The introduction of NGS panel tests in the Belgian healthcare system

Walli Van Doren
National Institute for Health and Disability Insurance Belgium

The introduction of NGS panel tests in the Belgian healthcare system

NGS is a new innovative technology = challenge

- Final goal = Integration of this technology into the existing nomenclature

- Pilot project
  - 2018-2020 (3 years)
  - A specific **convention** art 56 §1
  - NGS networks

Context

- Already in 2015 there was a clear political will to introduce the innovative targeted ‘Next-Generation-Sequencing’ (NGS) into the Belgian healthcare system

- The Ministry of health gave a mandate to the Cancer Center (WIV-ISP) to develop a Roadbook Personalised Medicine

“Introduction of Next-Generation-Sequencing in routine diagnostics in oncology and hemato-oncology”.

Preliminary steps

Pilot project

Preliminary steps:

- Evidence-based guidelines
- Specific criteria for the use of NGS
- Selection of patients
- Benchmarking study for the participating labs
- Dataregistration
- Training…..

The convention: objectives

To implement NGS under controlled conditions and to monitor closely

Technical aspects

- To perform NGS in optimal conditions from the moment the specimen is taken until the reporting of the result
- The implementation of a quality control system
- The selection of patients for which the new technology represents an added value
- To collect data (registration is mandatory)
- Guidelines:updated by COMPERMED

The convention: objectives

Regulatory aspects:

- The creation of NGS networks

Budgettary aspects

– Costeffectiveness of the new technique

– To investigate the budgettary impact under specific and verifiable conditions

The convention: objectives

- At the end of the pilotstudy a thorough evaluation will reveal whether this new molecular technology has improved diagnostics within the (hemato) oncology (therapy, survival rates….)
- At the end of the study we will be able to identify the bottlenecks
  - How to improve the data collection system?

- Can NGS be integrated in the nomenclature and generalised?

Guidelines

- Compermed delivered two lists with markers with proven clinical utility:
  - Solid tumors
  - Hematological cancers
- NGS = reimbursed if for a specific indication
  - the markers mentioned on the list are tested
  - The marker hasn't been tested before by another technique
  - Once per diagnostic phase (initial diagnose)
  - Relapse after one year = new diagnostic phase

Registration

- Registration of the test and the result are mandatory to reimbursement
- Health Data : registration tool “only once” principle
- Unique code
- This code will allow reimbursement

Convention budget

- Partly financed through article 33bis and article 33ter:
  - NGS will replace a combination of single more classical tests/routine tests (sequential tests)
- Partly financed by a forfait through article 56 of the convention
  - 2 million €

Per indication: specific nomenclature codes can be used

The forfait is considered as a supplement

Network

Convention will be signed with a network and not with a single hospital nor a single laboratory

Definition of network

An organisation of a group of hospitals (at least two) where NGS analyzes will be concentrated, including labs who perform NGS or not but all working under the same qualitysystem.

Network

Composition of the networkgroup

- Networks with all three labs (pathology, clinical biology and genetics) are privileged,
- Hereditary characteristics (BRCA): interpretation by a genetic center=mandatory

SLA=mandatory between all the partners within the network

Selection criteria for the participating networks: legal criteria

- **Pathology** Labs (RD of 5th of december 2011 concerning the recognition of the pathology labs)
- Labs for **Clinical Biology** (RD of 3th of december 1999 concerning the recognition of the labs for clinical biology)
- Centers for **Human Genetics** *(*RD of 14th december 1987)

➔Quality control by the WIV/ISP (scientific institute for health)

➔BELAC accreditation

Selection criteria for the participating networks: technical requirements

1. Belac accreditation ISO 15189 for NGS or

   application to obtain Belac accreditation ISO 15189 for NGS or

   Belac accreditation ISO 15189 for NGS for related human applications (genetic centers)
2. Participated in the benchmarking study
3. ICT infrastructure to connect to the health Data Platform
4. NGS lab procedure is described in validated laboratory protocols

Expertise within the network

- Medical Oncologists (two)
- Clinical Biologist or a Pathologist competent in NGS for the specific tumortype
- Onco-geneticist (hereditary impact like BRCA)
- Biomedical sciences (or equivalent, 4 years of relevant experience)(two)
- (Bio) Computer-scientist (or equivalent, 2 years of relevant experience) and a substitute within the network
- Bachelor in medical lab technology (one and a substitute)

Selection and scoring system

Score for networking:

- 2 hospitals (4 points)
- 4 hospitals (6 points)
- 6 hospitals (8 points)
- 8 hospitals (10 points)

Score for the number of MOC's

- 500 = 4 points
- 1000=6 points
- 1500=8 points
- 2000=10 points

Selection and scoring system

Selection-score = 0,5 x NW-score + 0,5 x M-score

Sel-score ≥ 7

Classification score

M-score \ NW-score	4	6	8	10
4	4	5	6	7
6	5	6	7	8
8	6	7	8	9
10	7	8	9	10

Classification score

Ex aequo

- Networks with all three labs (pathology, clinical biology and genetics) are privileged
- Networkscore > MOC's

Moc's can only be counted once.

A hospital can be part of more than one network (genetic center)

FOLLOW-UP

- Convention will be signed with the network
- Each lab performing NGS will use the nomenclature as indicated in the convention (art33bis and art33ter)
- Each lab performing NGS will register the data
- The network will send an invoice every quarter to RIZIV/INAMI in order to obtain the forfait for all the NGS panel testing done

Monitoring and evaluation

- Molecular advisory board within each network
- Reference to NGS in the MOC report
- Patient is better diagnosed and treated
- Patient satisfaction will be measured, collaboration of the hospitals is necessary
- Analyse data
- Evaluate the budgettary impact
- Identify the bottlenecks

NGS in the existing nomenclature by 2021

THANK YOU FOR YOUR ATTENTION