ARTIGO DE INVESTIGAÇÃO
RECEBIDO: 06 DEZEMBRO 2024; ACEITE: 24 MARÇO 2025
https//doi.org/10.31877/on.2025.51.03
e0291

NURSING BEST PRACTICE RECOMMENDATIONS FOR INTRAVESICAL INSTILLATION IN BLADDER CANCER: ADAPTATION TO THE PORTUGUESE ONCOLOGICAL CARE

Recomendações de boas práticas de enfermagem para instilação intravesical no cancro da bexiga: Adaptação para o cuidado oncológico português

AUTORES:

Filipa Isabel Quaresma Santos Ventura[1]
Concetualização, Investigação, Metodologia, Curadoria dos dados, Validação, Redação do rascunho original, Recursos, Redação – revisão e edição

Vânia Maria Azevedo Ribeiro[2]
Concetualização, Investigação, Metodologia, Curadoria dos dados, Validação, Redação do rascunho original, Redação – revisão e edição

Inês Gonçalves Vicente Claro[3]
Concetualização, Investigação, Metodologia, Curadoria dos dados, Validação, Redação do rascunho original, Redação – revisão e edição

Armando Luís Teixeira dos Santos Silva[4]
Concetualização, Investigação, Metodologia, Curadoria dos dados, Validação, Redação do rascunho original, Redação – revisão e edição

Ana Rita Águas Afonso Silva[3]
Concetualização, Investigação, Metodologia, Administração do projeto, Supervisão, Validação, Redação – revisão e edição

Susana Cláudia Fernandes Gonçalves Marques[5]
Concetualização, Investigação, Metodologia, Curadoria dos dados, Validação, Redação do rascunho original, Redação – revisão e edição

Maria Cecília Magalhães Girão[6]
Concetualização, Investigação, Metodologia, Curadoria dos dados, Validação, Redação do rascunho original, Redação – revisão e edição

Cristina Maria Oliveira Santos[7]
Concetualização, Investigação, Metodologia, Curadoria dos dados, Validação, Redação do rascunho original, Redação – revisão e edição

Raquel Chemela[8]
Concetualização, Investigação, Metodologia, Curadoria dos dados, Validação, Redação do rascunho original, Redação – revisão e edição

Maria Esmeralda Reis Barreira[5]
Concetualização, Investigação, Metodologia, Administração do projeto, Supervisão, Validação, Redação – revisão e edição

ABSTRACT

The study aimed to translate and adapt best practice recommendations for intravesical instillation of antineoplastic therapy by the European Association of Urology Nurses to the Portuguese oncological context. The work followed the ADAPTE methodology, involving three phases (preparation, adaptation, and finalisation), including external review using the Delphi method.

The translation and adaptation resulted in terminological standardisation and the exclusion of elements misaligned with the national context. Recommendations that did not reach consensus within the working group (n=16) were externally evaluated by expert nurses in intravesical antineoplastic therapy from various oncological contexts identified by intentional and snowball sampling (N=19 Round I, N=16 Round II). Four initial recommendations did not reach consensus; two were eliminated, and the remaining were evaluated in a second round.

This study successfully adapted the recommendations to the Portuguese context, promoting evidence-based practices. Validation by an expert panel confirms their relevance and applicability, strengthening oncological care in Portugal.

KEYWORDS: Administration, Intravesical; Bacillus Calmette–Guérin; Evidence-Based Practice; Mitomycin; Oncology Nursing.

RESUMO

O estudo teve como objetivo traduzir e adaptar as recomendações de boas práticas para a instilação intravesical de terapêutica antineoplásica da Associação Europeia de Enfermeiros de Urologia para o contexto oncológico português. Foi utilizada metodologia ADAPTE (preparação, adaptação e finalização) incluindo revisão externa pelo método Delphi.

A tradução e adaptação cultural resultaram na padronização terminológica e exclusão de elementos não alinhados com o contexto nacional. As recomendações que não alcançaram consenso dentro do grupo de trabalho (n=16) foram avaliadas externamente por enfermeiros peritos em terapia antineoplásica intravesical de vários contextos oncológicos identificados por amostragem intencional e em bola de neve (n=19 Fase I, n=16 Fase

[1] Unidade de Investigação em Ciências da Saúde: Enfermagem (UICISA:E), Escola Superior de Enfermagem de Coimbra (ESEnfC), Coimbra, Portugal

[2] ULS Gaia e Espinho, Vila Nova de Gaia, Portugal

[3] ULS Algarve – Unidade de Portimão, Portimão, Portugal

[4] Hospital de Dia do Centro Oncológico da ULS de TMAD, Vila Real, Portugal

[5] Oncology Nursing Research Unit IPO Research Center (CI-IPOP), Portuguese Oncology Institute of Porto (IPO Porto)/Porto Comprehensive Cancer Centre (Porto.CCC) & RISE@CI-IPOP (Health Research Network): Porto, PT

[6] CUF Açores, Lagoa, Portugal

[7] Serviço de Hematologia B/UTH, ULS Coimbra, Coimbra, Portugal

[8] IPO Lisboa, Lisboa, Portugal

Autor/a de correspondência:
Filipa Ventura
filipaventura@esenfc.pt

II). Quatro recomendações iniciais não alcançaram consenso; duas foram eliminados e os demais foram avaliados em segunda fase.

Este estudo adaptou as recomendações ao contexto português, promovendo práticas baseadas em evidências. A sua validação confirma a relevância e aplicabilidade, fortalecendo os cuidados oncológicos em Portugal.

PALAVRAS-CHAVE: Administração Intravesical; Bacillus Calmette–Guérin; Prática Baseada na Evidência; Mitomicina; Enfermagem Oncológica.

Introduction

In oncology, where therapies evolve rapidly, evidence-based practice is essential. Intravesical instillation, a key treatment for non-muscle invasive bladder cancer, is subject to significant variability in clinical practice, impacting its safety and effectiveness. A national round table of experts identified discrepancies across clinical settings, prompting the formation of a working group to review and standardise best practice recommendations for intravesical instillation.

Background

Bladder cancer is the 10th most common cancer worldwide, with approximately 573,000 new cases and 213,000 deaths annually. It is more prevalent in men, with an incidence rate of 9.5 per 100,000, nearly four times higher than in women[1].

In Portugal, bladder cancer is a significant health concern, particularly among males. According to the Global Cancer Observatory's 2022 data, bladder cancer ranks as the fourth most common cancer in Portuguese men, following prostate, colorectal, and lung cancers. Specifically, there were 2,660 new cases reported among males, accounting for 7.0% of all male cancer diagnoses. In contrast, bladder cancer is less prevalent among females, not appearing in the top five cancers for women in Portugal. When examining mortality, bladder cancer does not rank among the top three causes of cancer-related deaths in Portugal for either sex. However, its incidence remains notable, underscoring the importance of targeted prevention and treatment strategies[2].

Intravesical instillation is a key treatment for non-muscle invasive bladder cancer (NMIBC), which accounts for 70-80% of bladder cancer cases. Administering therapeutic agents directly into the bladder via a catheter ensures high local drug concentration with minimal systemic absorption, significantly reducing tumour recurrence and progression. This localized treatment minimizes side effects and maximizes efficacy, improving patient outcomes and quality of life[3, 4].

The primary agents used in intravesical instillation are Bacillus Calmette-Guérin (BCG) and Mitomycin-C. BCG, an immunotherapy, activates the immune system to attack bladder cancer cells, reducing recurrence and delaying progression, and is the gold standard for high-risk NMIBC[5]. Mitomycin-C, a chemotherapeutic, inhibits DNA synthesis, effectively reducing recurrence in intermediate-risk NMIBC, especially when BCG is unsuitable[6]. Together, these agents provide a comprehensive approach to treating bladder cancer.

Variability in practice directly affects outcomes, with studies showing that deviations from standard protocols increase tumour recurrence, progression, and complications such as infections and bladder irritation[3, 7]. Inconsistent use of personal protective equipment (PPE) and preparation areas also exposes healthcare workers to hazardous drugs, posing occupational health risks[8]. Standardizing practices is essential to ensure high-quality care and protect both patients and providers.

Standardized guidelines for intravesical instillation are essential to address the variability in clinical practice.

Evidence-based guidelines, like those from the European Association of Urology Nurses (EAUN), offer comprehensive recommendations for preparation, administration, and monitoring of intravesical therapy[9]. These guidelines aim to harmonize practices across healthcare settings, ensuring consistent, high-quality care for all patients. They also facilitate provider training, improving competency and confidence in administering treatments[4]. Adherence to these guidelines enhances treatment efficacy, reduces adverse events, and protects both patients and staff.

Research Question

This study aims to adapt the Nursing Best Practice Recommendations for Intravesical Instillation of Antineoplastic Therapy, developed by the EAUN[9], for use in Portuguese oncological care. The objectives are I) to translate and culturally adapt the recommendations for the Portuguese context, and II) to evaluate them through expert review in Portuguese urological oncological care. The goal is to preserve the integrity of the original guidelines while ensuring their relevance and applicability for nurses and oncology patients in Portugal, addressing the research question: how can the EAUN Best Practice Recommendations be adapted and evaluated for effective use in Portuguese oncological care?

Methodology

This methodological multi-method study follows the adapted ADAPTE approach (Amer et al., 2015), consisting of 12 steps to ensure the recommendations' integrity and applicability in Portuguese oncological care. A working group of expert nurses in intravesical antineoplastic therapy (with 3 to 20 years of experience) from five clinical contexts across mainland Portugal conducted the study.

Translation and Adaptation Process

Preparation Phase

A search for best practices in intravesical instillation of antineoplastic agents yielded no national results, but the European Association of Urology Nurses (EAUN) Best Practice Recommendations were identified internationally[9]. Developed by a multidisciplinary team, these guidelines followed a rigorous process involving specialist nurses, urologists, and safety representatives. The recommendations, based on the Oxford Centre for Evidence-based Medicine's grading system, integrate scientific knowledge, nursing experience, patient perspectives, and available resources into evidence-based practice.

Before this study began, permission was obtained from the original authors to adapt the recommendations for Portuguese oncological care. An update of the document is planned for 2025.

Adaptation Phase

This phase involved translating the document from English to European Portuguese while ensuring semantic and conceptual equivalence and occurred February to September 2024. Two working group members both fluent in English and native Portuguese speakers, shared the translation task. To ensure accuracy, all group members individually reviewed the translated version in a shared document, assessing its congruence with the original version and the relevance and applicability of the recommendations within the Portuguese context. They identified ambiguities and inconsistencies, which were systematically analysed in multiple joint meetings. Through these discussions, cultural, structural, and health policy barriers and facilitators were identified, and consensus was reached. An external review of the recommendations that did not reach consensus among working group members was conducted using the Delphi method in March and April 2024.

Finalisation and Documentation

The modified recommendations were reviewed for relevance and accuracy, ensuring alignment with the originals, and then integrated into the final document. A plan for implementation, evaluation, and monitoring was developed. The finalisation and documentation occurred from October to December 2024.

Delphi Methodology

The external review followed the Delphi method for its structured and iterative approach to gathering expert perspectives[10].

Expert nurses in intravesical antineoplastic therapy were invited to participate in the review panel through intentional snowball sampling. Each working group member reached out to their professional network to identify potential participants with relevant expertise, ensuring a diverse representation of professionals actively engaged in this field. The selection of experts was guided by established principles. Benner[11] defines expertise as the ability to intuitively grasp complex problems, distinguishing essential elements without being distracted by irrelevant details. Complementarily, the Portuguese Nursing[12] emphasizes that expert knowledge is fundamentally derived

from clinical experience, reinforcing the practical competencies essential for high-quality care in intravesical instillation.

Participants were selected based on their direct involvement in intravesical instillation and their ability to to provide meaningful contributions to the adaptation process, ensuring both representativeness and competence for valid results. Professional or academic degrees were not criteria for inclusion or exclusion. As recommended, we aimed to include 10 to 15 experts from diverse clinical contexts across Portugal, ensuring a breadth of professional experience and institutional representation.

Nurses who accepted the invitation received a confidential and anonymous link to the questionnaire, which compiled the recommendations that lacked consensus. No incentives were provided. Participants answered demographic questions and rated their agreement (0-10) and each recommendation's relevance/applicability (1-5). An open field allowed suggestions, ensuring both quantitative and qualitative feedback. The threshold for expert consensus was set at 75% agreement (votes ≥8) for acceptance, acknowledging the iterative nature of Delphi rounds in refining and validating the adapted recommendations[10, 13].

Responses were analysed using descriptive statistics to identify consensus and divergence. Based on the first round's feedback, recommendations were revised for a second round. To quantify expert consensus on relevance and applicability, the mean (M) and standard deviation (SD) for each recommendation's scores were calculated in both rounds. To assess the reliability of expert ratings, an Intraclass Correlation Coefficient (ICC: Two-Way Mixed Model, Consistency) was computed in Round I, where multiple recommendations were rated. This model was selected as it is appropriate when a fixed group of raters evaluates multiple items, aligning with established methodologies for inter-rater reliability assessment[14]. ICC values were interpreted following established thresholds[15], where ICC < 0.50 indicates poor reliability, 0.50–0.75 represents moderate reliability, 0.75–0.90 indicates good reliability, and values ≥ 0.90 represent excellent reliability. These categories provide a standardized approach for evaluating the consistency of expert ratings.

The final Delphi phase provided panel members with a summary of the collective opinions, including justifications for decisions. This allowed participants to review their responses considering the group consensus, resulting in the final, adapted recommendations.

Results

Translation and Cultural Adaptation

The two working group members fluent in English and native Portuguese speakers, who shared the translation task, had 38 years old and 40 years old, and 12 and 4 years of experience in oncology nursing. After reviewing the entire document, the Working Group integrated comments into the final version, ensuring linguistic and content coherence. Terminology was standardized (e.g., *paciente* to *utente*), and elements misaligned with the Portuguese context were excluded.

Bladder cancer incidence and NMIBC risk categorization were updated[1], along with procedure norms following EU-OSHA guidelines[16]. Discussions also addressed administration times, therapeutic regimens, and drug preparation methods.

Sections specific to the USA and other European contexts were removed to create a document tailored to the needs and clinical practice of nurses in Portugal, promoting its effective implementation.

The recommendations were adapted for the Portuguese oncological context, addressing medication preparation, protective equipment, treatment schemes for Mitomycin C and BCG, patient positioning, and professional training. Among these, sixteen recommendations did not reach consensus among working group members and were subsequently evaluated using the Delphi methodology (**Table 1** – supplementary file).

eDelphi

In the first Delphi round, 19 experts participated: 63% were nurses, 21% were specialist nurses, and 16% were nurse managers (Table 2). Regarding academic qualifications, 74% held a bachelor's degree and 26% a master's degree (Table 3). Nurses had a mean professional experience of 22.26 years (SD = 6.95), with a median of 20 years and a mode of 19 years. Their experience in the current clinical context had a mean of 14.05 years (SD = 6.53), with a median of 13 years and a mode of 19 years. The range of professional experience spanned 13 to 42 years, while experience in the current clinical context ranged from 4 to 30 years (Table 4).

Table 2. Professional title of the experts participating in Rounds 1 and 2

PROFESSIONAL TITLE	ROUND 1, N=19 N (%)	ROUND 2, N=16 N (%)
Nurse	12 (63)	7 (44)
Specialist Nurse	4 (21)	5 (31)
Nurse manager	3 (16)	4 (25)
Total	19	16

Table 3. Academic degree of the experts participating in Rounds 1 and 2

ACADEMIC DEGREE	ROUND 1, N=19 N (%)	ROUND 2, N=16 N (%)
Bachelor's Degree	14 (74)	13 (81)
Master's Degree	5 (26)	3 (19)
Total	19	16

Table 4. Professional experience of the experts participating in Rounds 1 and 2

STATISTIC	ROUND I		ROUND II	
	OVERALL	CURRENT CONTEXT	OVERALL	CURRENT CONTEXT
Mean (SD)	22.26 (6.95)	14.05 (6.53)	25.94 (9.93)	16.69 (12.65)
Median	20	13	24	12
Mode	19	19	19	40
Range (Min-Max)	13-42	4-30	14-42	2-20

In the second round, 16 nurses participated: 44% were nurses, 31% specialist nurses, and 25% nurse managers (Table 2). Academically, 81% held a bachelor's degree and 19% a master's degree (Table 3). Nurses had a mean professional experience of 25.94 years (SD = 9.93), with a median of 24 years and a mode of 19 years. Their experience in the current clinical context had a mean of 16.69 years (SD = 12.65), with a median of 12 years and a mode of 40 years. The range of professional experience spanned 14 to 42 years, while experience in the current clinical context ranged from 2 to 40 years (Table 4).

In the first round, significant contributions led to consensus on 12 recommendations, with discrepancies in four (Table 5, see supplementary file). Except for recommendations 4 and 5, all received applicability and relevance ratings above 3.5, with a minimum agreement of 63% for recommendation 9. Recommendations 4 and 5 were eliminated due to a lack of consensus above 75%. The reliability analysis yielded ICC = 0.898, 95% CI [0.189 – 0.559], $p < 0.001$, indicating good to excellent reliability in expert evaluations. One item was removed from the analysis due to zero variance in ratings.

Recommendation 4 (21%), suggesting that BCG and Mitomycin-C be prepared by two nurses, did not reach a consensus due to varied opinions. Discussions raised concerns about efficiency, safety, and resource limitations. Some experts argued that two nurses were unnecessary, as Mitomycin-C is prepared by pharmacy technicians and BCG often arrives pre-prepared. The emphasis shifted toward the importance of double-checking patient data rather than requiring two nurses.

Recommendation 5 (37%) on the administration of BCG and Mitomycin-C by two nurses also generated divided opinions, like Recommendation 4. While two nurses could enhance safety by reducing errors, experts acknowledged the practical limits of human resources. With proper protective equipment and a closed system, one nurse could safely manage administration, though dose validation and patient verification might still require two nurses. A well-trained nurse following proper procedures could perform the administration alone.

Based on open-response comments, recommendations 8 and 9 were merged and reformulated for the second round of expert scrutiny (Table 6, see supplementary file). Experts agreed with the statements but noted their interconnection, prompting the consolidation. As only one recommendation was rated in Round II, it was not possible to compute the ICC, as this measure requires multiple items to assess reliability.

Recommendation 1 (79%), stating that intravesical medication does not require preparation in a laminar flow chamber when using a closed system, generated productive comments. While BCG practices were accepted, Mitomycin-C was noted as requiring a laminar flow chamber due to handling needs.

Experts agreed that antineoplastic agents should be prepared in a laminar flow chamber, with differentiation between medications based on safety requirements. They emphasized strict protection during cytostatic handling and recognized closed systems for improving safety and reducing aerosol exposure. Additionally, process simplification was noted to save time and enhance treatment efficiency. This recommendation received a mean relevance score of 4.32 (SD = 0.58) and a mean applicability score of 4.17 (SD = 0.62).

Regarding **Recommendation 2** (95%), the experts agreed on the need for dedicated BCG preparation ar-

eas. Preventing contamination was deemed crucial, with unanimous support for separating BCG from other medications. Experts emphasized protocols for safe use, including inactivity periods and decontamination, to prevent cross-contamination. This recommendation received a mean relevance score of 4.84 (SD = 0.37) and a mean applicability score of 4.53 (SD = 0.84).

Recommendation 3 (100%) emphasized minimizing exposure risk during intravesical medication preparation and administration using personal protective equipment. Experts reinforced the importance of strict adherence to protective measures to ensure healthcare professionals' safety. This recommendation received a mean relevance score of 4.95 (SD = 0.23) and a mean applicability score of 4.95 (SD = 0.23).

Recommendation 6 (79%), advocated using the smallest possible intermittent urinary catheter for intravesical instillations, reaching clear consensus. Experts agreed that catheter size should be personalized based on patient conditions, with smaller sizes preferred to minimize trauma. Larger catheters may be necessary for patients with a history of leaks. It was also agreed that keeping the catheter clamped during treatment preserves a closed system, reducing contamination and injury risks. This recommendation received a mean relevance score of 4.11 (SD = 1.33) and a mean applicability score of 4.16 (SD = 1.30), indicating moderate to strong expert agreement on its importance and feasibility.

Regarding **Recommendation 7** (89%), advocating for luer lock catheters to minimize exposure risk during intravesical instillations, was widely accepted. Experts supported making it a standard, recognizing that the luer lock system reduces therapeutic leakage and enhances safety by providing a secure connection, minimizing accidental disconnections and exposure to hazardous substances. This recommendation received a mean relevance score of 4.47 (SD = 0.70) and a mean applicability score of 4.26 (SD = 1.10), reflecting strong expert agreement on its importance and feasibility.

Experts had differing views on **Recommendations 8 and 9**, particularly concerning bladder fullness and premature urination. Some felt positional changes were unnecessary unless discomfort required the patient to lie down. The consensus emphasized patient comfort, access to appropriate sanitary facilities, and continuous monitoring to manage potential complications. Proper waste management was also highlighted. The final reformulated recommendation received a mean relevance score of 3.75 (SD = 1.29) and a mean applicability score of 3.81 (SD = 1.17), indicating moderate consensus among experts. With over 50% agreement and supporting scientific evidence, the working group included both recommendations in the final document.

Recommendation 10 (84%) on bladder medication retention, specifying one hour for Mitomycin-C and two hours for BCG, was accepted. This aligns with clinical best practices and patient-specific conditions, with retention duration determined by the physician based on the patient's tolerance. This recommendation received a mean relevance score of 4.47 (SD = 1.02) and a mean applicability score of 4.32 (SD = 1.16)

Recommendations 11 (84%) and 12 (79%) on Mitomycin-C treatment regimens were widely accepted without major suggestions for modification. Experts emphasized that administration and treatment regimens should follow medical guidance and the usual practices of healthcare services and professionals. Recommendation 11 received a mean relevance score of 4.47 (SD = 0.77) and a mean applicability score of 4.53 (SD = 0.77), while Recommendation 12 received 4.37 (SD = 0.83) for relevance and 4.42 (SD = 0.84) for applicability, reflecting strong expert consensus on their importance and feasibility.

Recommendation 13 (84%), suggesting the first urination after intravesical instillation occur in the clinic before discharge, was considered with practical and safety concerns. Experts emphasized following hospital norms for urine elimination, including catheter drainage and closed-system waste disposal, to control drug-containing urine and ensure proper waste treatment.

While some experts suggested that home care guidelines could make in-clinic urination unnecessary, most agreed it reduces splashing and contamination, providing a safer environment for patients and cohabitants. This recommendation received a mean relevance score of 4.47 (SD = 1.07) and a mean applicability score of 4.32 (SD = 1.20).

Recommendation 14 (84%) suggesting the first spontaneous urination be performed sitting and followed by a double flush, was widely accepted. Experts highlighted this practice as crucial for minimizing splashing and contamination from the drug present in the urine after intravesical instillation. This recommendation received a mean relevance score of 4.42 (SD = 1.07) and a mean applicability score of 4.32 (SD = 1.29).

Recommendation 15 (95%), on marking the toilet used for the first urination after intravesical instillation for cleaning per institutional norms received consensus. It was recognized as important for reducing contamination risk.

However, some professionals raised concerns about the feasibility of dedicating a specific toilet due to high patient volume, making control and monitoring challenging. This recommendation received a mean relevance score of 4.68 (SD = 0.91) and a mean applicability score of 4.05 (SD = 1.65).

For **recommendation 16** (100%), comments unanimously highlighted the importance of specialized training for nurses administering intravesical medication. Training was considered essential as part of the nurse's professional integration and a necessary practice for any new procedure. This recommendation received a mean relevance score of 4.84 (SD = 0.37) and a mean applicability score of 4.84 (SD = 0.37).

Discussion

The adaptation of the EAUN Best Practice Recommendations to the Portuguese context yielded key findings aligned with best practices in oncology nursing. Standardised procedures, as noted in prior studies, are essential for reducing variability in clinical practices, directly impacting the safety and efficacy of treatments[17].

The process of terminological standardisation was critical for ensuring clarity and relevance to Portuguese healthcare professionals, facilitating easier implementation and adherence to best practices. High levels of consensus among the expert panel indicate that the adapted guidelines are well-suited to the specific needs of Portuguese oncological care.

For instance, recommendations on the use of closed systems for BCG preparation and the mandatory use of individual protective equipment highlight a strong emphasis on safety and infection control[18,19].

The use of closed systems for medication preparation and administration, as recommended in the current guidelines, is supported by studies highlighting their effectiveness in reducing contamination risks and improving safety outcomes[20]. Additionally, the focus on individual protective equipment and specific preparation areas for intravesical medications is consistent with best practices identified in prior studies. Research has shown that stringent infection control measures, including the use of personal protective equipment and dedicated preparation areas, are essential for preventing healthcare-associated infections and protecting healthcare workers from hazardous exposures[21,22].

Moreover, the adaptation process highlighted the importance of tailoring guidelines to accommodate local practices and resources. This includes recognising the distinct handling requirements for different antineoplastic agents and adjusting practices accordingly. For example, while closed systems were recommended for BCG to reduce exposure risk, Mitomycin-C was noted to require preparation under a laminar flow chamber, acknowledging its specific safety demands. Such distinctions are crucial for maintaining high standards of care and ensuring the safety of both patients and healthcare providers[23-25]

The recommendations that did not initially achieve consensus provided valuable insights into the practical challenges faced by healthcare providers. For example, the proposal that the preparation of Mitomycin-C and BCG should be conducted by two nurses was met with concerns regarding resource availability and efficiency. These discussions highlighted the need for evidence-based and practically feasible guidelines within the constraints of local healthcare settings[24].

These practical challenges identified in the current study, such as the resource constraints for having two nurses prepare or administer medications, mirror findings from other settings. Studies have reported similar issues, where the availability of trained personnel and the allocation of sufficient resources are critical factors influencing the implementation of clinical guidelines[23]. The adapted recommendations' flexibility in allowing for single-nurse administration under certain conditions is a pragmatic solution that balances safety with practical feasibility, ensuring that the final recommendations are both effective and implementable[25,26].

The study has some constraints that might limit the interpretation and generalization of the results. The translation process was conducted by two working group members rather than independent translators. However, all group members individually reviewed the translated version, identifying inconsistencies and discussing them in multiple meetings until consensus was reached. This approach was considered a viable alternative to enhance conceptual equivalence and maintain methodological rigor. Additionally, the Delphi process was conducted asynchronously, limiting real-time dialogue and the richness of feedback, though this approach was necessary to accommodate nurses' varying schedules. Additionally, the relatively small expert panel may not fully reflect the diversity of perspectives across Portuguese healthcare settings, and the reliance on subjective judgments introduces potential bias. Lastly, the recommendations were adapted to current Portuguese practices and resources, which may limit their applicability in different settings. Ongoing review and updates will be necessary to keep the guidelines relevant as medical knowledge evolves.

Conclusion

The adapted guidelines strengthen established oncology nursing practices, adding to the evidence supporting standardised care to improve patient outcomes and healthcare safety. By aligning with previous studies, these recommendations offer a solid framework for optimising intravesical instillation practices in Portugal.

The adapted guidelines have significant implications for clinical practice in Portuguese oncological care. Standardising intravesical instillation is expected to improve the consistency and quality of care for non-muscle invasive bladder cancer patients. Following evidence-based recommendations reduces treatment variability and enhances patient safety. Additionally, the successful adaptation of these guidelines can serve as a model for other countries, allowing Portugal to contribute to global efforts to standardise and improve oncological care by sharing lessons and best practices. Future research should focus on longitudinal studies to assess the implementation and long-term impact of the guidelines on patient outcomes, worker safety, and treatment efficacy. These studies would provide valuable data on real-world effectiveness and areas for improvement.

References

1. Bray F, Laversanne M, Sung H, Ferlay J, Siegel RL, Soerjomataram I, et al. Global cancer statistics 2022: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. CA Cancer Journal for Clinicians. 2024;74(3):229-63.
2. Ferlay J, Ervik M, Lam F, Laversanne M, Colombet M, Mery L, et al. Global cancer observatory: cancer today (version 1.1). Lyon, France: International Agency for Research on Cancer. 2024.
3. Liu G, Li B, Xu Z, Wang J, Ma S, Kan Y, et al. Bacillus calmette-guerin for the treatment of non-muscle invasive bladder cancer: history and current status. Discovery Medicine. 2022;33(169):85-92.
4. Witjes JA, Bruins HM, Cathomas R, Compérat EM, Cowan NC, Gakis G, et al. European Association of Urology guidelines on muscle-invasive and metastatic bladder cancer: summary of the 2020 guidelines. European Urology. 2021;79(1):82-104.
5. Lobo N, Brooks NA, Zlotta AR, Cirillo JD, Boorjian S, Black PC, et al. 100 years of Bacillus Calmette–Guérin immunotherapy: from cattle to COVID-19. Nature Reviews Urology. 2021;18(10):611-22.
6. Duan H, Deng Z, Zou J, Zhang G, Zou X, Xie T. The Efficacy and Safety of Hyperthermia Intravesical Chemotherapy in the Treatment of Non-Muscle-Invasive Bladder Cancer: A Meta-Analysis. Urologia Internationalis. 2024;108(4):322-33.
7. Li R, Li Y, Song J, Gao K, Chen K, Yang X, et al. Intravesical gemcitabine versus mitomycin for non-muscle invasive bladder cancer: a systematic review and meta-analysis of randomized controlled trial. BMC Urology. 2020;20:1-8.
8. Burroughs GE, Connor TH, Mead KR, Reed LD. Preventing occupational exposure to antineoplastic and other hazardous drugs in health care settings. CA Cancer Journal for Clinicians. 2006;56(6):354-65.
9. Lauridsen SV, De Blok W, Retinger NL, Jensen BT, Turner B, Villa G, et al. Intravesical instillation with mitomycin C or bacillus Calmette-Guérin in non-muscle invasive bladder cancer: European Association of Urology Nursing; 2015.
10. Keeney S, Hasson F, McKenna H. Consulting the oracle: ten lessons from using the Delphi technique in nursing research. Journal of Advanced Nursing. 2006;53(2):205-12.
11. Benner P. From novice to expert: Excellence and power in clinical nursing practice. Commemorative edition: Prentice-Hall International London; 2001.
12. Portuguese Nursing Order Parecer n.º 10/2017: Diferenciação das intervenções de enfermagem do enfermeiro especialista em enfermagem médico-cirúrgica em relação ao enfermeiro generalista, num serviço de urgência. 2017.
13. Kennedy HP. Enhancing Delphi research: methods and results. Journal of Advanced Nursing. 2004;45(5):504-11.
14. Gisev N, Bell JS, Chen TF. Interrater agreement and interrater reliability: key concepts, approaches, and applications. Research in Social and Administrative Pharmacy. 2013;9(3):330-8.
15. Koo TK, Li MY. A guideline of selecting and reporting intraclass correlation coefficients for reliability research. Journal of Chiropractic Medicine. 2016;15(2):155-63.
16. European Commission. Guidance for the Safe Management of Hazardous Medicinal Products at Work. 2023.
17. Peyton CC, Chipollini J, Azizi M, Kamat AM, Gilbert SM, Spiess PE. Updates on the use of intravesical therapies for non-muscle invasive bladder cancer: how, when and what. World Journal of Urology. 2019;37:2017-29.
18. Szewczyk Jr MT, Soefje SA. Development of an innovative delivery system for bacillus Calmette-Guérin bladder administration. American Journal of Health-System Pharmacy. 2021;78(1):60-4.
19. Marx AH, Nowicki DN, Carlson RB, Schultz KM, Sickbert-Bennett E, Weber DJ. Bacille Calmette-Guérin preparation and intravesical administration to patients with bladder cancer: risks to healthcare personnel and patients, and mitigation strategies. Infection Control & Hospital Epidemiology. 2024;45(4):520-5.
20. Liu S, Zhang C, Peng L, Lu Y, Luo D. Comparative effectiveness and safety of intravesical instillation treatment of interstitial cystitis/bladder pain syndrome: a systematic review and network meta-analysis of randomized controlled trials. International Urogynecology Journal. 2021;32:1061-71.
21. Simons A, Toland S. Protecting nurses against the risks of occupational exposure to systemic anticancer therapy agents. Cancer Nursing Practice. 2024;23(4).
22. Connor TH, McDiarmid MA. Preventing occupational exposures to antineoplastic drugs in health care settings. CA Cancer Journal for Clinicians. 2006;56(6):354-65.
23. Wang T, Tan J-YB, Liu X-L, Zhao I. Barriers and enablers to implementing clinical practice guidelines in primary care: an overview of systematic reviews. BMJ open. 2023;13(1):e062158.
24. Wang Z, Norris SL, Bero L. The advantages and limitations of guideline adaptation frameworks. Implementation Science. 2018;13:1-13.
25. Klaic M, Kapp S, Hudson P, Chapman W, Denehy L, Story D, et al. Implementability of healthcare interventions: an overview of reviews and development of a conceptual framework. Implementation Science. 2022;17(1):10.
26. Bora A-M, Piechotta V, Kreuzberger N, Monsef I, Wender A, Follmann M, et al. The effectiveness of clinical guideline implementation strategies in oncology—a systematic review. BMC Health Services Research. 2023;23(1):347.

Funding

No funding or sources of support.

Ethics Committee Approval

Does not require approval by the ethics committee.

Declaration of conflicting interests

The authors declare that there is no conflict of interest. The authors are responsible for the content and writing of the paper.

Supplementary File

Table 1, results from translation and cultural adaptation. Tables 5 and 6, results from Delphi rounds 1 and 2, respectively.

Table 1. Recommendations lacking consensus among the working group (original, forward-and back-translation versions).

RECOMMENDATIONS	ORIGINAL LANGUAGE	PORTUGUESE TRANSLATION	BACK-TRANSLATION
2	BCC should not be prepared in areas where intravenous drugs are prepared	O BCG não deve ser preparado em áreas onde são preparados outros medicamentos.	BCG should not be prepared in areas where other medications are prepared.
3	To reduce risk of exposure during drug preparation and administration personal protective clothing should be worn in accordance with local and hospital safety procedures. When performing intravesical instillations, healthcare workers should use protective equipment that protects them against contamination with medication	Para reduzir o risco de exposição durante a preparação e administração da medicação intravesical, deve ser usado equipamento de proteção individual de acordo com os procedimentos de segurança locais e hospitalares, nomeadamente luvas de proteção tipo B, bata impermeável, máscara FFP2, e óculos de proteção.	To reduce the risk of exposure during the preparation and administration of intravesical medication, personal protection equipment should be used in accordance with local and hospital safety procedures, namely type B protective gloves, a waterproof gown, an FFP2 mask, and protective goggles.
6	In intravesical instillations an intermittent catheter with the smallest size possible should be used	Nas instilações intravesicais deve ser utilizado um cateter de drenagem urinária intermitente com o menor calibre possível.	For intravesical instillations, an intermittent urinary drainage catheter with the smallest possible caliber should be used.
7	In intravesical instillations a luer lock catheter is recommended to reduce risk of exposure.	Nas instilações intravesicais recomenda-se um cateter luer lock para reduzir o risco de exposição.	In intravesical instillations, a luer lock catheter is recommended to reduce the risk of exposure.
8	The anatomy of the empty bladder allows the wall of the bladder to make contact with the intravesical medication, and the patient should be encouraged to mobilise as usual. In some hospitals and clinics, after the drugs are instilled, the patient is rotated side-to-side every 15 min. to enhance contact of the drug with the entire bladder mucosa. In the product description (SPC) of BCG Tice, patients are advised to rotate after instillation, whereas staying mobile is advised in SPC of BCG Medac. However, there is no evidence to support these practices	Atualmente nas instilações intravesicais não existe evidência que apoie a prática de alternância de decúbitos. A pessoa deve por isso ser encorajada a deambular, pois a anatomia da bexiga vazia permite que toda a superfície entre em contato com a medicação intravesical.	Currently, there is no evidence to support the practice of alternating positions during intravesical instillations. Therefore, the patient should be encouraged to ambulate, as the anatomy of the empty bladder allows the entire surface to come into contact with the intravesical medication.
10	The dwell time that is commonly practised is 1–2 h	O tempo de permanência dos medicamentos na bexiga é de 1 a 2 horas.	The retention time of the medication in the bladder is 1 to 2 hours.
11	Chemotherapy (MMC): one single immediate postoperative instillation; or immediate postoperative instillation followed by 6 weekly instillations and then, if cystoscopy is negative, monthly instillations for a period of 1 year	O tratamento com Mitomicina C pode contemplar: a) a administração em dose única no pós-operatório imediato; b) uma instilação no pós-operatório imediato seguido de 6 instilações semanais de indução e, se a cistoscopia for negativa, instilações mensais por um período de 1 ano.	The Treatment with Mitomycin-C may include: a) a single dose administration immediately postoperatively; b) one instillation immediately postoperatively followed by 6 weekly induction instillations, and if the cystoscopy is negative, monthly instillations for a period of 1 year.
12	BCG: there is no immediate postoperative instillation of BCG. Administration should not start sooner than 2 weeks after TUR-BT and consists of 6 weekly instillations: induction course followed by 3 weekly instillations (maintenance) at 3, 6, 12, 18, 24, 30 and 36 months, provided that cystoscopy and cytology are negative	No tratamento com o BCG não há instilação deste fármaco no pós-operatório imediato. A administração não deve começar antes de 2 semanas após a RTU-TV e consiste em 6 instilações semanais (indução) seguida de 3 instilações semanais (manutenção) aos 3, 6, 12, 18, 24, 30 e 36 meses, desde que a cistoscopia e a citologia sejam negativas.	In the treatment with BCG, there is no instillation of this drug immediately postoperatively. Administration should not begin before 2 weeks after TURBT and consists of 6 weekly instillations (induction) followed by 3 weekly instillations (maintenance) at 3, 6, 12, 18, 24, 30, and 36 months, provided that cystoscopy and cytology are negative.

RECOMMENDATIONS	ORIGINAL LANGUAGE	PORTUGUESE TRANSLATION	BACK-TRANSLATION
14	In some countries, it is advised to flush the toilet twice with the lid closed	A primeira micção espontânea deve ser realizada sentada na sanita, efetuando descarga dupla.	The first spontaneous urination should be performed while sitting on the toilet, with a double flush.
15	When the toilet is used by more persons, cleaning with normal detergent and water is advised	O WC utilizado para a primeira micção espontânea deverá ser sinalizado para limpeza posterior de acordo com a norma institucional.	The toilet used for the first spontaneous urination should be marked for subsequent cleaning according to institutional guidelines.
16	Nurse specialist administering intravesical therapies needs to be trained and assessed by a competent practitioner	O enfermeiro que administra medicação intravesical deve ser previamente formado, treinado e avaliado por um profissional com competência teórico-prática neste tipo de procedimento.	The nurse administering intravesical medication must be previously trained, educated, and evaluated by a professional with theoretical and practical competence in this type of procedure.

Table 5. Results of the first Delphi round.

RECOMMENDATIONS	RELEVANCE (1–5)	APPLICABILITY (1–5)	AGREEMENT (1–10)	
	MEAN (SD)	MEAN (SD)	MEAN (SD)	% ≥ 8
1. When a closed system is used, the medication for intravesical instillation does not need to be prepared in a laminar flow chamber	4,32 (0,58)	4,17 (0,62)	7,95 (3,06)	79
2. BCG should not be prepared in areas where other medications are prepared	4,84 (0,37)	4,53 (0,84)	9,58 (0,90)	95
3. To reduce the risk of exposure during the preparation and administration of intravesical medication, personal protection equipment should be used in accordance with local and hospital safety procedures, namely type B protective gloves, a waterproof gown, an FFP2 mask, and protective goggles	4,95 (0,23)	4,95 (0,23)	10,00 (0)	100
4. The preparation of BCG and Mitomycin-C should be carried out by two nurses	2,95 (1,47)	2,37 (1,61)	4,05 (3,75)	21
5. The administration of BCG and Mitomycin-C should be carried out by two nurses.	3,16 (1,46)	2,58 (1,68)	5,26 (4,15)	37
6. For intravesical instillations, an intermittent urinary drainage catheter with the smallest possible caliber should be used	4,11 (1,33)	4,16 (1,30)	8,47 (2,97)	79
7. In intravesical instillations, a luer lock catheter is recommended to reduce the risk of exposure	4,47 (0,70)	4,26 (1,10)	8,68 (3,13)	89
8. Currently, there is no evidence to support the practice of alternating positions during intravesical instillations. Therefore, the patient should be encouraged to ambulate, as the anatomy of the empty bladder allows the entire surface to come into contact with the intravesical medication	4,26 (1,15)	3,84 (1,50)	7,53 (3,31)	68
9. In special situations, the patient may remain catheterized and stay in bed during the time the medication is retained in the bladder (e.g., individuals with cognitive impairment, urinary incontinence). In these circumstances, due to bed immobility, positions should be alternated every 15 minutes	3,58 (1,68)	3,63 (1,71)	6,95 (4,13)	63
10. The retention time of the medication in the bladder is 1 to 2 hours	4,47 (1,02)	4,32 (1,16)	8,84 (2,52)	84

RECOMMENDATIONS	RELEVANCE (1–5)	APPLICABILITY (1–5)	AGREEMENT (1–10)	
	MEAN (SD)	MEAN (SD)	MEAN (SD)	% ≥ 8
11. The treatment with Mitomycin-C may include: (a) a single dose administration immediately postoperatively; (b) one instillation immediately postoperatively followed by 6 weekly induction instillations, and if the cystoscopy is negative, monthly instillations for a period of 1 year	4,47 (0,77)	4,53 (0,77)	9,11 (1,76)	84
12. In treatment with BCG, there is no indication of a single dose administration (immediately postoperative). Administration should begin not before 2 weeks after TURBT and consist of 6 weekly instillations (induction) followed by 3 weekly instillations (maintenance) at 3, 6, 12, 18, 24, 30, and 36 months, provided that cystoscopy and cytology are negative	4,37 (0,83)	4,42 (0,84)	8,95 (1,90)	79
13. The first spontaneous urination after intravesical instillation should be performed in the healthcare facility	4,47 (1,07)	4,32 (1,20)	8,89 (2,75)	84
14. The first spontaneous urination should be performed while sitting on the toilet, with a double flush	4,42 (1,07)	4,32 (1,29)	8,74 (2,66)	84
15. The toilet used for the first spontaneous urination should be marked for subsequent cleaning according to institutional guidelines	4,68 (0,91)	4,05 (1,65)	9,37 (2,31)	95
16. The nurse administering intravesical medication must be previously trained, educated, and evaluated by a professional with theoretical and practical competence in this type of procedure	4,84 (0,37)	4,84 (0,37)	9,89 (0,46)	100

Table 6. Results of the second Delphi round.

RECOMMENDATIONS	RELEVANCE (1–5)	APPLICABILITY (1–5)	AGREEMENT (1–10)	
	MEAN (SD)	MEAN (SD)	MEAN (SD)	% ≥ 8
Currently, there is no evidence to support the practice of alternating positions during intravesical instillations. Therefore, the patient should be encouraged to ambulate, as the anatomy of the empty bladder allows the entire surface to come into contact with the intravesical medication. Exceptions are made for special situations where the patient may remain catheterized in bed during the medication retention time in the bladder (e.g., individuals with cognitive impairment, urinary incontinence). In these bedridden circumstances, positions should be alternated every 15 minutes	3,75 (1,29)	3,81 (1,17)	6,31 (4,38)	56