

Electronically Verified Use of Internet-Based, Multimedia Decision Aids by Adolescents With Type 1 Diabetes and Their Caregivers

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Abstract

Decision aids (DAs) are central to shared decision making (SDM) interventions, yet little is known about patients' actual DA use. Adequate utilization of DAs could optimize SDM effectiveness. Electronic DAs enable more objective tracking and analysis of actual DA utilization than do paper DAs. This report is part of an ongoing randomized controlled SDM trial enrolling adolescents with type 1 diabetes and their caregivers ($n = 153$) who were considering use of an insulin pump or continuous glucose monitor. Extensive stakeholder engagement guided creation of two online DAs. After completing baseline measures, 133 dyads were randomized to SDM (access to the pertinent DA) or Usual Care (clinic routines for preparing candidates for adopting these devices). Utilization data showed that 80% of caregivers and 66% of youths logged into a DA at least once; youths and caregivers, respectively, dedicated a mean of 44.7 and 55.0 minutes to website use and viewed 72.2% and 77.4% of the DA content. Median total duration from enrollment to last DA logout was 48.2 days for adolescents and 45.6 days for caregivers. Bivariate comparisons showed that non-Hispanic, Caucasian females from households with higher socioeconomic status were significantly more likely to login to the assigned DA at least once. Hierarchical multiple regression showed that adolescent males with lower levels of health literacy demonstrated fewer DA logins ($F = 2.59$; $P < 0.009$), but identified no significant predictors of adolescents' or caregiver' duration of DA use or proportion of DA content viewed. Future SDM trials should seek to promote DA use, especially by non-White adolescents, perhaps with direct assistance with the initial DA login. Trials employing electronic DAs should routinely report and analyze utilization data.

Keywords

adolescence, continuous glucose monitor, insulin pump, shared decision making, type 1 diabetes

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For preference-sensitive medical decisions,^{1–3} interventions based on decision making that is shared among health care recipients and health care providers (HCPs) can improve decision quality, patients' knowledge of treatment options, patient engagement and satisfaction with their care, and health outcomes.^{4–7} Carefully prepared decision aids (DAs) are central to shared medical decision making interventions.^{1–7} In pediatrics, particularly when the patients are adolescents, the process of shared medical decision making is at least triadic in nature (i.e., patient, parent/caregiver, and HCP) and potentially quite complex.^{8–13}

Well-designed DAs present treatment options in a comprehensive, unbiased, and fair manner that prepare patients and caregivers to engage meaningfully in a well-informed conversation with their HCPs and possibly other stakeholders toward a goal of enabling each patient to make the best individual choice among available care alternatives.^{4–18} Historically, DAs have been

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primarily hard-copy documents and audio-video presentations.^{4,5,7,10,13-16} For the most part, these tools were designed as one-way communications to the user rather than as experiences that engage users in experiential activities designed to promote active decision making. More recently, interactive, Internet-based, multimedia DAs have been developed and evaluated,¹⁷⁻²⁶ including our own stakeholder-driven design, development, and testing of DAs targeting adolescents with type 1 diabetes (T1D) and their caregivers who are considering adoption of either the insulin pump or continuous glucose monitor (CGM) as a component of their diabetes self-management regimens.¹⁸

Much effort has been dedicated to the design and development of high-quality DAs in a wide variety of health care contexts,⁴⁻²⁶ but there has been less systematic research exploring if, how, when, and under what conditions targeted users actually utilize these tools and whether utilization patterns are associated with beneficial effects on outcomes such as users' decision-related knowledge, decision quality, engagement in care, and health status. A better understanding of these processes could lead to design of interactive DAs that are more likely to generate adequate DA use and therefore more likely to improve the outcomes of interest. Studies of informed consent for participation in research suggest that only a minority of prospective participants read the consent document completely, and an even smaller minority demonstrate adequate comprehension or retention of the content of the consent document.^{27,28} If shared decision making (SDM) participants are behaving similarly, then they may not realize the intended benefits of DA use and may therefore achieve diluted SDM treatment effects.

For SDM interventions employing DAs to be optimally effective, each participant would need to read, comprehend, retain, and apply all of the information

and analysis contained within the DA. Users' self-reports of the extent to which they have used the DAs they were provided are of suspect reliability. Stacey and colleagues, for example, tracked adoption of SDM among 23 Canadian cystic fibrosis centers and reported that clinicians' self-reported DA use increased from 29% to 92% during their study, but no objective indices of patients' use of those DAs were analyzed.²⁹ Wyatt and colleagues contributed a meta-analysis of clinicians' use of conventional, hard copy DAs, concluding that the mean proportion of fidelity with optimal DA use was 58.4% across six randomized trials.³⁰ In that study, fidelity to DA use was associated significantly with patient knowledge and extent of clinician involvement of the patient in decision making. Some studies have simply evaluated the effects of providing patients with access to DAs without measuring the extent to which participants actually read, understood, remembered, and used the DAs.^{4-17,31} Most SDM research employing DAs, then, does not permit a conclusion that DA use actually accounts for observed effects or to verify that the obtained effects are the best possible.

Although "electronic" DAs will likely become commonplace,²⁴⁻³⁰ studies employing electronic DAs have reported only basic analyses of participants' DA use. Compared to self-report measures used in other clinical or research contexts, objective measures of patient behavior tend to reveal a less positive picture. Hence, our design of Internet-based DAs for adolescents with T1D and their caregivers included a utility designed to capture patterns of DA use by individual users and in aggregate. Since there are no pertinent prior studies, the researchers proposed an a priori aim to analyze automated characterization of DA use by adolescents and caregivers. Participants were enrolled in an ongoing randomized controlled trial (RCT) evaluating their consideration of the insulin pump or CGM as part of their care.¹⁸ The researchers explored descriptive analyses of several indices of DA use, evaluated bivariate relationships among participants' demographic characteristics and indices of DA use, and investigated multivariable regression models to identify prediction of participants' DA use.

Methods

Decision Aids

A previous detailed report¹⁸ described our stakeholder-driven design and development of two Internet-based, multimedia DAs for adolescents with T1D and their caregivers who were considering use of an insulin pump

Nemours Children's Health System, Jacksonville, Florida (TW, LJ, AM, AT); Nemours Children's Hospital, Orlando, Florida (JP, MC); Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio (WBB); Nemours-Jefferson Pediatrics, Philadelphia, Pennsylvania (JF); Nemours Center for Health Delivery Innovation, Wilmington, Delaware (FH). The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article. The work reported in this article was supported by Research Contract #805 "Shared Medical Decision Making in Pediatric Diabetes" awarded to the first author as Principal Investigator by the Patient-Centered Outcomes Research Institute.

The decision aids described in this article are accessible by navigating to these links and registering as either a caregiver or adolescent user: <https://nemours.mycgmchoice.org> (CGM Decision Aid) and <https://nemours.mypumpchoice.org> (Insulin Pump Decision Aid).

or CGM as part of their care. A summary of that work appears in the Online Appendix.

Randomized Controlled Trial

Participants. DA use was evaluated during an ongoing RCT comparing usual clinical practice with SDM (i.e., DA access) with adolescents with T1D who were considered by their clinicians to be candidates for an insulin pump, CGM, or both, along with a parent or other legal caregiver. All participants were required to have Internet access using a desktop or laptop computer, tablet, or smartphone device. No prospective participants were excluded on the basis of this criterion. The enrollment objective was to recruit and randomize 166 adolescent-caregiver dyads. Adolescent-caregiver dyads were eligible for the RCT if they met the following criteria:

Adolescents: Age ≥ 11 years but < 18 years; T1D for ≥ 1 year or ≥ 6 months with most recent $\text{HbA}_{1\text{C}} \geq 7.5\%$; considered by treating HCP to be an appropriate candidate for an insulin pump and/or CGM; attended ≥ 2 clinic visits for T1D at a study site in the prior year; not currently participating in research in which treatment adherence or glycemic control are study outcomes; not on daily oral glucocorticoid treatment; considered developmentally normal by the treating clinician; able to read/comprehend questionnaires and DAs in English; not currently treated for a coincident medical condition that contraindicated study participation based on the physician's judgment; family must be able to access the Internet.

Caregivers: Either a biological parent or legal caregiver of the child; primary T1D caregiver of the child; routinely accompanies child for T1D care; can participate in conversations during visits; plans continued medical care for T1D at study site for a year; able to read/comprehend study questionnaires and DAs in English; no open abuse/neglect case with any child protection agency over the prior 3 years; no evidence of frequent changes in the adolescent's household or living arrangements.

Setting. Participants enrolled at any of five outpatient clinics of a large pediatric health care system in the Eastern United States or at a large pediatric diabetes center in the Western United States. Nemours IRB #1 (FWA 00000293) reviewed and approved the study before research procedures were begun and has maintained oversight of the project throughout its duration.

Procedure. Caregivers signed an institutional review board (IRB)-approved Parental Permission Form and adolescents signed an IRB-approved Assent Form prior to any research procedures. After being offered a conversation with a research team member, six dyads signed an IRB-approved electronic version of the Parental Permission and Assent forms and 147 signed a paper version. The constraints of completing the study on time and within budget, along with the limited availability of eligible dyads, impeded achievement of the enrollment objective with 153 dyads providing parental permission and assent rather than the goal of 166 dyads. After signing consent, participants received an Internet link to the baseline measures, which elicited information about demographic characteristics, pump/CGM knowledge, and health literacy and numeracy. Adolescents' glycohemoglobin levels ($\text{HbA}_{1\text{C}}$) were measured in clinic ($n = 149$) or via self-report from online participants. The 133 dyads who completed all baseline measures were randomized to Usual Clinical Practice (UCP; $n = 67$) or SDM ($n = 66$) for 1 year (20 consented dyads did not complete all baseline measures and thus were not randomized). UCP participants received the same routine multidisciplinary care and education regarding adoption of the insulin pump or CGM at the respective sites. In addition to receiving routine care, SDM participants received access to explore the pertinent DA(s) for as long as they wished (see "Duration of DA Use" in the Results). Some SDM dyads received access to one DA whereas others received access to both DAs, depending on whether they were candidates for one or both devices. Since the focus of this article is DA use, it presents data only for those participants in the SDM condition.

Questionnaires and Other Measures. Participants completed the questionnaires described below at baseline and these scores entered the analyses reported in this article. Participants were paid \$25 for completion of the baseline questionnaires. They were not paid for DA use. Additional outcome measures were obtained during the follow-up period of the RCT, but those data are not reported or analyzed in this article.

Predictor variables. The following measures were collected to serve as predictors of indices of DA use in planned statistical analyses:

Hollingshead Four-Factor Index of Social Status: Caregivers completed a Demographic Information Form that included details about family composition, caregiver occupation and education, household income category, and details of the adolescent's T1D-related

medical history and treatment regimen. The researchers used caregiver occupational status and educational attainment to calculate the Hollingshead Four-Factor Index of Social Status (A. B. Hollingshead, unpublished manuscript, Yale University, 1975; copy available from the first author of the present article on request), a widely used indicator of household socioeconomic status (SES).

Rapid Estimate of Adult/Adolescent Literacy in Medicine (REALM): The REALM is a validated and reliable screening tool for the assessment of health literacy in adults and adolescents.³⁶ It is completed in an interview format in which the respondent is asked to read and interpret health-related words and statements. Scores may range from 0 to 66.

Diabetes Numeracy Test (DNT): The DNT is a well-validated screening tool for the measurement of basic diabetes-related quantitative and computational skills.³⁷ Administered in an interview format, the DNT poses realistic problems to the respondent that require display of quantitative skills in domains such as carbohydrate counting, blood glucose monitoring, and insulin dosing. Scores may range from 0 to 14.

Glycohemoglobin (HbA_{1C}): HbA_{1C} is a common index of recent diabetic control that is considered to be an estimate of average glycemia during the preceding 2 to 3 months. High-performance liquid chromatography methods indexed against a Diabetes Control and Complications Trial reference laboratory were used at all performance sites.

Outcome variables. The variables listed below are electronically verified indices of various dimensions of participants' DA use during the 3-month study period in which the DAs were accessible by them. Results are reported and analyzed separately for adolescents and caregivers because the researchers did not attempt to determine which, if either, participant in a given dyad was responsible for their final decision about adoption of the insulin pump or CGM.

Categorization of Participants as DA User or Nonuser: Categorization as a DA User means that the participant logged into the assigned DA website at least once during the study. Nonusers are participants who never logged into the assigned DA website.

Frequency of DA logins: This variable consists of the number of distinct DA logins by a participant that lasted for at least 2 minutes before the participant logged out.

Duration of DA use: This variable was defined in two ways: 1) total duration of time in minutes between login and logout for a given DA use event; and 2) total

duration of time in hours between a given participant's first DA login and last DA logout.

Percentage of DA content viewed: This variable was defined as the percentage of DA sections that were accessed at least once by a given participant.

Use of Decision Slider: This variable consists of the number of times that a given participant moved the Decision Slider from its position at the beginning of the session to a different position indicative of greater likelihood of either accepting or declining the insulin pump or CGM.

Analysis Plan. For this article, the research team analyzed all the DA use data that were recorded during the trial. Participants were given the opportunity to use the DAs during the first 3 months of the RCT, and they were free to use the DAs for as often or as long as they wished during that period. The analysis plan focused on detailed description of DA use by adolescents with T1D and their caregivers and the associations of DA use with demographic variables. We used IBM-SPSS Version 22 for all analyses. We calculated the following:

1. Descriptive analyses of DA use by adolescents and their caregivers who were candidates for the insulin pump or CGM and who had enrolled in a RCT of an SDM intervention
2. Correlations between indices of DA use by adolescents and caregivers
3. Binomial logistic regression analyses of demographic characteristics, health literacy, and health numeracy as predictors of whether or not adolescents and caregivers logged in to the pertinent DA website(s) at least once
4. Multivariable linear regression analyses of demographic predictors of participants' frequencies of DA logins, total duration of DA use, and percentage of DA content viewed

We used linear regression modeling to evaluate measured variables as predictors of each participants' frequency of DA logins and total duration of DA use (hierarchical multiple regression) and membership among those who did (Users) and did not (Nonusers) log in to the DA website at least once (binomial logistic regression). Hierarchical linear multiple regression analyses were done to evaluate demographic predictors of the continuous measures of participants' DA use (i.e., login frequency, duration of use, proportion of content viewed). Login periods of 2 minutes or less did not enter these analyses since these were thought to represent fleeting periods of website access without meaningful

engagement with DA content. We fit separate models for adolescents and caregivers. For both binomial logistic and multivariable linear regression models, predictor variables were demographic characteristics including adolescent's gender, age, race, ethnicity, duration of diabetes, insulin delivery modality (insulin pump or multiple daily injections) and most recent HbA_{1C}, family income level, health literacy and numeracy scores, and SES as measured by the Hollingshead Four-Factor Index. For each of the analyses specified below, we entered demographic predictor variables in the following sequential blocks: Block 1—adolescents' gender and age; Block 2—race, ethnicity, SES, family income level, health literacy, and health numeracy; and Block 3—duration of diabetes, insulin delivery modality, and most recent HbA_{1C} level. The researchers included variables in the respective blocks in order of their estimated influence on family management of T1D from more distal (Block 1) to more proximal (Block 3).

Results

Sample Characteristics

Table 1 summarizes demographic characteristics of the enrolled adolescents and caregivers, separately for those who logged in to at least one session of DA use (Users) and those who did not (Nonusers). While both groups were demographically diverse, certain demographic differences emerged between those two groups, as detailed below. All 66 dyads randomized to SDM registered to utilize the DA(s); 56 registered for one DA (37 CGM, 19 insulin pump) and 10 registered for both DAs.

Frequency of DA Logins

Among the 66 dyads randomized to the SDM intervention group, 53 caregivers (80%) and 44 adolescents (67%) logged in at least once, while 13 caregivers and 22 adolescents never logged in. Among Users, caregivers logged in a mean \pm SD of 3.5 ± 2.8 times, while adolescents logged in a mean of 3.0 ± 3.4 times during the study period. DA Users differed significantly ($P < 0.05$) from Nonusers in adolescent gender (Users: 54.5% female, $n = 24$; Nonusers: 50.0% female, $n = 11$); race/ethnicity (more Users were non-Hispanic Caucasian; more Nonusers were African American or Hispanic); family income (% below \$25,000/year: Nonusers: 23.1%, $n = 3$; Users: 7.8%, $n = 1$); and mean Hollingshead Index of Socioeconomic Status (53 Users: 42.2; 13 Nonusers: 35.6). Although mean scores for health literacy (REALM) and numeracy (DNT) were slightly

higher among Users than Nonusers for both caregivers and adolescents, none of these effects achieved statistical significance. Users and Nonusers did not differ significantly along any other measured demographic characteristics.

Duration of DA Use and Proportion of Content Viewed

Based on preliminary DA testing, the research team estimated that exposure to all sections of the DA websites required a minimum of about 40 minutes. Among those who logged in at least once, mean \pm SD duration of DA use was 55.0 ± 44.7 minutes for the 53 caregivers and 46.2 ± 38.3 minutes for the 44 adolescents. Among participants with at least one DA login, the mean proportion of DA content viewed was 72.2% for caregivers and 77.4% by adolescents. Overall, 35 caregivers (66.0% of "Users") and 32 adolescents (72.7% of "Users") viewed 100% of the DA content. The "Decision Slider" enabled users to indicate if/how their preference had been affected by a given DA content element. The Decision Slider was used a mean \pm SD of 7.9 ± 8.6 times by adolescents and 5.7 ± 7.5 times by caregivers. A narrow minority of Decision Slider activations were in the direction of a more favorable stance toward adoption of the insulin pump or CGM among adolescents (46.8%), while caregivers tended slightly (55.3%) to indicate more positive views of these options.

Correlations Between Indices of DA Use by Caregivers and Adolescents

Extent of adolescent DA use and caregiver DA use were significantly and positively associated for all DA use variables. These included frequency of logins (Pearson $r = 0.35$; $P < 0.006$); total duration of DA use (Pearson $r = 0.44$; $P < 0.0001$); proportion of content viewed (Pearson $r = 0.70$; $P < 0.0001$); and frequency of Decision Slider adjustment (Pearson $r = 0.32$; $P < 0.004$).

Temporal Distribution of DA Logins

Figure 1 displays the intervals of time between successive episodes of DA use graphically, which depicts separately for caregivers and adolescents the median intervals between randomization to SDM and the first DA login, followed by the median interval between the end of each period of DA use until the subsequent login. Figure 1 shows that the intervals between successive episodes of

Table 1 Demographic Characteristics of DA Users and Nonusers

	Adolescents		Caregivers	
	Users (<i>n</i> = 53)	Nonusers (<i>n</i> = 13)	Users (<i>n</i> = 44)	Nonusers (<i>n</i> = 22)
Age (years), mean (SD)	13.9 (2.0)	14.1 (2.1)	42.5 (8.0)	42.2 (5.3)
Gender (%)				
Female	54.5	50.0	90.6	92.3
Race (%)				
Caucasian	77	81.8	90.6	91
African American	6.8	9.1	5.7	15.4*
Asian	—	—	2	4.5
Other	7.7	2.3	2	—
Information not available	—	4.5	—	—
Ethnicity (%)				
Hispanic	6.8	9.1*	3.8	15.4*
		Users		Nonusers
Insulin regimen (%)				
Pump		38.6		36.4
Injections		61.3		63.6
Duration of T1D in years, mean (SD)		5.7 (3.7)		4.5 (3.5)
Baseline HbA _{1C} , mean (SD)		8.6 (1.4)		8.4 (1.7)
Household income (%)				
< 10,000		3.8		15.4*
10,000–14,999		2		7.7*
15,000–24,999		2		—
25,000–34,999		15.1		7.7
35,000–49,999		7.5		7.7
50,000–74,999		17		15.4
75,000–99,999		17		23.1
100,000–149,999		15.1		—
150,000–199,999		7.5		15.4
>200,000		11.3		—
No information given		2		7.7
Household socioeconomic status, mean Hollingshead Index (SD)		42.2 (13.5)		35.6 (16.6)*
Health literacy and numeracy REALM mean (SD) total score		Adolescents: 62.1 (4.3) Caregivers: 65.4 (1.0)		Adolescents: 60.7 (5.4) Caregivers: 62.7 (9.6)
DNT mean (SD) total score		Adolescents: 10.9 (2.7) Caregivers: 12.5 (1.6)		Adolescents: 9.2 (4.0) Caregivers: 10.8 (4.5)

DA, decision aid; DNT, Diabetes Numeracy Test; HbA_{1C}, glycohemoglobin level; REALM, Rapid Estimate of Adult/Adolescent Literacy in Medicine; T1D, type 1 diabetes.

*Bivariate comparison significant at $P < 0.05$; all others nonsignificant.

DA use occurred at intervals measured in days, and that adolescents and caregivers who continued to use the DAs tended to do so relatively often. Both caregivers and adolescents logged in to the DA for the first time after a median interval of about 12 days, stabilizing at intervals of about 4 to 7 days between DA use episodes before discontinuing DA use. The mean duration of time from enrollment to the end of the last DA use was 1093.8 hours (45.6 days) for caregivers and 1156.3 hours (48.2 days) for adolescents.

Adolescents' and Caregivers' Status as User or Nonuser

Binary logistic regression modeling was used to predict adolescents' and caregivers' status as a DA User/Nonuser as a function of the various demographic characteristics at enrollment. The overall models for both caregivers and adolescents were nonsignificant, and no individual predictor variables were associated significantly with membership in the User/Nonuser groups.

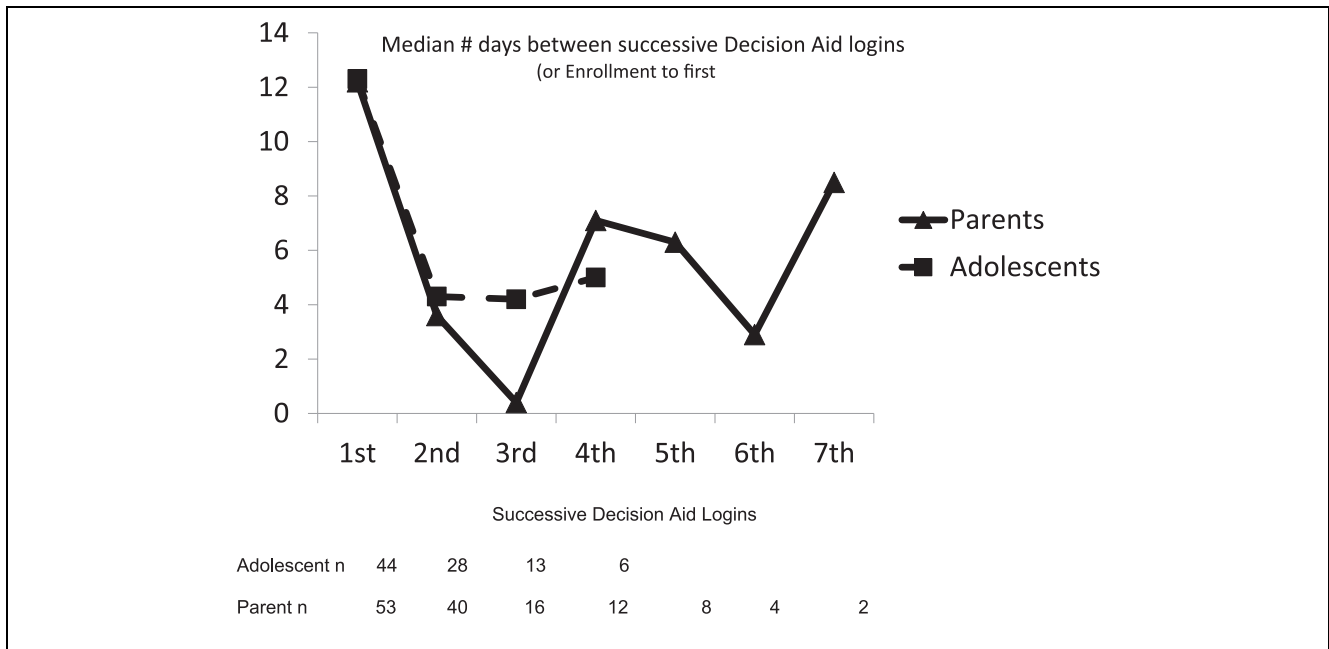


Figure 1 Median number of days between the end of the enrollment visit and first Decision Aid login and between successive Decision Aid logins thereafter. Data presentation continues until only one parent (after the seventh login) or one adolescent (after the fourth login) continued to use the Decision Aid.

Neither health literacy (REALM) nor health numeracy (DNT) scores emerged as significant predictors in these logistic regression models. The significant univariate associations reported above comparing Users and Nonusers did not remain as significant predictors in these multivariate analyses.

Adolescents' and Caregivers' Frequencies of DA Logins

For caregiver DA login frequency, the overall hierarchical regression model was nonsignificant, and no individual predictor variable was associated significantly with caregiver login frequency. For adolescent DA login frequency, the overall model was significant with $F(11, 61) = 2.59$ ($P < 0.009$). Significant predictors were gender (Standardized Beta = 0.23; $P = 0.05$) and REALM scores (Standardized Beta = -0.44 ; $P < 0.002$). Males with lower health literacy scores demonstrated fewer DA logins during the study.

Adolescents' and Caregivers' Duration of DA Use

For both adolescents' and caregivers' total duration of DA use, the overall hierarchical regression model was

again nonsignificant, and no individual predictor variable was associated significantly with caregiver duration of DA use.

Adolescents' and Caregivers' Proportion of DA Content Viewed

The overall models for both adolescent and caregiver percentage of DA content viewed were nonsignificant and no individual predictor variables were associated significantly with the proportion of DA content viewed for caregivers or adolescents.

Discussion

This article analyzes electronically recorded utilization of two web-based multimedia DAs that were designed with extensive stakeholder engagement for adolescents with T1D who were candidates for incorporating either an insulin pump or continuous glucose monitoring into their treatment regimens and their caregivers. The article reports descriptive analyses of several measures of participants' DA use, bivariate comparisons of DA Users and Nonusers, and regression models exploring demographic predictors of indices of DA use. The emergence of electronic DAs makes it increasingly possible to investigate

participants' actual utilization of DAs and for scientific study of these phenomena to yield a better understanding of the variables that influence the extent of use and potential benefit of DAs. Researchers and clinicians should not assume that SDM participants will actually use DAs, regardless of the care taken to develop them, and that efforts to both verify and encourage DA use may be very valuable. Future studies of electronic DAs should include reporting and analysis of DA use metrics as demonstrated in this article.

Others have advocated following principles of user-centered design in the development of mobile (m-health) or electronic (e-health) interventions targeting self-management behavior and shared medical decision making, such as the approach taken in developing the present DAs. Decision aids that are designed and built for delivery via the web or mobile applications have been emerging with increasing frequency.²³⁻²⁷ Only a few articles have reported analyses of participants' electronically verified DA use statistics. For example, Kim and colleagues²⁵ evaluated a computer-based DA to promote colorectal cancer screening and reported that mean viewing time was 19 minutes, although it was unclear whether those data were self-reported or electronically verified. Kassan and colleagues²⁶ evaluated men's use of an Internet-based DA for prostate cancer screening. Users averaged 1.3 logins, and a median of 38 minutes per login. The authors provided a summary of the more frequently used DA elements. Compared to nonusers, DA users were more likely to be White and to have greater Internet access and experience/facility in Internet use. Of note, self-reported DA use correlated only moderately with electronically verified utilization data. The present sample demonstrated more frequent DA logins (means: 3.0 for adolescents and 3.5 for caregivers) than did participants in the study by Kassan and colleagues²⁶ (mean 1.3), perhaps owing to the greater complexity of the medical decision of interest in the present study.

A substantial minority of adolescents and caregivers did not initiate website use. About 20% of caregivers and 33% of adolescents did not login to the assigned DA websites. Among participants who did initiate DA use, mean login frequency, duration of utilization, and proportion of content viewed were indicative of considerable DA use, approximating what the research team considered to be adequate exposure to DA content. Therefore, getting people to use the DA at least once should be a priority in future research and clinical SDM programs.

The present study adds to this literature and illustrates how the careful analysis of DA use and its determinants could drive a program of research that empirically

validates the characteristics of optimal DA design, development, and implementation. Regression analyses explored demographic variables that may be significant predictors of dimensions of DA use, including follow-through on the initial DA website login; frequency of logging in thereafter; total active time spent on the DA website; and proportion of total DA content viewed. In general, similar clusters of demographic variables were associated with participants' status on these dimensions. Being a non-White male with low health literacy and low SES predicted suboptimal DA use, affirming similar findings in the study by Kassan and colleagues.²⁶ In contrast, caregiver demographic characteristics consistently failed to emerge as significant predictors of their DA use. T1D-related measures of adolescents' metabolic control (HbA_{1c}), diabetes duration, and insulin delivery modality (insulin pump or multiple daily injections) were not significantly associated with measures of either caregiver or adolescent DA use. The findings indicating significant positive correlations among indicators of caregiver and adolescent DA use suggest that encouraging family members to discuss their DA use experiences with each other and assist each other with accessing DA content of special interest may enhance overall DA use.

The study results also yielded a characterization of the depth of DA use by participants. The mean number of DA logins was 3.5 for caregivers and 3.0 for adolescents, with a mean total of about 55 and 46 minutes of DA use, respectively. Caregivers and adolescents both tended to use the DAs for about 6 to 7 weeks (median = 45.6 and 48.2 days, respectively), and they viewed 77.4% and 72.7% of the available DA content, respectively. Although many participants did not login to a DA even once, the typical usage by those who did was of sufficient depth to enable participants to benefit from exposure to the DA content.

Scores for health literacy and numeracy obtained for caregivers and adolescents were negligible predictors of extent of DA use. Only adolescents' frequency of DA logins was associated significantly with scores on the health literacy measure. Although health literacy and numeracy would seem to be likely predictors of DA use in an SDM trial, patients with very limited abilities on these measures might not be considered by their HCPs to be appropriate candidates for CSII (continuous subcutaneous insulin infusion) or CGM and thus not eligible for participation in this study. A study enrolling patients with more variability in health literacy and numeracy skills might have yielded different results.

Participants' use of the DA Decision Slider function indicated that caregivers tended to be somewhat more

positively inclined toward the insulin pump or CGM after viewing relevant information presented by the DA than were adolescents. This may reflect a commonly observed caregiver-adolescent dynamic around these decisions in which caregivers tended to view adoption of these technologies as a solution to T1D problems, while adolescents often tended to view them as adding to T1D treatment burden. The clustering of Caregiver and Adolescent scores around 50% supports the argument that the DA content was not biased for or against the insulin pump or CGM, which was an important goal of DA construction.

Completion of the RCT that is in progress should yield additional information about the efficacy of the SDM intervention and the extent to which measures of DA use during the trial are associated with DA outcomes. That RCT is examining the effects of DA use on insulin pump or CGM knowledge, various measures of decision quality, satisfaction with DA use and, among those who acquire an insulin pump or CGM, the extent to which use of that device has become integral to the adolescent's T1D self-management. Finally, the RCT will explore predictors of beneficial effects of DA use on these outcomes, including demographic variables, diabetes self-management behavior, metabolic control of diabetes, and measures of health literacy and health numeracy.

The study did not include measurement of many other psychological variables that could mediate or moderate DA use such as health locus of control,³⁸ diabetes-related self-efficacy,³⁹ diabetes-related distress,⁴⁰ or family conflict.⁴¹ By including measurement of such mechanisms, future studies of DA utilization could illuminate the psychological processes that influence individuals' benefit from SDM interventions. The study also did not explore the triadic nature of SDM in this pediatric context. The eventual decisions reached by families could be dominated by caregivers or adolescents or yield a compromise or consensus solution negotiated between them. Research into the determinants and impact of the triadic nature of SDM in pediatrics would be valuable.

There are a number of noteworthy limitations of this study. These include the relatively small sample size (66 caregiver-adolescent dyads), the absence of meaningful study data from caregivers and adolescents who never logged in to the assigned DAs, and the fact that study participation may not represent caregiver and adolescent behavior in naturalistic settings since it occurred in the somewhat artificial context of an ongoing randomized, controlled trial. Participants received payment for study participation, a procedure that may have resulted in

people volunteering for the study who were not truly serious about their consideration of an insulin pump or CGM. A possible procedural adjustment for similar future trials would be to ensure that all participants receive supervised assistance logging into the DA site at the time of enrollment before leaving the clinic. Once people were exposed to the DA Welcome Tour section (see Online Appendix), they tended to revisit the website several times, to use the DA for an appreciable total duration, and to expose themselves to most of the DA content.

In conclusion, the present report extends the literature on patients' documented use of DAs in SDM interventions by exploring these phenomena in greater detail than has been done in previous similar studies, and by studying these processes in the contexts of a new clinical population (adolescents with T1D) and new medical decisions (insulin pump or CGM). The continuation of this work through the completion of an ongoing RCT of DA use should further amplify the contributions made by this work.


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Supplemental Material

The online supplementary appendix for this article is available on the *Medical Decision Making Policy & Practice* website at <http://journals.sagepub.com/home/mpp>.

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References

1. Edwards A, Elwyn G. *Shared Decision-Making in Health Care: Achieving Evidence-Based Patient Choice*. Oxford: Oxford University Press; 2009.
2. Bekker H, Thornton J, Airey C, et al. Informed decision-making: an annotated bibliography and systematic review. *Health Technol Assess*. 1999;3(1):1-156.

3. Elwyn G, O'Connor A, Stacey D, et al. Developing a quality criteria framework for patient decision aids: online international Delphi consensus process. *BMJ*. 2006; 333(7565):417. doi:10.1136/bmj.38926.629329.AE.
4. Mullan RJ, Montori VM, Shah ND, et al. The diabetes mellitus medication choice decision aid: a randomized trial. *Arch Intern Med*. 2009;169(17):1560–68. doi:10.1001/archinternmed.2009.293.
5. Crosby LE, Shook LM, Ware RE, Brinkman WB. Shared decision making for hydroxyurea treatment initiation in children with sickle cell anemia. *Pediatr Blood Cancer*. 2015;62(2):184–5. doi:10.1002/pbc.25124.
6. Fiks AG, Mayne S, Localio AR, Alessandrini EA, Guevara JP. Shared decision-making and health care expenditures among children with special health care needs. *Pediatrics*. 2011;129(1):99–107. doi:10.1542/peds.2011-1352.
7. Goel V, Sawka CA, Thiel EC, Gort EH, O'Connor AM. Randomized trial of a patient decision aid for choice of surgical treatment for breast cancer. *Med Decis Making*. 2001;21(1):1–6. doi:10.1177/0272989X0102100101.
8. Fiks AG, Grundmeier RW, Mayne S, et al. Effectiveness of decision support for families, clinicians, or both on HPV vaccine receipt. *Pediatrics*. 2013;131(6):1114–24. doi:10.1542/peds.2012-3122.
9. Fiks AG, Jimenez ME. The promise of shared decision-making in pediatrics. *Acta Paediatr*. 2010;99(10):1464–66. doi:10.1111/j.1651-2227.2010.01978.x.
10. Feenstra B, Boland L, Lawson ML, et al. Interventions to support children's engagement in health-related decisions: a systematic review. *BMC Pediatr*. 2014;14(1):109. doi:10.1186/1471-2431-14-109.
11. Brinkman WB, Hartl J, Rawe LM, Sucharew H, Britto MT, Epstein JN. Physicians' shared decision-making behaviors in attention-deficit/hyperactivity disorder care. *Arch Pediatr Adolesc Med*. 2011;165(11):1013–19. doi:10.1001/archpediatrics.2011.154.
12. Wyatt KD, List B, Brinkman WB, et al. Shared decision making in pediatrics: a systematic review and meta-analysis. *Acad Pediatr*. 2015;15(6):573–83. doi:10.1016/j.acap.2015.03.011.
13. Lipstein EA, Brinkman WB, Fiks AG, et al. An emerging field of research: challenges in pediatric decision-making. *Med Decis Making*. 2015;35(3):403–8. doi:10.1177/0272989X14546901.
14. Brinkman WB, Majcher JH, Poling LM, et al. Shared decision-making to improve attention-deficit hyperactivity disorder care. *Patient Educ Couns*. 2013;93(1):95–101. doi:10.1016/j.pec.2013.04.009.
15. Lipstein EA, Brinkman WB, Britto MT. What is known about parents' treatment decisions? A narrative review of pediatric decision-making. *Med Decis Making*. 2012;32(2):246–58. doi:10.1177/0272989X11421528.
16. O'Connor AM, Rostom A, Fiset V, et al. Decision aids for patients facing health treatment or screening decisions: systematic review. *BMJ*. 1999;319(7212):731–4. doi:10.1136/bmj.319.7212.731.
17. Fiks AG. Designing computerized decision support that works for clinicians and families. *Curr Prob Pediatr Adolesc Health Care*. 2011;41(3):60–88. doi:10.1016/j.cppeds.2010.10.006.
18. Wysocki T, Hirschfeld F, Miller L, et al. Consideration of insulin pumps or continuous glucose monitors by adolescents with type 1 diabetes and their parents: stakeholder engagement in the design of web-based decision aids. *Diabetes Educ*. 2016;42(4):395–407. doi:10.1177/0145721716647492.
19. Dabbs ADV, Myers BA, McCurry KR, et al. User-centered design and interactive health technologies for patients. *Comput Inform Nurs*. 2009;27(3):175. doi:10.1097/NCN.0b013e31819f7c7c.
20. Syrowatka A, Kromker D, Meguerditchian AN, Tamblyn R. Features of computer-based decision aids: systematic review, thematic synthesis, and meta-analyses. *J Med Internet Res*. 2016;18(1):e20. doi:10.2196/jmir.4982.
21. Witterman HO, Chipenda-Dansokho S, Colquhoun H, et al. User-centered design and the development of patient decision aids: protocol for a systematic review. *Syst Rev*. 2015;4:11. doi:10.1186/2046-4053-4-11.
22. Hoffman AS, Volk RJ, Saarimaki A, et al. Delivering patient decision aids on the internet: definitions, theories, current evidence, and emerging research areas. *BMC Med Inform Decis Mak*. 2013;13(Suppl. 2):S13. doi:10.1186/1472-6947-13-S2-S13.
23. Hoffman AS, Llewellyn-Thomas HA, Tosteson ANA, et al. Launching a virtual decision lab: development and field-testing of a web-based patient decision support research platform. *BMC Med Inform Decis Mak*. 2014;14(1):112. doi:10.1186/s12911-014-0112-8.
24. Lopez-Olivo MA, Ingleswar A, Volk RJ, et al. Development and pilot testing of multimedia patient education tools for patients with knee osteoarthritis, osteoporosis, and rheumatoid arthritis. *Arthritis Care Res (Hoboken)*. 2018;70(2):213–20. doi:10.1002/acr.23271.
25. Kim J, Whitney A, Hayter S, et al. Development and initial testing of a computer-based patient decision aid to promote colorectal cancer screening for primary care practice. *BMC Med Inform Dec Mak*. 2005;5:36. doi:10.1186/1472-6947-5-36.
26. Kassan EC, Williams RM, Kelly SP, et al. Men's use of an internet-based decision aid for prostate cancer screening. *J Health Commun*. 2012;17(6):677–97. doi:10.1080/10810730.2011.579688.
27. Palmer BW, Lanouette NM, Jeste DV. Effectiveness of multimedia aids to enhance comprehension of research consent information: a systematic review. *IRB*. 2012;34(6):1–15.
28. Nishimura A, Carey J, Erwin PJ, Tilburt JC, Murad MH, McCormick JB. Improving understanding in the research informed consent process: a systematic review of 54

- interventions tested in randomized control trials. *BMC Med Ethics*. 2013;14:28. doi:10.1186/1472-6939-14-28.
29. Stacey D, Vandemheen KL, Hennessey R, et al. Implementation of a cystic fibrosis lung transplant referral patient decision aid in routine clinical practice: an observational study. *Implemt Sci*. 2015;10:17. doi:10.1011.1186/s13012-015-0206-4.
 30. Wyatt KD, Branda ME, Anderson RT, et al. Peering into the black box: a meta-analysis of how clinicians use decision aids during clinical encounters. *Implemt Sci*. 2014;9:26. doi:10.1186/1748-5908-9-26.
 31. Arterburn D, Wellman R, Westbrook E, et al. Introducing decision aids at Group Health was linked to sharply lower hip and knee surgery rates and costs. *Health Affairs (Millwood)*. 2012;31(9):2094–104. doi:10.1377/hlthaff.2011.0686.
 32. Weissberg-Benchell J, Antisdel-Lomaglio J, Seshadri R. Insulin pump therapy: a meta-analysis. *Diabetes Care*. 2003;26(4):1079–87. doi:10.2337/diacare.26.4.1079.
 33. Olinder AL, Kernell A, Smide B. Missed bolus doses: devastating for metabolic control in CSII-treated adolescents with type 1 diabetes. *Pediatr Diabetes*. 2009;10(2):142–8. doi:10.1111/j.1399-5448.2008.00462.x.
 34. Wood JR, Moreland EC, Volkening LK, Svoren BM, Butler DA, Laffel LM. Durability of insulin pump use in pediatric patients with type 1 diabetes. *Diabetes Care*. 2006;29(11):2355–60. doi:10.2337/dc06-1141.
 35. Tansey M, Laffel L, Cheng J, et al. Satisfaction with continuous glucose monitoring in adults and youths with type 1 diabetes. *Diabet Med*. 2011;28(9):1118–22. doi:10.1111/j.1464-5491.2011.03368.x.
 36. Springer T, Kennen E, Bocchini JA, et al. Development and Validation of the Rapid Estimate of Adolescent Literacy in Medicine (REALMTeen): a tool to screen adolescents for below-grade reading in health care settings. *Pediatrics*. 2006;118:e1707–14. doi:10.1542/peds.2006-1139.
 37. Huizinga MM, Elasy A, Wallston KA, et al. Development and validation of the Diabetes Numeracy Test. *BMC Health Serv Res*. 2008;8:96. doi:10.1186/1472-6963-8-96.
 38. Wallston KA. The validity of the Multidimensional Health Locus of Control Scales. *J Health Psychol*. 2005;10(4):623–31. doi:10.1177/1359105305055304.
 39. Iannotti RJ, Schneider S, Nansel TR, et al. Self-efficacy, outcome expectations, and diabetes self-management in adolescents with type 1 diabetes. *J Dev Behav Pediatr*. 2006;27(2):98–105.
 40. Shapiro JB, Vesco AT, Weil LEG, Evans MA, Hood KK, Weissberg-Benchell J. Psychometric properties of the Problem Areas in Diabetes: Teen and Parent of Teen versions. *J Pediatr Psychol*. Epub Dec 18 2017. doi:10.1093/jpepsy/jsx146.
 41. Hood KK, Butler DA, Anderson BJ, Laffel LM. Updated and revised Diabetes Family Conflict Scale. *Diabetes Care*. 2007;30(7):1764–9. doi:10.2337/dc06-2358.