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

Objective

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

Scope

This SOP will cover all oncology and haematology protocols, including paediatrics and clinical trials. This will encompass NHSE, MHRA, EAM schemes, and complex supportive care regimens which require a protocol as identified by the Kent and Medway SACT Governance 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

Reference Sources

- KMCCEP020 Running reports in ARIA

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.	• Lead pharmacist oncology/haematology of Trust where error identified • Lead clinical trials pharmacist of Trust where error identified (as appropriate) • Lead paediatric 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) • Chemo e-prescribing system administrator (as appropriate)
Notify and agree the proposed course of action.	• A chief pharmacist (usually chief pharmacist EKHUFT) • Chair of the SACT Governance Group • KMCC pharmacist • Trust lead pharmacist oncology/haematology/clinical trials/paediatrics as appropriate • Research Delivery Team representative from each Trust (as appropriate) • Aseptic units of each Trust (if alternative SACT treatment proposed)
Major errors requiring withdrawal of protocol/regimen	
Organise deactivation of regimen on Chemo e-prescribing system	• Chemo e-prescribing system administrator
Organise removal of protocol from KMCC website and document management system	• KMCC Pharmacist or technician
All Major and non-major errors	
Identify patients affected by error using Aria report: *'Plans – Patients by Plan and Date Started'* which is called *'txlist_visit.rpt'* 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	• Chemo e-prescribing system administrator
Identify patients affected by error using KOMS report: *'146 General Purpose Action Sheet Report'*. 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 the chemo e-prescribing system yet. Forward report to chemo e-prescribing system Administrator for cross-checking.	• Lead pharmacist oncology/haematology/clinical trials/paediatrics • Chemo e-prescribing system administrator
Cross check patient reports and forward to KMCC pharmacist/Lead pharmacist oncology/haematology/clinical trials/paediatrics	• Chemo e-prescribing system administrator
Notify treating consultants of any patients affected	The following pharmacists as appropriate: • KMCC • Trust lead oncology/haematology/clinical trials/paediatrics
Complete Datix forms. One Datix for the patient incident and one for the protocol/regimen incident	
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 Trust should notify relevant users	
Subsequent actions	
Add review of protocol/regimen to the KMCC work-plan	• KMCC pharmacist/technician • Chemo e-prescribing system administrator

Ensure an investigation is carried out into the cause of the incident	The following pharmacists as appropriate: • KMCC • Trust lead oncology/haematology/clinical trials/paediatrics
Add to the agenda of the next SACT Governance Group to ensure shared learning and recording of the incident	• Chemo e-prescribing system administrator