

# BMJ Open Drug prescription for the management of gastrointestinal and skin symptoms in cancer patients by advanced practice nurses in China: a Delphi method

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## ABSTRACT

**Background** The authority to prescribe drugs has been reserved only for the medical community, mainly clinicians. Recently, more and more countries worldwide have begun implementing reforms to grant advanced practice nurses (APNs) the authority to prescribe from the legislative level. This study aimed to explore the prescription drugs and forms for gastrointestinal and dermatological symptom management of cancer patients that APNs can prescribe in China.

**Design** A qualitative study reported in accordance with Conducting and REporting of DElphi Studies guidelines. The modified Delphi technique with two-round email consultations among 36 experts was applied.

**Methods** We conducted a study from January 2022 to March 2022 to reach a consensus among medical, nursing and pharmacy experts about drugs that nurses may prescribe for gastrointestinal and dermatological symptom management in cancer patients.

**Results** The expert authority coefficients are 0.95 and 0.96, respectively. A total of 35 drugs in 16 categories could be prescribed by APNs for gastrointestinal and dermatological symptoms management in China. Among them, three drugs were determined to be prescribed collaboratively, and 32 drugs were determined to be prescribed independently.

**Conclusions** The drug prescription formulated in this study is the basis for APNs to prescribe drugs for controlling gastrointestinal and skin symptoms for cancer patients in mainland China. The results are important as a guide for formulating and implementing policies related to nurse prescribing and will provide some reference for future nurse prescribing in China.

## INTRODUCTION

The 2018 European Society for Medical Oncology Recommendation for Support/Palliative Care proposed that the concept of ‘patient-centred care’ should be adopted at the early stage of disease diagnosis and continued throughout the disease, which is also in line with the core goal of improving the quality of life of cancer patients.<sup>1</sup> However, over 80% of chemotherapy patients have gastrointestinal symptoms,<sup>2</sup> and more

## STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This study employed a rigorous Delphi method to establish expert consensus on nurse prescribing for gastrointestinal and skin symptoms in cancer patients.
- ⇒ The inclusion of multidisciplinary experts from oncology, nursing and pharmacy ensured a comprehensive perspective on nurse prescribing.
- ⇒ Despite high expert authority coefficients, the generalisability of the results might be constrained by the specific Chinese medical context and practices.
- ⇒ The expert panel was limited to eight provinces in China, which may affect the generalisability of the findings to other regions, especially highly developed areas.

than 70% of radiotherapy patients have skin symptoms.<sup>3–5</sup> The digestive tract and skin symptoms are the two most common and most disturbing treatment-related side effects of antitumour therapy, causing great pain to cancer patients and dramatically reducing the quality of life.<sup>6–9</sup> As the severity of these two symptoms increases, the impact on the patient’s physical condition also gradually increases. 20% of cancer patients’ fear of the above severe symptoms can reduce treatment compliance and even cause treatment termination. Therefore, preventing these side effects is critical. The judicious selection of pharmacological agents, thorough evaluation of drug properties, and timely implementation of symptom management strategies are critical considerations in optimising care for patients undergoing cancer treatment.

For a long time, the authority to prescribe drugs has been reserved only for the medical community, mainly clinicians.<sup>10</sup> Nurse-led models of care are particularly crucial in countries with large populations, making it imperative to develop models that maximise nurses’ roles, including prescribing medications, to improve patient care and optimise

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healthcare resources.<sup>11</sup> The International Council of Nurses (ICN) defines an advanced practice nurse (APN) as a registered nurse who possesses an advanced knowledge base, complex decision-making skills and clinical competencies for expanded practice. The scope and characteristics of APN roles are shaped by the regulatory and contextual frameworks of the country in which they are licensed to practise. Furthermore, the ICN recommends a master's degree as the entry-level qualification for APNs.<sup>12</sup> In recent years, a growing number of countries have initiated legislative reforms to authorise APNs to prescribe medications.<sup>13 14</sup> To date, 40 countries or regions, including the USA, the UK, Canada and New Zealand, have formally granted prescription rights to APNs.<sup>15</sup>

Factors driving nurses' prescribing rights include improved patient access to timely and effective medications, the need to mitigate physician shortages and reduce physician workload, the optimisation of nurses' knowledge and clinical skills and the development of advanced nursing roles.<sup>16</sup> Prescriptions from nurses were comparable to those prescribed by physicians, and patients reported similar or greater satisfaction with nurses than with physicians.<sup>17 18</sup> A Cochrane systematic review shows that APNs were just as practical as physicians when prescribing for a range of diseases, such as chronic diseases.<sup>19</sup> Internationally, nurse prescribing has been implemented under four main models: independent prescribing, collaborative prescribing, extension prescribing and adjustment prescribing. The introduction of nurse prescribing must be planned and informed by available evidence to support effective adoption, practice and patient outcomes.<sup>20</sup> As of 2019, 13 countries in Europe have adopted the nurse prescribing laws, 12 of which apply nationally and one to the Swiss Canton.<sup>21</sup> Over the past decade, the role of nurses has expanded in Europe, as evidenced by new laws on prescribing rights.<sup>21</sup> Asian countries have also gradually liberalised the prescribing rights of APNs. In Japan, APNs are certified and supervised by the Ministries of Health, Labour and Welfare to obtain professional qualifications.<sup>22</sup> Certified APN interns who progress well during an integrated APN internship can further their education to gain prescribing privileges through the National Collaborative Prescribing Programme in Singapore.<sup>23</sup> APN training courses in Hong Kong cover the relevant knowledge of prescription rights, including medical system, health policy, pathophysiology, pharmacology, health assessment and disease treatment.<sup>24</sup> APNs in Taiwan can prescribe tests and examinations.<sup>25</sup> Several hospitals in the Chinese mainland have launched APN programmes and conducted research on nurse prescribing.

Despite international advancements, there are no studies of nurse prescribing for managing gastrointestinal and skin symptoms in cancer patients in China. And there remains uncertainty about Chinese nurses' willingness to undertake prescribing responsibilities. A recent study indicated that while many cancer nurses acknowledge the

potential benefits of nurse prescribing, concerns about regulatory frameworks, education and training persist.<sup>26</sup> Therefore, the purpose of this study was to formulate a list of prescription drugs and prescription forms related to the gastrointestinal and skin symptoms in cancer patients for nurses and to provide this reference as an aid for the development of an authorised list of prescription drugs for APNs to prescribe in China.

## METHODS

### Design

This study was conducted between January 2022 and March 2022 using questionnaires covering entries and prescription models for digestive tract and skin system drugs. The Delphi technique was applied so that healthcare experts could reach a consensus on the medications nurses might prescribe for gastrointestinal and skin symptoms. It is reported that there is no fixed proportion of expert approval for the same problem. McKenna suggested that expert consensus should reach 51%,<sup>27</sup> while Green argued that it should be 80%.<sup>28</sup> Therefore, 51% and 80% were the consensus rates used as the entry deletion criteria in this study. The comments from experts were added or removed after careful discussion by our research team. After the deletion of illegible entries, the form of prescription for the remaining drugs was determined by the proportion of experts. We selected the two prescribing forms with the highest expert approval rate in the same entry. If the ratio of expert approval across the two prescribing forms was  $\geq 1.5$  (the ratio is determined as the major:minority), it was assumed that the majority of experts preferred the prescribing form for the drug; otherwise, the two prescribing patterns were similar.<sup>29</sup> The study was carried out according to the Conducting and REporting of DELphi Studies checklist guidelines (online supplemental file 1).

### Participants

The representativeness, diversity and authority of the experts consulted are the critical points to the Delphi method, with 15–50 people generally being appropriate.<sup>30 31</sup> We selected 13 medical experts, 10 nursing experts and 13 pharmacy experts in oncological gastrointestinal and dermatological system management from tertiary hospitals across 8 Chinese provinces/municipalities, namely Anhui, Gansu, Hubei, Heilongjiang, Chongqing, Guizhou, Guangxi and Yunnan. The selected experts all agreed to grant prescribing authority to nurses. The inclusion criteria for selection of authoritative experts were the following: (1) 10 or more years of work experience in the fields of tumour symptom management or pharmacy; (2) possession of a bachelor's degree or above in nursing or a master's degree or above in medicine or pharmacy and (3) an intermediate title or above in nursing, deputy senior title or above in medical and pharmacy. Those who met these criteria were included in this study.

## Questionnaire design

The research team reviewed the literature on nurse prescribing authority in several Western countries and searched the lists of APN-prescribed drugs in the USA, the UK, Australia and South Africa. Then translate the names of drugs related to symptoms management in oncology in the above prescription form and take the medications of the tumour digestive tract and skin system that APN can prescribe in two or more countries as the reference basis for developing this questionnaire. We then drafted a preliminary version of this questionnaire (online supplemental file 2) referring to the '*Clinical Handbook of Drugs (Fifth Edition)*' published by Shanghai Science and Technology Press in China. We selected three medical experts, three nursing experts and one pharmacist (the same as the Delphi method expert inclusion criteria) in the tumour digestive tract and skin system symptom management to conduct a semistructured interview of the questionnaire content (online supplemental file 3). After semistructured interviews and further discussions with our research team, the final questionnaire included 71 drugs across 29 categories. The questionnaire also included four nurse prescribing models: independent, collaborative, extension and adjustment prescribing. 'Independent' prescribing refers to the drugs that nurses can prescribe independently within national regulations through their assessment and diagnosis of patients. 'Collaborative' prescribing refers to the nurse who can prescribe within the specified range under the premise that the doctor authorises and signs the agreement in advance. 'Extension' prescription refers to the use of the original prescribed drugs and dose by the nurse after the doctor's diagnosis is confirmed and the medication is prescribed. 'Adjustment' prescribing is when the nurse changes the original prescribed drug and dose after confirming the diagnosis and prescribes the drug from doctors.

## Ethical considerations

This research received the approval of the Research Ethics Committee of the West China Hospital, Sichuan University (ID: 2023-1345). Following the principles of the Helsinki Declaration, all participants received information about the research and signed the informed consent form before participating in the study.

## Data collection

Data collection was conducted by one author (ZY) between January 2022 and March 2022. A purposive sampling method was used to select the participants. The participants were only informed of the aim of the study, and no prior relationship existed between the participants and the researchers. Researchers designed the interview themes in a questionnaire. All the main themes were identified in advance. The research data were collected via email.

## Statistical analysis

Statistical analysis was conducted by SPSS 22.0 (IBM, Armonk, New York, USA).

## Patient and public involvement

Patients and/or the public were not involved in this study.

## RESULTS

### Basic information of experts

The two rounds of expert email consultation included 36 experts (13 medical experts, 10 nursing experts and 13 pharmaceutical experts). The general characteristics of the experts involved in this study are shown in table 1. 77.78% of the consulting experts have worked for more than 15 years, possessing rich experience and a comprehensive understanding of digestive tract and skin system drugs. More than 80% of the consulting experts held master's and doctoral degrees.

### Coefficient and authority of experts

The positive coefficient of experts is expressed by the questionnaire recovery rate, which reflects the degree of interest in the research. Experts are highly motivated when recovery rates exceed 70.00%.<sup>29</sup> 37 questionnaires were issued in the first round of expert email consultation, and 36 valid questionnaires were recovered, with an effective recovery rate of 97.00%. We sent out 36 questionnaires in the second round of expert email consultation, and 36 valid questionnaires were recovered with an effective recovery rate of 100.00%.

The degree of expert authority is expressed by the authority coefficient (Cr), which is jointly determined by the judgement coefficient (Ca) and expert familiarity coefficient (Cs). Cr is the average derived from Ca and Cs, reflecting the experts' grasp of the research content. Generally, Cr > 0.80 is considered to be highly reliable.<sup>32</sup> In this study, the expert judgement coefficients for the two rounds are both 0.98; the familiarity coefficients are 0.91 and 0.93, respectively. The expert authority coefficients are 0.95 and 0.96, respectively (table 2).

### Expert consultation results

It is believed that the expert approval rate should reach at least 51%, and the items which do not meet this threshold should be deleted. So, in the first round of expert email consultation, 31 drugs in 14 categories were deleted. The specific drugs removed were as follows: (1) 5-HT<sub>3</sub> antagonist: palonosetron (47.22%), azasetron (47.22%) and ramosetron (47.22%); (2) proton pump inhibitors: esomeprazole (44.44%) and omeprazole (44.44%); (3) H<sub>2</sub>-receptor antagonists: ranitidine (47.22%), cimetidine (47.22%) and famotidine (47.22%); (4) glucocorticoid: dexamethasone (33.33%); (5) parenteral nutrition agent: alanyl glutamine (33.33%), sodium potassium magnesium calcium glucose (33.33%), fat emulsion injection (33.33%), ω-3 fish oil fat emulsion injection (33.33%), fat emulsion, amino acids (17) and glucose (11) injection (33.33%); (6) analgesics: lidocaine (44.44%), morphine

**Table 1** Characteristics of participants

Item	Nursing experts n=10	Medical experts n=13	Pharmacy experts n=13	Total	Percentage
Age (years)					
<40	2	3	3	8	22.22
40–45	4	4	6	14	38.89
46–50	0	4	4	8	22.22
>50	4	2	0	6	16.67
Working years					
10–15	2	3	3	8	22.22
16–20	0	4	6	10	27.78
21–25	4	4	4	12	33.33
26–30	0	2	0	2	5.56
>30	4	0	0	4	11.11
Education background					
Undergraduate	7	0	0	7	19.44
Master's degree	1	6	9	16	44.44
PhD	2	7	4	13	36.11
Job title					
Intermediate	4	0	0	4	11.11
Deputy senior	4	6	12	22	61.11
Positive senior	2	7	1	10	27.78
Position					
Director	0	6	0	6	16.67
Head nurse	10	0	0	10	27.78
Team leader	0	7	0	7	19.44
Pharmacy	0	0	13	13	36.11

(33.33%) and fentanyl (38.89%); (7) traditional Chinese medicine preparation: Shuanghua Lily Tablet. (38.89%); (8) other oral mucositis drugs: sodium bicarbonate (38.89%); (9) cytokines: recombinant human granulocyte macrophage stimulating factor (47.22%) and epidermal growth factor (41.67%); (10) other radioactive dermatitis drugs: silver sulfadiazine (44.44%), calendula ointment (47.22%) and hexantheobromine (50.00%); (11) glucocorticoids: mometasone furoate (44.44%), clobetasone (44.44%) and dexamethasone compound (44.44%); (12) antibacterial drugs: milocycline (38.89%) and (13) antihistamines: loratadine (47.22%). After these revisions, we conducted a second round of consultation via questionnaires.

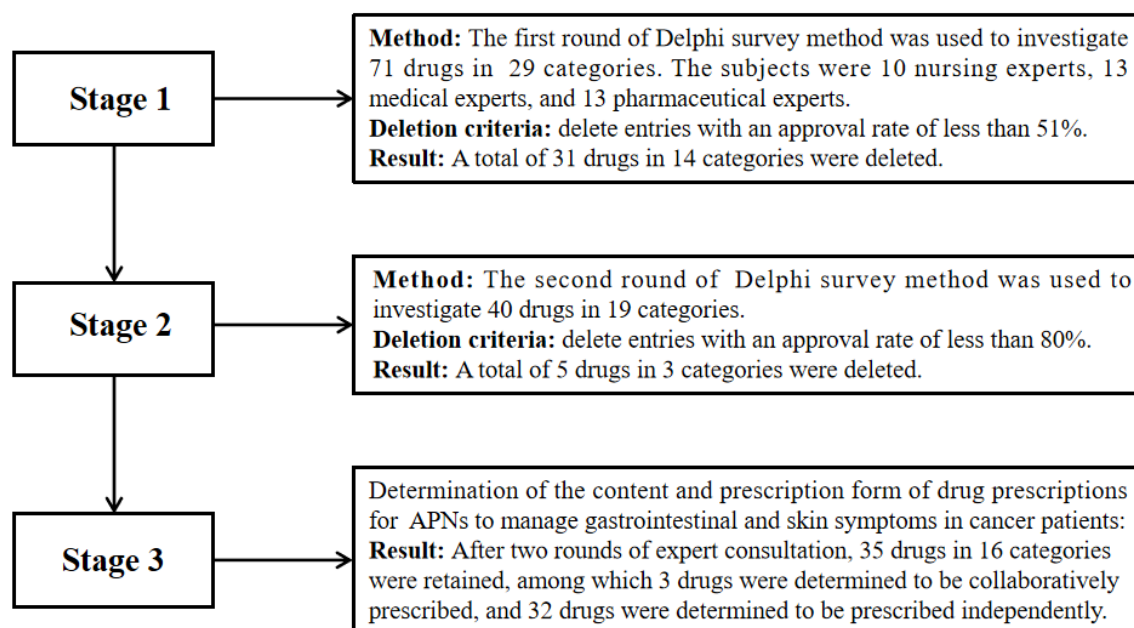
The criteria for deleting items in the second round of expert email consultation was that the expert approval rate was less than 80%. Five drugs in three categories were deleted: (1) other antiemetic drugs: olanzapine (61.11%), prochlorperazine (75.00%) and thalidomide (69.44%); (2) other antidiarrhoeal drugs: octreotide (77.78%) and (3) traditional Chinese medicine preparations: rash formula granules (77.78%).

After two rounds of expert consultation, 35 drugs in 16 categories were retained, of which three drugs were determined to be prescribed collaboratively, and 32 drugs were determined to be prescribed independently. The specific process of Delphi can be seen in figure 1. The final results are shown in online supplemental file 4.

**Table 2** Coefficient and authority of experts

Delphi survey	Positive coefficient of expert			Degree of expert authority		
	Distribute questionnaire	Recovery questionnaire	Recovery rate (%)	Judgement coefficient (Ca)	Familiarity coefficient (Cs)	Authority coefficient (Cr)
Round 1	37	36	97	0.98	0.91	0.95
Round 2	36	36	100	0.98	0.93	0.96





**Figure 1** The specific process of the Delphi method.

## DISCUSSION

This is the first study to assess drug prescription contents for gastrointestinal and skin symptom management of cancer patients by APNs in China. APNs are capable of providing holistic care to address the complex problems associated with multiple diseases and can assume responsibilities for uncomplicated medical care.<sup>33</sup> Their work focuses on assisting physicians in managing the diagnosis and treatment of patients in clinical practice. However, there are specific differences between nursing and medical care, and there should be certain limits and ranges for drugs and diseases prescribed for patients. In China, policies have recently been introduced to support the APN programme. Given the differences in medical habits and environments in different countries, it is very worthwhile to discuss which diseases and drugs advanced nurse practitioners can prescribe in large hospitals in China. In this study, we discuss the management of common gastrointestinal and dermatological symptoms in the treatment of cancer patients, as well as the use of prescription drugs and prescription forms, providing a reference for the formulation of the APN prescribing policy in the oncology departments in China in the future.

Reliability is closely related to the expert consultants' representativeness, authority and enthusiasm. In this study, more than 80% of the experts selected to participate in the email consultation held a master's degree or above. The average work experience of medical experts exceeded 20 years, while that of nursing experts was over 28 years, and pharmacy experts had an average of 12 years. All experts held senior associate titles or above and were also engaged in educational roles. They were able to provide scientific and practical suggestions and opinions on nurses' drug prescription rights from different

perspectives and other clinical settings, ensuring the reliability of the email consultation results. In addition, experts' positivity, authority and coordination were high, indicating that experts consistently and highly recognised the prescription programme.

We reviewed drugs commonly used by cancer patients to manage gastrointestinal and dermatological symptoms and side effects during treatment. Based on significant symptoms, nausea, vomiting, constipation, diarrhoea, malnutrition, oral mucositis, radiation dermatitis and skin reaction,<sup>34</sup> a total of 35 drugs in 16 categories were included in this study for APNs prescribing to manage gastrointestinal and dermatological symptoms in cancer patients. Nausea and vomiting, as one of the common adverse reactions to tumour drug treatment, occur in more than 70% of cancer patients. For nausea and vomiting, experts recommend authorising nurses to prescribe four types of 5-HT3 antagonist, two types of gastrointestinal motility agents, three types of NK-1 receptor antagonists and one type of gastric mucosal protective agent. After the first round of expert consultations, proton pump inhibitors and H-2 receptor antagonists, including omeprazole, ranitidine, cimetidine, etc, were removed. Although these drugs are routinely used for the treatment of peptic ulcer, long-term and overdose use is not recommended.<sup>35</sup> In cancer patients, their overuse will affect the efficacy of antitumour therapy, whether in chemotherapy, targeted therapy and immunotherapy are reflected.<sup>36</sup> Therefore, experts recommend deleting these drugs.

Experts recommend that APNs prescribe six types of laxatives, including magnesium sulfate, lactulose, macrogol, glycerine enema, Ma Ren Wan and phenolphthalein, and two types of antidiarrhoeals, including montmorillonite powder and loperamide. Laxatives are

divided into volumetric laxatives, irritant laxatives, lubricating laxatives, osmotic laxatives and other laxatives.<sup>37</sup> Lactulose, magnesium sulfate and glycerine are osmotic and lubricating laxatives, respectively, which are used mainly for the treatment of acute and chronic constipation, and the adverse reactions are small, so the prescription form tends to be an independent prescription. Macrogol and montmorillonite powder are conventional drugs, and the two forms tend to be independent/collaborative prescriptions. In addition, after expert consultation, the antidiarrhoeal octreotide was removed. The main reason may be that the octreotide drug price is high and not within the scope of medical insurance, involving the patient's economic affordability,<sup>38</sup> so it is not recommended that APNs prescribe it as a routine drug. In the UK, where intestinal management is generally considered to be the domain of nurses, patients with constipation are managed by nurses in most parts of the UK, thereby reducing the burden on physicians and providing better services to patients.<sup>39</sup> Qualified nurses can prescribe medicines such as methyl cellulose, lactulose, magnesium hydroxide, peanut oil, bisacodyl, paraffin, senna, loperamide and racemic cardotril.

For the symptoms of malnutrition, nutritional drugs were divided into enteral nutrition and parenteral nutrition. In this study, six types of parenteral nutrition were deleted after two rounds of consultation; three types of enteral nutrition preparations (TPF-D, TPF-T and TP) and one type of parenteral nutrition preparation (compound amino acid injection) were included in the study. Enteral nutrition is a general term for various products used in clinical enteral nutrition support. Because of its advantages in maintaining the integrity of intestinal mucosa and barrier function, enteral nutrition has been widely used in the world.<sup>40</sup> Enteral nutrition has high safety, avoids the appearance of air embolism, thrombosis, phlebitis and other complications, and the price is relatively low,<sup>41</sup> which is suitable for nurses in the initial implementation of prescription. Although experts advise nurses to prescribe the drug, there are significant differences in indications and contraindications for different enteral supplements. The nurse should consider the patient's age, gastrointestinal function, fat absorption, glucose tolerance and the patient's disease condition in the process of drug selection.

In addition, for some important drugs, such as central nervous system sedatives and analgesics, were removed. Opioids are listed as narcotic and psychotropic drugs and are specially controlled in China. Long-term use of sedative-hypnotics will increase patients' dependence, and there may also be risks when they are abruptly discontinued.<sup>29</sup> The Ohio Nurses' Prescription Set also states that some opioids used for treatment can only be prescribed by physicians. Therefore, nurses are not advised to prescribe the relevant medications. Most of the drugs retained after two rounds of expert consultation were those with few side effects and a wide range of safety.

The medical environment in China is very different from that in Europe and the USA. The follow-up of cancer patients mainly relies on patients seen by physicians in outpatient clinics. Due to the strain on medical resources, patients often do not receive a timely assessment of their condition by physicians. However, in actual clinical practice, senior nursing staff are very experienced in managing the complications of cancer patients. Studies have shown that medical staff shortages can be alleviated in countries where nurses are prescribed. Besides, nursing prescription can achieve interdisciplinary collaboration and bridge the distance between nurses and physicians, benefiting the entire team and enabling physicians to focus on more complicated clinical cases.<sup>42 43</sup> As APNs continue to evolve internationally, it is a perfect solution for medical needs that is worth implementing in the Chinese healthcare environment.

Our study had some limitations. First, although we employed the Delphi method to achieve expert consensus on nurse prescribing for gastrointestinal and skin symptoms in cancer patients, the study relied on a limited number of experts from specific regions in China. This may restrict the generalisability of our findings. Future studies should incorporate a larger and more geographically diverse panel of experts, particularly from economically developed regions, to enhance representativeness. Second, the study was conducted within a relatively short timeframe, which may have influenced the depth of expert deliberation and the evolution of consensus over time. Third, while our study identified a set of drugs and prescription forms that APNs could potentially use in oncology settings, we did not evaluate the real-world implementation of these recommendations. Future research should conduct clinical trials or observational studies to assess the safety, effectiveness and acceptance of APN-led prescribing in oncology practice.

## Conclusions

The trained APNs in the department of oncology could prescribe adjuvant drugs for the treatment of the gastrointestinal tract and medications for the skin system for cancer patients, including nausea and vomiting, antacids, adjuvant acid-resistant medicines such as gastric mucosa protective agents, partial laxatives, antidiarrheal medications, nutritional disorders, oral mucositis, radioactive dermatitis and other auxiliary drugs. 16 categories (35 drugs in total) related to the digestive tract and skin system can be prescribed in oncology, including 32 independent and three collaborative prescriptions. Our results support the need to adopt laws on nurse prescribing for APN development in China. In addition, continuing education in nursing should focus on nurse prescribing for APN, which is the basis for empowering nurses to prescribe. The development of prescribing of medicines in chemotherapy APNs would improve the quality of cancer care.

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**Contributors** ZY: data curation, investigation, and writing original draft; DZ: writing original draft, writing review and editing; MZ: conceptualisation, methodology and validation; JL: methodology, resources and supervision; RZ: conceptualisation and analysis of data. All authors approved the final version of the manuscript.

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**Patient and public involvement** Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

**Patient consent for publication** Not applicable.

**Ethics approval** This study involves human participants and was approved by the Research Ethics Committee of the West China Hospital, Sichuan University (ID: 2023-1345). Participants gave informed consent to participate in the study before taking part.

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