Consent to Examination and Treatment Policy

Version:	V2.0	
Summary:	This policy covers what consent is, who has the capacity to give consent and how consent should be obtained and documented. The policy also provides information about gaining consent from children and young adults.	
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Executive Director	Director of Nursing, AHP's & Quality	
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Review and Amendment Log

Version No	Type of Change	Date	Description of Change
2.0	Full scheduled review	March 2020	Policy fully reviewed and amended to align with up to date guidance.

Contents

1. Introduction

This policy document follows the layout and content of the Department of Health model consent policy, tailored to reflect local arrangements within Locala services. The policy acts as a reference Guide to Consent for Examination or Treatment.

It is legally and ethically agreed that valid consent must be obtained before starting treatment, physical investigation or providing physical care. Patients have a fundamental right to determine what happens to their own bodies and to information about their healthcare. Consent is therefore central to treatment as well as being a matter of common courtesy between health care professionals and patients.

The Department of Health (DOH) has issued guidance documents on consent (available at https://www.gov.uk/government/publications/reference-guide-to-consent-for-examination-or-treatment-second-edition) and these should be consulted for further details on good practice requirements for consent. This Policy sets out the standards expected and procedures in place within Locala services.

Where application of this policy cannot be achieved this should be added to the relevant Business Unit's Key Risks to allow implementation of remedial actions. Risk assessment relating to specific individuals would be stored confidentially in the patient record.

2. Purpose

The purpose of this Policy is to explain what consent is, who has the capacity to give consent and how consent should be obtained and documented. The policy also provides information about gaining consent from children and young adults.

3. Target Population

This Policy applies to all colleagues, students and bank colleagues, contractors, temporary workers and other Third Parties (including volunteers/patients/clients).

4. Explanation of Terms

Gillick Competence: relates to the concept that children who have sufficient understanding and intelligence may consent to medical treatment where they fully understand what is involved.

5. Duties

5.1 Individual colleagues

Colleagues are responsible for reading, complying with and maintaining up-to-date awareness of policies as laid down in job descriptions and

contracts of employment and for undertaking training as appropriate to enable them to comply with policies relevant to their roles and as colleagues of Locala**.**

5.2 Managers

It is the responsibility of all line managers to ensure that they and the people they manage are conversant with this policy and its contents.

5.3 Responsible committee

It is the responsibility of the Clinical Policy Overview Group to monitor the implementation and effectiveness of this Policy.

5.4 Chief Executive

The Chief Executive has overall responsibility for the strategic and operational management of Locala including ensuring that the organisation's procedural documents comply with all legal, statutory and good practice requirements.

6. What is Consent?

"Consent" is a patient's / service user's agreement for a health professional to provide care. Consent can be gained non-verbally (a patient / service user presents their hand for a pulse check), verbally or in writing.

For consent to be valid, it must be given voluntarily by an appropriately informed person who has the capacity to consent to the intervention in question. This relates to the patient where someone is over the age of sixteen, under the age of sixteen but deemed Gillick competent, someone with parental responsibility in those under sixteen, someone authorised to do so under a lasting power of attorney or someone who has the authority to make the decision as a court appointed deputy.

So in short the patient / service user must:

- Have capacity to make the decision.
- Have received appropriate information regarding the procedure or treatment.
- Not be acting under duress.

The context of consent can take many different forms ranging from an active request by a patient for a particular treatment to the passive acceptance of a medical professional's advice. In long standing illness consent can also be the agreement between the health care professional and the patient over a choice of treatment.

Historically the Bolam principle was followed in that:

"[A doctor] is not guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art … Putting it the other way round, a man is not negligent, if

he is acting in accordance with such a practice, merely because there is a body of opinion who would take a contrary view."

McNair J in *Bolam v Friern Hospital Management Committee [1957] 1 WLR 583*

This principle has since been amended to incorporate the case of Montgomery v Lanarkshire Health Board [2015] UKSC 11, this case highlights the need for the patient to have access to all relevant information so they may make a fully informed decision about their treatment.

GMC guidance now emphasises the need for clinicians to explain all options to the patient, setting out the risks and benefits, including the option to have no treatment. Patients must be treated as adults who accept responsibility for their own choices.

The clinician must ensure that the patient is aware of all material risks of injury relating to their treatment. These changes have led to a fundamental distinction between:

- Clinician's role when considering investigatory or treatment options (an exercise of professional skill and judgment, governed by the *Bolam* test)
- Clinician's role in discussing with the patient any recommended treatment and possible alternatives, and the risks of injury which may be involved. Dr's advisory role cannot be regarded as solely an exercise of medical skill without leaving out the account of the patient's entitlement to decide on the risks to their health which they are willing to run.

7. Capacity to Consent

Where an adult lacks the mental capacity (be it temporary or permanent) to give or withhold consent, any decision made must be in the patient's best interests.

An assessment of a person's capacity must be based on their ability to make a specific decision at the time it needs to be made and not their general decision making ability. A person is unable to make a decision if they cannot do one or more of the following:

- Understand the information given to them that is relevant to the decision.
- Retain that information long enough to make the decision.
- Use or weigh up the information as part of the decision making process.
- Communicate their decision- this could be talking, using sign language or simple muscle movements such as blinking of the eyes.

It is important that all practical and appropriate steps must be taken to enable a person to make decision for themselves.

The Mental Capacity Act (2005) introduced a duty on NHS bodies to instruct an Independent Mental Capacity Advocate (IMCA) in serious medical treatment decisions when a person who lacks capacity to make a decision has

no-one to speak for them. The act also allows people to plan ahead for a time when they may not have capacity to make their own decisions. This allows them to appoint a welfare attorney to make their medical and social care needs decisions for them.

Further guidance can be found in the Mental Capacity Act (2005) Code of practice and in Locala's Mental Capacity Act policy: https://elsie.locala.org.uk/Interact/Pages/Content/Document.aspx?id=2017

8. Documentation of Consent

It is best practice for health professionals to document clearly both a patient's agreement to the treatment or procedure and any discussions which lead up to the agreement. This can be done via a consent form (e.g. the form for the Local Safety Standards for Invasive Procedures) or through detailing it in a patient's notes (either manually or electronically on SystmOne/R4).

If a patient information leaflet is given it is also recommended that this is recorded in the patient notes.

Good practice also dictates that written consent (either via a form or recorded in the notes) is gained and evidenced if:

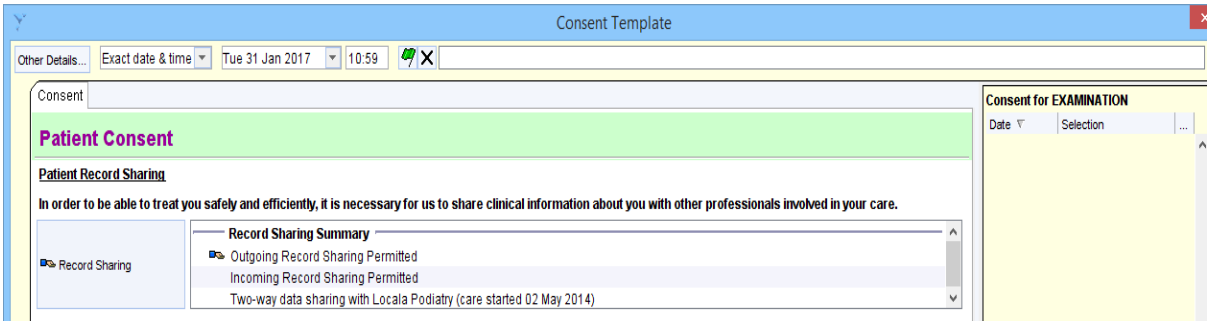
- The treatment or procedure is complex or involves serious risks/side effects.
- The procedure involves general/regional anaesthesia or sedation.
- There may be significant consequences to the patient's employment, social or personal life.
- The treatment is part of a project or programme of research.

9. Consent Recording on SystmOne

SystmOne has a series of templates that guide and allow consent to be documented electronically. It is important therefore that the different types of consent are explored within the system.

Data Sharing:

The first template relates to the sharing of information. The patient has the choice to allow their information to be shared with other professionals involved with their care, this can be within or external to Locala. The template can be seen in the screenshot below. Sexual Health services are excluded from this due to the sensitive nature of the service.

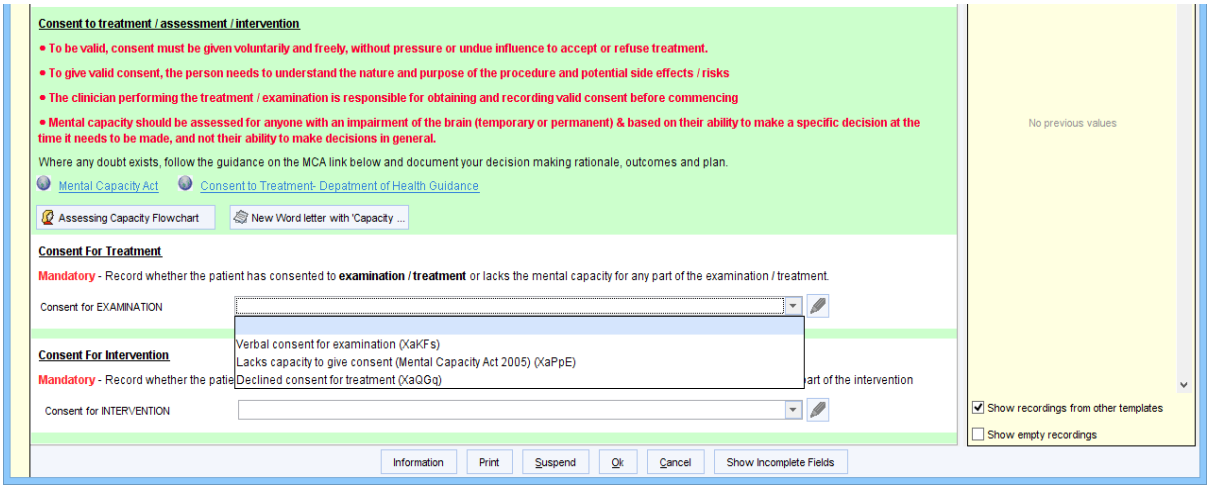


Data sharing applies to each episode of care i.e. if a patient agrees to data sharing, all the services within Locala will have access to their records until they are discharged.

Data sharing is automatically enabled for children's records for safeguarding purposes. This was made mandatory by the government following historic serious case reviews.

Consent for Treatment/Intervention

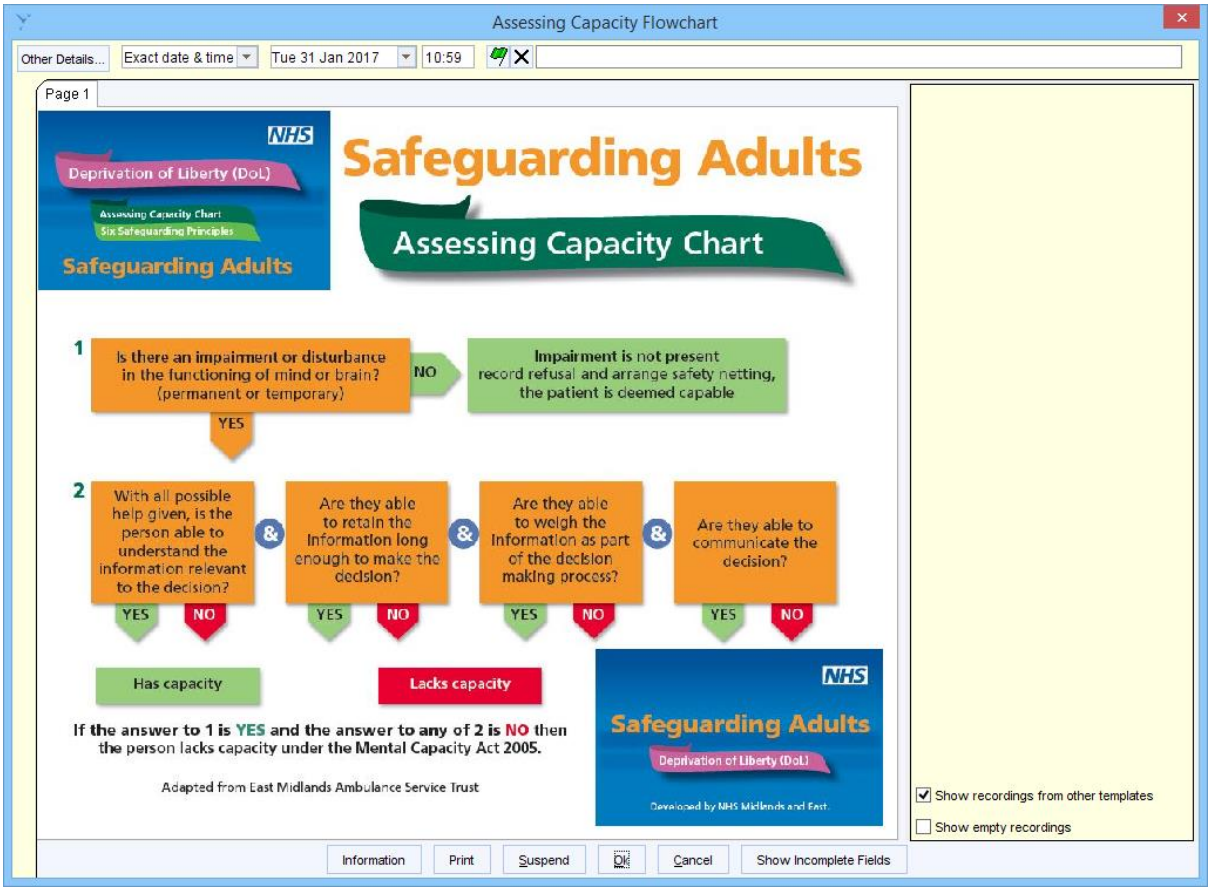
Consent for treatment and intervention are recorded separately and the drop down options can be seen below:



A patient can either give consent, decline consent or lack capacity at this time to give consent.

Recording capacity to give consent

The health care professional involved in treatment or intervention may question whether the patient has capacity to give consent. If this is the case they can access the 'Assessing capacity chart' on SystmOne. This is shown below:



This flowchart helps the professional to make a decision as to whether the patient has the capacity to consent. If they decide that the patient does have capacity they will either record that consent is given or declined.

Should the professional decide that the patient does not have capacity they will select 'Lacks capacity to give consent (Mental Capacity Act 2005)'.

It is then the responsibility of the clinician do decide whether the treatment or intervention is in the best interests of the patient. Once a decision is made it will either be recorded as given in the best interests of the patient or declined in the best interests of the patient.

10. When should consent be sought?

A patient formally giving their consent to an intervention is often just the end point to the consent process. Consent may be agreed on a single stage basis or over a series of meetings, depending on the seriousness or urgency of a patient's condition.

Single stage process:

In many cases it may be appropriate to gain consent immediately after discussing a procedure with a patient. In many such cases consent will be given verbally. If a proposed procedure carries significant risk it is recommended that written consent is recorded.

In some cases simple explanation of the diagnosis and care plan will

document consent. For example, if a patient attends for physio, documenting in the record that they are aware of the reason for their visit, plan of care and follow up would indicate that they have given informed consent.

Two or more stage process:

In most cases where written consent is being sought, treatment options will generally be discussed over more than one attendance. The first stage will therefore be the provision of information and discussion of the risks and benefits of all the options.

Following this the confirmation stage will occur where a patient decides on a course of treatment/procedure and consents to this.

11. Seeking consent for anaesthesia

Where an anaesthetist is involved in a patients care, it is their responsibility (not that of the surgeon) to seek consent for anaesthesia, having discussed the risks and benefits with the patient. The anaesthetist should ensure that the discussion with the patient and their consent is documented in the anaesthetic record.

In addition where general anaesthetic or sedation is being provided as part of dental treatment, the General Dental Council currently holds dentists responsible for ensuring that the patient has all the necessary information.

12. Children

The term children in this instance relates to children who are under the age of sixteen.

Generally only people with ‘parental responsibility’ are entitled to give consent on behalf of their children. Colleagues must be aware that not all parents have parental responsibility. If you are in any doubt as to whether the person with a child has parental responsibility you MUST check.

Currently:

- Mothers automatically have parental responsibility, in rare circumstances this may be removed by the court and transferred to Social Services.
- Fathers have parental responsibility if they were married to the mother at the time of the child’s birth, are recorded on the child’s birth certificate as such or have subsequently applied to the court to acquire this under Section 4 of The Children’s Act 1989.
- It is also acknowledged that on occasion children may present with someone who is not their parent (i.e. a grandparent). In this situation it is the responsibility of the clinician involved to ensure they are happy that the presenting adult is appropriate and the person with parental consent is happy for the procedure to go ahead. Assurance can either be gained by speaking with a parent/guardian or by their written consent e.g. in the child’s Parent Held Record book (red book) or by letter. This should be

clearly documented in the notes.

- Where verbal or non-verbal consent is being sought at the point of the procedure this should also be carried out by the health care professional responsible.

13. Gillick competence in children

Children under the age of 16 may be able to consent for their own treatment within the concept of Gillick competence.

Gillick competence relates to the concept that children who have sufficient understanding and intelligence may consent to medical treatment where they fully understand what is involved.

The concept relates to the child's increasing maturity.

Understanding required for different interventions may vary considerably. A child may have capacity to consent to some interventions but not others. The child's capacity to consent should be assessed in relation to each decision required.

If a child is Gillick competent and is able to give voluntary consent after receiving appropriate information then consent is valid and additional parental consent will not be required.

Gillick competence must be documented in the clinical record using the Locala Gillick Competence assessment form. Further information on Gillick competence can be found in Appendix B.

14. Young people aged 16-17

Section 8 of the Family Law Reform Act 1969 states that people aged 16 & 17 are presumed to be capable of consenting to their own medical treatment and any procedures involved in that treatment, such as anaesthetic. As with adults, consent is only valid if it is given voluntarily by an appropriately informed young person.

The mental capacity act (2005) also covers those aged 16 & 17.

15. Consent in Sexual Health Services

Due to the sensitive nature of sexual health services a local policy for consent gives the following more specific process for obtaining consent:

When to obtain consent

Legally, verbal and written consent are equally valid. Consent may be implied (non-verbal) or expressed (verbal or written).

It is recommended practice that explicit verbal consent (consent for the exact procedure taking place, with detail provided) is obtained for:

- The procedure to fit intra-uterine contraception

- The procedure to remove intra–uterine contraception
- The procedure to fit progestogen-only implants
- The procedure to remove progestogen-only implants
- The procedure to obtain a skin biopsy.

Explicit consent must be sought for the presence of medical students and other clinicians in training during consultations as observers and assistants, and for students performing clinical examinations. This may be given verbally and documented accordingly.

It will not usually be necessary to document a patient's consent to routine and low risk procedures, such as providing personal care or taking a blood sample where implied consent is sufficient. However, if the practitioner has any reason to believe that the consent may be disputed later or if the procedure is of particular concern to the patient (for example if they have declined, or become very distressed about similar care in the past) it would be recommended to do so.

A patient with capacity is entitled to withdraw consent at any time, including during the performance of a procedure.

Treatment of children

Children under 13 years:

Decisions about the treatment of children under the age of 13 years of age should be made only after discussion with a consultant (or Associate Specialist) within the service and a consultant paediatrician. Parents are also likely to be involved.

Those under the age of 13 years are considered unable to legally consent to sexual activity. Colleagues should know who to contact for advice and how to act on child protection issues in accordance with local policy and procedures.

Children aged 13-15 years:

The following is taken from the final judgement in the Gillick case and refers to a child's ability to consent for any proposed treatment:

"*Whether or not a child is capable of giving the necessary consent will depend on the child's maturity and understanding and the nature of the consent required. The child must be capable of making a reasonable assessment of the advantages and disadvantages of the treatment proposed, so the consent, if given, can be properly and fairly described as true consent."*

The NSPCC provide further detail: The Fraser guidelines refer to the guidelines set out by Lord Fraser in his judgement of the Gillick case in the House of Lords (1985), which apply specifically to contraceptive advice:

"...a doctor could proceed to give advice and treatment provided he is satisfied in the following criteria:

i. that the girl (although under the age of 16 years of age) will understand his advice;
ii. that he cannot persuade her to inform her parents or to allow him to inform the parents that she is seeking contraceptive advice;
iii. that she is very likely to continue having sexual intercourse with or without contraceptive treatment;
iv. that unless she receives contraceptive advice or treatment her physical or mental health or both are likely to suffer;
v. that her best interests require him to give her contraceptive advice, treatment or both without the parental consent."

Therefore when gaining consent from someone under 16 years of age the above criteria should be met and documented clearly.

When parents are involved in the provision of sexual health care the following should be noted:

i. The child's right to make her own decisions takes precedence over her parents' when she reaches a sufficient understanding and intelligence to be capable of making up his own mind on the matter requiring decision.

ii. Only people with 'parental responsibility' are entitled to give consent on behalf of their children.

iii. You must be aware that not all parents have parental responsibility for their children (for example, unmarried fathers do not automatically have such responsibility although they can acquire it).

If you are in any doubt about whether the person with the child has parental responsibility for that child, it is mandatory to ascertain the actual situation.

16. Clinical photography or digital video recordings

Photographic and video recordings made for clinical purposes form part of a patient's record. Although consent to certain recordings such as X-rays is implied in the patient's consent to the procedure, health professionals should always ensure that they make it clear in advance if any photographic or video recording will result from the procedure.

Mobile telephones that incorporate a digital camera are used as work related devices in some areas (e.g. Podiatry). Images taken on any work related device must be deleted as soon as the image is uploaded onto the clinical record.

It should also be noted that patients and visitors/carers should not use this technology to record patient sensitive information or procedures.

17. Equality Impact Assessment

Locala Community Partnerships aims to design and implement services, policies and measures that meet the diverse needs of our service, population and workforce, ensuring that none are placed at a disadvantage over others.

An Equality Impact Assessment Tool is used during ratification processes to establish whether its policies and practices would further, or had furthered, the aims set out in the section 149 (1) of the [Equality Act 2010]. Any outcomes have been considered in the development of this policy.

18. Consultation Process

A consultation process was carried out with key stakeholders in the development of this policy. These stakeholders included both clinical and managerial colleagues.

19. Dissemination and Implementation

19.1 Dissemination

The policy will be communicated through colleague briefing and a targeted and comprehensive communication plan. It will be placed in the relevant section of the Policies site on SharePoint. Where a review is identified and any changes made, these will be communicated.

The policy will also be shared at the Quality Summit and Quality Counts newsletter.

19.2 Competence/Training

Prior to ratification of this policy the required education and training needs for ensuring effective implementation and compliance have been reviewed.

There are no specific additional training requirements for this Policy.

20. Monitoring Compliance with the Document

20.1 Process for Monitoring Compliance

Locala services audit their clinical records on a monthly basis. Any instance where consent is not gained or documented will be highlighted through this process. Learning is then shared with the various teams in team meetings and appraisal.

20.2 Key Performance Indicators

There are no associated key performance indicators. Consent is however part of the clinical records audit and should always be documented (100% target). Complaints and concerns will also be monitored to ensure there are no issues with consent raised from patient feedback.

21. Associated Policy Documentation

The DOH has issued a number of guidance documents relating to consent, these should be consulted for advice on current law and good practice.

- A reference guide to consent for examination and treatment provides a

comprehensive summary of the current law on consent. See: http://www.dh.gov.uk/en/PublicationsandStatistics/Publications/PublicationsPolicyAndGuidance/DH_103643

- 12 Key points on consent. This one page document summarises the main aspects of the law on consent
- Department for Constitutional Affairs (2005) Mental Capacity Act 2005 Code of Practice. Mental Capacity Act Code of Practice
- Department of Health (2009) Reference Guide to Consent for Examination or Treatment. Second Edition. DH Consent to Treatment
- Locala's Clinical Record Keeping Policy

Appendix A – A guide to Gillick Competence

When consenting children to medical treatment, the terms ‘Gillick competence’ and ‘Fraser guidelines’ are frequently used interchangeably despite there being a clear distinction between them.

Gillick competence is concerned with determining a child’s capacity to consent. Fraser guidelines, on the other hand, are used specifically to decide if a child can consent to contraceptive or sexual health advice and treatment. By confusing them, we lose crucial details necessary for obtaining consent. This mythbuster clarifies the principles, laws and guidelines used when we assess children’s ability to make decisions about their treatment, as well as the differences between Gillick competence and Fraser guidelines.

Age of consent

In UK law, a person's 18th birthday draws the line between childhood and adulthood (Children Act 1989 s105) - so in health care matters, an 18 year old enjoys as much autonomy as any other adult. To a more limited extent, 16 and 17 year-olds can also take medical decisions independently of their parents. The right of younger children to provide independent consent is proportionate to their competence - a child's age alone is clearly an unreliable predictor of his or her competence to make decisions.

Gillick competence

Victoria Gillick challenged Department of Health guidance which enabled doctors to provide contraceptive advice and treatment to girls under 16 without their parents knowing. In 1983 the judgement from this case laid out criteria for establishing whether a child under has the capacity to provide consent to treatment; the so-called ‘Gillick test’. It was determined that children under 16 can consent if they have sufficient understanding and intelligence to fully understand what is involved in a proposed treatment, including its purpose, nature, likely effects and risks, chances of success and the availability of other options.

If a child passes the Gillick test, he or she is considered ‘Gillick competent’ to consent to that medical treatment or intervention. However, as with adults, this consent is only valid if given voluntarily and not under undue influence or pressure by anyone else. Additionally, a child may have the capacity to consent to some treatments but not others. The understanding required for different interventions will vary, and capacity can also fluctuate such as in certain mental health conditions. Therefore each individual decision requires assessment of Gillick competence.

If a child does not pass the Gillick test, then the consent of a person with parental responsibility (or sometimes the courts) is needed in order to proceed with treatment.

Fraser guidelines

The ‘Fraser guidelines’ specifically relate only to contraception and sexual health. They are named after one of the Lords responsible for the Gillick judgement but who went on to address the specific issue of giving contraceptive advice and treatment to

those under 16 without parental consent. The House of Lords concluded that advice can be given in this situation as long as:

1. He/she has sufficient maturity and intelligence to understand the nature and implications of the proposed treatment
2. He/she cannot be persuaded to tell her parents or to allow the doctor to tell them
3. He/she is very likely to begin or continue having sexual intercourse with or without contraceptive treatment
4. His/her physical or mental health is likely to suffer unless he/she received the advice or treatment
5. The advice or treatment is in the young person's best interests.

Health professionals should still encourage the young person to inform his or her parent(s) or get permission to do so on their behalf, but if this permission is not given they can still give the child advice and treatment. If the conditions are not all met, however, or there is reason to believe that the child is under pressure to give consent or is being exploited, there would be grounds to break confidentiality.

Fraser guidelines originally just related to contraceptive advice and treatment but, following a case in 2006, they now apply to decisions about treatment for sexually transmitted infections and termination of pregnancy.

Under 13

There is no lower age limit for Gillick competence or Fraser guidelines to be applied. That said, it would rarely be appropriate or safe for a child less than 13 years of age to consent to treatment without a parent's involvement. When it comes to sexual health, those under 13 are not legally able to consent to any sexual activity, and therefore any information that such a person was sexually active would need to be acted on, regardless of the results of the Gillick test.

16-17 year olds

Young people aged 16 or 17 are presumed in UK law, like adults, to have the capacity to consent to medical treatment. However, unlike adults, their refusal of treatment can in some circumstances be overridden by a parent, someone with parental responsibility or a court. This is because we have an overriding duty to act in the best interests of a child. This would include circumstances where refusal would likely lead to death, severe permanent injury or irreversible mental or physical harm.

Summary

Gillick competence is the principle we use to judge capacity in children to consent to medical treatment. Fraser guidelines are used specifically for children requesting contraceptive or sexual health advice and treatment. Where a person under the age of 16 is not Gillick competent and therefore is deemed to lack the capacity to consent, it can be given on their behalf by someone with parental responsibility or by the court. However, there is still a duty to keep the child's best interests at the heart

of any decision, and the child or young person should be involved in the decision-making process as far as possible.

Appendix B – Guideline Consultation Process with Key Stakeholders

For stakeholder comments please contact the Clinical Policy Overview Group Chair or Administrator.