Asia-Pacific Journal of Oncology Nursing 13 (2026) 100833

Contents lists available at ScienceDirect

Asia-Pacific Journal of Oncology Nursing

journal homepage: www.apjon.org

Original Article

Improvements of an oral anti-cancer drug safety management program for patients with cancer

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ARTICLE INFO

Keywords:
Knowledge
Behavior
Nurses
Neoplasms
Patients
Health education

ABSTRACT

Objective: To evaluate the impact of an oral anti - cancer drug safety management program on nurses and patients.

Methods: This study was a hospital-level quality-improvement evaluation (pre–post, quasi-experimental design) and was not registered as a clinical trial. It was conducted from August 2024 to December 2024 in a tertiary hospital in Beijing. The program comprised three stages: preparation, training, implementation and supervision. It included tiered training for nurses based on established nursing standards, standardized health education checklists for patients, and continuous support through virtual and in-person clinic visit. Associated improvements were evaluated using self-designed questionnaires. Data were collected from nurses before training and 2 months after program implementation, and from patients before and 1 month after education. Descriptive statistics and non-parametric paired sample tests were used for analysis.

Results: A total of 632 nurses participated in the program, of which 381 nurses completed both evaluations. The knowledge and behavior scores of nurses regarding on correct medication administration, protection against drug exposure, and early management of adverse reactions improved significantly ($P < 0.001$). The full-score rates for knowledge and behavior increased from 71.82% and 71.55% to92.65% and 94.49%, respectively ($Z = -11.462$, -13.104, respectively; both $P < 0.001$). A total of 643 patients received guidance, of which 384 patients completed both evaluations. The knowledge and behavior scores of patients also improved significantly ($P < 0.001$), with the full-score rates increasing from 59.46% and 68.29% to78.62% and 85.11%, respectively ($Z = -11.473$, -12.415, respectively; both $P < 0.001$).

Conclusions: Meaningful improvements were achieved through enhancements to the oral anti-cancer drug safety management program. Standardized training and structured implementation enabled nurses to provide evidence-based patient guidance, thereby enhancing patients' knowledge and skills in safe medication management.

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https://doi.org/10.1016/j.apjon.2025.100833
Received 17 October 2025; Accepted 17 December 2025

Introduction

In 2022, an estimated 4.82 million new cancer cases and 2.57 million cancer-related deaths were recorded in China.[1] Current cancer treatment methods include surgical therapy, chemotherapy, radiation therapy, minimally invasive interventional therapy, targeted therapy, and immunotherapy. Anti-cancer drugs are administered through various routes, including intravenous, intramuscular, oral, intracavitary, intrathecal, and intra-arterial chemotherapy. In recent years, oral anti-cancer drugs have gained considered recognition in clinical practice. Because of its non-invasive nature, efficacy, cost-effectiveness, and convenience, the oral administration of anti-cancer drugs has been increasing accepted by both patients and health care professionals.[2,3] A recent scoping review identified 110 types of oral anti-cancer drugs available in the European market.[4] Currently, the commonly used oral anti-cancer drugs in domestic clinical practice include chemotherapeutic agents such as capecitabine, temozolomide, etoposide, and tegafur, as well as molecular targeted drugs such as sorafenib, apatinib, and lenalidomide.

Various drugs exhibit distinct mechanisms of action and adverse reactions. Chemotherapy drugs selectively target and kill tumor cells but also affect rapidly dividing normal cells, including those in the hematopoietic system and gastrointestinal epithelium, leading to varying degrees of adverse drug reactions such as nausea, vomiting, diarrhea, bone marrow suppression, alopecia, and liver toxicity.[5] Drugs used for targeted therapy are characterized by high selectivity, sensitivity, and efficacy, with minimal damage to normal cells; however, they can still cause toxic side effects, including gastrointestinal, dermatological, and mucosal reactions and pulmonary and cardiovascular toxicities.[6] The adverse reactions associated with oral anti-cancer drugs not only reduce patients' quality of life but may also affect treatment compliance, thereby influencing therapeutic outcomes.[7] In recent years, skin toxicities reactions and organ-specific adverse effects of commonly used oral molecular targeted drugs have become increasingly prominent. Consequently, it is crucial to guide patients in proper medication administration and in preventing and managing adverse drug reactions. Most patients also receive oral anti-cancer drug therapy at home and often require assistance from family members. Given the cytotoxic nature of these drugs, improper storage or handling may pose health risks through environmental exposure or direct contact with family members, necessitating vigilance by health care professionals.

Local problem

In China, the nursing management of intravenous chemotherapy has traditionally received significant attention in clinical practice. However, treatment with oral anti-cancer drugs has shifted from hospital-based administration to home-based self-administration, transitioning from intravenous infusion to oral intake and from provider supervised to patient self-management. Safety management of oral anti-cancer drugs has received limited attention[8,9] and lacks a systematic management model.[10] Previous studies indicate that patients lack adequate knowledge regarding medication use and safe handling of oral anti-cancer drugs, and the medication process is often not supervised by health care providers.[11] Additionally, patients are often unaware of proper waste disposal methods for unused or expired drugs and correct drug storage procedures.[7] The current status of oral anti-cancer drug use and related interventional research remains in its early stages. Several surveys[12–14] have identified that influence medication adherence and contribute to adverse reactions, with primary research objectives focusing on improving patient medication adherence and symptom management. Nevertheless, despite growing research on the management of oral anti-cancer drugs, there is little evidence for effective interventions to ensure safe administration and sustained patient adherence.[15]

In our hospital, prior to implementing the Oral Anti-Cancer Drug Safety Management program, most patients received their oral anti-cancer drugs before discharge. During pre-discharge discussion, the physicians explained the rationale for selecting a specific oral anti-cancer drug and emphasized the critical importance of medication adherence for treatment efficacy. Patients were then instructed to manage drug administration independently at home. Information about these drugs was obtained from physician prescriptions, online sources, health education provided by nurses, and other sources; this approach was rather fragmented and lacking standardization. No structured process existed to ensure patient safety from the prescription stage through long-term self-management at home. Concurrently, most nurses have limited involvement in oral anti-cancer drug management and lacked specialized knowledge and skills in oral anti-cancer drug safety management, including proper storage, administration techniques, common adverse reactions, and corresponding nursing interventions. Consequently, practical guidance and safety behaviors were frequently underemphasized in routine patient care.

Intended improvement

The National Comprehensive Cancer Network safety management standards for oral anti-cancer drugs now include guidelines for their safe use and handling procedures.[16] The "Beijing Action Plan for Further Improving Nursing Services (2023–2025)"[17] proposes enhancement in nursing services through three approaches, with "expanding the scope of nursing and bringing nursing services closer to society" as a key direction. The plan encourages hospitals to innovate management models and provide continuous nursing services, such as home care guidance for discharged patients with ongoing nursing needs to meet post-discharged care requirements. This program addresses the current gap in management for patients with cancer taking oral anti-cancer drugs at home. A multidisciplinary project team was established to actively explore innovative management models and further reform patient care. Scientific and systematic intervention measures were developed, focusing on two core aspects: correct use of anti-cancer drugs and safety protection during home-based treatment. The goal was to meet the continuous care needs of oncology outpatients after discharge and ensue comprehensive medication safety throughout the treatment process.

Quality improvement question

This study was a hospital-level quality improvement and implementation evaluation (pre–post, quasi-experimental design) and was not registered as a clinical trial. It aimed to develop and implement an oral anti-cancer drug safety management program by introducing a series of health education-centered interventions to enhance institutional safety practice and provide professional safety management support for patients using these drugs. The initiative complemented existing physician-led education on oral anti-cancer drugs, not as a replacement of the physician's effort, but as an approach that adds value through a standardized, systematic nursing education process designed to address gaps in safety and self-management. The study also evaluated the impact of the safety management program on nurses involved in drug management and on patients using these drugs. Thus, this study thus addressed a critical gap by providing a replicable model for systematizing care in this high-risk domain.

Methods

Ethical issues

This project involved two groups: nurses and patients receiving oral anti-cancer drugs. To ensure equitable participation, all nurses underwent training as part of the program. After the implementation of the program in the clinical departments, to safeguard patient rights, all patients currently taking or newly prescribed oral anti-cancer drugs received standardized health education from nurses. Participation in the

baseline survey before program implementation and in the follow-up re-evaluation was voluntary for all patients, and confidentiality of personal information were ensured. Informed consent from all patients was obtained specifically for participation in the program, and for the use of their data to evaluate program improvements. The Institutional Review Board of Beijing Cancer Hospital reviewed and approved the project (Approval No. 2024YJZ84).

This study was approved as a 2024 high-quality development and reform innovation project for municipal hospitals (Approval No. 24GGCX022), established and governed by the Beijing Hospital Administration Center. The project required all applicants to focus on the standardization, refinement, and scientific aspects of hospital management, aligned with real-world institutional challenges. It emphasized a reform-oriented approach and encouraged innovation to strengthen hospital management capabilities. The program was independently managed and implemented at the hospital level, with the Beijing Hospital Administration Center supervising the project during initiation, mid-term, and final stages. No other conflicts of interest were involved in this project.

Setting

This project was conducted at a specialized oncology hospital in Beijing, China, comprising 33 departments, including 23 clinical departments, with a nurse-to-bed ratio of 1:0.68. The anti-cancer drugs available in the hospital include 19 chemotherapeutic agents (12 cytotoxic drugs and 7 hormonal drugs) and 58 targeted agents. The type and dosage of oral anti-cancer drugs administered to patients are prescribed by doctors on the basis of patients' diagnosis and clinical conditions. These drugs are often used in combination with other formulations and are prescribed and dispensed upon patient discharge. Physicians inform patients about drug requirements and briefly describe potential adverse reactions; the discharge instructions also specify the appropriate administration method. Because of the chronic nature of cancer, patients frequently undergo multiple hospitalizations for periodic treatments. During subsequent admissions, if oral anti-cancer drugs continue to be used, the nurses engage with patients to provide necessary guidance.

Planning the intervention

The "Oral Anti-Cancer Drug Safety Management Program" was a systematic and scientifically structured process involving all clinical department nurses and inpatients prescribed oral anti-cancer drugs. It consisted of three phases: preparation, training, implementation and supervision. The key stages of these phases are illustrated in Fig. 1. Program components included material development, systematic nurse training (with supervision), patient education and consultation, and evaluation of the improvements.

Preparation phase: Following literature retrieval and quality assessment, we extracted relevant measures and management strategies for oral anti-cancer drug safety management in patients with cancer. (1) Through discussion, synthesis, and analysis by the project team, a checklist of safety management strategies for the therapy of patients with cancer with oral anti-cancer drugs was developed. Surveys were conducted with stakeholders, patients undergoing oral anti-cancer drug therapy, and their caregivers. A Delphi method was employed with a panel of Chinese experts, including nursing managers, clinical nurses, physicians and pharmacists, from diverse specialties, ranks, positions, and experience levels. Subsequently, the *Oral Anti-Cancer Drug Safety Management Health Education Checklist* for oral anti-cancer drug safety management was completed[18] to enable nurses to deliver scientifically sound and effective health care education to patients. (2) In alignment with hospital management practices, the project team compiled the retrieved measures and management strategies into the '*Oral Anti-Cancer Drug Safety Nursing Management Practice Standards*', which were discussed and finalized with senior nursing staff from the hospital. Considering that patients with different types of tumors take different oral anti-cancer drugs with varying administration methods, side effects, and precautions, the *Practice Standards* include drug-specific usage precautions, nursing protocols for management adverse reactions, etc. (3) A home-based self-safety management education manual was developed for patients, covering topics such as home drug storage and protective measures, emergency response to drug exposure, and management of adverse drug reactions or symptoms. The manual was printed as a brochure. (4) In collaboration with the pharmacy

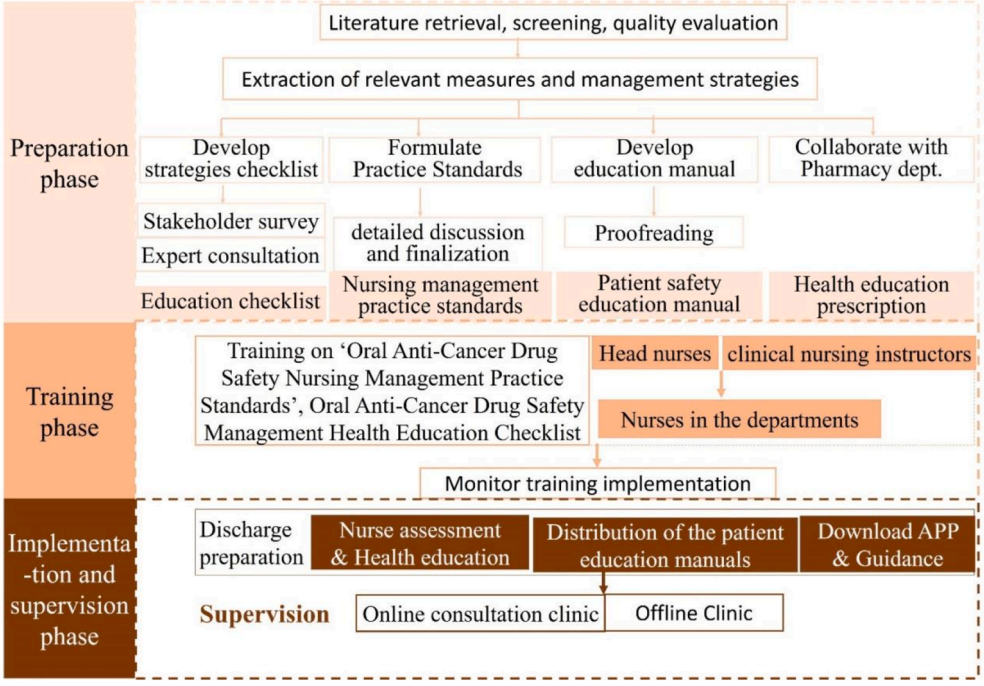

Fig. 1. Key stages of the intervention phases.

department, health education prescriptions for oral anti-cancer drugs were disseminated to patients for home access through the hospital's information platform (Beijing cancer hospital APP).

Training phase: (1) Head nurses and clinical nursing instructors were trained on the *Oral Anti-Cancer Drug Safety Nursing Management Practice Standards* (including *Oral Anti-Cancer Drug Safety Management Health Education Checklist*). (2) These instructors then delivered standardized training to nurses in their departments, covering interpretation of the content and key implementation points of the *Practice Standards*. During the departmental training, emphasis was placed on conducting in-depth learning based on actual patient medications in each department and consulting drug package inserts as needed. (3) The Nursing Department supervised the implementation of departmental training and reviewed the training process and assessment records to ensure that all clinical nurses had completed the training and mastered the use of the *Oral Anti-Cancer Drug Safety Management Health Education Checklist*.

Implementation and Supervision phase: For patients requiring continued oral anticancer therapy after discharge, the following steps were taken: (1) Nurses conducted a comprehensive assessment of the patient's treatment plan; understood the characteristics, administration methods, adverse reactions, and precautions of the prescribed oral anticancer drugs, and provided targeted health education to the patient according to the *Oral Anti-Cancer Drug Safety Management Health Education Checklist,* customized based on the patient's specific medication regimen. (2) The home self-safety management manual was distributed, and patients were taught to record medication times, dosages, adverse drug reactions, and appropriate responses. (3) Nurses assisted patients in downloading the Beijing Cancer Hospital APP and instructed them on scheduling online nursing consultation appointments and accessing personalized health education prescriptions for their medications.

Post-discharge management for inpatients: Online nursing and pharmacy consultation clinics provide home care guidance for oral anticancer drugs. Patients can schedule an online nursing consultation appointment if they encounter issues during home care. Nurses provide appropriate responses based on the specific concern; for dosage adjustments, nurses consult with physicians before responding to the patient. If an issue cannot be resolved online, patients are provided information for offline consultation or assisted in scheduling an in-person clinic visit.

Planning the study of the intervention

This study employed a prospective quasi-experimental design to evaluate program improvements through pre- and post-intervention self-control analysis. Nurses involved in the health education of patients taking oral anti-cancer drugs and patients themselves were selected by cluster sampling.

Inclusion criteria for nurses were as follows: (1) working as a registered nurse; (2) having over 1 year of experience in caring for patients taking oral anticancer drugs; and (3) providing voluntary consent to participate. Exclusion criteria included (1) trainee nurses, transferred nurses, and nursing interns; (2) inability to participate due to illness during the study period; and (3) those who declined participation or failed to complete the survey within the 1-week response window, which was considered “dropout” at the second assessment. Sample size was determined as follows: according to Kendall's standard, the sample size should be 5–10 times the number of items on the scale. Considering a 10% attrition rate, the sample size was N = number of questionnaire items × (5–10) / (1–10%), yielding: 31 × (5–10) / (1–10%) = 172–344 cases. A post hoc power analysis was conducted using G*Power 3.1.[19] Mean: Wilcoxon signed-rank test (matched pairs) was applied with $\alpha = 0.05$ (two tailed), an effect size of $d = 0.747$ (calculated from mean and SD of knowledge scores before and after intervention), and a total sample size of 381 nurses, resulting in a power (1-β) of 1.00; an effect size of $d = 0.776$ (calculated from mean and SD of the practice scores before and after intervention) and a total sample size of 381 nurses also yielded a power (1-β) of 1.00.

Inclusion criteria for patients taking oral anti-cancer drugs were as follows: (1) pathological diagnosis of cancer and currently receiving oral anti-cancer drug therapy; (2) age ≥ 18 years; and (3) providing voluntary consent to participate. Exclusion criteria were as follows: (1) patients unaware of their diagnosis; (2) those with a history of severe mental illness, intellectual disability, or cognitive impairment; (3) those with hearing or speech impairments, which prevented effective communication or survey completion; and (4) those who refused to participate in the follow-up survey or did not contact after three attempts were considered “dropout” at the second investigation. Sample size: calculation followed the same principle as that for nurses, N = number of questionnaire items × (5–10) / (1 - 10%), yielding 28 × (5–10) / (1 - 10%) = 156–312 cases. A post hoc power analysis was conducted using G*Power 3.1.[19] Mean: Wilcoxon signed-rank test (matched pairs) was applied with $\alpha = 0.05$ (two tailed). An effect size of $d = 0.612$ (based on Mean and SD of the knowledge scores pre- and post-intervention) and a total sample size of 384 patients with cancer yielded a power (1 - β) of 1.00; an effect size of $d = 0.687$ (based on mean and SD of the practice scores pre- and post-intervention) and a total sample size of 384 patients with cancer also yielded a power (1 - β) of 1.00.

Prior to training, a baseline survey (Round 1) was administered to nurses to assess their knowledge and practices regarding oral anti-cancer drug safety management. Two months after program implementation, a follow-up assessment (Round 2) on nurses’ knowledge and practices was conducted. During the intervention phase, patients taking oral anticancer drugs completed a baseline survey (Round 1), which evaluated their knowledge and behaviors regarding oral anti-cancer drug safety management prior to receiving health education. Following the initial survey, they received the intervention, and 1 month later, their knowledge and behaviors were reassessed (Round 2). Both pre- and post-surveys were conducted using online links, with system-level validation to detect missing responses; submission was possible only upon completion of all questions. For the baseline survey, patients could choose between an online link and a paper version; online responses were automatically checked for completeness, while paper versions were verified by investigators on-site. The follow-up survey was also monitored by investigators to ensure completeness.

The primary outcomes of this quality improvement project were changes in the overall knowledge and behavior scores and full-score rates among both nurses and patients, measured using validated self-report questionnaires across the two rounds. Secondary outcomes included changes in domain- and item-level scores and full-score rates for knowledge and behavior, which provided further insights into the mechanisms underlying the intervention's effects.

This study report adhered to the *Standards for Quality Improvement Reporting Excellence* (SQUIRE) guidelines[20] (Supplementary File 1).

Methods of evaluation

(1) For nurses

Part One: Demographic data and information related to oral anticancer drug therapy: age, gender, education level, professional title, years of work experience, types of oral anti-cancer drugs currently used in clinical practice, and primary sources of current knowledge regarding oral anti-cancer drugs.

Part Two: Questionnaire on Knowledge and Behavior Regarding Oral Anti-Cancer Drug Safety Management for Patients with Cancer (Nurse Version).

This self-designed questionnaire was developed based on the *Oral Anti-Cancer Drug Safety Management Health Education Checklist*,[18] and consists of two sections: knowledge and behavior, with 31 items in total-8 items on knowledge and 23 items on behavior. These items span three dimensions: correct medication administration, protection against drug exposure, and early management of adverse reactions. Each knowledge

item was scored on a 3-point Likert scale (1 = complete unawareness to 3 = complete awareness), with higher scores indicating greater of knowledge of oral anti-cancer drug safety management. The behavior items were rated from 1 point (never) to 4 points (frequently), with higher scores reflecting better oral anti-cancer drug safety management practices.

(2) For patients

Part One: demographic data and disease and treatment-related information: age, gender, place of residence, marital status, education level, current employment status, financial burden for oral anti-cancer drugs, prior education regarding oral anti-cancer drug management, and whether it was their first time taking such medications.

Part Two: Questionnaire on Knowledge and Behavior Regarding Oral Anti-Cancer Drug Safety Management for Patients with Cancer (Patient Version).

This self-designed questionnaire was also developed based on the *Oral Anti-Cancer Drug Safety Management Health Education Checklist*[18] and comprised two sections—knowledge and behavior—with 28 items in total: 12 knowledge items and 16 behavior items. The content covers the same three dimensions: correct medication administration, protection against drug exposure, and early management of adverse reactions. Knowledge items were scored on a 3-point Likert scale (1 = complete unawareness to 3 = complete awareness), with higher scores indicating greater knowledge regarding oral anti-cancer drug safety management. The behavior items were scored from 1 point (never) to 4 points (frequently), with higher scores representing more consistent safety behaviors.

Data analysis

Statistical analysis was conducted using SPSS 26.0 statistical software. Missing data in the knowledge and behavior sections were imputed using the sample mean. (1) Descriptive statistics were used to characterize the study population: frequency and percentages for categorical variables, and mean value with standard deviation for continuous variables. (2) Content validity of the self-designed questionnaires was assessed using the item-level content validity index (I-CVI), scale-level content validity index (S-CVI) and content validity ratio (CVR). The experts were asked to judge the relevance of each item to the intended measurement theme and had to score each item from 1 point to 4 points by using a 4-point scale (1 = irrelevant, 2 = weakly relevant, 3 = moderately relevant, 4 = completely relevant). Items rated 3 or 4 were considered relevant. I-CVI[21] is defined as follows: when the number of experts is ≤ 5, I-CVI should be 1.00, implying that all experts agree with the view that the item is well related to the concept being measured, thus indicating good content validity; when there are 6 or more experts, the standard can be lowered, but I-CVI should not be < 0.78. In this study, the mean value of all item I-CVIs on the scale was used to compute the average S-CVI, which was required to reach 0.90.[22] Baghestani et al.[23] proposed a Bayesian method to determine the critical CVR value. For a 7-expert panel, the critical CVR threshold was ≥ 0.71,[24] above which items were accepted as significant. (3) Construct validity was evaluated using confirmatory factor analysis (CFA). Model fitness was assessed using a set of fit indices, including the chi-square/degrees of freedom ratio (χ^2/df), root mean square error of approximation (RMSEA), incremental fit index (IFI), Tucker–Lewis index (TLI), comparative fit index (CFI), and standardized root mean square residual (SRMR). Acceptable model fit was defined as follows: $\chi^2/df < 5.00$, RMSEA < 0.08, IFI > 0.90, TLI > 0.90, CFI > 0.90, and SRMR < 0.10.[25,26] (4) Reliability of the self-designed questionnaire was measured by Cronbach's α coefficient. (5) Knowledge scores were calculated by summing the different responses, and the full-score rate was calculated by the proportion of respondents with complete awareness as follows: Full-score rate = number of fully aware respondents / total respondents × 100%. Scores were expressed as mean value and standard deviation. As the data did not follow a normal distribution, a non-parametric paired-sample test was used. (6) Behavior scores were similarly calculated, with the full-score rate based on frequent behavior: Full-score rate = number of respondents reporting frequent behavior / total respondents × 100%. The scores were expressed as mean value and standard deviation, and a non-parametric paired-sample test was used for the non-normally distributed data.

Results

(1) Sample description

A total of 632 nurses from 33 clinical departments at Beijing Cancer Hospital participated in the training program. Of these, 381 nurses directly involved in implementing the oral anti-cancer drug safety management program completed the post-intervention survey. Table 1 shows the general information of the nurses. Starting from October 8, 2024, the program was implemented for inpatients across clinical departments. By the end of November 2024, over 1700 patients with cancer taking oral anti-cancer drugs received structured guidance on the safety management of these drugs. A matched analysis was conducted on the survey results of 384 patients who met the eligibility criteria. Table 2 shows the general characteristics of the patients.

(2) Validity and Reliability Testing of the Questionnaire

To ensure the content validity of the questionnaire, the number of experts evaluating the content validity should not be fewer than five.[27] Ultimately, seven experts were included, comprising one from the field of pharmacology, one from the field of oncology medicine, and five from the field of oncology nursing. All experts had a bachelor's degree or higher, held mid-level or higher professional titles, and had over 10 years of experience in oncology-related work. Following expert evaluation, the I-CVI for the nurse version of the questionnaire ranged from 0.857 to 1.000, the S-CVI was 0.982, and the CVR ranged from 0.714 to

Table 1
General information of nurses involved in the program ($N = 381$).

Characteristics	*n* (%)
Age (years, mean ± SD)	32.28 ± 7.12 (Range: 20–55)
Sex	
Male	2 (0.52)
Female	379 (99.48)
Educational level	
Associate degree	58 (15.22)
Bachelor degree	315 (82.68)
Master degree	8 (2.10)
Professional title	
Senior	5 (1.31)
Secondary	123 (32.28)
Primary	199 (52.23)
None	54 (14.17)
Years of work experience	10.41 ± 7.53
Types of oral anti-cancer drugs currently used in clinical practice	
Fluorouracil oral emulsion (5-fluorouracil)	51 (13.39)
Xeloda (Capecitabine)	278 (72.97)
TS-1 (S-1)	200 (52.49)
Iressa/Yiruike (Gefitinib)	73 (19.16)
Navelbine (Vinorelbine)	41 (10.76)
Tarceva (Erlotinib)	41 (10.76)
Glivec (Imatinib Mesylate)	71 (18.64)
Others	73 (19.16)
Primary sources of current knowledge	
Continuing education and training in-hospital	304 (79.79)
New media network resources	94 (24.67)
Drug instruction manual	354 (92.91)
Others	50 (13.12)

SD, standard deviation.

Table 2
General information of patients taking oral anti-cancer drugs ($N = 384$).

Variables	*n* (%)	Variables	*n* (%)
Age (years, mean ± SD)	57.35 ± 11.05 (Range: 25–89)	**Financial burden**	
Sex		Full coverage of medical Insurance	53 (13.80)
Male	224 (58.33)	Partially self-paid	288 (75.00)
Female	160 (41.67)	Fully self-paid	27 (7.03)
Place of residence		Other	16 (4.17)
Urban area	212 (55.21)	**Prior education regarding oral anti-cancer drug management**	
Town	88 (22.92)	None	33 (8.59)
Countryside	84 (21.88)	Drug storage and disposal	238 (61.98)
Marital status		Drug–drug and drug–food interactions	207 (53.91)
Married	356 (92.71)	Prevention and response to adverse reactions	274 (71.35)
Divorced/Separated	9 (2.34)	Dietary guidance	223 (58.07)
Widowed	12 (3.13)	Self-management knowledge	140 (36.46)
Unmarried	7 (1.82)	Reexamination time and the significance of each examination	204 (53.13)
Education level		Instruct family members on how to take care of the patient.	143 (37.24)
Primary education and below	36 (9.38)	Other	9 (2.34)
Junior middle school	104 (27.08)	**Is this the first time taking oral anti-tumor drugs?**	
High /Secondary school	104 (27.08)	Yes	4 (1.04)
Junior college	60 (15.63)	No	380 (98.96)
Bachelor degree and above	80 (20.83)		
Current employment status			
Employed	95 (24.74)		
Retired	165 (42.97)		
Unemployed or without a job	71 (18.49)		
Other	53 (13.80)		

Table 3
Model fit of the nurses' and patients' safe management in the knowledge and behaviors sections.

Participant	Section	χ^2/df	RMSEA	IFI	TFI	CFI	SRMR
Accepted criteria[25,26]	–	< 5.00	< 0.08	> 0.90	> 0.90	> 0.90	< 0.10
Nurse ($n = 381$)	Knowledge	3.081	0.074	0.979	0.951	0.979	0.030
	Behaviors	3.406	0.0796	0.932	0.915	0.932	0.070
Patient ($n = 384$)	Knowledge	2.976	0.072	0.971	0.954	0.971	0.049
	Behaviors	2.688	0.066	0.945	0.911	0.944	0.057

RMSEA, root mean square error of approximation; IFI, incremental fit index; TLI, Tucker–Lewis index; CFI, comparative fit index; SRMR, standardized root mean square residual.

1.000. CFA indicated good model fit for both knowledge and behavior sections (Table 3 and Supplementary Fig. S1). Reliability analysis yielded Cronbach's α coefficient of 0.863 for the knowledge section and 0.952 for the behavior section. For the patient version of the questionnaire, the I-CVI ranged from 0.857 to 1.000, the S-CVI was 0.985, and the CVR ranged from 0.714 to 1.000. Model fit was also satisfactory for both knowledge and behavior sections (Table 3 and Supplementary Fig. S1). Reliability was high, with Cronbach's α coefficient of 0.913 for the knowledge section and 0.868 for the behavior section.

(3) Changes in the safety management knowledge and behavior of nurses

Following training, the safety management knowledge of the 381 nurses directly involved in program implementation significantly improved across all three dimensions: correct medication administration, protection to reduce drug exposure, and early management of adverse reactions ($P < 0.001$). The average full-score rate increased from 71.82% pre-training to 92.65% post-training and practice ($Z = -11.462$, $P < 0.001$). Detailed frequency distributions and scores of specific dimensions in the knowledge section are listed in Table 4. In the behavior section, the mean scores for all three dimensions increased significantly (all $P < 0.001$). The average full-score rate significantly increased from 71.55% before training to 94.49% after training and practice ($Z = -13.104$, $P < 0.001$). The frequency distribution and scores of specific dimensions in the behavior section are listed in Table 4. Additionally, the frequency distribution and comparison of Items Scores of Nurses' Safe Management in knowledge and behavior sections are provided in Supplementary Tables S1 and S2.

(4) Changes in the safety management knowledge and behavior of patients

Following the intervention, 384 patients showed significantly improvement in safety management knowledge across all three dimensions (all $P < 0.001$). The average full-score rate increased from 59.46% pre-intervention to 78.62% post-intervention ($Z = -11.473$, $P < 0.001$). Detailed frequency distribution and scoring of specific items in the knowledge dimensions are shown in Table 5. Behavior scores also improved significantly across all domains ($P < 0.001$). The average full-score rate for behavior increased from 68.29% pre-intervention to 85.11% post-intervention ($Z = -12.415$, $P < 0.001$. Table 5 shows detailed frequency distribution and scoring of specific dimensions in the behavior section. The frequency distribution and comparison of Items Scores of Patients' Safe Management in knowledge and behavior sections are provided in Supplementary Tables S3 and S4.

Discussion

The pre-post evaluation demonstrated that a systematic intervention can yield meaningful improvements in oral anti-cancer drug safety management, as reflected in outcomes from both nurses and patients. Designed to address gaps in home-based patient safety, this program integrated established strategies into a unified framework tailored to this high-risk context. The primary contribution of this work lies not in novel components but in the innovative integration and contextual adaptation of existing management approaches, creating a standardized care process focused on patient education and safety during home treatment. This model represents a foundational step toward enhancing

Table 4
Frequency distribution and score comparison of dimension scores of nurses' safe management in the knowledge and behaviors sections ($N = 381$).

Section	Dimensions	Round	Full score rate	Mean ± SD	*Z*	*P*	*Effect size Cohen's d*	95% CI
Knowledge	Correct medication administration	1	66.14	2.65 ± 0.44	−8.548	< 0.001	0.651	0.000, 0.250
		2	87.40	2.87 ± 0.30				
	Protection against drug exposure	1	72.77	2.72 ± 0.36	−10.666	< 0.001	0.838	0.125, 0.250
		2	94.82	2.95 ± 0.16				
	Early management of adverse reactions	1	75.59	2.75 ± 0.39	−8.128	< 0.001	0.616	0.000, 0.250
		2	93.57	2.93 ± 0.21				
	Total	1	71.82	2.71 ± 0.34	−11.462	< 0.001	0.913	0.125, 0.188
		2	92.65	2.93 ± 0.17				
Behavior	Correct medication administration	1	78.81	3.71 ± 0.41	−10.392	< 0.001	0.813	0.125, 0.188
		2	94.72	3.94 ± 0.16				
	Protection against drug exposure	1	61.55	3.34 ± 0.82	−12.715	< 0.001	1.038	0.400, 0.550
		2	93.68	3.92 ± 0.25				
	Early management of adverse reactions	1	79.95	3.76 ± 0.42	−8.719	< 0.001	0.666	0.000, 0.100
		2	95.75	3.96 ± 0.16				
	Total	1	71.55	3.56 ± 0.54	−13.104	< 0.001	1.079	0.217, 0.370
		2	94.49	3.93 ± 0.18				

SD, standard deviation; CI, confidence interval.

Table 5
Frequency distribution and score comparison of dimension scores of patients' safety management in the knowledge and behaviors section ($N = 384$).

Section	Dimensions	Round	Full score rate	Mean ± SD	*Z*	*P*	*Effect size Cohen's d*	95% CI
Knowledge	Correct medication administration	1	75.61	2.74 ± 0.37	−7.915	< 0.001	0.596	0.000, 0.000
		2	87.15	2.86 ± 0.25				
	Protection against drug exposure	1	53.86	2.39 ± 0.59	−10.723	< 0.001	0.839	0.167, 0.250
		2	75.39	2.69 ± 0.42				
	Early management of adverse reactions	1	54.51	2.49 ± 0.53	−10.054	< 0.001	0.779	0.167, 0.269
		2	76.56	2.76 ± 0.36				
	Total	1	59.46	2.50 ± 0.46	−11.473	< 0.001	0.910	0.125, 0.250
		2	78.62	2.75 ± 0.32				
Behavior	Correct medication administration	1	86.31	3.60 ± 0.47	−10.703	< 0.001	0.837	0.143, 0.214
		2	89.36	3.85 ± 0.26				
	Protection against drug exposure	1	63.98	3.42 ± 0.62	−11.031	< 0.001	0.868	0.167, 0.333
		2	82.12	3.76 ± 0.35				
	Early management of adverse reactions	1	63.89	3.54 ± 0.53	−9.471	< 0.001	0.727	0.000, 0.167
		2	81.16	3.79 ± 0.36				
	Total	1	68.29	3.52 ± 0.47	−12.415	< 0.001	1.002	0.156, 0.250
		2	85.11	3.80 ± 0.26				

SD, standard deviation; CI, confidence interval.
Thanks to the website (https://www.psychometrica.de/effect_size.html) for helping to calculate the effect size (*Cohen's d*).

systematic oral anti-cancer drug safety management under hospital settings.

While stratified training, checklists, and continuous care are individually well established, the innovation in the present context stems from their deliberate integration and contextual adaptation. First, synergistic linkages were established across the three stages: the checklist became the backbone of the continuous care process, and the stratified training equipped nurses with the specific competencies to execute both effectively. Second, this study responds to the call for more pragmatic, real-world implementation research.[28,29] The value of this work is not in discovering a new nursing principle, but in demonstrating how to successfully translate and bundle existing evidence-based strategies into a feasible, effective, and sustainable program within the clinical workflow. A baseline survey helped identify key barriers to safe management. The development of the standardized checklists and training modules represented tailoring of knowledge to local context. The implementation phase involved implementing sustained interventions through training and supervision, directly targeting and improving the knowledge and behavior outcomes measured. This theoretical approach positions the study not merely as a clinical report, but as a structured implementation effort. The generated "how-to" knowledge constitutes a valuable, often overlooked form of innovation in health care delivery, particularly for high-alert medications such as oral anti-cancer drugs, where system failures can have harsh consequences.

The developed safety management measures are scientifically grounded. The program was spearheaded by the Nursing Department of Beijing Cancer Hospital, with support from Pharmacy and Information Departments. An expert coordination team was formed, including comprising nursing staff and auxiliary personnel with extensive clinical experience in anti-cancer drug safety. The team comprised nursing managers, physicians, pharmacists, and IT specialists, collectively responsible for planning, coordination, and execution. In the preparation phase, a literature review was conducted using evidence-based methods, incorporating high-level evidence define core dimensions: timely and accurate medication administration, protection against drug exposure, and early management of adverse reactions as core dimensions. A strategic checklist for oral anti-cancer drug safety was drafted and refined through stakeholder feedback and a Delphi process, resulting in the health education checklist.[18] During the Delphi stage, 17 experts from 13 hospitals or universities across five provinces in China were engaged. Response rates were 100% over two rounds, with an authority coefficient of 0.93 and $P < 0.05$ for Kendall's W test, indicating reliable consensus. Based on these findings, the team developed the *Oral Anti-Cancer Drugs Safety Nursing Management Practice Standards*, which was finalized after consultation with senior nursing staff to ensure practical adaptability. Self-designed questionnaires were created in nurse and patient versions, with expert content validity testing to ensure scientific rigor.

The program substantially improved nurses' knowledge and behaviors, with the overall full-score rates exceeding 90%. This is particularly notable given baseline deficiencies: knowledge of correct medication administration (66.14%) and protective behavioral practices (61.55%)

were particularly low. These specific deficits likely reflect the historical reality in our setting, where nurses primarily focus on reactive management of adverse events after readmission, rather than proactive education before discharge. Compared to other studies reporting persistent challenges in oral anti-cancer drug management,[30] the improvements associated with our program may be attributed to its systematic nature rather than any single component. While Schlichtig et al.[31] rightly emphasize the multidisciplinary collaboration and the Oncology Nursing Society defines nurses as care navigators in oral anticancer drug management,[32] the present study demonstrates operationalization of these concepts. The key aspect was their integration into a tangible, standardized process: the multidisciplinary team co-created a definitive health education checklist, which then guided uniform training of nurses, ensuring that all nurses, regardless of their experience, received comprehensive instructions on oral anti-cancer drug storage, administration, and safety and adverse event management. The persistence of low performance in the "correct medication administration" domain even after intervention suggests that drug-specific nuances (e.g., timing relative to meals and drug–drug interactions) are less amenable to generic training. This finding aligns with implementation science principles emphasizing the need for both comprehensiveness and adaptability, suggesting that future iterations of our program should include repetitive, drug-specific drills or just-in-time digital tools to reinforce complex knowledge.

Following the implementation of the program, patients also showed significant improvements in their knowledge and behavioral aspects, with full-score rates increasing to 78.62% and 85.11%, respectively. This outcome can be understood by contrasting our structured approach with documented challenges. Qualitative studies reveal a common patient dilemma: recognizing the importance of adherence but lacking precise knowledge to manage dosing errors or side effects.[33] This gap was evident in a Saudi Arabian study where, despite 78% patients reporting receiving the required education, only 5% of them consistently wore gloves.[34] Our baseline survey confirmed similar patterns: patient competency was highest for simple tasks such as "taking medication on time" but lowest for complex tasks such as exposure protection and adverse reaction management. Our program addressed this "know-do" gap by replacing fragmented education, which probably contributed to the problems in the cited studies, with a structured, multicomponent support system. When a nurse identified a patient on oral anti-cancer therapy, the nurse did not offer generic advice but delivered targeted education using a drug-specific checklist and a take-home self-care manual. This approach was further reinforced by access to nursing clinics and pharmacist consultations, thereby positioning health care professionals as the primary, trusted information source.[34] This system countered the traditional reliance on physician-led, adherence-focused discharge discussions, which often omit practical safety instructions. By comprehensively educating on exposure protection and proactively coaching on early symptom management, the program empowered patients to manage side effects safely—a key factor linked to treatment persistence[35]—without self-interruption. The residual knowledge-behavior gap post-intervention suggests that some safety practices require ongoing reinforcement, highlighting a valuable area for future program refinement.

Post-intervention, patients' knowledge and behavior levels remained lower than those of nurses. In the knowledge section, the full-score rates ranged from 62.24% (awareness of handling accidental crushing or spillage in accordance with the "*Anti-Cancer Drug Spill Handling Process*") to 95.05% (awareness of correct dosage intake). In the behavior section, the rates ranged from 65.89% (prompt toilet flushing after using it during the oral anti-cancer drug period, at least twice, and sealing the waste with a double-layer garbage bag for disposal as hazardous waste) to 96.61% (correct timing of medication). These disparities highlight persistent misconceptions in patient self-management, indicating areas where nurses should focus their educational efforts. Attention to patient feedback during health education sessions is essential for delivering targeted, responsive guidance.

Limitations

This study has several limitations. The primary limitation is the pre-post design without a control group, conducted at a single institution. The absence of concurrent controls limits definitive attribution of observed improvements solely to the intervention, as confounding factors (e.g., temporal factors) and the Hawthorne effect may have influenced outcomes. The single-center setting may limit the generalizability of our findings to other health care settings with different resources, workflows, or patient populations. Another limitation is the scope of the self-reported outcomes. While we focused on the short-term knowledge and behaviors of nurses and patients—which were proximal and essential outcomes for evaluating the initial implementation and acceptance of our intervention—we did not assess other crucial dimensions of health care quality. Specifically, objective clinical outcomes (such as the actual reduction in medication error rates or adverse drug events, or long-term health-related quality of life) were beyond the scope of this initial quality improvement cycle. Future research should build on this foundation by incorporating these objective and patient-centered metrics for a more comprehensive and sustained evaluation of the intervention's significance. Lastly, we could not control for all confounding factors. We did not analyze how baseline characteristics, such as the diverse patient tumor types, departmental differences, or the professional experience levels of participating nurses, might have acted as potential effect modifiers, thereby limiting our understanding of the intervention's consistency and efficacy across different patient and nurse subgroups, which is an important direction for future studies.

Conclusions

This program has developed an evidence-based, high-quality approach to oral anti-cancer drug safety management in nursing practice, which has been proven to enhance patients' knowledge and behavioral skills. Additionally, the *Oral Anti-Cancer Drug Safety Management Practice Standards* and the accompanying implementation manual provide standardized, scientifically grounded guidance for clinical nurses. Ongoing application of these standards can deepen knowledge and improve safety-related behaviors. The intervention is now integrated into departmental quality supervision, ensuring sustained clinical use. The integrated model is scalable to other departments managing oral anti-cancer drugs. Future research should expand on this foundation by comparing its effectiveness against the routine care protocol in a multicenter randomized controlled trial and evaluating its cost-effectiveness.

CRediT authorship contribution statement

Hong Yang: Conceptualization, Project administration, Formal analysis, Visualization, Writing – Original Draft, Writing – Review & Editing. **Hong Zhang:** Conceptualization, Project administration, Formal analysis, Visualization, Writing – Review & Editing. **Jingjuan Zhou:** Conceptualization, Project administration, Writing – Original Draft. **Hongli LI:** Writing – Original Draft. **Renxiu Guo:** Investigation, Data Curation, Writing – Original Draft. **Hong Zhang:** Investigation, Data Curation. **Miaoning You:** Investigation, Data Curation. **Liyan Zhang:** Investigation, Data Curation. **Wanrong Liu:** Investigation, Data Curation. **Yuhan Lu:** Conceptualization, Project administration, Writing – Review & Editing. All authors have read and approved the final manuscript.

Ethics statement

Ethics approval was sought and obtained for the study from Institutional Review Board of Beijing Cancer Hospital (Approval No. 2024YJZ84). The participants were given detailed information about

the study, and they completed a consent form afterward. They were assured that participation is voluntary. Similarly, they were assured of anonymity and confidentiality.

This study was approved as a 2024 high-quality development and reform innovation project for municipal hospitals (Approval No. 24GGCX022), established and governed by the Beijing Hospital Administration Center. The program was independently managed and implemented at the hospital level, with the Beijing Hospital Administration Center supervising the project during initiation, mid-term, and final stages. No other conflicts of interest were involved in this project.

Data availability statement

The data that support the findings of this study are available from the corresponding author, YL, upon reasonable request.

Funding

This study received no external funding.

Declaration of competing interest

The authors declare no conflict of interest. The corresponding author, Prof. Yuhan Lu, is an editorial board member of *Asia–Pacific Journal of Oncology Nursing*. The article was subject to the journal's standard procedures, with peer review handled independently of Prof. Lu and their research groups.

Acknowledgment

We appreciate all respondents who took time to participate in the study and the reviewers for their helpful comments on this paper.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.apjon.2025.100833.

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