Arden&GEM

NHS
Arden and Greater East Midlands
Commissioning Support Unit

Leicester, Leicestershire and Rutland

Information Sharing Agreement

for the sharing of specified patient information from GP medical records for direct care purposes

between

GP Practices

and

NHS Organisations providing Secondary and Urgent Care

using the
Medical Interoperability Gateway (MIG)

June 2015

This Agreement will be executed in counterparts – it will be signed separately by each participating organisation and returned to Arden and GEM CSU. Each counterpart shall be deemed to be an original document and all of the counterparts taken together shall constitute one single agreement between the participating organisations. A full list of participating organisations will be maintained by the Arden and GEM CSU.

1. INTRODUCTION

1.1 Use of the Medical Interoperability Gateway (MIG) will allow qualified clinicians within participating NHS healthcare providers in Leicester City, Leicestershire and Rutland (LLR) to view patient information, as specified in this Agreement, which is held in a GP Practice clinical information system.

1.2 The MIG is based upon "look-up" technology which provides a read only view of data held within the GP clinical information system.

1.3 This is a local programme developed in line with the national information sharing and integrated care strategy. A key objective of the Department of Health's strategy is that information is recorded once, at first contact with professional staff, and shared securely between those providing care[1]. Key objectives of this local programme are to improve patient care and clinical safety and enhance collaborative working.

1.4 This local MIG programme also supports the recommendations of the Information Governance Review entitled "To Share or Not to Share" (also known as Caldicott 2), which has been endorsed by the Department of Health. Caldicott 2 highlights that healthcare professionals need access to relevant information about a patient in order to act in the patient's best interest. Enabling healthcare professionals to have access to relevant information from the GP records at the point of care, will enhance the care provided to the patient.

1.5 The dataset which will be available to view via the MIG is listed in paragraph 5.2.

1.6 All records will be technically enabled to be accessed by a viewing organisation (unless the patient has opted-out), but the viewing organisation has responsibility to ensure that a record is only accessed by a qualified clinician who has a legitimate relationship with the patient, who needs to access it for the direct care of the patient and where the patient has given explicit consent at the point of care.

1.7 Legally protected and highly sensitive data codes within EMIS Web clinical systems will automatically be excluded) and will not be available via the MIG to viewing organisations (note 1.8 below regarding SystmOne. A nationally defined list of exclusion codes (see Appendix A) will be used. The following is an example of the type of data which will be excluded:

- sexually transmitted infections
- terminations of pregnancy
- IVF treatment and other assisted reproductive technologies
- gender identity disorders and previous gender identity

1.8 Any entry marked as 'private' in an individual patient record within a SystmOne clinical system will not be available via the MIG viewing organisations. There is no automatic exclusion of legally protected or highly sensitive data codes (as in 1.7 above). The GP Practice will need to ensure that legally protected and sensitive data is marked as 'private'.

1.9 The three CCGs across LLR, namely, NHS Leicester City CCG, NHS East Leicestershire and Rutland CCG and NHS West Leicestershire CCG fully support the implementation of the MIG. They recognise the significant potential to improve patient care through the sharing of 'real-time' information from the GP clinical system and help reduce difficulties currently faced when access is not immediately available at the point of care.

[1] The Power of Information: putting all of us in control of the health and care information we need", Department pf Health, May 2012

1.10 This MIG information sharing programme is initially being launched as a one year pilot. If it is deemed successful, it is anticipated that the programme will continue indefinitely (subject to funding being available).

1.11 For purposes of this Agreement the words "data" and "information" are synonymous.

2. PURPOSE AND OBJECTIVES

2.1 Purpose and Objectives of the Information Sharing

2.1.1 The purpose of sharing information via the MIG is to allow GP Practices to share relevant 'real-time' patient information with participating organisations at the point of care.

2.1.2 This sharing will enable approved qualified clinicians (i.e. qualified care professionals responsible for assessment, diagnosis, prescribing, treatment and discharge of a patient) in multiple disciplines to have immediate access to relevant 'real-time' information from the GP clinical system. This will enhance patient care by enabling faster and better informed clinical decisions.

2.1.3 Deployment of the MIG is designed to increase the ability of GP Practices to share relevant patient information for direct care purposes, appropriately, efficiently, effectively, timely, legally and securely.

2.1.4 The MIG is solely for the purpose of direct patient care, by a qualified clinician who has a legitimate relationship with the patient. The use of the MIG for any other purpose is not permitted under this Agreement.

2.2 Purpose of this Agreement (ISA)

2.2.1 This Agreement has been developed to outline the terms and conditions to which signatory organisations must adhere when participating in the MIG information sharing programme.

2.2.2 This Agreement documents the purpose of the data sharing, the legal basis for sharing, the data which will be shared, who can have access, how patient rights and obligations to patients will be met along, with what information security controls will be in place to ensure the confidentiality, integrity, accuracy and availability of information.

2.2.3 This Agreement provides guidance on processes developed to support the MIG information sharing programme for direct care purposes.

2.2.4 Whilst this Agreement (ISA) has been developed in accordance with the Information Commissioner's Office Data Sharing Code of Practice, the ISA in itself does not provide any form of legal indemnity from action under the Data Protection Act 1998 (DPA) or other law. However, it will assist in demonstrating that due consideration, care and attention has been given to ensure compliance with legal obligations.

2.2.5 An organisation can only be included in information sharing via the MIG when they have signed this Agreement.

3. LEGAL BASIS FOR INFORMATION SHARING

3.1 The sharing of information via the MIG must be in accordance with legal requirements designed to protect the privacy, confidentiality and security of patient records.

3.2 Viewing organisations must ensure that all legal requirements have been met before they allow qualified clinicians to view the summary data from the GP record via the MIG.

3.3 The First Data Protection Principle (DPP) requires that "personal data shall be processed fairly and lawfully, and requires that at least one condition from Schedule 2 of the Act must be satisfied. In addition, for sensitive personal data, like healthcare data, at least one condition from Schedule 3 of the Act must be satisfied.

3.4 **Fair Processing –** In order to satisfy the fair processing obligations of the first DPP, GP Practices must take reasonable steps to ensure that all patients in their Practice have access to information about the sharing of information from their GP record with other healthcare providers via the MIG. GP Practices have a legal responsibility to ensure that patients are made aware that they can opt-out and how they can do this.

3.5 The following patient communication activities, as a minimum, will be undertaken in order to meet the fair processing requirements:

- 3.5.1 Posters and leaflets available within the Practice and viewing organisation
- 3.5.2 Inclusion on the Practice and viewing organisation websites
- 3.5.3 Up-to-date fair processing/privacy notices
- 3.5.4 Actively providing information at the time of registration at the Practice
- 3.5.5 Dissemination via local patient groups

3.6 As a minimum, patients must be informed:

- 3.6.1 Why their information will be shared
- 3.6.2 Which organisations their information may be shared with
- 3.6.3 That they have a choice as to whether to enable their records to be viewed, and how to opt-out
- 3.6.4 That their explicit consent must be obtained at the point of care, before the record can be viewed in another organisation (unless in exceptional circumstances as per paragraph 6.3)
- 3.6.5 That particular parts of a record within a SystmOne clinical system may be marked as 'private' and cannot be viewed via the MIG.
- 3.6.6 That there is an exclusion list of highly sensitive and legally restricted codes for all EMIS Web clinical systems (as per Appendix A)
- 3.6.7 How to access personal data held about them and how they find out who has viewed their records.

3.7 **Lawful –** In order to satisfy the lawful requirement of the first DPP, in addition to compliance with all 8 DPPs, organisations participating in the MIG must comply with the Human Rights Act (HRA) and Article 8 of the European Convention of Human Rights (right to respect for private and family life, home and correspondence) and the common law duty of confidentiality (duty not to misuse private information).

Compliance with the terms and conditions of this Agreement should satisfy the lawful processing requirement as it supports the important legitimate aims of increasing information sharing to improve patient care, but restricts access to a qualified clinician at the point of care when the patient has given explicit consent for their record to be viewed.

Schedule 2 of the Act provides a list of conditions, at least one of which must be satisfied. In addition, for sensitive personal data, which includes healthcare information, at least one

condition within Schedule 3 must also be satisfied.

3.8 **DPA Schedule 2 and 3**

3.8.1 Paragraph 1 of Schedule 2 and Schedule 3 of the DPA relates to obtaining patient consent ("The data subject has given his consent to the processing"). Reasonable attempts will be made to ensure that all patients are informed about the MIG information sharing programme and given the option to opt-out of technically enabling their record to be accessed. Therefore it is reasonable to rely on implied consent for the technical enablement. However explicit (informed and recorded) consent is required at the point of care, before a record can be viewed by a qualified clinician who has a direct clinical relationship with the patient, when they need to view it for the direct care of the patient.

3.8.2 Paragraph 4 of Schedule 2 and Paragraph 3 of Schedule 3 of the DPA relates to processing that is necessary in order to protect the vital interests of the patient. It is therefore reasonable to rely on these conditions in exceptional emergency circumstances where a patient is unable to give informed consent because they are unconscious, incoherent or in a life-threatening emergency

3.8.3 Paragraph 6 of Schedule 2 of the DPA can be relied upon – 'The processing is necessary for the purposes of legitimate interests pursued by the data controller or by the third party or parties to whom the data are disclosed, except where the processing is unwarranted in any particular case by reason of prejudice to the rights and freedoms or legitimate interests of the data subject.'

3.8.4 Paragraph 8 of Schedule 3 of the DPA can be relied upon – 'The processing is necessary for medical purposes and is undertaken by:

(a) a health professional, or

(b) a person who in the circumstances owes a duty of confidentiality which is equivalent to that which would arise if that person were a health professional.

In this paragraph "medical purposes" includes the purposes of preventative medicine, medical diagnosis, medical research, the provision of care and treatment and the management of healthcare services.

4. RESPONSIBILITY FOR INFORMATION SHARING

4.1 Each participating organisation (GP Practice or NHS provider organisation, as listed in Appendix B) is a Data Controller with existing responsibilities under the DPA 1998 for all personal information which they process. Each Data Controller is responsible for ensuring that they comply with their existing responsibilities and with those outlined in this Agreement.

4.2 This ISA establishes participating organisations as Data Controllers in Common in relation to the information shared via the MIG. (Further information on Data Controller responsibilities is available in Definitions - Section 16 of this Agreement.)

4.3 When a Data Controller discloses healthcare information to another Data Controller, each still carries full data protection responsibility for their part in the processing of the shared information. Where the disclosing Data Controller (GP Practice) satisfies DPA responsibilities prior to disclosure, they will not carry responsibility for the processing of the disclosed information within the viewing Data Controller organisation. Thus GP Practices are not liable for any breach of confidentiality or data protection breach by a viewing organisation, provided they have fulfilled their own responsibilities under the DPA.

4.4 Healthcare Gateway Ltd, which provides the MIG technical system, will be acting in the capacity of data processor within the meaning of DPA. A contract for the MIG will be in place

between Leicestershire Partnership Trust (LPT) and Health Care Gateway Ltd. LPT acts as contract lead for LLR. This is because LPT Procurement acts on behalf of LLR commissioners for all non-clinical IM&T procurements. However, LPT do not carry responsibility for the other Data Controllers. The contract with the data processing organisation (Healthcare Gateway Ltd) will include the following requirements:

- To have security in place that is equivalent to that imposed on a Data Controller by the seventh Data Protection Principle, that is, appropriate technical and organisational measures shall be taken against unauthorised or unlawful processing of personal data and against accidental loss or destruction of, or damage to, personal data.

- Confidentiality clauses

- To act only in accordance with the instructions received from LLR Better Care Together IM&T Enablement Group on behalf of the Data Controllers.

4.5 With regard to the technical/infrastructure elements of the MIG, this ISA establishes participating organisations as Joint Data Controllers.

4.6 After a GP Practice has signed this ISA, they will enable MIG access to the records of their patients who have not opted out, for other participating NHS provider organisations who have signed this ISA. Practices using EMIS Web, will enable this themselves, whereas Practices using SystmOne, will liaise with TPP regarding the enablement.

4.7 The MIG programme will be governed by the LLR Better Care Together IM&T Enablement Group which will maintain strategic oversight of the MIG. They will co-ordinate and represent the interests of all the participating organisations during the implementation stage and during normal operational use of the MIG after Go Live.

4.8 In the event that governance of the MIG programme switches from the LLR Better Care Together IM&T Enablement to another forum, all participating organisations will be notified, but this will not necessitate resigning of a new version of this Agreement.

4.9 Whilst the LLR CCGs fully support the MIG programme and are the commissioners of this programme, no CCG will have access to the MIG. Therefore, the CCGs are neither Data Controllers nor Data Processors within the meaning of the DPA.

4.10 NHS Arden and Greater East Midlands Commissioning Support Unit (Arden and GEM CSU) will support the implementation of the MIG programme. Their role is purely project delivery and they will not have any access to patient information. Therefore, the Arden and GEM CSU is neither a Data Controller nor a Data Processor within the meaning of the DPA.

4.11 Information available to viewing organisations may not be printed or electronically captured for incorporation into the viewing organisation's clinical records. The viewing qualified clinician may annotate their own records with relevant information from the GP record in accordance with the viewing organisation's own policies and procedures for record keeping.

4.12 All participating organisations agree to adhere to their respective information governance policies, professional codes of conduct and records management requirements in relation to their use of the MIG.

4.13 Participating organisations acknowledge their rights and responsibilities as Data Controllers in Common under this DSA.

5. INFORMATION AVAILABLE

5.1 Included Records

5.1.1 The record of each fully registered patient at the participating GP Practice will be included in the LLR MIG programme, provided that the patient has not chosen to opt out of this information sharing programme and provided that the record bears a fully traced NHS number.

5.1.2 If a patient leaves a participating GP Practice and registers with a Practice that is not a participant of the LLR MIG programme, then their record will not be included in the MIG irrespective of the patient opt-out status.

5.1.3 If a patient leaves a participating GP Practice and registers with a new Practice which is a participant of the MIG programme, their record will be included as soon as the record is 'live' in the new Practice, provided that it bears a fully traced NHS number and provided that an opt-out flag has not been applied. Opt-out status will automatically transfer with the patient record from the leaving Practice to the new Practice.

5.2 Information to be Shared

5.2.1 Data from the GP record are grouped based upon how the data was recorded and coded. The data is presented for viewing via the MIG in a series of ten 'tabs'. The data shared is as follows:

5.2.1.1 **Summary**, consisting of:
- Current problems
- Current medications
- Allergies
- Recent tests.

5.2.1.2 **Patient Details,** consisting of
- NHS number
- Full name and address
- GP details

5.2.1.3 **Problems,** consisting of:
- Current problems
- Past problems

5.2.1.4 **Diagnosis**, consisting of
- Current diagnosis
- Past diagnosis

5.2.1.5 **Medication,** consisting of**:**
- Current medication
- Past medication
- Medication issues

5.2.1.6 **Risks and Warnings**, consisting of:
- Allergies and Adverse Reactions
- Contraindication

5.2.1.7 **Procedures**, consisting of:
- Operations
- Immunisations/Vaccinations

5.2.1.8 **Investigations**, consisting of:
- Recent tests (previous 3 months)
- Biochemistry
- ECG
- Haematology
- Imaging
- Microbiology
- Cytology
- Physiology
- Urinalysis
- Others not mentioned

5.2.1.9 **Examinations**, consisting of:
- Blood Pressures

5.2.1.10 **Events**, consisting of:
- Encounters
- Admissions
- Referrals

5.3 Excluded Information

5.3.1 Free text consultation notes will not be included.

5.3.2 EMIS Web systems - legally protected and highly sensitive data in the following categories will automatically be excluded from the MIG, using a nationally defined list (see Appendix A):
- IVF, fertility treatment and embryology[2]
- Venereal disease and sexually transmitted diseases[3]
- Gender realignment[4]
- HIV/Aids
- Termination of pregnancy

5.3.3 Any data which is sealed as 'private' within a record within a SystmOne clinical system.

5.3.4 Users of the MIG must be made aware of the exclusion list applicable to EMIS Web clinical systems and have easy access to it. The exclusion list will be made available to patients upon request. Users must also be made aware that information sealed as 'private' within a SystmOne clinical system will not be available via the MIG.

5.4 Information Quality

5.4.1 **Accuracy**

5.4.1.1 All GP Practices have existing responsibilities to ensure that information they record in their clinical information systems is accurate and, where necessary, kept up to date (as required by DPA, Principle 4). All GP Practices will ensure that they have processes in place to ensure the accuracy of information that they share.

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2 Legally restricted by Human Fertilisation Act 1990 as amended by the Human Fertilisation and Embryology (Disclosure of Information) Act 1992

3 Legally restricted by NHS Trusts and Primary Care Trusts [Sexually Transmitted Diseases] Directions 2000

4 Legally restricted by Gender Recognition Act 2004

The method by which a GP Practice fulfils this requirement remains an individual choice; they can for example run audits to identify anomalies in data, such as, where a patient is on a chronic diseases register but there is no read code recorded to show this as an active or past problem.

5.4.1.2 Each viewing organisation remains responsible for any decisions taken within their organisation in reliance upon information from the GP record viewed via the MIG. Using the same principles as the national Summary Care Record, it is incumbent upon the viewing qualified clinician to validate the viewed information with the patient or other source as appropriate, as information is provided in good faith but its accuracy, as with any health record, cannot be guaranteed.

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5.4.2 **Data Conflict**
The lookup technology used by the MIG will have inbuilt validation controls to ensure that there is no technical interference or corruption during transmission.

5.4.3 **Timeliness**
To be of most value, and to enable access to up-to-date GP clinical information, such information should be recorded in the GP Practice system in a timely manner.

5.4.4 **Relevance**
It is a requirement of the DPA that only relevant information from the GP records is shared with relevant third parties, including other healthcare providers. Under the MIG programme, the full GP record is not being shared as this may not be proportionate in all circumstances.

5.4.5 **Retention**
As the MIG information sharing programme is view only, and it is not permitted to print or otherwise electronically capture information for incorporation into a Provider Trust's healthcare records, retention in accordance with DPA requirements in relation to this programme is not applicable.

6. CONSENT PROCESS

6.1 **Stage 1 –- Technical enablement of records to be shared via the MIG**

6.1.1 GP Practices are already required to provide information to patients explaining how their data will be used and what to do if they have any concerns or objections. GP Practices are required to make reasonable efforts to inform their patients about the MIG programme and give them an opportunity to opt out if they do not wish their records to be technically enabled for sharing via the MIG with other healthcare provider organisations (as already outlined in paragraphs 3.4 to 3.6).

6.1.2 Each GP Practice will assess all opt-out requests via the Practice's internal opt-out review process, discuss with the patient or a representative with legal powers of responsibility (such as parental responsibility, Power of Attorney for Health and Welfare) as appropriate and update the patient record accordingly.

6.1.3 Where a patient changes their mind about their opt-out status, the GP Practice will action all change requests promptly and within a maximum of 48 hours of receipt of the request.

6.1.4 Where a patient objects to their data being enabled for viewing via the MIG (even though it is subject to explicit consent at the point of care), the GP Practice should activate the MIG opt-out flag in their clinical system.

6.1.5 It is the responsibility of the GP Practice to review opt-out requests before they are actioned to ensure there is no conflict with the patient's best interests. This is in accordance with a healthcare professional's duty to ensure the safe and effective care of an individual. GP Practices will deal with this in accordance with the GMC Confidentiality Guidance for Doctors[5] and the Health and Social Care Information Centre's guide to confidentiality in health and social care, 2013[6].

6.2 **Stage 2 –- Permission to view information via the MIG**

6.2.1 Where a record is available via the MIG and it is necessary for a qualified clinician with a legitimate relationship with the patient to view the record for the direct care of the patient, explicit consent must be sought and recorded at the point of care, on every occasion. This is the responsibility of the viewing organisation.

Explicit consent is specific permission to view the GP record in response to a direct question to the patient. The answer must be clear and unmistakable. The consent must be voluntary and informed, and the person consenting must have the capacity to make the decision.

For consent to be informed, the patient must be provided with details of what information will be viewed, why it is necessary and that they have the option to decline. The significance of dissent should be explained to the patient.
(See further clarification on explicit consent in Section 16 of this Agreement – Definitions.)

6.2.2 Only a qualified clinician (i.e. a qualified professional responsible for assessment, diagnosis, prescribing, treatment and discharge of a patient) who has a legitimate clinical relationship with the patient), can view the GP record via the MIG, when they need to do so for the direct care of the patient.

6.2.3 Where a person with capacity (in accordance with the Mental Capacity Act 2005) does not give consent for their GP record to be viewed via the MIG, even after an explanation of the possible consequences, their decision should be respected.

6.2.4 Inappropriate viewing of the GP record will be regarded as a disciplinary offence and subject to disciplinary proceedings by the employing organisation.

[5] GMC Confidentiality Guidance for Doctors, 2009, paragraphs 51-52
http://www.gmc-uk.org/static/documents/content/Confidentiality_0513_Revised.pdf

[6] Health and Social Care Information Centre - A guide to confidentiality in health and social care, 2013, Rule 2.
http://www.hscic.gov.uk/media/12822/Guide-to-confidentiality-in-health-and-social-care/pdf/HSCIC-guide-to-confidentiality.pdf

6.3 **Who can give or withhold Consent**

6.3.1 A person with capacity in accordance with the Mental Capacity Act 2005 - the person must be capable of giving consent, which means they understand the information given to them, and they can use it to make an informed decision.

6.3.2 Anyone with parental responsibility for a child (under 16 years old), or with other legal powers of responsibility for an individual (such as Power of Attorney for Health and Welfare).

6.3.3 Those with parental responsibility for a child (under 16 years) who is mature enough to make decisions, should discuss this with their child and allow them to make their own decision, or involve them in the decision, where appropriate for them to do so.

6.4 **Withdrawal of Consent**

Patients have the right to change their mind at any stage about whether or not they wish their records to be available for access via the MIG. Where patients wish to change their mind, they should contact their GP Practice as it is the Practice that controls the enablement of viewing via the MIG. Patients may also withhold explicit consent, at the point of care, from any clinician that they do not wish to view their record.

6.5 **Exceptional Circumstance – Consent Override**

6.5.1 Where a GP record is available to view via the MIG and it is necessary to view it for the direct care of the patient, in exceptional circumstances, a qualified clinician may override the requirement to obtain explicit consent to view, that is, where a patient is unable to give informed consent because they are unconscious or in a life-threatening emergency.

6.5.2 In such circumstances where it is necessary to override standard consent requirements, the qualified clinician must record the reason for doing so.

6.5.3 All instances of consent override will generate an alert. Such instances of consent override will be reviewed and validated by the viewing organisation as part of their privacy impact measures.

7. SECURITY

7.1 In signing this Agreement, all participating organisations confirm that security measures will be in place to comply with the 7th data protection principle, which is to have appropriate technical and organisational measures against unauthorised or unlawful processing of personal confidential data and against accidental loss or destruction of, or damage to, personal data.

7.2 **Mandatory Safeguards** with which all participating organisations must comply, as a minimum:

7.2.1 the patient's explicit consent must be obtained and recorded before the GP patient record is accessed (unless in an exceptional circumstance – where a patient is unable to give informed explicit consent because they are unconscious or in a life-threatening emergency);

7.2.2 patient must be registered for treatment in the Provider Trust before the GP record is viewed via the MIG;

7.2.3 unauthorised staff or other individuals must be prevented from gaining access to the GP record via the MIG;

7.2.4 staff who view the shared information must receive appropriate training so that they understand the risks surrounding information security and what safeguards they can take to protect information, in accordance with existing obligations;

7.2.5 all organisations must ensure that staff understand and comply with the MIG consent process;

7.2.6 ensure that staff are aware of the data available via the MIG; and in particular are aware of the excluded data list for EMIS Web and the fact that anything marked as 'private' within SystmOne will not be available to view;

7.2.7 ensure that staff are aware that information should not be printed from the MIG or otherwise captured electronically and incorporated into their own healthcare records. They should be given guidance on the annotation of information from the MIG into their own records in accordance with the Provider Trust's record keeping policy;

7.2.8 ensure that access to the MIG is treated in accordance with their respective information governance policies and professional codes of conduct;

7.2.9 ensure that appropriate Human Resources disciplinary procedures are in place to deal with staff responsible for a personal data breach incident and all staff are made fully aware of the consequences of misuse of access to the GP record via the MIG. Inappropriate viewing of GP records via the MIG must be considered a disciplinary offence and staff must be made well are of this.

7.2.10 All participating organisations are required to complete their NHS Information Governance Toolkit annually and demonstrate a minimum of Level 2 compliance against the standards relevant to their organisation.

7.2.11 All participating organisations will adhere to the terms of the NHS Information Governance Statement of Assurance (which is the final part of the Information Governance Toolkit submission). This is in accordance with the existing terms and conditions of having an N3 connection and does not imposed additional requirements.

7.3 **Access control** - the requirements for access control for the MIG are similar to that used for role/position based access for national systems. As a minimum, they will consist of the following:

7.3.1 Only qualified clinicians *(*i.e. qualified care professionals responsible for assessment, diagnosis, prescribing, treatment and discharge of a patient) will be granted access to the GP record via the MIG;

7.3.2 staff identity and job role will be subject to verification tests consistent with Registration Authority checks, i.e. provide proof of identity and job role and have access requirements validated, by the employing organisation;

7.3.3 staff will not be granted access until they have agreed to the terms and conditions of MIG use and have undergone training especially around compliance with the consent model, within their employing organisation;

7.3.4 a full audit trail of access to the MIG and the data viewed will be maintained;

7.3.5 audits of access and legitimate relationships will be undertaken by participating organisations. An audit report (including findings and recommendations) will be submitted to the LLR Better Care Together IM&T Enablement Group on an annual basis, or sooner upon request, by each viewing organisation;

7.3.6 every instance of access which invoked consent override will be reviewed and validated by the viewing organisation. A report (including findings and recommendations) will be submitted to the LLR Better Care Together IM&T Enablement Group on an annual basis, or sooner upon request, by each viewing organisation.

7.4 **System Security**
The System Supplier will be required to ensure:

7.4.1 digital transmission is encrypted to minimum NHS standards.
7.4.2 The GP Practice will be provided with a full audit trail of what is viewed, by whom and when;
7.4.3 A system alert will be generated every time the consent override option is invoked.
7.4.4 MIG access to the GP record is only available through an N3 connection;
7.4.5 the technical solution will meet NHS Health and Social Care Information Centre Interoperability Toolkit (ITK) v1 and v2 and HL7 interoperability, along with ISO27001 Information Security Management System standards;
7.4.6 The MIG will be compliant with web standards based on the ITK guidelines such as WS-Security, WS-Addressing, XMLDSig.

8. BREACH

8.1 In the event of any suspected breach of confidentiality, or any other information governance breach, the organisation identifying the breach or potential breach, will immediately instigate an investigation following their existing Incident Reporting Policy and procedures.

8.2 Where the GP Practice identifies a suspected breach of confidentiality within a viewing organisation, that organisation must co-operate fully with any request from the GP Practice for information and/or undertake an investigation when requested to do so by the GP Practice.

8.3 Any investigation into a breach should be consistent with the current national requirements for incident reporting. At the time of writing this Agreement the current requirements are contained in the HSCIC document "Checklist Guidance for Reporting, Managing and Investigating Information Governance Serious Incidents Requiring Investigation" issued in June 2013, v2.0.

8.4 The identifying organisation will notify other affected organisations as appropriate. In particular the relevant GP Practice must be informed.

8.5 The identifying organisation must also inform the LLR Better Care Together IM&T Enablement Group which will monitor investigation progress and agree closure.

9. REQUESTS FOR DISCLOSURE OF INFORMATION

9.1 All recorded information held by public sector bodies is subject to the provisions of the Freedom of Information Act 2000 and the Data Protection Act 1998. Each organisation will continue to process requests in accordance with their statutory obligations under the Acts, as they currently do.

9.2 Subject access requests relating to the MIG information sharing programme will be processed by the patient's GP Practice. Patients will be advised of this via the information made available to them regarding the MIG and via 'fair processing/privacy' notices.

9.3 Organisations should provide reasonable assistance to the requestor if it is apparent that requests need to be made to other organisations.

10. COMPLAINTS

10.1 In the event that a patient has cause to complain about any aspect of the processing of their information via the MIG information sharing programme, they will be advised to direct any complaint to the GP Practice in the first instance. However, patients also have the option to make a complaint directly to NHS England, or they may choose to make a complaint to the Provider Trust.

10.2 Each GP Practice or provider organisation will deal with any complaints fairly and efficiently, in accordance their own Complaints Policy and the NHS Complaints Procedure[7].

10.3 Patients will be informed about the Complaints procedure in fair processing/privacy notices.

10.4 GP Practices and provider organisations will provide anonymised summary reports on MIG-related complaints, investigation outcomes and resolution to the LLR Better Care Together IM&T Enablement Group on annual basis, or sooner if requested.

11. REVIEW OF AGREEMENT

11.1 The Agreement will be reviewed on or before the first anniversary of issue. Thereafter, it will be reviewed at least bi-annually or sooner should circumstances warrant it.

11.2 As a minimum, each review will examine whether:

- 11.2.1 the sharing of information is having the desired effect;
- 11.2.2 access controls are appropriate and effective;
- 11.2.3 fair processing notices still provide an accurate explanation of the information sharing activity;
- 11.2.4 patients are able to access all the information they are entitled to;
- 11.2.5 all participating organisations are meeting agreed quality standards;
- 11.2.6 security remains adequate and whether any security breaches have been investigated and acted upon;
- 11.2.7 that the LLR Better Care Together IM&T Enablement Group is receiving audit reports on legitimate relationship user access and consent override (as per paragraphs 7.3.5 and 7.3.6).

11.3 This Agreement will remain in force until it becomes necessary to issue a revised version, for example because of legislative change; change in national or local policy; or because of changes that result from a scheduled or other ad hoc review.

12. TERMINATION OR SUSPENSION OF AGREEMENT

12.1 An organisation may withdraw from the MIG information sharing programme and terminate their participation in this Agreement.

- 12.1.1 Where the withdrawing organisation is a GP Practice, they should give notice of such intention in writing, to the LLR Better Care Together IM&T Enablement Group. This

[7] Local authority Social Services and National Health Service Complaints (England) Regulations 2009

NHS complaints procedures in England - Parliament - www.parliament.**uk**/briefing-papers/sn05401.pdf

Group will in turn inform all viewing organisations that are signatories of this Agreement.

12.1.2 Where the withdrawing organisation is a viewing organisation, they should give notice of such intention in writing, to the LLR Better Care Together IM&T Enablement Group. This Group will in turn inform all GP Practice signatories of this Agreement.

12.2 Any participating organisation can suspend this Agreement if security has been seriously breached, until such time as they are satisfied that an investigation has been carried out and measures have been taken to minimise the possibility of recurrence.

12.2.1 Where the organisation wishing to suspend is a GP Practice, they should give notice of such intention in writing, to the LLR Better Care Together IM&T Enablement Group. This Group will in turn inform all viewing organisations that are signatories of this Agreement.

12.2.2 Where the withdrawing organisation is a viewing organisation, they should give notice of such intention in writing, to the LLR Better Care Together IM&T Enablement Group. This Group will in turn inform all GP Practice signatories of this Agreement.

12.3 Conversely, if an organisation does not comply with the terms and conditions of this Agreement, they may be excluded from further participation until such time as adequate assurances have been gained. Such suspension will be approved and actioned by the LLR Better Care Together IM&T Enablement Group.

12.4 In the event the MIG information sharing programme is discontinued, the LLR Better Care Together IM&T Enablement Group will inform all signatory organisations and initiate decommissioning procedures.

13. DISPUTE RESOLUTION

13.1 If any dispute arises out of, or in connection with, this Agreement the parties in dispute shall first attempt to settle it by either of them making a written negotiation offer to the other and;

13.1.1 During the first seven days following receipt of the first such offer each of the parties shall negotiate and be represented by a senior person who has not had any day to day involvement in the MIG information sharing programme and who has authority to settle the dispute, and

13.1.2 During the next seven days the parties will be represented by their chief executive, director, board member or senior partner who has authority to settle the dispute.

13.2 No party, where practicable, will be represented by the same person under paragraphs 13.1.1 and 13.1.2.

13.3 If the parties in dispute are unable to settle the dispute by negotiation, the dispute will then be referred to the LLR Better Care Together IM&T Enablement Group who will make reasonable endeavours to resolve the dispute within a further 14 days.

13.4 If the LLR Better Care Together IM&T Enablement Group are unable to resolve the matter the parties shall within a further 7 days submit the dispute to mediation by the Centre for Effective Dispute Resolution (CEDR) or another independent body or organisation providing mediation services as agreed between the parties, such agreement not to be unreasonably withheld.

14. ADDITIONAL PARTICIPATING ORGANISATIONS

14.1 New organisations that provide NHS healthcare may wish to join the MIG information sharing programme. All such applications must be processed via the LLR Better Care Together IM&T Enablement Group. Initial approval to join must be obtained from a data controller group representing the GP Practices.

14.2 All current signatories of the MIG Information Sharing Agreement will be notified of the intention to add a new organisation and given an opportunity to raise an objection. Final approval to participate will be given by the LLR Better Care Together IM&T Enablement Group. It will not be necessary to re-sign this Agreement if a new organisation is approved provided this process is followed. Arden and GEM CSU will maintain an up-to-date register of signatories.

15. SIGNATURE

It is required that this Agreement is signed by the **Caldicott Guardian or other executive member** of each participating organisation (GP Practice and Viewing Provider organisation).

I, the undersigned, have read this Information Sharing Agreement and on behalf of my organisation, I agree to implement and abide by the terms and conditions outlined within it.

Signature: *(Caldicott Guardian or executive member of staff)	
Printed Name:	
Job Title:	
Organisation name and address:	
Date:	

The signed Agreement should be returned to:

imtpmo@lcr.nhs.uk

16. DEFINITIONS

Direct Care Purpose	That which directly contributes to the diagnosis, care and treatment of an individual.
Data Controller	A person/organisation who (either alone or jointly or in common with other persons) determines the purposes for which and the manner in which any personal data are, or are to be processed.
Data Controllers in Common	Data Controllers in Common share a pool of personal data but they process it independently of the other Data Controllers.
Joint Data Controllers	In relation to data controllers, the term jointly is used where two or more persons (usually organisations) act together to decide the purpose and manner of any data processing.
Data Processor	Any person/organisation (other than an employee of the data controller) that processes the data on behalf of the data controller. The data processor must only act upon the instructions of the data controller and cannot decide the purpose and manner of any data processing.
Explicit Consent	Explicit consent is specific permission to view the GP record in response to a direct question to the patient. The answer must be clear and unmistakable. The consent must be voluntary and informed, and the person consenting must have the capacity to make the decision. The permission must be voluntary and informed, and the person consenting must have the capacity to make the decision. • **Voluntary** – the decision to either consent or not to consent must be made by the person themselves, and must not be influenced by pressure from medical staff, friends or family. • **Informed** – the person must have been provided with all of the information about the information that will be shared, all including the benefits and risks. • **Capacity** – the person must be capable of giving consent, which means they understand the information given to them, and they can use it to make an informed decision.
Legitimate relationship	Where a qualified clinician is providing direct care for the patient. The patient must be registered for care in the viewing organisation.
N3 Connection	The NHS private Wide Area IP Network (WAN), connecting many different sites across the NHS within England & Scotland. It also connects to other networks via Gateways, notably to the Internet via the Internet Gateway.
Qualified clinician	Qualified care professionals responsible for assessment, diagnosis, prescribing, treatment and discharge of a patient

17. APPENDIX A – Data Excluded From Viewing via the MIG EMIS Web Systems only

Legally restricted and highly sensitive data, excluded from the MIG

1 HSA1-therap. Abort. Green form
2 h/o venereal disease
3 Hysterotomy and termination of pregnancy
4 Dilation cervix uteri & curettage products conception uterus
5 Curettage of products of conception from uterus NEC
6 Suction termination of pregnancy
7 Dilation of cervix and extraction termination of pregnancy
8 Termination of pregnancy NEC
9 Cervical Smear - Wart Virus
10 Gonorrhoea carrier
11 Venereal disease carrier NOS
12 AIDS carrier
13 Notification of AIDS
14 Introduction of abortifacient into uterine cavity
15 Treatment for infertility
16 Genital herpes simplex
17 Viral hepatitis B with coma
18 Viral (serum) hepatitis B
19 Viral hepatitis C with coma
20 Viral hepatitis C without mention on hepatic coma
21 Chronic viral hepatitis
22 Unspecified viral hepatitis
23 Cytomegaloviral hepatitis
24 Acquired immune deficiency syndrome
25 Human immunodef virus resulting in other disease
26 HIV disease resulting in cytomegaloviral disease
27 Chlamydial infection
28 Chlamydial infection of lower genitourinary tract
29 Chlamydial infection of anus and rectum
30 Chlamydial infection of pelviperitoneum oth genitourinary organs
31 Chlamydial infection, unspecified
32 Chlamydial infection of genitourinary tract, unspecified
33 Human papilloma virus infection
34 Papillomavirus as a cause of diseases classif to oth chapters
35 Syphilis and other venereal diseases
36 Trichomoniasis - trichomonas
37 Phthirus pubis - public lice
38 HIV disease resulting/other infection+parasitic diseases

39 Gender role disorder of adolescent or adult
40 Dementia in human immunodef virus (HIV) disease
41 Gender identity disorders
42 [Gender identity disorder, unspecified
43 Cystitis in gonorrhoea
44 Prostatitis in gonorrhoea
45 Prostatitis in tichomoniasis
46 Chlamydial epididymitis
47 Female chlamydial pelvis inflammatory disease
48 Chlamydia cervicitis
49 Legally induced abortion
50 Illegally induced abortion
51 Unspecified abortion
52 Failed attempted abortion
53 Complications following abortion/ectopic/molar pregnancies
54 Other specified pregnancy with abortive outcome
55 Pregnancy with abortive outcome NOS
56 Maternal syphilis in pregnancy/childbirth/puerperium
57 Maternal gonorrhoea during pregnancy/childbirth/puerperium
58 Other venereal diseases in pregnancy/childbirth/puerperium
59 Laboratory evidence of HIV
60 Complications associated with artificial fertilization
61 Asymptomatic human immunodeficency virus infection status
62 Hepatitis B carrier
63 Hepatitis C carrier
64 Pregnancy with history of infertility
65 Admission for administration of abortifacient
66 In vitro fertilization

18. APPENDIX B – PARTICIPATING ORGANISATIONS

1. University Hospitals of Leicester NHS Trust

2. Leicestershire Partnership NHS Trust

3. Northern Doctors Urgent Care Ltd;
    - Oadby and Wigston Walk-in Medical Centre –
    - Melton Mowbray Hospital Minor Injury and Illness Service
    - Market Harborough Minor Injury and Illness Unit
    - Rutland Memorial Hospital Minor Injury and Illness Unit

4. Central Nottingham Clinical Services –
    - LLR Out of Hours Service
    - Urgent Care Centre, Leicester

5. Derbyshire Health United – NHS 111

6. East Midlands Ambulance Service NHS Trust

7. George Eliot Hospital NHS Trust – Urgent Care Centre, Loughborough

8. SSAFA Care Community Interest Company – Merlyn Vaz Centre Walk in

19. APPENDIX C – DATA PROTECTION PRINCIPLES

Schedule 1 to the Data Protection Act 1998 lists the data protection principles in the following terms:

1. Personal data shall be processed fairly and lawfully and, in particular, shall not be processed unless –

   (a) at least one of the conditions in Schedule 2 is met, and

   (b) in the case of sensitive personal data, at least one of the conditions in Schedule 3 is also met.

2. Personal data shall be obtained only for one or more specified and lawful purposes, and shall not be further processed in any manner incompatible with that purpose or those purposes.

3. Personal data shall be adequate, relevant and not excessive in relation to the purpose or purposes for which they are processed.

4. Personal data shall be accurate and, where necessary, kept up to date.

5. Personal data processed for any purpose or purposes shall not be kept for longer than is necessary for that purpose or those purposes.

6. Personal data shall be processed in accordance with the rights of data subjects under this Act.

7. Appropriate technical and organisational measures shall be taken against unauthorised or unlawful processing of personal data and against accidental loss or destruction of, or damage to, personal data.

8. Personal data shall not be transferred to a country or territory outside the European Economic Area unless that country or territory ensures an adequate level of protection for the rights and freedoms of data subjects in relation to the processing of personal data.

20. APPENDIX D – DOCUMENT CONTROL

Document Creation			
Date	**Author**	**Version**	Description
03/03/15	Marie Matthews, Information Governance Consultant, Arden & GEM CSU	0.0.1	This is a subject specific Information Sharing Agreement (as opposed to an overarching protocol). Created following discussions with the Arden and GEM project team and management and based upon documents and information supplied about the MIG programme.
05/03/15	Marie Matthews	0.0.2	Document has been tweaked and additional clarification added in response to answers/feedback from reviewers
18/03/15	Marie Matthews	0.0.3	Clarifications added following discussion at LLR Better Care Together IM&T Enablement Group 12/3/15 and further discussions within the Information Governance Team.
14/4/15	Marie Matthews	0.0.4	No amendments other than the updating of this document control sheet and date, following approval in principle by CCG Caldicott Guardians. Version 0.0.4 for submission to LMC.
12/06/15	Lynne Wray	1.0	Draft watermark removed and for issuing to LLR GP Caldicott Guardians w/b 15/06/15.

Reviewers	
This document has been reviewed by the following	
Byron Charlton	Information Governance Consultant, Arden and GEM CSU
Lisa Wakeford	Head of Information Governance Services, Arden and GEM CSU
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Vikesh Tailor	Head of Systems Enablement, Arden and GEM CSU
Sue Cooke	Head of Strategy & Systems Enablement (Lead), Arden and GEM CSU
LLR Better Care Together IM&T Enablement Group	12 March 2015
Caroline Trevithick, Carmel O'Brien, Dawn Leese	CCG Caldicott Guardians (West Leicester CCG, East Leicester and Rutland CCG and Leicester CCG, respectively)