



Hepatic Artery Infusion Chemotherapy: A Quality Framework

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Despite well-established guidelines for screening and prevention, colorectal cancer remains highly prevalent in the USA with more than 150,000 new cases diagnosed annually.¹ Among this population, nearly 25% will develop liver metastases throughout their disease course and 50–75% of patients who undergo curative intent hepatic resection will experience hepatic recurrence.² As patient outcomes are primarily driven by the hepatic disease burden, a therapy specifically targeting the liver is fundamentally important to improving outcomes.

Hepatic artery infusion (HAI) chemotherapy is a liver-directed intraarterial regional treatment that can be used for patients with disseminated liver metastases, most commonly those with colorectal liver metastases (CRLM). The rationale of HAI is based upon the dominant blood supply of liver metastases from the hepatic artery as well as the near complete first-pass hepatic extraction of certain chemotherapeutic agents.³ Thus, high-dose chemotherapy is delivered directly to the liver by way of a surgically inserted catheter, most commonly into the gastroduodenal artery, which limits systemic toxicity, promotes conversion to resectable disease, and improves overall survival.⁴

Although HAI chemotherapy has largely been limited to select, highly specialized centers over the past several decades, recently, there has been exponential growth with new HAI programs opening across the world as institutions gain interest in offering HAI as a potential treatment modality

for this historically difficult-to-treat subset of patients. The current body of literature regarding HAI chemotherapy has primarily been published by investigators at Memorial Sloan Kettering Cancer Center (MSKCC), one of the pioneering institutions of HAI.^{5–7} However, due to the recent expansion of HAI programs, the HAI Consortium Research Network (HCRN) was established in 2020, consisting of more than 150 surgeons and medical oncologists from nearly 60 centers worldwide, which houses an international HAI database to facilitate research on patient selection and clinical outcomes.⁸

While most recent single- and multi-institutional studies using data collected for the HCRN have demonstrated the safety, feasibility, and efficacy of HAI, the delivery of HAI chemotherapy also poses unique risks that providers must be able to swiftly recognize and manage to minimize the potential consequences of HAI-specific complications.^{9,10} For example, close attention and avoidance of the development of biliary sclerosis as a result of HAI chemotherapy is critical as it may result in serious patient morbidity including infectious complications such as ascending cholangitis and hepatic abscesses.¹¹ Due in part to quality and safety concerns, several HAI programs developed over the past several years were unsustainable and unfortunately dissolved. However, the role of HAI in treating additional hepatic malignancies continues to expand as modern research increasingly demonstrates its benefit for patients with advanced liver disease, most recently hepatocellular carcinoma.¹² Thus, as HAI programs continue to grow and offer this therapy as an available treatment option, a quality framework for HAI best practices and comparative quality assessment is essential to maximize patient safety and program sustainability as well as minimize HAI toxicity.

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In recent years, hospital quality improvement collaboratives have proliferated where groups of hospitals participate to share knowledge, benchmark performance, and work on common quality improvement initiatives to improve patient care and outcomes. One of the largest and most successful surgical quality improvement collaboratives to date is the American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) Quality Verification Program (QVP).¹³ This standards-based verification program was designed to facilitate hospitals across the country in improving the quality of surgical care by leveraging ACS NSQIP data to provide benchmarked performance reports. Similarly, effective quality improvement collaboratives have been formed at the regional level such as the Illinois Surgical Quality Improvement Collaborative (ISQIC), a 56-hospital learning collaborative created through Northwestern University which has demonstrated success in improving the quality of surgical care in Illinois including reduced rates of venous thromboembolism, surgical site infections, and death or serious morbidities.^{14–16}

Quality improvement collaboratives extend beyond general surgical care and have proven their significance in the delivery of cancer care as well, the most notable of which is through the ACS Commission on Cancer (CoC).¹⁷ Likewise, the ACS CoC provides data reporting and feedback to their accredited hospitals through the use of the National Cancer Database to assess performance on quality measures and identify areas for improvement in cancer care. In addition, cancer quality improvement collaboratives have also formed at the regional level. Specifically, the Illinois Cancer Collaborative (ILCC) was a first-of-its-kind statewide cancer collaborative designed to partner Illinois hospitals together in a multidisciplinary learning collaborative to improve the quality and safety of care for patients with cancer in Illinois.¹⁸ For example, the ILCC has established initiatives to efficiently address the unique challenges in delivering cancer care during the coronavirus disease 2019 (COVID-19) pandemic through creation of a set of guidelines focused on the

appropriate triage and management of patients with cancer during this unprecedented time.¹⁹

Although these collaboratives differ in terms of their patient populations and scale, the same fundamental principles are applied across all successful quality improvement collaboratives which include defining best practices, benchmarked data, coaching, and shared strategies. However, HAI processes and outcomes are not captured by other quality programs such as ACS NSQIP or CoC. Using this structure, a HAI-specific quality improvement collaborative is under development through the HCRN which will serve as a multi-institutional network to improve outcomes among patients receiving HAI chemotherapy built upon these same principles (Fig. 1).²⁰

First, defining best practices will include development of novel quality measures for HAI chemotherapy delivery, driven by data leveraged from the HCRN database, the collective experience of multidisciplinary experts in the field, and a review of the literature (Table 1). As an example, these quality measures will provide recommended guidelines regarding postoperative and HAI-specific complications, HAI chemotherapy delivery, and oncologic outcomes. The second pillar of a HAI quality framework will focus on benchmarked data through augmentation of the current HCRN database to measure adherence to the previously defined quality measures. Comparative benchmark reports will be generated to provide a feedback mechanism to inform each individual program of their performance and identify specific areas for quality improvement. The aim of the third pillar is coaching. This includes organizing HAI disease management team meetings to discuss patient selection, difficult cases, treatment decisions, and management of complications which has already been established among HCRN members. Additionally, all HAI programs will have access to experienced peer-to-peer quality mentors to guide them through program-level quality improvement projects as a part of the coaching pillar. Lastly, shared strategies will involve the development of HAI-specific toolkits for

FIG. 1 Hepatic artery infusion chemotherapy quality framework model

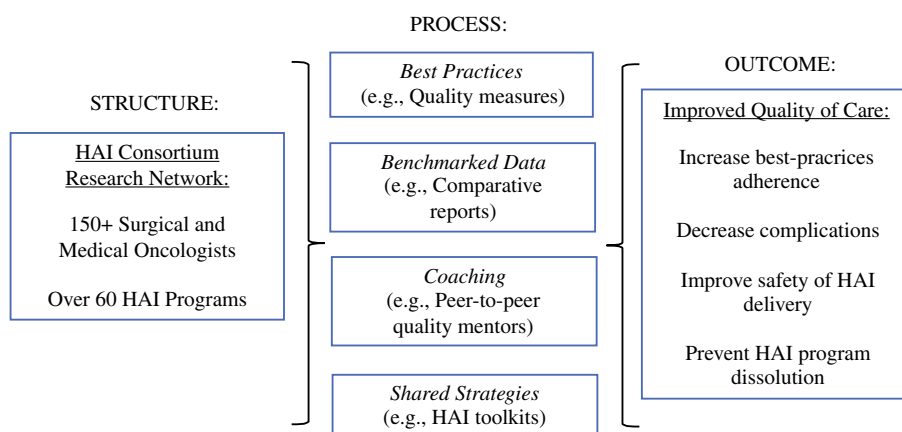


TABLE 1 Hepatic artery infusion chemotherapy quality framework principles

Quality pillar	Components
Best practices	Develop quality measures through: Analyzing HCRN data Consult with multidisciplinary HAI experts Perform a literature review Define best practices with regards to: HAI chemotherapy delivery Postoperative and HAI-specific complications Oncologic outcomes
Benchmarked data	Leverage HCRN data to measure adherence to quality measures in real time Provide annual comparative reports to inform HAI programs of their performance Identify areas for quality improvement at the program level
Coaching	Organize monthly HAI Disease Management Team Meetings to discuss: Patient selection Difficult cases Treatment decisions Management of complications Provide experienced peer-to-peer quality mentors to guide program-level quality improvement projects
Shared strategies	Create HAI-specific toolkits for both medical and surgical oncology Inform decision-making Guide best practices Develop annual, collaborative quality improvement projects across all HAI programs on an international level

decision-making and best practices for both medical and surgical oncology,⁸ as well as require hospitals to participate in annual, collaborative quality improvement projects. Importantly, the development of each pillar within this HAI quality framework will be driven by the collaboration of a multidisciplinary team, including both medical oncologists and surgical oncologists among other specialties as well.

Quality improvement is a vital aspect of both surgical and cancer care as it has demonstrated success in improving patient outcomes across multiple different collaboratives. Through leveraging the data and infrastructure already built within the HCRN, this HAI-specific quality improvement collaborative represents a first-of-its-kind effort through a learning collaborative approach to address HAI chemotherapy care. By utilizing previously defined collaborative strategies to drive quality improvement, the goal of this HAI-specific collaborative is to improve the safety, feasibility, and efficacy of HAI chemotherapy delivery by engaging HAI providers with high-quality comparative data. Like other quality improvement collaboratives as well, the long-range goal of this HAI-specific collaborative will work towards developing a formal HAI accreditation program, identifying centers of excellence based on volume and patient outcomes. Moving forward, each program will be able to measurably increase adherence to best-practice treatment guidelines, improve the quality and safety of care provided, potentially reduce costs, and prevent program dissolution for newly established HAI institutions.

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