



**Professional
Record
Standards
Body**

**Better records
for better care**

DIGITAL MEDICATION INFORMATION ASSURANCE

FINAL REPORT V1.5

JANUARY 2020

Copyright

This document has been prepared by the PRSB on behalf of NHS Digital. You may use and re-use the information featured in this document (not including logos or images) free of charge in any format or medium, under the terms of the Open Government Licence. Any enquiries regarding the use and re-use of this information resource should be sent to: support@theprsb.org. Where we have identified any third party copyright material you will need to obtain permission from the copyright holders concerned.

Information and content © PRSB 2020

Professional Record Standards Body

7-14, CAN Borough, Great Dover St
London, SE1 4YR

www.theprsb.org

support@theprsb.org

Community Interest Company No 8540834

Acknowledgements

NHS England

NHS England oversees the budget, planning, delivery and day-to-day operation of the commissioning side of the NHS in England as set out in the Health and Social Care Act 2012. It holds the contracts for GPs and NHS dentists. The Secretary of State publishes, annually, a document known as the mandate which specifies the objectives which the Board should seek to achieve. National Health Service (Mandate Requirements) Regulations are published each year to give legal force to the mandate.

NHS Digital

NHS Digital is the trusted national provider of high-quality information, data and IT systems for health and social care. NHS Digital collects, analyses and publishes national data and statistical information as well as delivering national IT systems and services to support the health and care system. The information services and products are used extensively by a range of organisations to support the commissioning and delivery of health and care services, and to provide information and statistics that are used to inform decision-making and choice.

The Professional Record Standards Body (PRSB)

The PRSB (www.theprsb.org) is the UK wide organisation enabling professional and patient organisations to work together with the healthcare IT community and relevant government departments (e.g. NHS Digital) for the development and widespread use of standards to enable high quality electronic health and social care records. PRSB was established in 2013 as a “not for profit” Community Interest Company.

Royal College of Physicians (RCP) Health Informatics Unit

The RCP led development of clinical documentation and generic record standards (CDGRS), which provide standards for the clinical structure and content of patient records. They were endorsed by the Academy of Medical Royal Colleges (AoMRC), published in July 2013 and adopted by the PRSB. In 2015/2017 the Health Informatics Unit (HIU) has supported the PRSB to develop information models to support transfers of care communications.

Document Management

Revision History

Version	Date	Summary of Changes
0.1	20.02.2019	First draft
0.2	04.03.2019	Second draft
1.0	29.03.2019	Final version
1.1	08.04.2019	Minor plain English revisions
1.2	28.04.2019	Additional clarification and limitation for use of trade family added to tables 6 & 7 for trade family use, and trade family added to the glossary.
1.3	30.04.2019	'Planned Review Date and Route for User Feedback' added to cover pages.
1.4	14.05.19	Minor updates to formatting of Appendices
1.5	14.01.2020	Updates to links to reflect that NHS Digital have uplifted dose syntax guidance from "Experimental" to "Alpha"

Approved by

This document must be approved by the following people:

Name	Signature	Title	Date	Version
Project Board	Approved		27.03.2019	1.0
PRSB Assurance Committee	Approved		27.03.2019	0.3

Planned Review Date and Route for User Feedback

The next maintenance review of this standard is planned for April 2022, subject to agreement with NHS Digital as the commissioning body.

Please direct any comments or enquiries related to the project report and implementation of the standard to support@theprsb.org.

Contents

1	Summary	6
2	Context, objectives and scope	6
3	Methodology	9
4	Consultation outcome	12
5	Recommendations	18
6	Next steps	19
7	Appendices	20
7.1	Appendix A – Survey questions	20
7.2	Appendix B – Glossary of Terms	21
7.3	Appendix C – References	22
7.4	Appendix D – Stakeholders	23
7.5	Appendix E – Medication standard	26
7.6	Appendix F – Translation process	28

1 Summary

Reducing medication related errors across the NHS is a national priority. We can help to facilitate this through the safe transfer and translation of medication information across all settings in health and care. Ensuring that medications information can be shared in a standardised way across systems will also create numerous opportunities to optimise the ways in which we deliver care and streamline the way that we work. To achieve this goal we need to implement structured dose instructions within the data sets that are shared between clinical systems.

NHS Digital and NHS England teams have developed draft implementation guidance to allow medication dose and timing information to be machine readable so it can be shared between different systems. This is done using structured definitions within the messaging systems (HL7 FHIR¹ INTEROPen CareConnect Profiles). The Professional Records Standards Body (PRSB) was commissioned to consult on the proposals within the implementation guidance, to ensure that they are fit for purpose.

This document outlines the methodology used to validate the implementation guidance, and identifies the changes required to PRSB medication models.

2 Context, objectives and scope

Project context

Relevant information about patient medications, including detailed dosage instructions, needs to be shared in machine readable form when a patient moves from one care setting to another. This includes, but is not limited to, moving between primary care into secondary care and secondary care into primary care. In addition, within a hospital setting, medicines information must be shared between electronic prescribing and administration systems (ePMAs) and pharmacy stock control systems where these systems are not integrated.

Outpatient / primary care and inpatient (secondary care) use different methods of prescribing. Outpatient prescribing is focused on patient self-administration and is product based e.g. paracetamol 500 mg tablets, two tablets to be taken every six hours. Inpatient prescribing is typically dose-based, for example the same prescription would be expressed as Paracetamol 1 gram every six hours. When a patient transfers between these settings, a process of translation is required to ensure the correct medicines and dosages are identified, prescribed and administered in the new care setting. This process is currently largely paper based, requires considerable manual intervention and is prone to errors.

Whilst discussions are ongoing about whether these different prescribing methods can be rationalised, any such change would require very significant retraining of current staff, substantial

¹ Fast Healthcare Interoperability Resources (FHIR, pronounced "fire") is a standard describing data formats and elements (known as "resources") and an application programming interface (API) for exchanging electronic health records

changes to prescribing systems, redevelopment of training materials, and almost certainly some legislative changes. Realistically we would potentially have to wait decades before any rationalisation could be safely implemented.

Previous attempts to identify information requirements, mapping and rules to enable automation of the translation process have been unsuccessful due to over-complexity and trying to address every eventuality at the first attempt, rather than allowing a more evolutionary approach. Learning from this, we are now using a more iterative approach at finding these solutions.

NHS England and NHS Digital have designed a proposed solution to address this issue. It comprises:

- the information models and technical FHIR components developed for the Transfer of Care, Digital Medicines and GP Connect medications components;
- standard dose structures to accommodate the most common scenarios (with guidance on handling limitations for the more complex cases);
- draft business rules for the dose/product translation process;
- technical implementation guidance²;
- industry consultation to review and verify the model and to scope views on how suppliers would construct dose and timing instructions and receive it into their own systems.

The overall purpose of the standard is to provide a way in which medication information can be shared between health and care systems in a standard machine-readable format with translation rules so that medication information can be machine transferred and translated to the appropriate prescribing syntax for professionals to review and action appropriately in the receiving system. The aim is to reduce manual translation and re-entering of medications information, areas prone to errors. This should provide safer care for patients, and more efficient and reliable and unambiguous information for professionals.

The benefits to patients and the system in terms of improved safety and efficiency of transmission of medicines information are significant and for this reason, this project has been identified as the top priority of the NHS England interoperability programme.

The PRSB has been asked to undertake a consultation and validation exercise to understand if the proposed solution is safe and workable and to gain broad clinical and patient support and acceptance of the proposals, leading to formal endorsement, inclusion/reference and potential updates to relevant PRSB standards.

Project objectives

The aim of this project is to support NHS England and NHS Digital to deliver an implementable package of structured medications messages including detailed dose-timing instructions (dose syntax) and defined use cases that have broad clinical and patient support and buy-in.

² FHIR Dose Syntax Implementation Guidance. <https://developer.nhs.uk/apis/dose-syntax-implementation-1-3-1-alpha/>

The specific objectives are:

1. To consult on the proposals for structured medicines exchange, including structured dose-timing instructions, in a form that is accessible to citizens and non-technical health and care professionals;
2. To consult health care professionals and citizens on the proposed solution, in order to:
 - engage them and inform them of the work;
 - validate the concept and identify any changes required;
 - verify it is clinically safe;
 - confirm it is implementable;
 - identify additional examples of complex dose-timing instructions to see if they can be implemented under the guidance or identified as exceptions to be addressed a later stage;
3. To develop a clinical safety report and associated hazard log;
4. To update PRSB information models to accommodate the standard; and to develop associated non-technical guidance suitable for use by front line clinicians and patients to support adoption;
5. To gain endorsement from relevant professional bodies and key stakeholders to the proposed standard and associated processes;
6. To raise awareness and build support for the proposed changes.

Project scope

In scope:

- Assurance and validation of the products developed by NHS Digital and NHS England to:
 - Test the model with clinical informaticians, healthcare professionals, system suppliers and citizens;
 - Check that it is considered clinically appropriate, safe, workable and implementable;
 - Understand the business impact, i.e. at a high level the scale and type of changes required both in terms of clinical systems and clinical practice to enable the standard to be widely implemented.
- Development of a clinical safety report to identify risks to patient safety and mitigations.
- Development of non-technical guidance to supplement the technical guidance.
- Updates to existing PRSB standards. The solution is based on the PRSB standards and the medications and medical devices information model which is common across the PRSB standards. However, changes will be required at a detailed level, for example to accommodate new structured dose-timing instruction values and associated implementation guidance.
- Preparation of materials for clinical and patient consultation – working with the NHS England team to make them accessible to a non-technical audience.

- Broad-based consultation and engagement with key stakeholder groups in health and care, citizens and vendors informing any relevant changes to the standards and dose-timing instructions.
- Incorporating input obtained through the first of type pilot as it becomes available.
- Formal endorsement through identified stakeholder organisations.

Out of scope:

- First of type and pilot testing of the standard – this is undertaken separately through NHS Digital.
- FHIR® curation following changes to the core content of medications arising from this work and to accommodate new use cases – this will be commissioned separately by NHS Digital if required.
- Human readable version of structured dose syntax – separate work has been undertaken by NHS Digital.
- Support for widespread implementation – separate work will be undertaken.
- User interface models.

3 Methodology

This section describes the approach taken to consult on the proposals and produce project deliverables.

Project initiation

A project brief was first produced, before being refined and extended into a project initiation document (PID). The PID gave the direction and scope of the project and formed the ‘contract’ between the project management team and the project board. For the project board membership, see Appendix D.

The PID also included an engagement and communications plan. This plan set out how engagement with stakeholders would be carried out from the start to ensure that they were aware of the project and engaged in the consultation.

Review of technical guidance

The core project team, including a clinical lead and clinical informatician adviser and the NHS England and NHS Digital team reviewed the documentation on the proposals and identified use cases.

Gaps and questions for consultation were identified based on which the materials for consultation were developed.

Through survey and webinars, interested clinical informaticians were invited to review the detailed guidance and submit their feedback either in a survey, by emailing PRSB or via the 'Ryver' forum³ hosted by INTEROPen⁴.

Consultation

The consultation was aimed at:

- clinical informaticians and systems suppliers – to get engagement in the work and validate the proposals and discuss potential issues;
- front line healthcare professionals from different care settings and disciplines who prescribe, administer or dispense medications, i.e. GPs and primary care professionals, pharmacists (both community and hospital based), hospital doctors and nurses – to raise awareness, gain engagement in the work, and understand complex prescribing examples from their practice;
- patients, carers and citizens – to inform them of the work, raise awareness and gather their input.

PRSB Advisory Board

A consultation session was held at the PRSB Advisory Board meeting on 30 January 2019. The advisory board represents a broad range of disciplines and the meeting included a discussion and feedback on specific questions about the proposals.

Survey

A consultation survey (see Appendix A) was designed as a question and answer questionnaire, providing extensive information to raise awareness about the project and to help focus the answers and allow for open responses.

The survey was circulated to a total of 118 fellows and founding fellows of the Faculty of Clinical Informatics. This was identified as the main audience for this project. The survey was also circulated to 650 other key stakeholder contacts and then further shared within their networks. The key networks included the Royal College of General Practitioners Health Informatics Group (HIG), Joint GP-IT Committee, patient and carer groups, PRSB member organisations and INTEROPen. Additionally, the survey was shared through PRSB and HIU newsletters and social media.

Table 1. Number of people who accessed and reviewed the survey

	n	%
Patients, carers and citizens	150	30%
Clinicians and informaticians	354	70%
Total	504	

³ <https://interopen.ryver.com/index.html#forums/1276343/posts>

⁴ www.interopen.org

Given the nature of the work and consultation objectives, there was good engagement from patient representatives. The number of patients, carers and citizens who provided an answer to at least one question was 47. It is suspected that some respondents did not feel they were able to make a meaningful contribution to the very specific questions asked e.g. additional benefits or complex examples that might not work with the guidance.

The number of clinicians / informaticians who provided an answer to at least one question was 116 and of those 95 included information about their role. Role breakdown is provided in the table 2. Please note that some pharmacists did not identify the setting and so the pharmacists' category may include some working in the community.

Table 2. Responses by role

Role	n
Pharmacist	22
Informatician	18
Other clinician	13
Secondary care physician	10
CCIO	7
Community pharmacist	7
GP	7
Business/manager	6
System supplier	7
Psychiatrist	5
Emergency care clinician	4
Nurse	4
Dentist	1

Webinars

Webinars were hosted with the aim of seeking engagement in the work, informing stakeholders about the project, getting feedback and discussing any issues. Three webinars were arranged in total. The organisation of each attending representative is listed in Appendix D.

Table 3. Webinar attendance

Consultation webinar	Webinar aimed at	Date	Total number of participants
#1	Healthcare professionals and patients	7 th February 2019	39
#2	Clinical informaticians	14 th February 2019	58
#3	Clinical informaticians	28 th February 2019	50

Final report

A final report (this document) has been produced, providing validation and recommendations for changes to the proposals in the technical implementation guidance, recommendations to support uptake and implementation, an outline of the process and methodology used and details of the consultation and participation. Separate clinical safety documents have been developed through two hazard workshops with clinical informaticians. The workshops explored potential clinical safety issues arising from the proposals as identified by project stakeholders through consultation and by using the clinical experience of workshop attendees.

Non-technical guidance

An associated non-technical guidance document (separate document) has also been produced for front line professionals who will be supporting adoption and implementing this standard. This guidance explains, in a non-technical way, the purpose and benefits of sharing medications information through system interoperability, the need for standards, what these standards will cover and what they won't.

4 Consultation outcome

This section describes the feedback received as part of the consultation. Stakeholders have provided feedback on:

- the potential benefits of this work (table 4);
- particular benefits identified as a priority (table 5);
- high-volume/value complex examples; these have been grouped into categories (table 6);
- potential safety issues (these have been considered separately as part of clinical safety case);
- potential usability and implementation issues (table 7).

The feedback has been analysed and where possible it was summarised and any items that were duplicated, not applicable or out of scope were removed. Some items not listed were out of scope for this work but will be considered in the future within the wider interoperable medications context.

The feedback was shared with NHS England and NHS Digital who have considered it and where appropriate amended the technical implementation guidance.

Table 4. Identified benefits

Potential benefits
<p>Supporting medicines reconciliation</p> <ul style="list-style-type: none"> • If the transfer of dose information was more accurate and persisted across care sector interfaces, this could help address workforce capacity issues as it could reduce the time taken in medicines reconciliation. For example, primary care reconciliation of medication data in hospital outpatient and discharge letters into the patient's record on the primary care clinical system. Likewise, pharmacy and doctor time in hospital reconciling medicines information from GP practices on admission and in outpatient clinics. Time could be saved in chasing, checking and resolving prescription queries and resulting issues. <p>Improving safety</p>

- Reduced medication error e.g. reducing the requirement for manual transcription of information to be undertaken and the linked risk of errors being made during the transcription process;
- Improved ability for patients to remain on a specific strength of a liquid preparation (if multiple strengths are available) - reducing errors relating to dosing;
- If things like "Take ONE daily until 28th February 2019" was persisted as part of the transfer of care, this could offer an additional safety net for acute items being sent into the community which shouldn't be commenced as long term by the GP e.g. painkillers post-op or anti-coagulants for a specific time post procedure.
- Ensuring a patient remains on a specific branded product where they need to do so (e.g. may have been chosen for a paediatric patient as it has reduced amounts of potentially harmful excipients);
- Improved communication between hospital pharmacy stock control and digital prescribing and administration systems, reducing time spent and safety risks associated with transcribing information manually;

Improving communication

- Access to full medication history for a patient;
- Potential for sharing medication information directly with community pharmacies, opticians, etc.;
- If the patient nominated a community pharmacy for their discharge record to be sent to, and this could pre-populate the pharmacy dispensing system prior to checking by a pharmacist which could reduce the risk of the patient being dispensed "old prescriptions" or "old directions" whilst waiting for the transfer of information between care settings.

Improving patient experience

- Direct input into a patient held record, for example for prescription re-ordering, prompting and monitoring of adherence, etc. Possible direct link from (agreed) patient app data to provide compliance information;
- Many frail/older people and some of those living with long-term conditions rely on one or more 'family' carers' for support and it may be the carer who manages and administers their medications. This work will make it easier for carers to look after their loved ones safely and with increased confidence as they have clear and consistent prescribing/administration instructions;

Improving dose calculation

- Automated calculation of amounts used for stock control;
- Calculation of correct and accurate dose, based on the weight of the patient;
- Tracking overall dose changes over time, graphically displaying changes on charts to help inform clinical decision making;
- Consistent identification of the medication. i.e. not various trade names mixed with actual chemical name;
- Adding more automated and standardised dose-timing instructions will allow for more accurate durations of prescriptions to be calculated. This will allow alerts for over and under prescribing in clinical systems to become more useful (currently for things like inhalers they are largely inaccurate).

Supporting secondary uses

- Ability to analyse prescribing data with other metrics/quality indicators/outcome measures to assess impact (e.g. data analysis, machine learning);
- Support more intelligent patient outcomes analyses for drug prescriptions;
- The ability for thorough and more robust insight into medicines adherence at a population level;
- National epidemiological data;
- Reduction in variation of dosage prescribing and administration. This will occur by documentation audit and resolution of disparities arising;

- By automating/making it easier for clinicians to code doses from a pre-populated transferable list, this could overcome the need for clinicians to use "as directed" as a dose-timing instruction. This would allow better visibility of how medicines are used (or intended to be used by the prescriber).

Other

- Driver for adoption of digital prescribing and administration systems as many organisations still use paper charts;
- With the help of vendors, enable the opportunity to display the information in the right format to the right person (patient, carer, pharmacist, healthcare professional etc.).

Table 5. Particular benefits identified through consultation as a priority

Benefits
<ul style="list-style-type: none"> • Supporting safer and more efficient medicines reconciliation between primary care and hospital pre and post discharge; • Reduce medication errors, e.g. omissions and incidents, and improve patient safety; • Increase confidence in the accuracy and availability of all clinical workflow data when managed by new computerised systems, with access to clear logs of all data entries, changes and deletions to allow clarification of potential errors; • Simpler clearer instructions to the patient, and highlighting any changes. Making it easier for patients to know that they are using the correct medication dose and timing.

Table 6. The type of prescribing supported

Type of prescribing	
Standard directions e.g. twice a day, four times a day	Supported
Alternate day dosing (e.g. 1 tablet every 2 days)	Supported
Very small doses e.g. 0.3mg	Supported
Prescribing of 'as required' doses (PRN)	Supported
Increasing or decreasing dosage regimens including those that are for multiple times of day. Including an infusion that begins at a slower rate for an initial period of time and then the rate is increased	Supported. Regimens that are dependent upon test results or clinical review would need to use free text to indicate review required.
Maximum and minimum course duration to be specified in a machine readable format or a specific time for the dose	Supported
Different doses at different times of day	Supported
Prescribing using evening, at night, before sleep or a specific time of day	Supported
Specifying a time for doses to be given	Supported. There is no flag to indicate time critical doses (e.g. Parkinson's medication)

	although this could be covered in future iterations.
Weekly prescribing with and identified day(s) of the week	Supported
Specifying doses once a month or on an identified date	Supported
Prescribing of the relevant dosage (drug, dose, route) including half or quarter of a tablet.	Supported. Where a portion of a unit dose is required to administer that dose it is likely to need human intervention to identify the best way to give that dose.
Prescribing at Virtual Therapeutic Moiety (VTM) level which allows for drug and dose without specifying an Actual Medicinal Product (AMP) or Virtual Medicinal Product (VMP)	Supported
The use of a coded Trade Family as the medication item with or without identifying a dose form	Supported
Brand name (AMP) prescribing	Supported
Identify the symptom the medication is intended to treat e.g. "when required for pain".	Supported
Loading doses where patients don't remain on initial high doses long-term	Supported
A deferred start time for a treatment course or dose	Supported
Identifying a dose duration for a single patch or infusion	Supported
Identifying a treatment course of 12 months	Supported

Table 7. The type of prescribing not supported and out of scope

Please note that these would still be communicated as human-readable text (iterative work will determine how that is to be done) and continued to be interpreted manually. The model is extensible and may support some of these in the future.

Type of prescribing	
The use of a coded Virtual Therapeutic Moiety (VTM) plus a coded Trade Family as the medication	Not supported
Medication free interval during the treatment course	Not supported
Irregular frequencies (once a day for one day, gap of two days, then twice a day)	Not supported
A general instruction of before a particular time e.g. "before 10am"	Not supported. Only identifying a specific offset.
Associating the dosage of one medication with the administration of another. This is the issue with combination packs and methotrexate/folic acid regimens	Not supported
The ability to identify time critical administration e.g. Parkinson's drugs	Not supported
Regimens where clinical evaluation or results of a test are required to decide the dosage e.g. dosing according to blood levels, Insulin doses, warfarin and pancreatic enzyme replacement therapy	Out of scope

Decision support for bio-equivalence requirements e.g. phenytoin suspension/capsules/injection equivalences	Out of scope. This work could help make decision support more effective.
Chemotherapy regimens	Out of scope
Complex infusions	Out of scope

Table 8. Potential usability and implementation issues

It is important to note and clarify that medication imported into a system should not be prescribable without clinical intervention. For example, prescription information should enter GP systems as prescribed in hospital. There is a need for a reconciliation module to allow GPs to decide what to accept and what not to. The same is true for information coming into pharmacy systems. There will always be a need for human intervention to confirm and accept medications. Clinicians should be verifying information with patients rather than automatically accepting.

Issue
<ul style="list-style-type: none"> • Primary care systems tend to use free text fields for dose instructions so moving to a structured approach at time of data entry would be a big change, as would converting existing repeat medication – unless an accurate parsing of the free text is introduced. • It will need dedicated expertise in mapping the actual / possible workflows and not just what people think they do or should do. • The user interface of the solution should be simple, user friendly and intuitive so as not to increase the workload for prescribers, pharmacists or any other professional viewing the medicines information. • Ensuring the conversion between frequency specified as textual e.g. in the morning and that of numerical e.g. at 08:00 is standardised where appropriate. In secondary care prescribing is clock time driven whereas in primary care it is more general. We need to ensure that the mapping between the two is defined across all systems e.g. “lunchtime” is always 12pm or 1pm in all systems. <p>Also consider how different systems handle frequency e.g. not all prescribing systems have a concept of a time range (4-6hrly) for PRN.</p> <ul style="list-style-type: none"> • Consideration to what is displayed in the user interface for a clinical user (needs the exact time in hospital setting) versus what needs to go on a printout for a patient (need a general time on the discharge medicine list). • Consider how to display the dosing for reducing regimens (e.g. steroid) on a screen so that it is easy to read and not overly long as that leads to readability issues as well as screen real-estate problems. If there is to be a cut off on the frequency after which a “general frequency” is written then that needs to be standardised across applications. • The example for the complicated gabapentin dosing (<i>Gabapentin – oral – 300mg at night for one day, then 300mg in the morning and at night for one day, then 300mg three times a day for one day, then 300mg in the morning, 300mg in the afternoon and 600mg at night for 4 days, then</i>

600mg in the morning, 300mg in the afternoon and 600mg at night for 1 day, then 600mg three times a day indefinitely) – if the dose persists to the primary care record, it may be inappropriate if the patient is in the middle or at the end of the complex dosing regimen (as when the drug information transfers to the clinical system, the start date in the hospital would be critical to reduce confusion), and may actually complicate or confuse matters, compared to if it said “as directed”. In order to overcome this, transmission of the start date of that drug and the complete dosing regimen would be necessary for the most clarity.

- EHRs should stop converting characters in the dose direction box into words without the user’s explicit authorisation. In one GP system the character ‘-’ is automatically converted into the word ‘or’. This can inadvertently result in the conversion of ‘take 1-8 sachets daily according to effect’ into ‘take 1 or 8 sachets daily according to effect’, which have very different meanings. With interoperable dose-syntax this error could be propagated into other systems. The solution is to ban the practice of auto-conversion of characters unless they are completely established as convention, for example QDS = four times daily and this is permissible because it is internationally standard and unambiguous.

5 Recommendations

This section sets out recommendations for NHS England, NHS Digital and partners to take forward as part of further work, supporting uptake and implementation.

1. PRSB⁵ and Care Connect⁶ medication information models should be updated. This will apply to all PRSB standards with medication and medical devices section.

Currently the PRSB information models include placeholder elements for structured dose amount, dose timing, dose directions and communicate this information as textual description. The suggested updates to these models are provided in Appendix E.

2. Medications dose and timing instructions should be implemented as part of the wider interoperable medications implementation work, addressing the wider, related challenges.
3. NHS organisations should be further made aware of this work. Engage with informatics departments and involve clinicians in a way in which they can understand the changes and what they mean for the future.
4. Lessons to share should be identified from early implementers (First of Type sites) prior to wider implementation.
5. Industry should be further engaged to understand how suppliers would construct dose and timing instructions within their systems.
6. Implementation should be encouraged by adding requirements in GP and secondary care procurement contracts.
7. As part of incorporating this work into clinical workflows and systems, consideration should be given to the user interface, so that it is intuitive, does not increase workload for prescribers, and is able to display dynamic information to appropriate clinical users.

⁵ e.g. <https://theprsb.org/standards/edischargesummary/>

⁶ <https://developer.nhs.uk/library/interoperability/care-connect-api/>

6 Next steps

This project is a highly focused piece of work to define how to use FHIR® technical standards to share medication and dosing information. It is part of a wider UK effort to create machine readable, sharable definitions of patient medication information so that this can be easily exchanged between different health IT systems/apps and different care-settings. It is anticipated that this work will demonstrate multiple benefits and serve as a catalyst for further iterative work.

This piece of work will deliver a critical part of the infrastructure needed to allow systems to exchange computable medication records, but there is still a lot of work for system suppliers to do, particularly to design and develop user interfaces and support clinical workflows, so that we do not add to the burden of clinicians when entering or importing medication records but improve efficiency and safety as expected.

Implementing sharing of medications between IT systems and care settings will mean changes in current processes and IT systems interfaces. This work is reliant on IT system suppliers implementing the proposed solutions. Nevertheless, many of the major UK suppliers are already starting to develop interfaces to their data using the standardised medication record formats. There are clear market advantages for suppliers that are using these standards and benefits in supporting innovation. NHS England and NHS Digital are working with NHS providers and systems vendors to technically confirm that this solution will deliver.

The updated Implementation Guidance⁷ is published on the Health Developer Network API Hub with changes noted in the release notes, and will continue to be updated.

The logic and rules for presenting the structured content as a human readable string⁸ as well as rules for medicines translation were not available within the project timescales for professional bodies to review and consult on. An online service termed the Medicines Interoperability and Logic Toolkit is in development by NHS Digital that will translate a CareConnect medication-related profiled resource and return a string suitable for use as the text narrative. It also provides suggestions for product-based options of the dose instructions ready to be reviewed and transferred into the receiving system.

The toolkit allows healthcare professionals and patients to understand the challenges faced and how the project will help. Please see *Appendix F* for examples of the functionality.

This experimental service is available as a demonstrator for use by system suppliers during their software prototyping and design phases. It could also be suitable as an operational service in the future so that system suppliers do not have to implement this complex logic within their own solutions. However, these are only examples as there are various ways to accomplish this, and further development and implementation of the rules for dose to product translation will be vendor driven as this is a software development exercise. Any translation rules will need to be tested, verified with clinician involvement and assured through clinical safety case.

⁷ <https://developer.nhs.uk/apis/dose-syntax-implementation-1-3-1-alpha/>

⁸ <https://developer.nhs.uk/apis/dose-syntax-implementation-1-3-1-alpha/dosage-to-narrative-overview.html>

7 Appendices

7.1 Appendix A – Survey questions

The below is a list of questions asked in the consultation survey. Please note that the survey itself included extensive background information and further context on each of the questions which are not provided here.

1. Please tell us, are you:
 - Healthcare professional / clinical informatician
 - Patient, carer / citizen

Clinician and clinical informatician survey version

2. Are there other benefits that we have not thought about?
3. If you had to focus on one particular benefit as priority, what would that be and why?
4. Please note any high-volume/value complex examples from your experience
5. What are the potential clinical safety issues you can think of?
6. What are the potential usability and implementation issues?
7. Do you want to share any additional feedback on the proposals?

Patient, carer and citizen survey version

2. Are there other benefits that we have not thought about?
3. If there was one particular benefit as a personal priority, what would that be?
4. Please note any complexities from personal experience you want captured
5. Do you have any concerns or think there are any safety issues with what is being proposed?
6. Do you want to share any additional feedback on the proposals?

7.2 Appendix B – Glossary of Terms

Term / Abbreviation	What it stands for
AMP	Actual Medicinal Product
dm+d	Dictionary of medicines and devices. It provides a standardised way of uniquely identifying specific medicines or medical devices in information systems and digital communications, used in the diagnosis or treatment of patients.
EHR	Electronic Health Record
EPR	Electronic Patient Record
EMPA	Electronic prescribing and medicines administration
FHIR®	Fast Healthcare Interoperability Resources is a standard describing data formats and elements (known as "resources") and an application programming interface (API) for exchanging digital health records.
FOT	First Of Type
GP	General Practitioner
HIU	Health Informatics Unit at Royal College of Physicians
NHS	National Health Service
NHS D	NHS Digital
NHS E	NHS England
PID	Project Initiation Document
PRSB	Professional Record Standards Body for health and social care
RCGP	Royal College of General Practitioners
RCP	Royal College of Physicians
SNOMED-CT	Systematized Nomenclature of Medicine - Clinical Terms
Trade Family	Trade Family is a SNOMED CT UK Drug Extension concept class that represents a brand group of medicinal products without further specifying dose form, presentation strength, or flavour.
ToC	Transfer of Care
VMP	Virtual Medicinal Product
VTM	Virtual Therapeutic Moiety

7.3 Appendix C – References

1. Closing the Loop Commission: Clinical Blueprint (2015). NHS Lanarkshire and NHS Greater Glasgow and Clyde and Clinical Change Leadership Group.
2. FHIR Dose Syntax Implementation Guidance. NHS Digital.
<https://developer.nhs.uk/apis/dose-syntax-implementation-1-3-1-alpha/>
3. Human readable version of structured dose syntax. <https://developer.nhs.uk/apis/dose-syntax-implementation-1-3-1-alpha/dosage-to-narrative-overview.html>
4. Medicines Interoperability and Logic Toolkit.
<http://ec2-18-130-128-118.eu-west-2.compute.amazonaws.com/>
5. HL7 UK INTEROPen Care Connect FHIR® API.
<https://developer.nhs.uk/library/interoperability/care-connect-api/>
6. HL7 FHIR® Resources. <http://www.hl7.org.uk/standards/fhir.asp>
7. PRSB structure and content of health and care records (2018).
<https://theprsb.org/standards/healthandcarerecords/>
8. PRSB Transfers of Care Medication information models, e.g.
<https://theprsb.org/standards/edischargesummary/>

7.4 Appendix D – Stakeholders

This appendix describes the stakeholders who were part of the core project team, members of the project board and attendees of the consultation webinars.

Project board membership

Organisation	Name
Professional Record Standards Body	Maureen Baker
Professional Record Standards Body	Lorraine Foley
Professional Record Standards Body	Martin Orton
Professional Record Standards Body	Helene Feger
NHS England	Ann Slee
NHS Digital	Libby Pink
Royal College of Physicians	Jan Hoogewerf
Royal College of General Practitioners / Scottish Government	Ian M. Thompson
Independent	Ian McNicoll
Patient and Carer Network, Royal College of Physicians	Richard Triffitt
Royal Pharmaceutical Society	Alistair Gray
Royal Pharmaceutical Society	Stephen Goundrey-Smith
Joint Speciality Committee for Clinical Pharmacology & Therapeutics, Royal College of Physicians	Yoon Loke

Core project team

Role / Organisation	Name
Project Senior Responsible Owner, NHS England	Ann Slee
Terminology Implementation Specialist, NHS Digital	Bill Lush
Senior Informatics Specialist, NHS Digital	Emma Melhuish
Project Manager, Royal College of Physicians HIU	Haroldas Petkus
Project Clinical Lead, Royal College of General Practitioners / Scottish Government	Ian M. Thompson
Project Clinical Informatician Adviser, Independent	Ian McNicoll
HIU Programme Manager, Royal College of Physicians	Jan Hoogewerf
Business Lead – Pharmacy Terminology, NHS Digital	Jo Goulding
Citizen representative	Richard Triffitt
Senior Technical Architect / author of the implementation guidance, NHS Digital	Rob Gooch

Webinar attendees

Please note that we were not able to record organisation information for all attendees therefore some organisations are unknown. In some instances, there were multiple attendees from the same organisation.

Organisation	Webinar		
	7 th Feb	14 th Feb	28 th Feb
Advanced		✓	
Alder Hey Children's NHS Foundation Trust	✓		
Australia Digital Health Agency			✓
Blue Wave Informatics		✓	
British Dietetic Association		✓	✓
Cambio Healthcare			✓
Cerner		✓	✓
Civica		✓	✓
Clanwilliam Group			✓
CSC		✓	✓
Dedalus Healthcare Ltd			✓
DXC		✓	✓
East London NHS Foundation Trust			✓
EMIS Health		✓	
Faculty of Clinical Informatics		✓	
First Databank		✓	
Hull and East Yorkshire Hospitals Trust			✓
Imperial College London		✓	
INPS			✓
JAC		✓	
Lancashire Teaching Hospitals NHS Trust	✓	✓	
Locum Relief LTD		✓	
Mid Essex Hospital Services NHS Trust		✓	
NEW Devon CCG		✓	
NHS Digital	✓	✓	✓
NHS England	✓	✓	✓
NHS Health Scotland		✓	
NHS National Services Scotland		✓	
NHS Wales	✓		
Norfolk and Suffolk NHS Foundation Trust		✓	
Northampton General Hospital NHS Trust		✓	
NProgram Ltd		✓	
Orion Health			✓
Patients Know Best			✓

Organisation (continued)	Webinar		
	7 th Feb	14 th Feb	28 th Feb
Pennine Care Trust			✓
PRSB	✓	✓	✓
Royal College of General Practitioners	✓	✓	✓
Royal College of Physicians		✓	
Royal College of Paediatrics and Child Health		✓	
Royal Cornwall Hospitals NHS Trust	✓	✓	
Royal Devon And Exeter NHS Foundation Trust	✓		
Royal Liverpool and Broadgreen University Hospitals NHS Trust		✓	
Royal Papworth Hospital	✓	✓	
Royal Papworth Hospital NHS Foundation Trust	✓		
Shine Health LTD		✓	
South Eastern Health and Social Care Trust			✓
Stockport NHS Foundation Trust		✓	
TPP			✓
University Hospital Southampton NHS Foundation Trust		✓	
University Hospitals Bristol NHS Foundation Trust		✓	✓
University Hospitals Plymouth NHS Trust	✓		
University of Manchester			✓
Warrington and Halton Hospital NHS Foundation Trust		✓	
Written Medicine			✓
Yeovil District Hospital NHS Foundation Trust			✓
Patient representatives	✓		
Other organisation or representative, n<26	✓		
Other organisation or representative, n=12		✓	
Other organisation or representative, n=7			✓

7.5 Appendix E – Medication standard

This is an excerpt of the PRSB medication model with only elements relevant to dose and timing included. Full model is available on the PRSB website⁹. Structured dose direction cluster will carry all information about dose-timing whilst plain text descriptors will carry unstructured information as previously.

Medications and Medical Devices				
Element	Description	Cardinality	Mandatory / Required / Optional	Values
Structured dose direction cluster	A structural representation of the elements carried by the dose syntax i.e. dose strength, dose timing, dose duration and maximum dose.	0 to many	optional	As per FHIR Dose Syntax Implementation Guidance (NHS Digital): https://developer.nhs.uk/apis/dose-syntax-implementation-1-3-1-alpha/
Dose directions description	A single plain text phrase describing the entire medication dosage and administration directions, including dose quantity and medication frequency. <i>Comment: e.g. "1 tablet at night" or "20mg at 10pm" This is the form of dosage direction text normally available from UK GP systems.</i>	0 to 1	optional	Text
Dose amount description	A plain text description of medication single dose amount, as described in the AoMRC medication headings. <i>Comment: e.g. "30 mg" or "2 tabs". UK Secondary care clinicians and systems normally minimally structure their dose directions, separating Dose amount and Dose timing</i>	0 to 1	optional	Text

⁹ PRSB Transfers of Care Medication information models, e.g. <https://theprsb.org/standards/edischargesummary/>

	<i>(often referred to as Dose and Frequency). This format is not normally used in GP systems, which will always import Dose and Frequency descriptions concatenated into the single Dose directions description.</i>			
Dose timing description	A plain text description of medication dose frequency, as described in the AoMRC medication headings.	0 to 1	optional	Text
	<i>Comment: e.g. "Three times a day", "At 8am 2pm and 10pm". UK Secondary care clinicians and systems normally minimally structure their dose directions, separating Dose amount and Dose timing (often referred to as Dose and Frequency). This format is not normally used in GP systems, which will always import Dose and Frequency descriptions concatenated into the single Dose directions description</i>			

7.6 Appendix F – Translation process

Translation to human readable dosage information

The Medicines Interoperability and Logic Toolkit (currently experimental) demonstrates how to convert machine readable FHIR Dosage structure instructions into an appropriate human readable dosage string as per example below. This is provided for information purposes only (as it is out of scope of this project) and details of this will continue to be updated in the technical implementation guidance.

The screenshot displays a user interface with three distinct output formats for dosage information, each with a corresponding label in a blue button:

- Plain Text:** A text box containing the string "Oxytetracycline - 250 milligram - 4 times a day - oral".
- HTML Multi Line:** A text box containing a structured HTML output:

```
Oxytetracycline  
DOSE 250 milligram  
ROUTE oral  
TIMING 4 times a day
```
- HTML Single Line:** A text box containing a single-line HTML output: "Oxytetracycline **DOSE** 250 milligram - oral - 4 times a day".

Dose to product translation

The Toolkit also returns a list of products that could fulfil the given dose-based instruction comprising of at least a product, plus optional route, form and dose strength. The returned list is sorted by least product divisibility, i.e. least quantity of the product to meet the ordered dose strength. Any additional filtering is subject to local requirements, e.g. stock availability, formulary, etc. It is not intended that this process auto-selects a single product. A human will ultimately decide on which product to use to fulfil the clinical need.

Shortlist of Products (suitable for further local filtering):

Product (VMP)	Quantity / Unit Dose Form
Oxytetracycline 250mg tablets [code:324095003]	1 tablet [Whole product divisible]
Oxytetracycline 250mg/5ml oral suspension [code:13003911000001104]	5 ml [Whole product divisible]
Oxytetracycline 125mg/5ml oral suspension [code:13003811000001109]	10 ml [Whole product divisible]
Oxytetracycline 500mg/5ml oral suspension [code:13004011000001101]	2.5 ml [Not whole product divisible]
Oxytetracycline 100mg/5ml oral suspension	12.5 ml