

PROCESS TO FOLLOW IN THE EVENT OF AN ERROR BEING FOUND IN A KMCC SACT PROTOCOL OR ARIA REGIMEN

OBJECTIVE

To describe the approved process to be followed in the event of an error being found in a KMCC SACT protocol or Aria regimen.

SCOPE

This SOP will cover all oncology and haematology protocols, excluding paediatrics. This will encompass NHSE MHRA EAM schemes, and complex supportive care regimens which require a protocol as identified by the Kent and Medway Chemotherapy Group. This SOP should also be used by individual Trusts for algorithm deviations, one-off requests, and access schemes offered by manufacturers (for licensed drugs which have not been through the NICE process).

LIMITATIONS

This SOP does not address the process for reporting patient incidents

METHOD

ACTION	RESPONSIBILITY
Immediate actions – within 24 hours	
Assessment of the severity of the error should be undertaken to identify if the protocol and/or regimen requires immediate removal from use or if the risk can be mitigated. Propose course of action.	<ul style="list-style-type: none"> • Lead pharmacist oncology/haematology of Trust where error identified • Lead clinical trials pharmacist of Trust where error identified (as appropriate) • Principal Investigator for Trial (as appropriate) • NOG/HOG chair or their deputy • KMCC pharmacist • KMCC technician (as appropriate) • Aria system administrator (as appropriate)
Notify and agree the proposed course of action.	<ul style="list-style-type: none"> • A chief pharmacist (usually chief pharmacist EKHUFT) • Chair of the e-prescribing group • Lead clinical trials pharmacist at each Trust (as appropriate) • Research Delivery Team representative from each Trust (as appropriate) • Aseptic units of each Trust (if alternative chemotherapy proposed)
Major errors requiring withdrawal of protocol/regimen	
Organise deactivation of regimen on Aria	<ul style="list-style-type: none"> • Aria system administrator
Organise removal of protocol from KMCC website and shared document management system	<ul style="list-style-type: none"> • KMCC Pharmacist or technician
All Major and non-major errors	
Identify patients affected by error using Aria report: ' <i>Plans – Patients by Plan and Date Started</i> ' which is called ' <i>txlist_visit.rpt</i> ' in the Report Name box to cover the last 6 months. (CAUTION: there are 2 reports with the same display name) . This report will need to be run for the regimen being reviewed (in all cases) and, for protocols containing multiple Aria regimens, for the regimen used before the regimen with the error to identify patients who may transfer to the affected regimen	<ul style="list-style-type: none"> • Aria system administrator
Identify patients affected by error using KOMS report: ' <i>146 General Purpose Action Sheet Report</i> '. This report should also identify patients who have an Action Sheet initiated for the regimen with the error but who may not have had treatment initiated on Aria yet. Forward report to Aria system Administrator for cross-checking.	<ul style="list-style-type: none"> • Lead pharmacist oncology/haematology • Aria system administrator
Cross check patient reports and forward to KMCC pharmacist/Lead pharmacist oncology/haematology	<ul style="list-style-type: none"> • Aria system administrator
Notify treating consultants of any patients affected	<ul style="list-style-type: none"> • KMCC pharmacist/Lead pharmacist oncology/haematology
Complete Datix forms. One Datix for the patient incident and one for the protocol/regimen incident	<ul style="list-style-type: none"> • KMCC pharmacist/Lead pharmacist oncology/haematology
Notify relevant users that the regimen and protocol have been withdrawn and summarise proposed course of action. Where a protocol/regimen is only used locally, the individual	<ul style="list-style-type: none"> • KMCC pharmacist/Lead pharmacist oncology/haematology

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Trust should notify relevant users	
Subsequent actions	
Add review of protocol/regimen to the KMCC work-plan	<ul style="list-style-type: none"> • KMCC pharmacist/technician • Aria system administrator
Ensure an investigation is carried out into the cause of the incident	<ul style="list-style-type: none"> • KMCC pharmacist/Lead pharmacist oncology/haematology • Lead clinical trials pharmacist of Trust where error identified (as appropriate)
Add to the agenda of the next chemo e-prescribing group agenda to ensure shared learning and recording of the incident	<ul style="list-style-type: none"> • Aria system administrator

REFERENCE SOURCES

- KMCCEP020 Running reports in Aria

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