

Background

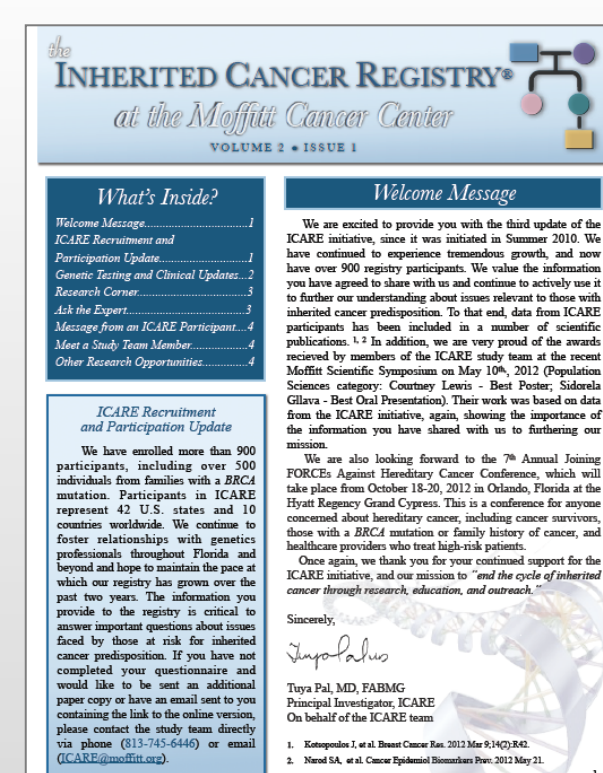
- ICARE is a five-year longitudinal study designed to recruit patients interested in participating in studies of inherited cancer into a research registry in order to better understand cancer risk management practices at both the patient and provider level.
- Participants are recruited through Genetic Risk Assessment Services at the Moffitt Cancer Center as well as through other external healthcare providers within the United States.
- Enrollment in ICARE involves securing signed informed consent. As well, each participant is asked to complete an initial questionnaire and provide copies of their genetic test results (or medical record release to obtain the results) and pedigree. During the course of their participation, participants receive an appreciation gift for returning their questionnaire, a bi-annual newsletter, and a birthday card.
- This project aims to determine the utility of various follow-up procedures through identification of factors associated with completion of participant research files.
- A complete research file was defined as having an initial questionnaire, genetic test results, and pedigree.

Methods

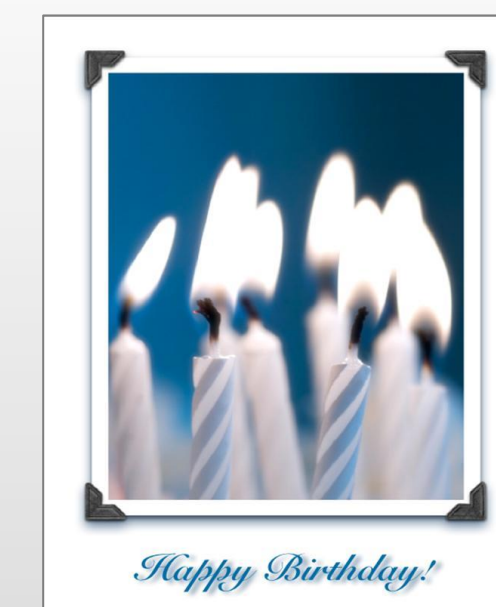
Eligibility Criteria: Female participants consented to ICARE (7/2010 - 1/2013) who reside in the United States, provided a date of birth, and self-reported that they carried a BRCA mutation

- Participant records and call logs were reviewed to collect data on demographics, recruitment method, and item completion dates.
- Rate of return of a research file component was calculated at baseline (up to one month prior to being mailed a newsletter) and within one month after being mailed a newsletter.
- Rate of return of a research file component was calculated within one month after being mailed a birthday card and appreciation gift.
- Logistic regression was used to identify whether demographics, recruitment method, and/or receipt of a birthday card or appreciation gift were associated with having a complete research file.

Selected Study Materials



ICARE
Newsletter



Birthday Cards



Lunch Bag



Tape Measure



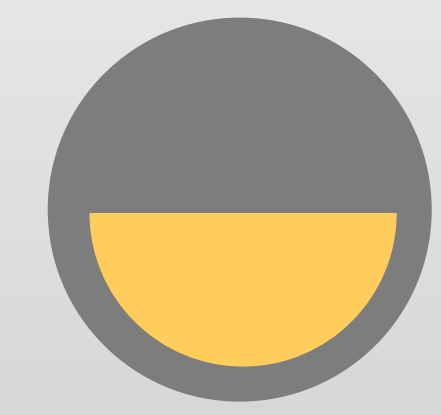
Alarm Clock

Components of Research File



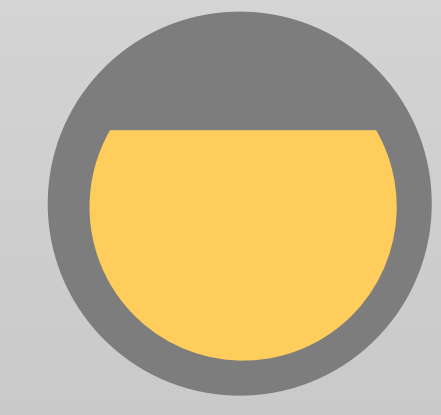
Informed
Consent

Recruits are given an enrollment packet and consented over the phone or in person.



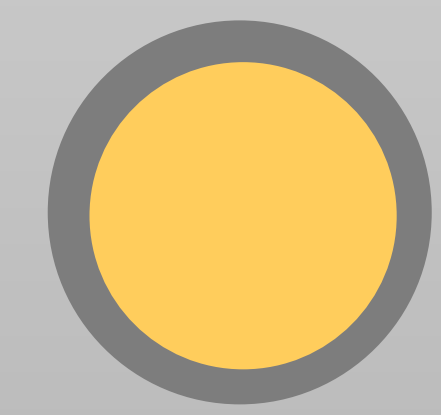
Initial
Questionnaire

Participants are given an initial questionnaire, which is available online or on paper and receive an appreciation gift upon completion.



Genetic
Test Results

Participants provide a copy of their genetic test results.



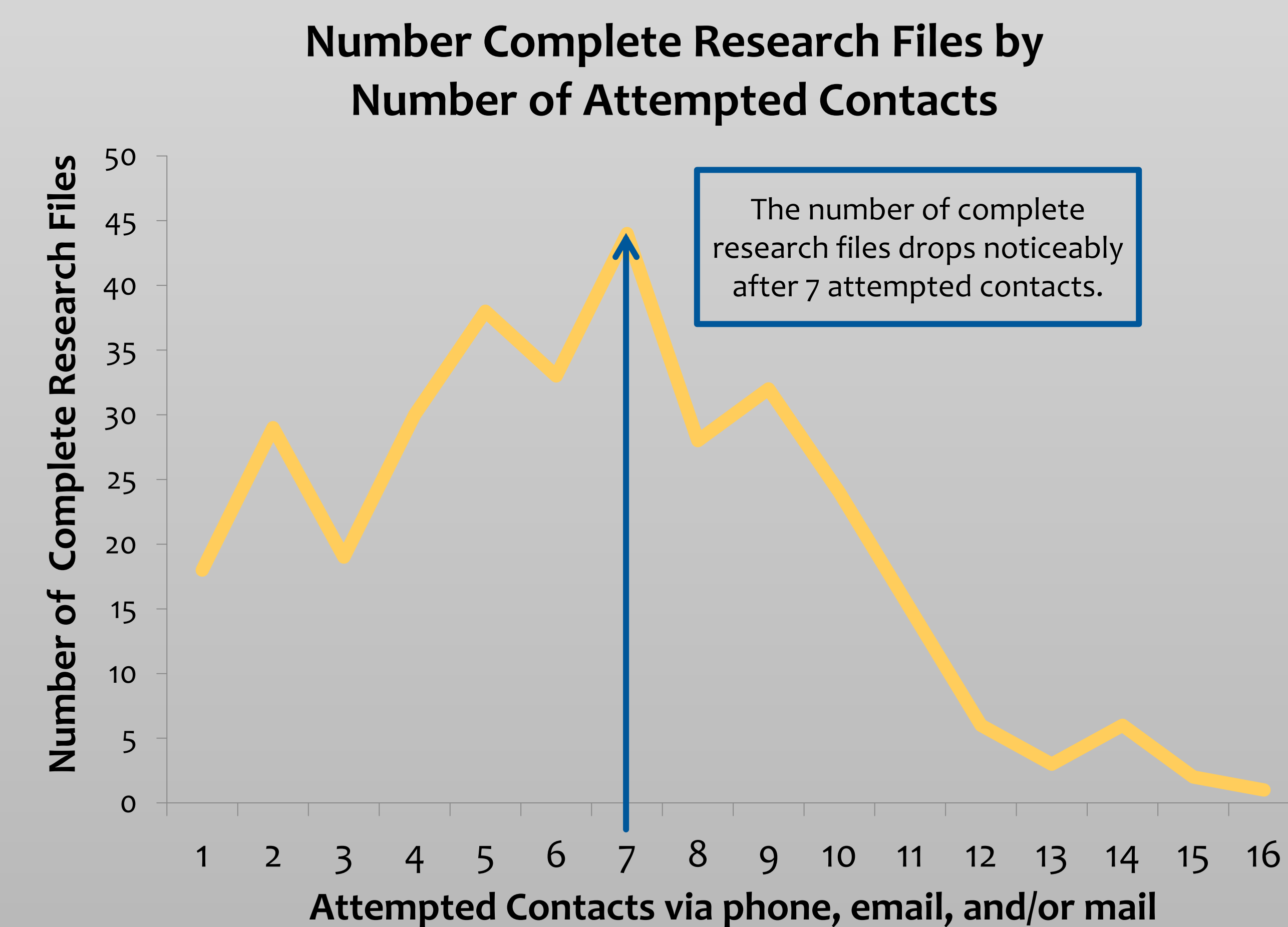
Pedigree

Participants provide a copy of their pedigree.

Key Findings

Rate of Return by Selected Factors

Factors	N	Baseline (%)	Rate of Return (%)
Newsletter 1	157	12	20
Newsletter 2	254	4	30
Newsletter 3	299	12	19
Appreciation Gift	200	N/A	23
Birthday Card 1	316	N/A	13
Birthday Card 2	71	N/A	4



Logistic Regression Model of the Relationship between Selected Predictors and Completeness of Participant Research Files

Parameter Estimates:	Final Model	Odds Ratio	95% CI
N=607			
Intercept	1.2400*		
Modifiable Variables			
Recruitment Source			
First Birthday Card			
Second Birthday Card			
Appreciation Gift	-1.1841***	0.306	(0.210, 0.446)
Non-Modifiable Variables			
Age at Consent	-0.0280**	0.972	(0.955, 0.990)
Cancer Status			
Goodness of Fit Statistics:			
AIC	692.169		
SC	722.223		
-2LL	678.169		
Associated GLH Tests:			
H ₀ ⁺	B _{CF} =0		
LR χ ²	54.3298		
Df	6		
P Value	<.0001		
Decision	Fail to Reject		

Key ~P<.10 *P<.05 **P<.01 ***P<.001
*Controlling for all other predictors present in the model

Results

- In the month prior to each of the three newsletter mailings 12%, 4%, and 12% of participants with an incomplete file returned at least one research file component, respectively. Higher rates of return were observed after the first (20%), second (30%), and third newsletter mailings (19%).
- Within one month of receipt of an appreciation gift 23% of participants with an incomplete file returned at least one research file component. The rates of return associated with the first and second birthday cards were lower than the rates of return associated with receipt of an appreciation gift and newsletter(s).
- Those who received an appreciation gift were 5.6 times (p<.05) more likely to have a complete research file.
- Older age is associated with having a complete research file (p<.05).
- A higher number of contacts between the participant and study team is associated with a complete research file. However, the number of complete research files drops off after 7 attempted contacts.

Conclusion

- We identified newsletter mailings and receipt of an appreciation gift to be associated with completion of participants' research files.
- Based on our findings, we will amend the study team's efforts to increase the number of complete research files while maintaining maximal efficiency.

Acknowledgements

This research was funded by the Bankhead-Coley Cancer Research Program (Grant ID#: 1BG-09) and conducted at the H. Lee Moffitt Cancer Center and Research Institute.