Clinical Product Evaluation Policy

1. Purpose

The use of clinical products can result in clinical, financial, and operational risks. This policy outlines the process for the evaluation of clinical products, prior to introduction into a clinical area, to minimise these risks. Clinical products for the purpose of this policy include medical equipment and consumables.

2. Policy

New clinical products are required to go through an evaluation process as described in this policy. This process involves consideration of safety, quality, value for money, service and maintenance costs, compatibility and environmental impact.

It is to be noted that the evaluation process is dependent on the clinical product type and risk assessment and may not always involve a trial. It is each region's Product Evaluation and Standardisation Committee (PESC) responsibility to determine the most appropriate course for clinical products presented.

Clinical products that are available to purchase from a contract are exempt from this policy. However, at the discretion of the Regional PESC, these clinical products may be submitted to the evaluation process described in this policy.

Clinical products that have been subjected to a Metropolitan PESC evaluation process can be approved for use at the discretion of the Regional PESC.

It is not recommended to evaluate and/or trial clinical products that are being evaluated under the scope of a current Procurement Process. However, if there is an essential operational requirement to do so, it will be at the discretion of the Regional PESC Chair to review and evaluate the product in question prior to use. Once the new contract is awarded the site will be required to comply with the mandatory contract. This means that if the evaluated product is not awarded on the contract the site will be required to transition to a contracted product.

The scope of this policy **excludes** the following:

- Telehealth applications, services and technology unless it has a component that could be deemed a clinical product
- Radiological equipment/ items requiring licensing under the *Radiation Safety Act 1975* (WA) should be referred to Area Chief Medical Imaging Technologist
- Point of Care Testing devices are to be referred to Point of Care Department PathWest
- Cleaning equipment must be referred to the relevant Regional Patient Support service, Work Health and Safety and Infection Prevention and Control
- Facilities / plant equipment must be referred to the Regional Facilities Manager
- Scheduled drugs, impregnated medical devices and drug delivery systems must be referred to the Regional Pharmacist
- Prosthetics / implantable devices must be referred to the Regional Medical Director

Clinical products related to the introduction of a new clinical procedure (which is not currently performed by WACHS) may need to be referred to the Credentialing and Scope of Practice (CASOP) Committee in accordance with the Medical Credentialing and Compliance Requirements Guideline. Where the value exceeds $1 million the proposal is to be managed in accordance with Health Technology Governance Policy.

The following scenarios provide strong evidence to undertake a Clinical Product Evaluation (CPE) process:

- proposed product is superior to the current one in use
- unmet / new clinical requirement / quality improvement initiative
- savings opportunity
- consolidation of multiple products
- contract compliance.

CPE's must not be progressed on the following scenarios.

- pressure from company representatives.
- additional funding has not been approved
- the product does not have TGA (Therapeutic Goods Administration) registration.

2.1 Process

Section 1 - Product Presentation

A designated senior Nurse or senior Clinician must be identified as the 'Clinical Sponsor' who is responsible for the implementation, coordination and compliance with policy during the CPE process. To initiate the process, Section 1 of the CPE Form must be completed by the Clinical Sponsor in Microsoft Word format and forwarded to the Product Liaison Officers (PLO's) prior to it being submitted for presentation at the relevant Regional PESC. The PLO will review the submission and either seek further clarification from the clinical sponsor or submit to the relevant Regional PESC secretariat for addition to next agenda. An overview can be seen of Product Evaluation Process Flowsheet Appendix A.

Section 2 - Initial PESC Review

The request is tabled and discussed at the Regional PESC meeting. Section 2 of the form is completed and signed by Regional PESC Chair to reflect one of the following potential outcomes of initial PESC review:

- Endorsed* for use subject to procurement and funding approval as per Authorisations Schedule
- Not endorsed*, no further action required
- Further evaluation is required via specialist team members from review from Work Health and Safety, Infection Prevention and Control, Sterilisation Services and Biomedical Engineering as relevant.
- Further evaluation required via a trial of product.

* In these scenarios, the PESC process is complete.

Section 3 - Specialist Review

The nominated specialists are to review the item and record their assessment on Section 3 of the CPE Form and returned to the PESC Chair. If a specialist deems the product 'not fit for purpose' any plan to trial must be postponed and referred to PESC.

Section 4 - Product Trial

Prior to the placement of clinical products within the clinical areas for trial, the Clinical Sponsor must ensure that the following pre-requisites have been met:

- PESC endorsement.
- Completed 'Deed of Agreement for the Provision of Medical Devices for the purpose of Product Evaluation (DOA). Not required for contracted products.
    - Supplier to complete form and obtain authorised representative signature and provide copies of insurance certificates, as per DOA Clause 15. If the supplier is unable to meet the insurance requirements the issue should be referred to the regional PESC to determine the most appropriate course
    - The public authorised signature must be Tier 5 or higher
- Educational resources available to product users.
- Evaluation form developed and available to product users (suppliers forms must not be used).
- Any medical equipment has been checked by BME and has an electrical safety check completed.
- Any costs associated with the trial have been approved.

During the trial process, the Clinical Sponsor is to oversee the process, manage any issues and determine the number of evaluation forms required to make an adequate assessment of product. Trials are to be concluded within twelve (12) weeks. Once the trial has concluded, the company representative must be advised, and any equipment or unused products returned. Section 4 of CPE Form is then to be completed, summarising the results prior to submitting it to the Regional PESC.

Section 5 – Final PESC Review

The results are tabled and discussed at the Regional PESC meeting. Section 5 of the CPE Form is completed and signed by the Regional PESC Chair to reflect one of the following potential outcomes of final PESC review:

- endorsed for use, fit for purpose
- not endorsed for use, not fit for purpose.

A summary of the evaluation outcome may be provided to the product company representative from either the Clinical Sponsor or the PLO. Copies of trial documentation are not to be shared with to any parties external to WA Health. Suppliers are to be advised that endorsement is not a commitment to purchase.

2.2 Trial Records

All CPE documents are to be retained in accordance with the WACHS Records Management Policy. Completed CPE Forms must be forwarded to the PLO for addition to the Product Evaluation Database to facilitate sharing of results with other sites.

2.3 Purchase following product evaluation process

If the trial item is to be purchased, it must be done in accordance with the relevant procurement policies and guidelines.

2.4 Implementation of clinical products

The introduction of any new clinical product must follow a planned implementation process to ensure a safe transition and may include additional training, policy and supply chain changes.

3. Roles and Responsibilities

The **Clinical Sponsor** is responsible for:
- the implementation and coordination of the clinical product evaluation process as described in this policy.

The **Product Company Representative** is responsible for:
- providing clinical product educational information, including manual /instructions for use and TGA registration certificates
- completing the DOA and providing copies of insurance certificates
- providing information, including any additional costs, which may be incurred with product usage over anticipated life.

The **Product Liaison Officer** (PLO) is responsible for:
- providing support and education as required to all stakeholders
- ensuring that the Clinical Sponsor has engaged with the Company Rep and/or other WA Health sites to check if the product has previously undergone an evaluation process, and sharing this with the Regional PESC where appropriate
- maintenance of CPE Register.

The **Regional PESC** is responsible for:
- ensuring that all new clinical products introduced into region are compliant with the WACHS CPE Policy
- reviewing CPE's undertaken by other WA Health sites and considering if findings support endorsement of the product for use within the Region.

All staff are required to work within policies and guidelines to make sure that WACHS is a safe, equitable and positive place to be.

4. Monitoring and Evaluation

4.1 Monitoring

The Regional Product Evaluation and Standardisation Committees monitor the application and compliance of the policy.

4.2 Evaluation

Periodic evaluation of the policy is coordinated by the Product Evaluation and Standardisation Committee in collaboration with the Regional Product Evaluation and Standardisation Committees.

5. Compliance

This policy is aligned to the *Health Services Act 2016*.

Failure to comply with this policy may constitute a breach of the WA Health Code of Conduct (Code). The Code is part of the Integrity Policy Framework issued pursuant to Section 26 of the *Health Services Act 2016* and is binding on all WACHS staff which for this purpose includes trainees, students, volunteers, researchers, contractors for service (including all visiting health professionals and agency staff) and persons delivering training or education within WACHS.

WACHS staff are reminded that compliance with all policies and procedures is mandatory.

6. References

Therapeutic Goods Administration [Internet] Australia: Department of Health and Aged Care [updated 2023 Sept 13]. Available from: https://www.ebs.tga.gov.au

7. Definitions

Term	Definition
Clinical Products	Medical devices, equipment or consumables purchased for the purpose of healthcare delivery.
Consumables	Items purchased for either independent use or use with a medical device or equipment that are used and then discarded.

8. Document Summary

Coverage	WACHS wide
Audience	All users of Clinical products
Records Management	Non Clinical: Corporate Recordkeeping Compliance Policy
Related Legislation	• Therapeutic Goods Act 1989 Cth • *Work Health and Safety Act 2020*
Related Mandatory Policies / Frameworks	• Clinical Governance, Safety and Quality
Related WACHS Policy Documents	• Clinical Products Complaint Policy • TGA Notification and recall for Medical Devices Policy • Medical Credentialing and Compliance Requirements Guideline
Other Related Documents	Nil
Related Forms	• Clinical Product Evaluation Request • Deed of Agreement for Provision of Medical Device for Purpose of Product Evaluation
Related Training Packages	Nil
Aboriginal Health Impact Statement Declaration (ISD)	ISD Record ID: 2607
National Safety and Quality Health Service (NSQHS) Standards	1.29, 3.12, 5.23
Aged Care Quality Standards	Nil
National Standards for Mental Health Services	Nil

9. Document Control

Version	Published date	Current from	Summary of changes
5.00	22 November 2023	22 November 2023	• Updated on to new template. • Improved clarity and detail in relation to presentation process, completion of deed and roles and responsibilities. • Addition of conducting evaluations during current procurement processes and referral to CSSD for reusable devices.

10. Approval

Policy Owner	Executive Director Nursing and Midwifery
Co-approver	Executive Director Medical Services Executive Director Business Services
Contact	Clinical Procurement Manager
Business Unit	Procurement and Contract Management Directorate
EDRMS #	ED-CO-14-79840

This document can be made available in alternative formats on request.

Appendix A: WACHS Clinical Product Evaluation Process Flowsheet