

Evaluation on five-dimensions of a patient counseling mHealth app in ambulatory care pharmacy: A cross-sectional study on pediatric caregiver's opinion

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Abstract: To improve a pediatric mHealth app for patient counselling, we developed a multi-dimensional evaluation method assessing caregivers' feedback via a cross-sectional survey. Using random questionnaires at a children's hospital outpatient department (967 valid: 478 pre-upgrade, 489 post-upgrade), we evaluated the app across five dimensions (transmission, accuracy, accessibility, completeness, experience). Validity was excellent (I-CVI/S-CVI=1.000), reliability acceptable (ICC 0.806-0.869), with no significant demographic differences between groups ($p>0.826$). Pre-upgrade, transmission, accuracy, accessibility, and completeness scored >3.50 , but experience scored <2.50 . All caregivers valued accuracy but reported poor experience. Those over 50 struggled with transmission/accessibility; caregivers <29 and >50 were dissatisfied with completeness. Post-upgrade significantly improved completeness across all ages. The revised app demonstrates excellent accuracy and satisfactory completeness, but requires time for adaptation among caregivers over 50 to transmission/accessibility, and still needs substantial user experience improvements. This multi-dimensional evaluation effectively identified targeted enhancements and ongoing challenges.

Keywords: Pediatric, caregiver, ambulatory care, patient counseling, mobile health application, questionnaire

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INTRODUCTION

The time that the dispenser spends with patients during the drug use process is referred to as dispensing or counselling time, which is an important indicator of the quality of service delivery (Cunha *et al.*, 2023). Studies have shown that a higher workload of dispensers, defined as the number of prescriptions dispensed per dispenser working hour, which means less dispensing or counselling time to provide patient counselling, has been identified as an important barrier to patient counselling (World Health Organization, 2009; Hirko *et al.*, 2018; Michael *et al.*, 2022).

The density of pharmacists in China is much lower than in developed countries (World Health Organization, 2021), and a shortage of pharmacy staff has led to increased workloads and time constraints. Five outpatient pharmacists have to deal with at least 3000 prescriptions in 8 h every day at a Children's Hospital. Each prescription is allocated less than 1 min to perform dispensing and patient counselling, which has a big gap with the minimum time (3 min) that the WHO recommends (Packer *et al.*, 2020). Other studies conducted in Saudi Arabia (Thorakkattil *et al.*, 2023; Alfadl *et al.*, 2018), Nigeria (Abdu-Aguye *et al.*, 2022; Abdu-Aguye *et al.*, 2021), South Korea (Yang *et al.*, 2016), and Ethiopia (Ali *et al.*, 2019; Gudeta *et al.*, 2019) also reported a problem similar to that of China.

To raise the efficiency of patient counselling, we provide common information about drug administration by an hospital-developed mobile health application (mHealth

app) which could obtain medical information from Hospital Information System and be used by patient for no-charge, this kind of app has been used to supplement a diverse range of self-management in medicine (Schrauben *et al.*, 2022; Choi *et al.*, 2019; Bennett *et al.*, 2018; Frias *et al.*, 2017; Owensby *et al.*, 2017), the traditional patient counselling would emphasize other demand about drug therapy.

Patient perspective is linked to the optimal use of medication because patients are more likely to adhere to and use their medications correctly when they are satisfied with the medication counselling (Nigussie *et al.*, 2018). It is a vital source of information for establishing effective pharmaceutical care to improve the quality of healthcare services (Salamatullah *et al.*, 2022). Because assessment of patients for pharmaceutical services is a multifactor concept that is very difficult to measure (Nigussie *et al.*, 2018), we set the following dimensions for the mHealth app to make the evaluation more concrete: ① transmission, transmit between different caregivers (82.1% families have more than one caregiver involved in parenting in China (iResearch Inc, 2022), which makes it necessary to transfer medication information between different caregivers); ② accuracy, the quality of being true or correct; ③ accessibility, easy to use; ④ completeness, include all the needed relevant information; ⑤ experience, comprehensive interaction between patients and medication counselling mode.

Because assessing medication counselling is an important step in evaluating the quality of pharmaceutical care and

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identifying areas needing improvement, we analyse caregivers' assessment of the original version and the revised version mHealth app (fig. 1-2), the latter one supplemented information about drug administration and storage based on the former one, from the above five dimensions to accomplish the aim of identifying if the improvement is responsive to caregivers' needs and improving the mHealth app persistently.

MATERIALS AND METHODS

We conducted a randomised survey before and after the upgrade using questionnaires among outpatient caregivers in workday. The inclusion criteria required that pharmacotherapy be accompanied by a willingness to cooperate in completing the questionnaires. Method of selection of participants was simple random sampling. When the caregivers waited for their drug to be prepared in the ambulatory care pharmacy, a trained researcher chose participants randomly among them. The caregivers who were pleasant to complete the questionnaire would be chosen as participants. Participants returned completed questionnaires on the spot after using the mHealth app on the test mobile phone to obtain medical information from a test prescription; the trained researcher explained unfamiliar concepts, told correct medical information to help the participants confirm its accuracy and made a quick check of the questionnaires to ensure that the survey was complete. We hope to address potential sources of bias through the above two efforts.

An anonymous questionnaire was designed consisting of 11 questions with multiple-choice or scoring questions (Supplementary materials). Questions 1–4 (Supplementary Questions Q1–Q4) were the basic information of patients and caregivers. Questions 5–9 (Supplementary Questions Q5–Q9) were the caregiver's appraisal on five dimensions. Questions 10–11 (Supplementary Questions Q10–Q11) were the willingness of caregiver to be return visit.

The sample size of each survey was calculated according to Sample Size Calculation for Normal Distribution ($n = Z^2 \sigma^2 / d^2$) with 95% confidence interval ($Z = 1.96$), 0.5 Population Standard Deviation (σ) and 5% Error range (E), it was necessary to have 384 valid questionnaires. Considering the invalid sample, we expanded the aimed sample capacity of each survey to 500.

Since the outcome was the evaluation on the application from five dimensions, the relationship between the patient and caregiver, the age of the patient and the age range of the caregiver were the predictors, when the caregiver's parenting experience was the potential confounder, the caregiver's skill in using the mobile Internet was the effect modifiers.

The panel of experts invited to assess the content validity of the questionnaire consisted of five experts in the field of

pharmacy who had been engaged in work related to outpatient pharmacies in pediatric hospitals for more than 10 years. Each expert evaluated the clarity and representativeness of the questionnaire content on a 4-point Likert scale, with 1 and 4 indicating the lowest and highest levels of clarity and representativeness, respectively.

To confirm the reliability of the survey over time through a test-retest procedure, we enquired about the willingness of the participants to complete the questionnaires. Those who were willing to return were asked to answer the questionnaire again by telephone seven days later.

Questionnaires with identical or regularly repeated answers to all the questions were excluded. The corresponding questions were all invalidated if the answer was irrelevant to the question or if the answers to different questions had logical errors in between.

The data used for questionnaire quality evaluation and descriptive statistical analysis were entered into Microsoft Excel version 16.01 and SPSS Statistics version 27.

The clarity and representativeness of each item were evaluated through the Content Validity Index for Items (I-CVI) (Gosak *et al.*, 2022), which is calculated by the number of experts who rated either "3" or "4" in each item divided by the total number of experts. The Content Validity Index for Scales (S-CVI) (Schrauben *et al.*, 2022), which is the arithmetic mean of the I-CVIs, was used to evaluate the clarity and representativeness of the entire questionnaire.

Participants who responded to the same questionnaire within a 7-day interval were included in the study. Test-retest reliability was assessed using Intraclass Correlation Coefficients (ICC) with 95% confidence intervals (CI).

The Mann–Whitney U test was performed to compare the patient-caregiver relationship, the age of patient and the age of caregiver between survey participants before and after the update.

RESULTS

In total, we received 1000 completed questionnaires from 1000 caregivers (500 for original version and 500 for revised version), of which 967 (478 for original version mHealth app and 489 for revised version) were deemed valid.

Five invited experts (one pharmacy department director who was in charge of pediatric ambulatory care pharmacy for 18 years, one pharmacy supervisor who worked in pediatric outpatient pharmacies for 20 years, and three senior pharmacists who worked in patient counselling rooms for 22, 11, and 10 years, respectively) evaluated the content validity of the questionnaire.

Table 1: Content validity and test-retest reliability of the questionnaire

Item	I-CVI ^a		ICC ^c	p value ^d
	Clarity	Representativeness		
patient-caregiver relationship	1.000	1.000	-	0.913
age of the patient	1.000	1.000	-	0.932
age range of the caregiver	1.000	1.000	-	0.826
education level of the caregiver	1.000	1.000	-	-
score on the transmission	1.000	1.000	0.855	-
score on the accuracy	1.000	1.000	0.833	-
score on the accessibility	1.000	1.000	0.869	-
score on the completeness	1.000	1.000	0.806	-
score on the experience	1.000	1.000	0.827	-
telephone return willingness	1.000	1.000	-	-
contact number for return visit	1.000	1.000	-	-
S-CVI ^b	1.000	1.000	-	-

a evaluated the clarity and representativeness of each item, the number of experts who rated either “3” or “4” in each item divided by the total number of experts

b evaluated the clarity and representativeness of the entire questionnaire, the arithmetic mean of the I-CVIs

c evaluated test-retest reliability with 95% confidence intervals (CI).

d compared the patient-caregiver relationship, the age of patient and the age of caregiver between survey participants before and after the update using the Mann-Whitney U test.

< 处方记录详情		< Details of prescription records	
[处方]维生素D滴剂（胶囊型）[400iu*30粒/盒]		[Prescription] Vitamin D Drops (Soft Capsules) [400IU*30 pills/box]	
处方编码：		Prescription NO.:	
处方发生时间：		Prescription time:	
就诊人		Patient	
医生姓名		Physician	
科室名称	内科门诊(河西)	Speciality	Internal-medicine
处方类型	临时处方	Prescription type	Temporary
处方列表	处方录入时间：	Prescription details	Prescription entry time
① 维生素D滴剂（胶囊型） 1盒		Vitamin D Drops (Soft Capsules) 1box	
用药方式：口服		Administration route: oral	
一次剂量：400IU		Single dosage: 400IU	
频 度：每天1次		Frequency: once every day	

Fig. 1: The original mHealth App and the translation of the interface

处方明细	
头孢地尼分散片	X1 ¥6.19
用药指导	口服 每天3次每次1粒，直接口服或溶于5-10毫升温水送服。
双歧杆菌三联活菌散	X1 ¥30.11
用药指导	口服 每天3次每次1袋，2-8℃冷藏保存。不超过40℃温水或牛奶冲服。
消旋山莨菪碱滴眼液	X1 ¥8.92
用药指导	滴眼 每晚1次每次1滴，开启后最多可使用四周。
盐酸左卡巴斯汀鼻喷雾剂	X1 ¥28.54
用药指导	喷鼻 每天2次每次1喷，用药前必须清洗鼻道，喷药时将药物吸入。

Detail of prescription	
Cefdinir Dispersible Tablets	X1 ¥6.19
Information about drug administration	Oral. 1 pill a time, 3 times a day. Take orally or dissolve in 5-10 ml warm water before taking.
Live Combined Bifidobacterium, Lactobacillus and Enterococcus Powder	X1 ¥30.11
Information about drug administration	Oral. 1 pill a time, 3 times a day. Store at 2-8°C. Dissolve in warm water or milk below 40°C.
Raceanisodamine Eye Drops	X1 ¥8.92
Information about drug administration	Drop into the eye. 1 drop a time, 1 time before sleep. Up to four weeks available after unsealing.
Levocabastine Hydrochloride Nasal Spray	X1 ¥28.54
Information about drug administration	Nose spray. 1 puff a time, 2 times a day. Clean the nasal passage before administration, inhale the medicine after spraying.

Fig. 2: The revised mHealth App and the translation of the interface

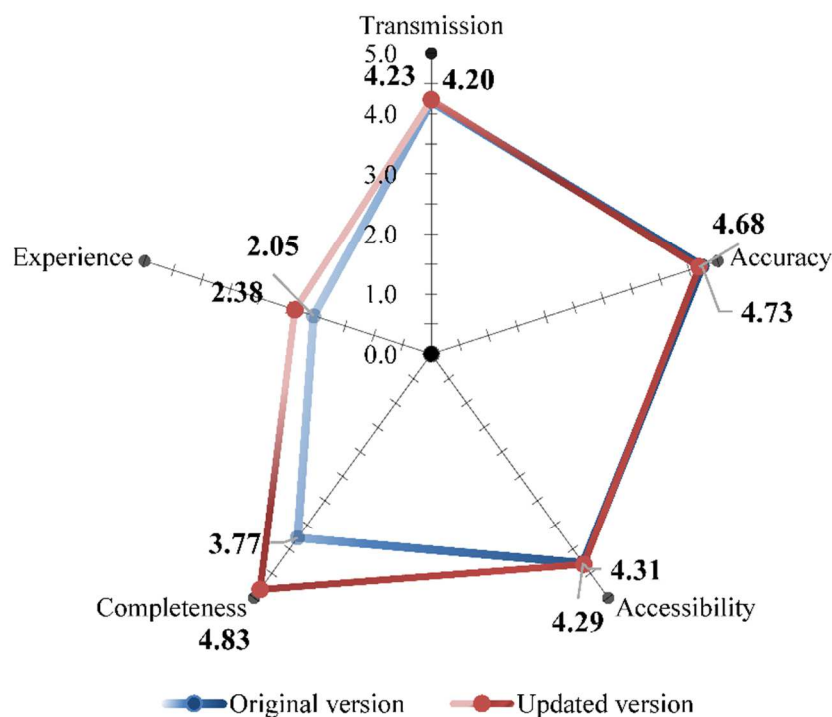


Fig. 3: The mean score of five dimensions

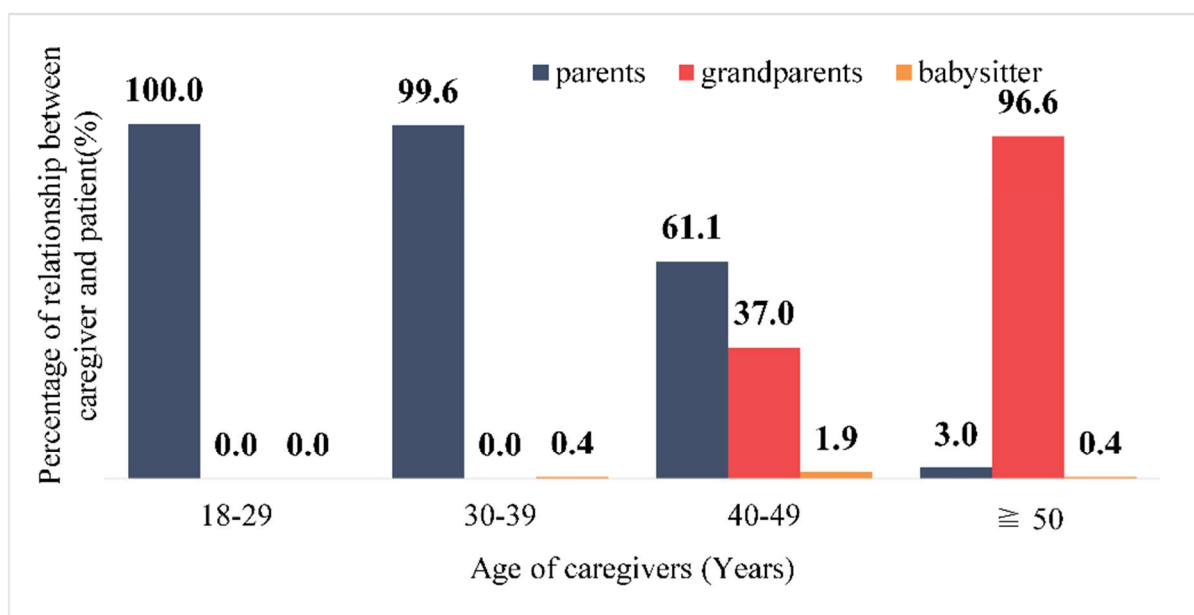


Fig. 4: Relationship between children and caregivers of different ages

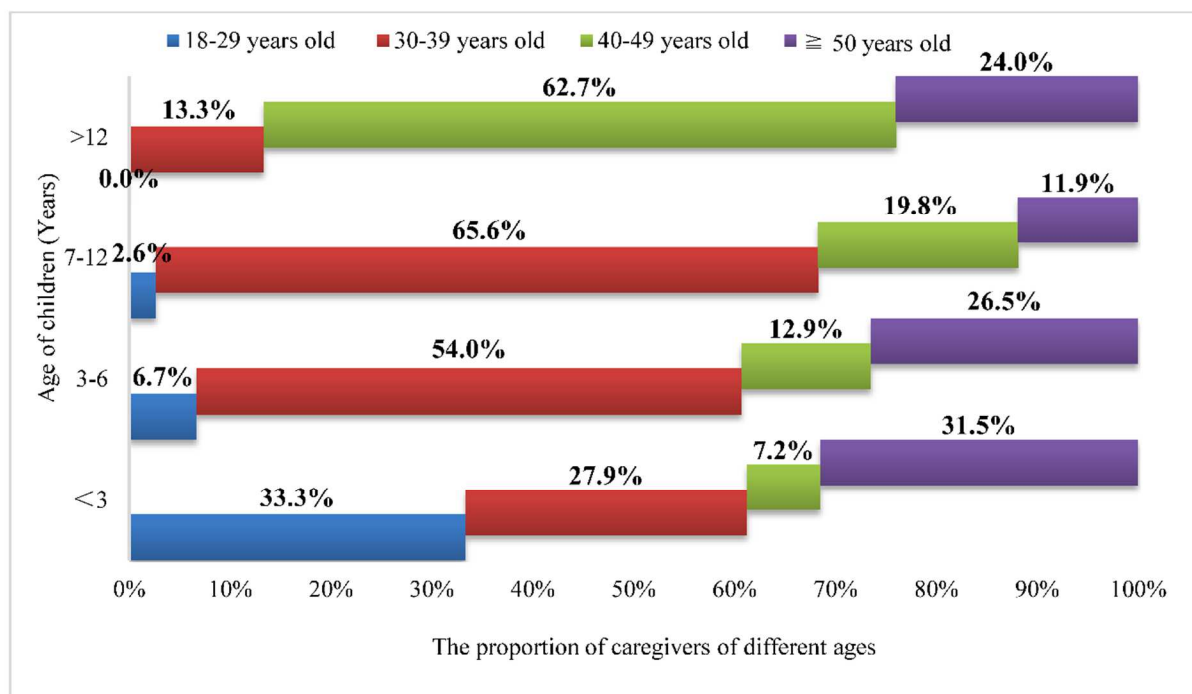


Fig. 5: Age of caregivers for children of different ages

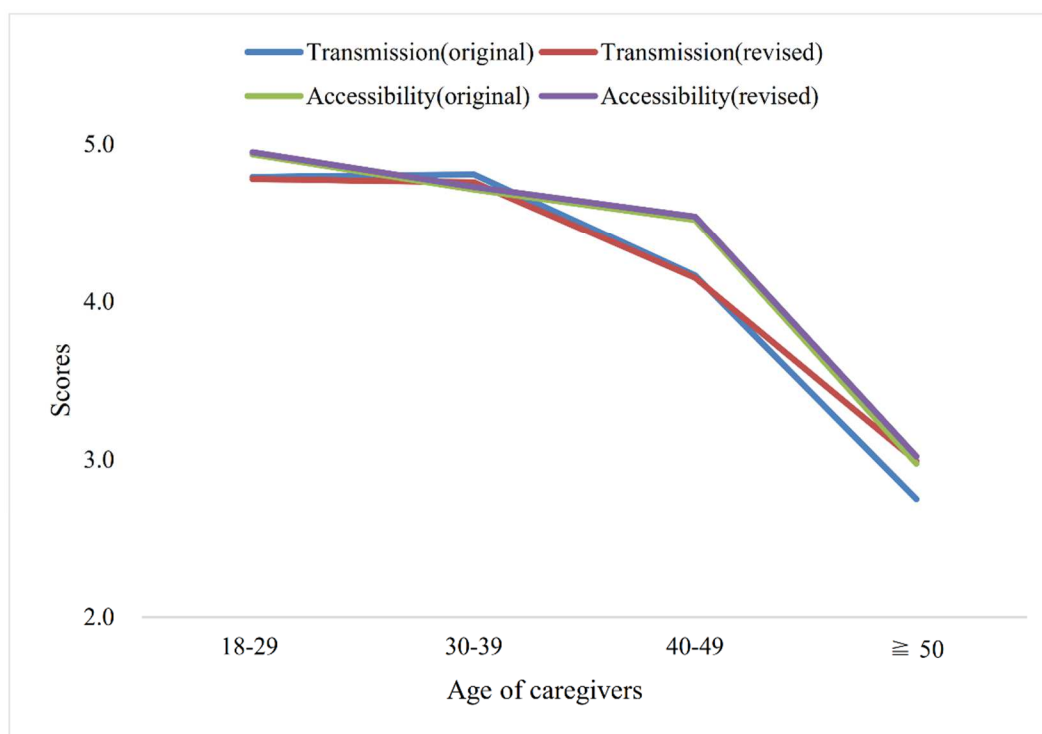


Fig. 6: Evaluation of transmission and accessibility of the original and revised mHealth App by caregivers of different ages

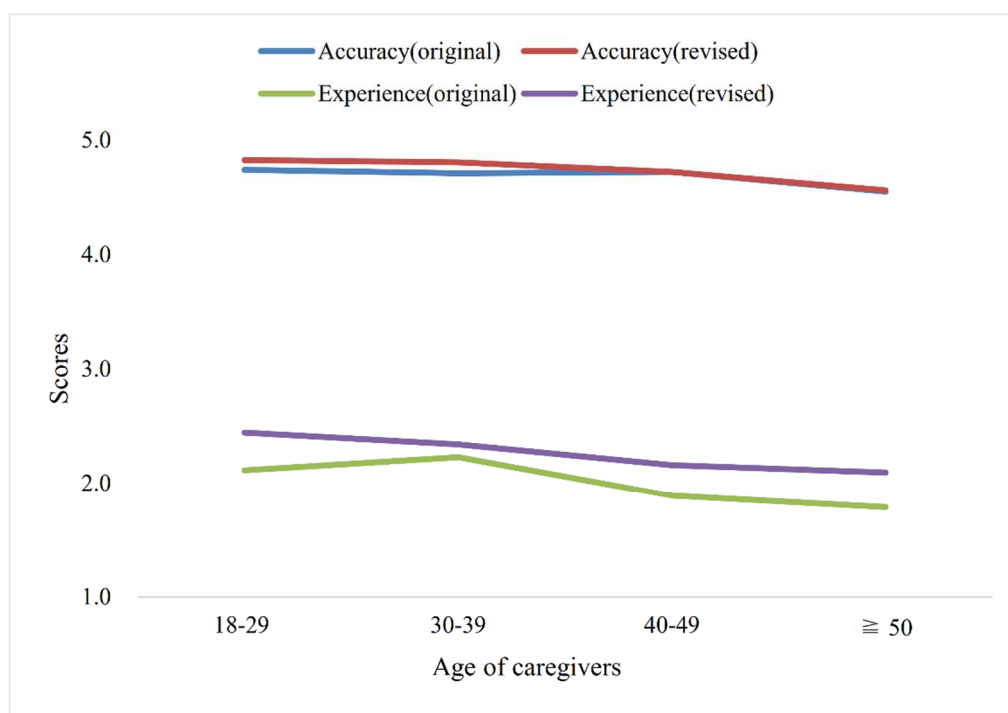


Fig. 7: Evaluation of accuracy and experience of the original and revised mHealth App by caregivers of different ages

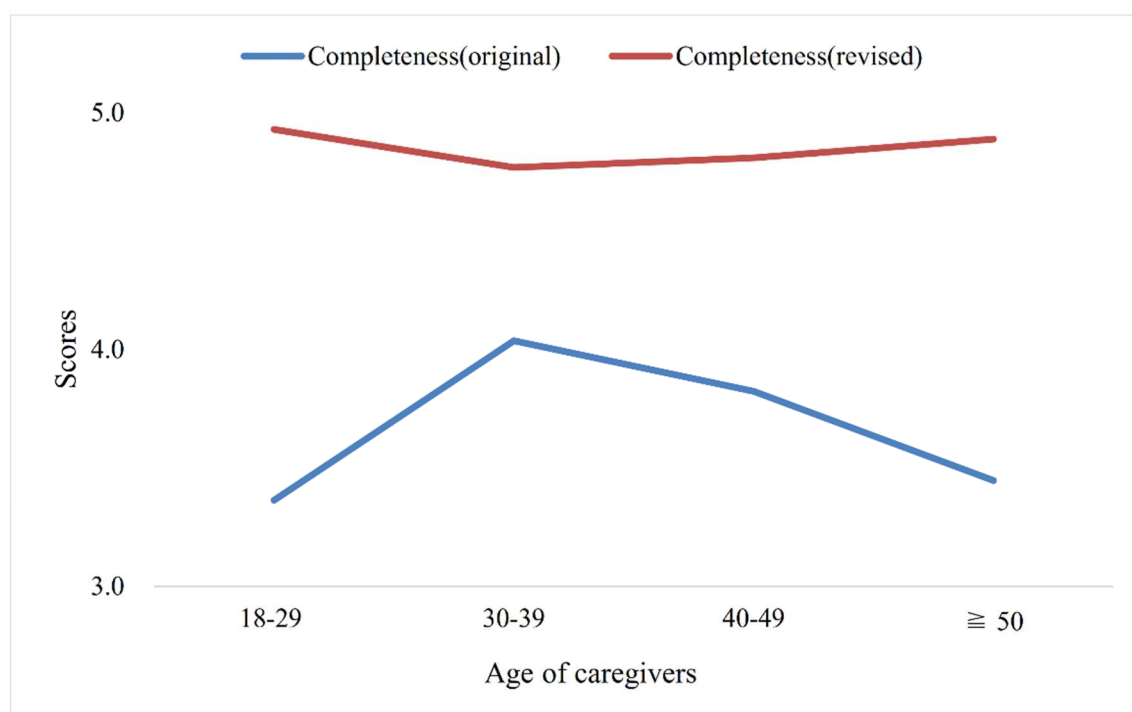


Fig. 8: Evaluation of completeness of the original and revised mHealth App by caregivers of different ages

The I-CVI value for all questions was 1.000, which is consistent with the I-CVI criteria given by previous research (Jansson *et al.*, 2022), as the number of experts was five, indicating that the questions were all clear and representative. The S-CVI value of 1.000 was within the acceptable range (Karthik *et al.*, 2023), confirming the content validity of the questionnaire (table 1).

Of the 147 caregivers willing to return, 138 participated in the test-retest reliability assessment, excluding 2 participants with incorrect phone numbers, 3 caregivers contacted by phone who were not the same caregivers who participated in the previous questionnaire, and 4 caregivers who changed their willingness. The ICC ranged from 0.806 to 0.869, indicating excellent reliability for all items (table 1).

The patient-caregiver relationship, the age of patient and the age of caregiver did not differ significantly between survey participants before and after the update ($p=0.913$, $p=0.932$ and $p=0.826$, respectively).

Transmission, accuracy, accessibility, and completeness of the original version and revised version were all accepted by the caregivers as the mean scores were more than 3.50 (out of 5.00), with the exception of experience (less than 2.50) (fig. 3).

Combined with the age of the children, the caregivers participated in two surveys were divided into different age

groups according to their relationship with the children: 18–29 years old (most parents of children below 3 years old), 30–39 years old (most parents of children from 3 to 12 years old), 40–49 years old (most parents of children over 12 years old and babysitters), and over 50 years old (most grandparents and babysitters) (figs. 4-5).

Before and after the update, in terms of transmission and accessibility, as caregivers' age increased, the scores decreased significantly (fig. 6), in terms of accuracy and experience, caregivers' ratings were in agreement regardless of age; the former characteristic was at the top, whereas the latter was at the bottom (fig. 7). For completeness of the original version, the mean score was between 3.0 to 4.0, the 30–49 age groups had slightly higher scores than the other age groups. In contrast, the mean score of completeness for the revised one improved in all age groups (fig. 8).

DISCUSSION

A complete patient counselling provides clear and comprehensible information on drug name, use and expected action, administration, side-effects, self-monitoring, storage, interactions, refill information, and actions taken in the event of a missed dose, etc (Gernant *et al.*, 2020). On account of the original version the mHealth app only provided information on usage and dosage, the mean score of its completeness was far from satisfactory and was particularly lower among caregivers below 29 and

above 50, who focused more on completeness and needed more medication information, as they made up 64.8% of the caregivers with children under 3 years old. Although the revised version only incorporated administration and storage into the original one, the mean score of its completeness underwent a notable improvement in all age groups, as it responded to nearly 60% medicine consultation according to a research published in 2023 from Beijing Friendship Hospital(Yingming *et al.*, 2023). If the caregivers needed it, they could access additional necessary information for complete patient counselling in the traditional patient counselling room as usual.

When the accuracy of the two versions mHealth app was endorsed by caregivers of different ages as all the information was printed, the experience gained the opposite, as it could not provide more communication about medication with pharmacists. The results suggest that, although patient counselling is the transmission of medication information, it is also the transmission of humanistic care, which can be embodied by communication. Humanistic care should not be omitted when focusing on the efficiency of patient counselling because of the particularities of the receiver and the content of the information.

The results indicated that the mean scores for transmission and accessibility of the two versions plummeted among caregivers over 50 years, probably because they could not use the mobile Internet proficiently. Although this age group accounts for more than one-third of the population (National Bureau of Statistics of China, 2022), it makes up only about a quarter of China's mobile Internet users (Quest Mobile, 2022). However, according to another research on the Silver Generation in China, the number of mobile Internet users over the age of 50, the main contributor to the growth of the number of Internet users, is close to 300 million (Quest Mobile, 2022). When they become more and more proficient in using the mobile Internet, the transmission and accessibility of the mHealth app will be increasingly recognised by them and in line with their needs. However, before that, we should maintain the traditional medication counselling model they are familiar with as they were the main caregivers of children in more than 50.0% of Chinese households (*iResearch Inc.*, 2022).

According to the characteristics and the needs of caregivers of pediatric patients in China, further research will focus on developing the app to a version that could provide communication with pharmacists to improve its experience.

Few studies have assessed the five dimensions of an mHealth app for patient counselling in outpatient pharmacies from a pediatric caregiver's perspective. Different cultures and types of patients may cause different evaluations of this type of mHealth app. Therefore, the five-dimensional assessment model of this study could be

used to evaluate other mHealth apps for patient counselling to make them more in line with the needs of users of different cultures or types.

Although the survey sample was from a single centre, which is the major limitation of this study, the sample sources were diverse and representative, as the patients of this regional hospital were not only from Jiangsu Province but also from its adjacent areas.

CONCLUSION

According to the opinions of caregivers of pediatric patients in outpatient pharmacies in this study, the completeness of the revised mHealth app satisfies the caregiver, the accuracy is excellent, the transmission and accessibility need to give the Silver Generation some time to accept and adapt, and the experience should be improved. Other mHealth apps for patient counselling should evaluate the corresponding users using this five-dimensional assessment model to improve themselves.

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Conflict of interest

There is no conflict of interest.

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