and limited surgery reduces the need for radical surgery in patients with genitourinary rhabdomyosarcoma.

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Orchidopexy before age of 10 is best for undescended testes

EDITOR,—Chris Dawson and Hugh Whitfield's article on common paediatric problems in urology suggests that an intra-abdominal testis diagnosed after the age of 2 should be left in situ to preserve hormonal function until after puberty, when orchidectomy could then be performed.¹ We are aware of the need for brevity in ABC series, but we think that this suggestion is unusual and open to debate.

The authors make no distinction between unilateral and bilateral cases of undescended testis. The policy that they advocate confers no obvious endocrine advantage in unilateral cases. In bilateral cases orchidectomy after puberty will necessitate long term hormone replacement treatment, whereas orchidopexy performed at the time of diagnosis and before the age of 10 years will obviate the need for such treatment while mitigating the potential for malignant degeneration.^{2,3} Recent studies with long term follow up have shown that even for the impalpable testis, high success rates are achievable with a variety of techniques, including microvascular techniques.^{4,5}

We assume that the advice in the flowchart for orchidopexy to be performed after puberty in those diagnosed after the age of 2 years is a typographical error as it is at variance with the advice given in the text.

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Laparoscopy has much to offer

EDITOR,—Chris Dawson and Hugh Whitfield's article on common paediatric problems in urology suggests that there is no difference between the management of non-palpable

unilateral and bilateral undescended testes.¹ The authors advocate laparoscopy as the method of choice for investigating the presence or absence of testes and recommend orchidectomy for children presenting after the age of 2, because their testes are likely to be sterile, though they say that this should be done only after puberty to avoid any problems with a low concentration of testosterone. This policy will lead to a large number of unnecessary orchidectomies.

For unilateral non-palpable undescended testis many surgeons still explore the groin. If a testis or a blind ending vas and vessels are found then the problem is solved. If not then extending the incision and opening the peritoneum may help. Laparoscopy is gaining wider acceptance as the investigation of choice to avoid negative findings and unnecessary extensive explorations of the groin. As most intra-abdominal testes are present near the deep ring, single stage laparoscopic orchidopexy is the operation of choice if a good quality testis is found.² For high testes a two stage laparoscopic Fowler-Stephens orchidopexy or microsurgical autotransplantation³ should be considered. All these operations should preferably be done before the age of 2 years to decrease the likelihood of sterile testes, but children presenting after the age of 2 should be offered the operation. Age is not a limitation, especially if good quality testes are present at the deep ring or peeping in and out of the inguinal canal.⁴

Children with bilateral non-palpable undescended testes should undergo XY karyotyping and human chorionic gonadotrophin and luteinising hormone releasing hormone stimulation tests. High concentrations of gonadotrophins with no increase in the testosterone concentration mean that no testicular tissue is present and operation can be avoided.⁵ If testicular tissue is present then laparoscopic orchidopexy for low testes and a two stage laparoscopic Fowler-Stephens or autotransplantation for high testes can be done. These operations should ideally be done in centres with a special interest in undescended testes. Age should be less of a consideration in these cases, and older children should be offered the treatment.⁴

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Authors' reply

EDITOR,—Sue J Vernon and colleagues question our comments about the management of urinary tract infection in children. The detail that can be supplied in an ABC article is limited, but we recognise that age has an important bearing on the investigation of children presenting with urinary tract infection.

Michael Hehir and Lawrence Walker's comments about staging of prostate cancer and the errors in the figure are correct. The diagram showing stage T3 disease should have been labelled T4 disease, and T3 prostate cancer should have been represented by a figure showing extension of cancer beyond the prostatic capsule.

Our article on common paediatric problems was aimed at doctors who are not specialists in paediatric oncology, and we therefore kept details to a minimum. Nevertheless, C R Pinkerton and colleagues' points are valid, and paediatric tumours are best dealt with by specialists.

G Humphrey and B R Squire criticise our comments about the treatment of rhabdomyosarcoma. Our short paragraph on this subject reflected the importance of this rare tumour to general urologists. We recognise that chemotherapy has a pivotal role.

J A Jibril and colleagues' comments about undescended testes are pertinent, and our article has given rise to confusion. All patients with bilateral undescended testes should undergo XY karyotyping. The presence of hormonally active testicular tissue can be confirmed by luteinising hormone releasing hormone and human chorionic gonadotrophin stimulation tests, although these are not useful in unilateral cases with a normally situated contralateral testis.

For children aged under 2 (regardless of whether one or both testes are undescended) the management is the same—that is, orchidopexy should be performed before the age of 2 if possible. If both testes are undescended then an orchidopexy should be performed on the second testis only after survival of the first testis has been assured. In prepubertal children over the age of 2 the undescended testis is likely to be sterile and early orchidopexy is not essential. Some urologists believe that operation should be deferred until after puberty as there is a risk of atrophy and loss of endogenous hormones from orchidopexy before this time, especially in bilateral cases. After puberty there is no possibility of an undescended testis being fertile. Orchidectomy is probably advisable in unilateral cases, and the decision to insert a prosthesis for cosmetic reasons can be made after counselling. The role of orchidectomy for bilateral undescended testes is less clear, but the testes must at least be moved to a position where they can be regularly and easily examined.

Finally, with regard to Sherif E Habib's letter, there was a typographical error in the text of our article, and orchidectomy should have read orchidopexy. We suggested that as undescended testes in children presenting after the age of 2 are likely to be sterile, orchidopexy is less urgent. Because orchidopexy by the Fowler-Stephens method is associated with atrophy rates in excess of 50%, loss of endogenous testosterone is an important complication, particularly in bilateral cases. Some authors have therefore suggested that orchidopexy in such cases be deferred until after puberty.

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Adjuvant treatment with tamoxifen

Care is necessary

EDITOR,—Michael Baum and Jack Cuzick¹ object to my comments about a clinical announcement by the National Cancer Institute that a trial comparing five years of adjuvant treatment with tamoxifen for breast cancer with a longer period of such treatment has been stopped.² They say that the announcement is a "dubious and previously discredited process" (why?) and is based on

Table 1—Data available from trial comparing short term (five years) treatment with adjuvant tamoxifen with longer term treatment (eight years and seven months) for breast cancer. Figures are numbers of women except where otherwise stated

	Short term treatment	Long term treatment
Survival (%)	96	94 (P = 0.11)
Event free survival (%)	92	86 (P = 0.016)
Recurrence	10	23
Death	13	23
Cancer in contralateral breast	5	6
Second primaries	16	24

unpublished data. Table 1 gives the data, which are available under the American Freedom of Information Act.

Baum and Cuzick believe that the statistical analysis is highly unreliable and that the National Surgical Adjuvant Breast and Bowel Project, the National Cancer Institute and its independent data safety monitoring committee, and the Food and Drug Administration met "to influence policy on the European side of the Atlantic." A more charitable view might be that they issued their clinical announcement for the benefit of patients.

There will be consternation among the Californian panel on carcinogenesis and a second group of experts who met recently at the International Agency against Cancer in Lyons. Their conclusion, that tamoxifen is a carcinogen,^{3,4} is dismissed as "absurd" by Baum and Cuzick. Newbold *et al* have recently shown that tamoxifen induces proliferative changes in the oviduct and uterus of mice treated with tamoxifen (100%) and at 12 months of age there is an increased incidence of endometrial cancer.⁵ They might be well advised to withdraw their abstract before Baum and Cuzick take them to task.

Sasco and Gendre point out that drugs other than tamoxifen are also carcinogenic.⁶ This does not stop such compounds being used, but they must be used with care rather than handed out like sweets, and the recipients should be informed of the risks involved.

Helena Earl and colleagues' letter about the aTTom trial states that there is "an ethical and scientific imperative to determine the optimum duration of treatment."¹ The design of their trial, however, does not seem to address the problem that some volunteers will not benefit from treatment and that the prognosis in others is so favourable that they also are not appropriate candidates for adjuvant treatment. Nor will the trial determine the costs of the treatment in terms of side effects, which Baum and Cuzick believe to be "anecdotal," since the end point is the number of dead in each arm.

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Informed consent and follow up in aTTom trial are inadequate

EDITOR,—The fact that women will be given adjuvant tamoxifen for more than five years despite the National Cancer Institute's warning that longer term treatment may do more harm than good is not the only reason why doctors and the public should reject the controversial aTTom (adjuvant tamoxifen treatment—offer more?) trial in breast cancer and its international counterpart, ATLAS (adjuvant tamoxifen—longer against shorter).^{1,2}

The megatrial was designed to "impose no extra workload on collaborators, other than randomizing and treating their patients, so that even the busiest clinicians can participate. There are no forms at all to complete, and no regular follow-up information is required—survival information will be obtained from national registries." There will be "no extra investigations, no extra clinic visits, infrequent follow-up, and no requirements for detailed documentation of initial status, toxicity, treatment compliance, health economic aspects, quality of life, and so on."³ Although patients are randomised "to at least 5 years of tamoxifen while some may be rerandomized after 5 years to lifetime tamoxifen,"⁴ the designers believe that it is not necessary to ensure that the 20 000 women are closely and uniformly monitored for gynaecological conditions associated with tamoxifen, including endometrial cancer. Nor will clinicians be required to monitor the women routinely and report other second tumours, liver toxicity, thromboembolism, ocular toxicity, depression, or bone loss in premenopausal women—conditions associated with longer term tamoxifen in clinical trials.

The process of gaining informed consent for the aTTom and ATLAS trials also leaves much to be desired, as is evident from a flyer issued by Wandsworth Health Authority's local research ethics committee in 1995:

Tamoxifen does cause some minor side effects in a few women, which either lessen if the treatment is continued or cease when the treatment is stopped. There is some evidence that there may be a small risk of an increase in diseases of the liver and womb if tamoxifen is taken for many years. Nobody knows for sure....

It is unclear if the invitation's wording is the product of a single research ethics committee's interpretation of the world literature or stems from a model developed by the national trialists, who have argued that "the recent trends towards extensive informed consent, careful quality of life assessment and measurements of economic costs of treatments in trials are often seriously inappropriate."⁵ The *BMJ* is to be commended for publishing an editorial questioning the ethics of such extended trials of tamoxifen.¹

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Specialist surgeons and survival in breast cancer

Observational studies are essential

EDITOR,—Several letters¹ have criticised the methods used and the conclusions drawn in

Charles R Gillis and David J Hole's study, which showed substantial improvements in survival from breast cancer among women referred to specialist surgeons.² The study used observational data from the West of Scotland Cancer Registry. It is argued that such data can never be appropriately controlled for differences in case mix and that only data from randomised controlled trials can be used to provide reliable evidence. We believe that this objection is invalid and negates the underlying importance of observational studies in health services research, which Nick Black has highlighted.³

We do not deny the obligatory role of randomised controlled trials in evaluations of alternative treatments. Specialist care, for which specialist surgeons were a marker in the Scottish study, is not simply about improved surgical technique or the optimum deployment of adjuvant treatment but includes treatment by a multidisciplinary team with access to all oncological and nursing facilities. This overall context can rarely, if ever, be evaluated by randomised controlled trials.

The evidence review prepared for the National Clinical Outcomes Subgroup on Breast Cancer Guidance (chaired by one of us (RAH)) identified 27 observational studies relating case volume and process to outcome, of which nine dealt with breast cancer. Five further studies dealt with the effect of specialisation on survival or mortality of patients with breast cancer. While a few studies were relatively small (under 1000 patients), four had over 5000 patients, of which two had over 10 000 patients. Controlling for case mix and patients' characteristics is a major problem, although in our analysis of survival in breast cancer among 13 000 women in Yorkshire, adjustment using crude but consistent indicators of prognosis had no impact on the results.⁴ This may be because potential biases that may operate with smaller numbers are minimised when large numbers are studied in a population context.

Population based research that uses data from sources such as cancer registries can quantitatively assess the experience of an entire community and compare it with that of another community. Such communities may live in different areas and be served by different hospitals or may live in the same area but follow different referral pathways from their general practitioners. Observed differences require explanation and in some cases may be artefactual. The observations need to be made, however, as a necessary component of rigorous evaluative research. This is not just a plea from academic research workers but also an increasing demand from patient and community groups.

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Treating a specified number of patients is no guarantee of quality

EDITOR,—The NHS Executive has recently written to trust executives about the development of