PHARMALINK

e-Engaging members in a pandemic era, and a great experience of cancer management in faith-based healthcare facilities

January 2022
## Acronyms and Abbreviations

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Full Form</th>
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<tbody>
<tr>
<td>AMR</td>
<td>Antimicrobial Resistance</td>
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<td>API</td>
<td>Active Pharmaceutical Ingredient</td>
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<td>BMJ</td>
<td>British Medical Journal</td>
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<td>BUFMAR</td>
<td>Bureau des Formations Médicales Agrées du Rwanda</td>
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<td>CHAL</td>
<td>Christian Health Association of Liberia</td>
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<td>CMC</td>
<td>Chemistry, Manufacturing and Controls</td>
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<td>COVID</td>
<td>Corona Virus Disease</td>
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<td>DIFAEM</td>
<td>German Institute for Medical Mission e. V.</td>
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<td>DRC</td>
<td>Democratic Republic of Congo</td>
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<td>DSO</td>
<td>Drugs Supply Organizations</td>
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<td>HIV</td>
<td>Human Immuno-Deficiency Virus</td>
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<td>ICT</td>
<td>Information and Communications Technology</td>
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<td>ITM</td>
<td>Institute of Tropical Medicine</td>
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<td>JMS</td>
<td>Joint Medical Stores</td>
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<td>JOPP</td>
<td>Journal of Pharmaceutical Practice</td>
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<td>LMS</td>
<td>Learning Management System</td>
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<td>LPV</td>
<td>Lopinavir</td>
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<td>MEDS</td>
<td>Mission of Essential Drugs and Supplies</td>
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<td>MS</td>
<td>Microsoft</td>
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<td>NGO</td>
<td>Non-Governmental Organizations</td>
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<td>PQM</td>
<td>Promoting Quality Medicines</td>
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<td>QA</td>
<td>Quality Assurance</td>
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<td>RSS</td>
<td>Regulatory Systems Strengthening</td>
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<td>SOPS</td>
<td>Standard Operating Procedures</td>
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<td>USA</td>
<td>United States of America</td>
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<td>USP</td>
<td>United States Pharmacopoeia</td>
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<td>WCC</td>
<td>World Council of Churches</td>
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<tr>
<td>WHO</td>
<td>World Health Organizations</td>
</tr>
</tbody>
</table>
# Table of Content

Table of Content..................................................................................................................................................ii  
Editorial from the Executive Director..................................................................................................................iii  
PART 1..................................................................................................................................................................1  
  Digitization and Membership...............................................................................................................................1  
  Quality of Medicines – A conversation about JOPP article on Checklist for visual inspection on e-Drug (e-drug Digest, Vol 18, Issue 49).................................................................................................................................1  
  The EPN Webinar Series - Cascading knowledge and sharing experiences across communities of practices................................................................................................................................................................................3  
    Webinar 1: February 2021 - Enhancing the delivery of good quality pharmaceutical services and products in the context of global challenge of the COVID-19 .................................................................................................3  
    Webinar 2: 24 April 2021 - Capacity building of pharmaceutical staff in church Health institutions: Gaps and way forward..................................................................................................................................................4  
    Webinar 3 – Joint EPN and PQM+ webinar: Rethinking assumptions about generic medicines cost and perceived quality: How managerial and regulatory systems help assure the quality of generic medicines........................................................................................................................................5  
    Webinar 4-18 October 2021 - Improving efficiency in procurement of quality-assured medicines across the faith-based pharmaceutical supply system in LMICs.................................................................................6  
  EPN Learning Management System (LMS) –Leverage technology in pharmaceutical capacity building .............................................................................................................................................................................8  
  Pooled procurement initiative- DSO Mentorship sessions .....................................................................................10  
  The Difäm-EPN Minilab Network experience .........................................................................................................14  
PART 2..................................................................................................................................................................20  
  The Management of Chemotherapy and Cancer Medicines in Low- and Middle-Income Countries (LMIC) – a Challenge for Pharmacists..............................................................................................................................20  
  EPN Resources Center............................................................................................................................................25
Editorial from the Executive Director

Dear Reader

Over the recent past, the global pandemic of Covid-19 has exerted pressure on healthcare systems across the world. Even though the impact of the pandemic has been adverse, there has been positive stories of resilience.

While recognizing this resilience, we too are reminded of the need to re-think and re-evaluate our strategies of building resilient health care systems especially in low resources settings. Notably, we have all realised the value and wealth in technology during this pandemic and made an effort to work with what we call the new “normal” and this has been a different way of conducting our everyday activities. Far beyond what we used to know, our innovativeness in healthcare is as important as the strategies we lay out. The role of technology in healthcare has gained focus in recent times more than ever.

This “Pharmalink” edition offers us a technical range of articles in which we highlight experiences and lessons from various programs that EPN has continued to undertake in efforts towards strengthening healthcare systems. It unleashes a wide spectrum of dynamic and technical skills and offers you solutions to current challenges in faith-based health facilities. We also share an experience from our members on cancer management in church-health facilities. We hope these experiences will inspire us all.

We highlight the EPN’s innovative approach through online learning to deliver its pharmaceutical capacity building trainings. For over 10 years, one of EPN core mandates has been training pharmaceutical healthcare workers to build skill, capacity and promote professionalisation in our faith-based healthcare systems. This has always been done through physical training workshops. These courses, however, have now been customized and offered through an online Learning Management platform which has now immensely grown and scaled. We are proud that we continue to reach more healthcare personnel and students working in various faith-based health facilities especially in low resource remote facilities. Over the last year, the LMS has now over 13 courses, over 300 registered learners. We thank our partners and members for the support for this program.

Occupying a vantage position in healthcare, Drug Supply organisations (DSOs) have always played a crucial role in determining various factors in availability, access, quality and affordability to medicines. Through DSO mentorship sessions, EPN is now involved in developing roles that DSOs can play in building capacities in their respective facilities within the EPN network.

EPN’s commitment to stay in touch with our members is steadfast. In 2021, with the aim of addressing global and network church health systems challenges, EPN hosted 4 topical webinars in February, May, July and October. The webinars are platforms where the EPN members, donors, partners and friends share experiences and best practices on various selected healthcare topics. Over 400 cumulative attendees attend ended the webinar sessions. Thereafter the The AGM was also successfully conducted.
We believe that our focus as a network is to attend to the needs of our members. This has been underscored in the vision of the new strategic plan 2021 - 2025 is “A united and growing Christian network, in which at least 50% of its members meet pharmaceutical standards to ensure access to resilient quality pharmaceutical services”. We hope to build from our past experience, virtually and physically engage our members more, assess their needs and identify solutions of supporting interventions to address these needs.

We incredibly appreciate the authors who contributed to this publication and hope that these contributions will inspire us to continue with efforts to better our health systems. I thank all our members and partners who contributed to this edition. I also congratulate the editorial team for their dedication that has resulted in the publication of this issue of the Pharmalink edition. For you, we have strived to look into what it was like in 2021 and what our members went through to adopt. As we commemorate EPN being 40, we thank you for the countless effort you have made as members to adjust to the new digital setting.

Enjoy every moment of this season as it comes with its own life teachings and we look forward to greater experiences.

Happy reading and may God bless you!

Richard Neci, 

Executive Director, EPN.
PART 1
Digitization and Membership
Quality of Medicines – A conversation about JOPP article on Checklist for visual inspection on e-Drug (e-drug Digest, Vol 18, Issue 49)

EPN Member Richard Laing in his discussion with e-drugers (readers in the e-drug) on the checklist for visual inspection stimulated a conversation around assessing the quality of medicines using a checklist and how they have now reduced this to a simplified 26 one-page document from the 68 questions which is included in the paper.
He commented that he had recently read an interesting article titled A simplified checklist for the visual inspection of finished pharmaceutical products: a way to empower frontline health workers in the fight against poor-quality medicines. Schiavetti, B., Wynendaele, E., Melotte, V., J Van der Elst, B. De Spiegler & R. Ravinetto. It was published in J of Pharm Policy and Pract 13, 9 (2020).
To read on this, use the link below: https://joppp.biomedcentral.com/articles/10.1186/s40545-020-00211-9#citeas
The article described how the research team from the Institute of Tropical Medicine in Antwerp developed a 68-item checklist to assess the quality of medicines in DRC. They had reduced this to a simplified 26 question one-page document which was included in the paper. He believed that this was a useful tool that could be applied in any medical store or hospital pharmacy that receives medicines for storage and distribution or dispensing.
His comments were as follows:

‘On the checklist itself Figure 1 there is no place for the name and signature of the person doing the assessment. In addition there is no place for remarks. I would suggest adding a line at the bottom of the page to say “Please add any remarks about this product that you may have observed on the other side of this checklist.” I would be encouraging comments about tablet dust or smell when opening the container. Also are the labels securely attached to the internal container, do the caps fit firmly? I am sure that some of these items were included in the 68 question checklist but I do believe that open ended questions can be useful to collect additional information.
The other aspect that I missed was the importance of keeping the documentation. I have always advised that a ledger (with numbered pages) be kept to document initial reception and inspection of products coming into the store or pharmacy.
I am unhappy if all there is documented is the delivery note signed by the security guard or storekeeper when the product was delivered. This should be kept but someone with training should take responsibility for checking that the correct product was delivered. In the paper, I would suggest that these checklist forms be numbered and kept in a file in order of completion so that they can be checked if the products fail in the future. The question often arises “Did the product fail due to poor storage after delivery or was it bad before it was delivered?”. I would be interested in comments from E-Druggers about their experience using this or their own checklist.’

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Comments that followed in the following issues were: e-drug Digest, Vol 18, Issue 52
Robert Verhage added that a key element for product receipt was to check the products received against the orders placed, especially related to the source (manufacturing site details) and the quality conditions agreed. The checklist for receipt should tally with these quality conditions.
He also commented that this "sounds like an open door, but I would be curious to know why the check against the order placed is still absent."
Rob Verhage - hera - right to health and development Belgium
JOPP article on Checklist for visual inspection (3) e-drug Digest, Vol 18, Issue 53

Richard Laing went on to respond in the next issue that he was in agreement that this was a relatively simple step and should be built into the procurement and reception process. Unfortunately, this function is often delegated to the gate guard or the storekeeper who is asked to sign for the delivery. This process of checking the actual delivery against the order documents requires a skilled person, ideally a pharmacist, who would have access to the purchase documents. If the procurement process has utilized a prequalification process those documents can be used as part of this checking process. One other aspect that he had seen occur in private or not for profit wholesalers is the taking of a sample of the product and retaining that sample in a temperature and humidity-controlled environment so that if there is a quality problem later it will be possible to determine if the problem occurred before delivery or due to bad storage conditions after delivery. Such samples would be kept until a year after the expiry date.
He had been surprised how often senior officials in Central Medical Stores obsess about having testing equipment available and yet fail to pay attention to simple aspects like documenting reception of goods with simple physical inspection.

Raffaella Ravinetto (Department of Public Health Institute of Tropical Medicine Antwerp, Belgium) responded to both remarks in the next edition Digest, Vol. 18, Issue 54, agreed that we are too often neglecting simple interventions that can improve stock management, traceability, and surveillance; and that, at the same time, the importance of apparently simple but key-activities like "medicines reception" is systematically downplayed.
Another interesting example was published last year in the Journal of Pharmaceutical Policy Practices. These real-life cases from Sudan suggest that a careful visual inspection is of paramount importance in monitoring the quality of medicines not only at the point of care, but also at central level:

The Visual Inspection checklist (shown beside) is also currently being used by EPN in Its Minilab project. The project is aimed at establishing good practices in pharmaceutical aid in the midst of the COVID-19 pandemic: Developing capacities in detecting substandard and falsified medicines using the minilab technology in four countries of Sub-Saharan Africa. The activities of the project are currently implemented in Cameroon, Democratic Republic of the Congo (DRC) Central African Republic (CAR), and Liberia. EPN reviewed the Checklist to customise for the setting of this project.
The EPN Webinar Series - Cascading knowledge and sharing experiences across communities of practices

EPN is a strong and rich network of members constituting individuals of different capacities, expertise, experience, and organization focused on varying programs and activities, all with a vision of a strong healthcare system for all. It is dedicated to the provision of quality pharmaceutical and healthcare services.

The disruptions resulting from the outbreak of Covid-19 pandemic might have hampered efforts to conduct physical meetings. However, with sustained efforts, EPN leveraged the opportunities of online meetings and networking. Since February 2021, through webinars, EPN brought together these members and industry players to share experiences and best practices on emerging issues in pharmaceutical health services within faith-based health facilities across Sub-Saharan Africa. These webinars were amazing opportunities for EPN members to fellowship, be inspired, and network. They unpacked various pharmaceutical delivery topics with the aim of equipping participants with current and expert information. These topics formed essential elements of EPN vision and strategic areas.

Webinar 1: February 2021 - Enhancing the delivery of good quality pharmaceutical services and products in the context of global challenge of the COVID-19

In Sub-Saharan Africa and all over the world, health care workers and stakeholders in pharmaceutical arena are responding to the challenges of the pandemic in different ways, to maintain the manufacturing capabilities and access health care. In February 2021, the series started with 2-day webinars focused on discussion on the two aspects of the main theme;

Session 1: Medical Products Supply chain, challenges related to Covid-19 in the church health systems and globally.
Session 2: Communication and information management in pharmaceutical settings of the pandemic.

The two sessions were moderated by Dr. Richard Neci, EPN Executive Director and featured presentations from;

- Marlon Banda, Chief of Pharmacy Services & Logistics of the Churches Health Association of Zambia, EPN Board Chair, on the topic, Medical Products Supply Chain in the Church health system – access to the COVID-19 vaccine.
Just and compassionate quality pharmaceutical services for all

- Francis Aboagye-Nyame, International Program Director MTaPS, on the topic, the impact of Regulations on Health Care Supply Chains.
- Raffaella Ravinetto, Senior Researcher and policy advisor at ITM Public Health, on the topic, Disruptions of pharmaceutical supply in the COVID-19 global context: manufacturing, availability, affordability, distribution, and prioritization.
- Jane Masiga, Managing Directors MEDS, on the topic, managing the entire supply chain proactively in the new normal (DSO: Availability at the Distribution center level).
- Christoph Bonsmann- Executive Director of Action Medeor International Healthcare, and EPN Board Vice Chairperson, Communication in health systems strengthening.
- Dominique Jordan- President, International Pharmaceutical Federation (FIP), Communication and information sharing in the pharmaceutical settings of the pandemic: improvements for agile decision-making processes.
- Pamela Steele- Supply Chain Transformation Director, PSA, Data management and information sharing in Supply Chain disruptions due to the pandemic (Communication with stakeholders in Pharmaceutical system strengthening).

Key highlights from the webinar were;
Covid-19 pandemic highlighted the importance of networking, solidarity and action as this will be very important in responding to the pandemic. Only with excellent evidenced-based communication, sharing data, information and best practices, can contribute to bringing the pandemic under control.
The pandemic demands the highest quality data, delivered at speed and in considerable volumes. This is especially useful in decision making.
While social distancing is redefining the data distribution strategies, data management requires proper policing to ensure reliability. Businesses and supply networks with cloud-centric data strategies will be in a stronger position.
Good data is needed. Managing various functions of the supply chain requires good planning capacity, data management systems and information sharing strategy for making informed decisions. Inter-professional communication, leadership skills, management of partner, client and supplier relations are crucial to maintaining quality pharmaceutical services and medical products.
Whenever the information we have to work with exceeds or doesn’t fit our processing needs and capacity, the result is ineffective communication. To strengthen the pharmaceutical system, we need to improve the flow of information/data and communication among key stakeholders: Manufacturers, distributors, regulatory authorities, partners, customers, patients and co-workers.
Regulation strives to promote and protect public health, thus, regulatory systems should have inbuilt mechanisms to respond to public health emergencies such as Covid-19 pandemic to allow for emergency provisions without being tied down to regulations in place. While health supply chains are complex, they require clear regulations and guidelines to ensure safe and quality assured products reach the end user.

Webinar 2: 24 April 2021- Capacity building of pharmaceutical staff in church Health institutions: Gaps and way forward
The second webinar of the series focussed on capacity and how faith-based institutions can leverage innovative training to continuously up skill their workforce. Moderated by Susanne Duff-MacKay, presentations were made by;

“Evidence counts nothing if we don’t care how, it can be transmitted through social media channels.”
Mrs. Agnes Njue, Capacity Building Manager, MEDS - MEDS Experience Capacity Building
Dr. Richard Neci, Executive Director, EPN - EPN’s renewed focus on capacity building.
Prof. Richard Laing’, Global Health Expert, Boston University, USA - Capacity building of pharmaceutical staff in church Health institutions: gaps and way forward.

The discussions broadly covered aspects of capacity building, from the experience of faith-based institutions, its role in strengthening health care systems and available opportunities beyond pandemic era. Some of the highlights were: Continuous learning for healthcare workers is fundamental. Apart from professional education, additional learning for pharmacists and the various staff at the different levels of healthcare facilities is required to maintain, improve their skills, adapt to changing trends of the healthcare systems and also improve quality of healthcare services delivery.

Identification of facility or case-specific skill gaps is useful in distinguish the facilities with most needs and the specific pressing training needs for a facility or a health institution. Facility-specific needs assessment offers reference points for priority areas and tracking of progress especially in low resource settings.

The prevailing global health situation of COVID-19 pandemic has been challenging, but has also opened a new window for faith-based institutions to leverage on in capacity development. Through e-learning, these institutions can provide flexible, user-centered, and easily updatable information for health worker training.

Meet the experts on different topics:
During the Webinar participants were broken into groups and asked to discuss possible topics for future “Meet the Expert” Webinars. During the discussion of EPN Strategic Plan, a number of possible topics were suggested. The task of webinar participants was to review the list and prioritize each group’s top five (5) webinar topics. In addition, participants were called to identify EPN members who could contribute to the different webinars.

Webinar 3 – Joint EPN and PQM+ webinar: Rethinking assumptions about generic medicines cost and perceived quality: How managerial and regulatory systems help assure the quality of generic medicines
An essential element of strong health systems is the availability, quality and affordability of medicines and medical products. In July 2020, EPN with core field-led extension partner of USAID’s Promoting the Quality of Medicines Plus (PQM+) program co-organized a webinar to stimulate discussions, share experiences and review best practices on key principles of assuring quality in the manufacture and regulation of generic medicines. The session was moderated by Richard Neci, Executive Director EPN with presentations from;
- Daniel Karimi, Senior Technical Advisor, Chemistry, Manufacturing and Controls (CMC) & Regulatory Systems Strengthening (RSS), PQM+
- Stephen Kigera, Head of Quality Services, Mission for Essential Drugs and Supplies (MEDS)
- Teferi Bedane, Technical Advisor at United States Pharmacopeia (USP), Promoting Quality of Medicines Plus, PQM+

Among others, the discussions delved into the role and need of quality medicines, generic medicines, local manufacture of medicines, and the role of National Medicines Regulatory Authorities (NMRAs) and National Quality Control Laboratories (NQCLs).
It was noted that effective supply chains determine the success of any public health program leading to increased program impact, enhanced quality of care and improved cost effectiveness and efficiency.
Quality assurance in the manufacture and regulation of generic medicines supply is of the utmost importance in helping meet healthcare needs in LMICs. Generic medicines improve patient compliance, advance universal health coverage, and solve exclusion dilemmas.

Assuring quality of generic medicines require well defined strategies including; Deliberate interventions to address promote supply and utilization of generic medicines, strategies that build transparent and strong health systems, to inspire confidence in quality and price of generic medicines and involvement of managerial and regulatory/enforcement interventions. Motivate manufacturers be efficient to compete NMRAs should take initiatives to enable local production of essential medicines.

Through collaboration with partners to conduct sectoral analysis to understand and remove barriers to local manufacturing, NMRAs are able to benefit from Pooled procurement system, market intelligence and information, discounted price and advance purchase system, financing option of local, technology of transfer, reliance and collaborative registration system.

Local manufactures are encouraged to set up quality assurance systems for the manufacture of medicines. If locally produced, procurement is also faster than importing the medicines. Besides, there can be more flexibility in manufacturing plans and delivery times to meet specific, urgent, or emerging needs. Webinar (24 May 2021) report: https://www.epnetwork.org/publications/report-of-epn-webinar-24th-may-2021.

Webinar 4-18 October 2021 - Improving efficiency in procurement of quality-assured medicines across the faith-based pharmaceutical supply system in LMICs

Among EPN membership are Drug supply organizations. These organizations provide essential distribution and delivery of pharmaceutical products to the most remote of the facilities, especially in Africa. What are some of the minimum best practices of pharmaceutical products selection, quantification and procurement that ensure the availability of quality assured products? This webinar was designed to provide a platform where the forum can share and learn on various aspects at supply chain that are most essential in ensuring delivery of medical products.

It was moderated by Guy Noel Mouffou, Pharmacist action Medeor e.V. with presentations from;

- Lisa Hedman (WHO) WHO’s experience in improving efficiency in Procurement
- Shushan (Action Medeor) Best Practices in Procurement of quality assured medicines
- Bildard Baguma (JMS): EAC Pooled Procurement Initiative as a Means of Accessibility and Affordability of Medicines in the Church Health System - How can the initiative be extended to all DSOs in EPN Network?
- Richard Laing’, Global Health Expert, Boston University, USA - Capacity building of pharmaceutical staff in church Health institutions: gaps and way forward.

No country can be considered exempt from the risk of poor-quality medicines. Regulatory strengthening measures are needed during the pandemic can and should enhance regulatory systems beyond it and more ideas to invest in local production by factoring long term plans. Quality assurance is a process that is built into the individual processes of supply. Establishing and implementing a quality assurance mechanism for supply chain (prequalification, purchasing, storage and distribution) of pharmaceuticals should be undertaken in stages.

Supplier qualification, Self-inspection, Customer qualification, Drug safety (monitoring and reporting of adverse events, recalls, safety measures), warehousing are vital processes that should be carried out in-line with laid out Standards Operating Procedures (SOPs). Maintaining a list of prequalified products ensures that quality products are obtained from qualified sources.
It LMICs, joint procurement are useful tools to ensure cost-saving by lowering of procurement costs through bulk purchasing, improving quality even utilizing good manufacturing practices (GMPs), built trust with and among suppliers, increase reliability among other benefits.

**Which has been your most informative webinar so far?**

For more details, presentations, recording etc. visit our website page here: https://www.epnetwork.org/epn-webinar-series. EPN webinars form key part of EPN information sharing, advocacy, and capacity building. EPN is looking forward to more engagements through similar forums. Notable challenges experienced by attendees include;

- Insufficient ICT infrastructure and unreliable internet to support online meetings
- With many events being held virtually, calendars are filling with invitations.
- Different time zones- It is not always possible to have meetings at time suitable for all at the same time.

**Conclusion**

The experience from these webinars show that webinars are useful avenues for sharing knowledge, building networks, engaging and advocating for efforts of strengthening our healthcare systems. In spite of above challenges, EPN webinars have attracted over 400. EPN commits to information sharing and capacity building and shall continue engaging members and industry players through such forums to share on various pharmaceutical and healthcare topics.
EPN’s mission is to support churches and church health systems provide and promote just and compassionate quality pharmaceutical services. For a long time EPN has been offering training to healthcare workers on pharmaceutical systems strengthening, this has been always done through physical training sessions. It has yielded lots of success with the beneficiaries of this programs bringing positive change and cascading knowledge among fellow colleagues.

As part of dedication to enhancing the capacity to reach more healthcare staff, EPN has rolled out virtual learning through online portals. The quest to expand this reach was heightened with the disruptions caused by the outbreak of Covid-19 as it was not possible to organize EPP trainings physically.

In 2021, EPN in partnership with member organization Mission of Essential Drugs and Supplies (MEDS) rolled out the first set of courses through an online learning management system. This partnership aims to build skills and capacities of frontline health workers and various hospital cadres to mitigate the threat of the pandemic within our network. EPN courses were customized from the EPP courses that
EPN has been offering for over 10 years through physical training. MEDS has a training department that in the past focused on physical classroom teaching model to build capabilities to strengthen health systems and improve efficiencies of health care workers. This joined efforts with EPN provided the much-needed learning opportunities, opening an avenue of continuous learning.


As of November 2021, over 300 students from EPN members healthcare facilities had enrolled in the courses and more are continuing to enroll. Some of the countries the students are registered include Tanzania, DRC, Kenya, Nigeria, Rwanda, Cameroon, Liberia, Burundi, Uganda, Ghana, Malawi, Sierra Leone, Liberia, Burundi, Uganda, Ghana, Malawi, Sierra Leone.

**Challenges and lessons learnt**

EPN e-learning portal has been instrumental and continues to build skills for essential healthcare workforce. The use however, does come with a few challenges especially among learners. These include technical issues, sufficiency of internet, overreliance of company desktop computers to training limits students from learning beyond company working hours, computer literacy, most courses are available only in English limiting some of the Francophone students, adaptability to new computer-based learning.

With this, EPN looks forward to building on and enhancing partnership with all its members through e-learning. Some of the plans focus on innovative tools in the portal to enhance learning process. It is also looking at adding more French courses. To enroll in a course, visit EPN online portal using the link: training.epnetwork.org. Enrolling to these courses is a benefit for EPN members and therefore is free of charge.
Pooled procurement initiative- DSO Mentorship sessions

In the year 2021, EPN started a series of virtual mentorship sessions for drug/medicine supply organisations. This offered a platform for sharing experiences and best practises to empower them in strengthening technical support which will be beneficial to the member facilities they serve. In September, the first two mentorship sessions were held on the themes; “overview of good distribution practises” and “Capacity building for sustainable healthcare”. Later in October and November, two other sessions on “Transport qualification” and “Capacity building approaches for sustainability: Development of organisational expertise” were held. Since the start, 10 DSOs have benefitted the program.

The DSO mentorship sessions became virtual with the aim of sharing experiences and knowledge on best practices. The topics were comprehensive with speakers from major EPN Member DSOs practicing quality assurance and control. So far 4 mentorship sessions have been conducted and the number of participants increased.

Conclusion: There is still room for more DSOs to join the sessions online as this improves capacities of existing DSOs and those that are upcoming. For quality to be ensured we believe that the aspiring ones would share their challenges and lessons learnt of building this to the top. There was a rise in attendance in participation by 63%

Challenges

- Unavailability of good infrastructure like laptops among attendees to join these meetings
- Insufficient Internet access, and expensive internet costs

The DSO mentorship meeting

The 1st session held on 22nd September 2021, covered the overview of good distribution practices featuring presentations from:

1) Judith Asin, Programme officer, EPN - DSO Baseline assessment results
2) Guy Noel Mouoffo, Pharmacist, German Medical Aid Organization action medeor e.V - Overview of Good Distribution Practices

Moderator for the session was: Richard Neci, Executive Director, EPN;

- It gave a summary of results from the DSO baseline assessment which was conducted in the month of February 2021 highlighting the major areas i.e. Infrastructure, Customers served,
Services Provided, Drug Selection & Procurement, Quality Assurance (QA) and Quality Control (QC), Inventory Control, Readiness in Covid-19 Management

- The presentation gave an overview of the general principles of GDP with a focus on; Personnel, Premises and Equipment, Self-inspection, Recalls and returns, Transportation and Contract activities.

Topics that were touched on included the GDP guidelines, Storage conditions, self-Inspection, Documentation and the Provision of maintenance/repair of hospital equipment services or manufacture of prosthetic equipment.

The 2nd session held 24th September 2021

The purpose of the meeting was to equip the DSOs with the necessary skills to be able to support the health facilities build their capacities e.g. training of healthcare workers and ensuring that the supply systems are responsive with adequate financing therefore ensuring sustainability at the facility level. This in turn guarantees consistent procurement and supply of quality affordable medicines from the DSOs. The meeting focused on the topic of ‘Capacity building for sustainable healthcare’;

Speaker/Facilitator: Agnes Njue, Capacity Building Manager, MEDS
Moderator for the session: Judy Asin, Programme Officer, EPN

The presentation gave an overview of the importance of capacity building and the various components of sustainability in healthcare. It focused majorly on the WHO 6 pillars of health as they need to interplay in order to bring out the overall health outcomes i.e. Improved health, responsiveness to the community, social and financial risk protection and Improved efficiency.

-These 6 pillars/building blocks of health include; Service delivery, Human resources for health, Health information systems, Health products and technologies, Healthcare financing and Leadership & Governance.

-It also showcased the journey of MEDS in capacity building and what they have achieved in health systems strengthening.

Key topics that were covered were on Strategies on strengthening healthcare delivery, Strengthening Healthcare financing, Strengthening Governance and Leadership. Supply chains systems strengthening, Strengthening health information systems, Optimization of sustainable health systems.

The 3rd session held on 28th October 2021
The 3rd session was scheduled for German medical aid organization action medeor e.V. to share their expertise on transport qualification and its relevance in the pharmaceutical supply chain. The purpose of the meeting was to equip the DSOs with the necessary skills in transport qualification. The session focused on transportation of medicines for in-house solutions or outsourced activities, in addition, importance in ensuring that the quality of medicines is maintained throughout transportation.

Speaker/Facilitator: Dr. Imgard Buchkremer-Ratzmann and Shushan Tedla, action medeor e.V.
Moderator for the session: Dr. Richard Neci, Executive Director EPN

The meeting was attended by a team from EPN, Action medeor e.V and DSO members from Bureau des Formations Médicales Agrées du RWANDA (BUFMAR), Cameroon Baptist Convention Health Services Central Pharmacy (CBCHCSP), CHAN-MEDIPHARM, Faith based central medical foundation (FBCMF), Depot Central Medico-Pharmaceutique (DCMP), Presbyterian Church in Cameroon (PCC-Central pharmacy) Cameroon and Joint Medical Stores (JMS).

The presentation gave an overview of the relevance of transportation as a good distribution practice; requirements for transporting medicines and sensitive goods, stakeholders involved, importance of maintaining transport conditions to avoid compromising on product quality, fleet management and the careful selection and prequalification of service providers.

Key topics discussed were relevance of GDP transport, Stability testing and Temperature logging system.

The 4th session held on 24th November 2021

The purpose of the meeting was to enlighten DSO members on the importance of capacity building in their organization so that in turn they can also offer technical support on this to the health facilities that they serve. The session focused on institutional capacity development including human resource capacity building. In addition, results from the mini-survey that was earlier conducted was also presented to the participants.

Speaker/Facilitator: Dr. Richard Neci, Executive Director EPN
Moderator for the session: Judith Asin, Programme Officer EPN
The meeting was attended by a team from EPN, DIFAEM and DSO members from; Cameroon Baptist Convention Health Services Central Pharmacy (CBCHCSP), CHAN-MEDIPHARM, Faith based central medical foundation (FBCMF), Depot Central Medico-Pharmaceutique (DCMP), CDMU-ODISHA, Christian health association of liberia (CHAL) (See annex 2).

The presentation gave an overview of institutional capacity development and its importance including human resource capacity building, challenges faced in order to achieve this was also addressed and how to improve and monitor the results of capacity development in an organization. Key topics discussed were around Introduction to capacity building (Institutional), Results of DSO assessment/Mini-survey, Design Institution Capacity development and Next steps in ensuring sustainability is achieved in the member health facilities.

Through these gaps we are able to identify the challenges DSOs are experiencing which will enable EPN support all DSOs in gaining best practices from experts and through this, a minimum standard level for a DSO shall be developed and therefore regular DSO mentorship sessions are encouraged.

Read more on the Minilab network and some of the activities conducted below.
The Difäm-EPN Minilab Network experience
Authors; Gesa Gnegel and Christine Häfele-Abah of Difaem (German Institute for Medical Mission)

Summary
Falsified and substandard medicines pose a threat to the patient’s health and the function of health care systems. To reduce the risk of such products within their own supply chains, members of the Difäm-EPN Minilab network successfully use a screening tool called GPHF Minilab as a part of their quality assurance. Thereby they contribute to assuring the quality of medicines within their own supply chain, raising awareness to the problem of falsified and substandard medicines and removing low-quality products from circulation. This article describes the function, outputs, challenges and perspectives of this project.

Background: The threat of substandard and falsified medicines
Irrespective of whether the disease is communicable or non-communicable, the treatment of a patient often requires the use of medicines. In addition to challenges such as the availability and accessibility of the appropriate medicine, the quality of the product is crucial to the success of the therapy. [9] The World Health Organization (WHO) defines substandard medicines as “authorized medical products that fail to meet either their quality standards or their specifications, or both” while falsified medicines are those “that deliberately/fraudulently misrepresent their identity, composition or source”. [10] The presence of the correct amount of the active pharmaceutical ingredient (API) and its release from the dosage form in an appropriate time span are core questions when investigating medicine quality and aiming to identify substandard and falsified products. To answer these questions completely, comprehensive laboratory analyses according to the pharmacopoeias are necessary. These require complicated and expensive equipment such as an HPLC, which is only available to a few partners in the Ecumenical Pharmaceutical Network (EPN). [4] As depicted in Figure 1, substandard and falsified medicines do not only affect the patient himself, but also have far-reaching consequences beyond. Furthermore, in a comprehensive study published in 2017, the WHO states that the prevalence of substandard and falsified medicines in low- and middle-income countries (LMICs) is as high as 10.5%. [10] Therefore, cheap but efficient tools allowing medicine quality screening are of great importance [5], especially among drug supply organizations (DSOs) within EPN.

Figure 1: impact of substandard and falsified medicines [10]
Basic medicine quality testing: The GPHF Minilab®

A widely used tool for medicine quality screening is the Minilab by the German Pharma Health Fund [6]. This laboratory in a suitcase comprises chemicals, reference standards, glassware and other equipment required for a three-step medicine quality check: in a first step, a visual inspection of the product is performed aiming to identify gross violations of good manufacturing or good distribution practices. Next, a simplified disintegration test can be performed in order to verify the label claims regarding rapid or delayed disintegration of tablets and capsules. In a third step, a semi-quantitative thin-layer chromatography provides information about the presence (or absence) of the correct active pharmaceutical ingredient and gives hints about the dosage. [3]

Figure 2: The GPHF™ Minilab [3]

Though screening tools like the Minilab are not meant to replace the extensive laboratory testing according to the pharmacopoeias, the Minilab is a useful and accessible option for the identification of products with no active pharmaceutical ingredient (API) or an incorrect API. For those products the Minilab has been proven to be extremely sensitive and specific when operated by trained EPN members (up to 100% sensitivity and specificity). [7] However, the Minilab is not designed for the detection of moderately substandard products which contain less than 100 but more than 80% of the declared amount of the correct API. [4] [7] Therefore, the Minilab is less sensitive regarding the identification of medicines with incorrect amounts of API or an insufficient dissolution. [7] [8] Considering the moderate purchase price and training effort compared to an HPLC, the Minilab can be a cost-benefit effective option for faith-based DSOs to supplement other quality assurance measures such as supplier qualification, good storage and distribution practices. This benefit applies especially to regions with a high prevalence of falsified medicines [4].

The Difäm-EPN Minilab Network

As early as 2010, the advantages and opportunities of the Minilab motivated Difäm and EPN to initiate a common project: by equipping the first two DSOs with a Minilab and training staff on its usage, the basis for Difäm-EPN-Minilab Network was created. [4] Eleven years later, the Network has grown and now comprises 16 members in 13 countries, 12 of which are in Africa, the 13th country is India (compare figure 3).
By their time of entering the network, the partners were equipped with a Minilab and received a several day training on the proper handling of the Minilab. A German pharmacist conducted the training of the first network partners. By now, new network partners receive their initial training from other more experienced network partners. Once a year all network members meet for a workshop offering the chance to refresh their Minilab skills, exchange experiences and receive further training. For example, during the 2020 meeting aspects of laboratory safety in resource limited settings were focussed (although the meeting had to take place online due to the Covid-19 pandemic). A safety guideline for Minilab users is now available at the Difäm (both in English and French) and can be obtained upon request.

The entire network performs as much as 1000 Minilab tests per year. Every three month, each partner shares an overview of his Minilab activities with the Difäm. However, cases of suspicious products are reported to Difäm immediately. The Difäm pharmacists carefully check these reports and give advice for the required further actions. Following the network’s standard procedure, suspicious samples are being sent to another network partner for a retest. If this retest confirms the suspicion, the sample is sent to a fully equipped laboratory, e.g. MEDS in Nairobi for a confirmatory analysis. Samples which have been confirmed to be substandard or falsified, are reported by Difäm to the WHO and other relevant authorities. Twice a year Difäm prepares a network newsletter, listing substandard and falsified medicines identified by the network. Difäm furthermore elaborates training and working materials, such as a guideline for risk-based sampling procedures, which was shared with the network members in 2020. The network also collaborates closely with the University of Tuebingen and network members contributed to several scientific studies already. [2] [6] [7]
Success stories, challenges and perspectives

During the Covid-19 pandemic, with its severe impact on medicine supply chains and its increased risk for the occurrence of falsified medicines [1], the network has once more proven its strength. As early as in March 2020, Minilab network partners hit upon suspicious chloroquine samples. By that time, (hydroxy-) chloroquine was discussed as a treatment option for Covid-19. The results of the Minilab analyses were rapidly confirmed at Tuebingen University: the products in question did not contain chloroquine or only very small amounts of this active pharmaceutical ingredient. [2] These results were shared with the WHO immediately and an international Medical product Alert was published on 9th of April 2020 [11]. In 2020 a total of 50 substandard or falsified products were discovered by the network. Nine of these products were subsequently included in WHO Medical Product Alerts [11] [12], and others led to local or national recalls.
Apart from international success stories, being a member of the Minilab network is also connected to local improvements: knowing that a DSO performs quality checks of the medicines they supply increases the trust and confidence of the DSO’s customers and the suppliers are deterred from delivering inferior goods. Furthermore, suppliers are discouraged to deliver medicines of doubtful quality. In addition, Minilab trainings offered by partners for local or national medicine regulatory authorities strengthen the cooperation of the faith-based and the governmental health sector.

Despite all success of the Minilab network, not all challenges are easy to overcome. As one Minilab analysis requires approximately 30 minutes worktime of a trained employee, it often is a major challenge to make sufficient human resource available to perform regular tests. In addition, it can be challenging to procure the required chemicals locally once the starter kit has been used up. Transport fees for international procurement can be high and local availability is not always good.

Currently preparations for the joining of the Christian Health Association of Liberia (CHAL) to the Minilab network are taking place – therefore the Minilab Network is looking forward to further grow and expand its work. A special focus will be on the even closer cooperation with EPN. For example, it is planned to share the overview of identified substandard and falsified medicines with all EPN members and search for further possibilities to make EPN members without a Minilab benefit from the Minilab networks achievements. As a good starting point for this even closer cooperation, we are happy that funded through the Austrian NGO plan:g EPN has recently hired a new employee responsible for Minilab activities: Austine Opiata. Also further scientific studies in cooperation with the University of Tuebingen are foreseen, giving even more Minilab network partners the possibility to participate in research.
For further information on the activities of the Minilab network, question or requests of the mentioned training materials, kindly send an email to Gesa Gnegel and/or Christine Häfele-Abah: gnegel@difaem.de and haefele@difaem.de.

References


PART 2
The Management of Chemotherapy and Cancer Medicines in Low- and Middle-Income Countries (LMIC) – a Challenge for Pharmacists
Experiences with a cooperation of the German Institute for Medical Mission (Difaem, Tuebingen, Germany) and the Kilimanjaro Christian Medical Centre (KCMC), Moshi, Tanzania
Authors: Peter Vollmer, and Christine Haefele-Abah of Difaem (German Institute for Medical Mission).

Preface
NCDs are by far the leading cause of death globally, responsible for 71% of all deaths in 2016. And, of the 15.2 million premature deaths, 4.5 million were due to cancer. In 2018, there were an estimated 18.1 million new cancer cases and 9.6 million deaths from cancer. Cancer is already responsible for one in six deaths globally (1).

By 2040, there will be an estimated 29.4 million new cases globally with the greatest increases in low-and middle-income countries (LMIC). 67% of annual cancer cases will be in LMIC (1). The management of cancer medicines, medicines for supportive and palliative care and the preparation of cytotoxic medicines are genuine tasks for pharmacists. Oncology pharmacists should be members of chemotherapy teams.
Main pharmaceutical challenges in the field of chemotherapy and cancer medicines in LMIC

1. The lack of resources and infrastructure is most often an essential problem. It is a demanding task to make cancer medicines available, accessible and affordable and to assure their quality. Another challenge is to build up the necessary infrastructure for adequate preparation and handling of cytotoxic medicines.

2. Chemotherapy is a very complex medical field. The International Classification of Diseases lists more than 600 types of cancer, most of which require unique diagnostic and management approaches.

3. In the preparation of cytotoxic medicines there is a big gap between the highly sophisticated technical requirements in high-income countries (e.g. cleanroom environment) and the possibilities in LMIC.

4. It is necessary to create awareness that cytotoxic medicines are toxic medicines and belong to the most toxic class of chemicals.

5. Safe handling of cytotoxic medicines is mandatory.

Difaem and KCMC Experience

About 16 years ago Difaem decided to support the Kilimanjaro Christian Medical Centre (KCMC) in Moshi/Tanzania with the necessary quantities of urgently needed Doxorubicin, Vincristine and Bleomycin for the treatment of Kaposi sarcoma. Later on, life-saving Methotrexate for the treatment of Choriocarcinoma was added to the yearly donation consignments as the cytotoxic medicine was not available locally.

However the question came up: How does the hospital staff handle these toxic medicines? Difaem’s senior hospital pharmacist visited the hospital to observe the daily praxis of handling cytotoxic medicines: There was no professional infrastructure to prepare cytotoxic medicines at all. Nurses or medical doctors just drew up medications from the vials in the ward room (see picture 1) or at the bedside wearing examination gloves and sometimes aprons.
In consequence, Difaem decided to conduct a first workshop on staff protection by using adequate Personal Protective Equipment (PPE) at the end of 2014. The next step was to find a separate room for the preparation of cytotoxic medicines and to train a pharmacist in the preparation procedure. Fortunately, with support from US sponsors, a Cancer Care Centre (CCC) was built at KCMC in 2016. The first two oncologists (one Tanzanian and one expatriate) started working at the CCC. The new Oncology Pharmacy got a safety cabinet (see picture 2) and a store room for cancer medicines. First one pharmacist and after some time a second pharmacist were assigned there permanently.

As cleanroom technology is extremely expensive and usually not available, a cytotoxic safety cabinet is the core of protection during preparation and a must for aseptic preparation technique. Safety cabinets have to be checked at least once a year by a specifically trained and equipped technician. But it is a challenge to find such maintenance support in LMIC.

In 2017, Difaem and KCMC started a continuous programme on „Safe Handling of Cytotoxic Medicines Training“ to educate the staff of the Oncology Pharmacy, oncology nurses, medical doctors and other staff involved in the handling of cytotoxic medicines. Such Safe Handling Trainings are most important to create awareness, to train the correct use of PPE and spill kits and to introduce a cytotoxic waste management system. A „Safe Handling Concept“ was to be implemented in the entire hospital as preparations of cytotoxic medicines were administered not only to out-patients in the Infusion Room of the Cancer Care Centre but also to inpatients in the wards. Education of the staff was done by a local team of oncology nurses and a pharmacist. This included the necessity to inform patients and caregivers not only about the treatment and its toxic effects, but also about how to handle contaminated body excretions, linen and clothes.

A special focus of this programme was to build up an appropriate infrastructure for the preparation of cytotoxic medicines and to train the pharmaceutical staff of the Oncology Pharmacy practically. Continuous training was needed in the handling of the new safety cabinet. In addition, SOPs have been elaborated by the Tanzanian colleagues, which describe all relevant procedures in the way they are done in practice.

It was a big challenge for the new Cancer Care Centre to get the necessary cancer and supportive medicines. When the centre started, not a single cytotoxic medicine was stocked by the hospital pharmacy of KCMC. A big problem was that Medical Stores Department (MSD), the supply institution
of the government, could not cover the needs. The ordered cancer medicines have either not been delivered at all or only after long periods of time.

Quality assurance is another challenge. How can be made sure that the purchased cancer medicines meet the quality standards? KCMC gets most of its cytotoxic medicines from Indian suppliers. Not all products are registered and quality-assured. A severe quality problem occurred with Cyclophosphamide. The vials of one consignment showed a coloured, melted and almost completely destroyed content (see picture 3), probably due to high temperature during transport. The colleagues are insisting now to get only temperature-controlled consignments with certificates of analysis.

It was essential for our cooperation not only to build up a good relationship with the colleagues in the Oncology Pharmacy and the Tanzanian oncologist in charge, but also to get the commitment from the hospital management. This was especially important in order to secure sufficient human resources. At least two pharmacists and one pharmacy technician must be trained and employed continuously at the Cancer Care Centre. A two-person team (preparing and assisting person) must always be available to assure the aseptic preparation of cytotoxic medicines.

Oncology pharmacy has to include palliative care. As many patients come to a hospital in late stages of their disease or stay at home without any diagnosis and treatment, palliative care is most important to give these patients as much help as possible. It is an essential task for pharmacists to make oral Morphine solution and other essential medicines available to the local care teams. Difaem is running a cooperation with KCMC to support several KCMC-based palliative home care teams working in Moshi and the surrounding districts.

Last but not least it is an important task for oncology pharmacists to control and to monitor the prices and costs of cancer medicines. Generic medicines and biosimilars are helpful to reduce the costs of the most often expensive or extremely expensive chemotherapy regimens.

**Conclusion**

It is complex and challenging but possible to build up an acceptable level of cancer care/chemotherapy within Cancer Care Centres in hospitals of LMIC. Under the difficult frame conditions, a lot of commitment from the local partners and international facilitators is indispensable.

The long-term objective must be to aim for a better supply situation, sustainable financing and comprehensive capacity building. Therefore, advocacy on a local, country and international level is necessary.

Pharmacists should play an essential role in the management of cancer medicines, supportive medicines, palliative medicines and chemotherapy. They have to be an indispensable part of all chemotherapy...
teams. Their genuine task is to prepare cytotoxic and other cancer medicines, they should take over responsibility for a „Safe Handling Concept“ in the hospital and should organize education and continuous training for all staff involved in the handling of cytotoxic medicines.

References


(2) German Institute for Medical Mission (March 2020) Management of Cancer in Low Income Countries, A guide to establishing cancer treatment – with a focus on pharmaceutical aspects of chemotherapy and handling of cytotoxic medicines.

EPN Resources Center

E-resources in healthcare are important for health information and advice not just for learning, but also for decision making. With over 40 years, EPN has been strengthening healthcare systems across the globe. The strength of EPN is founded on a strong network of members especially faith-based organizations that provide healthcare service to communities more so in far-to-reach regions. This has been enhanced by the impact that it has made overtime. With this experience, the network has expanded not only in capacity but also in experience and information. Through the EPN Resources Centre, EPN is sharing this experience.

The EPN Resources Centre is an online resources repository portal accessible through EPN website. We recognize that pharmaceutical care is a vast subject and knowledge needs vary. This online Centre provides information materials on multiple topics for learners, health professionals, public health workers and individuals seeking information on healthcare. We invite you to visit this portal and sample relevant resource that could cover;

- **Pharmaceutical capacity development**
  Pharmaceutical Capacity development is one of key areas of EPN programs. Some of the previous programs that EPN has undertaken focused on training of pharmaceutical personnel, promoting access to medicines, quality assurance of medicines among others. In this Pharmaceutical capacity development section, you will find resources that include, Standards of operational procedures (SOPS), pharmaceutical care among others.
  Link: [https://www.epnetwork.org/coe/pharmaceutical-services-capacity-development/](https://www.epnetwork.org/coe/pharmaceutical-services-capacity-development/)

- **Antimicrobial Resistance and Infection Prevention and Control**
  Here, find vast set resources for educating on infection prevention among people of different categories (students, communities, farmers, healthcare professionals etc.), policy making for AMR, HIV/AIDS, role of faith leaders in HIV/AIDS prevention, treatment guidelines, Call-To-Action etc.
  Link: [https://www.epnetwork.org/coe/ipc/](https://www.epnetwork.org/coe/ipc/)

- **Non-Communicable Diseases**
  You want to create awareness on diabetes care? Find materials for teaching and building knowledge on diabetes and its management, promoting access to medicines for Diabetes patients, training of pharmaceutical staff on management of diabetes etc.
  Link: [https://www.epnetwork.org/coe/non-communicable-diseases-ncds/](https://www.epnetwork.org/coe/non-communicable-diseases-ncds/)

- **Maternal, Child Health & Family planning and HIV/AIDS**
  Some of the previous EPN programs in this program areas included promoting access to children’s medicines, training of pharmaceutical staff on maternal and child care, advocacy for religious leaders on HIV/AIDS management among others. In the Maternal, Child Health & Family planning section, find resources on treatment guidelines, nutrition, and advocacy on family planning, tools for promoting family planning etc.
- **Covid-19**

Learn on strategies for maintaining essential health services: operational guidance for the COVID-19 context. Link: [https://www.epnetwork.org/coe/covid-19/](https://www.epnetwork.org/coe/covid-19/)

We acknowledge the role that these materials have played among our network members and those who have benefitted from them. EPN promotes access to these materials as highly useful for key persons in strengthening health systems. This has been very beneficial especially with the onset of Covid-19 pandemic. Even so, challenges of access still remain. These include the need for sufficient internet, skills in access among others.

Nevertheless, the quest for information has continuously improved. Some of the most read materials include; Standard Operating Procedures – How-To Manual for Drug Supply Organizations and Church Health Institutions, Type 2 Diabetes management- Guide for pharmacy staff, Requisition and Issue Voucher SOP, Pharmacy Practice in Church Health Institutions (CHIs).

We encourage you to visit: [https://www.epnetwork.org/centre-of-excellence](https://www.epnetwork.org/centre-of-excellence) and learn more, share and let us all learn together.
Ecumenical Pharmaceutical Network
P.O.Box 749-00606
Maisonette 1, Kirichwa Flats, LR No. 2/68, Kirichwa Road, Kilimani | Nairobi | Kenya.