



Clinical pathways in gastric cancer care

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Abstract

The diagnostic–therapeutic pathways (DTPs) are emerging as useful instruments for clinical management of complex diseases as gastric cancer, whose treatment is challenging and requires a multidisciplinary approach. However, the DTPs of patients with gastric cancer are still not defined yet. The aim of this study was to define the optimal DTP to be applied for patients with gastric cancer in the Veneto region. Rather than defining the ideal DTPs a priori, we conducted a preliminary research by analyzing the differences in the actual DTPs for patients with gastric cancer among different hospitals (hub and spokes) in Veneto. Then, the final DTP was elaborated based on the current available best clinical evidences; however, also the areas of homogeneity among the actual DTPs of the included centers as well as the critical issues that had emerged by our preliminary analysis were taken into account for pathway design. High heterogeneity in actual DTPs of patients with gastric cancer was observed among the analyzed centres. Moreover, some of the major criticisms have been found at crucial points of the current pathways. Based on these data, a reference path that is applicable to the whole-regional health network was constructed. The reference DTP is focused on multidisciplinary team management of patients with gastric cancer. Clinical pathways are essential tools to properly manage complex diseases such as gastric cancer. As such, more efforts should be done to implement their use.

Keywords Gastric cancer · Diagnostic–therapeutic pathways · Reference pathway · Critical issues · Implementation areas

Introduction

Despite the declining incidence, gastric cancer (GC) is still one of the leading causes of cancer death worldwide. Globally, in 2012, almost one million (952,000) of new cases

were estimated, while the number of deaths due to GC was 723,000 [1]. In Italy, in 2015, the total number of estimated new cases of GC was 13,987 [2]. In the same year, the number of gastric cancer-related deaths was 9247 [2]. The high lethality of GC reflects the complexity of the disease whose treatment is challenging and requires a multidisciplinary approach.

The diagnostic–therapeutic pathways (DTPs) are emerging as useful instruments for clinical management of complex diseases. They are defined [3] as “structured multidisciplinary care plans that explicitly articulate the essential steps in treating specific clinical problems”. They basically allow the identification of all the activities of the patient’s pathway in a specific clinical scenario as well as the detection of critical steps of the process. Moreover, through the adoption of quality indicators related to DTPs, healthcare performances can be accurately gaged. The main aim of DTPs application is the homogenization of patient’s care process according to the best available clinical evidences. As such, DTPs are also essential instruments of new models of hub-and-spoke networking in healthcare. Indeed, hub-and-spoke models distribute services delivery into a network consisting of a core center (hub) that offers a full array of services,

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complemented by secondary centers (spokes) that offer more limited sets of performances, centralizing those patients who need more intensive care to the hub for treatment [4]. In such kind of models, sharing DTPs among hub-and-spoke centers is fundamental as, on the one hand, DTPs clearly show which is the level of complexity needing patient's routing to the hub; on the other hand, they set the appropriate areas for clinical intervention of satellite centers, making the whole system working more efficiently.

The DTPs of patients with gastric cancer are not completely analyzed and defined yet [5].

The aim of this study was to define the optimal DPT to be applied for patients with gastric cancer in the Veneto region. However, rather than defining the ideal DTPs a priori, we conducted a preliminary research by analyzing the differences in the actual DTPs for patients with gastric cancer among different hospitals (hub and spokes) in Veneto. Then, the final DPT was elaborated based on the current available best clinical evidences; however, also the areas of homogeneity among the actual DTPs of the included centers as well as the critical issues that had emerged by our preliminary analysis were taken into account for pathway design. While the organizational findings have been previously discussed [6], in the present manuscript, we will report the clinical aspects of our research project on clinical pathways in GC care.

Methods

The centers involved in the project were all located in the Veneto region. Specifically, two hubs (the Verona University Hospital and the Veneto Institute of Oncology/Padova University Hospital) and three spokes (the Hospitals of Montebelluna Maggiore and Arzignano, Venice City Hospital and the Rovigo City Hospital) were included. The study lasted for 14 months (from November 2015 to December 2016). A steering committee composed by the researchers from the Institute of management of Scuola Superiore Sant'Anna of Pisa and Upper GI Surgery Division of Verona University was created. The methodology of the study was set by the research team from the Scuola Superiore Sant'Anna as previously reported [6]. First, a questionnaire was specifically developed with the aim of collecting data and detailed information on the organizational and managerial arrangements to care patients with gastric cancer in each center. The questionnaire was divided in distinct sections exploring, respectively, the organizational characteristics of the center, the types and the numbers of treated patients, the modality of diagnostic phase, the adopted treatment strategies, and, finally, follow-up schedules.

Then, in each of the analyzed centers, a dedicated working group was constructed. This included surgeons, medical oncologists, radiation oncologists, endoscopists, gastroenterologists, radiologists, nuclear medicine physicians,

pathologists, and nurses. Semi-structured interviews were conducted by the Scuola Superiore Sant'Anna Research team to each of the involved professionals through the administration of the above-mentioned questionnaire.

Based on the information collected during the interviews, the actual DTP of patients with gastric cancer in each center was mapped in the form of flowcharts. This allowed the representation of the logical and the time sequence of all the activities. Moreover, the flowchart maps enabled the easy comparison among the current paths of all the analyzed centers. The DTPs map drafts were discussed and agreed in a plenary meeting at each center before the final version.

In the final phase of the study, based on the best available clinical evidences in the treatment of gastric cancer [7–10], the reference DTP was elaborated. Of course, the results of the current pathways analysis were taken in consideration when constructing the DTP. Specifically, information on the activities and services that are available at all the centres is used for the definition of the core of the reference DTP, while the critical issues emerged during the interviews were of help in pathway implementation.

Results

Comparative analysis of DTPs between the five centers

Differences in the actual DTPs are reported for each clinico-organizational step as follows:

Diagnosis

The phase of diagnosis did not show significant differences between the five centers except for two points. First, the communication of pathological report of diagnostic gastric biopsies by the pathologist to the endoscopist or other physician who had required the upper GI endoscopy is not formalized in all the centres.

In addition, the delivery of the histological report of diagnostic gastric biopsies to the patient differs among centers. Indeed, in one of the spoke centers, external patients usually pick up the result of the biopsies at the "Report Delivery Center". Possible criticisms of this delivery modality are that the patient may forget to pick up and/or may be left alone while reading the diagnosis of gastric adenocarcinoma.

Staging

In all the centers, gastric cancer staging is performed through a thoraco-abdominal CT scan. Blood routine and tumor markers (CEA and CA19.9) examinations are always

taken. Only in case of not dirtied CT scan findings, the patient undergoes Magnetic Resonance and/or PET-CT. Unfortunately, a package of services including all the staging exams is not formalized in all the centres.

After clinical staging, a weekly multidisciplinary team (MDT) meeting, that is fundamental to choose the best therapeutic option for each patient, is formalized only in two centers. In one spoke center, the cases are discussed at MDT after surgery. In all the centers, nutritionists and psychologists are not routinely involved in the MDT.

Treatment

This phase showed the most striking differences among centers. Only in the two hubs, the possibility to perform an endoscopic resection in case of clinical mucosal early gastric cancer ≤ 2 cm, without ulceration, with well differentiated, Laurèn intestinal histotype and with no clinical evidences of nodal metastases, is considered.

In one of the Spoke centers, neo-adjuvant chemotherapy is not usually performed in patients with locally advanced gastric cancer, because MDT discussion is done after surgery.

Surgical procedures showed no significant differences from the organizational and clinical point of views, while the number of surgically treated patients differed with the hubs treating more than 40 patients per year; conversely, the spokes does not exceed 20 cases.

With regard to indications and regimens of the first- and second-line chemotherapy for metastatic gastric cancer, there were no significant differences. Of note, relevant differences exist for symptomatic metastatic patients in the chance to get simultaneous care. Indeed, only at one of the hubs, an outpatient service for simultaneous care is available. Moreover, difficulty in activating palliative home care was found in all centers.

Follow-up

Only minor differences were observed in the follow-up schedules among the included centers.

Elaboration of reference DTP for the patient with gastric adenocarcinoma in the Veneto region

Figure 1 shows the reference pathway representing the ideal sequence of activities that must be followed by a patient with gastric cancer depending mainly on his tumor burden at the time of diagnosis. To solve the issues emerged by the analysis of the actual DTPs, specific solutions are reported as areas of implementations (Fig. 1). In detail, the reference pathway provides that if a gastric adenocarcinoma is diagnosed on endoscopic biopsies, there is a formalized

communication of the diagnosis to the physician who requested the gastroscopy or alternatively to the endoscopist who has made the diagnostic endoscopy. Then, the professional who receive the pathological report have to communicate the diagnosis to the patient. In addition, it is desirable that who communicates the diagnosis would also plan an outpatient visit to let the patient access the path. Another fundamental point of the reference path is the multidisciplinary team (MTD) discussion that has to be formalized in each centre. MDT meeting should be taken soon after the completion of clinical staging to choose the best treatment option for each patient. MDT discussion is also needed after re-staging at the end of preoperative multimodal therapies as well as whenever there is the need of selecting among different treatment strategies (Fig. 1). Nutritionists and psychologists should be included in the team.

With regard to the therapeutic steps, the path remarks the need of centralization in case of complex procedures requiring dedicated expert professionals as endoscopic submucosal dissection for the early gastric cancer (Fig. 1).

Finally, the care of metastatic patients should be improved by the activation of simultaneous care outpatient clinics to support symptomatic patients during palliative treatments. In addition, formalized and efficient process for the activation of Integrated Home Care Services has to be established.

Discussion

The DTPs of patients with gastric cancer are not completely analyzed and defined yet [5]. A recent survey showed that there are some differences in clinical paths for GC across ten European countries highlighting the need of harmonizing the care process for this cancer.

Our study showed that, also in Italy, at regional level, there is high heterogeneity in actual DTPs of patients with GC. Moreover, some of the major criticisms have been found at crucial points of the current pathways.

With the aim to standardize the management of patients in our region, we defined a reference DTP showing the ideal sequence of all the activities that should be followed in case of GC diagnosis in agreement with the best evidence-based data. Of note, the preliminary analysis on actual DTPs allowed the construction of a path that is applicable to the whole-regional network in which the clinical activities requiring centralization of patients to the hub are clearly identified.

Among the key elements of the reference path are the routine multidisciplinary team discussion and management of patients and the need of centralizing the patients to the hubs in case of challenging procedures as endoscopic resection for GC. In addition, a better global care of metastatic patients is provided.

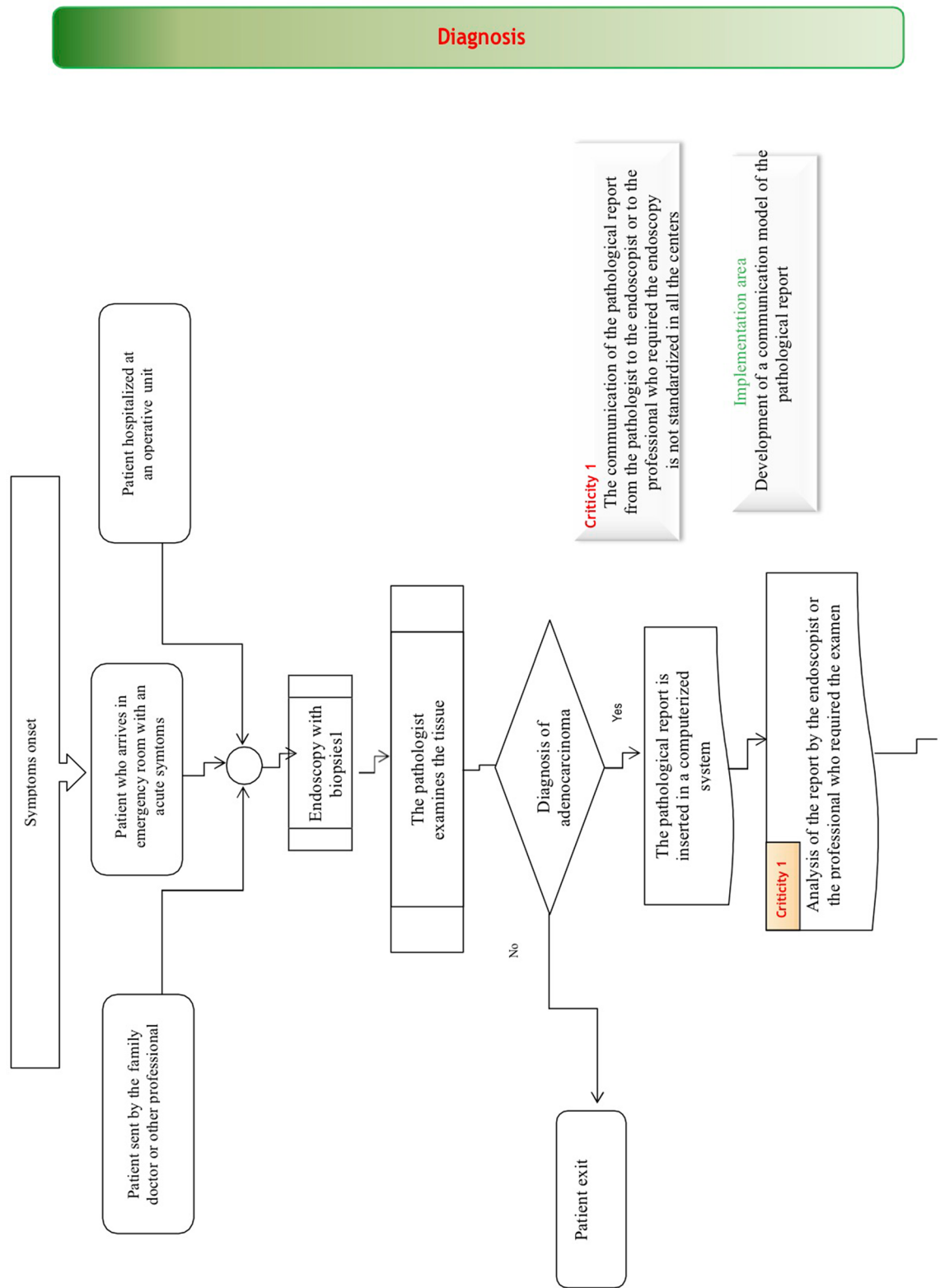


Fig. 1 represents the beginning and the end of the flowchart. represents every type of process/primary activity. represents a moment of evaluation and possible turning of the process. represents an eventual activity that it is not performed for all patients. represents a default activity: perform diagnostic procedures like blood examination, X-ray, etc. represents the release of a document: opening or closing of the medical record, the delivery of the diagnostic reports, etc. represents the access or the exit of different parts of the flowchart. represents the cross reference from one page to another

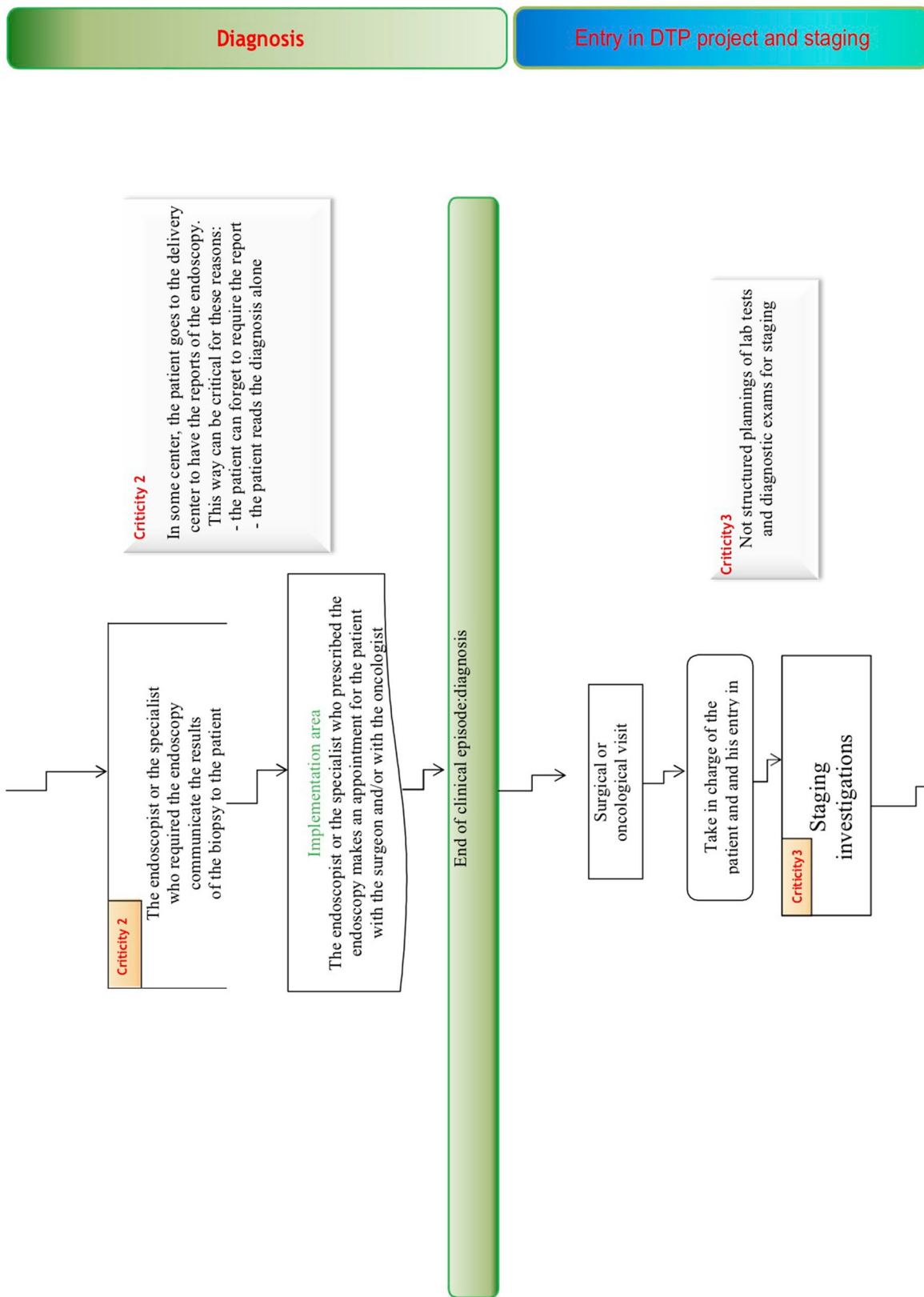


Fig. 1 (continued)

Entry in DTP project and staging

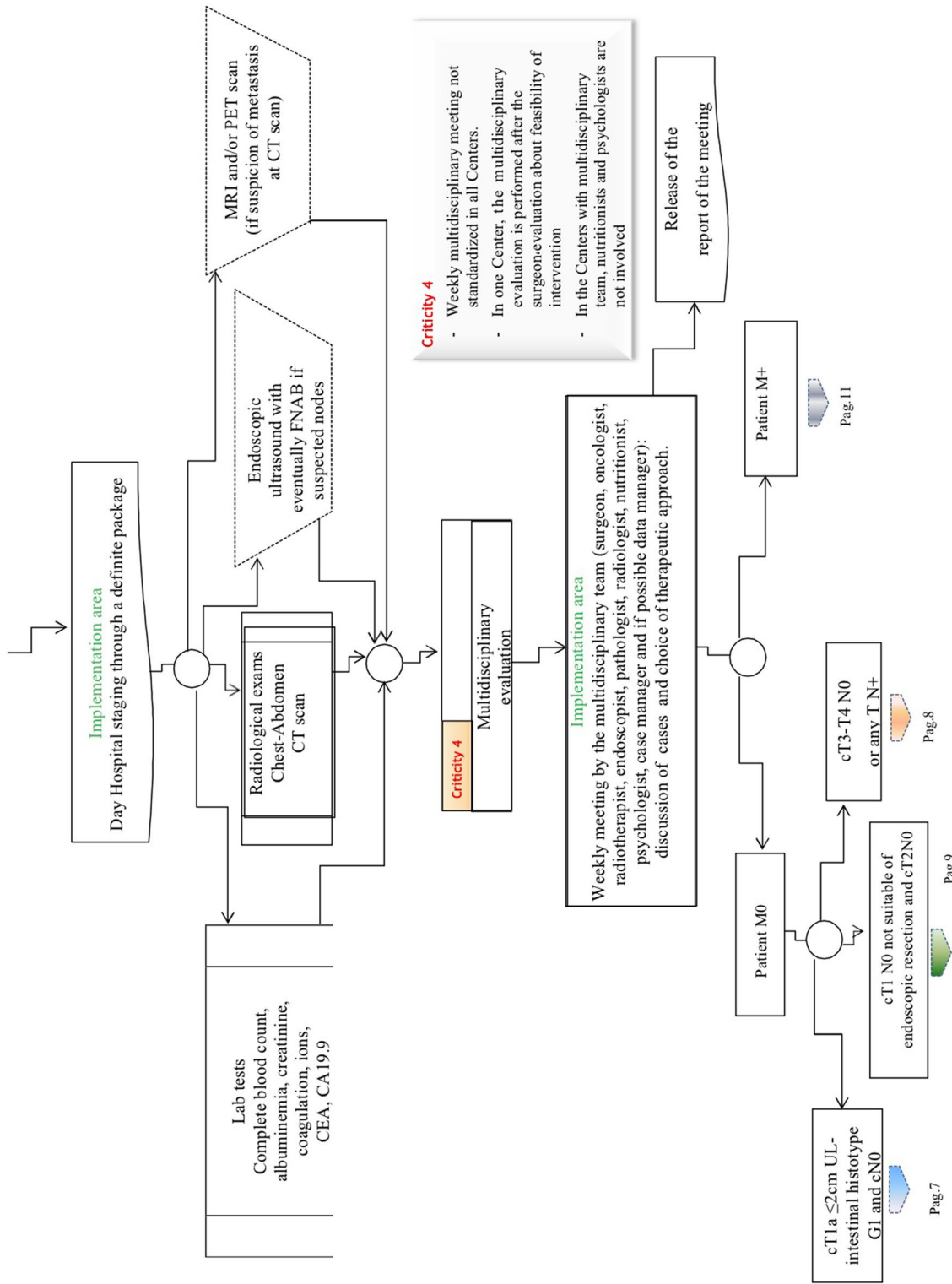


Fig. 1 (continued)

Treatment: patients cT1N0

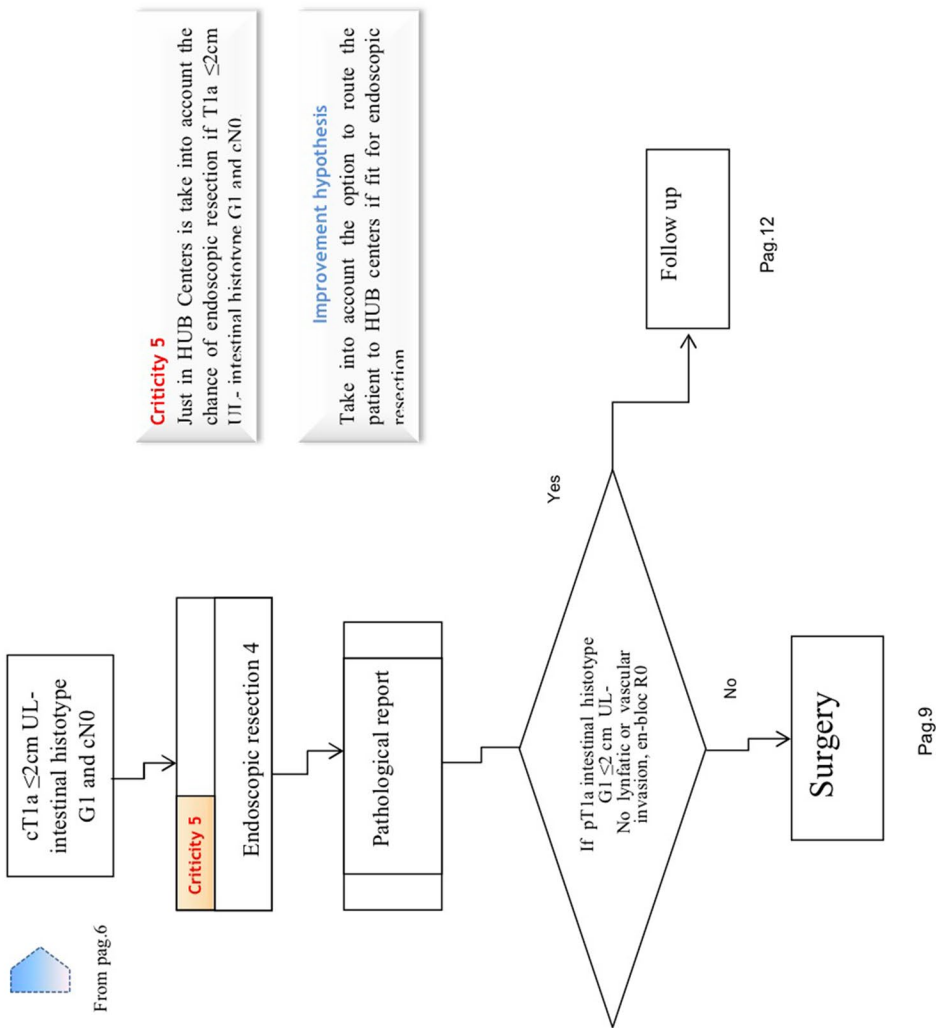


Fig. 1 (continued)

Treatment: patient cT3-T4 N0 or any N+

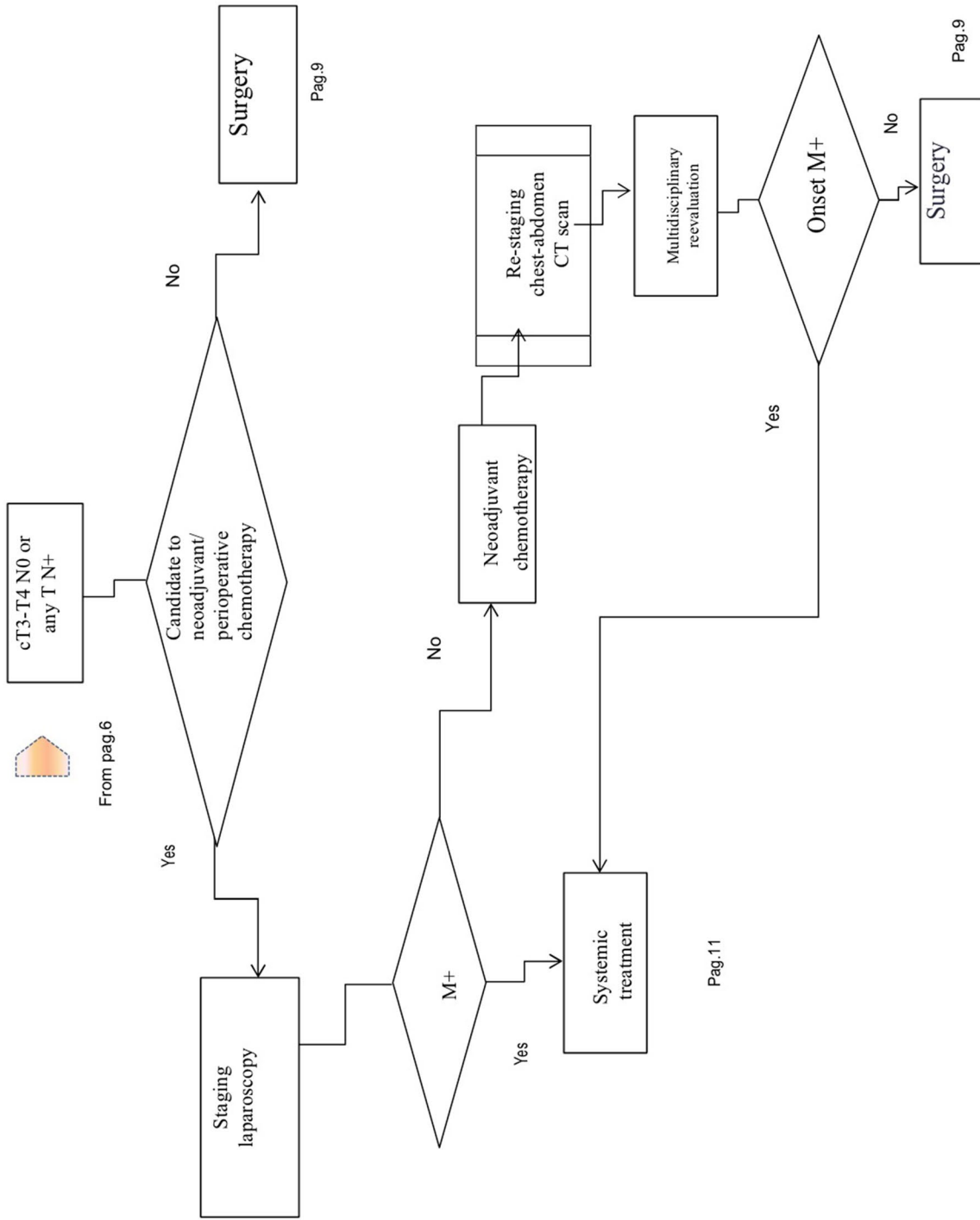
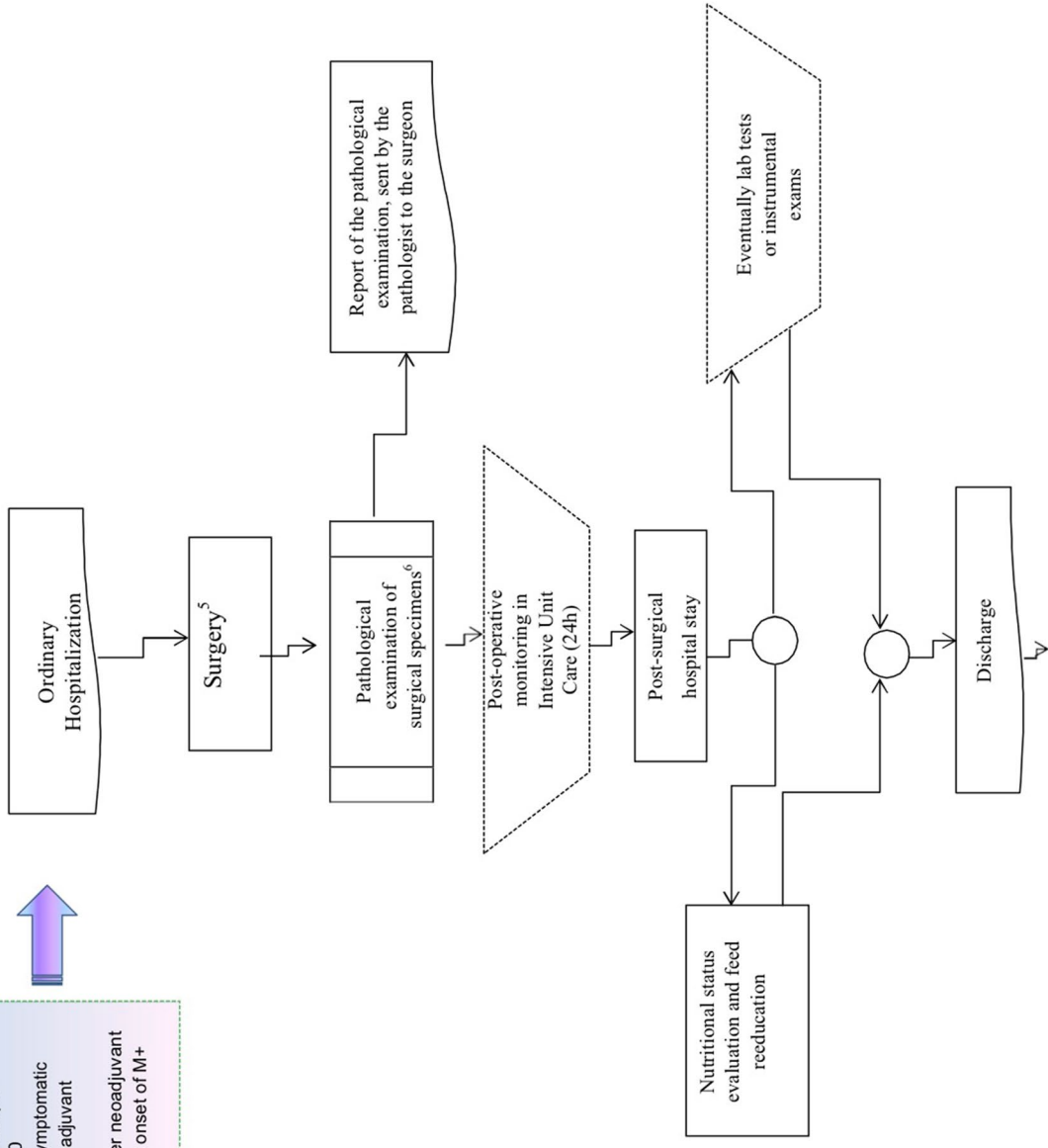


Fig. 1 (continued)

Treatment: surgery

Patient candidate to surgery:

- × Noncurative endoscopic resection
- × cT1 N0 not fit for endoscopic resection and cT2 N0
- × cT3–T4 N0 or N+ if symptomatic not indication to neoadjuvant chemotherapy
- × cT3–T4 N0 or N+ after neoadjuvant chemotherapy if no onset of M+



End of clinical episode: surgery

Fig. 1 (continued)

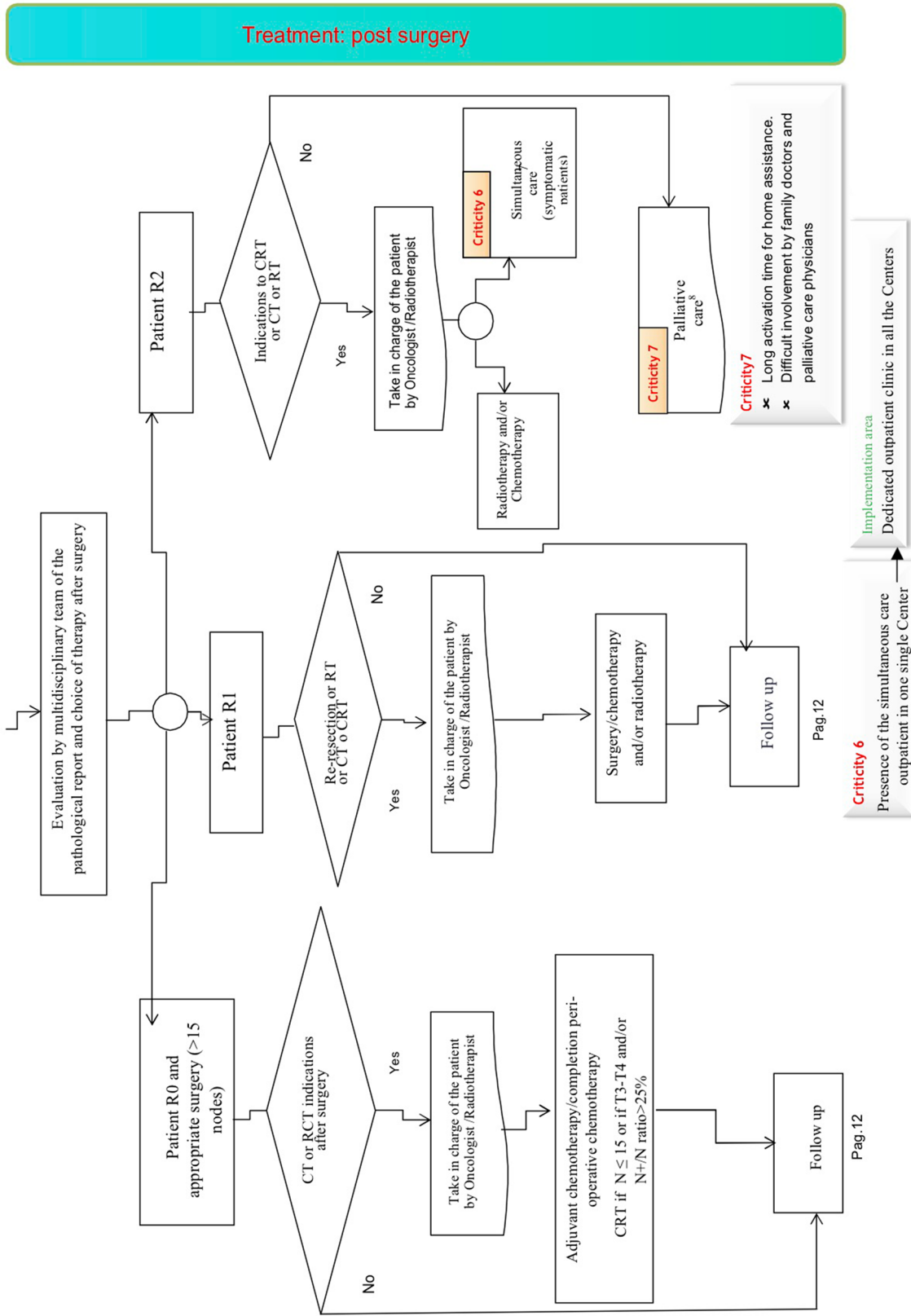


Fig. 1 (continued)

Treatment: patient M+

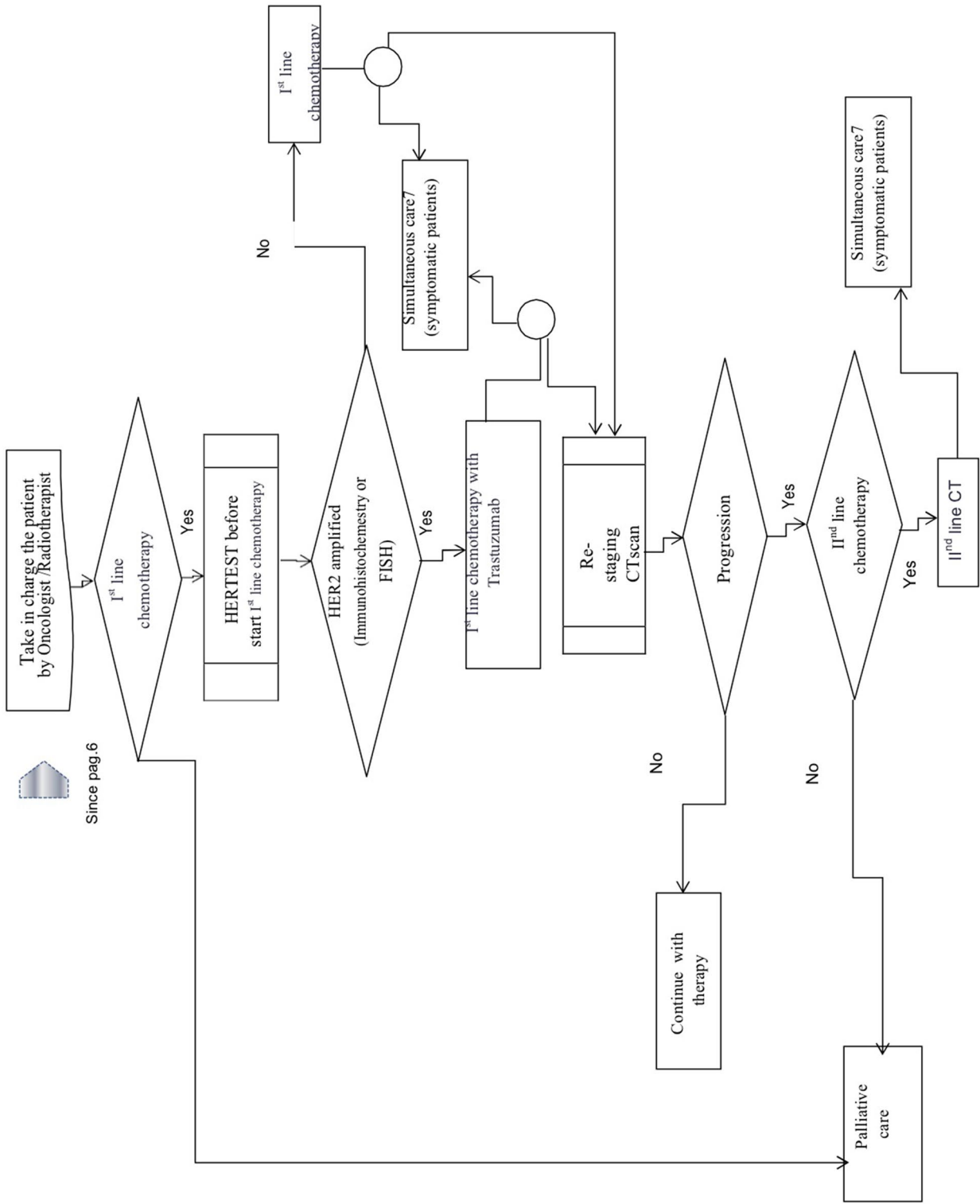


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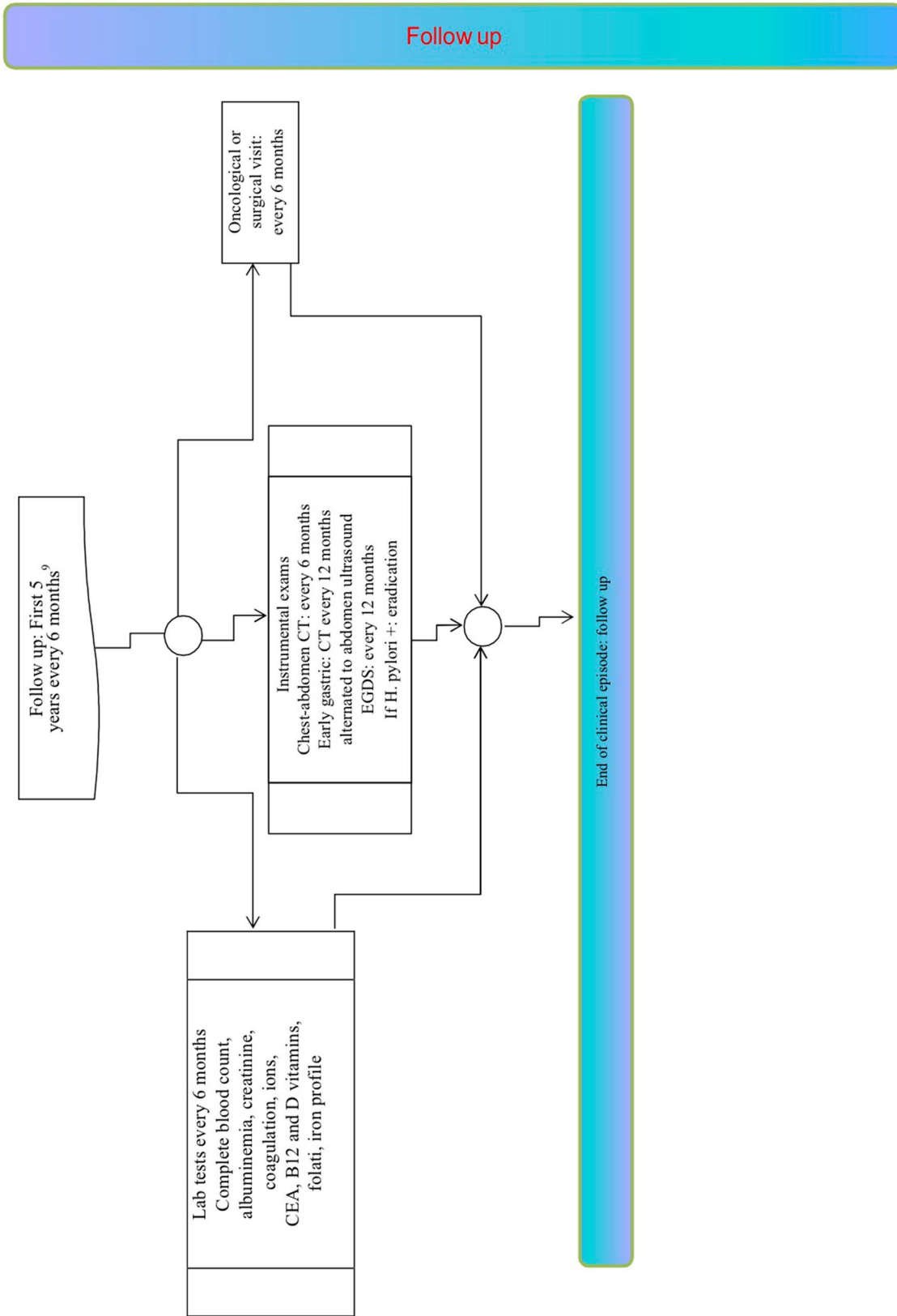


Fig. 1 (continued)

Sharing clinical pathways is fundamental to make health-care networks working efficiently. Even if, in the present study, quality indicators have not been defined, the adoption of our reference path at regional level would also improve the assessment of health performances. Indeed, indicators specifically related to care process activities are easily identifiable and applicable to clinical practice.

In conclusion, clinical pathways are the best way to follow the patient in his route from diagnosis to follow-up improving clinical outcomes and resources management. As such, DTPs are essential tools to properly manage complex diseases such as gastric cancer and more efforts should be done to implement their use.

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Compliance with ethical standards

Conflict of interest All authors declare that they have no conflict of interest.

Research involving human participants and/or animals The research does not involve human participants and/or animals.

Informed consent There was no need to get informed consent.

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