

DNA Collection Via Saliva Donations with a Large, Longitudinal Sample: A Comparison of Different Treatments and their Outcomes

Ken Croes and Kerryann DiLoreto Oliver

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Objective

- DNA collection phase of a large, longitudinal study
- Pilot in four experimental groups (N=400)
- Different treatments (phone calls, mailings, incentives, etc.)
- Effects on response rates, costs, and other project outcomes
- Production (N=8141)

Wisconsin Longitudinal Study Overview

Previous Waves of the Survey

- April 1957: School Survey of Graduates
- 1975: Telephone Survey of Graduates
- 1977: Telephone Survey of N=2000 Siblings
- 1992: Telephone/mail Survey of Graduates
- 1993: Telephone/mail Survey of N=5500 Siblings
- 2002: Telephone/mail Survey of Graduates
- 2003: Telephone/mail Survey of Siblings

Features of the Sample

- Random selection of 1/3rd of Wisconsin high school graduates in 1957
- List sample
- Began with N= 10,000
- Currently with N ~ 8141
- Cohort of men and women, born primarily in 1939, precedes by about a decade the bulk of the baby boom generation



Why move to collecting biomarkers?

- Broad desire to expand scope of data collection to include assays of DNA to assess specific hypotheses
- Aging sample group indicated that a sooner-rather-than-later strategy for biomarker collection would be wise
- Availability of less expensive yet viable DNA collection via saliva donation kits
- End goal: the ability to study the relationship of genes to health and well-being, including Alzheimer's disease, cancer, and depression

Why pilot in four groups?

- Ability to test varying advice from investigators on design and hypotheses about response rate and overall success
- To tease apart exactly which components of the treatment design were successful
- To measure the success of each treatment against its cost

Description of mailing elements: SAQ, consent form, saliva kit

- 4-page SAQ on Medicare Part D
- SAQ was unrelated to saliva / DNA collection
- 1-page consent form for donating saliva / DNA; copy of consent form was provided to R
- Oragene (OG-250) spit kit
- DNA Genotek instructions in kit; we supplemented with abridged, large-print instructions

Oragene OG-250

DNA Saliva Kit



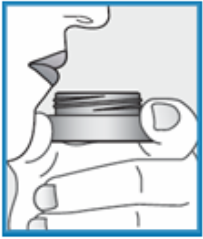

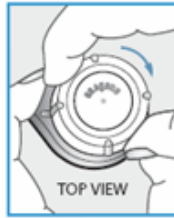



“Co-branded” kit sleeve



Abridged / larger-print kit instructions



Oragene™ DNA Self-Collection Kit User Instructions

<p>1)</p> 	<p>2)</p> <p>Fill to here with saliva</p>  <p>SIDE VIEW OF VIAL</p>	<p>3a)</p>  <p>TOP VIEW</p> <p>3b)</p>  <p>3c)</p> 	<p>4)</p> 
<p>Before using, rinse your mouth with drinking water to flush away food particles. After rinsing, discard or swallow drinking water. Then wait 5 minutes before spitting saliva sample. Step 1. Do NOT spit drinking water into the container.</p>			
<p>1</p> <p>Spit saliva into the empty container</p> <p>Picture #1</p>	<p>2</p> <p>Spit until the amount of liquid saliva (not foam) reaches the level shown in</p> <p>Picture #2</p>	<p>3</p> <p>Put the container on a flat surface. Screw the cap onto the container. Make sure that the cap is closed tightly as shown in picture #3c.</p> <p>Picture #3</p>	<p>4</p> <p>Tighten firmly and shake gently</p> <p>Picture #4</p>



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Pilot 2 ~ The “Hyundai” (Bundled)

- N=100
- Mail cover letter describing questionnaire and DNA collection effort, SAQ, results report, saliva collection kit, kit instructions, consent form
- Within 3 – 5 days: mail reminder postcard
- 1 week later: mail SAQ wave 2
- No incentive
- Total potential points of contact with respondents: 3



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Pilot 1 ~ The “Cadillac” (Unbundled)

- N=100
- Mail packet A: letter, SAQ, results report
- 2 weeks later: mail letter describing DNA collection, consent form, saliva collection kit, kit instructions, \$5 cash incentive
- Within 3 – 5 days: mail reminder postcard
- 1 week later: mail SAQ wave 2
- Total potential points of contact with respondents: 4

Pilot 3 ~ The “Saab” (Unbundled)

- N=100
- Mail packet A: letter, SAQ, results report
- 2 weeks later: send letter inviting Rs to participate in the DNA collection and remind Rs about SAQ
- Within 3 days: mail letter further describing DNA collection, consent form, saliva collection kit, instructions, \$5 cash incentive
- Within 3-5 days: mail reminder postcard
- 1 week later: mail reminder letter about saliva kit with toll-free number to call with questions
- 1 week later: mail SAQ wave 2
- Debriefing calls to respondents and non-Rs
- Total potential points of contact with respondents: 7

Pilot 4 ~ The “Rolls-Royce” (Unbundled)

- N=100
- Mail packet A: letter, SAQ, results report
- 2 weeks later: Phone call to invite R to participate in the DNA collection and remind R about SAQ
- Within 3 days: mail letter further describing DNA collection, consent form, saliva collection kit, instructions, \$5 cash incentive
- Within 3-5 days: mail reminder postcard
- 1 week later: Place reminder call to R about saliva kit; respond to questions / concerns; convert refusals; inquire about need to send second saliva kit
- 1 week later: mail SAQ wave 2
- Debriefing calls to respondents and non-Rs
- Total potential points of contact with respondents: 7



Comparison of Pilots 1 - 4 (N=100 in each pilot)

	Bundled?	Phone calls?	Cash incentive?	# of Points of Contact?	Debriefing calls?
Pilot 2	Yes	No	No	3	No
Pilot 1	No	No	Yes	4	No
Pilot 3	No	No	Yes	7	Yes
Pilot 4	No	Yes	Yes	7	Yes



Comparison of Pilots 1 - 4 (N=100 in each pilot)

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	SAQ Completes	SAQ Refusals	DNA Kit Completes	DNA Kit Refusals	Consent Form Completes	Consent Form Refusals
Pilot 2 POC: 3	71	1	41	7	41	7
Pilot 1 POC: 4	91	0	56	4	56	3
Pilot 3 POC: 7	89	2	67	12	67	12
Pilot 4 POC: 7	86	2	71	11	71	10

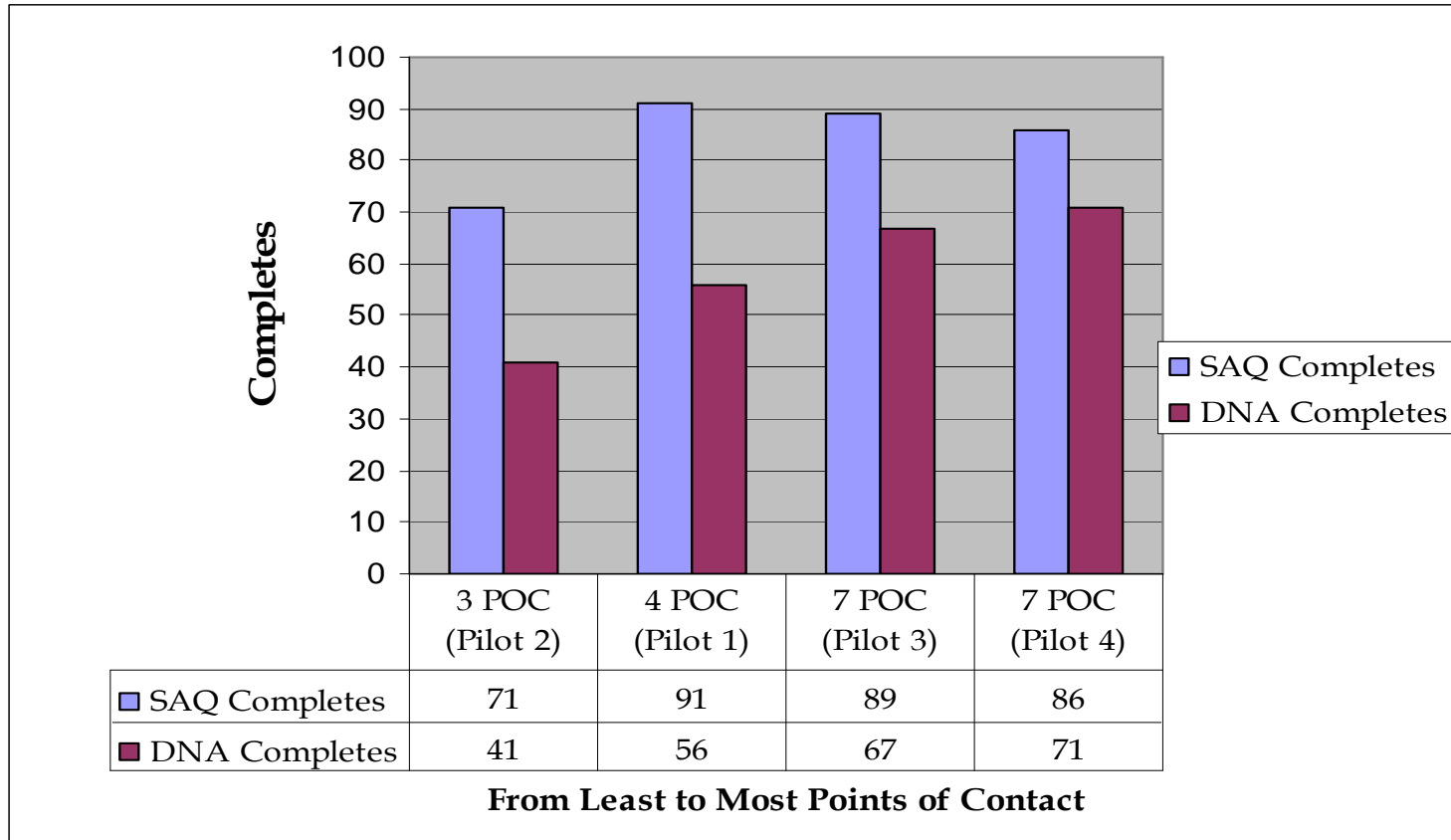


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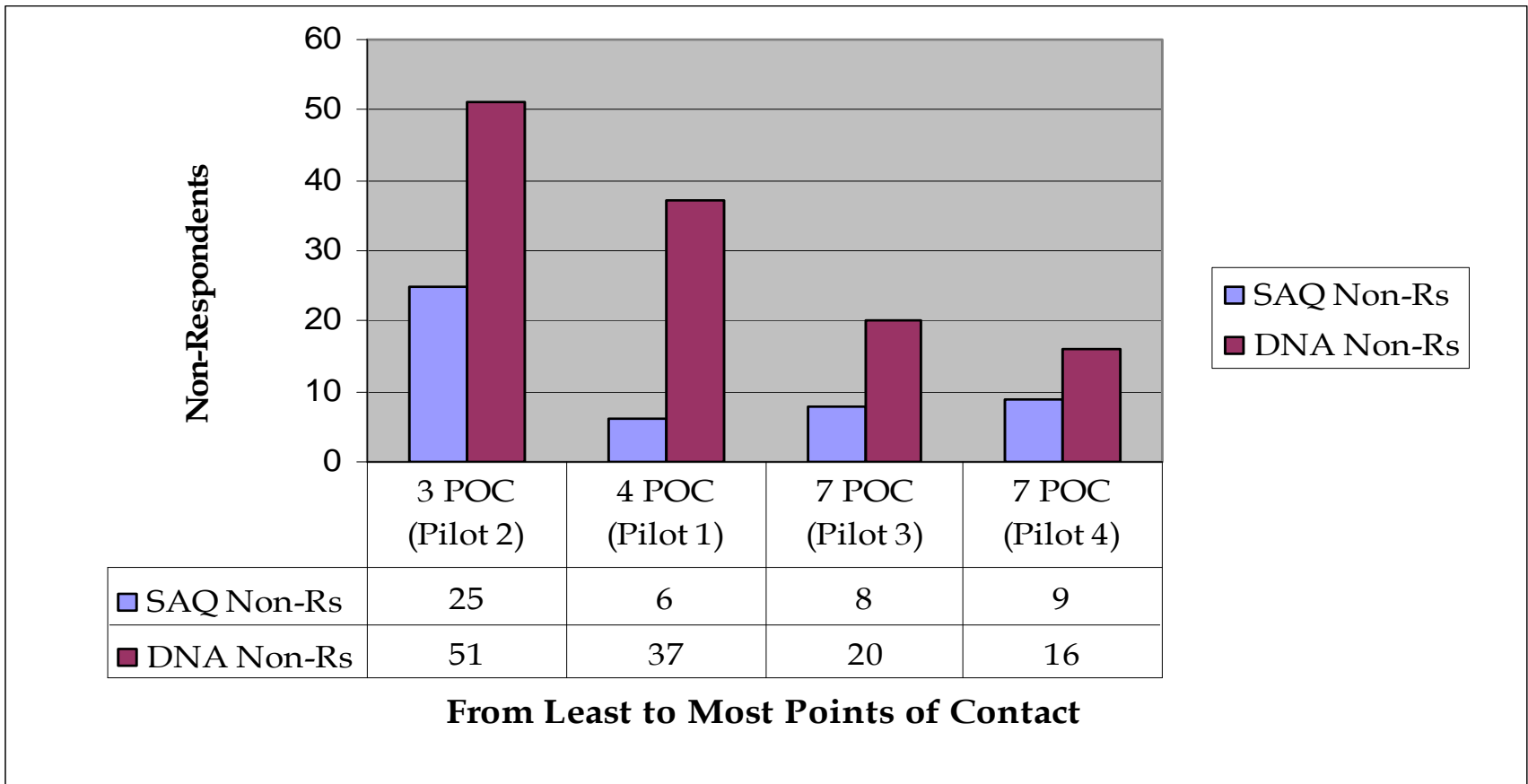
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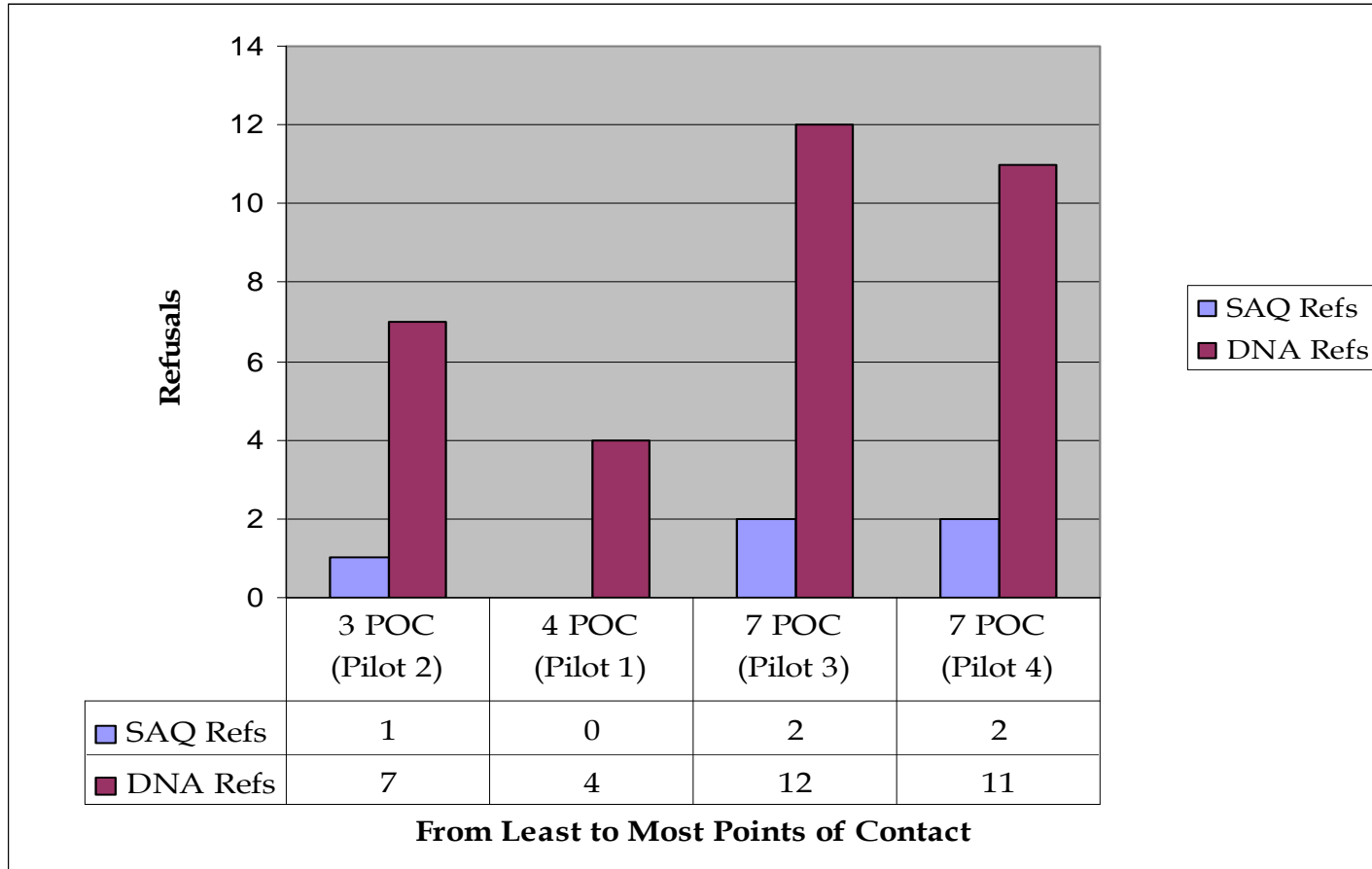
Effect of Number of Points of Contact on Completes



Effect of Number of Points of Contact on Number of Non-Respondents



Effect of Number of Points of Contact on Number of Refusals



Debriefing the Pilot Rs and Non-Rs

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- Attempted debriefing calls with total of 30 randomly-selected cases from Pilots 3 and 4
- 10 non-Rs; plus 5 Rs from Pilot 3 and Pilot 4
- Asked slightly different questions depending on participation in order to understand their reaction to / experience with the pilot treatment
- Findings:
 - No real surprises as far as Non-R and R reactions; typical reasons for non-participation / refusal / participation
 - All pilot 4 Rs expressed “appreciation” that we called to let them know to expect the saliva kit in the mail
 - Tracing needed to get current phone numbers for Pilot 3 non-Rs



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Taking Pilot 4 to Production

- Overall best “customer service” model
- Concern about expensive kits being tossed in the trash
- Information-gathering function of phone calls
 - Address confirmation
 - Deceased respondents
 - Incapacitated / ailing Rs
- Active refusal aversion / conversion function of phone calls

Production Outcomes

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	SAQ Completes	SAQ Refusals	SAQ Non- Responses	DNA Kit Completes	DNA Kit Refusals	DNA Kit Non- Responses
N=8,141	63%	8%	25%	60%	13%	25%
“Best Rs” N=3,434	75%	5%	18%	69%	10%	20%
“Worst Rs” N=239	13%	12%	53%	18%	17%	57%
Pilot 4 “Rolls Royce”	86%	2%	9%	71%	11%	16%

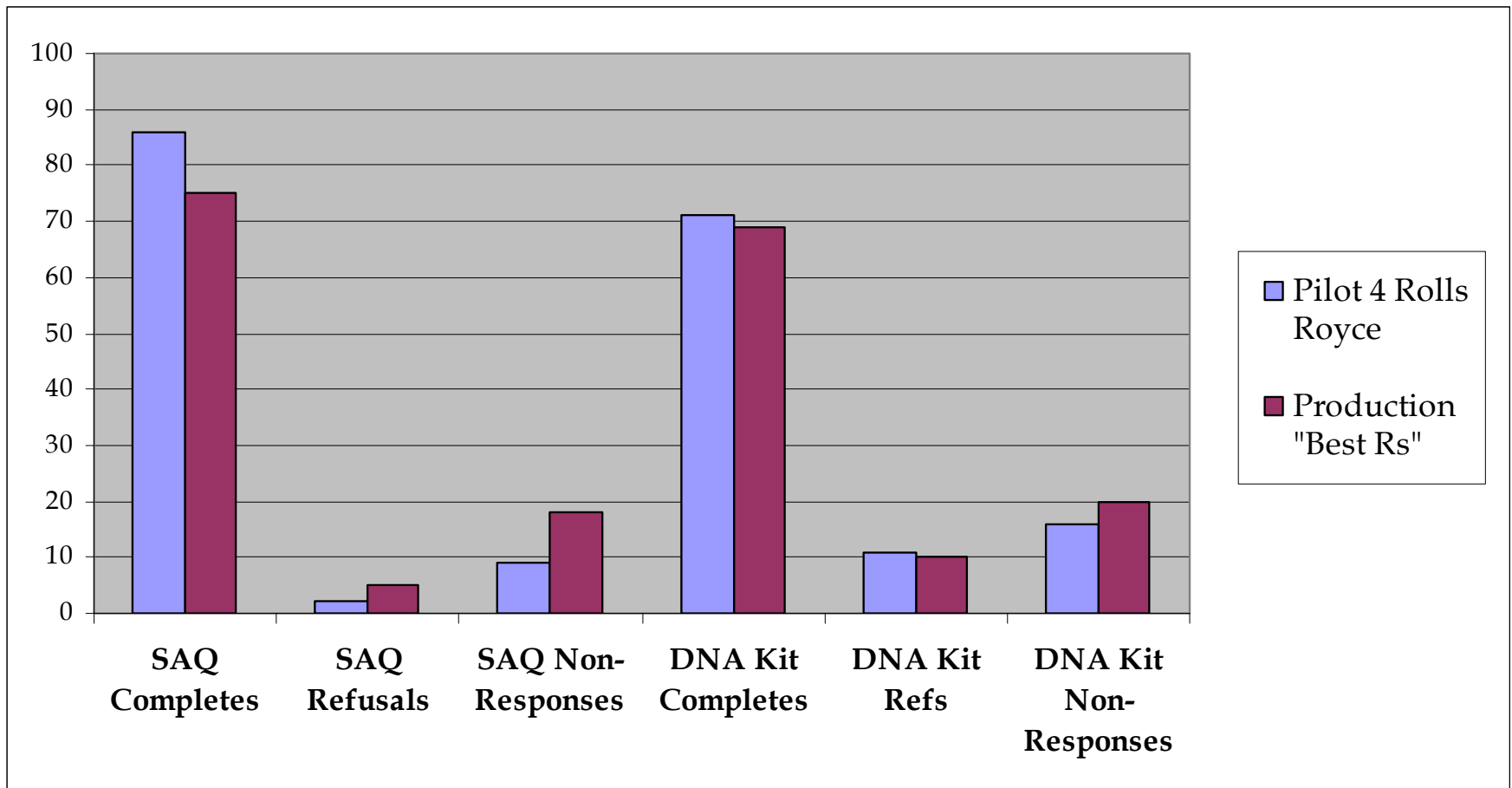


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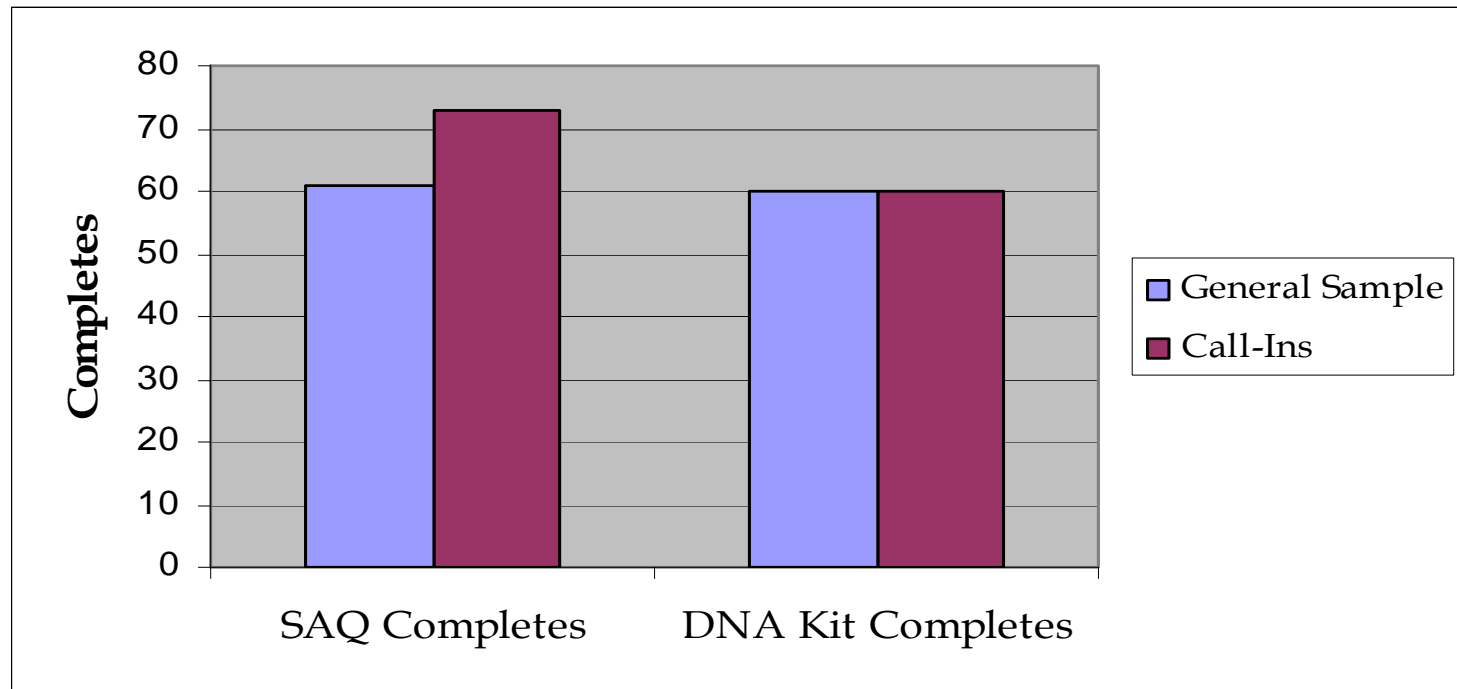


Predictability: Pilot and Production Comparison

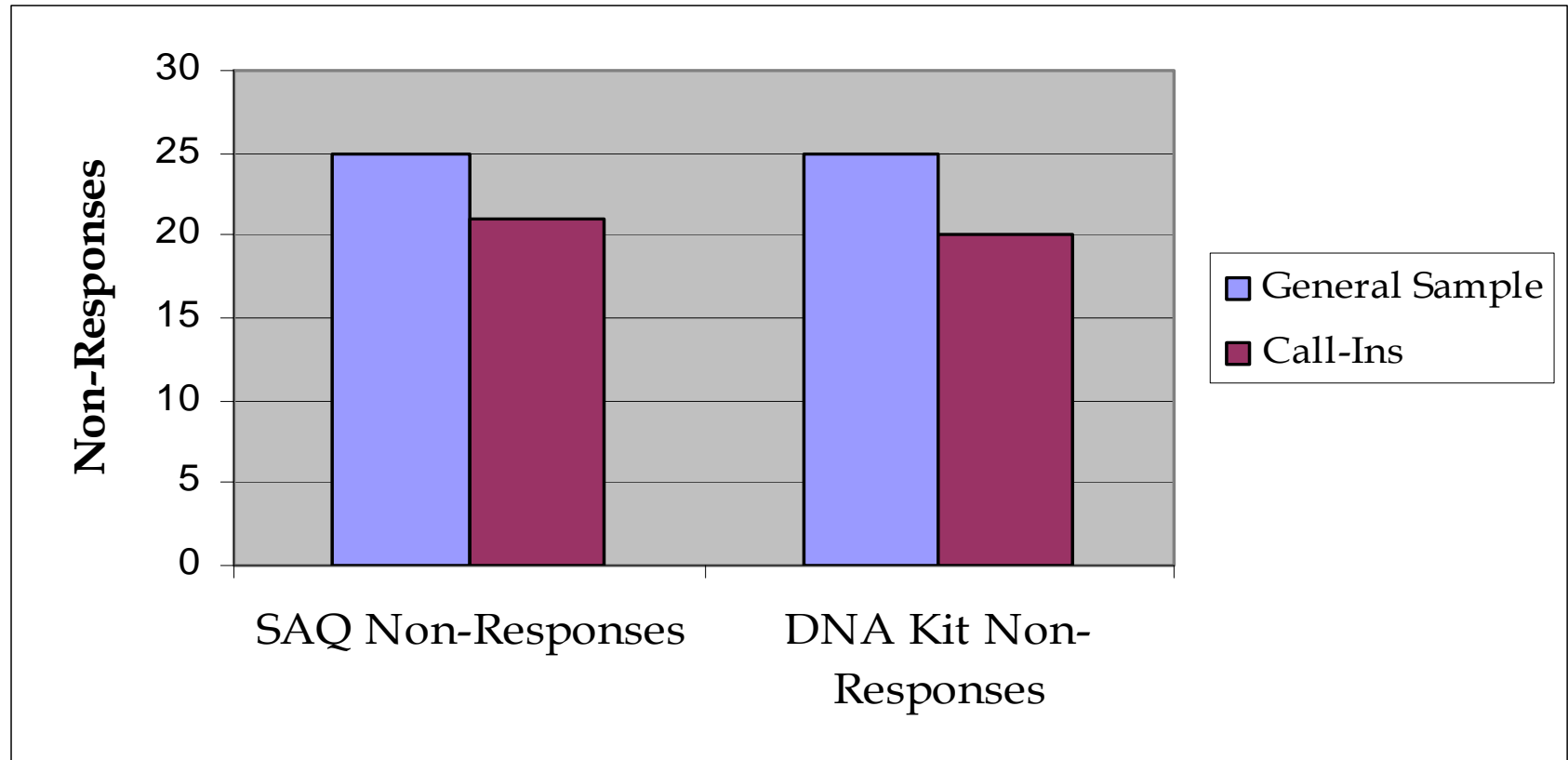


Production Phase Respondent Call-ins

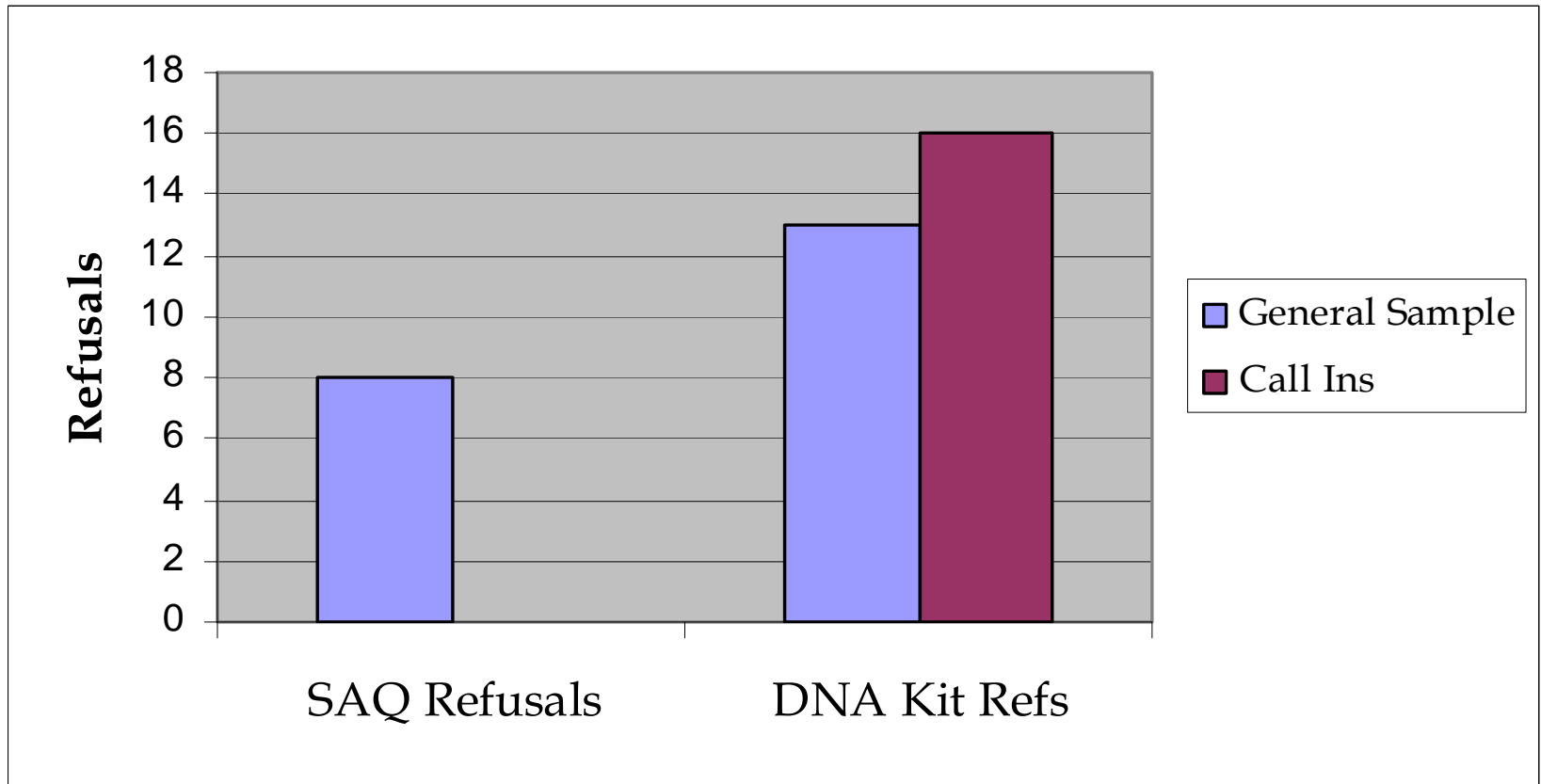
- Just under 200 respondents called in on a toll-free number provided on all points of contact.
 - How did the call-ins compare with the general sample?



Production Phase Respondent Call-ins



Production Phase Respondent Call-ins



DNA Kit Quality Checking (Returned Kits)

- Weighed each kit for saliva content
- Other quality checks:
 - Damaged bio bags / missing bags
 - Cap not screwed on properly
 - Visible saliva spillage
- Successful assays of pilot kits

Special considerations made for collecting sensitive biomedical material

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- Clearly stated consent form signed by respondents
- Saliva samples not accompanied by consent forms receive follow-up and may be “quarantined”
- Unique identifier for saliva kit not displayed on other mailings
- Sterile gloves for staff who are opening mailings
- Secure storage of saliva kits
- Attention to media reports about DNA testing



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Questions and Comments

Ken Croes

Mail Survey & DE Supervisor

University of Wisconsin Survey Center

630 W. Mifflin

Madison, WI 53703

608.261.1089; kcroes@ssc.wisc.edu

<http://www.uwsc.wisc.edu/>

Kerryann DiLoreto Oliver

Project Director

University of Wisconsin Survey Center

1800 University Avenue

Madison, WI 53726

608.265.6598; kdiloret@ssc.wisc.edu

<http://www.uwsc.wisc.edu/>



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