**RESEARCH STUDY PROTOCOL**

Evaluating the impact on in-hospital orthopaedic waitlists after the introduction of subsidised access to out-of-hospital allied health services for patients with chronic musculoskeletal conditions

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**Activity 2:** Following on from Activity 1, this activity aims to test the market for what patients are willing to pay for existing allied health services, and to determine if cost is a barrier to access. Participating GPs who refer patients to advanced physios, as above (Activity 1). General Practice Medical Centres will be randomised to one of four subsidy schemes. Following on from Activity 1, participating patients can then access existing allied health services, as per the subsidy arm allocated to their General Practice Medical Centre.

Subsidy A- Control arm- Allied Health Market rate (standard) fees + (MBS- GPMP/TCA- 5 subsidised visits)

Participant to fund additional costs at market rate

Subsidy B- Participants to receive additional 5 subsidised sessions (equivalent of 10 GPMP/TCA sessions)

Participant to fund additional costs at market rate

Subsidy C- As per subsidy B- Participants receive equivalent of 10 GPMP/TCA sessions

Participants contribute $10-20 per session toward market rate

Subsidy D - Participants receive equivalent of 10 GPMP/TCA sessions

 Participants to receive full gap payment (no out of pocket expenses)

**Activity 2**

**Background Activity 2:**

Many patients with chronic musculoskeletal conditions are better suited to allied health services, than orthopaedic surgery1. Patients referred for orthopaedic outpatient review may be better managed by physiotherapy services or a combination of AH therapies 2,3, than orthopaedic specialists3-5. Furthermore, multidisciplinary approaches to musculoskeletal condition management, from a range of settings, have been documented to improve outcomes for individuals 6-9. These include the incorporation of psychology in treatment plans, which can provide initial motivation assistance and help guide self-management support 10.

The MBS subsidy for PHC allied health services is a relatively new policy initiative in Australia11. The success of this policy hinges on several factors, notably, its ability to improve equity of access to allied health services, and generate improved health outcomes. However, within Australia, there is emerging evidence that reduced access to allied health professionals in primary health remains12. In the absence of bulk billing for allied health services, there is a cost barrier to access these services, especially for patients from lower socioeconomic groups. This has further implications when accessing multidisciplinary care, which collectively requires more sessions12. As access remains limited due to existing gap payments11, many have indicated that a review of Medicare-funded team care for chronic disease management in Australia is warranted 13, 14.

Lastly, the introduction of a co-payment as a subsidy option within the randomisation arms is evidenced by other initiatives. Co-payments can be a mechanism for increasing the value of the service, as viewed by patients, and report fewer appointment misses, or failure-to-attend (FTA). In studies where services were provided at no or low cost initially, these facilitated patient exposure to the benefits of allied health services first hand, and many patients continued paying for these services privately once the subsidised sessions were exhausted 11.

Currently consumer willingness to pay for services versus the market cost is unknown. The inclusion of a stepped subsidies/gap payment in this study design aims to establish what local markets are willing to pay for allied health services.

**Site/s you will be conducting your Research at:**

**Activity 2:** GPs: within the Cairns area (from the 16- 20 practices with the most orthopaedic referrals submitted in previous 12 months), will be recruited to manage and treat referred patients who have chronic musculoskeletal conditions; entry to the program via physio assessment Activity 1.

**Research Questions:**

Activity 2: Main research question

1. What does the local market determine is the most acceptable costing model for service delivery?

Sub-questions:

1. Does improved access to allied health in PHC lead to a reduction in referrals to orthopaedic outpatients?
2. Does improved access to allied health in PHC lead to a reduction in orthopaedic outpatient waitlists?
3. Are there differences in MDT treatment plan completion rates between the four arms of Activity 2 within the PHC setting?
4. How are costs distributed between state funded health services and commonwealth services between Activity 2 arms (GPMP records/ radiology/ pathology)
5. Are there differences between Activity 2 arms for patient costs of service delivery model
6. Are there differences between Activity 2 arms for failure-to-attend (FTA) rates?
	* + 1. Are there differences between Activity 2 arms in patient, GP and orthopaedic specialist satisfaction (GP-survey, ortho and patient survey)

**Methods:**

**Hypotheses: Activity 2**

Alternate hypotheses: The successful completion of planned MDT treatment plans differs between funding subsidy groups

***Aims and purpose***

***Activity 2 will address:*** *Improving access to existing Medicare-funded allied health services in primary health care (PHC) (Figure 1) and Testing the local market* *on acceptability of co-payments for PHC allied health services:* Existing PHC allied health services are fundedthrough Medicare Benefits Scheme (MBS). To test the palatability of different consumer costs, this study randomises GP practices to four gap payment options that they can discuss with their patients. This will test the local market to identify if barriers to use of current PHC allied health services are based on fee structures. The ‘control’ subsidy option offered is the currently available MBS item subsidy, with three other subsidy options offering less or no out-of-pocket expenses for patients.

***Intervention 2:*** To examine the local market this study will assess the acceptability of co-payments for PHC allied health services. General practices will be randomised to different funding subsidy access (A, B, C, D) for PHC allied health services.

RCT of four varying subsidy categories to assess localized willingness to pay. *Intervention 2:* General practices will be randomised to different funding subsidy access (A,B,C,D) for PHC AH services. Once the GP receives the patient individual treatment plan, the GP will advise their patient to seek existing AH services in PHC within the randomised funding support outcome. As the majority of existing ortho-AH patients require 8-10 sessions, the present MBS 721/723, which offer only 5 subsidised sessions (or up to 10 for Aboriginal/Torres Strait Islander patients) will be the control arm, and additional subsidised sessions will be offered in the subsidy arms. Patients will be requested to sign a consent form that includes a loyalty declaration (will not change GP practice) for the trial period, this will be obtained upon assessment by the physios. Standard care will be offered to patients who do not wish to receive this additional service, or participate in the study. Within the consent form will be a checklist identifying patients as eligible to receive Department of Veterans Affairs (DVA) funded allied health services and/or private health insurance extras, offering subsidised PHC allied health services.

Subsidy A- Control arm- standard fees (MBS- GPMP/TCA- 5 subsidised visits)

Participant to fund additional costs at market value

Subsidy B- Participants to receive additional 5 subsidised sessions (equivalent of 10 GPMP/TCA sessions)

Participant to fund additional costs at market value

Subsidy C- As above- Participants receive equivalent of 10 GPMP/TCA sessions

Participant contribution of $10-20 per session toward market value

Subsidy D - Participants receive equivalent of 10 GPMP/TCA sessions

 Participants to receive full gap payment (no out of pocket expenses)

Final assessment (by advanced physio): will determine if the MDT tailored patient treatment plan has been completed, if uncompleted due to insufficient funds – patient will be offered Subsidy Arm D to complete AH sessions (just for trial period), else findings from Activity 1 may be biased.

**Treatment completion** Patients will be clinically evaluated at the first physio assessment (Intervention 1) and at the final assessment (completion of therapy). Treatment completion is defined as completion of the recommended MDT treatment plan with full discharge from services (from orthopaedic care). The MDT plan includes functional and Quality of life assessments. Should a patient (from Subsidy arms B C D) not complete the program due to financial constraints (but who would otherwise be willing and able to complete it), they will be offered Subsidy arm A (no cost to patient) until they have completed their recommended sessions, else this may impact the outcome of Intervention One. This is a safety net built in to the trial to ensure patients who might otherwise be considered a treatment failure (and would then qualify for direct orthopaedic outpatient referral) remain out of hospital (Intervention 1) and maintained in the community over the trial period, else their failure to complete their treatment plan impact the Intervention One outcomes-as measured by orthopaedic outpatient waitlists.

**Study Design:**

Activity two applies a RCT of four varying subsidy categories to assess localized willingness to pay. The different funding streams are available to patients to access PHC allied health services.

GPs will be recruited from within the Cairns area (16- 20 practices- with the most orthopaedic referrals submitted in last 12 months)-existing referral information from Cairns Hospital will be accessed prior to approaching GP practices.

General practices will be randomised to different funding subsidy access (A, B, C, D) for PHC allied health services. Once the GP receives the patient individual treatment plan, the GP will advise their patient to seek existing allied health services in PHC within the randomised funding support outcome (out-of-pocket costs to patients for B, C, D). As the majority of existing ortho-allied health patients require 8-10 sessions, the present MBS 721/723, which offer only 5 subsidised sessions (or up to 10 for Aboriginal/Torres Strait Islander patients) will be the control arm, and additional subsidised sessions will be offered in the subsidy arms. Patients will be required to sign a consent form that includes a loyalty declaration (will not change GP practice) for the trial period, this will obtained upon assessment by the physios. Standard care will be offered to patients who do not wish to receive this additional service, or participate in the study. Within the consent form will be a checklist identifying patients as eligible to receive Department of Veterans Affairs (DVA) funded allied health services and/or private health insurance extras, offering subsidised PHC allied health services.

Existing subsidised arrangements:

1. DVA eligible for fully subsidised PHC allied health services
2. Private health insurance with extras for subsidised PHC allied health services

**Sample size and power calculation**

**Activity 2:** Over four treatment groups assuming 5% effect size and 50% within group variance (error) with 80% power to detect statistical significance at 5% alpha level a sample of 30 per group is required. When allowing for censoring a total of 150 will be required. Sample sizes were calculated using G\*Power 15 and STATA version 14, Texas. This study aims to recruit over 1000 participants over the 24 month study period with 200 in each subsidy arm for intervention 2 (activity 2).

**Data Analysis:**

**Statistical methods**

**Activity 2:** For intervention 2 we will apply a Generalised Estimating Equation (GEE) model across subsidy arms to assess treatment success as defined by completion of MDT treatment plan and discharge from orthopaedic care. GEE models are suitable for these analyses as they produce semi-parametric models which report population average effects; furthermore, they can adjust for potential biases from different GPs: patient level data may not be independent 16. For this analyses demographic factors and comorbidities will be included as fixed effects and individual GPs will be set as random effects to adjust for potential biases. All statistical tests will be two-sided and performed using a 5% significance level with no adjustment for multiplicity. Data analysis will be performed using STATA version 14 and Excel.

**Costing analyses**

Costs will be calculated as the sum of health care costs minus the cost of the FTA costs, as obtained from QH casemix (internal) data. The costing analyses will report costs post MDT treatment plan completion by patient, for each Tier 2 coding, within the participant sample. The out-of-pocket costs to DVA, private health insurance and patient out-of-pocket costs will not be measured, nor will productivity changes. Pre-trial costings: base cost, current practice: AH service assessment and service offered through outpatients department 100% funded through QH; will be undertaken from generic hospital records, based on set costs included in QH activity based funding model- health care purchasing framework 17. We will compare Intervention two: costs for each subsidy group (A, B, C, D).

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