Redesign of an Informed Consent Form to Increase Participation in a School-based Dental Program

Andres A. Mantilla Rodriguez, Armando Soto, & E. Angeles Martinez Mier

Abstract

Objectives: The study aimed to determine if modifications to the design of a consent form and consenting process increased participation rates in the Indiana University School of Dentistry's Mobile School-Based Dental Program (Seal Indiana).

Methods: Kaizen methodology was followed to identify problem areas in the consenting process. Additionally, stakeholders were invited to participate in focus groups and fill out surveys to identify issues preventing participation in the Seal Indiana program (N=48) and later to evaluate the changes made (N=48). The redesigned form and process were then used in a pilot study at 14 sites to determine the impact that changes had on levels of participation as measured by the number of consent forms completed and returned.

Results: There was a statistically significant increase in the number of consent forms returned. The measured change represented a 32% increase in program participation (p-value = 0.035). A statistically significant increase was observed in how participants viewed the attractiveness of the form and how easy it was to read and comprehend.

Conclusions: In order to increase consenting rates, our results indicate modifications to the consent form should be focused on the following characteristics: esthetics, ease of reading and comprehending information, and making the Health Insurance Portability

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and Accountability Act of 1996 (HIPPA) privacy regulations easier to read and comprehend.

Key words: Public health; School-based Dental Program, Community Dentistry; Community-Based Participatory Research; Consent Forms

Introduction

Based on sound evidence and to enhance the availability of preventive dental health services, many states have implemented school based/linked dental sealant programs (SBDSP) to target underserved communities.(1) Said programs strive to facilitate access to preventive and diagnostic dental care services, specifically dental sealants, for low-income children in the most effective manner. Unfortunately, such efforts have not completely addressed population needs, as at the national level 11% of 13-19 year olds, 17% of 6-9 year olds and 14.4% of 3-5 year olds still have untreated decay.(2) Much higher rates of untreated decay have been reported in children screened in the state of Indiana (approximately 50%) and other states (from 36.7% to 63%).(3–5)

In 2003, the Indiana State Department of Health and the Indiana University School of Dentistry forged a partnership to develop the Seal Indiana program and meet the Healthy People goal 2010 of having dental sealants available to Indiana's children.(6) At that time, taking dental services to where underserved children were located - Title I schools, Head Start programs, and homeless shelters was an innovative approach.(7) Since its inception, Seal Indiana's target population has comprised mainly of low-income, school-aged children experiencing barriers in accessing preventive dental services. One hundred percent of the schools served by Seal Indiana are Title I schools, which serve the highest percentages of children from low-income families.

As with any public health endeavor, challenges and opportunities to increase the reach of school-based dental sealant programs exist. Due to how effective these programs are in preventing oral disease when well implemented,(8–12) it is important to

identify barriers that may be contributing to inadequate implementation. The literature has identified low consenting rates as one of the barriers that hinders program implementation and appropriate reach.(13–15) Obtaining a signed informed consent has remained a serious challenge and can result in children, who are most in need of a dental exam and preventive services, including dental sealants, not receiving them. Some of the reported reasons why parents may not sign consent forms are: 1) failure to bring the consent form home or give it to the parents(13), 2) parents' lack of knowledge about the benefits of dental sealants(13,16,17), and 3) other health, social (low health literacy), cultural or family factors (differences in language spoken at home/by parents).(13,16,18)

The objective of the present study was therefore to address one of those barriers by determining the impact of redesigning the consent form and process of a SBDSP at increasing the program's consent rates.

Materials and Methods

The redesign of the consent form and process was accomplished in three phases. The first two phases were iterations necessary for design, while the third phase involved pilot testing of the redesigned form. The process followed to redesign our form is described in figure 1. Changes to the consent form are noted in figure 2.

IRB approval

The study was submitted to the Indiana University institutional review board (IRB) for review. It approved the study under protocol number 1308122949.

Preliminary identification of barriers in process and content

Preliminary identification of barriers was accomplished by the implementation of a Kaizen event with stakeholders. A Kaizen event is a structured performance evaluation for improving efficiency, commonly used by industry. It identifies and analyzes areas that require improvement with the goal of design and implements steps that add value and continues to improve the quality of, in this case, services.(19) The process consisted of the following steps:

1) An inter-departmental team was formed to analyze current waste or loss within different areas such as consenting process and form. Collaborators from; the Indiana University School of Public Health, Indiana University School of Dentistry and Herron School of Art and Design at Indiana University-Purdue University Indianapolis (IUPUI).
2) All steps of the process were outlined and included items like flow of applicable resources, quality measurements, equipment usage, physical distance between steps and the communication involved.
3) Gathered information of each step was considered and each item within each process step was determined to add-value, reduce-value, or non-value activities.
4) Reduce-value items were directed by the team to brainstorm ideas on how to improve consent.
5) Finally, new steps for eliminating or transforming reduce-value and non-value items were developed.

Recruitment/Inclusion criteria for stakeholders

Sites

Two school systems with standing participation in Seal Indiana were identified and approached for collaboration. Seal Indiana delivers dental screenings, sealants, and education throughout the state of Indiana. It takes advantage of school settings to facilitate the delivery of said dental preventive services and education to ensure preventive measures can reach those who need them the most. In order to allow for reproducibility as well as generalization across socio-economic strata, the percentage of children on free meals and student body demographics were used to ensure each school system selected complemented the other in terms of their racial, ethnic and economic make up. Both school systems are in the Indianapolis area and had been participating in the SBDSP for more than three years.

Participants

A health/wellness staff member from the school was the main point of contact for coordinating participant recruitment for the study at each site. After receiving IRB approval, potential participants were identified by the school and given a letter of invitation in their preferred language (Spanish or English). In addition to providing potential participants with a letter of invitation, staff reviewed it and explained that participation was voluntary. These participants were informed that they were being invited into a research study, independent from their children's participation in the SBDSP.

Participants' contact information was captured at that time if they were interested and forwarded to the research study coordinator for follow up. A letter of invitation was

also mailed to each school's parent association informing them about the study so that they could refer interested individuals. Additionally, other school staff were asked to identify possible participants. Interested participants were contacted by the research study coordinator, who extended invitations to participate in the study after inclusion criteria was verified. Eligible participants were encouraged with a small monetary non-coercive compensation. Participants were recruited based on the following criteria: 1) School parents who frequently utilize the health services provided at their child's school and do not have a dental provider; and 2) parents who have previously demonstrated interest in health topics, either because they have expressed a personal need or because they have pointed out the community's need for services. The number of focus groups was not determined a priority; they were conducted until we obtained saturation in each one of the identified categories of groups. We identified the following categories: 1) Parents who spoke English as a first language, 2) Parents who spoke English as a second language, and 3) Administrators. Saturation was defined as the moment when themes showed substantial agreement in each category of group. We planned to run a minimum of two groups per category with approximately 10 participants each, with the possibility of more groups if there was enough initial difference of opinion that it required more data to resolve our understanding of their perspective.

Form Development

Identification of perceived barriers by parents

Survey

Prior to their participation in their respective focus group, participants were asked to complete a survey. The survey evaluated their satisfaction with the consent process and forms through the use a 5-point Likert scale to determine “acceptability scores”,

Focus groups

Focus group methodology was followed to explore the applicability of previously identified barriers to accessing dental care, and to gain insight into parents’ existing knowledge about oral health and accessing the dental care system. Focus groups were guided by open ended questions that define the area to be explored, at least initially, and from where the interviewer or interviewee may diverge to pursue an idea in more detail. Groups were guided by a limited number of questions and dominated by the interviewees such as the following:

Consent:

1. Do you find the information provided easy to read?
2. Do you think the form is attractive (looks nice)?
3. Do you understand the information?
4. Do you understand what a dental sealant is?
5. Do you understand what HIPPA is?
6. Do you understand the value of our services?
7. What would you like different?

Consenting Process:

1. What would be the ideal way to ensure the consent form gets to you and is then returned?

2. What would be the easiest way for you to obtain the consenting form?

3. What could be done so that it is easier for you to turn in the consent form?

Referral Process:

1. What would be the ideal way to ensure the referral is followed through?

2. What would be the easiest way to follow through with the referral?

3. What could be done so that the referral is easier for you to follow?

Interviews were recorded once the interviewee received standardized introductory information. This stage was terminated when the interviewee addressed the list of questions, and no further information stated was relevant. The identification of important points during the interview was based on the researcher's notes. Data were then subject to content analysis.

Consent redesign

Results from the Kaizen event as well as data from focus groups and surveys on consent redesign were analyzed. Thematic analysis yielded areas of focus that were targeted for the redesign. Results from the qualitative analysis were integrated in a new redesigned form by an expert design firm.

Pilot of consent forms

After the consent form was redesigned, it was pilot tested in 14 sites, as part of the normal operation of Seal Indiana. The redesigned consent was used by the SBDSP to acquire consent for their services. Children and parents who received the redesigned form via the new process were not aware of the current study and were not informed that the form or process were new. They also did not receive compensation for returning the form.

Data Analysis

Content Analysis.

The content-analysis was undertaken by one researcher (AMR) with prior training in qualitative methods and a good understanding of dental terminology and issues. A separate investigator who is also familiar with qualitative methods undertook the reproducibility assessment (EAMM). The reliability was evaluated by establishing the stability (intra-coder variability) and the reproducibility (inter-coder variability) of coding in four transcripts randomly selected.

Outcome Measures for perceived changes in the consent form

Two domains for improvement were determined after review of the overall program implementation. A “form” domain included variables to assess form esthetics and ease of comprehension while a “process” domain included variables regarding knowledge components of the consenting process.

Outcome Measures for the effectivity of the consent form and process

To determine whether the redesign of the form had an impact on the number of consented children, return rates were calculated pre and post use of the redesigned form. Percentages were calculated by dividing the number of new consents signed by the total number of students in each grade targeted in each of the schools serviced per year of service.

Statistical Analysis

Pre and Post surveys were entered and cleaned. SPSS 23 was used to perform statistical analysis. Descriptive statistics such as frequencies, percentages and mean were also calculated. Non-parametric tests such as the Kruskal-Wallis Test and Wilcoxon signed-rank test were used. The Kruskal-Wallis Test was used to assess whether there was a statistically significant difference in the consenting process and form domains between pre and post sample points. Wilcoxon signed-rank test was used to assess whether there was a statistically significant difference in the rate of participation between pre and post sample points. Significance thresholds for all analysis were kept at 0.05.

Results

Preliminary identification of barriers in process and consent

Six stakeholders participated in the Kaizen event. Two focus groups with administrators (n = 8 for each focus group) and ten focus groups with parents (n = 8 to 10 per group) were conducted. Data from the Kaizen event and focus groups were analyzed for content. The themes identified by the content analysis in regard to barriers in process and consent are presented in table 1.

Pre and Post Redesign Participant's Perceptions

Investigators collected and examined a total of 96 survey responses (48 pre–redesign and 48 post–redesign). Table 2 shows the frequency distribution and level of significance of the pre–redesign and post–redesign comparison of the variables used to assess the consent form and the consenting process domains. The largest changes were observed in the form domain, in the areas of readability (the information was easy to read); esthetics (how attractive the consent was to the participant); and comprehension (how easily general information and HIPAA information were understood). With regards to the consent process domain, while trends were observed, none of the changes were statistically significant.

Impact of re-design on number of returned consents

Results of the analysis performed to determine whether there was a change in the number of consent forms returned are detailed in table 3. The redesigned consent form was pilot tested in 14 sites with a total population of 6176 children eligible for services. We were able to see a statistically significant increase in the number of completed and returned consent forms from 4.7% (292 out of 6235), to 6.2% (389 out of 6176). This accounted for an increase of 32% in the number of students that participated in the Seal Indiana program.

Discussion

The results of our study revealed key nuances that could be useful when public health professionals seek to improve their SBDPS. Our results showed that of the domains explored, changes to the design of the form itself influenced how easy the

information was to read and comprehend and their willingness to want to sign the consent. This is in agreement with the strategies described by Fletcher and Hunter,(15) who reported that the design of forms influences how clear and easy they are to read. They also concluded that this results in high return rates for consent forms. More specifically, improving the esthetics of the form proved to be the most useful in this endeavor. Making the consent form seem esthetically pleasing makes for a good first impression and sparks interest in its contents. Use of underline, bold and superscripts to concisely convey information can aid the reader and increase the probability that the actual content and substance of the form are given attention.

One area of interest are the forms that need to be distributed to comply with the Health Insurance Portability and Accountability Act of 1996 (HIPPA) regulations and how the perception of these forms relates to the overall experience. While HIPPA forms are mandatory to be distributed and kept by the parents, the language used tends to make the actual content less understandable. This is due to the fact that most of the time, if not all, the form is specifically designed by a program's legal department, with little to no input or regard to conveying message other than what is legally needed. In order to improve the consent form in a way that does not expose the program to legal liability, it is recommended that the legal department and designers are involved from the earliest stages of development or redesign. Doing so will ensure not only legal compliance by the program but also that those that are served by the program are capable to understand their rights under HIPPA privacy rules.

Our results comparing the perception of parents regarding the process of distributing the forms and obtaining consent are comparable to those found in a randomized

controlled clinical trial which compared five interventions to improve consent rates. (20) The authors of that study also reported that none of the interventions made a significant difference when compared to the control group. It is important to note that each school has different protocols and methods to get the forms and health information to caregivers. Standardizing a distribution protocol for every school fails to recognize the diversity not only in procedures that schools have but necessities of the population it is trying to serve. Trying to improve on the existing procedures, while always looking for possible avenues of change, is suggested but needs to be individualized to each school's needs, based on the findings of this study. Most established schools already have in place procedures that have undergone multiple improvement cycles. Seamless integration into this workflow is what is suggested.

Conclusion

Certain limitations of our study merit further discussion. Our results indicated that the recommendations for distribution of the consent forms varied widely and appeared to be influenced by each school's procedures to disseminate information. For that reason, we pose that recommendations for distributing the consent forms and obtaining consent should be individualized for each school. Therefore, generalizing our findings should be done with caution.

Another limitation of our study involves the fact that we cannot discard potential confounders that may have resulted in our observed change in return rates. While we did not create a statistical model to account for any of those variables, the parent population in all of our school is similar in education and socioeconomic level; therefore, we did not anticipate an impact.

Finally, we measured the impact of changes to the consent form by measuring changes in return rates. It can be argued that the true impact of an SBDSP should be measured by its ability to prevent dental caries. Our study was not designed to measure increases in numbers of sealants placed and/or reductions in caries incidence and we therefore cannot assess how changes to the consent form and process may impact these outcomes.

Our findings suggest that if public health professionals seek to increase consent form return rates, special attention should be given to the consent form itself. Moreover, the esthetical characteristics of the form, ensuring the form and HIPPA privacy ensuring the form and easy to read and comprehend will result in better return rates.

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Table 1

Content analysis thematic breakdown from Kaizen event and focus groups

Kaizen event	**Stakeholder focus group**
Consent form	
Ensure redesign form meets compliance standards	Too big
Ensure it is not hard to read	Print too small
	Too much information
Consenting process	
Ensure material is not being wasted	Do not distribute through child
Consent form return rate is low	Mail/email form directly to parent
	Have form available during registration
Referral process	
Referrals are not being followed up	Refer parent through phone or text directly

Table 2

Pre and Post Redesign Frequency Distribution of Participants' Perceptions

		Strongly Disagree		Disagree		Undecided		Agree		Strongly Agree	
		Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post
Consent form domains	The information was easy to read*	8.3	4.2	20.8	10.4	8.3	0.0	41.7	39.6	20.8	45.8
	The consent is attractive*	12.5	2.1	29.2	16.7	25.0	4.2	22.9	41.7	10.4	35.4
	The information is easy to understand	2.1	0.0	14.6	10.4	16.7	2.1	41.7	52.1	25.0	35.4
	It is easy to understand what a dental sealant is	2.1	0.0	10.4	4.2	8.3	2.1	50.0	56.3	29.2	35.4
	It is easy to understand what HIPAA is*	8.3	4.2	20.8	6.3	10.4	8.3	37.5	37.5	22.9	43.8
	It is easy to understand the value of services	6.3	2.1	8.3	4.2	6.3	12.5	43.8	39.6	35.4	41.7
	I would want to sign the consent	6.3	2.1	4.2	8.3	25.0	18.8	35.4	39.6	29.2	31.3
Consenting	I know who to get the consent form from	6.3	0.0	8.3	10.4	10.4	4.2	45.8	54.2	29.2	31.3

Referral process	I know who to give the consent form to	4.2	0.0	12.5	10.4	6.3	10.4	50.0	43.8	27.1	35.4
	I know when to return the consent form	4.2	2.1	14.6	8.3	10.4	8.3	37.5	45.8	33.3	33.3
	I know how to contact a dentist	6.3	4.2	8.3	6.3	16.7	2.1	27.1	37.5	41.7	50.0

* Difference in pre and post responses was statistically significant $p \leq 0.05$

Table 3

Consent Form Return Rates Pre and Post Redesign

	Pre – Redesign			Post – Redesign			P-value
	Returned consents	Sent consents	Rate	Returned consents	Sent consents	Rate	
Site 1	70	562	12.5	83	559	14.8	
Site 2	20	623	3.2	52	552	9.4	
Site 3	42	704	6.0	36	676	5.3	
Site 4	13	366	3.6	19	375	5.1	
Site 5	21	480	4.4	24	484	5.0	
Site 6	19	374	5.1	27	366	7.4	
Site 7	13	474	2.7	11	470	2.3	
Site 8	16	570	2.8	40	608	6.6	0.035
Site 9	14	395	3.5	15	410	3.7	
Site 10	19	418	4.5	16	420	3.8	
Site 11	14	306	4.6	12	316	3.8	
Site 12	15	261	5.7	16	250	6.4	
Site 13	2	477	0.4	15	457	3.3	
Site 14	14	225	6.2	23	233	9.9	
Total	292	6235	4.7	389	6176	6.2	

Figure 1. Seal Indiana form redesign process

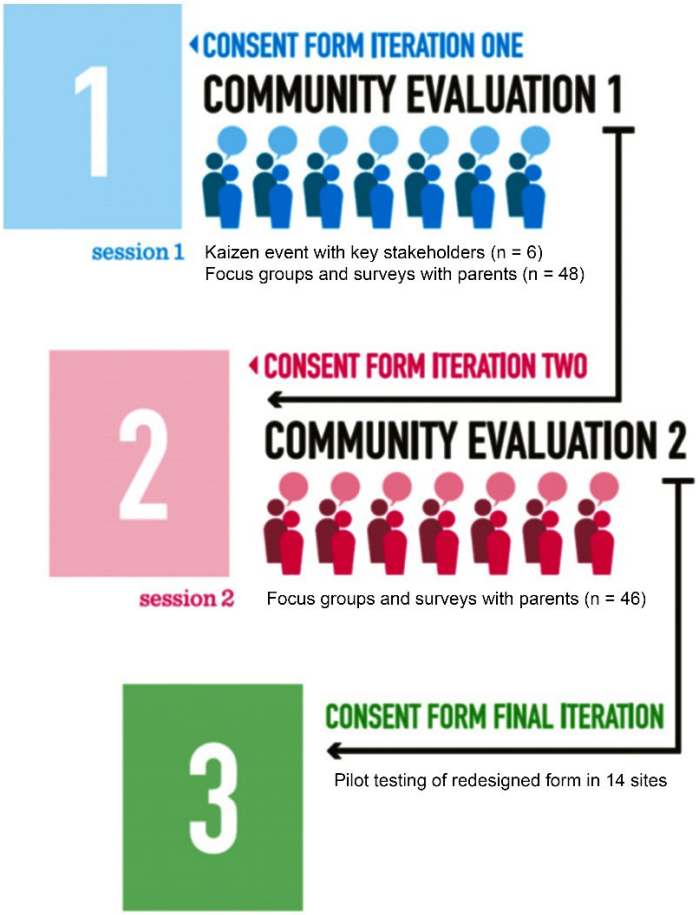
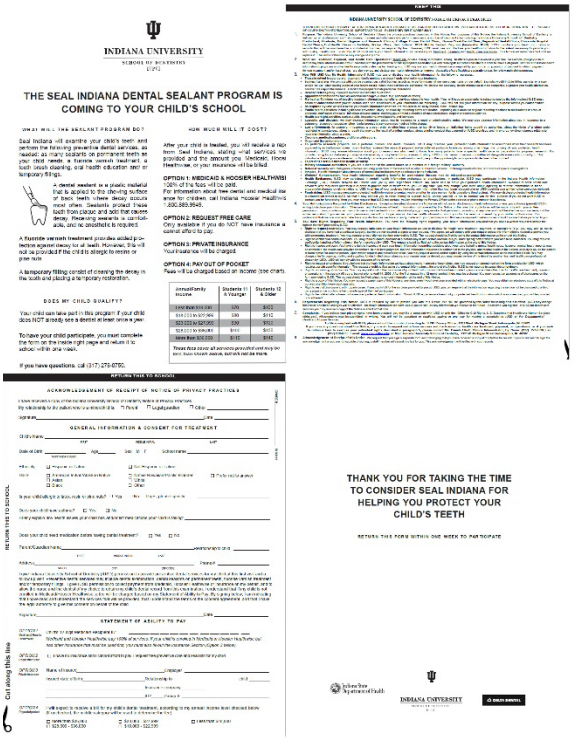


Figure 2. Comparison of Seal Indiana consent forms.

Redesigned form



INDIANA UNIVERSITY
SCHOOL OF DENTISTRY

THE SEAL INDIANA DENTAL SEALANT PROGRAM IS COMING TO YOUR CHILD'S SCHOOL

WHAT WILL THE SEALANT PROGRAM DO?

HOW MUCH WILL IT COST?

DOES MY CHILD QUALIFY?

RETURN THIS TO SCHOOL

ACKNOWLEDGMENT OF RECEIPT OF NOTICE OF PRIVACY PRACTICES

GENERAL INFORMATION & CONSENT FOR TREATMENT

STATEMENT OF ABILITY TO PAY

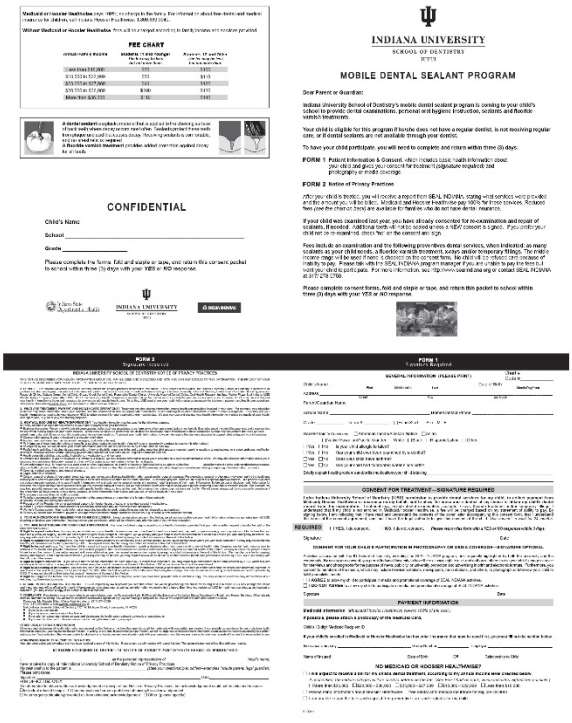
Cut along this line

THANK YOU FOR TAKING THE TIME TO CONSIDER SEAL INDIANA FOR HELPING YOU PROTECT YOUR CHILD'S TEETH

RETURN THIS FORM WITHIN ONE WEEK TO PARTICIPATE

INDIANA UNIVERSITY

Original form



FEE CHART

CONFIDENTIAL

Child's Name

School

Grade

INDIANA UNIVERSITY
SCHOOL OF DENTISTRY

MOBILE DENTAL SEALANT PROGRAM

Dear Parent or Guardian:

FORM 1 Patient Information & Consent

FORM 2 Notice of Privacy Practices

CONSENT FOR TREATMENT—SIGNATURE REQUIRED

PAYMENT INFORMATION

NO MEDICAID OR HOOSIER HEALTHWISE?