of processes and possible limits within the context of evaluating ethical case interventions.

While a detailed analysis of the potential contribution of research on complex interventions for the topic of evaluating ethical case interventions is part of ongoing work we perceived such a perspective as helpful in getting a better understanding of the actual intervention. Moreover and given the multidisciplinary nature of the research team which is necessary to conduct outcome research of ethical case intervention [16] (or in our case to conduct a systematic review on this topic) this approach also provided a good means to foster shared understanding of the intervention necessary to conduct joint research.

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