

This article describes the radiation monitoring results from the first mobile stroke ambulance unit in the United States equipped with a computed tomography (CT) unit after 1 y of operation.

Radiation Monitoring Results from the First Year of Operation of a Unique Ambulance-based Computed Tomography Unit for the Improved Diagnosis and Treatment of Stroke Patients

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Abstract: When a blood clot blocks the blood supply to the brain or when a blood vessel bursts, resulting in brain cell death, the medical condition is referred to as a “stroke.” Stroke is a main cause of death worldwide and is a common cause of disability. A common form of stroke, called ischemic stroke, is when blood flow to the brain is decreased. Clinical research has revealed that treatment within the very first hours of symptom onset is key for ischemic stroke with recanalization of occluded arteries by thrombolysis with alteplase. Computed to-

mography (CT) is one of the diagnostic tools used to determine if this treatment path is appropriate. To determine if health outcomes of possible stroke patients can be improved by decreasing the time from symptom presentation to treatment, the first mobile stroke ambulance unit in the United States was deployed by The University of Texas Health Science Center at Houston (UTHealth) in 2014, equipped with a computed tomography imaging system. The mobile stroke unit shortens the time to treatment for stroke patients by allowing pre-hospital treatment. Having completed its first year of operation, radiation-monitoring data describing the doses delivered to various entities have been characterized. The CT operator's cumulative deep dose equivalent for 1 y of operation was 1.14 mSv resulting from the care of 106 patients. Area monitors were deployed and measurements performed demonstrating that general public doses did not exceed 0.02 mSv h⁻¹ or 1.0 mSv year. *Health Phys.* 110(Supplement 2):S73–S80; 2016

Key words: operational topics; computed tomography; dosimetry; radiation, medical

INTRODUCTION

Stroke occurs when a blood clot blocks the blood supply to the brain or when a blood vessel bursts (CDC 2014). Stroke is an important cause of disability and reduced mobility. In 2010, the age-adjusted prevalence of stroke in the United States was 2.6% (CDC 2012). In 2012, the mortality from stroke was the fourth leading cause of death in the United States with 5.1% of the total deaths (Heron 2015). In 2011, on average, every 40 s someone in the United States experiences a stroke, and someone dies of a stroke approximately every 4 min (Mozzafarian et al. 2015). Stroke reduces mobility in more than half of stroke survivors age 65 y and over (Mozzafarian et al. 2015). Care for stroke survivors cost an estimated 18.8 billion U.S. dollars in the United States during 2008, and lost productivity and premature mortality cost an additional 15.5 billion U.S. dollars (Roger et al. 2012). Therefore, the risk of stroke is a major public health concern.

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Computed tomography (CT) along with a physical exam is one of the typical medical diagnostic tools for stroke. In an ischemic stroke, blood supply to part of the brain is decreased. Acute stroke patients may be treated with recombinant tissue-type plasminogen activator (r-tPA); however, the maximum time window for effectiveness is 4.5 h from stroke onset from the American Heart Association guidelines (Jauch et al. 2013). Stroke patients treated with r-tPA experienced improved health outcomes when treated closer to the time of symptom onset and within the 3-h window (Marler et al. 2000).

Implementation of recanalizing therapy within this narrow therapeutic window is difficult to achieve in clinical practice because neurological examination, imaging, and laboratory analyses are needed so that hemorrhagic stroke and other contraindications to thrombolysis can be excluded (Walter et al. 2012). The phrase “time is brain” emphasizes that human nervous tissue is rapidly lost as stroke progresses. Quantitative estimates of the pace associated with this phrase emphasize the time urgency in stroke care with the typical patient losing 1.9 million neurons each minute in which stroke is untreated (Saver 2006). Therefore, time to treatment is very important for stroke patients.

Shortening time to treatment for improving outcome in acute stroke patients treated with r-tPA is key (Parker et al. 2015). Most acute stroke patients reaching the emergency department receive treatment beyond a 2-h window, when r-tPA is less effective (Fonarow et al. 2011). The causes for delay to treatment are multifactorial and include delays in calling for emergency care, mobilizing emergency medical services, transporting patients to the right emergency department, and finally, the emergency department “door to needle time,” which stubbornly averages 50–60 min in even the best stroke centers, largely caused by the time necessary to

obtain the CT scan and having the decision-maker (e.g., neurologist) examine the case and make a decision after weighing all the variables (Grotta 2015). There are inherent delays within the emergency departments of hospitals caused by triage, registration, evaluation, testing, and treatment. The Mobile Stroke Unit (MSU) equipped with a CT scanner on an ambulance moves stroke treatment to the prehospital environment from the emergency department (Parker et al. 2015). The MSU strategy could dramatically transform how cases of acute stroke are managed in the United States (Rajan et al. 2015). Placing the diagnostic tools for acute stroke treatment in the prehospital environment allows for shortening the important time to treatment window.

MATERIALS AND METHODS

Two groups in Germany have placed CT scanners in ambulances (Ebinger et al. 2014; Walter et al. 2012; Weber et al. 2013). Despite the logic and preliminary success of the MSU concept, many questions remain before this concept can be advocated for wide-spread use and adoption in the United States (Parker et al. 2015). Two questions to address are: 1) Are there better outcomes with ultra-early treatment? and 2) What is the cost vs. benefit? (Parker et al. 2015). To address these questions, The University of Texas Health Science Center at Houston (UTHealth) and Memorial Hermann Hospital-Texas Medical Center along with colleagues at the Texas Medical



a



b

FIG. 1. a. Exterior of the Mobile Stroke Unit and b. Interior of the Mobile Stroke Unit.



FIG. 2. Mobile Stroke Unit with position of CT operator.

Center in Houston launched the MSU in the United States (Parker et al. 2015). The ambulance was custom manufactured for the CT scanner and MSU. Examples of important modifications included reinforcement of the walls and floor to accommodate CT scanner mounts, wiring extra shore power circuit to power the CT scanner's charging circuit, upgrading the generator to provide additional power for the CT scanner and modifying the floor for the gurney to be raised for aligning the patient's head when performing the scan (Parker et al. 2015). Fig. 1 provides a visual description of the exterior (a) and interior (b) of the MSU. The CT scanner is positioned against the forward wall of the rear compartment.

The MSU needed to operate within the current EMS transportation and triage system, which delivers acute stroke patients within a 30-min drive from the Texas Medical Center to one of the three comprehensive stroke centers (CSCs) (Grotta 2015). The ambulance provider license was obtained by the City of Houston Health Department and required collaboration from with multiple institutions within the Texas Medical Center (Parker et al. 2015). The registration for the use of radiation machines in the healing arts was obtained through the Texas Department of State Health Services Radiation Control.

The MSU is staffed with a vascular neurologist (VN), a registered nurse (RN) with advanced cardiac life support training, a credentialed CT radiology technician and a licensed paramedic (Parker et al. 2015). The CT technician stands at the side door of the ambulance and operates the CT machine with a laptop computer. Figs. 2 and 3 describe the position of the CT operator and the CT unit with the MSU. Even in cases of inclement weather, MSU staff and the laptop computer are equipped to operate outside the ambulance. All MSU staff are positioned outside of the ambulance during a CT scan unless medically necessary for the patient and patient care. In the case of the patient's medical need, the MSU staff

positioned within the ambulance wear leaded personnel protective equipment during the CT scan. In the German design, Weber et al. (2013) reports qualitative dosimetry values (e.g., "within normal limits") for the staff. Additionally, the MSU positioning of the CT operator differs from the German design where the CT operator and the physician stay within a protected compartment within the vehicle (Weber et al. 2013).

No published studies regarding the quantitative measured occupational dosimetry values were located regarding the operation of a similar CT machine on an ambulance. In the United States, the Federal Drug Administration's Center for Devices and Radiological Health (CDRH) regulates the manufacture of electronic radiation emitting products. Individual states regulate the use of these x-ray imaging devices (e.g. computed tomography) through recommendations and requirements for personnel qualifications, quality assurance and quality control programs, and facility accreditation. In Texas, the use of x-ray imaging devices requires a radiation permit. For mobile services in the healing arts or veterinary medicine, a permit holder must receive authorization before beginning the mobile service authorization x-ray imaging

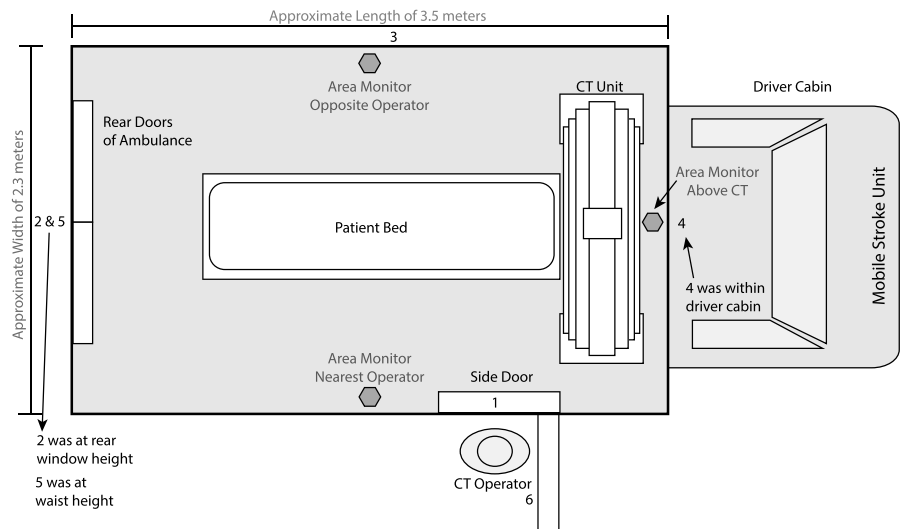


FIG. 3. Mobile Stroke Unit with interior area monitor positions and cabin exterior ion chamber measurement positions 1 through 6 with a head phantom in place.

devices on vehicles. Texas Radiation Control regulations for medical mobile services requires the application to include the primary parked location for the x-ray machine, the location of records, a sketch or description of the machine use including a floorplan and protective shielding considerations and the operating and safety procedures regarding radiological practices for protection of patients, operators, employees, and the general public (Texas Administrative Code 2013).

On 24 October 2013, UTHealth submitted an amendment request to add the MSU as a mobile service equipped with a CT unit to its existing x-ray registration. The application included a sketch of the configuration of the CT unit's use and the operator's position during exposures, manufacturer specifications and safety data sheets, the operating and safety procedures, and an estimate of the maximum general public dose. In the design phase, the estimated general public dose was less than 1.5 μSv per CT exam. This was calculated at the highest scatter radiation at the distance of the walls of the ambulance. Note, the predicted scatter radiation levels provided by the manufacturer did not consider the attenuation of the walls of the ambulance. One CT exam is performed per ambulance trip, and the ambulance would be dispatched to the area of the patient. Thus, the dose to any one member of the general public would be lower than a dose based on an estimated annual workload. On 29 November 2013, UTHealth received the amended registration that included the mobile service equipped with the CT unit.

The annual occupational dose limit set by the U.S. Nuclear Regulatory Commission is 50 mSv for the effective dose (U.S. NRC 2010) based on of recommendations by the National Council on Radiation Protection and Measurements (NCRP 1993) and the international occupational dose limit set by the

International Commission on Radiological Protection (ICRP) is 20 mSv for the effective dose averaged over 5 y (ICRP 2007). The annual general public dose limit for the effective dose is 1 mSv (U.S. NRC 2010; ICRP 2007). The effective doses measured needed to operate for occupational workers below the annual occupational dose limit and for the public in the vicinity of the mobile scanner below the annual general public dose limit.

The purpose of the dosimetry study for the MSU was to assess the occupational radiation dosimetry of the MSU staff and ensure the potential radiation doses to public in the vicinity of the mobile scanner do not exceed the general public dose limit. Due to heightened concerns about possible radiation dose associated with CT scanners for patients (Consumer Reports 2015; Gee 2012; Storrs 2013) as well as the public in the vicinity of the mobile scanner, an aggressive radiation dosimetry monitoring was implemented. Personnel dosimetry was provided to the MSU staff such as the CT technician, the RN, and paramedic. While the MSU staff for each MSU trip often changed, the CT technician has remained the same for the time from the first patient to the end of four complete quarters of radiation dosimetry measurements. The first patient case was performed on 16 May 2014. Because the personnel dosimetry for the MSU staff was not anticipated to exceed 10% of the regulatory dose limit, the personnel dosimeters were issued on a quarterly frequency. The first full quarter of radiation dosimetry began on 1 July 2014. For the study, the date range for the year was from 1 July 2014 to 30 June 2015. LUXEL dosimeters were utilized for both the personnel dosimeters and the area monitors. LUXEL dosimeters were supplied and read by Landauer Inc. (2 Science Road, Glenwood, IL 60425).

Additionally, area monitors were placed on the interior of three

walls of the ambulance in locations not to interfere with patient care. If area monitors were placed outside of the ambulance, unnecessary attention and concern would be anticipated regarding the reason for monitoring. Additionally, exterior vehicle area monitors would be more difficult to maintain with the weather and driving conditions. Fig. 3 indicates the position of the interior area monitors within the Mobile Stroke Unit. By the nature of being on an ambulance, the CT unit will be routed to different locations. Therefore, the radiation dose from interior area monitors would noticeably overestimate the general public annual dose.

To confirm the general public dose limit for 1-h exposures times was not exceeded, measurements on the exterior of the ambulance were also performed. The positions of the exterior measurements are indicated in Fig. 3. A phantom head was positioned where a patient head would be within the CT machine, and CT scans were performed on the phantom. Measurements were performed with a Victoreen Fluke ion chamber (Victoreen Model 451, Fluke Biomedical, 6920 Seaway Blvd., Everett, WA 98203) at select locations at the exterior of the rear compartment.

RESULTS

The CT technician's occupational deep dose equivalent per quarter was higher than the occupational deep dose equivalent per quarter of the other MSU personnel monitored. For the 1 y of the dosimetry study, only 1 CT technician operated the CT. Multiple qualified individuals filled each of the remaining three team member positions (VN, RN, and licensed paramedic) described earlier. Therefore, the other MSU personnel did not go on as many runs where the CT was utilized as the CT technician. Due to the CT technician's position during operation and division of the workload by other personnel, this skewing

was anticipated. If medically necessary for the patient's condition, generally one and no more than two MSU staff wearing lead apron (s) remained with the patient during the CT scan. The MSU staff consists of about 15 individuals who might go into the ambulance during CT exam to aid the patient's medical condition. For all four quarters, 10 other MSU staff besides the CT operator received measurable deep dose equivalents in a quarter. The other MSU personnel deep dose equivalents ranged in a quarter from minimal levels for the LUXEL to 0.09 mSv. The minimal measurable deep dose equivalent reported from the manufacturer of the LUXEL was 0.01 mSv. The average other measurable MSU deep dose equivalents was 0.024 mSv per quarter. The occupational and area monitoring doses are shown per quarter in Fig. 4. The number of patients treated is included as a reference point to compare the trends with the occupational doses to the trends with the area monitors. The cumulative occupational deep dose equivalent for the CT operator was 1.14 mSv from 1 July 2014 to 30 June 2015. This is well

below 10% of the current occupational dose limit of 5 mSv (U.S. NRC 2010). The cumulative annual interior area monitor dose was 0.23 mSv, 0.95 mSv, and 1.38 mSv for the area monitor opposite the CT operator, area monitor nearest the CT operator, and area monitor above the CT unit, respectively. These interior area monitors are not representative of the annual general public dose; in fact, these interior area monitors grossly overestimate the annual general public dose limit, as a member of the general public would be farther than these area monitors, and would be shielded with the wall and other equipment within the ambulance, and would be present for only one of the CT scans. Therefore, we were able to demonstrate that any one member of the general public would not exceed 1.0 mSv in a year.

Measurements were performed with a Victoreen Fluke ion chamber Model 451 on 22 June 2015 with a background (i.e., CT machine off) of 0.0258 nC kg⁻¹. The background measurements were observed over a period of 1 h at the ambulance while no CT scans

were performed. One measurement was taken for a single adult CT head scan. Two measurements within the same position were taken at the exterior positions indicated in Fig. 3. The higher of the two measurements is reported in Table 1. One CT scan takes approximately 68 s (34 slices), and one CT scan is performed per ambulance trip. Six measurement locations were performed with position 4 located within the driver cabin closest to the ambulance cabin. The operating procedures require that no personnel are in the driver cabin during CT operation. Additionally, the CT scans are performed while the MSU ambulance is within the parked position. The measurements with the ion chamber ranged from 0.0098 μC kg⁻¹ to 0.090 μC kg⁻¹. Using the conversion from C kg⁻¹ to Gy in air, the estimated (non-effective) dose in Sv can be estimated. Since the ambulance goes to different locations, any one individual in the vicinity of the scanner would only likely be near the CT scanner once a year. With a scan time of 68 s and a maximum exterior measurement of 0.090 μC kg⁻¹, the maximum estimated general public dose would be an estimated 0.00304 mSv compared to the general public dose limit for radioactive materials of 0.20 mSv in an hour and 1.0 mSv in a year (U.S. NRC 2010; ICRP 2007). The population of interest in estimating the general public dose would be any unique individual in the vicinity of the MSU who is not the MSU staff or the patient. Therefore, the potential general public dose is well below the general public dose limit in an hour. In comparison, the U.S. annual estimated dose per person on average is 6.2 mSv (NCRP 2009). These measurements are below these values.

A multi-year study that compares times from symptom onset to arrival of CT scanning for patients managed on the MSU compared to standard management

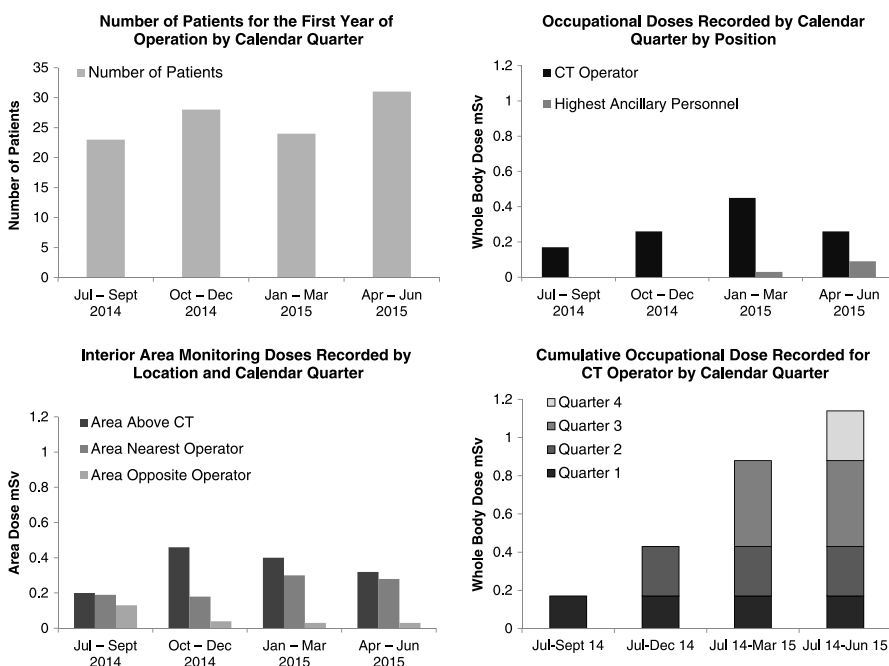


FIG. 4. Mobile Stroke Unit: Radiation doses compared to the number of patients for first year of operation from July 2014–June 2015.

Table 1. Ion chamber measurements ($\mu\text{C kg}^{-1}$) for 1 CT scan.^a

Position ^b on mobile stroke unit	Measured radiation levels ^c ($\mu\text{C kg}^{-1}$)	Estimated dose (μSv) at positions indicated for 1 CT scan
1	0.083	2.78
2	0.072	2.44
3	0.0098	0.33
4	0.090	3.04
5	0.023	0.79
6	0.090	3.04

^aThe background at the ambulance was $0.0258 \text{ nC kg}^{-1}$ with the CT machine off. The U.S. annual estimated dose per person on average is 6.2 mSv (NCRP 2009).

^bPosition as indicated in Fig. 3. Mobile stroke unit with interior area monitor positions and cabin exterior ion chamber measurement positions 1 through 6 with a head phantom in place.

^cOne CT scan takes approximately 68 sections (34 slices), and one CT scan is done per ambulance trip.

is currently underway, and the group data is blinded for the study. In the pilot phase of the project, the MSU “on-scene” time averaged 25 min, which includes the time from arrival to departure to the destination Emergency Department, during which time the history, physical exam, CT scan, and time of administration of tPA are collected (Bowry et al. 2015). This compares to the average “door to needle” time in U.S. stroke center Emergency Departments (which also includes the same things, e.g., history, exam, CT scan, and giving tPA) of 60 min (Fonarow et al. 2011). The speedy response time is promising for growth of the use of MSU.

DISCUSSION

This is perhaps the first published characterization of occupational doses for an ambulance based CT unit. In Germany, the CT operator and the physician were provided with a dosimeter to record the radiation exposure from the CT scanner on the ambulance. For the German design both the CT operator and the physician stay within a protected compartment within the vehicle (Weber et al. 2013). Weber et al reports the radiation levels recorded by the dosimeters remained within “normal limits” over the entire period (2013). The German design of the CT operator and physician position during exposure is different from the first MSU operator position in the United States. We were

unable to locate any other published studies describing measured occupational radiation doses for an ambulance based CT unit. In a 2003 letter-to-the-editor of *Stroke*, the *Journal of the American Heart Association*, the design of a mobile stroke unit equipped with a CT unit is described which includes the vehicle shielded by a 2-mm lead layer around a rear compartment and the operation console would be at the front of the vehicle on the other side from the CT unit of the lead layer (Fassbender et al. 2003). Note, in 2013, the layout is different from the 2003 letter with the CT scanner in the Germany MSU position in the back of the cabin and the CT workstation is within a shielded compartment (Weber et al. 2013). Thus, the positioning of the CT scanner and the CT operator and physician is different for this MSU compared to the Germany MSU.

For the MSU at UTHealth, the first patient case was performed in May of 2014. The Cleveland Clinic Mobile Stroke Treatment Unit (MSTU) launched on 18 July 2014 (John et al. 2016). The Cleveland Clinic MSTU utilizes a larger vehicle style than the UTHealth MSU. As popularity increases across the country, the use of the ambulance based MSUs is expected to grow.

The UTHealth MSU CT Operator’s dose equivalent of 1.14 mSv y^{-1} may be compared to other published occupational doses from medical modalities. For a high-volume hospital setting, the hospital

average deep dose equivalent was 1.5 mSv y^{-1} with select averages by section of 0.4, 1.1, and 1.6 mSv y^{-1} for inpatient nurse, fluoroscopically guided interventional (FGI) technician/nurse, and FGI physician, respectively (Dauer 2014). In another large medical center, the mean annual dose of the diagnostic radiation group was 0.80 mSv averaged over a 5-y period from 1995–1999 (Al-Haj and Lagarde 2002). In a hospital setting, medical staff may on occasion need to enter the CT room during a CT examination. One study reported the average frequency of entrance for nurses during CT exams was $1.2 \text{ times mo}^{-1}$ with an average of 2.5 mSv y^{-1} occupational dose equivalent to the nurses (Mori et al. 2014). The top three reasons self-identified by the nurses to perform the entrance actions were monitoring of contrast media extravasation, observation of patient’s condition, and physical restraint of patient’s body movement (Mori et al. 2014). When comparing the occupational doses of the MSU CT Operator and medical staff to traditional hospital uses, one should consider that stroke patients, on average, would need more medical care during a CT exam than the average CT patient within a hospital setting.

For the twelve month time period of this study, the CT technician remained the same for all 106 patients. While the other members of the MSU staff representing the vascular neurologist (VN), a registered nurse (RN), and licensed paramedic were dependent upon staffing availability. Additionally, the other members of the MSU staff would stay outside of the ambulance during the exam unless medically necessary for the care of the patient. If determined medically necessary, those inside the ambulance wore lead aprons and maintained distance from the gantry of the CT unit. In the future of this MSU or others that may be developed, more than one CT operator may be utilized.

The January through March 2015 operator dosimetry record was adjusted for being worn for an additional time period and may still include contributions from the other time periods. Additionally, perhaps the CT operator stood closer to the CT machine during this monitoring period. The October through December 2014 above CT area monitor dosimetry records was adjusted for an additional time period and may still include contributions from the other time periods.

The patient Computed Tomography Dose Index volumetric (CTDI_{vol}) was manufacturer displayed at 70.73 mGy for all of the patients during the year period. The CTDI_{vol} was calculated from measurements on 29 April 2014 using a 16-cm-diameter phantom to have a CTDI_{vol} of 67.5 mGy and an effective dose of 2.7 mSv. The protocol of the head image operated with the settings of 120 kVp, 6 mA with an exposure time per rotation of 4 s. The patient effective dose of 2.7 mSv is similar to typical adult head examinations with a CT scanner of a patient effective dose between 1 and 2 mSv (Mettler et al. 2008). One study provides an evaluation of portable (e.g., on wheels) CT scanners compared to stationary head CT scanners. The study found that head CT images acquired with the CereTom portable scanner are satisfactory for clinical use and diagnostically accurate (Rumboldt et al. 2009). The MSU uses the advantages of the portable CT within the hospital and mobilizes this diagnostic CT tool in the prehospital environment for the treatment of critical patients.

By placing area monitors on the interior of the walls of the ambulance and noting that the CT unit is mobile, the results noticeably overestimate the general public annual dose. While this is an overestimate, placing area monitors outside of the ambulance would have resulted in the monitors being subject to a greater chance of loss or tampering.

CONCLUSION

This study provided the quantification of the occupational doses for an ambulance based computed tomography unit. The cumulative occupational deep dose equivalent for the CT operator was 1.14 mSv and well below 10% of the current United States occupational dose limit. Should other institutions decide to launch an ambulance based CT unit, the information provided in this article may aid in the design and implementation. The information provided may also alleviate concerns of the community by providing quantification of the radiation doses. This MSU allows for prehospital diagnosis and treatment of possible stroke patients by delivering the tools and the decision maker to the patient.

Acknowledgments—The authors wish to express their sincere appreciation to the staff of the UTHealth Radiation Safety Program of Environmental Health & Safety for their active participation in the collection of the data used in the project. Additionally, the authors wish to express their sincere appreciation to William Hebel for the photographs and Steve David for graphic support. Finally, the authors wish to express their sincere appreciation for the MSU staff and MSU consortium.

Disclosure: The Mobile Stroke Unit (MSU) study receives funding from Medtronic, Genentech, and Frazer Ltd. Dr. Grotta receives grant support from Medtronic and Genentech as well as consulting fees from Stryker and Frazer Ltd.

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