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A survey on Artificial Intelligence and Big Data utilisation in Italian clinical laboratories

<https://doi.org/10.1515/cclm-2022-0680>

Received July 13, 2022; accepted August 25, 2022;

published online September 6, 2022

Abstract

Objectives: The Italian Society of Clinical Biochemistry and Clinical Molecular Biology (SIBioC) Big Data and Artificial Intelligence (BAI) Working Group promoted a survey to frame the knowledge, skills and technological predisposition in clinical laboratories.

Methods: A questionnaire, focussing on digitization, information technology (IT) infrastructures, data accessibility, and BAI projects underway was sent to 1,351 SIBioC participants. The responses were evaluated using SurveyMonkey software and Google Sheets.

Results: The 227 respondents (17%) from all over Italy (47% of 484 labs), mainly biologists, laboratory physicians and managers, mostly from laboratories of public hospitals, revealed lack of hardware, software and corporate Wi-Fi, and dearth of PCs. Only 25% work daily on clouds, while 65%—including Laboratory Directors—cannot acquire health data from sources other than laboratories. Only 50% of those with access can review a clinical patient's health record, while the other access only to laboratory information. The integration of laboratory data with other health data is mostly incomplete, which limits BAI-type analysis. Many are unaware of integration platforms. Over 90% report pulling data from the Laboratory Information System, with varying degrees of autonomy. Very few have already

undertaken BAI projects, frequently relying on IT partnerships. The majority consider BAI as crucial in helping professional judgements, indicating a growing interest.

Conclusions: The questionnaire received relevant feedback from SIBioC participants. It highlighted the level of expertise and interest in BAI applications. None of the obstacles stands out more than the others, emphasising the need to all-around work: IT infrastructures, data warehouses, BAI analysis software acquisition, data accessibility and training.

Keywords: Artificial Intelligence; Big Data; digitalization; Laboratory Information System; laboratory medicine.

Introduction

Artificial Intelligence (AI) tools represent cutting-edge technologies that are widely applied in a variety of technological and scientific domains. Of interest, AI has been also widely used in healthcare applications, especially because of the easy availability of big sources of patients' data (Big Data). As a result, research in numerous medical specialities have exploded recently [1, 2]. However, oddly, only a small number of these studies specifically address laboratory medicine (LM), the clinic's main source of quantitative, structured and coded data [3–5].

Despite the large number of applications published in scientific journals, the majority of these have been employed in specialised settings or for research purposes and only a small number are currently in use on a daily basis [6]. In other words, there appears to be a significant gap between a small number of laboratories that are capable of creating and utilising AI applications and the majority of laboratories that, on the other hand, only have a general understanding of these issues and lack the necessary tools and expertise for independent development [7].

Recently, the Italian Society of Clinical Biochemistry and Clinical Molecular Biology (SIBioC) created a specific working group (WG) on the topic of Big Data and AI (BAI). Once set-up, the WG started to conduct a series of educational and cultural initiatives to promote the development of a multidisciplinary and integrated network between the

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professionals of the LM and those of the world of information technology (IT) applied to medicine—a crucial prerequisite for BAI analysis [8]. A number of WG documents were developed by the WG to familiarise the LM experts with BAI disruptive issues [9–11], and certain research has been conducted by several members [5, 12–19].

The WG-BAI has promoted a survey with topic BAI to better frame the real situation of the Italian clinical laboratories, with a dual purpose: on the one hand to verify the technological status of the laboratories (adequacy of digital/IT equipment) and on the other to investigate human perspective (the knowledge, skills, projects underway in the BAI and technological predisposition for their development).

The purpose of this paper, through the evaluation of the responses received, is to assess current perspectives on the value of AI in Italian diagnostic laboratories and to identify the challenges that are likely to be faced by scientific society in promoting the introduction of AI in this field.

Materials and methods

The questionnaire was designed by the members of the WG and the SurveyMonkey platform (SurveyMonkey Inc.) was used to administer it. 1,351 SIBioC participants were invited to take part in the survey by email through the distribution of special newsletters (between April and July 2021), in which the participation of laboratory directors was strongly recommended, especially for organisational questions. Each member could only participate once in the survey. It was actually possible to skip some questions, hence in the presentation of the results, the total number of answers does not in all instances equal the total number of participants.

The survey questions listed in Table 1 were broken down into five categories:

- (1) **General characteristics (six questions).** This heading included the professional profiles of the participants, their demographic and geographical distribution, and the type of institution in which they are employed;
- (2) **Adequacy of digital instrumentation's (nine questions).** This section investigated the infrastructures from an IT perspective, in terms of hardware and software equipment, connectivity and use of cloud platforms;
- (3) **Access to health data (seven questions).** It focused on the degree of usability and integration of laboratory and clinical data, a crucial component for BAI applications;
- (4) **Laboratory data management and analysis (three questions).** Laboratory Information Systems (LIS) of clinical laboratories were here explored;
- (5) **BAI (nine questions).** The last section was aimed at surveying participants' levels of knowledge and expertise, their perceptions and opinions on the role of BAI in LM and the main barriers to its application, their training needs, and also left open-ended questions to present current projects on BAI in Italian laboratories.

The survey results were finally evaluated using the SurveyMonkey software and Google Sheets.

Results

Section 1: General characteristics (questions 1–6)

A total of 227 (17%) of 1,351 SIBioC participants, working in a total of 484 clinical laboratories of Italy, responded to the survey, with 30% participation among the audited laboratory directors.

The biologist was the most prominent professional, followed by lab physicians and technologists (Figure 1).

Within an age ranged from 20 to over 70 years, dividing the population into classes of 10 years, the majority of the interviewees were aged between 51 and 70 years ($n=89$, 39.2%; 63 females, 26 males). Female sex ($n=143$, 62.9%) prevails in all age groups (Fisher's exact $p=0.021$), except for the 31–40 age group (43.7%).

Interviewees worked primarily in public hospitals' National Health Service Laboratories (42.7%) or in hospital-universities (33.9%). Others worked in private laboratories (10.6%), in private hospitals or nursing homes (9.3%), in research hospitals (IRCCS, 1.3%), in diagnostics companies (0.9%) or in other non-clinical laboratories (1.3%).

Replies were received from all the 20 Italian regions as shown in Figure 2.

Participation in the survey collected data from laboratory facilities of various sizes regarding the usual number of examinations performed annually. The participants were evenly distributed between laboratories performing less than 1 million examinations per year (29%), between 1 and 3 (26%) million and between 3 and 6 million (31%), while a small proportion were in facilities performing more than 6 million examinations per year (14%).

Section 2: Adequacy of digital equipment (questions: 7–15)

This section examined the adequacy of technological resources, a fundamental requirement for Big Data analysis. Less than half of the participants (41%) reported a ratio of 1:1 of personal computers to employees, while in more than 30% of the responses only 1 PC per 3 employees or less was reported. Corporate Wi-Fi is available in almost two thirds of cases (66%).

The availability of webcams and microphones with the possibility of installing the necessary software for online meetings was restricted in most cases to a small number of workstations (62%) and was even completely absent in

Table 1: Characteristics of the survey.

Section	Question	Additional note when provided	
Section 1: General characteristics (questions 1–6)	(1) Professional profiles of respondents		
	(2) Sex		
	(3) Age		
	(4) Type of workplace organisation		
	(5) Region of Italy where the laboratory/facility is situated		
	(6) Average number of test/year performed in the lab		
Section 2: Adequacy of digital equipment (questions 7–15)	(7) How many laboratory workstations with Internet connection are there in relation to the number of operators?	Indicate the operator/workstation ratio	
	(8) Is a corporate Wi-Fi network available?		
	(9) Is the laboratory equipped with workstations for working and/or holding online meetings?	Webcam equipment, microphone, possibility to install appropriate software	
	(10) How would you rate the quality of connections in terms of speed and stability?	1: totally inadequate; 4: completely adequate	
	(11) How would you rate the software equipment of the workstations?	1: totally inadequate; 4: completely adequate	
	(12) How would you rate the hardware equipment of the workstations?	1: totally inadequate; 4: completely adequate	
	(13) How often do you use the cloud in your lab?	1: never; 4: always	
	(14) Which cloud platform(s) do you use in your laboratory?	Multiple items can be selected	
	(15) To what purposes do you use the cloud?	Multiple items can be selected	
	Section 3: Access to health data (questions 16–22)	(16) Besides laboratory data, do you have access to other patient data?	If the answer is NO, the following question is automatically skipped
		(17) What data do you have access to?	Multiple items can be selected
		(18) What modalities can you use to access other patient data?	Multiple items can be selected
		(19) What is the level of integration of the laboratory data collected in the LIS with the other patient health data collected in other databases in your company?	By integration, we imply the collection and combination of data from various internal sources within the company. Partial integration: collection of data from the disciplines of LM (clinical biochemistry, microbiology, genetics, haematology, immunohaematology, etc.). Full integration: incorporates clinical, imaging, and laboratory diagnostic data.
		(20) If you answered in the previous question that the data are integrated, please specify how they are integrated.	
		(21) Does your company have a total integrated data analysis system?	An integrated data analysis system means, for example, software that, by means of web pages or applications installed on computers, enables simple or complex analyses of data from the company's various internal sources.
(22) On the other side, does your company have a system for analysing partially integrated data or lab data?			
Section 4: Laboratory data management and analysis (questions 23–25)		(23) How does the LIS enable data extraction?	
	(24) How do you rate the adequacy of data extraction for the purposes of analysis with Artificial Intelligence methodologies in terms of speed and volume of data extracted?	1: totally inadequate; 4: completely adequate	
	(25) Which tools do you have in your company to analyse laboratory data?	Multiple items can be selected	

Table 1: (continued)

Section	Question	Additional note when provided
Section 5: Big Data and Artificial Intelligence (questions 26–34)	(26) How good is your level of knowledge on the subject of BAI?	1: inadequate knowledge; 4: excellent knowledge
	(27) Which is your level of competence with BAI methodologies?	1: inadequate competence; 4: excellent competence
	(28) Are there any BAI projects going on in your laboratory?	
	(29) Is there a position in the laboratory staff with expertise in the field of statistical solutions applicable to Big Data?	
	(30) Is your laboratory equipped with systems for analysing Big Data?	By systems we mean specific software, platforms /PCs with adequate computing power.
	(31) For the use of laboratory data in studies where it is not necessary to maintain the identity of the patient, please select one of the following modes.	Specify whether you are using a standard, homemade or other anonymization procedure or whether informed consent is still required.
	(32) What do you think could be the role of artificial intelligence in the laboratory?	
	(33) What are the greatest barriers to the application of artificial intelligence and big data in your organisation?	Give a score for each option, from 1 to 4, where 1: minimum barrier; 4: maximum barrier
	(34) Would you be interested in a BAI training course?	Multiple items can be selected.

Thirty-four questions are listed according to five different sections. Additional notes are indicated for individual questions when provided in the questionnaire. LIS, Laboratory Information System; LM, laboratory medicine; BAI, Big Data and Artificial Intelligence.

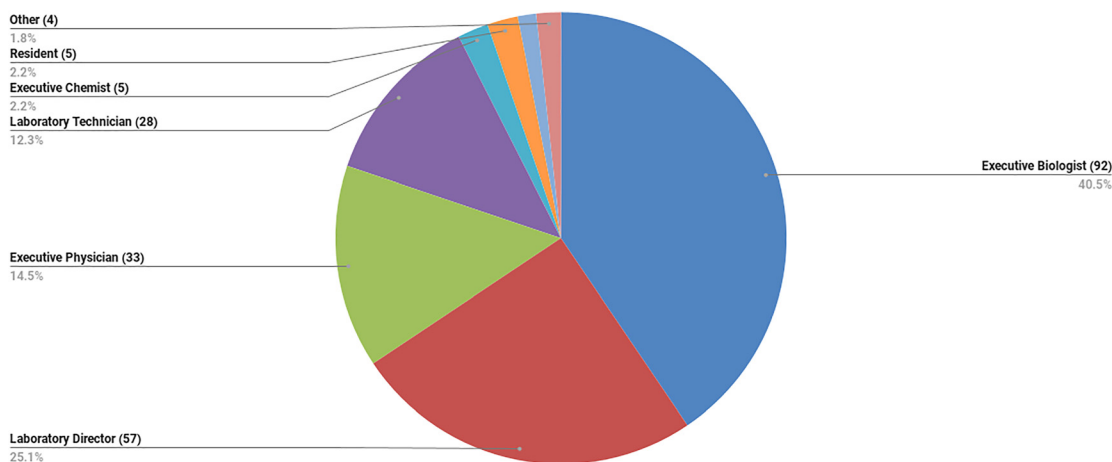


Figure 1: Professional profiles of respondents.

20% of the cases. There was disagreement over the adequacy of the connection in terms of speed and stability, and there was a general lack of satisfaction with respect both to the quality of software and to hardware equipment (Figure 3).

In this first set of questions concerning the adequacy of digital equipment, no differences were found between the

answers received from public or private institutions, and the answers did not depend on the number of tests performed by the laboratory either.

In the lab, just approximately a quarter (26%) of the participants regularly use IT solutions based on Cloud systems. Among the answers received, there are no differences between those from different professional

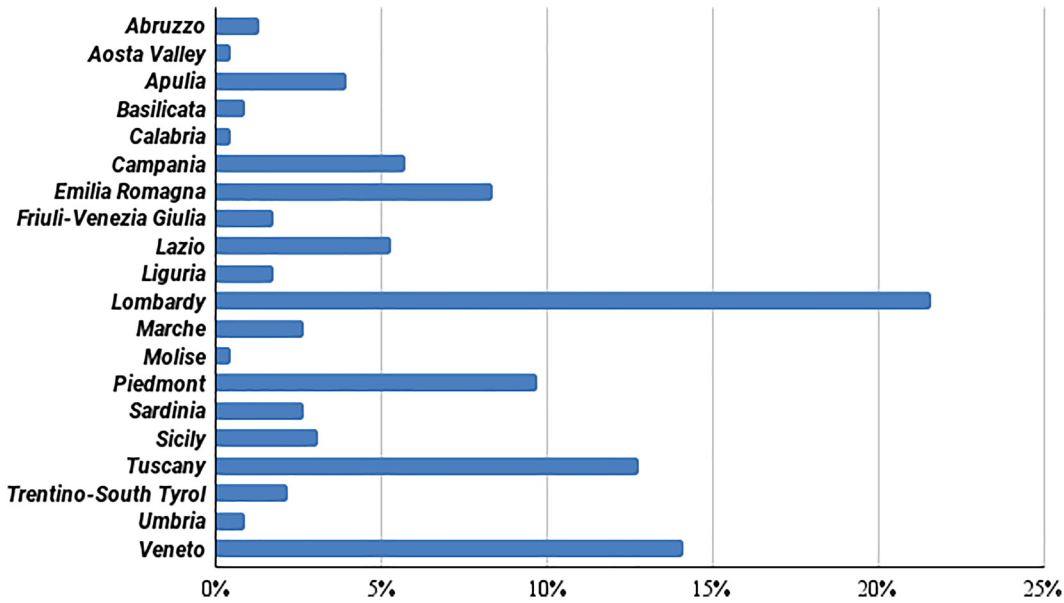


Figure 2: Region of Italy where the laboratory/facility is situated.

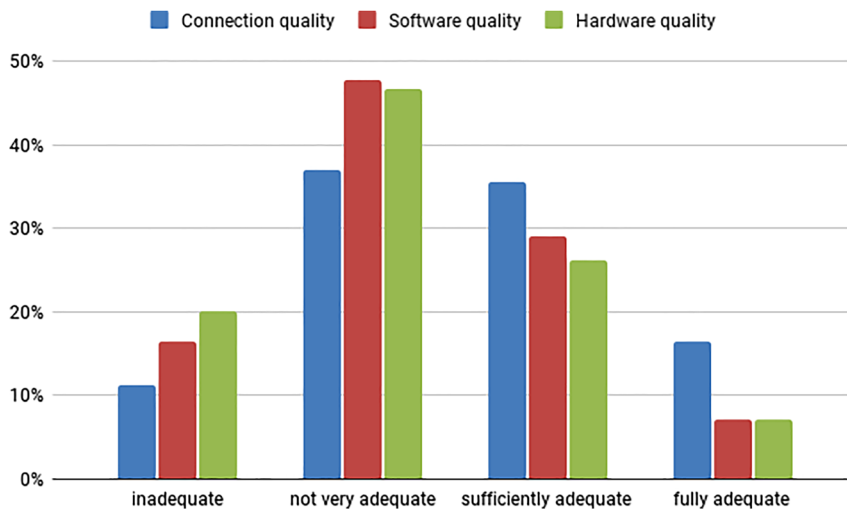


Figure 3: Judgement of the quality of connections and adequacy of software and hardware.

categories (biologist, physicians and technologists) and between laboratory directors and the others.

Among those who have indicated the use of a cloud platform (188/227), Corporate Clouds (41%) and Google Drive (38%) are the most popular platforms, followed by Dropbox (9%) and Microsoft One Drive (8%) and others (4%).

Only for a percentage of 25% of the respondents, the Cloud is also used as an integrated work environment, utilising the online versions of the offered software and services.

Section 3: Access to health data (questions 16–22)

When the possibility of accessing patient health data was investigated, it is interesting to note that almost two thirds of the 208 respondents (60%, 126 answers) do not have access to any data other than laboratory data (Figure 4).

There appears to be a general inability to access patients' non-laboratory health data, which evidently does not depend on credential restrictions reserved for

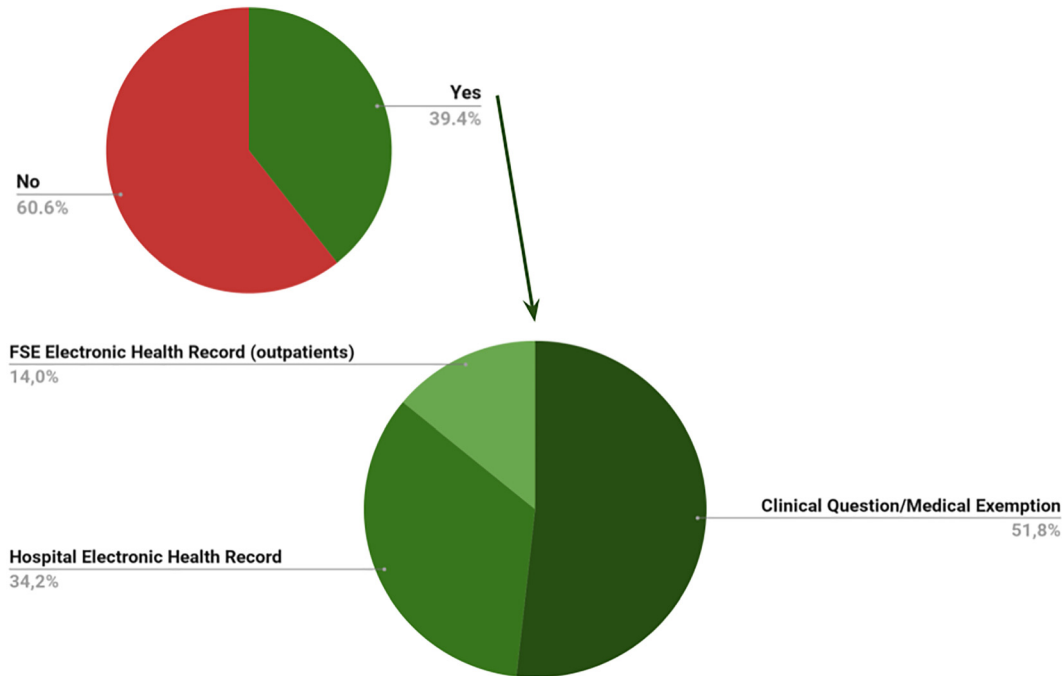


Figure 4: Limitations on access to non-laboratory health data and what kind of data are retrievable in those cases where it is allowed.

particular professions. In fact, this problem is also evident when filtering the sample for the Laboratory Director population (58% of them have no access).

Among those who have access to other non-laboratory health data, data related to the request for laboratory tests (diagnostic query/exemption) (52%), the hospital medical record (34%) or the electronic health record (14%) are mentioned as the types in order of frequency. Concerning the way the data are accessed, in half of the cases (53%) access is always possible with one's own credentials, in the other half (46%) access is only allowed to authorised laboratory staff, and in a few cases data are provided only upon request to special facilities outside the laboratory (1%).

In addition, the degree of integration of laboratory data collected in the LIS with other patient health data collected in the company databases was examined. By "integration" is meant the connection between different data that the company obtains from its various internal sources. This integration has been defined as either total (encompassing laboratory diagnostic, imaging and clinical data) or partial (covering only LM branches, such as clinical chemistry, microbiology, genetics, haematology and immunohaematology). The majority of respondents (63%) indicated the existence of some sort of integration of health data; however, among the 209 responses received, it was mostly partial integration (105 responses, 80%) rather than total integration (49 responses, 20%). A considerable

percentage of respondents are not aware of the level of integration in their company (30 replies, 14%).

Almost half of the interviewees (59 out of the 125 responses received to this question, 47%) were unable to offer any information on the type of platforms for storing integrated data, while from the responses received, data were integrated in the corporate data warehouse in the majority of cases (57 responses, 46%), and only in a few cases (9 responses, 7%) on cloud platforms.

In addition, the presence of total integrated data analysis systems in companies was investigated, such as software that, through web pages or applications installed on computers, allow simple or complex analyses of data from various sources within the company. Nearly half of the 197 answers in this field are ambiguous ("don't know", 95/197, 48%), followed by the disconfirmation of the existence of such software ("no", 71/197, 36%), while only in a small percentage of cases is the presence of software for descriptive analysis only (17/197, 9%) or for both descriptive and predictive analysis (14/197, 7%) reported.

Narrowing the field to software for analysing laboratory data, there was an increase in affirmative responses with the presence of software for descriptive analysis in 30% of cases (58 out of 196 responses) and for both descriptive and predictive analysis in 16% of cases (31 responses). In 22% of the responses (44), the absence of any such software was reported, and still 32% of the respondents (62) were unaware of the situation in their company.

Section 4: Laboratory data management and analysis (questions 23–25)

LIS data management was examined in the fourth section. More than half of the users (63%, 123 out of 195 responses to this question) are able to extract data from the LIS on their own, mainly using preset methods (42%) and only in one fifth of situations using a free, configurable method (21%). Other times, data extraction requires contacting IT support (28%) or in extremely rare circumstances data extraction is not possible (2%), or respondents are not aware about data extraction techniques (7%). Those who are able to autonomously extract data (63%) were asked in the subsequent question to assess the suitability of data extraction, in terms of speed and volume of extracted data, for the purpose of “analysis with Artificial Intelligence methodologies”: extraction speed and volume of data do not satisfy 73 and 68% of the respondents respectively (score 1–2). The ratings given to the speed and volume of extraction from the LIS are shown in Figure 5.

With regard to the tools available for data analysis, several answers could be selected. The majority have an integrated functionality in the LIS (61%) and use spreadsheets (49%). Only 16% refer to the use of more specific software. The most frequently used programmes among those mentioned by the respondents are MedCalc, R, Analyze-it, SPSS, GraphPad and Phyton. As R and Phyton are the most suitable software for analysing Big Data (BD), it is important to underline that only a very small number of respondents actually use them (only two answers for Phyton and four for R).

Section 5: Big Data and Artificial Intelligence (questions 26–34)

Only 20% of 183 respondents stated that they had a good (15%) or outstanding (5%) understanding of the BAI subject matter, and an even smaller percentage (12%) felt they had a good (9%) or excellent (3%) level of competence in BAI methodologies.

Among the possible applications of Artificial Intelligence, respondents gave greater consideration to expert systems for the release of lab results and the reference intervals estimation, while less importance was given to predictive algorithms, image recognition, language processing. In fact, the latter two (language and image comprehension) are currently less felt than in the field of radiology, although there are applications in haematology and urinary LM [20, 21].

In the majority of laboratories (91%, 166 out of 182 replies) there are no ongoing projects involving the use of BAI. Moreover, in most laboratories (62%, 110 out of 178 answers) there is not a professional position with expertise in the field of statistical solutions applicable to Big Data. However, almost a third (28%, 49 out of 178) declared to have active external collaborations with computer scientists. Only in 10% of the cases (19 out of 178) are there laboratory staff with specific expertise on BAI.

Similarly, specific software, platforms and PCs dedicated to BAI analysis are almost absent in the laboratories (145 replies out of 180, 80%), in a percentage of cases external partnerships are engaged (29 replies, 16%), while only seven stated that dedicated software is available.

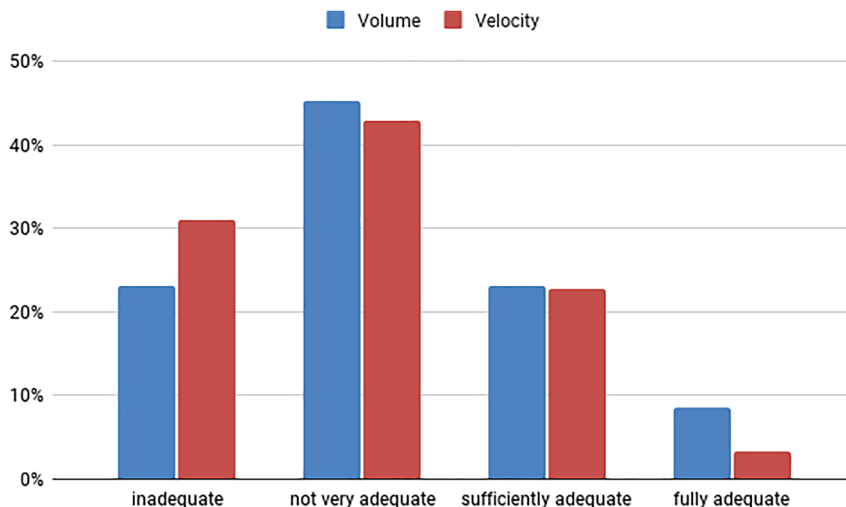


Figure 5: Judgements on speed and volume of data extraction from the Laboratory Information System.

The questionnaire examined the management of studies in which it is not necessary to maintain the patient's identity and on any anonymization procedures, with regard to the problem of privacy management in the use of large amounts of data. Most of the 170 respondents (60%) reported using a home-made anonymization procedure, while in 40% of cases informed consent is still required. No one reported the use of a standardised anonymization procedure.

The majority of the 170 respondents (91%) anticipates that AI will be used in LM to support professionals in their decision-making, whereas only a very small percentage (2%) envisages that the laboratory professional may eventually be replaced in some tasks, such as reading of peripheral blood smears or urine sediments. Only a tiny portion of the interviewees expects a marginal role (2%) or does not know what a conceivable role (4%) for AI in LM could be. Additionally, several interviewees anticipate that the AI might facilitate LM Research (free answer not provided among the options).

The most common responses, among the 168 received, to the question of what is the main barrier to the application of BAI, identified inadequate IT infrastructure and lack of specialised software as the major obstacles, followed by poor integration between different data sources, lack of expertise and difficulties in accessing data. Respondents, however, generally agreed that there is not one single obstacle to focus on, but rather that all the challenges mentioned are actually obstacles to the use of BAI in Italian clinical laboratories (Figure 6).

Finally, the vast majority of participants (95%, 162 out of 170 respondents) expressed interest in education on LM BAI. The majority of respondents said they would like to improve their skills in data management (35%) or data analysis (37%), while a third said they would benefit from attending a course on the subject (28%).

Discussion

This survey, which sought to highlight the level of expertise, knowledge and interest among Italian clinical laboratory professionals in the field of BAI and its applications in LM, received a relevant amount of feedback from SIBioC participants (227 responses), allowing to achieve a limited margin of error on overall answers (around 6% with a confidence level of 95%). The benefits of web-based survey have been already proven with respect to traditional methods [22] and, especially for health social science researchers [23]. Further, the representativeness bias (which could be present in web-based survey) could be excluded since all interviewed individuals used every day email for working tasks.

Another survey on the value of AI in LM was recently conducted by Paranjape and co-authors [24] in the United States in a small cohort of subjects (n=128), that included LM stakeholders, with a different target audience (top three participants were physicians, laboratory managers and pathologists), but similar age distribution. Moreover Paranjape and co-authors used “open” answers to questions, which made it possible to collect opinions but not numerical data. However, some findings were similar to that of our study.

Even Paranjape et al. pointed out a lack of specific knowledge on the subject of BAI in the medical community. In fact, the perceived value of AI observed does not differ from that of the general population and seems only to reflect the popularity of new technologies. Many respondents of that questionnaire were unsure about “why AI would or would not be valuable, what is needed to comfortably adopt AI, or how to be educated on AI”. As it is evident not only from our questionnaire, but also from the American survey, there is a need to introduce AI into

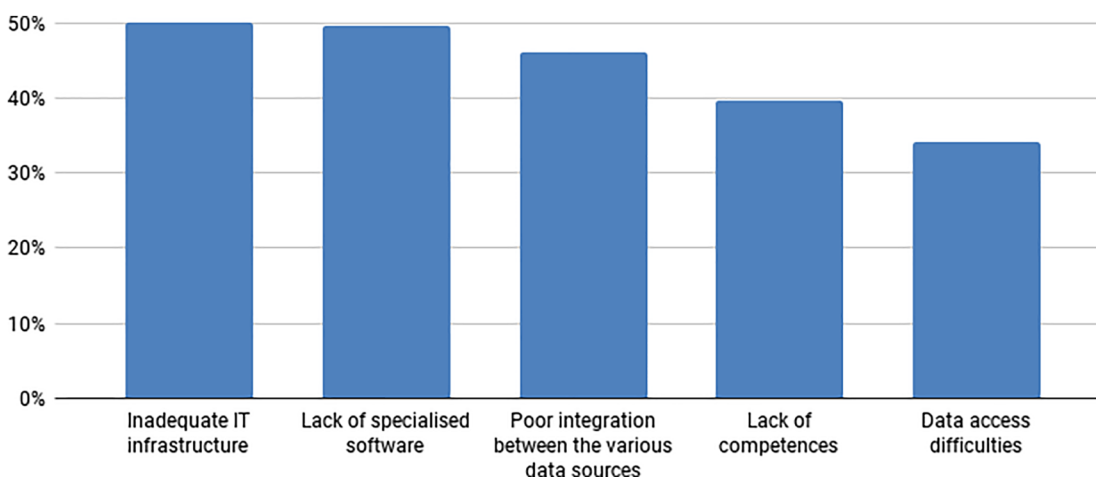


Figure 6: Opinion on the major barriers to the implementation of Big Data and Artificial Intelligence.

medical education. Paranjape et al. also call for responsible participation of the diagnostic companies for providing training and educational activities.

Other similar results concern infrastructure prerequisites, which were reported as deficient by both questionnaires. In particular, our findings reveal a general lack of hardware and software infrastructures, dearth of personal PCs, lack of corporate Wi-Fi networks, and a low level of subjective satisfaction with regard to both software and hardware equipment. Software and hardware interfaces are needed not only to manage Big Data, but also to use tools developed by AI or to share opinions in different hospitals or even within the other divisions of the hospital.

In addition, cloud resources are not well implemented in Italian laboratories, and this could make the implementation of AI cloud-based strategies difficult.

Besides, our survey highlights the fact that roughly two thirds of participants—including those in the category of Laboratory Directors—cannot easily acquire health data from sources other than laboratories. According to the respondents, the LIS does not ensure compliance with three of the five “V” that define Big Data because they only apply to laboratory data and volume and velocity are not complied [25]. This latter information represents a real barrier to AI study. Finally, only a small number of participants stated that their laboratory has a specific professional figure with expertise in data science.

In summary, overall results offer the opportunity of understanding relevant flaws on AI implementation in clinical laboratories; most Labs could only partially conduct research on AI, and are equipped with infrastructure not adequate for implementing high technological tasks, such as those required by AI. Although the lack of technological infrastructure might be due to a shortage of economic resources, unfortunately, updating computer software (such as laboratory LIS) still might not fill the gap necessary for the success of well conducted AI in laboratories. In order to be ready for future AI applications, LIS should be freely interfaceable with third-part applications and software manufacturers should include this possibility in their updated versions. Educational aspects and collaborative efforts are not secondary to the previous consideration. The role of LM specialists will not be to develop AI algorithms, but they must take responsibility for helping data scientists and engineers select the right algorithm on the basis of biological and medical information on laboratory measurands [26]. Ethical issues are an obstacle to the development of AI applications. Striking a balance between ethical concerns and domain rules might not be easy, as overly complicated rules might be more

easily overlooked or violated, and the preservation of privacy is of utmost importance, even considering the need to minimise the risk of data leaks. In their paper, Pennestri and Banfi underline these needs and state that “few clear rules, substantial clarity of purpose, simplification, flexibility and AI professional training probably represent a better approach that both the European framework and UK guidelines seem to have caught” [27]. Finally, scientific society and *in vitro* diagnostic manufacturers should establish a strong partnership not only for reciprocal improving knowledge in these fields, but also for developing functional and useful AI-based tools.

This study presents several limitations. Firstly, although there was a strong adherence to the questionnaire documented by the high number of responses, this is still a negligible percentage of the total number of Italian laboratories (estimated at around 4,000), and therefore the results are only a representation of the Italian state of the art. Secondly, the number of answers received related to Section 5 is lower than for the other sections. We hypothesised that this gap might be due to the specificity of the questions, which discouraged participants or that they were unable to answer them, thus supporting the results of the survey.

In conclusion, the opinions gathered show that none of the obstacles to the development of BAI in LM stand out more than the others, emphasising the need to improve many aspects that prevent the use of these new methodologies: from the adaptation of IT infrastructures (data warehouses that combine the various data sources, acquisition of specialised software for BAI analysis, the resolution of the limitations on accessibility and use of data in respect of privacy [27]), to the management of training and the acquisition of new skills. The role of scientific societies is of undoubted value with regard to the need for training, which was made explicit by the majority of respondents. Clinicians should spend time learning the fundamentals of these new technologies in order to evaluate clinical trial opportunities [28]. Indeed, the involvement of LM specialists is crucial to ensure that laboratory data are sufficiently available and conscientiously incorporated into clinically successful scientific projects [5].

Research funding: None declared.

Author contributions: All authors have accepted responsibility for the entire content of this manuscript and approved its submission.

Competing interests: Authors state no conflict of interest.

Informed consent: Not applicable.

Ethical approval: Not applicable.

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