inVita intelligence

INRstar CDSS - Information on Residual Risks (AFAP)

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1. Purpose

Anticoagulation is an inherently risky process. It offers measurable benefits to patients in the reduction of the risk thromboembolic events and in the treatment of established thrombotic episodes but, inevitably, it increases the risk of bleeding episodes. It is the aim of INRstar to reduce the risks and increase the benefits as far as possible. To meet these aims INRstar undergoes a process of full Clinical Risk Assessment at all stages of its design, development, and deployment. Standard approved risk assessment methods are used, and risks quantified using an appropriate risk matrix. Measures are implemented to reduce all identified clinical risks to an acceptable level but there are certain risks which it is not possible to fully mitigate. These residual risks are classified as AFAP risks ('As Far As Possible')

2. Scope

This document outlines the clinical risks assessed as AFAP within INRstar. Users should be aware of these residual risks and should be particularly careful when performing actions which contain them

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3. Areas of Risk

3.1. Adding a patient

3.1.1. Inappropriate selection of a maintenance dosing algorithm

Possible scenario:

User selects a maintenance dosing algorithm when adding a patient to the system. The patient has been initiated on warfarin elsewhere (e.g. in hospital) and is taking a loading dose. The patient attends the practice for review and is added to the system. The user selects a maintenance dosing algorithm when completing the clinical details screen. If a maintenance dosing algorithm is used before the patient is stably established on warfarin the dose suggestion will be inaccurate and could cause serious warfarin overdose. This could lead to significant bleeding, injury or death

Pre-control risk D4 High

Controls

- A warning message is displayed when a maintenance algorithm is selected as the dosing method. This explains the appropriate indications for the use of a maintenance algorithm.
- The entry of a new INR is prevented if the last historical treatment entered has a review period of less than 7 days.
- A dosing algorithm warning/confirmation message is displayed when a patient record is selected if there are fewer than 4 treatments in the record and the dosing method is a maintenance algorithm.
- A dosing algorithm warning/confirmation message is displayed when a patient record is selected if warfarin start date is less than 28 days ago and the dosing method is a maintenance algorithm.
- Addition or editing of Clinical details including selection of dosing method algorithms restricted to users with Clinical level 2 or 3 access permission.

Post Control Risk D2 Medium

Recommendation:

Selection of the appropriate dosing method is an area of risk and should only be undertaken by trained users with clinical knowledge and understanding of the significance of and differences between warfarin induction and maintenance dosing methods.

3.1.2. Inappropriate selection of an induction dosing algorithm

Possible scenario:

A user selects an induction dosing algorithm when adding a patient to the system. The patient has been taking warfarin for several months on a stable dose at a previous practice. The patient has now moved home and attends the new practice for review and is added to

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the system. The user selects a induction dosing algorithm when completing the clinical details screen. If a induction dosing algorithm is used when the patient is already established on warfarin the dose suggestion will be inaccurate and could cause serious warfarin overdose or under-dose. This could lead to significant bleeding, injury or death or risk of thromboembolic events.

Pre-control risk D4 High

Controls

- A warning message is displayed when an induction algorithm is selected as the dosing method. This explains the appropriate indications for the use of a induction algorithm.
- Warfarin induction is prevented if the last treatment entered has a n INR result of >1.3.
- An explanatory dialogue is displayed before the first induction treatment is produced.
- A warning message is displayed when the patient screen is accessed whilst on induction protocol.
- The warfarin induction screen has a different appearance from the usual maintenance treatment INR entry form.
- Addition or editing of Clinical details including selection of dosing method algorithms restricted to users with Clinical level 2 or 3 access permission
- The saving and printing of induction treatments is restricted to users with clinical level 2 or 3 access permission.
- Selection of induction algorithm is only enabled for new or re-activated patients.

Post Control Risk D2 Medium

Recommendation:

Selection of dosing method should only be undertaken by trained users with clinical knowledge and understanding of the significance of and differences between warfarin induction and maintenance dosing methods.

3.2. Editing patient clinical details

3.2.1. Inappropriate change of induction to maintenance dosing algorithm

Possible scenario:

The patient has been initiated on warfarin and is taking a loading dose using the induction protocol. The user changes the dosing method from induction to a maintenance algorithm by editing the clinical details before the patient has been fully initiated onto a stable dose of warfarin. If a maintenance dosing algorithm is used before the patient is stably established on warfarin the dose suggestion will be inaccurate and could cause serious warfarin overdose. This could lead to significant bleeding, injury or death

Pre-control risk D4 High

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Controls

- Confirmatory and explanatory dialogue displayed if user removes patient from induction algorithm.
- A warning message is displayed when a maintenance algorithm is selected as the dosing method. This explains the appropriate indications for the use of a maintenance algorithm.
- The entry of a new INR is prevented if the last historical treatment entered has a review period of less than 7 days.
- A dosing algorithm warning/confirmation message is displayed when a patient record is selected if there are fewer than 4 treatments in the record and the dosing method is a maintenance algorithm.
- A dosing algorithm warning/confirmation message is displayed when a patient record is selected if warfarin start date is less than 28 days ago and the dosing method is a maintenance algorithm.
- Addition or editing of Clinical details including selection of dosing method algorithms restricted to users with Clinical level 2 or 3 access permission.

Post Control Risk D2 Medium

Recommendation:

Selection and changing of dosing algorithms are a high-risk activity. Selection of dosing method should only be undertaken by trained users with clinical knowledge and understanding of the significance of and differences between warfarin induction and maintenance dosing methods.

3.3. Editing organisation-level settings

3.3.1. Inappropriate change of dosing or review period settings

Possible scenario:

An untrained user changes the default dosing or review period settings at the organisation level. These settings will then be applied to all locations within the organisation. For example: The percentage dose reduction suggested for INR results >5 is changed to 10% This setting will be applied to all locations and may result in an inappropriate dose reduction for patients with high INR results. This could lead to serious bleeding events, injury or death

Pre-control risk D4 High

Controls

- Editing of organisation-wide settings is restricted to the organisation clinical lead.
- Organisation clinical-lead status can only be granted by the organisation administrator.

Post Control Risk D2 Medium

Recommendation:

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The organisation clinical lead should be a clinician with an in-depth understanding of anticoagulation treatment. Organisation clinical lead status can only be granted by the organisation administrator and should not be granted to a user without sufficient training, experience and knowledge of the practice of oral anticoagulation treatment. We recommend that only one named person holds organisation clinical-lead status'

3.4. Performing a treatment

3.4.1. Incorrect selection of INR result when a new treatment is entered

Possible scenario:

A patient attends the clinic for an INR test. The result of the test is incorrectly entered as 1.2 instead of 2.2. The incorrect low INR will trigger a suggested dose increase. This would cause a significant overdose of warfarin which could lead to serious bleeding events, injury or death

Pre-control risk D4 High

Controls

- INR values selected from drop-down of valid figures.
- New INR must be confirmed in a confirmatory dialogue before new warfarin dose is calculated.
- No default INR value – result must be positively selected from list.
- INR entry and dose calculation is restricted to users with clinical level access permissions.

Post Control Risk D2 Medium

Recommendation:

Accurate entry of the new INR result is critical. Users should positively confirm that the result they have entered is correct when the confirmation dialogue is displayed. The confirmation dialogues should be regarded as a positive safety feature rather than a nuisance. Interfaces with the POCT coagulometers which directly import the result should be used, where available, to minimise the risk of transcription errors when entering new INR result.

3.4.2. Incorrect existing warfarin dose

Possible scenario:

A patient attends the clinic for an INR test. The last recorded dose in INRstar is 4mg/day. The patient had been admitted to hospital since last attending the practice anticoagulation clinic and had been discharged home taking 2mg. /day. Today's INR is in-range. The user enters today's INR but does not confirm that the patient is still taking the last recorded dose. The new dose suggestion is calculated based on the last recorded dose of 4mg/day. This would cause a significant overdose of warfarin which could lead to serious bleeding events, injury or death.

Pre-control risk D4 High

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Controls

- The user must tick a confirmatory message box to confirm that the last recorded dose is still current and accurate before a new INR can be entered.
- A new INR cannot be added if no previous dose is recorded.
- If the date of the last recorded dose is longer ago than the patient's maximum review period (and might therefore be out of date) a warning message is displayed.
- The last 6 doses are displayed chronologically on the new INR entry screen.
- The existing treatment details are archived when an inactive patient is reactivated – a new existing dose must be recorded before a new INR can be entered.
- INR entry and dose calculation is restricted to users with clinical level access permissions.

Post Control Risk D2 Medium

Recommendation:

This is a major area of risk. All dosing algorithms rely on the fact that the patient's current dose of warfarin is correctly recorded so that the new suggested dose is accurate. All users should be aware of the importance of confirming with the patient that the currently recorded warfarin dose is still current and correct before a new dose is calculated.

3.4.3. Incorrect date, INR, review details entered when recording a manual treatment

Possible scenario:

A patient attends the clinic for an INR test. The dosing method currently selected is Manual. This enables a clinician to enter an INR and a manually calculated dose and review period (without using INRstar's dose and review period suggestion algorithms). The manually calculated dose was entered incorrectly as 5mg instead of 0.5mg/day. This would cause a significant overdose of warfarin which could lead to serious bleeding events, injury or death.

Pre-control risk D4 High

Controls

- The user must confirm the new INR , dose and review period before saving the treatment.
- Manual INR and dose entry is restricted to users with clinical level 3 access permissions.

Post Control Risk D2 Medium

Recommendation:

Accurate entry of the manual INR and dose data is critical. Users should positively confirm that the result they have entered is correct when the confirmation dialogue is displayed. The confirmation dialogues should be regarded as a positive safety feature rather than a nuisance.

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3.4.4. Inappropriate override of suggested warfarin dose

Possible scenario:

A patient attends the clinic for an INR test. The INR is below-range and the dose suggested is increased to 2mg/day. The user decides to override the suggested dose to 2.5mg/day but mistakenly enters a new dose of 5mg/day. This would cause a significant overdose of warfarin which could lead to serious bleeding events, injury or death.

Pre-control risk D4 High

Controls

- Dose overrides > 20% must be confirmed by user before saving the treatment.
- Doses selected from pick list of valid doses. Limited to system-wide maximum dose.
- Previous treatment history displayed on dose override screen to aid clinical decision making.
- Full dose override enabled for clinical level 3 users only.
- Minor dose override(+/- 0.1mg) enabled for clinical level 2 users only.
- Save and Print of out-of-range treatments restricted to clinical level 2 or 3 level users.
- Dose overrides are disabled during induction protocol - warning message displayed on attempted override.

Post Control Risk D2 Medium

Recommendation:

Overriding of suggested doses is a safety critical area. Users should positively confirm that the new data they have entered is correct and appropriate in the context of the patient's current clinical situation. Confirmation dialogues should be regarded as a positive safety feature rather than a nuisance. Dose overrides are disabled during the induction protocol.

3.4.5. Inappropriate override of suggested review period

Possible scenario:

A patient attends the clinic for an INR test. The INR is below-range and the dose suggested is increased. The suggested review period is 7 days. The patient is unable to attend on that date and the user decides to override the suggested review period to 6 weeks (42 days) The increased warfarin dose might lead to overtreatment which would not be detected if the review period was extended inappropriately. This could lead to serious bleeding events, injury or death.

Pre-control risk D4 High

Controls

- Previous treatment history displayed on review period override screen to aid clinical decision making.

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- Review period override selected from a list of valid days. Limited to patient's maximum review period.
- Full review period override enabled for clinical level 3 users only.
- Minor review period override(+/- 7 days) enabled for clinical level 2 users only.
- Save and Print of out-of-range treatments restricted to clinical level 2 or 3 level users.
- Review period overrides are disabled during induction protocol - warning message displayed on attempted override.

Post Control Risk D2 Medium

Recommendation:

Overriding of suggested review periods is a safety critical area. Users should positively confirm that the new data they have entered is correct and appropriate in the context of the patient's current clinical situation. Confirmation dialogues should be regarded as a positive safety feature rather than a nuisance.

3.5. Warfarin induction

3.5.1. INR result falls outside the limits for the induction protocol

Possible scenario:

A patient is being induced onto warfarin treatment using the Tait induction protocol. They attend the clinic as arranged on day 5 for an INR test. This is 6.0 and falls outside the limits of the induction protocol. Continuing with the induction protocol might lead to overtreatment which could lead to serious bleeding events, injury or death.

Pre-control risk D4 High

Controls

- Patient is automatically removed from the induction protocol if the INR result >5. The user must then dose the patient manually until sufficiently stable to be dosed using a maintenance dosing algorithm.
- Induction treatments can only be performed by users with clinical level access permissions.
- Induction treatments can only be saved and printed by users with clinical level 3 access permission.
- The protocol must be strictly adhered to. Doses and review periods cannot be overridden and INR tests must be done on the dates specified in the protocol.

Post Control Risk D2 Medium

Recommendation:

Warfarin induction is a safety critical activity. It should only be carried out by users with clinical knowledge and experience in anticoagulation management. The user must be prepared to dose the patient manually if the INR falls outside the parameters of the induction protocol.

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Appendix

Risk Assessment (NPSA Risk assessment of anticoagulation therapy 2006)

1. Consequences (C)

A	Negligible: little or no effect	This is an unexpected or unintended incident which required extra observations or minor treatment and caused minimal harm to one patient
B	Marginal: medium term harm	This is an unexpected or unintended incident which resulted in further treatment, cancelled treatment, transfer to another area, possibly critical care and which caused short term harm to one patient
C	Critical: causes severe harm	This is an unexpected or unintended incident which caused permanent or long term harm to one patient
D	Fatality	This is an unexpected or unintended incident which caused death for one patient
E	Catastrophic	This is an unexpected or unintended incident which caused death for two or more patients

2. Likelihood (L) Projected incidences of harm / year in UK

Class	Likelihood
1	Improbable
2	~2
3	~20
4	~200
5	~2,000
6	20,000

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Risk Matrix

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