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TECHNICAL REPORT

Fostering collaboration in public health microbiology in the European Union

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Fostering collaboration in public health microbiology in the European Union

A needs analysis

This report was produced by the ECDC Microbiology Coordination team* with contributions from Member State appointed National Microbiology Focal Points ** and consultant Antoine Pierson.

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Abbreviations

ECDC	European Centre for Disease Prevention and Control
EU	European Union
IHR	International Health Regulations
ISO	International Standardization Organization
NMFP	National Microbiology Focal Point
NR	No Response
NRL	National Reference Laboratory
PH	Public health
PHM	Public health microbiology
PT	Proficiency testing
QA	Quality Assurance
QAM	Quality Assurance Manual
QMS	Quality Management System
SOP	Standard Operating Procedure
WHO	World Health Organization

Executive summary

As part of its overall mission of the European Centre for Disease Prevention and Control (ECDC) to identify, assess, and communicate current and emerging threats to human health from communicable diseases, ECDC shall encourage cooperation between expert and reference laboratories to foster capacity development within the European Community [1].

In 2007, the Member States officially nominated a group of representatives from all EU/EEA and candidate countries to support ECDC in the strategic development and implementation of microbiology collaboration activities and initiatives [3]. This group, the ECDC National Microbiological Focal Points (NMFPs), has met bi-annually since then to explore public health microbiology structures and systems, laboratory quality, biosafety, training, microbiology reference laboratory activities, and ECDC-funded projects. Individual NMFP representatives were selected on the basis of their ability to function as strategic and scientific partners of ECDC. The National Microbiological Focal Points represent their countries and not their institutions. They fulfil their role as ECDC's public health microbiology liaisons, transmitting information about ECDC's activities to their countries while contributing with information about their country's perspectives, and reporting national developments and trends to ECDC and the rest of the group.

The representatives in the current NMFP forum have a widely diverse background in microbiology, covering laboratory management and specific public health microbiology topics as well as broader policy making expertise in the field. This country-specific knowledge of how public health microbiology functions—in terms of the technical and administrative structures and how the various partners and components collaborate—is essential for effective work in the forum. The challenge for the NMFPs is to collect and coordinate input from national experts to deliver representative opinions and information, especially where the NMFP may not possess this specific expertise themselves.

In order to promote collaboration and foster capacity building in public health microbiology, it is important to have an overall understanding of the existing practices and structures in the Member States. This report describes the first steps towards finding a common vocabulary and building a knowledge base of the different national public health microbiology systems and structures. A survey and follow-up consultation approach was used. Aggregated country data is presented. Comments on the overall process are highlighted and areas of further work identified.

This study confirmed that definitions of public health microbiology, along with its organisation in the Member States, are heterogeneous. Nonetheless, common needs and areas of work where ECDC support is useful were identified; e.g., for production of guidance on norms and standards, quality assurance, biosafety, accreditation, and other areas specific for microbiology reference laboratories. In addition, specialised training for capacity building in public health microbiology was widely supported. A directory of microbiology reference laboratories, including contact information, pathogen/disease area, and main services were initiated but need to be further developed and validated by the Member States.

In summary, by providing coordination and scientific support to already existing public health microbiology structures, ECDC seeks to generate added value and thereby support individual Member States in meeting national and international health obligations. This report describes the first crucial steps of this collaborative approach and provides suggestions for areas of future work.

1 Background

The European Centre for Disease Prevention and Control's (ECDC's) mission is to identify, assess, and communicate current and emerging threats to human health from communicable diseases [1]. Most of these activities are based on high quality clinical and public health microbiological activities undertaken in the European Union (EU) Member States (MS).

There is a mandate for ECDC and the MS to cooperate in the field of microbiology to assess and ultimately improve Europe's laboratory capabilities and capacities. This is articulated in Article 5 of the ECDC Founding Regulation:

> '…by encouraging cooperation between expert and reference laboratories, the Centre shall foster the development of sufficient capacity within the Community for the diagnosis, detection, identification and

As a starting point for this cooperative approach, a strategy and framework of actions was prepared and endorsed by the MS [2]. Simultaneously, the MS officially nominated a group of National Microbiology Focal Points (NMFPs) [3] from all EU and European Economic Area (EEA) and candidate countries to support ECDC in the implementation of this strategy and to engage in specific joint technical work to further the understanding of public health microbiology in their countries. Individual NMFP representatives were selected on the basis of their ability to function as strategic and technical partners of ECDC. The National Microbiology Focal Points represent their countries and not their institutions. They fulfil their role as ECDC's public health microbiology liaisons, transmitting information about ECDC's activities to their countries while contributing country perspectives and reporting on information about national developments and trends to ECDC and the NMFP forum.

In addition to this dedicated group of microbiology representatives, ECDC coordinates a number of EU-wide laboratory networks and related projects as a follow-up to the long tradition and programme of the previously European Commission-funded dedicated surveillance networks (DSNs) [11].

This collaborative approach makes use of the already existing microbiological capacities, competencies and networks within the EU and aims to create added value to the MS by stimulating collaboration, including access to and/or sharing of resources, strengthening quality, and exchanging best practices.

2 Introduction

2.1 Scope and purpose

This report is a summary of work performed together with nominated MS representatives—in the field of public health microbiology—to obtain a common understanding of the systems and structures operating in EU countries. A survey, combined with expert consultations, was used to collect relevant information about definitions used in this field and extract an overview of key issues such as the application of norms, quality assurance, biosafety, education and training. A significant part of the study was focused on national reference laboratory activities, systems of selection and evaluation, and overall capacities.

The comprehensive goal of this study was to obtain an overview of the field of public health microbiology in the EU and identify national similarities and differences. Obtaining an exhaustive inventory of the systems, structures, and reference level capacities was not a part of the expected outcome; rather, this report was intended to identify gaps and common needs where there would be EU added value for collaboration. In the report conclusions, ECDC suggests concrete areas of further work towards fostering collaboration between countries in terms of exchange of good practices and the provision of guidance.

This study is an important step towards building a common understanding and robust network of microbiology laboratories in the EU.

2.2 How this report contributes to other available work in the field

There have been previous projects at the EU level providing an inventory of resources for infectious disease control [4]. These data were useful at the time of the study; however, much of the data require further validation and updating, especially considering the EU has expanded and further developed over the last 10 years.

The information collected in this report will be important in further capacity building and addressing main gaps in the field of public health microbiology in the EU. Also, it is a valuable resource to support EU countries in ensuring they have the capacity (or access to it) to meet the requirements of EU directives for communicable diseases [5] as well as International Health Regulations (IHR) [6].

2.3 What this document is

This document is a technical report. It is intended to provide information about the work undertaken by ECDC to understand and ultimately strengthen the public health microbiology systems in the EU. The data displayed in the appendices represent a snapshot of the public health microbiology systems as of 2008 and should be used in the context of a needs analysis.

2.4 What this document is not

This report is not a comprehensive inventory of existing public health microbiology systems and structures within EU. The data for reference laboratories does not reflect the detailed situation for specific pathogens; rather, it is a collection of knowledge about overall public health microbiology systems and structures.

2.5 Intended use and users

This report provides aggregated data from countries participating in this study and is intended to be used as a basis for further investigations on selected topics. Therefore, the data should not be used out of the context of the scope and purpose of this report.

The users of this report are public health professionals—particularly in the field of infectious disease epidemiology and public health microbiology—learned societies in the field of public health, the relevant sectors of the European Commission (EC), World Health Organization (WHO), EU/EEA countries, as well as candidate and potential EU candidate countries and other ECDC key stakeholders.

3 Materials and methods

Between 2007 and 2010, ECDC hosted seven meetings bringing together the NMFP group to obtain their technical input and strategic guidance on a number of key topics in public health microbiology. In 2008 ECDC, in collaboration with the NMFP group, executed a survey on the public health microbiology organisation and functions of the MS.

The survey contained 254 questions, 11 of which were for open comments. It was jointly developed by ECDC and the NMFP group. The following aspects of public health microbiology were covered in the survey under the following chapters

- Chapter 1 – general points (i.e. definitions of key terms);
- Chapter 2 – creating a directory of national reference laboratories;
- Chapter 3 – structures and systems;
- Chapter 4 – norms, quality assurance (QA);
- Chapter 5 – education and training; and
- Chapter 6 – gaps, needs and collaboration.

The main objectives of the survey included the following:

- Describing public health microbiology functions in the EU.
- Providing an overview of the national reference laboratories and/or general communicable disease diagnostic capacity in the MS.
- Identifying needs for action, the levels at which action has to be taken, and where coordination is needed (i.e., role of ECDC, WHO, MS, and the European Commission).
- Providing examples of good practices in the MS.
- Stimulating country cooperation and collaboration across identified areas.

The survey was completed by the NMFPs between May and July 2008. The questionnaire was sent to 30 countries: 27 EU countries, plus Iceland, Liechtenstein and Norway. The overall response rate of the survey was 90% (27/30). Results from England were used as a proxy for the UK. The European Centre for Disease Prevention and Control also received results from Wales, but these were not included in this report.

The main limitation of the study was missing country data and a number of questions that received low response rates. This resulted in difficulties in terms of data interpretation.

4 Questionnaire results

The full set of results from the ECDC public health microbiology survey 2008 can be found in Appendix 1. The major findings and conclusions are presented as well as follow-up work and methodological aspects of the different chapters of this survey

4.1 Chapter 1—General points

The aim of this section was to find a common understanding of the key terms used and, in case of national differences in perceptions, use the NMFP forum to agree upon common acceptable definitions to the terms. The terms investigated were 'public health microbiology' and 'national reference laboratory'. These key terms were considered essential for the interpretation of the questions in the remaining chapters. Countries with definitions for these terms were asked to append these when returning survey results. Results showed that there was no common definition of 'public health microbiology' (Annex 1.1). Seven MS provided feedback and comments on key aspects to include when agreeing upon a common definition.

Based on this feedback and in-depth consultations with the NMFP forum, the following definition of 'public health microbiology' was agreed upon:

> Microbiology is the study of microorganisms, including viruses, fungi, parasites and bacteria. Public health microbiology is a cross-cutting area that spans the fields of human, animal, food, water, and environmental microbiology, with a focus on human health and disease. It requires laboratory scientists with ability to work effectively across disciplines, particularly with epidemiologists and clinicians. Public health microbiology laboratories play a central role in detection, monitoring, outbreak response, and providing scientific evidence to prevent and control infectious diseases.

The agreed definition of the term 'public health microbiology' is applicable in a broad European context. Key elements of the term 'public health microbiology' include the following: presentation as an advancing, cross-cutting area of multiple fields of microbiology including human, veterinary, food, water and environmental microbiology; reference to the frontline work performed by these laboratories in terms of monitoring, alert, response, and scientific advice rather than only as a support function to public health in general or just a sub-task for clinical laboratories. Recognition and clear definition of these roles and responsibilities of public health microbiology laboratories, and the expert knowledge required, will help to focus attention on the steps needed to build a more stable and sustainable laboratory function across Europe.

Survey results also showed that there was no agreed definition to the term 'national reference laboratory' (Annex 1). This discrepancy initiated a separate work where the MS representatives agreed upon core functions of microbiology reference laboratories and their main activities in the field of communicable diseases. This work was presented in a separate technical report [7].

4.2 Chapter 2—Creating a directory of national reference laboratories

The aim of this section of the survey was to get an overview of existing national reference laboratories within the EU. The intention was not to create a full inventory of reference laboratories, but rather to capture a rough estimate of EU reference laboratory capacity to be used as a starting point for discussions and to facilitate sharing of reference services between countries.

To bypass conceptual discrepancies, the following working definition of the term 'national reference laboratory' was given:

> '…laboratories with national responsibilities with appropriate tools and skills to be able to collaborate in national surveillance and the capacity to deal with emergency situations [4].'

Data collected from laboratories falling under this definition included names of pathogens for which a laboratory serves reference functions, contact persons and laboratory addresses.

In total, 499 reference laboratories were identified. Information for national reference laboratories for all diseases falling under the remit of ECDC was collected. In addition, several countries submitted information on reference-level capacity for other infectious diseases or disease areas (Annex 2). Data was filed in a searchable laboratory directory format. To make this data a useful resource for public health and not only an instantaneous overview of current structures, a number of issues were identified. These included a need for data validation, a system for continuously updating the information, inclusion of data from countries that did not complete the survey,

security/data protection considerations and the need for appropriate permission from MS to share data with agreed user groups. Currently, ECDC is developing this information resource and working to find a solution for these issues.

4.3 Chapter 3—Structures and systems

This section of the survey focused on different aspects of national reference laboratory systems and structures. These play a key role in the overall public health microbiology system and are the laboratory structure to which ECDC has its strongest mandate for collaboration [1]. This subject was queried through a number of questions; for example, 'Do you have reference laboratories?', 'What is their status?', 'When was the laboratory system last updated?', 'How are laboratories selected?', 'How long do they act as reference laboratories?', 'How many different institutions host reference laboratories?', etc (Annex 1.2). Results showed that most countries have reference laboratories, but organisation of the systems differ widely.

The specific roles of existing national reference laboratories were examined. These roles were also scored according to perceived importance to the reference laboratory functions. The purpose of this exercise was to gain an understanding of the relative importance of each activity and ultimately identify which activities could be considered to represent core functions of reference laboratories. The data presented here was a good start to the discussion; however, a significant amount of work was focused on this topic, and a separate document establishes these core functions [7].

Overall, the data in this section should be interpreted with caution since the questions had interpretational limitations. At times, it was not clear if responses were either covering the full laboratory system or addressing capacities for a specific pathogen.

4.4 Chapter 4—Norms and quality assurance

This section of the survey focused on laboratory norms, accreditation and biosafety. The chapter included specific questions on the general legislative framework of the laboratories, national requirements for laboratory norms, antibiotic susceptibility testing norms, promotion of quality assurance at the national level, quality assurance management at the laboratory level, external quality control/proficiency testing, biosafety, national accreditation bodies and official recognition of laboratory quality levels.

The term 'laboratory norms' referred to a wide range of general laboratory practices including staff and equipment requirements, data protection and reporting policies, sample handling, etc. Most countries reported having regulatory norms covering day-to-day laboratory activities like safety, waste management and confidentiality but approximately half of the responding countries reported having no norms for requirements of staff number and quality assurance manager (Annex 1.3). Many countries reported the lack of a structure promoting quality assurance at the national level. This indicates that many countries are not applying available international standards for laboratories. Accordingly, the reported official recognition needed for laboratories was divided into three equal parts: international standards needed; national standards needed; or no recognition needed. To further understand and interpret the data collected on quality issues, ECDC brought laboratory quality experts together to look at the systems in place and in use [9]. The main conclusion here was that standards are used; however, when these deviate from internationally recognised standards, differences are not clear and therefore emerging data cannot be equally compared and validated.

The biosafety related questions also prompted further exploration by ECDC of the situation in the EU and areas that could be strengthened (manuscript in preparation). This work is being performed in collaboration with scientific experts in the field of biosafety under an ECDC funded initiative on biorisk issues. This group provides scientific advice to build a knowledge base in this field along with specific guidance on key issues in biorisk management, and aims to build capacity in this area for public health microbiology professionals and policy makers through training activities [8].

4.5 Chapter 5—Education and training

This section of the survey aimed to understand how MS organise basic and continuing training in microbiology, and to identify areas of work at the EU level that could complement the MS programmes. For basic training, questions were asked regarding whether microbiology is recognised as a specialty and how it relates to other disciplines, such as epidemiology and medicine. For continuous training, the relation to epidemiology and the roles of national reference laboratory in relation to training were investigated. In addition, there were also questions about the need for the development of common European laboratory guidelines and standard operating procedures (SOPs).

Most countries reported that they recognise microbiology as a specialty and also confirmed having specialised training for medical microbiologists and laboratory technicians; however, only a minority of the countries had training programmes focusing on public health microbiology at the basic level (Annex 1.4). This could be linked to the lack of a definition for the term public health microbiology, and also highlights a gap of training programmes

that include microbiological and epidemiological components. For continuing training, a majority of the countries confirmed that national reference laboratories organise specific training for microbiologists. Here, training with both microbiological and epidemiological components was also more frequently offered. A vast majority of the countries would accept international training sessions in quality assurance implementation, biosafety, accreditation, etc. The survey results also showed an equally high interest in developing common European guidelines and SOPs in these areas. Most countries also supported the idea of EU-level training for laboratory specialists, modelled like the European Programme for Intervention Epidemiology Training (EPIET) for epidemiologists.

4.6 Chapter 6—Gaps, needs and collaboration

The aim of this section of the survey was to identify gaps and needs, and suggested areas of collaboration to fill these gaps. Questions were asked about whether MS are accessing microbiology reference services in other countries and how national reference laboratories can be supported. In a scoring exercise, possible gaps were ranked (according to perceived negative impact). Most of the MS declared accessing reference activities in other EU countries and some in non-EU countries (Annex 1.5). The majority of the respondents stated that there is a need to establish and/or to support their national reference laboratories. In the gap analysis, sample transportation, financial resources for biosafety and data management were scored as the most urgent gaps, whereas overall financial resources and equipment quality and quantity where considered less problematic. The main limitation of the scoring exercise was that only the listed suggested gaps could be scored. Therefore, this data should be interpreted as only an indication of the relative importance of the gaps originally raised by the NMFP group.

5 Discussion

To foster the development of sufficient capacity within the European Community for the diagnosis, detection, identification and characterisation of infectious agents which may threaten public health, in-depth knowledge about current public health microbiology systems in the EU MS is required. The EU is built up by individual MS with public health microbiology systems that differ both in traditions, advancement level and resources. Apart from these differences, there are many aspects that unite the countries in this area. All MS have expectations from their citizens to offer adequate public health microbiology services. Member States are committed to sustain, or access through other states, a capacity for diagnosing and the timely reporting of data for a defined list of pathogens and the diseases that they cause [5]. According to the IHR, each country should have the capacity to provide support to regional and community levels for laboratory analysis of samples, domestically or through collaborating centres [6]. The previously established European Commission programme of dedicated surveillance networks and other initiatives have provided the foundations of effective networking at the EU level.

Based on these conditions, ECDC has chosen a collaborative approach to access public health microbiology capacities and competencies in the MS [2, 10]. This approach does not only contain a unidirectional flow of information to ECDC but also aims to strengthen the current system by coordination. The first step in this collaborative process is learning more about the MS systems and structures in order to identify needs at the EU level and to arrive at conclusions on how to assist in meeting these needs. The information collected from this study is the first step in this process. No country-specific information was provided since aggregated data provides the needed snapshot of the overall systems and structures in public health microbiology in the EU; it also avoids political and security sensitivities for the use of the data.

An agreed, common EU definition for public health microbiology—that could be applied to all EU MS—was established. There is no optimal way to define a concept such as public health microbiology, especially since the underlying systems and structures in the MS are so diverse and the field highly interdisciplinary. It was nonetheless agreed that this definition would be useful when discussing the microbiological capacities in a country. The agreed definition of the term 'public health microbiology' is intended to advocate and strengthen the point that this is a specialised interdisciplinary field that requires trained specialists as well as adequate funding and resources in order to achieve the whole spectrum of tasks expected.

Discussion of the terms of reference and the underlying activities of national reference laboratories was beyond the scope of this report, and is taken up in detail in a separate publication [7]. The existing data reported in this survey on national reference laboratory capacity in the EU were impressive in terms of the number of designated laboratories (499 for 27 EU/EEA MS) and the complete range of diseases covered. The information, however, was not detailed enough to understand the actual capacity, availability for sharing, and quality of reference laboratory services provided for all relevant pathogens and diseases.

For the next steps in the process of understanding current laboratory capacities in the EU, two complementary approaches have been identified. The first approach entails updating information and improving resolution of an EU laboratory directory. Previous experiences [4] have shown the complexity of this approach, in terms of validating information and keeping the data updated. On the other hand, an updated directory of capacities has many advantages. This is especially true when responding to disease outbreaks, complex emergency situations, or to have (rapid) access to experts in the field for the provision of scientific advice. For the MS, access to such a directory by competent authorities and the reference laboratories themselves would promote collaboration (i.e., exchange of materials, knowledge, and good practices and contract services for specific issues, as needed). The second approach involves a type of gap analysis to identify areas in which MS would benefit from the sharing of services and other collaborations between countries or at the EU level. This type of analysis would need clear criteria for defining a "gap" as well as specifications of how EU countries should interpret the requirements of core competencies for surveillance and response described in the IHR [6]

Following the mandate, ECDC can work with the MS to explore the identified gaps and needs in the next phase of the joint work, well timed with the deadline for full implementation of the IHR requirements for 2012. In terms of filling existing gaps, the ECDC approach to microbiology reference laboratory networks that fulfil core competencies in public health microbiology (i.e., detection, surveillance, alert and response, scientific advice, collaboration and research) is a flexible, responsive, and sustainable way forward to ensure good coordination, capacity building, and to meet the immediate needs to respond to health threats due to infectious diseases. The strengths and benefits of community-wide microbiology reference laboratory networks are further elaborated on the following page:

Strengths and benefits of coordinated Community-wide microbiology reference laboratory networks:

- Member State partner laboratories have equal opportunities to contribute as appropriately suits their needs and resources.
- Adequate spread of knowledge, capacity, and resources over the regions of the EU.
- De-centralised organisation (EU-wide networks) provides a wider reaching and robust platform to deal with microbiology issues at regional, national, and supranational levels.
- A neutral agency for coordination (ECDC) to support the networks strategically and technically ensures a high quality, fair, and transparent approach to meet the MS needs and gives ownership of the networks to the MS partners.
- Integration of laboratory and epidemiological surveillance data (done at local and national levels).
- Flexibility, sustainability, and close engagement between MS partners and technical experts at the ECDC.
- Effective platform for liaison and networking with other initiatives connected to different sectors of the European Commission, WHO, and other key stakeholders.

In summary, the most valuable results from this analysis include the following: the increased engagement with the MS by close collaboration with the NMFP forum; common working definitions for public health microbiology and list of existing activities of national reference laboratories in the MS; a start-up directory of microbiology reference laboratory capacity; and identified gaps and areas of future work.

6 Conclusions and next steps

This study provided the following key results:

- Common definitions and a good overview of MS systems and structure in public health microbiology.
- Directory of microbiology reference laboratory capacity in the EU
- Detailed activities for national reference laboratory activities leading to full elaboration guidance of the core functions of microbiology reference laboratories for communicable diseases in the EU.
- Overview of the gaps and areas of work that the MS would expect ECDC to follow up.

Based on these findings, ECDC shall further explore the following work areas with the MS:

- Validating and further tailoring the directory of microbiology reference laboratory resources.
- Providing scientific advice, guidance, and sharing of good practices on issues including norms, quality management/assurance, SOPs, biosafety, sample transportation, and other specific reference laboratory issues
- Continuing work on capacity building of microbiology reference laboratory core functions and common quality standards.
- Providing training through a European Public Health Microbiology Training Programme (EUPHEM) to establish a cadre of highly qualified specialists in this field.
- Offering support to meet the obligations indicated in the IHRs (i.e., scientific guidance, coordination, joint assessment of laboratory capacity/systems, and information on access to reference level capacity services).
- Advocacy for public health microbiology as a specialised field, requiring dedicated resources and trained professionals. This should include strengthening the role and effective contributions of the NMFPs.

The following is a list of the most valuable lessons learned from conducting this study:

- Long and detailed surveys are difficult to design, execute, and results can be difficult to interpret.
- Incomplete or inaccurate data are limitations of such a study.
- It is challenging for a single representative of microbiology in the MS to be able to answer all of these questions. A good network must be in place in the countries for the NMFPs to have access to all the expertise in issues ranging from selection of reference laboratories, to biosafety, to education and training needs.

The survey approach is a good starting point. To foster collaboration in public health microbiology, build knowledge of the MS systems and structures and, most importantly, assess the gaps and needs to guide joint actions, close collaboration and consultation with the MS are required. Here, the NMFP forum, as well as smaller focused working groups involving other specific field experts, has proved very effective. The European Commission, together with ECDC and WHO, can undertake mutually helpful work with MS to identify which mechanisms can best achieve these common goals in a coordinated way.

References

1) Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European centre for disease prevention and control. Official Journal of the European Union. 2004;L 142:1–11 (30 April 2004).

2) European Centre for Disease Prevention and Control. Strategic multi-annual programme 20072–013. Public health activities, disease specific programmes and multilateral partnerships. Stockholm: ECDC; 2010. Available here: http://ecdc.europa.eu/en/aboutus/Key%20Documents/071–3_KD_Strategic_multiannual_programme.pdf

3) European Centre for Disease Prevention and Control. National Microbiology Focal Points—Background information, 2010. Stockholm: ECDC; 2010. Available here: http://ecdc.europa.eu/en/activities/microbiology/Documents/100304_NMFPs_Background_information.pdf

4) European Commission Public Health. Inventory of Resources for Infectious Diseases in Europe (IRIDE). Available here: http://ec.europa.eu/health/index_en.htm

5) Official Journal of the European Communities. Decision No 2119/98/EC of the European parliament and of the council of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community. Available here: http://eur-lex.europa.eu/pri/en/oj/dat/1998/l_268/l_26819981003en00010006.pdf

6) World Health Organization (WHO). International health regulations (2005), second edition. Available here: http://whqlibdoc.who.int/publications/2008/9789241580410_eng.pdf

7) European Centre for Disease Prevention and Control. Core Functions of microbiology reference laboratories for communicable diseases. Stockholm: ECDC, 2010. Available here: http://www.ecdc.europa.eu/en/publications/Publications/1006_TER_Core_functions_of_reference_labs.pdf

8) European Centre for Disease Prevention and Control. BioRisk Initiative for Capacity building and Knowledge base development (2009). Stockholm: ECDC; 2010. Available here: http://ecdc.europa.eu/en/activities/microbiology/biosafety/Documents/101117_Bioriskproject_Description.pdf

9) European Centre for Disease Prevention and Control. Ensuring quality in public health microbiology laboratories in the EU: Quality control and areas in need of strengthening. Stockholm: ECDC 2009. Available here: http://www.ecdc.europa.eu/en/publications/Publications/0912_MER_Ensuring_Quality_in_Public_Health_Microbiology_Laboratories_in_the_EU.pdf

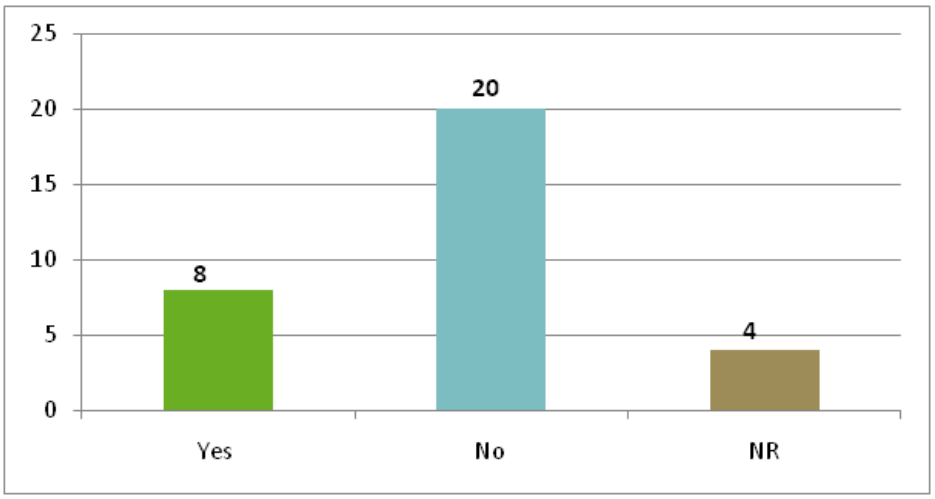
10) European Centre for Disease Prevention and Control. General strategy and framework of actions (2007–2013) for ECDC cooperations with microbiology laboratories and research institutes in the EU. Stockholm: ECDC; 2007. MB11/11. Available here: http://www.ecdc.europa.eu/en/activities/microbiology/Microbiology%20Documents/0711_MIC_GeneralStrategy_ECDC_Cooperation_with_Lab.pdf

11) European Centre for Disease Prevention and Control website. Projects—Microbiology cooperation. Available here: http://ecdc.europa.eu/en/activities/microbiology/projects/Pages/projects.aspx

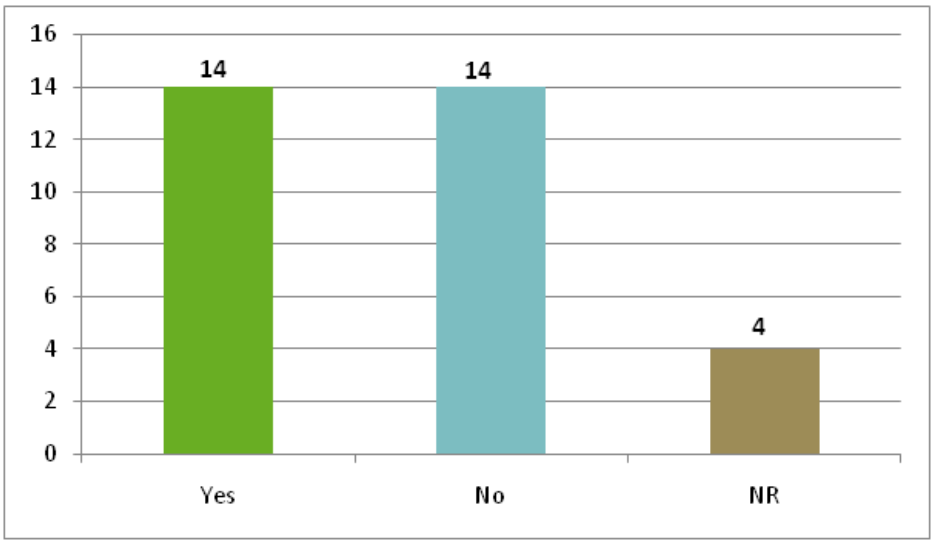
Annex 1: Questionnaire results

A1.1 General points

Q1: Does your country have a definition of 'Public Health Microbiology'?



Q2: Does your country have a definition of a 'National Reference Laboratory'?

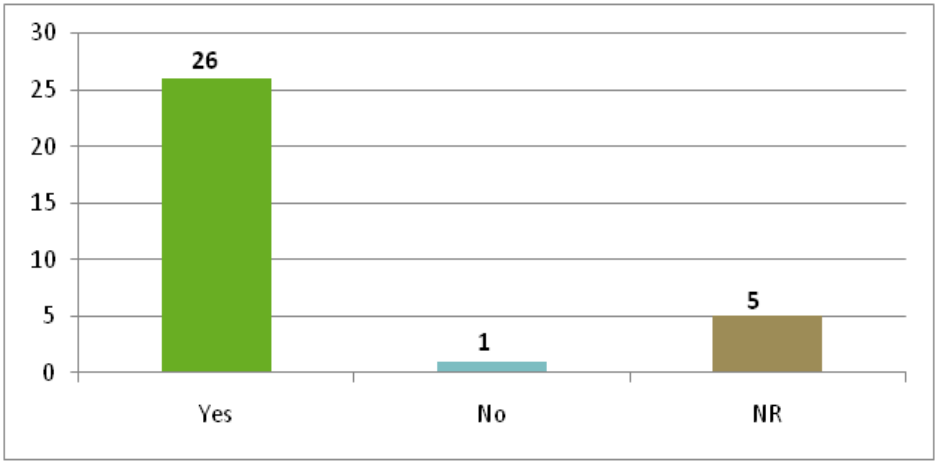


A1.2 Structure and system organisation

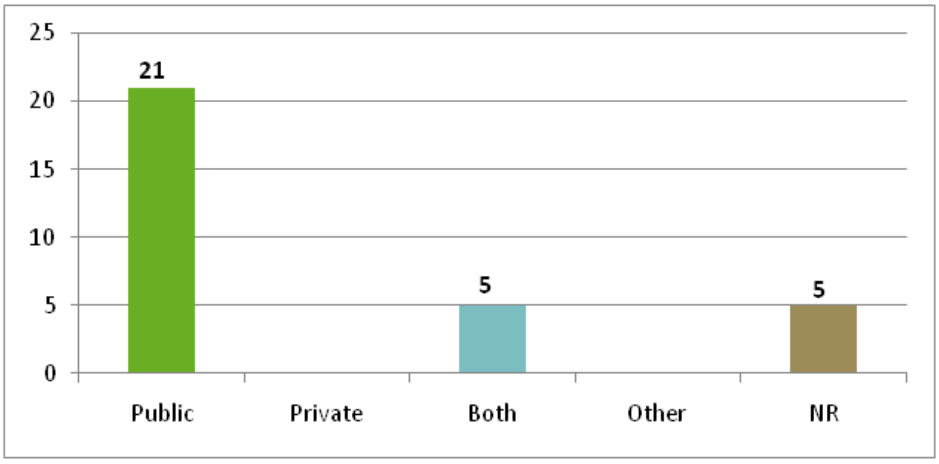
"…laboratories with national responsibilities with appropriate tools and skills to be able to collaborate in national surveillance and the capacity to deal with emergency situations".

Reference laboratories

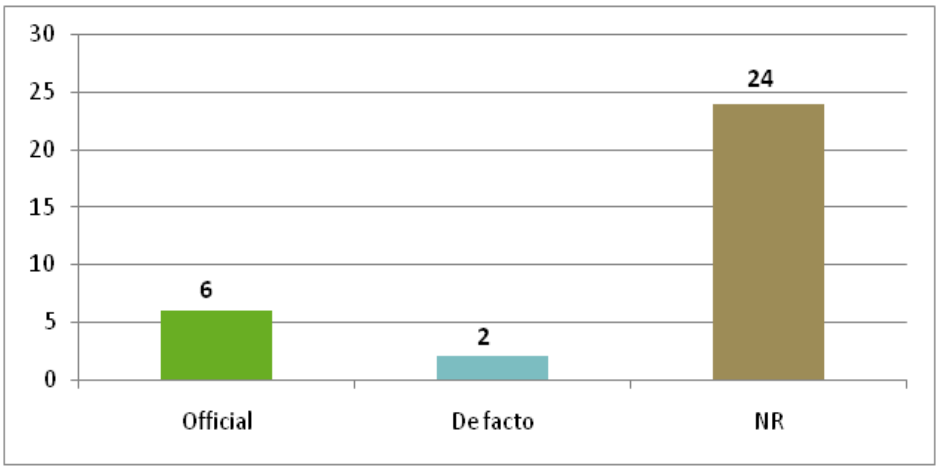
Q1: Using the above mentioned definition, do reference laboratories exist in your country?



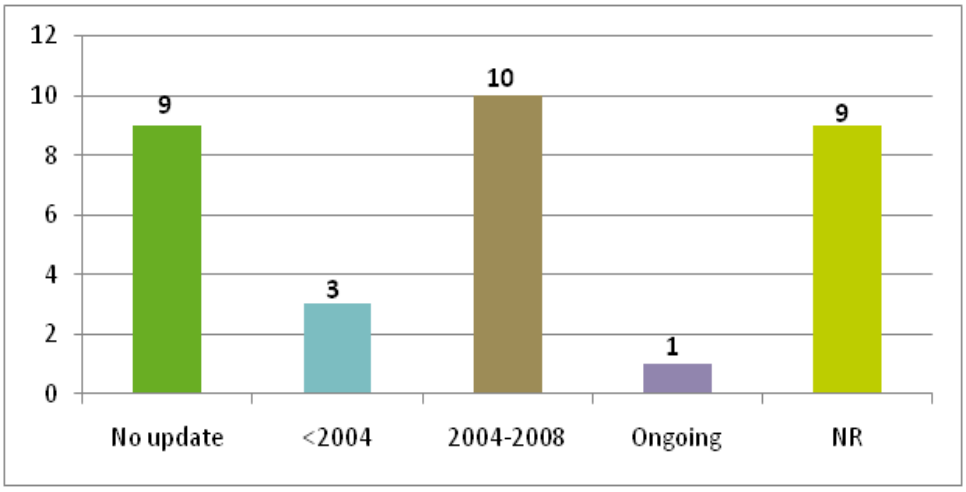
Q2: If yes: What is the status of these laboratories (public/private/both/other)?



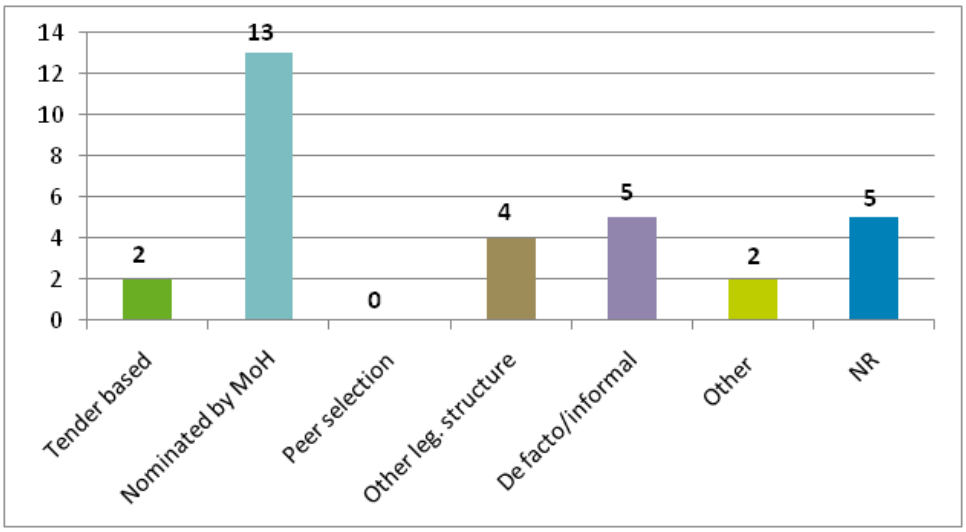
Q3: Are NRL officially appointed or are they 'de facto'?



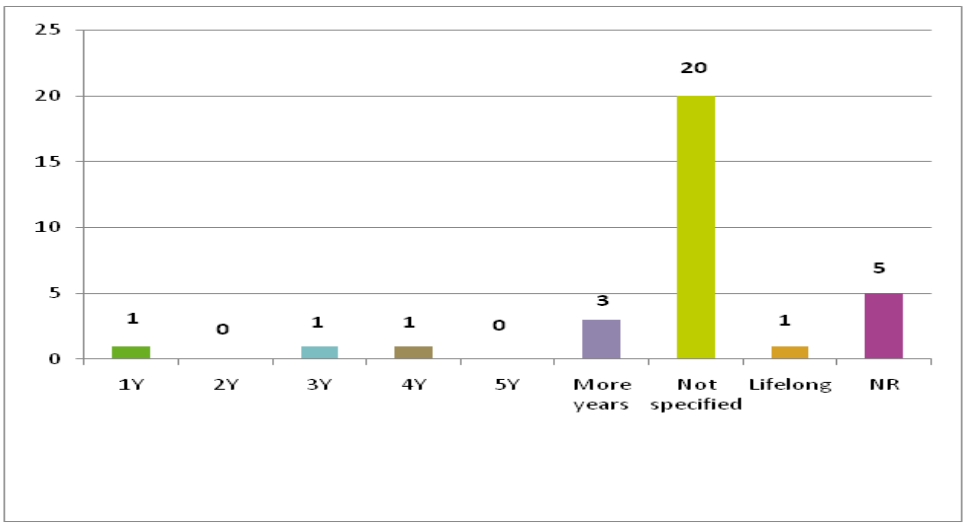
Q4: When (which year) was the last update of the NRL system organisation performed?



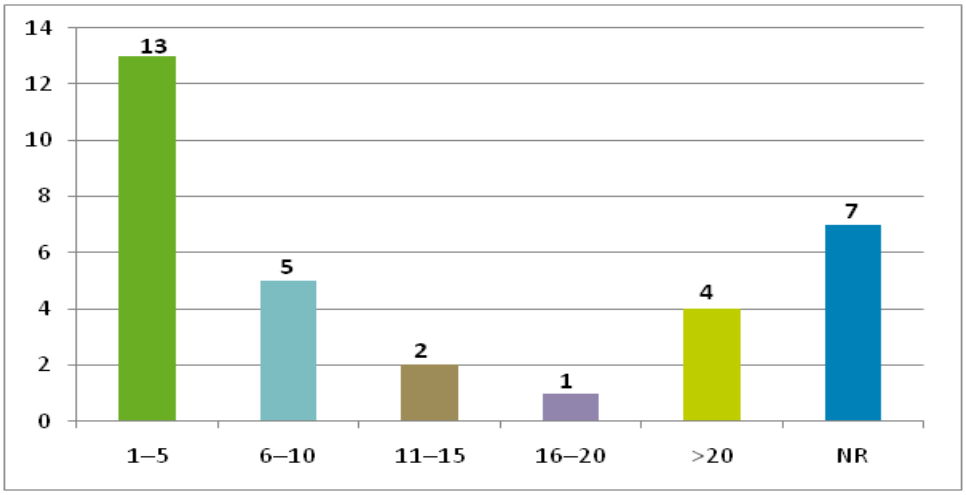
Q5: How are the NRLs selected?



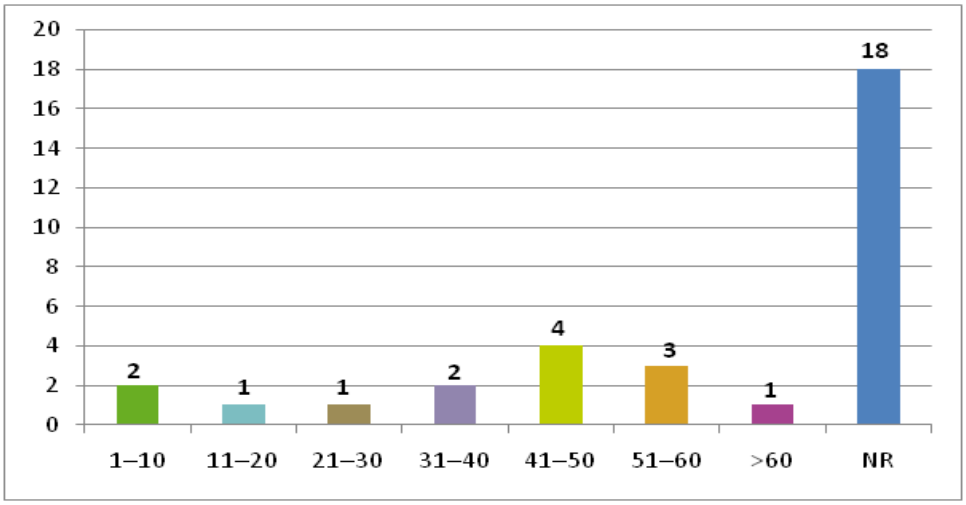
Q6: For what period of time have they acted as NRLs?



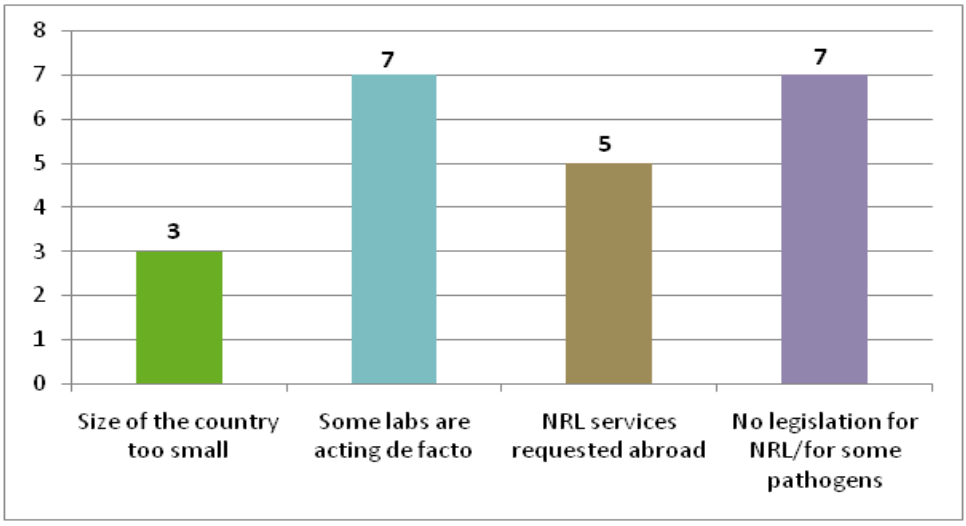
Q7: How many different NRLs (institutions, not pathogens) do you have in your country?



Q8: How many different pathogens are covered by them?



Q9: If no, please select in the list the possible reasons for this:

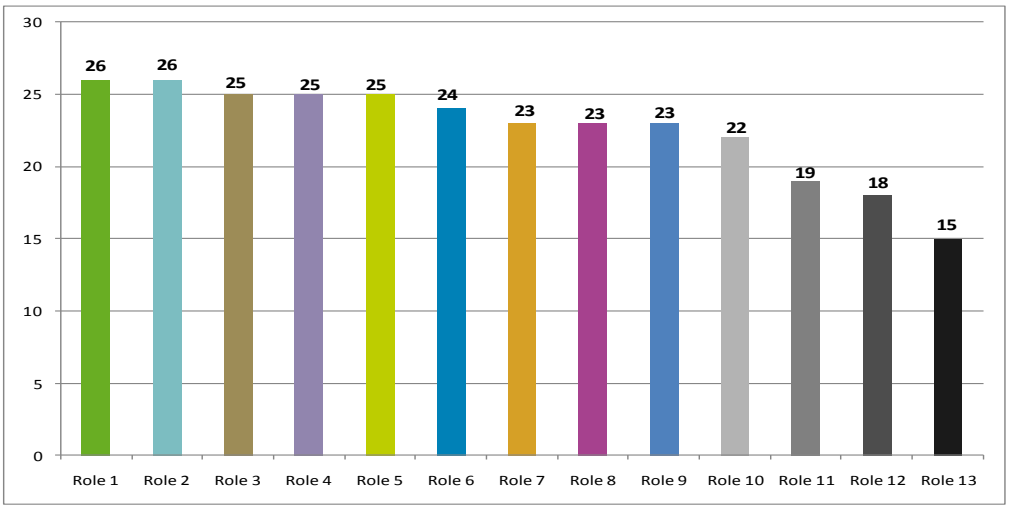


Roles of the reference laboratories

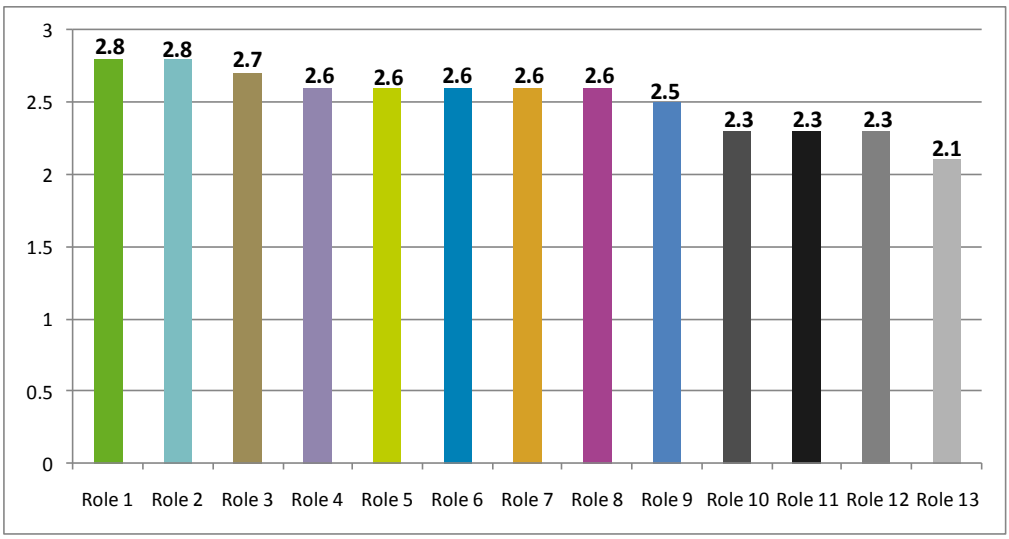
The following list summarises the possible roles of NRLs, which one(s) apply to your NRLs?:

Role 1: Definitive characterisation/confirmation of micro-organisms (identification, typing, resistance, virulence factors)
Role 2: Maintenance of a strain collection and provision of reference strains to requesting laboratories
Role 3: Contribution to epidemiological surveillance through meticulous and timely data management
Role 4: Contribution to epidemiological surveillance through data analysis and early warning in case of unusual phenomenon
Role 5: Participation in international surveillance networks
Role 6: Support to policy (vaccination advice, outbreak response, other)
Role 7: Participation in research (basic/applied) activities related to referral activity
Role 8: Development, validation and guidance concerning diagnostic techniques for other laboratories
Role 9: Organisation of specific training sessions for other laboratories
Role 10: Development of guidelines and diagnostic procedures related to referral activity, with national distribution
Role 11: Advice and recommendation to public health authorities at central level
Role 12: Help, with assistance of epidemiologists, in design and implementation of case definitions related to referral activity
Role 13: Participation in evaluation of new kits and reagents, in relation w/ref. activity, before eventual national registration

Q10: Are you performing these roles? (26 respondants)



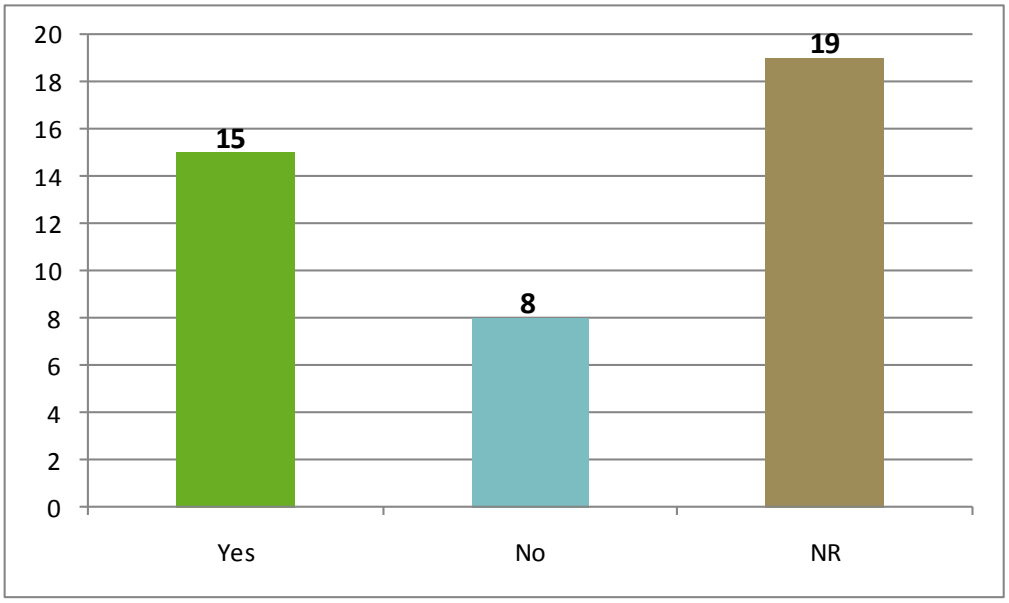
Q11: Please rate—from 1 (small importance) to 3 (high importance)—the importance of the different roles listed above. If a role is not played in your country enter "N"



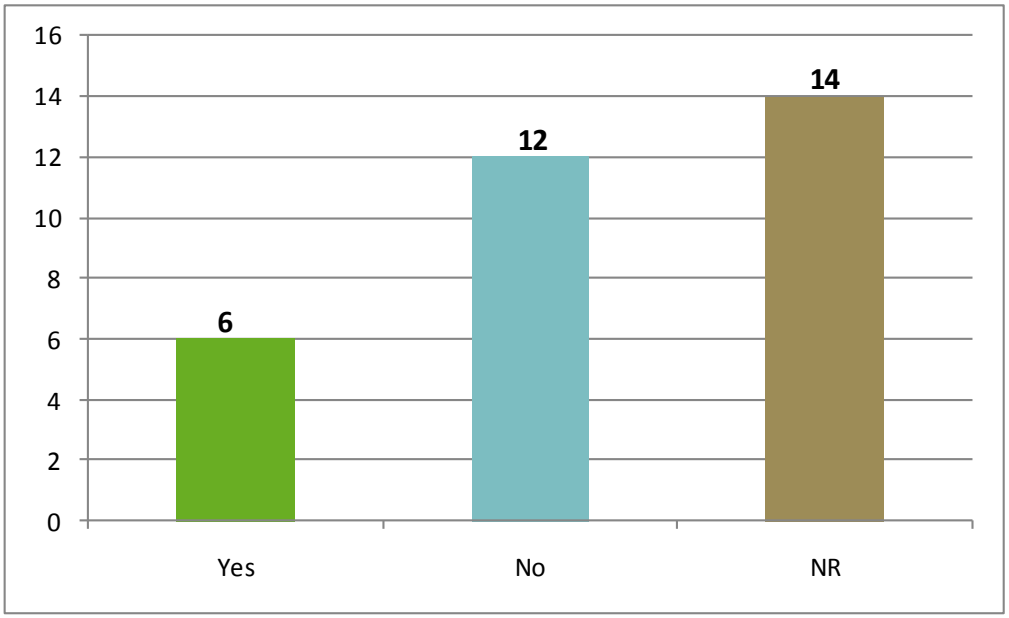
Follow up of reference laboratories work

Q12: Are reference laboratories audited or assessed?

Audit of formal NRL

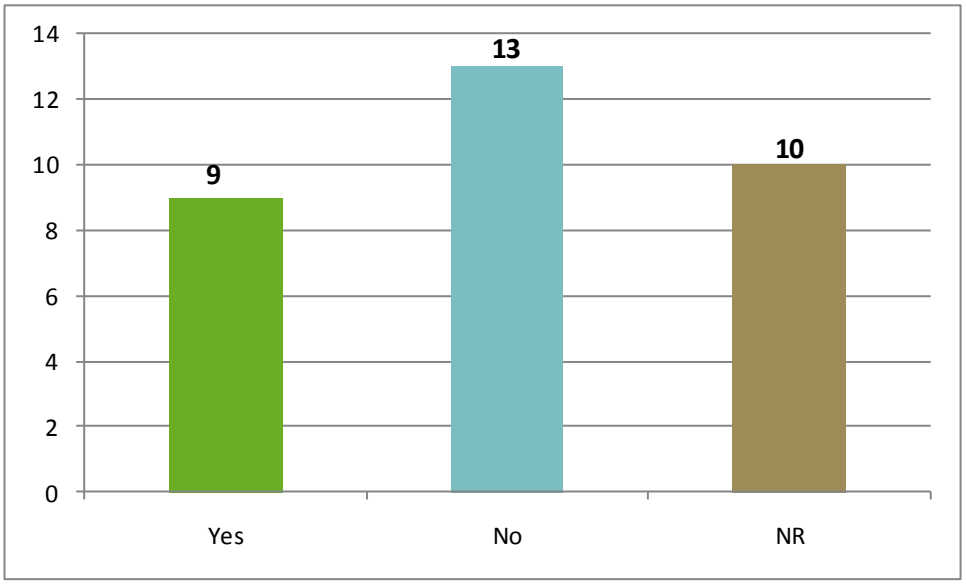


Audit of informal NRL

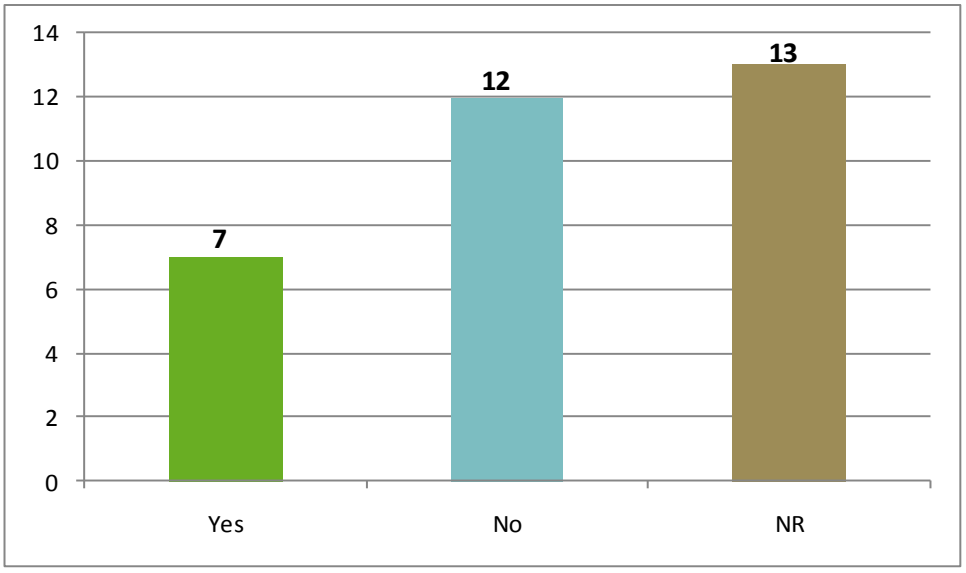


Q13: Are meetings of NRL focal points organised?

Meeting of formal NRL focal points

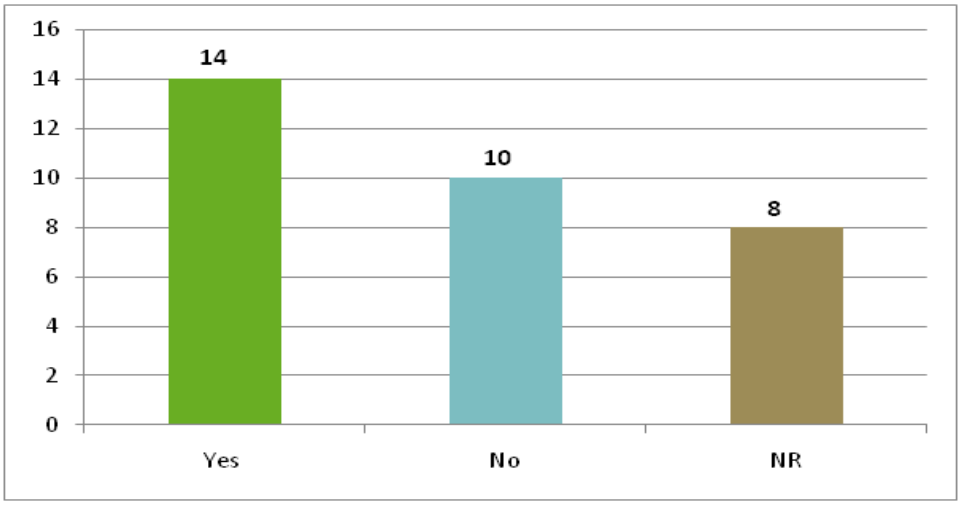


Meeting of informal NRL focal points

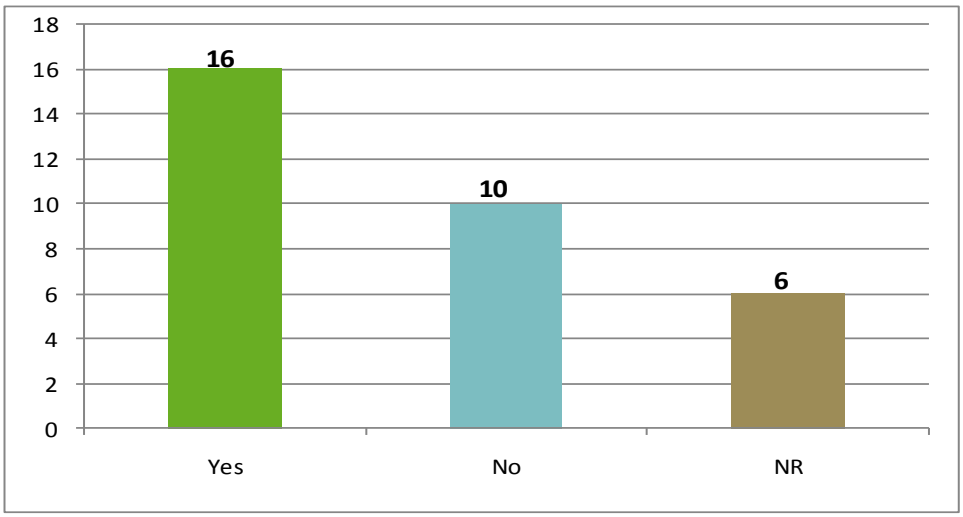


Funding of national reference laboratories

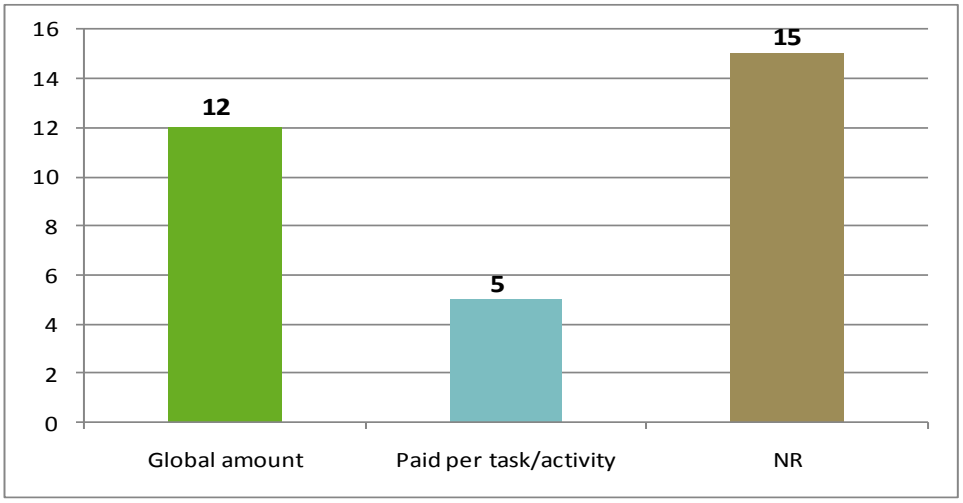
Q14: Is public health microbiology funded in the same way as other public health programs



Q15: Are your NRLs (official or de facto") receiving specific funding for any of their reference activities?

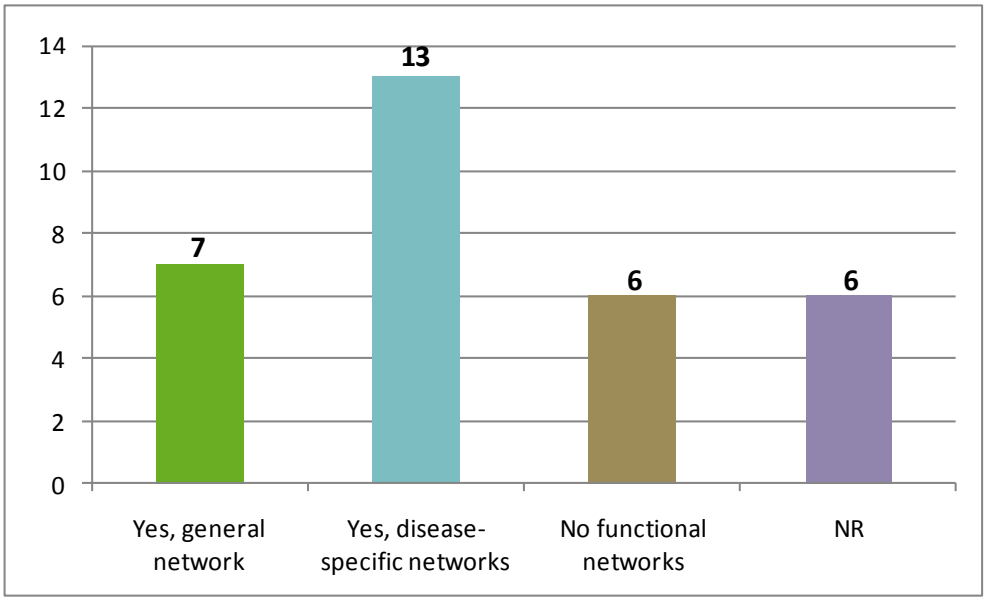


Q16: If yes, is this a 'global amount' or funding per task/activity

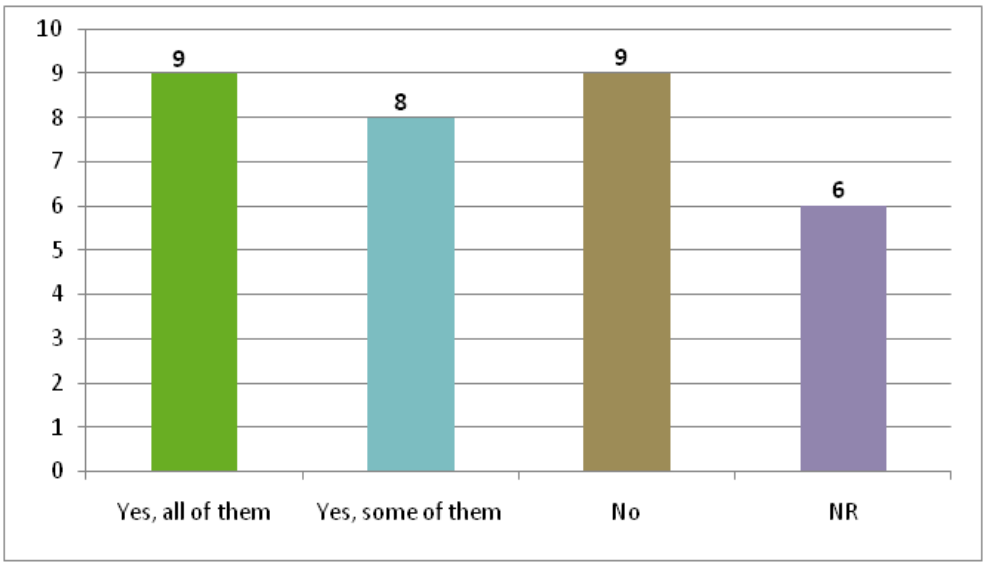


Organisation of laboratories and national reference laboratories

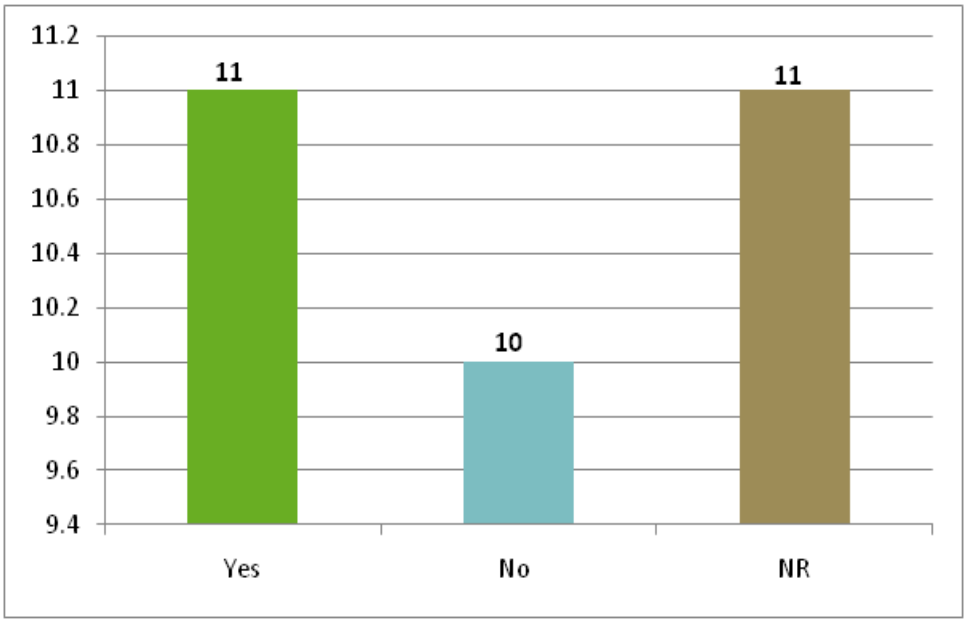
Q17: Is a network organisation for your laboratories available?



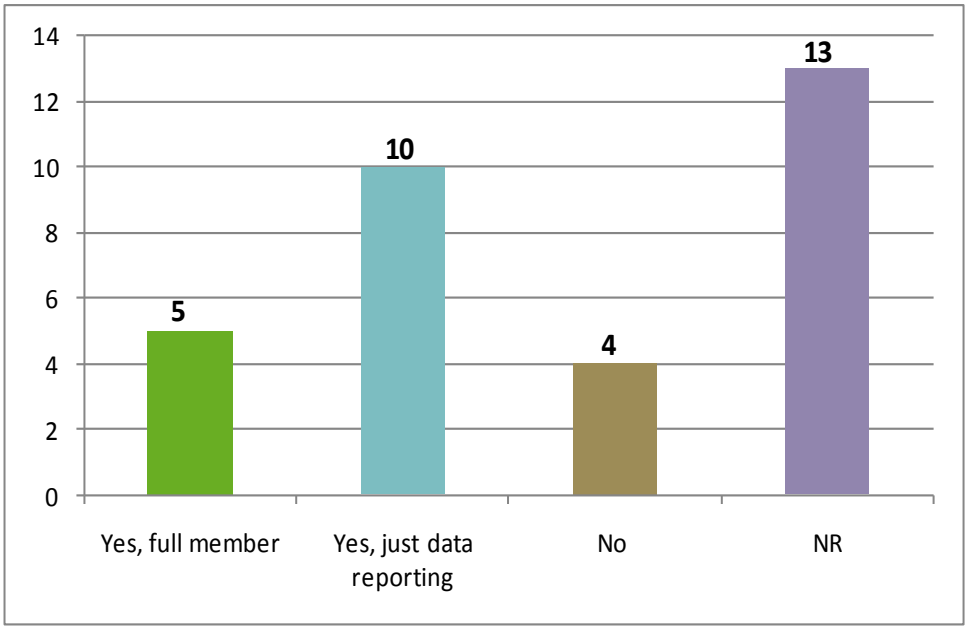
Q18: Are all public (i.e., non private) laboratories part of a national laboratory network?



Q19: If yes, is this network formalised in a document, law or decree?

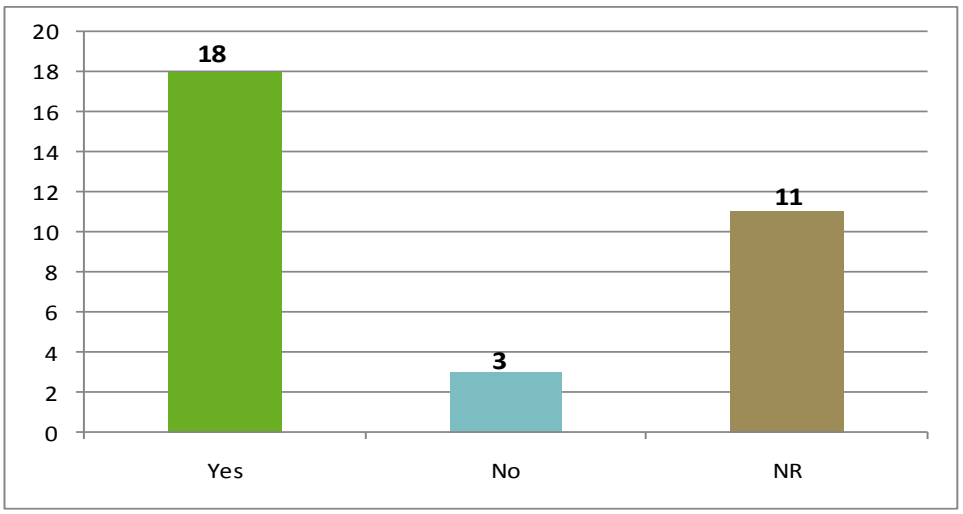


Q20: Are private labs part of it, at least for data reporting?

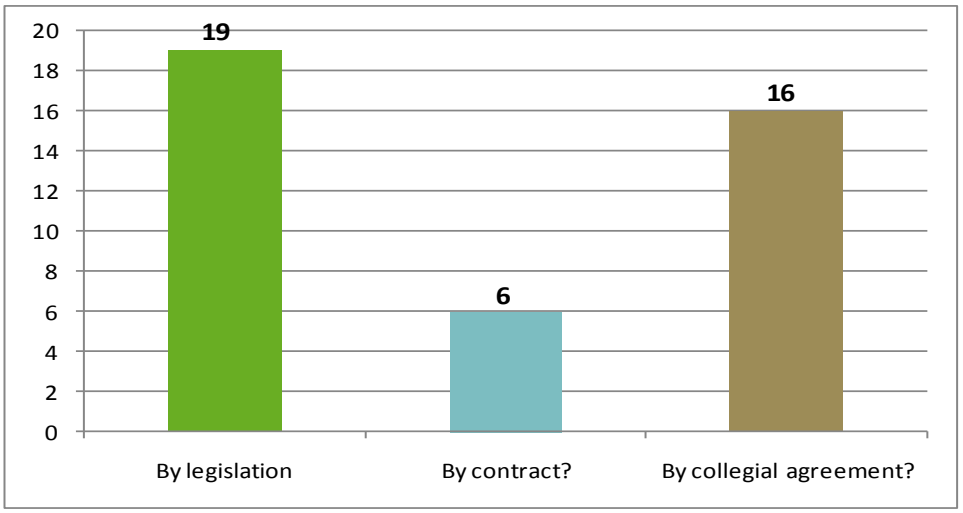


Relations with epidemiological/disease surveillance services

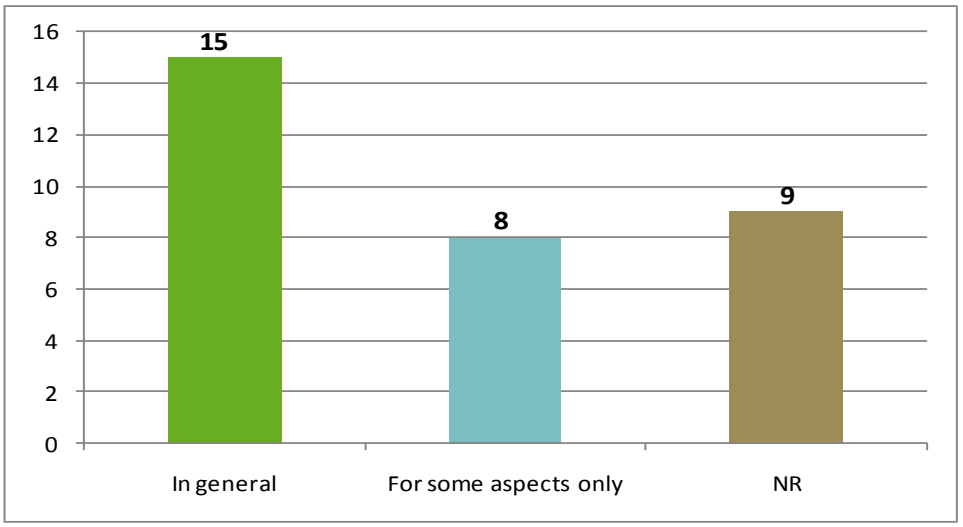
Q21: Is there an official structure/system in place for exchanges (data, information on surveillance and alerts) between public health microbiology laboratories and epidemiologists?



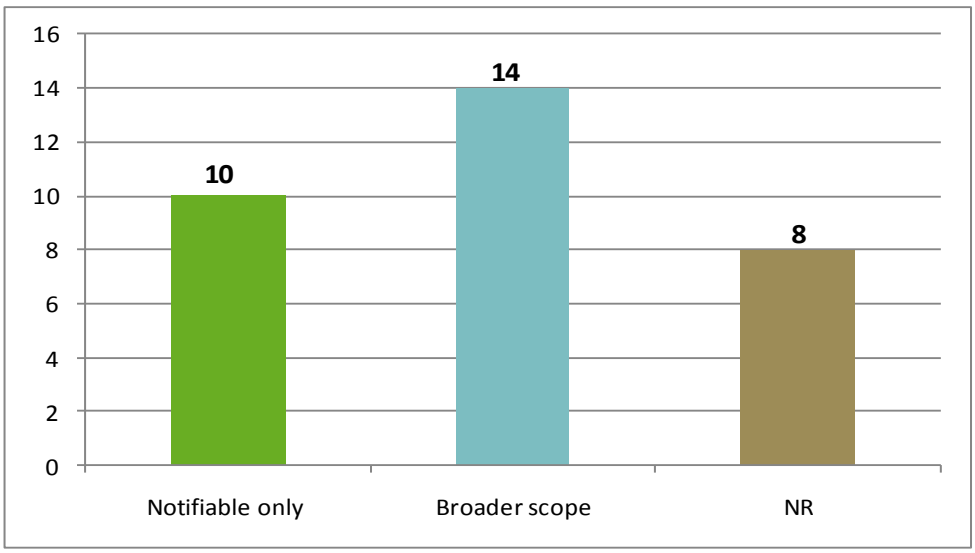
Q22: By legislation



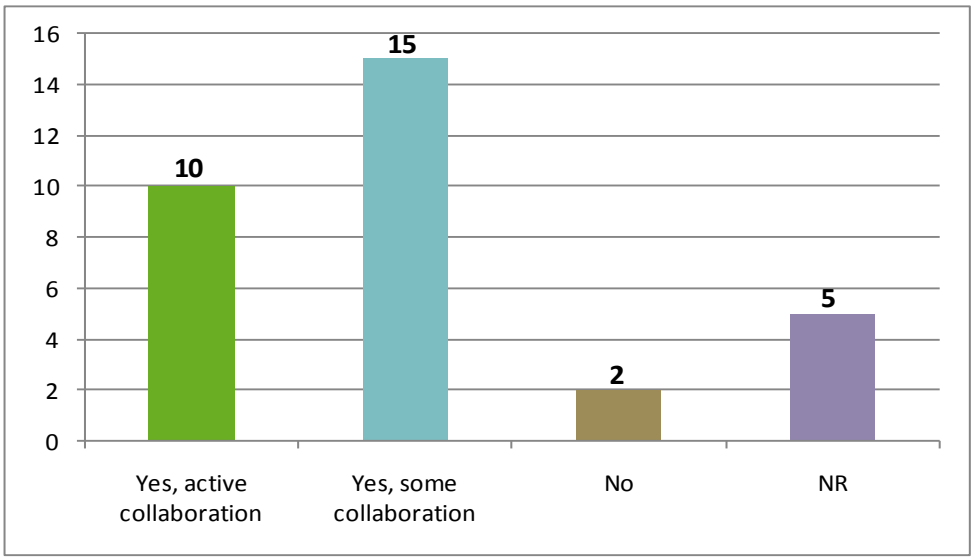
Q23: In general or only some aspects of this issue?



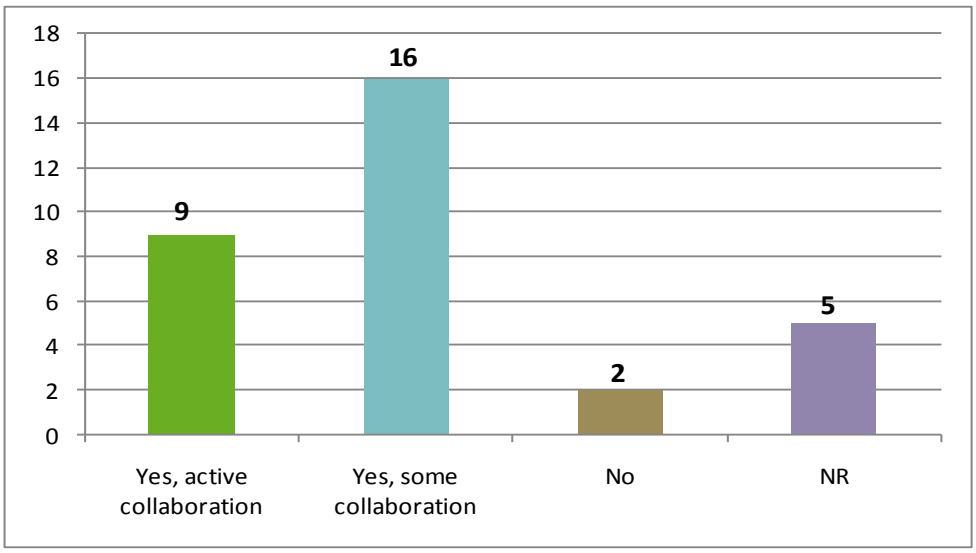
Q24: For notifiable diseases only or for a broader scope of diseases?



Q25: Are veterinary laboratories and human laboratories collaborating on common pathogens?



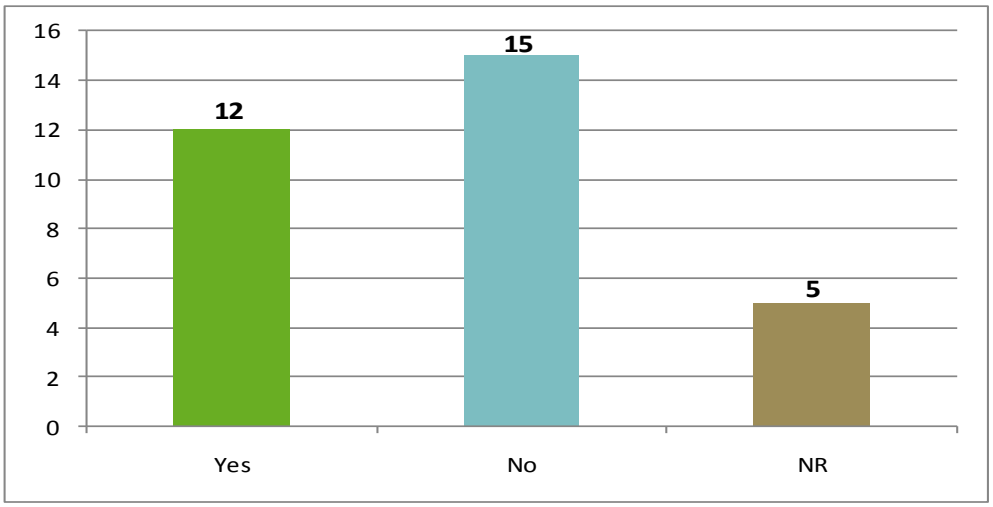
Q26: Are food laboratories and human laboratories collaborating on common pathogens?



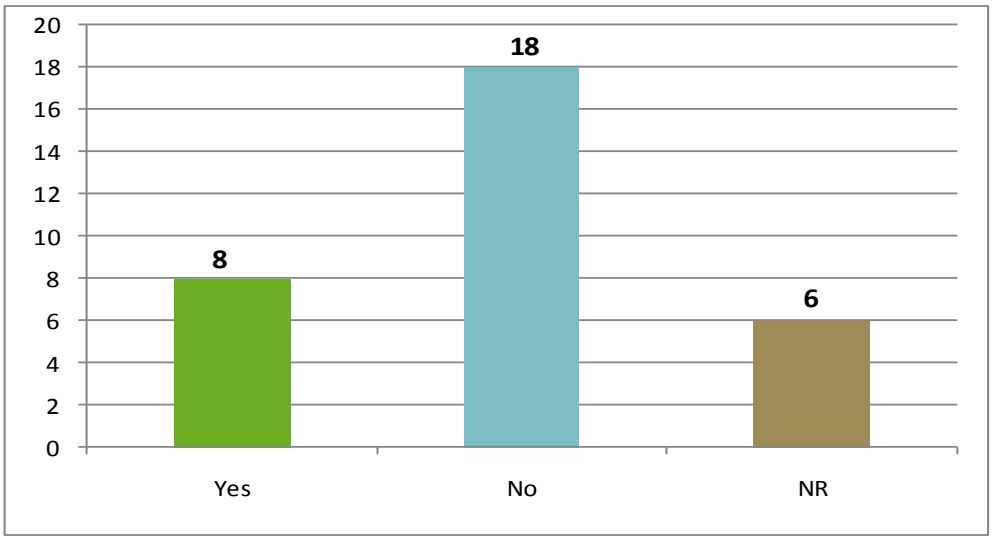
A1.3 Norms, accreditation and biosafety

Q1: Is there a national, up-to-date, register available for:

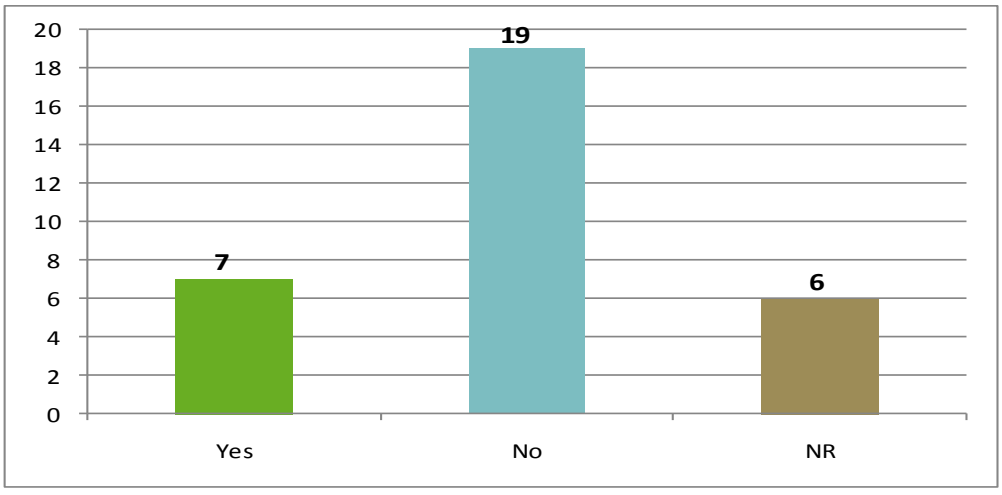
Public laboratories?



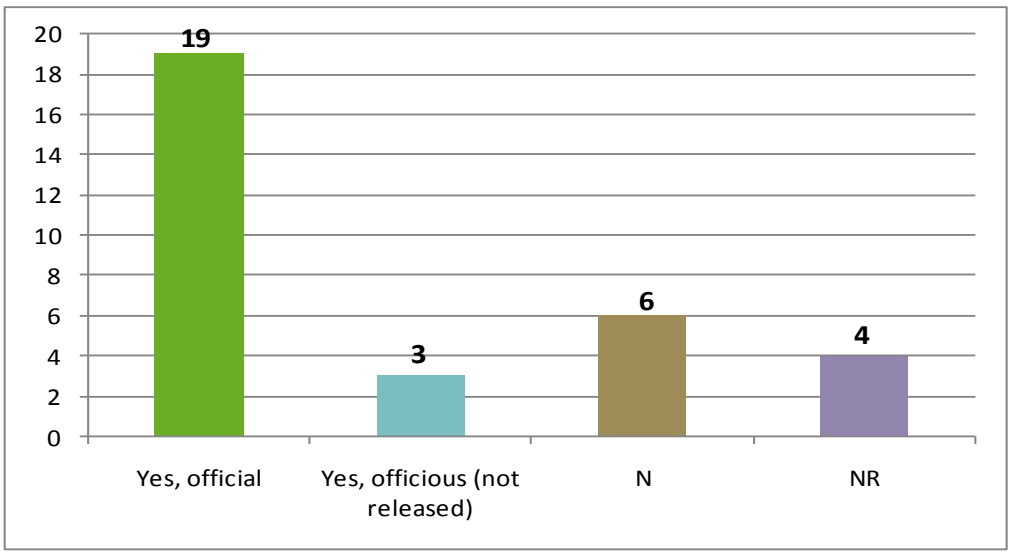
Private laboratories?



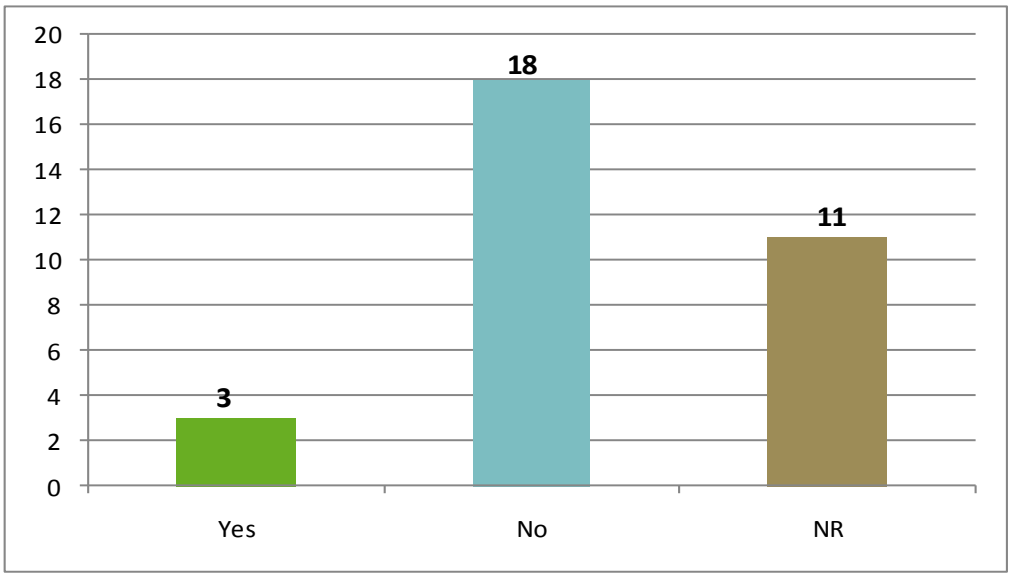
Research/University/other laboratories



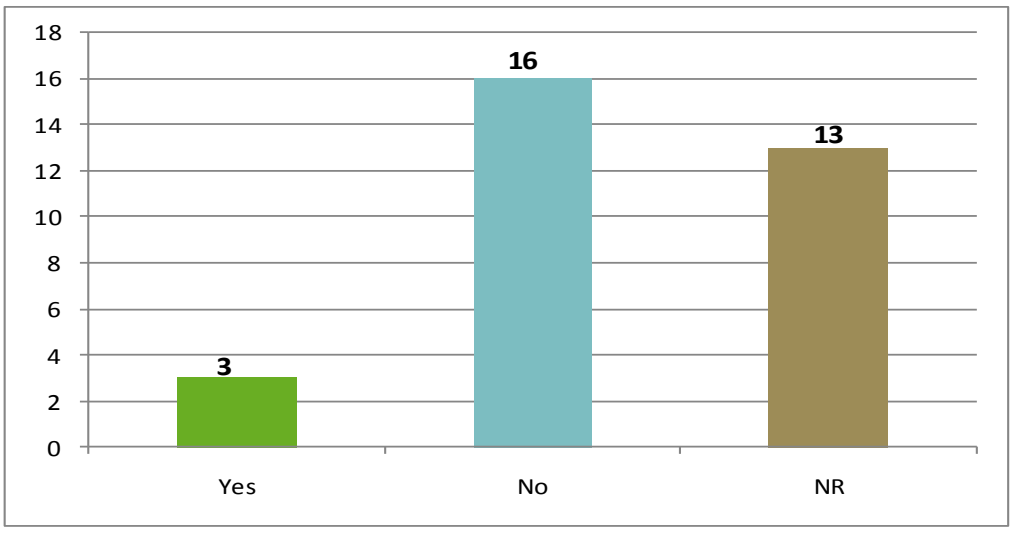
Q2: Are national norms (in general) for microbiology laboratories available



Q3: If yes, are they different for public/private/basic/hospital labs?

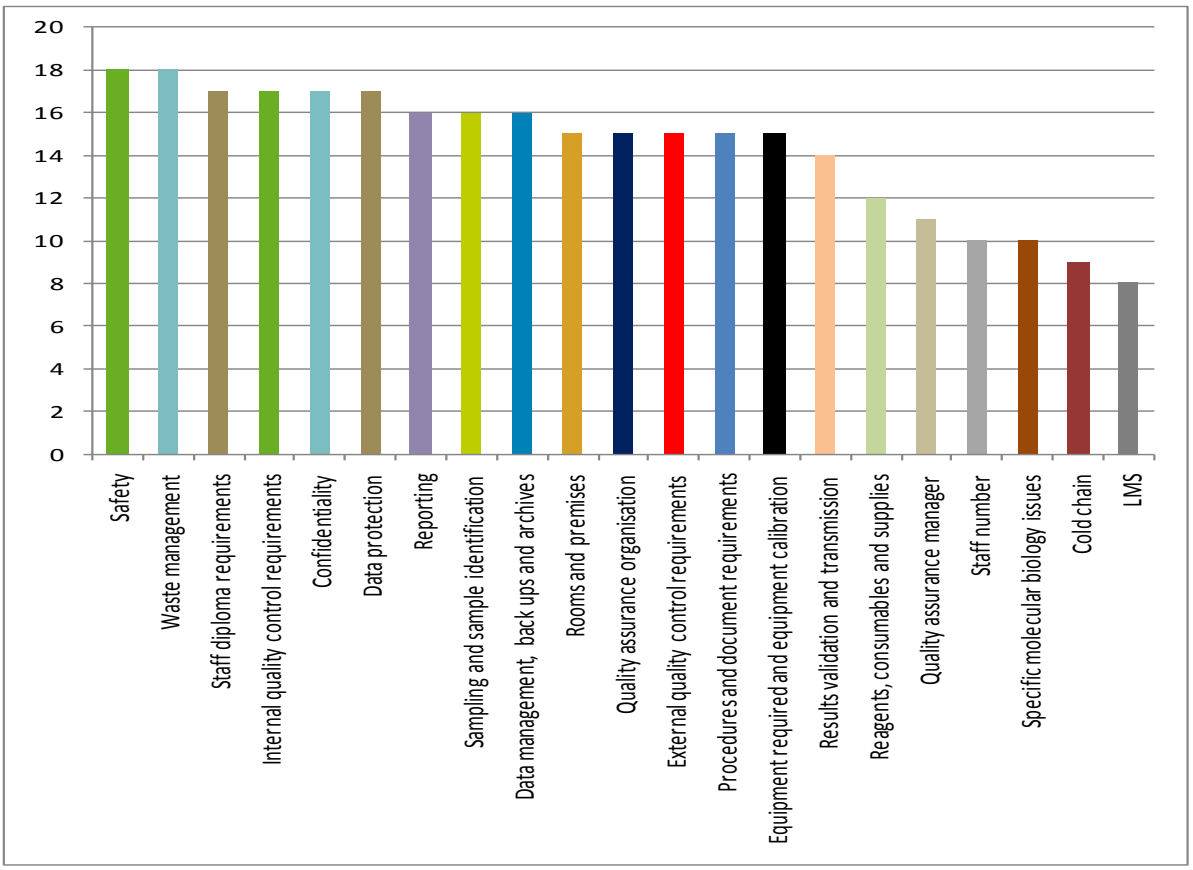


Q4: If yes, are they different for labs having contract with health insurance

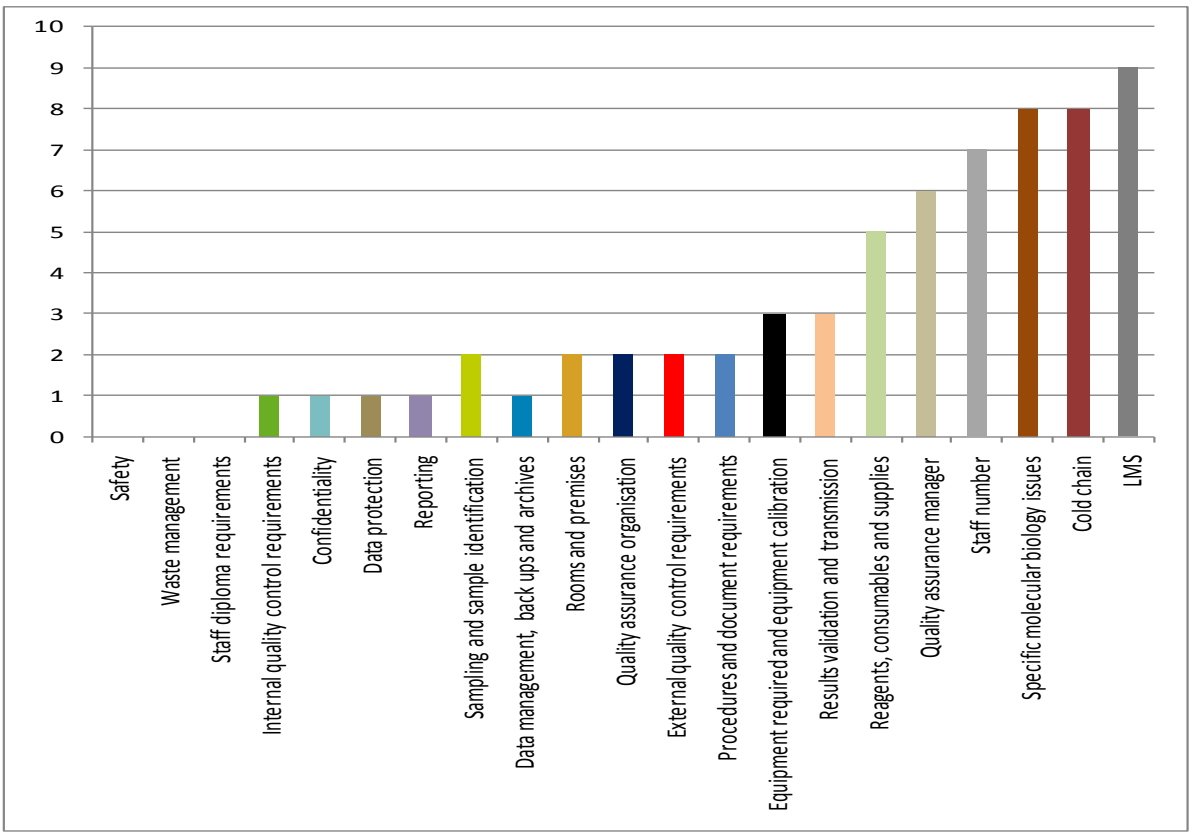


Q5: If yes, do these norms address the following topics:

19 replied yes for norms

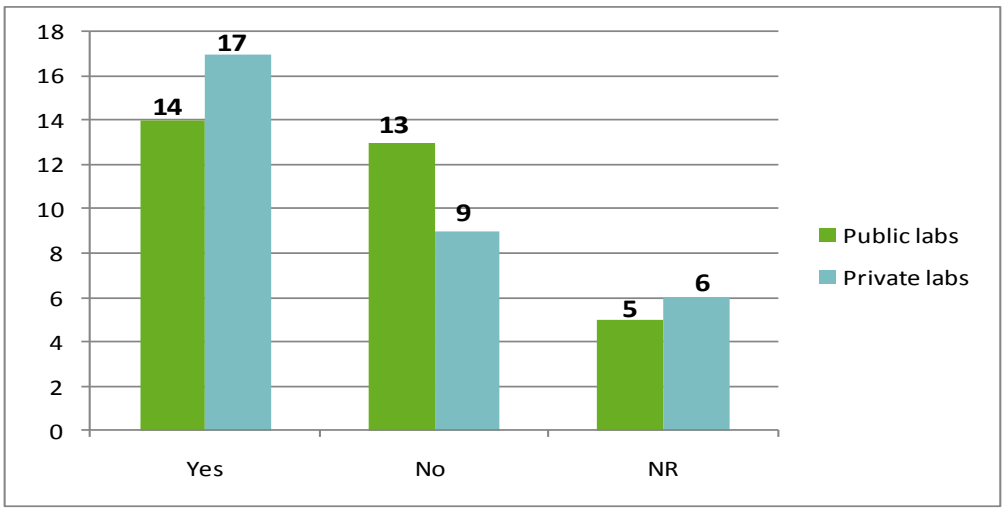


19 replied no for norms



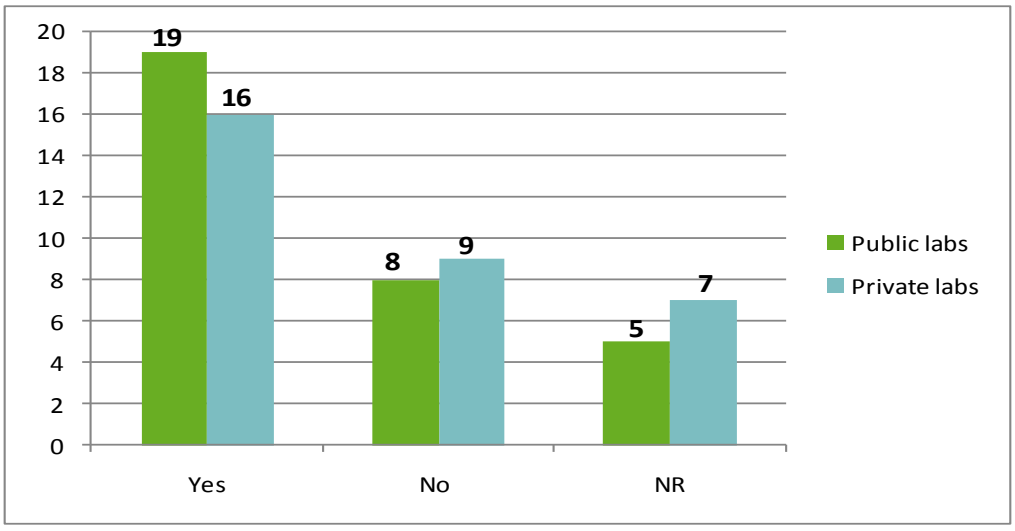
Licensing/opening authorisation

Q6: Do your laboratories request licensing prior to laboratory opening?

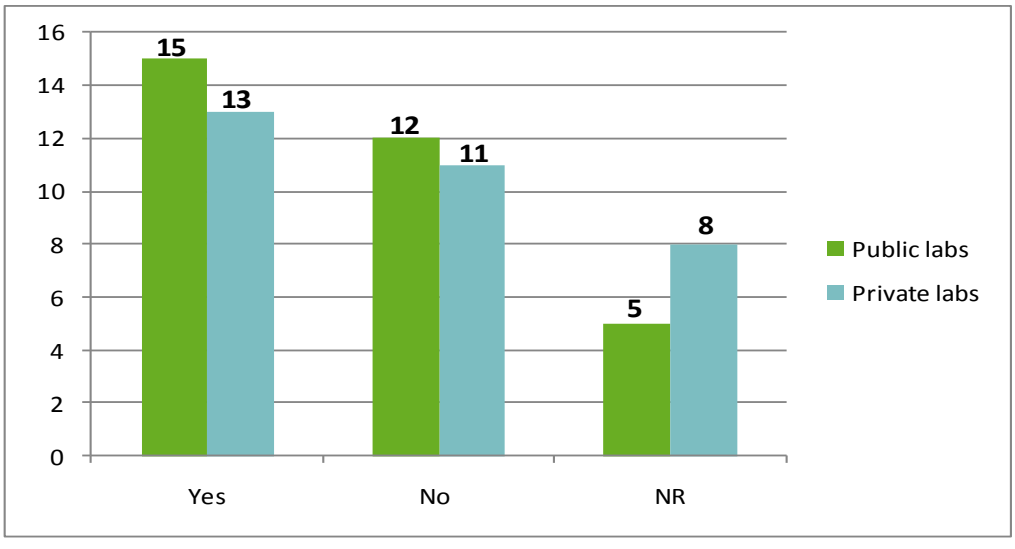


Specific case of AST norms (excluding TB and fungi)

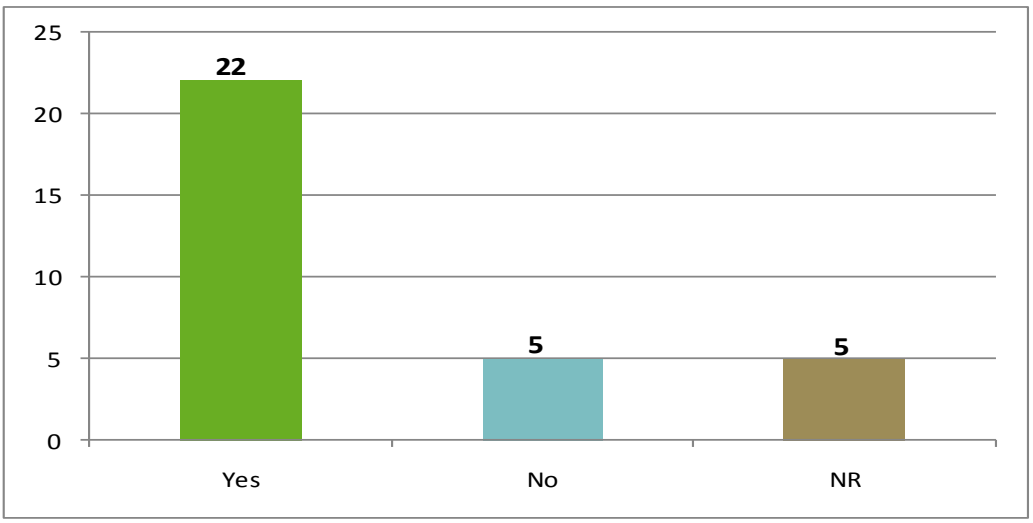
Q7: Does your country promote a norm/guideline for antimicrobial susceptibility testing?



Q8: Is antimicrobial susceptibility testing standardised at the national level?

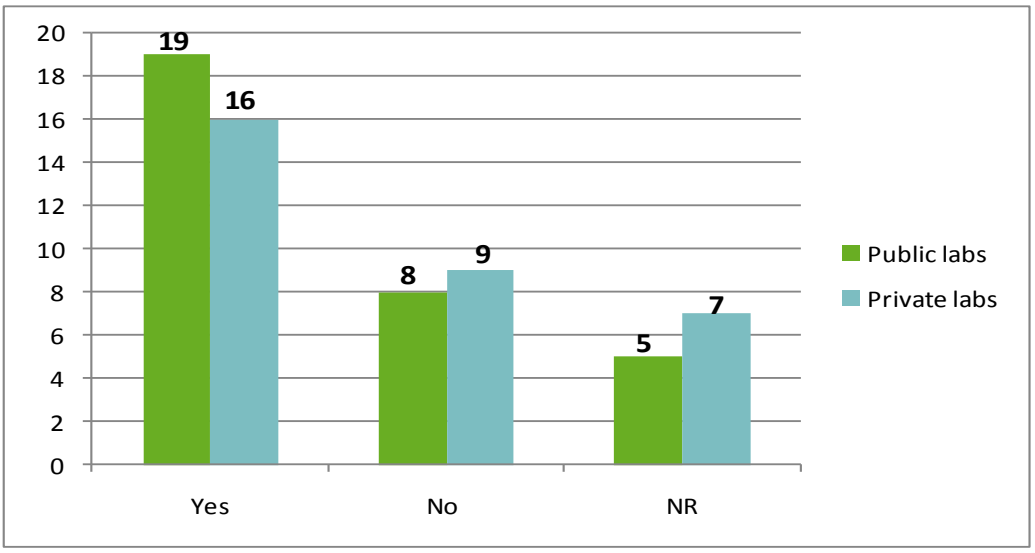


Q9: Is there a national programme for antimicrobial resistance surveillance in your country?



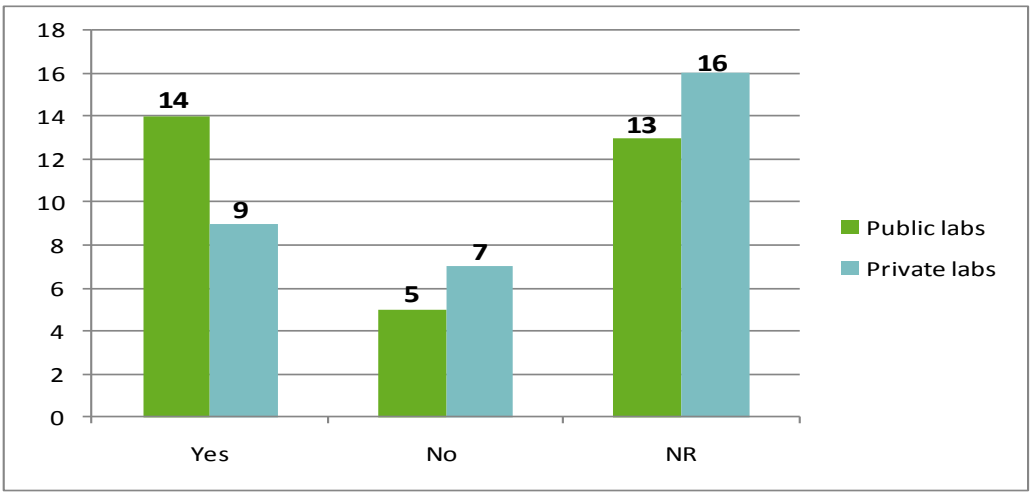
Promotion of QA at the national level

Q10: Is there a structure in charge of promoting QA at the national level?

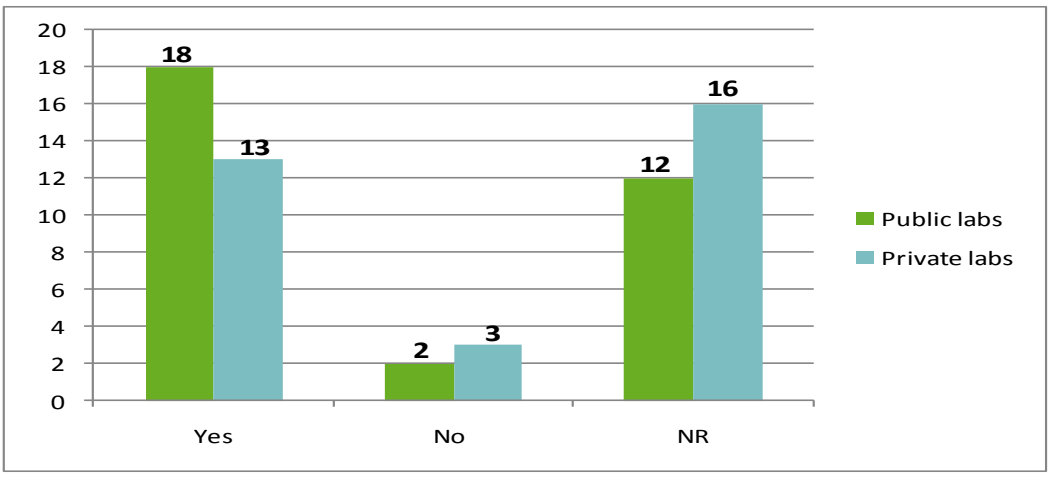


Q11: If yes, are they using the following activities:

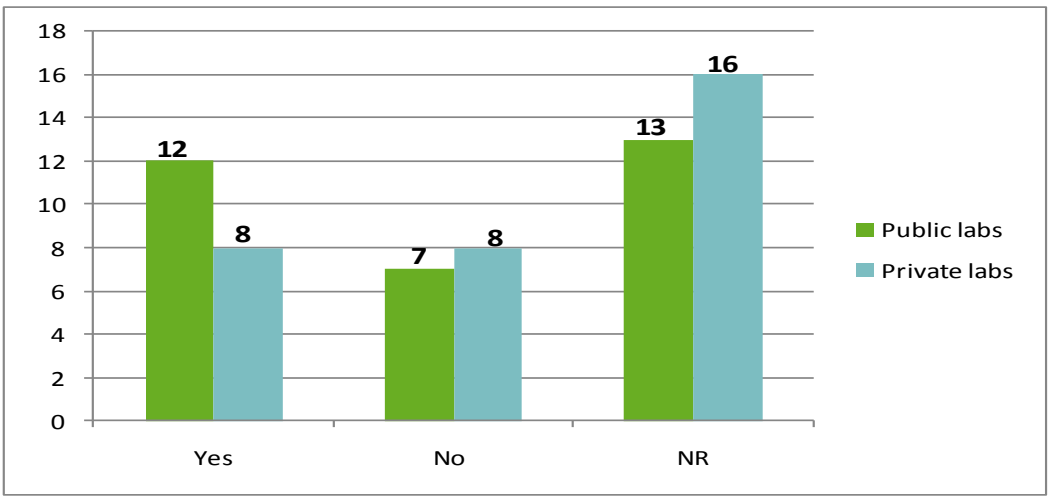
Production of guidelines?



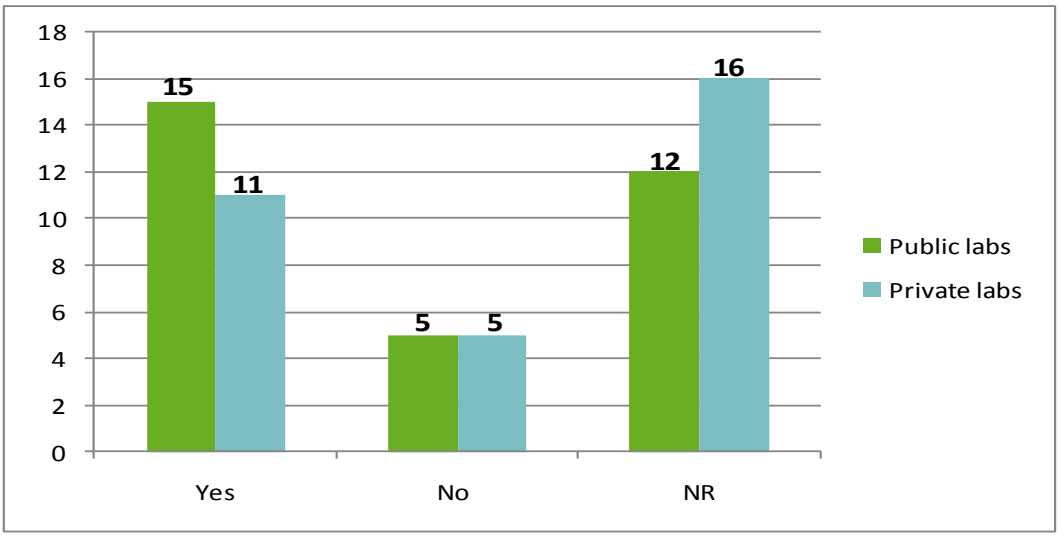
Laboratory evaluation and audits?



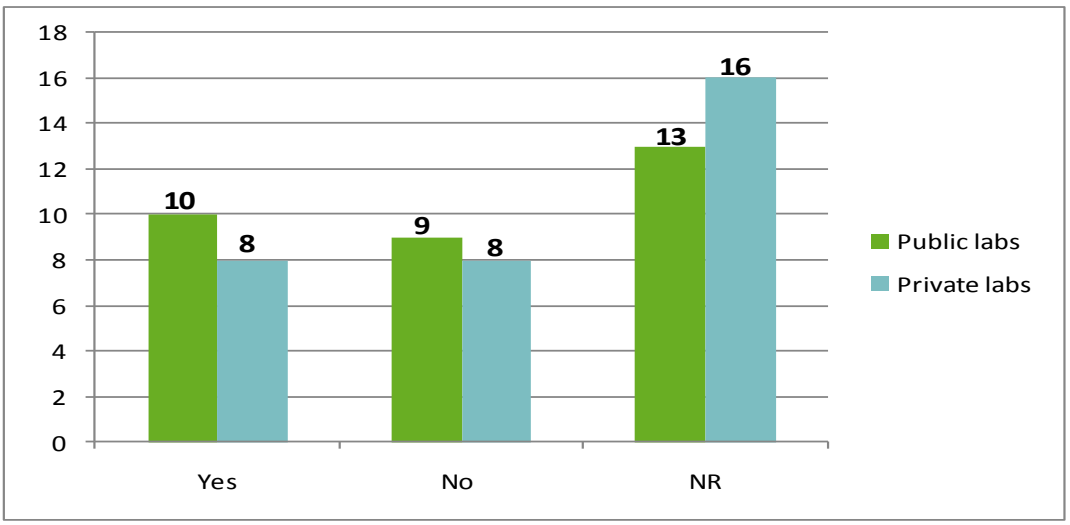
Organisation of continuous training?



Organisation/promotion of EQC schemes

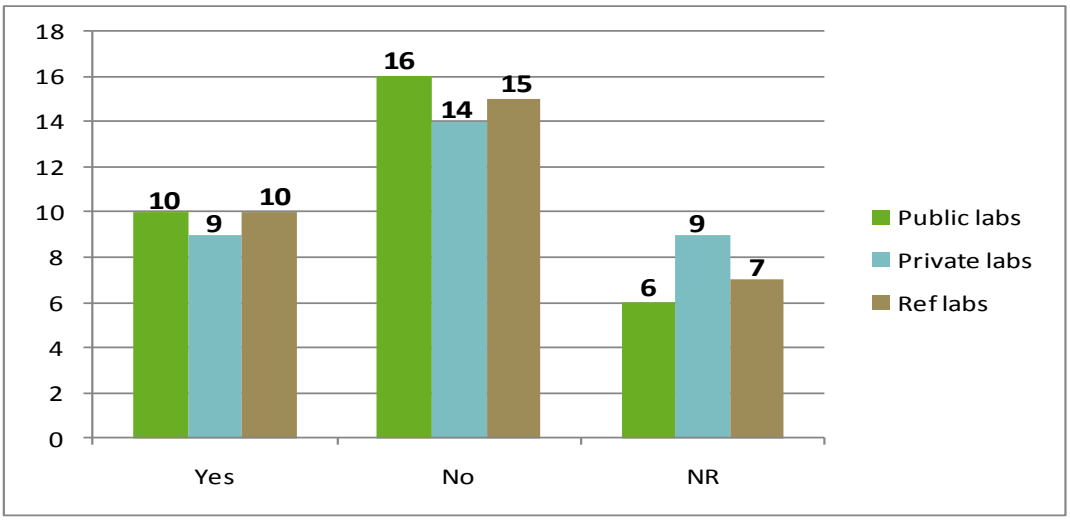


Repression if standards are not met

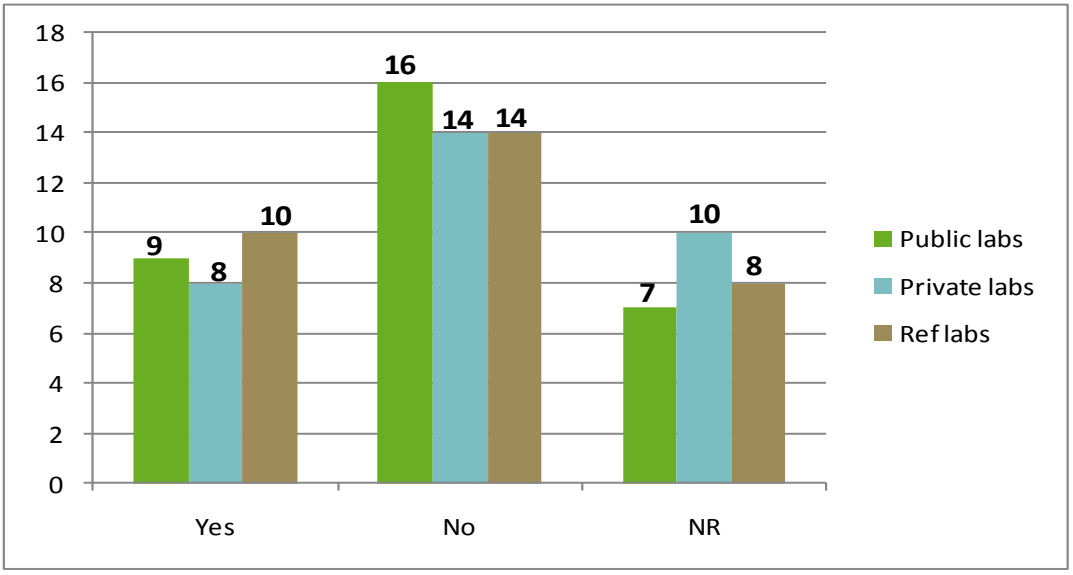


QA management at laboratory level

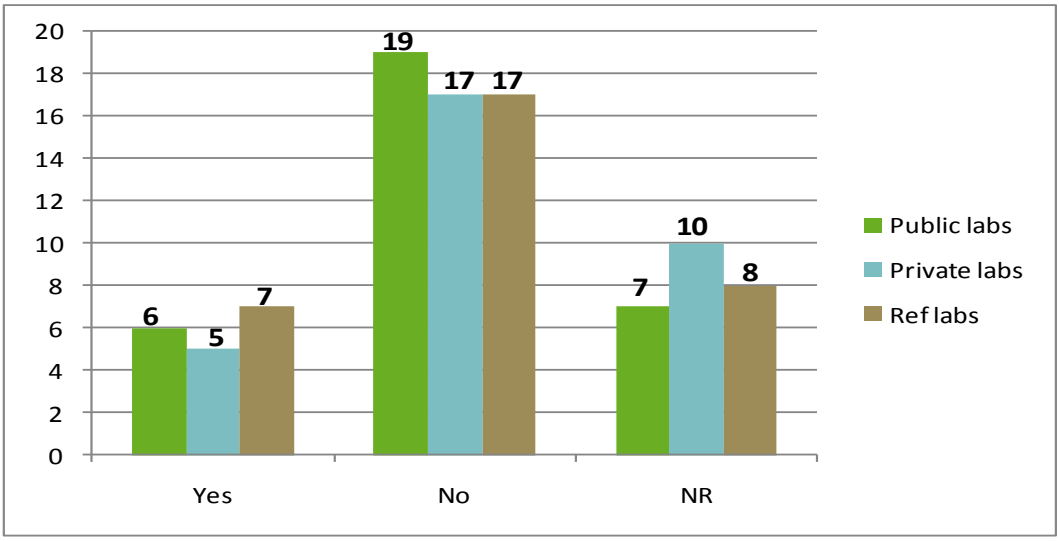
Q12: Is the position of QA manager mandatory?



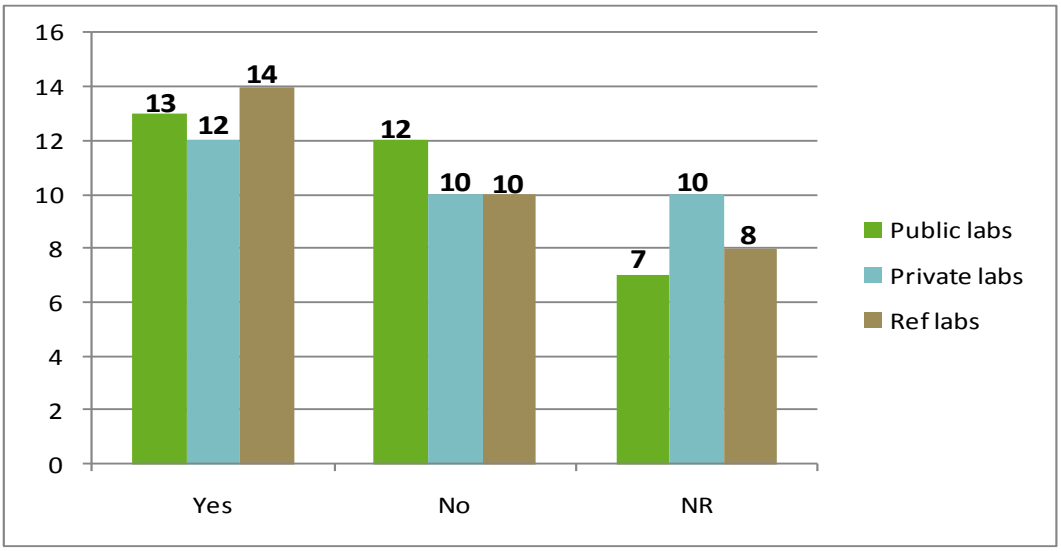
Q13: Is there a specific training for QA manager in their laboratory



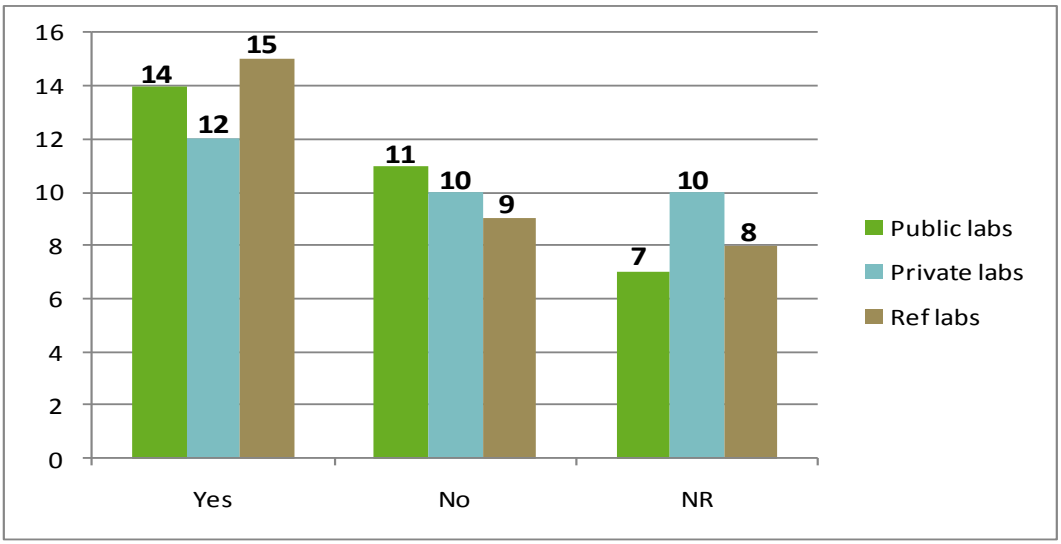
Q14: Is there a specific training for QA manager at the national level



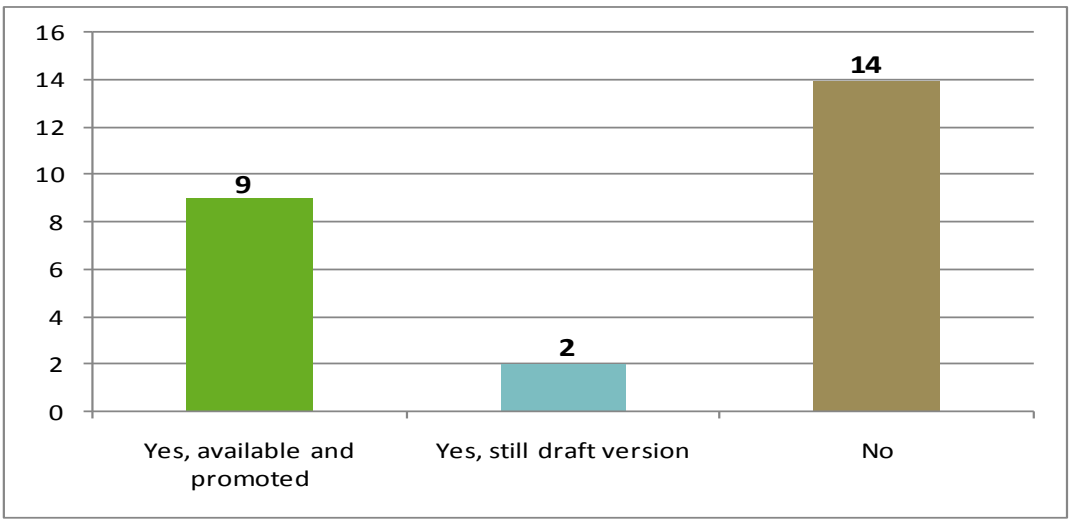
Q15: Is each lab required to develop a quality management system (QMS)



Q16: Is a QA manual (QAM) required in each lab?

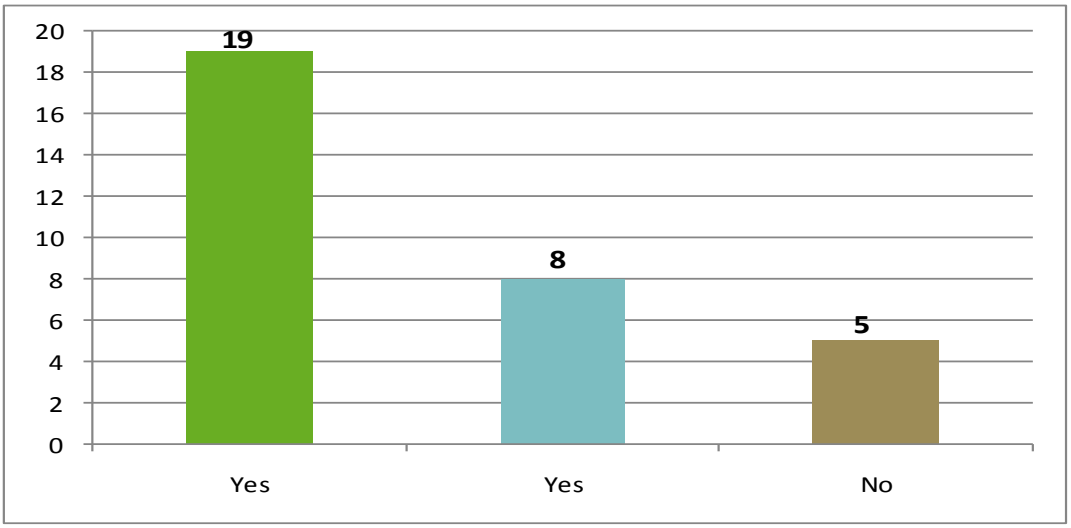


Q17: Is a national guideline for QAM production available and promoted?

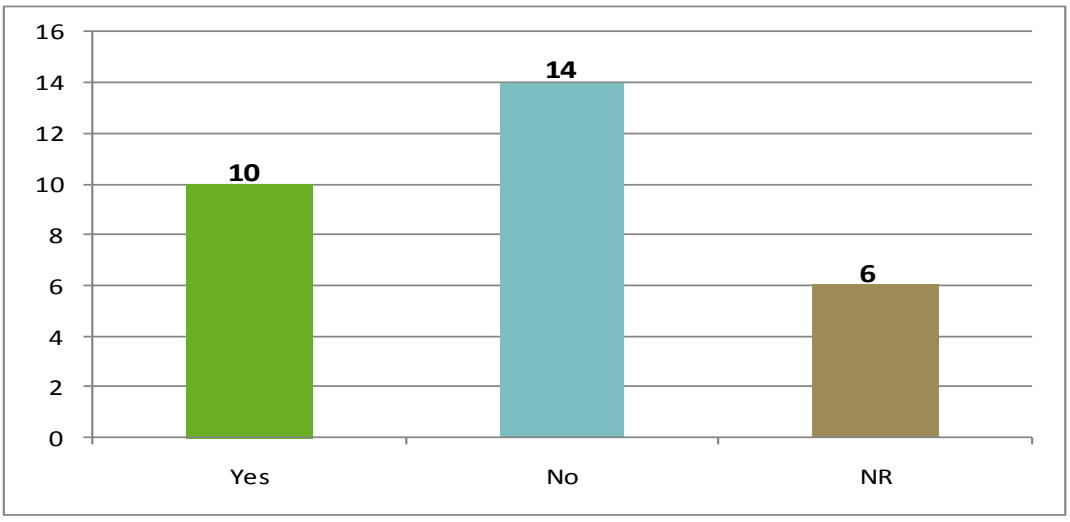


External Quality Control/Proficiency Testing (PT)

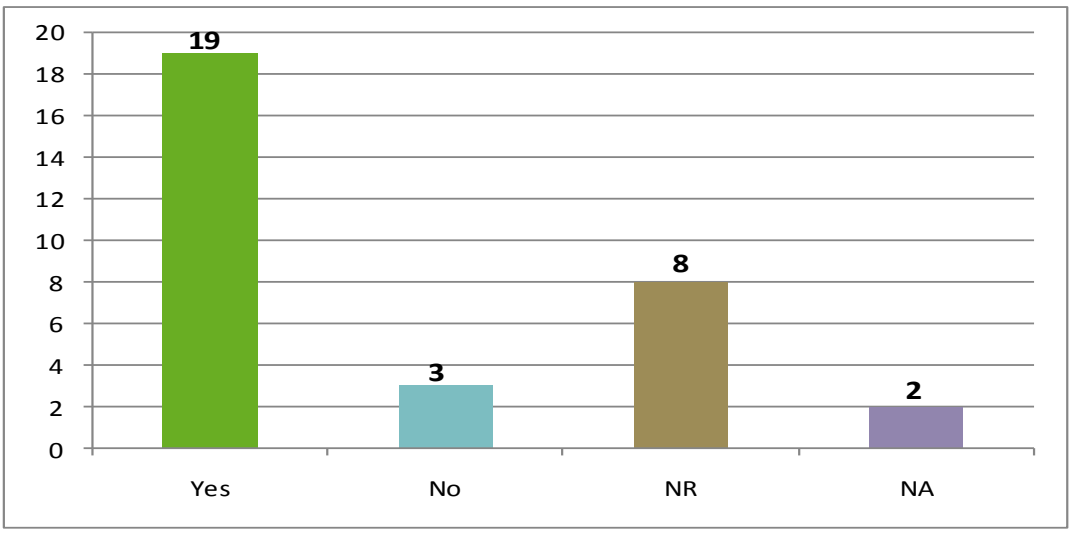
Q18: Does a PT organiser for microbiology exist in your country?



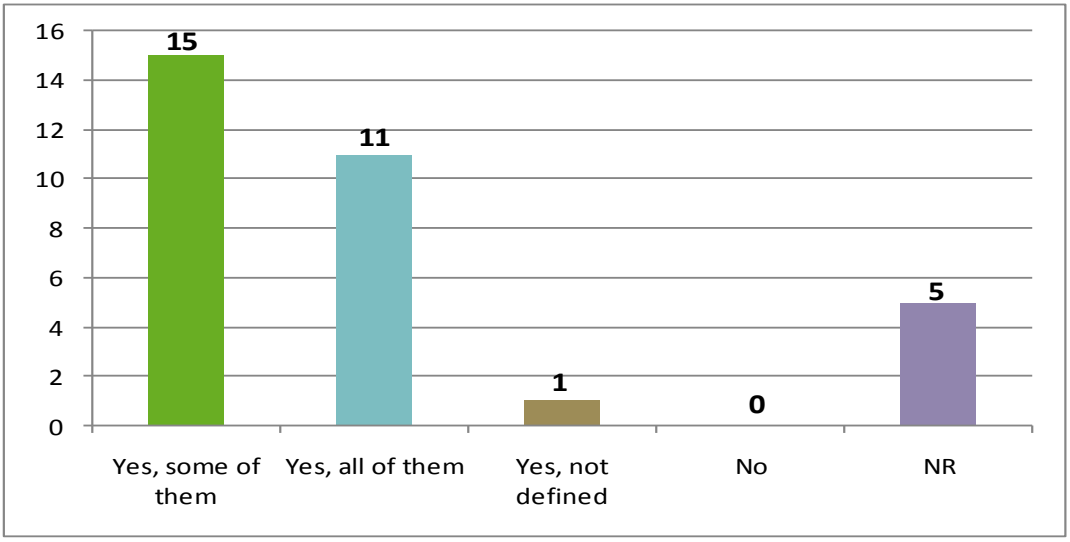
Q19: Does Ministry of Health have direct contact with this/these PT provider(s)?



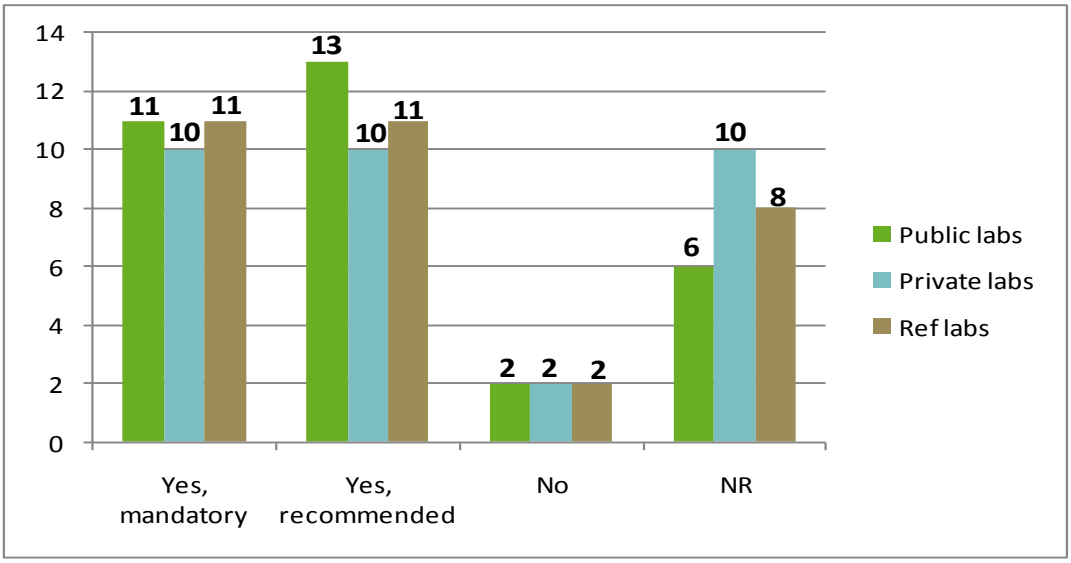
Q20: When a national provider is not available, are you using an international one?



Q21: Are NRLs participating in international PT programmes?

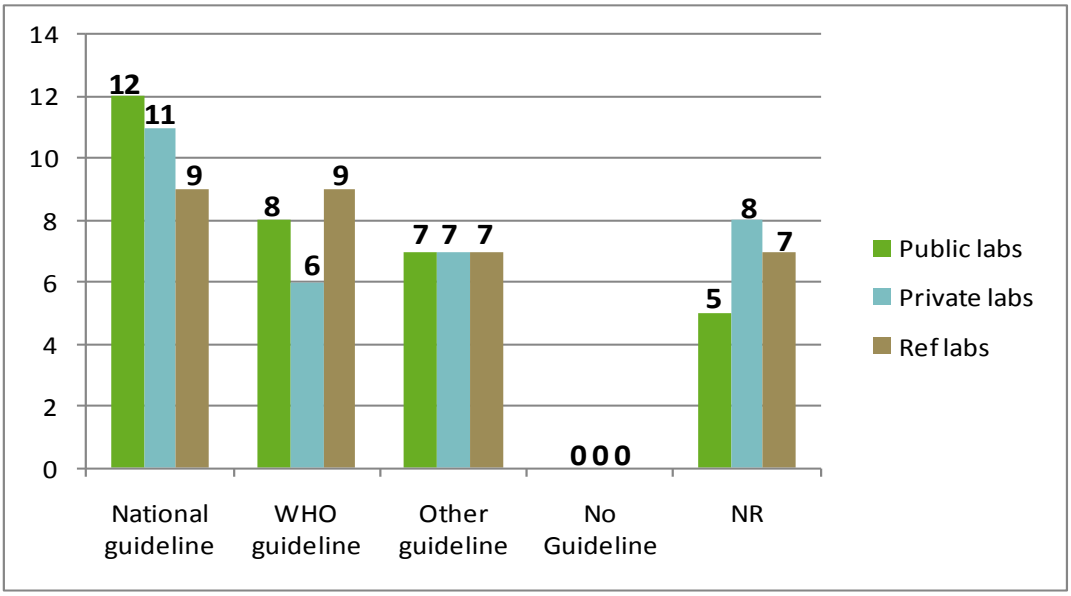


Q22: Is regular participation in PT programmes required?

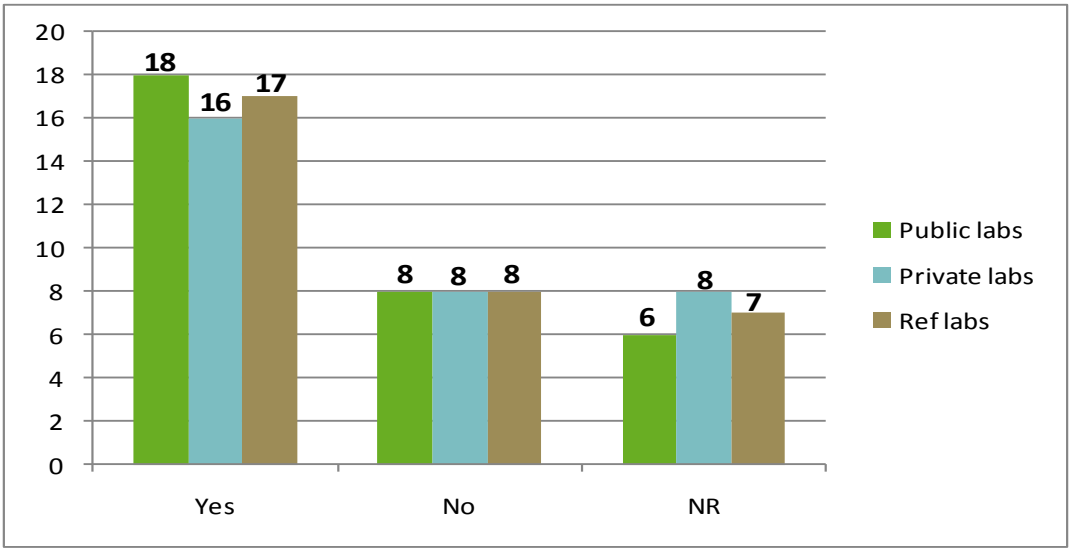


Biosafety issues

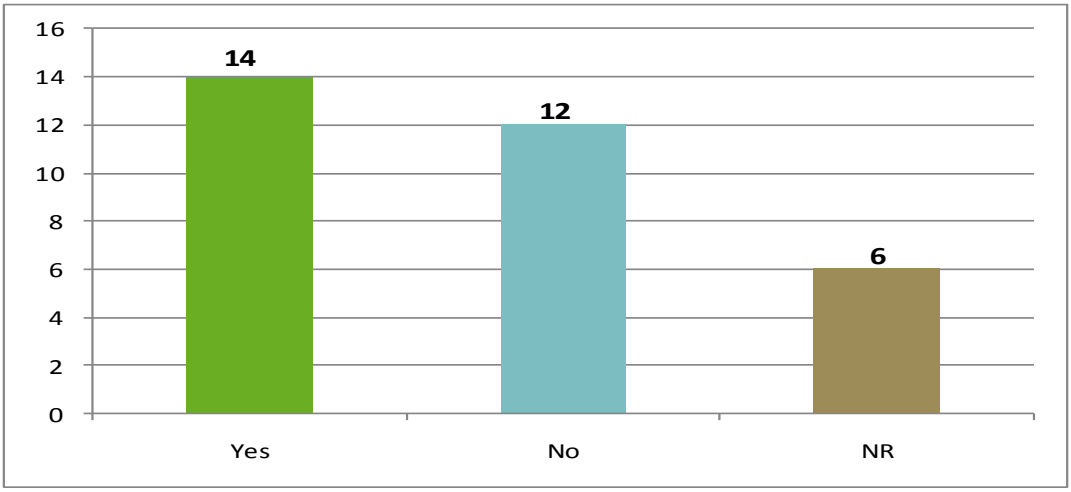
Q23: Do your laboratories use a biosafety guideline?



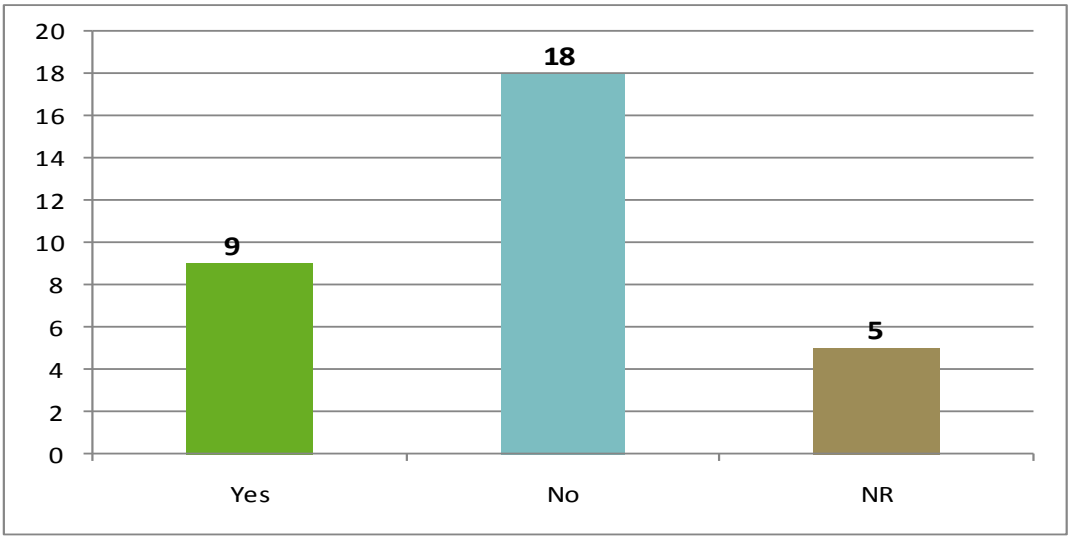
Q24: Is there any official national regulation stating laboratory biosafety levels and conditions



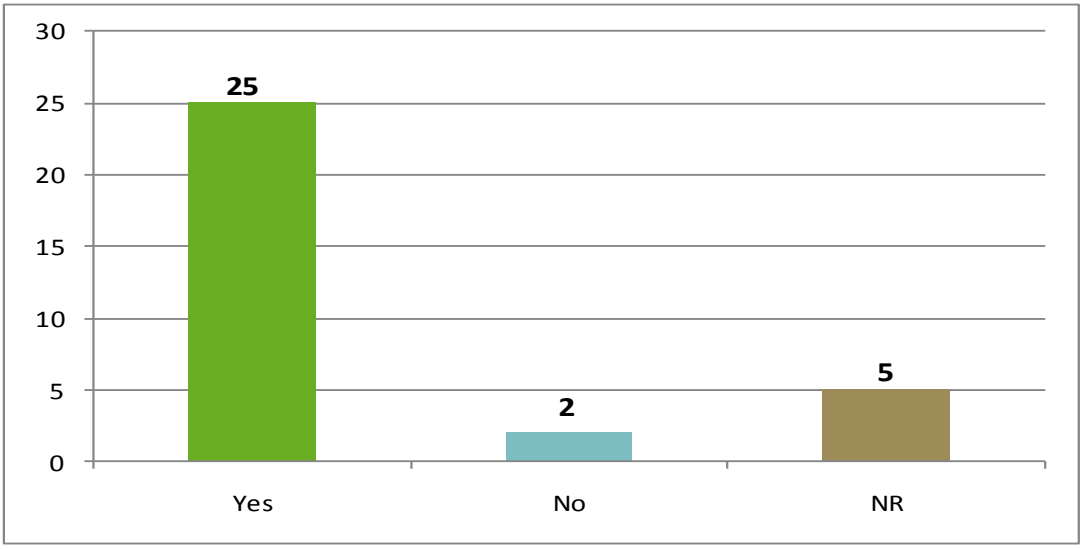
Q25: Is there any national institute commissioning BSL3/4 laboratories



Q26: Is any training in biosafety organised or promoted at national level?

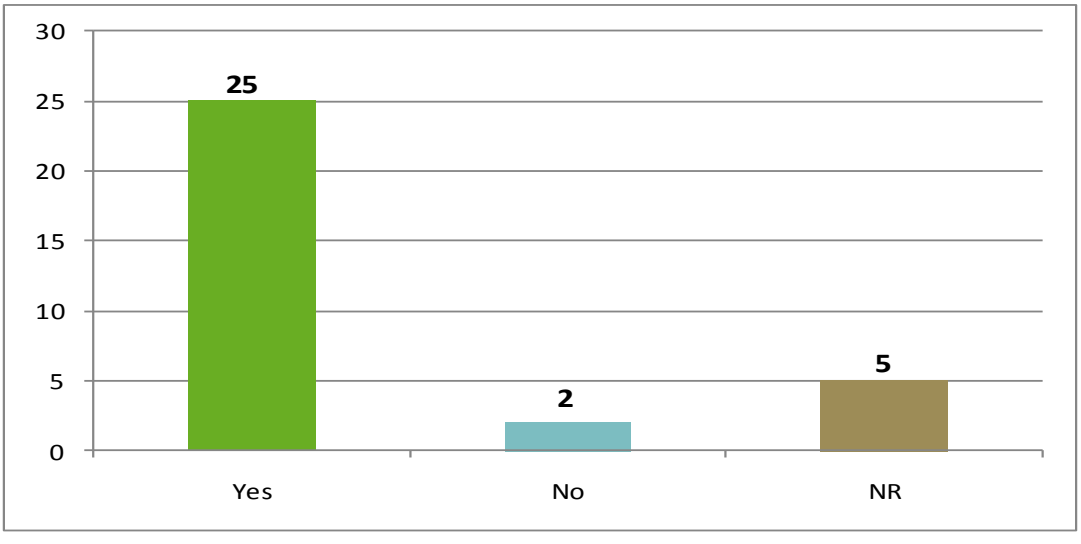


Q27: Is there any specific medical follow-up/vaccination for laboratory workers?



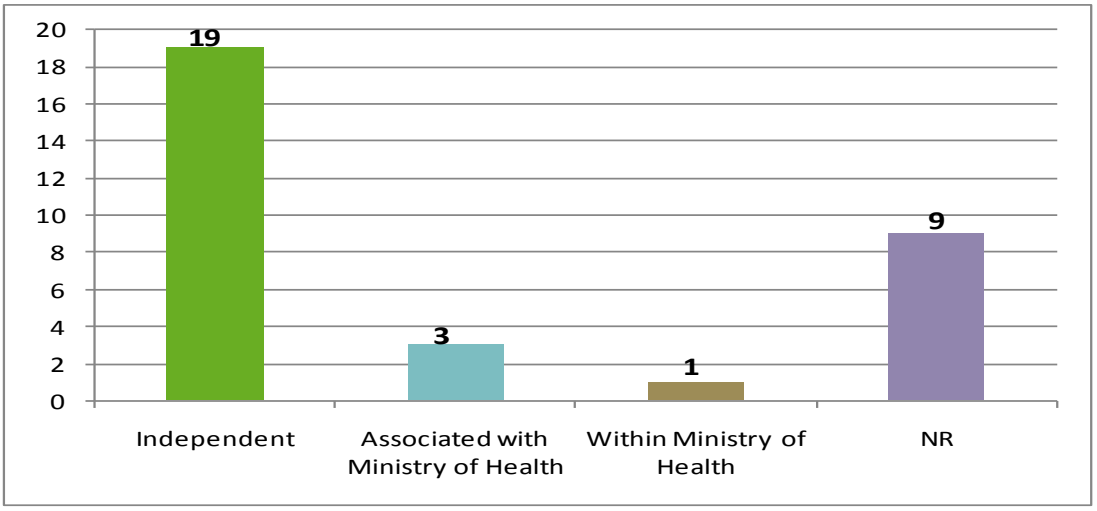
National accreditation body

Q28: Is there a national accreditation body

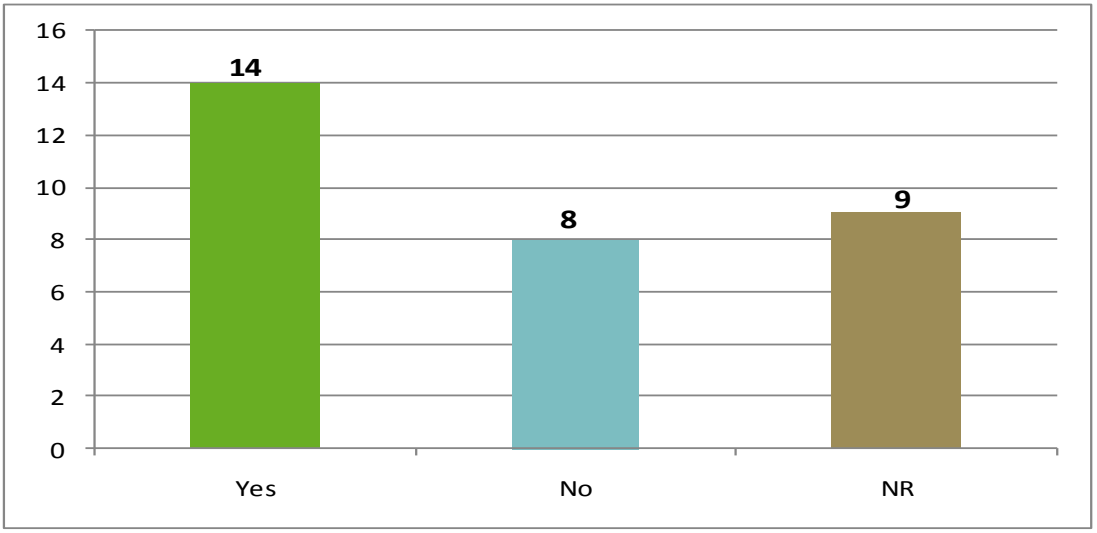


Q29: If yes:

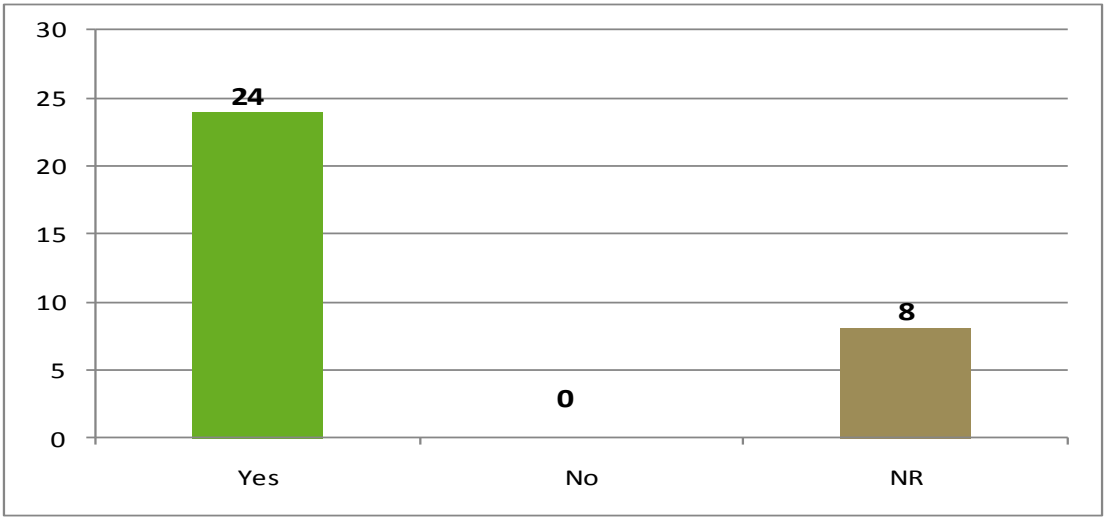
What is the national accreditation status?



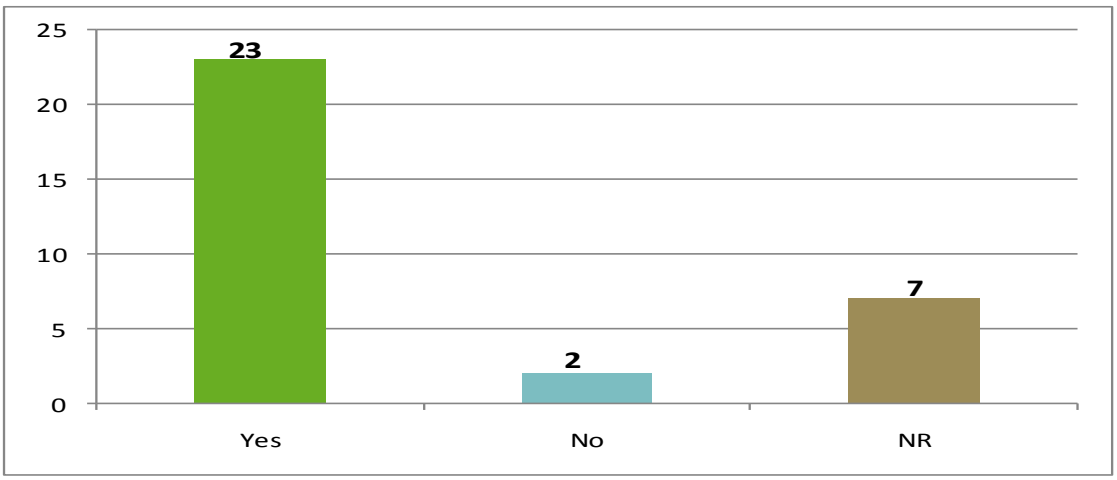
Are they issuing certification for "healthcare institutions" (ISO900X)?



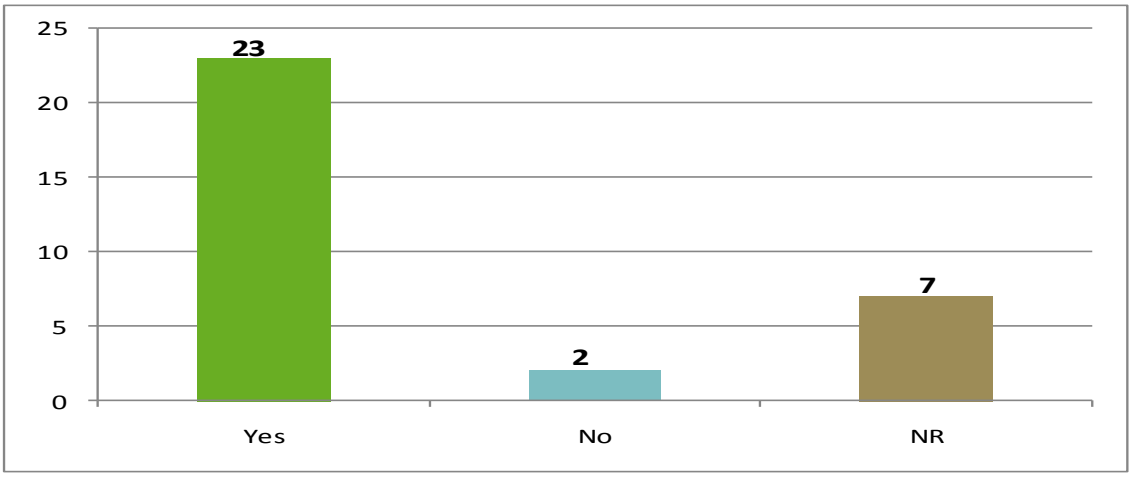
Are they using ISO standards?



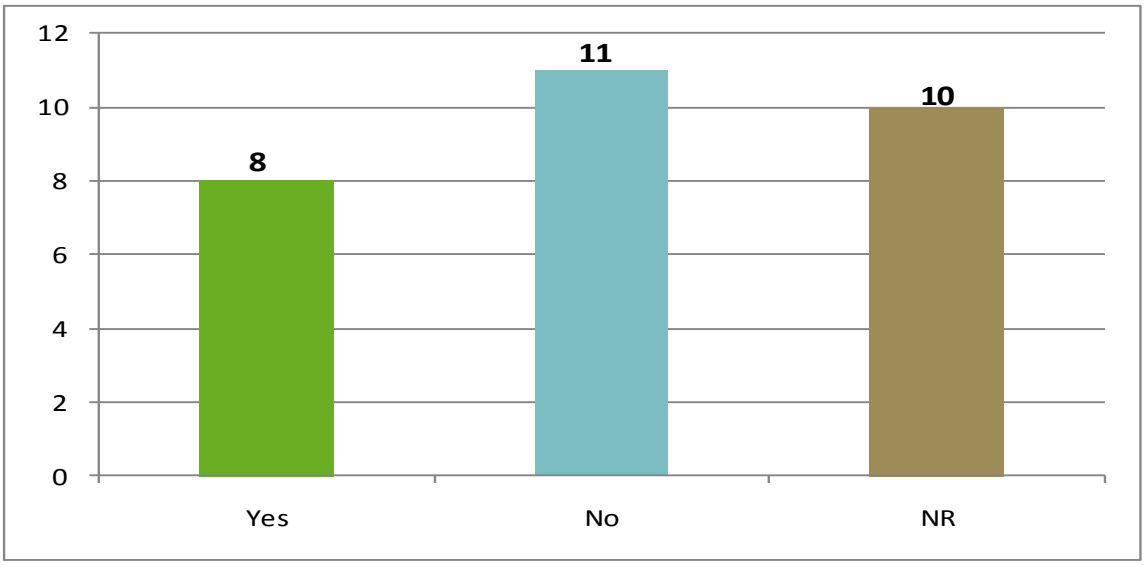
Are they issuing accreditation for trial laboratories (ISO17025)



Are they issuing accreditation for human laboratories (ISO15189)

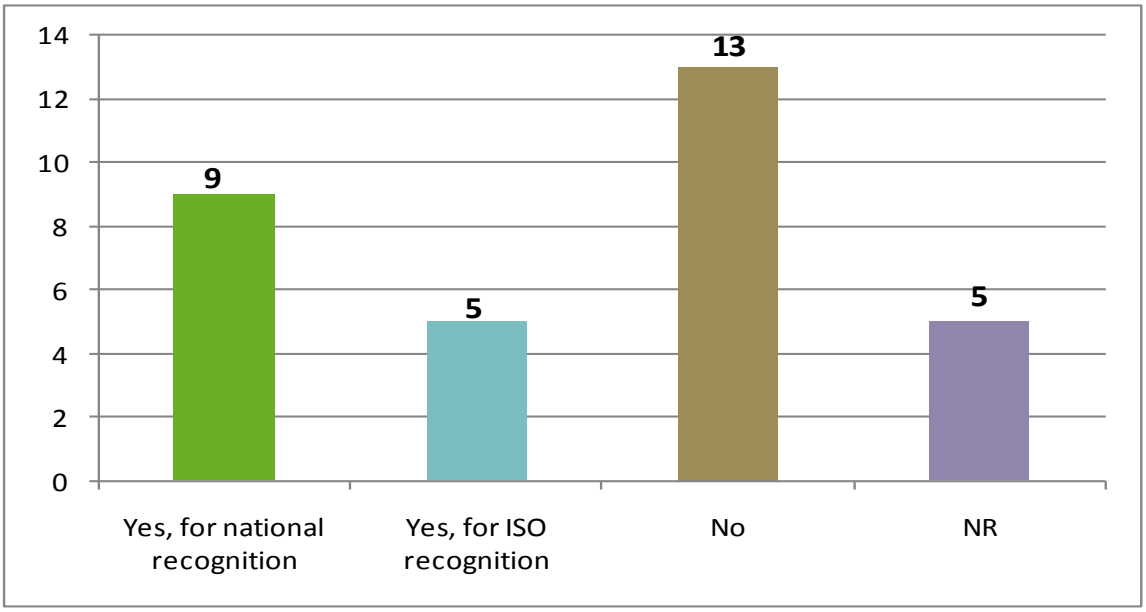


Are they using other laboratory related schemes?

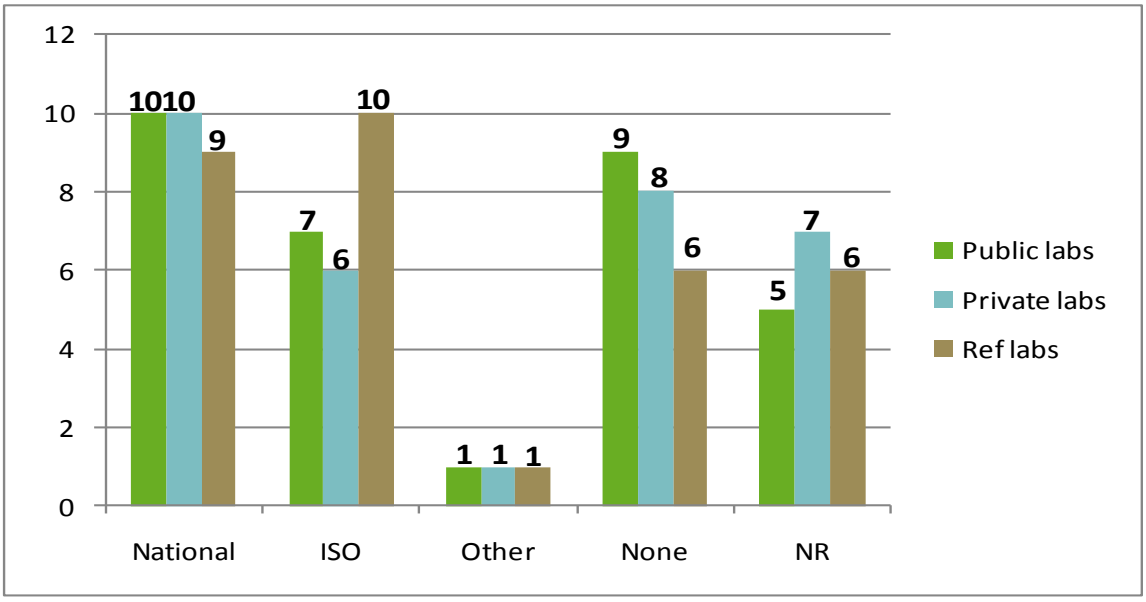


Official recognition of laboratory quality level

Q30: Is the Ministry of Health promoting and providing guidance for official recognition?



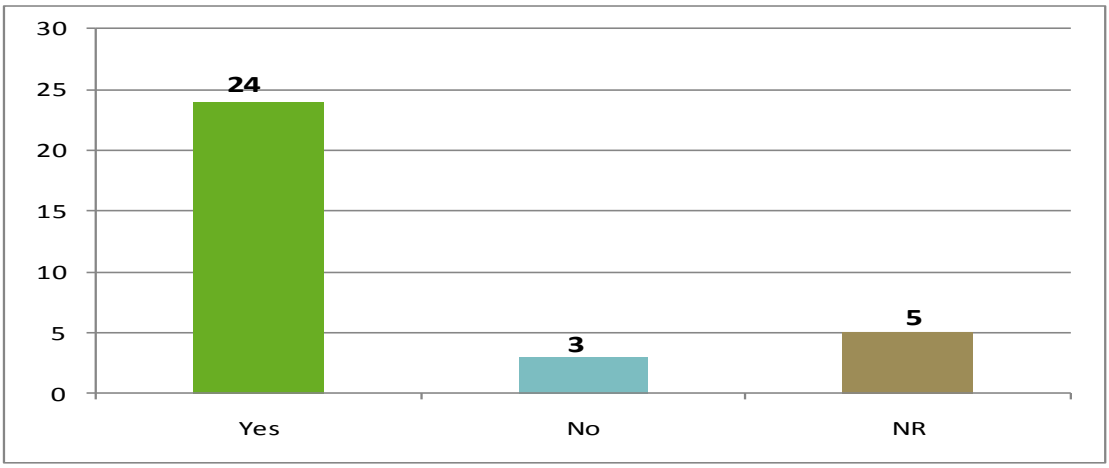
Q31: Is any type of official recognition required?



A1.4 Education and training

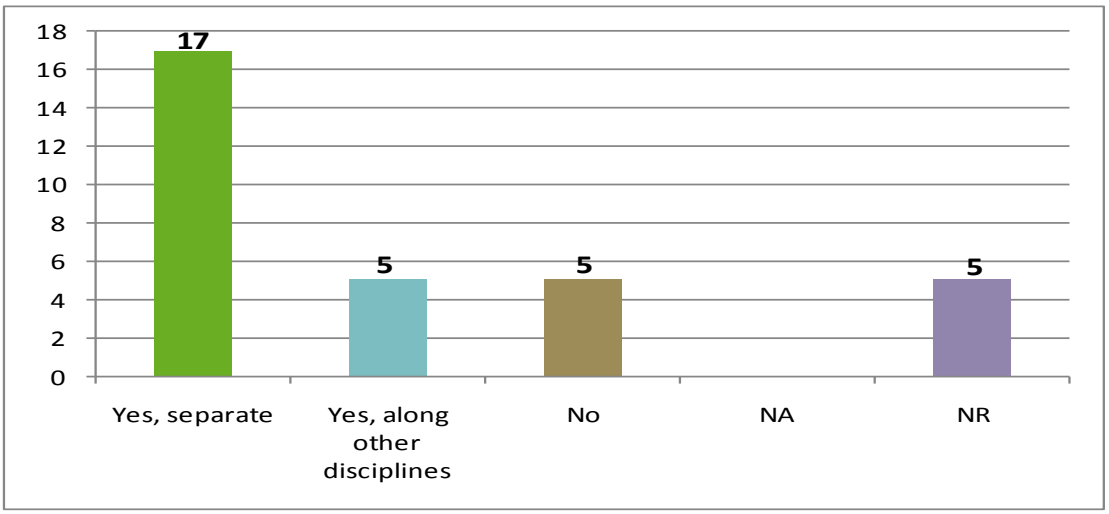
Initial training

Q1: Is microbiology recognised as a specialty separate from pathology?

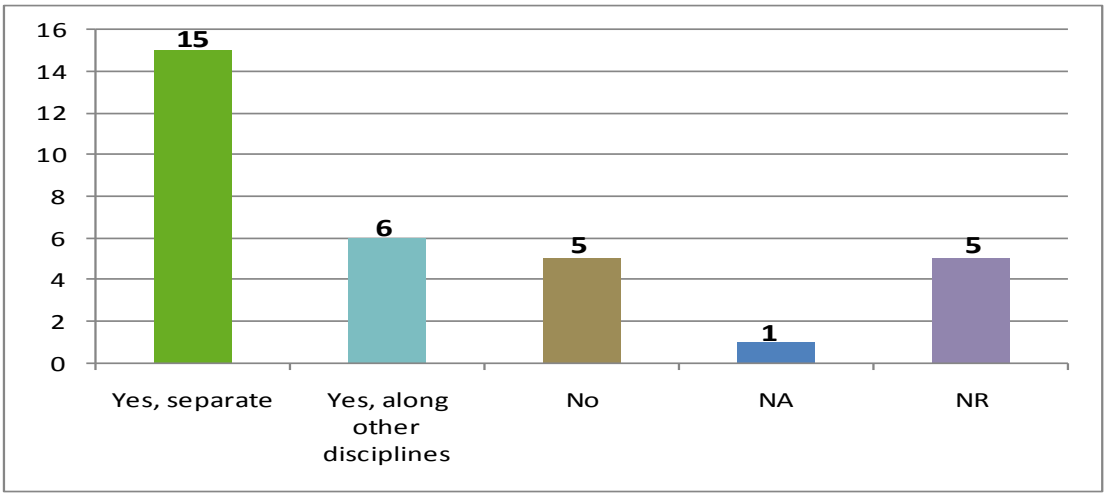


Q2: Is there any specialised microbiology training for:

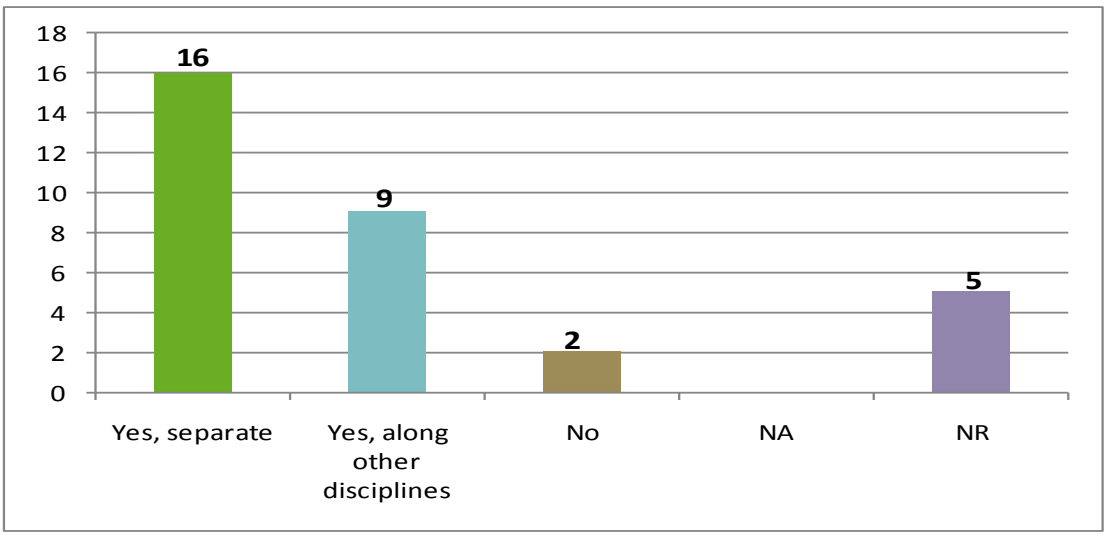
Medical microbiologist (human)?



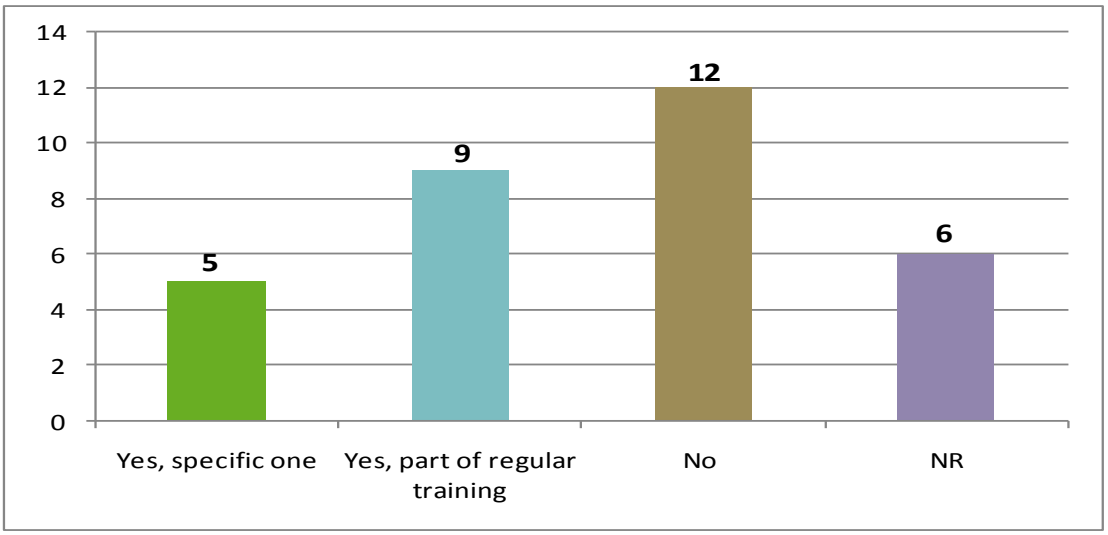
Q3: Non-medical microbiologist?



Q4: Laboratory technicians?

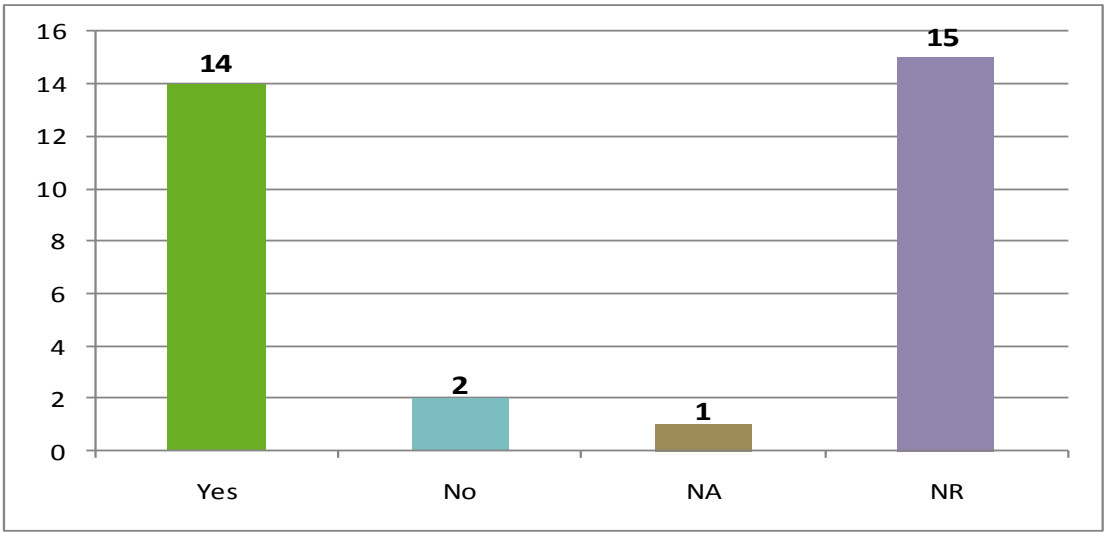


Q5: Is there any specialised public health microbiology training in your country?

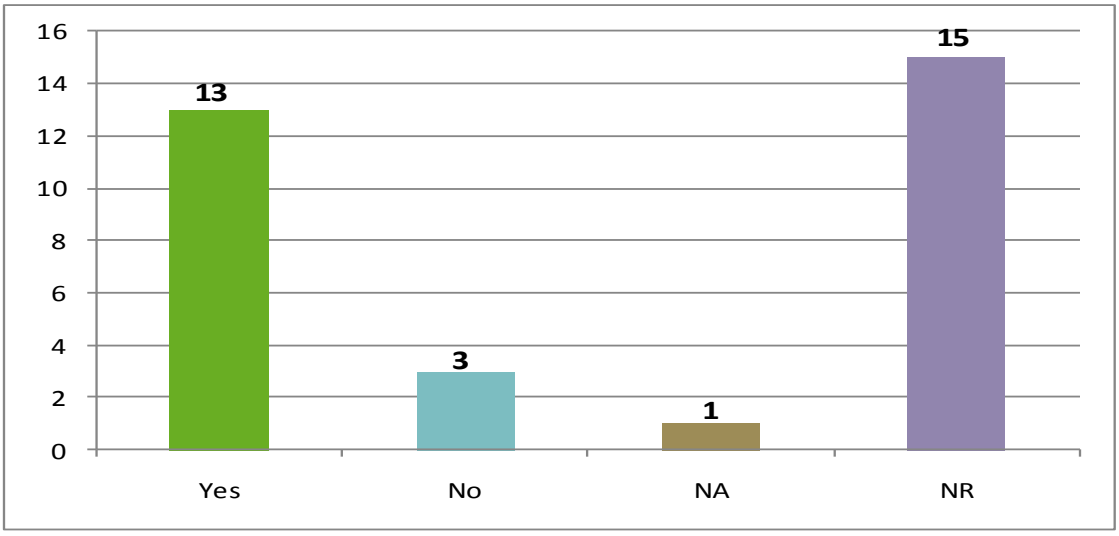


Q6: If yes,

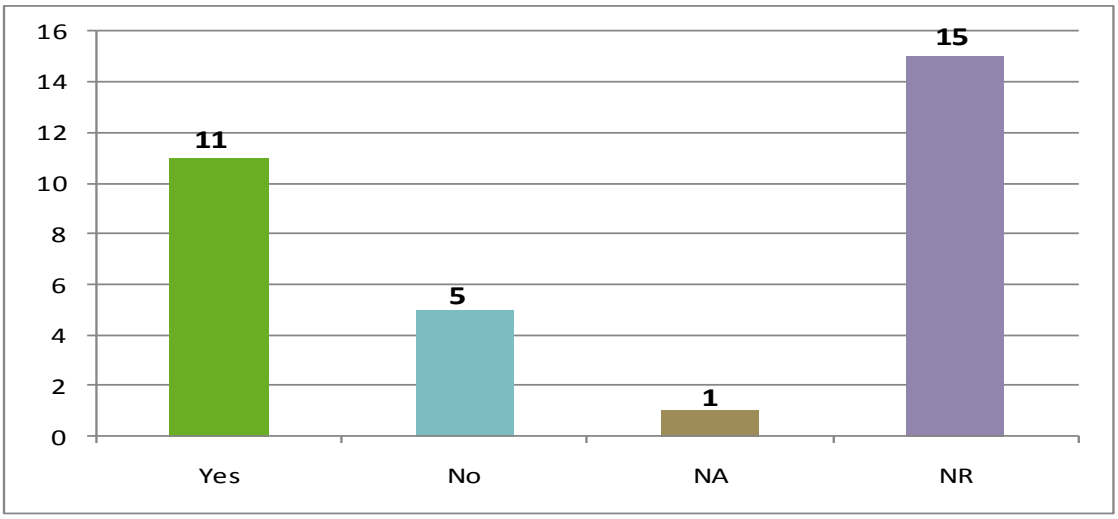
Does it include human microbiology?



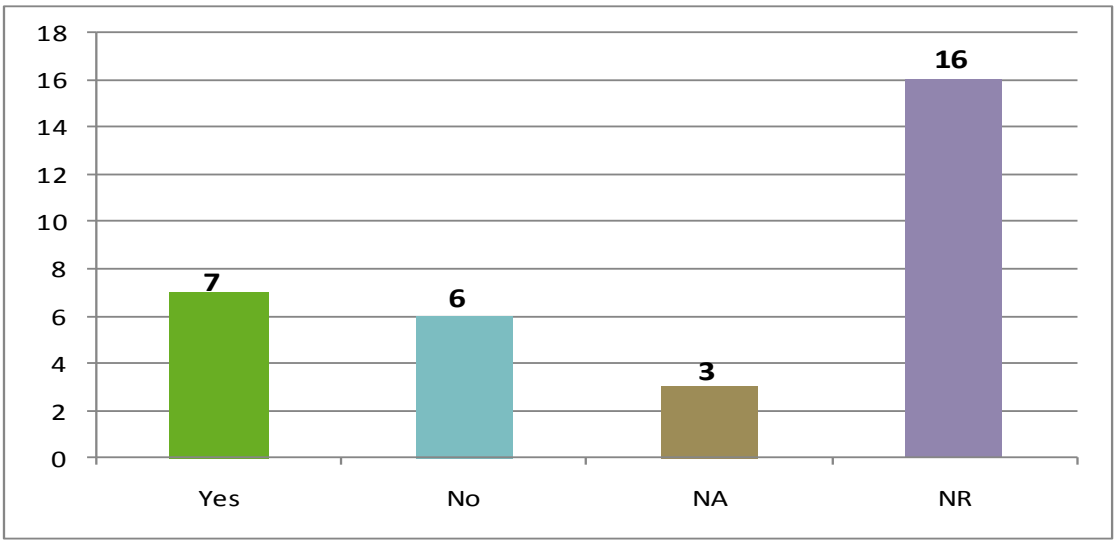
Q7: Does it include food and environmental microbiology?



Q8: Does it include any epidemiology training?

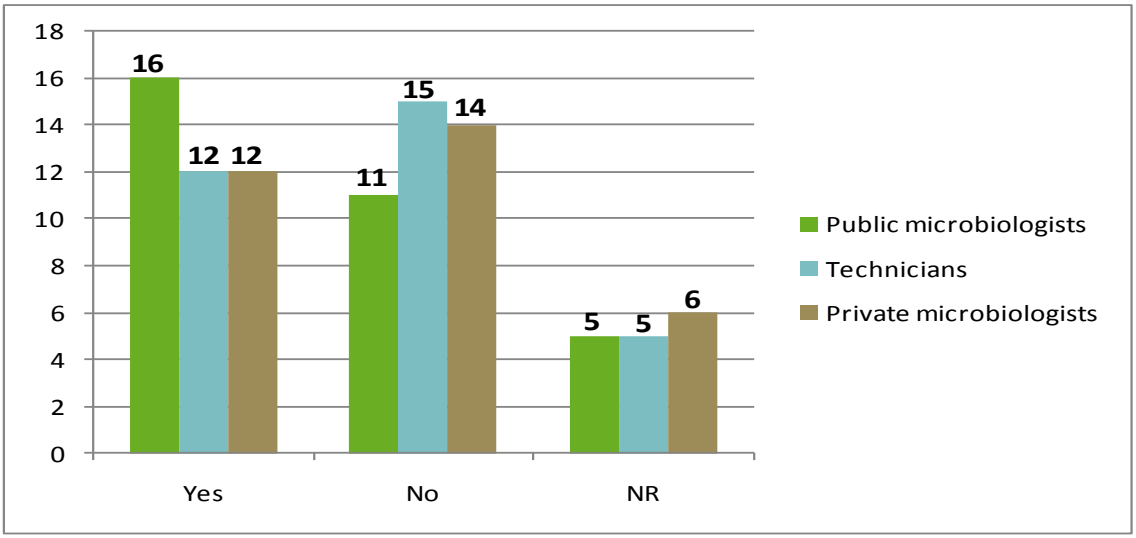


Q9: For any of the above mentioned training, is any accreditation process in place?

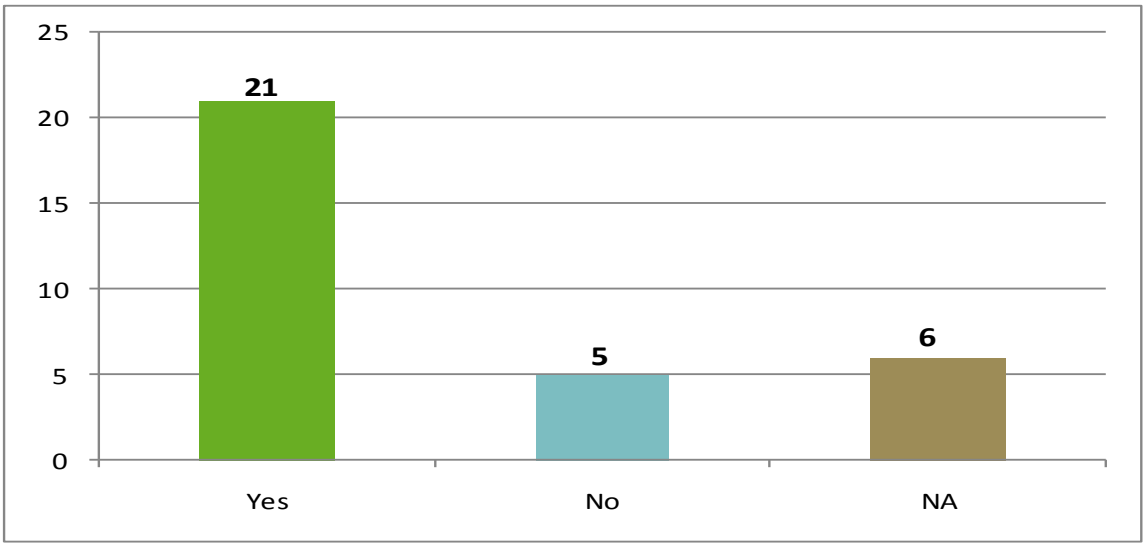


Continuous and specific training

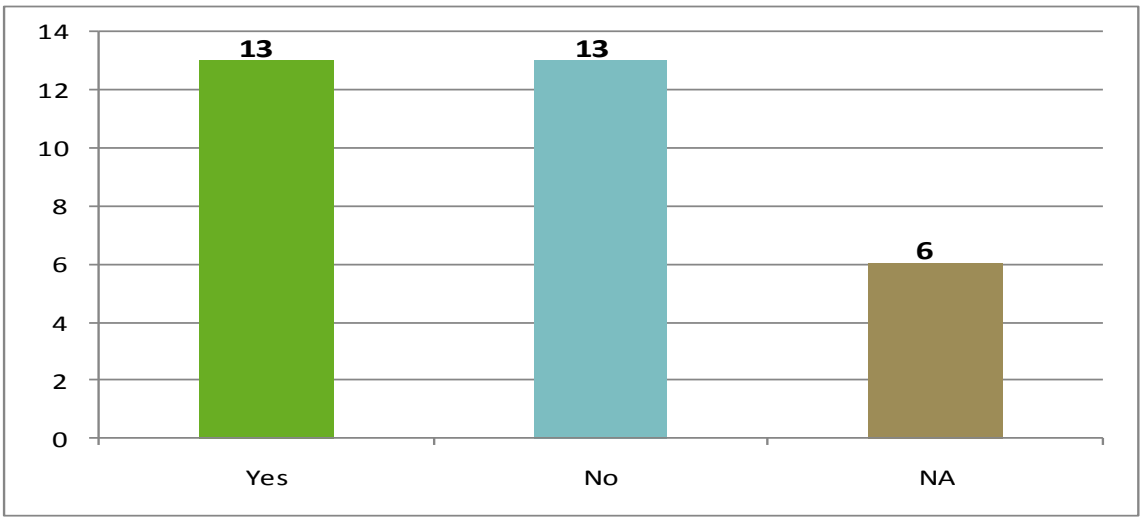
Q10: Are the following obliged to go through continuous professional education?



Q11: Do your NRLs provide such specific training?

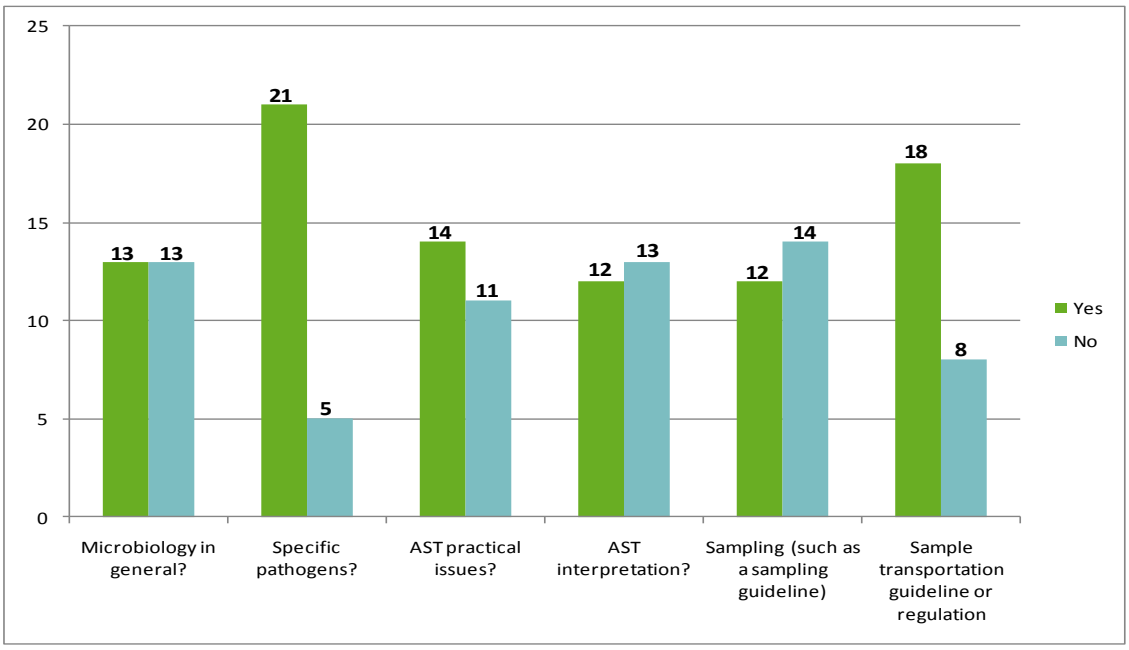


Q12: Are joined integrated microbiology/infectious diseases epidemiology training courses organised?

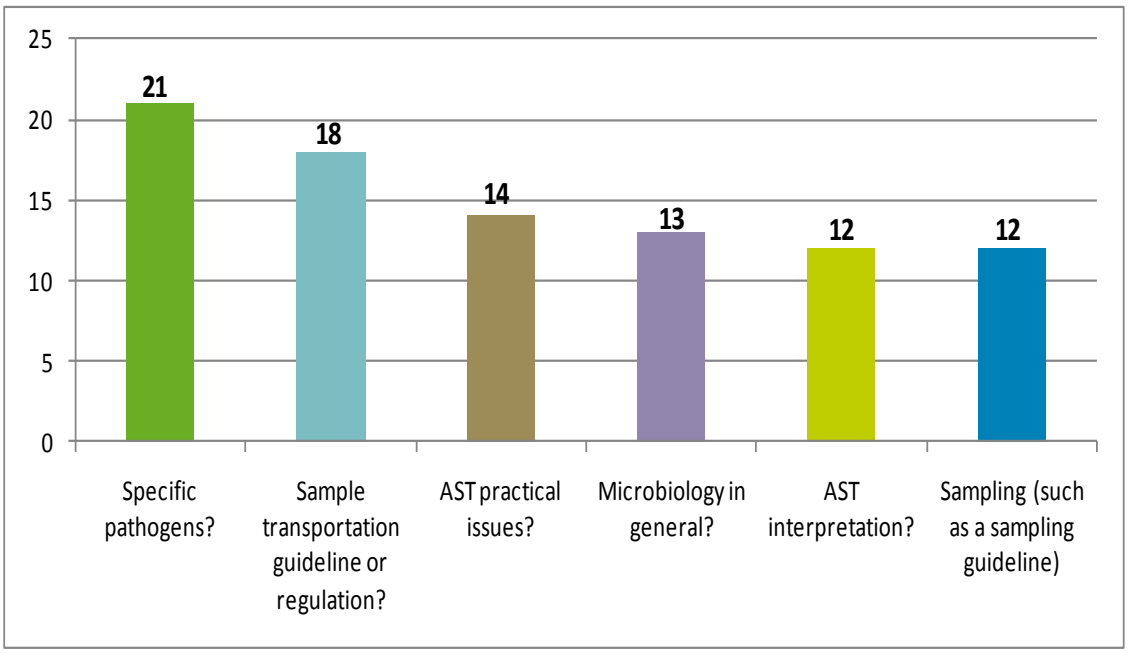


National guidelines

Q13: Do you have any national procedure and/or specific guidelines for:

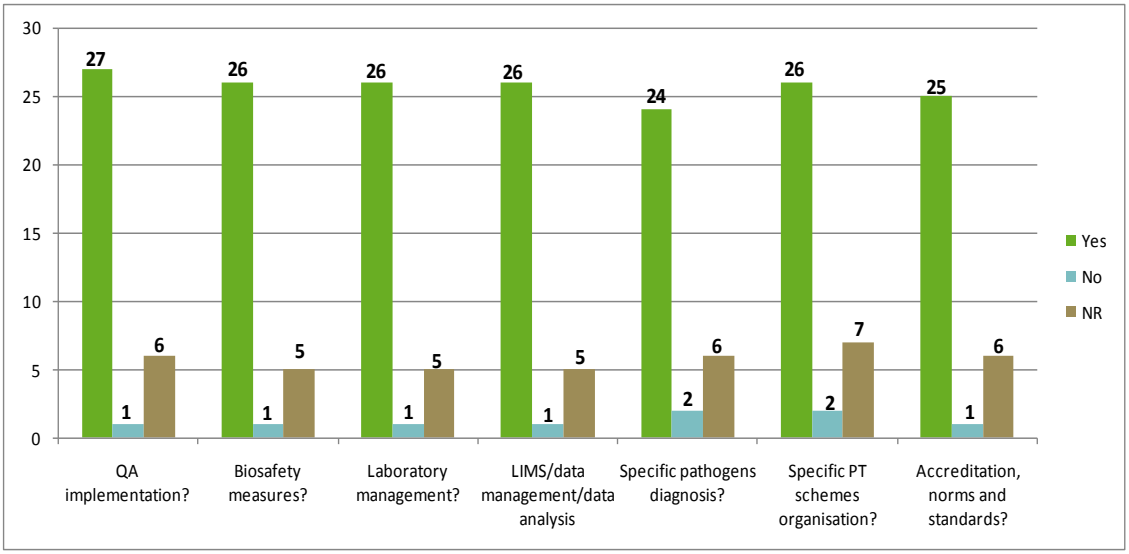


Availability of national guidelines:

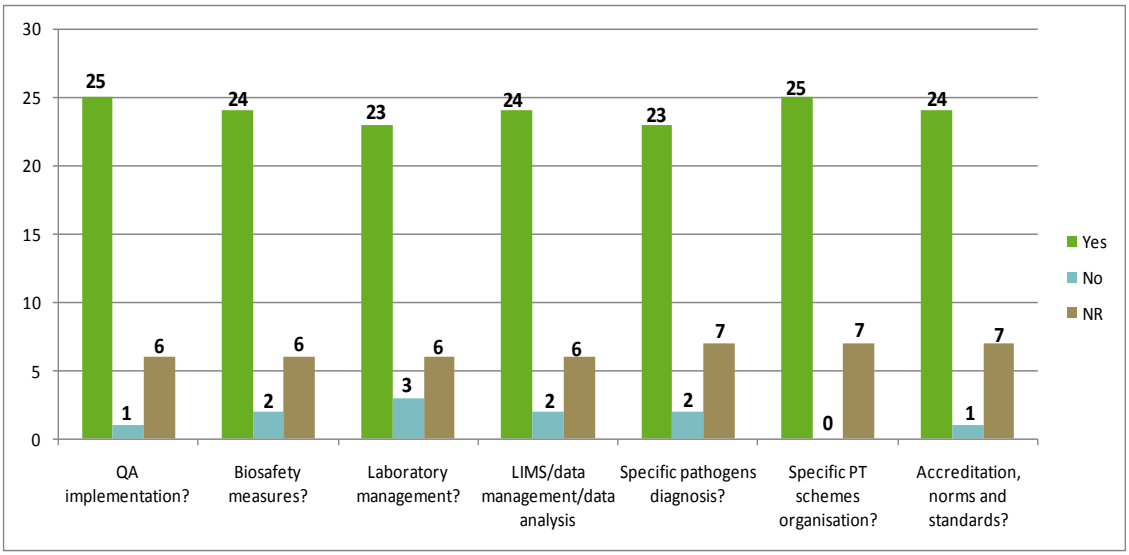


International trainings, guidelines and SOPs

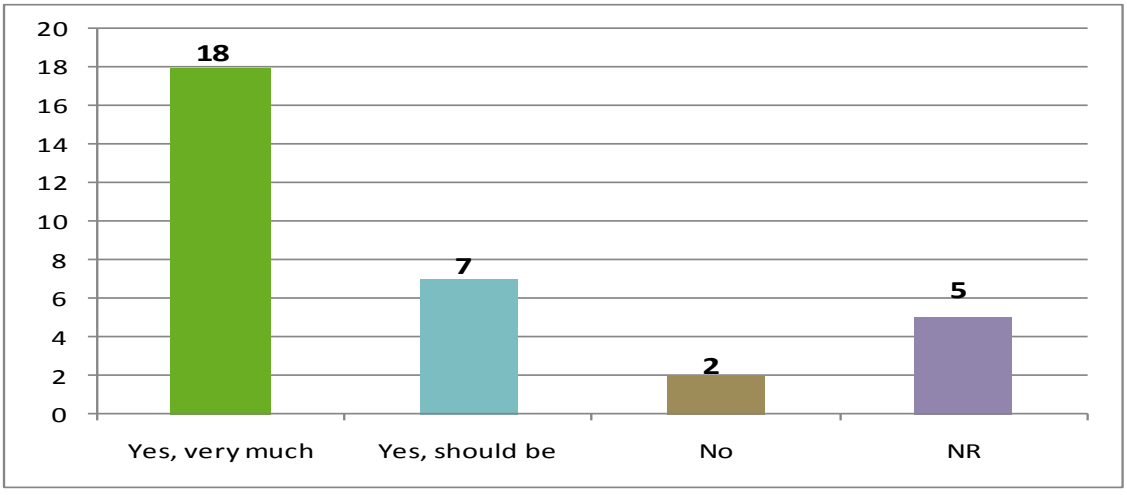
Q14: Would you accept multi-country training sessions about:



Q15: Would you be interested in the development of European guidelines/SOP about:



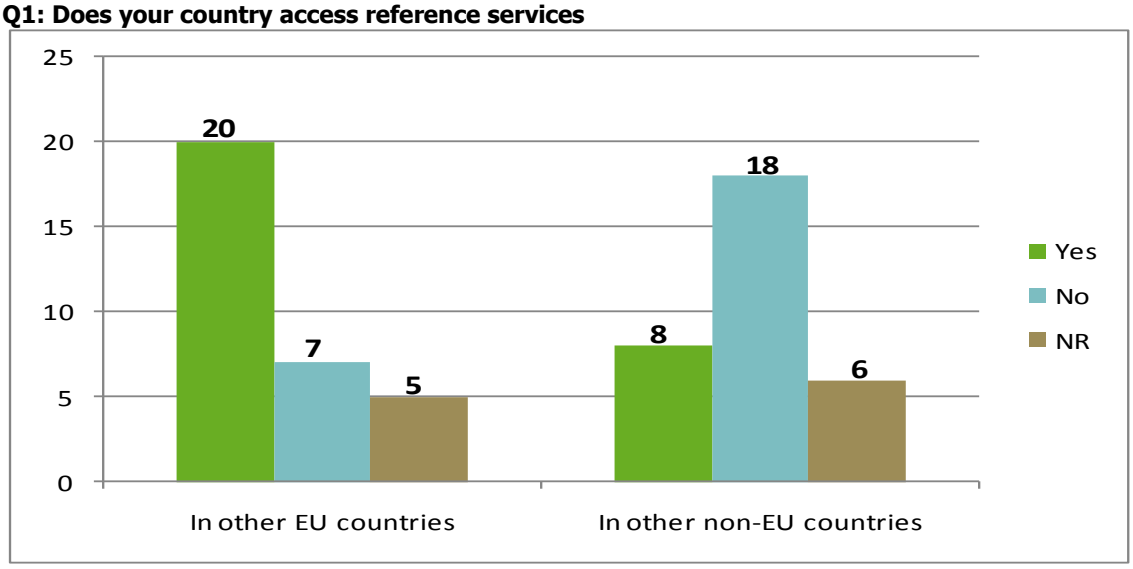
Q16: Do you think an EU-level training programme for PH laboratory specialists should be developed in the EU (modelled on the EPIET training for epidemiologists)?



A1.5 Gaps, needs and possible collaboration

Contracting reference activities abroad

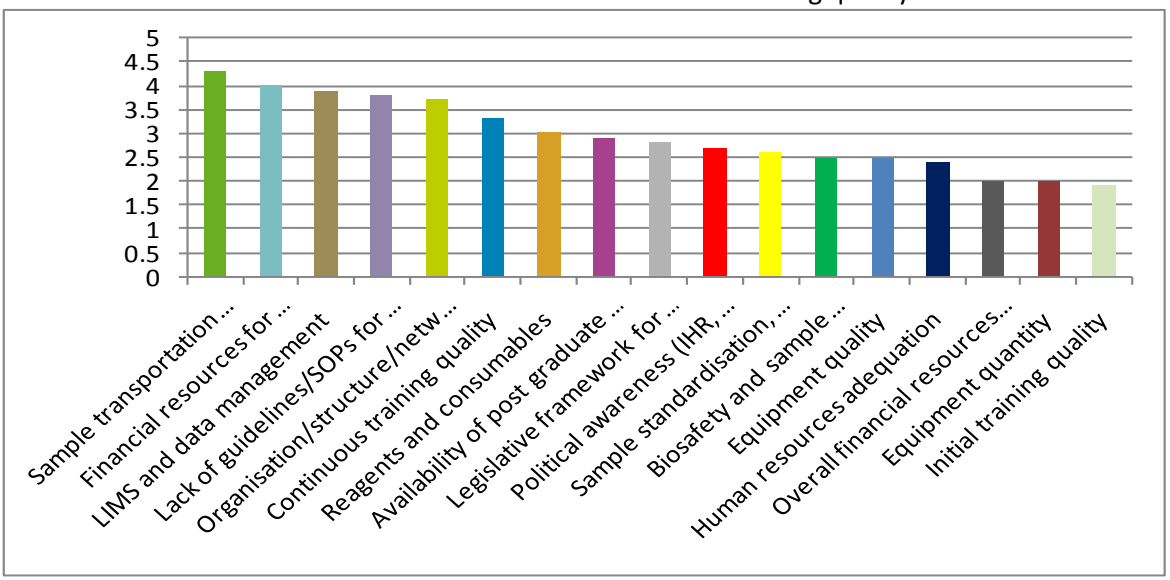
Q1: Does your country access reference services



Gap analysis

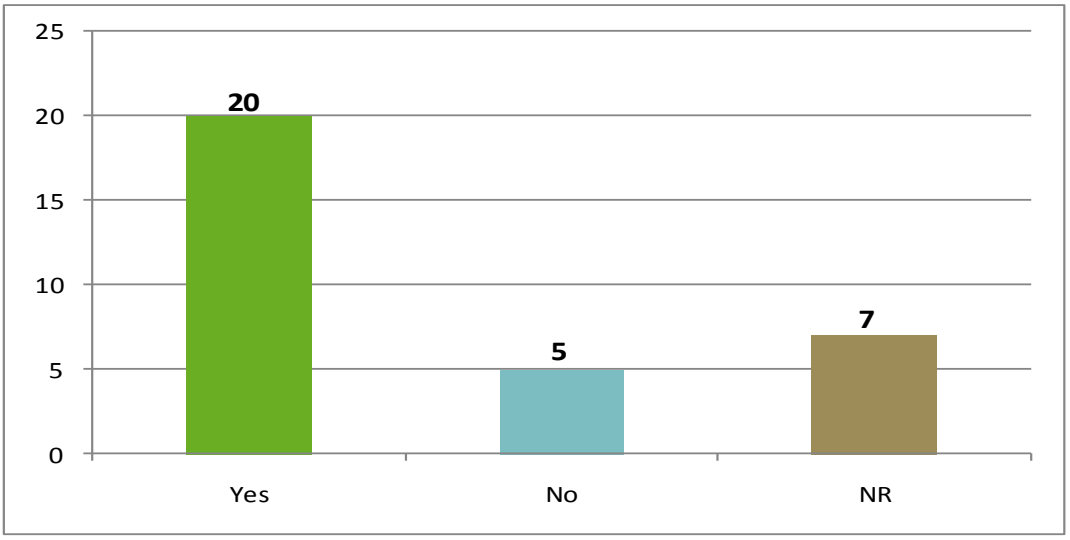
Q2: What are, in general, the biggest needs and gaps you did identify in your country/laboratory system? Grade from 0 (no negative impact) to 5 (substantially negative)

Sample transportation system (at national level)
Financial resources for ensuring required biosafety level
LIMS and data management
Lack of guidelines/SOPs for specific pathogens detections/diagnosis
Organisation/structure/networking of laboratories
Continuous training quality
Reagents and consumables
Availability of post graduate education for medical and non-medical microbiologist
Legislative framework for laboratories
Political awareness (IHR, European networks)
Sample standardisation, sample quality
Biosafety and sample manipulation
Equipment quality
Human resources adequation
Overall financial resources for laboratory activities
Equipment quantity
Initial training quality

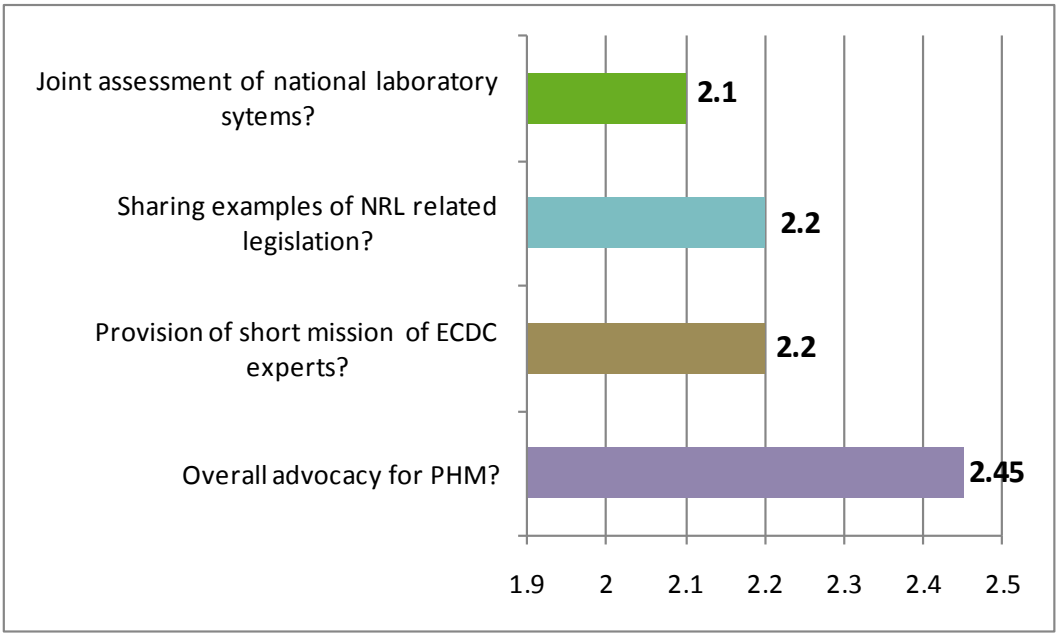


Specific support for NRLs

Q3: Is there any need to establish and/or to support NRLs in your country?



Q4: If yes, do you think ECDC could support you in the following areas (grade 0–3) by order of priority:



Annex 2: Diseases, pathogens and areas of work

Table 1: Diseases, pathogens, and areas of work not fully surveyed with the national microbiology focal points in all countries, but for which there is information for microbiology reference laboratory capacity

Acanthamoeba sp	Acinetobacter
Actinomycetes, Nocardia, Gordonia	Amoebiasis
Anaerobic bacteria identification	Anisakiasis
Arboviruses	Bartonella
Bartonella	Borrelia spp
Burkholderia pseudomallei	Candida spp
Clostridium difficile	Clostridium perfringens
Cysticercosis	Dengue
Diseases Caused by Exotic Parasites	Disinfection, sterilisation, pest control
Ehrlichia	Entamoeba histolytica
Enterobacteriaceae	Enterococcus
FSME	Fungi and antifungal treatment
Group A and B Streptococcal	Helicobacter pylori
Helminthozoonoses	Herpes
HTLV 1/II	Human pathogenic anaerobe
Infections	Intestinal helminthoses
Leishmania	Mycoses
Naegleria fowleri	Non-flu respiratory viruses, M. pneumoniae
Opisthorchiasis	Opportunistic parasites
Orthopox	Papillomaviruses
Parasitosis	Parvovirus
Pathogenic fungi	Pneumocystis jiroveci
Polyomarvirus	Q fever (Coxiella)
Rickettsia	Rotavirus
RSV	Streptococcus
Systemic mycoses	Taeniasis
TBE	tetanus
Toscana and other Phlebovirus	Toxocariasis
Trichomonas vaginalis	Trichomoniasis
Vaccines, Tropical Medicine, Travel Medicine	