A drug governance policy incorporating **cost-opportunity** in evidence-based recommendations produced with the GRADE method

Is cost-opportunity an effective strategy for drug expenditure governance?
The experience on oncology drugs of the Emilia-Romagna Region, Italy

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Background

- High cost oncology drugs challenge the sustainability of healthcare systems.
- The Emilia-Romagna Region (RER) implements a drug governance policy by producing evidence-based recommendations and monitoring them through quantitative indicators.

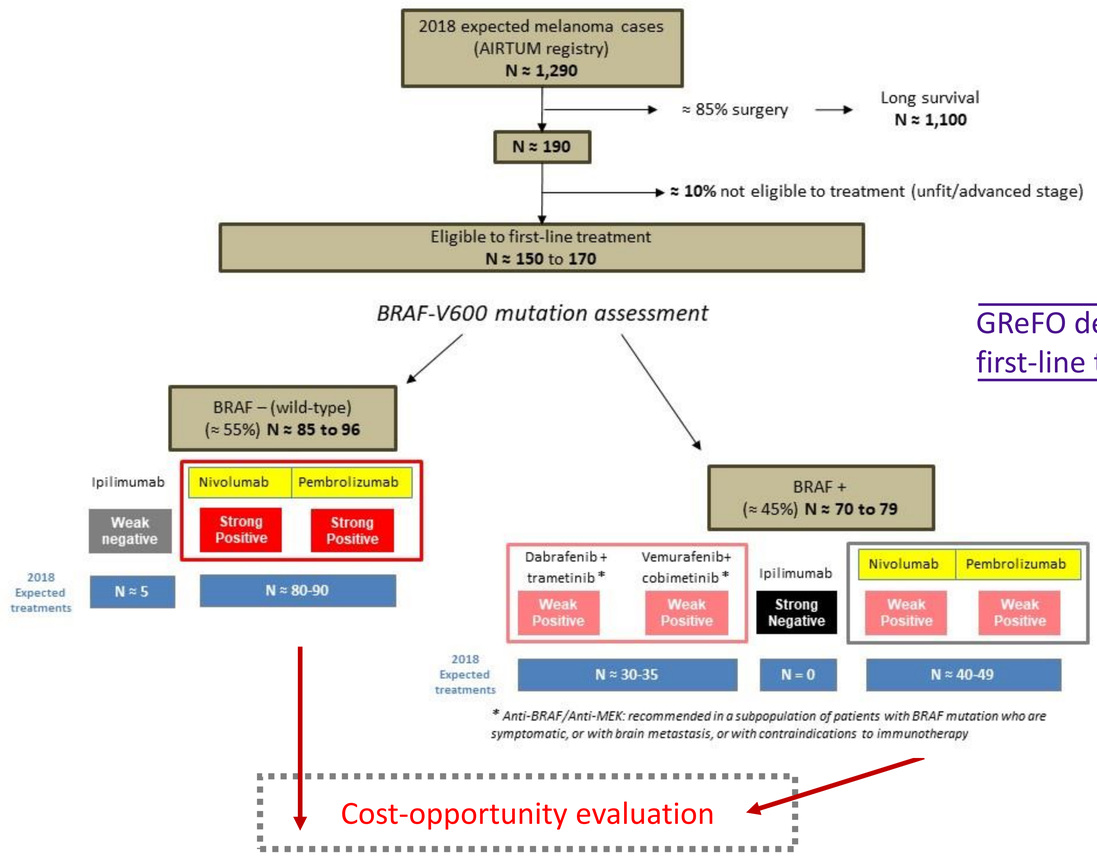
Methods

- The GReFO (Gruppo Regionale Farmaci Oncologici) is a RER multi-stakeholder oncology workgroup producing guidance by means of the GRADE method [1].
- Although formal cost-effectiveness analysis is not performed, if drugs of the same class show no difference in terms of efficacy and safety, cost-opportunity (prescribing the least expensive drug) is recommended and prescription rates are formally monitored.
- The aim is to optimize the use of financial resources while warranting appropriate and equitable use of medicines, and to foster competition among drug companies.
- We describe the financial impact of implementing such policy to the first-line treatment of advanced stage melanoma (ASM).
- Expected melanoma cases and expected prescription figures were based on the Italian Association of Cancer Registries (AIRTUM) data and extrapolated from epidemiological studies.

Results

- In 2017, licensed monotherapies for wild-type patients with ASM were nivolumab (Nivo), pembrolizumab (Pembro) and ipilimumab
- Patients with the BRAF-V600 mutation (BRAF+) were eligible also to anti-BRAF/anti-MEK associations (BMAs)
- Recommendations with the same strength and direction were issued by GReFO for Nivo and Pembro in wild-type (strong positive) and in BRAF+ (weak positive) patients.
- According to cost-opportunity issues, GReFO recommended, within the immunotherapy class, the least expensive drug (Nivo) in BRAF+ patients.
- Considered for analysis: a sample of **154 ASM patients** (70% of the total) undergoing immunotherapy in 2018.
- **76%** and **24%** of ASM patients were treated with Nivo and Pembro, respectively. The overall expenditure was € 5,826,509 (rough figure, without considering the median duration of treatment).
- Compared with a hypothetical treatment of 50% of patients with each drug, adherence to cost-opportunity recommendation produced an **estimated saving of 5%** on the observed overall expenditure.
- Considering an adjusted cost/patient/year estimate, the savings my have been up to **11%.**

[1] Atkins D et al. BMJ. 2004 Jun 19;328(7454):1490



GReFO decisional pathway for the first-line treatment of ASM

Patients with ASM (N = 154) treated with Nivo and Pembro (2018)	Nivo	Pembro	Overall
Observed patients' distribution	**76%**	**24%**	
Observed expenditure	4,303,910	1,522,599	**5,826,509 €**
Hypotetical patients distribution (no cost-opportunity recommendation)	*50%*	*50%*	
Estimated expenditure	*2,819,803*	*3,306,245*	***6,126,018 €***
Estimated difference			*- 299,509 €* *(- 5 %)*

Adjusted estimates (considering cost/patient/year) for Nivo and Pembro in 154 ASM patients (2018)	Nivo	Pembro	Overall
Cost/patient/year	55,900 €	87,414€	
Observed patients' distribution	**76%**	**24%**	
Estimated adjusted expenditure	*6,540,300 €*	*3,234,318 €*	***9,774,618 €***
Hypotetical patients distribution (no cost-opportunity recommendation)	***50%***	***50%***	
Estimated adjusted expenditure	*4,304,300 €*	*6,730,878 €*	***11,035,178 €***
Estimated adjusted difference			*- 1,260,560* *(- 11%)*

Prescription data on nivolumab and pembrolizumab, Emilia-Romagna, 2018

Conclusions

- An evidence-based drug governance policy involving multiple stakeholders and sharing context-specific issues is feasible in a public healthcare system.
- Incorporating cost-opportunity issues in the production of evidence-based recommendations may result in substantial savings

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