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 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 working towards patient access to more convenient location, shorter waiting times and easier scheduling relative to hospital inpatient and outpatient procedures improving their 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 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, neurodegeneration, or musculoskeletal disorders), has 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. 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**. 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**.

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 project generated from 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 aging population, improved diagnostics and extension of medical guidelines. Based on patient selection these procedures are proven suitable for ambulatory setting. 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, this will enable faster patient access to those surgeries and in the end reduce overall health care costs. It is important to stress that a treatment in ASCs requires good patient selection prior to the surgery based on medical classifications, like the ASA risk classification of the American Society of Anaesthesiologists 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 (outpatient TSA 40% decrease in charges [1]a.i.[3] and UKR saving up to $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. This reduces anxiety[1] and leads to an earlier mobility thus to a faster recovery time and quicker return to daily activities and in the end 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 ASC;

2) **Stakeholder acceptance:** non-clinical decision makers 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:** HCP 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 approach for quicker improved recovery - 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 proposed action

- Establish a multistakeholder advisory board leading and advocating the change in healthcare services. The advisory board will quantify the requirements for establishing ASCs in Orthopaedics and Cardiology including 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 performed in ASC facilities through the conduct of a medical cohort studies in orthopaedics joint replacement and another in cardiology cardiac ablation, assessing the risks, complications, patient selections and patient outcomes of ASC's in comparison to hospital based procedures;
- Generate and share protocols and best practices across multiple centres in same country and beyond borders;
- 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, plus put together an interoperable IT technology solution 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.

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) Change of payment systems (coding and reimbursement) allowing patient referral to ASC based on medical and clinical decision and provider capacity, and not on payment system;

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

6) Regulation and accreditation of ASCs facilities;

7) Comprehensive and interoperable digital solutions supporting people-centred care, disclosing entire patient treatment pathway and experience including points of access for patient;

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

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

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 12 004 000. ***NB: this amount is indicative and subject to change, pending approval by the IHI Governing Board.***
- The indicative in-kind contribution from industry beneficiaries is EUR 12 004 000. ***NB: this amount is indicative and subject to change, pending approval by the IHI Governing Board.***

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;
- Provide clinical training for medical technology required in new established ASCs;
- Support established ASCs in conducting training and sharing best practice;
- Research expertise in conducting studies and real world evidence;
- Economic modelling;
- Digital solution assets tracking patient pathways;
- 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 Ambulatory Surgical Centres (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 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, PROMs collection (patient reported outcomes), 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, EHR 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. 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 HTA 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.

References

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Glossary

Acronym	Meaning
ASCs	Ambulatory Surgical Centres
GDPR	General Data Protection Regulation
HCPs	health care providers
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