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review

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Quality assurance in the treatment of colorectal cancer: the EURECCA initiative

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Colorectal cancer is one of the most common cancers in Europe. Over the past few decades, important advances have been made in screening, staging and treatment of colorectal cancer. However, considerable variation between and within European countries remains, which implies that further improvements are possible. The most important remaining question now is: when are we, health care professionals, delivering the best available care to patients with colon or rectal cancer? Currently, quality assurance is a major issue in colorectal cancer care and quality assurance awareness is developing in almost all disciplines involved in the treatment of colorectal cancer patients. Quality assurance has shown to be effective in clinical trials. For example, standardisation and quality control were introduced in the Dutch TME trial and led to marked improvements of local control and survival in rectal cancer patients. Besides, audit structures can also be very effective in monitoring cancer management and national audits showed to further improve outcome in colorectal cancer patients. To reduce the differences between European countries, an international, multidisciplinary, outcome-based quality improvement programme, European Registration of Cancer Care (EURECCA), has been initiated. In the near future, the EURECCA dataset will perform research on subgroups as elderly patients or patients with comorbidities, which are often excluded from trials. For optimal colorectal cancer care, quality assurance in guideline formation and in multidisciplinary team management is also of great importance. The aim of this review was to create greater awareness and to give an overview of quality assurance in the management of colorectal cancer.

Key words: quality assurance, colorectal cancer, audit, multidisciplinarity, guidelines

introduction

Important objectives of health policies are improving quality, safety, patient satisfaction and health care efficiency. To achieve this in cancer care, measuring and monitoring cancer treatment are crucial to deliver the best care to every patient and to conclude whether quality was assured. Owing to the increasing complexity of cancer care, monitoring the quality of care is also becoming more complex. Integrated care pathways can be used as a tool to measure and monitor cancer treatment and can facilitate these processes. Besides, it is needed to develop minimal required standards of good clinical practice through expert consultation and international consensus-building processes. Providing up-to-date treatment guidelines with objective information on short-term, long-term and adverse effects might contribute to improvements in the quality of care.

The fact that cancer incidence still increases in Europe emphasises the importance to optimise the quality of cancer care [1, 2]. Currently, colorectal cancer is the second most common cancer in Europe, with 447 000 new cases and almost 215 000 deaths estimated to have occurred in 2012 [1]. EUROCARE, a European collaborative research programme, which was initiated to assemble survival data collected by national and regional cancer registries, showed that considerable variation in survival between and within European countries still exists [3, 4].

In contrast to the increasing incidence of colorectal cancer, mortality reduced across Europe as a result of changes in screening, surveillance, staging and treatment [2, 5]. Over time, especially younger patients, patients with earlier tumour stages and rectal cancer patients demonstrated a better survival [5]. Therefore, more advancement could be gained by changing the focus to, for example, elderly patients, patients with advanced stages of disease and colon cancer patients. Furthermore, it is of great importance that cancer management becomes increasingly individualised, since certain patient subgroups are more vulnerable for the adverse effects of medical treatment. Besides, in future

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research, traditional outcome measures such as cancer-specific survival, overall survival and disease-free survival are still of great value, but might fail to explain more patient-centred end points such as quality of life and functional outcomes after cancer treatment.

what is quality assurance?

Quality assurance in health care is definitely not a new concept. Probably, the first example of routine health outcome measurement with death as outcome was by Florence Nightingale who attempted to standardise nursing care in the Crimean war. In the early 1900s, Ernest Amory Codman (1869–1940), a Boston surgeon, developed the 'End Result' idea, which he defined as: 'The common sense notion that every hospital should follow every patient it treats, long enough to determine whether or not the treatment has been successful, and then to inquire, "If not, why not?" with a view to preventing similar failures in the future' [6]. This way, Codman demonstrated patient outcomes, but unfortunately, he did not receive any support and after he created an uproar at a public meeting, he was dismissed [6]. Currently, quality assurance programmes are gaining popularity and also extend to other disciplines than surgery.

Quality assurance is essential for good medical decision making and can be defined as all those planned and systematic actions necessary to achieve minimal requirements of good cancer care. Quality assurance programmes aim to optimise the quality of care by determining standards and assuring that these standards are met. This will result in reduced variability and continuous quality improvement. Therefore, quality assurance programmes should become obligatory for all centres that provide colorectal cancer care.

In clinical trials, quality control already showed to be very effective [7–13]. However, another effective instrument to monitor the quality of care and to improve outcome is auditing, which is closely related to quality assurance. Within an audit cycle, collected data will be compared with selected quality standards and provide continuous feedback to participating health care professionals on these standards and on outcomes (Figure 1).

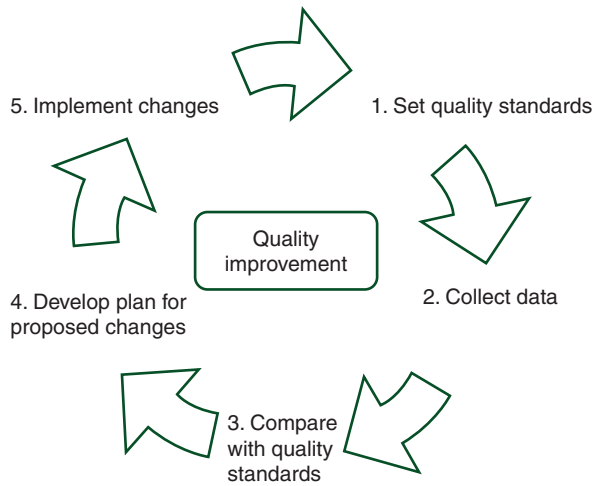

Figure 1. Audit cycle.

differences in quality

Various publications and reports demonstrated considerable variation in outcomes of care between countries, regions and hospitals [4, 5, 14, 15]. Birkmeyer et al. [14] showed that undergoing surgery in a high-volume hospital for selected cardiovascular and cancer procedures, including colectomy, significantly reduced the risk of operative death. In addition, several groups demonstrated that high surgeon volume was also associated with improved patient outcomes [16].

Surprisingly, in the Swedish Uppsala trial, it was found that half of the patients were operated by surgeons who carried out less than one rectal cancer operation per year [17]. Consequently, rectal cancer care was centralised to centres with specialised surgeons.

The decision of concentration of colorectal cancer care is preferably not only based on caseload, but also on other outcomes. Therefore, additional information on differences in, for example, case mix between hospitals, reasons for non-adherence to guidelines and the occurrence of recurrences is very important. A comprehensive European audit as EURECCA, which will be explained later, could provide in this.

european audits for colorectal cancer

Over the past few decades, audit structures are most frequently initiated in surgical oncology compared with other disciplines. Several European countries have organised national surgical colorectal cancer audits. Most of these audits were initially founded for rectal cancer because of poor outcomes before the 1990s. Main reasons for initiating these audits were to evaluate the effect of standardised TME surgery and to diminish variation in the outcome [18].

The Norwegian Rectal Cancer Project (now: the Norwegian Colorectal Cancer Project) was the first initiated national audit and included 3319 patients diagnosed with rectal cancer. Training courses and master classes were arranged and involved departments received regularly feedback together with the national average results for comparison and quality control. During this period of auditing, the proportion of TME surgery increased from 78% to 92%. Before auditing, the local recurrence rate in Norway was 28% and the mean 5-year survival rate 55%, whereas after 4 years of auditing, the local recurrence rate was 6% for patients who received TME surgery and the overall 4-year survival rate was 73% [19].

Another example is the Danish Colorectal Cancer Database that included >93% of all colorectal cancer patients. For rectal cancer, 5-year survival increased from 37% in males and 42% in females in the period 1987–1989 to 55% in males and 63% in females in the period 1994–1999 [20].

Several other European countries followed by establishing a national (colo)rectal cancer audit programme (Table 1) and showed remarkable improvements [18, 21–27].

In the EUROCARE-4 study, colorectal cancer patients diagnosed between 2000 and 2002 demonstrated a mean 5-year relative survival of 56.2%. However, there was large variation in survival among European countries. Especially North and Central Europe showed best survival rates, whereas survival rates in the Czech Republic and Poland were substantial lower

Table 1. National audits

Audit	Country	Year of foundation
Norwegian Colorectal Cancer Project	Norway	1993
Danish Colorectal Cancer Database	Denmark	1994
Swedish Colorectal Cancer Registry	Sweden	1995
Study group for Therapies Of Rectal Malignancies	Italy	1999
International Quality Assurance in Colorectal Carcinoma	Germany, Poland, Lithuania, Italy	2000
National Bowel Cancer Audit Programme	UK	2001
Project on Cancer of the Rectum	Belgium	2005
Spanish TME Project	Spain	2006
Dutch Surgical Colorectal Audit	Netherlands	2009

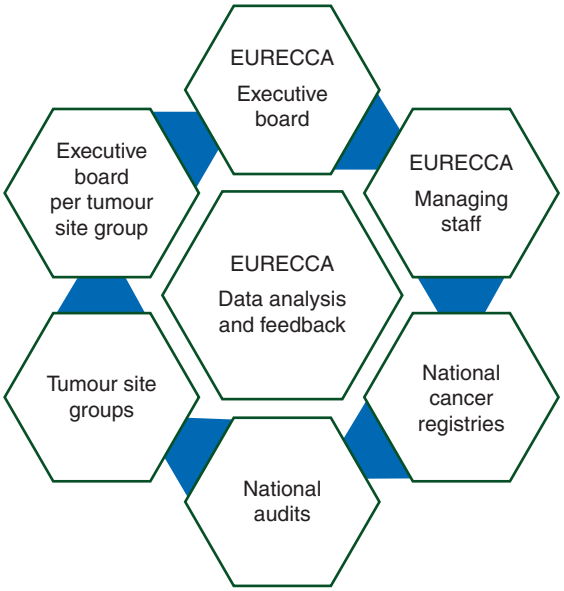

Figure 2. EURECCA structure.

(45.2% and 46.0%, respectively) than average. However, for countries without national coverage, the EUROCARE data are not representative for the entire colorectal cancer population. Nevertheless, the EUROCARE results point out the considerable differences in survival among European countries. These differences imply that further optimisation in colorectal cancer care is possible in order to improve outcomes and to reduce variability between European countries. EUROCARE is useful in identifying where the possibilities are to improve the quality of care. However, questions such as why these differences exist and how the survival rate can be improved cannot be answered by the EUROCARE database. The challenge is to define a standardised European dataset that will answer these questions, that will be subject of change as science progresses and that will contribute in optimising the quality of care.

the EURECCA initiative

EURECCA is the acronym for the European Registration of Cancer Care or in short European Cancer Audit [28]. By developing a European, outcome-based, multidisciplinary audit registry, EURECCA aims to reduce systematic variance by standardising and harmonising cancer care in Europe. EURECCA works with national audit registries and national cancer registries and collects patient and treatment data, which will be analysed. Subsequently, standards will be uncovered and will be fed back (Figure 2). Besides, subgroups as, for example, elderly patients and patients with comorbidities are mostly excluded from trials, leaving little evidence to define good cancer care for these patient groups. Therefore, to improve the quality of care for the entire population, a comprehensive audit as EURECCA, in which all the patients of a population are included, could be an effective instrument and can eventually result in evidence-based medicine for these subgroups by identifying and communicating about 'best practices' [18].

EURECCA has been initiated by the European Society of Surgical Oncology (ESSO) in partnership with the European Society for Radiotherapy and Oncology (ESTRO), the European Society for Medical Oncology (ESMO), the European Society of Coloproctology (ESCP), the European CanCer Organisation (ECCO) and the European Organisation for Research and Treatment of Cancer (EORTC). Patient organisations Europa Colon and EONS are also important affiliated partners.

Outcomes that will be considered within EURECCA are morbidity, mortality, recurrences and survival. Future plans are to implement more patient-centred parameters, such as quality of life and functional outcomes. The collected data will be analysed in order to identify where further quality improvement is needed and additional data will be collected to adjust for possible confounders. Furthermore, EURECCA could give insights into the amount of surgical procedures carried out in each hospital and by each surgeon.

Initially, EURECCA Colorectal has been established. Currently, 9 audit registries in 11 countries are participating in the EURECCA project. Mid-2011, all audit registries included over 400 000 patients with colorectal cancer. In 2012, a valuable core dataset for EURECCA Colorectal has been identified, consisting of a list of 45 data items including patient data, data about preoperative staging, surgical treatment, (neo)adjuvant therapy and follow-up, to facilitate future analyses with respect to national privacy legislations [29].

In December 2012, a multidisciplinary consensus meeting for EURECCA Colorectal was held to establish treatment guidelines by using the Delphi method. Representatives of European scientific organisations involved in colorectal cancer treatment formed the multidisciplinary expert panel during the consensus meeting in order to ensure a solid basis to reach health care professionals in the field. There was voted on 465 medical statements in several rounds. In 84% large consensus was reached (>80% agreement), 6% reached moderate consensus, 7% reached minimum consensus and 3% was disagreed by >50% of the

members [30, 31]. Besides EURECCA Colorectal, EURECCA Breast, EURECCA Hepatopancreaticbiliary (HPB), EURECCA Upper GI and EURECCA Urology have been initiated.

quality assurance in trials

Treating within clinical trials provides us information to optimise treatment strategies. Within trials, there is standardisation, better monitoring and better quality assurance of diagnostic and treatment processes, which might result in improved outcomes. However, trials are costly, time-consuming and there is selection bias which makes the results inapplicable for the entire population [13, 32]. Quality assurance was integrated in the Dutch D1-D2 gastric cancer trial and later in the Dutch TME trial [7, 8]. The Dutch TME trial was initiated to investigate the effect of short-term preoperative radiotherapy in combination with TME surgery compared with TME surgery alone [7]. It was considered crucial that surgical, pathological and radiotherapeutical techniques were standardised and controlled for quality. TME surgery was taught to surgeons through workshops, symposia and video instructions. A monitoring committee ensured adherence to surgical protocols. In each hospital, the first five TME procedures were supervised by an experienced instructor surgeon. Also for radiotherapy, exact descriptions of dose, volume, fields and simulation techniques were used. Pathologists were trained according to a strict protocol. Quality assurance was very successful in this trial. Local recurrence rates were reduced by >50%. Furthermore, there was an association between circumferential resection margin (CRM) involvement and outcome, which shows the importance of good surgical performance [33, 34]. According to these successful results, would not it be of great value to incorporate quality control in daily medical practice to provide the same standardised care and treatment as within trials?

Several studies have suggested that patients treated within clinical trials have better outcomes than those who receive similar treatment outside the framework of a trial [9–12]. Patients participating in trials have better management of their disease, because of more frequent evaluation with potentially earlier detection of problems and better management of side-effects. They are also more likely to maintain the scheduled dose and frequency of treatment [35].

quality assurance in other medical disciplines

Although quality assurance in cancer care is most advanced in surgery, it is also developing in other medical disciplines, such as radiology, radiation oncology, medical oncology and pathology.

The Mercury Study Group reported that preoperative staging of rectal cancer with magnetic resonance imaging (MRI) precisely predicts whether the CRM will be clear or not [36, 37], and several studies demonstrated that a positive CRM has an adverse effect on the local recurrence rate and on overall survival [38–40]. This demonstrates the importance of preoperative staging.

In Alberta, Canada, an electronic synoptic operative report template has successfully been introduced in order to replace the narrative operative record, with standardised dropdown menus to include patient and operative data. This did not only result in information about surgical practices, but it also provides insights in the utilisation of the health care system [41].

In radiation oncology, important features for quality assurance are, for example, the irradiated volume, portals technique, radiation modality, amount of fractions and the total tumour dose [32, 42]. As mentioned before, radiotherapy was standardised in the Dutch TME trial and led to considerable results [33, 34].

In medical oncology, the use of adjuvant chemotherapy is frequently defined in treatment guidelines, of which ESMO gives a yearly update and incorporates the most recent evidence from trials [42, 43]. However, older studies indicate that about half of the patients receive non-evidence-based schedules, which is, for example, related to age, patient preferences and comorbidities [44]. Unfortunately, there is no information available on more actual adherence to schedules, but difficulties certainly are dose reduction, toxicity management and dose intensity. Key questions are: is the right treatment being given? Is it well done? Is the patient as well as the disease treated? Good quality of care registration could help to give an insight in these challenges. Also in pathology, quality assurance has become an important part. Currently, there are, for example, protocols for cut-up and reporting, for minimum numbers of lymph nodes to be retrieved and for internal quality control [45]. However, to assure and improve quality of colorectal cancer care, further development of guidelines and multidisciplinary management could be very useful.

quality assurance in guideline formation

Guidelines for cancer management, as well as early detection and screening procedures, are essential for quality improvement, optimal use of the available resources and maximal reduction of unnecessary harm to patients. Knowledge of best measures for diagnosis and treatment is not universally available at the required highest level, and a strong, clinically highly relevant difference in expertise exists at all levels of cancer care between individuals, disciplines, hospitals, regions and countries. Therefore, in several countries, national guidelines have been developed, and European scientific societies have partially adopted this process and prepare or have published international/European guidelines and treatment recommendations for the major tumour types (e.g. ESMO, EUA or ESO). Although guidelines are not always completely up-to-date as science rapidly evolves, it is important to have guidelines as a basis for clinicians in the treatment of cancer patients.

There are some major essential points of importance regarding the methodology for the development and publication of national and international recommendations. Recommendations must be based on highest available evidence. If this is not available, expert opinion is a valuable surrogate, which however is often in danger and may not be guided or dominated by ‘eminence’ of politically or otherwise powerful representatives of the various disciplines. Besides, multidisciplinarity of the expert panel and, in particular important in international guidelines, a balanced distribution between the members of the different countries as well as the different disciplines are also important. Furthermore, a strictly followed scheme for the development of

the text of the guideline is of high value and should be based on preparation of the topics to be described by the different experts, discussion of the topics in the expert group and development of the consensus statement in the full expert group. The most critical point is the methodology to achieve consensus, since this is always a source of potential bias. To avoid this, guidelines should use objective methods for voting of statements, for example, the 'Delphi' method (as used in the EURECCA Colorectal multidisciplinary consensus conference [30, 31]), followed by personal discussion in the consensus group and further rounds of voting, or the more 'simple' direct method of personal voting in the consensus group, followed by discussion and final voting (e.g. used in the ESMO guidelines for colorectal cancer) [43].

Finally, the level of evidence on which the final statement is based (level I–IV), the level of recommendation (A–D), the level of agreement and percentage of disagreement (if existent and relevant) must be noted in the final document. Correct implementation of these methodologies and a clear definition and description of the instruments and methods used are of utmost importance for the final guideline document and its reliability and use.

There might be internationally different definitions of standards, based on the accessibility of diagnostic and therapeutic options within different countries. However, the standard must be defined according to the best available data, which are mostly based on best available tools for diagnosis and treatment. Besides, the document should also include recommendations for those situations where this is not the case.

quality assurance in multidisciplinary teams

Each discipline within the colorectal cancer care process plays an important role in determining outcome. Currently, multidisciplinary cancer management, in which the full complement of services is provided timely and in a safe, effective, efficient, but in a patient-centred way, has been implemented for most of Europe and forms an important component in guidelines [46]. Multidisciplinary teams have been introduced in cancer care, because cancer management has become increasingly complex. Owing to this complexity, it is important to involve different health care professionals in clinical decision making for individual patients to provide optimal medical care. Multidisciplinary teams need to consist of at least a radiation oncologist, medical oncologist, surgeon, pathologist, radiologist and a clinical nurse specialist. All new colorectal cancer patients should be discussed before neoadjuvant treatment or primary surgery as well as after surgery to decide on treatment strategies. Multidisciplinary teams should improve communication, coordination and decision making in the cancer care process between health care professionals and patients [47]. In a study by Blazeby et al. [48], the authors showed that the most important reasons for changing decisions within a multidisciplinary team were the result of comorbid disease, patient preferences and the availability of additional clinical information. Although multidisciplinary teams have been widely incorporated in cancer management, research into the effectiveness of multidisciplinary teams has led to inconclusive results. Hereby, it must be taken into account that poor study designs have been used to evaluate the effect of multidisciplinary cancer management. Furthermore, the findings are often confounded by changes over time including improved treatments, and technology and service changes [47, 49]. The efficacy of multidisciplinary teams needs to be studied more extensively, although it is without question that multidisciplinary discussions are of great value in cancer care. However, several studies demonstrated improvements in cancer care and diagnostic accuracy achieved by working in multidisciplinary teams [49–55]. The Mercury Study Group showed the importance of improved collaboration between different disciplines and a trained team to ensure standardisation of techniques and interpretation was demonstrated. In this study, the local recurrence rate was only 2.3% in patients with T3a/bN0 disease and even 0% in patients with T2N1, T3a/bN1 or T3bN2 disease [36]. In the UK, multidisciplinary management is associated with improved 5-year survival in colorectal cancer [52]. Furthermore, in a study by Burton et al. [53], 26% of the patients without discussion of the MRI by a multidisciplinary team had a positive CRM compared with 1% of the patients with discussion of the MRI by a multidisciplinary team.

In 2010, the National Cancer Action Team published the document 'The Characteristics of an Effective Multidisciplinary Team (MDT)' and offered recommendations regarding the multidisciplinary team itself, infrastructure for meetings, meeting organisation and logistics, patient-centred clinical decision making and team governance [56]. By achieving recommendations as the National Cancer Action Team formulated, multidisciplinary team meetings will be more effective. Of course, EURECCA fully supports the use of multidisciplinary teams to achieve optimal colorectal cancer care for every patient.

cost-effectiveness of quality improvement

Professor Wibe demonstrated during the Colorectal Conference in 2007 in St Gallen that the costs of the Norwegian Colorectal Cancer Project were EUR 120 000 per year, and that the costs for every saved life were less than EUR 700 [57]. In contrast, adjuvant therapy for colon cancer with fluorouracil, leucovorin and folinic acid costs around EUR 11 000 per saved life year [58]. These points out that a quality assurance project as an audit is very cost-effective compared with adjuvant chemotherapy.

Besides, an important goal of the Dutch Surgical Colorectal Audit (DSCA) is to reduce health care expenditures. The Boston Consulting Group demonstrated in a report in 2011 that complete implementation of quality registries in the Dutch health care system could result in a saving of EUR 2.3 billion per year in 2020 [59].

Despite relatively low costs of an audit, of course it still has to be financed. For example, the government can contribute to this, because of the cost-effectiveness of auditing. Besides, an European audit as EURECCA can result in a reduction of the use of unnecessary treatments and in an improvement of cancer outcome. Therefore, it is also interesting for health insurance companies to invest in an outcome-based European audit. Finally, cancer foundations and other grant giving institutes might be interested to contribute in quality improving initiatives [60]. Besides the financial aspect, there is also the need to

identify an organisation to perform audits. Such an organisation requires expertise, uniformity and the ability to benchmark across Europe.

future perspectives

Although there is increasing awareness of quality assurance, there is still much to improve. Multidisciplinary teams and integrated care pathways can contribute to this on hospital level, while a comprehensive European platform such as EURECCA, which organises international cancer care registry and feedback, can contribute to this on European level. EURECCA determines the core datasets per tumour type. For an optimal insight in cancer management, data on patient characteristics (comorbidities and fitness), tumour anatomy and biology, diagnosis, surgical treatment, neoadjuvant and adjuvant treatment will need to be collected. Data completeness and data accuracy are important goals to reach a good quality audit.

However, EURECCA has to deal with different privacy laws in different European countries. These laws currently limit international patient data collection. Moreover, there is no official structural funding yet for this international platform, which currently limits European expansion.

EURECCA, which is still in a developing phase, aims at rapid data processing and feedback and is patient centred. Furthermore, EURECCA aims to develop audit structures for all disciplines involved in cancer care. These audit structures are currently most advanced in surgical oncology. One of EURECCA's goals is to expand to all European countries and to cover all cancer registries and clinical audits. To achieve this, key opinion leaders are actively approached. In the near future, an international comparison on adjuvant treatment of rectal cancer and stage II colon cancer will be carried out, as well as an international comparison on treatment and survival for the oldest elderly patients with colorectal cancer. Colorectal cancer screening will be subject of future research. Ultimately, EURECCA wish to establish European guidelines for the treatment of cancer patients, with as goal that these guidelines will eventually substitute national and local guidelines. To establish quality assurance in cancer management, real-time measurement and feedback are crucial and not readily available yet. Initiatives such as EURECCA, which creates a platform to realise this, are necessary in the future to reflect on cancer care and improve cancer outcome. Large database analyses will offer the possibility of evidence-based and tailor-made treatment. Moreover, under- and overtreatment will be more easily detected.

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