Methodological approach towards a Gap Assessment of the Serbian microbiology system in the function of surveillance in line with EU standards and *acquis*

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Abstract
Introduction. Italian and Serbian Health authorities performed an in-depth Gap Assessment of the Serbian microbiology system in the function of communicable disease surveillance using a methodology adapted to context and information needs.
Methods. There were two study phases: a capacity based survey and an equipment mapping survey. Invited participants included national health authorities, heads of national reference laboratories and of public/private diagnostic laboratories in Serbia. Findings were analysed preliminarily and identified gaps were discussed, prioritized and validated through two *ad hoc* workshops involving all concerned institutions.
Results. The Gap Assessment was performed between September and December 2017. The overall response rate was 69% for phase one and 74% for phase two. Identified gaps were assessed as highly relevant during the project workshops.
Discussion. Gaps and priorities were highlighted, validated, and studied with a suitable level of detail to develop a concrete action-plan. The same methodological approach could be used to monitor progress in Serbia as well as in other EU candidate countries.

INTRODUCTION

As a European Union (EU) candidate country [1], Serbia has started the process of approximation to the European regulations and standards at all levels of health care as defined in the National Plan for the Adoption of the Acquis 2014-2018 (NPAA) [2], adopted in July 2014. As part of this process, Serbia has transposed the major concepts of the EU legislation related to communicable diseases and public health threats of infectious origin in the Law on Protection of Population from Communicable Diseases [3]. Case definitions of communicable diseases under surveillance have been aligned to the Commission Implementing Decision 2012/506/EU [4] and functions of National Reference Laboratories have been revised to match to current EU standards [5].

The challenge facing Serbia at this stage is to achieve an effective implementation of this legislation across its microbiology system that comprises the national level (i.e. the Ministry of Health of the Republic of Serbia

– MoH and the Institute of Public Health of Serbia – IPHS); all nominated National Reference Laboratories (NRLs) and public and private primary diagnostic laboratories. A thorough assessment of gaps was needed in all those levels, in order to identify priorities and design a road map to reach EU standards for the detection and/or confirmation of communicable diseases in line with EU case definitions in microbiology laboratories (including NRLs).

In 2016, Serbia tested an existing EU tool for the assessment of laboratory capacity (EULabCap) [6]. The EULabCap monitoring tool is composed of 60 performance indicators grouped into 12 targets which are equally distributed across the following three public health microbiology system dimensions: primary diagnostic testing, national microbiology reference laboratory services, and laboratory-based surveillance and epidemic response support. It quantifies capability and capacity of microbiology laboratories to provide essential public health functions, as defined in EU poli-

cies and action plans, the International Health Regulations (IHR), and technical standards through the use of indicators. The EULabCap comprises 38 indicators of laboratory capability and 22 of service capacity and is designed to be compiled in each country by one respondent at the national level. About three quarters of the indicators are based on EU policy targets or international technical standards, while the remainder assess EU surveillance and alert system contributions. The aim of this pilot was to explore the feasibility of all or part of the EULabCap indicators to identify public health microbiology laboratory strengths, compare the mean scores for EU/EEA countries for each target and indicator, and explore vulnerabilities and possible areas for national or regional capacity strengthening activities. The study results were published in February 2017 [7]. Although the pilot was successful, several indicators of the EULabCap monitoring system were found not to be applicable to EU enlargement countries leading to an under-estimation of capacities and capabilities (mainly due to limited relevance of some indicators for countries not fully under EU surveillance obligations: e.g. indicators based on data reporting to TESSy or participation in activities of EU surveillance networks) [8].

As part of a Twinning Light project, the Italian Institute of Health (Istituto Superiore di Sanità – ISS) and the IPHS designed and conducted an in-depth Gap Assessment using a revised and adapted methodology to cater for the context and information needs of Serbian authorities. The aim of the TWL Gap Assessment study was to inform an overall implementation approach with a series of achievable initiatives for improving microbiology diagnostic system quality in the function of surveillance of communicable diseases in compliance with EU *acquis* and EU standards, by focusing on public and private microbiology laboratory diagnostic capacities and on the core functions and capacities of NRLs. This paper presents this methodological approach and discusses its relevance for Serbia and possibly other EU enlargement countries.

MATERIALS AND METHODS

The study was designed in two phases *(Table 1)*. The first step included a capacity-based assessment on three functional levels: National System level, NRL core function level, and primary diagnostic level. The second step, restricted to responding public laboratories, was an equipment mapping survey. The capacity-based assessment was designed as a cross-sectional survey with multiple respondents and was delivered, translated in Serbian, using an online questionnaire created with a specialized software called SurveyMonkey. Results were analysed using an *ad hoc* indicator framework *(Supplementary material S1)*.

Prior to developing the methodology, the following documents were analysed: laws, bylaws, rulebooks; prior relevant assessments/studies; lists and terms of reference of NRLs; existing laboratory assessment tools and relevant international legislation [4, 9, 10]. Based on this documentation and on the general objective of the Gap Assessment, the team developed goals for each functional level *(Table 1)*.

Some of those goals aligned with the general structure of the EULabCap monitoring tool, which however was adapted and integrated to overcome the described limitations of this tool for countries in EU acceding status and to cater for the specific assessment requirements indicated by the Serbian authorities. In particular, Serbian partners stated that, to meet current information gaps, the assessment should be able to provide in depth information on laboratory capacity by addressing laboratories individually and that targeted laboratories should include NRLs, primary diagnostic public laboratories as well as to primary diagnostic private laboratories. The list of participating laboratories/central institutions was compiled by the Serbian Ministry of Health (MoH) and IPHS and included: i) one respondent from the central health system level (MoH/IPH); ii) all NRLs and iii) public diagnostic laboratories as well all the 40 private laboratories registered for inspection purposes with the MoH of Serbia.

While the EULabCap tool is not designed to be

Table 1

General structure of the Gap Assessment (phase 1 and phase 2)

Phase	Section	Goal	Function investigated	Target group
1. Capacity-based assessment	1	To map system components of the microbiology system in the function of surveillance	System and central functions	Ministry of Health / National Institute of Public Health
	2	To map core functions and capacities of National Reference Laboratories (NRLs)	Reference laboratory function to produce data/information for added public health value	National Reference Laboratories
	3	To map public and private laboratory diagnostic capacities in microbiology	Microbiology testing to meet diagnostic needs for the clinical management of patients	All Public/Private laboratories performing primary diagnostic activity. In Serbia this included National Reference Laboratories
2. Equipment mapping	-	To map availability of functional equipment in public laboratories	Reference laboratory function to produce data/information for added public health value and microbiology testing to meet diagnostic needs for the clinical management of patients	Public laboratories (including National Reference Laboratories) who responded to the phase 1 questionnaire

compiled by a number of individual laboratories, this is the case for the World Health Organization (WHO) Laboratory assessment tool [11]. For this reason, the statements included in both the ECDC EULabCap and WHO tools, relevant to the study objective and to the goals identified, were extracted and integrated in a single word file. Statements addressing similar areas in the two tools were grouped. This document was then circulated among all project experts. During two meetings in July 2017 in Belgrade, ISS and IPHS experts agreed upon the general methodology and on which statements to include in the TWL Gap Assessment study.

The selected statements with predefined multiple-choice answers were included in the capacity-based assessment questionnaire. This questionnaire was divided in three different sections that were answered by different target groups *(Table 1)*. These were introduced by an area in which respondent's details were collected (including the name of the institution, its public/private status and if it was responding as the central health system, as an NRL or as a diagnostic laboratory). The central level answered only section one, NRLs answered sections two and three and primary diagnostic laboratories only section three. In this way, the questionnaire was able to cater for the fact that in Serbia, as in many other countries, NRLs have both a reference and a primary diagnostic role [12].

Section one focussed on System and Central Functions including coordination mechanisms, laboratory networks, surveillance, quality assurance and biorisk management.

Within section two, the implementation of core functions of NRLs as defined by Serbian Law [3, 13] and by the ECDC [5] were explored. These functions were grouped as follows:
• Function 1. Reference diagnostics;
• Function 2. Reference material resources;
• Function 3. Scientific advice;
• Function 4. Collaboration and research;
• Function 5. Monitoring, alert and response.

In section three, primary diagnostic capacity as well as cross-functional issues such as infrastructure, laboratory equipment, IT (software and hardware), and human resources were assessed. For each pathogen under EU surveillance as per Decision 2012/506/EU [4] for which laboratory criteria are defined (i.e. all except for the Creutzfeldt-Jakob disease variant), laboratories were asked to state whether they were able, as of 2016, to diagnose according to EU laboratory criteria and if they had in place agreements with other laboratories inside or outside Serbia to do so. An official translation in Serbian of the laboratory criteria for notifiable pathogens under Decision 2012/506/EU [4] was available as a link in this section of the questionnaire for reference.

To complement this broad capacity-based assessment with more in-depth information, all public laboratories responding to the phase 1 questionnaire were also asked to participate in the second phase of the study and provide details of the equipment in place in their laboratories as of 2016. This data was collected with a separate questionnaire, with the aim to map availability of functional equipment in public laboratories *(Table 1)*.

Indicator framework

Once the statements in the Gap Assessment questionnaire and the content of the equipment mapping were defined and aligned to the study outcomes, indicators able to measure the outcome were designed *(Supplementary material S1)*.

Subsequently achievement targets for each indicator were defined in alignment with EU formal standards if available (or EU expected proficiency level if not) by subject-matter experts from ISS. These included scientific coordinators in charge of NRLs for each discipline: bacteriology, virology, mycology and parasitology. When also applicable to a non-EU context, EULabCap indicators were maintained. Once drafted, indicators and targets were shared and agreed upon with experts of the IPHS. Indicators were then grouped in "combined indicators" within each assessed outcome. This process led to the design of 148 indicators and targets *(Supplementary material S1)*. The indicators were organized according to the study phases, sections and relative functions *(Table 1)*. Within each function, relevant data were drawn from the different sections of the Gap Assessment questionnaire and of the equipment mapping questionnaire. In particular, the indicator framework comprised of:
• 26 indicators for function 1 (7 combined indicators);
• 36 indicators for function 2 (7 combined indicators);
• 77 indicators for function 3 and for cross-functional issues (10 combined indicators);
• 9 indicators for equipment mapping (2 combined indicators).

Validation of findings

Preliminary findings were validated in collaboration with experts of the IPHS during the entire project course as well as with the involved participants from concerned NRLs and diagnostic laboratories during two dedicated project workshops.

Both workshops were organized identically. During the first part of the morning, the workshops included presentations aimed at sharing the experiences by Italian and Serbian partners on the workshop topics. During the rest of the day group work was performed. This group work was carried out according to a standard methodology. The aim of the group work was:
1. to share preliminary findings of the Gap Assessment;
2. to identify priority gaps.

More specifically, relevant preliminary findings of the analysis and identified gaps were shared with participants to guide the subsequent group-work. Using a modified Delphi consensus generating methodology [14], the selected gaps were prioritized according to the following scoring criteria:
• the gap is an obstacle to implementing the new by-laws aligning Serbian communicable disease surveillance to EU acquis and EU standards;
• addressing this gap would support the development of sustainable institutional capacities to respond to serious public health threats of cross-border relevance;

- the impact on improving the microbiology function of surveillance in Serbia through an activity targeting this gap would be high (i.e. generate sustainable results);
- an activity targeting this gap would be feasible in the current context;
- including an activity targeting this gap in a roadmap would generate wide consensus among stakeholders in Serbia.

For each gap, participants were asked to score each of the above criteria from 1 (very unlikely) to 5 (very likely). Therefore, for each gap the minimum possible individual score was 5 and the maximum 25. The gaps were scored in pairs by people not belonging to the same Institution to foster discussion. During the workshop coffee break, the scoring sheets were collected and analysed in real-time. The results were then presented in plenary and the identified priority gaps were selected.

In advance of the workshops, Facilitators of IPHS and ISS were provided with a facilitator guide. Trainings and debriefings were organized the week before and the day after each workshop, respectively. One Serbian rapporteur per group was selected among the Facilitators in order to favour participation by leading discussions in the participants' native language and best report back findings. The results of the discussions were used to substantiate and validate the Gap Assessment.

Following the two workshops, the Gap Assessment dataset was analysed again by Italian Partners who prepared a preliminary report that was shared with the IPHS. Incoherent /dubious responses were identified and assessed by Serbian project partners who contacted when needed, by telephone, the contact points of the responding laboratory/ies. Incorrect responses due to a misinterpretation of the questionnaire statements were identified in this way and correct answers collected and inserted. The validated Gap Assessment dataset was downloaded on the 24th of November 2017.

Data analysis

Categorical variables were summarized by absolute frequency and percentage and continuous variables by median and range. Each indicator was analysed as per the definitions the indicator document *(Supplementary material S1)*.

The following variables were categorized: number of patients/clients that had used microbiology services in 2016; number of samples analysed in 2016 for bacteriology, mycology, virology and parasitology, and number of staff present in the laboratories in 2016.

The number of patients/clients that had used microbiology services in 2016 was used as a proxy of laboratory size and categorized as follows: 0-500; 501-10 000; 10 001-25 000; 25 001-50 000 and > 50 000. The number of samples analysed in 2016 for bacteriology, mycology, virology and parasitology were respectively categorized as follows: 0-25 000; 25 001-50 000 and > 50 000.

The number of staff present in the laboratory was categorized as follows and stratified by profession and type of contract (permanent vs temporary): 0; 1-5 and > 5.

Equipment was grouped in the following categories: general equipment, biosafety equipment, serology equipment and molecular equipment depending on its use.

All analyses were performed using STATA software (version 11.2; StataCorp, College Station, Tex). Maps were constructed using the SPMAP STATA command. Shape files of the Republic of Serbia were downloaded from the GADM database [15], version 2.5, July 2015.

RESULTS

The online questionnaire was piloted with Serbian project partners between the 6th and 12th of September 2017. Amendments were made based on their feedback to improve the clarity of statements and solve any technical issues that were found during the test.

The online Gap Assessment survey was officially launched on the 28th of September 2017. After two weeks from the invitation, the Italian partners prepared a report for the Serbian partners, listing responders/non-responders. The Italian partners also sent an automatic reminder to non-responders and to responders who had provided incomplete data.

A week after this first reminder, the Italian partner provided a second report to the Serbian partners listing responders/non-responders. A second reminder was sent to remaining non-responders and to responders who provided incomplete data.

After one week, Italian partners informed Serbian partners of any remaining non-responders and incomplete responders. Alternative contact points and email addresses were added if needed. As a final reminder, Serbian partners tried to directly contact any remaining non-responders and incomplete responders (via telephone or email) in order to increase response rates. The survey was officially closed on the 1st of November 2017, 5 weeks after the first invitation.

The overall response rate for the phase 1 study was 69% (one respondent from the MoH/IPH central level and 97 laboratories). The responding laboratories included all functioning NRLs, 94% of all public diagnostic laboratories and 33% of MoH registered private diagnostic laboratories. The response rate for the phase two study was 74%, including 69% of all NRLs and 76% of phase one responding public diagnostic laboratories.

The two project workshops took place on the 31st of October and on the 6th of November 2017. The first targeted 50 participants from: the MOH, IPHS, Regional Institutes of Public Health (RIPHs) and NRLs. The second workshop hosted 80 participants from the MOH, IPHS primary diagnostic microbiology laboratories (NRLs in their diagnostic function as well as additional public/private laboratories).

During the first workshop, preliminary results and the following tentative gaps for NRL functions were presented:
- External Quality Assurance (EQA) not organized in all NRLs;
- laboratory networks involving central, NRL and peripheral laboratories are not very strong;
- performance of molecular methods for pathogen diagnosis and for outbreak investigation is not widespread;

- lack of Guidelines and training for biosafety in the diagnostic labs; and
- lack of a BSL3 laboratory in Serbia.

During the second workshop, Gap Assessment results were presented with a focus on the primary diagnostic function of microbiology laboratories. In this context, the following tentative gaps were presented:

- laboratory networks involving central, NRL and peripheral laboratories are not very strong;
- diagnostic capacity towards EU laboratory confirmation criteria needs to be strengthened;
- minimum standards for Biosafety in diagnostic laboratories are missing;
- External Quality Assurance (by NRL offering participation to diagnostic labs) for key pathogens is missing;
- digitalization of information systems in microbiology in the function of surveillance is not widespread.

During the first workshop, 12 prioritization scoring sheets were submitted. The five gaps assessed scored on average between 20.5 and 22. As shown in *Figure 1*, the gap that was scored the highest was networking, albeit with the highest interquartile range (3.25). Following, there was the gap related to biosafety and at a similar level the gaps related to EQA and BLS3 laboratories. The performance of molecular methods for pathogen diagnosis and for outbreak investigation was scored the lowest.

During the second workshop, 27 scoring sheets were submitted. The five gaps assessed scored on average between 21 and 22. As shown in *Figure 2*, the gap that was scored the highest was gap 5: digitalization, albeit with the highest interquartile range (3.5). Following, there was the gap related to EQA followed, at a similar

1st quartile score, by the gaps related to laboratory networks, diagnostic capacity and biosafety, although the latter had a higher interquartile range.

DISCUSSION

The Gap Assessment study of the Serbian microbiology system in the function of communicable disease surveillance was conducted with a methodology that integrated elements from the EULabCap tool [7] and the WHO laboratory capacity assessment tool [8] focussing mainly on reported capacity.

Upon the Serbian authorities' request, the study was designed to provide more in-depth information than the EULabCap tool by addressing individual laboratories. The study sample included both NRLs and primary diagnostic laboratories and, among those, also laboratories from the private sector. While trying to maintain as much as possible the EULabCap approach and statements, that are fully in line with EU standards and *acquis,* this study aimed to overcome the fact that not all those statements are appropriate to assess a country that is not yet fully part of the EU [7, 8]. At the same time, the Gap Assessment was designed to be less detailed than the WHO tool to allow for its relatively fast implementation.

All phases of the methodology definition (including the design of the questionnaire and indicator framework) were conducted with the support of senior subject-matter experts of the Serbian IPHS and of the Italian ISS. Statements were selected based on applicability to the Serbian context and targets for the indicators were set according to EU standards and practice.

The two workshops planned during the TWL project were implemented in the allotted timeframe. In
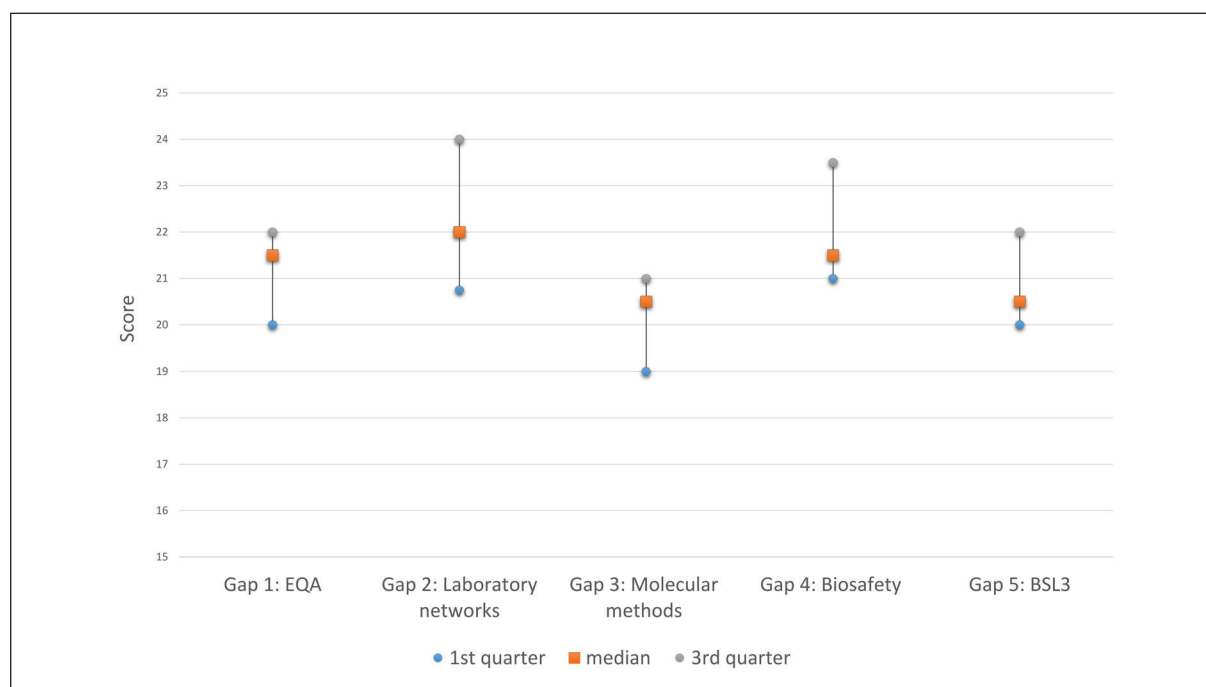
Figure 1
Prioritization results of the first workshop, N=12.
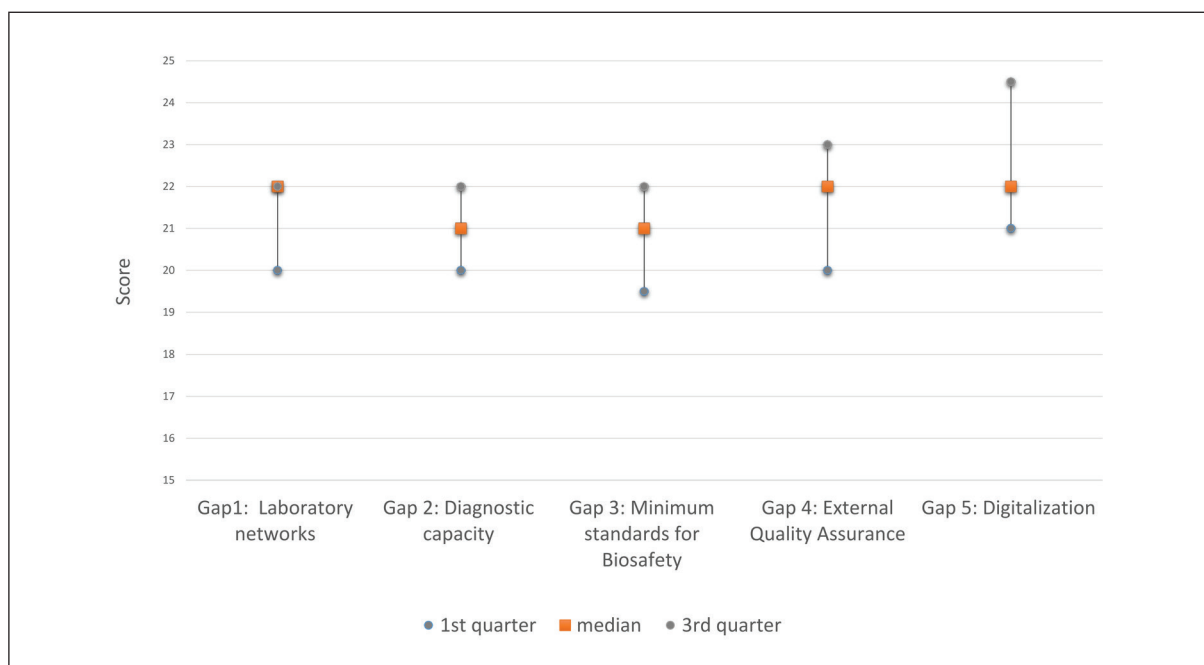
Figure 2
Prioritization results of the second workshop, N=27.

order for those opportunities of encounter with major stakeholders in the Serbian microbiology diagnostic and surveillance system to be conducive to validate the study findings, a standard methodology was developed. This approach required extensive advance preparation including the analysis of preliminary data of the Gap Assessment study, the preparation of group work materials and tools (e.g. prioritization criteria and the facilitator guide) and training of facilitators. However, on hindsight, this was a good investment. Both workshops were successfully carried out and generated relevant findings.

The prioritization exercise confirmed that all the gaps identified by the Gap Assessment study were highly relevant for participants with consistently very high median scores (between 20.5 and 22 over a maximum of 25). This finding validated the preliminary results of the study and indirectly confirmed that the Gap Assessment Methodology was successful in capturing gaps of relevance to the Serbian microbiology system in the function of surveillance. This exercise also consistently highlighted areas of highest priority in the fields of networking, quality, biosafety and digitalization. These were the areas that were targeted in a road map and action plan that was delivered at the end of the project.

The discussions, however, also identified some recurrent aspects ascribable to the common context of implementation that could not have been readily captured by the study questionnaires. These aspects were used as the backbone against which to analyse the main findings. Once elaborated, findings were assessed against prior assessment/ evaluation results [9, 16] and found to be consistent with the system's development process.

CONCLUSIONS

The methodology described in this paper was used to perform an in-depth assessment of the Serbian microbiology system in the function of communicable disease surveillance. Gaps and priorities were highlighted, validated, and studied with a suitable level of detail to develop a roadmap and a concrete action-plan. Further, the entire study was designed, developed and conducted in less than 8 months, of which approximately four months from survey launch to report submission. The indicator framework, through more detailed and adapted to a non EU context that the EULabCap, maintained its focus on EU standards and practice. Finally, the performance of two project workshops was useful in validating the gaps identified and prioritizing them. Discussion also added qualitative information that guided the interpretation of the data collected. For these reasons, we believe this is a promising approach to the assessment of gaps in the function of surveillance of microbiology systems that could be used again in Serbia to monitor progress as well as in other EU acceding countries who need to produce similar outputs.

LIMITS

The time allocated for the conduction of this study was relatively short. Therefore, the analysis has focused on perceived capacity and needs from a wide microbiology system perspective.

Findings were based on self-reporting. As a consequence, incorrect responses due to misinterpretation of questions or complacency/desirability bias are possible. However, as findings were repeatedly validated with stakeholders at central level (IPHS), NRL level and primary diagnostic level and as the identified gaps were

highly prioritized at all those levels, this methodological limit should not have affected the overall validity of findings.

By design, respondents were from laboratories under the jurisdiction of the Ministry of Health, from the Military Medical Academy under jurisdiction of Ministry of Defence and from three NRLs under the Ministry of Science, Education and Technical development. However, this assessment could be more comprehensive if existing microbiological capacity in other sectors, such as Animal Health, could be also considered.

The study by design addressed a wide number of issues rather broadly, limiting the level of detail with which each issue could be assessed. When more in depth studies were considered necessary to guide specific policy decisions (e.g. provide indication on specific items of equipment to buy for individual laboratories), this was indicated in the final report. Given a longer timeframe, such studies, including audits, could have been included in the study itself.

Conflict of interest statement

There are no potential conflicts of interest or any financial or personal relationships with other people or organizations that could inappropriately bias conduct and findings of this study.

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