

The Impact of Changes in Informed Consent Language

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Abstract

Requirements for providing informed consent to survey respondents vary greatly. Because informed consent is often one of the first concepts conveyed at an interview's onset, the wording can have an enormous impact on the interview's outcome, especially for telephone interviews. Working within the guidelines of survey research oversight bodies such as Institutional Review Boards is important but can make the task of obtaining informed consent challenging. Choosing language to be read to respondents is a delicate balance between meeting certain requirements and understanding how concepts are perceived. Finding this balance minimizes hang-ups and refusals before the interview can begin.

Since 2005, the informed consent language on the National Immunization Survey (NIS) has undergone several changes. These changes to the NIS informed consent statement provide the opportunity to examine the effects of different language. Our analyses show that certain changes in the informed consent statement can substantially increase break-offs and result in fewer completed interviews. In this paper we examine the impact of informed consent language on the break-off rates at the informed consent question, the overall study eligibility, and the number of completed interviews. Further, by examining the demographic characteristics of those who initially break off at informed consent but later are successfully converted to completed interviews, we explore the differential impact of certain wording changes. We conclude by discussing a data-driven theoretical framework for assessing the impact of changes to an informed consent statement.

The NIS is a nationwide, list-assisted random digit dial (RDD) survey conducted by NORC at the University of Chicago for the Centers for Disease Control and Prevention. The survey monitors the vaccination rates of children between the ages of 19 and 35 months. Each year, the NIS conducts interviews with approximately 24,000 households across the United States.

Key Words: Informed Consent, Break-offs, The National Immunization Survey

1. Introduction

Informed consent in survey research protects the investigator and the survey subject. It is a verbal or written statement offered by the investigator that delineates the risks, protections, and legal authorities related to the research and is usually provided prior to the collection of any survey data. Some of the elements of informed consent, such as guarantees of confidentiality, are considered to be reassuring, while others, such as length of interview, can put off respondents, causing them to refuse or break off an interview (Burks et al. 2005). Because the first few moments of an interview are critical to gaining cooperation, how this information is presented can have an enormous impact on the survey's outcome.

Concern about declining survey response rates over the past two decades, especially in random digit dial (RDD) surveys (Nathan 2001), and the concomitant decline in data quality has spawned research on how to avoid and convert refusals and, to a lesser extent, how to improve the interaction between interviewers and potential respondents at the point of contact (Campanelli et al. 1996; Groves and Couper 1996; Couper 1997). While some level of nonresponse is beyond the interviewer's control regardless of topic or technique, there is a segment of the population whose decision to participate in a survey is made during the first seconds of contact (O'Brien et al. 2006).

Standardized introductions in the form of a script exist to convey information in a consistent and concise manner but leave little room for the interviewer to maneuver the interview's progress. These scripts are not conversational in tone and alert the person answering the telephone to be on guard for an impending request. While the interviewer reads the script, he or she must obtain cues from the respondent to determine whether nonresponse avoidance techniques will be needed (Conrad et al. 2008; Groves et al. 2008). It is during this interaction that information is provided as part of the informed consent process.

Federal regulations (45cfr46§116) specify that human research must at least include a statement that the study involves research, the purpose of the research, the duration of participation, the procedures to be followed, the risks or benefits to participation, an assurance that confidentiality of records will be maintained, a way to contact the Institutional Review Board (IRB), and the information that participation is voluntary and can stop at any time. For RDD surveys, the requirement that written consent be obtained is usually waived. If the interview is recorded, this too must be part of the statement, as must be the survey's sponsor. This information must be conveyed in language that is simple to understand. IRBs review protocols for adherence to these requirements and interpretation of the law. Additional federal regulations about survey research require that the federal laws governing the research be provided upon request.

This analysis describes the impact on the behavior of respondents of wording changes in the delivery of the National Immunization Survey (NIS) informed consent statement. The findings and conclusions in this paper are those of the authors and do not necessarily represent the views of the National Center for Health Statistics, Centers for Disease Control and Prevention, and NORC at the University of Chicago.

The NIS is a nationwide, list-assisted random digit dial (RDD) survey conducted by NORC at the University of Chicago for the Centers for Disease Control and Prevention. The survey employs a quarterly data-collection cycle to monitor the vaccination rates of children between the ages of 19 and 35 months. In 2007, approximately 4.5 million telephone lines were dialed in order to screen 850,000 households for age-eligible children. Interviews were conducted with approximately 24,000 households. Approximately 19,000 of these respondents gave consent to contact their medical provider for shot records so that their child's immunization history could be verified.

Before the informed consent script is read in the NIS, the respondent is told who is calling and why and is then asked, "How many children between the ages of 12 months and 3 years old are living or staying in your household?" (NIS 2005 – 2007). If the respondent answers one or more children, the informed consent statement is read. Once the respondent gives consent, birth dates are obtained to determine study eligibility.

2. Analysis

2.1 Introduction

Since 2005, the NIS has implemented six versions of the information provided as part of the informed consent process (i.e., the informed consent script). Several of the changes in language were requested by the Institutional Review Boards and other regulatory entities. The goal of these changes was to make risks and respondents' rights clearer by providing all required information. It is critical that this information be provided to respondents, but there exists a delicate balance between informing respondents of their rights as study participants and losing respondents before the interview can begin. Due to this delicate balance, revisions to the informed consent statement have had significant effects in break-offs, overall study eligibility, and the number of completed interviews. Examining the impact of language changes in the informed consent script will help inform how this information can be presented to meet both goals of clarifying risks and respondents' rights and minimizing break-offs.

This analysis focuses on major wording changes in the mandatory informed consent script; minor wording changes in the mandatory script and the optional script read only upon request are not examined. We have divided the analysis into three sections. In the first section, language changes and loss of cases at the informed consent statement are discussed briefly for scripts used prior to 2007. In the second section, we examine the scripts used during 2007 data collection in greater depth. In this section, we examine cases that ever broke off at informed consent and the percentage of cases that were converted to give consent. We also investigate the number of cases that reached the informed consent statement and never moved past that point in the interview. We look at the loss and gain of eligible cases in relation to these informed consent statements. In the third section, we examine 2007 data for demographic differences in cases that broke off and eventually completed compared to those that completed and never broke off at the informed consent script.

Data collection in 2007 is the focus of our analysis for several reasons. First, there were two major changes in informed consent during 2007. Second, recent data are likely to better predict future performance related to informed consent than data from several years ago. Third, monetary incentives were offered throughout this time period, and other changes to the NIS questionnaire were minimal.

At the beginning of 2005, the following informed consent statement was read to respondents:

This study is voluntary and is authorized by the U.S. Public Health Service Act. By law, the information you give will be kept in strict confidence and will be summarized for research purposes only. You may choose not to answer any question you don't want to answer or stop at any time. In order to evaluate my performance, my

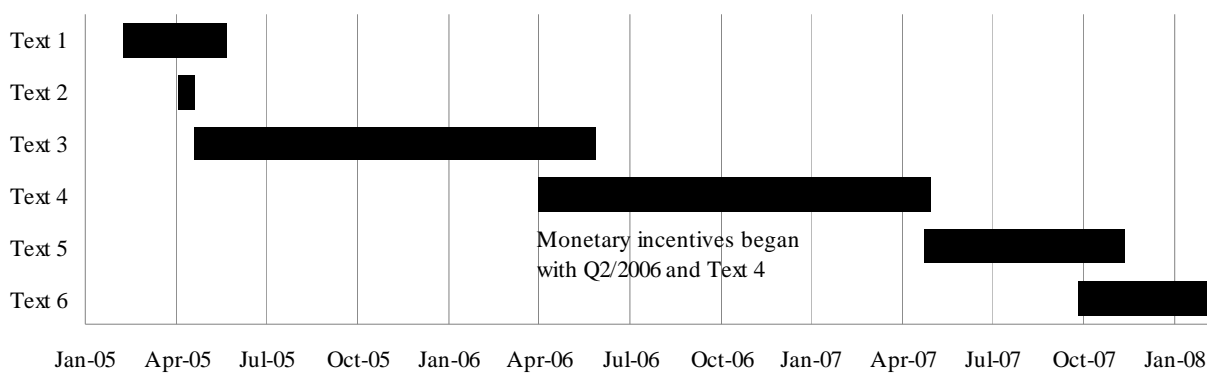
supervisor may record and listen as I ask the questions. I'd like to continue now unless you have any questions. (NIS Q1/2005)

The percentage of cases lost at informed consent was the lowest (at 7.1%) with this text compared to the other 5 texts examined. Over the last three years, the statement has evolved to the following:

Before we continue, I'd like you to know that taking part in this research is voluntary. You may choose not to answer any questions you don't wish to answer, or end the interview at any time. We are required by Federal law to develop and follow strict procedures to protect your information and use your answers only for statistical research. I can describe these laws if you wish. In order to review my work, my supervisor may record and listen as I ask the questions. I'd like to continue now unless you have any questions. (NIS Q4/2007 – Q2/2008)

The following timeline details when the six texts were fielded. The periods of time when multiple texts are in the field are when there are two quarters of data collection open and each quarter is using a different version of the informed consent statement.

Chart 1: Timeline of Informed Consent Text Changes



2.2 Examination of Texts Used Prior to 2007 Data Collection

2.2.1 Text 2 Changes

With Text 2, the informed consent statement was lengthened from 79 words to 99 words, a time estimate of interview length was added, and a sentence was reworded. The phrase “stop at any time” was revised to “end the interview without penalty” (NIS Q2/2005). These changes were implemented to more accurately address all of the required elements in the script. The combination of these changes resulted in a large and significant increase of the number of cases that were lost at the informed consent script and never moved past this statement (Chi-square=158.6, df=1, p<0.0001).

In this analysis, we use the terms “lost at informed consent” and “ever broke off at informed consent.” We define “lost cases” as those that broke off while the informed consent script was being read and for which the NIS was unsuccessful in gaining consent from the respondent on call-back attempts. These cases never moved further into the interview. “Ever break-off cases” are defined as cases that have ever ended the call while the script was being read and before giving consent; these cases may or may not have given consent to continue the interview on subsequent calls. Compared to Text 1, Text 2 had more than double the percentage of cases that were lost and never moved past informed consent at 14.9%.

2.2.2 Text 3 Changes

Given the apparent negative impact of Text 2, this consent script was quickly revised to Text 3. The informed consent statement remained long at 95 words. Text 3 shifted the time estimate to a later point in the screening process and returned to a phrasing similar to Text 1 of “end the interview at any time” (NIS Q2/2005 – Q1/2006). The NIS was able to move the time estimate for two reasons. First, eligibility for the detailed immunization interview based on the child's exact age is determined after the informed consent script is read. Second, the time estimate differs for age-eligible cases depending on whether the household has an immunization record available (i.e., information collected later in the screening process). Moving the time estimate until after these characteristics are known allowed an accurate and more precise timing to be given to all respondents.

Use of Text 3 was accompanied by a significant decrease in the loss of cases at the informed consent text from 14.9% to 13.0% (Chi-square=7.0, df=1, p<0.01).

2.2.3 Text 4 Changes

The change between Text 3 and Text 4 involved rephrasing two sentences that increased the word count of the statement to 105 words. The following two sentences were used in Text 3: “We are required by federal laws to keep your answers strictly private. I can describe these laws if you want” (NIS Q2/2005 – Q1/2006). They were changed in Text 4 to: “We are required by the Public Health Service Act to keep your answers strictly private. I can give you more information on this and other federal laws if you want” (NIS Q2/2006 – Q2/2007). This revision was determined necessary to acknowledge the Confidential Information Protection and Statistical Efficiency Act of 2002, which was described to respondents upon request. The expected impact would be a minor increase in break-offs due to the slightly lengthened statement. Unfortunately, we are unable to isolate the effects of these changes in language because monetary incentives were introduced at the time of this text change. It is not possible to differentiate the effect of the incentive from the effect of informed consent language, because some cases were offered an incentive before the informed consent statement had been read. Not surprisingly, the percentage of cases that never moved past informed consent significantly decreased from 13.0% to 10.2% with Text 4 and the introduction of monetary incentives (Chi-square=320.7, df=1, $p<0.0001$). The percent of cases lost at informed consent for each text fielded is summarized in Table 1.

Table 1: Cases Lost at Informed Consent

	Text 1	Text 2	Text 3	Text 4	Text 5	Text 6
Reached Informed Consent Statement	12,426	2,370	81,024	87,168	19,074	14,302
Informed Consent Read and Consent Given	11,545	2,017	70,463	78,244	16,662	12,836
Percent of Cases Lost at Informed Consent	7.1%	14.9%	13.0%	10.2%	12.6%	10.3%

2.3 Examination of Texts Used During 2007 Data Collection

We will now turn our attention to the language changes and their effects during 2007 data collection. In this analysis, we examine texts 4, 5 and 6 during 2007. Text 4 was fielded from Q2/2006 to the beginning of Q2/2007; in the analysis of 2007 data, only Q1/2007 Text 4 data are examined.

2.3.1 Text 5 Changes

Several major changes were made to the informed consent statement beginning in May 2007. First, the Institutional Review Board (IRB) required reinstatement of the phrase “stop at any time without penalty” (NIS Q2/2007 – Q3/2007). Second, the language promising strict confidentiality had to be modified subsequent to publicity surrounding confidentiality issues at other federal agencies. Text 4, below, did not take into account events outside of our control:

We are required by the Public Health Service Act to keep your answers strictly private. I can give you more information on this and other federal laws if you want. They guarantee that your answers will be used only for statistical research. (NIS Q2/2006 – Q2/2007)

To provide a promise of confidentiality that was technically accurate, Text 5 was reworded to the following:

We will take all possible steps to protect your privacy and are required by law to use your answers only for statistical research. I can describe these laws if you wish. (NIS Q2/2007 – Q3/2007)

As a result of these revisions, the word count decreased from 105 to 94. The number of cases that ever broke off at the informed consent script increased significantly from 18.5% with Text 4 to 23.5% with Text 5 (Chi-square=178.6, df=1, $p<0.0001$). Furthermore, it also became more difficult to convert respondents who had previously broken off under Text 5 to give consent. On the NIS, interviewers trained to handle refusal cases attempt to convert the refusal on call-backs. In this analysis, we are examining the refusal at the informed consent script and the conversion of respondents to give consent to continue the interview. Of cases that broke off at the informed consent statement, 48.9% were converted under Text 4 versus only 46.2% under Text 5 (Chi-square=7.1, df=1, $p<0.01$).

Due to the increase in cases breaking off at the informed consent statement and the decrease in converting these cases to consent, the percentage of cases lost at the script increased. With Text 4 in 2007,¹ 9.4% of cases that reached the informed consent statement were lost and never moved further into the interview, compared to 12.6% with Text 5 (Chi-square=123.2, df=1, $p<0.0001$).

2.3.2 Text 5 Impact on Study Eligibility

The informed consent statement is read after a household indicates it has one or more children between 12 months and 3 years old but before the actual birth dates are obtained. Reading the informed consent statement at that point affects how many eligible households are found. Any decrease in the informed consent rate results in finding fewer eligible cases and

¹ The 2007 analysis only examines Q1/2007 cases for Text 4, which is a subset of Text 4 cases Q2/2006 – Q1/2007.

thus obtaining fewer completes. This was the impact of Text 5 compared to Text 4. To calculate an estimate of lost eligible and completed cases, the four rates required are the informed consent rate, the screener completion rate, the eligibility rate and the interview completion rate. Had Text 4 been fielded instead of Text 5, we assume that all rates seen under Text 5 would have remained the same except for the informed consent rate. For the purpose of this illustration, the screener completion rate and eligibility rate are calculated differently than the NIS published rates. These rates are calculated for cases where the respondent reported that at least one child aged 12 months to 3 years old lives in the household. Age-ineligible households where the respondent reported zero children aged 12 months to 3 years are excluded from the calculation of both rates. Identified households that have not answered the question regarding the number of children 12 months to 3 years old are also excluded from the screener completion rate. These calculations are detailed in Table 2.

Table 2: Estimated Eligible Cases and Completed Cases Lost with Text 5

	Text 5		Net Result
	Actual	Estimate*	
Reached Informed Consent Statement	19,074	19,074	
Informed Consent Rate	87.4%	90.6%	
Informed Consent Script Read and Consent Given	16,662	17,275	-613
Screener Completion Rate**	90.1%	90.1%	
Screened Eligible/Ineligible	15,019	15,572	-553
Eligibility Rate**	50.6%	50.6%	
Eligible for Interview	7,606	7,886	-280
Interview Completion Rate	87.3%	87.3%	
Completed Household Interview	6,638	6,882	-244

* Estimated cases using Q1/2007 Text 4 Informed Consent Completion Rate of 90.6%.

** The Screener Completion and Eligibility Rates are calculated differently than the published NIS rates. For the illustration of eligible cases lost or gained, these rates are calculated for cases where the respondent reported that at least one child aged 12 months to 3 years old lives in the household. Age-ineligible households where the respondent reported zero children aged 12 months to 3 years are excluded from both rates. Identified households that have not answered the question regarding the number of children 12 months to 3 years old are also excluded from the screener completion rate.

We estimate that the Text 5 informed consent statement resulted in screening approximately 553 fewer cases. These 553 cases likely included 280 age-eligible cases, of which approximately 244 would have completed the NIS household interview. For the NIS, 280 eligible cases is a major loss due to the low household-eligibility rate for the survey. During this time period, the eligibility rate for the NIS was 3.08%; if these additional 553 households had been screened, the eligibility rate would have increased to 3.18%. Annually, approximately 30,000 additional households would require screening based on the Text 5 eligibility rate compared to the Text 4 eligibility rate.

2.3.3 Text 6 Changes

As a result of these findings, the NIS informed consent statement was revised to the current script, Text 6, beginning in the final quarter of 2007. At 95 words, Text 6 again replaced “stop at any time without penalty” with “end the interview at any time” (NIS Q2/2007 – Q4/2007). The language about confidentiality was replaced with the following:

We are required by Federal law to develop and follow strict procedures to protect your information and use your answers only for statistical research. (NIS Q4/2007 – Q2/2008)

This promise uses stronger language than Text 5, but it does not return to the absolute language used in the first 4 versions of the informed consent script. While the percentage of cases that ever broke off at the informed consent statement did not return to the Text 4 rate, it did significantly decrease from 23.5% with Text 5 to 21.3% with Text 6 (Chi-square=23.5, df=1, p<0.0001). Table 3 summarizes the differences in the ever break-off rates for the three texts.

Table 3: Percent and Number of Ever Break-offs by Informed Consent

	Text 4	Text 5	Text 6
Yes	18.5% (5,237)	23.5% (4,483)	21.3% (3,041)
No	81.5% (23,142)	76.5% (14,591)	78.7% (11,261)
Total	100.0% (28,379)	100.0% (19,074)	100.0% (14,302)

The conversion rate for cases that have broken off at the informed consent script also improved for Text 6 in comparison to Text 5. The conversion rate increased from 46.2% to 51.8% (Chi-square=22.7, df=1, p<0.0001). Table 4 summarizes the differences in the three conversion rates.

Table 4: Percent and Number of Cases Consenting After Previous Break-off at Informed Consent Script

	Text 4	Text 5	Text 6
Yes	48.9% (2,561)	46.2% (2,071)	51.8% (1,575)
No	51.1% (2,676)	53.8% (2,412)	48.2% (1,466)
Total	100.0% (5,237)	100.0% (4,483)	100.0% (3,041)

As a result, the percentage of cases lost at the informed consent statement decreased from 12.6% with Text 5 to 10.3% with Text 6 (Chi-square=45.7, df=1, p<0.0001).

2.3.4 Text 6 Impact on Study Eligibility

With Text 6, gains are also seen in eligible cases and completed interviews. We estimate that the Text 6 informed consent statement resulted in screening approximately 310 more cases than would have been screened with Text 5. These 310 cases likely included 154 eligible cases, of which approximately 135 completed the NIS household interview. To calculate an estimate of gained eligible and completed cases, we assume that the modified screener completion, the modified eligibility, and the interview completion rates seen under Text 6 remain the same and we apply the Text 5 informed consent rate. These calculations are detailed in Table 5.

During this time period, the eligibility rate for the NIS was 3.08%; if these 310 households had not been screened, the eligibility rate would have decreased to 3.00%. Annually, approximately 23,000 fewer households would require screening based on the Text 6 eligibility rate compared to the Text 5 eligibility rate.

Table 5: Estimated Eligible Cases and Completed Cases Gained with Text 6

	Text 6		
	Actual	Estimate*	Net Result
Reached Informed Consent Statement	14,302	14,302	
Informed Consent Rate	89.7%	87.4%	
Informed Consent Script Read and Consent Given	12,836	12,493	343
Screener Completion Rate**	90.4%	90.4%	
Screened Eligible/Ineligible	11,599	11,289	310
Eligibility Rate**	49.7%	49.7%	
Eligible for Interview	5,759	5,605	154
Interview Completion Rate	87.5%	87.5%	
Completed Household Interview	5,040	4,905	135

* Estimated cases using Text 5 Informed Consent Completion Rate of 87.4%.

** The Screener Completion and Eligibility Rates are calculated differently than the published NIS rates. For the illustration of eligible cases lost or gained, these rates are calculated for cases where the respondent reported that at least one child aged 12 months to 3 years old lives in the household. Age-ineligible households where the respondent reported zero children aged 12 months to 3 years are excluded from both rates. Identified households that have not answered the question regarding the number of children 12 months to 3 years old are also excluded from the screener completion rate.

2.4 Demographic Differences

Finally, it is important to understand if the respondents that break off at the informed consent script and do not complete the interview are demographically different than those that do complete the interview. While we do not know the demographics of the cases that never completed, we do have demographic information for cases that broke off at the informed consent statement and eventually completed. To measure the likelihood of demographic differences in the lost completes, demographic variables for cases that broke off at the informed consent statement and eventually completed versus those that completed and never broke off at the script are compared using 2007 data.

The demographic variables examined are number of children in the household, mother's education, mother's race/ethnicity, household income, and number of residential landline telephones. The demographic variables with significant differences between ever breaking off versus never breaking off at informed consent are mother's education and mother's race/ethnicity as can be seen in Table 6.

Table 6: Demographic Variable Chi-Square Tests on 2007 Data for Texts 4-6

Demographic	Definition	Chi-square	df	p-value
Number of Children	1, 2, 3+	1.46	2	0.48
Mother's Education	less than high school, high school or more	7.89	1	0.01
Mother's Race/Ethnicity	Hispanic, Non-Hispanic White, Non-Hispanic All Other Races	26.83	2	<0.01
Household Income	Below \$10000, \$10000 to \$19999, \$20000 to \$39999, \$40000 to \$59999, \$60000 or more	2.23	4	0.69
Number of Residential Landlines	1, 2, 3+	1.03	2	0.60

Mother's education level is more likely to be high school or more, and mother's race is more likely to be non-Hispanic non-white in cases that have broken off at the informed consent script compared to cases that have never broken off at the script. Therefore, when the NIS is unable to gain consent to continue, it is likely it is losing a higher proportion of mothers with an education level of high school or more and mothers who are non-Hispanic non-white. These demographic differences emphasize the importance of minimizing break-offs at informed consent.

Table 7: Summary of Language Changes to the Informed Consent Script

Element of the Informed Consent Script	Text 1	Text 2	Text 3	Text 4	Text 5	Text 6
Ability to End Interview	"stop at any time"	"end the interview without penalty"	"end the interview at any time"	"end the interview at any time"	"stop at any time without penalty"	"end the interview at any time"
Confidentiality	"By law, the information you give will be kept in strict confidence..."	"We are required by federal laws to keep your answers strictly private."	"We are required by federal laws to keep your answers strictly private."	"We are required by the Public Health Service Act to keep your answers strictly private."	"We will take all possible steps to protect your privacy..."	"We are required by Federal law to develop and follow strict procedures to protect your information..."
Time Length	Later in screener	15 – 25 minutes	Later in screener	Later in screener	Later in screener	Later in screener
Script Length	79 words	99 words	95 words	105 words	94 words	95 words
Percentage of Cases Lost at Script	7.1%	14.9%	13.0%	10.2%	12.6%	10.3%
Percentage of Cases that Ever Broke Off at Script	n/a	n/a	n/a	18.5%	23.5%	21.3%
Monetary Incentives	No	No	No	Yes	Yes	Yes

3. Discussion

The key elements of the examined NIS informed consent script are to inform the respondent that the survey is voluntary, to let him or her know the interview can end at any time, to assure that information will be kept confidential, to provide a time estimate of interview length, to explain that the interview may be recorded, and to ask if he or she has any questions. In this paper, we have investigated three of these items—ending the interview at any time, confidentiality, and interview time length. In addition, we have examined the effect of script length. These six texts reveal several important items to consider when developing an informed consent statement. Table 7 summarizes the history of language changes. It is important to acknowledge that a natural degradation in rates over the last three years also contributes to the impact on rates; however, we are unable to isolate effects due to text changes versus a rate decline that would be seen regardless of language changes.

Using the words “stop at any time without penalty” to inform respondents that they have the ability to end the interview appears to increase the number of break-offs. As a result, the NIS has used alternative wording, such as “end the interview at any time” to convey the same information. The data support the premise that the confidentiality information provided during the informed consent script is key in gaining respondents’ participation in the survey. In the NIS scripts, there were fewer break-offs at informed consent when the words to describe confidentiality were more concrete. Minimizing ambiguity in the confidentiality statement is likely to increase respondents’ participation. Also, the placement of the time estimate for the interview needs to be chosen carefully as increased break-offs occur at that point. The NIS moved its time estimate to a later point in screening in order to provide a better time estimate for respondents. It was also found that scripts with fewer words, that are thus shorter in length, have a smaller number of ever break-offs and lost cases at informed consent.

We have demonstrated that additional break-offs at the informed consent script have significant effects throughout the survey. The loss of cases at this statement affects the number of cases that are found to be eligible for the survey, and, in turn, the number of completed interviews. Based on our findings, it is likely that the cases lost at informed consent are demographically different than those that complete. Therefore, it is important to reduce the number of break-offs at the informed consent script in order to reach as many respondents as possible from different demographic groups.

These findings demonstrate the importance and the challenges of the informed consent script. The words used to convey informed consent impact the entire survey. The challenge is to meet the goal of providing all required information while maintaining or decreasing the break-off rate during the informed consent process.

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