INFORMED CONSENT IN BIOBANK RESEARCH: RECRUITING PATIENTS WITH HEALTH DISPARITIES IN RURAL MAINE

DG MORRISON[1], C FARAH[1], JM HOCK[1] MAINE INSTITUTE FOR HUMAN GENETICS & HEALTH, BREWER, ME[1]

ABSTRACT

The Biospecimen Research Network (BRN) seeks to improve availability and quality of human specimens needed for cancer research, including biospecimen collection from disadvantaged minorities. Rural non-agrarian whites are often under-represented in such initiatives because geographic isolation makes obtaining informed consent a challenge. We report a case series of 83 patients diagnosed with cancer at a rural community medical center who consented to donate biospecimens for research, and agreed to 2 subsequent requests unanticipated in the original protocol.

We used NCI and ISBER Best Practices to create biobank infrastructure after protocol review and approval by Eastern Maine Medical Center (EMMC) IRB and OHP HRPO. Informed consent forms were at Microsoft Word's Flesch-Kincaid 8th Grade reading level, and supplemented by NCI educational brochures. Of 108 patients identified, 2 declined to participate; cancer was not confirmed in 12; 4 died, and 7 were either ineligible or failed to maintain eligibility. 83 eligible patients (49 lung cancer, 21 breast cancer and 13 other cancers) consented to donate blood and surgically resected tissue specimens, and to complete extensive questionnaires. Of these cases, 63 donated blood and tissue samples, 8 donated only blood and 2 donated only tumor tissue. Two years later, 14 patients had died. Of 69 still alive, 60 (87%) were successfully re-contacted for permission to collect additional data on environmental risks, and to transfer biospecimens to NCI's biorepository. The majority of cases exhibited health disparities as co-morbidities with 1-3 chronic diseases (mostly cardiovascular) and long-term smoking and/or alcohol consumption. Nearly 90% reported relatives with cancer, while 30%, 51%, 16% and 3%, respectively, reported 0, 1, 3-4 or 2 prior cancers. Anecdotally, willingness to consent was based on altruistic hopes that research would generate knowledge to reduce cancer incidence. Our study shows that cancer patients from disadvantaged rural communities will consent to participate and support biobank research.

STATEMENT OF THE PROBLEM

- Maine is one of 9 US states with the lowest recruitment of cancer patients and elderly subjects (Sateren, W. B., et al., *J. Clin. Oncology,* 2002).
- Maine suffers health and cancer disparities related to poverty, geographic isolation and healthcare access.
- Rural counties in Maine have older populations. Among other groups, the elderly, individuals in rural populations and those of low socioeconomic status in general, are underrepresented in cancer clinical trials *(AHRQ,* 2005*).*
- Geographic isolation and travel distances to care are complicated by poor infrastructure, lack of public transportation and inclement weather. The availability of transportation has been cited in numerous studies as a barrier to participation (Colon-Otero, G., et al., *Cancer,* 2008).
- A sense of self-determination motivates altruistic behaviors in patients participating in biobanking research (Allen, J. & McNamara, B. *Bioethics,* 2011).

SPECIFIC AIM

To investigate the willingness of cancer patients at the time of diagnosis to provide informed consent for biobanking research, while receiving treatment at a tertiary community medical center serving a rural population with health and cancer disparities related to geographic isolation and poverty.

Highlights of the Informed Consent Form

- Allows unspecified future research.
- Includes clinical questionnaire and medical record data.
- No results will be returned to participants.
- States no personal benefit to participants.
- CRMS software (Medical Decision Logix, Inc, Baltimore, MD) allows electronic transfer of annual status updates from the record and from the Maine Cancer Registry.
- Approves use of specimens and data for product development.
- No monetary benefit to participant.
- Allows indefinite storage of biospecimens for research.

METHODS

New patients to EMMC cancer center were screened by hospital staff for eligibility. Their physician informed them of the study. Study staff explained the study and provided education materials that included a description of the study protocol, an informed consent form and a NCI educational brochure on biobanking. Interested participants contacted study staff, who consented them on their next clinic visit. If geographic distance was a challenge, study staff used either telephone or travelled to the homes to consent and collect data. Blood was collected on the same visit as questionnaires were completed (30-60 minutes), specimens were collected from the operating room at the time of surgery and taken immediately to the pathology lab for processing. All data were stored in CRMS (Medical Decision Logix, Ltd, Baltimore, MD), FFPE specimens were stored at room temperature and blood and derived specimens were stored in cryogenic freezers.

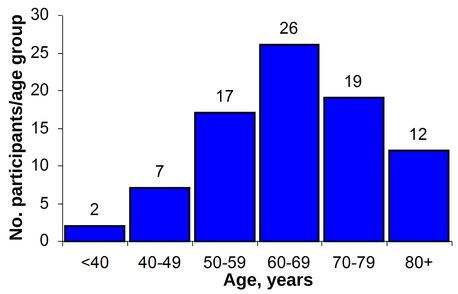
About 2 years after the original consent, we requested additional data and approval to transfer all specimens to NCI Tissue Repository to be available to more investigators for research.

RESULTS

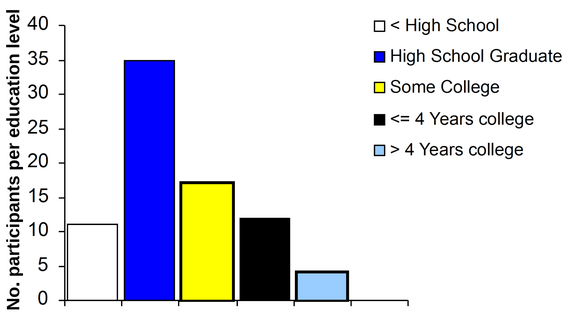
High Rate of Agreement to Consent

2009-2010: Recruited participants		Agreement
No. screened	108	
No. Eligible	85	
No. Consented	83	98%
No. Consented but not eligible	15	
2011: Re-contacted participants for new consent		
No. Deceased	14	
No. Eligible	69	
No. Consented	60	87%

Most consenting participants were 60 years or older



Education attainment not a barrier to consent



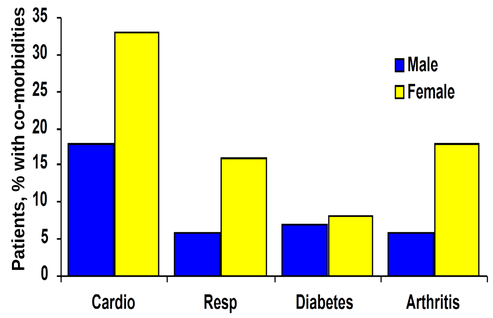
Genetic Risks

Cancer Genetics Risk Profiles	Lung	Breast	Other
Family History of Cancer			
Cases with 1st degree relatives, %	84%	72%	70%
No. 1st degree relatives/case (mean±sem)	2 ± .25	2 ± .50	1 ± .25
Cases with affected relatives, %	92%	91%	92%
Prior history of cancer			
Cases with 1 prior cancer	53%	67%	46%
Cases with 2 prior cancers	31%	33%	38%
Cases with 3+ prior cancers	16%	0	15%

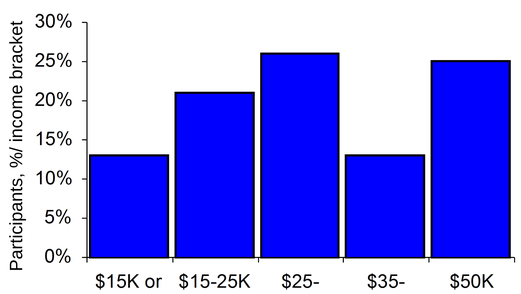
Multiple Lifestyle Risks over Many Years

	Alcohol	Tobacco	Second Hand Smoke	Narcotics
Exposure, % cases	80%	82%	80%	41%
Years of use, mean±sem	40 ± 2	34 ± 3	39 ± 3	4 ± 2
Moderate-heavy alcohol use, years, mean±sem,	36 ± 12			
Pack-years in smokers (Range 1-118) mean±sem		42 ± 5		

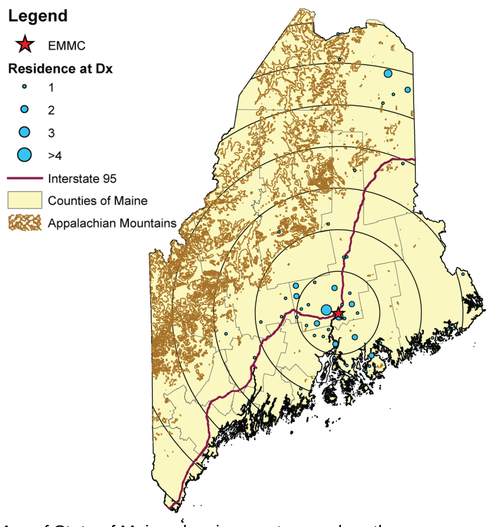
Multiple Co-morbidities Prior To Diagnoses



Income not a barrier to consent



Geographic Isolation of Participants



Map of State of Maine showing western and northern mountains (brown); single major thoroughfare (I-95) running north/south (maroon), and counties outlined in light gray. Participant zip codes represented by blue bubbles; differences in size reflect number of ases within that zipcode; red star represents the community tertiary medical center (Eastern Maine Medical Center, EMMC) serving participants. Concentric circles centered around EMMC are 25 miles apart.

DATA SUMMARY

- 98% participants from region with health disparities consented to participate in biobanking research.
- Participants agreed to data collection in person at the clinic, home or meeting place, or by telephone.
- Participants agreed to blood collection at the time of data collection or prior to surgery, and to specimen collection during surgery.
- 87% cases continued to participate in research two years later when contacted to consent to new questionnaire and transfer of specimens to NCI.
- Older age was not a barrier to consent; 68% participants were aged years 60 or older.
- Education attainment and income level were not barriers to consent.
- Participants reported family history of cancer, prior history of cancer and multiple comorbid non-communicable diseases.
- Self reports that family cancer history, and prior history of cancer prompted participation in research based on goals of self-determination and altruism.

CONCLUSIONS

In a rural state with cancer and health disparities related to geographic isolation, poverty and access to care, patients newly diagnosed with cancer were willing to participate in biobanking research and to be contacted on multiple occasions, irrespective of advanced age, education and income, family history of cancer and a history of prior cancers.

Acknowledgments: This work was funded by US Army Medical Research and Materiel Command research contract USAMRMC No. 0704400, PI JM Hock. We gratefully acknowledge the help of clinical research staff at EMMC CancerCare of Maine who screened, recruited and consented patients at the start of the study, allowing us to comply with hospital requirements for patient screening.