



# Integrating herbal medicine into oncology care delivery: development, implementation, and evaluation of a novel program

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## Abstract

**Objective** To evaluate the feasibility of a novel program facilitating patient-provider communication about appropriate use of herbal medicine at a large academic cancer center and its impact on patient wellbeing.

**Methods** In the Herbal Oncology Program (HOP), integrative medicine providers counseled patients about unmet symptom needs and prescribed traditional Chinese medicine (TCM) herbs when indicated, taking into consideration the clinical context, patient preference, and research evidence. To evaluate the feasibility and outcomes, we performed a retrospective analysis using medical record data (symptoms and other concerns that motivated patients to seek herbal products, types and numbers of dispensed TCM herbs, and demographic characteristics). We also conducted a survey to assess patient experience and satisfaction.

**Results** All 851 participants were outpatients, with 712 (84%) in active treatment. HOP dispensed 1266 herbal prescriptions for a range of symptoms, most commonly GI symptoms (467, 37%); pain (353, 28%); and treatment-related fatigue, sleep, and mood disorders (346, 27%). Of 269 patients invited to the survey, 107 (40%) completed it. A majority of respondents 70.9% (73/103) were satisfied with the effectiveness of dispensed herbs in relieving their symptoms, and few 6.7% (7/104) had experienced mild adverse events that resolved after discontinuing herbal use.

**Conclusions** The study's findings support the feasibility of integrating herbal medicine into an academic oncology setting. Patient satisfaction with HOP was high, with limited adverse events. The patterns of herbal prescriptions in HOP suggest future areas for clinical research to strengthen the evidence base around safe and effective use.

**Keywords** Shared decision-making · Herbal medicine · Cancer symptom burden · Patient satisfaction · Quality of life (QoL)

## Introduction

Many cancer patients and survivors use herbs and supplements for relief of symptoms and for improving quality of life. In the U.S., herbal products are the most commonly used complementary and integrative medicine (CIM) modality among cancer patients [1]. Nearly 60% of patients report self-prescribing herbal supplements during or after cancer treatments [2–4].

However, patients seldom communicate with health care providers about their CIM and herbal use [5]. Unsupervised use can lead to numerous adverse effects and herb-drug interactions, particularly in cancer patients undergoing active treatment. For example, herbs with strong antioxidant effects can interfere with radiotherapy and certain chemotherapy agents [6–8]; anticoagulant herbs may amplify the effects of anticoagulant/antiplatelet drugs, therefore, increasing the risk for bleeding [9]; phytoestrogenic herbs may interfere with hormonal therapies [10]; and immunomodulant herbs can render immunosuppressive drugs less effective [11]. Complicating unsupervised use is provider lack of knowledge or training about herbs [12]; most physicians are ill-prepared to discuss these important topics with patients [13–15].

Thus, herbal use reveals two interrelated care gaps: unmet patient needs for symptom relief and poor patient-provider

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communication about CIM. To address these critical gaps, the integrative medicine service (IMS) along with the Pharmacy department at Memorial Sloan Kettering Cancer Center (MSK) developed the Herbal Oncology Program (HOP) in 2019. HOP facilitates patient-provider communication about, and appropriate use of, herbs in the oncology setting. This study reports on the feasibility of development, implementation, and evaluation of this novel program.

## Methods

### Establishment of an herbal formulary and dispensary:

In collaboration with the MSK Pharmacy department, IMS established an herbal formulary and dispensary to offer patients quality-controlled traditional Chinese medicine (TCM) herbal formulas with evidence of empirical use, safety, and preliminary efficacy for mood [16], insomnia [17], and gastrointestinal issues such as constipation or diarrhea [18, 19], which are frequently encountered in oncology settings. This herbal formulary was prepared after careful discussions among experienced integrative medicine physicians on common, challenging symptoms encountered in our practice, where conventional medications do not meet the needs of some patients. In addition, we reviewed classic herbal medicine textbooks, conducted systematic reviews of the available literature [18–20], and had extensive discussions with TCM oncologists in China, where TCM herbs and formulas are commonly used to treat common cancer-related symptoms and sequelae associated with treatments [21].

The formulary was approved by MSK's Pharmaceutical and Therapeutics (P&T) committee with the understanding that all herbal products were to be treated the same as prescription drugs, with identical procedures for stocking, prescribing, and dispensing. An IMS pharmacist with training in both conventional pharmacy and TCM herbology (YNH) then identified suppliers. A rigorous quality assurance process [22] involved either obtaining a manufacturer-issued certificate of analysis confirming contaminant- and heavy metal-free products or utilizing an independent, subscription-based entity ([www.consumerlab.com/about/](http://www.consumerlab.com/about/)) that evaluates products based on FDA's Good Manufacturing Practices (GMPs) for dietary supplements, the amount of active components, and batch-to-batch consistency (using analytical methods that include high-performance liquid chromatography and mass spectrometry).

The dispensary was set up within the MSK outpatient pharmacy. YNH managed the inventory, trained MSK pharmacists on how to dispense herbal prescriptions, and worked with pharmacists and information technology (IT) staff to

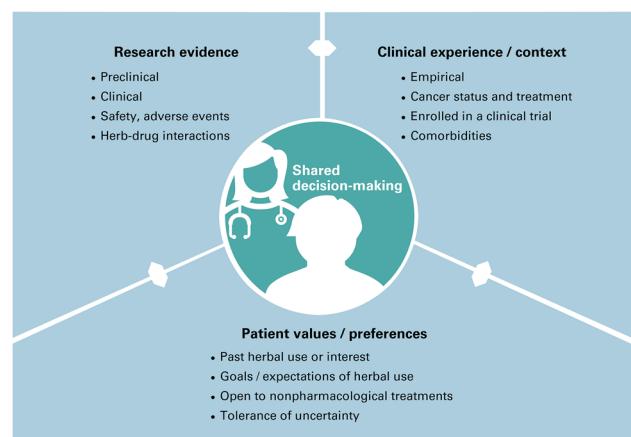
integrate the formulary into pharmacy dispensing software and MSK's electronic medical record (EMR) system.

### Discussion of herbal medicine use as part of integrative medicine consultation

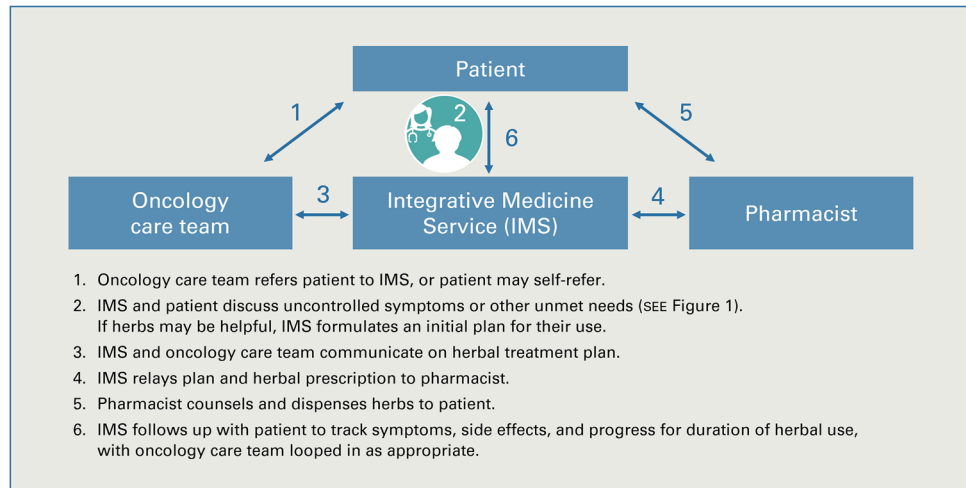
Discussion of use of herbal medicine as part of HOP was developed as an integral component of integrative oncology consultation [23, 24]. To improve patient outcomes, integrative oncology prioritizes safety and best available evidence to offer appropriate CIM therapies, including lifestyle modifications, mind-body practices, and natural products from diverse cultural traditions, alongside conventional care [25]. Consistent with evidence-informed care, we incorporate current available research evidence of safety and potential efficacy in the context of clinical experience and patients' preferences, values, or circumstances (Fig. 1) [26]. This open communication and shared decision-making about CIM therapies is vital to addressing unmet needs and preventing harms from unsupervised CIM use. Furthermore, by engaging patients as active participants in their care, integrative oncology can optimize health promotion and proactively address symptoms and adverse effects from cancer or its treatments with the goal of increasing adherence to conventional anti-cancer treatment (e.g., chemotherapy and targeted therapies) and improving quality of life.

### Process of integrating herbal medicine into oncology care

Figure 2 outlines the process of how HOP integrates herbal medicine into conventional cancer care. The process begins when an oncology team, comprising physicians and nurses, refers a patient to IMS, typically after the patient has expressed interest in or currently use herbal or other CIM



**Fig. 1** Evidence-based framework for shared decision-making of herbal use in oncology

**Fig. 2** Herbal oncology program (HOP) process

treatments. In some cases, patients may self-refer to IMS. At the patient's initial consultation, an IMS physician takes a complete patient history and learns what herbs the patient is interested in (or has begun self-prescribing) and why. Here, the patient and physician begin to engage in shared decision making around herbal use, with these detailed consults centering on symptoms and other reasons for seeking care, and the safety and efficacy of relevant herbal products. This usually involves the IMS physician clearly describing, in lay language, the potential risks, and benefits of TCM herbs. He or she will also explain other relevant options, including conventional approaches (e.g., medications and physical therapies) or other integrative therapies (e.g., acupuncture and meditation), and answer the patients' questions and concerns.

In circumstances when the IMS physician determines that risks of TCM herbs outweigh the potential benefits, he or she will attempt to dissuade the patient from herbal use. However, there are patients for whom TCM herbal medicines may be beneficial. Many of these patients are experiencing symptoms for which standard (pharmacological) care is either inadequate, associated with adverse effects, or poorly tolerated. In cancer patients and survivors, such symptoms commonly include fatigue, pain, gastrointestinal issues, sleep disruption, and psychological distress [27–30]. These symptoms, if left unaddressed, can diminish quality of life and reduce adherence to cancer treatment and may ultimately compromise survival.

Should the IMS physician determine that herbal medicines may help relieve the patient's symptoms, the potential benefits outweigh potential risks, and there are no good alternatives, he or she would recommend herbal prescription after discussing their rationale with the patient and with the oncology team as needed. If the patient is enrolled in a clinical trial, the principal investigator (PI) of the study will be contacted for whether herbal use will be allowed for the specific trial prior to prescription and in most cases concurrent

herbal use is not permitted. The IMS physician then sends an herbal prescription order to the MSK outpatient pharmacy. The herbal product is then labeled, verified, documented in the patient's EMR, and dispensed by the pharmacists in a procedure similar to that for other prescription drugs. An herbal pharmacist (YNH) is available to counsel the patient and answer questions about herbal treatments. The patient has the option of picking up the filled prescriptions from the MSK pharmacy, or at 9 other regional outpatient pharmacies. Delivery by mail is also available. Because herbal products and supplements are not considered prescription drugs, they are currently not covered by insurance. However, in many cases, a pre-tax health savings account or a flexible spending account could be used to pay for the dispensed products. IMS physicians and APPs then routinely follow up with the patient to assess herbal medicine use, discuss any benefits experienced by the patient, and document any adverse events.

### Implementation of HOP

The implementation of HOP started with one experienced IMS physician (JJM) testing the workflow and refining the process. After 12 months, recognizing that the net benefit outweighed potential harm, we developed systematic education content, including in-service PowerPoint presentations and a journal club, as well as held weekly group and individual trainings on specific herbal medicines for symptom control. To ensure safety and to document progress, we developed a data tracking system for detailed prescription patterns, fill patterns, and potential adverse events. During faculty meetings, we discussed cases in which we had success or challenges to promote shared learning. In addition, we conducted systematic reviews of the current evidence (mostly in Chinese literature) and identified gaps. We also presented our interim progress to the MSK P&T Committee

and senior leadership for guidance and feedback to ensure that workflow, communication, and further development are consistent with high quality and patient-centered care in the context of standard oncology care delivery.

## HOP evaluation

To determine the feasibility and to evaluate the outcomes of HOP, we collated medical record data of all patients participating in the program from February 1, 2019, to January 31, 2022, into a Microsoft Excel file. We conducted retrospective chart review including symptoms and other concerns that motivated patients to seek herbal products, types and numbers of dispensed TCM herbal prescriptions, and demographic characteristics.

To assess patients' perceived experiences of HOP, a brief 10-question survey (Table 3) was developed and distributed through email to all patients who received an herbal prescription between May 1 and August 31, 2021. The survey asked patients about the symptoms or concerns they hoped to address through HOP, their satisfaction with the program, and the herbal prescriptions dispensed, whether they experienced adverse effects, and how likely they were to recommend the dispensary program to other patients. Answer options were multiple choice, yes/no, or five-point Likert scales (extremely satisfied/likely to extremely dissatisfied/unlikely). The program evaluation process was approved by MSK's Institutional Review Board (IRB) and the survey was distributed via Research Electronic Data Capture (REDCap™) web application [31, 32].

## Results

### Program results

Between February 1, 2019, and January 31, 2022, 851 cancer patients received herbal consultations and prescriptions as part of the HOP program (Table 1). The median age was 61 (18–98 years-old); the majority were female (606, 71%), white (594, 70%), and publicly insured (498, 59%). Patients were being treated for a wide range of cancers, with breast (244, 29%), gastrointestinal (155, 18%), and gynecological (84, 10%) being the most prevalent. All were outpatients, with 712 (84%) in active treatment (including but not limited to hormonal-, targeted- and immune-therapies).

HOP prescribed patients a total of 1502 TCM herbal prescriptions during the study period, of which 1266 (84%) were dispensed. TCM herbal medicines were prescribed to address a range of symptoms and other concerns. The most common included GI symptoms (constipation, poor appetite, bloating, nausea and vomiting, acid reflux, and diarrhea) (467 prescriptions, 37%); pain (353 prescriptions, 28%); and treatment-related fatigue, sleep, and mood disorders (346

**Table 1** Patient characteristics ( $N = 851$ )

Characteristic	Value
Age, year, median (range)	61 (18–98)
Gender, $n$ (%)	
Female	606 (71)
Male	245 (29)
Ethnicity, $n$ (%)	
Non-Hispanic	746 (88)
Hispanic	55 (6)
Unknown/patient refused	50 (6)
Race, $n$ (%)	
White	594 (70)
Asian	128 (15)
Black	61 (7)
Unknown/patient refused	39 (5)
Other	27 (3)
Native American/Alaskan	1 (<1)
Native Hawaiian/Pacific Islander	1 (<1)
Cancer type, $n$ (%)	
Breast	244 (29)
Gastrointestinal	155 (18)
Gynecological	84 (10)
Hematological malignancies	68 (8)
Sarcoma	51 (6)
Thoracic	50 (6)
Genitourinary	46 (5)
Prostate	41 (5)
Head and neck	30 (4)
Neurological	29 (3)
Other	18 (2)
Endocrine	18 (2)
Melanoma	17 (2)
In active treatment, $n$ (%)	
Yes	712 (84)
Unknown	70 (8)
No	69 (8)
Insurance type, $n$ (%)	
Public	498 (59)
Private	348 (41)
Self-paid	5 (<1)

Note: numbers may not add up to 100%, due to rounding

prescriptions, 27%). Other TCM herbal medicines were prescribed for hot flashes, dizziness, cold and allergy, and cough (100 prescriptions, 8%) (Table 2).

### Survey results

From May to August 2021, 269 patients were invited to participate in the survey (Table 3). Of these, 107 (40%)

**Table 2** Top reasons for herbal prescriptions

Reason	Prescriptions ordered	Dispensed (distribution)	Prescriptions picked-up rate
GI symptoms	<b>555</b>	<b>467 (37%)</b>	
Constipation	262	226	86%
Poor appetite, bloating/indigestion	182	148	81%
Nausea/vomiting and acid reflux	62	54	87%
Diarrhea	49	39	80%
Pain and inflammation	<b>446</b>	<b>353 (28%)</b>	
Fatigue, mood, sleep	<b>386</b>	<b>346 (27%)</b>	
Fatigue	186	168	90%
Mood	123	111	90%
Sleep	77	67	87%
Other symptoms	<b>115</b>	<b>100 (8%)</b>	
Hot flashes	31	30	97%
Dizziness	33	29	88%
Cold/allergy	33	27	82%
Other	18	14	78%
<b>Total</b>	<b>1502</b>	<b>1266 (100%)</b>	

completed the survey, providing specific feedback about their experiences with HOP.

### Satisfaction with HOP consultations

Nearly all survey participants valued the ability to discuss herbal medicines with an integrative medicine provider, with 80.4% (86/107) rating this as very to extremely important. Similarly, 85.4% (88/103) reported being somewhat to extremely likely to recommend HOP to other patients.

### Satisfaction with HOP dispensary

The vast majority of survey participants 86.5% (90/104) found it somewhat to extremely easy to obtain TCM herbal medicines through the dispensary. Amid the COVID-19 pandemic, more than half of respondents 53.4% (55/103) said it was very to extremely important to receive their prescriptions through 2-day home delivery, rather than having to collect them in person.

### Purpose and effectiveness of TCM herbal medicines

Among 103 survey participants, the most common symptoms they hoped to address through HOP were gastrointestinal problems (bloating and indigestion, 21, 20.4%; constipation, 20, 19.4%; acid reflux, 12, 11.7%; nausea or vomiting, 10, 9.7%; and diarrhea, 8, 7.8%), fatigue (28, 27.2%), and pain (21, 20.4%). A large majority 70.9% (73/103) were

somewhat to extremely satisfied with the effectiveness of dispensed herbal medicines in relieving their symptoms.

### Side effects from herbal medicines

Few survey participants 6.7% (7/104) had experienced negative effects with prescribed herbal medicines. Reported side effects included constipation, bloating, heartburn, acid reflux, and skin discoloration and peeling; all side effects were mild and resolved after discontinuing product use.

### Discussion

Despite extensive use of herbal supplements by cancer patients [1], careful discussion and use of herbal medicine under medical supervision is seldom integrated into oncology care delivery. The HOP program demonstrates the feasibility of integrating TCM herbs into an academic oncology setting. Patient satisfaction with HOP among survey respondents was high, with few reported adverse events. Patients also strongly value the opportunities HOP affords for communication and shared decision making. Further, the patterns of TCM prescriptions in HOP can help identify future areas for clinical research to strengthen the evidence base around herbal use.

Our novel model of herbal oncology provided a unique space to help bridge the communication divide between patients and providers. Prior research found that while patients increasingly seek herbal remedies and other holistic

**Table 3** Satisfaction survey

Question	Response
1. How important is it for you to be able to discuss your herbal medication or dietary supplement with an Integrative Medicine doctor or nurse practitioner?	<i>N</i> = 107 Counts/frequency: Not at all important (1, 0.9%), Slightly important (3, 2.8%), Moderately important (17, 15.9%), Very important (36, 33.6%), Extremely important (50, 46.7%)
2. How important is it for you to receive your herbal medication or dietary supplement from the MSK Pharmacy rather than from an outside source (like a local health food store or online)?	<i>N</i> = 107 Counts/frequency: Not at all important (5, 4.7%), Slightly important (13, 12.1%), Moderately important (26, 24.3%), Very important (27, 25.2%), Extremely important (36, 33.6%)
3. What symptom(s) did you hope to address with the herbal medication or dietary supplement you received? Check all that apply.	<i>N</i> = 103 Counts/frequency: Acid reflux (12, 11.7%), Bloating and indigestion (21, 20.4%), Constipation (20, 19.4%), Diarrhea (8, 7.8%), Dizziness (3, 2.9%), Fatigue (28, 27.2%), Hot flashes (8, 7.8%), Inflammation (25, 24.3%), Insomnia (8, 7.8%), Mood (11, 10.7%), Nausea or vomiting (10, 9.7%), Pain (21, 20.4%), Other (Please specify) (36, 35.0%)
4. Overall, how satisfied were you with the effectiveness of the herbal medication or dietary supplement in addressing your symptom(s)?	<i>N</i> = 103 Counts/frequency: Extremely dissatisfied (7, 6.8%), Somewhat dissatisfied (6, 5.8%), Neither satisfied nor dissatisfied (17, 16.5%), Somewhat satisfied (36, 35.0%), Extremely satisfied (37, 35.9%)
5. Did you experience any negative side effects while taking the herbal medication or dietary supplement?	<i>N</i> = 104 Counts/frequency: No (97, 93.3%), Yes (7, 6.7%)
6. How easy was the process of receiving an herbal medication or dietary supplement prescription from your Integrative Medicine doctor or nurse practitioner?	<i>N</i> = 104 Counts/frequency: Extremely difficult (2, 1.9%), Somewhat difficult (5, 4.8%), Neither easy nor difficult (7, 6.7%), Somewhat easy (27, 26.0%), Extremely easy (63, 60.6%)
7. How important is it for you to be able to pick up your prescription from an MSK Retail Pharmacy location?	<i>N</i> = 103 Counts/frequency: Not at all important (31, 30.1%), Slightly important (16, 15.5%), Moderately important (29, 28.2%), Very important (15, 14.6%), Extremely important (12, 11.7%)
8. How important is it for you to receive your prescription through 2-day UPS Home Delivery?	<i>N</i> = 103 Counts/frequency: Not at all important (16, 15.5%), Slightly important (10, 9.7%), Moderately important (22, 21.4%), Very important (15, 14.6%), Extremely important (40, 38.8%)
9. Overall, how satisfied are you with the option to receive an herbal medication or dietary supplement from the MSK Outpatient Retail Pharmacy?	<i>N</i> = 103 Counts/frequency: Extremely dissatisfied (3, 2.9%), Somewhat dissatisfied (2, 1.9%), Neither satisfied nor dissatisfied (10, 9.7%), Somewhat satisfied (13, 12.6%), Extremely satisfied (75, 72.8%)
10. How likely are you to recommend MSK's Herbal Dispensary Program to other patients	<i>N</i> = 103 Counts/frequency: Extremely unlikely (1, 1.0%), Somewhat unlikely (1, 1.0%), Neither likely nor unlikely (13, 12.6%), Somewhat likely (14, 13.6%), Extremely likely (74, 71.8%)

treatments to manage symptoms that are inadequately controlled through conventional care, few patients disclose herbal supplement use to providers [5], and few providers are equipped to discuss these topics [13–15]. By providing patients with a safe, evidence-informed program for openly

exploring herbal, and other non-pharmacologic options with specially trained providers, HOP helps bridge this communication gap.

HOP may also facilitate shared decision making around herbal use and help guide patients to selectively use TCM

herbs for specific needs, thus averting unsupervised, unsafe, and ineffective use. HOP's quality-controlled procurement process also helps protect patients from adulterated or inaccurately labeled products, which are not uncommon in the marketplace. Most importantly, HOP may prevent or halt unsafe CIM use, particularly with herbs that can compromise oncologic treatment [33] or increase the risks of bleeding or hepatic and renal toxicities [34–37]. More, by directing patients who are on oncology clinical trials away from herbs to other non-pharmacological interventions, HOP can help ensure the results of clinical trials are not influenced by concurrent use of herbal products. For patients with advanced disease or in survivorship settings, when conventional approaches are inadequate to address the symptoms, use of herbal medicine may not only improve symptom control and quality of life but also enable patients to gain sense of control in their care.

The patterns of herbal prescription and reported benefits highlight how HOP helps meet the needs of patients. The majority of HOP patients responding to the survey reported relief from a variety of symptoms widely experienced in the oncology setting, including poor appetite, constipation, pain, and fatigue. The specific symptoms identified highlight opportunities for future research. The major challenge in herbal oncology practice lies in the limited evidence of efficacy, despite extensive empirical use in other cultures over long periods of time [38]. To this end, HOP is carefully tracking benefits and adverse events; we have also simultaneously conducted systematic appraisals of the existing literature on TCM and other CIM products, focusing on assessing the current evidence and identifying limitations and knowledge gaps [18–20]. Ultimately, however, more clinical trials are urgently needed to build a robust evidence base for the safety and effectiveness of these therapies in the contemporary oncology setting. This research is fundamental to addressing patients' unmet needs and improving their outcomes, particularly in countries where access to conventional oncology care is limited [39].

This study has several limitations. First, our project is based on methods for program development, implementation, and evaluation in real world setting, not a formal research protocol testing specific hypotheses in focused clinical population. Second, our survey findings are based on a sample of patients who self-selected for outcome evaluation, and therefore, our data may not be representative of the entire study population. Third, we only evaluated immediate symptom relief produced by TCM herbal medicines; as such, we cannot comment about the durability of these benefits. Fourth, the HOP program requires specialized staffing, institutional support, and other resources that may not be available in other settings. Fifth, patients were required to pay for the

recommended supplements (whether subsidized or not), which may have limited their ability to adhere to the co-designed treatment regimen. Sixth, as noted above, the evidence base for some of HOP's TCM herbal medicines is weak. However, systematic use and future studies will begin to generate empirical data that can guide more rigorous investigations.

Despite these limitations, our study findings support the feasibility and potentially beneficial impact of the novel integrative oncology program described, facilitating communication and shared decision making about appropriate use of herbal medicines in the oncology setting. HOP illustrates how TCM herbal medicines can be safely, effectively integrated into conventional cancer care for symptom relief and to avert potential harms from unsupervised herbal use. From open patient-physician communication to high patient satisfaction and other outcomes, HOP highlights the many potential benefits of this approach.

## Conclusions

Our program may be able to serve as a prototype for other oncology providers in the U.S. and elsewhere. Careful observation and hypotheses generated in patient care as part of HOP can inform future rigorous clinical trials to further increase the evidence base for safe, effective integration of TCM herbal medicine into oncology care, ultimately improving patient outcomes and experiences.

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**Author contribution** Jun J Mao, Yen-Nien Hou, and Gary Deng contributed to the study conception and design. Material preparation, data collection, and analysis were performed by Yen-Nien Hou and Jun J Mao. The first draft of the manuscript was written by Yen-Nien Hou, Jyothirmai Gubili, and Susan Chimonas. All the authors read, commented, and approved the final manuscript.

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## Declarations

**Ethics approval** IRB approval number Protocol # 17-481.

**Consent to participate** This is an IRB-approved retrospective study.

**Consent for publication** This is an IRB-approved retrospective study.

**Conflict of interest** Jun J. Mao reports grants from Tibet CheeZheng Tibetan Medicine Co. Ltd. and from Zhongke Health International LLC outside the submitted work. Yen-Nien Hou, Susan Chimonas, Jyothirmai Gubili, and Gary Deng declare no conflict of interest.

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