National Aseptic Error Reporting Scheme (NAERS)

Introduction

The NAER scheme has been running now since 2003. During this time there has been a deliberate choice not to review or update the scheme to allow current data to continue to be compared with historical data.

Recent discussions involving both the Pharmaceutical Aseptic Services Group (PASG) and the NHS Pharmaceutical Quality Assurance Committee (NHSPQAC) have led to the decision that despite the above expectations surrounding the reporting and investigation of errors have now moved on so that it is now necessary to review and relaunch the scheme to ensure that it remains relevant to current practice.

This has consisted of a review of the reporting categories and the associated reporting spreadsheet and a briefing document to clarify a number of long term points of confusion together with the reporting arrangements going forward.

Scope of the scheme

Data that should be reported into the scheme would not include prescription errors or those picked up at the clinical screening stage. It would start with the receipt of a screened prescription. So in this case the first possible point of error would be lack of authorisation to manufacture ie prescription received without having been screened.

The finish point for the error reporting scheme should be administration to the patient.

Dispensing errors associated with bought in products dispensed via the aseptic unit should be included.

Product defects in bought in products would not be (although these should be reported separately to AIC)

Data reported should include all errors and near misses between the start and end points defined above ie all non conformances in the process whether or not product affected or the incident has got to the next stage of the process. For example a selection error self detected and corrected by an operator before asking for a check would not be included but if it had been detected at the requested check by a second person it would be included.

Reporting of Data

From July 2020 all error reports should be e mailed to:

sue.renn1@nhs.net

All reports must be accompanied by workload figures for the period that the reported data relates to

Workload figures submitted with data should show number of *individual dose units* made in the period and the number of bought in items dispensed

Data should be submitted either every month or every quarter.

Any queries related to the reporting of data should be addressed via:

http://www.pasg.nhs.uk/contactform.php

Unlicensed units are reminded that reporting of data into the scheme is a requirement of the EL audit process.

All units should be aware that reporting data into the scheme was mandated by the Toft report into the Vinorelbine incident and the Paediatric and Neonatal Chief Pharmacists Groups report into the safety of Parenteral Nutrition.

NAERS data and local reporting systems

NAERS is not intended to replace local systems which would include investigations, CAPA, trending and review etc. Rather NAERS allows data to be pooled on a national level and underlying trends and learning opportunites to be identified in a way that is not achievable with single site data. This data can be used locally to improve practice and benchmark

Future developments

Work will take place to investigate the feasibility of an online / web – based data entry system
This will include the development of a site profile questionnaire which each site reporting into the scheme will need to complete initially and which will include: staffing establishment, computer system and electronic prescribing system if used, types of staff for each task including product approval, in process checks, use of barcoding, number and grade of rooms, workstations type and number, types of product, licensed status, use of vial sharing etc?

Licensed Status

A	Made under MS License
B	Made under Section 10
C	Bought in and dispensed
D	Clinical Trial

Product Category

A	Cytotoxic adult
B	Cytotoxic paediatric
C	Parenteral nutrition – adult
D	Parenteral nutrition – paediatric
E	Monoclonal Antibody
F	Other Aseptic Product

Error Type

Prescription Errors	Assembly errors
A1 - Inaccurate prescription / transcription verification	**E1 - Incorrect drug assembled**
	E2 - Incorrect strength assembled
Worksheet preparation error	**E3 - Incorrect quantity of drug vials assembled**
B1 - Incorrect patient name	**E4 - Incorrect formulation of drug assembled**
B2 - Incorrect drug name	**E5 - Incorrect diluent assembled**
B3 - Incorrect dosage calculation	**E6 - Incorrect strength of diluent assembled**
B4 - Incorrect diluent	**E7 - Incorrect quantity/volume of diluent assembled**
B5 - Incorrect volume of diluent	**E8 - Incorrect quantity of syringes**
B6 - Incorrect batch number for product	**E9 - Incorrect volume syringes provided**
B7 - Error in logging batch number for product in batch book	**E10 - Filters not provided**
B8 - Incorrect directions for administration	**E11 - Incorrect quantity of needles**
B9 - Copy of label not attached	**E12 - Incorrect quantity of alcohol wipes/swabs**
B10 - Use of incorrect worksheet	**E13 - Incorrect batch number for drug vials recorded on worksheet**
B11 - Incorrect quantity of product recorded	**E14 - Incorrect expiry date for drug vials recorded on worksheet**
B12 - Signature of worksheet preparer omitted	**E15 - Incorrect batch number for diluent vials recorded on worksheet**
	E16 - Incorrect expiry date for diluent

	vials recorded on worksheet
Label generation errors	E17 - Expired drug used
C1 - Incorrect patient details	E18 - Expired diluent used
C2 - Incorrect drug name	E19 - Signature of worksheet of staff responsible for assembly
C3 - Incorrect diluent name	
C4 - Incorrect drug strength	
C5 - Incorrect diluent volume	Product Preparation errors
C6 - Incorrect quantity of product	F1 - Incorrect volume of drug used
C7 - Missing/Incorrect dosage information	F2 - Incorrect volume of diluent used
C8 - Incorrect Route	F3 - Incorrect method of preparation
C9 - Incorrect batch number for product	F4 - Filters not used during preparation
C10 - Missing batch number for product	F5 - Volume checks not conducted
C11 - Incorrect directions for administration	F6 - Inappropriate volume checks
C12 - Missing/Incorrect storage information	F7 - Drug identity check not conducted
C13 - Incorrect expiry date / time	F8 - Product made on wrong day /session /time fo session
C14 - Incorrect preparation date	F9 - Powder not fully dissolved
C15 - Missing warning/cautionary label	F10 - Incorrect volume added to infusion bag
C16 - Incorrect warnings/cautionary labels	F11 - Incorrect final volume in syringe
C17 - Incorrect location details /ward	F12 - Incorrect container/ closure / syringe used
C18 - Incorrect quantity of labels	F13 - Product not physically intact
C19 - Spelling mistakes	F14 - Incorrect quantity prepared
C20 - Incorrect label used eg colour	F15 - Signature of product preparer omitted from worksheet
Labelling and packaging errors	Ancillary items
D1 - Labels not affixed to final product	G1 - Equipment specified on worksheet not supplied eg filter, protect from light bag
D2 - Labels not attached to outer light protectant packaging	G2 - Tamper evident cap missing
D3 - Labels inappropriately positioned on final product	
D4 - Signature of labeller omitted from worksheet	
Product approval checking errors	

H1 - Failure to check empty vials	
H2 - Final product not visually inspected	
H3 - Inadequate visual inspection	
H4 - Failure to check patient details on worksheet	
H5 - Failure to check method on worksheet	
H6 - Failure to check batch numbers of drugs and diluent	
H7 - Failure to check dosages	
H8 - Failure to check drug on worksheet	
H9 - Failure to check diluent on worksheet	
H10 - Failure to check formulation on worksheet	
H11 - Failure to check patient details on label	
H12 - Failure to check dosage instructions on label	
H13 - Failure to check drug details on label	
H14 - Failure to check diluent on label	
H15 - Failure to check batch number on label	
H16 - Failure to check formulation on label	
H17 - Failure to check expiry date on label	
H18 - Signature of product approver omitted from worksheet	

When was Error Detected

Was it detected at the first scheduled check in the process Y/N

A Prescription Verification check
B Worksheet and label check
C Check in preparation area
D In process check during preparation
E During labelling
F At final product check prior to release / approval
G At Product release/ approval stage
H After release, prior to administration
I After release during or after administration
J Other (must be qualified with details)

Contributory Factors

There may be more than one

A	Staff awareness of SOPs
B	Staff new / in training
C	Communication breakdown
D	Staff Knowledge
E	Automaticity
F	Facility / equipment fault
G	Poor quality of packaging and labelling of starting materials
H	Computer System Design
I	Process design
J	Poor storage / distribution practices
K	Workload pressures
L	Documentation design
M	Poor Segregation
N	Distraction
O	Interruptions
P	Deviation from Process
Q	Out of Hours working

GMP Failure Severity: H/M/L

GMP Failure Severity	Definition
High	Major breach of GMP which is likely to affect the suitability of the product for its end use, product cannot be released (or only can after significant event such as a change in prescription)
Medium	Significant breach of GMP but unlikely to affect the suitability of the product for its end use and upon balance of risk is suitable for release or A breach of GMP which may have impacted the product and the balance of risk is not to release
Low	Minor breach of GMP which does not impact on product suitability for its end use

Potential / Actual Outcome for Patient

If the error is spotted before administration, there should be no actual outcome. Therefore, for the report, staff should estimate the potential outcome if the error had not been spotted. If the medication has been administered to a patient, the actual outcome should be recorded.

Descriptor	Actual or potential unintended or unexpected impact on patient
Catastrophic	Could have caused patient death
Major	Could have caused serious harm
Moderate	Potential to cause patient harm
Minor	Unlikely to cause patient harm
None	No potential for patient harm

Did this lead to RCA / CAPA / Trust Incident Report Y/N

If Yes above, please provide comments.