REPORT OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CSAPH Report 4-A-13

Subject: Safety of X-Ray Security Scanners
(Resolutions 516 and 518, A-11)

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Referred to: Reference Committee E
(Lawrence K. Monahan, MD, Chair)

INTRODUCTION

Resolution 516-A-11 submitted by the Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island and Vermont Delegations and referred by the House of Delegates asked:

> That our American Medical Association (AMA) study the use of ionizing radiation in airport scanners and make appropriate recommendations to the federal government based on its findings.

Resolution 518-A-11 submitted by the New Mexico Delegation and referred by the House of Delegates asked:

> That our AMA study the available information concerning the safety of whole body backscatter X-ray airport security scanners, with the intent of providing recommendations of a public health nature, including whether (1) additional studies should be undertaken; (2) there is sufficient evidence to suggest that specific regulations should be put into place to ensure that the scanners are performing according to clearly established specifications on an ongoing basis; (3) there is sufficient concern to recommend that some or all those who travel on commercial aircraft should decline to be scanned by X-ray scanners; and (4) there is sufficient concern to recommend that the Transportation Safety Administration consider the preferential use of alternative technology such as millimeter wave scanners in lieu of backscatter X-ray scanners.

The imperatives raised in these resolutions are diminished somewhat based on the U.S. Transportation Security Administration's (TSA) decision early in 2013 to remove the backscatter models from U.S. airports by June 2013 and replace them with millimeter wave models.[1] This followed an October 2012 announcement that the TSA had removed backscatter scanners from the majority of large airports, placing them in smaller airports.[2] According to news reports, the backscatter models removed from airports in 2013 will likely be placed in federal buildings and other locations in which security measures are needed.[1] Depending on the frequency of exposure for employees and visitors of locations in which the backscatter units may eventually be placed, the concerns raised in the resolutions continue to warrant examination.

BACKGROUND

Action of the AMA House of Delegates 2013 Annual Meeting: Recommendations in Report 4 of the Council on Science and Public Health Adopted, and Remainder of Report Filed.

Several years ago, the TSA began installing and using advanced imaging technology (AIT) at airport passenger screening checkpoints as a secondary measure to detect security threats. Early in 2010, AIT was widely implemented as a primary measure. AIT is more effective at detecting weapons, explosives, and other hazardous and/or concealed items hidden under clothing than older metal detector-based screening units. The two main types of AIT used are "backscatter" models, which use low levels of ionizing radiation, and "millimeter wave" models, which use radio waves. Comparative information about millimeter wave and backscatter screening models can be found in the Appendix.

Substantial debate on AIT has focused on privacy issues, since both backscatter and millimeter units are capable of producing extremely detailed images of passengers' bodies. That concern has been addressed by a Congressional mandate that detailed images of passengers' bodies be replaced with generic images of bodies, and in the case of backscatter screening, separating the screening personnel viewing the images from the passengers themselves. However, the TSA has stated that the company manufacturing the backscatter models could not meet a deadline to ensure that its software effectively produced generic images, and thus its contract was not renewed.[1]

Debate also centers on exposure to ionizing radiation from backscatter screening. Although backscatter units use extremely low levels of ionizing radiation, concern exists that any increase in exposure to radiation is biologically dangerous. Although few data exist about the safety of millimeter wave scanners, they are not believed to have carcinogenic potential. This report will therefore focus on the safety concerns associated with backscatter scanners.

METHODS

Literature searches were conducted in the PubMed database for English-language articles using the search terms "backscatter" and "x-ray" along with the terms "airport," "security," and "scanner." Additionally, a Google search was conducted using the same search terms. Two comprehensive reports on the health effects of ionizing radiation,[3,4] as well as several studies on radiation exposure from backscatter security scanners,[5-9] also were consulted.

BIOLOGICAL EFFECTS OF EXPOSURE TO IONIZING RADIATION

Ionizing radiation refers to radiation that has sufficient energy to ionize atoms or molecules (cause separation of electrons from an atom) in biological systems. The electrons and positively-charged ions released as a result of ionization can cause cellular damage.[3] X-rays, gamma rays, beta particles (high-speed electrons), neutrons (heavy uncharged particles), and alpha particles (heavy charged particles) are the principal types of ionizing radiation encountered. Of these types, x-rays and gamma rays have the lowest rate of energy transfer.[4] Other types of radiation such as radio waves, visible light, and ultrasound do not produce ionization, and therefore have far less potential to cause biological damage.[3]

The free electrons generated by ionization of atoms in tissue are capable of causing DNA strand breaks and damaging nucleotide bases. Most damage to DNA can be repaired by the cell's own mechanisms; however, if damage is not repaired correctly, the cell may become senescent (irreversibly dormant), undergo apoptosis that could lead to permanent tissue or organ damage, or retain a change in genetic sequence that sometimes leads to aberrant cell behavior such as uncontrolled cell division. The extent of damage to DNA, and thus the biological effects, depends on the type of ionizing radiation encountered, the dose delivered, and the time over which delivery occurs.[3] For example, exposure to low-energy ionizing radiation such as x-rays produces far less biological damage than does exposure to the same dose of high-energy radiation such as alpha particles. In turn, cellular mechanisms can more effectively repair the damage caused by low-energy radiation.[4]

The average person is exposed to low levels of ionizing radiation during daily life from natural sources (background radiation) and other incidental or artificial sources, such as medical procedures and industrial or occupational exposure. The Table lists approximate exposure levels from common sources. The exposures are listed in Sieverts (Sv), a value that normalizes the biological effects of different types of ionizing radiation, leading to a calculation of equivalent dose that can be used to compare all types of ionizing radiation.[*] Total background radiation exposure, consisting of exposure to naturally-produced cosmic and terrestrial radiation, as well as inhaled and ingested radionuclides, is estimated to be 3.1 mSv per year for the average person.[3,4] Another common source of ionizing radiation exposure is medical procedures, which vary widely in equivalent dose depending on the procedure.[10] Air travel results in ionizing radiation exposure because of the increased exposure to cosmic rays at high altitudes; exposure during one minute at average flight altitude is estimated to be 0.04 μSv, with a transcontinental flight leading to an exposure of approximately 40 μSv.[11] Of note for the focus of this report, one backscatter scan has been reported to expose a person to 0.02-0.1 μSv.[5-7,12] For the average person, the annual ionizing radiation exposure from all sources combined is approximately 6.2 mSv per yer.[4]

Cancer Risk from Low Level Ionizing Radiation

Estimating cancer risks from low-level radiation is difficult and imprecise. No studies have been comprehensive enough to quantify the risk; extremely large sample sizes (on the order of several million) are needed to accurately estimate risks from low-level exposure, making it unlikely that direct estimates of risk from very low doses will ever be possible.[9] Instead, data from studies examining cancer risk from high-level radiation have been extrapolated to estimate the risk at low levels.[13] However, extrapolation methods have been the subject of some disagreement. Some believe that linear extrapolation is appropriate, leading to the conclusion that even the most miniscule amounts of radiation proportionally increase the risk of cancer.[4,14] Others argue that linear extrapolation is too simple and that thresholds exist under which cancer risk is nonexistent.[11,14] Other factors contribute to the difficulty in estimating risk. Cancer risk from radiation exposure is heavily dependent on a person's age during exposure, with risk steadily decreasing as a person ages. Cancer risk also is dependent on whether exposure occurs acutely (such as that occurring from a nuclear accident or explosion of an atomic bomb) or over a protracted period (such as that occurring from occupational exposure).

In general, protracted exposure to low-energy ionizing radiation such as x-rays is associated with lower cancer risk than that resulting from acute exposure at the same total dose.[9] The lowest acute dose thought to cause an increase in cancer risk is approximately 10-50 mSv.[9] Exposure to approximately 50 mSv above background radiation over one year, or to 100 mSV above background radiation over a lifetime, also have been associated with an increased risk.[9] For the general adult population, the excess lifetime risk for cancer is approximately 4.1-4.8% per Sv of exposure.[9,15] Given that the average person is exposed to 6.2 mSv per year from background and other incidental sources,[4] the excess risk of cancer from radiation exposure appears to be extremely low for most people.

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[*] Sievert (Sv) is the SI unit of radiation dose equivalent. 1 Sv = 100 rem. Absorbed dose of radiation is expressed in rads. Since different types of radiation produce different amounts of damage per rad of dose, the Seivert takes into account the greater effects of certain types of radiation. A Seivert expresses the effectiveness of a particular kind of ionizing radiation relative to that of x-rays.

Certain subsections of the population are especially sensitive to ionizing radiation. For example, neonates are roughly three times more sensitive to cancer-causing effects of radiation than is a 25 year-old adult.[9] For developing embryos and fetuses exposed to ionizing radiation, the risk of congenital malformations is typically an order of magnitude higher than that of cancer risk.[9] Some studies have suggested that 3-5% of the population is genetically hypersensitive to ionizing radiation, though no direct evidence exists identifying which subgroups have increased susceptibility to radiation-induced cancers, nor is it clear how significant the increase in risk may be for certain subgroups. Estimates for radiation-induced cancer risk for the general population are thought to be sufficiently stringent to protect the genetically sensitive subgroup.[9]

BACKSCATTER SECURITY SCANNERS

Backscatter scanning units direct an x-ray beam over the surface of the body; the x-rays are low intensity, and therefore do not travel deep into tissues or through the body as those of a medical x-ray would. Instead, the majority of the rays are reflected back from the skin. Detectors translate the reflection pattern into an image that is examined by security personnel. The backscatter pattern is dependent on material property, and thus distinguishes between organic and inorganic material.[8]

Radiation Exposure from Backscatter Scans

While most of the x-rays emitted during a backscatter scan are reflected back, a small number are absorbed by the body. Absorption is greatest in tissues located near the surface (skin, eyes, ribs, etc.), but lessens in deeper internal organs. Internal organs are estimated to absorb one-quarter of the radiation absorbed by the skin and other tissues near the surface of the body. Note that in the Table, the reported equivalent dose noted for one backscatter scan (0.02-0.1 μSv) pertains to the amount of radiation absorbed by the skin.

The amount of radiation exposure from one backscatter scan is exceedingly low. The National Council on Radiation Protection and Measurements (NCRP) considers a dose of 0.01 mSv or less per event to be negligible; exposure from a backscatter scan is approximately 100 times less than the negligible level.[16] Exposure to the x-rays in one backscatter scan is equivalent to 3-9 minutes of background radiation exposure that occurs as part of daily living,[17] and to 1-3 minutes of cosmic radiation exposure experienced during an airline flight. A person would have to undergo more than 50 backscatter scans to equal the amount of exposure from one dental x-ray, 4,000 scans to equal a mammogram, and 70,000 scans to equal one chest computed tomographic scan.[18]

Cancer Risks from Backscatter Scans

Note that many of the studies estimating cancer risks from backscatter scanners have assumed that millions of travelers would be exposed to them; as of June 2013 that will no longer be the case.

Extrapolated data point to a population risk of 0.08 cancers per Sv of exposure to ionizing radiation.[17] Using that estimate, the cancer risk due to backscatter scanners has been estimated for all flyers and frequent flyers. For all flyers (100 million passengers representing 750 million enplanements per year), six additional cancers would occur over the lifetime of the group resulting from backscatter scans.[17] However, it is important to note that 40 million cancers will occur over the lifetime of the group due to underlying cancer incidence. Among one million frequent fliers, four additional cancers could occur due to backscatter scans.[17] This should be compared to the 600 cancers that would occur from the exposure to radiation at flying altitudes, and the 400,000 cancers that would occur over the course of the group’s lifetime due to underlying cancer incidence. The number of additional breast cancers that would occur in 5-year old female frequent fliers due to backscatter scans also has been estimated.[17] For every two million women who travel one round trip per week, one additional breast cancer could occur over the lifetime of the group, compared to 250,000 breast cancers that will occur in this group over its lifetime due to the incidence of breast cancer.

Like the general public, segments of the population that are sensitive to radiation (pregnant women, children, and those who are genetically susceptible to cancer) appear to be in very little danger from backscatter scans. The NCRP dose limit of 1 mSv per year above background radiation was developed to include all segments of the population.[18,19] Accordingly, children and pregnant women (and the embryos or fetuses that they are carrying) are adequately protected when the recommended public dose limit is applied. For comparison, a pregnant woman or child would need to undergo more than 10,000 backscatter scans (figuring an equivalent dose of 0.1 μSv per scan) in one year to reach the NCRP dose limit. Estimations of cancer risk from low-level ionizing radiation for those who are genetically susceptible to cancer (e.g., those who carry mutations in genes that increase cancer risk) remain unclear. Studies have demonstrated increased radiosensitivity for cells carrying certain mutations that increase cancer risk, but no studies have directly measured cancer risk from the levels of radiation used in backscatter scanners in genetically susceptible populations.[4] As noted, the levels of radiation are so small that no study has been adequately powered to directly estimate cancer risks, and no extrapolated data exists suggesting that radiation doses from backscatter scanners are dangerous to those genetically predisposed to cancer.[9]

Oversight and Safety Evaluations of Backscatter Scanners

The Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) is responsible for the oversight of radiation-producing equipment. Manufacturers of products that emit ionizing radiation (other than medical diagnostic equipment) must comply with the electronic product radiation control provisions of the Federal Food Drug and Cosmetic Act (FFDCA). Manufacturers of any electronic products that emit x-rays, including backscatter security systems, are required to submit a radiation safety report to FDA before entering products into commerce and file annual radiation safety reports.[20] In 1998, the FDA began addressing x-ray security scanners directly, working with the American National Standards Institute (ANSI) and the Health Physics Society to develop radiation safety standards for backscatter units. The standards, first published in 2002 and updated in 2009, state that facilities using backscatter units should ensure that no individual scanned receives a dose of more than 0.25 mSv per year, and that no individual should receive a dose of more than 0.25 μSv per scan.[21] The standards also require that surveys be performed at regular intervals to measure emissions and ensure that ANSI limits are not being exceeded. The TSA requires that all AIT conform to the ANSI 2009 standards.

Additionally, under the provisions of the FFDCA, the manufacturer is required to investigate and report any accidental radiation occurrence and notify the FDA in the event that the manufacturer becomes aware of a defect. ANSI standards also require the manufacturer to establish and maintain records of any incidents involving unplanned exposures as reported by the user, and provide the information to the FDA.[21] Backscatter scanners have operational interlocks that function to terminate x-ray production when inconsistencies, over-voltage, or over-current occurs.[6]

Since the deployment of backscatter scanners at airport security checkpoints, several entities have tested the units and concluded that they are safe for use. In January of 2012, the U.S. Army Public Health Command conducted a study on the safety and operation of the Rapiscan 1000 (the most widely deployed backscatter model) at six airports across the country.[5] It concluded that the Rapiscan 1000 system operates within the ANSI limit of 0.25 μSv per scan, and that an individual could be scanned up to 5,000 times per year without exceeding the ANSI annual dose limit of 0.25

mSv.[5] In 2010, the Johns Hopkins University Applied Physics Laboratory was directed by the TSA to conduct a radiation safety assessment on the Rapiscan 1000 model, finding that individual doses were within ANSI limits, and below the NCRP negligible limit (0.01 mSv per event) as long as an individual underwent fewer than 684 screenings per year.[6] In 2006, as part of an agreement between the TSA and the FDA, CDRH's Ionizing Radiation Measurements Laboratory evaluated x-ray emissions and dose to humans from the Rapiscan 1000 model, concluding that the system met ANSI standard requirements, with an average adult exposed to 0.024 μSv per scan.[7] The Department of Homeland Security's Office of Inspector General (OIG) recently reviewed the TSA's standard survey and maintenance practices for backscatter units, and found that the TSA was in compliance with ANSI survey requirements, radiation exposure levels were within ANSI limits, and no accidental radiation overdoses have occurred.[8] In the report, the OIG recommended steps to be taken to improve the TSA's calibration practices, safety surveys following maintenance, and radiation safety training for screening personnel; the TSA agreed with the recommendations and is in the process of implementing them.[8]

In December of 2012, the Department of Homeland Security announced that it would award a contract to the National Academy of Sciences (NAS) to convene a committee to review previous studies and current processes used to estimate radiation exposure from backscatter units. The NAS will issue a report with recommendations on whether exposures comply with applicable health and safety standards, and whether the system design, operating procedures, and maintenance procedures are appropriate to prevent over-exposure to travelers.[22] In addition, the American Association of Physicists in Medicine has convened a Task Group to study radiation emission from the Rapiscan 1000 unit, and plans to release a report in 2013.[23] The American College of Radiology has stated that it is not aware of any evidence that points to biological effects for passengers who are screened with backscatter units.[24]

CONCLUSIONS

Despite concerns raised about ionizing radiation exposure from backscatter scanners, studies have concluded that exposure is exceedingly small, far less than the exposure considered negligible by the NCRP. No studies have demonstrated negative health effects in passengers scanned by backscatter units, and the cancer risk from exposure appears to be miniscule. The Council believes that no data currently exist to suggest that passengers should avoid being screened by backscatter scanners. However, it supports continued research on the safe use of the scanners, as well as maintenance, calibration, survey, and officer training procedures that are meant to ensure that the units operate as intended. The Council notes that passengers who do not wish to undergo backscatter screening may opt for alternative screening. The Council also notes that no adverse health consequences are known to occur from millimeter wave models that have replaced the backscatter models.[20]

RECOMMENDATIONS

The Council on Science and Public Health recommends that the following statement be adopted in lieu of Resolutions 516-A-11 and 518-A-11, and that the remainder of the report be filed.

> Our American Medical Association: (a) believes that as of June 2013, no data exist to suggest that individuals, including those who are especially sensitive to ionizing radiation, should avoid backscatter security scanners due to associated health risks; and (b) supports the adoption of routine inspection, maintenance, calibration, survey, and officer training procedures meant to ensure that backscatter security scanners operate as intended. (New HOD Policy)

Fiscal note: No significant fiscal impact.

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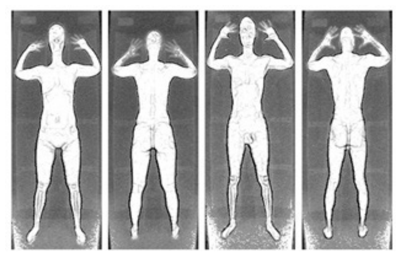
Table. Common sources of radiation exposure

Radiation Source	***Equivalent dose**[1-5,8-10]
Background (total)	3100 μSv/yr
Cosmic	270 μSv/yr
Terrestrial	190 μSv/yr
Inhaled (radon and other)	2290 mSv/yr
Internally deposited	310 μSv/yr
Ingesting one banana	0.1 μSv
Ingesting a 135 g bag of brazil nuts	5 μSv
Dental x-ray	5 μSv
Chest x-ray	20 μSv
Flight from New York City to Chicago	9 μSv
Transatlantic flight	70 μSv
Mammogram	400 μSv
Head CT scan	2000 μSv
Chest CT scan	7000 μSv
One minute at flight altitude	0.04 μSv
One backscatter security scan	0.02-0.1 μSv

* See footnote on page 3 of this report for an explanation of the Sv unit.

Appendix. Comparison of airport security scanners.[25]

	Millimeter Wave	Backscatter
What does the unit look like?		
How does it work?	Radio frequency waves are beamed over the body using two rotating antennas. The energy reflected back from the body is converted to an image and analyzed.	A low-intensity x-ray beam is directed over the surface of the body. Rays that are reflected back to detectors are converted into an image and analyzed.
What type of energy is used?	Millimeter waves	Low levels of ionizing radiation
What do security personnel see?	The body image appears as a generic "Gumby-like" figure. 	The body image appears as a chalky outline. 
What is the risk determin-ation process?	After the passenger stands in the phone-booth like scanner for a few seconds, a security officer inspects the image displayed on a monitor attached to the machine. If an irregularity is detected, a yellow box appears on the suspected part of the body and the passenger is inspected. If no irregularity is detected, a large "OK" sign is displayed.	After the passenger stands in the rectangular scanner for a few seconds, a security officer sitting in a different location looks at the image generated. If an irregularity is spotted, the officer attending to the passenger is notified and inspects the passenger. At the end of the process, the image is deleted.
Do safety standards exist?	Yes	Yes