A novel method to enhance informed consent: a prospective and randomised trial of form-based versus electronic assisted informed consent in paediatric endoscopy

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ABSTRACT

Objectives To evaluate the adequacy of paediatric informed consent and its augmentation by a supplemental computer-based module in paediatric endoscopy.

Methods The Consent-20 instrument was developed and piloted on 47 subjects. Subsequently, parents of 101 children undergoing first-time, diagnostic upper endoscopy performed under moderate IV sedation were prospectively and consecutively, blinded, randomised and enrolled into two groups that received either standard form-based informed consent or standard form-based informed consent plus a commercial (Emmi Solutions, Inc, Chicago, Il), sixth grade level, interactive learning module (electronic assisted consent). Anonymously and electronically, the subjects' anxiety (State Trait Anxiety Inventory), satisfaction (Modified Group Health Association of America), number of questions asked, and attainment of informed consent were assessed (Consent-20). Statistics were calculated using t test, paired t test, and Mann Whitney tests.

Results The ability to achieve informed consent, as measured by the new instrument, was 10% in the control form-based consent group and 33% in the electronic assisted consent group ($p<0.0001$). Electronically assisting form-based informed consent did not alter secondary outcome measures of subject satisfaction, anxiety or number of questions asked in a paediatric endoscopy unit.

Conclusions This study demonstrates the limitations of form-based informed consent methods for paediatric endoscopy. It also shows that even when necessary information was repeated electronically in a comprehensive and standardised video, informed consent as measured by our instrument was incompletely achieved. The supplemental information did, however, significantly improve understanding in a manner that did not negatively impact workflow, subject anxiety or subject satisfaction. Additional study of informed consent is required.

Clinical trial registration number ClinicalTrials.gov Identifier NCT00899392.

INTRODUCTION

Informed consent is a central ethical concept that impacts all medical and research specialties. Grounded in the ethical principle of respect for autonomy, informed consent is a process-based mechanism that aims to respect and facilitate patient self-determination by insuring that subjects possess adequate information, understanding, decision-making capacity and choice. With relatively few exceptions, failure to obtain informed consent is ethically and legally undesireable.[1] If respect for autonomy is neglected or informed consent is not obtained, then a subject's right to make a medical choice may be compromised or harmful research on subjects could occur. Paediatric consent offers an additional complexity because it involves parental proxies or adolescent assent. Despite the central role of consent, and even though its theories have been discussed in ethical, medical and legal literature for decades, little quantitative research has been done to understand and improve upon the practical process of optimally obtaining consent.[2] This has numerous implications for the ethical obligation to protect patients. In addition most of the research has occurred in adult medicine, neonatology or paediatric oncology.[3–8] Remarkably, despite the prevalence and importance of informed consent, there are no well-developed instruments to test its attainment, no effective methods of standardisation and numerous small, descriptive or sham studies that show its poor implementation.[3 4 9–12]

To study paediatric informed consent, we developed an instrument that could be broadly applied and tested it in a similar cohort of surrogate parental subjects whose children were undergoing a low-risk paediatric procedure. The primary aims were to assess the quality of paediatric informed consent in elective diagnostic EGD (upper endoscopy), and see if a commercially available, internet-based, home-administered, video module could improve it. The secondary aims were to address possible consequences that could be introduced by the addition of the programme: anxiety, satisfaction and number of questions asked to providers by parents.

METHODS

Subjects

Between October 2008 and March 2009, parents of 220 children scheduled for clinically indicated upper endoscopy were prospectively and consecutively contacted. In all, 190 subjects verbally consented to be in the study and 148 subsequently fully participated. There were 74 subjects assigned by alternating groups to form-based consent (control) and 74 to electronic assisted consent (EAC). This was the randomisation method.

Pilot

The first 47 recruited subjects piloted the consent instrument while the secondary outcomes of changes in anxiety, satisfaction and number of questions asked by subjects were assessed. Two control subjects and three EAC subjects were excluded from the data set for failing to complete the study or answering that their child had previously undergone endoscopy. The consent instrument pilot data was not included in the study data analysis but pilot data was used in secondary outcome analysis.

Study

The subsequent 101 subjects were randomised to form-based consent (51 subjects) or EAC (50 subjects). All subjects were studied for secondary outcomes. Three EAC and one control subject were excluded from the data set for failing to complete the study or answering that their child had previously undergone endoscopy. Fifty control subjects and 47 EAC subjects were subsequently eligible for consent data analysis. With the combined secondary outcome data from the pilot study, 123 subjects were eligible for anxiety analysis, 130 for satisfaction analysis and 123 for question analysis.

Subjects were recruited from the endoscopy schedule at The Children's Hospital of Philadelphia (CHOP). Subjects were required to be parents of children undergoing an elective, sedated (non-general anaesthesia), non-interventional, first time upper endoscopy. To avoid possible bias, subjects were blinded and prior to collecting any information the primary investigator randomised and assigned the participants by alternating numerical groups. Verbal consent and online consent were obtained as authorised by the CHOP Institutional Review Board (2008-6-6053). This study was disclosed on http://clinicaltrials.gov and assigned the identifier NCT00899392.

Physicians (individuals that obtained consent) and nurses

The grouped consent practices of 23 attending physicians and 10 fellows that practice paediatric gastroenterology at CHOP were studied. All physicians and the CHOP endoscopy suite nurses were blinded to the arm of the study participants. Specific practices of each physician, as requested, were not collected to protect individual's privacy.

Study sequence

During enrollment, subjects were randomised by alternating numbers to receive form-based procedural consent or form-based consent plus the required web-based, commercially available, sixth-grade level video module that covers the information required to be delivered by a physician obtaining informed consent (Emmi Solutions, LLC-Chicago, IL) (see figure 1). This is described in the study as EAC. The Emmi module was purchased specifically for this project. The video, through a monitored website, was viewed from home the night before endoscopy and required interaction to proceed through it. This video took a minimum of 20 min to complete, and families were able to pause and repeat sections as needed. Completion of the video was documented for all parents. Total time spent on the video was recorded. All participants were also asked to perform the state section of the State Trait Anxiety Inventory (S-STAI; Charles Spielberger, Mindspring, CA, USA) the night before their endoscopy (before watching the module if in the EAC group) and to record their questions about the video or the procedure.[13] On the day of the procedure, consent was obtained and immediately after signing the consent form, but before the procedure commenced, the parental subjects were asked to take the 20 question consent instrument (Consent-20: table 1), the Modified Group Health Association of America (Modified Group Health Association of America-9) endoscopy satisfaction survey and repeat the S-STAI.[14] All questions were read and answered in private. Answers were entered by the subject on a laptop computer and recorded electronically into a secure database.

Instruments

Consent instrument (Consent-20)

The consent instrument was written at a seventh/eighth-grade reading level and based on a study by Woodrow *et al*.[6] It was shortened and modified by two of our co-authors in an attempt to quantitatively measure the attainment of procedural informed consent[6] (table 1). The qualitative questions (1-5) were answered and then the quantitative questions were asked. Once the subjects entered the quantitative section, they could not return to correct any of their previous answers. The questions also represented the American Society for Gastrointestinal Endoscopy recommendations for consent.[15] This instrument was developed as an attempt to offer an effective way to study the achievement of a state of procedural informed consent. It is likely easily transferable to other areas of practice and easily scored. A correct answer is scored two points while an incorrect one is scored zero points. The instrument has a maximum score of 40. Based on pilot data 40 subjects per group were needed to achieve a power of 80, using two-sided α equal to 0.05, and determine a difference of 3.56 (10%).

Modified Group Health Association of America-9

The satisfaction instrument, as developed by the American Society for Gastrointestinal Endoscopy, is a nine-question instrument designed to assess the overall satisfaction of individuals undergoing endoscopy with 45 possible points.[14] . Nine questions were answered electronically using a 5-point Likert scale. The power analysis for Modified Group Health Association of America-9 was based on the Modified Group Health Association of America-9 used in Harewood[14] *et al*; sample size n=100, using two-sided α equal to 0.05, will yield a power of 80 to detect a difference of four between the two groups.

State Section of the State-Trait Anxiety Inventory

This instrument was developed for the assessment of anxiety at both a state and overall trait level. This method is validated.[13] Eighty points are possible. Twenty questions were answered electronically using a 4-point Likert scale. Based on instrument data given by Mindspring, 50 subjects per group were needed to achieve a power of 80 and determine a pre and post anxiety score difference of 2.79 (10%).

Demographics

Demographics were collected including age, gender, ethnicity, education level, exposure to previous endoscopy in a parent or family member and availability or previous exposure to medical education.

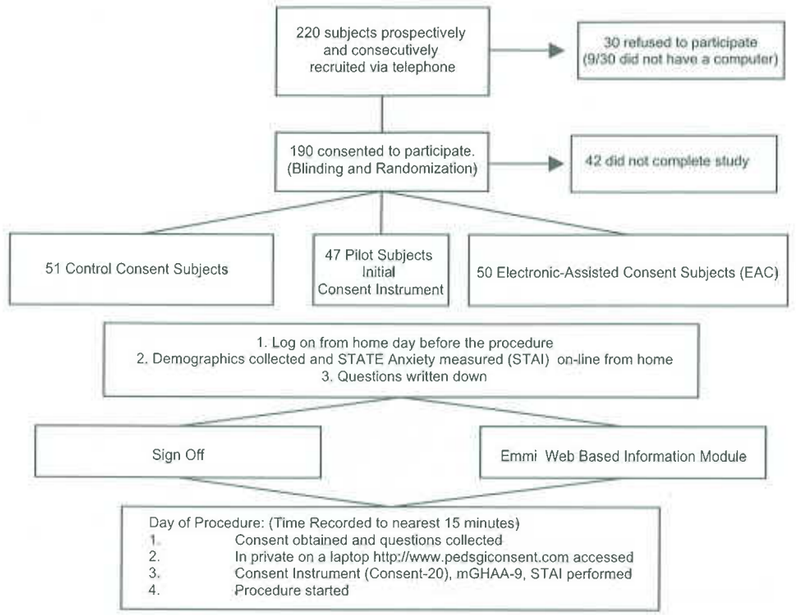
Questions

The total number of remaining parent questions from the night before through to the time of consent was recorded.

Statistics

Descriptive statistics were calculated and a χ^2 test of independence was generated to compare the differences in demographic

Figure 1 Study design and recruitment.



information between the two groups. The comparison of consent scores between the control and EAC groups were made using the Student t test (parametric). For analysis of satisfaction, quantitative consent (questions 6–19) instrument responses and number of questions asked, the Mann Whitney test (non-parametric) was performed. For analysis of each subject's matched anxiety score change before and after the procedure, a paired t-test was conducted. To determine the qualitative answer (questions 1–5) differences of the subjects in the consent instrument Pearson exact χ^2 test of independence was conducted. A series of analysis of variance models were used to determine predictive factors of any demographic variable on the consent or anxiety score. All these analyses used a significance level of $p<0.05$. Statistics were calculated using SAS V.9.1 and Graph Pad Prism V.5 (La Jolla, CA).

RESULTS

Demographics

Analysis of age, gender, religion, ethnicity, exposure to medical professional/education and exposure to previous endoscopy were analysed. Demographics were not significantly different between the groups and partially displayed in table 2 and the discussion section. Of the 220 subjects contacted, nine (4%) did not have access to a computer.

Table 1 Consent instrument

1. List a discomfort of the procedure:	11. Were you informed of the benefits of the procedure?
2. List a benefit of the procedure:*	12. Do you understand the risks of the procedure?
3. List a major and minor risk of the procedure:*	13. Do you understand the benefits of the procedure?
4. List one consequence of not having your procedure today:*	14. Were you informed of the rare possibility of a life threatening complication from the procedure?*
5. List one alternative to today's procedure:*	15. Were you informed of the common risk of abdominal discomfort or nausea after the procedure?
6. Do you understand why your child needs the procedure today?	16. Did you know that you could refuse the procedure?
7. Do you know enough about today's procedure that you could basically explain to another person how it will occur?	17. Were you given the opportunity to refuse the procedure?
8. Was the procedure explained to you?	18. Were you informed about alternatives to the procedure?*
9. Did you understand the explanation of the procedure?	19. Were you informed about possible consequences of not having the procedure today?*
10. Were you informed of the risks of the procedure?	20. Did you get all the information you need to make a good decision about the procedure?

*p<0.05.
2 points for each correct answer. 4 points possible question #3. Question 6–19 Yes/No. 2 points for Yes. 0 points for No. Question 20 descriptive only ('procedure' was replaced with specific name of procedure).

Table 2 Demographic distribution

Age	Subject number	No response	10–19 years	20–20 years	30–39 years	40–49 years	50–59 years
Total	N=97	3%	2%	6%	36%	47%	6%
Control consent	N=50	4%	2%	8%	32%	46%	8%
Treated consent	N=47	2%	2%	4%	41%	47%	4%
Full demographic including pilot	N=142	3%	2%	6%	39%	44%	6%
Control consent	N=74	4%	3%	9%	34%	43%	7%
Treated consent	N=68	3%	1%	3%	44%	44%	5%

Education	Subject number	No response	Elementary	High school	College	Grad school	χ^2
Total	N=97	4%	2%	18%	45%	31%	p=0.06
Control consent	N=50	6%	2%	26%	32%	34%	
Treated consent	N=47	2%	2%	11%	59%	26%	
Full demographic including pilot	N=142	3%	2%	20%	44%	30%	p=0.08
Control consent	N=74	5%	3%	26%	34%	32%	
Treated consent	N=68	2%	2%	14%	56%	26%	

ASSESSMENT OF INFORMED CONSENT OBTAINED BY PAEDIATRIC PHYSICIANS FROM PARENTAL SURROGATE DECISION MAKERS FOR ELECTIVE DIAGNOSTIC PAEDIATRIC UPPER ENDOSCOPY (CONSENT-20)

Pilot

There were 22 control and 21 EAC subjects eligible for the pilot analysis. The average score of the pilot control group was 33.8 (SEM 1.1 n=22) while the EAC group was 35.8 (SEM 0.6 n=21). A possible measurement bias was found in the pilot. To minimise bias and a possible misreading and measurement error the word 'told' in the pilot instrument was changed to 'informed of' for the actual study as noted below (table 1).

Study

Fifty control and 47 EAC subjects were eligible for study analysis. The average score of the control group was 33.20 (SEM 0.74 n=50) while the EAC group was 37.36 (SEM 0.39 n=47). The control group and EAC group represented 83% and 93% respectively of the maximum score of 40. The 10% difference between the groups was highly significant ($p<0.0001$) (figure 2). No demographic data was predictive of any improvement in consent instrument scores. Emmi viewing time ranged from 20–63 min (mean 25.2, mode 21, SEM 3). To better distinguish areas of change affected by EAC the answers of each question were analysed for differences between groups. Four of the qualitative questions and three of the quantitative questions reached values $p<0.05$ (table 1 and table 3): 2 ($p=<0.0001$), 3a-major ($p=0.03$), 4. ($p=0.03$), 5. ($p=<0.0001$), 14. (0.0052), 18. ($p=0.0005$), 19. ($p=0.0020$). The above questions involved being informed of and recalling benefits, alternatives, consequences of not undergoing the procedure, and rare life threatening complications. Although the grouped results above show relatively good average scores (80% and 90% respectively) shown as a distribution the differences in the results are more dramatic. The control consent group had a very wide distribution while the EAC group was shifted with a narrow distribution of scores. This likely reflects improved standardisation or repetition of the consent process introduced by the computer module.

Change in subject anxiety (S-STAI)

There were 63 matched pre-response and post-responses of the anxiety instrument (pilot n=21, study n=42 of total n=74) in the control consent group and 60 (pilot n=15, study n=45 of total n=69) matched in the EAC group. Many subjects that took the pre-consent anxiety instrument did not subsequently complete the post-consent anxiety instrument (logged out of system), and thus subjects from the pilot were included in the anxiety data. The control consent group had a baseline anxiety score of 37.17 (SD 12.56) and a pre-procedure anxiety score of 33.76 (SD 8.94). The difference was statistically significant ($p=0.0165$). The EAC group had a baseline anxiety score of 42.17 (SD 14.32) with a pre-procedure anxiety score of 38.77 (SD 12.79). The paired t test demonstrated the difference was also statistically significant ($p=0.0029$, figure 3). Comparing the differences between the groups was not statistically significant.

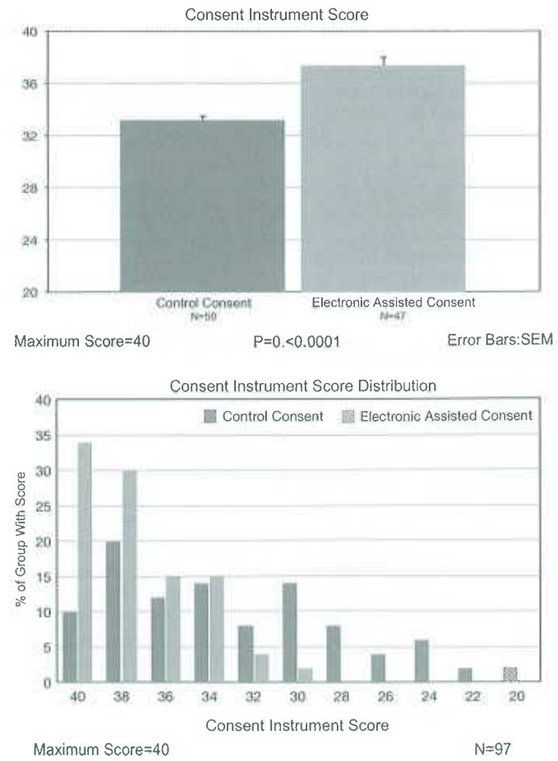


Figure 2 Consent instrument score.

Table 3 Qualitative answers

Write one discomfort: (p=ns)	Control consent	Electronic assisted consent
Throat irritation/pain	14	18
Air or device in abdomen	5	7
Fatigue	3	0
Waiting/anxiety	3	4
Preparation	3	3
IV	9	7
Nausea	2	2
None or incorrect answer	11	6
***Write one benefit: (p=<0.0001)**	**Control consent**	**Electronic assisted consent**
Make a diagnosis	28	21
See if something wrong	18	8
None or incorrect answer	4	1
Biopsy	0	6
Information	0	11
Write one major risk: (p=0.03)*	**Control consent**	**Electronic assisted consent**
Perforation	34	25
Bleeding	7	9
None or incorrect answer	6	2
Anaesthesia reaction/need for intubation	2	10
Other organ damage	1	0
Death	0	1
Write one minor risk (p=ns)	**Control consent**	**Electronic assisted consent**
Pain	6	11
Nausea	4	4
Bleeding	17	17
None or incorrect answer	16	9
Infection	0	1
Sedation	6	5
Blood transfusion	1	0
Write one consequence of not undergoing today's procedure: (p=0.03)*	**Control consent**	**Electronic assisted consent**
No diagnosis/answers	22	14
Non proper therapy	1	5
Not finding problems	3	11
Remaining ill	10	6
None or incorrect answer	9	4
Not having information	5	7
Write one alternative: (p=<0.0001)*	**Control consent**	**Electronic assisted consent**
Don't know or there is no alternative	29	6
Not doing it	9	7
Blood test	1	4
Empiric therapy	8	14
Radiology test	3	9
Pill capsule	0	7

*p<0.05.

Change in subject satisfaction

In total, 67 subjects completed the Modified Group Health Association of America-9 questionnaire in the control consent group while 63 did in the EAC group. The control score was 41.46 (SD 3.36) while EAC score was 41.79 (SD 3.646) p=ns.

Number of questions asked by subjects

Sixty-three questionnaires were collected from the control group while 60 were collected from the EAC group. The mean number of questions asked by the control group was 3.06 (median 3, range 0–9) while the electronic assistance group was 2.03 (median 1, range 0–14) p=0.0053. This value is statistically significant but a one-question difference is not clinically meaningful.

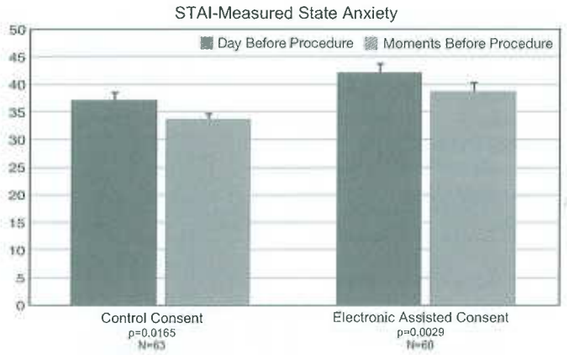


Figure 3 State Trait Anxiety Inventory—measured state anxiety.

DISCUSSION

As measured by our newly developed instrument, the data of this randomised and blinded trial shows that the paediatric practice of obtaining a parental surrogate based form-based informed consent fails to achieve its theoretical goals (decision making capacity, voluntariness, disclosure, recommendation, understanding, decision, authorisation).[1 16] That process was found to be significantly, but incompletely, improved by the addition of a commercially available electronic (EAC) module (p<0.0001).

We attempted to measure the attainment of informed consent quantitatively with a potential maximum score of 40. The tool was primarily designed to assess whether basic levels of disclosure of adequate information and surrogate comprehension of that information took place. In addition, the tool asked several questions meant to reveal whether the surrogate made a decision to have the procedure and whether that choice was voluntary. Surrogate decision-making capacity and physician recommendation were assumed and not tested by the instrument. Since the instrument was designed to assess a basic level of these theoretical components, the maximum score potentially represents a minimally acceptable level of informed consent. At the very least, scores less than the maximum should raise significant questions about why consented individuals were not able to provide basic information or did not feel as though they were given a choice.

Using this model, our study is one of the first protocols that attempts to measure the attainment of informed consent rather than simply describing its flaws.[4–6] We found that 10% of subjects in our control group were able to answer the instrument completely and correctly (table 1, table 3) while 33% could in the EAC group. While these numbers suggest that most subjects did not achieve a minimum standard of informed consent, one might be inclined to dispute that a perfect score represents a minimally acceptable standard for informed consent. However, if one analyses the data as revealing degrees of informed consent rather than all or nothing, the results are even more remarkable. As figure 2 demonstrates, the percent of correct answers and refinement of answers is dramatically improved (shifted to the left) in the EAC group. Although EAC did not reach perfect 40/40 scoring, 79% of the EAC group achieved 90% or better compared to 42% in the control. Analysis of the consent instrument suggests that this improvement was a result of a more standardised, repeated and earlier disclosure of information in the area of alternatives, benefits and consequences. Ultimately, perhaps a threshold of consent can be found with further study of this instrument, though more validation is needed to allow for what this number should be.

Informed consent is based on the well-developed ethical principle of respect for autonomy and an understanding that an individual has a right to be self-determining. The central components of the process are physician disclosure of relevant information, decision-maker comprehension, patient belief that they have been given sufficient information to make a reasonable choice, lack of coercion of the decision maker and decision-maker choice. While it is widely acknowledged that in practice there is no single correct method for accomplishing the theoretical goals of informed consent, it is generally accepted that these components are essential. In the paediatric setting, the informed consent process can be complicated even further by the fact that parents, rather than the paediatric patient, are the ones providing consent. Like all surrogate decision-making, this requires the medical provider to assure that the surrogate is protecting the interests of the patient rather than him or herself. Additionally, if an adolescent is involved, the physician may need to seek the patient's assent to properly respect the individual's growing autonomy. Nonetheless, it is our belief that the measurement of the basic theoretical components of informed consent is similar in paediatric and adult settings. Consequently, because of the complexities and the need to address all the areas of consent we sought to design a tool that could measure an ideal informed consent more simply and without the bias or assistance of an interviewer. As was pointed out in Schenker's recent review, much of the literature assesses understanding and knowledge using complex interview-based studies or complex research based tools such as the Mac Arthur Competency Assessment-CR.[17–19]

The Consent-20 attempted to quantify the attainment of the basic theoretical concepts of informed consent that should be discussed and understood in a process of shared-decision making. Our study showed that standard disclosure methods using forms provides an incomplete delivery of information to surrogates and an associated lack of understanding in key areas. Therefore the informed consent document and the standard paediatric surrogate process of obtaining it does not likely achieve the theoretical requirements of informed consent. Others have also demonstrated similar deficits using descriptive studies.[9 20] Subject answers to our instrument were widely variable as shown in figure 2, even when the cohort was highly educated with 60-80% college educated and above. EAC significantly improved the areas of deficiency. This was achieved without causing any meaningful changes to our measured secondary outcomes. Interestingly, despite the wide variability of scores on the instrument, 98% of both groups expressed that they received sufficient information to make an informed decision.

The study also analysed some potential consequences of enhancing consent methodology. Using the S-STAI as a validated measure of state anxiety, we assessed the change in anxiety from the day before and moments before the procedure in both the control and EAC groups.[13] Regardless of subject education, anxiety was decreased significantly in both groups. This challenges the common assumption that more information makes patients more anxious. In addition, EAC also delivered a more standardised and improved consent without consequences such as decreased endoscopy suite efficiency (data not shown), meaningful change in the number of questions asked by subjects, or subject satisfaction. The Modified Group Health Association of America-9 was used as a measure of satisfaction because of its recommended use for endoscopic studies.[14]

There are limits and potential shortfalls of this study. Possible criticisms of the study include that the tool is an improper consent assessment, the cohort represents a skewed demographic or the sample size is inadequate. Concerning whether the tool properly assesses consent, the instrument attempts to report the performance of information delivery, understanding and recall. Since the instrument reports the delivery and recall of a previously accepted set of standardised data, the instrument should be equally applicable to EAC and form-based consent. Subject understanding was measured in two ways. Subjects were first asked directly if they understood something. This entailed yes/no questions about a self-reported feeling of sufficiency and was easily measured by our instrument. Subjects were also asked to list theoretical components of a basic understanding, that is, benefits, risks, harms and so on. While some may claim recall evaluation is a poor measure of subject understanding, we believe it is likely the best way to assess it.

It is also possible that prior to the final review of consent materials, the parents may have made up their minds about the procedure. The subjects may not have paid full attention to the consent process because they felt the information was provided earlier. At the time of signing the consent form, the subjects could have been simply going through the formality of form-based consent. If this is correct, it might be that a minimally acceptable standard of consent was achieved earlier in the process, but the Consent-20 measured the components of consent too late. Alternatively, there is a possibility that informed consent may have been achieved at the measured time, but subjects misinterpreted the instrument questions. This would lead to a low score and possible incorrect conclusion. For example, the subjects' ability to recall alternatives was poor. One explanation is that subjects were not aware of their alternatives. Another potential explanation is that they felt the other options were not as good and thus did not record them as alternatives or potential choices. This may indicate a need to refine the tool or improve the delivery of information. Any of the above reasons may have led to incorrect conclusions. Finally, except for evaluation of decision making capacity, Consent-20 tests the fulfilment of all the other required areas of informed consent. We do not see this as a major limitation of the tool. The individual obtaining the informed consent should perform the assessment of the subject's decision-making capacity.

Another flaw is that this prospective study also had a surprisingly homogenous ethnic (60–70% Caucasian), religious (80% Christian) and educated (60–80% college educated) cohort (table 2). To attempt to categorise trends by demographics, the data were analysed for predictive factors but was found to be insignificant. Additionally this study also assessed surrogate decision-making rather than joint parent and adolescent decision-making. While we do not see this as an obvious criticism of the Consent-20 tool, it is possible that its application in joint parent-adolescent decision-making would yield different results. To address some of these concerns, including the limited sample size, larger demographic studies are planned to generate more powerful data.

The study suggests that more research is necessary. Why would a consent form, an electronic module and a physician discussion together still be unable to achieve a minimal standard of theoretical informed consent? Further, while unable to satisfy a basic theoretical standard for informed consent, a highly educated group of parents nonetheless felt they received

sufficient information to make a decision for their children. This prompts the question of whether the theoretical standard or the subjects' feeling of sufficient information is suspect. Once the Consent-20 is further validated it may offer a simple, standardised way to help understand, improve and test consent methods in numerous settings.

CONCLUSIONS

In conclusion, we developed an instrument that could be used to test the practical attainment of a minimally acceptable informed consent in pediatrics. We studied that instrument in a similar group of paediatric surrogate decision-making subjects whose children were undergoing first-time upper endoscopy and found that form-based consent is flawed. We then asked a blinded group of subjects to undergo EAC using a commercially available electronic patient information module (Emmi Solutions, LLC) and found significant, but still incomplete, improvement in deficient areas. This was without the introduction of other measurable meaningful consequences. Future studies to further validate the Consent-20 and use it in studies of shared decision-making are planned.

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Competing interests None.

Ethics approval This study was conducted with the approval of the The Children's Hospital of Philadelphia Institutional Review Board #2008-6-6053.

Contributors JAF, PM, DAP and GL jointly conceived and designed the project. JAF recruited, randomised, and blinded the subjects. GL and JAF designed the Consent-20 based on a previously published instrument in Woodrow *et al* (permission obtained). EZ gave conceptual advice. JAF prepared the manuscript. All authors discussed the results, jointly edited, and refined the manuscript. PF and AP coordinated the administration of the project in the endoscopy suite at CHOP. JAF and XZ performed statistical analysis.

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Should medicine assist a teenager to achieve a pregnancy?

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ABSTRACT

This article discusses a scenario of a teenager seeking medical assistance for infertility. Despite its apparent simplicity, the case poses a significant challenge to healthcare professionals. It requires consideration of maternal and child welfare and examination of the legitimate limits of doctors' role vis-à-vis the policy objective of reducing teenage pregnancy rate. The negative stereotypic representation of teenage pregnancy is an important confounding factor.

This article examines a case scenario of a young woman who was 1 month past her 17th birthday when she was referred by her general practitioner complaining of inability to conceive. She has been with her current partner, who is 4 months older, for 16 months. The couple, still living with their parents, had not achieved a pregnancy despite never using contraception. Recently, she had been treated for Chlamydia infection on two occasions, which points to possible tubal factor for infertility. She was becoming increasingly anxious, as other friends of hers have become pregnant over shorter periods of time. She attended a hospital clinic with her partner, and neither had any other significant medical history. Neither of the two teenage partners was in education or employment. She volunteered that her mother is aware of her pursuit of a pregnancy.

Planned teenage pregnancies are often attributed to naivety, family and community dysfunction, dependency on state benefit and low ambition. If this teenager had considered these representations or group stereotypes, she did not show any sign of being burdened by them. She did not voice her request as an expression of rebellion, but as an authentic concern about her fertility.

SETTING THE SCENE

The high incidence of teenage pregnancy is presented in medical literature, lay media and government policy as a problem.[1] Teenage pregnancy is linked to social deprivation and low educational achievement and is depicted as a social ill or as a manifestation of individual failure, ignorance or irresponsibility. In the UK, there were 40 298 conceptions under-18, including 7715 conceptions under-16 in 2007.[2] Recent efforts to reduce teenage pregnancy in the UK may have had some success, but the rate remains among the highest in rich countries.[3] Reducing teenage pregnancy remains high on the national agenda in many developed nations.[3 4] Against this background, fulfilling the teenager's request for fertility treatment will be at odds with policy direction and can, therefore, create tension.

The rates of teenage pregnancy in most western countries have declined significantly compared to the rates 30 years ago when there was less emphasis on education and employment for women.[3 5] While current characterisation of teenage pregnancy is negative, it has not always been viewed as a problem. In many parts of the world it is part of the norm, with women getting married at a young age surrounded by a supportive social structure of sorts. Indeed there is some evidence that supportive social structures can reverse at least some of the negative impact of early motherhood. Epidemiological research from developed countries paints a negative picture, with teenage mothers identified as more likely to achieve less than upper secondary education, to be unemployed, to be single and to live in households with low income.[1 3]

Not all teenagers fit the same stereotype.[6] The reasons why teenage women become pregnant, and why some may subsequently have an abortion, are complex. Not all teenage pregnancies are unplanned or unwanted. Some teenagers may (rightly or wrongly) believe that a pregnancy can offer them some social or financial reward including access to benefits, companionship, independence or a stronger link to a partner, others may view it as a fulfilment of motherhood, in a way that is not so dissimilar to the case of older prospective parents.[7]

Arguments against assisting this teenager in her quest for a pregnancy can rest on one of three possible reasons: her own welfare, the welfare of the child, or societal/public interest. These reasons will be considered separately below, but it is recognised that they may be interlinked or interdependent.

THE WELFARE OF THE MOTHER

Considerations of welfare are important in doctor-patient interaction, Beauchamp and Childress argue that in establishing a relationship with a patient, the physician makes an implicit or explicit promise to seek the patient's welfare.[8] The impact of teenage pregnancy could be categorised into obstetric risks linked to the pregnancy itself or other broader welfare issues that may arise subsequent to a pregnancy. Literature is inconclusive when assessing obstetric risks, and this leaves open three possibilities: (1) that pregnancy (at least in mature teenagers) is not linked to adverse obstetric outcomes; (2) that there is a small increased risk that is linked to young age per se, but mostly for the youngest teenagers; (3) that there is an increased risk but that risk is linked to socioeconomic status rather than age per se.