Examples of Reportable Adverse Events

Device Performance Issues

- **Incorrect Dosage Delivery -** An insulin pump malfunctions and delivers too much insulin, leading to hypoglycaemia
- **Mechanical Failure** - A wheelchair's brakes fail, causing the user to lose control and potentially injure themselves.
- **Allergic Reaction** - Someone experiences a severe allergic reaction to materials used in a medical device, such as a stent or catheter.
- **Infection** - A patient develops a serious infection after receiving a surgical implant, like a hip or knee replacement.
- **False Positive/Negative Result -** A pregnancy test kit/covid testing kit test yields a false positive or negative result, but the clinician verifies the result with a subsequent test, leading to no patient harm.

Labelling and Packaging Issues

- **Misleading Claims** - Home sexually transmitted diseases (STD) Testing Kit, some home testing kits are reliable, others may make exaggerated claims about their accuracy and comprehensiveness. Misleading results can lead individuals to either falsely believe they are free of infections or unnecessarily panic, affecting their health choices and relationships.
- **Mislabelled** - A box of contact lenses was mislabelled, indicating that the lenses were suitable for extended wear when they were actually designed for daily wear. Users may wear the lenses overnight, increasing the risk of serious eye infections or corneal damage due to reduced oxygen permeability.
- **Inadequate instructions** - An insulin pen was packaged without clear instructions regarding dosage adjustments for different patients (e.g., weight-based dosing).
- **Missing Instructions** - Blood pressure monitor, comes without any user manual, leading to incorrect use and inaccurate readings.

Malfunctions Leading to Injury or Potential Injury

- **Infusion Pump Error** - An infusion pump malfunctions and administers medication too quickly, causing adverse reactions in the patient.
- **Implant Displacement** - A hip joint implant shifts out of place due to a design flaw, causing pain and the need for revision surgery.
- **Incorrect Sensor Readings -** A pulse oximeter gives inaccurate readings, leading to delayed treatment for a patient with low oxygen levels.
- **Defibrillator Failure -** An automated external defibrillator (AED) fails to deliver a shock during a cardiac emergency, potentially endangering the patient's life.

Public Health Threats

- **Data Breach** - In recent years, certain models of insulin pumps have been vulnerable to cyberattacks due to inadequate security measures. Hackers could exploit these vulnerabilities to gain unauthorized access to user's health data, including insulin dosing information and personal identifiers.

- **Faulty Respirators** - A batch of respirators fails to filter out harmful particles, putting healthcare workers and patients at risk during a respiratory outbreak.
- **Hazardous Materials** - Metal Hip implant causes metal poisoning due to the leaching of the material used in the patient.

Poor Quality Issues

- **Inaccurate Blood Glucose Monitor -** A faulty blood glucose monitor provides incorrect readings, resulting in a patient receiving inappropriate insulin doses, causing severe hypoglycemia.
- **Leaking Catheter -** A urinary catheter develops a leak due to substandard materials, leading to urinary retention and an increased risk of infection for the patient.
- **Cracked Infusion Pump -** An infusion pump has a cracked casing, causing medication to leak. This results in inadequate dosing and puts the patient at risk of receiving subtherapeutic levels of medication.
- **Poorly Designed Orthopedic Implant -** An orthopedic implant has design flaws that cause it to fracture within a short period, necessitating revision surgery and causing pain and complications for the patient.
- **Faulty Pacemaker -** A pacemaker malfunctions due to quality control issues in its manufacturing process, leading to irregular heart rhythms and requiring immediate medical intervention.

Off Label Use

- **Use of Implantable Devices Beyond Approved Duration** - Spinal implant is left in place longer than recommended, resulting in adverse reactions or device failure/breakage.
- **Unapproved Use in High-Risk Patients** - A device is used in patients with multiple health issues despite not being approved for such populations, leading to serious complications.
- **Single use device used multiple time** – Cranial perforator is a single use device but due to financial constraints, it is used multiple times leading to complications in patients.

Near Miss Incident

- **Software Glitch in Imaging Device -** An imaging device displayed incorrect information due to a software glitch. The technician noticed inconsistencies and repeated the scan, obtaining accurate results.
- **Incorrect Flow Rate -** A home healthcare worker was preparing to deliver oxygen to a patient using a portable oxygen concentrator. Upon checking the settings, they noticed the flow rate was set incorrectly due to a previous user's adjustment. They corrected it before administering oxygen, preventing possible respiratory distress for the patient.
- **Device Breakage -** A nurse was preparing to administer a medication using a prefilled syringe. As the nurse was inspecting the syringe before use, they noticed a hairline crack in the plastic body of the syringe. The crack had not been visible during the initial inspection, and the nurse had not yet drawn the medication. The nurse immediately reported the issue to a supervisor and discarded the syringe. They replaced it with a new, intact syringe, allowing for the medication to be administered safely without any risk of breakage during the procedure.
- **Test Kit Deficiency Not Leading to Harm -** A batch of test kits shows a lower sensitivity than expected, but patients are retested using a different method, resulting in no negative outcomes.

- **Mechanical Failure Without Injury -** A device (e.g., a thermometer) malfunctions during use but does not result in patient harm or delay in treatment.

User error

- **Device Misuse -** A clinician uses a scalpel for a procedure that requires a different instrument, risking patient safety and surgical outcomes.
- **Failure to Calibrate -** A user neglects to calibrate a blood pressure monitor before use, leading to inaccurate readings that could affect patient management.
- **Improper Sterilization -** A surgical staff member fails to properly sterilize a surgical instrument, increasing the risk of infection.
- **Inadequate Training -** A clinician attempts to operate a new ultrasound device without sufficient training, resulting in poor image quality and delayed diagnosis.

Examples of Non-reportable adverse events

Malfunction Protection Operated Correctly

- After a malfunction of an infusion pump it gives an appropriate alarm and stops (e.g. in compliance with relevant standards). There was no injury to the patient.
- Microprocessor-controlled radiant warmer malfunctions, reverts to an appropriate default condition and provides an audible appropriate alarm (e.g., in compliance with relevant standards). There was no injury to the patient.
- During radiation treatment, the automatic exposure control is engaged. Treatment stops. In accordance with the relevant standards the actual dose is displayed. Although patient receives less than optimal dose, patient is not exposed to excess radiation.

Expected and Foreseeable Side Effects

- A patient who is known to have claustrophobia experiences severe anxiety in the confined space of a MRI machine which subsequently led to the patient being injured.
- A patient receives a second-degree burn during the use in an emergency of an external defibrillator. Risk assessment documents that such a burn has been accepted in view of potential patient benefit and is warned in the instructions for use. The frequency of burns is occurring within range specified in the device master record.
- Placement of central line catheter results in anxiety reaction and shortness of breath. Both reactions are known and labelled side effects.

Adverse Events Described in an Advisory Notice

- Manufacturer issued an advisory notice and recall of a coronary stent that migrated due to inadequate inflation of an attached balloon mechanism. Subsequent examples of stent migration were summarized in quarterly reports concerning the recall action and individual adverse events did not have to be reported

Temporary Discomfort

- A patient feels temporary discomfort or pain during the use of a medical device, such as a blood pressure cuff, but no long-term effects are noted.

User Confusion

- A clinician misinterprets the display of a medical device but corrects the interpretation quickly without impacting patient safety or outcomes.

Accidental Disconnection

- An infusion line is accidentally disconnected, but the nurse notices immediately and reconnects it without any adverse effects on the patient.