Radiation Oncology

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Implementation of a comprehensive clinical quality assurance system in radiation oncology

Anja Alessandra Joye[1], Matea Zosso-Pavic[1], Jeannifer Beckmann[1], Jérôme Bonzon[2], Sebastian Stolz[3], Jonas Willmann[1], Maiwand Ahmadsei[1], Sebastian M. Christ[1], Nicolaus Andratschke[1], Matthias Guckenberger[1], Stephanie Tanadini-Lang[1] and Michael Mayinger[1*]

Abstract

Objective The objective of this project was to develop and evaluate a comprehensive clinical quality assurance system for radiation oncology, and assess the system using definitive radiation therapy for prostate cancer as a first use case.

Methods The Zurich Clinical Quality Assurance System in Radiation Oncology (ZH-CLASSIC) was initiated to allow for continuous quality assurance in radiation oncology with respect to indication for radiation therapy, practice of radiation therapy and patient outcome. Data from the sources of the hospital information system, the Radiation Oncology Record and Verify System and a dedicated follow-up database were automatically retrieved, and combined using a unique patient-ID. Data aggregation, continuous analysis and reporting was performed using ten distinct patient care pathways as the basis which covers all aspects of radiation therapy treatments and indications as well as the different follow-up schemes (in-clinic, telemedicine, and external follow-up). The follow-up system was validated through analysis of patients with prostate cancer (≥ 18 years, cT1-3 cN0 cM0) who underwent curative, primary stereotactic radiation therapy. Survival, treatment effectiveness, tumor control, acute and late toxicity, and performance status were analyzed.

Results Since May 2021, a total of 4,515 individual patients were being managed in ZH-CLASSIC. Personal resources amounted to 0.75 full time equivalent (FTE) project manager for one year prior to implementation, 0.13 FTE physician and 1.00 FTE follow-up manager as ongoing expenses. Compliance with respect to reporting data into ZH-CLASSIC by the physicians increased from a mean of 54% in 2021 to 92% in 2024. For all patients, follow-up was performed as in-clinic visits (51%), via telephone (7%) or as an external query (43%), with missing information (5%) originating from external requests in 96%. Instead of an intended first in-clinic follow-up visit, telemedicine appointments were conducted in 10% and external follow-ups were performed in 22%. Oncological outcomes and toxicities were evaluated for all prostate cancer patients ($n = 209$) treated with daily online-adaptive SBRT on the MRIdian using 5×7.25 Gy every other day or 5×7.5 Gy weekly. After a median follow-up of 15 months (range, 6–41 months), 208/209 patients were alive. Over this time period, reported CTCAE toxicities included genitourinary grade 2: 12%, grade 3: 1%, and gastrointestinal grade 2: 3%, grade 3: 0%.

*Correspondence:
Michael Mayinger
michael.mayinger@usz.ch

Full list of author information is available at the end of the article

Conclusions The ZH-CLASSIC system allowed for automated and structured documentation and analysis of the quality with regards to the indication, treatment and outcome of radio-oncological cancer patients. Dedicated staff are needed in the start-up period but personal resources are expected to continuously decrease. Analyses of patients treated with SBRT for localized prostate cancer resulted in plausible results in agreement with reported values in the literature.

Clinical trial number Not applicable.

Keywords Follow-up, Care path, Radiation oncology, Patient outcomes

Introduction

As of today, patients in developed countries have access to an increasingly dense medical infrastructure [1, 2]. The focus is thus continuously shifting from ensuring sufficient treatment quantities towards increasing the treatment quality [3–5]. To ensure a high-quality treatment and assess potential shortcomings, the relevant data concerning radiation therapy indication, treatment and outcome quality need to be documented in a structured set-up and continually analyzed. While indication and treatment quality are frequently documented as part of the clinical routine in the respective radiation oncology departments, treatment outcomes are assessed within regular follow-ups according to the current clinical guidelines of each cancer entity. Cancer patients undergo these follow-ups either in the radiation oncology departments or in different institutions, such as at their treating general practitioner. A comprehensive quality assurance program needs to collect data from various sources, aggregate them in an automated way and allow for continuous data analysis.

Currently, many reports for patients treated in radiation oncology are recorded in open text format. This unstructured data format requires advanced statistical algorithms in natural language processing, machine learning or deep learning for analyzing the individual clinical texts automatically. Structured data capture systems facilitate interoperable data capture in patient care, clinical trials, cancer surveillance and public health needs, clinical research and computable care guidelines. However, the technology in this field is not fully developed, resulting in multiple challenges that hinder the full use of the documented unstructured data [6]. Relevant information about the patient, therapy, outcome and follow-up are thus inaccessible for a standard automatic analysis. A further shortcoming in this context is that patients may not be routinely monitored in a long-term set-up within the radiation oncology department, where they received their treatment, but are seen for follow-up by other internal or external service providers. Subspecialization in medicine can lead to autonomously organized departments with partially independent IT ecosystems, which may not be fully prepared to meet data integration challenges [7]. As a result of the lack of integrated information, the treatment of chronically ill patients is increasingly difficult and error prone [7]. Information on the further course of the disease and patients' well-being are thus incomplete or not available for assessment. Consequently, retrospective and prospective analyses, encompassing data of cancer patients treated using the highquality standards established in a university hospital setting, require an extensive additional workload as relevant data were not documented in a structured uniform set-up thereby limiting research quality and quantity. To continuously measure and improve treatment quality, especially regarding personalized medicine and chronically ill patients undergoing a multitude of treatments over the years, treatment protocols based on real world data containing a high number of patients and extensive follow-up periods, as well as comprehensive quality assurance systems are required [8–10].

The aim of this project was to develop and evaluate a comprehensive clinical quality assurance system for radiation oncology. The quality of the indication for radiation therapy, the treatment quality and patient outcome is collected from various in-hospital databases, automatically aggregated and analyzed. To this aim, a dedicated database, the Zurich **C**linical Qua**l**ity **A**ssurance **Sy**s**t**em in Radiation On**c**ology (ZH-CLASSIC), was created. The performance of the ZH-CLASSIC system was critically assessed by analyzing all prostate cancer patients undergoing curative, primary stereotactic radiation therapy from May 2021 until August 2024.

Methods

In order to assess the quality of the indication for radiation therapy, the quality of the radiation therapy treatment and patient outcome for all patients treated at the department of radiation oncology at the University Hospital of Zurich, encompassing more than 2,000 treatment courses per year, the ZH-CLASSIC was introduced in May 2021 and comprises:

1) An infrastructure for data collection in a structured format to enable efficient and automated analysis,
2) A process to ensure regular and continuous data collection in the clinic, and.

3) A tool for data visualization to consistently analyze indication, treatment and outcome quality.

Infrastructure and process for structured, regular and continuous data collection

In our department, patient data are routinely stored in two information systems, ARIA (ARIA, Varian Medical Systems, Palo Alto, United States) and KISIM (CISTEC AG, Zurich, Switzerland). ARIA harbors structured data with technical information of the treatment and KISIM structured data containing clinical variables (symptoms before radiation therapy, acute toxicities after radiation therapy and basic outcome data captured at follow-ups such as ECOG (Eastern Cooperative Oncology Group performance status), tumor control for patients treated with a curative intent, treatment evaluation for patients with a palliative intent and late toxicities). For the most complex tumor entities and radiation therapy treatments (oligometastatic disease, reirradiation, brain metastases, and head and neck cancer), additional documentation is performed in REDCap (Vanderbilt University, Nashville, United States), a platform designed to capture case report forms.

For ZH-Classic, a project manager specifically employed for this project was responsible for developing, programming and coordinating the required infrastructure in close collaboration with a clinical steering committee consisting of the clinical and research department leaders. A follow-up manager documented baseline information, such as patient age, clinical variables for baseline tumor information, in ARIA and/or REDCap (Fig. 1), created a care path for each patient and double-checked that for every task in the follow-up care path, the relevant information was collected. After receiving an individual introduction and training for the follow-up system, physicians reported clinical data as previously done during routine care, but now in a predefined structured format in KISIM. Data collection was performed on part of the physicians at the first consultation, after the start and completion of radiation therapy and for each follow-up. At the first consultation, symptoms before radiation therapy were reported using Common Terminology Criteria for Adverse Events (CTCAE) Version 5.0

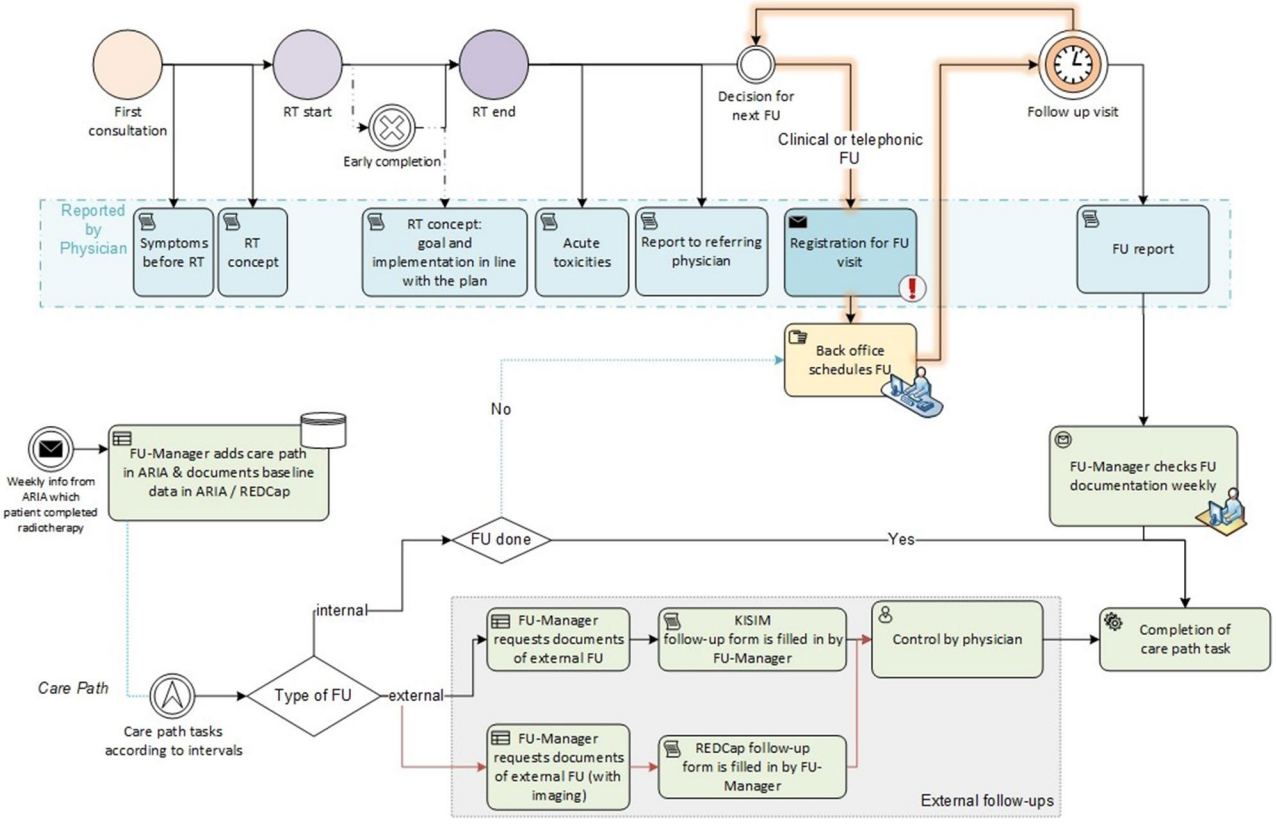

Fig. 1 Structured data collection path way (FU = follow-up, RT = radiation therapy): Physicians reported clinical data (e.g., symptoms before RT, RT concept, acute toxicites) at the first consultation, after the start and completion of RT and for each FU. After completion of RT treatment, FU manager added a care path in ARIA and documented baseline information in ARIA and REDCap. For the repeated internal (clinical and telemedicine) as well as external FUs, appointments were scheduled and performed according to the FU reports. FU manager checked all documentation and documented the completion of care paths tasks

and the radiation therapy concept (including dose and fractionation) were documented. After the start of radiation therapy (and potential early completion), it was evaluated whether radiation therapy treatment was delivered as planned and whether the treatments goals remained valid. After the completion of the radiation therapy treatment, the follow-up manager added a care path in ARIA. Physicians documented acute toxities and a report was sent to the referring physician including information for the next follow-up. For the repeated clinical, telemedicine and external (not in department; e.g. urological consultations) follow-ups, appointments were scheduled and performed according to the follow-up reports. For external follow-ups, the received data were used by the follow-up manager to fill in the follow-up forms, and subsequently double checked by the physicians.

The follow-up manager checked all documentation weekly and documented the completion of care paths tasks. To check the compliance of the implemented system as well the completeness of the tasks within the care path, data were analyzed weekly starting from May 2021 until August 2024 (cut off date: 31.08.2024).

Follow-up care pathways were developed for all oncological and benign radiation therapy indications, resulting in 10 different care paths (Appendix Table 1). These minimal follow-up times do not necessarily reflect the follow-up intervals recommended by oncological guidelines, as oncological follow-up is frequently performed outside of the radiation therapy department. The minimum follow-up times in ZH-CLASSIC represent time points at which a patient is scheduled for radiation oncology follow-up or data was collected from the treating physician or other institutions. The carepaths defined whether the follow-ups were done in person (patient visits clinic), via telemedicine or as an external query (documents requested from other institution). All follow-up schemes were implemented as care paths in ARIA.

Data visualization and statistical analyses for indication, treatment and outcome

For data analyses, a shiny dashboard (https://shiny.posit.co) within the statistical software package R (R Foundation for Statistical Computing, Vienna, Austria) was developed (Fig. 2). The information documented by the physicians and follow-up manager stored within different software packages were combined by patient ID before data was cleaned. To visualize and analyze indication, treatment and outcome, all relevant patient and tumor characteristics as well as technical data such as treatment plans (including stereotactic and online/offline adaptive plans) and planning-CT to RT intervals were displayed. The following end points were evaluated for quality assurance: survival, local treatment effectiveness (e.g. local tumor control, PSA control), systemic tumor control or progression, local acute and chronic toxicity according to CTCAE V5.0 and performance status according to ECOG. Data was descriptively analyzed and visualized using R and Excel (Microsoft Corporation, Redmond, Washington, US).

Exemplary care path for stereotactic radiation therapy prostate cancer patients

The structured follow-up system was evaluated by assessing all prostate cancer patients (18 years or older, cT1-3 cN0 cM0) undergoing curative, primary stereotactic radiation therapy. The total dose was equal or higher than 36.25 Gy with more than 7 Gy applied per fraction.

All toxicities were reported following the CTCAE (Table 3). For all toxicities ≥ grade 3, relation to radiation therapy was documented from 06/2023 on. The causality between the use of radiation therapy and the documented symptoms was assessed as certain, probable, likely, possible, unlikely, conditional/unclassified or unassessable/unclassifiable, in analogy to the WHO/UMC causality categories commonly used in the field of pharmacovigilance.

The investigation was approved by the Local Ethics Committee of the Medical Faculty of the University

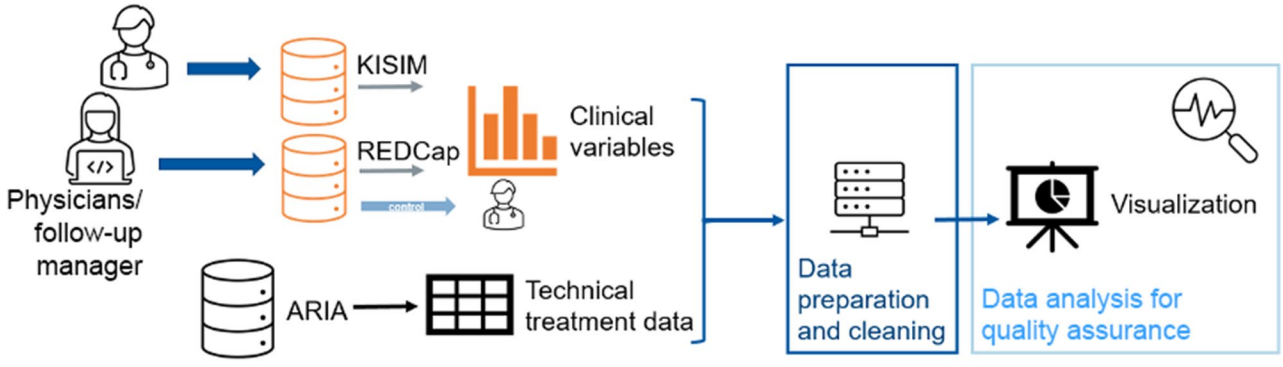

Fig. 2 Workflow for data visualization and analysis

of Zurich, University Hospital Zurich (BASEC-Nr. 2018 – 01794). The project was conducted in accordance with the Declaration of Helsinki, and patients were asked to provide a consent for scientific analysis. Patients refusing consent for scientific analysis were excluded.

Results

The ZH-CLASSIC project started in May 2020 and a training and introduction period was conducted between May and July 2021. The system was clinically implemented for all patients completing their treatment since May 2021. Until October 2024, a total of 4,515 individual patients, including 5,999 radiation therapy treatment courses, have been recorded in ZH-CLASSIC.

Resources

For development and implementation of ZH-CLASSIC, a project manager with a background in computer science was employed for one year, with the first 6 months in full time and then 50% (0.75 FTE), working in close collaboration with a clinical steering committee consisting of the clinical and research department leaders. For maintenance of ZH-CLASSIC, a follow-up manager (1 FTE) with a nursing background was employed.

The workflow of the physicians changed slightly in the way of reporting their findings, without a change in the time requirements. Physicians had to assign every patient to the corresponding follow-up care path. The required staffing resources for the maintenance of the follow-up care path for both physicians and the follow-up manager per year (mean from 2021 to 2024) were estimated (Table 1), with data collection from external sources proving to require the highest expenditure of time.

Table 1 Durations required for the maintenance of the follow-up care path for involved staff (physicians (P) and the follow-up manager (M)) per year (mean from 2021–2024) with estimated full-time equivalent (FTE)

Task	Staff	Time/patient (min)	#patients/year	h/year	FTE
Document baseline patient and tumor characteristics	M	35	1932	1127	0.61
Capture symptoms before RT	P	1.5	1932	48.3	0.03
Create care path	M	5	1932	161	0.09
Capture acute or late toxicities after RT	P	1.5	1932	48.3	0.03
Complete follow-up form including late toxicities	P	2	4200	140	0.08
Collect FU data from external sources	M	10	1800	300	0.17
Check completion of follow-up	M	4	3600	240	0.13
Total additional workload	P				0.13
	M				1.00

Compliance over time

To evaluate compliance for the follow-up care path within the department, the number of forms which were not created and completed directly by the physician, but were completed by the follow-up manager, were monitored. Overall, the proportion of follow-up forms which were created by the follow-up manager reduced over time (Fig. 3). Compliance increased from a mean of 54% forms created by the physicians in 2021 to 92% in 2024.

The follow-up manager double-checked that for each patient all necessary forms were present and that the data were consistent. This remained a relevant step to minimize missing information due to imperfect data capture in daily routine practice.

Overall, 12,414 (93.4%) individual follow-up tasks were completed, 377 (2.8%) were cancelled and 496 (3.7%) were in progress in October 2024. Follow-ups were cancelled because patients did not attend their appointments or were followed-up externally, but no follow-up information could be obtained from external physicians.

For all patients, the completion of each follow-up task in the corresponding follow-up forms was monitored. In the reported period, follow-up information was obtained and documented for 95.4% of all follow-ups. In total, 50.5% of all reported follow-ups were performed as an in-clinic visit, 7.0% via telephone and 42.5% as an external query. Follow-up information was missing for 4.6% of all follow-ups, with 3.0% resulting from in-clinic visits, 0.7% from telemedicine and 96.3% from external follow-ups. Missing information from external follow-ups occurred when no or only very limited information was provided despite multiple requests. Overall, information was missing for 0.3%, 0.5% and 11.0% of all completed clinical, telemedicine and external follow-ups, respectively. For 68 out of 4515 patients monitored in the follow-up care path, missing follow-ups were detected by our system and a process for a follow-up appointment for these patients was successfully initiated.

A change from a planned first clinical visit to a telemedicine or external request follow-up was performed in 10.0% and 22.0% of the patients upon individual decisions of the treating radiation oncologist.

Stereotactic radiation therapy prostate cancer patients

From May 2021 until May 2024, 221 patients were treated with definitive stereotactic body radiation therapy (SBRT) (Table 2). Ten patients were excluded because they had not provided consent for scientific analysis. Patients who underwent another, previous or nearly simultaneous radiation therapy course in the pelvic

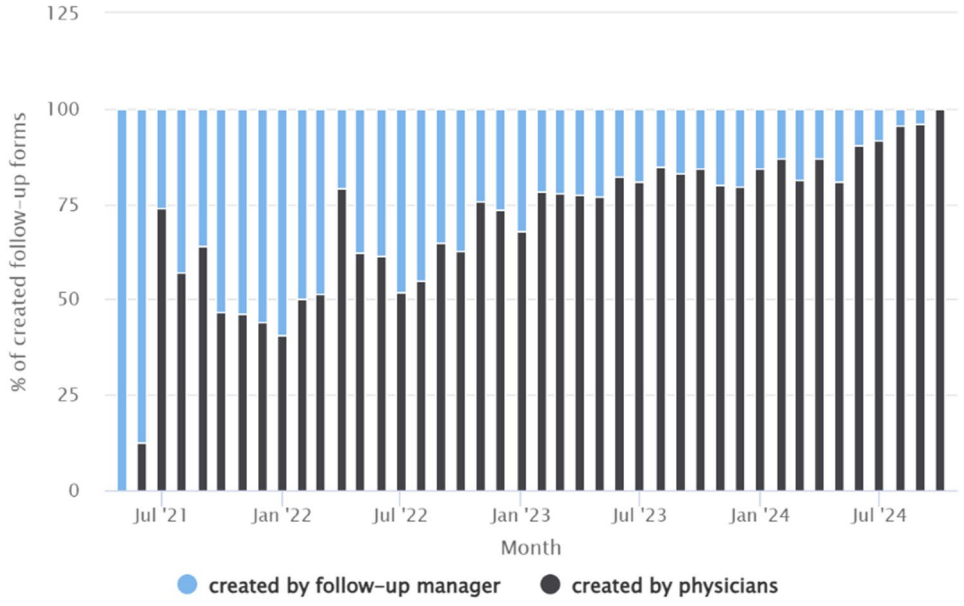

Fig. 3 Percentage of follow-up forms created by physicians or the follow-up manager

Table 2 Patient characteristics for stereotactic radiation therapy prostate cancer patients (NCCN = National comprehensive Cancer Network)

		# of patients
Total		209
Consent for scientific analysis	Approved	161
	Unknown	48
ECOG	0	164
	1	28
	2	2
	Unknown	15
Histology	Adenocarcinoma	208
	Unknown	1
T-stage	T1	10
	T1a	2
	T1b	1
	T1c	33
	T2	28
	T2a	32
	T2b	12
	T2c	41
	T3	6
	T3a	14
	T3b	13
	Not assessed	17
N-stage	0	209
M-stage	0	209
NCCN risk group	Very low	3
	Low	3
	Favorable Intermediate	88
	Unfavorable Favorable	34
	High	42
	Very high	33
	Unknown	6

region were excluded ($n = 2$). 209 patients were included, with an age of 71.7 ± 8.7 years (mean ± standard deviation) at radiation therapy start. For all patients, treatment indication was correctly documented according to current guidelines and published literature (e.g., National Comprehensive Cancer Network guidelines). Androgen deprivation therapy was not systematically documented in ZH-CLASSIC. In 200 patients (95.7%), the case was discussed in the interdisciplinary tumor board. Daily online adaptive SBRT was performed on the MRIdian system (ViewRay, Sunnyvale, CA) in all patients. The most common fractionation schemes used were 5 × 7.25 Gy every other day (70.8%) and 5 × 7.5 Gy weekly (29.2%), based on the treating physician's decision. A simultaneously integrated boost of 5 × 8 Gy to the CTV (clinical target volume) was applied in 28.7% of patients and to the dominant intraprostatic lesion in 20.0% of patients. All patients received all planned SBRT fractions.

Overall, 613 follow-ups were due since the introduction of ZH-CLASSIC, of which 596 (97.2%) were completed successfully, 6 (1.0%) were in-progress and 11 (1.8%) follow-ups tasks were cancelled as: patients could not be reached ($n = 2$), cancelled their appointment ($n = 1$), unknown or no follow-up within set time frame ($n = 8$). Out of the 596 completed follow-ups, the follow-up form was completed in for 555 cases (93.1%). Five patients had their follow-up care path terminated early as they did not wish to receive follow-up care ($n = 1$), received another radiation therapy ($n = 2$), moved abroad ($n = 1$) or two external follow-ups failed ($n = 1$).

Follow-up data was available for 191/195 of patients (97.9%) for the first 6 months after radiation therapy including information about biochemical tumor control

in 167/191 (87.4%) and toxicity in 189/191 (99.0%), for 86/105 (81.9%) at 6–14 months including information about biochemical tumor control in 85/86 (98.9%) and toxicity in 82/86 (95.3%), and for 34/39 (87.2%) within 14–26 months including information about biochemical tumor control in 31/34 (91.2%) and toxicity in 27/34 (79.4%).

Recurrences occurred after 7, 17, 32 and 34 months. Four patients had a local recurrence, thereof 1 patient with a distant progression. One patient died during the follow-up period, due to non-prostate cancer related reasons.

Maximum reported toxicities are shown in Table 3 and Fig. 4. For GU (genitourinary) toxicities, the most frequently reported CTCAE grade 2 or worse toxicities were urinary frequency ($n = 21$ (10.0%)) and urinary urgency ($n = 11$ (5.3%)). Average reported percentage of urinary frequency declined continuously after radiation therapy from 52.2% after radiation therapy to 6.0% after ≥24 months. For GI (gastrointestinal) toxicities, CTCAE grade 2 or worse toxicities were diarrhea ($n = 4$ (1.9%)) and proctitis ($n = 2$ (1.0%)). For general toxicities, Grade 2 or worse occurred for $n = 4$ (2.0%)). For erectile dysfunction, grade 2 or worse was reported in 25 (12.0%) patients. 13 patients (6.2%) experienced a grade ≥ 3 CTCAE toxicity at any time after their radiation therapy, presenting erectile dysfunction ($n = 11$), hematuria ($n = 1$), urinary tract obstruction ($n = 1$) and urinary urgency ($n = 1$). There were no toxicities higher than grade 3.

At 12 months, cumulative incidence rates of CTCAE grade 2 or worse GI and GU toxicity were 1.0% (95% CI 0–3.0, 1 event) and 5.3% (95% CI 0.6–9.8, 5 events) respectively. For the analysis of late toxicities, the time interval between 6- and 24-months post radiation therapy was analyzed (Fig. 5a and b).

The performance status according to ECOG score did not change from baseline to the first or second follow-up.

Discussion

Here we developed and evaluated a comprehensive quality assurance system for radiation oncology. We successfully established a system, which aggregates structured patient, disease and treatment characteristics and have added a structured follow-up protocol for all patients

Table 3 Worst CTCAE toxicity grades reported after radiation therapy (numbers indicate number of patients affected, with a total of 209 patients included)

Grade	0	1	2	3	4	not assessed
General toxicities eral toxicities						
Anemia	19					12
Dermatitis radiation	208	1				
Fatigue	161	46	2			
Lymphedema	209					
Lymphocyte count decreased	17					14
Nausea	209					
Neutrophil count decreased	17					14
Osteonecrosis	209					
Pain	189	19	1			
Peripheral neuropathy	209					
Platelet count decreased	17					14
Weight loss	207	1	1			
White blood cell count decreased	17					14
Genitourinary toxicities nitourinary toxicities						
Dysuria	139	65	5			
Hematuria	200	7	1	1		
Urinary frequency	73	115	21			
Urinary incontinence	185	21	2			1
Urinary tract obstruction	168	36	4	1		
Urinary urgency	127	70	11	1		
Gastrointestinal toxicities inal toxicities						
Constipation		2				
Diarrhea	187	18	4			
Fecal incontinence	206	3				
Proctitis	190	17	2			
Rectal hemorrhage	209					
Erectile dysfunction						
Erectile dysfunction	159	21	14	11		4

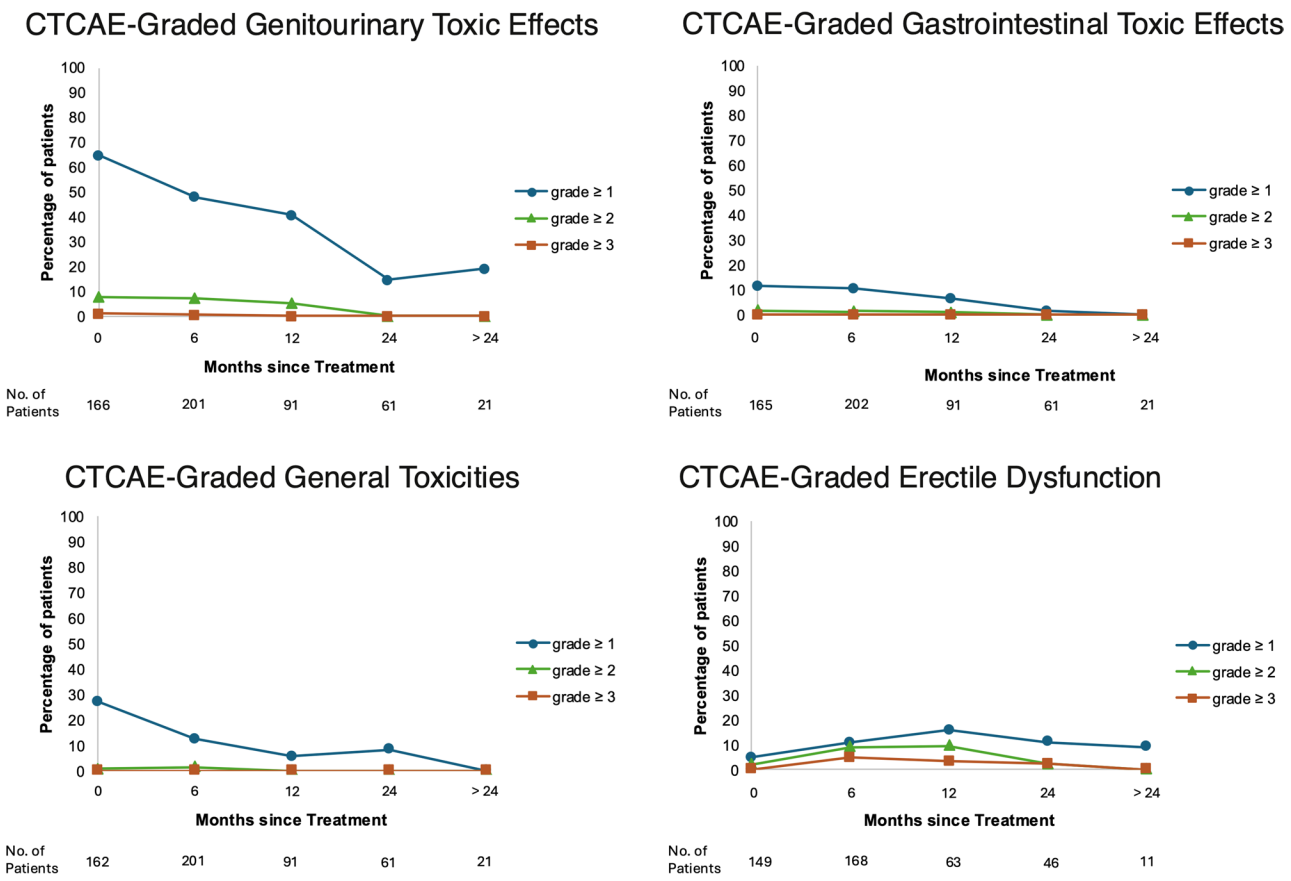

Fig. 4 Common Terminology Criteria for Adverse Events (CTCAE)–graded events: Genitourinary and Gastrointestinal Toxic Effects, General Toxicity and Erectile Dysfunction at 0, 6, 12, 24 or > 24 months after radiation therapy treatment

treated in routine practice, both for curative and palliative indications.

With more than 2,000 treatment courses included per year, the comprehensive follow-up system capturing real world outcome data shows enormous potential for quantitative data analysis, enabling prompt inquiries, a thorough evaluation of the treatment quality in comparison to predefined targets, predictive analytics and timely adaptions of therapeutic protocols in dependence of the observed treatment outcome. While the technical infrastructure required for the follow-up system is, in theory, available in every digitalized department and the exemplary care paths shown in this manuscript can be used as templates, the initial implementation and programming must be considered as substantial. Modifications of ZH-Classic to commonly available software systems such as Epic (Madison, Wisconsin, US) should be developed so that the proposed care pathways can be easily implemented in different settings. While advances in software development may render this step easier in the future, an employee (0.75 FTE) developed, programmed and coordinated the required infrastructure in close collaboration with the clinical steering committee for one year before patient inclusion was initiated. For the continuous data collection, the required personal resources were substantial, with one full time follow-up manager and a full time equivalent of 0.13 physicians. At the same time, synoptic reporting has been shown to effectively reduce time for the collection and integration of patient information in prostate cancer screening, while at the same time showing a positive effect on data quality parameters such as completeness, format, understandability and user satisfaction [11]. The benefit of an integrated data abstraction, aggregation, storage, curation and analytics software in the field of radiation oncology has already been shown, providing a tool to assess variations in radiation oncology practices and outcomes and determine gaps in radiation therapy quality delivered by different providers [12].

After the initial individual training, physicians showed a high compliance with the system, which was reflected by a high percentage of created follow-up forms and completion rates. This compliance did, however, show a decline in the first few months after the initial implementation. In the course of the analyzed period of three years, completion of the forms steadily rose to above 90%, with physicians getting used to the workflow and being trained by missing data points being continuously eliminated by repeated reminders and meetings with the

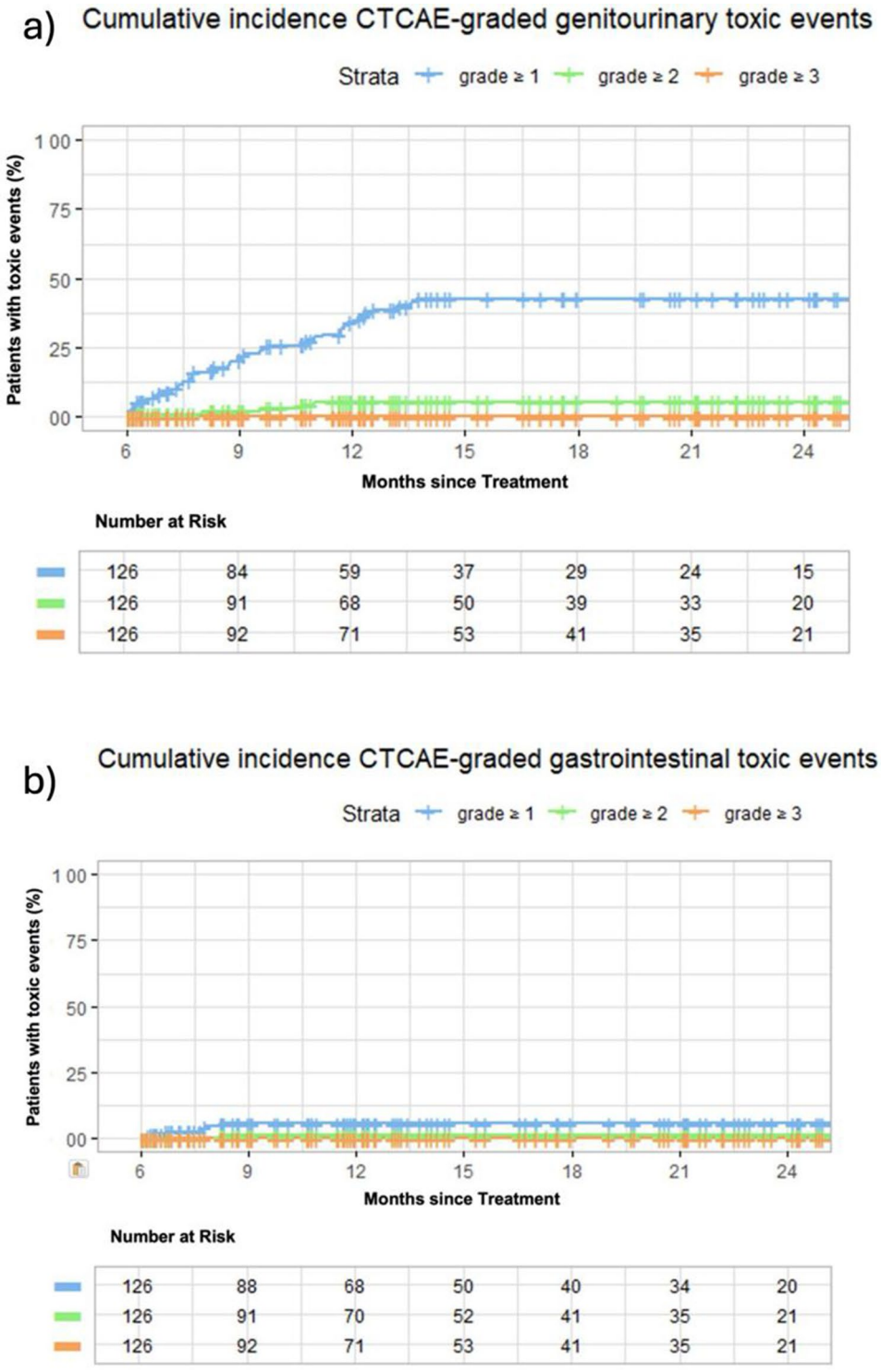

Fig. 5 **a**: Time to occurrence of first grade 1–3 CTCAE-graded genitourinary toxicity event between 6- and 24-months post-radiation therapy. **b**: Time to occurrence of first grade 1–3 CTCAE-graded gastrointestinal toxicity event between 6- and 24-months post-radiation therapy

follow-up manager. The benefit of educating oncologists on the importance of improving data collection has been shown for an oncology department aiming to certify for the quality oncology practice initiative. The department managed to surpass the quality threshold by evaluating potential causes for previously reported low performance and subsequent continuous education of the treating physicians [13]. This finding indicates that the full time

equivalent of the follow-up manager may be estimated too highly, as it represents the mean full time equivalent for the three analyzed years and will thus be lower for a continuously high compliance of the physicians.

As was to be expected, information in the follow-up forms showed a higher rate of completeness for in-clinic visits and telemedicine checkups, with a high majority of missing information originating from requests from other departments or institutions. While we hope that compliance with external physicians and departments will still increase over time with longer practice and better knowledge of the follow-up system on their part, this task will always represent a challenge, as externals may not fully see the benefits of the system in their daily routine, while the follow-up manager has limited leverage to ensure data completion. With all follow-up tasks being included in a care path and each task appearing automatically when a patient's follow-up was due, the implemented system reduced the workload of the follow-up manager. Within the system, absent follow-ups could be detected reliably.

Due to an individual decision of the treating radiation oncologist, the first follow-up appointment was conducted via telephone or as an external follow-up instead of an in person clinical visit in 10% and 22% of the cases. While this decision was made after prior contact with the patient and/or treating physician and taken in view of the patients' convenience and well-being, e.g., time constraints or insufficient performance status of the patient, quality of follow-up care may be lowered by insufficient data acquisition at this step. This may be of special concern for patients with a reduced performance status, as treatment related toxicities may be higher in these patients and require medical interventions [14]. To avoid this negative sequence of events, physicians should be advised to invariably follow the carefully predefined care paths and only deviate from them in exceptional circumstances, with the deviations reported in our system being too high.

The assessment of the plausibility of the proposed structured follow-up system by analyzing all prostate cancer patients undergoing curative primary stereotactic radiation therapy showed that the treatment indication was documented for 100% of the cases, ensuring a subsequent straightforward data analysis. All patients were treated using either 5×7.25 Gy every other day or 5×7.5 Gy weekly, with the patients at risk for more severe toxicities (high international prostate symptom score or prostate volume) being treated on a weekly basis [15–18]. In the current follow-up period of a maximum of 41 months, all but one of the 209 included patients were still alive. As the follow-up system did not automatically gather data about systemic therapy including androgen deprivation therapy, biochemical tumor control, while available, is not shown in this report. The system has since been updated to systematically include this information. CTCAE GU toxicity grade 2 was 12% and grade 3 1%, and thus lower or comparable to previously published data reporting a range of 23 – 43.4%, and 0 – 5.9%, respectively [15–17, 19–21]. This may be connected to the strict constraints on the urethra and mandatory use of a catheter for planning MRI, as well as all patients being adapted to the daily anatomy, which was not mandatory or possible in the other SBRT trials [15–17, 19–21]. The reported increase in urinary frequency showed a steep decline in the months after radiation therapy and can thus be regarded as an acute toxicity. CTCAE GI toxicity grade 2 was documented for 3% and grade 3 for 0% of the cases. This endpoint was thus lower or comparable to the previously published data reporting GI toxicities as 0 – 14.9% or 0 - <1% for grade 2 and 3, respectively [15–17, 19–21]. Paired with the performance status according to ECOG not changing from baseline, this data underlines the effectiveness and safety of daily adaptive treatment in not changing the patient's level of functioning during the studied period of time.

For prostate cancer patients, 97% of the follow-ups were performed, underlining the high compliance with the system. While follow-up data was available for 98% at 6 months, availability declined to 82% at 6–14 months, highlighting the difficulties with receiving data using external queries. Data completion increased at 14–26 months, where the care path indicated telemedicine follow-up. Information about toxicity and biochemical tumor control corresponded to the availability of the other follow-up data.

While the presented follow-up system, available on request from the authors, provides many benefits, the implementation in other departments may require an extensive preliminary workload, as software and hospital information systems vary. In this context, the future aim should be to provide different software packages that each department and institution can easily implement in their individual systems following an operating manual. By using common data elements, a structured and interoperable documentation of medical information could be achieved and information exchanged among different institutions [22].

Conclusions

The proposed follow-up system ZH-Classic allows for a structured and continuous documentation and analysis of the indication, treatment and outcome of radio-oncological cancer patients. This structured approach ensures data consistency, facilitates efficient, automated analyses and allows for a continuous tracking of treatment quality and outcome in comparison with predefined targets. Personal resources, especially during the implementation of the system, are high, but are expected to continuously decrease due to training and practice, as well as the observed high compliance of the involved personnel.

Appendix

Table 1 Minimum follow-up durations (in months) and follow-up modalities (C = Clinical, T = Telephone, Q = external request) for the different benign and oncological radiation therapy entities (SRT = Stereotactic radiation therapy, OMD = oligometastatic disease)

	6 W-3 M	6 M	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60	Comments
Curative primary radiation therapy	C	Q		T				C				Q				Q				C	Definitive RT of primary tumors. e.g. prostate, cervix, meningioma
Curative non-primary radiation therapy	C							T												T	Neo-/ adjuvant / additive RT
Local ablative, non-curative radiation therapy	C	Q		T		Q		Q		Q		Q		Q		Q		Q		Q	e.g. pancreas SBRT
Palliative radiation therapy	T			Q																	Symptom control, incl. palliative reirradiation for symptom control
Benign disease	T			T								T									Inflammatory disease: only after 3 months; Ossification prophylaxis: no appointments
OMD, reirradiation – internal aftercare	C	C	C	C	C (16)		C (20)	C		C		C		C		C		C		C	C: incl. PET
OMD, reirradiation - aftercare primarily via referring physicians	C	Q		T		Q		T		Q		T		Q		T		Q		T	C: incl. PET
Brain metastasis SRT – internal aftercare	C	C	C	C	C	C	C	C	C (28)	C (32)		C	C (40)	C (44)		C	C (52)	C (56)		C	Always incl. cMRI
Brain metastasis SRT - aftercare primarily via referring physicians	C	T	Q	T	Q	T	Q	T		Q		T		Q		T		Q		T	Always incl. cMRI
Head and neck tumors	C	Q	Q	C	Q	Q	Q	C		Q		C		Q		Q		Q		Q	Primary RT or adjuvant

Abbreviations

ZH-CLASSIC	Zurich Clinical Quality Assurance System in Radiation Oncology
FTE	Full-Time Equivalent
RT	Radiation Therapy
SBRT	Stereotactic Body Radiation Therapy
CTCAE	Common Terminology Criteria for Adverse Events
ECOG	Eastern Cooperative Oncology Group
CTV	Clinical Target Volume
PET	Positron Emission Tomography
SRT	Stereotactic Radiation therapy
OMD	Oligometastatic Disease
MRI	Magnetic Resonance Imaging
GI	Gastrointestinal
GU	Genitourinary
NCCN	National Comprehensive Cancer Network
WHO/UMC	World Health Organization/Uppsala Monitoring Centre

Author contributions

A.J.: Methodology, Software, formal analysis, data curation, visualization, writing review and editing M.Z-P.: Methodology, writing review and editing Je.Be.: Methodology, Investigation, writing review and editing Jé.Bo.: Methodology, writing review and editing M.A.: Writing review and editing S.C.: Writing review and editing S.S.: Writing review and editing J.W.: Writing review and editing N.A.: Conceptualization, writing review and editing, supervision M.G.: Conceptualization, writing review and editing, supervision S.T-L.: Conceptualization, writing review and editing, supervision M.M.: Conceptualization, Methodology, Formal analysis, Visualization, Writing - Original Draft, Visualization, supervision, project administration, writing review and editing.

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Data availability

No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate

Not applicable.

Competing interests

The authors declare no competing interests.

Author details

[1]Department of Radiation Oncology, University Hospital Zurich, Rämistrasse 100, Zürich 8091, Switzerland
[2]Department of Clinical Pharmacology and Toxicology, University Hospital of Zurich, Rämistrasse 100, Zürich 8091, Switzerland
[3]Department of Medical Oncology and Hematology, University Hospital of Zurich, Rämistrasse 100, Zürich 8091, Switzerland

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