Introduction

Gnosco’s experience is that clinical safety is the foundation of a successful teledermatology implementation, measured by user adoption, patient experience and the benefits experienced by our customer.

This guide explains how clinical safety links the core elements of a teledermatology business case and implementation plan.

What is clinical safety?

Gnosco’s definition and that of NHS Digital is the effective clinical risk management in deploying, developing and modifying health IT systems.

Clinical safety is the responsibility of both the IT health system supplier and the NHS organisation. Gnosco’s customer is integral to the application of clinical risk management in the deployment and use of teledermatology.

How is clinical risk managed?

NHS Digital provides excellent resources to support suppliers of Health IT systems (in this case – a teledermatology platform) and NHS organisations to comply with the standards that are mandatory under Section 250 of the Health and Social Care act 2012.

The reality is that both the supplier and the NHS organisation need to work as a team to mitigate clinical risk.

1Health and Social Care act 2012:
What standards need to be met?

There are two standards for managing clinical safety - DCB0129 and DCB0160 - as detailed under section 250 of the Health and Social Care Act 2012 by the Data Coordination Board (DCB).

These are important to comprehend from the beginning of your teledermatology implementation.

Information standards underpin national healthcare initiatives from the Department of Health, NHS England, the Care Quality Commission and other national health organisations.

Why are there two standards?

Your teledermatology implementation plan needs to include compliance with both standards. Planned compliance with these standards will manage clinically safe development of the teledermatology platform and the process in the deployment of that platform.

Your teledermatology supplier is responsible for achieving compliance with DCB0129, covering Clinical Risk Management: its Application in the Manufacture of Health IT Systems. This standard sets clinical risk management requirements for Manufacturers of health IT systems.

Your NHS organisation is responsible for achieving compliance with DCB0160, covering Clinical Risk Management: its Application in the Deployment and Use of Health IT Systems. This standard requires a health organisation to establish a framework within which the clinical risks associated with the deployment and implementation of a new or modified health IT system are properly managed.

Both supplier and NHS organisation are working together to mitigate clinical risk by being compliance DCB0129 and DCB0160.

Standards are the mechanism for introducing requirements to which the NHS, those with whom it commissions services and its IT system suppliers (in this guide, the teledermatology supplier), must conform.

Compliance with DCB0129 and DCB0160 is mandatory under the Health and Social Care Act 2012.
When is a teledermatology platform clinically safe to go live in the NHS?

Before a teledermatology platform goes live in the NHS, the IT supplier will have to undertake a formal review with NHS Digital of the clinical risk management activities conducted to ensure that the requirements for the clinical safety management system have been addressed.

This meeting includes representatives of the supplier and is the formal process, including the sign-off of the system using the Clinical Authority to Release (CATR)3 checklist document.

The meeting includes some or all of the following roles in the supplier’s organisation, including the teledermatology platform CSO or clinical safety lead.

The scale of this review should be commensurate with the scale of the overarching clinical risk management process but needs to be sufficient to ensure that executive management are appraised of the work conducted.

The review proves that the supplier’s clinical risk management plan has been implemented and the outcomes recorded. The residual clinical risk for each hazard has been deemed acceptable and appropriate methods are in place to obtain relevant post-deployment information and to feed these into the clinical risk management system.

Top management needs to be satisfied that all foreseeable hazards have been identified and that the clinical risk of each hazard has been reduced to acceptable levels. In all circumstances, the executive management of the supplier remains responsible for the release of the teledermatology platform.

Once the supplier’s teledermatology platform has been signed-off by NHS Digital, a CATR document is issued. The CATR should be readily available to show the NHS organisation.

Clinical safety project check list:

Ask the teledermatology suppliers that you are evaluating for:

- CATR document
- Evidence of compliance with clinical risk mitigation standard DCB0129
- Clinical safety case and Hazard log
- Who is their NHS Digital accredited clinical safety officer?
- Evidence of close working with NHS customers to mutually support the mitigation and reduction of clinical risk

In your NHS organisation:

- Identify who will be the clinical safety officer
- Ensure compliance with clinical risk mitigation standard DCB0160

For more information to support your successful implementation of teledermatology, please contact: Philip Daniels-May
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3 Clinical Authority to Release