Department of Health

DH Expert Working Party Response to the Committee on Medical Aspects of Radiation in the Environment's 16th Report "Patient radiation dose issues resulting from the use of CT in the UK"

May 2016

Title: DH Expert Working Party Response to: Committee on Medical Aspects of Radiation in the Environment (COMARE) 16th Report 'Patient radiation dose issues resulting from the use of CT in the UK'.
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Executive Summary

The aim of the 16th report from the Committee on Medical Aspects of Radiation in the Environment (COMARE) was to advise the Department of Health on the increased radiation dose issues resulting from the use of diagnostic CT scans within the UK.

The increased use of CT has raised concerns regarding the radiation dose to patients from CT scans. CT makes a larger contribution to the radiation exposure of patients when compared with other imaging modalities because of the greater doses of ionising radiation. There is particular concern about younger patients undergoing CT scans, owing to their greater radiosensitivity.

Officials in the Department of Health proposed that a Working Party of relevant experts should be formed to consider the recommendations of the COMARE 16 report, to offer practical guidance for healthcare providers and, if necessary, make recommendations to the Department of Health.

This document sets out the Working Party's response to the 7 recommendations made in the COMARE 16 report.

For the purpose of this report only conventional CT scanning has been considered; cone beam CT technology has been excluded.

Whilst this document specifically relates to CT examinations the over-arching principles that are proposed also act as an effective framework for all examinations using ionising radiation.

This response from England should be considered as applying across all four UK countries and the Working Party included representatives from organisations whose remit covers the entire UK.

Where the term 'Trust' has been used in this document any comments apply equally to Health Boards in Scotland and Wales.

Background and Introduction

The radiation dose from a CT scan varies depending on the type of procedure performed and the area(s) of the body scanned as well as the size of the patient. The management of some diseases can require patients to undergo multiple scans.

Certain groups are at higher risk from radiation exposure. Children have a greater radiosensitivity than adults at the same effective dose. Cancer risk is cumulative over a lifetime, with a contribution from each radiation exposure, resulting in CT scans giving a higher risk to children than to older adults.

CT has undergone dramatic technical advances, with the introduction of helical and also multi-slice scanners, dual-source and dual-energy scanners and modern iterative reconstruction techniques. The speed of scanning has also increased, allowing a greater volume to be scanned during a single breath hold.

There has been a focus on dose reduction technology since the turn of the century with each new development offering potential dose reductions depending on how it is employed. Since image quality is a key factor determining the extent of use of these dose reduction techniques, the evaluation of image quality, in conjunction with the measurement of dose, is paramount for quantification of these effects.

There is evidence from dose surveys that the radiation exposure from similar CT investigations can vary widely between different hospitals and, sometimes, even within the same radiology department. Optimisation of examination protocols is regarded as one of the most pressing needs in modern CT practice.

In the UK a wide range of services and support were provided to the CT scanning community by an independent evaluation group (ImPACT) until 2011. It may be argued that there remains a need for a group that is able to provide impartial, objective advice and technical data on CT scanners, to support information provided by manufacturers and underpin equipment purchasing decisions and ongoing advice with respect to optimisation, for the NHS and other health care providers.

Response to COMARE Recommendations

Recommendation 1

During the next 10 years, the importance of the radiosensitivity of high risk groups is expected to become more widely recognised as a factor in a range of clinical applications involving ionising radiation, including CT. We recommend that the UK is actively involved in further research in this area. Professional bodies and medical and scientific societies should continue to provide educational opportunities to increase the understanding of clinical staff regarding all of the potential risks to patients, and not just the dose received, from CT scans. This is particularly relevant for CT scans on children and other high risk groups.

Response

1. The Working Party (WP) recognises there is ongoing current research both in the UK and internationally in this field. To encourage and maintain a focus on research projects looking at radiosensitivity particularly in high risk groups the Chair of the WP has written to a number of research funding bodies requesting they consider prioritising funding research in this area. See Appendix 2
2. WP members agree that their respective professional bodies and organisations will continue to provide educational opportunities to support clinical staff with their understanding of all risks to patients from CT scans and will work to ensure that more emphasis is placed on the appropriate use of CT, dose optimisation and managing potential risks to patients, with particular reference to children and other high risk groups.
3. The inclusion of the potential risks associated with CT scans should also be part of continuing professional development (CPD), which is essential for accreditation/re-registration for healthcare professionals.
4. The professional bodies aligned to the healthcare teams who work in this area are committed to such training and several contributions in this sphere are described below.
5. Medical Physicists specialising in radiation protection (RP) and diagnostic radiology (DR) provide training on radiation risk and optimisation in DR to radiology professionals and other clinical staff at all levels. The importance of increased caution when dealing with radiation exposure of high-risk groups, such as paediatric patients, is highlighted.
6. The Institute of Physics and Engineering in Medicine (IPEM) encourages the full participation of all radiology professions in their one-day meetings on RP and DR topics, as well as in sessions on these subjects at the annual UK radiology congress (UKRC). Attendance at training seminars and courses concerning radiation risk, optimisation and associated legislation (such as IR(ME)R referrer and operator courses), organised at a local level, is also promoted.

7. The Society & College of Radiographers (SCoR) strongly advises its members that radiation protection is an essential part of their ongoing CPD. The SCoR, in support of both their members and the general public, provides dedicated radiation protection (RP) support, produces and offers access to a range of RP guidance, publishes articles and provides study days and e-learning opportunities. The College of Radiographers (CoR) ensures that, during the education course approval processes, radiation protection and associated risks are an integral part of the syllabus, with these being a mandatory element of the clinical assessment programme.
8. There are general radiation protection e-learning units available to clinical staff on the Health Education England (HEE) learning platform E-Learning for Health (www.e-learningforhealthcare.org.uk). The CoR plans to include additional learning units which incorporate medical exposure risks and highlight those associated with CT exposures.
9. The speciality training curricula of the Royal College of Radiologists in clinical and interventional radiology specify the requirement for acquisition of a broad base of knowledge about radiation risks and radiation protection by all trainee radiologists (section 4.11 of the 2014 curriculum).
   http://www.rcr.ac.uk/docs/radiology/pdf/Curriculum_CR_28_October_2014_FINAL.pdf
10. This knowledge is tested in the Fellowship of the Royal College of Radiologists (FRCR) examinations. Radiologists have a fundamental duty to protect patients as far as possible from the harmful effects of radiation.
11. Multidisciplinary training in radiation protection is provided by the British Institute of Radiology, where the clinical requirements for quality imaging and the versatility of the equipment are set alongside the radiation burden associated with the image acquisition. CPD accredited education events, webinars and other interactive online materials can be used for refresher or ongoing, up-to-date training in radiation safety for all professional groups.

Recommendation 2

The continuing development of technology and the growing range of clinical applications in CT suggest that individual and population dose from CT will continue to rise. We recommend that Public Health England should undertake more frequent UK dose surveys to provide data to support regular updating of national diagnostic reference levels, including those specifically regarding children. To facilitate this, the Department of Health should include within regulations a requirement for healthcare providers to submit patient dose data at a frequency which reflects the changes in the application of the modality.

Response

1. The UK has a long history of developing and generating national Diagnostic Reference Levels (DRLs) that is acknowledged worldwide by radiation protection experts. It is good practice for radiology departments to review their CT protocols to ensure that, if their local

DRLs are at the high end of the published national spectrum, there is either good reason for this, or protocols are changed to reduce patient dose.

2. Public Health England (PHE) currently gathers and collates patient dose data for common examinations from a sample of UK hospitals by means of manually compiled databases. The resulting national reference doses for standard sized patients are published and adopted by the Department of Health (DH) as new national DRLs.
3. It could be possible for PHE to undertake patient dose surveys, produce reports and update DRLs in a more timely manner through automated acquisition of dose information and submission of data to a central server. This is now technically possible with the help of appropriate software. There are, however, cost implications at both a local and national level to automate the process, and to provide this level of functionality. This may be something the PHE, professional body and DH Working Party (referred to in 2.5) could look into.
4. For establishing national DRLs only sample data is required, however there are wider objectives for a fully automated ‘all data’ registry, for example for epidemiology purposes or for tracking the dose history of patients who have undergone multiple CT scans throughout their lives.
5. PHE is currently establishing a PHE, professional body and DH Working Party, to explore the frequency of surveys, breadth of coverage, mechanisms of data collection and adoption processes of DRLs. It is recommended that DH develop this Working Party into a steering group to oversee a centrally funded data repository to ensure frequent updates of national DRLs.
6. The European Commission introduced a new radiation protection directive (Basic Safety Standards Directive 2013/59/Euratom) (BSSD) in December 2013 that includes medical exposures. The UK must transpose this directive into UK law by February 2018.
7. The wording in the directive gives no requirements on how national, or local, DRLs should be generated, only that Member States shall ensure that they are established, reviewed regularly and used. DH cannot interpret the article as a requirement to collect data for every x-ray exposure, nor from every diagnostic radiology facility. However, the WP agreed it would be highly advantageous to require submissions from all radiology facilities in order to provide a more uniform coverage.
8. If dose data submission is not a mandatory requirement, all NHS Trusts, private healthcare providers and military hospitals should be strongly encouraged to record and submit radiation dose data and to track the process of CT dose optimisation at a local level.

Recommendation 3

Optimisation of CT scanning can be best achieved when scanners include a full range of dose reduction features. We recommend hospitals should be required to include these features and options as part of any procurement process for new equipment. Manufacturers and suppliers should ensure the application and performance of these features is fully understood by customers and should be a major feature of initial and ongoing applications training for radiographers and radiologists. Employers should recognise the value of continued training as part of continuing professional development as well as for patient safety and should release staff so that the benefits of manufacturer training are maximised.

Response

1. The process of optimisation requires that examinations are undertaken as effectively and efficiently as possible, using the lowest radiation exposure practicable (ALARP).
2. On behalf of the WP, the Chair contacted NHS Supply Chain, who provide patient focused healthcare products and supply chain services to the UK's National Health Service, to emphasise the significance of including a comprehensive range of dose reduction features when involved in the procurement of CT scanning equipment.
3. The Ionising Radiation (Medical Exposure) Regulations 2000 [IR(ME)R] and 2006 and 2011 amendments, place the responsibility on the employer to ensure that their duty holders are adequately trained to perform the roles and tasks they are expected to undertake. Records of training, including practical training specific to equipment use, must be up to date and available for inspection.
4. All AXrEM (Association of Healthcare Technology Providers for Imaging, Radiotherapy and Care) CT manufacturers have agreed they will provide tailored, flexible training that meets clinical needs and expectations of customers to ensure optimum use of scanner diagnostic image acquisition and dose reduction technology. Training should be provided to radiographers, radiologists and medical physicists to enable them to maximise clinical knowledge and scanner capabilities to produce diagnostic images at optimised dose.
5. Such training will be undertaken by an application specialist with extensive clinical expertise in CT scanning. This would be implemented following initial discussions with nominated CT users with respect to their specific training requirements appropriate to the equipment purchased and intended clinical use.
6. All manufacturers agree that initial and follow up applications training will be provided. This will encompass all aspects of the system hardware, user interfaces, and related applications and features of image acquisition and post processing. It will also include all dose reduction and dose monitoring features available on the system.
7. Additional ongoing, on-site and remote education and training opportunities can also be utilised. Application training will be documented for both manufacturer and customer training records.

Recommendation 4

Although we recognise the value of a range of international initiatives on radiation dose in CT, there remains a need for detailed independent information on CT scanner performance. We recommend that the Department of Health reviews the sources of available information and, if necessary, provides funding to support an independent evaluation group, acting collaboratively where appropriate, but also providing assessments of CT scanners as and when required.

Response

1. Since the cessation of the national CT evaluation group in 2011, there has been a lack of centrally available, independent information and advice on CT technology and scanner performance.
2. The lack of a centrally funded expert group has resulted in additional resources being required by Trusts and manufacturers during the procurement and commissioning processes for new CT scanners. Specification data provided by manufacturers is no longer directly comparable or subject to the same scrutiny and so the process is less robust as well as more costly overall. It could be argued that adoption, and appropriate use, of dose reduction features has taken longer to achieve in some centres.
3. The members of the WP strongly agree that it would be greatly beneficial to the radiology community to have a centrally funded group re-established to provide independent information and advice on CT technology, image quality and dose.
4. The main functions of such a group (as modelled on the previous national evaluation group) would be to provide:
    - Independent comparative specification data (collating, scrutinising, reviewing and publishing),
    - A national source of dose output values for new CT scanner models, for inclusion in the national patient CT dose calculation spread sheet,
    - Independent assessment of imaging performance and dose of new CT scanner models to provide guidance on procurement of systems,
    - In depth, comparative assessment of new technological CT features to guide and assist users in the processes of procurement, commissioning and optimisation.
5. The additional benefits of such an independent, expert group include strong links with CT scanner manufacturers and a central source of expertise in dose reduction tools and other technical features. This feeds into the education of radiology professionals to ensure the safe and optimised operation of scanners.
6. An expert group such as described above would also be in a position to host a centralised source of information from CT users in radiology departments (physicists, radiographers, radiologists). Data, experience, reviews, and knowledge from CT users could be submitted and shared through web based processes.

Recommendation 5

Modern CT scanners are capable of providing precise detail of patient anatomy, but this is not always required. Requests for imaging should include a clear statement regarding the clinical question to be answered and the scan should be performed to provide this. We recommend that the Royal College of Radiologists should continue to work with referrers and its own fellows and members to ensure an appreciation that CT scans should be optimised, taking into account both image quality and dose.

Response

1. Attached as an appendix to the COMARE 16th report is a letter from the Royal College of Radiologists agreeing in principle with the statement that: 'where a specific clinical question has been asked by the referrer of a patient for CT scan, the CT examination should be carried out at the lowest dose required to answer the question accepting that other organs in the scan field may not be optimally visualised'.

   Appendix 1 Copy of the letter from the Royal College of Radiologists

2. This is an important principle, reaffirming the commitment of radiologists to optimise CT scans to answer a specific clinical question rather than to pursue the highest image quality on all occasions. Review and design of protocols accordingly will constitute one role of the team of radiation protection champions, which is discussed in detail in our response to Recommendation 7.

Recommendation 6

The most appropriate use of CT relies upon a range of factors involving the referring clinician and the radiologist or other clinician who justifies the scan. In many cases, the most appropriate outcome of a referral may be that the CT scan is not performed as an alternative diagnostic procedure may be more effective. We recommend that the Royal College of Radiologists, together with other appropriate organisations, continues to review and produce referral guidelines and includes within these an even greater emphasis on alternative imaging techniques using less or no ionising radiation. The Department of Health should continue to actively support this process by facilitating the availability of referral guidelines and, while doing so, highlight the importance of alternative techniques for patient groups who may have enhanced radiosensitivity.

Response

1. The Royal College of Radiologists has produced referral guidelines to assist clinicians in choosing the right imaging test for common clinical scenarios for over 20 years. These are now available electronically to NHS professionals across the UK health administrations. Initially published as “Making the Best Use of a Radiology Department (MBUR)”, the current (7th) edition was published in 2012 and is available to all NHS professionals as iRefer.
2. The RCR accepts a responsibility to continue this enterprise and has recently commenced working with the Royal College of General Practitioners and the College of Emergency Medicine on a revision. Recommendations to replace tests involving ionising radiation with those which do not – most commonly ultrasound and MRI – have always been at the heart of MBUR/iRefer and this will remain the case with any future editions.
3. Production of each edition of the guidelines involves a comprehensive evidence review using a Delphi process in which hundreds of radiologists as well as lay people participate. The process is accredited by NICE Evidence, which imposes a number of stringent requirements including editorial independence.

http://www.nice.org.uk/about/what-we-do/accreditation/accreditation-decisions

4. In England there are two different routes of access depending on whether or not the user has an NHS N3 connection. In 2010, when the access route was uniform across the UK, the guidelines received 1.6 million hits from NHS users. More recent figures show a significant drop. The guidelines are as relevant as ever and the drop in usage must therefore be attributable to the fact that access has become more fragmented and is not integrated with clinical decision routes. Improving access to iRefer for all NHS users will ensure use of guidelines, which will help limit exposure to medical radiation to the lowest levels possible.
5. The WP are in agreement that the Health Departments of all four UK nations should continue to support evidence based guidelines for all medical exposures including those using ionising radiation. The significance of easy web access to support the availability of guidelines is recognised by the WP. The Departments of Health should actively continue to support this process.

Recommendation 7

Optimisation of scanning protocols offers significant potential for dose reduction. This can only be achieved at local level through active promotion and cooperation between professional groups. We recommend that in conjunction with the production of new regulations for medical exposures, the Department of Health provides supporting guidance on optimisation, including a requirement for radiology services to consider formally appointing a team of radiation protection champions, consisting of a radiologist, a radiographer and a medical physicist.

Response

1. The WP members, each representing their professional bodies, recommend and strongly support the establishment of a team of radiation protection champions (RPC) as, if properly implemented, this approach should improve practice and achieve the best possible outcome for patients.
2. Selection of suitable CT technology and the optimisation and review of scanning protocols is fundamental to providing images of good diagnostic quality at the minimum radiation dose. This task can be achieved most satisfactorily if it is performed by a multidisciplinary team. Each of the three main radiology professions has expertise in different aspects of equipment selection and this should be fully utilised. It is envisaged that the roles would be complex in nature, carry a range of additional responsibilities, and would be a positive step in ensuring a safe and effective radiation protection culture.
3. The individuals involved should be appropriately trained, command sufficient authority and seniority and have details of their role, including available resource and management support, in writing from their employer.
4. An appropriate forum for the team could be as a sub-group of the most appropriate committee for local arrangements, for example the Medical Exposure Committee or the Radiation Safety Committee. They would be involved in the entire process, from equipment selection, acceptance and commissioning, to clinical use of the scanner. Practices and protocols should be regularly reviewed, particularly when new software or hardware changes are implemented and when new services are proposed and introduced. The team should keep abreast of new developments in the field and apply these to local practice where this is deemed appropriate. They should also audit ongoing training provision for imaging and radiation protection within their Trust.
5. A key element of training for radiologists, radiographers and medical physicists is radiation protection. Radiology professionals have always accepted their responsibility to safeguard patients and minimise patient dose. The WP endorse the proposal to create a team of radiation protection “champions” comprising a radiologist, radiographer and medical physicist with a specific remit to optimise radiation doses to patients in CT.
6. Representatives of all the professions involved have been asked to undertake further work to define the precise roles of the team and its individual members, giving due regard to existing roles such as Radiation Protection Advisor (RPA), Medical Physics Expert (MPE) and Radiation Protection Supervisor (RPS).

7. Potential roles for the radiation protection champions in CT might include but are not limited to:
    - Involvement in setting local DRLs
    - Monitoring compliance with national and local DRLs
    - Review of local procedures for justification as well as optimisation
    - Collation and review of incidents, including exposures much greater than intended and near misses to inform wider learning
    - Systematic review of cases in which individual patients are referred for multiple CT examinations in a short space of time and provision of advice for future imaging
    - Continuous/rolling review of adult and paediatric protocols for optimisation in light of evolving technology and local factors
    - Oversight of training in radiation protection for other professionals in the CT team
    - Supporting the Radiation Safety Committee and feeding into the wider Health and Safety forums
    - Participating in the “IR(ME)R Entitlement” process by ensuring that individuals are adequately trained
    - Oversight of all of the duties under IRR 1999 including prior risk assessments, local rules and personal protective equipment.
    - Oversight / provision of staff training in new procedures / techniques
    - Training referrers before entitlement
    - Highlighting CPD opportunities for all staff
    - Oversight of implementation of referral guidelines
8. The WP agreed the title Imaging Optimisation Team expresses the complex role the radiation protection champions (as suggested in Recommendation 7) may be expected to address. The term Imaging Optimisation Team has therefore been used in Appendix 3 which gives one approach to the operation of such a team - there may be others.
9. DH have confirmed there will be guidance notes available in conjunction with the new regulations in line with those available for IR(ME)R 2000. These will not be available in advance of the regulations and content is yet to be confirmed.

Summary of Responses

Recommendation 1

1.1 On behalf of the WP, the Chair has written to a number of research funding bodies asking them to consider prioritising funding for research into radiosensitivity in high risk groups.

1.2 The WP agreed their respective professional bodies will continue to provide educational opportunities to increase the understanding of all risks associated with medical exposures using ionising radiation especially for children and other high risk groups.

Recommendation 2

2.1 The WP agreed automated acquisition of dose information may help to facilitate Public Health England (PHE) to update diagnostic reference levels (DRLs) more frequently however there will be cost implications, both nationally and locally, associated with this change in process. A professional body and DH Working Party is being established by PHE to explore key issues around dose surveys.

2.2 The WP believes it would be advantageous for the new regulations to require submission of dose data.

Recommendation 3

3.1 The Chair contacted NHS Supply Chain to emphasise the significance of including a comprehensive range of dose reduction features when procuring CT scanning equipment.

3.2 The manufacturers of CT equipment have described their approach to delivering equipment specific training both at installation, ongoing and when equipment is updated.

Recommendation 4

4.1 The WP agreed there is a need for a centrally funded expert group to provide independent information and advice on CT technology, image quality and dose. This could provide a source of information for CT users for purchasing as well as to ensure safe and optimised ongoing operation of the equipment.

Recommendation 5

5.1 The Royal College of Radiologists (RCR) has provided a statement agreeing in principle that the CT scans should be carried out at the lowest dose required to answer the clinical question and agreed their professional commitment to ensuring CT scans are optimised.

Recommendation 6

6.1 The RCR confirm their commitment to producing referral guidelines and accept their responsibility to continue working with other professional bodies on a revision of this document.

6.2 The WP agreed the Departments of Health across the four UK nations should continue to support the availability of referral guidelines.

Recommendation 7

7.1 The professional bodies represented on the WP strongly support the establishment of multidisciplinary radiation protection champions (known as Imaging Optimisation Teams in Appendix 3) to consolidate expertise in order to consistently optimise all examinations using ionising radiation, including CT scans, for dose and image quality.

7.2 DH has agreed that guidance on the new regulations will be made available.

Acknowledgements

Professor Erika Denton, Chair of the Working Party, and National Clinical Director for Diagnostics, NHS England would like to thank all those who gave freely of their time and energy in writing this response:

Ian Chell, Department of Health (Observer)

Sue Edyvean, Public Health England

Ruby Fong, Society of Radiation Protection

Peter Hiles, British Institute of Radiology

Maria Lewis, Institute of Physics and Engineering in Medicine

Dr Giles Maskell, Royal College of Radiologists

Maria Murray, Society and College of Radiographers

Dawn Phillips, AXrEM

Anna Sedgwick, AXrEM

Gail Woodhouse, Public Health England (Secretariat)

Appendix 1

16th COMARE Report - APPENDIX D

LETTER FROM THE ROYAL COLLEGE OF RADIOLOGISTS

RCR
The Royal College of Radiologists

38 PORTLAND PLACE, LONDON W1B 1JQ
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20th April 2012

Dr Giles Maskell
Chair of the Medical Practices Sub-Committee
COMARE
c/o Health Protection Agency
CRCE
Chilton
Didcot
Oxon. OX11 0RQ

Dear Giles,

Re: CT Examination Dosage

Thank you for your letter dated 4th April 2012 addressed to Dr Jane Barrett, which I have been asked to reply to on behalf of the College.

The Clinical Radiology Officers discussed your letter and I confirm that we agree in principle with the statement that "where a specific clinical question has been asked by the referrer of a patient for CT scan, the CT examination should be carried out at the lowest dose required to answer the question, accepting that other organs in the scan field may not be optimally visualised".

Yours sincerely,

Dr Pete Cavanagh
Vice President and Dean
The Royal College of Radiologists

cc: Dr Jane Barrett, RCR President

Appendix 2

Contact details for 'further funding for research on radio sensitivity of high risk groups'.

Action 1 – List of Organisations and professional bodies

Name of Organisation	Address	Telephone
The Advisory Group on Ionising Radiation (AGIR)	Public Health England Centre for Radiation, Chemical and Environmental Hazards Chilton, Didcot Oxfordshire OX11 ORQ	01235 825086
Bart's Cancer Institute	Bart's & the London School of Medicine and Dentistry, Queen Mary University of London, Charterhouse Square, London, EC1M 6BQ.	020 7882 5555
Cancer Research UK	Angel Building, 407 St John Street London EC1V 4AD	020 7242 0200
The Carnegie Trust	Andrew Carnegie House, Pittencrieff Street, Dunfermline, KY12 8AW	01383 724 990
College of Radiographers Industry Partnership Scheme Research Grants (CoRIPS)	Quartz House, 207 Providence Square, London SE1 2EW	020 7740 7200
The European Commission	Europe House, 32 Smith Square London SW1P 3EU	020 7973 1992
The Genome Centre	John Vane Science Centre, Queen Mary, University of London, Charterhouse Square, London, EC1M 6BQ.	020 7882 2055

The Higher Education Funding Council for England	Finlaison House, 15 – 17 Furnival Street, London, EC4A 1AB,	0207 400 4100
Medical Research Council	Western General Hospital, Crewe Road South, Edinburgh EH4 2XU	0131 332 2471
Multidisciplinary European Low Dose Initiative	Bundesamt für Strahlenschutz Postfach 10 01 49 D-38201 Salzgitte	
The National Institute for Health Research (NIHR) Health Protection Research Unit (HPRU)	Newcastle University Newcastle upon Tyne Tyne and Wear NE1 7RU	
Prostate Cancer UK/CoR Clinical Research Fellowship	Quartz House, 207 Providence Square, London SE1 2EW	020 7740 7200
The NHS Scotland Chief Scientist Office	Chief Scientist Office, Scottish Government Health Directorates, St Andrew's House, Regent Road, Edinburgh, EH1 3DG	0131 244 2765
The Scottish Funding Council	Scottish Funding Council , Apex 2, 97 Haymarket Terrace, Edinburgh, EH12 5HD	0131 313 6500
The Stroke Association	Stroke Association House, 240 City Road, London, EC1V 2PR	020 7566 0300
Wolfson Institute of Preventive Medicine.	Bart's & the London School of Medicine and Dentistry, Charterhouse Square, London, EC1M 6BQ - Centre for Cancer Prevention - Centre for Environmental & Preventive Medicine	020 7882 3850 020 7882 3504 020 7882 6269

The Wellcome Trust	Gibbs Building, 215 Euston Road, London NW1 2BE Medical Humanities Section	020 7611 8888

Responses received

1. Multidisciplinary European Low Dose Initiative (MELODI)

Dear Professor Denton,

In response to your invitation to comment the pertinence of the recommendation from the COMARE Committee on the priority to be given to research towards the improvement of radiation protection in the field of CT scans, I would like to offer the following contribution.

- Generally speaking on the issue of the growing use of ionizing radiation in the medical context, I would recommend that UK experts and professionals in this field prepare to contribute to the drawing up of a comprehensive European Strategic Research Agenda (SRA) in the field of the prevention of radiological risks associated to medical uses of ionizing radiation. This work has begun under the framework of the project OPERRA of the EURATOM 7th research program, and will continue under the CONCERT EJP project, funded by H2020 EURATOM. The MELODI association for the research on low dose effects, and the European professional associations such as ESR are actively involved in these developments.

- More specifically, in the context of the continuous development of CT scan usage, priority should be given to:

1. Children, as a group of the population which could suffer from long term consequences of their exposure

2. The identification of reliable indicators for radio-sensitivity in the human population

3. The description and promotion of best practice with respect to the implementation of imaging protocols.

- On the first point, the UK is already participating to the Epi-CT study which will follow a large European cohort of children. Funding should be made available to analyze the results that will be drawn from this study, and where necessary develop complementary studies

- On the second point, it should be noted that so far, research in this area has not been able to define reliable indicators. It is likely, in view of the complexity of phenomena at work following an irradiation of living tissues, that research in this area should be reconsidered in the context of a wider field of investigation covering the effects of low doses of ionizing radiation. It could be recommended that the UK research prioritizes its efforts in the context of the MELODI SRA, which allows potentially a very wide spectrum of scientific collaborations on a multi-national and multi-disciplinary scale.

- On the third point, although this is not research as such, experience in France shows that large differences in professional practice, in theory for the implementation of an identical protocol, can lead to a wide distribution of doses, therefore offering a significant scope for optimization and reduction of risks. It is in France one of the attributions of IRSN to analyze these data, and make recommendations to the public health authorities. Investing together with professional bodies, through campaigns such as the EUROSAFE European campaign led by the ESR is therefore a worthwhile project.

I hope these comments will be useful, and I wish you every success in the definition of appropriate guidance for public authorities and professionals in the United Kingdom;

With my best regards,

Jacques Repussard

Director General of IRSN

President of MELODI (Multidisciplinary European Low Dose Initiative)

2. The European Commission

a) Dear Ms Woodhouse,

Thank you for your e-mail and Professor Denton's letter.

I contacted our colleagues in the Commission's Directorate-General for Research and Innovation who have suggested that research organisations monitor the calls for proposals under the Horizon2020 programme.

Calls – both open and forthcoming - can be found via the following link:

http://ec.europa.eu/research/participants/portal/desktop/en/opportunities/h2020/search/search_topics.html#c,topics=callProgramme/t/H2020/0/1/1&callProgramme/t/RFCS/0/1/1&callProgramme/t/COSME/0/1/1&callProgramme/t/3HP/0/1/1&callProgramme/t/CP/0/1/1&callStatus/t/Forthcoming/1/1/0&callStatus/t/Open/1/1/0&callStatus/t/Closed/0/1/0&+plannedOpeningDate/asc

The UK National Contact Points (NCP) for the thematic programmes, under Horizon2020, will be able to advise UK researchers on likely sources of support. The NCP contact details can be found via this link: https://www.h2020uk.org/national-contact-points

Best regards,

Jeff Lamb

Research Assistant

Political Section

Representation of the European Commission in the UK

b) Thank you for letter of 14 April 2015 on radiation protection research and more specifically on the risks associated to medical imaging both on children and other high risk groups.

Research consortia active in this area in the context of the Seventh Framework Programme of the European Atomic Energy Community (FP7-Euratom) do already involve a number of UK partners, some of which most certainly having working relationships with your organisation.

For example, , the Universty of Newcastle is involved in FP7-Euratom EPI-CT Project that should provide a refined assessment of radiation risks resulting from CT scans based on the analysis of data recorded from a cohort of one million European children, with more than one third of these data originated from the UK. The COMARE report makes reference to EPI-CT and we are thankful for this.

Another good illustration of the UK involvement is the coordinating role played by the Department of Health – Public Health England (DH-PHE) in two other major FP7-Euratom Projects, the FP7 SOLO Project on nuclear industry worker exposures and the RISK-IR Project on stem cell mechanisms possibly involved in ionising radiation effects.

The European Commission considers that data coming from cohorts of patients having been exposed to ionising radiation for medical imaging are extremely valuable for a more robust health risk evaluation of low dose radiation. This is essential for the protection of patients and the medical staff, but also for the elaboration of scientifically –sound radiation protection measures in general, including for example in relation to nuclear emergency.

In Horizon 2020, the successor of FP7, the Euratom programme will most certainly further support research that is making use of data from medical imaging to improve the overall risk assessment of low-dose ionising radiation. In this regard it is to be noted that the Euratom Multidisciplinary European Low-Dose Initiative (MELODI) has recently signed Memoranda of Understanding with five European medical associations [1]

Sustained interest from the UK for Euratom actions on radiation protection is most welcomed keeping in mind that support will be given on a competitive basis in the context of calls for proposals. The UK Contact Point for Euratom activities, Mrs Genevra Kirby, Department for Business, Innovation and Skills (Tel.: +44 (0) 20 7215 1355, E-mail: genevra.kirby@bis.gsi.gov.uk) may be contacted for further information.

3. Medical Research Council (MRC)

Dear Gail,

Many thanks for your recent letter referencing the recent COMARE report and research needs in the area of CT radiation exposure.

As you will be aware the MRC is always open to considering research focussed on important clinical/health questions and we would be happy to receive research proposals that wish to study the risks from CT irradiation on vulnerable groups.

In terms of prioritising research, my Board has recently held detailed discussions on this matter. The topic of CT exposure didn't feature specifically but it is clearly relevant key areas that were highlighted: understanding exposure risks, exploring novel biomarkers of exposure and investigating causal pathways of environmental exposure. One could easily see research on CT exposure and health being shaped within these areas.

Furthermore, the MRC maintains a highlight notice in Radiation oncology and biology which is also relevant – e.g. pathways involved in radiation carcinogenesis. Highlight notices aim to convey to

the research community particular areas of priority and opportunity for research advancement, with the aim of stimulating demand and investment.

I hope that this reassures you of MRC's keen interests in the broader area of exposures and health and the opportunities to shape the research needs you have identified within the scope of existing priority areas.

Best wishes,

Nathan

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Dr Nathan Richardson

Head of Molecular & Cellular Medicine

Medical Research Council

14th Floor, 1 Kemble Street,

London, WC2B 4AN

www.mrc.ac.uk

4. Public Health England (PHE)

Dear Gail, Erika,

Thank you for the letter concerning the recommendations of the 16th COMARE report, and apologies for the late reply.

Myself and colleagues at PHE recognise the potential need for variation in radiation sensitivity to be considered in radiation protection, including in clinical situations. You may be aware that PHE's predecessor body, the Health Protection Agency published a report on the topic of human radiosensitivity by the Advisory Group on Ionising Radiation in 2013 (https://www.gov.uk/government/publications/human-radiosensitivity). A number of recommendations, including research were made. PHE is involved in relevant research, largely through EC funded activities and would be supportive of further research into the impact of variation in radiosensitivity on radiation risk and the impact of this on approaches to radiation protection. I should note however that there are considerable challenges to identifying radiosensitive individuals following exposure to radiation doses in the range commonly encountered in medical diagnostics. Also, again given the dose levels, the range of risk associated with a given procedure compared to background cancer risk is likely to be small.

I hope the Working Group find these views useful.

Best wishes

Simon

Simon Bouffler

Radiation Effects Department

Centre for Radiation, Chemical and Environmental Hazards
Public Health England
Chilton, Didcot
Oxfordshire, OX11 0RQ.

Action 2 - Research Priorities at Public Health England

General Structure of PHE

Public Health England is divided into seven directorates: Health Protection, Health and Wellbeing, Chief Knowledge Officer, Operations, Strategy, Programmes, Finance and Commercial, Human Resources and Communications.

The two PHE directorates of specific interest for radiation research are the Chief Knowledge Officer's directorate (covering research strategy), and the Health Protection Directorate (covering radiation).

Within the Health Protection Directorate, the PHE centre at Chilton, Oxfordshire, deals with radiation. This is the CRCE (Centre for Radiation, Chemicals and Environmental Hazards).

The Chief Knowledge Officer's (CKO) Directorate

Research over all PHE is governed by the directorate of the Chief Knowledge Officer, Professor John Newton (John.Newton@phe.gov.uk).

The Chief Knowledge Officer is responsible for delivering an effective knowledge and intelligence service that covers research, statistics and know-how, to inform the practice of public health and public health improvement.

These responsibilities include:

national cancer intelligence network

drug treatment monitoring programmes

research and development programmes

Research and Development Division (within the CKO Directorate)

http://phenet.phe.gov.uk/Our-Organisation/Directorates/CKO/Pages/Research-and-Development-Division.aspx

The Research and Development Division lies within the CKO Directorate. The R&D Director is Professor Bernie Hannigan (bernie.hannigan@phe.gov.uk). She handles the development, updating and communication of the research strategy and vision.

Health Protection Directorate

The Director of Health Protection and Medical Director is Professor Paul Cosford (Paul.Cosford@phe.gov.uk).

The Director of Health Protection and Medical Director is responsible for:

national leadership for health protection, setting standards and leading programmes to reduce harm from infectious diseases, radiological, chemical and environmental hazards

professional leadership for public health in PHE and local government, including professional standards, quality and clinical governance

ensuring effective planning and responses to public health emergencies throughout England

Centre for Radiation, Chemicals and Environmental Hazards (CRCE), in Chilton (within the Health Protection Directorate)

The PHE Centre for Radiation, Chemicals and the Environment (CRCE) was formerly part of the Health Protection Agency, and prior to that was the National Radiation Protection board (NRPB). CRCE is part of the PHE Health Protection Directorate.

The Biological Effects Department at CRCE

The issue of human radiosensitivity is part of the Biological Effects Department. It undertakes some work on radiosensitivity in general, though not specifically on sensitivity to CT.

Contact: Simon Bouffler simon.bouffler@phe.gov.uk

The Medical Dosimetry Group at CRCE

The Medical (Radiation) Dosimetry Group has run National Radiation Dose Surveys for over 30 years and undertaken Monte Carlo dose calculations for CT and other diagnostic modalities since the 1980s. Produced a report on risk factors for paediatric and gender.

https://www.gov.uk/government/publications/medical-x-rays-radiation-risks-by-age-and-sex-of-patient

The current scope of the work and capability, includes and goes beyond the above areas, to cover diagnostic imaging technology, image quality and radiation dose (optimisation) in CT scanning in particular. However not all areas are live topics currently.

Contact: Sue Edyvean sue.edyvean@phe.gov.uk

Research Committees at PHE

PHE R&D group

Chair: Bernie Hannigan (R&D deputy director) Research & Development, R&D Office

CRCE (PHE/Chilton) membership of the R&D group:

Simon Bouffler CRCE Deputy Director, CRCE Research,

Tim Gant Head of Toxicology Department CRCE, PHE

Sotiris Vardoulakis Air Pollution and Climate Change, Toxicology Dept., CRCE

These people are also relevant:

John Newton as the Chief Knowledge Officer will have an overall responsibility (john.newton@phe.gov.uk)

Julia Verne - Environment lead of CKO (Chief Knowledge Officer's) directorate – (ex COMARE member). Director South West Knowledge and Intelligence Team (Julia.verne@phe.gov.uk)

PHE review group - looking into internal funding applications and submissions to the DH R&D Committee

This group has a slightly different membership from the above PHE R&D group

Chair: Bernie Hannigan (R&D deputy director) Research and Development Office

CRCE (PHE/Chilton) membership of the R&D Review group:

Simon Bouffler CRCE Deputy Director, CRCE Research,

Sotiris Vardoulakis Air Pollution and Climate Change, Toxicology

DH R&D Committee (March 2015)

Department of Health Research Committee:

Chair/Secretariat: Ursula Wells

Membership: Hilary Walker, others drawn from across DH policy areas and ALB type organisations

Advisory Group on Ionising Radiation (AGIR)

The Advisory Group on Ionising Radiation (AGIR) is responsible for advising PHE about the risks posed to human health by the use of ionising radiation. This applies to medical, occupational, public health and environmental exposures. The Group also advises on research priorities.

AGIR Report: Radiation: risk of solid cancers following exposure

AGIR's ninth report (RCE-19): covers the risk of ionising radiation on the development of solid cancers but excludes leukaemia and lymphoma.

RCE-19: risk of solid cancers following radiation exposure - estimates for the UK population Ref: ISBN 978-0-85951-705-8 PDF. Aug 2011

https://www.gov.uk/government/publications/radiation-risk-of-solid-cancers-following-exposure

AGIR Report: Human Radiosensitivity

AGIR's 10th report (RCE-21) reviews variation in human radiosensitivity and how this might impact on approaches to radiological protection.

RCE-21: Human Radiosensitivity Ref: ISBN 978-0-85951-740-9 PDF, 1 March 2013

Prepared by the sub-group on Human Radiosensitivity of AGIR

https://www.gov.uk/government/publications/human-radiosensitivity

HPA (PHE) documents relating to AGIR and AGNIR:

https://www.gov.uk/government/collections/radiation-hpa-rce-report-series

Report on risk sensitivity re age and sex (from PHE Medical Dosimetry Group and other PHE/HPA personnel):

https://www.gov.uk/government/publications/medical-x-rays-radiation-risks-by-age-and-sex-of-patient

Appendix 3

Suggestion for operation of an Imaging Optimisation Team (referred to as Radiation Protection Champions in Recommendation 7)

Aims

The practice of focused and continuous CT dose and image quality optimisation is a requirement for the radiological community. This could be delivered by establishing departmental dose management processes and this guidance aims to support that development

The first step is to create a team of Radiation Protection Champions, or the Image Optimisation Team, who will be responsible for setting up processes for dose management, evaluating their impact and communicating outcomes widely.

Establishing the Team

Identify key people to be involved. Define roles and responsibilities.

10. Roles and Responsibilities

A Leadership Sponsor: for example the Head of Department, or someone else who has a vision for the programme, defines it in measurable and time limited objectives and allocates dedicated time to the project for dose team members. For acceptance and accountability from the team, it is crucial to get the sponsor's involvement from the beginning of the project.

Team members: for example CT radiologists, CT radiographers, CT medical physicists. The team should be designed to include multidisciplinary experience, with each profession bringing specific expertise. From time to time, it may be necessary to invite application specialists to contribute to team discussions. It is important to define the process for communication of the project including modifying and implementing CT protocols.

A team leader: for example lead CT radiologist, lead CT radiographer or CT medical physics expert.

11. Define programme objectives and metrics

The dose team, and the sponsor, should agree on:

- The vision of the dose management work
- The goals of the programme
- The metrics by which to measure the goals
- The programme timescales and regular review periods

Examples of the Programme Vision:

Example 1

- Identify top five most common CT protocols
- Review dose and image quality optimisation
- Agree a methodology for dose and image quality evaluation

Implement and communicate patient safety outcomes

Example 2

- Define and implement a realistic CT dose alert process
- Communicate patient safety outcome

Examples of Programme Goals:

- Standardisation - for example workflow and operator dependent parameters; clinical tasks and required image quality
- Optimisation - for example dose level versus image quality
- Dose Alert - events monitoring

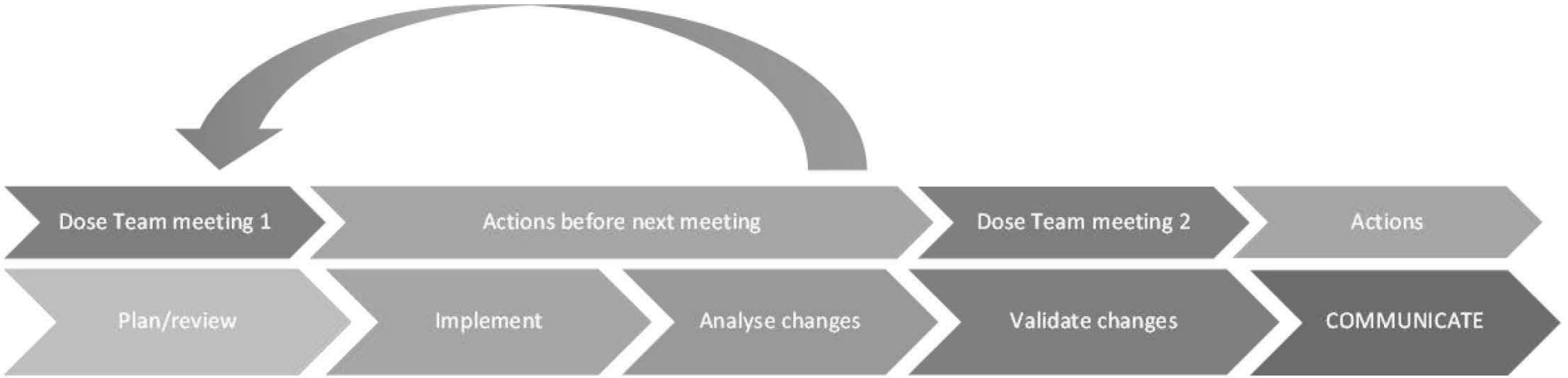
Meeting frequency

The Team may initially meet once a month to define an action plan and monitor the results. It is important to establish a regular meeting programme. Between each meeting the actions planned should be implemented so results can be reviewed and validated at the next meeting. There will then be a need to define and communicate the process for agreeing/changing protocols within the imaging department.

Dose Management process - examples

- Standardise the terminology – RIS codes, protocol descriptions, which protocols are for which patient group on each scanner – change the names if needed. Separate protocols that require modification for specific patient groups.
- Identify clinical task and image quality target
- Standardise the operator dependent parameters e.g. slice width, range, phases (radiographer input important here)
- Optimise standard protocols (significant medical physics input important here)
- Review the image quality and the dose (radiologist input important here)
- Communicate the results to sponsor, staff, clinicians

Process content example



Standardisation	Build a standard list of procedures based on clinical indications	Implement the standard list on device and Information System, make sure people are aware	Check if the standard list is used in routine and if there is only one practice behind a clinical	Validate the standard list and standard practice	COMMUNICATE on the new names to use and standard practices associated
Optimisation	Build a protocol optimization priority list	Optimise acquisition parameters and operator practices	Analyse impact on dose and Image quality	Validate new protocol settings and best practice	COMMUNICATE new protocol and optimisation results
Dose Alert events monitoring	Define and set up an adapted alert system	Review exams on alerts	Review alert causation	Validate the alert system	COMMUNICATE on the alert review process