TABLE OF CONTENTS

Introduction .......................................................................................................................... 3

What Safety Issues Are There? .......................................................................................... 3

What Key Safety Areas Have Been Identified? ................................................................. 5
  Correct Patient Identification .......................................................................................... 5
  Avoiding Transcription or Transposition Errors ............................................................. 5
  Managing Patients Appropriately ................................................................................... 5
  Checking Clarity of Dose Instruction to Patient / Healthcare Professional ...................... 5
  Losing Track of a Patient ............................................................................................... 5
  Ensuring Operational, Data and System Set-up Integrity ................................................ 5

Safety Check Lists ............................................................................................................ 6

User Checklists .................................................................................................................. 7
  Safety Check List for Patient Searching and Adding/Editing Patient's Details .............. 7
  Safety Check List for Adding/Editing Patient Treatment Plan Details ......................... 7
  Safety Check List for Adding Previous Treatment History ......................................... 8
  Safety Check List for Running Clinics / Monitoring Patient Results ......................... 8
  Safety Check List for Adding the Next Test Date/Time ............................................... 9
  Safety Check List for Adding/Editing/Deleting Letters/Messages ............................... 9
  Safety Check List for Adding/Editing/Deleting Patient Questionnaires ...................... 9

System Manager's Check List .......................................................................................... 10
  Safety Check List for Dose/Interval settings and Dose Instruction Formats ................. 10
  Safety Check List for Clinic Diary Settings ................................................................ 10
  Safety Check List for Defining Procedures, Letters and Events .................................. 10
  Safety Check List for Defining Look Up Information .................................................. 11
  Safety Check List for List View Settings ..................................................................... 11
  Safety Check List for Reports ...................................................................................... 11
  Safety Check List for Custom Modules ....................................................................... 11
  Safety Check List for Automatic Authorisation of INRs .............................................. 11
  Safety Check List for Questionnaire Definitions ......................................................... 12
  Safety Check List for Data and Operational Integrity ................................................... 12
Introduction

This document is intended to highlight potential safety issues that must be understood and addressed before using the DAWN Clinical Framework Anticoagulation module.

It is vital for the on-going safe operation of your software that users of the software are aware of the Safety Instructions as detailed in this manual. Please keep this manual in a safe place for ready referral by your staff.

What Safety Issues Are There?

The DAWN Clinical Framework web application provides the functionality to manage your anticoagulation patients. The application allows for INR results to be imported via an interface or entered manually and to calculate the next dose and next test date. If you are to import results via an interface, please also read the Interface Safety Manual.

The application should be seen as an aid to the Healthcare Professional. It is a condition of use that all instructions or information issued by the application are checked by a competent healthcare professional before instructing the patient.

WARNING

Inadequate checking of the Dose and Next Test Date could cause severe injury or death.

Check that each dose and next test date instruction are correct, clear and safe for each patient.

Use the software in accordance with the design intent as specified in the User Manual. e.g. use the Maintenance module for stable patients and the Induction module for initiating patients.

Segregate and manage patients by risk level e.g. unstable patients and patients in transition - stopping/starting/changing protocols/interacting medication changes, and previous thromboembolic or bleed events.

Use the appropriate treatment/management protocol and appropriate competent personnel for each patient’s indication and risk status.

Check that all non-attendees are followed up and every patient has an next test date appropriate to their risk level.

Appoint a competent healthcare professional to carry out the recommended checks.

Develop written procedures to use with this system to meet your local needs.

These procedures should incorporate not only necessary operational steps but safety steps. The computer system along with these written procedures should form part of a quality management system. Subject this system to external auditing by a suitable quality standards authority.

Train your staff in the use of the computer system.
DAWN Clinical Framework provides a number of checks and warnings to try and prevent errors. These include:

- alerts and warnings after each dosage calculation
- having limits outside which dosing cannot occur
- list views for identifying non-attendees and patients with no next test date
- front screen tallies for displaying some data more prominently
What Key Safety Areas Have Been Identified?

The following key safety areas have been identified:

**Correct Patient Identification**

It is critical that the users ensure that they have identified the correct patient before taking action such as editing information, dosing, reports or taking any clinical action.

**Avoiding Transcription or Transposition Errors**

Careful procedures should be derived and instituted to check that any transcription error or transposition of data cannot occur. The aim should be to eliminate completely any such potential for this type of error.

**Managing Patients Appropriately**

The DAWN AC maintenance module is designed for stable patients only. Patients who are not within this category should be segregated and managed differently, ie, by using the induction module or dosing manually. Some examples of patients who are not within the stable category are as follows for example:

- Patients with high INRs
- Patients with low INRs (e.g. especially those with mechanical heart valves)
- Patients recently admitted / discharged
- Patients on bridging or preparing for procedures e.g. cardioversion, colonoscopy
- Patients on induction therapy
- Patients with miss days dose instructions
- Patients with boost days dose instructions
- Patients starting and stopping interacting medications
- Patients who have had recent or recurring adverse events

**Checking Clarity of Dose Instruction to Patient / Healthcare Professional**

It is essential to ensure that any dose instruction messages printed / emailed / faxed are clear and unambiguous. As well as the format of the instruction itself, users need to check that the anticoagulant instructions are clear, ie, that the number of tablets or milligrams is displayed, any conditional entries such as any boost or miss days are correct and there is no scope for confusion. If your dosing instructions are configured to display decimals rather than fractions, the potential of misreading a decimal in the dosing instructions should be taken into account.

**Losing Track of a Patient**

It is vital that a patient does not get ‘lost’ within the system, e.g. treatment plan wrongly closed, no next test appointment made, no follow up on non-attendances.

**Ensuring Operational, Data and System Set-up Integrity**

It is essential that the system and procedures are critically examined initially and routinely to ensure that the whole system integrity is maintained at all times.
Safety Check Lists

Derived from identified safety considerations, your procedures should incorporate and address the following safety points presented in the form of a check list by functional area. This list is not intended as a complete and exhaustive list. Each user must determine their own safety procedures and ensure that they are operated correctly and consistently.

The checklists are in two sections as follows, one for the routine users of the system:

Adding/editing patient’s details
Adding/editing patient treatment plan
Adding previous treatment history
Running clinics / monitoring patient results
Adding the next test date/time
Adding/editing/deleting user letters/messages
Adding/Editing/Deleting Patient Questionnaires
And secondly, there are separate check lists for system managers to consider.

Dose/interval settings and Dose Instruction formats and messages (letters, email, faxes)
Clinic diary Settings
Procedures, Letters and Events
Look Up Information
List view settings
Reports
Custom modules
Automatic Authorisation of INRs
Questionnaire Definitions
Data and operational integrity
User Checklists

Safety Check List for Patient Searching and Adding/Editing Patient's Details.

When adding a new patient, the user should perform a thorough search to ensure the patient’s details have not been previously entered.

Be aware of name misspellings and transposing numerical identification numbers when searching.

Ensure all patient data (including all data entered via any of the tabs on the patient screen) has been entered and checked for correctness. Attention should be paid to the last name, first name, unit number and date of birth so that the patient can be uniquely identified every time.

Ensure all patient procedures that are entered into the system have been checked for correctness.

Ensure all patient events that are entered into the system have been checked for correctness.

Ensure all patient reminders that are entered into the system have been checked for correctness.

If you are using the maintenance module, ensure the patient is stable and has reached the maintenance dose (if the patient is a maintenance patient).

Ensure the patient has not been incorrectly marked as deceased or inactive.

Safety Check List for Adding/Editing Patient Treatment Plan Details

Ensure all treatment plan data (including all data entered via any of the tabs on the treatment plan screen) has been entered and checked for correctness. Attention should be paid to ensure:

the correct dosing regime has been selected i.e. the instruction of the tablets or pills to be taken by the patient.

the correct primary diagnosis has been entered for the patient.

the correct target INR range has been selected.

the correct start date has been entered.

if short term, the correct treatment duration in weeks has been entered.

the correct maximum % dose change and maximum test interval have been entered.

if a next test has been created, the correct test date and preferred clinic has been entered and the visit has been correctly scheduled into the appropriate clinic diary.

Ensure the treatment plan has the correct status and has not been suspended or stopped in error. The treatment plan should be activated before any dosing can be carried out.
Safety Check List for Adding Previous Treatment History

You MUST check that the previous treatment history has been entered correctly.

Ensure the correct dosage results and INRs have been entered for this patient.

Note DAWN AC is designed for only one INR/Dose record per day.

Be aware of the consequences of adding incomplete information – missing doses and INRs – entering zero values.

Safety Check List for Running Clinics / Monitoring Patient Results

Be aware with Maintenance Module that the computer recommended next dose is based on the last dose recorded for the patient – if that is wrong then the next dose will be wrong or inappropriate.

Be aware with Maintenance Module that the computer next test interval is based on the stability of the patient – indicated by the length of the last test interval and the INR this time. If the last test interval is wrong then the next interval will be wrong or inappropriate.

Be aware that with Maintenance Module the inbuilt algorithms do not take account of interacting medications, previous adverse events, previous and planned procedures.

Be aware that DAWN AC can provide visual warnings of the presence of any recorded and current interacting medication, previous adverse events, previous and planned procedures.

Ensure all entered INR results are correct and have been entered against the correct patient with the correct test date.

Check any manual override of the dose and next test date and always add a comment to say why the change was made.

Check any manual override of missing or boost days and always add a comment to say why the change was made.

The patient MUST be stable and reached a maintenance dose before using automatic dosing in the Maintenance Module.

Validate each dose and next date BEFORE “informing the patient”.

Where appropriate, consider calling patients to discuss any changes in their dose.

If patient record books with labels are being used, check the correct dosage instruction report is stuck in the correct patient’s record book.

Check the correct dosing information is copied by hand to the correct book or patient report.

Check that all patients (including non attendees) due on a particular day have been
dealt with completely. Ensure you assess and take into account the stability of each and every non attendee before deciding on the date to reschedule their appointment for.

Check that the wrong information is not communicated to a patient by letter, telephone or any other communication method.

Routinely ensure that each patient has a maximum percentage dose change and maximum interval limits.

Routinely ensure that all active patients have a future appointment.

Routinely check that all patients that are marked as admitted, active admitted or discharged within the system have been followed up and dealt with.

**Safety Check List for Adding the Next Test Date/Time**

Ensure that the patient has a next test date/time and is scheduled into the Diary.

Use the list view to ensure that all active patients have a next test date.

**Safety Check List for Adding/Editing/Deleting Letters/Messages**

Ensure all new, altered and imported letters / message templates have been checked for correctness, completeness, clarity in all situations e.g. miss days, boost days, and have been thoroughly tested before using them in a live situation.

Check the correctness of all letters/messages sent out from the system. This should be carried out for all available methods of communication including printed output, letters, labels, emails and faxes.

To prevent the wrong information being communicated to a patient or healthcare professional, include the clear patient identifiers in any printed output, emails and faxes (e.g. dose instructions).

To prevent the wrong dose instruction being communicated to a patient, include the current test date alongside the dose instruction.

Where printing user letters/messages for a group of patients, have a tally of the number of user letters you expect to produce and match that to the number of user letters actually produced, to avoid missing anyone out.

**Safety Check List for Adding/Editing/Deleting Patient Questionnaires**

If you have purchased and are using the questionnaire module:

Ensure all new, altered and imported questionnaire types have been checked for correctness and have been thoroughly tested before using them in a live situation.

When completing a patient questionnaire, check all the captured information is correct before saving or printing it.
System Manager’s Check List

Safety Check List for Dose/Interval settings and Dose Instruction Formats

Regimes

Check all regimes have been set up and checked for correctness and clarity. Validate the dosage (tablet) instructions on set-up or on changing.

Target Ranges

Check all target ranges have been set up and checked for correctness. For each target range:

Ensure the result status records (e.g. low, in range, high) have been defined with the correct lower and upper limit values.

Ensure all the INR triggers have been correctly defined. Particular attention should be paid to ensure the lower and upper limit values have been correctly entered together with the appropriate action (e.g. warning, calc. prevention).

Ensure all the interval rules have been correctly defined with the correct lower and upper limit values.

Ensure all the miss or boost rules have been correctly defined with the correct lower and upper limit values.

Safety Check List for Clinic Diary Settings

Ensure there are adequate time slots for a typical day’s patients list.

Check that any adjustment you have made to the diary for a clinic has been properly made in the diary.

Ensure your days are adjusted or excluded for known staff absences etc.

Ensure that the system settings are set to maintain a diary for the appropriate weeks ahead for your centre.

Ensure that the system settings are set to retain the diary for the appropriate weeks in the past for your centre.

Any deletion of diary slots should be undertaken under strictly controlled conditions and after a backup has been taken.

Safety Check List for Defining Procedures, Letters and Events

Ensure all procedures have been defined correctly in the Procedure look-up table and have been made available for use by the relevant departments.

Ensure all events have been defined correctly in the Event look-up table and have been made available for use by the relevant departments.
Ensure all letters have been defined correctly (via message templates) and have been set up to be created on the appropriate message events.

**Safety Check List for Defining Look Up Information**

Ensure all information defined in the system look-up tables has been entered and checked for correctness.

**Safety Check List for List View Settings**

Check that all the required list views have been set up correctly and are available for use.

For each list view, check that the correct fields are displayed.

For each list view, check that each filter brings up the correct patients and that no patients meeting the criteria are missing.

For each list view, make sure that users are aware of the correct filters to apply to select the correct subset of patients.

**Safety Check List for Reports**

Ensure all new, altered and imported reports have been thoroughly tested before using them in a live situation.

Check that all the required reports have been defined and are available for use.

For each report, check that the correct fields are included in the report.

For each report, check that the correct data is being generated.

**Safety Check List for Custom Modules**

If you have purchased and are using any custom modules:

Ensure all new, altered and imported custom modules have been thoroughly tested before using them in a live situation.

**Safety Check List for Automatic Authorisation of INRs**

If you have purchased and are using the automatic authorisation module:

Ensure thorough testing has been carried out on your practice system before switching on automatic authorisation in your live system.

Perform routine checks to ensure that only the correct INR’s are being automatically authorised.
Safety Check List for Questionnaire Definitions

If you have purchased and are using the questionnaire module:

Ensure all new, altered and imported questionnaire definitions have been set up and checked for correctness. For each questionnaire definition:

Ensure the questionnaire definition has been correctly defined with the correct name and code and has been assigned to the correct department.

Ensure all the options / calculations have been defined correctly.

Ensure all new, altered and imported questionnaire definition have been thoroughly tested in your practice system before using them in a live situation.

Safety Check List for Data and Operational Integrity

Ensure you have written procedures and physical arrangements for:

Checking all user profiles are properly set and are checked to be working

Checking that the system settings are appropriate to the environment and method of working and to optimise system performance within your organisation.

Only amending or deleting look-up and normal table settings after a backup has been taken. This will help minimise the potential loss of data should you inadvertently delete the incorrect settings and need to restore your database.

Checking the hardware for possible errors, especially the data disk storage.

Replacing backup media regularly - media only has a set storage life.

Backing up routinely at appropriate intervals and test if you are able to restore the data and programs if required.

Ensuring your backup procedures are working and are appropriate for your database. If your database recovery type is set to full, ensure you are taking transaction log backups at regular intervals.

Ensuring backup media is stored safely in a separate place from the computer system and is readily referenced.

Providing adequate protection from:

power failures, notebook/laptop battery discharge and interruptions.

staff inadvertently switching power off at the mains.

Checking for computer virus violation.

Documenting and reporting software and operational problems or ‘near misses’ to
DAWN Clinical Software and their own management.

Documenting all changes to system set-up to show they are properly controlled and validated.

Routinely checking that the DAWN Mailer program is operational and working correctly.

Ensure your procedures are complete i.e. no sections have been removed, and are kept in a safe and accessible place for ready reference by your users. Make frequent checks that this is the case.

Preventing and not allowing adding or editing of data in the underlying database by using a third party program or tool. All data access must be done through the DAWN Clinical Framework.

Keeping all the application files complete and together. Do not copy files from previous copies of the application into the current set of files. The application files have a high inter-dependency and require absolute referential integrity.

Encouraging use of the practice system to rehearse any infrequently used procedures before live execution.

Using the practice system to test out future upgrades before applying the upgrade to the live system.

Ensuring that users do not enter ‘real or live’ data into it your practice or test system and use it operationally.

Ensuring that the system is checked thoroughly after any upgrades / patches are installed on the live system.

Ensuring any old, out of date user manuals or ebooks are destroyed and the current versions are readily available with no sections missing in full or in part.

Have a contingency plan in place should your computer system hardware or software fail such that you can continue to manage your patients until the computer is operational again.