Herbal medicine use among pregnant women attending antenatal clinics in Lusaka Province, Zambia: a cross-sectional, multicentre study

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List of Abbreviations

AE	Adverse event
AIDS	Acquired Immune Deficiency Syndrome
FDA	Food and Drug Administration
HIV	Human Immunodeficiency Virus
HM	Herbal medicine
IQR	Interquartile range
SD	Standard deviation
TCAM	Traditional, complementary and alternative medicine
WHO	World Health Organisation

Chapter I – Introduction

The use of herbal medicines has been reported to be increasing across the world, especially among pregnant women [1-3]. Herbal medicines are defined by the World Health Organisation (WHO) as plant-derived materials or products with therapeutic benefits, which contain either raw or processed ingredients from one or more plants [4]. Herbal medicine use during pregnancy raises several concerns, which can be attributed to the herbal ingredient itself, interactions between a herbal product and a conventional medicine, and contamination of herbal products by unlabelled toxins. More importantly, there is still a significant lack of evidence regarding the potential harmful effects of herbal medicines on both the mother and the fetus [5].

Previous research has shown that herbal medicine use during pregnancy is quite common across sub-Saharan Africa [6]. However, in several sub-Saharan African countries including Zambia, there is a paucity of data on the use of herbal medicines among pregnant women. Accordingly, the present study aimed at determining the prevalence of herbal medicine use and the patterns of use among pregnant women attending antenatal clinics in Lusaka Province, the most populated province of Zambia. This study is of particular importance since it expands existing yet limited knowledge on a health practice that is culturally acknowledged in Zambia, yet largely unreported.

Prior to presenting the article, the following introduction presents an in-depth literature review which aimed to provide the best available information on herbal medicine: its definition, usage, regulations, and challenges. This review identified the prevalence of herbal medicine use during pregnancy across different regions and countries, as well as the indications and adverse outcomes of the most commonly used herbal medicines during pregnancy.

1. Traditional, complementary and alternative medicine (TCAM) — definition, prevalence and reasons for use

Traditional, complementary and alternative medicine (TCAM) can be loosely defined as a broad set of health care practices (indigenous or imported) that are not integrated into the mainstream health care system, used to maintain health, as well as to prevent, diagnose or treat physical and mental illnesses [7]. The use of TCAM has been gaining popularity worldwide. Several studies have reported that the prevalence of TCAM usage among adults in high-income countries ranges from 5.0% to 76.0% [8, 9]. In the United States, for instance, the proportion of adults using some form of TCAM was approximately 35% in both 2007 and 2012 [10]. In Europe, it was estimated that nearly 26% of the general population had used TCAM during the last 12 months [11].

Sub-Saharan Africa is one region of the world in which TCAM is traditionally and culturally acknowledged [12]. A recently published systematic review found a 58.2% average prevalence of TCAM use in the general sub-Saharan African population [12]. In many parts of sub-Saharan Africa, traditional medicine defines illness as a consequence of a breakdown of social balance (e.g., breaking codes of conduct in the present or in the past), ancestor spirits, as well as evil spirits [13]. Thus, African traditional medicine in its varied forms is holistic involving both the body and the mind [14]. Indeed, the most frequently used TCAM modalities in sub-Saharan Africa have been found to be herbal medicine, followed by faith-based healing practices (prayers/spirituality), and mind-body interventions (massage, traditional bone setting, mediation, and yoga) [12].

Although there are several common reasons motivating people to use TCAM, there are also many differences between individual countries and regions [7]. For instance, in Europe, typical motivations for TCAM use include dissatisfaction with medical doctors or Western

medicine, not wanting to take conventional drugs with associated side effects, a preference for natural care, a desire for more personalised and holistic care, preventive care, as well as improvements in subjective well-being [15]. In contrast, the widespread use of TCAM in sub-Saharan Africa can be mainly attributed to its affordability, flexibility of payment of TCAM products and services, and accessibility [12]. For instance, the ratio of traditional healers to the population in sub-Saharan Africa is 1:500, whereas the ratio of medical doctors to the population is 1:40,000, and most medical doctors are concentrated in urban areas and cities at the expense of rural areas [16]. Besides accessibility to traditional healers, TCAM practice was shown to be in line with the sociocultural, religious and spiritual values of the people who use it in sub-Saharan Africa [12].

2. Herbal medicine — definition, and methods of preparation and administration

As previously mentioned, herbal medicine represents the most commonly used form of TCAM across sub-Saharan African [14]. The WHO defines herbal medicines as plant-derived material or preparations perceived to have therapeutic benefits, containing raw or processed ingredients from one or more plants [4]. Herbal medicines include herbs, herbal materials, herbal preparations, and finished herbal products that contain parts of plants, other plant materials including leaves, barks, flowers, stems and roots, or combinations thereof as active ingredients [7]. Herbal remedies are currently used across different countries for the treatment of various chronic and acute conditions, including but not limited to cardiovascular diseases, prostate problems, depression, inflammation, insomnia, and to boost the immune system [17].

Herbs can be taken in different ways, using either fresh or dry plant materials [17, 18]. Apart from common routes such as oral, rectal, topical, and nasal, other administration methods of herbal medicines include smoking a crudely prepared cigar containing dried plant materials or by

passive inhalation. Others are steaming and inhaling the volatile essential oils arising from boiling plant materials. These can be used to relieve congestion, respiratory symptoms, or headaches. In addition, sitz baths can be used to relieve haemorrhoid symptoms [18].

Herbal extracts vary in the extraction temperature, time, and solvent [17]. They include infusions which are prepared by macerating the fresh or dried plant material for a short period of time in cold or boiling water, decoctions which are long-term boiled extracts of usually roots or barks, and tinctures which are alcoholic extracts. Other types of herbal preparations include lotions which are liquid preparations intended for skin application, porridges made from grains to which dried powdered plant materials are added to be taken orally, and capsules and tablets containing a ground or powdered form of a raw herb or its dried extract [17, 18]. Mixtures are prepared with at least two different plants to give a synergistic or a potentiating effect of the composite plants [18]. In many areas of sub-Saharan African, secrecy surrounds the practice of herbal medicine, with the components and preparation methods of herbal medicines, especially those intended for the treatment of serious ailments such as malaria and HIV/AIDS, exclusively residing with traditional healers [18, 19].

3. Medicinal plants — definition, health benefits, and toxicity

Plants used for their medicinal properties are generally referred to as medicinal plants, i.e., any plant which, in one or more of its parts, contains substances that can be used for therapeutic or prophylactic purposes or which are precursors for chemo-pharmaceutical semi-synthesis [20]. The therapeutic activity of a medicinal plant is due to its complex chemical nature; a single plant may contain more than 100 phytochemicals (e.g., alkaloids, glycosides, tannins, acids, coumarins, sterols, and phenols) responsible for various and specific therapeutic effects [18]. The same plant may, for example, contain anti-bacterial and anti-fungal tannins, diuretic substances that enhance

the elimination of waste products and toxins, alkaloids that enhance mood and give a sense of well-being, and phenols that can act as antioxidants and venotonics [21].

Many modern pharmaceuticals have been modelled on or were originally derived from phytochemicals [18]. Examples include: the cardiac stimulant digoxin from foxglove (*Digitalis purpurea* L.), aspirin synthesised from salicylic acid derived from white willow bark (*Salix alba* L.), and antimalarials such as quinine from the bark of *Cinchona pubescens* Vahl and artemisinin from sweet wormwood (*Artemisia annua* L.) [17, 18]. Moreover, it is estimated that more than 60% of anti-cancer drugs on the market or in testing are based on medicinal plants. For instance, vincristine and vinblastine are derived from Madagascar periwinkle (*Catharanthus roseus* (L.) G. Don), paclitaxel from the Pacific yew tree (*Taxus brevifolia* Nutt.), and camptothecin from the Chinese *Camptotheca acuminata* Decne tree [22]. Medicinal plant extracts are also widely used as active ingredients in the cosmetic industry [18].

Despite the major hypothetical advantage of medicinal plants which is the presence of multiple active compounds that work together synergistically and catalytically to produce a combined effect surpassing the total activity of the individual constituents [14], medicinal plants can also be poisonous, affecting the entire human body, with some plants containing several toxic compounds acting on different organ systems. Indeed, plants usually contain substances that act as defence chemicals against predators. Despite having medicinal properties at lower concentrations, these defensive chemicals can be poisonous resulting in adverse or lethal effects in humans. Examples of chemical defensive compounds are alkaloids, terpenoids, cardiac glycosides, lectins, and cyanogenic glycosides which are classified as extremely toxic [23]. For instance, jequirity bean (*Abrus precatorius* L.) and physic nut (*Jatropha curcas* L.), which are used in traditional medicine as treatments for bacterial and fungal infections, contain lectins which are

responsible for gastrointestinal problems such as diarrhoea and vomiting [23]. Similarly, the plant ma huang (*Ephedra sinica* Stapf), traditionally used in Chinese medicine for the treatment of central nervous, cardiovascular, and respiratory system diseases, can cause serious conditions such as stroke, infarction, and other heart complications due to its alkaloid constituents [24].

However, in TCAM, plants with toxic constituents are usually known, and are avoided or used cautiously in herbal product formulations (i.e., below toxic levels) [25]. Nevertheless, the fact that there are several plants used in African traditional medicine, for which little information is available on their constituents, can increase the risk of adverse reactions, particularly in vulnerable groups such as older adults, children, and pregnant women [18, 25].

4. Herbal medicine — challenges and regulations

According to the WHO, there are several challenges associated with the herbal medicine practice, which are related to regulatory status, assessment of safety and efficacy, quality control, safety monitoring, and lack of knowledge about TCAM within national drug regulatory authorities [26].

The diversity of herbal remedies and their uses between different countries makes scientifically evaluating and regulating them very challenging [17]. Hence, in some countries, herbal medicines are subjected to rigorous manufacturing standards, while in others, they are regarded as food supplements for which therapeutic claims are prohibited. For example, in Europe, the Directive 2001/83/EC and the Directive 2004/24/EC divide herbal medicines into two categories: “well-established herbal medicinal products” and “traditional herbal medicinal products”. For the first category, it is needed to demonstrate with sound bibliographic data that the herbal medicinal product has a well-established medicinal use with recognised efficacy and an acceptable level of safety. The time of accepted medicinal use in the European Union must be at least 10 years. For the second category, manufacturers of herbal medicines are required to

demonstrate that the safety and effectiveness of the traditional herbal medicinal product are based on long-standing medicinal use: 30 years worldwide, including at least 15 years in the European Union [17]. In the United States, by contrast, the Dietary Supplement Health and Education Act of 1994 classifies herbal products as dietary supplements, a product category that does not require pre-approval. Consequently, the manufacturer is responsible for ensuring that a herbal product is safe before it is marketed, and the Food and Drug Administration (FDA) can only take regulatory action against any unsafe herbal product after it reaches the market. Therefore, in contrast to prescription and newer over-the-counter medications, herbal products in the United States are usually marketed without the benefit of clinical trials to demonstrate either efficacy or safety [5]. In sub-Saharan Africa, the development of national policies and regulations for herbal medicines is substantially more limited, resulting in the proliferation of both locally produced and imported herbal remedies of dubious quality, safety, and efficacy [26]. For instance, in Zambia, although the Medicines and Allied Substances Act of 2013 mandates the Zambia Medicines Regulations Authority to regulate and control the sales of herbal medicines, there is neither a system of registration nor a post-marketing surveillance system for herbal medicines [26, 27].

Besides the use of inherently toxic medicinal plants, the toxicity problems of herbal medicines can be attributed to a lack of proper standardization and quality control in the formal herbal industry [18, 25]. Indeed, there is a close correlation between the safety and efficacy of herbal medicines and the quality of the source materials used in their production. The quality of source materials is, in its turn, determined by intrinsic (genetic) and extrinsic (environmental) factors (e.g., light exposure; water availability; temperature of processing; period, time and method of harvest; drying, packing, transportation and storage of raw herbal material, etc.). It is hence very difficult to perform quality controls on the raw materials of herbal medicines, especially given that

many countries lack operative machinery needed to implement good manufacturing practices [26]. In addition, there is very little research on whole herbal mixtures partially because the drug approval process does not accommodate undifferentiated mixtures of natural chemicals. To isolate every active ingredient from each herb would be extremely costly and time-consuming, and thus impossible in practice [17]. Another source of toxicity of herbal medicines that is important to mention is adulteration of herbal products with undeclared pharmaceutical drugs and other potentially toxic compounds such as other botanicals, pathogenic microorganisms, toxins, pesticides, agrochemical residues, and heavy metals (e.g., lead, mercury, arsenic) [25, 28]. For example, the FDA found that several products that were promoted as natural and dietary supplements to enhance sexual performance contained up to five of different hidden ingredients, such as sildenafil, tadalafil, dapoxetine, desmethyl thiosildenafil, thioaildenafil, aildenafil, vardenafil [29, 30]. Incorrect identification of plants may also lead to toxicity. Furthermore, toxicity may arise as a result of herb-drug interactions [18]. Herbs may change the pharmacokinetics of co-administered drugs by altering the drug's absorption (e.g., modulation of uptake and efflux transporters, complex formation, alterations in gastrointestinal motility and pH), distribution, metabolism (e.g., inhibition or induction of metabolic enzymes), or elimination/excretion [31]. For example, it has been shown that a pharmacokinetic interaction exists between the antimalarial drug amodiaquine and *Moringa oleifera* Lam., a commonly used medicinal plant with multiple health benefits, when given together or following a long period of ingestion of *Moringa oleifera* Lam. In the presence of *Moringa oleifera* Lam., the peak plasma concentration of amodiaquine decreased by up to 40%, as well as its area under the plasma concentration-time curve which decreased by approximately 11%, leading to a significantly delayed absorption of amodiaquine [31]. Overall, making a diagnosis of herbal toxicity can be

difficult. Even when herbal-related toxicity is suspected, a definitive diagnosis is difficult to establish without proper analysis of the product or plant material [18].

Because of the potential toxicity and safety concerns related to herbal products, there is a need to establish a pharmacovigilance system of herbal medicines that is integrated within communities and health facilities, so that data regarding their composition, preparation, indications, and side effects can be gathered [32]. The latency period between the use of a herbal product and the occurrence of an adverse event should also be determined, if possible, as this can help in causality assessment in pharmacovigilance management. Such information can facilitate decisions on further protective measures to be taken concerning the future use of herbal medicines [18]. Research is also needed to meet the challenges of identifying the active compounds in the plants, and there should be research-based evidence on the safety and efficacy of both whole herbs and extracted compounds [17].

Regrettably, the expanding herbal product market could drive overharvesting of plants and threaten the rich biodiversity in sub-Saharan Africa. In addition, poorly managed collection and cultivation practices could lead to the extinction of endangered plant species and the destruction of natural resources [17]. It has been suggested that 15,000 medicinal plant species are threatened with extinction [22]. Another negative consequence of this trend is that there will be essentially less choice for the future development of medicines, if the situation is not addressed [22]. Under these circumstances, forest laws are of considerable importance, as they have a role in ensuring the sustainable availability of medicinal plants. A number of countries in sub-Saharan Africa have enacted forest laws, including the Lesotho Forestry Act of 1978, the Tanzania Forest Act of 2002, the Namibia Forest Act No. 12 of 2001, the Mozambique Forest and Wildlife Act of 1999, the South Africa National Forests Act No. 84 of 1998, the Zambia Forests Act of 1999, and the

Zimbabwe Forest Amendment Act of 1999 [33]. However, like other existing laws, these forest laws have deficiencies, such as failure to link the forest sector development with economic and social development objectives, weak forest administrative structures, low or poor compensation being given to the local communities that are custodians of the forest resources, poor definition of legal and institutional frameworks regarding forest management and use, and land tenure problems [33]. Hence, more international efforts are needed for the preservation of plant populations.

5. Herbal medicine use during pregnancy

Pregnancy is characterised by significant physiological changes resulting in various symptoms, such as nausea, vomiting, heartburn, and constipation. These ailments often cause pregnant women to resort to self-medication including the use of herbal medicines [3]. Consequently, the use of herbal medicines has grown considerably worldwide among pregnant women [1-3]. The prevalence of herbal medicine use during pregnancy varies significantly, depending on the geographic location, ethnicity, cultural traditions, and socioeconomic status [34]. In a multinational, cross-sectional, internet-based study [1] conducted among 9,459 pregnant women from 23 countries in Western Europe (n=3,201), Northern Europe (n=2,820), Eastern Europe (n=2,342), North America (n=533), South America (n=346) and Australia (n=217), 28.9% of women reported herbal medicine use during pregnancy. Russia (69.0%), Poland (49.8%), and Australia (43.8%) had the highest reported rates of herbal medicine users [1]. The prevalence of herbal medicine use in pregnancy has also been reported in various other countries, including Iran (49.2%) [35], Egypt (27.3%) [36], Bangladesh (70.0%) [32], Iraq (53.7%) [37], Palestine (40.0%) [38], and Taiwan (33.6%) [39]. Similarly, evidence from sub-Saharan Africa suggests wide variability in the use of herbal medicines during pregnancy, from 2.0% as reported in a study conducted in the Tigray Region, Northern Ethiopia [40] to 100% according to another study in

Machakos District, Eastern Kenya [41]. It is difficult to ascertain whether these differences in prevalence across studies are caused by variability in study design, setting, data collection, and sampling techniques or whether they represent true differences in herbal medicine use [1, 42].

The indications for the use of herbal medicines during pregnancy may vary across regions and countries, and can be either mother- or child-related [34]. Herbal medicines may be used sometimes as part of maternal care to treat pregnancy-related problems, and often to improve the well-being of the mother and/or unborn child. The most commonly reported indications have been found to be nausea and vomiting, urinary tract infections, preparation for and/or facilitation of labour, common cold or flu, gastrointestinal problems (e.g., constipation, flatulence), pain conditions, improvement of foetal outcomes, prevention of miscarriage, anxiety, general health maintenance, anaemia, and oedema [1, 3, 6, 34]. The popularity of herbal medicines among pregnant women can be mainly attributed to the belief that herbal products, being natural, are safe with fewer adverse events compared to conventional drugs [43-45]. Additionally, several studies have shown that pregnant women in low- and middle-income settings, including sub-Saharan Africa, use herbal medicines because they consider them less costly and more accessible than conventional drugs [2, 32, 45].

As previously mentioned, safety concerns related to herbal products can be mainly attributed to the herbal ingredient itself, conventional drug-herbal medicine interactions, and contamination or adulteration of herbal remedies with potentially toxic compounds such as heavy metals [5]. However, herbal medicine use during pregnancy raises particular concerns, because many herbal products are specifically marketed for symptoms that occur commonly during pregnancy, such as nausea and vomiting [5, 46]. More importantly, there is a lack of data on the efficacy and safety of herbal medicine use during pregnancy, and the use of unstudied herbal agents

with unknown pharmacologic activity can pose a potential risk to both the pregnant women and their foetuses [32, 46]. In a 2004 study investigating herbal medicine use during pregnancy among 400 Norwegian women, approximately 40% of the 144 herbal medicine users consumed herbal products that were either potentially harmful or with missing information about their safety in pregnancy [47]. Similarly, in a large, multinational study which classified 126 different herbal medicines used in pregnancy according to their safety, only 28 herbs (22.2%) were deemed as safe to use in pregnancy based on current literature [48]. More recently, a systematic review, which aimed to determine whether herbal medicinal use during pregnancy was associated with adverse maternal or child outcomes, found that topical use of almond oil was significantly associated with preterm birth, oral raspberry leaf with caesarean delivery, and heavy liquorice consumption (greater than 500 mg/week) with early preterm birth [49]. In addition, the use of herbal medicines in pregnancy constitutes a major challenge for health care providers, since pregnant women often consume herbal medicines without consulting them [34]. Hence, in order to further advance research on the benefits and adverse effects of herbal medicine use during pregnancy, it is important to determine the extent of herbal medicine use during pregnancy in different settings and to find out which herbs pregnant women use.

6. Most commonly used herbal medicines during pregnancy

Due to differences in culture, traditions and climate, it is expected that herbal medicines used during pregnancy vary across countries and regions. In the multinational study by Kennedy et al. (2013) [1] in 9,459 pregnant women from 23 countries in Europe, North and South America and Australia, the most frequently used herbal medicines were *Zingiber officinale* Roscoe (ginger), *Vaccinium oxycoccus* L./*Vaccinium macrocarpum* L. (cranberry), *Valeriana officinalis* L. (valerian), *Rubus idaeus* L. (raspberry leaf), *Matricaria chamomilla* L. (chamomile), and *Mentha*

piperita L. (peppermint) [1]. The African continent, generally known for its rich biodiversity, has an estimated total flora of over 70,000 species [50]. This species richness was reflected in a systematic review by Ahmed et al. (2018) which aimed to assess the prevalence and diversity of herbal medicine use among 22,404 pregnant or lactating women across Africa [6]. In the review, a total of 274 different medicinal plant species from 87 plant families were reported to be used during pregnancy [6]. The most commonly cited medicinal plant species were *Zingiber officinale* Roscoe (ginger), *Allium sativum* L. (garlic), *Cucurbita pepo* L. (pumpkin), *Vernonia amygdalina* Delile (bitter leaf), *Ricinus communis* L. (castor oil), *Garcinia kola* Heckel (bitter kola), *Ocimum lamiifolium* Hochst. ex Benth. (Dama Kesse, in Amharic), *Azadirachta indica* A. Juss (neem), *Ruta chalepensis* L. (Tena Adam, in Amharic; fringed rue in English), and *Aloe vera* (L.) Burm.f. (*Aloe vera*) [6]. Table 1 presents the most commonly used herbal medicines during pregnancy, based on the Kennedy et al. [1] multinational study and the Ahmed et al. [6] systematic review.

Table 1. Most commonly used herbal medicines during pregnancy: indications and reported adverse events

Common name(s)	**Binomial name(s)**	**Indication(s)**	**Adverse events**	**References**
Ginger	*Zingiber officinale* Roscoe	Nausea, vomiting	Drowsiness, reflux, vomiting, heartburn, headache, abdominal discomfort, preterm delivery, smaller head circumference of newborns	[51-53]
Cranberry	- *Vaccinium oxycoccos* L. - *Vaccinium macrocarpon* L.	Urinary tract infections	Gastrointestinal upset, spotting in the second and third trimesters	[51, 52, 54]
Valerian	*Valeriana officinalis* L.	Sleep disorders	Diarrhoea	[55]
Raspberry leaf	*Rubus idaeus* L.	Nausea, increase in milk production, labour induction	Hypoglycaemia, higher percentage of cesarean deliveries versus non-users	[38, 56, 57]
Chamomile	- *Matricaria chamomilla* L. - *Chamaemelum nobile* (L.) All.	Gastrointestinal irritation, insomnia, joint pain, relaxation	Breast engorgement and tenderness, low birth weight, preterm delivery	[38, 53, 58]

Common name(s)	Binomial name(s)	Indication(s)	Adverse events	References
Peppermint	*Mentha piperita* L.	Nausea, vomiting, flatulence, indigestion, irritable bowel syndrome	Heartburn, dry mouth, belching, rash, dizziness, headache	[38, 59]
Garlic	*Allium sativum* L.	Prophylaxis of preeclampsia, preterm birth prophylaxis, enhancing the immune system	Foul odour, nausea	[60-62]
Pumpkin	*Cucurbita pepo* L.	Nutritional supplement, cough, fever, common cold, headache, heartburn, gastrointestinal irritation, oedema	No adverse events were identified in the literature	[6, 63]
Bitter leaf	*Vernonia amygdalina* Delile	Nausea, vomiting, fever, constipation, increasing appetite	Stimulation of uterine motility	[64]
- Castor oil - Castor bean	*Ricinus communis* L.	Inducing labour	Nausea	[52, 65]
Bitter kola	*Garcinia kola* Heckel	Nausea, vomiting	Weight loss, prolonged sleep duration, increased libido	[6, 66]
Dama Kesse (in Amharic)	*Ocimum lamiifolium* Hochst. ex Benth.	Headache, fever, inflammation, joint pain, back pain, common cold, cough	No adverse events were identified in the literature	[67]
- Neem - Nimtree - Indian lilac	*Azadirachta indica* A. Juss	Inducing labour, malaria, pain, haemorrhoids, enhancing foetal development	Vomiting, metabolic acidosis, encephalopathy	[6, 68, 69]
- Tena Adam (in Amharic) - Fringed rue	*Ruta chalepensis* L.	Nausea, vomiting, common cold, abdominal discomfort	Sedation, drowsiness	[6, 70]
Aloe vera	*Aloe vera* (L.) Burm.f.	Digestive problems, constipation, skin treatment	Itching, rash	[6, 71, 72]

7. Studies on herbal medicine use during pregnancy in sub-Saharan Africa

Studies conducted across sub-Saharan Africa have shown that herbal medicine use during pregnancy is widespread, but they also highlight research gaps in prevalence, patterns of use, women's perceptions and knowledge about medicinal plants, and predictors of herbal medicine

use [6, 73, 74]. In the previously mentioned systematic review by Ahmed et al. (2018) of 50 studies including a total of 22,404 African pregnant or lactating women, the average prevalence of herbal medicine use during pregnancy among the different African regions was between 32% (in Central Africa) and 45% (in East Africa) [6]. This systematic review [6] also found that herbal medicine use during pregnancy was statistically significantly associated ($p<0.05$) with a lower educational level, increasing age, being married, low socioeconomic status, lower educational level of the spouse, poor pregnancy outcomes, herbal medicine use in prior pregnancies, perception that medicinal plants are effective, large family size, self-employment, unemployment, and rural residence [6]. Table 2 illustrates the characteristics and findings of selected cross-sectional studies evaluating the use of herbal medicines among pregnant women in different sub-Saharan countries.

Table 2. Characteristics of cross-sectional studies evaluating herbal medicine use during pregnancy in sub-Saharan Africa

Authors and year of publication	Study setting	Sample size	Prevalence of use	Types of medicinal plants used	Indications	Characteristics of users	Disclosure of herbal medicine use to health care providers
Banda et al. (2007) [75]	Lusaka, Zambia	1,128	21%	Not reported	Not reported	- Users were not different from non-users in terms of age, education, ethnicity or income - Users were more likely to drink alcohol during pregnancy, have at least two sex partners, engage in "dry sex", initiate sex with their partner, report a previously treated sexually transmitted disease, and use contraception (all $p<0.01$)	64% of users did not want to share their use of herbal medicine to health care providers
Maluma et al. (2017) [76]	Lusaka Province, Zambia	273	32%	Indigenous local plants: "*Moono"*, *"Makole"*, "*Mulolo", "Sope"*	Inducing or accelerating labour	- Herbal medicine use in pregnancy was not associated with area of residence, age or education level - Sociocultural beliefs were the major factors that contributed to the use of herbal medicine during pregnancy - Most users were unaware of health risks associated with administering crude herbal extracts during different trimesters of pregnancy	Not reported
James et al. (2018) [42]	Freetown, Sierra Leone	134	62.7%	*Luffa acutangula* (L.) Roxb., lime leaves (*Citrus aurantiifolia* (Christm.) Swingle), ginger	Urinary tract infections, pedal oedema, to improve foetal outcomes	- Pregnant women who identified as Muslims were 3.4 times more likely ($p=0.006$) than Christian women to use herbal medicine - Perceived effectiveness and safety of herbal medicines over conventional	95.2% of users did not disclose their herbal medicine use to their conventional health care providers

Authors and year of publication	Study setting	Sample size	Prevalence of use	Types of medicinal plants used	Indications	Characteristics of users	Disclosure of herbal medicine use to health care providers
						medicines (70.2%) was the main reason for use	
Mureyi et al. (2012) [77]	Harare, Zimbabwe	248	52%	*Pouzolzia mixta* Sohms, cocktails of unknown herbs, okra (*Abelmoschus esculuntus* (L.) Moench)	For widening of birth canal, labour induction, nutritional supplement	- Herbal medicine use in pregnancy was significantly associated with being in the 20–25 age group (p=0.021), nulliparity (p=0.004), nulligravidity (p=0.002), and residing in a high-density neighbourhood (p=0.04) - Almost all herbal medicine interventions were employed from the beginning of the third trimester	Not reported
Mawoza et al. (2019) [78]	Rural Zimbabwe	398	69.9%	*Fadogia ancylantha* Schweinf., okra (*Abelmoschus esculuntus* (L.) Moench), chir pine (*Pinus roxburghii* Sarg.)	To facilitate childbirth, for widening of birth canal	No association was noted between herbal medicine use and any sociodemographic characteristic	Not reported
Godlove (2011) [79]	Mbeya, southwest Tanzania	400	55%	Not reported	Labour induction, to improve foetal outcomes	- The use of herbal medicines during pregnancy was associated with long distance to the nearest public health facility, and low education level (all p≤0.01) - The insufficient effectiveness of conventional medicines (64.1%) and the accessibility of herbal medicines (30.5%) were reported as the main reasons for use	Not reported

Authors and year of publication	Study setting	Sample size	Prevalence of use	Types of medicinal plants used	Indications	Characteristics of users	Disclosure of herbal medicine use to health care providers
Bayisa et al. (2014) [2]	Nekemte, Western Ethiopia	250	50.4%	Ginger, garlic, Tena Adam (*Ruta chalepensis* L.), eucalyptus (*Eucalyptus globulus* Labill.)	For treatment of nausea, morning sickness, vomiting, cough	- Age, educational status, marriage, ethnicity, and source of information were not associated with herbal medicine use - About 70% of users were pregnant women on their first trimester	Not reported
Laelago et al. (2016) [73]	Hossana, Southern Ethiopia	363	73.1%	Garlic, ginger, Tena Adam (*Ruta chalepensis* L.), Dama Kesse (*Ocimum lamiifolium* Hochst. ex Benth.), eucalyptus (*Eucalyptus globulus* Labill.)	Management of nausea, vomiting, abdominal pain, common cold	Being in the first trimester of pregnancy, having less education, and having less knowledge about herbal medicine favoured the use of medicinal plants	Not reported
Mekuria et al. (2017) [80]	Gondar, Northern Ethiopia	364	48.6%	Ginger, Dama Kesse (*Ocimum lamiifolium* Hochst. ex Benth.)	Common cold, inflammation	- Rural residency, having no formal education, and having an average monthly income <100 United States Dollars were found to be strong predictors of herbal medicine use - 68.4% of users consumed herbal medicines during their third trimester	89.8% of users had not consulted their doctors about their herbal medicine use
Fakeye et al. (2009) [81]	North Central, North West, and South West, Nigeria	595	67.5%	Not reported	Not reported	- Age (p=0.003), geographical zones (p=0.02), and educational status (p=0.04) were significantly associated with herbal medicine use - Users used medicinal plants because they perceived them as being more	Not reported

Authors and year of publication	Study setting	Sample size	Prevalence of use	Types of medicinal plants used	Indications	Characteristics of users	Disclosure of herbal medicine use to health care providers
						effective than conventional medicines (22.4%), and safe (21.1%) - 56.6% of participants did not support combining herbal medicines with conventional medications to forestall drug-herb interaction	
Tamuno et al. (2010) [82]	Kano, North West Nigeria	500	31.4%	Ginger, garlic	Not reported	- Use of herbal medicine was significantly associated with no formal education and low socioeconomic status ($p<0.05$ for both) - Over 40% of women reported combined use of herbs and drugs	Not reported
Duru et al. (2016) [83]	Owerri, South East Nigeria	500	36.8%	Bitter leaf (*Vernonia amygdalina* Delile), palm kernel oil (derived from *Elaeis guineensis* Jacq.), bitter kola (*Garcinia kola* Heckel)	Not reported	Being married ($p<0.001$), having no formal education ($p<0.001$), and having a monthly income >250 United States Dollars ($p=0.003$) were significantly associated with herbal medicine use during pregnancy	Not reported
Nergard et al. (2015) [74]	One urban and two rural regions, Mali	209	79.9%	*Lippia chevalieri* Moldenke, *Combretum micranthum* G. Don, *Parkia biglobosa* (Jacq.) R.Br. ex G.Don, *Vepris heterophylla* (Engl.) Letouzey	For general well-being, to treat malaria symptoms, oedema, urinary tract infection, tiredness	- Sociodemographic characteristics were not associated with the use of herbal medicines - Frequent use of herbal medicines was reported during the first semester	Pregnant women used herbal preparations without any supervision from their health care providers
Mothupi (2014) [84]	Nairobi, Kenya	333	12%	Not reported	To treat toothache, back	- The use of herbal medicine was associated with a lower level of	Only 12.5% of users disclosed the use of

Authors and year of publication	Study setting	Sample size	Prevalence of use	Types of medicinal plants used	Indications	Characteristics of users	Disclosure of herbal medicine use to health care providers
					pain, flu, indigestion, swollen feet	education (p=0.007), and use before the index pregnancy (p<0.001) - 51% of users reported use of combined herbs with pharmaceutical drugs	herbal medicines to health care professionals
Nyeko et al. (2016) [85]	Gulu District, Northern Uganda	383	20.4%	Local herbs (not reported)	To treat abdominal/waist pain, fever, skin problems, nausea and vomiting, and for induction of labour	- Women who used herbal medicines in their previous pregnancies were 8 times more likely to use them during the current pregnancy - Residing more than 5 km from the nearest health facility was associated with increased herbal medicine	89.7% of herbal medicine users did not disclose the use of local herbs to their health care providers
Adusi-Poku et al. (2015) [86]	Offinso North District, Ghana	384	6.5%	*Senna occidentalis* (L.) Link, *Sida acuta* Burm.f., *Cola gigantea* A.Chev.	To ease labour and to improve foetal outcomes	High usage was found among married women, and among those with no formal education, and women with median age of 25 years	Not reported

8. The Zambian context

Zambia is a landlocked country in Southern Africa with a population of approximately 18 million. Zambia has both a high under-five mortality rate (57.8 deaths per 1,000 live births) and a high maternal mortality rate (213 deaths per 100,000 births). Total fertility rate is 4.7 children born per woman, and HIV/AIDS is considered the leading cause of death, followed by neonatal disorders and lower respiratory infections [87].

Zambia is an ethnically diverse country, with a total of 73 ethnic tribes. English is Zambia's main official language; however, an estimated 70 local languages are spoken in Zambia, among which seven have official status: Bemba, Nyanja, Lozi, Tonga, Kaonde, Luvale, and Lunda [88]. Approximately 75% of the Zambian population is Protestant, while about 20% follow Roman Catholicism. Zambia is divided into ten provinces, namely: Central, Copperbelt, Eastern, Luapula, Lusaka, Northern, Muchinga, North Western, Southern, and Western. Lusaka is the capital city of Zambia and the seat of government [89].

Although it is the smallest province, Lusaka Province is the most populated of all the ten provinces of Zambia, with a population of over 3 million [89]. Lusaka Province covers 21,8961 km^2, with eight districts, namely: Lusaka, Kafue, Chongwe, Luangwa, Chirundu, Chilanga, Shibuyunji, and Rufunsa. In 2010, it was estimated that 79.7% of Lusaka's population is concentrated in its smallest district, Lusaka District, with a population of 1,747,152. In Lusaka Province, the Bemba form the largest ethnic group at 20.2%. Nyanja (61.9%) and Bemba (17.6%) are currently the most spoken languages in Lusaka Province [90].

Traditional medicine represents an important part of health practices in Zambia. The number of traditional healers in Zambia has been estimated to be 40,000 in comparison to 1,500 medical doctors [91]. The Zambian traditional healer is called *ng'anga* [92]. Traditional healers in

Zambia are of four different types: herbalists (specialising in the use of medicinal plants to treat various ailments), spiritualists (who can communicate with spiritual forces, such as ancestors, spirits, and deities), diviners (who can predict the future), and traditional birth attendants (who assist women during delivery and in the immediate postpartum period) [18, 92]. According to Ozioma and Chinwe (2019), there are six major types of herbal treatment in Zambia: drinking, eating, drinking as porridge, making small cuts on the skin and applying the herb, bathing with herbs, and steaming with boiling herbs [18].

9. Study rationale

The study of herbal medicine use which is related to maternal health, a public health priority in many sub-Saharan African countries including Zambia, has been limited [6]. To our knowledge, only two studies have been carried out in Zambia to investigate the use of herbal medicine during pregnancy [75, 76]. The first study, conducted by Banda et al. (2007) [75], found that 30% of 1,228 pregnant women surveyed in Lusaka, Zambia reported visiting a traditional healer in the past and 21% during their current pregnancies. However, this study examined the use of traditional medicine as a whole and not specifically herbal medicine use, and it did not assess the types of medicinal plants used nor the reasons for their use [75]. The second study by Maluma et al. (2017) [76], conducted among 273 pregnant women, reported that 32% of study participants used herbal medicines mainly for inducing or accelerating labour. In this study, various local names of indigenous plants were mentioned, such as *"moono"* leaves and roots, *"makole"* roots and leaves, *"mulolo"* roots, and "*sope*" leaves [76]. However, these medicinal plants were not botanically identified, and the study was carried out in only two towns of Lusaka Province (Kanakantapa and Chawama). Thus, the findings may not be generalisable to the entire province [76].

Hence, there remains a significant need to understand the extent to which herbal medicines are used in pregnant women in Zambia, the specific plants used, the reasons for which they are used, and factors which may predict which women in Zambia are most likely to use herbal and other natural products. The present study aims at filling this knowledge gap by describing the use of herbal medicines by pregnant women in Lusaka Province, the most populated province of Zambia. This study hopes to enable health care personnel all across Zambia to give proper counselling and relevant information to pregnant women to keep both them and their unborn babies safe.

10. References

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Chapter II – Paper:

Herbal medicine use among pregnant women attending antenatal clinics in Lusaka Province, Zambia: a cross-sectional, multicentre study

Research Article

Herbal medicine use among pregnant women attending antenatal clinics in Lusaka Province, Zambia: a cross-sectional, multicentre study.

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Abstract

Background: We aimed to determine the prevalence and patterns of herbal medicine (HM) use during pregnancy in Lusaka Province, Zambia.

Methods: A survey-based, cross-sectional, multicentre study was conducted in 446 adult pregnant women attending antenatal clinics in June/July 2019.

Results: 57.8% of participants reported using HM during their current pregnancy, with a mean of 2.0±1.5 remedies/woman. HM use was significantly associated with conventional medicine use ($p=0.032$), HM use in prior pregnancies ($p<0.001$), and willingness to use HM in the future ($p<0.001$). Most commonly used herbs were lemon for nausea/vomiting and common cold, soybean to boost energy, ginger for common cold and nausea/vomiting, and *Aloe vera* for skin care. The perceived safety of HM (37.6%) and its complementary action with conventional medicines (35.3%) were the main reasons for HM use.

Conclusions: Given the widespread use of HM, Zambian health care providers should educate pregnant women on risks and benefits of HM.

Keywords: Herbal medicine, Pregnancy, Maternal health, Lusaka Province, Zambia.

Highlights

- Herbal medicine use among pregnant women attending antenatal clinics in Lusaka Province, Zambia was widespread, at a prevalence of 57.8%.
- A wide range of herbal medicines was used, and in at least two trimesters of pregnancy.
- Herbal medicine use was significantly associated with conventional medicine use, herbal medicine use in prior pregnancies, and willingness to use herbs in the future.
- More than two-thirds of users did not disclose their herbal medicine use to health care providers.
- It is necessary for health care providers to discuss the use of herbal medicines with their pregnant patients in an open and non-judgmental way.

1. Introduction

In the past two decades, the use of herbal medicines has grown considerably worldwide, especially among pregnant women [1-3]. Herbal medicines are defined by the World Health Organisation as plant-derived material or preparations perceived to have therapeutic benefits, containing raw or processed ingredients from one or more plants [4]. They include herbs, herbal materials, herbal preparations, and finished herbal products that contain parts of plants or other plant materials as active ingredients [5]. The prevalence of herbal medicine use during pregnancy varies significantly across regions and countries [1]. A recently published systematic review assessing the prevalence of herbal medicine use among 22,404 pregnant or lactating women across Africa found an average prevalence rate of 32% to 45% [6]. This systematic review [6] also identified a substantial variation in the use of herbal medicines by pregnant women in the African continent, from 2% as reported in a study conducted in the Tigray Region, Northern Ethiopia [7] to 100% according to another study in Machakos District, Eastern Kenya [8].

Pregnant women use herbal medicines for different purposes, which include pregnancy-related ailments such as nausea and vomiting, improvement of foetal growth, inducing labour, or pregnancy-unrelated ailments, such as cold and flu symptoms and skin problems as well as for nutritional benefits [3, 6, 9]. The popularity of herbal medicines among pregnant women can be mainly attributed to the belief that herbal products, being natural, are safe with fewer adverse events (AEs) compared to conventional drugs [10, 11]. Moreover, pregnant women across Africa view herbal medicines as being more affordable and more easily accessed than conventional drugs [2, 6, 11]. Despite this common perception of safety, herbal medicines may have potent pharmacological actions, and can consequently produce AEs [12]. For instance, a recent systematic review [13], focusing on the safety of herbal medicines and which included 74 studies in a total of

1,067,071 pregnant or postnatal women, found that topical use of almond oil was significantly associated with preterm birth, oral raspberry leaf with caesarean delivery, and heavy liquorice consumption (greater than 500 mg/week) with early preterm birth [13]. In addition, the concomitant use of herbal remedies with conventional medicines can lead to potential synergistic effects or drug interactions resulting in increased toxicity and decreased efficacy of the conventional drug [14]. An example of this is the consumption of green tea concomitantly with folic acid yielding a diminished folic acid bioavailability [15]. Furthermore, herbal medicinal products are usually sold as unlicensed food or dietary supplements or as over-the-counter items, which are not regulated with the same scrutiny as conventional drugs, thus increasing the probability of contamination or adulteration with poisonous metals such as lead or mercury, non-declared herbs or conventional medicines [3, 16].

In Zambia, there is a paucity of data on the use of herbal medicines among pregnant women. To our knowledge, only two studies have been conducted there to investigate the use of traditional medicine during pregnancy [17, 18]. The first study, conducted by Banda et al. (2007) [17], found that 30% of 1,228 pregnant women surveyed in Lusaka, Zambia reported visiting a traditional healer in the past and 21% during their current pregnancies. However, this study examined the use of traditional medicine as a whole and not specifically herbal medicine use, and it did not assess the types of medicinal plants used nor the reasons for their use [17]. The second study by Maluma et al. (2017) [18], conducted among 273 pregnant women, reported that 32% of study participants used herbal medicines mainly for inducing or accelerating labour. In this study, various local names of indigenous plants were mentioned, such as *"moono"* leaves and roots, *"makole"* roots and leaves, *"mulolo"* roots, and "*sope*" leaves [18]. However, these medicinal plants were not botanically identified, and the study was carried out in only two towns of Lusaka Province

(Kanakantapa and Chawama). Thus, the findings may not be generalisable to the entire province [18]. Accordingly, the present study aimed at filling this knowledge gap by determining the prevalence of herbal medicine use, associated factors, and patterns of use among pregnant women attending antenatal care clinics in Lusaka Province. This study also aimed to identify the most frequently used medicinal plants in pregnancy and their indications.

2. Methods

2.1 Study design and setting

This was a facility-based, prospective, cross-sectional study, conducted from June 03 to July 09, 2019. Five antenatal clinics of public health facilities located across three districts of Lusaka Province, namely Lusaka District, Kafue District and Chongwe District, were selected. Although it is the smallest province, Lusaka Province is the most populated of all the ten provinces of Zambia, with a population of over 3 million [19]. At district level, Lusaka District is the most densely populated district in the province (4,853.2 persons per km^2) followed by Kafue (24.2 persons per km^2) and Chongwe (22.2 persons per km^2) [20]. Hence, the three districts were selected as the study locations based on their population size, and because they provided a representation of urban (Lusaka), peri-urban (Kafue), and rural (Chongwe) communities of Lusaka Province.

The study was approved by the Regional Committee for Medical and Health Research Ethics in Norway (REC West; 2019/378), the University of Zambia Biomedical Research Ethics Committee (UNZABREC; 009-04-19), and the National Health Research Authority of Zambia. Permission to conduct the study was also obtained at each health centre. The study results were kept confidential, and all computerised data were handled and stored anonymously.

2.2 Study population and sampling procedure

The target population of the study consisted of all adult pregnant women seeking antenatal care at the selected public health facilities in Lusaka Province. The study population consisted of adult pregnant women attending the selected antenatal care clinics during the data collection period who met the eligibility criteria. Women who were not mentally or physically capable of being interviewed were excluded. Moreover, foreign women were excluded from the study analysis, because they might have different health beliefs and practices, and should not be made to represent Zambian women. Written informed consent was obtained from all study participants.

The sample size for this study was calculated using the formula: $n = z^2pq/d^2$, where n = required sample size, z = standard normal deviate set at 1.96 (for a 95% confidence interval), p = estimated proportion of herbal medicine use among pregnant women, $q = 1-p$, and d = degree of desired accuracy set at 0.05. Taking p = 32% from the Maluma et al. (2017) study [18], the minimum sample size was estimated at 334. Assuming a non-response rate of 10%, the final required sample size was found to be 368. However, participant recruitment was continued even after reaching the desired sample size, since larger sample sizes lead to more reliable conclusions.

Pre-survey assessment was carried out to determine the average daily flow of pregnant women seeking antenatal care at the selected public health facilities. According to the expected number of women in the specified period of data collection, the sample size was proportionally allocated to each clinic. Given the disorganized and unstructured influx of women to the health facilities, we decided to consecutively recruit all women who met the inclusion criteria during the study period.

2.3 Data collection

After participants were briefed on the purpose of the study and informed consent was obtained, data were collected using a semi-structured, interviewer-administered questionnaire,

based on a previous study by Nordeng and Havnen (2004) [21] describing herbal medicine use during pregnancy among 400 Norwegian women. Several questions in the questionnaire were also adapted from similar cross-sectional studies conducted in other sub-Saharan African countries [14, 22, 23]. The questionnaire was first prepared in English, then later translated into the local languages (Nyanja and Bemba), and then re-translated back to English to check for its consistency. The following definition of herbal medicine was included in the information sheet [24], and was given to the study participants at the beginning of the interview: "any kind of product, such as a tablet, a mixture, a cream or a herbal tea, which is produced from plants and used to acquire better health".

The questionnaire was initially pilot-tested in its English version, on a sample of 10 participants from Lusaka District, and based on the findings, a few questions were revised. The final version of the questionnaire took approximately 15 minutes to complete, and contained 31 questions divided into five sections. The first section captured sociodemographic information of the participants (i.e., age, marital status, educational level, religion, ethnicity, area of residence, and occupation). The second section included pregnancy-related questions (i.e., stage of pregnancy, number of pregnancies prior to this one, parity, smoking during pregnancy, and conventional medicines taken regularly). The third and fourth sections comprised questions regarding herbal medicine use among respondents, including herbal medicine use during current and past pregnancies, potential herbal medicine use in the future, types of herbal medicines used and their indications, recommendation source(s), disclosure of use to health care professionals, reasons for use, preferred source of information, and sources to obtain herbal medicines. To reduce recall bias, the third section of the questionnaire also inquired about the use of five specific popular medicinal plants, namely ginger (*Zingiber officinale* Roscoe), garlic (*Allium sativum* L.), *Aloe vera*

(*Aloe vera* (L.) Burm.f.), moringa (*Moringa oleifera* Lam.), and soybean (*Glycine max* (L.) Merr.). These plants were selected based on the available literature on herbal medicine use during pregnancy in Africa [6], and on the pilot-testing results. The fifth and final section asked about the women's experience with any medical condition, such as nausea/vomiting/morning sickness, abdominal pain/indigestion, malaria, urinary tract infection, and if they had used any treatment against it.

Data were collected by the principal investigator (M.E.H.) and by two trained female research assistants (a graduate student in public health and a medical student) fluent in the local languages. All filled copies of the questionnaire were checked daily by the principal investigator to promote consistency and to ensure completion of data. Data cleaning was conducted at the end of data entry.

2.4 Statistical analysis

Data were presented as descriptive statistics. Categorical variables were summarised as counts and percentages, whereas continuous variables as mean, standard deviation (SD), median, range, and interquartile range. Prevalence was calculated as the proportion of study participants who used herbal medicines, with the denominator being all pregnant women enrolled in the study. Pearson's chi-square test and Fisher's exact test were used to determine the association between herbal medicine use (dependent variable) and sociodemographic and pregnancy-related characteristics (independent variables).

All statistical tests were two-sided and were performed at a 0.05 significance level. Statistical analyses were conducted using IBM SPSS Statistics for Windows, version 25 (IBM Corp, Armonk, NY, USA).

3. Results

3.1 Study participants and prevalence of herbal medicine use

Out of 497 pregnant women invited to participate, 461 completed the questionnaire giving a response rate of 92.8%. A total of 15 women were excluded because they did not meet the study eligibility criteria (i.e., 8 were foreigners and 7 were underage), leaving 446 in the final analysis. More than half of the study participants (258/446; 57.8%) reported using herbal medicines during their current pregnancy, while 122 (27.4%) reported the use of herbal medicines in past pregnancies. Overall, 209 women (46.9%) reported intending to use herbal medicines in the future (after giving birth or in future pregnancies).

Table 1 presents the sociodemographic and pregnancy-related characteristics of the overall study population and stratified by herbal medicine use in the current pregnancy. Most study participants resided in urban or peri-urban areas (77.8%), were younger than 30 years (64.8%), were married (85.2%), and had at least one child (67.3%). Half of the study population attained a secondary level of education. As for the number of pregnancies, 28.5% were primigravidae. Only 14 women (3.1%) self-reported being HIV-positive. Overall, 371 (83.2%) study participants reported using conventional medicines during their current pregnancy, with the most commonly used medications being folic acid for the prevention of neural tube defects (342/371; 92.2%), ferrous sulphate for the prevention or treatment of iron-deficiency anaemia (256/371; 69.0%), and sulfadoxine−pyrimethamine for the prevention of malaria (172/371; 46.4%).

Chi-square analysis detected no statistically significant differences between herbal medicine users and non-users in relation to sociodemographic factors as well as pregnancy-related characteristics. Only conventional medicine use (p=0.032), herbal medicine use in prior

pregnancies ($p<0.001$), and willingness to use herbal medicine in the future ($p<0.001$) were found to have a significant association with herbal medicine use during the current pregnancy.

3.2 Most commonly used herbal medicines and their indications

Table 2 presents the most commonly used herbal remedies in pregnancy and their indications. More than 40 different types of herbs were cited. The most frequently reported ones were *Citrus limon* (L.) Osbeck (lemon) (41.1%) mostly taken for nausea/vomiting/morning sickness and common cold, *Glycine max* (L.) Merr. (soybean) (31.0%) mainly used as an energy booster, *Zingiber officinale* Roscoe (ginger) (27.9%) mostly to treat common cold and nausea/vomiting/morning sickness, and *Aloe vera* (L.) Burm.f. (*Aloe vera*) (19.4%) primarily used topically to hydrate and moisturise the skin. Of the 258 herbal medicine users, six (2.3%) reported using herbal mixtures without knowing the ingredients.

The majority of herbal medicine users (167/258; 64.7%) used at least two types of herbs. The mean ± SD number of used herbal remedies in pregnancy was 2.0 ± 1.5 (median, 2.0; range, 1–11). The oral route was the most common route of administration of herbal medicines (213/258; 82.6%), followed by the topical (45/258; 17.4%) and the intra-vaginal (1/258; 0.4%) routes. Diverse plant parts were reported by the women who used herbal medicines, namely leaves, roots, barks, flowers, fruits or whole plants.

Five out of 258 herbal medicine users (1.9%) reported AEs: nausea (n=2) following oral infusion of avocado leaves (n=1) and after drinking ginger tea (n=1), vomiting (n=2) after eating raw garlic (n=1) and after drinking ginger tea (n=1), and rash following topical application of *Aloe vera* gel (n=1).

3.3 Patterns of herbal medicine use during pregnancy

Patterns of herbal medicine use among respondents are described in **Table 3**. Two-thirds of users (172/258; 66.7%) reported taking herbal medicines in at least two trimesters of pregnancy. Nearly half (47.7%) reported using herbal medicines occasionally. The use of herbal remedies was most commonly initiated on the woman's own initiative (53.1%) and/or after recommendations from family members (32.2%). Only two women (0.8%) had been recommended the use of herbal medicines by a traditional healer. Herbal remedies were mainly purchased from market places (57.8%) or gathered from the bushes (34.1%). For six women, soybeans were given to them free of charge by nurses at the antenatal clinics to gain weight.

When asked about the preferred source of information about herbal medicines in pregnancy, 46.9% of users preferred to seek advice from family or friends and 33.7% from health professionals. The majority of pregnant women who used herbal medicines (69.4%) did not disclose this use to their medical providers, and seven women (2.7%) disclosed the use of some herbs while not revealing the use of other herbal remedies because they were afraid of their medical provider's response.

Users of herbal medicines during pregnancy had several reasons for consumption of these products. The two most commonly stated reasons for using herbal medicines were "herbal medicines are safe in pregnancy" (37.6%) followed by "herbal medicines complement conventional medicines" (35.3%).

3.4 Common medical conditions in pregnancy and their treatment

Most study participants reported experiencing one or more medical conditions during their pregnancy, most commonly nausea/vomiting/morning sickness (67.3%), abdominal pain/indigestion (55.6%), and urinary tract infections (16.4%) (**Table 4**). These conditions were

246 treated in different ways and to a variable extent. Study participants who reported experiencing
247 back pain (81.8%), abdominal pain/indigestion (77.4%), nausea/vomiting/morning sickness
248 (70.0%), or vaginal problems (50.0%) did not receive any treatment in at least half of the cases.
249 Cough (81.3%) was the condition most commonly treated by herbal medicines (by ginger, lemon,
250 and/or garlic), followed by common cold (72.5%) (by ginger, lemon, and/or garlic). The highest
251 proportion of women using conventional medicines for the treatment of medical conditions was
252 found for urinary tract infections (75.3%), hypertension (72.7%), malaria (70.2%), and headache
253 (52.3%). Simultaneously, herbal remedies were not or barely administered to treat these four
254 conditions.
255

256 ## 4. Discussion

257 The findings of the present study indicate that herbal medicine use among pregnant women
258 attending antenatal clinics in Lusaka Province is common, and that a wide range of herbal
259 medicines is used. Herbal remedies were found to be used by 57.8% of the study participants. This
260 prevalence is quite high, especially given that more than three-quarters of the study population
261 resided in urban or peri-urban areas in proximity to health care facilities. However, we believe that
262 this figure can even be much higher, particularly in the Kafue and Chongwe Districts, given that
263 previous studies have shown that rural residence is significantly associated with herbal medicine
264 use during pregnancy [6]. Moreover, there is an information bias associated with a lack of
265 disclosure of herbal medicine use to researchers, particularly when a respondent is interviewed in
266 a health care setting [22]. This is supported by the fact that more than two-thirds of users admitted
267 that they did not disclose their use of herbal medicine to their health care providers.

Although the use of herbal medicines among pregnant women varied widely across different studies conducted in various sub-Saharan African countries, most studies from the region reported a relatively high prevalence of use [6]. For instance, all studies carried out in Zambia's bordering countries found a prevalence rate above 40%. In a study from Harare, Zimbabwe conducted in 248 pregnant women at 12 antenatal clinics, a 52% prevalence was noted [25]. In a more recent study from rural Zimbabwe in 398 women, 69.9% reported to have used traditional medicine during pregnancy and at childbirth [26]. Similarly, a study from Mbeya, southwest Tanzania conducted in 400 pregnant women found a 55% prevalence [27]. Likewise, a large study from Bukavu, eastern Democratic Republic of the Congo in 920 pregnant women reported a 45% prevalence of herbal medicine use [28]. Hence, the high herbal medicine use noted in our study is consistent with previous findings from Zambia's neighbouring countries. Nevertheless, it is difficult to ascertain whether the differences in prevalence across studies are caused by variability in study design, setting, data collection, and sampling techniques or whether they represent true differences in herbal medicine use [29-31].

In the present study, we found that sociodemographic characteristics were not associated with the use of herbal medicine in pregnancy. This is in line with other studies from sub-Saharan Africa [14, 26, 29], including the Maluma et al. (2017) study [18] conducted in the Kanakantapa and Chawama towns of Lusaka Province, in which herbal medicine use among pregnant women was not associated with area of residence, age, or educational level. This might be due to low statistical power to detect true differences in sociodemographic characteristics between users and non-users, or indicate that herbal medicine use is so common in Lusaka Province that sociodemographic factors do not impact on the use of herbal medicines.

Different herbal remedies were cited in the present study, with the most commonly used herbal medicines during pregnancy being lemon, soybean, ginger, and *Aloe vera*. The frequent use of lemon to treat nausea or vomiting, as found in our study, has been reported in previous studies from Bangladesh [32] and Pakistan [33]. Moreover, a double-blind, randomised, four-day study from Iran in 100 pregnant women found that inhaling the aroma of lemon essential oil was safe and more effective than placebo in reducing nausea and vomiting [34]. Similarly, several previous studies have shown that ginger is commonly used by pregnant women all over the world for nausea and vomiting during pregnancy [6, 23, 24, 31, 32]. A systematic review of 12 randomised controlled trials [35] involving 1,278 pregnant women found that ginger significantly improved the symptoms of nausea when compared to placebo ($p<0.001$). However, it did not have a significant impact on vomiting episodes, nor did it pose a risk for negative pregnancy outcomes [35]. Although the consumption of ginger in amounts used in food preparations was shown to be safe for both the mother and the foetus [35], using doses of dried ginger higher than 2.0 g per day is not recommended for pregnant women [36]. *Aloe vera* is perhaps one of the most widely used herbal remedies for topical skin conditions. *Aloe vera* extract improves skin moisture by a humectant mechanism [37], and prevents skin ulcers as it contains mucopolysaccharides, amino acids, zinc and water [38]. Although the topical application of *Aloe vera* is associated with infrequent AEs [38], orally ingested *Aloe vera* whole leaf extract has shown clear evidence of carcinogenic activity in rats, and was classified by the International Agency for Research on Cancer as a possible human carcinogen [39]. In addition, pregnant women are generally not advised to take oral preparations of *Aloe vera* because its cathartic property might result in stimulating uterine contractions, thereby increasing the risk for premature labour or miscarriage [39]. Regarding the frequent use of soybean that was reported in the present study, no previous

study to our knowledge has identified soybean as a commonly used herbal medicine by pregnant women. This might be partially due to the fact that some plants that are defined as medicinal plants are not regarded as such by many women [29]. During the course of the interviews for our study, we made sure to name several herbal medicines to capture their use by the study participants. Although there are possible health benefits associated with soy consumption [40], soy use during pregnancy was shown to alter the epigenome in mouse offspring [41]. Caution should therefore be practiced when some of these herbal medicines are being used, especially given that reliable, human data on the safety of most herbal medicines are currently lacking and often contradictory [6]. Nevertheless, the fact that some plant species are used by different societies could indicate their effectiveness and is pertinent for prioritising future studies on efficacy and safety [6].

Of great concern was the finding that 3.9% of herbal medicine users regularly ate soil mainly to treat nausea and vomiting of pregnancy. The deliberate consumption of soil, known as geophagy, is a traditional health practice that is prevalent among pregnant women across sub-Saharan African countries, such as Kenya, Zimbabwe, the Democratic Republic of the Congo, and Tanzania [25, 26, 42-44]. In the present study, it is very likely that underreporting of geophagy occurred for a variety of reasons, including embarrassment regarding the behaviour [43]. Although its health impacts remain controversial and inconclusive [43], geophagy was shown to be significantly associated with an increased risk of anaemia and lower concentrations of haemoglobin, haematocrit, and plasma zinc [45]. Moreover, African geophagic soil samples purchased from markets in sub-Saharan Africa, Europe and the United States were found to be highly contaminated with microbes (particularly aerobic bacteria and fungi) and contained potentially toxic heavy metals such as lead [46]. Lead exposure of pregnant women is dangerous for both the mother and the foetus, because this metal easily crosses the placenta resulting in

adverse effects in child neurodevelopment and physical growth even at relatively low exposure levels [43, 46]. Hence, geophagy is a major public health problem across the entire sub-Saharan African region, and particularly among pregnant women. Antenatal educational interventions are thus needed to improve pregnant women's understanding of the dangers of geophagy. The high use of herbal medicines during the first trimester of pregnancy as found in the present study (179/258; 69.4%) is another source of concern, as this is the most critical period of organogenesis, and taking herbs during the first trimester was found to be significantly associated with an increased risk of major congenital malformations [14, 47].

The perceived safety of herbal medicines was posited as the most common reason for herbal medicine use in the present study. A similar finding was reported in studies from Kenya [22], Sierra Leone [30], Nigeria [48], Ethiopia [9], and Bangladesh [32]. Such perception may be related to the implicit belief that herbal products, being natural, are necessarily safe [14]. The belief that herbal medicines complement conventional medicines, which was the second most commonly cited reason for herbal medicine use in our study, is also concerning, particularly when coupled with the finding that conventional medicine use was significantly associated with herbal medicine use during the current pregnancy. The concurrent use of conventional medicines and herbal preparations can pose a potential drug interaction hazard. Hence, continuous discussion and education around herbal medicine use in pregnancy should be part of routine antenatal practices to encourage the safe and effective administration of herbal preparations [30].

Alarmingly, more than 20% of respondents reported not receiving any treatment for serious diseases, such as malaria and urinary tract infections. This might be related to the economic burden of these infections or to inadequate evaluation of their symptoms. For instance, it has been shown that it is common for some patients not to visit health care facilities when they first feel

359 characteristic malaria symptoms, such as fever [49]. Nevertheless, there remains an urgent need to
360 improve the screening strategies and management practices of such potentially dangerous
361 conditions among pregnant women in Lusaka Province.

362 There are some limitations to the present study which must be acknowledged. As this study
363 was based on self-reported data obtained through interviews, it is prone to an interviewer bias and
364 to a recall bias, and underreporting is very likely. However, we tried to reduce recall bias by the
365 use of a semi-structured interview and by confining the enquiry to the current pregnancy. We also
366 attempted to reduce interviewer bias by the use of more than a single interviewer (the principal
367 investigator and a local research assistant) in the study. Moreover, since this study was conducted
368 in three districts of Lusaka Province and pregnant minors were excluded, its findings may not be
369 generalisable to other settings. Furthermore, this study adopted a non-probability sampling method
370 and did not take clustering into account, which could introduce bias in the selection of interviewed
371 subjects. Nevertheless, these limitations were balanced by several strengths, including the high
372 response rate (92.8%), the absence of missing data, and the exploration of some herbs that were
373 not previously studied. The specific naming of several different medicinal plants during the course
374 of the interviews contributed to making the women aware that plants they did not regard as herbal
375 medicines were indeed defined as such.

376

377 ## 5. Conclusions

378 More than half of women attending antenatal clinics in Lusaka Province, Zambia reported
379 using herbal medicines during pregnancy. A wide range of herbal remedies were cited by the study
380 participants, with the most commonly reported being lemon, soybean, ginger, and *Aloe vera*. Two-
381 thirds of users also admitted taking herbal remedies in at least two trimesters of pregnancy. Given

this high prevalence of herbal medicine use and the low disclosure rate found in the present study, it is necessary for health care providers to discuss the use of herbal medicines with their pregnant patients in an open and non-judgmental way. There remains a dearth of information on the pharmacological and ethnobotanical characteristics of the different medicinal plants used during pregnancy in Zambia. Thus, further research and classification of the safety of herbal medicines used among pregnant women across Zambia are warranted.

Abbreviations

AE, adverse event; HIV, human immunodeficiency virus; HM, herbal medicine; IQR, interquartile range; SD, standard deviation.

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Author contributions

M.E.H. and L.H. conceived and designed the study. M.E.H. collected and analysed the data. D.C.S. and B.V. contributed to the design of the study and facilitated data collection. M.E.H. drafted the manuscript. L.H., D.C.S, and B.V. supervised the project. All authors critically reviewed the manuscript and contributed to the final version of the manuscript.

Compliance with ethical standards

The study was approved by the Regional Committee for Medical and Health Research Ethics in Norway (REC West; 2019/378), the University of Zambia Biomedical Research Ethics Committee (UNZABREC; 009-04-19), and the National Health Research Authority of Zambia. Permission to conduct the study was also obtained at each health centre. Written informed consent was obtained from all study participants.

Declaration of interests

The authors declare that they have no competing interests.

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Table 1. Sociodemographic and obstetric characteristics and their association with herbal medicine use during pregnancy

Variable	Total (N=446)	Users of HM (N=258)	Non-users of HM (N=188)	Chi-square	p-value*
District					
Lusaka	237 (53.1)	130 (50.4)	107 (56.9)	5.322	0.07
Kafue	110 (24.7)	74 (28.7)	36 (19.1)		
Chongwe	99 (22.2)	54 (20.9)	45 (23.9)		
Mean ± SD age	28.1 ± 6.1	27.7 ± 6.0	28.6 ± 6.1	-	-
(median; IQR) – years	(28.0; 23.0–32.0)	(27.0; 23.0–32.0)	(29.0; 24.0–32.5)		
Age groups – years					
<25	133 (29.8)	81 (31.4)	52 (27.7)	2.630	0.621
25–30	156 (35.0)	93 (36.0)	63 (33.5)		
31–36	119 (26.7)	63 (24.4)	56 (29.8)		
≥37	38 (8.5)	21 (8.1)	17 (9.0)		
Marital status					
Married	380 (85.2)	213 (82.6)	167 (88.8)	3.393	0.065
Not married¶	66 (14.8)	45 (17.4)	21 (11.1)		
Ethnicity					
Bemba	127 (28.5)	79 (30.6)	48 (25.5)	35.871	0.074
Tonga	67 (15.0)	39 (15.1)	28 (14.9)		
Chewa	66 (14.8)	33 (12.8)	33 (17.6)		
Other¥	186 (41.7)	107 (41.5)	79 (42.0)		
Religion					
Protestant	310 (69.5)	180 (69.8)	130 (69.1)	3.774	0.287
Catholic	83 (18.6)	43 (16.7)	40 (21.3)		
Jehovah's witness	24 (5.4)	14 (5.4)	10 (5.3)		
Other§	29 (6.5)	21 (8.1)	8 (4.3)		
Education level					
No formal education	12 (2.7)	3 (1.2)	9 (4.8)	5.517	0.138
Primary education	48 (10.8)	28 (10.9)	20 (10.6)		
Secondary education	223 (50.0)	130 (50.4)	93 (49.5)		
College or university	163 (36.5)	97 (37.6)	66 (35.1)		

Variable	Total (N=446)	Users of HM (N=258)	Non-users of HM (N=188)	Chi-square	p-value*
Residential area					
High-density (low-income)	211 (47.3)	120 (46.5)	91 (48.4)	0.156	0.925
Medium-density (middle-income)	138 (30.9)	81 (31.4)	57 (30.3)		
Low-density (high-income)	97 (21.7)	57 (22.1)	40 (21.3)		
Employment status					
Formally employed	154 (34.5)	92 (35.7)	62 (33.0)	3.058	0.217
Informally employed	42 (9.4)	19 (7.4)	23 (12.2)		
Unemployed	250 (56.1)	147 (57.0)	103 (54.8)		
Trimester of pregnancy					
First	46 (10.3)	20 (7.8)	26 (13.8)	4.421	0.11
Second	204 (45.7)	120 (46.5)	84 (44.7)		
Third	196 (43.9)	118 (45.7)	78 (41.5)		
Prior pregnancies					
None	127 (28.5)	80 (31.0)	47 (25.0)	4.951	0.763
1	112 (25.1)	65 (25.2)	47 (25.0)		
2	77 (17.3)	44 (17.1)	33 (17.6)		
3	75 (16.8)	42 (16.3)	33 (17.6)		
≥4	55 (12.3)	27 (10.5)	28 (14.9)		
Parity					
No child	146 (32.7)	89 (34.5)	57 (30.3)	7.800	0.351
1 child	120 (26.9)	72 (27.9)	48 (25.5)		
2 children	92 (20.6)	50 (19.4)	42 (22.3)		
3 children	58 (13.0)	33 (12.8)	25 (13.3)		
≥4 children	30 (6.7)	14 (5.4)	16 (8.5)		
Conventional drug use					
Yes	371 (83.2)	223 (86.4)	148 (78.7)	4.622	**0.032**
No	75 (16.8)	35 (13.6)	40 (21.3)		
HM use in prior pregnancies					
Yes	122 (27.4)	103 (39.9)	19 (10.1)	70.004	**<0.001**
No	188 (42.2)	70 (27.1)	118 (62.8)		
Unsure/don't remember	10 (2.2)	5 (1.9)	5 (2.7)		

Variable	Total (N=446)	Users of HM (N=258)	Non-users of HM (N=188)	Chi-square	p-value*
Not applicable[&]	126 (28.3)	80 (31.0)	46 (24.5)		
Willingness to use HM in the future				81.835	**<0.001**
Yes	209 (46.9)	164 (63.6)	45 (23.9)		
No	113 (25.3)	31 (12.0)	82 (43.6)		
Unsure	124 (27.8)	63 (24.4)	61 (32.4)		

Data are expressed as n (%), unless otherwise indicated. Percentages are calculated as n/N.

*$p<0.05$ is considered statistically significant.

¶"Not married" includes: single, divorced, and separated.

¥Other ethnicities include: Chikunda, Ila, Kalubale, Kaonde, Lala, Lamba, Lenje, Lozi, Luba, Lunda, Lungu, Luvale, Mambwe, Namwanga, Ndebele, Ngoni, Nsenga, Senga, Shona, Soli, Tumbuka, Ushi, and Zulu.

§Other religions include: New Apostolic Church, Zion Christian Church, Old Apostolic Church, and Islam.

&"Not applicable" in cases of first pregnancy.

Abbreviations: HM, herbal medicine; IQR, interquartile range; SD, standard deviation.

Table 2. Overview of the most frequently used herbal preparations during pregnancy and their indications among the 258 herbal medicine users

Herb type: **Binomial name ─ common name**	**No. (%) of women reporting usage***	**Preparation** **(no. of women reporting usage)****	**Most common indication(s)** **(no. of women reporting usage)****
Citrus limon (L.) Osbeck ─ Lemon	106 (41.1)	Lemon tea (n=62) Lemons (n=38) Infusion of lemon leaves (n=3) Lemon juice (n=2) Lemon porridge (n=1)	Nausea/vomiting/morning sickness (n=40) Common cold (n=36) To increase appetite (n=16) Cough (n=4) General well-being (n=4)
Glycine max (L.) Merr. ─ Soybean	80 (31.0)	Soybean porridge (n=75) Roasted soybeans (n=4) Fried soybeans (n=1)	Energy boosting (n=55) Weight gain (n=15) Nutrition or as a dietary supplement (n=10) To promote foetal growth (n=8)
Zingiber officinale Roscoe ─ Ginger	72 (27.9)	Ginger tea (n=57) Chewing raw ginger (n=15)	Common cold (n=33) Nausea/vomiting/morning sickness (n=25) Cough (n=10) General well-being (n=2)
Aloe vera (L.) Burm.f. ─ *Aloe vera*	50 (19.4)	*Aloe vera* lotion (n=34) *Aloe vera* topical gel (n=7) *Aloe vera* soap (n=5) *Aloe vera* juice (n=4) *Aloe vera* tea (n=2)	Skin hydration and moisture (n=37) To reduce stretch marks (n=5) As an antibiotic (n=1), antifungal (n=1), or disinfectant (n=1) Abdominal pain (n=2)
Amaranthus spp. L. ─ Wild spinach (known locally in Zambia as "bondwe")	40 (15.5)	Leaves are boiled in water and infusion is drank (n=40)	To treat or prevent anaemia (n=40)
Beta vulgaris L. ─ Beetroot	29 (11.2)	Beetroot cooked as a vegetable (n=28) Beetroot tea (n=1)	To treat or prevent anaemia (n=29)

Herb type: **Binomial name ─ common name**	**No. (%) of women reporting usage***	**Preparation** **(no. of women reporting usage)****	**Most common indication(s)** **(no. of women reporting usage)****
Persea americana Mill. ─ Avocado	21 (8.1)	Infusion of avocado leaves (n=13) Avocados (n=8)	To treat or prevent anaemia (n=21) Energy boosting (n=1)
Brassica napus L. ─ Rapeseed	19 (7.4)	Leaves are boiled in water and infusion is drank (n=19)	To treat or prevent anaemia (n=19)
Allium sativum L. ─ Garlic	19 (7.4)	Eating raw garlic (n=10) Garlic tea (n=9)	Common cold (n=7) Cough (n=4) Sore throat (n=2) High blood pressure (n=2) As an antibiotic (n=1), or as an antifungal (n=1)
Soil¶	10 (3.9)	Eating dirt or clay bought from local markets (n=10)	Nausea/vomiting/morning sickness (n=8) Hypersalivation (n=1) Energy boosting (n=1)
Telfairia occidentalis Hook.f. ─ Fluted pumpkin (known locally in Zambia as "chibwabwa")	9 (3.5)	Pumpkin leaves cooked as a vegetable (n=9)	To treat or prevent anaemia (n=9)
Ficus sycomorus L. ─ Sycamore fig (known locally in Zambia as "mukuyu")	8 (3.1)	Infusion of leaves (n=7) Boiled decoction of bark (n=1)	To treat or prevent anaemia (n=8)
Moringa oleifera Lam. ─ Moringa	7 (2.7)	Moringa powder tea (n=3) Moringa leaf oral supplement (n=2) Moringa powder for hair (n=1) Decoction of moringa roots (n=1)	General well-being (n=2) To boost the immune system (n=1) High blood pressure (n=1) Bloating and gas (n=1) To stimulate hair growth (n=1) To induce labour (n=1)

Herb type: **Binomial name ─ common name**	**No. (%) of women reporting usage***	**Preparation** **(no. of women reporting usage)****	**Most common indication(s)** **(no. of women reporting usage)****
Rhynchosia heterophylla Hauman ─ Munkoyo	6 (2.3)	Munkoyo beverage¥	Energy boosting (n=6) To promote foetal growth (n=1)
Corchorus olitorius L. ─ Bush okra (known locally in Zambia as "delele")	6 (2.3)	Infusion of bush okra leaves (n=3) Bush okra cooked as a relish (n=3) Decoction of bush okra roots (n=1)	To induce labour (n=4) To increase appetite (n=3)

*Percentages are based on the number of women who used herbal medicines during their current pregnancy (N=258).
**More than one answer was possible.
¶Soil is not a herbal medicine, but its use for therapeutic purposes was reported by several study participants. This was hence included in the study analysis due to soil's potential health risks.
¥Munkoyo is a spontaneously fermented drink made from pounded roots of *Rhynchosia heterophylla* Hauman mixed with bits of maize.

Table 3. Patterns of herbal medicine use during pregnancy (N=258)

Variable	**Number (%)***
Trimester of pregnancy during which herbal medicines were used	
First trimester only	42 (16.3)
Second trimester only	31 (12.0)
Third trimester only	13 (5.0)
First and second trimesters	75 (29.1)
Second and third trimesters	35 (13.6)
First and third trimesters	2 (0.8)
All trimesters	60 (23.3)
Frequency of use	
Only once	9 (3.5)
Occasionally	123 (47.7)
Weekly	3 (1.2)
Twice or more per week	27 (10.5)
Daily	96 (37.2)
Source(s) of recommendation**	
Own idea	137 (53.1)
Family	83 (32.2)
Health professionals¶	46 (17.8)
Friends or neighbours	34 (13.2)
Seventh-day Adventist Church	4 (1.6)
Magazine or on social media	3 (1.2)
Traditional healers	2 (0.8)
Source(s) of herbal medicine**	
Market places	149 (57.8)
Gathered from the bushes	88 (34.1)
Family and/or friends	29 (11.2)
Staff at the antenatal clinic	6 (2.3)
Traditional healers or herbalists	2 (0.8)
Preferred source of information about herbal medicines	
Family or friends	121 (46.9)
Health professionals¶	87 (33.7)

Variable	Number (%)*
Google	31 (12.0)
Traditional healers or herbalists	10 (3.9)
Unsure	5 (1.9)
Religious leaders	4 (1.6)
Disclosed use of herbal medicines to doctor/nurse/pharmacist	
Yes	72 (27.9)
No	179 (69.4)
Partially	7 (2.7)
Reason(s) for using herbal medicines**	
Herbal medicines are safe in pregnancy	97 (37.6)
Herbal medicines complement conventional medicines	91 (35.3)
Herbal medicines are more accessible than conventional medicines	49 (19.0)
Herbal medicines are much cheaper than conventional medicines	44 (17.1)
Herbal medicines taste nice	42 (16.3)
Herbal medicines are more effective than conventional medicines	30 (11.6)
It is in my culture to use herbal medicine	21 (8.1)
Herbal medicines are more effective blood boosters than conventional medicines	13 (5.0)
Conventional medicines cause more side effects compared to herbal medicines	8 (3.1)
I use herbal medicine when conventional medicine fails	6 (2.3)

*Percentages are based on the number of women who used herbal medicines during their current pregnancy (N=258).
**More than one answer was possible.
¶Health professionals included: doctors, pharmacists, nurses, and nutritionists.

Table 4. Frequent medical conditions reported during pregnancy and their treatment status

Medical condition	**Women with condition n (% of total)**	**No treatment n (% of women with condition)**	**Pharmaceutical treatment only n (% of women with condition)**	**Treatment with herbs only n (% of women with condition)**	**Concomitant herbal and pharmaceutical treatment n (% of women with condition)**
Nausea, vomiting or morning sickness	300/446 (67.3)	210/300 (70.0)	16/300 (5.3)	66/300 (22.0)	8/300 (2.7)
Abdominal pain or indigestion	248/446 (55.6)	192/248 (77.4)	49/248 (19.8)	6/248 (2.4)	1/248 (0.4)
Urinary tract infection	73/446 (16.4)	18/73 (24.7)	55/73 (75.3)	0/73 (0.0)	0/73 (0.0)
Headache	65/446 (14.6)	30/65 (46.2)	34/65 (52.3)	1/65 (1.5)	0/65 (0.0)
Common cold	51/446 (11.4)	7/51 (13.7)	6/51 (11.8)	37/51 (72.5)	1/51 (2.0)
Malaria	47/446 (10.5)	14/47 (29.8)	33/47 (70.2)	0/47 (0.0)	0/47 (0.0)
High blood pressure	22/446 (4.9)	3/22 (13.6)	16/22 (72.7)	1/22 (4.5)	2/22 (9.1)
Cough	16/446 (3.6)	0/16 (0.0)	2/16 (12.5)	13/16 (81.3)	1/16 (6.3)
Back pain	11/446 (2.5)	9/11 (81.8)	2/11 (18.2)	0/11 (0.0)	0/11 (0.0)
Vaginal problems (i.e., itching, bleeding, abnormal discharge, infection)	10/446 (2.2)	5/10 (50.0)	4/10 (40.0)	0/10 (0.0)	1/10 (10.0)

Annexes

A. **Ethical Approvals**

B. **Information Sheet**

C. **Written Informed Consent**

D. **Questionnaire for the Use of Medicinal Plants among Pregnant Women in Lusaka Province, Zambia**

E. **Guide for Authors:** ***Complementary Therapies in Clinical Practice***

A. Ethical Approvals

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	Committee Secretary:	Phone:	Our date:	Our reference:
REK vest	Fredrik Rongved	+47 55978498	07.05.2019	2019/378/REK vest
			Your date:	
			01.04.2019	

Our reference must be stated on all requests

Lone Holst
Kalfarveien 31

2019/378 Bruk av urtemedisiner blant gravide kvinner i Lusaka, Zambia

Institution responsible for the research: Universitetet i Bergen
Project manager: Lone Holst

We refer to your application regarding the abovementioneded project, with the response recieved the 1st of April 2019. The Chair of REC Western Norway reviewed the response with authority of the Committee, pursuant to The Health Research Act § 10.

Project description
This study will describe the use of herbal medicines among pregnant women in Lusaka Province, Zambia. Data will be collected using a semi-structured, interviewer-administered questionnaire. We chose this data collection method because many of the pregnant women who receive antenatal care at the public clinics included in the study cannot read and write.The study will be conducted in four antenatal clinics, which provide a representation of rural, urban, and peri-urban communities of Lusaka Province. The research questions of the current study are: What is the prevalence of herbal medicine use during pregnancy in Lusaka? What are the most commonly used medicinal plants in pregnancy and for which indications are they used? Do the users inform healthcare personnel about the use of medicinal plants? Do the users of medicinal plants also use pharmaceutical drugs? What are the factors associated with the use of herbal medicines (e.g. sociocultural beliefs, sociodemographic characteristics)?

Assessment
Requested response:

REC West requested response to the following comments:

1. Inclusion of local research collaborators.
2. Documentation of approval from the local research ethics committee
3. A revised information sheet according to comments from the Committee
4. Clarification of use, storage and transfer of data in the project

Respons:

The Principal investigator (PI) has responded to all the comments.

1. PI has named two local collaborators affiliated with the Unversity of Zambia that will serve as local subervisors to the Master student during her data collection in Zambia.

Besøksadresse:
Armauer Hansens Hus (AHH), Tverrfløy Nord, 2 etasje. Rom 281. Haukelandsveien 28

Telefon: 55975000
E-post: post@helseforskning.etikkom.no
Web: http://helseforskning.etikkom.no/

All post og e-post som inngår i saksbehandlingen, bes adressert til REK vest og ikke til enkelte personer

Kindly address all mail and e-mails to the Regional Ethics Committee, REK vest, not to individual staff

2. No documentation of approval from the local research ethics committee (UNZABREC) is provided. UNZABREC requires a foreign research ethics committee approval letter *before* they can grant approval for the research project. The PI will send REC West Norway the local approval letter once they have it.
3. A revised information sheet is attached.
4. All paper data will be kept in a locked cabinet in the Master student's room during data collection. All paper data will be transferred electronically through the use of a password-protected fil space on the University of Bergen research server, entitled "SAFE". Individual files containing identifiable personal information will be password-protected as well. Alle data, on paper and in electronic form, will be deleted five years after the project has ended.

The Chair of REC West has assessed the response.

Assessment:

REC West has no further comments to the points 1 and 4.

Ad 2:
REC West anticipates a letter of approval once the PI has recieved it from UNZABREC.

Ad 3:
Regarding the information sheet, REC West see that there has been a misunderstanding. The Committee had no issues with the content of the previous information sheet, but found that the language was directed towards an academic audience. The present revision of the infomation sheet has cut information, yet kept the language (e.g. "antenatal", "oinment"). REC West has the following comments:

- The project should use the previous information sheet but revise the language.
- The previous information sheet should also add the contact information and the information about the PI from the present information sheet.

REC West will set this as a term for approval. A revised information sheet can be sent to post@helseforskning.etikkom.no. Write "REK vest" and the reference number "2019/378" in the subject title.

Terms:

REC West request a revised information sheet to be sent by email.

Decision

REC West has considered all the research ethical aspects of this project. The project is approved in accordance with the Health Research Act § 10 on the condition that the above mentioned terms are taken into account.

Further Information
The approval is valid until 31.01.2022. A final report must be sent no later than 31.07.2022. The approval is based on the grounds that the project is implemented as described in the application and the protocol, as well as the guidelines stated in the Health Research Act. If amendments need to be made to the study, the project manager is required to submit these amendments for approval by REC via the amendment form, cf. the Health Research Act § 11.

Access for appeal
The decision of the committee may be appealed to the National Committee for Research Ethics in Norway, cf. Forvaltningsloven § 28. The appeal should be sent to the Regional Committee for Research Ethics in

Norway, West. The deadline for appeals is three weeks from the date on which you receive this letter.

Sincerly,

Marit Grønning
Prof. dr.med.
Chair of REC West

Fredrik Rongved
Committee Secretary

Copy to: post@uib.no

UNIVERSITY OF ZAMBIA
BIOMEDICAL RESEARCH ETHICS COMMITTEE

Telephone: 260-1-256067
Telegrams: UNZA, LUSAKA
Telex: UNZALU ZA 44370
Fax: + 260-1-250753
Federal Assurance No. FWA00000338

Ridgeway Campus
P.O. Box 50110
Lusaka, Zambia
E-mail: unzarec@unza.zm
IRB00001131 of IORG0000774

30th May, 2019.

REF. No. 009-04-19.

Ms. Magalie El Hajj,
University of Bergen,
Centre for International Health,
Lobergsveien 85,
Bergen 5055,
Norway.

Dear Ms. Hajj,

RE: "USE OF MEDICINAL PLANTS AMONG PREGNANT WOMEN ATTENDING ANTENATAL CLINICS IN LUSAKA PROVINCE, ZAMBIA: PREVALENCE AND ASSOCIATED FACTORS" (Ref. No. 009-04-19)

The above-mentioned research proposal was presented to the Biomedical Research Ethics Committee on 30th May, 2019. The proposal is **approved**. The approval is based on the following documents that were submitted for review:

a) Study proposal
b) Questionnaires
c) Participant Consent Form

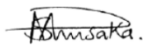
APPROVAL NUMBER : REF. 009-04-19

This number should be used on all correspondence, consent forms and documents as appropriate.

- **APPROVAL DATE : 30th May 2019**
- **TYPE OF APPROVAL : Standard**
- **EXPIRATION DATE OF APPROVAL : 29th May 2020**
  After this date, this project may only continue upon renewal. For purposes of renewal, a progress report on a standard form obtainable from the UNZABREC Offices should be submitted one month before the expiration date for continuing review.
- **SERIOUS ADVERSE EVENT REPORTING**: All SAEs and any other serious challenges/problems having to do with participant welfare, participant safety and study integrity must be reported to UNZABREC within 3 working days using standard forms obtainable from UNZABREC.
- **MODIFICATIONS**: Prior UNZABREC approval using standard forms obtainable from the UNZABREC Offices is required before implementing any changes in the Protocol (including changes in the consent documents).
- **TERMINATION OF STUDY**: On termination of a study, a report has to be submitted to the UNZABREC using standard forms obtainable from the UNZABREC Offices.

- **NHRA:** Where appropriate, apply in writing to the National Heath Research Authority for permission before you embark on the study.
- **QUESTIONS**: Please contact the UNZABREC on Telephone No.256067 or by e-mail on unzarec@unza.zm.
- **OTHER**: Please be reminded to send in copies of your research findings/results for our records. You're also required to submit electronic copies of your publications in peer-reviewed journals that may emanate from this study. Use the online portal: unza.rhinno.net for further submissions.

Yours sincerely,



Sody Mweetwa Munsaka, BSc., MSc., PhD
CHAIRPERSON
Tel: +260977925304
E-mail: s.munsaka@unza.zm

NATIONAL HEALTH RESEARCH AUTHORITY

Paediatric Centre of Excellence, University Teaching Hospital, P.O. Box 30075, LUSAKA
Tell: +260211 250309 | Email: znhrasec@gmail.com | www.nhra.org.zm

Ref No:…… **Date: 12th June, 2019**

Ms. Magalie El Hajj
University of Bergen
NORWAY

Re: Request for Authority to Conduct Research

The National Health Research Authority is in receipt of your request for authority to conduct research titled **"Prevalence and Factors Associated with Herbal Medicine use in Pregnant Women Attending antenatal clinics in Zambia: A mixed-methods study in Lusaka Province."** I wish to inform you that following submission of your request to the Authority, our review of the same and in view of the ethical clearance, this study has been **approved** on condition that:

1. The relevant Provincial and District Medical Officers where the study is being conducted are fully appraised;
2. Progress updates are provided to NHRA quarterly from the date of commencement of the study;
3. The final study report is cleared by the NHRA before any publication or dissemination within or outside the country;
4. After clearance for publication or dissemination by the NHRA, the final study report is shared with all relevant Provincial and District Directors of Health where the study was being conducted, University leadership, and all key respondents.

Yours sincerely,

Dr. Godfrey Biemba
Director/CEO
National Health Research Authority

B. Information Sheet

INVITATION TO PARTICIPATE IN A RESEARCH PROJECT

Master student: Ms. Magalie El Hajj

Project led by: Dr. Lone Holst

University of Bergen - Centre for International Health

You are kindly requested to participate in a research project aimed to gain knowledge about the use of herbal medicine among pregnant women attending pregnancy care clinics in Lusaka Province. You are being invited to take part in this research project because you are a pregnant woman and you are attending a pregnancy care clinic in Lusaka Province. Your participation in this study is voluntary. If you choose to participate, you may elect to withdraw your consent at any time.

WHAT IS THE PROJECT ABOUT?

The purpose of this study is to gain knowledge about the use of herbal medicine among pregnant women attending pregnancy care clinics in Lusaka Province. A "herbal medicine" is defined as any kind of product, such as a tablet, a mixture, a cream or a herbal tea, which is produced from plants and used to acquire better health. Today you will be asked to participate in an interview, which should take approximately 10 minutes to complete. Being in this study will not change your regular medical care from your doctor.

The project will collect and record personal information about you. Data will be collected on your age, marital status, educational level, ethnicity, profession, area of residence, and religion, on pregnancy-related factors (i.e., how many children you have and how many times you have been pregnant, current pregnancy month, smoking during pregnancy, and use of conventional medicines prescribed by your physician), the use of herbal medicines during pregnancy and their names, indications of use, sources of herbs, and what you think about the safety and efficacy of herbal medicines for both yourself and your foetus.

FORESEEABLE BENEFITS AND PREDICTABLE RISKS AND BURDENS OF TAKING PART

You will not receive any direct benefits from your participation in this study. Information from this study might help researchers better understand the extent of women's use of herbal medicine during pregnancy in Zambia, and might enable Zambian healthcare personnel to give relevant information to pregnant women to keep both them and their unborn babies safe. There are minimal risks involved in participating in this study.

VOLUNTARY PARTICIPATION AND THE POSSIBLITY TO WITHDRAW CONSENT

Participation in the project is voluntary. If you wish to take part, you will need to sign the declaration of consent. You can, at any given time and without reason withdraw your consent. If you decide to withdraw participation in the project, you can demand that your personal data concerning health be deleted, unless however, the personal data concerning health have already been analysed or used in scientific publications. If you at a later point wish to withdraw consent or have questions regarding the project, you can contact Magalie El Hajj via E-mail at: magaliehajj@hotmail.com or phone at: +260 76 49 21 307.

WHAT WILL HAPPEN TO YOUR PERSONAL DATA CONCERNING HEALTH?

Any personal data concerning health that has been recorded about you will only be used as described in the purpose of the project. You have the right to access information that has been recorded about you and the right to make sure that any error(s) in the information that is recorded is/are corrected. You also have the right to know which security measures have been/will be taken when your personal data concerning health is processed.

All information will be processed and used without your name or personal identification number, or any other information that is directly identifiable to you. A code links you and your personal data concerning health via an identifier list. Only Magalie El Hajj and Lone Holst will have access to this list.

Information about you will be anonymised or deleted a maximum of five years after the project has ended.

SHARING OF PERSONAL DATA AND TRANSFER OF PERSONAL DATA ABROAD

By agreeing to participate in the study, you are also consenting to that the information you provided during this interview can be transferred to another country as a part of research collaboration and publication. The project manager will therefore ensure that your personal data concerning health is kept safe.

The code that connects you and your personal data concerning health will not be released.

APPROVAL

Ethical approval to conduct the current study was obtained from the Regional Committee for Medical and Health Research Ethics (REC) in Western Norway. Simultaneously, ethical approval was also obtained from the University of Zambia Biomedical Research Ethics Committee (UNZABREC).

In accordance with the General Data Protection Regulation, the University of Bergen, Lone Holst and Magalie El Hajj are independently responsible to ensure that the processing of your personal data concerning health has a legal basis. This project has legal basis in accordance with the EUs General Data Protection Regulation, article 6a, article 9 nr.2 and your consent.

You have the right to submit a complaint on the processing of your personal health data concerning health to the Norwegian Data Inspectorate.

CONTACT INFORMATION

If you have any questions regarding the research project, please contact

Master student Magalie El Hajj via E-mail at: magaliehajj@hotmail.com or phone at: +260 76 49 21 307.

Dr. Doreen Sitali, University of Zambia, via E-mail at: sitalidoreen@yahoo.co.uk or phone at: +260 97 78 92 417.

Associate Professor Lone Holst, University of Bergen, via E-mail at: lone.holst@uib.no or phone at: +47 55 58 61 52.

Dr. Sody Mweetwa Munsaka, University of Zambia, via E-mail at: s.munsaka@unza.zm or phone at: +260 97 79 25 304.

You can also get in touch with the Norwegian Centre for Research Data (NSD)'s Data Protection Officer if you have any questions related to the use of your personal health data concerning health in the research project: nesstar@nsd.no.

C. Written Informed Consent

Master student: Ms. Magalie El Hajj

Project led by: Dr. Lone Holst

University of Bergen - Centre for International Health

My name is Magalie El Hajj. I am a Master student in Global Health from the University of Bergen, Norway. I am conducting a research study to get to know more about the use of herbal medicine among pregnant women attending antenatal care clinics in Lusaka Province.

Today you will be kindly requested to participate in an interview, which should take approximately 10 minutes to complete. It is up to you to decide whether or not to take part. If you do, you will be given this information sheet to keep and be asked to sign a consent form. You are still free to stop the interview at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive. All responses will be reported anonymously, and the signed consent form will be kept separate from your responses at all times.

If you have questions, you are free to ask them now.
If you have questions or concerns later, please contact:
Master Student **Magalie El Hajj** via E-mail at: magaliehajj@hotmail.com or phone at: +260 76 49 21 307.
Dr. **Doreen Sitali**, University of Zambia, via E-mail at: sitalidoreen@yahoo.co.uk or phone at: +260 97 78 92 417.
Associate Professor **Lone Holst**, University of Bergen, via E-mail at: lone.holst@uib.no or phone at: +47 55 58 61 52.
Dr. **Sody Mweetwa Munsaka**, University of Zambia, via E-mail at: s.munsaka@unza.zm or phone at: +260 97 79 25 304.

I CONSENT TO PARTICIPATING IN THE RESEARCH PROJECT

City/Town and Date	Participant's Signature or Thumbprint
	Participant's Name (in BLOCK LETTERS)

I confirm that I have given information about the research project.

Place and date	Signature
	Role in the research project

D. Questionnaire for the Use of Medicinal Plants among Pregnant Women in Lusaka Province, Zambia

Section 1: Sociodemographic Details

1. Please specify your age: ----------
2. Marital status:
   - ☐ Married
   - ☐ Single
   - ☐ Divorced
   - ☐ Widowed
   - ☐ Separated
3. Educational level:
   - ☐ Never been to school
   - ☐ Primary school
   - ☐ Secondary school
   - ☐ University Education
4. Religion:
   - ☐ Protestant
   - ☐ Catholic
   - ☐ Muslim
   - ☐ Other, please specify: ----------
5. Ethnicity: ----------
6. Area of residence: ----------
7. Occupation: ----------

Section 2: Pregnancy-Related Details

8. Please indicate the month of your pregnancy: ----------

9. Please indicate the number of pregnancies before this one: ----------

10. Do you have any children? ----------

11. Have you ever consumed any form of tobacco during your pregnancy?
    - ☐ Not at all
    - ☐ Now and then
    - ☐ Daily
    - ☐ I used to be a smoker before I became pregnant

12. Are you currently taking any pharmaceutical drugs, i.e., medicines acquired from pharmacies or clinics?
    - ☐ No
    - ☐ Yes

If "Yes", please complete the following table to indicate which medicine(s) you are taking and for what condition(s).

Medicine(s)	**Condition(s) taken for**

Section 3: Use of Herbal Medicines

13. Are you currently taking any herbal medicines or medicinal plants?
    - ☐ No
    - ☐ Yes

14. Have you ever used herbal medicines or medicinal plants in past pregnancies?
    - ☐ No
    - ☐ Yes
    - ☐ Unsure/don't remember

15. Do you think you will use herbal medicines or medicinal plants in the future?
    - ☐ No
    - ☐ Yes
    - ☐ Unsure

If you have not used herbal preparations during pregnancy, please proceed to Section 5.

Below is a list of medicinal plants. For each of the medicinal plants listed below please complete the following questions:

16. Ginger:

    Have you heard about this preparation?
    - ☐ No
    - ☐ Yes

    If "No", please proceed to question 17.

    Have you ever used during pregnancy?
    - ☐ No
    - ☐ Yes

    If "No", please proceed to question 17.

    What condition(s) did you use/take it for, and for how long?

17. Garlic:

    Have you heard about this preparation?
    - ☐ No

☐ Yes

If "No", please proceed to question 18.

Have you ever used during pregnancy?
☐ No
☐ Yes

If "No", please proceed to question 18.

What condition(s) did you use/take it for, and for how long?

18. Moringa:

Have you heard about this preparation?
☐ No
☐ Yes

If "No", please proceed to question 19.

Have you ever used during pregnancy?
☐ No
☐ Yes

If "No", please proceed to question 19.

What condition(s) did you use/take it for, and for how long?

19. Soya:

Have you heard about this preparation?
☐ No
☐ Yes

If "No", please proceed to question 20.

Have you ever used during pregnancy?
☐ No

☐ Yes

If "No", please proceed to question 20.

What condition(s) did you use/take it for, and for how long?

20. *Aloe vera*:

Have you heard about this preparation?
☐ No
☐ Yes

If "No", please proceed to question 21.

Have you ever used during pregnancy?
☐ No
☐ Yes

If "No", please proceed to question 21.

What condition(s) did you use/take it for, and for how long?

21. Did you use any other herbal preparations during your pregnancy?
☐ No
☐ Yes
☐ Unsure/don't remember

If "Yes", please complete the following table:

Product or plant name	**Condition(s) taken for**	**When taken (month of pregnancy)**	**Duration of use (number of days)**

Section 4: Herb Sources and Reasons for Herbal Medicine Use

22. Who recommended the use of herbal preparations to you? **Please tick all that apply**
    - ☐ My own idea
    - ☐ Family
    - ☐ Friends or neighbours
    - ☐ Traditional healers
    - ☐ Magazine or on social media
    - ☐ Doctor or pharmacist
    - ☐ Others, please specify: ----------

23. Please indicate the source(s) you use to obtain herbal medicine: **Please tick all that apply**
    - ☐ Self-preparation
    - ☐ Traditional healers or herbalists
    - ☐ Work places
    - ☐ Market places
    - ☐ Worship places
    - ☐ Family and/or friends

24. Did you inform your doctor/nurse/pharmacist about your use of herbal preparations during pregnancy?
    - ☐ Yes
    - ☐ No
    - ☐ Unsure/don't remember

25. If you want information about herbal preparations, who would be your primary source of information?
    - ☐ Health professionals
    - ☐ Traditional healers or herbalists
    - ☐ Religious leaders
    - ☐ Family or friends
    - ☐ Other, please specify: ----------

26. Please indicate the reasons(s) behind your use of herbal medicines during pregnancy: **Please tick all that apply**
    - ☐ Herbal medicines are more effective than conventional medicines
    - ☐ Herbal medicines are safe in pregnancy
    - ☐ Herbal medicines are much cheaper than conventional medicines
    - ☐ Herbal medicines complement conventional medicines
    - ☐ It is in my culture to use herbal medicines
    - ☐ I use herbal medicine when conventional medicine fails
    - ☐ Herbal medicines are more accessible than conventional medicines
    - ☐ Others, please specify: ----------

Section 5: Medical Conditions Experienced during Pregnancy and their Treatment

During your pregnancy, did you experience:

27. Nausea, vomiting or morning sickness?
    - ☐ No
    - ☐ Yes
    - ☐ Unsure/don't remember

If "Yes", please complete the following, otherwise proceed to question 28.

When did you experience it? **Please tick all that apply**
- ☐ During first trimester of pregnancy
- ☐ During second trimester of pregnancy
- ☐ During third trimester of pregnancy

Please state how you treated it in the box below:

28. Malaria?
    - ☐ No
    - ☐ Yes
    - ☐ Unsure/don't remember

If "Yes", please complete the following, otherwise proceed to question 29.

When did you experience it? **Please tick all that apply**
- ☐ During first trimester of pregnancy
- ☐ During second trimester of pregnancy
- ☐ During third trimester of pregnancy

Please state how you treated it in the box below:

29. Abdominal pain or indigestion?
    - ☐ No
    - ☐ Yes
    - ☐ Unsure/don't remember

If "Yes", please complete the following, otherwise proceed to question 30.

When did you experience it? **Please tick all that apply**

- ☐ During first trimester of pregnancy
- ☐ During second trimester of pregnancy
- ☐ During third trimester of pregnancy

Please state how you treated it in the box below:

30. Urinary tract infections?

- ☐ No
- ☐ Yes
- ☐ Unsure/don't remember

If "Yes", please complete the following, otherwise proceed to question 31.

When did you experience it? **Please tick all that apply**

- ☐ During first trimester of pregnancy
- ☐ During second trimester of pregnancy
- ☐ During third trimester of pregnancy

Please state how you treated it in the box below:

31. Have you experienced any other conditions during pregnancy?

- ☐ No
- ☐ Yes
- ☐ Unsure/don't remember

If "Yes", please complete the following table to indicate what other condition(s) you experienced and when, and how you treated it/them:

Condition	**Month of pregnancy**	**Treatment(s)**

Thank you very much for taking part in this study!

E. Guide for Authors: *Complementary Therapies in Clinical Practice*

(https://www.elsevier.com/wps/find/journaldescription.cws_home/704176?generatepdf=true)

COMPLEMENTARY THERAPIES IN CLINICAL PRACTICE

AUTHOR INFORMATION PACK

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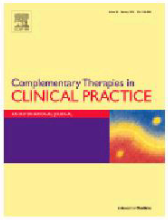

ISSN: 1744-3881

DESCRIPTION

Complementary Therapies in Clinical Practice is an internationally refereed journal published to meet the broad ranging needs of the healthcare profession in the effective and professional integration of **complementary therapies** within **clinical practice**.

Complementary Therapies in Clinical Practice aims to provide rigorous peer reviewed papers addressing research, implementation of complementary therapies (CTs) in the clinical setting, legal and ethical concerns, evaluative accounts of therapy in practice, philosophical analysis of emergent social trends in CTs, excellence in clinical judgement, best practice, problem management, therapy information, policy development and management of change in order to promote safe and efficacious clinical practice.
Complementary Therapies in Clinical Practice welcomes and considers accounts of reflective practice.

It will be of interest to all members of the healthcare profession including nurses, midwives, pharmacists, hospital doctors, general practitioners, physiotherapists, social scientists, psychologists, CTs researchers, practitioners of CTs, educationalists, managers, patients and individuals interested in CTs.

The Editor of *Complementary Therapies in Clinical Practice* invites authors to submit articles on all aspects of individual therapies, international news, book reviews, multimedia reports and correspondence.

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We now differentiate between the requirements for new and revised submissions. You may choose to submit your manuscript as a single Word or PDF file to be used in the refereeing process. Only when your paper is at the revision stage, will you be requested to put your paper in to a 'correct format' for acceptance and provide the items required for the publication of your article.
To find out more, please visit the Preparation section below.

The Editor of *Complementary Therapies in Clinical Practice* invites authors to submit articles on all aspects of individual therapies, international news, book reviews, multimedia reports and correspondence.

As a service to the community, this journal makes available online the accepted manuscripts as soon as possible after acceptance. At this stage, the author's accepted manuscript (in both full-text and PDF) is given a Digital Object Identifier (DOI) and is fully citable, and searchable by title, author(s) name and the full-text. The article also carries a disclaimer noting that it is an unedited manuscript which has not yet been copyedited, typeset or proofread. When the fully copyedited version is ready for publication, it simply replaces the author accepted manuscript version.

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You can use this list to carry out a final check of your submission before you send it to the journal for review. Please check the relevant section in this Guide for Authors for more details.

Ensure that the following items are present:

One author has been designated as the corresponding author with contact details:
• E-mail address
• Full postal address

All necessary files have been uploaded:
Manuscript:
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• Ensure all figure and table citations in the text match the files provided
• Indicate clearly if color should be used for any figures in print
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• A competing interests statement is provided, even if the authors have no competing interests to declare
• Journal policies detailed in this guide have been reviewed
• Referee suggestions and contact details provided, based on journal requirements

For further information, visit our Support Center.

BEFORE YOU BEGIN

Ethics in publishing

Please see our information pages on Ethics in publishing and Ethical guidelines for journal publication.

Studies in humans and animals

If the work involves the use of human subjects, the author should ensure that the work described has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for experiments involving humans. The manuscript should be in line with the Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals and aim for the inclusion of representative human populations (sex, age and ethnicity) as per those recommendations. The terms sex and gender should be used correctly.

Authors should include a statement in the manuscript that informed consent was obtained for experimentation with human subjects. The privacy rights of human subjects must always be observed.

All animal experiments should comply with the ARRIVE guidelines and should be carried out in accordance with the U.K. Animals (Scientific Procedures) Act, 1986 and associated guidelines, EU Directive 2010/63/EU for animal experiments, or the National Institutes of Health guide for the care and use of Laboratory animals (NIH Publications No. 8023, revised 1978) and the authors should clearly indicate in the manuscript that such guidelines have been followed. The sex of animals must be indicated, and where appropriate, the influence (or association) of sex on the results of the study.

Declaration of interest

All authors must disclose any financial and personal relationships with other people or organizations that could inappropriately influence (bias) their work. Examples of potential competing interests include employment, consultancies, stock ownership, honoraria, paid expert testimony, patent applications/registrations, and grants or other funding. Authors must disclose any interests in two places: 1. A summary declaration of interest statement in the title page file (if double-blind) or the manuscript file (if single-blind). If there are no interests to declare then please state this: 'Declarations of interest: none'. This summary statement will be ultimately published if the article is accepted. 2. Detailed disclosures as part of a separate Declaration of Interest form, which forms part of the journal's official records. It is important for potential interests to be declared in both places and that the information matches. More information.

Submission declaration and verification

Submission of an article implies that the work described has not been published previously (except in the form of an abstract, a published lecture or academic thesis, see 'Multiple, redundant or concurrent publication' for more information), that it is not under consideration for publication elsewhere, that its publication is approved by all authors and tacitly or explicitly by the responsible authorities where the work was carried out, and that, if accepted, it will not be published elsewhere in the same form, in English or in any other language, including electronically without the written consent of the copyright-holder. To verify originality, your article may be checked by the originality detection service Crossref Similarity Check.

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