



## Audit of two-week rule referrals for suspected testicular cancer in Cornwall, 2003–2005

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### ABSTRACT

**INTRODUCTION** The objective was to evaluate the two-week wait referral system for suspected testicular cancer and to compare waiting times from referral to treatment before and after the introduction of the two-week wait process.

**PATIENTS AND METHODS** We reviewed 241 case notes for patients referred under the two-week wait system with suspected testicular tumour during a complete 3-year period (2003–2005) and recorded information from the referral letter, findings in the urology clinic, results of ultrasound and final outcomes. We also identified 42 cases of testicular tumour treated during a complete 3-year period (1997–1999) just before the two-week wait system was introduced. The journey from referral to treatment for tumour cases was compared during these two periods.

**RESULTS** Testicular cancer was only found in 8% of patients referred by the two-week wait system. We judged the referral to be inappropriate in 48% of cases. Of referred cases, 78% required no surgical treatment. There was a significant improvement of 9 days in the average time from general practitioner (GP) referral to urology clinic attendance but all other journey intervals remained the same.

**CONCLUSIONS** The performance of GPs in examining scrotal swellings and applying the two-week wait guidelines was very poor, resulting in many unnecessary urgent clinic visits. The referral system speeds up the visit to a urology clinic but the overall effect is probably not of clinical significance. We suggest that it would be much more cost-effective for all these patients to have an ultrasound scan within 2 weeks instead of a urology clinic appointment.

### KEYWORDS

Testes – Tumour – Cancer – Two-week referral

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In February 2000, the UK Department of Health introduced a range of cancer rules and targets which directly impacted upon general practitioners (GPs) and hospital departments responsible for managing cancer patients. This was prompted by evidence that, in some areas of cancer treatment, cancer survival in the UK was inferior to figures from Europe and North America. A number of changes were introduced to tackle this problem and this included a series of speciality and tumour-specific 'two-week wait' rules. For urology this included suspected prostate cancer, bladder/urothelial cancer, kidney cancer, testis and penile cancer. Central guidance criteria were issued by the Department of Health covering each speciality and GPs were encouraged to fax referrals for cases which fitted the criteria direct to their local hospital centre. It should be noted that there were no preliminary studies to pilot this system and demonstrate benefit or cost-effectiveness.

For suspected testicular cancer, the 2000 referral guidelines stipulated 'swellings in the body of the testis'. In addition, some general guidance was included (Table 1).

In June 2005, the original guidance was replaced by guidance from the National Institute for Health and Clinical Excellence (NICE). The referral criterion was 'refer urgently patients with a swelling or mass in the body of the testis'. Within the full guidance document, the original general advice was replaced with the information given in Table 2.

This audit was stimulated by the impression of one consultant author (RGW) that a large proportion of two-week wait referrals for suspected testicular cancer seen in his clinic were inappropriate and often consisted of elderly men with clinically obvious hydroceles and epididymal cysts. We decided to audit these referrals, first to assess the quality of referrals, and second to see if the introduction of

**Table 1 Original February 2000 two-week wait referral guidance for testis cancer**

- Scrotal swellings are relatively common in general practice
- Solid swellings affecting the body of the testis have a high probability (> 50%) of being due to cancer
- Indeterminate swellings of the testicle have a low probability of being due to cancer especially in men over 55 years and should be considered for ultrasound before urological referral
- Swellings outside the body of the testis are hardly ever due to cancer and need not be referred urgently

**Table 2 Revised guidance from NICE, 2005, for testicular cancer**

- Any patient with a swelling or mass in the body of the testis should be referred urgently
- An urgent ultrasound should be considered in men with a scrotal mass that does not transilluminate and/or when the body of the testis cannot be distinguished

the two-week wait system made any significant difference to time taken from referral to treatment.

## Patients and Methods

Cornwall is a long, narrow peninsula and the county has a single major hospital. With the exception of areas in North Cornwall close to Plymouth and Barnstaple, we knew that the vast majority of testicular tumours from Cornwall would be seen and treated in the Royal Cornwall Hospital and that their histology would be accessible in our pathology laboratory. We also discovered that all two-week wait referrals to our hospital are processed by a single dedicated office with an electronic database and they were able to list all referrals for suspected testicular cancer.

We performed a retrospective audit for the period January 2003 to December 2005 inclusive and we asked for a list of referrals for suspected testicular cancer seen under the two-week wait system for all three urology consultants (RC, JSOR and RGW). The hospital notes were retrieved and

studied jointly by two of the authors (PK and RGW). A proforma was designed for data collection (PK) and a Microsoft Access database was created for data storage and analysis (RGW). The data fields used for this part of the study are listed in Table 3. For every referral, the description of physical signs from the GP letter was recorded verbatim and then compared with the two-week wait guidelines. A joint decision was agreed as to whether the referral was correct or not under this scheme. If there was any disagreement or doubt about the appropriateness of a referral, it was marked as valid.

It was, of course, possible that some two-week wait referrals might be missed and we approached the pathology department to see if we could double-check the list of tumour cases found from the review of notes. A print-out of all histology reports which included 'testis' was obtained for the study period 2003–2005 and was carefully vetted by one author (PK) to identify testicular tumours. This method was repeated for the 3-year period January 1997 to December 1999 to identify all testicular tumours treated in the 3-year period immediately before the introduction of the two-week wait rule. For all cases so identified, additional data were recorded (Table 4).

The intervals along the 'patient journey' from GP referral to orchidectomy were calculated for each patient and a comparison was made between those patients referred before the two-week wait rule was introduced (1997–1999, inclusive) and with those referred after the introduction of the two-week wait system (2003–2005, inclusive). Differences between these groups

**Table 3 Data collected from hospital notes**

- Name and hospital number
- Age at referral
- A history of a vasectomy
- Did the swelling relate to vasectomy?
- GP description of examination
- Did the referral fit the criterion for two-week wait referral?
- Urologist's findings
- Ultrasound findings
- Was a tumour found?
- Histology of tumours
- Final outcome

**Table 4 Additional data collected for proven cases of testicular cancer**

- Date of referral
- Date seen in clinic
- Date of operation
- Histology

**Table 5** Examples of inappropriate referrals

- Can feel the left testicle as normal...swelling attached to it
- Mass at lower pole of scrotum distinct from either testicle
- No testicular swelling or abnormality on examination
- A soft lump adjacent to [R] testis... I do not expect this to be a malignant lump
- Left hydrocele...transilluminates completely...to exclude underlying neoplasm
- He has a very large hydrocele...transilluminates...may be due to malignancy
- This may well be a cyst of the [R] epididymis
- Appears to have a hydrocele on the [L] side
- Swelling not attached to the [L] testis...feels like a varicocele
- Painless lump on his [R] testicle...appearance of epididymal cyst which transilluminates
- Cystic swelling separate from testis
- Lump in [L] scrotum...I felt it was a hydrocele

were analysed using the Kaplan–Meier survival analysis using orchidectomy for suspected tumour as the ‘survival’ end-point. This method was chosen on the advice of Dr Colin Pritchard, statistician to our hospital and he performed the analysis using SPSS software.

## Results

### Two-week wait referrals, 2003–2005 inclusive

A total of 241 patients were referred to the urology department under the two-week wait rule with suspicion of testicular cancer. The age range was 12–87 years of age (average, 42 years). We have compared this with the age distribution for all of the 65 testicular cancer patients found in our study (1997–1999 and 2003–2005). For these tumour cases, the age range was 19–82 years (average, 41.1 years). Therefore, the age characteristics of patients referred under the two-week wait rule were similar to the patients with testicular cancer.

For 37 patients, there was a history of a previous vasectomy; usually this was noted in the urology clinic and not in the GP referral letter. In 17 of these cases (46%), the referred swelling was thought to relate to the previous vasectomy. However, a previous vasectomy did not avoid a risk of tumour and three were subsequently diagnosed in this group (1 seminoma, 1 lymphoma and 1 benign Leydig cell tumour).

The two authors who reviewed the referral letters judged that, in 115 patients (48%), the referral did not fit the

**Table 6** Testicular tumours found in two-week wait referrals

Testicular tumours found ( $n = 23$ ) from 241 referrals (10%)

- Testicular carcinomas (20)
  - \* Seminomas (14)
  - \* Teratomas (2)
  - \* Embryonal/yolk-sac tumours (2)
  - \* Lymphomas (2)
- Benign tumours (3)
  - \* Leydig cell tumours (2)
  - \* Epidermoid cyst (1)

Overall cancer detection rate 8%

Only tumour cases from correct two-week wait referrals

guidelines. In 43 instances (18%), we judged that there was a flagrant breach of protocol. Some examples of these are given in Table 5. In two cases, the referral letter suggested that the GP had not actually examined the patient.

Overall, 158 (66%) of the two-week wait referrals underwent an ultrasound scan of the testes and every tumour found in our series had ultrasound confirmation before surgery.

Although GPs had referred 241 patients as suspected of having a testicular tumour, a diagnosis of testicular tumour was only made on initial examination in 29 cases by a urologist and a total of 23 tumours were subsequently confirmed. Therefore, the final yield of tumours was only 10% and for malignant tumours was just 8% of two-week wait referrals. The tumour characteristics are given in Table 6. It is important to note that not a single tumour was found from an inappropriate referral. Two testicular tumours were identified in patients thought to have a benign epididymal swelling on initial examination by a urologist; one was a benign adenomatoid tumour of the epididymis and the second was a spermatocytic seminoma in a 74-year-old patient.

The final outcomes for the 241 two-week wait referred patients is given in Table 7. The majority of patients (56%)

**Table 7** Outcomes in two-week wait referred cases ( $n = 241$ )

Orchidectomy for suspected tumour	26
Re-assured and discharged	134 (56%)
Follow-up with scans	8
Surgery for hydrocele, cyst, etc.	28
Treated for epididymitis	19
DNA follow-up	25
Other unrelated treatment	1

**Table 8** Average journey intervals in days ( $\pm$  SD)

Interval	Pre-two-week wait 1997–1999 ( $n = 42$ )	Post-two-week wait 2003–2005 ( $n = 23$ )	<i>P</i> -value
Referral to clinic	16 ( $\pm$ 13.2)	6.8 ( $\pm$ 5.1)	0.000
Clinic to operation	25.7 ( $\pm$ 31.3)	25 ( $\pm$ 25.5)	0.790
Referral to operation	41.8 ( $\pm$ 35.3)	31.8 ( $\pm$ 27.3)	0.297

Statistical comparison by Kaplan–Meier survival analysis.

were re-assured and discharged with no treatment after initial assessment. In total, 187 patients (78%) did not require any surgical intervention at all and only 28 (12%) went on to have elective surgery for hydroceles and epididymal cysts, *etc.* Overall, 74 cases (31%) received treatment of some kind following referral, including antibiotics.

When the pathology laboratory database was compared with this list of two-week wait referrals only two other tumour case were found one of which had been referred to the private sector and the other via a traditional letter.

#### Referral to treatment times before and after the two-week wait rule

In total, we found 23 patients with a testicular tumour from two-week wait referrals (2003–2005, inclusive) and identified a further 42 patients with tumours in the period 1997–1999 inclusive immediately before the two-week wait rules were introduced. Using the data collected as outlined in Table 4, we compared the patient's journey from referral to orchidectomy for tumour in these two groups and time periods. These data are summarised in Table 8.

#### Tumours in the over 55-year-old age group

It was apparent that the age characteristics of referred patients and tumour cases was higher than we expected. Of the 65 testicular tumours found from the two periods of this study, 14 (22%) were aged 55 years or over; Table 9 shows the tumour types found.

### Discussion

The impression that GPs in Cornwall were referring too many older men for suspected testicular cancer is correct in comparison to UK data. From the 241 cases referred under the two-week wait rule in this study, 30% of men were > 55 years of age. Cancer Research UK has published data on the internet suggesting that this type of malignancy affects only 8% of men > 55 years of age.<sup>1</sup> However, when we looked at the total series of 65 testicular tumour patients from the two phases of this study, we were surprised to find that 22%

were > 55 years of age. We have no data to explain this observation but it may reflect the popularity of Cornwall for retirement and a more elderly population in the county.

We carefully examined the notes and referral letter for evidence of a previous vasectomy. It is clear that the referring GP rarely mentioned such a history when this was identified by the urologist and it was obvious that hardly any GPs appreciated that vasectomy can cause swelling of the epididymis<sup>2</sup> or other masses such as a palpable vasectomy site or sperm granuloma. We have shown that vasectomy patients can develop a testicular tumour but, nonetheless, the frequent referral of worried men with no abnormality other than the postoperative features from a vasectomy might merit some discussion in guidelines.

The principal findings of this study are that GPs are very poor at examination of the scrotum and weak at interpreting their own findings. The nature of many of the referred swellings was easily determined using a pen torch and there was scant reference to trans-illumination in the referral letters. From the 241 referrals from GPs of suspected testicular tumour, only 29 tumours were suspected on clinical examination by a urologist, only 25 (10%) tumours confirmed by ultrasound and 20 (8%) of these were malignant. These cancer detection rates are lower than in another report where figures of 17% from two-week wait referrals and 15% for all suspected testicular tumour referrals were found.<sup>5</sup>

When comparing the GP's description of the examination with the guidelines, 48% of the referrals were judged not to fit the criteria and 18% flagrantly broke protocol.

**Table 9** Tumours found in men aged 55 years or older

• Lymphoma	5
• Spermatocystic seminoma	2
• Seminoma	6
• Leydig cell	1

From a smaller study in Liverpool, the authors found that up to 83% of their referrals were inappropriate.<sup>4</sup> In another report from Gloucestershire, it was observed that 81% of two-week wait referrals did not fit the guidance.<sup>5</sup> Clearly, many GPs feel that they have a right to over-ride the guidelines. However, our data clearly show that not a single tumour was found other than in correctly referred patients, a finding confirmed in the study from Liverpool.<sup>4</sup> This and our own study clearly show that GPs should strictly abide by the referral criteria and that to do so would dramatically reduce the burden from these patients in urology clinics.

The cases cited in Table 5 demonstrate a belief by some GPs that testicular tumour can hide behind an associated hydrocele. Whilst the original guidance from February 2000 (Table 1) was re-assuring in this regard, the revised guidance from NICE (Table 2) if anything tends to encourage this concern about hydroceles. From our study, there was no case where a testicular tumour was associated with, or concealed by, a hydrocele. A computerised population study from Denmark of 185 boys diagnosed with testicular cancer reported a higher risk associated with cryptorchidism, hypospadias, inguinal hernia, and hydrocele.<sup>5</sup> However, this relates to congenital patent processus variants and not adult (acquired) hydrocele. A literature search of PubMed failed to find any clear account of association between the common varieties of testicular tumour and adult hydrocele other than occasional case reports usually involving rare pathologies.

In Table 7, we list the outcomes for the 241 two-week wait referral cases. It is clear that the majority of these patients do not require anything other than re-assurance that they do not have cancer. Excluding those patients (29) who had an orchidectomy for suspected cancer, only 28 (12%) went on to have elective surgery for their scrotal swelling and a further 19 (8%) required antibiotic therapy for epididymitis. This latter group could, of course, have been treated by the GP.

The final part of our project was to assess the impact of the two-week wait system on the 'journey' from referral to orchidectomy for testicular cancer (Table 8). The data clearly show that the only significant change has been the shortened time from referral to being seen in the urology clinic (reduced by an average of 9 days). This reduction is almost certainly explained by the more streamlined process – faxing of the referral letters and direct booking of cases into clinic without preliminary vetting by the urologists. Once seen in the urology clinic, the interval from then until orchidectomy has not altered at all since the two-week wait rule was introduced, showing that urologists have always treated these cases expeditiously. Although we have no data on survival rates, we would doubt that the overall 10-day improvement from referral to orchidectomy would have any significant effect on cancer survival, especially as this tumour group has such a good survival prospect overall.

It is important to appreciate the invaluable role of ultrasound in assessing this group of patients. Ultrasound scanning has become the 'gold standard' in determining the presence of a testicular tumours<sup>6–9</sup> and is the final arbiter where there is doubt or dispute. Although the urologists dispensed with a scan in 34% of the referred cases, without doubt many patients were scanned to re-assure the patient in the face of opposing clinical diagnoses from GP and urologist. From the outcome data in Table 7, clearly this is what many patients and GPs require. Given the very small tumour and cancer detection rate and high probability that a scan will be required, we would argue that this group of patients would be better served by having an ultrasound scan within 2 weeks rather than being seen by a urologist. This conclusion has also been suggested by others.<sup>4,10</sup>

We have attempted to compare the costs between a 'scan first' or a 'urology clinic first' approach in Table 10. Although there are many pitfalls in constructing such estimates, there is little doubt that the 'scan first' method would save money for the NHS. It should also be borne in mind that, in order to meet waiting-time targets, all three urology consultants in our department are currently carrying out extra out-patient clinics and any process which reduces demand for clinic appointments would be beneficial.

Despite introducing such a costly fast-track referral system with no evidence-basis, it must be profoundly disappointing to all involved health professionals that there was also no attempt to put in place any on-going audit measures

**Table 10 Cost estimates**

**Based on:**

- Urology new appointment = £168 (includes subsequent investigations)
- Scrotal ultrasonography (trust tariff for GP) = £62.24

**Current two-week wait system**

241 appointments = £40,488

**Total = £40,488**

**A 'scan first' system**

Cases needing clinic after scan:

26 Underwent orchidectomy

8 Followed up with scans

28 Had benign surgery

**Total = 62**

62 appointments = £10,416

241 ultrasound scans = £15,000

**Total = £25,416**

(other than target compliance) to assess cost, benefit or improved outcomes. Several publications on the two-week wait system report high rates of inappropriate referral, low detection rates of cancer, large numbers of cancers coming via other referral methods and increased delays for non-two-week wait appointments.<sup>11–14</sup> One study has looked at differences in survival for colon cancer before and after the introduction of the two-week wait; no difference was found, although the 2-year survival figure used is rather short.<sup>15</sup> A survey of GPs suggested that they appreciated that they are over-referring cases under the two-week wait rule, in part because of concerns that cases referred by more traditional methods would inevitably wait longer.<sup>16</sup>

## Conclusions

The application of the two-week wait criteria for suspected testicular cancer by GPs is very poor and their ability to compare scrotal examination with referral guidelines is weak, resulting in a large number of unnecessary urology clinic appointments. The faster journey from referral to orchidectomy was not statistically significant and is almost certainly not clinically significant. We would suggest that the current two-week wait system should be modified to provide an ultrasound scan within 2 weeks so that urologists can concentrate their clinic service on those with a tumour confirmed or suspected on ultrasound.

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