Introduction

Informed consent (IC) is an essential communication between the patient and physician that acknowledges patient autonomy in medical testing and treatment. IC involves understanding of several key elements: (1) the nature of the procedure; (2) risks and (3) benefits of the procedure; and (4) alternatives to the procedure [1]. In pediatrics, parents/guardians assume responsibility for IC on behalf of the child/adolescent. However, youth under age 18 should not be excluded from medical decision-making. In 1995, the American Academy of Pediatrics recommended that youth should be included in health care decision making through the parallel process of assent [2].

While performance of IC for procedures involving significant risk is legally mandated, many IC studies of adult patients and parents of pediatric patients have demonstrated suboptimal comprehension of key IC elements [3–6]. Similarly, we demonstrated poor comprehension of key IC elements by children and adolescents undergoing pediatric endoscopy [7].

IC comprehension interventions have largely targeted adults. Effective interventions utilize various media formats [8]. Multimedia educational tools have also been effective in teaching youth, adolescents, and young adults (11–29 years) about health maintenance and their health conditions [9, 10]. In this study, we evaluated whether viewing an IC video in addition to standard IC discussions would lead to greater IC comprehension in youth undergoing endoscopic procedures and their parents.

Patients and methods

We employed a randomized controlled study design to evaluate the efficacy of a video intervention augmenting IC discussions in improving parental and youth IC comprehension. Sample size was based on our prior work and selected to detect a 30% difference in comprehension scores between the intervention v. control group [7]. The local Institutional Review Board approved the study. Informed consent and assent were obtained prior to all study procedures.

Subjects

Subjects were youth (ages 7–17 years) undergoing gastrointestinal endoscopy at a tertiary-care academic children’s hospital and their parents. The study population was a convenience sample of youth undergoing endoscopy at an academic children’s hospital and their parents.
sample, and youth and parents were recruited in pairs and were English-speaking.

Each youth-parent pair was randomly assigned to either (a) view a video detailing key elements of IC (intervention) along with standard of care or (b) receive standard of care (where the parent receives the consent form to read) prior to undergoing IC discussions with the proceduralist (blinded to study assignment group) on the day of the endoscopy. Randomization occurred at the time of enrollment using permuted blocks. Following IC discussions, youth and their parents underwent separate structured interviews in private rooms to assess IC comprehension. Demographic data were collected and medical charts were reviewed to collect health information and procedural data.

Video design
Short (2 minutes, 43 second), animated videos were designed addressing the nature of the procedure, risks, benefits, and alternatives for upper and lower endoscopy, respectively, using PowToon (www.powtoon.com), incorporating multimedia instructional design principles promoted by Mayer and Moreno [11] (e.g., combining words, graphics and/or audio to improve learning; using audio to explain graphics rather than words; avoiding unnecessary graphics, etc. to minimize cognitive load; keeping related pieces of information together and in usable smaller chunks; and using visual, auditory, or temporal cues to draw attention to critical elements of the lesson. Sixth grade language was used throughout the video. Videos were shown to youth and their parents on an iPad and are available for viewing under Supplemental Information.

IC process comprehension assessment
As performed in our prior study [7], youth and their parents underwent separate scripted, structured interviews in private rooms to assess comprehension of key IC elements (i.e., the nature, risks, benefits, and alternatives of the procedure). Interviewees received points for understanding key IC elements and reporting qualified answers (as determined by a single rater (not the proceduralist) and according to items listed in ▶Table 1a and predetermined based on prior work [7]). An Informed Consent Overall Score (ICOS: range 0–4) for comprehension was calculated from tallied points according to ▶Table 1a.

Statistical methods
Success of randomization was evaluated using the Student’s t-test or chi-squared analyses to examine demographic variable distributions by study group assignment. Youth (the entire cohort) were categorized into 2 age groups: child (age 7–12 years) v adolescent (13–17 years). IC comprehension outcomes were calculated as detailed in ▶Table 1a. Overall IC comprehension (represented as the informed consent overall score [ICOS]) was calculated based on whether key IC elements (nature, risks, benefits, and alternatives of the procedure) were understood (ICOS = nature of the procedure + risks of the procedure + benefits of the procedure + alternatives to the procedure) where 1 point was given for understanding of each key IC element; thus the ICOS range was 0 to 4. Because understanding the nature and risks of the procedure involved understanding of more than one information element (e.g. understanding of the nature of the procedure would require understanding that an instrument would be used, that biopsies and pictures would be taken, and where in the gastrointestinal tract the procedure would take place), these IC comprehension outcomes were calculated as subscores (▶Table 1b) and only if subscores reached a certain threshold (Subscore ≥ 3 for nature of the procedure and ≥ 2 for risks of the procedure) was 1 point given for understanding the key element for calculation of the ICOS. IC comprehension outcomes were compared according to study group assignment and by age group (▶Table 2). Complete comprehension (a perfect score) was also evaluated for the ICOS score and for key IC elements (i.e., nature of the procedure, subscore = 4; risks of the procedure, subscore = 3). Multivariate analyses of ICOS outcomes were performed entering study group assignment, age group, and whether parent or child had previously undergone the procedure (▶Table 3). Statistical analyses were performed using JMP 11 statistical software (Cary, NC).

Results

Study population
Seventy-seven youth-parent pairs participated with 37 pairs randomly assigned to the intervention group. Median (interquartile) age of youth participants was 13 years (range 9–15). Over half (53%) of participating youth were female and 38% were Hispanic. All youth underwent upper endoscopy and 23% underwent combined upper and lower endoscopy. All procedures were diagnostic with biopsies performed. Two control youth underwent polypectomy. Forty-three percent of youth (47% of controls and 38% of intervention group) had previously undergone the same endoscopy procedure, and 26% had a chronic gastrointestinal illness.

Comprehension outcomes by study group
Overall, intervention recipients demonstrated higher overall informed consent comprehension (ICOS) compared to control counterparts (mean (standard deviation): 3.6 (0.7) v. 2.9 (0.9), intervention v. control parents P = 0.0001; 2.7 (1.1) v. 1.1 (1.0), intervention v. control children, P = 0.0006; 4.2 (0.6) v. 2.2 (1.2), intervention v. control adolescents, P = 0.0001: ▶Table 2). Specifically, significantly higher comprehension scores were seen for the intervention group as compared to controls for risks of and alternatives to the procedure in parents; for nature of and risks of the procedure in adolescents, and for risks of the procedure in children.

In regards to complete understanding of key IC elements (ICOS score = 4), most intervention parents (69%) demonstrated complete understanding of key IC elements as compared to only 43% of controls (P = 0.0002, ▶Table 3). Among youth, none of the children demonstrated complete understanding of key IC elements, while more adolescents in the intervention group demonstrated complete understanding v. control adolescents (P = 0.03, ▶Table 3). In particular, intervention parents
demonstrated significantly higher complete comprehension of procedural risks (Risks of the Procedure subscore = 3) and alternatives, while intervention children demonstrated higher rates of complete comprehension of the risks of the procedure as compared to controls, and intervention adolescents demonstrated higher complete comprehension rates of the nature (Nature of the Procedure subscore = 4) and risks of the procedure (Table 3). Overall, adolescents demonstrated higher complete comprehension rates in all IC element areas (Table 3) and ICOS scores as compared to children (Table 2).

In multivariate analysis (Table 4a), intervention group and age continued to have significant effects on IC comprehension scores in youth, while repeat procedure did not. Similarly, in parents, only the intervention group continued to have significant effects on IC comprehension scores, while the repeat procedure group did not (Table 4b).

Discussion
To improve IC comprehension for pediatric endoscopy in youth and their parents, we designed a short, animated video intervention addressing key IC elements. We demonstrated higher levels of comprehension in parents and youth who viewed an instructional video in addition to the IC discussion as compared to parents and youth engaging in the IC discussion alone.

Health literacy is the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions [12]. Numerous studies have demonstrated that low health literacy leads to poor health outcomes such as higher utilization of emergency services, more hospitalizations, incorrectly taking medications, and, in certain populations, higher mortality [13, 14]. The National Center for Education Statistics (NCES) found that most adults read between 8th- to 9th-grade reading levels [15], and an updated NCES evaluation [16] demonstrated that 34% of adults tested had Below Basic or Basic

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**Table 1a** Calculation of overall informed consent comprehension (Informed Consent Overall Score (ICOS), nature of procedure, and risks of the procedure.

| Component of understanding | Points awarded if understood |
|---------------------------|-----------------------------|
| Nature of procedure (understood [if scored at least 3 points\(^1\)]; not understood) | 1 |
| Risks of procedure (understood [if listed at least 2 risks\(^1\)]; not understood) | 1 |
| Benefits of procedure (understood; not understood)\(^2\) | 1 |
| Alternatives to procedure (understood; not understood)\(^3\) | 1 |
| **Total available score** | **4** |

\(^1\) ICOS = nature of procedure + risks of procedure + benefits of procedure + alternatives to procedure.
\(^2\) Subjects need only list one of the benefits to the procedure to qualify for understood.
\(^3\) Subjects need only list one of the alternatives of the procedure to qualify for understood.

**Table 1b** Calculation of nature of procedure and risks of procedure subscores.

| Nature of procedure: Range 0–4 |
|-------------------------------|
| Element of understanding | Points awarded if understood |
| That a scope/camera/instrument would be used (understood: not understood) | 1 |
| That biopsies would be taken (understood: not understood) | 1 |
| That pictures would be taken (understood: not understood) | 1 |
| Identification of at least one location in the gastrointestinal tract that the scope would examine (e.g., stomach for upper endoscopy and large intestine for colonoscopy) | 1 |
| **Total available score** | **4** |

| Risks of procedure: Range 0–3 |
|------------------------------|
| Element of understanding | Points awarded if Understood |
| Bleeding | 1 |
| Infection | 1 |
| Intestinal perforation | 1 |
| **Total available score** | **3** |
document literacy skills, where basic literacy comprises adults who can read and understand information in short, commonplace prose texts and locate easy identifiable quantitative information to solve simple 1-step math problems. However, most health care materials are written at a 10th-grade reading level [17]. Recommendations to improve health literacy have included simplifying written materials to 6th-grade reading level, providing pictures, and correcting font size and text crowding [17].

With the increasingly common use of mobile technologies, health education methods are increasingly capitalizing upon media-based methods of communication that appear to improve comprehension independent of literacy and education levels [18, 19]. Similarly, we utilized a video format incorporating multimedia principles with language at a 6th-grade reading level to improve comprehension, which we demonstrated in parents. However, in children, intervention effect varied by age. Youth aged 7 to 12 years demonstrated lower comprehension scores than adolescents, suggesting that videos directed towards youth should target a lower grade reading level to maximize comprehension.

Effective IC interventions targeting adults have included audiovisual aids, enhanced consent forms with simplified language and diagrams, and decision trees [20]. The few studies that have been conducted in minors addressing IC comprehension have been for clinical trials and not for standard medical procedures [21 – 24]. In our study, we evaluated an IC intervention for a common invasive diagnostic procedure and demonstrate that youth and parents who received a multimedia informed consent intervention demonstrated significantly greater comprehension scores as compared to youth and parents who did not.

Obtaining consent from minors is controversial in the very young; however, as youth reach adolescence, obtaining assent prior to procedures and risky medical treatments is increasingly advocated [2]. A smooth transition from child-oriented to adult-based health systems is an important healthcare goal for youth with chronic disease advocated by national health agencies with initiation of the process by 14 years [25]. For youth with chronic gastrointestinal disease, repeat endoscopic procedures are often an obligatory part of medical surveillance and evaluation. Including these adolescents in the consent process for endoscopy should be part of transition preparation.

There were study limitations. First, our study was performed at a single pediatric tertiary care center. Second, we only studied English-speaking subjects and we did not perform a literacy assessment. Translation of our intervention to Spanish is an important next step in our line of investigation given the demonstrated higher prevalence of inadequate health literacy in Spanish-speaking patients v. English-speaking patients. [26]. Last, while we did standardize the intervention video, we could not standardize for the IC discussion between proceduralist and youth/parent. Nevertheless, entry of proceduralist as a covariate in performed analyses did not change study outcomes.

**Conclusion**

In this study, we demonstrated that short, animated videos addressing key elements of the IC process for pediatric endoscopy were effective in improving IC comprehension in both youth and their parents. Multimedia interventions can effectively improve IC comprehension and begin to address health literacy issues related to the IC process in this population.

**Editor’s note**

Video content is free to request from the authors.

| Comprehension score (range) | Intervention group | Control group | P value |
|-----------------------------|--------------------|---------------|---------|
| Overall comprehension score (0 – 4) | Parent (P): 3.6 (0.7) Youth (Y): 2.7 (1.1) | P: 2.9 (0.9) Y: 1.7 (1.1) | <0.0001 |
| Nature of procedure (0 – 4) | P: 3 (0.9) Y: 2.9 (1.1) | P: 3 (0.7) Y: 2.4 (0.9) | 0.6 |
| Benefits of procedure (0 – 1) | P: 1 (0) Y: 0.8 (0.4) | P: 1 (0.2) Y: 0.8 (0.4) | 0.16 |
| Risks of procedures (0 – 3) | P: 2.8 (0.5) Y: 2.5 (0.8) | P: 1.2 (1.0) Y: 0.6 (0.9) | <0.0001 |
| Alternatives to procedure (0 – 1) | P: 0.7 (0.5) Y: 0.2 (0.4) | P: 0.4 (0.5) Y: 0.2 (0.4) | <0.004 |

Results expressed as mean (standard deviation). Youth = Child (7 – 12 years) and Adolescent (13 – 17 years).
Table 3  Complete informed consent comprehension percentages by study and age group.

| Informed consent element                                                                 | Intervention group | Control group | P value |
|----------------------------------------------------------------------------------------|--------------------|---------------|---------|
| Nature of procedure (Subscore = 4)                                                     | Parent (P): 97 %   | P: 98 %       | 1       |
|                                                                                       | Youth (Y): 86 %    | Y: 55 %       | 0.003   |
|                                                                                       | Child (C): 79 %    | C: Child 44 % |         |
|                                                                                       | Adolescent (A): 94 % | A: Adolescent 63 % |       |
| Benefits of procedure                                                                  | P: 100 %          | P: 98 %       | 1       |
|                                                                                       | Y: 76 %           | Y: 83 %       | 0.58    |
|                                                                                       | C: 53 %           | C: Child 69 % |         |
|                                                                                       | A, 100 %          | A: Adolescent 92 % |       |
| Risks of procedures (Subscore = 3)                                                     | P: 92 %           | P: 48 %       | <0.0001 |
|                                                                                       | Y: 84 %           | Y: 15 %       | <0.0001 |
|                                                                                       | C: 68 %           | C: Child 0 %  |         |
|                                                                                       | A, 100 %          | A: Adolescent 25 % |       |
| Alternatives to procedure                                                              | P: 72 %           | P: 43 %       | 0.01    |
|                                                                                       | Y: 24 %           | Y: 15 %       | 0.39    |
|                                                                                       | C: 5 %            | C: 6 %        |         |
|                                                                                       | A, 44 %           | A: 21 %       |         |
| Complete informed consent comprehension (%)                                           | P: 69 %           | P: 25 %       | 0.0002  |
|                                                                                       | Y: 22 %           | Y: 8 %        | 0.11    |
|                                                                                       | C: 0 %            | C: 0 %        |         |
|                                                                                       | A: 44 %           | A: 13 %       |         |

Percentages presented reflect the % of the study group that completely understood the informed consent element. Youth = Child (7–12 years) and Adolescent (13–17 years).

Complete informed consent comprehension meant that the participant understood all key IC elements (nature of the procedure, benefits of the procedure, risks of the procedure, AND alternatives to the procedure).

Table 4a  Multivariate model of informed comprehension scores (ICOS) in youth subjects [ICOS is the dependent outcome].

| Independent variable                                                | Estimate | Standard error | P value |
|---------------------------------------------------------------------|----------|----------------|---------|
| Intervention group (relative to control)                           | +0.59    | 0.11           | <0.0001 |
| Adolescent 13–17 years (relative to child 7–12 years)               | +0.56    | 0.11           | <0.0001 |
| Prior procedure in youth (Yes relative to No)                       | +0.20    | 0.11           | 0.07    |

Table 4b  Multivariate model of Informed Comprehension Score (ICOS) in parent subjects.

| Independent variable                                                | Estimate | Standard error | P value |
|---------------------------------------------------------------------|----------|----------------|---------|
| Intervention group (relative to control)                           | +0.37    | 0.09           | <0.0001 |
| Prior procedure in youth (Yes relative to No)                       | -0.06    | 0.09           | 0.51    |
| Prior procedure in parent (Yes relative to No)                      | -0.11    | 0.10           | 0.28    |

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Competing interests

None
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