PERFORMANCE AUDIT REPORT

"Approved" by

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Performance Audit of Infection Prevention and Control

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ABBREVIATIONS AND ACRONYMS

Ministry – the Ministry of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Affairs of Georgia.

Minister – the Minister of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Affairs of Georgia.

NCDC – LEPL – L. Sakvarelidze National Center for Disease Control and Public Health.

Regulatory Agency – LEPL – State Regulation Agency for Medical Activities.

WHO – World Health Organization.

Inpatient Care Facility – an institution carrying out medical activities related to the prophylaxis, diagnostics, treatment, rehabilitation and palliative care[1] of diseases in an inpatient setting, for 24 hours or longer hospital stay.

EIDSS – Electronic Integrated Disease Surveillance System (EIDSS).

IPC – Infection Prevention and Control.

Nosocomial Infection – healthcare-associated infection acquired in an inpatient medical facility within 48 hours after hospitalization, which was neither manifested[2] nor incubating[3] when the patient referred to a healthcare service.

Healthcare-associated infection – infection that has developed after receiving a healthcare service (including outpatient and inpatient), and which was not manifested by the patient when s/he referred to a healthcare service.

Disinfection – the process of elimination of pathogenic microorganisms (with the exception of bacterial spores).

MPHC – Municipal Public Healthcare Center.

Monitoring – Inspection of inpatient care facilities by the Ministry in the area of infection prevention.

Control of Permit Conditions – Supervision by the Regulatory Agency over the fulfilment of permitconditions of inpatient care facilities.

1 Care of patients with incurable disease.

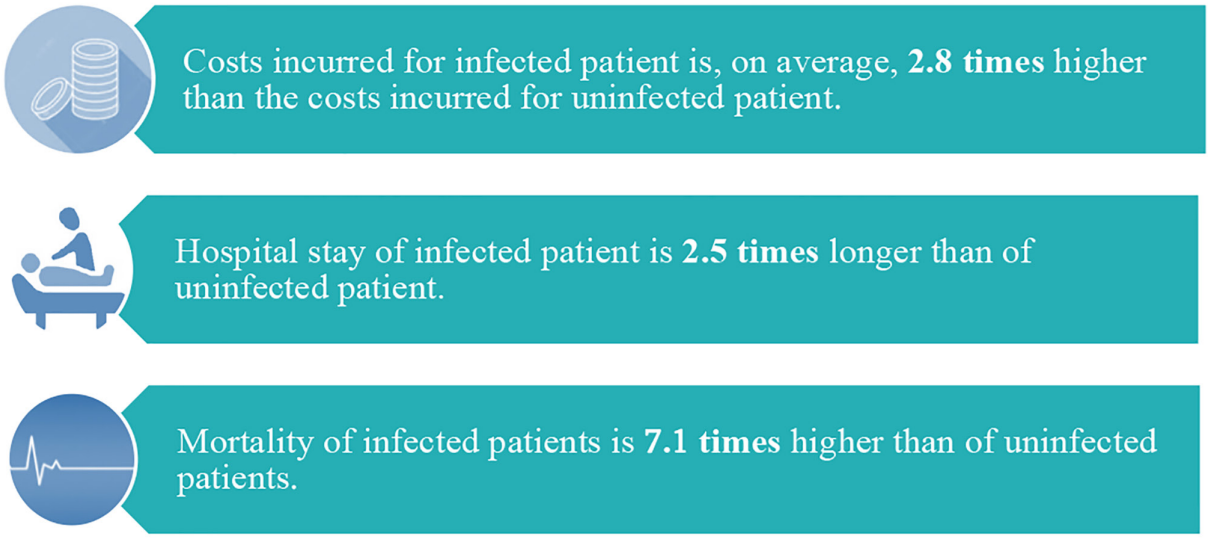
2 Symptoms of the disease that can be observed by a physician or perceived by the patient.

3 Period between infection and symptom exhibition.

EXECUTIVE SUMMARY

Infection Prevention and Control (hereinafter "IPC") measures is an important factor for maintaining an effective healthcare system. Healthcare-associated infections is a widely spread complication affecting both patient morbidity and mortality, and significantly increases costs of healthcare service. However, significant part of these infections can be avoided if an effective system of infection prevention and control is in place.[4]

Figure №1: Key facts about healthcare-associated infections[5]



The State Audit Office has carried out IPC system performance audit to identify how sufficient are the regulations and controls in place in the country for maintaining an effective system of infection prevention and control at health care facilities. The audit has found the shortcomings affecting the effective administration of the system:

- The country is missing national infection prevention and control strategy and respective action plan, which would ensure availability of nation-wide policy and measures to be taken to improve IPC system. These issues are only fragmentarily reflected in the 2017-2020 Antimicrobial Resistance and 2016-2020 Hepatitis C Elimination National Strategies which is not sufficient for policy development;

- Although the Ministry and NCDC have developed the mechanisms aiming to improve data gathering process on healthcare-associated infections in the country, they are not sufficient for ensuring its credibility. Therefore, the Ministry is not able to get a full picture of the actual situation existing in inpatient care facilities on this matter, which in return would make possible to identify the costs incurred for and to effectively manage nosocomial infections;

4 http://www.who.int/gpsc/core-components.pdf

5 England's example: https://www.nao.org.uk/wp-content/uploads/2000/02/9900230.pdf

- The legislation on the one hand requires accountability of nosocomial infections by the hospitals and on the other hand does not require having a microbiology laboratory being one of the means of confirmation of infections. Therefore, there is no mechanism developed at the initial stage of practicing the activity, which would enable identification, confirmation and accountability of nosocomial infections by the inpatient care facility;

- The legislation does not require inspection of whether dental care facilities meet the mandatory requirements at their start-up phase and nor there is a selection criterion of inspectees to inspect a newly opened dental care facility, which increases patient safety risks;

- In registering the disinfectants, in some cases documentation is incompletely provided. In addition, it is not specified what contents should be contained in mandatory documentation, which increases the risks of inconsistent approach;

- There is no detailed methodology developed which the Regulatory Agency should guide with in controlling hospital and this increases the risk of incomplete identification of the gaps of IPC at inpatient facilities.

The State Audit Office has made relevant recommendations on the circumstances and gaps identified, and in case they are considered the improved performance of this system would be feasible.

RECOMMENDATION TO THE MINISTRY:

Recommendation №1: For effective functioning of IPC at healthcare facilities, it is important to develop a single nation-wide strategy providing for availability of unified policy within the healthcare system and for coordinated work of its subordinated units.

RECOMMENDATION TO THE MINISTRY AND NCDC:

Recommendation №2: By facilitating the expansion and implementation of the existing mechanisms, introducing the new instruments, and improving the coordination between the IPC management units, reliability of information on nosocomial infections existing in the country should be ensured which will facilitate implementation of efficient measures by the Government in prevention and control of infections.

RECOMMENDATION TO THE MINISTRY:

Recommendation №3: In the conditions of reliable information, the Ministry should identify the costs incurred for the treatment of nosocomial infections to ensure effective management of these costs.

RECOMMENDATION TO THE MINISTRY:

Recommendation №4: For timely identification and management of nosocomial infections, before inpatient care facility starts practicing its activity, it should be confirmed that microbiology laboratory is in place.

RECOMMENDATION TO THE MINISTRY AND REGULATORY AGENCY:

Recommendation №5: Due to high prevalence risk of healthcare-associated infections containing increased threat to human life and health, the issue of dental practice as an activity subject to state regulation by permit should be reviewed and its legislative initiative should be made based on the relevant expert findings.

RECOMMENDATION TO NCDC:

Recommendation №6: To facilitate safe environment at healthcare facilities, registration of disinfectants should differentiate between the mandatory and preferable list of documentation, and the contents of each document should be specified in detail.

RECOMMENDATION TO THE REGULATORY AGENCY:

Recommendation №7: For the purpose of having detailed and unified approach to the control, it's important to elaborate detailed guidline in order to improve process of inspection of permit conditions at hospitals.

1. INTRODUCTION

1.1 AUDIT MOTIVATION

One of the important factors of public health safety is infection prevention and control, as highlighted by the World Health Organization (hereinafter "WHO") in its recommendations.

According to WHO data,[6] of every 100 hospitalized patients at any given time, on average 7 to 10 patients are infected with at least one healthcare-associated infection significantly worsening the mortality rate and increasing the financial expenditure for healthcare system.

In addition, information on healthcare-associated infections in developing countries is not reliable which is also proved by Georgia's example: annual average rate of healthcare-associated infections per 3.7 mln population in Georgia is 200, whereas in European countries[7] about 20 thousand incidences is reported per the same number of population.

10 (ten) inpatient medical facilities in Tbilisi have been monitored in 2016 at the Ministry's initiative.

As a result of monitoring, about 50% of hospitals failed to meet the requirements of the infection control measures such as:[8]

- Organizational support of infection controls system;
- Sterilization/Disinfection;
- Hand hygiene;
- Employees' health and safety;
- Safe injections practices;
- Nosocomial infections engineering controls.

In addition, the country has implemented high-priority and high-budget programs such as universal health coverage and hepatitis C elimination, the efficient and effective implementation of which is directly linked to the proper functioning of infection controls system in the country.

According to Hepatitis C Elimination Strategy[9], lack of infection prevention and control measures in Georgia is the most important risk factor of prevalence of hepatitis B and C.

According to 2017 data, 299 inpatient care facilities were enrolled in Universal Health Coverage Program in the country with GEL 574 mln spent on inpatient care of beneficiaries. Scarce data available on nosocomial infections in Georgia does not allow for identification of avoidable costs.

6 http://www.who.int/gpsc/country_work/gpsc_ccisc_fact_sheet_en.pdf

7 According to the data of the European Center for Disease Prevention and Control, annual average rate of healthcare-associated infections in the European countries is 4.1 mln with 0.55% of the total population.

8 Results of Monitoring of Functioning of Infection Control Systems at Medical Institutions.

9 2016-2020 National Hepatitis C Elimination Strategy in Georgia.

According to the UK National Audit Office 2009 report, during 2006-2008 national healthcare system in England saved about 97 – 204 mln pounds by reducing only one nosocomial infection by 41%.

The above-mentioned circumstances demonstrate the relevance of the issue and the risks of effective management of the system. Enhancement of the system is crucial for the country, which enables reduced rate of hospital stay and mortality caused by infections. In the event of properly functioning infection prevention and control system, it is possible for the government to save budgetary funds through avoidable infections.

1.2 AUDIT OBJECTIVE AND THE MAIN QUESTIONS

The objective of the audit is to assess effectiveness of infection prevention and control system, identify the existing gaps and issue relevant recommendations.

The following has been defined as the main question of audit:

To what extent the mechanisms in place in the country enable for the infection prevention and effective control?

Respective subquestions:

1. To what extent is the implementation of effective prevention and control of infections possible under the existing normative regulations?

2. To what extent do the entities enrolled in the existing system – NCDC and Regulatory Agency, ensure collection of information on, and prevention and control of infections?

1.3 AUDIT SCOPE AND METHODOLOGY

The Ministry of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Affairs of Georgia and agencies falling under its control has been identified as an auditee: LEPL L. Sakvarelidze National Center for Disease Control and Public Health, and LEPL State Regulation Agency for Medical Activities.

The audit period has been defined for the period of 2015-2017. Based on the audit objectives, post-audit period data have been also used. The following methods have been applied by the audit team for examining the issues:

- To study and analyze regulatory norms;
- To analyze documentary information;
- To analyze program management and administration procedures;
- To analyze databases;
- To familiarize with international practice and standards;
- To interview persons in charge.

The following auditory procedures have been performed to answer the audit questions:

1. To what extent is the implementation of effective prevention and control of infections possible under the existing normative regulations? – the audit team studied norms regulating the sector, which covered the analysis of the Ministry's strategy and action plan in the area of infection prevention, of inpatient care facility permit conditions, and of the rules of starting up a dental practice. Audit team studied the international practice covering the analysis of WHO recommendations, EU regulations on making available on the market of disinfectants, and the UK practice in dental care facilities registration procedures. In addition, interviews with the persons in charge were held and registration documentation of 59 disinfectants out of 106 registered ones were analyzed.

2. To what extent do the entities enrolled in the existing system – NCDC and Regulatory Agency, ensure collection of information on, and prevention and control of infections? The audit team examined the execution mechanisms of the regulatory norms relevant to the sector which covered the control over the observance of permit conditions by the Regulatory Agency in the area of infection prevention and control, and analysis of the monitoring of infection prevention and control by the Ministry. The audit team studied data of control carried out by the Regulatory Agency during 2015-2017, and the documentation submitted for meeting the permit conditions by 42 new hospitals during 2015-2018, as well as held the interviews with relevant responsible persons, and assessed to what extent do the mechanisms in place at NCDC enable reliable information on nosocomial infections.

1.4 AUDIT CRITERIA

To assess the effective functioning of the system, the following criteria have been used during implementation of audit procedures:

- Legislative and regulatory acts;
- Studies done by international organizations;
- Action plans of the relevant agencies;
- International practice.

APPLICABLE REGULATORY NORMS

Ordinance №385 of the Government of Georgia dated 17 December 2010 "On Approval of the Provisions on the Procedure and Terms and Conditions of the Issuance of Medical Activity License and Inpatient Care Facility Permit". The Resolution regulates the rule and the terms and conditions for issuing the permit of a hospital, defines key and additional requirements for the relevant profile inpatient care facilities. These conditions are inspected by the Regulatory Agency.

Ordinance №359 of the Government of Georgia dated 22 November 2010 "On Approval of the Technical Regulation of High-Risk Healthcare Facilities" – the document specifies the minimum requirements to medical practice of dental care facilities, in regard to medical devices, instruments, hygienic conditions and maintenance of medical records. Fulfilment of these require-

ments is supervised and register of dental care facilities is maintained by the Regulatory Agency.

Order №64/N of the Minister dated 19 March 2002 "On Improvement of Medical and Prophylactic Disinfectants in the Country" – defines the registration procedures of disinfectants, lists the required mandatory documentation, registration timeframes, terms and conditions.

Order №01-63/N of the Minister dated 19 September 2012 "On Operation of Internal System of Healthcare Quality Improvement and Patient Safety Evaluation at Inpatient Care Facility". According to the Order, for the purposes of improving the healthcare quality at the inpatient care facility and developing the patient-oriented healthcare services, the leadership at the inpatient care facilities should set up a quality management unit, which should be run by the instructions approved by the leadership under its internal order and should cover time-planned measures of quality assurance.

Order №01-38/N of the Minister dated 07 September 2015 "On the Rules of Epidemiological Surveillance, Prevention and Control of Nosocomial Infections". The Order prescribes the rules of accountability, management, surveillance, control and prevention of healthcare-associated and nosocomial infections for all healthcare providers, as required under the permit conditions.

INTERNATIONAL STANDARDS

WHO 2016 Guideline – "Guidelines on Core Components of Infection Prevention and Control Programmes at the National and Acute Health Care Facility Level". The objective of the document is to make evidence-based recommendations in the area of infection prevention and control to ensure development of infection prevention and control programme and strategy on the national and healthcare facility level and its adaptation to the local context. Eight key recommendations have been provided throughout the document.

2012 Regulation No 528/2012 of the European Parliament and of the Council "Concerning the Making Available on the Market and Use of Biocidal Products" – defines the conditions of making available on the market of disinfectants, registration procedures and time limits.

2. GENERAL INFORMATION

2.1 GENERAL INFORMATION ABOUT THE SECTOR

Nosocomial infection means a healthcare-associated infection acquired in a hospital after 48 hours of hospitalization, which was neither manifested nor incubating when the patient referred for a healthcare service. [10]

Infection prevention and control means a system of measures intended for preventing and controlling the emergence and dissemination of infectious diseases.

According to the WHO data, the following are the key risk factors of dissemination of nosocomial infections:[11]

Figure №2.1.1: Risk factors of nosocomial infections and solutions to the problem

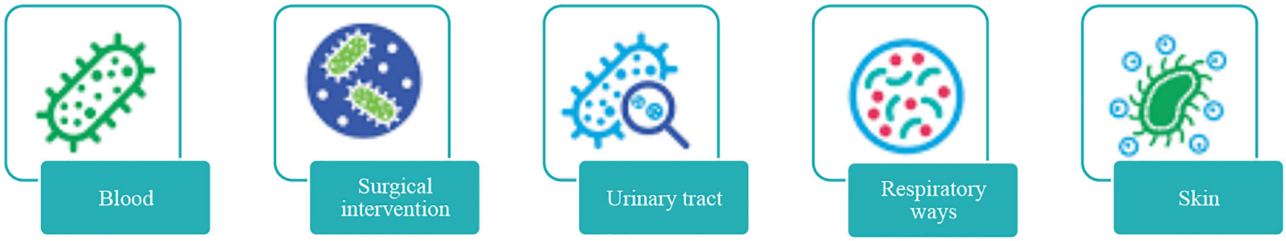
The following are the main ways of infecting the patients with nosocomial infections:[12]

10 Order №01-38/N of the Minister of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Affairs of Georgia dated 07 September 2015 "On Approval of the Rules of Epidemiological Surveillance, Prevention and Control of Nosocomial Infections".

11 http://www.who.int/gpsc/country_work/gpsc_ccisc_fact_sheet_en.pdf

12 https://www.nao.org.uk/wp-content/uploads/2000/02/9900230.pdf

Figure №2.1.2: Top five ways of dissemination of HAIs



According to England's 2006 National Prevalence[13] Survey data, on average 8% of patients is reported to have infections not manifested at the time of their admission to the medical facility. Based on the above example, the below table shows the most common infections and their top causes.

Figure №2.1.3: Top causes of HAIs[14]

Types of infection and percentage	Description	Risk factors	The main causing organisms
Urinary tract infections – 20%	Bacterium or sometimes fungus reaches through urinary tracts and infects the bladder. Usually urinary tract infections are treated with antibiotics but long-term catheterized patients can have problems due to generation of antibiotic resistant strains.	80% of urinary tract infections is associated with urinary catheters, catheterization method, length and patient sensitivity affects the risk of development of infection.	Majority of urinary tract infections are caused by gram-negative bacterium – especially by Escherichia coli.
Lower respiratory tract infections – 20%	Lower respiratory tract infection is associated with respiratory tubes (trachea and bronchi) and lungs. The most acute and life-threatening respiratory tract infection is pneumonia. 40% of the events are fatal.	The top causing risk factor of HAI associated pneumonia is mechanical ventilation. The risk of infection prevalence increases together with the length of ventilation.	Types of Acinetobacter and Staphylococcus
Surgical site infections – 14%	Surgical site infection is a wound infection emerging after the surgical procedure. Infection can involve a small fluid discharge from the wound or dangerous postoperative complications such as for example breastbone infection after open-heart surgery.	The risk factors of infection development are the length of surgical intervention, technique of intervention and preparation, existence of foreign material, length of hospital stay and antibiotic prophylaxis.	About 50% of surgical site infection is caused by Staphylococcus. As well as pseudomonas and other gram-negative bacteria.
Bacteraemia – 7%	Bacterium enters the bloodstream from the medical devices entering through vein or artery, or as a result of other infections present in the body. Infection can cause sepsis and develop septic shock. It is characterized by high mortality.	About 44% of infections is associated with invasive medical devices with 2/3 of which is caused by intravenously entering medical devices such as peripheral and central line catheters.	Escherichia coli and other gram-negative bacteria, as well as staphylococcus (about 13%)
Other HAIs – 39%			

2.2 GENERAL INFORMATION ON IPC MANAGEMENT IN GEORGIA

The key principles, institutional and procedural issues needed for successful functioning of infection prevention and control in Georgia are prescribed in the relevant requirements, methodology and administration rules published both as Minister's normative orders and as ordinance of the Government of Georgia.[15]

13 The total number of cases of specific disease in existence in a given population at a certain time.

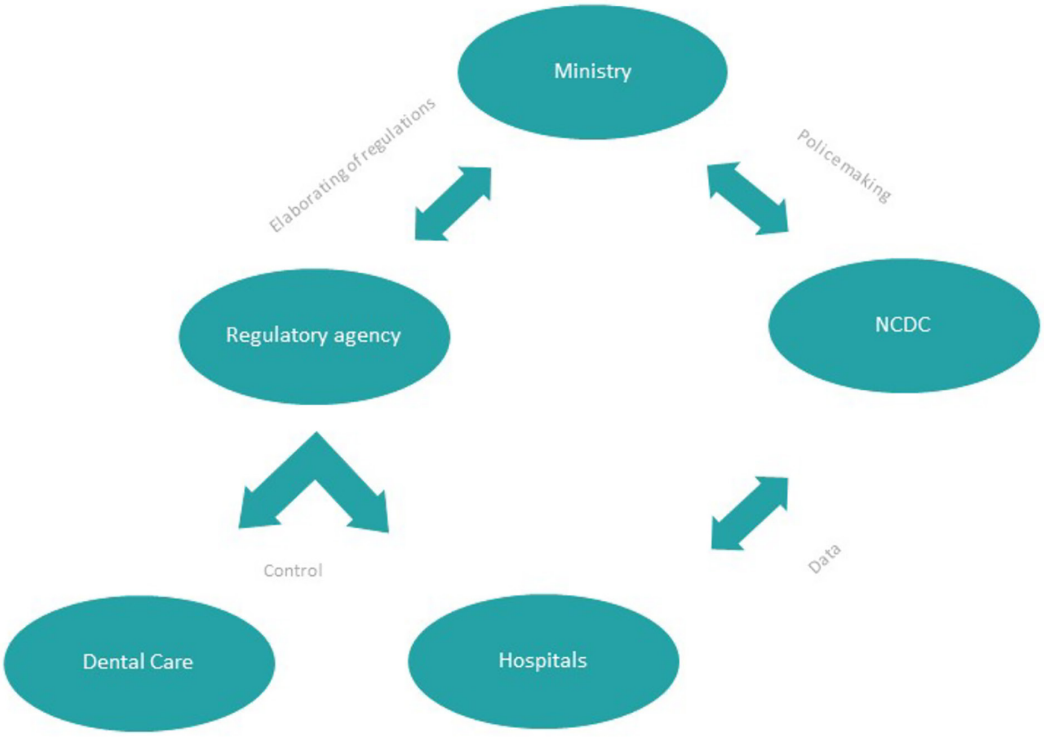
14 England's example, National Prevalence Survey Data, 2006.

15 http://moh.gov.ge/ka/479/

Infection prevention and control system in the country is carried out by the Ministry and agencies under its control: NCDC and Regulatory Agency.

The following entities are involved in the operation of IPC:

Figure №2.2.1: The system of infection prevention and control



As part of infection prevention and control, **the Ministry** develops policy and issues relevant legal acts, approves guidelines and delegates the rights and duties to the agencies under its subordination. Moreover, since 2016 the Ministry monitors the inpatient care facilities enrolled in the State Universal Health Coverage Program, in the area of infection prevention and control, with participation of the representatives of NCDC and Regulatory Agency together with the Ministry's employees (since 2018 the Regulatory Agency has been performing on-site checking of factual circumstances after the two-phase monitoring.)[16]

Permit conditions of inpatient healthcare facilities requires availability of infection prevention and control system. At the start-up phase of healthcare practice, the **Regulatory Agency** inspects the requirements of IPC, and later controls the observance of permit conditions. In addition, the Regulatory Agency inspects the conditions of technical regulation of high-risk medical activity at dental care facilities who are required to adhere to the IPC requirements.

16 https://matsne.gov.ge/ka/document/view/1852448?publication=0 Article 23, paragraph 41

NCDC is responsible for monitoring the effective functioning of epidemiological surveillance, detecting communicable diseases and noncommunicable diseases of public significance and health risks, for public policy and timely notification of public, including the collection and analysis of the information on nosocomial infections. NCDC lays down registration procedures and terms and conditions, and registers the disinfectants.

Moreover, to control epidemiological[17] situation of communicable diseases in the country, NCDC implements the **State Epidemiological Surveillance[18] Program** on annual basis, with one of the components being the epidemiological surveillance of nosocomial infections. It implies taking of sampling material from the inpatient care facilities selected based on the predefined criteria, for the purposes of collection of information about nosocomial infections, and analyzing the results.

Health care facilities are required to take infection prevention and control measures.[19] Nosocomial infections control committee should be operating at the **inpatient care facility** which ensures compliance of IPC practice with the requirements laid down under the legislation, by developing an IPC program – an action plan for nosocomial infections control. Person in charge for infection control should be appointed at dental care facility, to record, manage, supervise and control healthcare-associated infections, as well as to ensure patient safety and healthcare quality.

2.3 OVERVIEW OF INTERNATIONAL PRACTICE

WHO RECOMMENDATIONS ON NATIONAL IPC PROGRAM

The WHO 2016 recommendations provide for the key components to be covered by the National IPC program. The program should contain clear objectives, functions, appointed infection preventionists and a defined scope of responsibilities. As a minimum, the program should cover goals to be achieved for endemic[20] and epidemic infections[21] and recommendations for IPC process, as well as effective practices in preventing HAIs and reducing antibiotic resistance[22]. Technical team should be appointed for the implementation of the program who should have received special IPC training and have the authority to enforce the decisions taken, and dedicated budget should be allocated according to the planned activities. The program requires to be supported by Government authorities.

17 *Epidemic* – significantly increased occurrence of disease in a defined territory or certain community group in comparison to normal (underlying) expectancy.

18 Epidemiological surveillance – ongoing system of collection, analysis, and dissemination of public health related data.

19 Order №01-38/N of the Minister of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Affairs of Georgia dated 07 September 2015 "On Approval of the Rules of Epidemiological Surveillance, Prevention and Control of Nosocomial Infections".

20 Infections that are characteristic to a particular population, environment, or geographic area.

21 Increase, often sudden, in the disease rate in that population in that geographic area.

22 The ability of bacteria and other microorganisms to resist the effects of an antibiotic to which they were once sensitive.

IPC SURVEILLANCE – UK EXAMPLE

UK's healthcare budget is managed and allocated by the National Health Service.[23] The independent regulatory body Care Quality Commission (CQC) carries out registration of hospital and dental care providers and control of service quality,[24] financed from Healthcare Department[25] and is accountable to it.[26] During registration of providers and during further inspection, CQC inspects how compliant is the inpatient and dental care facility with the requirements of Health and Social Care Act 2008,[27] integral part of which is the set of infection prevention and control practices.[28] In addition, CQC publishes the rating of inpatient facilities and reports according to key 5 (five) criteria, one of which is safe treatment requirement, including, whether effective IPC system is in place at the inpatient facility.[29]

MAKING AVAILABLE ON THE MARKET OF DISINFECTANTS – EU EXAMPLE

For making available of biocidal products on the EU market, the product should go through authorization process.[30] Companies can choose between several alternative processes, depending on their product and the number of countries where they wish to sell it. There are following alternative procedures for a product to be placed on the market:

- National authorization – going through one country's authorization process is enough for a product to be made available on that country's market only;
- Mutual recognition – product will be placed on the market of several European countries;
- Union authorization – through one registration process the product will be placed on the market of all EU Member States.

Final decision on authorization of biocidal products on the Union level is made by the European Commission, based on the opinion of European Chemicals Agency[31]. The authorization process covers the following steps presented in the figure:[32]

23 https://www.nhs.uk/using-the-nhs/about-the-nhs/nhs-structure-explained/

24 An authority with similar power as Regulatory Agency.

25 An authority with similar power as Healthcare Ministry.

26 https://www.cqc.org.uk/sites/default/files/20151111_Coporate_Governance_Framework_August_2015.pdf

27 https://www.cqc.org.uk/guidance-providers/registration/what-registration

28 https://www.cqc.org.uk/sites/default/files/20150210_guidance_for_providers_on_meeting_the_regulations_final_01.pdf

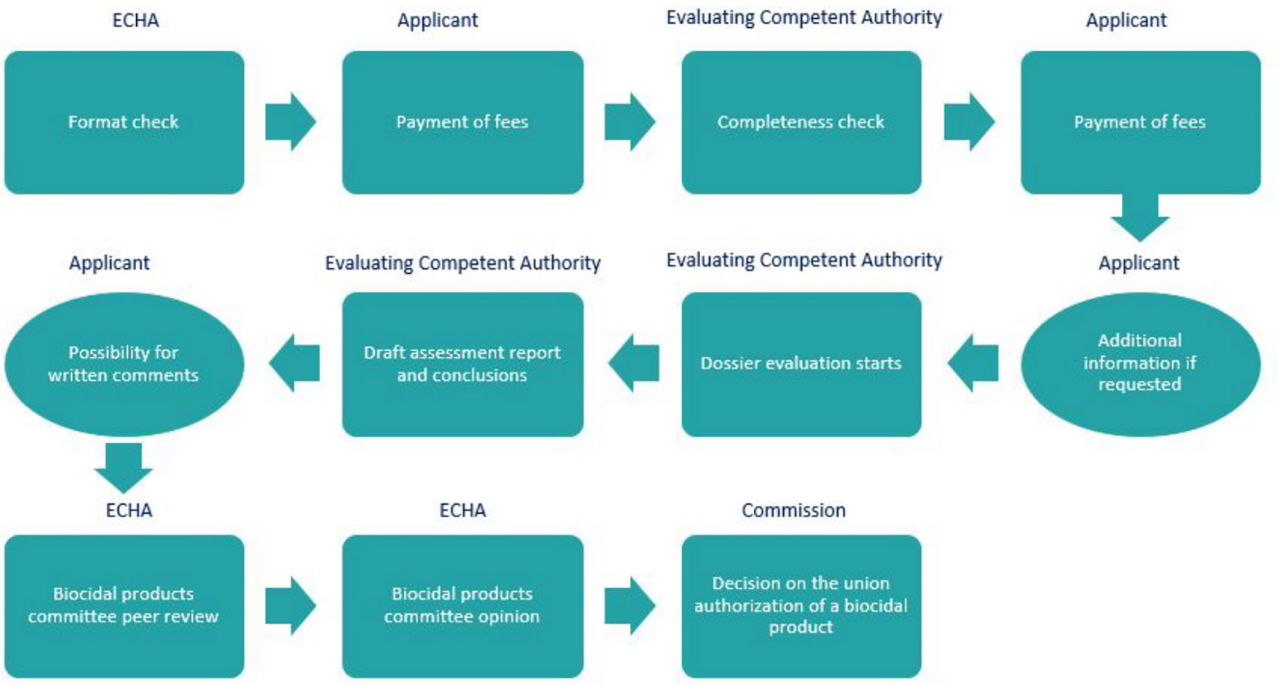
29 https://www.cqc.org.uk/search/services/all?f%5B0%5D=latest_inspections%3Amonth

30 https://echa.europa.eu/regulations/biocidal-products-regulation/authorisation-of-biocidal-products

31 In Georgia, similar function is performed by NCDC.

32 https://echa.europa.eu/regulations/biocidal-products-regulation/authorisation-of-biocidal-products/union-authorisation/dossier-submission
https://echa.europa.eu/regulations/biocidal-products-regulation/authorisation-of-biocidal-products/union-authorisation/evaluation-process

Figure №2.3.1: Biocidal product authorization process



COLLECTION AND USE OF INFORMATION ABOUT NOSOCOMIAL INFECTIONS – US AND UK EXAMPLES

US CDC's National Healthcare Safety Network[33] is the nation's most widely used healthcare-associated infection tracking system currently enrolling 17 000 medical facilities. Based on the information supplied by these healthcaer facilities, CDC provides the standard national measures for HAIs as well as analytic tools that enable each facility to assess its progress and identify where additional efforts are needed. In addition, this surveillance network is the source of information for government medical assistance programs[34] operating in the USA, how compliant is a medical facility with the requirements of mandatory reporting of infections. Data is publicly accessible for the patients and they can see the status of infections at healthcare facilities. Data reported in the network are analyzed by CDC and other stakeholders to assess the problems existing on local and national level and identify the areas requiring intervention. As well as to assess the progress in the reduction of HAIs based on national and local goals.[35]

US CDC collects on annual basis information about five key infections associated with healthcare and publishes the report about the progress of reduction of infections. According to the study, joint efforts of all parties to the healthcare makes it possible to reduce for example central line-associated blood stream infection by 70%.

33 In Georgia, similar function is performed by NCDC.

34 Medicare and medicaid – similar to state universal health coverage program in Georgia.

35 https://www.cdc.gov/nhsn/about-nhsn/index.html

Since 2004, inpatient care facilities in England[36] have been required to provide information about nosocomial infection; and since 2005, this information should also cover the patient data. These data are reported on daily basis in the electronic HAI surveillance program. Since 2013, once of the target nosocomial infections has been accompanied with additional data in the form of further overview of infection. This allows, in all confirmed infections, to analyze the causes and plan further measures for its prevention.

This information is public and published on monthly, quarterly and/or annual basis, according to the preliminarily agreed schedule. Patient informativeness is encouraged to raise their awareness about performance of healthcare facilities.

Database of mandatorily reportable nosocomial infections allows the country to survey the progress of control of infection prevalence and make informed decision about the ways of its reduction.

36 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/713604/Mandatory_Healthcare_Associated_Infection_Surveillance_Data_Quality_Statement.pdf

AUDIT FINDINGS

3. GAPS IN THE IPC MANAGEMENT

3.1 ABSENCE OF NATIONAL IPC STRATEGY

Important precondition for effective functioning of IPC in the country is a government level defined national strategy and respective action plan to ensure coordinated work of the institutions within the healthcare system in the area of infection prevention and control. Importance of this issue is also emphasized in the recommendations issued by WHO.

The guidelines on core components of infection prevention and control published by WHO in 2009 for member countries[37] states that national IPC program in the country should be developed by healthcare authority, which should define IPC-related country's policy, objectives, strategy, legal and technical regulation and surveillance.[38] This issue is again emphasized in the 2016 updated recommendations where experts and representatives of different countries bring examples demonstrating that effectively implemented sustainable national program has reduced the quantity of healthcare-associated infections.[39]

Despite the importance of national strategy, the country is lacking unified IPC strategy that would enable to have in place the single surveillance policy in the country on this matter. The elements of IPC are only scarcely contained in 2017-2020 Antimicrobial Resistance and 2016-2020 Hepatitis C Elimination National Strategies which is not sufficient for policymaking.

The aim of National Antimicrobial Resistance Strategy is to support policy implementation in this area at Georgia's healthcare facilities, being one of the important parts of IPC.

The following key objectives are contained in the strategy:

- Enhancement of infection control and prevention;
- Capacity building of microbiology laboratories;
- Raising awareness and education.

Activities to be implemented relevant to the objectives implies setting up of infection control committees at the inpatient care facilities and enhancement of surveillance of their actual functioning, as well as improvement of documents regulating infection prevention and control at medical facilities, improved quality of microbiology laboratory diagnostics, conduction of public awareness raising campaigns on healthcare associated infections and on use of antibiotics, enhancement of knowledge of healthcare personnel on infection control and on rational use of antibiotics. These activities are also provided in the Hepatitis C Elimination Strategy aiming at eradication of hepatitis C in the country, and consequently reducing grave effect of viral hepatitis on the public and economy. The strategy also sets out the measures of safe injection practices, disinfection-sterilization and waste management measures.

37 Georgia is a member of World Health Organization.

38 http://apps.who.int/iris/bitstream/10665/69982/3/WHO_HSE_EPR_2009.1_rus.pdf

39 http://www.who.int/gpsc/core-components.pdf p34.

Besides these issues, national IPC strategy should also include the issue of setting up by the government of **Surveillance System** of healthcare-associated infections, which would ensure **collection of reliable information** about the status of IPC at healthcare facilities and **measures needed for their prevention**, which are not part of the National Antimicrobial Resistance and Hepatitis C Strategies.

Absence of national strategy affects the activities carried out by the institutions subordinated to the Ministry. Namely, lack of single policy hinders coordinated work in the area of IPC improvement and reduction of nosocomial infections to optimal indicator.

National strategy and assessment indicators defined therein will allow the Ministry to assess progress achieved in infection prevention and to plan relevant measures.

3.2 GAPS IN THE INFORMATION ABOUT NOSOCOMIAL INFECTIONS

According to WHO 2016 recommendations, an ongoing IPC system monitoring and surveillance according to specific indicators should be undertaken in the country. In this process, it is especially important that HAI-related reliable and timely information collection mechanisms are in place.[40] IPC measures should respond to the actual needs for which effective surveillance system should be in place.

Low number of HAIs reported in the country is unreal compared to the developed countries and questions its credibility. In the absence of reliable information about nosocomial infections, the government is not able to plan effective preventive measures in reducing the number of nosocomial infections and, respectively, the costs incurred on their treatment.

Permit conditions require the inpatient care facilities to maintain statistical documentation in accordance with the procedure prescribed under the law, as regulated by the Order of the Minister.[41] All occurrences of nosocomial infectious diseases/conditions that are clinically diagnosed and/or laboratory confirmed, are subject to immediate notification and Public Healthcare Centers registers them into the Electronic Integrated Disease Surveillance System (EIDSS) to be administered by NCDC.

On annual basis, NCDC carries out government epidemiological surveillance program with one of the components being the epidemiological surveillance of nosocomial infections. Within the framework of the component, to confirm nosocomial infections, laboratory examination of sampling material provided by the hospitals selected based on the predefined criteria (existence of intensive care unit at the hospital, number of beds in intensive care unit ≥ 5) is conducted. The results of the examination are returned to hospitals who should ensure providing the information on the confirmed nosocomial infections into the EIDSS program.

Within the framework of epidemiological program, during 2015-2017, NCDC provided laboratory service to 11 medical facilities (Tbilisi – 8, Kakheti – 1, and Adjara -2).

In 2016 in Tbilisi, at medical facilities enrolled in the epidemiological surveillance program, NCDC confirmed 42 incidences, and hospitals have entered only 34 incidences of nosocomial infections

40 http://www.who.int/gpsc/core-components.pdf

41 Order №01-2/N of the Minister of Labour, Health and Social Affairs of Georgia dated 18 January 2016 "On the Rule of Maintaining and Providing Medical Statistical Information".

into the EIDSS program. The reason of these shortcomings is the fact that at the time of the audit period relevant mechanisms were not in place at NCDC, which would enable monitoring of complete and accurate entry of the data into the program by inpatient care facilities.

According to the data from 2015-2017, in total 518 nosocomial infection cases have been confirmed in the country out of 299 inpatient care facilities operating at that time point. 51% of detected nosocomial infections account for 11 inpatient facilities enrolled in the epidemiological surveillance program as confirmed by the government resources and involvement. The remaining 49% of nosocomial infections are reported by 288 inpatient facilities not enrolled in this program and shows the risk that inpatient facilities have incompletely presented the data.

Figure №3.2.1: Number of confirmed nosocomial infections by years

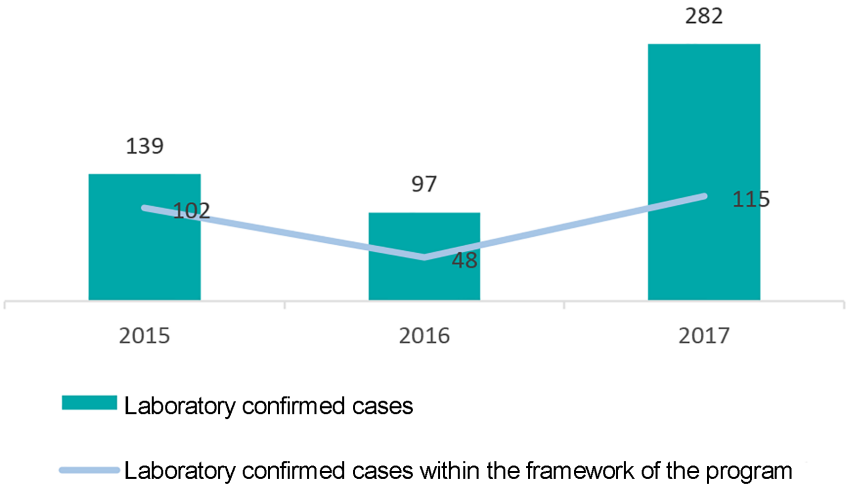
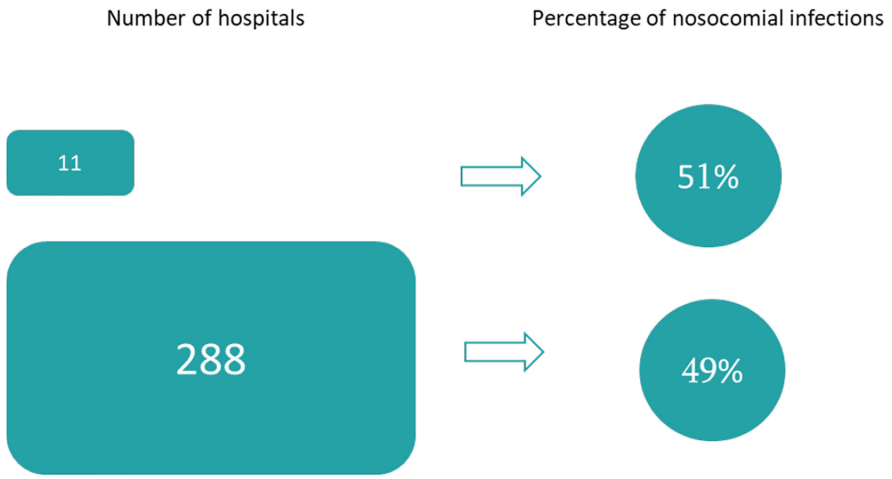


Figure №3.2.1: Percentage of nosocomial infections confirmed within the framework of government program and beyond



It should be noted that number of nosocomial infections reported by medical facilities in 2018 has increased in comparison to the similar period of 2017. Most probably, it was caused by infection control monitoring performed by the Ministry. Despite the positive dynamics, number of reported nosocomial infections is unrealistically low.

Table №3.2.1: Increase in the number of nosocomial infections reported during 2017-2018 by months

Year/month	January	February	March	April-May	Total
2018	49	74	42	33	198
2017	17	24	37	18	96

Irrelevance of information on number of nosocomial infections reported in Georgia is also demonstrated by the fact that according to EIDSS data, **133 confirmed incidences** of nosocomial pneumonia was reported during 2016-2017 in Georgia. However, according to the State Universal Health Coverage Program single database, it was estimated that **513**[42] occurrences of nosocomial pneumonia should have been reported in the same period.

Inconsistent information indicates about the risks of insufficient sharing of information by the organizations falling within the Ministerial system. LEPL Social Service Agency and NCDC hold the information, which is not coordinated and shared. More credible and complete data about nosocomial infections would have been possible for NCDC to be collected based on the analysis of this information

According to 2016 data of European Center for Disease Prevention and Control, surgical site infection (SSI) is the most common nosocomial infection associated with postoperative delayed stay, in addition to surgical interventions, intensive care unit treatment and high mortality. According to the data, of 630,551 various surgical interventions conducted in 16 European countries, the following percentage of nosocomial infections have been reported per 100 operations: [43]

Table №3.2.2: Estimated reportable number of SSIs in Georgia in 2016 in consideration of the data of ECDC[44]

	European countries[45]			**Georgia**	
Surgical intervention	Number of surgical interventions	Average percentage of nosocomial infections per 100 operations	Number of surgical interventions	Number of surgical interventions	Estimated number of SSI according to 2016 ECDC
Coronary bypass surgery[46]	27,597	2.8	773	-	-
Cholecystectomy[47]	55,190	1.7	938	6,038	103
Colon surgery	37,017	9	3,332	340	31
Caesarean section	99,886	1.9	1,898	12,538	238
Femoral replacement	225,746	1	2,257	2,772	28
Knee replacement	163,172	0.5	816	511	3
Laminectomy[48]	21,943	0.9	197	-	-
Total:	**630,551**	**2.5**	**10,211**	**22,199**	**402**

42 see subsection 3.3

43 https://ecdc.europa.eu/sites/portal/files/documents/AER_for_2016-SSI.pdf

44 On Georgia's example, the numbers are calculated by ECDC coefficient, and is accepted.

45 Belgium, Czech Republic, Estonia, France, Germany, Hungary, Italy, Lithuania, Luxemburg, Malta, Poland, Portugal, Slovakia, Spain, Scotland.

46 Surgical operation, which creates a permanent or temporary blood flow in replacement of damaged blood vessel for the artery feeding the heart.

47 Cholecystechtomy – removal of gallbladder.

48 Laminectomy – surgical operation: opening of spinal canal by removing vertebral arch plates.

According to the data of the State Universal Health Coverage Program, 22,199 similar types of surgical interventions were conducted in Georgia in 2016. According to the data from NCDC, in total **37 occurrences** of SSI were reported in 2016, significantly differing from the data calculated based on the ECDC coefficient given in the above table. According to this, estimated incidences of SSI to be reported in 2016 in Georgia should have been **402**.

Although the inpatient facilities are required to notify Public Healthcare Center about identified nosocomial infections in order to completely update the EIDSS program, the existing situation speaks contrary.

With reliable information, it is possible to identify the risks in the IPC management, to define benchmarks of nosocomial infections, and take relevant measures for their reduction.

3.3 IMPACT OF NOSOCOMIAL INFECTIONS ON HEALTHCARE COSTS

According to the data from Organization for Economic Cooperation and Development, annually on average 4 000 000 people are infected with HAIs in Europe. [49] Moreover, approximately **10%** of total healthcare costs are intended for correction of medical errors and for treatment of HAIs.

It is noteworthy that **20%** of these infections could have been avoided in the event of proper management of IPC.[50]

According to the ECDC annual report, in 2016 number of patients staying at ICU longer than two days made up 151,709. Of them, 8,4% presented with at least one nosocomial infection, and nosocomial pneumonia share was 75%, and urinary tract nosocomial infection – 11%.[51]

Since 2013, State Universal Health Coverage Program has been operating in the country, within the framework of which the government is financing the costs of various healthcare services.

Based on 2018 report published by ECDC, estimated number of nosocomial infections reported in the country has been assessed.

Below is discussed estimated financial effect of two nosologies of nosocomial infection, nosocomial pneumonia and urinary tract infection, on the costs incurred as part of the State Universal Health Coverage Program, according to the occurrences admitted to ICU as reported in the electronic database of this program.

According to the annual data[52] from single electronic database of the State Universal Health Coverage Program, occurrences of staying longer than two days at the ICU was reported as 8,252. By applying the rate reported in Europe 8.4% to the number of occurrences reported in Georgia,

49 https://www.oecd-ilibrary.org/docserver/9789264265592 en.pdf?expires=1539240848&id=id&accname=guest&checksum=C54335D-BEC2CF5D1022E709C9925D2DC p. 76

50 https://www.oecd.org/els/health-systems/Tackling-Wasteful-Spending-on-Health-Highlights-revised.pdf

51 Annual Epidemiological Report for 2016, Healthcare associated infections acquired in intensive care units, ECDC, May 2018

52 From May 2017 through May 2018.

nosocomial infection would have been reported presumably in at least 693 cases, of which nosocomial pneumonia should be 513, and urinary tract infection – 76.

During this period, on average GEL 710 is paid as part of the State Universal Health Coverage Program for treatment of each pneumonia occurrence. We can presume that the costs of treatment of nosocomial pneumonia incurred by the government is **GEL 364,190**. On average GEL 677 is paid for treatment of urinary tract nosocomial infection. Consequently, the costs of treatment of this infection is about **GEL 51,620**. Considering that data from the above study of OECD, potential for saving of government resources at the expense of avoidable infections is 20%, which is estimated **GEL 83,162** in the event of two nosocomial infections.

Table N 3.3.1: Estimated financial effect of nosocomial infection on annual costs incurred by the government

Name of nosocomial infection	Number of incidences	cost	Saving potential
Pneumonia	513	364,190	72,838
Urinary tract infection	76	51,620	10,324
Total	**589**	**415,810**	**83,162**

It should be mentioned that treatment of nosocomial infections also increases the out-of-pocket expense. On average, amount paid by patients makes 24% of total costs. Consequently, the expenses increased due to complicated events are directly proportional to the amounts paid by patients.

Presumably, number of nosocomial infections reported in the country must be higher than the cases discussed above which is proved by the prevalence survey results conducted by NCDC. In 2018 cross-sectional prevalence study[53] was conducted in Georgia covering the analysis of data on patients admitted to ICU of 10 inpatient facilities, in terms of nosocomial infections. According to this study, 28.6% of patients were presented with nosocomial infection, of which 64.7% was nosocomial pneumonia, and urinary tract infection – 5.9%, the remaining number is distributed among three different nosocomial infections.

The existing system does not allow for identification of costs incurred for treatment of nosocomial infections. As a result, the Ministry is not able to detect risky areas and plan relevant measures in the area of reduction of avoidable infections. This will on the one hand facilitate safe treatment of patients and on the other hand reduce the costs of healthcare service.

CONCLUSION

Despite the importance of IPC, the country is lacking single national strategy in this matter, which would enable the government to plan consistent and effective measures for the improvement of the system.

Although the Ministry and NCDC have developed the mechanisms for improvement of information about HAIs in the country, they are not enough for ensuring its reliability. Consequently, the

53 Results of the study are not applied to total population due to specificity and limited scope of the study.

Ministry is not able to have complete information on actual status of this matter at the inpatient care facilities, which would help to create the conditions for identification of costs incurred on nosocomial infections and for their effective management.

RECOMMENDATION TO THE MINISTRY:

Recommendation №1: For effective functioning of IPC at healthcare facilities, it is important to develop single nation-wide strategy to have unified policy in place in the healthcare system and coordinated work of its subordinated units.

RECOMMENDATION TO THE MINISTRY AND NCDC:

Recommendation №2: Expansion of the existing mechanisms – by supporting the implementation process, introducing new instruments and improving coordination between IPC management units, credibility of information on nosocomial infections existing in the country should be ensured. This will facilitate implementation of effective measures by the government in infection prevention and control.

RECOMMENDATION TO THE MINISTRY:

Recommendation №3: With reliable information, the Ministry should ensure to identify the costs incurred for treatment of nosocomial infections to enable effective management of these expenses.

4. GAPS IN THE REGULATORY NORMS

4.1 SHORTCOMINGS OF PERMIT CONDITIONS OF HEALTHCARE FACILITIES

PERMIT CONDITIONS OF DENTAL CARE FACILITIES

According to the Law of Georgia "On Licenses and Permits"[54], inpatient care facilities need to obtain a mandatory permit in order to start practicing activity. Under the permit conditions, medical institutions are required to have IPC system in place, which is inspected by the Regulatory Agency at the stage of starting the operation, and later, adherence to permit conditions is controlled on periodic basis.

Since 2014, dental care has been classified as a high-risk medical activity and, consequently, it has a mandatory obligation to notify[55] the Agency about starting the operation. Since dental care facilities are high-risk group of infection dissemination, the technical regulation obliges the facilities to have in place an infrastructural environment[56] needed for IPC and have human resources with relevant qualification. In 2018, technical regulation laid down the requirement to perform healthcare-associated infection prevention and control.[57] However, unlike inpatient care facilities, regulations applicable in Georgia do not provide for the inspection of mandatory requirements at the initial stage of starting the operation of dental care facility. Regulatory Agency inspects the IPC based on selective control once a year during the course of its operation.

Moreover, the Minister's Order lays down the criteria[58] of selective control, based on which the Regulatory Agency selects the medical facilities to be inspected. The list of these criteria does not provide for the selection of newly operating dental care facilities.

Figure №4.1.1: Control of Inpatient and Dental Care Medical Facilities

	Hospital	Dental Care
Control before starting the operation	✓	✗
Control during the course of the operation	✓	✓

54 Law of Georgia "On Licenses and Permits", Article 38.

55 Ordinance №359 of the Government of Georgia dated 22 November 2010 "On Approval of the Technical Regulation of High-Risk Medical Activity".

56 Water supply, washroom, hygiene and disinfectants.

57 Ordinance №359 of the Government of Georgia dated 22 November 2010 "On Approval of the Technical Regulation of High-Risk Medical Activity", Article 13, requirement №9.

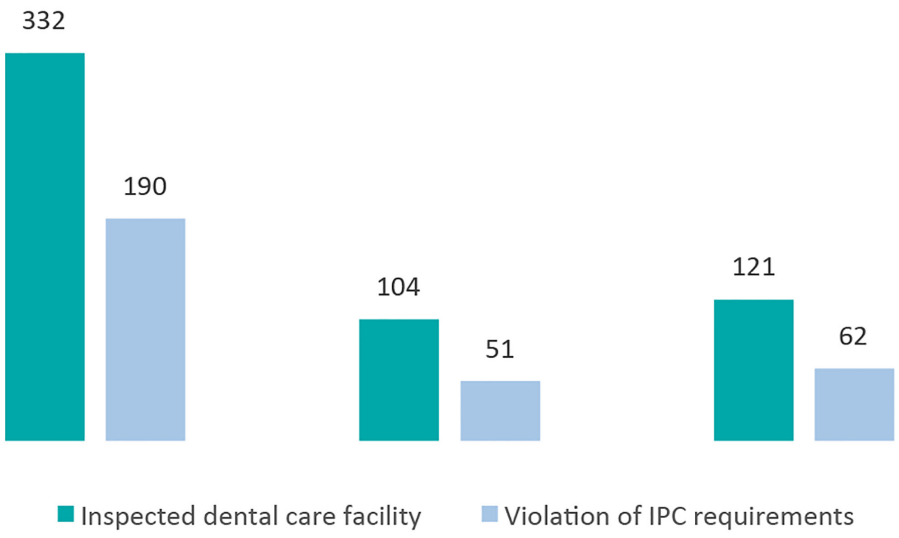
58 Order N01-51/N of the Minister of Labour, Health and Social Affairs of Georgia, Article 2.

The practice in European countries on this matter is diverse. For example, in England, for the purposes of healthcare service quality improvement and ongoing monitoring, the same organization registers and inspects the inpatient care and dental care facilities[59]. At the registration stage it is inspected how the facility complies with the mandatory requirements laid down for the respective service and then, based on the information from different sources, including from patient, ongoing follow up and periodic inspection is conducted on the facilities.

Failure to inspect the requirements of technical regulation before starting the operation or at the initial stage of starting of operation increases the risk that dental facilities will operate without observing the requirements until the Regulatory Agency performs their selective control. This could affect both patients' health condition as well as effective management of IPC.

Technical regulation sets IPC requirements to dental care facilities. As of May 2018, 1,526 dental facilities were operating in the country. After the inspection performed by the Agency during 2015-2017, it has been identified that 54% of the inspected dental facilities fail to meet the IPC requirements.

Figure №4.1.1: Inspected dental care facilities by years



The highest rate of violation of certain requirement of technical regulation in the area of IPC was found in the process of maintaining the proper regime and accountability of disinfection and sterilization (multiple-use medical tools, items and material): in 2015, this requirement was violated in 55% of dental care facilities inspected, in 2016 – in 48%, and in 2017 – in 51%.

Inspection of the requirements of technical regulation at the initial stage of operation will allow for detection of shortcomings at the initial stage and reduction of the violation rate through respective response, thus facilitating both patient safety and effective management of IPC.

59 https://www.cqc.org.uk/

PERMIT CONDITIONS OF INPATIENT FACILITIES

For the functioning of IPC at healthcare facilities, it is important to have properly operational infrastructure in place, one of the components of which is a microbiology laboratory,60 being the precondition for infection identification and proper treatment. 2016 WHO recommendations numberlessly points out that good quality microbiology laboratory service is critical for the detection and treatment of healthcare-associated infections.[61] In addition, National Antimicrobial Resistance Strategy highlights that healthcare facilites existing in the country are not using the advanced methods of microbiological examination. For this reason, improvement of the quality of laboratories is one of the component of the Strategy. [62] According to "2009 National Clinical Practice Recommendation – Infection Control at Healthcare Facilities", effective implementation of infection control significantly depends on the involvement of microbiology laboratory in all components of IPC program at medical facility and it is desirable that all inpatient care facilities have microbiology laboratory in place.[63] Pursuant to the Minister's Order of 2015[64], infection control through microbiology laboratories is feasible by having a laboratory within the structure of hospital or as a part of contract with other relevant laboratory.[65]

Under the permit conditions, medical facilities are required for accountability, management, supervision and control of nosocomial infections in accordance with the requirements laid down under the legislation.[66] Nosocomial infections can be confirmed by microbiology laboratory tests.[67] Moreover, for prescription of correct treatment and further prophylaxis, it is important to perform microbiology examinations. At the same time, under the permit conditions, inpatient care facilities are not required to have access to microbiology laboratories. Consequently, the legislation, on the one hand, obliges the facility to keep record of nosocomial infections and on the other hand does not require them to have access to the instrument needed for their confirmation. Thus, there is no mechanism in place at the starting stage of the operation, which would enable the hospitals to detect, confirm and account nosocomial infections.

60 Microbiology is the study of features of microorganisms causing main human infectious diseases, of the issues of microbiological diagnostics and treatment.

61 http://www.who.int/gpsc/core-components.pdf

62 2017-2020 National Antimicrobial Resistance Strategy, objective V.

63 National clinical practice guideline – infection control at medical institutions, p. 5.

64 Order №01-38/N of the Minister of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Affairs of Georgia dated 07 September 2015 "On Approval of the Rules of Epidemiological Surveillance, Prevention and Control of Nosocomial Infections".

65 Order №01-38/N of the Minister of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Affairs of Georgia dated 07 September 2015 "On Approval of the Rules of Epidemiological Surveillance, Prevention and Control of Nosocomial Infections". Article 7.

66 Ordinance №385 of the Government of Georgia dated 17 December 2010 "On Approval of the Provisions on the Procedure and Terms and Conditions of the Issuance of Medical Activity License and Inpatient Facility Permit".

67 Order №01-38/N of the Minister of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Affairs of Georgia dated 07 September 2015 "On Approval of the Rules of Epidemiological Surveillance, Prevention and Control of Nosocomial Infections", Article 7.

4.2 GAPS IN THE REGISTRATION PROCESS OF DISINFECTANTS

According to the WHO recommendations published in 2016, one of the key components of IPC is clean and hygienic environment at the medical institutions. Clean environment plays important role in prevention of nosocomial infections and reduction of dissemination.[68] Medical institutions should be practicing the sterilization and disinfection of medical items and premises, because insufficient handling of medical instruments and equipment often causes emergence of nosocomial infection.[69] This can be achieved through properly implemented disinfection/sterilization procedures, for which the healthcare facilities, pursuant to the Ordinance[70], should use the means registered by NCDC. According to the Regulation of the European Parliament, disinfectants and pesticides[71] represent different groups of biocidal[72] products and its negative effect on human health and environment is equally harmful. Circulation of pesticides in the country is regulated under the Law of Georgia and Ordinanc[e73] of the Government, which describe in detail the registration, importation/exportation procedures and timeframes. Also the registration body for pesticides is also defined by the Law. Before registering a new pesticide (active substance) in Georgia it should be subject to registration tests: possible assessment of their effectiveness, negative impact on human health and ecological evaluation of its use. Only the pesticides with positive assessment can be registered. The period for registration of active substance of pesticide is 10 years, and of its derived product – five years. After the expiry of this period, reregistration is possible. Although disinfectants, as well as pesticides are biocidal products, there are no similar regulations for disinfectants. The placing on the market of disinfectants is regulated under the Minister's Order[74], Ordinance of the Government[75], and the Order of the Director General of NCDC.[76]

The purpose of the Regulation of the European Parliament is to improve the free movement of biocidal products within the Union while ensuring a high level of protection of both human and animal health and the environment. To this end, safety of active substance contained in the biocidal product is tested and after undergoing the authorization process, its derived product is made available on the market.

Below is the comparison of the list of mandatory documentation required for registration of the agents pursuant to the EU regulation and regulations applicable in Georgia:

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68 http://www.who.int/gpsc/core-components.pdf

69 Order №01-38/N of the Minister of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Affairs of Georgia dated 07 September 2015 "On Approval of the Rules of Epidemiological Surveillance, Prevention and Control of Nosocomial Infections"., Article 10.

70 Ordinance №185 of the Government of Georgia dated 24 April 2015 "On Approval of Technical Regulation of Disinfection and Sterilization at Medical Facilities, Public Health Facilities and Institutions of Public Importance".

71 Pesticides – chemical or biological preparations used against diseases of plants and their carriers, against vermins and weeds, diseases of stored agricultural products, and pests, rodents, animal parasites, as well as for regulating the plant growth, for removing the leaves from plants (defoliants) and drying the plants (desiccants) before harvesting, for decontamination of storages, warehouses, vehicles, green houses, soil, plant and other products subjected to phytosanitary control.

72 Biocide – substance that kills all animals.

73 Law of Georgia "On Pesticides and Agrochemicals"; Ordinance №443 of the Government of Georgia dated 31 December 2013.

74 Ordinance №64/N of the Minister of Labour, Health and Social Affairs of Georgia dated 19 March 2002.

75 Ordinance №468 of the Government of Georgia dated 14 September 2015.

76 Order №06-6/O of the Direction of LEPL L. Sakvarelidze National Center for Disease Control and Public Health.

Table №4.2.1: List of mandatory documents in Europe and Georgia

EU regulation	Georgia
Application	Application
Identification of biocidal product	
Physical, chemical and technical specifications	
Physical threats and respective characteristics	
Methods for detecting and identifying the constituent substances	Data on identification of substances that are contained in disinfectant.
Effectiveness of action on target organisms	Opinion issued by NCDC about the disinfecting effect of the agent.
Instructions for use	Information on the scope, rules and conditions of disinfectant.
Toxic impact on humans and animals	In the case of **Imported*** product – document confirming the origin, quality and safety issued by the authorized official organ of manufacturing country.
Ecotoxicity tests	
Impact on environment	
Measures for human, animal and environment protection	Data on the rules of providing first-aid, prophylactic measures and technical safety in case of harmful impact of disinfectant.
Classification, marking and packaging	Data on marking, labelling, packaging, shelf life and storage conditions of disinfectants.

It is important to note that quality and safety-proving document issued by authorized official organ of the manufacturing country is required only in the case of imported products.

In addition, according to the EU regulation, biocidal product is registered for the term of 10 years, and according to the regulations applicable in Georgia – disinfectants are registered for indefinite term.

Out of disinfectants registered in the country, the audit team selectively studied the documentation submitted for the registration of 59 aproducts.

By each of the document, the Table gives the number and percentage of disinfectants on which the registration seeker incompletely provided the required documentation.

Table №4.2.2: Incompletely submitted registration documentation

Document name	Number of disinfectants	Percentage
Information on the scope, rules and conditions of disinfectant.	✓	-
Data on marking, labelling, packaging, shelf life and storage conditions of disinfectants.	✓	-
Data on the rules of providing first-aid, prophylactic measures and technical safety in case of harmful impact of disinfectant	✓	-
Data on identification of substances that are contained in disinfectant.	13	22%
Document evidencing the origin	46	78%
Document evidencing the quality	14	24%
Document evidencing the safety	8	14%
Bactericidal effect	✓	-

As explained by the auditee, the reason for such result is that in most cases applicant is required to submit only two mandatory documents: instructions for use of disinfectant, and document evidencing the safety. However, this requirement is not documented. Besides, in some cases there are registered products that are not present even in registration documentation, the above-mentioned so-called mandatory documentation. In addition, different documentation is provided for the registration of disinfectants manufactured in different countries.

Moreover, the European regulation provides detailed explanation of the content of each required document, unlike the requirements existing in Georgia, and this creates a possibility for inconsistent approach.

CONCLUSION

Improvement of regulatory norms is a precondition for effective government surveillance on IPC.

The elements of IPC are not inspected at the initial stage of the operation of dental care practice, which increases the risk that these facilities will practice without observing the requirements. Consequently, patient safety related risks are increasing.

Access to microbiology laboratory is not prescribed as a mandatory requirement for the operation of hospitals. This can reduce the possibility of detection and reporting of nosocomial infections.

One of the important components of IPC is the availability of clean and hygienic environment at the healthcare facilities for which disinfectants registered by NCDC are used. The existing registration procedures and requirements are not specific and this increases the risk that disinfectants not meeting the prescribed standards will be registered.

RECOMMENDATION TO THE MINISTRY:

Recommendation №4: In order to timely identify and manage the nosocomial infections, availability of microbiology laboratory should be confirmed before starting the operation of inpatient care facility.

RECOMMENDATION TO THE MINISTRY AND REGULATORY AGENCY:

Recommendation №5: Due to high risk of healthcare-associated infections prevalence that contains the increased threat for human life and health, the dental care should be considered as practice subject to government regulation under permit and, based on relevant expert opinions, its legislative initiation should be made.

RECOMMENDATION TO NCDC:

Recommendation №6: To facilitate safe environment at healthcare facilities, registration of disinfectants should differentiate between the mandatory and preferable list of documentation, and the contents of each document should be detailed.

5. GAPS IN IPC CONTROL OF INPATIENT CARE FACILITIES

5.1 GAPS IN CONTROL OF PERMIT CONDITIONS BEFORE STARTING THE OPERATION

WHO 2016 recommendations highlight the importance of IPC program in place on an inpatient care facility level, dealing with healthcare associated infection prevention and control. The program should cover clearly defined objectives based on epidemiological status and assessed risks of specific inpatient facility.[77]

Since 2012, under the permit conditions, inpatient care facilities are required to have internal assessment system in place, which would ensure healthcare quality improvement and patient safety. One of its functions is to manage the process of nosocomial infection control and accountability.[78] The system should operate in accordance with the instructions approved by the head of the hospital. It should cover the time-planned measures for implementing within the inpatient facility the requirements laid down under the legislation regulating the sector as well as under the institution's internal regulation (including rules, norms, standards and indicators), for monitoring and control of further processes, as well as for assuring the quality. The instructions should also provide for the plan for managing the expected risks during service provision and responding to the detected violations, depending on the institution's capacity and service specificity.

During 2015-2017, permit has been issued to 42 new inpatient care facilities of which **29 facilities have not submitted quality instructions** and instructions of 6 inpatient facilities are template-based.[79]

Since 10 October 2015, one of the requirements of common permit conditions is to ensure accountability, management, supervision and control of nosocomial infections – in accordance with the requirements laid down under the legislation. To this end, all inpatient care facilities should have nosocomial infections control committee to develop nosocomial infections control action plan – the infection control program. [80]

According to National Infection Control Guideline, each medical institution is unique in its way: by profile, healthcare personnel and patients, and infection control program must be adapted on case-by-case basis depending on the features and requirements of the institution.[81]

Since November[82] 2015 through May 2018, 35 new inpatient facilities started operation in the country. Of them 21 institutions have not submitted the program and the program presented by 14 of them are template-based and not adapted to the concrete institution.

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77 http://www.who.int/gpsc/core-components.pdf

78 Order №01-63/N of the Minister dated 12 September 2012 "On Operation of Internal System of Healthcare Quality Improvement and Patient Safety Evaluation at Inpatient Medical Institution".

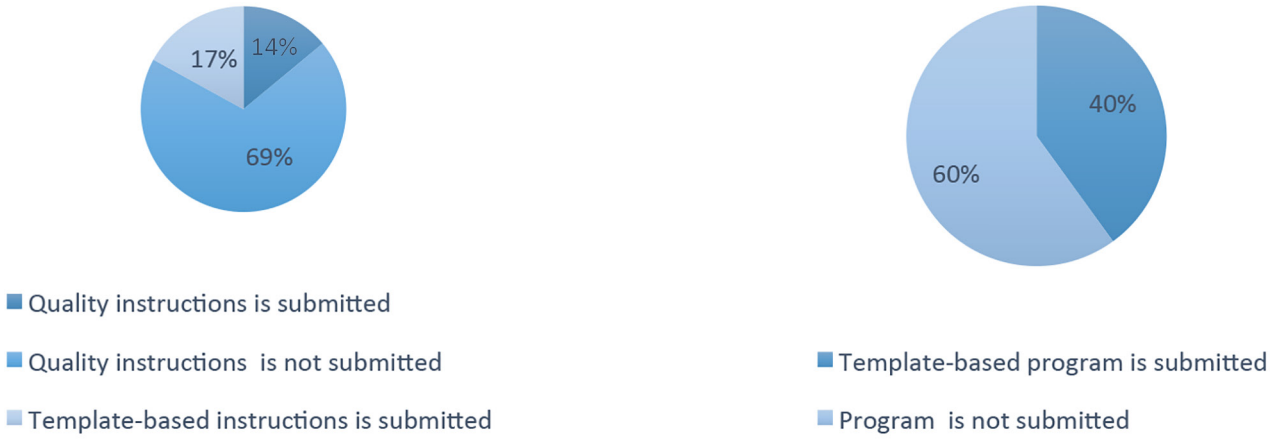
79 Requirements defined by medical facilities under the Minister's Order are transposed without adaptation.

80 Order №01-38/N of the Minister of Labour, Health and Social Affairs of Georgia dated 07 September 2015 "On the Rules of Epidemiological Surveillance, Prevention and Control of Nosocomial Infections".

81 National clinical practice guideline – infection control at medical facilities.

82 Under the Minister's 2015 Order №01-38/N, medical facilities have been assigned to have the committee and IPC program in place.

Figure №5.1.1: Documentation submitted by new inpatient care facilities for obtaining a permit



It is important to note that since October 2015, approximately **43%** of inpatient facilities started their operation without IPC program and quality instructions.

Consequently, at the stage of issuing the permit, the Regulatory Agency is not examining the program and quality instructions and limits itself only to inspecting the availability of the committee and quality team of hospital.

Without the IPC program adapted to the particular healthcare facility and the quality instructions, the Regulatory Agency is losing the assurance that service provider will handle identification and management of risks in timely detection and prevention of infections and, consequently, provision of safe environment for patients, which is a condition to consider when issuing the permit to practice the activity.

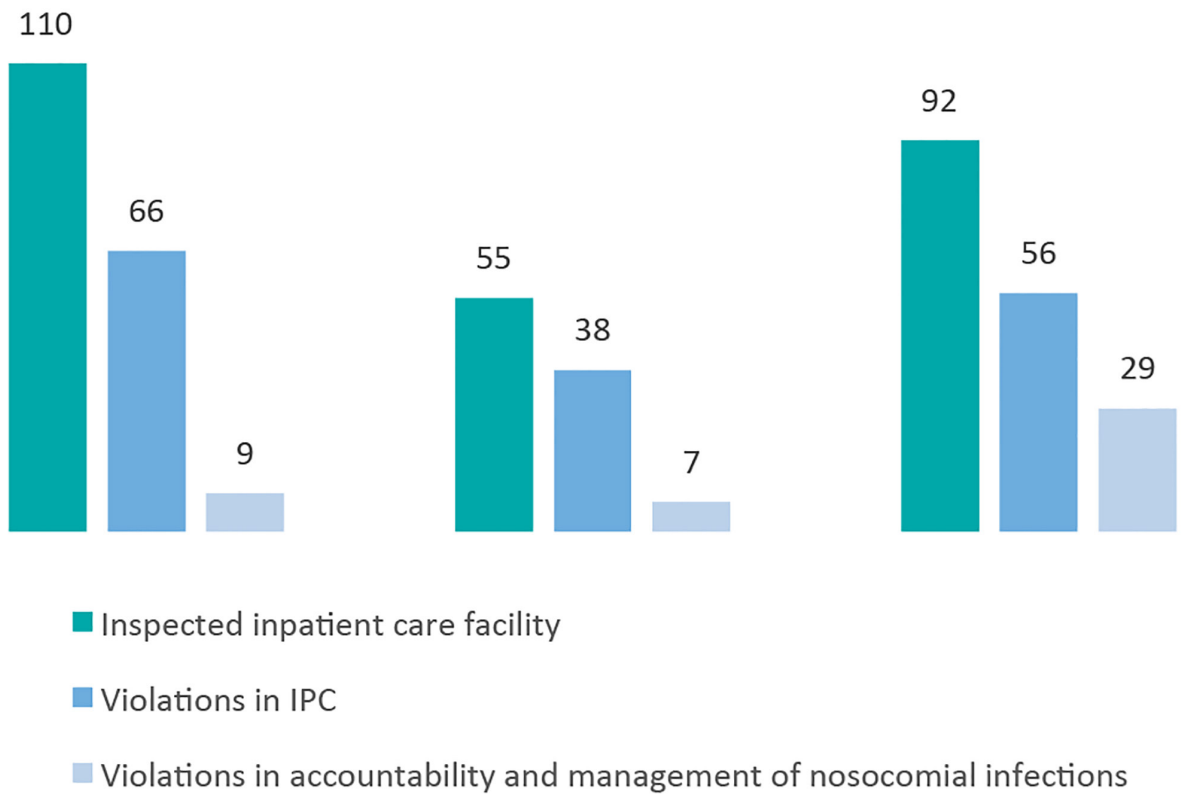
5.2 GAPS IN CONTROLLING THE OBSERVANCE OF PERMIT CONDITIONS

For effective surveillance of IPC, it is necessary for the controlling institution to have relevant quantity and qualification resources as well as the methodology for carrying out controls.

Regulatory Agency carries out control of inpatient care facilities without the detailed instructions, which would prescribe how to inspect each requirement of the permit conditions.

Permit conditions cover the requirements that hospital should meet to confirm the availability of IPC system. The results of control implemented during 2015-2017 showed that on average 55% of inspected inpatient facilities fail to meet IPC requirements.

Figure №5.2.1: Inspected inpatient medical facilities by years[83]



The highest percentages of violations by years was identified in the following areas of IPC:

Table №5.2.1: Percentages, by years, of violation of permit conditions in the area of IPC at the inspected inpatient care facilities

Permit conditions	2015	2016	2017	Three-year average rate
Infrastructure and resources to protect personal hygiene of staff and patients, cleaning and disinfection of the premises	23%	20%	23%	22%
Ensure proper regime and record disinfection and sterilization (multiple-use medical tools, items and material) in accordance with the procedure prescribed under the legislation	24%	35%	34%	31%
Ensure safe segregation, collection, storage, removal, utilization and/or destroy of medical waste in accordance with the procedure prescribed under the legislation	30%	29%	36%	32%

During 2016-2017, under the Minister's Order, functioning of the infection control system at 66 inpatient healthcare facilities enrolled in the State Universal Health Coverage Program was monitored. Representatives of both the Ministry and NCDC and Regulatory Agency were involved in

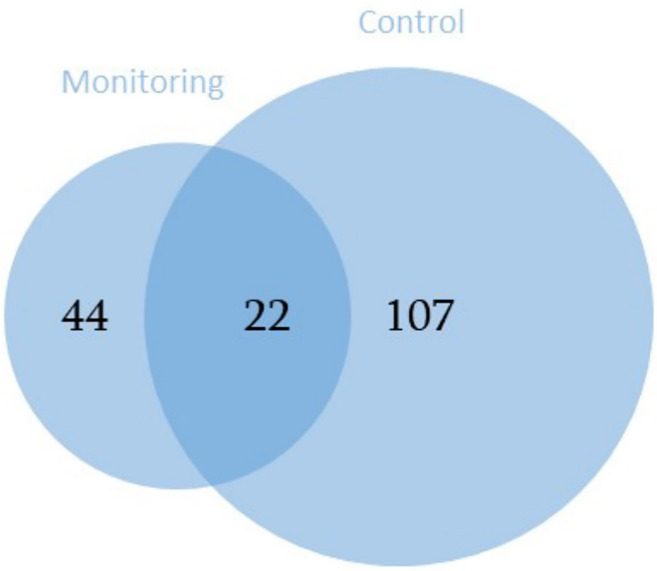
83 Note: Number of violations in IPC covers the number of violations in accountability and management of nosocomial infections.

the monitoring process. Monitoring covered three stages: first two stages covered assessment of IPC system at hospital and giving of recommendations. On the third stage, in 2018, Regulatory Agency was involved and it inspected the factual circumstances of functioning of IPC system and assessed the fulfilment of recommendations given. As part of the monitoring, IPC system is assessed based on the same regulatory norms that are used by the Regulatory Agency during control of observance of permit conditions.

Regulatory Agency controls of minimum requirements for ensuring patient safety based on which act of control is issued, while the office of the Ministry monitors the IPC system, covering the following: assessment of IPC, on-site detection of shortcomings, giving of recommendations and setting time frames for correction.

During 2016-2017, control of observance of permit conditions as well as monitoring of IPC has been carried out in 22 inpatient care facilities.

Figure №5.2.1: Number of inpatient facilities where control and monitoring were carried out during 2016-2017



The results show that violations detected during monitoring at 5 inpatient facilities, fulfilment of which by them was required under the permit conditions, was not reported in the violations detectied by the control process.

For instance, the first stage of monitoring conducted during February-May 2017 at one of the inpatient facilities, found violation of various requirements of IPC, including non-availability of disease-specific antibiotics use program. This violation is not reported in the results of control carried out in the same inpatient facility, which means that IPC system is not properly assessed at the control stage.

One of the reasons of these factual circumstances is that the Regulatory Agency is lacking the methodology for controlling the fulfilment of permit conditions as part of which the detailed rule for inspection of requirements prescribed under the legislation would have been laid down. While, unlike it, methodology for monitoring of infection control system is detailed for the monitoring team which allows for better detection of violation of IPC requirements.

CONCLUSION

At the stage of issuing of permit to inpatient care facilities, the Regulatory Agency fails to properly assess the IPC requirements. Namely, at the stage of issuing of permit the Regulatory Agency is not studying whether inpatient care facility has IPC program and whether this program is adapted to specific inpatient facility.

As a result, improperly implemented controls by the Regulatory Agency and absence of methodology increases the risk that IPC shortcomings existing at inpatient facilities will not be fully identified.

TO THE REGULATORY AGENCY:

Recommendation №7: For the purpose of having detailed and unified approach to the control, it's important to elaborate detailed guidline in order to improve process of inspection of permit conditions at hospitals.

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