ST VINCENT'S HEALTH AUSTRALIA

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St Vincent's Health Australia Group Policy

Policy Title:	**Introduction of New Clinical Services, Procedures and Other Interventions**
TRIM Number:	D/2018/44195[v2]
Version:	Version 2
Portfolio:	Clinical Governance
Keywords	New clinical services, technology, interventions, procedures
Policy Applicable to	All staff and contractors working at SVHA public, private and aged care facilities
Status	Revised
Review Officer/Author(s):	Clinical Governance
First Introduced:	September 2016
Summary of changes:	Addition of details related to conflict of interest (1.7), revision of terms regarding facility governance (2.1.1), Use of Proctors (3.8) and inclusion of an "application form" / checklist
Next Review Date:	November 2021
Committee Approval:	Board Clinical Governance and Experience Committee
Approved Date:	*11th November 2019*
Signature/ Date: *SVHA Group Clinical Governance and Experience Committee*	

All SVHA policies must comply with the Code of Ethical Standards for Catholic Health and Aged Care Services in Australia, the Ethical Framework for Mary Aikenhead Ministries and the SVHA Ethics Policy.

1. **Purpose:**
   SVHA attaches the greatest importance to safety and care of its patients and therefore considers it essential to provide effective and safe governance processes for the introduction of new clinical services, procedures and other interventions.

   SVHA requires that all decisions related to the introduction of new clinical services, procedures and other interventions are aligned with our Mission and Values and those of Catholic Health Australia. A clear organisational position is required to communicate these values to guide the delivery of services across SVHA.

   Approval for the introduction of all new clinical services, procedures and other interventions are linked to important areas of credentialing and scope of clinical practice assessments, evaluation of new products, and research ethics.

   The SVHA Group Policy aims to provide guidance to individual facilities to ensure streamlined and consistent implementation of the governance process.

2. **Risk Statement:**
   The importance of clinical governance in achieving safe, accountable and high quality health care systems has been identified by health organisations internationally and nationally. This policy provides a framework to ensure that all SVHA facilities are accountable for continuously improving the quality of the service, safeguarding high standards of patient care and creating an environment in which excellence in clinical care will flourish"..

3. **Definitions and Key Concepts:**
   Clinician is a health clinician or health service provider

   Medical product refers to any therapeutic device, diagnostic equipment, prostheses and/or consumable which is used in health care and can include a wide range of products such as medical gloves, bandages, syringes, electronic thermometers, infusion pumps, in vitro diagnostic medical devices, disinfectants, X-ray equipment, surgical lasers, pacemakers, dialysis equipment, baby incubators or heart valves

   New clinical services, procedures, or other intervention (including medical or surgical procedures, and the use of prostheses and implantable devices or diagnostic procedures) that is considered by a reasonable body of medical opinion to be significantly different from existing clinical practice. It includes a procedure that has not been performed at the Facility, as well as variations to an existing procedure or treatment where a new device or item of equipment is introduced.

   Proctor: Proctoring is an objective evaluation of a physician's clinical competence by a proctor who represents, and is responsible to, the medical staff. New medical staff members seeking privileges or existing medical staff members requesting new or expanded privileges are proctored while providing the services or performing the procedure for which privileges are requested. In most instances, a proctor acts only as a monitor to evaluate the technical and cognitive skills of another physician. A proctor does not directly provide patient care, has no physician-patient relationship with the patient being treated, and does not receive a fee from the patient.[1]

   Serious adverse event untoward medical occurrence resulting in complication resulting in disability and / or death and / or extended length of stay that is caused by the health care intervention and not by the patient's disease.

4. **Policy Procedures and Outcomes**:
   - To provide a framework for the safe introduction of new clinical services, procedures or other intervention into clinical practice

[1] Definition from American Academy of Family Physicians

- To encourage and protect innovation in clinical practice
- To promote clinical improvement
- To provide mechanisms for monitoring the efficacy, safety and efficiency of new interventions

5. Related Policies/Procedures/Guidelines:
SVHA Group Clinical Quality and Safety Policy 2019
SVHA Model By-Laws Version 10

6. Legal and Compliance:
Must comply with jurisdictional policy and legislation including:
- Health Practitioner Regulation National Law Act 2009
- Queensland – Health Practitioner Regulation National Law Act 2009
- New South Wales – Health Practitioner Regulation Act 2009
- Victoria – Health Practitioner Regulation National Law (Victoria) Act 2009
- Therapeutic Goods Act 1989
- Therapeutic Goods (Medical Devices) Regulations 2002
- Australia/New Zealand Standards, ISO 31000:2018: Risk Management Guidelines

7. Relevant References:
- Standard for Credentialing and Defining the Scope of Clinical Practice developed by the Australian Council on Safety and Quality in 2004 (Referred to as The National Standard)
- NSW Health Policy Directive PD2005_333 Model Policy for the Safe Introduction of New Interventional Procedures into Clinical Practice
- Royal Australasian College of Surgeons / ASERNIP-S (2007) General Guidelines for Assessing, Approving and Introducing New Procedures into a Hospital or Health Service. Royal Australasian College of Surgeons, Melbourne

8. Appendices
Application form

1. GENERAL PRINCIPLES

Regardless of the type of new interventional procedure, technology or treatment to be introduced, certain principles shall apply and all applications will need to address:

1.1. Health and Safety
The primary motivating concern of the actions described in this policy is the health and safety of consumers, the individual clinician, colleagues and other staff, and the community

1.2. Risk Management
This policy emphasises a risk management approach. The aim is to manage the introduction of new interventions into clinical practice, and thereby reduce the risk of adverse outcomes. Systems for support during the early stages of the introduction of the procedure should be given consideration.

1.3. Evidence based practice
Most techniques will have been evaluated or at least implemented elsewhere and the assessment of the procedure needs to consider the reliability of the evaluation as well as taking into consideration the particular conditions in which the procedure is being introduced. Where there is no evidence a well-reasoned scientifically based argument in support of the proposed innovation is required.

1.4. Ethics
Information regarding the current use of the procedure and the results of trials and other research findings should be included with the submission to NIPAC. If there are any concerns regarding the need for ethics approval then the application will be forwarded to the Human Research Ethics committee for advice.

1.5. Patient information and informed consent
Patient information and consent forms need to be developed at the time of application outlining the potential risks as accurately as possible and including any areas of uncertainty. The criteria for selection of patients for these procedures should also be included in the information and consent.

1.6. Costs and benefits
The introduction of any new procedure will have an opportunity cost. The new procedure will consume resources that need to be evaluated against the benefits of performing the procedure and the effect of taking these resources from existing services.

1.7. Conflicts of interest
These must be disclosed. There must be full disclosure of any relationship between the clinician or persons/entities related to the clinician or his/her family, and the supplier, developer or prior assessor of the new intervention that gives rise to a potential or real conflict of interest for the clinician e.g. a financial advantage for the clinician and/or related entities or individuals.

1.8. Training
Training needs to take into consideration all professionals who will be involved in the new procedure. This includes junior medical staff, nursing staff, allied health and support staff who may be involved in the sterilising or setting up of the equipment.

1.9. Monitoring
Any new procedure needs to be monitored after introduction. Systems to collect data should be established prior to introduction. Any adverse events are to be reported and the causes reviewed.

1.10. Equipment and Supplies
New equipment and supplies that may be required for the procedure are to be approved through the appropriate committees. Systems to obtain and maintain the equipment and supplies should be established.

2. GOVERNANCE REQUIREMENTS

To establish effective processes for introduction of New Clinical Services Procedures and Other Interventions all SVHA Facilities must

2.1 Ensure that the process is overseen by a committee with adequate representation

2.1.1 Each Facility CEO shall ensure the appointment of a Committee overseeing the introduction of new clinical services, procedures or other interventions. In some facilities, the demand may not require the appointment of a permanent Committee that meets on a regular basis. However, when the need arises, a Committee should be created, on an ad-hoc basis, whose constituency and procedures follow the parameters set out within this document.

2.1.2 The committee shall have within its terms of reference the following (or equivalent) function:
"Review any new or amended use of technology or procedures to treat patients (in accordance with SVHA Clinical Quality and Safety Policy and the facility's New Interventions policy); assessing the facilities of the Facility and other matters which are relevant, and make a recommendation on the amendment of the clinical privileges of an Accredited Practitioner"

2.1.3 Each Committee appointed for overseeing the introduction of New clinical services, procedures or other interventions shall have a Terms of Reference that defines:

- Composition
- Meeting Procedures and Quorum
- Notice of Meetings
- Voting
- Term of Office
- Reporting Arrangements

2.1.4 Each Committee appointed for overseeing the introduction of New clinical services, procedures or other interventions shall have within its composition a minimum of the following members:

- Director of Medical Services (equivalent or delegate)
- Director of Clinical Governance (equivalent or delegate)
- Member of the Medical Advisory Council (equivalent or delegate)

Each committee shall elect a chairperson who will convene the meetings and ensure that each member of the committee understands their role and responsibilities as a member of the committee

2.1.5 The committee shall have the power to co-opt additional clinicians with experience relevant to the scope of clinical practice being reviewed should it consider this necessary. That person shall not have voting rights at any meeting of the Committee overseeing the introduction of new clinical services, procedures or other interventions.

2.1.6 The committee overseeing the introduction of new clinical services, procedures or other interventions shall be responsible for engaging other relevant Facility committees as appropriate to assess issues including but not limited to ethical considerations, product evaluation and research governance.

2.1.7 Standard rules of conduct for committees apply. The committee should comply with all relevant legal requirements, including privacy, trade practices, whistleblower and equal opportunity legislation and operate according to the laws of procedural fairness, without conflicts of interest or bias.

2.2 Ensure that the committee is transparent and accountable

2.2.1 Each Committee appointed to oversee the introduction of New clinical services, procedures or other interventions shall have reporting responsibilities either directly to the

Chief Executive of the Facility or indirectly via the pre-existing Facility committee structure, including but not limited to the Medical Advisory Committee.

2.2.2 Each Committee shall appoint a secretariat who will maintain complete records of the assessment process for each application and ensure those records are available for audit

2.2.3 Each committee shall assess all applications with consideration of all factors outlined in assessment requirements and make recommendations to the facility CEO regarding the decision for the introduction of New clinical services, procedures or other interventions.

2.2.4 Each committee shall ensure that a process is established whereby the letter advising the applicant of a decision made is dispatched to the applicant within 14 business days of the date of Chief Executive Officer approval with a copy of the correspondence retained on record.

2.3 Ensure that all matters are dealt with expediently and effectively

2.3.1 Meetings of the Committee appointed to oversee the introduction of New clinical services, procedures or other interventions should be conducted regularly as defined by each jurisdiction. Ordinary meetings of the Committee shall be held not less than four times a year at a time and place to be determined by the chairperson provided that at least 14 days' notice shall be given for every ordinary meeting.

2.3.2 The chairperson may convene an extraordinary meeting where, in the opinion of the chairperson, a matter should not reasonably wait for the next scheduled meeting of the committee.

2.4 Ensure that relevant stakeholders are engaged

2.4.1 The Committee shall engage relevant stakeholders and take into consideration of all relevant factors listed in the assessment requirements to determine the recommendation for the introduction of new service, procedure or other interventions.

2.5 Ensure the principles of procedural fairness and natural justice apply

2.5.1 No application for Credentialing or Scope of Clinical Practice determination is to be decided upon or influenced by gender, ethnicity, nationality/national origin, religious beliefs or sexual orientation. All clinical appointments are to be made on merit. This requires that the person selected has the ability, qualifications, experience, work performance and personal attributes that meet the Facility's needs.

2.5.2 Members of committees participating in the Credentialing and defining Scope of Clinical Practice processes must ensure that any personal information obtained related to the applicant is kept in confidence.

2.5.3 Individuals should receive feedback on any unsuccessful application or variation in Scope of Clinical Practice but are not privy to the notes and documentation of the committee other than where so required by law.

2.5.4 Meeting outcomes must be clearly documented and open to audit and provide assurance to the Divisional Chief Executive Officer of the robust nature of the process, subject to any statutory immunity considerations.

3. ASSESSMENT REQUIREMENTS

To ensure the safe introduction of new clinical services, procedures or other interventions, all **SVHA Facilities must**:

3.1 Define the local requirements for the introduction of New clinical services, procedures or other interventions

3.1.1 Define who may request assessments and the process by which the Clinician may submit requests.

3.1.2 Ensure the assessment includes benefit to patients, clients or residents, risk, cost, efficacy, cost-benefit and fit within the broader health context of the SVHA Group Entity.
3.1.3 Define the individuals or committees authorised to make decisions regarding the introduction of these services and or interventions.

3.2 Determine the safety, efficacy and role of New clinical services, procedures or other interventions

3.2.1 Determine whether relevant ethics committee assessment has been sought and received
3.2.2 Consider the efficacy as reported by various credible sources including peer-reviewed literature, evidence-based assessments and research.
3.2.3 Determine whether the relevant professional college or association has established guidelines or criteria relevant to the safety, efficacy or role of the proposed new intervention or service.
3.2.4 Consider the clinical risks.
3.2.5 Advise on any clinical and non-clinical support services that are necessary to ensure the New service, procedure or intervention can be provided safely and at high quality.
3.2.6 Assess whether ethics approval is required.

3.3 Determine evidence of competence of individual Accredited Health Professionals / Accredited Practitioners to undertake the procedure

3.3.1 Ensure the Credentials are appropriate for the Clinician who has applied for inclusion of the proposed clinical service, procedure or other intervention. Ensure these Credentials are formally validated and evaluated according to Scope of Clinical Practice procedures
3.3.2 Ensure the Clinician applying for inclusion of the proposed New clinical service, procedure or other intervention possesses adequate indemnity insurance.
3.3.3 Identify any additional education and training requirements that staff affected by the New clinical service, procedure or other intervention may require.

3.4 Determine the financial and operational implications of the New clinical services, procedures or other interventions

3.4.1 Ensure that advice is provided on the financial and operational implication of the proposal.
3.4.2 Ensure that all new clinical products and equipment have been reviewed by relevant product evaluation committees
3.4.3 Ensure that the New clinical services, procedures or other interventions are in accord with relevant jurisdictional or licensing requirements for approval.
3.4.4 Ensure that education, training and resource requirements associated with new clinical services, procedures or other interventions are identified and appropriate actions implemented to support the safe introduction into the Facility
3.4.5 Ensure the Facility has available the appropriate clinical support services necessary to support the safe provision of the new clinical services, procedures or other interventions.

3.5 Approving the introduction of New clinical services, procedures or other interventions

3.5.1 Seek advice on insurance implications of providing the New clinical services, procedures or other interventions.
3.5.2 Determine indicators against which the New clinical services, procedures or other interventions will be monitored
3.5.3 Determine a time period after which the clinical outcomes, risks, costs and cost-benefit are evaluated.

3.6 Communication regarding the introduction of New clinical services, procedures or other interventions

3.6.1 Ensure that the outcome of the review is communicated to the delegated authority.
3.6.2 Ensure that the applicant is advised in writing of the outcome of the application for the introduction of new clinical services, procedures or other interventions.
3.6.3 Ensure that staff in the areas impacted by the new services, procedures or other interventions are appropriately informed of the changes and of their requirements including education and training.

3.7 Review of the introduction of New clinical services, procedures or other interventions

3.7.1 Each approved introduction of New service, procedure or other interventions shall be responsible for review, collation and production of Post Implementation Report in liaison with facility Governance unit

3.7.2 All equipment failures as a consequence to or associated with the introduction of New service, procedure or other interventions should be reported as per the Post Complaint Reporting Policy

3.7.3 Depending on the specialty, the medical college or specialist society may have very specific criteria required for review of ongoing competence at the time of Re-credentialing and confirming Scope of Clinical Practice.

These may include, but not be limited to:

3.7.4 Details of involvement in any clinical audits or peer review activities.

3.7.5 Where relevant, a summary of clinical activity undertaken, including the approximate number, type, procedures or other interventions performed, consultations undertaken.

3.7.6 Where available, objective data on the outcomes of the above clinical activity.

3.7.7 Other relevant information, such as incidents, complaints and patient satisfaction.

3.7.8 Patient satisfaction in professional interaction and clinical service provision.

3.7.9 Documented feedback from other health professionals.

3.8 Use of Proctors

Applicants wishing to undertake a new interventional procedure must be able to demonstrate that they have been trained to do so to a competent level. Proctors are a valuable source of advice about procedures that present particular technical challenges and/or for which special training is desirable. In the context of this document, a proctor is defined as an external practitioner who attends to supervise and train a clinician when he or she undertakes an approved new interventional procedure on SVHA premises.

3.8.1 Procedures to be followed in relation to proctors

The applicant will identify an appropriate proctor to ensure that the staff delivering the procedure are appropriately skilled and trained. Proctors must be of good standing with their own regulatory body and must have appropriate experience to undertake and supervise the new interventional procedure.

Prior to the proctor attending the facility, it must be determined that the Proctor has appropriate AHPRA registration. If the Proctor is from outside of Australia, a temporary registration must be arranged with AHPRA. The proctor must be adequately insured, and details of the insurance arrangements are to be provided to the SVHA facility before any procedures can be performed

3.8.2 The proctor must:

- Have appropriate experience to undertake the procedures themselves and to supervise an inexperienced practitioner.
- Discuss the specific case with the clinician undertaking the procedure prior to commencement of the procedure.
- Be present throughout the procedure being undertaken
- Ensure that the clinician has adequate prior training to undertake the new interventional procedure.
- Evaluate, on completion of the training, the performance of the clinician in undertaking the new interventional procedure, and the wider operating team.
- Provide a written evaluation of clinician performance which will either provide assurance that the proctor is assured of the competency of the operator in undertaking the procedure, or that further action / training is required before the operator can deliver the procedure independent of the proctor.

The evidence and documentation should be submitted to the Director of Medical Services, or equivalent, for approval.

INTRODUCTION OF NEW TECHNOLOGY

SUMMARY

Name of the health technology: Click or tap here to enter text.

Purpose of health technology (including clinical indications and target group): Click or tap here to enter text.

Attach additional information if required

Brief Description of the health technology: Click or tap here to enter text.

Attach additional information if required

APPLICATION FORM

1. Has the health technology been used elsewhere?

Yes ☐ No ☐

If yes, please attach details

2. Does this new health technology replace current health technologies?

Yes ☐ No ☐

If yes, Name of technology being replaced: Click or tap here to enter text.

3. If yes, does this new health technology have advantages over current health technologies?

Yes ☐ No ☐

If yes, please attach details

4. Has this health technology been independently evaluated elsewhere[2] (see footnote below)?

Yes ☐ No ☐

If yes, please attach details of a comprehensive literature review, research outcomes and/or published articles (not sponsored by the manufacturer).

5. Is this technology consistent with the Clinical Services Plan of the Health Service?

Yes ☐ No ☐

If yes, please attach details

6. Has advice been sought from the relevant Clinical Network?

Yes ☐ No ☐

If yes, please attach details

[2] 1 For example: Cochrane Collaboration (www.cochrane.org.au), International Network of Agencies for Health Technology Assessment (www.inahta.org), ASERNIP-S (www.surgeons.org/open/asernip-s.htm), Medical Services Advisory Committee (www.health.gov.au/MSAC), Therapeutic Goods Administration (www.health.gov.au/tga/), NSERNIP (UK), SERNIP (Safety and Efficacy Register of New Interventional Procedures), professional colleges, clinical trials, Uptodate, publications, information from internal and/or external peers. Hospital Library staff can assist you in undertaking literature searches and a search of the above databases.

7. Does this health technology have a Medicare Benefit Scheme item number?

Yes ☐ No ☐

If yes, please specify item number/s

8. Does the health technology entail a new medical device or drug?

Yes ☐ No ☐

If yes, please attach details regarding name of the drug or device, distributor, product information and any requirements for maintenance, cleaning and sterilisation.

9. If yes, has the device or drug been approved for this purpose by the Therapeutic Goods Administration (Commonwealth Department of Health and Aged Care)?

Yes ☐ No ☐

10. If the health technology includes the use of a drug, is the indication for which the drug is proposed a PBS listed indication?

Yes ☐ No ☐

10. Has this drug been approved for this purpose by a local Drug Committee?

Yes ☐ No ☐

Name of approving committee: Click or tap here to enter text

Date of approval: Click or tap here to enter text.

Note that if the new health technology includes the use of a new drug, or an existing drug for a new indication, and is not on the hospital formulary, a Formulary Submission Form needs to be completed and submitted with this application.

11. Are there discrete credentialing, 'scope of practice' or training requirements for the proposed health technology?

Yes ☐ No ☐

If yes, please provide the following in a separate attachment:

List the name/s, qualifications, evidence of relevant training and courses attended of those individuals who wish to be credentialed for use of this health technology.

12. What additional support would be required for use of the new health technology?

☐	**Operating rooms**	☐	**Procedure rooms**	☐	**Anaesthesia**
☐	**Emergency Department**	☐	**ICU / High dependency**	☐	**Central Sterilising**
☐	**Infection control**	☐	**Imaging**	☐	**Pathology**
☐	**Pharmacy**	☐	**Biomedical engineering**	☐	**Home nursing**
☐	**Allied health**	☐	**Outpatient or community services**	☐	**Ambulance or inter-hospital transport**
☐	**Waste management**	☐	**WHS, including chemical or radiation risks**	☐	**Other**

Please provide details on the additional support required for each item that has been ticked: Click or tap here to enter text.

13. Would the introduction of the health technology increase the patient's need for other diagnostic or therapeutic interventions, devices, equipment, programs or services?

Yes ☐ No ☐

If yes, and not already specified in response to the previous question, please specify: Click or tap here to enter text.

14. Would the introduction of the health technology reduce the patient's need for other diagnostic or therapeutic interventions, devices, equipment, programs or services?

Yes ☐ No ☐

If yes, please specify or attach details Click or tap here to enter text.

15. Would the introduction of the health technology require or lead to a change in which facilities provide the care, or a change in which services provides the care?

Yes ☐ No ☐

If yes, please specify or attach details Click or tap here to enter text.

16. Would the introduction of the health technology have an impact on patient transfers between facilities within SVHA?

Yes ☐ No ☐

If yes, please specify or attach details Click or tap here to enter text.

17. Would the introduction of the health technology have an impact on the staffing levels, mix or role?

Yes ☐ No ☐

If yes, please specify or attach details Click or tap here to enter text.

18. If the health technology carries with it a risk for adverse events are there criteria for reviewing outcomes before any further procedures are performed?

Yes ☐ No ☐

If yes, please specify the criteria or attach details Click or tap here to enter text.

19. Has a patient information sheet been developed?

Yes ☐ No ☐ Not Applicable ☐

If yes, please attach

20. Does introduction of the procedure require Human Research Ethics Committee approval?

Yes ☐ No ☐

Please outline any special consent issues Click or tap here to enter text.

21. How will outcomes be monitored? List 3 -5 Criteria that will be used to monitor outcomes. Click or tap here to enter text.

22. Conflicts of interest must be disclosed

Is there any potential conflict of interest[3]?

Yes ☐ No ☐

Please describe on a separate attachment any relationship between the proposing clinician and
a) Supplier(s) concerned and/or
b) Involvement in prior assessment or development of the procedure interest and/or
c) Any financial involvement (other than normal SVHA payment for clinical duties and/or
d) Other potential conflict of interest.

23. Proctors

Will the introduction of the technology require the attendance of a proctor[4]

Yes ☐ No ☐

If yes, has AHPRA registration been obtained for the proctor?

Yes ☐ No ☐

Please attach details of the proctor's insurance arrangements.

[3] If any individual associated with the procedure will gain financially from its introduction, or previously from its development, the nature of that conflict of interest must be outlined. This includes any benefits to associated third parties such as family members or trusts.

[4] Defined for this purpose as an external practitioner who attends to supervise and train a clinician when he or she undertakes an approved new interventional procedure on SVHA premises.