From Data to Diversity: Examining Clinical Trial Participation Trends in Gastrointestinal Cancer Research

Trisha Lam, Katherine Guthrie, Sarah Colby, Fred Hutchinson Cancer Research Center
Division of Sciences & Mathematics, University of Washington | Tacoma, Tacoma, WA 98402

Background of GI Clinical Trials

- Clinical trials are essential for advancing cancer and treatment.
- However, overall participation rates in clinic trials remain low -> Only 2% to 8% of adults with cancer engage in clinical trials (Unger et al., 2019; Brundage et al., 2021).
- Enrolled participants often do not represent the diverse patient population -> Trial participants tend to be younger, healthier, and less diverse than clinic patients (Duma et al., 2018).
- Underrepresentation in medicine affects trial participant demographics -> Only 4% to 5% of participants in FDA-submitted drug trials were marginalized groups (Knepper et al., 2018).

Objective: Evaluate the Proportion of Women and Minority Patients on SWOG Therapeutic Trials for Gastrointestinal Cancer (2011–2021).

Importance of Diverse Trial Participation:

- Lack of diversity may result in inequity in treatment access.
- Compromises generalizability and representation of study outcomes.
- Risks missing significant treatment effects among underrepresented groups.

Methodology

Our dataset comprises **gastrointestinal therapeutic interventional trials conducted between 2011 and 2021,** sourced through collaboration with SWOG. We engaged in a rigorous data collection process, leveraging SWOG's standardized protocols for data quality assurance. **The dataset encompasses a diverse array of patient demographics and medical indicators, facilitating multifaceted analysis.** Our project commenced with thorough research and analysis, followed by **extensive R coding to enhance data clarity and facilitate informed analysis.** Collaborative efforts with colleagues guided the crafting of comprehensive tables and addressed challenges, such as **standardizing zip code data through manual entry.** Towards the project's conclusion, we introduced **spatial analysis** to visually represent zip code distribution and uncover geographical patterns within trial participation diversity.

Mapping

Figure 1. Geographical Distribution of Trial Participants
This map visualizes the distribution of participants in gastrointestinal therapeutic interventional trials conducted between 2011 and 2021. Data was acquired through collaboration with SWOG, ensuring high-quality and standardized information. Each point on the map represents a participant's zip code, with color gradients indicating the density of participants in each area.

Categorization of Frequencies

Cancer Type	Freq	%
Adenocarcinoma of the colon	128	8.6
Adenocarcinoma of the esophagus	72	4.8
Adenocarcinoma of the gastroesophageal junction	94	6.3
Adenocarcinoma of the pancreas	533	35.9
Adenocarcinoma of the rectum	24	1.6
Adenocarcinoma of the stomach	122	8.2
Cholangiocarcinoma, intrahepatic and extrahepatic bile ducts (adenocarcinoma)	414	27.9
Colorectal cancer, NOS	8	0.5
Gall bladder carcinoma (adenocarcinoma)	91	6.1

Insurance	Freq	%
Medicaid	80	5.4
Medicaid & Medicare	26	1.7
Medicare	246	16.6
Medicare & Private	288	19.4
Military or VA	19	1.3
No insurance	49	3.3
Private	665	44.8
Unknown	113	7.6

Figure 2. Categorization of Frequencies in Insurance Types of Cancer Classifications
This figure represents the categorization of frequencies for different insurance types and cancer classifications, derived from our gastrointestinal therapeutic interventional trials (2011-2021). The categorization was achieved through extensive R coding, specifically utilizing the "Case_when"function to recategorize and enhance data clarity.

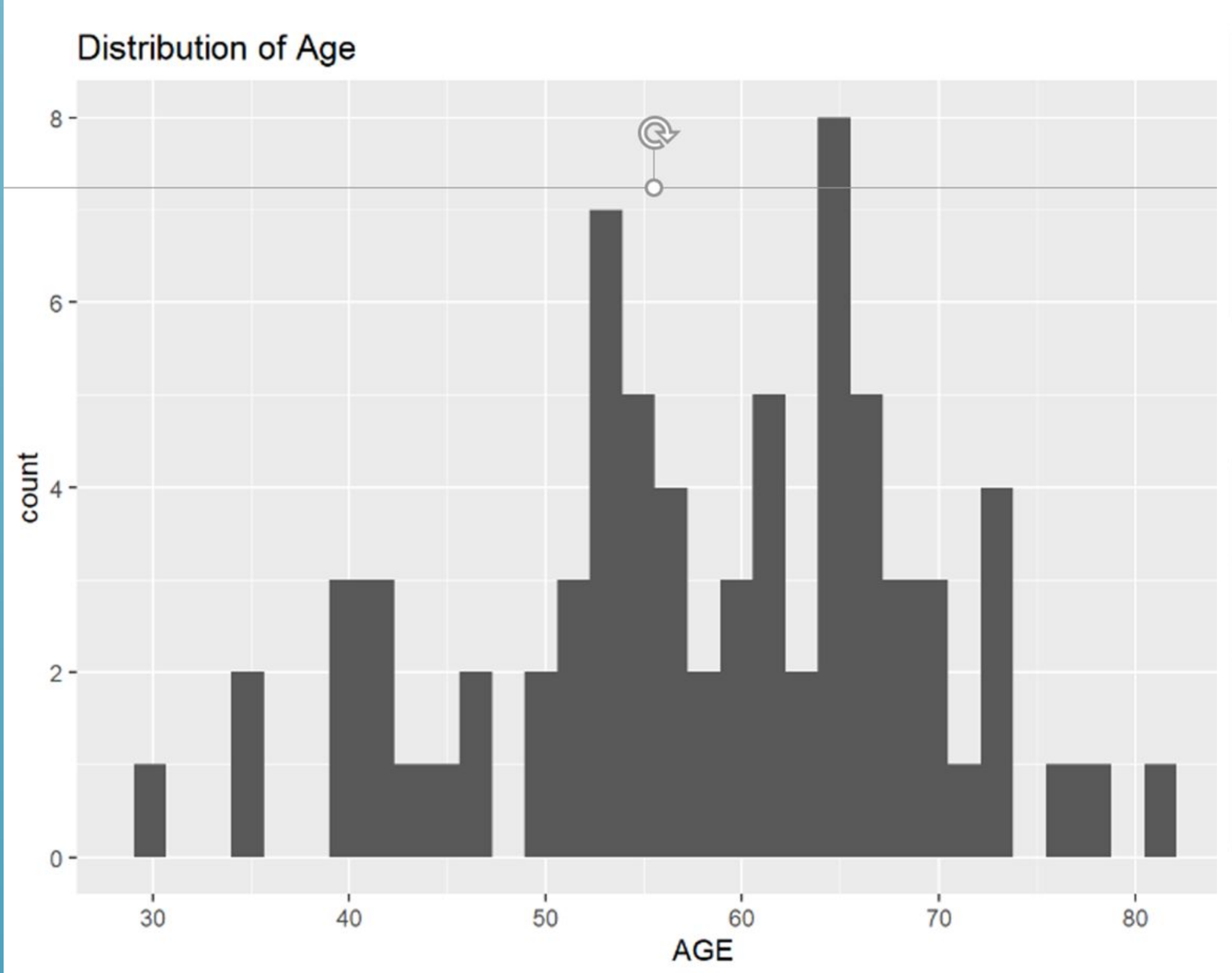
Categorization by Sex

Cancer Type	Female	Male
Adenocarcinoma of the colon	72	56
Adenocarcinoma of the esophagus	6	66
Adenocarcinoma of the gastroesophageal junction	17	77
Adenocarcinoma of the pancreas	258	275
Adenocarcinoma of the rectum	11	13
Adenocarcinoma of the stomach	43	79
Cholangiocarcinoma, intrahepatic and extrahepatic bile ducts (adenocarcinoma)	227	187
Colorectal cancer, NOS	5	3
Gall bladder carcinoma (adenocarcinoma)	57	34

Insurance	Female	Male
Medicaid	41	39
Medicaid & Medicare	19	7
Medicare	129	117
Medicare & Private	122	166
Military or VA	6	13
No insurance	17	32
Private	311	354
Unknown	51	62

Figure 3. Categorization of Frequencies in Insurance Types of Cancer Classifications
This figure presents the categorization of participants by sex, broken down across different cancer types and insurance types, from our gastrointestinal therapeutic interventional trials dataset (2011-2021). Comprehensive tables were created to facilitate this breakdown, supported by detailed R coding.

Variables by Study



Age

obs	Avg	SD	Min	Max	Median	Q1	Q3
75	58.88	11.74	30.3	86.7	59.3	52.6	66.6

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Sex

Sex	Freq	%
Female	23	30.7
Male	52	69.3

Hispanic

Hispanic	Freq	%
No	61	81.3
Unknown	1	1.3
Yes, NOS	13	17.3

Race

Race	Freq	%
Asian	8	10.7
Black	1	1.3
Unknown	3	4.0
White	63	84.0

Insurance

Insurance	Freq	%
Medicaid	4	5.3
Medicare	6	8.0
Medicare & Private	16	21.3
No insurance	7	9.3
Private	33	44.0
Unknown	9	12.0

Figure 4. Retrospective Analysis of Demographic Variables
This figure presents tables and a graph illustrating demographic variables across multiple studies within our gastrointestinal therapeutic interventional trials dataset (2011-2021). The data were grouped and summarized using R coding to provide a clear comparison across different studies.

On Going Studies

In conclusion, this project on GI cancer retrospective analysis showed the **need for greater diversity in clinical trial participation**, highlighting potential disparities that could **impact access to treatments.** By uncovering insights into patient demographics and participation patterns, we've laid the groundwork for informed decision-making and the creation of strategies that foster inclusivity in future trials. As we move forward, **potential next steps might involve more mapping to discover and research the population and diversity these clinics are located in to encourage wider representation.**

Recommendations

- **Engage Communities:** Partner with community organizations and healthcare providers to raise awareness and build trust.
- **Culturally Tailored Outreach**: Create materials and messages that resonate with diverse populations.
- **Patient Navigation Services:** Offer support for logistical barriers like transportation and childcare.
- **Patient-Centered Approaches:** Involve patients in decision-making and prioritize their needs.
- **Education Programs:** Provide training to increase awareness and address biases.
- **Advocate for Policy Initiatives:** Support policies that promote diversity in clinical trials.

References

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