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Protocol for Qualitative Systematic Review

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Protocol for Qualitative Systematic Review

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Review Title:

Describing the competences of regulatory scientists in sub-Sharan Africa for regulatory registration and inspection to improve the safety, quality and efficacy of medical products– A qualitative systematic review.

Research Question:

What are the competency needs of regulatory scientists in sub-Saharan Africa for regulatory registration and inspection?

Background

Regulatory scientists in sub-Saharan Africa is the population being studied in this research. There is no documentation in the literature of competencies required of regulatory scientists in sub-Saharan Africa. However, the literature shows that inadequate competent regulatory scientists is a challenge to ensuring safe, quality and effective medical products in sub-Saharan Africa (Drugs for Neglected Diseases initiative, 2013; Ekeigwe, 2019; Ndomondo-Sigonda, Miot, Naidoo, Dodoo, & Kaale, 2017; World Health Organization, 2019). Despite efforts by developmental agencies such as the WHO, United Nations Industrial Development Organization (UNIDO), to train regulatory scientists, the problem still persists as noted in the 2019 report of Mckinsey & Company on “Should sub-Saharan Africa makes its own drugs” (Conway, Sabow, & Sun, 2019). Insufficient competent regulatory scientists in sub-

Saharan Africa is a persistent problem and there is a dearth of academic research in developing the competences of regulatory scientists in sub-Saharan Africa.

Competency frameworks are the substrate for effective development of the capacity of regulatory scientists and any other profession. (Drago, Shire, & Ekmekci, 2016). The absence of a competency framework has resulted in a wide skills range among regulators in sub-Saharan Africa; NMRAs are not at the same level in the regulation of medical products and difficulty in the 'portability' of regulatory scientists in the region. This in turn leads to huge variations in the efficient and effective regulation of medical products and therefore impairs access to safe, quality and effective medicinal products. (World Health Organization, 2010). Therefore, it is important to describe the competences required of regulatory scientists in sub-Saharan Africa. This will serve as a template for developing curriculum, training, and recruitment processes. This review will focus on the competencies for regulatory scientists (regulators/regulatees) involved in the registration and inspection of medical products.

Relevance

Does the review topic have important implications for health (individual and/or public), as well as health care, policy and research?

Yes. The expected outcome of my research work is a description (in form of a model) of competences required that will inform the training of regulatory scientists in sub-Saharan Africa – this will indirectly affect general health outcomes in the region as it will help to build the capacity of regulatory scientists to ensure that only safe, quality and effective medical products are accessed in the region.

Rationale

Does the evidence (including existing systematic reviews) fail to answer the review question, and why?

There is no record of systematic or any kind of review done in this area for this population set.

There is no existing model for regulatory scientists in sub-Saharan Africa.

There are existing models of competency frameworks for regulatory scientists developed by The Organization for Professionals in Regulatory Affairs (TOPRA) and Regulatory Affairs Professionals Society) RAPS. (Drago, 2017; "Regulatory Competency Framework | RAPS," 2019). These models although comprehensive are generic and may need to be adapted to suit the diverse cultural contours and social sensitivities of the sub-Saharan region. In addition, there may also be other competencies in the literature that are not captured in these models. Thus, a comprehensive review of the literature will help to provide a detailed description of competences and development of a model for regulatory scientists involved in registration and inspection of medical products in sub-Saharan Africa.

Justification

Is the need for the review justified in the light of the potential health implications and current limitations of the evidence base?

Yes. This will indirectly impact on the health outcomes in the region. Competency frameworks/models and requirements is effective in developing curriculum, trainings and on-the-job coaching.(Drago et al., 2016). The description of the competency requirements of regulatory scientists in sub-Saharan Africa will guide the development of focused training by NMRAs and developmental partners such as WHO and the USP, intended to equip regulatory scientists with the requisite knowledge, skills, and critical thinking abilities in ensuring that only safe quality and effective medical products reach the populace.

Specification

What are the PICO components of the review question / objective?

PICO - Population, Intervention, Comparison and Outcome

Population – Regulatory scientists in countries with established competency frameworks

Intervention – Adoption of competency models/frameworks

Comparison – Regulatory scientists in countries without the adoption of a competency framework (i.e. Sub-Saharan Africa)

Outcome – Describing the competences required of regulatory scientists in sub-Saharan Africa to improve the safety, quality and efficacy of medical products

Methods

Search strategy - Which electronic databases will you search?

Web of Science

PubMed

Engineering Village

What are your key search terms?

Competency, Regulatory competence, Competency Framework, Professional competence, Pharmaceutical regulators, Drug regulators, Regulatory affairs professionals, Medicines regulators, and Competency based education, Skills framework

What other sources will you search?

Google Scholar

The websites of the following internationally recognized organizations -

World Health Organization (WHO),

Regulatory Affairs Professionals Society (RAPS),

The Organization for Professionals in Regulatory Affairs (TOPRA).

International Medical Devices Regulators Forum (IMDRF)

US FDA (United States Food and Drugs Administration)

International Medical Devices Regulators Forum (IMDRF)

What is your search strategy?

See Appendix 1

Selection criteria

What are the inclusion / exclusion criteria?

Inclusion criteria –

- Must include a discussion of potential competences or competences in use or areas of needs for training and capacity development of regulatory scientists in the medical products industry.
- Must be the most current version of the document
- Must be the complete and final version of the document, not a draft or summary

Exclusion criteria –

- Literature not discussing potential competences or competences in use or areas of needs for training regulatory scientists in the medical products industry.

- Documents in draft or summary version, or versions that have been replaced by another document.

Will you impose any additional limits, e.g. language, publication type, study design?

Only publications in English will be included.

How will study selection be performed?

All literature retrieved from searches will be initially screened by title, abstract, table of contents, and/or executive summaries by the graduate student. If more than one of these elements is available, all will be reviewed for relevance. A member of the team will check and confirm that the search was done in accordance with the strategy outlined in the protocol.

This will be followed by a second stage of screening – full text screening. A team of *2* researchers (graduate student and supervising professor) will determine the literature to be included or excluded from the study based on the eligibility criteria. Where there are disagreements, the team will discuss it to reach a consensus.

All literature that remains after the full text screening will be included in the review.

Quality assessment

What criteria will be used to assess methodological quality?

The Joanna Briggs Institute (JBI) Critical Appraisal Tool for text will be used to assess the quality of individual documents that are included in the review. The JBI Critical Appraisal Toolkit includes checklists for evaluating several types of studies. These appropriate checklists will be selected and used to measure the trustworthiness, relevance and results of published papers.

The Joanna Briggs Institute critical appraisal checklist for systematic review and research synthesis will also be used for the quality assessment of this systematic review

How will quality assessment be performed?

A quality assessment will be done by the graduate student working independently, then reviewed by the supervising professor. Both will confer where necessary to reach decisions regarding study quality and eligibility on the basis of quality.

Data extraction

What are the key data to be extracted?

Key data includes source organization, year published, by whom they were developed, intended audience, goal/objective of document, sources of evidence/resources cited, competencies mentioned in the document.

How will data extraction be performed, and how will extracted data be presented?

Some data will be extracted manually and others electronically. A form will be developed for extracting the data such as source organization, year published, by whom they were developed, intended audience, goal/objective of document, sources of evidence/resources cited. The software NVivo will be used to code the competences or areas of needs for training and capacity development of regulatory scientists in the medical products industry mentioned in the document. The primary reviewer, the graduate student, will do the extraction. The supervising professor will review the data extraction process and outcomes of the process.

Data synthesis

How will data be combined (statistical or narrative), and why?

Narratively, descriptive – qualitative research

Process

What resources are required to conduct the review, and are they available?

Relevant expertise: Available

Computing facilities: Available

Research databases: Available

Bibliographic software: Available

NVivo software: Available

How will the findings of the review be disseminated?

Target audience: All stakeholders in medical products regulation in sub-Saharan Africa.

Publication type: Journal Article

Communication media: Internet and hard copies

Review Team

1. Abigail Ekeigwe - Graduate Student
2. Bethany McGowan – Supervising Professor I
3. Kari Clase – Supervising Professor II
4. Steve Byrn - Supervising Professor III
5. Paddy Shivanand - Supervising Professor IV
6. Loran Parker - Supervising Professor V

Timetable

Item	Completion date	Responsibility
Update protocol for internal review	November 15, 2019	Prof. Kari Clase
Protocol for external review	November 20, 2019	Prof. Bethany McGowan
Developing search strategy	December 29, 2019	Prof. Bethany McGowan
Searching and study selection	March 30, 2020	Abigail Ekeigwe
Quality assessment: Briggs Checklist for critical appraisal	April 30, 2020	Abigail Ekeigwe and Prof. Bethany McGowan
Data Extraction and Analysis - Designed Form - NVivo	June 30, 2020	Abigail Ekeigwe and Prof Kari Clase
Draft report for peer review	July 15, 2020	Abigail Ekeigwe
Review of report	July 30, 2020	All supervising professors
Submit for publication	August 31, 2020	Abigail Ekeigwe and supervising professors
Celebrate publication	To be Determined	Team

Appendix 1 – Detailed search strategy

PubMed:

(Pharmaceutical education OR "Education, Pharmacy"[Mesh] OR training OR "Education, Graduate"[Mesh]) AND (regulatory scien* OR "Drug AND Narcotic Control"[Mesh]) AND (Professional competence OR competence)

Web of Science (All Databases):

(Pharmaceutical education OR drug quality or drug control) AND (regulatory scien*) AND (Professional competence OR competence)

Engineering Village:

(Pharmaceutical education OR drug quality or drug control) AND (regulatory scien*) AND (Professional competence OR competence)

Gray Literature Search

List of Search Terms

Search Number	Search term (S)
S1	Competency Framework
S2	Competency framework for regulatory Affairs Professionals
S3	Competency framework for medicines regulators
S4	Competency framework for drug regulators
S5	Skills for regulatory Affairs Professionals
S6	Skills for pharmaceutical regulators
S7	Skills for drug regulators
S8	Professional competence for medicines regulators

S9	Professional competences for drug regulators
S10	Professional competences for regulatory Affairs Professionals
S11	Competency
S12	Regulatory competence
S13	Professional competence

N/B – The search strategy includes “sort by relevance”. This is only applicable to gray literature sites. I noticed it helps you get all relevant documents

Google Scholar

Search Number	**Search strategy**
S1	Competency Framework
S2	Competency framework for regulatory Affairs Professionals
S3	Competency framework for medicines regulators
S4	Competency framework for drug regulators
S5	Skills for regulatory Affairs Professionals
S6	Skills for pharmaceutical regulators
S7	Skills for drug regulators
S8	Professional competence for medicines regulators
S9	Professional competences for drug regulators
S10	Professional competences for regulatory Affairs Professionals
S11	Competency
S12	Regulatory competence
S13	Professional competence

S14	S11 and S7
S15	S11 and S12
S16	S11 and S13
Sort by	Relevance
Limits	The first 5 pages
Date range	2016-2020

WHO Website

Search Number	**Search term (S)**
S1	Competency Framework
S2	Competency framework for regulatory Affairs Professionals
S3	Competency framework for medicines regulators
S4	Competency framework for drug regulators
S5	Skills for regulatory Affairs Professionals
S6	Skills for pharmaceutical regulators
S7	Skills for drug regulators
S8	Professional competence for medicines regulators
S9	Professional competences for drug regulators
S10	Professional competences for regulatory Affairs Professionals
S11	Competency
S12	Regulatory competence
S13	Professional competence

S14	S11 and S7
S15	S11 and S12
S16	S11 and S13
Advanced Search	Exact phrase
Language	English
File Format	'Only' 'any format'
Occurrences	Anywhere in the page
Domain	'Only' who.int
Sort	Sort by Relevance
Limits/ Number of Results	The first 50 publications
Date range	Website does not have date range. All articles up to 1st January 2020

RAPS Website

Search Number	**Search term (S)**
S11	Competency
S12	Regulatory competence
S1	Competency Framework
Sort by	Relevance
Limits	The first 50 publications
Date range	All years will be searched and search will be current

TOPRA Website

Search Number	Search term (S)
S11	Competency
S12	Regulatory competence
S1	Competency framework
Search by	Content
Limits	The first 50 publications
Date range	Website does not have date range. All articles up to 1st January 2019

IMDRF

Search Number	Search term (S)
S11	Competency
S12	Regulatory competence
S1	Competency framework
Search by	Any search words
Limits	The first 50 publications
Date range	Website does not have date range. All articles up to 1st January 2019

US FDA Website

Search Number	Search term (S)
S11	Competency

S12	Regulatory competence
S1	Competency framework
Search by	Relevance
Limits	The first 50 publications
Date range	All articles up to 1st January 2019

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