Perceive Analysis Plans

June 2013
Work Package 3 DOORWAY – Service User analysis

Summary
DOORWAY is a randomised control using a stepped-wedge design. The intervention to increase therapeutic activities is rolled out across wards gradually over time. Different service users were recruited and measured at each time point rather than being monitored over time. We have recruited an average of 13 service users per ward at each time point giving a total of 16 wards and 883 service users.

Stepped-wedge randomisation procedure

	T0 - baseline	T1 – 6 mths	T2 – 12 mths	T3 – 18 mths	T4 – 24 mths
Ward 1		Intervention	Intervention	Intervention	Intervention
Ward 2		Intervention	Intervention	Intervention	Intervention
Ward 3		Randomised	Intervention	Intervention	Intervention
Ward 4		Randomised	Intervention	Intervention	Intervention
Ward 5			Randomised	Intervention	Intervention
Ward 6			Randomised	Intervention	Intervention
Ward 7				Randomised	Intervention
Ward 8				Randomised	Intervention

No cost extension additional wards and timepoints

	T0 - baseline	T1 – 6 mths	T2 – 12 mths
Ward 9		Randomised	Intervention
Ward 10		Randomised	Intervention
Ward 11		Randomised	Intervention
Ward 12		Randomised	Intervention
Ward 13			Randomised
Ward 14			Randomised
Ward 15			Randomised
Ward 16			Randomised

Objectives
Primary Objectives:

1. To measure the impact of increasing therapeutic activities on patient perceptions of care
2. To determine the cost-effectiveness of increasing therapeutic activities on inpatient wards

Secondary Objectives

1. To measure the impact of increasing therapeutic activities on:
    a. number of violent episodes on the ward
    b. patient length of stay
    c. patient satisfaction
    d. patient symptoms and functioning
2. To investigate the sustainability of the positive effects – is this maintained over time or a boost at the initiation of the therapeutic activities which then drops off.

Outcome Measures
Primary outcomes
VOICE – Service user perceptions of inpatient care - continuous scale

Secondary outcomes
Patient measures
SSS-RES - Service satisfaction scale – residential– continuous scale, ~~high score~~ low score

(updated 29/11/2013 by Stephen Nash) indicates satisfaction.

Violent episodes, length of stay

Additional covariate data

Patient Demographics: age, gender, marital status, ethnicity, education, socio-economic status, accommodation, employment, diagnosis, admission date (hence age at admission and time since admission), time on ward, diagnosis history, medication history, violent incidents, PANSS, GAF, NOSIE, HONOS, activities and one-to-one time

Ward measures
Number of patients in last 30 days, Gender of patients in last 30 days, number of incidents (in 30days, 7 days, average per day), Nurse coverage, average length of stay, activities on the ward, percentage of bed occupancy, ward acuity (average PANSS, GAF or NOSIE)

Descriptive Analysis
Summary of patient sample characteristics at each time point
Summary of ward characteristics at each time point

Tabulation of patient characteristics by intervention or control arm.

Missing Data
Description of levels of missing data, comparison of missing data between the intervention and control arms. All analyses will account for missing data using weighting or imputations as appropriate.

Analysis of primary outcome
Aim: To measure the impact of increasing therapeutic activities on patient perceptions of care

Descriptive analysis
Mean and standard deviation of VOICE in control and intervention arms at each time point and overall, adjusted analysis for calendar effect of time.

Regression analysis
Linear regression model of VOICE including an indicator for intervention or control arm accounting for a clustering effect at the ward level.

Adjustment for confounders:
1. Adjust analyses for patient characteristics that are expected to be associated with outcome but are not expected to change with the intervention e.g. age, diagnosis, socio-economic status, education, employment, living situation
2. Adjust analyses for pre-intervention ward level characteristics that are expected to be associated with outcome e.g. acuity of the ward, patient turnover, average length of stay,
3. Adjust analysis for time since start of study/randomisation
4. Adjust analysis for number of activities/time spent on activities
5.

Type of analysis
Intention-to-treat analysis will be performed using intervention arm as the covariate of interest.

Analysis of secondary outcomes
Aim: To measure the impact of increasing therapeutic activities on number of violent episodes on the ward, patient length of stay and patient satisfaction

Outcomes:
patient satisfaction (SSS-RES)
patient length of stay

number of violent episodes to date

Descriptive analysis
Means and standard deviations of outcomes at each time point in intervention and control groups and overall

Regression analysis

Linear regression model of satisfaction and length of stay, poisson regression of number of violent episodes including an indicator for intervention or control arm accounting for a clustering effect at the ward level.

Adjustment for confounders:
1. Adjust analysis for patient characteristics that are expected to be associated with outcome but are not expected to change with the intervention e.g. age, diagnosis, socio-economic status, education, employment, living situation
2. Adjust analysis for pre-intervention ward level characteristics that are expected to be associated with outcome e.g. acuity of the ward, patient turnover, average length of stay,
3. Adjust analysis for time since start of study/randomisation
4. Restricted analysis to immediate post-intervention comparisons.
5. Adjust analysis for number of activities/time spent on activities.

We intend to include further consideration of the effects of time in this stepped wedge design (linear trend/non-linear trend, or categorical indicator variables for timepoints).

Type of analysis
Intention-to-treat analysis will use intervention arm as the covariate of interest.

The following covariates were each tested to see if they confounded or changed the effect of the intervention in WP3.

Service users: gender, age, ethnicity, primary diagnosis, first language, sectioned or voluntary

June 2013
Work Package 3 DOORWAY – Staff analysis

Summary
DOORWAY is a randomised control using a stepped-wedge design. The intervention to increase therapeutic activities is rolled out across wards gradually over time. Staff members are asked to complete the measures at each time point and so will change from being on a control to an intervention ward over the course of the study.

Stepped-wedge randomisation procedure

	T0 - baseline	T1 – 6 mths	T2 – 12 mths	T3 – 18 mths	T4 – 24 mths
Ward 1		Intervention	Intervention	Intervention	Intervention
Ward 2		Intervention	Intervention	Intervention	Intervention
Ward 3		Randomised	Intervention	Intervention	Intervention
Ward 4		Randomised	Intervention	Intervention	Intervention
Ward 5			Randomised	Intervention	Intervention
Ward 6			Randomised	Intervention	Intervention
Ward 7				Randomised	Intervention
Ward 8				Randomised	Intervention

No cost extension additional wards and timepoints

	T0 - baseline	T1 – 6 mths	T2 – 12 mths
Ward 9		Randomised	Intervention
Ward 10		Randomised	Intervention
Ward 11		Randomised	Intervention
Ward 12		Randomised	Intervention
Ward 13			Randomised
Ward 14			Randomised
Ward 15			Randomised
Ward 16			Randomised

Objectives
Primary Objectives:

3. To measure the impact of increasing therapeutic activities on staff perceptions of ward atmosphere.
4. To determine the cost-effectiveness of increasing therapeutic activities on inpatient wards.

Secondary Objectives

3. To investigate the effect (moderating or mediating) of nurses barriers to change on the impact of increasing therapeutic activities on patient and staff perceptions of the ward.
4. To investigate the sustainability of the positive effects – is this maintained over time or a boost at the initiation of the therapeutic activities which then drops off.

Outcome Measures
Primary outcome
VOTE – Staff perceptions of inpatient care – continuous scale

Covariates
Staff measures
IWS - Index of work satisfaction questionnaire – continuous scale

WAS - Ward atmosphere scale – continuous scale
GMI - Good Milieu Index – continuous scale
VOCALISE - Barriers to Change – continuous scale
MBI-HSS - Maslach Burnout Inventory-Human Services Survey – continuous scale

Staff demographics: age, gender, ethnicity, employment band, length of employment, previous wards/trusts, further educational awards

Ward measures
Number of patients in last 30 days, Gender of patients, number of incidents (in 30days, 7 days, average per day), Nurse coverage, average length of stay, activities on the ward, percentage of bed occupancy, ward acuity (average PANSS, GAF or NOSIE)

Descriptive Analysis
Summary of staff sample characteristics at each time point
Summary of ward characteristics at each time point

Tabulation of staff characteristics between wards randomised to intervention or not at each time point.

Missing Data
Description of levels of missing data, comparison of missing data between the intervention and control arms. All analyses will account for missing data using weighting or imputations as appropriate.

Analysis of primary outcome
Aim: To measure the impact of increasing therapeutic activities on staff perceptions of care

Descriptive analysis
Mean and standard deviation of VOTE in control and intervention arms at each time point and overall.

Regression analysis
Cross-sectional time series model of VOTE including time and an indicator for intervention or control arm which will change over time accounting for a clustering effect at the ward level.

Adjustment for confounders:
1. Adjust analysis for baseline staff characteristics that are expected to be associated with outcome e.g. band, length of employment, age
2. Adjust analysis for baseline ward level characteristics that are expected to be associated with outcome e.g. acuity of the ward, patient turnover
3. Include the staff measure of barriers to change to investigate the impact on and interaction with the treatment effect

Type of analysis
Intention-to-treat analysis will use intervention arm as the covariate of interest.

The following covariates were each tested to see if they confounded or changed the effect of the intervention in WP3

Staff: gender, age, ethnicity, first language, length of employment

Work Package 4 – BETTER pathways Service User analysis

Summary
BETTER is a comparison of the two systems of inpatient care (triage care system and routine care). Service users are recruited from wards run under the two models of care. They are recruited four times over a period of 18 months with new participants at every recruitment period.

In addition to BETTER PATHWAYS, there is a full dataset of full admissions (ADMIT) during the same time interval of the study.

Objectives
Primary objectives:

1. To investigate differences in patients' satisfaction and patients' perceptions of care between those treated under the two models of care (SSS-RES and VOICE respectively)
2. To investigate differences in ward environment between those treated under the two models of care
3. To compare cost of activities and staff contacts in the two models of care and their impact of patient outcome (I haven't detailed the health economic analyses here as they will be covered by the economics team)

Secondary objectives:

1. To determine the effects on length of stay and readmission of the two systems (ADMIT)
2. What are the predictors of lengths of stay within the two systems (ADMIT)
3. What are the predictors of patient satisfaction and patient perceptions within the two systems (BETTER PATHWAYS)

Outcomes Measures

Length of stay – individual patient length of stay until discharged from system
Readmission
VOICE – Service user perceptions of inpatient care – continuous scale
SSS-RES – Residential Form – continuous scale (total score)

Additional covariate data

Patient demographics: age, gender, marital status, ethnicity, education, socio-economic status, accommodation, employment, diagnosis, admission date (hence age at admission and time since admission), legal status, length of stay, time on ward, diagnosis history, medication history, GAF, HONOS, NOSIE

Ward data
Number of patients in last 30 days, Gender of patients, Nurse coverage, activities on the ward, average length of stay, number of incidents on ward (in 30 days, 7 days, average per day), acuity of ward (average GAF, NOSIE, HONOS)

Comparison of BETTER PATHWAYS dataset to ADMIT
In terms of important variables (socio-demographic and clinical including diagnosis).

Descriptive analysis
Characteristics of the two triage groups in terms of diagnoses, age, gender, employment etc. Test for differences using t-tests and chi-square tests.

Missing Data
Description of levels of missing data, comparison of missing data between the systems. Adjustment for significant predictors of missingness, as shown in univariate analyses. Analyses will account for missing data using weighting or imputations if appropriate.

Analysis of outcome

AIM: Identify factors that indicate a good model of triage care

We do not know what a good model of care is and so we will investigate this in two stages:

1. Appraise these differences in terms of patient perception and patient satisfaction using the VOICE and SSS-RES respectively (BETTER PATHWAYS)
2. Determine in what ways the two models of care vary e.g. turnover (how many people are admitted every month, length of stay re-admission (ADMIT)

AIM part 1: To investigate differences in patient satisfaction and patient perceptions of care between those treated under the two models of triage care

Descriptive analysis
Mean and standard deviation of VOICE (and its two factors, Interaction and Safety) in the two systems.
Comparisons between VOICE and ward level data (8 wards, 4 time points; 30 data points due to one ward closure); bed occupancy, length of stay, incidents.

Regression analysis
Linear regression of VOICE by system, adjustment for time and clustering at ward level.

Further exploratory analyses include adjustment for other predictors:
1. Adjust analysis for patient characteristics that are expected to be associated with outcome but are not expected to change with the intervention e.g. age, diagnosis, legal status, socio-economic status, education, employment, living situation
3. Adjust analysis for ward level characteristics that are expected to be associated with outcome e.g. acuity of the ward, patient turnover

AIM part 2: To determine the effects on turnover, length of stay, readmission and incident rates of the two systems (ADMIT).

Descriptive analysis
Mean and standard deviation, median and range if necessary of length of stay and proportions of readmission in the two triage arms.

Regression analysis
Linear regression of length of stay, logistic regression for readmission rates and poisson regression for incident rates, by system including an adjustment for clustering at ward level.

Further exploratory analyses include adjustment for other predictors:
1. Adjust analyses for patient characteristics that are expected to be associated with outcome but are not expected to change with the intervention e.g. age, diagnosis, socio-economic status, education, employment, living situation
2.Adjust analyses for ward level characteristics that are expected to be associated with outcome

Work Package 4 – BETTER pathways Staff analysis

Summary

BETTER is a comparison of two systems of care. Staff are recruited from wards run under the two models of care. They are followed up every 6 months and asked to repeat the measures.

Objectives

Primary objectives:

4. To measure differences in staff satisfaction (IWS), staff perceptions of care (VOTE) and levels of burnout (MBI) between those working under the two models of care
5. To compare cost of activities and staff contacts in the two models of care and their impact of patient outcome (I haven't detailed the health economic analyses here as they will be covered by the economics team)

Secondary objectives:

4. What are the predictors of staff satisfaction staff perceptions and staff burnout within the two systems (BETTER PATHWAYS)

Outcomes Measures

Primary outcome
VOTE – Staff perceptions of inpatient care - continuous scale
MBI-HSS - Maslach Burnout Inventory-Human Services Survey– continuous scale (Total and three subscales)
IWS - Index of Work Satisfaction

Secondary outcomes
VOCALISE - Barriers to Change – continuous scale
WAS - Ward atmosphere scale – continuous scale

Additional covariate data
Staff demographics: age, gender, ethnicity, employment band, length of employment, previous wards/trusts, further educational awards

Ward data
Number of patients in last 30 days, Gender of patients in last 30 days, Nurse coverage, activities on the ward, average length of stay, number of incidents on ward (in 30days, 7 days, average per day), acuity of ward (average GAF, NOSIE, HONOS), proportion of shifts undertaken by bank staff compared to the total number of shifts excluding student nurses.

Descriptive analysis

Characteristics of the two triage groups in terms of age, gender, employment band, length of employment comparison using t-tests and chi-square as appropriate

Missing Data
Description of levels of missing data, comparison of missing data between the systems. Analyses will account for missing data using weighting or imputations if appropriate.

Analysis of primary outcome

AIM:. To measure differences in staff satisfaction between those working under the two models of triage care

Descriptive analysis
Mean and standard deviation of VOTE in the two triage arms.

Regression analysis
Cross-sectional time series analysis of VOTE by system including time and an adjustment for clustering at two levels, staff level and ward level.

Further exploratory analyses include adjustment for other predictors:

1. Adjust analysis for staff characteristics that are expected to be associated with outcome e.g. band, length of employment, age
2. Adjust analysis for ward level characteristics that are expected to be associated with outcome e.g. acuity of the ward, patient turnover