Integrating a Telemonitoring Device into the Outpatient Management of Adult Patients with AML

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Management of AML

- AML patients receive intensive chemotherapy to achieve disease remission
- Preemptive hospitalization until blood count recovery to avoid infections/bleeding
- ~3–4 wks of hospitalization
- Oral prophylactic antimicrobials & transfusion support of outpatients
- Increasing shift from inpatient to outpatient settings
Inpatient costs driven primarily by length of hospital stay

In a study reviewing Medicare claims for 2,657 patients with AML

- Hospital reimbursement (84% of costs)
- Physician payments (7% of costs)
- Outpatient hospital/clinic payments (4% of costs)
- Home health care payments (2% of costs).

A longitudinal study on 275 older adults with AML treated at 28 U.S. hospitals from 2000–2003 showed that these patients incurred substantial hospital charges ~$145,000 for a mean length of stay of 23 days.

Shift to Outpatient Management for AML

- Potential harm with prolonged hospitalization after induction chemo.

- Current approach of “preemptive” hospitalization is
  - Medically unjustified
  - Economically more burdensome
  - Adversely affects health-related QOL
  - Prolonged hospitalizations → Decreased ability to resume independent functioning after discharge, → Significant productivity losses and costs due to morbidity

- Increasing attention to costs → desire to change management of AML from the inpatient to the outpatient setting.

- Coincided with improvements in supportive care to accomplish this goal.
  - Deliver transfusions in the OP setting
  - New, oral, broad-spectrum antimicrobials with high activity against organisms such as *Pseudomonas sp* and *Aspergillus sp*

Shift to Outpatient Management for AML

- Benefits of this shift:
  - Reduced need for medical resources
  - Improved QOL
  - Less nosocomial infections
  - Lower cost

- Increasing evidence indicates: Select AML patients undergoing intensive chemo can be discharged early & followed closely in a well-equipped and well-staffed OP facility safely and less costly.
Few retrospective and non–controlled prospective studies have investigated whether selected patients could be safely discharged after completion of induction chemotherapy for AML/MDS.

In 1995, Ruiz–Argüelles et al.

- Selected 24 patients
- (“7+3”)
- Discharged from 3 institutions in Mexico after completion of chemotherapy: no fevers, good PS.
- Rehospitalizations for infections in 7 pts
- No fatalities occurred
- OP management saved ~$2,600 per patient.

1 year later, Gillis et al. reported in a prospective study

- 29 AML patients
- Received a total of 86 induction or consolidation courses at Hadassah University Medical Center in Jerusalem, Israel.
- 50/86 TM cycles, patients could be discharged early and followed as outpatients.
- OP management was feasible 4/33 induction cycles, 46/53 consolidation cycles
- Unselected patients → an early discharge policy might be difficult to implement.

Exploration of OP Management Strategies

- Retrospective analysis between 1996 and 1998 in Toronto, Canada
- 19 AML patients that received induction chemotherapy with 7+3.
- 10/19 patients were discharged with 10 days
- All but one required readmission principally for episodes of neutropenic fever
- No fatalities
- 30% fewer in-hospital days than inpatient controls
- 57% fewer days of inpatient antibiotic therapy, while transfusion requirements were comparable.

Canadian prospective study between 2001 and 2002 at the Vancouver General Hospital and B.C. Cancer Agency:

- 70 AML after induction chemo.

Eligibility:

- Absence of fever
- Use of prophylactic antimicrobials
- Hemodynamic stability
- Resolution of coagulopathy
- Absence of serious comorbidities
- Accommodation with 60 min of treatment center
- Availability of suitable caregiver.

Patients were discharged after 25 / 71 induction therapy courses

9 patients required readmissions for neutropenic fever, and no fatalities occurred.

Study conducted at the National University Hospital in Copenhagen, Denmark, between 2004 and 2007
- 60 patients with acute leukemia (50 of which with AML)
- Eligibility: 120 km radius from the hospital, caregiver at night
- 48/73 induction or re-induction courses, patients were discharged after completion of chemo
- No readmission after 19 of these.
- A median of 8 and 6 days were spent at home with an absolute neutrophil count of $0.5 \times 10^9$/L and a platelet count $< 20 \times 10^9$/L.
- Readmissions were primarily for neutropenic fevers, no fatalities were observed.

Exploration of OP Management Strategies

- FHCRC pilot study to explore discharge of adult AML patients once induction chemotherapy was completed.
  - Included patients: Aged 18–60 Y, non APL– AML/ high grade MDS
  - Screened for medical criteria:
    - ECOG performance status of 0–1
    - Adequate liver, kidney, and cardiac function
    - No intravenous antimicrobial therapy
    - No active bleeding
    - No refractoriness to platelet transfusions.
  - Screened for logistic criteria:
    - Agreeable to close OP follow-up
    - Reliable caregiver
    - Residency within 30 minutes.

Patients who met the medical but not the logistic criteria served as inpatient controls and remained hospitalized until count recovery.

Patients were discharged on antimicrobial prophylaxis that was continued until the absolute neutrophil count (ANC) was $>500$.

Patients were seen by an outpatient oncology nurse 3x/week, and by a physician weekly.

To determine resource utilization and estimate cost, pertinent information was collected from medical records and electronic billing information (to capture professional and facility charges).

Since previous data from our center suggested an induction mortality rate of 5% in preemptively hospitalized patients receiving induction chemotherapy, the study was monitored to ensure that the rate of death on study did not exceed 5%.
April 2009 and April 2010, 39 patients. 19/39 patients did not meet medical early discharge criteria after completion of chemotherapy and were taken off study. 5/20 medically eligible patients did not meet logistic discharge criteria and remained hospitalized (controls; all 5 patients did not have permanent or temporary local housing) 15 met both medical & logistic criteria and were discharged after completion of chemo. 13/15 patients who were discharged early required readmission prior to count recovery With 6 patients being readmitted twice while on protocol. Causes for readmission were neutropenic fever (n=16), bleeding (n=2) and nausea/vomiting (n=1).
The patients who were discharged early spent a median of 8 days (range, 3–36 days) as outpatients over a median of 2 outpatient periods (range, 1–3).

The median total number of days spent in the hospital was 6 (range 0–28); in other words, patients who were discharged early spent a median of 53.8% (range, 28.6–100%) of the time from discharge until removal from study as outpatients. In contrast, the 5 inpatient controls patients were hospitalized for a median of 21 days (range, 10–21; p < 0.01 compared to patients discharged early) after completion of chemotherapy before removal from protocol.

No patient required intensive care unit (ICU)-level care, and no deaths occurred in either group.

Despite the small sample, the median daily total professional and facility charges were significantly lower for patients discharged early compared to inpatient controls over the study period ($3,270 vs. $5,467, p=0.01).

Daily charges per inpatient day were relatively similar between these 2 groups (p=0.40), suggesting that charges are not substantially higher if readmission is necessary.
A follow phase 2 study was conducted over 2 yrs, abstract presented at ASH 2013.
- 107 patients
- 18–75Y with high-risk MDS /AML
- 60 min radius.

Safety was monitored with early stopping if the early death rate was >7% in the ED group, with a predefined interim analysis after 30 patients.

- 27 did not meet criteria ➔ taken off study
- 18 met medical but not logistic criteria ➔ inpatient controls
- 60 early discharges.

- 3 deaths occurred in the ED group during the study period:
  - 2 of sepsis
  - 1 fungal sinusitis
A median number of 1 (1–3) readmission occurred in 53 of these patients, primarily for neutropenic fever
- 8 patients were readmitted twice
- 3 patients were readmitted 3 times prior to coming off study.

ED patients spent a total of 62.7% of the study time as outpatients.

Duration of IV antibiotics was similar in ED and control patients as was number of red blood cell transfusions. ED patients required fewer platelet transfusions.

Six patients in the ED group required between 1–6 days of intensive care unit (ICU) care versus none in the control group.

The median daily charges were significantly lower for patients discharged early compared to inpatient controls ($3871 vs $6283) over the study period.

In contrast, the daily charges per inpatient day were not significantly higher in the ED vs. control group.
Telemonitoring in HF Patients

- SR & Meta-Analysis of 30 RCTs (N = 10,193 patients) that examined:
  - Telephone support
  - Telemonitoring
  - Video monitoring
  - Electrocardiographic monitoring for HF patients

- Comprehensive search of the following databases
  - MEDLINE
  - EMBASE
  - CINAHL
  - The Cochrane Library.

- Studies were included if they reported
  - The primary outcome of mortality
  - Secondary outcomes: all-cause hospitalization and heart failure hospitalization.

- Compared to usual care, structured telephone support was found to reduce the odds of mortality (Odds Ratio 0.80; 95% CI [0.66 to 0.96]) and hospitalizations due to heart failure (0.69; [0.56 to 0.85]).

- Telemonitoring was also found to reduce the odds of mortality (0.53; [0.36 to 0.80]) and reduce hospitalizations related to heart failure (0.64; [0.39 to 0.95]) compared to usual post-discharge care.

Kotb A, Cameron C, Hsieh S, Wells G; Comparative Effectiveness of Different Forms of Telemedicine for Individuals with Heart Failure (HF): A Systematic Review and Network Meta-Analysis; 2015 Feb 25;10(2):e0118681
74 patients were enrolled in a Home Based Telemedicine group and 94 patients in the Usual Care group.

At baseline and at the end of the study, patients in both groups were seen in a cardiology office.

Patients in Home Based Telemedicine group additionally were followed by a physician–nurse, through scheduled and unscheduled telephone appointments.

These patients also received a BP measuring device that could transmit the readings to a central data monitor via secure data connection.

**Results:**
- Study period (80±25 days), a total of 17401BP readings
- 236±136 readings per patient
- Mean daily measurement of 3±1.7.
- Scheduled telephone contacts (initiated by the nurse) equaled to 5.2±4.3/patient (370 in total)
- Unscheduled telephone contacts (initiated by the patients) were 0.4 ± 0.9/patient (30 in total).
- Mean SBP values decreased from 153±19 mmHg to 130±15 mmHg at the end of the study
- DBP decreased from 89±10 mmHg to 76±11 mmHg
- In the Usual Care group, the mean SBP values decreased from 156±16 mmHg to 149±17 mmHg at the end of the study and DBP values decreased from 90±8 mmHg to 86±9 mmHg

Structured physician–nurse approach supported by remote telemonitoring of BP is likely to improve outcome in patients with uncontrolled hypertension.

RCT including patients 65 or older with COPD in GOLD stages II and III enrolled in a Pulmonary Medicine OP facility.

Patients were randomly assigned to receive a non-invasive system able to telemonitor vital signs vs Standard care:

- Oxygen saturation
- Heart rate
- Near-body temperature

Followed up for 9 months

The outcome measures were:

- Number of exacerbations
- Exacerbation-related hospitalization

50 in study vs 49 in the control group

Incidence rate of respiratory events was 28/100 person/years in the telemonitoring group vs. 42/100 person/years in the control group.

Hospital admissions where 13/100 person/years and 20/100 person/years

Lower rate of exacerbations and COPD-related hospitalizations compared to patients followed up using the standard model of care.

Integrating a Telemonitoring Device into the Outpatient Management of Adult Patients Following Intensive Chemotherapy for MDS and Non–APL AML: A Randomized Pilot Study
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Equipping patients with personalized electronic in-home monitoring devices may facilitate the care of these vulnerable patients providing:

- Simple way of recording & transmitting VS
- Identifying concerning symptoms
- Alerting providers with relevant data
- Allow quick responses
- Efficient, timely interventions
The Telemonitor

- iHealthHome (iHH) is a telemonitoring device:
  - Interactive capabilities that records biometric data
  - Guides decision-making regarding management of specific symptoms
  - Encrypted data transmission
  - Remote patient monitoring
  - Early symptom directed care interventions
iHealthHome

- Medicine Dispenser
- Door Sensor
- Weight Scale
- Motion Sensor
- Blood Pressure Cuff
- Glucometer
Features of iHH device

- Records VS as frequently as desired
- Uses Bluetooth medical devices which automatically communicate with the iHH touchscreen hub.
- Hub logs data → the encrypted data → iHH remote server → information viewable by care providers in near real time.
- Medication tolerance and compliance via shared electronic documentation system for the patient & family caregivers, viewable by the providers.
- Patients can:
  - Log personal observations & keep a journal
  - Respond to frequent questionnaires and surveys
  - Communicate with the care providers electronically
Features of iHH device

- Access to individualized educational material in various audio-visual formats
- Care providers can select the materials relevant to patient’s condition and “publish” to patient’s device
- “Virtual visits” via video chat/ Minimize travel to clinic for routine visits.
- Enables after-hours and weekend consultations for on-call staff. (Not intended to be an EMS)
- Caregiver support resources such as video education, etc., that can be “published” to the touchscreen to support family members with symptom identification & care management in collaboration with professional medical providers.
- Provider accessibility via any mobile device
iHH Software Platform
Data Security – Administrative Safeguards

- Access Authorization
- Log-in Monitoring – central logs are kept of log-ins, the originating IP address and which system was accessed.
- Unique User Identification
- Password Management
- Automatic Log Off
- Encryption/Decryption
- Data Back Up (Encrypted)
  - Full backup once a week
  - Incremental backup daily
  - Verified quarterly
  - Stored at a secure datacenter
  - Back up data is archived and kept for a minimum of 3 years and then securely destroyed.
Data Security – Physical Safeguards

- Data Center Facilities
  - Secure facility on secured servers
  - Audited annually for HIPAA Security & SAS 70 standards.
  - Authorized personnel only.
  - Manned 24/7 with trained security professionals.
Objectives

**Primary Objective**

- Feasibility of home telemonitoring for adult patients following intensive consolidation chemotherapy for MDS or non-APL AML.

**Secondary Objectives**

- Estimate the impact of the telemonitoring intervention on “health care resource utilization:
  - Duration of hospital stay
  - Use of emergency services
  - Visits to primary care physicians and specialists
  - Home visits
  - Telephone calls
- Evaluate the telemonitoring procedure in economic terms compared to usual care through a cost-effectiveness analysis.
- Estimate the impact on the quality of life of study participants.
- Assess the degree of satisfaction of the patients/caregivers and health care professionals with the telemonitoring intervention.
Patient Eligibility

- Age: 18–75 years.
- Diagnosis of MDS or AML other than APL with t(15;17)(q22;q12), (PML/RAR), or variants according to the 2008 WHO classification.
- Currently undergoing AML-like intensive consolidation chemotherapy, or planned to start such therapy within 1 week.
- Willingness to have close follow-up and treatment at the Clinic at the Seattle Cancer Care Alliance (SCCA) or at a local facility; patient will be seen at least 3 times per week, including at least once weekly in the SCCA.
- Permanent or temporary housing available within a 60 min commute from the SCCA.
- Available caregiver.
- Availability of data service coverage in their residential area.
- Willingness and ability to use the telemonitoring device.
- Provision of written informed consent.
Treatment Plan

- Pilot study: Enroll 40 subjects aged 18–75 years undergoing intensive consolidation chemotherapy for MDS or non-APL AML.
- Randomized in a 1:1 fashion to either:
  - Standard outpatient supportive care (control arm) OR
  - Standard outpatient supportive care plus use of the iHH device (intervention arm) for the duration of chemotherapy-induced cytopenia.
- No more than 2 individuals will be equipped with iHH telemonitoring devices and followed at any given time.

- Staff members from iHH will:
  - Assist with the installation/de-installation
  - Provide training to the patient and family member help with trouble-shooting
  - Provide free temporary wireless internet if no broadband internet connection is already available

- iHH has a Seattle office with trained staff members and a technical support service that is available 24/7
  - Ph: 1–800–683–4449
  - Email: info@ihealthhome.net.

- Device delivery within 48 hours post discharge.
- Next day follow-up to ensure internet connectivity.
- Ensure patient/caregiver comfort with the device and the parameters of monitoring.
- Trial run with patient taking a set of VS using the iHH.
- Track patient status through the duration of neutropenia (~3–4 wks)
Data Recording & Transmission

- 3 times/day transfer of the VS.
- Daily data check & sync-up with patient by the study team on weekdays.
- PRN telephone contacts if abnormal data.
- When the measurements fall outside the established limits, alerts will be triggered via the PDA terminal, & the study team will respond according to the medical condition of the patient.
- Patients will be informed to not rely on such triggered responses (no 24/7 staffing available)
- Advised to call the clinic nurse or physician on call as per institutional policies.
Questionnaires

- Patients will be asked to complete a set of brief questionnaires aimed at:
  - Assessing the patient's perception of his/her medical and functional condition
  - Satisfaction with the use of the telemonitoring device.
Patient Compliance & Device Reliability

- Patient compliance evaluated via frequency of data transmission.
- Provider compliance evaluated via the number of times they access the telemonitoring Web platform.
- Electronic monitoring to tell us which programs (teaching videos for dressing changes, fever guidelines, etc.) are used by patients and caregivers at home.
- Reliability, performance and security of the system will be assessed such as:
  - Malfunctions of the system
  - Problems concerning the transfer
  - Problems with reception and visualization of data
  - external attacks to the transmission system or server
Design & Goals

- Single-center randomized pilot study
- Assess the logistics and challenges of telemedicine using distance technology and nurse coaching by phone
- Estimating:
  - Proportion of patients who are willing to use the in-home telemonitoring device
  - Success of data transmission
  - Researchers’ ability to use the transmitted data to make timely interventions
  - Patient/caregiver satisfaction
  - Impact on healthcare resource utilization
- This trial is not powered to detect statistically significant differences between the study arms for these clinically important endpoints. Rather, the primary goal is to estimate outcomes in the 2 arms to inform a subsequent larger study, should follow-up investigations appear warranted.
- Patient considered evaluable if the device was used for at least 10 days