Evolution of the implementation of a quality management system in the Belgian laboratories for anatomic pathology

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INTRODUCTION

The Royal Decree (RD) of 5 December 2011, concerning the licenses of anatomic pathology laboratories has as purpose to monitor and guarantee the quality of the Belgian laboratories for anatomic pathology. Since the 1st March 2014 all Belgian anatomic pathology laboratories are licensed. Within the framework of this licensing the laboratories are obliged to elaborate a quality management system within five years. However, the requirements as stated in the articles 22, 24, 26, 27, 28 and 29 of the RD (see legend in figure 2), should be fulfilled within a time period of three months counting from the entry into force of the license. In order to follow up the implementation of the quality management system and the implementation of the above-mentioned articles of the RD in the Belgian anatomic pathology laboratories, a documentary audit by the department Quality of Medical Laboratories at the IPH has been performed.

METHODS

In 2014, in collaboration with the Commission of Anatomic Pathology, all licensed laboratories (n=97) were asked to fill out a table in which the percentages of implementation of each article (22/24/26/27/28/29), the corresponding procedures for each item and article and the validity date had to be indicated. In the course of 2015, during a second evaluation step, the laboratories (n=85) were asked to actualize the table presented in the survey of 2014. The tables were evaluated substantively for the presence of predefined items after which the percentage implementation for each article and an overall score (mean of percentages calculated for the articles 22, 24, 26, 27, 28 and 29) were calculated.

RESULTS

From the installation of the RD till 2015, the number of licensed laboratories diminished from 102 in 2013 to 97 in 2014 and to 85 in 2015, mostly due to cessation of laboratory activities of connexists (specialist physicians who perform acts of anatomic pathology exclusively for their own patients).
In 2014, 97 laboratories were included in the evaluation survey. 60 participants (62%) obtained an overall implementation score (all articles included) of more than 70%. During the second evaluation survey organized in 2015, among the 85 included laboratories, 77 (80%) received an overall implementation score of more than 70%.
In 2014 we counted 16 laboratories (16.6%) with an overall score of less than 25%. On the contrary, no single laboratory scored less than 25% in 2015.

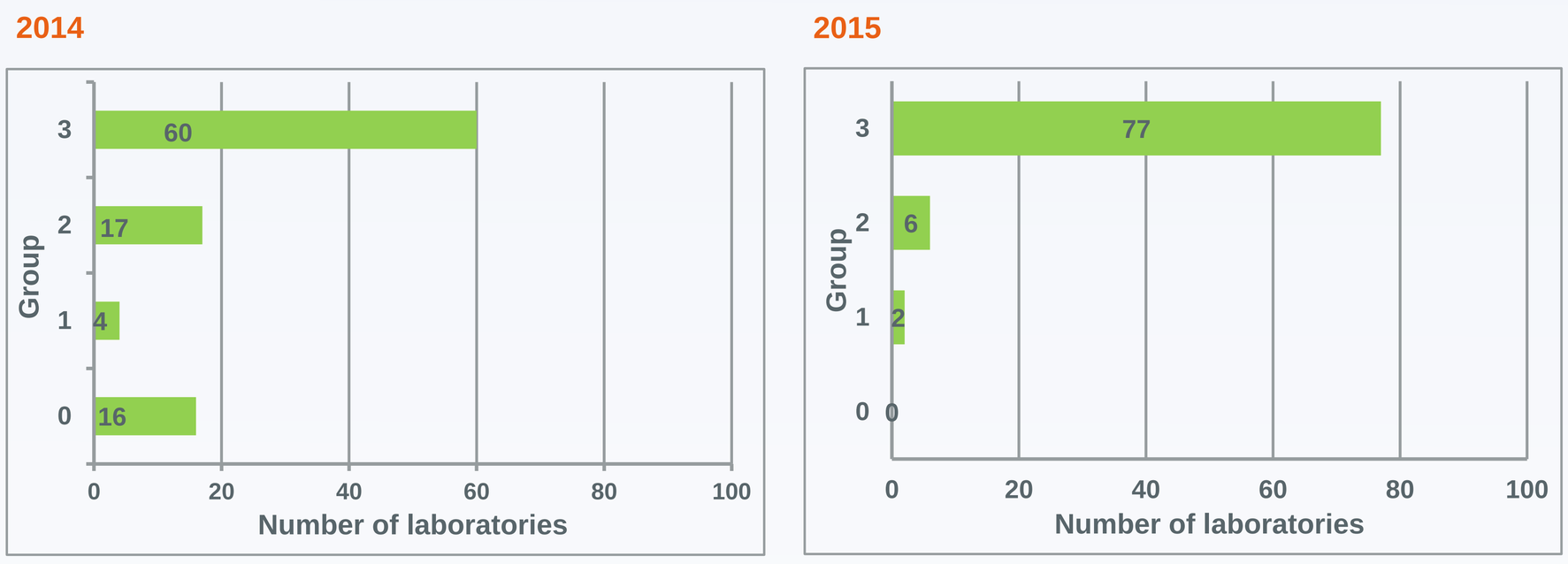

Figure 1: Number of laboratories with their overall scores for implementation of articles 22, 24, 26, 27, 28 and 29 in 2014 and 2015. The laboratories were grouped based on the overall score:
0 = overall score 0 ≤ x < 25%
1 = overall score 25% ≤ x < 50%
2 = overall score 50% ≤ x < 70%
3 = overall score 70% ≤ x ≤ 100%.

More detailed analysis of the obtained information revealed that the procedures on validation of methods and on management and validation of computerized systems seemed to be an issue. In 2014, only 60% of all laboratories had completely implemented the SOP on validation of methods, in contrast with 73% of the laboratories in 2015. In particular the implementation of article 29 (management and validation of computerized systems) seems to remain the biggest obstacle as only 34% of the laboratories had completely implemented this article in 2014 and still one third of all the laboratories are lacking this procedure(s) in 2015.

	Area management	Acces to areas	Storage	Temperature control	Safety	Calibration	Maintenance of equipment	Document control	Validation of examination procedures	Archiving	Reporting art.27	Reporting art.28	Management information system	Verification information system
2014	20.62%	38.14%	45.36%	40.21%	23.71%	55.67%	15.46%	23.71%	40.21%	58.76%	25.77%	17.53%	23.71%	65.98%
2015	3.53%	0.00%	23.53%	3.53%	11.76%	24.71%	5.88%	8.24%	27.06%	15.29%	4.71%	3.53%	32.94%	31.76%

Figure 2: Percentage of laboratories with incomplete implementation of the procedures with regard to the articles 22, 24, 26, 27, 28 and 29. The IPH evaluated for each laboratory which procedures were implemented with regard to the articles 22, 24, 26, 27, 28 and 29. Article 22 covers the procedures area management, access to areas, storage, temperature control and safety; article 24 the procedures on calibration and on maintenance of equipment; article 26 the procedures on document control and on validation of examination procedures; article 27 the procedures on archiving and on reporting (transmission, confidentiality); article 28 the procedure on reporting (content); article 29 the procedures on management and verification of information systems.

CONCLUSION

Collaboration between the laboratories and IPH has contributed to the awareness of the laboratories to work in a quality environment. Close monitoring, adjustment and support by the IPH and the Commission of Anatomic Pathology improved and is still improving the implementation of a quality management system as stated in the RD on licensing conditions of the Belgian laboratories for anatomic pathology.

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