Ethical Impacts of (Not) Sharing Nanosafety Data

RISK GONE

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Abstract

In RiskGONE, online tools have been developed to guide users through an ethical impact assessment (EIA), as part of a more encompassing modular risk governance framework. The EIA process is based on the CEN pre-standard on EIA (CEN CWA 17145-2:2017). In this poster, the possible added value of the EIA tools was analysed for addressing ethical impacts in decision making on whether or not, and how to share nanosafety data, based on limited open access information found on the internet, and incorporating responses to comments from ethics and data experts.

Keywords: nanosafety data, FAIR data, open access, ethics, health, liberties, equality, common good, environment, misuse

Methodology

The online tools developed in RiskGONE [1] guided users through the six-step Ethical Impact Assessment (EIA) procedure outlined below. The screening was guided by a checklist of nine categories of negative ethical impacts: health, privacy, liberties, equality, common good, environment, sustainability, military dual use, and misuse. The checklist allowed to determine the scope of the full-scale EIA, by selecting which ethical impacts were deemed relevant to decision making whether or not, and how to share nanosafety data. The severity of each issue was estimated on a five-point scale. In this case, a small EIA was deemed appropriate. Thereafter, a plan for performing this EIA was drafted, including the required resources and appropriate methodologies. Given the aim to use the case only as demonstration of the EIA tools, one ethicist identified and evaluated ethical issues using desk research and drafted recommendations for remedial actions. The draft EIA was reviewed by two external ethicists and an expert on data sharing.

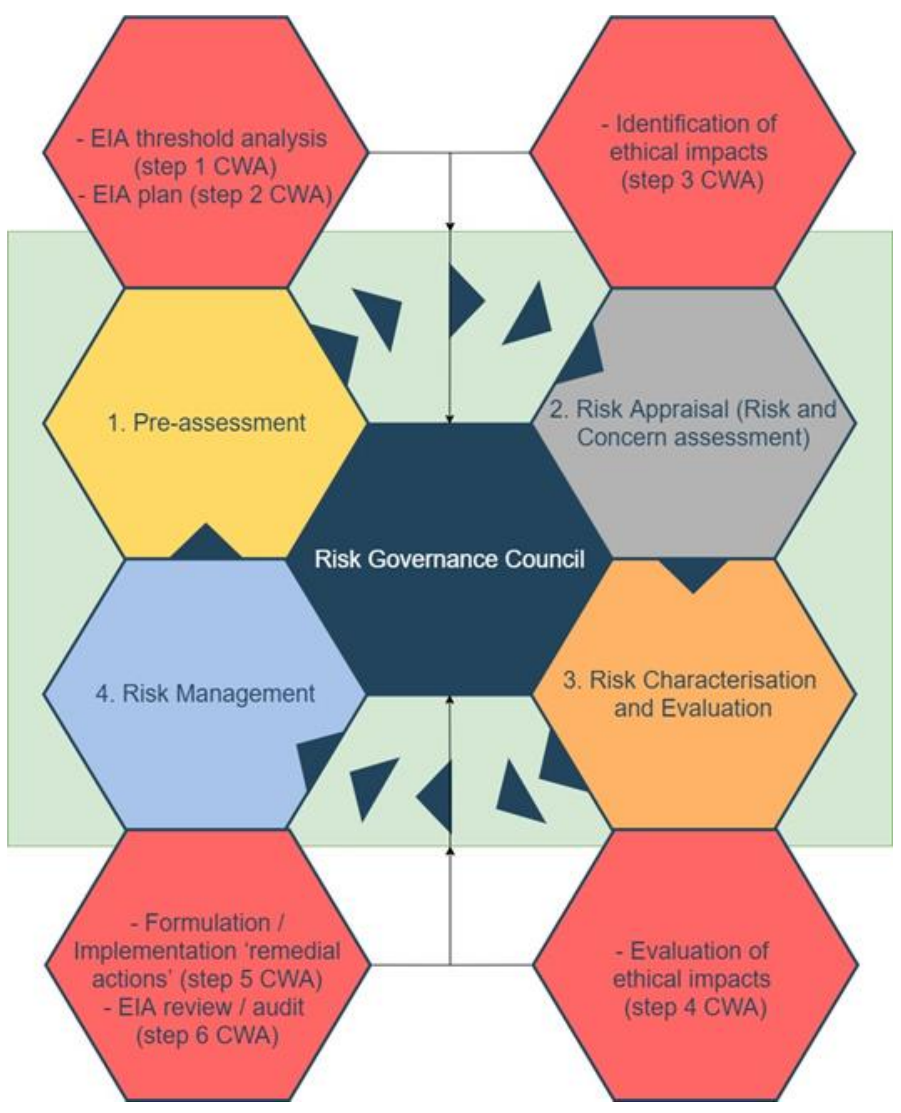

Figure 1: EIA procedure. Source: Malsch, I., Isigonis, P., Dusinska, M., Bouman E. A., Embedding Ethical Impact Assessment in Nanosafety Decision Support. Small 2020, 2002901, https://doi.org/10.1002/smll.202002901

The 6-step Ethical Impact Assessment procedure fits in the stages of the overall Risk Governance process:

1. **Threshold analysis** – self-assessment of foreseen ethical impacts by project leader to determine the need for and scope of the EIA
2. **EIA-planning** of resources, methodologies & stakeholder engagement
3. **Identify** ethical issues – desk research (optional stakeholder & expert engagement)
4. **Evaluate** ethical issues – desk research, engage stakeholder
5. **Remediate** ethical issues – draft recommendations, stakeholder consultation
6. **Review** the EIA – external ethicist

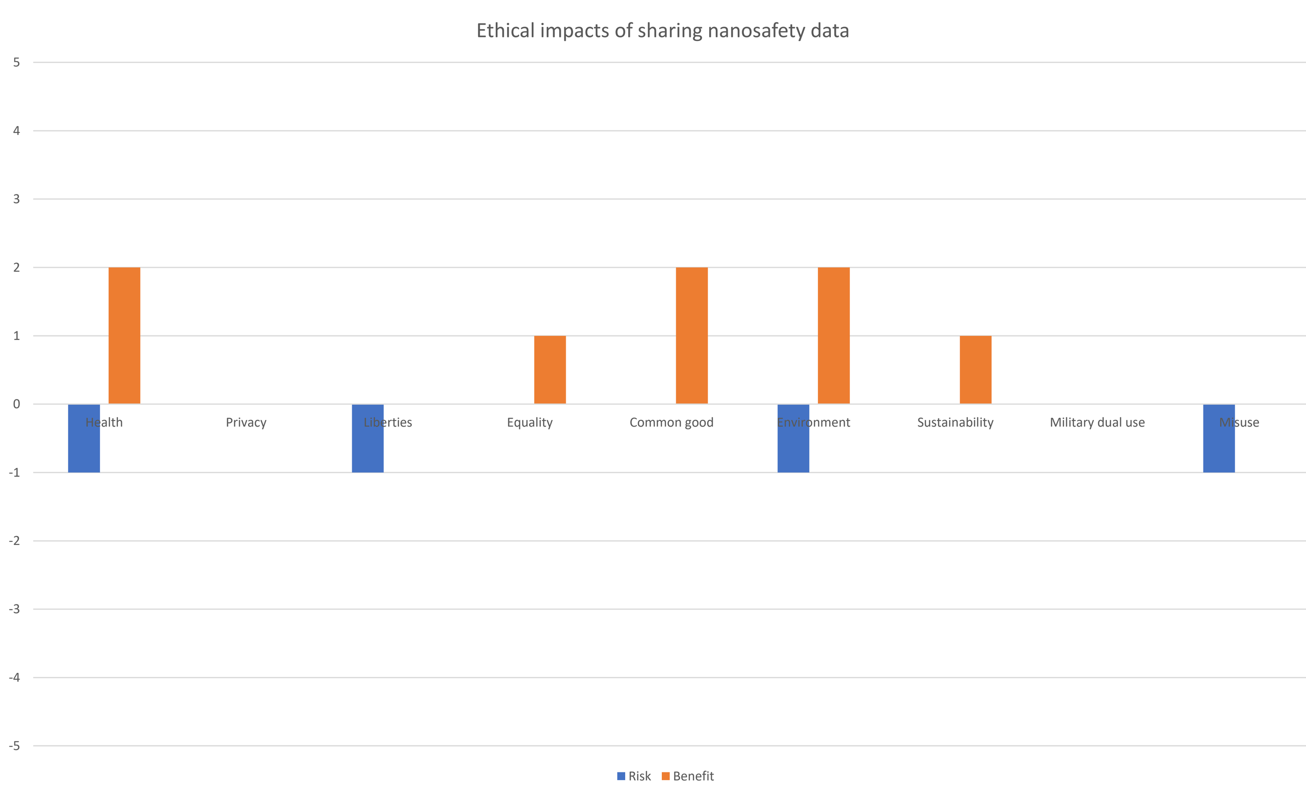

Figure 2: Self-assessment identified ethical risks of sharing nanosafety data for health, liberties, environment and misuse, and benefits for health, equality, the common good, environment and sustainability. The threshold analysis suggests a small Ethical Impact Assessment.

Identification and evaluation of ethical issues and values

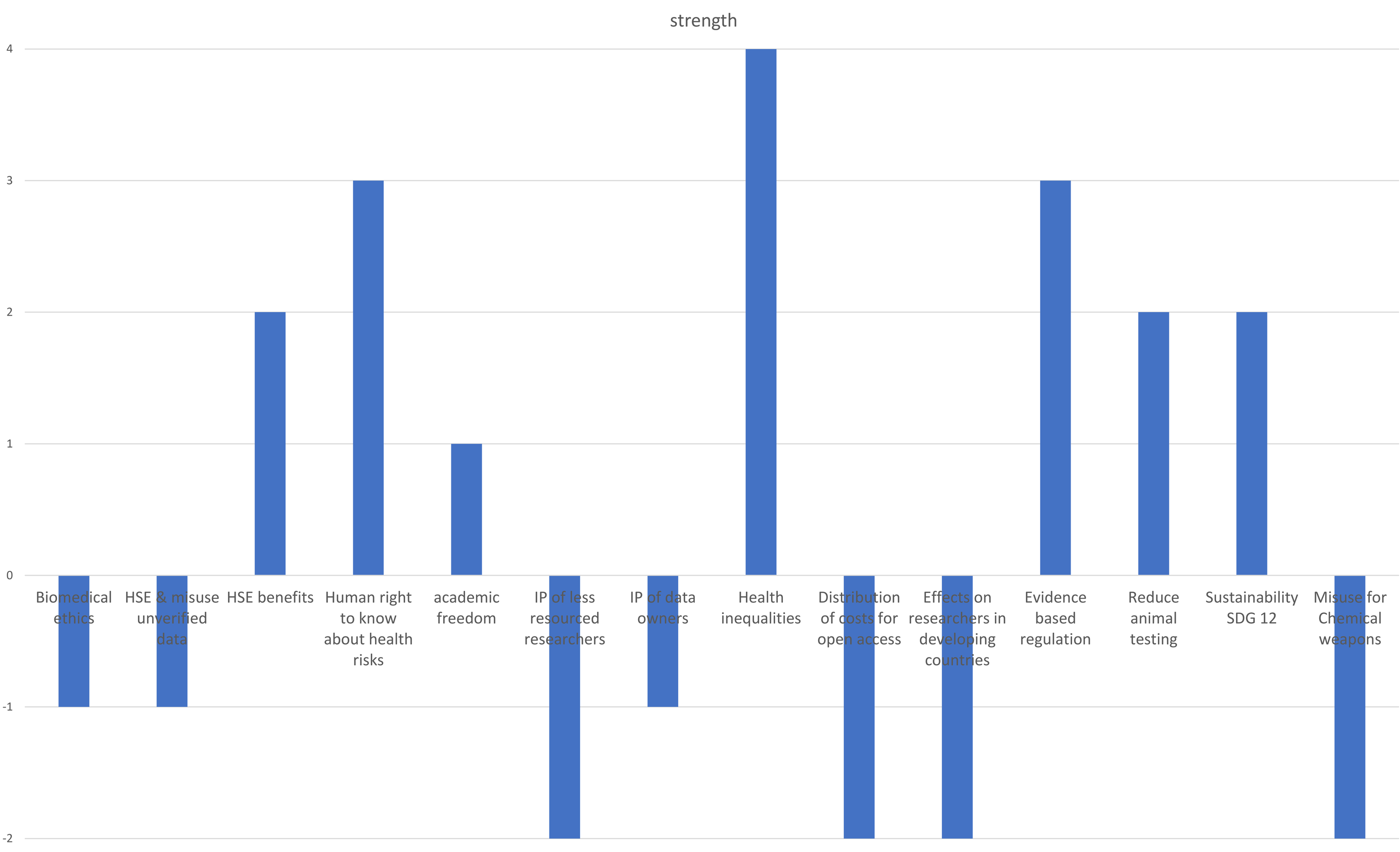

Figure 3: Further analysis of ethical issues identified in literature.

Analysing discussion of ethical impacts of comparable cases in literature with a more extensive checklist resulted in the identification of more detailed ethical issues, as presented in figure 3. The ethicist estimated the strength of each issue ranging from 1 (minor) to 4 (strong). While the expected benefits of sharing nanosafety data outweigh the foreseen risks, these estimates must be corroborated in stakeholder dialogue before being finalized. In addition, trade-offs between different ethical principles and values related to (not) sharing nanosafety data, presented in table 1, must be balanced and remediating measures taken to reduce negative ethical impacts of the decision to share nanosafety data.

Degree of violation	Identified principle/value	Degree of benefit
2	intellectual property	0
2	social justice	0
0	public health	4
2	dual use	0
0	environmental ethics	2
1	animal ethics	1

Table 1: Balancing expected ethical risks and benefits of sharing nanosafety data. 0 = no, 1 = minor; 2 = moderate; 3 =medium; 4= high; 5=severe or very high.

Draft recommendations open for discussion

Trade off public health - social justice: Bezuidenhout (2017) address **"binds of pace" in open data discourse,** including an expanded understanding of laboratory equipment and research speed to include all aspects of the research environment. This should be combined with **better engagement** with LMIC scientists regarding these challenges and the adoption of **frugal or responsible design principles in future open data initiatives**.

Balance responsibilities for open data and dual use: Bezuidenhout & Morrison (2016) focus more on **everyday practices** of laboratory scientists and less on abstract conceptions of data.

Management of research organisations producing nanosafety data: raise awareness of **research integrity** principles and train researchers in best practices (Kretser et al, 2019).

Managers & nanosafety researchers collaborating with researchers in developing countries and freelance researchers: implement **the Global code of conduct for research in resource poor settings** (2018).

Researchers using **animal testing**: comply with the **3Rs**: reduce the number of tests, refine the testing procedure, and replace animal testing with other methods (in vitro, in silico).

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