Background: Since 1978, the World Health Organization (WHO) has repeatedly called on Member States to recognize the role of traditional and complementary medicine (T&CM) in primary healthcare, improve safety, and accessibility by governing T&CM. In the 2019 Global Report on T&CM, the WHO reported that 40 out of 47 (85%) Member States from African Region had enacted governance policies, and 20 out of 47 (43%) had regulatory policies on herbal medicines. The primary barriers to implementing T&CM policy were identified as an absence of data and inadequate financial support for research. The objective of this protocol was to detail how to perform a scoping review that will examine the policy, legislative, and regulatory landscape for T&CM practitioners and products in sub-Saharan Africa.

Methods: Databases will be searched (AMED, CINAHL Plus with Full Text, MEDLINE Plus with Full text, Web of Science, Scopus, PubMed, Google Scholar) for relevant articles. Searches will be limited to English, French, Portuguese, and Spanish language studies in peer-reviewed journals (1963–2023) that substantively report on legislation, bills, policies, governance approaches and regulations on T&CM (including successes and/or challenges in their design and implementation). Actual legislation, policies, and regulatory documents on T&CM and peer-reviewed studies with emphasis on integrating T&CM and biomedicine into healthcare systems will be excluded.

Expected Outcomes: This protocol has formulated the objectives for a scoping review to identify, map, and synthesize evidence on the governance of T&CM in sub-Saharan Africa.

Keywords: health policy, legislation and jurisprudence, regulation, research, traditional medicine, WHO

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of hands-on healing (e.g., massage), and spiritual/faith-based healing practices [1,2,4]. In the African Region, medicinal plants are a fundamental component of the African traditional healthcare system, and traditional health practitioners (including spiritualists, diviners, traditional surgeons, midwives, bonesetters, and herbalists) are the most easily accessible and affordable health resource available to the local community, and at times, the only therapy that subsists. Whereas some types of T&CM are textually codified, the WHO recognizes (the 2019 definition of Indigenous TM) that many therapeutic approaches are “handed down from generation to generation” through oral tradition [4]. Furthermore, as explained by the former WHO Director-General, the integration of T&CM within health systems refers to contexts in which T&CM as well as biomedicine “blend together in a beneficial harmony, using the best features of each system, and compensating for certain weaknesses in each” [2]. In addition, the opening remarks of the current WHO Director-General at the WHO Traditional Medicine Global Summit held in Gujarat on 17 August 2023, emphasized that “The Gujarat Declaration (the main outcome of the summit) if effectively implemented, will enhance the appropriate integration of traditional medicine into national health systems.” He urged all countries “to commit to examining how best to integrate traditional and complementary medicine into their national health systems” [5].

2. Authoritative traditional, complementary, and integrative medicine-related documents in the African region

In 2004, the WHO’s regional office for Africa published formal tools for institutionalizing TM in health systems across the region [4]: Guidelines for registration of TM in the African region [6]; Guidelines on clinical study of TM in the African region [7]; and protocols for the conduct of clinical trials of TM based-therapies proposed for the COVID-19 response [8]; and the WHO regional framework for regulation of TM practitioners, practices and products in 2016. These tools and guidelines were adopted and adapted to the country’s unique situations and coupled with the implementation of global and regional strategies, as well as plans of action for the continental decade of TM, have resulted in some achievements.

3. Traditional, complementary, and integrative medicine governance progress in countries of sub-Saharan Africa

The WHO’s 2019 Global Report on T&CM indicated that 78 of 179 respondent nations across the 6 WHO regions have introduced regulatory strategies for governing T&CM practitioners, and 124 of 179 respondent countries have some form of herbal medicine-related legislation [9]. While WHO reporting indicates that T&CM usage is widespread across the 47 countries of the WHO, the African region (which includes the countries of sub-Saharan Africa and Algeria) related policies have been implemented across just over half of the region’s WHO Member States (28 out of 47 countries) [9].

The number of national policies for TM has risen from eight African region countries in 2000 to 40 in 2020, and from one legal framework for the practice of TM or a bill for traditional health practitioners in 2000, to 39 in 2020 [9]. In addition, there were 18 research institutes dedicated to TM in 26 countries in 2000 as compared with 34 in 2020 [9].

Furthermore, the number of countries national regulatory authorities that had included herbal medicines in their registration systems was 4 in 2000 compared with 23 in 2020 [9]. Moreover, the number of herbal medicine products registered from 14 countries (excluding those registered for emergency use during COVID-19) in accordance with the WHO guidelines was 20 in 2000 compared with > 100 in 2020, and over 45 herbal medicines have been included on the national list of essential medicines [9].

The WHO global report states that “within the WHO African Region, between 2005 and 2018, significant progress was made in the development of national policies, laws and regulations and national programs for T&CM. The region fares significantly better than the global scenario in most of the measurement indicators of T&CM, apart from regulation and registration of herbal medicines, which remain a challenge for the region” [9]. Notably, 83% (39 out of 47) of African region countries have developed legal frameworks for the practice of TM adapting the WHO/AFRO Model T&CM Practitioners Bill [4], which provides for the establishment of the professional regulatory body as statutory governance (Councils or Boards or Commissions), for the regulation of T&CM practitioners and their practice [9]. However, less than ten countries have established a professional regulatory body in the WHO African region [9].

At a continental governance level, the African Summit of Heads of State and Government declared the periods 2001-2010 and 2011-2020 as the First and the Second Decade of African Traditional Medicine in Lusaka, and Windhoek, respectively [10]. In addition, the Heads of State, and Government adopted the corresponding implementation plans of action for the decades of African Traditional Medicine in 2003, and 2012, respectively. Similarly, the first ever WHO Regional Strategy on Promoting the Role of Traditional Medicine in Health Systems, and the updated Regional Strategy on Enhancing the Role of Traditional Medicine in Health Systems were adopted, by their respective resolutions, by the WHO Regional Committee for Africa in 2000, and 2013, respectively [11]. One of the priority interventions of the plans of action for the Decades of African Traditional Medicine, and the Regional Strategy are: “Policy, legislation, and regulation of traditional
medicine, and implementation of national traditional medicine policies, strategies, and plans within national health systems.” In addition, the regional strategy calls for establishing a professional regulatory body to regulate traditional health practitioners and their practice.

4. Research and governance challenges

To date, relatively little has been formally documented about the implementation successes and challenges faced with reference to the African region’s many diverse T&CM practitioner communities. A few studies have characterized African nations and sub-regions’ policy contexts for T&CM practice [12-18]. However, more research is needed in this area since the statutory governance of T&CM practitioners represents a challenging undertaking owing to the field’s unique characteristics [19]. For example, many T&CM practitioners worldwide train “informally” through oral tradition, family lineage, and community-based apprenticeships. Furthermore, T&CM approaches are often culturally situated, rooted in pre-biomedical knowledge systems, and substantially variable in how they are used across local settings. This phenomenon may pose challenges for policymakers accustomed to governing biomedical health professionals trained in institutional settings, with reference to standardized, textually-based curricular requirements. In addition, calls for T&CMs “integration” into health systems are complicated by the hegemonic dominance of biomedical within health systems worldwide, which are historically rooted within European colonialism [20].

The impact of biomedical hegemony are similarly evident in the regulation of T&CM products. In many countries, National Medicine Regulatory Authorities/Agencies (NMRAs) are tasked by their respective governments to safeguard the public health of its citizens by evaluating whether applicable standards of quality, safety and efficacy of medical products have been met prior to release for public distribution [9]. These NMRAs espouse regulatory principles advanced by various local and international bodies. Such bodies include the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (which brings together global regulatory authorities with industry stakeholders to discuss scientific and technical aspects of pharmaceuticals [21]) and the WHO prequalification program (a service provided by the WHO to assess the quality, safety, and efficacy of medicinal products) [22]. Regulatory tools advanced by these organizations, which have become recognized as gold standards in governance, address such issues as premarket approval authorization of medical products; licensing and enforcement of personnel and premises; import and export control; pharmacovigilance and clinical trials control; and post-market surveillance. However, the regulatory concepts and mechanisms are rooted within the biomedical paradigm and have evolved with advancements in biomedical product development, and such tools may not be appropriate for addressing the distinct concerns pertinent to T&CM product governance [23]. As a case-in-point, the concepts used to describe the pathophysiology and pharmacology of traditional Chinese herbal medicines (which would fall within the “complementary medicine” category in the sub-Saharan African region) with reference to traditional Chinese medicine’s theoretical framework would confound most policy makers working within regulatory frameworks designed to govern biomedical pharmaceutical drugs. As a result, most of these traditional Chinese systems do not fall within the scope of NMRAs [24].

5. Challenges in policy-related reporting

Globally, there are many challenges associated with regulating T&CM practitioners and products. There is also a notable gap in international reporting of T&CM research. The WHO has published one primary source of related data in the form of Global Reports on T&CM, the most recent of which was published in 2019 [9]. In compiling these Global Reports, the WHO disseminates questionnaires to Member States to procure information pertaining to the statutory governance of T&CM via national policies, and practitioner and product regulations [1,2,9]. WHO regional and country offices typically disseminate these questionnaires to NMRAs, academic and research institutions, and ministries responsible for health. Returned data are checked by the regional offices. Subsequently, the data are centrally collated, analyzed, and reported by the WHOs Traditional, Complementary, and Integrative Medicine Unit. However, the resulting data reports may be incomplete and fraught with error. This gap in data reporting and error could also be attributed to the limited capacity and scarce level of human resources as well as the potential high turnover of staff as observed with institutions in some countries.

With respect to T&CM practitioner governance in the US, the WHO’s 2019 Traditional Medicine Report minimally indicated that such regulations were “delegated to each of the 50 states” and that reimbursement for related services was limited to “private health insurance” in that country [9]. It has been recently reported that over 300 pieces of legislation were enacted to regulate T&CM practitioners, although there is limited government reimbursement for T&CM therapeutics [25].” To ensure that analyses of T&CM-related policies across the globe are based on robust data, it is thus essential that scholars not rely exclusively on WHO reporting.

6. Study aims

The protocol for the scoping review aims will determine
the extent and range of existing scholarly literature pertaining to the statutory governance of T&CM practitioners, practices, and products across sub-Saharan Africa [26,27]. The scoping review method is appropriate as it remains unclear what more precise questions around T&CM policy in Africa might be posed by a systematic review [28]. A preliminary search of MEDLINE, the Cochrane Database of Systematic Reviews, and Joanna Briggs Institute (JBI) was undertaken. Evidence synthesis was conducted, and no current or underway systematic reviews or scoping reviews on the topic were identified.

7. Review question

What policy-focused scholarly literature is available on the governance landscape for T&CM practitioners and products across sub-Saharan Africa?

Materials and Methods

The proposed scoping review will be conducted in accordance with the JBI methodology for scoping reviews [29]. Keywords include health policy research, integration, regulation, WHO, and traditional medicine. The eligibility criteria will be based on inclusion and exclusion criteria. The concept in this protocol for a scoping review is based on research on policy, legislation, and regulation of traditional and complementary medicine practitioners, practices, and products in sub-Saharan Africa countries, regional blocs, or regional economic communities:

* Common Market for Eastern and Southern Africa (COMESA)
* Community of Sahel-Saharan States (CEN-SAD)
* East African Community (EAC)
* Economic Community of Central African States (ECCAS)
* Economic Community of West African States (ECOWAS)
* Intergovernmental Authority on Development (IGAD)
* Southern African Development Community (SADC)

1. Search strategy

The search strategy was designed to retrieve peer-reviewed published studies that substantively address policies, legislation, bills, regulations and other governance approaches of traditional health practitioners, practices, and products, as well as successes and/or challenges associated with their design and implementation. Therefore, articles that substantively address policies, legislation, bills, regulations and other governance approaches of traditional health practitioners, practices, and products that are not peer-reviewed, including but not limited to editorials, commentaries, letters to the editor, and government reports, will be excluded.

An initial limited search of MEDLINE, Cochrane, and JBI was undertaken to identify articles on the topic. The text contained in the titles and abstracts of relevant articles and the index terms used to describe the papers will be used to develop a complete search strategy for Allied and Complementary Medicine Database (AMED), Cumulative Index to Nursing and Allied Health Literature (CINAHL) Plus with Full Text (EBSCO), MEDLINE Plus with Full text (EBSCO), Web of Science, Scopus, PubMed and Google scholar and bibliographies of selected articles. The search strategy, including all identified keywords and index terms, will be adapted for each included database and information source. The reference list of all included sources of evidence will be screened for additional studies.

Studies published in English, French, Spanish, and Portuguese will be included. Studies published since 1963 will be included as the databases to be searched commence reporting that year. Coincidentally, this decade witnessed several sub-Saharan African countries attaining independence. The reporting commencement year is significant for this study as the scholarly articles should be on the legislation of post-colonial independent African countries.

The databases to be searched include AMED, CINAHL Plus with Full Text (EBSCO), MEDLINE Plus with Full Text (EBSCO), Web of Science, Scopus, and PubMed. The complete search string to be applied to the MEDLINE database can be found in Appendix A. The search string will be adapted for use in the other databases according to peculiar search strategies.

2. Study/source of evidence selection

Following the search, all identified citations will be collated and uploaded into Covidence, and duplicates removed. Following a pilot test, titles, and abstracts will be screened by 2 or more independent reviewers for assessment against the inclusion criteria for the review. Potentially relevant sources will be retrieved in full, and their citation details imported into Covidence. Two independent reviewers will assess the full text of selected citations in detail against the inclusion criteria. Reasons for excluding sources of evidence that do not meet the inclusion criteria at the full-text screening will be recorded and reported in the scoping review. Disagreements between reviewers at each stage of the selection process will be resolved by a senior colleague acting as a tiebreaker. The search results and the study inclusion process will be reported in full in the final scoping review and presented in a Preferred Reporting Items for Systematic Reviews and Meta-analyses extension for scoping review flow diagram [30].

3. Data extraction

Two or more independent reviewers will use a data ex-
traction form developed by the reviewers to extract data from articles included in the scoping review. The data extracted will include specific details about the concept, context, study methods, and critical findings relevant to the review question.

A draft extraction form has been built into Covidence. The draft data extraction form will be modified and revised as necessary during the process of extracting data from each included evidence source. Modifications will be detailed in the scoping review. Any disagreements that arise between the reviewers will be resolved through discussion or with an additional reviewer. If appropriate, authors of papers will be contacted to request missing or additional data, where required.

4. Data analysis and presentation

The data will be presented graphically, diagrammatically, or tabularly, with detailed descriptions of any illustrations. A narrative summary will accompany the tabulated and charted results and describe how the results relate to the review’s objective and question.

Supplementary Materials

Supplementary materials are available at doi: https://doi.org/10.56986/pim.2024.06.008

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Author Contributions

Tendayi R. Chihaka, Nadine Ijaz and Ossy Kasilo were the primary authors of this protocol, and the remaining authors contributed equal revisions.

Conflicts of Interest

There are no conflicts of interest to declare.

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Ethical Statement

No ethics approval was needed for this protocol.

Data Availability

All relevant data are included in this manuscript.

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