Original Article

The Evolution in the System Data of a Prototype Scale for Recording Discomfort During Childhood Vaccination

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Abstract
Introduction: The vaccination of children is a vital strategy for safeguarding both individuals and the global population against numerous diseases and pathogens. However, the vaccination process is not always a pleasant experience for all children, with many enduring varying degrees of discomfort, sometimes reaching unbearable levels. In our previous work of this study, we introduce VACS, a tool designed to measure the level of discomfort children experience during vaccination. VACS evaluates the entire vaccination process from the child's perspective, beginning from the moment they enter the doctor's office until they leave, and considers a wide range of discomfort indicators, including moaning, crying, facial expressions, and posture.
Aim: The purpose of this study is to expand our findings to a larger sample of children within the same age groups in order to strengthen them.
Materials and Methods: To objectively measure children's discomfort during vaccination, observations are based on doctors' assessments. The process is divided into four stages: Entrance, Examination, Procedure, and Completion. Various distress indicators are recorded at each stage, and weights are assigned to these parameters to calculate an overall discomfort score. The tool assigns a numerical value to the discomfort, ranging from 0 to 25, where zero indicates a smooth vaccination experience and 25 denotes extreme discomfort. We applied VACS to assess 40 vaccinations in children aged 2 to 12 and we presented our first results.
Results: The study included participants with a mean age of 7.3 years. The gender distribution was nearly equal. The updated findings reveal that 237 children (84.6%) have completed their full vaccination schedule. Using the VACS framework, the average discomfort score (SCORE) observed across all vaccinations was 6.74, with a standard deviation of 6.46, while the 57% exhibited varying levels of discomfort. The score distribution indicates that younger children, particularly those aged 2-3, generally experienced higher discomfort levels, with an average score of 9.16. Crying and supportability during several stages were significant predictors of the overall discomfort experienced by the children.
Conclusions: Further research is needed to confirm this observation with greater certainty. The development of VACS paves the way for more systematic efforts to reduce vaccination discomfort in children.

Keywords: scale; vaccination; discomfort; Crying

Introduction

It is well-established that enhanced vaccine coverage has led to a decrease in disease prevalence (Vanderslott et al., 2022, Alanazi et al., 2024, Bärnighausen et al., 2014) Vaccinations play a vital role in safeguarding public health by controlling the spread of viruses. However, recent data reveals a troubling decline in vaccination rates, with global coverage dropping from 86% in 2019 to 81% in 2021 (WHO). Some diseases see even lower coverage rates, putting both individuals and communities at heightened risk. Even in advanced countries, where vaccine access is generally unrestricted, there are areas with less-than-ideal vaccination rates. For example, several U.S. states report coverage levels below the CDC's recommended thresholds, risking potential outbreaks (Vanderslott et al., 2022).

Various factors contribute to lower vaccination rates, including limited access to healthcare, misinformation, concerns over vaccine side effects, and complex legal frameworks (Foschi et al., 2022. Beccia et al., 2022.) To counter this trend, it is essential to explore all possible tools to improve vaccine uptake. Evaluating and providing feedback on healthcare practices during vaccination has been shown to be effective in enhancing vaccine coverage. For instance, modifications to clinic procedures have led to notable improvements in influenza vaccine coverage (Norman et al., 2021, Nypaver, Dehlinger, and Carter, 2021.)

Despite the clear benefits of vaccination, the discomfort and fear associated with needles can make the process challenging, especially for young children. Research underscores that needle-related distress is a significant issue, particularly as immunization schedules require numerous vaccinations throughout childhood (Foschi et al., 2022.) For example, the UK's standard immunization schedule includes 27 vaccinations from birth to age 15, primarily delivered via needles, except for a few oral vaccines (Akeju, et al. 2025.)

Evidence suggests that the discomfort associated with vaccinations can be alleviated through procedural adjustments and supportive practices. Studies have demonstrated that changes in parental behavior and building trust between healthcare providers and children can reduce vaccination-related distress (Constantin et al., 2022, DeCosta, Skinner & Grabowski, 2021). However, existing research often lacks quantifiable measures of these interventions' effectiveness.

To address these gaps, this study aims to strengthen the tool VAccinationdisComfort Scale (VACS), a tool designed to quantify children's discomfort during vaccinations (Wallace, Antonopoulos & Poulopoulos, 2022). VACS assesses the entire vaccination experience, from the child's entry into the medical setting to their departure. The VAccinationdisComfort Scale (VACS) assigns a discomfort score ranging from 0 (no discomfort) to 25 (maximum discomfort) based on observations made by healthcare providers.

Materials and Methods

The structure and methodology of the VACS (Vaccination Comfort Scale) tool, developed to objectively measure the discomfort experienced by children during vaccination. The tool relies on observations made by the doctor from the moment the child enters the vaccination room until they leave, capturing various indicators of distress. At this stage of our work, we did not alter our procedure. It is described with the following steps.

VACS Structure: VACS divides the vaccination process into four distinct stages:

1. **Stage I—Entrance:** Observes the child's behavior as they enter the examination area.
2. **Stage II—Examination:** Focuses on the child's reactions during the preliminary examination by the doctor.
3. **Stage III—Procedure:** Monitors the child's behavior during the actual vaccination.
4. **Stage IV—Completion:** Assesses how the child reacts after the vaccination has been completed.

Each stage is associated with specific behaviors and reactions, and these are recorded and assigned weights to compute an overall discomfort score.

VACS Parameters:

The parameters were selected based on the experts' opinion, who in this case were deemed to be pediatricians.

- **Crying:** Ranges from no crying, to light moaning or intermitted crying, and loud, constant crying.
- **Hesitation:** Tracks the child's reluctance to enter the vaccination room, which can vary from no hesitation to outright refusal.
- **Activity:** Observes the child's physical behavior, ranging from a relaxed posture to tension or defensive positions.
- **Facial Expressions:** Evaluates expressions from relaxed and smiling to continuous grimacing or a clenched jaw.
- **Support Needed:** Measures the extent to which the child needs support to calm down, from being content to being inconsolable.
- **Cooperation:** Assesses the level of cooperation required to complete the vaccination, from the child's own compliance to the need for intervention by parents or clinic staff.

VACS Calculation: The total discomfort score is calculated by assigning points to behaviors observed in each stage. Different stages contribute differently to the final score, with the examination and procedure stages being the most critical, as they are more likely to cause discomfort. The pointsdistributionisasfollows:

- **Stage I—Entry:** Up to 5 points.
- **Stage II—Examination:** Up to 8 points.
- **Stage III—Procedure:** Up to 8 points.
- **Stage IV—Completion:** Up to 4 points.

These scores are summed to produce a VACS score, which ranges from 0 (no discomfort) to 25 (maximum discomfort). (Figure 1)

Clinical Settings: The VACS tool was implemented in clinical settings with children aged 2 to 12 years, across both public and private pediatric clinics. The observations were recorded without interfering with the vaccination process, ensuring the study's accuracy. In addition to the VACS score, the study also collected subjective assessments from doctors, parents/guardians, and the children themselves regarding the vaccination experience.

Ethical Issues: The protocol for the study was approved by the Research Ethics Committee of the University of Peloponnese. This detailed approach enables a systematic evaluation of discomfort during vaccination and offers insights into improving the vaccination experience for children. The accompanying parent/guardian has to be sufficiently fluent in Greek in order to provide written informed consent.

Results

The initial study (Wallace, Antonopoulos, and Poulopoulos, 2022), served as a feasibility study. The goal was to identify errors and difficulties in the process and correct them. Ultimately, no corrections were needed, and we proceeded with the collection of a larger volume of data. Following the procedure described the previous sections, vaccinations were carried out by three pediatricians in one public and two private pediatric clinics, with VACS parameters recorded for 280 vaccinations (previously 40). After filtering for children aged 2-12, the data considered in this study increased significantly, providing a broader and more statistically significant dataset. No parent/guardian refused the recording of information by the doctor. The mean age of the participants was 7.3 years old, with a minimum of 2 years and 1 month and a maximum of 12 years and 11 months. The distribution by gender was approximately equal, with boys comprising 50.7% of the participants and girls 49.3%. The representation of children in each age group examined (2-4, 5-7, 8-12) was much broader having at least 40 children in each of the groups (table 1).

Table 1. Demographics

AGE GROUP (years)	GENDER	PRICE	TOTAL
2-12	M	142	280
	F	138	
2 and 0/12 - 4 and 11/12	M	44	86
	F	42	
5and 0/12 - 7 and 11/12	M	35	74
	F	39	
8and 0/12 - 12 and 11/12	M	63	120
	F	57	

In the initial study, it was reported that thirty-one (77.5%) of the children had completed

their recommended vaccination schedule, while nine (22.5%) had skipped one or more vaccines recommended for their age group. However, in the expanded dataset of 280 children, the updated findings reveal that 237 children (84.6%) have completed their full vaccination schedule, while 43 children (15.4%) have not. This increase in the percentage of children with complete vaccinations reflects the broader and more comprehensive dataset. Analyzing step by step, we observe the following recorded parameters and their differences between the initial and final phase of our study.

Stage I

In stage I the system records the factors of hesitation and crying.

Hesitation

	Initial	Updated
Yes	65%	58%
No	35%	42%

Crying

	Initial	Updated
No	87.5%	80.5%
Light Moaning	5.0%	12.75%
Loud	7.5%	6.75%

Observations:

- Hesitation seems to lower forming an average of 60/40 in favor of Yes.
- Crying seems to have an average of 80% on No, while some kind of reaction records almost 20%.

Stage II

During this stage three parameters are recorded, “Facial Expressions”, “Crying” and “Activity”.

Facial Expressions

	Initial	Updated
Relaxed	60.0%	59.25%
Substained grimace	12.5%	31.5%
Grimaces	27.5%	9.25%

Crying

	Initial	Updated
No	85.0%	73.5%
Light Moaning	7.5%	20.75%
Loud	7.5%	5.75%

Activity

	Initial	Updated
Relaxed	80.0%	65.70%
Extensive	7.5%	22.15%
Defensive/fetal	12.5%	12.15%

During stage II there seems to be a big difference between relaxed activity and extensive activity compared to the initial results. The new dataset has a broader representation of the age groups that are researched consisting of more kids in younger ages (2-7) in comparison to the initial recorded. Despite this change, the percentage of children showing extreme reactions (loud crying and defensive/fetal activity) is relatively lower.

Stage III

During stage II we record the parameters of Support, Cooperation and Crying.

Support

	Initial	Updated
Relaxed	72.5%	45.5%
Whining	22.5%	44.5%
Inconsolable	5.0%	10%

Cooperation

	Initial	Updated
Alone	52.5%	30.75%
Parents	35.0%	50.0%
Parents and Staff	10.0%	15.75%
Staff	2.5%	3.5%

Crying

	Initial	Updated
No	72.5%	50.75%
Light Moaning	12.5%	26.5%
Loud	15.0%	22.75%

As already mentioned, and is clearer from the updated results, a broader representation of younger ages leeds to differentiation in parameters like support and cooperation. Especially in the parameter of cooperation, parents are present in more cases as the children are younger which is logical and expected.

Stage IV

Finally, stage IV comprises of crying and activity.

Crying

	Initial	Updated
No	72.5%	56.75%
Light Moaning	17.5%	30.5%
Loud	10.0%	13.5%

	Activity	
Initial	**Updated**	
Relaxed	82.5%	67.5%
Extensive	12.5%	24.0%
Defensive/fetal	5.0%	8.5%

In this stage it is also clear that crying parameter changes, once more as a result of a higher number of younger children in these ages. Going one step forward we applied clustering algorithms on the dataset and more specifically we decided to perform a cluster analysis. What we wanted to examine is the ability to separate the results into different groups and establish a connection with independent variables.

Knn (**It is a method of cluster analysis used to avoid specific confounding factors in statistical analysis**.) was applied to the data asking for a formulation of 3 clusters.

Cluster analysis grouped the participants into the following three distinct clusters:

Cluster 1: Children with low discomfort and cooperative behavior, primarily consisting of older children (ages 8-12).

Cluster 2: Children with moderate discomfort and moderate cooperation.

Cluster 3: Children with high discomfort and significant challenges in cooperation, primarily consisting of younger children (ages 2-3).

Discussion - Analysis

Using the VACS framework, the average discomfort score (SCORE) observed across all vaccinations was 6.74, with a standard deviation of 6.46. This is a slight increase compared to previous findings, reflecting a wider range of discomfort levels among a larger sample size. Notably, 43% of the vaccinations had a VACS score of zero, indicating no discomfort, while the remaining 57% exhibited varying levels of discomfort.

The score distribution indicates that younger children, particularly those aged 2-3, generally experienced higher discomfort levels, with an average score of 9.16. Children aged 4-7 also had elevated discomfort levels (average score of 8.09), while those aged 8-12 coped better with the procedure, exhibiting lower discomfort (average score of 4.06). Analysis of the data revealed that crying behaviors across different stages were highly correlated with the overall VACS score, particularly during Stages 1, 3, and 4. The correlation analysis confirmed that crying and supportability during these stages were significant predictors of the overall discomfort experienced by the children. (Figure 2).

According to the graph, crying across children gradually increases (no crying decreases with a similar pattern) meaning that crying in step 3 plays an important role in discomfort. According to this finding this is a step where the vaccination procedure can be researched to be altered to lower the discomfort of the children. (Figure 3). Activity as recorded in stages II and IV shows a similar pattern. It is obvious that children are more relaxed in the final stage while the comparison shows that high levels of activity in the stage just before stage III (vaccination process) are relatively high. Furthermore, we tried to examine if there is a correlation between fully vaccinated children and final score. From the final results, both children fully vaccinated and those who are not fully vaccinated have the same average score.

As a second step we examine if there is any correlation between children with previous bad experience and the score. The average "SCORE" for children without a previous bad experience is approximately 5.86, while the average score for those with a previous bad experience is significantly higher at around 10.04. This suggests that children with a previous bad experience tend to have noticeably higher scores compared to those without.

The important factor of the clustering procedure is the parameter of "age" was not one of the clustering parameters. Still, the groups created reveal an equal representation of boys and girls, while the groups almost "match" the age groups that we are examining in our experimental procedures. These findings emphasize the importance of Content, face, and construct validity are inherent in the scale's design, which quantifies a range of behavioral parameters.

Doctors empirically make observations to assess how children cope with vaccinations, ensuring that VACS reliably captures the level of discomfort.

tailoring the vaccination process to the specific needs of younger children, who are more likely to experience discomfort.

The ability of VACS to differentiate between acceptable and unacceptable discomfort from the doctors' perspectives continues to validate the scale's effectiveness.

The observation that the differentiation between acceptable and unacceptable discomfort holds true across all doctors in the clinical study reinforces the scale's reliability. As a result, the threshold for a smooth vaccination experience can now be more accurately defined at a VACS score of 10, rather than 19, reflecting the broader dataset and more refined insights.

FIGURE 1 : VACS

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VACS: VAccination Discomfort Scale

Date	
Time	
Researcher collecting the data	

Stage I – Entrance

Hesitation	No		Yes
Crying	No crying	Light moaning	Loud crying

Stage II – Examination

Facial expressions	Relaxed	Grimaces	Sustained grimace
Crying	No crying	Light moaning	Loud crying
Activity	Relaxed	Extensive	Defensive/fetal

Stage III – Procedure

Support	Relaxed	Whining		Inconsolable
Cooperation	Alone	Parent	Parent and staff	Staff
Crying	No crying	Light moaning		Loud crying

Stage IV – Completion

Crying	No crying	Light moaning	Loud crying
Activity	Relaxed	Extensive	Defensive/fetal
Final outcome	Successful		Unsuccessful

Assessment of experience

Child	Accepts to return		Does not accept to return
Parent/guardian	Smooth	Acceptable	Bad
Doctor	Smooth	Acceptable	Bad

Demographics

Gender	Girl	Boy
Date of birth		
Full vaccination	No	Yes
Former bad vaccination experience	No	Yes
Former vaccination side effects	No	Yes

FIGURE 2

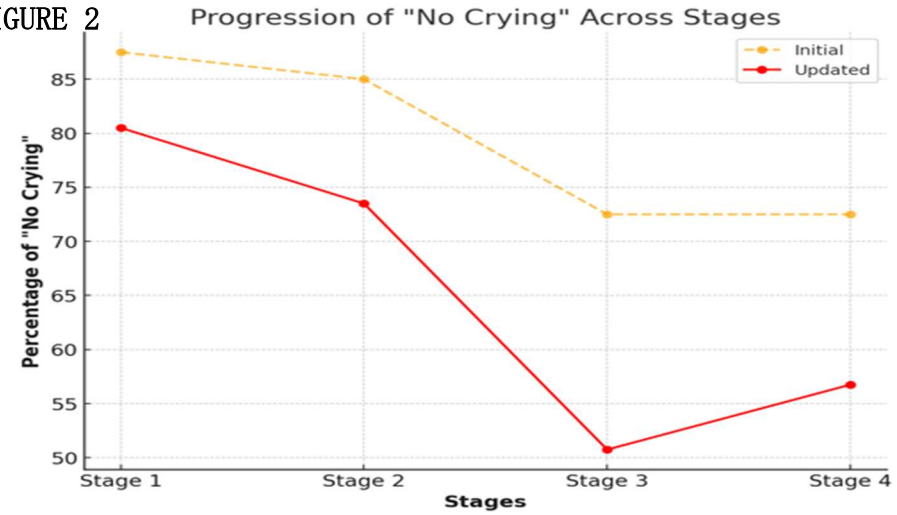
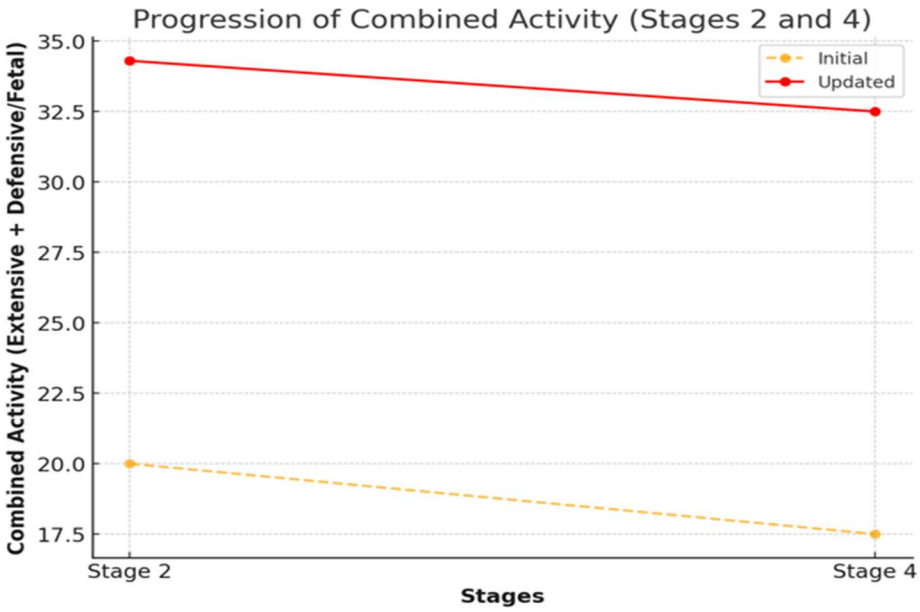


FIGURE 3



Conclusion: In this work, we present updated data on the VACS scale, a straightforward and easily applicable tool designed to assess the level of discomfort experienced by children aged 2-12 during vaccination. The VACS scale quantifies discomfort on a scale from 0 to 25, with 0 indicating no discomfort and 25 representing extreme, intolerable discomfort. Our study identified a subset of children who showed no signs of discomfort, resulting in a score of 0.The clinical study also provided insights into the updated dataset, revealing that doctors consistently classified vaccinations with a VACS score below 10 as smooth, while those with scores above 10 were considered merely acceptable. This updated analysis reinforces the notion that vaccination procedures deemed smooth by clinicians consistently produced lower VACS scores, whereas those perceived as less smooth yielded higher scores.

We observe that in the updated dataset, the doctors consistently considered vaccinations with a VACS score below 10 as smooth and those with scores above 10 as merely acceptable. Thisthreshold is lower than the previously suggested VACS score of 19, reflecting a more sensitive understanding of the children's discomfort. The updated analysis further supports that vaccination procedures deemed smooth by the doctors consistently produced lower VACS values, while less smooth procedures produced larger values.

Consequently, the threshold for what can be considered a smooth vaccination experience can now be more precisely set at a VACS score of 10, instead of the previously suggested 19, reflecting the expanded dataset and more refined understanding.

Our findings suggest that discomfort during vaccination is a significant issue for approximately 60% of children. The demographic variables and factors explored in our research, such as gender, completion of the state's recommended vaccination schedule, and even prior negative vaccination experiences, showed no significant correlation with VACS scores. However, there is an indication that age, particularly in children under 7, might correlate with VACS measurements, although further research is required to confirm this relationship.

Moreover, our study has categorized the levels of discomfort experienced by children during the vaccination process, identifying specific stages where discomfort peaks. The introduction of the VACS scale offers a foundation for advancing research and practice in several areas. Pediatric clinics and healthcare providers can now quantitatively evaluate their performance against established benchmarks to ensure the quality of care provided. Similarly, developers of vaccination methods and systems for children can utilize the VACS scale to assess and improve the effectiveness of their approaches. The key contribution of the VACS scale lies in its ability to transform previously subjective and qualitative assessments into objective and quantitative evaluations.

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