

Ethics Submission Form
Faculty of Education, Health and Well-being

The Wolverhampton Assessment Tool, a step towards remote monitoring of patient-reported wellbeing in the context of prostate cancer

Research protocol

1. Service user involvement in the development and/or completion of the research. Men with prostate cancer were involved in the creation of the Wolverhampton Assessment Tool, around which this research is centred; the Chief Investigator, who is also an expert patient, has metastatic prostate cancer; the research involves men with advanced and metastatic prostate cancer using the tool to report aspects of their wellbeing to their oncologist, thereby reducing greatly the need to attend hospital appointments, and hence reducing potential exposure to COVID-19.

2.1 The research questions

- To what extent do each of the five items in the WAT correlate to the patient's disease status?
- How do patients and clinicians feel about using the WAT?

2.2 Outline of the project

It is widely recognised that patient-reported outcomes give a measure of overall effect of clinicians' actions on patients and that they can be used to guide the management of the patient's condition (1-4). They can also have an empowering effect as the patient may feel that they are agents, and not just subjects, in their treatment pathway (5, 6). In the case of advanced and metastatic prostate cancer (i.e. cancer which has spread from the prostate to distant sites, the clinical means of assessing how the patient's disease is responding to treatment (Level of PSA [prostate specific antigen, produced normally in the prostate but also produced in prostate cancer cells], and radiological/magnetic scans) are somewhat imperfect as they do not take into account the impact on the patient's life and his response and reaction.

The Wolverhampton Assessment Tool (copy attached) is an objectively analysed, reproducible clinical assessment tool, developed from validated clinical study tools and piloted and refined with patient and clinician feedback to produce a simple 5-item questionnaire which asks patients how they feel normally in terms of pain, urinary frequency, eating, and tiredness. Patients are also asked to pick from a list the single statement which best represents them normally. The working hypothesis is that the patient's scores and his chosen statement correlate with the current state of his disease (7) and indicate whether the current treatment regimen needs clinician intervention.

The Tool allows assessment of the patient's disease status without him always needing to attend hospital and hence reduces potential exposure to Covid-19 for both patient and hospital staff. See attached *Oncology Interim Prostate Cancer Patient Management Guidelines* Royal Wolverhampton Hospital, March 2020 (8)

The aims of the present project are to:

- 1 evaluate how the Tool and the patient's clinical status correlate
- 2 examine patient and clinician attitudes to using the Tool

2.3 How the research will be conducted

In the light of the COVID-19 pandemic, oncologists at New Cross Hospital are advised to consider using the Tool (as per the *Oncology Interim Prostate Cancer Patient Management Guidelines* (8)) as a means of home monitoring of patients. The present project intends to provide robust evidence as to the clinical usefulness of Tool as well as insights into the drivers and barriers to its use by patients and clinicians.

This is a mixed-method study, incorporating both quantitative and qualitative elements. As such, it is both objective and subjective:

- a) It is subjective in that, in using the Wolverhampton Assessment Tool, the patient selects his response to each question on the basis of how he *feels* normally
- b) It is objective in that the tools to be used in the analysis of the quantitative data [i.e. statistical tests such as Mann Whitney-U, Spearman Rank Correlation etc.] are independent of the person using them
- c) Determining clinically the patient's disease status employs objective measures such as PSA, size, distribution and type of metastasis, frequency of night-time urination etc. as well as the clinician's professional judgment which contains both objective and subjective elements (9, 10)
- d) The researchers are not mirrors but they are rather prisms and hence the entire study from conception to analysis and report is a refraction of their experiences

The first phase of the research is a full pilot of the Wolverhampton Assessment Tool in New Cross Hospital, Wolverhampton. Patients who agree to use the Tool to self-monitor their aspects of their health will be invited to consent to share with the researchers their anonymised data from the Tool as well as linked, anonymised clinical data. The frequency of collection of data will be at the discretion of the clinician. Participating patients and clinicians will be invited to take part in a short, semi-structured interview on their experience of using the Tool. All patient data will be treated anonymously, and none linked back to the patient or to their clinician/s.

Clinicians will be asked to record any reasons given by patients who decline to use the Tool.

The clinical data sought on patients will include:

- a) Age
- b) Stage of cancer at diagnosis in terms of the primary tumour, and any presence of disease in lymph nodes and bones
- c) Current stage of cancer in terms of the primary tumour, and any presence of disease in lymph nodes and bones
- d) Level of PSA – prostate specific antigen, produced normally in the prostate but also produced in prostate cancer cells.
- e) Co-morbidities
- f) Current and previous treatments

The main outcome of the first phase will be to refine, as necessary, both the Tool and the research instruments as well as to establish proof of principle of the clinical utility of Tool.

2.4 Later phases of the project

The second phase is to invite oncologists across the West Midlands, many of whom have already expressed an interest, to join the study and to send the researchers anonymised, linked patient data and that from the Tool.

The third phase is to make the Tool available, free of charge, as an app on both the Android Store and the Apple App Store. This will allow patients to self-monitor aspects of their health and to share this as they wish with their clinician. Users will be asked to evaluate the app by the usual means on their app store.

Clinicians who choose to use it with their patients will be asked to share with the researchers anonymised, linked patient data and that from the Tool.

The target group for this research consists of anyone being treated for advanced and metastatic prostate cancer and their clinician/s. It does not involve persons under 18 years of age nor persons from a potentially vulnerable group.

2.5 How the data will be analysed

Quantitative data will be analysed by means of statistical tests such as Mann Whitney-U, Spearman Rank Correlation etc. using SPSS v.26. Qualitative data will be analysed using thematic analysis and the constant comparative method.

2.6 The ethical considerations involved in this project.

Patients and clinicians will be asked if they wish to opt into the study and be required to give their explicit consent, both for sharing data and, if they accept to volunteer, for interviews.

All patient data will be anonymised prior to its being shared with the researchers. Recording and notes of interviews will be anonymised. Only the research team will have access to any raw data. All data will be held in a manner that prevents any linking of it back to either the patient or their clinician.

All data held will be anonymous and will be held on a secure University or NHS server. Only the research team will have access to any raw data. All data will be held in a manner that prevents any linking of it back to either the patient or their clinician.

Participants will be given a participant information sheet, which will detail the risks and benefits of participating and of their right to refuse participation or withdraw from the research at any time.

2.7 References.

1. Basch E, Deal AM, Kris MG, Scher HI, Hudis CA, Sabbatini P, et al. Symptom monitoring with patient-reported outcomes during routine cancer treatment: a randomized controlled trial. *Journal of Clinical Oncology*. 2016;34(6):557.
2. Basch E, Deal AM, Dueck AC, Scher HI, Kris MG, Hudis C, et al. Overall survival results of a trial assessing patient-reported outcomes for symptom monitoring during routine cancer treatment. *Jama*. 2017;318(2):197-8.
3. Cella D, Grünwald V, Escudier B, Hammers HJ, George S, Nathan P, et al. Patient-reported outcomes of patients with advanced renal cell carcinoma treated with nivolumab plus ipilimumab versus sunitinib (CheckMate 214): a randomised, phase 3 trial. *The Lancet Oncology*. 2019;20(2):297-310.
4. Tombal B, Saad F, Penson D, Hussain M, Sternberg CN, Morlock R, et al. Patient-reported outcomes following enzalutamide or placebo in men with non-metastatic, castration-resistant prostate cancer (PROSPER): a multicentre, randomised, double-blind, phase 3 trial. *The Lancet Oncology*. 2019;20(4):556-69.
5. Tran C, Dicker A, Leiby B, Gressen E, Williams N, Jim H. Utilizing Digital Health to Collect Electronic Patient-Reported Outcomes in Prostate Cancer: Single-Arm Pilot Trial. *Journal of Medical Internet Research*. 2020;22(3):e12689.
6. Leech M, Katz MS, Kazmierska J, McCrossin J, Turner S. Empowering patients in decision making in radiation oncology-can we do better? *Molecular Oncology*. 2020.
7. Cella D, Traina S, Li T, Johnson K, Ho K, Molina A, et al. Relationship between patient-reported outcomes and clinical outcomes in metastatic castration-resistant prostate cancer: post hoc analysis of COU-AA-301 and COU-AA-302. *Annals of Oncology*. 2018;29(2):392-7.
8. Oncology Interim Prostate Cancer Patient Management Guidelines. Wolverhampton: New Cross Hospital; March 2020.
9. Gropman J. *How doctors think*: Houghton Mifflin Harcourt; 2008.
10. Roland D, Matheson D. New theory from an old technique: the Rolma matrices. *The clinical teacher*. 2012;9(3):143-7.

2.8 Appendix

Name
Hospital No.....
Address.....
Patient Label.

Clinical Assessment Tool

Please score your pain ticking the one number that represents your pain normally	0 none	1	2	3	4	5	6	7	8	9	10 As bad as I can imagine
Comment:											
I have problems when I urinate- please tick the number that best represents you normally	0 none	1	2	3	4	5	6	7	8	9	10 As bad as I can imagine
Comment:											
I have problems eating- please tick the number that best represents you normally	0 none	1	2	3	4	5	6	7	8	9	10 As bad as I can imagine
Comment:											
I feel tired- please tick the number that best represents you normally	0 none	1	2	3	4	5	6	7	8	9	10 As bad as I can imagine
Comment:											
Please tick which statement below best represents you normally											
I am fully completing my normal activities											10
I have minor restrictions in strenuous physical activity											9
I am active, but tire more quickly											8
I am experiencing greater restriction of activities and spend less time in work activities											7
I am up and around, but activities are minimal; I keep busy by being involved in quieter activities											6
I am lying around much of the day, but I get dressed; I do no active work but I participate in quiet activities											5
I mainly stay in bed and participates in some quiet activities											4
I stay in bed, needing assistance even for quiet activities											3
I sleep often and limited to very passive activities											2
I don't mobilise and I do not get out of bed											1
Patient is unresponsive											0
Thank you for your time											
Office Use:										Totals	
Date:	Treatment :			Cycle:		Day:					