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Health informatics — Datasets and data structure for clinical and biological evaluation metrics in radiotherapy

Informatique de santé — Jeux de données et structure de données pour les métriques d'évaluation clinique et biologique en radiothérapie

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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This document was prepared by Technical Committee ISO/TC 215, *Health informatics*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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Introduction

Radiotherapy or radiation therapy is a treatment method used mostly in cancer care. Due to rapid technical advances of the radiotherapy treatment modalities, it is becoming increasingly important to select an appropriate radiotherapy treatment modality for individual patients by considering patient conditions and the resources that are required.

In the case of external-beam radiation therapy (EBRT), where the therapeutic radiation beams are emitted from a machine outside the body of the patient, treatment planning is performed prior to treatment. When selecting a treatment modality from among possible candidates, treatment plans are made for the candidates, if necessary, and then the dosimetric indices and/or radiobiological metrics corresponding to the treatment plans are compared.

Tumour control probability (TCP) and normal tissue complication probability (NTCP) are among the metrics used in the comparisons. They are simple phenomenological models based on clinical observations which are described in ICRU 83[12] as clinical and biological evaluation metrics (CBEMs), along with other metrics such as equivalent uniform dose, conformity and homogeneity indices. Recently, more sophisticated models incorporating non-dosimetric patient factors, spatial dose metrics and -omics elements (e.g. radiomics and proteomics) have also received attention and some of them are starting to be referred to in clinical trials in some countries.

For wider and safer use of CBEMs in clinical practice and clinical trials, it is important to provide an effective framework for ensuring the traceability of calculated metrics. Standardization of data formats for reporting calculated CBEMs is one possible way. However, no attention has been paid to such standardization to date, while there is active research on new metrics or new models as well as increasing attention to transparent reporting of developed models.

This document describes datasets and data structure for the reporting of CBEMs, especially of simple model types of TCP and NTCP. Scientific aspects of reliability of CBEMs are not in the scope of this document. Because of the variety of CBEM models, when an evaluated CBEM is to be reported and/or referred to, it is important to report and/or refer to the value of the calculated CBEM along with information about the CBEM model itself as well as with dose information and non-dosimetric factors of the patient that are used in the calculation. It is also important to include descriptions about uncertainties, underlying assumptions, limitations and situations for application of the CBEM model. In general, the dose information of the treatment plan used in the calculations (dose-volume histogram (DVH) in most cases) is converted to match the model definition; for instance, adjusting the differences in fraction size between the plan of the patient and the reference fraction size of the CBEM model. This means that the apparent values of the doses (e.g. maximum dose and mean dose) used in the calculation are CBEM-model-specific. To ensure traceability, inclusion of the description about the process of such dose conversions along with the value of the representative dose values would be a great help. This document provides datasets and data structure for CBEM reporting by considering the above mentioned aspects.

While this document is not intended to cover the reporting of CBEMs by contemporary sophisticated models, the data structures described in this document can apply to the reporting of them as well.

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Health informatics — Datasets and data structure for clinical and biological evaluation metrics in radiotherapy

1 Scope

This document reports on the datasets and a data structure for reporting clinical and biological evaluation metrics (CBEMs). The reporting of radiation dose estimates is outside the scope of this document.

This document is applicable to CBEMs for external-beam radiation therapy (EBRT) modalities, but not CBEMs for brachytherapy or molecular radiotherapy.

Various types of radiotherapy treatment modalities are available for cancer care. Consequently, there is a growing awareness of the need for objective schemes that will contribute to enable the selection of an appropriate radiotherapy treatment modality for individual patients. The use of CBEMs, the metrics associated with a certain radiotherapy treatment plan for a patient, is attracting attention for clinical purposes in the field of EBRT. In anticipation of the clinical use of CBEMs, the importance of research on clinical and scientific aspects of CBEMs is increasing, in concert with the importance of establishing a standardized data format for reporting of specifics of a CBEM.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
data element
unit of data that is considered in context to be indivisible

Note 1 to entry: The definition states that a data element is "indivisible" in some context. This means it is possible that a data element considered indivisible in one context (e.g. telephone number) can be divisible in another context (e.g. country code, area code, local number).

[SOURCE: ISO/IEC 11179-1:2023, 3.3.4, modified — Example deleted.]

3.2
Digital Imaging and Communications in Medicine
DICOM
standard for the communication and management of medical imaging information and related data

Note 1 to entry: The DICOM Standard facilitates interoperability of medical imaging equipment.

Note 2 to entry: DICOM is defined in ISO 12052.

[SOURCE: ISO/IEC 39794-16:2021, 3.16]

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