Identifying Early Dehydration Risk With Home-Based Sensors During Radiation Treatment: A Feasibility Study on Patients With Head and Neck Cancer

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Background

Systems that enable remote monitoring of patients’ symptoms and other health-related outcomes may optimize cancer care outside of the clinic setting. CYCORE (Cyberinfrastructure for Comparative effectiveness REsearch) is a software-based prototype for a user-friendly cyberinfrastructure supporting the comprehensive collection and analyses of data from multiple domains using a suite of home-based and mobile sensors. This study evaluated the feasibility of using CYCORE to address early at-home identification of dehydration risk in head and neck cancer patients undergoing radiation therapy.

Methods

Head and neck cancer patients used home-based sensors to capture weight, blood pressure, pulse, and patient-reported outcomes for two 5-day periods during radiation therapy. Data were sent to the radiation oncologist of each head and neck cancer patient, who viewed them online via a Web-based interface. Feasibility outcomes included study completion rate, acceptability and perceived usefulness of the intervention, and adherence to the monitoring protocol. We also evaluated whether sensor data could identify dehydration-related events.

Results

Fifty patients consented to participate, and 48 (96%) completed the study. More than 90% of patients rated their ease, self-efficacy, and satisfaction regarding use of the sensor suite as extremely favorable, with minimal concerns expressed regarding data privacy issues. Patients highly valued the ability to have immediate access to objective, self-monitoring data related to personal risk for dehydration. Clinician assessments indicated a high degree of satisfaction with the ease of using the CYCORE system and the resulting ability to monitor their patients remotely.

Conclusion

Implementing CYCORE in a clinical oncology care setting is feasible and highly acceptable to both patients and providers.


The potential of communication and health information technologies to transform research and improve clinical care in cancer has only begun to be realized (1,2). There is a need for innovative strategies and technologies that enable the aggregation and analysis of clinical and research data (including real-time health-related outcomes) and that foster the translation of knowledge gained into improvements in patient care (2–4). The use of health information technologies may alter how health-care providers and patients interact with personal health information by facilitating the collection, analysis, and dissemination of data to enhance clinical decision making (3). In turn, patients may report symptoms more readily and be reassured knowing that their providers are better informed about all aspects of their treatment and care.

The American Society of Clinical Oncology has emphasized the need to use communication and information technology to better integrate clinical and translational research with patient care so that patients’ experiences can inform research and improve care (1). Accomplishing this goal requires a systems approach that enables greater and more rapid access to patient clinical information to better understand therapeutic responses, side effects, quality of life, and general health status (1). This approach may improve oncology care by synthesizing and distilling large amounts of data to identify earlier opportunities to manage treatment side effects and complications, as well as long-term survivorship issues (1,3).

Systems that enable remote and real-time monitoring of patients’ symptoms and other health-related outcomes may offer cost-effective strategies to optimize cancer care outside of the clinic setting (5,6). Remote collection and transmission of patient health-related data to facilitate clinical decision making have been used in the management of chronic diseases other than cancer (7–12), and this has been shown to improve patient quality of life and symptom control, decrease emergency room visits and unplanned hospitalizations, and decrease overall health-care costs (12–15).

Less is known about which patients and under which circumstances remote monitoring is most appropriate and effective, particularly in oncology (16,17). Studies evaluating remote real-time monitoring of
cancer patients have reported positive outcomes (5); however, empiric evidence includes the collection of patient-reported outcomes largely using currently available telecommunications technologies (17,18). Systems that include biometric and self-reported feedback for cancer patients have been conceptualized; however, there is limited evidence regarding their feasibility or efficacy (19,20).

This paper describes the results of an initial application of a novel system that incorporates data on environmental, psychological, treatment adherence, and lifestyle behaviors and the patient-reported outcomes into cancer treatment and research. The system, called CYCORE (Cumulative infrastructure for Comparative effectiveness REsearch), is a software-based prototype of a user-friendly cyberinfrastructure that supports the acquisition, storage, visualization, analysis, and communication of data across the cancer continuum, using a suite of home-based and mobile sensors (19). Health-related data collected include symptoms, quality of life, performance status, and physiological parameters that can signal how patients are self-managing their treatment.

The CYCORE prototype was rigorously tested in several diverse use cases that were grounded in challenging, real-world clinical problems in cancer prevention and treatment (19). One use case, which is the focus of this report, engaged head and neck cancer (HNC) patients in the use of home-based sensors for collecting and communicating blood pressure, pulse, weight, and patient-reported symptoms to their HNC radiation therapy (RT) clinicians. Clinicians reviewed these data outside of clinic visits for earlier identification of dehydration risk secondary to outpatient RT.

HNCs are highly curable, yet primary RT is physically and emotionally challenging for patients (21). RT involves a 6- to 7-week course of 5-day/week treatments and causes serious locoregional side effects. In its severe form, mucositis, which occurs in up to 80% of irradiated HNC patients, makes it very difficult for patients to drink adequate levels of fluids (22). As a result, dehydration and its accompanying physiological changes can develop rapidly, often between weekly physician visits that are standard of care during RT. When unresolved, dehydration can lead to acute episodes requiring hospitalization and/or emergency care visits that are costly and potentially preventable. The number of patients affected is substantial, as up to 27% of HNC patients may be admitted to inpatient or emergency care units during RT (23–25) (personal communication, E. Shinn). Dehydration may represent one of the largest incremental health-care expenses in treating mucositis and related side effects for HNC (23). The development of systems to closely monitor hydration status has been suggested as a potentially valuable intervention that may reduce hospitalization and health-care costs, in addition to improving quality of life (26–28).

Technology that supports remote monitoring of HNC patients during RT may enable greater access to clinical and patient-reported data that are currently unavailable, may provide greater insight into patients’ therapeutic response, and may help to identify opportunities for earlier and more effective intervention. In this context, CYCORE may serve as a new model of a communication architecture for improving clinical care and patient support outside of the clinic setting during critical periods of cancer treatment. This study evaluated the feasibility of using CYCORE to address early at-home identification of dehydration risk in HNC patients undergoing RT.

### Methods

**Use of CYCORE for Monitoring Dehydration Risk in HNC Patients**

CYCORE comprised a platform for the capture of biometric and other data collected at a remote location (in this study, in patients’ homes). Figure 1 depicts how patients, clinicians, and researchers interacted with CYCORE’s home-based sensors and the cyberinfrastructure. The system consisted of a miniature computer base station, called the “home health hub” and a server. The home health hub aggregated and encrypted the sensor data that were wirelessly transmitted from sensors used by the patient to the home health hub server; these data were then transmitted to a central server via the Internet or wireless data card depending on capabilities at the user’s home. The home health hub notified the CYCORE server database of new data events via a secure Web service interface. The wireless home-based sensors used in this study were a weight scale and a blood pressure monitor that also measured pulse. CYCORE also supported a customized ecological momentary assessment platform for collecting patient self-reported outcomes via a questionnaire-and-response application that was delivered via smart phones (29). Research staff registered and assigned sensors and smart phones (hereinafter referred to as “devices”) to patients. CYCORE’s data management system mapped incoming data to unique patient logs, and staff monitored its availability and handled technology issues that arose. Clinicians viewed patients’ data in CYCORE daily and determined whether clinical intervention was warranted.

**Participant Eligibility and Recruitment**

This study was approved by the MD Anderson Cancer Center Institutional Review Board. Eligible patients were those 1) receiving RT for HNC at MD Anderson, 2) diagnosed with HNC and treated with bilateral RT to neck and/or mucosa (including but not limited to stages 1–4b oropharyngeal, hypopharyngeal, nasopharyngeal, salivary gland, or oral cavity cancers and stages 3–4b laryngeal cancers), and 3) aged 18 years or older, able to read and speak English, and residing locally during RT. Eligible patients were recruited during their initial RT planning appointment.

**Study Procedures**

After providing written informed consent, patients were trained on home use of the devices. Patients used the devices for two 5-day test periods (Monday–Friday) during the 6–7 weeks of RT: first, within weeks 1 and 2 of RT; and, second, within weeks 4 and 5. Each morning during these time periods, patients took blood pressure and pulse (first sitting, and then standing) and weight readings. They also completed a questionnaire on the smart phone, which included diet and fluid intake, dehydration-related signs (eg, urine color), and symptoms (30). Completion of all patient assessments required about 5–10 minutes per day. HNC radiation oncologists or their physician assistants monitored the data on the same day through the secure cyberinfrastructure Web interface. When data indicated that a patient may be at risk for dehydration, clinicians contacted the patient within 24 hours to determine the need for intervention.
Measures
We assessed patients' perceptions of usability, acceptability, and satisfaction at seven time points across the study. After completing the training session, patients responded to a four-item questionnaire regarding ease of use and self-efficacy in regard to using each device. On days 2 and 4 of each test period, research staff administered—a six-item measure regarding device problems, medical concerns related to the devices, ability to use each device (and if applicable, reasons for not using a device or why using it was difficult), ease of use, and what was disliked about a device or what reduced the desire to use the device (31,32). This measure was readministered on day 6 of each test period with additional items that evaluated belief about the usefulness of automatic data provision to their clinician, concern about data privacy, helpfulness of the initial training session and printed instructions, importance of seeing the data collected, confidence in ability to use at home, and overall satisfaction with device use.

Clinicians' ratings of feasibility also were measured. At the end of the study, clinicians completed a questionnaire regarding their experience with the CYCORE system, including satisfaction with time spent using the system, whether the care quality for the patient improved, ease of use, whether patient data transmission time was adequate, the importance of receiving at-home patient data from each device, and whether they trusted the data confidentiality (31,32). Open-ended questions elicited additional general comments from both patients and clinicians.

Statistical Analysis
The primary endpoint was study completion as defined by completing the second, and final, day 6 assessment. Other endpoints of interest were accrual, acceptability, perceived usefulness of the intervention, and adherence to the monitoring protocol. Analyses were performed using Statistical Package for the Social Sciences, version 19. Nonlinear mixed models were run in SAS (Proc Glimmix). Demographic and clinical characteristics of participants and nonparticipants, in addition to study completion information, were compared using \( t \) tests and \( \chi^2 \) tests. Mean scores were calculated on measures of device usability and acceptability, and test–retest reliability was computed for scores for the two 5-day test periods. All tests were two-sided. Statistical significance was established at \( P \) values \( \leq .05 \). Open-ended responses to questionnaire items completed by patients and clinicians were analyzed using a constant comparative approach based on grounded theory (33).

We also analyzed sensor- and patient-reported data to determine whether dehydration-related events could be identified using CYCORE. We defined a dehydration-related event as a decrease in systolic blood pressure of at least 10 mmHg combined with an increase in heart rate of at least 10 points, when comparing patient readings taken first when sitting and then when standing. These are the same parameters used by RT clinicians at MD Anderson Cancer Center to define medically actionable events that require clinical assessment of hydration status. Using nonlinear mixed models, we examined whether dehydration-related events (dichotomized as yes/no) during the 2-week monitoring period were independently
correlated with symptoms (nausea, pain, thirst, vomiting, disturbed sleep, swallowing difficulty, weakness, drowsiness, and fatigue) self-reported that same morning. Symptom scores ranged from 0 (not at all) to 10 (extremely).

Results

During a 7-month period, 392 HNC patients were screened for eligibility. Of these, 85 were eligible and were invited to participate; 50 consented (59% participation) and completed training. For nonparticipants who consented to provide their demographic and clinical data (n = 17), we observed differences compared with participants in terms of age, sex, disease site, and previous treatment, with nonparticipants more likely to be women and older (Table 1). Forty-eight (96%) patients completed the study. There were no differences between those who did and those who did not complete the study in terms of demographic or clinical variables. Of the 341 study questionnaires administered to patients, 332 (97%) were completed.

Figure 2 summarizes patients’ mean scores on the final questionnaire. Responses indicated high levels of perceived importance of and satisfaction with using the sensors during RT, and high levels of ease of use and self-efficacy. The usefulness of providing data to their clinicians during active treatment and the importance of being able to see the data themselves were rated very highly. There were no differences between responses in the questionnaire provided during the first and the second test periods, indicating consistently positive ratings during the entire study period. Patients’ responses to open-ended questions during the final study debriefing reflected themes that were consistent with the questionnaire responses. Themes included perceived importance of providing frequent objective data to health-care providers during active treatment (eg, “I think it is good for [the doctors] to get the feedback instantly, and not rely on a patient to recall exactly what's going on”); perceived usefulness of having access to one’s own data (eg, “I learn a lot from the devices, [like] watching your weight or if you’re having any problems”); and, perceived value of being in closer partnership with their clinicians for monitoring their care (eg, [I liked] “the convenience of knowing you have [the devices] at home, and that someone is following the data, so if the reading had not been good, I’d be contacted”). Responses also indicated that having access to these data also motivated greater vigilance toward maintaining optimal hydration and nutrition. Responses indicated that the devices were easy to use and did not present an unsustainable burden during RT.

Of the eight radiation oncologists who see HNC patients at MD Anderson Cancer Center, seven agreed to enroll their patients in this study. All physicians who enrolled patients monitored patients’ data daily, either personally or via their physician assistant. Given the integral nature of the Internet and computer-based charting to daily practice, monitoring via CYCORE was easily incorporated into daily practice. Although not explicitly measured, data review typically took less than 2 minutes per clinician each day. Table 2 summarizes clinicians’ mean scores on responses to the exit questionnaire. Responses reflected high perceived value in having access to patients’ data on a daily basis, high ratings on ease of use of the Web interface, and high satisfaction with the data transmission time.

Sensor data identified dehydration-related events during the two test periods in which CYCORE was used: 60% (n = 29) of patients who completed the study had at least one event, and 35% (n = 17) had two or more events. Three symptoms were associated with having had a dehydration-related event: nausea (P = .004), vomiting (P = .0004), and swallowing difficulty (P = .004); the association with pain approached statistical significance (P = .073).

Conclusion

This study evaluated the feasibility and acceptability of using CYCORE for remote monitoring of HNC patients during RT as a potential strategy for early identification of treatment-related dehydration. Our results indicated that implementing this system in a clinical oncology care setting is both feasible and highly acceptable to patients and providers. The high rate of study completion by patients was particularly encouraging because treatment for HNC is complex, can be challenging to manage, and is distressing for patients and their families (21). Patients demonstrated excellent adherence to monitoring and assessment in spite of the challenging burden of undergoing daily RT. Patients also gave consistently high ratings to the importance and value of self-monitoring during the course of the study and strongly endorsed the utility of having their data readily available to, and actionable by, their health-care team.

Similarly, we observed a high level of participation and enthusiasm among clinicians for implementing CYCORE concurrently with RT, and their responses indicated that they perceived this activity to be of added value in the care of their patients. The perceived value of using CYCORE may have been underscored by the fact that the majority of patients’ sensor data indicated a potential need for clinical assessment of dehydration risk outside of clinic visits, which may have reinforced its relevance to patient care and support. We expect that dehydration-related events may be observed more frequently as treatment progresses, given the increasing severity of side effects during the course of RT. Reviewing patient data in CYCORE did not present an undue time burden relative to other clinical demands, and the system was perceived as being easy to use. Health-care providers’ willingness to adopt technology-based interventions is a critical factor in the successful diffusion of new applications such as CYCORE into clinical care (34,35). CYCORE was developed with extensive requirements gathered from a diverse group of stakeholders in an iterative process, including the HNC clinicians who participated in this study (19). Involving these clinicians throughout all aspects of the development and testing process helped ensure that CYCORE would add value to their work and would be perceived to be easy to adopt and implement (35).

A limitation of this study was its implementation at a single comprehensive cancer center. Moreover, although CYCORE enabled us to monitor patients’ usage of the sensors, clinician use of the system was assessed based on self-report. Future research should address, using a randomized controlled trial design, whether CYCORE improves the early detection of dehydration in HNC patients undergoing RT and, in turn, whether it reduces costs associated with hospital or emergency center admissions. Future studies also should test CYCORE in other settings,
including community-based oncology centers, and in other diverse patient populations, including patients who are similar to our nonparticipants.

Our findings suggest that CYCORE may serve as one model for integrating health information technologies with cancer treatment and for potentially increasing cancer patients’ engagement in their care (36). Patients in our study were willing to actively monitor their health during RT and to provide timely information to their clinicians, which may facilitate rapid decision making regarding their care. This exchange of potentially actionable health information may foster communication between patients and their clinicians to optimally manage side effects and toxicities during cancer treatment and should be directly explored in future research. Empowering patients and providers with access to these

| Table 1. Demographic and clinical characteristics of study participants and nonparticipants (N = 67) |
|---------------------------------------------------------------|---------------------------------|---------------------------------|----------------|
| Characteristic                                               | Overall (n = 67) | Enrolled (n = 50) | Refused* (n = 17) | P       |
| Mean age, y (range: 41–84)                                   | 60.2             | 58.8             | 64.1             | .040†   |
| % (n)                                                        | % (n)            | % (n)            | % (n)            |         |
| Age < 65 y                                                    | 63 (42)          | 68 (34)          | 47 (8)           | .123†   |
| Sex, women                                                   | 16 (11)          | 10 (5)           | 35 (6)           | .015†   |
| Race/ethnicity, white                                        | 87 (58)          | 86 (43)          | 88 (15)          | 1.000§  |
| Married                                                      | 70 (47)          | 72 (36)          | 65 (11)          | .570‡   |
| Primary disease site                                         | —                | —                | —                | .029†   |
| Buccal mucosa                                                | 2 (1)            | 0 (0)            | 6 (1)            | —       |
| Larynx                                                       | 8 (5)            | 2 (1)            | 24 (4)           | —       |
| Nasopharynx                                                  | 3 (2)            | 4 (2)            | 0 (0)            | —       |
| Neck metastases, primary unknown                             | 10 (7)           | 12 (6)           | 6 (1)            | —       |
| Pharyngeal wall (oropharynx)                                 | 5 (3)            | 4 (2)            | 6 (1)            | —       |
| Salivary gland                                               | 3 (2)            | 4 (2)            | 0 (0)            | —       |
| Tongue, base                                                 | 37 (25)          | 38 (19)          | 35 (6)           | —       |
| Tongue, oral                                                 | 10 (7)           | 8 (4)            | 18 (3)           | —       |
| Tonsil                                                       | 22 (15)          | 28 (14)          | 6 (1)            | —       |
| Previous treatment for current primary cancer diagnosis       | 15 (10)          | 10 (5)           | 29 (5)           | .052‡   |

* Group contains only those who consented to our collection of demographic data (total refusals = 28).
† Computed using t test (two-sided).
‡ Computed using Pearson χ² test (two-sided).
§ Computed using Fisher Exact χ² test (two-sided).

Figure 2. Participants’ responses to the final questionnaire regarding CYCORE (Cyberinfrastructure for Comparative effectiveness Research)’s feasibility, usability, and acceptability (n = 48). Response scale ranged from 0 to 10, with 0 indicating not at all and 10, extremely.
technologies may facilitate greater satisfaction with care, improved management of treatment side effects, and better quality of life during critical periods of cancer care that occur outside of the clinic setting.

**References**


**Table 2. Clinicians’ responses to questionnaires regarding CYCORE’s feasibility, usability, and acceptability**

<table>
<thead>
<tr>
<th>Item</th>
<th>Mean (Median)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I am satisfied with the time I spent using the CYCORE project interface during the feasibility trial*</td>
<td>6.0 (6.5)</td>
</tr>
<tr>
<td>The quality of my work for the patient improved when I used the CYCORE project interface*</td>
<td>5.7 (5.5)</td>
</tr>
<tr>
<td>It was easy for me to use the CYCORE project interface*</td>
<td>6.2 (6.0)</td>
</tr>
<tr>
<td>The time it took for patient data to be transmitted to me was adequate when I used the CYCORE project interface*</td>
<td>5.8 (6.0)</td>
</tr>
<tr>
<td>I trusted that confidentiality of data was maintained in the CYCORE project interface*</td>
<td>6.4 (6.5)</td>
</tr>
<tr>
<td>The CYCORE project interface is helpful in monitoring your patients on clinical trials*</td>
<td>8.4 (8.0)</td>
</tr>
<tr>
<td>The CYCORE project interface is helpful for collecting research data on clinical trials*</td>
<td>8.0 (8.0)</td>
</tr>
<tr>
<td>How important do you feel it to the care of your patients for you to receive at-home patient data from the following devices in between clinic visits?</td>
<td>7.9 (7.5)</td>
</tr>
<tr>
<td>Blood pressure</td>
<td>7.9 (7.5)</td>
</tr>
<tr>
<td>Pulse</td>
<td>7.9 (7.5)</td>
</tr>
<tr>
<td>Weight</td>
<td>8.3 (8.0)</td>
</tr>
<tr>
<td>Data on symptoms</td>
<td>8.4 (8.0)</td>
</tr>
</tbody>
</table>

* n = 6 clinicians who personally monitored patients using CYCORE.
† n = 8 (includes 2 HNC physicians who agreed to have their patients monitored using CYCORE but who delegated daily monitoring to midlevel providers).
‡ Response scale ranged from 1 (strongly disagree) to 7 (strongly agree).
§ Response scale ranged from 0 (not at all) to 10 (extremely).

**n** = 8 (includes 2 HNC physicians who agreed to have their patients monitored using CYCORE but who delegated daily monitoring to midlevel providers).


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