Quality assurance of the university medical education, hospital services and traditional pharmaceutical products of the Bhutanese So-wa-rig-pa health care system

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Abstract

Background

The Bhutanese So-wa-rig-pa medicine (BSM) was integrated with the allopathic (modern) health care system in 1967. Ever since the health care integration policy was implemented, the BSM has gone through many phases of quality improvement and changes including the establishment of one university-based institute, 58 hospitals and Basic Health Units (BHU)-based health care services, and one traditional medicine factory. The BSM provides primary health care services to more than 20–30 % of patients who visit hospitals and BHU on a daily basis. However, there has been no study covering the quality assurance system of BSM. Our paper addresses this information gap.

Methods

This study was an observational ethnographic study supported by phenomenological understanding and content analysis of the data. The information was triangulated...
The use of traditional medicine (TM) or complementary and alternative medicine (CAM) is widespread around the world. It is estimated that approximately 85–90 % of the world’s population including developed nations use traditional or alternative or herbal medicines [1]. Its use is increasing worldwide [2]. With the growing use of TM, demand has grown for evidence on the quality, safety and efficacy of TM products and practices. Even in Bhutan with a strong history of TM, few doctors with a scientific outlook express reservations or are skeptical about the purported benefits of TM. Therefore, scientific validation of TM and creation of standard research data or knowledge to address the issues of quality, safety and efficacy has become a pressing issue. Creation of such scientific knowledge can help create the basis for better health care integration and an evidence-based health system that is more respectful towards local practices [3] and foster better collaborations across medical professionals.

Realizing the importance of TM, the World Health Organization (WHO) exercised the following: a) a need for common understanding of what constitute TM, b) the integration of TM with allopathic medicine, and c) the measures to improve the quality, safety and efficacy of TM [4]. To facilitate the development of the quality control system, the WHO also developed general standard policies, strategies, frameworks, guidelines, protocols, standard operating procedures, regulations and bylaws [2, 4–7].

While the TM in many countries are struggling to meet these WHO quality requirements—mainly for the lack of government’s support, the Bhutanese traditional medicine (BTM) or the Bhutanese So-wa-rig-pa (pronounced as So-wa-rig-pa) medicine (BSM) has gained roots in the mainstream health care system of the country. The BSM enjoyed wider people’s acceptance, received the successive Kings’ and the government support and was integrated with the allopathic or modern medicine in 1967. It started with a small dispensary in 1968 and developed into one of the complex organizations in the country with three main BSM management sectors: Department of Traditional Medicine Services (DTMS), Menjong Sorig Pharmaceuticals (MSP), and the Faculty of Traditional Medicine (FoTM). The DTMS under the Ministry of Health (MoH), looks after one National Traditional Medicine Hospital (NTMH), two regional referral traditional hospitals (Monger and Gaylegphu), 17 traditional medicine hospitals and additional 38 traditional medicine units established alongside major Basic Health Units (BHU) in the country. These units treat more than 20–30 % of the total daily outpatients visiting the hospitals and other health centers on a daily basis [8]. The MSP conducts research, quality assurance and quality control of raw materials and manufactured herbal products, medicinal plants collections, and processing of traditional medicines, which are distributed freely to the traditional medical centers across the country. The medicinal plants collection program facilitates the economically disadvantaged yak herders and other farmers to earn income and elevate their socio-economic status. It also helps in the conservation of pristine environment and has potential to facilitate the growth of herbal industry as well as the biodiscovery projects based on their ethnobotanical information. The FoTM under the Khesar Gyalpo University of Medical Science of Bhutan (KGUMSB) trains human resources required for catering the traditional medical services to the people.

All these three organizations are together responsible for the preservation of rich traditional medical culture and in providing quality, safe and effective traditional health care services. Ensuring the quality or ethnoquality of the BSM has direct implications on its long-term sustainability and the preservation of rich traditional medical knowledge. We have coined the term ethnoquality for the first time here and we defined it as “The cross-cultural study of the traditional knowledge and customs of how various ethnic healers/traditional medicine practitioners perceive and monitor the quality of medicines”. In their continuous efforts (more than 46 years) to improve the ethnoquality and preserve this age-old medical tradition, the FoTM, DTMS and MSP has undertaken various programs, measures and strategies. However, there is lack of proper studies or published information on what has been done so far to improve the quality of BSM. Not many people are aware of (including Bhutanese) whether there exists any proper policy and the quality management system while providing traditional So-wa-rig-pa medicine in the country.

This raises many questions. Is this medical system accepted by the people as a complementary health care system? Is it financially supported and protected by the government to be an integral part of Bhutanese health care system? Whether or not if there is any problem with the quality, safety and efficacy of the So-wa-rig-pa medicine? What are the quality assurance systems, practices and pillars that have been developed by the FoTM, NTMH and MSP? How is the quality of traditional So-wa-rig-pa medical education monitored and maintained by FoTM? How is the quality of traditional health care services managed by the traditional medicine hospital/units in the country? How is the quality and safety of medicines/drugs monitored and managed by MSP? Is there any scientific quality parameters and standards developed for assuring the quality, safety and efficacy of the medicines? Is there any scientific research carried out to make the BSM evidence-based medicine? What are the current quality deficiencies and how can they be addressed?

Having these research questions answered would give insights into the quality assurance system and the practices of an integrated health care services of Bhutan that has potential for providing the managerial lessons for other So-wa-rig-pa practicing countries and TM entrepreneurs including Tibetan medicine. Therefore, this study was conducted to determine what has been achieved in relation to improving the quality, safety and effectiveness of the traditional So-wa-rig-pa education, health care services and medicine production. It also sheds light on the existing government policies and the regulations related to the BSM and provide future directions.
Methods

Concepts and design

This study was derived from an ongoing phenomenal changes involving Bhutanese So-wa-rig-pa medicine ever since its integration with the allopathic (western) medical system in 1967. The concept was to describe, explain, and present to an international audience its quality assurance system and practices that were either modified in-situ based on traditional empirical knowledge or borrowed from western medicine quality control systems. Thus, our study design/framework includes ethnography, phenomenology, and content analysis. In our ethnographic approach, we have associated ourselves as the researchers (both trained in western education system) for more than 13 years at the MSP and have worked closely with the Bhutanese So-wa-rig-pa communities—mostly traditional physicians at the FoTM, NTMH, and MSP. These engagements with the practitioners helped us gain insight into their condition and perception of health system while also shaping our phenomenological understanding including So-wa-rig-pa philosophy and historical events. Our own personal experience and first-hand observational work enabled us to compile and synthesise the existing information.

This observational data was then supported by the content analysis of the existing body of literature (both scientific and traditional) including traditional medical textbooks, health system policy documents, regulatory frameworks, traditional medicine education curriculum, disease classification and treatment guidelines, diagnostic methods and treatment practice records, quality assurance guidelines, standard manufacturing instructions, product profiles, medicinal plants collection reports and other documentation practices of three organizations (FoTM, NTMH, MSP) that were made available at the time of study. This information sources were extracted from the existing library, government websites, policy documents, acts, regulations, guideline books and the published scientific literature that are all retained in our research notes and listed in the bibliography. Some contents were obtained as previously described [8]. The search terms such as: ‘Bhutanese So-wa-rig-pa medicine’, ‘Bhutanese traditional medicine’, ‘Bhutanese medicinal plants’, ‘health policy’, ‘drug policy’, ‘medicine act’, ‘quality assurance’ and ‘quality control parameters’ were used for the content analysis involving the internet and relevant databases. For obtaining specific references and guidelines that are used for improving the quality of health care services, traditional medical education and the production of medicines, a standard data entry form was developed and distributed to relevant study participants representing FoTM, NTMH and MSP who were then requested to fill the form with the latest references used at these three organizations to guide the quality assurance practices. To clarify, crosscheck and authenticate the unstructured data that we have observed and recorded through ethnographic and content analysis methods, we have also consulted more than five Drungtshos (So-wa-rig-pa medicine physician), two smen-pas (traditional clinical assistant) and a Pharmacognosist of MSP (see Acknowledgement for their details) (total participant \(N=8\)). These expert participants were selected using convenience and purposive sampling method. They were consulted mainly based on their vast experience in the areas of traditional clinical practices, university lectureship, herbal formulations, field identification and collection of medicinal plants. The consultation with these experts especially on the clinical, teaching and medicinal plants identification practices were carried out using one-one in-depth question—answer sessions either through Facebook chat or an email correspondence. The topics of open discussions varied depending upon our understanding of the BSM practices.

The systematic process in documenting observations and learning from the focus group discussion was performed as previously described by Wangchuk et al. [8, 9]. Both the qualitative and quantitative information was gathered and retained in our research notes, Facebook chat account and the email correspondences. Drungtshos (\(N=5\)) (see details in the Acknowledgement) were involved to triangulate the data sources in this paper by engaging them to proofread the manuscript, authenticate the information and let them raise their comments, which we have incorporated in the paper.

Research team and reflexivity

While the first author obtained his M.Sc. and PhD credential in medicinal/natural products chemistry from the University of Wollongong in Australia, the second author obtained his higher national diploma quality assurance certification from Hull College, UK and postgraduate diploma in GMP from the Swinburne University of Technology in Australia. As a Senior Researcher and a Quality Manager at MSP for more than 13 years, we have worked closely with the Bhutanese So-wa-rig-pa communities—mostly traditional physicians at the FoTM, NTMH, and MSP through which the cumulative information was gathered, processed and reported here. During that timeframe we have observed, recorded, participated in many traditional So-wa-rig-pa meetings, conferences and group discussions, involved in translation of So-wa-rig-pa medical uses and terms, provided trainings to the traditional physicians and clinical assistants on modern research methodology, investigated many research problems and even helped them devise quality assurance parameters to strengthen So-wa-rig-pa medical system in Bhutan. More specifically, both the qualitative and quantitative information was gathered using the method as described in Wangchuk et al. [8, 9] and also through Facebook based-chat interviews and the email correspondences (conducted as the part of first author’s PhD work in between 2009 and 2014). The study participants were our office colleagues working at the FoTM, NTMH and MSP as the So-wa-rig-pa practitioners, lecturers, administrator, researchers and the quality specialist. We have avoided biasness in our reasoning and no assumptions were made to enhance the current practices of Bhutanese So-wa-rig-pa medicine. The study is much of a factual description based on our ethnographic and content analysis, which is presented as-it-is practiced in Bhutan.

Data analysis and reporting

Ethnographic data were recorded and were authenticated with the participants from FoTM, NTMH and MSP. The content analysis was used for synthesizing the data of oral accounts and the literature statements on the quality policy, regulation, safety and efficacy measures. The information was then compiled and represented into diagrammatic quality pillars for each organizations as: a) quality practices of university-based traditional medical education (FoTM), b) quality practices of hospital-based health care services (NTMH), and c) the quality practices of production-based medicines at MSP. Our first-hand experience as the researchers with the BSM for more than 13 years enhanced the data analysis, synthesis and discussions of this paper.

Study limitations

This study did not cover the patients’ perspectives or that of policy and decision makers at the Ministry of Health in Bhutan. It is purely an observational and content analysis study and is designed to present the quality assurance system that is in practice at FoTM, DTMS and MSP at the time of study. A separate cross-sectional study is necessary to understand the patients’ or general public’s perspectives on the quality of BSM.
Policy frameworks supporting the Bhutanese So-wa-rig-pa health care system

The content analysis revealed that even before the WHO policy of integration was formulated, the third King of Bhutan, Jigme Dorji Wangchuk integrated the BSM with allopathic medicine as early as 1967. During our 13 years of observations, we saw the BSM being transformed into a sophisticated organization. For example, the small training institute was being upgraded to FoTM under Khesar Gyalpo University of Medical Sciences, the NTMH was upgraded to the Department of Traditional Medicine, and the small Research and Quality Control Laboratory (RQCL) was upgraded to semi-mechanized MSP. Today, there are 58 traditional medical hospitals and units, which are established next to each modern hospital building, follows the mainstream medicine acts and regulations, and adheres to integrated policy of quality assurance system. The BSM has become one of the important cultural and traditional heritages of Bhutan and there are proper inspection and enforcement agencies to check if the quality of BSM is practiced at the acceptable level within Bhutan. This medical system is enshrined in the constitution [10] and it is stated that ‘The State shall endeavor to preserve, protect and promote the cultural heritage of the country’ and ‘shall provide free access to basic public health services in both modern and traditional medicines’. Bhutan 2020: A Vision for Peace, Prosperity and Happiness [11] states that, ‘We must continue to provide a place for traditional medicine in our system of health care and must seek to achieve further improvements in its quality. As these qualities become substantiated by scientific research, there is a growing need to integrate traditional medicine more effectively with the modern health care system’. The national health policy of the Ministry of Health [12] states that, ‘Focused efforts shall be directed towards making the BSM, the center of excellence in providing quality traditional medical services including wellness center that is recognizable at an international level’. The National Drug Policy [13], states that ‘The government shall promote and support research and local manufacture of pharmaceuticals including traditional medicines and that the Drug Regulatory Authority (DRA) shall be the agency that develops and implements most of the legislation and regulations related to quality, safety and efficacy of drugs and the accuracy of product information on pharmaceuticals’. The Medicines Act of the Kingdom of Bhutan [14] and Bhutan Medicine Rules and Regulation [15] mentions that ‘The pharmaceutical factories including the MSP shall conform to the current Pharmaceutical Inspection Convention/Co-operation Scheme (PIC/S) Guide to Good Manufacturing Practice (GMP) for medicinal products, shall have a separate quality control unit with qualified staff and appropriate equipment to carry out quality tests of raw materials and the finished products, and shall register the medicinal products with the DRA of Bhutan prior to making commercially available in the market’. The Quality Assurance and Standardization Division (QASD) [16] states that ‘QASD shall support the process of continuous quality improvement through policy development and adoption, establishment of quality standards, training and implementation of quality strategies at health facility and health program levels.’ Bhutan Medical and Health Council (BMHC) mandate states that ‘The medical and health professionals should be all registered to promote competency and ensure the safety of health of the public’. While the DRA and the BMHC are the independent external regulatory bodies that frame overall laws and regulate the quality of the medicines and services, the QASD is an internal body under the Ministry of Health which monitors and assess the quality of services and prepares the organizations for compliance to external regulatory requirements. Most of these policy frameworks, regulatory statements and the quality parameters are found accommodative of BSM concepts and requirements. This is a strong indication of the government support on the preservation, growth and promotion of BSM as a health care provider. The BSM, which is based on Buddhist philosophy, has strong quality and moral ethics, health concepts and manufacturing process, which can enrich the western-borrowed health quality concepts and parameters.

Quality assurance system and practices of the Bhutanese So-wa-rig-pa medicine

We have observed that the BSM has made decent progress in all areas of infrastructure, human resources and quality assurance system ever since its integration with allopathic/modern medicine in 1967. Traditionally, according to Drungtsho participants, the quality of BSM is defined by smen-pai-yu-drug (Physician’s six merit/criteria) and che-pai-yen-lag-b.duen (translated as ‘seven quality attributes of medical procedures’ or ‘seven affectionate branches of medical practices’). In essence, the quality of BSM is determined by how the diseases are diagnosed appropriately through compassionate patient-centered approach by the physicians and facilitates development of the patient’s balanced health - physically, mentally and spiritually. According to WHO [17], the quality of a health system is defined as a process of seeking continuous improvements in the dimensions of acceptability, accessibility, equity, affordability, efficiency, effectiveness, and safety. This study reveals that, the MoH have continuously strived to improve these six dimensions of quality in BSM through three main administrative and functional strategies: a) imparting quality BSM education and developing technically qualified and skilled practitioners at FoTM, b) establishing BSM hospitals alongside all modern hospitals and BHUs and providing free health care services throughout the country, and c) manufacturing quality medicines at MSP using pristine Himalayan medicinal resources.

University-based quality assurance of BSM education and human resource development

Most of the participants who contributed and authenticated the information in this study were the alumni of FoTM (previously known as NITM). The documents and the websites of FoTM highlighted the institute being a premier tertiary institute in the country (with more than 48 years of experience) in providing quality BSM education. Its vision and mission [18] states that: ‘The FoTM will strive to achieve excellence in the design, development and delivery of So-wa-rig-pa education programs through research and innovation, blending rich ancient wisdom and modern science to make the programs relevant for the current health needs of the people. It will incorporate the
of research that were carried out at NITM and the quality of research papers that were published in the journal. The first author of this paper (Phurpa Wangchuk), Drungtsho

Fig. 1

Eight pillars or strategies of quality assurance system practiced at FoTM in providing BSM education and training
These sets of FoTM’s practices resulted in producing high-quality graduates that have even surpassed other technical graduates from other modern technical universities both within the country as well as from abroad. These changes had ripple effects in quality of BSM education and students. For examples, in between 2007 and 2013, two FoTM graduates topped the Royal Civil Service (RCSC) examination [25] and all the graduates secured government job which were indicative of the quality of BSM education policy and courses offered by the institute. Getting selected in this RCSC examination is considered the stepping-stone to higher echelon of professional and leadership career in the country.

Hospitals/health centers-based quality assurance of BSM health care services

To the best of our knowledge, there exist no specific policy or NTMH statement that mentions the need to adhere to the WHO definition of quality while providing traditional health care services. However, we have observed that the DTMS under the MoH have strived hard to address and attain many dimensions of quality, which we have depicted in Fig. 2 as the eight dimensions of quality pillars that are in a way related to the WHO definition of the quality of a health system. The WHO dimensions of quality of health care system includes achieving acceptability, accessibility, equitability, efficiency, effectiveness, and safety. Since BSM is closely knit with Buddhism that is central to people’s beliefs, cultures and tradition, it has gained widespread acceptance from the king, government and the people. The Buddhist-based ethical principles and modern clinical norms practiced by the Drungtshos have also helped gain respect for the medical system. A study conducted in Thimphu by Lhamo and Nebel [26] showed that the attitude of people towards BSM was still good and encouraging, and that the treatment is sought by all ages, young and old and also across different levels of education. The practitioners themselves believe that BSM is a patient-centred health care delivery system where all patients are provided free access to it ever since its integration with modern health care system. Having the BSM alongside modern hospitals not only provided health care choices and access from the same building to the people but also helped preserve one of the country’s rich cultural heritages.

So-wa-rig-pa medicine dispensary was established at Dechencholing in 1968 and since then the government has expanded the services to all parts of the country with the objectives of making it more accessible. Currently, we found that there are 58 BSM centers/units attached to modern hospitals and Basic Health Units (BHUs), which are distributed equitably in all parts of the country. The health care integration policy enabled the BSM to share the modern hospital building and other health resources that expedited the establishment of the traditional treatment centers in a cost effective manner. Accommodating both modern and BSM in the same hospital have maximized resource utilization and facilitated efficient cross referral of patients between the two medical systems. Drungtshos and smen-pas, with whom the authors have consulted and worked with for more than 13 years, said that modern doctors often refer to them the patients with chronic diseases such as sinusitis, arthritis, rheumatism, digestive and nervous disorder. On the other hand, the Drungtshos refer the patients that require surgeries and antibiotic treatment to modern doctors. The BSM has niche health care services including preventative care that focuses on lifestyle or behavioral adaptations. Lifestyle changes involve personal adaptations to the ever changing seasons, climates, environment, diets and other societal norms. The information on lifestyle changes also forms part of the daily prescription advice and counseling services provided by the physicians. Mental health and general wellness activities have already been explored by the DTMS, MoH in Bhutan. The BSM treatments have improved the health outcomes for many individuals and communities. However, the treatments provided by BSM practitioners varied among the individual Drungtshos and smen-pas depending upon their knowledge and experience.

So-wa-rig-pa medicines are generally considered safe, but like modern drugs it can result in overdose and severe side effects if patients fail to adhere to the prescription.
Packaging materials. The raw materials include plants (as bulk ingredients), minerals, precious metals and animal parts. To ensure quality, the raw materials are subjected to laboratory-based quality control testing of raw materials, pre-processed materials and manufactured herbal products, and quality control of labels and packaging materials. The quality of the manufactured medicines has been monitored in three main tiers at MSP. They are: a) quality assurance in the field during the collection of medicinal plants, b) laboratory-based quality control testing of raw materials, pre-processed materials and manufactured herbal products, and c) quality control of labels and packaging materials. The raw materials include plants (as bulk ingredients), minerals, precious metals and animal parts.

Based on the information gathered during this study and also observed by the authors while working at MSP in between 1999 and 2014, it is evident that the MSP have capitalized on improving the eight pillars of quality assurance norms or practices while manufacturing the traditional medicines (as shown in Fig. 3). Our assessment found that the quality of the manufactured medicines has been monitored in three main tiers at MSP. They are a) quality assurance in the field during the collection of medicinal plants, b) laboratory-based quality control testing of raw materials, pre-processed materials and manufactured herbal products, and c) quality control of labels and packaging materials. The raw materials include plants (as bulk ingredients), minerals, precious metals and animal parts.

**Pharmaceutical industry-based quality assurance of medicine production**

Traditionally, the quality, safety, and effectiveness of any medicine/drug is believed to be determined by the quality of the raw materials and how they are handled through collection and production processes. Like modern medicine, the quality assurance of BSM production is very complex. What makes it even more complex is its multi-ingredient formulations. Some BSM has more than 100 ingredients with each ingredient possessing assembly of complex chemicals. Hence determining purity or impurity profiles for BSM formulations is harder to achieve. It requires cross-disciplinary approach and extensive collaborations with many stakeholders including; farmers, raw material suppliers, traders and businessmen, farmers, park managers, foresters, conservationist, environmentalist, ecologist, horticulturist, Drungtshos, smen-pas, chemist, pharmacognostist, pharmacist, pharmacologist, ethnobotanist, quality control manager, drug regulatory inspectors, planners and administrators. Besides, it requires careful approach to see that while modern scientific quality control protocols are introduced, the ancient wisdom of BSM is not lost or discarded. Therefore, it is apparent that huge financial resources is required to establish and run the mechanized BSM factory that is accommodative of both modern standards and empirical traditional practices.

From historical accounts of MSP, we found that between 1980s and 1990s, numerous international funding bodies including World Health Organization (WHO), Italian DISVI project, non-governmental organization and two successive European Union (EU) projects (Phase I in 1994–1998; Phase II in 2006–2009) were brought in to establish the MSP with modern infrastructure, mechanize the medicine production, strengthen human resource capacity, conceptualize corporatization of MSP and address the long term sustainable supplies of traditional medicines. Under these projects, various technical experts/assistants (TAs) from Europe, India and Thailand have been recruited in Bhutan and their technical inputs can be observed in the current MSP infrastructures, research activity settings, quality control system, Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP). While modern scientific approaches including the Good Manufacturing Practices (GMP), Good Laboratory Practices (GLP), Good Collection Practices (GCP), Good Dispensing Practices (GDP), and the Total Quality Control System (TQCS) were introduced, the ancient ethnoquality practices were retained, preserved or slightly adapted to meet the current needs.

These guidelines form the part of the continuing medical education (CME). The Drungtshos and smen-pas are trained on how to follow, operate and use these guidelines while providing the traditional medical health care services.

### Pharmaceutical industry-based quality assurance of medicine production

- **i. Traditional classification of diseases and related health problems-2005**
  - About 79 diseases that are prevalent in Bhutan are described, coded and standardized by this guidebook and helps the BSM practitioners in correct diagnosis and proper treatments.

- **ii. Standard treatment guide for traditional medicine-2006**

- **iii. National traditional medicine professional service standards-2007**

- **iv. Guidelines for detecting, reporting and managing adverse drug reaction-2007**

- **v. Therapy guidelines for traditional medicine practitioners-2008**

- **vi. Standard operating procedure for traditional medicine services-2008**

- **vii. Monographs on the use of traditional medicine in primary health care-2012**

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**Fig. 3**
Field-based quality control of the collection of medicinal plants

Collection of medicinal plants is the important activity of MSP. Correct identification of plants from the fields and the markets is considered the first crucial stage in assuring the quality, safety, and efficacy of medicines [9]. The field-based quality control protocol was reported previously [8]. In BSM, there exist an ancient written code of conduct or doctrine called *g.ches-pai-yan-lag-b.dun* (can be translated as ‘seven quality attributes of medicinal procedures’ or ‘seven affectionate branches of quality practices’), which ensure the quality of medicinal plants while collecting in the field. These seven quality doctrines include: a) correct identification of medicinal plants, b) collecting medicinal plants from the right natural habitat, c) following appropriate collection season and time, d) processing, drying, pre-processing and detoxifying the plants (wherever prescribed), e) using appropriate BSM recommended drying methods, f) proper storage and g) spiritual empowerment of herbs. The ethnoquality doctrine resembles ‘Good Collection Practices (GCP). During the collection season, the farmers’ responsibility is to collect the plant materials from the field based on the prior plant collection training they have received and the list provided to them by MSP. Other important post harvest care (as prescribed in the traditional medical texts), storage and spiritual empowerment are carried out by the MSP field-work team comprising pharmacy assistants, quality control staff and a *smen-pa*. Although detoxification of plants should be done during the fieldwork, they are currently carried out in the MSP because of lack of adequate facilities in the fields.

Laboratory-based quality control of raw materials

This field quality control system of the medicinal plants is supported by the laboratory-based scientific pharmacognostical and the phytochemical studies. In the context of quality-setting studies carried out at MSP, pharmacognostical studies mainly involve retention of herbarium specimen of each plant collected from the field for authentication, setting reproducible in house quality control standards and parameters for these medicinal plants, and developing plant monograph. Our literature search revealed that the WHO had released a series of plant monographs [6, 34–37] containing standardized methods, limits and other quality control parameters. However, our assessment of these documents showed that only few low altitude medicinal plants species have been covered by these WHO monographs and none of the 116 high altitude medicinal plants that are currently used in BSM were incorporated. Some of the quality parameters described in this monographs are beyond the affordability of many developing nations and are also very lengthy process, which is not feasible when hundreds of plants have to be screened for quality. As a result, an in-house quality control standards and parameters were developed by MSP, with the help of the chemist and pharmacognostist, for some high altitude medicinal plants (HAMP) following the formats and quality control protocols set by WHO [5, 38]. The MSP have later compiled two volumes of monographs on 40 HAMP [39, 40] and a Handbook on Quality Control of Raw Materials [41]. These monographs and quality control handbook are currently used as the standard references for the laboratory quality analysis of raw materials. The
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manufactured product quarantine, the quality control technicians test them for an overall quality following the prescribed quality control parameters in the product monograph. The quality parameters used for screening the quality of the manufactured products includes: a) description and organoleptic characteristics, b) hardness, c) friability, d) thickness, e) extractive value, f) uniformity of weight/dosage/weight per mL, g) pH value, h) disintegration, i) percentage loss on drying, j) bulk density, k) dosage forms and product identity, l) diameter m) thickness, and the o) HPTLC profile (Fig. 5). Quality control of label and packaging materials (includes dimensions, GSM, design, visual effect and defect and print quality) are also carried out to ensure their compatibility for packaging of manufactured product. The technical staffs responsible for the labeling and packaging section of MSP are required to sit for competency examination conducted by the DRAB. If the product fulfills the quality screening standards prescribed in the individual monograph, the products passes the quality test and are released to the Ministry of Health who distributes them to BSM hospitals and the BSM units across the country. However, if the final products don't meet the quality requirements prescribed in the monograph, they are either sent back for re-processing or rejected. Rejection of a manufactured drug is very expensive when produced in bulk as one product contain many expensive ingredients and therefore, all preventative process controls during the production are mandatory.

![HPTLC profile of two finished products](image)

**Tracks of Plate No: 10**

| VIsualization : UV 366nm |
|--------------------------|
| T1 = 'ba-sam-lha-lung' (Reference sample) |
| T2 = 'ba-sam-lha-lung' (Test sample) |
| T3 = a-ru-10 (Reference sample) |
| T4 = a-ru-10 (Test sample) |

**Mobile phase:** Toluene/Ethyl acetate/Formic acid

(9:9:2 V/V)

The medicines that are manufactured at MSP for the first time and are used for treating the diseases must be registered with DRA. The DRA regulations including the 'Bhutan medicine rules and regulations-2012'[15] and the 'Guideline for application for registration of medicinal products-2013' [56] states that all the finished products or BSM drugs must produce enough dossiers/documented to prove their quality, safety and efficacy before releasing them into the hospitals and BHUs. Gathering the existing documents in this regards, we found that there exist heaps of products registration documents which include: a) company profile, b) manufacturing license, c) product profile, d) quality profile, and e) guidance of documentation system. The company profile documentation comprises an organization chart, vision and mission statement, quality policy of an organization, overall list of human resources, list of qualified technical persons, types of medicines produced, capacity of production, list of available pharmaceutical machineries, list of quality control instruments, and the list of key competent persons in the production and the quality control. The product profile for each medicine submitted for registration must have the information including: batch manufacturing formula, list of raw materials, product name, batch size, dosage form, pack size, manufacturing instruction, in-process quality control procedures, list of ingredients, a copy of original So-wa-nig-pa text references for each ingredient, a copy of original So-wa-nig-pa text references of the finished product formulary, manufacturing process flow chart, pre-processing method of raw materials, labelling and packaging instruction, and the price structure. The quality profile includes: certificates of analysis (CoA) of raw materials, CoA of manufactured products, CoA of labelling, CoA of packaging, stability study report (both accelerated and real time), adverse drug reaction reporting protocol, QC methods, QC release procedures and the stability protocols. These CoAs and protocols are to be appended with products specifications, inserts and product samples.

Documentation system consists of three components a) product profile which defines description, strength, reference method, packaging type and dosage form, b) quality profile defines manufacturing process, list of equipment both in production and quality control laboratory, content of active ingredients in the manufactured products, official methods used, report of raw materials and test methods, labels and packaging material, c) pharmacology profile is currently limited to the traditional uses only and supplying the BSM literatures as references or as supporting documents suffices the legal requirement for this profile. Although these regulatory requirements are mostly based on the western-borrowed pharmaceutical concepts that are very often difficult to fulfill, it improved the systematic documentation system of the BSM manufacturing process and enhanced the overall quality of the medicines.

### Constraints, challenges and suggestions

We have observed that the quality assurance system of BSM have drastically improved in comparison to the day when it was first integrated with the modern health care system in Bhutan in 1967. Quality assurances have become part of the good governance system and all three organisations (FoTM, DTMS and MSP) try to constantly adjust to the current needs of the society in the country. There are also many health and drug related regulations and enforcement agencies to inspect and monitor the ethical practices of the practitioners, hospitals and manufacturer. However, despite many improvements and system in place, there are various issues confronting the quality of BSM and the triangulation of data obtained from content analysis, observations and open group discussions confirmed this. The FoTM lacks qualified and experienced lecturer who could conduct independent inquiry-based research on BSM. Research is a building block of any university or institution and for FoTM, it is even more crucial to have research component built in the curriculum. Without research component, both the lecturers and the students would be learning only what is being written in the ancient textbooks. These written concepts need validation through research, which would lead to the development of new knowledge. The KGUMSB, with new leadership, is expected to remodel FoTM into a research-based institute.

The DTMS has established a research section but there is need for qualified staff to lead the section. There are 58 BSM centres/units in total and few of these units’ lack Drungtshos. To provide quality and safe services, qualified and competent professionals must run all these units in the country. Therefore, there is need for more Drungtshos. In addition, Drungtshos and smen-pas have raised the issues of the shortage of medicine supply in their units. The short supply of required medicine can affect the quality of traditional health care services. While many standard treatment guidelines and standard operating procedures (SOPs) have been endorsed and implemented, there is concern that few freshly appointed Drungtshos and smen-pas lack confidence to deliver the standard services. The training on using guidelines and SOPs are conducted as a part of in-service CME. Instead of having the course as a CME component, it would be worthwhile to put them as a part of FoTM curriculum.

MSP is the nerve-centre of BSM and any shortfalls in the medicine productions would immobilise the whole traditional medical system of a country. Sometime the product fails to meet the quality standard and re-processing the formulation prolongs the release of the manufactured products on time. The content analysis showed that Lingzhi (in
Abbreviations

BHU, Basic Health Unit; BMHC, Bhutan Medical and Health Council; BSM, bhutanese So-wa-řig-pa medicine; BTM, Bhutanese Traditional Medicine; CAM, complementary and alternative medicine; CoA, certificate of analysis; DISVI, Italian Disarmo Sviluppo; DRAB, Drug Regulatory Authority of Bhutan; DTMS, Department of Traditional Medicine Services; EDL, essential drug list; EU, European Union; FoTM, Faculty of Traditional Medicine; GCMS, gas chromatography mass spectrometry; GCP, good collection practices; GDP, good dispensing practices; GLP, good laboratory practices; GMP, good manufacturing practices; GNH, gross national happiness; HAMP, high altitude medicinal plant; HPLC, high performance liquid chromatography; HPTLC, high performance thin layer chromatography; ILCS, Institute of Language and Culture Studies; IR, infrared; JCU, James Cook University; KGUMSB, Khesar Gyalpo University of Medical Sciences of Bhutan; LAMP, low altitude medicinal plant; MAPS, medicinal and aromatic plants section; MBBS, bachelor of medicine and bachelor of surgery; MoH, Ministry of Health; MS, mass spectrometry; MSJ, manjong sorig journal; NBC, National Biodiversity Centre; NTMH, National Institute of Traditional Medicine; NMR, nuclear magnetic resonance; NTMH, National Traditional Medicine Hospital; PIC, pharmaceutical inspection convention; PMSD, Post Marketing Surveillance Division; QASD, Quality Assurance and

Conclusions

The integration of BSM with the modern health care system in 1967, under the command of the third king Jigme Dorji Wangchuk, was the foundation for quality assurance system in Bhutan. Having received the government’s support and wider people’s acceptance, there is no reason for the BSM not to flourish and improve its quality of health care services. Three functional organizations including FoTM, NTMH and MSP have established their image and brand as ‘Man-jong So-wa-ṛig-pa’ (often spelt as ‘s-men-ljung-g.so-ba-ṛig-pa’) and have made decent progress over the decades. Drungtshos and s-men-pas receive free ancient medical education and knowledge delivered through integrated curriculum (traditional and modern pedagogy integrated). Unlike in the past, the traditional medical students are selected from the high achiever’s list of School of Language and Culture Study (ILCS) and most preferably with the science background. Continuous training for 5 years (Drungtsho course) and 3 years (s-men-pa course) supported by clinical attachments to NTMH, internship at MSP, and the field works at the collection centers prepares them to take up the highly coveted job in the government run district hospitals and Basic Health Units in the country.

Based on the job vacancies, the Drungtshos and s-men-pas are selected by the ROSC and are compulsorily registered with the BMHC (responsible for ensuring their ethical, professional and skills standards). The standard treatment guidelines, protocols and refresher course provided by NTMH guide them/BSM practitioners in providing quality and safe traditional health care services. Trained in health and sanitation, reporting adverse drug reactions, and good dispensing methods, the BSM practitioners are equipped to handle safety problems and work hand-in-hand with the modern doctors through cross-referral system in ensuring overall quality of the health services delivered through 58 TM centers.

The medicines that the BSM practitioners prescribe are manufactured at MSP using the country’s own organic medicinal plants that grows in the pristine Himalayan mountains. Monitoring the quality of medicinal plants at the sources and also in the laboratory using scientific quality control parameters ensure the total quality of the medicine manufactured. While ancient wisdom of BSM related to quality assurance system were retained, modern scientific studies were introduced, which made it unique by its own standing. Quality control system at MSP was inspired by the WHO guidelines and European GMP. The MSP have registered 75 polyingredient formulations with the DRA that regulates stringent (by local standard) manufacturing process and quality control measures through registration and regulatory audit in the country.

We argue that the quality control system in Bhutan manages to reach the high standards required by modern science while retaining and integrating traditional notions and measures of quality as enshrined by BSM. However, many efficacy and effectiveness stories remain anecdotal whose efficacies are based on the BSM textbooks or first-hand experience of Drungtshos. These claims need to be substantiated by the chemical and clinical studies, which is partially lacking at the MSP due to limited technical experts and financial resources. The safety and effectiveness of BSM can be substantiated only through clinical studies and such studies can be conducted at relatively low cost as studying traditional medicines does not require pre-clinical nor toxicology studies. Few studies carried out by the first author on 11 medicinal plants [57, 58] in collaboration with UW and JCU in Australia, and SU and BIOTEC in Thailand, resulted in the: a) elucidation of five new phytochemicals, b) verification of the ethnopharmacological uses of these medicinal plants, and c) discovery of new antimalarial drug lead candidates. These scientific data form the basis for developing plant monograph and quality control parameters with the known marker compounds. Remaining plants can be investigated using similar strategy and protocols. It is proper to focus on the scientific studies of single ingredient. The metabolomics involving mass Spectrometry (MS), Infrared Spectroscopy (IRS), Gas Chromatography Mass Spectrometry (GCMS) and Nuclear Magnetic Resonance (NMR) could help us understand the complex chemical mixture responsible for the efficaciousness of the BSM.

Immediate attention can be given to the following: a) focus on studying individual medicinal plants and creating metabolomics fingerprints of bioactive marker compounds including HPTLC profile which can be used for daily quality control evaluations, b) carry out advanced molecular and clinical studies on the finished products to substantiate the ethnopharmacological uses, c) check the chemical and bioactivity variations between the wild types and the cultivated species as chemical profile would be different depending upon their nutrient availability, which could affect the quality of medicines, and d) collaborate with other So-wa-ṛig-pa-practicing countries to identify existing differences and similarities in terms of education and clinical practices, plants uses and formulations, research and development activities, and the quality assurance of the raw materials and finished products.

The BSM including medicinal plants program in Bhutan is one of the sustainable vehicles of GNH. For patients - its formulations are a solace of treatment and cure; for BTM and So-wa-ṛig-pa practitioners - it is a source of employment; for pharmaceutical organizations - it is a potential chemotherapeutic pool waiting for biodiscovr [59]; and for farmers - it is a tool for income generation and poverty eradication [60]. Overall, it accelerates the health and well-being of the society and produces happy society. Failing to maintain the quality of BSM would negatively affect the sustainability of the health care system and the networks of medicinal plants stake holders including patients, farmers, brokers, business people and buyers, MSP, TMH, FoTM, MAPS and the NBC. Therefore, continuous efforts to improve the quality of BSM are essential and require immediate government investments in developing advance research and development facilities.

Abbreviations

BHU, Basic Health Unit; BMHC, Bhutan Medical and Health Council; BSM, bhutanese So-wa-ṛig-pa medicine; BTM, Bhutanese Traditional Medicine; CAM, complementary and alternative medicine; CoA, certificate of analysis; DISVI, Italian Disarmo Sviluppo; DRAB, Drug Regulatory Authority of Bhutan; DTMS, Department of Traditional Medicine Services; EDL, essential drug list; EU, European Union; FoTM, Faculty of traditional medicine; GCMS, gas chromatography mass spectrometry; GCP, good collection practices; GDP, good dispensing practices; GLP, good laboratory practices; GMP, good manufacturing practices; GNH, gross national happiness; HAMP, high altitude medicinal plant; HPLC, high performance liquid chromatography; HPTLC, high performance thin layer chromatography; ILCS, Institute of Language and Culture Studies; IR, infrared; JCU, James Cook University; KGUMSB, Khesar Gyalpo University of Medical Sciences of Bhutan; LAMP, low altitude medicinal plant; MAPS, medicinal and aromatic plants section; MBBS, bachelor of medicine and bachelor of surgery; MoH, Ministry of Health; MS, mass spectrometry; MSJ, manjong sorig journal; MSP, Menjong Sorig Pharmaceuticals; NBC, National Biodiversity Centre; NTMH, National Institute of Traditional Medicine; NMR, nuclear magnetic resonance; NTMH, National Traditional Medicine Hospital; PIC, pharmaceutical inspection convention; PMSD, Post Marketing Surveillance Division; QASD, Quality Assurance and
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Availability of data and materials

All the data are presented within the manuscript.

Authors’ contributions

PW conceptualized, collected information and wrote the manuscript. T cross-checked the information as well as the literature that are used as guidelines for quality assurance system in Bhutan. Most of the information was collected while working as a researcher at MSP for 13 years and few information are extracted from PhD project (unpublished) of PW. All authors read and approved the final manuscript.

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Competing interests

We declare that there is no competing interests whatsoever.

Consent for publication
Informed consents were obtained from study participants. Participants (mostly office colleagues) who took part in the open forum discussions or personalized online e-chats were based on our two-way consensus. Those participants who were involved in proofreading the paper and data authentication all agreed and gave their consent to pre-review the paper before distributing them the draft.

Ethics approval and consent to participate

Ethic approval was obtained from the Traditional Medicine Research and Development Committee of Bhutan.

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About this article

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- Quality assurance system
- Quality control parameter
- Bhutanese So-wa-rig-pa medicine
- Integrated health care services
- Traditional medical education
- Traditional medicine hospital
- Menjong sorig pharmaceuticals

Associated Content

Integration into healthcare
The course is based on the syllabus in the European-approved 'Qualified Person' (QP) study guide as used in the pharmaceutical industry. The course content includes all the diverse elements required to ensure that each batch of a medicinal product meets the quality requirements of the relevant product and manufacturer's licences. This includes: an understanding of the pharmacology and chemistry of the product's active and other ingredients, a knowledge of how the product was manufactured, how the product delivers the drug in the patient's body, how the patient's body responds to the drug, and how the product meets the quality requirements of the relevant product and manufacturer's licences. The global integration of traditional medicine in public health services envisioned by WHO depends on a coordinated approach by the following stakeholders: regulators, healthcare professionals/traditional practitioners, manufacturers and patients/public. In this chapter, we provide the reader with an overall picture of the challenges faced by each of the stakeholders and what are the current approaches to solve them. We deliberately will restrict the discussion to herbal medicines, specifically Phytotherapy, which is just one of the many types of traditional practices. Abbreviations. ADME.