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# Patient-reported outcome measures in multiple myeloma: real-time reporting to improve care (My-PROMPT) – a pilot randomized controlled trial

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**Short running title:** My-PROMPT: Real-time reporting of PROMs in multiple myeloma

**Keywords:** Multiple myeloma, Plasma cell neoplasms, Patient-reported outcome measures, Quality of life, Randomized controlled trial, Clinical trial

To the Editor:

Multiple myeloma (MM) is associated with a high burden of disease, compromising patients' health-related quality of life (HRQOL). With improvements in overall survival, HRQOL has become an increasingly important outcome. Patient-reported outcome measures (PROMs) are tools that collect patient-reported outcomes (PROs) – an individual's evaluation of their own health and wellbeing – and incorporate HRQOL. Routine monitoring of symptoms and other PROs to inform cancer care has been shown to improve patient outcomes including HRQOL[1,2] in solid tumours. However, few data exist for hematological malignancies[3,4], and even fewer for MM[4]. To design a randomized controlled trial (RCT) to assess the impact of real-time feedback of PROs, feasibility and acceptability to patients and clinicians of such an intervention needed evaluation. To achieve this, we designed the My-PROMPT pilot RCT to determine feasibility and appropriateness of study design, including acceptability to patients and clinicians, and to understand any change in HRQOL over time, to inform sample size calculation for a future trial.

This parallel, non-blinded RCT (ACTRN12618001878268, Figure S1) was conducted in hematology clinics in 4 Australian hospitals. Table S1 provides detailed study methods. Patients were ≥18 years with newly diagnosed MM (NDMM) and participants in the Australian and New Zealand Myeloma and Related Diseases Registry (MRDR[5]), which provided patient data and infrastructure for recruitment. Intervention patients completed the Myeloma Patient Outcome Scale (MyPOS[6]) before 4 clinic visits: baseline, 1, 6, and 10 months (Table S2). Clinicians received summaries of MyPOS results of concern before visits. Controls completed the MyPOS at baseline and 10 months with no feedback to clinicians. Primary outcome was feasibility and acceptability of the intervention for patients and clinicians (Table 1a). Further outcomes are in Table 1 b and c and change in patients'

MyPOS HRQOL score from T1 to 4 compared between groups in Figure S2. Interviews were conducted with 6 clinicians and 7 patients. The Alfred Hospital, Melbourne, Australia provided ethics approval as lead site.

My-PROMPT recruited 32 patients from 8 May 2017 to 31 October 2018, 16 to each arm (Figure S1). Median age in the intervention v control group was 66 y (59-76) v 69 (62-71); baseline characteristics were well matched other than a greater proportion of males in the control arm (81% v 25%, p=0.001, Table S3).

Proportion of completed MyPOS per time point was > 90% (T1: 100% [32/32], T2: 94% [15/16], T3: 94% [15/16], T4: 91% [29/32]), most in hardcopy (85%, 11/13), and without help (92%, 12/13). Most patients agreed MyPOS instructions were easy to follow and understand (92%, 11/12).

Median satisfaction score for patients was 5 (scale 1-5, 5=Very satisfied, n=13), and for 15 clinicians over all T1 to 3 visits (n=39) was 85 (scale 1-100, 100=Very satisfied, Table 1a).

- *Patients:* In evaluations (completed in intervention arm only), patients agreed that completing MyPOS helped convey concerns to doctors (85% [11/13]), their doctor discussed MyPOS results (62% [8/13]), and their doctor referred to results in the consultation (46% [6/13]).

- *Clinicians:* 80% (31/39) used results to discuss patient concerns, and >40% (17/39) took action after seeing results (Table 1c). Those who didn't take action and added free-text comments (n=2), explained none was required or the issue was not medically related. Over 50% (21/39) of clinicians thought the intervention was ready for routine use and most (83%) thought it had reduced, or had only minimal impact on visit duration. Most clinicians thought no training (68%), or only a brief familiarization (32%) was required.

- *MyPOS scores:* Median total MyPOS score was 18 (IQR 14, 39; range 6-51) in the intervention and 25 (IQR 16, 29.5, range 6-42) for controls at T1 (higher score=worse HRQOL), with no significant difference in change in total MyPOS score from T1 to 4 between groups (p=0.20, Figure S2A). The same held for change in MyPOS Symptoms and function (p=0.66), and Emotional response subscale scores (p=0.46, Figures S2B and C). Males had greater median reduction in MyPOS score from T1 to 4 than females in the same cohort (p=0.03, Figure S2D).

Tablets for MyPOS completion were provided to all sites, but only used at one. Reasons reported for not using tablets were: patient preference; internet access difficulties; leaving paper copies was easier; vigilance required with a valuable device; and technical issues launching the MyPOS. Two patients who used the tablets reported they were relatively easy to use.

Sites reported the following logistical challenges in delivering the intervention: ensuring MyPOS completion before visits, entering hardcopy results manually, providing summaries to clinicians before visits, and the short timeframe to complete all these tasks.

Themes and excerpts from patient interviews are summarised in Table S4. Interviewed patients had a median age of 61 years, and 57% were female. Patients reported that use of the MyPOS in the intervention helped prepare for their clinic visit, raise issues, and focus on their main issues. Several patients commented that through the intervention they now realized the range of topics they could raise with clinicians, apart from treatment. Patients indicated that those with more severe disease or those less forthcoming could potentially benefit more from the intervention; and some expressed a desire or expectation that MyPOS data would be used to track progress across consultations.

Themes and excerpts from clinician interviews are summarised in Table S5. One or two clinicians per site were interviewed; median age: 41 y, median years of clinical experience: 19, and 50% were female. According to one clinician, their focus is very treatment-centered (C5, Table S5), another

found that modifying their behaviour to patients' needs before visits helped optimize communication (C1). Clinicians indicated the intervention enhanced and streamlined patient/ clinician communication by summarising patients' self-reported status, which helped to focus on priorities (C1-3). While the intervention resulted in some action being taken (C6), not all concerns raised required additional resource use (C2). Clinicians reported the intervention had minimal impact or reduced workload by identifying patients' main issues to focus on upfront, however it had increased workload for study staff (C1). Clinicians also thought that less forthcoming patients could potentially benefit more from the intervention (C4).

Our findings from patient and clinician My-PROMPT evaluations and interviews suggested the intervention enhanced patient/clinician communication, in line with comparable interventions in solid tumours[2].

A RCT providing summaries from an interactive ePROM system to clinicians treating patients with blood cancers showed symptom outcomes were improved in intervention patients[3]. Our pilot results are not powered to detect such a difference; however, patient and clinician evaluations and interviews revealed the *potential* for the intervention to improve patients' symptoms by prompting discussion, and by focusing visits on patients' priorities. Furthermore, by making clinicians more aware of the *extent* of patients' problems through the intervention (Table S4 and S5), the possibility for symptom improvement is enhanced.

Some ePROM systems allow remote online completion of PROMs on demand[1,4], and generate reports for patients and clinicians to view and monitor progress. Some such systems have shown promise[3] and conferred clinical benefit[1] for patients. Incorporation of such a system with funding in

a future definitive trial would increase patient participation, could improve outcomes, and warrants consideration.

Our study sample was small but adequate for its purpose - to assess feasibility of this intervention for use in a larger RCT. The small sample size contributed to imbalance in baseline characteristics, mainly sex (Intervention: 25% males v Controls: 81%, p=0.001, Table S3). Males had greater median reduction in MyPOS score (lower score = better QOL) from T1 to 4 than females: -10 (-14, -2.5) v -2 (-6, +1), p=0.03, suggesting that over-representation of males in the control arm may have biased results for change in overall MyPOS score between groups (Figure S2A and D). Furthermore, the small sample size meant the comparison of change in MyPOS HRQOL score between groups was underpowered to detect a difference.

This is the first study looking at feedback of PROs to clinicians in a MM-only sample[3,4]. Focusing on a homogenous group may help demonstrate the impact of the intervention and its relevance in MM. In addition, with median age representative of the disease (Table S3), and patients sourced from hospitals similar to those at which many patients in a larger trial would be recruited, the generalizability of this feasibility trial to a future definitive trial in MM is enhanced.

My-PROMPT sites found some logistical aspects challenging, particularly ensuring patients completed the MyPOS and providing a summary to clinicians before patient visits in an often-limited timeframe. To reduce workload for site staff in a future trial, embedding a more sophisticated ePROM system in our registry would help ensure feasibility and sustainability of the intervention by streamlining remote online MyPOS completion and generating easily-accessed summaries for clinicians. The intervention could be scalable to current and future MRDR sites, unlike hospital-based ePRO systems that are built into existing hospital electronic medical record systems site by site, limiting scalability and increasing cost.

Development and uptake of systems to feed back ePROM results to clinicians treating cancer patients has been slow in Australia despite promising supportive evidence of benefits[1,2]. In addition, blood cancers have not been included in an important local trial in this area[7], so the data presented here show the importance of My-PROMPT and a future definitive trial in myeloma.

This pilot RCT confirms the feasibility and acceptability of real-time reporting of PROMs for patients with MM to their treating clinicians, and supports the rationale for proceeding, with some modifications, to a larger, definitive trial in this area.

**Funding**

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**Acknowledgement**

We thank participating patients, clinicians and sites for supporting this study.

**Conflict of Interest**

The Australian and New Zealand Myeloma and Related Diseases Registry (MRDR), which provided data and facilitated recruitment to this trial, has received funding from: Amgen, Celgene, Gilead, GSK, Janssen, Novartis, Sanofi, and Takeda.

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**Table 1. Patient and clinician outcomes**

**a. Satisfaction scores**

| | |
|---|---|
| 1. *Patient satisfaction score* for use of the MyPOS in the intervention: T3 (6 months). (1=Not at all satisfied, 5=Very satisfied), median (IQR) **(N=13)** | 5 (4-5) |
| 2. *Clinician satisfaction score* for use of the MyPOS in the intervention: T1 to T3 visits. (1=Not at all satisfied, 100=Very satisfied), median (IQR) **(N=39 questionnaires from 15 clinicians)** | 85 (65-90) |

**b. Patient evaluation, N=13**

| | | n (%) | |
|---|---|---|---|
| 1. My doctor discussed some of my responses to the survey in our consultation. | Strongly agree | 1 (7.7) | 61.6% |
| | Agree | 7 (53.9) | |
| | Neither agree or disagree | 5 (38.5) | |
| | Disagree | 0 | |
| | Strongly disagree | 0 | |
| 2. Completing the survey was a helpful way to communicate my concerns to my doctor. | Strongly agree | 4 (30.8) | 84.6% |
| | Agree | 7 (53.8) | |
| | Neither agree or disagree | 2 (15.4) | |
| | Disagree | 0 | |
| | Strongly disagree | 0 | |
| 3. My doctor referred to the survey in our consultation. | Strongly agree | 1 (7.7) | 46.2% |
| | Agree | 5 (38.5) | |
| | Neither agree or disagree | 7 (53.9) | |
| | Disagree | 0 | |
| | Strongly disagree | 0 | |
| 4. How would you rate the amount of time it took to complete the survey? **N=12** | Too short | 0 | |
| | About right | 12 (100) | 100% |
| | Too long | 0 | |
| 5. I felt comfortable answering the questions. | Strongly agree | 5 (38.5) | 92.3% |
| | Agree | 7 (53.8) | |
| | Neither agree or disagree | 1 (7.7) | |
| | Disagree | 0 | |
| | Strongly disagree | 0 | |

**c. Clinician evaluation, N=40**

| | | n | % |
|---|---|---|---|
| 6. Did you have any problems with accessing the results of the MyPOS survey report? | No | 40 | 100% |
| | Yes | 0 | |
| 7. Were the results available to you in a timely manner, i.e. before or at the time you were seeing the patient who completed the assessment? | Yes | 40 | 100% |
| | No | 0 | |
| 8. Did you use the survey results as a way of discussing the patient's concerns? **N=39** | Yes | 31 | 79.5% |
| | No | 8 | 20.5% |
| 9. Did you take any actions after seeing the results of the survey? **N=39** | Yes | 17 | 43.6% |
| | No | 22 | 56.4% |
| 10. Do you think the tool is practical for routine use? **N=39** | Yes | 21 | 53.8% |
| | No | 2 | 5.1% |
| | Maybe | 16 | 41.0% |

| | | | |
|---|---|---|---|
| 11. What impact did it have on your workload? **N=35** | Reduced | 5 | 14.3% |
| | None | 10 | 28.6% |
| | Minimal | 14 | 40.0% |
| | Increased | 6 | 17.1% |

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