NICE advice

Radiation dose monitoring software for medical imaging with ionising radiation

Medtech innovation briefing
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Summary

- The **technologies** described in this briefing are 8 radiation dose monitoring software technologies that automatically gather and analyse information on patients' exposure to ionising radiation from medical imaging and X-ray-guided procedures.
- The **innovative aspects** are that dose-related data from medical imaging with ionising radiation can be systematically collected, monitored and analysed in a largely automated way. The technologies are designed to improve image quality while minimising radiation exposure to the patient.
- The **intended use** would be instead of manual radiation dose data collection for people having medical imaging with ionising radiation.

- The **key points from the evidence** summarised in this briefing are from 10 studies investigating 3 of the included technologies. Most of the evidence comes from retrospective observational studies, 4 of which are available as conference abstracts only. The software ranges in technical features, allowing for various ways to acquire and analyse data from different kinds of imaging.
- **Key uncertainties** are that published evidence is only available for 3 of the included technologies. None of the studies were comparative.
- The **cost** of the technologies ranges from no cost to £20,000 per year, depending on local requirements. Some companies also charge a fee per modality price that varies according to patient numbers, whereas some offer the software as free and open source. With adequate resource input and time to implement the technologies, the **resource impact** may be faster and more detailed audits of radiation exposure data compared with standard manual audits.

This briefing describes technologies which fulfil a similar purpose. During development, every effort was made to identify and include relevant technologies but others may not have been identified, or key information was unavailable.

The technologies

Radiation dose monitoring software automatically gathers, stores and analyses information on patients' radiation exposure from medical imaging involving ionising radiation. Between 2012 and 2013, over 22.6 million X-rays and 4.7 million CT scans were done in the UK (NHS annual imaging and radiodiagnostic activity in England, 2012/13).

This briefing describes 8 software technologies that analyse patient-level radiation doses from different imaging modalities and examination types. Dose information can be collected:

- directly from the imaging device
- using the picture archiving and communication system (PACS), a technology that stores and handles medical images and related information **or**
- from the radiology information system.

The software uses digital imaging and communications in medicine (DICOM)-standard data sources to gather information relating to the radiation dose. DICOM (National

Electrical Manufacturers Association) is an international standard used in the NHS for storing and exchanging medical images and image-related information. The most common DICOM methods used by dose monitoring software for recording and analysing dose data are:

- Radiation dose structured report (RDSR), a report included in the DICOM dataset which contains various dose-related parameters, for example, the dose length product (DLP) and the volumetric CT dose index ($CTDI_{vol}$) for CT scans.
- Modality-performed procedure steps (MPPS), a report generated by the scanner that contains information about an examination including data about the images, length of scan and dose delivered.
- Dose reports using optical character recognition (OCR) of CT. Each CT machine generates a patient record, which consists of an image containing, among other information, the $CTDI_{vol}$ and DLP values. In newer scanners (produced in 2012 and onwards) or older scanners with newer software, the RDSR has replaced the need to retrieve data in this way.
- Image file header, which is part of each DICOM dataset that contains general parameters for the specific imaging examination.

The main functions of the software are to:

- Collect, store and monitor radiation dose data across different medical imaging modalities, regardless of the system manufacturer, hospital or hospital unit, including: CT scanners, interventional radiology systems, cardiovascular systems, mammography, radiography systems and surgical/mobile C-arms.
- Analyse radiation dose data, including:
  - change in the number of examinations done per year
  - radiation doses for all examinations done
  - a comparison of patient-level data with population-based information on radiation dose
  - set protocol-specific diagnostic reference levels (DRLs), which are pre-specified dose levels based on national or local criteria. DRLs are currently based on people with BMI of 20 to 25.

- Create reports and automated alerts, including:
  - run reports that review the range of doses given for each type of study and identify examinations with the highest dose
  - when an examination exceeds the DRL, the system can create alert notifications to display in a chart or to be sent by email.
- Using the dose index data to help find the lowest reasonable radiation dose for acceptable image quality.

Table 1 outlines the main characteristics, differences and similarities of the 8 technologies included in this briefing (adapted from Boos et al. 2016).

Table 1 Summary of included technologies

Technology name (company)	Data acquisition	Installation	User access	Modalities	CE mark*
DOSE (Qaelum)	RDSR, MPPS, OCR, header	Local	Web	CT, XA, DR, MG, RF, NM, PET	IIb
DoseM (Infinitt)	RDSR, MPPS, OCR, header	Local	Web	CT, XA, DR, MG, RF, NM, DXA	I
DoseMonitor (PACS Health)	RDSR, MPPS, OCR, header	Local	Web	CT, XA, DR, MG, RF, NM, DXA	I
DoseTrack (Sectra)	RDSR, MPPS, OCR	Cloud	Web	CT, XA, DR, MG, RF, PET	I
DoseWatch (GE Healthcare)	RDSR, MPPS, OCR, header	Local	Web	CT, XA, DR, MG, PET	I
DoseWise (Philips)	RDSR, MPPS, OCR, header	Local	App	CT, XA, DR, MG	I

OpenREM (OpenREM)	RDSR, header	Local	Web	CT, XA, RF, DR, MG	Not applicable*
teamplay (Siemens Healthcare)	RDSR, OCR, header	Local and cloud	Web	CT, XA, DR, MG, RF, NM, PET	Not applicable*

Abbreviations: DR, digital radiography; DXA, dual-energy X-ray absorptiometry; header, DICOM-Header; MG, mammography; MPPS, modality-performed procedure step; NM, nuclear medicine; OCR, optical character recognition; PET, positron emission tomography; RDSR, radiation dose structured report; RF, radiofluoroscopy; XA, angiography.

* NICE understands that the technology does not need CE marking as a medical device.

Innovations

The use of radiation dose monitoring software may improve the collection, analysis and reporting of radiation dose data compared with current manual or semi-automated methods. The detailed information provided by dose monitoring software allows for the best image quality possible while minimising radiation exposure to the patient.

Dose monitoring software can also be used to alert healthcare professionals to radiation exposure when DRLs are consistently exceeded. Some of the technologies may help facilitate management of protocols, contrast media and staff dose as well as image quality.

The systematic monitoring and analysis of radiation dose data can potentially reduce radiation exposure for people having multiple imaging procedures. It can also help hospitals meet legal and policy requirements. Based on the Medical Exposure Directive 97/43, in some European countries (currently including the UK), radiation protection legislation mandates the recording of individual patient doses (or parameters from which dose can be calculated). Current UK legislation includes Ionising Radiation (Medical Exposure) Regulations 2000 (IRMER) from the Department of Health, which details DRLs and what to do in cases of excessive radiation exposure. Systematic dose monitoring may also help to support quality assurance in terms of meeting directives such as the EU Council Directive 2013/59/EURATOM.

Current guidelines and arrangements

Public Health England currently gathers and collates radiation dose data for common examinations from a sample of UK hospitals through manually compiled databases. The Department of Health's response to COMARE's 16th report on the increased use of CT scans in the UK recommended that more frequent UK dose surveys need to be done. These surveys will provide data to support regular updating of national DRLs, including those specifically for children.

Manual and semi-automatic recording of radiation dose data requires data entry in the radiology information system, a spreadsheet or on paper. This is time consuming and may result in an error rate of up to 6% (Noumeir 2005, Boos et al. 2015).

The 2011 review of the Public Health England report CRCE-013: Doses from CT examinations in the UK specifies that for a national audit on radiation dose data, a healthcare professional (either a radiographer or a physicist) with access to PACS should acquire the data and a data manager (a radiographer or a physicist) should verify the data before transferring it to a spreadsheet or other record.

Population, setting and intended user

The technologies are likely to be used for retrospective analysis by healthcare professionals specialising in radiation protection and with appropriate training. These would most likely be medical physicists, radiographers and radiologists. The technologies would be used in secondary care in the NHS to record and analyse data in the trust.

Radiation dose data can be collected from anyone having medical imaging with ionising radiation.

Costs

Table 2 shows the costs associated with each technology.

Table 2 Costs of radiation dose monitoring software

Technology name (company)	Cost (excluding VAT)	Additional information
DOSE (Qaelum)	Average £10,000 to £15,000 (per hospital, per year; based on study volume).	–
DoseM (Infinitt)	Average £8,000 to £10,000 (per hospital, per year; based on multi-modality, multi-manufacturer data collection and archiving from ionising radiation sources through PACS and extending to modalities which do not support DICOM SR/MPPS).	–
DoseMonitor (PACS Health)	Average £10,000 to £15,000 (per hospital, per year; based on study volume).	–
DoseTrack (Sectra)	Average £10,000 to £15,000 (per hospital, per year; based on 30 modalities per year).	–
DoseWatch (GE Healthcare)	Average £10,000 to £20,000 (per hospital, per year).	Operational lease model for connecting all ionising radiation scanning equipment.
DoseWise (Philips)	£1,300 per modality, plus a server fee of £10,400 per year.	–
OpenREM (OpenREM)	Free to download and use.	Available under open-source licence (GPL V3).

teamplay (Siemens Healthcare)	£7,400 to £20,000 (per trust, per year). Basic version at no additional cost with Siemens scanners. Costs are per installation on a PACS system, which may be shared across a trust. Non-Siemens scanners/mixed fleets cost £7,400 per year.	Dose and usage monitoring apps for Siemens scanners.
Abbreviations: PACS, picture archiving and communication system; DICOM SR, digital imaging and communications in medicine, structured reporting; MPPS, modality-performed procedure steps.		

Costs of standard care

The main cost associated with manual dose data recording is the clinical time it takes. The cost of a hospital radiographer's time is £35 per hour (Agenda for Change band 5) and a medical physicist's time is £56 per hour (Agenda for Change band 7; Personal Social Services Research Unit [PSSRU] 2016). This includes all remuneration, qualifications, department overheads and capital costs.

The cost depends on whether data are recorded manually (by radiographers filling in forms) or downloaded from the radiology information system.

Specialist commentators estimate that it takes 20 minutes of a radiographer's time for data collection per examination. The data are then transferred to a medical physicist for verification of data entry, review, analysis and report production. This takes at least 1 hour per examination. Combining the radiographer's and medical physicist's time, the estimated average cost is £68 per examination.

If data are instead taken from the radiology information system, little or no radiographer time is needed. However, extra medical physicist input may be needed to understand the data, eliminate outliers, confirm the validity of results and remove zero values before the data can be analysed. One specialist commentator estimated that this is at least 1.5 hours of a medical physicist's time is needed per examination, with an estimated average cost of £84.

Resource consequences

If adopted, the technologies would likely to be used with the available ionising radiation imaging equipment. A mid-sized hospital trust could have an average volume of 100,000 images per year, whereas a large trust may do 250,000 images per year.

These technologies are software packages to be used with current hardware and so no additional facilities or technologies are likely to be needed. However, the hospitals will need to reallocate staff to manage information governance and software compatibility arrangements such that the technologies can be properly installed and used. This may be time consuming. The technologies will also need IT involvement to set up and staff to maintain them.

No published evidence on the resource consequences of adopting the technologies was found, including either economic evaluations or costing studies.

Equality considerations

NICE is committed to promoting equality, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. In producing guidance and advice, NICE aims to comply fully with all legal obligations to: promote race and disability equality and equality of opportunity between men and women, eliminate unlawful discrimination on grounds of race, disability, age, sex, gender reassignment, marriage and civil partnership, pregnancy and maternity (including women post-delivery), sexual orientation, and religion or belief (these are protected characteristics under the Equality Act 2010).

Successive radiation exposure increases a person's cumulative risk of developing cancer, with higher radiation doses contributing a higher risk. Children are at higher risk than adults because they are more sensitive to radiation. Pregnant women and their foetuses are also at higher risk of damage from radiation exposure. Age and pregnancy are protected characteristics under the Equality Act 2010.

Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the published process and methods. This briefing includes the most relevant/best publicly available

evidence relating to the clinical and cost effectiveness of the technologies. The literature search strategy and evidence selection methods are available on request by contacting mibs@nice.org.uk.

Published evidence

This briefing summarises 10 studies involving CT scans, fluoroscopically guided procedures (FGP), X-rays, positron emission tomography (PET) scans and PET/CT.

One study reported results using DoseTrack (Kim et al. 2016), 1 using OpenREM (Platten and Thomas 2015) and 8 using DoseWatch. No published evidence was found for the other technologies included in this briefing.

Table 3 summarises the clinical evidence as well as its strengths and limitations.

Strengths and limitations of the evidence

Published evidence is only available for 3 of the included technologies (DoseTrack, DoseWatch and OpenREM), most of which comes from retrospective observational studies. Although prospective data gathering ensures that important values such as patient weight are correctly documented, the same bias effect is not present for these software systems as for other medical technologies, because standard collection of data can be done retrospectively with equivalent accuracy. Five of the studies were only available as conference abstracts and so there was limited information on their methodology.

The 2011 review of the Public Health England report CRCE-013: Doses from CT examinations in the UK includes data from 47,000 patients across 127 centres (an average of 370 examinations per centre). The total number of CT examinations analysed in 3 single-centre studies included in this briefing equates to more than 1,000 examinations per centre, demonstrating that radiation dose monitoring technologies may be used to collect and analyse sufficiently large datasets (Boos et al. 2015, Heilmaier et al. 2016, Manco et al. 2016).

None of the studies provided any information on the amount of time and staffing needed to use the software.

Comparative studies assessing the usability or functionality of 2 or more of the technologies would improve the evidence base. Radiation dose monitoring technologies do not have any measurable directly related clinical outcomes, so studies should be designed to support their main functionality claims (particularly their ability to collect and analyse large datasets fast and efficiently).

Table 3 Summary of selected studies

De Bondt (2017)	
Study size, design and location	296 CT scans, retrospective observational study, multicentre, Belgium.
Intervention and comparator(s)	DoseWatch, no comparator.
Key outcomes	The radiation dose monitoring software identified that there was a consistent dose level between scanners in the same hospital. Large dose variations were observed between hospitals. The radiation dose monitoring software revealed that erroneous selection of adult protocols for children occurred.
Strengths and limitations	There was a relatively small sample size (<300). Results were pooled over 5 different scanners with technological differences, which can affect the lowest achievable radiation dose.
Heilmaier et al. (2015)	
Study size, design and location	357 FGP, prospective observational study, single-centre, Switzerland.
Intervention and comparator(s)	DoseWatch, no comparator.

Key outcomes	The software successfully transferred dose data from all the procedures. Highest dose values were seen during transarterial chemoembolisation procedures. Complex cases were associated with higher doses, whereas there was no direct correlation of dose and total fluoroscopy time.
Strengths and limitations	Although operators based their grading of case complexity of the FGP on predefined criteria, grading remains subjective to a certain degree. C-arm angulation was not recorded. It is well known that this is an important parameter in the calculation of the dose delivered.
Heilmaier et al. (2016)	
Study size, design and location	8,883 CT scans, retrospective observational study, single-centre, Switzerland.
Intervention and comparator(s)	DoseWatch, no comparator.
Key outcomes	A total of 316 alerts were generated by the system. The overall alerts percentage ranged from 2% to 5% and the main reasons were high BMI and patient being positioned off-centre.
Strengths and limitations	Scanners from only 1 company were used. In some patients, alerts may have been caused by more than 1 source, but the authors tried to estimate which of the causes might have been the principal reason.
Heilmaier et al. (2017)	
Study size, design and location	30,045 conventional digital X-ray images, retrospective observational study, single-centre, Switzerland.
Intervention and comparator(s)	DoseWatch, no comparator.

Key outcomes	Radiation dose values decreased significantly after implementation of the dose monitoring software. The software successfully transferred dose data from the procedures.
Strengths and limitations	Data were obtained from only 1 department, so radiographs of certain areas of the anatomy were limited. The department was fully equipped with digital detectors, so the data may not be representative of institutions still using film-screen systems.
Kim et al. (2016)	
Study size, design and location	5,359 X-rays, 413 CT scans, 98 PET scans, 82 PET/CT scans, retrospective observational study, single-centre, Korea.
Intervention and comparator(s)	DoseTrack, no comparator.
Key outcomes	The CT component of PET/CT scans contributed nearly half of the total cumulative dose in children with neuroblastoma. The radiation dose received from X-ray was higher than expected because of the large number of images. The software was used to analyse the cumulative radiation dose attributed to different imaging modalities in children having multiple imaging investigations because of cancer.
Strengths and limitations	The authors did not consider changes in study protocols or equipment models for the 12-year length of the study.
Manco et al. (2016), abstract only	
Study size, design and location	30,000 CT scans, retrospective observational study, single-centre, Italy.
Intervention and comparator(s)	DoseWatch, no comparator.

Key outcomes	Using an iterative reconstruction, average effect doses were reduced by 25% for thorax-abdomen scans and 30% for head scanning protocols. In addition, dose reductions of 52% on body and 30% on neurology CT scans were achieved.
Strengths and limitations	This study was published as an abstract so there is limited information to assess its methodological quality.
Pasquier et al. (2014), abstract only	
Study size, design and location	45 CT scans, retrospective observational study, single-centre, France.
Intervention and comparator(s)	DoseWatch, no comparator.
Key outcomes	5 examinations, representing 12% of the total, were above the dose alert threshold.
Strengths and limitations	This study was published as an abstract so there is limited information to assess its methodological quality. Additionally, the study is based on a limited number of scans.
Perry et al. (2016), abstract only	
Study size, design and location	1,393 interventional procedures (368 IR and 1,025 NIR), retrospective observational study, single-centre, US.
Intervention and comparator(s)	DoseWatch, no comparator.
Key outcomes	10 of 368 (2.7%) IR and 52 of 1,025 (5.1%) NIR procedures exceeded estimated doses of 5 Gy with reported reference point Air Kerma (kinetic energy released per unit mass of air). All IR cases were abdominal/pelvic trauma angiograms with/without embolisation; there were no reported tissue reactions. 5 of the 49 (10.2%) NIR patients reported skin/hair injuries, all of which were temporary.

Strengths and limitations	This study was published as an abstract so there is limited information to assess its methodological quality.
Platten and Thomas (2015), poster presentation only	
Study size, design and location	70 CT aortic angiograms, retrospective observational study, single-centre, UK.
Intervention and comparator(s)	OpenREM, no comparator.
Key outcomes	Mean DLP was 1,180 mGy cm for CT aortic angiograms with a median of 1,030 mGy cm, which is comparable to the national reference dose for this type of exam (1,040 mGy cm).
Strengths and limitations	This study was published as an abstract so there is limited information to assess its methodological quality. The sample size was relatively small.
Radice et al. (2016), abstract only	
Study size, design and location	2,165 FGPs, prospective observational study, single-centre, Italy.
Intervention and comparator(s)	DoseWatch, no comparator.
Key outcomes	From the 32 patients enrolled in the follow-up programme, 1 case of transient alopecia was observed at 1 month. Patients at risk of skin injuries because of high doses from FGPs were followed up as an integral part of the radiation dose management protocol.
Strengths and limitations	This study was published as an abstract so there is limited information to assess its methodological quality.
Abbreviations: DLP, dose length product; FGP, fluoroscopy-guided procedures; IR, interventional radiology; NIR, neuro-interventional radiology; PET, positron emission tomography.	

Recent and ongoing studies

No ongoing or in-development trials were identified.

Specialist commentator comments

Comments on this technology were invited from clinical and scientific experts working in the field and relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

All 5 specialist commentators were familiar with these technologies. One specialist used at least 1 of the technologies infrequently (approximately 5 times per year); another used them regularly (on a weekly or monthly basis).

Level of innovation

Two specialists stated that the radiation dose monitoring software technologies are a minor variation of current technology, automating an existing process by using modern IT standards to interconnect imaging devices with data collection devices. Four commentators thought that the technologies could potentially improve data collection and image quality, and minimise radiation doses. One of the specialists stated that the technologies are a significant development in allowing real-time evaluation of all systems in an organisation, helping to identify imaging systems in which problems may be developing.

All but 1 specialist commentator thought that some level of training would be needed to use the software.

Potential patient impact

Three specialists anticipated that the technologies would have little or no direct effect on patients. However, 3 other specialists felt that the software could reduce overall population radiation exposure by allowing for regular reliable audits, which would improve patient safety and reduce risk. Two specialists stated that the technologies would particularly benefit young people, and 1 felt that they could help to identify people with chronic conditions who have repeated examinations and therefore radiation exposure.

Three commentators thought that using the technologies could improve diagnostic accuracy and confidence, which would benefit patients. One stated that they may enable higher radiation doses to be used where appropriate to increase image quality. Another specialist stated that an alert system to identify relevant previous imaging might reduce a very small number of unnecessary examinations.

Potential system impact

The commentators agreed that the technologies would help to optimise images, which would be beneficial for the healthcare system. Three specialists felt that the automation would ease the burden of the current manual process of recording dose monitoring data. One specialist stated that the technologies would help identify variation in techniques within or between institutions, highlighting the need for optimisation of radiation dose and image quality. Two commentators stated that using this software would lead to multidisciplinary teams optimising their work, possibly reducing the amount of time spent by the team on analysing patient dose data. However, another commentator expressed doubt that the additional information would reduce time spent by medical physicists on collection, analysis and reporting, stating that more time will be needed for analysis and interpretation. One of the commentators added that additional staff resources would be necessary for maximum benefit from the systems.

All the specialist commentators acknowledged that the database system would need to connect to existing IT infrastructure: some systems would be able to work with existing IT infrastructure with minimal changes and updates, whereas others may need a larger investment (for example, an increase in server capacity).

Four specialists thought that the potential for NHS cost savings was unclear, and 1 stated that a detailed cost analysis would be necessary to assess the cost implications. Another commentator stated that the cost savings would be minimal, because the technologies provide quality improvements rather than to significant cost savings. One specialist stated that although dose monitoring systems may make data recording faster, the process is likely to include more examinations than would have been included with manual data entry. Another explained that some people may choose to pursue legal action over excess radiation exposures, so the technologies could reduce legal costs for the NHS.

General comments

One specialist noted that the Public Health England report called for patient-size measurements to be taken from the images, because this information is rarely available and is a significant factor in terms of variation in radiation dose; the commentator did not feel that dose monitoring technologies would eliminate this manual step. Two specialists noted that dose monitoring systems are most useful if they are connected to multiple modalities, information systems and shared across organisations.

One commentator stated that regional or national dose collection would be needed for setting and optimising interventional diagnostic reference levels (DRLs); the potential for collection of large-scale data offered by these technologies could transform the insight available. Another commentator expected the evidence to be generalisable across all technologies because the handling of data will have more of an effect than the technology itself.

One specialist pointed out that according to another Public Health England report, Medical and dental X-rays: frequency and collective doses in the UK (2010), 26% of medical imaging examinations with ionising radiation are for dental purposes and, despite their small dose contribution, the software will not be able to analyse most of these.

Specialist commentators

The following clinicians contributed to this briefing:

- Ian Honey, medical physicist, Guy's and St Thomas' NHS Foundation Trust. No relevant conflicts of interest.
- Dr Giles Roditi, consultant radiologist, NHS Greater Glasgow and Clyde. No relevant conflicts of interest.
- Andy Rogers, medical physicist, Nottingham University Hospitals NHS Trust. Mr Rogers is a member of the Philips Healthcare DoseWise Medical Physics Advisory Board, whose payments support his research activities and professional development.
- Dr Arun Sebastian, consultant radiologist, Colchester Hospital University NHS Foundation Trust. Dr Sebastian has obtained industry funding to attend conferences in the past.

- Lorna Sweetman, medical physicist, The Christie NHS Foundation Trust. Ms Sweetman received a one-off speaker fee for a presentation at a Bayer radiation protection event.

Additional reviewer:

- Sue Edyvean, head of medical (radiation) dosimetry group, Centre for Radiation, Chemical and Environmental Hazards (CRCE), Public Health England.

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