REDUCING READMISSIONS IN HEART FAILURE PATIENTS THROUGH PHARMACIST-FACILITATED TRANSITION-OF-CARE INTERVENTIONS

A thesis submitted in partial fulfilment

of the requirements for the award of

Doctorate in Pharmacy

Ivan Debono

Department of Pharmacy

University of Malta

2019

Faculty of
Medicine & Surgery
University of Malta
Msida MSD 2080, Malta

Tel: +356 2340 1879/1891/1167
umms@um.edu.mt

www.um.edu.mt/ms

DECLARATION OF AUTHENTICITY FOR DOCTORIAL STUDENTS

Student's I.D. /Code	75170M
Student's Name & Surname	Ivan Debono
Course	Doctorate in Pharmacy
Title of Dissertation/Thesis	

Reducing readmissions in heart failure patients through pharmacist-facilitated transition-of-care interventions

(a) Authenticity of Thesis/Dissertation

I hereby declare that I am the legitimate author of this Dissertation/Thesis and that it is my original work.
No portion of this work has been submitted in support of an application for another degree or qualification of this or any other university or institution of higher education.
I hold the University of Malta harmless against any third-party claims with regard to copyright violation, breach of confidentiality, defamation and any other third-party right infringement.

(b) Research Code of Practice and Ethics Review Procedure

I declare that I have abided by the University's Research Ethics Review Procedures.

✓As a Professional Doctoral student, as per Regulation 54 of the Professional Doctorate Regulations, I accept that my dissertation be made publicly available on the University of Malta Institutional Repository.

_____ _____

IVAN DEBONO Date

Dedicated to my family

Acknowledgements

I would like to thank my supervisor Professor Lilian M Azzopardi and co-supervisor Dr Louise Grech for their invaluable guidance and support throughout the Doctorate in Pharmacy Program. My sincere gratitude goes to Professor Robert G Xuereb, Mrs Charmaine Roberts and all the other cardiologists, doctors and nurses who supported me. It was an honour for me to have had the opportunity to work with a team of dedicated professionals.

I am grateful to the cardiologists who kindly accepted me to attend their ward rounds during the months preceding and throughout the conduction of the study and the focus group members who kindly accepted to offer their time to help me with the development of the transition-of-care pathway. I would also like to thank Professor Liberato Camilleri for helping me with the statistics.

A note of gratitude goes to my friends for their continuous support and encouragement. Finally, I would like to thank my wife Elvie and daughter Mireille, my parents, my sister and my parents-in-law for their love, patience and support throughout my studies.

Abstract

Consistent preventative pharmaceutical care interventions during care transitions with the aim of improving patient outcomes and quality care contribute to a shift towards value-based care. Value-based care may be monitored by assessing readmission rates. The aim of the study was to determine and apply pharmacist interventions during transition-of-care (TOC) to HF patients and study impact on readmission rate.

The study was conducted from 20th June 2018 to 31st January, 2019, in a teaching hospital in Malta. Phase 1 of the study involved a multi-perspective focus group supported with surveys and literature to determine pharmacist interventions for a TOC pathway. Patients suffering from HF who followed the usual TOC (Phase 2) acting as the control group (N=52) were compared to the intervention group (N=27) that followed the TOC pathway (Phase 3). Recruitment involved prospective convenience sampling using eligible criteria. The proposed pathway was validated in the intervention group. The primary outcome was 30-day all-cause unplanned readmission rate. The secondary outcomes were all-cause unplanned readmission rate during the observation period from day 31-60 post-discharge and the number and type of interventions.

The developed proposed pathway followed a ward-based pharmacist model with a case management approach that included medication reconciliation, medication-use education and telephone care management post-discharge. The 30-day all-cause readmission rate of the control group was 30.8% and that of the intervention group was 18.5% (p=0.242). The readmission rate between days 31-60 was 13.5% for the control group and 22.2% (p=0.211) for the intervention group. A total of 284 interventions with a mean of 10.5 per patient were performed as part of the pharmaceutical TOC pathway.

The piloted TOC pathway is a quality improvement composite indicative that pharmacist interventions contributed to a reduced readmission rate of HF patients during the immediate period after discharge. Further consolidated pharmacist interventions are necessary to impact long-term readmission rate. The results obtained remain exploratory and a study on a larger population with a matched control approach is warranted.

Keywords:

Pharmacist interventions; transition-of-care; readmission rate; heart failure

Table of Contents

List of Tables

List of Figures

List of Flowcharts

List of Appendices

List of Abbreviations

ACC	Anti-coagulant clinic
ACE	Angiotensin converting enzyme
ADE	Adverse drug event
AHA	American Heart Association
ARB	Angiotensin receptor antagonist
ARNI	Angiotensin receptor neprilysin inhibitor
BOOST	Better Outcomes for Older adults through Safe Transitions
CHF	Chronic Heart Failure
CHF	Congestive Heart Failure
CI	Confidence interval
CMW	Cardiac Medical Ward
COPD	Chronic obstructive pulmonary disease
CPAP	Continuous positive airway pressure
CPAS	Central Patient Administration System
CPU	Clinical Performance Unit
CRQ	Condition-related question
DifTPT	Difference of two proportions test
DRP	Drug related problems
ED	Emergency Department
FDR	Flexible diuretic regimen
GDMT	Guideline directed medication therapy
GP	General Practitioner

HF	Heart Failure
HFmrEF	Heart failure mid-range ejection fraction
HFpEF	Heart failure preserved ejection fraction
HFrEF	Heart failure reduced ejection fraction
HO	House officer
ICD	International classification of diseases
ISt-test	Independent samples t-test
INR	International normalised ratio
IT	Information technology
MAS	Medicines approval system
MDH	Mater Dei Hospital
ME	Medication error
MTM	Medication therapy management
NTproBNP	N-terminal pro b-type natriuretic peptide
NYHA	New York Heart Association
PC	Pharmaceutical care
PCI	Pharmaceutical care issue
PCNE	Pharmaceutical Care Network Europe
PCP	Primary Care Provider
PFD	Private family doctor
POYC	Pharmacy of your choice
RARE	Reducing Avoidable Readmissions Effectively
RED	Re-Engineered Discharge

RS	Resident specialist
SD	Standard Deviation
SHPA	Society of Hospital Pharmacists of Australia
TAQ	Treatment Adherence Questionnaire
TCM	Telephone care management
TDM	Therapeutic drug monitoring
TOC	Transition-of-care
UM	University of Malta
UREC	University of Malta Research and Ethics Committee
US	United States

1. Introduction

“If you have the courage to start, you have the courage to succeed”

Mel Robbins

Summary

This chapter sets the scene for the rationale of the research. It gives an overview of the concepts involved namely readmissions as an outcome measure, transition-of-care as a critical stage of care, heart failure patients as a cohort with particular needs and the pharmacist's role during care transitions. These are the components that constitute this research. The sections discuss how these concepts intertwine to ultimately effect patient outcomes. This brings to the current approach of combined care models for heart failure that revolve around interventions at the time of transitions-of-care. It is desirable that such models will eventually be implemented in Maltese healthcare and that pharmacists will be key contributors as advocated by the present research.

1.1 Hospital readmissions

Hospital care which involves processes that must align to ensure a quality service can be assessed by the rate of hospital readmissions because it demonstrates the effect of hospital care on the patient's health status after discharge (Bianco *et al,* 2012; Pham *et al,* 2019). On the whole hospital readmissions are a common occurrence, costly and associated with negative health consequences (Kahlon *et al,* 2015; Albert & Estep 2019). Most common cut-off points used by analysts are 30-day, 60-day, 90-day and 1-year readmission starting from the day of discharge.

Hospitals that are subject to financial penalties as a result of readmissions are taking on the role of enablers of quality care during the shift from the hospital setting to the out-patient setting for a period after discharge. This is because it is evident that readmission

as a quality indicator can hold true provided no significant process or pharmacotherapeutic shortcomings take place during the post-discharge phase (Bergethon *et al,* 2016).

As evidenced by literature, 30-day readmissions as a quality measure is disputable for various reasons (Axon & Williams 2011; Burke *et al*, 2013; Joynt & Jha, 2013). Although it may be rational to keep hospitals answerable for health issues that patients live through during the immediate days post discharge, readmissions taking place thereafter may progressively reflect patient self-management, out-patient follow-up services, level of community care, or the occurrence of new health issues that cannot be foreseen by the discharging hospital (Joynt & Jha, 2013; Jepma *et al*, 2019; Pham *et al*, 2019). The pharmacy profession remains at the forefront to establish specific interventions during transition-of-care in order to reduce readmission rates.

1.1.1 All-cause readmission and clinically related readmission

Different approaches to computing readmissions can produce different readmission profiles for the same institution. While less ambiguity may be attained with a clinically linked measure, readmissions unrelated to the original cause of admission may not impact hospital performance (Khouri *et al,* 2017). Comorbidities cause three-fourths of all readmissions in heart failure (HF) patients (Corrao *et al*, 2014). Disease states present with HF make up a greater expense than predominant HF alone (Liao *et al*, 2007). In real world quality-oriented practice patients are treated holistically meaning that clinical and pharmaceutical care issues (PCIs) unrelated to the index admission are addressed. This makes all-cause readmission a very powerful outcome measure.

1.1.2 Preventable versus non-preventable readmissions

The assessment of hospital readmissions is inherently complex by the non-preventable nature of readmissions irrespective of best care and indeed a fraction is foreseeable but not preventable. A hypothetically preventable readmission is one were there was a reasonable expectation that it could have been averted by one or a combination of the following: (1) the delivery of best care in the first admission, (2) appropriate discharge arrangements, (3) appropriate post-discharge ambulatory follow-up, or (4) optimised handoffs between inpatient and outpatient health care providers (Goldfield *et al*, 2008, Polanczyk *et al,* 2001).

1.1.3 Hospital readmissions and pharmaceutical care issues

One aspect in which the pharmacy profession is ethically and professionally obliged to contribute is the prevention of readmissions or potentially avoidable admissions attributable to PCIs including drug-related problems (DRPs) as a result of shortcomings during hospitalisation, at discharge and during the post-discharge phase.

A DRP is defined as "*an event or circumstance involving drug therapy that actually or potentially interferes with desired health outcomes*" (Strand *et al,* 1990; Westerlund & Marklund, 2009). DRP is a term that encompasses the occurrence of an adverse drug event (ADE) or a medication error (ME). While to some extent the likelihood of an adverse drug event occurring can be outweighed by the benefits of the drug, an ME is an unwanted occurrence.

The National Coordinating Council for Medication Error Reporting and Prevention states that the consequences of DRPs are increased hospitalisations, an increased hospital length of stay, lower patient satisfaction, and an upward cost of patient care. The avoidance of DRPs helps not only to improve patient's clinical outcomes, but also to curtail treatment expenses (Alghamdy *et al,* 2015).

In a recent systematic review by Suggett and Marriott, (2016), the ten risk factors most recurrently associated with DRPs were identified indicating those patients at risk of DRPs and subsequently at risk of unplanned readmissions. The use of drugs with high impact on physiology, polypharmacy, age, renal function, gender, multiple disease states, length of hospitalisation, history of hypersensitivity, adherence issues and hepato-function are factors that can give rise to DRPs especially if affecting the patient in combination (Suggett and Marriott, 2016).

1.2 Heart failure patients: a cohort at an increased risk

A category of patients who are particularly predisposed to readmissions and drug-related problems are HF patients because often they are burdened by a combination of factors.

HF is a high incidence disease associated with significant reduction in quality of life, death and cost for both the healthcare system, the patient and family. Around 1.8% (5.8 million) of Americans suffers HF with an incidence exceeding 650,000 cases newly diagnosed yearly. HF accounts for roughly $37 billion in healthcare spending each year

in the United States (Moye *et al*, 2018). Patients with HF make up a significant fraction of 30-day all-cause readmissions (Bradley *et al*, 2013).

The prevalence in Europe is 1-2% on average (Cowie, escardio.org [internet] 2015) meaning that an estimate for Malta would be around 8000 taking the higher end of the spectrum. According to Cowie the cost of heart failure is driven by hospitalisation which accounts for 60% of the cost while drugs account for 9% of the cost. This coupled with the significant readmission rate highlights the importance of addressing the latter for the benefit of both the patient and the healthcare system.

1.2.1 Heart failure readmissions over time and mortality

Addressing readmissions in this category of patients is important as studies have shown that the mortality rate after 30 days and 1-year post discharge can be as high as 12% to 23% respectively (Krumholz *et al*, 2014; Loehr *et al*, 2008). In a study conducted between 2009 and 2012 heart failure was the condition that experienced a slight increase in mortality post discharge as opposed to acute myocardial infarction which decreased and pneumonia which remained stable (Ranasinghe *et al*, 2014, Suter *et al*, 2014).

1.2.2 Causes of heart failure readmissions

In a review published in 2019 both clinical and socioeconomic factors were confirmed as causes of HF readmissions with health attitude considered a main factor (Su *et al,* 2019). This keeps relevant the consideration of issues like adherence with medications

or diet, inability for early symptom recognition, failure to seek care (Vinson *et al*, 1990) and non-compliance to fluid restriction (Bouvy *et al*, 2003). Other causative factors included inappropriate medication management, DRPs, inadequate discharge arrangements or follow-up and failed community wrap around (Ponniah *et al*, 2007). More than half of close-to-discharge readmissions in elderly patients with HF may be avoidable (Desai *et al*, 2012).

1.2.3 Clinical and non-clinical predictors of heart failure readmissions

Among the clinical predictors of heart failure readmissions are those that no intervention can be done that resolves or at the least appreciably modifies their course. These include age, left ventricular ejection fraction, NYHA class IV symptoms and worsening renal function. Clinical predictors which should be taken into account before the patient is discharged from hospital include anaemia, arrhythmia, depression, diabetes, hyponatremia, problems with respiration, suboptimal HF pharmacotherapy and uncontrolled hypertension (Lesyuk *et al*, 2018, Fonarow *et al*, 2008, Murray *et al,* 2009, Annema *et al*, 2009).

Modifiable non-clinical predictors of HF readmissions mainly manifest themselves once the patient is in the community and these include the inability of the patient to read labels on medication, medication and dietary nonadherence, low readiness for discharge, inconvenient or lack of early follow-up scheduled and fear of symptoms (Tong *et al*, 2018, Hernandez *et al*, 2010, Annema *et al,* 2009, Murray *et al*, 2009; Sevilla-Cazes *et al*, 2018).

1.2.4 Heart failure and medication therapy management

HF is a condition which is heavily dependent on the use of drugs and their appropriate combination for its management (Reed *et al*, 2014; Cobretti *et al*, 2017). A medication therapy management (MTM) approach is warranted in the light of specific medication management requirements in different heart failure types. MTM is crucial for optimising treatment by achieving target doses of guideline directed drugs for HF with reduced EF.

Management of HF symptoms through pharmacotherapy and lifestyle changes is of essence. Specifically, appropriate drug selection, dosing, availability of drugs on the formulary and the market and monitoring are typical domains in which the contribution of the pharmacist makes a difference. MTM clinics receive patients requiring assessment of adherence with medications for HF and probe nonadherence causes.

In a scientific statement by the American Heart Association (Albert *et al*, 2015) it is brought forward that the prevalent themes in a mixed-methods study by Oertle and Bal, (2010) with the goal of assessing nonadherence in HF included, clinical effects related to hypotension or bradycardia and renal impairment; suspicion about treatments and pessimism about symptom improvement; exclusions and errors with medication and dosing; patient factors related to multiple diseases and multiple medications, adherence when multiple dose changes are needed; and failure of proper handoffs from inpatient to outpatient care, especially related to medications.

Patients being discharged exhibiting any of these risk factors or a combination thereof are automatically candidates for close pharmacotherapeutic monitoring during transition of care (TOC) in order to prevent readmissions associated with treatment.

1.3 Transition of care and readmissions

TOC is a critical stage which predisposes patients to drug-related problems, medication safety issues and other PCIs. Specifically, the transition from hospital to the community setting after the patient is discharged is particularly vulnerable. Systematic reviews failed to identify any consistent evidence that specific but solitary interventions result in significant decreases in readmission rates. Multifactorial interventions linking the pre- and post-discharge periods seem to deliver the desired outcomes (Hansen *et al*, 2011; Leppin *et al*, 2014).

Recent evidence suggests the short to medium term hospital transition interventions should prioritise patients according to risk for a readmission by analysis of data while incorporating (a) technology-driven integration, (b) domestic support, (c) specialised transitional care staff, and (d) interventions targeting different stages along the care continuum (Kripalani *et al*, 2014).

In a review by Kripalani *et al,* (2014) various aspects were mentioned in order to come up with a set of interventions intended to reduce readmissions. Kripalani *et al,* (2014) also makes reference to a systematic review by Hansen *et al*, (2011) who categorise broad intervention components and respective subcomponents mainly: inpatient interventions (e.g., medication reconciliation, patient education, discharge planning, appointment scheduling), post-discharge interventions (e.g., follow-up within reasonable timeframes, timely family doctor (PCP) notification, follow-up telephone care management, patient hotline, domestic assistance) and connecting interventions (e.g., transition personnel, individualised discharge training, provider uninterrupted care flow). Kripalani *et al*, (2014) observes that, "*no studies have been published*

regarding the comparative effectiveness of these different approaches and subsequently it is challenging for health systems to know what combination of interventions to deploy". The Ideal Transition in Care is a framework that draws interventions from different approaches into one (Burke *et al*, 2013a; Burke *et al*, 2013b). This is a 10-component framework (Figure 1.1) which encompasses 61 interventions.

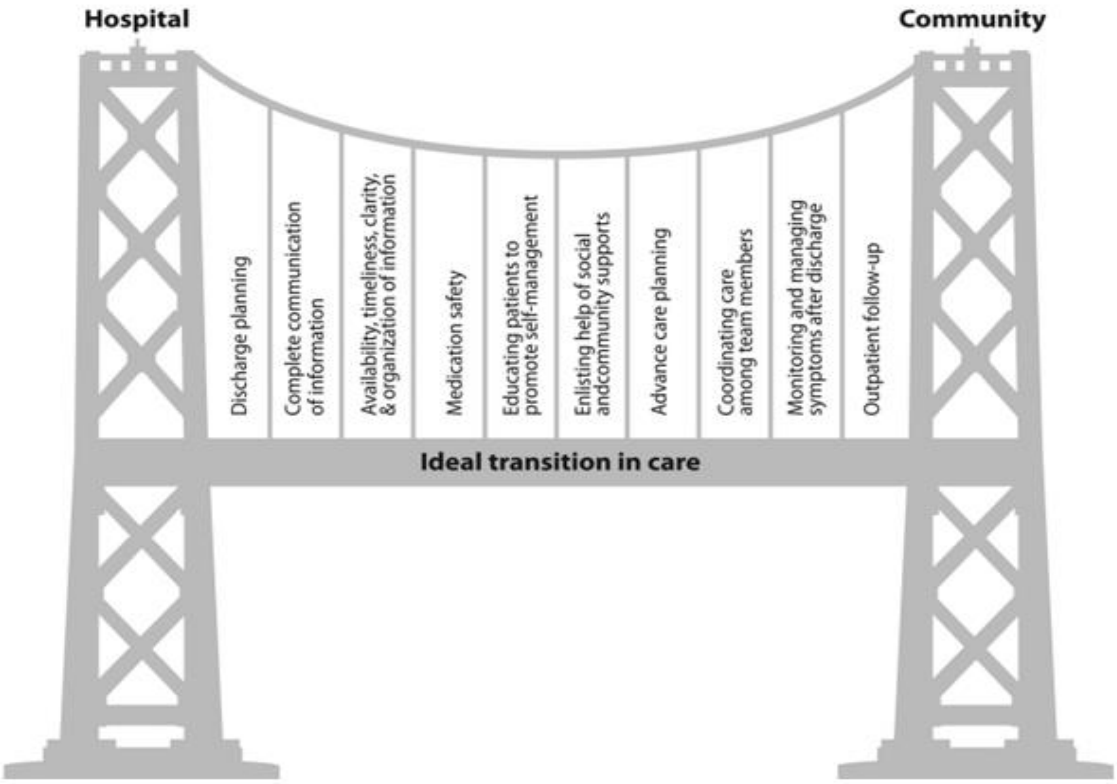


Figure 1.1 Ideal Transition in Care. Adopted from Kripalani S, Theobald CN, Anctil B, Vasilevskis EE. Reducing hospital readmission rates: current strategies and future directions. *Annu Rev Med*. 2014; 65:471–85.

An 'ideal' TOC program can only exist and its application successful if developed keeping the local healthcare scenario in perspective. For this reason, the present research seeks to put together a set of pharmacist-facilitated TOC interventions that can fit our needs as well as bridge the gaps in our service keeping in perspective the ability to be consistent and sustainability. For instance, in our national practice, the introduction of the pharmacy of your choice scheme (POYC) brought about new challenges as well as

opportunities. The positive contribution by pharmacists towards quality and effective transition of care TOC through MTM may be analysed in the local context.

A successful pharmacist-facilitated TOC intervention composite that sees through patients from hospital to a period after discharge and proper transition by concomitantly involving community pharmacists post-discharge, should be the direction taken to improve quality of care with the prospect of reducing unplanned readmissions. Setting the basics of a pharmaceutical care pathway through this intervention composite facilitates future quality improvement and expansion to a standardised multi-component HF program that possibly partners with community pharmacies for effective post-discharge MTM.

1.4 Transition of care and the discharge process

Effective TOC programs have common characteristics namely they are integrated, multidisciplinary and patient-centred (Albert *et al,* 2015). These characteristics manifest above all during the discharge process. Having an adequate discharge plan, the patient meeting pre-discharge stability criteria, use of checklists to ensure care quality and adequate handoffs is imperative (Comin-Colet *et al,* 2016).

1.4.1 Standardised discharge processes

Standardised discharge processes have shown to improve patient outcomes and avoid excessive expenses related to readmissions.

The key components of Project BOOST (Better Outcomes for Older adults through Safe Transitions) undertaken in the United States, includes a comprehensive risk assessment of patients, 3-day follow-up call for risk-prioritised patients, a patient-focused discharge arrangement, use of teach-back, easy to read discharge forms and transfer tools, follow-up appointment arranged during the discharge process and a standardised PCP handoff.

Across sites that adopted Project BOOST the mean readmission rates dropped from 14% to 11%, an outright reduction of 3%. Pre-BOOST versus post-BOOST intervention over six months resulted in a 2% upward readmission rate in the non-BOOST programs. Appreciable patient satisfaction was also recorded. Other encouraging early observations included reduced length of stay, emergency department visits, staff turnover and increased staff satisfaction (icsi.org [internet])[1].

RED (Re-Engineered Discharge) is a bundled program conducted at the Boston Medical Centre between 2003-04. Nurse TOC practitioners approached patients before their discharge, arranged appointments for follow-up with primary care physicians (PCPs), and sent case summaries to PCPs. Pharmacists performed telephone care within four days post-discharge for medication-review and liaison with PCPs in case of problems. This strategy decreased the overall rate of 30-day readmissions and emergency department (ED) utilisation by 30 percent. Total health care expenditure in the 30 days post-discharge decreased by 34 percent ($412 per patient) before factoring intervention-related costs (Dreyer, 2014).

---

[1]Project BOOST - Institute for Clinical Systems Improvement [internet]. Nagamine J. [cited 2018 Oct 6]. Available from: https://www.icsi.org/_asset/x4glet/Boost

The Care Transitions Intervention® established in the US is also known as the CTI® and the Skill Transfer Model®. During a 28-day plan, patients on the higher end of the risk stratum and family caregivers receive particular tools and practice with a Transitions Coach®, to develop self-care skills that will ascertain need-fulfilment during the hospital to domestic transition.

This is a relatively inexpensive, low-intensity proven intervention consisting of a domestic call and three telephone follow-ups (caretransitions.org [internet])[2].

The Guided Care® by Johns Hopkins Medicine is conducted by a 'Guided Care' nurse assigned to long-term or life-long care of a patient and performs domestic assessments, care-coordination, reinforces patient self-care, oversees health status periodically, applies motivational interviewing to boost self-management, makes available education resources, converges health care professional inputs, facilitates transitions along the care continuum, ensures family caregiver education and intervenes to ensure access to community resources (johnshopkinssolutions.com [internet])[3].

---

[2]caretransitions.org [internet]. The care transitions program®. [cited 2018 Oct 6] Available from: https://caretransitions.org/about-the-care-transitions-intervention/

[3]johnshopkinssolutions.com [internet]. Guided Care® by Johns Hopkins Medicine Nurse-based chronic care management. [cited 2018 Oct 6] Available from: https://www.johnshopkinssolutions.com/wp-content/uploads/2018/10/Guided_Care_Overview.pdf

1.5 Models of post-discharge care and readmissions

Takeda et al*,* (2012), classified post-discharge care models in three main categories. The clinic care model where nurses manage HF medications under the responsibility of a physician, the multidisciplinary care model with different services provided by different healthcare members, and the case management model which are basically TOC programs involving post-discharge monitoring. The study by Takeda deduced that compared with usual care, clinic care models did not reduce readmissions and mortality.

Case management reduced mortality beyond 6 months post-discharge, and case management and multidisciplinary care plans improved both pre and post six-month HF readmissions and all-cause readmissions. Vedel *et al,* (2015) classified TOC interventions as low, moderate or high. Low intensity bundled interventions or programs consist of structured telephone care follow-up or consistent clinic follow-up without domestic visits. Moderately intense programs involve home visits, telephone care with outpatient clinic follow-up or telemonitoring interventions. High intensity programs involve home visits as base combined to more than one of follow-up methods namely telemonitoring, clinic visits and telephone care. Reduced mortality was associated with high or moderately intense programs and reduced HF readmissions was associated with both high and low intense programs (Takeda *et al,* 2012).

1.6 TOC, readmissions and the pharmacist

Studies show that doctors and nurses are mostly involved in programs aimed at reducing readmissions. Specifically, reduction of readmission has been shown to take place when

nurses perform medication reconciliation (DiDomenico, 2017). Since pharmaceutical care issues seem to contribute significantly to the readmission rate of patients with HF, roping in pharmacists as part of the interdisciplinary team to focus on medication-related interventions could potentially benefit the institution and improve humanistic and health outcomes. Studies have shown that pharmacists can contribute to improve medication reconciliation, treatment optimisation, patient monitoring, development of disease management programs, adherence to treatment as well as patient education, identification/resolution of risk factors for readmission, direct communication with community doctors and pharmacists, home visit at one week and home based intensive counselling (Ponniah *et al,* 2007; Anderson & Marrs, 2018; Cheng, 2018). As new pharmacotherapy for HF become available, pharmacists can ensure medication safety by identifying potential side effects and drug interactions (Anderson & Marrs, 2018). A range of outcomes was reported in studies including increased adherence, increased exercise capacity, reduction in readmissions in general and specific to HF patients, reduction in clinical events, mortality, in-patient length of stay and reduced expenses (Bouvy *et al*, 2003, Ponniah *et al,* 2007, Szkiladz *et al*, 2013; Anderson & Marrs, 2018).

The American College of Clinical Pharmacy (2012) issued a white paper by Hume *et al,* (2012) on pharmacist roles to improve TOC. It is recommended that hospital pharmacists participate in medication reconciliation at TOC, patient and caregiver education, ward-rounds, discharge patient interviews, follow-up on DRPs, assess and address adherence issues, post-discharge follow-up within 2-4 days and collaborate with community pharmacists and doctors. All these activities lay the foundation for optimisation of treatment in line with HF guidelines as well as permit the patient to focus on medication self-management such as a flexible diuretic regimen.

Patients who are in transition between the settings along the care continuum can suffer ADEs when adequate handoffs and care coordination are lacking. With pressure to avoid bed blocking, care transitions are a crucial phase to intensify quality care to avoid readmissions. Pharmacists have skills that can make a positive difference during care transitions in all settings as part of the interdisciplinary providers (American College of Clinical Pharmacy, 2012).

1.7 Pharmaceutical care, TOC, readmissions and HF patients

Pharmaceutical care interventions during TOC targeting reduction in readmissions of HF patients have evolved in recent years. Treatment adherence and the understanding of a flexible diuretic regimen is particularly challenging. Pharmaceutical care programs aiming to educate patients on flexible diuretic therapy integrate lifestyle and self-management monitoring namely fluid restriction, adherence to recommended salt intake and adherence to daily weight monitoring (Moye *et al,* 2018).

The basics of pharmaceutical care such as medication reconciliation and patient education which are generalizable to other disease states should be in place before undertaking such programs. The development of HF pharmaceutical care pathways involving medication dosage titration and adjustment and development of pharmaceutical care tools to predict potentially avoidable readmissions of HF patients by pharmacists follow basic pharmaceutical care. As new medication for HF is incorporated in GDMT, pharmaceutical care through raising awareness of benefits associated with patient outcomes including reduction in readmission rate is warranted.

1.8 The Maltese Setting

Readmissions take place with a negative bearing on bed occupancy, hospital length of stay and delays at the emergency department (ED) leading to substantial financial burden and decreased patient satisfaction. Unpublished 2016 statistics compiled by the Clinical Performance Unit (CPU) at Mater Dei Hospital shows that the total number of patients admitted with heart failure as primary diagnoses was 1468 with an estimated percentage readmission rate of 25%[4].

In Malta, the social security system offers the possibility of elderly patients retiring in a state funded elderly home. Patients with frequent readmissions to the acute hospital setting become candidates for long term care facilities further increasing the financial burden. For this reason, it is of value to analyse and propose ways and means of reducing readmissions.

To date little research in Mater Dei Hospital was conducted related to readmissions and this was confined to reporting rates in particular disease states such as chronic obstructive pulmonary disease in relation to specific predictors. To the knowledge of the researcher no study has been conducted so far with interventions that intend to reduce readmissions.

Hospital quality improvement initiatives with the intention of specifically reducing readmissions are also lacking.

---

[4]Hospital Activity Analysis (HAA) database. Clinical Performance Unit, Mater Dei Hospital 2016.

The main concern of hospital management in recent years was with counteracting bed blocking and a shortage in hospital beds making hospital length of stay the outcome of focus. Addressing the shortage of medications within the POYC scheme might have contributed to reducing readmissions but no concrete data is available to support this statement.

Specific to HF patients, the heart failure clinic at MDH out-patient department follows the clinic care model and was an important quality improvement initiative that also has a bearing on post-discharge pharmaceutical care.

With multifactorial interventions showing to be more successful in reducing readmissions, each profession must be prepared to contribute with evidence-based information which is why this research was undertaken. Despite advances in HF treatment and management, pharmaceutical care is an unmet need during TOC prompting focus for research to develop a pharmaceutical care component that can fit within a wider holistic strategy other than the clinic care model.

For the purpose of the present study the research question to address is what the pharmacist can do in each of the following aspects: process/administrative shortcomings that arise during TOC (Kripalani *et al*, 2007), upgrade patient medication safety at hospital discharge (Hansen *et al*, 2011), strengthen medication reconciliation (Mekonnen *et al,* 2016b), improve handoffs from the inpatient to the outpatient setting (Mekonnen *et al,* 2016a) and keep abreast with cutting edge research that focus on interventions to decrease readmissions (van Seben *et al,* 2016).

1.9 Aim and Objectives

The aim of this research was to develop and apply a set of pharmacist-facilitated transition-of-care interventions directed to HF patients and study the impact of the interventions on reduction of hospital readmissions in this category of patients.

The study sought to address the following objectives:

1. To identify those pharmacist-facilitated interventions applicable in the local scenario during transition-of-care from hospital to community.

2. To determine impact of the pharmacist-facilitated interventions on hospital readmission rate of heart failure patients by comparing an intervention group to a control group that follows usual care.

3. To measure impact of pharmacist-facilitated interventions through reporting of resolved PCIs and pharmacist contributions within the interventions.

1.9.1 Hypothesis

A pharmacist-facilitated transition-of-care composite of interventions reduces readmission rates and improve quality of care of heart failure patients. This research tested the hypothesis that heart failure (ICD-10 code 150) patients that receive care through specific pharmacy-related interventions during transition-of-care have a lower all-cause unplanned 30-day readmission rate than patients that receive usual care.

2. Methodology

“If you can’t explain it simply you don’t know it well enough”

Albert Einstein

Overview

This chapter describes the research methodology used throughout the study, with a description of the steps involved throughout the data collection, interventions and analysis processes. The study was in three phases. The first phase consisted of a qualitative research approach by means of a multi-perspective focus group and semi-quantitative surveys to establish the interventions to be included in a pharmacist-facilitated TOC pathway (Flowchart 1). The second phase was carried out in 8 wards at Mater Dei Hospital (MDH). It involved administering patients with heart failure a treatment adherence questionnaire to establish an adherence score, condition-related questions and the collection of relevant medical and medication information from the patient medical records in order to establish baseline data. In this phase convenience sampling was used and patients were eligible after passing through pre-specified inclusion and exclusion criteria (Flowchart 2). The intent of this phase was to establish a cohort of patients with heart failure who would benefit from TOC interventions; relate the data collected on these patients to readmissions and retrospectively use this cohort of patients as controls for phase 3 of the study. Phase 3 was carried out in the same setting as phase 2 and patients were sampled and screened with the same methodology. The patients who accepted to participate in the TOC pathway were followed prospectively during their stay in hospital until 30 days after discharge with specific interventions and then until 60 days after discharge to check for hospital resource utilisation (Flowchart 3). This phase was intended to establish whether there was a difference in readmission rate between those who followed the pathway and the control group that followed the usual standard of care.

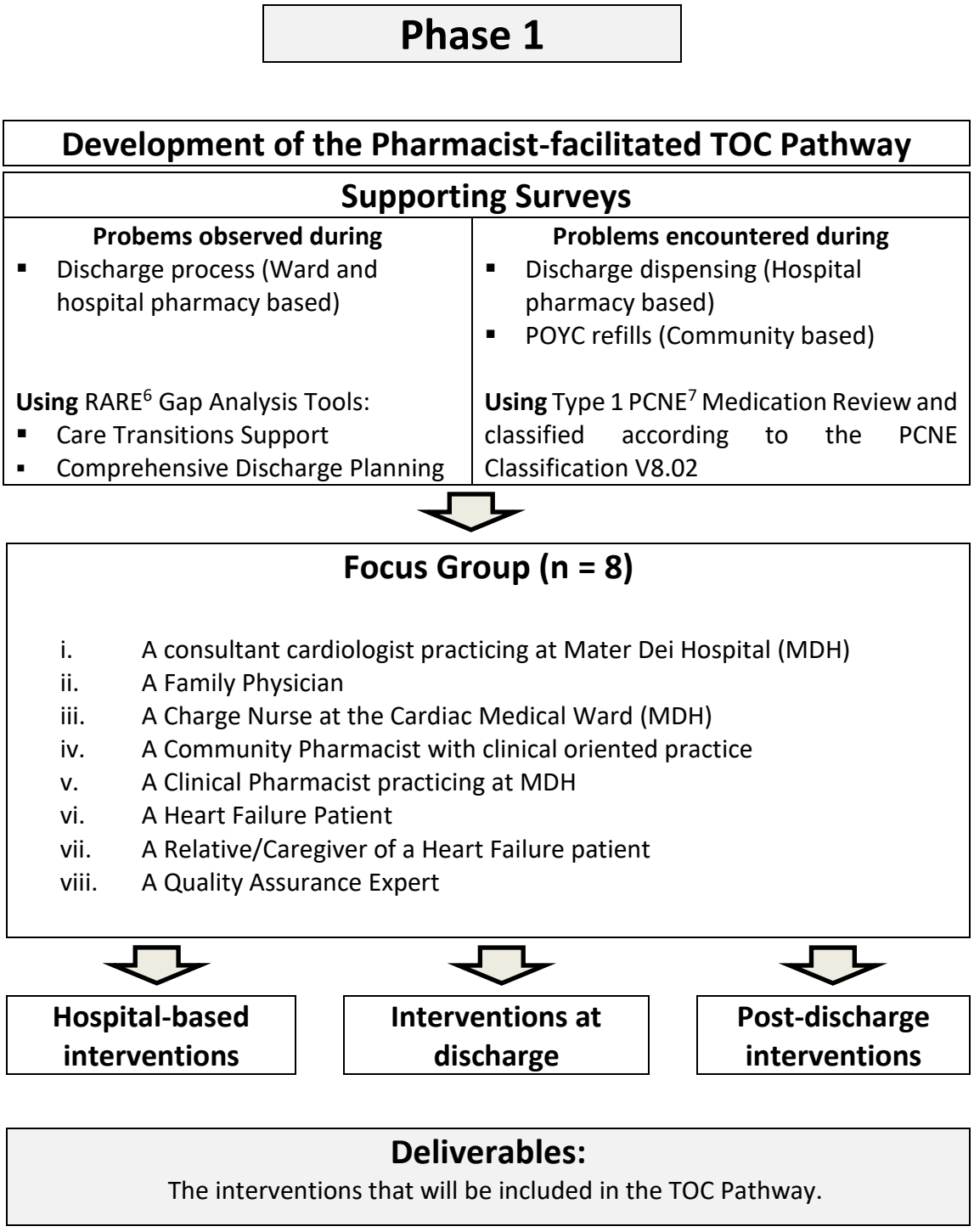
2.1 Phase 1 Design

In July 2018, a focus group discussion was organised to elicit the perspectives of the different stakeholders on the interventions to be included in a pharmacist-facilitated TOC pathway and how these interventions may be deployed. This qualitative method was preferred as it permits participants to discuss their own insights, thinking, ideas, doubts and tactics and allows interaction between the participants. The perceptions, ideas and views of the participants were supported by literature focusing on TOC interventions and by gap analysis by means of three surveys which scanned pharmaceutical care problems encountered at discharge and after discharge. One survey was an internal desktop analysis based on current policies and procedures supported by direct observation of the discharge process in eight wards in the same setting of the study. For this purpose, the Reducing Avoidable Readmissions Effectively (RARE)[5] campaign, Care Transitions Support and the Comprehensive Discharge Planning gap analysis surveys were used to identify shortcomings in the process that directly or indirectly impact pharmaceutical care (Appendix 1). RARE is an initiative by the Institute for Clinical Systems Improvement, the Minnesota Hospital Association, and Stratis Health in Minnesota[5]. The two other surveys were based on the problems encountered during dispensing to discharged patients at the hospital pharmacy in the same setting of the study and during dispensing within the Pharmacy of Your Choice (POYC) scheme in two private community pharmacies.

---

[5]rarereadmissions.org [internet]. Minnesota: RARE (Reducing Avoidable Readmissions Effectively) Institute for Clinical Systems Improvement, the Minnesota Hospital Association, Stratis Health. c2017 [cited 2018 Jan 22]. Available from: http:// www.rarereadmissions.org/.

Flowchart 1. Phase 1 of the study.



[6]rarereadmissions.org [internet]. Minnesota: RARE (Reducing Avoidable Readmissions Effectively) Institute for Clinical Systems Improvement, the Minnesota Hospital Association, Stratis Health. c2017 [cited 2018 Jan 22]. Available from: http:// www.rarereadmissions.org/.

[7]pcne.org [internet]. Classification for Drug related problems: The PCNE Classification V 8.02. Published November 5, 2017. [cited 2018 March 23] Available from: http://www.pcne.org/upload/files/230_PCNE_classification_V8-02.pdf

For the purpose of recording the problems encountered during discharge and POYC dispensing, the professional work diary of the researcher was used. The problems encountered were detected following a Type 1 Simple Medication Review according to the Pharmaceutical Care Network Europe (PCNE)[8] statement on medication review. The problems documented in the diary were then categorised according to the classification for drug related problems of the PCNE Classification V8.02[9]. In the PCNE Classification V8.02 documentation and technical problems encountered during the surveyed stages were included (Appendix 1). Information on drugs, such as recommended dosages, frequency and side-effects, was based on the British National Formulary and IBM Micromedex was used specifically for drug interactions. Only drug interactions classified as contraindicated were considered to have clinical significance.

2.1.1 Participants

Participants for the focus group were invited personally by the researcher. The number of participants approached exceeded the planned number of participants in the focus group to counteract for dropouts. The participants were purposively chosen to represent the key stakeholders along the care continuum during transition from hospital to the community.

---

[8] pcne.org [internet]. Statement on medication review. Published 2013. [cited 2018 March 23] Available from: https://www.pcne.org/upload/files/150_20160504_PCNE_MedRevtypes.pdf

[9] pcne.org [internet]. The PCNE Classification V 8.02. Published November 5, 2017. [cited 2018 March 23] Available from: http://www.pcne.org/upload/files/230_PCNE_classification_V8-02.pdf

Purposive selection was deemed suitable within this qualitative context, since the research objective of Phase 1 was informed a priori, through an existing body of literature on TOC programs. A focus group was required as interventions need to fit within current processes in which each stakeholder operates. The inclusion of patients in the focus group was deemed important since their needs and expectations help in optimising better-quality care. The multi-perspective focus group consisted of 8 persons, a consultant cardiologist, a private family doctor; a clinical pharmacist, a managing community pharmacist with a clinical oriented practice within the pharmacy of your choice (POYC) scheme, a charge nurse of a cardiology ward, a patient with heart failure, a relative who is the caregiver of a heart failure patient and a quality assurance expert.

It was recognized that patients and family caregivers might feel inhibited about discussing some experiences candidly in front of healthcare professionals (whom they might know), which reinforced the plan to select the participants keeping in mind self-confidence and open mindedness.

2.1.2 Interview guide and data collection

An interview guide to be used during the focus group was developed to explore the stakeholders' ideas about PCIs encountered during the transition from hospital to the community after discharge (Appendix 2). Results from the three surveys carried out for the gap analysis together with an extensive literature review were used to develop the interview guide. The technique used during the focus group session was to let a free discussion take place on a particular theme such as the problems experienced in daily

practice with regard to the discharge process followed by delving deeper into the key elements or attributes that should be present during the discharge process. This technique was used to avoid leading the participants to an end avoiding bias. This technique was repeated in a subsequent part of the session in which the focus was on the attributes that should be present once the patient is back in the community setting. Finally, feedback on patient and process elements that throw light on potential interventions that can be pharmacist-led were sought through rating sheets. The rating sheets also were used to stimulate further the discussion. A trial of the interview guide was done in a smaller group. Since the guide produced satisfactory results, no modifications were required, and the interview was used for the focus group session.

Participants gave written consent before the start of the discussion. Consent included information that the session would be audio recorded. Participants were assured that all comments would remain confidential. The focus group was led by the researcher and assisted by an assistant moderator who made field notes. The session lasted about 1 hour 20 minutes and the researcher delivered an overview after the session. Audio recordings were transcribed and reviewed without delay to check for clarity of comments and/or to link focus group members to their respective comments.

2.1.3 Analysis

The focus group session was transcribed verbatim. Each participant was assigned a code. The researcher studied the transcripts and emerging themes were identified. The information in each theme was reflected on and interpreted on its own merits and in a holistic approach.

2.2 Phase 2 Design

Following clearance by the University of Malta Research and Ethics Committee (UREC) a prospective cohort study was carried out at Mater Dei Hospital (Malta) between 20th June and 31st August 2018.

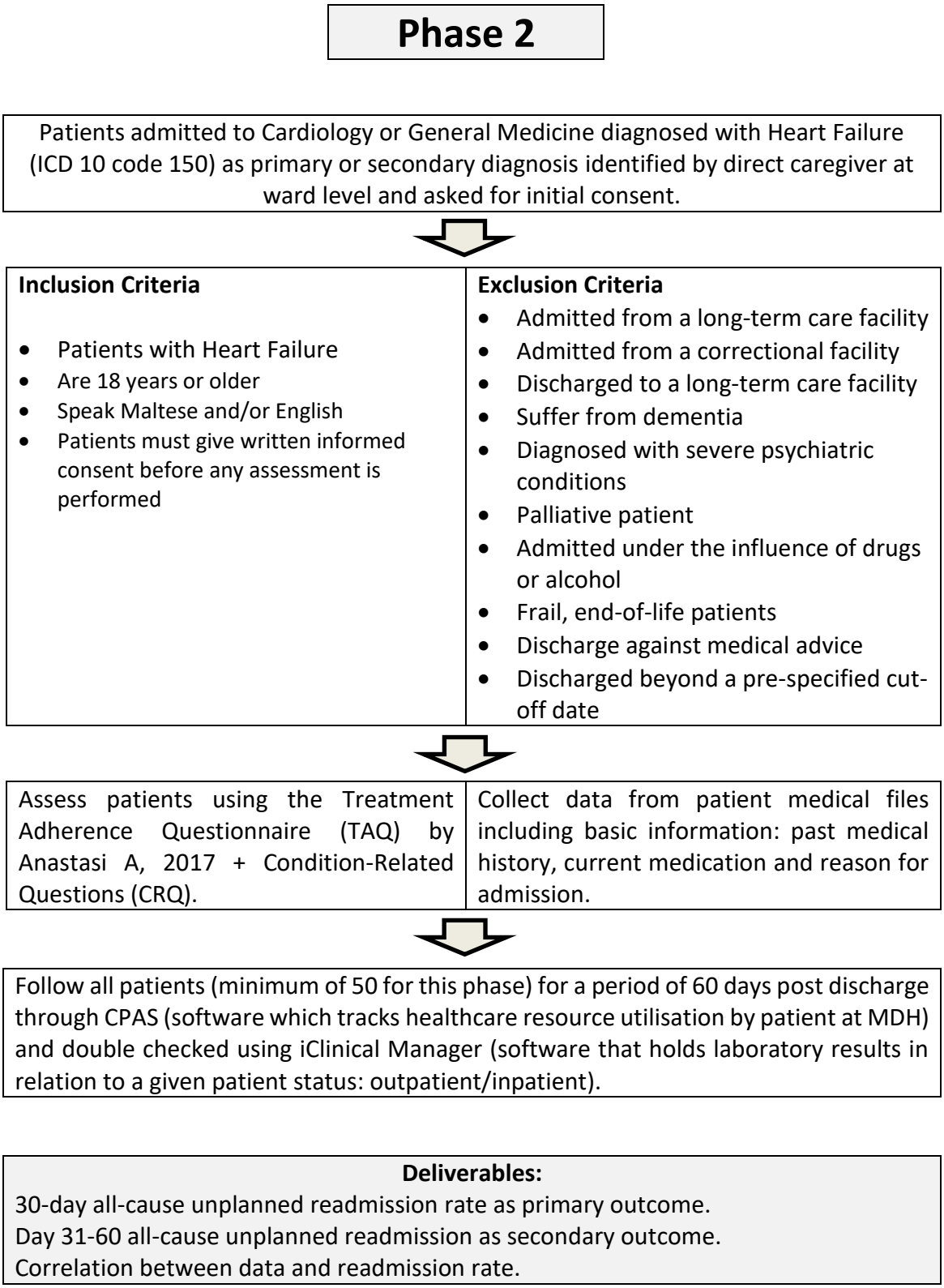
2.2.1 Setting

This phase of the study was performed at the cardiology and medical wards within Mater Dei Hospital in Malta. Mater Dei Hospital is the main acute tertiary level hospital in the Maltese islands. It is a 1000 bed teaching hospital and is government funded.

2.2.2 Participants

All the participants were patients with heart failure and convenience sampling was employed. A total of 60 subjects were recruited. Patients were eligible for the study if they were 18 years or older, spoke Maltese and/or English and gave signed informed consent.

Flowchart 2. Phase 2 of the study.



Patients who were admitted from a long-term care facility, admitted from a correctional facility, had the likelihood of being discharged to a long-term care facility, suffer from dementia, diagnosed with schizophrenia, psychosis or suicidal ideation, palliative patient, admitted under the influence of drugs or alcohol, frail end-of-life patients, those who requested discharge against medical advice and those discharged beyond a prespecified cut-off date were excluded from the study.

2.2.3 Recruitment

Participants were recruited following a specific procedure required by UREC. The direct caregiver (consultant, firm doctors, charge nurse) having the necessary knowledge of patients with heart failure being treated at the ward was required to act as an intermediary and invite patients to participate in the study. Following the initial verbal consent given to the charge nurse, who acted as the direct caregiver inviting the patients, the patient was approached by the researcher and was given a brief about the study. This was followed by written information about the study and the patient was then asked for signed informed consent.

Further data was collected from the medical files using a data collection form (Appendix 3). The patient was then administered the TAQ (Anastasi *et al,* 2017) followed by four condition-related questions (Appendix 4). The patient was thereafter followed for a period of 60 days after discharge to establish a readmission profile. Follow-up was carried out by accessing CPAS which is the software at MDH that tracks the movement of patients within the healthcare system and confirmed using iClinicalManager (ICM)

software that keeps a record of investigations according to patient status (i.e. inpatient or outpatient).

2.2.4 Data collection

Patient medical files were scrutinised to establish basic patient-related information including past medical history, current medication and reason for admission. Other information that indicates the likelihood of the patient having adherence issues to medication and risk of readmission were also recorded. This data included level of education; eyesight, hearing and manual dexterity issues and whether typical heart failure medications namely beta-blockers, ACE inhibitors and aldosterone antagonists were on target doses according to guideline directed medication therapy after screening for clinical reasons to justify for doses below target.

The patients were administered the TAQ and a total score was assigned to each patient depending on the responses. Patients were also asked four basic questions related to heart failure to further assess their potential to self-care and basic knowledge on their condition for which the percentage correct responses were assigned based on the scheme shown in Table 2.1.

Data collected during the 60-day period after discharge through CPAS included date of discharge and to where discharged. Confirmation using ICM was done to cover for missing or inaccurate data on CPAS and patients with direct ward admission (i.e. not through the ED) that might accidentally not feature on CPAS.

Table 2.1 Condition-related questions – guide to assess responses

Question	Correct response
What is the name of your water tablet?	The patient was able to name the diuretic. Inappropriate pronunciation considered acceptable. Visual recognition not considered acceptable.
Do you weigh yourself every day and if yes what is the significance of a 2kg increase in two days?	The patient is at least able to associate a rapid increase in body weight with fluid overload or the need of weight monitoring to check fluid overload.
Do you add salt to your prepared food or seasoning cubes while preparing food?	The patient is at least able to understand that he/she should be on a salt-restricted diet. Deliberate non-adherence considered unsatisfactory.
Which symptoms (related to heart failure) should you report to your doctor?	The patient is at least able to mention two of the following: sudden weight gain; swelling of the feet, ankles or abdomen; shortness of breath and/or increasing cough episodes and unusual fatigue.

2.2.5 Primary outcome

The primary outcome of Phase 2 was 30-day all-cause unplanned readmission rate. ED visits and subsequent observation were not considered owing to the culture of ED utilisation secondary to relatively short distances from hospital. Direct admissions by consultants to cardiology wards offering a period of observation which lasts less than 24 hours were also not considered. Direct admissions are those advised by a cardiologist as a precautionary measure until proper clinical assessment is carried out. Direct admissions usually take place after hours when the heart failure clinic is not open. This phase of the study sought to find the relationship between hospital readmission and specific factors including adherence, length of stay, admissions in the previous year before the current admission, social history, medication history, type of HF and co-morbidities in heart failure patients.

2.2.6 Secondary outcomes

The secondary outcomes in phase 2 were day 31-60 all cause unplanned readmission rate which was assessed using the same method as for the primary outcome. Adherence score, mean grade for CRQs and the percentage and type of admissions or readmissions due to drug-related problems were other secondary outcomes.

2.2.7 Analysis

Statistical analysis to compare means was carried out using the Independent samples t-test[10] (ISt-test) and percentages were compared using the Difference of two proportions test[11](DifTPT). The ISt-test was used to compare mean scores between two independent groups. The null hypothesis specifies that the mean scores are comparable and is accepted if the *p*-value exceeds the 0.05 level of significance. The alternative hypothesis specifies that the mean scores vary significantly and is excepted if the *p*-value is less than the 0.05 criterion. The DifTPT was used to compare two percentages and determine whether they differed significantly or not. The null hypothesis specifies that the two percentages are comparable and is accepted if the *p*-value exceeds the 0.05 level of significance. The alternative hypothesis specifies that the two percentages differ significantly and is accepted if the *p*-value is less than the 0.05 criterion. Both the ISt-test and the DifTPT cater for comparison between two different sample sizes. Significance was reported with the 95% confidence interval (CI) at $p < 0.05$ (two-tailed).

---

[10]Microsoft excel (2010); t-test: Two-sample assuming equal variances [cited 2019 Jan 26].

[11]Stangroom J. Z Score Calculator for 2 Population Proportions. Social Science Statistics. https://www.socscistatistics.com/tests/chisquare2/Default2.aspx [cited 2019 Jan 26].

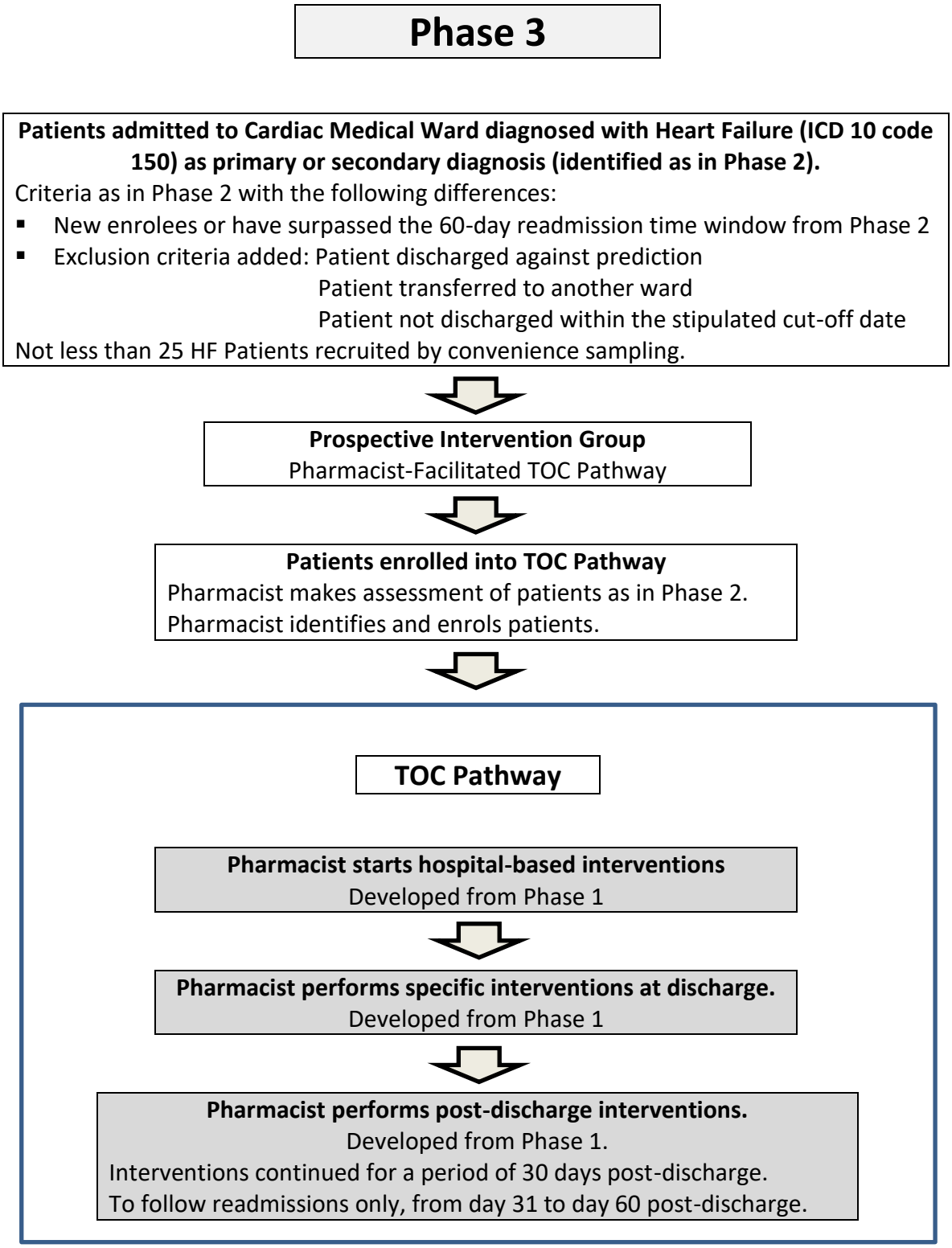
2.3 Phase 3 Design

Phase 3 was a study to validate the pharmacist-facilitated TOC pathway developed in Phase 1. In this phase patients were new enrolees or had surpassed the 60-day follow-up of Phase 2. Eligibility was also identified using inclusion and exclusion criteria as in phase 2 of the study.

The setting, method of recruitment, data collection, primary outcomes and secondary outcomes and analysis were the same or included those in Phase 2 of the study. The exclusion criteria included some differences (Flowchart 3). Patients who were discharged against prediction (decision to discharge taken in late afternoon when researcher was not present) and those transferred to another ward were excluded because these patients suffered interruption of the pharmaceutical care pathway as planned within the ward-based pharmacist model applied. A final cohort of not less than 25 patients was ensured.

The eligible patients were offered to follow the TOC pathway developed in Phase 1 which was the bundle of interventions by the pharmacist researcher intended to access impact on readmission rate. Patients from Phase 2 (the control cohort) acted as retrospective controls for the primary and secondary outcomes. Each patient from Phase 3 who was willing to participate and gave signed informed consent was administered the TAQ and condition-related questions and patient data was collected as in Phase 2. During day 31 to 60 the patients were re-administered the CRQs for purposes of reassessment. This was carried out at week six post discharge.

Flowchart 3. Phase 3 of the study



2.3.1 Documentation of accomplishments during the interventions

For each intervention, a record of what was carried out or achieved with each patient was kept. Further interventions required as a result were also documented.

2.3.2 Comparison of Non-intervention and Intervention Groups

All baseline data, primary and secondary outcomes between the non-intervention and intervention groups was statistically analysed using the same tests for Phase 2 as mentioned in section 2.2.7.

2.4 Justification of key elements of the study design

This section describes the reasons behind the choice of the features that make up the backbone of the study, that is the primary outcome measure and experimental design.

2.4.1 Selection of the primary outcome

TOC including the discharge process, comorbidities, complicated treatment regimens and patient characteristics such as lack of adherence to treatment and age are predictors of hospital readmissions and risk factors for medication-related problems. A category of patients who are particularly predisposed to readmissions are heart failure patients because often are burdened by a combination of these factors. Rate of readmissions is also a quality metric in the healthcare system and the reduction of

readmission rate is considered a means of reducing healthcare costs and the disease burden on patients. The understanding of heart failure, its treatment, the shortcomings during TOC and the burden of readmissions to patients, relatives and the healthcare system has led to the choice of 30-day all cause readmission as primary endpoint.

2.4.2 Choice of a Focus Group to establish the interventions

A focus group discussion was organised to elicit perspectives on the choice and deployment of the pharmacist-facilitated TOC interventions within the pathway. This was deemed essential since the interventions needed to fit within existing hospital policies and procedures. A focus group as a means of qualitative research was chosen taking advantage of logistical attributes as well as focus group characteristics as a research tool. The availability of a venue, participants working or residing in close proximity to the venue and the fact that a focus group would take less time than to interview the participants individually were considered. This qualitative research method allows for exchange of views, building from other's answers and new concepts are more likely to emerge if group interaction is enabled. The limitation of not being able to determine saturation of viewpoints because only one focus group was conducted, and the complexity of the processes involved during care transitions were counteracted by conducting three surveys covering three stages during the transition from hospital to community.

2.4.3 Choice of surveys serving three purposes

The initial conduction of three surveys at three critical stages along the care continuum during the transition from hospital to community served four purposes. As a means of gap analysis to establish shortcomings within processes and practices both professional and administrative. As one of the means of developing the interview guide including rating sheets to be used during the focus group session. To complement the perceptions and views of the participants of the focus group and to obtain tangible information serving the researcher to establish a TOC checklist to be applied during the discharge process.

This technique would move the process towards saturation of arguments and observations leading to sound conclusions on what interventions should be included and how they should be deployed in the TOC pathway.

2.4.4 Choice of a retrospective control group

The choice of a retrospective control group served five fundamental principles. For a project to be conducted by a single researcher, from a logistical viewpoint it would have been impossible to run a control arm and an interventional arm concurrently. A Phase 2 cohort recruited and analysed by the researcher intended to act as retrospective control served the researcher to get to know the lay of the land in relation to pharmaceutical care during the hospital stay and discharge. The Treatment Adherence Questionnaire and condition-related questions coupled with patient data from their medical records in Phase 2 of the study allowed for in-depth analysis of any particular

factors contributing to readmissions. This in turn would influence the adaptability of the TOC pathway in Phase 3. Ethical issues would have been a concern in a parallel design scenario, if the patients following the TOC pathway would show an immediate marked benefit in terms of primary and secondary outcomes. This allowed for flexibility with regards to the commencement of Phase 2 as long as it preceded Phase 3 but not necessarily following Phase 1.

2.4.5 Choice of an interventional prospective group

For matters of feasibility and sustainability during Phase 3 of the study an interventional prospective group of 25 patients was chosen. This can be considered as a pilot study to establish the potential to put into practice the TOC interventions as a pharmaceutical care service within the hospital setting.

3. Results

“The greatest danger for most us is not that our aim is too high and we miss it, but that it is too low and we reach it.”

Michelangelo

3.1 Phase 1 results

The Phase 1 results follow chronological sequence of results obtained for the supporting surveys for the focus group discussion and focus group emerged themes.

3.1.2 Reducing avoidable readmissions effectively (RARE) surveys

Table 3.1 shows gaps/opportunities categorised according to four characteristics revealed using the *care transitions support* gap analysis survey.

Table 3.1 Gaps identified that impact pharmaceutical care during TOC

Lack of consistency	• Who is responsible for the patient's pharmaceutical care and contact details after discharge? • Durable medical equipment such as home oxygen not always arranged prior to discharge • Guide to patients: Medication on discharge not always given and explained to patients/family caregivers • Documentation for medication entitlement not always checked during discharge dispensing • Medication reconciliation not always done, and reconfirmation of discharge medication not done
Lack of timeliness	• PCIs detected during dispensing often involve having to send the patient/caregiver back to the ward • Follow-up at out-patient clinics can take weeks after discharge and follow-up with the primary care provider (PCP)ǂ depends on the patient • Post-discharge providers (PCP and POYC pharmacist) do not always have pertinent information in a timely manner to support TOC and depends on the patient making it subject to patient awareness
Deficiency	• Not always ensured that the patient or family caregiver is at least able to understand when and how to take medication. No techniques like teach-back are employed to assess understanding • No process in place to assure the patient knows and understands what issues require immediate intervention and why • No support system in place to follow-up with patient post transition (coaches, calls, telehealth). Commcare® nurses can be of benefit with respect to adherence • No cardiology clinical or ward pharmacist that can facilitate pharmaceutical care during TOC
Lack of standardisationn	• The discharge prescription, case summary and last updated treatment chart not necessarily congruent and no official guide to regulate this aspect of the discharging process

ǂ PCP is equivalent to the private family doctor (PFD) or health centre doctor within the Maltese health care system

Table 3.2 shows the gaps/opportunities identified using the *comprehensive discharge planning* gap analysis of best practices/strategies for improvement survey, categorised according to 4 domains and applied specifically to pharmaceutical care.

Table 3.2 Gaps/opportunities that impact pharmaceutical care – Discharge planning

Discharge planning - process	• Ensure patient/caregiver is at least able to understand when and how to take medication • Ensure patient/caregiver knows were to refer for the discharge medication if the case summary is available and if not enhance explanation regarding new and stopped medication
Discharge planning - content	• Make arrangement for durable medical equipment such as home oxygen, before discharge • Ensure patient knows whom to contact in case of difficulty regarding medication • Ensure that pharmaceutical care-related information on case summary is explained in plain language and considering patient culture
Care Coordination	• Carry out medication review at ward level so that pertinent information such as laboratory results are available, and any problems will be resolved at source • Conduct post discharge telephone care management (TCM) to check for pharmaceutical care issues and perform pharmaceutical care follow-up
Health literacy/ Patient-provider communication	• Ask basic questions during TCM to reinforce patient awareness on aspects that impact pharmaceutical care. • Ensure patient is given a complete and written pharmaceutical care plan • Use teach-back to ensure patient/caregiver understands medication-use and medication entitlement procedures • Ensure patient/caregiver is given written material as back-up related to procedures to get medication entitlement and discharge medication

3.1.3 Pharmaceutical care issues at discharge and POYC refills

Figure 3.1 depicts the problems encountered during dispensing at discharge and during prescription POYC refills in two private community pharmacies. A total of 141 and 119 PCIs were identified for 209 discharges and 177 POYC prescription refills respectively during a two-month period from March – April 2018. Fifty-two percent of discharges and 49% of refills had at least 1 problem to address. The average number of medications was four for both discharges and POYC refills. The largest proportion of PCIs in both stages was documentation problems (35% and 46.6%). The second largest proportion was dispensing problems in the POYC setting (23%) and dose selection (17%) at discharge.

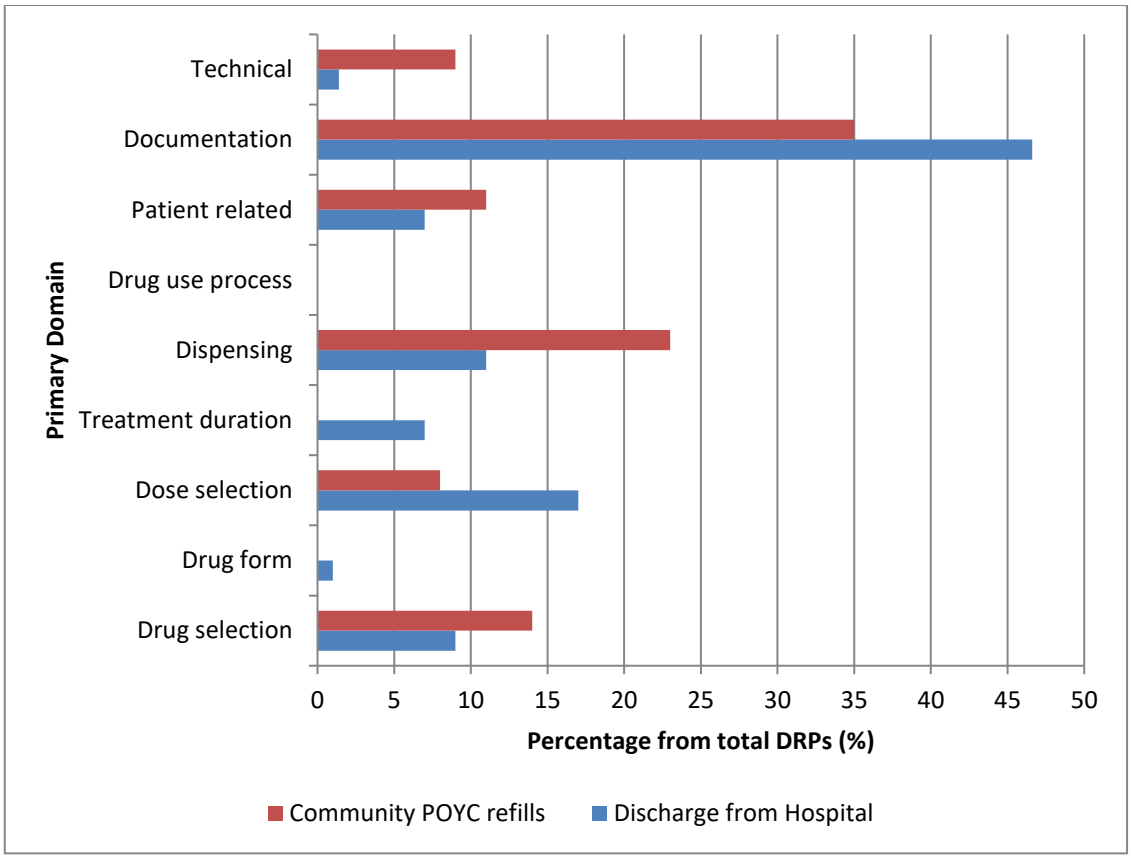


Figure 3.1 Problems encountered during TOC. Discharged from hospital (N=209) and chronic medication prescription refills in two private community pharmacies (N=177) classified according to the PCNE Classification V8.02.

The most frequent documentation problems (Table 3.3) encountered during patient discharge were missing or inappropriate prescriptions (n=42, 65.6%), missing or incomplete entitlement documents (n=12, 18.8%) and the discharge case summary was not available or with missing information (n=8, 12.5%). The most frequent documentation problems encountered during POYC refills were missing prescriptions or entitlement documents (n=25, 60%), expired permits or no entitlement (n=11, 26.8%) and multiple or outdated prescriptions from different doctors (n=4, 9.8%). Technical problems accounted for 1.4% and 9% of the problems within the discharge and POYC refills respectively. Technical problems included look-alike medication or package, different packages for the same medication and problems related to accessing the POYC software.

Table 3.3 Most frequent documentation problems encountered – Discharges/POYC refills

Discharge from Hospital (n = 64)		
n	**%**	**Description of the encountered problem**
42	65.6	Missing or inappropriate prescriptions
12	18.8	Missing or incomplete entitlement documents
8	12.5	Case summary not available or with missing information
POYC Refills (n = 41)		
n	**%**	**Description of the encountered problem**
25	60.0	Prescriptions or entitlement documents missing
11	26.8	Expired permits or no entitlement
4	9.8	Multiple or outdated prescriptions from different doctors

3.1.4 Focus group

A total of four themes emerged from the focus group, pharmacist's role in TOC, communication, practical process considerations and patient education. Table 3.4 gathers the focus group members' contributions within the themes.

Table 3.4 Contributions by focus group members within emerged themes

Pharmacist's role in TOC	• Participants positively perceived the integration of a ward-based pharmacist • The pharmacist ensures accurate medication reconciliation on admission and at discharge and overall pharmaceutical care
Communication	• Proper communication with post discharge providers is lacking and the lack of a system does not help either • The pharmacist at the ward has a pivotal role to ensure proper communication with post discharge providers
Process considerations	• Consistent and proper use of tools such as the blue card (Guide to Patients: Medication on Discharge). Other versions of the original document should be prohibited • Double checking during the discharge process should take the form of independent reconfirmation of discharge medications
Patient education	• Patient education considered imperative to improve adherence and pharmacist input should be along the continuum of care • Education through repetition will help patients especially the elderly to remember

In general most of the issues raised by the focus group participants were related to lack of consistency or complete omission of procedures such as medication reconciliation, patient education, communication and in-built quality checks stemming from lack of available time, competing priorities and lack of designated personnel such as pharmacists to do the job. It was agreed that a major barrier is the absence of a ward pharmacist to focus on pharmaceutical care issues. Optimization of co-ordination mechanisms during discharge and clear handoffs emerged as important elements during TOC. All participants seemed to have a good feel of the problems within the setting and their opinion was to a greater or lesser extent in line with the results of the surveys. Not all participants showed the same level of consciousness about the extent of certain problems as revealed by the surveys. All participants agreed that a flexible approach should be adopted when applying the interventions as this would permit a greater proportion of patients to follow the pharmaceutical care pathway.

The focus group participants also responded to a set of rating sheets concerning five characteristics during the discharge process and five characteristics when the patient is back in the community setting after hospital discharge. The results graphically shown in Appendix 2 supported the overall discussion and confirmed the main components of the pharmaceutical care pathway to be adopted.

3.1.5 The proposed interventions and pharmaceutical care pathway

Table 3.5 depicts the proposed adaptive pharmacist-facilitated TOC interventions, based on the results of the gap analysis surveys and focus group discussion. Table 3.6 shows a description of the proposed interventions.

Table 3.5 Adaptive pharmacist-facilitated TOC interventions based on focus group discussion and gap analysis surveys.

Intervention	Boundaries	Who decides and/or what determines
Pharmacist-led pharmaceutical TOC pathway at ward*		
Medication reconciliation at admission and at discharge*		
Administration of the Treatment Adherence Questionnaire and Condition-Related Questions*		
Patient medication-use education	Short session on the day of discharge/ Extended session on a day close to end of hospital stay	Pharmacist/No of medications; use of high-risk medications; treatment adherence score; potential to self-care; family caregiver support
Caregiver medication-use education	No caregiver education applicable/session on a day close to end of hospital stay	Pharmacist/No of meds; use of high-risk medications; patient treatment adherence score and potential to self-care
Patient individualised pre-discharge education	In conjunction with medication-use education, separate session or concurrently with TAQ and CRQs	Pharmacist/History, medication regimen, responses to TAQ and CRQs
Screening of documentation for medication entitlement*		
Clinical check for drug-related problems*		
3 days discharge medication brought to the bedside by the pharmacist	Required/Not required	Pharmacist/depending on changes in drug regimen
Telephone care management via calls to discuss problems related to medication during the 30 days after discharge.	1-3 calls as required	Pharmacist/depending on up-titration plan/tail down of medications/new medications/patient requirements including refill and entitlement needs
Pharmacist contact number to discuss problems related to medication with the pharmacist (same as the one on the Study Information letter)	Required/Not required	Patient preference to discuss with hospital/POYC pharmacist
Direct communication of hospital pharmacist with POYC pharmacist/ PFD regarding recently discharged patients	No intervention/Discharge Medication List Form sent as a PDF document via email or direct call to the POYC pharmacist/PFD	Case summary available and reliability of patient/caregiver to inform POYC pharmacist/PFD

*Mandatory interventions; all other interventions are adaptive. *TAQ – Treatment adherence questionnaire; CRQ – Condition-related questions; POYC – Pharmacy of your choice; PFD – Private family doctor.*

Table 3.6 Description of the transition-of-care interventions

Intervention	What is going to be done
Pharmacist-led pharmaceutical TOC pathway at ward	Pharmacist will be present during normal working hours (7:30 to 15:30) at the cardiac medical ward (CMW) to implement the interventions
Medication reconciliation (admission and discharge)	Reconfirming the accuracy of home medication prescribed with that of last updated POYC documents; MAS permits; through patient and/or caregiver interview. Reconfirmation of discharge prescriptions with last updated treatment chart and case summary in the context of the patient's medication plan and GDMT
Administration of the treatment adherence questionnaire (TAQ) and condition-related questions (CRQ) – (see Appendix 4)	Using these tools as part of the care pathway as a means of identifing weak areas of medication use, and condition-related knowledge with the intent of individualising pre-discharge education, assessing improvement of the patient's knowledge and assessing effectiveness of the education given
Patient medication-use education (see Appendix 6)	Using teach-back method with the aid of the standard Guide to patients – medication on discharge chart (blue card)
Caregiver medication-use education (see Appendix 6)	Using teach-back method with the aid of the standard Guide to patients – medication on discharge chart (blue card)
Patient individualised pre-discharge education (see Appendix 6)	Based on the history, treatment regimen and responses given to the TAQ and CRQs the patient is given targeted educational support that impacts pharmaceutical care
Screening of documentation for medication entitlement at discharge (see Appendix 5)	Schedule V applications are complete; Prescriptions are complete; Applications for non-formulary items are complete using the Pharmacist interdisciplinary TOC planning checklist
Clinical check for drug-related problems (see Appendix 1)	Using PCNE Type 3 advanced medication review and intervening accordingly
3 days discharge medication brought to the bedside by the pharmacist	A way of increasing patient satisfaction and engaging for education reinforcement
Telephone care management via calls to discuss medication related aspects during the 30 days after discharge and encourage follow-up appointments (see standard TCM follow-up guide – (see Appendix 6) Pharmacists contact number given to patient.	Depends on patient medication list and treatment plan. Includes medication reminders; reminders to inform POYC pharmacist/PFD about recent admission; side effects of newly prescribed medication; readministration of CRQs. Heart failure medication-related issues dicussed using British Heart Foundation Everyday Guide 2017 edition Patient given contact number to call the pharmacist to discuss medication-related problems that might arise after discharge
Direct communication of hospital pharmacist with POYC pharmacist and or PFD regarding recently discharged patients	By telephone or email to inform about changes in medication (Discharge Medication List form – (see Appendix 5) or making post-discharge provider aware of patient characteristics (e.g. non-adherent to fluid restriction)

POYC – Pharmacy of your choice; MAS – Medication approval system; GDMT – Guideline directed medication therapy; TAQ – Treatment adherence questionnaire; CRQ – Condition-related question; TOC – Transition-of-care; PCNE – Pharmaceutical care network Europe; ACC – Anticoagulant clinic; PFD – Private family doctor

The TOC pathway (Figure 3.2) followed by HF patients started from admission and extended beyond discharge when the patient was back in the community.

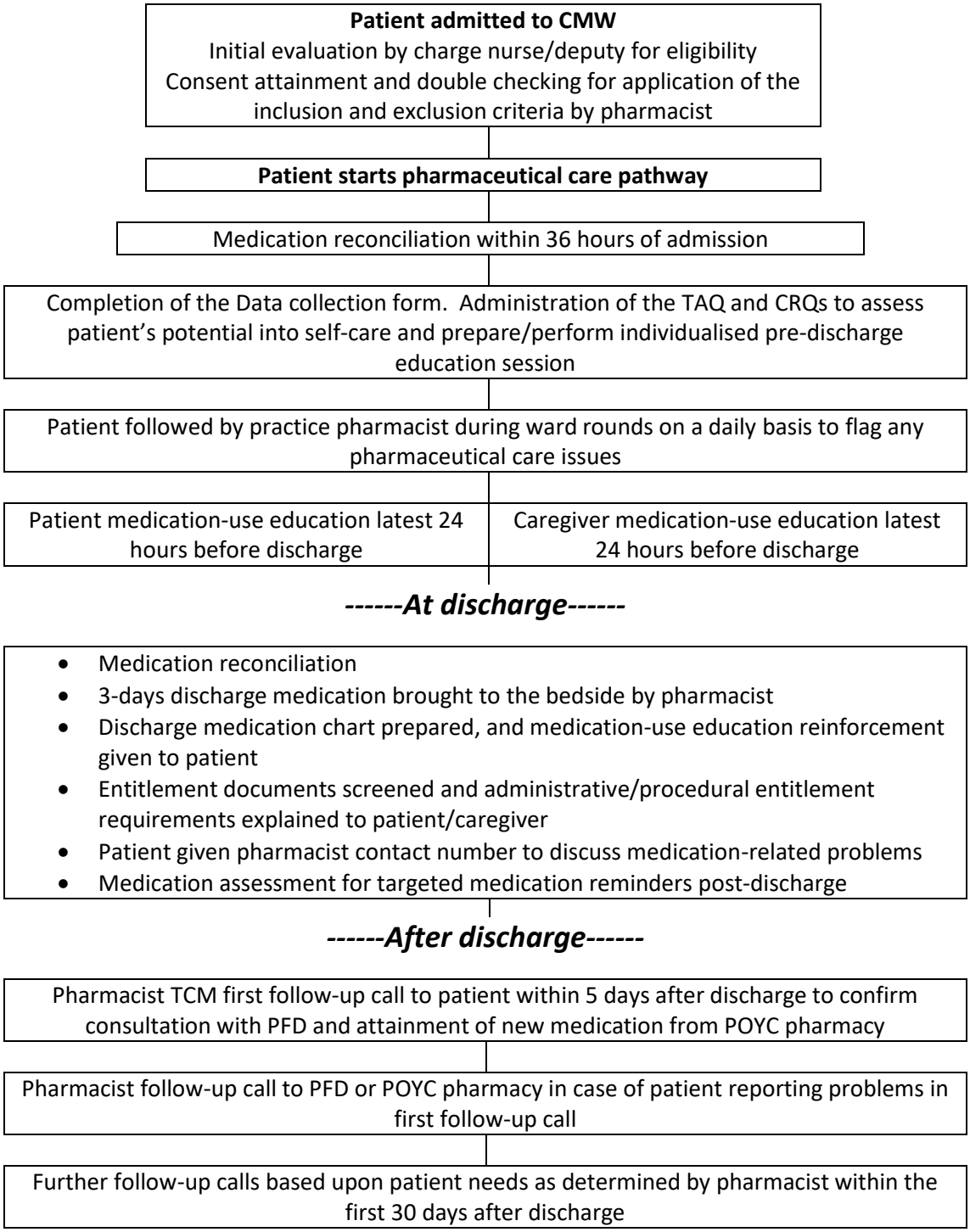
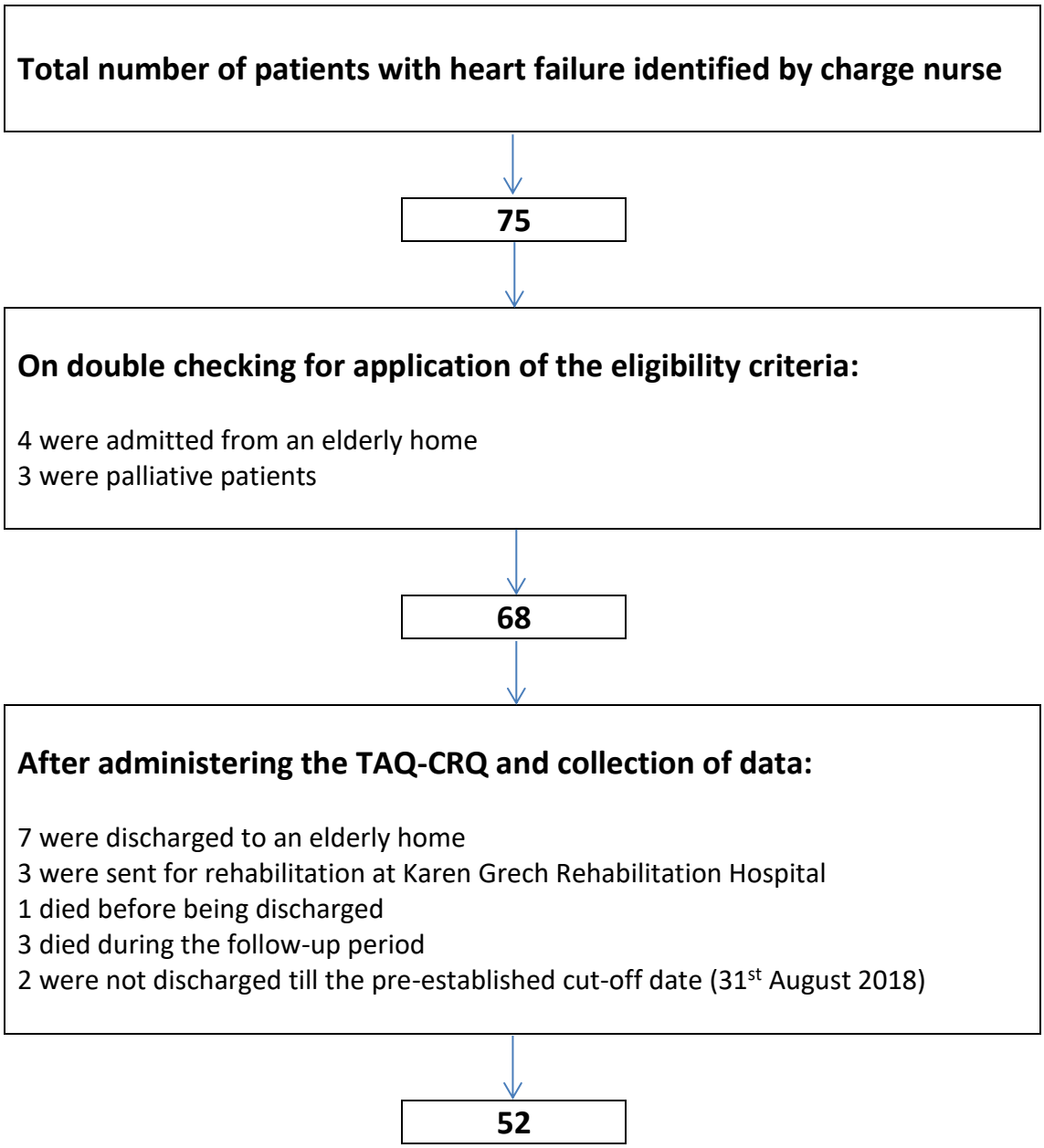


Figure 3.2 Pharmaceutical care pathway of HF patients applying the adaptive pharmacist-facilitated TOC interventions.

3.2 Phase 2 results

From 20th June 2018 through August 2018 a total of 75 patients were identified by the charge nurse of the respective cardiac or medical ward. The final cohort consisted of 52 patients (Table 3.7).

Table 3.7 Final Phase 2 non-intervention cohort of patients with heart failure after applying the inclusion and exclusion criteria



Phase 2 carried out from 20th June 2018 to 31st August 2018. 60-day follow-up period up to 31st October 2018.

Table 3.8 depicts the baseline data of all the patients (N=52) within the cohort and the patients that were readmitted (n=16) within the 30-day time window. Considering the complete cohort and the readmitted sub-group, patients within the readmitted group had a mean age of 70.7 ± 9.7 which was younger than that of the complete cohort. All patients were Caucasian of which 68.4% in the complete group and 73.3% in the readmitted group were male. TAQ score was higher for readmitted patients with a mean of 73.2 as compared to 70.9 of the complete group. The readmitted sub-group had a higher number of above average TAQ score that benefitted from strong family caregiver support. The potential of patients into self-care was lower in the readmitted subgroup, 35.9% ± 20.3 versus 43.3% ± 23.3 (Debono *et al* 2019). The mean hospital stay in days for the readmitted group was more than that of the complete group. Considering HF investigations, the readmitted sub-group had the same percentage of patients with a reduced ejection fraction (<40%) and a higher percentage of patients with an NTproBNP of greater than 1800pg/ml. Considering co-morbidities, all patients had multiple co-morbidities. The readmitted subgroup had a higher percentage of patients with diabetes, COPD or asthma, coronary artery disease and thyroid disorders. The difference between the readmitted subgroup and the whole cohort was statistically significant with respect to COPD/asthma. Considering social history, the readmitted subgroup had a higher percentage of patients who smoke or are ex-smokers. Considering medication, 4 patients were on the newer HF drugs (ARNI and ivabradine) of whom 2 were among those readmitted. Beta-blockers, ACE/ARBs and aldosterone antagonists seemed to require dose optimisation indicating a potential margin for up-titration (depending on patient condition) leading to potential issues with tolerance and adherence.

Table 3.8 Baseline data of patients within the Phase 2 non-intervention cohort

Characteristic or Variable	All cohort (N = 52)	Readmitted (n = 16) 30-day all-cause	z-score t-score	*p*-value
Age, Mean ± SD, year	73.7 ± 9.7	70.6 ± 9.7	1.127	0.264
Male, no (%)	38 (73.1)	12 (75.0)	0.153	0.881
Ethnicity, Caucasian, no. (%)	52 (100)	16 (100)	-	-
Mortality-related loss to follow-up, no/discharged(%)	3/55 (5.5)	Not applicable	-	-
Treatment adherence score, Mean ± SD	70.9 ± 10.4	73.2 ± 11.0	0.771	0.444
>70 without family caregiver support, no. (%)	17 (32.7)	4 (25.0)	0.582	0.562
>70 with family caregiver support, no. (%)	10 (19.2)	5 (31.3)	1.013	0.313
Potential engagement into self-care, Mean % ± SD ǂ	43.3 ± 23.3	35.9 ± 20.3	1.132	0.262
Hospital stay, Mean ± SD, days	6.9 ± 7.4	7.4 ± 12.3	0.205	0.838
Number of admissions in previous year, Mean ± SD	1.2 ± 1.5	2.0 ± 1.9	1.66	0.101
Ejection fraction, no (%)				
≤40%	13 (25.0)	4 (25.0)	0.000	1.000
≥41≤49	3 (5.80)	1 (6.3)	0.072	0.944
Unknown or with preserved EF	36 (69.2)	11 (68.8)	0.036	0.968
NT-proBNP, no (%)				
>125pg/ml	8 (15.4)	3 (18.8)	0.320	0.749
>900pg/ml	8 (15.4)	1 (6.3)	0.943	0.247
>1800pg/ml	27 (51.9)	11 (68.8)	1.185	0.234
Unknown	9 (17.3)	1 (6.3)	1.092	0.276
Comorbidities, no (%)				
Hypertension	35 (67.3)	8 (50.0)	1.256	0.208
Coronary artery disease	21 (40.4)	10 (62.5)	1.553	0.121
Diabetes	29 (55.8)	6 (37.5)	1.279	0.201
COPD or Asthma	17 (32.7)	10 (62.5)	2.131	0.033
Obstructive sleep apnoea	5 (9.6)	2 (12.5)	0.332	0.741
Renal disease	8 (15.4)	2 (12.5)	0.285	0.779
Arrhythmia	17 (32.7)	5 (31.3)	0.108	0.192
Anaemia	2 (3.8)	0 (0.0)	0.796	0.424
Myocardial infarction	10 (19.2)	4 (25.0)	0.499	0.617
Thyroid disorder	3 (7.0)	2 (12.5)	0.902	0.368
Depression, Anxiety or Insomnia	5 (5.8)	3 (18.8)	0.992	0.322
Social history, no (%)				
Smoker	1 (1.9)	1 (6.3)	0.896	0.368
Ex-Smoker	18 (34.6)	8 (50.0)	1.107	0.267
Alcohol use	1 (1.9)	1 (6.3)	0.896	0.368
Private family doctor	41 (78.8)	13 (81.3)	0.834	0.208
Discharge medications, no (%)				
Beta-blocker (BB) [margin for dose up-titration, no (%)]*	25 (48.1) [5 (55.6)]	8 (50.0) [1(50.0)]	0.135 0.143	0.897 0.889
Diuretics	48 (92.3)	14 (87.5)	0.593	0.555
ACEs and/or ARBs [margin for dose up-titration, no (%)]*	31 (59.6) [6 (50.0)]	11 (68.8) [2(66.7)]	0.658 0.518	0.509 0.603
Nitrates	18 (34.6)	6 (37.5)	0.211	0.834
Calcium channel blocker	13 (25.0)	5 (31.3)	0.496	0.617
Aldosterone antagonist (AA) [margin for dose up-titration, no (%)]*	20 (38.5) [8 (88.9)]	6 (37.5) [2(66.7)]	0.069 0.894	0.944 0.373
Warfarin or NOAC	20 (38.5)	8 (50.0)	0.820	0.412
Digoxin	5 (9.6)	1 (6.3)	0.415	0.674
Hydralazine	3 (5.8)	2 (12.5)	0.902	0.368
ARNI and/or Ivabradine	4 (7.7)	2 (12.5)	0.593	0.555

ǂ Potential engagement into self-care defined as the percentage sum of correct answers to four basic questions in relation to required knowledge on heart failure.

* Proportion expressed as a percentage of patients on a BB, ACE/ARB or AA who are HFrEF or HFmrEF

3.2.1 Hospital 30-day and day 31-60 readmission rate

From 52 patients with a primary or secondary diagnosis of heart failure 16 (30.8%) were readmitted within 30 days from discharge excluding ED visits and 36.5% including ED visits. Four patients were readmitted more than once within the first 30 days from discharge. Seven patients were readmitted within 60 days of whom 5 were also readmitted in the first 30 days.

3.2.2 Drug-related admissions or readmissions

Twelve patients (23.1%) were admitted with a suspected or confirmed drug-related event of whom 2 patients out of 16 (12.5%) were a readmission (Table 3.9). Beta Blockers (5 patients) and diuretics (3 patients) were most often implicated in the identified drug-related admissions/readmissions with bradycardia and exacerbation of congestive heart failure being the main consequences.

Table 3.9 Suspected or confirmed drug-related admissions or readmissions within the Phase 2 non-intervention cohort

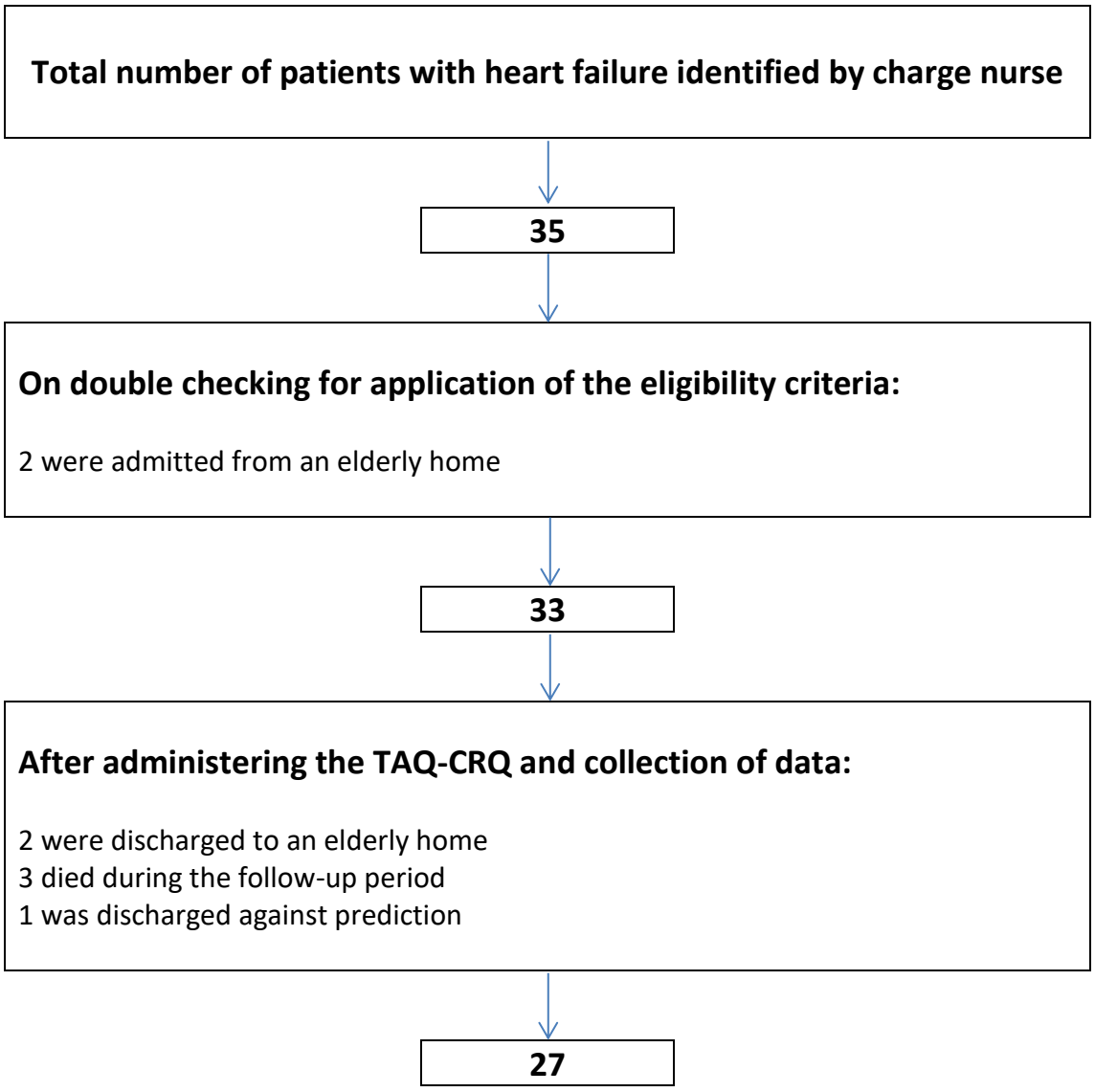
Complaint/Diagnosis on admission/readmission	Drug/device implicated
Exacerbation of CHF	Stopped Bumetanide (diuretic)
Shortness of breath	Mistook symptom as asthma - took prednisolone 40mg ŧ
Exacerbation of CHF	Stopped Bumetanide (diuretic)
Exacerbation of CHF	Serum digoxin below therapeutic level
Exacerbation of CHF	CPAP not used, often skips diuretic dose
Bradycardia	Started on Atenolol; Valsartan stopped
Shortness of breath	Inappropriate inhaler technique
Bradycardia	Atenolol 25mg
Bradycardia	Atenolol 100mg; Amlodipine stopped for 1 month
Bradycardia; High INR	Nebivolol; interaction warfarin - escitalopram
CHF exacerbation; anaemia	Warfarin causing recurrent anaemic episodes
Bradycardia	Carvedilol 25mg bd started previous admission for 4 days ŧ

ŧ Implicated cause of readmission

3.3 Phase 3 results

From 15th October 2018 through November 2018 a total of 35 patients were identified by the charge nurse of the respective cardiac ward. The final cohort consisted of 27 patients (Table 3.10).

Table 3.10 Final Phase 3 intervention cohort of patients with heart failure after applying the inclusion and exclusion criteria.



Phase 3 carried out from 15th October 2018 to 30st November 2018. 60-day follow-up period up to 31st January 2019.

Table 3.11 depicts the baseline data of all the patients within the cohort and the patients that were readmitted within the 30-day time window. Considering the complete cohort and the readmitted sub-group, patients within the readmitted group had a mean age of 78.4 ± 5.6 which was older than that of the complete cohort. All patients were Caucasian of which 74% in the complete group and 80% in the readmitted group were male. TAQ score for readmitted patients and complete group was similar with a mean of 77%. The readmitted sub-group had a higher number of above average TAQ score that benefitted from strong family caregiver support. The potential of patients into self-care was lower in the readmitted subgroup, 25% ± 0.0. versus 38.9% ± 24.4. The mean hospital stay in days for the readmitted group was more than that of the complete group. Considering HF investigations, the readmitted sub-group had a higher percentage of patients with a reduced ejection fraction (<40%) and a higher percentage of patients with an NTproBNP of greater than 1800pg/ml. Considering co-morbidities, the majority of patients had multiple co-morbidities. The readmitted subgroup had a higher percentage of patients with, COPD or asthma, coronary artery disease and thyroid disorders. Considering social history, the readmitted subgroup had a higher percentage of patients who are ex-smokers. Considering medication, 2 patients were on the newer HF drugs (ARNI and ivabradine) none of whom were among those readmitted. Beta-blockers, ACE/ARBs and aldosterone antagonists' doses indicated a potential margin for up-titration leading to potential issues with tolerance and adherence. The number of readmitted patients on digoxin was significantly higher when compared to the whole group (p = 0.049). Three of the patients were admitted as a consequence of suspected non-adherence to diuretics.

Table 3.11 Baseline data of patients within the Phase 3 intervention cohort

Characteristic or Variable	All cohort (N = 27)	Readmitted (n = 5) 30-day all-cause	z-score t-score	*p*-value
Age, Mean ± SD, year	73.6 ± 9.6	78.4 ± 5.6	1.080	0.289
Male, no (%)	20 (74)	4 (80.0)	0.281	0.779
Ethnicity, Caucasian, no. (%)	27 (100)	5 (100.0)	-	-
Mortality-related loss to follow-up, no/discharged, (%)	3/30 (10)	Not applicable	-	-
Treatment adherence score, Mean ± SD	77.5 ± 7.6	77 ± 6.2	0.143	0.887
>70 without family caregiver support, no. (%)	14 (51.8)	3 (60.0)	0.335	0.728
>70 with family caregiver support, no. (%)	10 (37.0)	2 (40.0)	0.126	0.897
Potential engagement into self-care, Mean % ± SD ǂ	38.9 ± 24.4	25.0 ± 0.0	1.258	0.218
Hospital stay, Mean ± SD, days	5.8 ± 3.4	6.6 ± 3.2	0.484	0.632
Number of admissions in previous year, Mean ± SD	1.3 ± 1.8	0.8 ± 0.4	0.667	0.510
Ejection fraction, no (%)				
≤40%	14 (52.8)	3 (60.0)	0.335	0.728
≥41≤49	3 (11.1)	1 (20.0)	0.552	0.582
Unknown or with preserved EF	10 (37.0)	1 (20.0)	0.737	0.459
NT-proBNP, no (%)				
>125pg/ml	2 (7)	0 (00.0)	0.887	0.373
>900pg/ml	4 (15)	0 (00.0)	0.920	0.358
>1800pg/ml	17 (63)	4 (80.0)	0.737	0.459
Unknown	4 (15)	1 (20.0)	0.293	0.772
Comorbidities, no (%)				
Hypertension	19 (70.4)	4 (80.0)	0.440	0.660
Coronary artery disease	15 (55.5)	5 (100.0)	1.886	0.059
Diabetes	14 (51.8)	1 (20.0)	1.311	0.190
COPD or Asthma	7 (25.9)	2 (40.0)	0.643	0.522
Obstructive sleep apnoea	0 (00.0)	0 (00.0)	-	-
Renal disease	9 (33.3)	2 (40.0)	0.288	0.772
Arrhythmia	11 (40.7)	4 (80.0)	1.616	0.105
Anaemia	0 (00.0)	0 (00.0)	-	-
Myocardial infarction	4 (14.8)	1 (20.0)	0.293	0.772
Thyroid disorder	1 (03.7)	1 (20.0)	1.383	0.168
Depression, Anxiety or Insomnia	2 (07.4)	0 (00.0)	0.628	0.529
Social history, no (%)				
Smoker	3 (11.1)	0 (00.0)	0.783	0.435
Ex-Smoker	13 (48.1)	4 (80.0)	1.311	0.190
Alcohol use	1 (3.7)	0 (00.0)	0.437	0.660
Private family doctor	22 (81.5)	4 (80.0)	0.078	0.936
Discharge medications, no (%)				
Beta-blocker [margin for dose up-titration, no (%)]*	21 (77.7) [13 (86.7)]	5 (100.0) [3 (75.0)]	1.169 0.569	0.242 0.569
Diuretics	27 (100)	5 (100.0)	-	-
ACEs/ARBs [margin for dose up-titration, no (%)]*	19 (70.3) [12 (92.3)]	4 (80.0) [2 (66.7)]	0.440 1.211	0.660 0.226
Nitrates	8 (29.6)	2 (40.0)	0.460	0.646
Calcium channel blocker	5 (18.5)	1 (20.0)	0.078	0.936
Aldosterone antagonist [margin for dose up-titration, no (%)]*	19 (70.4) [11 (100)]	4 (40.0) [3 (100)]	0.440 -	0.660 -
Warfarin or NOAC	10 (37.0)	3 (60.0)	0.960	0.337
Digoxin	5 (18.5)	3 (60.0)	1.968	0.049
Hydralazine	0 (00.0)	0 (00.0)	-	-
ARNI and/or Ivabradine	2 (07.4)	0 (00.0)	0.629	0.529

ǂ Potential engagement into self-care defined as the percentage sum of correct answers to four basic questions in relation to required knowledge on heart failure.

* Proportion expressed as a percentage of patients on a BB, ACE/ARB or AA who are HFrEF or HFmrEF

3.3.1 Hospital 30-day and day 31-60 readmission rate

From 27 patients with a primary or secondary diagnosis of heart failure 18.5% were readmitted within 30 days from discharge. No ED visits were recorded. One patient was readmitted more than once within the first 30 days from discharge. Six patients were readmitted between day 31 and day 60 whom 2 were also readmitted in the first 30 days and one patient had 2 readmissions within this time window.

3.3.2 Condition-related questions

With regards to condition-related questions, the answers were considered to be correct responses according to the scheme shown in Table 2.1. The mean grade of the cohort for the four questions was 38.9% (range: 0%-100%) with 11 patients giving an unsatisfactory answer to at least 3 of the questions. 16 patients were unable to name their diuretic. 24 patients knew that salt should be avoided. 5 patients added salt-containing seasoning deliberately while cooking. 24 patients were unable to give a satisfactory answer related to the need of weight monitoring to check fluid overload and again only associated weight with body fat. 22 patients were unable to mention at least 1 basic symptom apart from shortness of breath. Chest pain was a symptom mentioned by 10 patients not included in the list for correct responses. 10 of the patients exhibited a mismatch between the TAQ score and the percentage grade to the knowledge questions (medium-high TAQ score versus low grade 0-25% to CRQs).

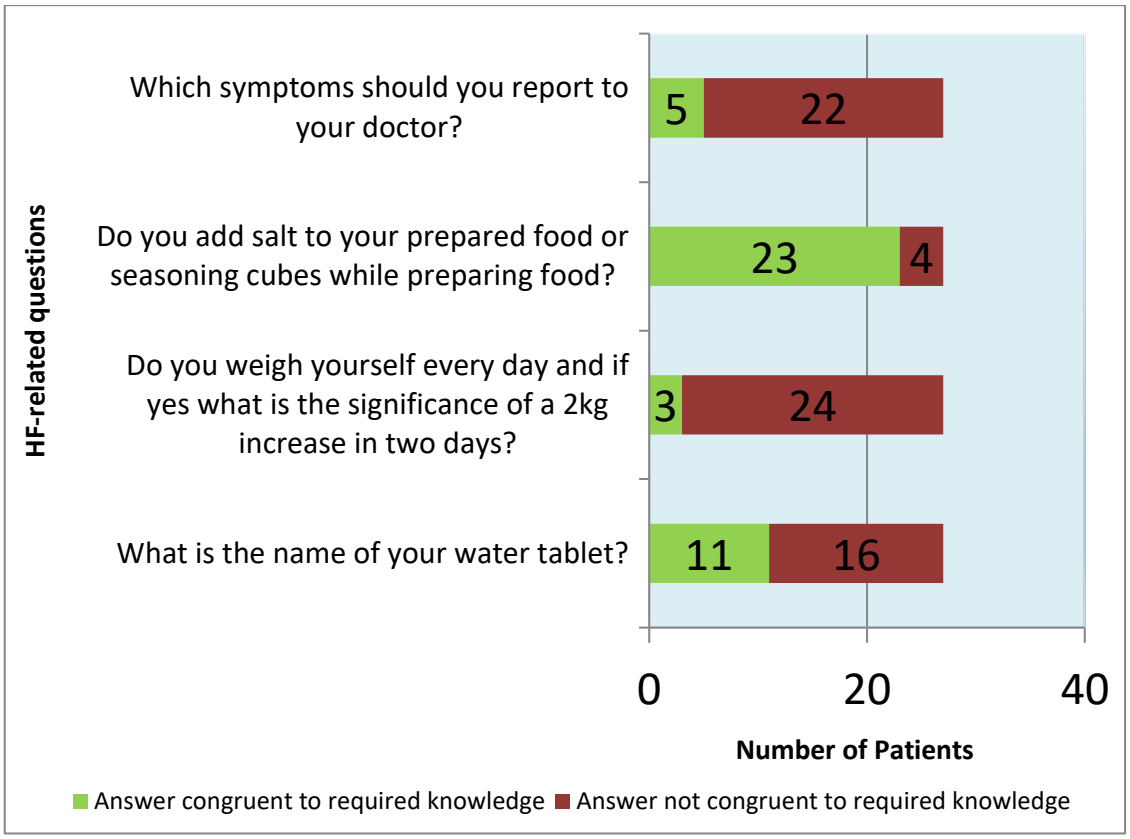


Figure 3.3 Patient's response (N = 27) to condition-related questions on HF. ***The mean grade of the cohort for the four questions was 38.9% (range: 0%-100%)***

3.3.3 Comparison of the non-intervention and intervention cohorts

Table 3.12 compares the baseline data of non-intervention (Phase 2) and intervention (Phase 3) cohorts. No statistically significant difference was observed between groups with respect to age, sex, co-morbidities, hospital length of stay, NT-proBNP levels and social history. TAQ score for the intervention group was significantly higher than that of the non-intervention group with a mean of 77.5% ± 7.6 and 70.9% ± 10.4 respectively (p = 0.004). The non-intervention group had a higher number of above average TAQ score that benefitted from strong family caregiver support. The potential of patients into self-care was lower in the intervention group, 38.9% ± 24.4 versus 43.3 ± 23.3. This

difference was not statistically significant. Considering HF investigations, the intervention group had a higher percentage of patients with a reduced ejection fraction (p = 0.017) and a lower percentage of patients with preserved/unknown ejection fraction (p = 0.006). Considering medication, the intervention group had significantly higher percentages of patients on Beta-blockers (p = 0.011) and aldosterone antagonists (p = 0.007). At 95% confidence interval and $p < 0.05$ level of significance the control group and the intervention cohort statistically significantly differed with respect to TAQ score, percentage of patients with reduced ejection fraction, percentage of patients with preserved ejection fraction and percentage of patients on a beta-blocker and an aldosterone antagonist. With regards to mortality the control group and the intervention group did not differ significantly although the percentage of patients who were lost to follow-up within the intervention group was higher than within the non-intervention control group.

Regarding the readmission-related primary and secondary outcomes (Table 3.13), with respect to the 30-day all-cause unplanned readmission rate, there was a 12.3 absolute percentage drop from Phase 2 to Phase 3 (p = 0.242) which was partially reversed between day 31-60 (secondary outcome) were there was an 8.7 absolute percentage point increase (p = 0.211). Taking the first 60 days post-discharge, the absolute percentage difference between the two cohorts was a 3.6% drop between Phase 2 and Phase 3. The results were not statistically significant.

Table 3.12 Comparison of baseline data of patients within the Phase 2 non-intervention and Phase 3 intervention cohort

Characteristic or Variable	Non-intervention cohort (N = 52)	Intervention cohort (N = 27)	z-score t-score	*p*-value
Age, Mean ± SD, year	73.7 ± 9.7	73.6 ± 9.6	0.060	0.953
Male, no (%)	38 (73.1)	20 (74)	0.095	0.920
Ethnicity, Caucasian, no. (%)	52 (100)	27 (100)	-	-
Mortality-related loss to follow-up, no/discharged (%)	3/55 (5.5)	3/30 (10)		
Treatment adherence score, Mean ± SD	70.9 ± 10.4	77.5 ± 7.6	2.933	0.004
>70 without family caregiver support, no. (%)	17 (32.7)	14 (51.8)	1.654	0.099
>70 with family caregiver support, no. (%)	10 (19.2)	10 (37.0)	1.726	0.084
Potential engagement into self-care, Mean % ± SD ǂ	43.3 ± 23.3	38.9 ± 24.4	0.781	0.437
Hospital stay, Mean ± SD, days	6.9 ± 7.4	5.8 ± 3.4	0.738	0.463
Number of admissions in previous year, Mean ± SD	1.2 ± 1.5	1.3 ± 1.8	0.270	0.788
Ejection fraction, no (%)				
<40%	13 (25.0)	14 (52.8)	2.387	0.017
≥41≤49	3 (5.80)	3 (11.1)	0.850	0.395
Unknown or with preserved EF	36 (69.2)	10 (37.0)	2.752	0.006
NT-proBNP, no (%)				
>125pg/ml	8 (15.4)	2 (7)	1.011	0.313
>900pg/ml	8 (15.4)	4 (15)	0.067	0.944
>1800pg/ml	27 (51.9)	17 (63)	0.937	0.347
Unknown	9 (17.3)	4 (15)	0.283	0.779
Comorbidities, no (%)				
Hypertension	35 (67.3)	19 (70.4)	0.278	0.779
Coronary artery disease	21 (40.4)	15 (55.5)	1.284	0.201
Diabetes	29 (55.8)	14 (51.8)	0.332	0.741
COPD or Asthma	17 (32.7)	7 (25.9)	0.620	0.535
Obstructive sleep apnoea	5 (9.6)	0 (00.0)	1.665	0.097
Renal disease	8 (15.4)	9 (33.3)	1.841	0.658
Arrhythmia	17 (32.7)	11 (40.7)	0.709	0.478
Anaemia	2 (3.8)	0 (00.0)	1.032	0.303
Myocardial infarction	10 (19.2)	4 (14.8)	0.488	0.624
Thyroid disorder	3 (7.0)	1 (03.7)	0.397	0.689
Depression, Anxiety or Insomnia	5 (5.8)	2 (07.4)	0.328	0.741
Social history, no (%)				
Smoker	1 (1.9)	3 (11.1)	1.767	0.077
Ex-Smoker	18 (34.6)	13 (48.1)	1.168	0.242
Alcohol use	1 (1.9)	1 (3.7)	0.478	0.631
Private family doctor	41 (78.8)	22 (81.5)	0.276	0.779
Discharge medications, no (%)				
Beta-blocker	25 (48.1)	21 (77.7)	2.531	0.011
[margin for dose up-titration, no (%)]*	[5 (55.6)]	[13 (86.7)]	1.704	0.891
Diuretics	48 (92.3)	27 (100)	1.479	0.139
ACEs and/or ARBs	31 (59.6)	19 (70.3)	0.941	0.347
[margin for dose up-titration, no (%)]*	[6 (50.0)]	[12 (92.3)]	2.354	0.019
Nitrates	18 (34.6)	8 (29.6)	0.447	0.653
Calcium channel blocker	13 (25.0)	5 (18.5)	0.651	0.516
Aldosterone antagonist	20 (38.5)	19 (70.4)	2.691	0.007
[margin for dose up-titration, no (%)]*	[8 (88.9)]	[11 (100)]	1.134	0.258
Warfarin or NOAC	20 (38.5)	10 (37.0)	0.124	0.904
Digoxin	5 (9.6)	5 (18.5)	1.129	0.258
Hydralazine	3 (5.8)	0 (00.0)	1.273	0.204
ARNI and/or Ivabradine	4 (7.7)	2 (07.4)	0.045	0.960

ǂ Potential engagement into self-care defined as the percentage sum of correct answers to four basic questions in relation to required knowledge on heart failure.

* Proportion expressed as a percentage of patients on a BB, ACE/ARB or AA who are HFrEF or HFmrEF

Table 3.13 Comparison of primary and secondary outcomes within the Phase 2 non-intervention and Phase 3 intervention cohort

Outcome	Phase 2 (N = 52)	Phase 3 (N = 27)	Absolute difference (%)	*p*-value
30-day all-cause readmission rate	(30.8%)16	(18.5%)5	12.3↓	0.242
Day 31-60 all-cause readmission rate	(13.5%)7	(22.2%)6	8.7↑	0.211
Pharmacist interventions	-	284	-	-
Discharge time	-	No effect	-	-

3.3.4 Comparison of the readmitted patients

Table 3.14 compares the baseline data of the readmitted patients within the non-intervention and intervention cohorts. Statistically significant difference was observed only with respect to medications. These were Beta-blockers (p = 0.044) and digoxin (p = 0.008) for which the readmitted patients within the intervention cohort had a higher percentage.

Table 3.14 Comparison of baseline data of readmitted patients within the Phase 2 non-intervention and Phase 3 intervention cohort

Characteristic or Variable	Readmitted (Non-intervention) (n = 16)	Readmitted (Intervention) (n = 5)	z-score t-score	*p*-value
Age, Mean ± SD, year	70.6 ± 9.7	78.4 ± 5.6	1.693	0.107
Male, no (%)	12 (75.0)	4 (80.0)	0.229	0.818
Ethnicity, Caucasian, no. (%)	16 (100)	5 (100.0)	-	-
Mortality-related loss to follow-up, no/discharged (%)	Not applicable	Not applicable		
Treatment adherence score, Mean ± SD	73.2 ± 11.0	77 ± 6.2	0.732	0.473
>70 without family caregiver support, no. (%)	4 (25.0)	3 (60.0)	1.449	0.147
>70 with family caregiver support, no. (%)	5 (31.3)	2 (40.0)	0.362	0.719
Potential engagement into self-care, Mean % ± SD ǂ	35.9 ± 20.3	25 ± 0.0	1.181	0.252
Hospital stay, Mean ± SD, days	7.4 ± 12.3	6.6 ± 3.2	0.148	0.884
Number of admissions in previous year, Mean ± SD	2.0 ± 1.9	0.8 ± 0.4	1.355	0.191
Ejection fraction, no (%)				
≤40%	4 (25.0)	3 (60.0)	1.449	0.147
≥41≤49	1 (6.3)	1 (20.0)	0.914	0.363
Unknown or with preserved EF	11 (68.8)	1 (20.0)	1.923	0.549
NT-proBNP, no (%)				
>125pg/ml	3 (18.8)	0 (00.0)	1.046	0.294
>900pg/ml	1 (6.3)	0 (00.0)	0.573	0.569
>1800pg/ml	11 (68.8)	4 (80.0)	0.486	0.624
Unknown	1 (6.3)	1 (20.0)	0.914	0.363
Comorbidities, no (%)				
Hypertension	8 (50.0)	4 (80.0)	1.183	0.238
Coronary artery disease	10 (62.5)	5 (100.0)	1.620	0.105
Diabetes	6 (37.5)	1 (20.0)	0.725	0.472
COPD or Asthma	10 (62.5)	2 (40.0)	0.887	0.373
Obstructive sleep apnoea	2 (12.5)	0 (00.0)	0.831	0.407
Renal disease	2 (12.5)	2 (40.0)	1.367	0.171
Arrhythmia	5 (31.3)	4 (80.0)	1.923	0.055
Anaemia	0 (0.0)	0 (00.0)	-	-
Myocardial infarction	4 (25.0)	1 (20.0)	0.229	0.818
Thyroid disorder	2 (12.5)	1 (20.0)	0.418	0.674
Depression, Anxiety or Insomnia	3 (18.8)	0 (00.0)	1.046	0.294
Social history, no (%)				
Smoker	1 (6.3)	0 (00.0)	0.573	0.569
Ex-Smoker	8 (50.0)	4 (80.0)	1.183	0.238
Alcohol use	1 (6.3)	0 (00.0)	0.573	0.569
Private family doctor	13 (81.3)	4 (80.0)	0.062	0.952
Discharge medications, no (%)				
Beta-blocker [margin for dose up-titration, no (%)]*	8 (50.0) [1(50.0)]	5 (100.0) [3 (75.0)]	2.001 0.612	0.044 0.452
Diuretics	14 (87.5)	5 (100.0)	0.831	0.407
ACEs and/or ARBs [margin for dose up-titration, no (%)]*	11 (68.8) [2(66.7)]	4 (80.0) [2 (66.7)]	0.486 -	0.624 -
Nitrates	6 (37.5)	2 (40.0)	0.101	0.920
Calcium channel blocker	5 (31.3)	1 (20.0)	0.486	0.624
Aldosterone antagonist [margin for dose up-titration, no (%)]*	6 (37.5) [2(66.7)]	4 (40.0) [3 (100)]	1.661 1.095	0.097 0.271
Warfarin or NOAC	8 (50.0)	3 (60.0)	0.391	0.697
Digoxin	1 (6.3)	3 (60.0)	2.672	0.008
Hydralazine	2 (12.5)	0 (00.0)	0.831	0.407
ARNI and/or Ivabradine	2 (12.5)	0 (00.0)	0.831	0.407

ǂ Potential engagement into self-care defined as the percentage sum of correct answers to four basic questions in relation to required knowledge on heart failure.

* Proportion expressed as a percentage of patients on a BB, ACE/ARB or AA who are HFrEF or HFmrEF

3.3.5 Interventions within the phase 3 cohort

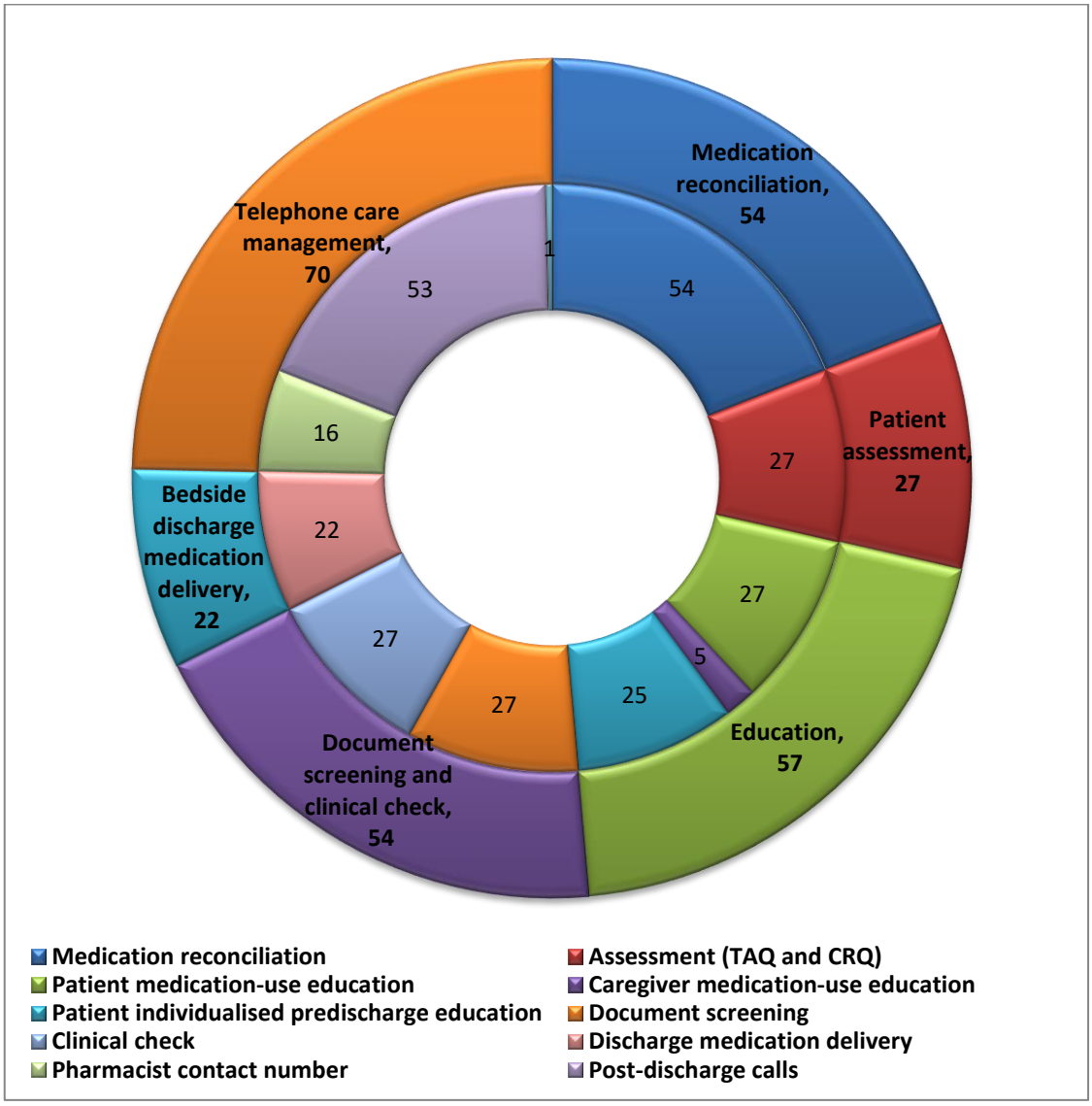
A total of 284 interventions were performed as part of the pharmaceutical TOC pathway. These were carried out during attendance at the ward for 33 sessions between 7.30 to 15.30. The pharmaceutical TOC pathway yielded a total of 348 contributions that addressed PCIs. The presence of a pharmacist at the ward and during ward rounds yielded 46 pre-discharge contributions, 19 of which were pharmacotherapeutic interventions. Thirteen contributions were information given to queries by doctors regarding medication or entitlement procedures 3 of which were bedside drug information. Contributions which were pharmacist initiated included 12 dose adjustments. One contribution involved an explanation to doctors about the importance of the case summary, discharge prescriptions and last updated treatment chart being in agreement. Two contributions following daily reviews were related to contraindicated concomitant use of drugs requiring temporary omission of one of the drugs and one contribution requiring monitoring if two drugs were kept on the regimen. One contribution involved the extension of treatment for an intravenous antibiotic. Two contributions involved changes in medication due to deteriorating renal function. One contribution involved the flagging of a patient for Commcare®[12] nursing services. One contribution involved the co-ordination for changes in medication resulting in Schedule V applications having to be issued by three different consultants - cardiology, nephrology and endocrinology. One contribution involved the pre-arrangement of home oxygen therapy.

---

[12]Commcare® is a non-government organisation that gives home care services including preparation of adherence aids such as dossette boxes to elderly patients.

Eleven contributions were requests by patients related to the use of medication, entitlement to free medication, timely delivery of medication to POYC pharmacy and replacement of a malfunctioning insulin pen.

Figure 3.4 depicts the proportion of pharmacist interventions according to the six pillars of the developed pharmaceutical TOC pathway. A breakdown of each pillar is represented. Table 3.15 follows from Figure 3.4 to further include the PCIs addressed.



Medication reconciliation – admission/discharge, two sessions represented together. Patient assessment – TAQ/CRQs, one session

Figure 3.4 Pharmacist interventions according to the six-pillar pharmaceutical TOC pathway and corresponding breakdown

Table 3.15 depicts the frequency of the interventions performed by the pharmacist and the corresponding contributions to address PCIs other than those performed during ward rounds.

Table 3.15 Pharmacist interventions, frequency and PCIs addressed during TOC

Pharmacist intervention	Interventions frequency	Number/type of PCIs addressed
Medication reconciliation at admission and at discharge	54	16
Administration of the treatment adherence questionnaire and condition-related questions	27	Education need
Patient medication-use education	27	Education need
Caregiver medication-use education	5	Education need
Patient individualised pre-discharge education	25	193
Screening of documentation (prescriptions, case-summary, entitlement documents)	27	1
Clinical check for drug-related problems	27	6
3 days discharge medication brought to ward by the pharmacist	22	Access need
Pharmacist contact number to discuss medication-related problems	16	3
Telephone calls to discuss medication related problems during the 30 days after discharge	53	82
Direct communication of hospital pharmacist with post-discharge providers (PDP)* regarding recently discharged patients	1	1

**PDP = POYC pharmacist and/or private family doctor (PFD)*

Medication reconciliation was performed on admission and at discharge. Out of 16 discrepancies only 2 were detected at discharge. The medications implicated on admission were vitamins, pain killers, bisphosphonates, medication for benign prostatic hyperplasia and medication for vertigo. Dose identification was also a problem during

drug history taking. The TAQ and CRQs were administered to all patients with two patients being more challenging as they suffered from hearing problems. This was also the case with medication-use education. Caregiver medication-use education was limited by the timing the relatives payed visits to the patient which frequently was after 16:00 making it difficult to reach. Only five caregivers were given the medication-use education. The pharmacist researcher performed 25 individualised pre-discharge education interventions with a total of 17 themes that were cumulatively invoked 193 times during patient education (Table 3.17). Screening of documents for medication entitlement resulted in 1 contribution related to an expired permit for a non-formulary drug. Screening of drug-related problems resulted in 6 pharmacist contributions which were related to dose selection, previously reported cough to ACE inhibitors and the lack of available valsartan dosage form that can be split. The 3-day discharge medication supply which was brought to the ward by the pharmacist took place 22 times. There was no effect on the discharge time but permitted medication-use reinforcement and reduced the waiting time burden as it relieved the patient or family caregiver from going to the pharmacy. The pharmacist was contacted by telephone 3 times by patients and the problems were related to the supply of medication from the POYC pharmacy and one call was related to a presumed omission of a drug on the Schedule V application which however was not the case. TCM involved a total of 53 calls which dealt with 82 contributions. Table 3.18 shows a breakdown of the themes addressed during this intervention. Direct communication with post-discharge providers was used only once to ensure a patient takes the right doses of insulin as during drug history taking claimed to take a higher dose than that on which he was discharged in his previous admission. The patient was suffering from hypoglycaemia. The Discharge Medication List form

which was developed for the purpose was not used because of the co-operation demonstrated by the discharging doctors to issue congruent discharge prescriptions and case summaries with the last updated treatment chart. Another document bearing the same details was therefore useless.

3.3.6 Individualised pre-discharge education

Responses triggered through the TAQ, the condition-related questions, the patient's treatment regimen and history were used to develop individualised pre-discharge education. In addition to the basic education about the use of the 'Guide to Patients: Medication on Discharge', medication-use tips (Table 3.16) and general advice, the intervention cohort benefitted from targeted sessions which were performed after or concurrently with the administration of the TAQ and CRQs.

Table 3.16 Standard education given to all patients

How to use the Guide to Patients: Medication on Discharge	Medication-use
How to take the medication and at what time	Medication-use
What is the medication used for	Medication-use
What to do if the medication package is different	Medication-use
What to do if a dose is missed	Medication-use
Instructing patient to remove all old prescriptions from POYC pouch	General advice
Importance of follow-up with PFD/Specialist/POYC pharmacist post-discharge	General advice
Encourage attendance to follow-up appointments (heart failure clinic, ACC etc.)	General advice

Excluding those sessions associated with patients who were later lost to follow-up Table 3.17 depicts the number of patients benefiting from the individualised pre-discharge education.

Table 3.17 Number of patients benefiting from individualised pre-discharge education broken down according to theme (N=27).

Theme for individualised pre-discharge education	Source of information	No of patients benefiting
Importance of asking your doctor or pharmacist questions about your condition and medication	TAQ	20
Taking prescribed medication at the prescribed times allowing for some flexibility regarding diuretic dosing	TAQ	19
Checking for interactions with OTC medication especially if not buying the medication from the usual POYC	TAQ	14
Explain why companies are required to list all side-effects on medication leaflet	TAQ	5
Use of adherence aids namely dossette boxes	TAQ	4
Importance of not stopping medication without consulting your doctor	TAQ	4
Explain that heart failure treatment involves increase of doses even if you are feeling well	REGIMEN/TAQ	14
Use of devises such as inhaler technique, spacers, tablet cutters etc.	REGIMEN/TAQ	5
Explain benefits of new medication not available on the formulary	REGIMEN/TAQ	2
Which medication is temporary, and which is indefinite (indicate clearly on Guide)	REGIMEN	4
Importance of immunisation particularly the influenza vaccine	HISTORY	4
Importance of stopping smoking, reducing alcohol consumption and information about availability of nicotine patches	HISTORY	3
Emphasising the symptoms that should be immediately reported to the doctor (depends on patient's response)	CRQ	25
Introducing the concept of daily weight monitoring to check for fluid overload	CRQ	24
Supporting instructions given by doctors regarding fluid restriction	CRQ	24
Knowing and recognising the name of the diuretic on different packages	CRQ	17
Emphasising the importance of a salt restricted diet and the availability of salt-free seasoning	CRQ	5

3.3.7 Post-discharge telephone care management

Post discharge telephone care management (TCM) was adaptive according to the individual needs of the patient. All calls were kept less than 20 minutes. A total of 53 calls were performed. Table 3.18 describes the topics impacting pharmaceutical care addressed during TCM and the number of patients benefiting.

Table 3.18 Number of patients benefiting from TCM broken down according to theme (N=27)

Theme	Description	Number of patients benefiting
Reminders regarding communication with PFD and POYC pharmacist	Reminding patient about the importance of informing PFD and POYC pharmacist about recent admission with an emphasis on changes to medication	24
Reinforcement of education	General reinforcement regarding adherence and asking again the CRQs to establish the concept of teaching through repetition across the care continuum	24
Side-effects of new medication prescribed	Probing about side-effects of newly prescribed medication and/or increase in doses and how the patient is dealing with them	13
Refill and entitlement issues	Resolving of refill and entitlement issues which may arise post-discharge including MAS* check before telephone call	8
Medication reminders	Reminding patient about pre-established changes to the medication regimen within the treatment plan at discharge such as tailing down of doses of amiodarone and steroids, anticoagulant INR monitoring of newly started patients and continuation of antibiotics and their respective duration of treatment	6
Probing about medication changeovers	Probing about changeover to medication that were temporarily unavailable and are back in stock or a permanent alternative established	6
Rescheduling of missed appointments	Rescheduling for a missed appointment for Holter monitoring.	1

**MAS – Medicines approval system – software that shows approval for medicine entitlement on a named-patient basis*

The mean percentage grade to the CRQs during TCM was 48.1% which was a 9.2 percentage point increase over the baseline grade obtained during the hospital stay. This increase was not statistically significant. Figure 3.5 depicts the post discharge responses during TCM for the CRQs broken down according to question.

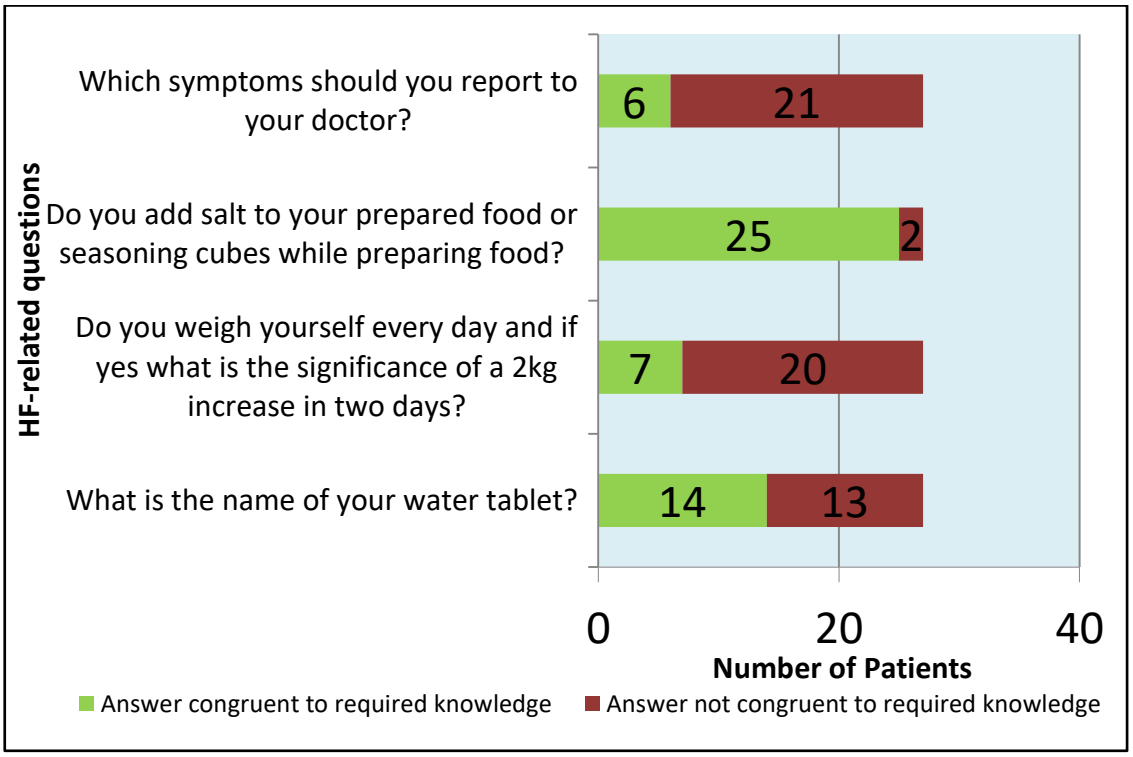


Figure 3.5 Patient's response (N = 27) to condition-related questions on HF during TCM. ***The mean grade of the cohort for the four questions was 48.1% (range: 0%-100%)***

Improvement was recorded in all questions mostly with the weight monitoring question followed by the name of the diuretic. Patients who showed improvement with respect to weight monitoring also reported attendance to the HF clinic at MDH. One patient who in the baseline assessment obtained 25% did not return the call during TCM and 2 patients were difficult to communicate on telephone. For comparison purposes it was assumed that these patients have made no improvement.

3.4 Summary of findings

Table 3.19 Summary of findings classified according to phase of study

Phase 1 – Surveys and focus group
Gaps within the process of TOC took the resemblance of inconsistency, lack of timeliness, deficiencies or lack of standardisation.
Problems with documentation were the most frequent pharmaceutical care issues encountered during discharge dispensing (46.6%) and POYC refills (35%).
The pharmacist-facilitated TOC interventions were to take the patient through a pathway consisting of 6 pillars: Medication Reconciliation, Patient Assessment, Patient/Caregiver Education, Document screening and clinical check, Bedside discharge medication delivery and Telephone care management all based on a ward pharmacist
Phase 2 and Phase 3 – TAQ* and CRQs*
Patient assessment through the TAQ and the CRQs demonstrated a medium to high adherence, strong family caregiver support and the lack of potential engagement in self-care did not reflect a low adherence to treatment.
The intervention cohort showed an overall improvement in CRQ grade from 39% obtained during baseline assessment to 48% after the interventions during TCM (p = 0.165).
Phase 2 and Phase 3 – Primary outcome and secondary outcomes
The 30-day all-cause unplanned readmission rate of the non-intervention cohort was 30.8% and day 31-60 was 13.5%. Patients with COPD/asthma as co-morbidity were more likely to be readmitted (p = 0.033).
The 30-day all-cause unplanned readmission rate of the intervention cohort was 18.8% and day 31-60 was 22.2%. Patients on digoxin were more likely to be readmitted (p = 0.049).
The difference between the non-intervention and intervention cohort with respect to 30-day readmission rate (intervention period) was 12.3 percentage points reduction. This was not statistically significant (p = 0.242).
The difference between the non-intervention and intervention cohort with respect to day 31-60 readmission rate (just observation) was an 8.7 percentage point increase. This was not statistically significant (p = 0.211).
The pharmacist delivered a total 284 interventions of which medication education and counselling was the most frequent followed by medication reconciliation. No effect on discharge times was recorded.

** TAQ – Treatment adherence questionnaire; CRQs – Condition-related questions*

4. Discussion

“Great minds discuss ideas, average minds discuss events, small minds discuss people”

Eleanor Roosevelt

4.1 Rationale that supports service development

In the final chapter of this thesis one can reflect on how the findings fit in the context of published studies, what does this thesis demonstrate and contribute to the field of study and from a pragmatic viewpoint, what is the takeaway that can be translated into action in practice.

The research departed with the rationale that every hospital aspiring to shift to value-based care within an integrated healthcare system must investigate patient outcomes including readmission rate. The obvious question at that point was, “how does a preventative approach to PCIs during TOC affect this rate?” Heart failure patients were chosen as the subjects for the study because readmission rate is comparatively high; the condition is heavily dependent on medication for its therapeutic management and the fact that the cardiology department is one of the most dynamic departments at MDH but still lacks the services of a clinical/ward pharmacist that can see through the medication- management process during TOC.

Preventative pharmaceutical TOC interventions can be defined as: *Those interventions intended to ward off pharmaceutical care issues which can perpetuate beyond the point of care transition by properly directing the interventions at the right place and the right time.*

Perception based on work experience alone was not enough to develop a pharmaceutical TOC pathway. The perceptions of the researcher led to the hypothesis that had to be tested and any conclusions had to be supported with evidence. The need for evidence led to Phase 1 of this study. What are the problems that can be encountered during the stages in care transitions? What problems can be foreseen and

prevented? Which are the attributes that should be present in a quality TOC service and in turn what actions do these attributes dictate? These questions formed the rationale behind the utilisation of the gap-finding tools and the undertaking of surveys which in turn supported the opinions of purposefully selected participants in a focus group convened to help the researcher identify the most desirable elements of a pharmaceutical TOC pathway.

Utilising gap-finding tools developed by specialised institutions, automatically enabled comparison of the state of affairs at MDH with universally applicable TOC best practices. The gap-finding tools and surveys helped the researcher to establish both the big picture, identify specific problems during TOC and support the focus group. The participation of professional key players, a patient and a family caregiver ensured a balanced discussion during the focus group. Patient satisfaction is considered to be a balance measure meaning that it can tilt the balance in favour or against an intervention even though the intervention can be feasible and improves outcomes. That is why the presence of patients and caregivers on the focus group was deemed important to establish the pharmacist interventions.

Pharmacist interventions within the hospital setting can bring about significant improvement in humanistic, clinical and economic outcomes. The study added to the body of literature on the impact of TOC interventions on clinical outcomes. Whereas previous studies have been largely carried out within healthcare systems and institutions geared to assess clinical outcomes, this study evaluated the impact of basic pharmaceutical care services provided by a strategically placed practice pharmacist in a teaching hospital operating within a healthcare system still tending towards fragmented

care. The researcher believes that any evaluation of this study warrants giving this fact its due consideration.

4.2 The study in perspective

It is appropriate to evaluate the present study from the perspective of authorities operating in this field. One such authority is the American Heart Association (AHA) which published a scientific statement on TOC programs (Albert *et al* 2015). The contribution of this thesis does not lie in innovative interventions but attempted to bring together a set of well described interventions making the study replicable. The lack of well described interventions was a major criticism put forward in the scientific statement by the AHA on TOC programs. All interventions were simple and basically address what patients expect and at times insist on receiving from pharmacy services in daily practice. Having satisfied this requisite, the thesis pulls out from analysing somewhat predictable outcomes such as patient satisfaction. Rather it attempts to explore readmission rate which is less obvious even though the reasons for its occurrence can be both predictable and preventable. The unpredictability of readmission especially the all-cause type was counteracted by the basic well described nature of the interventions which makes it easier to identify confounders.

The AHA observes that often, TOC modules used composite interventions, making it difficult to analyse the efficiency and effectiveness of individual interventions. The proposed pathway did not consist of bundled interventions involving nurses and other professions performing specific interventions like home visits and telemedicine. In any setting and any profession involved, a vision of improved healthcare quality must get

the basics right before aspiring to move on to more sophisticated high-end processes. This also applies to pharmaceutical care pathways facilitated by pharmacists. Although this study involved a pharmacy related composite of interventions these were mostly limited to those for which their specific usefulness is evidenced by literature, they are quality improvement initiatives and could be carried out by the researcher single handed. Evaluation of each component demonstrates that the interventions proposed in this study should be intentionally deployed together and in synchrony thus overriding the problem of not knowing what contribution each intervention is making towards the desired goal which in this case is reduction in readmission rate. This TOC pathway being validated can be considered low to moderately intensive given the current literature (Comin-Colet *et al,* 2016; Vedel *et al,* 2015). Probably, it is the combination of interventions that achieves outcomes of the order of readmission rate.

To the remark by the AHA as reported by (Albert *et al,* 2015) that "*further HF transition care research is needed to ensure best practices related to economically and clinically effective and feasible transition interventions that can be broadly applicable*", it is the view of the researcher that at least, the interventions described in the present study can be broadly applied as standard even to other conditions with the exception of the condition-related questions.

The AHA statement emphasises that increasing more services provided may not be the way to address readmission rates in HF but improvement on already existing ones should be considered. As already mentioned in this chapter, one of the main weaknesses encountered during Phase 1 of this thesis was the lack of consistency with the provision of already established services and utilisation of available tools. Most

interventions proposed in the present study although ideally forming part of a standard quality service are not carried out by a designated healthcare professional making their provision highly dependent on the work ethic and consistency of different healthcare professionals. The reduction in 30-day readmission rate observed in the present study might as well be that fraction of readmissions which was avoidable through these basic interventions.

As already described in the introduction the AHA scientific statement describes 3 models of TOC programs with which outcomes are associated. The proposed pathway in this thesis can be classified as a case management model with low to moderate pharmaceutical care-oriented interventions (Takeda et al, 2012; Vedel *et al,* 2015). This was chosen since MDH operates a clinic care model by means of the heart failure out-patient clinic which operates during normal working hours (7.30 to 14.30) and besides routine out-patient follow-ups of HF patients is also responsible for post-discharge optimization of GDMT and assessment of clinical stability. The proposed pathway augments this service and from the available evidence possesses the potential to reduce readmission rate.

The AHA statement considers that TOC programs that include services provided during hospitalisation such as education on the disease are optimal in-hospital care and not so much of TOC. To all intents and purposes, the present study utilised condition-related questions to identify those weak areas of knowledge which have a bearing on self-care when the patient is back in the community. Post-discharge phone calls can be considered a means to uphold care rather than improving transitions across different care settings. Phone call use was limited primarily to medication reminders related to

the discharge pharmaceutical care plan, getting feedback on problems related to medication access, discussing problems with adherence and side-effects and assess knowledge improvement. The intention of the post-discharge phone calls (TCM) was short-term goals targeting the safe transition from previous home medication to the recent discharge treatment.

Another factor to be considered is that rehospitalisation and mortality may have an intricate relation in that low HF rehospitalisation rate may reflect best quality care or low-quality inpatient treatment, conducive to premature death. The AHA recognises that some patients will succumb to severe HF irrespective of medical or intervention excellence. In the present study this problem should be taken into consideration. The number of patients who were lost to follow-up due to mortality was higher in the intervention group than in the control group. The fact that the intervention group had a higher percentage of patients with reduced ejection fraction must have contributed to this outcome (Cheng *et al,* 2014).

Regarding the role of the person directing the interventions the AHA states that nurses were the most frequently described providers, but their educational preparation varied across programs and was not always defined. The present study was conducted by a hospital pharmacist with 25 years of experience focusing on the medication needs of discharged patients which reflects the interventions proposed within the pathway. Even when it comes to teach-back, this technique was not used beyond the medication-use education and understanding of entitlement procedures by patients or family caregivers. The researcher deemed this appropriate as no formal training was carried out on teach-back methodology.

The AHA states that interventions applied, were based on other transition programs with no evidence for selecting intervention combinations (Albert *et al,* 2015). It is the view of the researcher that the choice of intervention combinations in quality improvement initiatives is heavily dependent on practicality and logistical constraints making it difficult to compare evidence.

4.3 Impact of Study

The study evaluated the impact of a ward pharmacist-based transitional care pathway on 30-day all-cause unplanned readmission in heart failure patients. The statistical analysis illustrated that compared with usual discharge care; the TOC pathway was not associated with significantly lower 30-day all-cause readmission. The 12.3 absolute percentage drop in readmission rate constitutes clinical significance especially in the context of PCIs prevented or resolved which were previously to the TOC pathway unmet needs. The 8.7 absolute percentage point increase in day 31-60 readmission rate associated with the TOC pathway was not statistically significant and should be interpreted in the light that no intervention was carried out during that period. This showed that patients are still vulnerable during this period warranting extended support. The rebound increase in readmission rate during day 31-60 in the intervention group confirms results found in literature that interventions which are not highly intensive must be implemented for a longer duration (Vedel *et al,* 2015). Not applying interventions during the late phase of the observation period was perhaps an oversight considering that this period was well into a seasonal phase characterised by chest infections, a known risk factor for hospitalisations and variations in transpiration and

perspiration as a result of cooler temperatures leading to increased susceptibility to congestion. The first 60 days post discharge as a whole still demonstrated a drop in readmission rate but the gap was reduced.

The comparisons shown in the results chapter yielded four points that merit attention. The first point is that the comparison between the complete non-intervention cohort and the readmitted subgroup in Phase 2 has shown that HF patients with COPD are at an increased risk of readmission. This result confirms that COPD is a predictor of readmission as evidenced by literature (Hartl *et al,* 2016; Richardson *et al,* 2016) and should be a factor if prioritisation of patients to follow a TOC pathway is applied. This result also supports the inclusion of individualised pre-discharge education to patients as it inevitably captured patients who needed improvement on inhaler technique and also captured an unmet need in pharmacotherapy as evidenced by the lack of available long-acting muscarinic antagonists on the formulary which are known to reduce readmissions (Maia *et al,* 2017).

The second point is the difference in TAQ score between Phase 2 and Phase 3. It is established in literature (Fitzgerald *et al,* 2011; Rosen *et al,* 2017; Hood *et al,* 2018) that patients with high adherence to treatment are less prone to readmissions. This means that patients within the intervention cohort *prima face* were less likely to be readmitted even though both groups demonstrated a mean score which can be considered as medium to high adherence.

The third point is the fact that the intervention cohort had a higher percentage of patients with HFrEF and a lower percentage of HFpEF. As evidenced by literature, both HFrEF patients and those with preserved ejection fraction bear the same risk to being

admitted with non-heart failure causes (Goyal *et al,* 2018). On the other hand, patients with reduced ejection fraction are at an increased risk of being admitted with acute decompensated heart failure (Caughey *et al,* 2018). The higher percentage of patients on beta blockers and aldosterone antagonists in the intervention group reflects the higher HFrEF patients since these two medication categories are well established within GDMT of HFrEF (Ponikowski *et al,* 2016).

At this point one must ask how do the differing factors between the non-intervention cohort and intervention cohort effect readmission rate. Although both differences are confounders, readmission rate may be interpreted in the context of their mutually compensating nature. To what extent these factors balance out at the end of the day is difficult to say when considering the sample size.

The fourth point is that 60% of the readmitted patients within the intervention cohort were on digoxin. This result differs with previous studies showing that patients on digoxin are at a reduced risk of 30-day readmission if also on a beta-blocker (Lam *et al,* 2018). Digoxin use and higher readmission rates have been associated for any reason following hospital discharge at six, 12, and 24 months (Alkhawam *et al,* 2019).

4.4 Transition-of-care – The epicentre of the Pharmacist's expertise

Weighing in the findings of the gap tools enhanced the opinion of the focus group that the first step to any clinical pharmacy services at the cardiology wards should be a ward-based pharmacist attending and participating in ward-rounds who enabled the provision of pharmaceutical TOC accurately, consistently and in a timely manner, optimising

medication-use during TOC. It was later evident that a pharmacist involved in TOC at ward level increased confidence among doctors and nurses when pressed with pharmaceutical care issues and reduced time devoted to addressing these PCIs.

The proposed pharmaceutical TOC pathway was developed based on preliminary fieldwork for the researcher to gain experience with the use of TAQ. In Phase 2, the TAQ served as a surrogate marker of patient compliance merely to compare the Phase 2 and Phase 3 cohorts. Adherence to treatment assessed using the TAQ developed by Anastasi *et al,* (2016), was chosen because its validation was carried out on heart failure patients making it the right tool for this study.

The researcher perceived the opportunity to utilise this tool as a means of identifying the adherence weaknesses of the patient and addressing them during individualised pre-discharge education. In turn, during the same preliminary interviewing sessions, the first two questions of the TAQ related to the patient's self-reported requirements of information about the condition and the medication led to the question, "What does the patient know in actual fact?" This led the researcher to develop the four CRQs that gave a relatively quick and practical means of obtaining an indication of the patients' self-care potential. Eventually the responses were utilised in Phase 2 for assessment purposes and in Phase 3 to individualise pre-discharge education and after discharge, assess the patient's knowledge improvement and the effectiveness of the researcher's teaching and possibly that of other providers. The CRQs were based on standard education material available in literature and were purposefully selected because knowledge about them was the basis for an important aspect of heart failure, learning to recognise warning signs of worsening HF and to manage a flexible diuretic regimen

(FDR). Individualised pre-discharge counselling was kept to introducing the concept to the patients not teaches the patients FDR.

As regards the utilisation of the TAQ and the CRQs, patients besides giving an answer were also left to elaborate further enabling nonthreatening assessment of attitudes towards medication use and condition-related knowledge. This facilitated drawing up of the individualised counselling.

Once it was decided that individualised pre-discharge education was to address medication-use, adherence issues and condition-related knowledge, the next question to answer was "What should be the timing of these sessions?" The focus group and criticism by a member of the academic staff during the 2018 UM Pharmacy Symposium, regarding the extra waiting time required during discharge from the MDH discharge lounge as a result of the pharmacist performing medication reconciliation and education prompted the decision to ensure any pre-discharge education to take place in advance of the discharge date. This exploited the advantage of a ward-based pharmacist who attended ward rounds and had a sound indication of when the patient will be discharged. On the day of discharge education was limited to reinforcement of how and when to take medication and provision of information on entitlement procedures for which a guide was also given. All this was facilitated by the researcher bringing the discharge medication supply to the ward motivating the patient by the prospect of not needing to go to the pharmacy.

Reduction in time devoted to addressing PCI's was also achieved through the compiling of a Pharmacist Interdisciplinary TOC Planning Checklist based on the problems encountered during discharge dispensing and POYC refills of which documentation

problems constituted the majority. The resolution of these PCIs from the respective pharmacy was lengthy, tedious and often involved having to send the patient or relative back to the ward or office. At discharge the patient should have all the required documents for a smooth TOC and the pharmacist should be guided by the see a problem, fix a problem concept but more important prevent a problem in the first place. Experience gathered during Phase 2 of the study led the researcher to refine the checklist by including the pathway components. The utilisation of the checklist by the pharmacist prior to discharge ensured that the patient left hospital without pending PCIs at least those which fall within the competency of the hospital.

Medication reconciliation is a standard in leading hospitals that operate readmission reduction strategies (Kash *et al,* 2019) because it is associated with patient safety. In most TOC programs medication reconciliation was recommended both at admission and at discharge (Mekonnen *et al,* 2016; Kreckman *et al,* 2018). This was also the case in this study owing to the contribution by members of the focus group who stressed the importance of establishing a correct list of home medication. Medication reconciliation on admission and at discharge ensured the most accurate list of medication and helped screening of DRPs by performing a concurrent clinical check to identify issues within the regimen including interactions, inappropriate doses and monitoring needs (Messerli *et al,* 2016; Silva *et al*, 2019).

An accurate list communicated to the patient, family caregivers and post-discharge providers in a clear manner was achieved through two main initiatives derived from the gap findings and focus group respectively. The first is the intervention to make aware discharging doctors that the discharge prescriptions and case summary should be in

accordance with the last updated treatment chart. This was a very important single intervention that based on the findings of the surveys saved much time on potential interventions to tackle problems of incongruences between these documents.

The second intervention was the utilisation of the 'Guide to patients – Medication on discharge' often referred to as the blue card. The main problem with this tool as revealed by the gap findings and focus group was its inconsistent use and the lack of available copies at the wards leading to its numerous printed versions often leaving out important information including name of patient, date of issue, what the medication is used for and when the medication should be stopped in case of temporary medication. The consistent use of the official version of this tool was deemed essential by the focus group. The only detail added by the researcher to the official version was the date of issue which was deemed essential for future reference by other providers.

The Guide to patients – Medication on discharge served mainly communication with the patient and family caregivers during pre-discharge medication-use education. Patients and caregivers were advised by the researcher to keep this tool together with the other documents as they move across transitional settings and ask for its update if changes to medication are made ensuring continuity of care. Medication-use education was an important intervention because it is paradoxical to ensure the most accurate and appropriate list of medication, but the patient is then unable to make appropriate medication-use because of lack of understanding of how and when to take the medication. Secondly, it is well established that pharmacists involved in patient education are associated with reducing poor outcomes including readmissions (Bach *et al,* 2018; Rottman-Sagebiel *et al,* 2018).

Exposing the patient and family caregiver to pre-discharge medication-use education was facilitated through assessment of the patient for adherence potential and condition-related knowledge but also brought about the need of a method of effective teaching. The teach-back method (Ha Dinh *et al,* 2016; Cabilan *et al,* 2019) encountered in the gap-finding tools was already being used by the researcher during discharge dispensing but this was only confined to whether the patient or family caregiver understands how and when to take medication and information on medication entitlement. Teach-back was namely limited to the researcher's experience in all individualised pre-discharge education.

In the present study no educational resources were utilised except for the 'Guide to patients – medication on discharge' and the 'Guide to obtaining entitlement'. Patient education other than medication-use was individualised and took the form of counselling without written material. It was purposefully done to avoid the law of diminishing returns setting especially in a patient population not used to getting this type of service.

As regards caregivers, it was evident from the TAQ that a good number of patients were dependent on their spouse or one of their children for their medication needs. The present study did not attempt to assess the preparedness of family caregivers with regards to condition management even though this may have had a bearing on readmission and healthcare resource utilisation in general. Education was limited to the appropriate administration of medication, importance of adherence and general counselling about HF derived from the CRQs. In general, family caregivers were appreciative of the service provided and the only problem was with the timing because

visiting hours in the afternoon were incompatible with the time during which the researcher was present. The researcher was able to speak to family caregivers either during the morning visiting hours or by phone. The scope of involving family caregivers was also to ensure that problems encountered during discharge dispensing and POYC refills as described in Phase 1 of the study were avoided. These were believed to be a risk to readmission.

Although home visits were beyond the scope of the present study, their role within TOC programs was appreciated by the researcher through experience within community pharmacy services that often made good for requests by elderly patients asking for home delivery of medication and subsequent sorting out of outdated, expired and inappropriately stored medication. These add on to the risk of adverse effects and readmission. The researcher appreciates that detecting medication discrepancy through follow-up phone calls is weak compared to face-to-face in-home encounters.

Phase 1 of the study demonstrated lack of emphasis on the importance of a follow-up visit at the PFD for whom a case summary was made available at discharge. The case summary issued at MDH includes information about the patient's diagnosis, signs and symptoms, hospital events, latest diagnostic results, procedures performed, therapies implemented, what changes have been carried out to home medication, discharge medications ordered and the discharge plan of care including appointments. Counselling to patients addressed this gap and follow-up was even confirmed during the first follow-up phone call.

Encouraging patients to make an early follow-up visit to the PFD turned out to be fruitful and direct communication (Scotten *et al,* 2015) of the researcher with the PFDs was not

required. In the case of POYC pharmacists (Hockly *et al,* 2018; Wright *et al,* 2019), direct communication was only required in one case because the patient tended to memorise doses and frequency. In this case an intervention was required during his hospital stay as the medication history bore an insulin dose based on patient interview during history taking at ED. The dose was higher than that indicated in the available pre-admission prescriptions and was causing significant glycaemic fluctuations. Direct communication with the POYC pharmacist was also not widely utilised owing to the researcher's intervention from the outset to encourage discharging doctors to ensure a congruent discharge prescription, case summary and the last updated treatment chart. A prescription bearing the complete and verified list of discharge medication acted as a standalone handoff document between the hospital and the POYC pharmacist. Pre-discharge counselling and the need to collect further stocks of medication facilitated timely follow-up at the POYC pharmacy and eliminated the need to send the discharge medication list directly.

The researcher believes that further research is required in this field to develop an IT driven prescription handoff on which the POYC pharmacist can prepare the required medication in advance of the patient's follow-up visit to the community pharmacy. Any other electronic type of handoff would be solely for information purposes and it is likely that the POYC pharmacist would not access it until the patient does the follow-up visit in which case the prescription and case summary will suffice making it a futile intervention in the case of patients discharged from the ward. It was the belief of the researcher that a significant TOC improvement would be achieved through hospital-POYC partnership in which access to handoff material was both functional and patient-necessity driven.

As regards the 3-days discharge medication supply brought to the ward instead of the patient going to the pharmacy, this had four important spinoffs. First, it was a quality improvement measure that ensured full capture of the discharge prescriptions (Marr *et al,* 2018). It is always desirable to capture discharge prescriptions because in this way the patients benefit from another round of checks that improve outcomes (Lam *et al,* 2019). Secondly it saved the patient or caregiver the burden of having to go to the pharmacy. Thirdly, it gave the opportunity to the pharmacist to reinforce the medication-use education and lastly by preparing the medications, the pharmacist had the opportunity to perform a more precise prescription clinical check because doing it turns out to be better than just checking it. This process improvement engaged further the patient towards reinforcement of medication-use education at a time when family caregivers are also likely to be present. MDH being the only acute state-owned hospital in Malta has a long-established policy of a 3-day discharge supply to be brought from the pharmacy by the patient or family caregiver. This intervention was likely to increase patient satisfaction and in turn galvanise their attention during counselling reinforcement. The pharmacist researcher had the opportunity to witness in person the humanistic benefits of this move.

Patient education was one of the pillars of the TOC pathway because it addressed PCIs only captured as a result of the pharmacist researcher working at ward level. Patient related problems were not captured enough during the Phase 1 surveys (Figure 3.1a) because medication was not always collected by the patient. The counselling need to patients (and caregivers) was an important PCI to address especially in the context of TOC whereby the information given influences the patient's attitude towards the

medication during the post-discharge period and has a major bearing on the incidence of other PCIs.

The assessment of the TAQ, CRQs, history and treatment regimen yielded several counselling topics for individualised pre-discharge education (Table 3.17). The most common general topic was encouraging patients not to shy away from asking the doctor or pharmacist questions about their condition and medication. Interviews showed that either the patient seemed not interested to know or as in most of the cases, the patient did not feel at ease to ask for information. Asking for information ensures longitudinal learning across the care continuum enhancing adherence to treatment and lifestyle changes.

The importance of basing individualised education on the TAQ and CRQs stems from the fact that lack of adherence is a modifiable risk factor for readmissions (Rosen *et al,* 2017). Besides, patients who obtained high scores still exhibited weaknesses or misconceptions that required clarification.

Another common topic was more specific and discussed with patients the symptoms of heart failure that should be reported to the doctor. The CRQs revealed that no patient was able to give a response that would absolve him/her from counselling. The interviews revealed that procrastinating to seek medical advice was a common attitude. It was important to counsel the patients on symptom recognition and early referral as this frequently prevents readmissions (Lam *et al,* 2013; Schumacher *et al,* 2018).

Reinforcing the patient's need to understand the importance of fluid restriction and significance of sudden weight gain was another topic. Fluid restriction not given as an instruction but explained to patients in plain language with appropriate analogy

(comparing the heart to a water pump) was important as this forms the basis for prevention of fluid overload in heart failure and has a significant bearing on readmission risk. Explaining to patients the significance of sudden weight gain and importance of daily weights was equally common to fluid restriction. The teaching-to-implement related to sudden weight gain and daily weights requires additional resources and assessment which was beyond the scope of the present study.

Pre-discharge education addressed the confusion that many patients seemed to have why doses are increased especially those with HFrEF. Reassurance that increasing doses even if they feel well is part of their condition's management was deemed important as this has a bearing on adherence to treatment. This was the reason why during the collection of data patients with a margin for dose optimization of beta-blockers, ACE inhibitors and aldosterone antagonists were recorded.

Taking prescribed medication at the prescribed times was emphasised with 19 patients. This stemmed from the response patients gave regarding the inconvenience of taking diuretics. It was deemed important to emphasise the importance of keeping the timing for medications but allow for some flexibility regarding diuretic dosing. Elderly patients in Malta are used to going to the church or do errands in the morning and advising patients that on these instances one can postpone but not skip the diuretic dose was important.

A topic which was discussed with only two patients was that of medications on GDMT that were recommended by the consultant but were not available on the formulary meaning that out-of-pocket financing was required. The patients showed concern about whether the benefits justified the expense. For this reason, the pharmacist researcher

explained the benefits in terms of mortality and readmission rate highlighting the role of the pharmacist to explain in plain language the findings reported in literature based on real world practice.

Post-discharge telephone care management was an intervention intended to reinforce education and target aspects of medication therapy management that might be overlooked by patients or family caregivers.

Reminders about the importance of informing the PFD and POYC pharmacist about the recent admission with an emphasis on changes to medication and general reinforcement regarding adherence was intentionally the most common theme discussed with the patients. Alerting the post-discharge providers about changes to medication and adhering to the new regimen was deemed important and an essential element for transition to community.

Probing about side-effects of newly prescribed medication and/or increase in doses and how the patient was coping with them was the second most important theme during TCM. A case example was of a 72-year-old male patient for whom the carvedilol dose was increased and was complaining of feeling dizzy/tired. Having encountered a case of readmission in Phase 2 with carvedilol-associated bradycardia the researcher probed further, and it transpired that this patient had missed his Holter appointment pointing to a predictable and avoidable readmission. His appointment was rescheduled, and the patient was reassured that if the beta-blocker was the cause of this side-effect, this would be revealed by the test. In a second call to the same patient toward the end of the 30-day post-discharge period the wife reported that the patient had put up 10 kg in one week. She explained that she was becoming apprehensive and would call the heart

failure clinic the next morning. The pharmacist asked if the patient was suffering from shortness of breath which was not the case. Since the call was in the late afternoon, the pharmacist advised the wife to call the PFD, CMW or visit ED and not wait. It was agreed that action was to be taken immediately. The case was followed through CPAS and iClinicalManager. The patient was not admitted, and no mortality was reported. This case demonstrates that a pharmacist can bridge medication management and general interdisciplinary interventions avoiding poor outcomes.

Medication reminders regarding tailing down or stopping temporary medication was the third theme mostly discussed with patients. A case example was a 68-year-old male patient who had to tail down amiodarone from 200mg three times daily at 1 week and again to 200mg daily at 2 weeks after discharge. The patient's treatment plan also involved the tailing down of digoxin from 0.125mg to 0.0625mg after 2 weeks. Other medication reminders included steroid tail-down, INR monitoring due dates after loading doses, antibiotic stop dates and starting of NOACs. Targeted calls were performed on the days of tail down or stop/start date and the only priority was the prevention of PCIs showing the role of the pharmacist as a proactive contributor to the patient's wellbeing rather than a reactive contributor to solving PCIs.

An equally discussed theme to medication reminders was the change back to previously unavailable medication for which a temporary alternative was found. Six patients benefitted from this intervention and primarily concerned the change back to valsartan. The study period coincided with a worldwide shortage of valsartan due to a contaminant in the active pharmaceutical ingredient. The temporary availability of candesartan on the formulary constituted a challenge when reverting to valsartan as this was a risk to

adherence. No problems were reported in this case but there was one case example of a patient who was discharged on candesartan 4mg for whom reverting was not possible at least within the follow-up period as the dosage form of valsartan 80mg which was then available on the formulary was in capsule form and could not be split. Again, the intention was always prevention not cure.

Change to new formulations or devices were also covered during TCM. A case example was that of a 75-year-old female patient who was on formoterol (Foradil®) inhaler. The study coincided with salmeterol metered-dose inhaler replacing formoterol on the formulary. PCIs were prevented in this case by predicting the possibility of under-dosing and under-supply. The equivalent dosing of formoterol 12mcg and salmeterol 25mcg is one is to two. The patient was using one puff twice daily of formoterol meaning that the dose of salmeterol should have been two puffs twice daily and the number of inhalers dispensed from POYC for a period of eight weeks should have been two inhalers not one. When the patient was discharged, she still had one pack of Foradil® conducting the researcher to include checking of this changeover during follow-up TCM.

It may be concluded that even if no direct impact on readmission rate was produced, these interventions constituted a tangible quality improvement making the pharmacist an asset within an interdisciplinary healthcare team. Most definitely if these interventions were not proactively done by the pharmacist someone else must have reactively acted to problems which evolved later in the care continuum and perhaps even deviated from the necessary focus at that stage.

4.5 Service recommendations

Research shows its relevance when leading to implementation in real practice scenarios. The researcher believes that expansion of clinical pharmacy services at MDH focusing on TOC will be effective and feasible. The development of a comprehensive readmission prevention program for heart failure patients involving a pharmacy component is warranted. This pathway can also be adapted for other disease states such as COPD which are also associated with high readmission rates.

Finally, the pathway can be validated for its use as part of continuous professional development and teaching programs for pharmacy students because preparing people is part and parcel of successful implementation.

4.6 Limitations of the study

The study had limitations that may have influenced the outcomes. The study was designed as a quality improvement initiative to evaluate the impact of a clinically oriented ward pharmacy service with the propensity of being incorporated in a broader TOC program. For this reason, the study cohorts were non-randomised.

Logistical necessity pointed to a study design that saw the time periods for the control and intervention group to differ. It can be argued that patients being admitted during the summer period (control group) were more likely to be readmitted due to an increased propensity of non-adherence to fluid restriction. Similarly, patients being admitted during the autumn period were more likely to be readmitted due to the

increased incidence of chest infections. How these factors balance out at the end of day is difficult to analyse and was beyond the scope of this study.

The strict exclusion criteria necessary to obtain a similar intervention and usual care group coupled with the logistical necessity of a small sample size due to the relative short period available for the study impinged on the generalisability of the study.

For ethical reasons pathway-related data collected for the intervention group such as medication discrepancies on admission and at discharge and data related to post-discharge follow-up calls were not collected for the usual care cohort (control) which prevented a complete baseline. The detection of PCIs in the control cohort would have ethically obliged the researcher to intervene and this may have influenced the outcome.

Recall bias might be a factor that impacted the Treatment Adherence Questionnaire which in turn impinged on the quality of the individualised pre-discharge education delivered to the patients.

Competing priorities such as the necessity to perform medication reconciliation of a newly admitted patient and preparing the necessary interventions for a discharged patient, difficulty to attain information from other entities regarding the home medication, the time gap until the schedule V card is made available by relatives (those who did not bring it with them on admission) and waiting time for operator-assisted post-discharge phone calls were major factors affecting the provision of interventions within the proposed pathway.

Finally, as is the case with all studies based on data derived from hand written notes and databases, there was the potential for inaccuracies even though these would have

probably been systematically balanced between the usual care and intervention cohorts.

4.7 Strengths of the study

The average age of the patients was over 70 in both the intervention and the control groups. The cohorts included patients with the highest risk for rehospitalisation such as those with prior rehospitalisation and multiple comorbidities.

No patients were excluded on the basis of socioeconomic status. The procedure to attain consent from patients resulted in all patients accepting to participate indicating a clear trend. This eliminated the question of how many would have declined participation in the control cohort and whether these should have been included for statistical analysis.

The success of the study was ensured through complete support from the staff at the CMW including nurses, doctors, cardiologists and the cardiology and pharmacy leadership.

The usual care and intervention patients were discharged from the same hospital (being a single-centre study) which minimised the potential for bias due to disparity in standard of care.

4.8 Recommendations for research

As research aimed at improving TOC fundamentally builds on prior intervention studies, the pathway should be tested on a larger sample using a matched-control design and

preferably minimising exclusion criteria to widen generalisability. The pathway should also be tested for other outcome measures namely patient experience, patient safety and mortality which are considered at the same level of readmission rate with regards to importance. Further research with pharmacist interventions extending beyond 30 days post-discharged should also be undertaken.

4.9 Conclusion

In conclusion, this research demonstrated that making transition-of-care the epicentre of pharmacist interventions will address service limitations. The spinoffs addressed patient needs, improved the service, possibly improved outcomes and made a shift to value-based care. In this respect, the research fulfilled its rationale. The pharmaceutical TOC pathway implemented in this research worked well with heart failure patients whose management is considered challenging. Readmission rate, the research primary outcome, showed encouraging results in the immediate 30-day post discharge period that may be determined if the study is replicated in a larger population with a matched-control approach. The pharmaceutical TOC pathway has ensured the prevention of pharmaceutical care issues and enhanced medication management by targeting points of failure of the system, the providers or the patient which would have otherwise perpetuated along the care continuum making it increasingly difficult to address.

The TOC pathway given as a service in this study has been demonstrated feasible for implementation with HF patients and may be adopted as a model to be taken to a next level of service development in other chronic conditions.

References

Albert C, Estep JD. Economic impact of chronic heart failure management in today's cost-conscious environment. *Card Electrophysiol Clin*. 2019; 11(1):1-9. doi: 10.1016/j.ccep.2018.11.002. Epub 2018 Dec 22.

Albert NM, Barnason S, Deswal A, Hernandez A, Kociol R, Lee E, et al. Transitions of care in heart failure: a scientific statement from the American Heart Association. *Circ Heart Fail.* 2015; 8:384-409.

Alghamdy MS, Randhawa MA, Al-Wahhas MH, Al-Jumaan MA. Admissions for drug-related problems at the emergency department of a university hospital in the kingdom of Saudi Arabia. *J Family Community Med.* 2015; 22(1):44–8.

Alkhawam H, Abo-Salem E, Zaiem F, Ampadu J, Rahman A, Sulaiman S, Zaitoun A, Helmy T, Vittorio TJ. Effect of digitalis level on readmission and mortality rate among heart failure reduced ejection fraction patients. *Heart Lung.* 2019; 48(1):22-27. doi: 10.1016/j.hrtlng.2018.07.006. Epub 2018 Aug 30.

American College of Clinical Pharmacy, Hume AL, Kirwin J, Bieber HL, Couchenour RL, Hall DL, Kennedy AK, LaPointe NM, Burkhardt CD, Schilli K, Seaton T, Trujillo J, Wiggins B. Improving care transitions: current practice and future opportunities for pharmacists. *Pharmacotherapy*. 2012; 32(11): 326-37. doi: 10.1002/phar.1215. Epub 2012 Oct 26.

Anastasi A. Constructivism in innovative models of pharmaceutical care bridging administrative and clinical pharmacist intervention: Heart Failure Model. Ph. D. [Dissertation]. University of Malta, Malta: 2017.

Anderson SL, Marrs JC. A review of the role of the pharmacist in heart failure transition of care. *Adv Ther*. 2018; 35(3):311-23. doi: 10.1007/s12325-018-0671-7. Epub 2018 Feb 27.

Annema C, Luttik ML, Jaarsma T. Reasons for readmission in heart failure: Perspectives of patients, caregivers, cardiologists, and heart failure nurses. *Heart Lung*. 2009; 38(5): 427-34. doi: 10.1016/j.hrtlng.2008.12.002.

Axon RN, Williams MV. Hospital readmission as an accountability measure. *JAMA.* 2011; 305:504–5.

Bach QN, Peasah SK, Barber E. Review of the role of the pharmacist in reducing hospital readmissions. *J Pharm Pract.* 2018; 1:897190018765500. doi: 10.1177/ 0897190018765500. [Epub ahead of print]

Bergethon KE, Ju C, DeVore AD, Hardy NC, Fonarow GC, Yancy CW, Heidenreich PA, Bhatt DL, Peterson ED, Hernandez AF. Trends in 30-Day readmission rates for patients hospitalized with heart failure - Findings from the get with the guidelines-heart failure registry. *Circulation: Heart Failure.* 2016; 9

Bianco A, Mole` A, Nobile CGA, Di Giuseppe G, Pileggi C, Angelillo IF. 2012; Hospital readmission prevalence and analysis of those potentially avoidable in southern Italy. *PLoS ONE* 7(11): e48263. doi:10.1371/journal.pone.0048263

Bouvy ML, Heerdink ER, Urquhart J, Grobbee DE, Hoes AW, Leufkens HG. Effect of a pharmacist-led intervention on diuretic compliance in heart failure patients: a randomized controlled study. *J Card Fail.* 2003; 9(5):404-11.

Bradley EH, Curry L, Horwitz LI, Sipsma H, Wang Y, Walsh MN, Goldmann D, White N, Piña IL, Krumholz HM. Hospital strategies associated with 30-day readmission rates for patients with heart failure. *Circ Cardiovasc Qual Outcomes*. 2013; 6(4):444-50. doi: 10.1161/CIRCOUTCOMES.111.000101.

Burke R, Guo R, Misky GJ. Identifying keys to success for reducing readmissions: using the Ideal Transition in Care framework. *J. Gen. Intern. Med.* 2013; 28:94

Burke RE, Kripalani S, Vasilevskis EE, Schnipper JL. Moving beyond readmission penalties: creating an ideal process to improve transitional care. *J. Hosp. Med.* 2013; 8:102–9.

Cabilan CJ, Boyde M, Currey E. The effectiveness of pharmacist-led discharge medication counselling in the emergency department (ExPLAIN): A pilot quasi-experimental study. *Patient Educ Couns.* 2019 Jan 25. pii: S0738-3991(19)30032-1. doi: 10.1016/j.pec.2019.01.020. [Epub ahead of print]

Caughey MC, Sueta CA, Stearns SC, Shah AM, Rosamond WD, Chang PP. Recurrent acute decompensated heart failure admissions for patients with reduced versus preserved ejection fraction (from the Atherosclerosis Risk in Communities Study). *Am J Cardiol.* 2018; 122(1):108-114. doi: 10.1016/j.amjcard.2018.03.011. Epub 2018 Mar 28.

Cheng JW. Current perspectives on the role of the pharmacist in heart failure management. *Integr Pharm Res Pract*. 2018; 9(7):1-11. doi: 10.2147/IPRP.S137882. eCollection 2017.

Cheng RK, Cox M, Neely ML, Heidenreich PA, Bhatt DL, Eapen ZJ, Hernandez AF, Butler J, Yancy CW, Fonarow GC. Outcomes in patients with heart failure with preserved, borderline, and reduced ejection fraction in the Medicare population. *Am Heart J*. 2014; 168(5):721-30. doi: 10.1016/j.ahj.2014.07.008. Epub 2014 Jul 22.

Cobretti MR, Page RL, Linnebur SA, Deininger, Ambardekar AV, Lindenfeld J, Aquilante CL. Medication regimen complexity in ambulatory older adults with heart failure. *Clin Interv Aging.* 2017; 12: 679–86. Published online 2017 Apr 12. doi: 10.2147/CIA.S130832

Comín-Colet J, Enjuanes C, Lupón J, Cainzos-Achirica M, Badosa N, Verdú JM. Transitions of care between acute and chronic heart failure: critical steps in the design of a multidisciplinary care model for the prevention of rehospitalization. *Rev Esp Cardiol (Engl Ed).* 2016; 69(10):951-961. doi: 10.1016/j.rec.2016.05.001. Epub 2016 Jun 6. Review.

Corrao G, Ghirardi A, Ibrahim B, Merlino L, Maggioni AP. Burden of new hospitalization for heart failure: a population-based investigation from Italy. *Eur J Heart Fail*. 2014; 16(7): 729-36

Cowie MR. The global burden of heart failure [internet]. Imperial College London (Royal Brompton & Herefield – NHS Trust). *Heart Failure* 2015 Seville May 23-26 [cited 2018 Oct 6]. Available from: https://www.escardio.org/ static_file/Escardio/Web/ Congresses/Slides

Debono I, Grech L, Xuereb RG, Azzopardi LM. 4CPS-217 Assessing medication adherence and condition-related knowledge of heart failure patients. 24th Congress of the EAHP, 27th March – 29th March 2019

Desai AS, Stevenson LW. Rehospitalization for heart failure – predict or prevent? *Circulation*. 2012; 126: 501-06

DiDomenico RJ. Improving the management of chronic heart failure: focus on the importance of transitions of care. [internet] 2017 [cited 2018 Oct 3]. Available from http://symposia.ashp.org/lms/content/chfcare/

Dreyer T, Care Transitions: Best Practices and Evidence-based Programs. Center for Healthcare Research & Transformation. January 15, 2014

Fitzgerald AA, Powers JD, Ho PM, Maddox TM, Peterson PN, Allen LA, Masoudi FA, Magid DJ, Havranek EP. Impact of medication nonadherence on hospitalizations and mortality in heart failure. *Journal of Cardiac Failure.* 2011; 17(8): 664-69

Fonarow GC, Abraham WT, Albert NM, Stough WG, Gheorghiade M, Greenberg BH, O'Connor CM, Pieper K, Sun JL, Yancy CW, Young JB, OPTIMIZE-HF Investigators and Hospitals. Factors identified as precipitating hospital admissions for heart failure and clinical outcomes: findings from OPTIMIZE-HF. *Arch Intern Med.* 2008; 168(8): 847-54. doi: 10.1001/archinte.168.8.847.

Goldfield NI, McCullough EC, Hughes JS, Tang AM, Eastman B, Rawlins LK, Averill RF. Identifying Potentially Preventable Readmissions. *Health Care Financ Rev*. 2008; 30(1): 75–91.

Goyal P, Loop M, Chen L, Brown TM, Durant RW, Safford MM, Levitan EB. Causes and temporal patterns of 30-Day readmission among older adults hospitalized with heart failure with preserved or reduced ejection fraction. *J Am Heart Assoc*. 2018; 23;7(9). pii: e007785. doi: 10.1161/JAHA.117.007785.

Ha Dinh TT, Bonner A, Clark R, Ramsbotham J, Hines S. The effectiveness of the teach-back method on adherence and self-management in health education for people with chronic disease: a systematic review. *JBI Database System Rev Implement Rep*. 2016; 14(1):210-47. doi: 10.11124/jbisrir-2016-2296.

Hansen LO, Young RS, Hinami K, Leung A, Williams MV. Interventions to reduce 30-day rehospitalization: a systematic review. *Ann. Intern. Med.* 2011; 155:520–28.

Hartl S, Lopez-Campos JL, Pozo-Rodriguez F, Castro-Acosta A, Studnicka M, Kaiser B, Roberts CM. Risk of death and readmission of hospital-admitted COPD exacerbations: European COPD Audit. *Eur Respir J*. 2016;47(1):113-21. doi: 10.1183/13993003.01391-2014. Epub 2015 Oct 22.

Hernandez AF, Greiner MA, Fonarow GC, Hammill BG, Heidenreich PA, Yancy CW, Peterson ED, Curtis LH. Relationship between early physician follow-up and 30-day readmission among Medicare beneficiaries hospitalized for heart failure. *JAMA*. 2010; 303(17): 1716-22. doi:10.1001/jama.2010.533.

Hockly M, Williams S, Allen M. Transfer of care - a randomised control trial investigating the effect of sending the details of patients' discharge medication to their community pharmacist on discharge from hospital. *Int J Pharm Pract*. 2018; 26(2):174-182. doi: 10.1111/ijpp.12364. Epub 2017 Mar 27.

Hood SR, Giazzon AJ, Seamon G, Lane KA, Wang J, Eckert GJ, Tu W, Murray MD. Association between medication adherence and the outcomes of heart failure. *Pharmacotherapy*. 2018; 38(5):539-45. doi: 10.1002/phar.2107. Epub 2018 Apr 30. https://www.powerpak.com/course/print/114569

Jepma P, Ter Riet G, van Rijn M, Latour CHM, Peters RJG, Scholte Op Reimer WJM, Buurman BM. Readmission and mortality in patients ≥70 years with acute myocardial infarction or heart failure in the Netherlands: a retrospective cohort study of incidences and changes in risk factors over time. *Neth Heart J*. 2019 Feb 4. doi: 10.1007/s12471-019-1227-4. [Epub ahead of print]

Joynt KE, Jha AK. A path forward on Medicare readmissions. *N. Engl. J. Med.* 2013; 368: 1175–7.

Kahlon S, Pederson J, Majumdar SR, Belga S, Lau D, Fradette M, Boyko D, Bakal JA, Johnston C, Padwal RJ, McAlister FA. Association between frailty and 30-day outcomes after discharge from hospital. *CMAJ.* 2015; 187(11):799–804.

Kash BA, Baek J, Cheon O, Manzano JM, Jones SL, Paranilam J, Phillips RA. How leading hospitals operationalize evidence-based readmission reduction strategies: A mixed-methods comparative study using systematic review and survey design. *Am J Med Qual*. 2019 Feb 4:1062860618824410. doi: 10.1177/1062860618824410. [Epub ahead of print]

Khouri RK, Hou H, Dhir A, Andino JJ, Dupree JM, Miller DC, Ellimoottil C. What is the impact of a clinically related readmission measure on the assessment of hospital performance? *BMC Health Serv Res.* 2017; 17: 781. Published online 2017 Nov 28. doi: 10.1186/s12913-017-2742-x

Kreckman J, Wasey W, Wise S, Stevens T, Millburg L, Jaeger C. Improving medication reconciliation at hospital admission, discharge and ambulatory care through a transition

of care team. *BMJ Open Qual.* 2018; 20;7(2): e000281. doi: 10.1136/bmjoq-2017-000281. eCollection 2018.

Kripalani S, Jackson AT, Schnipper JL, Coleman EA. Promoting effective transitions of care at hospital discharge: a review of key issues for hospitalists. *J. Hosp. Med.* 2007; 2:314–23.

Kripalani S, Theobald CN, Anctil B, Vasilevskis EE. Reducing hospital readmission rates: current strategies and future directions. *Annu Rev Med.* 2014; 65:471–85.

Krumholz HM, Normand ST, Wang Y. Trends in hospitalizations and outcomes for acute cardiovascular disease and stroke: 1999–2011. *Circulation.* 2014; 130(12): 966–975. Published online 2014 Aug 18. doi: 10.1161/CIRCULATIONAHA.113.007787

Lam C, Smeltzer SC. Patterns of symptom recognition, interpretation, and response in heart failure patients: an integrative review. *J Cardiovasc Nurs*. 2013; 28(4):348-59. doi: 10.1097/JCN.0b013e3182531cf7.

Lam PH, Bhyan P, Arundel C, Dooley DJ, Sheriff HM, Mohammed SF, Fonarow GC, Morgan CJ, Aronow WS, Allman RM, Waagstein F, Ahmed A. Digoxin use and lower risk of 30-day all-cause readmission in older patients with heart failure and reduced ejection fraction on receiving β-blockers. *Clin Cardiol.* 2018; 41(3):406-12. doi: 10.1002/clc.22889. Epub 2018 Mar 22.

Lam SW, Sokn E. Effect of pharmacy-driven bedside discharge medication delivery program on day 30 hospital readmission. J Pharm Pract. 2019 Feb 6:897190019825961. doi: 10.1177/0897190019825961. [Epub ahead of print]

Leppin AL, Gionfriddo MR, Kessler M, Brito JP, Mair FS, Gallacher K, et al. Preventing 30-day hospital readmissions: a systematic review and meta-analysis of randomized trials. *JAMA Intern Med.* 2014; 174:1095–107.

Lesyuk W, Kriza C, Kolominsky-Rabas P. Cost-of-illness studies in heart failure: a systematic review 2004–2016. *BMC Cardiovascular Disorders*. 2018; 18:74 https://doi.org/10.1186/s12872-018-0815-3

Liao L, Anstrom KJ, Gottdiener JS, Pappas PA, Whellan DJ, Kitzman DW. Long-term costs and resource use in elderly participants with congestive heart failure in the cardiovascular health study. *Am Heart J*. 2007; 153(2): 245–52.

Loehr LR, Rosamond WD, Chang PP, Folsom AR, Chambless LE. Heart failure incidence and survival (from the Atherosclerosis Risk in Communities study). *Am J Cardiol*. 2008; 101(7): 1016-22. doi: 10.1016/j.amjcard.2007.11.061. Epub 2008 Feb 14.

Marr TD, Pinelli NR, Jarmul JA, Waldron KM, Eckel SF, Cicci JD, Bates JS, Amerine LB. Continuous care provided through comprehensive medication management in an acute care practice model. *Ann Pharmacother*. 2018; 52(4):314-324. doi: 10.1177/1060028017738071. Epub 2017 Oct 27.

Maia IS, Pincelli MP, Leite VF, Amadera J, Buehler AM. Long-acting muscarinic antagonists vs. long-acting β 2 agonists in COPD exacerbations: a systematic review and meta-analysis. *J Bras Pneumol.* 2017; 43(4):302-312. doi: 10.1590/S1806-37562016000000287.

Mekonnen AB, McLachlan AJ, Brien JA. Pharmacy-led medication reconciliation programmes at hospital transitions: a systematic review and meta-analysis*. J Clin Pharm Ther.* 2016; 41(2):128-44.

Mekonnen AB, McLachlan AJ, Brien JA. Effectiveness of pharmacist-led medication reconciliation programmes on clinical outcomes at hospital transitions: a systematic review and meta-analysis. *BMJ Open.* 2016; 6(2).

Mekonnen AB, Abebe TB, McLachlan AJ, Brien JA. Impact of electronic medication reconciliation interventions on medication discrepancies at hospital transitions: a

systematic review and meta-analysis. *BMC Med Inform Decis Mak*. 2016; 22;16:112. doi: 10.1186/s12911-016-0353-9.

Messerli M, Blozik E, Vriends N, Hersberger KE. Impact of a community pharmacist-led medication review on medicines use in patients on polypharmacy - a prospective randomised controlled trial. *BMC Health Serv Res.* 2016; 16: 145. Published online 2016 Apr 23. doi: 10.1186/s12913-016-1384-8

Morimoto T, Gandhi TK, Seger AC, Hsieh TC, Bates DW. Adverse drug events and medication errors: Detection and classification methods. *Qual Saf Health Care.* 2004; 13:306–14.

Moye M, Chu PS, Pounds T, Miller Thurston M. Impact of a pharmacy team-led intervention program on the readmission rate of elderly patients with heart failure. *Am J Health-Syst Pharm.* 2018; 75:183-90

Murray MD, Tu W, Wu J, Morrow D, Smith F, Brater DC. Factors associated with exacerbation of heart failure include treatment adherence and health literacy skills. *Clin Pharmacol Ther*. 2009; 85(6): 651-8. doi: 10.1038/clpt.2009.7.

Oertle M, Bal R. Understanding non-adherence in chronic heart failure: a mixed-method case study. *Qual Saf Health Care.* 2010; 19:37.

Pham PN, Xiao H, Sarayani A, Chen M, Brown JD. Risk factors associated with 7- versus 30-day readmission among patients with heart failure using the nationwide readmission database. *Med Care*. 2019; 57(1):1-7.

Polanczyk CA, Newton C, Dec GW, Di Salvo TG. Quality of care and hospital readmission in congestive heart failure: an explicit review process. *J Card Fail*. 2001; 7(4): 289-98.

Ponikowski P, Voors AA, Anker SD, Bueno H, Cleland JGF, Coats AJS, Falk V, González-Juanatey JR, Harjola VP, Jankowska EA, Jessup M, Linde C, Nihoyannopoulos P, Parissis

JT, Pieske B, Riley JP, Rosano GMC, Ruilope LM, Ruschitzka F, Rutten FH, van der Meer P; ESC Scientific Document Group. 2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure: The Task Force for the diagnosis and treatment of acute and chronic heart failure of the European Society of Cardiology (ESC)Developed with the special contribution of the Heart Failure Association (HFA) of the ESC. *Eur Heart J.* 2016; 14;37(27):2129-2200. doi: 10.1093/eurheartj/ehw128. Epub 2016 May 20.

Ponniah A, Anderson B, Shakib S, Doecke CJ, Angley M. Pharmacists' role in the post-discharge management of patients with heart failure: a literature review. *J Clin Pharm Ther.* 2007; 32(4):343-52.

Press VG, Au DH, Bourbeau J, Dransfield MT, Gershon AS, Krishnan JA, Mularski RA, Sciurba FC, Sullivan J, Feemster LC. Reducing chronic obstructive pulmonary disease hospital readmissions. An official American Thoracic Society workshop report. *Ann Am Thorac Soc.* 2019; 16(2):161-70. doi: 10.1513/AnnalsATS.201811-755WS.

Ranasinghe I, Wang Y, Dharmarajan K, Hsieh AF, Bernheim SM, Krumholz HM. Readmissions after hospitalization for heart failure, acute myocardial infarction, or pneumonia among young and middle-aged adults: a retrospective observational cohort study. *PLoS Med*. 2014; 11(9):e1001737.

Reed BN, Rodgers JE, Sueta CA. Polypharmacy in heart failure: drugs to use and avoid. *Heart Fail Clin.* 2014; 10(4):577-90.

Retrum JH, Boggs J, Hersh A, Wright L, Main DS, Magid DJ, Allen LA. Patient-identified factors related to heart failure readmissions. *Circ Cardiovasc Qual Outcomes*. 2013; 6(2): 171-7. doi: 10.1161/CIRCOUTCOMES.112.967356.

Richardson A, Tolley E, Hartmann J, Reedus J, Bowlin B, Finch C, Sands CW, Self T. Evaluation of Chronic Obstructive Pulmonary Disease (COPD) and reduced ejection fraction heart failure (HFrEF) discharge medication prescribing: Is drug therapy concordant with national guidelines associated with a reduction in 30-day readmissions? *Respir Med.* 2016; 119:135-40. doi: 10.1016/j.rmed.2016.09.008. Epub 2016 Sep 8.

Rommers MK, Teepe-Twiss IM, Guchelaar HJ. Preventing adverse drug events in hospital practice: An overview. *Pharmacoepidemiol Drug Saf.* 2007; 16:1129–35.

Rosen OZ, Fridman R, Rosen BT, Shane R, Pevnick JM. Medication adherence as a predictor of 30-day hospital readmissions. *Patient Prefer Adherence.* 2017; 11:801-10. doi: 10.2147/PPA.S125672. eCollection 2017.

Rottman-Sagebiel R, Cupples N, Wang CP, Cope S, Pastewait S, Braden H, MacCarthy D, Conde A, Moris M, Gonzalez EY, Espinoza S. A Pharmacist-Led Transitional Care Program to Reduce Hospital Readmissions in Older Adults. *Fed Pract.* 2018; 35(12):42-50.

Schumacher C, Hussey L, Hall V. Heart failure self-management and normalizing symptoms: an exploration of decision making in the community. *Heart Lung.* 2018; 47(4):297-303. doi: 10.1016/j.hrtlng.2018.03.013. Epub 2018 Apr 23.

Scotten M, Manos EL, Malicoat A, Paolo AM. Minding the gap: Interprofessional communication during inpatient and post discharge chasm care. *Patient Educ Couns.* 2015; 98(7):895-900. doi: 10.1016/j.pec.2015.03.009. Epub 2015 Mar 17.

Sevilla-Cazes J, Ahmad FS, Bowles KH, Jaskowiak A, Gallagher T, Goldberg LR, Kangovi S, Alexander M, Riegel B, Barg FK, Kimmel SE. Heart failure home management challenges and reasons for readmission: a qualitative study to understand the patient's perspective. *J Gen Intern Med*. 2018; 33(10):1700-07. doi: 10.1007/s11606-018-4542-3. Epub 2018 Jul 10.

Silva ROS, Macêdo LA, Santos GAD Júnior, Aguiar PM, de Lyra DP Júnior. Pharmacist-participated medication review in different practice settings: Service or intervention? An overview of systematic reviews. *PLoS One.* 2019; 14(1): e0210312. doi: 10.1371/journal.pone.0210312. eCollection 2019.

Strand LM, Morley PC, Cipolle RJ, Ramsey R, Lamsam GD. Drug-related problems: Their structure and function. *DICP.* 1990; 24:1093–7.

Su A, Al'Aref SJ, Beecy AN, Min JK, Karas MG. Clinical and socioeconomic predictors of HF readmissions: A review of contemporary literature. *Mayo Clin Proc.* 2019; 94(7):1304-20

Suggett E, Marriott J. Risk factors associated with the requirement for pharmaceutical intervention in the hospital setting: A systematic review of the literature. *Drugs-Real World Outcomes.* 2016; (3)241-63.

Suter LG, Li SX, Grady JN, Lin Z, Wang Y, Bhat KR, Turkmani D, Spivack SB, Lindenauer PK, Merrill AR, Drye EE, Krumholz HM, Bernheim SM. National patterns of risk-standardized mortality and readmission after hospitalization for acute myocardial infarction, heart failure, and pneumonia: update on publicly reported outcomes measures based on the 2013 release. *J Gen Intern Med*. 2014; 29(10): 1333–40. Published online 2014 May 14. doi: 10.1007/s11606-014-2862-5

Szkiladz A, Carey K, Ackerbauer K, Heelon M, Friderici J, Kopcza K. Impact of pharmacy student and resident-led discharge counselling on heart failure patients. *J Pharm Pract.* 2013;26(6):574-9.

Takeda A, Taylor SJ, Taylor RS, Khan F, Krum H, Underwood M. Clinical service organisation for heart failure. *Cochrane Database Syst Rev*. 2012; 9:CD002752. doi: 10.1002/14651858.CD002752.pub3.

Tong L, Arnold T, Yang J, Tian X, Erdmann C, Esposito T. The association between outpatient follow-up visits and all-cause non-elective 30-day readmissions: A retrospective observational cohort study. *PLoS One.* 2018; 13(7): e0200691. doi: 10.1371/journal.pone.0200691.

van Seben R, Geerlings SE, Verhaegh KJ, Hilders CG, Buurman BM. Implementation of a Transfer Intervention Procedure (TIP) to improve handovers from hospital to home: interrupted time series analysis. *BMC Health Serv Res*. 2016; 16:479.

Vedel I, Khanassov V. Transitional care for patients with congestive heart failure: a systematic review and meta-analysis. *Ann Fam Med.* 2015; 13:562-71.

Vinson JM, Rich MW, Sperry JC, Shah AS, McNamara T. Early readmission of elderly patients with congestive heart failure. *J Am Geriatr Soc.* 1990; 38(12): 1290-5.

Westerlund T, Marklund B. Assessment of the clinical and economic outcomes of pharmacy interventions in drug-related problems. *J Clin Pharm Ther.* 2009; 34:319–27.

Wright EA, Graham JH, Maeng D, Tusing L, Zaleski L, Martin R, Seipp R, Citsay B, McDonald B, Bolesta K, Chaundy K, Medico CJ, Gunderman S, Leri F, Guza K, Price R, Gregor C, Parry DT. Reductions in 30-day readmission, mortality, and costs with inpatient-to-community pharmacist follow-up. *J Am Pharm Assoc (2003).* 2019; pii: S1544-3191(18)30478-3. doi: 10.1016/j.japh.2018.11.005. [Epub ahead of print]

Appendix 1

Gap-analysis checklists & PCNE Classification V8.02

RARE Reducing Avoidable Readmissions Effectively

Care Transitions Support

Gap Analysis of Best Practices/Strategies for Improvement

Best practice/Strategy	Present	Gap/Opportunity
System in place to define care accountability for the patient between discharge and the first follow-up appointment, if issues arise Process in place to inform the patient who is responsible for their care and how to contact them post-discharge An after-hospital care plan is given to patient that includes patient diagnosis, test results, prescribed medications, follow-up appointments, who to call with issues and what issues to look for. Patient understanding of the discharge plan is assessed by asking them to explain in their own words the details of the plan (teach-back) Process in place to assure that the patient has a follow-up appointment with their provider 5 – 7 days post-hospitalization prior to discharge System in place to assure the patient has the means to keep the appointment (e.g., transportation, reminders) Process in place to assure the patient knows and understands what issues require immediate intervention and why (teach-back, simple instructions) System in place ensuring post-discharge providers (clinic, LTC, HH, other) have pertinent information in a timely manner to support effective transition of care Support system in place to follow-up with patient post transition (coaches, calls, telehealth) Community network established to help address patient and care giver needs. Post discharge outpatient services and medical equipment arranged prior to discharge. Patient and family informed of the providers and services they should expect and when.		

RARE Campaign www.rarereadmissions.org

RARE Reducing Avoidable Readmissions Effectively

Comprehensive Discharge Planning
Gap Analysis of Best Practices/Strategies for Improvement

Component	Best practice/Strategy	Present	Gap/Opportunity
Discharge Planning - Process	Conduct pre-discharge assessment of ability of patient/family to provide self-care (includes problem solving, decision making, early symptom recognition, and taking action, quality of life, depression and other cognitive and functional ability factors) Develop a comprehensive shared care plan using a shared decision making approach – consider patient values and preferences, social and medical needs Discharge summary and medication plan are complete and up to date Work with patient/family to prepare for the post discharge visit planning (goals, questions, concerns) Work with patient/family to complete advance directives as appropriate		
Discharge Planning – Content	Written discharge plan includes the following: • Reason for hospitalization • Medications to be taken post discharge, including, as appropriate, resumption of pre-admission medications. • Self-care activities such as diet, activity level or limitations, weight monitoring • DME/supplies that patient will need for care • Symptom recognition and management – what to do if patient has a question, a problem arises or condition changes, including of symptoms of which to notify health care provider • Coordination and planning for follow-up appointments • Coordination for follow up of test and studies for which confirmed results are not available at the time of discharge. • Coordination of community resources patient will utilize, such as: o Home Health Care o Meals on Wheels o Adult Day Care		

	○ PT, OT, ST The written discharge plan should be easy to read: • Include only essential education on health condition • Utilize plain language - clear, straightforward expression, using only as many words as necessary • Use universal principles of health literacy to specify reader-friendly written materials: simple words, large font, short sentences, short paragraphs, no medical jargon, headings and bullets, highlighted or circled key information, lots of white space, use visual aides		
Care Coordination	Make appointments for follow-up and post-discharge testing, with input from the patient regarding time and date Use personal health records or patient portals so patients have access to necessary information (lab results, radiology results, request prescription refills, ability to email doctors, nurses, and staff with questions) All care providers have a complete discharge summary All care providers know their care roles and responsibilities Conduct post discharge telephone care management		
Health Literacy/ Patient-Provider Communication	Educate the patient about diagnosis throughout the care continuum Embed health literacy principles into all patient education and interactions Give the patient a complete and written discharge plan		

	Employ teach back to ensure patients/families understand the care plan, information and explanations given and that their questions are answered Provide culturally and linguistically appropriate care Ensure continuity in care in order to build trust Use a shared decision making approach Ensure enough time is available for consultation Discuss with the patient any tests or studies that have been completed and who will be responsible for following up the results Confirm the medication plan with the patient Ensure provider contact and follow-up information is provided to the patient Review with the patient appropriate steps of what to do if a problem arises		

RARE Campaign www.rarereadmissions.org

Classification for Drug related problems

V8.02

Contact: info@pcne.org

This classification should be referred to as 'The PCNE Classification V 8.02'
This version is not directly backwards compatible with versions before V8.0.

Introduction

During the working conference of the Pharmaceutical Care Network Europe in January 1999, a classification scheme was constructed for drug related problems (DRPs). The classification is part of a total set of instruments. The set consists of the classification scheme, reporting forms and cases for training or validation. The classification system is validated and adapted regularly. The current version is V8, which has been developed during an expert workshop in February 2016 and a subsequent specialist meeting in April 2017. It is no longer compatible with previous versions because a number of major sections have been revised. In V 8.01, a necessary code C3.5 (which had dropped out) is re-added.

The classification is for use in research into the nature, prevalence, and incidence of DRPs and also as a process indicator in experimental studies of Pharmaceutical Care outcomes. It is also meant to help health care professionals to document DRP-information in the pharmaceutical care process. Throughout the classification the word 'drug' is used, where others might use the term 'medicine'. The hierarchical classification is based upon similar work in the field, but it differs from existing systems because it separates the problems from the causes. Quality experts will recognise that the causes are often named 'Medication Errors' by others. The following official PCNE-DRP definition is the basis for the classification:

> ***A Drug-Related Problem is an event or circumstance involving drug therapy that actually or potentially interferes with desired health outcomes.***

The basic classification now has 3 primary domains for problems, 8 primary domains for causes and 5 primary domains for Interventions. In V7 a new section, called 'Acceptance of the Intervention Proposals' was added, including 3 domains. However, on a more detailed level there are 7 grouped sub domains for problems, 35 grouped sub domains for causes and 16 grouped sub domains for interventions, and 10 subdomains for intervention acceptance. Those sub-domains can be seen as explanatory for the principal domains. In 2003 a scale has been added to indicate if or to what extend the problem has been solved, containing 4 primary domains and 7 sub domains.

J.W.Foppe van Mil/ Nejc Horvat / Tommy Westerlund

Zuidlaren, April/May/June/October 2017

Changes between V8.01 and 8.02

The confusing term 'Therapy failure' has been removed from P1.1.

An omission has been corrected: C6.6 Administration via wrong route, cause code added.

Changes between V8.0 and 8.01

An omission has been corrected Code C3.5 had dropped out of the tables, and has been reinserted.

PCNE Classification scheme for Drug-Related Problems V8.02 - Page 1

The basic classification

	Code V8.01	Primary domains
Problems (also potential)	**P1**	**Treatment effectiveness** There is a (potential) problem with the (lack of) effect of the pharmacotherapy
	P2	**Treatment safety** Patient suffers, or could suffer, from an adverse drug event
	P3	**Others**
Causes (including possible causes for potential problems)	**C1**	**Drug selection** The cause of the DRP can be related to the selection of the drug
	C2	**Drug form** The cause of the DRP is related to the selection of the drug form
	C3	**Dose selection** The cause of the DRP can be related to the selection of the dosage schedule
	C4	**Treatment duration** The cause of the DRP is related to the duration of treatment
	C5	**Dispensing** The cause of the DRP can be related to the logistics of the prescribing and dispensing process
	C6	**Drug use/process** The cause of the DRP is related to the way the patient gets the drug administered by a health professional or carer, in spite of proper instructions (on the label)
	C7	**Patient related** The cause of the DRP can be related to the patient and his behaviour (intentional or non-intentional)
	C8	**Other**
Planned Interventions	**I0**	**No intervention**
	I1	**At prescriber level**
	I2	**At patient level**
	I3	**At drug level**
	I4	**Other**
Intervention Acceptance	**A1**	**Intervention accepted**
	A2	**Intervention not accepted**
	A3	**Other**
Status of the DRP	**O0**	**Problem status unknown**
	O1	**Problem solved**
	O2	**Problem partially solved**
	O3	**Problem not solved**

PCNE Classification scheme for Drug-Related Problems V8.02 - Page 2

The Problems

Primary domain	Code V8.01	Problem
1.Treatment effectiveness There is a (potential) problem with the (lack of) effect of the pharmacotherapy	**P1.1** **P1.2** **P1.3**	No effect of drug treatment Effect of drug treatment not optimal Untreated symptoms or indication
2. Treatment safety Patient suffers, or could suffer, from an adverse drug event	**P2.1**	Adverse drug event (possibly) occurring
3. Others	**P3.1** **P3.2** **P3.3**	Problem with cost-effectiveness of the treatment Unnecessary drug-treatment Unclear problem/complaint. Further clarification necessary (please use as escape only)

□	Potential problem
□	Manifest problem

PCNE Classification scheme for Drug-Related Problems V8.02 -Page 3

The Causes (including possible causes for potential problems)

N.B. One problem can have more causes

	Primary domain	Code V8.01	Cause
Prescribing	**1. Drug selection** The cause of the (potential) DRP is related to the selection of the drug	C1.1	Inappropriate drug according to guidelines/formulary
		C1.2	Inappropriate drug (within guidelines but otherwise contra-indicated)
		C1.3	No indication for drug
		C1.4	Inappropriate combination of drugs or drugs and herbal medication
		C1.5	Inappropriate duplication of therapeutic group or active ingredient
		C1.6	No drug treatment in spite of existing indication
		C1.7	Too many drugs prescribed for indication
	2. Drug form The cause of the DRP is related to the selection of the drug form	C2.1	Inappropriate drug form (for this patient)
	3. Dose selection The cause of the DRP is related to the selection of the dose or dosage	C3.1	Drug dose too low
		C3.2	Drug dose too high
		C3.3	Dosage regimen not frequent enough
		C3.4	Dosage regimen too frequent
		C3.5	Dose timing instructions wrong, unclear or missing
	4. Treatment duration The cause of the DRP is related to the duration of treatment	C4.1	Duration of treatment too short
		C4.2	Duration of treatment too long
Disp	**5. Dispensing** The cause of the DRP is related to the logistics of the prescribing and dispensing process	C5.1	Prescribed drug not available
		C5.2	Necessary information not provided
		C5.3	Wrong drug, strength or dosage advised (OTC)
		C5.4	Wrong drug or strength dispensed
Use	**6. Drug use process** The cause of the DRP is related to the way the patient gets the drug administered by a health professional or carer, despite proper dosage instructions (on the label)	C6.1	Inappropriate timing of administration and/or dosing intervals
		C6.2	Drug under-administered
		C6.3	Drug over-administered
		C6.4	Drug not administered at all
		C6.5	Wrong drug administered
		C6.6	Drug administered via wrong route
	7. Patient related The cause of the DRP is related to the patient and his behaviour (intentional or non-intentional)	C7.1	Patient uses/takes less drug than prescribed or does not take the drug at all
		C7.2	Patient uses/takes more drug than prescribed
		C7.3	Patient abuses drug (unregulated overuse)
		C7.4	Patient uses unnecessary drug
		C7.5	Patient takes food that interacts
		C7.6	Patient stores drug inappropriately
		C7.7	Inappropriate timing or dosing intervals
		C7.8	Patient administers/uses the drug in a wrong way
		C7.9	Patient unable to use drug/form as directed
	8. Other	C8.1	No or inappropriate outcome monitoring (incl. TDM)
		C8.2	Other cause; specify
		C8.3	No obvious cause

PCNE Classification scheme for Drug-Related Problems V8.02 -Page 4

The Planned Interventions

N.B. One problem can lead to more interventions

Primary domain	Code V8.01	Intervention
No intervention	**I0.1**	No intervention
1. At prescriber level	**I1.1**	Prescriber informed only
	I1.2	Prescriber asked for information
	I1.3	Intervention proposed to prescriber
	I1.4	Intervention discussed with prescriber
2. At patient level	**I2.1**	Patient (drug) counselling
	I2.2	Written information provided (only)
	I2.3	Patient referred to prescriber
	I2.4	Spoken to family member/caregiver
3. At drug level	**I3.1**	Drug changed to ….
	I3.2	Dosage changed to ….
	I3.3	Formulation changed to …..
	I3.4	Instructions for use changed to …..
	I3.5	Drug stopped
	I3.6	New drug started
4. Other intervention or activity	**I4.1**	Other intervention (specify)
	I4.2	Side effect reported to authorities

Acceptance of the Intervention proposals

N.B. One level of acceptance per intervention proposal

Primary domain	Code V8.01	Implementation
1. Intervention accepted (by prescriber or patient)	**A1.1**	Intervention accepted and fully implemented
	A1.2	Intervention accepted, partially implemented
	A1.3	Intervention accepted but not implemented
	A1.4	Intervention accepted, implementation unknown
2. Intervention not accepted (by prescriber or patient)	**A2.1**	Intervention not accepted: not feasible
	A2.2	Intervention not accepted: no agreement
	A2.3	Intervention not accepted: other reason (specify)
	A2.4	Intervention not accepted: unknown reason
3. Other (no information on acceptance)	**A3.1**	Intervention proposed, acceptance unknown
	A3.2	Intervention not proposed

PCNE Classification scheme for Drug-Related Problems V8.02 -Page 5

Status of the DRP

N.B. This domain depicts the outcome of the intervention. One problem (or the combination of interventions) can only lead to one level of solving the problem

Primary domain	Code V8.01	Outcome of intervention
0. Not known	**O0.1**	Problem status unknown
1. Solved	**O1.1**	Problem totally solved
2. Partially solved	**O2.1**	Problem partially solved
3. Not solved	**O3.1**	Problem not solved, lack of cooperation of patient
	O3.2	Problem not solved, lack of cooperation of prescriber
	O3.3	Problem not solved, intervention not effective
	O3.4	No need or possibility to solve problem

PCNE Classification scheme for Drug-Related Problems V8.02 -Page 6

The Causes (including possible causes for potential problems)

Primary Domain 8 – Other (Documentation and Technical problems)

Primary domain 8	Code V8.01	Cause
C8.2.1 Documentation (Discharge and Community POYC setting) Missing, illegible, incomplete, misleading, wrong or illegal required documents	C8.2.1.1	Case summary not available at time of discharge.
	C8.2.1.2	Schedule V application not complete at time of discharge.
	C8.2.1.3	Schedule V application does not indicate retention of previous medication.
	C8.2.1.4	Schedule V application includes medications not covered under specified index condition.
	C8.2.1.5	Patient told that Schedule V application will be sent by post from ward to POYC office.
	C8.2.1.6	Patient told that he/she will get first 2 months medication refill from hospital pharmacy
	C8.2.1.7	No 3-day discharge prescription.
	C8.2.1.8	Psychotropics and narcotics not written on proper prescriptions.
	C8.2.1.9	Discharge prescription includes medication not on discharge medication list case summary or vice versa.
	C8.2.1.10	Oxygen not considered as a medication. Prescriptions bearing no instructions regarding flowrate in L/min and duration.
	C8.2.1.11	Patient not discharged from the ward indicated at the bottom of the prescription.
	C8.2.1.12	Off-licence or unlicensed forms not done or unlicensed medication prescription not signed by authorised prescriber.
	C8.2.1.13	Medication prescribed is not approved for patient's condition.
	C8.2.1.14	Wrong protocol quoted for protocol-regulated drug.
	C8.2.1.15	Patient given discharge documents of another patient.
	C8.2.1.16	Newly prescribed medication from hospital not yet delivered to pharmacy from POYC stores.
	C8.2.1.17	Newly prescribed medication is on Schedule V card but no approval from DPA.
	C8.2.1.18	Newly prescribed medication is on Schedule V card, has approval but medication list not updated on POYC software.
	C8.2.1.19	Patient has discharge prescription for newly prescribed medication but has no case summary, no Schedule V application and no medication including resent refills.

	C8.2.1.20	Patient comes to the pharmacy with all applications thinking all will be processed through this end and immediately.
	C8.2.1.21	Patient failed to renew permits and medication was deleted from POYC software and no stock was sent.
	C8.2.1.22	Schedule V card and/or control card not renewed.
	C8.2.1.23	Prescriptions or entitlement documents missing.
	C8.2.1.24	Patient claims that he/she was asked for own medication on admission but was left behind at time of discharge.
	C8.2.1.25	Multiple prescriptions from different prescribers including old and resent prescriptions.
	C8.2.1.26	Exceptional Medication Treatment Request Form required
C8.2.2 Technical (Discharge and Community POYC setting). Problems to execute dispensing operations; inappropriate procedures; look alike medications/packages; item not available on the formulary/market	C8.2.2.1	POYC IT system is down
	C8.2.2.2	Patient not active due to failing to collect refills
	C8.2.2.3	Look alike medications
	C8.2.2.4	Different brands for same medication
	C8.2.2.5	Frequent change of brands for same medication
	C8.2.2.6	Medication not available on the market
	C8.2.2.7	Same day service for named patient basis medication failed to take place.
	C8.2.2.8	Resent refill went missing during transition home-hospital-home and patient has no medication.

PCNE statement on medication review 2013

PCNE recognises three basic types of medication review. The three PCNE types of medication review assume that all dispensing information for all medicines that a patient takes (receives)/has taken (received) in the recent past is available to the pharmacists.

What form of intermediate medication review is feasible, depends on the pharmacy system in a country.

Types of medication review

PCNE Type 1: **Simple MR**: A simple medication review is based on the available medication history in the pharmacy.

- Reveals: drug interactions, some side-effects, unusual dosages and some adherence issues.

PCNE Type 2A: **Intermediate MR**: An intermediate medication review can be performed when the patient can be approached for information. Such a review is based on medication history and patient information.

- Reveals: drug interactions, some side-effects, unusual dosages, adherence issues, drug-food interactions, effectiveness issues, side effects, and problems with OTC

PCNE Type 2B: Intermediate MR: An intermediate medication review can be performed if GP information is also available. Such a review is based on medication history and medical information.

- Reveals: drug interactions, some side-effects, unusual dosages, adherence issues, drug-food interactions, effectiveness issues, indication without a drug and drugs without indication

PCNE Type 3: **Advanced MR**: An advanced medication review is based on medication history, patient information and clinical information.

- Reveals: drug interactions, some side-effects, unusual dosages adherence issues, drug-food interactions, effectiveness issues, side effects, problems with OTC, indication without a drug and drugs without indication, dosage issues

V3. 01012013

Appendix 2

Focus group question guide, rating sheets results

and thematic analysis

Focus group on Transitions-of-Care from hospital to home/*dwar it-Tranżizzjoni tal-Kura mill-isptar għad-dar*

Introduction/*Introduzzjoni* (*for use by moderator*)

Welcome and thank you for joining.

This focus group is being organised as part of my PharmD dissertation and the intention is to explore medication and pharmacy aspects during transition of patients from hospital back to the community.

We will basically talk about experiences/inconveniences/issues and solutions/strategies related to medication during the discharge process and beyond and also what you think works well during this transition-of-care.

The aim is to come up with a set of TOC interventions that can be done by a pharmacist that cover the discharge process and a period after discharge.

You were selected because you are all in one way or another involved in transition-of-care with years of experience.

My job is to guide the discussion and ensure we finish on time.

Introduce assistant modeator any say he/she will take field notes. Tell participants to speak slowly.

The session will be recored and this is important because it is not always possible to write what you express so well quickly.

In your folder you will find a letter of consent which gives me permission to record the session and use the information in my study.

Ground rules and clarifications/*Regoli u kjarifiki (for use by moderator)*

Mobile phones – please keep them in quiet mode and if you have to answer you can leave the room and obviously come back.

No wrong answers, just people have different experiences/***Ma jeżistux tweġibiet ħżiena***

Help yourself to some food

Short presentation/*Preżentazzjoni qasira* (for use by moderator)

Engagement questions (*for use by moderator*)

1. What do you think about transition-of-care? Does it pose a risk to patients?
   X-taħsbu fuq it-Tranżizzjoni tal-Kura mill-isptar għad-dar'? Taħsbu li din toħloq xi riskju għall-pazjent?

Exploration questions (*for use by moderator*)

2. What are the inconveniences/problems you encounter related to medication during the discharge process? (*short pause technique to encourage open discussion*)
   X'inhuma l-problemi li tiltaqgħu magħhom meta pazjent jiġi illiċenzjat mill-isptar? (pawsa qasira biex tinkuraġġixxi diskussjoni)

3. What interventions should be done to ensure a safe transition from hospital to the community? (*use list technique and give sheet of paper to participants to write down the 3 most important interventions to counter any shortcommings*) – (*after give rating sheets 1 and 2*)
   X'għandu jinkludi programm li jassigura tranżizzjoni tal-kura tal-pazjent mingħajr problemi bejn l-isptar u d-dar?

4. Should the TOC program be adaptive according to the patient's needs or should all components be mandatory irrespective of the patient?
   Il-programm għandu jkun adattabbli skond l-eżiġenzi tal-pazjent jew għanda tkun mandatorja u l-istess għal kullħadd?

5. Do you think that such interventions are generalisable to all patients? How can the program be specific to Heart Failure patients?
   Taħsbu li dawn l-interventi jistaw jiġu applikati għal kull pazjent? Kif il-programm jista jkun aktar specifiku għal pazjenti b'heart failure?

*Rating sheet **1** for the following question **(for use by moderator)***

During the discharge process, please *rate* the following as:

Waqt il-proċess ta' illiċenzjament mill-isptar ikklassifika skont din il-lista:

1 - not important/*mhux importanti*

2 – important/*importanti*

3 – very important/*importanti ħafna*

a. Patient and/or caregiver education regarding medication.
Li teduka l-pazjent jew qarib tiegħu dwar l-użu tal-mediċina.

b. Accurate and complete documentation regarding medication entitlement.
Applikazzjonijiet u dokumenti kompluti u preċiżi rigward l-intitolament tal-mediċina.

c. Discharge prescription mirrors treatment on discharge on case summary.
Ir-riċetti li jinħarġu waqt l-illiċenzjament ikunu jirriflettu dak li hemm imniżżel fuq is-sommarju tal-każ.

d. Administrative/procedural plan regarding medication entitlement explained to patient/caregiver.
Il-proċeduri amministrattivi rigward approvazzjoni ta' intitolament ta' mediċini jiġu spjegati sew lill-pazjent/qarib.

e. Adequate discharge medication cover from the hospital pharmacy.
Ammont adegwat tal-mediċina preskritta tingħata mill-ispiżerija tal-isptar lill-pazjent qabel jitlaq.

1 During the discharge process, please *rate* the following as:

Waqt il-proċess ta' illiċenzjament mill-isptar ikklassifika skont din il-lista:

1 - not important/***mhux importanti***

2 – important/***importanti***

3 – very important/***importanti ħafna***

	NOT IMPORTANT ***MHUX IMPORTANTI***	**IMPORTANT** ***IMPORTANTI***	**VERY IMPORTANT** ***IMPORTANTI HAFNA***
Patient and/or caregiver education regarding medication. ***Li teduka l-pazjent jew qarib tiegħu dwar l-użu tal-mediċina.***			
Accurate and complete documentation regarding medication entitlement. ***Applikazzjonijiet u dokumenti kompluti u preċiżi rigward l-intitolament tal-mediċina***			
Discharge prescription mirrors treatment on discharge on case summary. ***Ir-riċetti li jinħarġu waqt l-illiċenzjament ikunu jirriflettu dak li hemm imniżżel fuq is-sommarju tal-każ.***			
Administrative/procedural plan regarding medication entitlement explained to patient/caregiver. ***Il-proċeduri amministrattivi rigward approvazzjoni ta' intitolament ta' mediċini jiġu spjegati sew lill-pazjent/qarib.***			
Adequate discharge medications cover from the hospital pharmacy. ***Ammont adegwat tal-mediċina preskritta tingħata mill-ispiżerija tal-isptar lill- pazjent qabel jitlaq.***			

*Rating sheet **2** for the following question **(for use by moderator)***

After discharge and patient is again in a community setting, please *rate* the following as:

Wara li l-pazjent ikun illiċenzjat mill-isptar u jirritorna lura d-dar, iklassifika skont din il-lista:

1 - not important/***mhux importanti***

2 – important/***importanti***

3 – very important/***importanti ħafna***

a. Adherence to treatment.
Kemm wieħed jimxi skont l-istruzzjonijiet tat-tabib rigward il-mediċini.

b. Keeping single private family doctor.
Li jżomm tabib wieħed tal-familja.

c. Timely medication refill through POYC.
Il-mediċini tal-POYC jingħatawlek fil-ħin.

d. Careful utilisation/appropriate selection of OTC medication.
Użu tajjeb u addatt ta' mediċini li m'hemmx bżonn riċetta tat-tabib biex jinxtraw.

e. Reducing medication risk factors such as multiple brands of same medication.
Li wieħed inaqqas riskji rigward mediċini bħal ħafna ditti tal-istess mediċina.

2 After discharge and patient is again in a community setting, please *rate* the following as:

Wara li l-pazjent ikun illiċenzjat mill-isptar u jirritorna lura d-dar, iklassifika skont din il-lista:

1 - not important/***mhux importanti***

2 – important/***importanti***

3 – very important/***importanti ħafna***

	NOT IMPORTANT ***MHUX IMPORTANTI***	**IMPORTANT** ***IMPORTANTI***	**VERY IMPORTANT** ***IMPORTANTI HAFNA***
Adherence to treatment. ***Kemm wieħed jimxi skont l-istruzzjonijiet tat-tabib rigward il-mediċini.***			
Keeping single private family doctor. ***Li jżomm tabib wieħed tal-familja.***			
Timely medication refill through POYC. ***Il-mediċini tal-POYC jingħatawlek fil-ħin.***			
Careful utilisation/appropriate selection of OTC medication. ***Użu tajjeb u addatt ta' mediċini li m'hemmx bżonn riċetta tat-tabib biex jinxtraw.***			
Reducing medication risk factors such as multiple brands of same medication. ***Li wieħed inaqqas riskji rigward mediċini bħal ħafna ditti tal-istess mediċina.***			

*Rapid feedback - speak up if you don't agree/**tkelmu jekk ma taqblux** **(for use by moderator)***

What should a TOC program include?

X'għandu jinkludi programm li jassigura tranżizzjoni tal-kura tal-pazjent mingħajr problemi bejn l-isptar u d-dar.

a. Early identification of patients/clients at risk of readmissions. **[mandatory]**
Li wieħed jidentifika dawk il-pazjenti li huma f'riskju li jispiċċaw lura l-isptar wara ftit.

Patients at risk: **(*For use by moderator only*)**

1. Diagnosis associated with high admissions.
2. Co-morbidities.
3. The need for numerous medication/high risk medication.
4. A history of readmissions.
5. Psychosocial factors.
6. The lack of a family member/caregiver.
7. Older age.
8. Financial distress.
9. Deficient living environment.

b. Medication reconciliation. **[mandatory]**
Li wieħed jiċċekkja sew il-medicina li l-pazjent suppost qed jieħu.

c. Patient education starting NOT on the day of discharge but before. **[adaptive]**
Li wieħed jeduka l-pazjent dwar l-użu tal-mediċina minn ġranet qabel jiġi illiċenzjat u mhux eżatt qabel jitlaq mis-sala.

d. Caregiver education. **[adaptive]**
Li wieħed jeduka wkoll lill-qarib li jieħu ħsieb lill-pazjent lura d-dar.

e. Screening of documentation for medication entitlement. **[mandatory]**
Li wieħed jiċċekkja d-dokumenti u applikazzjonijiet rigward mediċini qabel imur bihom l-uffiċċju għall-approvazzjoni.

f. Screening for drug-related problems. **[mandatory]**
L-ispiżjar jiċċekkja jekk xi mediċina tista toħloq xi problema lill-pazjent.

g. Early visit to private family doctor after discharge and attendance to heart failure clinic if referred by cardiologist. **[adaptive]**

Il-pazjent imur għand it-tabib tal-familja fi żmien qasir wara li jiġi illiċenzjat u jmur il-klinika tal-HF meta referut mill-kardjoloġista.

h. Patient hotline to discuss medication problems with a pharmacist. **[adaptive]**
Il-pazjent ikun jista` jċempel lill-ispiżjar biex jiddiskuti problemi rigward mediċina.

i. Home visit after first POYC refill to solve any problems. **[adaptive]**
L-ispiżjar jagħmel żjara d-dar tal-pazjent biex isolvi xi problemi li jistgħu jiżviluppaw.

j. Telephone calls to discuss medication related problems during the 30 days after discharge. **[adaptive]**
L-ispiżjar jagħmel telefonati lill-pazjent f'xi ġranet fl-ewwel 30 jum wara l-illiċenzjament biex jiddiskuti problemi rigward mediċina.

k. Direct communication of hospital pharmacist with POYC pharmacist regarding recently discharged patients. **[adaptive]**
Ikun hemm kommunikazzjoni bejn l-ispiżjar tal-isptar u dak fl-ispiżerija tal-kommunita` rigward pazjenti li jkunu illiċenzjati riċentement.

l. Direct communication of hospital pharmacist with private family doctor. **[adaptive]**
Ikun hemm kommunikazzjoni bejn l-ispiżjar tal-isptar u t-tabib tal-familja rigward pazjenti li jkunu illiċenzjati riċentement.

m. Dedicated personnel including pharmacists from hospital with the specific duty to see through patients during the transition-of-care and during the first 30 days after discharge.
Ikun hemm impjegati apposta fosthom spiżjara mill-isptar li xogħolhom ikun speċifikament li jaraw li kollox imur sew minn meta pazjent jiġi illiċenzjat sal-ewwel 30 jum wara l-illiċenzjament.

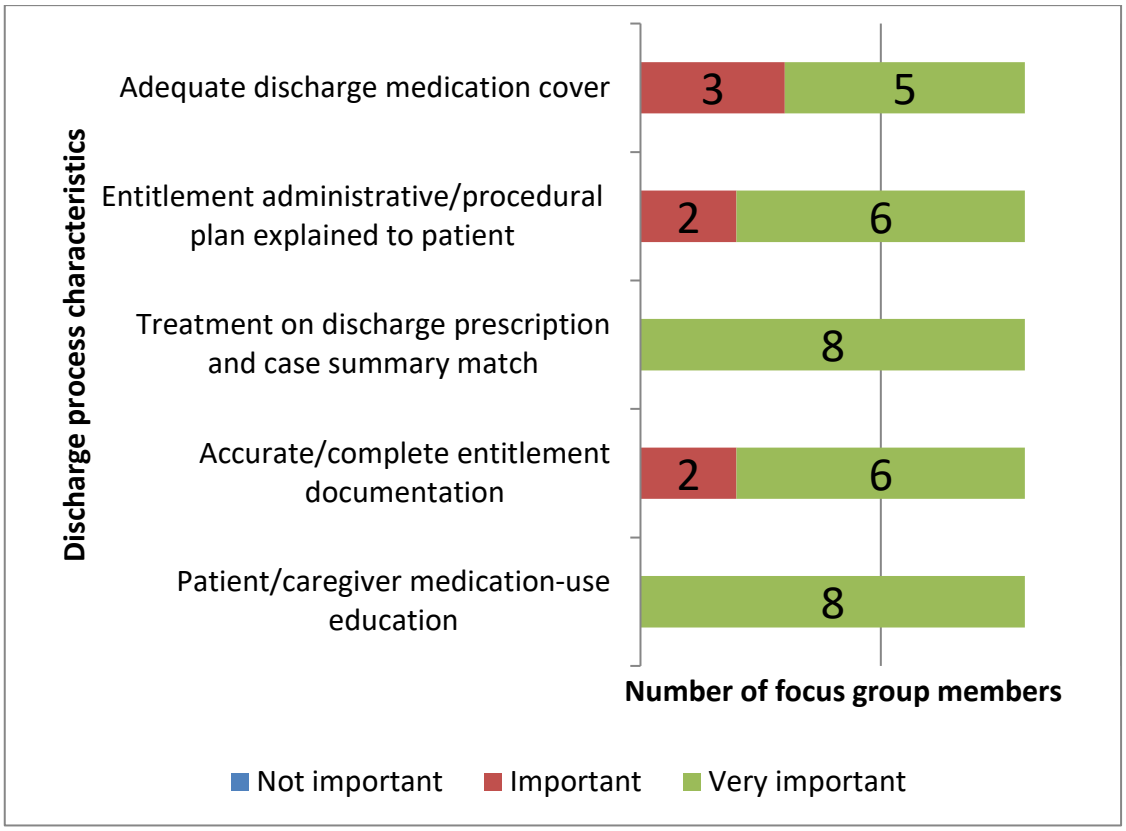


Figure 4. Rating of focus group members on five characteristics about the discharge process.

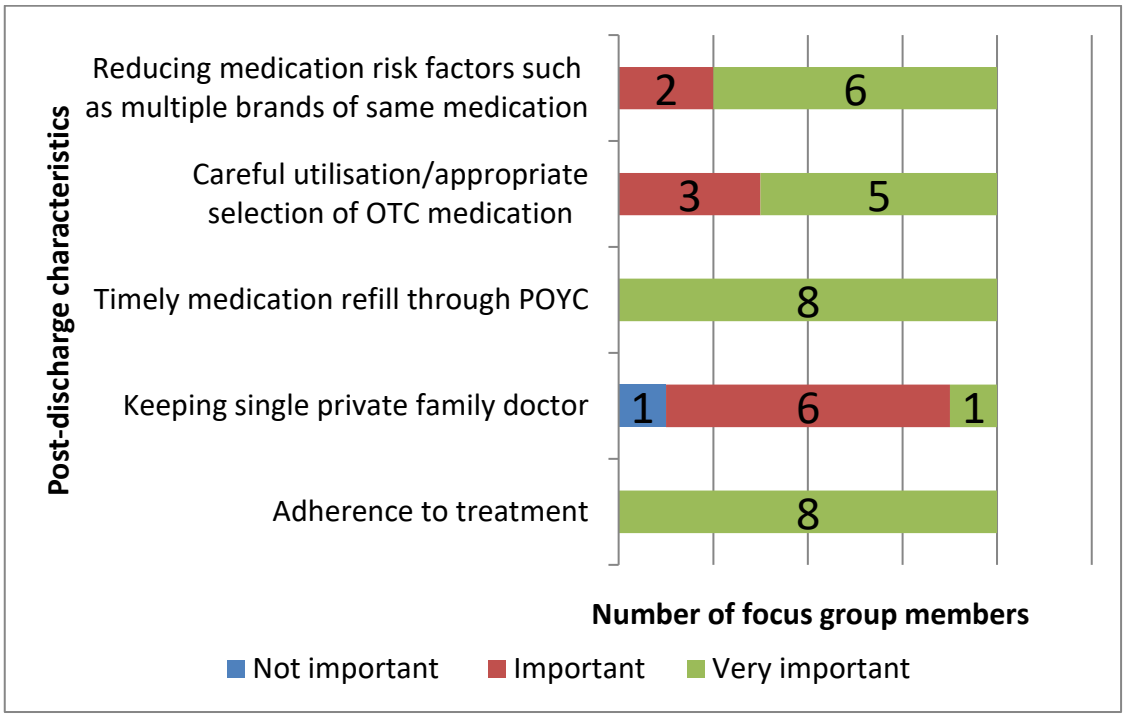


Figure 5. Rating of focus group members on five characteristics when the patient is back in the community setting after hospital discharge.

Thematic analysis

Pharmacist's role in TOC

In regard to the pharmacists' role, the participants positively perceived the integration of a ward-based pharmacist as important to ensure medication reconciliation on admission and at discharge and apply pharmaceutical care as part of the process while the patient is at the ward.

"…the blue card is filled in at the ward to guide the patient but if the prescriptions or treatment chart have errors than this will be repeated. Having a pharmacist on the ward will facilitate all this and on days not covered like Sundays this can be covered by nurses/doctors because not many discharges take place anyway. Today I have ten discharges so if I have a pharmacist doing reconciliation less mistakes happen and the patient understands what is happening as well." (P2)

"…Drug reconciliation should start during drug history taking on admission not just before discharge. The important thing is that you have a process that picks up problems and the loop is closed. The ward pharmacist should also be supported with retrospective review. 100% drug order verification is impossible to make it concurrently or prospectively." (P1)

Communication

The problem of lack of proper communication was also raised during the focus group and mainly focused on the deficiencies within the system as well as the lack of who and how should changes to medication be communicated.

"The POYC program should cater for changes and if doctor A changes a medication it is written as such, doctor A prescribed drug X and then POYC pharmacists, health centre doctors and private doctors should have access to the software." (P7)

"… ideally drug changes can be communicated directly to the POYC pharmacists because I am not always sure about changes in medication." (P7)

"… ideally when the patient is discharged the discharge medication is imputed from the hospital and is picked up from the POYC pharmacy. In that way you have a guarantee that no other medication is given or other prescriptions used. A bad system always beats a good person and this is all a problem with communication between the discharging hospital and the post-discharge providers." (P1)

"Patients or relatives come with the pouch so that I do their prescriptions,… I have a record on my pc of what the patient takes which I update but then by chance I find that they have a case summary in the pouch… if I do not check, nobody would have told me about the recent, or not so recent admission". (P6)

Process considerations

The participants came up with a number of process considerations the practicality of which was discussed.

"…Abroad a dossette box is given by the hospital on discharge (so not just medication) if the patient is above a certain age. Patients are also given a green bag so they put all the medication in it so it does not get lost. The patients are told to grab the bag and bring it to ER if anything happens. Sometimes you find other things in the bag but it still helps us to know what the patient is taking". (P8)

"…we go to the extent that we affix tablets to the blue card so that the patient knows which tablet to take but this is obviously time consuming and cannot be done to everyone, you have to adapt to the needs of the patient". (P2)

"…the blue card should also bear for what the medication is being taken. For example we had a patient being admitted because the private doctor changed atenolol because he taught that it was for hypertension when in fact it was for arrhythmia.. the patient was obviously admitted for arrhythmia. Like the problem of valsartan, what is the patient taking it for, heart failure or hypertension?, this would make a difference if you want to change". (P5)

"…sometimes instead of the blue card the patient is given a printed version which in a short time becomes a white paper like all the others and nobody notices it".(P2)

"Double checking is important at ward level… It is expected that drug history taking at casualty results in mistakes because the patient is in shock or confused. This is inevitable". (P5)

"Double checking has to be independent, reconfirmation across the board …otherwise if it is done in the presence of the other it will lead to poor outcomes... if you ask your colleague to double check probably he tells you OK, meaning I trust you and this is not double checking". (P1)

Patient education

In regard to patient education the participants agreed that patient education is imperative to improve adherence to medication and the pharmacists' input across the care continuum.

"Half of the patients have no idea what they take and come with no yellow card etc . You ask the patient whether some medication has been changed and the answer you get is I forgot, I don't know, etc. When medications are changed at hospital you find records somehow but when changes take place in the community it is very difficult to know what is happening. In England you get a treatment card which is updated every time changes are done by the GP. Locally no one updates anything when changes are done. I am not exaggerating half of the patients we get do not know what they take. In this scenario you cannot check whether they are adherent" (P5)

"we should seek to educate patients at every opportunity, repetition will help especially with elderly patients" (P7)

Appendix 3

Patient Data Collection Form

Patient Data Collection Form

General information

Name: _____ Age: ____ Gender: M / F ID No. _____

Caregiver Name: _____ Contact No: _____

Admissions: First, Second, More Readmissions: YES NO

Referred to Heart Failure Clinic: YES NO Attended Heart Failure Clinic: YES NO

NYHA Functional Class: I, II, III, IV Ejection Fraction: ____ NT-proBNP level: ____

POYC: _____ Private Family Doctor: _____

Medical History

(1) ____ (2) ____ (3) ____ (4)____ (5)____(6)____ (7) ____(8)____

Eyesight: N I Hearing: N I Manual dexterity: Good Weak

Social History

Smoker: YES NO Ex-smoker Alcohol consumption: YES NO

Education: LITERATE Primary/ Secondary / Tertiary ILLITERATE

Lives alone: YES NO Next of Kin also an elderly person: YES NO NOT APPLICABLE

Medication on admission:

(1) _____ (4) _____ (7) _____ (10) _____

(2) _____ (5) _____ (8) _____ (11) _____

(3) _____ (6) _____ (9) _____ (12) _____

Medication at discharge:

(1) _____ (4) _____ (7) _____ (10) _____

(2) _____ (5) _____ (8) _____ (11) _____

(3) _____ (6) _____ (9) _____ (12) _____

Specialty Medication: YES NO Narrow Therapeutic Index Drug: YES NO

Dose that involves splitting a tablet: YES NO

Number of Medications at admission: _____ Drug Allergy: YES NO

Drug	On target dose	Below target dose	Missing dose data
Beta blocker			
ACE inhibitor			
Mineralocorticoid			

SHPA[1] guidelines to prioritise patients according to risk factors *(for guidance purposes only)*

• have medication misadventure as the known or suspected reason for their presentation or admission	
• are aged 65 years or older	
• take 5 or more medicines	
• take more than 12 doses of medicines per day	
• take a medicine that requires therapeutic monitoring or is a high-risk medicine	
• have clinically significant changes to their medicines or treatment plan within the last 3 months	
• have suboptimal response to treatment with medicines	
• have difficulty managing their medicines because of literacy or language difficulties, dexterity problems, impaired sight, confusion/dementia or other cognitive difficulties	
• have impaired renal or hepatic function	
• have problems using medication delivery devices or require an adherence aid	
• are suspected or known to be non-adherent with their medicines	
• have multiple prescribers for their medicines	
• have been discharged within the last 4 weeks from or have had multiple admissions.	

1. shpa.org.au [internet]. Medication reconciliation. Standards of Practice for Clinical Pharmacy Services. Published October 28, 2016. [cited 2018 March 23]. Available from: https://www.shpa.org.au/sites/default/files/uploaded-content/website-content/SOP/ sop_clinical _pharmacy_s6-s12_chapter1.pdf

Pharmaceutical Care Plan – Phase 3 intervention cohort

ACTIVE PROBLEMS

Date of onset	Diagnosis	Comments	Date resolved

CURRENT MEDICATION

Known Sensitivities/ADRs:

Drug	Form	Dose	Regimen	Route	Start date	Stop date

PHARMACEUTICAL CARE ISSUES

Date	Care Issue	Proposed Action	Desired Outcome

GUIDE TO PHARMACEUTICAL CARE ISSUES

Need for additional drug	Risk of interaction
Unclear/unconfirmed indication	Monitoring need
Unnecessary treatment	Counselling need
Improper drug selection	Seamless care need
Dosage too low	Inappropriate compliance
Dosage too high	Non-adherence to protocol
Risk for ADR	

Appendix 4

Treatment Adherence Questionnaire and Condition-related Questions

TREATMENT ADHERENCE QUESTIONNAIRE (TAQ)

Patient Reference Number:

Part A and Part B include questions on medicine use, compliance and the effect on the patient. After each question circle the 0, 1, 2, 3, 4 or 5 depending on your selected answer. The maximum total score (Part A + Part B) is equal to 100. High adherence is shown by a high score.

Part A:	**Never**	**Rarely**	**Occasionally**	**Sometimes**	**Often**	**Always**
1. Do you feel you need to understand your condition more clearly?	0	1	2	3	4	5
2. Do you feel you need to understand your treatment more clearly?	0	1	2	3	4	5
3. Do you have anyone to assist your daily needs with the management of your condition?	0	1	2	3	4	5
4. Do you obtain your medicines for free?	0	1	2	3	4	5
5. If any of your medicines are not available for free, do you agree to buy them?	0	1	2	3	4	5
6. When buying non-prescription medicines from the pharmacy, do you check if they can cause any interactions with the prescribed medicines?	0	1	2	3	4	5
7. Do you take your prescribed medicines?	0	1	2	3	4	5
8. Do you take your medicines at their prescribed times?	0	1	2	3	4	5
9. If you travel abroad, do you take along your medicines?	0	1	2	3	4	5
10. When you go abroad do you take along with you the relevant documents containing information on your prescribed medicines?	0	1	2	3	4	5
A: High score indicates high adherence						**Score: 50**

Anastasi A. Constructivism in Innovative Models of Pharmaceutical Care Bridging Administrative and Clinical Pharmacist Intervention: Heart Failure Model. Ph. D. [Dissertation]. University of Malta, Malta: 2017.

TREATMENT ADHERENCE QUESTIONNAIRE (TAQ)

Patient Reference Number:

Part B:	Never	Rarely	Occasionally	Sometimes	Often	Always
1. Were there any occasions were you stopped taking your medicine out of your own free will?	5	4	3	2	1	0
2. Do you ever miss a dose?	5	4	3	2	1	0
3. Did you miss / stop treatment, because you:						
i Forgot?	5	4	3	2	1	0
ii Experienced adverse effects?	5	4	3	2	1	0
iii Did not collect your medicine on time?	5	4	3	2	1	0
iv Have too many medicines and you got confused on how they should be administered?	5	4	3	2	1	0
v. Did not understand why you are taking the said medicine and the effect it has on you?	5	4	3	2	1	0
vi Were concerned after reading the 'Patient Information Leaflet'?	5	4	3	2	1	0
vii Needed expensive medicine?	5	4	3	2	1	0
viii Felt good and decided that you did not need the medicine?	5	4	3	2	1	0
B: High score indicates high adherence						**Score: 50**

Anastasi A. Constructivism in Innovative Models of Pharmaceutical Care Bridging Administrative and Clinical Pharmacist Intervention: Heart Failure Model. Ph. D. [Dissertation]. University of Malta, Malta: 2017.

KWESTJONARJU GĦALL-UŻU TAL-MEDIĊINA U L-PAZJENT (KUMP)

Numru tar-riferenza tal-pazjent:

Taqsima A u Taqsima B include jinkludu mistoqsijiet li qegħdin janalizzaw it-teħid tal-mediċina u l-effett fuq il-pazjent. Fejn kull mistoqsija, ġħamel ċirku madwar wieħed min-numri 0, 1, 2, 3, 4 jew 5 skont it-tweġiba li tagħżel. It-total massimu (Taqsima A + Taqsima B) huma ta' mija (100). Skor għoli juri li l-pazjent jipparteċipa b'mod attiv fit-trattament tiegħu għax jemmen li jagħmillu tajjeb skont ir-rikommandazzjoni tal-kliniku.

Taqsima A:	**Qatt**	**Rari**	**Xi Kultant**	**Ftit drabi**	**Ħafna drabi**	**Dejjem**
1. Tinforma ruħek biżżejjed fuq il-kundizzjoni tiegħek?	0	1	2	3	4	5
2. Tinforma ruħek biżżejjed fuq il-mediċina li qiegħed/qegħda tieħu?	0	1	2	3	4	5
3. Għandek lil xi ħadd li jgħinek fil-bżonnijiet tiegħek ta' kuljum fil-kura tal-kundizzjoni tiegħek?	0	1	2	3	4	5
4. Kien hemm xi drabi fejn int kont intitolat/a għall-mediċina b'xejn?	0	1	2	3	4	5
5. Jekk xi mediċina preskrita lilek, ma tingħatax b'xejn, int tixtriħa?	0	1	2	3	4	5
6. Meta tixtri mediċina mill-ispiżerija mingħajr riċetta tat-tabib, tiċċekja jekk tistax teħodha mall-mediċina preskritta?	0	1	2	3	4	5
7. Il-mediċina preskritta teħodha?	0	1	2	3	4	5
8. Il-mediċina teħodha fil-ħinijiet stipulati?	0	1	2	3	4	5
9. Meta ssiefer tieħu l-mediċina miegħek?	0	1	2	3	4	5
10. Meta ssiefer tieħu miegħek id-dokumenti ta' tagħrif fuq il-mediċina li qiegħed/qegħda tieħu?	0	1	2	3	4	5
A: Skor għoli jfisser li t-teħid tal-mediċina huwa adekwat u effettiv fuq il-pazjent						**Skor: 50**

Anastasi A. Constructivism in Innovative Models of Pharmaceutical Care Bridging Administrative and Clinical Pharmacist Intervention: Heart Failure Model. Ph. D. [Dissertation]. University of Malta, Malta: 2017.

KWESTJONARJU GĦALL-UŻU TAL-MEDIĊINA U L-PAZJENT (KUMP)

Numru tar-riferenza tal-pazjent:

Taqsima B:	**Qatt**	**Rari**	**Xi Kultant**	**Ftit drabi**	**Hafna drabi**	**Dejjem**
1. Kien hemm xi drabi fejn waqqaft mediċina minn jheddek?	5	4	3	2	1	0
2. Kien hemm xi drabi fejn qabbiżt xi doża?	5	4	3	2	1	0
3. Qabbiżt doża u/jew waqqaft mediċina għax:						
i Insejt?	5	4	3	2	1	0
ii Tgħmillek id-deni?	5	4	3	2	1	0
iii Il-mediċina spiċċat u ma lħaqtx ġibt iktar?	5	4	3	2	1	0
iv Hemm wisq mediċini u titgerfex kif trid teħodhom?	5	4	3	2	1	0
v. Ma tifhimx għaliex qiegħed/qegħda tieħu l-mediċina u x'effett għandha fuq il-ġisem tiegħek?	5	4	3	2	1	0
vi L-informazzjoni fuq il-mediċina li taqra fuq il- 'Patient Information leaflet' tbeżżgħak?	5	4	3	2	1	0
vii Trid tixtri l-mediċina u tiswa hafna?	5	4	3	2	1	0
viii Tħossok tajjeb/tajba u għalhekk tiddeċiedi li ma hemmx bżonn li tieħu l-mediċina?	5	4	3	2	1	0
B: Skor għoli jfisser li t-teħid tal-mediċina huwa adekwat u effettiv fuq il-pazjent						**Skor: 50**

Anastasi A. Constructivism in Innovative Models of Pharmaceutical Care Bridging Administrative and Clinical Pharmacist Intervention: Heart Failure Model. Ph. D. [Dissertation]. University of Malta, Malta: 2017.

Condition-related Questions

What is the name of your water tablet?

X'jisimhom il-pilloli tal-pp?

Do you weigh yourself every day and if yes what is the significance of a 2kg increase in two days?

Inti tintiżen kuljum u jekk iva xi tifisser għalik jekk tiżdied zewġ kilos fi żmien jumejn?

Do you add salt to your prepared food or seasoning cubes while preparing food?

Inti żid melħ ma l-ikel jew dadi tal-ħwawar waqt li tkun qed isajjar?

Which symptoms related to heart failure should you report to your doctor?

X'sintomi li għandhom x'jaqsmu mall-kondizzjoni tal-qalb tiegħek taħseb li għandek tkellem tabib minnufih dwarhom?

Appendix 5

Discharge checklist and Guiding documents

PHARMACIST INTERDISCIPLINARY DISCHARGE PLANNING CHECKLIST

	Document Type/Task/Service	What to look for/what to do	Action required
Entitlement documents	Is the patient entitled to free medication ☐	Check about citizenship/employment etc.	If not confirm availability of medication on the market and inform patient/caregiver accordingly
	Schedule V application done? ☐	Previous medication retained – has the box been ticked	If not, confirm with house officer (HO) and tick accordingly
	☐	Protocol number specified if applicable	If not, confirm with HO and fill in as appropriate
	☐	Appropriate condition ticked	If not, confirm with HO and medical file and tick accordingly
	☐	Is it signed by the consultant or delegate?	Refer to HO to get it signed by consultant
	Patient has Schedule II ☐	Is it expired or expires soon?	If yes inform patient and caregiver to renew
	Protocol regulated medication approval ☐	Is it expired or expires soon?	Inform patient/caregiver or take document to respective consultant/delegate for signature and hand it to POYC office
	Exceptional treatment application ☐	Is it filled in exhaustively?	If no rectify problem then process through pharmacy
	Protocol regulated treatment form ☐	Is it required?	If yes, ensure application is done
	Guide to getting entitlement ☐	Is it required?	If yes, give to patient/caregiver

Prescriptions	3-day discharge prescription/s	☐	Check drug, dose, frequency	If problems notify HO to correct
	Prescription for controlled drugs	☐	Should be separate from other drugs and on current hospital approved prescription	If not, notify HO to correct
	8-week/2month prescription	☐	Same as for 3-day prescription	Same as for 3-day prescription
	Prescriptions for UMPs	☐	Signed by authorised prescriber	If not, notify house officer to fill in Form 1 or get signature of authorised prescriber
	Prescriptions for non-formulary medication	☐	Ensure that prescription is for private use	If not, notify HO to correct
	Prescriptions for medication not available on the market	☐	Check against last updated list by pharmacy	Inform patient about how to go about procuring the medication
	Prescriptions home oxygen/nebulisers	☐	Assess prescriptions reflect patient requirements based on flowrate and number of hours to be in use	If not, notify HO and make pre-arrangements if possible

Appointments	Does the patient have an ACC referral	☐	Which date?	If not, notify HO; If yes, remind patient
	Does the patient have an Heart failure clinic appointment	☐	Which date?	If yes, remind patient
	Other TDM appointments	☐	Which date?	If yes, remind patient

Pharmacist - tasks	Medication reconciliation performed	☐	Prescriptions and case summary agree with last updated treatment chart	If not, notify HO to correct
		☐	GDMT applied and deviations justified	If not, discuss with HO
		☐	Appropriate doses, frequencies and instructions	If not, notify HO to correct
		☐	Clinically significant interactions	If yes, discuss with HO and involve RS
	Patient/caregiver education performed	☐	How to use the *Guide to Patients: Medication on Discharge* (blue card)	If yes, ensure patient has been given the filled in blue card
		☐	How to take the medication	Reinforce whenever possible
		☐	How to use adherence and other medication-related devices	Assess needs of patient and instruct on the use of: Dossette boxes, spacers, pill cutters, nebuliser machines, oxygen delivery equipment, blood glucose and blood pressure monitors
	Speciality medication	☐	Most likely to take longer than 3 days to be delivered to POYC	If yes, secure entitlement documents ahead of discharge and perform all arrangements while patient is at hospital
	Ancillary advise	☐	Make a follow-up appointment with PFD. Show case summary/discharge note to PFD and POYC pharmacist.	Reinforce idea of informing PFD and POYC pharmacist of recent admission and to take case summary/discharge note in case of health centre visits.
	Whom to contact in case of difficulty	☐		Give contact details to patient or caregiver

Entitlement administrative/procedural information for patients:	Where to go to get the Schedule V application approved and Schedule V issued ☐	POYC office at MDH - Same day discharge service till 1pm Monday to Friday POYC office at SLH - 8am-1pm Monday to Friday (Tel. no 22481800) What other documents to take when applying: ID card Previous Schedule V card	Verbally remind patient/caregiver and ensure a guide is made available
	What to do if you are not registered with POYC ☐	Inform officer at POYC office. You will be asked from which pharmacy you would like to get the service. The officer will call the pharmacy to inform them. You will then be given a temporary code to be used by the pharmacy to access the POYC software.	
	Bridging supply till next refill from POYC ☐	New medication added to previous home medication	Explain to patient to secure supply from POYC till next refill so that all medication will eventually be refilled together

Post-hospital services	POYC pharmacy ☐		Secure details
	Private Family Doctor ☐		Secure details
	Commcare® nursing ☐		Ensure entity informed and patient knows about it

Guide to patients: Documents on discharge

At discharge you have been given the following documents:

Case Summary	☐	*3-days discharge prescription*	☐
Schedule V application (yellow card)	☐	*2-months prescription*	☐
Medication on discharge Guide (blue card)	☐		☐

Case Summary

This is an important document. It holds important details about your recent admission to hospital. Show this to your private family doctor and POYC pharmacist.

Schedule V Application (yellow card)

This will entitle you to free medication. A Schedule V card (yellow card) will be issued. You need to take this application to the:

POYC office at Mater Dei on the day of discharge only - Monday to Friday 8am to 1pm

or

- POYC office at St. Luke's Hospital, G'Mangia – Monday to Friday 8am to 1pm
- POYC office, 124 Triq l-Arċisqof Pietru Pace, Victoria – Monday to Friday 8am to 1pm

3-day discharge prescription

You need to take this prescription to Mater Dei Pharmacy before you leave. This prescription will entitle you for free medication for the first 3-days after discharge until your Schedule V (yellow card) is issued and be able to get your medication from your POYC.

2-months prescription

This is the prescription you will use to get your medication from your POYC after your Schedule V card (yellow card) has been issued. Get new medication until your next refill date, then refill with the medication that was retained.

Gwida għall pazjent: Dokumenti

Inti ġejt illiċenzjat u se jingħatawlek dawn id-dokumenti:

Sommarju tal-każ (Case Summary)	☐	Riċetta għal xaharejn	☐
Applikazzjoni għal Skeda V (kartuna s-safra)	☐	Riċetta għal tliet t'ijiem	☐
Gwida għall-pazjent (blue card)	☐		☐

Sommarju tal-ka (Case Summary)

Dan huwa dokument importanti. Fih jinstabu dettalji mportanti dwar l-aħħar darba li ġejt rikoverat l-isptar. Uri dan id-dokument lit-tabib privat tiegħek u lill-ispiżjar tal-għażla tiegħek (POYC).

Applikazzjoni għal Skeda V (kartuna s-safra)

Dan huwa dokument li jwassal biex inti tkun intitolat għall-mediċini mingħajr ħlas. Jinħariġlek dokument Skeda V (kartuna s-safra). Trid tieħu din l-applikazzjoni:

Fl-uffiċċju tal-POYC ġo Mater Dei fil-ġurnata li ġejt illiċenzjat/a biss – Mit-Tnejn sal-Ġimgħa 8am sa 1pm

jew

- Fl-uffiċċju tal-POYC Sptar San Luqa, G'Mangia – Mit-Tnejn sal-Ġimgħa 8am sa 1pm
- Fl-uffiċċju tal-POYC, 124 Triq l-Arċisqof Pietru Pace, Victoria – Mit-Tnejn sal-Ġimgħa 8am sa 1pm

Riċetta għal tliet t'ijiem

Ħu din ir-riċetta l-ispiżerija ta' Mater Dei qabel titlaq biex tinqeda. Din ir-riċetta tintitolak għal tliet t'ijiem mediċina mingħajr ħlas wara li tiġi lliċenzjat u sakemm jinħariġlek id-dokument ta' Skeda V (kartuna s-safra) li biha tkun tista' ġġib il-mediċina mill-ispiżerija tal-għażla tiegħek (POYC).

Riċetta għal xaharejn

Din hija r-riċetta li trid tuża biex iġġib il-mediċina mill-ispiżerija tal-għażla tiegħek wara li jkun inħariġlek id-dokument ta' Skeda V (kartuna s-safra). Ġib il-mediċini l-ġodda sal-ġurnata li jmissek tiġbor il-mediċina, biex imbgħad tiġbor kollox f'daqqa.

DH 1184

Guide to Patients: Medication on Discharge

Firm/s: _____

To: _____ I.D. No.:_____ Allergies: _____ Filled By: _____

Name of Medicine	 6 AM	 NOON	 2 PM	 6 PM	 10 PM	What is it used for	Other comments	Date Started	Date Stopped	Signature

Always carry this card with you especially when you come to hospital or visit your doctor. *Continued overleaf...*

Discharge Medication List Form (Not a Prescription)

Reference copy for:
- POYC Pharmacist
- Family Physician
- Out-Patient Clinic Nurse
- In-Patient Pharmacist

Patient name:		**ID No:**		**Age:**	

Doctor/Nurse Reg No:		**Pharmacist:**		**Date:**		**Time:**	

Medication Allergies/Intolerances	**Describe Reaction**
1.	
2.	

List all medications (including insulin, eye drops; inhalers) and non-prescription medications such as Vitamins and herbs.

Discharge Chronic Medication List	**Dose**	**How Often**	**How Taken**	**New Medication**	**Next Dose Due After Discharge**

Discharge Medication Reconciliation Performed	
_____ Date: __/__/____ Time: _____ Pharmacist's Signature	☐ **No changes to the home medications** ☐ **Discharge prescriptions have been issued**

Temporary Medication	**Dose**	**How Often**	**How Taken**	**Comments/ Till Date**	**Next Dose Due After Discharge**

Discharge and Home medications have been reviewed with Patient/ Family caregiver.

Pharmacist's Signature: _____ Date: __/__/____

Patient/Caregiver Signature: _____ Date: __/__/____

What teaching has been done

How to use the Guide to Patients: Medication on Discharge	☐
Recognition of the medication	☐
How to take your medication and at what time	☐
What to do if the medication package is different	☐
Understand what your medications are for	☐
What side effects can be expected	☐
What to do in case of side effects	☐
What medication-related checks do you need	☐
What to do if you miss a dose	☐
What about OTC/alternative/complementary meds	☐
What to do in case you need an OTC	☐

Dear healthcare colleague,

Please reinforce the above teaching

Appendix 6

Pre-discharge education checklist

and

Question Guide for TCM

Individualised pre-discharge education checklist based on TAQ and CRQs

Patient Name: | **ID Number:**

Importance of asking your doctor/pharmacist about your condition and medications	☐
Importance of checking for interactions when buying OTCs	☐
Importance of taking your medication	☐
Importance of taking your medication on time	☐
Importance of taking your medication + documents when you go abroad	☐
Importance of not stopping your medication without the doctor's advice even if you feel well	☐
What to do if you miss a dose	☐
What is your medication for	☐
Why is there a list of side-effects on the package insert	☐
What can you do if you have many medications	☐
How to use a dossette box	☐
Inhaler technique; use of spacer; use of nicotine patches	☐
The name of your water tablet and why you need it	☐
The significance of sudden weight gain and importance of daily weights	☐
Importance of fluid restriction	☐
Importance of salt restriction and use of alternatives	☐
Signs and symptoms that warrant referral	☐

Standard medication-use education – To be given to all patients

Patient Name: | **ID Number:**

How to use the Guide to Patients: Medication on Discharge ☐

How to take your medication and at what time ☐

What is the medication used for ☐

What to do if the medication package is different ☐

What to do if a dose is missed ☐

Instructing patient to remove all old prescriptions from POYC pouch ☐

Importance of follow-up with PFD/Specialist/POYC pharmacist post-discharge ☐

Encourage attendance to follow-up appointments (heart failure clinic, ACC etc.) ☐

Telephone Care Management follow-up guide

Patient Name: | **ID Number:**

How are you?	
Have you attended your appointments? (Remind patients regarding any upcoming appointments – ACC, HF clinic)	
Did you speak to your doctor about your resent admission? (Counsel accordingly)	
Did you have problems with getting your medications from POYC? (Act according to response)	
Have you had any changes to your medications after discharge? (Probe especially during calls towards the end of the 30-day follow-up)	
Can I remind you on changes you need to make with regards to your medication? (Medication reminders: tail-down etc.)	
What concers do you have with your new medication? (side-effects, how and when to take etc.)	
Have you got any questions regarding your medication that you would like to discuss with me?	

Condition-related questions:

Do you remember the name of your water tablet?	
Are you adding salt to your prepared food or during cooking?	
Are you weighing yourself and what does it mean if you have a sudden weight gain?	
Which symptoms would you immediately report to your doctor?	

Appendix 7

Consent forms; information sheets and ethics approval

Information sheet for subjects

Dear Sir/Madam,

You are being invited to participate in a study being carried out on patients admitted to hospital with heart failure. This information sheet contains details about the study and what it involves. I encourage you to read through this sheet before accepting to participate and put forward any questions you may have. If you agree to participate you will be asked to sign a form giving your consent. Participation is strictly on a voluntary basis. Taking part in this study is completely voluntary and will have no effect on the quality of care you will receive. You may decline to take part without any consequences.

Background Information.

Heart failure patients are particularly predisposed to unplanned readmissions and this occurs even within the first 30 days after discharge. This is an unwanted burden on the patient, relatives and healthcare resources. One of the stages which is crucial to prevent this from happening is a proper transition-of-care process. The transition-of-care is that stage when the patient is discharged and returns to the community. Many problems encountered by heart failure patients during the course of treatment are pharmacy and medication related because heart failure is heavily dependent on medication for its management. Therefore, having the appropriate input by pharmacists during the transition-of-care process is key to prevent medication-related problems and unplanned readmissions.

The aims of the study.

The purpose of the study is to differentiate heart failure patients between those who are most likely to have problems with medication use and those that do not. For those who are most likely to have problems related to medication, a transition-of-care program will be developed. Ultimately patients are asked to participate in this program with the aim of preventing an unwanted readmission after discharge.

What the study involves.

The study will consist of 3 phases:

- In Phase 1 a focus group will be organised to establish what kind of interventions are required by pharmacists working at hospital to ensure a smooth transition of care from hospital to the community when the patient is discharged.
- In Phase 2, patients who give consent will be asked a few questions regarding their attitudes towards the use of medications and basic medical details will be recorded from their medical records and their readmissions if any are recorded.

- In Phase 3, patients who give consent will be given the service consisting of the interventions established in Phase 1 and their readmissions if any recorded.

If you agree to participate in this study you will be involved in Phase 2/Phase 3 of the study. You will be asked some questions by the researcher in a short interview that will take about 15 minutes. The questions asked will mostly be related to your attitudes regarding the use of medication.

The researcher will also take note of some medical details which are relevant to the study from your medical record at ward level. With regards to the transition-of-care program, this will consist of a set of initiatives to help you receive the best possible care with regards to obtaining your medications and assistance regarding how to take your medications. Other services such as the possibility of you calling the pharmacist to discuss any medication-related problems such as side-effects depends on you and is not obligatory.

Confidentiality.

The data collected in this study will be strictly confidential. Only the researcher, supervisor and examiners may have access to the data, as this may be required for verification purposes. Your identity number will only be used to verify whether you have been admitted to hospital during the study period. Any data published will not include any personal information and all data will be destroyed as soon as the study is complete.

Taking part in this study is purely voluntary and you may decline to participate. If you agree to take part in this study, you may stop at any time without giving a reason.

If you require any further information and details please feel free to ask me.

Thank you for your time and cooperation.

Ivan DeBono BPharm(Hons)
Senior Pharmacist (Mater Dei Hospital)
Chief Investigator
Email: ivan.debono.94@um.edu.mt
Mobile number: 99879530

Informazzjoni Għall-Parteċipanti

Għażiż Sinjur/a,

Ġejt mistieden biex tieħu sehem fi studju fuq pazjenti li jidħlu l-isptar b'mard tal-qalb. Hawn taħt ser issib dettalji dwar l-istudju u x'jinvolvi. Nixtieq li tinforma ruħek qabel taċċetta li tipparteċipa f'dan l-istudju. Jekk taċċetta li tieħu sehem fl-istudju, ser ikollok tiffirma fuq dokument uffiċċjali li int aċċettajt li tieħu sehem. Parteċipazzjoni f'dan l-istudju huwa kompletament volontarju, tista' tagħżel li ma tipparteċipax u dan ma jkollu l-ebda effett fuq il-kwalita ta' kura li tirċievi. Tista wkoll tirrifjuta li tipparteċipa bl-ebda konsegwenzi għalik.

Informazzjoni.

Pazjenti li jidħlu l-isptar b'mard tal-qalb huma suġġetti li jispiċċaw jerġgħu jidħlu l-isptar f'qasir żmien speċjalment fl-ewwel 30 jum wara li jiġu illiċenzjati. Dan joħloq piż żejjed fuq il-pazjent, il-qraba kif ukoll fuq is-sistema tas-saħħa. Wieħed mill-metodi biex tevita dan huwa li tassigura li l-pazjent ikollu nkonvenjenzi u problemi mill-anqas fil-proċess meta jgħaddi mill-kura fl-isptar għal dik fil-kommunita` wara li jiġi illiċenzjat, kif ukoll jiġi ppreparat u edukat tajjeb dwar l-użu tal-mediċina. Ħafna mill-problemi li jkollhom pazjenti b'mard tal-qalb wara li jiġu illiċenzjati huma marbuta mal-użu tal-mediċina u aspetti oħra ta' natura farmaċewtika għaliex it-trattament jiddependi ħafna fuq l-użu tal-mediċina. Għalhekk huwa importanti li l-ispiżjar jintervjeni f'dan il-proċess biex ikunu evitati problemi għall-pazjent fejn tidħol użu ta' mediċina u konsegwentement dħul l-isptar.

L-għan tal-istudju.

L-għan tal-istudju huwa li jagħmel distinzjoni bejn pazjenti li x'aktarx ikollhom problemi rigward użu tal-medicina u dawk li ma jkollhomx. Għal dawk li x'aktarx ikollhom problemi rigward użu tal-mediċina ser jiġi żviluppat programm li wieħed isegwi fil-proċess meta pazjent jgħaddi mill-kura fl-isptar għal dik fil-kommunita'. Dawk il-pazjenti li jaċċettaw li jipparteċipaw, isegwu dan il-programm. L-għan aħħari ta' dan il-programm ikun li jiġu evitati problemi relatati mal-mediċina u dħul l-isptar mhux ippjanat.

X'jinvolvi l-istudju?

L-istudju se jkun jikkonsisti fi tliet fażijiet:

- Fl-ewwel fażi se jiġi organiżat grupp ta' diskussjoni biex jiġi mħejji programm ta' inizjattivi li jkunu mwetqa minn spiżjara tal-isptar bil-għan aħħari li jkun faċilitat u mtejjeb is-servizz relatat mal-mediċini meta tkun illicenzjat/a mill-isptar.

- Fit-tieni fażi l-pazjenti li jgħatu l-kunsens tagħhom ikunu mistoqsija ftit domandi dwar kif jieħdu u x'jaħsbu dwar il-mediċini li jieħdu. Tittieħed ukoll xi nformazzjoni dwar saħħithom mir-rekords mediċi tal-isptar u tittieħed nota tad-drabi li jiġu mdaħħla l-isptar.
- Fit-tielet fażi l-pazjenti li jgħatu l-kunsens tagħom jingħataw il-programm ta' inizjattivi stabbilit fl-ewwel fażi u tittieħed nota tad-drabi li jiġu mdaħħla l-isptar.

Jekk inti taqbel li tipparteċipa f'dan l-istudju tkun involut fit-tieni fażi tal-istudju. Ir-riċerkatur ser ikun qed jagħmillek ftit mistoqsijiet f-forma ta' intervista qasira li tieħu madwar ħmistax il-minuta. Il-mistoqsijiet huma prinċipalment relatati ma' kif inti tagħmel użu mill-mediċina.

Ir-riċerkatur jieħu wkoll nota ta' xi dettalji mediċi relevanti għall-istudju mir-rekords mediċi tiegħek li jinsabu fis-sala ta' l-isptar. Rigward il-programm ta' inizjattivi, dan se jkun jikkonsisti f'numru ta' interventi li permezz tagħhom tirċievi l-aħjar servizz ma dak li għandu x'jaqsam mal-mediċina li tieħu. Servizzi bħall-possibilita' li ċċempel lill-ispiżjar biex tiddiskuti xi problemi marbuta mal-mediċini li tieħu bħal effetti ħziena li jistgħu jagħmlulek mhix obligatorja.

Kunfidenzjalita'

L-informazzjoni miġbura f'dan l-istudju hija kunfidenzjali u kull informazzjoni ppublikata ma tkunx tinkludi dettalji personali. Ir-riċerkatur, il-persuna li ser twettaq is-superviżżjoni u l-eżaminatur biss ser ikollhom aċċess għal din l-informazzjoni minħabba raġunijiet ta' verifika. In-numru tal-karta ta' l-identita' tiegħek ser tiġi użata biss biex titieħed nota jekk inti tidħol l-isptar fil perjodu tal-istudju. Kull informazzjoni miġbura tiġi meqruda hekk kif jispiċċa l-istudju.

Parteċipazzjoni f'dan l-istudju hija volontarja u tista' tagħżel li ma tipparteċipax. Jekk taċċetta li tipparteċipa f'dan l-istudju, tista' tieqaf f'kull ħin mingħajr ma tagħti ebda spjegazzjoni.

Jekk għandek xi mistoqsijiet tista` tagħmel dan lili.

Nirringrazzjak tal-ħin u l-kooperazzjoni tiegħek.

Ivan DeBono BPharm (Hons)
Spiżjar anzjan (Sptar Mater Dei)
Investigatur Prinċipali
Email: ivan.debono.94@um.edu.mt
Numru tal-mobajl: 99879530

Information sheet for Focus Group Participants – Patient and Caregiver

Dear Sir/Madam,

You are being invited to participate in a focus group as part of a study being carried out on patients admitted to hospital with heart failure. This information sheet contains details about the study and what it involves. I encourage you to read through this sheet before accepting to participate and put forward any questions you may have. If you agree to participate you will be asked to sign a form giving your consent. Participation is strictly on a voluntary basis. Taking part in this study is completely voluntary and will have no effect on the quality of care you will receive. You may decline to take part without any consequences.

Background Information.

Heart failure patients are particularly predisposed to unplanned readmissions and this occurs even within the first 30 days after discharge. This is an unwanted burden on the patient, relatives and healthcare resources. One of the stages which is crucial to prevent this from happening is a proper transition-of-care process. The transition-of-care is that stage when the patient is discharged and returns to the community. Many problems encountered by heart failure patients during the course of treatment are pharmacy and medication related because heart failure is heavily dependent on medication for its management. Therefore, having the appropriate input by pharmacists during the transition-of-care process is key to prevent medication-related problems and unplanned readmissions.

The aims of the study.

The purpose of the study is to differentiate heart failure patients between those who are most likely to have problems with medication use and those that do not. For those who are most likely to have problems related to medication, a transition-of-care program will be developed. Ultimately patients are asked to participate in this program with the aim of preventing an unwanted readmission after discharge.

What the study involves.

The study will consist of 3 phases:

- In Phase 1 a focus group will be organised to establish what kind of interventions are required by pharmacists working at hospital to ensure a smooth transition of care from hospital to the community when the patient is discharged.

- In Phase 2, patients who give consent will be asked a few questions regarding their attitudes towards the use of medications and basic medical details will be recorded from their medical records and their readmissions if any are recorded.
- In Phase 3, patients who give consent will be given the service consisting of the interventions established in Phase 1 and their readmissions if any recorded.

If you agree to participate in this focus group session you will be involved in Phase 1 of the study. Participants in the focus group will be a consultant, a community pharmacist, a nurse, a clinical pharmacist, a quality assurance officer, a family doctor, a patient and a family caregiver. The researcher will seek your views and suggestions about improving the service during and after hospital discharge. The session will take about one and a half hours.

Confidentiality.

The data collected in this study will be strictly confidential. Only the researcher, supervisor and examiners may have access to the data, as this may be required for verification purposes. All data collected and transcripts will not be stored under your name or identity card number but will be coded in full respect of your privacy. Any data published will not include any personal information.

All audio files will be deleted after transcript and all transcripts with be destroyed as soon as the study is complete. Taking part in this study is purely voluntary and you may decline to participate in this study. If you agree to take part in this study, you may stop at any time without giving a reason.

If you require any further information and details please feel free to ask me.

Thank you for your time and cooperation.

Ivan DeBono BPharm(Hons)

Senior Pharmacist (Mater Dei Hospital)

Chief Investigator

Email: ivan.debono.94@um.edu.mt

Mobile number: 99879530

Informazzjoni Għall-Parteċipanti fill-'Focus Group' – Pazjenti/Qraba

Għażiż Sinjur/a,

Ġejt mistieden biex tieħu sehem ġo 'focus group' (fejn wieħed jagħti parir fuq tema partikolari) bħala parti minn studju fuq pazjenti li jidħlu l-isptar b'mard tal-qalb. Hawn taħt ser issib dettalji dwar l-istudju u x'jinvolvi. Nixtieq li tinforma ruħek qabel taċċetta li tipparteċipa f'dan l-istudju. Jekk taċċetta li tieħu sehem fl-istudju, ser ikollok tiffirma fuq dokument uffiċċjali li int aċċettajt li tieħu sehem. Parteċipazzjoni f'dan l-istudju huwa kompletament volontarju, tista' tagħżel li ma tipparteċipax u dan ma' jkollu l-ebda effett fuq il-kwalita ta' kura li tirċievi. Tista wkoll tirrifjuta li tipparteċipa bl-ebda konsegwenzi għalik.

Informazzjoni.

Pazjenti li jidħlu l-isptar b'mard tal-qalb huma suġġetti li jispiċċaw jerġgħu jidħlu l-isptar f'qasir żmien speċjalment fl-ewwel 30 jum wara li jiġu illiċenzjati. Dan joħloq piż żejjed fuq il-pazjent, il-qraba kif ukoll fuq is-sistema tas-saħħa. Wieħed mill-metodi biex tevita dan huwa li tassigura li l-pazjent ikollu nkonvenjenzi u problemi mill-anqas fil-proċess meta jgħaddi mill-kura fl-isptar għal dik fil-kommunita` wara li jiġi illiċenzjat, kif ukoll jiġi ppreparat u edukat tajjeb dwar l-użu tal-mediċina. Ħafna mill-problemi li jkollhom pazjenti b'mard tal-qalb wara li jiġu illiċenzjati huma marbuta mal-użu tal-mediċina u aspetti oħra ta' natura farmaċewtika għaliex it-trattament jiddependi ħafna fuq l-użu tal-mediċina. Għalhekk huwa mportanti li l-ispiżjar jintervjeni f'dan il-proċess biex ikunu evitati problemi għall-pazjent fejn tidħol użu ta' mediċina u konsegwentement dħul l-isptar.

L-għan tal-istudju.

L-għan tal-istudju huwa li jagħmel distinzjoni bejn pazjenti li x'aktarx ikollhom problemi rigward użu tal-medicina u dawk li ma jkollhomx. Għal dawk li x'aktarx ikollhom problemi rigward użu tal-mediċina ser jiġi żviluppat programm li wieħed isegwi fil-proċess meta pazjent jgħaddi mill-kura fl-isptar għal dik fil-kommunita'. Dawk il-pazjenti li jaċcettaw li jipparteċipaw, isegwu dan il-programm. L-għan aħħari ta' dan il-programm ikun li jiġu evitati problemi relatati mal-mediċina u dħul l-isptar mhux ippjanat.

X'jinvolvi l-istudju?

L-istudju se jkun jikkonsisti fi tliet fażijiet:

- Fl-ewwel fażi se jiġi organiżat grupp ta' diskussjoni biex jiġi mħejji programm ta' inizjattivi li jkunu mwetqa minn spiżjara tal-isptar bil-għan aħħari li jkun faċilitat u mtejjeb is-servizz relatat mal-mediċini meta tkun illiċenzjat/a mill-isptar.

- Fit-tieni fażi l-pazjenti li jgħatu l-kunsens tagħhom ikunu mistoqsija ftit domandi dwar kif jieħdu u x'jaħsbu dwar il-mediċini li jieħdu. Tittieħed ukoll xi nformazzjoni dwar saħħithom mir-rekords mediċi tal-isptar u tittieħed nota tad-drabi li jiġu mdaħħla l-isptar.

- Fit-tielet fażi l-pazjenti li jgħatu l-kunsens tagħhom jingħataw il-programm ta' inizjattivi stabbilit fl-ewwel fażi u tittieħed nota tad-drabi li jiġu mdaħħla l-isptar.

Jekk inti taqbel li tipparteċipa f'dan il-'focus group' inti ser tkun involut/a fl-ewwel fażi ta' istudju. Il-parteċipanti tal 'focus group' ser ikunu konsulent mediku, spiżjar/a tal kommunita', infermier/a, spiżjar/a kliniku, uffiċjal speċjalizzat fil-kwalita, tabib/a tal-familja, pazjent/a u xi ħadd li jieħu ħsieb marid. Ir-riċerkatur ser ikun qed jieħu l-fehmiet u s-suġġerimenti tiegħek dwar kif jista jittejjeb is-servizz meta wieħed jiġi lliċenzjat mill-isptar u b'hekk inti tkun qed tgħin biex jiġi żviluppat dan il-programm. Is-sessjoni tieħu madwar siegħa u nofs.

Kunfidenzjalita'

L-informazzjoni miġbura f'dan l-istudju hija kunfidenzjali u kull informazzjoni ppublikata ma tkunx tinkludi dettalji personali. Ir-riċerkatur, il-persuna li ser twettaq is-superviżżjoni u l-eżaminatur biss ser ikollhom aċċess għal din l-informazzjoni minħabba raġunijiet ta' verifika. Kull informazzjoni miġbura mhux ser tiġi merfugħa taħt ismek jew in-numru tal-karta tal-identita' tiegħek iżda tiġi kondifikata b'rispett sħieħ lejn il-privatezza tiegħek. Kull awdjo fajl jiġi mħassar wara li jkun maqlub bil-miktub u kull informazzjoni bil-miktub tiġi meqruda hekk kif jispiċċa l-istudju.

Parteċipazzjoni f'dan l-istudju hija volontarja u tista' tagħżel li ma tipparteċipax. Jekk taċċetta li tipparteċipa f'dan l-istudju, tista' tieqaf f'kull ħin mingħajr ma tagħti ebda spjegazzjoni.

Jekk għandek xi mistoqsijiet tista` tagħmel dan lili.

Nirringrazzjak tal-ħin u l-kooperazzjoni tiegħek.

Ivan DeBono BPharm (Hons)
Spiżjar anzjan (Sptar Mater Dei)
Investigatur Prinċipali
Email: ivan.debono.94@um.edu.mt
Numru tal-mobajl: 99879530

Information sheet for Professionals

Dear Sir/Madam,

You are being invited to participate in an interview as part of a study being carried out on patients admitted to hospital with heart failure. This information sheet contains an abstract of the proposed study. I encourage you to read the abstract before accepting to participate and put forward any questions you may have. If you agree to participate you will be asked to sign a form giving your consent. Participation is strictly on a voluntary basis. You may decline to take part without any consequences.

Reducing readmissions in heart failure patients through pharmacist-facilitated transition-of-care interventions.

Abstract

Background: A critical stage which predisposes patients to drug-related problems and medication safety issues is during transitions-of-care, specifically the transition from hospital to the community setting after the patient is discharged. The discharge process, comorbidities, complicated treatment regimens and also patient characteristics such as lack of adherence to treatment and age are predictors of hospital readmissions and risk factors for drug-related problems. A category of patients who are particularly predisposed to readmissions as a consequence of drug-related problems are heart failure (HF) patients because often are burdened by a combination of these factors. The aim of this research is to locally adapt and apply a set of pharmacist-facilitated transition-of-care interventions such as medication reconciliation to a sample of HF patients and find out whether the interventions have a bearing on reducing hospital readmissions in this category of patients.

Objective: To develop and assess the impact on care quality of a pharmacist-facilitated readmission prevention program during transitions-of-care for heart failure patients.

Methods/Design: This prospective, matched-controlled study will be conducted from 1st June, 2018 to 31st October, 2018, in an acute 1000 bed teaching hospital in Malta. Patients who suffer from heart failure (aged ≥18 years) will either follow a pharmacist-facilitated readmission prevention program (PFRPP) or follow the usual transition-of-care. Matching will be carried out after admitted eligible patients are assessed for risk of drug-related problems and readmissions and likelihood of medication adherence problems using a structured interview with a treatment adherence score component. A qualitative research with multi-perspective focus-group approach will be used to develop the PFRPP. The focus group will consist of 8 persons.

Participants in the focus group will be a consultant, a community pharmacist, a nurse, a clinical pharmacist, a quality assurance officer, a family doctor, a patient and a family caregiver. The primary outcome will be hospital resource utilization within 30 days of discharge, and drug-related problems.

The secondary outcomes will be level of patient adherence to medication and reduction in medication-related risk factors.

Impact of study: This study will seek to demonstrate that a pharmacist-facilitated readmission prevention program will reduce heart failure patient readmissions and/or contributes to improved quality of care in eventual more comprehensive readmission prevention programs that include a pharmacist intervention component.

Participation.

If you agree to participate in this focus group the researcher will seek your views and suggestions about improving the service during and after hospital discharge.

Confidentiality.

The data collected in this study will be strictly confidential. Only the researcher, supervisor and examiners may have access to the data, as this may be required for verification purposes. All data collected and transcripts will not be stored under your name or identity card number but will be coded in full respect of your privacy. Any data published will not include any personal information.

All audio files will be deleted after transcript and all transcripts with be destroyed as soon as the study is complete. Taking part in this interview is purely voluntary and you may decline to participate. If you agree to take part in this study, you may stop at any time without giving a reason.

If you require any further information and details please feel free to ask me.

Thank you for your time and cooperation.

Ivan DeBono BPharm(Hons)
Senior Pharmacist (Mater Dei Hospital)
Chief Investigator
Email: ivan.debono.94@um.edu.mt
Mobile number: 99879530

CONSENT FORM for the TREATMENT ADHERENCE QUESTIONNAIRE (TAQ) and DATA collection

I am a Maltese citizen and I am over eighteen (18) years of age. I have been asked to participate in a research study entitled:

'Reducing readmissions in heart failure patients through pharmacist-facilitated transition-of-care interventions.'

The purpose and details of the study have been explained to me by Mr. Ivan DeBono and any difficulties which I raised have been adequately clarified. I have also been given a copy of the information sheet and I understand that a copy of this consent form will be given to me should I agree to participate.

I give my consent to the Principal Investigator or his delegate to make the appropriate observations including data collection from my medical record. I am aware of the inconveniences and possible risk and discomfort which this may cause. I am aware that this research may be of benefit to me through improvement in services rendered.

I understand that the results of this study may be used for medical or scientific purposes and that the results achieved from the study in which I am participating may be reported or published. However, I shall not be personally identified in any way. I understand that only the researcher, supervisor and examiners may have access to the data, as this may be required for verification purposes. I understand that all data will be destroyed as soon as the study is complete.

I am under no obligation to participate in this study and I am doing so voluntarily. I may withdraw from the study at any time, without giving any reason. This will not influence in any way the care and attention and treatment normally given to me. I have also the right to access, rectify, and erase the data concerning me.

I am not receiving any remuneration for participating in this study. In case of queries during the study I may contact Mr. Ivan DeBono on mobile number 99879530.

Signature of participant	**_____**
Name of participant	**_____**
Signature of Chief Investigator	**_____**
Name and ID of Chief Investigator	**Ivan DeBono, 75170M**
Residence	**8, Boheme, Triq Il-Plejju, B'Kara**
Email:	**ivan.debono.94@um.edu.mt**

FORMULA TAL-KUNSENS għall-KWESTJONARJU GĦALL-UŻU TAL-MEDIĊINA U L-PAZJENT (KUMP) u ġbir tad-DATA

Jien/a ċittadin/a Malti/ja u għalaqt tmintax (18)-il sena. Talbuni biex nieħu sehem fi studju riċerka bl-isem ta':

'Reducing readmissions in heart failure patients through pharmacist-facilitated transition-of-care interventions.'

Il-għan u d-dettalji ta' l-istudju spejgahomli s-Sur Ivan DeBono li wkoll iċċarali xi mistoqsijiet li għamilt. Ingħatajt ukoll kopja tal-informazzjoni għall-parteċipanti w nifhem li ser ningħata kopja ta' din il-formula ta' kunsens jekk jiena naqbel li nipparteċipa.

Nagħti l-kunsens tiegħi lill-persuna responsabbli għal din ir-riċerka u l-assistenti tiegħu biex jagħmlu l-osservazzjonijiet li hemm bżonn inkluż ġbir ta' nformazzjoni mir-rekords mediċi tiegħi u nifhem li dan jista' jkun ta' inkonvenjent għalija kif ukoll possibilment ta' riskju jew skomdu. Nifhem ukoll li dan l-istudju jista jkun ta' benefiċċu għalija minħabba li jista jwassal għal titjieb fis-servizz.

Jiena nifhem li r-riżultati ta' dan l-istudju jistgħu jintużaw għal skopijiet xjentifiċi u jista` jiġi ppubblikat rapport bil-miktub. Jekk isir hekk b'ebda mod ma nista' nkun identifikat/a, individwalment jew bħala parti minn grupp. Nifhem li r-riċerkatur, il-persuna li ser twettaq is-superviżżjoni u l-eżaminatur biss ser ikollhom aċċess għal din l-informazzjoni minħabba raġunijiet ta' verifika. Nifhem li kull informazzjoni tiġi meqruda hekk kif jispiċċa l-istudju.

Jiena ma għandi l-ebda dmir li nieħu sehem f'dan l-istudju u dan qed nagħmlu b'rieda ħielsa. Jiena nista', meta rrid, ma nkomplix nieħu sehem fl-istudju, u mingħajr ma nagħti raġuni. Jekk nagħmel hekk xorta nibqa' nieħu l-kura li ssoltu tingħatali. Għandi wkoll id-dritt li jkolli aċċess, nikkoreġi jew inħassar informazzjoni li tikkonċerna lili.

Jiena mhux qed nitħallas biex nieħu sehem f'dan l-istudju. Jekk ikolli xi diffikulta' waqt l-istudju, nista' nistaqsi għas-Sur Ivan DeBono fuq in-numru tal-mobajl 99879530.

Firma tal-parteċipant	**_____**
Isem tal-parteċipant	**_____**
Firma tal-persuna responsabbli għal din ir-riċerka	**_____**
Isem u ID tal-persuna responsabbli għal din ir-riċerka	**Ivan DeBono, 75170M**
Residenza	**8, Boheme, Triq Il-Plejju, B'Kara**
Email:	**ivan.debono.94@um.edu.mt**

CONSENT FORM for patients and relatives to participate in a FOCUS QROUP

I am a Maltese citizen and I am over eighteen (18) years of age. I have been asked to participate in a research study entitled:

'Reducing readmissions in heart failure patients through pharmacist-facilitated transition-of-care interventions.'

The purpose and details of the study have been explained to me by Mr. Ivan DeBono and any difficulties which I raised have been adequately clarified. I have also been given a copy of the information sheet and I understand that a copy of this consent form will be given to me should I agree to participate.

I give my consent to the Principal Investigator or his delegate to make the appropriate observations. I am aware of the inconveniences and possible risk and discomfort which this may cause. I am aware that this research may be of benefit to me through improvement in services rendered.

I understand that the results of this study may be used for medical or scientific purposes and that the results achieved from the study in which I am participating may be reported or published. However, I shall not be personally identified in any way. I understand that only the researcher, supervisor and examiners may have access to the data, as this may be required for verification purposes. I have no objection to the use of an audio recorder, as I know that the raw data will be kept in a secure place and used solely for research purposes. I understand that all audio files will be deleted after transcription and the transcribed information will be coded to protect my identity and will be destroyed as soon as the study is complete.

I am under no obligation to participate in this study and I am doing so voluntarily. I may withdraw from the study at any time, without giving any reason. This will not influence in any way the care and attention and treatment normally given to me. I have also the right to access, rectify, and erase the data concerning me.

I am not receiving any remuneration for participating in this study. In case of queries during the study I may contact Mr. Ivan DeBono on mobile number 99879530.

Signature of participant	**_____**
Name of participant	**_____**
Signature of Chief Investigator	**_____**
Name and ID of Chief Investigator	**Ivan DeBono, 75170M**
Residence	**8, Boheme, Triq Il-Plejju, B'Kara**
Email:	**ivan.debono.94@um.edu.mt**

FORMULA TAL-KUNSENS għall–pazjenti u qraba għall-parteċipazzjoni f-*FOCUS GROUP* (fejn wieħed jagħti parir fuq tema partikolari)

Jien/a ċittadin/a Malti/ja u għalaqt tmintax (18)-il sena. Talbuni biex nieħu sehem fi studju riċerka bl-isem ta':

'Reducing readmissions in heart failure patients through pharmacist-facilitated transition-of-care interventions.'

Il-għan u d-dettalji ta' l-istudju spejgahomli s-Sur Ivan DeBono li wkoll iċċarali xi mistoqsijiet li għamilt. Ingħatajt ukoll kopja tal-informazzjoni ghall-parteċipanti u nifhem li ser ningħata kopja ta' din il-formula ta' kunsens jekk jiena naqbel li nipparteċipa.

Nagħti l-kunsens tiegħi lill-persuna responsabbli għal din ir-riċerka u l-assistenti tiegħu biex jagħmlu l-osservazzjonijiet li hemm bżonn u nifhem li dan jista' jkun ta' inkonvenjent għalija kif ukoll possibilment ta' riskju jew skomdu. Nifhem ukoll li dan l-istudju jista jkun ta' benefiċċju għalija minħabba li jista' jwassal għal titjieb fis-servizz.

Jiena nifhem li r-riżultati ta' dan l-istudju jistgħu jintużaw għal skopijiet xjentifiċi u jista` jiġi ppubblikat rapport bil-miktub. Jekk isir hekk b'ebda mod ma nista` nkun identifikat/a, individwalment jew bħala parti minn grupp. Nifhem li r-riċerkatur, il-persuna li ser twettaq is-superviżżjoni u l-eżaminatur biss ser ikollhom aċċess għal din l-informazzjoni minħabba raġunijiet ta' verifika. M'għandi l-ebda oġġezzjoni għall-użu ta' awdjo rikorder, għax naf li l-informazzjoni miġbura ser tinżamm f'post sikur u tintuża biss għall-skopijiet ta' riċerka. Nifhem li l-awdjo rikordings se jkunu mħassra minnufih wara li jiġu maqluba bil-miktub u dak kollu bill-miktub ser jigi kodifikat biex tiġi protetta l-identita tieghi u wara kollox jiġi meqrud hekk kif jispiċċa l-istudju.

Jiena ma għandi l-ebda dmir li nieħu sehem f'dan l-istudju u dan qed nagħmlu b'rieda ħielsa. Jiena nista`, meta rrid, ma nkomplix nieħu sehem fl-istudju, u mingħajr ma' nagħti raġuni. Jekk nagħmel hekk xorta nibqa nieħu l-kura li ssoltu tingħatali. Għandi wkoll id-dritt li jkolli aċċess, nikkoreġi jew inħassar informazzjoni li tikkonċerna lili.

Jiena mhux qed nitħallas biex nieħu sehem f'dan l-istudju. Jekk ikolli xi diffikulta' waqt l-istudju, nista` nistaqsi għas-Sur Ivan DeBono fuq in-numru tal-mobajl 99879530.

Firma tal-parteċipant	**_____**
Isem tal-parteċipant	**_____**
Firma tal-persuna responsabbli għal din ir-riċerka	**_____**
Isem u ID tal-persuna responsabbli għal din ir-riċerka	**Ivan DeBono, 75170M**
Residenza	**8, Boheme, Triq Il-Plejju, B'Kara**
Email:	**ivan.debono.94@um.edu.mt**

CONSENT FORM for professionals to participate in a FOCUS GROUP

I have been asked to participate in a research study entitled:

'Reducing readmissions in heart failure patients through pharmacist-facilitated transition-of-care interventions.'

The purpose and details of the study have been explained to me by Mr. Ivan DeBono and any difficulties which I raised have been adequately clarified. I have also been given a copy of the information sheet and I understand that a copy of this consent form will be given to me should I agree to participate.I give my consent to the Principal Investigator or his delegate to make the appropriate observations. I am aware of the inconveniences and possible risks and discomfort which this may cause. I am aware that this research may be of benefit to me through improvement in services rendered.

I understand that the results of this study may be used for medical or scientific purposes and that the results achieved from the study in which I am participating may be reported or published. However, I shall not be personally identified in any way. I understand that only the researcher, supervisor and examiners may have access to the data, as this may be required for verification purposes. I understand that my participation will have no effect on my professional responsibilities.

I have no objection to the use of an audio recorder, as I know that the raw data will be kept in a secure place and used solely for research purposes. I understand that all audio files will be deleted after transcription and the transcribed information will be coded to protect my identity and will be destroyed as soon as the study is complete.

I am under no obligation to participate in this study and I am doing so voluntarily. I may withdraw from the study at any time, without giving any reason. This will not influence in any way the care and attention and treatment normally given to me. I have also the right to access, rectify, and erase the data concerning me.

I am not receiving any remuneration for participating in this study. In case of queries during the study I may contact Mr. Ivan DeBono on mobile number 99879530.

Signature of participant	**_____**
Name of participant	**_____**
Signature of Chief Investigator	**_____**
Name and ID of Chief Investigator	**Ivan DeBono, 75170M**
Residence	**8, Boheme, Triq Il-Plejju, B'Kara**
Email:	**ivan.debono.94@um.edu.mt**

CONSENT FORM for the PARTICIPATION IN THE TRANSITION-OF-CARE PROGRAM

I am a Maltese citizen and I am over eighteen (18) years of age. I have been asked to participate in a research study entitled:

'Reducing readmissions in heart failure patients through pharmacist-facilitated transition-of-care interventions.'

The purpose and details of the study have been explained to me by Mr. Ivan DeBono and any difficulties which I raised have been adequately clarified. . I have also been given a copy of the information sheet and I understand that a copy of this consent form will be given to me should I agree to participate.

I give my consent to the Principal Investigator or his delegate to make the appropriate observations including a Treatment Adherence Questionnaire (TAQ) and data collection from my medical record. I am aware of the inconveniences and possible risks and discomfort which this may cause. I am aware that this research may be of benefit to me through improvement in services rendered. I give my consent to the Principal Investigator to make the subsequent interventions:

Medication-use education; medication reconciliation; follow-up by means of post-discharge phone calls and/or home visit and informing POYC pharmacist and private family doctor about changes to my medication.

I understand that the results of this study may be used for medical or scientific purposes and that the results achieved from the study in which I am participating may be reported or published. However, I shall not be personally identified in any way. I understand that only the researcher, supervisor and examiners may have access to the data, as this may be required for verification purposes. I understand that all data will be destroyed as soon as the study is complete.

I am under no obligation to participate in this study and I am doing so voluntarily. I may withdraw from the study at any time, without giving any reason. This will not influence in any way the care and attention and treatment normally given to me. I have also the right to access, rectify, and erase the data concerning me.

I am not receiving any remuneration for participating in this study. In case of queries during the study I may contact Mr. Ivan DeBono on mobile number 99879530.

Signature of participant	**_____**
Name of participant	**_____**
Signature of Chief Investigator	**_____**
Name and ID of Chief Investigator	**Ivan DeBono, 75170M**
Residence	**8, Boheme, Triq Il-Plejju, B'Kara**
Email:	**ivan.debono.94@um.edu.mt**

FORMULA TAL-KUNSENS għall-PARTEĊIPAZZJONI FI PROGRAMM META NIĠI LLICENZJAT MILL-ISPTAR

Jien/a ċittadin/a Malti/ja u għalaqt tmintax (18)-il sena. Talbuni biex nieħu sehem fi studju riċerka bl-isem ta':

'Reducing readmissions in heart failure patients through pharmacist-facilitated transition-of-care interventions.'

Il-għan u d-dettalji tal-istudju spejgahomli s-Sur Ivan DeBono li wkoll iċċarali xi mistoqsijiet li għamilt. Ingħatajt ukoll kopja tal-informazzjoni għall-parteċipanti u nifhem li ser ningħata kopja ta' din il-formula ta' kunsens jekk jiena naqbel li nipparteċipa. Nagħti l-kunsens tiegħi lill-persuna responsabbli għal din ir-riċerka u l-assistenti tiegħu biex jagħmlu l-osservazzjonijiet li hemm bżonn li jinkludu l-Kwestjonarju għall-użu tal-mediċina u l-pazjent (KUMP) u ġbir tad-data. Nifhem li dan jista' jkun ta' inkonvenjent għalija kif ukoll possibilment ta' riskju jew skomdu. Nifhem ukoll li dan l-istudju jista jkun ta benefiċċu għalija minħabba li jista' jwassal għal titjieb fis-servizz. Naghti l-kunsens tiegħi lill-persuna responsabbli għal din ir-riċerka biex jagħmel l-interventi sussegwenti:

Edukazzjoni dwar użu tal-mediċini; Skrutinju tal-mediċini li jieħu l-pazjent; telefonati jew viżita d-dar biex jiġi żgurat użu tajjeb tal-mediċina u li l-ispiżjar u t-tabib privat jiġu nfurmati dwar xi bidliet fil-mediċini li ser nieħu.

Jiena nifhem li r-riżultati ta' dan l-istudju jistgħu jintużaw għal skopijiet xjentifiċi u jista` jiġi ppubblikat rapport bil-miktub. Jekk isir hekk b'ebda mod ma nista' nkun identifikat/a, individwalment jew bħala parti minn grupp. Nifhem li r-riċerkatur, il-persuna li ser twettaq is-superviżżjoni u l-eżaminatur biss ser ikollhom aċċess għal din l-informazzjoni minħabba raġunijiet ta' verifika. Nifhem li kull informazzjoni ser tiġi meqruda hekk kif jispiċċa l-istudju.

Jiena m'għandi l-ebda dmir li nieħu sehem f'dan l-istudju u dan qed nagħmlu b'rieda ħielsa. Jiena nista', meta rrid, ma nkomplix nieħu sehem fl-istudju, u mingħajr ma' nagħti raġuni. Jekk nagħmel hekk xorta nibqa nieħu l-kura li ssoltu tingħatali. Għandi wkoll id-dritt li jkolli aċċess, nikkoreġi jew inħassar informazzjoni li tikkonċerna lili.

Jiena mhux qed nitħallas biex nieħu sehem f'dan l-istudju. Jekk ikolli xi diffikulta' waqt l-istudju, nista' nistaqsi għas-Sur Ivan DeBono fuq in-numru tal-mobajl 99879530.

Firma tal-parteċipant	**_____**
Isem tal-parteċipant	**_____**
Firma tal-persuna responsabbli għal din ir-riċerka	**_____**
Isem u ID tal-persuna responsabbli għal din ir-riċerka	**Ivan DeBono, 75170M**
Residenza	**8, Boheme, Triq Il-Plejju, B'Kara**
Email:	**ivan.debono.94@um.edu.mt**

L-Università ta' Malta

Faculty of
Medicine & Surgery

University of Malta
Msida MSD 2080, Malta

Tel: +356 2340 1879/1891/1167
umms@um.edu.mt

www.um.edu.mt/ms

Ref No: **FRECMDS_1718_038**

Wednesday 20th June 2018

Mr Ivan Debono
8
Boheme
Triq il-Plejju
Birkirkara

Dear Mr Debono,

Please refer to your application submitted to the Research Ethics Committee in connection with your research entitled:

Reducing readmissions in heart failure patients through pharmacist-facilitated transision-of-care interventions

The Faculty Research Ethics Committee granted ethical approval for the above mentioned protocol.

Yours sincerely,

Dr. Mario Vassallo
Chairman
Research Ethics Committee

Appendix 8

Publications

Debono I, Grech L, Azzopardi LM. OP7.218 Pharmaceutical care problems across transitional care: from hospital to community. X Malta Medical School Conference, 29th Nov – 1st Dec 2018.

OP7.217

Pharmacogenetic testing in precision medicine for statin use

J. Cerda Inesta1 , F. Wirth1 , G. Zahra2 , R. G. Xuereb3 , C. Barbara22, A. Serracino-Inglott11

1 Department of Pharmacy, Faculty of Medicine and Surgery, University of Malta, Msida, Malta 2 Molecular Diagnostics Unit, Department of Pathology, Mater Dei Hospital, Msida, Malta 3 Cardiac Catheterisation Suite, Department of Cardiology, Mater Dei Hospital, Msida, Malta

Introduction: The SLCO1B1 c.521T>C gene variant is associated with higher serum simvastatin concentrations and increased risk of simvastatin-induced myopathy. The aim of the study was to classify a cohort of cardiac patients on simvastatin according to SLCO1B1 genotype, SLCO1B1 function and myopathy risk.

Methods: Patients on simvastatin (N=110) were recruited by convenience sampling from the cardiac catheterisation suite at Mater Dei Hospital. Genomic DNA was extracted from an EDTA-blood sample and real-time PCR SLCO1B1 genotyping was performed using the Sacace® Biotechnology kits and Rotor-Gene™ 6000/Q for fluorescence detection. Patients were classified into three genotypes namely TT (homozygous wild-type), TC (heterozygous) or CC (homozygous variant).

Results: The 110 patients (90 male, all Caucasian, mean age 65 +1.02 years) were genotyped as TT (78.2%, n=86), TC (20.0%, n=22) and CC (1.8%, n=2), corresponding to normal, intermediate and low SLCO1B1 function, respectively. Fifteen patients genotyped as TC or CC were on a higher dose of simvastatin (40mg/day) than suggested by the Clinical Pharmacogenetics Implementation Consortium guideline for SLCO1B1 and simvastatin induced myopathy.

Conclusion: Patients genotyped TC (n=22) have mild myopathy risk, while patients genotyped CC (n=2) have high myopathy risk. The guideline suggests decreasing the dose of simvastatin from 40mg to 20mg daily or prescribing an alternative statin (rosuvastatin/pravastatin) in TC and CC patients. This study serves as an example of pharmacogenetic testing to achieve precision medicine.

Disclosures: University of Malta Research Grant (PHRRP12-17).

OP7.218

Pharmaceutical care problems across transitional care: from hospital to community

I. Debono, L. Grech, L. M. Azzopardi

Department of Pharmacy, Faculty of Medicine and Surgery, University of Malta, Msida, Malta

Introduction: The aim of the study was to perform gap analysis to identify pharmaceutical care shortcomings in transition of care from Mater Dei Hospital to community.

Methods: Two Reducing Avoidable Readmissions Effectively (RARE) campaign gap analysis surveys were carried out to identify shortcomings within the process of discharge planning and transition of care. Quantitative surveys targeted the identification of problems encountered during dispensing to discharged patients at Mater Dei Hospital pharmacy and during dispensing within the community-based Pharmacy of Your Choice (POYC) scheme. Problems encountered during dispensing were categorised according to an adapted classification for drug related problem of the PCNE Classification V8.02.

Results: Lack of time available for assessing the patients' understanding of the discharge plan; lack of a system to ensure that post-discharge providers have pertinent information in a timely manner to support effective TOC, lack of support to ensure that the patient or family caregiver is at least able to understand when and how to take medication and that discharge case summary and medication plan are complete and up to date are among the shortcomings revealed by the RARE campaign tools. From the 209 discharges studied, 137 pharmaceutical care issues were identified and from the 177 POYC refills studied, 116 pharmaceutical care issues were identified.

Conclusion: This research identified gaps within current processes. Further research work to establish a pharmacist-facilitated TOC programme that starts while the patient is at Mater Dei hospital Malta and extends for a period beyond discharge is warranted. **Disclosures:** Nothing to disclose. No funding.

OP7.219

Setting up a 24-hour drug information service

J. Cassar, L. M. Azzopardi, L. Grech

Department of Pharmacy, Faculty of Medicine and Surgery, University of Malta, Msida, Malta

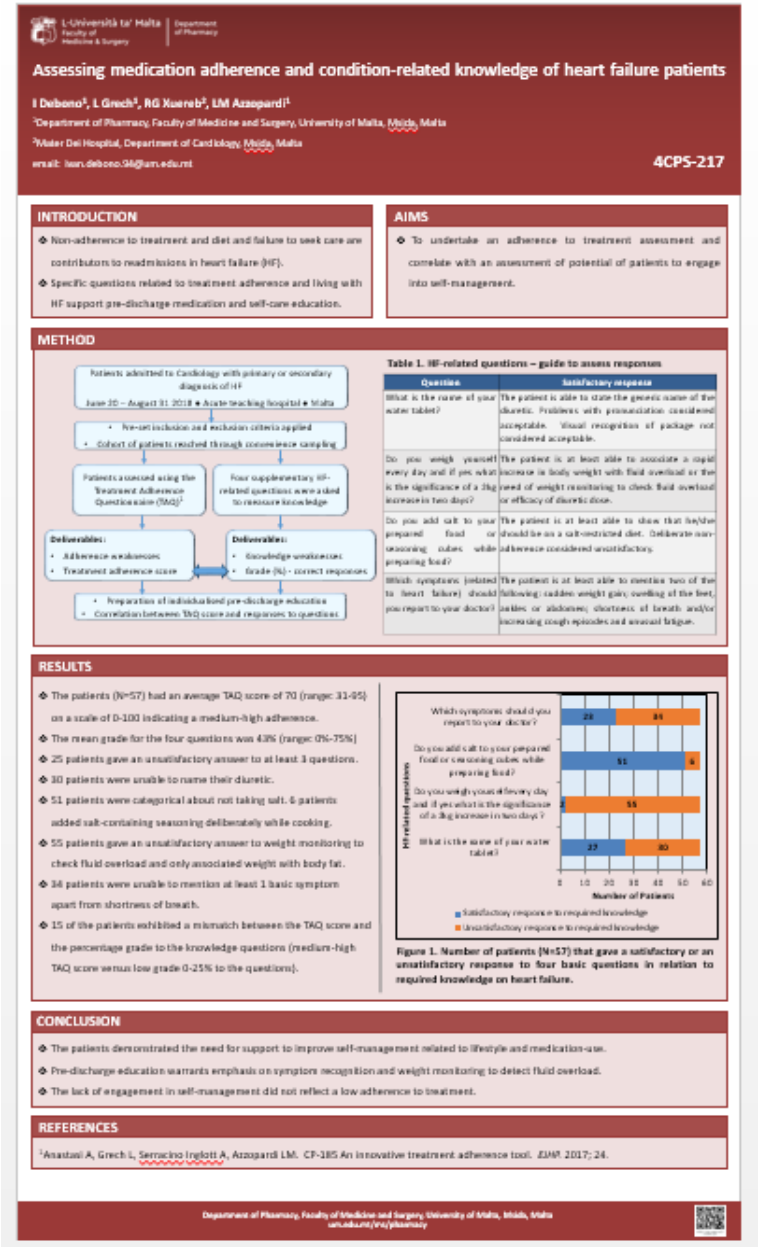
Introduction: The Pharmacy Department at Mater Dei Hospital (MDH) operates a 24-hour drug information service (DIS) via its Medicines Information section during normal working hours and through shift pharmacists afterhours. This study aimed to identify deficiencies of the afterhours DIS and propose improvements required.

Methods: A three-week research observation placement was attended at the drug information centre at the University of Illinois in Chicago, USA, to detect the framework used. Subsequently, a focus group consisting of nine members was set up to discuss improvements identified based on the observational framework and which are required in the after-hours DIS at MDH. The participants of the focus group included the Head of Pharmacy Services at MDH, one pharmacist from each of the following sections: Medicines Information, Quality Assurance, and after-hours shift pharmacists; two staff nurses, two hospital doctors, and one community pharmacist.

Results: Proposed improvements from the focus group and the three-week observation placement include introducing a pharmacist to serve as a liaison between the Medicines Information section and after-hours pharmacists, increasing training for after-hours pharmacists, organising online and physical after-hours information resources, setting up journal clubs and clinical-based discussions for after-hours pharmacists, introducing an audit system and documentation of clinically relevant requests.

Conclusion: Eliminating weaknesses in the after-hours DIS ensure the constant delivery of high-quality drug information to users of the system, thereby improving patient care and allowing for a 24-hour seamless DIS.

Debono I, Grech L, Xuereb RG, Azzopardi LM. 4CPS-217 Assessing medication adherence and condition-related knowledge of heart failure patients. 24th Congress of the EAHP, 27th March – 29th March 2019



L-Università ta' Malta | Department of Pharmacy

Assessing medication adherence and condition-related knowledge of heart failure patients

I Debono[1], L Grech[2], RG Xuereb[2], LM Azzopardi[1]

[1]Department of Pharmacy, Faculty of Medicine and Surgery, University of Malta, Msida, Malta

[2]Mater Dei Hospital, Department of Cardiology, Msida, Malta

email: ivan.debono.04@um.edu.mt

4CPS-217

INTRODUCTION

- Non-adherence to treatment and diet and failure to seek care are contributors to readmissions in heart failure (HF).
- Specific questions related to treatment adherence and living with HF support pre-discharge medication and self-care education.

AIMS

- To undertake an adherence to treatment assessment and correlate with an assessment of potential of patients to engage into self-management.

METHOD

Patients admitted to Cardiology with primary or secondary diagnosis of HF

June 20 – August 31 2018 • Acute teaching hospital • Malta

- Pre-set inclusion and exclusion criteria applied
- Cohort of patients reached through convenience sampling

Patients assessed using the Treatment Adherence Questionnaire (TAQ)[1]

Four supplementary HF-related questions were asked to measure knowledge

Deliverables:
- Adherence weaknesses
- Treatment adherence score

Deliverables:
- Knowledge weaknesses
- Grade (%) - correct responses

- Preparation of individualised pre-discharge education
- Correlation between TAQ score and responses to questions

Table 1. HF-related questions – guide to assess responses

Question	Satisfactory response
What is the name of your water tablet?	The patient is able to state the generic name of the diuretic. Problems with pronunciation considered acceptable. Visual recognition of package not considered acceptable.
Do you weigh yourself every day and if yes what is the significance of a 2kg increase in two days?	The patient is at least able to associate a rapid increase in body weight with fluid overload or the need of weight monitoring to check fluid overload or efficacy of diuretic dose.
Do you add salt to your prepared food or seasoning cubes while preparing food?	The patient is at least able to show that he/she should be on a salt-restricted diet. Deliberate non-adherence considered unsatisfactory.
Which symptoms (related to heart failure) should you report to your doctor?	The patient is at least able to mention two of the following: sudden weight gain; swelling of the feet, ankles or abdomen; shortness of breath and/or increasing cough episodes and unusual fatigue.

RESULTS

- The patients (N=57) had an average TAQ score of 70 (range: 31-95) on a scale of 0-100 indicating a medium-high adherence.
- The mean grade for the four questions was 43% (range: 0%-75%)
- 25 patients gave an unsatisfactory answer to at least 3 questions.
- 30 patients were unable to name their diuretic.
- 51 patients were categorical about not taking salt. 6 patients added salt-containing seasoning deliberately while cooking.
- 55 patients gave an unsatisfactory answer to weight monitoring to check fluid overload and only associated weight with body fat.
- 34 patients were unable to mention at least 1 basic symptom apart from shortness of breath.
- 15 of the patients exhibited a mismatch between the TAQ score and the percentage grade to the knowledge questions (medium-high TAQ score versus low grade 0-25% to the questions).

Figure 1. Number of patients (N=57) that gave a satisfactory or an unsatisfactory response to four basic questions in relation to required knowledge on heart failure.

CONCLUSION

- The patients demonstrated the need for support to improve self-management related to lifestyle and medication-use.
- Pre-discharge education warrants emphasis on symptom recognition and weight monitoring to detect fluid overload.
- The lack of engagement in self-management did not reflect a low adherence to treatment.

REFERENCES

[1]Anastasi A, Grech L, Serracino Inglott A, Azzopardi LM. CP-185 An innovative treatment adherence tool. *IJMR* 2017; 24.

Department of Pharmacy, Faculty of Medicine and Surgery, University of Malta, Msida, Malta
um.edu.mt/ms/pharmacy

Poster available from: https://eahp.eu/sites/default/files/4cps-217_0.pdf

of relevance to the oncology, paediatric and endocrinological oncology areas.
The total amount currently authorised is C¼ 2,049,425.
Conclusion Since these off-label treatments would be formerly paid for by the hospital, thanks to this path they are instead completely reimbursed by the AIFA 5% Fund.
The results obtained demonstrate how the integration of the pharmacist into clinical management obtains an excellent balance between the prescriptive appropriateness and the economic sustainability in rare or highly complex diseases through access to the AIFA Fund 5%.

REFERENCES AND/OR ACKNOWLEDGEMENTS
1. Law 326/2003 G.U. 274 25 November 2003.
No conflict of interest.

4CPS-216 PRESCRIPTION OF FALL-RISK-INCREASING DRUGS IN PATIENTS SUFFERING A FALL WITH MAJOR LESIONS DURING ADMISSION AT AN INTERMEDIATE CARE CENTRE

AM De Andrés*, E Romano, M García-Salmones, LM Pérez, M Inzitari. *Parc Sanitari Pere Virgili, Barcelona, Spain*

10.1136/ejhpharm-2019-eahpconf.365

Background Falls in the elderly increase morbidity, affect quality of life and increase healthcare costs. Several pharmacological groups have been associated with falls, which are grouped as 'Fall Risk Increasing Drugs' (FRIDs). Despite awareness of the risk, the prescription of FRIDs is highly prevalent.
Purpose To assess prescription patterns in patients experiencing a fall which resulted in major lesions during admission at an intermediate care centre. To determine the prevalence of FRIDs before and after the fall.
Material and methods Observational and retrospective study of patients admitted to an intermediate care centre of 350 beds in an urban area, who experienced a major lesion (reported below) due to a fall during a 3 year period (2015–2017). They were identified by the inpatient fall register. Data regarding treatment was collected from the digital health record. The main outcome was the prescription of FRIDs. The following variables were collected: demographics (age, sex), type of lesion, and number and type of drugs (ATC codes) prior to fall and at discharge. The FRIDs list was built from a literature review and included: cardiovascular drugs (CV); psychotropic; and others (NSAIDS, opioids, anti-epileptics). Statistical analysis was performed with Stata v15.
Results We included 50 patients (mean age ±SD=79.3 ±11.4, 54% males). The consequences of the fall were: traumatic brain injury (n=11), wound requiring stitches (n=15), fracture (n=17) and others (n=7). Prior to the fall, the average number of total drugs/patient was 11.1±3.2: 96% received at least one FRID (42% ≥4 FRIDs, 3.4 ±1.8 FRIDs/patient). One-hundred and seventy-one prescriptions of FRIDs were identified: 44.4% CV drugs, 40.35% psychotropic drugs and 15.2% others. Eighty per cent of patients received a psychotropic drug (mainly benzodiazepines or quetiapine) prior to the fall. Twenty-eight patients were discharged home or to a long-term care facility (n=5 exitus, n=17 acute care). Of these, 92.9% received a FRID prior to discharge (50%≥4 FRIDs, 3.6±2.1 FRIDs/patient). Only in eight patients (28.6%) were some FRIDs discontinued (10 FRIDs). Conversely, 11 new FRIDs were initiated in eight patients.
Conclusion Despite being a well-known modifiable risk factor for falls, the prescription of FRIDs is highly prevalent among the elderly. In our sample, the withdrawal of FRIDs appears not to be a usual practice, even after a relevant adverse event.

REFERENCES AND/OR ACKNWLEDGEMENTS
No conflict of interest.

4CPS-217 ASSESSING MEDICATION ADHERENCE AND CONDITION-RELATED KNOWLEDGE OF HEART FAILURE PATIENTS

1 I Debono*, 1 L Grech, 2 RG Xuereb, 1 LM Azzopardi. 1 *University of Malta, Pharmacy, Msida, Malta; 2 Mater Dei Hospital, Cardiology, Msida, Malta*

10.1136/ejhpharm-2019-eahpconf.366

Background Non-adherence to treatment and diet, and failure to seek care are contributors to readmissions in heart failure (HF) patients. Specific questions related to treatment adherence and living with HF improve prioritisation of patients for pre-discharge medication management and self-care education.
Purpose The objective was to undertake an adherence to treatment assessment and correlate with an assessment of the potential of patients to engage in self-management. This was defined as the percentage grade of correct answers to four questions that demonstrate knowledge of living with HF.
Material and methods The study was conducted between 20 June–31 August 2018 in an acute hospital. Patients who qualified for the study through pre-set inclusion and exclusion criteria were administered the Treatment Adherence Questionnaire (TAQ).1 Four supplementary questions were asked to measure the knowledge of patients concerning their diuretic treatment, the use of salt in food preparation, weight monitoring and alarm symptoms warranting referral.
Results The cohort of patients (n=57) had an average TAQ score of 70 (range: 31–95) on a scale of 0–100 indicating a medium-high adherence. The mean cohort grade to the four questions was 43% (range: 0%–75%). Twenty-five patients gave an unsatisfactory answer to at least three of the questions; thirty patients were unable to name their diuretic; 51 patients were categorical about not taking salt and all knew that salt should be avoided; six patients added salt deliberately while cooking; 55 patients failed to relate the need of weight monitoring to check fluid overload and only associated weight with body fat; 34 patients were unable to mention at least one basic symptom apart from shortness of breath; and 15 patients exhibited a mismatch between the TAQ score and the percentage grade to the knowledge questions (medium-high TAQ score versus low grade 0%–25% to questions).
Conclusion The patients demonstrated the need for support in improving self-management related to lifestyle and medication knowledge. The lack of engagement in self-management did not reflect a low adherence to treatment.

REFERENCES AND/OR ACKNOWLEDGEMENTS
1. Anastasi A, Grech L, Serracino Inglott A, Azzopardi LM. CP-185: an innovative treatment adherence tool HP 2017;24:
No conflict of interest.

ESCP congress 2019 - ESCP19SY-1192 – Accepted for oral communication

Reducing readmissions in heart failure patients through pharmacist-facilitated transition-of-care interventions.

I Debono[1], L Grech, RG Xuereb, LM Azzopardi

[1]Department of Pharmacy, Faculty of Medicine and Surgery, University of Malta, Msida, Malta

Background and Objective. Consistent preventative pharmaceutical care interventions during care transitions with the aim of improving patient outcomes and quality care are imperative for a shift towards value-based care. The impact of pharmacist interventions on readmission rate of heart failure (HF) patients is a target outcome measure. Finding the most appropriate and practical intervention combination to be applied during transition from hospital to community is challenging. The objective was to determine and apply pharmacist interventions during transition-of-care (TOC) to HF patients and study impact on readmission rate.

Setting and Method. The study was conducted from June 20, 2018 to January 31, 2019, in a teaching hospital in Malta. A multi-perspective focus group supported with surveys and literature was used to determine pharmacist interventions for a TOC pathway. Patients suffering from HF who followed the pathway were compared to a control group that followed the usual TOC. Recruitment involved prospective convenience sampling using eligible criteria. The study involved two phases starting with the control group (n=52). The proposed pathway was then validated in the intervention group (n=27). The primary outcome was 30-day all-cause readmission. The secondary outcomes were all-cause readmission during the observation period from day 31-60 post-discharge and the number and type of interventions.

Main outcome measure: Pathway of pharmacist intervention with HF patients discharged from hospital, assessment of readmission rate.

Results. The proposed pathway followed a ward-based pharmacist model with a case management approach that included medication reconciliation, individualised pre-discharge education and telephone care management post-discharge. The 30-day all-cause readmission rate of the control group was 30.8% and that of the intervention group was 18.5% (p=0.242). The readmission rate between days 31-60 was 13.5% for the control group and 22.2% (p=0.211) for the intervention group. A total of 284 interventions with a mean of 10.5 were performed as part of the pharmaceutical TOC pathway.

Discussion. The piloted TOC pathway is a quality improvement composite indicative that pharmacist interventions delivered at the right place and the right time may reduce readmission rate of HF patients during the immediate period after discharge. The impact beyond 30 days without reinforcement is not confirmed.