POLICY BRIEF FOR THE LEGAL FRAMEWORK ON INFECTION PREVENTION AND CONTROL
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| **ACRONYMS** |
|-----------------|--------------------------------------------------|
| **Africa CDC**  | Africa Centres for Disease Control and Prevention |
| **AMR**         | Antimicrobial Resistance                         |
| **AU**          | African Union                                    |
| **HAI**         | Healthcare-associated Infections                 |
| **IPC**         | Infection Prevention and Control                 |
| **WHO**         | World Health Organization                        |
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This Policy brief is a result of a literature review and consultations from the African Union Member States and stakeholders. The African Union Taskforce on AMR acting through the Africa Centres for Disease Control and Prevention (Africa CDC) acknowledges the contribution and support of Infection Control Africa Network (ICAN), United States Centres for Disease Control (USCDC) and World Health Organisation (WHO). We gratefully acknowledge the leadership, guidance and contributions to the quality assurance and review of the policy brief provided by Dr John Nkengasong (Africa CDC), Dr. Justin Maeda (Africa CDC), Dr Mohammed Abdulaziz (Africa CDC), Dr Jay Varma (US CDC) and Dr. Elizabeth Bancroft (USCDC).

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The Authors consulted prior literature from various stakeholders, experts, and actors from the African Union Member States, WHO, Development partners, Civil Society Organisations and International Organisations.

This policy brief aims to inform the African Union Specialized Technical Committee on Health, Population and Drug Control and the Specialized Technical Committee on Justice and Legal Affairs on the different measures Africa CDC has taken to draft the Legal Framework for Infection Prevention and Control.
1. INTRODUCTION

The Infection Prevention and Control (IPC) Legal Framework comes before the Specialized Technical Committee on Health and Drug Control for adoption and endorsement. The IPC Legal Framework is designed to guide Member States in the review and strengthening of laws and policies that support IPC at both the national level and in healthcare facilities. In developing this IPC Legal Framework, the Africa Centres for Disease Control and Prevention (Africa CDC) is furthering its mandates to harmonize disease control and prevention policies and promote the prevention and control of diseases by building capacity of public health institutions in Member States.

2. RATIONALE FOR THE IPC LEGAL FRAMEWORK

In October 2017, Africa CDC officially launched its Framework for Antimicrobial Resistance (AMR) Control, 2018-2023. One major component of this strategy involves decreasing the burden of antimicrobial resistance, particularly in healthcare settings. In April 2018, Africa CDC held a workshop with Member States and partners to define priorities for implementing the Africa CDC Framework for Antimicrobial Resistance Control. A major recommendation was that Africa CDC should define minimum standards for Infection, Prevention and Control (IPC) standards for healthcare facilities. The minimum standards should include the implementation of IPC structures and processes at the national, sub-national, and facility level, including a system for surveillance of healthcare–associated infections and antimicrobial resistance. In April 2019, Africa CDC and World Health Organization, held a technical consultation with Member states to develop the minimum standards and guidelines for health care facilities and developed a plan for IPC for African Union member states. A key outcome of the meeting was to develop a legal framework that would guide and underpin IPC operations within Africa and would capture areas such as accountability mechanisms and resources required for implementation, leadership structure, monitoring and evaluation. Accordingly, Africa CDC initiated a project to develop a legal framework for IPC that will guide the development or strengthening of IPC programmes in Member States and contribute to the establishment of a socio-professional environment adapted to the requirements in this area.

3. BACKGROUND AND FINDINGS ON THE CRITICAL IPC CONCERNS IN AFRICA

Healthcare-associated infections (HAI) are a critical public health challenge globally, including Africa, with approximately 1.4 million people worldwide (1 in 10 in developing countries) contracting a HAI while receiving treatment in a healthcare facility [1]. The prevalence of HAI in low- and middle-income countries ranges from 5% to 20%, and within intensive care units (ICU) 1 in 3 patients are at risk of acquiring a HAI [2]. Although more research on HAI in developing countries is needed, available data indicates that 40% of these infections could be prevented [3]. In addition, across Africa, antimicrobial resistance (AMR), including those associated with healthcare infections, is a growing concern. According to the WHO, one of the key strategies for limiting transmission of AMR in the healthcare setting is the effective use of IPC measures [2].

A lack of appropriate, effective IPC measures has been devastating during recent outbreaks and has resulted in lives lost among healthcare workers and patients. Insufficient tuberculosis (TB) IPC measures in South Africa put South African healthcare professionals’ likelihood of acquiring active TB three times greater than of the general population [4]. During the West Africa Ebola outbreaks, Severe Acute Respiratory Syndrome (SARS) and Middle East Respiratory Syndrome (MERS) outbreaks, as well as the ongoing COVID-19 outbreak, a shortage of personal protective equipment (PPE) along with an absence of many IPC measures, has resulted in healthcare workers becoming infected at higher rates [5][6]. The COVID-19 pandemic has shown how critical IPC is not just for AMR but for the protection of all healthcare workers. Inadequate IPC has led to deaths
of an estimated thousands of healthcare workers due to COVID-19. Stronger laws for IPC will help Member States protect their workers from COVID-19 and other epidemic prone diseases.

In November, 2016, the WHO published the Guidelines on Core Components of Infection Prevention and Control Programme at the National and Acute Health Care Facility Level ("Guidelines on Core Components") [7] They were the "first international evidence-based guidelines on the core components of IPC programmes," and "applicable for any country and suitable to local adaptations." [7].

The Guidelines on Core Components describes eight components ("Core Components"). They concern:

1. A national IPC programme and IPC programme at the acute health care facility
2. Development and implementation of evidence-based guidelines
3. Education and training at the national level and facility level
4. Surveillance at the national level and facility level
5. Using multimodal strategies in IPC activities at the national and facility level
6. Monitoring, audit, and feedback of compliance at the national and facility level
7. Workload, staffing, and bed occupancy at the facility level
8. Facility level-built environment, materials, and equipment

The prevention of HAI, including AMR-HAI, at the healthcare facility level can be strengthened through the implementation of IPC programmes at national and healthcare facility level. In addition, compliance with evidence-based IPC guidelines is important for reducing financial burdens on a healthcare system and preventing extended hospital stays for patients. Adoption of and compliance with IPC guidelines was one of the core strategies to successfully slow down the transmission during the 2014-2016 West Africa Ebola outbreak [8]. Mitigating efforts can be challenging if healthcare workers do not have the training or resources needed to follow the guidelines [9] [10]. Healthcare facilities face many barriers to implementing effective IPC programs [11] [12]. Insufficient support from management roles [11], lack of power and water, and limited sanitation supplies are just a few examples [9].

4. THE NEED FOR AN IPC LEGAL FRAMEWORK

The WHO has published toolkits for implementation of the Core Components at both the national and facility levels [13][14]. However, "implementation effectiveness will be influenced by existing health systems in each country, including available resources and the existing capacity and policies" [7]. And while facility-level core components "are typically implemented at facility level, leadership, coordination and policy development by the national authorities supporting these components are critical" [13]. Thus, the IPC Legal Framework can be used as a tool to support additional coordination and policy development.

5. PROCESS OF DEVELOPING THE IPC LEGAL FRAMEWORK

The draft IPC Legal Framework has undergone several stages of revisions and validation. A technical working group at Africa CDC began the initial draft zero of the IPC Legal Framework in August of 2019 and shepherded the document through regional consultations described below. An in-person regional consultation meeting was held in December 2019, in Abuja, Nigeria. However, further regional consultations faced unique and significant challenges due to the COVID-19 pandemic. In-person meetings were postponed due to safety measures and border closures, and the attention of IPC experts was needed to attend to the emergency. Nevertheless, thanks to the dedication of the IPC experts who recognized the fundamental importance of establishing legal frameworks in Member States to support IPC, the consultations were able to move forward through virtual platforms.
a) Development of an initial draft of the IPC Legal Framework and IPC Standards under the supervision of the Technical Working Group
   i. Africa CDC commissioned Infection Control Africa Network (ICAN) to review existing laws and policies on IPC across the continent to provide baseline information for the Legal Framework. A technical working group of IPC and Legal experts was set up to develop an initial draft of the IPC Legal Framework, the group completed this process by determining the legal authorities necessary to support the WHO Guidelines on Core Components. Africa CDC set up an IPC expert panel group with IPC experts from African Union Member States and other technical partners to provide guidance to the working group and serve as champions to get country buy-in for the endorsement of the Legal Framework.
   ii. Electronic review and feedback: Africa CDC sent a Note Verbale to all Member States seeking feedback and comments on the IPC Legal Framework, IPC Standards, and the accompanying Background Document, and feedback was provided electronically from Member State representatives.
   iii. Consultations: Inputs from Member States, international and regional partners, and subject matter experts in IPC and law were critical to the creation of the current draft of the IPC Legal Framework. Regional consultations with IPC experts and legal experts from Member States were held in December 2019 in Abuja, Nigeria, February 2022 in Lusaka, Zambia and May 2020 & January 2021, virtually to review and validate the IPC Legal Framework.

The purpose of the Consultations and electronic review and feedback was to:

- Gather the opinions of stakeholders to revise the scope and language of the IPC Legal Framework and IPC Standards;
- Highlight and contextualise Member States’ experiences about the necessity for legal measures that can support IPC at the national level and in healthcare facilities;
- Learn from international and regional IPC organizations as well as Member States that had recently revised legal frameworks to support IPC; and
- Coordinate stakeholders, IPC experts, and policymakers of Member States from all regions concerning the use of the IPC Legal Framework to support IPC measures.

6. CONTENT OF THE IPC LEGAL FRAMEWORK

The IPC Legal Framework is organized into six groups that summarize the topics that might be addressed in a Member States’ laws, decrees, or regulations which support IPC activities. They concern:

1. Domain 1: Establishment of a national IPC programme: this section describes how legal instruments can create a national programme to coordinate national and facility-based IPC measures.
2. Domain 2: Development and adoption of evidence-based guidelines: this section describes how legal instruments can grant authority to a national programme to set IPC standards at the healthcare facility level.
3. Domain 3: Creation of education and training at the national level and facility level: this section describes how legal instruments can grant authority to a national programme to educate and train healthcare workers in IPC.
4. Domain 4: Incorporation of HAIs, including HAI-AMRs, into surveillance at the national level and facility level: this section describes how legal instruments can grant authority to a national programme to coordinate surveillance of disease threats, including and HAIs and HAI-AMRs.
5. Domain 5: Establishment of a programme (which may be included in the national IPC programme) to monitor, audit, and receive feedback of compliance at the national and facility level: this section describes how legal instruments can grant authority to a national
programme to coordinate the monitoring and audit of compliance to IPC standards at the facility level.

6. Domain 6: Requirements for establishing IPC programmes at the healthcare facility level: this section describes how legal instruments can require that healthcare facilities meet certain IPC standards set by a national programme.

African Union endorsement of the IPC Legal Framework aligns with the following requests outlined in the Assembly/AU/Decl.3(XXXIII) Declaration On African Common Position On Antimicrobial Resistance [15]:

1. Advocate for Member States, Regional Economic Communities, and other relevant organizations to adopt policies and laws to enable long-term prevention and control of AMR; and
2. Support human resources development for AMR prevention and control among African Union human, animal, plant, and environmental agencies.

7. CHALLENGES AND BENEFITS OF THE IPC LEGAL FRAMEWORK

At the validation meetings for the IPC Legal Framework held in December 2019, May 2020 and January 2021, Member State representatives discussed the challenges that may be faced when working to strengthen their existing IPC legal capacity. The current COVID-19 has further widened the gaps and challenges in their national IPC capacities. Challenges identified by Member States are listed here along with an explanation of potential benefits the IPC Legal Framework may provide to Member States facing those potential challenges.

• Political Commitment: For the IPC Legal Framework to guide Member State driven policy change, Member States may face the challenge of obtaining political commitment for IPC activities, including key stakeholders understanding the importance of IPC.
  • Benefit of the IPC Legal Framework: AU endorsement of the IPC Legal Framework will help foster political commitment among the Member States and support IPC champions who are already working to bring stakeholders together to discuss Member State driven policy change.

• Financial Resources: Stakeholders may face challenges around identifying financial resources needed to put IPC legal mandates into practice.
  • Benefit of the IPC Legal Framework: The IPC Legal Framework can help to identify areas in which legal instruments can identify authorizing budgets and direct financial resources to IPC programmes and in healthcare facilities.

• Conflict of Law: As some Member States may have legal instruments already that support IPC activities, Member States could face challenges in aligning and harmonizing current policies with the potential legal instruments outlined in the IPC Legal Framework.
  • Benefit of the IPC Legal Framework: The IPC Legal Framework is a high-level document that considers the diversity of Member State legal systems and can inform the process of identifying legal instruments that strengthen IPC as well as any conflicts with existing legal systems.

• Enforcement Mechanisms: Some types of legal enforcement mechanisms have a potential to create financial burdens or other hardships on healthcare systems; Member States may face a challenge of identifying context-specific and effective enforcement mechanisms that do not cause additional financial strain on healthcare systems.
  • Benefit of the IPC Legal Framework: The IPC Legal Framework and guidance document takes into account the variety in Member State legal systems and can inform the process of identifying legal instruments that monitor, evaluate, and enforce IPC standards while authorizing budgets and direct financial resources to IPC programmes and in healthcare facilities.
8. CONSIDERATIONS FOR IMPLEMENTATION

The process for adopting new legal instruments or adapting existing legal instruments to support IPC measures will be context specific for every Member State. The process depends on the Member State’s current legal instruments and other policies, the legislative process and rule-making process, and available resources. These steps include: (1) assessing the current legal capacity to support IPC using environmental scans of legal instruments and assessing stakeholder engagement and commitment; (2) identifying the policies that can be strengthened through legal instruments; (3) determining which type of legal instrument would work best in the Member State’s context; (4) tailoring the legal instruments using a phased-in strategy; and (5) evaluating and revising the chosen legal instrument at each step to ensure adoption is feasible at all levels of government – both national and sub-national.

9. POLICY RECOMMENDATIONS (LEGAL PERSPECTIVE)

It is recommended that the African Union Members States endorse the IPC Legal Framework and IPC Standards with a key strategy of limiting healthcare transmission of infections through the implementation and strengthening of IPC in healthcare facilities. Benefits of using legal instruments to support the Core Components include a greater potential for achieving the following priorities outlined in the Assembly/AU/Decl.3(XXXIII) Declaration On African Common Position On Antimicrobial Resistance endorsed by the African Union on February 2020 [15]:

a. Increase the proportion of healthcare facilities implementing infection control and prevention programmes and antimicrobial stewardship programmes (Recommendation 3(a));

b. Increase access to clean water, sanitation, and hygiene in healthcare facilities, farms, schools, households, and community settings (Recommendation 3(c));

Sustainable IPC programmes at the national and healthcare facility level may help support the context in which individuals at the facility level can work to comply successfully with recommended IPC measures recommended in the Core Components [16]. Legal instruments that establish a national IPC programme may increase facility capacity to adopt and comply with IPC guidelines and mitigate HAI and disease outbreaks. Legal instruments that require the recommendations provided in the Core Components, including national standards for IPC, education and training, surveillance, monitoring for compliance, and facility level programmes, have the potential to create sustainable programmes for carrying out IPC measures and reducing HAI. All together, these legal instruments may more easily create sustainable IPC programmes [7].

10. CONCLUSION

As supportive national legal systems have the potential to strengthen IPC activities, Africa CDC has developed the IPC Legal Framework and IPC Standards to serve as an effective tool for harmonization of legal frameworks in Member States relating to IPC at the National and healthcare facility level. It is recommended that the African Union Members States endorse the IPC Legal Framework and IPC Standards with a key strategy of limiting transmission of infections including those associated with health care provision, in order to improve Infection Prevention and Control (IPC) in healthcare facilities.

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