Patient agreement to systemic anti-cancer therapy (SACT)

MMM (Mitomycin, Methotrexate and Mitoxantrone)

Hospital/NHS Trust/NHS Board:

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Responsible consultant:

Name: ______________________________

Job title: ______________________________

Patient details

Patient's surname/family name:

____

Patient's first name(s): ________________

____

Date of birth: ______________________

NHS number: ______________________
(or other identifier)

Special requirements:
(eg other language/other communication method)

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Name of proposed course of treatment (include brief explanation if medical term not clear)

☐ MMM (Mitomycin, Methotrexate and Mitoxantrone) chemotherapy for the treatment of breast cancer.

☐ Mitomycin, Methotrexate and Mitoxantrone are given intravenously. Methotrexate and Mitoxantrone are given on day 1, every 21 days for 6 cycles. Mitomycin is given on day 1 of cycles 1, 3 and 5 only* OR

☐ Mitomycin is given on day 1, of cycles 1, 2, 4 and 6 only* (*delete as appropriate).

Where will I have treatment?

☐ Outpatient ☐ Day unit/case ☐ Inpatient ☐ Other: ______________________

Statement of health professional

(to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in the hospital/Trust/NHS board's consent policy)

☑ Tick all relevant boxes

☐ I confirm the patient has capacity to give consent.

☐ I have explained the course of treatment and intended benefit to the patient.

The intended benefits (there are no guarantees about outcome)

☐ Curative – to give you the best possible chance of being cured.

☐ Disease control or palliative – the aim is not to cure, but to control or shrink the disease and improve both quality of life and survival.

☐ Adjuvant – therapy given after surgery or radiotherapy to reduce the risk of the cancer coming back.

☐ Neo-adjuvant – therapy given before surgery or radiotherapy to shrink the cancer, allow treatment and reduce the risk of the cancer coming back

Statement of health professional

Patient identifier/label

You may have one or more of the side effects listed

Common side effects:

Affecting more than 10 in every 100 (>10%) people

☐ An increased risk of getting an infection from a drop in white blood cells - it is harder to fight infections and you can become very ill.

☐ **If you have a severe infection this can be life-threatening. Contact your doctor or hospital straight away if:**

- **your temperature goes over 37.5°C or over 38°C, depending on the advice given by your chemotherapy team**
- **you suddenly feel unwell (even with a normal temperature)**

☐ Feeling sick (nausea), being sick (vomiting), sore mouth and ulcers, loss of appetite, taste changes, diarrhoea.

☐ Thinning of the hair or hair loss, tiredness and feeling weak (fatigue), gritty and sore eyes.

☐ Anaemia (low number of red blood cells), bleeding or bruising (due to low platelets).

Occasional side effects:

Affecting between 1-10 in every 100 (1-10%) people

☐ Nail changes (brittle nails,change in colour), skin changes (rash, dry or itchy skin, sensitivity to sunlight, darkening of the skin).

☐ Changes in liver and kidney function (monitored with blood tests).

☐ Difficulty in breathing

☐ Mitoxantrone can affect the way your heart works and can be harmful. As a precaution your doctor may arrange for you to have an ECG (heart tracing) or other tests to check your heart before your treatment.

☐ Inflammation of the lungs (pneumonitis) may lead to a cough, chest pain or breathlessness. Tell your doctor if you have difficulty breathing or shortness of breath at rest or with gentle activity.

Other risks:

☐ All intravenous drugs may leak out of the vein while it is being given (extravasation) and candamage the tissue around the vein. Tell the nurse straight away if you have any stinging, pain, redness or swelling around the vein. It's uncommon but important to deal with quickly.

☐ Late effects include problems with your heart.

Other risks continued:

☐ Mitomycin can cause haemolytic uraemic syndrome (HUS). HUS is a condition that destroys cells which help with clotting causing anaemia and kidney failure.This may appear 6 months after the drug has been given.

☐ Steroids can raise your blood sugar. This usually goes back to normal after treatment. If you have diabetes, it may lead to higher blood sugar levels.

☐ Side effects with the anti-sickness medication may include: constipation, headaches, indigestion, difficulty sleeping and agitation.

☐ Before treatment you may have blood tests to check for viruses (Hepatitis B or C, HIV, or unusual infections). Treatment may weaken your natural defence (immune) system so infections like this may worsen or become active if you've had them before. You may have medicines to prevent or treat infection.

☐ Changes in your memory, concentration or ability to think clearly. There can be many causes including your treatment, diagnosis, or both.

☐ Cancer and treatment for cancer can increase your risk of developing a blood clot (thrombosis). A blood clot may cause pain, redness and swelling in a leg, or breathlessness and chest pain. Tell your doctor straight away if you have any of these symptoms.

☐ Some anti-cancer medicines can damage ovaries and sperm. This may lead to infertility and/or early menopause (hot flushes, vaginal dryness).

☐ Some anti-cancer medicines may damage the development of a baby in the womb. It is important not to become pregnant or make someone else during treatment and for 6 months afterwards. Use effective contraception throughout. Speak to your doctor or nurse.

☐ Complications of treatment can very occasionally be life-threatening and may result in death. The risks are different for every individual. Potentially life-threatening complications include those listed on this form, but other exceedingly rare side effects may also be life-threatening.

Statement of health professional

Patient identifier/label

Any other risks and information:

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☐ I have discussed the intended benefit and risks of the recommended treatment, and of any available alternative treatments (including no treatment).

☐ I have discussed the side effects of the recommended treatment, which could affect the patient straight away or in the future, and that there may be some side effects not listed because they are rare or have not yet been reported. Each patient may experience side effects differently.

☐ I have discussed what the treatment is likely to involve (including inpatient/outpatient treatment, timing of the treatment, blood and any additional tests, follow-up appointments etc) and location.

☐ I have explained to the patient, that they have the right to stop this treatment at any time and should contact the responsible consultant or team if they wish to do so.

☐ I have discussed concerns of particular importance to the patient in regard to treatment

(please write details here): ___

___

Clinical management guideline/Protocol compliant (please tick):

☐ Yes ☐ No ☐ Not available If No please document reason here:

___

The following written information has been provided:

☐ Information leaflets for Mitomycin, Methotrexate and Mitoxantrone

☐ 24 hour alert card or SACT advice service contact details

☐ SACT treatment record (cruk.org/treatment-record)

☐ Other, please state: ___

___

Health professional details:

Signed: ___

Date: ___

Name (PRINT): ___

___

Job title: ___

___

Statement of interpreter (where appropriate)

Interpreter booking reference (if applicable):

I have interpreted the information above to the patient to the best of my ability and in a way in which I believe they can understand.

Signed: ___

Date: ___

Name (PRINT): ___

Job title: ___

Statement of patient

Patient identifier/label

Please read this form carefully. If your treatment has been planned in advance, you should already have your own copy of the form which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. If you have any further questions, do ask – we are here to help you. You have the right to change your mind at any time, including after you have signed this form.

☐ I have had enough time to consider my options and make a decision about treatment.

☐ I agree to the course of treatment described on this form.

A witness should sign below if the patient is unable to sign but has indicated their consent. A person with parental responsibility will be asked to sign for young people under the age of 16 years.

Patient's signature: ______________________________

Name (PRINT): ______________________________ Date: ______________

Person with parental responsibility/witness' signature: ______________________________

Name (PRINT): ______________________________ Date: ______________

Copy accepted by patient: yes / no (please circle)

Confirmation of consent

(health professional to complete when the patient attends for treatment, if the patient has signed the form in advance)

On behalf of the team treating the patient, I have confirmed that the patient has no further questions and wishes the course of treatment/procedures to go ahead.

Signed: ______________________

Date: ______________________

Name (PRINT): ______________________

Job title: ______________________

Important notes: (tick if applicable)

☐ See also advance decision to refuse treatment

☐ Patient has withdrawn consent (ask patient to sign and date here)

Signed: ______________________

Date: ______________________

Further information for patients

Contact details (if patient wishes to discuss options later):

____

Contact your hospital team if you have any questions about cancer and its treatment.

Cancer Research UK can also help answer your questions about cancer and treatment. If you want to talk in confidence, call our information nurses on freephone 0808 800 4040, Monday to Friday, 9am to 5pm. Alternatively visit cruk.org for more information.

These forms have been produced by Guy's and St. Thomas' NHS Foundation Trust as part of a national project to support clinicians in ensuring all patients are fully informed when consenting to SACT.

The project is supported by Cancer Research UK. This does not mean you are taking part in a clinical trial.

CANCER RESEARCH UK

Guidance for health professionals

(to be read in conjunction with the hospital's consent policy)

Patient identifier/label

What a consent form is for

This form documents the patient's agreement to go ahead with the treatment you have proposed. It is not a legal waiver – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients are also entitled to change their mind after signing the form, if they retain capacity to do so. The form should act as an aide-memoir to health professionals and patients, by providing a checklist of the kind of information patients should be offered, and by enabling the patient to have a written record of the main points discussed. In no way should the written information provided for the patient be regarded as a substitute for face-to-face discussions with the patient.

The law on consent

See the following publications for a comprehensive summary of the law on consent. Consent: Patients and doctors making decisions together, GMC 2020 (gmc-uk.org/guidance). Reference guide to consent for examination or treatment, Department of Health, 2nd edition 2009 (doh.gov.uk).

Who can give consent

Everyone aged 16 or over is presumed to have the capacity to give consent for themselves, unless the opposite is demonstrated. For young people, it is good practice to involve those with parental responsibility in the consent discussions, unless specifically asked not to. A person with parental responsibility must sign this form for a child or young person under the age of 16. Such patients should be given the opportunity to 'assent' to treatment if they wish. If a patient has the capacity to give consent but is physically unable to sign a form, you should complete this form as usual and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

When NOT to use this form

If the patient lacks the capacity to give consent, you should use an alternative form available for this purpose (dependent on patient age). A patient lacks capacity if they have an impairment or disturbance of the brain, affecting the way their mind works. For example, if they cannot do one of the following:

- understand information about the decision to be made
- retain that information in their mind
- use or weigh this information as a part of their decision making process, or
- communicate their decision (by talking, using sign language or any other means)

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives cannot be asked to sign a form on behalf of an adult who lacks capacity to consent for themselves, unless they have been given the authority to do so under a Lasting Power of Attorney or as a court deputy.

Information

Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'significant, unavoidable or frequently occurring' risks. If patients make clear they have particular concerns about certain kinds of risk, you should ensure that they are informed about these risks, even if very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on the consent form or in the patient's notes.

NHS Scotland

NHS Scotland staff should refer to Healthcare Improvement Scotland. Guidance on consent for SACT and local NHS Board guidance on consent aligned to the Scottish legal framework.

References

1. Summary of Product Characteristics for individual drugs: medicines.org.uk/emc
2. Cancer Research UK: cruk.org/about-cancer/treatment/drugs
3. Macmillan Cancer Support: macmillan.org.uk/cancer-information-and-support/treatments-and-drugs
4. Guy's and St. Thomas' NHS Foundation Trust, Chemotherapy consent form