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Practices and attitudes of herbalists regarding informed consent in Uganda: a qualitative study

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Abstract

Background Informed consent (IC) is a fundamental principle in medical ethics that upholds respect for patient autonomy. Although widely applied in healthcare, its feasibility and implementation in herbal medicine have been underexplored. This study therefore aimed to explore the practices and attitudes of herbalists regarding informed consent.

Methods To achieve these objectives, a qualitative cross-sectional study was conducted from June to December 2020. Twenty-one in-depth interviews with herbalists and four key informant interviews with leaders of the different traditional medicine organizations were conducted. The data were analyzed thematically using NVivo version 12 software.

Results Sixteen of the twenty-one participants acquired oral herbal medicine knowledge from their relatives. Although a positive inclination toward obtaining IC was evident, the focus was on disclosing basic information. Discussions of alternative treatments and herbal specifics were less frequent. Disease management decisions often involve shared responsibility within families or societies. Documented IC procedures are rare among herbalists, who deem consent forms unnecessary, although they recognize the potential benefits of IC in fostering trust and professionalism. Challenges hindering IC implementation included regulatory gaps, inadequate skills, and the absence of mechanisms to protect the intellectual property rights of herbal medicine.

Conclusion This study illuminates how educational, cultural, familial, and regulatory factors influence herbalists' practices and attitudes toward informed consent.

Keywords Herbal medicine, Informed consent, Communal consent, Ethical principles

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Background

In medical ethics, informed consent (IC) is an ethical imperative that reflects respect for a person's autonomy and right to self-determination [1–3] and the fiduciary responsibilities of the patient and healthcare provider [4, 5]. The IC process involves providing patients with sufficient information for autonomous decision-making, and ensuring clarity and freedom from coercion [6, 7]. Essential information includes details of the procedure, benefits, risks, alternative treatments, treatment costs and consequences of abandoning the treatment [8]. While IC is well established in conventional medicine, questions arise about its compatibility with traditional medicine (TM), which is prevalent in developing countries such as Uganda, where 70–80% of the population relies on traditional healers, particularly herbalists [9, 10]. Herbal medicines have been preferred by the communities due to their accessibility, perception of these medicines being more natural and safer compared to the conventional medicine [11]. Communities have been reported to utilize herbal medicines to access antenatal services, cases of infertility among men and women and treatment of non-communicable diseases and recently during the Covid-19 pandemic [12]. Despite the wide preference and use of herbal medicines by communities in Uganda, they are generally sold by herbalists with little or no formal education in medicine not even medical ethics [13]. The ability of practitioners to effectively execute IC has been shown to be associated with having had some training in this topic or medical ethics [7]. It is therefore important for health officials to safeguard the communities against quacks who may masquerade as herbalists, and establish well-regulated frameworks to ensure safety profiles of herbal medicines hence minimize harm that may arise from use of herbal medicines some of which are toxic and have the capacity to affect their health [14]. A study by Caspi et al. reported variance and a lack of standards in the conduct of IC practices among complementary and alternative medicine (CAM) therapies [15], and these practices have been reported to vary based on different jurisdictions and cultures.

Informed consent is basically of three forms which include; Verbal consent where a patient states their consent to a procedure verbally but does not sign any written form. This is adequate for routine treatment such for diagnostic procedures and prophylaxis, provided that full records are documented. Written consent (IC) is considered a basic principle of medical practice which involves providing information and sharing knowledge between the physician and patient and creates a shared-decision-based healthcare plan. In this regard, IC must include both a form that patients are required to read and sign, and oral communication to ensure adequate understand-

ing to facilitate voluntary willingness to either accept or refuse the treatment proposed by the clinician. Additionally, implied consent refers to when a patient passively cooperates in a process without discussion or formal consent and this is usually not documented [16]. It is therefore imperative to ascertain the kind of informed consent practiced by herbalists and their attitudes regarding its implementation.

Regulation of herbal medicine practice

The World Health Organisation (WHO) in a manner to uplift traditional medicines through its traditional medicines' strategy 2014–2023 called for promotion of safe and effective use of traditional medicine through the regulation of products, practices and practitioners. In response to the WHO call, Uganda enacted the Traditional and Complimentary Medicines Act 2019 (TCM ACT), which called for the formation of a National Council responsible to register and license practitioners; promote and protect the professions; provide regulation of herbal medicine and herbal practices; define acceptable scope and standard of traditional and complimentary medicines (TCM) practices as well as unacceptable malpractices ultimately serving as a regulatory body responsible for overseeing the practices, registration and licensure of traditional medicine practitioners including herbalists.

The TCM ACT 2019 outlines the code of conduct that traditional medicine practitioners ought to abide by including the process of obtaining informed consent from patients and indicates that violation of the law can make a practitioner liable in court and prone to liability.

Whereas medical litigation cases have been seen in Ugandan courts due to negligence and malpractices by healthcare providers in the conventional medicine sector, not many situations have seen herbalists in court especially due to failure to obtain informed consent as one of the ethical principles violated according to the Ugandan law.

In addition to the TCM ACT 2019, Uganda relies on the Patient CHARTER to foster respect for autonomy and the principle of obtaining informed consent through a statement that says " Every patient has the right to be given adequate and accurate information about the nature of one's illness, diagnostic procedures, the proposed treatment for one to make a decision that affects one of these elements. The information shall be communicated to the patient at the earliest possible stage in a manner that he/she is expected to understand in order to make a free, informed, and independent choice" [17]. Whereas the Patient Charter is not a legal document that may not have a force of law, it declares principles that have been recognized in human rights instruments and the common law. It is therefore important that herbalists

practice informed consent based on the different laws and medicine regulatory guidelines within the This country. Despite this obligation, little is known whether herbalists practice IC, understand what it entails and whether they are familiar with the consequences of not implementing it during their interactions with the patients. study therefore aimed to investigate the knowledge gap among herbalists by exploring and documenting their practices and attitudes regarding IC implementation in Uganda. The study provides detailed analysis into how herbalists currently approach informed consent highlighting the key facilitators and barriers to informed consent implementation. It expands the discourse on informed consent within the contact of herbal medicine which has been underexplored in this regard, hence impacting both medical ethics and herbal medicine.

Methods

Study design

This study had a cross-sectional design and used in-depth interviews (IDIs) and key informant interviews (KIIs) to collect the data. The design and method of data collection were chosen because the team needed to attain a deeper understanding of the practices and attitudes of the herbalists regarding the use of informed consent.

Study setting

The study was conducted in the Wakiso and Mpigi districts through Prometra Uganda, a non-governmental organization (NGO) that promotes traditional medicine and the preservation of indigenous traditional knowledge, including herbal medicine. These districts were chosen because they host institutions that train, educate and bring together herbalists from different parts of the country.

Sampling procedure

Participants for the 21 IDIs were identified and purposively selected based on their specialty and expertise in herbal medicine from Prometra Uganda. Herbalists who were unreachable by phone were visited at their premises to schedule appointments for the interviews. Four key informants were recruited from different traditional medicine organizations responsible for coordinating traditional medical practitioners within the Wakiso and Mpigi districts. Two key informants were recruited from each of the districts respectively for equal representation. These included the National Chemotherapeutics Institute (NACRI), Uganda Nédaggala Lyayo, PROMETRA, and the National Council for Traditional Healers and Herbalists Associations (NACOTHA). These were contacted through phone calls for appointments regarding the dates and times they would be available for the interviews. Interviews were conducted in silent places

chosen by the participants to ensure that the recording and confidentiality of the participants' information were not interrupted.

Data collection enumerators

Data collection was conducted from June to December 2020 by a team of two people who were both females i.e. SN as the interviewer and DN being the note taker. SN is the principal investigator, who holds a Master of Health Sciences degree in Bioethics, and a Bachelor of Science majoring in Biochemistry. The second, who was a research assistant, holds a Master of Health Sciences degree in bioethics and a Bachelor of Social Sciences with a focus on political science. Both of them had over two years of experience in conduct of qualitative research and training in qualitative data collection methods, which included conducting in-depth interviews and key informant interviews, as well as obtaining informed consent from potential participants.

Data collection tools and procedure

An interview guide comprising questions assessing herbalists' practices and attitudes toward informed consent, based on the elements of IC, such as assessing patients' competency, information disclosure, voluntariness, understanding, and consent (decision and authorization), was utilized to conduct the interviews. The interview guides were pilot tested among three traditional healers who were not part of the study team. Participants were individually informed about the study in silent rooms, given time to ask questions, and freely agreed to participate and provided written informed consent for participation. These interviews were conducted in Luganda, a local language preferred by all participants who could read and fully comprehend it. The interviews, which lasted between 40 and 90 min, were audio-recorded, transcribed verbatim, translated into English, and analyzed thematically. In total, 21 IDIs and four key KIIs were detected.

Data analysis In-depth interviews were conducted until saturation that no new ideas were being obtained from the participants. All the data were analyzed thematically using NVivo (version 12) software. A coding framework based on six transcripts that were manually reviewed and coded to generate the initial set of codes was developed. All transcripts were imported into NVivo software, and open coding was performed. Two members of the research team (SN and AT) independently reviewed the interviews and created inductive codes, which were organized in a codebook. SN and AT discussed and resolved inconsistencies in coding, and the final codes were established by consensus between the coders. The coded text was then categorized into themes. Illustrative quotations

for each emergent theme were selected for results narration. The study followed the COREQ checklist [18] for reporting and analyzing the data.

Results

Demographics

In this study, demographic data were collected from 25 study participants (21 herbalists who underwent in-depth interviews and four herbalists' association leaders who were key informants). The in-depth interview participants' average age was 54.7 ± 10.3 years and 14 had attained up to primary education only. Ten herbalists had more than 20 years of experience in their field. A summary of the demographics of the 21 in-depth interviewees is presented in Table 1. The key informants included one female and 3 were males with a mean age of 46 ± 8.6 years. All four leaders held a bachelor's degree and had more than five years of working experience as herbalists.

Analysis of the data yielded five themes: description of the herbalist and source of herbal medicine knowledge, attitudes of herbalists toward the IC, practices of obtaining IC, factors that prompted them to obtain IC, and barriers that hindered them from practicing IC adequately.

Description of the herbalist

The participants described herbalists in the following categories: (i) individuals who treat patients' diseases using naturally occurring plants, including their leaves, flowers, seeds, stems and roots; (ii) individuals who do not attend to patients but teach other people herbal medicines; and (iii) individuals who collect and process herbs from forests and gardens but do not directly attend to patients. The herbalists were further categorized into different

specialties, such as traditional birth attendants, bone setters, and dispensers by the participants;

"I am looking at an herbalist as an individual who is approached by a patient, examines their health status and, depending on what the patient explains to them, picks certain herbs, roots, leaves, stems or any plant material, mix and prepare them to treat the patients' ailment." (KII_Male_4).
A 'herbalist is one who treats diseases using naturally occurring elements such as trees and herbs that were created by God' (IDI_Female_04).

Source of knowledge on herbal medicine

The majority of participants reported acquiring herbal knowledge orally and informally from their relatives. They noted that herbalism has a robust foundation in traditional healing. Some participants had also undergone formal training in herbalism schools, learned from colleagues, and gained knowledge and experience through long-term use of various herbs for a range of diseases, such as malaria, skin diseases, diarrhea, and sexually transmitted diseases. Patients with chronic diseases also provided antenatal care services and managed the side effects of long-term drug medication.

"I got this knowledge from my grand-parents, then from my father who used to work with Nakalooli brothers in Kisubi." (IDI_Male_12).
"There is a category of herbalists who have undergone training and been educated. They go to medical schools or natural chemotherapeutics, and they learn about the herbs; there are some who read from the internet and start practicing." (KII_Male_4).

Table 1 Sociodemographic characteristics of the IDI participants

Population Demographics	Number (N= 21)
Age	
30–40 years	2
41–50 years	7
51–60 years	5
61–70 years	7
Gender	
Male	6
Female	15
Education status	
Primary education	14
Secondary education	6
Tertiary	1
Experience working as a herbalist	
< 5 years	1
5–10 years	3
11–20 years	7
> 20 years	10

Herbalists' attitudes toward informed consent

The majority of the study participants regarded ICs as essential for adequately disclosing information about the proposed treatment to the patient and for identifying the misconceptions people have about herbal medicine (safety and side effects). The authors suggested that disclosure should include treatment benefits, costs, dosage, and side effects.

"It is beneficial to inform the patient about the medicine's benefits, risks, and potential side effects to ensure they leave satisfied, confident, and well informed based on the explanation provided. Nevertheless, there are instances when withholding certain information becomes necessary, particularly if revealing everything might induce fear and panic in

the patient, potentially exacerbating their problems.” (IDI_Female_09).

“While there is a common belief that these herbs are entirely safe and natural, there are instances where improper consumption can lead to harm. Thus, it is essential to clarify to patients what they should anticipate after taking the medication.” (IDI_Female_05).

“It is very good practice to explain to the patient thoroughly what the treatment entails, such that they can make valid and informed decisions.” (IDI_Male_13).

However, there was nearly unanimous agreement among them that revealing information about alternative treatments and the specific components of herbal mixtures was not necessary for patients, and they believed it could have negative financial and professional implications for them.

“Some individuals, upon learning about the herbs used in a formulation, may falsely claim to be herbalists without understanding the proper preparation, usage, dosage, and comprehensive applications. Subsequently, they may misinform others, attributing their newfound knowledge to the original herbalist. This is why I limit the information I share with patients to avoid potential harm to my profession and reputation from unqualified individuals misrepresenting themselves as herbalists.” (IDI_Female_005).

“I do not reveal the specific herbs I blend to create the formulation. Instead, I focus on preparing the most effective medicine tailored to treating the patient’s specific ailment. This approach eliminates the need for the patient to seek alternative treatments, as I consistently provide the best treatment within my knowledge.” (IDI_Female_007).

The study participants did not perceive it necessary to inquire whether patients voluntarily accepted or refused the suggested treatment. The patients’ arrival at the herbalists’ premises was automatically construed as their acceptance of the impending treatment. Consequently, the herbalists did not inquire about their patients’ perspectives regarding the treatment offered by the herbalist.

“Only the herbalist is allowed to make decisions and not the patient; patients do not tell us what to do, and therefore, they take whatever we as herbalists choose (KII_Male-1).

“A patient is not supposed to make any decisions because he or she does not have knowledge regarding the treatment.” (IDI_Female_02)

Some herbalists emphasized the significance of shared decision-making between themselves and the patient because this approach allowed for mutual advice and education during discussions, and the herbalist did not possess an absolute right to make decisions for the patient.

“The herbalist should not assume to know everything and decide alone. Patients may possess knowledge that the herbalist lacks. We need to collaborate and engage in discussions, and I, as the herbalist, must inquire whether the patient accepts or rejects the suggested treatment. It is the herbalist’s responsibility to educate the patient ensuring they are informed about their choices.” (IDI_Female_04).

“You have to explain to the patient; you then give them a chance to decide for themselves either to accept or refuse the treatment.” (IDI_Female_09).

The participants did not believe that signing consent forms was necessary. Moreover, some herbalists were unable to write, making it impractical for them to sign such forms. The participants viewed signing consent forms as irrelevant to herbal medicine and time consuming and asserted that the significance of the consent forms was associated with the use of conventional medicine for administrative purposes.

“The patients trust us; therefore, there is no need for the patient to sign anywhere because by the time they approach you for medicine, they trust you..... Usually, there is no time to ask much or even sign consent forms.” (IDI_Female_09).

Practices of herbalists on obtaining informed consent

Herbalists who disclosed information to patients felt the need to do so, because they had more knowledge and information about treatment than patients. At times, the information shared was based on the kind of questions asked by the patients. The information shared by almost all study participants included common herbal side effects, the cost of medicine and the dosage of the formulation provided, dietary restrictions and any known drug interactions with the herbs provided.

“You clarify the risks linked to the formulation, emphasizing that some individuals erroneously believe herbal medicine is devoid of side effects or the possibility of overdosing, despite the reality that it does have both side effects and the potential for overdoses.” (IDI_Female_02).

“I tell the patient the cost of the treatment before I prepare the medicine, such that we can agree. I also

tell them about the dosage, and I encourage them to first eat food before taking the medicine.” (IDI_Female_12).

“I further teach them about diet, encourage them to eat vegetables and roughage, not to drink sugar in case they are diabetic. I generally give them health education, and it is that which consumes most of our time.” (IDI_Male_16).

Some participants refrained from disclosing the patient's diagnosis if they anticipated family conflict or increased stress. Additionally, for some illnesses perceived not as an individual's burden but rather as a communal or family matter, the latter often take precedence in receiving information about the patient's diagnosis and making treatment decisions about the patients themselves.

Another consideration that hindered study participants from disclosing their diagnosis to them was the fear of self-medication following media advertisements about different herbs.

“Now, if we talk about informed consent from a communal perspective, in our culture and setting, illness is not an individual person's issue but rather a community or family concern. The patient's family asks you not to disclose information to the patient; rather, all the information and decisions are made by them.” (KII_Male_4).

In addition, herbalists considered a patient's capacity to comprehend information to determine whether to initiate discussions, which in turn determined their decision-making practices. For instance, guardians or parents may engage in discussions and decision making for the child's treatment. Similarly, for very ill patients, a designated proxy, often a family member, was furnished with the information and assumed the responsibility of making decisions regarding the patient's treatment choices.

Assessment of patients' understanding of the information given

Participants highlighted various methods for assessing patient understanding of provided information. This evaluation involved utilizing questions, interpreting body language, and conducting follow-up phone calls to gauge adherence to prescribed treatments. However, some participants neglected to employ any verification methods to confirm patient comprehension, placing less importance on whether patients understood the shared information, as long as discussions centered around treatment dosages.

“I rephrase a question... I paraphrase it again and ask it again to be sure that the patient has understood what I have told them.” (KII_Male_2).

“I do not know how. I just explain and leave the rest to God, for him to have mercy on the patient and help him/her understand and remember whatever you have told them.” (IDI_Female_03).

Documentation of informed consent

Participants emphasized a practice founded on trust, honesty, and voluntarism. The majority of the studies solely recorded patients' personal details, medical history, and prescribed medication. Informal communication typically determines treatment acceptance or refusal. Patients did not sign any informed consent documents but provided implied consent through verbal agreement to take the medicine. Additionally, some herbalists reported that some of the herbalists' lack writing skills and cannot therefore practice documenting informed consent. A key informant mentioned that, despite being considered necessary in medical ethics, informed consent documentation is not applied in herbal medicine since neither the patient nor the herbalist deems it necessary.

“I have never let a patient sign anywhere. However, we agree verbally; they then take the medication..... and imply they have accepted.” (IDI_Female_02).

“Some of us don't know how to write, and we also do not see the importance of making the patient sign those consent forms. I don't know whether any herbalists practice written informed consent.” (KII_Male_4).

“We have a registry book and referral forms; however, we do not have consent forms on which patients signed. It is usually a verbal consent.” (IDI_Female_05).

Notably, a few of the participants reported documenting consent for patients or relatives, especially for patients with a terminal illness such as cancer, to avoid blame in case the patient died. Finally, there is a need for evidence in case queries from relatives on the treatment presented at some point.

“Some patients arrive critically ill with cancer. After administering medication, they are at risk of succumbing, and if that occurs, accusations may arise linking their deaths to the prescribed medicine. To address such situations, consent forms are signed, and I keep a copy along with the patient's relative during this process.” (KII_Male_1):

“I document whether the patient accepted or declined the treatment, though the patients them-

selves does not sign or write anything. This practice ensures that when their relatives visit, I can promptly provide assistance. It also serves as confirmation that I provided treatment at my center.” (IDI_Female-20).

Factors that facilitate the practice of IC among herbalists

For participants who practiced and perceived informed consent to be important, this was because they perceived it to be a way to enhance the good relationship between the patient and the herbalist, to attract more patients, and to portray trust and honesty, which enhanced the good relationship between the patient and the herbalist.

“It is very good as it enables you to establish a good relationship with the patient such that they can easily open up to you, create awareness of whatever is going on, avoid stressing the patient unnecessarily, and know that they have come to the right person and place.” (IDI_Female_18).

Some participants felt that IC would help them avoid blame and false accusations from patients or blame by the public and relatives if a sick person experienced harm after receiving medicine. In this case, documenting consent was considered a protective measure against potential liability.

The correct procedure would have been to document and sign informed consent forms (ICFs), but we have not been following it. The patient might accuse you of providing medication that caused harm, even if they had visited another herbalist who gave them the medicine that led to harm. With proper documentation, you are protected from false accusations and blame.” (IDI_Male_11).

“Disclosure and discussion of side effects with the patients is the only thing that can protect the herbalist from being sued in court because they can clearly confirm that they informed the patients of the side effects before they dispensed it to them.” (KII_Male_02).

Most participants reported that sharing information and proper explanations during the consent process would help patients adhere to the treatment, restore hope, and hence improve treatment outcomes.

“It helps a lot because the patient gets to know that you are honest and trustworthy, you understand what you are doing... such that they are confident about the treatment you give them that they will be well.” (IDI_Female_17).

Practicing IC was perceived as a sign of transparency and professionalism among providers and ethically added value to their job and ensured the safety of their patients.

“If you don’t tell them, you will have done injustice to them. You need to tell the patient because some women come in while pregnant; this means that there are certain kinds of herbs you cannot give them, as they may lead to miscarriages. You have to tell the patient exactly what to take and not take to ensure their safety.” (IDI_Female_04).

Factors that hindered herbalists from providing informed consent

Various structural challenges also hinder herbalists from implementing IC processes, such as limited time at the premises of the herbalist. A unique aspect of this finding was that most female patients visited herbalist practices without their husbands’ permission, necessitating a quick return home. In view of such short visits, the women received information only about the use and dosage of medicines.

“Occasionally, patients arrive in a rush, leaving little time for extensive information about the treatment. In such cases, they are mainly interested in knowing the dosage and how to take it. A significant portion of these hurried patients are often married women who leave their homes without their husbands’ approval, necessitating a prompt return home.” (IDI_Female_02).

Most participants said they lacked the knowledge, skills, and self-efficacy to practice IC and that they had not had any form of training or had not heard of the IC concept or its value and obligations.

“...therefore, the question of providing adequate information has to be resolved by systematic training that would lead to someone somewhere formulating an herbal product that would come with information regarding effectiveness, safety, and contraindications, which will now guide this person going to use it to inform the other user” (KII_Female_03).

Some participants did not see the meaning or importance of signing IC forms or patients having choices as to whether they accepted or refused the herbalist’s treatment. The perception that IC should be used only for very risky health procedures, such as surgery-hindered IC practices by herbalists since they do not perform major surgeries

"Written consent is obtained in most cases when major surgeries are going to be conducted like operations...for us in herbal medicine, we do not sign these forms because we do not perform major surgeries." (KII_Male_04).

Few participants disclosed much information to the patients because they feared losing the market for their medicines. Patients may notice that the drugs are readily available and accessible in the environment.

"If we disclose all that information to the patient, we will not attract a market for our medicines. Once we have shared all the details they need to know about their treatment, there's little incentive for them to return to us when they can access the information on their own." (IDI_Female_17).

Some participants said that patients are generally not educated and have poor literacy; moreover, they do not know their rights or, thus, what to ask or expect from the herbalist.

"The majority of herbal medicine consumers lack education on what they should request or expect. However, if they were mentored, they would be more inclined to ask. Unfortunately, it would be problematic if the patient were to inquire when the herbalist lacks the knowledge to provide an answer." (KII_Female_03).

Support needs that herbalists reported that could enable them to effectively practice informed consent

The participants also suggested the following ways to help motivate them to implement IC in their practice: receiving training in aspects of IC and strengthening collaboration with conventional medical practitioners.

"In case the herbalists are trained on what to do, they can implement the IC practice very well because it is very good practice. (IDI-Male-19)

Participants also requested that the government strengthen intellectual property protection for herbalists' property rights and innovations. They need to assure that their knowledge will not be stolen or misused, especially after information disclosure about the herbs to the patients.

"There is also another law that handles intellectual property. Once somebody gets to know the benefit, then they share more, knowing that their knowledge can be protected... Therefore, it is all about giving

confidence regarding intellectual property to the herbalists." (KII_Female_3).

Although adopting IC was suggested by some participants, there were concerns, on the other hand, that there is a need for it to be contextualized into our African cultural context.

"Now, in light of informed consent, I think there is need to be much more contextualized into our African setting. We should not import the Western concept to the traditional African way of living." (KII_Male_4)

The introduction of the law in Uganda that prompts herbalists to obtain IC from their patients and build their capacity to do so would promote this practice. Participants reported that if the law obligates the practice of IC, they would abide by it if they were skilled enough and would know what to do.

"The government should enact laws that guide the practice of traditional medicine and aim to uplift and enhance the capacity of herbalists. The existence of these laws is crucial, as some individuals enter the field by emulating others without proper training. The government's support in regulating and building the capacity of herbalists will help maintain standards in the practice." (KII_Female_03).

Discussion

This study investigated herbalists' practices and attitudes regarding the IC process, focusing on the application of key elements such as information disclosure, competency, understanding, and voluntariness in the context of herbal medicine. The necessity of obtaining patients' informed consent in clinical care including the need to discuss risks and side effects associated with the treatment are referenced from the landmark case of *Esterhuizen V, Administration, Transvaal* in South Africa where the judge emphasized the need to inform the patients expected side effects and risks associated with any procedures and treatments to be provided to them [19]. This is important to enable the patient make an informed choice emphasizing the need to respect patients' autonomy especially in the situation where patients assume herbal medicines are safe and free of any side effects or dosages. Informed consent has developed from a mere principle of ethics to a legal requirement as stipulated in the different countries' legislature documents including the Uganda constitution 1995 which calls for a person's right to information (Article 41), and particularly the TCM ACT 2019. Valid informed consent requires a competent

individual with the ability to understand and weigh medical information to make decisions [20] free of coercion or undue influence [21]. This study revealed various sources of herbal medicine knowledge among herbalists, influencing their attitudes and practices toward IC. According to Nzaumvila et al.'s research in the Congo, among practitioners, informed consent was associated with their ability to exercise information disclosure and this related to their history of having had formal training in medical ethics and IC [7]. Herbalists with formal education who obtained herbal medicine knowledge through structured programs may tend to exhibit more positive attitudes toward informed consent than those with informal education, those who rely on internet sources or those who have experiential knowledge acquisition. Herbalists often receive insufficient or no training in IC practices since many tend to have acquired knowledge and skills on herbal medicine informally from relatives which knowledge is transferred in a generational manner, leading to potential misinterpretations or inadequate understanding of the requirements and legal standards of IC. Looking at the different elements of informed consent, participants' attitudes and practices were as follows:

Information disclosure

Most participants expressed a positive attitude towards information disclosure as an element of informed consent referencing it as a key measure, in dispelling misconceptions about herbalists being "quacks", empowering and educating patients to enable them to actively participate in their healthcare decisions. These findings resonate with those of Nzaumvila et al., who examined the knowledge and practices of seeking informed consent by healthcare workers in the Congo, and Langworthy, who explored the procedures for providing consent among chiropractors in the United Kingdom [5, 7, 22]. Their results further align with Uganda's constitutional right to information and the Uganda Patients' Rights and Responsibilities Charter [23, 24].

At a minimum, the information disclosed should entail the diagnosis, the procedure and its risks, the benefits, and the alternatives, including choosing nothing [20, 25]. The kind and amount of information shared by herbalists were determined using the reasonable physician standard, where healthcare providers (HCPs) disclose only that information that any reasonable physician would disclose to a patient in such a situation [20, 26]. This kind of disclosure has been considered by some writers to limit patient autonomy as it tends to promote a paternalist approach. Given that herbal medicine relies on trust and patients are treated individually, adopting a subjective reasonable standard for information disclosure would be ideal. This approach tailor's information based on each person's unique needs, ensuring more patient-centered

care [18, 22]. On the other hand, considering that herbalists commonly perform straight forward medical procedures, can we view full disclosure of all the relevant details unnecessary? Does an incomplete discussion of these factors invalidate the consent obtained by the herbalist? Patients visiting herbalists tend to use the referral system from relatives or friends with previous knowledge and belief of the capability of herbalist. This could be one of the reasons some herbalists do not deem sharing all this information necessary.

The study participants' decision to selectively disclose information to patients may be considered reasonable for preventing social harm and potential stress to the patient and family resulting from the information provided during IC. This finding is similar to that of Jose and Alhajri, who argue that discussing side effects can alleviate patient anxieties; however, this finding differs from Akpa et al.'s findings, where traditional health practitioners unanimously supported discussing side effects with patients [27], attributing it to improve satisfaction, and assisting in informed decision-making [28].

Although discussion of the diagnosis with the patient was also recommended by many herbalists, a few stated that it was not necessary as this could promote self-medication which could result into harm to the patients. Additionally, with the various increasing advertisements of the different herbalists in different media including radios, televisions, and social media may prompt patients to self-medicate upon knowledge of the diagnosis. The herbalists therefore considered disclosure of such information unnecessary. Therefore, it is crucial to strike a balance between providing adequate information and avoiding potential harm.

Patient comprehension

Information disclosure should be followed by an herbalist to ensure adequate comprehension of the information shared with the patient [29]. Since there exists no standard way of assessing understanding patients' information disclosure, study participants reported assessing comprehension through body language, nonverbal cues, follow-up sessions, asking patients to repeat what the herbalist would have explained and question-answer approaches, and some of these have been reported to be effective methods of ensuring comprehension by patients [30]. Relying on body language aligns with a patient-centered communication approach, fostering trust and reducing the risk of miscommunication. Recognizing patient understanding provides herbalists with an opportunity for immediate clarification, promptly addressing signs of confusion or uncertainty. In cases of limited patient capacity, such as children or those who are mentally unstable, herbalists obtain IC from a competent adult or proxy.

Voluntariness and decision making

Regardless of patient knowledge level, it is reassuring that herbalists feel obligated to educate and guide decision-making through information disclosure and hence facilitate decision-making. Study participants recognize patients' opinions and knowledge, challenging the herbalist's role as the sole decision maker [31] and emphasizing patient autonomy. Shared decision-making (SDM) between herbalists and patients was considered ideal by participants, fostering mutual advice and education during treatment discussions and aligning with SDM's goal of respecting, protecting, and promoting patient autonomy [31, 32]. Decisions were generally guided by community or societal preferences, emphasizing the notion that societal illness is considered a communal concern rather than an individual burden, further exhibiting Ubuntuism and social responsibility. In many African cultures, family values take precedence over individual decision-making, a departure from the common medical practice that tends to prioritize the individual [33]. In 2007, Terry reported that in conflicts between a patient's advance directive and family wishes, more than half of the patients preferred family decisions over their own [20]. Despite the recognized patients' right to make decisions, some patients often prefer not to make decisions independently but desire SDM with family or physicians or entrusting others to decide on their behalf. In addition to the crucial role of sharing treatment information, patient decisions may also be influenced by patient-herbalist relationships and trust, particularly among referred patients familiar with the effectiveness of herbal treatments [3]. Sensitivity to cultural values must always be an important consideration when obtaining IC.

Documentation

Written documentation of ICs is a standard practice in medical practice and research [21]. However, herbalists, as revealed in this study, seldom utilize it for IC but rather utilize verbal consent and in many cases, they embraced implied consent. Verbal consent is a form of explicit consent given orally rather than in writing or through physical gestures. It involves clearly expressed agreement to a proposed action, condition, or arrangement, ensuring that all parties understand and agree to what is being proposed. The dislike for and hence absence of IC forms among herbalists may stem from a lack of writing skills and the perception that signed forms are unnecessary, especially for nonsurgical procedures. This aligns with the perspectives of complementary and alternative medicine (CAM) practitioners by Caspi et al. who viewed the IC process as a legal nuisance [30, 34]. Although some herbalists in this study expressed fear of legal consequences, many relied on trust-based patient-herbalist relationships in close-knit communities. The perceived

impracticality and time consumption of signing consent forms also hindered the fulfillment of some aspects of the informed consent process. Participants in this study highlighted the concept of implied consent, evident in patients accepting referrals and simply visiting the herbalist, signaling agreement with the herbalist's suggestions. Implied consent is a type of consent which is not expressly granted by a person but rather inferred from a person's actions, the facts and circumstances of a particular situation, or, in some cases, by a person's silence or inaction [35]. Therefore, sophisticated procedures such as signing consent forms were considered unnecessary and uncommon. This type of consent aligns with common practices in healthcare, such as patients extending their arms for routine procedures such as blood drawing or blood pressure checks. In such cases, patients are presumed to be aware of the procedure's implications, obviating the need for additional explanations [7, 21, 35]. However, should we consider this kind of consent adequate in herbal medicine? In the case of *Esterhuizen Vs. Administration, Transvaal*, the judge emphasized that "by a man entering a hospital does not submit himself to such surgical treatment as the doctors in attendance upon him might think necessary.... By going to hospital, he does not waive or give up his right of absolute security of a person....." [36]. This means that herbalists should not assume patients agree to whatever treatments and medicines offered, implied consent should not be used as a standard method of informed consent.

Limitations of this study include the absence of observation of herbalists attending patients, hindering the assessment of their informed consent practices. An ethnographic study could address this gap by involving herbalists and observing their daily incorporation of informed consent principles in practice.

Conclusions

Herbalists generally have positive attitudes towards informed consent with a bias to verbal consent and implied consent. It is however imperative to know that implied consent although utilized by many herbalists it should not be used as a legitimate way of obtaining informed consent. It is important for herbalists to be trained the legal and ethical implications of IC, advantages of utilizing documentation. Further research should be conducted exploring patients' experiences and preferences of informed consent with their interaction with herbalists.

Abbreviations

CAM	Complementary and Alternative Medicine
CM	Conventional medicine
HCP	Health Care Provider
IC	Informed consent
IDI	In-depth interviews
KII	Key informant interviews

REC	Research Ethics Committee
SBS	REC School of Biomedical Sciences Research Ethics Committee
TCM	Traditional and Complementary Medicine
THP	Traditional Health Practitioners
TM	Traditional medicine
WHO	World Health Organization

Supplementary Information

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Supplementary Material 1

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Author contributions

N.S: Initiated the concept, contributed to the study design, conducted data collection and analysis, and drafted the manuscript. P.K: Contributed to the conceptualization, study design, reviewed all proposal drafts, participated in data interpretation, and substantially reviewed and revised all manuscript drafts. A.T: Conducted data analysis and interpretation of results, prepared Table 1; reviewed and revised all manuscript drafts. D.K-M: Contributed to data analysis and interpretation of results, reviewed and revised all manuscript drafts. S.K.N: Contributed to the conceptual review, study design, reviewed and guided proposal development, supervised the entire research process, and reviewed all manuscript drafts. All authors approved the final version of the manuscript.

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Data availability

Data availability: The study data have been documented in this manuscript and any further information about the study is available from the corresponding author upon request.

Declarations

Ethics approval

The study received ethics approval from the Makerere University School of Biomedical Sciences Research ethics committee (SBS-File743). Administrative clearance was obtained from Prometra Uganda, and written informed consent was obtained from all participants for participation in the study. Participants' informed consent forms that contained identifying information were kept under lock and key. All transcripts were deidentified, and the results were reported using unique codes that could not be used to identify participants to ensure confidentiality and privacy.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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