Standards for Reducing Risks Associated with e-Prescribing Systems for Chemotherapy

British Oncology Pharmacy Association

www.bopawebsite.org

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1. The Purpose of the BOPA Standards

1.1. NHS England in its service specification for provision of chemotherapy\(^1\) requires all chemotherapy to be prescribed using an e-prescribing system.

1.2. Although e-prescribing systems are known to improve the safety of chemotherapy prescribing their introduction does not eliminate prescribing errors and may introduce their own specific risks\(^2\).

1.3. This document outlines steps that can be considered to be best practice in reducing the risks of errors arising from the introduction and use of e-prescribing systems for chemotherapy.

1.4. In recognising that there are a number of different manufacturers of e-prescribing systems, these standards aim to make generic recommendations that are universal.

1.5. The recommendations set out in these standards are intended to reduce the risk of errors arising at different stages of the operation of e-prescribing systems including the set-up, validation, prescribing, verification and administration of chemotherapy regimens facilitated by these systems.

2. The Scope of the BOPA Standards

2.1. This document does not describe any novel clinical practice; it brings together established practice and presents it in the form of standards. This will allow all Chemotherapy Services to assure themselves that chemotherapy prescribed using their e-prescribing systems meets the required standard.

2.2. The guidance applies to the electronic prescribing of chemotherapy and other systemic anti-cancer therapy (e.g. monoclonal antibodies, oral therapies and other novel systemic therapies). For intrathecal chemotherapy the requirements of the relevant national guidance must also be considered\(^3\).

2.3. The standards are generic and aim to be applicable to all e-prescribing systems, either as standalone chemotherapy prescribing systems or wider e-prescribing systems which are also being used to prescribe chemotherapy. Further requirements specific to certain prescribing systems must also be considered and applied as applicable.

2.4. These standards should be used by staff involved in the provision of chemotherapy services where e-prescribing systems are implemented.

3. Limitations

3.1. These standards are intended for guidance only and aim to represent the minimum requirements for the safe use of chemotherapy e-prescribing systems. Healthcare professionals must exercise professional judgement in assessing the
service needs with the functional capability of the e-prescribing system to meet those needs.

3.2. Although generic it is recognised that the availability of different systems may result in variation of how the standards are put into practice. In all cases professionals responsible for implementing chemotherapy e-prescribing systems should use these standards in conjunction with training and documentation supplied by system providers. At all times the standards set out in ISB0160 should be followed and compliance with ISB0129 obtained from the supplier to ensure that any residual risks are identified and handed across openly to the user organisation.

3.3. The standards have made no recommendations on workforce requirements for implementation and ongoing maintenance of electronic chemotherapy regimens. Each organisation should have investigated these requirements within a business case for electronic prescribing.

3.4. The standards have not included the impact of linking (interfacing) the e-prescribing system to other systems (e.g. pharmacy dispensing, manufacturing and stock control systems, pathology results, patient administration systems and other e-prescribing systems) and its effects on safety. The impact of using multiple unlinked e-prescribing systems in parallel is also outside the scope of these standards.

3.5. Where an e-prescribing system is part of a system that falls under Annex 11: Computerised Systems of the European Guidelines for Good Manufacturing Practice(GMP), then the worksheet, labelling and compounding functionality should be validated to those standards and the prescribing functionality also needs to be included in the Validation Master Plan for that system.
4. The BOPA Standards

4.1. Training

4.1.1. All personnel operating chemotherapy e-prescribing systems must be appropriately trained in the relevant task(s) required of their specific role (e.g. set-up, validation, prescribing, verification, administration) and their training records retained.

4.1.2. Training should involve demonstrations of different types of prescriptions that may be encountered in various scenarios (for example dose reductions and how these are applied). Practicing with realistic patient scenarios will provide the best preparation prior to use of a live system.

4.1.3. Effective mechanisms must be implemented to segregate test data used in training and live data.

4.1.4. Retraining should take place at suitable intervals according to local requirements and as appropriate following system upgrades.

4.1.5. Additional training should be undertaken when a new risk identifies training issues.

4.1.6. Systems must be put in place to ensure trainees granted security access during training are unable to act as a final signatory for a designated task until formally signed off as competent.

4.2. Set-Up

4.2.1. General Set-Up

4.2.1.1. Security access enabling personnel to set-up or build chemotherapy regimens on e-prescribing systems must only be granted to approved staff who have undertaken the appropriate training.

4.2.1.2. Set-up of treatment regimens in chemotherapy e-prescribing systems should be performed by approved staff familiar with chemotherapy.

4.2.1.3. The set-up must follow the relevant institutional or clinical trial protocol for each specific regimen. The minimum requirements for inclusion in a protocol are outlined in measure 14-3S-116 in the Manual for Cancer Standards Chemotherapy Measures.

4.2.1.4. Subsequent sections on Validation and System Governance should be referred to in conjunction with this section.
4.2.2. **Nomenclature**

4.2.2.1. Naming of chemotherapy drugs and regimens must be unambiguous and applied to avoid confusion with other drugs or regimens (e.g. trastuzumab and trastuzumab emtansine). Recommendations are made in ‘Design for patient safety: guidelines for the safe on-screen display of medication information’.

4.2.2.2. In all instances the chemotherapy regimen must be clearly identified with the name used by the institution and in such a way to avoid misinterpretation with similarly named regimens.

4.2.2.3. Regimens where alternative dosing, route of administration or administration schedules exist must be clearly identified to avoid selection error (e.g. BEP 3-Day v BEP 5-Day).

4.2.2.4. For clinical trials the name of the trial must be clearly identifiable as well as the specific trial arm and/or regimen and protocol version number (where applicable) to which it applies.

4.2.3. **Dosing**

4.2.3.1. Ensure the correct dosing schedule and dose calculation method are adopted (e.g. fixed dosing, BSA, weight, GFR/AUC etc.). The formula used for calculating the BSA (e.g. DuBois, Mosteller, Haycock, Boyd etc.) and GFR (Cockroft & Gault, Wright, etc.) must be appropriate for your organisation.

4.2.3.2. When applying dose banding or rounding ensure that this equates to a measurable dose for preparation and falls within acceptable locally agreed limits of the actual calculated dose. Some systems may have dose banding/rounding rules or limits. Personnel involved with set up of regimens must familiarise themselves with these rules.

4.2.3.3. Where applicable maximum single and lifetime cumulative doses should be incorporated into the regimen build.

4.2.3.4. Ensure the correct route(s) of administration is applied according to the regimen protocol. Consideration should be given to restricting the ability to change the route of administration where possible.

4.2.4. **Schedule**

4.2.4.1. Ensure correct dosing schedule is applied, particularly for multiple dosing days with a treatment cycle (e.g. day 1 and day 8 repeated every 21 days).
4.2.4.2. Regimens should be built so that all agents including supportive care and accompanying fluids are prescribed in the correct order of administration.

4.2.4.3. Ensure correct cycle length and number of cycles.

4.2.5. Diagnosis

4.2.5.1. Where systems allow, ensure that appropriate linkages are made between diagnosis, intent and line of therapy and regimens thereby reducing the risk of selecting an inappropriate regimen.

4.2.5.2. Where relevant apply the correct diagnosis (ICD-10 or ICD-O3 codes) and relevant OPCS or other codes to enable data collection e.g. SACT dataset\textsuperscript{10}(England only).

4.2.6. Testing

4.2.6.1. Once the chemotherapy regimen has been set up in the e-prescribing system run a test prescription using a simulated ‘test’ patient to check the regimen has been correctly set up, technically and clinically.

4.2.6.2. The degree of testing needs to be proportionate to the level of complexity of the regimen (e.g. testing calculations at extremes of BSA to ensure that limits are appropriately triggered where these have been configured).

4.3. Validation

4.3.1. Once the set-up is complete, the input and test prescription should be independently checked by a clinical cancer pharmacist to ensure all input is accurate according to the above recommendations and relevant protocol for the specific regimen.

4.3.2. An appropriate consultant oncologist or haematologist specialising in the cancer site the regimen applies to, should check the regimen set-up and/or test prescription to ensure the dosing and schedule match the relevant protocol and to consider any other relevant prescribing aspects (e.g. nomenclature).

4.3.3. A nurse specialist responsible for administering or supplying the relevant chemotherapy regimen should also check the regimen set-up and/or test prescription to ensure the administration details are clear and unambiguous according to the relevant protocol.

4.3.4. A system of recording signatures verifying the above steps have been completed by the appropriate personnel must be retained.
4.3.5. A regimen must not be made available for prescribing until the above steps (4.3.1 to 4.3.4) have been and there must be checks put in place to ensure that only the validated regimen is made available for prescribing.

4.3.6. When e-prescribing systems link to pharmacy worksheet/label production, aseptics services staff will need to perform additional validation checks in line with Annex 11 of the European Guidelines for Good Manufacturing Practice.

4.3.7. A Standard Operating Procedure for the validation of the incorporation of individual regimens onto the e-prescribing should be written to include as a minimum the recommendations of Standard 14-3S-125 of the Manual of Cancer Standards Chemotherapy Measures.

4.4. Prescribing

4.4.1. Security access enabling personnel to prescribe chemotherapy on e-prescribing systems must only be granted to approved prescribers who have undertaken appropriate training and competency assessment.

4.4.2. Reference should be made to institutional policies to ensure appropriate access rights for prescribers are granted.

4.5. Verification

4.5.1. Security access enabling personnel to verify chemotherapy prescriptions on e-prescribing systems must only be granted to approved clinical pharmacists who have undertaken the appropriate training and competence assessment.

4.5.2. A clinical pharmacist check of chemotherapy prescribed on e-prescribing systems must be undertaken according to the BOPA verification standards.

4.5.3. Where paperless systems are in place, an electronic signature indicating the check has taken place must be utilised.

4.5.4. There must be appropriate safeguards in place to ensure any subsequent changes to the prescription are identified.

4.5.5. Where printed prescriptions generated by the e-prescribing system are utilised the paper copy may also be signed by the verifying clinical pharmacist.

4.6. Administration

4.6.1. Security access enabling personnel to record the administration of chemotherapy on e-prescribing systems must only be granted to approved staff who have undertaken the appropriate training and competence assessment.
4.6.2. Appropriate security access may also be required and granted for staff responsible for issuing oral chemotherapy.

4.7. Security

4.7.1. Levels of access or security must be determined and applied to different staff groups and/or individuals according to their professional roles and responsibilities and who have undertaken appropriate training and competency assessment.

4.7.2. Certain identified staff (e.g. super-users) may require a higher level of access (e.g. to place, amend or discontinue prescriptions).

4.7.3. Restrictions may need to be put in place for some prescriptions (e.g. intrathecal chemotherapy).

4.7.4. Regimens should only be made available for use at the sites at which they are authorised to be used.

4.8. Monitoring

4.8.1. Errors detected at all stages of the e-prescribing process should be recorded and closely monitored as part of standard institutional practice. Trends or isolated incidents encountered may require action to prevent recurrences including re-training, re-configuration of regimen set-up and notification to system providers to implement changes to improve patient safety.

4.8.2. Establish key performance indicators to monitor e-prescribing system effectiveness to drive continuous improvements. Recommended KPI’s should be agreed locally.

4.9. System Governance and Policies

4.9.1. At all times the recommendations outlined in ISB0160 must be followed.

4.9.2. Develop local standard operating procedures for system set up and system use. Many of the suppliers will have templates or examples for local adaptation.

4.9.3. Develop procedures for scheduled downtime, business continuity and disaster recovery.

4.9.4. Develop policies for requesting new regimens or changing existing regimens. This may be incorporated within a current medicines policy. It should include a process for approval and sign-off time-scales.

4.9.5. Develop procedures for users to report faults or seek training and support.
4.9.6. A change control process must be in place to ensure that any changes made to existing regimens and other system configurations are undertaken with appropriate documentation.

4.9.7. There must be a system in place to ensure changes or additions are communicated to the appropriate personnel.
5. Glossary of Terms

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<th>Acronym</th>
<th>Description</th>
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<tr>
<td>BSA</td>
<td>Body Surface Area</td>
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<tr>
<td>GFR</td>
<td>Glomerular Filtration Rate</td>
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<td>AUC</td>
<td>Area Under Curve</td>
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<td>ICD</td>
<td>International Classification of Diseases</td>
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<td>OPCS</td>
<td>Office of Population Censuses and Surveys</td>
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<td>SACT</td>
<td>Systemic Anti-Cancer Therapy</td>
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<td>ISB</td>
<td>Information Standards Board</td>
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6. Useful Resources

User groups and discussion forums are a valuable resource and participation in them is strongly encouraged.

The ePrescribing Toolkit for the NHS is a useful resource to support NHS hospitals to plan, implement and use e-prescribing systems. It can be accessed at: [http://www.eprescribingtoolkit.com](http://www.eprescribingtoolkit.com)

Anti-cancer medicines – a themed review by the NPSA (October 2010) [http://www.nrls.npsa.nhs.uk/resources/?entryid45=754755](http://www.nrls.npsa.nhs.uk/resources/?entryid45=754755)

Implementing an electronic prescribing and medicines administration system: a good practice guide. NHS Scotland. It can be accessed at: [http://www.healthcareimprovementscotland.org](http://www.healthcareimprovementscotland.org)

7. References

1. NHS England Chemotherapy Service Specification


4. ISB 0160 Clinical Risk Management: its Application in the Deployment and Use of Health IT Systems version 2.0 January 2013


8. Acknowledgements

The authors would like to thank the following contributors who provided many helpful comments on the draft form of this document:
## 9. Document Control

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<th>BOPA: Standards for Reducing Risks Associated with e-Prescribing Systems for Chemotherapy</th>
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| Proposed Target Audience | Oncology and Haematology Pharmacists, Provider Trust Chief Pharmacists, NHS Scotland Boards Directors of Pharmacy, Oncologists and Haematologists, PCT Prescribing Advisors, Cancer Networks, SHA, Welsh and NI Health Board(s). |

| Proposed Circulation List | BOPA Members, FCP Members, Chief Pharmaceutical Officers for each home country, UKONS, Provider Trust Chief Pharmacists, NHS Scotland Boards Directors of Pharmacy, RCP, PCT Prescribing Advisors, Heads of Schools Pharmacy, RSPGB/PLB, NES Scotland, Paediatric Oncology Pharmacists |

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