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RESEARCH ARTICLE

Emergency compounding of COVID-19 medicines: A readiness programme to up-skill pharmacy graduates in Namibia

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Abstract

Background: The COVID-19 pandemic has exacerbated inequitable access to medicines in sub-Saharan Africa, mainly due to limited capabilities for local manufacture. **Aim:** To describe priority medicine lists and critical skill sets required for an emergency compounding of COVID-19 medicines training programme. **Methods:** An evaluation of the COVID-19 emergency compounding readiness programme for the University of Namibia pharmacy graduates. The main outcomes were enhanced skill sets in compounding, quality control, and regulation of priority COVID-19 medicines. Data on outcomes were thematically analysed. **Results:** Fifty-eight pharmacy graduates demonstrated competence in emergency compounding, quality control, regulation, and provision of therapeutic information of COVID-19 medicines. A priority list and a skills set for emergency compounding of COVID-19 medicines were developed. **Conclusions:** The upskilling of pharmacy graduates on emergency compounding of COVID-19 medicines has the potential to address inequalities in the rapid response and control of epidemics.

Introduction

Globally, experiential industrial training is a key component of pharmacy curricula to equip graduates with skills in good manufacturing practices of quality medicines (Ramia *et al*., 2016). In Namibia, the industrial pharmacy placement is a 35-credit module in the Bachelor of Pharmacy degree curriculum offered by the University of Namibia (UNAM). Through experiential learning in the pharmaceutical industry, pharmacy students acquire indispensable skills and competences in production, quality control, and medicine regulation (Rennie *et al.*, 2014). Namibia has one accredited facility for industrial pharmacy training, Fabupharm (Pty) Ltd., respectively. As a consequence, the industrial pharmacy placement has, since its inception, been completed through international support at training facilities in Uganda, Zimbabwe, and South Africa. Nevertheless, the COVID-19 state of emergency lockdowns and travel restrictions declared in

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March 2020 threatened the local and international experiential industrial training pharmacy programme (Ogunleye *et al*., 2020).

In response to COVID-19-related travel restrictions, the UNAM school of pharmacy remodelled the placement to harness the existing in-country capacity for industrial training while maintaining the quality of education as prescribed by the curriculum. Overall, the placement emphasised key competencies and outputs required by pharmacists in responding to emergency situations such as COVID-19 (Aruru, Truong & Clark, 2020). The placement also served as a wakeup call for the school of pharmacy to support COVID-19 response efforts in the local manufacture of hand sanitisers and related medicines. The placement up-skilled students for emergency compounding, given the rampant shortages of essential medicines during the COVID-19 pandemic caused by reduced importation of pharmaceuticals into Namibia due to the closure of international borders (Kibuule et al., 2020; Ogunleye et al., 2020). In addition, the aim of the industrial placement was to produce some of the items such as hand sanitisers, which were in short supply for local consumption. Further, given an increase in the use of off-label medicines during the pandemic, pharmacy students were placed at the Therapeutics Information and Pharmacovigilance Center (TIPC) to emphasise the pharmacist's role in the provision of information on COVID-19 and related illnesses (Paumgartten et al., 2020). In addition, the placements emphasised the pharmacy graduates' ability to efficiently evaluate the quality of medicines. Quality testing of pharmaceuticals, being the most important aspect of pharmaceutical manufacturing, was adequately covered during the placement.

Nevertheless, the challenges facing education programmes to prepare local pharmacy graduates for a rapid response to the COVID-19 outbreak through the acquisition of skills in manufacturing, quality assurance, and regulation of COVID-19 essential medicines have not been evaluated in a resource-limited country such as Namibia. The findings of this study will inform curriculum development efforts with regard to pharmacy graduates' emergency preparedness and response to epidemics.

Methods

Design: An evaluation of the implementation of experiential industrial pharmacy training for emergency compounding of COVID-19 essential medicines to prepare pharmacy graduates for small-scale production in public and private healthcare sectors was undertaken. Three skills were assessed, namely the production, quality control, and regulation of COVID-19 essential medicines. Qualitative data were collected from trainers and students regarding the priority COVID-19 medicines for the emergency compounding programme, the skill sets required for emergency compounding of COVID-19 medicines, and the implementation of the emergency compounding training programme.

Population: The target population included trainers who facilitated the emergency compounding programme. This included pharmacists and pharmaceutical scientists at the University of Namibia, Africure Pty. pharmaceuticals, the quality control surveillance laboratory, and the Therapeutics Information Pharmacovigilance Center. Also, feedback reports and formative assessment reports of a cohort of 58 year-three Bachelor of Pharmacy degree students undertaking experiential pharmacy industrial training at the UNAM School of Pharmacy were included.

COVID-19 emergence compounding programme: The industrial pharmacy placement was implemented in three phases or rotations. The three rotations included small-scale production of COVID-19 related commodities, quality testing of COVID-19 medicines, and regulations pertaining to the medicines. The experiential training on the compounding of COVID-19 medicines was conducted at the school of pharmacy's pharmaceutics laboratory and complemented with training on good manufacturing practices at the Africure Pty, a state of the art pharmaceutical packaging plant in Windhoek. The pharmaceutics laboratory was remodelled to simulate processes for emergence manufacture of medicines in a small-scale pharmaceutical industry. These simulated processes were aimed to expose the students to a typical industrial pharmacy setting and the workflow and use of pharmaceutical equipment in compounding emergence pharmaceutical formulations. The set up was made according to good manufacturing practices and the standards set by the Health Professions Council of Namibia, based on the Pharmacy Act no. 9 of 2004. The compounding was tailored to COVID-19 preventative medication such as hand sanitiser and disinfectant solutions, analgesics, and immune boosters among others.

Data collection: Three priority lists of COVID-19 medicines (A, B, and C) and their formulations were developed based on a needs assessment and expert opinions of hospital and community pharmacists, the review of literature, and the availability of raw materials on the market. Data on priority COVID-19 medicines and skill sets required for emergency compounding, as well as the implementation of the COVID-19 emergency compounding programme, were collected through feedback reports from trainers and students' placement reports. Data on priority lists, skill-sets, and the implementation of the programme were obtained from the programme trainers through debrief meetings using a semi-structured questionnaire at the end of each of the three rotations, i.e., compounding, quality assurance, and medicines regulation and information, over a three-week period (06–24, July 2020). Data on the attainment of the necessary skill sets by students to compound emergency medicines and quality control and to regulate COVID-19 medicines were determined using formative practical assessments, presentations, and placement reports.

Data analysis: Qualitative data on challenges, successes, and skill sets required for emergency compounding of COVID-19 medicines were analysed using thematic analysis. The main outcome measures were the competencies in production and non-sterile compounding of various of COVID-19 related medicines, quality assurance, and the regulation of medicines produced. Themes regarding priority COVID-19 medicines, emergency compounding skill sets, and the implementation of the training programme were subsequently developed.

Ethics: The study was an evaluation of a training programme on COVID-19 emergency compounding and used secondary data, mainly feedback reports from trainers and students. The requirement for consent was thus waived.

Results

Priority list of COVID-19 medicines for the readiness compounding programme

Three lists of COVID-19 medicines were prioritised for the emergency compounding programme. Firstly, priority list A comprised medicines used in the prevention and/or management of the disease. These medicines included sanitisers and disinfectants, immune boosters, and analgesics. The ingredients of these medicines were locally available. The hand sanitiser manufacturing project

Table I: Priority list of COVID-19 essential medicines compounded

Dosage form	Formulation	Product compounded	Rationale for inclusion	Compounding (references)
Priority list A of COVID-19 medicines				
Liquids	Solutions	• Alcohol-based hand sanitiser	Preferred COVID-19 antiseptic/disinfectant	World Health Organization guidelines
		• Simple syrup BP	Vehicle for formulations e.g. cough mixture	(Santoveña-Estévez, Suárez-González, Vera,González-Martín,Soriano & Fariña, 2018)
		• Paracetamol Elixir Pediatric BPC	Analgesic, antipyretic in COVID-19	(Marriot, Wilson, Langley & Belcher, 2010)
	Emulsions	• Cod liver oil BP	Immune booster in COVID-19	(Marriot, Wilson, Langley & Belcher, 2010)
Semi-solid	Gels	• Aspirin gel	Skin, mucus membrane analgesic, antipyretic, anti-inflammatory	(Sparks & McCartney, 2017)
Solid	Capsules	• Aspirin	Analgesic, antipyretic, anti-inflammatory, antiplatelet	(Sparks & McCartney, 2017)
	Tablets	• Paracetamol	Analgesic, antipyretic, anti-inflammatory	(Ngwuluka, Idiakhoa, Nep, Ogali & Okafor, 2010)
Priority list B of COVID-19 medicines				
Liquids	Solutions	• Tincture of Iodine	Skin antiseptic	(Bakker,Woerdenbag, Gooskens, Naafs, van der Kaaij & Wieringa, 2012)
		• Lodine solution	Wound antiseptic	
	Suspensions	• Calamine lotion BP	Mild itches, dries oozing skin, soothes skin irritation	(Marriot, Wilson, Langley & Belcher, 2010)
		• Magnesium trisilicate mixture BP	Anti-acid	
Semi-solids	Creams	• Aqueous cream	Moisturising dry skin, baby/dermatitis soap	(Bakker,Woerdenbag, Gooskens, Naafs, van der Kaaij & Wieringa, 2012)
	Ointments	• Compound Benzoic Acid ointment BP	antifungal	(Marriot, Wilson, Langley & Belcher, 2010)
		• Emulsifying ointment	Baby/dermatitis soap	(Bakker,Woerdenbag, Gooskens, Naafs, van der Kaaij & Wieringa, 2012)
	Pastes	• Compound Zinc Oxide paste BP	Protect wounds, keep medication on wound, soothe	(Marriot, Wilson, Langley & Belcher, 2010)
Priority list C of COVID-19 medicines				
Other formulations	Formulations of essential medicines which were not procured due to limited resources. These included hand sanitiser gels, bleach disinfectants, effervescent powders, and suppositories.			

was successful in producing and delivering sufficient hand sanitiser to Namibia's highest referral hospital and some private sector establishments. Secondly, priority list B consisted of essential medicines which were not available locally due to the closure of international borders. These medicines were mainly topical formulations. Medicines on priority list B were compounded in anticipation of shortages due to the closure of borders during the lockdown. Thirdly, priority list C was composed of formulations of essential medicines which were not procured due to limited resources. These included hand sanitiser gels, bleach disinfectants, effervescent powders, and suppositories. Consequently, the readiness programme was designed to impart skills on manufacture/ compounding, quality control and testing, regulatory affairs and medicines information, and using the priority medicines (Table I).

Emergency compounding: training skills regarding COVID-19 medicines

Three competences and skills were identified for emergency compounding of COVID-19 medicines; these were the use of compounding references, good compounding practices, and documentation. The week-long compounding contact sessions conducted under lockdown conditions were aimed at building the capacity of pharmacy graduates to undertake non-sterile compounding in times of need.

- **Compounding references:** Pharmacy students were trained on how to obtain and objectively use working formulae in compounding COVID-19 medicines. The key reference sources included pharmacopoeia (USP, BP, BPC, and Martindale), World Health Organisation (WHO), and Centre for Diseases Control and Prevention (CDC) guidelines for the compounding of emergency medicines (Table I). The training on compounding priority COVID-19 formulations was implemented through hands-on training of small groups consisting of ten to 15 Bachelor of Pharmacy, year-three students from the 17th July to 24th July 2020. Specifically, the good manufacturing practice training simulated industrial tabletting processes for paracetamol and aspirin.
- **Good compounding practices:** These included the development and use of standard operating procedures for the preparation of priority COVID-19 medicines and a batch compounding report. Pharmacy students also acquired skills in the packaging and labelling of the priority medicines in accordance with guidance of the Medicines and Related Substances Control Act of Namibia, 2003. The various stages of compounding of the priority medicines were assessed using a rubric on competences such as the accurate measurement of ingredients, the mixing of ingredients, and the presentation of the finished, compounded product. Other compounding skills included pharmaceutical calculations, weighing, trituration, levigation, spatulation, size reduction, granulation, drying powders, sieving, compliance to SOPs, use of compounding equipment, selection of ingredients, selection of dosage forms, grades of pharmaceutical/ chemical ingredients, packaging, labelling, compounding records, writing laboratory reports, assigning beyond-use dates, use of capsule capacity tables, compounding records, and storage of finished products.
- **Documentation:** Students were required to complete and present a report on the processes pertaining to the compounding of each priority COVID-19 medicine. The key documentation related to the application of SOPs, batch compound records, and quality management system related records.

Quality control of COVID-19 medicines: readiness programme training skills

Through collaborative efforts with the Quality Surveillance Laboratory in the Ministry of Health and Social Services (MoHSS) of Namibia, the compounded preparations of priority COVID-19 medicines were tested to ensure quality throughout the manufacturing process. In addition, students acquired skills on the regulatory requirements to ensure quality medicines, i.e., to prevent counterfeits or impurities.

Therefore, as part of the readiness programme, Bachelor of Pharmacy year-three students were attached to the Quality Surveillance Laboratory (QSL), Namibia's medicine testing laboratory, for three weeks in three different groups to learn different analytical techniques to conduct quality control tests on pharmaceutical products as well as documentation and certification required for such purposes. This partnership with MoHSS enabled the school of pharmacy to train students in applying their theoretical knowledge in the field of quality control and assurance of priority COVID-19 pharmaceutical products as well as the regulatory processes pertaining to the manufacture, registration, inspection, and surveillance of the products by the Namibia Medicine Regulatory Council (NMRC) and the National Standards Institute (NSI). This was done so that students would appreciate the need to ensure the safety and efficacy of medicines. The need to protect the public from untoward effects of poor-quality medicines was also emphasised.

- **A model of 'A is for aspirin' labs:** was adopted for imparting skills on the quality control of COVID-19 related medicines. This consisted of a series of seven laboratory sessions that were imparted on specific days of the industrial pharmacy placement. During practical sessions, students were taught on different aspects of aspirin, namely extraction, synthesis, and lastly quality analysis. All students were expected to complete a lab report or practical quiz for assessment.
- **Basic quality control tests:** This consisted of product identification tests, quality control tests, the ferric chloride test, melting point determination, and thin-layer chromatography. These tests were applied to the aspirin preparations prepared during the placement. Quality control of hand sanitisers was undertaken. Pharmacy students attained skills in the assay of ethanol content for the raw material and finished pharmaceutical product. The ethanol content assay was determined using the titrimetric method (Walters et al., 1968).
- **Advanced QC tests:** These comprised quality-control tests entailing analytical methods and instrumentation of pharmaceutical products as well as obtaining and interpreting data from chemical analysis. Students were exposed to the use of titrimetric analysis, ultraviolet spectroscopy, high-performance liquid chromatography, and Fourier-transform infrared spectroscopy to analyse aspirin and paracetamol tablets (Walters *et al*., 1968).
- **Experiential QC training:** This site visit gave students the opportunity to participate in the analysis of medicines. The QC tests carried out by students included the identification, friability, dissolution, and uniformity of content and specific assays conducted on different medicines. Students tested the quality of the synthesised paracetamol using quantitative and qualitative analysis (Ellis, 2002).
- **Synthesis of paracetamol:** In addition, students were exposed to skills in synthesis and quality analysis of paracetamol from phenol (Ellis, 2002).

Regulation of COVID-19 medicines: readiness programme training skills

The school of pharmacy collaborated with the Namibia Medicines Regulatory Council (NMRC). Students were attached to the NMRC for three weeks in three different groups to learn about the regulation of COVID-19-related or emergency medicines, including fast track registration, inspection, provision of therapeutic information, and quality control of medicines.

- **Medicine registration:** Students took part in reviewing dossiers for the registration of medicines with emphasis on the fast-tracking of emergence medicines and compassionate clearance. The process of registration involved the submission of a registration application to regulatory authorities in a dossier format, hence making it easier to harmonise registration procedures among different regulatory authorities of the world.
- **Inspection of manufacturing sites and practices:** Students were exposed to processes underlying the inspection of various facilities, including the small-scale manufacture plant. Students also had an opportunity to take part in active surveillance and inspection of different entities involved in the pharmaceutical business such as manufacturing, wholesale, and retail. Students under the supervision of pharmacists also participated in providing therapeutic information to healthcare providers and the public.
- **Therapeutic medicine information and pharmaco-vigilance:** Students were exposed to the principles of communicating therapeutic information on the safety and efficacy of COVID-19 related medicines as well surveillance, handling medicine information and queries, and adverse drug monitoring.

DISCUSSION

Most resource-limited settings in Sub-Saharan Africa have a too limited pharmaceutical workforce to effectively respond to the COVID-19 pandemic (Schneider & Ho Tu Nam, 2020). This is particularly problematic for sustaining the supply chain of COVID-19 medicines, which has been broken by the institution of states of emergency during the pandemic as well as limited local production capacity for pharmaceuticals (Govindan et al., 2020; Schneider & Ho Tu Nam, 2020). In this study, the authors present a model of a readiness training programme to equip pharmacy graduates to effectively respond to emergency compounding of COVID-19 medicines in the communities (i.e., hospitals and community pharmacies). Previous reports indicate that countries in Africa are least prepared against the COVID-19 pandemic (Gilbert et al., 2020). This is a concern, given their high burden of infectious diseases such as HIV and tuberculosis and weak healthcare systems (Jacobsen, 2020).

The readiness programme highlights priority lists of COVID-19 medicines in three categories (A, B, and C) depending on the usefulness of the products in the fight against COVID-19, the availability of the raw materials on the local market as well as the possibility that the supply of the product may be hampered by border closure during the state of emergency. Currently, few studies report on a training programme based on priority medicines used in a resource-limited country such as Namibia (Amimo *et al.,* 2020; Guan *et al*., 2020). It is important that countries have local capacity to respond to a pandemic instead of relying on other countries for support, as this was not possible due to the increasing demand of COVID-19 related supplies coupled with a breakdown in cross-border transport between nations (Guan et al., 2020; Lone & Ahmad, 2020; Lumu, 2020).

This paper also highlights key training skills and competences that the readiness programme for emergence compounding of COVID-19 medicines should include. In particular, the authors highlight basic good compounding practices, basic quality control tests, and regulatory roles that pharmacy graduates can employ in the workplace to ensure a rapid and adequate response to pandemics and emergencies. In addition, skills pertaining to emergency preparedness and infection control were emphasised in the programme. These included the provision of accurate information to the public regarding the pandemic and interventions used in the control of the pandemic. Few studies report on the changing roles of a pharmacist in the era of epidemics, even though the pharmacist may need to devise a rapid mechanism to respond to crisis (Da Costa et al., 2020; Schellack et al., 2020).

The findings of the study should be interpreted with the following limitations. First, this is an evaluation of an emergency ad-hoc training programme conducted in one institution, the University of Namibia, during a global pandemic. Secondly, the programme did not follow conventional processes of development of a curriculum and training programme, given that the programme also aimed to urgently respond to shortages in essential medicines during the pandemic. Nevertheless, the findings of this emergence compounding programme provide a framework and implementation of rapid emergency compounding of medicines during emergencies such as epidemics to scale up access to essential medicines in resource-limited settings, particularly in sub-Saharan Africa.

The study concludes that there is a need for countries to prioritise their training needs, based on the pandemic control interventions instituted by the respective governments, the availability of raw materials, and the projections of the impact of the breakdown of cross-border trading during pandemics. The current readiness programme may be adopted by pharmacy institutions in resource-limited countries, particularly in Sub-Saharan Africa, to equip their graduates for rapid emergence compounding and quality control of pharmaceuticals during pandemics.

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