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Medication Education for Dosing Safety (MEDS): A Randomized Controlled Trial

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Abstract

Objective: To determine whether a brief intervention at the time of emergency department (ED) discharge can improve safe dosing of liquid acetaminophen and ibuprofen by parents/guardians.

Methods: We performed a randomized controlled trial of parents/guardians in the ED of children aged 90 days-11.9 years discharged with acetaminophen and/or ibuprofen. Families were randomized to standard care or a teaching intervention combining lay language, simplified handouts, provision of an unmarked dosing syringe, and teach-back to confirm correct dosing. Participants were called 48-72 hours and 5-7 days after ED discharge to assess understanding of correct dosing. The primary outcome was defined as parent/guardian report of safe dosing at the time of first follow-up call. Our primary hypothesis was that the intervention would decrease the rate of error from 30% to 10% at 48-72 hour follow-up.

Results: We enrolled 149/259 (58%) eligible subjects; 97 /149 (65%) were reached at first follow-up call, of whom 35/97 (36%) received the intervention. Among those receiving the intervention, 25/35 (71%) were able to identify a safe dose for their child at the time of the first call compared to 28/62 (45%) of those in the control arm. Difference in proportions was 26% (95% CI 7%-46%). There was a 58% increase in reporting safe dosing in the intervention group compared to the control group (RR 1.58, 95% CI: 1.12-2.24), and remained significant after adjustment for health literacy and language (adjusted relative risk 1.50, 95% CI: 1.06-2.13).

Conclusions: A multi-faceted intervention at the time of ED discharge – consisting of a simplified dosing handout, a teaching session, teach-back, and provision of a standardized dosing device – can improve parents' knowledge of safe dosing of liquid medications at 48-72 hours.

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Introduction:

Background:

Acetaminophen and ibuprofen are among the most common medications given to children under 12 years old.[1] However, most parents do not know that the dose for these medications is based on a child's weight,[2,3] and up to 70% of parents make dosing errors when measuring over the counter (OTC) liquid medications in observed settings.[4–7] While under-dosing can lead to inadequate symptomatic control, unintentional over-dosing errors (especially involving acetaminophen) can result in potentially fatal complications.[8] Inappropriate administration continues to place a large burden on the United States health care system, with preventable emergency department (ED) visits due to unintentional under-dosing[9] and nearly 7,000 phone calls to poison control centers each year following unintentional acetaminophen overdoses in children.[10] Challenges around safe dosing of liquid medications disproportionally affect parents with low health literacy [2,5,11–13] and those with limited English proficiency (LEP).[11,14]

Importance:

Liquid ibuprofen and acetaminophen are frequently recommended as part of post-discharge care for children following visits to the ED. This transition from the ED to home is a known high-risk moment in health care, and misunderstanding of medication dosing and instructions after discharge is common.[14–18] In one study, nearly a third of parents made an acetaminophen dosing error after receiving a dosing instruction sheet at ED discharge. The rate was even higher for parents who spoke Spanish as their primary language, with over half making an error.[14]

Our research group previously conducted in-depth interviews with parents to identify potential strategies to improve communication at ED discharge; the participants' recommendations included use of simplified language and demonstration of medication measurement.[19] In prior studies, similar strategies have shown promise for improving dosing understanding.[6,20] Teach-back, an educational method in which the learner is asked to repeat the reported information back to the teacher, is an established strategy for discharge teaching,[6,21] and interviews with families with varied health literacy revealed that they are generally accepting of this strategy.[22]

Goals of This Investigation:

Based on these findings, we hypothesized that a brief intervention at the time of ED discharge that combined a simplified handout, dosing demonstration with dispensed syringe, and teach-back for confirmation of understanding would improve parental ability to identify appropriate weight-based dosing for acetaminophen and ibuprofen at the time of a follow-up phone call 48-72 hours after discharge as compared to parents/guardians who did not receive this intervention. Our primary hypothesis was that the intervention would decrease the rate of error from 30% to 10% at 48-72 hour follow-up. We further examined the effects of adjustment for language and literacy on our primary results, given anticipated small sample sizes, and also assessed differences in rates of error at 5-6 day follow-up.

Patients and Methods:

Study design and setting:

This study was a randomized controlled trial. It was not possible to blind participants and the research assistant to randomization status, but treating providers were aware of neither the components of the intervention nor which patients were randomized to receive the intervention. We prospectively enrolled participants at our large urban ED between October 2017 and August 2018. Subjects were enrolled during hours in which a bilingual research assistant (RA) was available. Subjects were consecutively approached by the RA in the order in which they were seen by ED providers. The RA was a premedical student who was trained in the research protocols by two authors (CNL and MSK).

At the study ED, discharge paperwork was usually prepared by resident physicians in the electronic medical record (EMR) and reviewed with the parent or guardian by the patient's registered nurse, although this final step was sometimes completed by the resident or attending physician. If prescriptions were written, the names of those medications and dose in both milligrams (mg) and milliliters (mL) were automatically printed on the discharge paperwork. Recommended OTC medications and dosing instructions only appeared in the paperwork if they were typed into the discharge instructions by the physician. All providers had access to pre-printed handouts in both English and Spanish that listed dosing for acetaminophen or ibuprofen, and some chose to give families a copy upon discharge. These handouts include dosing recommendations for a broad range of weights and medication formulations, and providers often circled the correct dose for that child's weight prior to giving the paper to the parent or guardian. Use of this resource varied greatly between providers. The discharge processes of all enrolled patients were observed by the RA and data were recorded using a standardized checklist.[23]

This study was designed as a single center proof-of-concept pilot to demonstrate feasibility prior to implementation at multiple sites. This study was approved by the Partners Health Care Institutional Review Board and was registered with Clinicaltrials.gov (NCT03223246).

Selection of Participants:

Eligible participants were defined as parents or guardians of children between ages 90 days and 11.9 years who were being discharged with a plan for use of liquid acetaminophen (any enrolled age) and/or ibuprofen (only children >6 months old). Inclusion criteria included parental fluency in English or Spanish, reported ability to be reached by telephone over the next seven days, and planned discharge home. Exclusion criteria included presence of a complex chronic condition[24] in the child, planned use of a non-standard weight-based medication dose, and children not accompanied by a parent or legal guardian.

We used our prior work's finding that 32% of parents made an acetaminophen dosing error at ED discharge, despite provision of an instruction sheet for the power calculations for this study.[14] To detect an improvement from 30% error to 10% error and achieve 80% power, it was calculated that at least 124 participants were needed.

During the enrollment process, the study RA screened the electronic medical records of all children in the designated age range who arrived in the ED. Prior to approaching the parent to introduce the study, the RA confirmed with the treatment team that the patient was planned for discharge home, that standard doses of acetaminophen and/or ibuprofen would be recommended upon discharge, and that there were no situational contraindications to approaching the family for inclusion in the study. Parents or guardians provided verbal informed consent for inclusion in the study. This consent strategy was approved by the Institutional Review Board in order to limit barriers to inclusion for those with limited health literacy. Parents or guardians who consented to participation completed a demographic survey, and health literacy and numeracy were assessed via the Newest Vital Sign, a tool that has been validated in both English and Spanish.[25]

After consent, families were randomized to either the control or intervention arm (Figure 1) by the research assistant; assignments were made to parallel groups via simple randomization using a computer-generated list.

Intervention:

All families in the study received standard discharge teaching as above. Immediately following the standard discharge, patients randomized to the intervention arm received an intervention composed of four components. First, families were provided with a simplified dosing handout that showed the correct dose for only the child's weight range without extraneous information (Figure 2). The weight ranges associated with each dose on these handouts were unchanged from the ranges on the institution's standard handout to minimize the risk of patients receiving conflicting written information. Second, the RA used a standardized medication syringe to demonstrate how to measure the proper dose of acetaminophen and/or ibuprofen for the child's weight using a standardized script. Demonstrations were performed for acetaminophen and/or ibuprofen as recommended by the child's treatment team. Third, a teach-back for confirmation of understanding was completed. The parent or guardian was given an identical syringe and bottles containing the recommended medication, then asked to demonstrate the amount of liquid acetaminophen and/or ibuprofen they would draw up to administer to their child. If the correct dose was not measured, the RA re-stated the correct dose and demonstrated again how to draw up the correct amount using standardized language for each patient encounter. This cycle was continued until the parent demonstrated the correct dose, and the number of required teach-back cycles was recorded. Finally, the syringe was given to the parent to take home at the end of their ED visit. Patients were eligible for inclusion if they were taking or prescribed other liquid medications, but teaching about dosing was not provided for medications other than acetaminophen or ibuprofen; if the families had questions about other prescribed medications, they were directed to ask those questions of their ED providers. The RA was observed once per month for the first three months of the trial, then once per quarter to ensure consistency of the intervention.

Parents/guardians enrolled in the trial were called at 48-72 hours after ED discharge to assess their knowledge of appropriate dosing. They were again contacted at 5-7 days after ED discharge to assess retention of knowledge. If the parent or guardian from either

randomization group reported an unsafe dose at the time of either follow-up call, the RA informed them of the correct dose. Although all families expressed willingness to participate in follow-up phone calls and provided preferred windows of time when consenting to participation in the study, many initially did not answer the RA's phone calls. At 93 patients into the study, we noted a low rate of completion of follow-up calls with a 60% (53/93) completion rate for the first call and 41% (38/93) for the second call. The IRB was amended to allow the RA to send a text message prior to the follow-up calls. Following the change, we enrolled 65/158 (41%) with 63% (41/65) answering the first call and 40/65 (62%) answering the second call. A minimum of two attempts were made to reach each family.

Protocols were in place if any serious safety concerns were raised at the time of follow-up calls. In particular, every return visit within 72 hours following study enrollment was reviewed by a team of clinicians who were not participating in the study (safety monitoring board). Children whose condition worsened and required admission to the hospital following randomization were excluded from the study as the educational and clinical interventions provided in the hospital were expected to overshadow the effect of the study intervention. Families received a $20 gift card by mail as compensation after completion of the first follow-up phone call. The trial ended at completion of the scheduled and funded enrollment period.

Outcomes:

The primary outcome was parent/guardian report of safe dosing at the time of first follow-up call, which was defined as a dose within 20% of the weight-based dose provided at time of discharge. This 20% threshold was chosen as it has been used as a safe margin of error in multiple prior studies.[4–7,20,26] The secondary outcome was parent/guardian report of safe dosing at the second follow-up call.

Analysis:

Data were collected in REDCap[27] and analyzed using Stata (Version 14.2, Stata Corporation, College Station, TX) and SAS (Version 9.4, Cary, NC). Patients with missing data on the primary outcome or covariates of interest were excluded. We used standard descriptive statistics to compare rates of error between intervention and control groups. Randomized trials are not always free of confounding or selection bias [28]. In RCTs, chance imbalance between treatment and control groups on baseline covariates can potentially confound the relationship of interest. Since subjects are randomized in RCTs, it is not appropriate to perform inferential tests comparing baseline covariates. Hence, we compared treatment and control groups using standardized differences, computed as the difference in means or proportions divided by a pooled estimate of the standard deviation. Unlike traditional significance testing, standardized differences are less sensitive to sample size and are useful in identifying meaningful differences. A standardized difference of greater than 0.2 is usually considered meaningful. Given the anticipated small sample size in this single-center trial, and the importance of language and literacy in the literature on understanding of discharge instructions, we adjusted for health literacy and language, which were chosen *a priori* as the primary covariates of interest. No interaction terms were considered. Multicollinearity and overdispersion of count data was evaluated for the model. We

estimated relative risk and confidence intervals for the effect of dosing safety education intervention on safe dosing using Poisson regression with robust error variance.

Results:

Characteristics of study subjects:

Six hundred fifty-seven parent/child dyads were assessed for eligibility, of which 398 did not meet inclusion criteria. Of the 259 families who were eligible, 149/259 (58%) consented to participation in the study and were randomized. Sixty-six of the 149 (44%) were allocated to the intervention group and 83/149 (56%) to the control group. (Table 1). Sixty-three of the 66 (95%) families assigned to the intervention group received the full intervention; the discharges of two families were missed because multiple families were discharged simultaneously, and one family asked to leave partway through the intervention.

Primary outcome:

For those in the intervention group, the number of teach-back cycles required for the parent/guardian to demonstrate correct dosing ranged from one to three, with 48/64 (75%) demonstrating an appropriate dose on the first attempt. Prior to the first follow-up phone call, two patients from the intervention group and one from the control group re-presented for care and were admitted to the hospital; phone calls to these families were not attempted, and they were considered lost to follow-up.

Thirty-five out of 66 (53%) families in the intervention group and 62/83 (75%) in the control group were reached at the first phone call (Table 2).

Twenty-five of 35 (71%) parents and guardians from the intervention group reported a safe dose of acetaminophen and/or ibuprofen for their child at the first follow-up call in contrast to 28/62 (45%) of those from the control group (Relative Risk [RR] 1.58, 95% CI: 1.12-2.24). The difference in proportions was 26% (95% CI 7%-46%). This effect remained significant when adjusted for parental language and health literacy (aRR 1.50, 95% CI 1.06-2.13) (Table 3).

Secondary outcomes:

53 out of 76 (70%) who were reached at the second call had also been reached at the first call. Of those reached at the second phone call, more parents and guardians in the control group reported that the dose they reported at the first phone call was corrected by the RA (Table 2). In the control group, 54% (22/41) correctly reported dosing as compared to 74% (26/35) in the intervention group. The difference in proportions was 21% (95% CI −0.41%-42%). Rates of reporting safe dosing at the second follow-up phone call are reported in Table 4.

There was not a difference between the groups with regards to contact with another physician, either at an in person visit or over the phone, at the time of either phone call. No serious safety concerns were identified during either phone call.

Limitations:

Our study had several potential limitations. Generalizability of this pilot study is limited as it was performed at a single academic center, and although a proportion of the participants were non-English speaking and/or had limited health literacy, future multicenter studies are needed to further assess the impact of this intervention on patients in varied settings.. The study RA was not blinded to the randomization groups, but we attempted to minimize potential bias through the use of objective outcome measures.

Our study relied on parental report of dose rather than directly observed measurements. However, this method of evaluation has been used in prior research,[2,3,29] and reported dose and direct observation of dose measurement yielded similar rates of error when both were assessed in a cohort of parents.[20] We decided that correcting dosing at the first follow-up phone call regardless of randomization group was the safest course of action, as omitting a correction could be interpreted as an unspoken agreement with the dose. This correction provided additional teaching to members of the control group that they would not have received outside of the study, and we were therefore unable to separate the effects of this teaching on the results at the second call.

Given the high rate of loss to follow-up in our study, further studies will be needed to understand if this differential follow-up was an event limited to our study or if it reflects participant attitudes toward the intervention. Finally, while the research assistant's main role in the emergency department was to provide the intervention to the study participants, providers using the intervention during their usual clinical practice will have other conflicting priorities and may not include the intervention with each discharge or may not incorporate all components. However, this would be a limitation of any intervention that requires action by clinical providers.

Discussion:

A brief, multi-faceted, intervention at the time of ED discharge significantly increased the odds that parents and guardians would be aware of the safe dose of acetaminophen and/or ibuprofen for their child 48-72 hours after the ED visit. This difference did not persist at 5-7 days. The absence of a difference at the second phone call (5-7 days) may be attributable to to additional teaching provided to those who reported incorrect dosing at the first call. The RA's correction of their misinformation was required for ethical reasons, but is likely to reduce any potential differences between the groups. Our findings build upon prior work that found improved written instructions, provision of safe dosing devices, and teach-back strategies can improve knowledge of safe dosing of liquid medications for children in a variety of settings.[6,12,20,21] Our data, combined with these prior reports, make a strong case for implementing a dosing education intervention in the ED.

EDs present unique challenges for intervention development and implementation. Not only do they serve patients and families from a broad range of backgrounds, pressures around patient flow encourage quick decision making and discharge processes, which often leaves providers with limited time to assess individual educational needs. An ideal intervention

would therefore benefit and be acceptable to patients from all backgrounds. Promisingly, we found that our intervention remained effective when adjusted for health literacy and language and required only a few cycles of teach-back to improve understanding. Because we had input from patients and parents with varied cultural and educational backgrounds during development of the intervention, [19,22] we anticipate that these strategies will be an acceptable addition to discharge practices for most families.

Future research will include implementation studies to evaluate the barriers to and efficacy of this intervention when integrated into providers' workflows. As part of this future investigation, we will include measurements of the length of time required for the intervention. We anticipate that measurements of time as part of that investigation will be valuable to emergency departments considering implementation of our intervention, as the time required by a provider with conflicting responsibilities but more experience may differ from the time required by a research assistant whose sole job was to carefully follow a research protocol. While the combination of these four intervention components increases parent and guardian awareness of safe dosing, these data do not show whether all of these components are essential. Additional future work will include evaluation of individual elements to determine whether a simplified intervention would remain effective. While this intervention was designed for use in EDs, other clinical settings that provide care to pediatric patients face similar educational challenges around liquid medication dosing. We anticipate that this intervention could be applied in primary and specialty care clinic settings, and further studies will help to evaluate its effectiveness in these areas. Finally, while this pilot study was not adequately powered to evaluate for effect of language or health literacy, we look forward to evaluating the effect of these variables in future studies.

In conclusion, a brief intervention at the time of ED discharge can improve safe medication dosing by parents and guardians in the immediate post-discharge period. Future work will further refine this intervention and expand upon this pilot study to assess generalizability to other sites and clinical settings.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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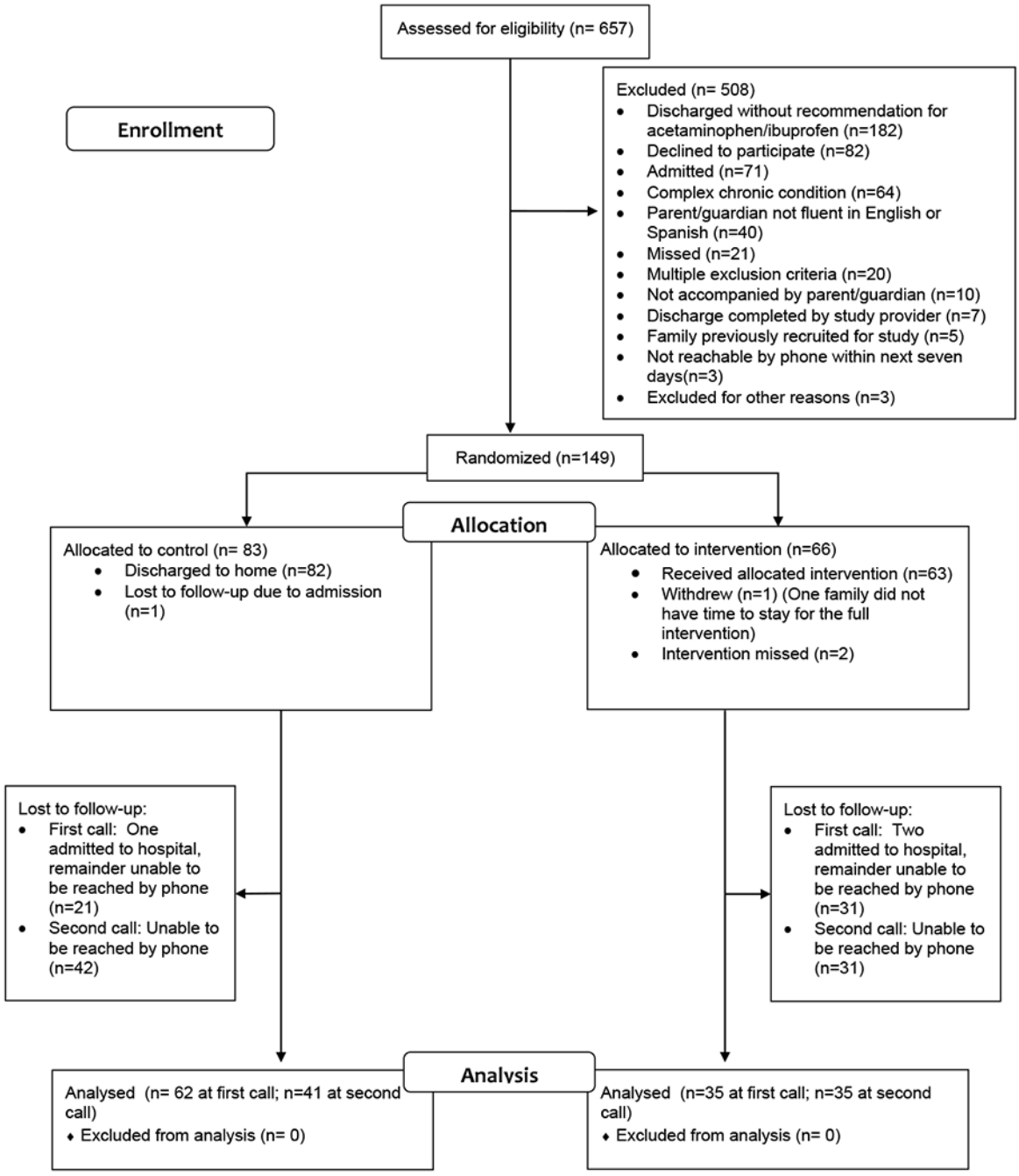

Figure 1:
CONSORT Flow Diagram

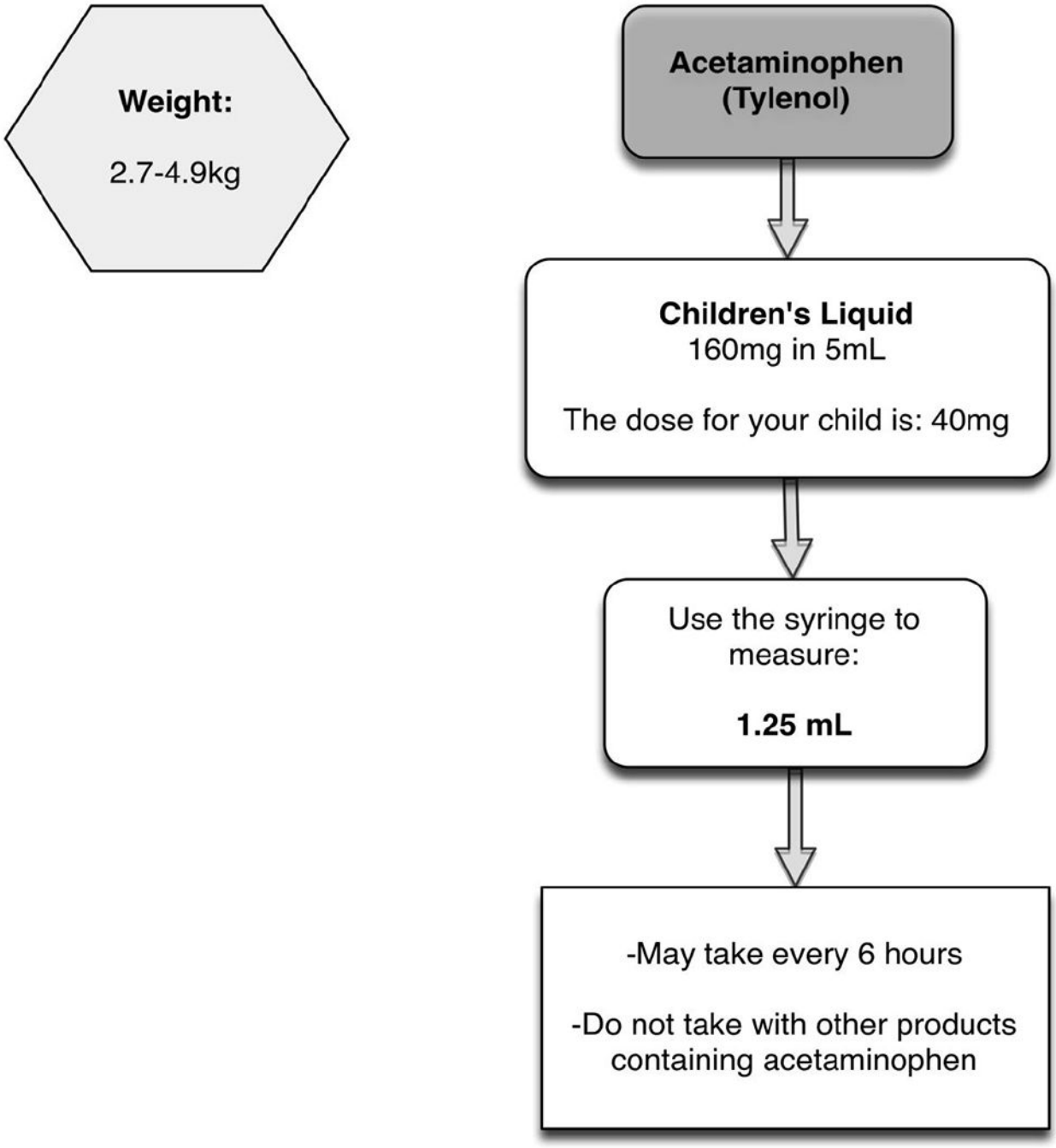

Figure 2:
Sample Handout

Table 1:

Baseline characteristics by randomly-assigned group

	Control (n=83)	Intervention (n=66)
Language of study administration, n (%)		
English	59 (71)	51 (77)
Spanish	24 (29)	15 (23)
Parent/guardian gender, n (%)		
Male	22 (27)	12 (18)
Female	61 (73)	54 (82)
Parent/guardian age in years, median (IQR)	33 (29-39)	34 (30-37)
Child's age in years, median (IQR)	3 (1-6)	2 (1-6)
Child's Race/Ethnicity, n (%)		
Non-Hispanic, White	28 (34)	25 (38)
Non-Hispanic, Black	7 (8)	8 (12)
Hispanic	43 (52)	30 (45)
Other	5 (6)	3 (5)
Health literacy as measured by Newest Vital Sign, median (IQR) *	4 (2-6)	4 (2-6)
Limited health literacy n (%)	39 (47)	30 (46)
Adequate health literacy n (%)	44 (53)	35 (54)
First child, n (%)	34 (56)	22 (63)

* health literacy data missing for one subject

Table 2:

Baseline characteristics at each call by randomly-assigned group

	Call 1			Call 2		
	Control (n=62)	**Intervention (n=35)**	**Standardized difference**	**Control (n=41)**	**Intervention (n=35)**	**Standardized difference**
Language of study administration, n (%)						
English	45 (73)	27 (77)	−0.11	29 (71)	27 (77)	−0.15
Spanish	17 (27)	8 (23)		12 (29)	8 (23)	
Adult gender, n (%)						
Male	17 (27)	7 (20)	0.18	10 (24)	5 (14)	0.26
Female	45 (73)	28 (80)		31 (76)	30 (86)	
Race/Ethnicity, n (%)						
Non-Hispanic, White	20 (32)	13 (37)	0.19	9 (22)	14 (40)	0.53
Non-Hispanic, Black	5 (8)	4 (11)		4 (10)	5 (14)	
Hispanic	32 (52)	15 (43)		23 (56)	15 (43)	
Other	5 (8)	3 (9)		5 (12)	1 (3)	
Health literacy as measured by Newest Vital Sign, median (IQR) *	4 (2-6)	4 (2-6)	0.09	3 (2-5)	4 (2-6)	0.18
Limited health literacy	30 (48)	13 (38)	−0.21	23 (56)	16 (46)	−0.21
Adequate health literacy	32 (52)	21 (62)		18 (44)	19 (54)	
Dose Corrected by RA at First Call, n (%)						
Yes				21 (51)	5 (14)	−0.86

* health literacy data missing for one subject

Standardized difference is the difference in means or proportions divided by the standard error

Table 3:

Call 1: Adjusted Poisson regression models for the association between safe dosing and dosing safety education intervention

	aRR (95% CI)
Intervention status	
Control	1.00 Reference
Intervention	1.50 (1.06-2.13)
Newest vital sign	
Limited health literacy	1.00 Reference
Adequate health literacy	1.36 (0.85-2.17)
Language of study administration	
English	1.00 Reference
Spanish	0.82 (0.46-1.48)

Abbreviations: RR, relative risk; CI, confidence interval; aRR, adjusted relative risk

* Relative risk estimation by Poisson regression with robust error variance

Table 4:

Call 2: Adjusted Poisson regression models for the association between safe dosing and dosing safety education intervention

	aRR (95% CI)
Intervention status	
Control	1.00 Reference
Intervention	0.97 (0.74-1.27)
Additional Teaching at First Call	
Yes	1.00 Reference
No	3.67 (1.79-7.55)
Newest vital sign	
Limited health literacy	1.00 Reference
Adequate health literacy	1.08 (0.81-1.43)
Language of study administration	
English	1.00 Reference
Spanish	1.05 (0.71-1.54)

Abbreviations: RR, risk ratio; CI, confidence interval; aRR, adjusted risk ratio.

Table 5:

Dosing Errors

	High	Low	Did not know dose	Total families with errors
Call 1, n (%)				
Control	9 (29)	24 (77)	9 (29)	31
Intervention	4 (40)	8 (80)	1 (10)	10
Call 2, n (%)				
Control	6 (38)	12 (75)	2 (13)	16
Intervention	3 (33)	5 (56)	1 (11)	9

Note: Respondents are listed under multiple categories if multiple error types were made (i.e. differed between acetaminophen and ibuprofen)