OPeRA-HF study design (Monitoring Arm): an **O**bservational study to assess and **Pre**dict the in-patient course, risk of **R**e-**A**dmission and mortality for patients hospitalised for or with **H**eart **F**ailure

A. Shoaib[1], K.M. Goode[2], A. Crundall-Goode[1], G. Geleijnse[3], J.J.G. de Vries[3], E. Robson[1], K. Dobbs[1], K. Wong[1], A.L. Clark[1], J.G. Cleland[1]

(1) Centre for Cardiovascular and Metabolic Research, Hull York Medical School, Hull, UK; (2) Faculty of Health & Social Care, University of Hull, Hull, UK; (3) Philips Research, Eindhoven, The Netherlands

Background:

Heart failure (HF) is a common reason for hospital admission especially amongst older people. Despite the proven success of treatment, many patients with a diagnosis of HF do not receive optimal management to improve their quality of life and prognosis. Mortality rates in patients with HF due to left ventricular systolic dysfunction are substantially reduced by key medical treatments such as ACE-inhibitors, ARBs, beta-blockers, and MRAs; but is uncertain whether other groups of patients benefit.

A National Audit of HF conducted in England & Wales (2011) showed that patients cared for by cardiologists had a better survival but greater length of hospital stay compared to those receiving non-specialist care. This could reflect more time spent on diagnosis and implementing evidence-based treatment before discharge. Recent analyses of large clinical trials (e.g. ASCEND) suggests that longer lengths of stay are associated with a lower rate of re-admission and a reduction in bed-days occupancy in the 6 months after admission.

Few data exist on the most efficient and effective means of monitoring the in-patient course of patients with HF and deciding on the optimal time for discharge.

PANEL A: Study aims (Monitoring arm)

1. Develop objective methods to assess readiness for and barriers to discharge.
2. Identify barriers to discharge within seven days (a feasible target for many patients)
3. Check adherence to relevant management guidelines (NICE and ESC)
4. Asses feasibility and utility of discharge criteria published by expert groups (e.g. Pang et al., Eur Heart J, 2008; Gheorghiade et al. Eur Heart J, 2010).
5. Evaluate contribution of monitoring to predicting early re-admission and death

Study Design:

This is an observational study. Patients with HF will be enrolled during their hospital admission (current median duration 10 days in UK). Demographic, clinical and psychosocial data will be collected during the admission. The overall study consists of two components (1) in-patient monitoring (the focus of this poster) which is nested within (2) a risk stratification.

The study aims are shown in ***Panel A*** and the inclusion and exclusion criteria in ***Panel B***.

Study methods:

Data Collection:

Patients will first be enrolled into the Risk Stratification arm of this study in the post-acute phase of their care, generally 3-7 day after admission. Data will be collected at enrolment and on or close to the day of discharge according to the Risk Stratification arm schedule (see Risk Stratification poster).

If they also meet the inclusion and exclusion criteria as set out in ***Panel B*** and consent to this study arm, then they will follow a more intensive monitoring schedule as set out in ***Table 1***. Clinicians will have access to monitoring data, which may be used to guide treatment. Patient written consent will be obtained by a doctor or research nurse. Ethics approval was sought and granted in October 2012.

Patient follow-up:

Subsequent to discharge, further clinical information will be collected from routine hospital clinic visits, community HF nurses and the patients' general practitioners. No additional patient visits or tests are required during follow-up. All deaths and hospitalisations will be recorded.

Patients will be followed according to their consultant's instructions. They may be discharged back to their General Practitioner or followed up in a medical, cardiology or HF clinic. Follow up will be for up to ten years after the last patient is enrolled.

Measurement	Frequency
Symptom severity	Daily
New medical problem *(e.g. haemorrhage, infection, stroke, pulmonary embolism, etc)*	Daily
Oedema severity	Daily
Orthopnoea Testing	Daily
Blood pressure (lying & standing)	Daily
Heart rate & rhythm	Daily
Weight (bio-impedance scales)	Daily
50m walk test (+/- bio-impedance vest)	Daily when able
Biochemistry profile	When done
Haematology profile	When done
NT-proBNP	Day of discharge
Medication	Daily
Investigators rating of stability	Daily
Expected date of discharge	Daily
Bio-impedance (NICAS)	Daily
Finger photoplethysmography (Nexfin)	Daily
Research blood sample	Day of discharge
HF knowledge questionnaire	Day of discharge
Hospital anxiety & depression scale	Day of discharge

Table 1: Monitoring arm measurement schedule

PANEL B:

Risk Stratification Arm

Inclusion criteria for Risk Stratification Arm:

(a) Age > 18 years; (b)Hospitalised (any reason)

(b) Usual residence is in the catchment region for Hull & East Yorkshire Hospitals NHS Trust

(c) Either treated with loop diuretics or with a clinical diagnosis of HF

(d) Willing and able to consent and comply with the risk stratification protocol.

Monitoring Arm

Inclusion criteria for Monitoring Arm:

- Heart failure as a dominant diagnosis;
  Meaning that there is objective evidence of cardiac dysfunction as evidenced by a least ONE of the following:
  a. left ventricular ejection fraction ≤ 40%
  b. left atrial dimension >4.0 cm (or >2.5 cm/m in height)
  c. NT-proBNP > 400 pg/ml (BNP >150 pg/ml) if in sinus rhythm OR >1,200 pg/ml (BNP >450pg/ml) if in atrial fibrillation

Exclusion criteria for Monitoring Arm:

- Diagnosis other than heart failure likely to dictate duration of admission
- Patients with infective endocarditis, major stroke disability or major cognitive impairment

Conclusion:

This study will be one of the first to make a holistic assessment of patients admitted with worsening HF, the time-course of their response to conventional treatments, the criteria for readiness for discharge and their relationships to outcome.

This study is funded by Philips with additional funding from Hull City Health Care Partnership.

PHILIPS

University of Hull

HYMS The Hull York Medical School

NHS City Health Care Partnership CIC a co-owned business