RESPONSE EVALUATION OF CANCER CHEMOTHERAPY

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Global cancer incidence

- **The Americas**: 21.0% 
  Number of cases: 3,792,000
- **Europe**: 23.4% 
  Number of cases: 4,230,000
- **Asia**: 48.4% 
  Number of cases: 8,751,000
- **Africa**: 5.8% 
  Number of cases: 1,055,000

New Global Cancer Data: GLOBOCAN 2018
18.1 million new cases

9.6 million deaths
Figure 1. Trends in Age-adjusted Cancer Death Rates* by Site, Males, US, 1930-2015

*Age adjusted to the 2000 US standard population. †Mortality rates for pancreatic and liver cancers are increasing.

Note: Due to changes in ICD coding, numerator information has changed over time. Rates for cancers of the liver, lung and bronchus, colon and rectum, and uterus are affected by these coding changes.


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TREATMENT FOR CANCER

THE BEST STRATEGY FOR FIGHTING CANCER IS PREVENTION - I.E., MAKING CHANGES IN LIFE-styles TO REDUCE CANCER RISK. NEVERTHELESS, EVEN IF WE WERE TO APPLY ALL THAT WE KNOW ABOUT PREVENTING CANCER, ONE OUT OF FOUR CANCERS WOULD STILL OCCUR. BECAUSE OF THIS, THERAPIES THAT TARGET MALIGNANCIES AFTER THEY HAVE DEVELOPED WILL CONTINUE TO BE IMPORTANT FOR SOME TIME TO COME.

THE MOST COMMONLY USED TREATMENT MODALITIES FOR CANCER INCLUDE SOME COMBINATION OF SURGERY, RADIATION THERAPY, AND CHEMOTHERAPY.

NEWER FORMS OF TREATMENT CONTINUE TO EMERGE (IMMUNOTHERAPY, TARGETED AND HORMONAL ).
Types of drugs used in cancer treatment

Conventional chemotherapy agents (cytotoxic)
- Agents mainly directly targeting DNA structure or segregation of DNA as chromosomes in mitosis.

Targeted agents
- Small molecules or "biologicals" designed and developed to interact with a defined molecular target important in either maintaining the malignant state or selectively expressed by the tumour cells.

Hormonal therapies
- Capitalize on the biochemical pathways underlying estrogen and androgen function and action as a therapeutic basis for approaching patients with tumours of breast, prostate, uterus, and ovarian origin.

Biologic therapies
- Macromolecules that have a particular target (e.g., antigrowth factor or cytokine antibodies) or may have the capacity to orchestrate or regulate the host immune response to kill tumour cells.
Chemotherapy

Over 50 different chemotherapy drugs

Administered as an outpatient or inpatient depending on toxicity

Modes of administration include:
• Oral e.g. Methotrexate, Hydroxyurea
• IV: Canula/Indwelling Central Venous Catheter
• Sub cut
• Intracavity e.g pelvic cavity, bladder
• Intrathecal. Can be fatal if wrong drug administered!
If you're about to go for your first round of chemotherapy, you may have lots of questions along with some fears. Your oncologist will talk about the drugs you will receive and potential side effects, as well as how often you will need to be seen. Yet there are many tips that don't often make their way into those conversations, and if they do, you'll likely have more questions when you get back home.

Here are some tips on how to be as prepared as possible to have a good experience during your chemotherapy infusions and prevent problems and complications later on.

1. **Eat Light and Stay Well-Hydrated**
INFORMATION GIVEN TO PATIENTS, 11-97% PATIENTS NOT BE GIVEN ADEQUATE INFORMATION REGARDING THE MECHANISM of CHEMO, THE GOAL and THE SCHEDULE and THE EFFECTIVENESS, COMMON SIDE EFFECTS AND HOW TO DEAL WITH SIDE EFFECTS, AND HOW THE TREATMENT WILL INTERFERE WITH THEIR SOCIAL LIFE.

THE QUALITY AND QUANTITY OF INFORMATION ARE ALSO VARIED ACCORDING TO CANCER TYPES, TRUSTS, AND THE AVAILABILITY OF A CANCER CARE COORDINATOR.

THE COORDINATOR WILL PREPARE CANCER PATIENT AGAINST PSYCHOLOGICAL DISTRESS THAT WILL COMPROMISE THE RECOVERY AND THE COMPLIANCE WITH TREATMENT GIVEN

WALLER ET. AL., 2014.
Chemotherapy Classes

- **Alkylating agents**
  - nitrogen mustards
  - thiotepa, busulfan
  - nitrosoureas, mitomycin
  - procarbazine, dacarbazine

- **Taxanes**
  - paclitaxel, docetaxel
  - nab-paclitaxel

- **Topoisomerase II inhibitors**
  - etoposide

- **Platinum Complexes**
  - cisplatin, carboplatin
  - oxaliplatin

- **Anthracyclines**
  - doxorubicin, daunorubicin
  - idarubicin, mitoxantrone

- **Antimetabolites**
  - methotrexate
  - purine antagonists
  - pyrimidine antagonists

- **Tubulin interactive agents**
  - vincristine, vinblastine

- **Miscellaneous agents**
  - bleomycin
  - asparaginase
  - hydroxyurea
<table>
<thead>
<tr>
<th>Drug class</th>
<th>Mechanism of action</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alkylating agents</td>
<td>Impair cell function by forming covalent bonds on important molecules in proteins, DNA and RNA. Classified by their chemical structure and mechanism of covalent bonding.</td>
<td>Cisplatin, carboplatin, chlorambucil, cyclophosphamide, ifosfamide.</td>
</tr>
<tr>
<td>Anti-metabolites</td>
<td>Structural analogues of naturally occurring metabolites involved in DNA and RNA synthesis. They either substitute for a metabolite that is normally incorporated into DNA or RNA or compete for the catalytic site of a key enzyme.</td>
<td>5-Fluorouracil, methotrexate, pemetrexed, mercaptopurine, gemcitabine.</td>
</tr>
<tr>
<td>Anti-tumour antibiotics</td>
<td>Intercalate DNA at specific sequences, creating free radicals which cause strand breakage. Anthracyclines are products of the fungus <em>Streptomyces</em>, also have mechanism of action of topoisomerase I and II, required for the uncoiling of DNA during replication.</td>
<td>Bleomycin, anthracyclines (doxorubicin, epirubicin)</td>
</tr>
<tr>
<td>Topoisomerase inhibitors</td>
<td>Topoisomerases are enzymes that control the 3-D structure of DNA. Topoisomerase I and Topoisomerase II are enzymes responsible for the uncoiling of DNA during replication.</td>
<td>Topoisomerase I — irinotecan, topotecan Topoisomerase II — etoposide</td>
</tr>
<tr>
<td>Tubulin-binding drugs</td>
<td>Vinca alkaloids bind to tubulin, and prevent the formation of the microtubule, which is important during mitosis, but also for cell shape, intracellular transport and axonal function. Taxoids prevents the disassembly of the microtubules, thereby inhibit normal function.</td>
<td>Vinca alkaloids — vincristine, vinorelbine Taxoids — docetaxel, paclitaxel</td>
</tr>
</tbody>
</table>
Cancer Chemotherapy and Cell Cycle

- **$S$** DNA synthesis
  - S PHASE-SPECIFIC: cytosine arabinoside, hydroxyurea
  - S PHASE-SPECIFIC, SELF-LIMITING: 6-mercaptopurine, methotrexate

- **$G_1$** pre-mitotic interval

- **$G_2$** mitosis
  - M PHASE-SPECIFIC: vincristine, vinblastine, paclitaxel

- **$G_0$** resting phase

**PHASE-NONSPECIFIC:** alkylating drugs, nitrosoureas, antitumor antibiotics, procarbazine, cis-platinum, dacarbazine
Goal of Chemotherapy to:
- Cure patients
- Prolong survival
- Palliative care symptom control
Indication of Chemotherapy

As induction for advance disease
As adjuvant to local methods of treatment
As neo adjuvant (primary) when local treatment inadequate
As direct instillation agents into sanctuary sites

DeVita et al., 2018.
Kerr et al., 2018
FACTORS TO CONSIDER WHEN CHOOSING WHICH DRUGS TO USE

THE TYPE OF CANCER
THE STAGE OF THE CANCER (HOW FAR IT HAS SPREAD)
THE PATIENT’S AGE
THE PATIENT’S OVERALL HEALTH
OTHER SERIOUS HEALTH PROBLEMS (SUCH AS HEART, LIVER, OR KIDNEY DISEASES)
TYPES OF CANCER TREATMENTS GIVEN IN THE PAST
Because children’s bodies process drugs differently, dosages for children and adults differ, even after BSA is taken into account. Children may have different levels of sensitivity to the drugs, too. For the same reasons, dosages of some drugs may also be adjusted for people who:

- Are elderly
- Have poor nutritional status
- Are obese
- Have already taken or are currently taking other medicines
- Have already had or are currently getting radiation therapy
- Have low blood cell counts
- Have liver or kidney diseases
CHEMOTHERAPY IS COMMONLY GIVEN AT REGULAR INTERVALS CALLED CYCLES. A CYCLE MAY BE A DOSE OF ONE OR MORE DRUGS FOLLOWED BY SEVERAL DAYS OR WEEKS WITHOUT TREATMENT.

THIS GIVES NORMAL CELLS TIME TO RECOVER FROM DRUG SIDE EFFECTS. SOMETIMES, DOSES MAY BE GIVEN A CERTAIN NUMBER OF DAYS IN A ROW, OR EVERY OTHER DAY FOR SEVERAL DAYS, FOLLOWED BY A PERIOD OF REST. SOME DRUGS WORK BEST WHEN GIVEN CONTINUOUSLY OVER A SET NUMBER OF DAYS.
PRINCIPLES USED TO SELECT DRUGS FOR INCLUSION IN COMBINATION CHEMOTHERAPY REGIMENS:

DRUGS KNOWN TO BE ACTIVE AS SINGLE AGENTS
DRUGS THAT INDUCE CR SHOULD BE INCLUDED.
DRUGS WITH DIFFERENT MECHANISMS OF ACTION
DRUGS WITH DIFFERING DOSE-LIMITING TOXICITIES
DRUGS SHOULD BE USED IN THEIR OPTIMAL DOSE AND SCHEDULE.
DRUGS SHOULD BE GIVEN AT CONSISTENT INTERVALS.
DRUGS WITH DIFFERENT PATTERNS OF RESISTANCE

DeVita, 2018; Kerr et al., 2016
Incremental improvements in median survival of colorectal cancer with combination therapy

- Best supportive care – 6 months
- 12.1 months 5FU / leucovorin (Meverhardt et al, NEJM 352:476–487, 2005)
- 17 months FOLFOX / FOLFIRI (Colucci G et al, JCO 23:4866–4875, 2005)
- 20.3 months IFL + bevacizumab (Hurwitz et al, NEJM 350:2335–2342, 2004)
DOSING CHEMOTHERAPY

MOST CHEMOTHERAPY AGENTS HAVE A STEEP DOSE-RESPONSE RELATIONSHIP AND A NARROW THERAPEUTIC INDEX.

BSA HAS BEEN USED FOR MOST CYTOTOXIC AGENTS AND SOME THERAPEUTIC MONOCLONAL ANTIBODIES (E.G. RITUXIMAB AND CETUXIMAB). RESEARCHERS HAVE NOT FOUND A BETTER DOSING METHOD THAN BSA, EXCEPT FOR AN AREA UNDER THE CURVE (AUC) BASED DOSING FOR CARBOPLATIN.

SINCE THERE IS NO TRIAL DATA COMPARING THE SUPERIORITY OF SPECIFIC FORMULA, AMERICAN SOCIETY OF CLINICAL ONCOLOGY (ASCO) STATED THAT ANY OF THE FORMULAE CAN BE USED

Griggs et. al., 2006
Eaton et al., 2017
EVALUATION OF THE RESPONSE

TOXICITY
SEVERITY SCALES HAVE BEEN DEFINED
QUANTITATIVE MEASUREMENT TO EVALUATE HEMATOLOGICAL

EFFICACY
TUMOR NECROSIS
IMAGING TECHNOLOGIES (PET-scan)
OR LONGTERM RESPONSE (ie. SURVIVAL)

....................... CLINICALLY
## Performance status

<table>
<thead>
<tr>
<th>Karnofsky Scale</th>
<th>Zubrod Scale</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Normal, no evidence of disease</strong>&lt;br&gt;Able to perform normal activity with only minor symptoms</td>
<td>100&lt;br&gt;90</td>
</tr>
<tr>
<td><strong>Normal activity with effort, some symptoms</strong>&lt;br&gt;Able to care for self but unable to do normal activities</td>
<td>80&lt;br&gt;70</td>
</tr>
<tr>
<td><strong>Requires occasional assistance, cares for most needs</strong>&lt;br&gt;Requires considerable assistance</td>
<td>60&lt;br&gt;50</td>
</tr>
<tr>
<td><strong>Disabled, requires special assistance</strong>&lt;br&gt;Severely disabled</td>
<td>40&lt;br&gt;30</td>
</tr>
<tr>
<td><strong>Very sick, requires active supportive treatment</strong>&lt;br&gt;Moribund</td>
<td>20&lt;br&gt;10</td>
</tr>
</tbody>
</table>
New response evaluation criteria in solid tumours: Revised RECIST guideline (version 1.1)

E.A. Eisenhauer\textsuperscript{a,*}, P. Therasse\textsuperscript{b}, J. Bogaerts\textsuperscript{c}, L.H. Schwartz\textsuperscript{d}, D. Sargent\textsuperscript{e}, R. Ford\textsuperscript{f}, J. Dancey\textsuperscript{g}, S. Arbuck\textsuperscript{h}, S. Gwyther\textsuperscript{i}, M. Mooney\textsuperscript{g}, L. Rubinstein\textsuperscript{g}, L. Shankar\textsuperscript{g}, L. Dodd\textsuperscript{g}, R. Kaplan\textsuperscript{j}, D. Lacombe\textsuperscript{c}, J. Verweij\textsuperscript{k}

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\textsuperscript{b}GlaxoSmithKline Biologicals, Rixensart, Belgium
\textsuperscript{c}European Organisation for Research and Treatment of Cancer, Data Centre, Brussels, Belgium
\textsuperscript{d}Memorial Sloan Kettering Cancer Center, New York, NY, USA
\textsuperscript{e}Mayo Clinic, Rochester, MN, USA
<table>
<thead>
<tr>
<th>Characteristic</th>
<th>RECIST</th>
<th>WHO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Objective response (OR) (LD is the longest diameter)</td>
<td><strong>Target lesions</strong> change in sum of LDs, maximum 5 per organ up to 10 total (more than one organ)</td>
<td><strong>Measurable disease</strong> change in the sum of the products of LDs and greatest perpendicular diameters, no maximum number of lesions specified</td>
</tr>
<tr>
<td>Complete response (CR)</td>
<td>Disappearance of all target lesions, confirmed at $\geq 4$ weeks</td>
<td>Disappearance of all known disease, confirmed at $\geq 4$ weeks</td>
</tr>
<tr>
<td>Partial response (PR)</td>
<td>$\geq 30%$ decrease from baseline, confirmed at $\geq 4$ weeks</td>
<td>$\geq 50%$ decrease from baseline, confirmed at $\geq 4$ weeks</td>
</tr>
<tr>
<td>Progressive disease (PD)</td>
<td>$\geq 20%$ increase over smallest sum observed or appearance of new lesions</td>
<td>$\geq 25%$ increase in one or more lesions or appearance of new lesions</td>
</tr>
<tr>
<td>Stable disease (SD)</td>
<td>Neither PR nor PD criteria met</td>
<td>Neither PR nor PD criteria met (no change)</td>
</tr>
</tbody>
</table>
### TABLE 3: Comparison of Version 1.0 Versus Version 1.1 of Response Evaluation Criteria in Solid Tumors (RECIST)

<table>
<thead>
<tr>
<th>Criterion</th>
<th>Version 1.0</th>
<th>Version 1.1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimum size of target lesion</td>
<td>$\geq 10$ mm on helical CT; $\geq 20$ mm on nonhelical CT and MRI</td>
<td>$\geq 10$ mm on helical CT or MRI; $\geq 20$ mm on chest radiography</td>
</tr>
<tr>
<td>Overall tumor burden</td>
<td>Maximum of 10 target lesions total (maximum of 5 per organ)</td>
<td>Maximum of 5 target lesions total (maximum of 2 per organ)</td>
</tr>
<tr>
<td>Measurement</td>
<td>1D longest diameter of tumor</td>
<td>1D longest diameter of tumor; short axis of lymph nodes</td>
</tr>
<tr>
<td>New lesions</td>
<td>None</td>
<td>Clarified</td>
</tr>
<tr>
<td>Measurement of bone and cystic lesions</td>
<td>None</td>
<td>Clarified</td>
</tr>
<tr>
<td>Lymph node measurements</td>
<td>None</td>
<td>Lymph nodes $\geq 15$ mm are target lesion; lymph nodes $&lt; 10$ mm are nonpathologic</td>
</tr>
<tr>
<td>Response criteria for target lesions (PD)</td>
<td>20% increase over smallest sum on study or new lesions</td>
<td>20% increase over smallest sum on study and at least 5 mm increase or new lesions</td>
</tr>
<tr>
<td>Response criteria for nontarget lesions (PD)</td>
<td>Unequivocal progression considered as PD</td>
<td>More detailed description of “unequivocal progression”</td>
</tr>
<tr>
<td>Confirmation of CR and PR</td>
<td>After at least 28 d</td>
<td>Only required if response is primary endpoint and not randomized</td>
</tr>
<tr>
<td>$^{18}$FDG PET</td>
<td>None</td>
<td>Used only to support CT if PD or to confirm CR</td>
</tr>
</tbody>
</table>

Note—CR = complete response, PR = partial response, PD = progressive disease.
Table 1. RECIL 2017: Response categories based on assessment of target lesions

<table>
<thead>
<tr>
<th>% Change in sum of diameters of target lesions from nadir</th>
<th>CR</th>
<th>PR</th>
<th>MR&lt;sup&gt;a&lt;/sup&gt;</th>
<th>SD</th>
<th>PD</th>
</tr>
</thead>
<tbody>
<tr>
<td>% change from baseline</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Complete disappearance of all target lesions and all nodes with long axis &lt;10mm.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- ≥30% decrease in the sum of longest diameters of target lesions (PR) with normalization of FDG-PET</td>
<td>≥30% decrease in the sum of longest diameters of target lesions but not a CR</td>
<td>≥10% decrease in the sum of longest diameters of target lesions but not a PR (&lt;30%)</td>
<td>&lt;10% decrease or ≤ 20% increase in the sum of longest diameters of target lesions</td>
<td></td>
<td>&gt;20% increase in the sum of longest diameters of target lesions</td>
</tr>
<tr>
<td>FDG-PET</td>
<td>Normalization of FDG-PET (Deauville score 1-3)</td>
<td>Positive (Deauville score 4-5)</td>
<td>Any</td>
<td>Any</td>
<td>Any</td>
</tr>
<tr>
<td>Bone marrow involvement</td>
<td>Not involved</td>
<td>Any</td>
<td>Any</td>
<td>Any</td>
<td>Any</td>
</tr>
<tr>
<td>New lesions</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes or No</td>
</tr>
</tbody>
</table>

CR, complete response; CT, computerized tomography; FDG-PET, [<sup>18</sup>F]-2-fluoro-2-deoxy-D-glucose; MR, minor response; PD, progression of disease; PR, partial response; SD, stable disease.

<sup>a</sup>A provisional category.
# RESPONSE CRITERIA IN AML

<table>
<thead>
<tr>
<th>RESPONSE CRITERION</th>
<th>TIME OF ASSESSMENT</th>
<th>NEUTROPHILS (µL)</th>
<th>PLATELETS (µL)</th>
<th>BONE MARROW BLASTS (%)</th>
<th>OTHER</th>
</tr>
</thead>
<tbody>
<tr>
<td>EARLY TREATMENT ASSESSMENT</td>
<td>7-10 DAYS AFTER THERAPY</td>
<td>NA</td>
<td>NA</td>
<td>&lt; 5</td>
<td></td>
</tr>
<tr>
<td>MORPHOLOGIC LEUKEMIA-FREE STATE</td>
<td>VARIES BY PROTOCOL</td>
<td>NA</td>
<td>NA</td>
<td>&lt; 5</td>
<td>FLOW CYTOMETRY EMD</td>
</tr>
<tr>
<td>MORPHOLOGIC CR</td>
<td>VARIES BY PROTOCOL</td>
<td>&gt; 1,000</td>
<td>&gt; 100,000</td>
<td>&lt; 5</td>
<td>TRANSFUSION EMD</td>
</tr>
<tr>
<td>CYTOGENETIC</td>
<td>VARIES BY PROTOCOL</td>
<td>&gt; 1,000</td>
<td>&gt; 100,000</td>
<td>&lt; 5</td>
<td>CYTOGENICS-NORMAL, EMD</td>
</tr>
<tr>
<td>MOLECULAR CR</td>
<td>VARIES BY PROTOCOL</td>
<td>&gt; 1,000</td>
<td>&gt; 100,000</td>
<td>&lt; 5</td>
<td>MOLECULAR-NEGATIVE, EMD</td>
</tr>
<tr>
<td>PARTIAL REMISSION</td>
<td>VARIES BY PROTOCOL</td>
<td>&gt; 1,000</td>
<td>&gt; 100,000</td>
<td>&lt; 50 OR DECREASE TO 5-25</td>
<td>BLASTS &lt; 5% IF AUER ROD POSITIVE</td>
</tr>
</tbody>
</table>

Abbreviations: AML, acute myelogenous leukemia; EMD, extramedullary disease; CR, complete remission.
Common Toxicities

• Most chemotherapy drugs are active in cells that are rapidly multiplying
  – Chemotherapy may not be very active in indolent or slow growing tumors

• Because of cytotoxic action on rapidly dividing cells they are toxic to normal cells that are actively multiplying
  – Bone marrow, GI tract, hair follicles are all rapidly multiplying

• Thus common toxicity of chemo agents are -
  – Neutropenia, anemia, and thrombocytopenia (collectively called myelosuppression or bone marrow suppression)
  – Mucositis, diarrhea (GI toxicity)
  – Nausea and vomiting
  – Alopecia
  – Sterility/Infertility (especially sterility in males)

• Common Toxicity Criteria Grading System (CTC)
  – Grade 0 – 4
Common toxicities of chemotherapy: Mucositis

Skin toxicity

Methotrexate

Docetaxel

Erlotinib

Cetuximab acneiform rash

Common toxicities of chemotherapy: Alopecia
RISK OF SECONDARY MALIGNANCY AFTER CHEMOTHERAPY FOR SOLID TUMORS
MYELOID NEOPLASIA

Evolving risk of therapy-related acute myeloid leukemia following cancer chemotherapy among adults in the United States, 1975-2008

Lindsay M. Morton,1 Graça M. Dores,1,2 Margaret A. Tucker,1 Clara J. Kim,1 Kenan Onel,3 Ethel S. Gilbert,1 Joseph F. Fraumeni Jr,1 and Rochelle E. Curtis1

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JAMA Oncology | Original Investigation

Association of Chemotherapy for Solid Tumors With Development of Therapy-Related Myelodysplastic Syndrome or Acute Myeloid Leukemia in the Modern Era

Lindsay M. Morton, PhD; Graça M. Dores, MD, MPH; Sara J. Schonfeld, PhD, MPH; Martha S. Linet, MD, MPH; Byron S. Sigel, BA; Clara J. K. Lam, PhD; Margaret A. Tucker, MD; Rochelle E. Curtis, MA

TESTICULAR CANCER

Risk of solid cancer after chemotherapy

Chunkit Fung and Lois B. Travis

Platinum-based chemotherapy continues to be linked with the subsequent development of various solid tumours. In a large analytical study of >5,800 survivors of testicular cancer, Groot and colleagues observed statistically significant dose-dependent increases in gastrointestinal cancer incidence after platinum-based chemotherapy, providing evidence for a potential dose-dependent relationship.
• Chemotherapy is a major treatment in curing or prolonging survival in cancer patients
• It has a wide range of side effects depending on the drugs given.
• Nurses have a key role to play in caring for a patient receiving chemotherapy
• Safety issues are paramount in administration.
The potential benefit to the patient of treatment as an option must always outweigh the toxic effects.

THANK YOU