Safety Alert
Revised July 2016

Risk Management of Blood Glucose monitoring in Designated Centres
1. What is the Risk?

Monitoring of blood glucose levels involves taking of a sample of capillary blood with a
fingerprick lancing device and testing it with a blood glucose monitor.

People with diabetes in designated centres who monitor their blood glucose levels may be
at risk of contracting hepatitis B virus or other blood-borne virus infections such as hepatitis
C and HIV, if the procedure is not managed appropriately.

The increasing prevalence and diagnosis of diabetes among an ageing Irish population
along with increased reliance on assisted blood glucose monitoring services indicate a
growing risk.

2. Recent Incidents

Hepatitis B presents the greatest risk of all blood borne viruses; it is highly infectious and
environmentally stable. There have been many reported outbreaks of hepatitis B infection in
long-term care and assisted living facilities in the US, UK and Europe, associated with blood
-glucose monitoring.

The outbreaks have been attributed to confusion between different types of lancing devices,
the inappropriate and incorrect use of lancing devices, and to poor infection prevention and
control practices, e.g., inadequate cleaning of glucose monitors or surfaces, failure to
change gloves between patients and inadequate hand hygiene. In particular, using the
finger stick devices on multiple patients although they are designed for single-patient use
has been a cause of some of these incidents. In addition, the inappropriate use of insulin
pens and vials poses a potential risk of cross infection.

Note: The risk of cross-contamination with insulin pens is not the subject of this safety
alert. Further information about this topic is available on the Irish Medication Safety

3. Guidance

The Health Information and Quality Authority convened a Working Group in conjunction
with the Health Service Executive, to develop guidance for providers on proactive measures
to eliminate the risk of cross infection, associated with blood glucose monitoring.
4. Blood Glucose Monitoring Equipment

There are three components of a diabetes monitoring system: a blood glucose monitor, a lancing device and blood glucose test strips. To use a lancet device, a person with diabetes draws blood, which is then applied to the test strip. The test strip is placed into the blood glucose monitor which detects how much blood glucose is present.

4.1 The lancing device

The lancing device has two components:
1. The needle which punctures the skin, known as the lancet.
2. The firing mechanism, which shoots the lancet into the skin.

There are different types of lancing devices in common use, including the following:

1. Single use Safety Lancet:
   • A lancing device which incorporates both the lancet and the firing mechanism in a single unit. The entire device is used once and then disposed of after use. These devices are commonly known as single use safety lancets.

2. Single patient use:
   • A lancing device with reusable firing mechanism and a drum of multiple lancets. The used lancet retracts into the drum and a new lancet is selected. When all lancets are used, the drum is replaced. This is not suitable for use on multiple patients.
   • A device with reusable firing mechanism and one visible lancet for each use. The firing mechanism must not be used on more than one person. The lancet is not a safety lancet and poses a sharps injury risk to health and social care workers.

There is also a device with a reusable firing mechanism and a single use safety lancet. The firing mechanism is licensed for use on multiple patients. Cleaning and disinfection of the firing mechanism in line with the manufacturer’s instructions is required after each use. The lancet is single use only.

When selecting a lancing device facilities should consider:

- Compliance with the EU Sharps Directive to reduce the risk of sharps injuries to staff.
- Eliminating the risk of blood borne virus transmission for residents/clients
- Supporting independence/self care for residents /clients
- The potential for confusion where multiple devices are in use (i.e., single patient use device could be used inappropriately for multiple residents/clients)

4.2 Blood glucose monitor

A blood glucose monitor is provided to a person with diabetes for their individual use and should not be shared. In hospital and care settings, specifically designed blood glucose monitors should only be used with multiple patients/residents by appropriately trained staff.
5. Risk Assessments and Key Responses

Providers and managers of social and health care settings need to develop/review the standard operating procedures (SOP) for blood glucose monitoring, to ensure that they reflect current best practice. They must also undertake a risk assessment to ensure that blood glucose monitoring is carried out in line with the standard operating procedure and that equipment is used according to the manufacturer’s instructions.

The risk assessment should include the following:

- Avoiding unnecessary blood glucose monitoring.
- Blood glucose monitoring equipment is used and decontaminated (where applicable) in line with the manufacturer’s instructions and appropriately stored.
- Staff, residents and clients receive appropriate education on safe practices for blood glucose monitoring. Education should include the prevention of transmission of blood borne viruses.
- Implementation of Standard Precautions for all residents/clients at all times.
- Hepatitis B vaccination for relevant staff and residents/clients in accordance with the National Immunisation Guidelines.
- A process is in place to ensure that alerts from the regulators, including the Health Products Regulatory Authority are received and responded to appropriately.
- Ongoing audits are undertaken to monitor and improve practice.

5.1 Hepatitis B Vaccination

Hepatitis B vaccine is a safe and effective vaccine for the prevention of hepatitis B infection. Hepatitis B vaccination is recommended for at risk groups in accordance with the national immunisation guidelines. At risk groups include healthcare workers and other people at occupational risk, residents/clients with chronic kidney and liver diseases or immunosuppression, residents and staff in services for people with learning disability.

5.2 Management of Blood Glucose Monitoring Equipment

The lancet devices used must:

- Comply with the Regulations relating to prevention of sharps injuries. Further information is available from the Health and Safety Authority.
- Be used as per manufacturer’s instructions (i.e., single patient use devices must only be used for one person).

Where a blood glucose monitor is used for monitoring multiple patients, it is crucial to ensure that the device used is intended by the manufacturer to be used by professionals in a multi-patient setting. Recommended precautions for the prevention of transmission of blood-borne viruses must be adhered to. It is essential to follow the manufacturer’s
guidance in relation to the proper cleaning and disinfection and storage of the device as outlined in the User Manual.

In designated centres the following is recommended:

- Insofar as is reasonably practicable, each resident/client who requires routine blood glucose monitoring should have their own blood glucose monitor.
- The blood glucose monitor must be marked with the resident's/client's details. It must be thoroughly cleaned after use and subsequently stored in an hygienic appropriate area such as a cupboard or at the bedside.
- Where devices are not individually allocated and a blood glucose monitoring device is used for monitoring multiple patients, the device must be appropriately cleaned and disinfected after each use, according to manufacturer's instructions. A copy of these instructions must be retained for reference.
- In residential care facilities, it is recommended that an individual’s glucose monitor, test strips and insulin pen are disposed of when no longer required or else given to the resident on their discharge/transfer.
- In day care settings, if clients require blood glucose monitoring, it is preferable that the client is asked to bring their own blood glucose monitoring equipment.

Where trays with integral sharps bins are used, the following is relevant:

- Clean trays with only the equipment required for one procedure with one person should be brought to the resident's/client’s bedside or other suitable area. Where residents/clients have individual trays, these should be cleaned on a regular basis.
- When trays are used for multiple procedures, the glucose monitor and other used equipment must not be returned to a clean area or placed on a tray that holds clean supplies.
- Following the glucose monitoring procedure the tray should be emptied of all items, cleaned and disinfected using a disinfectant known to be effective against non-enveloped viruses.
- Clean trays should be stored in the clean area of the treatment/clinical room.

6. Standard Precautions

The following five standard precautions must be implemented to reduce the risk of transmission of blood-borne viruses associated with blood glucose monitoring. The elements of Standard Precautions that apply to blood glucose monitoring are:

1. Hand hygiene.
2. Personal protective equipment.
4. Safe disposal of sharps and waste.
5. Decontamination of patient equipment.
6.1 **Hand Hygiene**

Hands should be decontaminated with an alcohol hand rub or a plain liquid soap and water, before and after carrying out blood glucose monitoring. Washing with soap and water is essential if the hands are visibly contaminated (WHO 2009, SARI 2005).

6.2 **Personal Protective Equipment**

Non-sterile disposable nitrile or latex gloves should be worn when carrying out blood glucose monitoring. The following steps should be taken:

- Decontaminate hands prior to putting on gloves.
- Remove gloves and decontaminate hands **after** handling objects that may be blood contaminated (such as the blood glucose monitor) and **before** handling clean items (such as a resident's record cards or insulin pen).
- Gloves do not replace hand hygiene practices; hand hygiene must be undertaken before putting on and after removing gloves.
- Gloves must be changed and hand hygiene undertaken between residents/clients.

6.3 **Safe Injection Practices**

Persons in charge have a responsibility for ensuring that the right devices are provided for taking blood samples from multiple residents and that safe injection practices are adhered to, in line with WHO guidelines on drawing blood (2010).

- It is recommended that the health and social care workers who undertake blood glucose monitoring use disposable, single-use safety lancets, where the firing mechanism and the lancet are both discarded as one single unit.
- With the exception of lancing devices, specifically designed for multi-patient use, lancing devices must never be shared or used on more than one person.
- Residents/clients should be supported to self monitor, and there must be systems in place to ensure that self-monitoring devices are never shared.
- Lancets used in a reusable pen style firing device must be removed by the resident/client themselves or by staff using a safety device.

6.4 **Disposal of Sharps and Waste**

- A clean tray with integral sharps bin should be brought to the area where the procedure is to be carried out.
- Dispose of sharps as a single unit immediately after use into an approved sharps container (Health and Safety Authority 2014).
- Waste should be segregated and disposed of appropriately (Department of Health and Children 2010).
6.5  Decontamination of glucose monitoring equipment

- Reusable patient equipment (such as blood glucose monitors) must be adequately decontaminated after use to prevent transmission of infection.
- Manufacturer's instructions for reusable blood glucose monitoring equipment must be followed to ensure adequate decontamination.

7. Legislation, Regulation, Standards and Guidelines


Health Act 2007 (Care and Welfare of Residents in Designated Centres for Older People) Regulations 2013.

Health Information and Quality Authority, National Quality Standards for Residential Care Settings for Older People in Ireland, Revised December 2015.

Health Information and Quality Authority (2013) National Quality Standards for Residential Services for Adults with Disabilities.


Resources

MDA/2006/066 - Lancing devices used in nursing homes and care homes. 6 Dec 2006.
http://www.mhra.gov.uk/Publications/Safetywarnings/MedicalDeviceAlerts/CON2025400


http://ndsc.newsweaver.ie/epiinsight/1q4knv6wsxjzeqw6u8rbkx

