QA108 - DCB0160 Guidance

Revision History

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69	24/11/2021	AG	Addition of ‘alert’ filter function overview

Full edit and release history available in the live version of this document

Release Authority

This document is approved when the corresponding release of the parent parent QA107_PSF Clinical Safety Case is approved.

Note on document control

Version history is based in line with the current release number of the product. Releases where this document remains unchanged are not mentioned separately.

Table of Contents

Introduction

The purpose of this document is to provide guidance and advice on how to use the products that are part of Engage Health Systems' (EHS) portfolio. General information resides in the body of this document, with product specific information in the annexes.

Our obligation to deliver a clinically safe service doesn't stop at the point of sale. We are committed to ensuring that users and administrators of our services are aware of, understand and accept, the liabilities and responsibilities that come with operating one of our services. Guidance on best practice in using the product will always be given, but users have the ultimate liability for the choices they make in terms of set up and utility. This document is not meant to be seen as discussing all possible risks, and our products should always be used and treated as a responsible part of General Practice service provision.

The DCB0160 standard applies to healthcare organisations who are implementing healthcare IT systems. Organisations are required to have undertaken a risk assessment of any purchased technology including at a minimum, a Clinical Risk Management Plan, Clinical Safety Case Report and Hazard Log. This document has been provided by EHS to help with that process and to assist organisations in thinking about risk assessment at their end.

Feedback

Delivering a clinically safe service is our primary consideration; that's why we have created this document. If you are unsure about the wording or the implications of anything contained herein, please get in touch - we're here to help, and your comments could help your colleagues elsewhere to deliver a better, safer service.

Annex A - Engage Consult

Medical Indemnity

We are not aware of any specific guidance from NHS Resolution (the CNSGP scheme) or the medical defence organisations around the use of online consultations. We have spoken to NHS Resolution, the MDU, MDDUS and the MPS; they have clearly stated that they do not endorse individual products and that it is up to GPs to choose any technology they might use and to use it responsibly. They have further indicated that they see the responsible use of this type of technology as part of normal General Practice and we are not aware of any effects on practice insurance levels or levels of indemnity.

From our conversations with NHS Resolution, the following information was received by email which explained their current position (from Oliver Carson, CNSGP (sic)):

"To be clear, over under the Clinical Negligence Scheme for General Practice (CNSGP) is linked to the form of contract that the services are provided under. It covers activities which are commissioned under a GMS, PMS or APMS contract or as an enhanced primary care elements under Schedule 2L of the NHS Standard Contract (each a "Primary Care Contract"). Cover also extends to services that are delivered under a direct sub-contract to a Primary Care Contract. Coverage is not determined by the method or means by which services are provided. Services delivered via the online-consultation system would therefore not be treated differently to those provided on the phone or face to face. Of course NHS Resolution makes no comment in respect of the quality or particular merits or otherwise of the system in question."

Finally, the GP Forward View Team has also issued advice here outlining that "Additional premiums are not required for GPs who consult with their NHS patients online."

Product guidance

Risks and considerations associated with this product are listed below:

General Summary

The software is intended to supplement, not substitute for, the expertise and judgement of physicians, pharmacists or other healthcare professionals. All information is provided on the basis that the healthcare practitioners responsible for patient care will retain full and sole responsibility for deciding any treatment to prescribe or dispense for all patients and, in particular, whether the use of information provided by the software is safe, appropriate, or effective for any particular patient or in any particular circumstances.

Response times, Service Hours and surgery obligations

Engage Consult is an application designed to be used by patients registered with a General Practice and can also be used by Parents or Carers of registered patients requesting medical and other help on their behalf.

Engage Consult is highly configurable, supporting a variety of ways of working at individual practices and it is important to periodically review how the product is set up in order to provide good communication between patients and practice staff and also to ensure safe and effective use.
It is important that Practices understand the setting up of "Response times" and their responsibility to provide a timely response within those times. Configuration of the Engage Consult patient application is easily managed through the secure web portal known as "MyEHS".

It is EHS' default position that messages or requests submitted should be looked at or at least reviewed within the same working day of submission. EC is not an auto-triage solution and does not claim to ensure with 100% accuracy that symptoms can be looked at at a later date. Even auto-triage providing services cannot claim that fact and potentially it is a risky practice to leave consultations unread. That said, if practices wish to delay or defer decisions or reviews to subsequent working days, they can do, but it is entirely their responsibility to do so (if they wish to change, for example, the messaging around response times or their default working practice around how quickly they respond to patient requests). This should be codified clearly in their 0160 documentation risk assessment. At EHS, the automated response (that is the email that is sent to patients after submission) can be altered by practices - the default we have currently is within 3 hours.

Settings in MyEHS include response times, portal view links and "Alert Messages". These need to be reviewed regularly to ensure that the Practice is happy that they are providing a quality service. Practices are able to allow the use of Engage Consult Out of hours and it is made very clear to users that their messages WILL NOT even be looked at until the next working day. It is the Practice's responsibility to decide whether or not Engage Consult is used out of hours.

From release 67, customers will be able to use 'embedded links' as part of the offering. This allows customers to have specific links to certain questionnaires in specific places. For example, a pharmacy can have EC functionality through a link but to only accept minor ailments or a care home professional can use a dedicated link to upload requests on behalf of their patients. Essentially this provides another route of service for professional users. Within the demand management screen however, there is a tick functionality for allowing embedded links to override the preset demand management parameters (open hours, out-of-hours refusal of requests). Customers using these links should be aware that only healthcare professionals should use these on behalf of patients, having made an assessment that the presenting complaint is acceptable for this service and that ticking the override box is appropriate in terms of their risk profile (the box is unticked as a default). They should not send any emergency patients through this route at all (as with the usual product routes). If patients do happen to deteriorate, they should call 111 or generate a hospital visit.

Service monitoring

The practice should nominate a 'Super User' to monitor the system's usage in respect of:
1. Patient Requests and replies from 2-way messaging.
2. Forwarded messages.
3. Covering of work

Practices should also be acutely aware of monitoring their potential requests when they are considering leaving the service or changing their workflows. License expiries or using the NHS App interface can lead to requests being unseen if not properly dealt with. For practices that are considering leaving EC and not reviewing messages in LT, they must contact EHS beforehand to ensure that the patient-facing side of EC is also disabled so requests cannot be missed. For practices using the NHS App, as soon as the DPA is signed, they should monitor the message inbox twice a week just in case patients find a link to their surgery (EHS will also provide automated updates for any outstanding requests).

Restricting access by age

This option is practice configurable as concerns have been raised about the use of Engage Consult for minors. As with the rest of the service, monitoring and timely response is important.

Blocking teenagers is a potential Clinical Safety risk because it can deny adolescents access to services that they may need. This demographic is exceptionally digitally engaged and on-line is their preferred form of communication. To force them to use another channel might dissuade them from seeking advice of a sensitive nature (Sexual health issues, for example). When deciding on any age restrictions the Practice should balance the risks and benefits carefully and accept the responsibility for that decision.

Interpreting patient entered data

There are several aspects of the service that allow a patient to send information to the surgery, ranging from a simple free text admin request to a detailed medical history as part of the Engage Consult Service. Although our service is highly structured, patients might select the wrong answer accidentally or as a result of misunderstanding the intent of the question being asked. Patients are asked to review their answers and confirm their accuracy before submitting a request. Nevertheless, users should consider the need to verify the accuracy and intent of any information presented by the patient that is making a significant contribution on their decision of how to proceed.

Responsibility for Portal Links

The responsibility for the accuracy and appropriateness of any locally defined links, presented to users, remains with the Practice as these are locally configurable within MyEHS.

Responsibility for Notification Text

It is the responsibility of the local Practice to ensure that any locally configured text, notifications, alerts, information, instructions etc, is appropriate and matches the service that they are providing. This includes the “same day response times”, any information that might have been supplied by their CCG, and the default information supplied by the Engage Consult Service. Any local configuration is entirely the responsibility of the practice.

Verification of ID

Verification of user/patient ID is the responsibility of the practice, Engage Consult has a workflow for this that is based on the RCGP guidelines. If practices issue standing orders to their staff to attach Engage Consult Reports directly to patient records in the Principle Clinical System verification of ID remains the responsibility of the practice. This is analogous to any other situation where it is decided to add information to a patient’s electronic medical record, a decision is made that this is appropriate information to add to the specific record. The method of verification is logged and viewable in the LT Reports.

Attaching to record

It is the responsibility of individual Practice staff to ensure that Engage Consult summaries of activity / Reports are attached to the local EMR as soon as is appropriate.

Appropriate Completion of Requests

Requests for help initiate an episode within Encompass LT. Once the documentation of the episode is sent to the GP Clinical System the Practice should ensure that the episode is “completed” appropriately. This will remove it from the general view of messages and also stop users from being able to continue to send messages via 2-way messaging.

2-way messaging

A 2-way messaging function exists to enable messages about individual Requests to be sent and replied to by Practice Staff. This is totally controllable by the Practice and is secure. The system can be used for all users (patients and proxies) who set up an account and it is important that Practice staff take heed of the warnings about the verification status of users when sending messages. We deliberately allow messages to users with a low level of verification as this allows simple messages about the reported request, for instance “We have made an appointment for you at 1400” or “Have you coughed up any blood” to be sent. Practice staff must make sure that they do not reveal any information from the Clinical Record to someone who has not had their identity verified. This is analogous to current telephone or email conversation practice.

It is the responsibility of the practice to make sure that all messages are responded to in a timely fashion plus also the liability from any issues arising from their use of the messaging system. Practices can configure the use of 2-way communications and they are totally under the practice’s control.

Monitoring of access to system and reporting issues.

The service continues to demonstrate a high level of availability. We employ automated test and monitoring techniques, but if a Practice should notice any problems with the availability of a service it is their responsibility to report it as soon as possible.

Use of Encompass LT

The workflow and integration module of Engage Consult, Encompass LT, is designed to be used through our bespoke browser, the Engage Client (formerly ‘Vixie’), it can be accessed via any browser but there will not be any integration without using the Engage Client. This allows remote monitoring of Requests and response to messages, even though there is no integration.

Video/remote Consultations

EC now has the ability to provide video and remote consultation facilities. End-users should be aware of the national guidelines as they progress around video and remote consultations, and amend their utility of the service in line with the guidelines as/if they change. At the time of writing, the latest GMC advice on clinical assessments for remote/video consultations can be found at https://www.gmc-uk.org/-/media/files/key_principles_for_intimate_clinical_assessments_undertaken_remotely_in_response_to_covid19_v1-(1).pdf?la=en&hash=0A7816F6A8DA9240D7FCF5BDF28D5D98F1E7B194.

Information Text and Alerts

Engage Consult provides Information Text and Alert Message functionality. This is not designed to be a replacement for medical overview, or to be a comprehensive automated symptom checker that will flag up every single possibly worrying symptom. Information/self help links are based on NHS choices and other trusted links, and patients are warned in several places not to use the system for emergencies. Practices and local organisations are able to add to or change these links if they wish (via MyEHS). If practices change the links or the information in these alerts, it is **entirely** their own

responsibility for these alerts, EHS does not provide review or bespoke authoring services and any bespoke alerts must be reviewed internally by their clinical teams and signed off in their DCB0160 documentation.

A sample set of Alerts and “did you know” texts are provided and the Practice is able to add to or change these as they wish; again via MyEHS. A practice should not rely on these Alerts to filter out *all* worrying symptoms and should make sure that processes are in place to provide timely responses. The same vigilance should be applied as with telephone requests today. From release 69, practices are able to filter ‘alerts’ raised by patients in one go, through the filter function within the LT interface.

Medical Scales/Tools Utility

Engage Consult uses multiple medical scoring scales and tools as part of the product. These are represented without change in EC and only consist of basic calculations created by the originator of the scales anyway. EC passes the information through to the clinician as any other consultation process.

From a disclaimer perspective, EHS fulfils any and all contractual obligations including disclaimers for any license associated with any particular scale. These disclaimers are highlighted in the EC flow as appropriate. It should also be noted that not all scales may be officially optimised or validated for an electronic version (many are electronic representations of paper copies). As such, any results from the scales communicated by EHS should always be considered by a healthcare professional in the context of the consultation and the final decision on management is their responsibility. Full details of any supporting disclaimer, copyright and information sections on specific scales are given in Appendix A.

Collaboration and Outbound

As of February 2021, EHS, through Engage Consult, will provide additional functionality through ‘Collaboration’ and ‘Outbound’ work. The scope of the collaboration work allows requests to be sent to other third-party groups or services from the usual clinical hub (e.g. a GP practice) that has Engage Consult, for review or actioning. The scope of outbound is that rather than waiting for a patient to initiate contact, a practice can initiate contact to their patients. Practices can contact patients without the patient having contacted them for a number of expected reasons including, but not limited to, questionnaires, health campaigns, vaccinations, QOF reviews and requesting additional information from a previous consult.

There exists some associated risks with this new work (outlined in QA103_PSF0145-0149), but also practice responsibilities that should be recognised. For any collaboration work, practices should have data sharing agreements with any third-parties that they may be sharing patient data with, and should have a rigorous onboarding period with them as well to ensure clear, defined responsibilities and protocols (set up of groups, forwarding/sharing principles etc.). For outbound, as with any patient communication, practices should ensure that messages are appropriate to the patient/patient groups being sent to and that IG is appropriately covered. If any pressing or potentially emergency messages are required, consideration should be given to other channels of communication if time-dependent. Finally, any links or directions to external sources raised in an outbound message is the responsibility of the practice and/or practice user to check that they are relevant and functioning. Patients can of course reply if links are broken or wrong, and the risk here is minimal regardless.

Intended Use and Medical Device Eligibility

Using the MHRA and EU MDR flowcharts/guidelines on software as a medical device, it has been internally assessed as <u>not</u> being a medical device. The evidence behind these statements can be

provided on request. The Intended Use of Engage Consult is a digital front door to General Practice that facilitates communication between Practice Staff and patients. The system itself does not supply any personalised specific or automated advice as standard and does not meet any of the criteria by which medical devices are judged.

However, it is important to note end-users' requirements in respect to authoring Alert messages in maintaining this position. Practices are able to author their own messages for a variety of Alerts and pop-ups in the system. Practices should not however author any of the following in any bespoke message creation:

- Provide specific advice tailored to individual patients
- Provide any information that could be construed as diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease
- Provide any information that could be construed as being different from simple communication or search
- Provide any direction to patients on potential treatment/management except broad signposting to generic websites or resources
- Provides any information that could be filtering symptoms by red flags, severity or probabilities of matches with diseases

Annex B - Engage Touch

This class of service has no significant considerations.

Appendix A - Medical Scales supporting documents

University of Keele

Disclaimer

Keele University, National Institute for Health Research and their affiliates designed the Keele STarT MSK Tool Self-report and Clinical versions for use by health care providers. The Keele STarT MSK Tool was designed to be used to stratify back, neck, knee, shoulder or multi-site pain problems into low, medium and high risk subgroup according to risk of persistent pain and poor physical function.

Whilst any development of the Keele STarT MSK Tool Self-report version can be used by the general public, the Keele STarT MSK Tool was not designed for use by the general public and the results should be interpreted in consultation with a health care practitioner.

Validity of the Tool has been established for a self-reported paper versions of the questionnaire, and we have not yet validated an electronic version. Keele University does not endorse or recommend any of the service providers or third parties who may support or develop the Keele STarT MSK Tool Self-report or Clinical versions in any way.

Information Section

The Keele STarT MSK Tool Self-report and Clinical versions (https://www.keele.ac.uk/startmsk/) are used to profile individual risk of poor prognosis in relation to pain and physical function outcomes at 2 and 6 months. This tool was the innovation of Keele University.

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Oxford University Innovation (OUI)

IP and Copyright (Reproduced from the contractual agreement)

Applies to: Manchester Oxford Foot Questionnaire (MOxFQ), Oxford Hip Score (OHS), Oxford Knee Score (OKS), Oxford Shoulder Score (OSS).

4. Intellectual Property

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