Implementing a proficiency test provider for sphygmomanometers in Brazil

B A Rodrigues Filho¹, R F Farias¹ and W Anjos²
¹National Institute of Metrology, Quality and Technology – INMETRO
²Weights and Measures Institute of São Paulo – IPEM/SP
E-mail: bafilho@inmetro.gov.br

Abstract. Self-verification represents a level of control in legal metrology where manufacturers are responsible for the conformity assessment of measuring instruments. To solve the independence and impartiality concerns, accreditation is introduced as a tool to monitor the competence of laboratories providing self-verification tests. Especially in health measurements, an inaccurate measurement may lead to misdiagnoses. To support the traceability of accredited laboratories, a proficiency test due to interlaboratory comparison is necessary in order to assess the conformity of measurements of manufacturers of sphygmomanometers for blood pressure measurement. Then, this study presents the implementing process of a proficiency test provider laboratory for sphygmomanometers based on legal metrology requirements in order to fulfill the necessity of an interlaboratory comparison among manufacturers that assess the conformity of sphygmomanometers. We also show a comparison of the measurement tests for three distinct manufacturers in order to identify divergences of processes.

1. Introduction and motivation

In order to provide accuracy and precision for measurements that impact the society, an unbroken calibration chain is required. Then, metrological traceability due to a documented unbroken chain of calibrations to a reference is necessary to provide confidence to the results, the measurements [1].

Accreditation is a consolidate methodology applied to disseminate traceability, applying formal, international well-known and standardized procedures, evaluating the competence, infrastructure, methods, standards, training, independence, impartiality, proficiency and several others aspects of accredited laboratories [2-3].

In this context, an interlaboratory comparison is a tool applied in order to check the comparisons of measurement uncertainties among the parties and it is widely used in accreditation due to proficiency tests to validate the competence of the accredited bodies. Consequently, deviations provide feedback to the laboratories to correct eventual problems in their processes.

However, accreditation in legal metrology is a relatively new area and publications regarding it are still sparse [4].

Although the working bodies in legal metrology use standards calibrated in accredited laboratories, accreditation for legal metrology tests is still incipient. There are some critical points for manufacturers that run self-verification tests that can undermine the interlaboratory comparison, such as:

¹ bafilho@inmetro.gov.br
• The tests required by legal metrology requirements also demand administrative tests, sealing marks checking, constructive features, and usage conditions since the instrument is used in the field and it is exposed to several environmental aspects such as temperature, mechanical impacts, and others;
• There is a resistance of manufacturers participating in interlaboratory comparison due to commercial issues.

Sphygmomanometers are generally under the metrology regulation as they are widely used in diagnoses in medicine, as an example, diagnoses and treatment of hypertension. Then, an accurate measurement is vital to an adequate medical treatment since a deviation in the measurement might either induce an unnecessary treatment or provide treatment to an inexistent disease. Consequently, the instruments must be accurate and precise [5].

Small systematic deviations in blood pressure measurements may cause large variations in the proportion of false positive diagnosis of hypertension. A deviation of +3 mmHg increases in 68% the false positives of patients with blood pressure superior to 90 mmHg, and a deviation of –3 mmHg, 44% of hypertension patients would not be diagnosed. A deviation of +1 mmHg would decrease it to 20% [6]. Furthermore, in 2015, in the United Kingdom, 28% of the mechanical sphygmomanometers and 42% of the mercury-based ones presented measurement errors of +4 mmHg [7].

In Brazil, in 2015, the self-verification process was responsible for 45% (2,668,086) of sphygmomanometers tests and it is estimated that in 2017, approximately 100% of the instruments might have their conformity assessed due to self-verification processes.

Then, to support the traceability and conformity for all aspects involving legal metrology, the present project proposes the implementation of a third part independent facility to provide the interlaboratory comparison based on tests required by legal metrology requirements, focusing on sphygmomanometer accredited laboratories for self-verification.

2. Methodology

A partnership between the National Institute of Metrology, Quality and Technology – INMETRO, Brazilian National Metrology Institute (NMI) and the Weights and Measurement Institute of São Paulo – IPEM/SP enables the implementation of the interlaboratory comparison incorporating the already existing infrastructure of an ISO/IEC 17025:2005 accredited laboratory. The State Institute is a public body and it has an INMETRO delegation for legal metrology activities, including sphygmomanometers verification and inspection. Therefore, the project uses both accredited laboratory and legal metrology expertise of the Pressure Laboratory of the State Institute in order to conduct the present project, which will play a role as a proficiency test provider.

As an OIML member, Brazil adopts the procedures for sphygmomanometer tests based on the International Recommendation R 16 -1 and 2 for Non-Invasive Sphygmomanometers. Additionally, the laboratory conducts tests using an Onneken calibrator OM-HM 621-S having a measuring interval from 0.0 to 375.0 mmHg and resolution of 0.1 mmHg, adequate for sphygmomanometer tests. Moreover, the traceability is assured by periodic comparisons of the Onneken calibrator to a dead weight tester, traced to the national pressure standard in Brazil.

Figure 1 shows the steps to be followed in order to implement the interlaboratory comparison laboratory for sphygmomanometer tests based on legal metrology requirements.
3. Results of a comparison among manufacturers

Since Brazil is an OIML Member, the tests for sphygmomanometer are based on the OIML Recommendation R 16, which defines the maximum permissible errors (MPE) for initial verification measurement tests in ± 3 mmHg [8-9].

Then, in order to illustrate the importance of a proficiency test provider in legal metrology, we collected a sample of results of tests conducted by three already working laboratories of distinct manufacturers. The samples were collected according to the technical standard ABNT NBR Sampling Procedures for Inspection by Attributes [10]. The samples were also collected considering similar sphygmomanometers (automated) and the same period of time, representing the production during September/2016.

The results of the pressure test for three different manufacturers are shown in figure 2 and 3 for two distinct points (P) of the measurement test, P = 80 mmHg and P = 160 mmHg.

Figure 2. Comparison among three different manufacturers for pressure test (P = 80 mmHg).
Figure 3. Comparison among three different manufacturers for pressure test (P = 160 mmHg).

Figure 2 and 3 show that the mean for measurement tests are according to the MPE enforced by the national regulation. However, it is possible to note that the maximum values presented by the manufacturer A for both 80 mmHg and 160 mmHg surpass the MPE. It is also possible to conclude that manufacturer C presents the minimum variation between maximum and minimum values for the tests, demonstrating more precision when compared to A and B.

Figures 4 and 5 show the confidence interval for the mean of the points P = 80 mmHg and P = 160 mmHg for the three analyzed manufacturers.

![Figure 3](image)

![Figure 4](image)

Based on the confidence interval for the mean, it is possible to conclude that all manufacturers are according to MPE, considering an interval of confidence of 95.45%.

We also conducted a Tukey test in order to determine the independence of the results to analyze the difference of significance of the results produced by different manufacturers. Table 1 and 2 show the results for the test comparing A vs B, A vs C and B vs C for the points P = 80 mmHg and P = 160 mmHg [11].
Figure 5. The confidence interval for the mean of the pressure test (P = 160 mmHg) for the tested manufacturers.

Table 1. Tukey Test for the samples for the pressure test (P = 80 mmHg).

| Treatments pair | Tukey HSD p-value | Tukey HSD inference |
|-----------------|------------------|---------------------|
| A vs B          | 0.001005         | ** p<0.01           |
| A vs C          | 0.001005         | ** p<0.01           |
| B vs C          | 0.002322         | ** p<0.01           |

Table 2. Tukey Test for the samples for the pressure test (P = 160 mmHg).

| Treatments pair | Tukey HSD p-value | Tukey HSD inference |
|-----------------|------------------|---------------------|
| A vs B          | 0.53693          | insignificant        |
| A vs C          | 0.00101          | ** p<0.01           |
| B vs C          | 0.00101          | ** p<0.01           |

Although A, B and C are within the MPE (± 3 mmHg), the Tukey test for P = 160 mmHg, shows that the results of manufacturer C are different when compared to A and B for a confidence interval of 95.45%. For P = 80 mmHg, differently from the previous test, A, B and C present different results for the same confidence interval.

4. Discussion

As the methodology applied to the tests follows the international recommendation, OIML R 16, and based on figure 4 and 5, it is possible to conclude that all manufacturers are according to the MPE within a confidence interval of 95.45%. Additionally, according to the Tukey test, considering both P = 80 mmHg and P = 160 mmHg, A, B and C produce independent results.

We also note a significant difference when comparing C to A and B, which results are more precise and accurate.

Additionally, based on figures 4 and 5, to P = 80 mmHg, the results of A, B and C are within ± 1 mmHg considering the confidence interval, and ± 0.6 mmHg from the reference value to P = 160 mmHg.

Although the selected samples represent similar sphygmomanometers, the devices present minor differences as they are produced by distinct manufacturers, consequently, it is not possible to conclude if the divergence in precision can be explained by quality or by the competence of the producer.

It is worth noting the importance of a proficiency provider in order to confirm the results produced by the laboratories. Based on the results of A, B and C, it would also be possible to decrease the MPE for initial verifications improving the accuracy, consequently impacting the misdiagnoses.

As a proficiency test provider, the IPEM/SP’s laboratory will give a panorama of the sphygmomanometer manufacturers’ uncertainties allowing the authorities to survey deviations processes, providing a market surveillance tool improving the efficiency in legal metrology control.
Moreover, the IPEM/SP’s laboratory acting as proficiency test provider will also be an important independent and impartial body allowing comparisons in legal metrology level for the manufacturers, preventing commercial disputes.

Although manufacturer’s laboratories are accredited for legal metrology tests, once a deviation in a measurement is identified in a proficiency test, the authorities will be able to suspend authorizations for self-verification, eliminating bad-practices of the market. It will also be a tool to ensure penalties in legal metrology level. Consequently, it will provide harmonization and standardization for self-verification bodies and initial verification, permitting fair competition among competitors.

Consequently, once the market is properly surveyed, we expect to guarantee blood pressure measurements of devices in initial verification level, increasing the reliability of the legal metrological control once approximately 100% of the devices should be self-verified in 2017.

5. Conclusion

A proficient test provider due to an interlaboratory comparison of measuring instruments under the legal metrology control, conducted by IPEM/SP’s laboratory will allow authorities ensuring conformity in blood pressure measurement field. It will also permit authorities to identify and enforce legal actions to laboratories which practices are not in conformity with legal metrology requirements.

In addition, the implementation of a proficiency testing provider in legal metrology also allows evaluating whether laboratories are able to detect nonconforming instruments through interlaboratory comparisons that use as reference sphygmomanometers purposely altered.

The comparison among different manufacturers also presented the importance of a reference, in order to check the accuracy and precision of producers.

The IPEM/SP’s laboratory will also permit decrease the MPE, therefore improving the accuracy of blood pressure leading to a decrease of misdiagnoses, and consequently, the costs involving in treatments as well as the health issues involved in either non-necessary and mistreatments.

Acknowledgments

The authors acknowledge FAPESP proc. nº 2017/50173-0 for the financial support.

References

[1] International Vocabulary of Metrology—basic and general concepts and associated terms. JCGM 200:2012.
[2] Lagauterie, G.; Pecchioli, G. Accreditation and legal metrology in France. OIML Bulletin, v. LII, n. 2, p. 19–29, Apr. 2011.
[3] ILAC. 2015. Available in: http://ilac.org/about-ilac/. Accessed in: 14 Oct. 2016
[4] Rodrigues Filho, B. A.; Gonçalves, R. F. Legal metrology, the economy and society: A systematic literature review. Measurement, v. 69, p. 155–163, Jun. 2015.
[5] Serafim, T. S. et al. Avaliação das condições de uso de esfigmomanômetros em serviços hospitalares. Acta Paulista de Enfermagem, v. 25, n. 6, p. 940–946, 2012.
[6] Turner, M. J.; Baker, A. B.; Kam, P. C. Effects of systematic errors in blood pressure measurements. Blood Pressure Monitoring, v. 9, n. 5, p. 249–253, Oct 2004.
[7] Hathway, P. et al. Comparative study of two ambulatory blood pressure monitors that use differing methods of calibration to determine central aortic blood pressure from the brachial waveform. Journal of Hypertension, v. 33, p. e181–e182, Jun. 2015.
[8] OIML. R 16-1 Non-invasive mechanical sphygmomanometers, 2002. Available in: https://www.oiml.org/en/files/pdf_r/r016-p-e02.pdf. Accessed in 04/04/2017.
[9] OIML. R 16-2 Non-invasive automated sphygmomanometers, 2002. Available in: https://www.oiml.org/en/files/pdf_r/r016-p-e02.pdf. Accessed in 04/04/2017.
[10] ABNT NBR 5426. Technical Standard - Sampling procedures for inspection by attributes, 63 p., 1985.
[11] Tukey test available in: http://astatsa.com/OneWay_Anova_with_TukeyHSD/.