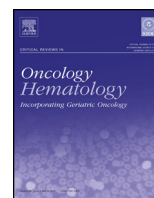




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## A systematic literature review of the economic implications of chemotherapy-induced diarrhea and its impact on quality of life

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### ABSTRACT

**Introduction:** Chemotherapy-induced diarrhea (CID) diminishes physical performance, raises anxiety and depression levels, and increases healthcare resource utilization.

**Objective:** To understand the impact that CID has on health-related quality of life (HRQoL) and on healthcare resource utilization.

**Methods:** Systematic searches were conducted in MEDLINE, EMBASE, DARE, and the NHS EED databases.

**Results:** A total of 22 articles were retrieved for full review ( $n = 17$ , HRQoL;  $n = 5$  healthcare resource utilization). Only 2 studies had assessed HRQoL in patients experiencing CID, while cost studies demonstrated that CID episodes are unnecessarily expensive and can be avoided if diagnosed and treated early.

**Conclusions:** Better management of CID has the potential to reduce overall economic burden and improve patients' HRQoL. Available evidence also relays the need to conduct larger studies that assess HRQoL and consider cost beyond direct medical costs in order to understand the full impact of CID on HRQoL and healthcare resource utilization.

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## 1. Introduction

Patients suffering from cancer also report experiencing diarrhea. Diarrhea can occur due to radiotherapy, chemotherapeutic agents, and infections (Stein et al., 2010). Chemotherapy-induced diarrhea (CID) symptoms include fever, excessive thirst, dizziness, abdominal cramps, watery stool, bloody stool, and refractory diarrhea (Stein et al., 2010). It can also result in dehydration, electrolyte imbalance, and even death (Maroun et al., 2007; Zachariah et al., 2010). The worldwide incidence of CID has been reported to be 50%–80% (Benson et al., 2004; Gibson and Stringer, 2009). Episodes of CID can lead to dose delays, dose reductions, decrease in dose density, and in some cases, dose discontinuation, all of which reduce the effectiveness of chemotherapy, leading to worse patient health outcomes (Zachariah et al., 2010; Arbuckle et al., 2000; Citron et al., 2003; Arnold et al., 2005).

In the late 1990s, the lack of agreement among oncologists on the most effective way to treat individuals suffering from CID motivated the development of evidence-based diagnostic and treatment guidelines. The guidelines were based on clinical evidence from published trials and unpublished data, and included recommendations to accurately assess diarrhea, type of pharmacologic agents (sequence, dose, duration of administration), and type of care needed by the patients (Wadler et al., 1998). The tool used for assessing the severity of CID was developed by the National Cancer Institute (NCI) and is known as the Common Terminology Criteria (CTC). This tool has several limitations, as it does not consider factors such as the onset and duration of diarrhea, stool volume and consistency, current medication, dietary and fluid intake, weight loss, and the site and stage of cancer (Kornblau et al., 2000; Cope, 2001). Another common criticism of the CTC tool is that diarrhea diagnosis should be based on the pretreatment baseline bowel movement of the individual, which is of critical importance for CID assessment and treatment (Saltz, 2003). A more recent CID clinical review also reinforced the need for a more comprehensive instrument for assessing CID in which risk factors are also considered (Richardson and Dobish, 2007).

In the clinical review by Richardson and Dobish, one of the recommendations for improving CID diagnosis and treatment is to encourage a closer relationship between the oncology nurse and the patient, in order for the patient to be well-informed and aware of diarrhea-inducing drugs, tests, symptoms, and treatment. A second recommendation is weekly assessments by a nurse or physician in combination with timely patient reporting of CID symptoms (eg, diarrhea for the first time during treatment, blood in the stool or around the anal area, or severe abdominal pain or cramping), which could help the patient in achieving optimal clinical outcomes (Richardson and Dobish, 2007).

Alongside the clinical impact of CID, the health-related quality of life (HRQoL) of individuals with CID has been reported to deteriorate significantly (Benson et al., 2004). CID raises the levels of anxiety and depression among patients and limits, or completely inhibits, their normal activities, including work, travel, and social interaction (Viele, 2003). Furthermore, it substantially increases healthcare resource utilization through an increased number of hospitalization days, emergency department visits, adoption of palliative treatment, and by increasing the care-giving burden (Arbuckle et al., 2000; Dranitsaris et al., 2005a; Nonzee et al., 2008).

This systematic literature review considers 2 specific questions: (1) What is the impact of CID on HRQoL? This question will be answered by identifying the tools that are used to assess changes in HRQoL and by determining which aspects of HRQoL are affected; and (2) What is the impact of CID on healthcare resource utilization? This question will be answered by describing which resource utilization items are the cost drivers in a CID episode.

## 2. Methods

### 2.1. Identification of studies

The principles of the preferred reporting items for systematic reviews and meta-analyses (PRISMA) were employed in this review (Moher et al., 2009). Searches were conducted in 4 databases: MEDLINE, EMBASE, the Database of Abstracts of Reviews of Effects (DARE), and the National Health Service Economic Evaluation Database (NHS EED). While the searches had an open starting date, the end date was week 2 of December 2013. The search strategies used for economic studies were specific for EMBASE (McKinlay et al., 2006) and for MEDLINE (Sassi et al., 2002; Wilczynski et al., 2004), while a less restricted search was used for the DARE and NHS EED databases. Since HRQoL studies do not have a published specific search strategy, the authors adopted the search strategies used in Health Technology Assessment reports published by the National Institute of Health Research in the United Kingdom to identify HRQoL studies (Fitzpatrick et al., 1998). The searches were used in combination with free-text words (chemotherapy induced diarrhea/diarrhoea and CID). The search strategy is presented in Appendix A. Limits were only applied to remove animal studies. The full text of potentially relevant articles was obtained. Included references were downloaded in Endnote (X6; Thomson ISI ResearchSoft) and Microsoft Excel 2010 software for further assessment and handling.

### 2.2. Inclusion and exclusion criteria

Articles were considered if they were written in English, Italian, or Spanish. Only studies that elicited patient preferences from adults ( $\geq 18$  years old) were considered. Articles were included if the abstract mentioned a HRQoL measure (generic or specific), and/or utilities or health states related to CID. Studies that identified, measured, and valued healthcare resources were also included and reviewed. All titles and abstracts of citations retrieved by the searches were screened independently by 2 reviewers; disagreements about inclusion or exclusion were resolved through consensus.

Details of the study type, study population, chemotherapy drugs inducing CID, treatments for CID, health outcomes, HRQoL instruments, and parameters of healthcare resources were extracted by 1 reviewer, and verified by a second reviewer; disagreements were resolved through discussion.

### 2.3. Critical appraisal

All included studies were assessed for methodologic quality using Cochrane recommendations and the criteria suggested by the Centre for Reviews and Dissemination for conducting systematic reviews in healthcare (Higgins and Green, 2011; Centre for Reviews and Dissemination, 2009). These criteria were adapted in order to address the needs of this review and were extracted by 1 reviewer and checked by a second reviewer; consensus of disagreement was derived by discussion. Data were synthesized through narrative review. Results of the quality checks were used for descriptive purposes and transparency of the overall quality of the studies included in the analysis. The quality checks of studies included in this report are available upon request.

## 3. Results

### 3.1. HRQoL studies

Of the 209 hits obtained, 135 were identified in MEDLINE, 53 in EMBASE, and 21 in DARE and NHS EED databases (Fig. 1

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