

**ASSESSING PHYSICIAN-PARENT COMMUNICATION DURING EMERGENCY MEDICAL
PROCEDURES IN CHILDREN: AN OBSERVATIONAL STUDY OF THE EFFICACY OF THE INFORMED
CONSENT PROCESS IN A LOW-LITERACY LATINO PATIENT POPULATION**

A Thesis submitted to the University of Arizona College of Medicine -- Phoenix
in partial fulfillment of the requirements for the Degree of Doctor of Medicine

Aaron Dahl
Class of 2015

Mentor: Madhumita Sinha, MD

Dedication: To my great mentor Dr. Sinha, without whom this project would not have been possible. To Allie and Eli, my constant inspirations.

Abstract:

Objective: Effective physician-patient communication is critical to the clinical decision making process. The informed consent process for any intervention can be one of the most important moments for effective physician-patient communication in regards to outcome and liability. We studied parental recall of information provided during an informed consent discussion process prior to performance of emergency medical procedures in a pediatric emergency department of an inner city hospital with a large bi-lingual population. **Methods:** Parent/child dyads undergoing emergency medical procedures were surveyed prospectively in English/Spanish, post-procedure for recall of informed consent information. Logistic regression analysis was used; outcome variables were the ability to name a risk, a benefit, and an alternative to the procedure and predictors were language, education, and acculturation. **Results:** Fifty-five parent/child dyads completed the survey. Logistic regression analysis showed that respondents with less than high school education were approximately 80% less likely to be able to name a risk or a benefit, while respondents with a high school education were approximately 24 times *more* likely to be able to name an alternative procedure. **Conclusion:** A gap in communication exists between physicians and patients during the consent taking; it is significantly impacted by socio-demographic factors like education level, language and acculturation.

Table of Contents:

Introduction/Significance 1
Research Methods 2
Results 6
Discussion..... 14
Future Directions/Conclusions 16
References 17

List of Figures and Tables:

Table 1. Comparison of demographic characteristics between English and Spanish respondents 8

Table 2a. Summary of results from the regression model to predict the ability to name a risk associated with the procedure 9

Table 2b. Summary of results from the regression model to predict the ability to name a benefit from the procedure. 10

Table 2c. Summary of results from the regression model to predict the ability to name an alternative to the procedure 11

Table 3: Parental satisfaction rating with individual components of the informed consent discussion process using a Likert scale 12

Table 4: Barriers to effective communication 13

Introduction/Significance (Background):

The informed consent process typically involves a personal exchange of information between a physician and a patient prior to a medical intervention. The physician provides the information so that the patient becomes “informed” and the patient then “consents” or agrees to the procedure.¹ This interaction between a physician and a patient constitutes the essence of informed consent. The signed form is the record that this interaction did indeed occur, but it is not the informed consent itself. There are four critical elements involved in any informed consent process: i) disclosing the nature of the procedure, including whether it is therapeutic or diagnostic, the duration of the procedure and body parts affected; ii) risks involved, general and specific; iii) benefits; and iv) alternatives to the proposed procedure. However, physicians often consider the informed consent process to be an unavoidable medico-legal exercise rather than an opportunity for discussion and information sharing.^{3, 4, 5}

The issue of adequate or effective informed consent has been studied extensively in a variety of clinical and research settings with a variety of outcome measures. One study focused on comprehension of the informed consent process by parents for inclusion of their children with malignant solid tumors in a randomized control trial (RCT) treatment (Germany⁶). Another study measured recall of parents of children requiring emergency surgery as well showing poor recall.⁷ Parents for children requiring a laceration repair in a pediatric emergency department were given the choice of varying types of anesthesia. The elements of informed consent were adhered to, but the outcomes measured were whether or not the parents felt they wanted to be active in the decision-making process.⁸

It is generally accepted that patients and parents should be included in the decision-making process as well as studies demonstrating poor recall. However, literature relating to adequacy of informed consent and parent comprehension of information provided to them for medical procedures in an emergency department is surprisingly lacking. Additionally, in an underserved population, physician-patient communication is likely to be hindered further by factors such as language, education, and socio-cultural barriers. These barriers contribute to the poor health literacy skills of patients and parents. Studies have shown that almost 25% of parents in the

United States have limited health literacy that is likely to affect their ability to obtain and process health-related information needed to make health-related decisions for their children.⁹ The objective of the present study was to assess parent/guardian recall of information provided to them during the informed consent process prior to performance of medical procedures in the pediatric emergency department (ED) of an inner-city hospital serving primarily a low-literacy population and those with English as a second language (ESL). We also sought to identify barriers to effective communication in this environment.

Research Methods:

Study Design:

A convenience sample of pediatric patients who presented to the pediatric ED and required a specific medical procedure for which an informed consent was mandated were enrolled prospectively over a 6-month period between August 2012 and February 2013. The Institutional Review Board of the hospital approved the study.

Study Setting:

The study was conducted in the pediatric ED of a 449-bed inner-city tertiary care teaching hospital with an annual volume of approximately 19,000 visits. The pediatric ED serves a predominantly low-socioeconomic, low-literacy Latino patient population. A prior study published in the same ED assessed access to health care issues and recruited a sample of 385 patient families; 91.7% of these patient families were Hispanic most were poor (67.8% families reported household incomes less than 100% of the Federal Poverty Level), and 80.8 % used Spanish as their primary language at home. ¹⁰

Study Subjects:

Patients (0-18 years) registered in the pediatric ED who required a specific medical procedure during their ED stay for which a pre-procedure informed consent was mandated from a parent/guardian underwent a detailed post-procedure survey addressing each discrete element of informed consent information. Specific medical procedures included lumbar puncture, incision and drainage of abscesses, repair of complex lacerations, excision of ingrown toenail, and fracture reduction. Patients with life-threatening emergencies, where informed consent is deferred and emergency procedures are performed with two-physician concurrence, were excluded, as well as incarcerated patients and patients from juvenile detention facilities.

Parents/guardians of eligible patients were offered participation by a Research Assistant or a trained ED staff member after their child had undergone the medical procedure but prior to discharge. The research staff explained the study purpose to parents in detail, including potential risks and benefits of participation. If parents expressed interest in study participation,

the staff provided the survey in the either English or Spanish, as they preferred. The research staff was available on site to answer any queries and explain contents of the survey via certified bilingual (English/Spanish) interpreters who are available at all times in our institution. English and Spanish-speaking families represent the majority of the patient population for this pediatric ED, therefore, the survey and instruction was available in only these two languages. Participants returned the completed survey to the ED staff prior to their departure from the ED.

Data Collection:

Demographic data, including age of the parent providing the consent for procedure, parent's gender, ethnicity, and level of education, were obtained and entered into a data collection form. The data collection form also included the name of the procedure, and parent/guardian acculturation was assessed using the Brief Acculturation Scale for Hispanics-BASH (Norris 1996).

¹¹The BASH uses language as a measure of acculturation. It consists of a brief 4-item questionnaire pertaining to the subject's choice of language in different situations.

Survey Instrument:

A post-procedure survey was designed to assess parental recall of informed consent information and potential barriers to communication (Appendix 1a & 1b). The survey was anonymous, deployed in both English and Spanish, self-administered, and had two specific components: Part I of the survey comprised questions designed to assess parent/guardian's comprehension and understanding of the procedure that their child underwent. This section of the survey specifically addressed the four elements considered key to any informed consent discussion process: nature of the procedure, risks, benefits, and alternatives to the procedure. Parents were asked to grade their experience and satisfaction with the physician-patient discussion and information delivery process on a 5-point Likert scale (*Excellent* =5 and *Very Poor* = 0). Mean aggregate and individual scores for each category were calculated. In addition, respondents were asked to recall at least one benefit, one risk from the procedure, and one alternative to the procedure that their child had undergone. Part II of the survey included questions designed to assess factors likely to impact physician-patient

communication, including barriers such as language, literacy, limited time, stress with hospital visit, and personal beliefs (physician status/role).

The English and Spanish versions of the survey were pretested using the Flesch-Kincaid readability test ¹² at a 7th-8th grade reading level (Flesch-Kincaid) and pilot-tested on a select group of prototype patients prior to study commencement to ensure adequate flow, length, and ease of navigating the questions; minor changes were made to suit the target sample in a busy ED environment. The Institutional Review Board waived informed consent requirements for the study due to the survey being anonymous and low risk to the patient.

Statistical Analysis:

We used descriptive statistics to summarize sample attributes and *t*-tests or chi-square tests to compare demographic and clinical characteristics, and satisfaction scores between English and Spanish respondents. We also used logistic regression to assess the influence of demographic factors on health literacy. ¹³ Outcome variables were the ability to name a risk, the ability to name a benefit, and the ability to name an alternative to the procedure. Predictors were language, education, and acculturation. For all statistical tests, we used a significance criterion of 0.05.

Results:

A convenience sample of 55 parent-child dyads undergoing medical procedures for which an informed consent was mandated were recruited prospectively in the pediatric ED over a six-month period between August 2012 and February 2013. Thirty-two (58.2%) parents completed the post-procedure survey in English, while Spanish was the language of choice in 23 (41.8%) cases. Complex laceration repair (36.4%) was the commonest procedure for which consent was obtained, followed by lumbar puncture (23.6%), incision and drainage of abscesses (10.9%), fracture reduction (9.1%), excision of ingrown toe nail (7.3%), and other unspecified procedures (12.7%). Approximately half (49.1%) of the parents who provided consent for their child's procedure were between 25-34 years of age, and a majority of the respondents were female (83.6%) and Hispanic (78.2%). Comparison of demographic characteristics between English and Spanish respondents showed that parents whose language of choice was Spanish tended to be female, with predominantly less than a high school education and an overwhelmingly low acculturation level (Table 1).

Results of the regression analysis showed that respondents with less than a high school education were approximately 80% less likely to be able to name a risk or a benefit (Table 2a and 2b), while respondents with a high school education were approximately 24 times *more* likely to be able to name an alternative procedure (Table 2c). This latter finding should be interpreted with caution, however, due to the rather large confidence interval of the odds estimate. Of the respondents with less than a high school education, 29% were between the ages of 18 and 34, and 16% were older than 35. Of the respondents with a high school education, 22% were between the ages of 18 and 34, and 9% were older than 35.

Parental satisfaction with informed consent discussion: Parental satisfaction with the discussion process on individual components of informed consent information was rated on a 5-point Likert scale. Mean scores were calculated based on individual parental ratings and showed high satisfaction levels (*mean scores >4.5 in all components*) among both English and Spanish respondents for all components of the informed consent discussion (Table 3).

Potential barriers to physician-patient communication: Parents were also asked if they had any unanswered questions which they would have liked to have clarified but did not do so and the reason for withholding their question. Of those who responded affirmatively, a majority held the belief that their physician knew what was best for their child, thereby affirming the paternalistic role of a physician. A few also cited language as being a barrier to communication (Table 4).

Table 1. Comparison of demographic characteristics between English and Spanish respondents.

Demographic characteristics	English Respondents N=32	Spanish Respondents N=23	P value
Gender <ul style="list-style-type: none"> Female 	24 (75%)	22 (95.6%)	0.04 ^{!*}
Age (SD) <ul style="list-style-type: none"> 18-24 Years 25-34 years 35-44 years 45-54 years 55-64 years 65 years or older 	9 (28.12%) 16 (50%) 3 (9.38%) 4 (12.5%) 0	2 (8.7%) 11 (47.82%) 7 (30.43%) 2 (8.7%) 1 (4.35%)	0.11 ^{\$}
Highest level of education completed by parent? <ul style="list-style-type: none"> Less than high school High School College or above 	8 (25%) 12 (37.5%) 12 (37.5%)	17 (73.9%) 5 (21.75%) 1 (4.35%)	0.001 ^{!*}
Acculturation using the Brief Acculturation Scale for Hispanics (BASH) <ul style="list-style-type: none"> Low 	6 (30%) [N=20 parents Hispanic]	23 (100%)	0.00 ^{!*}

[!] Chi square test, ^{\$} Fisher exact, *P<0.05

Table 2a. Summary of results from the regression model to predict the ability to name a risk associated with the procedure.

Predictor	Coefficient	SE	z value	p value	Odds ratio	95% CI
Language <i>(English vs. Spanish)</i>	1.34	1.04	1.29	0.20	3.81	0.49, 31.96
Education <i>(Less than high school)</i>	-1.69	0.78	-2.16	0.03*	0.18	0.04, 0.83
Acculturation <i>(Low vs. high)</i>	-0.20	1.13	-0.18	0.86	0.82	0.09, 8.24

* $p < .05$, coefficient = regression weight, SE = standard error, z = standardized test statistic

Table 2b. Summary of results from the regression model to predict the ability to name a benefit from the procedure.

Predictor	Coefficient	SE	z value	p value	Odds ratio	95% CI
Language (English vs. Spanish)	-0.19	1.29	-0.15	0.88	0.82	0.03, 8.36
Education (Less than high school)	-1.58	0.84	-1.88	0.06*	0.21	0.04, 1.03
Acculturation (Low vs. high)	-1.37	1.29	-1.06	0.29	0.25	0.01, 2.68

*Marginally reliable at alpha = .05, coefficient = regression weight, SE = standard error, z = standardized test statistic

Table 2c. Summary of results from the regression model to predict the ability to name an alternative to the procedure.

Predictor	Coefficient	SE	z value	p value	Odds ratio	95% CI
Language (English vs. Spanish)	2.19	1.80	1.22	0.22	8.92	0.22, 505.03
Education (High school)	3.17	1.27	2.49	0.01*	23.87	2.77, 632.35
Acculturation (Low vs. high)	-0.01	1.58	-0.01	0.99	0.99	0.03, 31.98

* $p < .05$, coefficient = regression weight, SE = standard error, z = standardized test statistic

Table 3: Parental satisfaction rating with individual components of the informed consent discussion process using a Likert scale (Excellent =5 and Very Poor = 0)

Constructs	Mean Score (SD) N=55	Mean Score (SD) English Respondents N=35	Mean Score (SD) Spanish Respondents N=23	P*
Told procedure name	4.87 (\pm 0.39)	4.88 (\pm 0.34)	4.87 (\pm 0.46)	0.96
Told what the procedure was being done for	4.91 (\pm 0.29)	4.94 (\pm 0.25)	4.86 (\pm 0.35)	0.37
Specified body part/s involved	4.91 (\pm 0.29)	4.94 (\pm 0.25)	4.87 (\pm 0.34)	0.40
Discussion regarding risks involved	4.78 (\pm 0.53)	4.8 (\pm 0.59)	4.7 (\pm 0.45)	0.62
Discussion regarding benefits involved	4.80 (\pm 0.45)	4.81 (\pm 0.48)	4.78 (\pm 0.42)	0.81
Discussion regarding alternatives to procedure	4.6 (\pm 0.97)	4.63 (\pm 0.91)	4.57 (\pm 1.08)	0.85

* *Independent Samples Test*

Table 4: *Barriers to effective communication.*

Barriers identified	Percentage
<p>Language:</p> <ul style="list-style-type: none"> • I do not speak English well. 	<p>5 (9.1%)</p>
<p>Literacy:</p> <ul style="list-style-type: none"> • I could not understand what was written on the form. 	<p>2 (3.6%)</p>
<p>Situational anxiety:</p> <ul style="list-style-type: none"> • I did not have time to think through all questions I would like to ask. • I was too anxious because of my child's illness. 	<p>1 (1.8%)</p> <p>1 (1.8%)</p>
<p>Physician role/status:</p> <ul style="list-style-type: none"> • I feel the doctor knows what is best for my child. • I do not feel comfortable questioning the doctor. 	<p>17 (30.9%)</p> <p>1 (1.8%)</p>

Discussion:

Health literacy is an important contributor to disparities in healthcare.^{14, 15} Health literacy relates to a person's ability to understand health-related information and use that information to make appropriate health choices for themselves and their families.¹⁶ In an ED setting, one of the frequent instances in which health literacy issues come into play is during the consent-taking process. Although informed consent for medical procedures is an ethical and legal necessity, there is not only little uniformity in its deliverance² but also lack of awareness among healthcare providers regarding the need to assess a patient's health information comprehension and assimilation capabilities. In an ED environment, time constraints and an inherent urgency for rapid clinical decision making and execution may override an in-depth discussion process, leading to inadvertent omission or insufficient explanation of one or more of the critical elements of informed consent to the patient. This is the first study that attempts to document actual parent understanding of informed consent information for procedures in an ED setting. In addition, we have also focused on barriers to physician-parent communication in the setting of a low-literacy bilingual patient population.

Historically, physicians have assumed a paternalistic role and decided what was best for their patient. However, current practice advocates empowering patients so that they are well informed and able to participate as equal partners in the medical decision-making process. However, in our study we observed that parents' education level was correlated with the ability to recall specific details of an informed consent discussion such as naming a benefit, risk, or alternative. In a recent study, Yin et al. assessed health literacy and numeracy among Spanish-speaking parents of young children and found these parents to have significant difficulty in understanding basic health information related to the care of their children.¹⁷ Bottrell et al., in a prior study, reviewed informed consent for procedure forms from different institutions nationwide and found that only 26.4% of the 540 different informed consent forms included all four of the principal elements.²

Our study has a few limitations. It was conducted at a single center with a unique patient population, and the results may not necessarily be generalizable. Although the survey was anonymous, it was vulnerable to the usual potential bias associated with self-reporting.

Parents may not have been completely forthcoming with their assessment of the quality of informed consent decision and may also have been influenced by social desirability bias so that they reported being very satisfied with the discussion without full comprehension of the contents and details of the discussion. This was evidenced by the high parent satisfaction scores in spite of the inability of some parents to specifically name at least one risk, benefit, or alternative in the large majority of cases. Additionally, because the informed consent experience between the physician and parent was not recorded or scripted, it would be difficult to distinguish cases where a physician did not include all essential elements of an the informed consent vs. the information was not comprehended.

Another limitation of this study includes the number of participants, representing a low power. While we recognized that a larger subject pool was optimal, our recruitment of participants was limited by on the on the general flow of the pediatric ED as well as a small number of research and medical staff trained in enrolling participants. This study in turn acts as a convenience study that a larger future study can follow and further confirm its results.

Future Directions/Conclusions:

To ensure effective health communication, the gap in physician-patient communication needs to be well understood and closed. Future studies should involve devising effective strategies to standardize the informed consent process and create consistency in its delivery, recognize specific barriers to communication, and tailor the message in a culturally sensitive manner so that a patient is a well-informed stakeholder and decision maker in his/her own medical care. This may lead to an improvement in the overall quality of care and the outcomes of medical treatment.

References:

1. Devettere RJ, Making Health Care Decisions (Chapter IV), in, Practical Decision Making in Health Care Ethics, Georgetown Univ. Press, 2010
2. Bottrell MM, Alpert H, Fischbach RL, Emanuel LL. Hospital informed consent for procedure forms: Facilitating quality patient-physician interaction. *Arch Surg.* 2000;135(1):26-33.
3. Gaeta T, Torres R, Kotamraju R, Seidman C, Yarmush J. The need for emergency medicine resident training in informed consent for procedures. *Acad Emerg Med.* 2007;14(9):785-789.
4. Katz JN, Daltroy LH, Brennan TA, Liang MH. Informed consent and the prescription of nonsteroidal anti-inflammatory drugs. *Arthritis Rheum.* 1992;35(11):1257-1263.
5. Engel KG, Heisler M, Smith DM, Robinson CH, Forman JH, Ubel PA. Patient comprehension of emergency department care and instructions: Are patients aware of when they do not understand? *Ann Emerg Med.* 2009;53(4):454-461.e15.
6. Chappuy H, Bouazza N, Minard-Colin V, et al. Parental comprehension of the benefits/risks of first-line randomised clinical trials in children with solid tumours: A two-stage cross-sectional interview study. *BMJ Open.* 2013;3(5):10.1136/bmjopen-2013-002733.
7. Li FX, Nah SA, Low Y. Informed consent for emergency surgery--how much do parents truly remember? *J Pediatr Surg.* 2014;49(5):795-797.
8. Yamamoto LG, Young LL, Roberts JL. Informed consent and parental choice of anesthesia and sedation for the repair of small lacerations in children. *Am J Emerg Med.* 1997;15(3):285-289.
9. Yin HS, Johnson M, Mendelsohn AL, et al. The health literacy of parents in the United States: a nationally representative study. *Pediatrics.* 2009;124(Suppl 3):S289-S298.
10. Ferayorni A, Sinha M, McDonald FW. Health issues among foreign born uninsured children visiting an inner city pediatric emergency department. *J Immigr Minor Health.* 2011 Jun;13(3):434-44.
11. Norris, A, Ford, K, Bova, C (1996). Psychometrics of a Brief Acculturation Scale for Hispanics in a Probability Sample of Urban Hispanic Adolescents and Young Adults. *Hispanic Journal of Behavioral Sciences* 1(18): 29-38.

12. Flesch-Kincaid Grade Level Test. Available at <http://office.microsoft.com/en-us/word-help/test-your-document-s-readability-HP010148506.aspx>. Accessed on 06/05/12.
13. R Core Team (2012). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. Available at <http://www.R-project.org/> Accessed on 04/08/13.
14. Sanders LM, Thompson VT, Wilkinson JD, et al. Caregiver health literacy and the use of child health services. *Pediatrics*. 2007;119: e86–e92.
15. Osborn CY, Paasche-Orlow MK, Davis TC, et al. Health literacy: an overlooked factor in understanding HIV health disparities. *Am J Prev Med*. 2007;33(5):374–378.
16. Schwartzberg JG, Van Geest JB, Wang CC, eds. *Understanding Health Literacy: Implications for Medicine and Public Health*. Chicago, Ill: AMA Press; 2005.
17. Yin HS, Sanders LM, Rothman RL, Mendelsohn AL, Dreyer BP, White RO, et al. Assessment of health literacy and numeracy among spanish-speaking parents of young children: validation of the Spanish Parental Health literacy Activities Test (PHLAT Spanish). *Acad Pediatr*. 2012;12:68–74.