

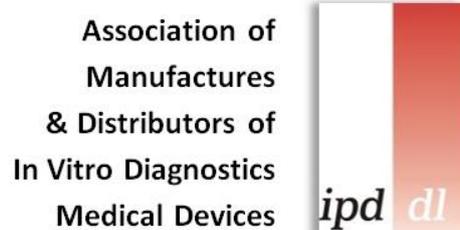


LABORATORY MEDICINE IN POLAND COST EFFICIENCY

Executive Summary

June 2017

LABORATORY MEDICINE IN POLAND COST EFFICIENCY



Deloitte.

Executive Summary

1. The belief that increasing the number of laboratory tests helps diagnosing diseases at less advanced stages – and thus reducing the cost of treatment – is supported by numerous studies conducted by medical associations with many years of medical practice. Verification of this view sufficient to meet scientific requirements was difficult in the past due, inter alia, to limitations on data availability and methodological shortcomings.
2. The "**Laboratory Medicine in Poland – Cost Efficiency**" report presents the results of over two years of work and is unique on the Polish market for several reasons:
 - **Interdisciplinary research** in medical and economic knowledge has led to the development of a methodology suitable for practical application.
 - **Several sources of information** were interlinked, including epidemiological and laboratory data provided by central and voivodships' divisions of NHF (National Health Fund) broken down by primary health care, outpatient specialist care and hospitals, supplemented by questionnaire data from a statistical sample of laboratories in Poland and national and foreign publications.
 - **The selection of five different disease entities** allowed for statistical analysis of the laboratory diagnosis process and for two of them – those which are characterised by stages of development (diabetes and chronic kidney disease – CKD) – **to build two econometric models**. The models provided evidence that the increase in the number of laboratory tests leads to the diagnosis of diseases at less advanced stages.
 - **Cost-efficiency analysis of early diagnosis** of diabetes and CKD was performed on the basis of estimated costs of medical procedures in line with medical practice and the estimated number of patients and using econometric models.
 - **The conservatism of estimates** is due to the highest possible diligence in the selection and elaboration of data, precautionary assumptions and the precision of the econometric modelling. This process used consultations with top specialists in different fields of medicine.
3. **The detection of analysed disease entities is based on laboratory diagnosis**, which indicates that there are medical and economic factors justifying preventive diagnosis and monitoring the treatment:
 - **Cardiovascular diseases:** atherosclerosis develops asymptotically for many years and usually reaches advanced stages before the advent of cardiovascular disease.
 - **Hepatitis B:** the acute phase may manifest itself clinically in a way that the virus is not obvious and many patients undergo latent infection. In the case of **hepatitis C**, a large proportion of patients undergo asymptotically both the acute and the chronic phases. The earlier the detection of chronic hepatitis B and hepatitis C, the greater the chance to stop the development of liver cirrhosis and the risk of *Hepatocellular carcinoma* and/or the need for transplantation. The earlier the treatment, the more effective and less expensive it is.
 - **Throat infection/tonsillitis:** the distinction between bacterial and viral infections can reduce the unjustified use of costly antibiotics that leads to dangerous antibiotic resistance among the population.

- **Chronic kidney disease:** the disease may remain asymptomatic until the last stage of renal failure; treatment might only be effective in the first and second stages; in stage III the goal is usually to stop progression of the disease; IV stage is preparation for dialysis/transplant in stage V.
 - **Diabetes:** in principle, diabetes mellitus can be asymptomatic until the stage of diabetes with complications, but even a small increase in blood glucose starts the process of degeneration of blood vessels, which is the cause of serious and costly complications. Regular monitoring of the level of diabetes can help stop vascular destruction. Therefore, the earlier the treatment is taken and monitored regularly, the more effective and less expensive it is.
4. Although in 2014-15 the growth rate of expenditure on IVD (in vitro diagnostic medical devices) significantly accelerated in Poland, its level is still among the lowest in Europe (8.5 euros per capita). The small expenditures here reflect the low level of development of Poland compared to other countries, accounting for 0.78‰ of GDP, i.e. above the EU-15 average (0.72‰ of GDP), although, for example the Czech Republic and Slovakia spend more than Poland not only nominally but also in relation to GDP (over 1‰ of GDP).
5. **In the majority of the analysed laboratory tests in 2012-15 we observed an upward trend.** At the same time, the prevalence rates of laboratory tests improved, i.e. the number of laboratory investigation in relation to the number of patients or the frequency of their visits at the doctor. However, data **from the Czech Republic** (a country with similar socio-economic and demographic characteristics) **indicate much more intensive use of laboratory tests in the diagnosis and treatment of selected diseases:**
- The frequency of testing the cardiovascular risk per 1,000 insured persons is 2-3-fold higher than in Poland.
 - ALT and HBsAg markers per 1,000 insured persons are four- to fivefold higher than in Poland. The disproportion in the outpatient care segment is even greater.
 - In the Czech Republic, swabs with antibiogram are taken on any patient, regardless of age and the nature of the infection – over 1,000 swabs per 1,000 throat and tonsils infections, against only 70 in Poland.
 - Creatinine markers per 1,000 insured patients are performed twofold more (more than 3 times for outpatients), urine albumin – over threefold (almost 12 times higher in outpatient segments).
 - The number of glucose tests (including OGTT – oral glucose tolerance test) in relation to all insured persons is more than threefold higher than in Poland (the same proportions after the exclusion of hospitals).
 - Czechs perform 30% more than in Poland of glycated hemoglobin on 1,000 patients with diabetes, especially in the context of primary health care, as the general prevalence of glycated hemoglobin in outpatient specialist care is lower than in Poland.
6. **The main shortcomings in the analysed laboratory medicine in Poland are as follows:**
- A full lipid profile in outpatient care is performed in the case of approximately 2/3 of total cholesterol determinations; there is a low prevalence of cardiovascular risk tests

(less than 150 lipid profiles per 1,000 patients covered by this sort of medical advice) in outpatient specialist care.

- HBV and HCV infection is poorly diagnosed in primary health care and is (partially) compensated by ALT markers. Covering with HBsAg test only part of HBV risk groups recommended by PGE HBV (Polish Group of Experts in HBV) would require at least 3.2 million tests annually, compared with 0.3 million currently performed (excluding tests performed at blood donation units).
 - The rate of creatinine in outpatient specialist care is low compared to selected advice (148 tests of creatinine per 1,000 nephrological, cardiovascular, diabetic and urological counselling). Estimates of diagnostic needs arising from the recommendations would require at least 12 million creatinine tests annually, against 6 million currently implemented.
 - The number of albumin determinations is negligible compared to the high proportion of GFR results > 60 ml/min – the total number of albumin in primary health care and outpatient specialist care is less than 2% of all creatinine tests.
 - Monitoring of the course of diabetes treatment with glycosylated hemoglobin is rare in primary health care (234 per 1,000 patients with diabetes). The number of glycosylated hemoglobin tests resulting from the PTD (Polish Diabetes Association) recommendation is approximately 3.5 million, while those under primary health care and outpatient specialist care is less than 0.8 million.
 - The test prevalence varies considerably between voivodships: disparities in primary health care prevalence between extreme groups of voivodships range from almost twofold to fourfold and within the framework of the outpatient specialist care from almost twofold to 32-fold. The highest prevalence outcomes within primary health care are noted for the voivodships of Dolnośląskie, Wielkopolskie and Zachodniopomorskie (the last one with a small exception); the least in the provinces of Podkarpackie and Kujawsko-Pomorskie. In the provinces of Wielkopolskie and Zachodniopomorskie in turn, but also in Łódzkie, one finds the least tests in relative terms under the outpatient specialist care. The "leader" in terms of the number of tests within the outpatient specialist care are the provinces of Mazowieckie and Lubelskie.
7. According estimates of the overall market, based on surveys conducted in a statistical sample of laboratories, **more than half (56%) of the market in the group of analysed tests is covered by National Health Fund contracts**. Private diagnostics complements the gap mainly in virological tests and to a lesser extent in the case of CRP, glucose in combination with OGTT, creatinine and ALT, but to a small degree in the case of the remaining tests (6-30% of the market).
8. **The cost gradations in treatment of disease entities for which cost-efficiency analysis was conducted (that is chronic kidney disease and diabetes) is very significant**. The average annual cost of treating a CKD patient in the I-III stage was estimated at PLN 120-138, compared to PLN 1,937 in stage IV and PLN 35,799 in stage V (a nearly 300-fold difference between I and V). For patients with diabetes-related conditions, the annual cost was estimated at PLN 5 in pre-diabetes compared to PLN 9,269 in diabetes with complications (an over 1800-fold difference).

9. Results from the CKD Model:

- From the CKD Model, which depicts the relationship between the number of patients in different stages of CKD and the number of performed creatinine tests, the higher the number of tests, the earlier the disease is diagnosed and the lower the cost of treatment.
- **Cost-efficiency analysis has shown that a 25% increase in creatinine testing results in savings to the National Health Fund of PLN 93-197 million per year at 2013 prices (direct medical costs), i.e. 5-9% of the annual costs, after taking into account the expenditure on additional tests.**
- Analysis has a static character and shows potential savings for the Payer from the moment of the full disclosure of the costs of treatment for those who would have been diagnosed earlier in the intensive testing variant. This moment appears in the tenth year from the start of the simulations. In an accumulated approach accrual with a 25% increase in the number of tests and a cautious progression of the disease over 10 years assumed, cumulative savings appear in the system after nine years. On other hand, it should be remembered that – firstly – the cost estimate is conservative and secondly, that the increase in the cost of treating CKD in the Variant of intensified testing is due to the medical care of people who are *de facto* suffering from the disease and who, due to insufficient diagnostics, are unaware, while in the Base Variant they are undergoing delayed care in many cases at a more advanced stage. The postponement of this cost in the Base Variant is a failure to the patient and finances of the healthcare system. Thirdly, the analysis was limited to direct medical costs only. Taking into account the indirect costs for the economy and the social costs of advancing in disease stages would further enhance the cost efficiency of early diagnosis in the case of CKD.

10. Results from the Diabetes Model:

- From the Diabetes Model, which describes the relationship between the number of patients with diabetes and the number of glucose tests, the higher the number of tests, the earlier the disease is diagnosed and the lower the cost of treatment.
 - **Cost-efficiency analysis has shown that, with an increase in glucose testing of 25%, annual National Health Fund savings for diabetes costs (direct medical costs) would be close to PLN 0.5 billion a year at 2013 prices, i.e. 11% of the annual costs, after taking into account the expenditure on additional tests.**
 - Taking into account indirect costs for diabetes resulting from reduced patient productivity increases the combined benefits for the economy to more than PLN 0.8 billion per year.
1. Taking into account demographic projection allows for a performing of dynamic simulations. Assuming that the pace of the disease progression in the Base Variant is consistent with the demographic prediction of diabetic patients, the savings for the National Health Fund – due to an intensification of testing by 25% – would increase gradually up the amount of PLN 0.5 billion within six years, however, cumulatively they would show up after two years already. The presented cost-efficiency analysis of laboratory medicine in the example of CKD and diabetes treatment is consistent with current medical and economic knowledge. Savings from direct medical costs of around 10% a year are significant, but together with indirect cost savings of minimum two thirds of the direct costs

savings imply macroeconomic impact on public finances and the economy as a whole. Therefore, **intensification of preventive diagnostics for other disease entities using cost-efficiency analysis should shape health policy in the medium and long term, i.e. from several to over a dozen years. The report has proved that prevention is cheaper than treatment.**

2. The model analysis for CKD and diabetes also shows that increasing the number of creatinine and glucose tests in the current diagnostic model **can increase the detection of a disease only to a certain degree. Therefore, systemic changes are necessary,** which:
 - Firstly, increase motivation for medical staff to systematically use preventive diagnostics (especially in the primary health care area).
 - Secondly, screen procedures for people at risk that are currently beyond primary health care regular coverage.
 - Thirdly, it is necessary to establish clear and common procedures and criteria for referring patients to testing within primary health care and, if necessary, to specialist care.
13. Work on the report and expert consultations have shown significant shortcomings in the quality and availability of statistical data needed to conduct cost-efficiency analyses. **The data should be rigorously collected at primary health care, outpatient specialist care and hospital levels, consolidated in NHF voivodship branches, verified at the NHF head office and regularly (e.g. quarterly) published by the Ministry of Health** (in the form of files available for calculation programmes). The above transparency in access to public data would contribute to interdisciplinary research and publicising analyses, which would allow for more effective use of limited public resources for health policy, which in turn – given the aging population – will require increasing funding.
14. This project was undertaken for **the Chamber of Manufacturers and Distributors of Laboratory Diagnostics** by a team of **Deloitte Consulting** experts: Rafał Antczak, Katarzyna Piętka-Kosińska, and Katarzyna Lada. Consultations on medical knowledge were provided by recognised experts: prof. Leszek Czupryniak, prof. Robert Flisiak, prof. Zbigniew Gaciong, prof. Waleria Hryniewicz, prof. Bogdan Solnica, prof. Tomasz Stompór and prof. Tomasz Zdrojewski. During the project the representatives of **the Chamber of Manufacturers and Distributors of Laboratory Diagnostics shared their best knowledge as well**, including the President Andrzej Banaszekiewicz, General Manager Józef L. Jakubiec, Members of the Board: Jarosław Wyligala, Norbert Krysiuk, Marian Chabuda and Sylwia Szelałowska – Assistant to the Board. However, the final content of the report is the responsibility of the authors.

