振興醫療財團法人振興醫院

胃癌治療準則

癌 症 委 員 會

胃癌多專科醫療團隊

注意事項：這個診療準則主要作為醫師和其他保健專家診療癌症病人參考之用。
假如你是一個癌症病人,直接引用這個研究資訊及診療準則並不恰當，
只有你的醫師才能決定給你最恰當的治療。2010 年 2 月初訂 2014 年 12 月 12 日修訂

Abbreviations

1. Bx=Biopsy
2. C/T=Chemotherapy
3. C/R=Chemoradiation
4. R/T= Radiotherapy
5. Cap.=Capecitabine
6. FluoroP=Fluoropyrimidine
7. LUV=Leucovorin
8. EMR=Endoscopic Mucosal Resection =>ER
9. ESD=Endoscopic Submucosal Dissection

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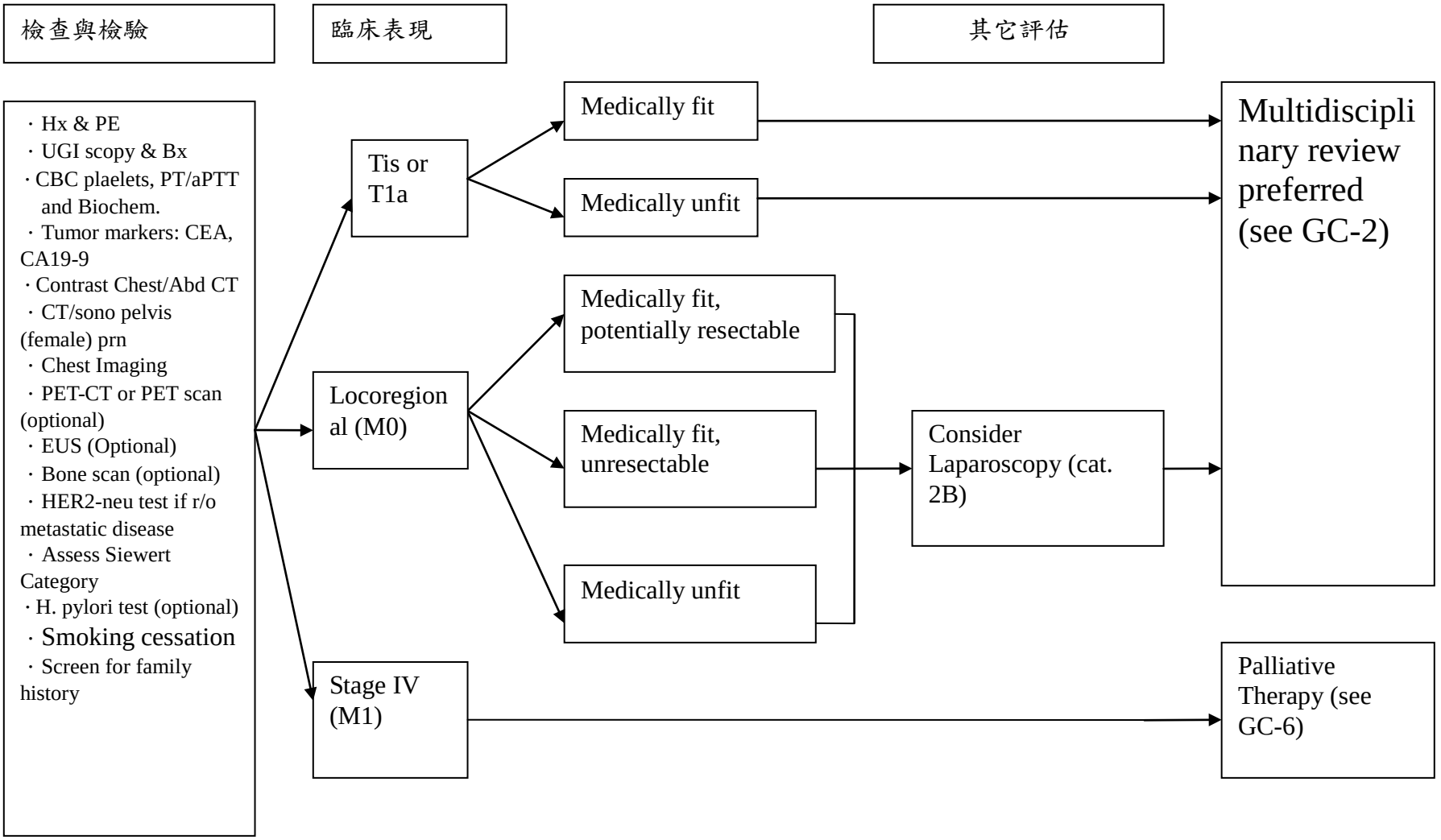

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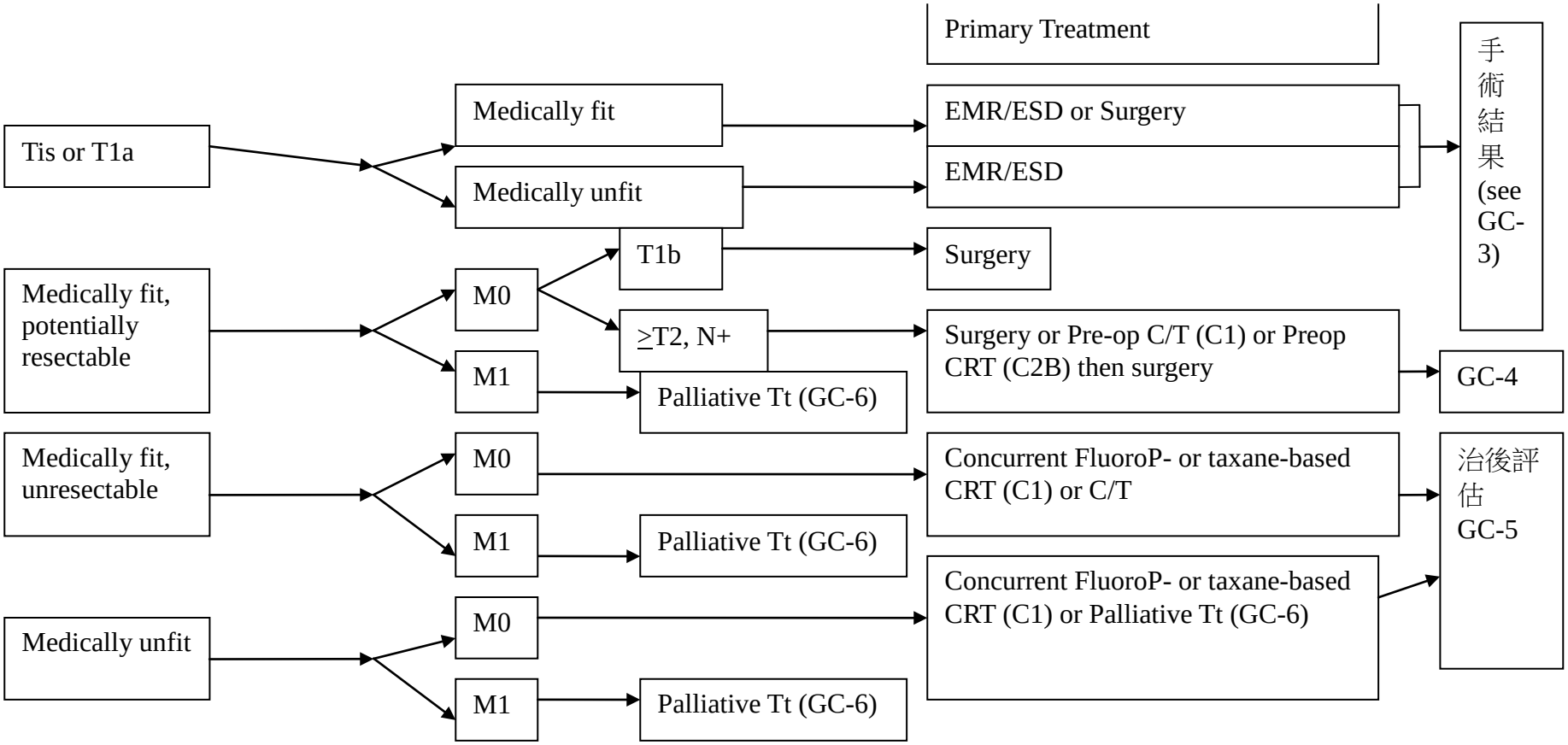

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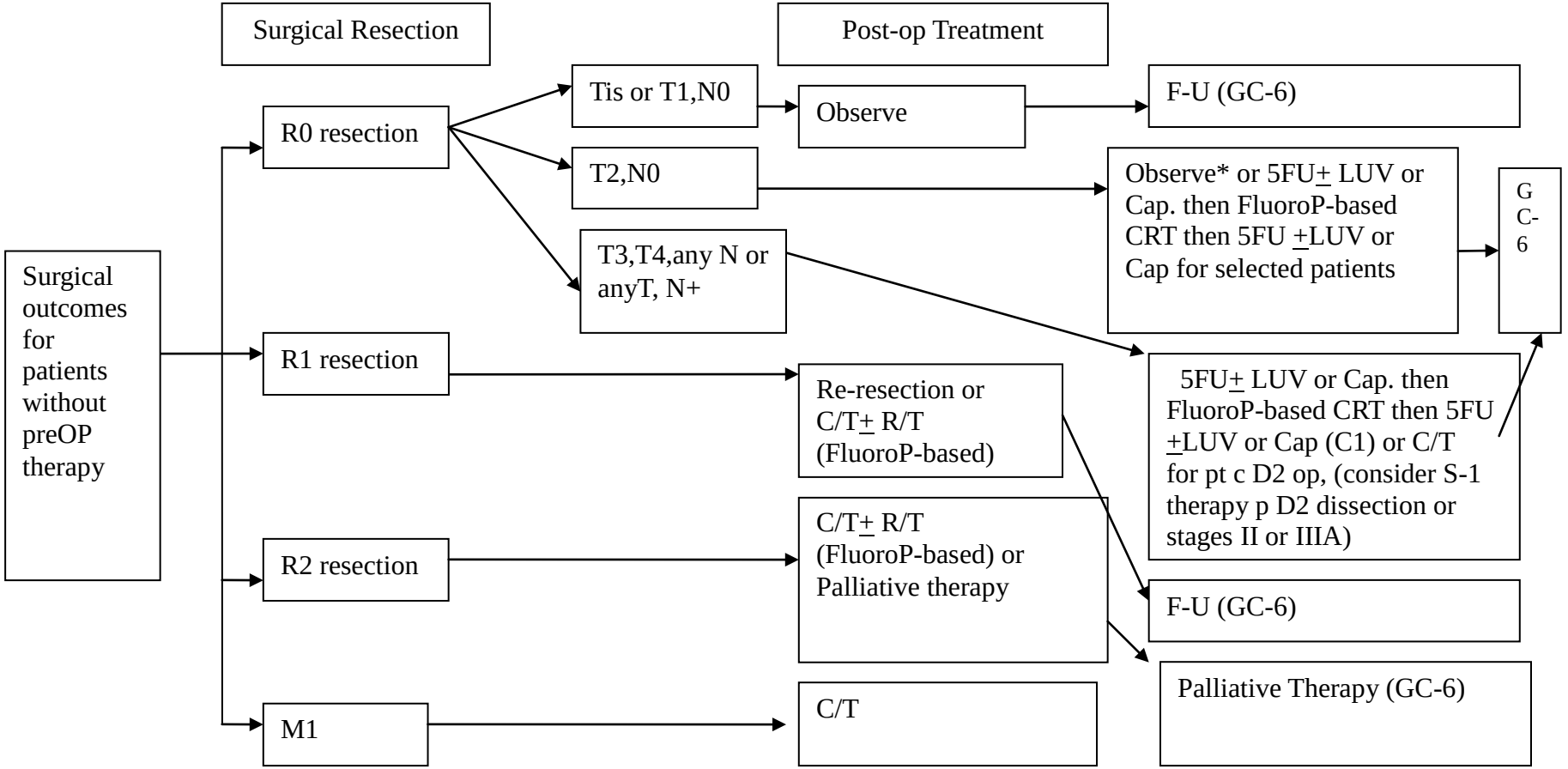

* **High risk features**: poorly differentiation or higher grade, lymphovascular invasion, neural invaision or < 50 y/o

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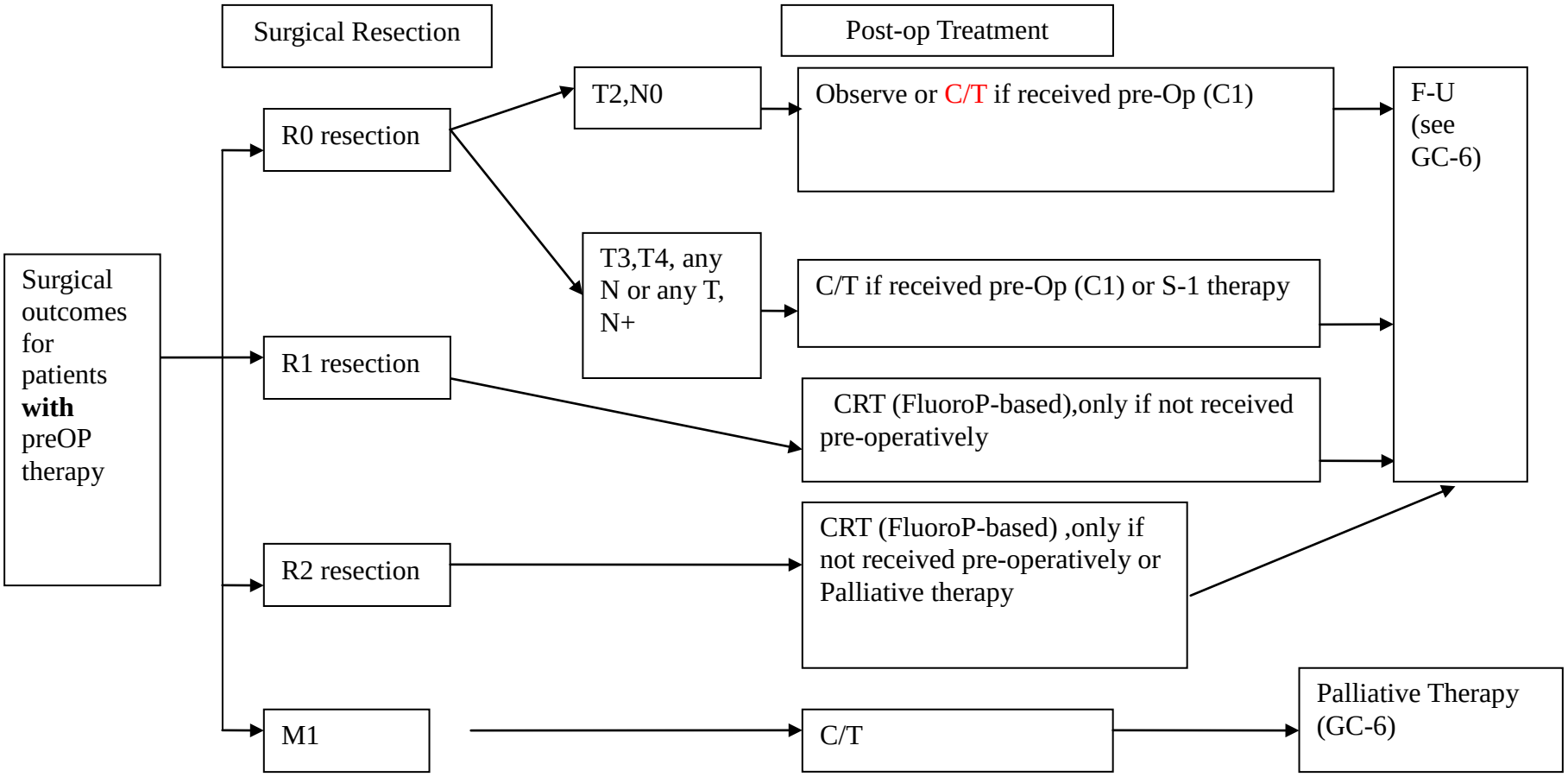

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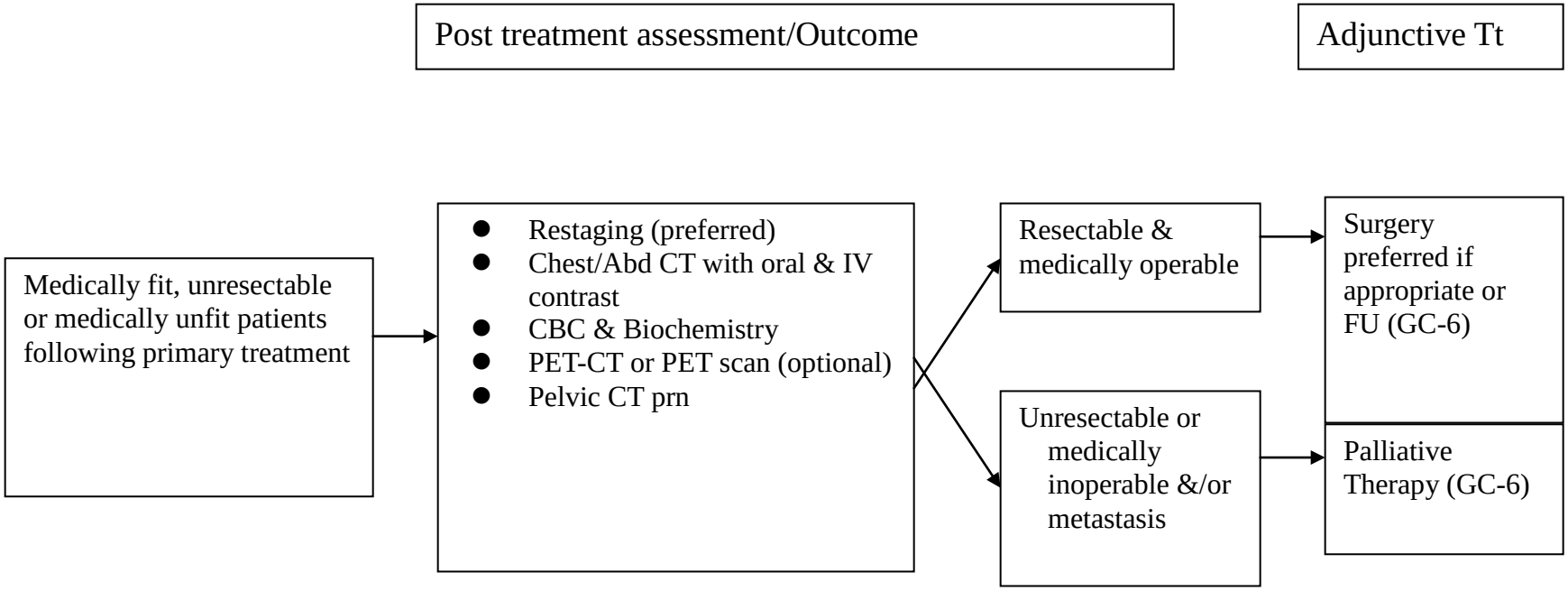

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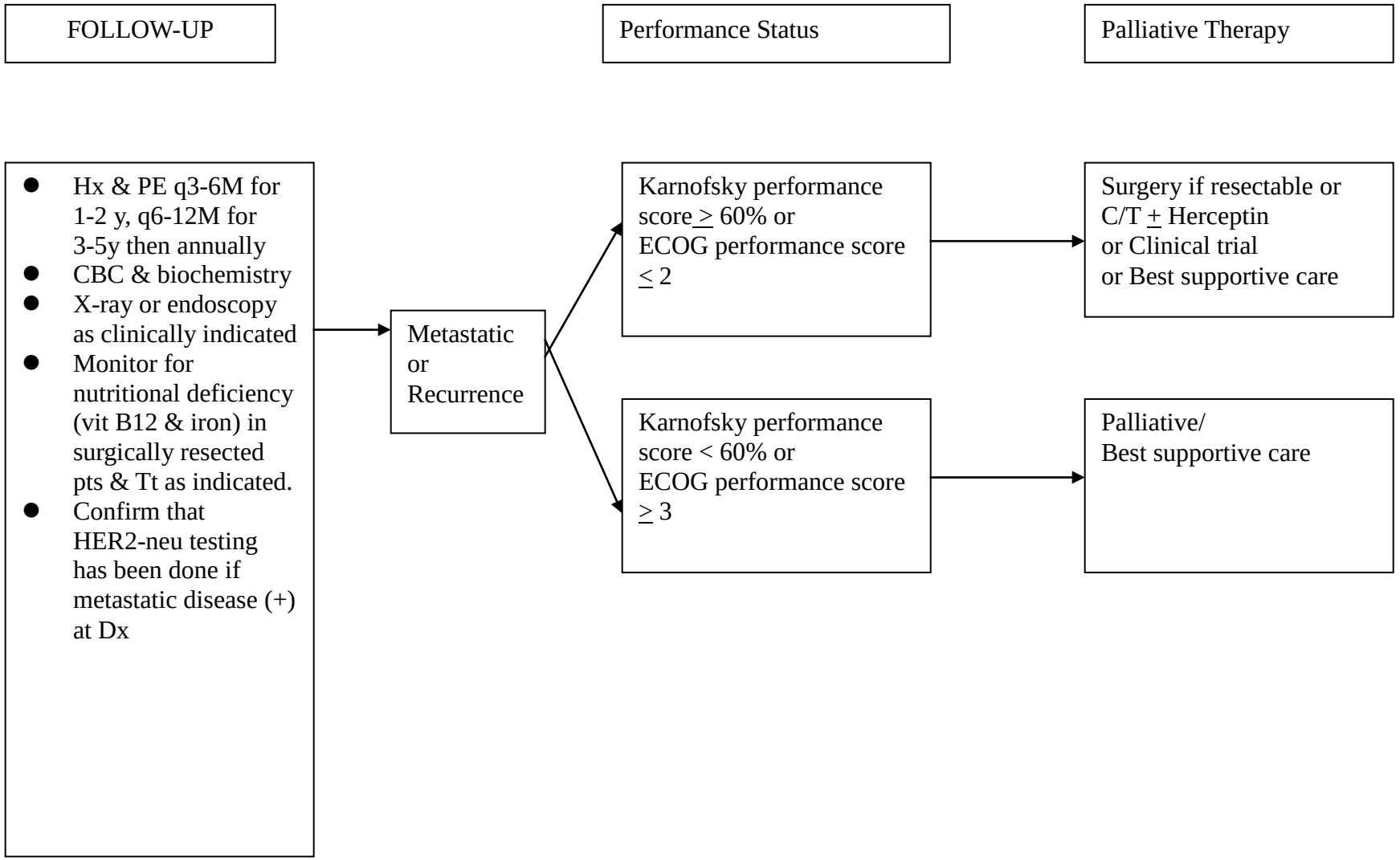

Principle of Surgery

- Staging

  Determine extent of disease with CT scan ± EUS

  Laparoscopy may be useful in selected patients in detecting radiographically occult metastatic disease.

- Criteria of unresectability for cure
  - Locoregionally advanced
  - Level 3 or 4 lymph node highly suspicious on imaging or confirmed by biopsy
  - Invasion or encasement of major vascular structures
  - Distant metastasis or peritoneal seeding (including positive peritoneal cytology)

Resectable tumors

- Tis or T1 tumors limited to mucosa (T1a) may be candidates for endoscopic mucosal resection
- T1b-T3 : Adequate gastric resection to achieve negative microscopic margins (typically 4 cm from gross tumor).
- Distal/Subtotal/ total gastrectomy
- T4 tumors require en bloc resection of involved structures
- Gastric resection should include the regional lymphatics-- perigastric lymph nodes (D1) and those along the named vessels of the celiac axis (D2), with a goal of examining 15 or greater lymph nodes
- Routine or prophylactic splenectomy is not required. Splenectomy is acceptable when the spleen or the hilum is involved.

Unresectable tumors (palliative procedures)

- Palliative gastric resection could be performed in symptomatic patients.
- Lymph node dissection not required.
- Gastric bypass with gastrojejunostomy to the proximal stomach may be useful in palliating obstructive symptoms in symptomatic patients.
- Venting gastrostomy and/or jejunostomy tube may be considered
- Stent implantation for pyloric obstruction may be considered.

PRINCIPLES OF RADIATION THERAPY

General Guidelines

• Prior to simulation, pertinent radiographs, procedure notes and pathology reports should be reviewed by a multidisciplinary team including surgical, radiation, medical oncologists, gastroenterologists, radiologists and pathologists. This will allow an informed determination of treatment volume and field borders prior to simulation.

• In general, Siewert I and II tumors should be managed with radiation therapy guidelines applicable to esophageal cancers. Depending on the clinical situation, Siewert III tumors, may be more appropriately managed with radiation therapy guidelines applicable to either esophageal or gastric cancers. These recommendations may be modified depending on where the bulk of the tumor is located.

- **Siewert classification** is anatomical classification of the location of esophago-gastric junction (EGJ) tumors. (1996)

Type I adenocarcinoma of distal part of the esophagus (center located within between 1-5cm above the anatomic EGJ)
Type II adenocarcinoma of the real cardia (within 1cm above and 2cm below the EGJ)
Type III adenocarcinoma of the is subcardial stomach (2-5cm below EGJ)

PRINCIPLES OF SYSTEMIC THERAPY

1. **Chemotherapy regimens recommended for advanced esophageal/esophagogastric adenocarcinoma, squamous cell carcinoma of the esophagus, and gastric adenocarcinoma may be used interchangeably (except as indicated).**
2. **Regimens should be chosen in the context of performance status, medical comorbidities, toxicity profile, and HER2-neu expression (for adenocarcinoma only).**
3. **The use of three-drug regimens for advanced disease should be reserved for patients who are medically fit, with a good performances status (ECOG performance status of 0 or 1), and with access to frequent toxicity assessment.**
4. **Modifications of category 1 regimens or use of category 2A or 2B regimens may be preferred (as indicated), with evidence supporting more favorable toxicity profile without a compromise of efficacy.**
5. **Doses and schedules for any regimen that is not derived from category 1 evidence is a suggestion, and subject to appropriate modifications depending on the circumstances.**
6. **Alternate combinations and schedules of cytotoxics based on the availability of the agents, practice preferences, and contraindications are permitted.**
7. **Infusional 5-FU and capecitabine may be used interchangeably (except as indicated). Infusion is the preferred route compared with bolus 5-FU.**
8. **Cisplatin and oxaliplatin may be used interchangeably depending on toxicity profile.**
9. **For localized esophagogastric/gastric cardia adenocarcinoma, preoperative chemoradiation is the preferred approach.**
10. **For localized stomach cancer, perioperative chemotherapy or postoperative chemotherapy plus chemoradiation is the preferred approach.**

***Recommended regimens for adjuvant chemotherapy**

1. TS-1 (or S-1)[1]: TS-1 80mg/m2 per day (Bid) for 4 weeks every 6 weeks for 1 year

2. Xelox[2] (capecitabine/oxaliplatin)

Oxaliplatin 135mg/m2 on D1, Capecitabine 1000mg/m2 BID for 14 days every 3 weeks for 6 months

Or

Oxaliplatin 85mg/m2 on D1, Capecitabine 1000mg/m2 BID for 10 days every 2 weeks for 6 months

3. High dose PFL[3]

Cisplatin 30 mg/m2 IV, folinic acid 500 mg/m2 IV, 5-FU 2200 mg/m2 CIVD for 22 h, weekly for 6 months.

4. Ufur 2# bid for 16 months (健保只有在轉移性胃癌才有給付 ufur)

***Recommended regimens for recurrent or metastatic gastric cancer**

First-line therapy regimens:

1. **Xelox (capecitabine/oxaliplatin, *preferred regimen*)**[4]

   Oxaliplatin 130-135 mg/m2 on D1, Capecitabine 1000mg/m2 BID for 14 days every 3 weeks

   Or

   Oxaliplatin 85mg/m2 on D1, Capecitabine 1000mg/m2 BID for 10 days every 2 weeks

2. **High dose PFL (cisplatin/fluorouracil/leucovorin)**

   Cisplatin 30mg/m2 IV, folinic acid 500 mg/m2 IV, 5-fluorouracil (5-FU) 2200 mg/m2 CIVD for 22 h, weekly

   Or

   Cisplatin 75-100 mg/m^2 IV on Day 1

   Fluorouracil 750-1000 mg/ m^2 IV continuous infusion over 24 hours daily on Day 1-4

   Cycled every 28 days

3. **TS-1 + cisplatin**[5]

   TS-1:40-60 mg BID for 21 days every 5 weeks, Cisplatin 60mg/m2 on D8

4. Cisplatin and capecitabine

Cisplatin 80 mg/m^2 IV on Day 1

Capecitabine 1000 mg/m^2 PO BID on Day 1-14

Cycled every 21 days

5. 5-FU and Oxaliplatin

Oxaliplatin 85 mg/m^2 IV on Day 1

Leucovorin 400 mg/ m^2 IV on Day 1

Fluorouracil 400 mg/ m^2 IV on Day 1

Fluorouracil 1200 mg/ m^2 IV continuous infusion over 24 hours daily on Day 1 and 2

Cycled every 14 days

6. Weekly OFL[8]

Oxaplatin 65 mg/m2 IV, Leucovorin 300 mg/m2 IV, 5FU 2600 mg/m2 CIVD for 24 hrs, weekly.

7. DCF

Docetaxel 40 mg/ m^2 IV on Day 1

Leucovorin 400 mg/ m^2 IV on Day 1

Fluorouracil 400 mg/ m^2 IV on Day 1

Fluorouracil 1000 mg/ m^2 IV continuous infusion over 24 hours daily on Day 1 and 2

Cisplatin 40mg/m^2 IV on Day 3
Cycled every 14 days

or

Docetaxel 50 mg/ m^2 IV on Day 1
Oxaliplatin 85mg/m^2 on Day 1
Fluorouracil 400 mg/ m^2 IV on Day 1
Fluorouracil 1200 mg/ m^2 IV continuous infusion over 24 hours daily on Day 1 and 2
Cycled every 14 days

8. ECF

Epirubicin 50 mg/ m^2 IV on Day 1
Cisplatin 60mg/m^2 IV on Day 1
Fluorouracil 200 mg/ m^2 IV continuous infusion over 24 hours daily on Day 1-21
Cycled every 21 days
Cycled every 14 days

9. Trastuzumab + chemotherapy in HER-2 (+)[9]

***Second-line therapy regimens**

-Taxane based

1. DCF regimen[10]

Docetaxel 75mg/m2 IV and Cisplatin 75mg/m2 IV on D1

5-FU 750mg/m2 CIVD on D1-5, every 3 weeks

2. TCF[11]

Paclitaxel 100 mg/m^2 and Cisplatin 30 mg/m2 IV on D1 and 8

UFT 300 mg/m2 plus LV 90 mg per day on D1-14, every 3 weeks

3. Irinotecan

Irinotecan 250-350 mg/ m^2 IV on Day 1

Cycled every 21 days

Or

Irinotecan 150-180 mg/ m^2 IV on Day 1

Cycled every 14 days

Or

Irinotecan 125 mg/ m^2 IV on Day 1 and 8

Cycled every 21 days

4. Irinotecan based[12]

Irinotecan 80 mg/m2 IV, folinic acid 500 mg/m2 IV, 5-fluorouracil (5-FU) 2000 mg/m2 CIVD for 22 h, for 6 weeks every 7 weeks

5. Irinotecan and cisplatin

Irinotecan 65 mg/ m^2 IV on Day 1 and 8
Cisplatin 25-30 mg/ m^2 IV on Day 1 and 8
Cycled every 21 days

6. Docetaxel

Docetaxel 75-100 mg/ m^2 IV on Day 1
Cycled every 21 days

7. Paclitaxel

Paclitaxel 135-250 mg/ m^2 IV on Day 1
Cycled every 21 days

Or

Paclitaxel 80 mg/ m^2 IV on Day 1 weekly
Cycled every 28 days

Or

Paclitaxel 80 mg/ m^2 IV on Day 1, 8, and Day 15
Cycled every 28 days

8. Docetaxel and Irinotecan

Docetaxel 35 mg/ m^2 IV on Day 1 and 8
Irinotecan 50 mg/ m^2 IV on Day 1 and 8
Cycled every 21 days

9. Mitomycin and Irinotecan

Mitomycin 5 mg/ m^2 IV on Day 1

Irinotecan 125 mg/ m^2 IV on Day 1

Cycled every 14 days

10. Trastuzumab + chemotherapy in HER-2 (+)[9]

11. Ramucirumab

Ramucirumab 8 mg/kg IV on Day 1

Cycled every 14 days

12. Ramucirumab + paclitaxel

Ramucirumab 8 mg/kg IV on Day 1 and Day 15

Paclitaxel 80 mg/m2 on Day 1, 8, and Day 15

Cycled every 28 days

**Principles of Systemic therapy for Gastric cancer (NCCN V1. 2014) (Please refer to the Reference # of NCCN guideline)

Preoperative Chemoradiation (EGJ and gastric cardia):

*Preferred Regimens:

-Paclitaxel and carboplatin (category 1)[1]

-Cisplatin and fluorouracil (category 1)[2,3]

-Oxaliplatin and fluorouracil (category 1)[4,5]

-Cisplatin and capecitabine[6]

-Oxaliplatin Capecitabine[7]

Postoperative Chemoradiation (including EGJ):

5FU and leucovorin

Postoperative Chemotherapy

-Capecitabine & Oxaliplatin[20]

-Capecitabine & Cisplatin[21]

*Other Regimens for Pre-op CRT:

-Irinotecan and cisplatin (category 2B)[8]

-Taxane and fluoropyrimidine (category 2B)[9,10]

Perioperative Chemotherapy (including EGJ adenocarcinoma) (3 cycles preoperative and 3 cycles postoperative):

ECF (epirubicin, cisplatin and fluorouracil) (category 1)[11]

ECF modifications (category 1)[12]

- Epirubicin, Oxaliplatin and fluorouracil
- Epirubicin, Cisplatin and capecitabine
- Epirubicin, Oxaliplatin and capecitabine

Fluorouracil and cisplatin (category 1)[13]

Staging

Table 1

American Joint Committee on Cancer (AJCC)
TNM Staging Classification for Carcinoma of the Stomach
(7th ed., 2010)

Primary Tumor (T)
TX Primary tumor cannot be assessed
T0 No evidence of primary tumor
Tis Carcinoma in situ: intraepithelial tumor without invasion of the lamina propria
T1 Tumor invades lamina propria, muscularis mucosae or submucosa
T1a Tumor invades lamina propria or muscularis mucosae
T1b Tumor invades submucosa
T2 Tumor invades muscularis propria*
T3 Tumor penetrates subserosal connective tissue without invasion of visceral peritoneum or adjacent structures**,***
T4 Tumor invades serosa (visceral peritoneum) or adjacent structures**,***
T4a Tumor invades serosa (visceral peritoneum)
T4b Tumor invades adjacent structures

Regional Lymph Nodes (N)
NX Regional lymph node(s) cannot be assessed
N0 No regional lymph node metastasis§
N1 Metastasis in 1 - 2 regional lymph nodes
N2 Metastasis in 3 - 6 regional lymph nodes
N3 Metastasis in seven or more regional lymph nodes
N3a Metastasis in 7 - 15 regional lymph nodes
N3b Metastasis in 16 or more regional lymph nodes

Distant Metastasis (M)
M0 No distant metastasis
M1 Distant metastasis

Histologic Grade (G)
GX Grade cannot be assessed
G1 Well differentiated
G2 Moderately differentiated
G3 Poorly differentiated
G4 Undifferentiated

* Note: A tumor may penetrate the muscularis propria with extension into the gastrocolic or gastrohepatic ligaments, or into the greater or lesser omentum, without perforation of the visceral peritoneum covering these structures. In this case, the tumor is classified T3. If there is perforation of the visceral peritoneum covering the gastric ligaments or the omentum, the tumor should be classified T4.

**The adjacent structures of the stomach include the spleen, transverse colon, liver, diaphragm, pancreas, abdominal wall, adrenal gland, kidney, small intestine, and retroperitoneum.

***Intramural extension to the duodenum or esophagus is classified by the depth of the greatest invasion in any of these sites, including the stomach.

§A designation of pN0 should be used if all examined lymph nodes are negative, regardless of the total number removed and examined.

Continued...

Staging

Table 1 - Continued

American Joint Committee on Cancer (AJCC)

TNM Staging Classification for Carcinoma of the Stomach

(7th ed., 2010)

Anatomic Stage/Prognostic Groups

Stage 0	Tis	N0	M0
Stage IA	T1	N0	M0
Stage IB	T2	N0	M0
	T1	N1	M0
Stage IIA	T3	N0	M0
	T2	N1	M0
	T1	N2	M0
Stage IIB	T4a	N0	M0
	T3	N1	M0
	T2	N2	M0
	T1	N3	M0
Stage IIIA	T4a	N1	M0
	T3	N2	M0
	T2	N3	M0
Stage IIIB	T4b	N0	M0
	T4b	N1	M0
	T4a	N2	M0
	T3	N3	M0
Stage IIIC	T4b	N2	M0
	T4b	N3	M0
	T4a	N3	M0
Stage IV	Any T	Any N	M1

NCCN Categories of Evidence and Consensus

- **Category 1:** The recommendation is based on high level evidence (e.g. randomized controlled trials) and there is uniform NCCN consensus.
- **Category 2A:** The recommendation is based on lower level evidence and there is uniform NCCN consensus.
- **Category 2B:** The recommendation is based on lower level evidence and there is nonuniform NCCN consensus (but no major disagreement).
- **Category 3:** The recommendation is based on any level of evidence but reflects major disagreement.
- All recommendations are category 2A unless otherwise noted.

KARNOFSKY PERFORMANCE STATUS SCALE DEFINITIONS RATING (%) CRITERIA

Able to carry on normal activity and to work; no special care needed.	100	Normal no complaints; no evidence of disease.
	90	Able to carry on normal activity; minor signs or symptoms of disease.
	80	Normal activity with effort; some signs or symptoms of disease.
Unable to work; able to live at home and care for most personal needs; varying amount of assistance needed.	70	Cares for self; unable to carry on normal activity or to do active work.
	60	Requires occasional assistance, but is able to care for most of his personal needs.
	50	Requires considerable assistance and frequent medical care.
Unable to care for self; requires equivalent of institutional or hospital care; disease may be progressing rapidly.	40	Disabled; requires special care and assistance.
	30	Severely disabled; hospital admission is indicated although death not imminent.
	20	Very sick; hospital admission necessary; active supportive treatment necessary.
	10	Moribund; fatal processes progressing rapidly.
	0	Dead

ECOG PERFORMANCE STATUS*	
Grade	**ECOG**
0	Fully active, able to carry on all pre-disease performance without restriction
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work
2	Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours
3	Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours
4	Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair
5	Dead

* As published in Am. J. Clin. Oncol.:

Oken, M.M., Creech, R.H., Tormey, D.C., Horton, J., Davis, T.E., McFadden, E.T., Carbone, P.P.: Toxicity And Response Criteria Of The Eastern Cooperative Oncology Group. Am J Clin Oncol 5:649-655, 1982.

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