BASO ~ The Association for Cancer Surgery Yearbook 2011

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BASO ~ ACS National Committee

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ASSOCIATION INFORMATION

BASO ~ ACS Membership

There are five categories of membership:

Full Members

Professors, Senior Lecturers, Consultants, Associate Specialists, Staff Grades and Breast Physicians.

Associate Members

Specialist Registrars, Clinical Assistants and Senior House Officers.

Affiliate Members

Clinical Nurse Specialists, Specialist Breast Nurses, Researchers and Allied Health Professionals.

Overseas Member

Professionals working in surgical oncology outside the UK. Members from the Republic of Ireland can choose to join as Full, Associate or Affiliate members or as an Overseas member.

Senior Retired

Professionals, who have retired from practice.

Membership benefits include:

- Annual subscription to the EJSO
- Affiliate membership of ESSO
- Reduced delegate rates at the BASO ~ ACS Scientific Conference

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Download the **BASO** ~ **ACS membership form** at www.baso.org.uk



BASO ~ ACS Scientific Conference

The Scientific Conference of BASO ~ The Association for Cancer Surgery will take place in London at the usual venue of the Royal College of Surgeons.

The meeting will start on Monday 7th November with two parallel sessions with submitted papers to be presented, one in competition for the

Ronald Raven Prize. Mr. Jayant S. Vaidya and Dr. Erik van Limbergen will discuss face to face the promising avenues of intra-operative radiotherapy for breast cancer. The advantages and the limitation of TARGIT and IORT will be analysed and critically appraised.

We are delighted that Professor The Lord Ajay Kakkar has accepted to lecture on the thrombo-prophylaxis of cancer surgery, a frequent but often neglected complication. His lecture will certainly improve knowledge and

optimise standards.

An update on commissioning will be provided by Professor Garth Cruickshank in the afternoon of Monday 7th November. We are honoured to have Dr Armando Giuliano from Santa Barbara, U.S. to present on how sentinel lymph node biopsy has changed cancer management. This exciting overview will be followed by a discussion session. The day will be completed with poster viewing and a drinks reception, which will then be followed by the Society Dinner at the Apothecaries Hall.

On the second day two parallel sessions will start the meeting, with one being for the BJS prize papers. Professor Richard M Satava has agreed to give the EJSO Lecture on the Future of Surgery. This is an outstanding presentation which will certainly revolutionise our surgical approach and will help us to re-think the way we offer surgical care. This will be followed by an exciting symposium on the treatment of stage IV cancer. The symposium will be opened with an outlook on use of the Cyberknife for bone metastases. Surgery for breast cancer presenting with metastatic spread will be discussed by Mr Zenon Rayter. The role of lung metastasectomy will be discussed by Professor Tom Treasure and the need for liver metastasectomy will be summarised by Mr Graeme Poston.

A Plenary session will follow and Professor Umberto Veronesi from the European Institute of Oncology, Milan has agreed to give the EJSO Lecture on an overview from the beginning to

the future of breast cancer care.

The Alan Edwards Poster Prize Session will be assigned, rewarding the best posters presented.

Finally a symposium on controversies in reconstructive surgery will conclude the meeting. Mr Dick Rainsbury will present on skin sparing mastectomy. Professor Gilles Toussoun will discuss the largest series of lipofilling concluded so far. Mr Sat Parmar will summarise his vast experience of facial reconstruction for oral cancer.

The Association for Cancer Surgery Trainees will also hold a session at the

The first symposium will then

focus on advanced imaging and cancer management, Mr Peter Jones will discuss the use of microbubbles for sentinel node detection. Professor Gina Brown will present on the latest and most advanced surgical techniques associated with MRI imaging and computer aided surgical planning in the treatment of soft tissue sarcoma will be discussed. The symposium will be completed by a presentation on PET scanning.

On the same day a symposium will focus on the role of keyhole surgical oncology in the management of lung resection, mastectomy and gynaecological oncology. end of day one. This is intended to promote recruitment of young trainees with an interest in cancer surgery. This year's meeting marks a remarkable opportunity to rejoin with fellow surgical oncologists and address crucial issues which are not uniquely related to the management of breast cancer and cover all aspects of surgical oncology.

I am looking forward to meeting you there.

Professor Riccardo Audisio Meetings Secretary



President's Address - Looking to the Future!

Welcome to the first BASO ~ The Association for Cancer Surgery Yearbook. BASO ~ ACS is the association that speaks as an umbrella organisation for surgical specialties treating people with malignant diseases. BASO was founded in 1971 by Ronald Raven, Surgical Oncologist, as a forum for surgical research and training for the benefit of patients with cancer.

The Association represents surgeons and their centers across the United Kingdom & Ireland and has influence beyond. It owns, with the European organisation, ESSO, the European Journal of Surgical Oncology, EJSO – the highly respected research journal. Over 700 surgeons and affiliated colleagues comprise the BASO ~ ACS membership. The decision to float its branch, the Association of Breast Surgery, as a stand-alone organisation is allowing BASO ~ ACS to renew its links across many different surgical specialties.

Our mission statement is to promote the science and art of cancer surgery, for the benefit of the patient, and to encourage and showcase cancer research for public good. Almost two thirds of all people with malignant tumours are diagnosed and treated initially by surgeons and their multidisciplinary teams – MDTs. Surgery alone is sometimes the only treatment needed, but as research progresses increasingly surgery is used in conjunction with other treatment modalities, such as chemotherapy and radiotherapy, and now monoclonal antibody therapy.

The cancer surgeon increasingly works across specialty boundaries and has the advantage of a broad horizon to treat the patient. BASO ~ ACS surgeons were some of the first to bring immediate reconstructive surgery techniques into use at the same time as removing cancer bearing tissue. Such combined operations - oncoplastic surgery – are progressing rapidly not only in breast cancer care but also in head and neck malignancy, and in pelvic tumours.

Every November in London BASO ~ ACS hosts its Annual Scientific Conference on Cancer Surgery, with invited plenary speakers and presentations of scientific merit. Last year the Scientific Conference was exceptional with the range and eminence of the speakers and the depth of their presentations. Plenary lecturers were invited to cover a broad field of cancer surgery topics that crossed traditional specialties and informed and challenged.

BASO ~ ACS is a resource to help develop and influence the training of cancer surgeons, as well as supporting and publicising research. We hope that the inauguration of a BASO ~ ACS Trainees' Group will further lead to an enthusiastic and vibrant membership.

If you are a surgeon who is looking after patients with cancer in any specialty, we welcome you to join us, to become part of the UK's largest surgical oncology body.

In this yearbook we have gathered together examples of the work of BASO ~ ACS's member surgeons in advancing the art and science of surgery which have been showcased at our Annual Scientific Conference. They show the breadth of surgical oncology and testify to the huge advances surgeons continue to make to cancer care and to improved outcomes. BASO ~ ACS will continue to provide a leading role in advancing surgical oncology research and innovation by means of its annual scientific meeting, its support for junior surgeons just entering research, and awarding honours to esteemed leaders in the field.

Mr Andrew D Baildam

President



Honorary Secretary's Report

This is the first yearbook that BASO ~ The Association for Cancer Surgery has produced, at least for many years. It is an appropriate time to indulge in this project given the amicable separation of the Association of Breast Surgery from BASO ~ ACS which occurred in 2010 and gives BASO ~ ACS the opportunity to restate the

purpose and function of the organisation and in many ways "return to its roots".

As a member of BASO ~ ACS for many years (and by default a member of ABS) I have seen breast surgery evolve over the last two decades into a recognised subspecialty and it was time that the ABS became independent. This will allow it to pursue the training and research in benign breast surgery which some members of the association may have felt did not sit so comfortably with BASO ~ ACS, an association clearly devoted to cancer. With other members of the National Executive, I was involved in the discussions to separate the two organisations and negotiate the service level agreement referred to by Stewart Nicholson in the ABS yearbook of 2011. This agreement means that ABS collects the subscription monies for the two organisations which is then apportioned to the two Associations according to the size of the membership in each. It is still worth pointing out that BASO ~ ACS still has over 700 members and it will be interesting to see how many members who primarily see themselves as members of ABS continue to subscribe to BASO ~ ACS over the next few years.

Why should surgeons continue to be members of both organisations? My personal view is that cancer surgery involves many disciplines which range from basic science, medical and radiation oncology, genetics, radiology, pathology and oncology nursing. Different surgical subspecialties will continue to learn from each other. Whether it is in the application of new technology in one discipline which can then be transferred to another, the organisation of a service (for example the organisation of colorectal cancer screening and what it can learn from 20 years of the National Breast Screening Programme) or just multidisciplinary team working, these can surely be best compared and discussed in meetings which bring together specialists from a range of disciplines and surgeons operating on different organ sites. One of the themes for the forthcoming scientific meeting of BASO ~ ACS this year is the management of metastases and it is certain that subspecialties will face many similar problems and challenges.

What else will BASO ~ ACS do in the future besides put on scientific meetings? A major function of BASO ~ ACS now is the interface it has with the Government of the day, the media and the public. The President of BASO ~ ACS chairs the Cancer Services Committee of the Royal College of Surgeons and I as Honorary Secretary and the Vice President also attend. This committee has representatives of all the surgical cancer organisations including upper and lower GI surgeons, head and neck/ENT surgeons, orthopaedic, neurological and urological surgeons and endocrine, thoracic and sarcoma surgeons. A major achievement has been our ability to interface with the Government's Cancer Tsar, Sir Mike Richards who now openly champions the importance of surgery as the major curative modality in 80% of common solid tumours and BASO ~ ACS, I think, has been successful in reaffirming the importance of cancer surgery to the Ministry of Health. There are however, further challenges ahead and as cancer surgeons in general, we will face the problems of any changes in commissioning and organisation which will impact on cancer surgery due to reorganisation driven through by politicians.

On a lighter note, the National Executive Committee continues to encourage trainees of all the cancer subspecialties to become members of BASO ~ ACS. Currently we have offered free membership to presenters of oral/poster papers for a fixed period of time and will continue to offer discounted rates to members of other subspecialty organisations so be sure to look out for the "special offers".

We also have a number of travelling fellowships which trainees can apply for and intend to do more in the future to encourage trainees into research.

The last four years have been immensely satisfying and challenging and I do not underestimate the challenges for the future in continuing to ensure the Association remains successful. However, I and the other members of the National Committee are determined to ensure that BASO ~ ACS will continue to represent all the surgical specialties which deal with cancer both to the Government and to patients, and do everything we can to encourage teaching, training and research in the surgical specialties.

Mr Zenon Rayter Honorary Secretary

PRIZES & SCHOLARSHIPS

The Ronald Raven Prize, 2010

Mr Sijie Heng

4th Year Medical Student. School of Medicine, University of Glasgow

Prostate cancer poses a clinical challenge of distinguishing the aggressive tumours that men die of from the indolent tumours that men eventually die with.

This problem is amplified on a population level, where prostate cancer represents a substantial healthcare and economic burden. The total annual expenditure for prostate cancer, including screening, diagnosis, treatment and monitoring, reached £92.8 million in 2002 in the UK and over \$10 billion in the USA where screening is more prevalent. Notwithstanding differences in healthcare systems, current risk stratification strategies are inclined towards overtreatment of the disease. This not only causes dilution of services to patients with aggressive disease who would benefit from radical treatment, but also treatment-relatedharm to those with indolent disease who would not. Given that almost all men would develop histological evidence of prostate cancer if they lived long enough and that prostate cancer is already the most prevalent male cancer in the developed world, the issue of risk stratification would be even more important in this era of widespread prostatespecific antigen (PSA) screening as well as an ageing population.

> Prostate cancer represents a substantial healthcare and economic burden - the total annual expenditure for prostate cancer, including screening, diagnosis, treatment and monitoring, reached £92.8 million in 2002 in the UK

Prostate cancer, which is predominantly prostatic adenocarcinoma, is unique in its biological dependence on the androgen receptor (AR). AR-negative prostate cancers are extremely rare and even in the castrate-resistant state, prostate cancer cells remain exquisitely dependent on the AR, as evidenced by the renewed expression of PSA (a ARdependent gene product) in patients relapsing on androgen blockade therapy. Although multiple mechanisms may interact to modify the biological behaviour of prostate cancers, the AR may be the final common pathway through which these various mechanisms exert their effect on the tumour phenotype. Phosphorylation, a highly endergonic process, represents a significant investment of cellular energy and is likely to have significant functional effects on the AR. Indeed, experimental evidence has supported the role of phosphorylation in the promotion of AR transactivation and transcriptional activity as well as the prevention of AR degradation. Furthermore, recent evidence suggests that the significance of phosphorylation may be site-specific on the AR. It is plausible that the phosphorylation status of the AR may indicate or indeed, underlie the biological behaviour of prostate cancers. Working under Dr Joanne Edwards, we are interested in the significance of AR phosphorylation in prostate cancer in the clinical setting. Previous work by the team has already shown the clinical significance of AR phosphorylation in the transition of prostate cancer from the hormone naïve to the castrate resistant state. Leading on from





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this, we were interested in whether levels of site-specific AR phosphorylation in hormone-naïve prostate cancers were associated with disease-specific survival. Our results from a preliminary cohort of 92 patients showed an association with disease-specific survival with AR phosphorylation on a few sites, but only AR Ser-515 phosphorylation retained significance on multi-variate Cox-regression independent of other clinicopathologic parameters. Not only may this allow us an insight into the biology of prostate cancer, we hope that this would eventually aid the identification of patients with aggressive tumours who would benefit from radical treatment, as well as those who would not. However, as this is a relatively small cohort, further validation in larger cohorts would be needed to ascertain the value of AR phosphorylation as a prognostic marker.

I first started my research work under the tutelage of Dr Joanne Edwards whilst pursuing my intercalated degree in medical school. I find research a stimulating and enriching activity in itself that requires good communication, teamwork, problem-solving and attention to detail. Above all, my short experience in research thus far has brought me immense satisfaction in being able to contribute in some way, however small, to the understanding of the human body and its afflictions. At the same time, treating and caring for people is a privilege I relish and look forward to. I feel that clinical care and research can complement each other in a synergistic fashion to achieve better outcomes for patients, as exemplified by the field of surgical oncology. Although surgery has long been the mainstay of treatment in many cancer patients, the outcomes of cancer patients have improved tremendously over the past few decades through concurrent audit, research and consequent refinements to clinical practice. In my career, I hope to provide excellent clinical care for the public through advancing medical knowledge on one end and being a practitioner delivering care on the other.

The Ronald Raven Prize:

The Ronald Raven Prize is awarded annually to the best presenting author in the Ronald Raven Prize Session of the BASO ~ ACS Scientific Conference.

Previous winners of the Ronald Raven Prize:

2005	Miss S Dua
2006	Mr N Alkahmesi
2007	Mr S Somasundaram
2008	Mr Daniel Marsh
2009	Dr Gillian McColl
2010	Mr Siiie Heng



The Ronald Raven Travelling Fellowship 2009

Ms PG Roy

National Oncoplastic Fellow, Nottingham City Hospital visited Dr Scott Spear's Oncoplastic Unit in Washington

I was very keen to visit an international institution of excellence to broaden my horizon, so visited Georgetown University Hospital, Washington DC, USA for a period of 2 weeks as an observer in 2010, whilst working as an Oncoplastic Breast Fellow at Nottingham City Hospital.



company depending upon the circumstances.

I had the opportunity to see various patients who wished to have correction surgery for their previous augmentation or reconstruction. Some of them were more than 10 years out from their cancer and change in body weight had resulted in asymmetry thus wishing for a symmetrization procedure. The

other group comprised the cancer patients who were being counselled for their reconstruction options.

The results achieved with implant-alone reconstruction in Dr. Spear's hands are very impressive. All the potential choices of

In the USA, breast cancer surgery is a two-team approach whereby breast (general) surgeons perform the operation to remove the breast cancer and plastic surgeons deal with all the aspects of reconstruction.

Dr. Scott Spear is an eminent plastic surgeon with a special interest in breast reconstruction and aesthetic surgery. His book on breast surgery is well known to people in the field of Oncoplastic breast surgery. One of his current main areas of interest is in implant based reconstruction with use of acellular dermal matrix (Alloderm, Lifecell), which I was particularly interested in.

I am very thankful to BASO ~ ACS for their financial support for this trip (Ronald Raven travelling scholarship 2009).

GUH is located in a beautiful suburb of Washington DC, very conveniently located in terms of access to public transport and places of interest. Dr. Spear and his associate, Dr. M. Nahabeedian are the two plastic surgeons who perform breast reconstruction. Dr. Spear is supported by a very pleasant and organized team; consisting of very experienced clinical nurse practitioners, a fellow and a chief resident.

In the USA, breast cancer surgery is a two-team approach whereby breast (general) surgeons perform the operation to remove the breast cancer and plastic surgeons deal with all the aspects of reconstruction; as was mostly the case in the UK 5 - 10 years ago. The health service is based on a private sector model where the cost of the treatment is either paid by the patients (e.g. cosmetic surgery) or by their insurance reconstruction are discussed with the patient during the preoperative counselling, although the preference is usually for implant or DIEP, with few LD flaps being performed. The implant-based reconstruction is offered to the patients irrespective of the likelihood of need for post-op radiotherapy to the chest wall. Dr. Spear believes (which is well supported by the data presented at the meeting held in Coventry, UK in July 2010) that alloderm significantly reduces the risk of capsule formation, even in patients who receive chest wall radiotherapy. Quite a few patients choose to have bilateral mastectomies, which makes bilateral reconstruction with implants a suitable option for them.

Dr. Spear performs 2-staged implant-based reconstruction with alloderm. The first stage involves a skin sparing mastectomy and insertion of a tissue expander under the cover of the pectoralis major muscle and alloderm on the inferior and lateral aspect. This creates a reasonable sized pocket and therefore allows the expander to be inflated to 60-70% of the final volume. The expander is inflated fully in 1-2 stages 3-4 weeks after the operation. Patients are brought back roughly 6 months later (a little longer if they have had radiotherapy) to exchange the tissue expander for a definitive implant (commonly used implants are round, smooth surface implants; the anatomical implants are under trial at present). Surprisingly, there was very little capsule behind the alloderm in 2 patients that underwent exchange following radiotherapy during my stay. He alters the pocket to match the opposite side and inserts the implant with another sheet of alloderm to superimpose the dissected area if needed. The short term results are believed to be very good, although long term results are awaited. In addition to breast reconstruction, he is also using alloderm for selected cases of revision augmentation and to correct symmastia following reconstruction or augmentation. Most operations (except the first stage involving mastectomy and insertion of tissue expanders) are performed as day cases and patients are sent home with drains in situ which necessitates more frequent post-op visits in the first few weeks. Patients were surprisingly very cooperative with this approach, some of them were actually driving more than 1 hour each way for every post-op visit.

I had a great time observing the team in all their clinical activities. Dr. Spear's entire team was very friendly and welcoming and I really enjoyed being amongst the whole staff for the entire 2 weeks. The patients were very helpful and did not mind my presence as a visitor.

In addition to a brilliant clinical experience, I had a fantastic time on the social front. My family accompanied me on this trip, which meant that I could enjoy sight-seeing in the evenings and on the weekend. I visited during Easter time, the weather was very warm and this was the perfect time to visit because of the cherry blossom festival. It was just beautiful all around the Washington monument. All these made the whole trip very memorable.

Previous award holders have included:

2005	Sri Lanka Tour;
	Mr B Piramanayagam, Mr C K Khoo, Mr H Ramesh, Mr P Kiruparan, Mr R Nadeem, Mr A Burns,
2006	Mr G Morris-Stiff
2007	Mrs K Hogben
2008	IASO Conference;
	Mr S Balasubramanian, Mr A Goyal, Mr S Menakuru, Mr H Ramesh, Mr A Subramanian, Mr V Upasani
2009	Ms P Roy
2010	Mr R Jones & Mr I Whitaker

THE 2011 RONALD RAVEN TRAVELLING SCHOLARSHIPS



Submissions are invited for the BASO ~ ACS Ronald Raven Travelling Scholarship Award for 2011. The funds for this award are provided by the Ronald Raven Trustees in memory of Ronald Raven, founder of the Association. The award this year is a maximum of £2,000 and can be awarded to one or several individuals as considered appropriate by the BASO ~ ACS National Committee when considering the merits of the applications.

The scholarship is open to trainees or recently appointed consultants, who have gained the

Fellowship of one of the British or Irish Colleges.

Applicants need not be members of BASO ~ The Association for Cancer Surgery, but applications must relate to the aims and objectives of the Association.

Applications should be submitted to Mr Zenon Rayter by Friday 30th September 2011 and should be submitted in the following format:

- (i) A personal statement outlining the details of the use to which you wish to put the scholarship and also the benefits you wish to obtain from the visit. Please also include details of any other sponsorship/ scholarships obtained and whether you are applying for the full scholarship or part of it.
- (ii) Curriculum Vitae (brief version 3 pages maximum)
- (iii) A letter of support from an independent referee/ supervisor in the UK as to your suitability for this scholarship.
- (iv) A letter of invitation from the Unit/ Institution to be visited, showing that approval has been given for the intended programme.

Please send applications as detailed above to arrive no later than the 30th September to:

Mr Zenon Rayter, Honorary Secretary, BASO ~ ACS, at the Royal College of Surgeons of England, 35 - 43 Lincoln's Inn Fields, London, WC2A 3PE.

For further information please contact Rebecca Murchie at the above address or by e-mail: rebeccamurchie@baso.org.uk

The Genesis and History of BASO ~ ACS

Professor Michael Baum

Professor Emeritus of Surgery and visiting Professor of Medical Humanities at University College London

> My relationship with BASO ~ ACS has moved through three phases, initially wild enthusiasm, next polite indifference and finally a rekindling of interest.

My initial involvement with BASO was in the early 1970s when I was an ambitious young senior lecturer in the academic department of surgery in Cardiff, headed up by Prof. Les. Hughes. I

remember well how flattered I was, to receive an invitation from Mr. Ronald Raven, to become a founder member of the association and speak at their first conference that was to be held at the Royal College of Surgeons.

Now Mr. Raven was an interesting man, living and working in Harley Street and working part time at the Royal Marsden Hospital. He had an Edwardian air about him, courtly and dapper in pin stripped trousers and black morning coat. He also had an extraordinary conversational style. He never just spoke to me, but used every rhetorical technique to rouse me from my slumber. A chat with Ronnie Raven was a bit like being at the receiving end of an Henry Vth speech "once more into the breech dear friends..." or Churchill's speech in the commons, "We will fight them on the beaches....".

To him the treatment of cancer was a battle against a foreign enemy with the knife cutting out the primary focus of attack together with the enemy's outriders occupying the lymph nodes draining the primary. Considering I was beginning to make a name for myself by challenging the radical dogma of surgical oncology, I was mystified as to why I was to be one of the chosen that was "to dress in my armour and draw my sword in the front line of the war against cancer". To this day I'm not sure if he really understood what I was on about or if he was showing intellectual integrity by providing a platform for an alternative view on surgery for cancer. Whichever it was I certainly didn't want to lose this chance of selfpromotion. Furthermore I had the naïve idea that setting myself up as a "surgical oncologist", I would have all the sarcomas and melanomas referred to me together with a smattering of oesophageal and parotid tumours. In those days we were also called upon to do staging laparotomy for lymphoma, a short lived period in the history of onco-idiocy.

However it didn't work out like that as all the general surgeons who weren't surgical oncologists manqué had no intention of giving up their work to some young upstart like me. So in the fullness of time in Cardiff and as professor at Kings and the Royal Marsden, as my breast cancer workload grew and grew, I settled at being a breast cancer specialist who incidentally was a surgeon by training.

This then lead to the second phase in my relations with BASO ~ ACS. I stopped going to surgical meetings and my academic calendar started to revolve around the British Breast Group, The Nottingham breast cancer conference, the motor- cycle museum annual meeting, San Antonio, ASCO and biennial meetings of St. Gallen and the EBCC.



A chat with Ronnie Raven was a bit like being at the receiving end of an Henry Vth speech or Churchill's speech in the commons.

So throughout 20 years of my career surgical art and craft was of no real interest to me but merely a means to an end. In fact most of my foreign friends and colleagues on this circuit weren't aware of my guilty secret of being a closet surgeon.

This linkage served me well in particular for my role as principle investigator of multi-centre and multi-national trials. In this role I had to hold my own with medical and radiation oncologists as well as endocrinologists and statisticians. Also, although I could never master their secret language, I, like most of my colleagues, was being seduced by the glamour of the molecular biologists.

The third phase in my on/off affair with BASO ~ ACS came about in two ways. Firstly the growing realisation that molecular biology was a long way from replacing surgery and in fact a long way from delivering on its promises. Secondly whilst my back was turned, what was happening in breast cancer was happening in all other divisions, branches and sub-specialities of surgery. All of us have been guilty of turning our back on the art and craft of our discipline, unfaithful to our wedded professional engagement, we have been chasing the seductive siren call of other disciplines as a result of which, surgery as an academic subject has been abandoned. So much so there is now a movement afoot to describe "academic surgery" as an oxymoron and many famous academic departments of surgery have folded or been subsumed into divisions of "interventional medicine" or some such other ugly neoglism.

I have recently, on a few occasions been called in to advise on the future of surgical research and academic surgical units. To my mind the best definition of surgical research is as follows; research done by surgeons on pathological conditions that are referred to surgeons. But alongside that is the recognition that surgeons can't be Jack's of all trades and that the best kind of surgical research is carried out as part of a neural network that shares nodes in common with pathology, radiology, molecular biology, epidemiology, statistics and so on. This is why we need to reclaim our slice of the high-ground and to demonstrate to the other disciplines that they need us as much we need them. In fact when I look back at the major advances in surgical oncology, they were mostly initiated by skilled surgeons making clinical observations, formulating hypotheses and then, only then, bringing in reinforcements from the basic scientists. This I believe is the future of BASO ~ ACS - back to the future!



A Mission in Almaty, Kazakhstan

Mr Andrew Baildam Consultant Oncoplastic Breast Surgeon and President of BASO ~ ACS

Professor Riccardo A Audisio Professor of Breast Surgery and Meetings Secretary of BASO ~ ACS

BASO ~ ACS members have played a key role in promoting the development of cancer care in Kazakhstan recently. The 'Masterclass on Breast Cancer' organised by ESO, the European School of Oncology, in collaboration with the Institute of Oncology of Kazakhstan and BASO ~ ACS members was held in Almaty in November 2010.

The course aimed to provide educational and methodological support to improve the management of breast cancer in Kazakhstan. All areas of practice were to be covered, including screening and imaging, pathology and curative and reconstructive surgery. This followed the Kazakh government's decision to redouble their efforts to reduce the high toll of breast cancer deaths in the country. Survival still only averages 50%, roughly equivalent to UK rates 50 years ago and the mastectomy rate exceeds 80%.

The European School of Oncology, under the lead of Prof. Marco Rosselli del Turco, President of EUSOMA, set up a comprehensive program of education; all areas of interest were addressed, from imaging to methodological aspects of breast screening, pathology, medical oncology and surgical issues were discussed. Mr Andrew Baildam and Professor Riccardo A. Audisio had the honour to be involved in this mission. We were warmly welcomed and felt hugely appreciated.

Time for discussion was made available and speakers were glad to be approached during the breaks to answer questions. Despite this open and collegial approach, the main problem encountered was communication; this is because the large majority of the audience were not fluent in English. To overcome this difficulty, the organisers arranged for simultaneous translations. Slides were also translated into Russian. Dr. Shinar Talayeva, lead breast surgeon, organised two surgical procedures to take place. These were presented to the audience through video links from theatre.

Mr. Baildam operated on a young lady requiring a skin sparing mastectomy and immediate reconstruction. In this case the nipple-areola complex was preserved. Mr. Audisio was asked to perform a mastectomy with axillary dissection with use of no drains as is his practice. Both procedures went very well. There were numerous questions from the audience and our interaction was greatly facilitated by Dr. Nikolay Malishev who was fluent with English, Russian, Kazakh and Italian.

We were impressed with the number of operations that were performed as well as the equipment available. Anaesthetic equipment was new and efficient and thoracoscopic surgery was being performed with a modern armamentarium. The technical skills of our Kazakh colleagues are certainly excellent; advanced cancer procedures were performed and

surgeons showed an active interest in optimizing their surgical skills. Despite our lack of knowledge of the Kazakh or Russian languages the interaction was very pleasant and we felt genuinely welcome.

Interestingly, we noticed that the surgical armamentarium is not disposable: similar to what used to be in our western reality some years ago, the use of disposable tools is not wide spread. There is also the issue of adequate sterilization as the use of catgut and linen is now forbidden in Western Europe due to the lack of adequate sterilization but is still widely used in Kazakhstan.

Finally, we would like to thank Prof. Arzykulov who leads the Cancer Institute; he should be congratulated for his vision and interest in improving the present situation.





BASO ~ The Association for Cancer Surgery

Improving Cancer Outcomes: The role of New Surgical Techniques

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THE ROLE OF NEW SURGICAL TECHNIQUES

The majority of human solid tumours are only ever definitively cured by complete surgical removal and UK surgeons have been at the forefront of developing and improving the quality of surgery for many years. The following series of articles, themed around recent presentations at the BASO \sim ACS Annual Scientific meeting, showcase some of the most exciting developments in surgical techniques.

The LOREC initiative for rectal cancer

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The multidisciplinary approach to cancer management has revolutionized patient outcomes, particularly for rectal cancer. Improvements stemmed from the recognition in the 1980's that involved specimen margin rates at pathological assessment

correlated with local recurrence rates. The contemporaneous publications on the concept of total mesorectal excision (TME) by Heald have subsequently been summarized as "specimen orientated surgery". focus to low rectal cancer with optimal outcomes reported for patients with advanced low rectal tumours treated by what has been termed extra levator APE (ELAPE) in selected cases. The National Cancer Action Team in England has taken on board the complexity of low rectal cancer and has funded a national low rectal cancer development programme with details accessible on www.lorec.nhs.uk. This initiative aims to optimize outcomes in the most challenging cancers where quality of life, and function, have to be considered in combination with optimal oncological management. The optimal strategy for low rectal cancer continues to evolve and the LOREC programme is timely and will advance global knowledge in this complex field.

In rectal cancer this has culminated in a focus on optimal pre-operative staging, preoperative treatment for selected patients with involved or threatened margins, with TME and careful macroscopic and microscopic assessment of the specimen as quality control of all aspects of treatment.

However for low rectal cancer, defined as tumours at, or below, the level of the levators (generally within 6cm of the anal verge) margin involvement and local recurrence rates are suboptimal, particularly in those who have an abdomino-perineal excision (APE). A combination of surgical and pathological co-operation has shifted the



THE ROLE OF NEW SURGICAL TECHNIQUES

Improving rectal cancer surgery through pathological feedback - the 2010 Ernest Miles Lecture

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Background

Rectal cancer is a common disease in the West with 14,334 new cases diagnosed in the UK during 2007.¹ While outcomes have markedly improved over recent years, the five year survival remains around 50% making colorectal cancer (CRC) the second commonest cause of cancer related mortality. Significant improvements in outcomes largely followed the introduction of multidisciplinary teams (MDT) to co-ordinate the care of CRC patients.

This coincided with improvements in the quality of surgery and pathology, and the introduction of preoperative magnetic resonance imaging (MRI) and radiotherapy. Rectal cancer is currently only definitively cured by surgery, when the primary tumour is removed along with all potential routes of metastatic spread. A small amount of additional benefit can be gained through adjuvant chemotherapy in cases with a high risk of recurrence. This review will focus on the developments in rectal cancer surgery over recent years and discuss how pathologists have contributed to this process through audit and feedback.

CRM, TME and the rectal cancer story

In the 1980's researchers from Leeds showed that incomplete removal of rectal cancers at the circumferential resection margin (CRM) was strongly linked to local disease recurrence.² In this landmark study, CRM involvement was noted in 27% of cases (defined as tumour cells at or within 1mm of the non-peritonealised margin). This coincided with the time surgeons from Basingstoke reported very impressive outcomes following total mesorectal excision (TME) for the



resection of rectal tumours.³ TME surgery is based on the principle of careful dissection along embryological tissue planes, producing an intact fascial-lined package containing the primary tumour along with all potential routes of vascular, lymphatic and nodal spread. A move towards TME surgery and MDT-led care dramatically improved outcomes in large population series and randomised clinical trials.⁴⁻⁶ Both local disease recurrence and disease free survival were significantly improved over historical data.

Pathologists subsequently demonstrated that a switch to TME surgery was associated with reduced CRM involvement thus explaining the lower rate of local recurrence.⁷ CRM status can therefore be used as an immediate indicator of the quality of surgery and is mandatory for pathologists to report in rectal cancer specimens. Pathological feedback was later extended to include a description of the plane of mesorectal dissection followed by careful assessment of the specimen (table 1). Five subsequent studies have now confirmed that mesorectal grading is related to patient outcomes.⁸⁻¹² In one of these, the MRC CR07 trial, the overall mesocolic plane

resection rate was 52%, however feeding back the CRM status and plane of dissection to surgeons throughout the trial led to a consistent improvement in both parameters.¹⁰

Abdominoperineal excision

Low rectal cancers treated by abdominoperineal excision (APE) are well recognised to be associated with poorer outcomes when compared to higher tumours treated by anterior resection.¹³⁻¹⁴ There is a higher rate of CRM involvement and intraoperative perforations due to the anatomical reduction in mesorectal tissue volume in the distal mesorectum. This is compounded by poor visualisation of the tissue planes when using a standard approach resulting in frequent deviations into the sphincter muscles, submucosa or even lumen.

It is now over 100 years since Ernest Miles

published his description of a wide approach to APE surgery including dissection outside of the levator muscles to produce a cylindrically shaped specimen.¹⁵ Over the intervening years the technique was modified resulting in the removal of less tissue in the distal rectum and producing the classic APE specimen with a marked surgical waist at the level of the puborectalis muscle.¹⁶

However, in the last few years surgeons have begun to promote variations of the original Miles operation. Extended APE,¹⁷ and abdominosacral resection,¹⁸ both involve dissection outside of the levator muscle plane although less

> It is now over 100 years since Ernest Miles published his description of a wide approach to APE surgery including dissection outside of the levator muscles to produce a cylindrically shaped specimen

Grade	Short description	Long description
Mesorectal Plane	Good surgery	Intact smooth mesorectal surface with only minor irregularities (<5mm). No distal coning and smooth CRM on slicing
Intramesorectal Plane	Moderate surgery	Moderate bulk to mesorectum but irregularity of the surface. Moderate distal coning. Muscularis propria not visible with the exception of levator insertion. Moderate irregularity of CRM
Muscularis propria Plane	Poor surgery	Little bulk to mesorectum with defects down onto the muscularis propria and/or very irregular CRM. Includes infraperitoneal perforations

Table 1: mesorectal grading according to the plane of surgery as assessed at the time of pathological dissection by noting the presence and extent of any mesorectal defects.

perineal skin and ischiorectal fat is usually removed when compared to the original Miles technique. Extralevator APE (EL-APE) removes significantly more tissue in the sphincter area to protect the CRM from tumour involvement and perforation.¹⁹ A large multicentre European study looked at 176 EL-APEs from 11 surgeons and 124 standard APEs from a single centre.²⁰ They showed that EL-APE removed more tissue around the tumour resulting in a reduction in both CRM involvement (50% vs. 20%) and perforations (28% vs. 8%) when compared to standard specimens. Extra tissue was removed in all directions, including anteriorly where the CRM is most frequently threatened. A small number of surgeons attempted EL-APE surgery in the lithotomy position, and while the CRM status was not compromised there was an increase in the number of perforations (6% vs. 21%). Longterm outcomes for EL- APE are still awaited, however, the early results appear promising with local recurrence rates in curative surgery as low as 4% and five-year survivals between 68% and 76%.17,18,21

Pathologists play an equally important role in the feedback of APE surgery to help improve the quality of the specimen and outcomes for patients. Features such as CRM status and perforations should be reported in addition to grading the plane of surgery both in the mesorectum and the sphincter/levator area. The sphincter/levator grading system was initially devised for the Dutch TME study where one third of specimens had defects in the sphincter/levator muscle complex with the remainder being in the sphincteric plane.

There were no cases of extralevator surgery at this time.²²

EL-APE is generally now regarded as the oncologically superior operation for low rectal cancers that cannot undergo restorative surgery, however, some questions still remain about the level of morbidity associated with such a destructive procedure. The multicentre European study demonstrated an increase in perineal complications with the EL-APE technique when compared to standard surgery (38% vs. 20%), hence optimising the perineal reconstruction requires further investigation.

Discussion

While rectal cancer outcomes have improved significantly over recent years, patients undergoing APE for low rectal cancer continue to have a poorer prognosis when compared to higher tumours

undergoing restorative surgery. Pathological

studies have significantly helped to determine the scientific basis for the increased rate recurrence in these patients. Through audit/feedback of CRM status and perforation rates, and by reporting the plane of dissection we believe we can help to improve the quality of the specimen produced as was previously demonstrated following the introduction of TME for higher tumours.

Regional low rectal cancer training courses have already been undertaken in the Trent region of the UK and across the whole of Denmark. Now we have received government funding for the first national UK pilot programme, LOREC, that begins in March 2011. The aims of this course will be to educate MDTs in the optimum management of low rectal cancer patients and particularly advocate the use of EL-APE, where appropriate, and discuss the options for perineal reconstruction. It is hoped that this will reduce the high rates of CRM involvement and perforations and therefore improve outcomes for patients.

Many questions still remain and with the introduction of the National Bowel Cancer Screening Programme resulting in earlier stage disease, less aggressive approaches including

Grade	Short description	Long description
Extra-levator Plane	Good surgery	The specimen has a cylindrical shape due to the presence of levator muscle removed en bloc with the mesorectum and sphincters. Any defects must be no deeper than 5mm. No waisting of the specimen. Smooth CRM on slicing.
Sphincteric Plane	Moderate surgery	The specimen is waisted and the CRM in this region is formed by the surface of the sphincter muscles which have been removed intact
Intramuscular/ submucosal plane/perforation	Poor surgery	The specimen is waisted and includes deviations into the sphincter muscle complex, submucosa and complete perforations

Table 2: sphincter/levator grading according to the plane of surgery as assessed at the time of pathological dissection noting the presence and extent of any defects below the mesorectum in the sphincter/levator muscle complex.

> radical chemoradiotherapy with local excision and salvage may be an option for some patients. Until this time we should recognise the primacy of modern rectal cancer surgery and resource it effectively in order to obtain surgical excellence. Cuthbert Dukes once said "I should not chose the operation but I should chose the surgeon to do it, and I should chose him with great care". We entirely agree and would strongly encourage surgeons not to sit back but to observe new techniques, compare their specimens and results with peers, encourage pathological audit and feedback, take part in clinical trials and ultimately take action to improve their own results.

In summary we believe that Ernest Miles would be pleased with recent developments. His 102 year old operation has undergone a reinvention to improve low rectal cancer surgery, which along with a reduced incidence of rectal cancer, the identification of earlier stage disease and reduced APE rates should ultimately result in better outcomes for patients.

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Recent advances in hepatobiliary surgery

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Hepatobiliary surgery for malignant disease has now come of age! Just over twenty years ago only one or two surgeons in the UK attempted liver resectional surgery for cancer and they were regarded as mad, conventional contemporary surgical wisdom branding them as heretics!

Liver resection was highly dangerous, associated with massive blood loss, high operative mortality, and if you did survive the surgery, the cancer would inevitably return, sooner rather than later. Things could not be any different in 2011. Granted the surgery remains technically difficult and challenging, but it is now safer than any other operation for gastrointestinal malignancy (including primary colorectal cancer) and the outcomes (disease free survival and overall survival) are superior to those of all operations for gastrointestinal cancer apart from primary colorectal cancer.

These advances have been achieved philosophically, technically, pharmacologically and organisationally. The philosophic cause has been the large scale publication of our outcome data which demonstrate both the operative safety and survival benefit of such surgery¹.

The technical advances have come both in surgery, anaesthesia and radiology. The surgical advances are firstly the better understanding of the segmental anatomy of the liver which allows us to resect individual segments, preserving liver function and so facilitating any future liver resection if disease recurs. The second is the use of intraoperative ultrasound (IOUS) with or without contrast that now allows precise anatomical detection of lesions as small as 2-3 mm during surgery. The third has been in resectional techniques. Although it is mandatory that no liver surgeon should operate on the liver if not familiar with traditional techniques of Kellyclasia and finger fracture (in the event of technical failure rendering the liver dissecting equipment unusable), many such technologies (CUSA, harmonic scalpel etc.) are now available and may speed up the surgery and lead to diminished blood loss. The biggest breakthrough in anaesthesia has been the acceptance of low-CVP anaesthesia, in which the patient is fluid restricted during surgery, leading to zero or negative pressure in the IVC and so resulting in minimal intra-operative bleeding. The major advances in radiology have come with the introduction of liver-specific contrast MRI and the adoption of PET-CT to identify, locate and characterise liver-specific lesions, and at the whole patient level exclude inoperable extra-hepatic disease that would render hepatectomy futile.

The pharmacological advances have been in chemotherapy, largely in the treatment of metastatic colorectal cancer in which induction chemotherapy using modern regimens converts 10-30% of inoperable but liver restricted disease to operability with curative intent (Fig. 1). Secondly, the use of peri-operative chemotherapy, either in the neoadjuvant or adjuvant setting does appear to improve both progression-free and overall survival following hepatectomy.



Figure 1. Examples of a patient with metastatic colorectal cancer (A and C) downsized with chemotherapy to resectability (B and D) with curative intent

The major organisational advance has been confined to the UK through the implementation of the 2000 Cancer Plan. Hepatobiliary surgery for cancer is now confined to cancer network designated high surgical volume regional centres of excellence. Data confirm that concentrating such complex cancer surgery into high volume centres improves short and long term outcomes.

The first hepatectomy for metastatic colorectal cancer was performed by Cattell at the Lahey Clinic in 1943 and is now practised worldwide. Up until the turn of the century, only those patients with 3 or fewer metastases, confined to one lobe of the liver, resectable with at least 1 cm margin of surrounding healthy liver, smaller than 5 cm and detected metachronously were considered resectable with curative intent. As such, less than 10% of all patients with liver-only disease were considered for surgery. Ten years on, the definition of resectability has changed considerably. Using a variety of treatment strategies (including two stage hepatectomy, pre-operative portal vein embolisation, combination with tumour ablation), we will now offer liver resection to patients whose hepatic disease burden can be resected while preserving 25-30% healthy viable liver (either de novo or after being made resectable following induction chemotherapy), even in the presence of low-volume resectable extra-hepatic diseases, regardless of number, size, position of their metastases. As such, nearly 40% of all patients with liver-dominant metastatic disease are now candidates for hepatectomy with curative/long-term survival intent. Presently, most contemporary studies report 5 yr survival in excess of 60% and 10 yr survival exceeds of 25%, with operative mortality rates of 1-2%.

> Liver resection was highly dangerous, associated with massive blood loss, high operative mortality, and if you did survive the surgery, the cancer would inevitably return,

The evidence to support this radical change in the definition of resectability with curative potential comes from a number of sources, (the CRUK sponsored systematic review¹, the English population based



Figure 2. US scan of liver showing three metastases behind the right portal vein

audit², and LiverMetSurvey³, the European liver metastasis resection registry).

The most recent meta-analysis⁴ summarised post-operative mortality and morbidity, health care resource utilization costs, quality of life and clinical guidelines. Seven prognostic factors of mortality were considered: grade, tumour size, extrahepatic disease, number of hepatic metastases, number of positive lymph nodes, carcinoembryonic antigen level, and positive resection margin. 142 studies met the inclusion criteria. Post-operative mortality ranged from 0-4%. The three most common post-operative fatal complications were hepatic failure (23.8%), sepsis (15.5%), and myocardial infarction (14.3%). Post-operative blood transfusions occurred in 36% of patients, a reduction from 64.3% reported previously¹. 5-year survival varied from 16%-71% (mean 39%, median 38%), an improvement from the mean of 30-35% previously reported1. 40 studies were included in the meta-analysis: hazard ratios (and 95% confidence intervals) were: node positive primary [1.5 (1.4-1.7); p-heterogeneity (ph)=0.606; number of studies (n)=13]; extra-hepatic disease [1.4 (1.2-1.7); ph=0.056; n=6)]; and poorly differentiated tumour [1.3 (1.1-1.5), ph=0.059; n=4].

With regard to ablation of metastases the only randomized trial that possibly demonstrates a survival benefit for patients receiving radiofrequency ablation (RFA) for unresectable liveronly disease come from the EORTC CLOCC Trial⁵. This trial was originally conceived as a 400 patient phase III study of patients with up to 9 unresectable liver-only metastases randomized to either oxaliplatin-based systemic chemotherapy or chemotherapy plus RFA (open, laparoscopic or percutaneous) with or without concomitant resection of easily resectable lesions. This was an extremely ambitious project, and recruitment was understandably extremely difficult. Due to poor accrual, the trial was reduced to a randomized Phase II study with an actual accrual of 119

patients. Although there was a significant improvement in the secondary end-point of 3 year progression free-survival (PFS) of 27.6% for RFA + chemotherapy compared to 10.7% for chemotherapy alone (p=0.025), OS at 30 months (primary study end point) was no better for RFA + chemotherapy (63.8%) over chemotherapy alone (58.6%) (p=0.218). The study was never originally powered to demonstrate a significant result for its primary end point with such low numbers, and it is extremely unlikely that such a study will ever be repeated. RFA is now being superseded by microwave technology which appears equivalent in efficacy and safety but is considerably faster in delivery.



Fig: 3 Couinaud segmental anatomy of the liver

The majority of patients will present with liver metastases from CRC that are unresectable or not optimally resectable based on their size, number, or location at the time of initial assessment. In this setting conversion therapy is used in appropriately selected patients with liver

metastases that may become resectable if a reduction in size can be achieved with preoperative chemotherapy. The focus is therefore on achieving sufficient downsizing of the metastases that will allow an opportunity to perform surgery, not necessarily achieving a maximal response. Achieving a maximal response, particularly a complete radiologic response may hinder surgical resection. This was first demonstrated in the mid 1990s° but subsequently confirmed in numerous studies (Fig. 3). Presently conversion rates to resectability exceed 40% when biologics are combined with cytotoxics to achieve tumour response rates in excess of 80%⁷.

The recent EORTC-CRUK EPOC trial of peri-operative FOLFOX and surgery versus surgery alone, patients randomized to chemotherapy received 6 cycles of chemotherapy before surgery and 6 cycles after surgery⁸. A partial or complete response was seen in 43% in patients receiving chemotherapy. Surgery was performed in 83% of patients randomized to chemotherapy and in 84% of patients randomized to surgery alone. A non-significant increase in PFS was seen in patients receiving chemotherapy. The trial failed to show significance at its primary end point (improved 3-year PFS for those receiving peri-operative chemotherapy) for all patients randomized as some were found to be inoperable in both arms. However there was a significant improvement (9%) in 3-year PFS in the 150 patients who received peri-operative chemotherapy and were successfully resected over the 150 who were randomized to and underwent surgery alone.

Advances in surgery for primary liver tumours (hepatocellular carcinoma [HCC], cholangiocarcinoma and gallbladder cancer) have been less spectacular. Probably the most important recent advance has been the relaxation of criteria for liver transplantation in the UK for HCC from the original Milan criteria of a maximum tumour diameter of 5 cm to now one of 7 cm (double the tumour volume), providing the tumour can be stabilised (using trans-arterial chemoembolisation or chemotherapy with sorafinib) for a minimum of 6 months before placing the patient on the waiting list for transplantation.

Unfortunately we have seen little progress in the management of primary biliary cancers. The majority of these cancers are inoperable at presentation. One area of possible hope is in greater awareness by surgeons of the possibility of early gallbladder cancer. T1A tumours are cured by cholecystectomy alone and require no further treatment apart from monitoring. However T1B and T2 tumours, which have a 20% 5 year survival chance following simple cholecystectomy, will have an 80% 5 year survival if the gallbladder resection is combined with resection of the surrounding liver tissue ('radical cholecystectomy'). The vast majority of T1B/T2 tumours are visible on ultrasound, and since nearly all gallbladder cancers are associated with the presence of gallstones then should be detected during the diagnostic work up for patients with symptomatic cholelithiasis. Therefore, any such suspicion on the part of the investigating clinician of possible early gallbladder cancer should automatically trigger referral of the patient to the regional hepatobiliary surgery centre for radical cholecystectomy, which in the majority of such cases can be performed laparoscopically.

In conclusion, hepatobiliary surgery has come of age over the last two decades. When conducted in appropriately staffed high volume centres of excellence, the outcomes (immediate and long term) for the treatment of hepatobiliary cancers exceed those seen for all other GI cancers except primary colorectal cancer.

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THE ROLE OF NEW SURGICAL TECHNIQUES

Surgery and Hyperthermic Intra Peritoneal Chemotherapy, (HIPEC) for Selected Patients With Peritoneal Malignancy

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Traditionally peritoneal malignancy has been considered as end-stage disease not amenable to any curative strategy. Whilst this remains unfortunately true for the majority, an emerging strategy of macroscopic tumour excision (entitled

cytoreductive surgery) combined with Hyperthermic Intraoperative Intraperitoneal Chemotherapy (HIPEC) can be curative in selected patients. relatively unique in commissioning treatment for PMP in two centres, namely Basingstoke since 2000 and Christies Hospital Manchester since 2002. This has allowed these units to have high volume experience such that both are now amongst the most experienced centres in the world in the management of pseudomyxoma. A recent paper from Basingstoke⁵ outlines the early, and 10 year, outcomes in a large cohort of 456 patients. In two thirds complete tumour removal, combined with HIPEC, was achieved with 5 and 10 year predicted survival of 87% and 74% respectively⁵. In the whole series the mortality was 1.6% and improved over time, a feature of the learning curve in this complex strategy⁵.

Suitable patients comprise patients with primary peritoneal tumours with favourable pathology, such as multicystic peritoneal mesothelioma1 or secondary peritoneal tumours, either with non invasive features, and therefore confined to the peritoneum^{2,3} or if invasive localized within the peritoneal cavity, and generally involving less than one quadrant of the abdomen. The surgery involves complete macroscopic tumour removal by the principles of peritonectomy^{2,3} combined with HIPEC to address the issue of remaining miscoscopic disease. The most suitable tumour for these techniques is pseudomyxoma peritonei (PMP) which is a rare clinical entity characterized by mucinous ascites classically originating from a ruptured mucinous neoplasm, generally of low-grade, and predominantly arising in the appendix^{2,3,4}. The incidence of PMP is approximately 2 per million per year such that few centres have a major experience. The UK is



Figure 1 Large omental cake of tumour originating from a perforated appendiceal neoplasm resulting in pseudomyxoma peritonei

Case selection is crucial as the morbidity, and indeed mortality, is high for this complex surgery.

The basis for this treatment strategy lies in the pathophysiology of the disease process and revolves around the phenomenon of "redistribution" whereby mucinous tumour cells accumulate at specific sites with relative sparing of the motile organs in the abdominal cavity, namely the small bowel, stomach and to a lesser extent other parts of the gastrointestinal tract^{2,4}.

Peritoneal tumour accumulates due to the effects of gravity and the concentrating effects at the sites of peritoneal fluid absorption which mainly comprise the greater and lesser omentum and the undersurface of the diaphragm, particularly the right side.

The techniques developed initially with PMP are now being applied in other peritoneal malignancies, in particular selected cases with colorectal carcinomatosis⁶ and abdominal mesothelioma¹. Whilst scepticism persists as to the benefit of this strategy, it is pertinent to note that there has been a favourable randomized controlled trial to support this approach in colorectal carcinomatosis with significantly better outcomes in patients treated with surgery and HIPEC compared with those treated by optimal systemic chemotherapy.⁷

Case selection is crucial as the morbidity, and indeed mortality, is high for this complex surgery. The average operating time for complete tumour removal and HIPEC for an extensive PMP case is 10 hours and generally involves a right and left abdominal parietal peritonectomy, a right hemicolectomy, a radical greater omentectomy with splenectomy, a right and left diaphragmatic peritonectomy, a cholecystectomy and liver capsulectomy, a pelvic peritonectomy with rectosigmoid resection in many and in females bilateral salpingo-oophorectomy with hysterectomy ^{2,4,5}. It is also pertinent, as reported by Youssef et al⁵ and others^{2,3,4}, that favourable pathology does not necessarily mean that the tumour is completely resectable if it involves

the small bowel. Indeed over one third of cases assessed by the Basingstoke team were not considered likely to benefit from surgery and in one third of those who underwent surgery, a complete tumour removal was unachievable, mainly due to extensive small bowel involvement. Additionally, needless to say, patients need to be generally fit for such extensive surgery and many will be unsuitable due to advanced age or for other major co-morbidity reasons. For this reason it is prudent not to overestimate the potential for surgery and HIPEC based on the pathology and review of the patient, scans and images by an experienced team from a



Figure 2 Appearances over the right liver and undersurface of right hemidiaphragm in the same patient. A liver capsulectomy has been commenced on the infero-medial aspect of the right lobe of the liver.

specialist centre is needed to quantify the risk benefits and select patients most likely to benefit either by complete tumour removal in many or by maximal debulking of the tumour in others. It is also pertinent to note that many patients with mucinous adenocarcinoma may be erroneously labelled as PMP, often based on a percutaneous biopsy demonstrating abundant mucus and a few abnormal cells under the microscope. Caution is required as expectations may be elevated by the pathology report when the clinical presentation, often with muscle wasting, gross mucinous ascites, elevated tumour markers etc suggest a more aggressive disease not amenable to treatment with curative intent by surgery and HIPEC and liason with specialist centres is recommended prior to labelling such patients.

Whilst patients with the more common conditions, such as colorectal carcinomatosis, generally have to have disease confined to approximately one quadrant of the abdomen, have to be amenable to complete tumour removal and have to be fit to undergo this major surgery, nevertheless some will benefit (6). Long-term survival, and cure is possible in highly selected cases. Optimal outcomes in colorectal carcinomatosis are achieved in patients with localized disease, ideally where the peritoneal disease can be treated at the same time as the primary tumour and in experienced centres6. Additionally some cases with metachronous colorectal carcinomatosis may benefit from this strategy, though selection of suitable cases continues to be hampered by the limits of imaging to detect low volume disease. None of the techniques, which have revolutionized staging and management of many cancers, such as CT, MRI or functional imaging, such as PET/CT, are able to detect, and stage, low volume peritoneal carcinomatosis. The best methods for diagnosis and staging continue to be invasive, in the form of laparoscopy and laparotomy. The hope for the future is that this aspect will improve over time to optimize the case selection to those most likely to benefit. Additionally the increase in laparoscopic colorectal surgery will allow early detection of limited peritoneal disease in some cases at initial diagnostic laparoscopy, with a willingness to abandon the procedure and refer to a specialist treatment centre to facilitate curative treatment. Further advances in molecular biology, and tumour characterisation, may also help in the guest for optimal case selection for this complex disease amenable to cure in selected patients. Ongoing research, increased clinical experience and dissemination of the techniques hold promise for the future.

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THE ROLE OF NEW SURGICAL TECHNIQUES

Advances in Retroperitoneal Sarcoma Surgery

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Introduction

Retroperitoneal sarcomas (RPS) are rare tumours and in the UK there are estimated to be between 250 and 300 new retroperitoneal sarcoma diagnosed each year.¹ They constitute a therapeutic challenge because of relative late presentation and anatomical location, often in close relationship with vital structures in the retroperitoneal space, which impacts on the ability to perform a radical wide resection.

Retroperitoneal tumours further

constitute a diagnostic challenge as the retroperitoneum can host a wide spectrum of pathologies, including a variety of rare benign tumours and other malignant neoplasms. Malignant tumours of the retroperitoneum occur four times more frequently than benign lesions with sarcomas comprising a third of retroperitoneal tumours.²

Complete surgical resection offers the only opportunity for cure in patients with primary RPS. The development of local recurrence after surgical resection is the main cause of disease-related mortality, ranging from 40 to 80 per cent. Seventy-five per cent of sarcoma-related deaths involve uncontrolled local recurrence. Given that local failure remains the main cause of death after surgery in patients with RPS, there is great interest in strategies that might improve local control.^{3,4} Two observational studies investigated the role of liberal visceral compartmental resection in an attempt to include an envelope of normal tissue around the tumour in the hope of improving outcome.^{5,6} The role of radiotherapy to assist in obtaining local control remains undefined with no prospective randomized controlled trials available to define indications, dose, route of administration and impact on overall survival. No effective chemotherapy exists to influence survival in RPS.⁷

High surgeon volume and specialized centres are associated with improved patient outcome in major oncology resections and complex surgery.^{8,9} This has also been investigated in sarcoma surgery and concluded that retroperitoneal tumours should be treated exclusively in high-volume centres to improve both short-term surgical outcomes and superior long-term local recurrence and overall survival rates.¹⁰ Therefore, the treatment of RPS should be centralised to a few experienced multidisciplinary high-volume units.

Background

The retroperitoneum represents a complex potential space with multiple vital structures. Due to the inaccessibility of the region and since these tumours often give non-specific or no symptoms until they have reached a substantial size, they are usually large at presentation.⁴ Sarcoma comprise a third of retroperitoneal tumours with two histological subtypes predominates namely liposarcoma (70%) and leiomyosarcoma (15%).11 Because RPS accounts for only onethird of retroperitoneal tumours, other diagnoses must be considered when the radiological appearance is not typical of a retroperitoneal liposarcoma. Metastatic testicular neoplasm should be considered in younger male patients with a midline retroperitoneal lesion and investigated by testicular ultrasound and tumour markers (AFP and B-HCG). In patients presenting with a retroperitoneal tumour, where the radiological appearance is uncertain or when the radiological appearance suggest a pathology where neoadjuvant treatment may be appropriate as induction therapy (e.g. GIST, Ewing sarcoma, teratoma), a preoperative biopsy is mandatory. A preoperative core needle biopsy is safe and when indicated offers the opportunity of identifying a chemo-sensitive tumour or a benign tumour which may not necessarily require resection.^{12,13} Intra-abdominal lymphoproliferative tumours (Hodgkin's and non-Hodgkin's lymphoma) are not uncommon and may present as a midline mass, which can displace or encase the aorta, cava or iliac vessels. The histological diagnosis can often be made on percutaneous core needle biopsy.14 Benign tumours can cause concern and are often an incidental finding during investigation for unrelated symptoms. The most common benign pathologies encountered in the retroperitoneum include benign neurogenic tumours (Schwannomas, neurofibromas), paragangliomas (functional or non-functional), fibromatosis, renal angiomyolipomas and benign retroperitoneal lipomas. Other retroperitoneal neoplasms include epithelial tumours (renal, adrenal, pancreas) or might represent metastatic disease from known or unknown primary sites (carcinomas, melanomas).²

Presentation

Most patients who have a retroperitoneal tumour present with abdominal swelling/increase in girth, early satiety, abdominal discomfort, and most patients have a palpable mass.¹² Although the gastrointestinal and urinary tracts are often displaced, they are rarely invaded and gastrointestinal or urinary symptoms are unusual.¹³

Initial Evaluation

The imaging investigation of choice is a contrast-enhanced computed tomography (CT) of the thorax, abdomen and pelvis. The size, location, relationship to adjacent organs and presence or absence of metastases can be determined. Liposarcoma (LPS) demonstrate a characteristic appearance





Figure 1a and 1b

Computer tomography (CT) of a 47yr female patient showing a large left-sided retroperitoneal dedifferentiated liposarcoma causing displacement of the left kidney and involving the left colon, distal pancreas and left crus, and lying in close proximity to the aorta. The CT attenuation reflects the histological subtype with the higher grade component (between L kidney and aorta) showing increased density with solid attenuation and contrast enhancement. The less dense, predominant fatty component with diffuse stranding on the lateral aspect of the left kidney reflects lower grade welldifferentiated liposarcoma.



Intra-operative photo of dedifferentiated retroperitoneal liposarcoma of patient with CT scan shown in Figure 1. The retroperitoneal sarcoma involved the left colon mesentery, left organ resection to obtain a complete clearance of all

with a predominantly fatty component causing displacement of kidney, colon and other organs. The CT attenuation reflects the histological subtype for liposarcomas, specifically the amount of fat in the mass, with low grade well-differentiated LPS entirely or predominantly fatty while high grade LPS show increased density with solid attenuation and contrast enhancement.^{4,11} (Figure 1a,b) The performance of a preoperative biopsy for these lesions is controversial and in patients where the radiological characteristics of retroperitoneal liposarcoma are not in doubt, a preoperative biopsy is not required.

Surgical Management

Complete surgical resection is the only potential curative treatment available for retroperitoneal sarcomas. The prognostic factors that are known to govern local recurrence and overall survival in RPS are tumour grade, complete macroscopic excision, multifocality and histological subtype. Retroperitoneal sarcoma carries a much worse prognosis than extremity sarcomas with 5-year local recurrence-free survival after complete resection ranging between 55 - 78% and 5year overall survival between 39 - 68%. This disparity between limb and retroperitoneal sarcoma is because RPS are generally larger and arise in an anatomically complex and surgically inaccessible site with surrounding vital structures limiting wide margins.^{3-6,13,15-17} The Royal Marsden Hospital series, looking at 200 primary RPS treated over a 19 year period, achieved a 5-year local recurrence-free survival of 55

per cent and a 5-year disease-specific survival of 69 per cent. In this series, the median weight of tumours was 4.0 kg and median maximum diameter 27 cm. Macroscopic clearance was achieved in 170 patients (85%) and resection of adjacent organs was required in 126 patients (63%). The most common organs requiring resection are the colon, kidney, pancreas and spleen. Postoperative mortality rate was 3 per cent. The inability to obtain macroscopic clearance at resection and high-grade tumours were significant predictors for local recurrence and disease-specific survival.4

The likelihood of a complete margin-negative surgical resection depends on tumour biology, invasion of adjacent visceral organs and vascular structures and may be influenced by surgical experience and management in highvolume centres.^{3-6,10,13,15-17} Resection of adjacent involved organs is frequently required, and rates of resection of Figure 2 adjacent viscera are reported in large series from 34 to 93%, while macroscopic clearance was obtained in 55 - 93%. 3-6,13,15-Our unit's surgical approach involves a low threshold for kidney, left crus, distal pancreas and splenic hilum. macroscopic disease. This is performed as an en bloc resection of the sarcoma and contiguous organs that are macroscopically involved by tumour or enveloped by the tumour in order to gain complete macroscopic clearance, but with no attempt to routinely resect organs (aorta, IVC, duodenum etc.) that merely lay adjacent to the tumour but were not involved.¹⁴ (Figures 2 - 4)

Recurrent Disease



Figure 3

Resection specimen showing an en bloc resection of the tumour, left colon and peritoneum, left kidney, distal pancreas and spleen, left crus of the diaphragm and fascia overlying the psoas muscle.

Local recurrence is common for RPS and remains the major cause of death. Tumour biology reflected in tumour grade is a significant prognostic factor for patients with recurrent RPS; local recurrence rates are higher in patients with high-grade tumours, and occur at an earlier interval compared to



Figure 4.

The left retroperitoneum post-resection demonstrating resection of the tumour and adjacent organs. The adventitia over the aorta and fascia overlying the psoas muscle were included in the resection.

patients with low grade tumours.^{3,13,15-19} Most reports on this subject are retrospective with different surveillance and management strategies with variable results. CT is indicated when patients exhibit new symptoms or a mass is palpable on clinical examination. Further surgery is advised if the patient develops significant symptoms or if further delay will make eventual surgery more difficult. The likelihood of obtaining negative margins is significantly lower at the time of local recurrence and each successive operation is more difficult than the last.^{3,13} Resection should however be considered in symptomatic patients with first and subsequent local recurrence as it provides good palliation and a possible improved survival for selected patients.^{18,20} Palliative surgery (incomplete resection leaving irresectable tumour) for recurrent sarcoma of low or intermediate grade can be offered for symptom control and may improve quality of life.19,20

Radiotherapy

The high rate of local failure has prompted investigation of combined-modality treatment (surgery with radiotherapy) in an attempt to lower the rate of local recurrence.⁷ Radiotherapy improves local control in extremity sarcomas and has become standard practice. Retroperitoneal sarcomas

however present several radio-therapeutic challenges. These tumours are often adjacent to radiosensitive structures with low radiation tolerance. Retroperitoneal sarcomas compose of a heterogeneous group of pathologies with variable radiosensitivity. Several retrospective and observational studies have been published to evaluate the feasibility and outcome of preoperative, intra-operative and postoperative radiotherapy in the management of RPS.²¹⁻²⁵ The advantages of preoperative radiotherapy include the tumour being clearly demarcated for radiotherapy planning and the tumour displacing some of the radiosensitive adjacent organs. Postoperative radiotherapy makes it possible to select patients at highest risk for recurrence based on the grade and margin status. However, in the postoperative setting, the adjacent organs will move into and become adherent to the tumour bed, increasing the risk of radiation-associated toxicities. In an attempt to reduce the radiation toxicities, studies have evaluated the treatment planning with conformal therapies such as intensity-modulated radiation therapy or the use of intra-operative radiotherapy.²¹⁻²⁵ The paucity of randomised controlled trials and diverse variables in observational and retrospective studies make it impossible to define the exact and appropriate role of radiotherapy in the management of RPS. A prospective randomized EORTC study comparing preoperative radiotherapy followed by surgery to surgery alone, performed in high-volume centres, will start accruing patient soon.

Chemotherapy

Neo/adjuvant chemotherapy for the majority of histological subtypes has not shown consistent evidence of disease-free survival benefit, although there may be certain situations where it is advantageous. For subtypes such as the Ewing's sarcoma family tumours, for which chemotherapy is an essential part of primary management, chemotherapy has definitely improved survival. There is a role for agents such as doxorubicin and ifosfamide in the palliation of symptomatic advanced sarcoma. There is increasing specialization of chemotherapy according to histological subtype, such as the use of taxanes for angiosarcoma, gemcitabine and docetaxel for leiomyosarcoma, and trabectedin for leiomyosarcoma and myxoid/round cell liposarcoma.²⁶

Improving Outcomes

An important development in surgery during the last decade has been the concept of concentrating rare surgical conditions and complex operations in high-volume specialist centres.^{8,9} High surgeon volume and specialized centres are associated with improved patient outcome in major oncologic surgery including hepatobiliary/pancreatic surgery and oesophago-gastric surgery. This has also been investigated in sarcomas, and the recommendation from a

study comparing the outcome between low-volume and highvolume centres, was that patients with large, high-grade and especially retroperitoneal tumours should be treated exclusively in high-volume centres to ensure both improved short-term surgical outcomes and superior long-term local recurrence and overall survival rates.(10) Therefore, the treatment of RPS should be limited to a few experienced multidisciplinary units. This will also reflect favourably on training and research.

Research into tumour biology focuses on the molecular and genetic heterogeneity of sarcomas, and will hopefully lead to the development of novel biological therapies to target the various molecular pathways, similar to the success demonstrated in treating gastrointestinal stromal tumours with tyrosine kinase inhibitor.

The appropriate role, dose and timing of radiotherapy in improving local control need to be established in randomised control trials.

Conclusion

The retroperitoneum can host a wide spectrum of rare pathologies, including benign and malignant tumours. Retroperitoneal tumours are best evaluated with good quality cross-sectional imaging and preoperative histology by core needle biopsy is required when imaging is non-diagnostic. Complete surgical resection is the only potential curative treatment modality for retroperitoneal sarcomas and is best performed in high-volume centres by a multidisciplinary sarcoma team. Local recurrence occurs in a large proportion of patients the ability to completely resect a retroperitoneal sarcoma and tumour grade remain the most important predictors of local recurrence and disease-specific survival. Further research is required to define the role of radiotherapy and develop novel biological therapies to target the various molecular pathways.

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Skin Sparing Mastectomy

Mr Andrew D Baildam Consultant Oncoplastic Breast Surgeon and President of BASO ~ ACS



Oncoplastic breast surgery has been defined as provision of appropriate cancer resection, skin-sparing techniques, reconstruction with a full range of techniques - both immediate and delayed - for wide local excision and mastectomy, and correction for any resultant breast asymmetry

using implants/expanders, reduction or mastopexy for the contralateral breast¹.

Conceived just over a decade ago, skin-sparing mastectomy (SSMx) with immediate breast reconstruction has truly been an advance for the benefit of women with breast cancer. The traditional legacy of ablative breast resection with modifications of the historical mastectomy incisions used transverse or oblique skin resections, aiming to minimise breast local recurrence as well as remove 'excess' skin and tighten the soft anterior chest wall tissue. The acceptance that breast reconstruction could be achieved at the same time as mastectomy has allowed innovation in mastectomy incision planning, deleting the traditional scar and facilitating individualised incision placement. Carlson described four main types of SSMx incision³. As the majority of breast cancers are now diagnosed preoperatively on core biopsy, the most used are those of circumareolar skin incision and the technique based on the reduction mammaplasty, the Wise pattern.

Fundamental to SSMx is patient selection and the anticipation of adjuvant treatment, particularly chemotherapy and radiotherapy. The main issue for the surgeon is the essential requirement not to leave behind any residual malignancy, which would lead to unacceptably high local recurrence rates. There is a body of publications based on cohort studies, usually with small patient numbers, and followed up for limited time. There are no randomised controlled trials, there is little prospective data and few multi-centre reports. The largest series of 539 patients reported at 65 months' median follow up reported local recurrence of 5.5%. 30.6% of the cancers were non-invasive, in-situ disease⁴. In this study local recurrence with SSMx was related to tumour grade, size, the presence of lymphovascular space invasion and node positivity, all conventional prognostic factors. Other studies have found similarly acceptably low rates - but in all the patients were highly selected for SSMx, and rates of adjuvant radiotherapy and chemotherapy were inconsistent. What seems appropriate is that SSMx be offered to those women with the smaller and good prognostic tumours, multifocal insitu disease being the closest application demonstrating this. The role of SSMx in more advanced disease, such as T3, is less clear. Certainly inflammatory breast cancer is more appropriately managed by conventional skin-removing mastectomy without immediate breast reconstruction. We do not know the place of SSMx after neoadjuvant chemotherapy to diminish tumour size.



Figure 1. Right skin sparing mastectomy and immediate reconstruction with latissimus dorsi flap and implant, nipple reconstruction and nipple and areolar tattooing.

Increasingly women are being offered radiotherapy after mastectomy, usually for grade, size and nodal involvement. There are little data on the effect of radiotherapy on the SSMx and aesthetic and functional outcome of immediate breast reconstruction. A randomised trial, the QUEST study, has been launched in the United Kingdom that will look at the outcomes comparing implant assisted LD flap immediate



Figure 2. Bilateral wise pattern skin sparing mastectomies with immediate submuscular implant reconstructions, nipple reconstructions and nipple and areolar tattooing.

reconstruction and autologous LD flaps. Radiotherapy effects and quality of life will be studied.

What is clear is that the factors that promote local recurrence, should be well regarded and considered in the planning of SSMx or conventional mastectomy. The use of sentinel node biopsy increasingly allows a majority of women to avoid full axillary node clearance. In some units the sentinel node procedure is undertaken electively at a time before the SSMx, as node positivity and its extent does impact on postoperative radiotherapy use.

The whole range of breast reconstruction techniques is used in conjunction with SSMx. These are tissue expander, and implant based techniques and myocutaneous tissue flaps. These may be pedicled, such as the latissimus dorsi (LD) flaps and the now less-used transverse rectus abdominis myocutaneous (TRAM) flaps, and increasingly the microvascular free flaps, particularly the deep inferior epigastric (DIEP) abdominal tissue flaps. In some units other flaps such as those from the buttocks (SGAP, IGAP flaps) or inner thigh (TMG flaps) are part of the available surgical options.

The aim of SSMx is both to treat the cancers effectively and to optimise aesthetic, cosmetic and functional outcome. As women are increasingly surviving longer after breast cancer diagnosis, and in many cases may be considered 'cured', so

the visible and functional long term issues become even more important. The possible future need for further surgery, scar or implant revision for example, need to be part of the consent process at the outset. The surgeon and team need to have the tools to plan and deliver surgery in meticulous manner with close attention to detail, and with care to optimise aesthetic as well as oncological long term results. Precision of technical surgery is mandatory for SSMx to be delivered with minimised complications and low revision surgery rates. Breast skin flap necrosis is a risk that has been reported at an incidence of 11%⁴. Breast skin necrosis is difficult to manage and impacts in a major way not only in the delay of necessary adjuvant therapy but also in cosmetic outcome, and should be avoided at all costs. In many cases surgeons trained in oncology surgery as well as breast plastics and reconstruction can provide the whole surgical remit, in other departments teams of those with the appropriate surgical skills and experience can focus to deliver care to the individual woman. What is important is that the care delivered should be within the concept of a full multidisciplinary team, including the whole adjuvant therapy oncology team, breast specialist nurses and pathologists.

SSMx occupies the common ground between surgical oncology and plastic and reconstructive breast surgery. Guiding principles of cancer surgery are layered with

> Conceived just over a decade ago, skin-sparing mastectomy (SSMx) with immediate breast reconstruction has truly been an advance for the benefit of women with breast cancer.
understanding of aesthetics - breast volume, shape, skin surface area, ptosis, base diameters and unique nipple areola morphology and colouring.

For women with diagnosed breast cancer traditional surgical thought dictates removal of the nipple areola complex (NAC). This impacts hugely on the cosmetic result. Techniques of NAC reconstruction are sophisticated and commonly involve local flaps and tattooing as a final procedure. But some units have advocated preservation of the natural NAC, with low NAC involvement on pathology in women diagnosed with non-invasive in-situ disease⁵. Whether or not the NAC can be safely conserved in women with invasive breast cancer is not clear: a number of studies are underway, but based again on cohorts, not randomised trials.

The importance of surgery in preventing recurrence and contributing positively to survival is recognized, and becomes more relevant with earlier diagnosis and smaller cancers. But additionally SSMx is now an accepted intervention for risk reduction surgery for women at high risk of breast cancer but who have not been as yet affected. The dramatic reduction in breast cancer incidence of over 90% in high risk women by virtue of gene mutations and family history, affirms the continuing role of SSMx in this disease²

The increasing reality of long term breast cancer survival drives the need to develop better cosmetic outcomes with associated improvement in quality of life. SSMx fulfils this need, but we rely on cohort studies from mostly single institutions - randomized controlled trials against conventional surgery will be difficult to achieve.

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BASO ~ The Association for Cancer Surgery

Improving Cancer Outcomes: Enhanced Training

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ENHANCED TRAINING

The challenges of introducing the European Working Time Directive and yet maintaining the quality and experience of newly appointed consultants in the UK have been huge and have necessitated more formalised and rigorous training programmes and re-doubled efforts on the part of trainers. The following articles provide an overview of some of the issues and in particular focuses on trainees in research.

Surgical Training: the New Era

Mr Charlie Chan

Consultant Breast Surgeon, Cheltenham General Hospital and BASO ~ ACS EJSO Rep



The last 10-15 years have seen a dramatic change in the vista of surgical training. The European Working Time Directive, the Calman Report and then Modernising Medical Careers have led to draconian reductions in the training time available to surgical trainees.

Allied to the hours reduction has been a parallel reorganisation of the training structure with core training (CT) and specialist training (ST). In a generation, the link between 'General Surgery' and the other surgical specialities has been almost erased. No longer does a neurosurgical or ENT trainee need to hone their basic surgical craft in General Surgery prior to specialist training.

Hence, we now have a situation whereby surgeons in different specialities can relate less and less to their professional colleagues. Multi-disciplinary working can overcome some of this.

Sadly, Cancer and its associated problems does not respect the isolationism and problems of post-modern surgical training. Increasingly younger surgeons are less knowledgable about spheres outside their immediate speciality. General surgeons know precious little about urology and neurosurgeons know little about general surgery. Yet we now work in an increasingly sophisticated and co-operative manner. BASO ~ ACS recognises that young cancer surgeons in differing specialities are now less aware of each others' skills and contributions towards cancer patient care. As a result, BASO ~ ACS will be starting a Surgical Oncology Trainees Association later this year. We will be inviting representation from all the surgical training groups involved in cancer care from urologists to gynaecologists, orthopaedic and plastic surgeons, ENT, maxillo-facial and neurosurgeons, as well as all the General Surgical Training groups.

Membership will be open to all young surgeons who have an interest in cancer surgery, irrespective of their primary speciality. We will establish a forum for trainees from different specialities to share common ground and to learn from each other. In the fullness of time, we intend to have training days where trainees of all specialities can meet.

The re-establishment of close links between cancer surgeons from all groups can only improve our understanding of each other and ultimately enhance the care of our patients.

ENHANCED TRAINING

Current state and future prospects for academic surgery in the United Kingdom

Professor Malcolm Reed Professor of Surgical Oncology, University of Sheffield, UK, Immediate past President of BASO ~ ACS



Introduction

Many senior surgeons will recall with some affection the hay day of academic surgery in the UK twenty or thirty years ago when every medical school had at least one Professor of Surgery, with a number of clinical senior lecturers and lecturers in thriving departments

actively pursuing a wide range of research projects and closely involved in undergraduate teaching and assessment. The Surgical Research Society and BASO ~ ACS were flourishing organisations with two scientific meetings per year, each attended by up to 200 trainees. Reading a paper in the Patey Prize session of the SRS was a major achievement and a cause of significant anxiety where the trainee could expect to be subjected to a barrage of hostile

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questions from a front row comprising most of the senior academic surgeons of the day.

Even a cursory review of the state of academic surgery in the UK (and worldwide) would confirm that there has been a substantial decline in this area over the past two decades. There are many reasons for this, including:

- Major revisions to the way in which undergraduate medical education is delivered have resulted in a systems rather than a discipline based approach.
- Teaching has been centralised in academic teaching units and this has substantially decreased the influence (and resources) for traditional academic departments. This has affected all disciplines with some (eg Anaesthetics, Pathology) having been virtually wiped out in many Universities.
- The ethics, clinical and financial governance framework involved in undertaking clinical research projects has substantially increased the time and resources required. This has significantly reduced the opportunities for surgical trainees to undertake research projects.
- Similar increases in the regulation and cost of laboratory and animal based research has also substantially excluded surgical trainees from undertaking basic science projects.
- Increasing pressure on NHS surgeons, both academic and non-academic, with rising workloads and pressure to meet service targets has also had a significant impact on the ability of academic surgeons to successfully balance teaching and research activity with the demands of contributing to routine NHS services.

However, surgeons have led the way in undertaking research and development into simulation and training for practical skills such as simulated laparoscopic surgery and this has resulted in large successful randomised trials in a number of areas (eg the CLASSIC Trial in laparoscopic colorectal surgery and the New Start programme arising from the ALMANAC



Figure 1 Pathway for Surgical Training

Trial for the validation and implementation of sentinel node biopsy).

A recent policy review conducted by the European Cancer Research Managers Foundation revealed many interesting findings. This review (Eckhouse and Sullivan 2008) identified that less than 2% of total spending by the UK Clinical Research Collaboration and CRUK in contrast to the majority of spending on pharmaceutical developments and the identification of new cellular targets. Radiotherapy research received approximately three times the funding that was allocated to surgery but this was still minimal in comparison to pharmaceutical and cellular research.

This study also demonstrates the significant reduction by 50% in the number of lecturers in surgery between 2000 - 2006. With an overall reduction of 20% in the total number of clinical academics in surgery in the same time period. This will clearly have a major impact on the pool of suitably trained candidates for senior academic posts in the future, even if Universities are willing to replace retiring senior academic surgeons.

Surgery is by no means the only academic speciality to have experienced such decline and it was against this background that the Walport Report (2005) was commissioned to address this problem and develop a new training programme for future academic clinicians. This far reaching report addressed academic training from undergraduates through to consultant appointments. Crucially the report recommended that a parallel academic training track should be developed throughout postgraduate training, with the introduction of academic foundation posts, academic clinical fellowships and clinical lectureships running in parallel with the standard foundation, core training and SPR training programmes. A similar model was proposed for graduates wanting to train in educational theory and research as well as traditional academic research training. The pathway for surgical training is shown in Figure 1.

The timings of personal fellowships are indicative - there should be flexibility according to individual career progression.

Substantial funding has been provided to support the implementation of this training programme, for instance the introduction of 200 new blood clinical senior lecturer-ships and full funding for the Foundation and ACF programmes. However, it appears that only a small proportion of these posts have been allocated to surgical disciplines which relate to the treatment of cancer (Table 1).

Table 1 - Academic Clinical Fellows in Surgery 2005-2010(total numbers of ACF in all surgical disciplines - 190)

Discipline	Number of posts
Gastrointestinal	5
General Surgery	17
Surgical Oncology	4
Breast Surgery	3
Total	29

In addition, through the National Institute of Health Research, funding has been made available for training fellowships and clinical scientist fellowships to support trainees in doctoral and postdoctoral research. However, there have been major challenges for surgical trainees in engaging and fully participating in this programme, which has been implemented alongside the introduction of the European working time directive in the UK. This has resulted in trainees trying to balance the acquisition of the practical skills required to become an accomplished surgeon, success in postgraduate examinations, such as the MRCS, and the production of research outputs in order to be successful in the application for a PhD Training Fellowship. Although no clear data are available it appears that the attrition rate, particularly for aspiring academic surgeons at the completion of academic foundation programmes may be high. It is also apparent that only a very small number of the new blood clinical senior lecturer-ships have been awarded to academic surgeons.

Therefore, at best, we can see that the implementation of the Walport training proposals has been a welcome, if somewhat limited, innovation where academic surgery is concerned.

With regard to future policy recommendations Eckhouse and Sullivan (2008) recommend the following:

• Ring-fencing investment to support research and development as surgical technologies (eg health technology assessment programme).

- Continuing and increased support for surgical participation in clinical trials, and the promotion of clinical trials of surgical technologies (greater representation by surgeons on national cancer research network clinical studies groups).
- An integrated approach between funders and training bodies to support young surgeons following an academic path (targeted NIHR funded fellowships).

There is no doubt that the changes introduced following the Walport review represent a serious and significant attempt to revitalise academic medicine in the UK. Unfortunately, for a variety of reasons highlighted in this brief review, there is a real risk that surgery and other craft specialities will not benefit fully from this investment. The continued support of those trainees who have entered the ACF and CL programmes is essential if we are to maintain a credible contribution to teaching and research.

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The Academic Foundation Programme

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Academic Foundation Trainee 2008-2010. Academic Clinical Fellow, ENT, Newcastle



I decided to apply for an academic job for my foundation training after doing an intercalated research degree at medical school. During this year I had designed my own project, an epidemiological study about alcohol-related mortality. I enjoyed the

opportunity it gave me to write and present and felt this was something I would like to develop during my foundation training.

Once I had been appointed to an Academic Foundation Programme (AFP) I was able to choose a supervisor from a range of clinical specialities. I wanted to do predominantly clinical research relevant to surgery. I chose to work in the Department of Surgical Oncology at Sheffield University. The AFP in Sheffield is designed with a four month block during FY2 dedicated to research with no clinical commitments. I met with my supervisor at the start of FY1 so I had time to design a project, a qualitative study into decision making about the management of breast cancer risk in women at increased familial risk of breast cancer. This consisted of a systematic review and semi-structured interviews with 20 high risk women. I wrote the protocol and ethics applications during FY1 as well as discussing the project with a range of clinicians, researchers and service users. This was invaluable to my understanding of clinical research design and management . It was also useful to develop skills in critical review of literature. I was able to start recruiting participants as soon as my academic time began and finished the systematic review as well as conducting the interviews with at risk women during my placement. The interviews were an excellent opportunity to discuss women's experiences of making difficult decisions in depth and to consider the psychosocial impact of surgery; it is rare to have so much time for this in clinical practice especially at a junior level. Analysing the interviews and identifying important themes was a revealing and interesting part of the project and several ideas from this analysis can be directly incorporated into clinical practice which is very rewarding.

As part of the research block I was also involved in teaching medical students; I led small group tutorials for groups of first and second year medical students on a weekly basis and helped some more senior students with audit projects. All of the AFPs had some formal training about teaching techniques which was also useful since this is an important responsibility of an academic.

During the AFP I have had many opportunities to present my qualitative project and other smaller projects as posters and oral presentations at both local and national meetings including being chosen to present for the Alan Edwards Poster prize at BASO~ACS. I have also been able to meet more experienced clinical academic surgeons who have been influential and helpful in planning my career, and I feel much more confident presenting than I used to.

One concern I had when entering the academic programme was that I would miss out on clinical training but I think the benefits of the academic placement more than made up for this. I really enjoyed the Academic Foundation Programme and have decided that I would like to continue with academic surgical training. I am particularly interest in head and neck surgery and am now an Academic Clinical Fellow in ENT in Newcastle.



Academic Clinical Fellow, (ACF)

Ms Rebecca West

Academic Clinical Fellow in Surgical Oncology, Academic Surgical Oncology Unit, University of Sheffield



I knew I wanted to be a clinical academic before I started medical school. From childhood I have been fascinated by scientific attempts to rationalise and explain our complex world and so I studied Biochemistry (UMIST) to explore the

fundamentals of life sciences at a molecular and sub-cellular basis.

As a postgraduate I undertook an MSc in Clinical Neuroscience under Professor Wood at Queens's Square (UCL); he was an inspirational mentor who mixed clinical neurology with running a molecular genetics laboratory and lecturing. His example inspired me to apply to medical school so I could gain the clinical experience that is vital in building links between the daily problems faced in clinical practice and scientific attempts to overcome them.

In medical school (St George's) I realised that I enjoyed and had an aptitude for surgery. Of all the surgical disciplines, surgical oncology appealed the most because of the complicated clinical, oncological and psychological aspects of cancer care. It is therefore no exaggeration that my current post as ACF in Surgical Oncology is my dream job.

I have found the most valuable aspect of my ACF programme is the opportunity to work long-term with a dedicated academic unit, enabling development of mentoring and supervisory relationships. I have been fortunate to receive unstinting support with laboratory training, including developing my own research ideas, applying for grants and preparing manuscripts for publication. Additionally the strong academic environment has enabled me to work with academic clinicians of every level from junior doctors (F2s) to Professors, providing role models and advice concerning academic career progression.

The second most valuable aspect is the nature of the career structure provided by the Fellowship, enabling me to

implement ongoing strategies of personal development and research projects with long term goals. Academically this has enabled me to develop skills through an MSc in Clinical Research, including critical appraisal, research methodology, good clinical practice and systematic review techniques. The long term approach of training has also enabled me to explore my own research interests in breast cancer angiogenesis and breast cancer reconstruction.

The clear training pathway has also helped focus my clinical training, which is essential as I am expected to complete the same standards for ST3 entry as my surgical colleagues in two thirds of the time. Having clear career targets enables prioritisation of training areas I need to concentrate on and has motivated me to achieve the requirements of my clinical training. The long term nature of the ACF programme has also provided the opportunity for stability for my family, which is uncommon at my stage of training.

Recently a consultant colleague advised me that if anyone did not find surgical training difficult then they were not being trained in surgery. Combining what is already a demanding career pathway with academic work and improving my research skills through an MSc is undoubtedly tough. However the adage of, "you get out what you put in" is pertinent and I've found that through a sustained work ethic all these demands can be managed. However the expectations for academic trainees have been much higher than I initially realised and trying to achieve excellence in the combined fields of clinical, surgical and academic training is exceptionally difficult, especially gaining the relevant operating skills in my restricted training time.

After 18 months I can honestly say this is still my dream job. However it is much tougher than I imagined it would be and enthusiasm alone is not sufficient to get you through. The supportive team I work with, the reassuring structure I work within and the needs of the patient population I work for sustain my motivation to succeed in this career pathway.

ENHANCED TRAINING

Clinical Lectureship

Dr Jonathan Rees

MBChB. MRCS, PhD. NIHR Lecturer in Surgery and Honorary Specialist Registrar in Hepatobiliary Surgery. University of Bristol and University Hospitals Bristol NHS Foundation Trust



Career so far

I trained in Bristol and completed basic surgical training in the South West and South Wales before embarking on a PhD as an MRC/DoH Clinical Research Training Fellow at the University of Cambridge in the MRC Cancer

Cell Unit and the CR-UK Cambridge Research Institute.

My PhD provided excellent training in basic and advanced laboratory techniques such as cell culture, semi-quantative PCR, immunohistochemistry, western blotting, array comparative genomic hybridisation and real time PCR. It also provided me with a range of transferable skills including the management of complex databases, use of command line driven data analysis tools, the writing and review of research manuscripts. I then returned to the South West and joined the Severn and Peninsula Higher Training Scheme before making the transition to the Lecturer post in 2010.

"Striking a balance and learning to say no"

One of the key early challenges has been striking the balance between clinical and research work. Pressures of clinical work can make it difficult to focus on research so I have chosen to divide my time by alternating clinical and research weeks to ensure 50:50 split of academic and surgical training, although I participate fully in the general surgery on call rota. This has been possible because of a supportive clinical team of consultants and registrars who understand my dual commitments and try to ensure that I optimise operative learning opportunities and maintain agreed targets. My academic supervisor, Professor Blazeby who is also an Upper Gl surgeon is also able to provide support for this process.

It has not all been plain sailing, however, and I am learning when to say 'yes' or when to say 'no' and I continue to find the latter difficult. I have competing pressures of under and post graduate teaching, organising meetings, managing of clinical issues as well as research. So I monitor and regularly review commitments, often in discussion with my academic and clinical supervisors. In addition, I try to ensure that each and every research and clinical training opportunity is utilised fully and I ring fence time away from work to recharge.

"The buzz of research"

My research is based in the surgical research unit at the School of Social and Community Medicine at the University of Bristol and this academic environment with expert multidisciplinary research support facilities has allowed me to very rapidly become conversant with a new area of research. My work in now in the area of health services research including outcome measurement and methodological and applied issues surrounding randomised surgical trials. This has been challenging, because it is completely different to my laboratory based PhD. I am also completing a distance learning MSc through the London School of Tropical Medicine in Epidemiology which is equipping me with the skills and necessary understanding to design high quality studies to evaluate surgery and its impact on clinical practice in the future. Having dedicated research time, being immersed in an atmosphere conducive to effective study is very valuable. It allows time to think, read, write and research, and I find that the contrast from one type of work to another is refreshing.

In the future I hope to extend the scope of my research area, develop collaborations with other Hepatobiliary research centres and grow into an independent academic clinician.

ENHANCED TRAINING

The Academic Senior Clinical Lecturer

Mr Ramsey Cutress

Clinical Senior Lecturer in Surgery, Cancer Research UK Senior Lecturer in Breast Surgery, Southampton



Introduction

Clinical academic surgery is challenging and rewarding. The learning curve as a new Senior Lecturer is very steep, but the work also provides enormous job satisfaction. I am a Senior Lecturer in Breast Surgery within the Southampton Cancer Research UK Centre and a Consultant Surgeon in

the Southampton Breast Unit. I was appointed in October 2009 but had worked full-time for the NHS as a Locum Consultant in Southampton for 6 months prior to this. The post was created through joint funding from the NHS and Cancer Research UK, and had been in discussion for a period whilst I was a higher surgical trainee in Wessex and one of the National Oncoplastic Fellows in Portsmouth.

Surgical provision and subspecialisation as a Lecturer

A clinical academic surgeon will have to make difficult decisions relating to the nature, extent and degree of specialisation of clinical practice that will be possible, simply because of the constraints of what can be achieved within the clinical half of a working week. I decided that it would not be possible for me to continue with any general or endocrine surgery but was very keen to provide the entire range of breast surgical treatment including oncological aspects, reconstruction and oncoplastic surgery, and breast screening. My working week therefore includes a diagnostic breast clinic, a combined oncological clinic, a breast screening clinic and joint reconstructive/oncoplastic clinics with plastic surgical colleagues. Once operating time and an MDT is also added to this I felt that there was simply no space for surgical subspecialties other than breast surgery within the NHS half of a job plan. One advantage of this specialisation is that it enables close alignment of clinical and research activities and is beneficial in terms of maximising opportunities for recruitment to clinical trials and other research activities.

Academic development and research

There is increasing recognition of the importance of academic surgery nationally since of the 12 million NHS hospital admissions each year at least 30% involve surgery (1). Further academic surgical development is important however, since despite surgery forming a significant component of NHS admissions, it is underrepresented in terms of research funding such that in 2006-7 only 1.3% of Government medical research spending was devoted to surgery¹.

One of the most attractive features of an academic career is the constant opportunity for variety and academic stimulation along with great intellectual freedom. There is the expectation that one will attend meetings and conferences widely and the desire that the results of one's work might eventually lead to improvements in clinical treatments. In comparison to NHS job planning which typically accounts every minute of time, my university commitment does not define any set hours of work, with a greater freedom to deliver the work required in the way one feels is most appropriate. There is greater freedom from NHS service delivery pressures, cost improvement initiatives, and other targets.

Challenges of the job do however include a constant pressure to deliver; both in terms of publications and grant funding. Currently my small translational research group costs over £100,000 a year to run and whilst I have complete control over the direction, research plans and utilisation of funding I am also totally responsible for ensuring sufficient income comes in to pay the bills. Whilst I have funded my laboratory successfully for a year and have funding for a further year obtaining research income in an extremely competitive setting will certainly be a major factor that determines any future success. I have been pleased to secure a pump priming grant from the Royal College of Surgeons of Edinburgh for consumables, and my clinical research fellow and Ph.D. student obtained a Cancer Research UK Fellowship funding her salary and consumables. Time management is a constant issue in what might effectively be considered two jobs. On the academic side one is competing with full-time nonclinical academics for research funding, and on the clinical side one is keen to work as an equal partner in a team with clinicians who might not have obligatory academic commitments.

Career Pathway

The career pathway into academic surgery is becoming better defined, and these improvements should smooth the future transition between a higher degree, higher surgical training including post-doctoral research and a possible Clinical Lectureship, and Senior Lectureship. My personal pathway included reading my Ph.D. in Southampton in the gap between basic and higher surgical training. As part of my research I demonstrated that the expression of the protein BAG-1 in breast cancer was associated with clinical outcome. Furthermore the largest BAG-1 isoform, BAG-1L which was first described within the laboratory, potentiates oestrogen dependent transcription. I was delighted several years later when BAG-1 was subsequently included as one of 16 genes within the Oncotype DX multigene commercial assay. It seemed natural therefore to continue with this work on appointment, and I lead a small translational research laboratory investigating the role and function of BAG-1 in breast cancer. I have a postdoctoral research fellow who is performing biochemical screens for novel potential drug like BAG-1 inhibitor molecules. I also have a clinical research fellow who is investigating the influence of BAG-1 on

epidermal growth factor receptor signalling pathways. Further work will include determining if BAG-1 can play a role in modulating crosstalk between oestrogen receptor signalling and EGFR signalling. As a clinician it is important to translate such laboratory-based research into a clinical setting. A particular ambition is to recruit to, and participate in surgical studies and clinical trials, and I am local Principle Investigator for four NCRN portfolio clinical trials. These trials have recruited almost 100 patients in Southampton and I am keen to become involved in the planning and development of new studies.

Conclusion

For any new Consultant supervision and mentorship is extremely important. I am lucky to have had excellent support encouragement both from fellow academics and NHS colleagues, within Southampton and beyond. I am extremely grateful for this, and would consider this essential for the career development of any academic surgeon. I would certainly urge anyone thinking about a career in Academic Surgery to examine the various initiatives, fellowships and lectureships on offer and to seriously consider this exciting and rewarding career.

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Figure 1. A tissue microarray enables the simultaneous analysis of tissue from multiple patients on a single slide and is shown as an example of the work performed in the laboratory. Shown here is BAG-1 immunohistochemistry with representative expression patterns. A: Negative, B: Cytoplasmic, C: Nuclear, D: Nuclear and Cytoplasmic. BAG-1 is one of 16 genes included within the Oncotype Dx assay. Immunohistochemistry is with the antibody 3.10 G3E2 produced and optimised within the laboratory.

BASO ~ The Association for Cancer Surgery

Improving Outcomes Through Screening

Lung Cancer CT Screening - The UKLS trial is an opportunity for the UK

IMPROVING OUTCOMES THROUGH SCREENING

Screening has been one of the major drivers for improved cancer outcomes in recent decades and BASO ~ ACS /ABS surgeons have led the way with their input into the NHS Breast Screening Programme. Newer forms of screening are just beginning to be implemented (colorectal cancer) or are under active investigation. Professor Field is leading the drive to establish lung cancer screening with his UK Lung Screening trial, which he presented to the BASO ~ ACS meeting in 2010. Here he outlines the case in support for this initiative.

Lung Cancer CT Screening - The UKLS trial is an opportunity for the UK

Professor John K. Field

Personal Clinical Chair in Molecular Oncology at the University of Liverpool. Cancer Research Centre, Department of Molecular and Clinical Cancer Medicine. Visiting Professor at University College London. Director of Research of the Roy Castle Lung Cancer Research Programme, Chair of the EU-US Spiral CT collaborative group and PI for the UK Lung Cancer Screening Trial (UKLS).



In the UK in 2008, over 33,500 patients died from lung cancer and there were over 38,500 new diagnoses^{1,2} Five year survival was only 6.5%, with some improvement since 2005 but still amongst the lowest in Europe. There are a number of reasons, however, the main one is delay in diagnosis as

highlighted in the National Awareness and Early Diagnosis Initiative (NAEDI) provisional pathways³.

The delayed presentation of cancer within the primary care setting has been attributed to lack of patient awareness, inadequate early lung cancer diagnostic tests, which could confirm or exclude cancer as the underlying cause of a patient's symptoms⁴, together with the varying surgical

resection rate. The potential of Lung cancer screening is therefore an important area for clinical trials⁵ since it offers the potential to detect pre-symptomatic cancer at a much earlier stage when it is more likely to be successfully surgically resected and before it has had an opportunity to take its toll on the patient's fitness. In addition, Smoking cessation programmes, have to be continued as a national policy and incorporated into a future national lung cancer screening programme.

Major randomised clinical trials (RCT) have been launched internationally to determine whether CT screening does reduce the mortality from lung cancer. The NLST CT Screening trial has been undertaken in the USA which randomised 53,000, current and former heavy smokers from ages 55 to 74 into a CT screen or a Chest X ray arm. In November, 2010, the Director of the National Cancer Institute reported that the NLST trial showed that CT screening resulted in a 20% reduction in lung cancer-related

mortality⁶. The publication of NLST data is expected in 2011. The NLST is the first RCT for lung cancer screening to ever show a significant mortality benefit.

A major European randomised clinical trial has also been launched in high risk current and former smokers - the Dutch Belgian randomised lung cancer screening trial (NELSON)⁹ - as well as several other collaborating trials in Europe⁷⁻¹¹, NELSON is due to report in 2015.

There is now a major initiative in the UK to assess CT screening for early lung disease, facilitated by the recent funding of the pilot UK Lung Screening (UKLS) trial, by the National Institute for Health Research Health Technology Assessment (NIHR HTA)¹². The UKLS is based at the Liverpool Cancer Research Centre, University of Liverpool, the pilot sites are based at the Liverpool Heart and Chest Hospital and Papworth Hospital, Cambridge, the CT scan second read quality control is undertaken at the Royal Brompton & Harefield NHS Foundation Trust, London.

The UKLS pilot trial will randomise 4,000 high risk patients identified by the Liverpool Lung Project (LLP) Risk Prediction Model¹³. The UKLS recruits will be selected if they have a 5% risk of developing lung cancer over 5 years as predicted by the LLP risk model. The "Wald Single Screen" Design has

Major randomised clinical trials (RCT) have been launched internationally to determine whether CT screening does reduce the mortality from lung cancer.



been chosen for the UKLS RCT¹². If the pilot shows that a trial is feasible, a further submission will be made to undertake a trial randomising 28,000 subjects from seven centres in the UK. The aim of the main UKLS trial is to establish whether a mortality advantage of at least 30 percent can be achieved in a UK population as well as to determine the cost effectiveness of CT screening in the UK. It is imperative to proceed with the current European CT screening trials as well as the UKLS trial, in order to establish whether CT screening for early lung cancer in a UK population, can achieve an important reduction in mortality and is cost effective. Furthermore, prior to the implementation of a UK National CT Screening early lung cancer programme we need to: (i) define optimal risk populations who will benefit from screening; (ii) what is the cost effectiveness of CT screening; (iii) harmonisation of the CT screening protocols to an acceptable level of consistent performance, utilising volumetric analysis; (iv) define the value of the individual work-up techniques, standardisation of performance and defining appropriate sequence; (v) define the optimal surgical management of patients with screen-detected nodules and (vi) define the optimal screening interval and the number of screening rounds for both screen-negative as well as screenpositive individuals.

We thus await the outcome of the UK screening trial to guide National Health Service decision makers on the future of lung cancer screening within the UK.

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BASO ~ The Association for Cancer Surgery

Improving Cancer Outcomes: Enhanced data collection, MDTs and Audit

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ENHANCED DATA COLLECTION, MDTS AND AUDIT

One of the key developments of the past decade has been our improved understanding of our cancer outcomes. One of the main supports of this has been good quality data collection via the cancer registries and via primary research. Breast surgery has undoubtedly led the way with the NHS BSP data collection and the BCCOM audit but other cancer sites are now realising the potential and engaging with their lead registry to maximise their use of data. Here, we present articles about data collection at registry level, at local MDT level and as part of trials.

Improving Outcomes in Cancer using Cancer Registration Data

Dr Gill Lawrence Head of the West Midlands Cancer Intelligence Unit (WMCIU), University of Birmingham

Mrs Sally Vernon Deputy Director of Cancer Registration, WMCIU

Mr Matthew Francis Cancer Analysis Development Manager, WMCIU

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The National Cancer Intelligence Network and National Lead Cancer Registries:

The National Cancer Intelligence Network (NCIN) was launched in June 2008 as a UK wide initiative, working to drive improvements in cancer outcomes by using and improving the information collected about cancer patients. Working under the slogan 'Using information to improve quality and choice' the NCIN has focused firmly on reaching Professor Sir Mike Richards' goal of wanting to have 'the best cancer information service in the world by 2012'.

One of the first significant achievements of the NCIN was the building of a common national repository for cancer, bringing together data from all the regional cancer registries. The creation of a single dataset containing data on all cancers diagnosed in England enables data to be analysed consistently across the whole of the country. This is particularly powerful for the rarer cancer sites, where it is only through using national data that there are enough cases to understand trends in incidence, treatment and mortality.

The improved access to national cancer registration data meant that it was essential to co-ordinate national analysis of the data. To facilitate this, each of the English cancer registries has taken the role of National Lead Registry for one or more tumour sites. The mapping between sites and registries is illustrated in Figure 1. The West Midlands Cancer Intelligence Unit (WMCIU) is the lead registry for breast cancer and for bone and soft tissue sarcoma.









The work programme for each lead registry is steered by a national Site Specific Clinical Reference Group (SSCRG). The SSCRGs are co-ordinated and hosted by the NCIN, but draw their members widely from experts with a specialist interest in the cancer site in question. A typical SSCRG will consist of surgeons, pathologists, oncologists, radiologists, nurses and patients, as well as representation from the NCIN, the lead cancer registry, the National Cancer Action Team, the cancer networks, peer review and the Information Centre. This diverse group of people is uniquely placed to identify the key questions which can make a real difference to patient outcomes, and also to understand the limitations of cancer registry data when used to address these questions.

Cancer registries have traditionally collected reliable epidemiological data. Registries have direct feeds of pathology reports and oncology notes and employ highly trained coders, producing robust and consistently coded national data on the site of the tumour and the morphology. Cancer registries also receive automatic feeds of death certificates for all cancer patients, enabling long term followup and survival calculations. However, the treatment information available from cancer registries is more limited. The strength of the new National Cancer Data Repository (NCDR) is that for the first time it links cancer registration data to Hospital Episode Statistics (HES) data at a national level. HES data focus on recording admissions to hospitals, with data relating to where and when the patient was admitted, who was the responsible clinician, and what treatment the patient received. HES records do not attempt to collect data such as morphology and stage, and do not code the tumour type as consistently as the cancer registries. It is only by linking together cancer registry data and HES data that the full power of the data collected can be utilised. The NCDR provides for the first time the best available data on both cancer epidemiology and cancer treatment, linking registry data and HES data together for the whole of England.

Improving Data Quality

The NCDR is a great leap forwards for cancer analysis in England, but there remain limitations in the quality of the data available. As well as creating the NCDR, the NCIN has identified key areas where improvements in data quality are needed and is striving to achieve this.

Each lead registry has been commissioned to write a data quality report on the NCDR for their lead cancer sites. These reports cover key data items such as patient identifiers, tumour characteristics, treatment information, information about the patient's death, and staging information.

Figure 2 shows a sample graph from the data quality report for bone sarcoma. This graph reports on the completeness of the cause of death field for all bone sarcoma patients in the





dataset. Generally, cause of death is well completed, with the majority of registries recording the cause of death for over 90% of deceased patients. However, there is a clear outlier (Registry 7) where 30% of the cases do not have a cause of death recorded. Registry 8 has performed superbly and recorded a cause of death for all patients registered as having died.

These data quality reports allow the limitations of the NCDR to be known and quantified, and identify areas where poor data quality limits the analysis possible. They also highlight poor performers, and enable the NCIN to feed back to those registries where the data quality falls significantly below the national average, as well as encouraging the sharing of best practice from registries where data quality is good.

In parallel to analysing the current data quality of the NCDR, the NCIN has co-ordinated the review of the Cancer Outcomes and Services Dataset (COSD). Each SSCRG has identified the key data items needed to monitor outcomes for their cancer sites. The full COSD contains data items that range from the very high level (name, age and ethnicity) to the very detailed (type of resections, site specific staging systems, and receptor status). The collection of the dataset has been piloted in Trusts across England, and the full dataset was publicly consulted on in March 2011.

Initial analysis

The lead registries have already begun to produce analyses using the NCDR. The NCIN has published high level data briefings for the majority of cancer sites, along with fuller reports on key topic areas. These can be found on http://www.ncin.org.uk/publications/default.aspx

As the lead registry for bone and soft tissue sarcoma, the WMCIU has produced two data briefings. The first focussed on bone sarcoma, and examined changes in incidence rates and survival rates over a 25 year period. The incidence of bone sarcoma has increased slightly, but after correcting for the aging population by age standardising the rates there has been no statistically significant change over the time period studied (Figure 3). Five-year relative survival has increased from 40% to nearly 60% over the time period studied, but much of this increase was in the first 10 years, and rates have reached a plateau over the past decade. An accompanying data briefing on soft tissue sarcomas has also been released. Unlike bone sarcoma, the recorded incidence of soft tissue sarcomas has increased over the past 18 years; although this may be due to improved reporting rather than true increased incidence. Incidence rates for soft tissue sarcomas with differing morphologies vary widely on a very short timescale, which is most likely a reflection of changing and improving diagnostic techniques.

As well as the high level, publicly available in data briefings, the SSCRGs have commissioned more in-depth reports into key topics. As lead registry for bone sarcoma, the WMCIU has investigated the specialisation of care in England. Data in the NCDR were analysed to show the likelihood of being seen by a specialist bone sarcoma centre, and the likelihood of getting surgical treatment. It was found that very elderly patients were much less likely to be referred into specialist centres, and that patients who presented with sarcomas of the







limbs were more likely to be seen by a specialist centre than patients with rarer bone sarcomas such as the face, ribs, or vertebral column. These findings were presented at the 2011 British Sarcoma Group conference.

Future work

The initial analyses of the NCDR have provided information on cancer outcomes nationally for the majority of cancer sites. But as the NCIN strives to improve the quality of the data in the repository, it is essential that similar efforts are made to continue to improve the analyses done. Key to this is effective engagement with the clinical community. Working with the clinicians who were responsible for treating the patients enables the best validation of the national data, and also encourages debate and discussion around the outcomes of the analyses - which in turn highlights the main areas for further clinical audit and research.

The lead registries are also developing their role as the first port of call for ad-hoc information requests. If clinicians or researchers have a quick query that can be answered by the NCDR, they can submit this directly to the site-specific lead

> registry as an information request. If they are interested in a more detailed piece of work, then this can be taken to the SSCRG to be approved as a project.

> The first three years of the NCIN has changed the ways that cancer registries work, encouraging co-ordination of information at a national level, improving the quality of data available, and engaging with the clinical community to discuss findings. As 2012 approaches, the goal of having 'the best cancer information service in the world' is nearer than ever before.

Figure 2

ENHANCED DATA COLLECTION, MDTS AND AUDIT

The multidisciplinary team process: The next steps

Mr David Rew

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This article was originally published as an editorial (DR) in the EJSO in 2010 (EJSO 36 (2010) 221-223). It has been updated with material relating to the analysis of MDT Decision making in Bristol (ZR).

Introduction

The multidisciplinary team (MDT) now has a central role in decision making in the management of all cancers. The logic of multidisciplinary teamworking in cancer care is persuasive^{1, 2}, although the evidence base for a treatment benefit is as yet weak³. However, the evolution of the MDT as a clinical management tool is incomplete.

At its best, the MDT process allows for substantial improvement in the management of cancers. A little more than a decade ago, the treatment of individual cancers was something of a lottery, in which the choice of adjuvant modalities was often governed by the attitudes and beliefs of individual clinicians, and often determined by surgeons alone. The introduction of a formal MDT structure, centred upon the regular MDT meeting, has helped to standardise cancer treatments. It has brought together general and specialist surgeons, medical and radiation oncologists, diagnosticians, allied health professionals and data managers into a coherent structure for the management of each tumour type. MDTs are costly however and it is appropriate to question whether they serve the purposes for which they were intended, and whether and how they should be further improved.

The intentions of the MDT are to standardise and harmonise decision making in cancer management around perceived best practice and to introduce all components of decision making in advance of critical interventions.

However, the MDT process also promotes a fundamental shift in responsibility for decision making from the individual clinician to the group, thus diffusing the critical responsibility for events and outcomes. The groups and committees feel empowered to take decisions that no single member would take individually. The consequence is that the accountability of the individual consultant to the individual patient is in danger of being undermined by anonymised group decision making. MDT group decisions also remain subject to the vagaries of human nature, personalities and people interactions. They are made outwith the presence of the patient under discussion, whose immediate contact remains the named and responsible consultant, who is often the surgeon, and who must represent and "humanise" the MDT decision to the patient.

The need for more informative data systems

The most important factor which presently impedes the effectiveness of the MDT is the quality of data available to MDT members. A wide range of data must be considered for each case including: age, pathological subtype of cancer, disease stages, co-morbidities, body mass indices, drug and treatment histories, social attitudes, backgrounds, economic circumstances and lifestyle choices. It is therefore essential that the MDT data reflects all of these variations and nuances.

The MDT decision making process for individual patients is necessarily directed by the available evidence base. However, this will be largely drawn from clinical trials, which in turn represent a highly selected group of patients who are treated by enthusiasts for the trials process. These data may be modified and refined by meta-analysis and by software tools such as Adjuvant On-Line. Unfortunately, this is invariably an abstraction which does not accurately represent "ground truth", encompassing the full range of factors including age, disease and co-morbidity, which will determine the outcome in the individual patient in the immediate catchment population before the local MDT.

The question thus arises as to how the MDT process can help us to learn more about the contributions of the component therapies to outcome for each and every cancer. The "first generation" MDT has largely been focussed upon the decision making process at the outset of an individual treatment pathway. In most cases there will be a clear indication for a both primary and adjuvant therapies, there will always be grey areas in which the final decision will be influenced by a number of factors, including the local skill and resource mix, and the influence of the protagonists for the various clinical strategies in the discussion for each patient.

The critical deficiency is that as yet, there are no readily available computerised systems which aid the collection of all treatment and clinical event data relevant to each case which would both facilitate decision making and permit outcome analysis broken down by treatment type and patient and disease characteristics.

Such systems with the capabilities for massive data warehousing and mining, and for extraordinarily advanced

statistical analysis, as evidenced by the functioning of Internet search engines such as Google, exist for various applications in the commercial world, but they have yet to be adapted to and adopted into clinical practice.

Closing the MDT data loop

The computer-enabled and networked MDT meeting provides the ideal focal point for populating and updating such clinically informative data systems. The systematic collation and accumulation of information through the MDT, including registration data, all cancer treatments and their time sequencing will allow very large data banks to be built up rapidly. Using standard software systems across multiple sites locally, regionally, nationally and internationally, it will soon become possible to optimise the treatment for individual patients by matching each patient most closely to all others in the historical treatment population with similar epidemiological and clinical characteristics. This in turn will provide far greater global utility on a daily basis than individual clinical trials and will substantially improve the objectivity of MDT decision making.

Common-user software systems containing information collated and validated through the MDT process will allow the rapid accumulation of knowledge based upon very large data sets across local and national health systems. The political and intellectual attractions of investment in an MDTmoderated system which would so clearly reveal the benefits and limitations of all components of treatment are considerable. An internationally standardised system between cooperating national subspeciality groups would allow even more rapid accumulation of data for analysis.

An Analysis Of MDT Decision Making in Bristol

The MDT process is assumed to provide the best opinion on the management of a patient's cancer but how can the effectiveness of MDT working be assessed? Recently, a number of studies have attempted to do this in a variety of tumour sites by examining aspects of MDT decision making.

In gynaecological cancer for example, it was found that tumour characteristics were central to the decision making process whereas patient characteristic (such as patient choice and co-morbidity) where more peripheral⁴. Furthermore, the discussions tended to be more prolonged for the more complex cases and these cases were the ones which were more likely not to have a clearly defined treatment plan. In another study of an upper gastrointestinal MDT, an analysis of the decisions made by the MDT were performed⁵. Of 273 decisions analysed, 41 (15.1%) were discordant (ie not implemented in the clinical setting). The reasons for nonimplementation of the decisions were mostly related to patient co-morbidity and patient choice 32 of 41. Lack of all relevant information required to make a decision was found in eight decisions. Interestingly discordance was more common in gastric and pancreatic cancer patients than in oesophageal patients. In a recent study in breast cancer, discordant decisions only occurred in 7% of patients and most were due to patient choice, especially by elderly patients6. On a positive note however, MDTs have been shown to increase recruitment into randomised controlled trials7.

It therefore seems that MDT decision making can be improved by taking into account patient factors. This in turn suggests that more input from cancer nurse specialists is required. Ensuring that missing data was kept to a minimum would also make MDT's more efficient.

Further development of the MDT process

In order to fulfil the potential of MDT-moderated cancer outcome data, we will have to expand and extend the MDT process from initial treatment decision making into a medium and long term post-treatment review of outcomes and complications. Natural review stages will occur when the initial adjuvant therapy cycle is concluded; at the time of recurrences and secondary adjuvant therapies; and on death. In this way, lessons are continuously learned, data bases are updated, and decision making on new cases is continuously refined by the growing knowledge base of existing patients and case matches. This will also rebalance the MDT, such that the work of medical and radiation oncologists becomes as accountable as is that of the surgeons at the outset of treatment.

The expansion of the MDT process from a pre- and immediate treatment decision making exercise into the realm of intermediate and long term post treatment review and assessment will have considerable resource implications for local units and services. The introduction of a review element will add considerably to the workload, resource and time demands upon clinical and administrative members of the MDT. Weekly MDT sessions which currently take 60-120 minutes may well need to be extended into full sessions. In order to control this workload, MDTs will need to set specific review dates for individual cases, which might be at the one year, five year and ten year points, or on notification of a major outcome event, such as proven recurrence or death. The latter data will in turn mandate networking to regional and national mortality registries.

The increased time needed to complete the enhanced MDT process will be justified over time by the substantial gain in insight into the effectiveness of treatment strategies for each and every patient, and by better individual treatment.

In conclusion, the MDT process is evolving. The immediate challenge is to design and roll out robust data systems which will support the analytical capabilities of all MDTs. There is an opportunity for surgeons to lead the process as a definitive strategy for validating the efficacy of all cancer treatments and indeed of the MDT itself.

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ENHANCED DATA COLLECTION, MDTS AND AUDIT

The CoMET initiative: Data standardisation in research

Professor Jane Blazeby Professor of Surgery and Consultant Upper GI Surgeon, University of Bristol



There are many different clinical and patient reported outcome measures used to evaluate benefits and risks of surgery for cancer. Identifying the best measures to use in trials is therefore difficult and evidence shows that trials frequently measure all sorts of

different outcomes and definitions for these outcomes vary widely. This leads to difficulties for those summarising trial results in systematic reviews and variations may make it difficult or impossible to compare, contrast or combine the studies.

One way to address all these difficulties would be through the adoption of an agreed minimum set of core outcomes for each surgical condition¹. Consistent measurement and reporting of these "core" outcomes in all clinical trials in surgical oncology would reduce the potential for selective outcome reporting, since trial reports would always report, at least the core outcome data (as well as additional outcomes of interest). Using core outcomes set in surgical oncology would make it easier to compare results across different studies and would enhance systematic reviews and the combination of results in meta-analyses. Statistical power would be increased and the potential for bias in the overall estimates reduced, because fewer studies would have to be omitted.

Over the last couple of decades, several groups have been working on core outcome sets in specific areas of health care, including rheumatology, pain and maternity care. Now core outcome sets are being developed for oesophageal and colorectal cancer and also for breast reconstruction surgery. In January 2010, the COMET (Core Outcome Measures in Effectiveness Trials) initiative was launched at a meeting in Liverpool to try to encourage, highlight and facilitate such activities more widely. More than 100 people, including those working on core outcome sets, journal editors, regulators, consumers, clinicians, policy makers, trial funders, trialists and systematic reviewers, discussed what had already been achieved and the opportunities for the future. The presentations are available from the COMET website (see below).

The COMET initiative is an international network bringing together individuals and organisations interested in the development, application and promotion of core outcome sets. We aim to collate relevant resources, both applied and methodological, facilitate exchange of ideas and information, and foster methodological research. Further information about COMET can be found at the website http://www.liv.ac.uk/nwhtmr/ and we should be delighted to hear from anyone interested in this topic. The website will include examples of a matrix of outcomes that could be used within systematic reviews.² We encourage authors of Cochrane reviews to consider including these in their reviews and, if they wish, to send them to us for the collection of examples. Where a core outcomes set has been established in their topic area, Cochrane authors might also wish to draw attention to the use of these outcome measures within their Implications for research.

We are holding a second meeting this year in Bristol in July 11th /12th and registration and further details can be obtained at the website www.liv.ac.uk/nwhtmr/comet/comet.htm

Jane Blazeby, Professor of Surgery and Honorary Consultant Surgeon, University of Bristol

Paula Williamson, Professor of Medical Statistics, University of Liverpool

Doug Altman, Professor of Statistics in Medicine, Director of the Centre for Statistics in Medicine, Oxford

Mike Clarke, Professor of Clinical Epidemiology, Director of the UK Cochrane Collaboration Centre

BASO ~ The Association for Cancer Surgery

Improving Cancer Outcomes: Increasing Patient Engagement

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INCREASING PATIENT ENGAGEMENT

Lastly, but by no means least, outcomes have been increasingly examined in the context of what patients want, with a focus on quality of life and the patient experience. Patient input into research projects and also patient feedback on cancer services have all assumed increasing importance in recent years. We review these 2 significant developments below.

Patient and Public Involvement in Health Research

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Over the last 10-15 years, patient and public involvement (PPI) has become an established theme within UK health research policy,¹⁻⁶ with PPI being recognised as an essential force in the drive to improve the quality of services and research. These developments have been particularly rapid in the cancer field, where there have been many initiatives to promote PPI in research^{7,8}. PPI in research can be conceptualised as, "doing research 'with' or 'by' the public, rather than 'to', 'about' or 'for' the public"5.

Three main levels of PPI have been identified:

(1) consultation (where researchers seek the views of the public on key aspects of the research);

(2) collaboration (an on-going partnership between researchers and the public throughout the research process);

(3) 'publicly-led' (where the public designs and undertakes the research and where researchers are only invited to participate at the invitation of the public)⁵. This UK policy commitment to PPI in research can be seen in a number of respects:

(1) the establishment of INVOLVE in 1996, to promote PPI in research in England;

(2) the requirement that researchers submitting bids to funding streams such as 'Research for Patient Benefit' demonstrate that the public will be actively involved in the research if it is funded⁹

(3) the establishment, through the National Institute for Health Research, of regional Research Design Services, that are responsible for bringing clinicians, academics and members of the public together to develop research ideas into fully-developed protocols and grant applications.⁹

Underpinning this policy commitment, the case for PPI in research rests on three main arguments¹⁰ -

(1) it is morally and ethically correct¹¹;

(2) it has potential benefits in terms of improving the quality, relevance and impact of health research¹²; and

(3) it is theoretically justified¹³.

There are a number of different models and approaches to PPI in research^{10,14}. The model developed within the North Trent Cancer Research Network (NTCRN)^{8,15}, known as the North Trent Cancer Research Network Consumer Research Panel (NTCRN CRP) was the first of its kind to be established at the local level within the UK11,15. The local panel was established to: encourage cancer and palliative patients and carers to engage with health professionals and academics; and to provide the opportunity for patients and the public to influence the research agenda and to contribute to the research process from the outset - from the generation of research questions, through to protocol development and offering advice on issues such as ethics and patient recruitment, through to full involvement as co-researchers, co-presenters at conferences and co-authors of peer-reviewed papers. By providing a PPI perspective at all stages of the research cycle locally and nationally, this panel has become a core sustainable element of NTCRN's work. This model has since been replicated in other cancer networks across the UK and held up as a beacon of good practice by the National Cancer Research Network and INVOLVE. Similar panels have since been established in disease areas other than cancer by a range of organisations including clinical research networks and university departments, to provide an opportunity for patients and members of the public to influence the design and delivery of health research projects. Such panels provide an important opportunity for the public to get actively involved in the design and delivery of health research projects by way of being 'experts by experience'15.

A key challenge for those engaged in PPI in research is to demonstrate the value-added nature of its impact on research processes and outcomes. It is difficult to assess objectively the impact of PPI on the nature, quality, relevance and effectiveness of health research14,16-19. Findings from a recent systematic review of the PPI in research literature¹⁴ reported that although the evidence 'comprised mainly gualitative or case study reflections of PPI, or cross-sectional studies reporting individual or organisational views of PPI, with relatively little critical evaluation', positive PPI impacts on research in terms of patients and the public developing research questions, identifying and prioritising topics and developing commissioning briefs were apparent. The review also found evidence of patients and the public developing and commenting on research protocols, adapting and improving the sensitivity of research language in patient information sheets and invitation letters, and identifying poorly worded questions in draft questionnaires¹⁴. The review also found evidence that PPI helps to foster important links with the community and can help researchers to access participants and improve response rates (including recruitment rates from seldom heard groups). PPI can also help researchers develop a greater sense of empathy with

their research participants, thus improving the guality of the informed consent process, leading to more informed research participants. Evidence was also found of patients and the public helping to develop research instruments, making them more acceptable to potential participants, and improving the timing of interventions and data collection points, based on their knowledge of the progression of a particular condition and its treatment and care pathway. Patients and the public were also found to be involved in the dissemination and implementation of research findings, in some cases through the development of a cohort of advocates who disseminate key findings. The review also reported on impacts of PPI on key stakeholders, with some evidence to suggest that PPI helps to improve the skill level and personal confidence of individual patients, carers and service users who get involved in research. However, we know less about the impact of PPI in relation to individual researchers, research participants, community, policy makers, journals and funders¹⁴.

Other challenges to PPI in research have also been reported. These can be summarised as follows: a lack of time and funding available to researchers to involve the public in a meaningful way in research; tensions between different stakeholder groups when developing and conducting health research; researchers' reported concerns about the level of understanding of the public of certain health research methods (in particular the rationale for randomisation in clinical trials); the potential of the public to be put off by unfamiliar language and jargon; researchers being unfamiliar about the practical implications of involving the public in research; and researchers' concerns that those members of the public who get involved in research may not necessarily be representative of potential research participants¹⁰. Additionally, several commentators are critical of the ability of patients, carers and service users to provide objective scientific critiques of research, arguing that they can only provide a non-scientific subjective view, based on their individual, highly variable experiences, which runs counter to the medico-scientific paradigm of knowledge development²⁰. Addressing the issue of representativeness, Boote et al¹⁰ argue that, although individual patients or the public cannot be assumed to represent the views of all members of a particular patient group, their incorporation into a research team can provide an added dimension to the conduct and outcome of a research project which would otherwise be lacking. The challenges to PPI raised in this paragraph can be addressed by researchers providing to patients and service users: a lay summary of the planned research project at the start of their involvement; a glossary of key terms; ongoing guidance and support; and an environment of mutual respect¹⁰.

In conclusion, PPI in research is now an established theme within UK health research policy, with a number of different

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models and approaches to PPI emergent. Despite its challenges, PPI provides considerable opportunities for patients and the public to work collaboratively with health care professionals and researchers to influence the research agenda, with the contribution of patients and the public to the research process being integral to the entire process from the outset, rather than appended to it. It is also important that health care professionals and researchers considering involving patients and the public in their research should seek guidance from professionals and organisations who have substantial expertise in this field (e.g. INVOLVE, the National Institute for Health Research's Research Design Services) to ensure good practice and to optimise mutual benefit from all PPI activity.

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Patient Reported Outcome Measures, PROMs

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There is currently an international commitment by commissioners of health care such as the NHS, NICE and the FDA to judge the quality of a medical effort based on standardised clinical and patient reported outcome measures (PROMs)². The UK Department of Health recently

published a white paper stating its intention to extend PROMs across the NHS wherever practicable³. A similar strategy has been proposed by the Kings Fund².

A PROM should assess the impact of disease, treatment and surgical intervention on various aspects of a patient's outcome, as well as being clinically meaningful, scientifically sound and practical⁴. In assessing clinical effectiveness, there is increasing evidence as to the importance of examining not only patient morbidity and mortality, but also patient perceptions of the results of surgery⁵. PROMs may be more informative in terms of clinical outcomes as they may differ significantly from those of the clinical evaluator. The validity of PROMs must however be clearly proven using internationally established criteria as defined by international bodies such as the Scientific advisory committee of the Medical Outcomes Trust and the European organisation for the Research and Treatment of Cancer (EORTC). Both comprise multidisciplinary professionals working in assessing health status with the aim of developing questionnaires for the assessments of HRQL in international clinical trials6-7. Eight defined attributes have been proposed (e.g. conceptual and measurement model, reliability, validity, responsiveness, interpretability, administrative burden, forms of administration as well as cultural and language adaptations) as well as the criteria for reviewing instruments6. PROMs that have not been developed in this vein, may fail to allow comparisons to other studies in the UK or internationally or to detect

clinically meaningful information. Challenges in the field of breast reconstruction have demonstrated such issues, where a systematic review of PROMs showed only 2 out of 223 to be applicable to breast reconstruction with neither being developed in keeping with current internationally accepted criteria⁴. Another systematic review of HRQL outcomes in all types of immediate and delayed breast reconstructions from 1978 to 2009, showed no validated PROMs in breast reconstruction(6). To this end, there are two breast reconstruction specific questionnaires under development; one in collaboration with the EORTC and the other being developed in the USA called the BREAST-Q⁷⁻⁸. A groundbreaking attempt to venture into this domain has commenced with the national commitment of all practising breast cancer and plastic surgeons to participate in the first national mastectomy and breast reconstruction audit in which 6,882 (84%) women completed the BREAST-Q at 3-6 months after breast reconstruction⁹. There is much complexity in the interpretation of such questionnaire data however organisations such as the Association of Breast Surgeons have had the courage to dip their "toes in the water" and the clinical community will await these results with the expectation of significantly improving information provision and clinical evidence.

PROMs are likely to become a key part of how all health care is funded, provided and managed²⁻³. A recent qualitative study identified that key patient goals and concerns about breast reconstruction after mastectomy relate to the magnitude of surgery and recovery with the majority of women reporting, that concerns over the number of operations, duration of recovery, and risk of complications strongly affected their decision-making¹⁰. In a systematic review of PROMs in Breast Reconstruction since 1978, the reporting of complications is variable, poorly conceived and ad hoc with little a priori stratification of the levels of severity or the timings post-operatively^{6,11}. In response to this need, the National UK Mastectomy and Breast Reconstruction audit is attempting to report such data⁹. Of concern are the high levels of early (within 24 hours) post-operative pain in 16-

20% of Breast reconstruction patients with persistence at 3 months in 40-50% of reconstructed women⁹. Existing preventative strategies comprising high volume 0.25% bupivacaine infiltration subcutaneously or via drains¹², including epidural anaesthesia, pleural nerve blocks and the titration of analgesia using a Visual Analogue Scale¹²⁻¹⁴ may reduce acute post-operative pain which was found to be a determinant of long-term pain and physical functioning in a prospective study evaluating PROMs in 600 women¹⁵.

The descriptive reporting of higher local complications requiring further treatment or surgery within 3 months should be rationalised in the context of potentially confounding variables such as neoadjuvant and adjuvant chemotherapy, as well as the sequelae of post-mastectomy radiotherapy effects on skin and the differential diagnosis of possible bacterial infection which may also emulate the effects of fat necrosis particularly in the context of a high Body Mass Index, diabetes and the performance of autologous breast reconstructions (pedicled or free flaps)^{14, 16}. In this regard, the audit reporting doesn't distinguish between the sites of infections as either the breast or donor site, the latter of which may be compounded by the high frequency of fluid collections (or seromas) requiring repeated needle aspirations¹⁴. A Randomised controlled trial has identified significant reductions in donor site seromas following quilting sutures after the harvesting of back flap tissues and urges a cognisance of the published clinical evidence by practising clinicians¹⁴. In the development of a breast reconstruction specific PROM, there is emphasis on the reporting of satisfaction that covers important subscales such as the patients' levels of satisfaction with information and care encompassing both the surgeon and the medical team¹⁷. Despite the majority of patients in the audit, reporting having received "excellent" and "very good care" within 3 months after their breast reconstruction⁹, it will be important to establish whether there is in fact a correlation between the PROMS and the 3 month reporting of complications in the audit^{1,15}. Notwithstanding this possible correlation, it is timely to accurately stratify the levels of severity as well as quantitate the extent of early complications after breast reconstruction as these may impair health related guality of life^{1,15}.

In a further bold step and a world-first, is the multicentre phase III randomised clinical trial in breast reconstruction called QUEST (QUality of life after mastectomy and brEast reconstruction) that will use PROMs in women undergoing immediate and delayed Latissimus Dorsi breast reconstruction¹⁸. It is in the application of validated PROMs within well designed prospective longitudinal cohort studies¹⁹, as well as clinical trials that we will start to establish a solid foundation of clinical evidence in this field of surgical practice.

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