



## Original Article

## Best Practice Recommendations for the Retention of Radiotherapy Records



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Received 10 February 2017; received in revised form 8 June 2017; accepted 15 June 2017

## Abstract

This paper offers best practice recommendations for the maintenance and retention of radiotherapy health records and technical information for cancer programmes. The recommendations are based on a review of the published and grey literature, feedback from key informants from seven countries and expert consensus. Ideally, complete health records should be retained for 5 years beyond the patient's lifetime, regardless of where they are created and maintained. Technical information constituting the radiotherapy plan should also be retained beyond the patient's lifetime for 5 years, including the primary images, contours of delineated targets and critical organs, dose distributions and other radiotherapy plan objects. There have been increased data storage and access requirements to support modern image-guided radiotherapy. Therefore, the proposed recommendations represent an ideal state of radiotherapy record retention to facilitate ongoing safe and effective care for patients as well as meaningful and informed retrospective research and policy development.

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**Key words:** Data retention; patient record storage; radiotherapy; retention of health records

## Introduction

The demands for clinical information management in radiation oncology have evolved significantly over the years. Electronic medical records (EMR) are commonplace and computer-based radiation oncology information systems (ROIS) have become the central resource for co-ordinating core aspects of care for radiotherapy. The ROIS serves as the repository for technical information, clinical notations, scheduled patient visits, treatment records and workflow co-ordination. It also co-ordinates treatment

delivery and manages the radiotherapy patient record, including records of treatment intent, type of radiotherapy, schedule, technical aspects describing the treatment plan and image-based target localisation, and other related activities. The ROIS stores laboratory reports and correspondence pertinent to the patient's care, but frequently operates separately and in parallel with more general hospital-based EMR systems.

This paper recommends 'best practices' for the maintenance and retention of radiotherapy records. Appropriate retention of radiotherapy patient records is an essential aspect of ongoing patient safety and quality of care because the data are used for clinical follow-up, particularly in instances of re-treatment of recurrent disease or therapy for new primary malignancies [1,2]. For the significant proportion of patients requiring re-treatment, the assessment

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of previous interventions is essential for safe and effective planning of subsequent treatment [3–13]. Inadequate access to a complete clinical and technical history could result in clinically important complications relating to improper delivery of additional radiotherapy [6].

Accurate research to assess the value and efficacy of radiotherapy, as well as the risk of second primary malignancies, complications and other long-term radiotherapy outcomes requires access to long-term clinical and technical data, potentially from thousands of patients. It has been suggested that comprehensive and accurate cancer outcomes research requires registries containing 20–25 years of health records of surviving and deceased patients [14–18]. These data are also valuable to public and hospital policy makers who can analyse the collected data to forecast trends and project future needs [19].

Cancer Care Ontario, a provincial cancer agency in Ontario, Canada, recognised the importance of this issue and commissioned a ‘best practice’ report to guide radiotherapy health records and other pertinent technical information retention. This document offers guidance to radiation oncologists and allied health professionals who provide continuing care over the lifetime of cancer patients. It is intended to support clinical needs and inform public health policy, and may exceed requirements outlined by professional organisations and existing laws defining and governing general health records. The recommendations represent a minimum requirement to assure access to radiotherapy records and technical information to facilitate safe and effective care, especially for patients who may require several distinct courses of therapy over their lifetime.

## Methods

Our analysis attempts to incorporate some basic principles of health information technology practice as proposed by Holden and Karsh [20]. This theoretical model of health information technology best usage, intended for a wide range of information technologies, suggests that designers, implementers and administrators should adhere to 12 principles (Table 1). Efforts were made to ensure principles 1, 2, 4, 8 and 11 were considered as radiotherapy retention requirements were analysed and recommendations drafted.

The recommendations put forth in the ‘best practice’ report were informed by a literature search, an environmental scan of pertinent healthcare professional organisations, relevant provincial legislation and expert opinion collected by a survey of radiotherapy programmes across multiple jurisdictions. Literature published in English was systematically searched via the MEDLINE (1946 to November 2015) and EMBASE (1996 to November 2015) databases using the following search terms: medical records, health records, storage, retention, management and destruction. Articles were excluded if they were not related to radiotherapy. An environmental scan of unpublished literature was undertaken via Google Scholar using search terms relating to retention and destruction of healthcare data, records or information.

**Table 1**

Holden and Karsh's [20] principles of health information technology (HIT) usage behaviour

Principle 1	HIT use should meet, not jeopardise user needs.
Principle 2	HIT use should be easy (low effort), not difficult.
Principle 3	HIT use should lead to observable outcomes.
Principle 4	HIT use outcomes should be positive/useful.
Principle 5	User self-efficacy will influence HIT use decisions.
Principle 6	Feedback after HIT usage behaviour will influence future usage behaviour.
Principle 7	HIT usage behaviour is an interaction of multiple environmental and personal factors. There is no one cause and no one solution.
Principle 8	HIT usage behaviour is based on users' beliefs and the attitudes, norms and perceptions of control produced by these beliefs.
Principle 9	One's social and cultural environment affects the desirability of HIT use.
Principle 10	The degree to which HIT use is voluntary, or controllable, will have an effect on HIT usage behaviour.
Principle 11	Successful HIT design depends on the fit between characteristics of the HIT and characteristics of the work system.
Principle 12	Successful HIT outcomes depend on the fit between elements within the work system where the HIT is implemented.

An informal survey of retention policies in other jurisdictions was carried out by contacting radiotherapy programmes and experts in British Columbia, Alberta, the UK, Ireland, the Netherlands, Sweden and the USA. The survey involved semi-structured telephone interviews and e-mail communication with key informants. Additional policy documents were identified through these discussions.

Finally, the draft guidance document was presented for review and approval by heads of radiation oncology, medical physics and radiotherapy at 14 Ontario cancer centres and presented for feedback at a provincial government agency committee of senior clinical leadership representing all clinical cancer services (e.g. prevention, screening, imaging, surgery, radiotherapy, nursing and psychosocial care, patient education, etc.).

## Results

The literature search located 994 articles. However, only three were identified as relevant after title and abstract review [21–23]. Upon full-text review, all of these articles were excluded as they did not offer radiotherapy-specific information. The environmental scan located five documents [6,24–29] discussing data retention policies related to radiotherapy. All documents were published by well-known healthcare organisations or professional associations (Table 2). In addition to suggesting data retention timelines, all but one of these documents [6] also provided information regarding the importance of retaining records for medico-legal reasons. Three of the documents [24,25,29] briefly

**Table 2**  
Summary of environmental scan results

Legislation/organisation	Country/date	Relevant recommendations
American Society for Radiation Oncology (ASTRO) [6]	USA/2000	<ul style="list-style-type: none"> <li>■ All medical records associated with radiation treatment should be preserved for a minimum of the <b>patient's lifetime plus 5 years</b></li> </ul>
The Royal Australian and New Zealand College of Radiologists & The Faculty of Oncology (RANZCR FRO) [24]	Australia/New Zealand/2005	<ul style="list-style-type: none"> <li>■ Medical record, oncology record, prescription sheet, localisation images, isodose distribution, set-up details should be retained for at least the <b>patient's lifetime plus 5 years</b></li> <li>■ Images, dose volume histograms, calculation sheets should be retained for at least 7 years after treatment, and ideally for the <b>patient's lifetime</b> (original or hardcopy); or the <b>compatibility lifetime</b> (proprietary digital format)</li> </ul>
Australasian College of Physicists in Science, Engineering, and Medicine (ACPSEM) [25]	Australia/1996	<ul style="list-style-type: none"> <li>■ All data relevant to diagnosis and treatment, including simulator and portal films, treatment plans, and treatment records for therapeutic course should be retained for the period of time detailed in the <b>institution-specific policy</b>, which should include applicable statutory requirements as a minimum standard</li> </ul>
National Health Service	UK/2009 [26]	<ul style="list-style-type: none"> <li>■ Records should be kept for a <b>minimum of 30 years</b>, as per the Public Records Act.</li> <li>■ For deceased patients records should be retained for 8 years after death.</li> <li>■ Records should be retained on a computer database if possible.</li> <li>■ Consider the need for <b>permanent preservation</b> for research purposes.</li> </ul>
	UK/2016 [27]	<ul style="list-style-type: none"> <li>■ 30 years or 8 years after the patient has died</li> <li>■ Review and consider transfer to a place of deposit</li> <li>■ For the purposes of clinical care the diagnosis records of any cancer must be retained in case of future reoccurrence. Where the oncology records are in a main patient file the entire file must be retained</li> <li>■ Retention is applicable to primary acute patient record of the cancer diagnosis and treatment only. If this is part of a wider patient record then the entire record may be retained</li> <li>■ Any oncology records must be reviewed prior to destruction taking into account any potential long-term research value which may require consent or anonymisation of the record</li> </ul>
	2001 [28]	<ul style="list-style-type: none"> <li>■ Oncology records should be retained for <b>8 years after the conclusion of treatment</b>, especially when surgery only involved</li> <li>■ Consideration of Royal College of Radiologists oncology-specific recommendations suggested</li> </ul>
The Royal College of Radiologists (RCR) [28]	UK/2006	<ul style="list-style-type: none"> <li>■ Radiotherapy and chemotherapy records must be retained for the patient's lifetime and should be retained for the <b>patient's lifetime plus 5 years</b></li> <li>■ For minors (up to 20 years of age at the time of diagnosis) radiotherapy or chemotherapy records should be kept not only for the duration of the patient's lifetime, but <b>as a permanent record</b></li> <li>■ Simulation films for minors should be kept <b>permanently</b>, either as a hardcopy or as digital computer records</li> <li>■ For radical treatment, data should be kept as a permanent record on a computer database, and a hardcopy of the records and similar films should be kept for the <b>patient's lifetime plus 5 years</b></li> <li>■ Prospective records for both adult and child patients should be kept <b>permanently on a computer database</b> and should include sufficient details of radiotherapy and chemotherapy to enable reconstruction of these treatments at a later date</li> </ul>

mentioned that data retention periods should take into consideration legal requirements. The guidance document from New Zealand [24], offers brief but radiotherapy-specific recommendations suggesting that 'the latent nature of late radiation effects (sometimes 10–20 years) means that good risk management in this area requires at least a minimum

data set be stored for the patient's lifetime'. The three documents from the UK [26–28] offer extensive information related to legal obligations and good practice guidelines, but they were not radiotherapy specific.

The informal survey included 17 key informants (medical physicists and IT professionals) who provided information

on radiotherapy-specific data retention policies in their jurisdictions (Ontario [nine], Alberta [one], British Columbia [one], the UK [one], Ireland [one], the Netherlands [one], Sweden [one], the USA [two]). All key informants reported a lack of guidelines or policies beyond generic statutory requirements in their jurisdictions. However, they noted that there is a common practice of retaining radiotherapy records beyond the patient's lifetime. All jurisdictions reported that they were reviewing their practices and had recognised the need to address long-term secure storage and disposal of oncology records, as well as the challenges presented by evolving technical standards and innovation in clinical practice.

#### *Data Retention Practices in Canada*

In Ontario, the Public Hospitals Act [30] and College of Physicians and Surgeons of Ontario [31] instruct that medical records should be retained for 10 years after the date of patient discharge, last visit, last date of entry in the record or death for adult patients and that diagnostic imaging records specifically should be retained for 5 years. However, these requirements are not specific to oncology records. In 2014, Cancer Care Ontario developed a strategic roadmap [32] for EMR in oncology programmes. However, the recommendations put forth in this report were presented as high-level standards for practice and were not radiation specific. The lack of guidelines specific to the retention of radiotherapy patient records in Ontario and the large regional variation in practice regarding the retention of radiotherapy records was the impetus for this work. During consultation on the draft report, Ontario key informants confirmed that there were no known provincial guidelines.

In British Columbia, all radiotherapy patient data (treatment plans, records and related imaging) have been centralised in a provincial warehouse since 1999–2000. The system has been maintained and expanded to keep all patient data online and easily accessible in a single commercially available ROIS system (ARIA, Varian Medical Systems, Palo Alto, CA, USA). According to British Columbia informants, the system currently had no practical tools that would allow specific patient records to be marked for archival or disposal under any age- or date-based policy. At the time of the interview, the more general health records (i.e. of host hospitals and the British Columbia Cancer Agency) did not have archive data warehousing capabilities. As a consequence, all records are currently retained. Informants from the Alberta Health System described a similar practice. Key informants from Ontario, British Columbia and Alberta indicated that they were not aware of any other provinces having radiotherapy data retention policies in place.

#### *Data Retention Practices in Europe*

In the UK, the National Health Service developed a Code of Practice [26,27] that provides guidance regarding the retention of medical records. For oncology records (including radiotherapy patient records), a minimum

retention period of 30 years is recommended or 8 years after death. This recommendation is aligned with the UK's Public Records Act, which also recognises that there are scenarios in which organisations will need to retain records for more than 30 years and indicates that mechanisms are in place for organisations to co-ordinate record storage for longer retention periods. Further guidance was issued by the Royal College of Radiologists [29], who indicate that radiotherapy records must be retained for the patient's lifetime and ideally for the patient's lifetime plus 5 years. Additionally, permanent storage is recommended in particular scenarios (minors) and for certain aspects of the radiotherapy records (e.g. treatment planning data, medical images). The report highlights the importance of retaining sufficient detail to reconstruct patient treatment plans at a later date. The environmental scan also located a National Health Service Health Service Circular document from 2001 [28], which recommends that oncology records (not radiotherapy specific) should be retained for at least 8 years after treatment. With regards to radiotherapy specifically, consideration of requirements issued by the Royal College of Radiologists is recommended.

Jurisdictions across Europe and the UK seems to have a similar 'situational approach'; clinical needs often exceed local legal requirements and all records have been retained as available resources have permitted. This is frequently the case after a major project to implement, upgrade or replace a ROIS system. In the Netherlands, the NVRO (Dutch Society for Radiation Oncology) recommends the retention of radiotherapy records for the patient's lifetime or at least 20 years after the completion of his/her treatment. In practice, this has meant that all radiotherapy institutes had kept historical paper files indefinitely and that this practice was then carried forward with electronic records. The adoption of indefinite storage of electronic records reflects, in part, that there are currently no software systems to easily implement more high-level retention policies with select records, or parts thereof, being discarded with different timescales. Electronic radiotherapy planning data, including images, are archived, preferably in Digital Imaging and Communications in Medicine (DICOM) format [33] by most institutions.

The views of the informants differed regarding the retention of target localisation images (portal images and cone beam computed tomography). By and large, the practice is to maintain documented set-up correction protocols and to link the protocols with decisions regarding image guidance placed in the patient record. This often includes initial photographic images of the patient set-up. In practice, most institutions regard localisation images as 'working documents' and therefore retain the images for a limited period of time (typically 3–12 months). The question of how the data is stored after the completion of treatment prompted variable responses from informants, with a number of facilities in Europe undergoing a process of scanning older paper-based documents into digital formats and storing them as pdf files. However, it was noted that such data will not be easily searched in the future. The question of how the records will be used in the future

yielded different responses. As one key informant indicated, there is legislation to retain data for 25 years, for example, but a practical means of retrieval is challenging as clinical practice and software systems evolve.

#### *Data Retention Practices in Australia and New Zealand*

The environmental scan located two documents [24,25] relevant to data retention from Australia and New Zealand. A position paper issued by the Australasian College of Physicists in Science, Engineering, and Medicine [25] recommends that all data relevant to the diagnosis and treatment of a patient treated with radiotherapy shall be kept in 'some recoverable form' for the period of time detailed in institution-specific policies, taking into account applicable legislative requirements as a minimum standard. A more detailed policy regarding medical and dosimetry record storage requirements for radiotherapy was developed by the Royal Australian and New Zealand College of Radiologists and the Faculty of Radiation Oncology (RANZCR FRO) [24]. The policy describes specific short- and long-term documentation storage needs for radiation oncology, for both hardcopy and electronic storage media. The document's introduction notes that the unique technical and medical aspects of patient care related to radiotherapy are not well understood outside of the profession and that the policy was prepared with the goal of providing a national policy and consistent approach on this issue. RANZCR FRO recommends that records should be retained for at least the patient's lifetime, and ideally for the patient's lifetime plus 5 years. Shorter retention periods are noted as sufficient for a subset of the record.

#### *Data Retention Practices in the USA*

The American Society for Radiation Oncology (ASTRO) issued a statement regarding data storage and disposal for radiotherapy records over a decade ago [6]. ASTRO recommends that medical records associated with radiotherapy should be preserved for a minimum of 5 years after the patient's death. This includes all of the radiation oncologist's records, regardless of whether they are controlled by the radiation oncologist, a hospital or other treatment facility.

Integrating the Health Enterprise (IHE) is an initiative supported by healthcare professionals and commercial vendors to improve the way computer systems used in healthcare share information (<http://www.ihe.net>). IHE promotes the co-ordinated use of established data exchange standards, such as DICOM and Health Level Seven (HL7). In the radiation oncology domain (IHE-RO), the community works closely with ASTRO and American Association of Physicists in Medicine members to highlight and solve the issues regarding managing information for radiotherapy [34]. The IHE-RO does not specifically address long-term storage or disposal of health records, but it does make evident that the amount of storage required is only the starting point for considering data retention; one must also be able to archive and transfer data to the point of need. The

IHE initiative notes a lack of explicit support in hospital-based picture archiving and communication system (PACS) systems for exchanging data and supporting clinical radiation oncology workflows [35]. Correspondence with the IHE-RO technical committee indicated that continuing clinical and technical innovation in radiotherapy is creating pressure to modify DICOM-RT standards in order to support more open data exchange within the clinical process and to support new concepts, such as deformable registration, dose reconstruction and adaptive radiotherapy.

## **Recommendations and Discussion**

The following recommendations for the retention of radiotherapy records were derived from the literature above and a review of jurisdictional practices and expert opinion from various key stakeholders. These best practice recommendations should guide the development of institutional or local policies and procedures regarding radiotherapy record retention.

#### *Working Assumptions*

It is assumed that continuing innovation in clinical care will motivate commercial providers to rely on their own proprietary database formats for health records and technical data. The requirements for exchange of data between such software systems and databases require the ability to export health records and treatment planning data in open-standard formats (HL7 and DICOM-RT) specified by the cooperation of industry and the international clinical community [33]. The maintenance of these standards is an important aspect of data retention, archiving and retrieval, particularly in the following situations:

- (i) In the event of upgrades or a change in commercial supplier, open standards for data exchange must support complete and accurate transfer of historical records to new software applications to maintain retrospective access for review (at a minimum).
- (ii) When there is a requirement to share patient records for review between cancer centres and healthcare providers in other jurisdictions.
- (iii) When there is an obligation to support research of clinical outcomes and health policy.

#### *Recommendations*

In order to support ongoing care of patients, cancer programmes and host hospitals should align with the following recommendations:

1. Complete health records (i.e. in the ROIS or more general hospital-based EMR) for oncology patients should be retained for 5 years beyond the patient's lifetime, regardless of where records are created and maintained.
2. Technical information constituting the radiotherapy plan, including the primary images, contours delineating targets and critical organs, dose distribution and

other radiotherapy plan objects, should be retained for a period of 5 years beyond the patient's lifetime.

- (a) At a minimum, a document summarising the treatment plan should be stored with the health record in the ROIS, e.g. as a document in pdf format.
  - (b) Full support of the issues outlined in this report requires an accurate and complete record of the treatment plan stored or exportable as a series of DICOM and DICOM-RT objects (computed tomography image, structure sets, plan and dose distribution).
3. Images used to support the treatment planning process (e.g. magnetic resonance and positron emission tomography studies) should be archived in an image data storage facility, where their maintenance and disposal will occur according to the laws of the appropriate jurisdiction. This process is independent of recommendation 2.
  4. Records of treatment delivery, including documentation of the interpretation of images used to guide target localisation, together with notes describing treatment process and patient status over the course of treatment, should be stored in the ROIS and managed as part of recommendation 1.
  5. Software systems and appropriate data infrastructure should be maintained to store, retrieve and display oncology information; unless processes are in place to support the migration of data in conjunction with software upgrades.
  6. When EMR/ROIS software is updated, steps should be taken to ensure past oncology information data can be stored, retrieved and displayed by migrating data in conjunction with the software upgrade, or by maintaining the legacy EMR/ROIS software.
  7. When developing policy regarding images acquired and used to support treatment delivery, i.e. in image-guided target localisation or image-guided radiotherapy consider:
    - (a) Localisation images are considered working documents. They are interpreted for the purposes of achieving accurate and precise patient positioning and for the evaluation of anatomical changes over the treatment course. Interpretation, numerical calculations and decisions made using these images should be stored in the ROIS and managed according to recommendation 1.
    - (b) After the completion of treatment, localisation images (e.g. portal images and cone beam computed tomography) should be archived and managed for disposal according to the laws of the appropriate jurisdiction.

These recommendations for data retention apply to both the complete oncology health record, maintained by the host hospital, and any supporting documentation, whether they are created, maintained or stored as a single database or hosted in separate distributed records.

At a minimum standard, radiotherapy oncology records and technical information must be maintained for the lifetime of the patient, and beyond, to meet statutory obligation specified by jurisdictional laws. It must be emphasised that the complete oncology record extends beyond the

radiotherapy chart or ROIS, and includes records stored in the host hospital system.

Permanent storage of all treatment details is considered ideal, in terms of supporting long-term access to retrospective data for clinical and health policy research. However, this could be technologically and financially challenging, given the change driven by rapid innovation in software and hardware technology. In practical terms, a sufficient window should be created to allow data abstraction for policy and research purposes, and additional infrastructure and funding may be required to support longer term clinical and health policy research enterprises.

Continuing innovation in information support systems and work practices is necessary to maintain and improve efficient access to safer, high-quality care. As the clinical implications, workflow and relationships between imaging for treatment planning and delivery continue to evolve and improve, cancer programmes and funding models must develop plans for the expenditures associated with data storage, networking, software systems and appropriate training to maintain a skilled workforce. Clinical data must be available, accurate and displayed in a readily accessible format to quickly serve patient needs.

Finally, it is important to emphasise that appropriate data retention practices are essential to maintaining patient safety and improving the quality of care. These data are not only critical for accurate patient follow-up and re-treatment of disease, but will also play an important role in research assessing value, efficacy as well as complications and long-term radiotherapy outcomes.

### *Limitations*

These recommendations represent an ideal state of radiotherapy record retention. They do not provide practical guidance of how the recommended actions should or can be achieved, nor estimates of the potential costs, IT infrastructure requirements and other resource implications associated with implementation. Further guidance would be useful to adequately plan for and implement proper record retention and retrieval mechanisms at the institutional level.

This work intentionally focused on the retention of radiotherapy records as there are unique aspects to these records, which warrant their long-term storage and retention in specific formats and operating systems. However, similar recommendations may be warranted for other cancer treatment modalities (e.g. surgery, systemic therapies, etc.) as well as other disease areas and healthcare services. As many patients receive combined modality treatment, additional analysis of oncology record retention may benefit from engagement with professionals from other disciplines and the development of multidisciplinary recommendations.

### **Conclusions**

The demands for information technology and data management in radiotherapy result from an increasing necessity for accuracy and precision in patient-specific

treatment planning and delivery. As a consequence, there are increased data storage and access requirements to support image-guided treatment planning and delivery. Consistent access to imaging information improves safety and quality of care. Therefore, the trend towards more comprehensive use of imaging information will continue across all radiotherapy modalities and indications and will require appropriate and consistent data retention policies.

## Acknowledgements

We acknowledge the health professionals who reviewed and commented on the draft recommendations and the key informants who shared insights regarding their institutional practices.

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