All information regarding future IHI Call topics is indicative and subject to change. Final information about future IHI Calls will be communicated after approval by the IHI Governing Board.

Topic 5: Establishing ortho and cardiology ambulatory surgical centres in Europe

Expected outcomes

With advances in clinical and surgical techniques, medical technology, pain management as well as pre- and post-surgical care, more procedures that have been traditionally performed in hospital settings can now be performed in facilities outside hospitals with no overnight stays required, easing the demand on overstretched hospitals and reducing hospital acquired infections. These facilities are referred to as ambulatory surgical centres (ASCs).

The actions under this topic contribute to all the following outcomes:

1. consensus-based understanding on the hurdles, needs and requirements to establish ASCs within a European healthcare setting with a regional/national expert committee driving the community involved and acting as reference opinion leaders;

2. comprehensive framework and 'know how' for establishing ASC facilities with details on infrastructure, medical technology, protocols and healthcare resources required for establishing new facilities;

3. training schemes and programmes including care pathways and enhanced recovery protocols for all health care providers (HCPs) involved in ASCs in orthopaedics and cardiology, operating safe scalable models that achieve high quality results;

4. creation of a clinical database and generation of economical evidence forming a basis towards European acceptance, standardisation and funding allowing establishment of ASC services as an integrated part of healthcare services provided;

5. the availability of an interoperable IT technology solution required to integrate clinical data from multiple stages of the patient journey and the related digital health solutions for patient preparation, post-discharge management and home monitoring.

Target group for the outcomes are:

- hospital managers, healthcare system providers, medical technologies and digital companies seeking solutions in European, national and regional healthcare services, to address capacity and efficiency hurdles in hospitals in the fields of orthopaedics and cardiology;

- HCPs establishing ASCs in orthopaedics and cardiology to further provide and advance healthcare services and efficiency;

- patient groups and carer associations working towards patient access to more convenient locations, shorter waiting times and easier scheduling (relative to hospital inpatient and outpatient procedures). This will improve patient experience, satisfaction and outcomes from pre-procedure to recovery at home;

- HCPs and researchers working on incorporating advanced medical technology in and out of hospital settings for improved patient outcomes and healthcare efficiency;

- reimbursement bodies as well as HTA bodies providing guidelines and innovative payment schemes.

Scope

The EU's ageing population and a rising burden of diseases and disorders, in particular noncommunicable diseases (such as cardiometabolic diseases, cancers, neurodegenerative or musculoskeletal disorders), have resulted in increasing health care costs and limited procedural capacity in operating rooms and cath labs (catheterisation laboratory). Lack of specialists is also an issue. This delays patient access to health care and increases the need for alternative and more cost-effective forms of care [1]a.i.[5]. The shift of inpatient surgeries and treatments to ambulatory surgical centres (ASCs) could potentially provide a solution to the hospital capacity problem as well as reducing hospital acquired complications and providing improved access to healthcare services for patients in rural areas. ASCs are healthcare facilities focused on providing same-day surgical care, including diagnostic and preventative procedures for patients who do not require overnight stays. It is believed that ASCs can transform the outpatient experience for patients by providing them with a more convenient alternative to hospital-based outpatient procedures. ASCs can be operated by private or public healthcare services.

Numerous factors influence whether surgical procedures can be carried out within ambulatory surgical centres. The key drivers are changes and further development in clinical practice and medical technology. The action funded under this topic will be focused on ASCs specialised in orthopaedics for knee and hip joint replacement surgery as well as ASCs specialised in cardiology for cardiac ablation procedures and elective rhythmology. All of these procedures are elective and will increase in the next years due to the ageing population, improved diagnostics and extension of medical guidelines. Based on patient selection, these procedures have been proven suitable for ambulatory settings. This is reinforced by the downward trend in length of stay in hospitals for these procedures in recent years. This also reflects developments in medical technology in these procedures over the last years, that have led to more precise, faster, easier, gentler and more patient-specific interventions. Shifting those procedures from hospitals into ASCs can help to relieve inpatient capacities, enabling faster patient access to those surgeries and in the end reducing overall health care costs. It is important to stress that treatment in ASCs requires good patient selection prior to the surgery based on medical classifications – like the American Society of Anaesthesiologists' risk classification for estimating the perioperative risk – and social factors, such as the individual domestic situation of the patient, to make the intervention in ASC successful. Severe and complicated cases will still have to be treated in hospitals.

ASCs offer a lot of benefits to the health care system and can address some problems associated with inpatient treatments in hospitals. Studies show that outpatient procedures are safe and can achieve similar or superior functional outcomes compared to inpatient procedures and, for example, the early mobilisation facilitated by outpatient pathway in hip and knee replacement surgeries contributes to faster recovery timelines [1]a.i.[1] [1]a.i.[2].

Due to the fact that the costly infrastructure of the hospital is not needed, and patients go home the same day after an outpatient procedure, the shift of procedures into the outpatient setting results in significant cost savings (an outpatient total shoulder arthroplasty (TSA) results in a 40% decrease in charges [1]a.i.[3] and unicompartmental knee replacement (UKR) saving up to roughly EUR 18 000 [USD 20 500] per patient [1]a.i.[4]). Enhanced healthcare resource utilisation and reduced patient waiting times are additional benefits. Additionally, there are also some patient-related benefits of outpatient procedures. It is proven that patients benefit from recovering in familiar home setting, with various technologies to help monitor their recovery and provide them with access to HCPs. This reduces anxiety [1]a.i.[1] and leads to earlier mobility, thus a faster recovery time and a quicker return to daily activities. Overall, this enhances patient satisfaction [1]a.i.[1][1]a.i.[2]. On top of that, ASCs decrease the risk of nosocomial infections with the reduced exposure to hospitals environment.

Effective implementation of ASCs faces multiple hurdles including:

1. reimbursement models: lack of reimbursement and funding procedures, limiting financial incentives to move procedures from in-hospital to ASCs;

2. stakeholder acceptance: non-clinical decision-makers are not fully comfortable with ASC as a part of the solution to the capacity and demand problem;

3. evidence: lack/limitation of safety and quality data measuring performance and outcomes;

4. human resource readiness: HCPs are not trained to perform in ASCs and run them efficiently;

5. digital infrastructure: data privacy hurdles, interoperability, digital exclusions;

6. protocols: lack of standardised care models across different therapies. Limited implementation of patient-centred evidence-based approaches for quicker and improved recoveries – enhanced recovery programmes;

7. patient readiness: patient expectations and previous experiences making them unwilling to accept procedures in ASCs;

8. home recovery and care system: lack of integration of ASCs with the broader healthcare systems.

Applicants should envisage the following activities as part of the action funded under this topic:

- Establish a multistakeholder advisory board leading and advocating for change in national and regional healthcare services. The advisory board will quantify the requirements for establishing ASCs in orthopaedics and cardiology including different financial and resource models, training modules, reimbursement pathways, digital health solutions for patient preparation and post-discharge management, registry databases as well as clinical and economical end points required for studies and reimbursement pathways;

- Demonstrate the safety of targeted procedures for patients performed in ASC facilities through the conduct of two medical cohort studies: one in orthopaedic joint replacement and another in cardiology cardiac ablation. These studies will assess the risks, patient medical eligibility complications, and patient outcomes of ASCs in comparison to hospital-based procedures;

- Generate and share protocols and best practices across multiple centres in same country and beyond borders, including a strategy for contextual adaptation for ASC scalability across Europe;

- Create a network of selected ASCs, with successful ASCs leading in sharing best practice, protocols, trainings, and efficiency models;

- Collect real world evidence (RWE) to demonstrate and model the cost-effectiveness of ASCs vs hospital-based procedures. The study should be multicentre and will establish a registry database answering proposed research questions;

- Develop a shared framework for clinical data interoperability, and combine an interoperable IT technology solution to integrate clinical data collected at multiple stages of the patient journey with the related digital health solutions that are used for patient preparation, post-discharge management and home monitoring. Adequate consideration should be given to relevant ethical and privacy aspects.

- Provide a sustainability strategy for the maintenance, update, and validation of the project's results beyond the project duration.

Applicants should consider learnings and synergies with relevant initiatives at national and European level to maximise the potential impact of the future project.

Expected impacts

The action under this topic is expected to achieve the following impacts:

1. Contribute to IHI JU SRIA objectives, driving cross-sectoral health innovation for a competitive European health industry;

2. Infrastructure funding initiatives establishing ASCs in orthopaedics and cardiology;

3. New long term healthcare strategy, planning and funding in HCP recruitment and training as well as digital solutions and medical technology for efficient ASC services;

4. Implementing new payment systems (coding and reimbursement) allowing for patient referral to ASC based on medical and clinical decisions and provider capacity, rather than on payment system;

5. Establishment of a sustainable network of ASCs followed by the creation of national and regional ASCs associations;

6. Regulation and accreditation of ASC facilities;

7. Comprehensive and interoperable digital solutions supporting people-centred care, disclosing entire patient treatment pathways and experiences including points of access for patients;

8. Treatment database/registry as a source of evidence enabling research, decision making, further development and improvement of ASCs.

The action will also support the EU political priority to boost European competitiveness and contribute to a number of European policies/initiatives, which include the European Commission's European Health Data Space Regulation (EHDS)[1] and the EU Artificial Intelligence Act[2].

Why the expected outcomes can only be achieved by an IHI JU action

Changing trajectory and practice from in-hospital procedures to ambulatory surgical centres will depend on the involvement of a range of stakeholders: hospital management, healthcare providers, technology developers, academics, health insurance companies, reimbursement agencies, patient organisations as well as medical technology companies. IHI facilitates this collaboration by fostering cross-sector cooperation which is unique and a pivotal requirement for initiatives of complex scale.

Pre-identified industry consortium

The pre-identified industry consortium that will contribute to this cross-sectoral IHI JU project is composed of the following medical technology industry beneficiaries ('constituent or affiliated entities of private members'):

- Medacta
- Medtronic
- Johnson & Johnson
- Smith & Nephew
- Stryker
- Zimmer Biomet (Lead)

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L_202500327

[2] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32024R1689

In the spirit of partnership, and to reflect how IHI JU two-stage call topics are built upon identified scientific priorities agreed together with a number of proposing industry beneficiaries (i.e. beneficiaries who are constituent or affiliated entities of a private member of IHI JU), it is envisaged that IHI JU proposals and actions may allocate a leading role within the consortium to an industry beneficiary. Within an applicant consortium discussing the full proposal to be submitted for stage 2, it is expected that one of the industry beneficiaries may become the project leader. Therefore, to facilitate the formation of the final consortium, all beneficiaries, affiliated entities, and associated partners are encouraged to discuss the weighting of responsibilities and priorities regarding such leadership roles. Until the role is formalised by execution of the Grant Agreement, one of the proposing industry beneficiaries shall, as project leader, facilitate an efficient drafting and negotiation of project content and required agreements.

Indicative budget

- The maximum financial contribution from the IHI JU is up to EUR 12 351 000.
- The indicative in-kind contribution from industry beneficiaries is EUR 12 351 000.

Due to the global nature of the participating industry partners, it is anticipated that some elements of the contributions will be in-kind contributions to operational activities (IKOP) from those countries that are neither part of the EU nor associated to the Horizon Europe programme.

The indicative in-kind contribution from industry beneficiaries may include in-kind contributions to additional activities (IKAA).

Indicative duration of the action

The indicative duration of the action is 60 months.

This duration is indicative only. At the second stage, the consortium selected at the first stage and the predefined industry consortium may jointly agree on a different duration when submitting the full proposal.

Contribution of the pre-identified industry consortium

The pre-identified industry consortium expects to contribute to the IHI JU project by providing the following expertise and assets:

- Facilitate logistics and communication for advisory board establishment and ASC network;
- Access to the latest medical technologies and equipment, ensuring that ASCs can offer high-quality care;
- Assistance with training medical and administrative staff, ensuring that ASCs have skilled personnel to deliver excellent patient care;
- Facilitate partnerships with other healthcare providers, organisations and established ASCs, which can conduct training, share best practices in enhancing service offerings and patient care
- Research and regulatory expertise and guidance in conducting studies, setting databases and real world evidence generation;
- Health economics modelling;
- Digital solutions for tracking patient pathways to streamline and enhance patient experience;
- Project management.

Applicant consortium

The first stage applicant consortium is expected, in the short proposal, to address the scope and deliver on the expected outcomes of the topic, taking into account the expected contribution from the pre-identified industry consortium.

The consortium must demonstrate the ability to jointly deliver innovation, evidence generation, and implementation across various healthcare systems in Europe.

This may require mobilising the following expertise and/or resources:

1) Hospitals and healthcare providers - required expertise:
   - Experience in performing orthopaedic and cardiac procedures, including joint replacement and ablation;
   - Involvement in outpatient care models or previous piloting of ASCs;
   - Capacity to lead and contribute to clinical studies comparing inpatient and ASC-based interventions;
   - Insight into patient pathways, clinical protocols, and integration with home recovery services.
2) Academia and research and technology institutions - required expertise:
   - Design and conduct of health services research and clinical studies, including RWE (real world evidence) and health economics;
   - Capability to lead evidence generation on safety, efficacy, and cost-effectiveness of ASCs;
   - Methodological support for patient selection criteria, Patient Reported Outcomes Measures (PROMs) collection, and statistical evaluation.
3) Medical technology companies - required expertise:
   - Developers and providers of surgical devices, diagnostics, and digital tools used in orthopaedics and cardiology;
   - Capacity to adapt or develop technology suited for ASC environments;
   - Expertise in digital health solutions including remote monitoring, electronic health records integration, and telemedicine platforms.
4) Digital health and IT Providers - required expertise:
   - Deployment of interoperable health information systems across care settings;
   - Data security and privacy compliance (e.g. General Data Protection Regulation, 2016 ‘GDPR’) and digital infrastructure support;
   - Tools for patient management, telehealth, and care navigation;
   - Development of ASC registries and clinical databases.
5) Patient organisations - required expertise:
   - Insight into patient expectations, preferences, and concerns regarding surgical care in ASCs;
   - Contribution to communication strategies and patient-centred design of care pathways;
   - Support in recruitment for surveys and qualitative research.
6) Payers and reimbursement bodies - required expertise:
   - Understanding of current reimbursement frameworks and their gaps;
   - Co-development of innovative payment models adapted to ASCs;
   - Guidance on defining clinical and economic endpoints relevant for reimbursement acceptance.
7) Policy and regulatory experts - required expertise:
   - Knowledge of national healthcare policies and regulations affecting outpatient and ASC settings;

- Development of recommendations for ASC recognition, quality assurance, and standardisation;.
- Engagement with health technology assessment bodies and regulators to support project sustainability.

8) Professional medical societies and networks - required expertise:
   - Support in standardisation of care protocols and guidelines for ASC procedures;
   - Dissemination of training materials and best practices;
   - Endorsement and outreach to accelerate uptake across member organisations.

At the second stage, the applicant consortium selected at the first stage and the pre-identified industry consortium will form the full consortium. The full consortium will develop the full proposal in partnership, including the overall structure of the work plan and the work packages, based upon the short proposal selected at the first stage.

Dissemination and exploitation obligations

The specific obligations described in the conditions of the calls and call management rules under 'Specific conditions on availability, accessibility and affordability' do not apply.

Eligibility for funding

The specific conditions whereby applicants may receive funding in Call 11 will be published together with the Call 11 topic text.

References

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Glossary

Acronym	Meaning
ASCs	Ambulatory Surgical Centres
GDPR	General Data Protection Regulation
HCPs	Health care providers
HTA	Health technology assessment
IHI JU	Innovative Health Initiative Joint Undertaking
IKAA	in-kind contributions to additional activities
IKOP	in-kind contributions to operational activities
PROMs	patient reported outcomes measeures
RWE	Real World Evidence
SRIA	Strategic Research and Innovation Agenda
TSA	Total shoulder arthroplasty
UKR	Unicompartmental knee replacement