



## National Chemotherapy Board

### GOOD PRACTICE GUIDELINE: Promoting Early Identification of Systemic Anti-Cancer Therapies Side Effects: – Two Approaches.

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The National Chemotherapy Board (NCB) has a remit to provide guidance, oversight and support for the continued development of high quality systemic anti-cancer services for cancer patients. It is attended by members who are involved in the delivery of systemic anti-cancer therapies and includes the ACP, RCR, JSC/RCP, RCPATH, UKONS, BOPA, PheSACT, NHSE CRG and lay representatives.

#### Summary

This guidance has been produced by the National Chemotherapy Board in response to concerns that patients often delay reporting serious Systemic Anti-Cancer Therapy (SACT) side effects to dedicated help lines. Two complementary approaches to improve side effect reporting are suggested:

- Empowerment focuses on equipping patients to take responsibility for identifying and reporting important side effects and may be mediated via technology.
- Proactive monitoring includes clinician interventions (e.g. telephone support or home visits).

#### Scope

For the purposes of this document, the term Systemic Anti-Cancer Therapy (SACT) is used to refer to all drugs with direct anti-tumour activity including conventional cytotoxic drugs, monoclonal antibodies and targeted treatments (for example imatinib) and drugs such as thalidomide. These recommendations are the minimum standards expected of providers and it is recognised that certain drugs or regimes may require more intensive patient follow up and monitoring. This should be determined at a local level based upon a risk assessment that includes patient-related and drug-related factors.

#### Background

In the UK, it is estimated that one in two people born after 1960 will be diagnosed with cancer.<sup>1,2</sup> Increasing cancer incidence coupled with new lines of treatment has increased demands on SACT services.<sup>2</sup> Patients undergoing intravenous or oral SACT are required to recognise and report side effects because these commonly occur at home. SACT consent appointments and nurse/pharmacy led pre-treatment consultations focus on side effects that patients should report to dedicated 24-hour help lines. These include likely side effects such as nausea and vomiting and mucositis and those that are life-threatening such as neutropenic sepsis, diarrhoea and thrombosis. Despite this preparation, patients often underestimate and delay reporting SACT side effects to clinicians<sup>3-8</sup> which can cause treatment delays, increased hospitalisation, reduced quality of life<sup>9</sup> and fatal consequences.<sup>5</sup> Limited evidence suggests delayed reporting may relate to patient frailty<sup>3-4</sup> and confusion about severity of symptoms to report.<sup>10,11</sup> Delays may also be affected by a lack of clinician support for patients at home between SACT treatments. UK survey data suggests patients perceive SACT side effects to be poorly managed.<sup>12</sup> Patients and carers can also feel overwhelmed by the responsibility for identifying and reporting important SACT side effects.<sup>11,13</sup> They may further not have relationships with clinicians that encourage symptom reporting.<sup>11</sup> Emotional, practical, psychological and spiritual needs are often not addressed during SACT.<sup>14</sup> Access to a Clinical Nurse Specialist (CNS) is associated with perceptions of better side effect control<sup>12</sup>. However CNS's are not always available to support patients during SACT and oncologists and chemotherapy nurses can be perceived as drug delivery focused and too busy to approach for symptom advice.<sup>11</sup>

## Two approaches to promote early side effect identification

### Approach one: Empowerment

A working party established to review experiences and care for acute cancer patients' states:

*"...there should be systematic adoption of emergency contingency planning with people with cancer and their carers. This should cover the likely situations that might require urgent care, plus any specific problems where prompt and correct management will be critical..."*

(Royal College of Physicians and Royal College of Radiologists 2012 page xiv)

Empowerment describes the knowledge, skills and confidence a person has to manage their own healthcare. Patient activation is an important predictor of health outcomes and can be measured.<sup>15</sup> Cancer clinicians may encourage avoidance and passivity through delivering generic SACT information, rather than focusing on individual concerns, needs and empowerment.<sup>11,16</sup> Patients can feel overwhelmed by repeated side effect information at a time when they are worried about starting SACT.<sup>11,17,18</sup> Limited evidence suggests patients may be empowered to report SACT symptoms by traffic light symptom reporting tools<sup>19-20</sup> (appendices 1-2) and an emergency planning wallet.<sup>8</sup> Conduction of a holistic needs assessment (HNA)<sup>21</sup> prior to SACT may also assist patient empowerment, through first identifying and addressing supportive care needs. It is not clear though, how well this tool is used by UK SACT clinicians.

Carers can also feel ill equipped to support patients to recognise and report side effects.<sup>8,16,22</sup> A facilitated group SACT education session for carers with a DVD and written information significantly improved carers understanding of SACT symptoms and side effects.<sup>23</sup> However, around 23% of cancer patients in the UK do not have an identified carer<sup>24</sup> and may require additional support and monitoring from clinicians during SACT.

Technology enables patients to enter SACT symptoms into electronic devices that trigger symptom management advice, and alerts chemotherapy nurses to severe symptoms.<sup>25,26</sup> An American study<sup>25</sup> involving 358 patients found this type of intervention to be associated with significantly fewer patient days with moderate/severe SACT symptoms ( $P < .001$  for each). Within the UK, the Advanced Symptom Management System (ASyMS) thus far tested with 300 patients appears simple to use<sup>26</sup> and to improve confidence in symptom pattern recognition and management.<sup>27</sup> It improves communication with clinicians<sup>26</sup> and appears to detect serious side effects earlier.<sup>27</sup> The Qtool, a web based programme developed by the Leeds Psychosocial Oncology Group currently within research has thus far reported there is a high rate of adherence to the program.<sup>28</sup>

### Approach two: Proactive monitoring

SACT symptoms to report urgently can be difficult to distinguish from normal, expected side effects,<sup>10</sup> so proactive monitoring in addition to patient empowerment may be of benefit. There is some evidence that patients find pro-active calls from nurses supportive and reassuring during SACT.<sup>29-31</sup> This also creates opportunities to answer questions and to reinforce key patient safety messages<sup>30</sup> at a time after treatment has started, and when patients may be more receptive. Current evidence suggests that proactive monitoring results in earlier symptom management than

patient self reports.<sup>29-33</sup> A UK study found that intensive nurse led home visits and telephone monitoring for patients taking capecitabine for colorectal cancer reduced symptom severity, when compared to a control.<sup>34</sup> A follow up study that reviewed proactive calls made by nurses who also reviewed patients in clinics, but without home visits, found similar effects for some symptoms (i.e. vomiting, oral mucositis), but this was not as effective for others (e.g. diarrhoea and insomnia).<sup>30</sup> Limited evidence suggests home monitoring during SACT reduces hospital admissions<sup>33,34</sup> and may be most effective after cycle 1<sup>31</sup> or within cycles 1 and 2.<sup>34</sup> The assumption from these studies is that proactive support prevents escalation of symptoms and delayed contact with clinicians. Stronger evidence is required to substantiate or refute this position and to better understand any differences between home visits and telephone interventions. Cost-effectiveness and optimal timing of proactive support and any difference in need related to patient, disease or treatment characteristics also require further study.

### Recommendations for providers

1. Develop chemotherapy nursing to equally focus on holistic care (ongoing tailored support and information) and drug delivery.
2. Consider introduction of HNA within nurse led SACT consultations to identify and address patient and carer issues that may influence self-management.
3. Assess carer status and consider:
  - a. providing specific education opportunities for carers, e.g. encourage carers who live with patients to attend pre-treatment consultations or consider the intervention developed by Tsiannakas et al.,<sup>23</sup>
  - b. additional pro-active monitoring where there is no identifiable carer.
4. Consider motivational interview training for clinicians who educate patients about SACT side effects.
5. Consider use of tools like the Kings' Fund patient reported measure for patient activation.<sup>15</sup>
6. Ensure patients and carers have access to methods such as traffic light systems to self manage and report SACT symptoms.
7. Develop and evaluate individualised risk based protocol dependent approaches to plan pro-active patient calling. Evaluations should include a cost benefit analysis.

### Recommendations for further research

1. Randomised controlled trial (RCT) to explore any impact of self-management tools on SACT symptom reporting.
2. Explore any benefits of a holistic nursing approach to earlier symptom reporting.
3. Identify patient or disease specific risk factors for delayed reporting of SACT symptoms.
4. RCT to determine effects of home care and/or proactive calling on hospital admissions and morbidity and mortality from SACT.
5. Determine optimal timing for proactive monitoring.
6. To understand patient preferences (e.g. by age) for proactive calls/community health worker visits or technological approaches.

## Conclusion

Patients may delay reporting SACT side effects to clinicians, including those that are life-threatening. Two approaches are suggested to promote earlier symptom reporting that relate to empowerment and pro-active support. Recommendations for clinical practice include a more holistic approach to patient support during SACT. Studies should also be conducted to inform patient empowerment approaches and to better understand benefits of proactive support for individual patients and the health service.

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## Appendix 1: Example traffic light symptom reporting tool<sup>19</sup>

Symptom	None/No more than usual	Mild/Occasionally	Moderate/Often	Severe
<b>Fatigue /Tiredness</b>	None/No more than usual	Fatigue relieved by rest	Fatigue <b>NOT</b> relieved by rest, I had difficulty doing some things I normally do e.g. shopping	Fatigue <b>NOT</b> relieved by rest, unable to take care of myself e.g. dressing
<b>Nausea /Feeling sick</b>	None/No more than usual	I felt a bit sick, but I was able to eat and drink the <b>SAME AMOUNT</b> as usual	I felt quite sick, and I ate and drank <b>LESS THAN</b> normal	I felt very sick and was <b>NOT</b> able to eat or drink
<b>Vomiting</b>	None/No more than usual	I have vomited 1-2 times in one day	I have vomited 3-5 times in one day	I have vomited more than 6 times in one day
<b>Mucositis /Sore mouth</b>	None/no more than usual	My Mouth was <b>A BIT</b> sore	My mouth was <b>QUITE</b> sore but I could still eat and drink soft foods	My mouth was <b>VERY</b> sore and I could not eat or drink
<b>Diarrhoea /Loose stools</b>	None/No more than usual	I have had diarrhoea and opened my bowels 2-3 times <b>MORE</b> than before treatment	I have had diarrhoea and opened my bowels 4-6 <b>MORE</b> than before treatment	I have had diarrhoea and opened my bowels 7 times <b>MORE</b> than before treatment
<b>Constipation /Hard stools</b>	None/No more than usual	I have had occasional constipation which was relieved by changing my diet or taking laxatives	I have had to change my diet or taken laxatives <b>EVERYDAY</b> to relieve persistent constipation	I have had <b>SEVERE</b> stomach pain along with constipation
<b>Alopecia/Hair loss</b>	None/No more than usual	I have had a little bit of hair loss	I have had quite a bit of hair loss	I have lost all my hair
<b>Rash</b>	None/No more than usual	I have had a small area of skin rash <b>WITHOUT</b> itching or burning	I have had a skin rash <b>WITH</b> itching or burning	I have had a skin rash affecting a large area of my body <b>WITH</b> itching or burning
<b>Erythema /Skin changes</b>	None/No more than usual	My skin was a bit red but was <b>NOT</b> painful	My skin was red or cracked or blistered and <b>QUITE</b> painful	My skin was <b>VERY</b> painful
<b>Sensory Neuropathy /Numbness or Tingling</b>	None/No more than usual	I had <b>A BIT</b> of tingling or numbness often when handling hot or cold objects	I <b>OFTEN</b> had tingling or numbness and I had difficulty doing some things I normally do e.g. shopping	I had <b>CONSTANT</b> tingling or numbness, and I was unable to take care of myself e.g. dressing
<b>Pain</b>	None/No more than usual	I had <b>MILD</b> pain or discomfort	I had <b>MODERATE</b> pain or discomfort and I had difficulty doing some things I normally do e.g. shopping	I had <b>SEVERE</b> pain or discomfort and I was unable to take care of myself e.g. dressing

## Appendix 2: Example traffic light symptom reporting tool<sup>20</sup>

### Side effects

Although not experienced by everyone, some medicines can cause unwanted reactions which are commonly called side effects. If you experience side effects then it is very important that you report these to your hospital team, as soon as you identify them. Delay in reporting side effects may result in them becoming worse and potential treatment interruptions may occur. Below is a guide to common side effects and recommended actions.



**RED**



#### CALL 999

- › Chest pain
- › Difficulty breathing

#### Call the hospital immediately

- › Generally unwell
- › Shivery episodes or flu like symptoms
- › Temperature 37.5°C or above or below 36°C
- › Being sick (vomiting)
- › Diarrhoea (4+ loose bowel movements in 24hrs)
- › Bleeding or unusual bruising
- › Swollen or painful legs
- › Sore mouth that stops you eating or drinking



**AMBER**



#### Call the hospital within 24 hours

- › Sore mouth but can still eat and drink
- › Itchy or painful skin changes
- › Sore, watery eyes
- › Increase in pain
- › Constipation
- › Feeling sick (nausea)
- › Diarrhoea (2-4 loose bowel movements in 24hrs)



**GREEN**



#### Call the hospital within 48 hours

- › Tiredness
- › Skin changes that are not itchy or painful
- › Mood changes
- › Difficulty in coping with the treatment
- › Loss of appetite