I SIMPOSIO NACIONAL de ONCOLOGÍA de PRECISIÓN

Vigo, del **28** de **febrero** al **1** de **marzo** de **2019**

Aspectos Legales y Eticos

Dr. F. J. Barón Duarte
Oncologia Medica
Hospital Universitario de A Coruña

NORMAS:

Ley

Deontologia

Ética

	Ley	Deontologia profesional	Ética
Chek Point	Regulación que la sociedad establece a través de sus gobernantes y la legislación	Orientada al deber….el deber profesional	Referencia que procede de la conciencia de cada ciudadano de lo que es bueno
Regla	normativa	normativa	No normativa
origen	Las leyes están hechas en base a la ética como un principio rector.	Normas que un colectivo profesional se da a si mismo (el deber se relaciona con lo bueno)	Proviene de los valores personales Es individual y motivadora
Régimen	Sancionable	Sancionable	No sancionable
Nivel de exigencia	Exigible a todos los ciudadanos	Exigible al profesional	No exigible
Ámbito	Mínimo común	Mínimo común a ese colectivo	Se preocupa de los Máximos

XUNTA DE GALICIA
CONSELLERÍA DE SANIDADE

SERVIZO GALEGO de SAÚDE | Dirección Xeral de Asistencia Sanitaria

INSTRUCCIÓN 8/18 DE ORDENACIÓN DAS PROBAS DE ANÁLISES XENÉTICAS NO ÁMBITO DO SERVICIO GALEGO DE SAUDE

O Real Decreto 1030/2006, do 15 de setembro, polo que se establece a carteira de servizos comúns do Sistema Nacional de Saúde e o procedemento para a súa actualización contempla, no seu ANEXO III, a Carteira de Servizos Comúns de Atención Especializada. O parágrafo 5.3.10 recolle que dentro do ámbito da atención especializada prevese a atención aos pacientes e familiares na área xenética que comprenderá o consello xenético e as análises xenéticas. Tamén se prevé que os equipos que realicen estas actividades terán como apoio as normas de organización, funcionamento e réxime dos Servizos de Saúde.

En virtude do anterior, e no marco das competencias que ten atribuído do Servizo Galego de Saúde de conformidade co artigo 6 da Lei 40/2015, do 1 de outubro, de réxime xurídico do sector público, e polo que se ditan as seguintes

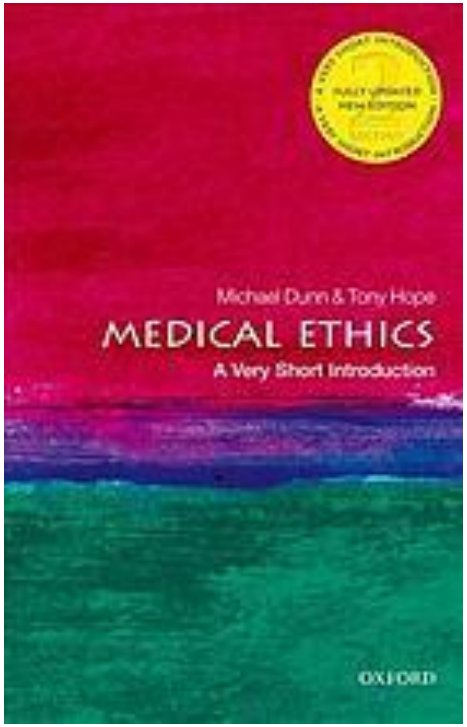
INSTRUCCIÓNS

LEGISLACIÓN CONSOLIDADA

Real Decreto 1720/2007, de 21 de diciembre, por el que se aprueba el Reglamento de desarrollo de la Ley Orgánica 15/1999, de 13 de diciembre, de protección de datos de carácter personal.

Ética Medica- Bioética

- Clarifica conceptos
- Opera como un tábano
- Identifica huecos del conocimiento
- Proporciona soporte clínico en la toma de decisiones



Medical Ethics: A Very Short Introduction Sec Ed . 2018 Michael Dunn; R A Hope

What is the difference between precision medicine and personalized medicine? What about pharmacogenomics?

- According to the National Research Council, "personalized medicine" is an older term with a meaning similar to "precision medicine." However, there was concern that the word "personalized" could be misinterpreted to imply that treatments and preventions are being developed uniquely for each individual; in precision medicine, the focus is on identifying which approaches will be effective for which patients based on genetic, environmental, and lifestyle factors. The Council therefore preferred the term "precision medicine" to "personalized medicine." However, some people still use the two terms interchangeably.

- Pharmacogenomics is a part of precision medicine. Pharmacogenomics is the study of how genes affect a person's response to particular drugs. This relatively new field combines pharmacology (the science of drugs) and genomics (the study of genes and their functions) to develop effective, safe medications and doses that are tailored to variations in a person's genes.

https://ghr.nlm.nih.gov/primer/precisionmedicine/definition

INDIVIDUALOMA

Los consumidores reclaman un nuevo concepto: “individualoma”

ONCOLOGIA DE PRECISION

«Tratar el paciente adecuado con la dosis adecuada de la sustancia terapéutica adecuada siempre ha representado el ideal de una medicina eficaz y eficiente» (Paul, & Fangereau, 2006, 1721

Este ideal es el mismo perseguido por la medicina personalizada y de precisión que tiende a llevar una mayor certidumbre científica aplicada a los pacientes individuales en medicina

Tipos de Oncología de Precisión

ONCOLOGIA INTEGRAL DE PRECISION Genes y Nemes (La verdadera Oncología de Precisión)

ONCOLOGIA DE PRECISON Genes y Omicas

All Hierarchical or MultiscaleLevels of Biological Information—Are Modified by Environmental Signals

DNA

RNA

Protein

Protein interactions and biomodules

Protein and gene networks

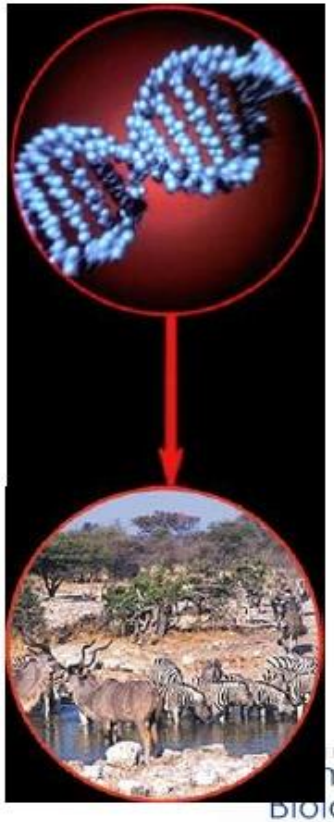
Cells

Organs

Individuals

Populations

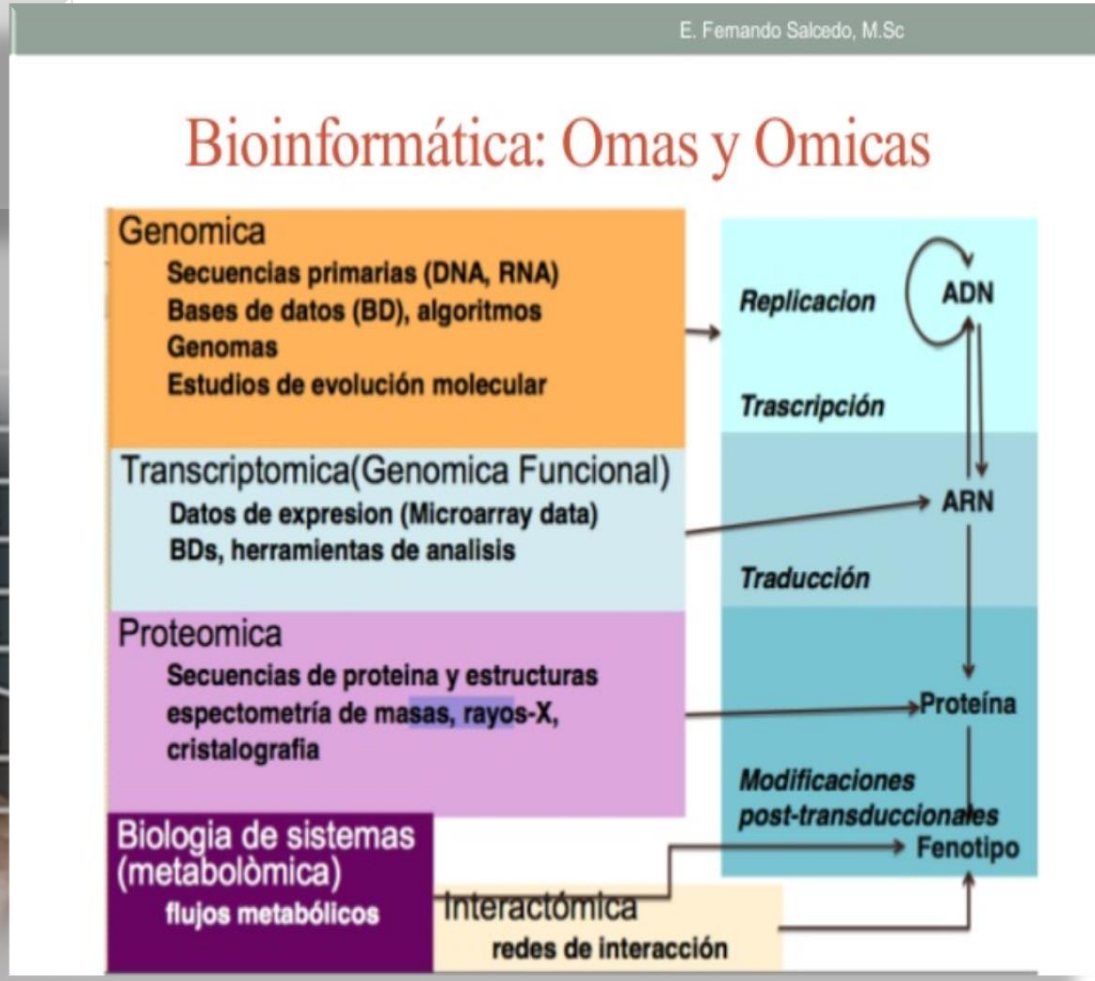
Ecologies



El Lenguaje *Omico*

INTELIGENCIA ARTIFICIAL EN MEDICINA: P.A.D

Plataformas y **A**lgoritmos de **D**atos..para la toma de decisiones



Nube de los cuidados de salud / Internet of Medical Things IoMT

INTELIGENCIA ARTIFICIAL Y BIG DATA

CIFAR
CANADIAN INSTITUTE FOR ADVANCED RESEARCH

EL PAIS 29-1-2018

CONVERSACIONES CON FUT

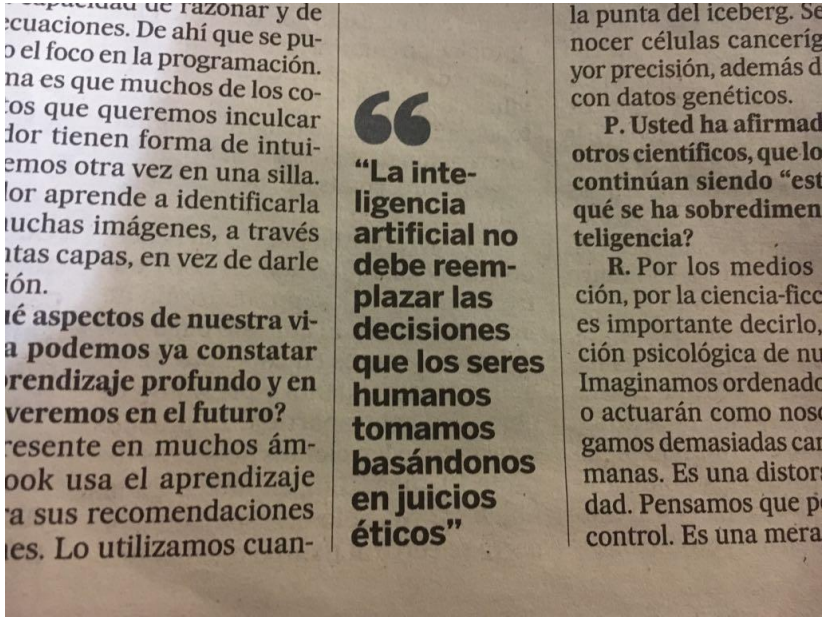
"Humanizamos demasiado a los ordenadores"

Yoshua Bengio

Experto en inteligencia artificial. Profesor de la Universidad de Montreal, está considerado *como una referencia mundial en el campo del aprendizaje intuitivo de las máquinas*

POR JAIME PORRAS FERREYRA

de neuronas. Decimos que es profundo porque los cálculos se efectúan a



ecuaciones. De ahí que se pu- o el foco en la programación. na es que muchos de los co- os que queremos inculcar dor tienen forma de intui- emos otra vez en una silla. lor aprende a identificarla uchas imágenes, a través ntas capas, en vez de darle ión.

ué aspectos de nuestra vi- a podemos ya constatar rendizaje profundo y en veremos en el futuro?

resente en muchos ám- ook usa el aprendizaje a sus recomendaciones es. Lo utilizamos cuan-

"La inteligencia artificial no debe reemplazar las decisiones que los seres humanos tomamos basándonos en juicios éticos"

la punta del iceberg. Se nocer células cancerig yor precisión, además d con datos genéticos.

P. Usted ha afirmad otros científicos, que lo continúan siendo "est qué se ha sobredimen teligencia?

R. Por los medios ción, por la ciencia-fic es importante decirlo, ción psicológica de nu Imaginamos ordenado o actuarán como nos gamos demasiadas ca manas. Es una distor dad. Pensamos que p control. Es una mera

Guest Editorial

Hyposkillia

Deficiency of Clinical Skills

Herbert L. Fred, MD, MACP

The medical profession today faces many problems. We march to bureaucratic drummers, we have lost our autonomy, our prestige has spiraled downward, and our professionalism is sagging.[1,2] But our woes don't end there.

© 2005 by the Texas Heart® Institute, Houston

Texas Heart Institute Journal

number or test result pertains. And by using so many sophisticated tests and procedures, they inevitably and unwittingly acquire a laboratory-oriented rather than a patient-oriented mindset. Contributing to this mindset, incidentally, are the health maintenance organizations that force physicians to care for a maximum *number* of patients, in a minimal *number* of minutes, for the lowest *number* of dollars.

selves, received. Most of today's medical teachers were trained after the early 1970s—the time when modern medical technology began to burgeon. High-*tech* medicine is all they've ever seen, all they know, and, therefore, all they can teach. Through no fault of their own, they have no real sense of high-touch medicine.

What do I mean by high-*touch* medicine? I mean medicine based on a carefully constructed medical history coupled with a pertinent physical examination and critical assessment of the information thus obtained. One then determines which

High tech low touch Medicine

“The new technomedicine paradigm”

nature medicine

The advent of the 'unpatients'

Nature Medicine **volume 2**, pages 622–624 (1996)

"Predictive diagnosis by molecular methods will change the scientific basis of prognostics. At the same time, it will change the ethical dimensions of the relation among patients, their doctors and other providers of care".

Albert R. Jonsen, Sharon J. Durfy, Wylie Burke & Arno G. Motulsky

bioethics.net
Where the World Finds Bioethics

Precision Medicine Has Imprecise Ethics

Posted on February 18, 2015 at 1:59 AM

In his State of the Union Address, President Barack Obama outlined his $215 million "Precision Medicine" initiative. The idea is to use knowledge of genetics, health threats, and individual responses.

This report forms the foundation of President Obama's proposed initiative. By using human genome sequencing technology, biomedical analysis tools, and the power of big data, a new era of precise medicine will be fostered. The short-term goals for the project are drug trials for targeted cancer treatments.

Craig Klugman, Ph.D. is a professor of bioethics and health humanities at DePaul University where he co-directs the Bioethics & Society minor program. Dr. Klugman also serves on the ethics committee at Northwestern University Hospital.

This approach presumes that disease is mainly managed and directed by genetics—it nearly eliminates the notion of environmental factors as causal factors of disease. It also assumes that health and disease can easily be mapped to genes. Given that many diseases are related to a number of genes, finding precise answers may be fairly difficult for many conditions.

From a bioethics standpoint, there may be great opportunities here. The Human Genome Project provided funding that created the subfield of genetic ethics (or genethics). The **NIH BRAIN program** has led to research and funding opportunities in neuroethics. Might **Precision Medicine** lead to a **"precision bioethics**" where we can help you make decisions based on your own genetic make up? The notion that this will be a boon for bioethics can be seen on the White House's own webpage about the project: "commitment to protecting privacy…solicit[ing] input from patient groups, **bioethicists**, privacy, and civil liberties advocates, technologists, and other experts in order to identify and address and legal and technical issues related to the privacy and security of data in the context of precision medicine."

Privacy is the main bioethical issue raised by the framers of this initiative. Given the record of companies and institutions with maintaining online privacy, I'm not sure we should yet be confident that privacy could be assured. And then consider that health information will be collected via mobile devices and transmitted wirelessly presenting additional opportunities for privacy breaches.

This could be the beginning of a new subfield of bioethics or just an overpriced promise that comes to nothing. While the name may be precise, the science and the ethics are anything but.

ONCOLOGIA DE PRECISON Y TOXICIDAD IMPRECISA

Annals of Oncology 28 (Supplement 4): i119–i142, 2017
doi:10.1093/annonc/mdx225

CLINICAL PRACTICE GUIDELINES

Management of toxicities from immunotherapy: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up†

Downloaded from https://academic.

Cardiovascular toxicities associated with immune checkpoint inhibitors: an observational, retrospective, pharmacovigilance study

Joe-Elie Salem, Ali Manouchehri, Melissa Moey, Bénédicte Lebrun-Vignes, Lisa Bastarache, Antoine Pariente, Aurélien Gobert, Jean-Philippe Spano, Justin M Balko, Marc P Bonaca, Dan M Roden, Douglas B Johnson, Javid J Moslehi

www.thelancet.com/oncology Vol 19 December 2018

Harvard Medical School
Bioethics Journal

Precision Medicine

What is the price of progress?

by Sarah Bates and Jeffrey Gruenglas

CENTER FOR BIOETHICS
HARVARD MEDICAL SCHOOL

Wharton
UNIVERSITY of PENNSYLVANIA

TECHNOLOGY
Does the Hype Exceed Reality for Precision Medicine?

Apr 27, 2017 Health Economics North America

American healthcare is expensive, and the political debate continues to rage about how best to pay for it and reduce costs, particularly for Obamacare. One sign of the financial stress: "Medical bills have become the single-largest cause of personal bankruptcy," notes a recent article in the Journal of the American Medical Association (JAMA).

PETER PISTERS, PRESIDENTE DEL MD ANDERSON CANCER CENTER

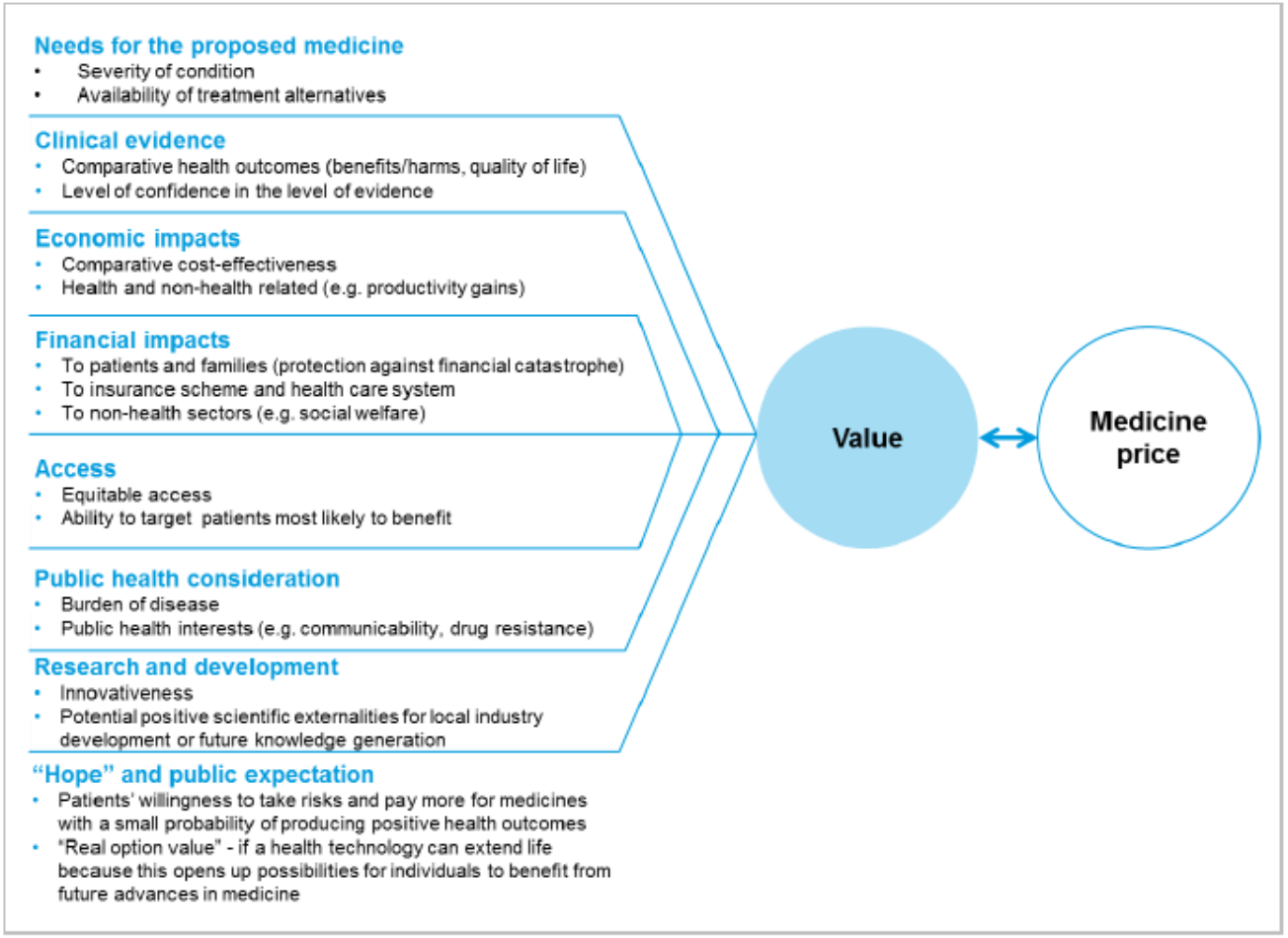
“No tiene sentido desarrollar medicamentos para el 1% más rico”

El director del MD Anderson afirma que la inmunoterapia no va a ser el bálsamo de Fierabrás de la oncología

Madrid 8 OCT 2018 - 16:43 CEST

Pricing of cancer medicines and its impacts

Fig. 3.8: Dimensions that may be considered for determining the value of medicines



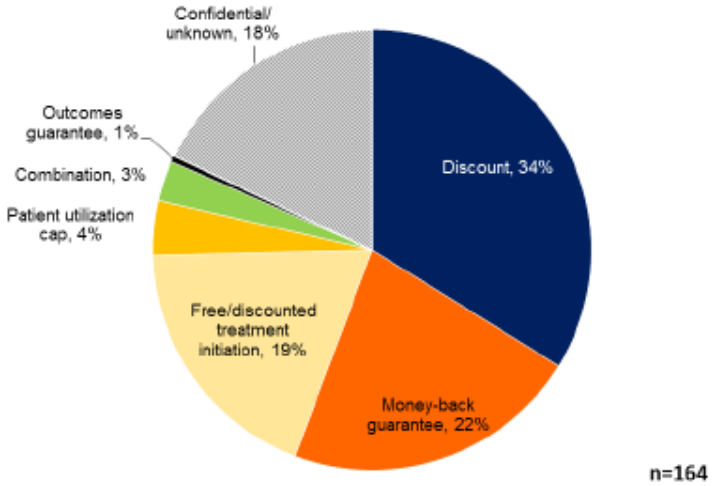
World Health Organization

© World Health Organization 2018

Another method for setting medicine prices indirectly is the use of a Managed Entry Agreement (MEA), which has been commonly used for newer cancer medicines (*192,193*). MEA has been defined as:

> an arrangement between a manufacturer and payer/provider that enables access to (coverage/reimbursement of) a health technology subject to specified conditions. These arrangements can use a variety of mechanisms to address uncertainty about the performance of technologies (e.g. clinical efficacy, efficacy and cost-effectiveness), and to manage the adoption of technologies in order to maximize their effective use, or limit their budget impact (p.79) (*194*).

Fig. 3.10: Types of MEA applied for cancer medicines in European countries



EL PAIS

SANIDAD
1-02-2019

La carrera de fármacos oncológicos dispara los precios la inequidad

La OMS alerta de una “evolución incontrolada y muy dispersa” de lo que se cobra por estos medicamentos

Mujeres yemeníes reciben su tratamiento contra el cáncer en un centro oncológico en Saná. KHALED ABDULLAH

Bioética. Justicia distributiva

	COSTE TRATAMIENTO AÑO	Importe (€)
PEMBROLIZUMAB	200 mg c/21dias. 18 ciclos	69.541
NIVOLUMAB	240 mg c/14 dias, 26 ciclos	52.348
CRIZOTINIB	250 mg c/12h X 12 meses	83.616
ALECTINIB	600 mg c/12, x12 meses	48.147
OSIMERTINIB	80mg c/24, 12 meses	52.408
PERTUZUMAB	840mg+420mg c21 días x12 meses	43.501

Teresa Calleja Chuclá

Servicio de Farmacia
Hospital Universitario de la Coruña
Tlf: 981-176003 ó 981-178000 ext- 292858

Clin Transl Oncol (2017) 19:341–356
DOI 10.1007/s12094-016-1535-8

RESEARCH ARTICLE

Equity, barriers and cancer disparities: study of the Spanish Society of Medical Oncology on the access to oncologic drugs in the Spanish Regions

J. Salvador[1,17] · J. A. Urtasun[2] · F. J. B. Duart[3] · R. García-Campelo[4] · R. G. Carbonero[5] · P. Lianes[6] · A. Llombart[7] · D. I. Casado[8] · J. M. Piera[9] · M. M. Mateu[10] · J. Puente[11] · F. Rivera[12] · C. A. Rodríguez[13] · J. A. Virizuela[14] · M. Martín[15] · P. Garrido[16]

EQUIDAD DE ACCESO Y EQUIDAD DE RESULTADOS

ESMO Open
Cancer Horizons

Check for updates

Precision oncology: separating the wheat from the chaff

Jordi Remon,[1] Rodrigo Dienstmann[2]

ABSTRACT

Precision oncology based on next-generation sequencing (NGS) test is growing in daily clinical practice. However, the real impact of this strategy in patients' outcome on a large scale remains uncertain. In this review, we summarise existing literature on this topic, limitations for broad NGS implementation, bottlenecks in genomic variant interpretation and the role of molecular tumour boards.

ESMO Open: first published

clinical practice. The balance between the cost of precision oncology strategy and patient benefit according to defined scales is also needed. Undoubtedly, today's era of precision medicine brings with it as many challenges as it does opportunities. It is our job to continuously advance this field of research.

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 JULY 12, 2018 VOL. 379 NO. 2

Adjuvant Chemotherapy Guided by a 21-Gene Expression Assay in Breast Cancer

breast cancer.[32] The results of our trial suggest that the 21-gene assay may identify up to 85% of women with early breast cancer who can be spared adjuvant chemotherapy, especially those who are older than 50 years of age and have a recurrence score of 25 or lower, as well as women 50 years of age or younger with a recurrence score of 15 or lower. Ongoing clinical tri-

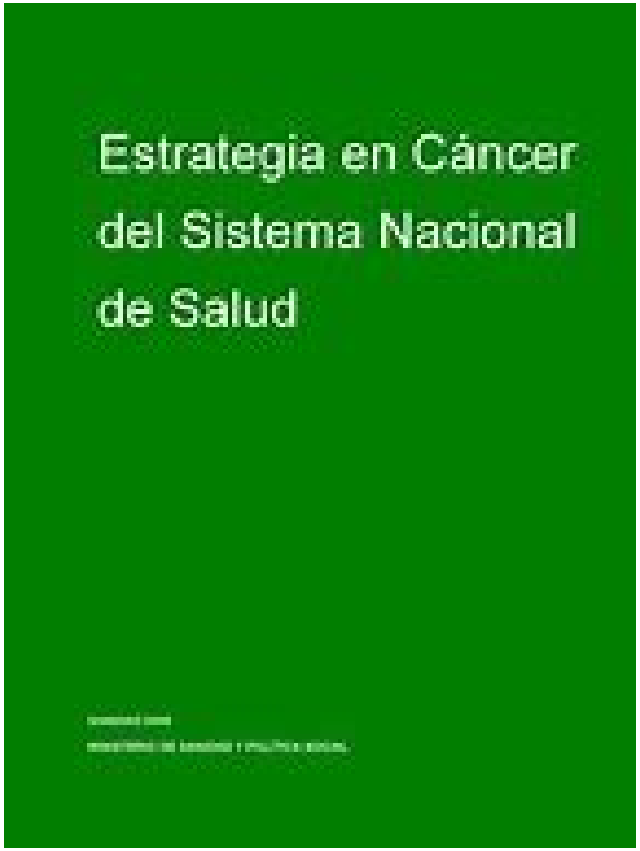
www.thelancet.com/oncology Vol 18 August 2017

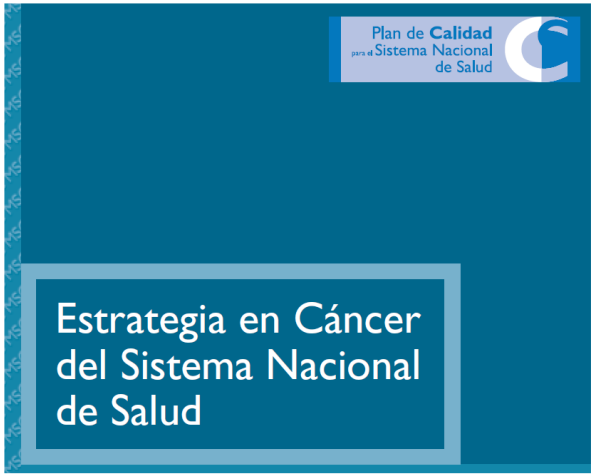
Calling time on the immunotherapy gold rush

At the 2008 annual meeting of the American Society of Clinical Oncology, results from an early phase trial of ipilimumab heralded a remarkable turnaround in fortunes for immunotherapy—an intervention previously considered to be a dead end, limited to underwhelming outcomes with interleukin-2. Results from the pivotal CA184-024 phase 3 trial on the same drug 3 years later proved beyond any doubt that targeting the immune validation is needed to ensure robust understanding and clinical correlation. The complexity of the immune system far exceeds our existing knowledge, and many of the combinatorial approaches being tested in trials are based on outmoded philosophies that were more appropriate for cytotoxic chemotherapies. Lessons can be learned from some of the EGFR and VEGF inhibitor trials, which have resulted in many failures because the biology wasn't

kasto80/iStock

A fundamental problem with the current speed of development is the lack of time and research invested into understanding the reasons why a trial failed or, for that matter, why it succeeded. Furthermore, because the reproducibility of preclinical studies and their translatable findings to the clinic are often overestimated, more thorough translational research with independent validation is needed to ensure robust understanding and clinical correlation





¿Es Oncología de precision? (Oncologia Invisible)

2.3. ASISTENCIA ADULTOS

2.3.1. Objetivos

Objetivo 11

El tiempo transcurrido desde la decisión terapéutica hasta el inicio efectivo del tratamiento se ajustará progresivamente a las siguientes recomendaciones:

— Tratamiento quirúrgico: recomendable 2 semanas.

— Quimioterapia: recomendable una semana.

— Radioterapia: recomendable 4 semanas (incluyendo el proceso de planificación).

¿Hay una plataforma técnica única y publica para tener un acceso equitativo y homogéneo a los test genéticos y genómicos que permitan plantear terapias?

Estas tecnologías son complejas y solo un centro de referencia puede ofrecer con equidad el acceso a las mismas a todos los pacientes gallegos

Dr. Fernando Domínguez

CIMUS & Fundación Publica Gallega de Medicina Genómica
Universidad de Santiago de Compostela

¡GRACIAS!