UNIVERSITY OF BASEL

Institute of Nursing Science

Building Research Initiative Group: Chronic Illness Management and adHerence in Transplantation study

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for the BRIGHT Study Consortium

1. BACKGROUND

- Non-adherence (NA) to health behaviors (ie. medication taking, smoking, diet, alcohol consumption, physical activity, sun protection, and appointment keeping) is high among heart transplant patients and frequently related to poor clinical and economic outcomes
- Currently, there is limited data about the prevalence of NA to these health behaviors across different countries/health care systems
- Only a few studies exist that focus on health care system factors to explain adherence to Immunosuppressive Medication (IM) in transplant patients

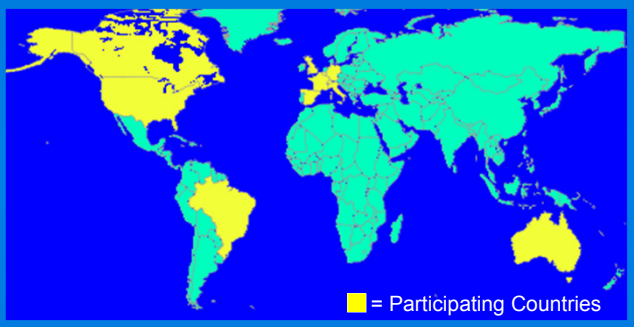
2. PURPOSE

1) To assess prevalence and variability across countries/health care systems with regards to adherence to health behaviors
2) To determine patient, micro-, meso-, macro- system level factors related to IM non-adherence
3) To determine whether the Integrated Model of Behavioral Prediction (IMBP) has explanatory value as a conceptual framework describing determinants of NA at the patient level
4) To benchmark participating centers, countries, continents in relation to adherence with IM and system level factor variables identified as significantly associated with adherence with IM

3. METHODS

Design

- International, multi-center, cross-sectional study



Sample & setting

- Convenience sample of heart transplant centers:
  North America: N= 20, Europe: N= 20, Australia: N= 3, South America: N= 3
  Inclusion criteria for centers:
  - ≥ 50 HTx between 1-5 years ago
  - Located in North America, Europe, South America, or Australia
  - Approval of study protocol by local institutional review board (IRB)
  - Formal commitment to collect required data for study
  - Letter of support from medical/administrative director
- Proportional randomized sampling of patients within centers:
  small center: N= 25, medium center: N= 40, large center: N= 60
  Inclusion criteria for patients:
  - Adult heart transplant patients (≥ 18 years of age)
  - Transplanted and followed up in one of the participating centers
  - First transplant
  - Between 1 and 5 years post-transplant
  - Able to read, understand and provide written informed consent
  Exclusion criteria for patients:
  - Patients involved in adherence intervention research in the last 6 months
  - No knowledge of any of the languages used in the study (Dutch, English, French, German, Italian, Portuguese, Spanish)
- Randomized sampling of transplant clinicians if >5 within center (maximum of 5 nurses included per center):
  Inclusion criteria for transplant clinicians:
  - Working in the transplant program > 6 months
  - Employed 50% or more in direct clinical practice
  - Familiar with the post-transplant outpatient care of the transplant program
  Exclusion criteria for transplant clinicians:
  - No knowledge of any of the languages used in the study (Dutch, English, French, German, Italian, Portuguese, Spanish)

4. VARIABLES AND MEASUREMENTS

Health Behaviors (self-reported)

- Adherence to the **medication regimen**: Basel Assessment of Adherence with IM Scale (BAASIS) (n=6)
- Adherence to **smoking cessation**: Swiss Health Survey (n=1)
- Adherence to **dietary modifications**: Investigator developed questions (n=2)
- Adherence to **alcohol use**: Investigator developed questions (n=4)
- Adherence to **physical activity**: Brief Physical Activity Assessment tool (n=2)
- Adherence to **sun protection**: Swiss study on the health of people with cancer, leukemia, or tumor in childhood; Cambridge University Hospitals' perception of skin cancer in transplant recipients scale (n=7)
- Adherence to **appointment keeping**: Number of the last 5 appointments missed (n=1)

Patient Level

- **Demographic variables**: Age, gender, marital status, employment status and education level (n=11)
- **Attitudes toward IM taking**: Investigator developed scale (n=32)
- **Medication taking self-efficacy**: Long-Term Medication Behavior Self-Efficacy Scale (n=24)
- **Barriers to IM taking**: IM Adherence Barriers scale (n=28)
- **Intentions for medication taking**: Investigator developed questions (n=5)
- **Sleep quality and daytime sleepiness**: Based on Dialysis Outcome and Practice Patterns Study and Epworth Sleepiness Scale (n=2)
- **Depression**: Depression Anxiety Stress Scales (n=7)
- **Health literacy**: Health literacy screening questions (n=3)

Micro level: Patient-provider interaction

- **Patient satisfaction with the interpersonal dimension of care**: Westaway Patient Satisfaction Scale (part I) (n=12)
- **Trust in transplant team**: Wake Forest University Trust scale (n=10)
- **Received social support**: Social Support Questionnaire (n=17)

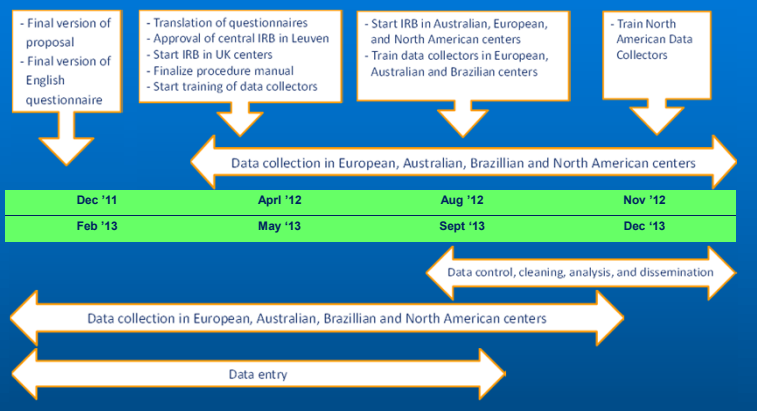
Meso level: Transplant center

- **Level of chronic illness care implemented (health care professional perspective)**: Chronic Illness Management Implementation - Building Research Initiative Group: Chronic Illness Management and Adherence in Transplantation survey (n=70)
- **Level of chronic illness care implemented (patient perspective)**: Patient Assessment of Chronic Illness Care (n=11)

Macro level: Health care system

- **Country**: Health care system data
- **Perceived financial burden of treatment and insurance status** (n=8)

5. TIMELINE



6. DATA ANALYSIS

Data Description: Measures of central tendency, dispersion, and use of frequencies will be employed depending on the measurement level of each variable

Psychometrics: Multi-item instruments will be checked for dimensions before use in further analyses

Inferential Statistics: Multi-level determinants/correlates of non-adherence will be examined using mixed effects regression analysis, using center as a random variable. A separate model will be used to test the patient-level variables outlined in the IMBP

Benchmarking: Each transplant center will receive feedback on their performance using results benchmarked on system factors against the mean of all transplant centers

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