



Clinical Trials in Rural Nebraska

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Conflicts of interest

- None relevant to the presentation

Objectives

- Cancer Care in Rural Area
- Importance of clinical trials for patients in rural area
- Clinical trials in Rural Nebraska
- Research at Great Plains Health
- Conclusion



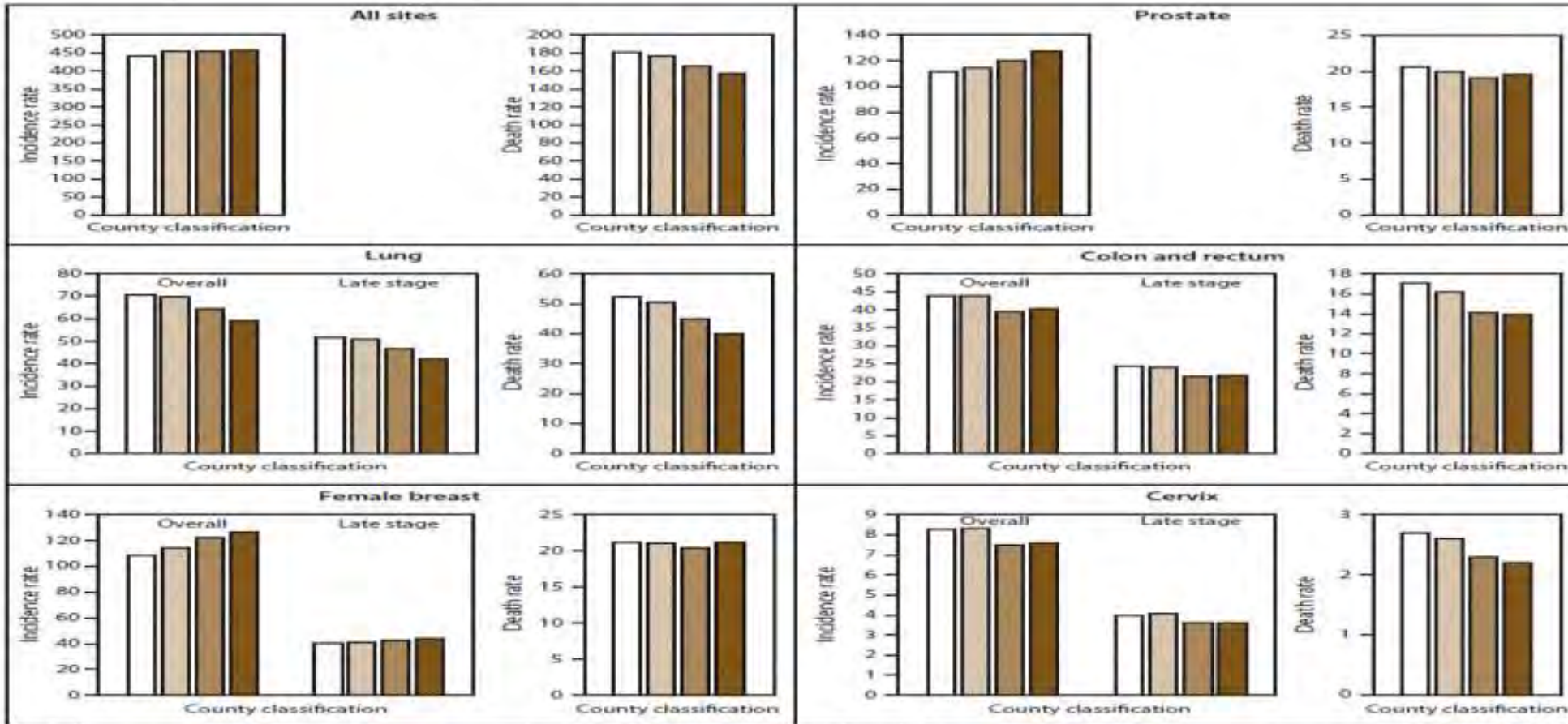


Cancer Care in Rural Area

- Depending on the definition of rural area, 15-19% of total US population lives in rural area.
- Rural Residence is a strong predictor of outcome during cancer care.
- Incidence rates of cancer higher in urban areas, but death rate higher in rural areas.



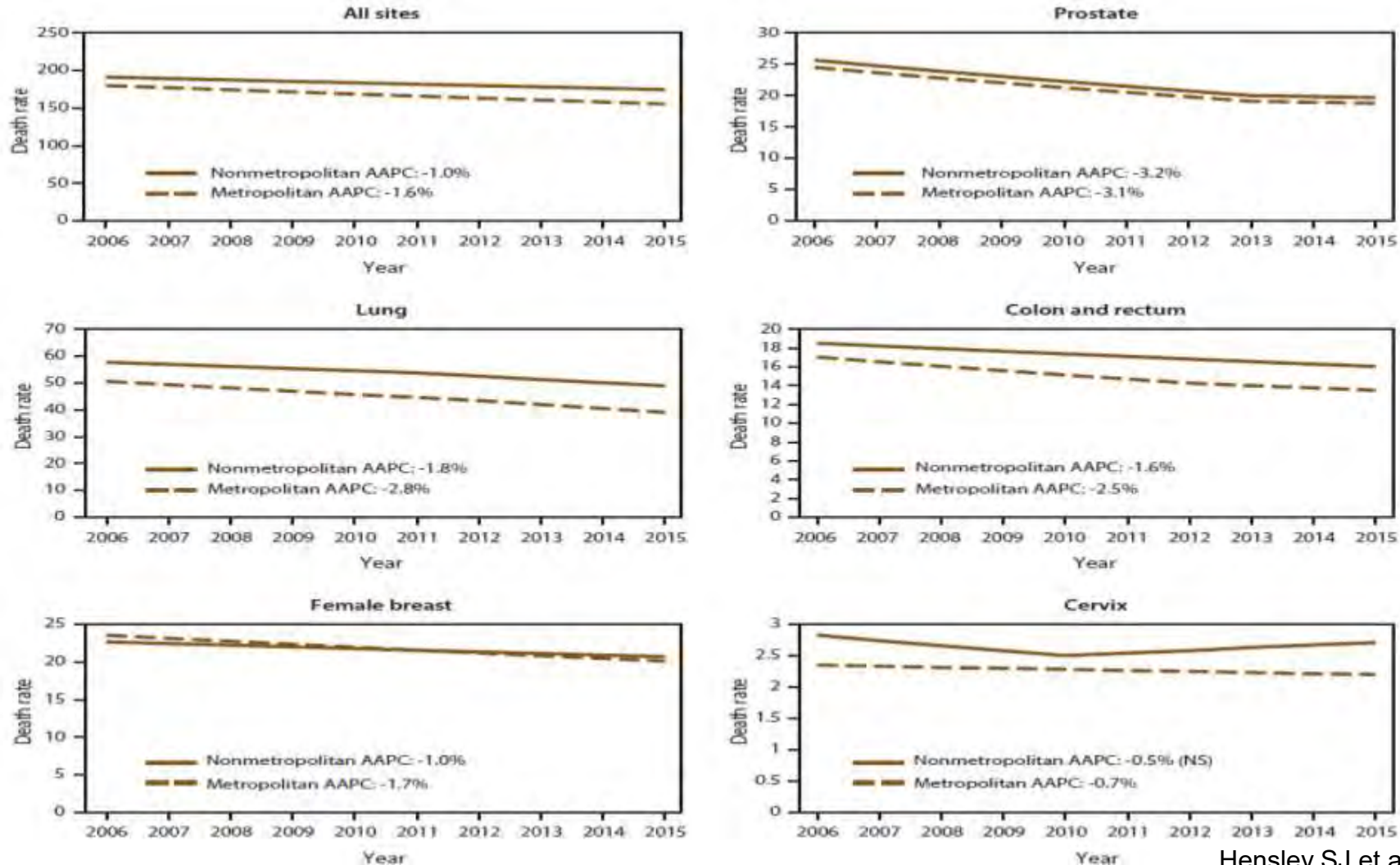
Incidence and death rates of Common Cancer



Nonmetropolitan rural
 Nonmetropolitan urban
 Metropolitan with <1 million population
 Metropolitan with ≥1 million population

* Per 100,000 persons, age-adjusted to the 2000 U.S. standard population.

Death rate from cancer decreasing but slower in rural areas



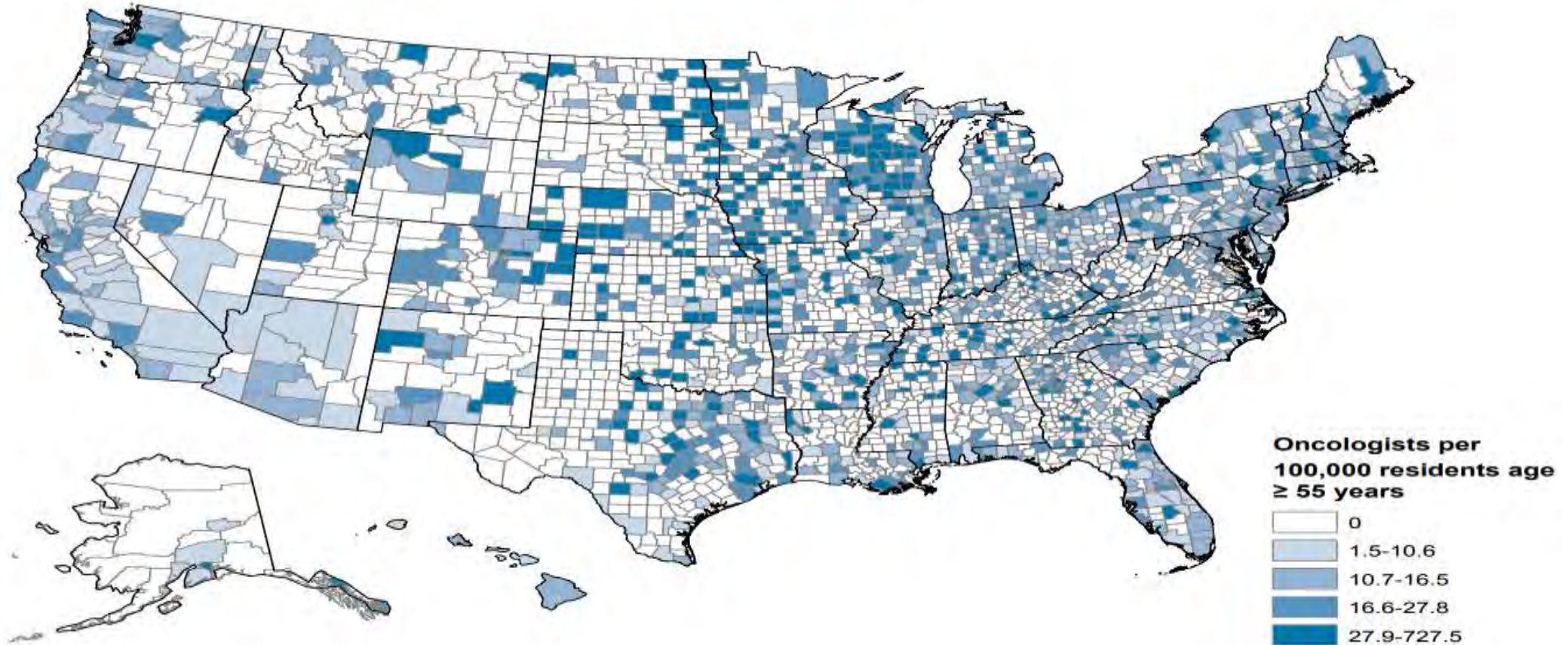
Factors leading to disparities in cancer care

- Social, Demographic and Personal
- Geographic distribution of Services
- Multidisciplinary care needs
- Travel distance and cost
- Financial burden and health insurance
- Clinical Trial infrastructure

Fewer Oncologist in Rural Area

- Since 2014 ASCO has catalogued oncology practice locations and spatially overlaid them with US Census demographic area.
- Oncologist practicing in rural areas have increased from 5.5% to 7.4% in 2019. Using alternate definition of rural area, percentage is around 12-15%.

Uneven distribution of oncologists



Barriers causing underrepresentation of rural patients in clinical trials

- Geographic accessibility (Clinical trials available at Academic or big metropolitan centers).
- Rural hospitals lack research staff.
- Rural patients may not fit the narrow eligibility criteria for a study.
- Failure by oncologists, PCPs and other professions to discuss clinical trial enrollment process.

Importance of clinical trials for patients living in rural area



Outcome of patients by rural vs urban residency

JAMA
Network | **Open**



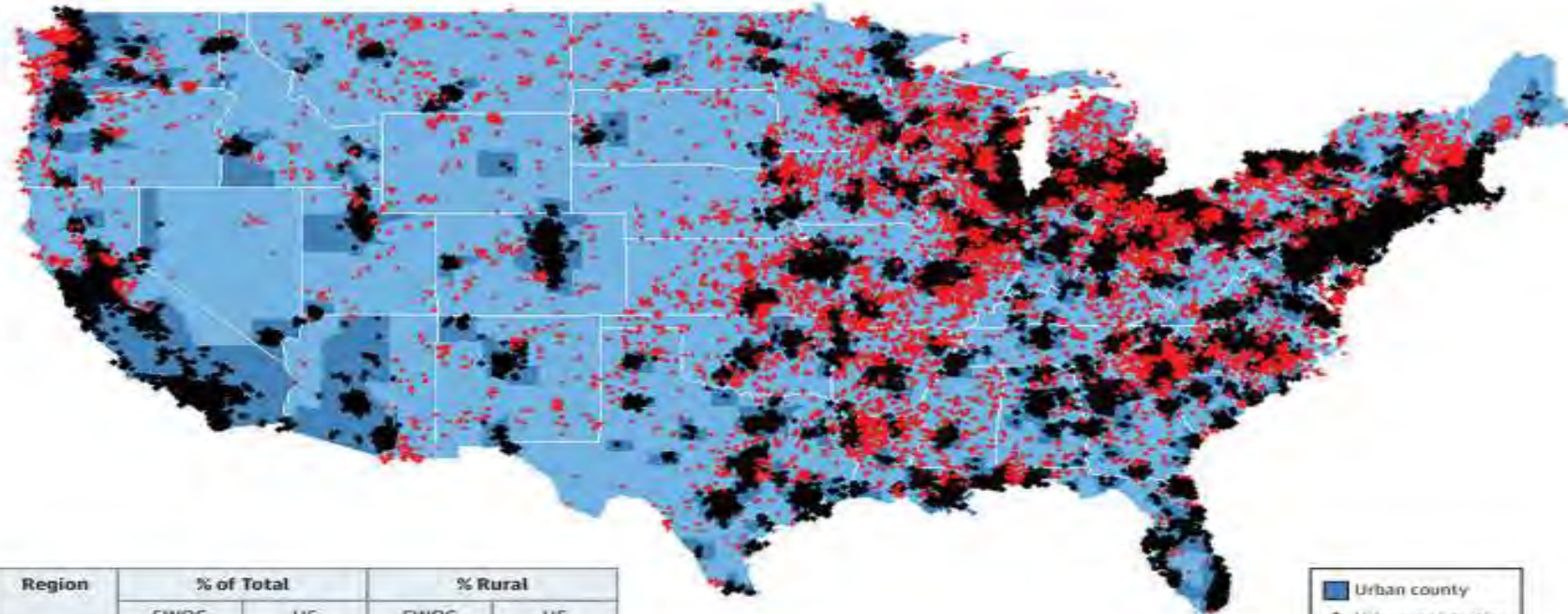
Original Investigation | Health Policy

Geographic Distribution and Survival Outcomes for Rural Patients With Cancer Treated in Clinical Trials

Joseph M. Unger, PhD, MS; Anna Moseley, MS; Banu Symington, MD; Mariana Chavez-MacGregor, MD, MS; Scott D. Ramsey, MD; Dawn L. Hershman, MD

- Main objective of this study was to compare geographic distribution and survival outcomes for rural vs urban patients with cancer treated in clinical trials.
- Retrospective cohort analysis of 36,995 patients enrolled in 44 phase III or phase II/III SWOG treatment trials from Jan 1, 1986 to December 31, 2012.

Figure 1. Map Showing 36 995 SWOG Enrollments From 1986 to 2012 by Rural vs Urban County Origin



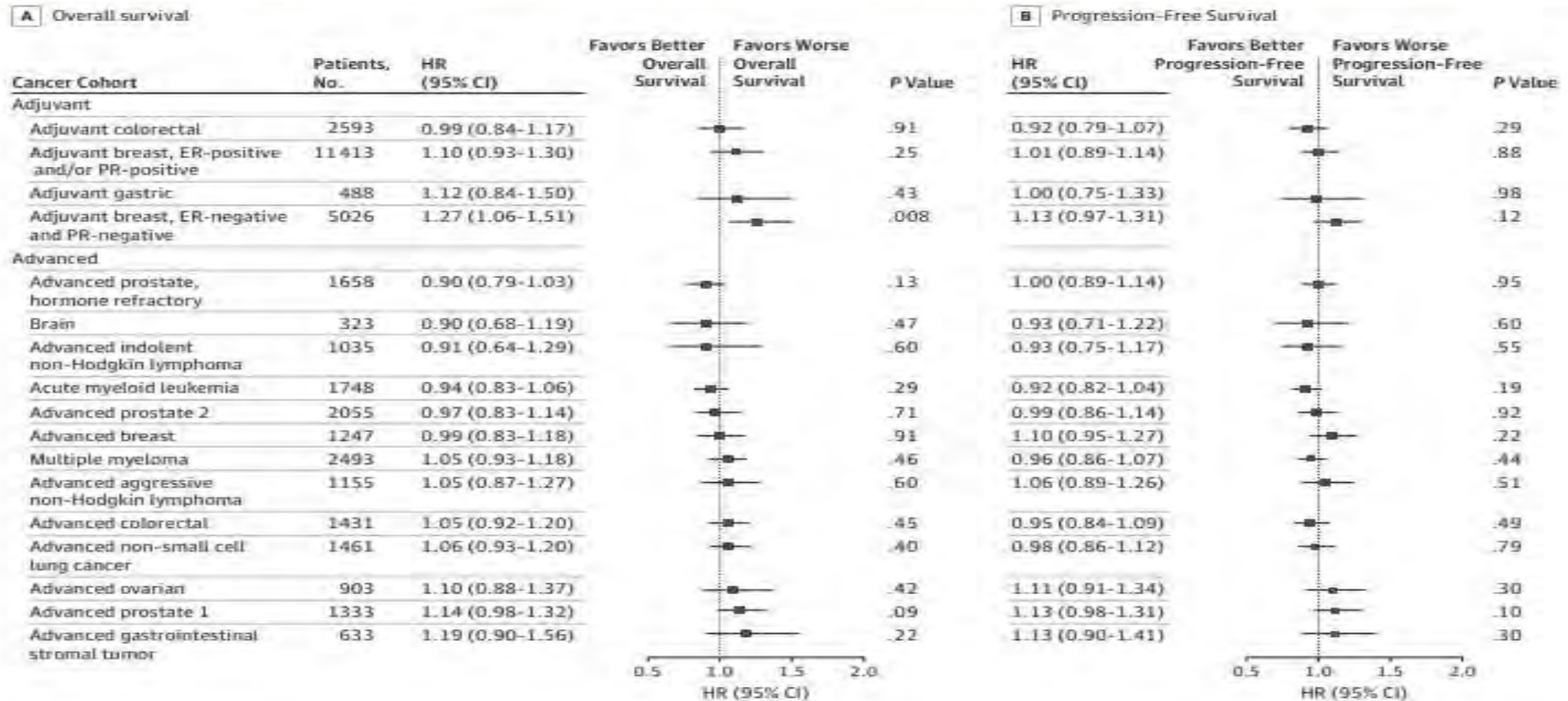
Region	% of Total		% Rural	
	SWOG	US	SWOG	US
West	23	23	13	11
Midwest	39	21	23	22
South	24	37	23	24
Northeast	14	18	14	16



The percentage of total SWOG and US cancer population cases by region are shown in the table, along with the estimated proportion in rural areas for each region.

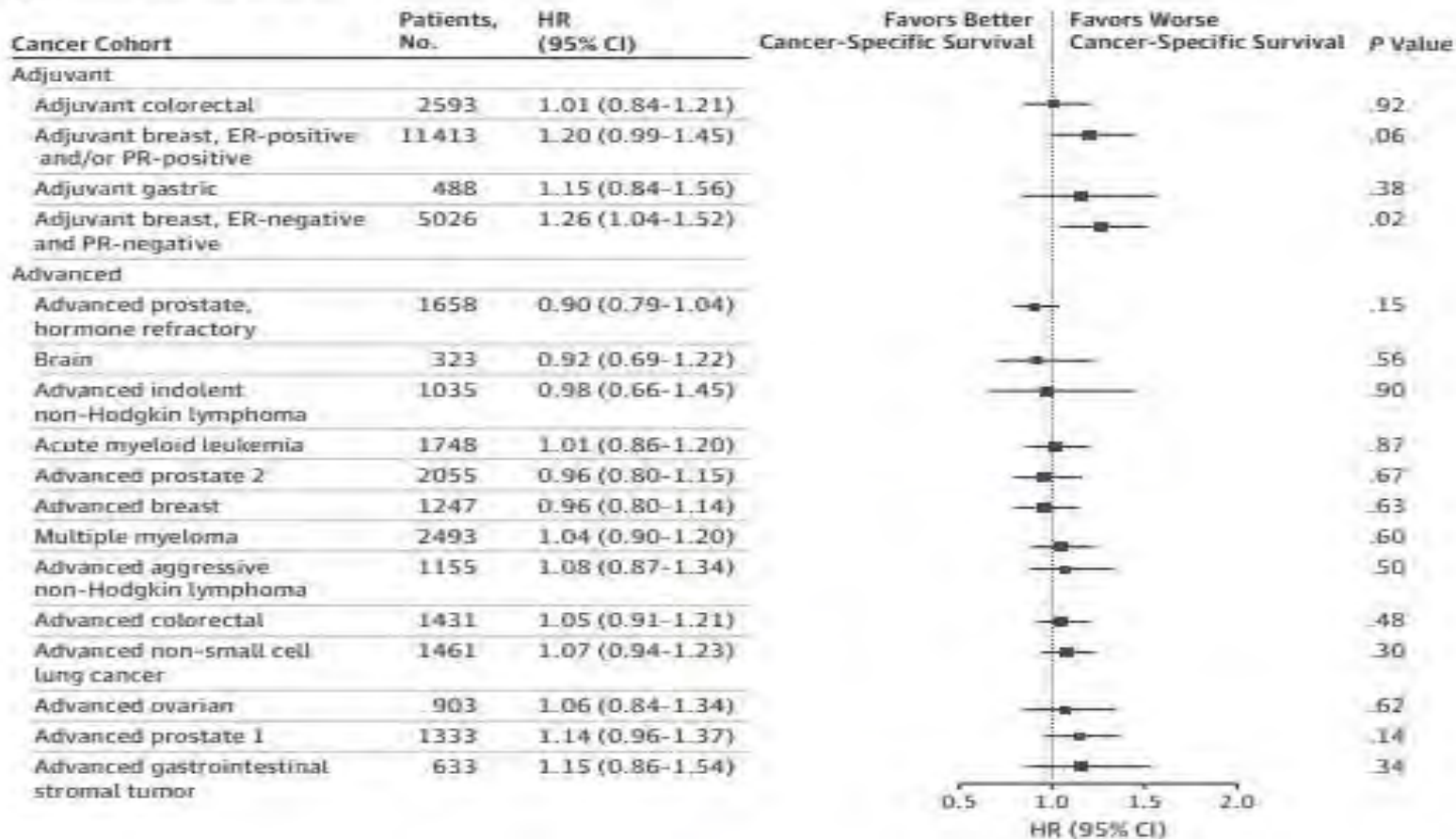
Clinical trials enrollment show similar outcomes

Figure 2. Forest Plot Showing the Association of Rural Residence and Survival Outcomes From Cox Regression Analyses



Cancer specific survival similar except adjuvant breast ER-/PR-

C Cancer-specific survival



Clinical Trials in Rural Nebraska

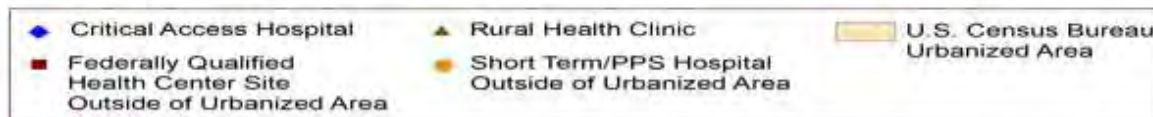
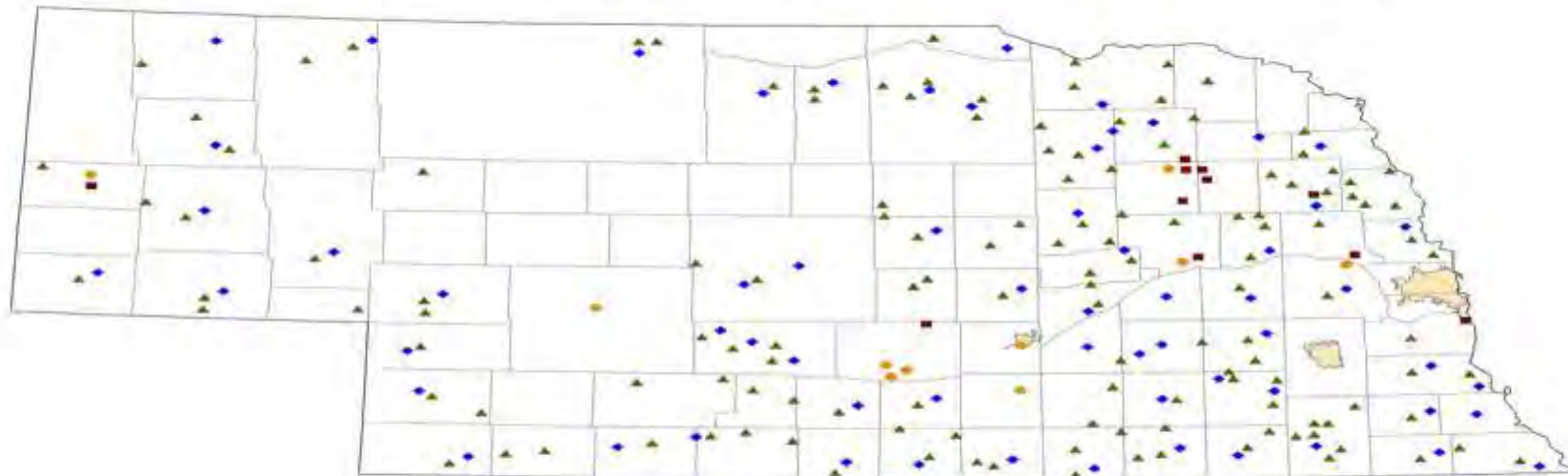




Rural vs Urban areas in Nebraska

- Approximately one third of Nebraska population lives in rural area.

Selected Rural Healthcare Facilities in Nebraska





NCORP in NE- CommonSpirit Health Research Institutes

Nebraska		
Alegent Health Bergan Mercy Medical Center	7500 Mercy Road Omaha, Nebraska	CommonSpirit Health Research Institute
Alegent Health Immanuel Medical Center	6901 North 72nd Street Omaha, Nebraska	CommonSpirit Health Research Institute
Alegent Health Lakeside Hospital	16901 Lakeside Hill Court Omaha, Nebraska	CommonSpirit Health Research Institute
CHI Health Good Samaritan	Ten East 31st Street Kearney, Nebraska	CommonSpirit Health Research Institute
Creighton University Medical Center	601 North 30th Street Omaha, Nebraska	CommonSpirit Health Research Institute
Midlands Community Hospital	1111 South 84th Street Papillion, Nebraska	CommonSpirit Health Research Institute
Nebraska Cancer Specialists/Oncology Hematology West PC	2730 West Faidley Avenue Grand Island, Nebraska	CommonSpirit Health Research Institute
Nebraska Cancer Specialists/Oncology Hematology West PC - Hastings	2727 West 2nd Street, Suite 314 Hastings, Nebraska	CommonSpirit Health Research Institute
Saint Elizabeth Regional Medical Center	555 South 70th Street Lincoln, Nebraska	CommonSpirit Health Research Institute

Research at Great Plains Health



History

- Strong foundation of conducting clinical trial

Had interventional drug trial for breast cancer, head and neck cancer and for COVID 19.

- Paved way for implementation of the Clinical Research Institute (CRI)

Vision

The vision, ***to make Great Plains Health's Clinical Research Institute a preferred location for clinical research trials while maintaining the highest clinical and regulatory standards***, will be addressed through three strategic pillars:

1. Physician engagement
2. Industry partnerships
3. Serving the North Platte community

Physician Engagement

Objectives

- Competitively recruit top-physician talent to Great Plains Health
- Retain physicians by supporting research career goals

Action Plan

- Build a network of experienced investigators to promote best practices
- Publish and promote successes
 - To build appreciation as an attractive and competitive region for conducting clinical research

Industry Partnership

Objectives

- Leverage strategic partnerships with:
 - Academic institutions
 - Pharmaceutical companies
 - Government agencies

Action Plan

- Grow relationship with UNMC
 - EPIC for Research
 - CRANE project with federal funding opportunities
- Open new industry-sponsored studies in 2022

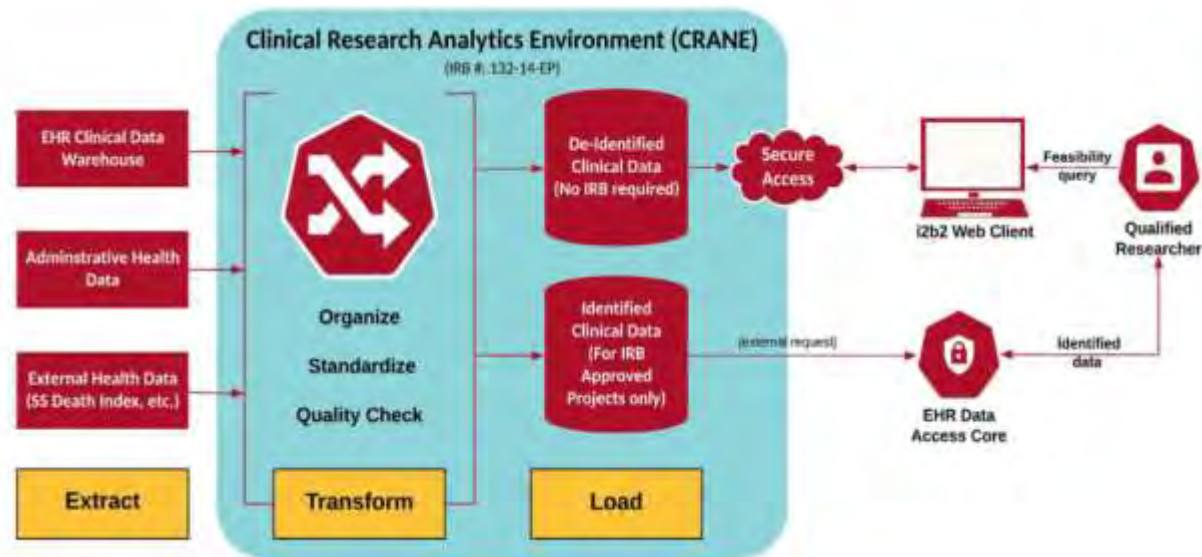
UNMC Partnership

EPIC for Research

- Enhance coordination between ancillary services
- Align with organization's reporting and billing processes

Clinical Research Analytics Environment (CRANE)

- The system is an IRB approved data registry to allow for secondary use of de-identified EHR data
- Supports collaborative research networks to share data derived from clinical care
 - National PCORnet (pcornet.org) and Greater Plains Collaborative (GPCnetwork.org)



Serving the North Platte Community

Objectives

- Build patient and public awareness and confidence in clinical trial participation
- Promote the health, social and economic value of clinical trials and the impact on GPH
- Establish educational strategies to support successful patient recruitment and retention
- Address diversity and inclusion unmet needs

Action Plan

- Public-facing website implementation
 - Inform public of benefits and positive outcomes of participation
- Employ clinical best practices to enhance the patient experience
- Spanish (US) translation for all patient-facing materials, including Informed Consent Form

Current Studies

Service Line	Study Title	Type	Indication
Sleep Medicine	HBS-101-CL-010: A Double-Blind, Placebo-Controlled, Randomized Withdrawal Study to Evaluate the Safety and Efficacy of Pitolisant in Adult Patients with Idiopathic Hypersomnia	Intervention - Investigational Drug	Adult Idiopathic Hypersomnia
	HBS-101-CL-011: An Open-Label Study to Evaluate the Long-Term Safety and Effectiveness of Pitolisant in Adult Patients with Idiopathic Hypersomnia who Completed Study HBS-101-CL-010	Intervention - Investigational Drug	Adult Idiopathic Hypersomnia
Pulmonology	SAFE-001: Assessment of the dynamic change of population immunity and susceptibility to emerging influenza antigenic variants in the United States	Observational	Influenza
	02-MX-002: Screening for High Frequency Malignant Disease (SHIELD)	Intervention - Device, Low-dose CT scan	Lung Cancer Screening
Nephrology	AKB-6548-CI-0039: A Randomized, Open-label, Active-controlled Study Evaluating the Efficacy and Safety of Dose Conversion from a Long-acting Erythropoiesis-stimulating Agent (Mircera®) to Three Times Weekly Oral Vadadustat for the Maintenance Treatment of Anemia in Hemodialysis Subjects	Intervention - Investigational Drug	Anemia associated with chronic kidney disease (CKD)
Medical Oncology	KCP-8602-801: Phase 1/2 Open-Label Study of the Safety, Tolerability and Efficacy of the Selective Inhibitor of Nuclear Export (SINE) Compound Eltanexor (KPT-8602) in Patients with Newly Diagnosed and Relapsed/Refractory Cancer Indications	Intervention - Investigational Drug	Myleodysplastic Syndrome (MDS)
	XPORT-MEL-033: A Phase 2 Open-Label Multicenter Study to Evaluate the Safety and Efficacy of Selinexor in Combination With Pembrolizumab in Recurrent Advanced Melanoma	Intervention - Investigational Drug	Locally Advanced Unresectable or Metastatic Melanoma

Working Towards the Future

- Upcoming studies:

Oncology:

A phase III study of Rusfertide in patients with Polycythemia Vera (VERIFY) (NCT05210790)

Nephrology:

A study of renal autologous cell therapy in DM II and CKD (NCT05099770)

Combined Dose-Finding and CV outcomes study with CSL300 in adult subjects with ESKD undergoing dialysis (NCT05485961)

Conclusion

- Clinical trials is one of way to improve cancer care in rural areas.
- Recruitment of healthcare personnel in rural areas challenging.
- Partnership to open more clinical trials important.
- NCORP expansion needed in Nebraska.

Thank You

- Ivan Mitchell, CEO
- Lance Arterburn, Senior Director of Ethics and Compliance
- Joseph Rubyal, MS, Director of Clinical Research
- Jamil Mattar, MD, Clinical Research Coordinator
- Lisa Kosmacek, RN, Research Nurse in Oncology

Thank you

Q&A



Boni Edwards