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Radionuclide calibrator comparisons and quality improvement in nuclear medicine

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Abstract

The traceability of activity measurements performed during the development phase of the radiopharmaceutical and in its clinical application is essential for establishing the comparability of clinical results reported in the nuclear medicine field. This paper presents and discusses the evaluation over time of the quality of activity measurement results obtained in Cuban nuclear medicine, on the basis of statistical samples taken during the radionuclide calibrator comparison program. An attempt is also made to evaluate the role played by such comparisons in quality measurement improvement in nuclear medicine, on the basis of results obtained in a number of countries and published by several authors over a period of time. Specifically, improvements of the measurement performance over time assessed by such exercises were found dissimilar in magnitudes for different countries. Two phases could be distinguished in the improvement process over time. Firstly, a fast improvement can be obtained resulting from the improvement in measurement accuracy of devices. After that, the achievement of new and sustained improvements goes slowly and requires an application of quality assurance programs where the qualification upgrading of personnel become an essential point.
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1. Introduction

The amount of radioactivity, contained in drugs that are injected in the nuclear medicine practice, determines the dose to the patient. Therefore, the ability to accurately measure that activity prior to its administration in the clinic is an important factor for the safe and effective use of these drugs. Furthermore, the traceability of activity measurements performed during the development phase of the radiopharmaceutical and in its clinical application is essential for establishing the comparability of clinical results reported in this field.

The Radionuclide Metrology Department of the Isotope Center of Cuba (CENTIS-DMR), as the national metrological laboratory for radioactivity, has developed a national program of comparisons for assaying gamma-emitting radiopharmaceuticals for amount of radioactivity in radionuclide calibrators that have been operating since 2000. This program has been organized in collaboration with the Centro de Control Estatal de Equipos Médicos (CCEEM), the Cuban regulatory authority concerned with the use of medical equipment in the country. That co-operation has allowed the technical and regulatory capabilities to be linked in such a way that the comparisons are able to actively act as a tool for quality improvement of measurements in nuclear medicine. Results of this program have been previously published (Oropesa et al., 2003, 2005, 2006).

This paper presents and discusses the evaluation over time of the quality of activity measurement results obtained in Cuban nuclear medicine, on the basis of statistical samples taken during the radionuclide calibrator comparison program. An attempt is also made to evaluate the role

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played by radionuclide calibrator comparisons in improvement of measurement quality in nuclear medicine on the basis of comparison results obtained in a number of countries and published by several authors over a period of time. Data of gamma-emitters, such as ^{99m}Tc, ^{201}Tl, ^{67}Ga, and ^{131}I, are employed for this analysis. A χ^2 test is applied to determine the character of association between the observed performance and the period of time when the exercises were organized at a significance level of α equal to 0.05.

2. Cuban comparisons

2.1. Comparison protocols

Two kinds of protocol have been adopted in Cuban comparisons. One of them tries to simulate the whole administration procedure of a radiopharmaceutical by injection of an a priori planned amount of radioactivity to a patient, attempting to evaluate in a more complete way the accuracy of the administered activity value in comparison with the prescribed one. Outcomes of that test were recently discussed and published (Oropesa et al., 2006), and they are beyond the scope of this paper.

The comparison results discussed in this contribution were obtained in accordance with the following protocol (Oropesa et al., 2003, 2005): solutions of a single radionuclide are calibrated for radioactivity content and distributed in containers of the type commonly used in nuclear medicine services, as blind samples to the participants. The participants perform activity measurements exactly as would normally be done in their facility and report the values back to the organizer. The participants' results are compared with the reference activity values determined by CENTIS-DMR, and a comparison report is compiled and discussed at a workshop of participants, CENTIS-DMR, and CCEEM personnel. In such a manner, problems related to the instrument, measurement procedure, and personnel making measurements can be highlighted and potential remedies discussed.

For all radionuclides used in comparisons, the reference activity, X_{ref}, of each individual vial or syringe was established with a relative combined standard uncertainty of 1.9%, by means of its measurement in a reference radionuclide calibrator, previously calibrated at CENTIS-DMR for the specific radionuclide and sample geometry (Oropesa et al., 2002, 2003; Oropesa and García-Toraño, 2004). These CENTIS-DMR calibration capabilities have been already published in Appendix C of the Key Comparison Data Base maintained by the International Bureau of Weighs and Measures (see www.bipm.org).

The z-score statistic (ISO/IEC 43-1, 1997)

$$z = \frac{(X_{\mathrm{med}} - X_{\mathrm{ref}})}{0.033 X_{\mathrm{ref}}} \tag{1}$$

was calculated to evaluate the participant's performance. In the above written equation X_{med} is the sample activity reported by the participant decay-corrected to the reference time and X_{ref} is the sample activity calibrated at CENTIS-DMR decay-corrected to the reference time.

The radionuclide half-life employed for decay corrections were taken from database Nucléide (Nucléide, 1998).

The Cuban regulations require a 10% accuracy limit, corresponding to about three standard deviations (Guía, 2002). The above stated z-score statistics takes into account this 10% value and the participant's performance is regarded as "acceptable" provided that the absolute value of the corresponding z-score is not greater than 3. Otherwise, the performance is "not acceptable".

2.2. Hypothesis testing

When the sample size is large enough, a χ^2 test is applied for testing the hypotheses about the independence of given characteristics of the comparison results, at a significance level of $\alpha = 0.05$. The respective contingency tables are created and a two χ^2 statistics calculated from the observed, f_i, and expected frequencies, F_i:

$$\chi^2 = \sum_{i=1}^{k} \frac{(f_i - F_i)^2}{F_i}, \tag{2}$$

$$\chi_c^2 = \sum_{i=1}^{k} \frac{(|f_i - F_i| - 0.5)^2}{F_i}, \tag{3}$$

where the sum is taken over all cells in the performance table. The expected frequencies are calculated from "marginal" totals (Spiegel, 1961). If both χ^2 values lead to the same conclusion regarding a hypothesis, such as rejection at 0.05 level, difficulties are rarely encountered.

2.3. Comparison results

The relative frequency histograms for comparison results reported by the participants in 2000, 2002, 2003, and 2004 are presented in Fig. 1. These results are the sum of reported values for all radionuclides and geometries used in the comparisons. Classes in the histograms are settled on differences between the reported and CENTIS-DMR values and are expressed in terms of the calculated, according to Eq. (1), z-score statistic.

2.3.1. Year 2000

As can be seen from the Fig. 1, the available data from 2000 year comprises only of 12 results and only 58% of them were considered acceptable. Actually, there were a small number of radionuclide calibrators functioning at Cuban hospitals (seven instruments) and approximately 50% of them were not correctly calibrated for measurements—calibration coefficients used had been determined several years ago by the manufacturer. For instance, one instrument had not been calibrated for more than 10 years. In another case, the device response had deteriorated

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