Submission No. 115
AUTHORISED: 10/5/06

The Australian Proton Project Working Party

196 Glenmore Road
Paddington, NSW 2021

29 March, 2006

Hon Alex Somlyay MP
Chairman
Standing Committee on Health and Ageing
House of Representatives
Parliament House
CANBERRA ACT 2600
E-mail: haa.reps@aph.gov.au

Dear Mr Somlyay

Re: Commonwealth Parliamentary Enquiry into Health Funding.

The Australian Proton Project Working Party is grateful to the Chairman of the Joint Standing Committee on Health & Ageing for the opportunity to present a Submission calling for the development of Australia's first Proton Therapy Facility.

This submission will focus on item "c" of the Terms of Reference. "
"...considering **how** and whether accountability to the Australian community for **the quality and delivery of** public hospitals and **medical services can be improved."**

For the foreseeable future, surgery and radiotherapy will continue to play a major role in the control of primary cancers in Australia, therefore it is necessary to improve the established methods - surgery and radiotherapy.

This submission will centre on improving radiotherapy. Proton Therapy is the next technological advance in radiotherapy.

The attached document will present the Standing Committee with a proposal to develop at least one Proton Therapy Facility in Australia, in a capital city, adjacent to a major teaching hospital, drawing patients from Australia and its near neighbours in South East Asia.

Despite the significant capital investment required, proton therapy is being developed or is already established, in 41 centres in the USA, Europe, Asia and Africa. Evidence collected over the past 30 years and emerging, supports the assertion that protons provide superior clinical outcomes, safely and with fewer side effects from radiation.

We hope that our submission will be the platform from which this project will proceed and accept with pleasure, the invitation extended by the Chairman, Hon Alex Somlyay, MP to present to the Committee at a date and time convenient to the Committee.

Yours truly,

Susanne Bleasel
Proton Technology and Business Development
Australian Proton Project Working Party

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Submission Summary

In Australia, cancer is estimated to affect 1:3 men and 1:4 women before the age of 75. The total cost of cancer including the indirect costs, bring the total cost to the community to approximately $5b per year.

Despite the advances in drug treatment and surgical procedures, radiotherapy is still a major component of cancer therapy with 52% of all Australian cancer patients requiring radiotherapy at some time during their illness. Radiotherapy involves targeting cancer with X-ray radiation and, in doing so, indirectly damages surrounding healthy tissue.

Conversely, proton therapy which involves focusing proton radiation at the cancer, has **two** to **three times less** radiation being absorbed by the surrounding tissue, and therefore causes significantly less damage to healthy tissue. As a result, proton therapy provides better clinical outcomes for most cancers where radiation therapy is the recommended treatment. It also produces highly favourable results for certain tumours that are not effectively controlled by conventional radiotherapy; and is especially important in the treatment of paediatric tumours.

Proton therapy is more effective in destroying cancer and is less likely to damage surrounding tissue because of the unique ability of proton radiation to release the majority of its energy at the site of the cancer.

Although more expensive than conventional X-ray therapy, the proposed average cost of $25,000 per course of treatment, is still competitive with other modes of treatment such as drug or surgical therapies.

Proton therapy centres are established or being developed, in 41 centres in 15 countries around the world and is recognised by experts in the field as superior to conventional radiotherapy.

Full Submission on following pages

Proton Therapy reference sites

National Association for Proton Therapy. http://www.proton-therapy.org
Loma Linda University Proton Center, Southern, CA. http://www.llu.edu/proton
Rinecker Proton Therapy Centre, Munich Germany. http://www.rptc.de/english
University of Texas, MD Anderson Cancer Centre PTC, Houston Texas: http://www.stylesco.com/index.asp, www.mdanderson.org/care_centers/radiationonco/ptc
MidWest Proton Radiotherapy Institute, Bloomington, Indiana, USA http://www.mpri.org`
Particle Therapy Co-Operative Group, PSI Switzerland, http://ptcog.web.psi.ch

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SUBMISSION

Background

Since 1998 planning has been under way to build Australia's first proton therapy facility. Radiation oncologists, medical oncologists, physicists, financiers, project developers and technology providers have all contributed to what is now a considerable body of knowledge.

Total cost of the project is between $110 and $150M. The cost of a course treatment is estimated to be $25,000 per patient. If the project is to benefit all Australians, funding the project will depend upon treatment reimbursement by Medicare.

Two feasibility studies have been undertaken. The first, by the Australian National Proton Therapy Project Steering Committee in June 2001, found that Australia could support at least one proton therapy facility at a major teaching hospital on the east coast of Australia. The other was undertaken by the NSW State Government in 2003, and the findings of this were not made public.

Development of the project slowed after May 2004 due to lack of funding. In August 2005, a revitalization of interest was brought about by Federal Government request for information. At a presentation in Canberra in September, 2005, an invitation was extended to submit a proposal for an Australian Proton Therapy Facility to the Joint Standing Committee for Health & Ageing.

The Facility would primarily be for the treatment of cancer and other medical conditions, but would also be the first proton accelerator for physics and engineering research in Australia. The fields of scientific research that will benefit from such a facility will form a separate submission to the Committee.

Cancer and Treatment

In Australia, cancer is estimated to affect 1:3 men and 1:4 women before the age of 75.

In 2005 there were 100,000 new cases of cancer reported. It is the single most common cause of death in Australia. The health cost for new cancers is estimated to be $1.7b per annum, however, the total cost of cancer including the indirect costs, bring the total cost to the community to approximately $5b per year.

Cancer diagnosis rates are also rising as a result of early improved diagnosis. Screening plays an important role in early detection as do the continually improving diagnostic tools such as CT, MRI, and PET/CT that are used to provide enhanced tumour definition through 3-D imaging.

This trend toward early detection will increase the role of, and demand for, treatments that provide effective local control of cancer.

Cure from cancer can be achieved for about 45% of all cancer patients using currently available therapeutic strategies: surgery, radiation therapy and chemotherapy. For about 2/3 of patients, the disease is localised when the cancer is diagnosed. For these patients the chance of cure using a local therapy, surgery or radiation therapy or a combination of both, are reasonably good.

However, despite the best current advances in early detection, 10,000 patients per annum in Australia suffer from failure to control the localised tumour – that is, the tumour is either not discovered before it has spread, or if it has been discovered, the means by which it is treated, is not effective. This is an area for improvement.

In many cases, surgical excision of the disease is the preferred therapeutic choice. The earlier the diagnosis and the smaller the tumour, the better the chance for a good therapeutic outcome. Surgery is the most successful therapy contributing 22% to the overall cure rate.

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Radiation therapy is used for treatment when the tumour is still localised to one area, but difficult to excise or when surgery would produce significant side effects. Radiotherapy contributes 12% to the cure rate alone and 6% when combined with surgery[1]. 52% of all Australian cancer patients are estimated to require radiotherapy at some time during their illness.

When the disease has spread to other parts of the body (called metastasis), chemotherapy is used with the intention of eliminating the diffused cancer cells. Chemotherapy account for 5% of the total cure rate. Chemotherapy may also be used to increase the effectiveness of surgery or radiotherapy in localised tumours.

Much cancer research today is undertaken by pharmaceutical companies on new developments based on biological science; the most promising of which is genetic technology. However, like all other systemic therapy, these methods will face the problem of unwanted side effects of drugs which are inevitably spread through the body.

It is the opinion of experts that for the foreseeable future, surgery and radiation therapy will continue to play a major role in the control of primary solid tumours. Therefore, it is necessary to **improve the established local methods, surgery and radiotherapy**.

What is Radiotherapy?

Radiotherapy is a treatment using ionising radiation to kill or prevent the reproduction of cancer cells. The aim of radiotherapy is to eradicate all cancerous cells in the tumour, whilst damaging as little healthy tissue as possible. Radiotherapy can either be delivered by a machine that directs radiation into the body, or by means of brachytherapy where radiation is delivered, by various means, directly to the cancer inside the body.

Since 1922 when X-ray [2] radiation for patient therapy moved into the clinical routine, numerous developments in radiotherapy have been accomplished. These improvements have included the development of the linear accelerator for higher energy radiation, patient table designs to enable radiation from a variety of angles and directions, the implementation of lead shutters and other beam shaping devices to precision shape the radiation beams, and the use of CT, PET, MR and other imaging modalities to create 3-D tumour models for more precision treatment targeting. Lastly, intensity modulated radiotherapy (IMRT) where computers control the radiation field size and intensity so that dose can be accurately shaped to match the tumour; whilst reducing unwanted dose to healthy tissue .

These improvements have all been undertaken for X-ray radiotherapy and it is difficult to envisage any further significant progress in this technology.

Science has always known, however, that because of the physical properties of a proton, proton therapy would provide superior quality radiotherapy. Progression to protons was delayed because the accelerators needed to accelerate such a heavy particle were too large for the hospital setting.

In 1990 the first hospital-based accelerator for proton therapy was installed in the Loma Linda University Proton Therapy Center in California USA. World-wide there are now 41 facilities either operating or in the planning stage.

What is Proton Therapy and Why?

Proton therapy is the most precise and advanced form of radiation treatment today.

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[1] "Will we need proton therapy in the future?" Europhysics News (2000) Vol. 31 No.6. E. Pedroni, Paul Scherrer Institute, Division of Radiation Medicine, CH-5232 Villigen PSI, Switzerland.

[2] X-rays can be produced in parcels of energy called photons.

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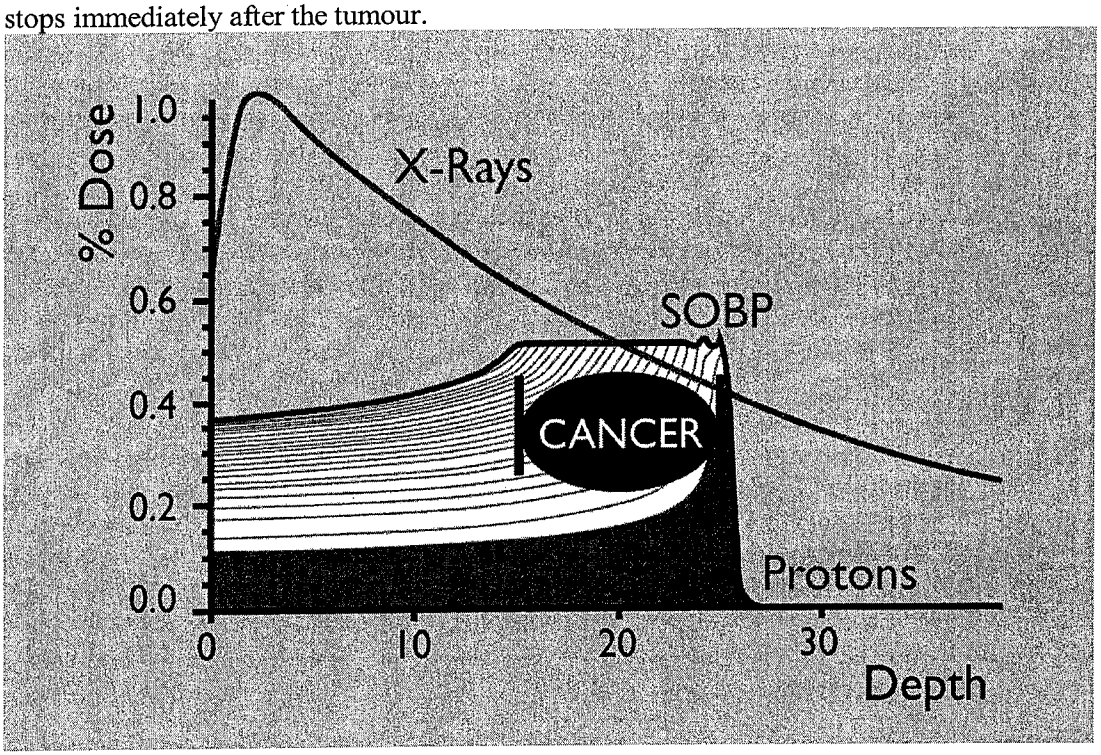
Protons form part of the nucleus of an atom. Protons are stable, positively charged subatomic particles with a mass 1830 times that of an electron. This enables the dose of proton radiation to be controlled to an exact shape and depth within the body. The penetration through tissue of a proton is a function of the energy and the tissue density through which it passes. As the proton passes through tissue, it is slowed down and the slower it moves the more energy it deposits until there is no more energy and it finally comes to a stop.

In comparison to X-ray therapy, protons deliver high doses of radiation very accurately to a tumour (utilizing the properties of the Bragg peak), with a much lower dose to surrounding normal tissue. The total dose of radiation to normal tissue during proton treatment is **two** to **three times less** than with X-rays – this leads to more effective treatment and fewer side effects. Proton therapy is especially important in childhood cancers and tumours close to vital organs.

The image illustrates a spread out Proton Bragg Peak that provides maximum dose to the tumour but stops immediately after the tumour.



Protons provide better clinical outcomes for most cancers where radiation therapy is the recommended treatment; they also produce highly favourable results for certain tumours that are not effectively controlled by conventional radiotherapy; and are especially important in the treatment of paediatric tumours. Protons are also used to treat other non-cancerous conditions such as arterio-venous malformations, acoustic neuroma and age related macular degeneration.

The Introduction of Proton Therapy in Australia

Proton Therapy is an established cancer treatment which has been used throughout the world to treat more than 42,000 patients with various primary cancers.[3]

Although more expensive than conventional X-ray therapy, the proposed average cost of $25,000 per course of treatment, is still competitive with other modes of treatment.

[3] Refer http://www.proton-therapy.org/

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Proton Therapy is usually delivered in daily doses and a full course can take from one day to seven weeks depending on the tumour site.

In Australia, an exhaustive literature search on proton therapy treatment for various cancers and sites has been undertaken. The results of this will form the basis of the submission to the Medical Services Advisory Committee when a Medicare rebate for proton therapy is sought.
Proton Therapy treatment is reimbursed in the USA, Japan and some countries in Europe. (Patients from EU member states, are also entitled to reimbursement for proton therapy in France and Germany)[4].

Proton Therapy is used to treat tumours in the following areas:

- Paediatric
- Head and Neck
- Brain
- Bone and Joint
- Genito-Urinary
- Digestive System
- Respiratory System
- Breast

Promising results for proton therapy have been shown in cancers of head and neck, eye, prostate, lung, liver and para-nasal sinus. Further improvements in breast and bowel cancers can be expected from proton scanning (IMPT) which is incorporated in the Australian proposal.

Clinicians and scientists agree that for specific paediatric tumours, there is no better treatment than proton therapy.

Unfortunately, there are known long term side-effects when irradiating with X-rays. These can occur frequently and with significant severity and are a particular concern in children. Long term effects in children include compromised endocrine function, decreased growth and a risk of second cancers which can be up to cumulative 1% per year.

Statistics from the Australian Institute of Health and Welfare reveal that there were a total of 603 new cases of cancer in children in 2001.[5]

An Australian Proton Therapy Facility

The Australian Proton Facility project already combines a number of critical success factors:

1. A proven well understood medical technology that provides superior clinical outcomes to cancer patients.
2. Major Teaching Hospitals as sources of patient referrals, clinical staffing and expertise.
3. An anticipated Medicare reimbursement rate that will permit profitable operation as well as patient affordability.
4. A model to potentially develop additional proton therapy facilities in Australia and South Asia.

Total construction and equipment costs for the facility are estimated at between $110 and $150 million with the major components being the proton therapy equipment ($50-80 million), facility construction ($50-$60 million) and the treatment planning, diagnostic and information systems ($8 million).

[4]Refer http://www.rptc.de/english/index.htm.
[5] Australian Institute of Health & Welfare http://www.aihw.gov.au

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The proposed facility could be fully Government owned and operated, privately funded and operated, or Government owned and privately operated.

Situated close to a major hospital, the facility would comprise four levels, and a footprint of between 5,000m2 and 8,000m2. The facility would provide state-of-the-art equipment including 4 treatment rooms comprising, two with rotating gantries (3 stories high), and two with horizontal and/or vertical beam lines, a proton accelerator system including spot scanning technology, as well as a diagnostic equipment and patient support services. There would be an additional horizontal beam line in a separate area for research.

Estimated new patients per year from 500 in year one, to 2500 in year five - each receiving an average of 20-25 fractions (or doses of treatment). Estimated operating cost between $7 and 10M in year one stepping to between $15M and $20M in year 5.

The Vision

This project has captured the hearts and imagination of the people who have contributed to it.

It should be built in a city with strong local and state leadership, a radiation oncology group keen to develop it, and easily accessible to Australians and people from South East Asia.

The vision for the Australian proton facility is as the cornerstone of a high volume, full service, radiation therapy facility where all types of cancers and benign disorders are treated with *the optimal source of radiation*. Protons will play the key role in a significant number of malignancies as either sole treatment or in combination with conventional therapy. In some clinical situations cancers will be managed with protons entirely, whilst in others, treatment will be a combination of proton or conventional radiotherapy which could be delivered entirely in the facility or in conjunction with community based radiation programs.

The facility would also provide protons for physics and other scientific research, in a separate area, accessible by scientists. This will form the subject of a separate submission. The Centre for Medical Radiation Physics at Wollongong University in NSW has post-graduate medical physics students training in proton centres around the world in preparation for operating an Australian facility.

The facility will provide the latest in precision diagnostic tools including PET/CT, an essential compliment to precision radiotherapy.

Clinical collaborations with other centres around the world will contribute to world-class research by identifying improved ways of using protons in combination with other treatments - such as with chemotherapy and gene therapy.

Patients receiving the highest priority in the first instance will be paediatric patients, patients with central nervous system or head and neck tumours, eye disorders, lung cancer, prostate cancer and breast cancer. With more than 9000 Australia-wide who would benefit from proton therapy, there will be little difficulty in filling the ultimate 3000 proton patient slots from either the Sydney, Melbourne, Brisbane or Gold Coast population centres, or from Western Australia and Australia's SE Asian neighbours.

Anyone whose cancer treatment included radiotherapy, would choose proton therapy.

The Centre would also provide quality accommodation for overseas and country patients.

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5 April, 2006

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Dear Mr Somlyay

Re: Commonwealth Parliamentary Enquiry into Health Funding.

The Australian Proton Project Working Party wishes to add the following Annexure to the current Submission (dated 29.3.06) which calls for the development of Australia's first Proton Therapy Facility.

- Annexure I "Clinical Success with Protons"

Yours truly,

Susanne Bleasel
Proton Technology and Business Development
Australian Proton Project Working Party

Annexure I
Clinical Success with Protons

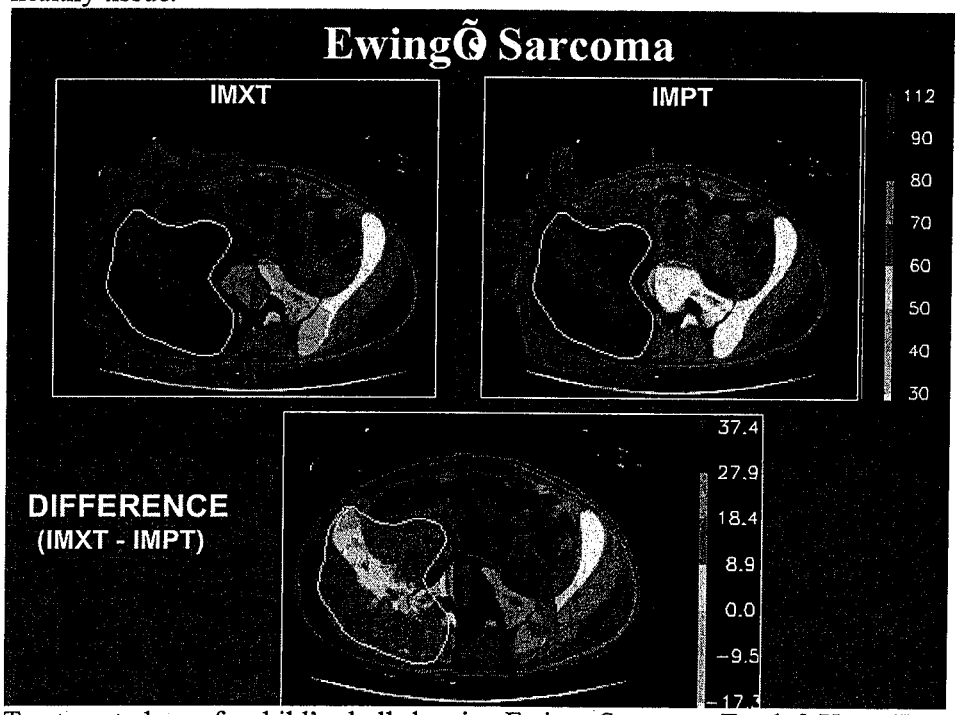
Proton therapy is a treatment that improves local cancer control as well as the quality of life for the cancer patient. Unlike its surgical counterpart, treatment with proton therapy provides for the anatomic and functional preservation of tissues and organs.

As discussed in the Submission to Health & Ageing dated 29/3/06, Proton Therapy is an established treatment with data available from more than 42,000 patients.[1] In this annexure are presented some clinical outcomes following proton therapy.

A window of opportunity exists between the time a cancer begins to form and regional and/or distant metastases occur. Within this time frame local treatments must work effectively; if they do, controlling the disease is tantamount to curing the patient. Thus, the importance of loco-regional control and the reduction of treatment morbidity are the fundamental reasons why proton treatment is being developed around the world.

Because of the nature of a proton, the dose of radiation absorbed by the tumour is maximized whilst the collateral damage to surrounding healthy tissue is dramatically reduced.

An ideal way to illustrate the benefits of proton therapy is to compare protons to the best quality X-ray therapy available today - Intensity Modulated Radiotherapy (IMRT). The two comparative treatment plans below demonstrate that protons deliver maximum dose to the tumour and little to the surrounding healthy tissue.



Treatment plans of a child's skull showing Ewings Sarcoma. Top left X-ray IMRT ; Right Proton Treatment; bottom, dose difference between the two plans.

[1] Refer http://www.proton-therapy.org/

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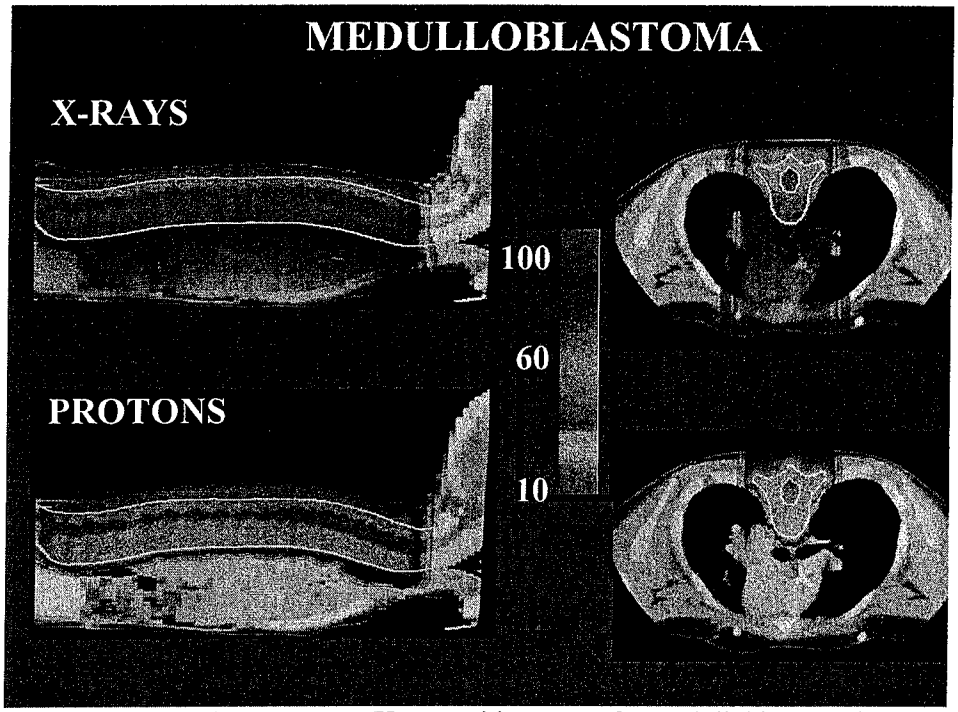

These treatment plans compare X-rays with protons for medulloblastoma in the child.

Specific Results.
Some specific results that have been achieved with proton therapy are summarised below[2].

- **Base of Skull tumours (Chordoma, Chondrosarcoma)**[3]
  There is no question that clinically improved results are produced by proton therapy in the base of skull tumours. For some, there is **no other effective treatment.**
  These tumours are not well treated by conventional X-ray therapy as they are too close to vital structures such as the brain and spinal cord and only 30% of patients survive for 5 years. However, in a study of patients with base of skull chordoma and chondrosarcoma receiving 3-D proton radiotherapy the overall survival is 80% for chordoma and 100% for chondrosarcoma. There was a 5-year actuarial local control of 75% for chondrosarcoma and 60% for chordoma.
- **Paediatric Oncology**
  Comparative Study by Miralbell et al[4], assesses the potential influence of improved dose distribution with protons compared to the most advanced X-ray radiotherapy (IMRT) on the incidence of treatment-induced secondary cancers in paediatric oncology. Conclusion: Protons provided at least a two-fold reduction in the incidence of secondary cancers in comparison to IMRT.
- **Medulloblastoma (paediatric)**
  Now that more children are surviving this disease, researchers are investigating ways to reduce the side effects from standard combination of surgery, radiation and chemotherapy. This study, that compares the latest X-ray radiation modality (IMRT) with protons showed that protons offer

[2] Courtesy of Dr Al Smith, Professor and Director, Proton Physics, University of Texas, MD Anderson Cancer Center.
[3] J Neurosurg. 1999 Sep;91(3):432-9.
[4] Int. J. Radiation Oncology Biol. Phys. Vol 54, No 3, pp. 824-829 2002

substantial benefits and protons emerged as superior in sparing nearby brain tissues whilst delivering the most conformal treatment to the tumour. [5]

The base-case results showed that proton therapy was associated with 23,600 in cost savings and 0.68 additional quality-adjusted life-years per patient. The analyses showed that reductions in IQ loss and hormone growth deficiency contributed to the greatest part of the cost savings and were the most important parameters for cost-effectiveness[6].

- **Isolated brain metastases (adult & paediatric)**
  Proton radiation therapy is used to relieve symptoms from isolated brain metastases. A high dose of radiation can be delivered in a few treatments, sufficient to reduce symptoms and improve quality of life.
- **Melanoma of the Eye (or Uveal Melanoma)** [7]
  Some ophthalmologists treat ocular melanomas by removing the eye. However, for more than 1000 patients receiving proton therapy the 5 year actuarial local control rate was 96% and eye preservation rate was 90%.
- **Acoustic Neuroma**[8]
  Study carried out in Boston in the period 1992 –2000 showed two and five year actuarial tumour control rates at 95.3% and 93.6%. Conclusion: a high degree of local control after proton with excellent facial and trigeminal neuro-functional outcome.
- **Meningioma**
  A study using combined X-rays and protons vs proton therapy found improved local control in the protons group, with 80% versus 17% at 5 years[9]
- **Cancer of Oropharynx**[10]
  Patients with localized Stage II-IV oropharyngeal cancer received accelerated X-ray and proton vs X-ray radiation. The 5-year actuarial control for local disease was 88%, and for neck node disease, 96%; yielding an 84% loco-regional control rate at 5 years. All results "impressively" better for proton and X-ray, than with X-rays alone.
- **Paranasal sinus**[11]
  In a study to compare tightening of normal tissue constraints using latest X-ray therapy (IMRT) and protons, concluded that both provide comparable target volume conformation and sparing of critical structures with nominal dose constraints. However, protons provided the only method by which critical structures were spared at all dose levels, whilst simultaneously providing acceptable dose homogeneity with the target volume.
- **Medically inoperable Stage I Non-Small Cell Lung Cancer (NSCLC)**
  Clinical results of NSCLC patients treated with proton therapy between 1983 and 2000, compared results of 2 year survival following conventional X-ray radiotherapy of 15-43% to proton therapy which provided overall and disease free survival of 60% and 59%.[12]
- **Breast**[13]
  A 2003 Swiss study using comparative treatment planning to investigate potential improvements for loco-regional treatment of complex target breast cancer revealed that compared to the best X-ray therapy(IMRT), only protons had the potential to preserve target dose homogeneity while simultaneously minimizing dose to lungs, heart and the contra-lateral breast.

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[5] March 1 2004 issue of the International Journal of Radiation Oncology*Biology*Physics
[6] Jonas Lundkvist, Stockholm Health Economics, Klarabergsgatan 33, 111 21 Stockholm, Sweden
[7] Ophthalmology. 1992 May;99(5):760-6.
[8] Neurosurgery Vol 53(3) Sept 2003
[9] Hug et al 2000
[10] Int J Radiat Oncol Biol Phys. **2005 Jun 1;62(2):494-500.**
[11] Radiother Oncol. **2003 Jan;66(1):11-8.**

[13] Int. J. Radiation Oncology Biool. Phys.m Vol 55, No 3, pp. 785-792, 2003

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- **Liver**
  Japanese analysis shows the 7 year local control and survival rates of patients treated by proton techniques were 94% and 26.7% respectively as compared to a 4-year survival of 20% following hepatic artery fluorodeoxyuridine and high dose 3-D X-rays[14].
- **Prostate**
  More than 2,500 patients have been treated successfully with proton therapy for prostate cancer at Loma Linda University Hospital Proton Centre. [15]
  In a study of patients with early prostate cancer , the overall 5-year clinical and biochemical disease-free survival rates were 97% and 88%, respectively. These results were comparable to surgery, however, radical prostatectomy is usually associated with significant side effects such as decline in sexual and urinary function.[16]
  The following table illustrates the remarkable reduction in side effects when prostate cancer is treated by Protons - relative to the traditional conventional X-ray radiotherapy and prostatectomy.

Long-Term complications associated with the treatment of prostate cancer[17]			
Chronic Toxicity	Protons	Conventional X-ray	Prostatectomy
Impotence	30%	60%	60%
Incontinence Requiring a pad	<1%	1.5%	32%
Bladder Neck Contracture	0%	3%	8%
Chronic Cystitis	0.4%	5%	N/A
Grade 3 Genito-Urinary toxicity • Severe frequency q 1 hr • Dysuria	0.3	2%	36%
Grade 3 Gastro-intestinal toxicity • rectal bleeding requiring transfusion • severe pain (>70 Gy)	0%	7%	N/A
Rectal Stricture	0%	0.5%	N/A

[14] Intern Med 1995:34(4):302-304
[15] http://www.llu.edu/proton.
[16] Urology. 1999 May;53(5):978-84., Int J Radiat Oncol Biol Phys. 2004 Jun 1;59(2):348-52
[16] International J. Radiation Oncology Biol Phys., Vol 56, No 1, pp.7-13.2003

[17] www.oncolink.org/treatment

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