Investigating the Impacts of Generative AI in Pediatric Oncology: Identifying Ethico-Legal Best Practices and Addressing Patient Community Concerns

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Goal

To examine how generative AI is being integrated into pediatric oncology and to develop evidence-based ethico-legal guidance informed by both the scientific literature and the perspectives of persons with lived experience.

Objectives

- Map current and emerging uses of generative AI in pediatric oncology through a scoping review and identify associated ethical and legal issues, with particular attention to data governance.
- Compare international and national policy and normative frameworks to assess best practices, gaps, and regulatory approaches relevant to the safe and equitable integration of generative AI in health.
- Capture youth perspectives on trust, risks, and expectations regarding AI-enabled tools through two focus groups, using case-based discussions to ground their reflections.
- Reflect scientific findings and the perspectives of people with lived experiences (PWLE) in two outcomes that are tailored to patients, caregivers, clinicians, and researchers, and that support responsible implementation of generative AI in pediatric oncology.

Outcomes

Findings will be mobilized through::

- An information guide: an easy-to-understand educational resource, exploring how generative AI functions and its use to enhance patient care in pediatric oncology
- A guidance document: a comprehensive list of good practices that address both the ethical and legal issues & patient community concerns and recommendations
- A research manuscript: it draws on the scoping review of literature and our focus group discussions, and it is aimed at the broader pediatric oncology research community.
- A scientific presentation: it draws on the scoping review of literature and our focus group discussions, and it is aimed at the broader pediatric oncology research community.

Start date - End date

March 2025 - March 2027

Study methods

1.1. Scoping review

Objectives:

- Investigate how generative AI is currently being used and will be used for pediatric oncology research and clinical decision-making
- Identify the associated ethical and legal considerations

Methodology:

- → Searches were completed in Compendex, Scopus, Medline, and Web of Science
- → Exclusion criteria encompass non-generative models, non-pediatric or non-pediatric focused, and other than the oncology field.
- → Results will be reported using the PRISMA reporting guidelines[1]

1.2. Comparative normative analysis

Objectives:

- Determine how generative AI and its associated key challenges are addressed in laws and policies worldwide.

Methodology:

- → Comparative analysis of international and national policy documents, ethical frameworks, and legal guidance related to generative AI in health.
- → We assess the kind of regulatory approaches, requirements, recommendations, principles or other normative content the norms provide to address issues such as accountability, privacy, fairness and equity.

2. Focus groups with PWLE community

Objectives:

- Explore perceptions, concerns, and levels of trust regarding generative AI.

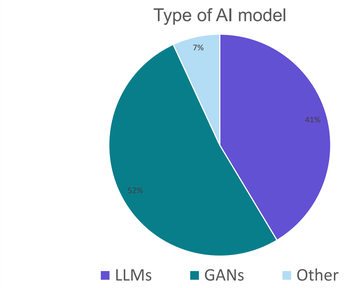
Methodology:

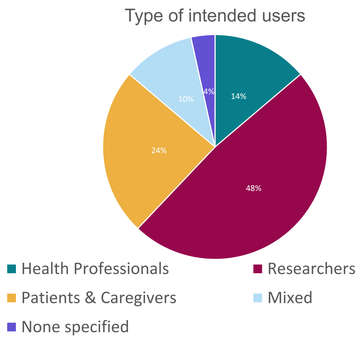
- → We will conduct 4 online focus groups[2] with 6-8 youth (14+) participants from the pediatric oncology community.
- → We will recruit them through the ACCESS PWLE network and broader pediatric oncology community. We will ensure representation of those directly affected by the integration of generative AI into pediatric oncology, and to capture both youth and caregiver perspectives on trust, concerns, and perceived benefits. Recruitment aims to reflect meaningful demographic diversity across age, province, race, ethnicity, gender identity, and socioeconomic background, in line with ACCESS's EDI guidelines.
- → Participants will take part in semi-structured discussions guided by short use cases illustrating typical uses of generative AI in pediatric oncology. They will be asked questions regarding their perceptions and expectations, levels of trust, comfort with AI and ethical and legal considerations.
- → Discussions will be coded and analyzed following thematic analysis in order to inform the co-created ethico-legal guidance document.
- → Expected to begin in Spring 2026.

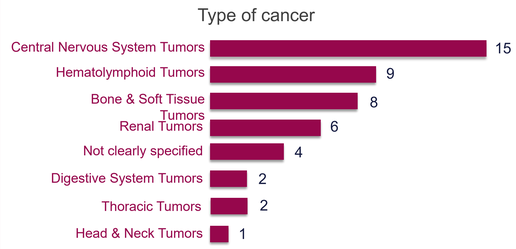
Results

1.1. Scoping review

We have identified 850 results. After first screening (title and abstract), and second assessment for eligibility (full text), we have selected 29 studies for the final data extraction and analysis.



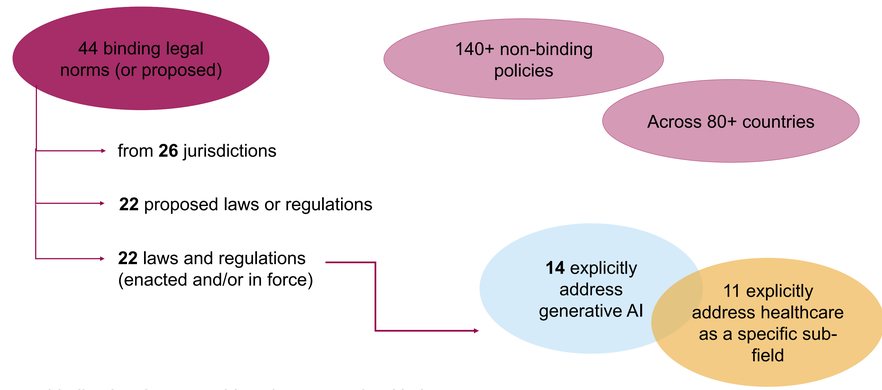




Most of the results mentioned ethical, legal or social issues (21/29). The most prominent one relates to data-related issues (e.g., data availability and scarcity due to disease rarity, discrepancies between real-world data and data from controlled or idealized settings).

1.2. Comparative analysis

The search scope included national and international legal instruments and policies that explicitly and specifically regulate AI on the one hand, and those that explicitly apply to AI-enabled health products or services on the other hand.



Among binding legal norms addressing generative AI, the most common addressed issues concern the identifiability, by users, of content that is artificially generated or modified by AI, particularly where such content can mislead them or involves non-consensual deepfakes[3].

These obligations are followed by requirements relating to transparency and traceability of training data used[4] (e.g., for purposes of transparency and compliance with copyright or other intellectual property rights).

Interested in knowing more about the project? Please contact:

REFERENCES

1. Tricco, A. C., et al. (2018). PRISMA extension for scoping reviews (PRISMA-ScR): Checklist and explanation. *Annals of Internal Medicine*, 169(7), 467-473 ; Arksey H. and L. O'malley. "Scoping studies: towards a methodological framework." International journal of social research methodology 8.1 (2005): 19-32 ; Levac, et al.. "Scoping studies: advancing the methodology." Implementation science 5.1 (2010): 69

2. Woodyatt, C. R., et al. (2016). In-person versus online focus group discussions: A comparative analysis of data quality. Qualitative Health Research, 26(6), 741-749; Heary, C. M., & Hennessy, E. (2002). The use of focus group interviews in pediatric health care research. Journal of Pediatric Psychology, 27(1), 47–57

3. E.g., Chile, China, South Korea, EU, USA incl. California, Maine, Texas & Pennsylvania.

4. E.g., Brazil, China, France, South Korea, USA incl. California.