P-PROM ROCK Statistical Analysis Plan

Please note, as this is a pilot trial, most analyses are descriptive.

Description of objectives, outcomes, and methods of analysis:

OBJECTIVE	OUTCOME & OUTCOME MEASURE	METHODS OF ANALYSIS
Primary		
To evaluate the feasibility and acceptability of a generic paediatric patient reported outcome measure (P-PROM) in routine outpatient care at The Royal Children's Hospital compared with standard care.	Acceptability outcomes: *Patient/caregiver reported:* - attitude about complete generic P-PROM. Based on response to follow-up survey question adapted from theoretical framework of acceptability (TFA).[1]* - burden to complete generic P-PROM. Based on response to follow-up survey question adapted from TFA.[1]* - relevance of generic P-PROM questions. Based on patient/caregiver response to follow-up survey question adapted from a previous similar P-PROM study.[2]* - ease understanding summary of generic P-PROM results. Based on patient/caregiver response to follow-up survey question adapted from a previous similar P-PROM study.[2]* - usefulness of results in clinical encounter. Based on patient/caregiver response to follow-up survey questions adapted from TFA and a previous similar P-PROM study.[1, 2]* - opportunity cost of discussing generic P-PROM in clinical encounter. Based on response to follow-up survey question adapted from TFA.[1]* - intervention coherence of generic P-PROM (i.e., clarity regarding how generic P-PROM could improve child's care). Based on response to follow-up survey question adapted from theoretical framework of acceptability (TFA).[1]* - self-efficacy completing generic P-PROM in future. Based on response to follow-up survey question adapted from theoretical framework of acceptability (TFA).[1]*	Most acceptability and feasibility outcomes will be assessed using descriptive statistics. For example, the proportion of patient/caregivers allocated to the intervention arm who completed the PROM will be described. Focus group data will be analysed using qualitative framework analysis (described below).

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	- **helpfulness of resources provided** alongside generic P-PROM. Based on patient/caregiver response to follow-up survey Likert scale study deigned question.* - **acceptability of using generic P-PROM in outpatient care**. Based on clinician response to follow-up survey questions adapted from TFA and study designed.[1]* - **ease using RCH patient portal** to complete generic P-PROM, view results, and view resources. Based on patient/caregiver response to follow-up survey Likert scale study deigned question and data automatically captured via portal (such as time taken to complete and number of clicks to complete).* *Clinician reported:* - **ease locating** generic P-PROM results in EPIC. Based on clinician response to follow-up survey likert scale study deigned question * - **ease interpreting** results of generic P-PROM. Based on clinician response to follow-up survey likert scale study deigned question.* - **usefulness of results in clinical encounter**. Based on clinician response to follow-up survey questions adapted from TFA and a previous similar P-PROM study.[1, 2]* Also based on clinician response to weekly during trial study designed survey question. - **intervention coherence of generic P-PROM** (i.e., clarity regarding how generic P-PROM could improve care provided to children). Based on clinician response to follow-up survey question adapted from TFA.[1]* - **helpfulness of training** at beginning of trial. Based on clinician response to follow-up survey Likert scale study deigned question. - **helpfulness of resources** document (clinician decision support tool/ clinician & family resources). Based on clinician response to follow-up survey Likert scale study deigned question - **confidence addressing concerns arising from generic P-PROM.** Based on clinician response to follow-up survey Likert scale study deigned question.	

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	- **attitude about use of generic P-PROM in routine outpatient care**. Based on clinician response to follow-up survey question adapted from TFA.[1]* - **burden using generic P-PROM in routine outpatient care**. Based on clinician response to follow-up survey question adapted from TFA.[1]* - **self-efficacy using generic P-PROM in outpatient care routinely in future**. Based on clinician response to follow-up survey question adapted from TFA.[1]* - **opportunity cost of using generic P-PROM in outpatient care**. Based on clinician response to follow-up survey question adapted from TFA.[1]* - **ethicality of using generic P-PROM in outpatient care**. Based on clinician response to follow-up survey question adapted from TFA.[1]* - **acceptability of using generic P-PROM in outpatient care**. Based on clinician response to follow-up survey questions adapted from TFA and study designed.[1]* - **perception on acceptability** based on semi-structured qualitative focus groups. Feasibility outcomes: - Proportion of patients/caregivers allocated to the intervention who **complete the generic P-PROM**.* - Proportion of patients/caregivers allocated to the intervention who **report wanting to discuss at least one of the domains** of the generic P-PROM with their clinician.* - Proportion of generic P-PROM **results opened or viewed by clinician** where PROM result available. Based on proportion of times Synopsis tab in EPIC (where generic PROM result stored) is opened during clinical encounter with child allocated to intervention group and how long this was open for.***** - **How patients/caregivers complete** the generic P-PROM (via portal (web versus app) and paper).***** - **Resources required to implement** the intervention, including EMR support time, clinician time for training, clinician time to discuss and action PROM results, and researcher time to get patients/caregivers to complete generic P-PROM. Resources	

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	will be converted into Australian dollars to provide an estimate of intervention cost.* - **Additional consultation time** arising from the P-PROM. As reported by clinicians in weekly during trial and follow-up survey study designed questions. Also measured by a research assistant recording a random subset of face-to-face encounters from the waiting room, timing from when the patient enters the room to when the patient exits the room (a minimum of 20 patient encounter times will be recorded, 10 from each trial arm). - **Clinician perception on feasibility** of use of generic P-PROMs in routine clinical outpatient care based on semi-structured qualitative focus groups. ***Intervention arm only**	
Secondary		
To determine the impact of a generic paediatric patient reported outcome measure (P-PROM) on **discussion of HRQoL domains** in routine outpatient care at The Royal Children's Hospital.	Discussion of relevant quality-of-life domains in clinical encounter. Based on proportion of patients/caregivers who report discussing quality of life domains that were relevant to them in their most recent clinical encounter in the 1-day follow-up survey and notes from EMR that capture if quality of life domains were discussed with patient. Relevant quality of life domains will be determined from baseline survey.	Descriptive & inferential statistics. Proportion of patients/caregivers who report discussing quality of life domains that were relevant to them in their most recent clinical encounter. Responses will be compared between participants in intervention and control arm using a chi-squared test. A p value <0.05 is considered significant.
To determine the impact of a generic paediatric patient reported outcome	Holistic care provided in clinical encounter. Based on proportion of patients/caregivers who report their most recent clinical encounter included discussion of aspects of health beyond just the physical condition they were present for (such as emotional, social, school, hobbies, and spiritual wellbeing) as reported in the 1-day follow-up survey.	Descriptive & inferential statistics. Proportion of patients/caregivers who report discussion of aspects of health beyond just the physical

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measure (P-PROM) on **providing more holistic care** in routine outpatient care at The Royal Children's Hospital.		condition they were present for (such as emotional, social, school, hobbies, and spiritual wellbeing) in their most recent clinical encounter. Responses will be compared between participants in intervention and control arm using a chi-squared test. A p value <0.05 is considered significant.
To determine the impact of a generic paediatric patient reported outcome measure (P-PROM) on **detecting new health problems** in routine outpatient care at The Royal Children's Hospital.	Proportion of clinical encounters where a new health problem was detected. Based on detecting new health problems patient/caregiver report in the 1-day follow-up survey and notes from EMR that capture if new problem was identified.	Descriptive & inferential statistics. Proportion of patients where a new health problem was detected in their most recent clinical encounter. Responses will be compared between participants in intervention and control arm using a chi-squared test. A p value <0.05 is considered significant.
To determine the impact of a generic paediatric patient reported outcome measure (P-PROM) on **supporting patients to address new health problems** in routine outpatient care at	Proportion of patients who received support (i.e., change medication, referral, connection with support service, connection with online resource) for a health/quality of life problem(s) in their most recent clinical encounter. Based on patient/caregiver report in the 1-day follow-up survey and notes from EMR that capture if support was provided.	Descriptive & inferential statistics. Proportion of patients who report receiving support for a health or quality of life problem in their most recent clinical encounter. Responses will be compared between participants in intervention and control arm using

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The Royal Children's Hospital.		a chi-squared test. A p value <0.05 is considered significant.
To determine the impact of a generic paediatric patient reported outcome measure (P-PROM) on **patient satisfaction with care** in routine outpatient care at The Royal Children's Hospital.	Patient satisfaction with care in routine outpatient care based on responses to patient satisfaction questionnaire (PSQ).[3]	Descriptive & inferential statistics. The 5 items (ask participants to report on a scale of 0-100) covered by the PSQ for patients will be descriptively assessed, where a mean and standard deviation will be provided for each item. Responses for each item will be compared between participants in intervention and control arm using a t-test. A p value <0.05 is considered significant.
To determine the impact of a generic paediatric patient reported outcome measure (P-PROM) on **patient - clinician communication** in routine outpatient care at The Royal Children's Hospital.	Patient - clinician communication. Based on patient/caregiver report to a study designed Likert question in the 1-day follow-up survey	Descriptive & inferential statistics. Description of patient's report of patient-clinician communication in their most recent clinical encounter. Responses will be compared between participants in intervention and control arm using a chi-squared test. A p value <0.05 is considered significant.

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To determine the impact of a generic paediatric patient reported outcome measure (P-PROM) on **child quality of life**.	Improvements in child health related quality of life, measured using the CHU9D (Appendix B) and based on change between baseline and 4-week follow-up. [4, 5]	Descriptive & inferential statistics. The mean difference and standard deviation of CHU9D total and/or utility score (calculated using available Australian utility weights for CHU9D) between baseline and 4-week follow-up for participants in intervention and control arm will be reported. Differences between participants in intervention and control arm will be assessed using a t-test. A p value <0.05 is considered significant.

Sub-group analysis:

Some sub-group analyses maybe conducted where appropriate. Sub-groups may include child age, child gender, PROM report type (self versus proxy), PROM completion method (paper versus portal), appointment type (face to face versus telehealth), and outpatient clinic. For sub-group analyses, the p value threshold of significance will be adjusted for multiple comparisons.

Economic evaluation:

If appropriate, an economic evaluation may also be conducted.

Qualitative data analysis:

All qualitative data, including transcripts and notes from focus groups will be uploaded into NVivo. The focus group transcripts will be analysed using a qualitative framework approach.[6] The analysis of qualitative data using the qualitative framework approach involves seven stages: 1) transcription, 2) familiarisation with the transcription, 3) coding, 4) developing analytical framework, 5) applying analytical framework, 6) charting data into the framework, and 7) interpreting the data.[6]

References:

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3. Thayaparan AJ, Mahdi E. The Patient Satisfaction Questionnaire Short Form (PSQ-18) as an adaptable, reliable, and validated tool for use in various settings. Med Educ Online. 2013;18:21747.
4. Stevens K. Developing a descriptive system for a new preference-based measure of health-related quality of life for children. Qual Life Res. 2009;18(8):1105-13.
5. Stevens K. Assessing the performance of a new generic measure of health-related quality of life for children and refining it for use in health state valuation. Applied Health Economics and Health Policy. 2011;9(3):157-69.
6. Gale NK, Heath G, Cameron E, Rashid S, Redwood S. Using the framework method for the analysis of qualitative data in multi-disciplinary health research. BMC Med Res Methodol. 2013;13:117.