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Research article

Continuous quality improvement project to reduce the downtime of medical linear accelerators: A case study at Zhejiang Cancer Hospital

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A R T I C L E I N F O

Keywords:
Medical linear accelerators
Quality control circle
Risk weight
Mean time to repair
Mean time between failure
Medical equipment management

A B S T R A C T

Objective: To analyse and continually improve existing issues in the quality improvement process of medical linear accelerators (LINACs) and enhance the quality control management of LINACs.
Methods: Data were collected from eight LINACs (sourced from three manufacturers) at Zhejiang Cancer Hospital using Excel diaries between January 2019 and December 2020. The data description and analysis were performed using the analytic hierarchy process, SPSSAU and Excel software, and mean-time-to-repair (MTTR)/mean-time-between-failure (MTBF) metrics. Continuous quality improvement was executed using the quality control circle (QCC) quality management method.
Results: After quality improvement, the risk frequency of 'LINAC down' events decreased by 43.63% and downtime was reduced by 40.45%. The weight of downtime risk improved by 73.69%. The MTTR recovery value increased by 31.90%, and MTBF reliability increased by 2.97 h. The simulation results demonstrated that the proposed quality improvement measures could effectively decrease the frequency and duration of downtimes, consequently extending the normal operational time of LINACs.
Conclusion: Transitioning from instant repair to preventative maintenance can enhance the operational efficiency of equipment and yield economic benefits for hospitals. The QCC method and the event risk evaluation model are effective in reducing the downtime of LINACs and improving their quality control management.

1. Introduction

Over the past decade, the incidence and mortality rates of malignant tumours in China have continued to rise. Studies indicate that approximately 70% of patients with malignant tumours necessitate radiotherapy during their multidisciplinary comprehensive treatment [1–4]. Currently, many provincial and municipal tertiary hospitals, as well as clinical institutions, in China are equipped with radiotherapy departments. Initially, these departments predominantly relied on Cobalt-60 machines and medical linear

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accelerators (LINACs). Maintenance of these devices was primarily performed through autonomous maintenance and engineering maintenance, undertaken by clinical medical engineers with assistance from manufacturers. However, this approach presented challenges, such as lengthy maintenance periods and low efficiency. The rapid advancements in clinical diagnosis, treatment, and scientific research have heightened the demands for quality control of medical equipment [5,6]. In comparison to the survey data from 2019, which showed that radiotherapy units in Chinese mainland counties (cities) had an average of 1.58 units per million population, the number of accelerators per capita in Zhejiang Province in 2020 (1.92 units per million population) remained below the minimum standard of 2–4 units per million population recommended by the World Health Organization (WHO) [7,8].

Linear accelerators represent the most advanced and widely used radiotherapy equipment in modern clinical settings. They generate high-energy X-rays or electron beams to irradiate tumours, thereby aiming to eradicate cancer cells [9]. However, LINACs are complex and sophisticated devices requiring regular maintenance and rigorous quality control to maintain their safety and precision. The downtime of LINACs can lead to substantial challenges for both patients and hospitals, including treatment delays or interruptions, diminished patient satisfaction, prolonged waiting times, and reduced revenue [10]. Therefore, minimising the downtime of LINACs and enhancing their quality control management are critical and pressing concerns for medical engineers and managers.

Existing solutions for reducing the downtime of medical LINACs chiefly comprise preventive maintenance (PM), corrective maintenance (CM), and predictive maintenance. Preventive maintenance involves scheduled maintenance tasks to prevent or mitigate equipment failures by replacing or repairing parts before they fail [11]. Corrective maintenance is a reactive form of maintenance undertaken after a failure has occurred, with the objective of restoring the equipment to its normal operating condition. Predictive maintenance, a proactive approach, utilises data analysis and machine learning techniques to monitor equipment conditions and predict potential failures before they occur. Each of these maintenance strategies has distinct advantages and disadvantages [12]. Preventive maintenance can lessen the frequency and severity of failures but may lead to increased costs and resource wastage. Corrective maintenance, although potentially saving on maintenance costs and time, can heighten the risk and impact of failures. Predictive maintenance aims to optimise maintenance scheduling and enhance equipment performance, yet it requires advanced technical skills and complex data processing [13].

This paper analyses and discusses factors that influence the frequency of LINAC downtime, focusing on improving the quality control management of medical equipment, thereby alleviating the pressure on equipment configuration demands. We propose an innovative approach to reduce LINAC downtime and enhance quality control management, employing the quality control circle (QCC) method and the event risk evaluation model.

The primary contributions and innovative aspects of this paper are threefold. First, we apply the QCC method and the event risk evaluation model to reduce the downtime of LINACs and enhance their quality control management. This approach is novel in the field, as, to our knowledge, no prior studies have employed these specific methods for such purposes. Second, our research utilises an extensive and detailed data set comprising eight LINACs from three different manufacturers based in Zhejiang Cancer Hospital between January 2019 and December 2020. This data set is comprehensive, encompassing a wide array of types and causes of equipment failures, alongside their impacts on the operational reliability and efficiency of the LINACs. Finally, we report substantial improvements in several key metrics – specifically, the event risk frequency, event risk weight, mean time to repair (MTTR), and mean time between failures (MTBF) – following the implementation of our proposed quality improvement measures.

2. Information and methodology

2.1. General information

Between January 2019 and December 2020, a study was conducted involving 643 ‘LINAC down’ events, with equipment manufacturers also included as participants [14–16]. The inclusion criteria included the following: 1) LINAC faults, 2) the involvement of eight LINACs from three manufacturers, and 3) the application of varied improvement measures for different faults. We collected 330 event logs between January and December 2019 as the control group and 309 event logs from the same months in 2020 as the observation group. The eight LINACs in the study included one Primus-Plus model (Siemens Medical Systems, Erlangen, Germany), equipped with an 82-leaf multileaf collimator (MLC), one Precise Beam Modulator model (Elekta, Stockholm, Sweden), one Precise EPID model (Elekta), one Precise model (Elekta), and one Synergy IGRT model (Elekta), all equipped with an 80-leaf MLC. Additionally, there was one Clinac 23EX (Varian Medical Systems, Palo Alto, CA, USA) and two Trilogy models (Varian Medical Systems), all equipped with the Millennium™ 120-leaf MLC. These units varied in their years of service: one had been used for 5 years, four for 5–10 years, and three for 10–15 years, averaging 8.5 ± 2.875 years. The fault occurrences in 2019 comprised 173 functional, 52 parametric, 49 software, 21 sudden, 13 operational, 13 avoidable, and 9 allowable faults. In 2020, there were 142 functional, 41 parametric, 71 software, 25 sudden, 10 operational, 10 avoidable, and 10 allowable faults. These data sets were analysed using the Kolmogorov–Smirnov test and the F-test [17,18], revealing that the sample data from different groups displayed a normal distribution and consistent volatility ($P > 0.05$).

Medical LINACs are sophisticated devices that employ electromagnetic waves to accelerate electrons to high velocities. These electrons are then directed towards a target material, such as tungsten or gold, to generate high-energy X-rays or electron beams. Various components, including MLCs, beam modulators, and electronic portal imaging devices, are utilised to shape and modulate these beams. This modulation allows the beams to conform to the specific shape and size of a tumour. Linear accelerators are capable of delivering varying types and doses of radiation at different depths within the tumour, thereby minimising damage to the surrounding healthy tissues.

Linear accelerators are extensively used in contemporary radiotherapy for treating a wide range of cancers, including lung, breast, prostate, head and neck, and brain cancers. Furthermore, they can be integrated with other advanced technologies, such as image-guided radiotherapy, intensity-modulated radiotherapy, stereotactic radiosurgery, and stereotactic body radiotherapy. These integrations enhance the precision and accuracy of radiation delivery, considerably improving treatment outcomes.

2.2. Methods

2.2.1. Survey

In terms of survey content and building upon the analysis and discussions around the quality control of the MLC of a LINAC from 2019, we formed a quality improvement team consisting of eight engineers. Each engineer was proficient in the QCC activities, grounded in QCC methodology [19–25]. The QCC method is a participative approach to quality management involving a group of workers who voluntarily identify, analyse, and solve work-related problems. The method comprises seven steps: 1) problem identification, 2) problem analysis, 3) goal setting, 4) solution generation, 5) solution implementation, 6) solution evaluation, and 7) standardisation. For continuous quality improvement in LINAC operations, the control group adopted a routine management approach involving PM every 6 months and biannual maintenance by the manufacturer's engineers. We also established a quality index evaluation system for equipment downtime events, utilising the QCC. This system included nine quality control indicators and a weighted formula [26–30]. The quality control indicators included the following: 1) downtime, 2) spare parts cost, 3) failure recurrence, 4) operational errors, 5) uncontrollable factors, 6) weight allocation, 7) event frequency, 8) event risk weight, and 9) MTTR/MTBF ratio. The weighted formula was employed to calculate the score of each indicator based on the event risk evaluation model.

2.2.2. Investigation

To investigate the event data from the eight LINACs produced by three different manufacturers used at our hospital during 2019, we collected and analysed the log content, which included the causes and durations of equipment downtime. The events were categorised into seven types: software, functional, parametric, sudden, avoidable, allowed, and operational failures. The QCC group members identified existing problems based on the five main factors impacting the quality management of equipment: people, machines, materials, methods, and environment. Subsequently, quality control steps were systematically developed.

The causes of downtime were classified into 11 categories: parts loss, circuit board faults, parameter deviation, software suspension, improper operation, power interruption, abnormal temperature and humidity in the computer room, lack of responsibility, unclear specifications, load overuse, and communication failure (Fig. 1). During discussions, engineers highlighted the importance of scheduling equipment maintenance on weekdays rather than weekends to enhance working efficiency and reduce equipment failure rates. Additionally, feasibility analyses and verification of the improvement measures were conducted [31–33].

2.2.3. Statistical methods

The analytic hierarchy process (AHP) was employed to construct the downtime events evaluation index system to develop an event-risk evaluation hierarchical structure model. MATLAB R2018a (version: 9.4, release date: March 2018) was utilised for data processing and quantitative analysis.

Six indices were derived from a questionnaire survey, focusing on the importance of the evaluation factors of events. The fault-risk evaluation index system's assessment matrix was constructed by comparing downtime, spare parts cost, failure recurrence, operational errors, uncontrollable factors, and weight allocation (Table 1) [33–36]. The correlation degree analysis method determined the correlation level between different indicators, and MATLAB was used again to ascertain the matrix's consistency level and calculate the weight values (Fig. 2). Relative importance was represented on a scale from 1 to 9, where 1 indicated equal importance of both indicators, 3 denoted slight superiority of the first indicator over the second, and 9 signified substantial superiority of the first indicator over the second. The weight of each index was determined by multiplying each row vector of the assessment matrix with the normalised column vector. These vectors were summed and averaged to derive the final weight vector, which was used to establish the relationship between the weights and predict event trends. The formula for calculating the weight vector w is given as $w = (A \bullet n)/\sum(A \bullet n)$, where A is the assessment matrix and n is the normalisation result of the column vectors [37–45].

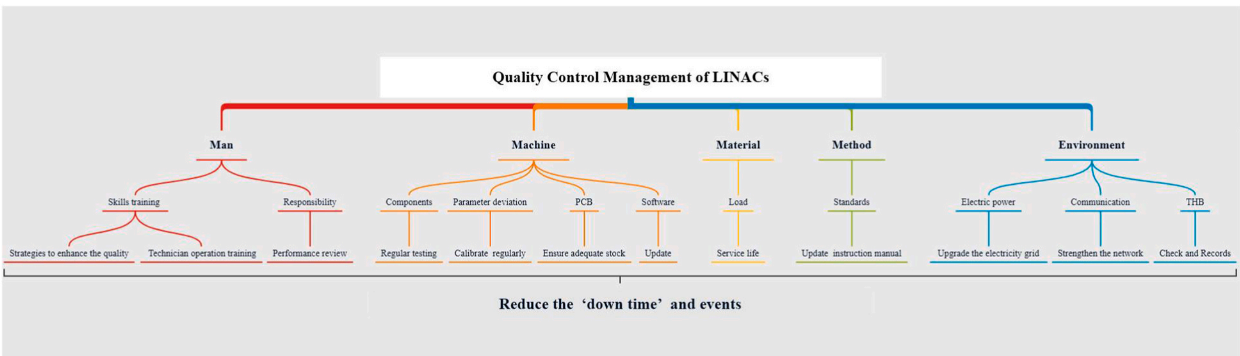

Fig. 1. Quality control management of LINACs. Note: LINACs, linear accelerators; PCB: Printed Circuit Board; THB: Temperature, Humidity, Bias.

Table 1
Judgment matrix A.

$$A = \begin{bmatrix} 1 & 2 & 1 & \frac{1}{3} & 2 & 3 \\ 1 & 1 & 1 & \frac{1}{2} & 1 & 2 \\ 1 & 1 & 1 & \frac{1}{2} & 2 & 3 \\ 2 & 2 & 2 & 1 & 3 & 5 \\ \frac{1}{2} & 1 & \frac{1}{2} & \frac{1}{3} & 1 & 2 \\ \frac{1}{3} & \frac{1}{2} & \frac{1}{2} & \frac{1}{5} & 1 & 1 \end{bmatrix}$$

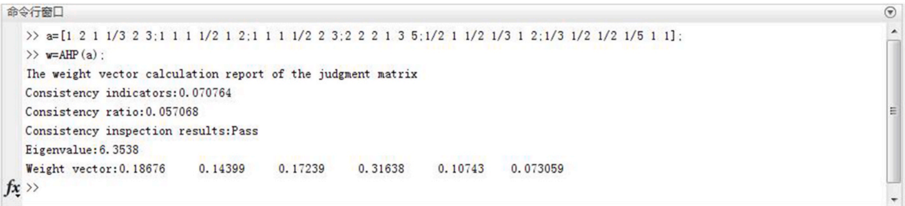

Fig. 2. Weight vector test.

2.2.4. Data analysis

Data processing software included Microsoft Excel (version 15; release date 2013) and SPSSAU (version 23.0; release date 2023). An independent-sample *t*-test was utilised to examine the difference between X (reasons for the downtime) and Y (downtime event), and a homogeneity of variance test was applied to assess whether notable differences existed in the data fluctuation (i.e. the standard deviation) of each group. The equipment operation reliability parameters, MTTR (denoting the time elapsed from the initial detection of a fault point to the resumption of operation) and MTBF (indicating the expected duration between one fault and the next in a normal operational process) were employed to evaluate the efficacy of the continuous quality improvement measures [46,47].

3. Results

3.1. Analysis of general data

The analysis of event data in the control group (Table 2) revealed 173 cases of functional faults, 47 cases of parametric faults, 41 cases of software faults, and 29 cases of sudden faults among the seven types of events identified. The frequency of these four fault types constituted 88% of the events (Fig. 3). Furthermore, 85% of events were attributed to component loss (43%), circuit board failure (19%), parameter deviation (14%), and software discontinuation (9%) (Fig. 4). The MTTR for events with unclear specifications was 533.33 min, whereas MTTRs for wear of parts and temperature, humidity, and bias (THB) conditions were 75.44 and 66.67 min, respectively. The MTTR for events related to lack of responsibility was the lowest, recorded at 28.33 min. Notably, component failure and circuit board failure showed direct proportionality to the frequency of events and the associated downtime. These two factors accounted for 62% of the event frequency and 65.91% of the downtime. In line with the 80/20 rule (also known as the Pareto principle), these two factors were identified as key areas for improvement, with the target improvement set at 3.80%.

Table 2
Test of normality.

Name	Sample Size	Average value	Standard deviation	Skewness	Kurtosis	Kolmogorov-Smirnov test	
						Cohen's d	P
Subjects	2	1.500	0.707	null	null	0.260	0.733
Name of device	9	5.000	2.739	0.000	−1.200	0.101	0.998
Downtime Event	2	319.500	14.849	null	null	0.260	0.733
Fault Classification	7	4.000	2.160	0.000	−1.200	0.108	0.999
4M1E	5	3.000	1.581	0.000	−1.200	0.136	0.991
Causes	11	6.000	3.317	0.000	−1.200	0.090	0.999
strategy	12	6.500	3.606	0.000	−1.200	0.089	0.998

*$p < 0.05$; **$p < 0.01$.

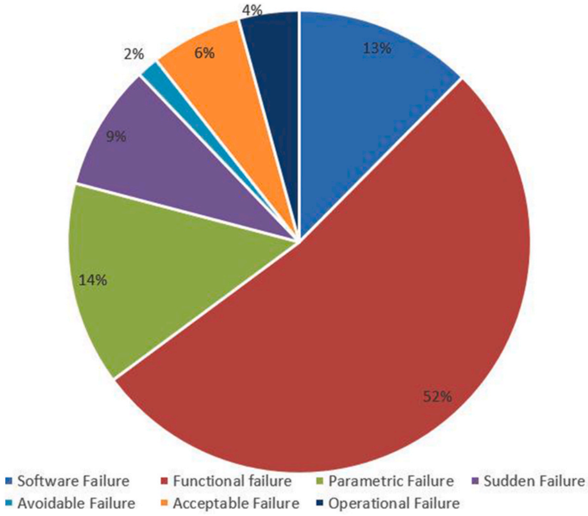

Fig. 3. Proportion of downtime events in the control group.

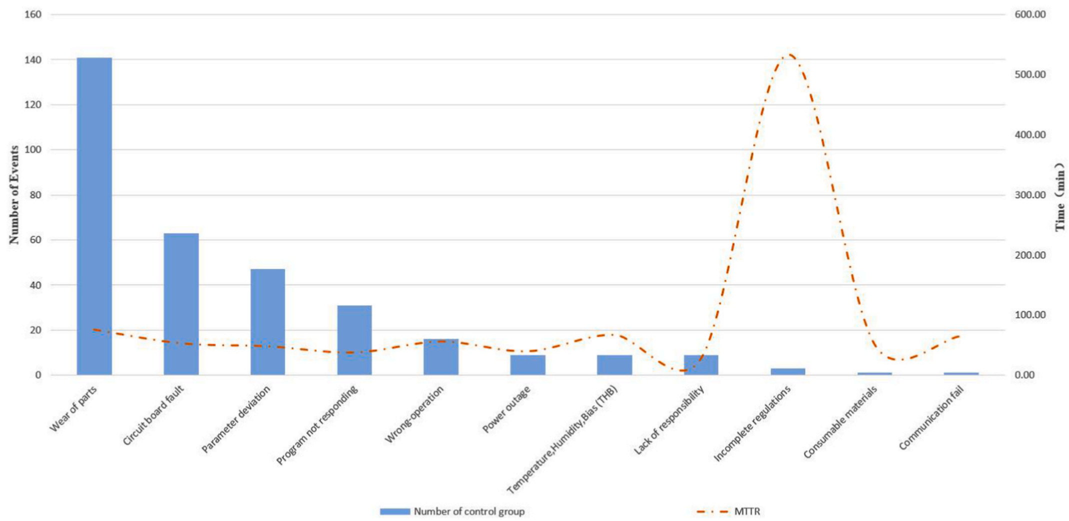

Fig. 4. The cause and time of the control group.

Table 3
Risk weights for events.

Goals	First level indicator	Weights	secondary index	Weights
			Parameter deviation	0.01946
			Lack of responsibility	0.04153
			Wrong-operation	0.10258
	Man	0.08060	THB	0.10099
	Machine	0.06208	Power outage	0.07626
Fault risk assessment	Material	0.03121	Circuit board fault	0.06889
	Method	0.13891	Incomplete regulations	0.13891
	Environments	0.08815	Consumable materials	0.20578
			Program not responding	0.02682
			Communication fail	0.07961
			Wear of parts	0.07801

Note:Temperature.Humidity, Bias(THB).

3.2. Comparison of quality improvement measures

3.2.1. Risk evaluation indicators for downtime events

As presented in Table 3, in life-threatening events, the highest weight factor assigned was 0.31638, followed by 0.18676 for downtime interrupting the patient's treatment progress and 0.17239 for instances of the same failure frequency with a higher weight factor. The weight was multiplied by the corresponding score to calculate the fault risk assessment score and identify the direction for improvement. The analysis indicated that the weight for excess use load was 0.20578 and for unclear specifications was 0.13891, highlighting these as the principal factors contributing to a high risk of downtime events. The target for improvement was established at 0.68%.

3.2.2. Statistical analysis and comparison

Table 4 presents the results of the independent-sample *t*-test employed to examine the differences between downtime durations and their causes. The findings indicated that the differences in downtime and causes across the comparison samples were significant ($P < 0.05$). Specifically, the comparison between downtime durations and causes yielded a significance level of 0.05 ($t = 2.509$, $P = 0.012$), with the mean downtime duration of the control group (64.17 min) being substantially higher than that of the observation group (44.99 min). Additionally, the control group exhibited a larger standard deviation (119.55) compared with the observation group (63.35).

As depicted in Fig. 5, the implementation of continuous quality improvement measures resulted in a declining trend in the frequency of events attributed to lack of responsibility, THB conditions, circuit board faults, and incomplete regulations. These factors were identified as the primary causes of functional and parametric faults, which constituted 88% of the event frequency and 65.91% of the downtime in the control group. The target for improvement in these areas was set at 3.80%, with an actual improvement achievement of 3.15%. Conversely, the frequency of events related to parameter deviation, communication failure, power outages, consumable materials, and program non-responsiveness exhibited a slight increase, but the associated downtime decreased. These factors were mainly responsible for software and sudden faults. The improvement target for these issues was 0.68%, with the actual improvement recorded at 0.11%. The improvement measures for these causes included updating software versions, enhancing communication skills, installing uninterruptible power supplies, regularly replacing consumable materials, and restarting programs.

Table 5 details the results from the analysis of variance (ANOVA), which was conducted to assess the differences in downtime across 11 identified causes of events. No notable differences in downtime were observed for wear of parts, THB conditions, lack of responsibility, incomplete regulations, consumable materials, or communication failure. However, substantial differences were noted in the cases of circuit board failure, parameter deviation, program non-responsiveness, incorrect operation, and power outages.

3.2.3. Equipment reliability description

The MTTR and MTBF metrics were employed to evaluate the operational reliability of the LINACs. As indicated in Tables 6 and 7, the MTTR decreased from 64.173 to 44.994 min, and the MTBF increased from 10.521 to 13.449 h following the implementation of continuous quality improvement measures. The current event risk frequency value was 6.08%, with the target set at 3.80% and the actual improvement achieved at 3.15%. Similarly, the current risk weight value was 0.72%, the target value was 0.68%, and the actual improvement value was 0.11%.

Fig. 6 demonstrates that in the observation group, there were 26 cases with spare parts costing less than 10,000 RMB, 61 cases costing between 10,000 and 50,000 RMB (a decrease of 25.6% compared with the control group), 1 case costing between 50,000 and 150,000 RMB (a 75% decrease compared with the control group), 1 case costing between 150,000 and 300,000 RMB, and no cases costing over 300,000 RMB (a 100% decrease compared with the control group).

This study focused on reducing the frequency and downtime of events and improving the quality of LINAC control management, primarily through the use of the AHP to construct an event risk evaluation model. The 80/20 principle was applied to determine the frequency of events, with wear of parts and circuit board failure identified as key improvement targets. The event risk-weighted improvement goals included addressing incomplete regulations and consumable materials. The effectiveness of the improvement measures was evaluated using incident management metrics (MTTR/MTBF) [48,49]. A comparison between the control and observation groups revealed a 43.62% improvement in event risk frequency, a 73.69% improvement in event risk weight, a 29.89% increase in MTTR recovery for equipment events, and a 2.93-h increase in MTBF reliability.

According to the QCC analysis, among the 11 causes of events, wear of parts accounted for 66.4% of functional events and 19.6% of circuit board failures, with parameter deviation events being the primary cause of functional faults. The status quo value for event risk

Table 4
Results of T-test analysis of two groups.

T test analysis results				
	Downtime vs.Cause (mean ± SD)		t	p
	Control Group (n = 330)	Experimental Group (n = 309)		
Downtime (min)	64.17 ± 119.55	44.99 ± 63.35	2.509	0.012*
Cause	7.40 ± 3.78	6.73 ± 4.03	2.151	0.032*

*$p < 0.05$,**$p < 0.01$.

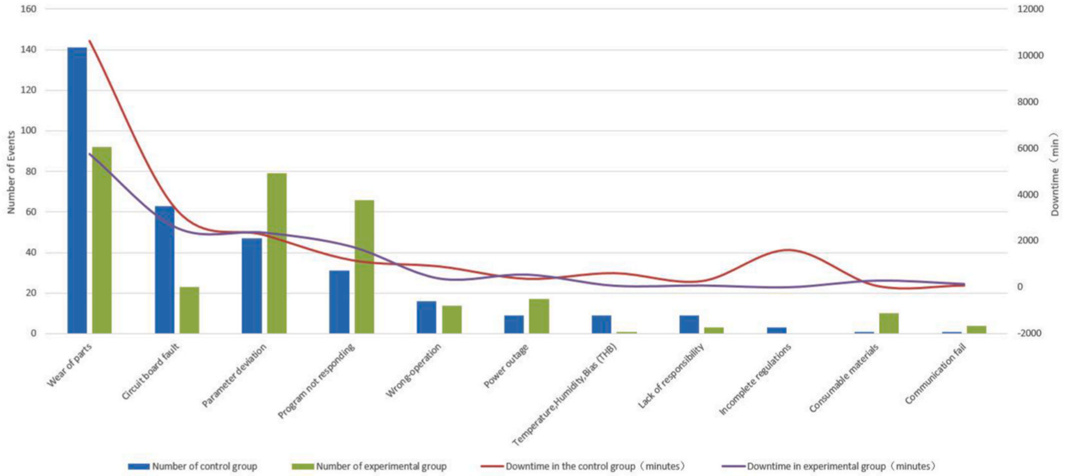

Fig. 5. Comparison of the frequency and downtimes of two groups after.

Table 5
Variance analysis of downtimes after improvement.

Analysis of variance				
	Downtime by cause (mean ± SD)		F	p
	Control group (n = 141)	Experimental group (n = 92)		
Wear of parts	75.44 ± 136.37	62.52 ± 81.15	0.670	0.414
Circuit board fault	52.70 ± 30.44	111.30 ± 139.06	10.067	0.002**
Parameter deviation	47.77 ± 27.91	29.82 ± 15.79	21.276	0.000**
Program not responding	37.42 ± 12.17	26.52 ± 9.61	22.817	0.000**
Wrong-operation	55.63 ± 32.19	26.79 ± 7.50	10.685	0.003**
Power outage	39.44 ± 8.46	32.06 ± 6.14	6.555	0.017*
Temperature，Humidity，Bias	66.67 ± 35.27	65.00±null	0.002	0.965
Lack of responsibility	28.33 ± 9.01	25.00 ± 5.00	0.357	0.563
Incomplete regulations	533.33 ± 785.45	0.00±null	0.346	0.616
Consumable materials	50.00±null	28.50 ± 11.80	3.020	0.116
Communication fail	65.00±null	53.75 ± 57.50	0.031	0.872

*$p < 0.05$,**$p < 0.01$.

Table 6
Equipment operation reliability parameters.

	MTTR (Min)	MTBF(Hour)
Control group	64.173	10.521
Experimental group	44.994	13.449

Note: mean time to repair (MTTR), mean time between failure (MTBF).

Table 7
Results of improvement.

	Current situation value	Target value	Value of improvement	Magnitude of improvement
Risk frequency	6.08%	3.80%	3.15%	43.62%
risk weights	0.72%	0.68%	0.11%	73.69%

frequency decreased from 6.08% to 3.15% following interventions, surpassing the improvement target of <3.8% [50]. The establishment of the event risk assessment system was aimed at achieving predictability for certain events and reducing the improvement value of the risk weight from 0.72% to 0.11%.

The test analysis results indicated that the comparison samples, assessed at different times and for various causes, exhibited significant differences in downtime events ($P < 0.05$). The one-way ANOVA revealed that the improvement measures substantially reduced circuit board faults, parameter deviation, program non-responsiveness, incorrect operation, and power outages ($P < 0.05$).

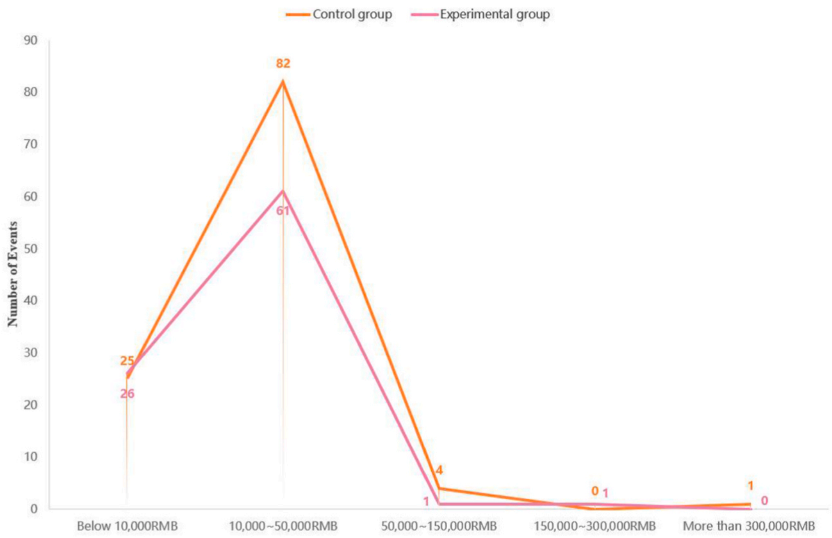

Fig. 6. Distribution of spare parts costs.

There were notable differences between the two groups in these respects. Although parts loss, wear of parts, total harmonic distortion, lack of responsibility, and incomplete regulations did not demonstrate significant differences ($P > 0.05$), these four factors were identified as substantially different upon the direct comparison of the frequency and duration of downtime events. The investigation into consumable materials and communication failures revealed no notable differences. The primary causes identified were external environmental factors, notably the increased frequency of mains instability and abnormal ambient temperatures in the machine room due to air conditioning failure.

Analysis of the operational reliability parameters of the data equipment demonstrated that the MTTR of the observation group was more efficient, and the MTBF reliability was higher. Additionally, the average number of patients undergoing radiotherapy per device increased by 84 in 2020. These findings suggest that the quality control management measures proposed in this study effectively reduce the frequency of downtime events and extend the operational duration of LINACs.

In 2020, the International Agency for Research on Cancer published a report on the global cancer burden. This report revealed that, assuming there are 4.4 million new cancer cases per year, 50% of these cases require radiotherapy, with each accelerator treating approximately 500 patients annually [51]. As of 2022, the number of radiotherapy machines per million people in Zhejiang Province, China, stood at 1.92, while the number of simulators was 83. This figure indicates that the gap between the actual number of radiotherapy machines in Zhejiang Province and the WHO recommendation of 2–4 machines per million people has narrowed [51–55]. However, due to the uneven distribution of resources, there remains a notable disparity in the utilisation rates of LINACs across different regions.

Furthermore, maintenance personnel constitute only 2.6% of radiation therapy practitioners. Notably, there is a considerable discrepancy between the actual allocation of maintenance engineers in Zhejiang Province and the International Atomic Energy Agency's (IAEA) recommendation. The IAEA guidelines suggest one engineer per two megavoltage units, or one engineer for a megavoltage unit and a simulator if the equipment is maintained in-house (Table 5) [56,57].

4. Conclusions

By observing and analysing the results of this quality improvement project, we can gain a deeper understanding of the operational situation of LINACs and the implementation of effective measures. This understanding is crucial for extending the lifecycle of medical devices, particularly in the realm of radiotherapy equipment. Considering the allocation of resources and the uneven distribution of regional populations, the quality control management of medical equipment can substantially alleviate the pressure on medical institutions' radiotherapy services.

In this study, we proposed a novel approach to reduce the downtime of LINACs and enhance their quality control management, utilising the QCC method and the event risk evaluation model. Our findings offer valuable insights and recommendations for medical engineers and managers on strategies to decrease LINAC downtime and bolster quality control management. Furthermore, we discussed the implications and limitations of our study, suggesting avenues for future research.

Ethics approval and consent to participate

This study was conducted in accordance with the Declaration of Helsinki and approved by the Research Ethics Committee of Zhejiang Cancer Hospital. No patient or public participation.

Consent for publication

Not applicable.

Data availability statement

Data will be made available on request.

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Obtaining financing

None.

CRediT authorship contribution statement

Qi-Peng Lu: Writing – review & editing, Writing – original draft, Validation, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Yong Wu:** Writing – review & editing, Writing – original draft, Validation, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Xiao-Dong Mao:** Writing – review & editing, Writing – original draft, Resources, Methodology, Investigation, Data curation, Conceptualization. **Hua-Jun Wan:** Writing – review & editing, Writing – original draft, Resources, Project administration, Methodology, Investigation, Data curation, Conceptualization. **Jian Shao:** Writing – review & editing, Writing – original draft, Resources, Methodology, Investigation, Data curation, Conceptualization. **Qi-Kai Yu:** Writing – review & editing, Writing – original draft, Project administration, Methodology, Formal analysis, Data curation. **Wei Zhang:** Writing – review & editing, Writing – original draft, Methodology, Investigation, Conceptualization. **Yue Zhao:** Writing – review & editing, Writing – original draft, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Ci-Yong Wang:** Writing – review & editing, Writing – original draft, Methodology, Investigation, Formal analysis, Data curation, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Not applicable.

References

[1] Latest Global Cancer Data Cancer Burden Rises to 19.3 Million New Cases and 10.0 Million Cancer Deaths in 2020, EB/OL, 2021-06-28. https://www.iarc.fr/fr/news-events/latest-globalcancer-data-cancer-burden-rises-to-19-3-million-new-cases-and-100-million-cancer-deaths-in-2020.
[2] H. Sung, J. Ferlay, R.L. Siegel, et al., Global cancer statistics 2020: GLOBOCAN Estimates of incidence and mortality worldwide for 36 cancers in 185 countries, CA Cancer J Clin 71 (3) (2021) 209–249, https://doi.org/10.3322/caac.21660.
[3] X.Z. Chen, Y.X. Liu, C.Y. Lu, Y.T. Yang, J. Zhu, T. Zhu, X.D. Cheng, Analysis of the development status of cancer radiothera-py in Zhejiang Province in 2022, China Cancer 32 (6) (2023) 475–481, https://doi.org/10.11735/j.issn.1004-0242.2023.06.A011.
[4] Y. Zhang, J.L. Yi, W. Jiang, et al., Survey on the basic information of personnel and facilities of radiotherapy in Chinese mainland in 2019, China Cancer 29 (5) (2020) 321–326, https://doi.org/10.11735/j.issn.1004-0242.2020.05.A001.
[5] D. Zhang, M. Liao, T. Liu, Implementation and promotion of quality control circle: a starter for quality improvement in Chinese hospitals, Risk Manag. Healthc. Pol. 13 (2020) 1215–1224, https://doi.org/10.2147/RMHP.S261998. Published 2020 Aug 18.
[6] L. Swanson, Linking maintenance strategies to performance, Int. J. Prod. Econ. 70 (3) (2001) 237–244, https://doi.org/10.1016/S0925-5273(00)00067-0.
[7] IAEA, Setting up a Radiotherapy Programme Clinical Medical Physics Radiation Protection and Safety Aspects Z, Wien IAEA, 2008.
[8] Expert Group for the 14(th)-Five-Year Plan of Radiotherapy Equipments Development and Allocation, J. Qiu, B. Yang, S. Chai, L.H. Wang, F.Q. Zhang, Infrastructure of radiation oncology in China: a national survey for development and allocation of radiotherapy equipment during the 14 th Five-Year Plan period, Chinese Journal of Radiation Oncology 31 (5) (2022) 405–409, https://doi.org/10.3760/cma.j.cn113030-20211022-00426.
[9] B.W. Raaymakers, A.J. Raaijmakers, A.N. Kotte, D. Jette, J.J. Lagendijk, Integrating a MRI scanner with a 6 MV radiotherapy accelerator: dose deposition in a transverse magnetic field, Phys. Med. Biol. 49 (17) (2004) 4109–4118, https://doi.org/10.1088/0031-9155/49/17/019.
[10] C.E. Agnew, S. Esteve, G. Whitten, W. Little, Reducing treatment machine downtime with a preventative MLC maintenance procedure, Phys. Med. 85 (2021) 1–7, https://doi.org/10.1016/j.ejmp.2021.04.012.
[11] M. Molęda, B. Małysiak-Mrozek, W. Ding, V. Sunderam, D. Mrozek, From corrective to predictive maintenance-A review of maintenance approaches for the power industry, Sensors 23 (13) (2023) 5970, https://doi.org/10.3390/s23135970. Published 2023 Jun 27.
[12] M. Pecht, J. Gu, Physics-of-failure-based prognostics for electronic products, Trans. Inst. Meas. Control 31 (3–4) (2009) 309–322, https://doi.org/10.1177/0142331208092031.
[13] P. Tamilselvan, P. Wang, Failure diagnosis using deep belief learning based health state classification, Reliab. Eng. Syst. Saf. 115 (2013) 124–135, https://doi.org/10.1016/j.ress.2013.02.022.
[14] J.D. Hoisak, G.G. Kim, T.F. Atwood, T. Pawlicki, Operational insights from the longitudinal analysis of a linear accelerator machine log, Cureus 13 (6) (2021) e16038, https://doi.org/10.7759/cureus.16038. Published 2021 Jun 29.

[15] J. Li, Y. Mao, J. Zhang, Maintenance and quality control of medical equipment based on information fusion technology, Comput. Intell. Neurosci. 2022 (2022) 9333328, https://doi.org/10.1155/2022/9333328. Published 2022 Oct 13.

[16] B. Liu, L. Tong, Y. Liu, Z. Guo, Maintenance and management technology of medical imaging equipment based on deep learning [retracted in: contrast media mol imaging. 2023 jul 19;2023:9806074], Contrast Media Mol. Imaging 2022 (2022) 6361098, https://doi.org/10.1155/2022/6361098. Published 2022 Jul 1.

[17] M. Aslam, O.H. Arif, R.A.K. Sherwani, New diagnosis test under the neutrosophic statistics: an application to diabetic patients, BioMed Res. Int. 2020 (2020) 2086185, https://doi.org/10.1155/2020/2086185. Published 2020 Jan 22.

[18] R. Debelak, I. Koller, Testing the local independence assumption of the rasch model with Q3-based nonparametric model tests, Appl. Psychol. Meas. 44 (2) (2020) 103–117, https://doi.org/10.1177/0146621619835501.

[19] C. Moustakis, F. Ebrahimi Tazehmahalleh, K. Elsayad, F. Fezeu, S. Scobioala, A novel approach to SBRT patient quality assurance using EPID-based real-time transit dosimetry : a step to QA with in vivo EPID dosimetry, Strahlenther. Onkol. 196 (2) (2020) 182–192, https://doi.org/10.1007/s00066-019-01549-z.

[20] T.Y. Lim, I. Dragojević, D. Hoffman, E. Flores-Martinez, G.Y. Kim, Characterization of the HalcyonTM multileaf collimator system, J. Appl. Clin. Med. Phys. 20 (4) (2019) 106–114, https://doi.org/10.1002/acm2.12568.

[21] C.B. Saw, S. Li, Basic therapeutic medical physics, Hematol. Oncol. Clin. N. Am. 33 (6) (2019) 915–928, https://doi.org/10.1016/j.hoc.2019.08.009.

[22] A.H. Zamzam, A.K.I. Al-Ani, A.K.A. Wahab, et al., Prioritisation assessment and robust predictive system for medical equipment: a comprehensive strategic maintenance management, Front. Public Health 9 (2021) 782203, https://doi.org/10.3389/fpubh.2021.782203. Published 2021 Nov 17.

[23] C.N. Kabat, D.L. Defoor, P. Myers, et al., Evaluation of the Elekta Agility MLC performance using high-resolution log files, Med. Phys. 46 (3) (2019) 1397–1407, https://doi.org/10.1002/mp.13374.

[24] Halcyon: efficiency, simplicity and consistency. Accessed: March 9, 2020: https://www.varian.com/products/radiotherapy/treatment-delivery/halcyon.

[25] K. Liu, Z. Xu, X. Wang, Y. Chen, X.D. Mao, The application of quality control circle to improve the quality of samples: a SQUIRE-compliant quality-improving study, Medicine (Baltim.) 99 (21) (2020) e20333, https://doi.org/10.1097/MD.0000000000020333.

[26] N. Youssef, W.A. Hyman, A medical device complexity model: a new approach to medical equipment management, J. Clin. Eng. 34 (2) (2009) 94–98, https://doi.org/10.1097/JCE.0b013e31819fd711.

[27] N.H. Abd Rahman, A.K. Ibrahim, K. Hasikin, N.A. Abd Razak, Critical device reliability assessment in healthcare services, J Healthc Eng 2023 (2023) 3136511, https://doi.org/10.1155/2023/3136511. Published 2023 Feb 20.

[28] Z. Ruan, L. Fang, S. Xie, Design and development of medical equipment lifecycle management system based on structured information flow architecture, Zhongguo Yi Liao Qi Xie Za Zhi 44 (5) (2020) 463–466, https://doi.org/10.3969/j.issn.1671-7104.2020.05.019.

[29] International Electrotechnical Commission, Medical electrical equipment, Part 1: general requirements for safety, Rep. IEC 601-1, IEC, Geneva (1988).

[30] International Electrotechnical Commission, Medical electrical equipment, Part 2-29, particular requirements for the safety of radiotherapy simulators, Rep. IEC 601-2-29, IEC, Geneva (1999).

[31] N. Defourny, L. Perrier, J.M. Borras, et al., National costs and resource requirements of external beam radiotherapy: a time-driven activity-based costing model from the ESTRO-HERO project, Radiother. Oncol. 138 (2019) 187–194, https://doi.org/10.1016/j.radonc.2019.06.015.

[32] M. Ridgway, Optimizing our PM programs, Biomed. Instrum. Technol. 43 (3) (May/June 2009) 244–254.

[33] J. Joseph, S. Madhukumar, A novel approach to data driven preventive maintenance scheduling of medical instruments, in: Proc. Of Intr. Conf. on Systems in Medicine and Biology. IEEE Eng. Med. Biol. Soc., India, 2010, pp. 193–197.

[34] Y.M. Li, J.W. Gu, H.J. Zhang, F. Wu, X.G. Yang, J.C. Yuan, Y.Y. Xu, Development of overall health risk model and its convergent validity and reliability assessment, Chinese Journal of Health Management 7 (2) (2013) 112–116, https://doi.org/10.3760/cma.j.issn.1674-0815.2013.02.012.

[35] L.M. Wroe, T.A. Ige, O.C. Asogwa, et al., Comparative Analysis of Radiotherapy Linear Accelerator Downtime and Failure Modes in the UK, Nigeria and Botswana [published correction appears in Clin Oncol (R Coll Radiol). 2023 May;35(5):e347], Clin. Oncol. 32 (4) (2020) e111–e118, https://doi.org/10.1016/j.clon.2019.10.010.

[36] R.A. Ion, P.J. Sonnemans, T. Wensing, Reliability prediction for complex medical systems, Annual Reliability and Maintainability Symposium (2006) 368–373, https://doi.org/10.1109/RAMS.2006.1677402.

[37] L.A. Hadidi, M.A. Khater, Loss prevention in turnaround maintenance projects by selecting contractors based on safety criteria using the analytic hierarchy process (AHP), J. Loss Prev. Process. Ind. 34 (2015) 115–126, https://doi.org/10.1016/j.jlp.2015.01.028.

[38] A. Kokangül, U. Polat, C. Dag, A new approximation for riskassessment using the AHP and Fine Kinney methodologies, Saf. Sci. 91 (2016) 24–32, https://doi.org/10.1016/j.ssci.2016.07.015.

[39] I. Otay, B. Öztayşi, S. Çevik, C. Kahraman, Multi-expert performance evaluation of healthcare institutions using an integrated intuitionistic fuzzy AHP&DEA methodology, Knowl. Base Syst. 133 (2017) 90–106, https://doi.org/10.1016/j.knosys.2017.06.028.

[40] F. Rajabi, M. Jahangiri, F. Bagherifard, S. Banaee, P. Farhadi, Strategies for controlling violence against health care workers: application of fuzzy analytical hierarchy process and fuzzy additive ratio assessment, J. Nurs. Manag. 28 (4) (2020) 777–786, https://doi.org/10.1111/jonm.12989.

[41] H. Alvaro, S. Salas, Gilder Cieza Altamirano, Rafaél Artidoro Sandoval Núñez, Analytical solution to a third-order rational difference equation, Sci. World J. (2023) 8971590.

[42] X. Chen, Z. Chai, J. Shang, B. Shi, Multiple-relaxation-time finite-difference lattice Boltzmann model for the nonlinear convection-diffusion equation, Phys. Rev. E 104 (3–2) (2021) 035308, https://doi.org/10.1103/PhysRevE.104.035308.

[43] H. Sheng, C. Yang, PFNN: a penalty-free neural network method for solving a class of second-order boundary-value problems on complex geometries[J], J. Comput. Phys. 428 (2020) 110085, https://doi.org/10.1016/j.jcp.2020.110085.

[44] S.H. Streipert, G.S.K. Wolkowicz, An alternative delayed population growth difference equation model, J. Math. Biol. 83 (3) (2021) 25, https://doi.org/10.1007/s00285-021-01652-9. Published 2021 Aug 7.

[45] J. Han, A. Jentzen, W. E, Solving high-dimensional partial differential equations using deep learning, Proc Natl Acad Sci U S A. 115 (34) (2018) 8505–8510, https://doi.org/10.1073/pnas.1718942115.

[46] K. Sun, X. Feng, A second-order network structure based on gradient-enhanced physics-informed neural networks for solving parabolic partial differential equations (Basel), Entropy 25 (4) (2023) 674, https://doi.org/10.3390/e25040674. Published 2023 Apr 18.

[47] X.L. Wang, H. Wang, H.Y. Xu, The existence of solutions of q-difference-differential equations, SpringerPlus 5 (2016) 556, https://doi.org/10.1186/s40064-016-2179-4. Published 2016 May 4.

[48] M.S. Huq, B.A. Fraass, P.B. Dunscombe, et al., The report of Task Group 100 of the AAPM: application of risk analysis methods to radiation therapy quality management, Med. Phys. 43 (7) (2016) 4209, https://doi.org/10.1118/1.4947547.

[49] T. Pawlicki, M. Whitaker, A.L. Boyer, Statistical process control for radiotherapy quality assurance, Med. Phys. 32 (9) (2005) 2777–2786, https://doi.org/10.1118/1.2001209.

[50] A. Al-Bashir, et al., Building medical devices maintenance system through quality function deployment, Jordan Journal of Mechanical and Industrial Engineering 25 (1) (February 2012) 25–36.

[51] Report on cancer: setting priorities, investing wisely and providing care for all Geneva. World Health Organization. 20.

[52] J.Y. Lang, P. Wang, D.K. Wu, H.L. Zhong, B. Lu, X.W. Deng, L.H. Wang, An investigation of the basic situation of radiotherapy in China's Mainland in 2015, Chinese Journal of Radiation Oncology 25 (6) (2016) 541–545, https://doi.org/10.3760/cma.j.issn.1004-4221.2016.06.001.

[53] R.S. Zheng, S.W. Zhang, K.X. Sun, R. Chen, S.M. Wang, L. Li, H.M. Zeng, W.Q. Wei, J. He, Cancer statistics in China, 2016, Chin. J. Oncol. 45 (3) (2023) 212–220, https://doi.org/10.3760/cma.j.cn112152-20220922-00647.

[54] B.J. Slotman, B. Cottier, S.M. Bentzen, G. Heeren, Y. Lievens, W. van den Bogaert, Overview of national guidelines for infrastructure and staffing of radiotherapy. ESTRO-QUARTS: work package 1, Radiother. Oncol. 75 (3) (2005) 349–354, https://doi.org/10.1016/j.radonc.2004.12.005.

[55] World Health Organization, Quality Assurance in Radiotherapy, WHO, Geneva, 1988.
[56] Technical Specifications of Radiotherapy Equipment for Cancer Treatment, World Health Organization WHO and International Atomic Energy Agency IAEA, 2021.
[57] I. Aslan, Ranking and comparing occupational health and safety system performance indicators in hospitals by the analytic hierarchy process, Int. J. Occup. Saf. Ergon. 28 (3) (2022) 1937–1947, https://doi.org/10.1080/10803548.2021.1943167.