

PTCOG 54

May 20, 2015

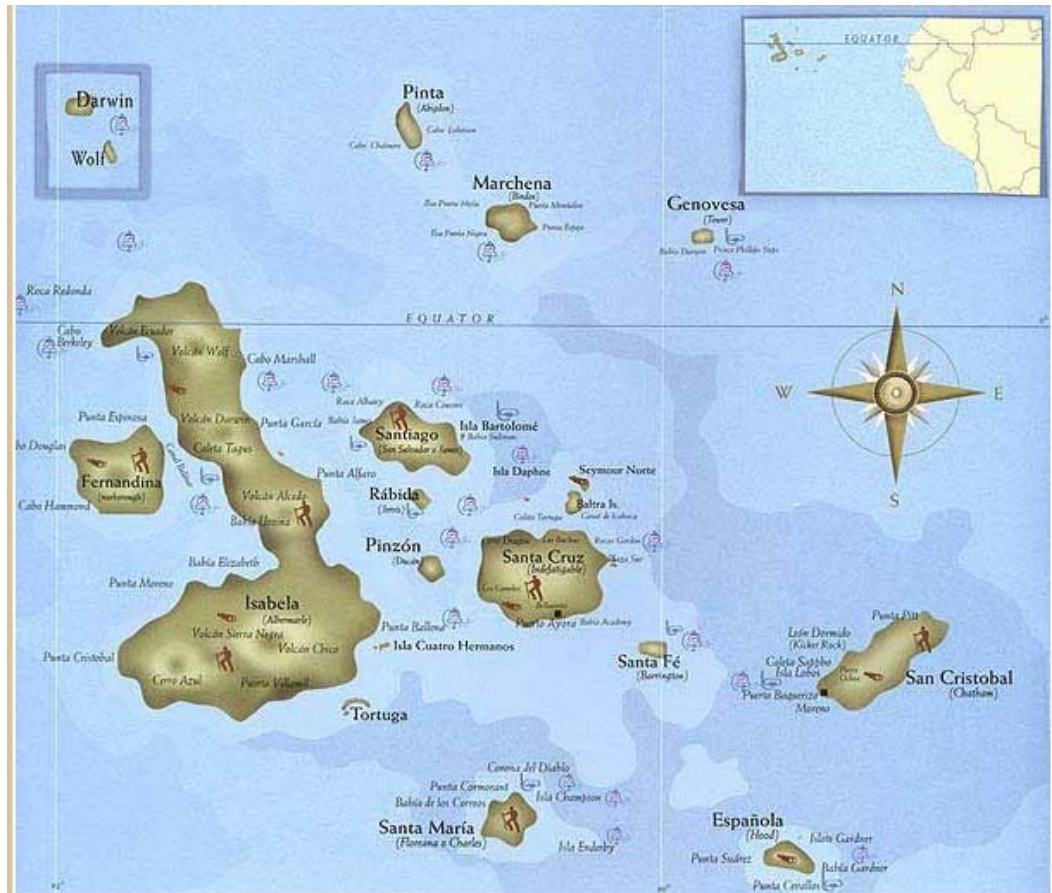
Nancy Price Mendenhall

Future Outlook for Proton Therapy

Future Outlook for Proton Therapy PTCOG 54

Future Outlook for Proton Therapy

Lessons from
the
Galapagos...



Future Outlook for Proton Therapy

PTCOG 54: Lessons from the Galapagos

- The Environment
- Survival
- Successful strategies
- All is changing.....

Future Outlook for Proton Therapy PTCOG 54 – Lessons
from the Galapagos:

The Environment: Challenging and Changing

Future Outlook for Proton Therapy PTCOG 54

Lessons from Galapagos: Challenging Environment

1535-Bishop de
Berlanga: “What
earth there is....is
like slag,
worthless...”



Lessons from Galapagos: Challenging Environment

1835-Charles Darwin:
“A broken field of
black basaltic lava,
thrown into the most
rugged waves, and
crossed by great
fissures, is
everywhere covered
by stunted, sunburnt
brushwood, which
shows little signs of
life...”



Lessons from Galapagos: Changing Environment

1825-Benjamin
Morrell:

“while the stillness
of death reigned
everywhere”

...Fernandina had
“broken forth with
accumulated
vengeance”“a
crack of doom”



Lessons from Galapagos: Changing Environment

1854-Herman

Melville: “There is dire mischief going on ...there toil the demons of fire, who, at intervals, irradiate the nights with a strange spectral illumination for miles and miles around.”



Lessons from Galapagos: Changing Environment

- “The natural history of those islands is eminently curious, and well deserves attention.”

-Charles Darwin, 1845.



Lessons from Galapagos: Changing Environment

- The Galapagos have provided enormous insight into evolutionary, geologic and meteorologic processes, as well as man's impact on the earth.



Lessons from Galapagos: Changing Environment

- “No area on Earth of comparable size has inspired more fundamental changes in Man’s perspective of himself and his environment than the Galapagos Islands.”

-Robert Bowman,
1984.



Challenging and Changing Environment for Particle Therapy

- Dosimetric evidence no longer justifies changes in care.....
- Increased focus on value (cost)
- Correlative outcomes trump clinical
- Healthcare decisions no longer in hands of patients and/or doctors

Challenges

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Costly Cancer Therapy Dinged

Proton-Beam Treatment for Prostate Tumors No Better Than Radiation,

By MELINDA BECK

Dec. 13, 2012 7:58 p.m. ET

In a finding likely to add fuel to the debate over treatments for prostate cancer, proton-beam therapy provided no long-term benefit over traditional radiation despite far higher costs, according to a study of 30,000 Medicare beneficiaries published Thursday in the Journal of the National Cancer Institute.

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Prostate-Cancer Therapy Comes Under Attack

Some Insurers Stop Covering Expensive Proton Beams to Battle Prostate Cancer

By **RON WINSLOW** and **TIMOTHY W. MARTIN**

Aug. 28, 2013 8:09 p.m. ET

Health insurers are pushing back against one of medicine's most expensive technologies amid growing evidence it may not be better for patients than cheaper options.

At least three major insurers have recently decided to stop covering proton beam therapy for early stage prostate cancer or are reviewing their policy, saying that while it is an effective treatment, it is much



Challenges



Proton-beam therapy is given at Massachusetts General Hospital. *THE BOSTON GLOBE/GETTY IMAGES*

Faith in the superiority of proton therapy by some has sparked an arms race among major medical centers. Ten proton accelerators are in operation in the U.S., and nine more are in development, including two by the Mayo Clinic and one by Memorial Sloan-Kettering Cancer Center and a consortium of other hospitals in New York City.

Challenges



The **National Association** for **Proton Therapy**

NEWS RELEASE

April 23, 2015

NAPT: Oregon's Proposed Proton Therapy Coverage Guidance Ignores Clinical Evidence

New Coverage Guidelines Put Children & Adults Diagnosed with Cancer at Risk

The Oregon Health Evidence Review Commission (HERC) recently released a proposed state policy position that, if finalized, could put access to life saving treatment at risk for one of Oregon's most vulnerable populations, children on



PROTON THERAPY INSTITUTE | ●●●●●

Medicaid diagnosed with cancer.

Challenges

HEALTH EVIDENCE REVIEW COMMISSION (HERC)

COVERAGE GUIDANCE: PROTON BEAM THERAPY

As posted for public comment 2/25/2015 to 8 a.m. March 30, 2015

HERC Coverage Guidance

Proton beam therapy (PBT) is recommended for coverage for malignant ocular tumors (*strong recommendation*).

Proton beam therapy is not recommended for coverage for adult malignant brain and spinal tumors (*weak recommendation*).

Proton beam therapy is not recommended for coverage for pediatric malignant tumors (*weak recommendation*).

Proton beam therapy is not recommended for coverage for cancer of the bone, head and neck, esophagus, liver, lung, or prostate (*weak recommendation*).

Proton beam therapy is not recommended for coverage for any other cancerous or noncancerous condition (*weak recommendation*).



Challenges

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN™

aspho American Society of PEDIATRIC HEMATOLOGY ONCOLOGY

OPS Oregon Pediatric Society

April 30, 2015

Oregon Health Evidence Review Commission
1225 Ferry Street, Suite C
Salem, Oregon 97301

Re: Health Evidence Review Commission Coverage Guidance: Proton Beam Therapy

Dear Commission Members,

The American Academy of Pediatrics (AAP) and its Section Hematology/Oncology Oregon AAP Chapter and the American Society of Pediatric Hematology/Oncology appreciate the opportunity to review and provide input to the Oregon Health Evidence Review Commission (HERC) draft policy regarding Proton Beam Therapy (PBT).

The draft policy and the response that was submitted by the American Society for Radiation Oncology (ASTRO) are attached for your review.

ASTRO
TARGETING CANCER CARE

March 19, 2015

Oregon Health Evidence Review Commission
1225 Ferry Street, Suite C
Salem, Oregon 97301

Re: Health Evidence Review Commission Coverage Guidance: Proton Beam Therapy

Dear Commission Members:

The American Society for Radiation Oncology* (ASTRO), appreciates the opportunity to comment on the Oregon Health Evidence Review Commission (HERC) Coverage Guidance on Proton Beam Therapy. We are concerned that the HERC Coverage Guidance is restrictive, inconsistent with current literature, and will have a detrimental effect on populations who derive the most benefit from access to proton beam therapy.

Proton beam therapy (PBT) is neither a new nor an experimental technology for

PTCOG-NA Particle Therapy Co Operative Group North America

March 24, 2015

Eugen Hug, MD
President
Particle Therapy Cooperative Group – North America (PTCOG-NA)
ptcog_na@gmail.com
Via email submission (HERC.Info@state.or.us)

Oregon Health Evidence Review Commission
1225 Ferry Street, Suite C
Salem, Oregon 97301

Re: Coverage Guidance on Indications for Proton Beam Therapy (PBT)

Dear Oregon Health Evidence Review Commission:

On behalf of the Particle Therapy Cooperative Group – North America (PTCOG-NA)¹, we respectfully submit comments on Oregon's Health Evidence Review Commission (HERC) Coverage Guidance on Proton Beam Therapy (PBT).

While we were pleased to see the strong recommendation for coverage of malignant ocular tumors, we have significant concerns with many of the other recommendations. We were especially surprised and disappointed with the lack of a positive coverage recommendation for

PTCOG-NA urges you to postpone finalizing this coverage guidance and reconsider your methodology of reviewing clinical evidence. We offer the assistance of our clinical leadership to assist you with any review.

team in a pediatric cancer center. Long term monitoring will facilitate identification of "harms" as survivors enter extended observation as outcomes improve through multi therapy. The over-arching goal is to make PBT available to all pediatric patients who benefit from it.

Consequently, we support the comments submitted by ASTRO and feel that the Oregon Health Evidence Review Commission should strongly consider them as the guidance policy is finalized.

proton beam therapy is ongoing with their respective clinical sites currently across three disease sites at the more than 14 proton therapy treatment centers around the world.

In June 2014, ASTRO released a PBT Model Policy that identifies cancer diagnoses covered by ASTRO's evidence-based standards that should be covered by private insurers. This Model Policy recommends two coverage groups for PBT: 1) patients with diagnoses for which PBT has been proven to be effective; and 2) patients with diagnoses for which there is a need for continued clinical evidence development and comparative analyses for the appropriate use of PBT. For the patients in group two, coverage development is recommended for patients if they are enrolled in clinical trials or a multi-institutional registry to collect data and inform consensus on the role of proton therapy.

patients. We believe eliminating coverage of PBT for pediatric patients is inconsistent with the current state of evidence and would be harmful to a population of patients who would most benefit from the reduced amount of radiation received in the course of PBT treatment.

¹ PTCOG-NA is the North American chapter of the International PTCOG. We are a professional membership society created to enhance collaboration between members, create a platform for scientific exchange, and develop treatment guidelines, education, and training initiatives for particle therapy.



* ASTRO is the premier radiation oncology society in the world, with more than 10,000 members who are physicians, nurses, biologists, physicists, radiation therapists, dosimetrists and other health care professionals that specialize in treating patients with radiation therapies. As the leading organization in radiation oncology, the Society is dedicated to improving patient care through professional education and training, support for clinical practice and health policy standards, advancement of science and research, and advocacy. ASTRO publishes two medical journals, International Journal of Radiation Oncology, Biology, Physics (www.ijro.org) and Practical Radiation Oncology (www.practicalradonc.org); developed and maintains an extensive patient website, www.radiation.org; and created the Radiation Oncology Institute (www.roinstitute.com), a non-profit foundation to support research and education efforts around the world that enhance and confirm the critical role of radiation therapy in improving cancer treatment. To learn more about ASTRO, visit www.astro.org.

Lessons from Galapagos: Changing Environment

- Can we view the challenging and changing healthcare environment with curiosity?
- Is it possible that the pressures exerted on us today will force changes that lead to better patient outcomes?



Future Outlook for Proton Therapy PTCOG 54-Lessons from
the Galapagos:

Survival: Proliferation or Extinction?

Lessons from Galapagos: Survival

- **Uplift in 1954-**
~5 m in Urbina Bay, Fernandina,
- Coral dies and with it marine life.



Lessons from Galapagos: Survival

- **Drought-1977**
- Researchers documented death of 8/10 medium ground finches on Daphe Island



Female medium ground finch, South Plaza Island, Galápagos
(Photo, Kookr, Flickr Creative Commons)

Lessons from Galapagos: Survival

- **El Nino in 1982**
- $\geq 14^{\circ}$ C increase in ocean temperature...
- 2/3 marine iguanas died in 1982



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Lessons from Galapagos: Survival



Volcanic eruptions- $\geq 20^{\circ}$ C increase in ocean temperature....
All nearby marine flora and fauna die – some species are lost.

Is Survival really a question for Particle Therapy?

Some who might say so.....

- Previous proponents of hyperthermia and neutrons
- Some proton technology developers and vendors
- Some institutions who have invested in proton facilities

Survival of particle therapy is not guaranteed.....

Our challenging environment has shed light on two weaknesses that must be overcome for survival

- A paucity of quality clinical evidence
- The excessive expense of particle facilities

Future Outlook for Proton Therapy PTCOG 54-Lessons from
the Galapagos:

Successful Strategies

Future Outlook for Proton Therapy PTCOG 54

Lessons from Galapagos: The Blue-footed Booby and Focus on Outcomes

*Why does the
blue-footed
booby have
blue feet?*



Lessons from Galapagos: Focus on Outcomes

Why does the male flaunt his blue feet in courtship dances?

- Do they make him smarketable?
- Are they more expensive?



Lessons from Galapagos: Focus on Outcomes

The female chooses the male with the bluest feet because his offspring are more likely to survive.



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Lessons from Galapagos: Focus on Outcomes

A focus on outcomes that are most important is likely to be successful.



Focus on Outcomes

The outcomes that matter most to patients:

- Disease control and survival
- Freedom from significant morbidity and dysfunction.
- Less important are temporary side effects and treatment convenience, duration, and cost.

The outcomes that matter most to other decision makers may differ:

- Value-based medicine (short term costs).

Need to understand these but keep focus on the patient.

Lessons from Galapagos: Focus on Outcomes

- *Remember outcomes of importance may differ*
- Integral dose.
- Critical organ avoidance.
- Dose escalation.
- Hypofractionation.



Lessons from Galapagos: The Flightless Cormorant and old paradigms

If you don't need to fly, wings are just in the way, so let them go...

- Number of fields.
- Dose per fraction.
- 8 hour workdays.



Lessons from Galapagos: The Woodpecker Finch and Creativity

Make the most of your tools....

- *Treatment planning, range verification, delivery time, spot size, on-line 3D imaging....*
- *Understand "RBE" and leverage it... ..*



Lessons from Galapagos: Marine Iguanas and Adaptability

If you are a land iguana and there is no food on land, you must learn to swim....

- Use what is available creatively-patient mix and technology.



Lessons from Galapagos: Marine Iguanas and Adaptability

- *If El Nino comes and you are in hot water, shrink.....*
- Adult iguanas have a flexible skeleton that shrinks when food is scarce
- After El Nino 1982, the 1/3 marine iguanas who survived had the ability to shrink the most...



Lessons from Galapagos: Daphne Finches and Adaptability

- *In drought, change your beak size....*
- The size & shape of the finch beak is under genetic control and governs what they eat...
- With the drought of 1977, 8 of 10 ground finches died.
- The survivors had larger beaks suited to different food sources.

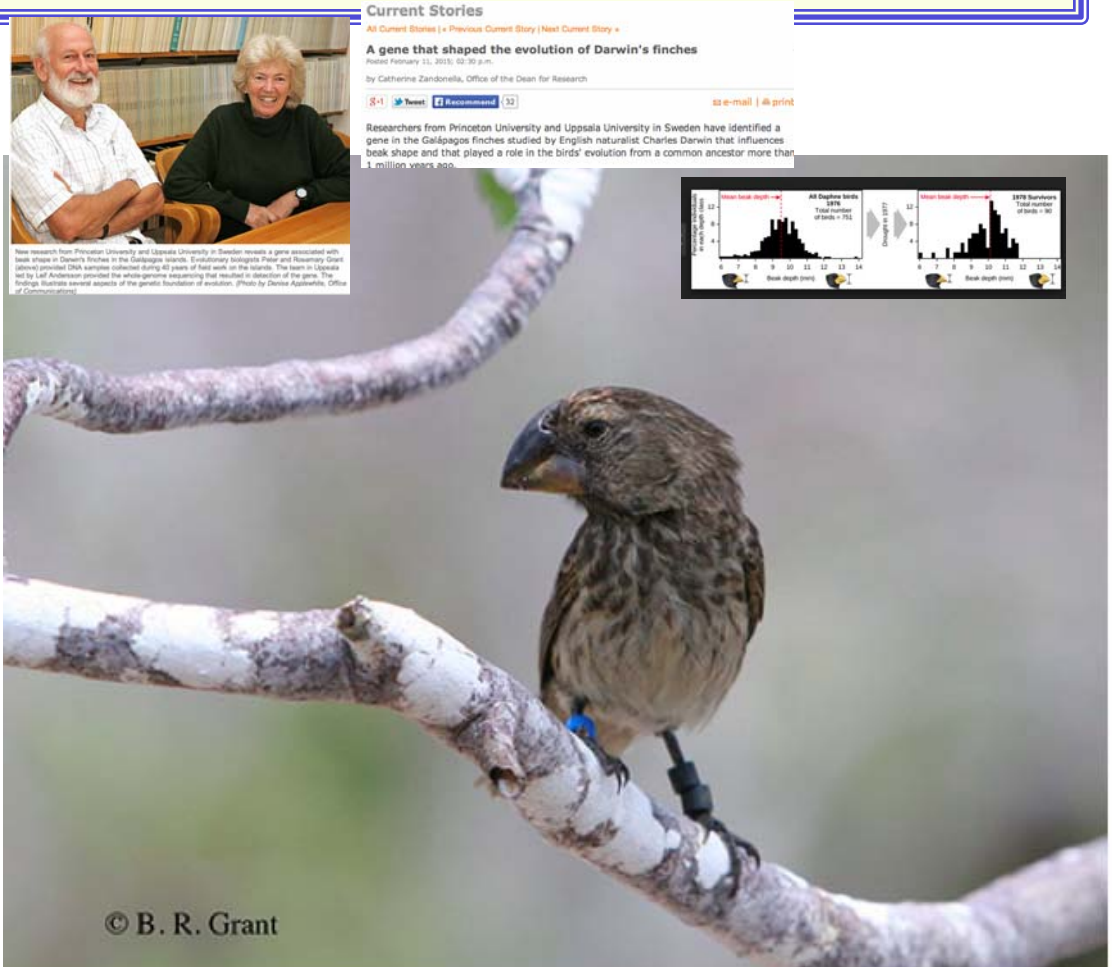
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A gene that shaped the evolution of Darwin's finches

Posted February 21, 2015, 12:30 p.m.
by Catherine Zambonella, Office of the Dean for Research

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Researchers from Princeton University and Uppsala University in Sweden have identified a gene in the Galápagos finches studied by English naturalist Charles Darwin that influences beak shape and that played a role in the birds' evolution from a common ancestor more than 1 million years ago.



© B. R. Grant

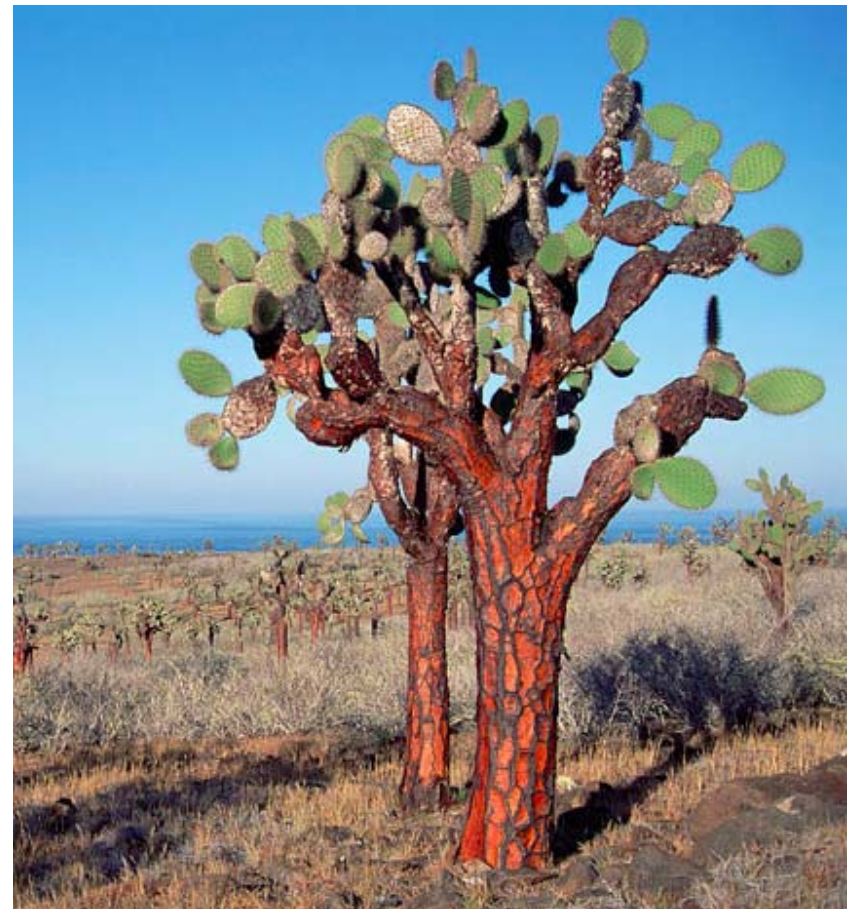
Lessons from Galapagos: Opuntia, Tortoises, and the Competition

- *Giant Tortoise and The Opuntia-1*



Lessons from Galapagos: Opuntia, Tortoises, and the Competition

- *The Opuntia-2*



Lessons from Galapagos: Opuntia, Tortoises, and the Competition

- *The Giant Tortoise-3*



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Lessons from Galapagos: Understanding the Competition

*The Opuntia
and the
Saddle-backed
Tortoise-4*



Lessons from Galapagos: Understanding the Competition

- *New Competition (human introduced goats -5*



Invasive goats and a Galapagos giant tortoise in Alcedo volcano, Isabela Island.

Foto: Tui de Rov



Lessons from Galapagos: Understanding the Competition

- *In the 1970's a systematic effort began to eliminate the goats, but it is not complete and several islands (Pinta) lost almost all tortoises & opuntia.*



Lessons from Galapagos: Understanding the Competition

Lonesome George

The last of
the Pinta
tortoises
died in
2012.

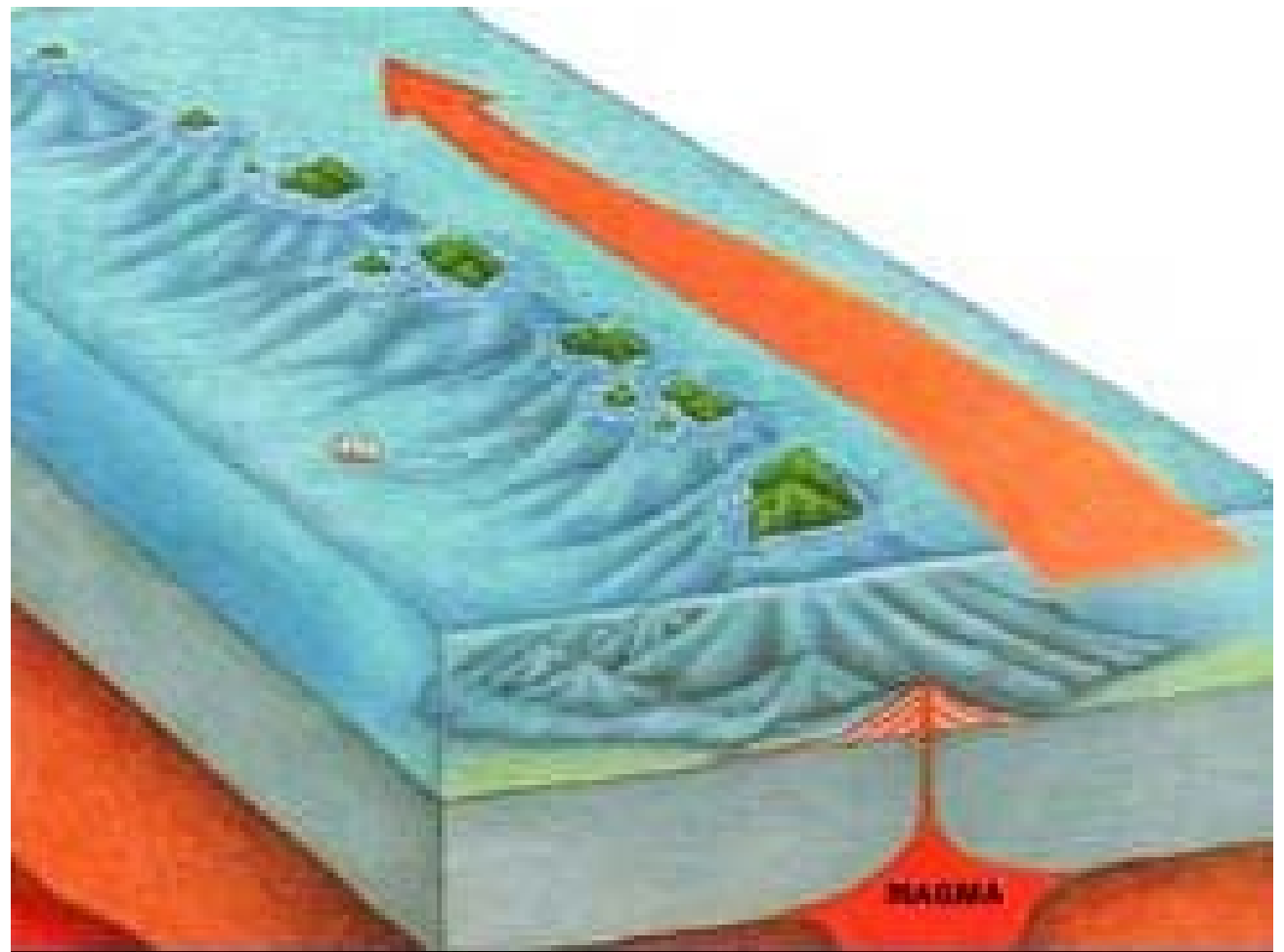


Future Outlook for Proton Therapy PTCOG 54-Lessons from
the Galapagos:

All is changing.....

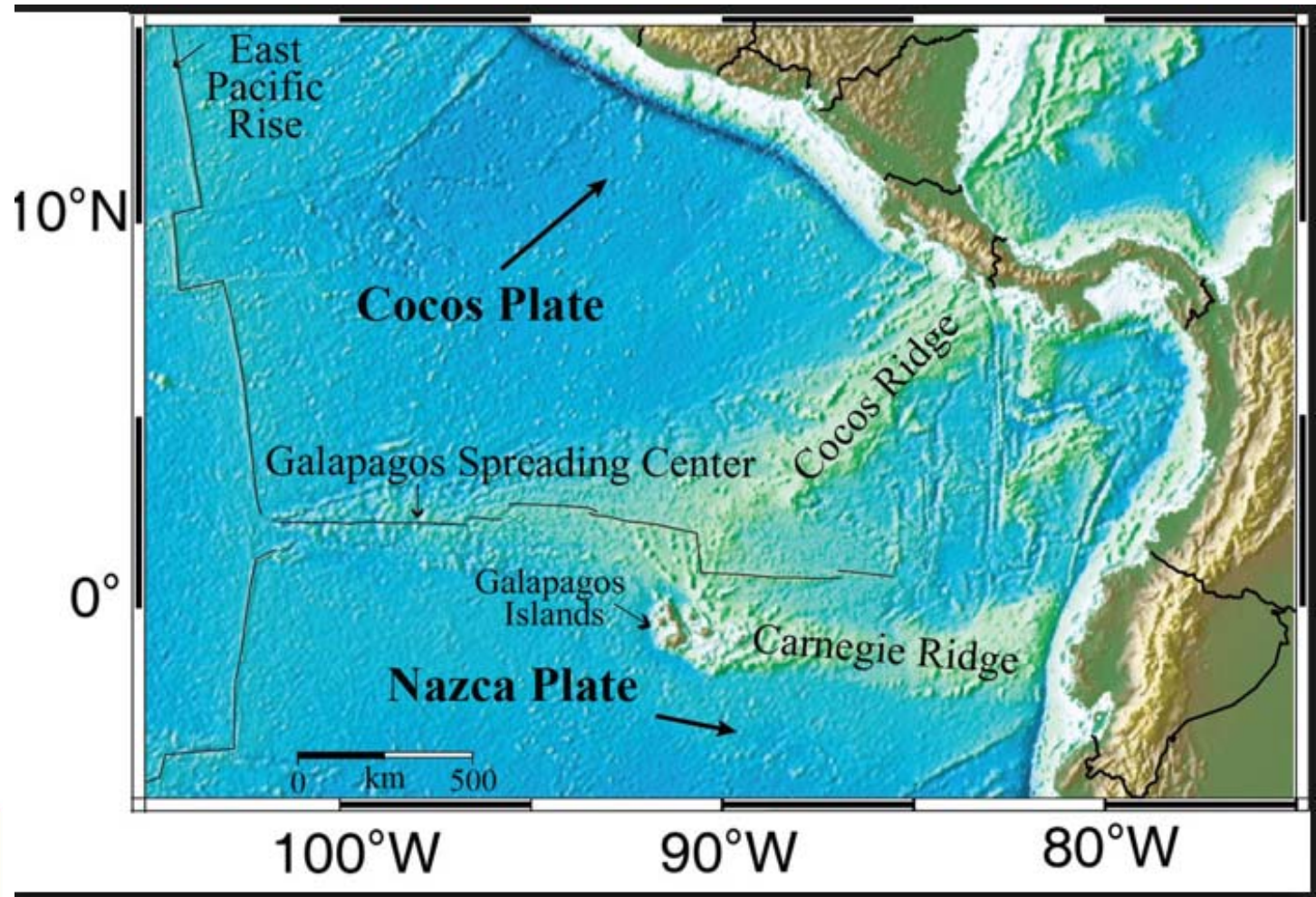
All is changing....Hot Spots, Tectonic Plates, and The Galapagos

New islands form from volcanoes over "hot spot," then migrate with their tectonic plate east, flattening with erosion over time.



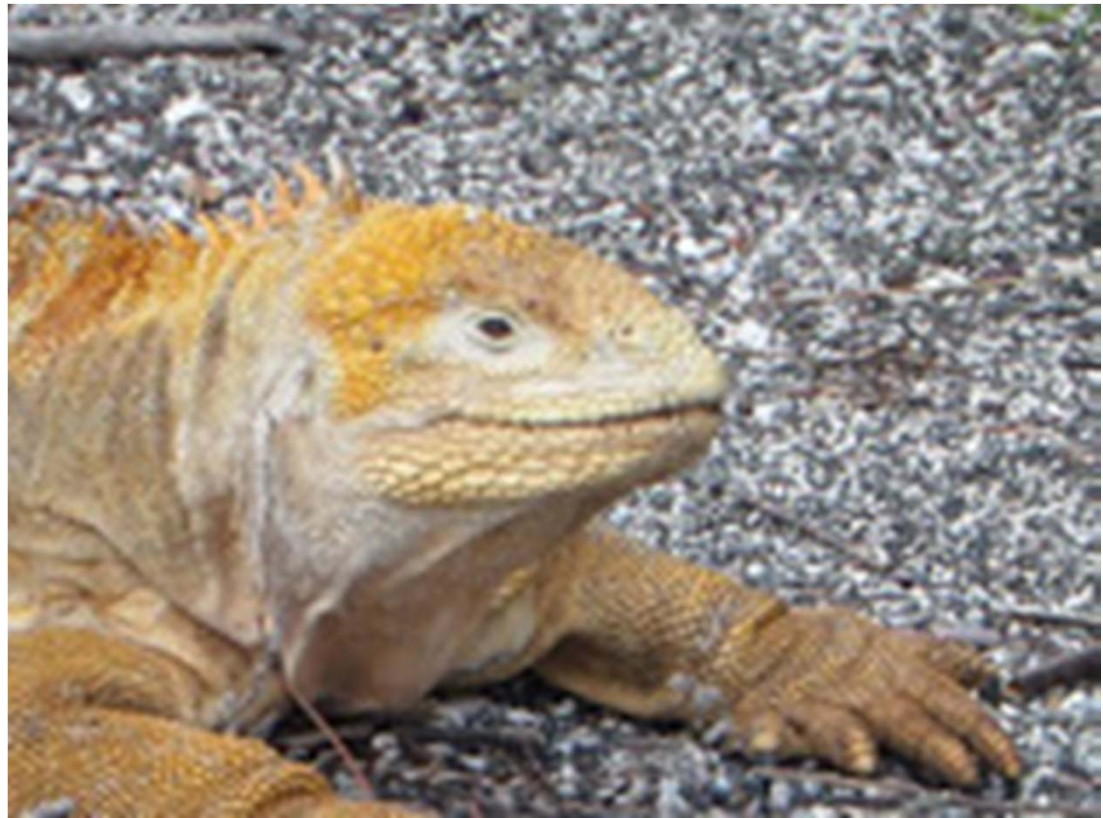
All is changing.....The Carnegie Ridge

Former Galapagos islands now submerged below sea level in Carnegie Ridge.



All is changing.....The Carnegie Ridge

Genetic studies indicate the land iguanas evolved on islands that are now submerged, suggesting that more than 3 m yrs ago, they “hopped” to new islands, when theirs sank below the sea.



Focus on Outcomes

- ❖ **Clear that environment has changed and is challenging our survival.**
- ❖ **Strategies likely to be successful***
 - A focus on what is important to patients...
 - Creativity in all aspects of our work...
 - Adaptability....
 - An understanding of the environment and competitors

*Clinicians, researchers, physicists, biologists, engineers, vendors, administrators, financiers.

Strategies for Survival

- ❖ Reliance on sound first principles of radiation therapy....
- ❖ We cannot control the environment or its changes and challenges, but may be able to survive, adapt and flourish.

Challenging and Changing Environment for Particle Therapy

Perhaps the pressure of our current environment will enhance our perspective, hone our survival strategies, make us more creative and effective in the future.....





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PROTON THERAPY
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