



www.icona2021.it

HIV & Coinfections

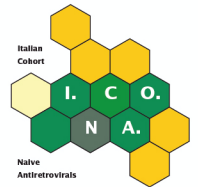
7th ICONA FOUNDATION MEETING
February 25-26 2021 *webinar edition*



Patient reported outcomes to value innovation in HIV treatment

Oriana Ciani, PhD

CERGAS, SDA Bocconi



Fondazione Icona
ITALIAN COHORT NAIVE ANTIRETROVIRALS
Conceived by Professor Mauro Moroni



Materiali di lavoro
su sanità e salute
della Fondazione
Smith Kline

Con il patrocinio di



POSITION PAPER

Misurare il valore delle nuove terapie attraverso i Patient Reported Outcomes (PROs): il caso dell'infezione cronica da HIV

Prefazione

Executive Summary

Introduzione:

Gli abilitanti delle innovazioni terapeutiche

L'evoluzione dell'outcome research nella cura dei tumori

Value Based Healthcare e accesso alle cure

Core outcome set per la valutazione e la valorizzazione di nuove terapie e gli esiti riferiti dai pazienti: PROs e PROMs

Evoluzione dell'outcome research nell'HIV

PRO, la visione del clinico: l'esigenza odierna dei PROs nella valutazione clinica del paziente

Horizon Scanning sullo sviluppo di nuove terapie per il trattamento dell'infezione da HIV

Utilizzo degli esiti riportati dal paziente (PROs) negli studi comparativi di differenti regimi antiretrovirali nel trattamento dell'infezione da HIV

I bisogni e le preferenze delle persone con HIV

Conclusioni

Passoni
EDITORE

Indice

POSITION PAPER

Misurare il valore delle nuove terapie attraverso i Patient Reported Outcomes (PROs): il caso dell'infezione cronica da HIV

- Massimo Andreoni, Università Tor Vergata, Roma;
- Andrea Antinori, IRCCS Spallanzani, Roma;
- Giovanni Apolone, Fondazione IRCCS Istituto Nazionale Tumori, Milano;
- Elio Borgonovi, CERGAS, SDA Bocconi e Fondazione Smith Kline;
- Cinzia Brunelli, Fondazione IRCCS Istituto Nazionale Tumori, Milano;
- Oriana Ciani, CERGAS, SDA Bocconi;
- Antonella Cingolani, Università Cattolica del Sacro Cuore, Policlinico "A. Gemelli", Roma;
- Lucio Da Ros, Fondazione Smith Kline;
- Claudio Jommi, CERGAS, SDA Bocconi;
- Simone Marcotullio, Consulente Socio Sanitario;
- Paolo Rizzini, Fondazione Smith Kline;
- Stefano Vella, Università Cattolica del Sacro Cuore, Roma.

What is value in healthcare?

Value assessment frameworks are instruments developed for the explicit identification of dimensions important for the evaluation of drugs, devices, or policy interventions to be applied in specific empirical contexts.



Agenzia Italiana
del Farmaco

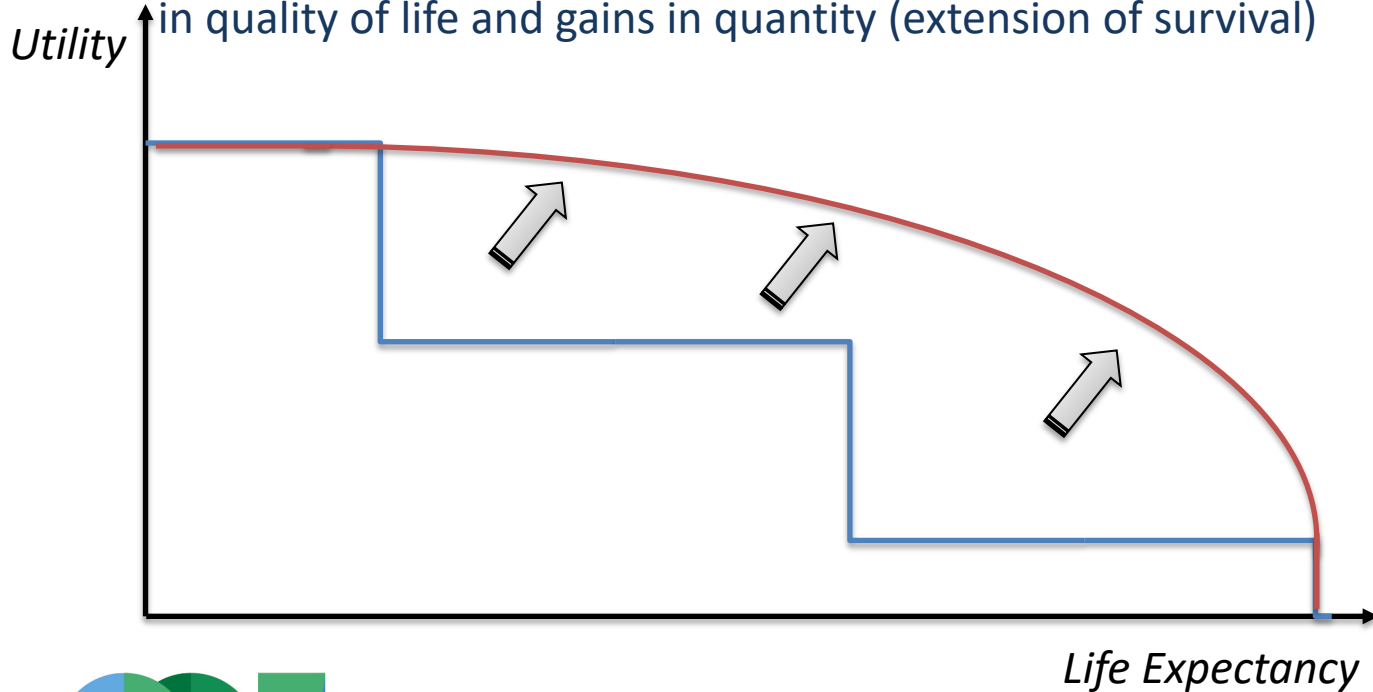
Segui

innovativi o meno, il valore è dato dall'utilità marginale che il paziente, il SSN e/o la società possono ottenere dalla sua acquisizione. Al riguardo, la misura degli anni di vita guadagnati in piena qualità di vita (QALY - *quality-adjusted life years*) è diffusamente applicata ai medicinali in diversi contesti regolatori, seppur con la consapevolezza che non sia in grado di cogliere tutti gli elementi che concorrono al valore.



What is a QALY

Quality-Adjusted-Life-Year (QALY) is a composite outcome measure that combines gains in quality of life and gains in quantity (extension of survival)



Among **people who started HIV treatment with a CD4 count of 500 or higher**, life expectancy in the 2011-2016 period was 87, compared to 85 for HIV-negative people.

“Increased Overall Life Expectancy but Not Comorbidity-Free Years for People with HIV,” Conference on Retroviruses and Opportunistic Infections (CROI). March 8-11, 2020. Boston. Abstract 151.

HIV & Coinfections
7th ICONA FOUNDATION MEETING

PRO

Physical
function
ing

PROMs

WHOQOL-HIV INSTRUMENT

The next few questions ask about **how well you were able to move around**, in the **last two weeks**. This refers to your physical ability to move your body in such a way as to allow you to move about and do the things you would like to do, as well as the things that you need to do.

F9.1(F11.1.1) How well are you able to get around?

Very poor 1	Poor 2	Neither poor nor good 3	Good 4	Very good 5
----------------	-----------	----------------------------	-----------	----------------

F9.3(F11.2.2) How much do any difficulties in mobility bother you?

Not at all 1	A little 2	A moderate amount 3	Very much 4	An extreme amount 5
-----------------	---------------	------------------------	----------------	------------------------

F9.4(F11.2.3) To what extent do any difficulties in movement affect your way of life?

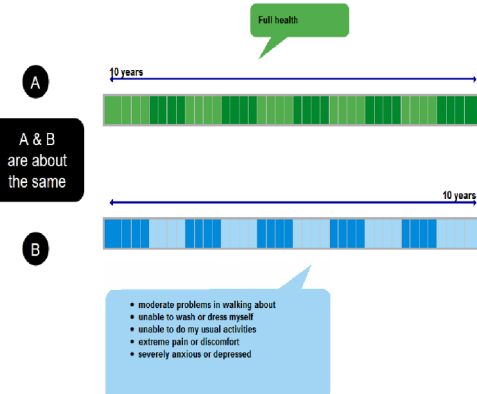
Not at all 1	A little 2	A moderate amount 3	Very much 4	An extreme amount 5
-----------------	---------------	------------------------	----------------	------------------------

F9.2(F11.2.1) How satisfied are you with your ability to move around?

Not at all 1	A little 2	A moderate amount 3	Very much 4	An extreme amount 5
-----------------	---------------	------------------------	----------------	------------------------

PREFERENCE-
BASED

Which is better, Life A, Life B, or are they about the same?





EQ-5D-5L

EQ-5D is a common **preference-based** measure. CERGIS is currently finalizing the **EQ-5D-5L Italian Valuation Study** that will report the utility values for different health states, reflective of the Italian population.

Indicare quale delle seguenti affermazioni descrive meglio il suo stato di salute OGGI, segnando con una crocetta (☒/così) una sola casella di ciascun gruppo.

CAPACITA' DI MOVIMENTO

- Non ho difficoltà nel camminare
- Ho lievi difficoltà nel camminare
- Ho moderate difficoltà nel camminare
- Ho gravi difficoltà nel camminare
- Non sono in grado di camminare

CURA DELLA PERSONA

- Non ho difficoltà nel lavarmi o vestirmi
- Ho lievi difficoltà nel lavarmi o vestirmi
- Ho moderate difficoltà nel lavarmi o vestirmi
- Ho gravi difficoltà nel lavarmi o vestirmi
- Non sono in grado di lavarmi o vestirmi

ATTIVITÀ ABITUALI (per es. lavoro, studio, lavori domestici, attività familiari o di svago)

- Non ho difficoltà nello svolgimento delle attività abituali
- Ho lievi difficoltà nello svolgimento delle attività abituali
- Ho moderate difficoltà nello svolgimento delle attività abituali
- Ho gravi difficoltà nello svolgimento delle attività abituali
- Non sono in grado di svolgere le mie attività abituali

DOLORE O FASTIDIO

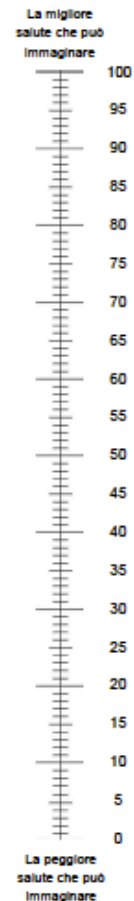
- Non provo alcun dolore o fastidio
- Provo lieve dolore o fastidio
- Provo moderato dolore o fastidio
- Provo grave dolore o fastidio
- Provo estremo dolore o fastidio

ANSIA O DEPRESSIONE

- Non sono ansioso/a o depresso/a
- Sono lievemente ansioso/a o depresso/a
- Sono moderatamente ansioso/a o depresso/a
- Sono gravemente ansioso/a o depresso/a
- Sono estremamente ansioso/a o depresso/a

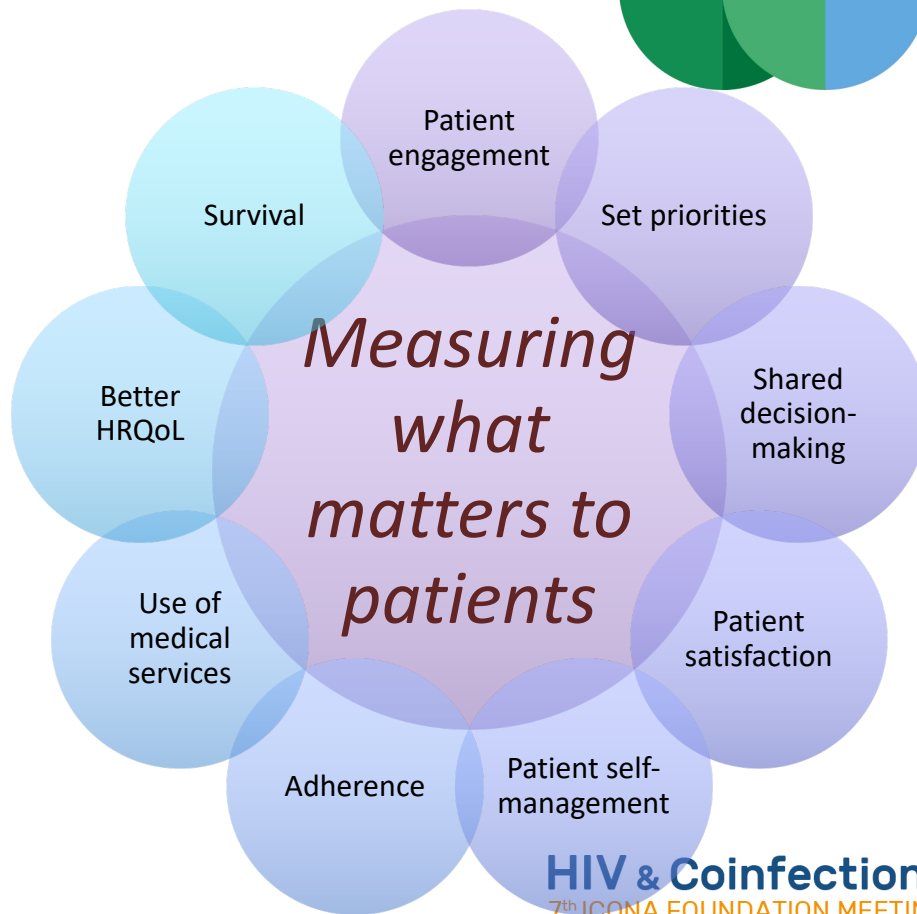
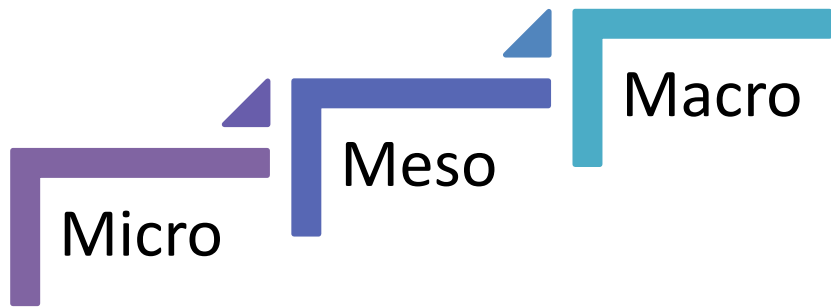
- Vorremmo sapere quanto è buona o cattiva la sua salute OGGI
- Questa è una scala numerata che va da 0 a 100
- 100 rappresenta la migliore salute che può immaginare
- 0 rappresenta la peggiore salute che può immaginare
- Segni una X sul punto della scala numerica che indica quanto è buona o cattiva la sua salute OGGI
- Adesso, scriva nella casella qui sotto il numero che ha segnato sulla scala numerata

LA SUA SALUTE OGGI =





Why PROs?





Core Outcome Set

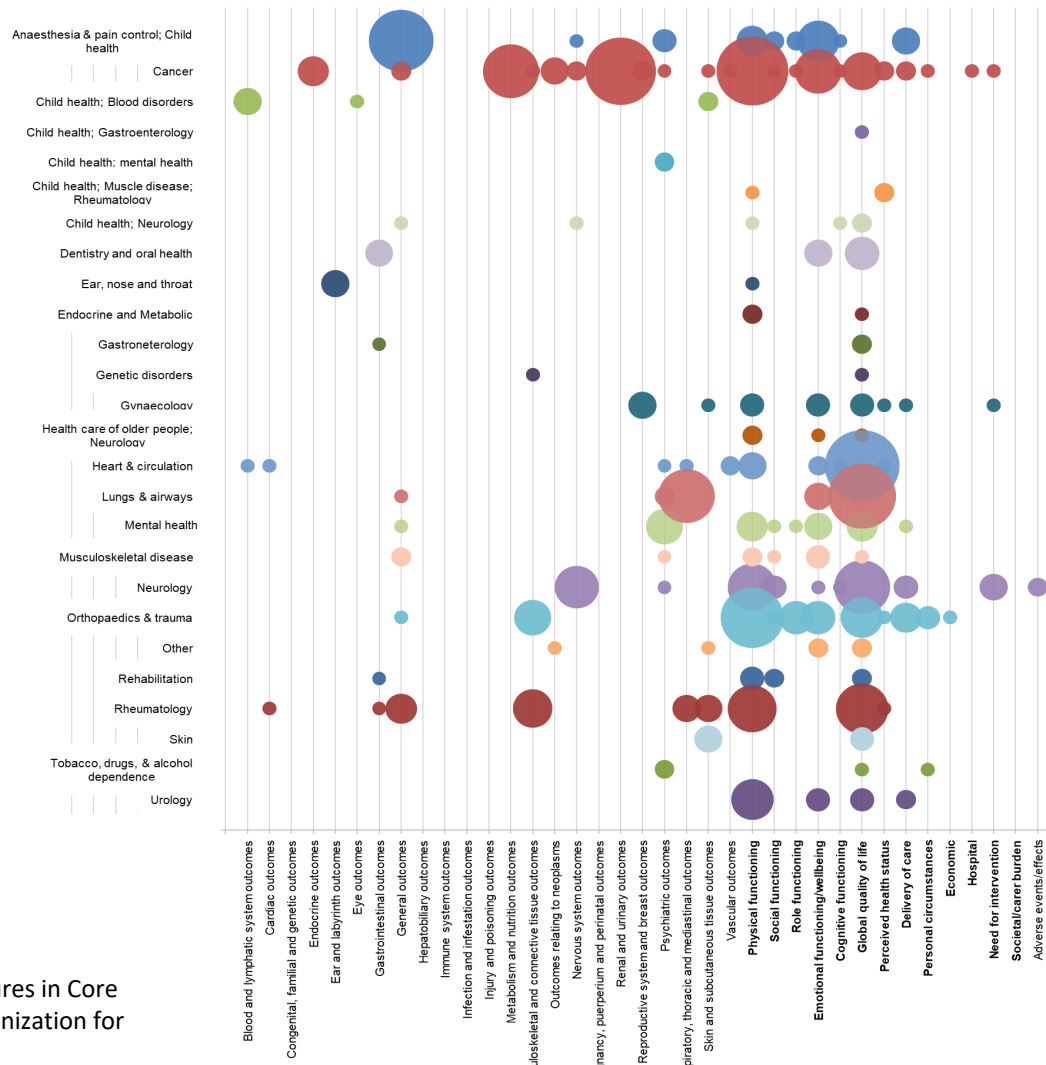
“a **standardised set of outcomes** which should be measured and reported, as a minimum, in all effectiveness trials for a specific health area. This will allow results of studies to be compared, contrasted and combined as appropriate, as well as ensuring that all trials contribute usable information. The COMET (Core Outcome Measures for Effectiveness Trials) Initiative aims to support the development, reporting and adoption of COS.”



The screenshot shows the homepage of the COMET Initiative. At the top, there is a navigation menu with links for Home, About COMET, Search, Events, and Resources. The main content area features a section titled "COMET Initiative" with a sub-header "COMET Initiative". Below this, there is a paragraph explaining the initiative's purpose: "The COMET (Core Outcome Measures in Effectiveness Trials) Initiative brings together people interested in the development and application of agreed standardised sets of outcomes, known as 'core outcome sets' (COS). These sets represent the minimum that should be measured and reported in all clinical trials of a specific condition, and are also suitable for use in clinical audit or research other than randomised trials. The existence or use of a core outcome set does not imply that outcomes in a particular trial should be restricted to those in the relevant core outcome set. Rather, there is an expectation that the core outcomes will be collected and reported, making it easier for the results of trials to be compared, contrasted and combined as appropriate; while researchers continue to explore other outcomes as well. COMET aims to collate and stimulate relevant resources, both applied and methodological, to facilitate exchange of ideas and information, and to foster methodological research in this area. [The COMET Handbook Version 1.0](#) is available [here](#)." Below this paragraph, there is a note: "When searching the COMET database, please note that a systematic review is currently underway to identify eligible material, and we are continually updating the database as we identify eligible studies. Therefore, the records retrieved by any search might increase on a daily basis." The page also features two sidebars. The left sidebar is titled "Search COMET database" and contains a search box with the text "HIV" and a "Search" button. Below the search box, it states: "The COMET database currently contains 1291 references of planned, ongoing and completed work." and "The keyword used for the search will be compared with study title, abstract and author's surname." There is a link "View full search options" and a partially visible link "To view a demonstration of how to search the". The right sidebar is titled "Core resource pack" and contains a megaphone icon. It states: "Useful references for core outcome set developers." and "This includes an overview of the problems with outcomes in trials, key issues to consider in the development of a core outcome set, examples of core outcome set development, and things to think about once a COS is agreed. To read more, [click here](#)."

PROMs in COS

- 323 unique PROMs were recommended for use across 94 COS and 26 disease areas
- A fragmented landscape of recommended PROMs in COS calls for better harmonization of PRO selection and measurement
- Each COS included a median of 4.5 instruments
- Overall, global quality of life (25%) and physical functioning (22%) were the most frequently targeted health outcome domains



Ciani O. et al. A cross-sectional analysis of Patient-Reported Outcome Measures in Core Outcome Sets reveals overlap on target outcome domains but lack of harmonization for recommended instruments, *Journal of Clinical Epidemiology (in press)*

A new COS for HIV?

[Home](#)

[Search the COMET Database](#)

[Resources](#)

[COS Endorsement](#)

[COS Uptake](#)

[Patients and the Public](#)

[Events](#)

[About us](#)

[COMET VIII](#)



Development of a Core Outcome Set for HIV/AIDS

Using ICHOM methodology, the group, led by the Nova School of Business and Economics have brought together a multidisciplinary, international team of experts to create a core outcome set for daily clinical practice.

Contributors

Joao Marques Gomes

Further Study Information

Current Stage: Ongoing

Date: September 2020 - 2020

Funding source(s): Gilead Sciences

Linked Studies

No related studies

Related Links

No related links

Health Area

Disease Category: Infectious disease

Disease Name: HIV/AIDS

Target Population

Age Range: 18 - 120

Sex: Either

Nature of Intervention: Any



Thank you

oriana.ciani@unibocconi.it

