

Evaluation of the TrueNTH UK Supported Self-Management and Follow-Up Care Programme

FINAL REPORT

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EXECUTIVE SUMMARY

E1. The number of UK men living with and beyond prostate cancer is set to double by 2030. Clinics are already struggling to cope with these increasing numbers, a problem compounded by workforce challenges. This project developed and evaluated a new model of stratified follow-up, with the majority of men supported to self-manage their condition post-treatment, freeing up resources and time in clinic for patients with more complex needs. An implementation toolkit (including detailed guidelines) has been developed to allow other healthcare providers to adopt this new model of care.

E2. The key elements of the new model of care are:

- Ongoing access to a support worker, who introduces the supported self management programme at the final clinic appointment
- A supported self-management workshop
- Ongoing patient access to an online IT service that allows them to view test results, complete assessments, view information and message their clinical team.
- Ongoing remote monitoring of Prostate Specific Antigen (PSA) results – using a PSA tracking system – with individually tailored support as required

E3. The project ran from 2014 to 2017, and tested the methodology across 5 NHS Trusts. Over this time, 2675 men were enrolled on the programme and over 250 supported self-management workshops were delivered.

E4. To deliver the new model of care, three new innovations were needed – the new support worker role, the supported self-management workshop, and the IT service.

E5. A new support worker role was based on early work by Macmillan Cancer Support. Whilst there was some variation across the different participating NHS Trusts as to the precise role description, key tasks included: identifying and enrolling suitable patients; holding an initial consultation with men to introduce them to the programme; co-facilitating

the support self-management workshop; serving as the first point of contact for men on the programme; and setting men up on the Patient Online Service and PSA Tracking System.

E6. The Supported Self-Management Workshops were piloted and then rolled out as part of this project. They were co-facilitated by a nurse specialist and the support worker, lasted 4 hours, and had between 8 and 10 men in attendance. The key topics included understanding supported self-management; PSA monitoring; contacting the clinical team; common side effects and symptoms; emotional concerns; healthy lifestyles; moving forward; and using the patient online service.

E7. A new PSA Tracking system was designed and built as part of the project. This allowed men to access their PSA results online as soon as these results were available to clinicians. Although there were concerns from clinical teams about patients having such access before clinicians had assessed them, the project showed that men were not adversely affected by this, even if their test results were abnormal.

E8. Four participating NHS sites were involved in a formal evaluation, comparing outcomes of men on the programme with a pre-service change cohort of men who received their hospital's usual follow up care. Patients from both groups were sent questionnaires and a subset took part in semi-structured interviews, as did a selection of staff. There was also an evaluation of the use of the IT service, and an economic evaluation.

E9. Key findings from the evaluation included:

- Outcomes for men in the programme group were for the most part equivalent to men in the comparator group, with very modest improvements in the programme group in relation to quality of life and unmet needs.
- The direct per patient cost over the 8 month follow up period was higher in the programme group compared with the comparator group (£102 vs £59). However, the overall per patient cost was lower (£289 vs £327). This is because wider health service utilisation was lower in the programme group.

- The programme meets NICE cost-effectiveness criteria for recommended adoption.
- Successful implementation of the programme required behavioural and cultural change on behalf of the clinical team. These included adopting new processes, and developing trust in self-management, and the role of the support worker.
- The programme was perceived to improve the quality of care provision.
- The introduction of the support worker role was seen as overwhelmingly positive, providing significant support for nurse specialists.
- The workshop is considered a fundamental part of the programme. Training was needed in facilitation skills, and the less directive delivery style was initially counter-intuitive for some nursing staff.
- The workshops are appropriate for men with a variety of treatment experiences.
- The better the PSA Tracker was integrated into the incumbent IT systems, the more useful it was. There were workload implications when the integration was not completed, with clinical teams having to spend additional time manually inputting data into the system.
- Six out of every ten men signed up to use the IT system, though not all of them used the service regularly. The remaining 4 out of ten chose not to sign up, and their follow up was managed by telephone and letter.

E10. The project identified a number of implications for a wider implementation of this new care programme. They included:

- The need for flexibility to meet the needs and preferences of patients, such as alternative options for those not engaging with the workshops or with the online service.

- Further development of the support worker role
- The need for facilitation skills training for nurse specialists and support workers
- Further development of the IT service
- The importance of robust communication between staff delivering the supported self-management programme and the responsible consultants.
- The need to develop national tariffs and reference costs for activities such as workshops and PSA tracking clinics.
- The need to develop guidelines on the frequency and duration of PSA testing in prostate cancer follow up

E11. A number of areas of further research and evaluation have been identified, including: how best to extend the programme to patients with more complex needs; and how best to embed Holistic Needs Assessment and Patient Reported Outcome Measures in a remote surveillance pathway.

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Appendix B: Evaluation of the TrueNTH UK Supported Self-Management and Follow-Up Care Programme. Technical Report Number 2. HEALTH ECONOMIC EVALUATION

Appendix C: Evaluation of the TrueNTH UK Supported Self-Management and Follow-Up Care Programme. Technical Report Number 3. QUALITATIVE EVALUATION

Appendix D: Evaluation of the TrueNTH UK Supported Self-Management and Follow-Up Care Programme. Technical Report Number 4. IT SERVICE EVALUATION

Appendix E: Supported Self-Management for Men with Prostate Cancer: Development and Piloting of a Workshop to Transition Men after Treatment to Remote Monitoring and Follow-up

Appendix F: The Toolkit: A guide to implementing the TrueNTH UK Supported Self-Management and Follow-Up Care Pathway

1. INTRODUCTION

1.1 TrueNTH, established by the Movember Foundation, is an international partnership of over 300 healthcare professionals, academics, and volunteers from countries around the world that aims to '*significantly improve the lives and experiences of men with prostate cancer, as well as the experience of their partners, caregivers and family members*'. In the UK, TrueNTH is delivered in partnership with Prostate Cancer UK. The Supported Self-Management and Follow-Up Care programme is one of eight TrueNTH projects supported in the UK ^[1].

1.2 The TrueNTH UK Supported Self-Management and Follow-Up Care programme, led by the University of Southampton, commenced in January 2014 with the aim of designing, introducing and evaluating a prostate cancer follow-up pathway. The evaluation reached its conclusion in October 2017.

1.3 This report aims to provide an overview of:

- the rationale and evidence base underpinning this new model of care;
- a description of the model of care and the process of its development and implementation;
- a description of activities that have taken place to promote adoption and sustainability;
- The evaluation methods and key findings; and
- The implications of this work for future research and service improvement.

1.4 Further detail on the evaluation methods and findings can be found in the technical appendices of this document.

2. BACKGROUND

2.1 An estimated 330,000 men are living with and beyond a diagnosis of prostate cancer in the UK ^[2]. Over recent decades, survival rates for prostate cancer have improved dramatically, and 90% of men diagnosed with Stage 1 or 2 disease live at least five more years ^[3]. This improvement in survival means that cancer services must adapt to managing prostate cancer as a long-term condition. Normally, men receive regular clinic-based follow-up appointments for several years despite clear evidence that this model of care is unsustainable and does not meet men's needs.

2.2 Men with prostate cancer report high levels of unmet needs despite regular clinic attendance. Commonly reported issues include urinary and bowel dysfunction; hormone therapy side effects such as fatigue, hot flushes and weight gain; loss of self-confidence, fear of recurrence, anxiety or depression; and sexuality-related unmet needs ^[4]. In the UK, a number of Patient-Reported Outcome Measure (PROM) initiatives are currently underway ^[5 6,7,8]. These initiatives will provide us with a deeper understanding of the prevalence of these issues amongst this population of men.

2.3 The National Cancer Patient Experience Surveys ^[9] have highlighted widespread dissatisfaction amongst men with prostate cancer in relation to their care:

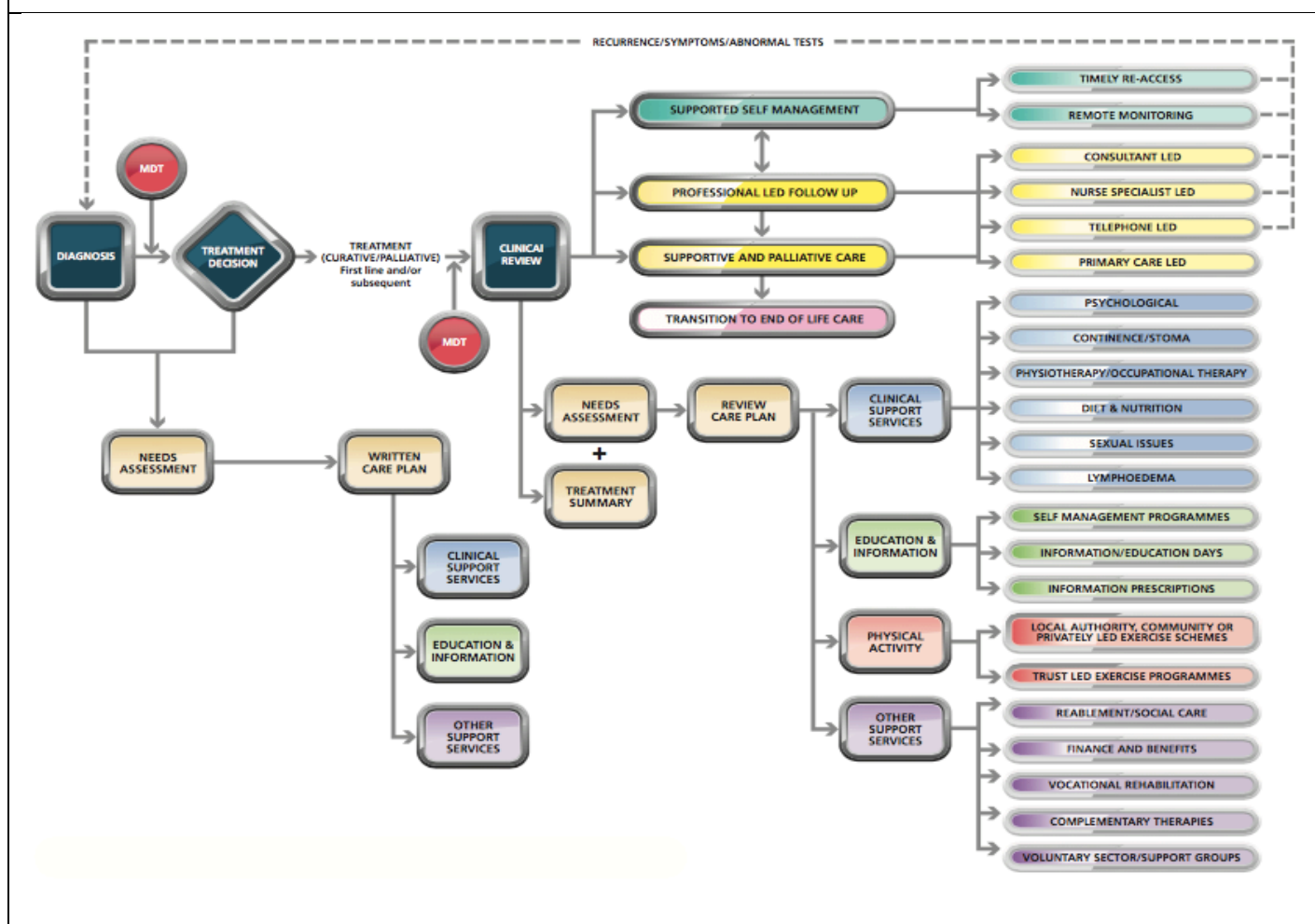
- more than a quarter feel that the side effects of their treatments were not well explained, and nearly 40% report they are not offered practical advice about managing the side effects of treatment;
- one in ten men with prostate cancer report they were not given the details of a named Clinical Nurse Specialist (CNS);
- over half of the men with prostate cancer report that they did not receive a care plan to address their ongoing needs;
- four out of ten men with prostate cancer in the UK feel abandoned by the healthcare system once their treatment is complete.

2.4 Cancer services must address the inadequacy of the current follow-up model against a backdrop of increasing numbers of patients and a shortage of clinical nurse specialists (CNSs). The number of men living with and beyond prostate cancer is set to double by 2030^[10]. Services will struggle to cope with rising patient numbers. There is already significant pressure on clinics—29% of men with prostate cancer report that they have to wait too long to receive an appointment ^[9]. This pressure is compounded by workforce challenges. A UK-wide nursing workforce survey undertaken by Prostate Cancer UK in 2014 ^[11] highlighted that, in addition to increasing caseloads

and staff vacancies, nearly half of uro-oncology CNSs plan to leave the profession within the next 10 years.

2.5 Policy makers in England have mandated the introduction of stratified pathways in breast, colorectal and prostate cancer follow-up care by 2020^[12] (Fig1). It is becoming increasingly accepted that the principles of supported self-management should underpin follow-up care for the majority of people living with and beyond a diagnosis of cancer. If implemented successfully, stratification of follow-up should release clinic capacity and clinical nurse specialist time, enabling clinics to focus on patients with more complex needs.

Fig1: This diagram, produced by NHS Improvement^[19], identifies the key components involved in cancer follow up and the demonstrates stratification of follow up pathways: supported self-management, professional led follow up, supportive and palliative care and transition to end of life care.



2.6 An estimated 70-80% of people living with long-term conditions can learn to be active participants in their own care with the right support ^[13]. There is a growing body of literature supporting the effectiveness of self-management interventions for cancer survivors. Reviews of

interventions, specifically for men with prostate cancer, have shown evidence of a consistent, positive effect on distress levels and on sexual and urinary functioning ^[14].

2.7 There are various ways to deliver the information men need to give them the knowledge, confidence and skills to manage their prostate cancer. Examples include written information, one-to-one appointments, videos, and group workshops. Evidence suggests that interventions that combine psychological and educational techniques in a group setting have the most consistent impact in terms of quality of life and symptom relief ^[15]. Men in particular benefit from self-management support interventions delivered in an environment where they can share experiences with their peers ^[16]. The timing of these interventions is important. The end of treatment has been identified as a ‘teachable moment’ when men may be more receptive to learning about the management of their own health ^[17].

2.8 In 2013, a design team led by the University of Southampton was established to develop the funding proposal for this project. Members included men living with or beyond prostate cancer, clinicians, academics, third-sector representatives, IT specialists and others. Given the mounting evidence base and emerging policy direction, it was agreed that the proposal should focus on designing, delivering and evaluating a new prostate cancer follow-up pathway based on the principles of supported self-management. In January 2014, the University of Southampton was awarded funding by the TrueNTH programme to deliver this proposal.

3. DEVELOPMENT WORK

3.1 Site selection

3.11 In February 2014, prostate cancer services across England were invited to express an interest in participating in the project. In May 2014, the project steering group formally selected five pilot sites from a long list of 34 potential sites:

- Dartford and Gravesham NHST (DGNT)
- Royal Cornwall Hospitals NHST (RCHT)
- Royal United Bath NHSFT (RUH)
- St Helens and Knowsley Teaching Hospitals NHST (STHK)
- University Hospital Southampton NHSFT (UHS)

3.2 The development process

3.21 The design and development work for this project commenced in 2013 and reached completion in December 2014. This process engaged a wide range of stakeholders and involved design workshops, evidence reviews, and a great deal of piloting, feedback and iteration. The project engaged two ‘development sites’—UHS and RUH—to undertake the initial piloting and feasibility testing of the prototype supported self-management programme. A total of 232 men were recruited to the pilot programme between July 2014 and December 2014. Semi-structured interviews and questionnaires with men and staff were undertaken in late 2014 to inform the final version of a prototype supported self-management workshop.

3.22 The design and development process drew upon a wide evidence base including guidance produced by the Health Foundation ^[18], the National Cancer Survivorship Initiative ^[19] and Macmillan’s One-to-One Support project ^[20]. The project also had a great deal of internal expertise:

- UHS and the University of Southampton had previously undertaken work with Macmillan Cancer Support to introduce supported self-management (referred to locally as ‘Patient Triggered Follow-Up’) in breast, colorectal, testicular, lymphoma and endometrial cancer follow-up ^[21]. Furthermore, UHS was a Macmillan One-to-One Support Pilot site and had experience of implementing a new support worker role across a number of multidisciplinary cancer teams.
- RUH had over a decade of experience in remote surveillance of prostate cancer, and had implemented a local electronic PSA tracking system ^[22]. The lead urologist and lead uro-

oncology Clinical Nurse Specialist from RUH acted as clinical advisors throughout the duration of the project.

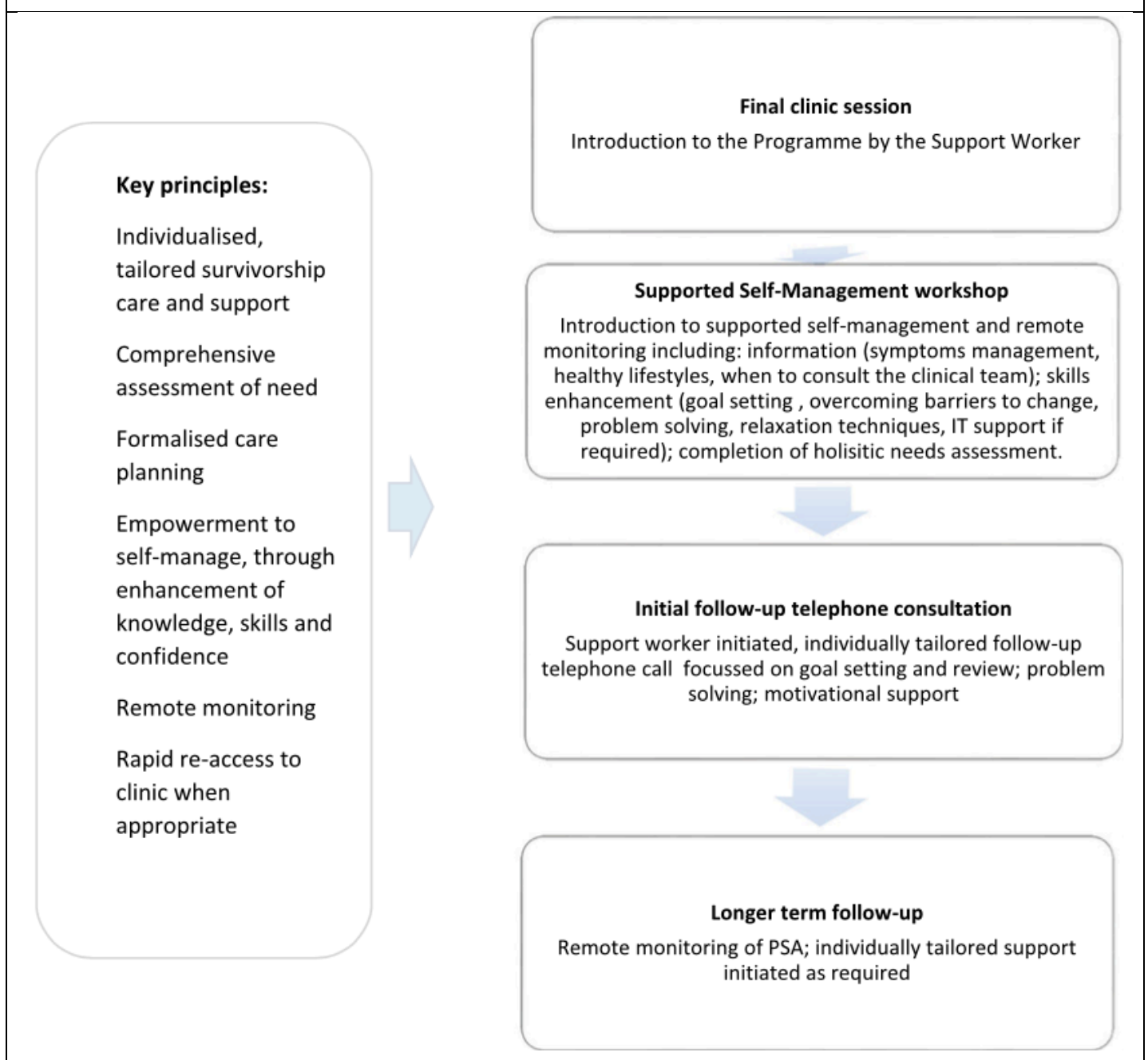
- The project employed the expertise of two psychologists involved in the development of the diabetes self-management programmes DAFNE (Dose Adjustment for Normal Eating) and DESMOND (Diabetes Education and Self-Management for Ongoing and Newly Diagnosed).
- The UHS IT department had begun to implement a patient-facing online health record, My Medical Record™, across a number of chronic conditions including Inflammatory Bowel Disease, Maternal Diabetes and Testicular Cancer.
- Academics from the University of Surrey had substantive experience delivering self-management interventions to men with prostate cancer in a group setting.

3.3 The Prototype Supported Self-Management Programme

3.3.1 The funding proposal outlined a prototype care programme (Fig 2) that had the following components:

- *Support Worker:* Every man should have access to a support worker who acts as his key worker for the duration of his follow-up.
- *Workshop:* All men should be invited to a supported self-management workshop. This workshop aims to give men the knowledge, skills and confidence to 'self-manage' their prostate cancer.
- *Patient online service:* All men should be given the opportunity to sign up with a Patient Online Service where they can access Prostate Specific Antigen (PSA) results, Holistic Needs Assessments and health information and should be able to use an electronic messaging function to contact their support worker.
- *Remote monitoring:* Men should no longer be required to attend face-to-face clinic appointments. Nurse-led PSA Tracking Clinics should be held using an electronic PSA tracking system. Men should only be recalled to the clinic if their PSA results or symptoms warrant further investigation.

Fig 2. Components of the programme and underlying principles



3.32 Further detail on the prototype programme can be found in Appendix F.

3.4 Scoping existing practice and developing guidelines

3.41 An extensive exercise was undertaken to examine existing follow-up practices across the five sites. The patient pathway, including administrative processes, was mapped in detail at each site to help the project team identify the processes that needed to change in order to implement supported self-management. This exercise revealed significant variation in the frequency, duration and format of follow-up. Some sites employed more nurse-led follow-up than others. Three of the sites operated some telephone follow-up clinics. There was variation in the frequency and duration of follow-up amongst clinicians within sites, as well as further variation in these practices between sites.

3.42 The project, working in partnership with the clinical teams, developed detailed eligibility criteria and monitoring criteria to reduce variation in practice and support the delivery of safe and effective follow-up (see Appendix F). The eligibility and monitoring criteria centred around time since treatment completion or commencement, PSA level, clinical need (e.g. urinary dysfunction) and ability to self-manage. These criteria were used to screen clinic lists so potentially eligible men were flagged to clinicians for review. Men were considered for supported self-management as early as six weeks following the completion of treatment. Standardised PSA testing schedules were also established.

3.43 Developing guidelines that would be accepted by clinical teams across five sites was a challenge. There was a great deal of debate and disagreement before consensus was reached. The input and influence of the project clinical advisors was integral to gaining the confidence and consensus of clinicians across the project.

3.44 A simple Concerns Checklist (akin to holistic needs assessment) was developed for use during the project. Men use it to highlight issues that affect them and indicate if they would like support from the clinical team. This assessment tool was administered when men were enrolled on the supported self-management programme. It was also agreed the assessment tool (to become known as the Health MOT) should be made available to men for the duration of their follow-up as a means of identifying and communicating problems to the clinical team.

3.45 A risk assessment of the programme was undertaken to highlight potential safety issues (e.g. PSA results going unchecked, men becoming lost to follow-up). Specific processes, audit guidelines and quality standards were developed to mitigate these risks (see Appendix F). Roles and responsibilities of members of the clinical team were clearly defined, and it was stressed that consultants remain responsible for this patient group although they no longer attended clinic (see Appendix F).

3.5 The Supported Self-Management Workshop

3.51 The development of the workshop format was led by the University of Surrey. The prototype workshop format—duration, content, size, content and delivery style—was shaped and agreed upon over the course of several design sessions. Men, clinical teams and academics were invited to contribute to this process. A significant amount of theory and evidence underpinned the workshop design.

3.52 The prototype workshops were piloted in each development site three times (six workshops in total between July 2014 and September 2014). Workshops were observed by a clinical psychologist who had expertise delivering self-management interventions in a group setting. Feedback was sought from the observer, men and staff following each workshop, and changes to the format were made prior to the delivery of the following workshop. A quality assurance framework was developed to assess facilitators during workshop observations.

3.53 The workshop content was outlined in a workshop delivery manual that helped to ensure the workshop was delivered consistently over time and across clinical teams. An accompanying information booklet for workshop participants was also developed. The final workshop format:

- Adopted a one-off, four-hour approach, ideally delivered within 12 weeks of a man being enrolled on supported self-management.
- Had two facilitators, a nurse specialist and support worker, and had between 8 and 10 men in attendance.
- Covered the following topics: what is supported self-management? understanding PSA monitoring; how to contact your clinical team; common side effects and symptoms; emotional concerns; healthy lifestyles; moving forward and goal setting; using the patient online service.

3.54 More information about the workshops can be found in Appendix F.

3.6 The Support Worker Role

3.61 The band 4 support worker role was based on the job description developed as part of the Macmillan One-to-One Support pilots. Advertisements for this role included a high number (30+) of high-quality applicants for each position. The project team felt that strong communication and organisational skills were essential for this role. There was consensus that this role should be within the urology team, and that support workers should be line managed by a clinical nurse specialist.

3.62 Throughout the project, there was debate as to what tasks and responsibilities were appropriate to delegate to support workers. There was consensus that this be tailored to individual support workers (especially as they had varied backgrounds) and that the CNS would delegate further responsibilities as and when they felt the support worker was ready. The project team decided the following core duties should be undertaken by all support workers:

- Screening clinic lists to identify men potentially eligible for the care programme and liaising with clinicians to enrol eligible men
- Holding an initial consultation to introduce men to the care programme
- Undertaking administrative duties, such as setting men up on the PSA tracker, registering men on the Patient Online Service, and preparing the supported self-management workshops
- Co-facilitating supported self-management workshops
- Undertaking duties relating to PSA tracking clinics
- Serving as the first point of contact for men via phone call or electronic message
- Undertaking Holistic Needs Assessment and developing care plans
- Undertaking telephone consultations as required
- Triaging men to the wider clinical team, as appropriate
- Undertaking audits and reporting

3.63 More information on the support worker role can be found in Appendix F.

3.7 The IT Service

3.71 Design workshops to determine the specification of need for the patient-facing online service and the interfaced PSA tracking system were held in August 2013 and January 2014. This process drew heavily on RUH's experience of using a PSA tracking system and UHS' experience of delivering patient-facing online systems across a number of chronic conditions. Once the original specification of need was outlined, UHS's IT department was commissioned to develop and deliver the system. UHS worked closely with the University of Southampton and clinical teams to develop a detailed specification of need. The system was built between April and July 2014 and piloted between August and December 2014.

3.72 The UHS IT department provided training to staff on use of the PSA tracking system and the process of registering men on the online service. These training sessions were also used as an opportunity to gain staff feedback on the IT systems.

3.73 The IT service should be integrated with the pathology lab, thus allowing men to access their PSA results online as soon as these results are available to clinicians. At the project outset, many clinicians felt uncomfortable with this and asked that results were released to men only after they had been checked by the clinical team. Initial piloting in the development sites showed that men were not adversely affected by accessing their test results, even if these were abnormal. This allayed the concerns of clinical teams. Men are encouraged not to check their results at a times when they cannot contact a health professional to discuss them if they know an abnormal result would cause them high levels of anxiety (e.g. at 11pm on a Friday evening).

3.74 Initial piloting showed that men had varying levels of IT literacy and willingness to engage with the IT system. Initially men with limited IT skills found it very difficult to complete the sign-up process required to access the online service. The sign-up process was simplified significantly as a result of this learning.

3.75 Tablets with built-in 3G were available for men to borrow if they did not have access to a computer, so that lack of IT access did not present a barrier to men accessing the online service.

3.76 For more information on the IT service, refer to Appendix D and Appendix F.

4. IMPLEMENTATION

4.1 The care programme was rolled out to three additional sites—DGNT, RCHT AND STHK—in March 2015. Each site was provided with resources for 0.2 FTE clinical nurse specialist time for one year, and 1.0 FTE band 4 support workers for two years.

4.2 A number of activities were undertaken in these support sites:

- Each site was provided with a project plan outlining the key activities involved in setting up the Pathway. Each clinical team was provided with project management support by the University of Southampton. This included intervention to resolve local project issues.
- Resources such as job descriptions and clinical protocols were provided.
- A series of webinars were set up to encourage peer support between the sites and give the three new sites the opportunity to learn from the experience of the two development sites.
- Site visits to development sites
- Learn and share events
- Workshop facilitation training and workshop observations
- Training on the IT system. Customisation of the IT system for local needs (e.g. local letterheads and patient information).
- Central design and production of printed materials

4.3 The UHS IT department worked with the Trust IT teams to integrate the PSA tracker and online patient services with the Trust pathology systems and patient administration systems. This enabled test results, as well as patient information such as GP details and treatment details, to feed into the PSA tracking system and online service. One Trust was unable to integrate these systems; thus, the clinical team had to rely on manual data entry methods for the duration of the project.

4.4 Between July 2014 and October 2017, 2675 men had been enrolled onto the care programme and over 250 workshops had been delivered.

5. PROMOTING ADOPTION AND SUSTAINABILITY

5.1 The approach taken at the design and development stages of this project has promoted adoption and sustainability of the care programme. The programme was co-designed by the University of Southampton and a wide range of stakeholders (including men living with and beyond prostate cancer and clinicians). This helped to ensure that the programme was acceptable to men and clinical teams. The project team were mindful of the multiple competing priorities and pressures faced by uro-oncology services, taking a pragmatic approach to the design of processes. The care programme was piloted in two sites, and was shaped to ensure it was feasible to implement. Efforts were made to ensure developments aligned with the direction of travel of wider health policy. All of these factors maximised the potential for adoption and sustainability.

5.2 The project team has given a number of presentations over the course of the project:

- Poster presentations at the Multinational Association of Supportive Care in Cancer (2015), International Psycho-oncology Association (2015), American Society of Clinical Oncologists (2016), National Cancer Research Institute (2014), UK Oncology Nursing Society (2016), and British Association of Urological Nurses (2016)
- Project learning events in 2015 and 2016 with attendance from pilot sites, other TrueNTH project teams, University College London Hospitals, Queens University Belfast, Irish Cancer Society, Stoke University Hospital, and hospitals in Galway and Dublin.
- A presentation to all Cheshire and Merseyside Clinical Commissioning Groups in 2015 (leading to a strong ongoing relationship and promotion of the model of care across the region).
- A webinar presentation (hosted by Prostate Cancer UK) to over 40 health professionals in 2015.
- A webinar presentation (hosted by NHS England) to all cancer alliances in January 2017.
- A presentation to the Cancer Translational Research Group, Belfast in 2016.
- An information stand at 2016 BAUN conference led to discussions with over 100 delegates

5.3 These presentations and engagement exercises have led to a great deal of interest in the project, placing additional demands on the project team. Fortunately, in 2015, the team was awarded additional TrueNTH funding to promote the adoption of supported self-management beyond the five project sites. Activities included:

- Providing support specifically to Cheshire and Merseyside Clinical Network and University College London NHSFT to implement project learning locally. Support included advisory support, participating in stakeholder engagement events, provision of training and facilitating site visits to TrueNTH project sites.
- Developing an Implementation Toolkit (Appendix F) that includes practical resources and advice for organisations that would like to implement the care programme. This Toolkit was launched at the British Association of Urological Nursing conference in November 2016.
- Developing an online induction programme for support workers involved in the delivery of supported self-management. This programme was developed in conjunction with the urology team at the Royal Marsden NHSFT and will be ready for online publication in January 2018.

5.4 Over the course of the project, resources have been shared with over 100 organisations, and there is evidence that learning from this TrueNTH project is being implemented at over 35 sites.

5.5 In 2016, the UHSFT IT department received the Health Service Journal (HSJ) award in the *Using Technology to Improve Efficiency* category and an E-Health Insider (EHI) award for the IT system developed as part of this TrueNTH project. In 2017 the TrueNTH UK Supported Self-Management and Follow-Up Care Project was shortlisted as a finalist for an HSJ award in the *Self Care* category.

5.6 In December 2016, NHS England invited all cancer alliances to apply for service transformation monies to deliver improvements in key areas, including the implementation of stratified pathways in cancer follow-up care. The University of Southampton is working closely with nine NHS Trusts across the Wessex region to support the roll-out of supported self-management. Furthermore, as part of this work stream, the University has been awarded funding to translate the learning from the TrueNTH project to develop workshops and protocols for breast and colorectal cancer care. The University also regularly responds to queries from cancer alliances across England that are implementing stratified pathways and are part of the NHS England work stream.

5.7 The project team recognise that more work needs to take place to share learning and promote adoption in Wales, Scotland, Northern Ireland and beyond. A proposal, currently under review, has been developed to explore ways of achieving this.

6. METHODS

6.1 A formal evaluation was undertaken at four of the implementation sites. . The evaluation used a mixed methods approach, including a quasi-experimental design to compare outcomes of men on the programme with a pre-service change cohort of men who received their hospital's usual follow up care before the service change. The study aimed to assess the effectiveness of the programme across key outcomes, the impact of the programme on costs, and the process of implementing the programme, in order to identify any facilitating and inhibiting factors. A protocol paper outlining detailed evaluation methods was published in BMC Cancer in September 2017 [23]. The paper can be accessed at <https://bmccancer.biomedcentral.com/articles/10.1186/s12885-017-3643-4>

6.2 Four sites were included in the controlled cohort study (Table 1).

Table 1: Pilot sites involved in the study					
Site	Diagnoses per year (approx.)	Type of centre	Population served	Usual care	Treatment types included in the study
Dartford and Gravesham NHST	275	District General Hospital	Catchment population of around 350,000 -suburban	Consultant led clinics Nurse led clinics Telephone clinics	Radical prostatectomy Radiotherapy Primary Hormone Therapy
Royal Cornwall NHST	350	District General Hospital	Catchment population of around 450,000 – predominantly rural	Consultant led clinics Nurse led clinics Telephone clinics	Radical prostatectomy Radiotherapy Primary Hormone Therapy
Royal United Hospitals Bath NHSFT	350	District General Hospital	Catchment population of around 500,000 -rural and urban	Consultant led clinics Nurse led clinics	Radical prostatectomy Radiotherapy Primary Hormone Therapy
St Helens and Knowsley Teaching Hospitals NHST	250	District General Hospital	Catchment population of around 350,000 – predominantly suburban	Consultant led clinics Nurse led clinics	Radiotherapy Primary Hormone Therapy

6.3 Eligible patients were approached to participate in the study between September 2014 and June 2015. Patients were eligible for the study if they met the clinical criteria for supported self-management and had undergone radical prostatectomy or completed radiotherapy in the previous 36 months, or had commenced primary androgen deprivation therapy in the previous 36 months.

6.4 Patients who agreed to participate in the study were sent questionnaires at three time points (baseline, four months and eight months). Questionnaires included a variety of Patient Reported Outcome Measures that examined health-related quality of life, cancer-related unmet needs, lifestyle factors such as smoking, alcohol consumption and diet and exercise. A small group of

men were invited to participate in semi-structured interviews held between October and December 2016.

6.5 Staff were invited to participate in semi-structured interviews held between April and November 2016. Normalisation Process Theory informed the structure of these interviews.

6.6 The economic evaluation compared costs and health outcomes of men in the programme and the comparator group of men receiving usual care. The primary analysis was undertaken from a health service perspective. Data were sourced from patient questionnaires, hospital information systems and provider interviews. Clinical teams kept prospective records of activity such as telephone contacts and conducted timed observations to provide average times for various activities involved in delivering care. Average per-patient costs were then calculated for men in the care programme and men in the comparator group.

6.7 A total of 627 men were included in the final study analysis: 334 in the comparison group and 293 in the care programme group. There were no statistically significant differences in baseline characteristics between these groups.

6.8 An in-depth evaluation of the IT service was commissioned in July 2017. This evaluation examined service utilisation and user experience. Activities included an online survey of men who used the IT service; interviews with men who did not use the service; interviews with staff and focus groups; and the analysis of service utilisation data. Data from this evaluation were triangulated with interview data from the cohort research study.

6.9 In addition to the cohort study and IT evaluation, other sources of learning have contributed to the findings in this report. These include notes from interviews, design workshops, learning events and other engagement exercises during the development and delivery phases of the project. The observations and reflections of the project team are also taken into account.

7. PROJECT LEARNING

7.1 The programme is now fully embedded in routine service delivery across the five project sites. We have demonstrated that the programme can be successfully embedded into a urology department and is valued as an effective and sustainable model of follow-up care provision and a robust alternative to face-to-face clinic follow-up. There is also recognition within project sites of the value of the model for other cancers and other conditions.

7.2 Successful implementation required behavioural and cultural change on the part of the clinical teams. Numerous examples of these shifts were observed over the course of the project:

- Adoption of new processes, such as screening clinic lists for men who met the eligibility criteria. The nurse specialists in particular had to embrace radically new ways of working (e.g. delivering workshops).
- Clinicians 'letting go' and developing trust in men to self-manage and confidence in the staff members who support men in this process.
- Clinical teams developing confidence and trust to delegate patient-facing tasks to someone who had not received clinical training (i.e. the support worker).
- Clinical teams' attitudinal change in appreciating that 'legitimate' work is not necessarily face-to-face in a clinic setting.
- Clinicians overcoming initial reluctance that patients have access to their own health records and test results online.

7.3 Outcomes for men in the programme group were, for the most part, equivalent to outcomes for men in the comparator group. Very modest improvements were observed in relation to quality of life and unmet needs. Subgroup analysis confirmed that these outcomes were consistent taking into account a range of factors, including age, presence of co-morbidity, level of deprivation and time since treatment.

7.4 The programme was perceived to improve the quality of care provision. Nurse specialists and support workers in particular value the holistic and person-centred approach. The programme is acceptable to men and their clinical teams. Men understand the principles and processes involved and contact their clinical team if they require support. They value the reassurance of easy access to support if needed. The support workers made efforts to build a good rapport with the men in clinic, in the workshops and during the follow-up phone call to help men feel at ease getting in touch.

7.5 There was an overwhelmingly positive response to the introduction of the support worker's role. This role provides significant support for the nurse specialists, who often had to learn new skills such as line management and effective delegation. Careful adjustment of the skill mix within the team was required to ensure that support workers were given appropriate tasks, and this was largely dependent on the aptitude of individual support workers. A flexible and supportive environment with carefully delivered training and supervision was vital to getting maximum value from the support worker's role. Concerns were expressed about staff retention and job progression opportunities. Two of five support workers left their roles during the project, stating that they would like more face-to-face patient contact.

7.6 The workshop is considered a fundamental part of the programme for those staff involved in its delivery. It gives men the opportunity to compare experiences and symptoms with their peers and gauge where they are in relation to others, normalising symptoms and contributing to wellbeing and ability to self-manage. The effective delivery of the workshop requires the development of new skills for the clinical team. The facilitation style used to support the delivery of the workshops was critically important to their success. The project team was keen to avoid workshops where health professionals provided lots of information to a passive group of men. In contrast, the project set out to deliver workshops that empowered men and supported the discussion and exchange of information between them. This non-didactic delivery style was counter-intuitive for some nursing staff who had been giving information and directive instructions to patients in clinic-based settings for years. A focus was placed on training and supporting CNSs and support workers to develop the strong facilitation skills required to run these workshops. A clinical psychologist played a critical role in this training and support.

7.7 Men in the workshop groups had a variety of treatment experiences: radical prostatectomy, radiotherapy, primary hormone therapy and watchful waiting. Initially, the project team had concerns regarding the practicality of delivering workshops to cater for such a diverse range of experience and needs; however, the pilot process showed not only was this feasible, but also the breadth of views and experience added to the quality of the workshop delivery. The project team also considered whether or not to include partners and carers in the workshop. Feedback from men highlighted that many would feel embarrassed talking about intimate experiences in the presence of the partners of other men. For this reason, the decision was taken that carers and partners would not be invited to the workshop.

7.8 The IT service is perceived as valuable by clinical staff and the patients who use it. Men who use the service say it has helped them manage their condition and that it is easy to use and well

designed. The IT service is recognised as fundamental to the efficiency of the programme by clinical teams, and the responsiveness of the UHS IT team to problems and queries was highly valued. Several areas of the IT service have potential for improvement and development, in particular exploring the best mechanism to support men who are wary and struggle to engage with the system at the outset. Apart from accessing PSA test results and messaging clinical teams, the other functions of the system (the option to complete a holistic needs assessment and patient information) were not well used.

7.9 Since this system was newly designed and built for this project, support workers sometimes kept records that operated in parallel (e.g. a list of men on the PSA tracker and when their next test was due). Once the tracking system had been proven safe and effective, some support workers still continued to keep duplicate records, despite no longer being required.

7.10 There was variation between NHS Trusts and their ability to integrate the incumbent IT systems (e.g. pathology) with the TrueNTH IT service. One Trust completed this process in fewer than five days, whereas one Trust had still not completed integration at the time of writing this report. The absence of integration poses workload implications for the clinical team which must spend additional time manually inputting data to the system.

7.11 There was significant variation in needs and preferences amongst men in relation to different elements of the programme. For example:

- The workshop was a positive experience for most men; however, some found this format too challenging.
- Six out of every 10 men signed up to use the IT system. Some of these men required support to do so, and not all of these men used the service regularly. Four out of 10 men chose not to sign up to the online service, and, in these cases, their follow-up was managed by telephone and letter.
- While men valued the support they received from their clinical team, there is a real sense that many men were well, stable and wanting to move on from their prostate cancer and did not see the value of activities such as engaging in ongoing holistic needs assessment, while others found this exercise reassuring.

7.12 Engaging the wider clinical team (and other hospital staff) in implementation was important for a number of reasons:

- During the initial implementation of the programme, each site had core members of the team who acted as clinical champions (typically nurse specialists, support workers and

urologists). Education and engagement activities were undertaken to ensure staff members understood the pathway, were supportive and referred men appropriately.

- Some team members value face-to-face follow-up care above remote methods. New ways of working for nurses, such as running workshops and virtual clinics, may not be regarded as legitimate work by the wider team and management, and this can cause tension. As such, further education and engagement are required to promote understanding of the value of these new ways of working.
- The consultants responsible for patients on supported self-management no longer hear first-hand feedback regarding their progress. It is important that the core team managing this patient group provide feedback to their responsible clinician in a structured way.

7.13 The supported self-management programme is perceived as improving the safety of follow-up care. The robust call-recall system embedded within the PSA tracker and the increased staff capacity to support men to comply with the PSA testing schedules was thought to reduce the chance that men become lost to follow-up. The clinical monitoring protocols work in practice, with men being recalled appropriately and seen in clinic in a timely manner. There are a number of examples of men who were recalled to clinic, underwent investigations and further treatment, and are now back on supported self-management.

7.14 This model of care releases a great deal of clinic capacity. While clinics are still very busy, clinical teams have stated that this has given consultants more time to spend with complex patients. There is also an impact on the work of nurse specialists (both direct and indirect patient contact) in that the support worker can perform a number of administrative functions and act as first point of triage for email and telephone calls from patients on remote surveillance.

7.15 The direct per patient cost of delivering the care programme over the eight-month follow-up period was higher than for the comparator group (£102 programme vs £59 comparator). Men in the comparator group had an average of one face-to-face follow-up appointment over the eight-month period—some of these were consultant led and others nurse led. There was also telephone clinic activity. The overall per patient cost of the programme over the eight-month follow-up period was lower than for the comparator group (£289 programme vs £327 comparator). This cost is due to the fact that wider health service utilisation (GP appointments, counselling, physiotherapy etc.) was lower in the programme group. Cost savings may be higher over a longer time frame, as the more costly aspects of the programme (e.g. the workshop) are delivered in the initial months. From this point onwards, a PSA review of the PSA tracking system costs significantly less than a traditional follow-up consultation.

7.16 A cost-effectiveness analysis taking into account Quality Adjusted Life Years (QALYs) was undertaken. The National Institute for Health and Care Excellence (NICE) has set a willingness to pay (WTP) threshold of £20,000-£30,000 per QALY gained in order to deem a new treatment cost-effective, when compared to the next best alternative. If a treatment is less expensive than this threshold, when compared to the next best alternative, it should be adopted. The cost-effectiveness analysis demonstrates that, at a £20k WTP threshold, there is a greater than 62% chance the programme would be deemed cost effective; at £30k, this rises to approximately 68%. In conclusion, the programme meets the NICE cost-effectiveness criteria for recommended adoption.

7.17 Project sites have committed to ongoing funding for supported self-management programme (this principally involves licence for the IT service and the costs of the support worker). However, there is uncertainty and debate surrounding the payment arrangements between commissioners and NHS Trusts for this type of work. The cost elements involved in delivering a digital pathway are not yet reflected in national reference costs. Moreover, despite very positive feedback regarding workshop value, some felt it challenging to justify a four-hour workshop in the context of significant financial pressures faced by many services, particularly if Trusts were already delivering wellbeing events in other areas of care provision.

8. IMPLICATIONS FOR PROGRAMME IMPLEMENTATION

8.1 A flexible approach should be taken for the delivery of the programme to ensure it meets the variety of needs and preferences of the men it supports. For example, alternative options should be available for men who are unable to engage with the workshops, and parallel processes should remain in place for men who do not engage with the online service.

8.2 The support worker's role is a relatively new one in cancer care. Further work must be done to develop training and support, competency frameworks and career-progression frameworks. There are general opportunities for structured training and development (e.g. trainee nurse associate programmes). More focus is required on the skills and knowledge relating to remote medicine and supported self-management—this would be advantageous across many long-term conditions.

8.3 The ongoing quality and integrity of the workshops rely on the sustainable delivery of facilitation skills training for nurse specialists and support workers. Localities could potentially draw on the expertise of those who provide training in advanced communication skills. A 'train the trainer'-style module may help support such individuals in providing the training required to deliver the TrueNTH workshops.

8.4 Ongoing evaluation of the IT service has led to the identification of a number of areas for improvement. For example, work is currently underway to:

- Build in automated follow-up protocols that prompt testing schedules and action when test results fall out of an acceptable range.
- Build in features to support an audit schedule that checks that PSA tracking system records are kept up-to-date and accurate and that actions raised by the system (e.g. reviewing results and responding to messages) is undertaken in a timely manner.
- Expanding the functionality so that detailed telephone communications can be written in the notes section of the PSS tracker patient records.

8.5 Consultants remain responsible for the care of their patients, despite the fact that they no longer see them face-to-face in clinic. It is vital that robust communication and feedback mechanisms between the staff delivering the supported self-management programme and

the responsible consultants are in place. Some sites chose to provide feedback during the multidisciplinary team meeting details of men who would benefit from recall to clinic (e.g. due to a PSA rise); other sites liaise with the consultant on call. Quarterly reports give details of service activity and patient outcomes. Several consultants have recommended that these reports present this information by individual consultant so they have an ongoing understanding of the care of their patients on supported self-management.

8.6 The development of national tariffs and reference costs for various activities involved in the delivery of the programme (e.g. workshop delivery and remote PSA reviews) would support services to reach consensus on how this work should be funded, hence promoting adoption. Currently, each locality is negotiating local tariffs and fees. Not only is this a duplication of effort, it also delays implementation of the programme.

8.7 The majority of activity to promote adoption of the programme has been undertaken in England. Further work with policy makers and health services across Wales, Scotland, Northern Ireland and beyond is required to maximise the impact of this work.

9. IMPLICATIONS FOR FUTURE RESEARCH AND EVALUATION

9.1 The programme observed variation amongst men in terms of needs, preference and capacity to self-manage. Further research is required to define the factors that promote and inhibit self-management in the context of a remote surveillance pathway and how best to identify those men who might struggle on the pathway to recovery.

9.2 Services are now beginning to tailor the programme for delivery to men on active surveillance. Further work is required to explore how a blended approach of remote surveillance and face-to-face follow-up could be successfully implemented to support men with more complex needs at higher risk of disease recurrence/progression.

9.3 Further work should be undertaken to understand the role and value of Holistic Needs Assessment and Patient-Reported Outcome Measures in the context of a remote surveillance pathway. For example, does application of regular HNA / PROMs lead to improvements in quality of life? To what extent do men engage with regular HNA / PROMs, and what steps can be taken to increase participation? This learning would also support the roll out of the NHS England Cancer Quality of Life Measure ^[24].

9.4 The study observed a great deal of variation in practice across sites, particularly relating to the frequency of PSA testing throughout follow-up and the duration of follow-up. A number of project participants have highlighted the need to develop detailed guidelines on these aspects of follow-up care, in order to reduce variation and promote good practice.

9.5 Some cancer alliances across England have chosen to promote models of primary care-led prostate cancer follow-up. For example, South London general practices have undertaken extensive work in this area ^[25]. It would be useful to explore the feasibility of delivering the care programme in a primary care setting and evaluate the impact in terms of outcomes and cost-effectiveness.

9.6 The study population was predominantly White British. The implications of delivering the programme in a more diverse population should be explored. In particular, the feasibility of

delivering the workshop and online service to men who struggle to understand spoken and written English should be examined.

9.7 The health economic analysis incorporated data over an eight-month follow-up period, whereas men are normally followed up over the course of several years. From a service-planning perspective, it would be beneficial to undertake a more speculative analysis to determine the potential extent of cost savings over the full duration of follow-up.

9.8 The processes involved in delivering the programme are refined on an ongoing basis. For example, an increasing number of tasks are delegated to support workers. Further sensitivity analysis to assess the impact of these changes to cost-effectiveness would be of interest to service planners.

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