

Economic Impact of Implementation of Next Generation Sequencing (NGS) and Adoption of Molecularly Guided Treatment Options (MGTOs) into Routine Oncology Practice in Bulgaria



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OBJECTIVES

The current study explores the opportunities for implementation of NGS/CGP and MGTOs into routine oncology practice in Bulgaria and its possible economic consequences.

BACKGROUND

- **Next Generation Sequencing/ Comprehensive Genomic Profiling (NGS/CGP)** technologies may improve decision making in oncology, especially in enabling personalized approach based on systematic examination of the cancer genome;
- **Knowing the tumor genetic profile** and certain biomarkers, **could improve risk-based stratification of patients and therapy outcomes.** Oncologists are now able to use data from tumour molecular profiling and **MGTO to enhance patients’ management.**

METHODS

- We performed two-step study evaluating the opportunities and possible barriers for implementation of NGS/CGP and MGTO in Bulgaria:
- **First:** We studied the current health care background and regulatory framework in terms of diagnostics and therapy resource allocation and possible ways to use NGS/CGP and MGTO;
 - **Second:** based on experience in other countries, to create a list with recommendations for gradual economic implementation of NGS/CGP and MGTO in Bulgaria.

RESULTS

- Currently in Bulgaria most drug regimes in oncology require results of different validated biomarker tests;
- hence **NGS/CGP can be an alternative to multiple tests** by simultaneously examine broad spectrum of genes;
- In this respect, **adoption of NGS/CGP could reduce depletion of scarce materials and decrease cost and time for result;**
- Recommended therapeutic regimes are included in the reimbursement lists and recently suggested legislation changes could provide possibilities for off-label use in certain cases, which could be a possible pathway to introduce MGTOs
- Expected changes in the medical devices legislation in Bulgaria provide possibilities for public funding and improved market access, including NGS/CGP.

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RESULTS

Regulatory environment for introduction of NGS/CGP and MGTO

Changes in legislation

- HTA for MDs/ other technologies:
- For inclusion within a list of MD/technologies, to be covered with public resources;
- Assessment of cost-effectiveness and budget impact;
- MGTO to became part of local reality

Amendment and update of regulatory bodies registers (BDA, NHIF)

- BDA list of MDs is expected to include 16 different groups of MD’s, including in vitro-diagnostics where NGS/CGP belongs;
- Only MD included within the list of MD’s of BDA could apply for funding with public resources (NHIF budget or MoH budget)

Development of rules for budget and economic impact of the new technology

- NHIF to assess complex assessment of the expected budget expenditure and set list of criteria for cost-effectiveness of medical devices;
- HTA should be performed for all new medical devices for inclusion in the reimbursement list;
- On yearly base the manufactures should submit to NHIF data for clinical, social and economic effect

Annual economic impact assessment

- Manufacturers to provide data for annual budget impact of the new medical device

Recommendations

Update in the clinical guidelines

- Update in the Bulgarian oncology guidelines to include possibilities for NGS/CGP and MGTO in compliance with ESMO and NCCN;
- One step more toward patient-centred care

Creating genomic database

- Oncologists can be provided with important information and insights for the disease and potential treatments, to predict who might benefit most
- More patients, more data, better treatment, better results

Establishment of patients database connected with international oncology databases

- Would facilitate collaboration between cancer registries, defines data collection standards, etc;
- Would facilitate monitoring of cancer incidence and mortality in the country

Shortening of approval period

- Improved access to treatment of patients with unmet needs

CONCLUSIONS

NGS/CGP and MGTO facilitate treatment choice and **could improve clinical and policy decision making**, especially in terms of health care resources allocation and optimization of costs. The **expected changes** in the **regulatory environment** in Bulgaria and flexibility of pharmaco-therapeutic guidelines **could provide pathways to introduce NGS/CGP in Bulgaria.** Further analyses are necessary to evaluate funding options, data management and other important implications.