Clinical Safety Interweave

Interweave has a Clinical Risk Management System, a Clinical Safety Officer and a Clinical Assurance Process. The definitions and context of these are detailed in this document.

Clinical Risk Management System.

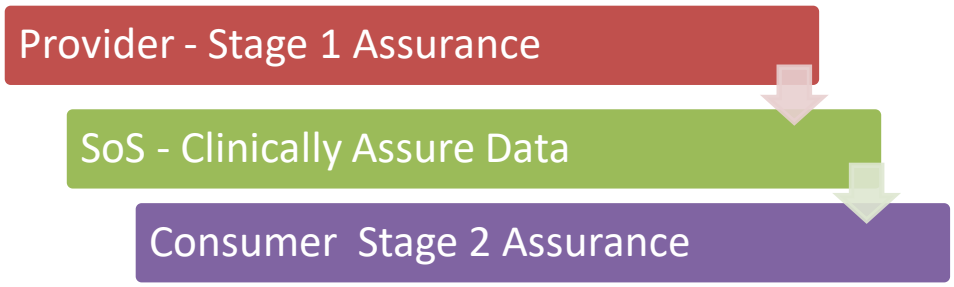
The Clinical Risk Management System (CRMS) outlines the processes to be followed to ensure that all new development's, and/or changes to the System of System (SoS) are developed and implemented while complying with the NHS Clinical Safety Standards. The CRMS provides a framework that promotes effective risk management for potential health IT related hazards and operational incidents. The CRMS addresses the requirements of DCB 0129 and DCB 0160 and follows best practice as promoted by NHS Digital. Interweave are responsible for the DCB 0129 standard- Clinical Risk Management: it's Application in the Manufacture of Health IT Systems including Software

Clinical Safety Officer.

Interweave has an accredited Clinical Safety Officer (CSO) who holds a current professional registration, and is suitably trained and qualified in clinical risk management. The CSO for the Interweave also works with the middleware company while assisting in the assurance of the product System of Systems (SoS). The CSO works with on-boarding healthcare organisations to ensure they are aware and comfortable with the clinical safety work required enabling them to use SoS safely.

Clinical Assurance Process.

Interweave has a 2 stage Clinical Assurance Process. Any on-boarding site wishing to provide data will be clinically assured, the data flowing into the SoS is analysed and evaluated. Once complete a report is generated and any issues found are reported to the providing site. This is stage 1 of the process. The 2nd stage is for the data flowing through the SoS to be checked at the consuming site. The CSO working for Interweave completes this assurance. However it is also the responsibility of the consumer to test and assure the data and ensure it is displayed in the user interface accurately. The CSO's work together with the test teams and clinician's to ensure the data is flowing correctly and most importantly the context and terminology are accurate. Any issues identified are actioned and discussed prior to any Go-Live decisions.



The diagram above shows the Clinical Assurance Process.

Hazard Log

Interweave manage a central Hazard Log- this contains the SoS hazards and gives examples to both providers and consumers to consider. When a new site on-boards into the Interweave SoS they are asked to provide the Interweave CSO with their own Hazard log. This is then incorporated into the central Hazard Log. This enables all Hazards to be visible to any consumer or site wishing to on-board. The transparency of these hazards are available for evaluation and mitigation, if the hazard is relevant and transferable. Regular updates are applied to the hazard log to reflect any additions or changes where necessary. It is the organisations responsibility to ensure they provide the Interweave with the latest version if changes occur.

Clinical Safety Case Report

Interweave has developed two Clinical Safety Case Reports, the first Clinical Safety Case was released in relation to the Wave 1 sites only. Since the development of SoS and the expanding sites on-boarding the report has recently been amended to reflect this. The safety case is the backbone of the system and provides evidence to the mechanism used to assure SoS clinically.

Engagement with Clinicians and CSO's.

Interweave have engaged with clinical safety from the start of the programme, we ask for full engagement from the clinical teams and CSO's at the sites on-boarding. Interweave's CSO works with the clinical teams to ensure they are aware of the responsibility of the clinical safety activities which must be completed to comply with the standard DCB0160.

Governance.

Interweave have 2 weekly team meetings where clinical safety is discussed, regular mini project meetings are held weekly for regular updates. The Clinical Technical Design Authority Group meet bi-monthly to discuss any clinical topics, clinical safety is also discussed here. The Go-Live checklist for any site or function for SoS includes Clinical safety, this is to ensure the assurance work has been completed to a satisfactory and safe threshold.