Second line hormone therapy

- Some patients will respond to second-line hormone therapy with the addition of an anti-androgen, to achieve combined androgen blockade (CAB) With further progression anti-androgen withdrawal responses are seen in approximately 25% of cases who have been treated with first-line CAB or have had substantial (>1 year response) to second-line CAB.
- A common second-line treatment is the addition of an anti-androgen. A retrospective analysis of 122 patients who received the addition of bicalutamide 50 mg to goserelin for PSA and clinical progression showed a >50% decrease in PSA concentration in 30% of patients (responders) and a reduction in PSA concentration in 75% of all patients. The median duration of response from start of bicalutamide 50 mg was 291 days for responders and 193 days for the population as a whole. Those patients with a short duration of response to goserelin monotherapy (<1 year) appeared less likely to respond to CAB with the addition of bicalutamide 50 mg than those who had a longer response (1–2 years).
    - There are reports of PSA responses as a result of anti-androgen withdrawal in men whose disease is progressing on CAB. A recently reported multi-institutional, prospective study demonstrated PSA decreases of ≥50% in 21% (16% to 27%) of 210 men with progressive prostate cancer who discontinued the anti-androgen component of their CAB therapy [Sartor AO, *et al* 2008].
    - Median PFS was 3 months; however, 19% of responders had 12-month or greater progression-free intervals. Longer duration of initial anti-androgen use was shown to be a significant predictor of PSA response.

Side-effects of hormone therapy

- LHRH agonists and GnRH antagonists have a similar tolerability profile: side-effects include erectile dysfunction and loss of libido, reduction in bone mineral density, hot flushes and sweating, and weight gain and injection-site reactions (GnRH antagonists) and metabolic syndrome.
- Anti-androgen side-effects include gynaecomastia and breast tenderness. Mild to moderate gynaecomastia (68.8%) and breast pain (73.6%) are the most common adverse events described.

Castration Resistant Prostate Cancer: Management Options

Prostate cancers that progress despite castrate levels of testosterone are considered castration resistant and not hormone refractory. This is based on findings that the cancer is not uniformly refractory to further hormonal manipulation. Castration-resistant prostate cancer (CRPC), which is still hormone sensitive, has been clearly characterized, with new drugs targeting the androgen receptor, such as enzalutamide, or androgen biosynthesis, via CYP 17 inhibition, such as abiraterone acetate

There are a number of options for therapy for CRPC but the exact sequencing remains undetermined and will depend on both tumour characteristics (e.g. Gleason Score, PSA velocity) patient comorbidities and fitness for therapy and patient choice. The results of sequencing studies are awaited.

Further hormone therapies for CRPC

- Corticosteroids alone have definite activity against prostate cancer (approximately 20% response rate) and provide significant palliation in terms of anorexia, pain and depression. The optimal drug and dose have not been determined, but even prednisone at a dose of 5 mg bid resulted in subjective and PSA responses in one randomised trial [Tannock IF, *et al* 1996].
- Dexamethasone has been shown to be effective for men with progressive metastatic CRPC [Venkitaraman R, *et al* 2008]. In a study of 102 patients treated with oral dexamethasone (0.5 mg daily), 49% had a confirmed PSA response. The median time to PSA progression for the entire cohort was 7.4 (1-28) months and in responders, the median duration of the PSA response was 11.6 (1-24) months.
- Abiraterone acetate is a non-steroidal ester that selectively and irreversibly inhibits both 17α-hydroxylase and the C17, 20-lyase function of CYP17A1, a cytochrome involved in the production of dehydroepiandrosterone (DHEA) and androstenedione (precursors of testosterone). Abiraterone inhibits androgen biosynthesis at all three key sources in prostate cancer: the testes, adrenal glands and prostate tumour cells. It is administered in combination with glucocorticoids to prevent elevated levels of other steroid hormones and associated fluid balance abnormalities.
- Abiraterone in combination with prednisolone (5 mg twice daily) has been investigated in the pre-docetaxel setting in the COU 302 study in asymptomatic or minimally symptomatic men with a performance status of 0 to 1 and progressive castration resistant prostate cancer [Ryan CJ, *et al* 2013]. This multi-centre, double blind study randomised 1088 patients to abiraterone acetate 1000 mg daily and prednisolone versus placebo plus prednisolone. The study was unblinded after a planned interim analysis that was performed after 43% of the expected deaths had occurred. Results showed a significant improvement in radiographic progression-free survival with a median of 16.5 months with abiraterone-prednisone and 8.3 months with prednisone alone, HR 0.53; 95% CI 0.45 to 0.62; P<0.001). Over a median follow-up period of 22.2 months, overall survival was improved with abiraterone-prednisone (median not reached, vs. 27.2 months for prednisone alone; HR, 0.75; 95% CI, 0.61 to 0.93; P=0.01) but did not cross the efficacy boundary. Abiraterone-prednisone showed superiority over prednisone alone with respect to time to initiation of cytotoxic chemotherapy, opiate use for cancer-related pain, prostate-specific antigen progression, and decline in performance status. Toxicity included mineralocorticoid-related adverse events and abnormalities on liver-function testing were more common with abiraterone-prednisone, but mainly grade 1 or 2.
- Oestrogen therapy with DES demonstrated a comparable efficacy to castration in 1977 and was one of the first initial promising hormone manipulations. However the first Veterans studies showed that early treatment of advanced prostate cancer with DES 5 mg did not increase OS when compared to placebo, as the drug was associated with an increased incidence of cardiovascular deaths [Byar DP 1972].
- A second study compared the DES 5 mg dose to 1 mg and the results showed that this lower dose was equally effective but was associated with a much lower incidence of cardiovascular deaths. The risk of cardiovascular events may require the concomitant use of aspirin/anticoagulants [Robinson MR (a), *et al* 1995].
- Other new agents such as enzalutamide and orteronel are currently under evaluation in the prechemotherapy setting.
- There is now evidence for further use of hormone therapies after docetaxel (see below) The choice between these drugs or the use of second line chemotherapy remains unclear and sequencing studies are urgently awaited.

- Abiraterone has also been investigated in the COU 301 study [Fizazi K, *et al* 2012]. This was multicentre, prospective double blind randomised trial of 1195 patients with metastatic CRPC who were randomly assigned (ratio2:1) abiraterone acetate 1000 mg daily plus prednisolone (5 mg twice daily) or placebo and prednisolone (5 mg twice daily). All patients had progressive disease after docetaxel therapy (with a maximum of two previous chemotherapeutic regimens). After a median follow-up of 20.2 months, the median survival in the abiraterone group was 15.8 months compared to 11.2 months in the placebo arm (HR: 0.74, P < 0.001). The median time to PSA progression was 8·5 months, CI 8·3-11·1, in the abiraterone group vs. 6·6 months, 5·6-8·3, in the placebo group; HR 0·63, 0·52-0·78; p<0·0001), median radiologic progression-free survival (5·6 months, 5·6-6·5, vs. 3·6 months, 2·9-5·5; HR 0·66, 0·58-0·76; p<0·0001), and proportion of patients who had a PSA response (235 [29·5%] of 797 patients vs. 22 [5·5%] of 398; p<0·0001) were all improved in the abiraterone group compared with the placebo group. The most common grade 3-4 adverse events were fatigue (72 [9%] of 791 patients in the abiraterone group vs. 41 [10%] of 394 in the placebo group), anaemia (62 [8%] vs. 32 [8%]), back pain (56 [7%] vs. 40 [10%]), and bone pain (51 [6%] vs. 31 [8%]).The benefit was observed irrespective of age, baseline pain intensity, and type of progression.
- Enzalutamide is a novel oral antiandrogen that targets multiple steps in the androgen-receptor-signalling pathway and has shown a significant survival benefit for men with CRPC following docetaxel chemotherapy
- In the AFFFIRM study 1199 men with castration resistant prostate cancer after docetaxel chemotherapy were randomly assigned them, in a 2:1 ratio, to receive oral enzalutamide at a dose of 160 mg per day or placebo (399 patients) [Scher HI, *et al* 2012]. The study was stopped after a planned interim analysis at the time of 520 deaths. The median overall survival was 18.4 months (95% CI, 17.3 to not yet reached) in the enzalutamide group versus 13.6 months (95% CI, 11.3 to 15.8) in the placebo group (hazard ratio for death in the enzalutamide group, 0.63; 95% CI, 0.53 to 0.75; P<0.001). All the secondary objectives were in favour of enzalutamide. the proportion of patients with a reduction in the PSA level by 50% or more (54% vs. 2%, P<0.001), the soft-tissue response rate (29% vs. 4%, P<0.001), the quality-of-life response rate (43% vs. 18%, P<0.001), the time to PSA progression (8.3 vs. 3.0 months; hazard ratio, 0.25; P<0.001), radiographic progression-free survival (8.3 vs. 2.9 months; hazard ratio, 0.40; P<0.001), and the time to the first skeletal-related event (16.7 vs. 13.3 months; hazard ratio, 0.69; P<0.001). Rates of fatigue, diarrhoea, and hot flashes were higher in the enzalutamide group with a lower incidence of grade 3-4 side effects in the enzalutamide arm. Seizures were reported in five patients (0.6%) receiving enzalutamide.

Chemotherapy

An alternative treatment for advanced CRPC is chemotherapy. Docetaxel is now recommended as first line chemotherapy.

Side-effects of chemotherapy depend on the exact treatment regime, but usually include fatigue, nausea and vomiting, diarrhoea, hair loss and bone marrow suppression with increased susceptibility to infection. Specific therapies to handle these side-effects may be necessary to improve the patient's quality of life.

- A prospective study by Tannock in 1996 compared the benefits of mitoxantrone 12 mg/m² every 3 weeks plus prednisone 5 mg twice-daily with prednisone alone in 161 men with symptomatic HRPC [Tannock IF, *et al* 1996].
    - The primary endpoint was palliative response defined as a 2-point decrease in pain as assessed by a 6-point pain scale.
    - There was a significant advantage to the chemotherapy combination with a 29% pain response compared to 12% with steroids alone.
    - The duration of palliation was 43 weeks versus 18 weeks ($p<0.0001$) in favour of mitoxantrone and prednisone.
    - There was no difference in PSA or survival. It was therefore concluded that chemotherapy with mitoxantrone and prednisone provides palliation for some patients with symptomatic HRPC.
- The TAX 327 study randomised 1006 men with advanced prostate cancer to three treatment regimens [Tannock IF, *et al* 2004].
    - These were docetaxel 75 mg/m² administered every 3 weeks, docetaxel 30 mg/m² every week and mitoxantrone 12 mg/m² every 3 weeks, each with prednisone 5 mg twice-daily.
    - Initial results were published in 2004 and showed a significant improvement in median survival with 3-weekly docetaxel plus prednisolone (18.9 months), compared with the comparator arm of mitoxantrone plus prednisolone (16.5 months) ($p<0.001$).
    - A total of 45% of those in the docetaxel arm had a PSA reduction ≥50% compared to 32% of those having mitoxantrone ($p=0.0005$).
    - Increased benefits in pain response (35% versus 22%, $p=0.01$) were demonstrated in favour of docetaxel.
    - Quality of life was improved in 13% of patients receiving mitoxantrone, 22% of patients receiving 3-weekly docetaxel ($p=0.009$) and 23% of patients receiving weekly docetaxel ($p=0.005$).
- Further results have recently been reported and the survival benefit with 3-weekly docetaxel has persisted with extended follow-up [Berthold DR, *et al* 2008].
    - Median survival was 19.3 months for 3-weekly docetaxel versus 16.3 months in the mitoxantrone arm ($p=0.006$) with respective 3-year survival figures of 17.9% versus 13.7% in favour of docetaxel.
    - This study has confirmed the benefits of docetaxel chemotherapy.
    - The extended analysis of the TAX 327 study included subgroup analyses and demonstrated survival benefits for men both <65 years and >75 years of age.

- Cabazitaxel is a novel tubulin-binding taxane drug with antitumour activity in docetaxel-resistant prostate cancers. Positive results were seen for cabazitaxel from a large prospective randomised, phase III trial (TROPIC study) [de Bono JS, *et al* 2010]. In this study, 755 men with metastatic castration-resistant prostate cancer whose disease had progressed during or after treatment with a docetaxel-containing regimen were treated with 10 mg oral prednisone daily, and were randomly assigned to receive either 12 mg/m2 mitoxantrone intravenously or 25 mg/m2 cabazitaxel intravenously every 3 weeks. An overall survival benefit (15.1 vs. 12.7 months, P < 0.0001) was observed in the cabazitaxel arm. There was also a significant improvement in PFS (2.8 vs. 1.4 months, P < 0.0001), objective response rate according to RECIST criteria (14.4% vs. 4.4%, P <0.005), and PSA response rate (39.2% vs. 17.8%, P < 0.0002). The most common clinically significant grade 3 or higher adverse events were neutropenia (cabazitaxel, 303 [82%] patients vs mitoxantrone, 215 [58%]) and diarrhoea (23 [6%] vs. one [<1%]). 28 (8%) patients in the cabazitaxel group and five (1%) in the mitoxantrone group had febrile neutropenia.

Bone targeted agents

Bisphosphonates

- The benefits of zoledronic acid, in combination with hormone therapy have been investigated in a study by Saad in men with HRPC and bone metastases [Saad F, *et al* 2002]. This was a multicentre, randomised, placebo-controlled trial evaluating the efficacy of zoledronic acid 4 mg administered every 3 weeks in 422 patients with HRPC for 15 months, with an option to continue for an additional 9 months.
    - At the 2-year analysis, treatment with zoledronic acid was found to significantly reduce the percentage of patients with at least one skeletal-related event (SRE; defined as radiation for bone pain or to prevent pathological fracture/spinal cord compression; pathological fracture; spinal cord compression; surgery to bone; change in antineoplastic therapy) compared with placebo (38% versus 49%; p=0.028). All SREs were delayed.
    - Zoledronic acid also significantly delayed the time to first SRE by around 6 months (median 488 versus 321 days; p=0.009). Furthermore, patients in the zoledronic acid group had consistently lower incidences of all types of SRE than the placebo group. Pain scores were consistently lower in patients taking zoledronic acid 4 mg than placebo, and significantly at 3, 9, 18, 21 and 24 months (p<0.05).
- In the MRC PR05 and PR04 trials, men with advanced prostate cancer were randomised to sodium clodronate 2080 mg/day or placebo for up to 3 years (metastatic disease) or up to 5 years (non-metastatic disease) [Dearnaley DP, *et al* 2009].
    - A benefit of sodium clodronate versus placebo in men with metastatic disease was demonstrated for OS (HR: 0.77; 95%CI: 0.60–0.98; p=0.032).
    - However, no benefit of sodium clodronate versus placebo for OS in men with non-metastatic disease was demonstrated (HR: 1.12; 95%CI: 0.89–1.42; p=0.94).

Side-effects

- Bisphosphonates are generally well tolerated.
- Side-effects include: hypophosphataemia, anaemia, influenza-like symptoms, gastrointestinal effects, headache, conjunctivitis, very rarely osteonecrosis of jaw and renal impairment.
- To avoid this, patients on bisphosphonates should avoid dental surgery and extractions. If required this should be performed before starting treatment.
- In the study by Saad *et al*., zoledronic acid was generally well-tolerated [Saad F, *et al* 2002]:
    - Bone pain, nausea and constipation were reported most frequently both by patients receiving zoledronic acid and by those in the placebo group
    - In the zoledronic acid group, fatigue, anaemia, myalgia, fever and lower limb oedema occurred in at least 5% more patients than that observed in the placebo group
- In uncommon cases, patients treated with intravenous zoledronic acid have reported osteonecrosis of the jaw (ONJ) [Marx RE, *et al* 2005].
    - Risk factors associated with the development of ONJ include concomitant chemotherapy and corticosteroids, the patient's underlying disease, and other co-morbid risk factors (e.g. anaemia, local infection, pre-existing oral disease) [Zometa SPC].

RANK ligand inhibitors

- Denosumab is a fully human monoclonal antibody directed against RANKL and a key mediator of osteoclast formation, function, and survival.
- The efficacy and safety of denosumab (n = 950) compared with zoledronic acid (n=951) in patients with metastatic CRPC was assessed in a large randomised phase III trial [Fizazi K, *et al* 2011]. In this multicentre phase 3 study, 1904 men with CRPC and no previous exposure to intravenous bisphosphonate were randomised to receive 120 mg subcutaneous denosumab plus intravenous placebo, or 4 mg intravenous zoledronic acid plus subcutaneous placebo, every 4 weeks until the primary analysis cutoff date. Supplemental calcium and vitamin D were strongly recommended. Median duration on study at primary analysis cutoff date was 12·2 months (IQR 5·9-18·5) for patients on denosumab and 11·2 months (IQR 5·6-17·4) for those on zoledronic acid.
- Results showed that denosumab was superior to zoledronic acid in delaying or preventing SREs, as shown by time to first on-study SRE (pathological fracture, radiation or surgery to bone, or spinal cord compression) of 20.7 vs. 17.1 months, respectively (HR 0.82; P = 0.008). Denosumab also extended time to first and subsequent on-study SRE (HR 0.82; P = 0.008). Both urinary NTX and BAP were significantly suppressed in the denosumab arm compared with the zoledronic acid arm (P < 0.0001 for both). There was no overall survival benefit seen. Adverse events were recorded in 916 patients (97%) on denosumab and 918 patients (97%) on zoledronic acid, and serious adverse events were recorded in 594 patients (63%) on denosumab and 568 patients (60%) on zoledronic acid. More events of hypocalcaemia occurred in the denosumab group (121 [13%]) than in the zoledronic acid group (55 [6%]; p<0·0001). Osteonecrosis of the jaw occurred infrequently (22 [2%] vs. 12 [1%]; p = 0·09).

Systemic radionuclide therapy

Strontium

- Metastatic pain can be palliated effectively with systemic radionuclide therapy with strontium chloride.
- Relief of bone pain starts within 2 weeks. Possible initial bone pain flare may occur within 2 days, lasting 2–4 days.
    - Pain relief lasts 4–15 months.
    - 75–80% of patients experience significant palliation of pain.
- A Canadian collaborative study showed significant improvement in quality of life, increased time to further metastases, significant reduction in the amount of additional radiotherapy needed, and significant falls in PSA and alkaline phosphatise [Porter AT, *et al* 1993].
- Strontium is not associated with improvements in OS [Brundage MD, *et al* 1998].
- Four randomised clinical trials have reviewed the use of strontium [Robinson RG (b), *et al* 1995].
    - One trial reported significant improvement in pain control, two trials reported fewer new sites of pain.
    - One trial showed no significant difference in pain control compared to a placebo but an improved 2-year survival rate.
- A randomised clinical trial examining strontium versus placebo found a significant increase in median time to progression, but no significant effects on median OS or clinical response [Tu SM, *et al* 2001].

Side-effects

- The most notable side-effect of strontium is mild haematological suppression with a fall in circulating platelet and leukocyte counts recognised in most patients.
    - With usual therapeutic doses, platelets typically fall by 30% and leucocytes by 20%.
    - Clinically significant toxicity is rare, but its use is not recommended in patients with severely compromised bone marrow, platelet count <100, superscan prior to therapy, or impending spinal cord progression.

Radium 223

- Radium-223 dichloride (radium-223) is an alpha emitter which selectively targets bone metastases with alpha particles.
- The efficacy and safety of radium-223 was assessed in the ALSYMPCA study [Parker C, *et al* 2013]. In this multicentre, phase 3, randomized, double-blind, placebo-controlled study, 902 men , who had received, were not eligible to receive, or declined docetaxel, were randomly assigned in a 2:1 ratio, to receive six injections of radium-223 (at a dose of 50 kBq per kilogram of body weight intravenously) or matching placebo; one injection was administered every 4 weeks. In addition, all patients received the best standard of care. At the interim analysis, which involved 809 patients, radium-223, as compared with placebo, significantly improved overall survival (median, 14.0 months vs. 11.2 months; hazard ratio, 0.70; 95%CI, 0.55 to 0.88; two-sided P=0.002). The updated analysis involving 921 patients confirmed the radium-223 survival benefit (median, 14.9 months vs. 11.3 months; hazard ratio, 0.70; 95% CI, 0.58 to 0.83; P<0.001). Assessments of all main secondary efficacy end points also showed a benefit of radium-233 as compared with placebo. Radium-223 was associated with low myelosuppression rates and fewer adverse events.

Palliative Care

Overview

- Radiotherapy has been a mainstay in the palliation of painful metastatic bone lesions. Palliative radiotherapy can also aid other complications of metastatic disease, such as compression of the spinal cord or a nerve root, haematuria, ureteric obstruction, perineal discomfort caused by the local progression of prostate cancer, and symptomatic metastatic lymphadenopathy.

Clinical evidence

- Good evidence for the role of radiotherapy in palliation comes from McQuay *et al*. This systematic review covered 20 trials, which reported on 43 different radiotherapy fractionation schedules, and eight studies of radioisotopes [McQuay HJ, *et al* 1997].
    - Radiotherapy produced complete pain relief at 1 month in 395 out of 1580 (25%) patients, and at least 50% relief in 788 out of 1933 (41%) patients at some time during the trials.
    - In the largest trial, which included 759 patients, 52% achieved complete pain relief within 4 weeks and the median duration of complete relief was 12 weeks.
    - The study found no difference between the use of radioisotopes (such as strontium) and EBRT for generalised disease, a finding supported by the work of Quilty *et al* [Quilty PM, *et al* 1994].
    - In this latter study, 284 patients with prostate cancer and painful bone metastases were treated with local or hemi-body radiotherapy or strontium. Median survival was non-significantly different between groups (33 weeks with strontium versus 28 weeks with radiotherapy; p=0.1) [Quilty PM, *et al* 1994].
    - Both radiotherapy and strontium provided effective pain relief that was sustained for 3 months in 63.6% of patients after hemi-body radiotherapy compared with 66.1% of patients after strontium, and in 61% of patients after local radiotherapy compared with 65.9% of patients in the comparable strontium group.
    - Fewer patients reported new pain sites after strontium than after local or hemi-body radiotherapy ($p<0.05$) and radiotherapy to a new site was required by 12 patients in the local radiotherapy group compared with two receiving strontium ($p<0.01$).

Ongoing Support

The MDT team should ensure regular communication with the primary care team.

This may mean:

- Timely provision of detailed discharge or outpatient summaries
- Explanation of why a treatment route has been decided upon
- The patient's response to the chosen treatment
- Sharing of protocols
- Online educational resources
- Agreement on prescribing policies
- Provision of contact numbers for requests for information

The local patient support network, e.g. partner/family, must be included in the information/education process through the use of:

- Patient information materials
- Audio visual materials such as videos, DVDs and Web-based information

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Southern Health and Social Care Trust

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Urology MDT

Annual Report for January – December 2016

Presented to the MDT on: 1st September 2017

Agreed by the Urology MDT and signed on their behalf by Mr Anthony Glackin, MDT Lead Clinician on 1st September 2017

CONTENTS

1.0 INTRODUCTION

This annual report relates to the operational period 01/01/2016 – 31/12/2016 for the Southern Trust Urology Multi-disciplinary Team (MDT) and the clinical data presented relates to patients diagnosed in this period.

2.0 KEY ACHIEVEMENTS

Whilst 2016 had begun with 6 Consultant Urologists in post, one consultant, Mr Suresh, subsequently left in October 2016. This post was filled by Locums.

Perhaps our achievements during this past year or more have been crowned by the award of the Trust Excellence Award to the Thorndale Unit in June 2016.

3.0 KEY CHALLENGES

Oncology and Radiology

The greatest challenge for the MDT during the past year has been the inadequacy of the availability of a clinical oncologist and or a radiologist at all MDMs. The inadequacy in both cases has essentially been due to the inability to recruit adequate numbers of clinical oncologists and radiologists to the post where they are required. The inadequacy has been addressed with the appointment authorities.

Red Flag Referrals

There had been a 40% increase in the number of Red Flag referrals throughout Northern Ireland during the past few years, up from 2902 in 2013 to 4761 in 2015/16. The greatest increase was to the Southern Trust, with an increase of 84% from 410 in 2013 to 753 in 2014. The increase has continued throughout 2015/16 – there were 1878 red flag referrals in 2016.

Performance

Even though there has been an increase in Red Flag referrals over the past few years, the increased compliment of Consultant Urologists has enabled the MDT to absorb the increased demand and complete the assessment of patients and enact their definite management within the agreed time period of 62 days.

This has been reflected in the Cancer Performance data. The monthly average waits for an appointment between September-December 2016 were as follows:

Prostate: 22 day wait
Haematuria: 23 day wait
Others: 15 day wait

The diagnostic and operative activity has been reflected in an increase in the numbers of specimens received by the Cellular Pathology Laboratory at Craigavon Area Hospital, Tissue specimens increased from 874 in 2014 to 903 in 2016.

Even though not all tissue specimens were known, suspected or found to be cancerous, the analysis of the tissue type below demonstrates the varied spread of organ biopsies and resections. Biopsies and resections of prostate and bladder comprise the bulk of urological pathological diagnostic activity.

SPECIMENS	2012	2013	2014	2015	2016
Prostate Biopsies	**345**	**225**	**248**	**340**	**318**
TURP	**158**	**141**	**163**	**176**	**147**
Bladder Biopsies	**182**	**253**	**224**	**205**	**180**
TURBT	**78**	**70**	**115**	**120**	**123**
Testis Biopsies	**-**	**-**	**4**	**8**	**5**
Testis	**28**	**37**	**36**	**38**	**32**
Renal Biopsies	**-**	**-**	**24**	**14**	**12**
Kidney	**28**	**33**	**46**	**76**	**77**
Penile Biopsies	**6**	**9**	**13**	**13**	**7**
Penis	**4**	**3**	**1**	**3**	**2**

It is notable that there has been an increase in the numbers of Prostate biopsies which reflects the use of MRI to avoid unnecessary TRUS biopsy. The increase in kidney biopsies is in part due to cases being referred from outside the Southern Trust.

New Clinics

The introduction of the New Patient Clinics in October 2014 has contributed significantly to the ability of MDT to absorb the increased Red Flag referrals and meet the target times in all cases by early 2015. For 2016, the 31 day performance for the SHSCT was 100% and the 62 day performance was 81% - this reflects the marked increase in GP red flag referrals for the trust.

Operative Capacity

The main limiting factor in providing a complete cancer service is operating theatre capacity and operator time. Though the MDT has provided for the increased demand on Red Flag pathways, it has been at the expense of patients having, or suspected of having, recurrent bladder tumours, and those awaiting prostatic resection to facilitate their progress to radical radiotherapy for prostatic carcinoma having to wait increasingly longer periods of time for surgery, in addition to all those with non-cancerous pathology. This is a common and concerning experience across Northern Ireland, and will remain an increasing challenge until operative capacity is increased.

Conduct of MDM

The quality of the conduct of MDM has been a singular achievement these past six years. The quality of participation has been enhanced by increasing the number of persons chairing, and by having time allocated for preview.

Development Priorities

In addressing the concerns raised at Peer Review and the findings of Patient Satisfaction Surveys, it has been agreed that we could and should endeavour to make substantial progress in the implementation of Key Worker, Holistic Needs Assessment, Communication and having a Permanent Record of Patient Management. With the appointment of two more Nurses to the Thorndale Unit and Clerical Staff, all newly diagnosed patients have a Key Worker appointed, a Holistic Needs Assessment conducted, adequate communication and information, advice and support given, and all recorded in a Permanent Record of Patient Management which will be shared and filed in a timely manner. It is intended that patients newly diagnosed as inpatients will be included.

Conclusion

While a firm MDM foundation has now been established, and while much success has been achieved during the past year, there remain inadequacies and challenges which are to be addressed in the coming year.

4.0 MDT ATTENDANCE 2016

The Urology MDM takes place every Thursday from 2.15 pm to 5 pm (at the latest) in Tutorial Room 1, Craigavon Area Hospital, with videoconferencing available to Daisy Hill Hospital. The attendance is monitored by the MDT Coordinator. There were 47 meetings held in 2017. The dates of the MDT meetings can be seen in **Appendix 1** along with an attendance spread-sheet for core members and extended members.

Table: Urology MDT Attendance record January 2016 – December 2016

Name	Role	Attended	DNA	% Attended	% Attendance by core /cover
	Surgeon				**100%**
Mr A Glackin*	Surgeon	41	6	87	
Mr M Haynes	Surgeon	33	14	70	
Mr A O'Brien	Surgeon	32	15	68	
Mr R Suresh (left Trust in Oct 2016)	Surgeon	28	19	60	
Mr J O'Donoghue	Surgeon	36	11	77	
	Radiologist				**51%**
Dr M Williams	Radiologist	24	23	51	
Vacant	Radiologist				
	Pathologist				**91%**
Dr G McClean	Pathologist	37	10	79	
Dr R Shah	Pathologist	3	46	6	
A Pathologist	Pathologist	3	7	6	
	Clinical Oncologist				**28%**
Dr Ciara Lyons	Clinical Oncologist	1	46	2	
Dr Jolyne O'Hare	Clinical Oncologist	7	40	15	
Dr Keith Rooney	Clinical Oncologist	3	44	6	
	Urology Specialist Nurse				**98%**
Kate O'Neill**	Urology Specialist Nurse	39	8	83	

Dolores Campbell	Urology Clinical Sister	6	41	13	
	Palliative Nurse Specialist				**100%**
Stephanie Reid	Palliative Nurse Specialist	36	11	77	
A Palliative Nurse Specialist	Palliative Nurse Specialist	10	37	21	
	MDT Co-ordinator				**100%**
Shauna McVeigh	MDT Co-ordinator	38		81	
A MDT Co-Ordinator	MDT Co-ordinator	9		19	

- *Responsible for clinical trials & research
- **Responsible for users issues and patient information

The MDT quorum for 2016 was 11% with Radiology and Clinical Oncology presence being the key issues.

4.1 Attendance at Network Clinical Reference Group Meetings 2016

There was only one meeting of the Urology Clinical Reference Group (CRG) held on 29th January 2016. Details of the attendees are listed below.

Mr O'Brien has since stepped down as Clinical Lead of the Urology CRG. Following an expression of interest process in autumn of 2016, Mr Mark Haynes has been appointed as the new Clinical Lead.

29th January 2016
Aidan O'Brien
Gareth McClean
Kate O'Neill
Gerry Millar

5.0 MDT Workload January to December 2016

Workload	Number
Meetings	47
Number of discussions	1565
Number of patients	910
Number of new patients	746

5.1 Number of New Diagnoses 2016

Final MDM Diagnosis	Number
Prostate	277
Bladder	68
Kidney	64
Testicular	14
Penile	1
Total	**424**

5.2 Cancers by referral source 2016

Referral type	No. of referrals
GP Red Flag	**1878**
Consultant Upgrade	**424**
Other consultant referrals	**868**
Total	**3170**

5.3 Breakdown of first definitive treatments in 2016

The table below provides a breakdown of first definitive treatments of Urology patients on 31 and 62 day pathways during 2016.

Breakdown of first definitive treatments between 1st Jan 201-31 Dec 2016

Pathway	Surgery	Pall	Chemo	Radio	Brachy	Other treatment	No treatment	Active monitoring	Watchful waiting	Total
31 day	67	1	48	3	2	18	1	33	12	185
62 day	84	0	60	2	8	33	0	29	10	227
										412

5.4 Breakdown of cancer waiting times performance

The table below summarizes the performance of Urology patients on 31 and 62 day pathways. Cancer Access Standards mandate that 98% of patients have their definitive treatment within 31 days of decision to treat (when the treating consultant agrees the

treatment with the patient) and 95% of patients on a 62 day pathway are given their first definitive treatment within 62 days of suspect GP referral or consultant upgrade. The 31 day performance for the SHSCT was 100% in 2016 and the 62 day performance was 81%. Pathway breaches are considered at Trust Performance meetings and reasons detailed and escalated as appropriate. The majority of breach reasons are due to the complexity of the pathway, with multiple investigations and discussions often required to obtain a diagnosis and agree a treatment plan.

	31 Day Performance				62 Day Performance			
	Over Target	Within Target	Total	% Within Target	Over Target	Within Target	Total	% Within Target
Jan 16	0	26	26	100%	1	14	14	93%
Feb 16	0	36	36	100%	2	14	14	88%
Mar 16	0	26	26	100%	4	15	15	79%
Apr 16	0	34	34	100%	1	21.5	21.5	96%
May 16	0	29	29	100%	1.5	11.5	11.5	88%
Jun 16	0	31	31	100%	4	15	15	79%
Jul 16	0	33	33	100%	5.5	15	15	73%
Aug 16	0	22	22	100%	2	11.5	11.5	85%
Sep 16	0	28	28	100%	1.5	14.5	14.5	91%
Oct 16	0	33	33	100%	4	16	16	80%
Nov 16	0	24	24	100%	3.5	11	11	76%
Dec 16	0	24	24	100%	3	10.5	10.5	78%
Totals	0	346	346	100%	33	169.5	169.5	81%

Trends for breaches

- Delay in 1st out-patient appointment
- Delay in reporting of MRI scans / delay in discussion at MDT due to no radiologist being present
- Accessing TRUSB appointments due to capacity issues
- Complex cases requiring multiple MDT discussion

6.0 Advanced communication skills training

This has been identified as an area for development. The following members of the MDT have participated in Advanced Communication Skills training and the remaining core members will be offered a position when courses are available in 2017/18:

NAME	ROLE
Aidan O'Brien	Consultant Urologist
Kate O'Neill	Clinical Nurse Specialist
Stephanie Reid	Palliative Nurse Specialist
Joanne Frazer	Palliative Nurse Specialist
Tony Glackin	Consultant Urologist
John O'Donoghue	Consultant Urologist
Mark Haynes	Consultant Urologist
Leanne McCourt	Clinical Sister

7.0 Patient Experience

The Public Health Agency with support from Macmillan Cancer Support commissioned a regional Cancer Patient Experience Survey (CPES) in 2015. This was the first time the survey was undertaken in Northern Ireland and was based on similar surveys used in England and Wales. The survey was issued to over five thousand patients in active treatment for cancer during December 2013 – May 2014, including Urology patients and there was a 62% response rate i.e. 3,217 respondents across the 5 trusts. The results from the survey can be benchmarked against England and Wales and reports are available at a regional and trust level.

It showed overall 91% of patients in Southern Trust rated their care as excellent or very good which was similar to the NI score (92%) and higher than the NHS England score (89%).
Access to a clinical nurse specialist came out as a key issue although those who were given the CNS contact details found it much easier to contact the CNS compared to England.

Areas where SHSCT scored high or higher than the NI score included:

- Possible side effects explained in an understandable way: NI-78%; SHSCT-82% (highest**)
- Patient given written information about side effects: NI – 78%; SHSCT – 80% (highest**)
- Got understandable answers to important questions: NI – 93%; SHSCT – 95% (highest**)
- Hospital staff explained what would be done during operation: NI – 89%; SHSCT – 91% (2/5)
- Given clear written information about what to do / not do post discharge: NI – 85%; SHSCT – 89% (2/5)

- GP given enough info about patient's condition & treatment: NI – 96%; SHSCT – 95%

Access to a clinical nurse specialist came out as a key issue and this is reflective of the disparity of clinical nurse specialists across some of the tumour sites. Cancer research was an area for improvement which reflects the paucity of trials open for some of the tumour sites. Other areas where scores were lower included:

- Patient told about side effects that could affect them in future: NI – 58%; SHSCT – 59%
- Hospital staff gave information on getting financial help: NI – 66%; SHSCT – 67%
- Patient's family had opportunity to talk to doctor: NI – 69%; SHSCT: 63% (**lowest trust)
- Patient offered written assessment and care plan: NI – 21%; SHSCT – 27%

451 patients responded to the survey from the SHSCT and 17% of these were patients with urological cancer.

Further details regarding feedback from the SHSCT CPES report is available in **Appendix 2.**
A local survey was also carried out with Urology patients in August 2016, a report is available in **Appendix 3.** Following these surveys, a service development action plan has been developed, see **Appendix 4.**

8.0 Communication of diagnosis to GPs

When a patient is given a diagnosis of Urological Cancer, the aim of the MDT is that the patient's GP is informed by the end of the next working day of the consultation via a typed letter from the responsible consultant. An audit of GP timeliness of communication was carried out. Please refer to **Appendix 5** for results of the audit.

9.0 Audit

The MDT reviews its data and discusses the progress of its audits annually as part of the MDT annual report at one of the MDT business meetings.

Please refer to **Appendix 7** for results of the following audits:

- Audit on Bladder Cancer Access Standards for non-superficial disease, Mr David Curry, 2016
- Audit of Nurse Provided TRUS Biopsy Service in 2016, Sr Kate O'Neill
- Nephrectomy dashboard - data submitted to the British Association of Urological Surgeons (BAUS) Data and Audit database in 2016

10.0 Clinical Trials

The Urological clinical research activity in Craigavon during 2016 is detailed below:

Urology open studies:

HaBio: Haematuria Biomarker Study

12 patients

UKGPCS: The UK Genetic Prostate Cancer Study
4 patients

See **Appendix 6** for further details of open trials from the NI Cancer Trials Network

Appendix 1: MDT Attendance spreadsheet 2016

MDM Date	MDM Location	Suspect Tumour Site - Description	Mr Anthony Glacklin	Mr Mark Heynes	Mr Aidan O'Brien	Mr Ram Suresh	Mr Michael Young	John O'Donoghue	Consultant Urologist X 2	Dr Marc Williams	Con. Radiologist x1	Dr Gareth McClean	Dr Rajeev Shah	A Pathologist	Pathologist x1	Dr Ciara Lyons	Dr Jolyne O'Hare	Dr Keith Rooney	Clinical/Medical Oncologist x1	Kate O'Neill	Dolores Campbel	Urology Nurse Specialist	Stephanie Reid	palliative nurse cover	Palliative Nurse x 1	Shauna McVeigh	A MDT Co-Ordinator	MDT Co-ordinator x1	Quorate
07/01/2016	CAH	Urological Cancer	1	1	1	1	0	0	2	1	1	1			1			0	0	1		1	1		1	1	0	1	NO
14/01/2016	CAH	Urological Cancer	1	0	1	1	0	1	2	0	0	1			1			1	1	1		1	1		1	1	0	1	NO
21/01/2016	CAH	Urological Cancer	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM
28/01/2016	CAH	Urological Cancer	1	1	1	1	1	1	2	0	0	1			1			1	1	1		1	1		1	1	0	1	NO
04/02/2016	CAH	Urological Cancer	1	1	1	1	0	1	2	0	0	1			1			0	0	0		0	0	1	1	0	1	1	NO
11/02/2016	CAH	Urological Cancer	1	0	1	1	0	1	2	0	0	1			1			1	1	1		1	1		1	1	0	1	NO
18/02/2016	CAH	Urological Cancer	1	0	1	1	0	1	2	1	1	1			1			0	0	1		1	0	1	1	1	0	1	NO
25/02/2016	CAH	Urological Cancer	1	1	0		0	1	2	0	0	0		1	1			0	0	1		1	1		1	1	0	1	NO
03/03/2016	CAH	Urological Cancer	1	1	0	1	0	1	2	1	1	1			1			0	0	1		1	1		1	1	0	1	NO
10/03/2016	CAH	Urological Cancer	1	1	1	1	1	1	2	1	1	1			1		1	0	1	0	1	1	1		1	1	0	1	YES
17/03/2016	CAH	Urological Cancer	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM
24/03/2016	CAH	Urological Cancer	0	1	1	1	0	1	2	1	1	1			1			0	0	1	0	1	1		1	1	0	1	NO
31/03/2016	CAH	Urological Cancer	1	0	1	1	0	1	2	1	1	0	1		1		1	0	1	1	0	1	1		1	1	0	1	YES
07/04/2016	CAH	Urological Cancer	0	1	1	1	0	1	2	0	0	1			1		1	0	1	1	0	1	1		1	1	0	1	NO
14/04/2016	CAH	Urological Cancer	1	1	1	1	0	0	2	1	1	1			1			0	0	1	0	1	1		1	1	0	1	NO
21/04/2016	CAH	Urological Cancer	1	1	1	1	1	1	2	0	0	1			1		1	0	1	1	0	1	1		1	1	0	1	NO
28/04/2016	CAH	Urological Cancer	1	1	0	1	0	0	2	1	1	0	1		1			0	0	1	0	1	0	1	1	1	0	1	NO
05/05/2016	CAH	Urological Cancer	1	0	0	1	0	1	2	1	1	0	1		1			0	0	1	0	1	1		1	1	0	1	NO
12/05/2016	CAH	Urological Cancer	1	0	0	1	0	1	2	0	0	1	0		1			0	0	1	0	1	1		1	1	0	1	NO
19/05/2016	CAH	Urological Cancer	1	0	1	1	0	0	2	0	0	1	0		1			0	0	1	0	1	1		1	0	1	1	NO
26/05/2017	CAH	Urological Cancer	1	0	1	1	0	0	2	1	1	1	0		1			0	0	1	1	1	1		1	1	0	1	NO
02/06/2016	CAH	Urological Cancer	1	0	1	1	0	1	2	1	1	1	0		1			0	0	1	0	1	1		1	1	0	1	NO
09/06/2016	CAH	Urological Cancer	0	1	1	0	0	1	2	0	0	1	0		1		1	0	1	1	0	1	1		1	1	0	1	NO
16/06/2016	CAH	Urological Cancer	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM
23/06/2016	CAH	Urological Cancer	1	0	0	0	0	1	2	1	1	1	0		1		1	0	1	1	0	1	1		1	1	0	1	YES
30/06/2016	CAH	Urological Cancer	0	1	1	0	0	0	2	1	1	1	0		1		1	0	1	1	0	1	0	1	1	1	0	1	YES
07/07/2016	CAH	Urological Cancer	0	0	1	1	1	0	2	1	1	1	0		1		0	0	0	1	0	1	1		1	0	1	1	NO
14/07/2016	CAH	Urological Cancer	1	0	0	0	1	0	2	0	0	0	0	1	1		0	0	0	1	0	1	0	1	1	1	0	1	NO
21/07/2016	CAH	Urological Cancer	1	0	1	1	1	1	2	0	0	0	0	0	0		0	0	0	1	1	1	1		1	1	0	1	NO
28/07/2016	CAH	Urological Cancer	1	1	1	0	1	0	2	1	1	0	0	1	1		0	0	0	1	0	1	1		1	1	0	1	NO
04/08/2016	CAH	Urological Cancer	1	0	1	0	0	1	2	1	1	1	0	0	1		0	0	0	1	0	1	0	1	1	1	0	1	NO
11/08/2016	CAH	Urological Cancer	1	1	0	1	0	1	2	0	0	1	0	0	1		0	0	0	1	0	1	0	1	1	1	0	1	NO
18/08/2016	CAH	Urological Cancer	1	1	1	1	0	1	2	0	0	1	0	0	1		0	0	0	0	1	1	0	1	1	1	0	1	NO
25/08/2016	CAH	Urological Cancer	0	1	1	1	0	0	2	0	0	1	0	0	1		0	0	0	1	0	1	0	1	1	1	0	1	NO
01/09/2016	CAH	Urological Cancer	1	1	1	1	0	1	2	1	1	1	0	0	1		0	0	0	1	0	1	1		1	1	0	1	NO
08/09/2016	CAH	Urological Cancer	1	1	1	1	1	1	2	1	1	1	0	0	1		0	0	0	1	0	1	1		1	1	0	1	NO
15/09/2016	CAH	Urological Cancer	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM
22/09/2016	CAH	Urological Cancer	1	1	1	1	0	1	2	0	0	1	0		1		0	0	0	1	0	1	1		1	1	0	1	NO
29/09/2016	CAH	Urological Cancer	1	1	1	1	0	1	2	0	0	1	0		1		0	0	0	1	0	1	1		1	1	0	1	NO
06/10/2016	CAH	Urological Cancer	1	1	1	0	0	1	2	1	1	1	0		1		0	0	0	1	0	1	1		1	1	0	1	NO
13/10/2016	CAH	Urological Cancer	1	1	1	0	1	1	2	1	1	0		0	0		0	0	0	1	0	1	1		1	0	1	1	NO
20/10/2016	CAH	Urological Cancer	1	1	1	0	0	1	2	0	0	1	0		1	1	0	0	1	1	0	1	1		1	1	1	1	NO
27/10/2016	CAH	Urological Cancer	1	1	0	0	0	1	2	1	1	1	0		1	0	0	0	1	0	1	1	1		1	1	1	1	YES
03/11/2016	CAH	Urological Cancer	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM
10/11/2016	CAH	Urological Cancer	1	1	0	0	0	1	2	1	1	1	0		1	0	0	0	0	1	0	1	1		1	1	0	1	NO
17/11/2016	CAH	Urological Cancer	1	1	0		0	1	2	1	1	0	0	0	0	0	0	0	0	1	0	1	1		1	0	1	1	NO
24/11/2016	CAH	Urological Cancer	1	1	0		0	1	2	0	0	1	0	0	1	0	0	0	0	1	0	1	1		1	0	1	1	NO
01/12/2016	CAH	Urological Cancer	1	1	0		0	1	2	1	1	1	0	0	1	0	0	0	0	0	1	1	0	1	1	0	1	1	NO
08/12/2016	CAH	Urological Cancer	1	1	0		0	1	2	0	0	1	0	0	1	0	0	0	0	1	0	1	1		1	0	1	1	NO
15/12/2016	CAH	Urological Cancer	1	1	0		0	1	2	0	0	1	0	0	1	0	0	0	0	1	0	1	0	1	1	1	0	1	NO
22/12/2016	CAH	Urological Cancer	1	1	1		0	0	2	0	0	1	0	0	1	0	0	0	0	1	0	1	1		1	1	0	1	NO
29/12/2016	CAH	Urological Cancer	1	1	1		0	1	2	0	0	0	0	0	0	0	0	0	0	1	0	1	1		1	0	1	0	NO
Weeks Attended			41	33	32	28	9	36	47	24	24	37	3	3	43	1	7	3	13	39	6	46	36	10	47	38	9	47	5
47 Week Year			87%	70%	68%	60%	19%	77%	100%	51%	51%	79%	6%	6%	91%	2%	15%	6%	28%	83%	13%	98%	77%	21%	100%	81%	19%	100%	**11%**

Appendix 2: Feedback from the NI Cancer Patient Experience Survey 2015

Southern Health and Social Care Trust

Quality Care - for you, with you

NI Cancer Patient Experience Survey – SHSCT results from Urology patients (17% of ST respondents i.e.77)

Questions highlighted in yellow - % difference is +5% less than NI average (-)
Questions highlighted in red - % difference is +5% more than NI average (+)

Question number	Detail	Southern %	NI Average %	Difference %
Q1	Saw GP once/twice	82	74	+8
Q2	Pt thought seen as soon as necessary	87	86	+1
Q4	Pt's health got better or remained about same while waiting	82	84	-2
Q6	Staff gave complete explanation of purpose of test	86	84	+2
Q7	Staff explained what would be done during test	89	88	+1
Q8	Given easy to understand written info about test	83	88	-5
Q9	Given complete explanation of test results in understandable way	80	80	-
Q11	Pt told could bring friend when first told they had cancer	71	76	-5
Q12	Pt felt they were told sensitively that they had cancer	83	86	-3
Q13	Pt completely understood explanation of what was wrong	76	77	-1
Q14	Pt given written info about type of cancer they had	54	48	+6
Q15	Pt given a choice of different type of treatment	67	81	-14
Q16	Pt's views taken into account when discussing treatment	63	69	-6
Q17	Side effects explained in an understandable way	77	75	+2
Q18	Pt given written information about side effects	61	64	-3
Q19	Pt told about side effects that could affect them in future	53	51	+2
Q20	Pt definitely involved in decisions about care and	71	75	-4

	treatment			
Q21	Pt given the name of the CNS in charge of their care	48	53	-5
Q22	Pt finds it easy to contact their CNS	88	82	+6
Q23	CNS listened carefully last time spoken to	90	95	-5
Q24	Get understandable answers to important questions all/most of the time (CNS)	90	89	+1
Q25	Hospital staff gave info about support groups	47	67	-20
Q26	Hospital staff gave info about impact cancer could have on work/education	55	60	-5
Q27	Hospital staff gave info on getting financial help	33	41	-7
Q28	Pt saw cancer research info in hospital	84	79	+5
Q29*	Taking part in cancer research discussed with patient	1	9	-8
Q36	Got understandable answers to important questions all/most of time(doctors)	72	74	-2
Q37	Pt had confidence and trust in all doctors treating them	90	86	+4
Q38	Doctors did not talk in front of pt as if they were not there	86	80	+6
Q39	Pt's family had opportunity to talk to doctor	56	58	-2
Q40	Got understandable answers to important questions all/most of time from (ward nurses)	71	75	-4
Q41	Patient had confidence and trust in all ward nurses	81	79	+2
Q42	Nurses did not talk in form of pt as if they were not there	84	86	-2
Q43	Always/nearly always enough nurses on duty	47	60	-13
Q44	Pt did not think hospital staff deliberately misinformed them	81	86	-5
Q45	Pt never thought they were given conflicting info	83	84	-1
Q46	All staff asked pt what name they preferred to be called by	71	67	+4
Q47	Always given enough privacy when discussing condition or treatment	79	81	-2
Q48	Always given enough privacy when being examined or treated	93	94	-1
Q49	Pt was able to discuss worries or fears with staff during visit	67	69	-2
Q50	Hosp staff did everything to help control pain all of the time	83	84	-1

Q51	Always treated with respect and dignity by staff	86	88	-2
Q52	Given clear written info about what should/should not do post discharge	84	78	+6
Q53	Staff told pt who to contact if worried post discharge	78	81	-3
Q54	Family definitely given all info needed to help care at home	68	59	-9
Q55	Pt definitely given enough care from health or social services	59	51	+8
Q57	Staff definitely did everything to control side effects of chemo	82	82	-
Q58	Staff definitely did everything they could to help control pain	78	80	-2
Q59	Hospital staff definitely gave patient enough emotional support	71	75	-4
Q61	Doctor had the right notes and other documentation with them	98	97	+1
Q62	GP given enough info about pt's condition and treatment	91	94	-3
Q63	Practice staff definitely did everything they could to support patient	81	79	+2
Q64	Hospital and community staff always worked well together	78	73	+5
Q66	Given the right amount of info about condition and treatment	83	85	-2
Q67	Pt offered written assessment and care plan	9	11	-2
Q68	Pt did not feel that they were treated as 'a set of cancer symptoms'	78	84	-6
Q69	Pt's rating of care excellent/very good	90	90	-

Appendix 3: Feedback from local patient experience survey August 2016

Urology Cancer Patient Experience Survey

August 2016

The Urology cancer team, as part of their service improvement plan to seek feedback from patients on the service, issued a patient feedback survey to 20 patients who were diagnosed with a urological cancer in 2015.

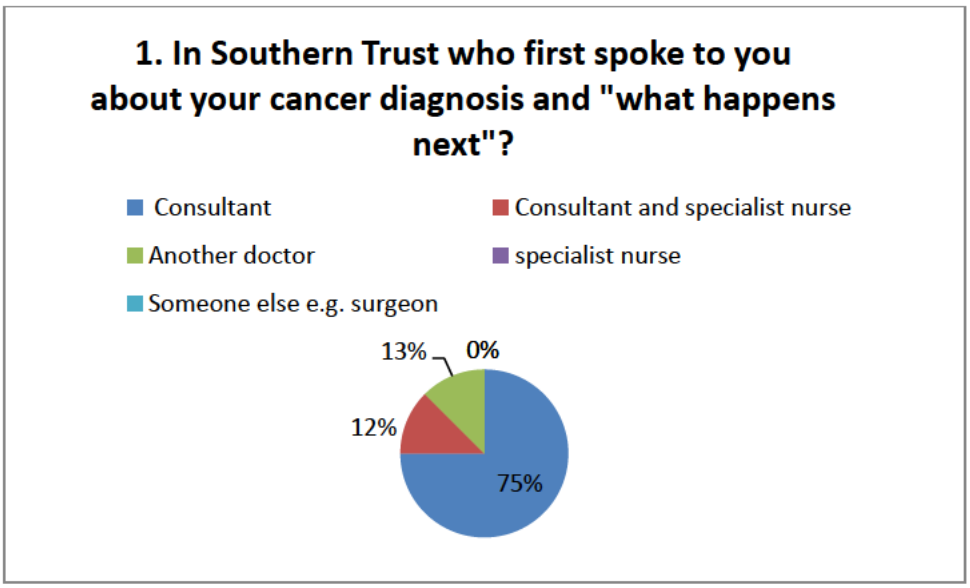
The survey asked questions in relation to their hospital visit and the results from the survey along with the feedback from the NI Cancer Patient Experience Survey will help the team to look at the service currently provided and to plan for the future to make sure they are meeting the on-going needs of patients and families.

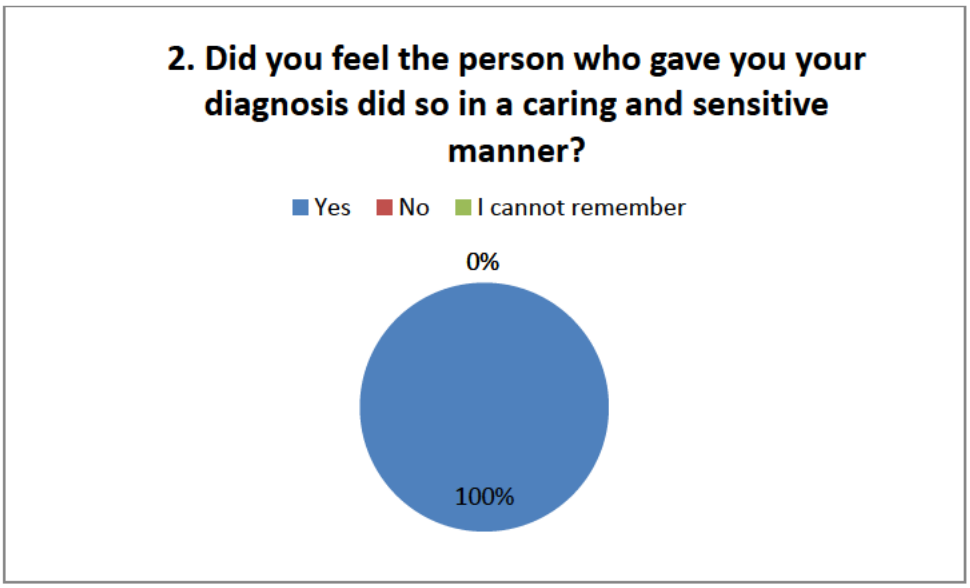
Summary of responses:

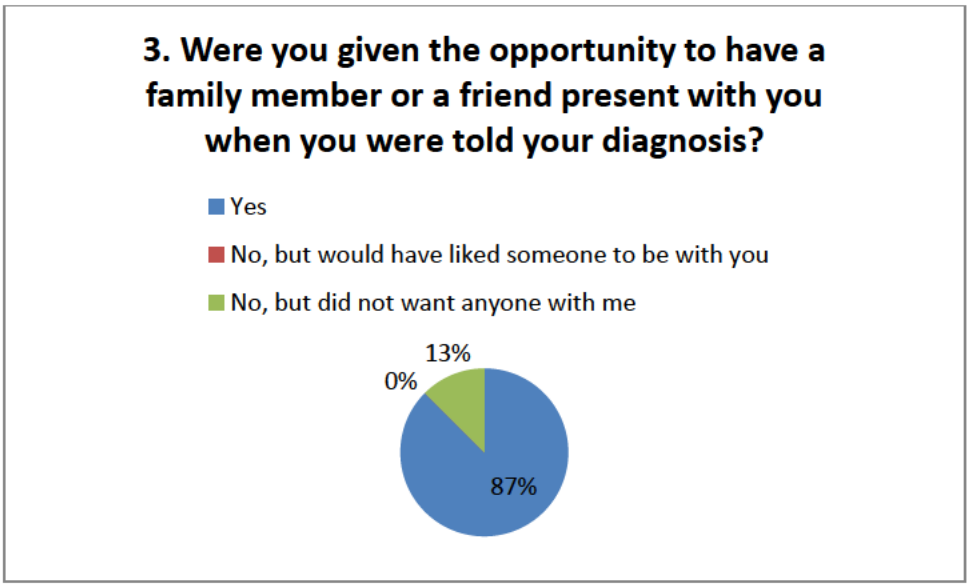
- 8 people completed and returned the questionnaires n = 8 (40%). The age range of the respondents was from 55-75 years & 75% were male. Three respondents were diagnosed with prostate cancer, 2 with bladder cancer and 2 with kidney cancer. All were treated in Craigavon Hospital.
- All patients (100%) were told their diagnosis in person, in a private environment, and felt that the person who gave the diagnosis did so in a caring and sensitive manner.
- All respondents (100%) that they had the opportunity to ask questions.
- 50% of respondents got answers to questions that they could completely understand and 50 % got answers that they understood to some extent
- 87% had the opportunity to have a family member or a friend present
- 75% had the opportunity to meet or speak to a clinical nurse specialist and 12% required further information and support from the CNS in addition to their clinic appointment
- 50% were provided with contact details of a clinical nurse specialist / key worker
- 75% were given a written record of their consultation
- 62% were offered information about their cancer, 12% were offered but did not want it
- 12% were offered printed information about the team looking after them, 37% were not and 38% can’t remember
- Other sources of printed information provided to patients were: Local support centre (17%), other hospital services (16%), Local/regional support groups (50%), Psychological/emotional support (17%).
- 43% felt their holistic needs were addresses, 29% felt they were addressed to some extent

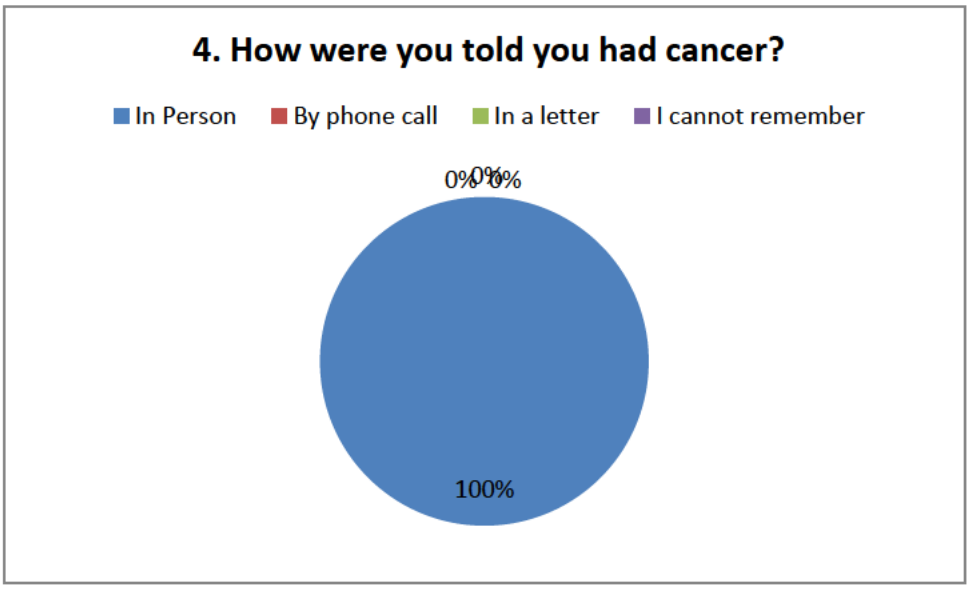
- The respondents rated the quality of information as excellent (37%), or very good / good (37%) and 62% thought the quantity was about right

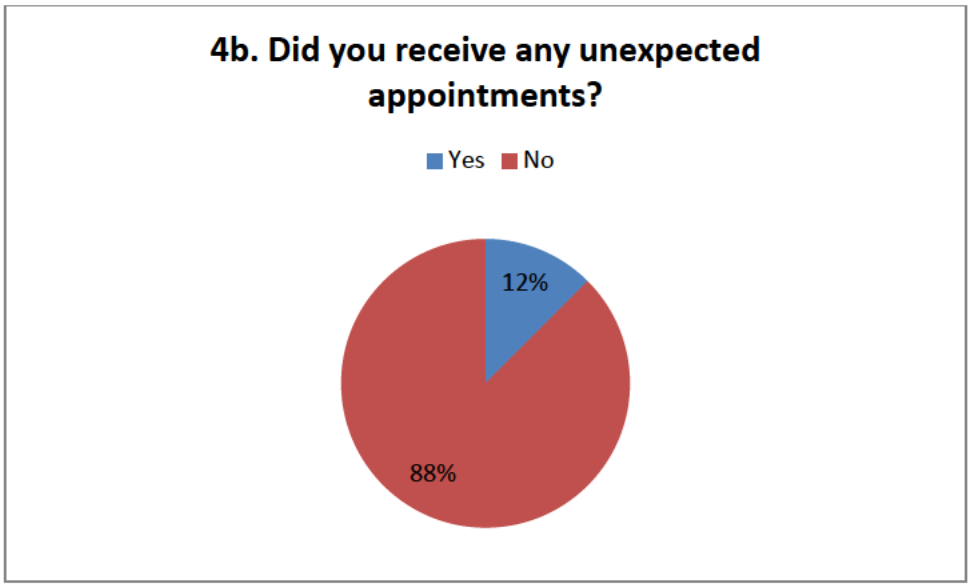
8/20 responses (40%)

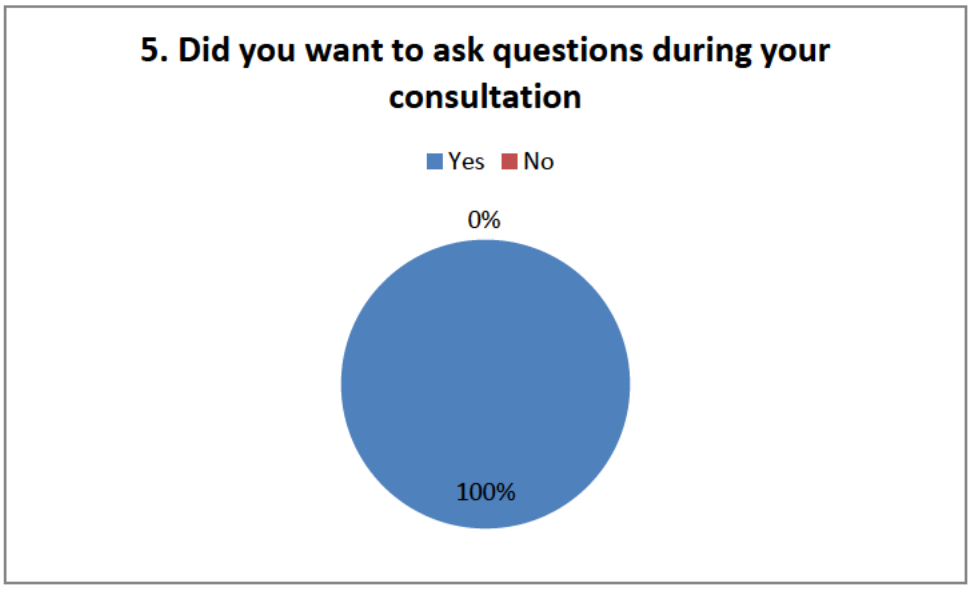


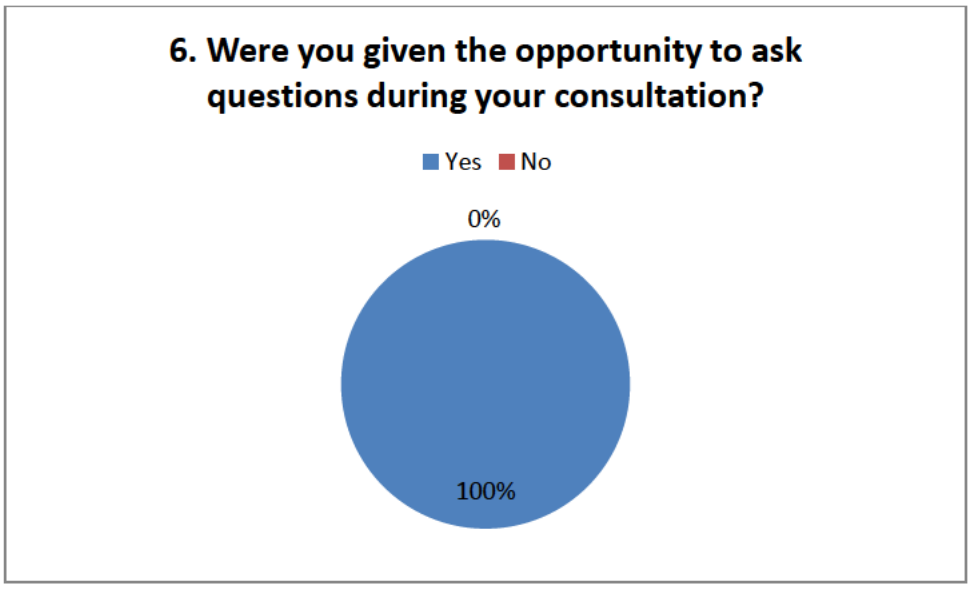


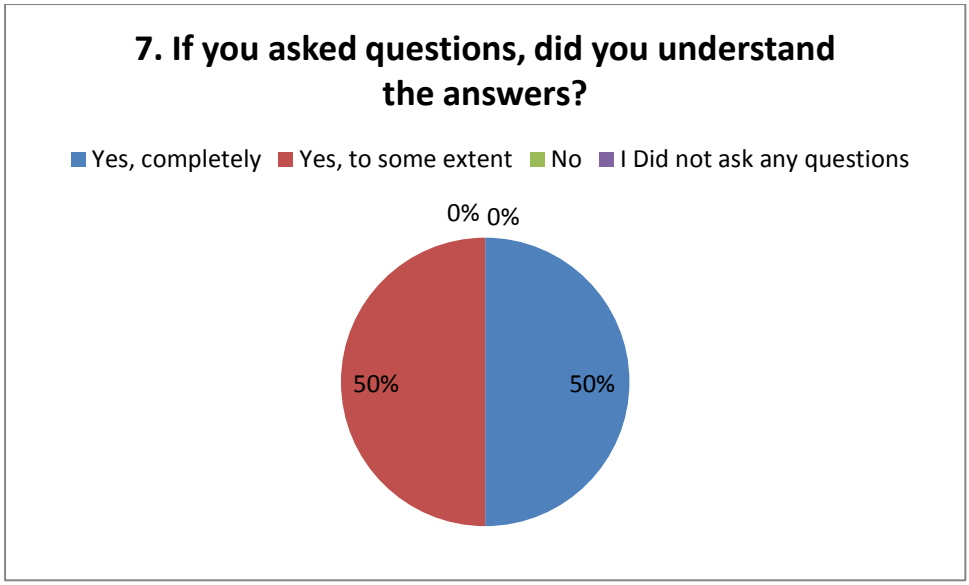


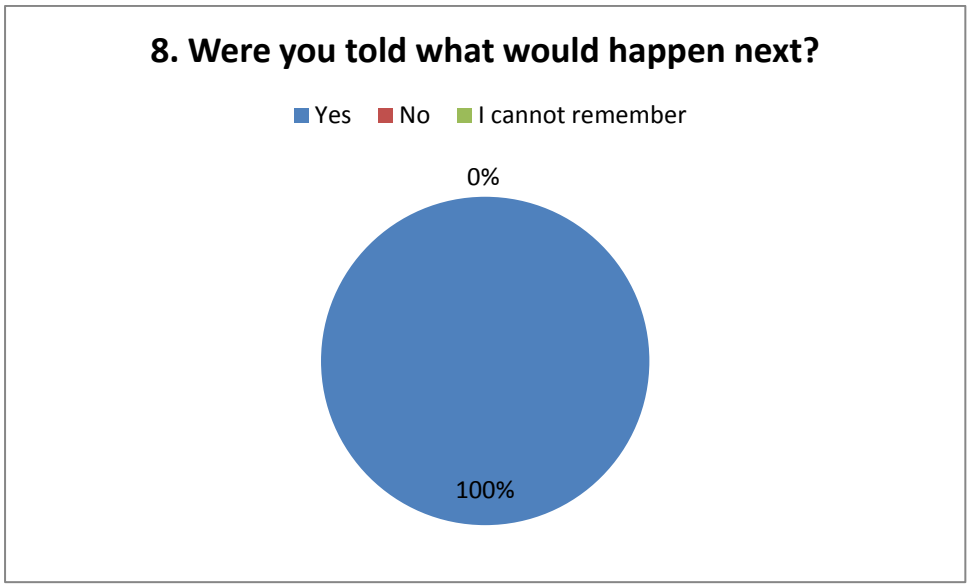


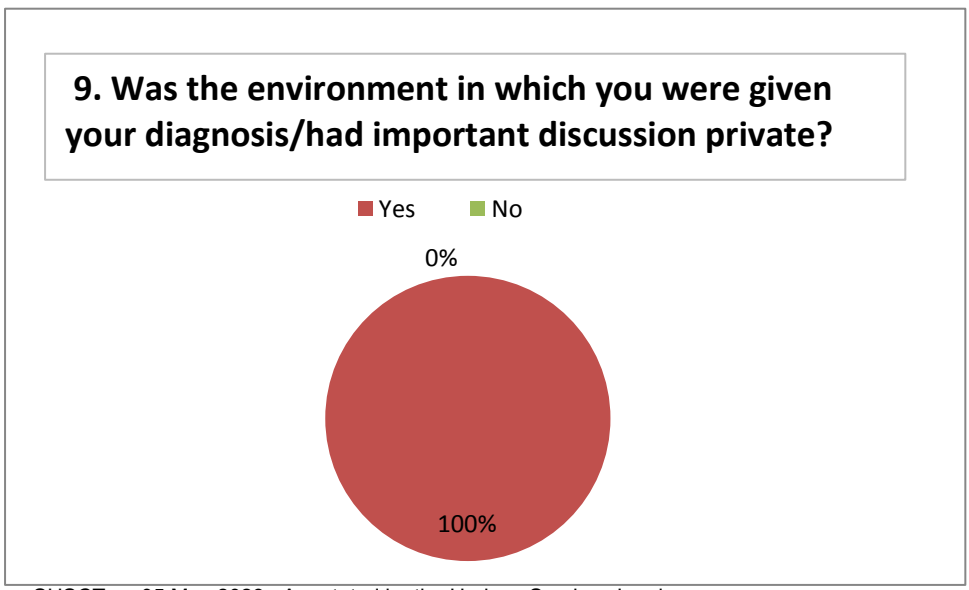


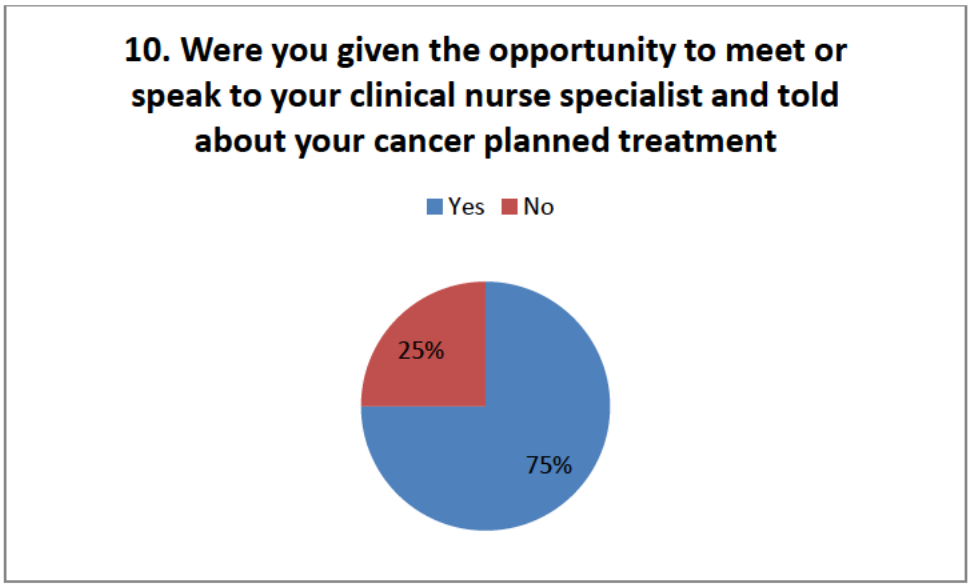


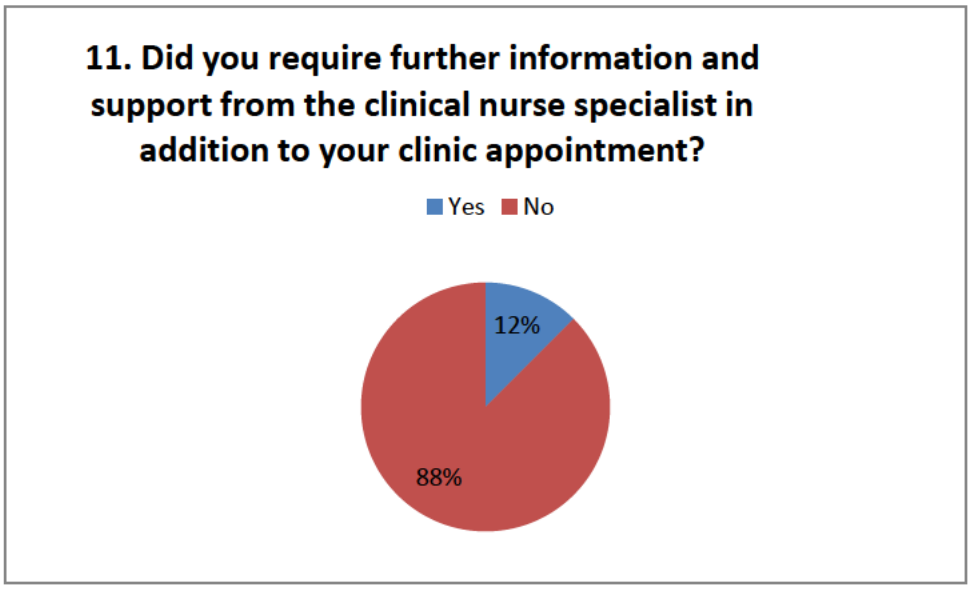




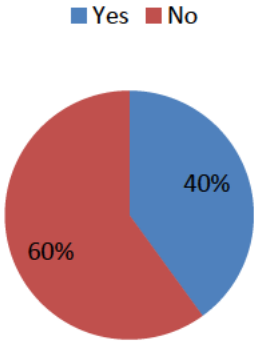




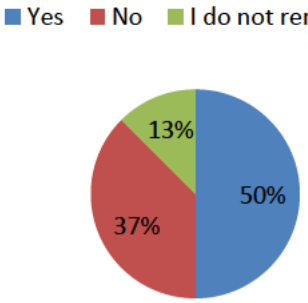


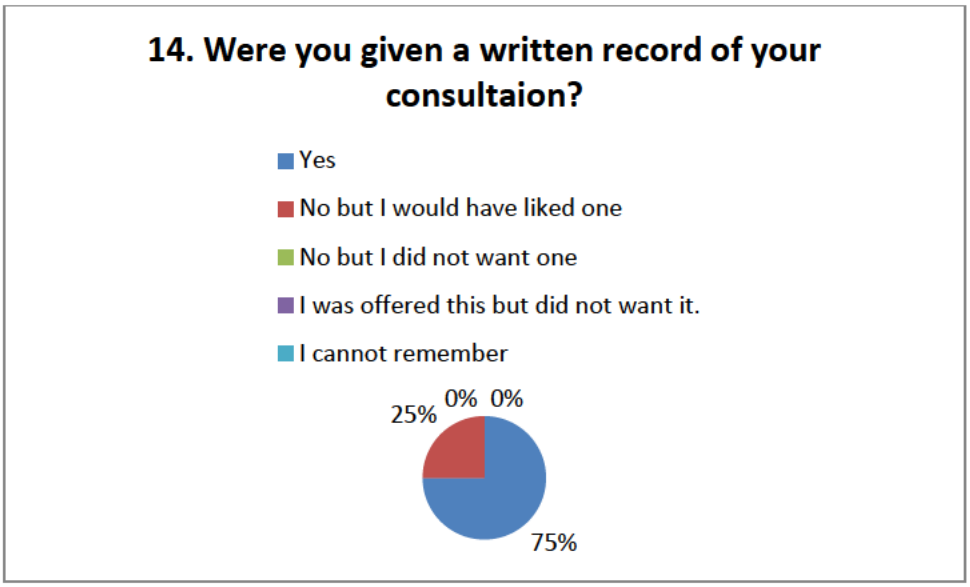


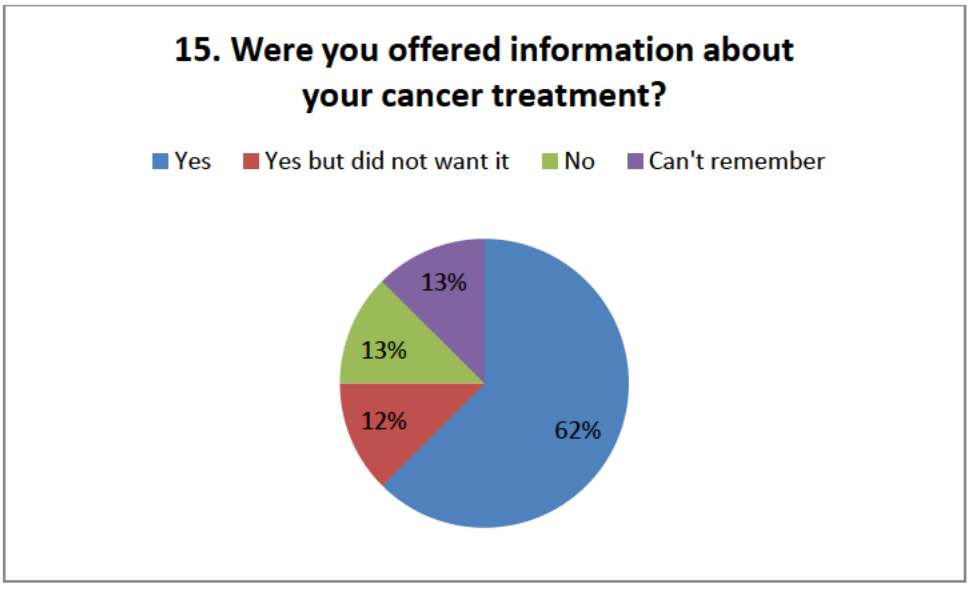
12. If you did require further information and support from the clinical nurse specialist, did you find this beneficial?

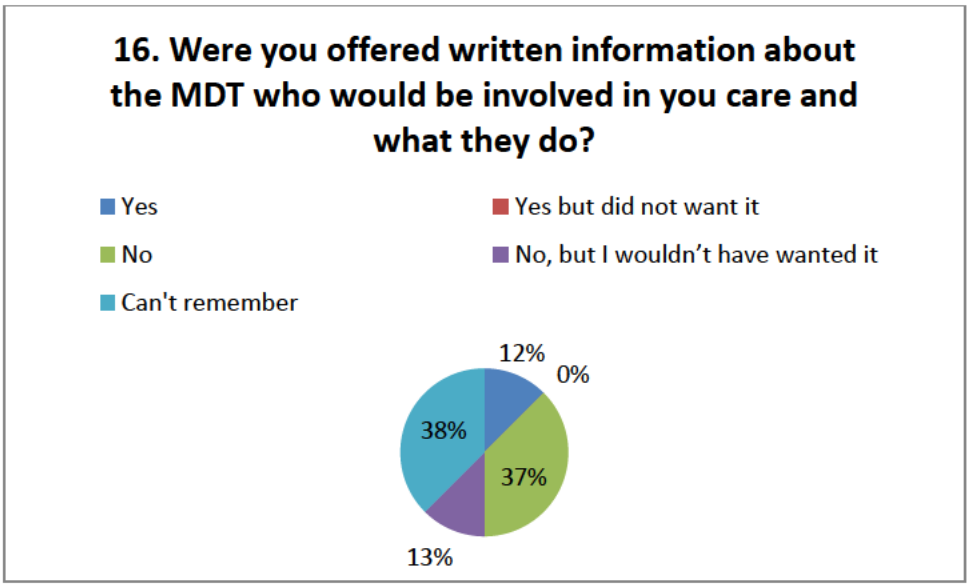


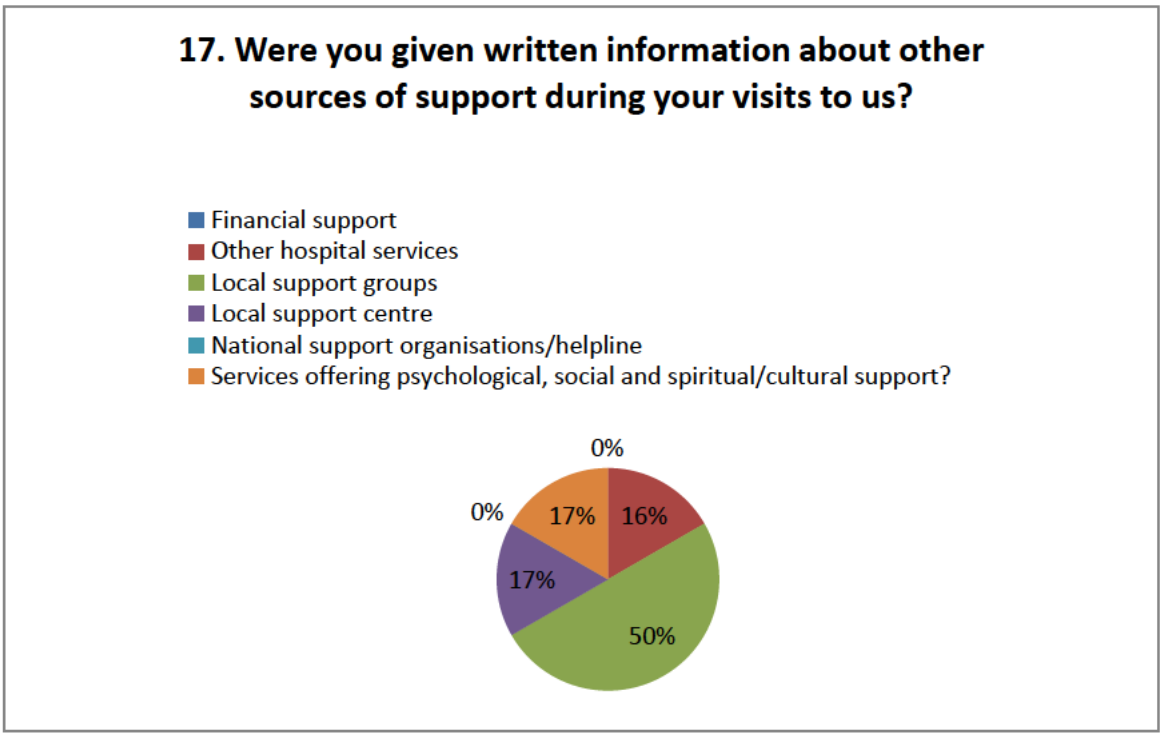
13. Were you given contact details of a clinical nurse specialist/key worker in cae you needed more information and support or had questions about your illness or treatment?

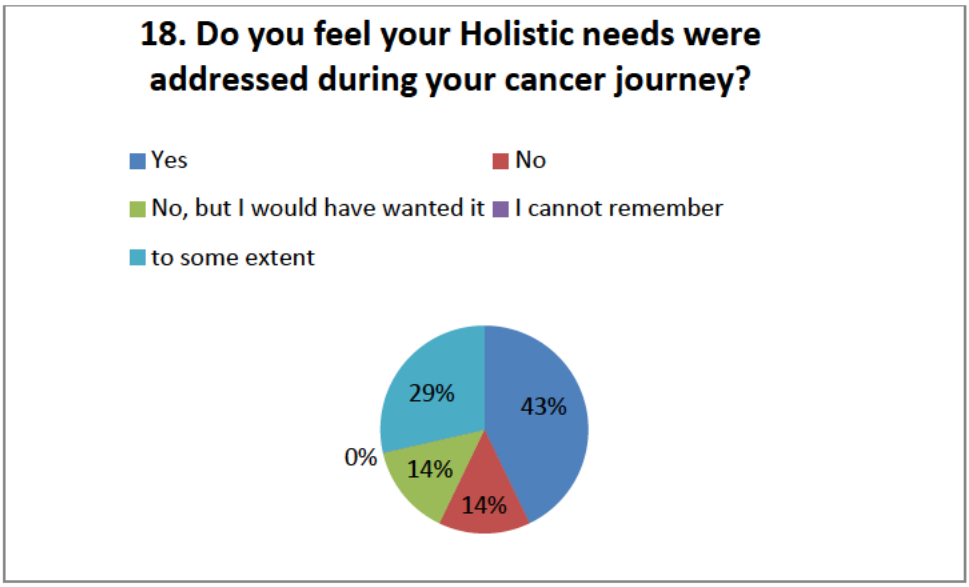


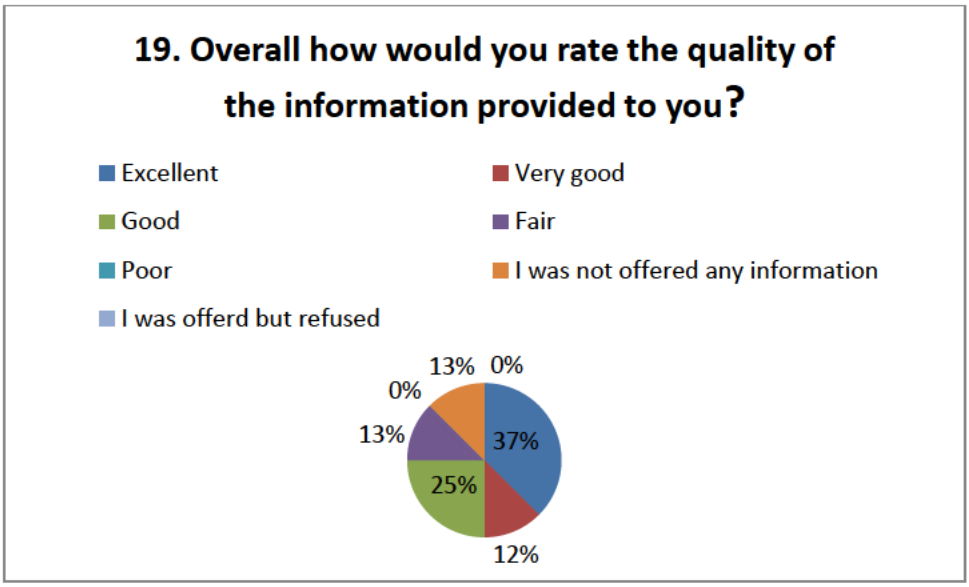


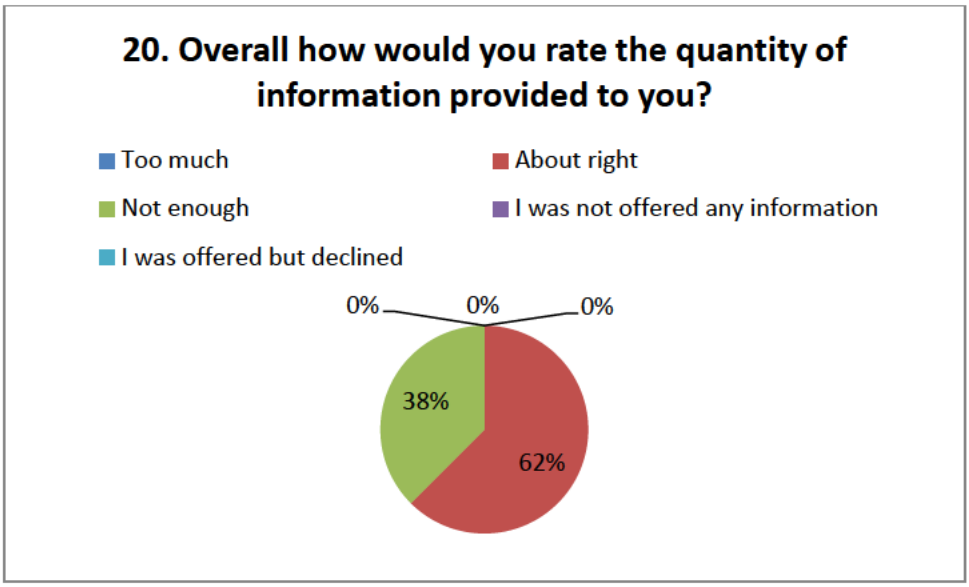


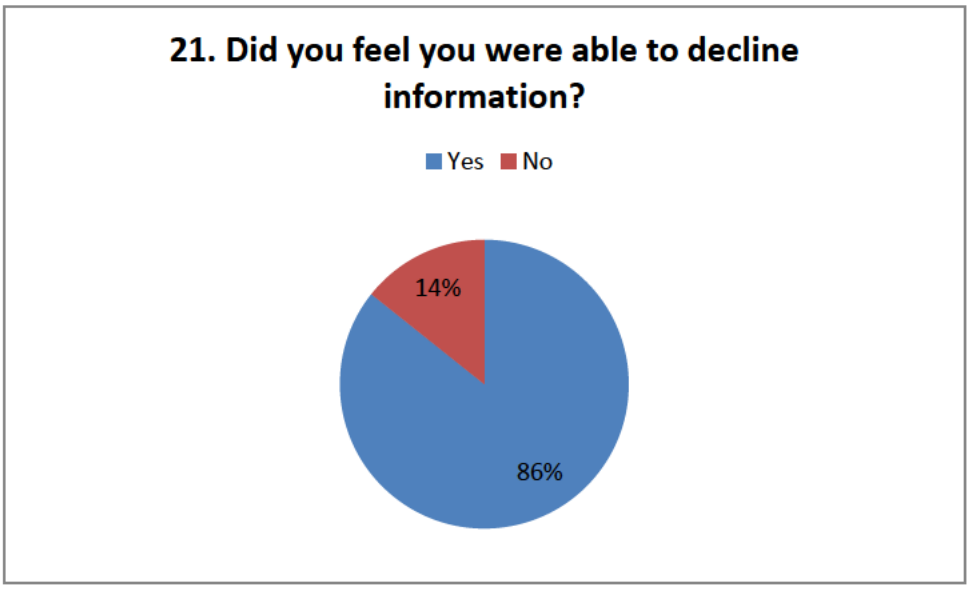












Qualitative Feedback

Was there anything particularly good about the care you received?

- Mr Glackin and his team were excellent throughout the journey, thank you and well done.
- I feel I received good care and when I was diagnosed by the consultant I was treated very quickly and the staffs were very helpful.
- The staff was brilliant in looking after me.
- The treatment from I was red flagged in A&E was quick efficient and positive. Consultants and staff excellent and outcome positive
- Getting all care needed at moment.

Was there anything that could be improved?

- When the machine he was assigned to broke down, sometimes they forgot to put up on board you were left sitting wondering why you weren't called.

- It would have been nice to talk to someone about financial help.

- A&E experience horrendous. 7 hour wait following ambulance admission after collapsing at home with major haematuria; was told again at 4 hours I was next. That took another 3 hours even though my wife explained I was deteriorating. I was left in the minors with a repetitive message on the TV for 7 hours and no seat only a wheelchair if we managed to get.

Any other comments?

- Once seen by a doctor in A&E after 7 hours, care was excellent. Referral and follow up second to none. Only problem was following theatre procedure to diagnosis cancer. I was handed a leaflet in word to read about chemo I just received in theatre; and I didn't even know I had cancer until they give me the leaflet and walked away. I was traumatised as on my own.

- Staff and consultants at Craigavon are very caring and professional.

Appendix 4: Service Improvement Action plan based on patient feedback 2016/17

Area	Lead responsibility	Date	Update
Appointment of two extra nurses to the Thorndale Unit	Martina Corrigan /Kate O'Neill	Dec 2016	Two new clinical sisters have been appointed and will take up post early 2017
Allocation of Clerical staff to the Thorndale Unit	Martina Corrigan	Dec 2016	New clerical staff member appointed to the unit
Allocation of named Key Worker to all newly diagnosed patients	Urology consultants / CNS's	Dec 2016	All newly diagnosed patients are allocated a key worker and contact details provided to the patient along with the core information pack and site specific information
Ensure a Holistic Needs Assessment is completed for all newly diagnosed patients	Kate O'Neill / CNS's	Ongoing	Due to appointment of new staff, work is ongoing to ensure that an assessment is being completed for all newly diagnosed patients
Pilot a Permanent Record of Management for all newly diagnosed patients.	Urology consultants / nurses	Oct-December 2016	Permanent record of management form developed and implemented for 3 months. Patient evaluation to be completed and results shared with Urology team for further consideration.
Pilot a community prostate review clinic	Martina Corrigan / urology team / Mary Haughey	June 2017	Steering group established to take forward community based review clinics for stable prostate cancer patients

Appendix 5: Audit of Communication of Diagnosis to GPs

Standard

One of the local peer review measures outlined by NICaN relates to communication with the patient's GP following the diagnosis of a cancer; the standard states:

"The MDT should have an agreed policy whereby after a patient is given a diagnosis of cancer the patient's general practitioner (GP) is informed of the diagnosis by the end of the follow working day"

Methodology

To test if the MDT is meeting this standard and if GPs are receiving timely information on all patients diagnosed with cancer an audit was carried out. 10 patients from the Southern Trust who were discussed at the MDT held between January and December 2016 were selected at random. The audit was carried out by using the Northern Ireland Electronic Care Record (NIECR) to establish when the patient was given their diagnosis, when the letter was typed and then by phoning the GP practices to establish when the letter was received.

Results

Four GP practices out of 10 received notification of the patient's diagnosis within 1 day. The letters of four of the patients were received by GP Practices within 4-7 days, the letter of one patient was received within 13 days and one patient letter was received within 16 days. Six of the letters were typed on the same day as the patient was given their diagnosis and therefore these would have been available on the NIECR for the GP to view. Two letters were typed within 1 day and two were typed within 4 days.

Time between patient being informed of diagnosis and GP receiving Clinic letter:

	Southern Trust
Shortest time	1 days
Longest time	16 days
Median	6 days

Time between diagnosis given to patient and letter typed:

	Southern Trust
Shortest time	0 days
Longest time	5 days
Median	1 day

Appendix 6: Clinical Trial Activity 2016

UROLOGY CANCER TRIAL ACTIVITY 2016

During the past year urological cancer clinical trial activity in NI has contributed significantly to the overall NICTN portfolio with 20 trials being open to recruitment during this time. In total 1266 participants were recruited into urology cancer studies, with 79 participants being recruited into interventional trials. No Teenage and Young Adult patients were recruited to urology trials in 2016.

Prostate cancer trials continue to dominate urology clinical trial activity with 17 trials recruiting 1160 participants (1055 non-interventional, 75 interventional). Activity in testicular cancer was limited to one open trial; **UKGTC**, a genetic epidemiology study in testicular cancer open at all Cancer Units. This study closed in June 2016, recruiting no patients in the current reporting period. Only one randomised controlled trial was available for patients with renal cell cancer (**STAR**). A further 4 patients were recruited in 2016. One Belfast Trust sponsored study in bladder haematuria (**HaBio**) continued to recruit steadily in Belfast but was extended to recruit patients within the South Eastern and Southern Health and Social Care Trusts due to the exceedingly challenging recruitment target and timeframe set for this study. The study has now closed to recruitment.

Appendix 1 gives recruitment details on a per trial per site basis.

Urological cancer clinical trial activity is still predominantly conducted within the Belfast Cancer Centre, although activity at the Cancer Units is increasing, not only in their role as Patient Identification Centres, but also in supporting full trial activity for studies such as **UKGPC**, **HaBio** and **Life After Prostate Cancer Diagnosis**. At the Cancer Centre, Professor Joe O'Sullivan and Dr Suneil Jain have driven the establishment of an extensive portfolio of prostate cancer clinical trials and following the success of being awarded Movember Centre of Excellence in 2014, activity in this area is set to grow. The portfolio already includes randomised controlled trials of investigational medicinal products, radionuclide and radiotherapy studies, translational biomarker studies and delivers a good balance of commercial, non-commercial and investigator-led studies; however there is now a very real increase in investigator led activity and a number of 'Born in Belfast, Led by Belfast' studies have been developed. These include **ADRRAD**, a trial looking at neo-adjuvant androgen deprivation therapy, pelvic radiotherapy and radium-223 in prostate cancer patients. This study developed by Professor O'Sullivan opened to recruitment in January 2016, and has recruited 21 patients to date (14 in 2016). Recruitment to Dr Jain's **SPORT** feasibility study evaluating stereotactic body radiotherapy in men with high-risk prostate cancer commenced in August 2016 and has recruited 7 patients to date, 5 within this reporting period. A further Belfast led study, **CASPIR** opened in November 2015. This prospective feasibility study assesses calcifications as an alternative to surgically implanted fiducial markers for Prostate Image Guided Radiotherapy and has currently recruited 55 patients. To facilitate the fiducial insertion associated with CASPIR, PACE and SPORT, a dedicated research clinic (the **FAST Clinic)** has been developed using a multidisciplinary approach. Trial patients are now routinely seen at this bimonthly clinic.

The Phase II PARP inhibitor trial **TOPARP** recruited a further two patients in 2016 and remains open to recruitment. The screen failure rate is high with 15 patients screened and found to be ineligible in 2016. The **PROSPER** trial remains open in Belfast and recruited a further 4 patients in 2016, a total of 9 to date. The **PACE** study also continued to recruit patients in the current reporting year, 11 patients entered the trial, bringing the total recruitment to 15. Seven patients were recruited in total to the **BAYER 15396** study before enrolment closed in August 2016. The **Janssen Prostate Study** opened to recruitment in March 2016 and recruited 4 patients before closing in February 2017. The **Life After Prostate Cancer Diagnosis** study, a UK wide questionnaire study opened in April 2016 and recruited 1028 patients regionally. The radiographer led study **TRUFU** opened to recruitment in August and completed enrolment of its target of 30 patients in November.

Several further prostate studies have been presented to the Northern Ireland Cancer Trials Coordinating Committee in 2016 and are currently in set up or are now open. These include:

RE-AKT: A randomised phase II study of Enzalutamide (MDV3100) in combination with AZD5363 in patients with metastatic castration – resistant prostate cancer (PI: Dr S Jain). This study was presented in January 2016 and was initiated in August 2016. The study did not open to recruitment within the reporting period (opened in March 2017) and has not yet recruited to date.

Core: **A randomised trial of conventional care versus radioablation (stereotactic body radiotherapy) for extracranial metastases** (PI: Dr S Jain). This study will recruit patients with breast, prostate and NSCLC primaries. The study was presented in January 2016. Set up has been delayed due to requirements for pulmonary function tests and finalising IRMER requirements, as well as delays in receiving all relevant documents from the coordinating centre.

Add-Aspirin:

A phase III, double blind, placebo controlled, randomised trial assessing the effects of aspirin on disease recurrence and survival after primary therapy in common non-metastatic solid tumours (PI: Professor R Wilson). The Add Aspirin trial was adopted to the portfolio is January 2016 and will recruit across the disease sites of colorectal, prostate, breast and gastro-

oesophageal cancers. R&D approval was granted in September 2016 and study should open to recruitment in June 2017.

TRUFU: **Therapeutic radiographer undertaking follow-up for prostate cancer patients** (PI: Ms Stacey Hetherington). This study was presented in February 2016 and opened to recruitment in August 2016. The target recruitment was met in November and the study closed to recruitment.

GAP 4: **Intense exercise for survival among men with metastatic castrate-resistant prostate cancer (INTERVAL – MCRPC): A multicentre, randomized, controlled phase III study** (PI: Dr S Jain). The study was adopted into the portfolio in April 2016. Submission to R&D has been delayed as the lead site has not yet obtained ethics approval.

Enzalutamide Extension Study:

A phase 2 open-label extension study for subjects with prostate cancer who previously participated in an Enzalutamide clinical study (PI: Professor J O'Sullivan). This study is the extension of two Enzalutamide studies (TERRAIN and AFFIRM) which have now closed. Opening this study will allow patients continue Enzalutamide treatment. The study was presented in November 2016. R&D approval is awaited.

CTC Stop: **Utilising Circulating Tumour Cell (CTC) Counts to optimize systemic therapy of metastatic prostate cancer** (PI: Dr S Jain). This study was presented by Dr Jain in November. The study has been submitted to Research Governance and approval is awaited.

ARASENS Bayer 17777:

A randomized, double-blind, placebo-controlled Phase III study of ODM-201 versus placebo in addition to standard androgen deprivation therapy and docetaxel in patients with metastatic hormone-sensitive prostate cancer (PI:

Professor Joe O'Sullivan). This study was presented in November 2016 and is currently with Research Governance for approval.

MADCAP: **A phase I/randomised phase II trial of abiraterone acetate with or without RO5503781 in patients with metastatic castrate resistant prostate cancer (mCRPC) who have not previously received docetaxel** (PI: Dr V Coyle). Although presented in 2013 significant delays encountered with the sponsor has resulted in the local decision to only open the phase II component of this study in late 2016, however phase II of this study is no longer proceeding.

Appendix 1: PROSTATE STUDIES OPEN TO RECRUITMENT 2016

Trial	Principal Investigator	Site	Open to recruit.	Close to recruit.	Target	Total recruited (31/05/17)	% of Target	Recruit. 2016	Project status
RADIATION BIOMARKER STUDY	**A Study Examining Serum Biomarkers Of DNA And Tissue Damage In Patients Undergoing Radical Radiotherapy For Prostate Cancer**								
	O'Sullivan, Prof Joe	BHSCT	01/11/2011	01/11/2016	50	39	78%	1	Suspended
RADICALS (MRC PR10)	**Radiotherapy and Androgen Deprivation In Combination After Local Surgery - A RCT in prostate Cancer**								
	O'Sullivan, Prof Joe	BHSCT	26/11/2009	30/06/2016	5 per year	27	84%	0	Open
RAPPER	**Radiogenomics: assessment of polymorphisms for predicting the effects of radiotherapy**								
	O'Sullivan, Prof Joe	BHSCT	03/06/2011	31/08/2018	15-20 per annum	141	101%	3	Open
	Mitchell, Dr Darren	WHSCT - patient identification and consent only				13	N/A	0	Open
STAMPEDE	**Systemic Therapy in Advancing or Metastatic Prostate Cancer: Evaluation of Drug Efficacy**								
	O'Sullivan, Prof Joe	BHSCT	16/12/2005	01/01/2017	Original Target 50 (now 200)	191	95%	5	Open
UKGPC	**UK Genetic Prostate Cancer Study (formerly Familial Prostate Cancer Study)**								
	O'Sullivan, Prof Joe	BHSCT	27/10/2006	31/12/2017	240	211	88%	5	Open
	Harney, Dr Jackie	SEHSCT	02/03/2009		NK	17	NK	9	Open
	Carser, Dr Judith	SHSCT	21/01/2009		NK	50	NK	4	Open
	McAleese, Dr Jonathan	NHSCT	25/11/2013		NK	25	NK	1	Open
	Mitchell, Dr Darren	WHSCT	22/03/2008		NK	50	NK	4	Open
PROMPTS	**Prospective randomised phase III study of observation versus screening MRI and pre-emptive treatment in castrate resistant prostate cancer patients with spinal metastasis**								
	Jain, Dr Suneil	BHSCT	30/05/2014	02/05/2017	21	7	33%	1	Closed
	Mitchell, Dr Darren	WHSCT - patient identification and consent only				0	0	0	

Trial	Principal Investigator	Site	Open to recruit.	Close to recruit.	Target	Total recruited (31/05/17)	% of Target	Recruit. 2016	Project status
TOPARP	**Phase II Trial of Olaparib in Patients with Advanced Castration Resistant Prostate Cancer**								
	Jain, Dr Suneil	BHSCT	09/04/14	28/2/2017	15	4	20%	2	Open
PROSPER	**A multinational, phase 3, randomized, double-blind, placebo-controlled, efficacy and safety study of Enzalutamide in patients with non-metastatic castration-resistant prostate cancer**								
	Jain, Dr Suneil	BHSCT	27/08/2014	31/12/2018	10	9	90%	4	Open
BUSTIN	**A randomised trial comparing 2 bladder filling instruction sheets in achieving bladder volume consistency using an ultrasonic bladder scan device and biomarker analysis during intensity modulated prostate radiotherapy**								
	Hynds, Mrs Sharon	BHSCT	05/11/2012	24/12/2018	100	45	45%	0	Open
BAYER 15396	**A phase III randomized, double-blind, placebo-controlled trial of radium-223 dichloride in combination with abiraterone acetate and prednisone/prednisolone in the treatment of asymptomatic or mildly symptomatic chemotherapy-naïve subjects with bone predominant metastatic castration-resistant prostate cancer (CRPC)**								
	O'Sullivan, Prof Joe	BHSCT	14/07/2015	22/08/2016	10	7	10%	3	Closed - in FU
PACE	**PACE - International Randomized Study of Laparoscopic Prostatectomy vs Robotic Radiosurgery and Conventionally Fractionated Radiotherapy vs Radiosurgery for Early Stage Organ-Confined Prostate Cancer**								
	Jain, Dr Suneil	BHSCT	22/10/2015	01/09/2016	20	15	75%	11	Open
CASPIR	**Calcifications as an alternative to surgically implanted fiducial markers for Prostate Image guided Radiotherapy: A prospective feasibility study**								
	O'Sullivan, Prof Joe	BHSCT	20/11/2015	30/10/17	90	55	61%	26	Open
ADRRAD	**Neo-adjuvant Androgen Deprivation Therapy, Pelvic Radiation and RADium-23 for new presentation of T1-4 N0/1 M1B adenocarcinoma of prostate (ADRRAD Trial)**								
	O'Sullivan, Prof Joe	BHSCT	21/01/2016	31/07/2017	30	21	70%	14	Open
SPORT	**A Randomised Feasibility Study Evaluating Stereotactic PrOstate RadioTherapy in High-Risk Localised Prostate Cancer with or without Elective Nodal Irradiation (SPORT High-Risk Trial)**								
	Jain, Dr Suneil	BHSCT	18/01/2016	18/01/2018	30	7	23%	5	Open

Trial	Principal Investigator	Site	Open to recruit.	Close to recruit.	Target	Total recruited (31/5/17)	% of Target	Recruit. 2016	Project status
Janssen Prostate Study	**A Phase 3 Randomized, Placebo-controlled Double-blind Study of JNJ-56021927 in Combination with Abiraterone Acetate and Prednisone Versus Abiraterone Acetate and Prednisone in Subjects with Chemotherapy-naive Metastatic Castration-resistant Prostate Cancer (mCRPC)**								
	Jain, Dr Suneil	BHSCT	08/03/2016	11/02/2017	10	4	40%	4	Closed – in FU
LAPCD	**Life After Prostate Cancer Diagnosis**								
	Mitchell, Dr Darren	BHSCT	22/04/2016	31/12/2018	4000	1028	171%	1028	Closed
	McAleese, Dr Jonathan	NHSCT							
	Harney, Dr Jacqui	SEHSCT							
	Glackin, Dr Anthony	SHSCT							
TRUFU	**Therapeutic Radiographer undertaking Follow-Up for Prostate Cancer Patients**								
	Hetherington, Stacey	BHSCT	22/06/2016	03/11/2016	30	30	100%	30	Closed

TESTICULAR

Trial	Principal Investigator	Site	Open to recruit.	Close to recruit.	Target	Total recruited (31/5/17)	% of Target	Recruit. 2016	Project status
UKGTC	**Identification of testicular germ cell tumour susceptibility genes**								
	Dr Olabode Oladipo	BHSCT	19/01/2010	01/06/2016	500	334	67%	0	Closed

RENAL

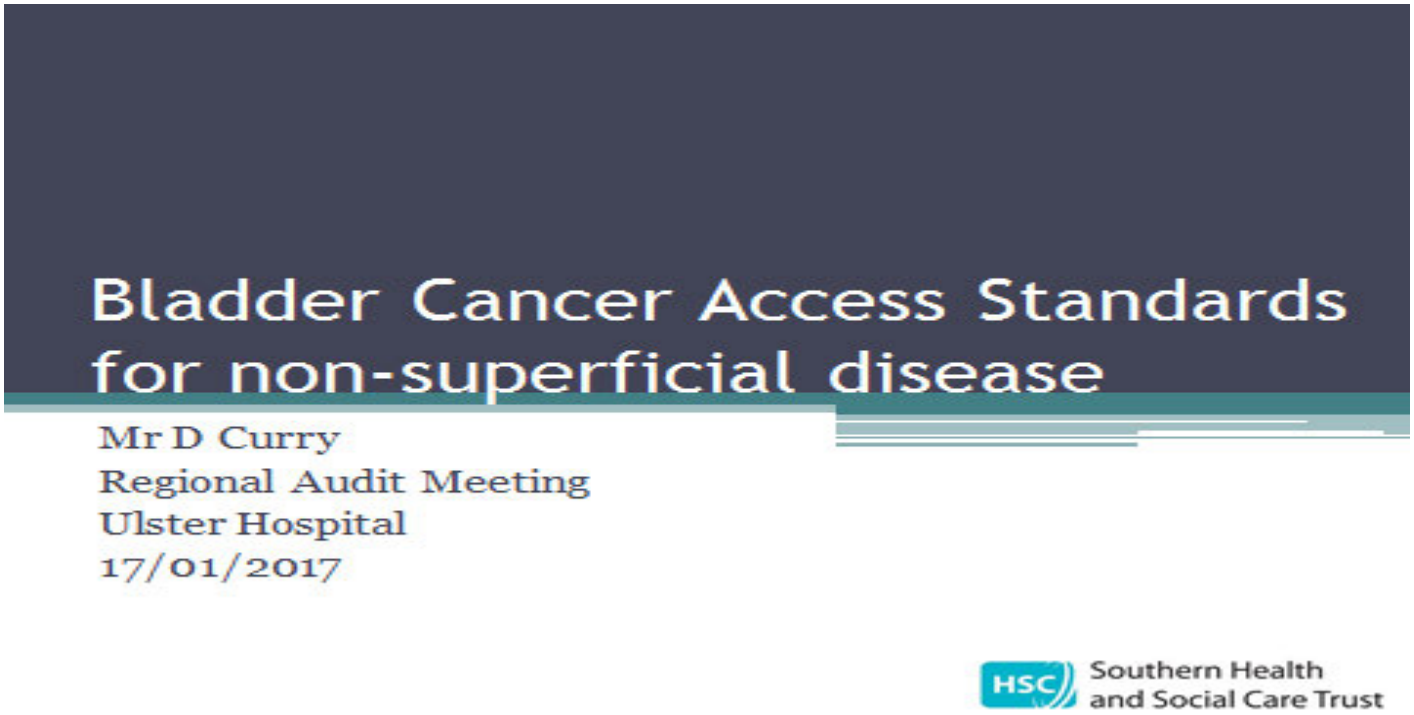
Trial	Principal Investigator	Site	Open to recruit.	Close to recruit.	Target	Total recruited (31/5/17)	% of Target	Recruit. 2016	Project status
STAR	**A randomised multi-stage phase II/III trial of Sunitinib comparing temporary cessation with allowing continuation, at the time of maximal radiological response, in the first-line treatment of locally advanced and/or metastatic renal cancer**								
	Clayton, Dr Alison	BHSCT	30/08/2013	03/04/2018	72	13	18%	4	Open

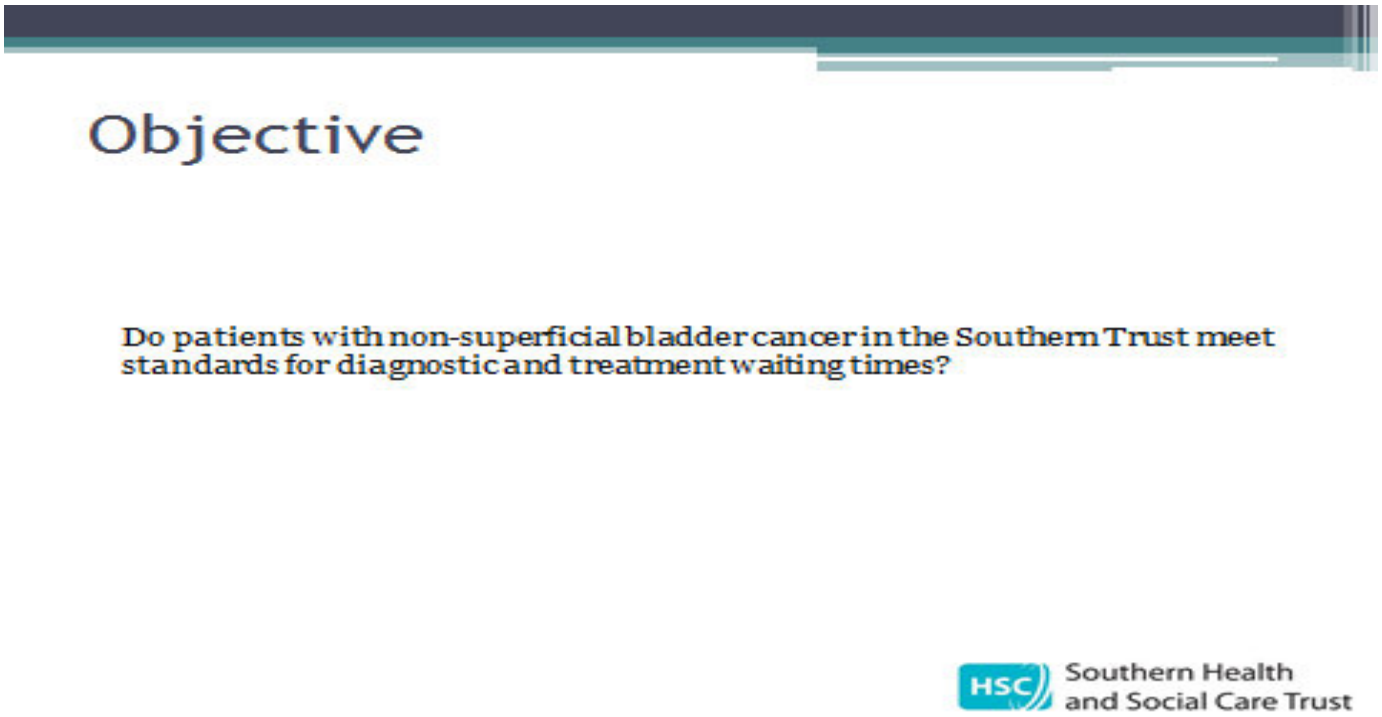
BLADDER

Trial	Principal Investigator	Site	Open to recruit.	Close to recruit.	Target	Total recruited (31/5/17)	% of Target	Recruit. 2016	Project status
HaBio	**Haematuria Biomarker Study**								
	O'Kane, Dr Huge	BHSCT	10/10/2012	30/06/2016	333 pts 666 cont.	585	66%	78	Closed – in FU
	Duggan, Dr Brian	SEHSCT	02/06/2014			75		12	
	Glackin, Mr Anthony	SHSCT	NK			17		12	

Appendix 7 AUDITS

7.1 Audit on Bladder Cancer Access Standards for non-superficial disease





Standards - NICE

Bladder cancer

1.6.4 Refer people using a suspected cancer pathway referral [for an appointment within 2 weeks] for bladder cancer if they are:

- aged 45 and over and have:
  - unexplained visible haematuria without urinary tract infection **or**
  - visible haematuria that persists or recurs after successful treatment of urinary tract infection, **or**
- aged 60 and over and have unexplained non-visible haematuria **and** either dysuria or a raised white cell count on a blood test. **[new 2015]**

1.6.5 Consider non-urgent referral for bladder cancer in people aged 60 and over with recurrent or persistent unexplained urinary tract infection. **[new 2015]**

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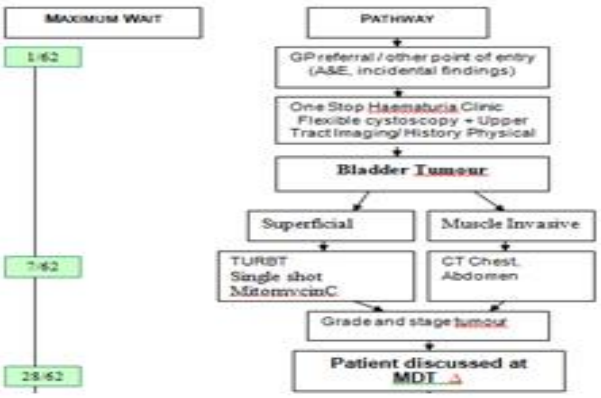
Standards -NICaN - CAH



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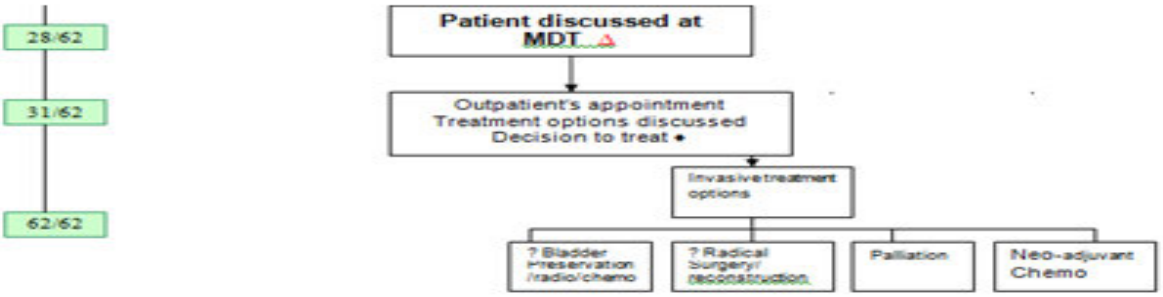
Standards - NICaN - CAH/BCH



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Standard 1-Red Flag Referral n=18

1.6.4 Refer people using a suspected cancer pathway referral (for an appointment within 2 weeks) for bladder cancer if they are:

- 18/25 Patients triaged red flag
- Median Time from ref to 1st review – 16 days (IQR 14-17)
- 7/18 (38.9%) seen within 14 days
- 14/18 (77.8%) seen within 21 days
- Longest 42 days – however appointment at 25 days cancelled by patient

- NHS England target is 93%

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Materials and Methods

- Review of all bladder cancer patients through MDT Aug 2015 –Aug 2016
- Retrospective review of electronic records.
- 82 bladder cancer patients through MDT
- 25 (30.5%) had MIBC or required tertiary referral

- Mean age 76 (Range 56-90)
- 10 Female/ 15 Male

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Results - Demographics

- 25 (30.5%) had MIBC or required tertiary referral
  - Small cell carcinoma - 2 (8%)
  - Lymphoma - 1 (4%)
  - Squamous Cell Carcinoma - 3 (12%)
  - Transitional Cell Carcinoma – 19 (76%)
    - 2 BCG Refractory/ 17MIBC
- Referral Pathways
  - Emergency - 4 (16%)
  - Red Flag – 18 (72%)
  - Routine – 1 (4%)
  - Upstaged – 2 (85)

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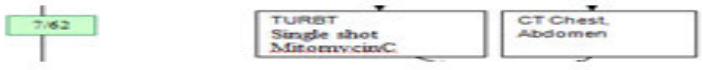
Standard 1-Red Flag Referral n=18

1.6.4 Refer people using a suspected cancer pathway referral (for an appointment within 2 weeks) for bladder cancer if they are:

- 18/25 Patients triaged red flag
- Median Time from ref to 1st review – 16 days (IQR 14-17)
- 7/18 (38.9%) seen within 14 days
- 14/18 (77.8%) seen within 21 days
- Longest 42 days – however appointment at 25 days cancelled by patient
- NHS England target is 93%

HSC Southern Health and Social Care Trust

Standard 2 n=18



- Cystoscopy to TURBT
  - Median Time 23 days (IQR 13-32)
  - 2/18 (11%) within 7days
  - 10/18 (55.6%) >21 days

HSC Southern Health and Social Care Trust

Standard 3 n=22

- **Referral to MDT**
  - Median time 37days (IQR 31-56)
  - 5/22 (22.7%) within 28 days
  - 6/22 (27.3%) >56 days
- **TURBT to MDT**
  - Median Time -10 days (IQR 8-13)

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Standard 4 -

- **MDT to Results (n=21)**
  - Median Time 12 days (IQR 5-25)
  - 6/21 (28.6%) seen within 3 (working) days
  - 9/21 (42.9%) seen with 7 days
- **Referral to Results (n=22)**
  - Median Time 54 days (IQR 37-63days)
  - 5/22 (22.7%) within 31 days

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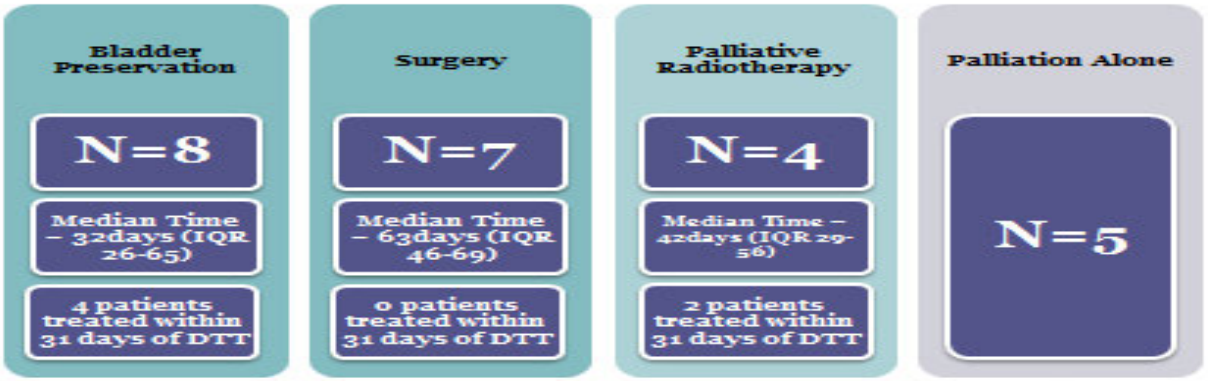
Standard 5 -

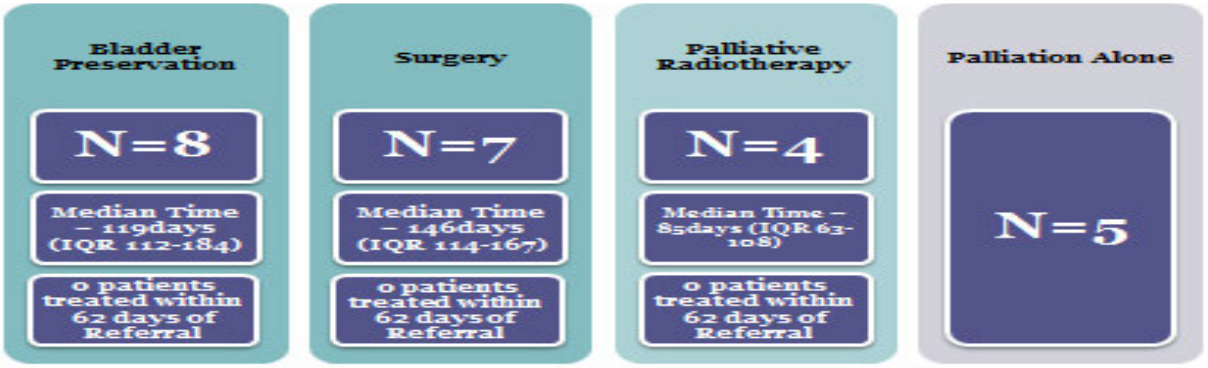
Decision to Treat (DTT) to Intervention – 31days



HSC Southern Health and Social Care Trust

Standard 6 -

Referral to Definitive Treatment – 62days



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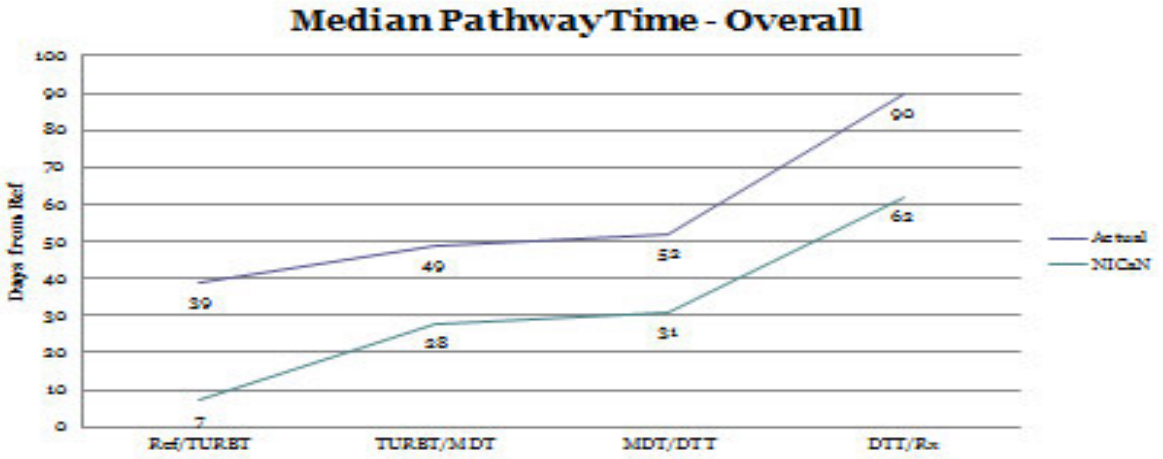
Overall Pathway



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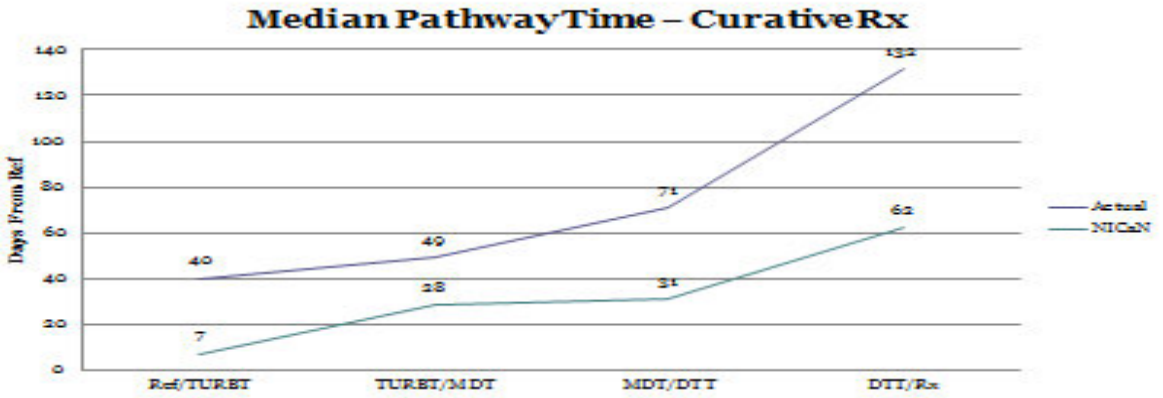
Pathway for Curative Rx



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TURBT to Radical Therapy

J Urol. 2003 Jan;169(1):110-5; discussion 115.

An interval longer than 12 weeks between the diagnosis of muscle invasion and cystectomy is associated with worse outcome in bladder carcinoma.

Sánchez-Ortiz RF[1], Huang WC, Mick R, Van Arsdalen KN, Wein AJ, Malkowicz SB.

J Urol. 2003 Oct;170(4 Pt 1):1085-7.

Delaying radical cystectomy for muscle invasive bladder cancer results in worse pathological stage.

Chang SS[1], Hassan JM, Cookson MS, Wells N, Smith JA Jr.

- Radiotherapy (n=6)
  - Median 107 days (IQR 87-131)
  - 67% >90days
- Surgery (n=7)
  - Median 89 days (IQR 79-110)
  - 42.8% >90days

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Summary

- Failure to meet NICE/NICaN access standards
  - Red flag Cystoscopy
  - Initial TURBT
  - MDT to DTT
  - DTT to Treatment
- Improvements?
  - Fast cystoscopy access
  - Dedicated pooled red flag GA lists/slots
  - Results - clinic timing and ref pathway
  - Regional discussion

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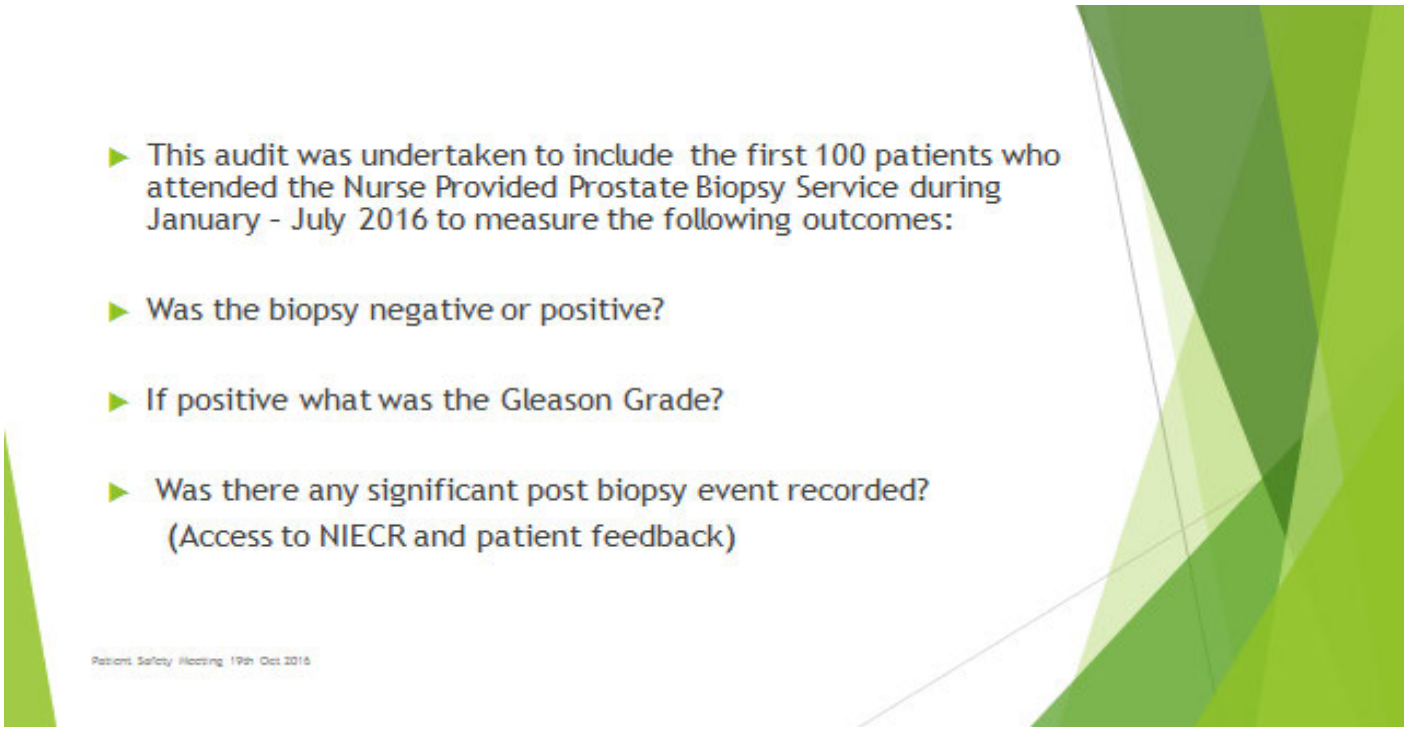
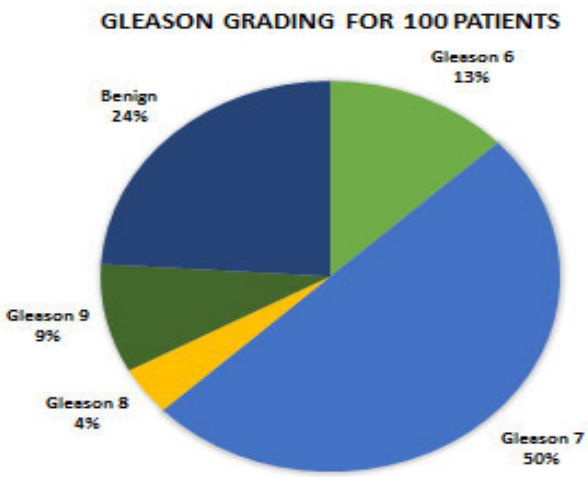
7.2 Audit of Nurse Provided TRUS Biopsy Service 2016





Patient Safety Meeting 19th Oct 2016

Significant Post Biopsy Events

- **Attendance at Out Of Hours services**
  - 1 x Day 1 attendance with Retention of Urine (successful TROC followed)
  - 1 x Day 6 attendance with Dysuria (antibiotic prescribed)
- **Attendance at Emergency Department**
  - 1 x Day 8 attendance with UTI (antibiotic prescribed)
- **Admission to Hospital**
  - 1 x admission on the day with Bradycardia (Pacemaker inserted that PM)
  - 1 x admission Day 1 post biopsy with Pyrexia (Treated with IV antibiotics for 4 days. Negative Blood Cultures, no evidence of MSSU collected)

Patient Safety Meeting 19th Oct 2016

Biopsies Performed By Colleagues

(During same period Jan - July 2016)

Name	TRUS	GA- Biopsy	Total
Mr Glackin	10	7	17
Mr Haynes	11	2	13
Mr O' Donoghue	11	2	13
Mr Suresh	18	2	20
Radiology	31	0	31
Overall Total			94

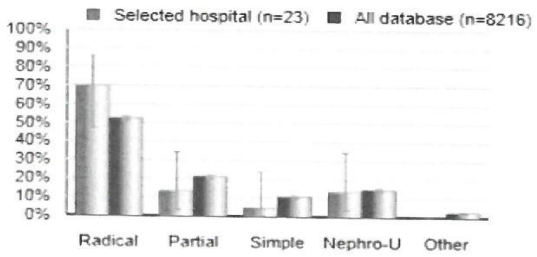
Patient Safety Meeting 19th Oct 2016

7.3 BAUS Data and Audit System

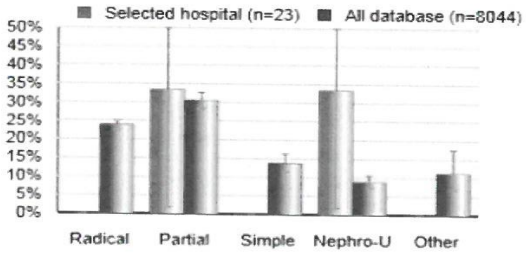
BAUS Data and Audit System

Nephrectomy dashboard
All the data for Craigavon Area Hospital, Portadown
Period between 01 January 2016 and 31 December 2016

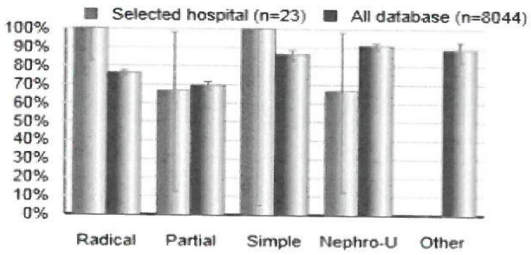
Kind of nephrectomy



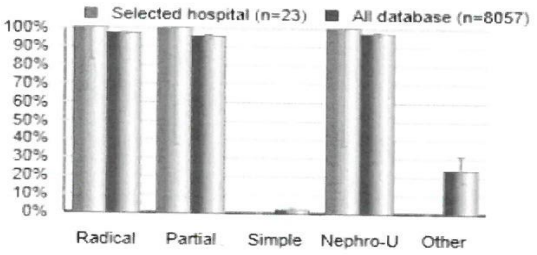
Open approach used



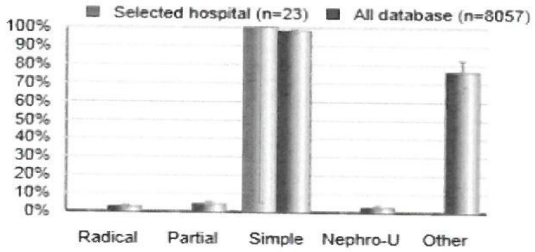
Use of minimally invasive surgery



Malignant diagnosis



Non-malignant diagnosis



Network	NICaN
Trust	Southern Health and Social Care Trust
MDT	Urology
MDT Lead Clinician	Anthony Glackin
Date	21st September 2017

Key Themes
Please provide comments including details of strengths, areas for development and overall effectiveness of the team. Any specific issues of concern or good practice should also be noted in the following sections. It is important to demonstrate any measurable change in performance compared to previous assessments.

Structure and function of the service
Comment in relation to leadership, membership, attendance and meeting arrangements, operational policies and workload.

The Urology MDT is held every Thursday from 2.15pm, with the exception of public holidays. There are video-conferencing facilities to Belfast Cancer Centre. Mr Anthony Glackin, Consultant Urologist, is the Lead Clinician of the MDT.
The Urology MDT is a well-structured MDT. Overall weekly attendance is good, however on some occasions this can be difficult due to competing demands.

The greatest challenge for the MDT during the past year has been the inadequacy of the availability of a clinical oncologist and or a radiologist at all MDMs. The inadequacy in both cases has essentially been due to the inability to recruit adequate numbers of clinical oncologists and radiologists to the post where they are required. The inadequacies have been escalated to trust senior management team and are being addressed with the appointment authorities.

With increasing numbers of consultant urologists, the functions of Lead Clinician and of Chair of MDM have been separated to enhance active participation in and responsibility for MDM. The Chair of each MDM will have been decided when scheduling takes place at least one month previously. Scheduling has also ensured that time is allocated to the appointed Chair to preview in detail each Wednesday all of the cases to be discussed at MDM the following day. All of the required clinical summaries, results and reports of investigations will have been provided to the appointed Chair for preview. It also enables all multidisciplinary participants to preview cases and to prepare their contributions to the discussion of cases. This provision has greatly enhanced the quality of scrutiny and preparation for discussion of each case.

The quality of the conduct of MDM has been a singular achievement these past six years. The quality of participation has been enhanced by increasing the number of persons chairing, and by having time allocated for preview.

There had been a 40% increase in the number of Red Flag referrals throughout Northern Ireland during the past few years, up from 2902 in 2013 to 4761 in 2015/16. The greatest increase was to the Southern Trust, with an increase of 84% from 410

in 2013 to 753 in 2014. The increase has continued and in 2016 there were 1878 red flag referrals.

For 2016, the 31 day performance for the SHSCT was 100% and the 62 day performance was 81% - this reflects the marked increase in GP red flag referrals for the trust.

The diagnostic and operative activity has been reflected in an increase in the numbers of specimens received by the Cellular Pathology Laboratory at Craigavon Area Hospital. Tissue specimens increased from 874 in 2014 to 903 in 2016.

It is notable that there has been an increase in the numbers of Prostate biopsies which reflects the use of MRI to avoid unnecessary TRUS biopsy.

Progress is ongoing in relation to the full implementation of the Key Worker, Holistic Needs Assessments, Communication and ensuring all patients are offered a Permanent Record of Patient Management. With the appointment of two more Nurses to the Thorndale Unit and Clerical Staff, all newly diagnosed patients have a Key Worker appointed, a Holistic Needs Assessment conducted, adequate communication and information, advice and support given, and all recorded in a Permanent Record of Patient Management which will be shared and filed in a timely manner. It is intended that patients newly diagnosed as inpatients will also be included.

Coordination of care/patient pathways
Comment on coordination and patient centred pathways of care, network guidelines and communication.

The MDT adheres to the regional Urology Clinical Reference Group guidelines & patient pathways and these have been agreed at an MDT meeting. There are clear pathways in place for the management of Urology cancers. The network has agreed a pathway for the management of Teenage and Young Adult (TYA) cancer patients. When TYA's are discussed at MDM, the cancer tracker will inform the Trust TYA nurse who will ensure appropriate onward support / referral to the TYA regional service.

Patient experience
Comment on patient experience and gaining feedback on patients' experience, communication with and information for patients and other patient support initiatives.

Patient feedback and experience is very important in planning service development. Patients' views are taken on board through compliments, complaints and feedback through patient surveys. These are considered by the MDT to identify areas for improvement.

A regional cancer patient experience survey (NICPES) was carried out during 2015. 17% of the Southern Trust respondents were from Urology cancer patients. The majority of patients (90%) rated their care as excellent/very good.

A local patient survey was also undertaken in 2016. Response rates were overall complimentary of the service provided. Staff were said to be caring towards patients, giving sensitive but clear explanations of diagnosis and treatment. Verbal information was reinforced by written materials and patients were given adequate time and opportunity to ask questions. Results of the survey have been reviewed and discussed at an operational meeting and an action plan developed to address areas of weakness.

Patients are offered information by appropriate staff in a phased manner relevant to the stage of their journey. An MDT patient information leaflet has been developed and is provided to all patients along with core and site specific information.

For patients with sensory, cognitive or language difficulties bespoke information can be arranged via the Macmillan Health & Wellbeing Manager.
Additionally a regional interpreting service is offered with trained health related interpreters. The Trust also has a contract with the 24 hour telephone interpreting service to ensure that patients have support in the planned or emergency situation. For teenager and young adults, additional support is provided through the Regional Teenager and Young Adult (TYA) service, and appropriate information leaflets are available.

Clinical outcomes/indicators
Where available the data from the clinical indicators should be used. You should comment on the top five clinical priority issues for your team.

The urology MDT holds an annual business meeting to discuss the MDT workload over the previous 12 months. The figures are presented.

At this meeting audit activity is reviewed and suggestions made for future audit activity. There were two audits presented in the past year and data was also submitted to the British Association of Urological Surgeons (BAUS) Data and Audit database:

-Audit on Bladder Cancer Access Standards for non-superficial disease, Mr David Curry, 2016
-Audit of Nurse Provided TRUS Biopsy Service in 2016, Sr Kate O'Neill
-Nephrectomy dashboard - data submitted to the British Association of Urological Surgeons (BAUS) Data and Audit database in 2016

Good Practice/Significant Achievements
Identify any areas of good practice.

Trust Excellence Award to the Thorndale unit

Increased consultant capacity to meet 31 and 62 day targets

Four new clinics per week to provide equitable access to all Red flag referrals.

Appointment of two additional nurses and clerical staff to the unit

Allocation of named key worker to all newly diagnosed patients

Implementation of holistic needs assessment for all newly diagnosed patients

Development of permanent record of patient management

New MDT patient leaflet developed and provided to all patients

Specify Immediate Risks

Refer to the guidance on identifying concerns.

An "Immediate Risk" is an issue that is likely to result in significant harm to patients or staff or have a direct serious adverse impact on clinical outcomes and therefore requires immediate action.

Specify Serious Concerns

A "Serious Concern" is an issue that, whilst not presenting an immediate risk to patient or staff safety, is likely to seriously compromise the quality of patient care, and therefore requires urgent action to resolve.

Update on serious concerns highlighted from peer review assessment 2016:

Single handed radiologist with no cover arrangements in place **– Update**: this is still ongoing - radiology cover is a regional issue.

Only 11% of MDT meetings quorate due to low clinical oncology representation and lack of radiology cover **– Update:** arrangements have been made with Belfast Trust to ensure clinical oncology representation at MDT meetings.

Wait for routine referrals: **Update**: all referrals are triaged by consultants and may be upgraded to red flag or urgent which will reduce risk to patients

Nephron sparing surgery being undertaken locally **– Update:** this is no longer happening as Mr Mark Haynes is providing support to undertake nephron sparing surgery in Belfast City Hospital

Concerns

A concern is an issue that is affecting the delivery or quality of the service that does not require immediate action, but can be addressed through the work programmes of the services.

Highest percentage increase in red flag referrals across the region

Operating theatre capacity and operator time

Summary of the validation process
Describe how the process was undertaken..

A working group was established to examine documentation. The group consisted of Urology Clinical Lead, Urology Clinical Nurse Specialist, Head of Service & Service Improvement Lead. At regular intervals the documentation was circulated to MDT members for review and comments. Feedback was received and documents were adjusted accordingly. The Self-assessment was carried out by the Clinical Lead for the Upper GI MDT, the UGI Nurse Specialist, the Head of Service and a Lay reviewer, who also reviewed the patient information evidence.

Organisational Statement		
	Name & Role	Date
MDT lead agrees this is an honest and accurate assessment	Anthony Glackin MDT Lead Clinician	21st September 2017
Agreed by CEO representative		

Health and Social Care Board

Procedure for the Reporting and Follow up of Serious Adverse Incidents

November 2016
Version 1.1

CONTENTS

SECTION TWO - APPENDICES

SECTION THREE - ADDENDUM

FOREWORD

Commissioners and Providers of health and social care want to ensure that when a serious event or incident occurs, there is a systematic process in place for safeguarding services users, staff, and members of the public, as well as property, resources and reputation.

One of the building blocks for doing this is a clear, regionally agreed approach to the reporting, management, follow-up and learning from serious adverse incidents (SAIs). Working in conjunction with other Health and Social Care (HSC) organisations, this procedure was developed to provide a system-wide perspective on serious incidents occurring within the HSC and Special Agencies and also takes account of the independent sector where it provides services on behalf of the HSC.

The procedure seeks to provide a consistent approach to:

- what constitutes a serious adverse incident;
- clarifying the roles, responsibilities and processes relating to the reporting, reviewing, dissemination and implementation of learning;
- fulfilling statutory and regulatory requirements;
- tools and resources that support good practice.

Our aim is to work toward clearer, consistent governance arrangements for reporting and learning from the most serious incidents; supporting preventative measures and reducing the risk of serious harm to service users.

The implementation of this procedure will support governance at a local level within individual organisations and will also improve existing regional governance and risk management arrangements by continuing to facilitate openness, trust, continuous learning and ultimately service improvement.

This procedure will remain under continuous review.

Valerie Watts
Chief Executive

SECTION ONE - PROCEDURE

1.0 BACKGROUND

Circular HSS (PPM) 06/04 introduced interim guidance on the reporting and follow-up on serious adverse incidents (SAIs). Its purpose was to provide guidance for HPSS organisations and special agencies on the reporting and management of SAIs and near misses.

http://webarchive.proni.gov.uk/20120830142323/http://www.dhsspsni.gov.uk/hss(ppm)06-04.pdf

Circular HSS (PPM) 05/05 provided an update on safety issues; to underline the need for HPSS organisations to report SAIs and near misses to the DHSSPS in line with Circular HSS (PPM) 06/04.

http://webarchive.proni.gov.uk/20120830142323/http://www.dhsspsni.gov.uk/hssppm05-05.pdf

Circular HSS (PPM) 02/2006 drew attention to certain aspects of the reporting of SAIs which needed to be managed more effectively. It notified respective organisations of changes in the way SAIs should be reported in the future and provided a revised report pro forma. It also clarified the processes DHSSPS had put in place to consider SAIs notified to it, outlining the feedback that would then be made to the wider HPSS.

http://webarchive.proni.gov.uk/20120830142323/http://www.dhsspsni.gov.uk/qpi_adverse_incidents_circular.pdf

In March 2006, DHSSPS introduced Safety First: A Framework for Sustainable Improvement in the HPSS. The aim of this document was to draw together key themes to promote service user safety in the HPSS. Its purpose was to build on existing systems and good practice so as to bring about a clear and consistent DHSSPS policy and action plan.

http://webarchive.proni.gov.uk/20120830142323/http://www.dhsspsni.gov.uk/safety_first_-_a_framework_for_sustainable_improvement_on_the_hpss-2.pdf

The Health and Personal Social Services (Quality Improvement and Regulation) (Northern Ireland) Order 2003 imposed a 'statutory duty of quality' on HPSS Boards and Trusts. To support this legal responsibility, the Quality Standards for Health and Social Care were issued by DHSSPS in March 2006.

www.health-ni.gov.uk/publications/quality-standards-health-and-social-care-documents

Circular HSC (SQS) 19/2007 advised of refinements to DHSSPS SAI system and of changes which would be put in place from April 2007, to promote learning from SAIs and reduce any unnecessary duplication of paperwork for organisations. It also clarified arrangements for the reporting of breaches of patients waiting in excess of 12 hours in emergency care departments.

http://webarchive.proni.gov.uk/20120830142323/http://www.dhsspsni.gov.uk/hss__sqsd__19-07.pdf

Under the Provisions of Articles 86(2) of the Mental Health (NI) Order 1986, the Regulation & Quality Improvement Authority (RQIA) has a duty to make inquiry into any

case where it appears to the Authority that there may be amongst other things, ill treatment or deficiency in care or treatment. Guidance in relation to reporting requirements under the above Order previously issued in April 2000 was reviewed, updated and re-issued in August 2007. (Note: Functions of the previous Mental Health Commission transferred to RQIA on 1 April 2009).

http://webarchive.proni.gov.uk/20101215075727/http://www.dhsspsni.gov.uk/print/utec_guidance_august_2007.pdf

Circular HSC (SQSD) 22/2009 provided specific guidance on initial changes to the operation of the system of SAI reporting arrangements during 2009/10. The immediate changes were to lead to a reduction in the number of SAIs that were required to be reported to DHSSPS. It also advised organisations that a further circular would be issued giving details about the next stage in the phased implementation which would be put in place to manage the transition from the DHSSPS SAI reporting system, through its cessation and to the establishment of the RAIL system.

https://www.health-ni.gov.uk/sites/default/files/publications/dhssps/HSC%20%28SQSD%29%2022-09.pdf

Circular HSC (SQSC) 08/2010, issued in April 2010, provided guidance on the transfer of SAI reporting arrangements from the Department to the HSC Board, working in partnership with the Public Health Agency. It also provided guidance on the revised incident reporting roles and responsibilities of HSC Trusts, Family Practitioner Services, the Health & Social Care (HSC) Board and Public Health Agency (PHA), the extended remit of the Regulation & Quality Improvement Authority (RQIA), and the Department.

https://www.health-ni.gov.uk/sites/default/files/publications/dhssps/HSC%20%28SQSD%29%2008-10.pdf

Circular HSC (SQSD) 10/2010 advises on the operation of an Early Alert System, the arrangements to manage the transfer of Serious Adverse Incident (SAI) reporting arrangements from the Department to the HSC Board, working in partnership with the Public Health Agency and the incident reporting roles and responsibilities of Trusts, family practitioner services, the new regional organisations, the Health & Social Care (HSC) Board and Public Health Agency (PHA), and the extended remit of the Regulation & Quality Improvement Authority (RQIA).

https://www.health-ni.gov.uk/sites/default/files/publications/dhssps/HSC%20%28SQSD%29%2010-10.pdf

In May 2010 the Director of Social Care and Children HSCB issued guidance on 'Untoward Events relating to Children in Need and Looked After Children' to HSC Trusts. This guidance clarified the arrangements for the reporting of events, aligned to delegated statutory functions and Departmental Guidance, which are more appropriately reported to the HSCB Social Care and Children's Directorate.

In 2012 the HSCB issued the 'Protocol for responding to SAIs involving an alleged homicide'. The 2013 revised HSCB 'Protocol for responding to SAIs involving an alleged homicide' is contained in Appendix 14.

Circular HSS (MD) 8/2013 replaces HSS (MD) 06/2006 and advises of a revised Memorandum of Understanding (MOU) when investigating patient or client safety incidents. This revised MOU is designed to improve appropriate information sharing and co-ordination when joint or simultaneous investigations/reviews are required when a serious incident occurs.

www.health-ni.gov.uk/sites/default/files/publications/dhssps/hss-md-8-2013.pdf

DHSSPS Memo dated 17 July 2013 from Chief Medical Officer introduced the HSCB/PHA protocol on the dissemination of guidance/information to the HSC and the assurance arrangements where these are required. The protocol assists the HSCB/PHA in determining what actions would benefit from a regional approach rather than each provider taking action individually.

http://intranet.hscb.hscni.net/documents/Governance/Information%20for%20DROs/002%20%20HSCB-PHA%20Protocol%20for%20Safety%20Alerts.pdf

Circular HSC (SQSD) 56/16 (21 October 2016) from the Deputy Chief Medical Officer advises of the intention to introduce a Never Events process and that information relating to these events will be captured as part of the Serious Adverse Incident Process. The circular indicates the Never Events process will be based on the adoption of Never Event List with immediate effect.

https://www.health-ni.gov.uk/sites/default/files/publications/health/HSC-SQSD-56-16.pdf

2.0 INTRODUCTION

The purpose of this procedure is to provide guidance to Health and Social Care (HSC) Organisations, and Special Agencies (SA) in relation to the reporting and follow up of Serious Adverse Incidents (SAIs) arising during the course of their business or commissioned service.

The requirement on HSC organisations to routinely report SAIs to the Department of Health (DoH) {formerly known as the DHSSPS} ceased on 1 May 2010. From this date, the revised arrangements for the reporting and follow up of SAIs, transferred to the Health and Social Care Board (HSCB) working both jointly with the Public Health Agency (PHA) and collaboratively with the Regulation and Quality Improvement Authority (RQIA).

This process aims to:

- Provide a mechanism to effectively share learning in a meaningful way; with a focus on safety and quality; ultimately leading to service improvement for service users;

- Provide a coherent approach to what constitutes a SAI; to ensure consistency in reporting across the HSC and Special Agencies;

- Clarify the roles, responsibilities and processes relating to the reporting, reviewing, dissemination and implementation of learning arising from SAIs which occur during the course of the business of a HSC organisation / Special Agency or commissioned/funded service;

- Ensure the process works simultaneously with all other statutory and regulatory organisations that may require to be notified of the incident or be involved the review;

- Keep the process for the reporting and review of SAIs under review to ensure it is fit for purpose and minimises unnecessary duplication;

- Recognise the responsibilities of individual organisations and support them in ensuring compliance; by providing a culture of openness and transparency that encourages the reporting of SAIs;

- Ensure trends, best practice and learning is identified, disseminated and implemented in a timely manner, in order to prevent recurrence;

- Maintain a high quality of information and documentation within a time bound process.

3.0 APPLICATION OF PROCEDURE

3.1 Who does this procedure apply to?

This procedure applies to the reporting and follow up of SAIs arising during the course of the business in Department of Health (DoH) Arm's Length Bodies (ALBs) i.e.

- ***HSC organisations (HSC)***
  - Health and Social Care Board
  - Public Health Agency
  - Business Services Organisation
  - Belfast Health and Social Care Trust
  - Northern Health and Social Care Trust
  - Southern Health and Social Care Trust
  - South Eastern Health and Social Care Trust
  - Western Health and Social Care Trust
  - Northern Ireland Ambulance Service
  - Regulation and Quality Improvement Authority

- ***Special Agencies (SA)***
  - Northern Ireland Blood Transfusion Service
  - Patient Client Council
  - Northern Ireland Medical and Dental Training Agency
  - Northern Ireland Practice and Education Council

The principles for SAI management set out in this procedure are relevant to all the above organisations. Each organisation should therefore ensure that its incident policies are consistent with this guidance while being relevant to its own local arrangements.

3.2 Incidents reported by Family Practitioner Services (FPS)

Adverse incidents occurring within services provided by independent practitioners within: General Medical Services, Pharmacy, Dental or Optometry, are routinely forwarded to the HSCB Integrated Care Directorate in line with the HSCB Adverse Incident Process within the Directorate of Integrated Care (September 2016). On receipt of reported adverse incidents the HSCB Integrated Care Directorate will decide if the incident meets the criteria of a SAI and if so will be the organisation responsible to report the SAI.

3.3 Incidents that occur within the Independent /Community and Voluntary Sectors (ICVS)

SAIs that occur within ICVS, where the service has been commissioned/funded by a HSC organisation must be reported. For example: service users placed/funded by HSC Trusts in independent sector accommodation, including private hospital, nursing or residential care homes, supported housing, day care facilities or availing of HSC funded voluntary/community services. These SAIs must be reported and reviewed by the HSC organisation who has:

- referred the service user (this includes Extra Contractual Referrals) to the ICVS;

or, if this cannot be determined;

- the HSC organisation who holds the contract with the IVCS.

HSC organisations that refer service users to ICVS should ensure all contracts, held with ICVS, include adequate arrangements for the reporting of adverse incidents in order to ensure SAIs are routinely identified.

All relevant events occurring within ICVS which fall within the relevant notification arrangements under legislation should continue to be notified to RQIA.

3.4 Reporting of HSC Interface Incidents

Interface incidents are those incidents which have occurred in one organisation, but where the incident has been identified in another organisation. In such instances, it is possible the organisation where the incident may have occurred is not aware of the incident; however the reporting and follow up review may be their responsibility. It will not be until such times as the organisation, where the incident has occurred, is made aware of the incident; that it can be determined if the incident is a SAI.

In order to ensure these incidents are notified to the correct organisation in a timely manner, the organisation where the incident was identified will report to the HSCB using the HSC Interface Incident Notification Form (see Appendix 3). The HSCB Governance Team will upon receipt contact the organisation where the incident has occurred and advise them of the notification in order to ascertain if the incident will be reported as a SAI.

Some of these incidents will subsequently be reported as SAIs and may require other organisations to jointly input into the review. In these instances refer to Appendix 13 – Guidance on Joint Reviews.

3.5 Incidents reported and Investigated/ reviewed by Organisations external to HSC and Special Agencies

The reporting of SAIs to the HSCB will work in conjunction with and in some circumstances inform the reporting requirements of other statutory agencies and external bodies. In that regard, all existing local or national reporting arrangements, where there are statutory or mandatory reporting obligations, will continue to operate in tandem with this procedure.

3.5.1 Memorandum of Understanding (MOU)

In February 2006, the DoH issued circular HSS (MD) 06/2006 – a Memorandum of Understanding – which was developed to improve appropriate information sharing and co-ordination when joint or simultaneous investigations/reviews are required into a serious incident.

Circular HSS (MD) 8/2013 replaces the above circular and advises of a revised MOU Investigating patient or client safety incidents which can be found on the Departmental website:

www.health-ni.gov.uk/sites/default/files/publications/dhssps/hss-md-8-2013.pdf

The MOU has been agreed between the DoH, on behalf of the Health and Social Care Service (HSCS), the Police Service of Northern Ireland (PSNI), the Northern Ireland Courts and Tribunals Service (Coroners Service for NI) and the Health and Safety Executive for Northern Ireland (HSENI). It will apply to people receiving care and treatment from HSC in Northern Ireland. The principles and practices promoted in the document apply to other locations, where health and social care is provided e.g. it could be applied when considering an incident in a family doctor or dental practice, or for a person receiving private health or social care provided by the HSCS.

It sets out the general principles for the HSCS, PSNI, Coroners Service for NI and HSENI to observe when liaising with one another.

The purpose of the MOU is to promote effective communication between the organisations. The MOU will take effect in circumstances of unexpected death or serious untoward harm requiring investigation by the PSNI, Coroners Service for NI or HSENI separately or jointly. This may be the case when an incident has arisen from or involved criminal intent, recklessness and/or gross negligence, or in the context of health and safety, a work-related death.

The MOU is intended to help:

- Identify which organisations should be involved and the lead investigating body.

- Prompt early decisions about the actions and investigations/reviews thought to be necessary by all organisations and a dialogue about the implications of these.

- Provide an understanding of the roles and responsibilities of the other organisations involved in the memorandum before high level decisions are taken.

- Ensure strategic decisions are taken early in the process and prevent unnecessary duplication of effort and resources of all the organisations concerned.

HSC Organisations should note that the MOU does not preclude simultaneous investigations/reviews by the HSC and other organisations e.g. Root Cause Analysis by the HSC when the case is being reviewed by the Coroners Service and/or PSNI/HSENI.

In these situations, the Strategic Communication and Decision Group can be used to clarify any difficulties that may arise; particularly where an external organisation's investigation/review has the potential to impede a SAI review and subsequently delay the dissemination of regional learning.

3.6 Reporting of SAIs to RQIA

RQIA have a statutory obligation to investigate some incidents that are also reported under the SAI procedure. In order to avoid duplication of incident notification and review, RQIA will work in conjunction with the HSCB/PHA with regard to the review of certain categories of SAI. In this regard the following SAIs should be notified to RQIA at the same time of notification to the HSCB:

- All mental health and learning disability SAIs reportable to RQIA under Article 86.2 of the Mental Health (NI) Order 1986.

- Any SAI that occurs within the regulated sector (whether statutory or independent) for a service that has been commissioned/funded by a HSC organisation.

  It is acknowledged these incidents should already have been reported to RQIA as a ***'notifiable event'*** *by the statutory or independent organisation where the incident has occurred (in line with relevant reporting regulations). This notification will alert RQIA that the incident is also being reviewed as a SAI by the HSC organisation who commissioned the service.*

- The HSCB/PHA Designated Review Officer (DRO) will lead and co-ordinate the SAI management, and follow up, with the reporting organisation; however for these SAIs this will be carried out in

conjunction with RQIA professionals. A separate administrative protocol between the HSCB and RQIA can be accessed at Appendix 15.

3.7 Reporting of SAIs to the Safeguarding Board for Northern Ireland

There is a statutory duty for the HSC to notify the Safeguarding Board for Northern Ireland of child deaths where:

- a child has died or been significantly harmed (Regulation 17(2)(a)

AND

- abuse/neglect suspected **or** child or sibling on child protection register **or** child or sibling is/has been looked after Regulation (2)(b) (see Appendix 17)

4.0 DEFINITION AND CRITERIA

4.1 Definition of an Adverse Incident

'Any event or circumstances that could have or did lead to harm, loss or damage to people, property, environment or reputation'[1] arising during the course of the business of a HSC organisation / Special Agency or commissioned service.

The following criteria will determine whether or not an adverse incident constitutes a SAI.

4.2 SAI criteria

4.2.1 serious injury to, or the unexpected/unexplained death of:

- a service user, (including a Looked After Child or a child whose name is on the Child Protection Register and those events which should be reviewed through a significant event audit)
- a staff member in the course of their work
- a member of the public whilst visiting a HSC facility;

4.2.2 unexpected serious risk to a service user and/or staff member and/or member of the public;

4.2.3 unexpected or significant threat to provide service and/or maintain business continuity;

[1] Source: DoH - How to classify adverse incidents and risk guidance 2006
http://webarchive.proni.gov.uk/20120830142323/http://www.dhsspsni.gov.uk/ph_how_to_classify_adverse__incidents_and_risk_-_guidance.pdf

4.2.4 serious self-harm or serious assault (*including attempted suicide, homicide and sexual assaults*) by a service user, a member of staff or a member of the public within any healthcare facility providing a commissioned service;

4.2.5 serious self-harm or serious assault *(including homicide and sexual assaults*)

- on other service users,
- on staff or
- on members of the public

by a service user in the community who has a mental illness or disorder (*as defined within the Mental Health (NI) Order 1986*) and/or known to/referred to mental health and related services *(including CAMHS, psychiatry of old age or leaving and aftercare services*) and/or learning disability services, in the 12 months prior to the incident;

4.2.6 suspected suicide of a service user who has a mental illness or disorder (*as defined within the Mental Health (NI) Order 1986*) and/or known to/referred to mental health and related services *(including CAMHS, psychiatry of old age or leaving and aftercare services*) and/or learning disability services, in the 12 months prior to the incident;

4.2.7 serious incidents of public interest or concern relating to:

- any of the criteria above
- theft, fraud, information breaches or data losses
- a member of HSC staff or independent practitioner.

ANY ADVERSE INCIDENT WHICH MEETS ONE OR MORE OF THE ABOVE CRITERIA SHOULD BE REPORTED AS A SAI.

Note: The HSC Regional Risk Matrix may assist organisations in determining the level of 'seriousness' refer to Appendix 16.

5.0 SAI REVIEWS

SAI reviews should be conducted at a level appropriate and proportionate to the complexity of the incident under review. In order to ensure timely learning from all SAIs reported, it is important the level of review focuses on the complexity of the incident and not solely on the significance of the event.

Whilst most SAIs will be subject to a Level 1 review, for some more complex SAIs, reporting organisations may instigate a Level 2 or 3 review immediately following the incident occurring. The level of review should be noted on the SAI notification form.

The HSC Regional Risk Matrix (refer to Appendix 16) may assist organisations in determining the level of 'seriousness' and subsequently the level of review to be

undertaken. SAIs which meet the criteria in 4.2 above will be reviewed by the reporting organisation using one or more of the following:

5.1 Level 1 Review – Significant Event Audit (SEA)

Most SAI notifications will enter the review process at this level and a SEA will immediately be undertaken to:

- assess what has happened;
- assess why did it happened;
  - what went wrong and what went well;
- assess what has been changed or agree what will change;
- identify local and regional learning.

(refer to Appendix 5 – Guidance Notes for Level 1 – SEA & Learning Summary Report; Appendix 9 – Guidance on Incident Debrief); and Appendix 10 – Level 1 Review - Guidance on review team membership)

The possible outcomes from the review may include:

- closed – no new learning;
- closed – with learning;
- requires Level 2 or 3 review.

A SEA report will be completed **which should be retained by the reporting organisation** (see Appendices 4 and 5).

The reporting organisation will then complete a **SEA Learning Summary Report** (see Appendices 4 and 5 – Sections 1, 3-6), which should be signed off by the relevant professional or operational director and submitted to the HSCB within **8 weeks** of the SAI being notified.

The HSCB will not routinely receive SEA reports unless specifically requested by the DRO. This process assigns reporting organisations the responsibility for Quality Assuring Level 1 SEA Reviews. This will entail engaging directly with relevant staff within their organisation to ensure the robustness of the report and identification of learning prior to submission to the HSCB.

If the outcome of the SEA determines the SAI is more complex and requires a more detailed review, the review will move to either a Level 2 or 3 RCA review. In this instance the SEA Learning Report Summary will be forwarded to the HSCB within the timescales outlined above, with additional sections being completed to outline membership and Terms of Reference of the team completing the Level 2 or 3 RCA review and proposed timescales.

5.2 Level 2 – Root Cause Analysis (RCA)

As stated above, some SAIs will enter at Level 2 review following a SEA.

When a Level 2 or 3 review is instigated immediately following notification of a SAI, the reporting organisation will inform the HSCB within 4 weeks, of the Terms of Reference (TOR) and Membership of the Review Team for

consideration by the HSCB/PHA DRO. This will be achieved by submitting sections two and three of the review report to the HSCB. (Refer to Appendix 6 – template for Level 2 and 3 review reports).

The review must be conducted to a high level of detail (see Appendix 7 – template for Level 2 and 3 review reports). The review should include use of appropriate analytical tools and will normally be conducted by a multidisciplinary team (not directly involved in the incident), and chaired by someone independent to the incident but who can be within the same organisation. (Refer to Appendix 9 – Guidance on Incident Debrief); and Appendix 11 – Level 2 Review - Guidance on review team membership).

Level 2 RCA reviews may involve two or more organisations. In these instances, it is important a lead organisation is identified but also that all organisations contribute to, and approve the final review report (Refer to Appendix 13 Guidance on joint reviews/investigations).

On completion of Level 2 reviews, the final report must be submitted to the HSCB within 12 weeks from the date the incident was notified.

5.3 Level 3 – Independent Reviews

Level 3 reviews will be considered for SAIs that:

- are particularly complex involving multiple organisations;
- have a degree of technical complexity that requires independent expert advice;
- are very high profile and attracting a high level of both public and media attention.

In some instances the whole team may be independent to the organisation/s where the incident/s has occurred.

The timescales for reporting Chair and Membership of the review team will be agreed by the HSCB/PHA Designated Review Officer (DRO) at the outset (see Appendix 9 – Guidance on Incident Debrief); and Appendix 12 – Level 3 Review - Guidance on Review Team Membership).

The format for Level 3 review reports will be the same as for Level 2 reviews (see Appendix 7 – guidance notes on template for Level 2 and 3 reviews).

For any SAI which involves an alleged homicide by a service user who has a mental illness or disorder *(as defined within the Mental Health (NI) Order 1986)* and/or known to/referred to mental health and related services (*including CAMHS, psychiatry of old age or leaving and aftercare services*) and/or learning disability services, in the 12 months prior to the incident, the Protocol for Responding to SAIs in the Event of a Homicide, issued in 2012 and revised in 2013 should be followed (see Appendix 14).

5.4 Involvement of Service Users/Family/Carers in Reviews

- Following a SAI it is important, in the spirit of honesty and openness to ensure a consistent approach is afforded to the level of service user / family engagement across the region. When engaging with Service Users/Family/Carers, organisations should refer to addendum 1 – *A Guide for Health and Social Care Staff Engagement/Communication with Service User/Family/Cares following a SAI.*

- In addition a 'Checklist for Engagement/Communication with the Service User/Family/Carers following a SAI' must be completed for each SAI regardless of the review level, and where relevant, if the SAI was also a Never Event (refer to section 12.2).

- The checklist also includes a section to indicate if the reporting organisation had a statutory requirement to report the death to the Coroners office and that this is also communicated to the Family/Carer.

6.0 TIMESCALES

6.1 Notification

Any adverse incident that meets the criteria indicated in section 4.2 should be reported within **72 hours** of the incident being discovered using the SAI Notification Form (see Appendix 1).

6.2 Review Reports

LEVEL 1 – SEA

SEA reports must be completed using the SEA template which will be retained by the reporting organisation (see Appendices 4 and 5). A SEA Learning Summary Report (see Appendices 4 and 5 – Sections 1, 3-6) must be completed and submitted to the HSCB within **8 weeks** of the SAI being reported for all Level 1 SAIs whether learning has been identified or not. The Checklist for Engagement/Communication with Service User/Family/Carer following a SAI' must also accompany the Learning Summary Report.

If the outcome of the SEA determines the SAI is more complex and requires a more detailed review, timescales for completion of the RCA will be indicated by Trusts via the Learning Summary Report to the HSCB.

LEVEL 2 – RCA

For those SAIs where a full RCA is instigated immediately, sections 2 and 3 of the RCA Report, outlining TOR and membership of the review team, must be submitted **no later** than **within 4 weeks** of the SAI being notified to the HSCB.

RCA review reports must be fully completed using the RCA report template and submitted together with comprehensive action plans for each recommendation identified to the HSCB **12 weeks** following the date the incident was notified. (see Appendix 6 – Level 2 & 3 RCA Review Reports and Appendix 8 – Guidance on Minimum Standards for Action Plans).

LEVEL 3 – INDEPENDENT REVIEWS

Timescales for completion of Level 3 reviews and comprehensive action plans for each recommendation identified will be agreed between the reporting organisation and the HSCB/PHA DRO as soon as it is determined that the SAI requires a Level 3 review.

Note: Checklist for Engagement/Communication with Service User/Family/Carer following a SAI must accompany all SAI Review/Learning Summary Reports which are included within the report templates.

6.3 Exceptions to Timescales

In most circumstances, all timescales for submission of reports **must be** adhered to. However, it is acknowledged, by exception, there may be occasions where a review is particularly complex, perhaps involving two or more organisations or where other external organisations such as PSNI, HSENI etc.; are involved in the same review. In these instances the reporting organisation must provide the HSCB with regular updates.

6.4 Responding to additional information requests

Once the review / learning summary report has been received, the DRO, with appropriate clinical or other support, will review the report to ensure that the necessary documentation relevant to the level of review is adequate.

If the DRO is not satisfied with the information provided additional information may be requested and must be provided in a timely manner. Requests for additional information should be provided as follows:

- Level 1 review within **2 week**
- Level 2 or 3 review within **6 weeks**

7.0 OTHER INVESTIGATIVE/REVIEW PROCESSES

The reporting of SAIs to the HSCB will work in conjunction with all other HSC investigation/review processes, statutory agencies and external bodies. In that regard, all existing reporting arrangements, where there are statutory or mandatory reporting obligations, will continue to operate in tandem with this procedure.

In that regard, there may be occasions when a reporting organisation will have reported an incident via another process before or after it has been reported as a SAI.

7.1 Complaints in the HSC

Complaints in HSC Standards and Guidelines for Resolution and Learning (The Guidance) outlines how HSC organisations should deal with complaints raised by persons who use/have used, or are waiting to use HSC services. While it is a separate process to the management and follow-up of SAIs, there will be occasions when an SAI has been reported by a HSC organisation, and subsequently a complaint is received relating to the same incident or issues, or alternatively, a complaint may generate the reporting of an SAI.

In these instances, the relevant HSC organisation must be clear as to how the issues of complaint will be investigated. For example, there may be elements of the complaint that will be solely reliant on the outcome of the SAI review and there may be aspects of the complaint which will not be part of the SAI review and can only be investigated under the Complaints Procedure.

It is therefore important that complaints handling staff and staff who deal with SAIs communicate effectively and regularly when a complaint is linked to a SAI review. This will ensure that all aspects of the complaint are responded to effectively, via the most appropriate means and in a timely manner. Fundamental to this, will obviously be the need for the organisation investigating the complaint to communicate effectively with the complainant in respect of how their complaint will be investigated, and when and how they can expect to receive a response from the HSC organisation.

7.2 HSCB Social Care Untoward Events Procedure

The above procedure provides guidance on the reporting of incidents relating to statutory functions under the Children (NI) Order 1995.

If, during the review of an incident reported under the HSCB Untoward Events procedure, it becomes apparent the incident meets the criteria of a SAI, the incident should immediately be notified to the HSCB as a SAI. Board officers within the HSCB will close the Untoward Events incident and the incident will continue to be managed via the SAI process.

7.3 Child and Adult Safeguarding

Any incident involving the suspicion or allegation that a child or adult is at risk of abuse, exploitation or neglect should be investigated under the procedures set down in relation to a child and adult protection.

If during the review of one of these incidents it becomes apparent that the incident meets the criteria for an SAI, the incident will immediately be notified to the HSCB as an SAI.

It should be noted that, where possible, safeguarding investigations will run in parallel as separate to the SAI process with the relevant findings from these investigations/reviews informing the SAI review (see appendix 17).

On occasion the incident under review may be considered so serious as to meet the criteria for a Case Management Review (CMR) for children, set by the Safeguarding Board for Northern Ireland; a Serious Case Review (SCR) for adults set by the Northern Ireland Adult Safeguarding Partnership; or a Domestic Homicide Review.

In these circumstances, the incident will be notified to the HSCB as an SAI. This notification will indicate that a CMR, SCR or Domestic Homicide Review is underway. This information will be recorded on the Datix system, and the SAI will be closed.

7.4 Reporting of Falls

Reporting organisations will no longer be required to routinely report falls as SAIs which have resulted in harm in all Trust facilities, (as defined in the impact levels 3 – 5 of the regional risk matrix - see appendix 16). Instead a new process has been developed with phased implementation, which requires HSC Trusts to do a timely post fall review debrief to ensure local application of learning. See links below to Shared Learning Form and Minimum Data Set for Post Falls Review:

http://intranet.hscb.hscni.net/documents/Governance/Information%20for%20DROs/033%20Falls_Shared%20Learning%20Template_%20V2_June%202016.rtf

http://intranet.hscb.hscni.net/documents/Governance/Information%20for%20DROs/032%20Regional%20Falls%20Minimum%20Dataset%202016_V2_June%202016.pdf

Local learning will be shared with the Regional Falls Group where trends and themes will be identified to ensure regional learning.

Reporting organisations will therefore manage falls resulting in moderate to severe harm as adverse incidents, unless there are particular issues or the subsequent internal review identifies contributory issues/concerns in treatment and/or care or service issues, or any identified learning that needs to be reviewed through the serious adverse incident process.

7.5 Transferring SAIs to other Investigatory Processes

Following notification and initial review of a SAI, more information may emerge that determines the need for a specialist investigation.

This type of investigation includes:

- Case Management Reviews
- Serious Case Reviews

Once a DRO has been informed a SAI has transferred to one of the above investigation s/he will close the SAI.

7.6 De-escalating a SAI

It is recognised that organisations report SAIs based on limited information and the situation may change when more information has been gathered; which may result in the incident no longer meeting the SAI criteria.

Where a reporting organisation has determined the incident reported no longer meets the criteria of a SAI, a request to de-escalate the SAI should be submitted immediately to the HSCB by completing section 21 of the SAI notification form (Additional Information following initial Notification).

The DRO will review the request to de-escalate and will inform the reporting organisation and RQIA (where relevant) of the decision as soon as possible and at least within **10 working days** from the request was submitted.

If the DRO agrees, the SAI will be de-escalated and no further SAI review will be required. The reporting organisation may however continue to review as an adverse incident or in line with other HSC investigation/review processes (as highlighted above). If the DRO makes a decision that the SAI should not be de-escalated the review report should be submitted in line with previous timescales.

It is important to protect the integrity of the SAI review process from situations where there is the probability of disciplinary action, or criminal charges. The SAI review team must be aware of the clear distinction between the aims and boundaries of SAI reviews, which are solely for the identification and reporting learning points, compared with disciplinary, regulatory or criminal processes.

HSC organisations have a duty to secure the safety and well-being of patients/service users, the review to determine root causes and learning points should still be progressed **in parallel** with other reviews/investigations, ensuring remedial actions are put in place as necessary and to reduce the likelihood of recurrence.

8.0 LEARNING FROM SAIs

The key aim of this procedure is to improve services and reduce the risk of incident recurrence, both within the reporting organisation and across the HSC as a whole. The dissemination of learning following a SAI is therefore core to achieving this and to ensure shared lessons are embedded in practice and the safety and quality of care provided.

HSCB in conjunction with the PHA will:

- ensure that themes and learning from SAIs are identified and disseminated for implementation in a timely manner; this may be done via:
  - learning letters / reminder of best practice letters;
  - learning newsletter;
  - thematic reviews.

- provide an assurance mechanism that learning from SAIs has been disseminated and appropriate action taken by all relevant organisations;

- review and consider learning from external/independent reports relating to quality/safety.

It is acknowledged HSC organisations will already have in place mechanisms for cascading local learning from adverse incidents and SAIs internally within their own organisations. The management of dissemination and associated assurance of any regional learning is the responsibility of the HSCB/PHA.

9.0 TRAINING AND SUPPORT

9.1 Training

Training will be provided to ensure that those involved in SAI reviews have the correct knowledge and skills to carry out their role, i.e:

- Chair and/or member of an SAI review team
- HSCB/PHA DRO.

This will be achieved through an educational process in collaboration with all organisations involved, and will include training on review processes, policy distribution and communication updates.

9.2 Support

9.2.1 Laypersons

The panel of lay persons, (already involved in the HSC Complaints Procedure), have availed of relevant SAI training including Root Cause Analysis. They are now available to be called upon to be a member of a SAI review team; particularly when a degree of independence to the team is required.

Profiles and relevant contact details for all available laypersons can be obtained by contacting seriousincidents@hscni.net

9.2.2 Clinical/Professional Advice

If a DRO requires a particular clinical view on the SAI review, the HSCB Governance Team will secure that input, under the direction of the DRO.

10.0 INFORMATION GOVERNANCE

The SAI process deals with a considerable amount of sensitive personal information. Appropriate measures must be put in place to ensure the safe and secure transfer of this information. All reporting organisations should adhere to their own Information Governance Policies and Procedures. However, as a minimum the HSCB would recommend the following measures be adopted when

transferring patient/client identifiable information via e-mail or by standard hard copy mail:

- E-Mail - At present there is not a requirement to apply encryption to sensitive information transferred across the HSC network to other HSC organisations within Northern Ireland. Information transferred between the HSCB, Trusts and Northern Ireland Department of Health is not sent across the internet. If you are transferring information to any address that does not end in one of those listed below, it is essential that electronic measures to secure the data in transit, are employed, and it is advised that encryption is therefore applied at all times to transfers of sensitive / personal information.

  List of email addresses **within the Northern Ireland secure network:**
  '.hscni.net',
  'n-i.nhs.uk'
  'ni.gov.uk' or
  '.ni.gov.net'

  No sensitive or patient/service user data must be emailed to an address other than those listed above unless they have been protected by encryption mechanisms that have been approved by the BSO-ITS.

  Further advice on employing encryption software can be sought from the BSO ICT Security Team.

  Note: Although there is a degree of protection afforded to email traffic that contains sensitive information when transmitting within the Northern Ireland HSC network it is important that the information is sent to the correct recipient. With the amalgamation of many email systems, the chances of a name being the same or similar to the intended recipient has increased. It is therefore recommended that the following simple mechanism is employed when transmitting information to a new contact or to an officer you haven't emailed previously.

  Step 1 Contact the recipient and ask for their email address.
  Step 2 Send a test email to the address provided to ensure that you have inserted the correct email address.
  Step 3 Ask the recipient on receiving the test email to reply confirming receipt.
  Step 4 Attach the information to be sent with a subject line 'Private and Confidential, Addressee Only' to the confirmation receipt email and send.

- Standard Mail – It is recommended that any mail which is deemed valuable, confidential or sensitive in nature (such as patient/service user level information) should be sent using 'Special Delivery' Mail.

Further guidance is available from the HSCB Information Governance Team on: Tel 028 95 362912

11.0 ROLE OF DESIGNATED REVIEW OFFICER (DRO)

A DRO is a senior professional/officer within the HSCB / PHA and has a key role in the implementation of the SAI process namely:

- liaising with reporting organisations:
  - on any immediate action to be taken following notification of a SAI
  - where a DRO believes the SAI review is not being undertaken at the appropriate level

- agreeing the Terms of Reference for Level 2 and 3 RCA reviews;

- reviewing completed SEA Learning Summary Reports for Level 1 SEA Reviews and full RCA reports for level 2 and 3 RCA Reviews; liaising with other professionals (where relevant);

- liaising with reporting organisations where there may be concerns regarding the robustness of the level 2 and 3 RCA reviews and providing assurance that an associated action plan has been developed and implemented;

- identification of regional learning, where relevant;

- surveillance of SAIs to identify patterns/clusters/trends.

Whilst the HSCB will not routinely receive Level 1 SEA reports these can be requested, on occasion, by a DRO.

An internal HSCB/PHA protocol provides further guidance for DROs regarding the nomination and role of a DRO.

12.0 PROCESS

12.1 Reporting Serious Adverse Incidents

Any adverse incident that meets the criteria of a SAI as indicated in section 4.2 should be reported within 72 hours of the incident being discovered using the SAI Notification Form (Appendix 1) and forwarded to seriousincidents@hscni.net

HSC Trusts to copy RQIA at seriousincidents@rqia.org.uk in line with notifications relevant to the functions, powers and duties of RQIA as detailed in section 3.6 of this procedure.

Any SAI reported by FPS or ICVS must be reported in line with 3.2 and 3.3 of this procedure.

Reporting managers must comply with the principles of confidentiality when reporting SAIs and must not refer to service users or staff by name or by any other identifiable information. A unique Incident Reference/Number should be utilised on all forms/reports and associated