ORIGINAL RESEARCH

Effects of a Video on Organ Donation Consent Among Primary Care Patients: A Randomized Controlled Trial

J. Daryl Thornton, MD, MPH^{1,2}, Catherine Sullivan, MS, RD, LD¹, Jeffrey M. Albert, PhD³, Maria Cedeño¹, Bridget Patrick, MS¹, Julie Pencak¹, Kristine A. Wong, MPH⁴, Margaret D. Allen, MD, DrSC(Hon)^{5,6}, Linda Kimble, MEd, CHES⁷, Heather Mekesa, MBA⁸, Gordon Bowen, MS, CPTC⁸, and Ashwini R. Sehgal, MD^{1,3,9}

¹Center for Reducing Health Disparities, MetroHealth Campus of Case Western Reserve University, Cleveland, OH, USA; ²Division of Pulmonary, Critical Care, and Sleep Medicine, MetroHealth Campus of Case Western Reserve University, Cleveland, OH, USA; ³Department of Epidemiology and Biostatistics, Case Western Reserve University, Cleveland, OH, USA; ⁴Oakland, CA, USA; ⁵Benaroya Research Institute, Seattle, WA, USA; ⁶University of Washington, Seattle, WA, USA; ⁷Cleveland Minority Organ Tissue Transplant Education Program (MOTTEP), Cleveland, OH, USA; ⁸LifeBanc, Cleveland, OH, USA; ⁹Division of Nephrology, MetroHealth Campus of Case Western Reserve University, Cleveland, OH, USA.

BACKGROUND: Low organ donation rates remain a major barrier to organ transplantation.

OBJECTIVE: We aimed to determine the effect of a video and patient cueing on organ donation consent among patients meeting with their primary care provider.

DESIGN: This was a randomized controlled trial between February 2013 and May 2014.

SETTING: The waiting rooms of 18 primary care clinics of a medical system in Cuyahoga County, Ohio.

PATIENTS: The study included 915 patients over 15.5 years of age who had not previously consented to organ donation.

INTERVENTIONS: Just prior to their clinical encounter, intervention patients (n = 456) watched a 5-minute organ donation video on iPads and then choose a question regarding organ donation to ask their provider. Control patients (n = 459) visited their provider per usual routine.

MAIN MEASURES: The primary outcome was the proportion of patients who consented for organ donation. Secondary outcomes included the proportion of patients who discussed organ donation with their provider and the proportion who were satisfied with the time spent with their provider during the clinical encounter.

KEY RESULTS: Intervention patients were more likely than control patients to consent to donate organs (22 % vs. 15 %, OR 1.50, 95%CI 1.10–2.13). Intervention patients were also more likely to have donation discussions with their provider (77 % vs. 18 %, OR 15.1, 95%CI 11.1–20.6). Intervention and control patients were similarly satisfied with the time they spent with their provider (83 % vs. 86 %, OR 0.87, 95%CI 0.61–1.25).

LIMITATION: How the observed increases in organ donation consent might translate into a greater organ supply is unclear.

CONCLUSION: Watching a brief video regarding organ donation and being cued to ask a primary care provider a question about donation resulted in more organ donation discussions and an increase in organ donation

consent. Satisfaction with the time spent during the clinical encounter was not affected.

TRIAL REGISTRATION: clinicaltrials.gov Identifier: NCT01697137

KEY WORDS: randomized controlled trial; organ donation; donor designation; minority donation; organ transplantation; public attitudes; racial disparities.

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INTRODUCTION

More than 120 000 individuals are actively waiting for an organ to transplant, but fewer than 30 000 transplant operations are performed each year, largely due to a shortage of available organs. As a result, many patients die while waiting for a transplant. An increase in organ donation would help narrow the gap between supply and demand, while extending the duration and quality of life of organ recipients.

Our prior work demonstrated that a brief organ donation video intervention could be effectively implemented outside of branches of the Ohio Bureau of Motor Vehicles.¹ However, some persons remained reluctant to consent to donation. While most people who consent for organ donation do so at the bureau of motor vehicles when obtaining their driver's license,² the licensing office staff generally do not have the training to provide sufficient information and to answer personal questions regarding donation. Provision of information has been cited as one of the most common facilitators to organ donation.³ In our prior work, 34 % of bureau of motor vehicle patrons reported not receiving the information necessary to allay their fears and concerns sufficiently to provide informed consent for donation.¹ Other studies have demonstrated that the general public would like to discuss donation with their primary care physicians.^{4–6} Preceding work has also demonstrated that primary care physicians believe it is within their scope of practice to discuss donation with their patients, but

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they do so infrequently because of lack of time, training, and comfort initiating the topic.⁷ As a result, few efforts have actively targeted physicians and their patients for intervention. We sought to determine the impact of a video intervention for patients and cueing for their primary care providers on the proportion of patients who discussed organ donation with their provider and on the proportion of patients who consented to donate organs.

METHODS

Study Overview

The DECIDE study (Donation Education Completed in Doctor Encounters) was a randomized controlled trial conducted at 18 primary care clinics located within one of nine ambulatory centers of the MetroHealth System. The MetroHealth System is the safety net medical system for Cuyahoga County and is one of the largest healthcare providers in Northeastern Ohio, with over 1 million ambulatory visits each year. Recruitment occurred during normal clinic operating hours (Monday through Saturday) from February 2013 until the target sample size was reached in May 2014. Study documents and interventions were pilot tested, with 38 patients not enrolled in the final study.

The electronic medical record, EpicCare Ambulatory Clinical System (EPIC Systems, Madison, WI), was used to determine patient eligibility. English-proficient patients over 15.5 years of age (the youngest age for first person consent in Ohio) who had not previously consented for organ donation were eligible for inclusion if they had a primary care [family medicine, internal medicine, pediatrics, or combined internal medicine and pediatrics (Med-Peds)] visit with their regular provider planned in the upcoming week. We verified organ donor status of patients by asking them, reviewing documentation in their electronic medical records, and examining their driver's licenses. Regular primary care providers were physicians or nurse practitioners who had at least two health maintenance visits with the patient over the last 3 years. Study coordinators arranged to meet with patients 45 minutes prior to their visit with their primary care provider. On the day of the clinic appointment, coordinators approached patients as they entered the clinic, described the study in more detail, and determined the patient's willingness and eligibility to participate. For patients younger than 18 years of age, consent was obtained from a parent or legal guardian and from the patient. Study patients were given \$20 at the end of the study to thank them for their participation. The institutional review board of the MetroHealth System approved this study.

PRIMARY PROVIDER EDUCATION

Three months prior to the start of the study each primary care provider of the MetroHealth System received a letter detailing

the study and encouraging their participation, an instructional pamphlet regarding organ donation, and a laminated pocket card of frequently asked questions and answers regarding donation. Physicians were encouraged to contact study staff with any questions they might have regarding donation.

RANDOMIZATION

The patient was the unit of randomization. Study staff visited specialty clinics at each ambulatory center in an order and time determined using computer-generated random assignments. Clinic blocks were defined according to 5-hour intervals when patients were scheduled to meet with providers. Thus, a given clinic could have morning, afternoon, or evening blocks on weekdays and a single clinic block on Saturdays. Medical records were reviewed to identify eligible patients who were scheduled to visit with their provider during a given clinic block. Staff telephoned the eligible patients several days in advance and arranged to meet with patients 45 minutes prior to their scheduled appointment. At the beginning of the study, computer-generated randomized group assignments were created and placed in sealed, consecutively numbered, opaque envelopes. At the clinic site, after obtaining informed consent, study staff opened the envelopes revealing study arm designation. Patients then completed control or intervention tasks.

INTERVENTION GROUP

Organ Donation Video

Study patients viewed a 5-minute video intervention on iPads (Apple, Cupertino, California) with noise-cancelling headphones. The professionally-produced video (Palazzo Intercreative, Seattle, Washington) had previously been shown to be effective in increasing consent for organ donation.¹ It addressed concerns that have been expressed in organ donation research by depicting an impromptu discussion among an ethnically diverse group of 20 persons of various ages with various relationships to organ donation and transplantation. Both living and deceased organ donation were discussed.

Patient Cueing

After viewing the video, patients were asked to choose one of 12 possible questions regarding barriers to organ donation to discuss with their primary care provider. Patients could also choose their own question if they so desired. The chosen question was printed on card stock and handed to the patients to give them to their providers at the beginning of the clinical encounter. After the encounter, study coordinators interviewed patients.

CONTROL GROUP

After consenting to participate, patients in the control group met with their primary care provider in the usual manner. Upon exiting the encounter, they were interviewed by a study coordinator in the same manner as intervention patients.

INTERVIEW CONTENT

Study staff interviewed patients using a standardized form to assess their age, gender, race/ethnicity, religiosity, and self-reported health status. Patients were also asked if they had previously completed advance directives. Staff recorded any mention of adverse effects of the study by patients and asked all intervention patients if they had viewed and heard the video intervention in its entirety. Patients were asked if they discussed donation or advance directives with their provider during the clinical encounter, and if so, who initiated the discussion and what questions were asked. Patients were asked if they were satisfied with the answers provided by their provider and if

they were satisfied with the time spent with their provider. The staff concluded the interview by asking patients if they would like to consent to organ donation. Patients who chose to consent electronically provided information on the organ donation website of the Ohio Bureau of Motor Vehicles using study iPads. Existing data suggests that many people prefer consent via donor cards to the electronic donor registry due to concerns such as medical distrust.^{6,8} Patients who were reluctant to consent online completed organ donor cards that went to staff at the Ohio Bureau of Motor Vehicles. For both means of donation consent, study staff observed the entire process to verify that the patient had provided valid consent.

OUTCOMES

The primary outcome was organ donor designation on the Ohio electronic donor registry or by completion of a donor card. The secondary outcomes were self-reported willingness to donate, willingness to donate a kidney while living,

Figure 1. Study eligibility and enrollment.

frequency of patient discussions with their primary care provider, patient satisfaction with the time spent with their primary care provider, and discussions of living wills.

STATISTICAL ANALYSIS

Based on prior work on organ donation rates in Ohio,⁹ we anticipated that 35 % of the control patients and 45 % of intervention patients would consent to donation. To detect an effect size of 10 % would require 792 total patients with a two-tailed α level of 0.05 and 80 % power. The sample size was increased by 5 % to account for potential clustering of patients by physicians, and by 10 % to allow for possible dropouts, leading to a final sample size of 915 patients.

Analyses were conducted according to original randomized assignment, regardless of protocol adherence. Study patients were the unit of analysis. A generalized estimating equations (GEE) approach, with a logit link and an exchangeable working correlation structure (with physician as the cluster) for each binary outcome or a cumulative logit link with an independent working correlation structure for each ordinal outcome, was used to assess the effect of the randomized intervention on each outcome. The indicator variable, study arm assignment—the effect of which was of primary interest—was included as a covariate in the GEE (generalized linear) model. Also included in this model, for any needed adjustment of the intervention effect, were the following baseline patient variables: gender, race, ethnicity, education, age, religion, and religiosity. As some patients were missing values for some of these covariates, we used a multiple imputation. Missing dichotomous variables were imputed using the logistic regression method, and missing values for religiosity were imputed using the predictive mean matching method.¹⁰

To be conservative, outcome variables, which also had some missing values, were not imputed. Instead, we assumed that the three control patients with missing values consented to donate and the five intervention patients with missing values did not consent to donate. A similar process was used for secondary outcome variables. All analyses were performed using Stata Statistical Software (Release 12.1, Stata Corporation, College Station, TX) and SAS (Release 9.2, SAS Institute, Cary, NC). All *p* values represent two-side hypothesis tests, and the significance level was 0.05.

RESULTS

Patients

Of the 8264 primary care patients who were screened, 3611 did not meet eligibility criteria (had already consented to organ donation; had significant cognitive, visual, or auditory impairment; or were not English proficient), 1950 did not arrive by their scheduled clinic appointment time, and 1788 declined to participate. The remaining 915 patients were enrolled into the

Table 1 Demographics of Study Participants and the Population of Cleveland

	Study	Cleveland
Male, %	32 %	48 %
Race		
Black	77 %	53 %
White	20 %	33 %
Other	3 %	14 %
Hispanic	3 %	10 %
Education		
High school graduate	66 %	77 %
Bachelor's degree or higher	11 %	15 %

study, randomized and included in the intention-to-treat analysis (Fig. 1). The study population resembled that of Cleveland (Table 1). The majority (82 %) of intervention patients reported viewing the video in its entirety and were able to choose a question to ask their provider before being called back by clinic staff to meet with their provider. Both study arms had similar baseline characteristics (Table 2). Family medicine (38 %) and internal medicine clinics (38 %) enrolled the most patients followed by internal medicine-pediatrics (23 %) and pediatrics (1 %). Very few patients had a living will (15 %) or health care power of attorney (18 %).

Consent for Organ Donation

Intervention patients were more likely than control patients to consent to donate organs [22 % vs. 15 %; adjusted odds ratio (OR), 1.50 (95 % CI, 1.10–2.13)] (Table 3). Intervention patients were also more willing to sign up in the near future compared to control patients [adjusted OR, 1.38 (95 % CI, 1.06–1.78)]. There was no difference in the proportions of intervention and control patients who expressed a willingness to donate a kidney while living [20 % vs. 14 %; adjusted OR, 1.26 (95 % CI, 0.98–1.61)].

Table 2. Characteristics of Study Patients *

	Intervention (n = 456)	Control (n = 459)
Age, mean (SD), y	51 (13)	52 (12)
Male, No. (%)	144 (32)	154 (34)
Race, No. (%)		
Black	331 (73)	339 (75)
White	96 (21)	94 (21)
Other	25 (6)	18 (4)
Hispanic, No. (%)	18 (4)	10 (2)
Education, No. (%)		
Less than high school	91 (20)	78 (17)
High school	156 (35)	156 (34)
Some college	203 (45)	223 (52)
Religion, No. (%)		
Christian	386 (86)	375 (82)
None	43 (10)	47 (10)
Other	21 (5)	35 (8)
Self reported health, mean (SD)	6.8 (1.8)	6.8 (1.8)
Living will, No. (%)	61 (13)	78 (17)
Health care power of attorney, No. (%)	72 (16)	95 (21)
Influence of religion, mean (SD)	8.3 (2.3)	8.1 (2.4)

* *p* values for all comparisons > 0.06

Table 3. Outcomes Assessed Among Study Patients*

	Intervention Group n/N (%)	Control Group n/N (%)	Unadjusted Odds Ratio (95% CI)	P Value	Adjusted Odds Ratio (95% CI)	P Value
Consented to organ donation	100/456 (22%)	71/459 (15%)	1.53 (1.10 – 2.13)	.012	1.50 (1.10 – 2.13)	.015
Willingness to donate						
Do not want to donate	50/456 (11%)	85/459 (18%)	1.40 (1.09 – 1.81)	< .001	1.38 (1.06 – 1.78)	.016
Thinking about it, but have not made up mind	239/456 (52%)	249/459 (54%)				
Plan to sign in next 6 months	67/456 (15%)	54/459 (12%)				
Would like to sign up now	100/456 (22%)	71/459 (15%)				
Willing to make a living kidney donation	92/456 (20%)	65/459 (14%)	1.20 (0.94 – 1.53)	.14	1.18 (0.92 – 1.51)	.19
Discussed donation with primary care provider	347/456 (76%)	83/459 (18%)	14.6 (10.7 – 19.9)	< .001	15.1 (11.1 – 20.6)	< .001
Satisfaction with time spent with provider						
Very dissatisfied	6/456 (1%)	4/459 (1%)	0.85 (0.6 – 1.20)	.36	0.87 (0.61 – 1.25)	.45
Somewhat dissatisfied	3/456 (1%)	4/459 (1%)				
Somewhat satisfied	68/456 (15%)	57/459 (12%)				
Very satisfied	379/456 (83%)	394/459 (86%)				
Discussed living will with primary care provider	88/456 (19%)	57/459 (12%)	1.69 (1.14 – 2.50)	.009	1.66 (1.12 – 2.47)	.012

*Odds ratios derived from a generalized estimated equation by using logit link for binary outcome and an exchangeable working correlation structure (with physician as the cluster) adjusting for gender, race, ethnicity, education, age, religion, and religiosity. See text for details

Donation Discussions

Intervention patients were much more likely than control patients to have discussions with their primary care provider regarding organ donation [76 % vs. 18 %, adjusted OR, 15.1 (95 % CI, 11.1–20.6)]. Among visits that involved a donation discussion, patients, not providers, initiated the majority of discussions in both groups (95 % in both groups, $p = 0.92$). The most common question asked by patients was: “Will I be

able to be an organ donor given my existing medical conditions and/or medications I am taking?” (38 %) (Table 4). Patients rated their provider’s answers to donation questions as helpful (18 % somewhat agree, 81 % strongly agree for both groups, $p = 0.98$).

Intervention patients were also more likely to have discussions with their primary care providers regarding living wills and advanced directives compared to control patients [19 % vs. 12 %, adjusted OR, 1.66 (95 % CI, 1.12–2.47)]. Patients

Table 4. Questions Intervention Patients Selected to Ask Their Primary Care Providers

Question	Frequency (%)
Will I be able to be an organ donor given my existing medical condition(s) and/or medications I am taking?	144 (38)
Will the hospitals and doctors try to save me if they know I am an organ donor?	57 (15)
What medical conditions exclude a person from donating organs?	32 (8)
Am I too old to be an organ donor?	14 (4)
Will organ donation affect my looks or funeral arrangements?	13 (4)
How is it decided who would get my organs?	13 (4)
Will my decision to be an organ donor affect the quality of my medical care?	6 (2)
Will my family have to pay for my organ donation?	3 (1)
Other question	69 (18)
No question	24 (6)

who discussed organ donation with their primary care provider were more likely to discuss living wills compared to those patients who did not discuss donation (24 % vs. 8 %, $p < 0.001$).

Patient Satisfaction with Clinical Encounter

The majority of patients in both the intervention and control groups were very satisfied with the time spent with their providers during the clinical encounters [83 % vs. 86 %, adjusted OR, 0.87 (95 % CI, 0.61–1.25)].

Adverse Effects

There were no reported adverse effects from the study interventions.

DISCUSSION

We found that a brief video coupled with patient cueing was successful in increasing organ donation discussions among patients and their primary care providers, and in increasing patient consent for organ donation. The interventions were not associated with a decrease in patient satisfaction with the amount of time spent with their provider. Our results have implications for patients, clinicians, researchers and policy makers, as the results of this study suggest that the primary care setting may be a viable means to advocate for consent for organ donation.

The positive effects of the interventions on both discussions and donation consent suggest that patient–provider discussions are an important step in increasing patients' willingness to donate. Patients have significant reservations about donation that often involve distrust of the healthcare system and lack of information about the organ donation process.¹¹ Primary care providers can use their established relationships with their patients to provide factual information and address patient concerns to help navigate around these barriers.¹²

Patient–provider discussions regarding organ donation are not currently the standard of care.^{13,14} When asked about barriers to discussing organ donation with their patients, 68 % of primary care physicians agreed that it was not a high priority in the care of their patients and a similar proportion felt they were too busy and had too little time.⁷ The interventions in this study were inexpensive and easy to administer prior to the clinical encounter, allowing for minimal disruption to clinic operations and no change to patient satisfaction.

Many medical societies advocate for more physician involvement in organ donation decision making. Opinion 2.151 in the American Medical Association's *AMA Code of Medical Ethics* states, "Physicians should participate in efforts to increase organ donation including promotion of voluntary donation."¹⁵ The American College of Physicians proclaims, "Ideally, physicians will discuss the option of organ donation with patients during advance care planning as part of a routine office visit, before the need arises."¹⁶

Another benefit of patient–primary care provider discussions regarding organ donation is it allows the patient's preferences to be documented in the medical record and easily accessible should the patient become eligible for donation. Such documentation of the patient's wishes would be helpful to other medical providers and to family members and caregivers. Knowing patients' preferences for donation is regarded as the strongest influence on donation consent among family decision makers.^{17,18} Providers could also use this information to promote discussion between patients and their family members, thereby further reducing the additional barriers to organ donation posed by uninformed or misinformed families while reducing the burden of making such decisions during periods of stress.^{19–21}

A review of the literature identified one other randomized trial on organ donation in the primary care setting. Bidigare et al. compared the effects of an informational brochure to the brochure and a brief, scripted verbal statement by the treating physician encouraging completion of organ donor cards among 300 patients visiting a family medicine clinic in Detroit.²² They found that 33 % of patients had reported consenting to organ donation prior to the study. Among those patients who had not consented to organ donation, there was no difference in subsequent consent to donate between those patients who received the brochure alone compared to those who had received the brochure and the scripted message from their physician (42 % vs. 30 %, $p = 0.16$). This study was limited by not having a control group, nor an intention-to-treat analysis, and lack of verification of whether patients had actually consented to become organ donors.

Although not the primary focus of the study, we found that patients in the intervention group were also more likely to discuss living wills with their primary care providers compared to patients in the control group. In fact, there was a strong association between discussing donation with a primary care provider and discussing living wills. These findings may not be surprising, given that patients who are asked about end-

of-life preferences are more likely to complete advance directives.²³ These results are consistent with those of a prior cross-sectional study that found a positive relationship between patient–primary care physician end-of-life discussions, completion of living wills, and patient willingness to donate.⁴ Addressing living wills, health care powers of attorney, and organ donation concomitantly in the primary care setting may be an efficient way to address all three important topics. Such discussions may have the added potential benefit of long-term improvement in patient satisfaction.²⁴

The rates of consent for organ donation in the intervention and control arms compared favorably to that of other studies,² but were lower than those seen when the same video was shown to individuals applying for their first driver's license at the bureau of motor vehicles.¹ One potential reason for the difference was the disparate study populations. This study population was older, had existing medical conditions, and was more likely to be minority—all potential barriers to consent for organ donation.²⁵ Another possible explanation was the high percentage of screened patients who were excluded from this study because they had previously consented to organ donation (3375/8264 or 41 %). Thus, this study focused on individuals who had previously declined to become organ donors.

There are limitations to the study that should be considered when interpreting our results. Approximately 22 % of patients declined to participate. However, this proportion is less than the 39 % who declined to participate in a prior randomized controlled trial of organ donation.¹ About one-sixth of control patients discussed organ donation with their providers and signed up to become organ donors. Thus, it appears that simply participating in an organ donation study (without the video or cueing interventions) was sufficient to encourage some patients to have discussions and sign up to be donors. Our informed consent process for all study patients explained that the study outcome was the proportion of patients who consented to organ donation. Therefore, consent may have cued control and intervention patients to consent to donate. However, intervention patients were much more likely to have discussions and somewhat more likely to become organ donors. The effect of the interventions may not be applicable to ambulatory settings outside of northeastern Ohio. Also, the study staff was not blinded to study arm assignment, which could have biased the results. The multifaceted nature of the intervention makes it difficult to determine which component was more effective in increasing donation consent. Finally, while the interventions were successful in the primary care setting, it remains unclear if this is the ideal setting for such interventions.

In summary, we found that a brief video intervention coupled with patient cueing administered in the primary care setting increased discussions of, and consent for, organ donation. This approach allows the topic of organ donation to be introduced and addressed among populations that otherwise would be hesitant to donate. Patients and their providers

should view the primary care setting as an opportunity to discuss end-of-life care and organ donation.

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Conception and design: J. Thornton, C. Sullivan, M. Allen, L. Kimble, H. Mekesa, A. Sehgal.

Collection and assembly of data: J. Thornton, J. Albert, C. Sullivan, M. Cedeño, B. Patrick, J. Pencak.

Analysis and interpretation of the data: J. Thornton, J. Albert, M. Cedeño, B. Patrick, J. Pencak, L. Kimble, H. Mekesa, G. Bowen, A. Sehgal.

Drafting of the article: J. Thornton, C. Sullivan, J. Albert, M. Allen, A. Sehgal.

Critical revision of the article for important intellectual content: All authors

Statistical expertise: J. Thornton, C. Sullivan, J. Albert, A. Sehgal.

Obtaining of funding: J. Thornton, C. Sullivan, M. Allen, A. Sehgal.

Administrative, technical, or material support: J. Thornton, M. Cedeño, B. Patrick, J. Pencak, J. Albert, L. Kimble, H. Mekesa, G. Bowen, A. Sehgal.

Study supervision: J. Thornton, C. Sullivan, A. Sehgal

Corresponding Author: J. Daryl Thornton, MD, MPH; Center for Reducing Health Disparities, MetroHealth Campus of Case Western Reserve University, 2500 MetroHealth Drive, Rammelkamp R209A, Cleveland, OH, USA (e-mail: daryl.thornton@case.edu).

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