LE RETI ONCOLOGICHE REGIONALI

Presente, Problematiche e Prospettive future

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Roma, Camera dei Deputati, 29 Settembre 2009

INTRODUZIONE

IL “LABORATORIO” ONCOLOGIA NEL PANORAMA SANITARIO NAZIONALE

ONCOLOGIA ITALIANA:

Performance scientifica:Anni 2006-07

- IV posizione internazionale per rapporto PIL/N° pubblicazioni in Oncologia
- V posizione internazionale per numero assoluto di pubblicazioni in Oncologia
- V posizione assoluta per valore di “Impact factor” delle pubblicazioni
- II paese dopo USA per contributi scientifici al convegno nazionale ASCO

Tumori, 95: 133, 2009

ONCOLOGIA:

Disciplina con elevata propensione alla sperimentazione di protocolli assistenziali innovativi

- Collaborazione con AIFA per l'innovazione e sostenibilità economica della spesa farmaceutica
  - ***Cost sharing***
  - ***Payment by results***
- Accreditamento all'Eccellenza per la Qualità
- Approccio multidisciplinare al malato quale principio fondamentale della "Clinical Governance"
- Continuità terapeutica
- Modelli di integrazione laboratorio-clinica

La rete oncologica regionale



FARMACI ANTITUMORALI SOGGETTI A MONITORAGGIO AIFA

SOSTENIBILITA' IN SANITA'

Garantire agli assistiti una appropriata copertura della domanda di cura a costi compatibili con il livello di sviluppo economico della società

SOSTENIBILITA' ED INNOVAZIONE





The NEW ENGLAND JOURNAL of MEDICINE

Perspective

SEPTEMBER 24, 2009

Doctors as the Key to Health Care Reform

Arnold S. Relman, M.D.

Experts agree that sustainable health care reform requires reining in rising costs, but few people understand that the control of medical expenditures is largely in the hands of the medical profession. Doctors, in consultation with their patients — not insurance companies, legislators, or government officials — make most of the decisions to use medical resources, thereby determining what the United States spends on medical care.

Most doctors are paid on a fee-for-service basis, which is a strong financial incentive for them to maximize the elective services they provide. This incentive, combined with the continued introduction of new and more expensive technology, is a major factor in driving up medical expenditures. The same incentive is attracting more and more young doctors into specialties that command much higher fees — and therefore guarantee much greater income — than those earned by primary care practitioners. Primary care is rapidly becoming an endangered specialty; an important, but not the only, reason is its relatively low economic rewards.

A system like ours, which is grossly deficient in primary care physicians and dominated by specialists who are trained to use expensive tests and procedures, is inevitably costly, particularly when most specialists practice as independent small businesses, competing for patient referrals and for income. Adjusting the fees paid by insurers, with increases for primary care and decreases for specialized procedures, or basing fees on the quality or outcome of care won't solve this problem, because specialists can easily control the volume and kinds of services they provide. Furthermore, competition doesn't lower prices in medical care as it does in other markets, because physicians usually choose the services to be provided and are paid largely by insurance — not by the consumers for whose business they would compete if this were an ordinary market.

To judge from the health care reform proposals getting serious attention in Washington, there is little evidence that lawmakers are aware of, or understand the significance of, these facts — or that, even if they did, they would



LIFE IN THE BALANCE

How do researchers and policy-makers decide on the value of health? **Daniel Cressey** looks at Britain's National Institute for Health and Clinical Excellence.

In May 2008, a research report concluded that it would be too expensive to keep some British people with kidney cancer alive.

The 290-page review and economic evaluation had been put together to assess the effectiveness of four new treatments — bevacizumab, sorafenib, sunitinib and temsirolimus — for renal-cell carcinoma. The research team concluded that there was some evidence that patients could benefit from these treatments, in some cases even doubling the time that they lived without their disease worsening from five to ten months. However, "the probability that any of these interventions would be considered cost effective" in Britain's nationalized health system, it said, "is zero"[1]. A few months later, an expert panel from Britain's National Institute for Health and Clinical Excellence (NICE) confirmed that prediction, stating in an August decision based heavily on the report that the four drugs "are not recommended as treatment options for advanced and/or metastatic renal cell carcinoma".

The critics erupted. The drug manufacturers and patients were furious. "They are saying to me, as a cancer patient, that I don't deserve the right to live, whether it's for one month, two months, six months or even years," a person with kidney cancer told the BBC. Britain's leading cancer charity Cancer Research UK said that it was "very disappointed" with the decision, and that "NICE needs to consider how it can reconcile making recommendations so clearly at odds with current clinical opinion". "We were not aware at the start that this was going to be controversial," says Jo Thompson Coon, a researcher at the Peninsula Medical School in Exeter, UK, and the corresponding author of the research report.

This is the brutal reality of NICE, the body that decides which medical treatments the nation can afford to buy. To some, NICE is a world-leading body — one at the forefront of 'comparative effectiveness' research, which compares one treatment with another, and exemplary for the tough decisions it makes on cost effectiveness. To others it is a loathed body ready to deny people life-giving treatment with little justification.

Which of these portraits is more accurate has implications for people far beyond the United Kingdom. NICE's decisions and its decision-making methods have already been adopted by several other countries (see 'NICE abroad', overleaf). Some health economists say that the United States — where the debate over health-care reform has reached fever pitch — will have to incorporate techniques similar to those that NICE uses if the country is serious about reining in its more than $2-trillion health-care

Nature, 461: 336, 2009

LA STRADA DEL “NICE”

(Brit’s Nat Inst for Health and Clin Excellence)

Quota fissa di costo farmaceutico/anno

↓

“Utility Value”
(valore QV)

↓

“Quality Adjusted Life Year” < £ 30.000/anno
(Valore QV dello stato di salute nel tempo)

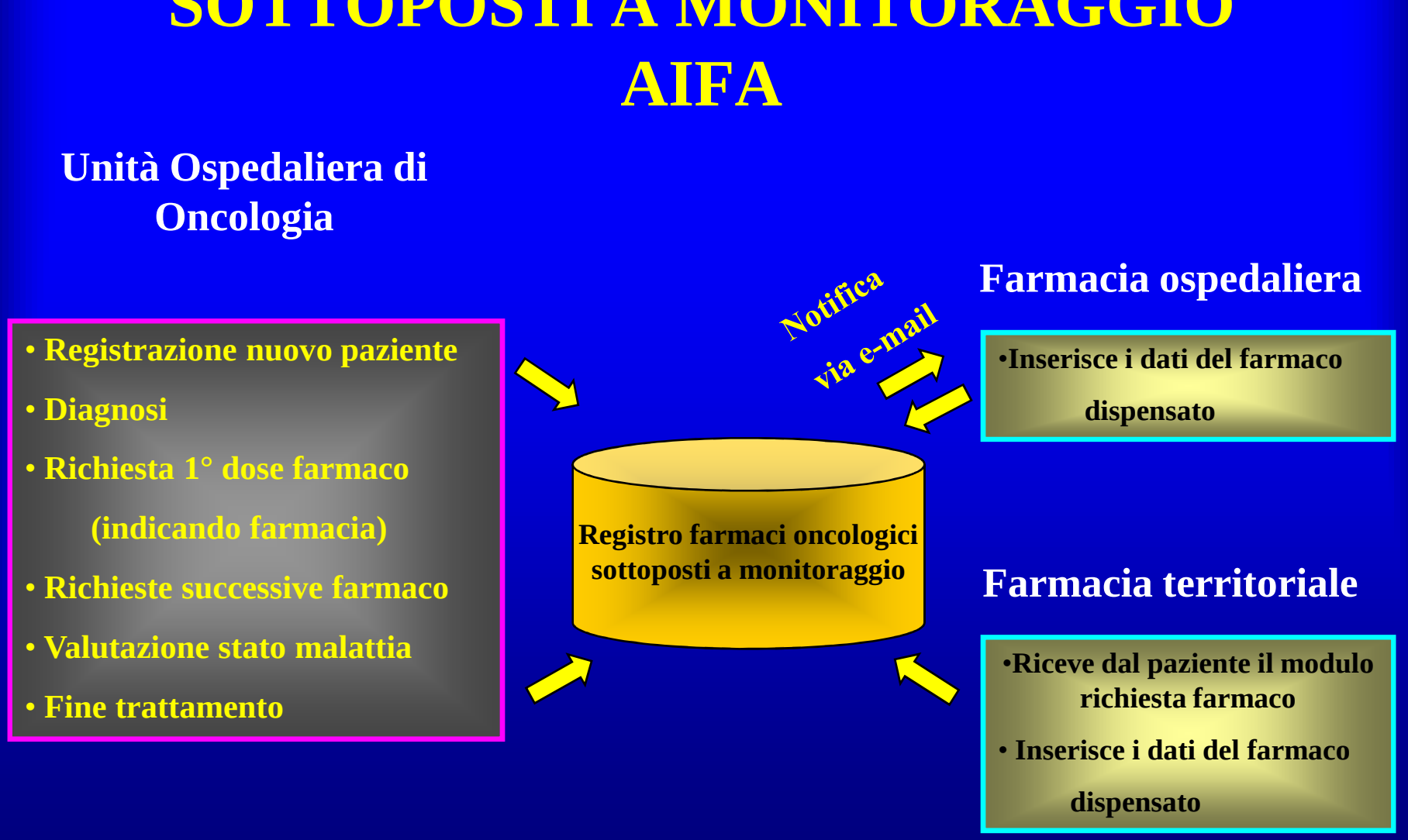
↓

“Life Extending for pts with short life expenctancy” > £ 30.000/anno

LA STRADA ITALIANA

- **Gli scopi:**
  - **Ridurre il tempo decisionale**
  - **Rendere disponibili i nuovi farmaci senza discriminazione**
  - **Costruire un legame tra rimborso e beneficio clinico**

LA REGISTRAZIONE DEI FARMACI SOTTOPOSTI A MONITORAGGIO AIFA



AIFA

Agenzia Italiana del Farmaco

REGISTRATI | SCHEDE | NORMATIVA | FAQ | INFORMAZIONI ed AGGIORNAMENTI New | HELP

Registro farmaci oncologici sottoposti a monitoraggio

- Alimta
- Atriance
- Avastin
- Erbitux
- Nexavar
- Revlimid
- Sprycel
- Sutent
- Tarceva
- Tasigna
- Thalidomide Celgene
- Torisel
- Tyverb
- Vectibix
- Velcade + 648
- Yondelis
- Zevalin

- Revlimid - legge 648/96

Arruolamento chiuso (solo aggiornamento dati):

- Eloxatin adiuvante
- Emend
- Faslodex
- Foscan
- Gliadel
- Herceptin adiuvante
- Kepivance
- Herceptin - legge 648/96

Con specifiche Determinazioni dell'AIFA pubblicate in varie Gazzette Ufficiali, l'utilizzo di alcuni farmaci oncologici richiede la compilazione di schede di raccolta dati al fine di garantire l'appropriatezza d'uso degli stessi.

AIOM e SIFO supportano tale iniziativa e invitano i rispettivi soci ad adoperarsi affinchè la raccolta delle schede sia fatta al meglio e per il tempo necessario, allo scopo di consentire da una parte la verifica dell'appropriato uso di questi farmaci e dall'altra di produrre dati sul loro uso nella pratica clinica, che potranno in alcuni casi essere utili ad integrare le conoscenze emerse dalle sperimentazioni condotte a fini registrativi. Inoltre, la realizzazione da parte di AIFA di un sistema informatico semplice ed efficace, oltre che ridurre al minimo l'impegno richiesto per la compilazione delle schede costituisce elemento per una fattiva collaborazione tra Istituzioni e Società Scientifiche. Tale collaborazione va vista con grande interesse, in un periodo in cui è necessario individuare le soluzioni che aiutino a trattare gli ammalati di cancro sempre al meglio.

STATO DELL'ARTE IN ITALIA: APRILE 2009

Cost Share

7 Farmaci

- Erlotinib (NSCLC)
- Sunitinib (RCC)
- Sorafenib (RCC)
- Bevacizumab (tutti)
- Lenalidomide (Mieloma)
- Panitumumab (mCRC)
- Bortezomib (Mieloma)

Payment by results

7 Farmaci

- Sorafenib (HCC)
- Dasatinib (Leucemia)
- Nilotinib (Leucemia)
- Temsirolimus (RCC)
- Trabectedina (STS)
- Lapatinib (Mammella)
- Cetuximab (CRC)

REGISTRO DEI FARMACI ONCOLOGICI SOTTOPOSTI A MONITORAGGIO AIFA

Dati aggiornati al 20 aprile 2009



SISTEMA DI MONITORAGGIO AIFA

VANTAGGI

- Nuovo Farmaco accessibile a tutti
- Disponibilità in tempi brevi
- Feedback con l'Industria riguardo a:
  - -Monitoraggio e farmacovigilanza
  - -Metodiche di selezione

LIMITAZIONI

- Non applicato in tutte le istituzioni
- Non idoneo per le terapie adiuvanti
- Non ottimale per le terapie di combinazione

CIPOMO

SIQuAS

AMCLIS
Associazione per il Management e la qualità nelle Organizzazioni per la Salute

LA S.C. DI ONCOLOGIA MEDICA

DELLA A.C.O. SAN FILIPPO NERI

DIRETTA DAL DOTT. ***GIAMPIETRO GASPARINI***

HA OTTENUTO

L'ACCREDITAMENTO ALL'ECCELLENZA

DIMOSTRANDO DI APPLICARE, NELL'ESPLETAMENTO DELLE ATTIVITA' DI DIAGNOSI E CURA DEI TUMORI, PROCEDURE DI ELEVATA QUALITA'.

Il Presidente del CIPOMO
dott. Giorgio CRUCIANI

Roma, 31 Ottobre 2008

APPROCCIO MULTIDISCIPLINARE AL MALATO QUALE PRINCIPIO FONDAMENTALE DELLA "CLINICAL GOVERNANCE"

- **Il Dipartimento di Oncologia**

  35,5% / *totale (Onco-ematol = 14,4 %)*

- **La centralità del paziente:**

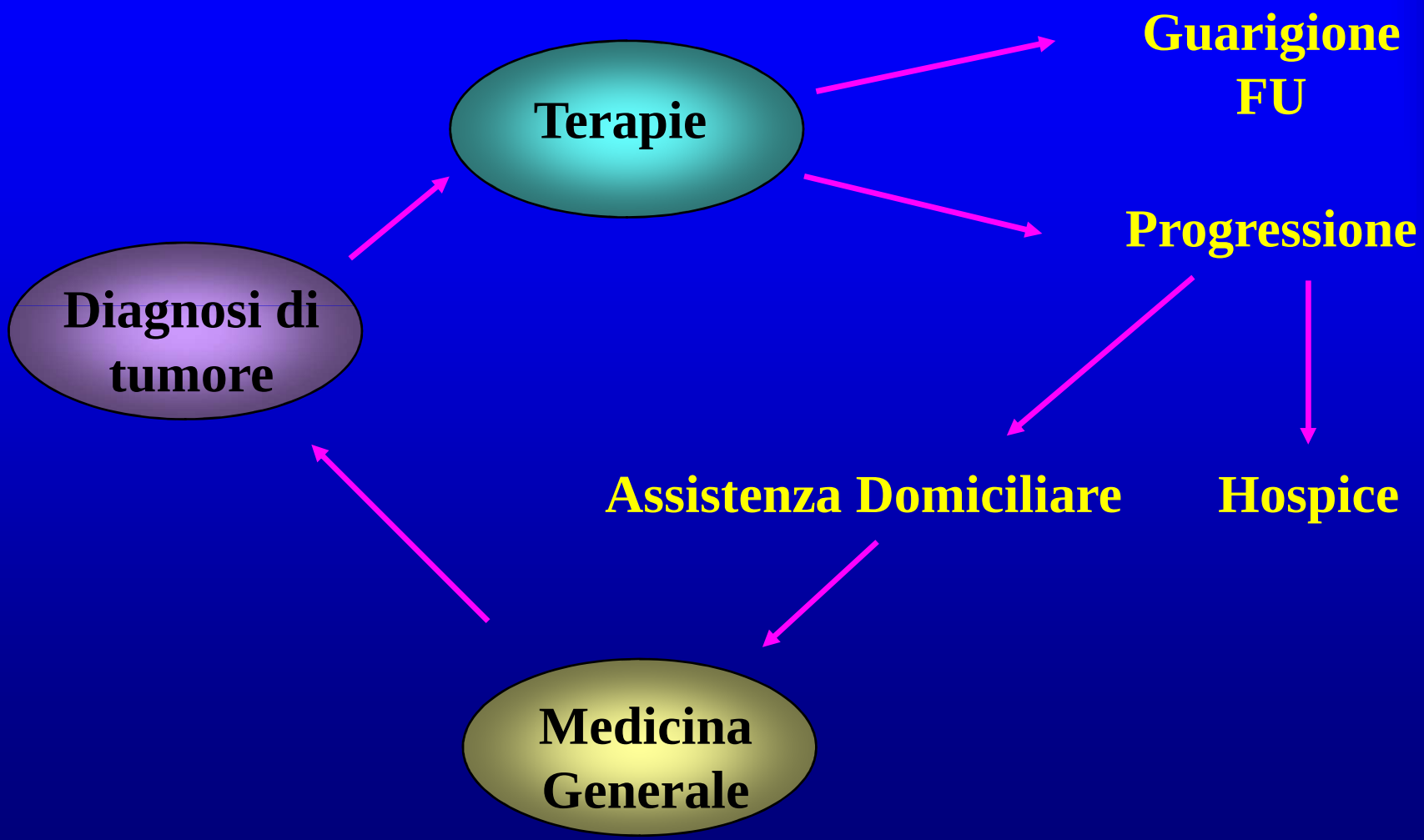
  gli ambulatori multidisciplinari

- **La priorità:**

  pacchetti ambulatoriali complessi

  (P.A.C)

CONTINUITÀ TERAPEUTICA



INTERAZIONE LABORATORIO-CLINICA:

Il modello K-RAS

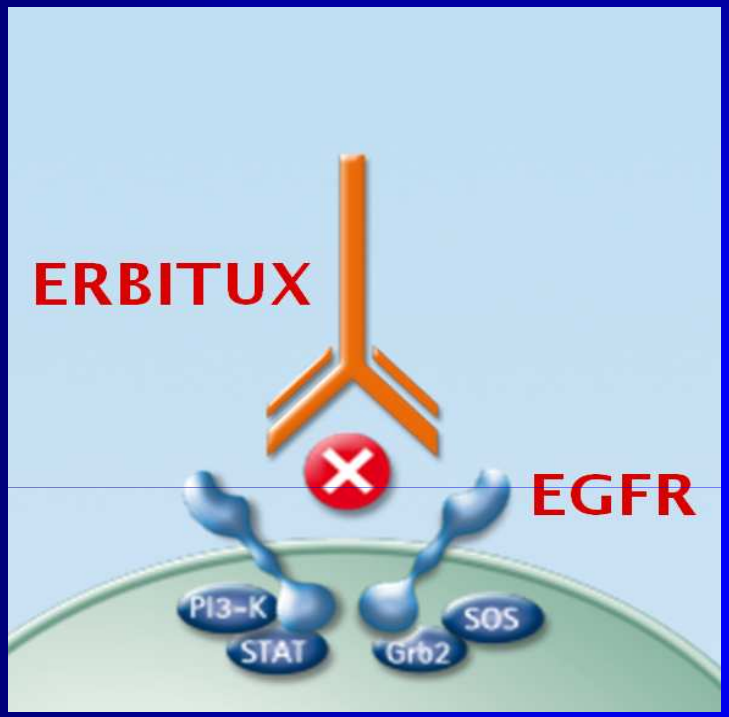
CANCRO COLORETTALE (CRC) IN ITALIA

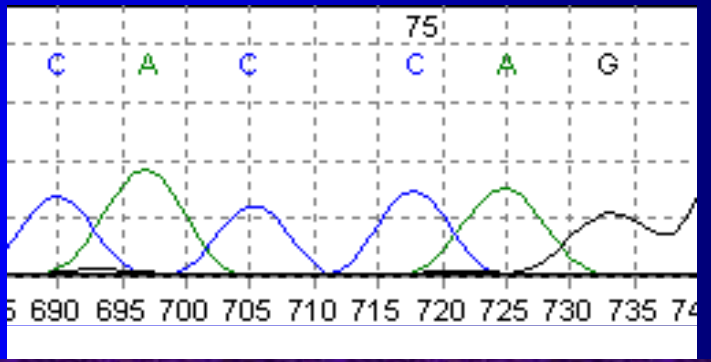


Incidenza:
35.000 casi annui

Circa 17.000 pazienti
Con malattia metastatica

NUOVE STRATEGIE TERAPEUTICHE





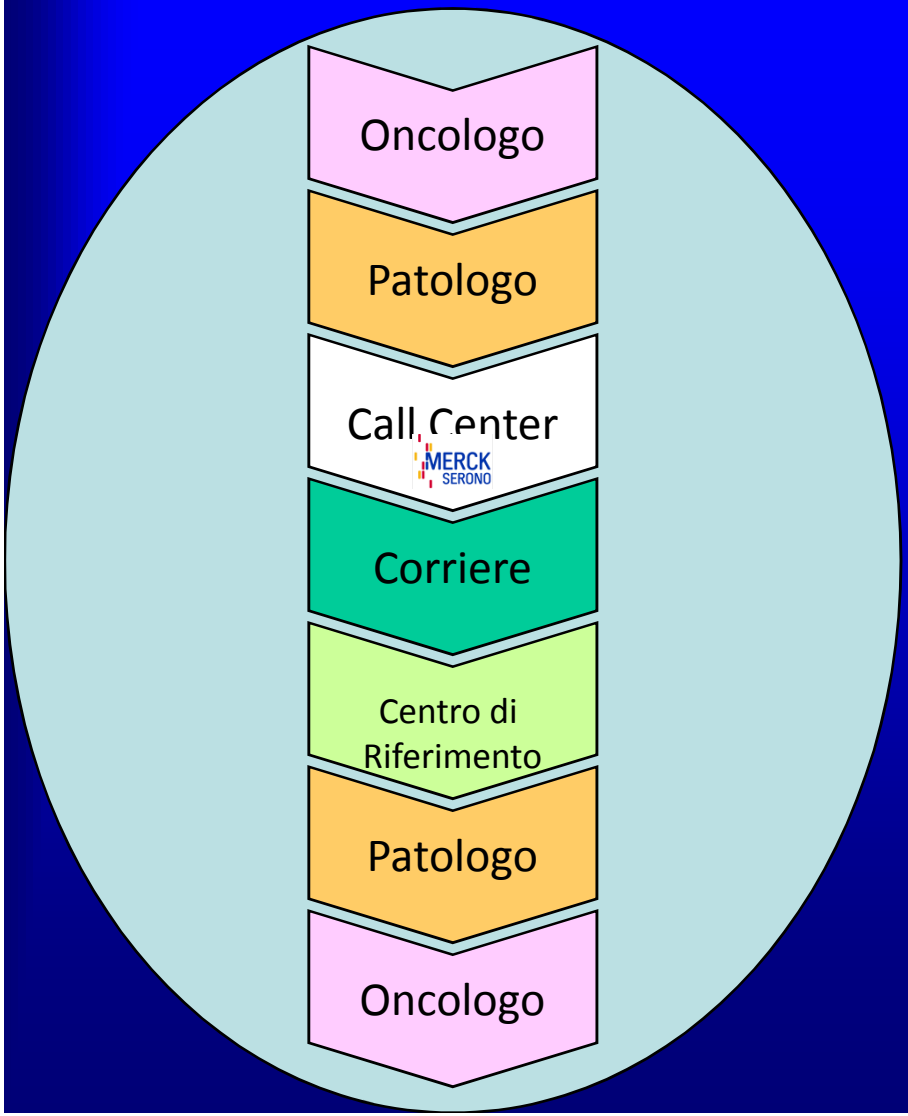
Wild-type Kras

- **Anticorpi monoclonali anti-EGFR**

TRE BUONE RAGIONI PER TESTARE K-RAS PRIMA DELLA TERAPIA CON ANTICORPI ANTI-EGFR

- Evitare tossicità non necessarie
- Eliminare costi aggiuntivi
- Beneficio clinico aggiuntivo nei casi Kras wild type

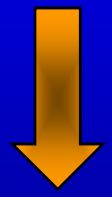
LA PROCEDURA





LA RETE ONCOLOGICA REGIONALE

Modello di Efficienza



Traguardo organizzativo obbligato