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Exposure of Staff and Members of the Public to Ionising Radiation Procedure

Introduction and Aim

The Cardiff and Vale University Health Board (UHB) uses ionising radiation for a variety of clinical and other applications and this use presents a potential hazard to a range of people including patients, staff and members of the public.

The UHB has an Ionising Radiation Risk Management Policy the aim of which is to ensure that we manage the use of ionising radiation in such a way as to minimise adverse effects on people, provided that this is consistent with any desired clinical or related outcome.

This Procedure supports the Policy and translates its aim into practical implementation measures as regards the potential adverse effects of ionising radiation on staff and members of the public.

Objectives

We will achieve our aim by:

- Providing a robust framework for the management and safe use of ionising radiation
- Ensuring that managers and staff are aware of their roles in the safe use of ionising radiation
- Keeping radiation doses and dose rates as low as reasonably practicable (ALARP)
- Restricting the use of ionising radiation to practices that are justified and ensure that each intentional exposure of a human subject is individually justified
- Optimising exposure to ionising radiation in order to reduce radiation dose, provided that this is consistent with any desired clinical or related outcome
- Keeping radiation doses to staff and members of the public within statutory dose limits
- Managing radiation equipment in accordance with accepted best practice
- Ensuring that the use of ionising radiation is compliant with current legislation, standards and guidance
- Demonstrating compliance through record keeping and audit
- Entitling duty holders associated with the exposure of human subjects to ionising radiation
- Appointing Radiation Protection Adviser(s), Medical Physics Experts, Radiation Waste Adviser(s) and Radiation Protection Supervisors

Scope

This procedure applies to all of our staff in all locations including those with honorary contracts.

Equality Impact Assessment	An Equality Impact Assessment (EqIA) has not been completed, the procedure aligns to current ionising radiation legislation compliance.
Health Impact Assessment	A Health Impact Assessment (HIA) has not been completed the procedure aligns to current ionising radiation legislation compliance.
Documents to read alongside this Procedure	• Ionising Radiation Risk Management Policy • Exposure of Patients • Radioactive Substances Risk Management Policy • Radioactive Substances Risk Management Procedure • Health and Safety Policy • Medical Equipment Management Policy • Risk Management Policy
Approved by	Radiation Protection Group
Accountable Executive or Clinical Board Director	Executive Director of Therapies and Health Science
Author(s)	Medical Physics Experts, Clinical Scientist, Director of M.P.C.E.

Disclaimer

If the review date of this document has passed please ensure that the version you are using is the most up to date either by contacting the document author or the Governance Directorate.

Summary of reviews/amendments

Version Number	Date of Review Approved	Date Published	Summary of Amendments
1	25/07/2019	04/09/2019	New Document
2			Updated with current legislation and minor amendments

Contents

1 Definition of terms

Absorbed dose
The fundamental type of radiation dose defined as the energy deposited by ionising radiation in unit mass of irradiated material.

Alpha radiation
Particulate ionising radiation in the form of helium-4 nuclei (a combination of two protons and two neutrons) emitted by nuclei during radioactive decay.

Beta radiation
Particulate ionising radiation in the form of electrons or positrons emitted by nuclei during radioactive decay.

Deterministic effect
An effect of ionising radiation on living tissue in which the severity of the effect increases with radiation dose above a threshold dose (below which the effect does not occur).

Diagnostic Reference Level (DRL)
Value of radiation dose, or administered activity in nuclear medicine, for typical diagnostic examinations in groups of standard-sized patients for broadly defined types of radiation equipment.

Dose constraint
A restriction on the prospective radiation dose to an individual that may result from a defined source of exposure.

Effective dose
The sum of the product of equivalent dose and tissue weighting factor taken over all irradiated tissues and organs.

Electron
A negatively charged particle that is one of the constituents of the atom.

Equivalent dose
The product of absorbed dose and radiation weighting factor for a particular irradiated tissue or organ.

Gamma rays (gamma radiation)
Ionising radiation in the form of photons emitted by nuclei during radioactive decay.

Gy
The gray, which is the unit of absorbed dose (equal to 1 joule of energy per kg).

Ionising radiation
Radiation that is sufficiently energetic to cause ionisation through the release of inner electrons in atoms of high atomic number.

Neutron
An uncharged particle that is one of the constituents of the atomic nucleus.

Particle
A unit of radiation that has mass e.g. electron, beta particle, proton, alpha particle and neutron.

Photon
A unit (quantum) of electromagnetic radiation such as infra-red, visible, ultra-violet, x and gamma radiation.

Proton
A positively charged particle that is one of the constituents of the atomic nucleus.

Radiation
A stream of energy, usually in the form of photons or particles, emitted from a source, moving through a material and interacting with it to deposit energy in the material.

Radiation dose
A measure of the energy deposited by ionising radiation in a material and its potential harmful effects.

Radiation employer
An employer who in the course of a trade, business or other undertaking carries out, or intends to carry out, work with ionising radiation.

Radiation weighting factor
A quantity that indicates the relative harmfulness of different types of ionising radiation to living tissue.

Radioactive decay or disintegration
The transformation of one nuclide (a radionuclide) into another with the emission of ionising radiation.

Radioactive substance (material)
Substance (material) that contains one or more radionuclides.

Radioactive waste
Any material that is either radioactive in its own right or is contaminated by radioactive substances and for which no further use is envisaged.

Radioactivity
The phenomenon associated with radioactive decay or disintegration.

Radiopharmaceutical
A radioactive medicinal product that is administered to human subjects for medical diagnosis or treatment or a related purpose such as medical research.

Radiosensitivity
The sensitivity or susceptibility of different tissues and organs to the harmful effects of radiation.

Stochastic effect
An effect of ionising radiation on living tissue in which the probability of the effect occurring increases linearly with radiation dose without a threshold.

Sv
The sievert, which is the unit of equivalent dose and effective dose.

Tissue weighting factor
A quantity that indicates the relative sensitivity or susceptibility of different tissues and organs to the harmful effects of ionising radiation.

Tissue reaction
This is the same as a deterministic effect.

X-rays (x-radiation)
Ionising radiation in the form of photons emitted by electron interactions in atoms, possibly as a consequence of radioactive decay.

X-ray tube
An evacuated chamber in which electrons are accelerated towards a target to produce x-rays.

2 Use and harmful effects of ionising radiation

Ionising radiation takes the form of either high energy photons (such as x-rays and gamma rays) or high energy particles (such as alpha radiation, beta radiation, electrons, protons and neutrons). It is produced by electrical radiation generators (such as x-ray tubes) and by radioactive substances.

Ionising radiation has a wide range of beneficial applications but it also has the potential to cause harm.

The UHB uses ionising radiation at Barry Hospital, Cardiff Royal Infirmary, St David's Hospital, University Hospital Llandough (UHL), the University Hospital of Wales (UHW) (including the Children's Hospital and the Dental Hospital) and at community medical and dental sites in the following practices:

- Production of radioactive products (including radiopharmaceuticals and radioactive sources)
- Application of radioactive tracers (for medical and biological techniques)
- Diagnosis (medical)
- Treatment (medical)
- Medical and biomedical research
- Examinations performed for insurance or legal purposes without a medical indication
- Teaching including further and higher education and training
- Ionising radiation metrology
- Transport of radioactive material

All these practices are justified [1-3] i.e. they produce sufficient benefit to individuals exposed to ionising radiation or to society in general to offset the detriment that they cause. Justification is one of the basic tenets of radiation protection, the others being optimisation and dose limitation [4].

The majority of the above practices are associated with radiology (diagnostic and interventional) and nuclear medicine (diagnostic and therapeutic). In radiology, human subjects are exposed to x-rays from an external source (x-ray tube). Radiology is practised widely throughout the UHB. Nuclear medicine, on the other hand, involves the administration of radioactive substances (in the form of radioactive medicinal products or radiopharmaceuticals) to humans such that the subjects are irradiated internally by beta and gamma rays. Nuclear medicine is practised only at UHW and UHL.

The potential of ionising radiation to cause harm is usually expressed in terms of radiation dose, which is a measure of the energy deposited by radiation and its impact on living tissue [4]. The basic quantity is absorbed dose, which is an expression of the energy deposited by ionising radiation per unit mass of the material which it irradiates; its unit is the gray (Gy). Absorbed dose is used to quantify the energy deposited by ionising radiation in tissues and organs.

The same absorbed dose delivered to living tissue by different types of ionising radiation causes biological damage to different extent. This variation is expressed by the radiation weighting factor. A radiation weighting factor of one is used for absorbed dose calculations in x, beta and gamma radiation with a weighting factor of 20 utilised in alpha radiation. [4] The equivalent dose is given by the absorbed dose multiplied by the radiation weighting factor. It is an indicator of harm to a particular tissue or organ due to ionising radiation irrespective of the type (and energy) of the radiation; its unit is the sievert (Sv).

In addition, some living tissues and organs are more sensitive or susceptible to the harmful effects of ionising radiation. This variation is expressed by the tissue weighting factor, which is relatively larger for those tissues and organs which are most radiosensitive (i.e. most susceptible to the harmful effects of radiation). The effective dose is the sum of the equivalent dose multiplied by the tissue weighting factor for all irradiated tissues and organs. It is an indicator of harm to the whole body from either total or partial exposure to radiation regardless of the number of tissues and organs exposed; it is also expressed in Sv.

There are two broad types of harmful effect of ionising radiation: deterministic effects (also called tissue reactions) and stochastic effects [4]. Deterministic effects occur in the irradiated individual and are characterised by a threshold absorbed dose (below which the effect does not occur) and the fact that the severity of the effect increases with absorbed dose (above the threshold). An example would be erythema (reddening) of the skin with a threshold of 2-5 Gy and progression to blistering and ulceration as absorbed dose increases.

For stochastic effects, the probability of the effect occurring increases in proportion to effective dose; there is no threshold. Stochastic effects may occur in irradiated individuals and in future generations. The most important stochastic effect is the induction of cancer in an irradiated individual. For a general population, the risk of fatal cancer is about 5% per Sv, although the risk varies with age and is greater for children than for adults [4].

Irradiation of the embryo and foetus may cause both deterministic and stochastic effects [4].

An inevitable consequence of the clinical use of ionising radiation is the exposure of members of staff as well as those receiving treatment or diagnostic investigations. Staff are also exposed as a result of non-clinical work with ionising radiation. To some extent, the use of ionising radiation also leads to the exposure of members of the public. In this context, members of the public include all those who are not subject to medical exposure or are not regarded as staff (e.g. visitors). The radiation doses received by individual members of staff are much lower than those received by those receiving

clinical investigation or treatment. The doses received by individual members of the public are lower still.

3 Regulation of ionising radiation

The use of ionising radiation is governed by legislation that is designed to control its adverse effects on people and the environment. This involves keeping radiation doses as low as reasonably practicable (ALARP). The legislation is supported by codes of practice and guidance and compliance is assessed through a programme of inspections by statutory external agencies.

The exposure of patients to ionising radiation is governed by the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) 2017 and a subsequent amendment to the regulations [5,6]. The regulations are supported by official and professional body guidance [7,8]. They apply to the deliberate exposure of human subjects to ionising radiation as follows:

- To patients as part of their medical diagnosis or treatment
- To individuals as part of health screening programmes
- To patients or other persons voluntarily participating in medical or biomedical, diagnostic or therapeutic, research programmes
- To carers and comforters
- To asymptomatic individuals
- To individuals undergoing non-medical imaging using medical radiological equipment

For the purposes of this Procedure, those subject to exposures in these categories are collectively called ‘patients’. Practices that involve the deliberate exposure of humans under circumstances other than the above do not fall within the scope of IR(ME)R 2017. Such practices are permitted only if their justification is confirmed by the most recent version of the national Justification Register [1-3, 9].

The regulations are enforced by Healthcare Inspectorate Wales (HIW), which reports on its activities. In England, similar reports are published by the Care Quality Commission (previously Healthcare Commission) [10-11].

In nuclear medicine, radiopharmaceuticals may be administered to humans only by a person who holds an ARSAC licence from licensing authority or someone acting under the authority of such a person. In addition, a separate licence is required by the employer at each site where such administrations take place [12]. Radiopharmaceuticals are prepared in a specialised Radiopharmacy at UHW under a regime [7,13-15] that is regulated by the Medicines and Healthcare products Regulatory Agency (MHRA).

The Ionising Radiations Regulations (IRR) 2017 [16] address all aspects of work with ionising radiation. They are made under the Health and Safety at Work Act 1974 [17] and are supported by an Approved Code of Practice (ACOP) and official guidance [18] as well as professional body guidance [7]. IRR 2017 deal with the radiation protection of workers and the members of the public who are exposed as a result of work with ionising radiation. The regulations specify the responsibilities of a radiation employer; these include making risk assessments, appointing a Radiation Protection Adviser (RPA) and one or more Radiation Protection Supervisors (RPSs) and writing Local Rules. IRR 2017 are enforced by the Health and Safety Executive (HSE).

Radioactive material is kept on UHB premises in accord with the stipulations of the Environmental Permitting (England and Wales) Regulations (EPR) 2016 [19-20] and under conditions that are specified in Environmental Permits issued by Natural Resources Wales (NRW). The same applies to the accumulation and disposal of radioactive waste. The permits are site-specific for UHW and UHL. In addition, there is a requirement [21] to appoint a suitable Radioactive Waste Adviser (RWA). Radioactive materials are transported in a manner [22-23] that is consistent with the requirements of the Office for Nuclear Regulation, which includes the appointment of a Dangerous Goods Safety Adviser (DGSA). Regulations governing the keeping and transportation of radioactive substances and the management of radioactive waste do not have a direct impact on the radiation safety of patients.

4 General arrangements for the protection of staff and members of the public against the harmful effects of ionising radiation

For staff and the public, the goals of radiation protection are to restrict exposure as much as possible, i.e. to keep radiation doses ALARP, and to ensure that dose limits are not exceeded. The mechanisms for achieving these goals are the justification of practices and the optimisation of processes and procedures, although additional limitation measures may be necessary under some circumstances. As regards the effects of ionising radiation, this means minimising the risk of stochastic effects and avoiding deterministic effects. IRR [16] provides a regulatory framework within which the UHB works to achieve these goals.

The exposure of patients to ionising radiation is mainly carried out in three Clinical Boards within the UHB: Specialist Services, Clinical Diagnostics & Therapeutics and Surgery.

The Employer as defined in the regulations is the UHB and the Chief Executive takes overall responsibility for compliance with legislation on behalf of the UHB. The Chief Executive has delegated the task of ensuring compliance with radiation safety legislation to the Executive Director of

Therapies and Health Science (DoTH). The DoTH has further delegated this task to individuals throughout the UHB's line management structure. This includes the identification and appointment of Radiation Protection Advisers and Radiation Protection Supervisors.

The UHB has established a Radiation Protection Group (RPG) that reports to the Quality, Safety and Patient Experience Committee and onwards to the Executive Board. The RPG discusses all aspects of radiation safety including the exposure of members of staff and members of the public.

5 Specific arrangements for the limitation of radiation dose to staff and the public

The UHB should put in place a range of procedures to limit radiation dose to members of staff and the public that arise as a result of its work with ionising radiation. Those procedures that apply throughout the UHB, especially at corporate level, are addressed in this document. More detailed procedures are tailored to the work of individual services. The content of these procedures may vary considerably from one service to another, reflecting the diversity of the UHB's clinical, research and other work.

Before undertaking any work with ionising radiation, the UHB should notify the HSE, register that work with the HSE or obtain the HSE's consent for that work as appropriate. In addition, they should carry out a suitable and sufficient radiation risk assessment in order to identify the measures needed to restrict exposure to staff and the public.

While performing work with ionising radiation, the UHB should implement a range of measures to restrict exposure. These include:

- Writing standard operating procedures including Systems of Work for all aspects of work with ionising radiation
- Identifying and designating controlled and supervised radiation areas
- Writing Local Rules for designated radiation areas
- Providing personal protective equipment
- Providing training for radiation workers and RPSs
- Making suitable arrangements for members of staff who are pregnant or breast-feeding
- Making suitable arrangements for outside workers

In general, Local Rules should be provided for all areas where ionising radiation is used. They should be regularly reviewed and available in the locations to which they refer. Controlled areas should be identified in the Local Rules and staff and visitors should only enter in accordance with Systems of Work. Outside workers are members of staff of other employers

who carry out work in a UHB controlled area; they should be subject to special procedures as outlined in Local Rules.

In addition, the UHB should put in place a programme of personal and area radiation dose monitoring. Staff who regularly work with ionising radiation and who have to enter controlled areas should be monitored; the type and frequency of monitoring should be determined by means of a risk assessment. Members of staff who are regularly monitored must wear their dosimeters whenever they enter a controlled area. The dosimeter must be worn in the approved manner. Employees must return any dosimeters supplied to them in a timely manner at the end of each monitoring period.

Doses should be kept under regular review and investigation levels set to minimise the risk of exceeding a dose limit; the investigation levels should be stated in the Local Rules. Dose records must be kept for a minimum of two years. Annual summaries of radiation doses received by staff should be prepared, reviewed by the RPA and reported to the RPG.

Particular attention should be paid to those members of staff who receive relatively high doses and the possibility that they might need to be designated as classified persons. Special procedures, including annual medical investigations, should apply to such persons.

Incidents involving ionising radiation should be promptly and thoroughly investigated and, where appropriate, reported to external agencies; these include incidents involving radiation doses much greater than intended [24].

6 Duties

To ensure the implementation of its Ionising Radiation Risk Management Policy as regards the exposure of members of staff and the public, the UHB assigns the duties described here.

The duties of the Executive Director of Therapies and Health Science include:

- Ensuring that the UHB executive provides suitable management arrangements, including sufficient resources and competent persons, to comply with legislation and guidance governing the safe use of ionising radiation
- Providing assurance to the UHB Board that the use of ionising radiation is managed in compliance with the UHB's policies and procedures
- Informing the UHB Board about issues related to the use of ionising radiation
- Establishing a UHB Radiation Protection Group
- Appointing suitably qualified and experienced RPAs in writing
- Delegating duties to other managers as appropriate

The duties of Clinical Board Directors include:

- Providing assurance to the Executive Director of Therapies and Health Science that the use of ionising radiation is managed in compliance with policies and procedures and regulatory requirements
- Ensuring that Directorate Clinical Directors have arrangements in place for the appointment of RPSs and the writing and implementation of Local Rules and Systems of Work
- Communicating and liaising with the Chair of the Radiation Protection Group, RPAs, Clinical Directors and other managers about issues related to the use of ionising radiation
- Disseminating information about reported incidents within the UHB as appropriate
- Reporting incidents where classified dose limits are exceeded, or likely to be exceed to the HSE
- Delegating duties to other managers as appropriate

The duties of Directorate Clinical Directors include:

- Delegating duties to duty holders and other managers as appropriate
- Ensuring that members of staff are aware of their roles and duties as regards radiation safety
- Ensuring that the radiation dose received by members of staff and other persons are appropriately monitored
- Appointing RPSs in writing and maintaining a list of such appointments
- Ensuring that RPSs and members of staff are adequately trained, receive update training as appropriate and participate in continuous professional development
- Maintaining training records and making such records available for inspection
- Providing SOPs, Systems of Work and Local Rules and ensuring that they are regularly reviewed and updated
- Ensuring that radiation risk assessments are undertaken in association with RPA and that such assessments are reviewed regularly
- Ensuring that radiation equipment is selected, installed, critically examined, commissioned, maintained and replaced in accordance with regulations and guidance
- Ensuring that a risk assessment is made of the working conditions of a members of staff who declares that they are pregnant and that any required changes to working conditions are implemented
- Investigating suspected radiation incidents in association with the RPA and reporting confirmed incidents to the Clinical Board Director and the Head of the Health, Safety
- Keeping records of incidents for the appropriate time

In nuclear medicine:

- Ensuring that a risk assessment is made of the working conditions of a members of staff who declares that they are breast feeding and that any required changes to working conditions are implemented

The duties of the Chair of the UHB Radiation Protection Group include:

- Reviewing relevant UHB policies and procedures related to ionising radiation
- Providing advice on the implementation of relevant UHB policies and procedures
- Reviewing compliance with relevant UHB policies and procedures
- Reviewing relevant UHB policies and procedures at least every three years and ensuring that they are amended and updated as necessary
- Reviewing summary reports from RPAs and taking action as necessary
- Liaising with members of the Radiation Protection Group and others as necessary

The duties of the Head of Health and Safety include:

- Acting as UHB's primary contact with the HSE as appropriate.
- Reporting incidents of regulatory non-compliance to HSE (excluding incidents where individual radiation dose limits have been exceeded).
- Ensuring that the Executive Director of Therapies and Health Science, the Chair of the UHB Radiation Protection Group and the relevant Clinical Director and Clinical Board Head of Operations and Delivery are aware of all reports made to external regulatory bodies ones you deal with.
- Delegating duties to other managers as appropriate.

The duties of the Radiation Protection Adviser (RPA) include:

- Implementing requirements as to controlled and supervised areas
- Examining plans for installations and the acceptance into service of new or modified sources of ionising radiation in relation to engineering controls, design features, safety features and warning devices provided to restrict exposure
- Regularly calibrating equipment provided for monitoring ionising radiation dose and dose rate and checking that such equipment is serviceable and correctly used
- Periodically examining and testing engineering controls, design features, safety features and warning devices and checking Systems of Work including any written arrangements provided to restrict exposure to ionising radiation
- Performing critical examinations of newly installed or repaired equipment or articles for work with ionising radiation
- Estimating radiation dose to members of staff and members of the public
- Participating in inspections by statutory authorities

- Providing radiation protection training
- Liaising with the MPE and agreeing on the demarcation of duties associated with radiation safety and compliance with legislation
- Liaising with MPEs as regards the design and construction of clinical and related radiation facilities
- Advising on risk assessments and contingency plans
- Advising on the form and content of Local Rules for each designated controlled and supervised area
- Advising on the conduct of incident investigations and the content of subsequent reports
- Advising on dose assessment and recoding, including personal and area monitoring
- Advising on the selection and use of appropriate personal protective equipment
- Advising on quality assurance programmes for radiation equipment
- Advising on arrangements for outside workers
- Advising on the designation of classified workers
- Advising on information and instructions for pregnant members of staff
- Advising on training for dealing with emergencies
- Advising on the radiation protection of comforters and carers in association with the MPE

In nuclear medicine:

- Liaising with the RWA and DGSA as regards the storage and transportation of radioactive substances and the accumulation and disposal of radioactive waste
- Advising on radiation protection advice to patients leaving hospital after radiopharmaceutical administration and to those who care for or come into contact with such patients, in liaison with MPEs
- Advising on the design of radiopharmacies and radionuclide laboratories and associated protocols
- Advising on information and instructions for breast-feeding members of staff

The duties of the Radiation Protection Supervisor (RPS) include:

- Exercising close supervision of work with ionising radiation to ensure that it is done in accordance with Local Rules and Systems of Work and in compliance with IRR 2017
- Notifying managers of any proposed changes in or additions to work with ionising radiation
- Notifying managers of any change of equipment usage or conditions, which might affect radiological safety
- Notifying managers of any monitoring instrument used to demonstrate compliance with regulations that has not been calibrated to accepted standards

- Notifying managers of any incident involving or suspected incident resulting in exposure much greater than intended
- Helping to ensure that controls for the restriction of exposure are used in accordance with Local Rules and Systems of Work
- Observing, from time to time, all procedures involving ionising radiation and issuing instructions necessary to maintain radiation doses ALARP
- Attending courses and receiving training as recommended by the RPA
- Promulgating Local Rules and Systems of Work to ensure that necessary safety information and guidance is given to staff, outside workers and any other persons who enter controlled or supervised radiation areas
- Performing additional tasks as agreed with managers

In nuclear medicine

- Notifying managers of any damage to a radioactive source or any spillage, loss or suspected loss of a radioactive substance

The duties of the Director of Medical Physics and Clinical Engineering include:

- Recommending suitably qualified and experienced members of staff and other persons to the Executive Director of Therapies and Health Sciences for appointment as RPAs to the UHB
- Delegating duties to members of staff as appropriate

The duties of all individual members of staff working in radiation areas:

- Following SOPs and Systems of Work and complying with Local Rules
- Wearing personal dosimeter at all times during occupational exposure to ionising radiation
- Making full and proper use of any personal protective equipment that has been provided
- Reporting any defects or suspected faults in radiation and protective equipment to the RPS and the Directorate Clinical Director through the line management structure
- Reporting suspected radiation incidents to the RPS and the Directorate Clinical Director through the line management structure
- Informing the line manager and the Directorate Clinical Director through the line management structure as soon as they know or suspect that they are pregnant

In nuclear medicine:

- Informing the line manager and the Directorate Clinical Director through the line management structure as soon as they are pregnant or start to breast feed

7 References

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