# Professional and Ethical Considerations Regarding the Document: "Regulations of the Waiting List Protocol to Be Applied During the Use of Hip and Knee Endoprosthesis Surgeries"

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# Executive Summary

This document provides a professional and ethical analysis of the recently introduced "Waiting List Protocol for Hip and Knee Endoprosthesis Surgeries" in Hungary. Drawing on over three decades of clinical experience in both Hungarian and UK healthcare systems, and four years of ethical leadership within the Hungarian Medical Chamber, the author highlights several critical concerns regarding the protocol's medical justification, ethical soundness, and practical applicability.

Key findings include:

- The absence of **relative contraindications**, which limits individualized medical decision-making.
- Restrictive use of **BMI thresholds**, diverging from international best practices and potentially exacerbating social inequities.
- **Lack of multidisciplinary perspectives** and insufficient integration of patient autonomy and rights.
- Vague and inconsistently applicable criteria, such as those for prioritization and exclusion.
- Ethical risks in **steering patients toward private care** due to unmet needs in the public system.

The analysis proposes actionable recommendations to enhance the protocol's fairness, transparency, and clinical integrity. These include the adoption of a **multidisciplinary framework**, the **removal of absolute BMI cutoffs**, the development of **standardized yet flexible clinical guidelines**, and the implementation of **publicly funded lifestyle support programs**.

Incorporating these considerations would not only align the protocol with international standards but also reinforce its **professional credibility** and **ethical legitimacy** in the eyes of patients, providers, and policymakers alike.

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# 1. Introduction

These professional and ethical reflections are based on over three decades of experience in elective hip and knee joint replacement in Hungary, along with two decades of practice in the United Kingdom, as well as my expertise in medical ethics and leadership activities in this field. Since I am directly involved in both public and private healthcare systems in Hungary and the UK, this critical analysis reflects a dual professional perspective.

In the United Kingdom, I work in an major joint replacement center that is among the best-performing institutions in the country according to long-term results of the National Joint Registry. The protocols and care practices applied there are continuously validated through daily clinical practice and are therefore directly based on the highest level of professional standards. The formulation of the current critical remarks has been driven solely by professional and ethical improvement intentions; they do not reflect any political or non-professional considerations.

The NEAK waiting list protocol, published on April 1, 2025, could represent an important step forward in unifying major joint replacement care and establishing an objective surgery scheduling system and its implementation monitoring. However, it reveals such significant professional and ethical conceptual deficiencies that its practical execution neither aligns with international best practices nor harmonizes with the fundamental principles of medical ethics.

# 2. General Professional and Ethical Deficiencies of the Protocol

## 2.1. Application of Ethical Principles

In evaluating the current protocol, not only medical professional criteria but also ethical principles are indispensable. Among these, the following are of particular importance:

- **Non-maleficence ("Do no harm")**: A core medical principle is to avoid causing unnecessary or avoidable harm to patients. Unjustified delays in surgery – such as those resulting from unrealistic administrative barriers or overly strict exclusion criteria – can cause significant physical, psychological, and social disadvantages to the patient. Rules that do not reduce risk in themselves but increase patient vulnerability and suffering should be avoided in the protocol's application.
- **Justice**: According to the principle of fair access, all patients must be given a chance to receive care, regardless of their social status, BMI, or age. The protocol should avoid disproportionate exclusions and ensure equal opportunities for vulnerable groups.
- **Benefit maximization**: Priority decisions should be based on where the greatest functional improvement, gain in quality of life, or independence can be achieved. Therefore, decisions should not be based solely on age, BMI, or administrative criteria but also on the potential “benefit” for the patient.
- **Distributive justice**: The distribution of healthcare resources – including surgical capacities – should be organized in a way that reduces, rather than increases, social disparities. The protocol serves this purpose well if it distributes benefits not only to the patients in the best condition but also to those most in need.

The conscious incorporation of these principles is essential for the protocol to function not merely as an administrative regulation but as a morally defensible, equitable, and professionally sound decision-making framework.

## 2.2. Lack of Relative Indications and Contraindications

The protocol completely lacks the concept of relative indications and relative contraindications. This is an unorthodox solution even by international standards and inherently carries the risk that the protocol's practical implementation will fail to achieve the very goals its authors have rightly set.

The so-called “temporary contraindications” included in the protocol are not equivalent to relative contraindications. These impose time-based restrictions on both the patient and the treating physicians, removing the benefit/risk assessment entirely from the hands of the clinical team. They also prevent the patient from meaningfully participating in such assessments.

By not allowing for relative judgments, the protocol eliminates one of the most essential aspects of medical professionalism: individualized, nuanced decision-making that takes into account each patient’s specific condition, risks, and potential benefits. As a result, decisions become rigid, overly rule-bound, and detached from clinical realities, which can undermine both the quality of care and the ethical soundness of the healthcare system.

## 2.3. Absence of a Multidisciplinary Perspective

It is important to emphasize that the responsibility for placing a patient on a surgical waiting list and deciding on operability does not lie solely with the operating surgeon, but with the entire care team – including the anesthesia team. A multidisciplinary approach is essential in such a professional protocol, as is the enforcement of patients’ rights and the inclusion of the patients’ perspectives and voices.

Reading through the protocol, it is concerning that neither patients, patient organizations, patient rights advocates, nor bioethics experts appear to have been involved in its development.

Such lack of involvement may result in a document that, while administratively functional, lacks ethical legitimacy and practical applicability due to the absence of real-world perspectives from those directly affected by the regulations.

## 2.4. Lack of Sources and International Best Practices

The protocol lacks references and source citations, and it includes no mention of international best practices. This is particularly problematic because, in practice, such references can serve as crucial guidance for users when faced with implementation dilemmas.

This omission does not mean that certain elements of widely accepted clinical guidelines cannot be recognized in the document. However, the mere general allusion to such principles

without proper referencing is insufficient in a professional document of this significance — both in terms of credibility and practical usability.

In international practice, well-documented and evidence-based references are foundational to protocol legitimacy. Their absence in this case undermines the scientific grounding and transparency of the document, and may result in inconsistencies during implementation.

## 2.5. Issues of Objectivity and Verifiability

Surgical indications and contraindications cannot be determined strictly in black-and-white terms. While it is understandable that decision-makers aim to define criteria for waiting list inclusion or prioritization based on clear professional and administrative rules — to make supervision and monitoring easier — this approach has serious limitations.

If such rules are unclear, insufficiently detailed, or diverge significantly from current international standards, they may open the door to ambiguity, misinterpretation, and even abuse, rather than supporting the system. Instead of fostering a unified, nationwide standard practice, the protocol as currently written creates a regulatory environment that — due to the lack of relative indications and room for professional judgment — encourages divergent institutional and individual practices.

This leads to a fragmented system where access to care becomes inconsistent, the patient pathway unpredictable, and the protocol open to varied interpretation. Over time, this could undermine the transparency and legitimacy of the healthcare system.

The protocol also reflects a mindset in which physicians are viewed more as subjects of oversight than as autonomous partners in the system. This is evidenced by the protocol's reliance on rigid, binary criteria and the lack of scope for specialist discretion through relative indications or contraindications.

Such a narrow regulatory framework risks sidelining medical judgment, while responsibility for outcomes still rests with providers. Ideally, the protocol would set out clear professional guidelines but also allow room for documented medical decision-making — especially in complex or borderline cases. This would allow the regulation to serve not only as a control mechanism but also as a genuine decision-support tool in clinical practice.

## 2.6. Need for Regular Review of the Protocol

To ensure the long-term credibility and applicability of the protocol, it is essential to define how often and by what mechanisms it will be reviewed and updated. Introducing a revision cycle — ideally on an annual or biennial basis — would allow the content to evolve based on practical experience, international recommendations, and ethical feedback.

Predefining the review criteria and assigning responsibility to a specific committee would guarantee transparency and promote continuous professional development. Such a process would also help maintain alignment with evolving standards of care and ethical expectations.

Without this regular update mechanism, the protocol risks becoming outdated, misaligned with current best practices, and ultimately losing both its relevance and effectiveness in practice.

# 3. Application of Professional and Ethical Aspects at Key Points of the Protocol

## 3.1. Issues in the Use of Body Mass Index (BMI)

Following the publication of the protocol, media coverage most frequently focused on the restrictive criteria related to body mass index (BMI), though this is far from the only issue of concern from a professional and ethical standpoint.

Nonetheless, the temporary contraindication based on BMI values included in the protocol unquestionably requires reconsideration from both a professional and ethical perspective.

According to current NICE recommendations, specifying any BMI threshold as a criterion for access to elective hip and knee replacement surgeries is considered counterproductive and discriminatory. Prolonged postponement of surgeries for patients with higher BMI often leads to worsening general or psychological condition, and even further weight gain. In such cases, the aim of surgery is no longer primarily quality of life improvement, but rather a vital intervention — for example, enabling the patient to get out of a wheelchair, to mobilize, and to prevent serious complications associated with immobility (e.g. pneumonia, pressure ulcers, infections, cardiovascular complications, thrombosis, pulmonary embolism, etc.).

The protocol currently lists BMI values over 35–40 as a temporary contraindication for all hip and knee joint replacements. However, stating a 35–40 range makes little sense if a value over 35 is already considered a contraindication. Mentioning this range is thus misleading, as it falsely implies that the physician can make a nuanced judgment within it.

Classifying patients with BMI over 35 as being in a postponed status contradicts international practices. For example, both NICE (UK)[(1)] and the British Orthopaedic Association (BOA)[(2)] guidelines clearly state that access to elective joint replacements must not be restricted based solely on BMI. The BOA emphasizes that decisions should be based on the individual's clinical status and recognizes that deferring surgery purely based on BMI can lead to inequality in access to care.

In the United States, the American Academy of Orthopaedic Surgeons (AAOS)[(3)] does not issue specific BMI thresholds as exclusion criteria, while in Sweden[(4)], patients with BMI >35 regularly undergo surgery. In Germany[(5)], although some recommendations treat BMI >40 as a relative contraindication, this still does not automatically exclude patients from surgery.

Instead, decisions are made through individual assessment and multidisciplinary team discussions.

The updated NICE guideline (October 2022) ( https://www.nice.org.uk/guidance/ng246 ) regarding arthritis clearly states that BMI must not be used as an exclusionary factor for surgical referral. Nevertheless, in some regions of the UK, local policies still restrict access to elective surgeries based on BMI, highlighting a disconnect between national guidelines and local practice — a gap that in itself threatens equality of access and ethical consistency in clinical decision-making. (https://bmcmedicine.biomedcentral.com/articles/10.1186/s12916-023-02899-3)

Hungarian regulation is thus stricter than many international norms and should be reviewed to determine whether it aligns with the principles of equal access and individualized consideration.

## 3.2. Indirect Impact of the Protocol on Steering Patients Toward Private Healthcare

Due to its restrictive criteria — particularly the exclusions based on BMI and narrow priority settings — the current protocol may result in some patients being unable to receive timely care within the publicly funded healthcare system. As a consequence, they may feel compelled to seek private healthcare alternatives.

This not only increases health inequities, but may also indirectly incentivize market actors to target patients who are excluded or deprioritized by the protocol. In fact, private healthcare advertisements have already emerged that specifically offer surgical options to patients who were turned away or postponed due to BMI restrictions. (Example: Facebook advertisement)

This trend undermines the principle of equitable access to healthcare and jeopardizes the solidarity principle of social insurance-based systems. It is crucial that the developers of such protocols consider these indirect effects and implement regulations that do not push disadvantaged patients toward out-of-pocket solutions.

## 3.3.1. Malignancy requiring active oncological treatment

From a medical standpoint, it may be justified to postpone joint replacement surgery if the patient is undergoing active oncological therapy (e.g. chemotherapy or radiotherapy), as such treatments increase the risks of infection, impaired wound healing, and bleeding.

However, the decision to delay surgery should always be made in consultation with an oncologist and within a multidisciplinary team involving the surgeon, anesthesiologist, and rehabilitation specialist. This decision must take into account the stage of the tumor, the timing of treatment, the expected quality of life, and the patient's personal preferences.

It is equally important to specify that the postponement should apply only during the period of active cancer therapy, and that the case must be re-evaluated afterward.

From an ethical perspective, informing and involving the patient is essential, as pain and limited mobility often significantly diminish the quality of life for cancer patients as well. A transparent, patient-centered process respects autonomy and supports dignity — even in complex oncological situations.

### 3.3.2. Use of Anticoagulants

The use of anticoagulant medications alone does not justify postponing surgery, as established perioperative protocols exist for the temporary suspension or bridging of most modern anticoagulants.

This criterion would only be medically justified in specific cases where anticoagulation cannot be interrupted — for example, in patients with a recently implanted mechanical heart valve. In such rare instances, the surgical risk may outweigh the potential benefit.

Therefore, the protocol should refine this criterion to avoid blanket exclusions. From an ethical perspective, it is problematic to automatically exclude all patients on anticoagulation therapy without individual risk assessment. Each case should be evaluated based on the specific indication for anticoagulation and whether appropriate perioperative management can be implemented.

An individualized and documented assessment — involving the treating physician, anesthesiologist, and possibly a cardiologist or hematologist — ensures that decisions remain medically sound and ethically defensible.

### 3.3.3. Insufficient Patient Cooperation or Social Circumstances

This is a particularly sensitive category that easily lends itself to discrimination. From an ethical standpoint, it would be entirely unacceptable for social conditions alone to serve as grounds for exclusion from surgical care.

Instead of using social disadvantage as a reason to deny treatment, the appropriate response should be to activate support structures — such as social services, home care programs, or involvement of caregivers and family members.

From a professional standpoint, the evaluation must determine whether the patient's limited cooperation would genuinely hinder postoperative rehabilitation. This is a complex issue that may require assessment by a multidisciplinary team, including a psychiatrist, rehabilitation specialist, social worker, or case manager. Only through their collective input can an objective and fair judgment be made.

It is also crucial to define how such conditions should be reviewed over time, as a patient's capacity for cooperation can improve — especially with appropriate support.

All such decisions must be properly documented, and the patient should be monitored and supported throughout. Only this approach ensures fair and ethical access to care and avoids unjust exclusion based on social vulnerability.

### 3.3.4. Temporarily Excluding Conditions by Other Medical Specialties

In this category, it would be important to include concrete examples and require specific specialist input.

Conditions such as untreated hypertension, unstable diabetes, acute infections, or uncontrolled epilepsy may be legitimate reasons for temporarily excluding a patient from surgery. However, such decisions should not be arbitrary or undocumented.

A professionally sound approach would require that the temporary exclusion be clearly justified by the relevant medical specialist (e.g. internist, diabetologist, neurologist), and that the decision be based on objective findings and current clinical guidelines.

Furthermore, the protocol should ensure that patients are informed about the reasons for exclusion and are given clear instructions on what needs to be addressed — and when they can expect to be re-evaluated for surgical eligibility.

### 3.3.5. Newly Discovered Preoperative Obstacles

This is a realistic and common scenario — during preoperative assessments, new findings may emerge that temporarily prevent the surgery from proceeding.

However, the protocol should clearly define how long such temporary exclusions are valid, and when re-evaluation must occur. There should also be a structured process for reactivating the patient's status on the waiting list once the issue has been resolved.

Without such procedural clarity, patients risk being left in limbo — excluded from surgery indefinitely due to treatable or time-limited conditions. A transparent mechanism for follow-up and reinstatement supports both professional integrity and ethical fairness.

## 3.4. Detailed Professional-Ethical Critique of Absolute Contraindications

### 3.4.1. Total Lack of Cooperation

It is medically justified to deny surgery if the patient is entirely incapable of cooperating postoperatively, making effective rehabilitation impossible.

However, it is essential to clearly define **who** determines this lack of cooperation and **based on what objective criteria**. Ideally, this judgment should be made by qualified specialists such as a psychiatrist, neurologist, geriatrician, or rehabilitation physician.

Without such definitions, the decision becomes subjective and potentially inconsistent, increasing the risk of unjust exclusion.

Documented, specialist-based assessment ensures transparency and ethical defensibility — especially in cases involving cognitive impairment, psychiatric conditions, or other complex factors influencing cooperation.

### 3.4.2. Severe Cardiorespiratory Insufficiency

This can be a realistic and legitimate absolute contraindication for surgery. However, it is essential to define the **objective criteria** that determine the severity of the condition.

For example:

- New York Heart Association (NYHA) Class IV heart failure
- Left ventricular ejection fraction (EF) below 20%
- Dependence on continuous oxygen therapy

The protocol should require a **multidisciplinary decision-making process**, involving an anesthesiologist, cardiologist, and pulmonologist, to ensure an accurate and well-founded assessment.

Such a structured approach helps differentiate between cases where surgery is truly unsafe and those where it could still be justified with careful planning and appropriate support.

### 3.4.3. Severe, Non-Improving Limb Circulatory Disorders

This is a medically valid criterion, but it would be appropriate to specify:

- **Which diagnostic tools** are to be used for assessment — such as Doppler ultrasound or angiography
- **Which specialist** (e.g. vascular surgeon or angiologist) is responsible for making the decision

Defining these elements helps ensure that decisions are based on measurable, reproducible findings and not on subjective impressions. It also ensures consistent and equitable application of the protocol across different institutions.

Objective diagnostic confirmation and documented expert input are essential to uphold both the clinical soundness and ethical fairness of the exclusion.

### 3.4.4. Certain Cases of Apoplexia Cerebri

This phrasing is extremely broad and ambiguous. The term *"certain cases"* is undefined and not medically specific, which creates significant legal and clinical uncertainty.

The protocol must clarify:

- **How recent** the stroke occurred
- **What kind of residual symptoms** are present
- **What level of functional status** constitutes an exclusion

Not all patients who have experienced a stroke should be automatically excluded. Many recover sufficiently to benefit from joint replacement surgery, particularly in terms of pain relief, mobility, and independence.

Therefore, these cases should always be assessed through a **multidisciplinary team**, ideally including a neurologist, rehabilitation specialist, and geriatrician. Together, they can evaluate the patient's postoperative rehabilitation potential and ability to regain functional independence.

Without clear criteria and team-based evaluation, the current formulation risks unfairly denying care to patients who might otherwise benefit significantly from the surgery.

### 3.4.5. Neurogenic Arthropathy

This may be a medically justified contraindication, but it requires more specific definition.

For example, **active-phase Charcot joint** may indeed represent a contraindication to surgery due to instability, risk of infection, or poor healing. However, in a **stable phase**, surgery could still be considered on a case-by-case basis.

Therefore, the protocol should not treat all forms or stages of neurogenic arthropathy as absolute exclusions. Instead, it should support individualized evaluation — considering the disease stage, neurological function, infection risk, and patient mobility goals — ideally through a multidisciplinary consultation.

This ensures that decisions are clinically appropriate and ethically proportional to the patient's actual condition.

### 3.4.6. Gluteus Medius/Minimus or Quadriceps Dysfunction (0–1 Muscle Strength)

This is a valid clinical consideration, as severe muscle weakness in these key stabilizing muscle groups can compromise the functional outcome and stability of joint replacement surgery.

However, it is important to clarify that this should only be considered a contraindication **if the postoperative stability and function would be severely impaired and not improvable through rehabilitation**.

In some cases, prehabilitation or post-surgical physical therapy may improve muscle function sufficiently to allow a safe and beneficial procedure. Therefore, a blanket exclusion is not appropriate.

Assessment should be based on:

- Objective clinical tests of muscle strength
- Functional evaluation
- Multidisciplinary input from orthopedic surgeons, rehabilitation specialists, and physiotherapists

This nuanced approach supports individualized care and avoids unjustified exclusion based solely on initial muscle function measurements.

### 3.4.7. Short Life Expectancy (<3–6 Months)

This is a logically sound clinical criterion, but it must be applied with great care due to its ethical sensitivity.

Importantly, any assessment of limited life expectancy should be **confirmed by an oncologist or another relevant specialist**, and must be based on realistic, medically grounded prognostic tools. Even so, predictions about life expectancy are often uncertain, and should **never override a patient's right to autonomy**.

From an ethical perspective, the patient's **preferences and values** — especially regarding pain relief, mobility, and quality of life — must be taken into account in every case.

There are scenarios where **joint replacement may be justified even in palliative care**: for example, to enable mobility, reduce severe pain, or restore partial independence. In such cases, the decision should be made jointly by a **multidisciplinary team** (e.g. oncologist, anesthesiologist, rehabilitation specialist) in collaboration with the patient, and it should be **clearly documented**.

Rather than applying this criterion as a rigid exclusion, it should be integrated into a flexible and individualized decision-making process that respects patient dignity and clinical realities.

### 3.4.8. Internationally Recognized Contraindications Listed by Other Specialties

This phrase is overly vague and lacks specificity. Simply referring to "contraindications listed by other specialties" does not provide clear guidance for clinical decision-making or ensure transparency.

For example, internationally accepted contraindications by other disciplines might include:

- **Uncontrolled bleeding disorders** (e.g. severe hemophilia)
- **Active psychiatric conditions** that significantly impair cooperation
- **Severe, decompensated metabolic diseases**, such as unstable diabetes or liver failure

At a minimum, the protocol should include **examples and references** to help define which types of conditions fall under this category. It should also require that any such exclusion be based on a **documented, specialist opinion**, not merely on subjective judgment.

Clearer definition would improve consistency in implementation, prevent overuse of this category, and ensure that exclusions are based on objective, evidence-based criteria.

## 3.5. Evaluation of Priority Criteria

According to the protocol, musculoskeletal pain that can only be relieved with narcotic analgesics qualifies as an urgent surgical indication. However, it is unclear **how the operating surgeon is expected to verify** this criterion in practice.

To prevent misuse, it is recommended to clarify:

- The **timeframe**, **dosage**, and **documentation requirements** for the use of narcotics
- The involvement of **primary care physicians**, **treating specialists**, and, where appropriate, **pharmacists** in verifying this information

Such documentation should include:

- Objective pain assessment (e.g. using a Visual Analogue Scale [VAS])
- Type and dose of medication used
- Duration of use
- Lack of adequate pain relief despite therapy

Only on this basis can the determination of urgent surgical need be professionally and ethically justified. It would also ensure **equal and fair access** to care.

However, the mere fact that a patient uses narcotic painkillers — similar to the patient's age or wheelchair use — should **not automatically qualify** them for high-priority status. It should be considered as one of **several possible relative indications**, evaluated as part of a **case-by-case decision**.

This clarification would also help prevent misuse, such as situations where patients might **request narcotic medications solely to move ahead on the waiting list**, even without genuine medical necessity. Therefore, proper **documentation and verification by general practitioners or specialists** is especially important.

The protocol also grants urgent priority to patients whose hip degeneration impairs self-care or who rely on a wheelchair. However, it does not define **who assesses eligibility** or **how this is verified** in practice.

In such cases, the involvement of **general practitioners** and, if needed, the **social care system** (e.g. home assistance services) would be advisable to objectively confirm the situation. Criteria could include:

- **Duration and extent** of wheelchair use
- **Degree of loss of independence** in daily activities

Similarly, wheelchair use **should not automatically trigger priority status**, but rather serve as one factor among others in a **multifactorial, individualized evaluation**.

The protocol also rightly notes that for **working-age adults**, the potential to regain ambulation and work ability may serve as a consideration for prioritization. However, in practice, it is unclear **how this is verified**. In these cases, the **involvement of occupational health specialists** is recommended. They can objectively assess:

- The patient's current work capacity
- The expected impact of surgery on return-to-work outcomes

Still, as with other factors, the potential to return to work **should not serve as an automatic prioritization criterion**, but rather one of several **relative indications**, considered alongside clinical and quality-of-life factors.

The protocol's positive feature is that it allows **patients over 80 years old**, who are otherwise medically fit for surgery, to be placed in a faster-track queue. However, this **does not guarantee** that such patients will actually receive surgery within 3 months. This is because the protocol still prioritizes **chronological order** among patients with similar priority.

Thus, even an eligible patient over 80 may be postponed if others with similar priority were registered earlier. Furthermore, introducing an **age cutoff at exactly 80 years** raises ethical questions. Why not 75 or 85? Age does not always reflect functional condition — a 65-year-old may be in greater need than an 80-year-old.

Therefore, relying on calendar age is both **imprecise and potentially discriminatory**. Instead, the protocol should place greater emphasis on **biological age**, **functional status**, and **expected quality of life**, using these to guide priority classification.

In summary: age, like other factors, should be treated as a **relative, non-dominant criterion**, weighed alongside individual clinical and functional considerations.

## 3.6. The Issue of Subjective Pain

Among the acute priority criteria in the protocol is the occurrence of "sudden significant pain, which cannot be effectively relieved due to disease progression or internal medical conditions (e.g. active peptic ulcer, liver or kidney failure)."

While this clause aims to address important clinical scenarios, its current wording is problematic in several ways:

- The terms **"sudden"** and **"significant"** pain are **entirely subjective**, lacking any reference to objective measurement or documentation standards.
- The phrase **"cannot be effectively relieved"** is also vague — it does not clarify what level of pain, what types of pain management attempts, or what time frame constitutes "ineffective relief."
- It is not defined **who is responsible** for confirming these conditions — whether it's the general practitioner, specialist, or the treating institution.

This vagueness leaves room for **misinterpretation or abuse**, such as cases where a patient might exaggerate or misrepresent their symptoms in hopes of being moved forward on the waiting list. Alternatively, providers may apply the rule inconsistently due to lack of guidance.

To improve fairness and clarity, the criterion should be **more precisely defined**, including:

- A minimum pain level (e.g. **VAS ≥ 7** on a standardized pain scale)

- **Documented failure** of pain relief using conventional treatments
- A **confirmation by a general practitioner or specialist** stating that the pain cannot be effectively managed through standard care

For internal medical conditions (e.g. contraindications to NSAIDs due to bleeding risk), the protocol should also require **appropriate documentation** to support the indication. This ensures that the urgency is both **legally valid and professionally well-founded**.

# 4. Application of Professional and Ethical Aspects in Other Sections of the Protocol

## 4.1. The Question of Multiple Joint Involvement

One of the protocol's positive features is that it explicitly states: in cases of **severe bilateral hip or knee joint involvement**, surgery on one side may be prioritized as a subacute procedure. This is a forward-thinking provision.

However, the protocol does not address situations where **two different types of major joints** (e.g. one hip and one knee) are simultaneously severely affected and both require prosthetic replacement. Similarly, it does not consider more **complex cases** involving three or even four major joints (e.g. both hips and one knee, or both knees and one hip).

In such situations, it would be appropriate for the patient to enjoy the **same prioritization rights** as in the case of bilateral hip or knee involvement. For example, in the UK's NHS practice, the patient becomes eligible for subacute timing only after the **first surgery** has been completed — thereby maximizing its benefits and supporting the rehabilitation process.

It is recommended that the Hungarian protocol adopt a similar principle, ensuring equitable treatment for patients with multiple joint involvement regardless of the specific combination of affected joints.

## 4.2. Timeliness Requirements of Imaging Studies

The protocol currently requires that patients must have **a two-view hip X-ray, CT, or MRI taken within the past 3 months** in order to be placed on the surgical waiting list. It also states that imaging older than 3 months is only acceptable if the surgical indication is still present.

However, this wording is **ambiguous and clinically unclear**, particularly regarding:

- **Who decides** whether the indication still applies
- **How such a decision is to be documented** if the imaging is outdated

In many cases, joint degeneration progresses **slowly**, and symptoms may not significantly change over time — meaning that the indication for surgery may remain valid even if the imaging is older than 3 months.

According to international practice — for example, the NICE guideline (UK) — the **clinical relevance** of the imaging is the primary factor, **not its age**. If the available imaging clearly supports a surgical indication, and the patient's clinical condition hasn't changed, new imaging **is not necessarily required**.

Therefore, it is recommended that the Hungarian protocol adopt a **more flexible, clinically grounded approach**. A professionally and ethically sound formulation could be:

"For surgical planning, imaging performed within the last 3 months is recommended. However, for inclusion on the waiting list, earlier imaging may be accepted — provided that the patient's condition has not changed significantly and the treating physician confirms the continued validity of the indication."

A time limit (e.g. **6 to 9 months**) could still be defined for practical purposes, but only in a **supportive**, not exclusionary, role.

This adjustment would align the protocol with principles of **clinical relevance**, **justice**, and **cost-effectiveness**.

## 4.3. Standardizing the Dental Criteria and Providing Guidelines

Preoperative dental assessment — and treatment if necessary — is indeed an important step in preventing prosthetic joint infections. However, the current system lacks a **uniform, nationally accepted protocol or guideline** defining:

- Which dental conditions warrant surgical postponement
- Which findings are not considered obstacles to elective joint replacement

As a result, dental care practices vary widely, leading to:

- **Over-treatment** in some cases (e.g. unnecessary tooth extractions or surgery delays)
- **Under-treatment** in others (e.g. active infections going undetected or undocumented)
- **Patient confusion**, with many unsure why a surgery is accepted or refused based on dental evaluation

This inconsistency contradicts the principles of **evidence-based medicine** and increases inequalities in care. Drawing from international examples — such as NICE or the Philadelphia Consensus[6] — a **clear and practical guideline** should be developed and provided to dental professionals.

Such a guideline should include:

- Which dental pathologies **require urgent treatment** (e.g. active abscess, untreated root infections)

- Which conditions **do not delay elective surgery** (e.g. stable, asymptomatic periodontal status)
- How the **dental opinion** should be formulated and communicated to the orthopedic surgeon

This would support coordinated patient care, reduce confusion and financial burden on patients, and promote both **professional accountability and patient safety**.

# 5. Development Possibilities of the Protocol

## 5.1. Involvement of Patient Organizations and Civil Society

During the development of the protocol, it would be highly beneficial to **systematically involve**:

- **Patient advocacy groups**
- **Patient rights representatives**
- **Bioethicists**
- And other stakeholders from **civil society**

Such involvement would significantly enhance the **ethical and social legitimacy** of the document and ensure that the **patient perspective** is appropriately reflected in its content.

Engaging a broader range of voices would also help identify potential blind spots or ethical dilemmas that might not be evident from a purely clinical or administrative viewpoint. This inclusive process is in line with international best practices and reinforces trust in the healthcare system.

## 5.2. Strengthening Multidisciplinary Team Decision-Making

In surgical decision-making, the **shared responsibility** of the **multidisciplinary team** — including the surgeon, anesthesiologist, and case manager — should play a more prominent role.

This team-based approach allows for:

- **Balanced risk–benefit assessment**
- **Tailored, patient-specific decisions**
- **Flexible application of the protocol** in complex clinical situations

Such collaboration ensures that no single specialist is forced to make unilateral decisions in difficult cases and that patients benefit from a **holistic evaluation** of their medical, social, and ethical circumstances.

Strengthening multidisciplinary decision-making structures also supports accountability, reduces subjective bias, and enhances ethical fairness — especially in borderline cases or those involving relative contraindications.

The protocol should explicitly encourage and formalize this **team-based decision-making framework**.

## 5.3. Importance of Introducing Relative Contraindications

The current version of the protocol **lacks the concept of relative contraindications**, which is a significant deviation from international standards. In global practice, this concept allows the treating surgeon and anesthesiology team — through **multidisciplinary collaboration** — to make individualized decisions about whether surgery is feasible, even in higher-risk scenarios.

Introducing **relative contraindications** would make it possible to:

- Avoid rigid, automatic exclusions
- Acknowledge **nuanced clinical judgment**
- Document decisions transparently while still maintaining safety

Rather than functioning as strict exclusionary or delaying factors, relative contraindications would support a **flexible framework** where complex cases are **carefully evaluated** based on a combination of clinical, functional, and ethical criteria.

This adjustment would bring the Hungarian protocol into closer alignment with **international best practices** and enhance its practical, ethical, and professional integrity.

## 5.4. Rethinking Exclusions Based on BMI

The **Body Mass Index (BMI)** should **not function as an automatic exclusionary or delaying factor** in surgical decision-making.

Instead, BMI-related considerations should fall under the category of **individual, documented medical assessment**, where:

- The **patient's overall health status**,
- The **expected surgical risks**,
- And the **potential benefits of the procedure** are all carefully weighed

International guidelines — including those from NICE (UK), BOA, and AAOS — emphasize that **access to elective joint replacement surgery should not be restricted solely on the basis of BMI**.

The protocol should be revised to reflect this principle, moving away from fixed numerical thresholds and allowing for a **more nuanced and ethically sound evaluation**, which also takes into account the patient's **quality of life, mobility**, and **clinical trajectory**.

This change would promote fairness, align with evidence-based practice, and reduce inequities in access to care.

## 5.5. Risks of Low BMI

It would be professionally appropriate to incorporate the potential risks associated with **low BMI** (e.g. **BMI <18.5**) into the protocol.

In patients with low BMI, the following factors may lead to **increased surgical and postoperative risks**:

- **Malnutrition**
- **Reduced muscle mass and strength**
- **Lower bone density**
- **Delayed wound healing**

These conditions may compromise recovery and increase the likelihood of complications.

Therefore, just as obesity should not lead to automatic exclusion, **underweight status** should also be considered as a **relative risk factor**, not an absolute one. Each case should be **individually assessed** by the care team — possibly with input from a nutritionist, rehabilitation expert, or internist.

This balanced approach supports **safe surgery** while also **respecting the principles of equity and individualized care**.

## 5.6. Assessment Based on Health Condition and Quality of Life

The protocol should explicitly include the principle of **assessment based on overall health status and quality of life**.

Instead of relying solely on **numerical criteria** (such as BMI or age), decision-making should take into account:

- The patient’s **functional capacity**
- Their **level of pain and mobility limitation**
- The **expected improvement** in quality of life following surgery

- The **patient's own goals and preferences**

This approach reflects the core principles of **patient-centered care**, respects autonomy, and aligns with international ethical and clinical guidelines.

By incorporating these considerations, the protocol would support **more equitable, individualized**, and **ethically sound medical decisions**.

## 5.7. Social and Ethical Considerations

It must be clearly stated that **no form of discrimination** is acceptable in access to healthcare based on:

- Gender
- Religion
- Nationality
- Race
- Sexual orientation
- Intelligence quotient
- Insurance or financial status
- Social relationships
- Age
- Or disability

**None of these factors** may be used to restrict access to care. Decision-making based on such criteria is **unethical**, and in extreme cases, may even carry **criminal consequences**.

Similarly, prioritizing patients based on their **perceived social utility** — for example, evaluating them by their societal role or economic "value" — is also **unethical, discriminatory, and unlawful**.

Every patient's **human dignity** carries **equal value**, and this must be reflected in every healthcare-related decision. Upholding this principle is essential for **maintaining trust**, ensuring fairness, and safeguarding the moral integrity of the healthcare system.

## 5.8. Ethical Aspects of Professional Competence Boundaries

In clinical practice, it may occur that certain surgeons — due to a **lack of experience with more complex cases**, **outdated knowledge**, or even **personal fears** — decline to perform surgeries that could, in fact, be safely carried out in a different setting or with a more experienced team.

If the **reason for refusal is not the patient's medical condition**, but rather the **limitations of the surgeon's or institution's competence**, then this raises serious **professional and ethical concerns**.

According to the principles of **autonomy** and **beneficence**, the surgeon has an obligation to **clearly inform the patient** when a procedure is not feasible at the given facility — not because of the patient's status, but because **the necessary expertise or conditions are lacking** locally.

At the same time, the surgeon should take responsibility for **referring the patient** to another institution or specialist **where the procedure could be safely performed**.

Currently, the protocol does **not provide clear guidance** on how to handle such situations. Therefore, an ethical recommendation should be included to ensure:

- **Transparency** regarding competence limitations
- And a **professional duty to redirect patients** appropriately

This protects both patient rights and professional integrity.

## 5.9. Distinction Between Traumatic and Elective Care — Substantive and Practical Considerations

Although the protocol primarily addresses **elective major joint replacement surgeries**, it occasionally includes phrasing that refers to **acute or subacute conditions**, such as trauma-related mobility loss or sudden inability to walk.

While these may be clinically relevant in certain contexts, the lack of **clear separation between emergency and elective care** is **confusing and potentially misleading** in everyday clinical practice.

In international healthcare systems — such as the **NHS (UK)**, and those in **Sweden** and **Germany** — **emergency/trauma surgeries and elective procedures** are managed under **separate protocols**, with distinct waiting lists and funding frameworks. This is based on the understanding that:

- **Urgent cases** require immediate attention and are handled via hospital emergency or trauma units
- **Elective surgeries** are planned in advance, following an optimized scheduling process and criteria

Blending these patient groups under a single prioritization framework can result in:

- **Unfair competition for resources**
- **Unclear responsibilities among providers**
- **Lack of transparency** in waiting list management

Therefore, the protocol should **clearly state** that:

- The waiting list applies **only to elective indications**
- **Traumatic or urgent cases** fall under different clinical pathways

- And that the two care models should **not be conflated** — conceptually, administratively, or financially

This distinction is essential for a **transparent, efficient, and ethically grounded system**.

### 5.10. Need for an Interpretive Guide and FAQ

To improve the **clarity and practical applicability** of the protocol, it is essential to issue an **official interpretive guide**, handbook, or **FAQ-style supplement**.

Without such supporting materials, there is a high risk of:

- **Varying local interpretations**
- **Inconsistent implementation**
- And **misunderstandings or misuse** of the rules in clinical practice

A clear interpretive guide would help:

- Ensure consistent application across institutions
- Clarify ambiguous points in the protocol
- Support healthcare providers in **ethical and legally sound decision-making**
- And help patients **better understand their rights and options**

This type of supplementary documentation is standard in many healthcare systems and significantly enhances both the **usability and legitimacy** of clinical protocols.

# 6. System-Level Developments Supporting the Protocol

### 6.1. Improving Patient Information and Care Pathway Management

In the practical implementation of the protocol, it is critically important that the **operating team** has access to **user-friendly and functional tools** for patient information and care pathway coordination.

There may be situations where a given institution — due to limited ICU capacity, restricted equipment, or narrower surgical expertise — **cannot safely provide care** to a patient. In such cases, simply **refusing treatment is not enough**.

From both an **ethical and professional standpoint**, healthcare providers are obligated to offer **clear, up-to-date, and timely information** to the patient about:

- **Which institution** is capable of performing the surgery

- **Who the appropriate specialist or team** is
- And **what timeframe** can be realistically expected for the intervention

This kind of **proactive and patient-centered communication** supports the principles of **autonomy** and **beneficence**, while also helping reduce healthcare disparities and patient vulnerability caused by lack of information.

Therefore, the system should include a **structured referral and information-sharing mechanism**, one that truly serves the patient's best interests and promotes **efficient, ethical navigation** through the healthcare system.

## 6.2. Patient-Friendly, Understandable Communication

For the protocol to be applied **effectively, ethically, and transparently**, it is essential that **not only healthcare professionals**, but also **patients themselves** fully understand its content.

Although the current regulation defines key professional criteria and rights, these are often **difficult for the average patient to interpret**.

Therefore, it is strongly recommended to publish a **patient-friendly, plain-language information document** that summarizes the most important points, including:

- **What conditions** qualify a patient for placement on the waiting list
- **What factors** can lead to prioritization (e.g. age, mobility limitation)
- **What medical tests** are required before referral
- **When and how** a patient may be transferred to another institution
- **How and when** the patient must be informed of delays or denial of treatment

Such communication:

- Promotes **patients' right to self-determination**
- Increases **trust in the healthcare system**
- And ensures that the protocol is not only **technically valid**, but also **accessible and fair** from the patient's perspective

Ultimately, **clear and understandable communication** must not be optional — it should be a **mandatory component** of the system.

## 6.3. Accessibility of Publicly Funded Weight Loss and Lifestyle Programs

Regardless of whether **BMI thresholds are included** in the protocol, it is ethically and professionally justified to ensure that patients have access to **publicly funded weight management and lifestyle improvement programs**.

Such services are essential because:

- Excess weight often contributes to joint degeneration, surgical risks, and slower recovery
- Lifestyle interventions can enhance **preoperative fitness**, reduce complications, and improve **postoperative outcomes**
- They promote **preventive care**, not just reactive treatment

However, in the current system, many patients — especially those with **lower income or limited access to care** — struggle to participate in such programs, as **availability is inconsistent**, and **financial or geographical barriers** may exist.

For a fair and effective system, the following should be guaranteed:

- Nationwide access to **free or subsidized** lifestyle support programs
- Integration of these services into the **preoperative care pathway**
- Proactive referral of patients by healthcare providers

Even if BMI is not used as an exclusionary criterion, offering structured support for lifestyle change is essential for **ethical, patient-centered, and preventive orthopedic care**.

**These considerations would significantly support the protocol's credibility — both professionally and ethically.**

## 7. References


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