HHS Public Access

Author manuscript

Am J Perinatol. Author manuscript; available in PMC 2024 May 23.

Published in final edited form as:

Am J Perinatol. 2024 May ; 41(Suppl 1): e187–e192. doi:10.1055/a-1863-2141.

Video-assisted informed consent in a clinical trial of resuscitation of extremely preterm infants: Lessons learned

Namrita J. Odackal, DO,
Neonatology, North Denver Envision Group; 8318 Cole St, Arvada, CO 80005

Catherine G. Caruso, DO,
Department of Pediatrics, Oregon Health & Science University

Melissa Klitzman, MD,
Division of Neonatal-Perinatal Medicine, Indiana University School of Medicine

Monica Rincon, MD, MCR,
Department of Obstetrics and Gynecology, Oregon Health & Science University

Bobbi J. Byrne, MD,
Division of Neonatal-Perinatal Medicine, Indiana University School of Medicine

Jameel Winter, MD,
Division of Neonatology, University of Minnesota Medical School

Gina R. Petroni, PhD,
Department of Public Health Sciences, University of Virginia

Karen D. Fairchild, MD,
Division of Neonatology, University of Virginia School of Medicine

Jamie B. Warren, MD, MPH
Department of Pediatrics, Oregon Health & Science University

Abstract

OBJECTIVE: Obtaining informed consent for clinical trials is challenging in acute clinical settings. For the VentFirst randomized clinical trial (assisting ventilation during delayed cord clamping for infants <29 weeks' gestation), we created an informational video that sites could choose to use to supplement the standard in-person verbal and written consent. Using a post-consent survey, we sought to describe the impact of the video on subject recruitment, satisfaction with the consent process, and knowledge about the study.

STUDY DESIGN: Descriptive survey-based sub-study.

Corresponding author: Namrita J. Odackal, DO, Neonatology, North Denver Envision Group; 8318 Cole St, Arvada, CO 80005, namrita.j.odackal@gmail.com.

Author Contributions*:* NJO designed this study and is primary author of this manuscript. JW created the consent video. MR did the Spanish video translation. NJO, CC, MK, MR, BB, KF and JBW recruited and surveyed participants for the study. All authors were involved in editing the manuscript.

Conflict of Interest: The authors have no conflicts of interest or competing financial interests in relation to the work described.

RESULTS: Of the four sites participating in the VentFirst trial that chose to allow use of the video to supplement the standard informed consent process, three elected to participate in the survey sub study. From February 2018 to January 2021, 82 women at these three sites were offered the video and completed the post-consent survey. Overall, 73 of these 82 women (89%) consented to participate in the primary study, 78 (95%) indicated the study was explained to them very well or extremely well, and the range of correct answers on 5 knowledge questions about the study was 63%-98%. Forty-six (56%) of the 82 women offered the video chose to watch it. There were no major differences in study participation, satisfaction with the consent process, or knowledge about the study between the women who chose to watch or not watch the video.

CONCLUSION: Watching an optional video to supplement the standard informed consent process did not have a major impact on outcomes in this small sub-study. The ways in which audiovisual tools might modify the traditional informed consent process deserve further study.

Introduction:

The informed consent process is a critical part of the ethical conduct of clinical research, allowing potential study subjects to make voluntary decisions based on knowledge of possible benefits and risks of study participation. In the acute or critical care setting, there are numerous barriers to optimal informed consent, and despite recommendations that informed consent forms (ICF) should be short and written at a 6th grade reading level, a report from one large research center found that ICFs were, on average, 10 pages long and written at a 12th grade reading level [1]. Important aspects of clinical trials are often misunderstood [2,3] and educational level may impact understanding and participation [2,4]. Additional challenges exist when obtaining consent from a woman with threatened preterm birth for her newborn's participation in a clinical trial involving delivery room resuscitation. Development of tools to facilitate and enhance the consent process could be useful.

A small body of evidence demonstrates the utility of audiovisual tools in improving participant understanding of clinical trials as well as satisfaction with the consent process [5,6]. A Cochrane Review of 16 trials (some real and some mock studies) found that the addition of audiovisual elements to the standard informed consent process may marginally improve knowledge about the trial but may not impact willingness to participate [7]. A study using a hypothetical clinical scenario in pregnant women reported that addition of a video to the consent process improved consent rates and retention of trial-based knowledge [8].

We developed a short, supplemental video to improve information delivery and facilitate the standard consent process for a randomized clinical trial involving delivery room resuscitation of extremely preterm infants (VentFirst RCT). All sites participating in the VentFirst trial were given the option to use the video to supplement the standard consent process involving a written Informed Consent Form (ICF) and giving potential subjects an opportunity to ask questions about the trial. Three sites chose to use the video, with Institutional Review Board (IRB) approval. To begin to understand the impact of video-assisted consent, we conducted a survey of women offered the video as part of the consent process. We sought to compare outcomes including decision to participate in the trial,

knowledge about the potential benefits and risks, and satisfaction with the consent process in the women who chose to watch or not watch the optional video.

Materials/Subjects and Methods:

Primary Study:

In the VentFirst multi-center randomized clinical trial (NCT02742454), mothers expected to deliver at an estimated gestational age of 23 0/7 to 28 6/7 weeks' gestation are approached for consent to be randomized to a standard delivery arm (delayed cord clamping for 30-60 seconds with respiratory support after cord clamping) or an intervention arm (delayed cord clamping for 120 seconds with respiratory support given by a neonatology provider starting 30 seconds after birth while still attached to the placental circulation). The primary outcome is decreased incidence of intraventricular hemorrhage (IVH) of any grade on head ultrasound 7-10 days from birth.

A video was created to supplement the standard verbal and written informed consent process at sites that chose to use it. The video is approximately 7 minutes long and was made available to parents through a website for viewing on a computer, phone, or tablet device. The video describes the study, including the primary outcome and potential risks, and shows a simulated resuscitation in the standard and intervention arms. A version translated into Spanish was also available.

Consent Process:

The standard consent process at all VentFirst study sites involves an IRB-approved written ICF given to potential subjects by a study team member trained in the consent process. The study is explained and potential subjects are allowed time to read the ICF and have questions answered prior to deciding whether to participate. All VentFirst study sites were offered the opportunity to use the consent video, which required site IRB approval.

Of the 12 sites participating in the VentFirst RCT, four sites elected to use the consent video, and individuals trained in the consent process were given the option of offering the video. If the video was offered, the mother and other family members were encouraged to watch the video either with a study team member or on their own.

Questionnaire Sub-study:

Three of the four study sites that chose to use the video elected to participate in the survey sub-study, University of Virginia (site 1), Oregon Health & Science University (site 2), and Indiana University (site 3). A brief questionnaire was developed, IRB approved, and administered with consent to women who were approached about the VentFirst study from February 2018 to January 2021. Women were approached up to 5 days after completing the consent process for the primary study and asked to participate in the questionnaire sub-study. If the mother consented, the questionnaire was administered by study personnel in person or over the phone, in English or with a Spanish interpreter. Survey questions included preferred learning mode (seeing, hearing, reading), education level, and comfort level with reading medical information such as information about prescription medications.

Eight questions specific to the VentFirst consent process were included in three categories: decision to participate in the RCT (1 question), knowledge about the study (5 questions), and satisfaction with the consent process (2 questions).

Statistical Methods:

Data in the tables are presented as number (percent). The Chi-square test was used to assess differences in the characteristics of the mothers in the two study populations, “watched video” and “did not watch video” (Table 1). P <0.05 was considered statistically significant. Differences in the proportions that responded ‘correctly’ to survey questions about recruitment, knowledge, and satisfaction in the two study populations (Table 2) were presented as absolute differences with 95% Agresti-Caffo confidence intervals (CI). Differences in responses to survey questions based on whether the mothers’ preferred learning method was seeing versus hearing or reading (Table 3) were similarly presented as absolute differences with 95% Agresti-Caffo CIs.

Results:

During the 3-year time period of this questionnaire sub-study, 206 women were approached for consent for the VentFirst RCT at the 3 sites that had IRB approval to use the consent video. Of these, 146 were approached about the questionnaire sub-study, and 100 consented and completed it. Eighteen women indicated on the survey that they did not remember being offered the video. We limited subsequent analysis to the 82 women who completed the questionnaire and remembered being offered the opportunity to watch the consent video. Of these, 46 (56%) chose to watch the video and 36 (44%) chose not to watch. Characteristics of mothers completing the survey are shown in Table 1. Women who watched the video were more likely to indicate their preferred learning method was “seeing” (Chi-square p-value = 0.006). There was not a significant difference in watching or not watching the video based on the mothers’ level of education or reporting needing help reading medication prescriptions.

Table 2 shows a summary of survey responses based on whether mothers chose to watch or not watch the video, including the absolute difference in percentages with 95% CIs for a favorable response in the “watched video” compared to the “did not watch” groups. No major differences were noted between responses as indicated by the 95% CIs including 0%; however, larger true differences are feasible based upon assessments of the upper and lower limits of the CIs. Generally, understanding was lowest for questions concerning jaundice and timing of initiating respiratory support in the two arms of the study (correct answers ranging from 63-70%). The impact of the study intervention on IVH, the primary outcome of the study, was answered correctly by 76% of mothers who watched the video and 83% who did not watch, an observed difference that was not significant (absolute difference −7% (−24,11)). Of the mothers who answered the IVH question correctly, 89% consented to participate in the VentFirst study and of those who answered it incorrectly 88% consented.

Though numbers are small, the significant observed difference in the study populations for preferred learning method prompted further evaluation of answers to the eight survey questions based on whether women preferred to learn by seeing (32/82 or 39%) versus

learn by hearing or reading (25/82 or 30% each). Results are displayed in Table 3. A larger percentage of women who learn best by seeing and who did watch the video consented to participate in the VentFirst trial when compared to women who learn best by seeing and did not watch the video. Although most intervals still include 0, the magnitude of observed differences and CI limits support the need for further research in a more targeted population.

Discussion:

Since obtaining informed consent for a clinical trial can be difficult in the setting of threatened preterm birth, we created a video to supplement the standard consent process for the VentFirst RCT, which involves providing respiratory support during delayed cord clamping for extremely preterm infants. Only 4 of 12 participating sites elected to use the video and for those sites, offering the video was optional, as was participating in the post-consent questionnaire sub-study. We undertook this study to assess the impact of watching the video, and though conclusions are limited by the small number of questionnaires completed, we present a description of our findings as well as lessons learned. The main findings were that, for this population, watching the video did not impact the decision to participate in VentFirst RCT, knowledge about the VentFirst RCT, or satisfaction with the consent process. The main lesson learned is that larger, more rigorous studies are needed to determine the ways in which a video might (or might not) improve a variety of different outcomes for potential study subjects and for the research team.

Generally, we found that decision to participate, knowledge about the trial, and satisfaction with the consent process were high among all women who completed the video questionnaire, irrespective of whether they chose to watch the consent video. We developed the video with several goals in mind. First and foremost, we sought to better inform potential study participants of potential benefits and risks of the research, in light of increasing emphasis on ethical conduct of clinical trials, particularly in vulnerable populations [1–4]. We felt that having the opportunity to view the video one or more times, and to share it with other family members, could reinforce information presented in the ICF. Another motivation for creating the video was to facilitate the consent process off-hours when research coordinators may not be available and instead physicians working in the NICU who may be less familiar with the details of the study are responsible for carrying out the consent process.

Interactive media tools are increasingly accessible and a number of advantages of video-assisted informed consent have been suggested. A Cochrane review of 16 trials of adding a video to the traditional informed consent process (including both real and mock trials) reported a trend toward greater satisfaction and knowledge about the trial with videos[7]. We did not find differences in consent rates, knowledge about the trial, or satisfaction among women who chose to watch the video we created. Knowledge about the primary outcome (reduced IVH) was not increased among women who watched the video and completed the questionnaire. In fact, the observed trend was in the opposite direction, but this was not significant. This raises the possibility that offering a short video to supplement the traditional consent process might not have the intended consequence of better understanding of potential benefits and risks, as has been reported in other studies [7]. An additional

consideration is that a one-size-fits-all approach to informed consent may not be appropriate. Learning styles may impact which consent tools lead to greater understanding, as suggested by the positive trend among women in this study who indicated a preferred learning style of "seeing," watched the video, and answered knowledge questions about the study correctly.

There are a number of limitations to this survey, the major one being that only four of the study centers chose to use the consent video and only three participated in the post-consent survey. We speculate that centers that chose not to use the video felt their research teams could provide sufficient explanation of key aspects of the study to complement the detailed informed consent form. Another limitation is that we did not assess satisfaction of the research team members with the consent process at the three sites that used the video. Despite these limitations, including the small number of survey respondents, we feel it is important to describe our experience and findings, adding to a small number of reports involving informed consent for research in a stressful environment in which parents are asked to provide consent for their child. Obtaining consent for research is particularly difficult in the setting of threatened preterm birth, in which many women are under tremendous physical and emotional stress and may be on medications such as magnesium, which could impact their ability to fully participate in the informed consent process. Additionally, there is often limited time to obtain consent. For these reasons a number of clinical trials involving immediate post-birth resuscitation have allowed deferred consent [9–12]. This and other alternatives to the traditional informed consent process may be required in order to complete adequately powered trials involving resuscitation of extremely preterm infants [13].

Conclusions:

Although we cannot draw definitive conclusions about the value of the consent video we developed for the VentFirst RCT, we can comment on lessons learned. First, it is possible that a video does not have a large impact on subjects' understanding of important aspects of the study, beyond the knowledge gained from the traditional consent process with a lengthy ICF and a research team member explaining and answering questions about the study. Second, we did not study the impact of the video on research team members' satisfaction with or time required for the consent process. It is possible, particularly in acute situations such as threatened preterm birth, that a video will make the consent process feasible when time and resources are limited. And finally, the ability to carry out large clinical trials involving delivery room resuscitation will be improved with further study of innovative methods of obtaining informed consent, or the increased use of alternatives such as verbal assent followed by full informed consent after delivery are allowed, but this must be done within the bounds of ethical conduct of research.

Acknowledgements:

The authors would like to acknowledge the mothers that consented to participate in this sub-study.

Funding:

The primary VentFirst trial is funded by NIH (HD087413).

References:

1. Larson E, Foe G, Lally R. Reading level and length of written research consent forms. Clinical and Translational Science. 2015;8(4):355–356. [PubMed: 25580939]
2. Joffe S, Cook EF, Cleary PD, Clark JW, Weeks JC. Quality of informed consent in cancer clinical trials: a cross-sectional survey. Lancet. 2001;358(9295):1772–1777. [PubMed: 11734235]
3. Behrendt C, Golz T, Roesler C, Bertz H, Wunsch A. What do our patients understand about their trial participation? Assessing patients' understanding of their informed consent consultation about randomised clinical trials. Journal of Medical Ethics. 2011;37(2):74–80. [PubMed: 21098797]
4. Alexa-Stratulat T, Neagu M, Neagu AI, Alexa ID, Ioan BG. Consent for Participating in Clinical Trials - Is it Really Informed? Developing World Bioethics. 2018;18(3):299–306. [PubMed: 29933502]
5. Fanaroff AC, Li S, Webb LE, et al. An observational study of the association of video-versus text-based informed consent with multicenter trial enrollment. Circulation: Cardiovascular Quality and Outcomes. 2018;11(4):1–10.
6. Sonne SC, Andrews JO, Gentilin SM, et al. Development and pilot testing of a video-assisted informed consent process. Contemporary Clinical Trials. 2013;36(1):25–31. [PubMed: 23747986]
7. Synnot A, Ryan R, Prictor M, Fetherstonhaugh D, Parker B. Audio-visual presentation of information for informed consent for participation in clinical trials (Review). Cochrane Database of Systematic Reviews. Published online 2014.
8. Weston J, Hannah M, Downes J. Evaluating the benefits of a patient information video during the informed consent process. Patient Education and Counseling. 1997;30(3):239–245. [PubMed: 9104380]
9. Katheria A, Reister F, Essers J, et al. Association of umbilical cord milking vs delayed umbilical cord clamping with death or severe intraventricular hemorrhage among preterm infants. JAMA. 2019;322(19):1877–1886. [PubMed: 31742630]
10. Duley L, Dorling J, Pushpa-Rajah A, et al. Randomized trial of cord clamping and initial stabilization at very preterm birth. Archives of Disease in Childhood, Fetal and Neonatal Edition. 2018;103(1):F6–F14. [PubMed: 28923985]
11. Katheria A, Poeltler D, Durham J, et al. Neonatal resuscitation with an intact cord: a randomized clinical trial. The Journal of Pediatrics. 2016;178:75–80.e3. [PubMed: 27574999]
12. Kirpalani H, Ratcliffe SJ, Keszler M, et al. Effect of sustained inflations vs intermittent positive pressure ventilation on bronchopulmonary dysplasia or death among extremely preterm infants: the SAIL randomized clinical trial. JAMA. 2019;321(12):1165–1175. [PubMed: 30912836]
13. Rich WD, Katheria AC. Waived consent in p/neonatal research - when is it appropriate? Frontiers in Pediatrics. 2019;7:493. [PubMed: 31850290]

Key points:

Informed consent in acute clinical contexts is difficult.

Videos offer an alternative communication tool.

Continued research is necessary to optimize the consent process.

Table 1:

Characteristics of mothers completing survey

		Watched video (n=46)	Did not watch video (n=36)	Total participants (n=82)	Chi-sq p-value
Site		**n (%)**	**n (%)**	**n (%)**	
	1	21 (46%)	19 (53%)	40 (49%)	0.23
	2	13 (28%)	13 (36%)	26 (32%)	
	3	12 (26%)	4 (11%)	16 (19%)	
Preferred learning method					
	Seeing	25 (54%)	7 (19%)	32 (39%)	0.006
	Hearing	11 (24%)	14 (39%)	25 (30%)	
	Reading	10 (22%)	15 (42%)	25 (30%)	
Highest level of education					
	6^{th}-8^{th} grade	1 (2%)	0	1 (1%)	0.09
	9^{th}-12^{th} grade	22 (48%)	10 (28%)	32 (39%)	
	Undergraduate	19 (41%)	17 (47%)	36 (44%)	
	Graduate	4 (9%)	9 (25%)	13 (16%)	
Need help reading medical information					
	Often	0	2 (6%)	2 (2%)	0.10
	Sometimes	9 (20%)	8 (22%)	17 (21%)	
	Rarely	14 (30%)	16 (44%)	30 (37%)	
	Never	23 (50%)	10 (28%)	33 (40%)	
Primary language					
	English	42 (91%)	35 (97%)	77 (94%)	0.27
	Spanish	4 (9%)	1 (3%)	5 (6%)	

Table 2:

Survey responses from women offered the consent video

		Watched Video (*n*=46)	Did not watch video (n=36)	Absolute Difference watched vs did not
Survey questions, favorable or correct response in *bold italics*:		***n* (%)**	***n* (%)**	***Abs Diff % (95% CI)***
Recruitment	Q1: Did you agree to participate in the study? ***Yes***	42 (91%)	31 (86%)	5% (−9, 20)
Knowledge	Q2: Do you get to choose which study arm you are in? ***No***	43 (93%)	32 (89%)	4% (−8, 18)
	Q3: What is the potential effect on risk of intraventricular hemorrhage? ***Decreased***	35 (76%)	30 (83%)	−7% (−24, 11)
	Q4: What is the potential effect on hyperbilirubinemia (jaundice)? ***Increased***	29 (63%)	23 (64%)	−1% (−21, 20)
	Q5: When is the umbilical cord clamped in the intervention arm? ***Later***	45 (98%)	35 (97%)	1% (−8, 10)
	Q6: When is respiratory support given in the intervention arm? ***Sooner***	32 (70%)	24 (67%)	3% (−17, 23)
Satisfaction	Q7: How well was the study explained to you? ***Extremely/Very well***	44 (96%)	34 (94%)	2% (−9, 13)
	Q8: How well do you feel you understand the study? ***Extremely/Very well***	40 (87%)	32 (89%)	−2% (−16, 13)

Table 3:

Difference in correct/favorable survey responses for women who watched versus did not watch the video, based on preferred learning style.

		Prefer Seeing (n=32)	**Prefer Hearing/Reading (n=50)**
Watched the video n (%)		25 (78%)	21 (42%)
Survey questions		***Abs Diff Watched vs Did not (95% CI)***	***Abs Diff Watched vs Did not (95% CI)***
Recruitment	Q1 consent	21% (−11, 55)	0% (−18, 18)
Knowledge	Q2 study arm	−4% (−19, 26)	4%(−16, 22)
	Q3 IVH	13% (−19, 49)	−19% (−42, 5)
	Q4 bilirubin	−14% (−39, 25)	−7% (−33, 21)
	Q5 cord clamp time	All correct both groups	−1% (−17, 12)
	Q6 resp. support time	43% (2, 72)	−9% (−33, 16)
Satisfaction	Q7 explanation	Same in both groups	−3% (−20, 14)
	Q8 understanding	−8% (−24, 24)	−5% (−27, 16)