LETTER

Safety of chemotherapy prescription and production software: proposal of specific guidelines to test new versions

Medicinal treatment of cancer is critical for patient safety. In fact, anticancer drugs present a narrow therapeutic index with potentially lethal adverse events. Many studies have highlighted the benefit of computerised prescription (CP) in oncology.^{1,2} However, CP may lead to the emergence of new errors defined as e-iatrogenesis that can result in unintended consequences.³ Unfortunately, prescribing software errors are more common than they should be, especially in a high-risk field such as oncology. Such errors, and their putative patient consequences, may occur following software version upgrading. Thus, even if software publishers routinely realise regression tests for the new versions, security alerts from health authorities remain recurring. For instance, CHIMIO software (Computer Engineering, Paris, France), the most used oncology CP system in France, was concerned by two major security alerts in 2010 and 2014.^{4,5} These alerts were due to errors that were undetected during regression tests and that randomly appeared according to local hospital software settings. Consequently, a French national consensus started to emerge to recommend to users to perform specific tests for each new software version. Nevertheless, there are not yet any national or European learned association recommendations. Thus, we present to the European hospital pharmacists community a proposal for a 12-item guideline grid in order to secure this specific point.

When a validation of version is required?

1. Choose to upgrade the software as regularly as possible.
2. Perform tests for each new version.

Who has to perform the tests?

3. All software users, and in detail:
  - The oncology pharmacists for the whole workflow (prescription, pharmaceutical validation, production, dispensation, administration), as well as for specific databases completion (drugs, products, protocols, stabilities, etc).
  - The oncologists for protocol thesaurus building, prescription and administration (if necessary, for instance, if they use drugs administered by intrathecal route).
  - The nurses for administration.
  - The informatics directorate for specific financial or interfacing aspects.

How to conduct the tests?

4. On a test version updated by informatics services.
5. With settings identical to the current version.
6. With a formalised test grid.
7. With a scenario approach to mimic local routine software use (ie, paediatrics' specificities, prescription and production anticipation, dose banding, etc).
8. By retesting specific scenarios that have induced errors during previous versions tests.
9. On the basis of new functionalities, evolutions or corrections that have to be listed and provided by the software publisher.

How to analyse test results and what are the actions that have to be taken?

10. Evaluate the risk level of each observed defect during tests as follows:
  - Level 1: slow risk, routine use thinly disturbed
  - Level 2: slow risk but routine use largely disturbed
  - Level 3: high risk: resolution without delay
  - Level 4: unacceptable risk
11. Forward test results to the publisher support service and require analysis, explanation and corrections, if necessary.

12. If a specific corrective patch is provided by the publisher, redo all the tests in order to be sure that the patch has not impacted other software functionalities.

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