OPTIMIZATION OF CARE FOR PATIENTS WITH MULTIPLE SCLEROSIS IN POLAND - FROM EBM TO VBHC

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Health and Disease Management Institute

EBHC, Kraków, Poland, 7.10.2019

Research & Lecture supported by Biogen

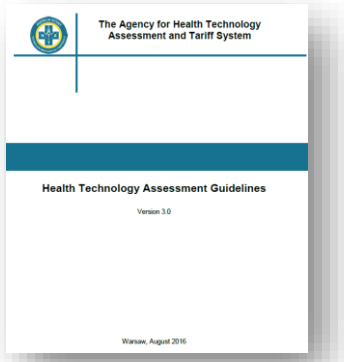
EVOLUTION FROM EBM TO VBHC IN POLISH HEALTHCARE SYSTEM

EBM

1990 – Workshops: Prof. Roman Jaeschke & Prof. Gordon Guyatt z McMaster University (Hamilton, Ontario, Canada). Support: Medycyna Praktyczna/ Centrum Monitorowania Jakości w Ochronie Zdrowia (CMJ)

HTA

2007 – HTA guidelines PolAHTA [1]



VBHC

2019 - VBHC workshops and reports [2]

NHF Strategy for 2019-2023 (Effectiveness) [3]

1. http://www.aotm.gov.pl/www/wp-content/uploads/wytyczne_hta/2016/20160913_Wytyczne_AOTMiT.pdf
2. https://www.infarma.pl/raporty/raporty-infarmy/raport-VBHC.pdf/ https://innowo.org/userfiles/publikacje/Raport_otwarcia_VBHC.pdf
3. https://nfz.gov.pl/aktualnosci/aktualnosci-centrali/narodowy-fundusz-zdrowia-ze-strategia-rozwoju,7327.html

EVOLUTION FROM EBM TO VBHC IN MUTIPLE SCLEROSIS CARE IN POLAND

EBM

Clinical standards: Losy, 2016 [4]


REKOMENDACJE

ISSN 1734-5251

www.neuroedu.pl OFICJALNE PORTALE INTERNETOWE PTN www.ptneuro.pl

Leczenie stwardnienia rozsianego — zalecenia Polskiego Towarzystwa Neurologicznego

Jacek Losy[1, 2], Halina Bartosik-Psujek[3], Anna Członkowska[4], Katarzyna Kurowska[4], Zdzisław Maciejek[5], Dagmara Mirowska-Guzel[4, 6], Andrzej Potemkowski[7], Danuta Ryglewicz[8], Adam Stępień[9]

HTA

Recommendations for reimbursement by PolAHTA

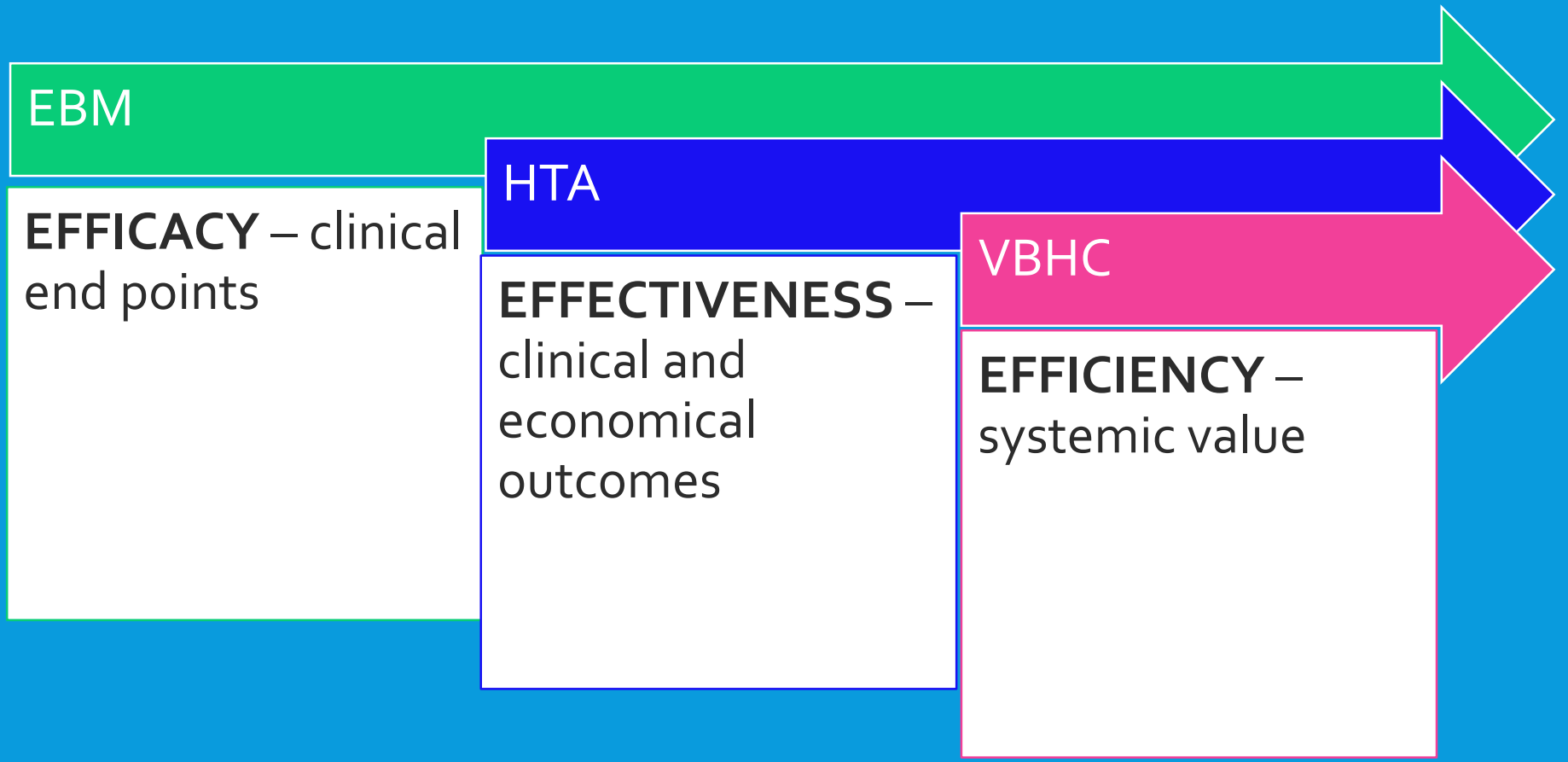
- new drugs
- >5 years treatment

VBHC

Coordinated care – NHF KOSM project [5]

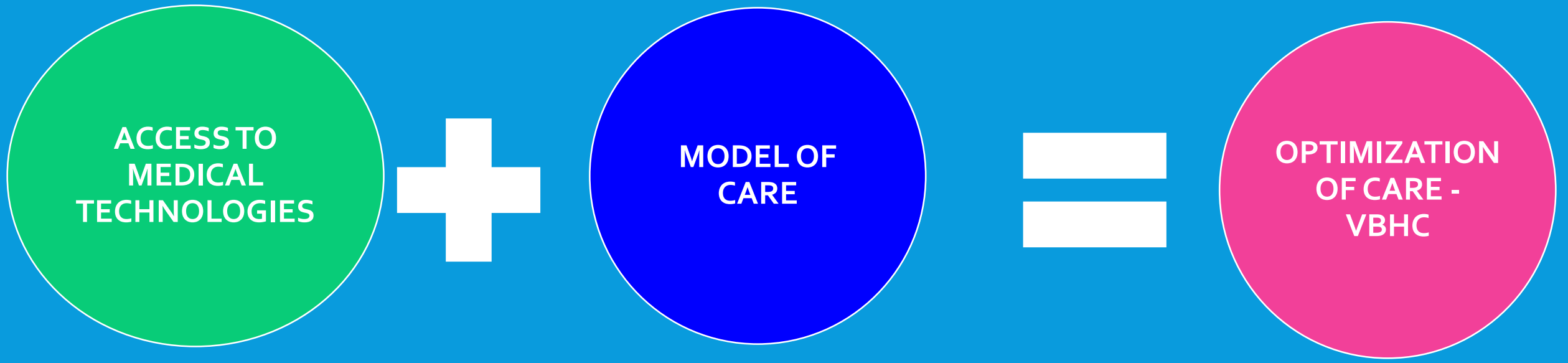
[4] https://journals.viamedica.pl/polski_przeglad_neurologiczny/article/view/48570
[5] https://www.nfz.gov.pl/zarzadzenia-prezesa/projekty-zarzadzen/projekt-zarzadzenia-program-pilotazowy-w-zakresie-leczenia-szpitalnego-kompleksowa-opieka-w-stwardnieniu-rozsianym-kosm,6594.html

EVOLUTION FROM EBM TO VBHC IN MUTIPLE SCLEROSIS CARE IN POLAND



Source: Jakub Gierczyński, 2019

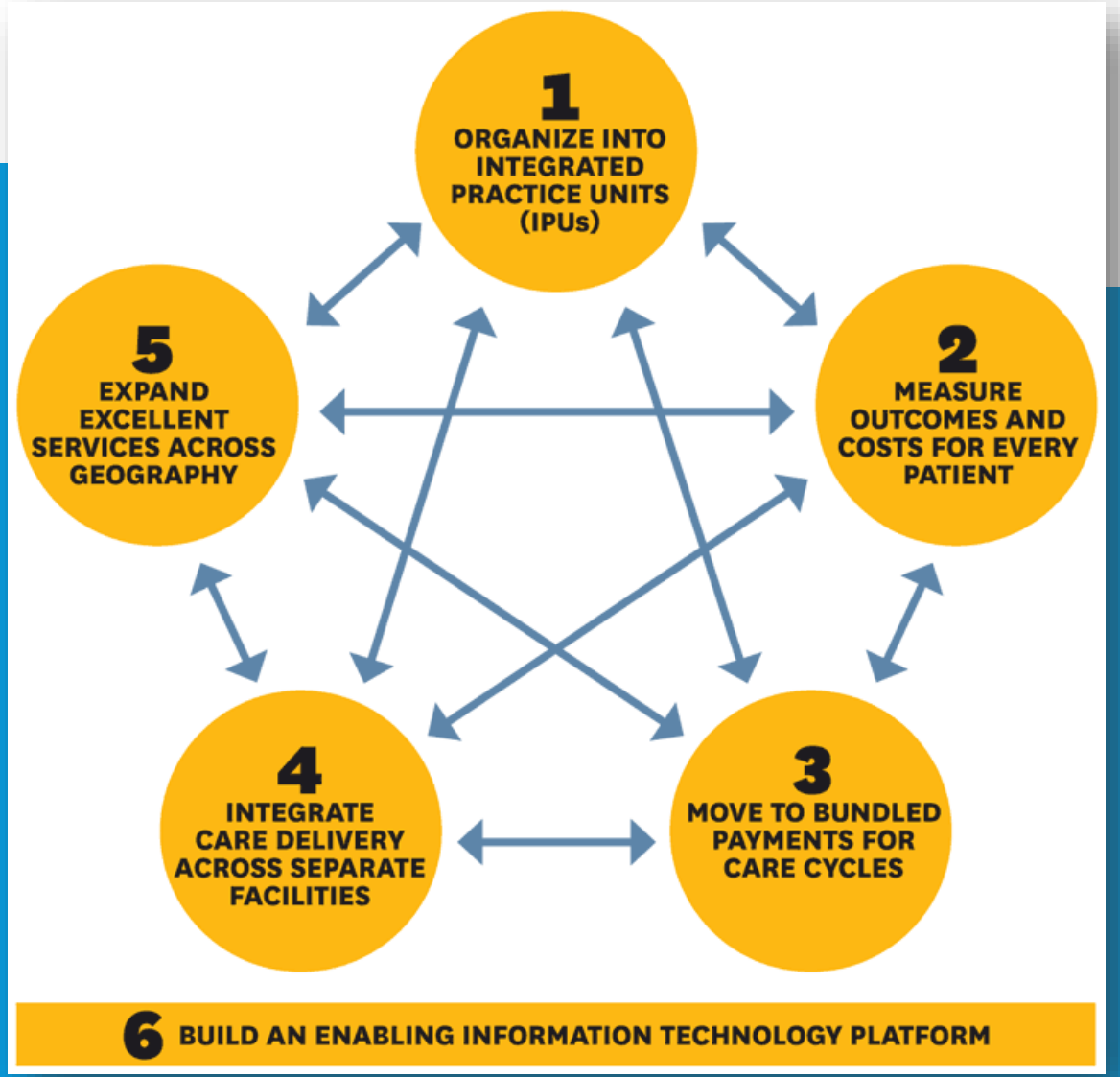
OPTIMIZATION OF CARE FOR PATIENTS WITH MULTIPLE SCLEROSIS



[5] https://www.hsph.harvard.edu/eugene-litvak/institute-for-healthcare-optimization-wwwihoptimizeorg/

VBHC INDICATORS

- **Integrated and coordinated model of care**
- **Outcomes:**
  - **Time** to diagnosis/ time from diagnosis to DMT treatment
  - Patient's **access to DMT:** treated vs. diagnosed / waiting for DMT / old vs. new DMT
  - Indicators/Registries
  - PROMs/PREMs [6]
- **Total costs:** Nationa Health Fund (NFZ)/Social Insurance Institution (ZUS)



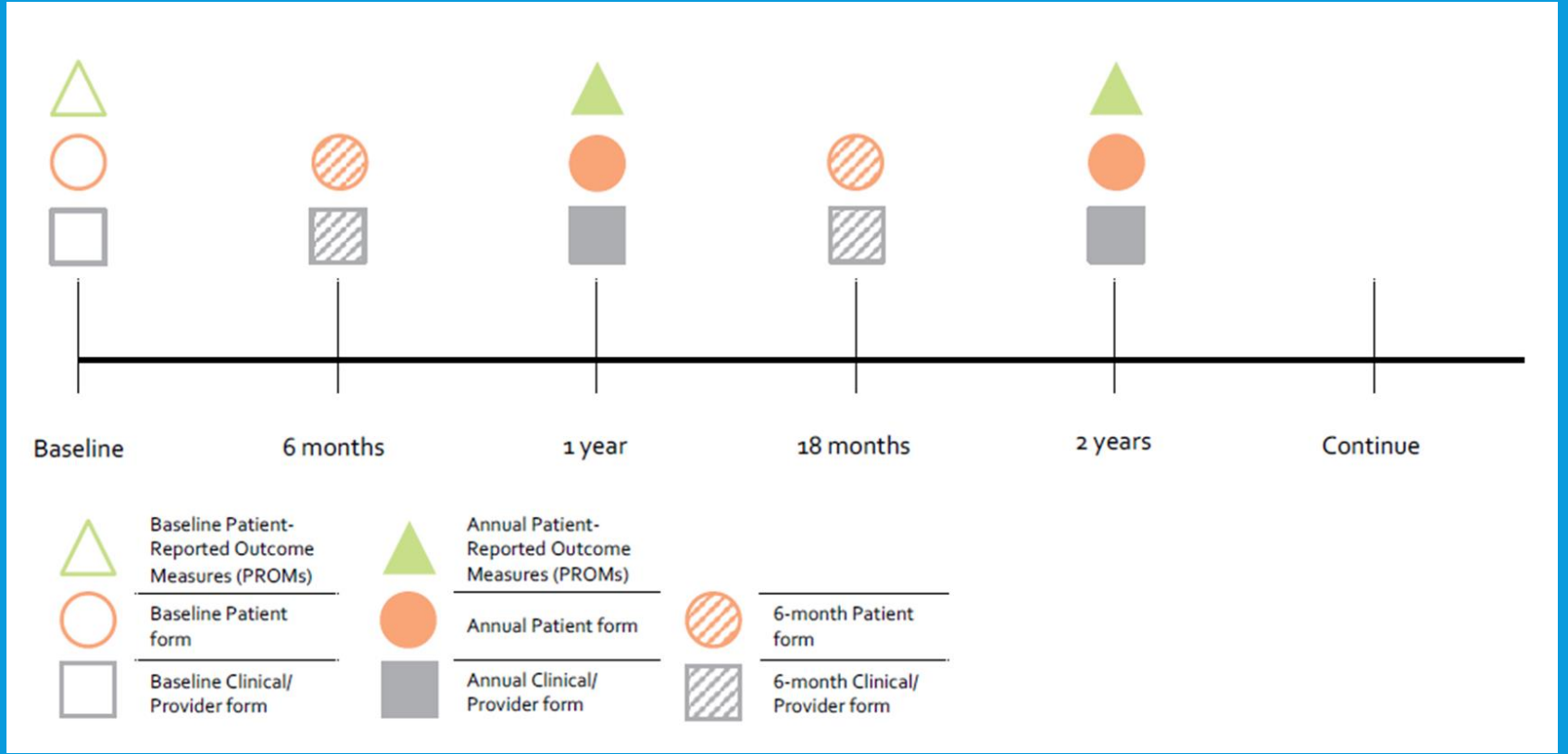
[7] https://hbr.org/2013/10/the-strategy-that-will-fix-health-care

[6] PROMs in standard MS care ECTRIMS Online Library. Solari A. Sep 12, 2019; 279486; 195

INTEGRATED AND COORDINATED MODEL OF CARE

OPTIMIZATION OF CARE FOR PATIENTS WITH MULTIPLE SCLEROSIS

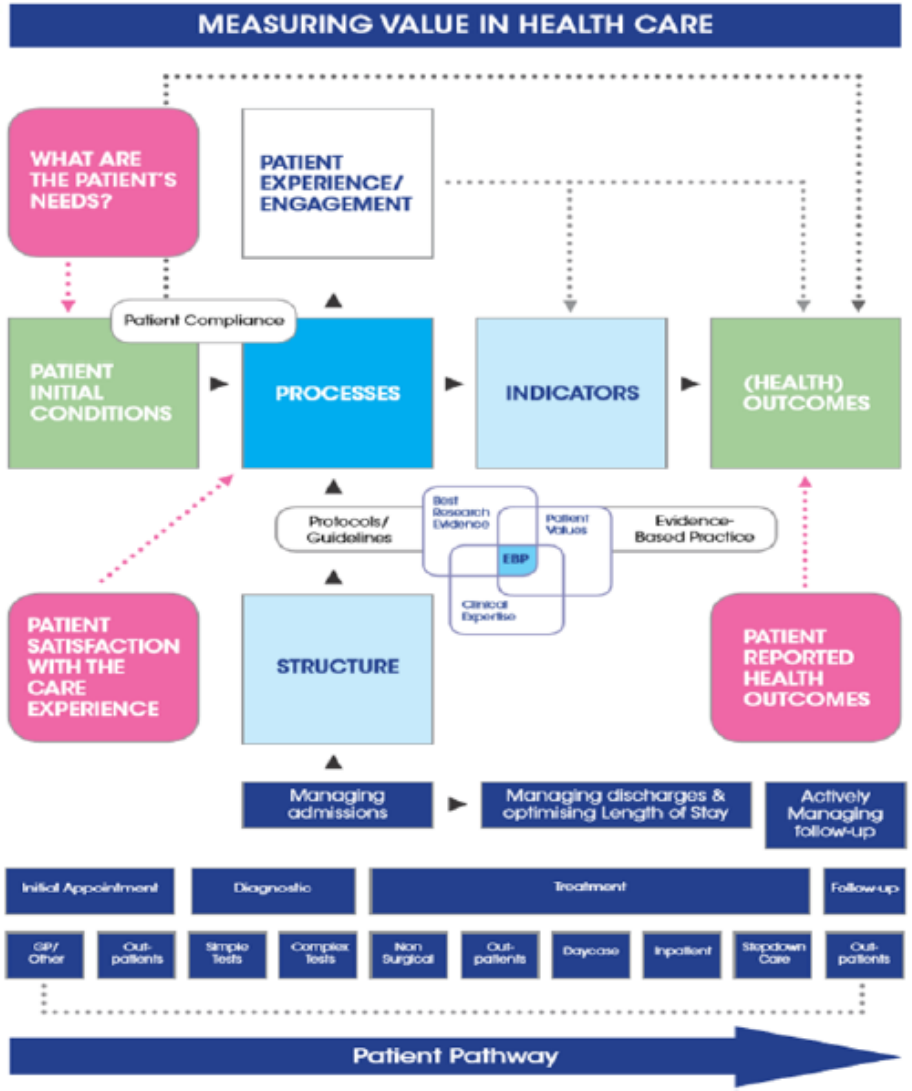
A very important aspect is monitoring the path of each patient in terms of inhibition or reduction of complications related to MS and paying healthcare providers for the effect (value) achieved in a defined period of time [8]



[8] https://ichom.org/files/medical-conditions/diabetes-in-adults/dia-reference-guide.pdf

The Care Pathway Approach

Optimizing healthcare processes with an outcomes-based approach: care pathways enable health systems (and other health care organizations) to make evidence-based decisions about where to focus improvement efforts for better outcomes.



Source: Adapted from M.E. Porter What is value in healthcare? NEJM 2014 ;363 :2477-2481.

[9] https://www.infarma.pl/assets/files/2019/VBHC/Prezentacja_Vinciane_Quoidbach.pdf

CURRENT CLINICAL STANDARDS ECTRIMS/EAN

[10] https://journals.sagepub.com/doi/pdf/10.1177/1352458517751049

MULTIPLE SCLEROSIS JOURNAL | MSJ

Clinical Guideline

ECTRIMS/EAN Guideline on the pharmacological treatment of people with multiple sclerosis

Multiple Sclerosis Journal
2018, Vol. 24(2) 96–120
DOI: 10.1177/1352458517751049

Xavier Montalban, Ralf Gold, Alan J Thompson, Susana Otero-Romero, Maria Pia Amato, Dhia Chandraratna, Michel Clanet, Giancarlo Comi, Tobias Derfuss, Franz Fazekas, Hans Peter Hartung, Eva Havrdova, Bernhard Hemmer, Ludwig Kappos, Roland Liblau, Catherine Lubetzki, Elena Marcus, David H Miller, Tomas Olsson, Steve Pilling, Krysztof Selmaj, Axel Siva, Per Soelberg Sorensen, Maria Pia Sormani, Christoph Thalheim, Heinz Wiendl and Frauke Zipp

Abstract

Background: Multiple sclerosis (MS) is a complex disease with new drugs becoming available in the past years. There is a need for a reference tool compiling current data to aid professionals in treatment decisions.

Objectives: To develop an evidence-based clinical practice guideline for the pharmacological treatment of people with MS.

Methods: This guideline has been developed using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology and following the updated EAN recommendations. Clinical questions were formulated in Patients–Intervention–Comparator–Outcome (PICO) format and outcomes were prioritized. The quality of evidence was rated into four categories according to the risk of bias. The recommendations with assigned strength (strong and weak) were formulated based on the quality of evidence and the risk-benefit balance. Consensus between the panelists was reached by use of the modified nominal group technique.

Results: A total of 10 questions were agreed, encompassing treatment efficacy, response criteria, strategies to address suboptimal response and safety concerns and treatment strategies in MS and pregnancy. The guideline takes into account all disease-modifying drugs approved by the European Medicine Agency (EMA) at the time of publication. A total of 21 recommendations were agreed by the guideline working group after three rounds of consensus.

Conclusion: The present guideline will enable homogeneity of treatment decisions across Europe.

Keywords: Multiple sclerosis, guideline, disease-modifying therapies, GRADE methodology

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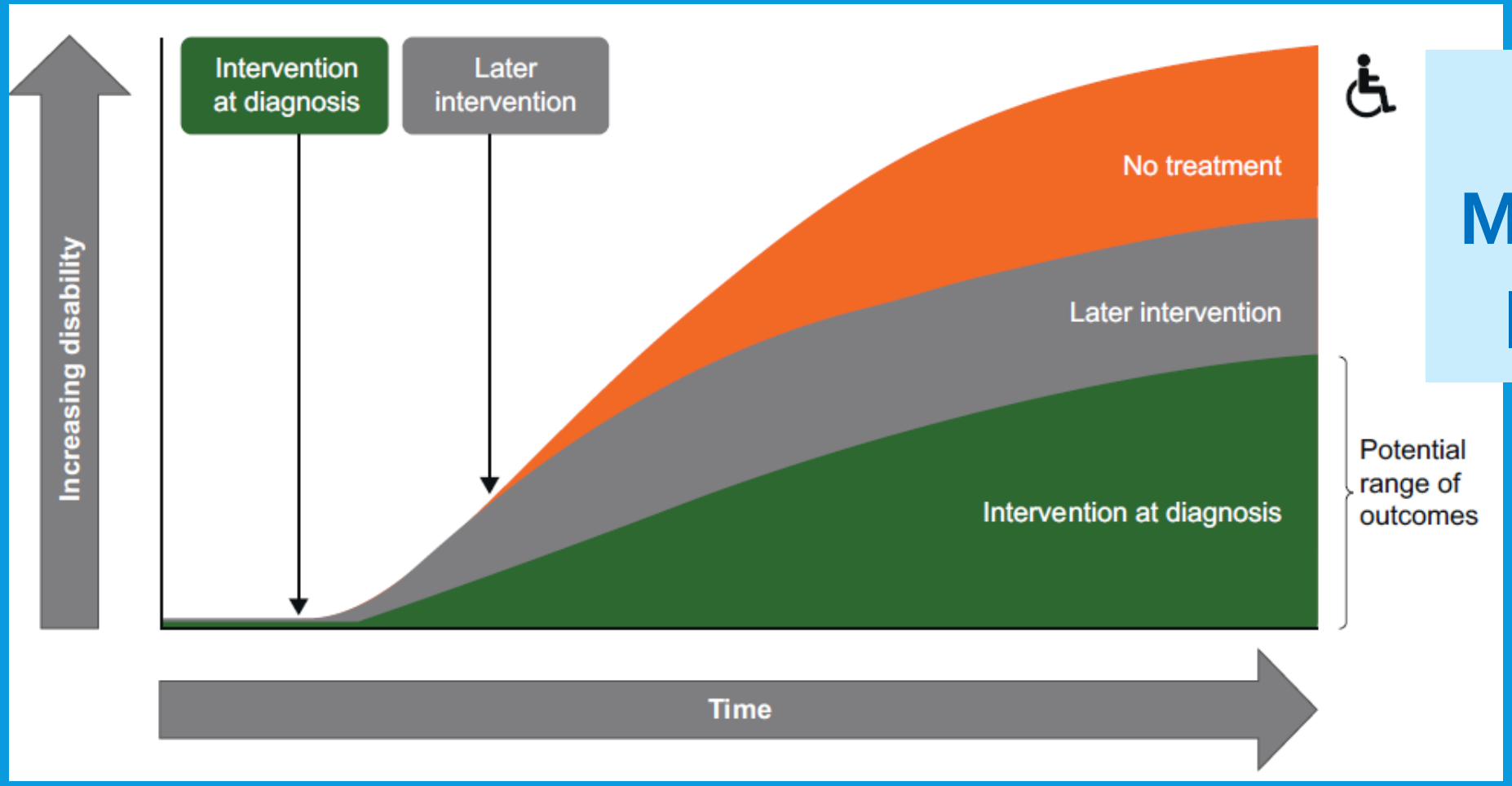
Background and scope

Multiple sclerosis (MS) is an inflammatory-demyelinating disease of the central nervous system (CNS) that is characterized by inflammation, demyelination and degenerative changes. MS usually begins around the age between 20 and 40 years and affects two to three times as many women as men; it also constitutes the most frequent cause of non-traumatic disability in the young adult population.[1] The incidence of MS varies across regions, with rates as high as 8 to 10 new cases per 100,000 in high latitudinal regions.[2,3] Current estimates suggest that over 700,000 people are affected in Europe, with over 2.5 million cases worldwide,[4] which represent a significant burden in terms of impact on quality of life, societal costs and personal expenses.[5,6] Most patients (85%–90%) have a relapsing course from onset that is characterized by relapses and remissions of neurological symptoms

TIME

EARLY INTERVENTION WITH A DMT IN MS GIVE THE BEST LONG-TERM PROGNOSIS,
GIOVANNONI ET AL, 2016 [11]



TIME MATTERS IN MS!

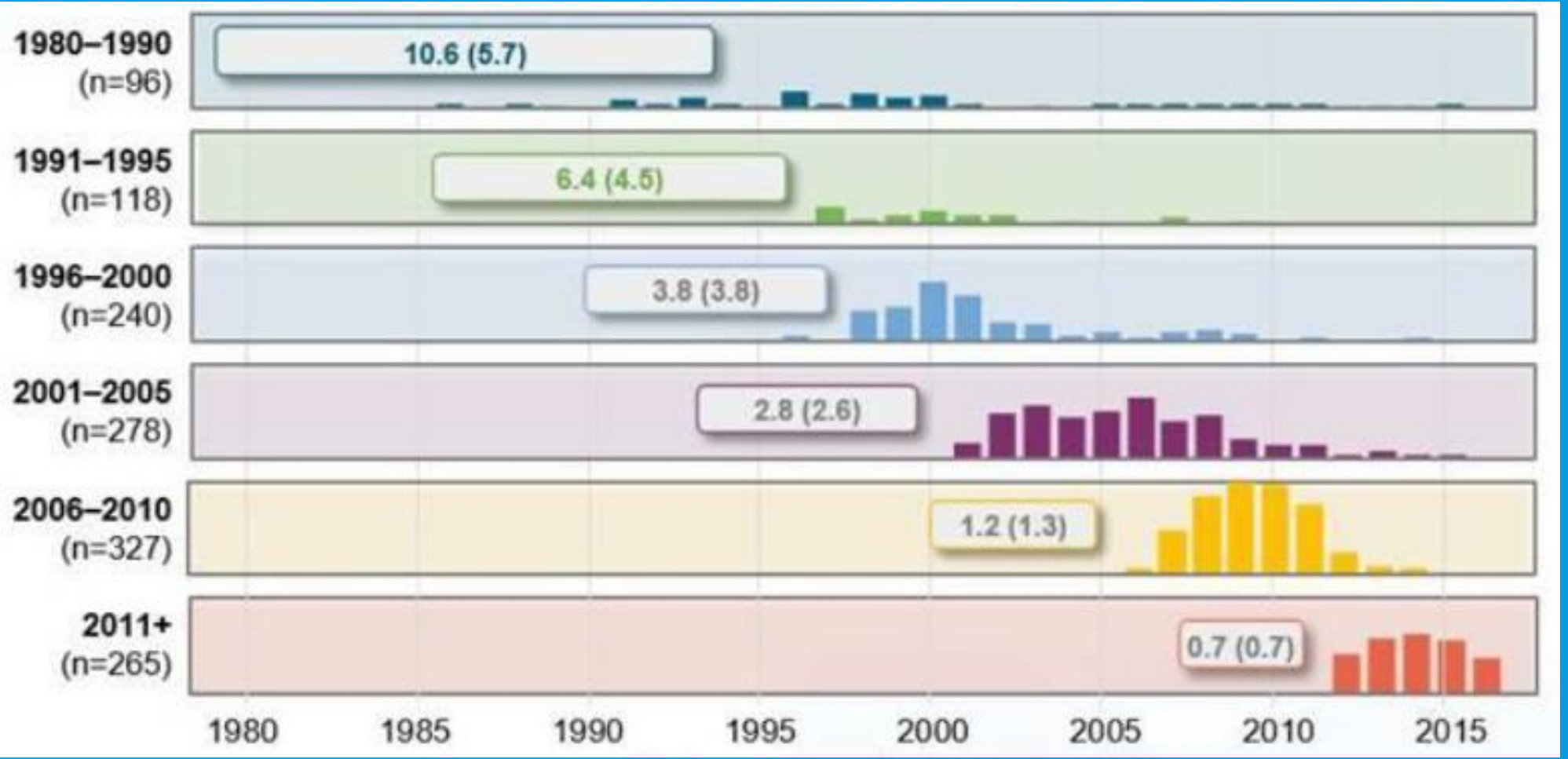
[11] https://www.sciencedirect.com/science/article/pii/S221103481630102X

TIME TO MS DIAGNOSIS

	Core	Achievable	Aspirational	Reporting first symptoms
(a) Referral and diagnosis	4 weeks	10 days	5 days	■ Anyone experiencing for the first time symptoms that might be related to MS should report them to a healthcare professional within [ ] of noticing them
	4 weeks	10 days	5 days	■ Anyone who reports symptoms that might be related to MS to a healthcare professional should be referred to a neurologist within [ ]
	4 weeks	2 weeks	5 days	■ An initial MRI scan should be performed within [ ] of first referral to a neurologist for diagnosis (if not performed earlier)
	2 months	4 weeks	7 days	■ The MS team should complete a diagnostic workup for MS within [ ] of referral to a neurologist
	4 weeks	10 days	5 days	■ The results from a diagnostic workup for MS should be discussed within [ ] of completion, during an appointment with the patient
	2 months	4 weeks	2 weeks	■ An accurate diagnosis of (uncomplicated) MS should be made and communicated to the patient within [ ] of their referral to a neurologist
	30 minutes	45 minutes	1 hour	■ Following MS diagnosis, patients should be offered an initial appointment of at least [ ] to discuss the implications of the diagnosis

[12] Hobart J. at al. International consensus on quality standards for brain health-focused care in multiple sclerosis. Multiple Sclerosis Journal. 2018 Nov 1
https://www.ncbi.nlm.nih.gov/pubmed/30381987

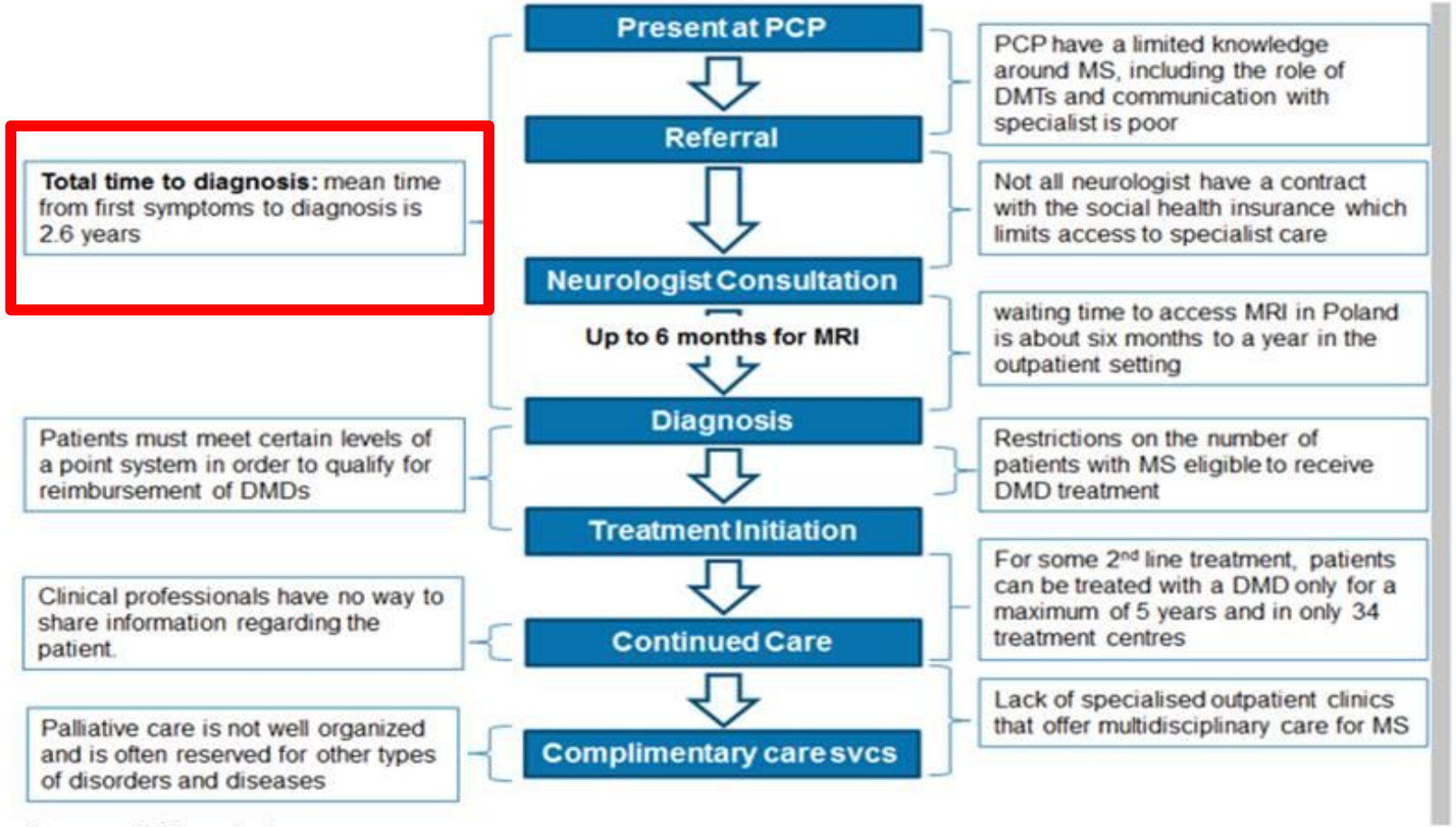
TIME FROM MS DIAGNOSIS TO DMT INITIATION, 30 YEARS OBSERVATION



[13] Capra R et al. *Mult Scler*. 2017;23:1757-1761.

TIME TO DIAGNOSIS

Figure 11: Challenges to access along the MS care pathway – Poland



Source: CRA analysis

[14] Policy proposals to improve access to multiple sclerosis treatments in Europe Final report. March 2016. CRA Project No. D21082

TIME TO DIAGNOSIS

	Kobiety	Mężczyźni	Wszyscy
Liczba pacjentów	972 (68%)	412 (32%)	1384
Płeć – K:M	-	-	2,4:1
Średni wiek (±SD)	37,6 ± 8,9 (od 17 do 76 lat)	39,7 ± 9,6 (od 19 do 82 lat)	38,5 ± 11,9 (od 17 do 82 lat)
Średni czas trwania choroby	15,1 ± 8,7 (od 0 do 48 lat)	14,2 ± 8,3 (od 1 do 52 lat)	14,5 ± 8,5 (od 0 do 52 lat)
Wiek, w którym wystąpiły pierwsze objawy	29,6 ± 7,8	31,6 ± 10,2	30,8 ± 9,8
Okres od pierwszych objawów do rozpoznania	2,7 ± 1,8	2,2 ± 1,4	2,4 ± 1,6 (od 0 do 15 lat)
Miasto/wieś (%)	61,3%/58,7%	56,8%/43,2%	54%/46%
Przypadki rodzinne	3,9%	4,4%	4,2%

[15] Brola W at al. Polski rejestr chorych na stwardnienie rozsiane - stan obecny, perspektywy i problemy. Aktualn Neurol 2015;15(2):68-73

TIME TO DIAGNOSIS AND FROM DIAGNOSIS TO DMT TREATMENT, POLAND 2019 [16]

	Median	Mode	Mean ± SD		
Delay between the 1 st symptom and MS diagnosis (weeks)	17	0	73 ± 144	18 m	1,5 y
Delay between MS diagnosis and starting 1T. N = 252	36	0	119 ± 189	30 m	2,5 y
Delay between 1 st symptom and starting 1T. N = 252	104	0	193 ± 231	48 m	4 y
Duration of the 1 T. N = 246	158	208	187 ± 141		
Delay between 1 st symptom and starting 2T.	346	329	400 ± 261		
Delay between Termination of 1T and starting 2T. N = 246	4	0	28 ± 64		

[16] A. Walczak, et al. Real-world effectiveness of fingolimod in Polish group of patients with relapsing-remitting multiple sclerosis. Clinical Neurology and Neurosurgery 184 (2019) 105453.

TIME FROM DIAGNOSIS TO DMT TREATMENT

Core	Achievable	Aspirational	Patient decides to start DMT
4 weeks	2 weeks	7 days	■ Treatment with a DMT should commence within [ ] of a patient with MS agreeing this approach with their neurologist
–*	4 weeks	2 weeks	■ If a patient's response to their current DMT is judged to be suboptimal, an appropriate, alternative DMT should be offered within [ ]

[12] Hobart J. at al. International consensus on quality standards for brain health-focused care in multiple sclerosis. Multiple Sclerosis Journal. 2018 Nov 1
https://www.ncbi.nlm.nih.gov/pubmed/30381987

TIME FROM DIAGNOSIS TO DMT TREATMENT

The time period that cannot be exceeded

Plánované hrazené služby	Lhůta časové dostupnosti, kterou nelze překročit
Náhrada kyčelního kloubu	52 týdnů
Náhrada kolenního kloubu	52 týdnů
Artroskopie	8 týdnů
Angiografie nekoronárních tepen a vaskulární intervenční výkony	8 týdnů
Echokardiografie	10 týdnů
Operace katarakty	30 týdnů
Endoskopické vyšetření	4 týdny
Denzitometrie	16 týdnů
Skiagrafie a sonografie	2 týdny
Počítačová tomografie	3 týdny
Magnetická resonance	5 týdnů
Mamografické vyšetření	6 týdnů
Zahájení biologické léčby roztroušené sklerózy	**4 týdny**

4 weeks

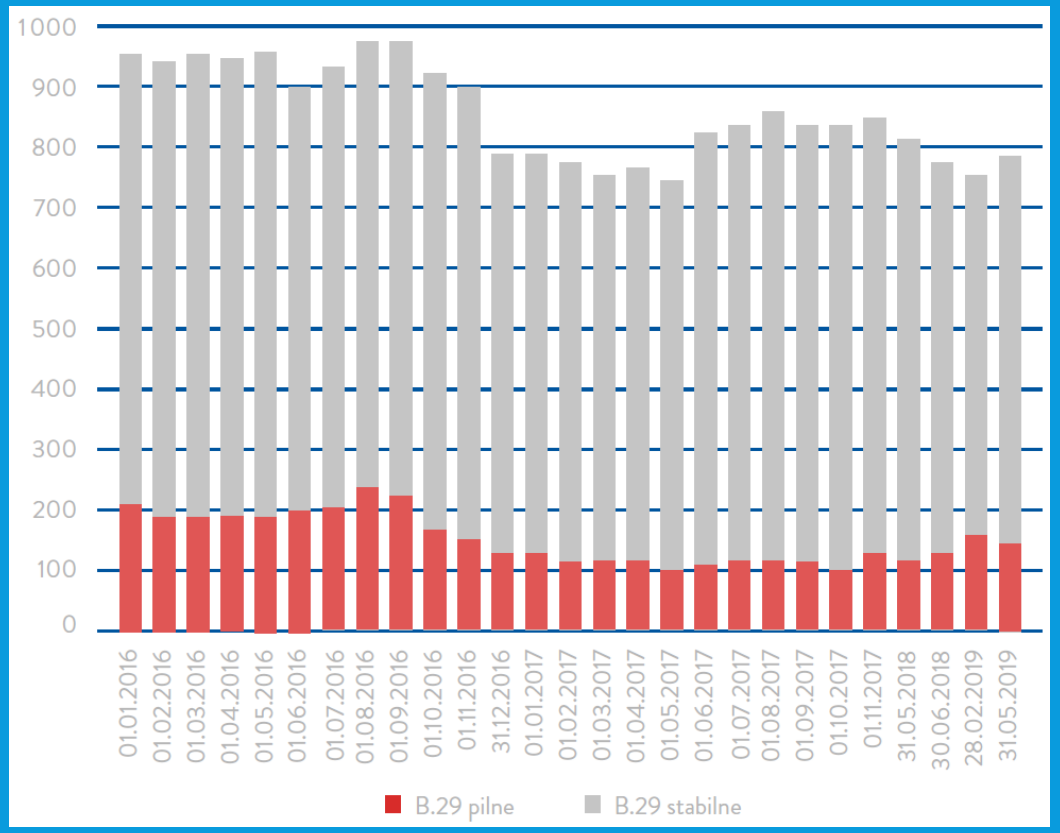
Beginning of biological treatment of multiple sclerosis

[17] https://www.zakonyprolidi.cz/cs/2012-307

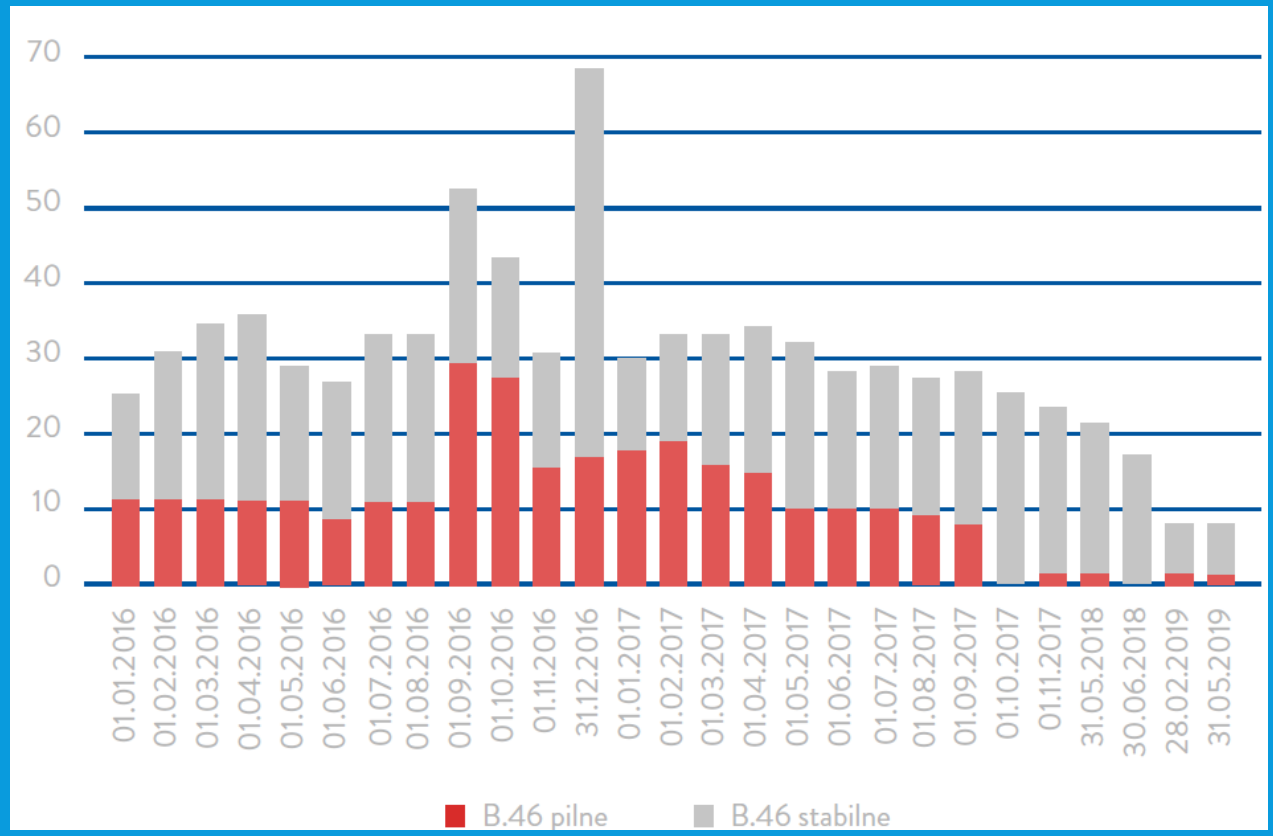
NUMBER OF WAITING MS PATIENTS, 2016-2019

What does it mean in MS: stable vs urgent?

Number of waiting MS patients B.29



Number of waiting MS patients B.46



[18] Obarska I., Stajszczyk M. Raport: Wycena świadczeń w programach lekowych istotnym elementem budowania budowy strategii zwiększania dostepu do innowacyjnych terapii w chorobach autoimmunizacyjnych, HealthCare System Navigator, Warszawa 2019.

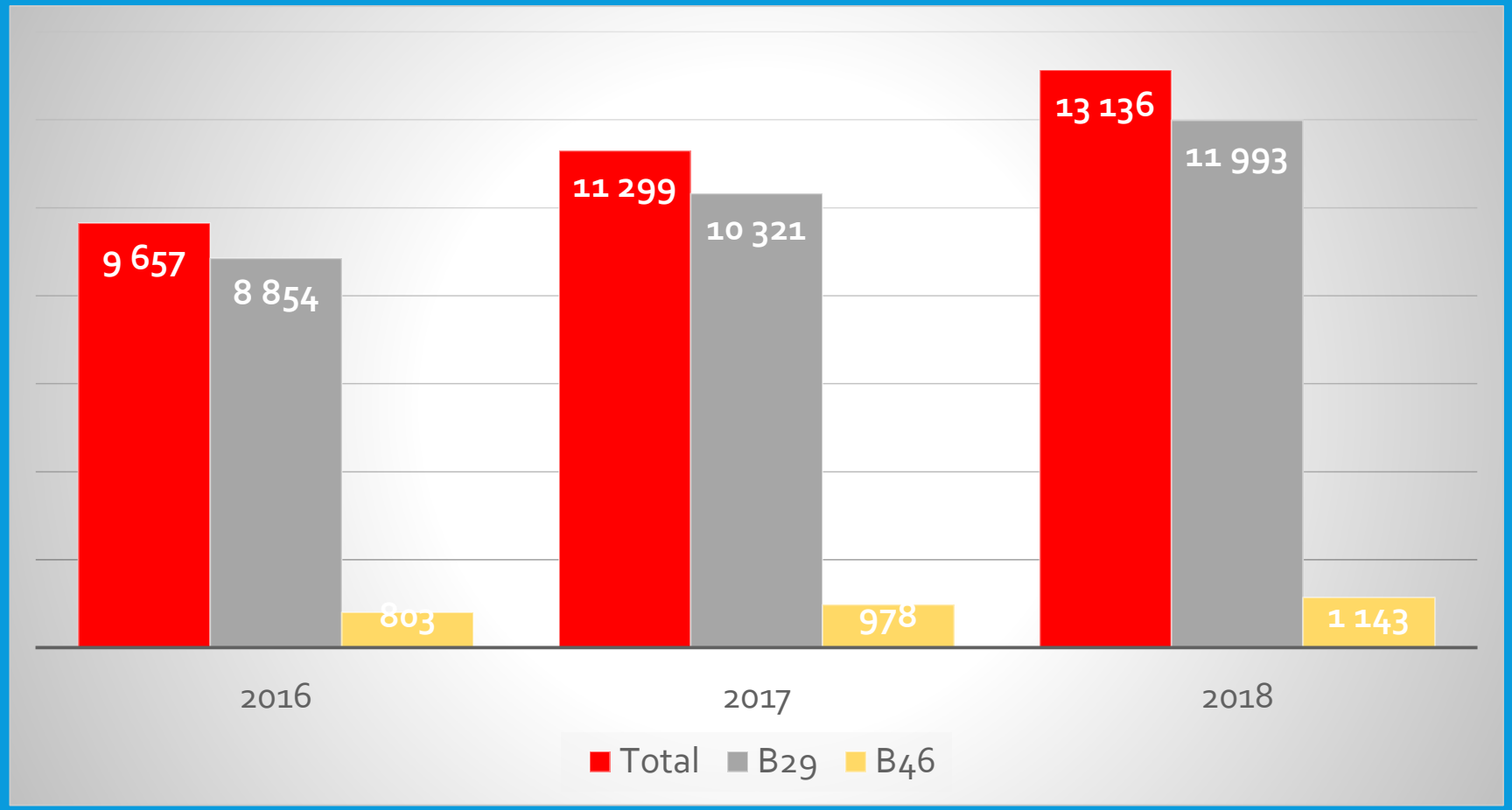
ACCESS TO DMT

PATIENT'S ACCESS TO DMT - TREATED VS. DIAGNOSED

Country	Population	Prevalence	MS patients diagnosed	MS patients on DMT
Poland	38 mln	56 000 = 100%	45 000 = 80%	12 800 = 28%
Czech	11 mln	17 000 = 100%	17 000 = 100%	11 000 = 65%
Germany	83 mln	189 000 = 100%	180 000 = 95%	120 000 = 67%

[19] Data on file, Biogen. December 2018

NUMBER OF PATIENTS TREATED IN 2 DRUG PROGRAMS (B.29 & B.46) IN 2016-2018



Total number of diagnosed SM patients in Poland = 45 000

- DMT 2018 - 29%
- DMT 2017 - 25%
- DMT 2016 – 21%

[18] Obarska I., Stajszczyk M. Raport: Wycena świadczeń w programach lekowych istotnym elementem budowania budowy strategii zwiększania dostepu do innowacyjnych terapii w chorobach autoimmunizacyjnych, HealthCare System Navigator, Warszawa 2019.

PATIENT'S ACCESS TO DMT - POLAND VS. EUROPEAN COUNTRIES, 2015

Countries	% of population who received DMD treatment
Austria	80%
Belgium	70%
Bosnia and Herzegovina	10%
Bulgaria	30%
Croatia	35%
Czech Republic	50%
Denmark	44%
Estonia	50%
Finland	50%
France	70%
Germany	60%
Greece	65%
Hungary	30%
Iceland	100%
Ireland	44%
Italy	65%
Lithuania	60%
Malta	100%
Moldova	3%
Norway	45%
Poland	15%
Portugal	70%
Romania	75%
Russia	40%
Serbia	10%
Spain	65%
Sweden	80%
Switzerland	80%
United Kingdom	40%

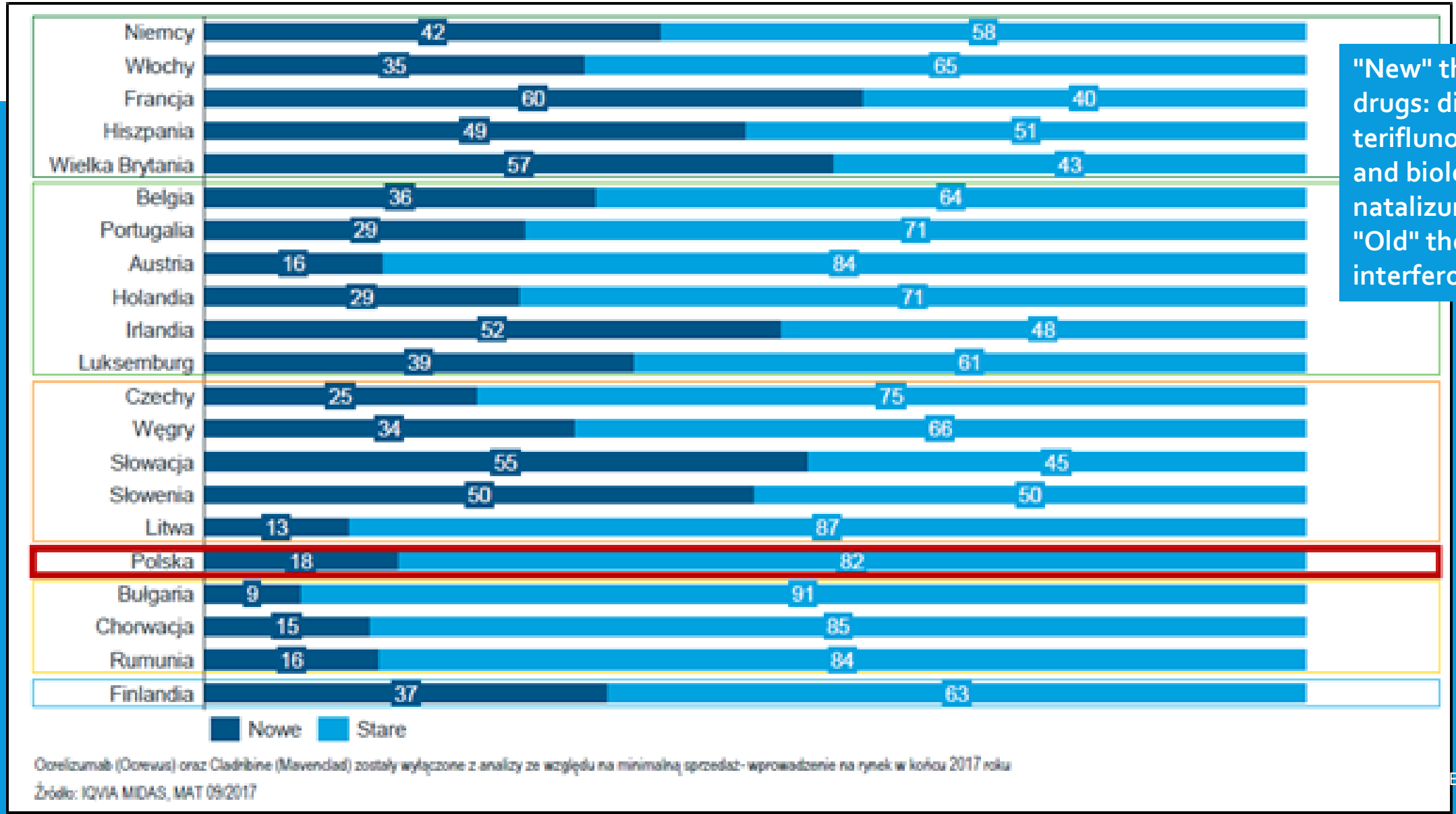
MSBarometer 2015 - European Multiple Sclerosis Platform ®

MEDIAN % OF PATIENTS ON DMT IN **EU**

- 60%

[20] MS Barometer 2015
http://www.emsp.org/projects/ms-barometer/

PATIENT'S ACCESS TO DMT - PATIENTS ON „OLD" AND „NEW" DMT

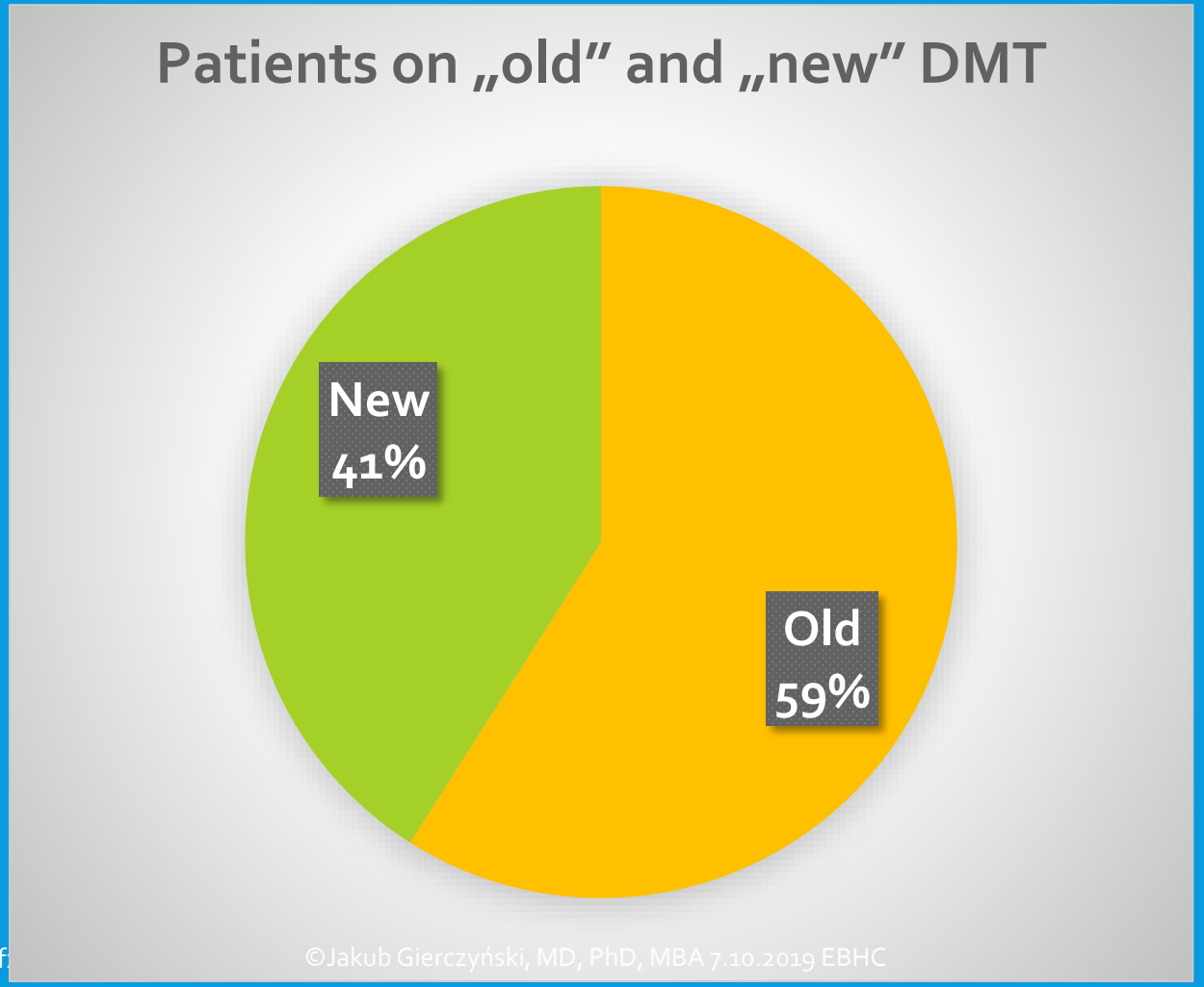


"New" therapies are oral drugs: dimethyl fumarate, teriflunomide, fingolimod and biological drugs: natalizumab,alemtuzumab
"Old" therapies are interferons and glatiramer

[21] Kluszczyński T. Krajobraz Stwardnienia Rozsianego w Europie. Polska na tle krajów europejskich. IQVIA, 2018 http://90c.pl/programywneurologii/files/6015/2352/7900/SM_Polska_na_tle_krajow_Europy__Programy_Lekowe_08.02.2018.pdf

PATIENT'S ACCESS TO DMT - PATIENTS ON „OLD" AND „NEW" DMT

Product	2016	2017	2018
Glatiramer	2 112	2 180	2 346
Interferon beta 1A a 30 mcg	2 357	2 043	1 776
Interferon beta 1A a 44 mcg	1 230	1 167	1 196
Interferon beta – 1B	4 275	3 839	3 380
Peginterferon beta – 1A	101	277	416
Dimethyl fumarate	785	2 264	4 429
Alemtuzumab		6	44
Teriflunomide		18	613
Natalizumab	357	402	448
Fingolimod	634	719	796



[22] Opracowano na podstawie Uchwał NFZ; Raporty z działalności NFZ za rok 2016,2017,2018 ;www.nf

NEUROLOGY CENTERS ACCOMPLISHING NHF DRUG PROGRAMS

March 2019

- **127** – total
  - **51** - I + II line
  - **76** - I line only

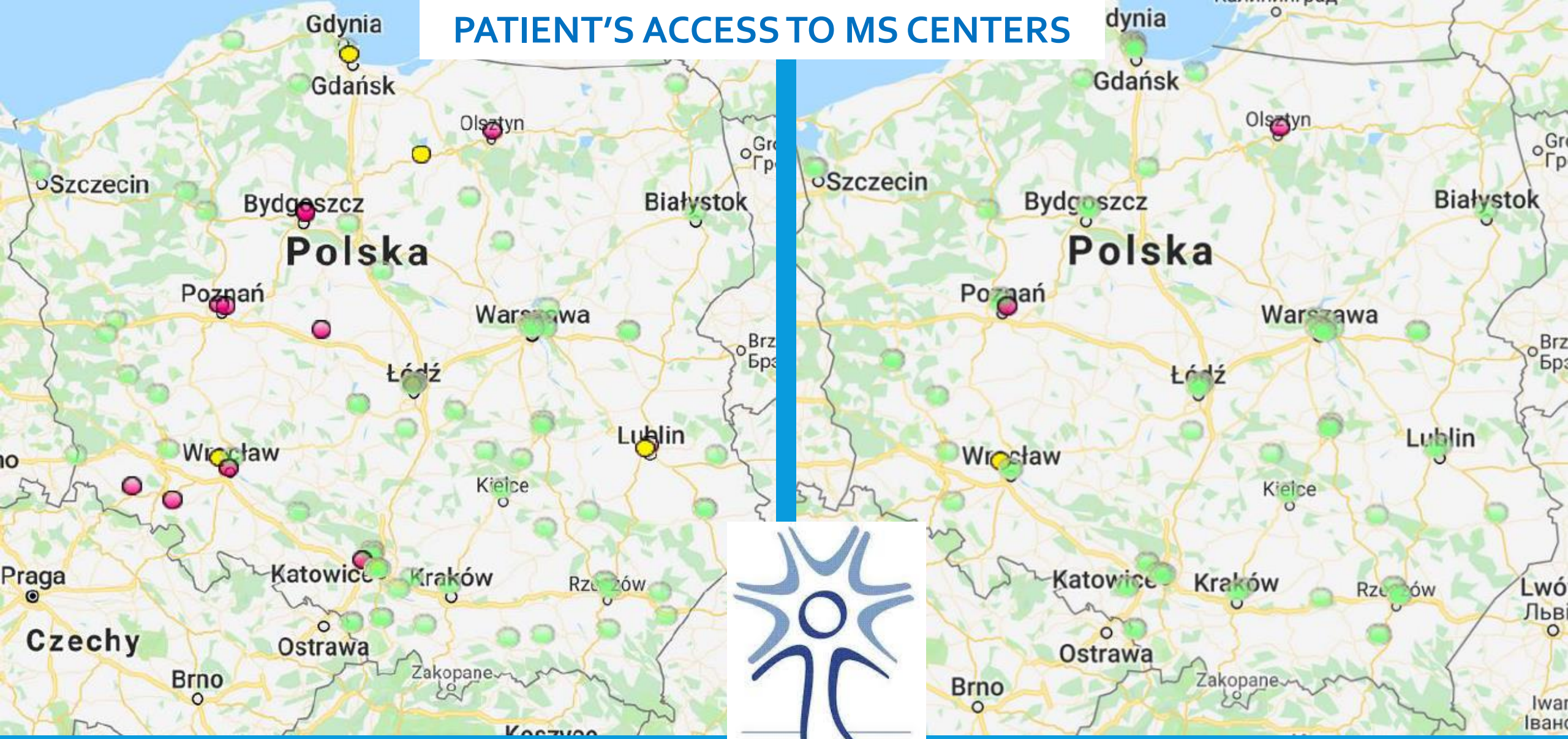
May 2019

- **128** – total
  - **59** - I + II line
  - **69** - I line only (~4 000 patients)

[23] http://www.nfz.gov.pl/o-nfz/informator-o-zawartych-umowach/

[24] https://www.politykazdrowotna.com/45227,debata-o-sm-rozwoj-medycyny-szansa-na-zatrzymanie-postepu-choroby-relacja

PATIENT'S ACCESS TO MS CENTERS



POLSKIE TOWARZYSTWO STWARDNIENIA ROZSIANEGO ODDZIAŁ WIELKOPOLSKA

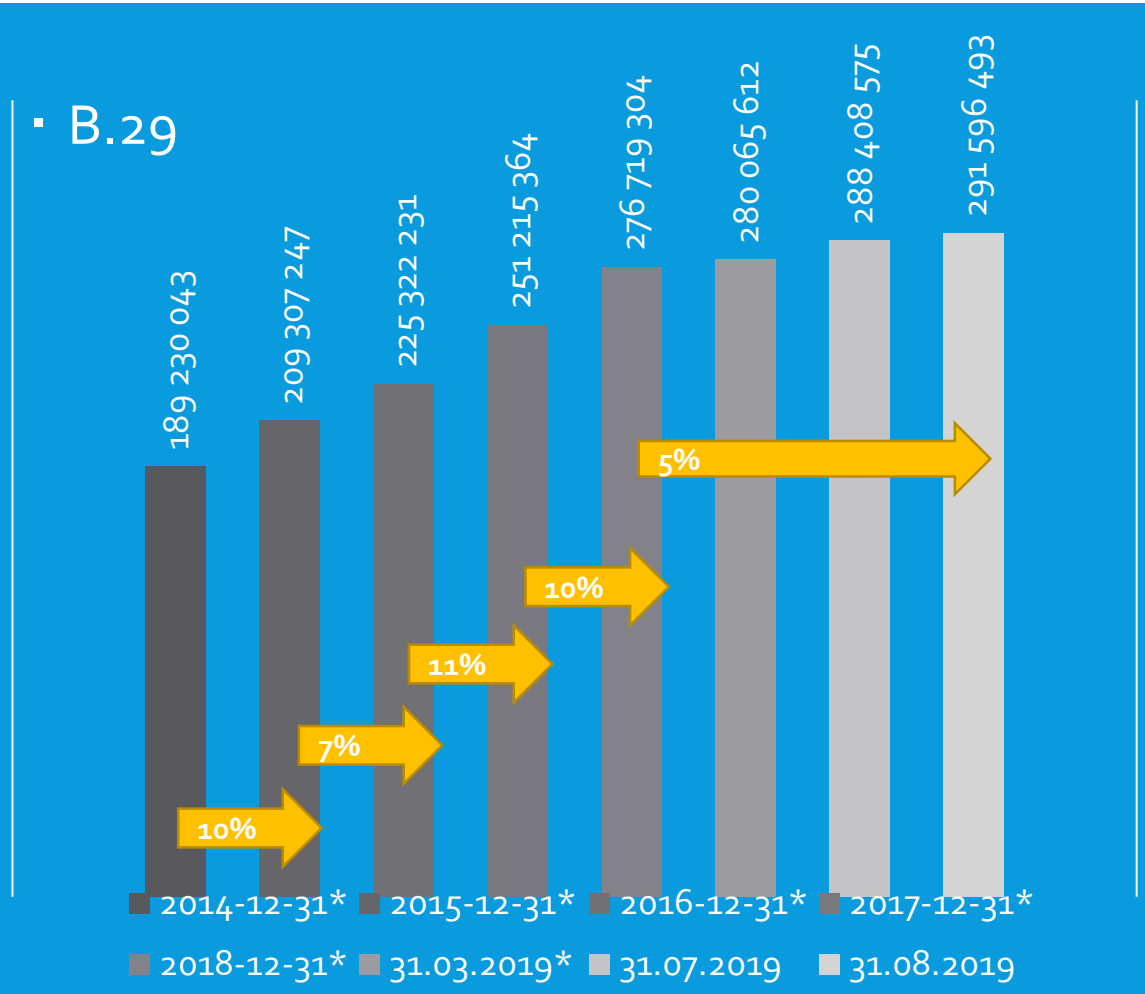
I line – 90 centers

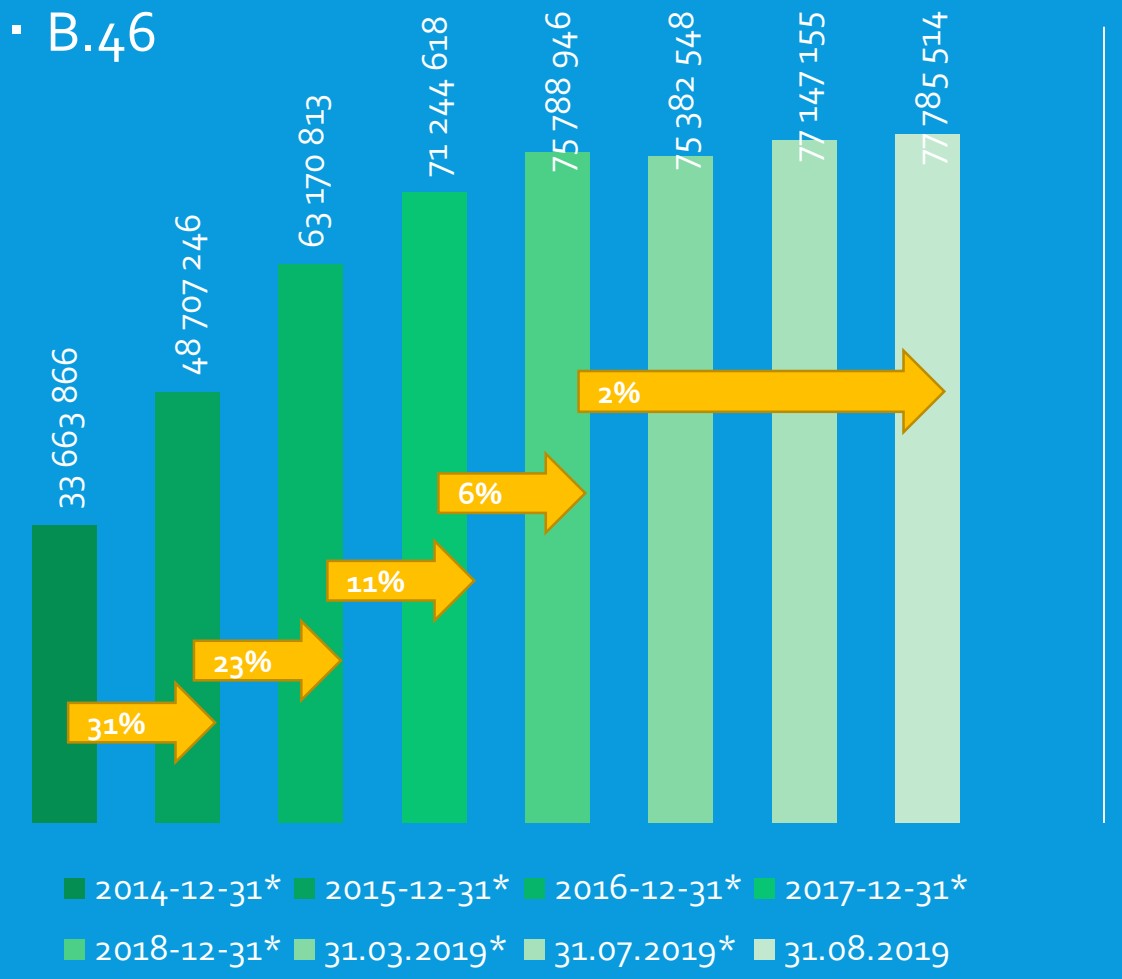
II line – 71 centers

[25] https://ptsr.org.pl/mapasm,112.asp

TOTAL COSTS

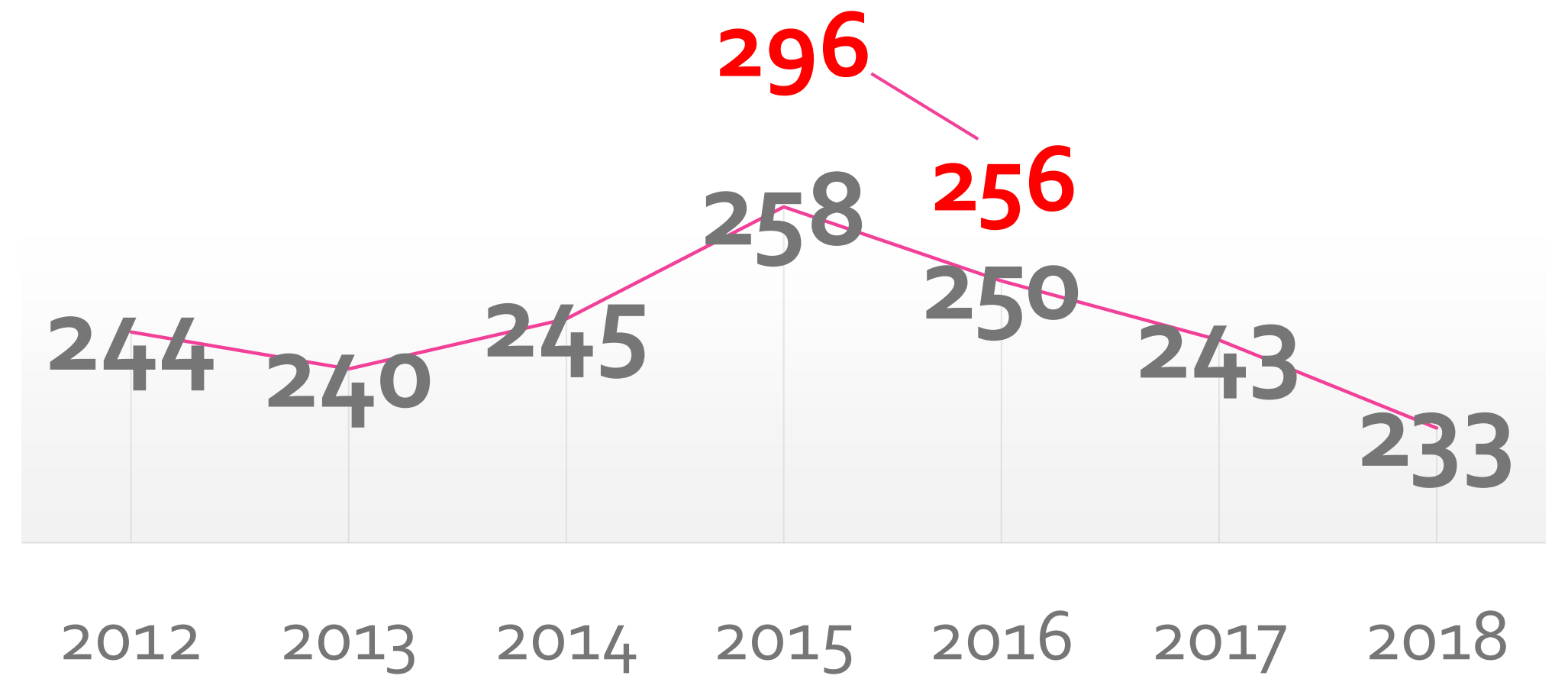
NHF DMT FINANCING, CONTRACTS 2014-2019





[26] https://aplikacje.nfz.gov.pl/umowy/search.aspx

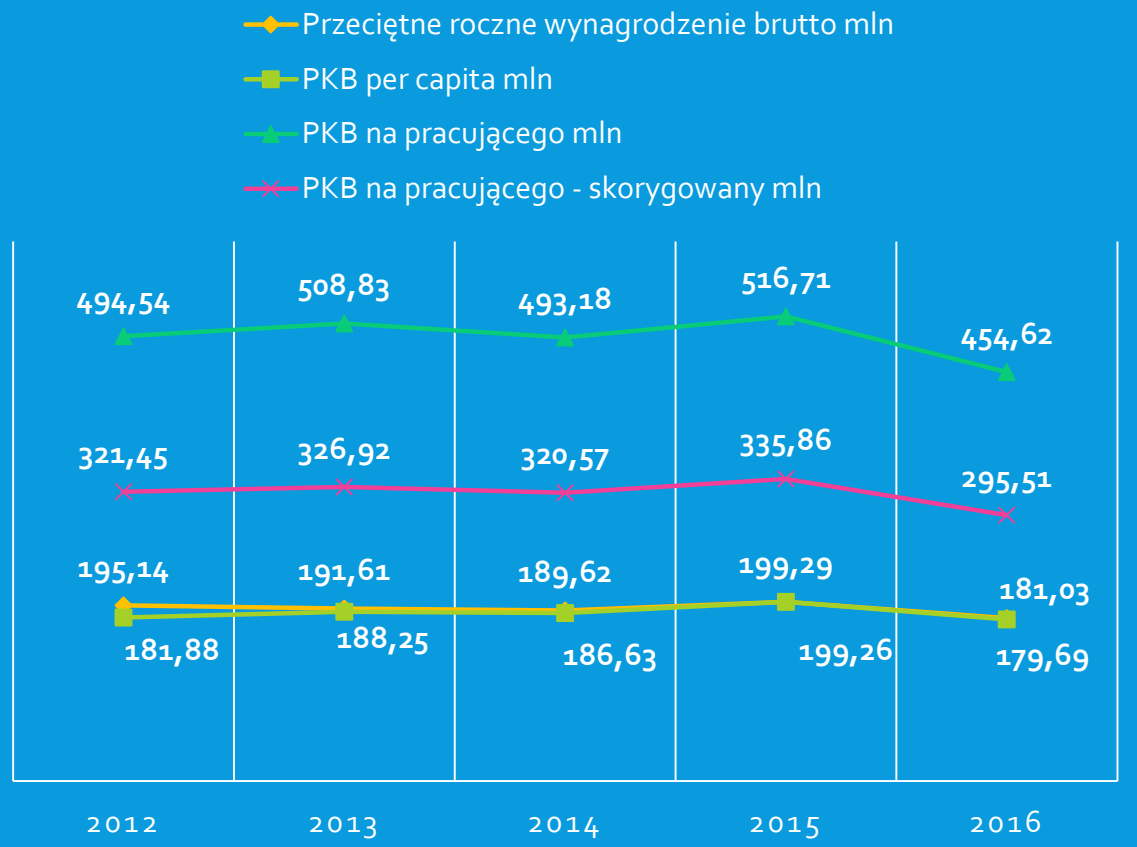
SOCIAL CONSEQUENCES OF INEFFECTIVE OR DELAYED MS TREATMENT, THOUSAND DAYS AND MLN ZŁ



[27] Social Insurance Institution (ZUS) http://www.zus.pl/baza-wiedzy/statystyka/opracowania-tematyczne/absencja-chorobowa

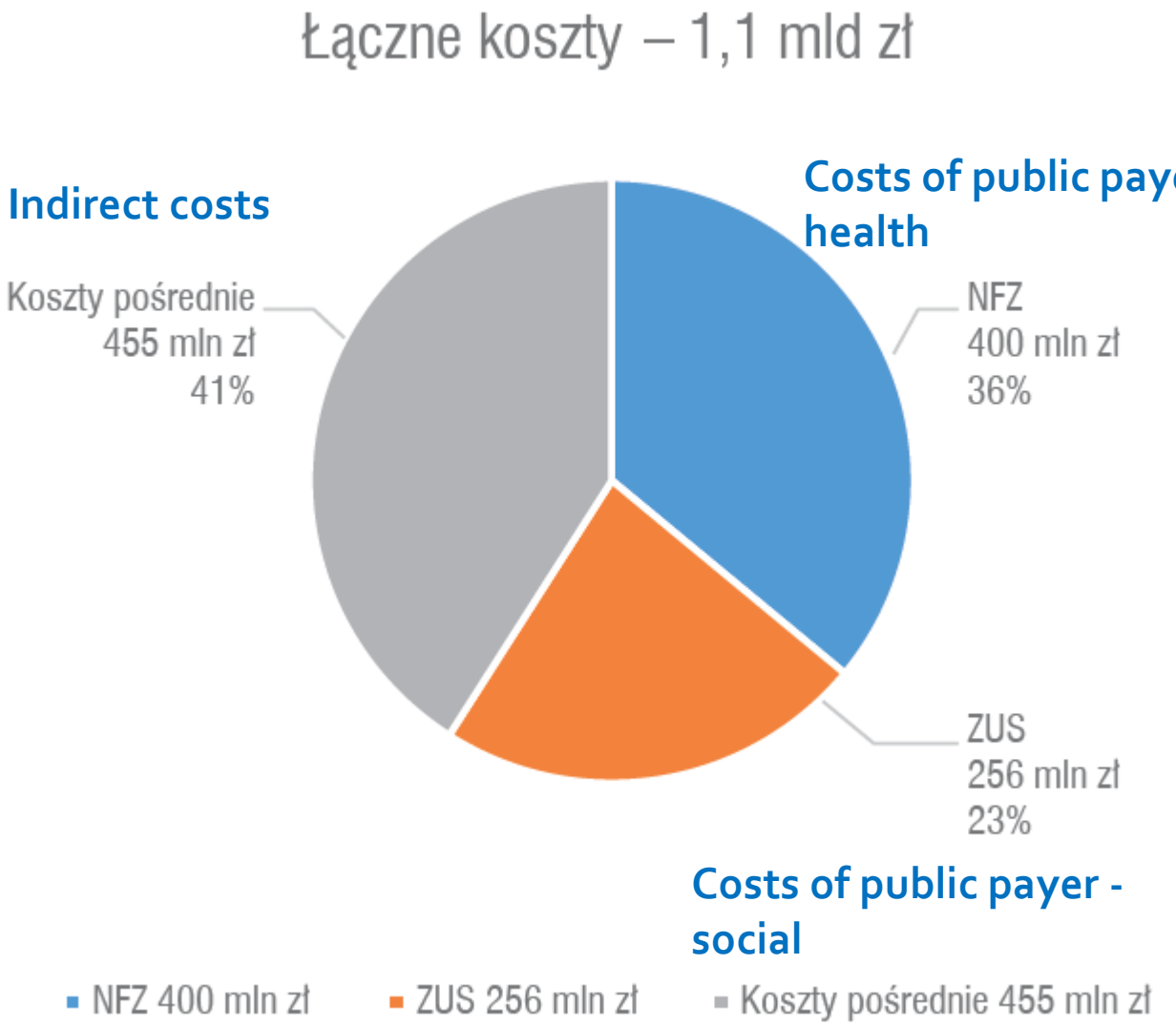
INDIRECT COST OF MS IN POLAND- ABSENTEISM

- Depending on the adopted method of estimating human capital, indirect costs of MS were at the level of:
  - 2012 - from PLN 181.88 million to PLN 494.54 million;
  - 2013 - PLN 188.25–508.83 million;
  - 2014 - 186.63–PLN 493.18 million; 2015 - PLN 199.26–516.71 million,
  - 2016 - PLN 179.69–454.62 million
- Taking into account all variants of human capital, the highest indirect costs of lost productivity caused by multiple sclerosis was noted in 2015, and the lowest - in 2016. So it occurred dynamic (12%) decrease in indirect costs as a result of loss of productivity of MS patients in 2016 compared to2015. One of the factors that had an impact on this may be improving year-on-year access of patients in Poland for modern therapies.



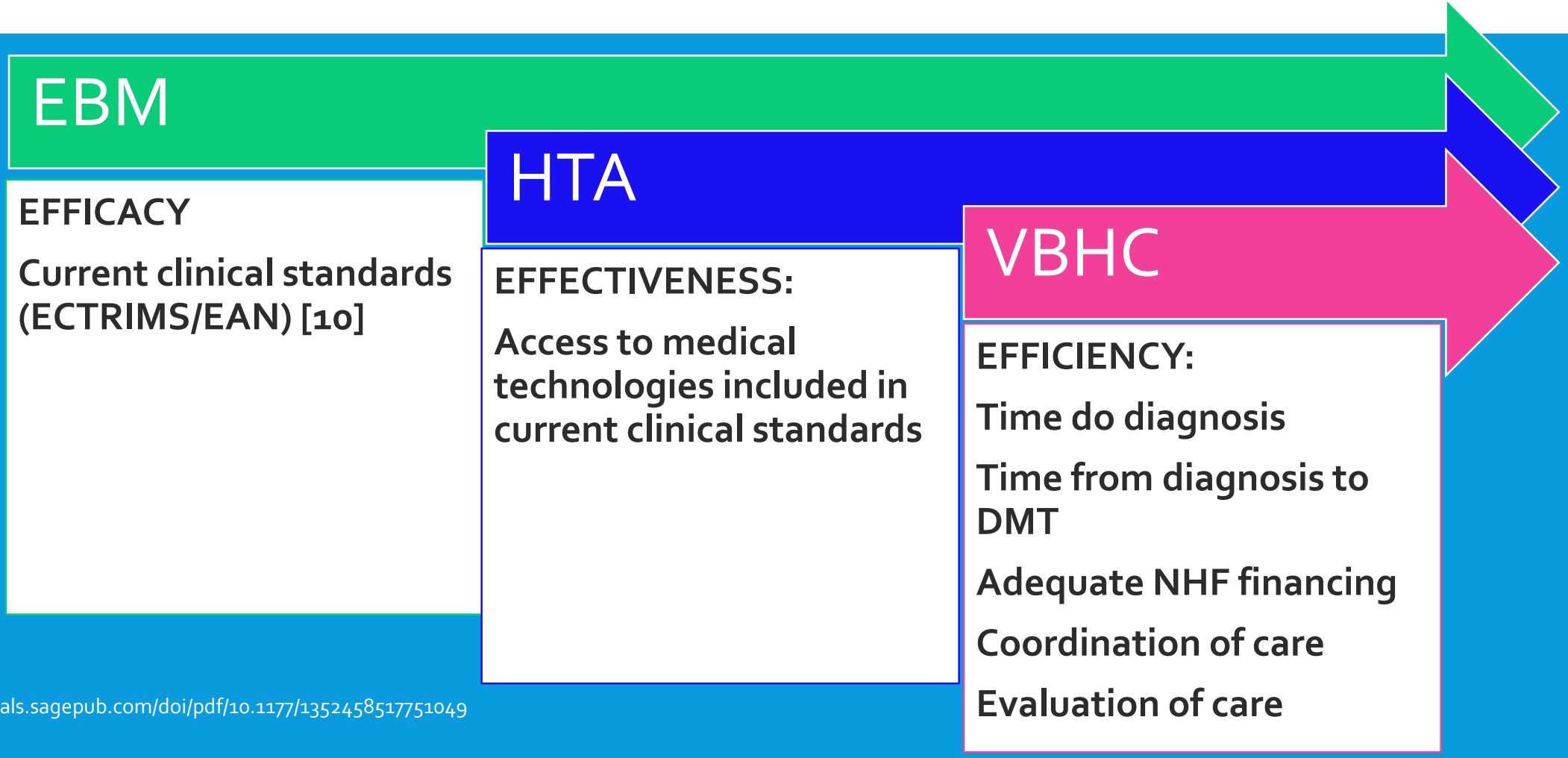
[27] Jakub Gierczyński, Małgorzata Sobotka-Gałązka, Ekonomiczno-społeczne skutki stwardnienia rozsianego, IZWOZ 2018
https://izwoz.lazarski.pl/fileadmin/user_upload/Raport_SM_05.10.18_ISBN.pdf

TOTAL COSTS OF MS IN POLAND, 2016



[28] Jakub Gierczyński, Małgorzata Sobotka-Gałązka in Brain Plan for Poland, 2019
https://www.researchgate.net/publication/336013801_Brain_Plan_for_Poland_Strategic_report_for_brain_health_Brain_Plan_dla_Polski_Strategiczny_raport_dla_zdrowia_mozgu

EVOLUTION FROM EBM TO VBHC IN MUTIPLE SCLEROSIS CARE IN POLAND - CONCLUSIONS



[10] https://journals.sagepub.com/doi/pdf/10.1177/1352458517751049

Source: Jakub Gierczyński, 2019

THANK YOU

https://www.researchgate.net/profile/Jakub_Gierczynski