Evaluating the feasibility of using an electronic patient-reported outcome (ePRO) Smartphone Application (app) and Biosensor by Patients with Cancer undergoing Systemic Treatments.

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Background
• Almost half of the nearly 370,000 patients with cancer who receive chemotherapy in the United States each year experience emergency department (ED) visits and unplanned hospital inpatient (IP) stays during treatment, largely due to poorly controlled symptoms. Preliminary qualitative interviews with patients with cancer and providers in Washington state showed that a better system for communication and symptom management between the care team and patients is crucial for preventing ED visits during chemotherapy.
• Recent studies have shown that utilizing PRO information in oncology practice can improve symptom management and patient outcomes. In a randomized study, Basch et al. showed that more patients receiving outpatient chemotherapy for advanced solid tumors assigned to an intervention with electronic symptom reporting had improved health-related quality of life, and fewer had worsened health-related quality of life, compared with those who received usual care. In addition, patients in the intervention group were less frequently admitted to the ED (34% vs. 41%, p=0.02) or hospitalized (45% vs. 49%, p=0.08) and remained on chemotherapy for longer. The recent adoption of wearable biosensors, including activity trackers and watches, provides an opportunity to collect passive biometric information that can be used to inform patients’ health status alongside PRO information. Our study aims to examine the feasibility and usability of a PRO app paired with a biosensor to identify patients who are at high risk for ED and IP visits.

Study design
• This prospective observational study is designed to evaluate the feasibility and usability of a clinician-provided smartphone app and smartwatch biosensor for monitoring patients undergoing systemic cancer treatment. The study is divided into two phases: (1) vanguard (n=30); (2) operational (n=70) (Figure 1). Patients will be asked to wear the biosensor and enter daily PROs into the app, initially for 2 weeks (vanguard), then for 6 weeks (operational). During the vanguard phase, 10 patients selected at random from the three participating oncology community clinics will be recruited as is standard for initial device and software testing and development.

Electronic patient-reported outcomes app
• The app collects PROs (PRO-CTCAE), app usability and satisfaction (modified mHealth App Usability Questionnaire [mMAUQ]), and patient satisfaction with the biosensor (modified Quebec User Evaluation of Satisfaction with Assistive Technology [QUEST 2.0]). The 15 symptoms included in the PRO-CTCAE were selected based on the most common reasons for hospitalization and/or ED visits for patients with cancer based on claims data. These include nausea, vomiting, constipation, diarrhea, pain in the abdomen, shortness of breath, cough, rash, dizziness, fatigue, headaches, itching, anxiety, and chills. In addition, patients are asked about any ED visits or hospitalizations they had in the 2-week (vanguard) or 6-week (operational) observation period. The data collected from the vanguard phase will inform modifications to the app for the operational phase. The operational phase sample size is sufficient to assess data capture completion and clinical trial recruitment procedures in diverse practice settings (e.g., low volume vs. high volume, rural vs. urban) (Figure 2).

Biosensor
• The biosensor used for this study is the Samsung Galaxy Watch3. This device collects information on heart rate, oxygen saturation, activity (e.g., steps per minute), sleep, and falls. Patients will be asked to wear the watch every day and charge the watch at night while sleeping (Figure 2).

Study objectives and endpoints
Vanguard phase
• In the vanguard phase, the primary objectives are to evaluate the feasibility and usability of the app and sensor technology by assessing patient recruitment and protocol adherence, completeness of data capture, app usability, and user satisfaction with the biosensor.

Operational phase
• In the operational phase, the study team will measure the validity of self-reported hospital visits and the feasibility of using electronic case report forms, as well as re-evaluating the vanguard phase primary objectives in the larger sample size of 70 patients.

Inclusion criteria:
• 18–80 years of age.
• Have a biopsy-proven current diagnosis of cancer.
• Patients may present with an original diagnosis, evidence of systemic recurrences, or progression of previously diagnosed disease.
• Cancer may be metastatic or non-metastatic.
• Cancer type must be a solid tumor; patients with current blood cancers (either as their only diagnosis or in addition to the current solid tumor diagnosis) are not eligible.
• However, patients who have a history of a blood cancer, have completed therapy at least 12 months prior to enrollment, and are considered ‘no evidence of disease’, are eligible.
• Scheduled to receive, or within 4 weeks following first dose of intravenous cancer therapy or oral cancer therapy, as an initial treatment for their current disease.
• This treatment may be neoadjuvant chemotherapy, adjuvant chemotherapy, metastatic and/or palliative systemic therapy, including chemotherapy, targeted agent, immunotherapy, and/or concurrent chemoradiation.
• Able to use the Samsung Galaxy Watch3 daily and as advised by the manufacturer’s device instruction manual.
• Able to provide informed consent, understand and provide information for, study forms, an in-app ePRO survey, and questionnaires in English.
• Eastern Cooperative Oncology Group performance status of 0–2 at enrollment.

Exclusion criteria:
• Patients will be excluded from the study if any of the following are present:
• Current intravenous or oral systemic cancer therapy started more than 4 weeks prior to the date of enrollment.
• Plan to receive radiation or hormone therapy only.
• Diagnosed with non-melanoma skin cancer only.
• Diagnosed with hematolog in English only.
• Wearing pacemakers, implantable cardioverter defibrillators, cochlear implants, and/or neurostimulator devices.
• Living in a nursing home or skilled nurse facility at the time of enrollment.
• In a clinical trial.
• Citizen of the European Union.
• Pregnant.

Trial status
As of May 22, 2022, there are three sites actively enrolling patients in the vanguard phase. A total of 31 patients have consented, 24 patients have completed the study, and four patients are active in the study.

Two patients have withdrawn from the study.

Endpoints for vanguard phase
• Feasibility of the study recruitment protocol measured by the number of patients screened, the proportion of patients who are eligible, and the percentage of eligible patients who consent to participate each month.
• Feasibility of the onboarding protocol as measured by the percentage of consenting patients with a successfully activated app and sensor, and the percentage of consenting patients who successfully complete the app ePRO survey and record and store/transmit sensor data within 24 hours of enrollment.
• Completeness of data as are measured by:
• The percentage of completed ePRO app surveys successfully transmitted, stored, and retrieved from the secure cloud environment during the observation period or prior to discontinuation.
• The percentage of sensor data collected from each patient, successfully recorded or transmitted, stored, and retrieved from the secure cloud environment during the observation period or prior to discontinuation.
• The number of days sensor data was successfully collected during the observation period.
• Patient assessment of usability of the app as evaluated by:
• The mMAUQ average score.
• The time average to complete the ED visits/IP admissions questions and the symptoms questions within the app ePRO survey.
• The time spent on each screen.
• The screens on which patients selected/dressed more cancellation operations.
• Patient overall satisfaction with the app as measured by Item 12 of the mMAUQ.
• Patient satisfaction with the biosensor as measured by the modified QUEST 2.0 average score.
• Patient adherence to the app ePRO survey (PRO-CTCAE) as measured by the ratio of the completed ePRO surveys to the number of required completed ePRO app surveys prior to discontinuation or end of the observation period.
• Patient adherence to wearing and synchronizing the biosensor as measured by:
• The ratio of days with any biosensor data to the number of days prior to discontinuation or end of the observation period.
• The percentage of the total required time (12 hours, 7 days) the patient wears the biosensor during the observation period prior to discontinuation or end of the observation period.

Endpoints for operational phase
• In addition to the endpoints of the vanguard phase primary objectives, the endpoints listed below also will be evaluated:
• Validity of self-reported ED and in-patient hospital visits as measured by the percentage of true positive self-reported ED visits/AD admissions, compared with a chart review.
• Feasibility of electronic case report form (eCRF) data collection and submission as measured by the number of patients with electronic data capture (EDC) flags (incomplete or incorrect eCRF entries) and the number of EDC flags for those patients at the end of the operational phase.

References
3. Kate Watabayashi,1 Elaine Yu,2 Richa Wilson,2 Marianne Chacon,2 Scott Ramsey1

Conflicts of interests
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