Terapia antivirale e farmacogenomica

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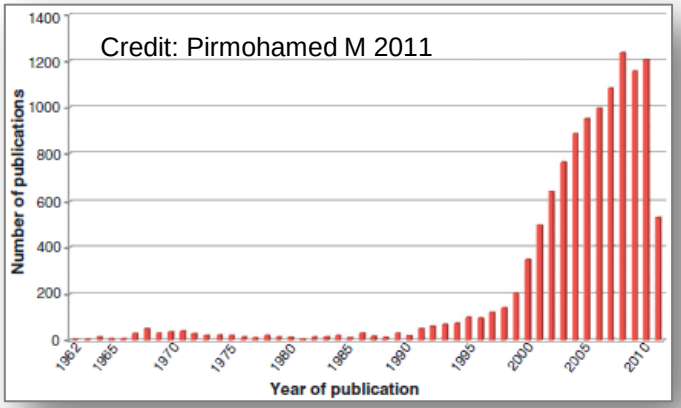
Pharmacogenomics

[…or Pharmacogenetics?]



- Arno G. Motulski. Drug reactions enzymes, and biochemical genetics. *J Am Med Assoc* 1957

  "… drug reactions … may be considered pertinent models for demonstrating the interaction of heredity and environment in the pathogenesis of disease"

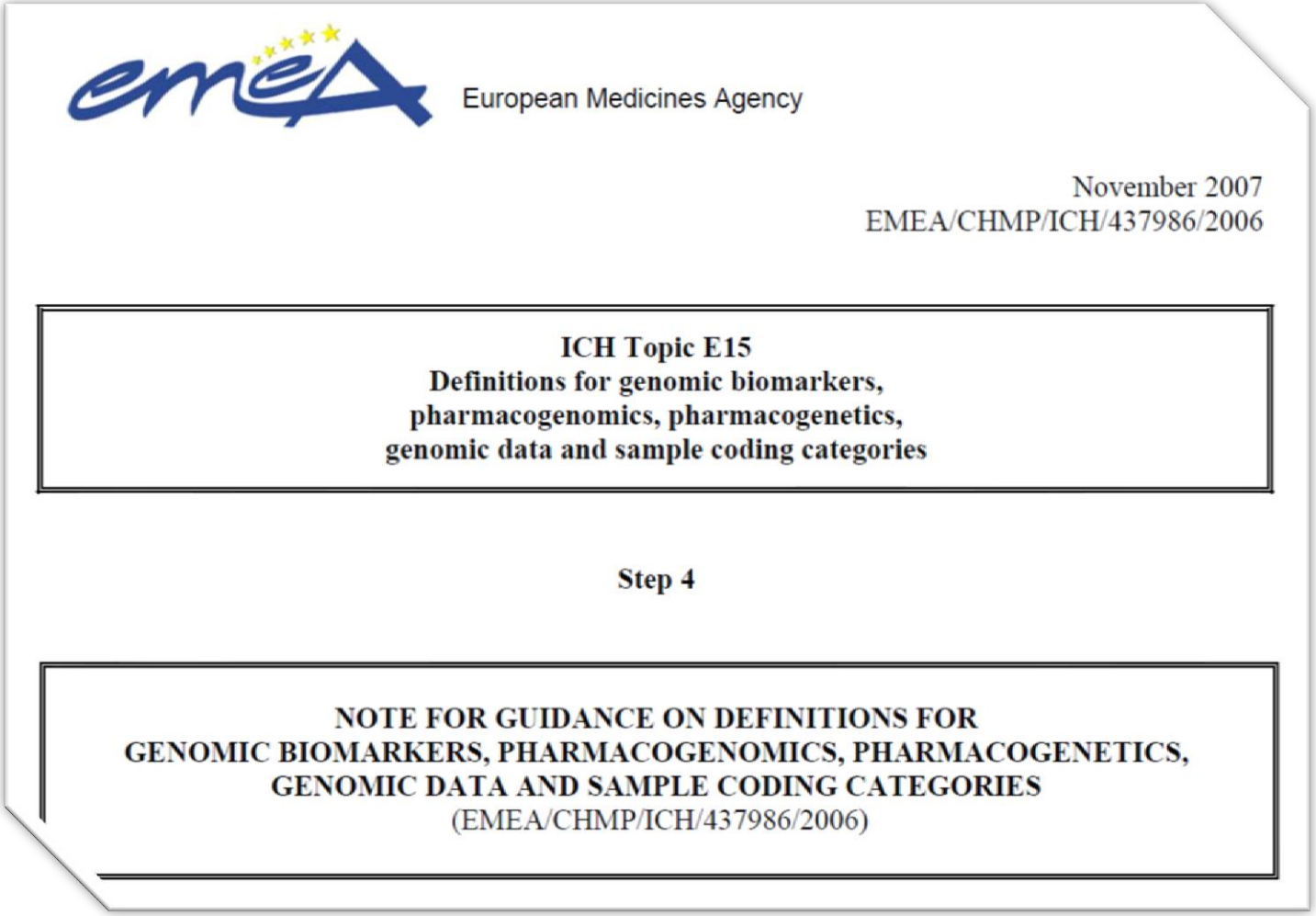
- Friedrich Vogel. Moderne problem der humangenetik. *Ergeb Inn Med U Kinderheilk*. 1959

  "Pharmacogenetics: the study of the role of genetics in drug response"

- Cordes W. Experiences with plasmochin in malaria. 1926
- Pitagora. VI sec. a.C.

  "meglio la morte che attraversare un campo di fave"

Definitions



European Medicines Agency

November 2007
EMEA/CHMP/ICH/437986/2006

ICH Topic E15
Definitions for genomic biomarkers, pharmacogenomics, pharmacogenetics, genomic data and sample coding categories

Step 4

NOTE FOR GUIDANCE ON DEFINITIONS FOR GENOMIC BIOMARKERS, PHARMACOGENOMICS, PHARMACOGENETICS, GENOMIC DATA AND SAMPLE CODING CATEGORIES
(EMEA/CHMP/ICH/437986/2006)

Definitions

European Medicines Agency

PHARMACOGENOMICS AND PHARMACOGENETICS

Definitions

PHARMACOGENOMICS

Pharmacogenomics (PGx) is defined as:

The study of variations of DNA and RNA characteristics as related to drug response.

PHARMACOGENETICS

Pharmacogenetics (PGt) is a subset of pharmacogenomics (PGx) and is defined as:

The study of variations in DNA sequence as related to drug response.

1. The term *drug* should be considered synonymous with investigational (medicinal) product, medicinal product, medicine and pharmaceutical product (including vaccines and other biological products).
2. PGx and PGt are applicable to activities such as drug discovery, drug development, and clinical practice.
3. Drug response includes the processes of drug absorption and disposition (e.g. pharmacokinetics, (PK)), and drug effects (e.g. pharmacodynamics (PD), drug efficacy and adverse effects of drugs).

Presidenza del Consiglio dei Ministri

CONFERENZA PERMANENTE PER I RAPPORTI
TRA LO STATO, LE REGIONI E LE PROVINCE AUTONOME
DI TRENTO E BOLZANO

Intesa, ai sensi dell'articolo 8, comma 6, della legge 5 giugno 2003, n. 131, tra il Governo, le Regioni e le Province autonome di Trento e di Bolzano sul documento recante: "Linee di indirizzo sulla genomica in sanità pubblica".

Rep. Atti n. 62/CSR del 13 marzo 2013

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Definizioni

Per genomica in sanità Pubblica (GSP), traduzione dell'espressione Public Health Genomics, si intendono le politiche per trasferire in maniera responsabile, efficace ed efficiente in sanità pubblica tutte le conoscenze e le tecnologie utili all'analisi del genoma per il miglioramento della salute della popolazione.

Ambiti di applicazione

Nell'ambito del presente documento, la GSP riguarda sia i test diagnostici predittivi di malattia, sia la farmacogenomica, nonché altri aspetti di rilevante importanza sistemica che si rende necessario considerare per attuare lo scopo di "governo della genomica".

US CDC initiative

CDC Home

Centers for Disease Control and Prevention
CDC 24/7: Saving Lives. Protecting People.™

SEARCH

A-Z Index A B C D E F G H I J K L M N O P Q R S T U V W X Y Z #

Genomics and Health Impact Blog

A blog devoted to discussing best practices and questions about the role of genomics in disease prevention, health promotion and healthcare.

Public Health Genomics > Genomics and Health Impact Blog

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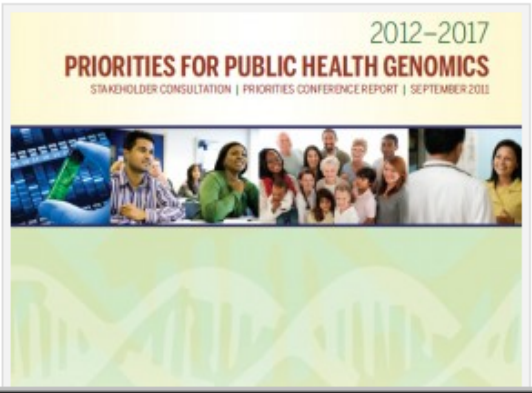
Beyond Base Pairs to Bedside: A Community Consultation on Closing the Gap between Genomic Discoveries and the Public's Health

Categories: genomics

December 1st, 2011 12:35 pm ET - Muin J Khoury, Director, Office of Public Health Genomics, Centers for Disease Control and Prevention

In June 2011, the CDC Office of Public Health Genomics launched a community wide consultation process to develop priorities for the field of public health genomics in the next 5 years. This process was initiated as part of strategic visioning for integrating the emerging tools of genomics into practice and assuring the success of these new tools in improving population health. The process was conducted at a time of a widening gap between the rapid scientific advances in genomics and their impact on improving population health. The University of



Blog Categories

- colorectal cancer
- EGAPP
- epidemiology
- evidence-based medicine
- family history
- genetic counseling
- genomics
- heart disease
- investigation
- obesity
- personal genomics
- personalized medicine

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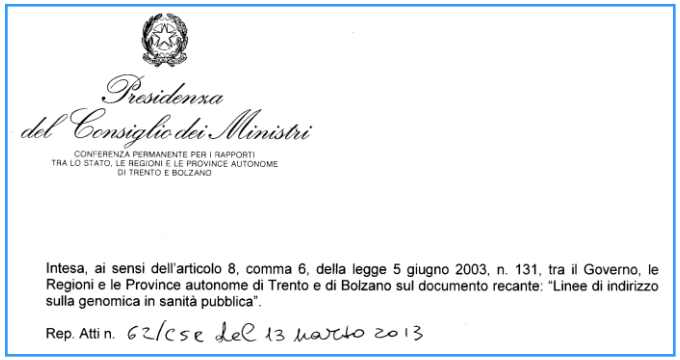

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Rep. Atti n. 62/CSE del 13 marzo 2013

2.1 Raccolta e diffusione delle prove di efficacia e di costo/beneficio per le principali tecnologie nel campo della prevenzione e della farmacogenomica.

Premessa. Al momento, uno dei limiti maggiori a una diffusione ampia della genomica nella Sanità pubblica è la mancanza di un quadro omogeneo di evidenze scientifiche, e, più specificamente, di valutazioni complete e sistematiche delle nuove tecnologie genomiche (prevalentemente in forma di *health technology assessment*, HTA). Tale difficoltà non riguarda solo il mero campo delle evidenze scientifiche ma anche gli assetti di sistema e le regole fondamentali rispetto alle quali valorizzare e sinergizzare le capacità, gli interessi e le risorse disponibili e già, in qualche modo, attive nell'ambito del sistema sanitario. La necessità di dotare il nostro paese di una "infrastruttura" di raccolta e analisi delle evidenze scientifiche è stata identificata anche dal PNP 2010-12 ed inclusa tra le azioni centrali prioritarie (DM 4/8/11) e ha portato alla definizione di un network di centri esperti in Evidence based Prevention (EBP) a supporto del Ministero e delle Regioni per la pianificazione/ programmazione / progettazione in prevenzione.

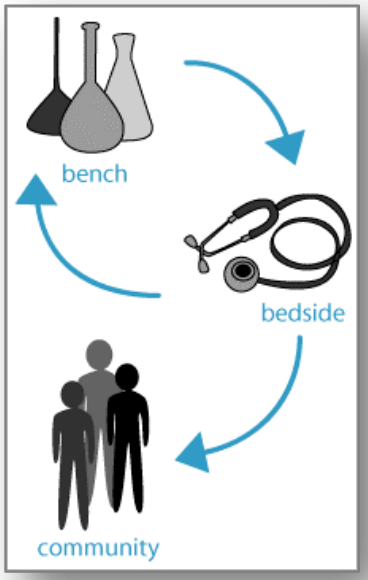
Health Technology Assessment - HTA

A multi-disciplinary process for the assessment of health technologies,

born to fill the gap between the limited resources of the national health system

and the growing demand for innovative technology.

Battista RN, Hodge Mj, 1999



Approccio multidisciplinare

finalizzato a supportare scientificamente i vari livelli decisionali

in ordine all'introduzione, cioè al finanziamento, delle nuove tecnologie.*

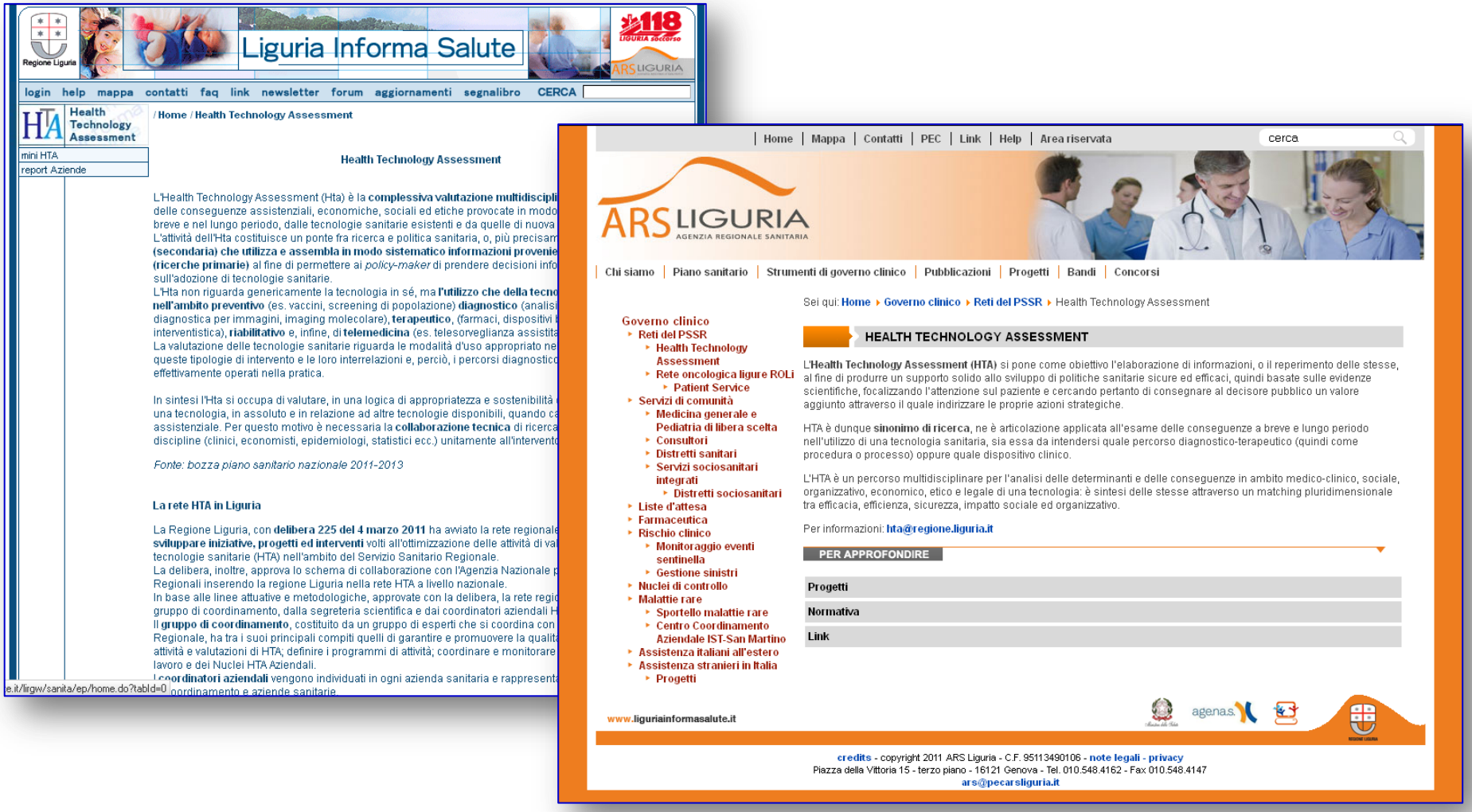
AGENAS

*Tecnologia sanitaria:

insieme dei mezzi tecnici procedurali messi a disposizione dalla scienza e dalla ricerca per gli operatori sanitari per la loro attività di prevenzione, diagnosi, cura e riabilitazione.

La Rete Ligure HTA

- obiettivo: introdurre l'HTA nel Sistema Sanitario Regionale, quale componente fondamentale dei processi decisionali



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Battista RN, Hodge Mj, 1999

I NOVE DOMINI DEL MODELLO HTA CORE (adattata da Lampe K et al., 2009) [16]
1. Il problema della salute e l'uso attuale della tecnologia in esame
2. Descrizione e caratteristiche della tecnologia
3. Sicurezza
4. Efficacia (compresa l'accuratezza)
5. Costi e valutazione economica
6. Analisi etica
7. Aspetti organizzativi
8. Aspetti sociali
9. Aspetti legali

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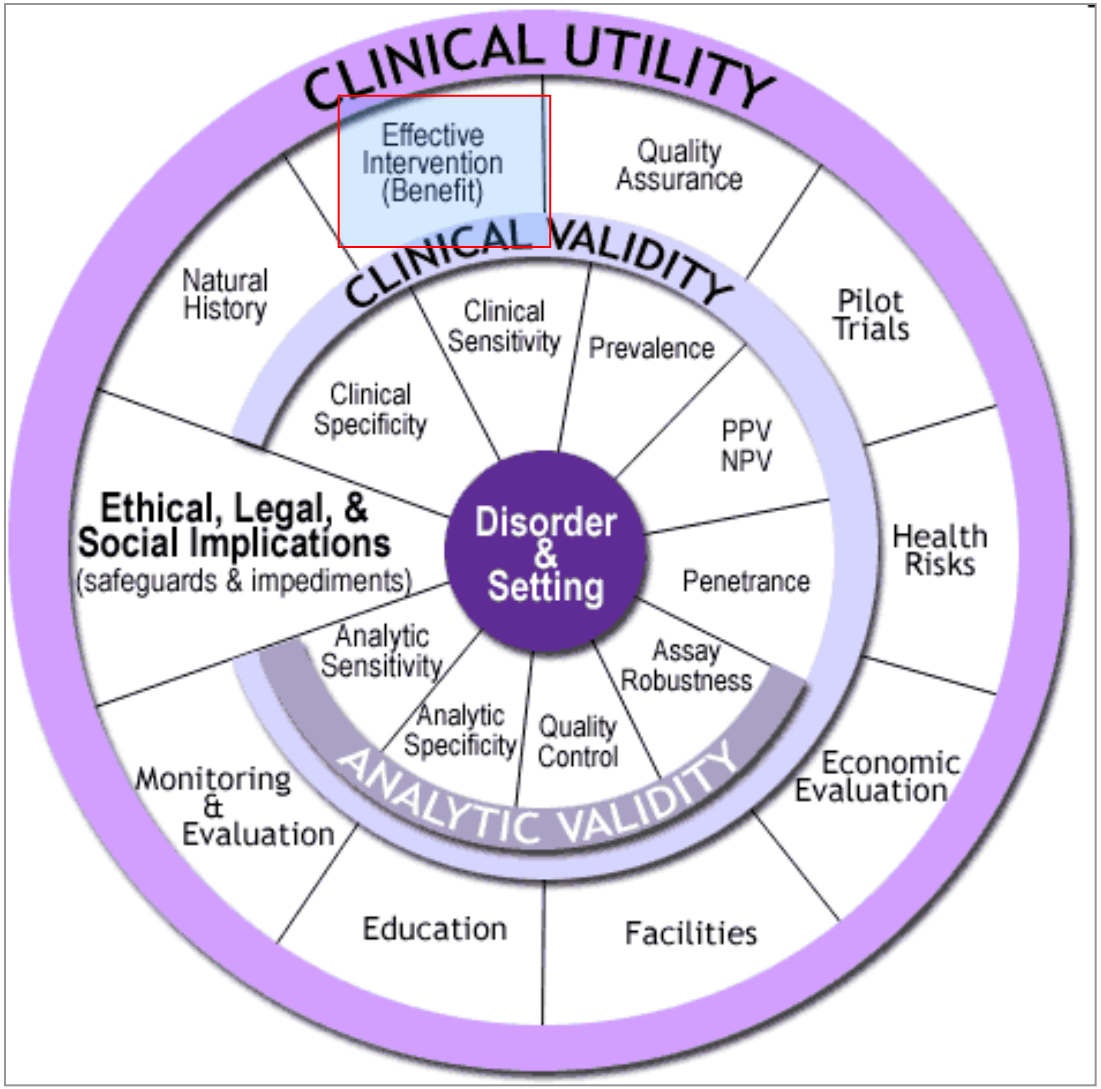
HTA & Genetics



Analytic validity

Clinical validity

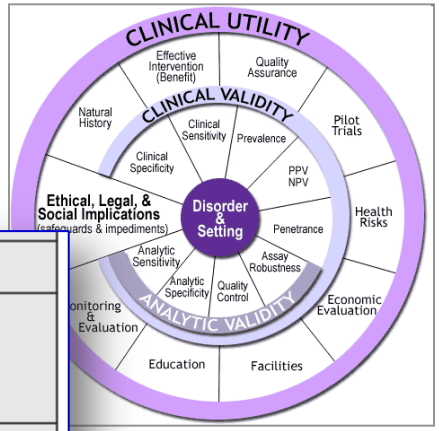
Clinical utility

Ethical, legal and social implications

The ACCE model

Table 2: A Framework for Genetic Test Evaluation

Domain	Specific Element	Focus of evaluation	
Pre-evaluation definition	Clinical Utility		
	Test Purpose	*Legitimacy*	Conformity to the social preferences expressed in ethical principles, values, norms, mores, laws and regulations
Assay		*Efficacy*	Potential of test and associated services to deliver health benefit
		Effectiveness	Actual delivery of health benefit in routine clinical setting
		Appropriateness	Expected health benefit exceeds expected negative cons quences by a sufficiently wide margin that the test is worth doing
Clinical Validity	Feasibility of Test Delivery	*Acceptability*	Conformity to the wishes, desires, and expectations of patients and their families
		Economic *Efficiency*	Ability to lower the costs of care without diminishing benefits
		Optimality	Balancing improvements in health against costs of improvements
		Equity	Just and fair distribution of health care and its benefits among members of the population.



Analytic validity
Clinical validity
Clinical utility
ELSI


MCHUMOR.COM by T. McCracken
"Off hand, I'd say you're suffering from an arrow through your head, but just to play it safe, I'm ordering a bunch of tests."

Esempio:1

APPLICAZIONI CLINICHE DELLA FARMACOGENOMICA: TERAPIA ANTIVIRALE DELL'INFEZIONE DA HCV

Farmacogenetica della terapia per HCV

Genotipo di IL28B

Genetic variation in *IL28B* predicts hepatitis C treatment-induced viral clearance

Dongliang Ge[1], Jacques Fellay[1], Alexander J. Thompson[2], Jason S. Simon[3], Kevin V. Shianna[1], Thomas J. Urban[1], Erin L. Heinzen[1], Ping Qiu[3], Arthur H. Bertelsen[3], Andrew J. Muir[2], Mark Sulkowski[4], John G. McHutchison[2] & David B. Goldstein[1]

GENOMIC BIOMARKER

Definition

A genomic biomarker is defined as follows:

A measurable DNA and/or RNA characteristic that is an indicator of normal biologic processes, pathogenic processes, and/or response to therapeutic or other interventions.

Additional Information

1. A genomic biomarker could, for example, be a measurement of :

- The expression of a gene
- The function of a gene
- The regulation of a gene

2. A genomic biomarker can consist of one or more deoxyribonucleic acid (DNA) and/or ribonucleic acid (RNA) characteristics.

3 DNA characteristics include, but are not limited to:

- Single nucleotide polymorphisms (SNPs)
- Variability of short sequence repeats
- Haplotypes
- DNA modifications, e.g. methylation
- Deletions or insertions of (a) single nucleotide(s)
- Copy number variations
- Cytogenetic rearrangements, e.g. translocations, duplications, deletions or inversions

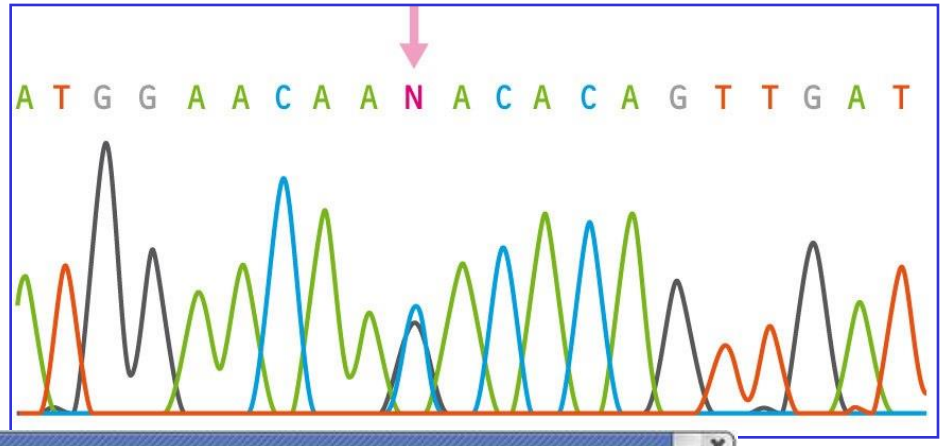
4. RNA characteristics include, but are not limited to:

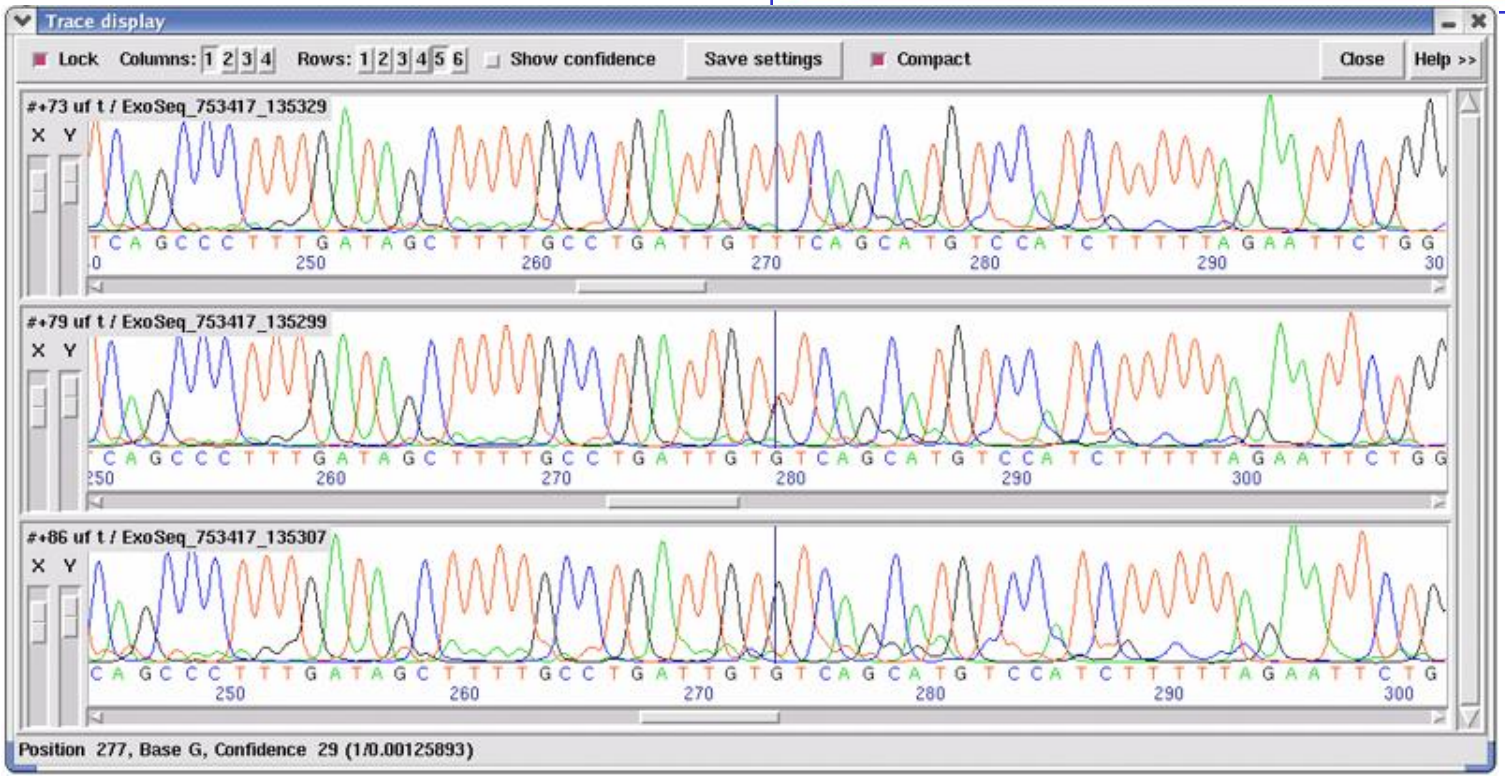
- RNA sequences
- RNA expression levels

RNA processing, e.g. splicing and editing
microRNA levels

DNA markers: Single Nucleotide Polymorphisms

- ✓ > 50 milioni identificati nell'intero genoma
- ✓ > 7 milioni all'interno di geni
- ✓ Dati disponibili in databases pubblici
- ✓ Tecnologia di tipizzazione accessibile





Farmacogenetica della terapia per HCV

Genotipo di IL28B

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Dongliang Ge[1], Jacques Fellay[1], Alexander J. Tho
Erin L. Heinzen[1], Ping Qiu[3], Arthur H. Bertelsen[3],
& David B. Goldstein[1]

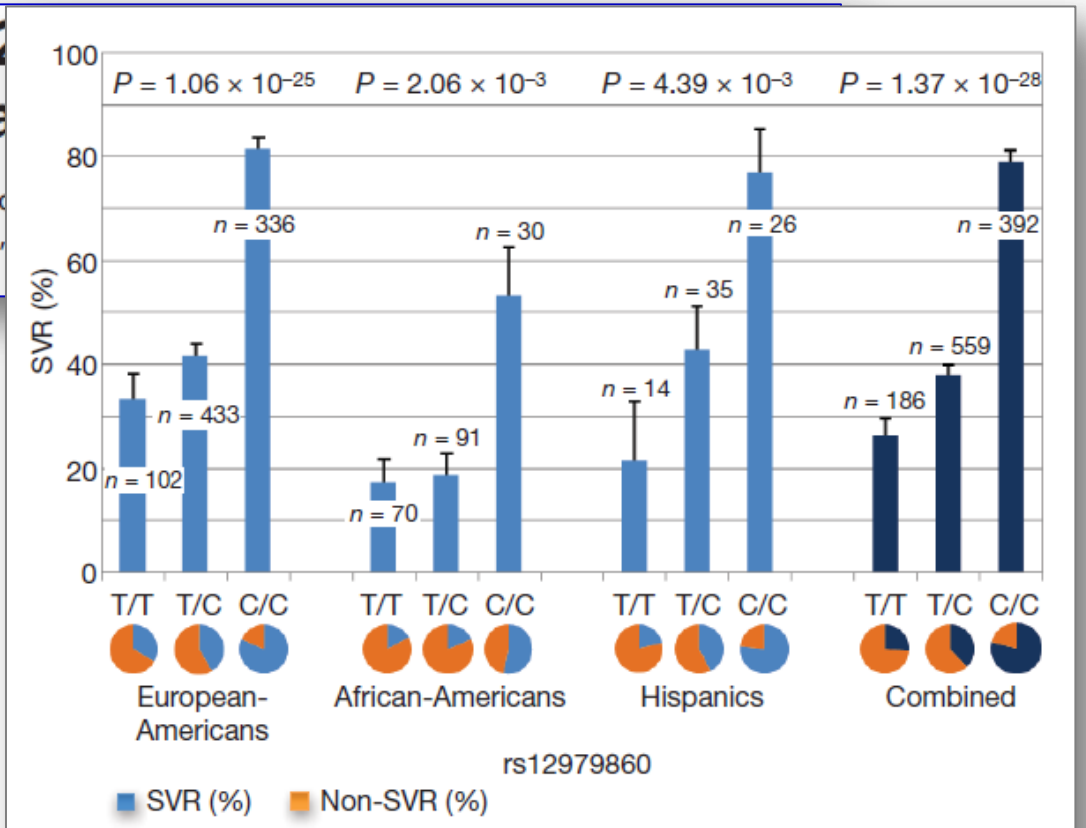


Figure 1 | Percentage of SVR by genotypes of rs12979860. Data are percentages + s.e.m.

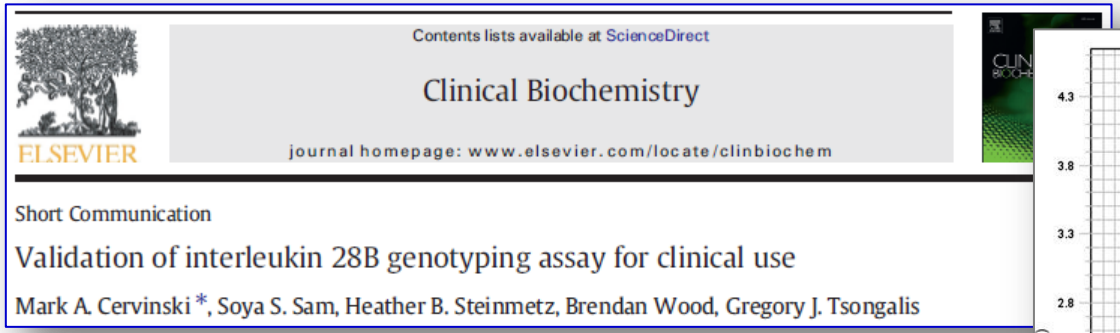
HTA & Genetics - HCV pharmacogenetics: IL28B genotyping

Analytic validity

The ability of a test to detect the measure of interest:

the genetic variant(s) that the test is aiming to identify

- real-time PCR assay of the **rs12979860** single nucleotide polymorphism
- test procedure is robust and was reported to be readily implemented in the workflow of molecular pathology laboratories



Contents lists available at ScienceDirect

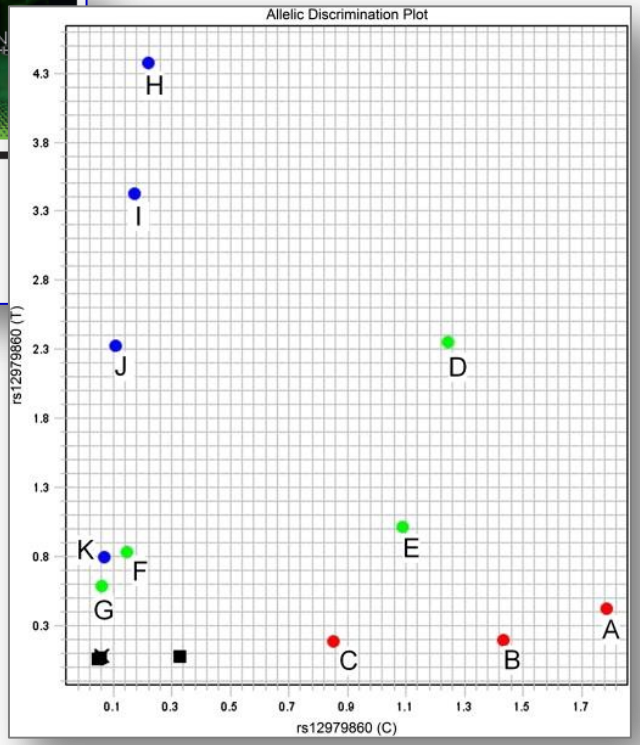
Clinical Biochemistry

journal homepage: www.elsevier.com/locate/clinbiochem

Short Communication

Validation of interleukin 28B genotyping assay for clinical use

Mark A. Cervinski *, Soya S. Sam, Heather B. Steinmetz, Brendan Wood, Gregory J. Tsongalis



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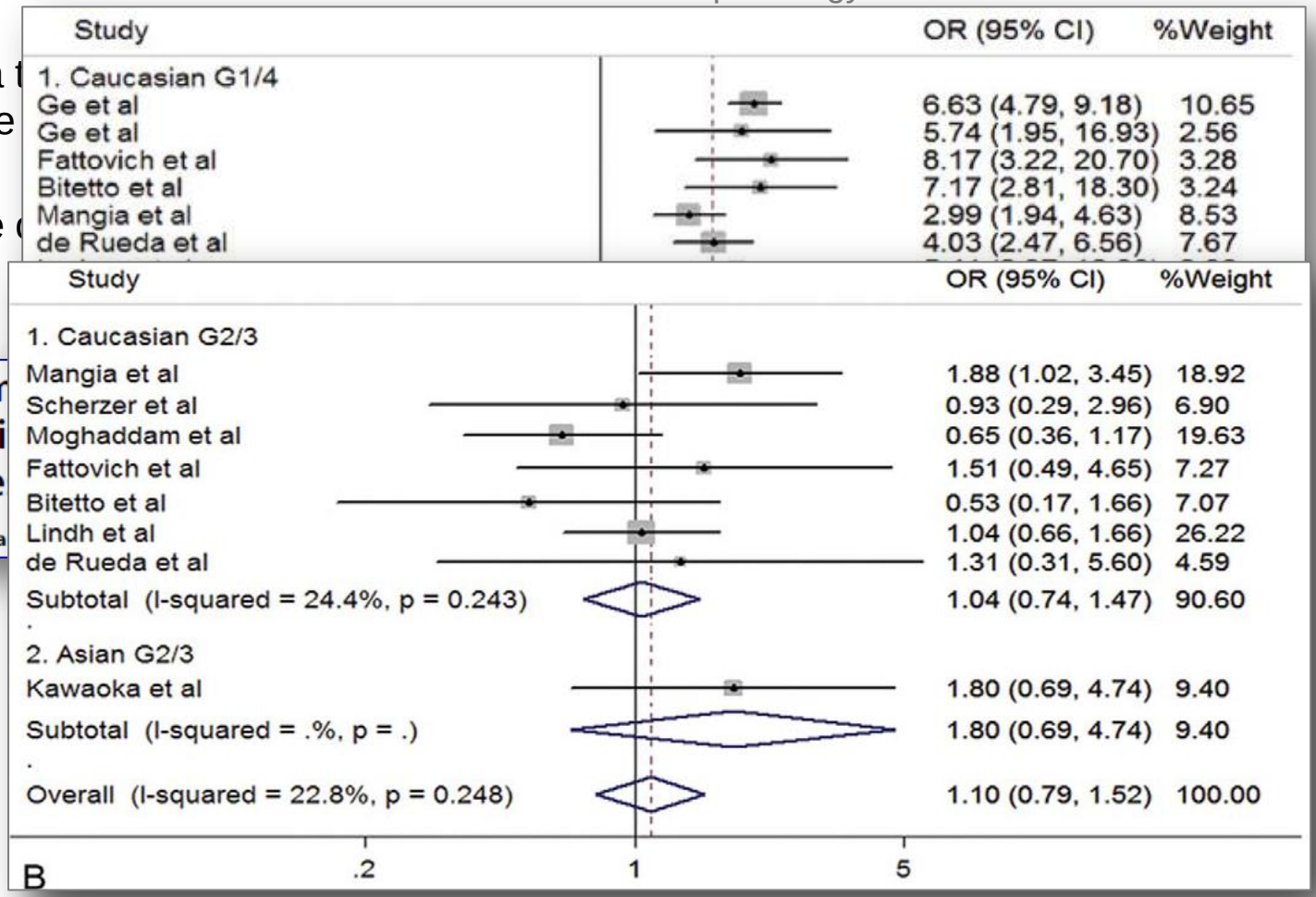
Clinical validity

The likelihood that a t
correctly predicts the
interest:

presence of disease
treatment

Test of IL28B Polym
Patients Treated wi
HCV Genotypes: Re

Zhifang Jia[19], Yanhua Ding[29], Suya



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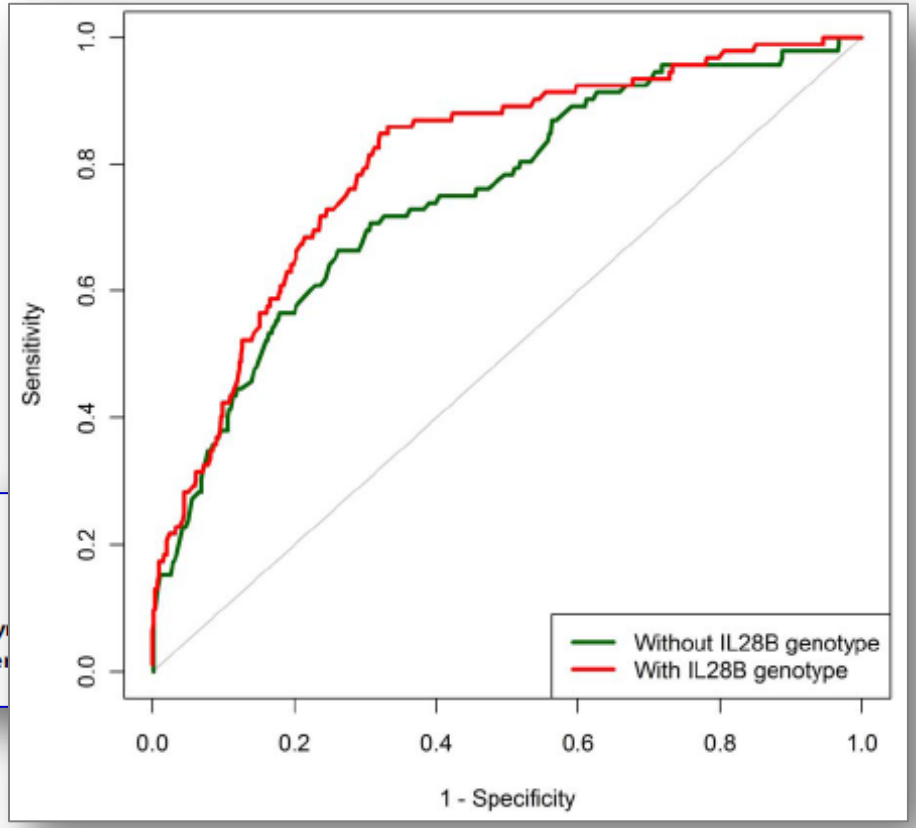
Clinical validity

The likelihood that a test result correctly predicts the phenotype of interest:

presence of disease or response to treatment

An *IL28B* Genotype-Based Clinical Prediction
Treatment of Chronic Hepatitis C

Thomas R. O'Brien[1]*, James E. Everhart[2], Timothy R. Morgan[3,4], Anna S. Lok[5], Ray
Yongwu Shao[7], Mitchell L. Shiffman[8], Myhanh Dotrang[9], John J. Sninsky[10], Herbe
Ruth M. Pfeiffer[1], and the HALT-C Trial Group



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- The genotype of the IL28B rs12979860 polymorphism is a valid predictor of **SVR** in **previously untreated patients**
- Carriers of the CC genotype show a more favourable response rate
- Genotyping of other polymorphisms is not suggested
- Association demonstrated for **HCV genotype 1 and 4**, not confirmed in genotype 2 and 3
- *The association with other endpoints was not extensively studied.*

Clinical Pharmacogenetics Implementation Consortium (CPIC) Guidelines for *IFNL3* (*IL28B*) Genotype and PEG Interferon-α–Based Regimens

AJ Muir[1], L Gong[2], SG Johnson[3,4], MTM Lee[5,6,7], MS Williams[8], TE Klein[2], KE Caudle[9] and DR Nelson[10]

Description	Genotype definitions	Genotype rs12979860
Increased likelihood of response (higher SVR rate) to PEG-IFN-α and RBV therapy as compared with patients with unfavorable response genotype	An individual carrying two favorable response alleles	CC
Decreased likelihood of response (lower SVR rate) to PEG-IFN-α and RBV therapy as compared with patients with favorable response genotype	An individual carrying at least one unfavorable response allele	CT or TT

HTA & Genetics - HCV pharmacogenetics: IL28B genotyping

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Clinical utility

The degree to which a test result guides clinical management and improves patient outcomes

- No evidence was found that a regimen guided by IL28B genotyping is associated with a more favourable clinical outcome with respect to standard protocol
- No clinical measure was consistently evaluated in primary studies; occurrence of adverse events was not explored
- Clinical pathways incorporating the pharmacogenetic test of IL28B were not formally evaluated

Esempio:2

APPLICAZIONI CLINICHE DELLA FARMACOGENOMICA: TERAPIA ANTIVIRALE DELL'INFEZIONE DA HIV

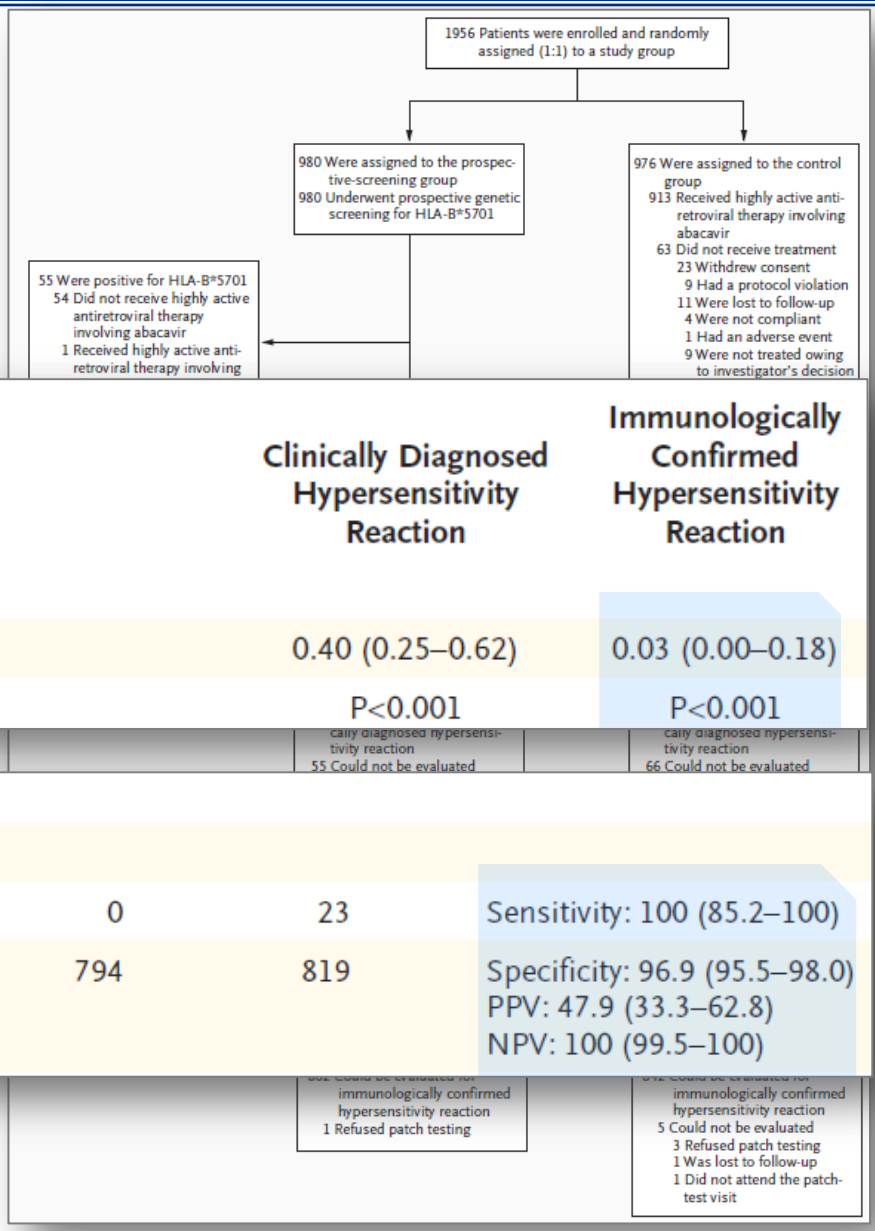
HTA & Genetics - HIV pharmacogenetics: HLA genotyping

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

HLA-B*5701 Screening for Hypersensitivity to Abacavir

Simon Mallal, M.B., B.S., Elizabeth Phill
Jean-Michel Molina, M.D., Cassy Workm
Eva Jägel-Guedes, M.D., Sorin Rug
Juan Flores Cid, M.D., Phillip Hay, M.
Sara Hughes, M.Sc., Arlene Hughe
Nicholas Fitch, Ph.D., Daren Thorborn, Pl
for the PREDICT-1



Covariate	Clinically Diagnosed Hypersensitivity Reaction	Immunologically Confirmed Hypersensitivity Reaction
Prospective screening, vs. control		
Odds ratio (95% CI)	0.40 (0.25–0.62)	0.03 (0.00–0.18)
P value	P<0.001	P<0.001

Immunologically confirmed hypersensitivity reaction				
Total population that could be evaluated				
Hypersensitivity reaction	23	0	23	Sensitivity: 100 (85.2–100)
No hypersensitivity reaction	25	794	819	Specificity: 96.9 (95.5–98.0) PPV: 47.9 (33.3–62.8) NPV: 100 (99.5–100)

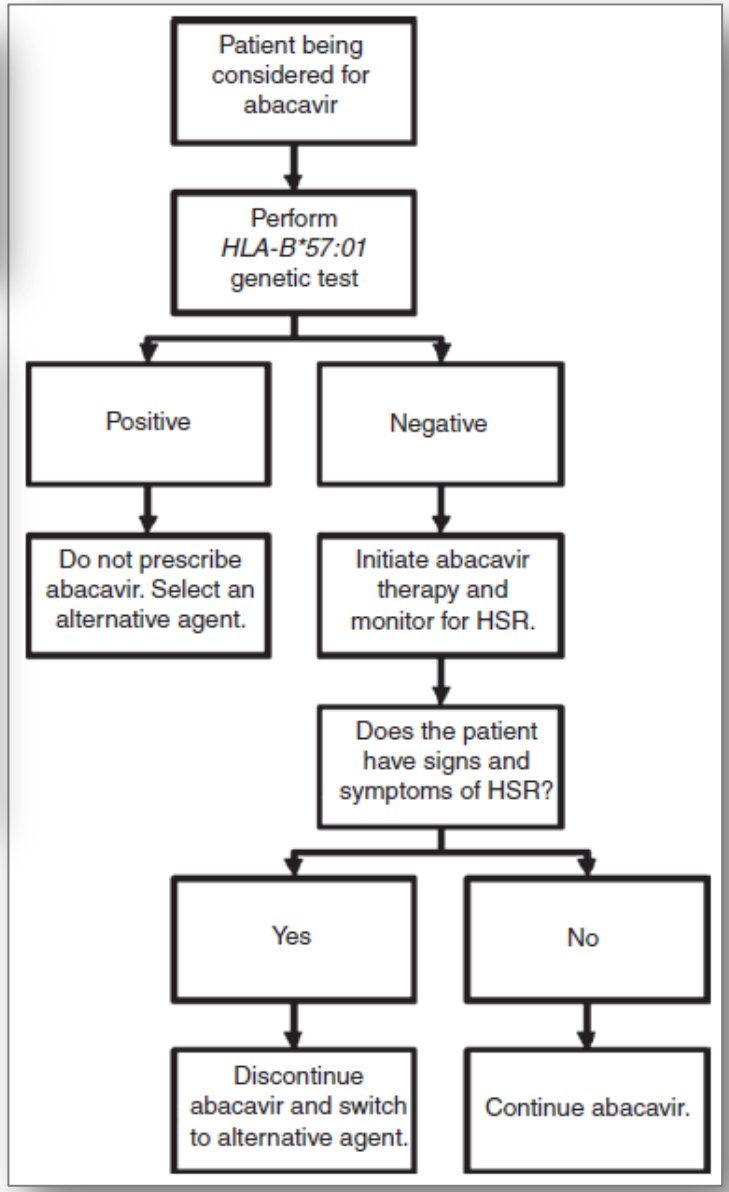
HTA & Genetics - HIV pharmacogenetics: HLA genotyping

Clinical Pharmacogenetics Implementation Consortium Guidelines for *HLA-B* Genotype and Abacavir Dosing

MA Martin[1], TE Klein[2], BJ Dong[3], M Pirmohamed[4], DW Haas[5–7] and DL Kroetz[1]

Table 2 Recommended therapeutic use of abacavir in relation to *HLA-B* genotype

Genotype	Implications for phenotypic measures	Recommendations for abacavir	Classification of recommendations[a]
Noncarrier of *HLA-B*57:01*	Low or reduced risk of abacavir hypersensitivity	Use abacavir per standard dosing guidelines	Strong
Carrier of *HLA-B*57:01*	Significantly increased risk of abacavir hypersensitivity	Abacavir is not recommended	Strong



HTA & Genetics - HCV pharmacogenetics: IL28B genotyping

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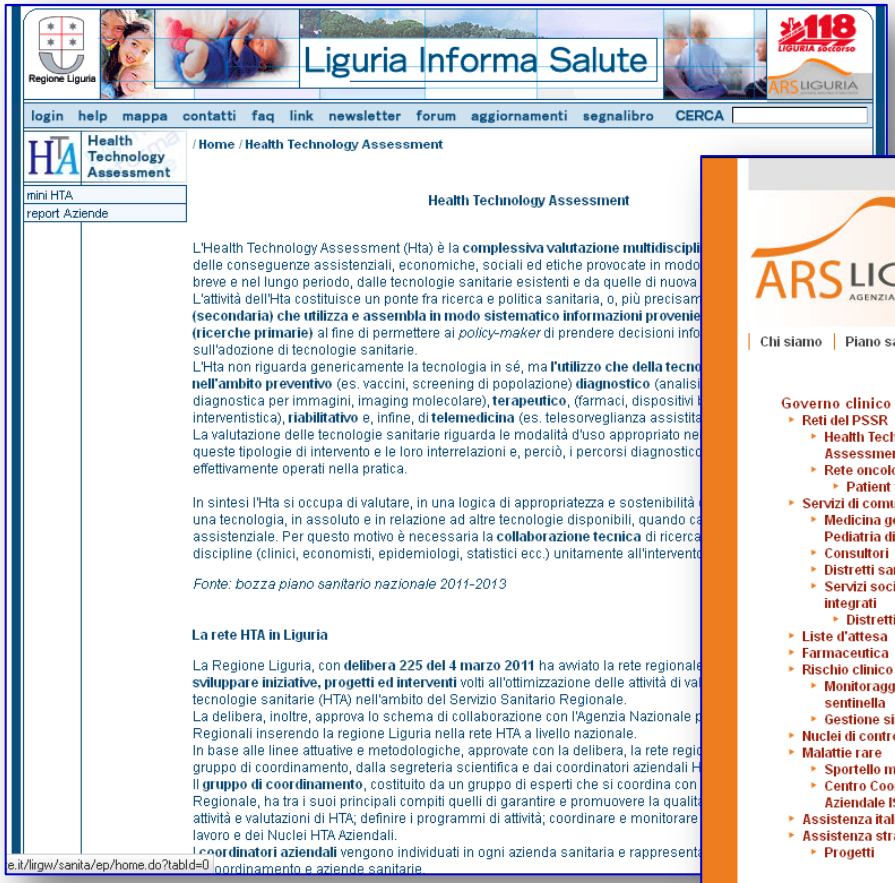
- No clinical measure was consistently evaluated in primary studies; occurrence of adverse events was not explored
- Clinical pathways incorporating the pharmacogenetic test of IL28B were not formally evaluated

Impact? Context?

- can the pharmacogenetic-based algorithm be implemented in the local health system?
- are the emerging costs sustainable for the health system?
- …

La Rete Ligure HTA

- obiettivo: introdurre l'HTA nel Sistema Sanitario Regionale, quale componente fondamentale dei processi decisionali



HTA & Genetics - HCV pharmacogenetics: IL28B genotyping

Analytic validity

The ability of a test to detect the measure of interest: the genetic variant(s) that the test is aiming to identify

- real-time PCR assay of the **rs12979860** single nucleotide polymorphism
- **test procedure is robust and readily implemented in the workflow of molecular pathology laboratories**

Clinical validity

The likelihood that a test result correctly predicts the phenotype of interest: presence of disease or response to treatment:

- **The genotype of the IL28B rs12979860 polymorphism is a valid predictor of SVR in previously untreated patients**
- Carriers of the CC genotype show a more favourable response rate
- Genotyping of other polymorphisms is not suggested
- Association demonstrated for **HCV genotype 1** and 4, not confirmed in genotype 2 and 3.
- The association with other endpoints was not extensively studied

Clinical utility

The degree to which a test result guides clinical management and improves patient outcomes

- **No evidence was found that a regimen guided by IL28B genotyping is associated with a more favourable clinical outcome with respect to standard protocol**
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Health Technology Assessment

A multi-disciplinary process for the assessment of health technologies, aimed at filling the gap between the limited resources and the demand for innovative technology

- 3 labs offer pharmacogenetic IL28B testing: 550 test/year. It should further evaluated:
  - to what extent efficiency can be improved by gathering samples in one laboratory
  - to what extent laboratories guarantee a timely response

HTA & Genetics - HCV pharmacogenetics: IL28B genotyping

La Rete Ligure HTA

Rete Ligure HTA

Brief HTA report:

Genotipo di polimorfismi del gene dell'IL28B (*IFNL3*): utilizzo clinico in pazienti con HCV

Redazione a cura di:
Francesco Cardinale, Emilio Di Maria, Gaddo Flego
per il Gruppo di Coordinamento della Rete Ligure HTA

Febbraio 2014

Indice:

HTA & Pharmacogenetics - Summary

Use of pharmacogenomics in the clinical context

- ✓ Pharmacogenomics is – by definition – a clinical application
- ✓ Drug administration and monitoring are patient-centred procedures

Research question:

[PICO paradigm should be applied]

Clinical validity

- ➢ clinical validity must be supported by evidence with major strength

Clinical utility

- ➢ clinical utility must be assessed
  - ➢ once clinical validity is established
  - ➢ by using structured procedures [i.e. RCTs]

Health Technology Assessment

- ➢ HTA procedures are warranted, according to GCP and current rules
  - ➢ no health technology should be prematurely transferred to clinical practice
  - ➢ local context must be appraised

9 Aprile 2014
Starhotels President
Genova

FOCUS SU EPATITE C E TERAPIE DI NUOVA GENERAZIONE

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