



Development and Assessment of a Pictographic Pediatric Constipation Action Plan

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Objective To assess the Uniformed Services Constipation Action Plan (USCAP) as an evidence-based, personalized, clinical action tool with pictograms to aid clinicians and families in the management of functional constipation.

Study design The USCAP facilitates the management functional constipation by using a health literacy-informed approach to provide instructions for pharmacotherapies and lifestyle modifications. This study included part 1 (pictogram validation) and part 2 (assessment). For part 1, pictogram transparency, translucency, and recall were assessed by parent survey (transparency $\geq 85\%$, mean translucency score ≥ 5 , recall $\geq 85\%$ required for validation). For part 2, the USCAP was assessed by parents, clinical librarians, and clinicians. Parental perceptions ($n = 65$) were assessed using the Consumer Information Rating Form (17 questions) to gauge comprehensibility, design quality and usefulness. Readability was assessed by 5 formulas and a Readability Composite Score was calculated. Clinical librarians ($n = 3$) used the Patient Education Materials Assessment Tool to measure understandability (19 questions) and actionability (7 questions) ($>80\%$ rating was acceptable). Suitability was assessed by clinicians ($n = 34$) using Doak's Suitability Assessment of Materials (superior $\geq 70\%$ rating).

Results All 12 pictograms demonstrated appropriate transparency, translucency, and recall. Parental perceptions reflected appropriate comprehensibility, design quality, and usefulness. The Readability Composite Score was consistent with a fifth-grade level. Clinical librarians reported acceptable understandability and actionability. Clinicians reported superior suitability.

Conclusions The USCAP met all criteria for clinical implementation and future study of USCAP implementation for treating children with chronic functional constipation. (*J Pediatr* 2021;229:118-26).

Constipation accounts for 3% of pediatrician visits, and up to 30% of pediatric gastroenterology appointments.¹⁻⁴ Functional constipation is frequently the result of longstanding withholding behaviors. It is often associated with infrequent and/or painful defecation, fecal incontinence, and abdominal pain.⁵ This problem can be challenging to manage in the clinic and at home, with nearly 40% of children failing therapy and progressing to chronic symptoms.⁶⁻⁸ Functional constipation has been shown to cause lower health-related quality of life and to increased health costs, school absenteeism, and parental workdays missed.^{5,9,10}

Validated clinical tools have been developed to empower both providers and parents to care successfully for children with chronic diseases, including asthma, eczema, and anaphylaxis action plans. Some of these tools have been shown to improve both clinical outcomes and health-related quality of life.¹¹⁻²⁶ Despite the vast number and potential combinations of pharmacotherapies and lifestyle modifications available to manage functional constipation in children, there is currently no validated, symptom-based clinical action tool to assist in the care of children with constipation.

We aimed to develop and assess an evidence-based, personalized pictogram-based constipation action plan (CAP) to aid providers, parents, and patients in the management of functional constipation in children.

AHRQ	Agency for Healthcare Research and Quality	PEMAT-P	Patient Education Materials Assessment Tool for Printable Materials
CAP	Constipation action plan		
CIRF	Consumer Information Rating Form	SAHLE-E	Short assessment of health literacy-English version
FG	Fry Graph	SAM	Suitability Assessment of Materials
FRE	Flesch Reading Ease		
NASPGHAN	North American Society for Pediatric Gastroenterology and Nutrition	SES	Socioeconomic status
Hepatology		U/A	Understandability and actionability
OCPS	Overall CIRF percentile score	USCAP	Uniformed Services Constipation Action Plan

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Methods

This study consisted of 2 parts: development and assessment, which produced the Uniformed Services CAP (USCAP) (Figure 1, available at https://wrnmmc.libguides.com/pat_ed/ped_stomach). Appendix 1 (available at www.jpeds.com) provides a summary of the study methods, outcomes, and assessment tools.

Part I: Development

CAP Design. The USCAP was designed to support provider-parent communication at the time of discharge from the clinical setting as well as home management of functional constipation. The USCAP facilitates home management by guiding families in the stepwise management of constipation in response to signs and symptoms they observe in the child. We used a health literacy-informed approach to convey information on evidenced-based pharmacotherapies and lifestyle modifications to optimize knowledge transfer from clinicians to patients and their families. The USCAP is intended to be used as part of a universal precautions approach to decrease disparities in functional constipation outcomes related to low health literacy. We present the development and assessment of the USCAP from the initial conception of version I (December 2018), to the evolution of version II (July 2019), version III (September 2019), and finally version IV (March 2020) (Appendix 2; available at www.jpeds.com).

The research team reviewed the literature regarding the use of action plans for other chronic, pediatric conditions.^{11,13-15} We identified key, evidence-based concepts, including imagery, comprehension, quality, usefulness, readability, understandability, actionability, and suitability upon which to build the USCAP.

The North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition (NASPGHAN) clinical practice guideline provides evidence-based recommendations for the management of functional constipation.^{5,27} Based on this evidence, we included 4 sections in the USCAP: a cleanout section, a green (good) maintenance section, a yellow (bad) acute section, and a red (worse) severely acute section, which is reflected in version I. Subsequent improvements included enabling a fully electronic plan with drop-down fields for commonly used medications per the NASPGHAN clinical practice guideline and an Agency for Healthcare Research and Quality (AHRQ)-recommended Universal Medication Schedule (version II), the addition of clinically-relevant pictograms (version III), and an AHRQ-recommended “teach-back” USCAP video summary (version IV).²⁶⁻²⁸

Pictogram Design. Pictograms were designed using methods from Mok and Yin’s action plans for anaphylaxis and asthma, respectively.^{12,15,29} Key elements selected for depiction in the USCAP included (1) eating, (2) play, (3) belly pain, (4) stool form, (5) negative sensations during defecation, and (6) defecation accidents. The clinical

progression (green to yellow to red) of each sign or symptom would be captured in a series of 3 images known as the storyboard. Several recommended lifestyle changes were depicted, including improved toilet posturing, use of a defecation posture modification device, and reinforcing appropriate hydration and nutrition.^{27,30} The medical graphic designer was given artistic freedom when developing storyboards. The images were subsequently approved by the project team after appropriate editing.

Part II: Assessment

Survey Distribution Strategy. A web-based convenience sample was obtained via email to parents of children enrolled in the Military Health System and through relevant, publicly available special interest groups via Facebook and included Parents of Children with Constipation, Chronic Constipation in Kids-Support Group, and Parents of children with Behavioral Problems. From May 13, 2020, to May 27, 2020, parent participants accessed the web-based survey either by email from the study group (procured from the Military Health System electronic medical record) or accessed the survey link through sharing directly from Facebook. All respondents were invited to participate anonymously. We excluded participants who could not communicate in English or who did not complete the entire survey (first survey $n = 23$, second survey $n = 38$). Written, informed, electronic consent was obtained prior to participation in the private survey session on SurveyMonkey.³¹

Pictogram Validation (Parent Survey). Four separate storyboards (12 images total) were created to illustrate the key elements listed above. SurveyMonkey was used to capture responses to the pictogram assessment. Using this platform, we were able to measure whether each pictogram demonstrated transparency, translucency, and recall. Each participant was presented with storyboards in random order, and images within each storyboard were also presented in random order.

Transparency refers to the ability of an individual to guess an image’s innate significance or meaning without being provided details beyond the pictogram.³² Transparency was assessed by showing the participant a single storyboard and asking them to match each of the images (presented in random order) to text which best described each picture. For this project, we adhered to the American National Standards Institute standard for adequate transparency: correct identification of each image by at least 85% of participants.

Translucency refers to the strength of the relationship between the picture and its intended meaning.³³ Translucency was evaluated by showing the parent the individual pictogram from the storyboard in conjunction with the appropriate, key clinical text to be paired with it on the USCAP. Respondents were asked to what degree the illustrations resembled the key clinical element based on a 7-point visual analog scale (from 1 [no relationship] to 7 [very strong relationship]). The accepted standard for translucency is a mean score of at least 5.¹⁵



My Constipation Action Plan



Reset Form

Patient Name: _____ Date of Birth: _____ Identification Number: _____

Provider Name: _____ Today's Date: _____ Child's Weight: _____ Kg

CLEAN-OUT MEDICINES**HOW MUCH****HOW OFTEN****OTHER INSTRUCTIONS**

 Special instructions when I am: ● *feeling good*, ● *feeling bad*, ● *feeling worse*
GOOD**EVERY DAY MEDICINES****HOW MUCH****HOW OFTEN****OTHER INSTRUCTIONS**

GREEN ZONE



- Eating well
 - Normal play
 - No belly pain
 - 1 soft poop every day
 - Clean underwear
- ☐ Schedule or more potty times every day
☐ Use a Potty Stool with every scheduled potty time

BAD**YELLOW ZONE MEDICINES****HOW MUCH****HOW OFTEN****OTHER INSTRUCTIONS**

YELLOW ZONE



- Eating less
- Playing less
- Some belly pain
- Harder poops
- No poop in 3 days
- Poop streak in underwear


 After 24 to 48 hours in **Yellow (Bad) Zone**, move to **Red (Worse) Zone**.
WORSE**RED ZONE PLAN:**

RED ZONE



- Not eating
- No play
- More belly pain
- Bigger belly (bloating)
- Pooping hurts
- Poop accident in underwear

Video Summary

Send a message to your team by Secure Messaging or Call your clinic. Telephone:

Teachers: Please let this child use the bathroom as needed.

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Figure 1. USCAP. Version IV of the USCAP for use in pediatric patients with functional constipation. A downloadable version of this form is available at www.jpeds.com.













Intended Pictogram Meaning	Key Graphic Elements	Images	Transparency Correct n (%)	Translucency Mean score \pm SD	Recall Correct n (%)
Non-painful defecation Soft, fluffy stools	Happy expression PBSFS 4		196 (98.0)	6.5 \pm 0.92	191 (99.5)
Some pain with defecation Harder poops	Expression of discomfort Has some difficulty pooping PBSFS 2		191 (95.5)	6.5 \pm 0.93	178 (89.0)
More pain with defecation Rocky, hardest poops	Expression of pain Has the most difficulty pooping PBSFS 1		194 (97.0)	6.9 \pm 0.51	180 (90.0)
Happy child Ready to play No abdominal pain	Smiling child Hero pose No signs of abdominal pain		198 (99.0)	6.9 \pm 0.43	194 (97.0)
Child with mild to moderate abdominal pain	Unhappy child, closed mouth, flushed cheeks, one hand holding stomach		198 (99.0)	6.6 \pm 0.83	179 (89.5)
Child with severe abdominal pain and bloating	Frowny face, bent forward, two hands holding stomach, belly distension, wincing motion graphics		195 (97.5)	6.8 \pm 0.75	182 (91.0)
Child with normal appetite, eating well	Happy, smiling child, eagerly holding a utensil in each hand, plate is empty, glass is empty		194 (97.0)	6.8 \pm 0.56	190 (95.0)
Child with decreased appetite	Frowny face child, plate is only half eaten, glass is half empty, not holding any utensils		191 (95.5)	6.1 \pm 1.2	177 (88.5)
Child with no appetite, refusing to eat	Child sticking tongue out in disgust, plate is full, glass is full, not holding any utensils		169 (85)	6.7 \pm 0.91	174 (87.0)
Child with clean underwear, no accident	Smiling child, clean underwear		197 (98.5)	6.9 \pm 0.10	192 (96.0)
Child with small stooling accident	Despondent child with small accident, fecal streak/smear in underwear		199 (99.5)	6.6 \pm 0.79	187 (93.5)
Child with large stooling accident	Sad child with frowny face and large fecal accident or underwear soiling		198 (99.0)	6.9 \pm 0.54	190 (95.0)

Figure 2. Intended pictogram meaning, key graphic elements, pictogram design, Transparency, Translucency, and Recall for the USCAP. Proposed and intended meaning for each image in conjunction with the visual key graphic elements selected to portray each meaning. The image is attached on the same row with the accompanying transparency (n, %), translucency (Likert score 1-7, where 1 = no relationship and 7 = very strong relationship; mean and SD), and recall (n, %). PBSFS, Pediatric Bristol Stool Form Scale.⁵²

Recall involves determination of a patient's comprehension of the image meaning using short-term memory after an appropriate distraction part. Following the translucency assessment, each participant responded to the AHRQ Short Assessment of Health Literacy-English version, which served as a distraction event to distinguish between desirable, short-term recall memory and working memory. Participants were then asked to recall the individual pictograms from each storyboard for their intended meanings using free response. The threshold for acceptable recall is when at least 85% of the participants correctly recall the image.¹⁵

CAP Assessment (Parent, Clinical Librarians, and Clinicians). Once pictogram validation was completed, the images were added back into the USCAP. The USCAP was assessed for parent perceptions, readability, understandability and actionability (U/A), and suitability using similar methods and definitions by Alqurashi et al.²⁹

Parent Perceptions of USCAP (Parent Survey). The same methods used for pictogram validation were used to obtain a convenience sample of parents to assess parent perceptions. Specifically, the Consumer Information Rating Form (CIRF) was used to directly measure parents'

perceptions of the comprehensibility, design quality, and usefulness (17 items in total) of written medical information of the USCAP using a 5-point Likert scale.^{29,34,35} An overall CIRF percentile score (OCPS) was calculated: the numerator was the sum of the mean scores for each category and the denominator was the ideal CIRF score of 83. This survey collected additional demographics including socioeconomic status (SES) and health literacy. Low SES was measured using a validated questionnaire and health literacy was measured using the Newest Vital Sign.³⁶⁻³⁹

Readability Assessment. Readability is a measure of the ease with which a text can be read and understood. Readability was assessed by multiple formulas, including the Flesch Reading Ease (FRE) score, Flesch-Kincaid Grade Level, Gunning Fog, Powers, and The Simple Measure of Gobbledygook Index.⁴⁰⁻⁴⁴ The FRE was converted to grade level using previous methods from Yin et al.¹³ A readability composite score was calculated which sought to balance the strengths and weaknesses of each formula, and increase reliability, by averaging reading levels across the scored formulas.

U/A Assessment (Clinical Librarian Survey). Clinical librarians from our institution with additional certification in Consumer Health Education Specialization were asked to measure the USCAP for understandability (19 questions) and actionability (7 questions) using the AHRQ-Patient Education Materials Assessment Tool for Printable Materials (PEMAT-P).^{45,46} The team followed the AHRQ PEMAT-P user guide to assess the USCAP.⁴⁷ All items have the answer option of agree (1 point), disagree (0 points), and not applicable (questions answered with not applicable are excluded when calculating points, decreasing the total possible points). The total score was divided by the total possible points and multiplied by 100 to report a percentage score. Higher scores correlates with greater U/A of the document. Three librarians participated on August 4, 2020, and there were no discrepancies in their responses. A PEMAT-P score of 70% or less has been associated with materials that are difficult to understand and not actionable. Therefore, our team targeted a priori score of 80% or greater for the USCAP to be considered understandable and actionable.^{29,48}

Suitability Assessment (Clinician Survey). A convenience sample of general pediatricians and pediatric gastroenterologists who cared for children with constipation were recruited from multiple centers across the Military Health System via email from May 28, 2020, to June 09, 2020, to respond to a separate survey that assessed the suitability of the USCAP. Suitability refers to whether materials appropriately incorporate principles of adult learning that facilitate understanding and positive behavior change.^{13,14,49,50} We assessed the suitability of the USCAP by using the modified Suitability Assessment of Materials (SAM), which eliminates the cultural appropriateness scale because this action plan was created for general audiences rather than a specific target population.⁵¹ For the 19 judged criterion, a modified SAM scoring

system (0 = not suitable, 1 = adequate, 2 = superior) was used to grade each factor. Because 34 clinicians assessed suitability, our team only assigned a superior rating for a factor if at least 85% of the clinicians scored the factor as a 2. The final scores (overall suitability score) for each category were then used to calculate the total SAM score. Total SAM score was calculated by dividing the sum of the assigned overall suitability scores for each factor by the total number of applicable items; a 70% rating was considered to be superior.

Data Analyses. Survey response data were presented as mean \pm SD. Frequency data were reported as counts and percentages. This project was reviewed and deemed exempt by the Walter Reed National Military Medical Center Institutional Review Board.

Results

Demographics

A summary of parent demographics is shown in [Appendix 3](#) (available at www.jpeds.com).

Pictogram Survey Demographics. Two hundred respondents completed the pictogram survey for this project. Parents comprised 86% (n = 172) of participants (mean age, 45.2 \pm 14.1 years).

Parent Perceptions of USCAP Survey Demographics. Sixty-five parents (mean age, 37.8 \pm 13.3 years) responded to the CIRF; 17% of parents (n = 11) had participated in the first pictogram survey. In this cohort, 6.2% of parents (n = 4) met criteria for low SES and 13.8% of parents (n = 9) displayed low health literacy.³⁶⁻³⁸ Demographics were not collected from clinical librarians at our institution.

Clinician Survey Demographics. General pediatricians (n = 20) and pediatric gastroenterologists (n = 14) responded to the survey.

Pictogram Validation

All pictograms were found to be transparent by at least 85% of participants. A score of 5 or higher on translucency was achieved for all images. More than 85% of participants correctly recalled the images. Transparency, translucency, and recall values obtained for the final pictograms are listed in [Figure 2](#).

USCAP Assessment

Parent Perceptions of the USCAP. The USCAP was found to have high comprehensibility, design quality, and usefulness ([Table 1](#)). For the 65 respondents, the OCPS was 92.5%. A CIRF subanalysis showed high levels of comprehensibility, design quality, and usefulness for participants with low SES (OCPS = 88.9%) and participants with low health literacy (OCPS = 86.6%). Participants also perceived large improvements in knowledge and understanding. Their

probability of reading, using, and keeping the USCAP were high across all demographic groups.

Readability. The USCAP Readability Composite Score was 5.4, consistent with a fifth-grade level ([Appendix 4](#); available at www.jpeds.com).

U/A. U/A was assessed by analyzing the responses of 3 clinical librarians who completed the PEMAT-P ([Appendix 5](#); available at www.jpeds.com). The U/A of the USCAP was deemed acceptable. The understandability score of 100% and the actionability score of 100%.

Suitability. Suitability criteria were assessed by analyzing the responses of 34 clinicians who completed the SAM ([Table II](#)). The overall suitability score generated was 89.4%, consistent with superior material. Version IV of the USCAP was vetted after assessment by the team for implementation ([Figure 1](#)).

Discussion

This study focused on the design and assessment of a low literacy pictographic CAP for the care of functional constipation in children. As opposed to anaphylaxis and asthma clinical practice guidelines, which recommend action plans, there are currently no recommendations to incorporate a CAP in management strategies for children with functional constipation.⁵³⁻⁵⁵ Given the previous lack of validated CAP tools available to providers, and a subsequent lack of literature to support the use of CAP tools in children, our USCAP has the potential to improve individualized care within the patient-centered medical home model and inform the development of clinical practice guideline recommendations.⁵⁶ Many clinicians encounter the need for longer-term treatment and management for functional constipation.⁸ Because there are limited standardized recommendations for long-term treatment, the USCAP represents an essential tool within our armamentarium to better personalize the management of chronic functional constipation symptoms. Expert opinion from NASPGHAN suggests maintenance therapy should be continued for 2 months, therapy should only be stopped when toilet training is achieved, and that symptoms of functional constipation should be resolved for at least 1 month before discontinuation of pharmacotherapy.²⁷ With these requirements in mind, the USCAP can be a useful tool for any clinician caring for children with chronic constipation.

Although there have been other CAPs designed at tertiary pediatric care facilities, ours includes pictograms.⁵⁷⁻⁶¹ All 12 images received a score above the international standard for validation. Using a multidisciplinary team enabled us to design and validate clinically relevant imagery that captured the patient's attention, were easily understood, and facilitated comprehension. Furthermore, in contrast to other available CAPs, the pictograms incorporated into the USCAP

Table I. Parent's perspective on quality control of the USCAP

Items	Response (n = 65)
Comprehensibility, mean (SD) (1 = strongly disagree, 5 = strongly agree)	
Read	4.6 (0.6)
Understand	4.6 (0.6)
Remember	4.4 (0.6)
Find information	4.7 (0.5)
Keep	4.5 (0.6)
Subscore total	22.8
Design quality (1 = worst, 5 = best)	
Organization	4.8 (0.5)
Attractiveness	4.7 (0.5)
Print size*	3.2 (0.6)
Tone	4.3 (0.7)
Helpfulness	4.7 (0.5)
Spacing	4.3 (0.8)
Subscore total	26
Usefulness (1 = strongly disagree, 5 = strongly agree), subscore total	4.8 (0.5)
Perceived improvements with CAP (1 = small, 5 = great)	
Knowledge	4.5 (0.8)
Understanding	4.7 (0.5)
Subscore total	14
Self-predicted participant behaviors with CAP (1 = very unlikely, 5 = very likely)	
Likelihood of reading the CAP	4.6 (0.9)
Likelihood of using the CAP	4.7 (0.6)
Likelihood of keeping the CAP	4.7 (0.5)
Subscore total	14
OCPS	
Total CIRF score	76.8
Ideal CIRF score	83.0
CIRF percentile score	92.5

Values are mean (SD). The ideal CIRF score is the total sum of perfect scores from each subcategory.

*Print size scale was: 1 = too small, 5 = too big, with ideal score = 3 (ie, appropriate size).

supplement the written material and enhance its value by emphasizing symptom recognition and recommended pharmacologic lifestyle interventions for the care of functional constipation. As has been demonstrated in other pictogram-enhanced plans for other disease processes, we believe that incorporation of pictograms into the USCAP will improve adherence to the prescribed therapeutic regimen.⁶²

Development of the USCAP was strengthened by a multi-staged approach involving first validating the pictograms alone and then assessing the USCAP with pictograms included. Our goal was to mitigate the effects of low health literacy by developing a written action plan that conveys recommendations of clinicians in a clear and actionable manner.

The analysis of the USCAP indicated that those with basic, fifth-grade literacy would understand the text. The 2020 update from Program for the International Assessment of Adult Competencies showed that 34% of adults within the United States have basic (at fifth-grade level) literacy.⁶³ We believe that by aligning with federal recommendations for written medical information to be presented at or below the sixth-grade level, the USCAP's low grade level readability will enhance compliance with prescribed interventions for functional constipation by accommodating the diverse health literacy backgrounds of patients and their families.

Table II. Clinician assessment of the suitability of the USCAP

Recommended criteria	Subcategory	0 (Not suitable) N (%)	1 (Adequate) N (%)	2 (Superior) N (%)	Mean suitability score (SD)	Overall suitability score
Content	Purpose	0 (0)	1 (3)	33 (97)	2.00 ± 0.17	2
	Content about behaviors	0 (0)	3 (9)	31 (91)	1.90 ± 0.29	2
	Scope	0 (0)	3 (9)	31 (91)	1.90 ± 0.29	2
	Summary	6 (18)	5 (15)	23 (68)	1.50 ± 0.79	1
Literacy demand	Reading grade level	—	—	—	5	2
	Writing style, active voice	1 (3)	3 (9)	30 (88)	1.90 ± 0.44	2
	Vocabulary uses common words	0 (0)	3 (9)	31 (91)	1.90 ± 0.29	2
	Context is given first before new information	0 (0)	7 (51)	27 (79)	1.80 ± 0.41	1
	Learning aids by 'Road Signs'	1 (3)	2 (6)	31 (91)	1.90 ± 0.41	2
Images and graphics	Cover graphics	—	—	—	—	—
	Types of images	0 (0)	1 (3)	33 (97)	1.90 ± 0.17	2
	Relevance of illustrations	0 (0)	2 (6)	32 (94)	1.90 ± 0.24	2
	Graphics: list, tables, etc. explained	1 (3)	7 (21)	26 (77)	1.70 ± 0.51	1
	Captions used for graphics	2 (6)	2 (6)	30 (88)	1.80 ± 0.52	2
Layout and typography	Layout factors	0 (0)	2 (6)	32 (94)	1.90 ± 0.24	2
	Typography	0 (0)	2 (6)	32 (94)	1.90 ± 0.24	2
	Subheadings or "Chunking" Used	0 (0)	7 (21)	27 (79)	1.80 ± 0.41	1
Learning, stimulation, motivation	Interactiveness	1 (3)	4 (12)	29 (85)	1.80 ± 0.46	2
	Behaviors are modeled and specific	1 (3)	5 (15)	28 (82)	1.80 ± 0.48	1
Cultural appropriateness	Motivation	0 (0.0)	4 (11.8)	30 (88.2)	1.90 ± 0.33	2
	Cultural match: logic, language, experience	—	—	—	—	—
	Cultural image and examples	—	—	—	—	—
Total possible points on SAM						38.0
Overall suitability score						34.0
% Score						89.4

Values are number (%) or mean ± SD. This table shows the output from the modified Suitability Assessment Module. Note, for Literacy demand, a Readability Consensus Score of 5 was incorporated for scoring purposes. There is no cover graphic so this subcategory was not scored, per SAM instructions.

Parents perceived the USCAP to have a high level of comprehensibility, design quality, and usefulness. This finding suggests that the USCAP will be well-received when included as part of clinical care, and that benefits, such as improved compliance, may be seen across patients and parents with diverse socioeconomic backgrounds. The USCAP was also found to be easily understood and highly actionable by clinical librarians. The USCAP U/A scores were similar to other published written action plans for other chronic diseases of childhood.²⁹

The USCAP was also found to be superior with respect to suitability. No previous study has examined the suitability of CAPs. There were no unsuitable scores assigned to any category by any of the clinician respondents. By including graphics and common words, and through the elimination of medical jargon and difficult words whenever possible, clinician perceptions of the comprehensibility of the USCAP for parents was maximized.

The current recommended therapies for constipation focus on laxative pharmacotherapy and behavioral (ie, lifestyle) interventions. Unfortunately, these interventions have been incompletely effective. The implementation of the USCAP into the patient-centered medical home model may represent that next step in therapeutic progress needed to empower parents and improve outcomes.⁸

There are a number of limitations to our project. The USCAP was developed in English only, and only English-speaking patients and parents were surveyed in the pictogram validation process and assessments of perceived

USCAP quality. The convenience sample method was used due to the novel coronavirus 2019 pandemic and was not ideal. This factor serves as a potential source for bias due to exclusion of those without internet access. The Facebook links were public and shareable; thus, not all respondents may have come from special interest groups. This factor may weaken the generalizability of our findings to parents of children with functional constipation. Moreover, although our results indicate that the parent respondents with low SES or low health literacy perceived the USCAP to have high quality, the small capture rate of parents with low SES or low health literacy brings the applicability of the USCAP to these demographic groups into question. Finally, the use of the USCAP as part of clinical care, and the effectiveness of the USCAP in improving adherence has not yet been studied. Future studies will need to analyze the effectiveness of implementing a constipation-specific action plan, along with constipation education, in a multi-disciplinary model that incorporates behavioral interventions, diet, pharmacotherapies, and other lifestyle changes with the goal of improving parent confidence, health-related quality of life, and functional constipation clinical outcomes.

The USCAP met all criteria for clinical implementation during five separate assessments with parents, clinical librarians, and clinicians. The USCAP has the potential to become an important tool to be used in the care of children with functional constipation, improving both quality-of-care and clinical outcomes. ■

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References

- Walia R, Mulhearn N, Khan R, Cuffari C. Chronic constipation in children: an overview. *Pract Gastroenterol* 2013;37:19-34.
- Sonnenberg A, Koch TR. Physician visits in the United States for constipation: 1958 to 1986. *Dig Dis Sci* 1989;34:606-11.
- Freed G, Nahra T, Venus P, Schech S, Wheeler J. The research advisory committee of the American Board of Pediatrics: changes in the proportion and volume of care provided to children by generalists and subspecialists. *J Pediatr* 2005;146:14-9.
- Van Den Berg MM, Benninga M, Di Lorenzo C. Epidemiology of childhood constipation: a systematic review. *Am J Gastroenterol* 2006;101:2401-9.
- Robin SG, Keller C, Zwiener R, Hyman PE, Nurko S, Saps M, et al. Prevalence of pediatric functional gastrointestinal disorders utilizing the Rome IV criteria. *J Pediatr* 2018;195:134-9.
- Mugie SM, Benninga MA, Di Lorenzo C. Epidemiology of constipation in children and adults: a systematic review. *Best Pract Res Clin Gastroenterol* 2011;25:3-18.
- Mugie SM, Di Lorenzo C, Benninga MA. Constipation in childhood. *Nat Rev Gastroenterol Hepatol* 2011;8:502-11.
- Sondheimer J. Constipation: is there a new approach? *J Pediatr Gastroenterol Nutr* 2002;34:357-8.
- Youssef NN, Langseder AL, Verga BJ, Mones RL, Rosh JR. Chronic childhood constipation is associated with impaired quality of life: a case-controlled study. *J Pediatr Gastroenterol Nutr* 2005;41:56-60.
- Vriesman MH, Rajindrajith S, Koppen IJN, van Etten-Jamaludin FS, van Dijk M, Devanarayana NM, et al. Quality of life in children with functional constipation: a systematic review and meta-analysis. *J Pediatr* 2019;214:141-50.
- Howe CJ, Barnes DM, Estrada GB, Godinez I. Readability and suitability of Spanish language hypertension and diabetes patient education materials. *J Community Health Nurs* 2016;33:171-80.
- Yin HS, Gupta RS, Mendelsohn AL, Dreyer B, van Schaick L, Brown CR, et al. Use of a low-literacy written action plan to improve parent understanding of pediatric asthma management: a randomized controlled study. *J Asthma* 2017;54:919-29.
- Yin HS, Gupta RS, Tomopoulos S, Wolf MS, Mendelsohn AL, Antler L, et al. Readability, suitability, and characteristics of asthma action plans: examination of factors that may impair understanding. *Pediatrics* 2013;131:e116-26.
- Stringer T, Yin HS, Gittler J, Curtiss P, Schneider A, Oza VS. The readability, suitability, and content features of eczema action plans in the United States. *Pediatr Dermatol* 2018;35:800-7.
- Mok G, Vaillancourt R, Irwin D, Wong A, Zemek R, Alqurashi W. Design and validation of pictograms in a pediatric anaphylaxis action plan. *Pediatr Allergy Immunol* 2015;26:223-33.
- Ducharme FM, Zemek RL, Chalut D, McGillivray D, Noya FJD, Resendes S, et al. Written action plan in pediatric emergency room improves asthma prescribing, adherence, and control. *Am J Respir Crit Care Med* 2011;183:195-203.
- Zemek RL, Bhogal SK, Ducharme FM. Systematic review of randomized controlled trials examining written action plans in children: what is the plan? *Arch Pediatr Adolesc Med* 2008;162:157-63.
- Agrawal SK, Singh M, Mathew JL, Malhi P. Efficacy of an individualized written home-management plan in the control of moderate persistent asthma: a randomized, controlled trial. *Acta Paediatr* 2005;94:1742-6.
- Mangione-Smith R, Schonlau M, Chan KS, Keesey J, Rosen M, Louis TA, et al. Measuring the effectiveness of a collaborative for quality improvement in pediatric asthma care: does implementing the chronic care model improve processes and outcomes of care? *Ambul Pediatr* 2005;5:75-82.
- Dinakar C, Van Osdol TJ, Wible K. How frequent are asthma exacerbations in a pediatric primary care setting and do written asthma action plans help in their management? *J Asthma* 2004;41:807-12.
- Chisolm SS, Taylor SL, Balkrishnan R, Feldman SR. Written action plans: potential for improving outcomes in children with atopic dermatitis. *J Am Acad Dermatol* 2008;59:677-83.
- Sauder MB, McEvoy A, Ramien ML. Prescribing success: Developing an integrated prescription and eczema action plan for atopic dermatitis. *J Am Acad Dermatol* 2016;75:1281-3.
- Sauder MB, McEvoy A, Sampson M, Kanigsberg N, Vaillancourt R, Ramien ML, et al. The effectiveness of written action plans in atopic dermatitis. *Pediatr Dermatol* 2016;33:e151-3.
- Shi VY, Nanda S, Lee K, Armstrong AW, Lio PA. Improving patient education with an eczema action plan: a randomized controlled trial. *JAMA Dermatol* 2013;149:481-3.
- Rork JF, Sheehan WJ, Gaffin JM, Timmons KG, Sidbury R, Schneider LC, et al. Parental response to written eczema action plans in children with eczema. *Arch Dermatol* 2012;148:391-2.
- Morrison AK, Glick A, Yin HS. Health literacy: implications for child health. *Pediatr Rev* 2019;40:263-77.
- Tabbers M, DiLorenzo C, Berger M, Faure C, Langendam MW, Nurko S, et al. Evaluation and treatment of functional constipation in infants and children: evidence-based recommendations from ESPGHAN and NASPGHAN. *J Pediatr Gastroenterol Nutr* 2014;58:258-74.
- Padova T. Adobe Acrobat 9 PDF bible, 536. Hoboken (NJ): John Wiley & Sons; 2008.
- Alqurashi W, Awadia A, Pouliot A, Cloutier M, Hotte S, Segal L, et al. The Canadian anaphylaxis action plan for kids: development and validation. *Patient Educ Couns* 2020;103:227-33.
- Modi RM, Hinton A, Pinkhas D, Groce R, Meyer MM, Gokulakrishnan B, et al. Implementation of a defecation posture modification device: impact on bowel movement patterns in healthy subjects. *J Clin Gastroenterol* 2019;53:216-9.
- Waclawski E. How I use it: Survey monkey. *Occup Med* 2012;62:477.
- Katz MG, Kripalani S, Weiss BD. Use of pictorial aids in medication instructions: a review of the literature. *Am J Health Syst Pharm* 2006;63:2391-7.
- Roberts NJ, Mohamed Z, Wong P-S, Johnson M, Loh L-C, Partridge MR. The development and comprehensibility of a pictorial asthma action plan. *Patient Educ Couns* 2009;74:12-8.
- Koo MM, Krass I, Aslani P. Evaluation of written medicine information: validation of the consumer information rating form. *Ann Pharmacother* 2007;41:951-6.
- Krass I, Svarstad BL, Bultman D. Using alternative methodologies for evaluating patient medication leaflets. *Patient Educ Couns* 2002;47:29-35.
- Warsh J, Chari R, Badaczewski A, Hossain J, Sharif I. Can the newest vital sign be used to assess health literacy in children and adolescents? *Clin Pediatr* 2014;53:141-4.
- Shealy KM, Threatt TB. Utilization of the Newest Vital Sign (NVS) in practice in the United States. *Health Commun* 2016;31:679-87.
- Weiss BD, Mays MZ, Martz W, Meriam Castro K, DeWalt DA, Pignone MP, et al. Quick assessment of literacy in primary care: the newest vital sign. *Ann Fam Med* 2005;3:514-22.
- Cohen S. The Common Cold Project- PCS3 Socioeconomic Status Questionnaire 1.1. 2017. www.cmu.edu/common-cold-project/measures-by-study/psychological-and-social-constructs/objective-socioeconomic-status-measures/index.html. Accessed May 1, 2020.
- AHRQ. Readability Formulas for Quality Reports. 2015. www.ahrq.gov/talkingquality/resources/writing/tip6.html. Accessed May 1, 2020.
- Dale E, Chall JS. A formula for predicting readability: instructions. *Educational Research Bulletin* 1948;27:37-54.
- Klare GR. Assessing readability. *Reading Research Quarterly* 1974;10:62-102.
- Klingbeil C, Speece MW, Schubiner H. Readability of pediatric patient education materials: Current perspectives on an old problem. *Clin Pediatr* 1995;34:96-102.

44. ReadabilityFormulas.com. Automatic Readability Checker. 2020. <https://readabilityformulas.com/free-readability-formula-tests.php>. Accessed May 1, 2020.
45. Shoemaker SJ, Wolf MS, Brach C. Development of the Patient Education Materials Assessment Tool (PEMAT): a new measure of understandability and actionability for print and audiovisual patient information. *Patient Educ Couns* 2014;96:395-403.
46. Consumer Health Information Specialization. MLA Webinars 2020. www.mlanet.org/p/cm/ld/fid=329. Accessed May 1, 2020.
47. Shoemaker SJ, Wolf MS, Brach C. The patient education materials assessment tool (PEMAT) and user's guide. Rockville (MD): Agency for Healthcare Research and Quality; 2013.
48. Lipari M, Berlie H, Saleh Y, Hang P, Moser L. Understandability, actionability, and readability of online patient education materials about diabetes mellitus. *Am J Health Syst Pharm* 2019;76:182-6.
49. LaPier TK. Evaluating content and suitability of written patient education materials. *Cardiopulm Phys Ther J* 2000;11:135.
50. Lewis SL. Implementing the Suitability Assessment of Materials (SAM) to improve health literacy at a rural community health center [undergraduate thesis]. Greenville (NC): East Carolina University; 2014.
51. Doak CC, Doak LG, Root JH. Teaching patients with low literacy skills. Greenville (NC): East Carolina University's Institutional Repository; 1985.
52. Lane MM, Czyzewski DI, Chumplitzi BP, Shulman RJ. Reliability and validity of a modified Bristol Stool Form Scale for children. *J Pediatr* 2011;159:437-41.e431.
53. Muraro A, Werfel T, Hoffmann-Sommergruber K, Roberts G, Beyer K, Bindslev-Jensen C, et al. EAACI food allergy and anaphylaxis guidelines: diagnosis and management of food allergy. *Allergy* 2014;69:1008-25.
54. Becker A, Bérubé D, Chad Z, Dolovich M, Ducharme F, D'Urzo T, et al. Canadian pediatric asthma consensus guidelines, 2003 (updated to December 2004): introduction. *CMAJ* 2005;173(Suppl 6):S12-4.
55. National Asthma Education and Prevention Program. Expert Panel Report 3 (EPR-3): guidelines for the diagnosis and management of asthma—summary report 2007. *J Allergy Clin Immunol* 2007;120(Suppl 5):S94.
56. Bharucha AE, Lacy BE. Mechanisms, evaluation, and management of chronic constipation. *Gastroenterology* 2020;158:1232-49.e3.
57. Guglielmo MD. Adherence/outcomes after use of constipation action plan. <https://clinicaltrials.gov/ct2/show/record/NCT03821532?term=pediatric&cond=Constipation+-+Functional&cntry=US&rank=1>. Accessed May 1, 2020.
58. Webster J, Lourie E, Shaw K, Huang E. Implementation of a constipation action plan in primary care clinics to decrease referrals to pediatric gastroenterology: a quality improvement initiative. *Gastroenterology* 2018;154:E48-9.
59. Kaufman TC, Williams D, Rosen J. Implementation of a constipation action plan in pediatric gastroenterology outpatient clinic. *J Pediatr Gastroenterol Nutr* 2018;67(1).
60. Michel BW, Miller B, Srinath A. An action plan for pediatric constipation education. *J Pediatr Gastroenterol Nutr* 65(2).
61. Howell L, Stump J, Schmidt B, Cole L. Guide for managing constipation in children: a tool kit for parents. 2013. www.autismspeaks.org/sites/default/files/2018-08/Constipation%20Guide.pdf. Accessed September 16, 2020.
62. Sletvold H, Sagmo LAB, Torheim EA. Impact of pictograms on medication adherence: a systematic literature review. *Patient Educ Couns* 2019;103:1095-103.
63. Competencies PftIAoA. What's the latest U.S. literacy rate? 2020. www.wyliecomm.com/2019/03/us-literacy-rate/. Accessed May 1, 2020.

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