Royal Australasian
College of Surgeons

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250–290 Spring Street
East Melbourne VIC 3002 Australia
Telephone +61 3 9249 1200
www.surgeons.org
ABN 29 004 167 766

Conjoint Associate Professor Carolyn Hullick PhD FACEM
Chief Medical Officer,
Australian Commission on Safety and Quality in Health Care
Level 5, 255 Elizabeth Street,
Sydney NSW 2000

Email: emergingissues@safetyandquality.gov.au

Dear Conjoint Associate Professor Hullick,

On behalf of the Royal Australasian College of Surgeons I am writing to express our sincere gratitude for the invitation to comment on the draft *"Guidance for health service organisations on the introduction of new interventional procedures"*, and to provide our critique from a surgical perspective.

The development of this guidance by the Australian Commission on Safety and Quality in Health Care is a commendable effort to ensure the safe and effective introduction of new interventional procedures into clinical practice. The objectives outlined, including fostering innovation in clinical practice, and ensuring decisions are made with consideration of clinical context, scientific evidence, ethics, resource implications, credentialing, and training, are crucial for advancing healthcare quality and safety.

Additionally, the emphasis on regular evaluation of approved procedures and the safe transition between new interventions and evidence-based clinical practice underscores the commitment to continuous improvement and patient safety. The alignment of this guidance with the National Safety and Quality Health Service Clinical Governance Standard is also highly valuable. However, there are some areas which require closer investigation, and comment. We will examine the following in line with the prescribed documents provided in relation to their strengths and weaknesses, as well as our recommendations.

- **Introduction of new interventional procedures and clinical practice innovations**
- **Principles for the introduction of new interventional procedure and clinical practice innovations**
- **RACS Recommendations**

INTRODUCTION OF NEW INTERVENTIONAL PROCEDURES AND CLINICAL PRACTICE INNOVATIONS

Introduction – Strengths and Weaknesses

The guidance on introducing new interventional procedures is commendable for its comprehensive framework, structured process, robust governance, and focus on credentialing, training, and evidence-based decision-making, ensuring thorough consideration and minimizing risks. It outlines a clear pathway from application to post-implementation, streamlining procedures and establishing accountability through the New Interventional Procedures [NIP] Committee. However, complexity and bureaucracy could cause delays, particularly in urgent cases, and the resource-intensive nature might strain smaller organizations. The rigorous process may deter clinicians from proposing innovations, and the reliance on high-quality evidence could delay the adoption of promising early-stage procedures.

Strengths:

Comprehensive Framework:

The guidance covers all aspects of introducing new procedures, from initial application to post-implementation monitoring. This ensures thorough consideration and minimizes risks associated with new interventions.

Structured Process:

Having a clear process with milestones and detailed application forms helps streamline the introduction of new procedures, making expectations clear for all stakeholders.

Governance and Accountability:

The establishment of the New Interventional Procedures [NIP] Committee and clear pathways for feedback ensure robust oversight and accountability. This is crucial for maintaining safety and quality standards.

Credentialing and Training:

Credentialing and training ensure that only qualified clinicians perform new procedures, which is vital for patient safety and successful outcomes.

Evidence-Based Decision Making:

Requiring high-quality evidence and comprehensive medical literature reviews promotes informed decision-making and helps avoid reliance on potentially biased information from manufacturers.

Weaknesses:

Complexity and Bureaucracy:

The detailed processes and the possible introduction of multiple committees involved could lead to bureaucratic delays. In urgent cases, this might hinder the timely adoption of beneficial innovations.

Resource Intensive:

Implementing and maintaining such a comprehensive framework requires significant resources, including administrative support, training programs, and regular evaluations. Smaller health service organizations and surgical specialities associations might struggle with this.

Potential Resistance to Change:

The structured and rigorous process might discourage clinicians from proposing new procedures, especially if they perceive the process as overly burdensome or time-consuming.

Dependence on High-Quality Evidence:

While essential, the requirement for high-quality evidence might delay the adoption of potentially beneficial procedures that are still in early stages of research but show promise.

Training and Proctoring Challenges:

Ensuring that external proctors are properly credentialed and effective training is provided can be logistically challenging, particularly for innovative procedures that require specialized expertise not readily available locally.

PRINCIPLES FOR THE INTRODUCTION OF NEW INTERVENTIONAL PROCEDURE AND CLINICAL PRACTICE INNOVATIONS

Introduction – Strengths and Weaknesses

The principles associated with the new interventional procedures possess several strengths from a surgical perspective, including comprehensive ethical oversight, a dual approach to risk management, and adherence to evidence-based practices. It emphasizes thorough informed consent, cost-benefit

analysis, training and competency maintenance, robust monitoring, and sustainability considerations. However, potential weaknesses do exist in relation to bureaucratic delays, resource intensiveness, overemphasis on consent forms, and the need for clearer conflict of interest protocols. Additionally, it notes that sustainability integration and variable interpretation of criteria may pose challenges for consistent implementation across organizations.

Strengths:

Comprehensive Ethical Oversight:
Emphasizing the need for ethics committee approval ensures robust ethical scrutiny, protecting patient welfare and fostering transparency.

Risk Management Focus:
The dual approach of pre-evaluation and post-monitoring addresses potential patient safety issues, ensuring continuous quality control.

Evidence-Based Practice:
Mandating reliable evidence or scientific rationale before implementation aligns with best practices, ensuring interventions are effective and safe.

Patient-Centered Informed Consent:
A thorough consent process supports patient autonomy and shared decision-making, enhancing trust and compliance.

Comprehensive Cost-Benefit Analysis:
Evaluating broader costs and resource implications ensures responsible resource allocation, preventing financial strain on healthcare systems.

Training and Competency Maintenance:
Ensuring adequate training for all involved personnel minimizes risks associated with the introduction of new procedures.

Monitoring and Continuous Evaluation:
Establishing robust monitoring systems and independent reviews promotes ongoing assessment and early detection of adverse events.

Sustainability Considerations:
Addressing environmental impact reflects a forward-thinking approach, aligning with global sustainability goals.

Weaknesses:

Potential Bureaucratic Delays:
Extensive ethical reviews and multiple committee approvals may delay the introduction of beneficial innovations, potentially hindering timely patient access to advanced treatments. Jurisdictional issues will prevail whereby every different area needs a new application. There should be a national based program for approval of new technologies that is applied across the country.

Resource Intensiveness:
Comprehensive evaluations, training, and monitoring require significant resources, which might be challenging for smaller health service organizations with limited budgets.

Possible Overemphasis on Consent Forms:
While thorough informed consent is critical, an overemphasis on detailed documentation might overshadow the quality of patient-clinician communication.

Conflicts of Interest Disclosure:
While disclosure is essential, the guidelines could benefit from more specific protocols on managing disclosed conflicts to ensure unbiased decision-making.

Sustainability Integration:
The integration of sustainability considerations, while commendable, may require additional investments and adjustments that some health services might find difficult to implement immediately.

Potential for Variable Interpretation:
Criteria for ethical review, risk management, and cost-benefit analysis might be interpreted differently across organizations, leading to inconsistencies in implementation.

RACS RECOMMENDATIONS

The guidance provides a robust framework for safely introducing new interventional procedures and clinical practice innovations. While its comprehensive nature ensures thorough evaluation and monitoring, the potential for bureaucratic delays and resource intensiveness are notable concerns. Balancing thorough oversight with efficiency and flexibility will be key to its successful implementation. The principles prioritize patient safety, ethical integrity, and evidence-based practice. However, consistent interpretation across different health service organizations is crucial for optimal implementation.

RACS' recommendations following our review of these documents are as follows -

1. There is a need for proctoring or oversight by a neutral authority, until competence is established, to be mentioned regularly throughout the document.
2. The maintenance of a funded database to evaluate results and patient-reported outcome measures (PROMS) should be mandatory, with dissemination of results strategy clearly defined.
3. If ethics has not be sought, there should be an explanation why it hasn't been.
4. The criteria for credentialing must be determined by New Interventional Procedures [NIP] Committee or Hospital, and NOT by the sponsoring company. Ideally consideration could be given to a national approval for use of a technology to avoid duplication across jurisdictions.
5. Representatives from a sponsoring company should be allowed to be present in the operating room for the procedure to ensure new intervention is being used according to manufacturer's specifications.

Following our feedback, we look forward to contributing to the consultation process for the forthcoming "Credentialing and defining scope of clinical practice for clinicians guide." We thank you once again for including us in this important consultation process. We appreciate the opportunity to contribute to the advancement of healthcare safety and quality in Australia.

Yours sincerely,

Associate Professor Kerin Fielding
President, RACS

Professor Mark Frydenberg
Chair, Health Policy & Advocacy Committee