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LETTERS TO THE EDITOR

RESEARCH

Pilot and feasibility deployment of an advanced remote monitoring platform for COVID-19 in long-term care facilities

INTRODUCTION

Older adults in long-term care facilities (LTCFs) are at a significantly higher risk for hospitalization and death due to coronavirus disease 2019 (COVID-19).[1,2] Prolonged stays, close aggregation, and low functional status compound poor prognosis of this vulnerable population.[3] Wearable devices have increasingly emerged as novel tools to track and mitigate outbreaks given continuously collected and wirelessly transmitted physiological data.[4,5] Devices for older adults in LTCFs must consider low technical literacy, medical complexity, cognitive decline, skin fragility, overburdened caregivers, and limited technical staff expertise. Though recent studies have used wearables like AppleWatch and FitBit to identify COVID-19 infections, they systematically underrepresent older adults and fail to measure key symptoms, including cough, fever, and shortness of breath.[4,6] This study evaluated the feasibility of remotely deployed bio-integrated wireless sensors to comprehensively measure vital signs in high-risk, residential older adults.

METHODS

This is a fully virtual single-arm, prospective observational study of older adults in two LTCFs (Chicago, IL) of the ANNE One (Sibel Inc.), an Food and Drug Administration (FDA)-cleared physiological monitoring system (Figure 1A), consisting of two medical-grade silicone patches. A chest sensor is positioned at the suprasternal notch by biocompatible, conductive adhesive, while the second is wrapped around the index finger. The chest unit has a 1-lead electrocardiogram, 3-axis accelerometer, and temperature sensor, capturing continuous heart rate (HR), respiratory rate (RR), chest wall movement, snoring, respiratory sounds, seismocardiography, body position, and temperature.[7] The ANNE limb sensor has a photoplethysmograph, and temperature sensor, capturing pulse oxygenation, HR, perfusion index, and peripheral arterial tonometry. The two units are time-synchronized generating pulse transit time and continuous blood pressure.[8] Sensors record data and automatically download it to the cloud and tablet via encrypted Bluetooth.[7]

Patients with active skin conditions, major psychiatric disorders, or inability to consent were excluded. LTCF staff were virtually trained and applied the system to patients, after virtual consent. Participants wore sensors for up to 14 days and completed questionnaires regarding comfort and usability. Skin was evaluated for injury after sensor removal. Patient demographics, HR, RR, pulse oxygenation, cough count, position, and snoring were collected. Advarra Institutional Review Board (STU00213706) approved the trial.

RESULTS

Twenty-two patients (median age 84 years old; 65–95 years) enrolled between January 27 and May 13, 2021. Hypertensive (66%) and neurocognitive disorders (55%) were common. Eighty-seven gigabytes of data were collected from 2738 monitoring hours. Participants completed an average of six sessions (131 total sessions, averaging 161 h or ~ 6 days per participant). Figure 1B demonstrates the system's outputs. Patient and population-level summary statistics are generated, including HR, RR, SpO_2, blood pressure, snoring, cough, and fall events. No adverse events or data transfer failures occurred. Overall, 45% of participants reported remote monitoring made them feel safer, while 61% felt it provided helpful information for their physicians. A total of 55% described sensor use as easy or very easy, with 61% preferring the ANNE One system to wired hospital monitors.

DISCUSSION

We demonstrated feasibility, safety, and acceptability of remote monitoring of medically complex, residential

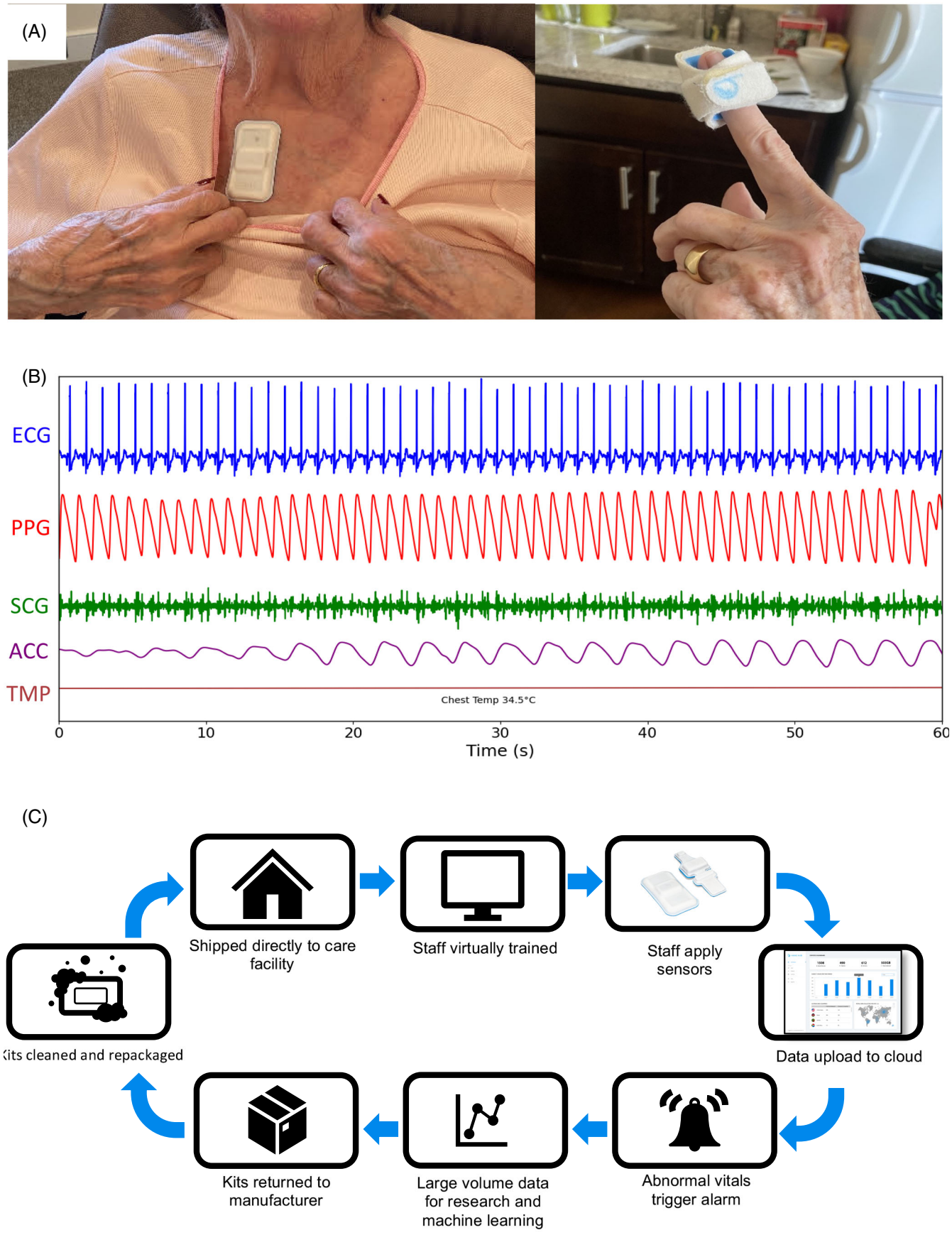

FIGURE 1 The ANNE sensor system is shown deployed on an older adult LTCF resident (A). In panel (B), the data outputs in a 60-second snapshot are shown with continuous 1-lead ECG for heart rate and respiratory rate), photoplethysmograph (PPG) for SpO2, seismocardiograph (SCG) for heart sounds and respiratory sounds, accelerometry (ACC) for motion, and temperature (TMP). (C) Scalable model for remote deployment of an advanced wireless continuous monitoring system for LTCFs during pandemic situations

older adults with low profile, bio-integrated wearable sensors. Though nearly 70% of participants were 80 years or older with multiple comorbidities, the system was correctly applied over 100 times by LTCF staff without injury or device failure. The design, deployment, and validation of remote monitoring systems intended for older adults should consider age, comorbidities, cognitive decline, limited mobility, skin fragility, and low technical literacy.[9] The sensor system presented here addresses many of these challenges. Figure 1C illustrates the model for sustainable and scalable programs for remote staff training and patient onboarding with automatic transmission of real-time data for healthcare decision-making at both the patient and population level. The ergonomic, waterproof, and wireless design is unobtrusive providing continuous, Intensive care unit (ICU)-grade vital sign monitoring without interrupting sleep or requiring confinement to bed or bulky bases, minimizing fall risk, disorientation, and delirium. Elderly skin is 50% thinner with increased vulnerability to shear or frictional injuries and slower healing. There were no skin injuries as a result of the hydrogel adhesives—prior work using the sensors in premature neonates demonstrated similar safety profiles.[10] This study is not without limitations. It was a small pilot at two different urban LTCFs. Therefore, our findings may not be generalizable. Conventional consumer wearables may not provide relevant biomarkers with sufficient accuracy to achieve disease prevention and surveillance. We demonstrate successful deployment of the ANNE ecosystem with a contactless trial design, virtual training, and device reusability cumulatively suggesting a viable path for scalable, sustainable distribution in LTCFs.

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CONFLICT OF INTEREST

Jessica R. Walter: Spouse with equity interest in company commercializing technology. Dong-hyun Kim, BS, Jong Yoon Lee, Elena Kulikova: Sibel Health employees have interest in the company commercializing technology. Shuai Xu: Equity interest in company commercializing technology. Royalty interest in patents associated with technology.

AUTHOR CONTRIBUTIONS

Jessica R. Walter, Jong Yoon Lee, Dong-hyun Kim, Elena Kulikova, Brooke Snoll, Marc Hill, Lily Nguyen, and Shuai Xu contributed directly to project conception, material preparation, manuscript and figure generation and editing, and data analysis. Katherine Fagan and Raclyn Cauinian assisted with participant recruitment and study support. All authors contributed to editing of the manuscript.

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Jessica R. Walter and Dong-hyun Kim shared first authorship.

[Correction added after first online publication on February 14, 2022. Degree for Mark Shapiro has been changed to PhD.]

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COMMENTS

Leukocytoclastic vasculitis in possible relation to the BNT162b2 mRNA COVID-19 vaccine

Mr. Editor:

Older people have been the most affected by the disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) being the first ones to be vaccinated. In Spain, the vaccines used in the older population were the mRNA BNT162b2 (Pfizer/BioNTech) and the mRNA-1273 (Moderna).[1] By the end of October 2021, a total of 46,573 vaccine-related adverse events had been reported by the Spanish Pharmacovigilance System for Medicinal Products for Human Use. Of these adverse events, 9430 were considered serious, and 4574 occurred in people older than 65 years old.[2] The most reported adverse events after administration of the mRNA BNT162b2 SARS-CoV-2 vaccine were fever (35%), headache (25%), myalgia (18%), injection site pain (12%), weakness (12%), fatigue (8%), nausea (7%), shivering (7%), lymphadenopathy (7%), and asthenia (7%).

We present the case of a 91-year-old woman, who was admitted to the hospital for the study of palpable purpuric lesions, predominantly on the lower limbs (Figure 1A). She had a relevant pathological history of moderate dementia, hypertension, and diabetes mellitus. No previous history of autoimmune diseases or introduction of new drugs for chronic use was found. He had received two doses of BNT162b2 mRNA COVID-19 vaccine (Pfizer/BioNTech). The appearance of the lesions began 4 days after the last inoculation of the vaccine. The lesions were biopsied and found to be compatible with leukocytoclastic vasculitis. Accordingly, management with oral prednisone at a dose of 0.5 mg/kg/day, for 1 month, was indicated, with subsequent resolution of the lesions, and no recurrences until today (Figure 1B,C,D).

To make a differential diagnosis, autoimmunity tests were performed with negative results (notably negative rheumatoid factor and negative antinuclear antibodies). In regards to malignancy, she did not have constitutional symptoms or signs of hematological disease. A chest and abdominal computed tomography was performed, which ruled out lesions. In regards to infection, the patient did not have fever during the hospital stay, and normal liver function tests, negative blood culture, negative urine culture, and echocardiography without evidence of vegetations were found. Other diagnostic possibilities such as idiopathic thrombocytopenic purpura and disseminated intravascular coagulation were also ruled out.