

BUDGET IMPACT ANALYSIS OF DIAGNOSTICS OF UNEXPLAINED AND/OR RECURRENT SYNCOPE USING AN IMPLANTABLE LOOP RECORDER

Objective

Syncope remaining unexplained after a conventional evaluation is a common and vexing medical problem. An implantable loop recorder (ILR) is a new diagnostic device used in diagnostics of recurrent syncope of unexplained etiology (NO). The aim of this analysis was to estimate the impact of ILR reimbursement in NO diagnostics on the public payer's budget in Poland.

Methodology

An implantable loop recorder is a small device implanted subcutaneously. It has the ability to record the electrical activity of the heart, store rhythm disturbances within set parameters and can be triggered by the patient to store cardiac events occurring during a syncope episode.

In accordance with the European Society of Cardiology (ESC) guidelines, implantation of an ILR is recommended in case of syncope of etiology remaining unexplained despite full diagnostic evaluation. An implantable loop recorder is especially indicated for patients with recurrent syncope or with documented history of injury during a syncope episode. Guidelines do not precise what diagnostic tests are required before ILR implantation, but, due to its relatively high cost, suggest application of ILR after comprehensive conventional evaluation using all currently available diagnostic methods.

According to the indications mentioned above, the target population for ILR application in this analysis may be defined as follows:

- adults aged over 18 years with at least one syncope episode,
- syncope with a history of injury or recurrent syncope,
- the mechanism of syncope remaining unexplained after conventional diagnostic evaluation.

In the analysis application of ILR was compared with repeated application of conventional diagnostic tests currently reimbursed in Poland, including methods presented in Table 1.

Table 1. Conventional diagnostic tests used in diagnostics of syncope

Conventional diagnostic tests in diagnostics of syncope	
Initial evaluation (including history taking, physical examination and baseline electrocardiography)	• Exercise test • ATP test • Coronary angiography • External loop recorders (ELR) • Electroencephalography (EEG) • Computed tomography (CT)
24-hour ECG (Holter) monitoring	• Magnetic resonance imaging (MRI)
Echocardiography (ECHO)	• Carotid Doppler ultrasonography
Electrophysiological testing	• Neurological consultation
Carotid sinus massage	• Psychiatric consultation
Tilt testing	

The analysis was performed in a 5-year time horizon from the public payer's (National Health Fund; NHF) perspective. It was assumed that the only change in the reimbursement principles in Poland concerning diagnostic tests used in the analyzed indication will be introduction of full ILR reimbursement for patients with NO. Prognosis of financial consequences of this decision for the public payer's budget was the aim of this analysis.

Current Polish reimbursement system allows for three variants of ILR funding in patients with NO. Brief description of these solutions is presented in Table 2. Costs incurred by the public payer for health care services do not differ between the listed variants and therefore results of the analysis are presented regardless of the solution applied.

Table 2. Considered variants of ILR funding in patients with NO

Variant	Description
New DRG	In the DRG system patients are classified into groups according to the principal diagnosis, disease status, age and other relevant criteria. Each group consists of patients, in whom clinically similar treatments are applied and roughly the same level of resources is used. In this variant it was assumed that a new DRG group would be created for patients with NO diagnosed using an ILR device.
New health care service	In this variant it was assumed that a new, separately contracted health care service will be created in the Polish system. The service would be reimbursed according to the NHF catalogue point value.
Therapeutic program	A therapeutic program would include all diagnostic procedures related to ILR application (implantation and removal of an ILR device as well as patient monitoring). These would be reimbursed jointly with a lump sum.

The costs taken into account in the analysis included:

- costs of the initial evaluation of patients in the target ILR population,
- costs related to the use of an ILR device (including the cost of the device itself, its implantation and removal, and costs of patient monitoring),
- costs of conventional diagnostic evaluation (using conventional diagnostic tests).

Costs of hospitalizations and outpatient visits were also considered. Cost data were obtained from data made publicly available by the National Health Fund. Data concerning medical resource use were taken directly from the PL-US registry – a source of information on Polish clinical practice in diagnostics of patients with NO. In sensitivity analysis data reported in epidemiological studies and the ESC guidelines were considered.

In the analysis two scenarios were compared:

- current scenario (ILR reimbursement only in special cases),
- predicted scenario (full ILR reimbursement).

In the predicted scenario two options for financing of patient monitoring after ILR implantation were analyzed – AOS and KAOS. In either option different methods of funding were assumed, resulting in generation of different costs. Description of both options is presented in Table 3.

Table 3. Reimbursement options of patient monitoring after ILR implantation.

Option	Description	Reimbursement level
AOS	Health care services are reimbursed separately, according to the NHF catalogue point value.	
KAOS	All health care services provided within one year are reimbursed jointly, according to annual value established in the NHF catalogue	100% reimbursement

Summary

Objective: Syncope remaining unexplained after a conventional evaluation is a common and vexing medical problem. An implantable loop recorder (ILR) is a new diagnostic device used in diagnostics of recurrent syncope of unexplained etiology (NO). The aim of this analysis was to estimate the impact of ILR reimbursement in NO diagnostics on the public payer's budget in Poland.

Methods: The analysis was performed in a 5-year time horizon from the public payer's perspective. Information regarding target population and medical resources was extracted from literature and the PL-US registry. Data in the PL-US registry were collected in the years 2006-2008 in 18 Polish centres. Cost data were obtained from the National Health Fund. In the analysis two scenarios were compared: current (ILR reimbursement only in special cases) and predicted (full ILR reimbursement). In the predicted scenario two options for financing of patient monitoring after ILR implantation were analyzed – AOS and KAOS. One-way sensitivity analysis was performed for the key input parameters.

Results: The size of the ILR implantation target population in Poland is stable – approximately 2,370 patients. In the current scenario, the estimated annual public payer's expenditure for NO diagnostics in the years 2010-2014 was approximately 9.00 million PLN, including the ILR cost of 0.25 million PLN. Assuming reimbursement of the ILR, the estimated public payer's expenditure for NO diagnostics in the AOS option was 9.77 million PLN in 2010 and 16.76 million PLN in 2014, including the ILR costs of 1.44 million PLN and 11.34 million PLN, respectively. In the KAOS option the public payer's expenditure was 9.86 million PLN in 2010 and 18.49 million PLN in 2014, including the ILR costs of 1.53 million PLN and 13.07 million PLN, respectively.

Conclusion: Our findings suggest that a positive decision concerning ILR reimbursement should not lead to a higher increase in the public payer's total expenses on NO diagnostics than 0.95 million PLN in 2010 and 10.00 million PLN in 2014.

Target population

Estimation of the target population size in Poland was based on data obtained from European epidemiological studies and the PL-US registry. The PL-US (PoLish patients with Unexplained Syncope) registry is a special internet database which includes detailed demographic and clinical characteristics of 669 patients diagnosed with NO in Poland. Data in the PL-US registry have been collected in the years 2006-2008 in 18 Polish cardiology centres and reflect clinical practice in diagnostics of syncope of unexplained etiology in Poland.

Introduction of a new technology to the reimbursement list will probably change market shares of currently reimbursed diagnostic tests. The number of implantable loop recorders used in consecutive 5 years in Polish patients with NO was estimated based on the sales data from 5 European countries (Great Britain, Germany, the Netherlands, Finland and Sweden), where ILR has already been reimbursed in that indication. Application of ILR in patients with NO requires a specially qualified staff and full diagnostic equipment, enabling complete evaluation of a patient with syncope. Due to these conditions, in the first years after introduction of ILR reimbursement probably not all Polish cardiology centres will be fully capable of ILR application. Estimated numbers of patients (Figure 1) diagnosed with NO and implanted with an ILR in the years 2010-2014 in Poland reflect this limitation.

In the current scenario it was assumed that an ILR device was used in 40 Polish patients annually (in special cases, financed by the public payer).

One-way sensitivity analysis was performed for the key input parameters. The values and sources of the parameters considered are presented in Table 4. Values printed in bold were used in the basic analysis.

Structure of the analysis is illustrated in Figure 2.

Table 4. Parameters considered in one-way sensitivity analysis

Parameter	Variant	Value	Source
Prevalence of syncope	Mean value	0.088%	
	Minimum value	0.080%	Alshekhee 2009
	Maximum value	0.093%	
Proportion of patients with NO	Mean value	8.67%	The PL-US registry
	Minimum value	6.33%	Epidemiological studies
	Maximum value	10.30%	
The ILR market share in the Polish target population	Market share according to sales data	42.27% - 2010 57.35% - 2011 66.16% - 2012 72.42% - 2013 77.27% - 2014	Sales data
	Market share according to the PL-US registry	72.41% in each year	The PL-US registry
	Market share according to studies	58.13% in each year	Epidemiological studies
	Data from the PL-US registry		The PL-US registry
	According to the ESC guidelines		The ESC guidelines
Conventional diagnostic tests use	Minimum cost	Cost of MRI and CT without contrast agent	
	Maximum cost	Cost of MRI and CT without or with contrast agent	
			Epidemiological studies

Figure 1. Estimation of the target population size for ILR application

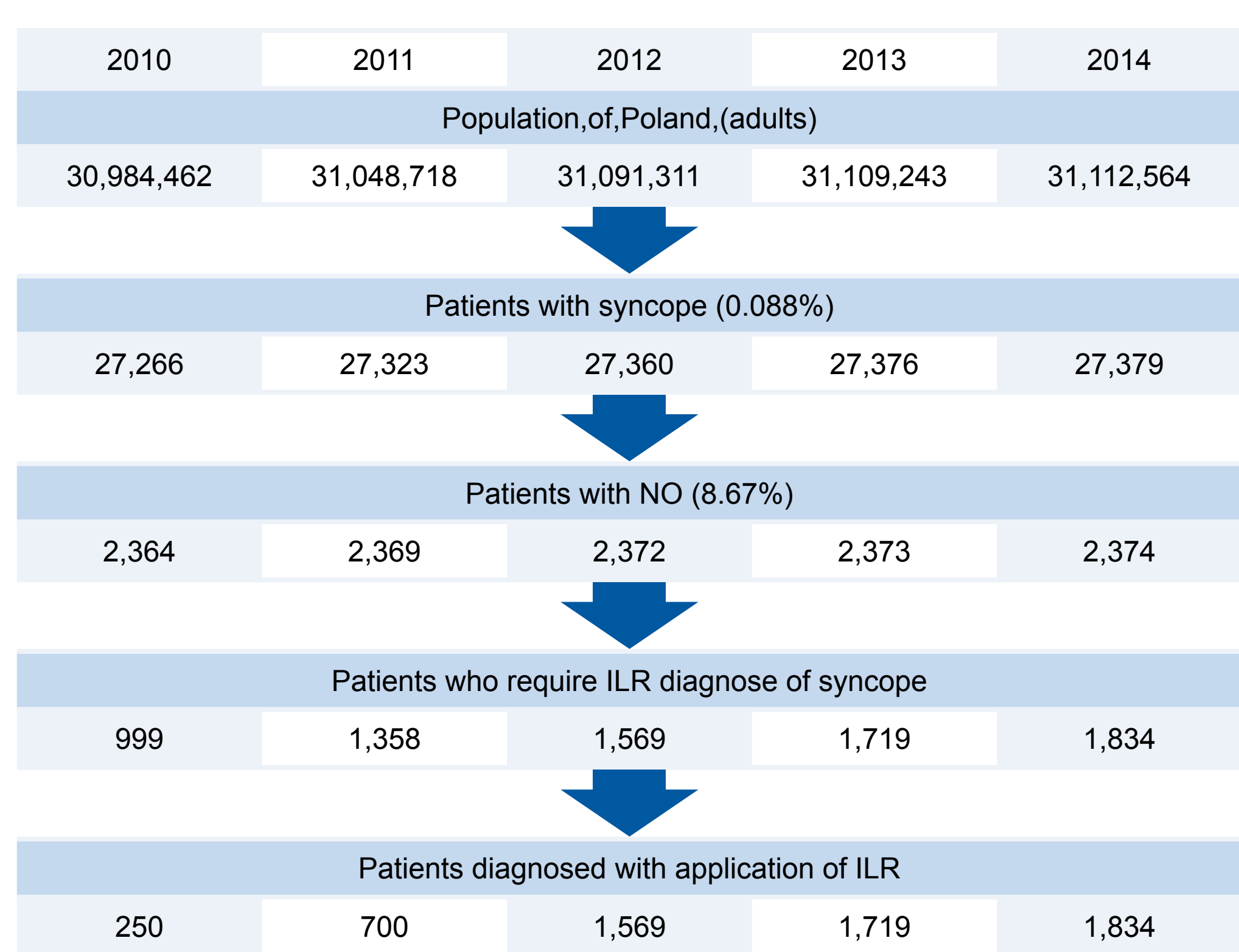
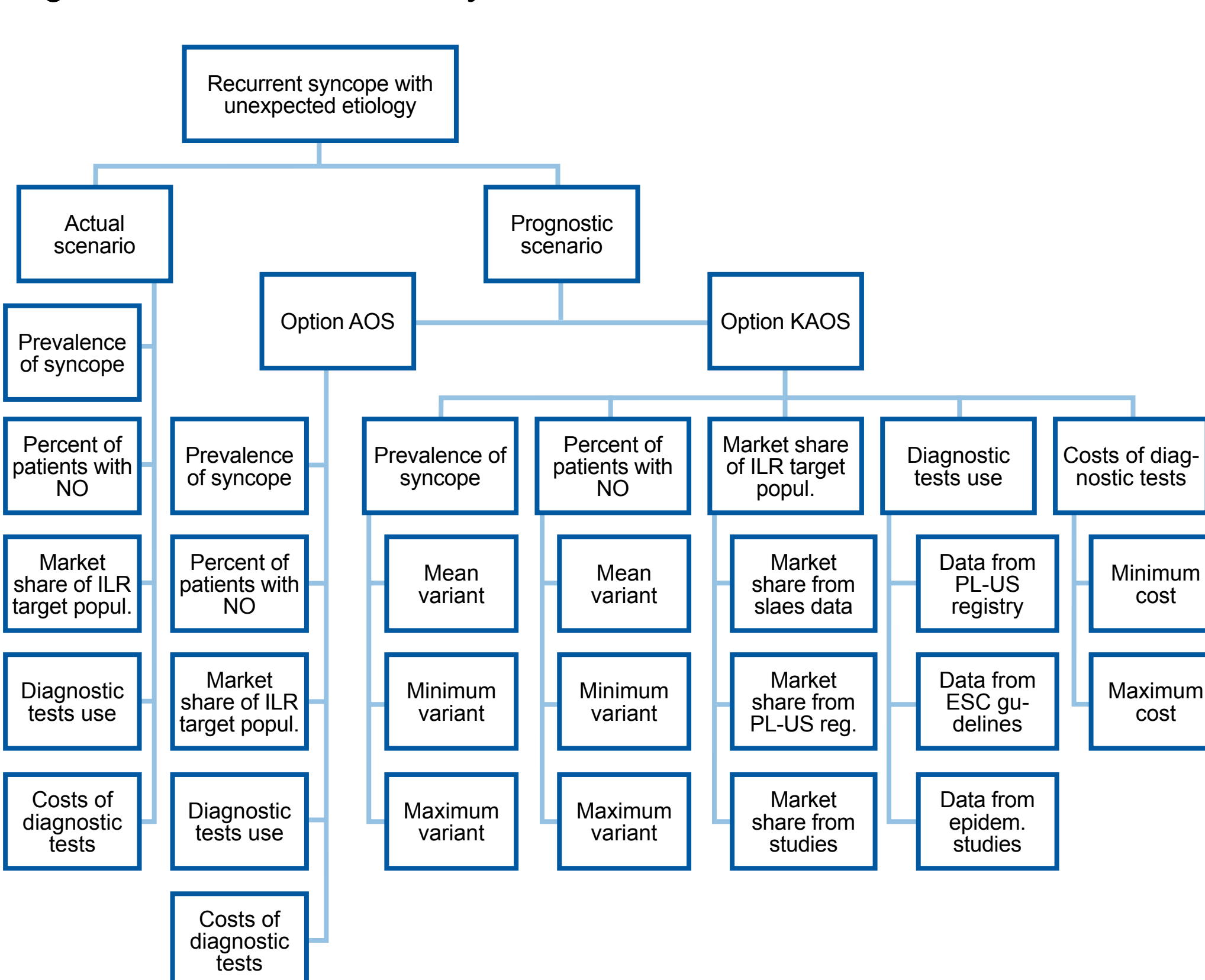


Figure 2. Structure of the analysis



Conclusion

The aim of this analysis was to predict the impact of full ILR diagnostics reimbursement on the public payer's budget in the years 2010-2014 in Poland. In the analysis two alternative funding options for monitoring of patients with ILR were considered:

- AOS – the services provided are reimbursed separately, according to the NHF catalogue point value,
- KAOS – all services provided within one year are reimbursed jointly, with a lump sum established by the NHF.

Expected changes in total public payer's expenditure on NO diagnostics resulting from ILR reimbursement in both options are presented in Table 10.

Assuming introduction of ILR reimbursement, expected total change in the public payer's expenses incurred on NO diagnostics is 0.80 million PLN in 2010 and 7.75 in 2014 in case of the AOS option and 0.89 million PLN and 9.48 million PLN, respectively, in case of the KAOS option. Findings of sensitivity analysis suggest that a positive decision concerning ILR reimbursement should not lead to a higher increase in the public payer's total expenses on NO diagnostics than 0.86 million PLN in 2010 and 8.27 million PLN in 2014 in case of the AOS option, and 0.95 million PLN in 2010 and 10.0 million PLN in 2014 in case of the KAOS option. Prevalence of syncope turned out to be the uncertainty factor having the highest effect on predicted public payer's expenditure on NO diagnostics among the parameters considered in the analysis.

Results

Current scenario (reimbursement of ILR only in special cases)

In the current scenario it was assumed that an ILR device was used in 40 patients with NO.

In the current scenario estimated annual public payer's expenditure for NO diagnostics (2010-2014) was approximately 9.00 million PLN, including the ILR cost of 0.25 million PLN.

Table 5. Predicted ILR target population size in the years 2010-2014 (current scenario)

Diagnostic strategies	2010	2011	2012	2013	2014
ILR	40	40	40	40	40
Conventional diagnostic strategy	2,324	2,329	2,332	2,333	2,334
Target population	2,364	2,369	2,372	2,373	2,374

Table 6. Predicted public payer's expenditure on reimbursement of NO diagnostics in the years 2010-2014 (current scenario)

Cost categories	2010	2011	2012	2013	2014
Initial evaluation	4.40	4.41	4.42	4.42	4.42
ILR	0.25	0.25	0.25	0.25	0.25
ILR implantation	0.02	0.02	0.02	0.02	0.02
Cost of the ILR device	0.20	0.20	0.20	0.20	0.20
ILR removal	0.02	0.02	0.02	0.02	0.02
Cost of other diagnostic tests	0.00	0.00	0.00	0.00	0.00
ILR monitoring	0.01	0.01	0.01	0.01	0.01
Conventional diagnostic evaluation	4.33	4.34	4.34	4.34	4.34
Total cost of NO diagnostics	8.98	9.00	9.01	9.01	9.01

Predicted scenario (full ILR reimbursement)

Assuming full ILR reimbursement in consecutive 5 years, the estimated number of patients diagnosed with NO and using an ILR device would gradually increase from 250 in 2010 to 1,834 in 2014.

Table 7. Predicted ILR target population size in the years 2010-2014 (predicted scenario)

Diagnostic strategies	2010	2011	2012	2013	2014
ILR	250	700	1,569	1,719	1,834
Conventional diagnostic strategy	2,114	1,669	803	655	540
Target population	2,364	2,369	2,372	2,373	2,374

AOS option

Assuming the AOS option in the predicted scenario, estimated public payer's expenditure for NO diagnostics was 9.77 million PLN in 2010 and 16.76 million PLN in 2014, including ILR costs of 1.44 million PLN and 11.34 million PLN, respectively.

Table 8. Predicted public payer's expenditure on reimbursement of NO diagnostics in the years 2010-2014. (predicted scenario, AOS option)

Cost categories	2010	2011	2012	2013	2014
Initial evaluation	4.40	4.41	4.42	4.42	4.42
ILR	1.44	4.00	9.06	10.20	11.34
ILR implantation	0.13	0.36	0.81	0.88	0.94
Cost of the ILR device	1.27	3.54	7.94	8.70	9.28
ILR removal	0.02	0.02	0.13	0.36	0.81
Cost of other diagnostic tests	0.01	0.03	0.08	0.08	0.09
ILR monitoring	0.01	0.04	0.10	0.18	0.22
Conventional diagnostic strategy	3.94	3.11	1.49	1.22	1.00
Total cost of NO diagnostics	9.77	11.51	14.97	15.84	16.76

KAOS option

Assuming the KAOS option in the predicted scenario, estimated public payer's expenditure for NO diagnostics was 9.86 million PLN in 2010 and 18.49 million PLN in 2014, including ILR costs of 1.53 million PLN and 13.07 million PLN, respectively.

Table 9. Predicted payer's expenditure on reimbursement of NO diagnostics in the years 2010 - 2014. (predicted scenario, KAOS option)

Cost categories	2010	2011	2012	2013	2014
Initial evaluation	4.40	4.41	4.42	4.42	4.42
ILR strategy	1.53	4.30	9.86	11.62	13.07
ILR implantation	0.12	0.34	0.76	0.83	0.88
Cost of the ILR device	1.27	3.54	7.94	8.70	9.28
ILR removal	0.02	0.02	0.12	0.34	0.76
Cost of other diagnostic tests	0.01	0.03	0.07	0.07	0.08
ILR monitoring	0.11	0.38	0.97	1.68	2.07
Conventional diagnostic tests	3.94	3.11	1.49	1.22	1.00
Total cost of NO diagnostics	9.86	11.82	15.77	17.25	18.49

Table 11. Abbreviations

CT	Computed tomography
ECG	Electrocardiography
ESC	European Society of Cardiology
DRG	Diagnosis Related Groups
ILR	Implantable loop recorder
MRI	Magnetic resonance imaging
NHF	National Health Fund
NO	Recurrent syncope of unexplained etiology
PL-US	PoLish patients with Unexplained Syncope Registry

Table 10. Predicted changes in the payer's expenditure on NO diagnostics reimbursement in the years 2010-2014

Cost categories	2010	2011	2012	2013	2014
Changes of the public payer's expenditure on ILR					
AOS	1.19	3.75	8.81	9.95	11.09
KAOS	1.28	4.05	9.61	11.37	12.82
Changes of the public payer's expenditure on conventional diagnostic tests					
AOS	-0.39	-1.23	-2.85	-3.13	-3.34
KAOS	-0.39	-1.23	-2.85	-3.13	-3.34
Total changes in the public payer's expenditure on NO diagnostics					
AOS	0.80	2.52	5.96	6.83	7.75
KAOS	0.89	2.82	6.76	8.24	9.48