

American Society of Clinical Oncology Position Statement: Inclusion of SDOH Data Collection and Intervention Evaluation in Pediatric NCTN Trials

Background

Approximately 15,000 children are diagnosed with cancer annually in the United States—a majority of whom will be treated on a pediatric cooperative group trial if one is available. This model of care delivery reflects the reality that conducting disease-specific, statistically powered interventional research outside of the national cooperative group setting is infeasible in pediatrics. As stated in ASCO's 2024 Policy Statement on Social Determinants of Health (SDOH) and Cancer Care,¹ interventions on social needs will require data collection as well as a research pipeline to develop, refine, and determine feasibility for interventions, before ultimately evaluating their efficacy. Because of a current lack of federally supported funding infrastructure for these purposes, integrating SDOH data collection and intervention research into existing research infrastructures will be critical. While it may be the case that a parallel, funded clinical trial infrastructure dedicated to SDOH interventions may be necessary or even optimal in the long-term, this would be feasible only for adult cancer populations. In pediatric cancer populations, the small numbers of patients will require that researchers leverage the existing pediatric National Clinical Trials Network (NCTN) Children's Oncology Group (COG) to accrue disease-specific studies.

Obstacles and Opportunities for SDOH Data Collection and Intervention

Addressing SDOH-associated disparities in pediatric cancer populations requires (1) SDOH data collection and intervention evaluation as an integrated component of the pediatric clinical trial infrastructure and (2) development of SDOH-targeted interventions designed to scale across over 100 centers. These pediatric-specific considerations will require alignment of funding and infrastructure unique from adult populations. At the same time, pediatrics may serve as a demonstration population in which to establish the feasibility of trial-embedded SDOH data collection and trial-embedded SDOH-intervention evaluation that could later be extended to adult oncology populations.

Unfortunately, efforts to integrate SDOH data collection or social needs-related interventions into treatment protocols through the COG are often unsuccessful. This is due to concerns at the National Cancer Institute (specifically, the Cancer Therapy Evaluation Program [CTEP] and Division of Cancer Prevention [DCP]), regarding alignment of such research with the scope and purview of NCTN and NCORP cooperative group funding, budgetary concerns, and concerns regarding infrastructure burden at individual sites to enable data collection. This is problematic because, in addition to the reasons already discussed, recent pediatric cooperative group studies indicate that

¹ Reggie Tucker-Seeley et al., Social Determinants of Health and Cancer Care: An ASCO Policy Statement. *JCO Oncol Pract* 20, 621-630(2024). DOI:10.1200/OP.23.00810

the collection of SDOH data in this context is both feasible and highly successful.^{2,3} In fact, the most recent research blueprint from the COG's Diversity and Health Disparities Committee came to a similar conclusion, recommending the routine collection of SDOH data on COG treatment trials in order to help increase access to trials, to improve trial diversity, and to reduce disparities in outcomes for diverse pediatric cancer populations.⁴

The evaluation of social needs interventions must also be prospectively integrated into COG treatment trial statistical design given the explicit goal of improving event-free and overall survival outcomes in these trials.⁵ Beyond the need to align funding and infrastructure for the relatively small pediatric cancer population, social needs interventions are also necessary to fund and carry out because of the long-term negative impacts of some SDOH on outcomes in adult survivors of pediatric cancers.⁶ The benefits of this investment would extend past the pediatric population, enabling the clinical research infrastructure for pediatric oncology to be leveraged for the benefit of adult survivors of cancer.

As this is an emerging area for research, specific subdomains for data collection or intervention related to SDOH may vary. Nevertheless, efforts should begin by focusing on the commonly accepted framework inclusive of: economic stability (e.g., parental employment), parental education, neighborhood and built environment (e.g., housing stability, transportation), type of health care coverage, and social/community context (including measures of community engagement).^{7,8} Maintaining such a focus will serve to explore how specific SDOH and unmet social needs may impact pediatric populations differently from adults with cancer.

ASCO Recommendations

There are efforts to harmonize data collection, including SDOH, within COG trials, and ASCO supports the rapid completion of these efforts. We are currently unaware of federal guidance to support the inclusion of social needs interventions into COG treatment protocols, but such integration is no less imperative. To that end, and given the research needs in this relatively small

² Aziz-Bose R, Zheng DJ, Umaretiya PJ, et al. Feasibility of oncology clinical trial-embedded evaluation of social determinants of health. *Pediatr Blood Cancer*. 2022;69(11):e29933. doi:10.1002/pbc.29933

³ Emily Jones et al., Feasibility and acceptability of social determinants of health data collection in the context of a Children's Oncology Group trial.. *JCO* 41, 10010-10010(2023). DOI:10.1200/JCO.2023.41.16_suppl.10010

⁴ Winestone LE, Beauchemin MP, Bona K, et al. Children's Oncology Group's 2023 blueprint for research: Diversity and health disparities. *Pediatr Blood Cancer*. 2023;70 Suppl 6(Suppl 6):e30592. doi:10.1002/pbc.30592

⁵ H Tran Y, Coven SL, Park S, Mendonca EA. Social determinants of health and pediatric cancer survival: A systematic review. *Pediatr Blood Cancer*. 2022;69(5):e29546. doi:10.1002/pbc.29546

⁶ Jinbing Bai et al., Social determinants of health and neurocognitive and psychosocial outcomes in adult childhood cancer survivors: A report from the childhood cancer survivor study (CCSS). *JCO* 41, 12084-12084(2023). DOI:10.1200/JCO.2023.41.16_suppl.12084

⁷ Asare M, Flannery M, Kamen C. Social Determinants of Health: A Framework for Studying Cancer Health Disparities and Minority Participation in Research. *Oncol Nurs Forum*. 2017 Jan 2;44(1):20-23. doi: 10.1188/17.ONF.20-23. PMID: 28060469; PMCID: PMC5583708.

⁸ Reggie Tucker-Seeley et al., Social Determinants of Health and Cancer Care: An ASCO Policy Statement. *JCO Oncol Pract* 20, 621-630(2024). DOI:10.1200/OP.23.00810

patient population, ASCO makes the following recommendations related to SDOH data collection and social needs interventions within NCTN, COG, and CTEP trials:

- Embedded SDOH data collection on pediatric clinical trials should be prioritized and funded both federally and privately; failure to support such data collection in treatment trials should require scientific rationale.
- The inclusion of optional, embedded social needs or health equity interventions in COG research protocols should be prioritized and funded because the development and evaluation of these interventions can improve cancer-specific and long-term survivorship outcomes.

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