Patient details Patient agreement to Patient's surname/family name: systemic anti-cancer therapy (SACT) Patient's first name(s): Gemcitabine -Carboplatin Date of birth: NHS number: (or other identifier) Hospital/NHS Trust/NHS Board: Special requirements: (eg other language/other communication method) Responsible consultant: Name: Job title: _____ Name of proposed course of treatment (include brief explanation if medical term not clear) Gemcitabine and Carboplatin chemotherapy for the treatment of breast cancer. Gemcitabine and Carboplatin are given intravenously. Gemcitabine is given on day 1 and 8, and Carboplatin is given on day 1, every 21 days for up to 6 to 8 cycles. 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

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and reduce the risk of the cancer coming back

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You may have one or more of the side effects lited

| Common side effects: | Other risks: |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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 | ☐ Gemcitabine and Carboplatin may leak out of the vein while it is being given (extravasation) and can damage 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. ☐ Gemcitabine contains alcohol. This may affect your ability to drive or operate machinery. If this is a problem tell your doctor, nurse or pharmacist. ☐ Carboplatin may cause an allergic reaction |
| normal temperature) | when given. |
| Feeling sick (nausea), being sick (vomiting), tummy pain, tiredness and feeling weak (fatigue), flu-like symptoms (chills, headaches, fever, muscle pain). Thinning of the hair or sometimes complete hair loss, allergic skin rash and/or itchy skin with Gemcitabine. Fluid build-up in legs and ankles, swelling of the face (usually resolves after stopping treatment), shortness of breath. Anaemia (due to low red blood cells), bruising or bleeding (due to low platelets), low mineral levels (sodium, potassium, calcium and magnesium), changes in kidney and liver function (monitored), | Very rare side effects include posterior reversible encephalopathy syndrome (PRES) causing seizures, headache, change in mental status, visual disturbances. Other rare effects of Gemcitabine include heart problems, changes in blood pressure, capillary leak syndrome and haemolytic uraemic syndrome (HUS). HUS destroys cells which help with clotting, causing anaemia and kidney failure. Side effects of anti-sickness medication include constipation, headaches, difficulty sleeping, agitation and indigestion. Steroids can raise your blood sugar. This |
| blood and/or protein in the urine. | usually goes back to normal after treatment. If |
| Occasional side effects: Affecting between 1-10 in every 100 (1-10%) people Numbness or tingling in hands and feet (may be temporary or permanent). Sore mouth and ulcers, loss of appetite, weight loss, taste changes, diarrhoea, constipation. High levels of bilirubin in the blood causing yellow skin (jaundice). Cough, runny nose, headache, difficulty sleeping, feeling drowsy, increased sweating, back pain, muscle and joint pain. Changes in lung tisses (scarring/inflammation) may cause breathlessness, cough, wheezing during treatment or developing in the future. Tell your doctor if you have symptoms at rest or with gentle activity. Hearing changes (ringing in the ears, changes in hearing and uncommonly high frequency hearing loss which may be permanent), eye problems (change in vision). | you have diabetes, it may lead to higher blood sugar levels. Changes in your memory, concentration or ability to think clearly. There can be many causes including your treatment, diagnosis, or both. 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. Cancer and its treatment can increase your risk of developing a blood clot (thrombosis), causing pain, redness and swelling in an arm or leg, breathlessness, chest pain or stroke. Tell your doctor straight away if you have any symptoms. Continue on to the next page |
| Heart and blood vessel problems including risk of stroke. | |
| | |

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Other risks continued:

| 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

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| Any other risks and information: | | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------|--|
| | | |
| ☐ I have discussed the intended benefit and risks of available alternative treatments (including no treatments) | , | |
| ☐ I have discussed the side effects of the recommendate straight away or in the future, and that there may be rare or have not yet been reported. Each patient may | e some side effects not listed because they are | |
| ☐ I have discussed what the treatment is likely to it timing of the treatment, blood and any additional test | ` • • • • • • • • • • • • • • • • • • • | |
| ☐ I have explained to the patient, that they have the should contact the responsible consultant or team if | • | |
| ☐ I have discussed concerns of particular importar | | |
| (please write details here): | | |
| Clinical management guideline/Protocol cor | mpliant (please tick): se document reason here: | |
| | | |
| The following written information has | Health professional details: | |
| been provided: Information leaflets for Gemcitabine and | Signed: | |
| Carboplatin | Date: | |
| 24 hour alert card or SACT advice service contact details | Name (PRINT): | |
| SACT treatment record (cruk.org/treatment-record) | Job title: | |
| Other, please state: | | |
| | 1 | |
| Statement of interpreter (where a Interpreter booking reference (if applicable): | ppropriate) | |
| I have interpreted the information above to the patier believe they can understand. | nt to the best of my ability and in a way in which I | |
| Signed: | Date: | |
| Name (PRINT): | loh title: | |

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| your own copy of the form which describes the be | has been planned in advance, you should already have enefits and risks of the proposed treatment. If not, you r questions, do ask – we are here to help you. You have ng after you have signed this form. |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| ☐ I have had enough time to consider my option | ns 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 unabparental responsibility will be asked to sign for yo | ele to sign but has indicated their consent. A person with ung people under the age of 16 years. |
| Patient's signature: | |
| Name (PRINT): | Date: |
| Person with parental responsibility/witness' signa | ture: |
| Name (PRINT): | Date: |
| 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 | Further information for patients Contact details (if patient wishes to discuss options later): |
| have confirmed that the patient has no further questions and wishes the course of treatment/procedures to go ahead. Signed: | Contact your hospital team if you have any questions about cancer and its treatment. |
| Date: | Cancer Research UK can also help answer your questions about cancer and treatment. If you |
| Name (PRINT): | 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 |
| Job title: | |
| Important notes: (tick if applicable) | more information. |
| ☐ See also advance decision to refuse treatment☐ Patient has withdrawn consent (ask patient to sign and date here) | 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. |
| Signed: | The project is supported by |
| Date: | Cancer Research UK. This does not mean you are |

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taking part in a clinical trial.

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

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