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I CONSENT TO EVERYTHING

Consent is invariably central to a clinician's discussion with a patient. Professional regulators set out guidance on how to comply. The GMC in their detailed 2008 "Guidance on Consent" state in the opening paragraphs:

If patients have capacity to make decisions for themselves, a basic model applies:

The doctor uses specialist knowledge and experience and clinical judgement, and the patient's views and understanding of their condition, to identify which investigations or treatments are likely to result in overall benefit for the patient. The doctor explains the options to the patient, setting out the potential benefits, risks, burdens and side effects of each option, including the option to have no treatment. The doctor may recommend a particular option which they believe to be best for the patient, but they must not put pressure on the patient to accept their advice.

Many clinicians make a presumption that having ensured a patient has given consent to treatment this is also consent by the patient to process the patient's personal data and this provides a lawful basis to process that data. The result of this presumption is usually an invalid lawful basis and a breach of GDPR.

This article examines the lawful bases for processing data under GDPR, why consent is not an appropriate lawful basis and which lawful basis a clinician should rely on for the processing of personal data.

The Law on Consent to Process

The current law on processing personal data is governed by the General Data Protection Regulations 2016 (GDPR) and the Data Protection Act 2018.

Organisations need to process (use) personal data of patients and to do so the starting point is a lawful basis which could also be called a lawful reason.

Processing includes any operation which is performed on personal data such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, erasure or destruction.

To process the personal data the controller needs a lawful basis. The controller will be the organisation itself but in a small GP Practice the controller will be the partners. The lawful basis often chosen is consent.

Article 6 of GDPR sets these out and in respect of consent states:

“the data subject has given consent to the processing of his or her personal data for one or more specific purposes.”

In addition, article 7 states:

- 1. Where processing is based on consent, the controller shall be able to demonstrate that the data subject has consented to processing of his or her personal data.*
- 2. If the data subject's consent is given in the context of a written declaration which also concerns other matters, the request for consent shall be presented in a manner which is clearly distinguishable from the other matters, in an intelligible and easily accessible form, using clear and plain language. Any part of such a declaration which constitutes an infringement of this Regulation shall not be binding.*
- 3. The data subject shall have the right to withdraw his or her consent at any time. The withdrawal of consent shall not affect the lawfulness of processing based on consent before its withdrawal. Prior to giving consent, the data subject shall be informed thereof. It shall be as easy to withdraw as to give consent.*
- 4. When assessing whether consent is freely given, utmost account shall be taken of whether, inter alia, the performance of a contract, including the provision of a service, is conditional on consent to the processing of personal data that is not necessary for the performance of that contract.*

Further guidance is provided in the Recitals to GDPR;

Recital 32 - Consent should be given by a clear affirmative act establishing a freely given, specific, informed and unambiguous indication of the data subject's agreement to the processing of personal data relating to him or her, such as by a written statement, including by electronic means, or an oral statement.

Recital 43 - In order to ensure that consent is freely given, consent should not provide a valid legal ground for the processing of personal data in a specific case where there is a clear imbalance between the data subject and the controller, in particular where the controller is a public authority and it is therefore unlikely that consent was freely given in all the circumstances of that specific situation. Consent is presumed not to be freely given if it does not allow separate consent to be given to different personal data processing operations despite it being appropriate in the individual case, or if the performance of a contract, including the provision of a service, is dependent on the consent despite such consent not being necessary for such performance.

GDPR requires an additional hurdle or second lawful basis for the processing of special category data which includes data on health. In article 9.1 (a) explicit consent is provided as

a lawful basis for processing special category data and this is often relied on by the health sector.

What does all this mean?

1. Consent by a patient (data subject) to process their personal data under GDPR must be a clear affirmative act which is specific to the personal data and specific to the processing operation. If there are several different processing operations then there needs to be consent to each one. Importantly if a patient is consenting to treatment they are not at the same time consenting to the processing of their personal data.
2. The patient must be told prior to giving the consent that they can withdraw the consent at any time.
3. If there is an imbalance between the patient and the controller it is unlikely consent to process personal data can be freely given.

Before any decision is reached from a consideration of the law let us also review guidance by the Information Commissioners Office (ICO).

ICO Guidance

The ICO has provided guidance as to how they will interpret consent under GDPR. Extracts from this guidance are of special interest when considering a patient's consent to process data:

1. *It follows that if for any reason you cannot offer people a genuine choice over how you use their data, consent will not be the appropriate basis for processing. This may be the case if, for example:*
 - *you would still process the data on a different lawful basis if consent were refused or withdrawn;*
 - *you ask for 'consent' to the processing as a precondition of accessing your services; or*
 - *you are in a position of power over the individual – for example, if you are a public authority or an employer processing employee data.*
2. *If you would still process the personal data on a different lawful basis even if consent were refused or withdrawn, then seeking consent from the individual is misleading and inherently unfair. It presents the individual with a false choice and only the illusion of control. You must identify the most appropriate lawful basis from the start.*
3. *Consent will not usually be appropriate if there is a clear imbalance of power between you and the individual. This is because those who depend on your services, or fear adverse consequences, might feel they have no choice but to agree – so consent is not considered freely given. This will be a particular issue for public authorities and employers.*

4. *If you are a public authority or are processing employee data, or are in any other position of power over an individual, you should look for another basis for processing, such as 'public task' or 'legitimate interests'.*
5. *If you rely on consent, this will affect individuals' rights. People will generally have stronger rights when processing is based on consent – for example, the right to erasure (also known as the right to be forgotten) and the right to data portability.*

Is Consent the Appropriate Lawful Basis?

The short answer is no. A clinician or controller should consider when processing personal data of a patient:

1. Are we able to ensure specific, and granular consent to all the processing operations on personal data or will this not be possible when trying to ensure there is full and informed consent to treatment and care?
2. Is the fact that the patient wishes to access treatment and will feel they must consent to the processing of their personal data for the access to be given such that there is an imbalance of power; meaning that the consent is not freely given? With regards to imbalance the Information Governance Alliance have commented - “*With this in mind, consent assumed or obtained in the context of health or care provision is unlikely to establish a lawful basis under the GDPR*”
3. Could we still process the personal data if the patient refused consent or withdrew consent? The answer is that you can and therefore using consent is misleading and unfair. It is not providing the patient with a valid choice. This should be contrasted with consent to treatment in that if the patient refuses then, except in unusual circumstances, the patient's decision will prevail.

Which Lawful Basis to Use.

In the patient/clinician relationship, consent to process personal data is usually an inappropriate lawful basis and should be avoided. The appropriate lawful bases to consider are:

1. Article 6.1 (e) - *processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller.* This will invariably be the most appropriate lawful basis for any clinician working in any public authority or organisation with a similar authority.
2. Article 6.1 (b) - *processing is necessary for the performance of a contract to which the data subject is party or in order to take steps at the request of the data subject prior to entering into a contract.* This will be appropriate for any private or non NHS work and should also be included in any Privacy Policy even where the clinician or controller could use the public interest lawful basis.

3. Article 6.1 (f) - *processing is necessary for the purposes of the legitimate interests pursued by the controller or by a third party, except where such interests are overridden by the interests or fundamental rights and freedoms of the data subject which require protection of personal data, in particular where the data subject is a child.* This is unlikely to apply in public authority and will be more appropriate to clinicians who cannot use public interest as the lawful basis.
4. For special category data Article 9.1 (f) - *processing is necessary for the purposes of preventive or occupational medicine, for the assessment of the working capacity of the employee, medical diagnosis, the provision of health or social care or treatment or the management of health or social care systems and services on the basis of Union or Member State law or pursuant to contract with a health professional.*

Is Consent Still Relevant?

Consent remains important in the clinician/patient relationship:

- It is central to the decision making on treatment and care.
- It can be the appropriate lawful basis for processing personal data when no other lawful basis is available.
- It is important when asking for a release from confidentiality.

However, the availability of other lawful bases to process personal data, which are often far easier to comply with, means that in the health sector consent should never be the default basis.