Exposing Exposure: Enhancing Patient Safety through Automated Data Mining of Nuclear Medicine Reports for Quality Assurance and Organ Dose Monitoring¹

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Purpose:

To develop and validate an open-source informatics toolkit capable of creating a radiation exposure data repository from existing nuclear medicine report archives and to demonstrate potential applications of such data for quality assurance and longitudinal patient-specific radiation dose monitoring.

Materials and Methods:

This study was institutional review board approved and HIPAA compliant. Informed consent was waived. An open-source toolkit designed to automate the extraction of data on radiopharmaceuticals and administered activities from nuclear medicine reports was developed. After iterative code training, manual validation was performed on 2359 nuclear medicine reports randomly selected from September 17, 1985, to February 28, 2011. Recall (sensitivity) and precision (positive predictive value) were calculated with 95% binomial confidence intervals. From the resultant institutional data repository, examples of usage in quality assurance efforts and patient-specific longitudinal radiation dose monitoring obtained by calculating organ doses from the administered activity and radiopharmaceutical of each examination were provided.

Results:

Validation statistics yielded a combined recall of 97.6% $\pm$ 0.7 (95% confidence interval) and precision of 98.7% $\pm$ 0.5. Histograms of administered activity for fluorine 18 fluorodeoxyglucose and iodine 131 sodium iodide were generated. An organ dose heatmap which displays a sample patient's dose accumulation from multiple nuclear medicine examinations was created.

Conclusion:

Large-scale repositories of radiation exposure data can be extracted from institutional nuclear medicine report archives with high recall and precision. Such repositories enable new approaches in radiation exposure patient safety initiatives and patient-specific radiation dose monitoring.

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There has been growing scrutiny of radiation exposure in the medical literature (1–4) and the lay media (5). While most of the attention to date has focused on computed tomography (CT), patient safety initiatives related to radiation exposure should ideally include all sources of ionizing radiation. CT accounts for approximately 49% of the general population's exposure to ionizing radiation from medical imaging (6). Nuclear medicine additionally contributes approximately 26% (6), and similar to CT, imparts a relatively high radiation exposure per examination (7). For the medical community to engage in systematic and large-scale patient safety initiatives related to radiation exposure, it must first have the tools to capture radiation exposure data on a large scale, not only for CT, but for nuclear medicine as well (8).

In the absence of definitive data directly testing carcinogenesis risk at the low radiation doses encountered at diagnostic imaging, there is ongoing controversy about the shape and slope of the dose-response curve in this dose range. Questions remain about the effects of periodic small exposures from medical imaging in comparison to the larger one-time exposures of the atomic bomb blasts that formed the primary basis for the Biological Effects of Ionizing Radiation VII risk model (9). The epidemiology studies needed to directly test cancer risk models from low-dose medical imaging will require large-scale patient data repositories of accurate dosimetry information linked to cancer

development to detect small changes above the large background cancer incidence. Informatics tools are needed to extract the relevant patient data from existing large-scale data archives, including the substantial contributions from nuclear medicine.

Some estimated population distributions of radiation exposures from nuclear medicine have previously been explored, including high-volume examinations such as positron emission tomography/CT (10) and cardiac stress tests (11–13). These studies have relied on typical examination doses from the research literature. To our knowledge, no prior studies have extracted examination- and patient-specific dosimetry from medical records on a large scale.

In nuclear medicine, the primary determinants of radiation dose are the type of radiopharmaceutical used and the administered activity. Knowledge of the biodistribution and pharmacokinetics of radiopharmaceuticals (14) permits the straightforward calculation of organ doses, which are relatively insensitive to patient size (15) in contrast to CT dosimetry (16,17). In nuclear medicine, the most comprehensive sources of patient-specific exposure information are typically institutional archives of text reports within the radiology information system or other

components of the electronic medical record. Large-scale extraction of these data would enable the creation of more accurate patient dosimetry than is currently available (2,10–13), facilitating new directions in patient safety, quality assurance, and radiation monitoring and reduction efforts.

We hypothesized that an accurate large-scale repository of patient-specific radiation exposure data could be extracted automatically from nuclear medicine text report archives by using informatics tools. The purpose of this study was to develop and validate an open-source informatics toolkit capable of creating a radiation exposure data repository from existing nuclear medicine report archives and to demonstrate potential applications of such data for quality assurance and longitudinal patient-specific radiation dose monitoring.

Materials and Methods

Study Setting and Data Source

Institutional review board approval was obtained for this Health Insurance Portability and Accountability Act compliant study, with waiver of informed consent for retrospective medical record review. The source of nuclear medicine reports was the radiology information

Advances in Knowledge

- Large-scale repositories of radiopharmaceutical administration data can be extracted from existing archives of unstructured nuclear medicine reports by using an open-source informatics tool, with data extraction recall of $97.6\% \pm 0.7$ and precision of $98.7\% \pm 0.5$.
- Such large-scale data repositories allow for the calculation of organ doses for longitudinal patient-specific dose monitoring.

Implications for Patient Care

- The inclusion of nuclear medicine radiation exposures enhances dose monitoring efforts, because nuclear medicine accounts for approximately 26% of the radiation dose from medical imaging to the general population of the United States.
- Radiation exposure repositories may help to enhance patient safety and quality assurance programs intended to monitor operations and maintain exposures as low as reasonably achievable.
- The automated creation of radiation exposure databases by using informatics tools may provide the necessary data for patient-specific radiation dose estimates.

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Abbreviation:

FDG = fluorine 18 fluorodeoxyglucose

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See also the editorial by McCollough in this issue.

system (IDXRad, version 9.9.7; IDX [a subsidiary of GE Healthcare], Burlington, Vt) for our 750-bed adult urban tertiary academic medical center (comprising inpatient, outpatient, and emergency department visits) and affiliated facilities, including an outpatient cancer center, a community hospital, and outpatient imaging centers. In combination, these sites resulted in 10613 nuclear medicine procedures during the 2010 fiscal year.

Cohort Selection and Software

Nuclear medicine reports for all examinations in our radiology information system were obtained between September 17, 1985 and February 28, 2011, totaling 204561 reports. These reports contain unstructured text, including the administered activity and the radiopharmaceutical name. We created an open-source toolkit, PARSE (Perl Automation for Radiopharmaceutical Selection and Extraction) (18), to extract radiation exposure data from the reports. The code was written in Perl (Practical Extraction and Report Language, version 5.10.0; O'Reilly Media, Sebastopol, Calif). Software was used to import data from the radiology information system (Access 2003; Microsoft, Seattle, Wash) and to view source code output files (Excel 2008; Microsoft).

Data Extraction Mechanics

Text reports were exported from the radiology information system to a single aggregate comma-delimited text file for processing. The toolkit first converts nuclear medicine reports entirely to lowercase to avoid capitalization errors and removes duplicated text segments (an artifact of addendum creations). Output is placed into a comma-delimited file for statistical analysis.

Within each report, all units of radioactivity are converted to a standardized format ("mCi" for millicurie and "uCi" for microcurie). Each unit of radioactivity is then used as an anchor point to search for numeric expressions of administered activity within a set text boundary. Next, a broader search from the unit of radioactivity is performed to match a user-defined array of radiopharmaceuticals. This regular expression

search process iterates for each instance of a unit of radioactivity to account for examinations with multiple radiopharmaceutical administrations (Fig 1). Reports lacking a unit of radioactivity are labeled in output as "null," while reports with other missing or undetected radiation exposure data fields are labeled as "uncertain."

Data Extraction Validation

Five thousand nuclear medicine reports from the study time period were randomly selected for the validation process. Iterative code training was performed on the first 1500 reports in the validation set to optimize the array of radiopharmaceuticals used at our institution and tailor the text search pattern for variations in report formatting. Manual validation of toolkit output was then performed on the remaining reports in the validation set until a minimum of 150 reports was reviewed for each of three distinct nuclear medicine administration scenarios: (a) single radiopharmaceutical with single administration, (b) single radiopharmaceutical with multiple administrations, and (c) multiple distinct radiopharmaceuticals with multiple administrations.

Validation necessitated the evaluation of three essential radiation exposure data fields: unit of radioactivity (millicurie or microcurie), numeric quantity of administered activity, and radiopharmaceutical. Reports missing any of the three required data fields were excluded from statistical analysis, because complete data extraction was not possible without the minimal amount of required data present. Any valid data not extracted or extracted incorrectly were counted as a failure of data extraction for the entire report in an all-or-nothing manner. Recall and precision with 95% confidence intervals were measured for each administration scenario, as well as combined. Recall (analogous to sensitivity) is the proportion of complete reports from which all data fields were correctly extracted. Precision (analogous to positive predictive value) is the proportion of reports with extracted data that is correct.

Toolkit processing time was recorded for the creation of the data

Figure 1

"...IV administration of 14 mCi and 31 mCi of Tc-99m Sestamibi at rest and during peak stress, respectively..."

- 1) ...of 14 mCi and 31 mCi of Tc-99m Sestamibi at...
- 2) ...of 14 mCi and 31 mCi of Tc-99m Sestamibi at...
- 3) ...of 14 mCi and 31 mCi of Tc-99m Sestamibi at...

14 mCi Tc-99m Sestamibi
- 4) ...of 14 mCi and 31 mCi of Tc-99m Sestamibi at...
- 5) ...of 14 mCi and 31 mCi of Tc-99m Sestamibi at...
- 6) ...of 14 mCi and 31 mCi of Tc-99m Sestamibi at...

31 mCi Tc-99m Sestamibi

Figure 1: Toolkit mechanics for a nuclear medicine cardiac stress test. The toolkit searches for (1) the unit of radioactivity (mCi) and (2) the numeric quantity of administered activity and (3) matches radiopharmaceutical and outputs extracted data (blue boxes). For separate occurrences of a unit of radioactivity (4), the process repeats (5, 6). IV = intravenous, Tc-99m = technetium 99m.

repository from the entire institutional nuclear medicine archive.

Data Repository Applications for Patient Safety

Radiation exposure variation.—After validation, the entire nuclear medicine report archive (204561 reports) underwent toolkit processing. From the resultant data repository, we examined the distributions of administered activity for fluorine 18 fluorodeoxyglucose (FDG) during the past 11 years, with special focus on 6 months before and after an April 2010 change in the FDG administration protocol. Administered activities greater than 25 mCi were manually reviewed. The distribution of administered activity for iodine 131 (¹³¹I) sodium iodide from the entire institutional report archive was also examined.

Patient-specific radiation dose monitoring.—Data from an adult patient with numerous nuclear medicine examinations was used to demonstrate the calculation of patient-specific radiation doses from the data repository. Organ doses (OD) (in milligrays) were calculated from the administered activity (AA) and radiopharmaceutical-specific

Toolkit Validation Statistics and Error Analysis of Data Extraction

Parameter	One Radiopharmaceutical, One Administration	One Radiopharmaceutical, More than One Administration	More than One Radiopharmaceutical, More than One Administration	Uncertain Report*	Null Report†	Combined
No. of reports	1606	373	152	182	46	2359
Prevalence (%)	68.1	15.8	6.4	7.7	1.9	100
Recall (%)‡	97.1 ± 0.8 (1538/1584)	99.5 ± 0.8 (368/370)	98.7 ± 1.8 (148/150)	...	...	97.6 ± 0.7 (2054/2104)
Precision (%)‡	98.6 ± 0.6 (1538/1560)	99.2 ± 0.9 (368/371)	98.7 ± 1.8 (148/150)	...	...	98.7 ± 0.5 (2054/2081)
Recall errors						
No. of total recall errors	49	2	3	...	...	54
Library lacking exact radiopharmaceutical	67 (33)	0 (0)	33 (1)	...	...	63 (34)
Typographical error	4 (2)	0 (0)	0 (0)	...	...	4 (2)
Unique formatting variation	29 (14)	100 (2)	67 (2)	...	...	33 (18)
Precision errors						
No. of total precision errors	4	3	1	...	...	8
Extra unit of radioactivity	50 (2)	67 (2)	0 (0)	...	...	50 (4)
Unique formatting variation	50 (2)	33 (1)	100 (1)	...	...	50 (4)

Note.—Unless otherwise indicated, data are percentages, with source data numbers or reports in parentheses.

* Reports with missing or undetected radiopharmaceutical name.

† Reports lacking a unit of radioactivity.

‡ Data are percentages ± 95% binomial confidence intervals. Data in parentheses are numbers used to calculate percentages.

conversion factors (CF) by using the following: $OD = AA \cdot 37 \cdot CF$. The number 37 allows for the unit transition from millicurie to milligray. Organ conversion factors account for the bio-distribution and pharmacokinetics of the relevant radiopharmaceutical (14).

Statistical Analysis

Toolkit validation results of recall and precision were calculated with 95% binomial confidence intervals. One hundred fifty reports of each administration scenario powers the validation for 95% binomial confidence intervals no wider than 5% at outcomes of 90% or greater. Statistical analyses and graphics were generated by using Excel (Microsoft) and R software (version 2.12.1, R Foundation for Statistical Computing, Vienna, Austria).

Results

Data Extraction Validation

After code training, 2359 reports were selected from the remainder of the

validation set. A total of 9.7% (228 of 2359) of reports did not contain all three requisite data fields and were thus excluded from the validation. The “null” reports (46 [1.9%] of 2359) lacked a unit of radioactivity because they had been generated for administrative purposes without any clinical information. The manual validation statistics are summarized in the Table. Toolkit validation yielded a combined recall of $97.6\% \pm 0.7$ (95% confidence interval) (2054 of 2104) and precision of $98.7\% \pm 0.5$ (2054 of 2081). Individual administration scenario statistics all exceeded 97%.

Data extraction errors for recall were categorized into the following three types (Table), all of which resulted from the toolkit not recognizing the correct radiopharmaceutical: (a) lacking radiopharmaceutical from the array, (b) typographic errors, and (c) rare formatting variations of the report. The largest error type for recall was lack of a radiopharmaceutical (63% of all recall errors combined), which was

encountered for rarely used radiopharmaceuticals not observed during iterative code training (eg, chromium-51-tagged red blood cells). Typographic errors prevented exact string matching with the trained list of radiopharmaceuticals. An example of report formatting that reduced data extraction recall was the placement of the administered activity between the radioisotope and its associated pharmaceutical (eg, “red blood cells were labeled with 27 mCi of technetium 99m”). Similar recall errors had been readily resolved during code training with a more inclusive radiopharmaceutical array.

Reductions in the precision of data extraction were equally attributable to two causes (Table): (a) Some reporting templates already contained the unit of radioactivity, and the reporting physician included a different unit of radioactivity, resulting in an “extra dose” error. (b) The precision statistic was also reduced by unique report formats such as addenda or the breakdown of the radiopharmaceutical administration into

Figure 2: Graphs show distributions of administered activity for FDG and ^{131}I sodium iodide for patient safety and quality assurance. **(a)** Reported FDG administrations during 11 years and surrounding an April 2010 protocol change. Manual review reveals that values greater than 25 mCi are reporting errors, not actual administrations. **(b)** Iodine 131 sodium iodide administration since the beginning of report archival shows a large range of administered activity. *F-18* = fluorine 18.

“pre-injection,” “post-injection,” and “net-injection” values.

With the utilization of a standard desktop computer, processing took 10 minutes 57 seconds for the entire 25.5-year institutional archive of 204 561 reports, including output to the data repository.

Data Repository Applications for Patient Safety

Radiation exposure variation.—In April 2010, an image acquisition protocol

changed, with a resultant reduction in FDG administered activity. There were 17562 administrations of FDG during the prior 11 years, with 1264 and 1241 administrations in the 6 months preceding and following the April 2010 protocol change, respectively (Fig 2a). While the toolkit accurately extracted the radiation exposure data contained within these reports, all values greater than 25 mCi were caused by erroneous reporting of the preinjection activity drawn

into the syringe rather than the net injection amount after subtracting the residual postinjection amount remaining in the syringe. All values greater than 30 mCi were appropriate amounts of rubidium 82 for cardiac perfusion examinations incorrectly reported as FDG because of improper editing of report templates.

There were 1437 administrations of ^{131}I sodium iodide since the beginning of report archival (Fig 2b). The numerous peaks of administered activity relate to a variety of clinical indications and disease severity. Values of 0–2 mCi were used for diagnostic imaging, 5–30 mCi for hyperthyroidism treatment, and various peaks greater than 30 mCi for thyroid cancer therapy (depending on the stage of the disease and variations in physician practice). Multiple distinct peaks of administered activity occurring over a very broad range contraindicate the use of a statistical mean for patient-specific dosimetry.

Patient-specific radiation dose monitoring.—Figure 3 demonstrates the application of extracted radiopharmaceutical administrations for detailed radiation dosimetry calculations for a 57-year-old patient with stage IV breast cancer. While organ doses are relatively higher for areas targeted for repeated imaging (bone surfaces because of bone scans, heart wall because of ventriculography), other bystander organs receive substantial doses due to the biodistribution and pharmacokinetics of the radiopharmaceuticals. As expected, dose to the urinary bladder accrues most rapidly resulting from renal excretion of the radiopharmaceutical (19), and upper abdominal organs accrue dose in part because of their proximity to target organs.

Discussion

Patient safety initiatives relevant to radiation exposure require informatics tools to capture pertinent exposure data on a large scale, ideally including all substantial sources of a patient's exposure to ionizing radiation. Our open-source toolkit enabled the capture of patient-specific radiation exposure data from institutional archives of nuclear medicine reports. The resultant data repositories may enable new avenues in patient safety, quality

Figure 3

Figure 3: Patient-specific examination timeline and cumulative organ dose heatmap. X-axis tick marks indicate the timeline of examinations. The color heatmap displays cumulative organ doses accrued from left to right and is arranged with the highest organ doses at the top to facilitate identification of organs receiving the greatest doses. *MDP* = methylene diphosphonate, *RBC* = red blood cell, *Tc-99m* = technetium 99m.

assurance, and longitudinal patient-specific radiation dose monitoring.

Validation yielded recall and precision exceeding 97%. Incorporation of missing entries in the radiopharmaceutical array (included in toolkit version 1.1) may further improve recall by correcting this dominant source of recall errors. Flagging reports with output of “uncertain” indicates incomplete data extraction, enabling the identification and addition of missing entries to the radiopharmaceutical array to improve subsequent recall.

In our institutional report archives, 9.6% of the reports did not contain complete information about the radiopharmaceutical administration. Errors in recall add incrementally to the number of examinations with incomplete data extraction. In contrast, errors in precision have the potential to create an “extra dose” entry in the patient data

repository. If used directly in patient-specific dose tracking, cumulative dose calculations could mistakenly increase, although effect is small because of their rarity of occurrence in 1.3% of reports (98.7% combined precision). Comparison against the typical number of radiopharmaceutical administrations for each examination could safeguard against duplication errors by flagging discordance for manual review, thus improving precision statistics.

No informatics tool can operate in autonomy but must be integrated into surrounding systems both to monitor and improve the tool itself and to meaningfully apply the resultant data. For quality assurance purposes, outlier values for each examination can be identified by comparing against predefined acceptable ranges. Linked notification schemes can trigger quality assurance review of improper administrations

and can prompt examination of reporting practices, as was the case for the outliers of the FDG distributions. The data repository can be used to monitor protocol changes over the course of time and could be further used to benchmark against other practices, guidelines, or regulations.

Meaningful patient-specific longitudinal radiation dose monitoring requires accurate collection of available radiation exposure data and robust methods to convert this data into relevant dose to the patient. To perform internal dosimetry with reasonable accuracy, patient-specific information about administered activity is needed (20). The use of population averages fails to capture changes in protocol over time or other variations in administered activity. Organ doses are considered the standard of reference in radiation dose monitoring (21). Obtaining them

is a reasonable goal in nuclear medicine internal dosimetry because of the relative insensitivity to patient size (15); this is unlike CT, where organ doses vary substantially with patient size because of the shielding effects of soft tissues on externally incident x-rays (16,17). Calculating organ doses for each examination retains the full granularity of the radiation exposure history but results in a large amount of information. An organ dose heatmap can facilitate visualization of organ dose accumulation, which may also be combined to a summary effective dose by applying current International Commission on Radiological Protection tissue-weighting factors (22,23). If one wishes to proceed to radiation risk estimation, these organ doses can then be mapped to associated risks of radiation-induced carcinogenesis by using the Biological Effects of Ionizing Radiation VII report (9) or an alternative risk model of choice.

Effective dose is the weighted sum of organ doses intended to represent the uniform whole-body equivalent dose expected to produce the same overall cancer risk as the heterogeneous exposures encountered in practice. While not intended for use in individual patients, effective dose is nonetheless commonly used as a single dosimetry metric to compare the risks of distinct exposures, even if they are to different parts of the body or involve different imaging modalities. Typical effective dose estimates cited in the literature (7,12,21) have been used in some studies (2,10,11,13). However, the tissue-weighting factors used to capture the relative radiation sensitivities of the various internal organs (22) are population averages and do not retain the known risk dependence on age and sex. Effective dose was thus designed as a meaningful measure only for large populations of patients and is generally not recommended for use in patient-specific dosimetry or dose monitoring (22,24,25). There is, unfortunately, no alternative single dose metric relevant at the level of the individual patient. When accurate dosimetry is possible, organ doses are thus preferred for patient-specific dose monitoring. In nuclear medicine, well-studied radiopharmaceutical

biodistribution and pharmacokinetics, combined with known rates of radioactive decay, allow reasonably accurate organ dose estimates, which may then be recorded and monitored in radiation data repositories.

Limitations of our study included the single-institution nature of this retrospective study. The toolkit uses a trained array of radiopharmaceuticals, which may require customization prior to implementation at each institution. It is currently designed only for English language reports and syntax. While further customization of the programming code may incrementally improve recall and precision, some data extraction errors are unavoidable because of the dictation of extra units of radioactivity, misspelled radiopharmaceuticals, and other typographical errors. The toolkit cannot fill in missing data or correct erroneous report content, although associated safeguards can be implemented to flag potential errors for manual review.

In summary, the large-scale automated creation of radiation exposure databases from unstructured nuclear medicine reports was possible by using informatics tools and may potentially enhance patient safety efforts in both nuclear medicine quality assurance and radiation dose monitoring. In particular, radiopharmaceutical administrations can be readily mapped to organ doses, opening new avenues in longitudinal patient-specific dose monitoring and risk assessment and potentially enhancing physician-patient communication and informed decision making.

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