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Francesco Cellini , Leonardo Consoletti , Massimo Di Maio , Diego Maria Michele Fornasari ,
Gianpaolo Fortini , Marta Gentili * , Marco Krengli , Ernesto Maranzano , Silvia Natoli

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Expert Consensus Develops Multidisciplinary Pathway for Cancer Pain Management in Italy: A Delphi Study

Francesco Cellini [1,2], Leonardo Consoletti [3,4], Massimo Di Maio [5,6], Diego Maria Michele Fornasari [7,8], Gianpaolo Fortini [9,10,11], Marta Gentili [12,*], Marco Krengli [13,14], Ernesto Maranzano [15], Silvia Natoli [16,17,18] and on behalf of The Cancer Pain Management in Italy Working Group

[1] University Department of Diagnostic Imaging, Oncologic Radiotherapy and Hematology, Università Cattolica del Sacro Cuore, Roma, Italy
[2] Dipartimento di Diagnostica per Immagini, Radioterapia Oncologica ed Ematologia, Fondazione Policlinico Universitario "A. Gemelli" IRCCS, Roma, Italia
[3] Pain Management Unit, "Policlinico Riuniti" University Hospital of Foggia, Foggia, Italy
[4] President of Ferderdolore - SICD
[5] Department of Oncology, University of Turin, AOU Città della Salute e della Scienza di Torino, Turin, Italy
[6] Presidente AIOM (Associazione Italiana di Oncologia Medica)
[7] Department of Medical Biotechnology and Translational Medicine. Università degli Studi di Milano, Milan, Italy
[8] President of the Italian Association for the Study of Pain
[9] Direttore SC Cure Palliative Integrate ASST Sette Laghi – Varese
[10] Presidente della Società Italiana di Cure Palliative
[11] Referente Tecnico per l'ambito di Cure Palliative e Terapia del Dolore DG Welfare – Regione Lombardia, Milan, Italy
[12] President of Fondazione Nora e Alberto Gentili Ets
[13] Department of Surgical, Oncological and Gastroenterological Sciences (DISCOG), University of Padua, Padua, Italy
[14] Division of Radiotherapy, Veneto Institute of Oncology IOV IRCCS, Padua, Italy
[15] Department of Radiation Oncology, University of Perugia, Perugia, Italy
[16] Department of Clinical-Surgical, Diagnostic and Pediatric Sciences, University of Pavia, Pavia, Italy
[17] Pain Unit, Fondazione IRCCS Policlinico San Matteo, Pavia, Italy
[18] SIAARTI Section Chief of Pain Medicine and Palliative Care
* Correspondence: presidente@fondazionegentili.it

Abstract

Background: Cancer pain remains highly prevalent and undertreated despite established guidelines. In Italy, Law 38/2010 mandates systematic pain assessment, yet only 26% of clinicians routinely evaluate pain at each clinical visit, and fewer than one-quarter have received formal training in pain medicine or palliative care. A national multidisciplinary roundtable, convened in Rome in March 2025, formally identified four systemic gaps – insufficient education, fragmented care pathways, unclear professional roles, and challenges in implementing shared diagnostic and therapeutic pathways – and planned the development of a structured Delphi consensus. ***Methods:*** A Delphi study was conducted in accordance with CREDES guidelines. The Steering Committee, comprising representatives of six Italian scientific societies (AIRO, AIOM, AISD, Federdolore-SICD, SICP, ACD-SIAARTI) and a patient advocacy group (Fondazione Nora e Alberto Gentili), developed 15 clinical statements addressing pain assessment, management, referral criteria, monitoring, and documentation. Sixty-six Italian clinicians from various specialties were invited to participate. Consensus was defined as ≥75% agreement (scoring 4 or 5 on a 5-point Likert scale). ***Results:*** Fifty-

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six clinicians completed the voting rounds (response rate: 84.8%), representing medical oncology, radiation oncology, pain therapy, and palliative care specialties. All statements reached consensus in the first round (78–100%), precluding the need for a second voting round. Panelists' qualitative comments informed minor wording refinements; substantial content was unchanged. ***Conclusions:*** The Delphi process produced a validated, multidisciplinary clinical pathway for cancer pain management in the Italian NHS - National Health System. The pathway establishes structured roles for the clinical reference physician and specialist consultants, objective decision thresholds for analgesic titration and referral, and minimum requirements for standardized pain documentation. These consensus-based statements provide actionable clinical guidance that may help address analgesic undertreatment and support the implementation of Law 38/2010 across Italian oncology centers.

Keywords: cancer pain management; clinical pathway; Delphi consensus; multidisciplinary approach; opioid prescribing; pain assessment; palliative care

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1. Introduction

Pain is one of the most frequent and debilitating symptoms in patients with cancer. Landmark epidemiological studies estimate an overall prevalence of approximately 44.5%, rising to more than 50% in patients undergoing active treatment and exceeding 65% in patients with advanced or metastatic disease [1,2]. Moderate-to-severe pain affects around one third of patients, with profound consequences for quality of life, psychological well-being, and functional autonomy [1]. Despite decades of research and the availability of established guidelines, the problem of analgesic undertreatment remains unresolved: the Pain Management Index (PMI) has documented a portion of inadequately treated patients that, while slowly declining from 43% in the 1994–2007 period, still stood at approximately 40% between 2014 and 2020 [3–5].

The Italian landscape presents distinctive challenges. Although Law 38/2010 introduced a statutory requirement for systematic pain assessment and documentation across all healthcare settings, its implementation can be seen as still suboptimal. Recent national surveys indicate that only 26% of clinicians routinely assess pain at every visit, only 17% monitor it daily during hospitalization, and merely 23.5% have completed formal training in pain medicine or palliative care [6–8]. Underutilization of validated assessment tools (Numeric Rating Scale [NRS], ESAS, DN4), suboptimal analgesic sequencing and modest use of opioids remain widespread [4,9,10]. These clinical deficiencies are compounded by marked regional heterogeneity in infrastructure and prescribing policies, fragmented care pathways, and limited interdisciplinary integration – all of which contribute to pain management that is frequently delayed or inadequate [6].

To address these gaps, a national roundtable was convened in Rome on 28 March 2025, bringing together representatives of the major Italian scientific societies involved in cancer pain management [AIRO (Associazione Italiana Radioterapia Oncologica – Italian Association of Radiation Oncology), AIOM (Associazione Italiana Oncologia Medica – Italian Association of Medical Oncology), AISD (Associazione Italiana Studio Dolore – Italian Association for the Study of Pain), federDolore-SICD (federDolore Società Italiana dei Clinici del Dolore – federDolore Italian Society of Pain Clinicians), SICP (Società Italiana Cure Palliative – Italian Society of Palliative Care), ACD-SIAARTI (Area Culturale Dolore e Cure Palliative della Società Italiana di Anestesia, Analgesia e Rianimazione e Terapia Intensiva – Pain and Palliative Care Cultural Area of the Italian Society of Anesthesia, Analgesia, Resuscitation and Intensive Care]. and a patient advocacy group (Fondazione Nora e Alberto Gentili, Nora and Alberto Gentili Foundation). The roundtable identified four critical areas: insufficient education and training, fragmented care pathways, undefined professional roles, and challenges in implementing shared diagnostic and therapeutic pathways (PDTAs). As a result, the roundtable formally mandated the development of a structured Delphi process to translate the proposals into shared, actionable clinical recommendations [6].

The Delphi methodology is a well-validated tool for achieving expert consensus in complex clinical domains, including cancer pain management and palliative care [11]. Several prior initiatives have demonstrated their applicability in this field, from the development of multidimensional needs assessment instruments [12,13] to the validation of standardized forms for pain documentation in oncology [14].

The primary objective of the present study was to achieve a multidisciplinary consensus on a shared clinical pathway for cancer pain management in the Italian oncology setting, including the definition of criteria and timelines for interdisciplinary referral.

2. Methods

2.1. Study Design

The Delphi technique was selected for its established suitability in developing clinical guidance within oncology and palliative care settings [11]. The study was conducted and reported in accordance with the CREDES (Conducting and REporting DElphi Studies) guidelines [11].

2.2. Statement Development

Fifteen clinical statements were developed by the Steering Committee, drawing on current evidence and the four thematic gaps identified at the 2025 national roundtable [6]: interdisciplinary role definition, pain assessment standards, standardized clinical documentation, and referral criteria and monitoring timelines. The statements spanned the domains of pain assessment, pharmacological and non-pharmacological management, specialist referral, and clinical documentation.

2.3. Steering Committee and Panel Composition

The study was overseen by a multisociety Steering Committee comprising representatives from AIRO, AIOM, AISD, Federdolore-SICD, SICP, and ACD-SIAARTI. A total of 66 Italian clinicians were invited to participate as Delphi panelists. Candidates were identified and proposed by Steering Committee members on the basis of their recognized clinical and research experience in the field of cancer pain management, ensuring a multidisciplinary and geographically representative sample across the specialties of medical oncology, radiation oncology, pain therapy, and palliative care.

2.4. Delphi Process

The survey was administered online via SurveyMonkey across two voting rounds; however, only one round was necessary (see Results). Panelists rated their agreement with each statement using a 5-point Likert scale (1 = total disagreement, 5 = total agreement). All responses were anonymous. Each item also allowed open-ended qualitative comments, which were collected and summarised to inform the second round, where applicable. Consensus was defined a priori as ≥75% of respondents scoring 4 or 5 for a given statement. Statistical analysis comprised the calculation of response frequency distributions and the determination of consensus attainment for each statement across both rounds.

3. Results

Of 66 clinicians invited to participate, 56 completed the voting round, corresponding to a response rate of 84.8%. Respondents represented a broad multidisciplinary spectrum: medical oncologists (23.3%, n=13), radiation oncologists (25.0%, n=14), pain therapists (26.7%, n=15), palliativists (25.0%, n=14).

Consensus (defined as ≥75% of respondents scoring 4 or 5 on the 5-point Likert scale) was reached for all 15 statements in the first round (Table 1). Agreement rates ranged from 78% (Statement 5) to 100% (Statements 4 and 10). Given that all statements met the pre-defined consensus threshold in the first round, a second Delphi round was not conducted. However, the panelists' qualitative comments were reviewed by the Steering Committee, and minor refinements were applied to the wording of selected statements to improve clarity and precision, without altering their substantial content.

Table 1. Results of the first-round Delphi survey on cancer pain management (n=56 respondents).

No.	Statement	n	1	2	3	4	5	Consensus (4+5)
Domain 1 – Pain Assesment								
1	The first phase of care for cancer patients with uncontrolled pain (absence of therapy or inadequate therapy – in terms of efficacy or side effects) requires the referent physician to perform a multidimensional pain assessment and to initiate first-line analgesic medical therapy, according to their competence and available guidelines.	54	0%	0%	2%	11%	87%	**98%**
2	The clinical referent of the cancer patient should also assess the possible presence of uncontrolled non-cancer pain, in line with Italian Law 38/2010, and encourage the patient to initiate an appropriate management pathway with the relevant specialists.	53	0%	0%	2%	19%	79%	**98%**
3	If the clinical referent has any doubts regarding pain therapy management, they must immediately request the involvement of other specialists.	54	0%	0%	4%	20%	76%	**96%**
Domain 2 – Treatment Initiation and Monitoring								
4	After initiating analgesic therapy, monitoring (by phone, outpatient visit, or digital means) within the first 3–7 days is essential to assess efficacy and the occurrence of any side effects.	54	0%	0%	0%	13%	87%	**100%**
5	If the initiated treatment does not achieve a reduction of at least 30% in pain intensity within 7 days of therapy titration, it should be considered ineffective.	54	2%	7%	13%	44%	33%	**78%**
6	Local therapy can also help minimise pharmacological intervention, to which adverse effects may be associated. Therefore, even in cases of satisfactory response to pharmacological therapy, in the presence of localised pain it is appropriate to refer the patient to local therapy specialists, in order to reduce exposure to potentially adverse-effect-associated drugs.	54	2%	2%	15%	30%	52%	**81%**
Domain 3 – Escalation and Multimodal Management								
7	In the case of partial response to analgesic treatment, defined as a reduction ≥30% in pain intensity but with NRS ≥4, re-modulation of therapy (titration of the same molecule or add-on) is indicated to achieve adequate pain control.	54	0%	0%	11%	31%	57%	**89%**

8	If, despite an adequate titration process within 7 days, pain is not controlled (NRS ≥4 or intensity reduction <30%), a specialist consultation is indicated (Pain Therapist, Radiation Oncologist, Palliativist).	53	2%	2%	9%	15%	72%	**87%**
9	In the presence of significant or difficult-to-manage adverse effects with ongoing therapy, re-modulation of therapy with clinical reassessment is required.	53	2%	2%	4%	30%	62%	**92%**
10	In the presence of pain with a local component (e.g., from metastases or primary tumour), consultation with a Radiation Oncologist and/or specialists in local invasive or mini-invasive techniques (Pain Therapist, Orthopaedic Surgeon, Neurosurgeon, Interventional Radiologist) is indicated; when possible, an interdisciplinary approach is recommended.	53	0%	0%	0%	21%	79%	**100%**
11	Whenever the characteristics of pain require multimodal intervention, management must become collegial.	54	0%	0%	6%	17%	78%	**94%**
Domain 4 – Documentation and Clinical Record								
12	It is desirable that the clinical record integrates a standardised form for pain assessment and monitoring, to ensure symptom traceability, uniformity of collected data, and care continuity, in line with Italian Law 38/2010.	53	0%	2%	0%	8%	91%	**98%**
13	The clinical pain assessment form must include at least pain localisation, qualitative characteristics, and intensity, measured with validated scales such as the NRS.	53	0%	0%	4%	8%	89%	**96%**
14	The clinical form must report the ongoing analgesic therapies and the results obtained in terms of clinical response.	53	0%	0%	2%	4%	94%	**98%**
15	In the clinical form, it is recommended to include an assessment of the impact of pain on the patient's quality of life.	53	0%	0%	4%	15%	81%	**96%**

For each of the 15 statements, the table reports the number of respondents who rated that item, the percentage distribution of responses across the 5-point Likert scale (1 = total disagreement, 5 = total agreement), and the combined percentage of responses scoring 4 or 5 (consensus rate). Consensus was defined a priori as ≥75% of respondents rating a statement 4 or 5. All 15 statements reached consensus in the first round.

Statements 1 through 3 addressed the role of the clinical reference physician in initiating and coordinating pain management, achieving consensus of 98%, 98%, and 96%, respectively. Statement 4, concerning early post-initiation monitoring within 3–7 days, reached unanimous consensus (100%). Statement 5, which proposed a 30% reduction in pain intensity at 7 days as the threshold for defining treatment inefficacy, achieved the lowest – though still qualifying – consensus rate of 78%. Statements 6 through 11 addressed indications for specialist referral and multidisciplinary collaboration, with agreement ranging from 81% (Statement 6) to 100% (Statement 10). Statements 12 through 15,

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focusing on standardized clinical documentation and the content of the pain assessment form, all achieved a consensus of 96% or higher (range 96–98%).

4. Discussion

The present Delphi consensus gives operational form to the mandate established by the national multidisciplinary roundtable held in Rome on 28 March 2025 [6]. That meeting identified four major systemic gaps in Italian cancer pain management: insufficient education and training, fragmentation of care pathways, lack of clarity regarding professional roles, and difficulties in implementing shared diagnostic and therapeutic pathways (Percorsi Diagnostico-Terapeutici Assistenziali, PDTAs). The present study addresses each of these gaps through a structured, evidence-based, and expert-validated consensus process. In our view, the main strength of this Delphi consensus lies in the high number of respondents, with 85% of invited panelists that completed the survey, a response rate that compares favorably with benchmarks for Delphi studies in clinical medicine [11]. In a domain where engagement with structured quality-improvement initiatives has historically been uneven, this level of participation reflects a genuine and broad interest among the Italian clinical community. It reinforces the representativeness of the consensus achieved.

A scheme of the pathway is provided in Figure 1. The pathway begins with the medical oncologist – or, more broadly, another specialist acting as the clinical reference physician – as the primary responsible actor for pain assessment and first-line analgesic-based pain management. Statements 1 and 2, both achieving 99% consensus, establish that the initial evaluation of the oncological patient with uncontrolled pain must include a multidimensional pain assessment and should also screen for the possible presence of non-oncological pain, consistent with Law 38/2010. Statement 3 (97%) further affirms that when doubts arise regarding the management of analgesic therapy, the clinical reference physician must seek promptly for other specialists' involvement. This foundational triad of statements reflects a deliberate attempt to lower the competency threshold required for adequate first-line pain management, addressing the educational gap identified by the roundtable and consistent with evidence that only a minority of Italian oncologists currently assess pain at every clinical visit [7,8].

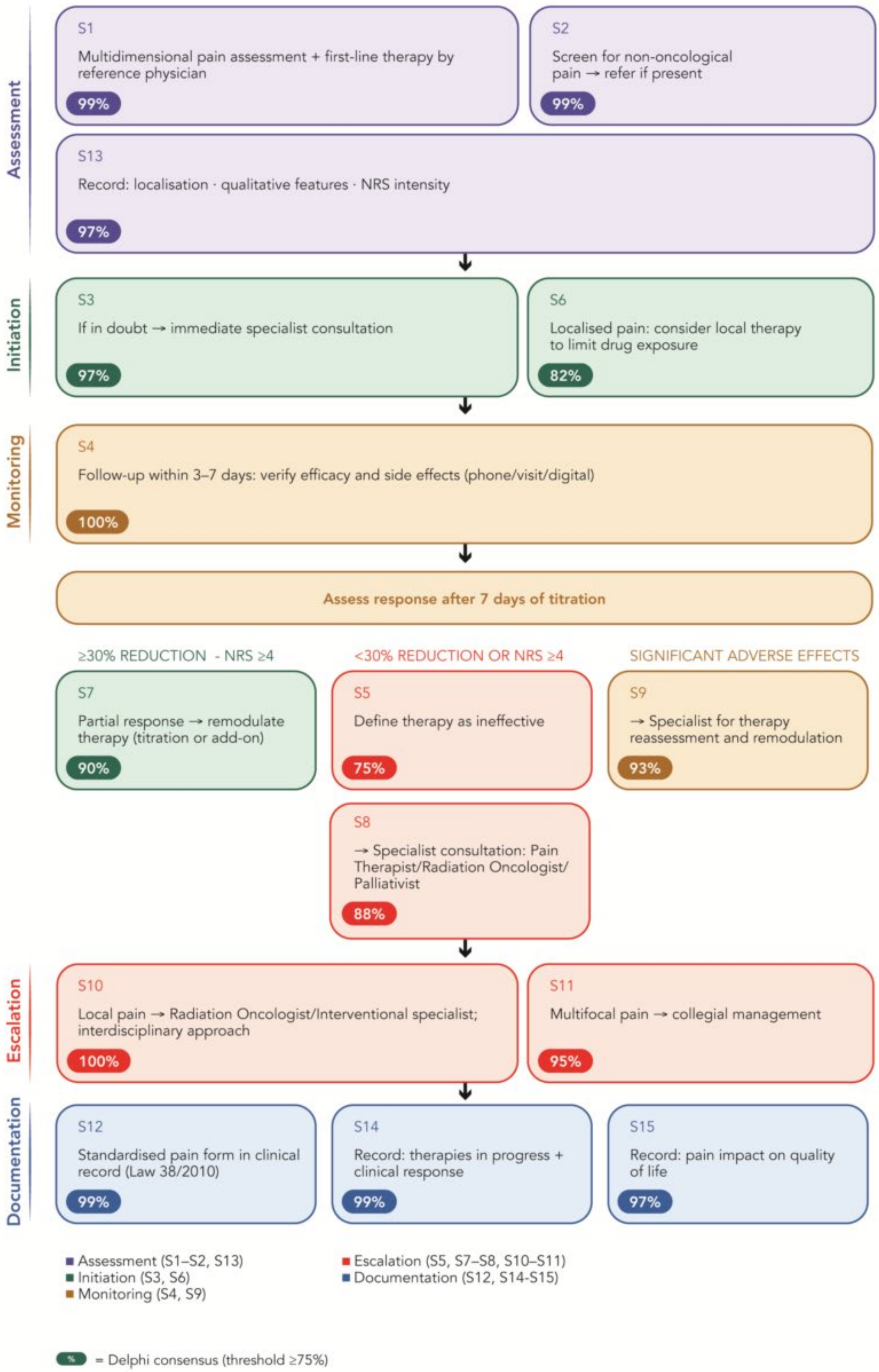

Figure 1. Delphi-validated multidisciplinary pathway for cancer pain management. The figure illustrates the five-phase clinical pathway derived from the 15 Delphi consensus statements (S1–S15). Starting from multidimensional pain assessment by the reference physician (Assessment phase, S1–S2, S13), the pathway

proceeds to therapy initiation (S3, S6) and mandatory early monitoring within 3–7 days (S4). At the decision branch, response is evaluated after 7 days of titration: partial response (≥30% NRS reduction but NRS ≥4) triggers therapy re-modulation (S7); inadequate response (<30% reduction or NRS ≥4) defines therapy as ineffective (S5) and mandates specialist referral (S8); significant adverse effects prompt immediate specialist reassessment (S9). Complex or localized pain requires collegial and interdisciplinary escalation (S10–S11). Standardized pain documentation in compliance with Italian Law 38/2010 – including therapies, clinical response, and quality-of-life impact – underpins all phases (S12, S14–S15). The percentage reported on each statement badge represents the proportion of Delphi panelists scoring 4 or 5 on the 5-point Likert scale (consensus threshold: ≥75%). NRS: Numerical Rating Scale.

Once analgesic therapy is initiated, the pathway establishes strict monitoring timelines. Statement 4 – a statement achieving 100% consensus across all respondents – affirms that follow-up on an outpatient basis (by telephone, outpatient consultation, or digital means) within the first 3–7 days is essential to verify efficacy and/or the onset of adverse effects. This unanimous endorsement reflects a convergent clinical view that early monitoring is not optional but essential for adequate pain management. The therapeutic target is a reduction of at least 30% in NRS score within 7 days of titration initiation; failure to reach this threshold defines treatment inefficacy (Statement 5, 78%). In cases of partial response, defined as a reduction in NRS of at least 30% with a residual NRS score of 4 or higher, treatment re-modulation is indicated, either through dose titration of the same agent or by adding adjunctive therapy (Statement 7, 90%). These sequential thresholds provide the clinical reference physician with an objective, time-anchored decision framework that mitigates the risk of anchoring bias and therapeutic inertia, two well-documented contributors to analgesic undertreatment in oncology [3,4].

A defining feature of the validated pathway is its non-sequential, criteria-driven approach to another specialist referral – a deliberate departure from the hierarchical cascade that has historically delayed access to pain specialists and palliative care [15,16]. If pain is not controlled despite adequate titration within 7 days (NRS ≥4 or intensity reduction <30%), specialist consultation with a pain therapist, radiation oncologist, or palliative care specialist is indicated (Statement 8, 88%). Equally, when adverse effects are important or difficult to manage with the current therapy, specialist reassessment must be sought (Statement 9, 93%). Crucially, whenever pain has a local component – such as that arising from bone metastases or direct tumor involvement – prompt consultation with a radiation oncologist and/or specialists in minimally invasive local techniques is indicated, preferably within an interdisciplinary setting (Statement 10, 100%). Whenever pain characteristics require multimodal intervention, its management must become collegial (Statement 11, 95%). Taken together, these statements establish a model in which any member of the team can trigger specialist involvement on the basis of objective clinical parameters, rather than only after a fixed sequence of prior steps has been exhausted.

The evidence base underlying each specialist's contribution to this framework is well established. Palliative radiotherapy achieves clinically meaningful pain relief in approximately 60–75% of patients with bone metastases and other localized pain syndromes [17–19]. Moreover, a recent meta-analysis revealed that the majority (85%) of studies investigating the efficacy of radiofrequency ablation of painful spinal metastasis reported highly effective pain management (≥4-point pain score reduction) [20]. Statement 6 (82%) extends this logic further: even when pharmacological therapy is producing a satisfactory response, referral to local therapy specialists is appropriate if a localized pain component is present, in order to reduce overall drug exposure and the associated risk of adverse effects. Pain therapy specialists offer access to interventional approaches – nerve blocks and/or ablation, neuromodulation, intrathecal drug delivery – with demonstrated efficacy in neuropathic and refractory pain states [1]. Palliative care integration from early in the disease trajectory has been associated with improved symptom control, reduced emergency admissions, and better alignment with patient goals [12,21]. The interdisciplinary management model endorsed in

Statement 11 institutionalizes shared decision-making without displacing individual specialist authority.

Although an improvement has been observed in the last decades, a persistent structural barrier to appropriate pharmacological management in Italy is the modest use of opioids – prescribing hesitancy rooted in knowledge gaps, regulatory concerns, and sociocultural attitudes – which leads to systematic underutilization of opioid analgesics even in patients with moderate-to-severe cancer pain [22]. The decision thresholds validated in Statements 1–9 are designed in part to counteract this barrier: by providing objective, consensus-backed criteria for analgesic initiation, titration, and escalation, the pathway makes guideline-concordant opioid prescribing a structurally supported clinical behavior rather than a matter of individual discretion. Non-pharmacological and integrative approaches are equally recognized: Statement 6 affirms the value of local therapies in reducing pharmacological burden, and the broader literature supports the integration of psychological, rehabilitative, and complementary interventions within a multimodal pain management strategy [10,23].

Among the most unambiguous outcomes of the Delphi process is the near-unanimous endorsement of a standardized, integrated pain record as a structural component of the oncological clinical record. All four statements pertaining to the standardized pain documentation record – Statements 12 through 15 – achieved consensus rates between 96% and 98%. Statement 12 (98%) establishes that the clinical record should incorporate a standardized form ensuring symptom traceability, data uniformity, and care continuity, in compliance with Law 38/2010. Statement 13 (96%) defines the mandatory minimum content: pain localization, qualitative characteristics, and intensity measured with a validated scale such as the NRS. Statement 14 (98%) requires documentation of analgesic therapies in progress and their clinical outcomes. Statement 15 (96%) recommends inclusion of an assessment of pain’s impact on the patient’s quality of life, coherently with the increasing recognition of the importance of patient-reported outcomes in the continuum of care for patients with cancer [24]. Italy’s Law 38/2010 has mandated systematic pain documentation since 2010, yet adherence has remained fragmented, particularly outside specialist centers [6,14]. In a previous Delphi consensus among Italian medical oncology specialization school directors, a form was validated, which provides a concrete, widely endorsed instrument to close this implementation gap and simultaneously enables longitudinal symptom traceability and inter-center care medical continuity [14].

The recommendation of including quality of life as an assessment dimension (Statement 15) also reflects the fundamental inseparability of pain and QoL across all phases of the cancer care continuum. Pain and fear of recurrence represent the two Health-related-QoL subdomains most consistently rated as important by patients at all stages of disease [13]. Uncontrolled pain is associated with social isolation, loss of daily functioning, psychological distress, financial toxicity, and – in patients with advanced cancer – shortened survival [12,16,25].

From a methodological standpoint, the study presents several strengths. Adherence to CREDES guidelines ensured procedural rigor and reporting transparency [11]. The steering committee comprised representatives of six major Italian clinical societies, and the Delphi panel included 56 multidisciplinary clinicians with broad geographic representation. Consensus was defined at a pre-specified threshold of ≥75% of respondents rating a statement 4 or 5 on a 5-point Likert scale. It was reached for all 15 content statements, with multiple items approaching or attaining 100% agreement. Anonymous voting and open qualitative comment collection in each round further reinforced validity. Nonetheless, several limitations must be acknowledged. The pathway was developed specifically within the Italian NHS framework and reflects its regulatory context, regional infrastructure, and specialty organization; adaptation to other healthcare systems would require contextual revision. The caregiver voice was not directly represented in the panel – a gap that future iterations of the pathway should address by incorporating caregiver-reported perspectives among primary inputs. No pediatric component was included, which would require separate development. Finally, and importantly, the present study produces a consensus-validated framework; its clinical impact on patient outcomes in real-world practice remains to be evaluated through prospective implementation research. The present consensus is therefore best understood as a necessary but not sufficient step in a longer continuum: from the national roundtable that identified the gaps, to this Delphi that translates them into actionable clinical statements, to the implementation and evaluation work that must follow.

Author Contributions: Conceptualization: M.G.; Methodology: M.G., F.C., S.N.; Statement development: All; Data curation and formal analysis: All; Writing – original draft: MG., F.C., S.N.; Writing – review and editing: all authors; Approval to submit: all authors.

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Institutional Review Board Statement: This study involved voluntary, anonymous survey responses from healthcare professionals, selected by national professional associations. No patient data was collected. In accordance with applicable Italian and international regulations, formal ethical approval was not required for this type of expert consensus study. Participation in the Delphi survey implied informed consent to data collection and analysis.

Informed Consent Statement: Any research article describing a study involving humans should contain this statement. Please add “Informed consent was obtained from all subjects involved in the study.” OR “Patient consent was waived due to REASON (please provide a detailed justification).” OR “Not applicable.” for studies not involving humans. You might also choose to exclude this statement if the study did not involve humans. Written informed consent for publication must be obtained from participating patients who can be identified (including by the patients themselves). Please state “Written informed consent has been obtained from the patient(s) to publish this paper” if applicable.

Data Availability Statement: The aggregated, anonymized data supporting the findings of this study are available from the corresponding author upon reasonable request. Individual panelist responses are not publicly available in order to preserve participant confidentiality.

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Conflicts of Interest: In the last 2 years, DF has received fees as a consultant or speaker congress from the following pharmaceutical companies: Abiogen, Alfasigma, Angelini, Chiesi, Laborest, Istituto Gentili, Grunenthal, Sandoz, SPA, Viatris and Zambon. Massimo Di Maio reports financial relationships including advisory board participation with Astellas, AstraZeneca (consultancy on osimertinib in adjuvant NSCLC), Daiichi Sankyo (trastuzumab deruxtecan in gastric cancer), GlaxoSmithKline (clinical training on quality of life and patient-reported outcomes), Janssen (hormone-sensitive prostate cancer treatments), Merck Sharp & Dohme (olaparib in pancreatic and prostate cancer and immunotherapy in lung cancer), Novartis (clinical trial methodology and interpretation), Resilience (scientific committee consultation), and Viatris (remote symptom monitoring in oncology), as well as institutional research funding as local principal investigator for trials sponsored by BeiGene (tislelizumab in hepatocellular carcinoma), Exelixis (cabozantinib and atezolizumab in advanced hepatocellular carcinoma), Merck Sharp & Dohme (pembrolizumab in hepatocellular carcinoma), Pfizer (sasanlimab in non–muscle invasive bladder cancer), and Roche (atezolizumab and bevacizumab in advanced hepatocellular carcinoma). He reports no other relevant financial interests. Non-financial interests include a leadership role as President of the Italian Association of Medical Oncology (AIOM) for the term November 2025–November 2027.

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