CLINICAL SAFETY REPORT FOR CEG CLINICAL TOOLS: 2019

This clinical safety report covers CEG clinical templates/protocols/documents/searches and APL clinical tools – APL-AF, APL-HF, APL-Hypoglycaemia, Asthma Prescribing, Falling eGFR, Cancer Patient Analysis Tool.

This includes the Clinical Hazard Risk (CHR) and Mitigation in purple

OVERALL DESIGN

1. **The content** is clinically agreed to have a robust evidence base and stakeholder consensus that the use of CEG clinical tools is safe, effective, efficient and for patient benefit.
2. **Development:** The code sets for searches/templates/protocols are agreed by the responsible clinicians, created by the data analyst/facilitators. Search outputs are checked by the clinicians/facilitators/GP practices. Template content checked by commissioners/clinicians.

   It is of note that these tools may contain clinical algorithms which if incorrect could result in "considerable" clinical hazard risk (level 2) for individual patients – the Clinical Safety Officer has given particular scrutiny to these elements of the tools, both their content and mitigation of any risk.
3. **Tool delivery** – any issues with delivery mechanism
4. **Review of modifications** or user identified concerns

TOOL DESIGN: CLINICAL HAZARD RISK: = 1 minor. There is no clinical hazard at this stage

MITIGATION OF RISK: The design use of our tools may improve with user feedback over time

CONTENT

All CEG tools are supported by current clinical guidance developed in conjunction with stakeholders. The wide stakeholder group including a range of content specialists and the process of developing this guidance ensures quality of the evidence and that decisions for implementation are sound and appropriate to the clinical and organisational context in which they were developed.

TOOL CONTENT: CLINICAL HAZARD RISK: = 1 minor
MITIGATION OF RISK: Review of guidelines annually or more frequently if appropriate

Low CHR 1: Up-to-date: Maintenance of clinical guidance up-to-date revisions – annual review of guidance and impact on tools. For example change in CHADS2 to CHADSVASC was incorporated into the new AF guidance and tool. Searches/templates/protocols are reviewed annually to ensure in line with recent guidance and CCGs enhanced service specifications.

Low CHR 1: Errors in text: These are identified in the production process including review by content specialists/stakeholders – further typos or inconsistencies can be reported by users and if necessary an addendum to the guidance is circulated and if necessary the tool revised. (This has not been necessary so far).

TOOL DEVELOPMENT

PERSONNEL: Responsible clinician(s): Responsible data analyst(s): Responsible facilitator(s)

These personnel will ensure the following actions around Testing, Delivery, Modification and Review.

APL and Trigger Tools

These tools consist of an EMIS or MIQUEST search, exported to an Excel macro – this is used to identify individual patients for HER or actual review.

1. SEARCH: Typically identified for display are age, gender; a management factor such as a treatment, and some clinical character such as a high blood pressure or a low indicator of blood glucose or renal function.
2. EXCEL MACRO: These searches are they imported into an excel spreadsheet which then displays characteristics of individually identified practices.
3. PATIENT RECORD: The responsible clinician or staff acting under their direction can then identify the individuals of interest and review their record and if necessary the patient to consider management options.

Suite of EMIS/Miquest Searches

CEG construct a suite of searches for clinicians to support QoF/Enhanced Services/Medicine management. These searches are used to identify individual patients for review. The searches are run by the practices on clinical systems and enable practices to review patient records and used for recall. Searches also provide data for payment and quality reports.

Suite of EMIS Templates

Templates are constructed for EMIS/Vision and System One. Templates are constructed using READ codes. The aim of the templates is to facilitate data entry, using standard coding, comply with QOF and enhanced service standards and enable best practice based on most recent clinical guidance. Templates use hyperlinks, include telephone numbers for other services, and links to word documents.

EMIS Protocols

Protocol alerts are constructed for EMIS clinical systems. These are built using concepts and alert clinicians if missing data in patient records.

EMIS Word Documents

Referral forms, care plans, discharge summaries are constructed in EMIS clinical system for practice use. The majority of the documents have been created in word by other providers and CEG import documents into EMIS. These documents will contain mail merge fields using Read codes.

TOOL DEVELOPMENT: CHR

1.	That the correct codes are used – any issue here will be picked up in beta clinical pilot testing.	Risk Minor = 1
2.	That the tool runs as expected: - again issues identified in beta-testing	Risk minor = 1
3.	The risk that an individual patient will be incorrectly identified is very small	Risk minor = 1
4.	That any associated clinical algorithm – CHADSVASC score/eGFR trigger is accurate	Risk considerable = 2

TOOL DEVELOPMENT: MITIGATION

CHR 1 Should any issue be identified 1-3 above then they will be picked up in the pilot testing or by reports from users after delivery.

CHR 2 The severity if there is an incorrect algorithm could be considerable =3. However, the risk of an incorrect algorithm is small <1.

Algorithms are checked by content specialists on a range of individual patients. Clinicians are advised that the tool simply identifies people at potential risk and that this does not replace the clinicians judgement based upon their own EHR and clinical judgement.

If an error were identified in the algorithm software all recipients would be notified to suspend use until the error had been corrected and the nature of the error explained to users so that they might take any necessary action.

TESTING

Clinical testing: CEG tools are initially beta-tested and 'run' in two or more pilot clinical settings to check functionality. The APL and trigger tools are clinically reviewed to check that accuracy of the output in the Excel macro matches the factors listed in the patients medical record. CEG has clinical links with a number of GP practices to allow such identifiable checks to be securely made by the patients own clinicians. The final version of new tools is run in local CCGs before being made publicly available, though individual copies are made available on request. Practices are informed when new/revised templates/protocols/word documents are available and a small number of practices are asked to test new tools before general release.

Each APL/Trigger tool has an accompanying instruction manual. Templates have an accompanying template guide.

For all CEG tools/templates/searches/protocols includes advice that such tools are

a. an aid to clinical decision making
b. they do not replace clinical judgement in each individual patient
c. these tools are not predictive – they simply identify patients with particular characteristics for clinical review because these characteristics are known to be associated with increased clinical risks.

RISK: Minor = 1 There are few if clinical risks in testing as the tool is not used clinically at this stage

TOOL DELIVERY

APL and Trigger Tools

These tools are delivered by zipped email files containing the .xml search, the excel file and the instruction manual. There is an email address and telephone number for any queries and comments. Where there are local arrangements searches can be directly transferred to IT systems. CEG facilitators are available to deal with practice queries about these tools and contact details are provided.

Templates/Protocols/Word Documents

EMIS clinical system with resource publisher – CEG are a publishing organisation and can publish all resources directly to practices that have signed a data sharing agreement. Tools are published activated so practices can access tools immediately.
For other clinical systems or for EMIS practices still on template manager resources are delivered by zipped email with instruction manuals. There is an email address and telephone number for any queries and comments. CEG facilitators are available to deal with practice queries.

Suite of searches

EMIS clinical system enables CEG to publish directly to practices. All searches have version control. If searches are edited then practices are informed of new version. It is the practice responsibility to ensure correct version is on their system.

RISK: The main risk is that the user does not follow instructions and cannot run the tool. Details of support from CEG are given in the instruction manual. There is no clinical hazard.
MITIGTION: Advice from CEG on correct use

TOOL MODIFICATION

These tools are reviewed when from time to time there is a change in clinical knowledge, clinical guidance or procedures. Any changes would be reviewed as part of the above cycle.
A new or revised tool will be agreed by the Responsible Clinician and the Clinical Safety Officer

RISK AND MITIGATION: As in the development, the same cycle is followed. Any modification is logged in the clinical risk management plan and additional risks noted with any mitigation actions.