

Signs, Symptoms, and Situations of Moral Distress During the Pursuit of Research Excellence

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Disclosure Statement

I am employed by Genentech, a member of the Roche Group

I own stock in Roche

What is Moral Distress?

*Moral distress occurs when researchers experience emotional suffering or anguish during product development when **scientific procedures appear to conflict with one's personal values or obligations****.

Recognizing Moral Distress: Signs and Symptoms



- Frustration, Withdrawal, Powerlessness, Anger, Sadness, Decreasing job satisfaction, and Burnout
- Can result in physical illness both real and psychosomatic (caused by or aggravated by a mental factor such as internal conflict or stress)

Background

Moral Distress in a Research Setting



- Programs to support researchers experiencing moral distress are **non-existent or limited** at most research organizations.
- Roche is a global healthcare research organization developing drug, device, and diagnostic products with programs in ethically complex areas.
- Roche launched a formal Moral Distress Consult Service in July 2023.

Method

- Data from the Ethics Consultation Service log (January 2023 - April 2024) reviewed for the tag “moral distress” as well as general topic area.
- Google Scholar and PubMed were reviewed (English language, any time) for articles about moral distress in the research setting using keywords, “moral distress”, “research”, “bioethics”.

Results

- 40 of 172 (23%) ethics consultations evidenced a moral distress component.
- Situations triggering moral distress include:
 - Drug access/equity (14, 35%)
 - Vulnerable populations and rare disease (9, 23%)
 - Study design (7, 18%)
 - Project termination (5, 13%)
 - Organizational ethics (4, 10%)
 - Reproductive health (1, 2.5%)
- Moral distress in the research setting has been rarely explored, with only 5 articles identified.



Recommended Safeguards to Protect Against Moral Distress

- Ethics consultation using **RESTORE method*** enabling discussion and processing of experience, hearing different moral perspectives, and providing an opportunity for closure on a troubling experience
- Advisory report provided to the researcher; service quality tracked through feedback reporting



*RESTORE method: 1) Individual **R**eflects on their experience 2) **E**valuation by Bioethics@Roche 3) **S**trategize to **r**eintegrate self

The Connection between Moral Distress and Research Excellence

- If researchers feel powerless amid their moral distress, this could allow an existing situation of research misconduct to go unreported.
- In settings of moral distress in a research team member(s), research participants could be exposed to harm, instead of protection. This is not research excellence.

Asking for waivers for eligibility for clinical trials for patients who are not appropriate for the trial

PI saying adverse events were not related, but they clearly were

From Showalter BL. 2020 PhD Dissertation: MORAL DISTRESS IN CLINICAL RESEARCH NURSES. <https://twu-ir.tdl.org/server/api/core/bitstreams/4ecdfaa8-3d78-4054-8271-9ff88bd5fed2/content>

The Connection between Moral Distress and Research Excellence

Fostering an **open research culture** where research integrity dilemmas can be discussed could mitigate research misconduct.

Discussing research dilemmas could promote transparency, decrease secrecy and a lack of trust among researchers, and promote research integrity.

- *Netherlands Code of Conduct for Research Integrity* (2018) includes a chapter on institutions' duties of care that states: "Institutions provide a working environment that promotes and safeguards good research practices. They ensure that researchers can work in a safe, inclusive and open environment where they feel responsible and accountable, can share concerns about dilemmas.

Interviewees also expressed that they felt that "**outsiders**" **bring a fresh perspective to the case**, whereas insiders may have prejudices toward certain people involved or insiders may find it hard to suppress prior knowledge about the case.

Ethics consultations could be considered a helpful tool for developing moral competencies to navigate research integrity dilemmas [analysis and solutions].

Conclusion

- The research integrity ecosystem must include [recognizing and addressing moral distress](#) in researchers.
- Preventing and responding to moral distress in researchers could be potential risk mitigation for research misconduct or sloppy science.
- [Moral Distress Consultation](#) can be a tool to respond to researchers experiencing moral distress.



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