

## The Dan Markingson Case: A case study analysed by the method of Moral Case Deliberation

### Introduction

Dan Markingson was a mentally ill research subject recruited into Dr. Stephen Olson's study in Psychiatry department at the University of Minnesota. Despite objections from Dan's mother, he was signed up for an antipsychotic drugs study ("CAFÉ trial") funded by AstraZeneca (Dan Markingson Blog 2013; Patient Safety Movement Foundation [n.d.]).

### Description

The aim of this virtual Moral Case Deliberation (MCD) is to examine whether Dan Markingson's suicide during a clinical trial was a consequence of research ethics violations and whether it could have been prevented by a better oversight mechanism (Stolper et al. 2016). The participants of the MCD are Dan's mother, Mary Weiss (the case presenter), an independent bioethicist, a representative from the REC that was overseeing the CAFÉ trial and a facilitator.

### Analysis

#### ➤ *Presentation of the case*

The presenter describes her conviction that her son died as a consequence of being enrolled on a clinical trial, the CAFÉ study, that was neither scientifically nor ethically appropriate. She claims that her son's suicide resulted from him not being withdrawn from the study despite her request. She feels that neither her son's nor her own autonomy was respected. She feels that the study leaders did not take her concerns seriously and that the trial and Dan's death involved negligence and professional inadequacy.

#### ➤ *Formulating the moral question and the dilemma*

Dr. Olson – Dan’s psychiatrist at the time of enrolment – informed Dan that participation in the CAFÉ trial was the only way he could avoid involuntary confinement at Anoka Metropolitan Regional Treatment Centre. Though Mary understands this, she believes that this alternative was not a true alternative and that Dan was not able to make important treatment and participation decisions on his own. She, therefore, asks, ‘Was Dan’s involvement and oversight in the study ethically appropriate?’

➤ *Clarification in order to place oneself in the situation of the case presenter*

Mary describes her situation as follows:

- She felt that her requests were not taken into consideration.
- She was in contact with Dan during the trial.
- She had concerns about her son’s well-being and psychic condition.
- Nobody responded to her concerns.
- Shortly before Dan’s enrolment on the trial, his condition was assessed by his physician, who deemed that he was not able to make decisions for himself.
- She would have preferred a process of substituted decision making.
- After Dan was invited to ‘consent’ to participate, his decision-making capacity ‘soon’ returned, thereby, excluding her from the decision-making process.
- She feels that Dan was used as a mere means in the trial and that his interests were not taken into consideration.

➤ *Analysing the case in terms of perspectives, values and norms*

Perspectives	Values	Norms
MARY	Respect for Persons / Informed Consent	Dan’s consent should not have been accepted because he seemed to lack appropriate decision-making capacity.
	Respect for Persons / Voluntary Informed Consent	He was not in a position to refute participation. Rather, he was pushed into a ‘dichotomy’ between being confined or ‘choosing’ to participate in the study

	Appropriate risk/benefit assessment	She, informed the trial investigators on multiple occasions about her deep concerns that Dan might harm himself and/or others.
BIOETHICIST	<p>Same Concerns as Mary plus Appropriate Oversight</p> <p>Vulnerability</p> <p>Appropriate risk/benefit assessment</p>	<p>It is questionable whether the pertinent COIs were adequately disclosed and handled.</p> <p>Dr. Olson served as Dan's physician and his enroller. Such a situation generate dependency, making participants such as Dan vulnerable to coercion.</p> <p>CAFÉ study coordinator, Ms. Kenney, a clinical social worker, carried out study-related tasks beyond her competency and made serious errors.</p>
REC member	<p>Compliance with research practices and regulations</p> <p>Aiming to comply with the study sponsors requirements</p>	<p>The REC member did not believe the situation (in which the study investigator was also the participant's therapist) to be unprecedented.</p> <p>They did not consider the enrolment of a vulnerable patients onto a clinical trial to be unprecedented. –</p> <p>Since 30 study participants needed to be found, they believed that any patients fulfilling the basic requirements should be enrolled, regardless of their legal capacity (i.e. stay of commitment)</p>

➤ *Looking for alternatives*

All the members agree that patients not under a stay of commitment might have been more fitting study participants. They agree that participation in the trial was not necessarily a better nor the only alternative to involuntary confinement. However, the REC member does not agree that Dr. Olson violated regulatory and legal standards.

➤ *Making an individual choice and making explicit one's considerations*

Mary and the bioethicist both claim that:

- a) It is not morally justifiable to invite Dan to join the study due to the lack of decision-making capacity and because he was under a stay of commitment;
- b) Mary tried to inform the study investigators on multiple occasions about the deterioration of Dan's condition.

The REC representative, contrarily, insists that:

- a) Dan's enrolment was morally justifiable because, at the time of enrolment, legislation did not ban the recruitment of patients under a stay of commitment. Furthermore, Dan's decision-making capacity had changed significantly by the time of enrolment. Finally, because of the nature of the study, Dan's participation did not carry a greater risk of harm than any other treatment regimen.

➤ *Dialogical inquiry*

Though both sides accept that the main question concerns the validity of Dan's consent to participate in the study, the REC representative insists that formally, and from a legislative perspective, Dan had consented and was able to consent. The REC representative does not seem willing to revise this understanding.

➤ *Conclusion*

No consensus could be reached during the course of the MCD. Mary and the bioethicist still believe that it was ethically inappropriate to enrol Dan onto the study.

➤ *Evaluation*

At the same time, the REC representative admits that simply being in compliance with the actual regulations might not be sufficient ethical grounds for assessing the problem in question. Thus, all parties welcome the new legislation restricting participation of patients under a stay of commitment.

## References

Dan Markingson Blog. (2013, July 8). *Investigate the Death of Dan Markingson*. Accessed 10 April 2019. <https://danmarkingson.wordpress.com/about/>

Patient Safety Movement Foundation. (n.d.). *Dan Markingson • Patient Safety Movement*. Patient Safety Movement. Accessed 10 April 2019. <https://patientsafetymovement.org/advocacy/patients-and-families/patient-stories/dan-markingson/>

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