African Union

AFRICA CDC
Centres for Disease Control and Prevention
Safeguarding Africa's Health

IPC

Infection Prevention and Control

Legal Framework, Background and Annotations

CONTENTS

ABBREVIATIONS

Africa CDC	Africa Centres Of Diseases Control And Prevention
AMR	Antimicrobial Resistance
HAI	Health Care-Associated Infection
HW	Health Worker
IPC	Infection Prevention And Control
SOP	Standard Operating Procedures
WASH	Water Sanitation And Hygiene
WHO	World Health Organization

PREFACE

In healthcare facilities, Infection Prevention and Control (IPC) requires a scientific approach to prevent harm caused by infection to patients and healthcare workers. Healthcare-acquired infections (HAIs), which include healthcare-associated antimicrobial resistance (HAI-AMR), are a major threat to health and safety. First, health systems have an ethical duty to "do no harm" when patients receive medical care and the responsibility to protect their employees, volunteers, and visitors. This is an issue of urgency given the expansion of universal healthcare in Africa. Second, Member State signatories to the African Charter on Human and Peoples' Rights have obligations, including under Article 16, to protect the health of their people. Third, healthcare facilities accelerate and amplify emerging infectious diseases, such as COVID-19 and Ebola. Preventing such infections through the implementation of a routine IPC programme can help limit disease transmission during community outbreaks. Fourth, healthcare facilities help drive emergence and transmission of antimicrobial resistant (AMR) infections, due to the heavy use of antimicrobial agents in the treatment of infections. Effective IPC programmes can reduce the prevalence of AMR infections in hospitals.

As such, healthcare facilities play a key role in effective preparedness and response. By ensuring IPC standards are implemented appropriately, healthcare facilities can provide safe services not only on a daily basis but also when there is a surge in healthcare need.

In October 2017, the Africa Centres for Disease Control and Prevention (Africa CDC) officially launched its Framework for Antimicrobial Resistance Control, 2018-2023 (1). One major component of this strategy involves limiting transmission of infections in healthcare facilities. 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 safe healthcare facilities, IPC structures and processes at the national, sub-national, and facility level, and surveillance for healthcare –associated infections. In April 2019, Africa CDC and the World Health Organization (WHO) held a technical consultation with Member States to develop these minimum standards for healthcare facilities and IPC programmes in African Union Member States. A key outcome of the meeting was to develop a model public health law and legal framework that would guide and underpin the operations of IPC within Africa and would address areas such as accountability mechanisms, resources required for implementation, leadership structure, and monitoring and evaluation.

Developing this legal framework for IPC within the African Union requires extensive consultation with IPC and legal experts within Ministries of Health, national public health institutes, civic organizations, and other relevant entities.

Africa CDC, a specialized institution of the African Union, is mandated with the responsibility of promoting the prevention and control of diseases and is committed to ensure that the African Union Member States have a comprehensive and strong legal foundation for IPC that will promote safe health care facilities, patient safety and quality universal health coverage which is relevant to health workers and patients at every single health-care encounter in Africa (2).

WHO GUIDELINES ON CORE COMPONENTS AND NEED FOR AN IPC LEGAL FRAMEWORK

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

The Guidelines describes eight components ("Core Components").

They include (3):

1. Establishing a national IPC programme and IPC programmes at the acute health care facility;

What is meant by legal instruments?

Legal documents that are agreed to by national or sub-national levels of government. The types of legal instruments vary depending on the Member State's legal system. An example of some legal instruments are: a constitution, acts of legislation such as laws and decrees, regulations, and applicable international agreements.

2. Developing and implementing evidence-based guidelines;
3. Providing education and training at the national level and facility level;
4. Incorporating HAIs into surveillance at the national level and facility level;
5. Using multimodal strategies in IPC activities at the national and facility level;
6. Monitoring, auditing, and receiving feedback of compliance at the national and facility level;
7. Establishing standards for workload, staffing, and bed occupancy at the facility level; and
8. Implementing standards for facility-level built environment, materials, and equipment used (3).

The WHO has published toolkits for implementation of the Core Components at both the national (4)and facility levels(5) . However, "implementation effectiveness will be influenced by existing health systems in each country, including available resources and the existing capacity and policies (3)."

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 (5)."

Authorize: The IPC Legal Framework uses the phrase "authorize" when describing the legal authorities of a National IPC Programme and other units responsible for IPC activities. This word signifies that the legal instrument gives the National IPC Programme the legal authority necessary to carry out that activity. A Member State's legal instrument can also explicitly require the National IPC Programme to carry out that activity or ensure that activity is performed.

A Member State's legal system can be strengthened to support IPC by adopting legal instruments that address the Core Components. The type of legal instrument utilized and the level of government that is responsible for executing the legal instrument will be determined by each Member State based on what is appropriate for its legal system. For example, a national-level document – such as a decree or law – might establish a National IPC Programme and provide an overview of its mission, functions, and leadership positions, while a regulation might define the IPC standards for healthcare facilities. Depending on the legal system, these types of legal instruments may require approval by the legislature or by the Council of Ministers, or other appropriate body. In other Member States, where regional governments are the designated authority for public health functions, additional legal instruments may apply national standards in those regions. There also may be internal regulations that can be approved at the ministerial level. Together, these legal instruments set the rules, rights, and duties of the government, its citizens, and other entities.
A Member State's legal system can support the implementation of the Core Components through the following:

- Establishing a national programme to coordinate national and facility-based IPC measures;
- Granting authority to set national IPC standards;
- Granting authority to educate and train health care workers in IPC;
- Granting authority to coordinate surveillance of disease threats, including HAIs;
- Granting authority for monitoring of compliance with IPC standards;
- Granting authority to ensure compliance with standards at the national and healthcare facility level
- Establishing duties to ensure practices align with IPC Standards; and
- Establishing accountability mechanisms for those entities carrying out authorities and duties.

Member States may currently use a combination of policies and informal collaboration, or best practice guidance to set standards for IPC and support measures at the healthcare facility level. Legal instruments may be used to further strengthen the Member State's IPC framework in harmony with existing structures and policies. The process of strengthening a legal system to support IPC can be thought of as continuous or iterative. A more in-depth discussion of scaling up legal systems to support IPC is in Appendix B.

Potential benefits of using legal instruments to support the Core Components include:

- Providing authority to coordinate IPC measures at the national and subnational level;
- Providing authorities to set enforceable standards at healthcare facilities, providing a system of accountability;
- Facilitating continuity of leadership and government support during transitional times; and
- Providing a strong basis for IPC funding.

The IPC Legal Framework is a tool that serves two purposes: first, it may be used by a Member State to guide review of existing legal instruments to more fully understand its existing legal capacity to support infection prevention and control; second, the IPC Legal Framework identifies ways that a Member State's legal instruments could be amended to increase support for infection prevention and control programmes.

ORGANIZATION OF THE IPC LEGAL FRAMEWORK

The IPC Legal Framework is organized into six groups called "domains" (Fig. 1). Domains summarize the topics from the eight WHO Core Components that might be addressed in the laws, decrees, or regulations which influence infection prevention and control activities.

They concern:

1. Establishment of a national IPC programme;
2. Development and adoption of evidence-based guidelines;
3. Creation of education and training at the national level and facility level;
4. Incorporation of HAIs into surveillance at the national level and facility level;
5. Establishment of a programme to monitor, audit, and receive feedback of compliance at the national and facility level; and
6. Requirements for establishing IPC programmes at the healthcare facility level.

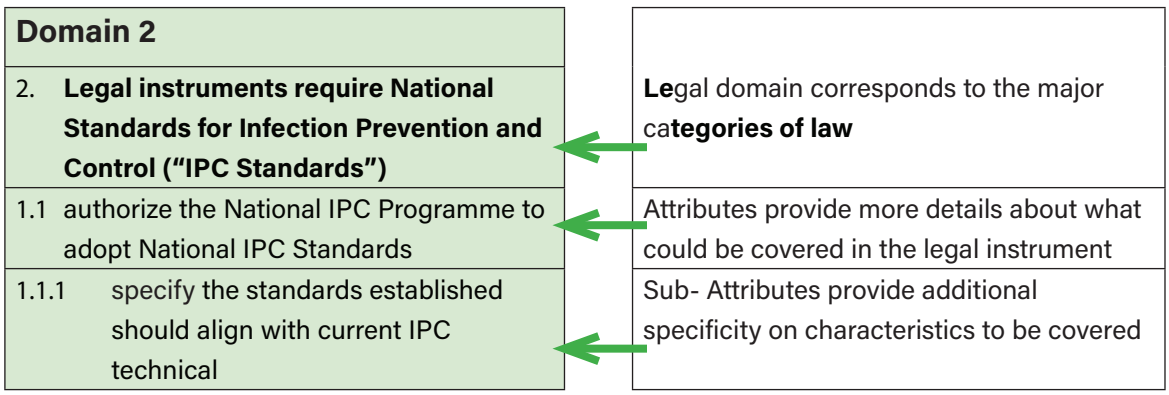
Each domain is made up of a list of attributes, which are characteristics of the domains. For example, a domain that establishes a national IPC programme might have attributes describing the members of the IPC programme and the source of funding of the IPC programme. Each attribute provides more detail about how legal instruments might include provisions to address an important aspect of the domain. A sub-attribute then provides details on how legal instruments might address an important aspect of its corresponding attribute. Each attribute and sub-attribute can be reviewed to consider what current legal authorities provide to support the IPC activities relevant to that domain.

HOW TO READ THE IPC LEGAL FRAMEWORK

The IPC Legal Framework describes legal instruments that may support IPC. Because Member States have diverse legal systems, the IPC Legal Framework contains attributes that may apply differently in each legal system

For example, authorities in some Member States are divided between national and regional governments in different manners. The IPC Legal Framework does not determine where any authority or duty should reside definitively for all Member States, but rather the IPC Legal Framework is a tool that can help Member States understand where that authority may already exist or encourage discussion about where it should be placed. Although it is likely that most Member States will have legal systems that would support creation of a national IPC programme at the national level, some Member States may give more authority to regional governments instead of a national programme. Legal experts can be consulted to better understand current legal systems and optimize legal approaches for the establishment of legal authorities for IPC.

Fig. 1 Understanding how to review domains, attributes, and sub-attributes



The IPC Legal Framework and descriptions above describe the domains and attributes often addressed in the legal instruments establishing core components of IPC at national and healthcare facility levels. Below are general provisions of all legal instruments to consider. Member States will work with legal experts to ensure legal instruments are consistent with requirements applicable to that Member State.

- **Definitions**: Many legal instruments will include definitions of terms used in the instrument. Definitions particular to the Member State's legal system will be drafted by the Member State. Definitions related to technical aspects of IPC will align with international definitions contained in the WHO's Guidelines on Core Components.

- **Purpose**: Legal instruments may include an overview, including topics such as the purpose of the legal instrument and need for IPC at the healthcare facility level.

- **Role of the legal instrument**: The role of individual legal instruments supporting IPC measures might be discussed in relation to any other legal instruments within the legal system supporting IPC to help a reader understand the larger framework. In some legal systems, legal instruments must include a section indicating how the new legal instrument works with existing legal instruments.

- **Date the legal document goes into effect**: The effective or commencement date (i.e., the date the legal document has force of law) may be stipulated and any prerequisites for the legal document to go into effect made clear.

- **Legal documents that will be repealed, explicit transfers of functions and resources**: Because legal instruments supporting IPC may build on pre-existing organizations or programmes, there may be existing legislation, rules, or regulations that may not be aligned with the new legal instrument. These may need to be repealed or modified. If human, financial, or other resources are to be transferred, the terms for these transfers may be addressed.

During the validation meetings, Member State representatives and technical experts identified challenges that Member States may face when using the IPC Legal Framework. These identified challenges and the factors set forth below whelped revise IPC Legal Framework and may serve as important examples as Member States use the IPC Legal Framework.

Identifying conflicts with Existing Legal Documents Or Information Practices

An important step in developing a legal system that supports IPC at the national and facility level is to identify existing legal mandates or practices that may already be in place. It is important to understand the potential for conflict among existing authorities or for potential conflict if new authorities are to be granted. For example, Member States might already have national laws that create a system of surveillance for infectious disease. Where new legal instruments create a surveillance programme specific to infection prevention and control in healthcare facilities, consideration should be given to avoid creation of duplicate surveillance efforts or requirements established in law. In addition, there may be existing policy guidance on IPC at the healthcare facility level. If a national IPC programme is given the authority to set enforceable standards for IPC at the healthcare facility, understanding existing guidelines is key so that individuals are not asked to follow multiple, potentially conflicting, guidelines. Questions that can be asked to aid that understanding

Understanding Legal Frameworks

The IPC Legal Framework is a tool whereas a country's legal system is an existing set of legal instruments you review with the tool.
Here is a way to understand the differences between both:
A country's legal system

- existing set of documents
- legally binding
- country specific
- agreed-to by the national, district, or local government
- made up of legal instruments that formally establish a country's infection prevention and control programmes

The IPC Legal Framework

- a reference list
- not country specific
- validated by Member States at the African Union level
- used as a tool to review the legal instruments formally establishing a country's legal framework

include: Do current guidelines work? Are they enforceable? Do they need to be changed or amended?

Legal instruments do not exist in a vacuum. Infection prevention and control must work coherently within existing programmes and laws, including where there are licensing requirements for healthcare facilities and workers, laws establishing requirements, public health surveillance, infectious disease reporting emergency response laws, laws regarding liability for harm, patient rights laws, and privacy laws.

SUPPORT FOR DEVELOPMENT OF THE IPC LEGAL FRAMEWORK

Regardless of the legal mechanism used, support from the highest levels of government is critical. Because details included in legal instruments that support IPC measures at the national and facility level have implications for the Ministry of Health as well as other agencies, the support of the Minister of Health, multi-sectoral high-level officials from other Ministries is essential. Developing a legal system that supports IPC requires extensive discussion and negotiation, with stakeholder involvement from multiple sectors, including non-governmental stakeholders such as medical and non-clinical professional bodies. The discussion and negotiation take place from the earliest stages and include sensitization of leadership to the need for a legal system to support IPC measures. Moreover, in order assist stakeholders in their efforts to translate policies that support IPC into law, it is important to include Member State legal experts at each stage in the process, starting with initial discussions and negotiation. Incorporating legal experts at an early stage can also provide the advantage of sensitizing a greater audience to the importance of IPC and how laws can best support IPC activities according to the legal system of each Member State.

BALANCE BETWEEN DETAIL AND SPECIFICITY

One of the challenges in drafting legal instruments that set standards for IPC at the healthcare facility is developing a document that is specific enough to provide the necessary framework to support those measures, but not so specific that it will soon become outdated. For example, providing extensive detail about specific IPC measures may be very beneficial to ensuring all healthcare facilities have specific guidance, but because the context in which IPC measures are employed may vary between different healthcare facilities and may need to change over time as new and better methods or technologies are introduced, numerous amendments would be needed. Passage of amendments through the legislature or Council of Ministers is usually time-consuming and can be difficult. Therefore, Member State may choose to supplement legal instruments by using additional, more detailed guidance documents that set out specific IPC standards, as detailed in the IPC Standards document. Policies and guidance documents are more easily approved and modified at the Ministerial level. This approach allows IPC standards to adapt as needs change.

THE IPC LEGAL FRAMEWORK

This Section describes the six legal domains, or major categories, to consider in legal instruments establishing a national infection prevention control programme and supporting infection prevention and control at the facility level.

DOMAIN 1: NATIONAL INFECTION PREVENTION AND CONTROL PROGRAMME

A national infection prevention and control programme ("National IPC Programme") refers to the authority and duty to conduct and coordinate IPC activities at the national level to reduce HAIs, along with the individuals who provide leadership for those activities. This National IPC Programme may be established by governments through legal instruments. The legal instruments that provide for a national level programme often outline characteristics of the programme that are important for its sustainability and effectiveness. Characteristics include those that define the membership and purpose of the program, powers and duties, resources available to support the national program's functions and activities, and how the national programme will coordinate with and relate to other national and sub-national government agencies. The characteristics listed in this framework are high-level and non-exhaustive. Each country will develop, implement, or further support a programme based on existing organizations, legal structures, and intended IPC activities. The IPC Legal Framework and IPC Standards provide guidance on essential characteristics frequently found in programme enabling legislation. Included below are some initial guiding questions to assist Member States as they think through incorporating characteristics of National IPC Programs into legal instruments:

- Who will be members of the National IPC Programme?

  Legal instruments can provide requirements for the leaders of the National IPC Programme, referred to as members, how individuals will become members, and the types of professional backgrounds members need. It is critical that membership on the National IPC Programme be multi-disciplinary and come from government, civil organizations, and institutions of learning.

- What are the objectives of the National IPC Programme?

  Legal instruments can be used to clarify objectives of the programme. To achieve those objectives, the functions and activities of the programme may be listed. Where the programme needs legal powers to achieve those objections, those legal authorities may accompany the objectives. Where any activities are essential to the programme achieving its objectives, the activities may be listed as duties of the program.

- How will the National IPC Programme and IPC activities in healthcare facilities be funded?

  To help the programme itself be more sustainable, legal instruments may set out a budget for the National IPC Programme. Budgets at the national level may also include budget for IPC activities at the sub-national level which will enable the national programme to support sub-national levels of government and healthcare facilities. Those budgets support the program's required functions and activities and so will vary by country and by year, depending on needs at the national and sub-national levels.

- What are the other national and sub-national programmes or organizations with which the National IPC Programme need to coordinate?

  Coordination between the national programme and any sub-national administrative programmes is key to the successful implementation of infection prevention and control measures at the healthcare facility level. Legal instruments can outline the way the National IPC Programme can or must collaborate with other programmes.

Below are the domain and attributes of a legal instrument that may create a National IPC Program.

1. **Legal instruments establish a national programme for infection prevention and control**

   1.1. establish a National Infection Prevention and Control Programme ("National IPC Programme")

      1.1.1. specify terms of reference

         1.1.1.1. specify how full-time/dedicated national IPC focal point and members will be appointed (including terms for changing or adding members as needed)

         1.1.1.2. specify clear objectives of the Programme

         1.1.1.3. specify clear functions and activities of the National IPC Programme and

roles of each member (including any legal authority and duties)

1.1.2. specify membership criteria

1.1.2.1. include professional qualifications

1.1.2.2. include professionals from multiple disciplines

1.1.2.3. include term of membership

1.2. establish a budget to support all activities, functions, and objectives of the National IPC Programme

1.2.1. require budget to be detailed in a National annual plan for public health activities, or the equivalent

1.3. identify sub-national administrative units (local authorities) responsible for implementing National IPC Programme functions and activities at each administrative level

1.4. authorize the National IPC Programme to collaborate and coordinate functions and activities with relevant ministries or other government agencies and relevant professional societies and institutions

DOMAIN 2: NATIONAL STANDARDS FOR INFECTION PREVENTION AND CONTROL

National standards for IPC measures help create consistency across jurisdictions. Legal instruments may require a National IPC Programme or other national authority to adopt IPC standards that apply to healthcare facilities and may dictate the areas of IPC that the standards must address. As discussed above, however, specific standards and technical guidance may be set forth in regulation or other guidance documents because these standards and guidelines may change more frequently than legal instruments can practically be altered.

Legal instruments, while leaving specifics of standards up to subject matter experts, can require the standards:

- be based on international guidance and evidence based best practices;
- remain updated through required review and revision of the IPC Standards at regular intervals and the incorporation of evidence-based practices;
- include mechanisms for incorporating evidence-based practices include pilot programmes, required evaluation and revision periods, and reliance on international recommendations; and
- be consistent by making sure the Ministry of Health review and approves of the National IPC Standards.

Compliance with Standards

The WHO recommends a blame-free environment for IPC. During the validation process, Member State representatives concluded that the purpose of using an enforcement mechanisms is to ensure compliance with IPC Standards for patient, healthcare work, and visitor safety, so enforcement should not undermine the purpose of the laws. Additionally, some types of enforcement mechanisms, such as penalties imposing heavy fines, could destabilize already fragile health care system. Alternatives to those types of enforcement mechanisms exist. Therefore, Member States should take impact of enforcement into account when fashioning the manner of ensuring compliance. Member States seeking to use enforcement authority may consider:

- The resources needed to comply with IPC Standards: some healthcare facilities may not be able to comply with all IPC Standards without additional resources, including training. Member State representatives at the validation meetings determined that enforcement mechanisms that provide a penalty should not be used where the reason for not adhering to IPC standards is a lack of resources.
- The entity responsible if IPC Standards are not met: Member States may consider what entity in government and in the healthcare facility system is liable, for a lack of IPC Standard compliance or a lack of IPC resources. Member State representatives emphasized this should be done in a manner that empowers, and does not penalize, healthcare workers who do not have power to address issues that might underlying a lack of compliance, including a lack of resources or inadequate flow of information and training.
- The entity responsible for implementation and ensuring compliance: the IPC Legal Framework describes on a high-level the responsibility to implement and ensure compliance with IPC Standards (2.5), but the IPC Legal Framework does not address with specificity what entities are responsible for implementation and enforcement. Those details must be determined by each Member State. In some cases, the national

level of government is not the entity responsible for implementation or enforcement of IPC Standards. The important part is that legal instruments identify which entities are responsible.

- The way compliance can be ensured: consider enforcement mechanisms that incentivize compliance or allow empower patients, such as public reporting requirements.
- How to provide additional support to healthcare facilities: including resources and training, to healthcare facilities unable to meet IPC Standards.
- Using existing enforcement mechanisms where there is malfeasance: a Member State's existing legal authorities may include mechanisms to address issues of malfeasance, including loss of licensure or accreditation standards. Member States can review existing mechanisms and update them to ensure they are evidence-based and in line with National IPC Standards and the WHO's Core Components.

Below are the domain and attributes of a legal instrument that may support adoption of national standards for IPC at the facility level.

2. **Legal instruments require National Standards for Infection Prevention and Control ("IPC Standards")**

    1.1 authorize the National IPC Programme to adopt National IPC Standards

        1.1.1 specify the standards established should align with current IPC technical evidence, including International Standards and Guidelines

        1.1.2 authorize the National IPC Standards to set requirements for healthcare facilities

        1.1.3 authorize the National IPC Programme to coordinate with relevant sub-national health authorities and health care facilities to adapt the National IPC Standards to local context

    1.2 authorize National IPC Programme to review and revise National IPC Standards at regular intervals but no less than once every five years

    1.3 ensure alignment among legal instruments so that the relevant body (such as the Ministry of Health) is in charge of approving National IPC Standards

    1.4 authorize National IPC Programme to ensure the National IPC Standards are implemented at all administrative levels

DOMAIN 3: EDUCATION AND TRAINING IN INFECTION PREVENTION AND CONTROL

Legal instruments may require the National IPC Programme to create and/or coordinate education and training for IPC at healthcare facilities. IPC education and training will require significant coordination among the ministry of education, ministry of employment and labor relations (or other similar ministries), and the ministry of health. Legal instruments can include provisions that help coordination and collaboration between ministries responsible for curriculum.

Evaluation of education and training is an essential component of IPC programmes, and the curriculum must be coordinated with the monitoring of the effectiveness of the training. A legal instrument can also authorize the creation or adoption of a system to evaluate IPC education and training.

Below are the domain and attributes of a legal instrument that may require education and training of IPC.

Where a Member State wishes to expand the amount of existing reporting, there are two recommendations on how to scale up a program: first, the member state can utilize two different frameworks of mandatory and/or sentinel reporting. Second, a phasing-in of new reporting requirements may relieve overburdening of new tasks and data.

3. **Legal instruments require education and training of healthcare personnel and IPC professionals**

3.1. authorize development of IPC education and training curricula

3.1.1. for all healthcare personnel

3.1.1.1. authorize training to be conducted upon hiring and at specified intervals

3.1.2. for pre-graduate and post-graduate education

3.1.3. for other persons who support health service delivery, including administrative and managerial staff

3.1.3.1. authorize training to be conducted upon hiring and at specified intervals

3.2. authorize the National IPC Program to coordinate with other relevant ministries and government agencies in development or revision of IPC education and training curricula

3.2.1. authorize National IPC Program to ensure the training and education described in (3.1) aligns with National IPC Standards

3.3. designate responsible party, such as healthcare facility, to ensure healthcare personnel are trained

3.3.1. designate responsibility to ensure IPC training is provided upon hire

3.4. designate responsibility to ensure IPC training is taken at a minimum once annually

DOMAIN 4: NATIONAL SURVEILLANCE FOR HEALTHCARE-ASSOCIATED INFECTIONS

Legal instruments may establish a national Surveillance System for HAIs, including HAI-AMRs or enable coordination between existing surveillance mechanisms and the National IPC Programme. Many Member States already have formally or informally adopted surveillance systems for AMR or infectious diseases in general.

The IPC Legal Framework domain 4 assists Member States in reviewing any legal instruments currently supporting existing national surveillance systems to determine whether a national surveillance system supports surveillance of HAI or how surveillance of HAI can be integrated into pre-existing national surveillance systems. If a Member State does not have legal instruments that support a national surveillance system, the IPC Legal Framework encourages development of those legal instruments, incorporating HAI.

Below are the domain and attributes of a legal instrument that may support a national system for surveillance of HAIs.

4. **Legal instruments require a national system of surveillance for healthcare-associated infections and healthcare-associated antimicrobial resistance**

4.1. authorize creation of a multidisciplinary national system to conduct surveillance for healthcare-associated infections and healthcare-associated antimicrobial resistance ("Surveillance Programme")

4.1.1. specify clear objectives of Surveillance Programme

4.1.2. specify required professional background of the Surveillance Programme members

4.1.3. specify clear activities and functions for Surveillance Programme, including

1.1.1.1 development of a national strategic plan for surveillance of healthcare-associated infections and healthcare-associated antimicrobial resistance

1.1.1.2 adoption of a set of standard definitions to be used nationally

1.1.1.3 adoption of a process for data validation, analysis, and reporting to appropriate authority

1.1.1.4 creation of a method for providing regular and timely feedback of surveillance data to healthcare personnel and other relevant stakeholders

1.1 authorize National IPC Programme and other relevant ministries to set facility surveillance requirements

1.1.3 specify requirements to be set based on type of facility and on laboratory capacity

1.1.4 specify requirements are to be set based on international and national recommendations

1.2 authorize the use of funding to support healthcare facility compliance with surveillance requirements

1.3 authorize surveillance of healthcare-associated infections and healthcare-associated antimicrobial resistance

1.4 authorize National IPC Programme and Surveillance Programme to coordinate with or utilize any existing or newly established national surveillance initiatives

1.5 address the protection of health data

DOMAIN 5: MONITORING COMPLIANCE WITH IPC STANDARDS AT THE FACILITY LEVEL

Legal instruments may establish formal programmes for monitoring and evaluating compliance with IPC Standards at the healthcare level. Many Member States may already have a formal or informal system for monitoring and evaluating strategies and goals at healthcare facilities. This domain may be used to review whether legal instruments support pre-existing monitoring and evaluation systems and review whether those programmes incorporate IPC activities. The IPC Legal Framework provides a high-level review of how legal instruments may support monitoring and evaluation mechanisms into legal frameworks, but it does not provide specifics about which mechanisms are to be used. For example, some Member States may choose to an audit of professional practices or review boards on IPC practices as one mechanism that is supported by but not specifically described in the IPC Legal Framework.

Below are the domain and attributes of a legal instrument that may support a national system for monitoring compliance with IPC Standards.

5. Legal instruments require a national system for monitoring compliance with National IPC Standards at the facility-level

5.1. authorize the creation of a system, which may be part of the National IPC Programme, for monitoring compliance with National IPC Standards ("Monitoring System")

5.1.1. specify required professional background of the Monitoring System members

5.1.2. specify clear activities and functions of Monitoring System

5.2. authorize the Monitoring System to conduct activities for monitoring and providing feedback on National IPC Standards compliance

5.3. authorize a process for data validation, analysis, and reporting that will guide the National IPC Program

5.4. addresses how non-compliance of healthcare facilities will be remedied

5.5. addresses liabilities for negligence or malfeasance or utilize an independent government agency to investigate where standards are not being met or enforced

DOMAIN 6: INFECTION PREVENTION AND CONTROL AT THE FACILITY LEVEL

Legal instruments may require both public and private healthcare facilities to have an infection prevention and control programme consistent with IPC Standards and linked to the National/regional programmes. Given that public and private healthcare facilities may be regulated differently in each country, authorities of regional or district level programmes over Facility IPC Programmes may need to be identified so that there can be a clear line of communication between the National IPC Programme and healthcare facilities.

KEY DEFINITION

The legal instrument should include a definition of "health care facilities" that will be required to establish a Facility IPC Programme and meet IPC Standards based on national and local context.

Because IPC Standards apply to individuals who work at healthcare facilities as well as the healthcare facilities themselves, an important legal aspect that will need to be considered are the individual liabilities, the facility liabilities, and the protections for both in the case of malfeasance.

Below are the domain and attributes of a legal instrument that may require Facility IPC Programmes. See the discussion of ensuring compliance in Domain 2 above for further information.

6. Legal instruments require infection prevention and control at the facility level

- 6.1. authorize health care facilities to have a programme for IPC ("Facility IPC Programme")
  - 6.1.1. specify terms of reference of the Facility IPC Programme
    - 6.1.1.1. specify responsibilities of the Facility IPC Programme
    - 6.1.1.2. specify membership of Facility IPC Programme is set according to National IPC Standards
    - 6.1.1.3. Specify minimum numbers of members required
  - 6.1.2. specify professional requirements for members of Facility IPC Programmes
- 6.2. authorize health care facilities to have a dedicated budget for Facility IPC Programme
- 6.3. authorize Facility IPC Programmes to develop IPC standard operating procedures ("Facility SOP") consistent with the National IPC Standards and international guidelines
  - 6.3.1. authorize facilities to adapt National IPC Standards to reflect the local context
  - 6.3.2. require healthcare personnel to be trained on Facility SOP
- 6.4. authorize health care facilities to ensure the recommended number and cadre of personnel trained in IPC are staffed at healthcare facility
- 6.5. authorize Ministry of Health or other relevant ministry or government agency to issue regulations governing health care facilities, including ward design standards
  - 6.5.1. authorize Ministry of Health to consult with National IPC Programme when setting standards

THE IPC STANDARDS

1. Establishment of an IPC program in health care facilities

1.1. IPC programs in primary care facilities must include the following personnel:
- 1.1.1. At least one part-time, trained IPC focal point in each primary health care facility
- 1.1.2. At least one IPC trained health care officer at the above administrative level (e.g., district) to supervise IPC focal points in primary health care facilities

1.2. IPC programs in secondary health care facilities must include the following:
- 1.2.2.1. At least one full-time trained IPC focal point
- 1.2.2.2. The minimum requirement for number of trained IPC focal points is one per 250 beds
- 1.2.2.3. Dedicated budget for carrying out IPC implementation

1.2.1. Professional requirements include:
- 1.2.1.1. Trained IPC focal point must be a doctor or a nurse
- 1.2.1.2. Trained IPC focal point must have dedicated time to carry out the IPC activities regardless of the number of beds

1.3. IPC programs in tertiary health care facilities must include the following personnel:
- 1.3.1.1. At least one full-time trained IPC focal point
- 1.3.1.2. The minimum requirement for number of trained full-time IPC focal points is one per 250 beds
- 1.3.1.3. A multidisciplinary committee to oversee implementation
- 1.3.1.4. Dedicated budget for carrying out IPC implementation

1.3.1. Professional requirements include
- 1.3.1.1. The trained IPC focal point must be a doctor or a nurse
- 1.3.1.2. The trained IPC focal point must have dedicated time to carry out the IPC activities regardless of the number of beds

2. Evidence-based IPC standard operating procedures, based on National IPC Guidelines, to be developed and implemented by health care facilities to reduce healthcare-associated infections (HAI) and antimicrobial resistance (AMR).

2.1. All health care facilities (i.e. primary, secondary, tertiary) must have facility-adapted standard operating procedures (SOPS)

2.2. At a minimum, facility SOPs must include:
- 2.2.1. hand hygiene
- 2.2.2. decontamination of medical devices and patient care equipment
- 2.2.3. environmental cleaning
- 2.2.4. healthcare waste management
- 2.2.5. injection and sharps safety
- 2.2.6. respiratory hygiene and cough ettiquete
- 2.2.7. occupational safety program (at minimum: screening staff, post-exposure prophylaxis, vaccinations)
- 2.2.8. aseptic techniques
- 2.2.9. screening, triage and isolation
- 2.2.10. cohorting of patients and staff
- 2.2.11. linen and laundry management
- 2.2.12. transmission-based precautions (e.g., detailed, specific SOPs for the prevention of airborne pathogen transmission)
- 2.2.13. system for managing facility supply chain

2.3. Secondary and tertiary care facilities must have additional SOPS on:
- 2.3.1. aseptic technique for invasive procedures including surgery
- 2.3.2. monitoring and preventing of the most prevalent HAIs based on local context and epidemiology

3. IPC education and training for health care workers at health care facilities

3.1. IPC training using National IPC curriculum is required for all health care frontline clinical staff and non-clinical staff (e.g., cleaners) at all levels of health care facilities (i.e., primary, secondary, tertiary) upon hire and at periodic (i.e., at least annually) refreshing trainings

3.2. Education & training on the facility IPC guidelines and SOPs is required for all front line clinical staff and non-clinical staff (e.g., cleaners) upon hire and at periodic (i.e., at least annually) refresher trainings

3.3. IPC-specific training is required for all IPC link professionals in health care facilities and IPC staff at the district level upon hire and at periodic (i.e., at least annually) refresher trainings

4. Systems for reducing overcrowding; optimizing staffing levels and standardizing bed occupancy

4.1. The following must be in place at all levels of health care facilities according to existing National IPC guidelines:

4.1.1. A system for patient flow

4.1.2. A triage system, including referral system

4.1.3. A system for management of consultations

4.1.4. A system for assessment of appropriate staffing levels and development and implementation of an appropriate staffing plan

4.2. Additional specifications at secondary and tertiary care facilities include:

4.2.1. A system to manage the use of space in the facility

4.2.2. Establishment of standard bed capacity for the facility (overall occupancy should not exceed the designed total bed capacity of the facility) and must abide by the following;

4.2.2.1. No more than one patient per bed

4.2.2.2. Spacing between beds must be at least 1 meter

5. Ensure adequate resources (i.e., materials, equipment) at health facilities for WASH and IPC practices in health care facilities

5.1. In primary health care facilities:

5.1.1. An improved water source must always be available within 500 meters of the healthcare facility for basic IPC measures, including hand hygiene, environmental cleaning, laundry, decontamination of medical devices and health care waste management

5.1.2. Functional hand hygiene facilities must always be available at points of care and toilets

5.1.3. There must be a minimum of 2 functional, improved sanitation facilities available on-site, one for patients and one for staff

5.1.4. The facility layout must allow adequate natural ventilation

5.1.5. The facility must have a dedicated space for decontamination and reprocessing of reusable medical devices

5.1.6. The facility must must allow for triage and space for temporary cohorting and isolation

5.1.7. Sufficient and appropriate supplies and equipment, including personal protective equipment, and reliable power/electricity must be available for performing all IPC measures, including standard and transmission-based precautions, according to guidelines/SOPsWaste must be safely segregated into at least three bins

5.1.8. Sharps and infectious waste must be treated and disposed of safely

5.2. In secondary and tertiary health care facilities:

5.2.1. Safe and sufficient quantity of piped water must be available on premises to perform all required IPC measures and specific medical activities

5.2.2. Functional[ii] hand hygiene facilities[iii] must always be available at points of care[iv], toilets and service areas

5.2.3. There must be at least 2 functional[v], improved[vi] sanitation facilities that safely contain waste available for outpatient *and* 1 per 20 beds for inpatient wards
5.2.4. The facility must be designed to allow adequate ventilation (natural or mechanical, as needed) to prevent transmission of pathogens
5.2.5. The facility must have a dedicated space for performing decontamination[viii] and reprocessing of medical devices (i.e., decontamination unit) according to guidelines and SOPs
5.2.6. The facility must have a dedicated space to segregate and process linens according to guidelines and SOPs
5.2.7. The facility must have adequate isolation rooms or at least one room for cohorting[viiii] patients with similar pathogens, if the number of isolation rooms is insufficient
5.2.8. Waste must be safely segregated into at least three bins
5.2.9. Sharps and infectious waste are treated and disposed of safely.
5.2.10. Sufficient and appropriate supplies and equipment, including personal protective equipment, and reliable power/electricity must be available for performing all IPC measures, including standard and transmission-based precautions, according to guidelines/SOPs

6. HAI surveillance and HAI-AMR surveillance at health care facilities (Legal domain 4)

6.1. Active surveillance of HAI and HAI-AMR must be conducted at tertiary health care facilities
6.1.1. Enabling structures and supporting resources must be in place, including medical records, trained staff, and laboratories capable of culture identification and antibiotic susceptibility testing
6.1.2. Surveillance activities should be directed by the local context and epidemiology
6.1.2.1. Timely and regular feedback must be provided at least monthly to key stakeholders, in particular to the hospital administration, in order to guide preventive measures, best practices, and appropriate action

7. Regular auditing and monitoring of IPC practices in health care facilities (Legal domain 5)

7.1. Hospital administration are responsible for enforcing the auditing and monitoring system
7.2. In secondary and tertiary care facilities, hospital administrators must identify an individual responsible for the conduct of periodic or continuous monitoring of selected indicators for process and structure (informed by the priorities of the facility or the country)
7.2.1. Hand hygiene is an indicator that must be monitored at all secondary and tertiary care facilities
7.2.2. Timely and regular feedback must be provided at least monthly to key stakeholders, in particular to the hospital administration, in order to guide preventive measures, best practices, and appropriate action

GLOSSSARY

Cohorting: Grouping of patients who are colonized or infected with the same resistant organism with the aim to confine their care to one area and prevent contact with other susceptible patients (for example, all patients infected or colonized with a carbapenem-resistant Enterobacteriaceae in a specific cohort and all patients colonized with methicillinresistant Staphylococcus aureus in a different cohort).

Decontamination of medical devices: Removes soil and pathogenic microorganisms from objects so they are safe to handle, subject to further processing, use or discard.

Health care-associated infection (also referred to as "nosocomial" or "hospital infection"): An infection occurring in a patient during the process of care in a hospital or other health care facility, which was not present or incubating at the time of admission. Health care-associated infections can also appear after discharge. They represent the most frequent adverse event associated with patient care.

Health worker: all people primarily engaged in actions with the primary intent of enhancing health. Examples are: Nursing and midwifery professionals, doctors, cleaners, other staff who work in health facilities, social workers, and community health workers, etc.

Improved sanitation facilities: Toilet facilities that hygienically separate human excreta from human contact. Examples include flush/pour flush to a piped sewer system, septic tank or pit latrine,

Improved water source: Defined by the WHO/UNICEF Fund Joint Monitoring Programme as a water source that by its nature of construction adequately protects the source from outside contamination, particularly faecal matter. Examples include: public taps or standpipes; protected dug wells; tube wells; or boreholes.

Infection prevention and control (IPC) minimum requirements: IPC standards that should be in place at both national and health facility level to provide minimum protection and safety to patients, health care workers and visitors, based on the WHO core components for IPC programmes.

IPC focal point: IPC professional appointed to be in charge of IPC at the national, sub-national or facility/ organization level.

Multimodal strategy: A multimodal strategy comprises several elements or components (three or more; usually five, http://www.ihi.org/topics/bundles/Pages/ default.aspx) implemented in an integrated way with the aim of improving an outcome and changing behaviour.

Points of care: any location in the health care facility where care or treatment is delivered (e.g., consultation/ exam rooms).

REFERENCES

1. Africa-CDC-AMR-Framework-eng. Available form www.africacdc.org. 2018 Apr 28;
2. Africa-CDC Brochure March 2019: Vision [Internet]. 2019.
   Available at: www.africacdc.org
3. World Health Organization. Guidelines on core components of infection prevention and control programmes at the national and acute health care facility level. 2016.
   Available at:https://www.who.int/infection-prevention/publications/ipc-components-guidelines/en/
4. World Health Organization. Interim Practical Manual supporting national implementation of the WHO Guidelines on Core Components of Infection Prevention and Control Programmes [Internet]. 2017.
   Available at: https://www.who.int/infection-prevention/tools/core-components/facility-manual.pdf?ua=1
5. World Health Organization. Interim practical manual supporting implementation of the WHO Guidelines on Core Components of Infection Prevention and Control Programmes. 2018.
   Available at: https://www.who.int/infection-prevention/tools/core-components/cc-implementation-guideline.pdf

Africa Centres for Disease Control and Prevention
(Africa CDC)
Roosevelt Street, Old Airport Area, W21 K19
P. O. Box 3243, Addis Ababa, Ethiopia
Tel: +251 11 551 7700
Email: africacdc@africa-union.org