SVHNS Introduction of New Clinical Services, Procedures and Other Interventions Policy

Links to Policy:	
Applicable:	All clinical service providers at SVHNS
Classification:	
Date Introduced:	
Date Approved:	November 2016
Approved by:	
Revision No.:	
Last Review Date:	
Scheduled Review Date:	November 2019
Responsible for Review:	Executive Committee
Key Words:	Interventions, technologies, treatments,

1. Context and Purpose

St Vincent's Health Network Sydney (SVHNS) will ensure that all new clinical services, procedures and other interventions are introduced only after consideration and approval through the appropriate governance structures, and based on expert advice which considers the issues of safety, efficacy and cost effectiveness.

2. Policy Statement

The purpose of this policy is to assist clinicians to introduce new clinical services, procedures and other interventions by providing a standard process for assessment and approval, to ensure patients, clinicians and managers can be confident that new procedures are supported by evidence of efficacy, safety and effective resource utilisation, and can be safely performed within the available resources.

SVHNS requires that all decisions related to the introduction of new interventional procedures are aligned with our Mission and Values and those of Catholic Health Australia.

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.

This policy applies where there is significant variation to an existing intervention or technology, such that the variation is likely to adversely impact on efficacy, safety or cost effectiveness, or the impact in these domains is unknown and needs to be formally evaluated.

The introduction of new devices for a procedure requires prior evaluation and approval by the Therapeutic Goods Administration (Commonwealth Department of Health & Aged Care). The Therapeutics Goods Administration has a number of publications outlining guidelines with respect to access to unapproved therapeutic goods which can be referenced from the TGA website at http://www.tga.gov.au/docs/html/unapp.htm

New interventional procedures, technologies or treatments which are experimental in nature and require introduction within a research framework will be considered by the St Vincent's Hospital Human Research Ethics Committee (HREC). Whilst the HREC will generally consider all matters concerning ethics and efficacy, broader consideration is also required with respect to cost effectiveness and the appropriate utilisation of resources within St Vincent's Hospital. This consideration will be made by the St Vincent's Hospital New Interventional Procedures Assessment Committee (NIPAC).

This policy does not apply to the following:

- Introduction of new TGA approved medications which is the jurisdiction of the St Vincent's Hospital Drug Committee.
- Introduction of new interventional procedures that require state-wide or national planning.
- Emergencies where a procedure or intervention is considered by an attending physician to be required urgently to prevent or minimise harm to a patient.

Where a clinician is unsure whether the procedure falls within the scope of this Policy, advice should be sought from the Director Clinical Governance.

Expected Outcomes

New clinical services, procedures and other interventions will be introduced into SVHNS through a defined process, which considers safety, efficacy and cost effectiveness.

A register of applications and approved procedures will be maintained, by the Director of Clinical Governance in association with the St Vincent's Hospital Research Office TRIM database.

The monitoring requirements for the introduction of the new procedures will be outlined through approval letters from HREC and/ or NIPAC.

Staff will be delineated clinical privileges for the introduction of a new interventional procedure only following approval by NIPAC.

Definitions

Interventional Procedure	A procedure involving any invasive contact with the patient. Examples include surgical operations, endoscopy, certain radiological procedures, chemical or other therapies, eg ventilation.
New clinical services, procedures, or other intervention	Those 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.
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 or heart valves
Clinician	A health clinician or health service provider
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.
NIPAC	New Interventional Procedures Advisory Committee

3. Mission and Strategic Fit

SVHNS is a mission based organisation. SVHNS ensures that committee establishments and processes are provided in accordance with the Mission and Values of St Vincent's Health Australia as well as the frameworks of the Mary Aikenhead Ministries, Catholic teachings, the Code of Ethical Standards for

Catholic Health and Aged Care Services in Australia and the NSW Ministry of Health.

4. 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:

A. 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.

B. 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.

C. 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.

D. 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.

E. 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.

F. 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. The specific benefit to patients must be outlined.

G. Conflicts of interest

These must be disclosed. There must be full disclosure of any relationship between the clinician and the supplier concerned or other significant party or involvement in prior assessment of the procedure any financial involvement that could result in a conflict of interest.

H. 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.

I. 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.

J. 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.

5. Governance Requirements

All new clinical services, procedures and other interventions will be introduced with the oversight of the New Interventional procedures Committee (NIPAC). NIPAC has the responsibility for assessing and recommending applications for approval to the SVHNS Chief Executive Officer.

All applications shall follow the procedure outlined. All applications will be assessed with consideration of all factors as outlined in the general principles A to J above. Where required relevant stakeholders may be engaged to provide expert opinion on the consideration of an application for new clinical services, procedures and other interventions.

NIPAC is an advisory committee, which provides advice to the Chief Executive Officer about safety, efficacy and cost effectiveness. If the required decision is about an extension of an existing procedure of proven safety and effectiveness that is manageable within budget, it is not expected that approval will be required by NIPAC unless the Chief Executive Officer needs further advice about a specific aspect.

From time to time the Chief Executive Officer may wish to refer to NIPAC, a procedure or a variation of a procedure which has already been established and in place at SVHNS, but over which safety concerns have arisen. This process of consideration by NIPAC will be the same as above.

6. Procedure for Application

1. The clinician/s or unit wishing to introduce the new clinical service, procedure and/or other intervention is required to complete the Application Form for the Safe Introduction of a New Interventional Procedure.
2. Each clinician who will be performing the new procedure will need to be credentialed to do so. This means where the new procedure requires training in new skills and the use of equipment, evidence of this training is required to be provided.

3. The clinician/s or unit making the application should forward it to their Departmental Manger, who will, in turn forward it to the relevant Clinical Stream Director.

4. If the proposed new interventions involves a TGA unapproved device or experimental surgical procedure, a separate HREC application as a research project to the St Vincent's Hospital HREC is also required. This requires submission of the Site Specific Assessment form to gain research governance site authorisation.

5. If the Clinical Stream Director is supportive, the Application Form for the Safe Introduction of a New Interventional Procedure will be forwarded to the secretariat of the NIPAC, acknowledged and submitted to the next NIPAC meeting for consideration (provided the application is complete with all necessary supporting documentation).

6. The Chair of the NIPAC will advise the Chief Executive Officer of the NIPAC recommendations, and forward the Application Form for the Safe Introduction of a New Interventional Procedure for approval.

7. The secretariat of the NIPAC is responsible for communicating the outcome of decision to NIPAC and to the applicant.

8. The Director Clinical Governance will ensure that the credentialing process has been instigated where appropriate.

9. The Clinical Stream Manager will be responsible for updating NIPAC on progress with the new procedure through progress reports as specified by NIPAC.

10. The sponsor/s of an unsuccessful application may appeal to the Chair of NIPAC or the SVHNS Chief Executive Officer.

7. Compliance and Evaluation

The Director Clinical Governance shall monitor processing time from date of application to the date the applicant is advised of outcome of Credentialing process.

The Director Clinical Governance shall monitor the progress reports and take any actions required to reduce risks and maximise benefits from undertaking the procedure.

8. References

- **Supporting Evidence:**
    - NSW Health Policy Directive PD2005_333 Model Policy for the Safe Introduction of New Interventional Procedures into Clinical Practice
    - 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)
    - 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

    - **Legal and Compliance Considerations**

    Must comply with jurisdictional policy and legislation including:

    - Health Practitioner Regulation National Law Act 2009
    - New South Wales – Health Practitioner Regulation Act 2009
    - Therapeutic Goods Act 1989
    - Therapeutic Goods (Medical Devices) Regulations 2002
    - Australia/New Zealand Standards, (2006) AS/NZS 3806: Compliance Programs Australia / New Zealand Standards, (2004). AS/NZ 4360: Risk Management

-

- **National Standards:**
- **Related SVH, SVHNS & SVHA Policies & Procedures:**
- **Related Documentation:**
- **Related risk register identification/incident number:**