Actual Versus Theoretical Pediatric Radiopharmaceutical Dosage

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During calendar year 1978, the Food and Drug Administration's Center for Devices and Radiological Health conducted a nationally representative survey of United States hospitals to collect in vivo diagnostic nuclear medicine patient data. These hospital patient data were initially used for the identification of radiopharmaceutical and procedure trends. We have extracted the pediatric data from the sample and reviewed the administered activity of radiopharmaceuticals used. These data basically illustrate that higher than necessary levels of radiopharmaceutical activities were administered to children. Therefore, the Center has undertaken an educational effort to alert the nuclear medicine community to this concern.

The Center for Devices and Radiological Health's activities not only evaluate nuclear medicine experience trends, but also attempt to reduce unnecessary medical radiation. The Center has contributed to the development of new short-lived radionuclides to replace those with higher radiation dosage levels, and has been instrumental in the implementation of quality assurance programs to improve the diagnostic quality and reliability of nuclear imaging procedures. One project was designed to collect and analyze in vivo diagnostic nuclear medicine patient data obtained using the Medically Oriented Data System (MODS). Analysis results have raised the concern that pediatric patients may have been receiving a higher level of administered activity than necessary for obtaining adequate diagnostic results.

MATERIALS AND METHODS

The MODS used a survey mechanism developed by the Food and Drug Administration to collect experience data from a nationally representative group of U.S. hospitals located throughout the 48 contiguous States. A MODS pilot study was conducted and a publication describing the MODS pilot study results was published in 1976 (*1*). The MODS was then implemented and in vivo diagnostic nuclear medicine patient data were collected for the period of August 1, 1977 through July 31, 1978. Overall results have been presented at a Society of Nuclear Medicine meeting (*2*), and a description of the MODS is available from the Center (*3*).

In 1982, the MODS pediatric patient experience data (2,194 procedures) were separated from the total data base and independently analyzed from several standpoints. MODS pediatric data have provided the Center with a profile of nuclear medicine experience by recording various parameters on a case-by-case basis, including procedures performed, radiopharmaceuticals selected, activities administered, and weight and ages of patients. These profiles have allowed analysts to define areas of concern that warrant further investigation. Table 1 lists the five most frequently reported pediatric nuclear medicine procedures in the MODS data. Several accepted methods of calculating administered activity are detailed in the literature (*4*). In 1978, the methods for calculating administered pediatric activity in use by MODS participating hospitals were: on the basis of a proportional relationship between child and average adult patient weight; ratio of pediatric target organ mass divided by average adult target mass raised to the two-thirds power; and an empirical relationship that approximates the pediatric body weight raised to the two-thirds power for a wide range of children's ages.

For the purposes of this paper, the authors elected to use the weight relationship to calculate the theoretical value for administered activity. The determination of an acceptable value for administered activity was then calculated using the maximum recommended value of adult radiopharmaceutical dose and the standard adult weight of 70 kg.

However, it should be recognized that the methods do not allow for the special cases where allowances must be made for dynamic imaging procedures, adaptation to specific instrumentation, critical patients, or those patients where physical damage requires higher levels of administered activities (*5*). It is also important to note that the methods of calculating administered activity do not include any determination of minimum dose (*6*).

RESULTS AND DISCUSSION

Detailed findings of the analysis of MODS pediatric data have been presented (*7*) and provide evidence that, during the survey period, administered activity levels substantially exceeded theoretical values. Using graphic techniques, careful analysis of the MODS data have allowed comparison of actual and theoretical radiopharmaceutical activity administered for pediatric nuclear medicine examinations. Bone imaging doses with polyphosphate or pyrophosphate are presented in Fig. 1. The theoretically administered activity was calculated and plotted using the weight rule. The resultant theoretical

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TABLE 1. Five Most Frequently Reported MODS Pediatric Procedures

Procedure and Radiopharmaceutical	Recommended Adult Maximum Dose (mCi)	Actual Pediatric Dose (mCi)		Total Number of Procedures	Number of Procedures by Patient Age Group			
		Average	Range		<4 Yr	4–9 Yr	10–15 Yr	16–18 Yr
Liver imaging: Tc-99m sulfur colloid	3	3.07	1.0– 8.0	257	61	46	67	83
Brain imaging with vascular flow Tc-99m pertechnetate	15	16.00	3.0–26.0	182	26	52	80	24
Brain imaging with vascular flow Tc-99m DTPA	15	18.22	2.0–30.0	174	12	21	58	83
Bone imaging: limited area Tc-99m polyphosphate or pyrophosphate	15	13.89	2.0–20.0	175	22	32	76	45
Bone imaging: limited area Tc-99m EHDP	15	11.12	5.0–25.2	147	33	31	47	36

values have been plotted as a line representing the calculated maximum pediatric administered activity while actual patient data are plotted as individual points. Under normal circumstances, actual administered activities should not exceed these values. Most of the actual pediatric values exceeded the maximum calculated administered activity for this graphic comparison. This was also the case with the vast majority of other MODS pediatric procedures.

Over the last few years, changes have taken place in both the types and numbers of nuclear medicine procedures being performed. These trend changes are due to the introduction of new equipment and instrumentation that has altered the numbers and types of nuclear medicine examinations being performed. New imaging technologies, such as computed tomography, nuclear magnetic resonance, and ultrasound, are having a large impact on the entire medical imaging field (*8*). The most pronounced change resulting from these new technologies within the diagnostic field has been the reduced number of in vivo nuclear medicine brain examinations performed in U.S. hospitals. The data presented in Fig. 2 indicate

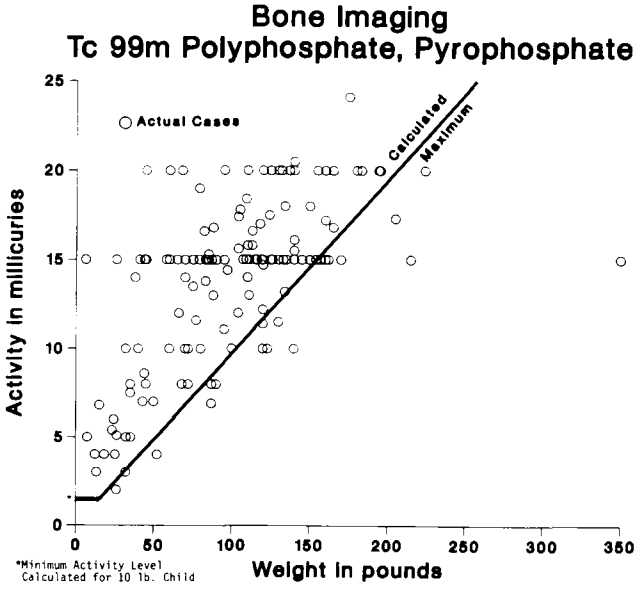

FIG. 1. Estimated nuclear medicine examinations performed in U.S. hospitals by type of procedure, 1975–1983. (Source data: Adapted from Market Measures, Inc., Orange, NJ.)

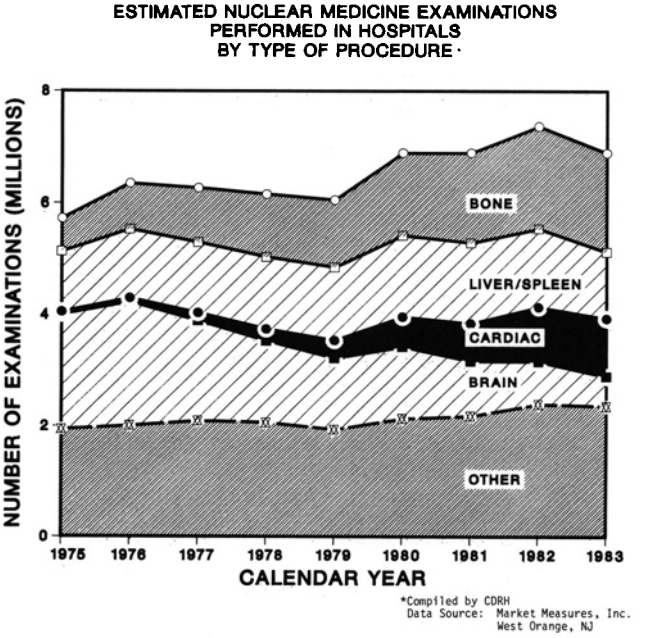

FIG. 2. Bone imaging Tc-99m polyphosphate/pyrophosphate.

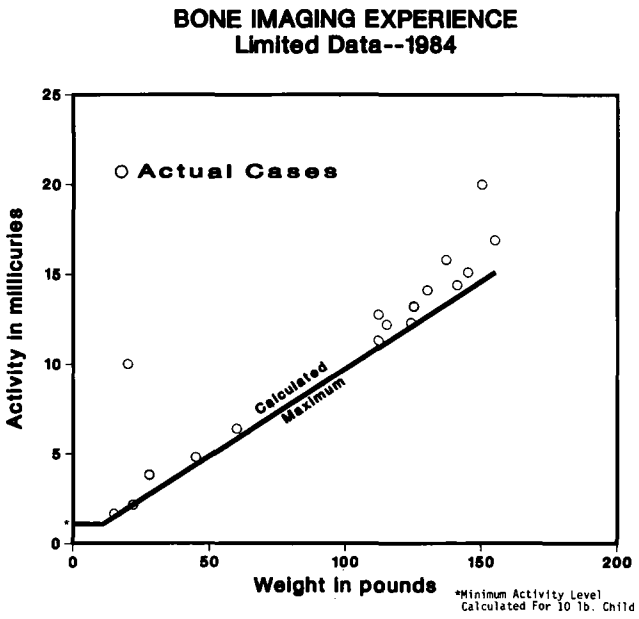

FIG. 3. Bone scanning experience (limited data—1984).

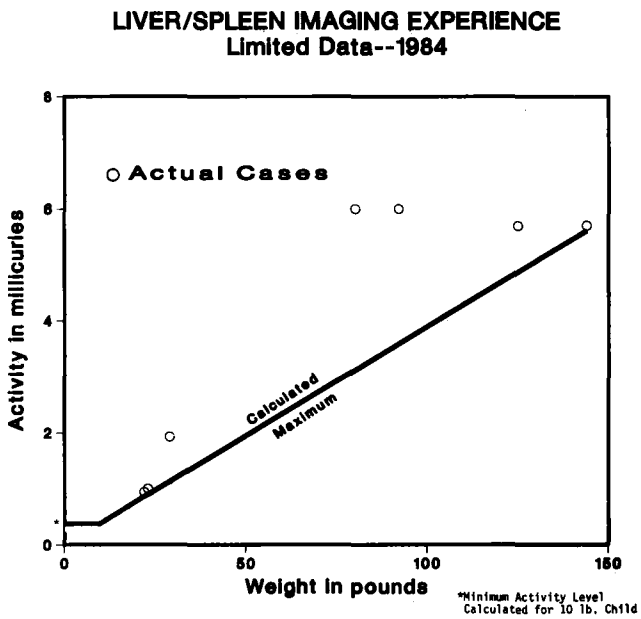

FIG. 5. Liver/spleen imaging experience (limited data—1984).

that nuclear medicine brain examinations have decreased from an estimated 2,063,000 examinations in 1975 to an estimated 537,000 examinations in 1983, a decrease of 74 percent. The introduction of new nuclear imaging procedures, such as cardiac studies, have resulted in a continued increase in the total number of procedures performed.

Although the character and treatment patterns have changed since 1978, the Center is concerned that current pediatric nuclear medicine procedures are still being performed using higher than necessary radiopharmaceutical levels. Therefore, the Center collected pediatric nuclear medicine patient data on a limited number of cases (61 procedures over a 3-mo period) to determine if unnecessarily high radiopharmaceutical activities were still being administered.

These 1984 pediatric nuclear medicine experience data have been analyzed and compared with theoretical values calculated on the basis of weight. As previously noted, there should be few, if any, actual cases that have radiopharmaceutical administered activity values greater than the calculated maximum line. Preliminary results of this analysis for three imaging procedures commonly performed are presented in Figs. 3, 4, and 5.

Review of these data indicates that a pattern of administering unnecessarily high radiopharmaceutical activity levels still exists, although this pattern may be improved. Discussions with various radiologists suggest that physicians' desire for diagnostic images of low noise and high quality account for high administered activity. In addition, the calculated maximum dose for renal imaging (Fig. 4) is not based on the required activity for a flow study; that may vary with individual equipment.

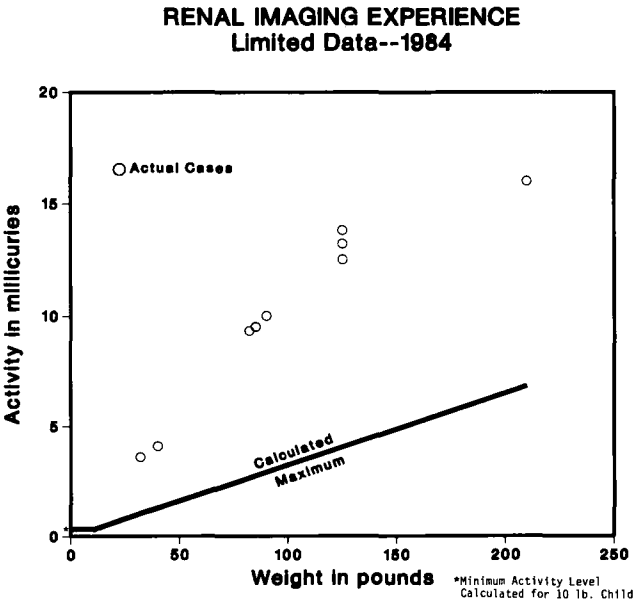

FIG. 4. Renal imaging experience (limited data—1984).

CONCLUSIONS

Pediatric behavior and associated problems also affect the selection of radiopharmaceuticals and administered activities. A recent article (*9*) "Children Are Not Small Adults" describes many of the difficulties such as the possible need for restraints or more technical considerations related to the fact that children have higher metabolic rates than adults. In spite of the difference between adult and pediatric patients, there is reason to believe that a tutorial, educational approach may provide nuclear medicine professionals with an appreciation for using current methods for calculating low administered activities that provide adequate diagnostic quality images.

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