PATIENT AGREEMENT TO SYSTEMIC ANTI-CANCER THERAPY: Accelerated M-VAC (methotrexate-vinblastine-doxorubicin-cisplatin)

**NAME OF PROPOSED COURSE OF TREATMENT**

- [ ] Methotrexate, vinblastine, doxorubicin, and cisplatin chemotherapy for the treatment of bladder cancer.
- Methotrexate, vinblastine, doxorubicin, and cisplatin are given intravenously. Treatment is given every 14 days for 3 to 6 cycles.
- Methotrexate is given on day 1, and vinblastine, doxorubicin and cisplatin are given on day 2.

**WHERE THE TREATMENT WILL BE GIVEN:**

- [ ] outpatient
- [ ] day unit/case
- [ ] inpatient
- [ ] other:______________________________

**STATEMENT OF HEALTH PROFESSIONAL**

I have explained the procedure/treatment to the patient. In particular, I have explained:

- [ ] all relevant boxes

**THE INTENDED BENEFITS**

- [ ] CURATIVE – to give you the best possible chance of being cured.
- [ ] DISEASE CONTROL/PALLIATIVE – the aim is not to cure but to control or shrink the disease. The aim is to improve both quality of life and survival.
- [ ] ADJUVANT – therapy given after surgery to reduce the risk of the cancer coming back.
- [ ] NEO-ADJUVANT – therapy given before surgery/radiotherapy to shrink the cancer, allow radical treatment and reduce the risk of the cancer coming back.
STATEMENT OF HEALTH PROFESSIONAL (continued)

SIGNIFICANT, UNAVOIDABLE OR FREQUENTLY OCCURRING RISKS

COMMON SIDE EFFECTS:
More than 10 in every 100 (>10%) people have one or more of the side effects listed:

- Bruising or bleeding, anaemia (low number of red blood cells), tiredness and feeling weak (fatigue), feeling sick (nausea) and being sick (vomiting), sore mouth and ulcers, hair loss, discoloured urine, watery eyes, sensitivity of the skin to sunlight, hearing changes, and changes in the way the kidneys work.

- 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 you doctor or hospital straight away if:
- your temperature goes over 37.5°C (99.5°F) or over 38°C (100.4°F), depending on the advice given by your chemotherapy team
- you suddenly feel unwell (even with a normal temperature)

OCCASIONAL SIDE EFFECTS:
Between 1 and 10 in every 100 (1-10%) people have one or more of these effects:

- Darkening of the skin or an itchy rash. Brown markings can occur in the skin following the line of the vein where the chemotherapy is injected. If you've had radiotherapy (either recently or in the past), the area that was treated may become red or sore.

- Loss of appetite, taste changes, diarrhoea, constipation, ringing in the ears, numbness or tingling in the fingers and toes, allergic reactions, fever and chills, nail changes, jaw pain, changes in the way the heart works (including abnormal heart rhythms), and changes in the way the liver works (usually temporary).

OTHER RISKS:

- Vinblastine and doxorubicin may leak outside of the vein while it is being given; this is called extravasation. If this happens when you’re having vinblastine and doxorubicin it can damage the tissue around the vein. Tell the nurse straight away if you have any stinging, pain, redness or swelling around the vein. Extravasation is not common but if it happens it’s important that it’s dealt with quickly.

- Late effects of doxorubicin include a very rare chance of a second cancer and problems with your heart.

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

- Cancer can increase your risk of developing a blood clot (thrombosis), and having treatment with anti-cancer medicines may increase this risk further. A blood clot may cause pain, redness and swelling in a leg, or breathlessness and chest pain - you must tell your doctor straight away if you have any of these symptoms.

- Some anti-cancer medicines can damage women’s ovaries and men’s sperm. This may lead to infertility in men and women and/or early menopause in women.

- Some anti-cancer medicines may damage the development of a baby in the womb. It is important not to become pregnant or father a child while you are having treatment and for at least 6 months afterwards. It is important to use effective contraception during and for at least 6 months after treatment. You can talk to your doctor or nurse about this.

- Very rarely complications of treatment with anti-cancer medicines can be life-threatening or even result in death. The risks are different for every individual. You can talk to your doctor or nurse about what this means for you.

TO BE RETAINED IN PATIENT NOTES
Prepared by Pharmacist: Rena Chauhan
Checked by Pharmacist: Lisa Yuen
Checked by Consultant: Deborah Enting

Date of issue and version: Apr-17; Version 1;
Review date: Apr-20
Approved by: Janine Mansi (National Chemotherapy Board)
Check www.cruk.org/sact_consent for latest version
STATEMENT OF HEALTH PROFESSIONAL (continued)

ANY OTHER RISKS:

☐ 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 discussed the intended benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient.

THE FOLLOWING LEAFLET HAS BEEN PROVIDED:

☐ Information leaflet for M-VAC chemotherapy and/or for the individual drugs (methotrexate, vinblastine, doxorubicin and cisplatin).

☐ Other, please state:

☐ 24 hour chemotherapy service contact 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 s/he can understand.

Signed: ________________________________ Date: ________________________________

Name (PRINT): ________________________________

Job title: ________________________________
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 with the patient that s/he has no further questions and wishes the procedure 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 /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 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 www.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

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GUIDANCE FOR HEALTH PROFESSIONALS
(to be read in conjunction with the hospital’s consent policy)

WHAT A CONSENT FORM IS FOR
This form documents the patient’s agreement to go ahead with the investigation or 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, however, 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 Department of Health’s Reference guide to consent for examination or treatment 2nd Edition for a comprehensive summary of the law on consent (also available at www.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. If a child under the age of 16 has "sufficient understanding and intelligence to enable him or her to understand fully what is proposed", then he or she will have capacity to give consent for himself or herself. Young people aged 16 and 17, and younger children with capacity, may therefore sign this form for themselves, but may like a parent to countersign as well. If the child is not able to give consent for himself or herself, someone with parental responsibility may do so 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 best to ensure that the patient receives at least very basic information about what is proposed. Where information is best to ensure that the patient receives at least very basic information about what is proposed.

WHEN NOT TO USE THIS FORM
If the patient is 18 or over and lacks the capacity to give consent, you should use a substitute form (form for adults who lack the capacity to consent to investigation or treatment) instead of this form. A patient lacks capacity if they have an impairment of the mind or brain or disturbance affecting the way their mind or brain works and they cannot:
• 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)

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. In addition if patients make clear they have particular concerns about certain kinds of risk, you should make sure they are informed about these risks, even if they are 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.

REFERENCES
1. Summary of Product Characteristics (SPCs) for individual drugs: https://www.medicines.org.uk/emc/
4. Guy’s and St. Thomas’ NHS Foundation Trust, Chemotherapy consent forms.

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Patient identifier/label
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