THE PHARMACIST´S ROLE IN THE DRUGS AND THERAPEUTICS COMMITTEE

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Department of Pharmacy of the University Hospital of Vigo (Spain)

23rd Congress of eahp
european association of hospital pharmacists
making the difference in medication

HOSPITAL PHARMACISTS - SHOW US WHAT YOU CAN DO!

21st - 23rd March 2018 | Gothenburg, Sweden

Disclosure

Conflict of interest:
nothing to disclose

Learning Objectives

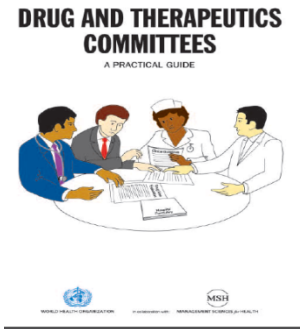
1) To describe the objectives of the DTC.
2) To identify the role of hospital pharmacists at the DTC.
3) To share a model for drug evaluation.
4) To compare the role of the pharmacist in local and regional committees.
5) To discuss the need for professional training of the hospital pharmacist before joining the DTC.
6) To identify new challenges for the DTC.

Spanish Society of Hospital Pharmacy

Group for Innovation, Assessment, Standardisation and Research in the Selection of Drugs

Questionnaire 2018

What is a Drug and Therapeutic Committee?



2004

"DTCs are a forum to bring together all health professionals to jointly work to improve health care delivery, whether in hospitals or other health facilities".

" To ensure that patients are provided with the best possible cost-effective and quality care through determining what medicines will be available, at what cost, and how they will be used".

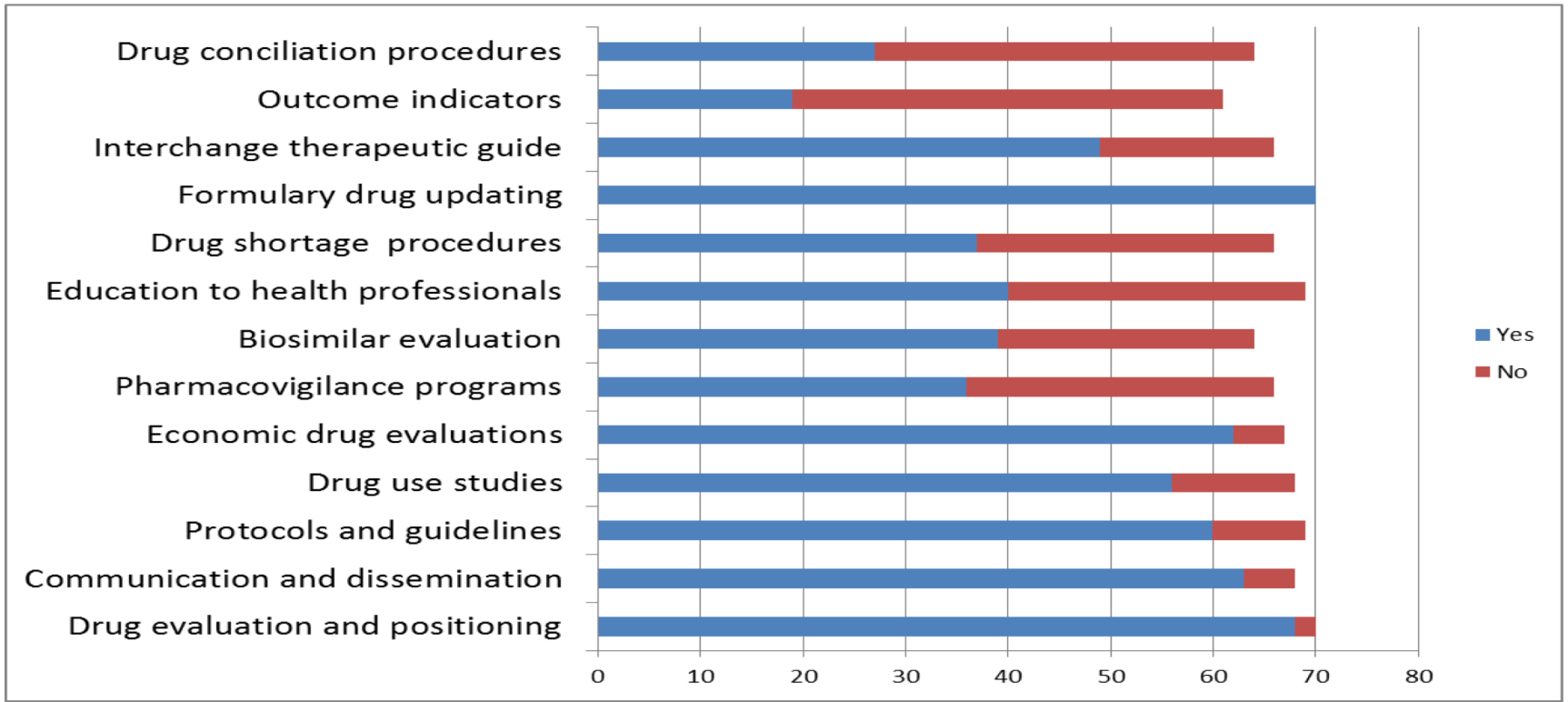
Objectives of the DTC

- Decision-making process: PRIORITISE.
- Efficiente use: SUSTAINABILITY.
- EQUAL ACCESS.
- Multidisciplinary groups: effectiveness, safety and efficiency.
- OUTCOMES of the treatments.

What are the functions of the DTC in Spain?

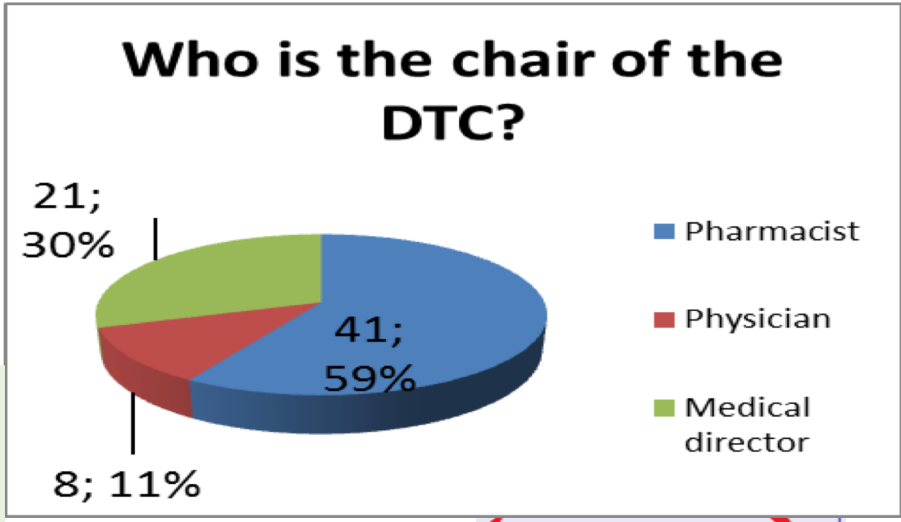
PRELIMINARY

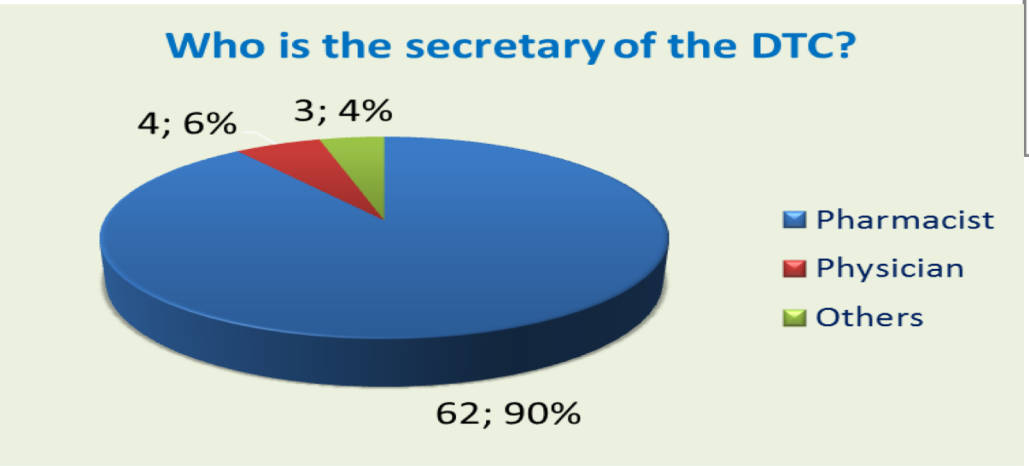
2018



Who are the chair and secretary at the DTCs in Spain?

PRELIMINARY





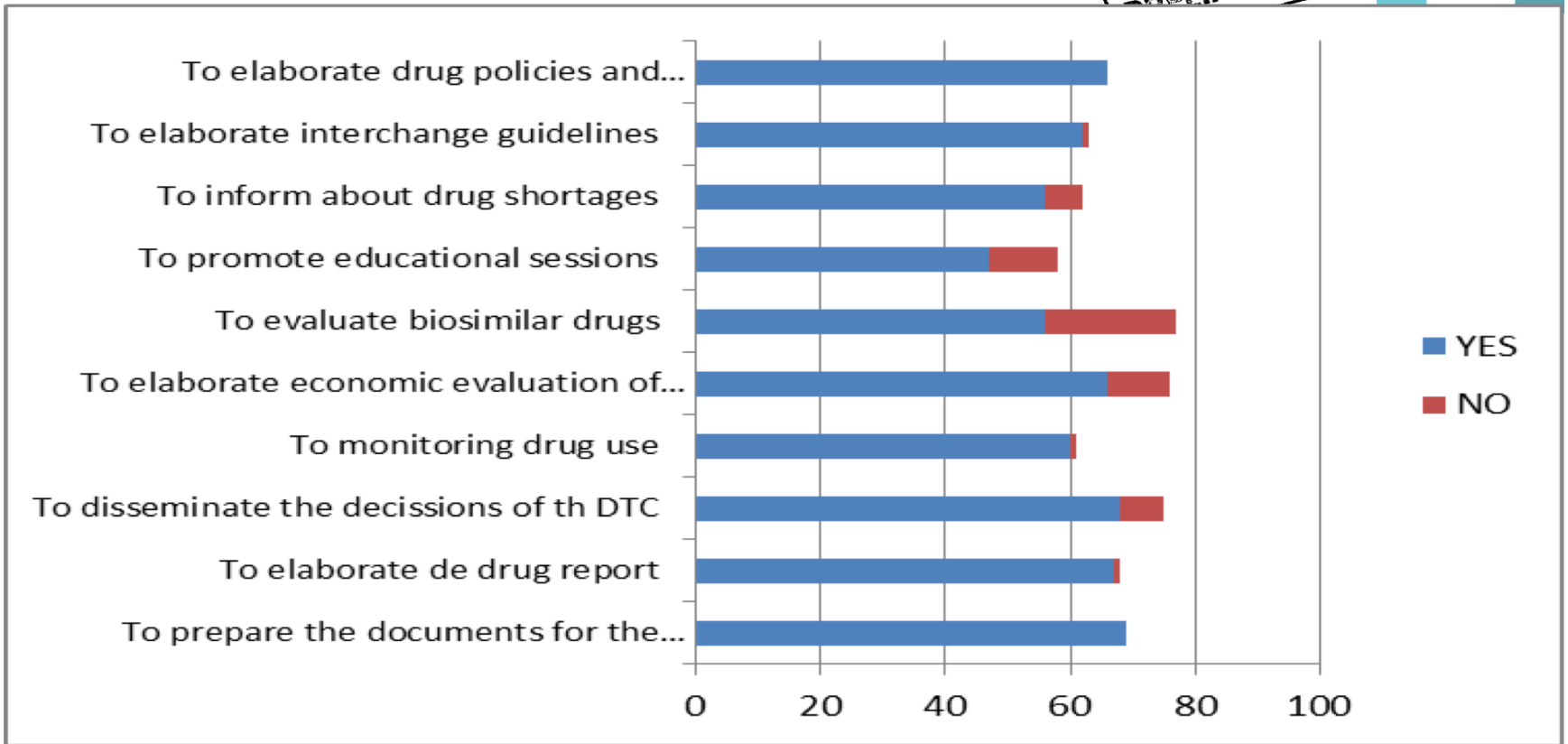
+13 years

Spain 2005
Pharmacist 42.5%
Pharmacist 87%

What is the role of the pharmacist at the DTC in Spain?

PRELIMINARY

2018




Don't miss the boat!

Statement 1.6

Coordinating the activities of multi-disciplinary, organisation-wide DTC: oversee and improve all medicines management policies.

1. Low perception of team work between the health workers and/ or DTC members.
2. Time constraints.
3. Poor communication.
4. Lack of understanding of the role and responsabilities of other members of the team.
5. Types of DTCs: hospitals vs primary care.

Statement 1.6

Coordinating the activities of multi-disciplinary, organisation-wide DTC: oversee and improve all medicines management policies.

PHARMACIST TOOLS:

- SKILLS:

  Teamwork + Positive + Engagement
- TRAINING
- COMMUNICATION
- QUALITY
- DTC: primary+hospital

Professional **training** of the hospital pharmacist at the DTC

Drug evaluation: expert in evidence- based medicine.
Expertise and knowledge regarding treatments for the elderly, biotechnological therapies, precision medicines…
Understanding of the biosimilar evaluation process.
Pharmacoeconomics.
Indirect comparisons.
Real world analysis.

Required **aptitudes** of the hospital pharmacist at the DTC

To appraise medical literature critically.

To work in multidisciplinary groups.

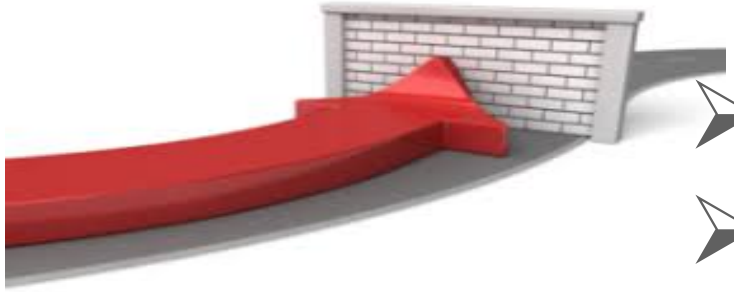
To engage and communicate.

To have a global perspective of diseases and treatments.

To be independent in their opinions and decisions.

Statement 2.1

Be involved in the complex process of procurement of medicines: ensure transparent procurement processes following the principle of safety, quality and efficacy of medicines.



- Conflicts of interest.
- Time constraints to consider.
- Training for critical drug evaluation.

Statement 2.1
Be involved in the complex process of procurement of medicines: ensure transparent procurement process and based on the principle of safety, quality and efficacy of medicines.

GENESIS
Sociedad Española de Farmacia Hospitalaria

14 → **117**

Objectives:

1. TOOLS AND INFORMATION: selection process of Spanish hospitals.
2. COLLABORATION among pharmacy services: efficiency, quality, speed and independence.
3. APPLICATION of the report model.

Statement 2.1

Be involved in the complex process of procurement of medicines: ensure transparent procurement process and based on the principle of safety, quality and efficacy of medicines.

mother

Ref: Marín R, Puigventos F, Fraga MD, Ortega A, Lopez-Briz E, Arocas V, Santos B. Group for Innovation, Assessment, Standardisation and Research in the Selection of Drugs (GENESIS) of the Spanish Society of Hospital Pharmacy (SEFH). Support method for decision making in assessment and appraisal of medicines (MADRE). Version 4.0. Madrid: SEFH (ed.), 2013. ISBN: 978-84-695-7629-8.

Phases for the preparation of a GENESIS report

1. Selection of drug.
2. Search of authors, tutor and reviewer.
3. Elaboration of DRAFT REPORT.
4. Allegations: scientific societies, pharmaceutical companies, …
5. Answer to the allegations.
6. Positioning: FINAL REPORT

Statement 2.1

Be involved in the complex process of procurement of medicines: ensure transparent procurement process and based on the principle of safety, quality and efficacy of medicines.

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Form to disclosure of conflicts of interest

Potential conflicts of interest in preparing evaluation reports are considered when they exceed the amount of 2,000 euros per year (last three years).

- Name:

- Institution where you work:

- An institution that relates to the report. Eg: scientific societies, group work, etc... (Answer only if different from above):

Participation in the evaluation report as: 1- Author 2- Tutor 3- External Reviewer

After having read and understood the information provided on the declaration of conflicts for this report, make the following statement:

A- Personal interests (please specify) ☐YES ☐NO

	Activity	Institution	Date
Funding for meetings and conferences, attending courses (registration, travel bags, accommodation ...)			
Fees as a speaker (conferences, courses ...)			
Funding of educational programs or courses (staffing, facility rental ...)			
Funding for participating in an investigation			
Consulting for a pharmaceutical company			
Shareholder or business interests in a company			
Economic interest in a private company related to health (owner, employee, shareholder, private consultation ...), which can be significant in relation to the authorship of the report			
Conflicts of interest of non-economic nature that may be significant in relation to authorship in the report			

B- Non-personal interests (please specify) ☐YES ☐NO

	Activity	Institution	Date
Funding or financial assistance for the unit or service			
Contracting or financial aid to recruit in the unit or service			
Financial support for research funding			
Funding of educational programs or courses for the unit			

C- Other potential conflicts of interest not mentioned in previous sections (specify)

Statement 2.1

Be involved in the complex process of procurement of medicines: ensure transparent procurement process and based on the principle of safety, quality and efficacy of medicines.

EFFICACY

GENESIS

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1. Evaluation of RESULTS of the clinical trials (*recent vs long time approval*).
2. Evaluation of the validity ("bias") and clinical relevance of the results.
3. Assessment of the screening test used.
4. Published systematic reviews.
5. Indirect comparisons.
6. Secondary sources.

VEDOLIZUMAB
Crohn's disease
GENESIS-SEFH report

Report for the GENESIS group prepared according to the method and procedures of shared evaluation established by this working group of the SEFH.

Date: March 16, 2015
ISBN: 978-84-606-8467-1
Legal deposit: M-17018-2015

EFFICACY

GENESIS

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Population GEMINI III Anti-TNF failed

Study GEMINI III. Clinical trial phase III

Table 7. Sands BE, Feagan BG, Rutgeerts P, Colombel J-F, Sandborn WJ, Sy R, et al. Effects of Vedolizumab Induction Therapy for Patients with Crohn's Disease in whom Tumor Necrosis Factor Antagonist Treatment Failed. Gastroenterology 2014; 147:618-627

-Number of pacients
-Design:
-Treatment of the active group and treatment of the control group:
-Inclusion criteria:
-Exclusion criteria:
-Losses:
-Sample size calculation

Results: Population with failure prior to Anti-TNF

Variable evaluated in the study	*Vedolizumab N (158)*	*Placebo N (157)*	*Difference (CI95%)*	*P*	*NNT (CI95%)*
Main result - Week 6 clinical remission for patients with previous failure to anti-TNF	**15.2%**	**12.1%**	**3.1% (-4.5-10.7)**	0.433	-----
Secondary results of interest - Clinical remission week 10	26.6%	12.1%	14.5% (5,9-23,1)	0.001	7 (5 a 17)
- Clinical remission week 6 and 10	12%	8.3%	3.7%	0.276	np

Clinical remission at week 6 vedolizumab vs placebo: 15.2% vs 12.1%; p=0.433

MAINTENANCE PHASE:
GEMINI III: better clinical remission at week 10: NNT: 7 (5-17).

González Chávez J, Asensi Diez R, Tamayo Bermejo R, Alegre del Rey E, Martínez López de Castro N. Vedolizumab en enfermedad de Crohn. Marzo 2015. Informe compartido del Grupo GENESIS-SEFH (revisor). MADRID: SEFH (ed.), 2015. ISBN: 978-84-606-8467-1. [Fecha de la consulta].

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Sociedad Española de Farmacia Hospitalaria

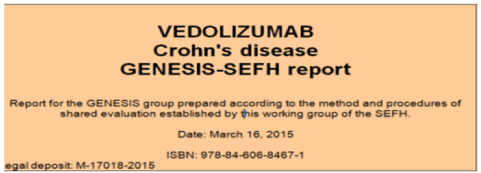
Reference: Sandborn WJ, Feagan BG, Rutgeerts P, Hanauer S, Colombel JF, Sands BE, et al. Vedolizumab as Induction and Maintenance Therapy for Crohn's Disease. N Engl J Med 22 de August de 2013; 369:711-21

Study GEMINI II. Clinical trial phase III

Adverse events that affect 5% of patients who received Vedolizumab

Safety variable evaluated in the study	*Vedolizumab N (814)*	*Placebo N (301)*	*ARR (CI 95%)*	*P*	*NNH (CI95%)*
Exacerbation of Crohn's disease	*20.1%*	*21.6%*			
Arthralgia	*13.5%*	*13.3%*			

González Chávez J, Asensi Diez R, Tamayo Bermejo R, Alegre del Rey E, Martínez López de Castro N. Vedolizumab en enfermedad de Crohn. Marzo 2015. Informe compartido del Grupo GENESIS-SEFH (revisor). MADRID: SEFH (ed.), 2015. ISBN: 978-84-606-8467-1. [Fecha de la consulta].



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COST COMPARISON AMONG ALTERNATIVES	VDZ 300 MG	IFX 100 MG	ADA 40 MG
Cost (€)	3,466	557.73	534.56
COST of INDUCTION (€)	10,398	3,904.11	2,138.24
COST of MAINTENANCE	17,330	11,712.33	12,829.44
DIRECT ASSOCIATED COSTS: Day Hospital administration	21.732,6 €	12.648,93 €	13.898,56 €
INCREMENTAL COST	VDZ	-12,111.56	-14,009.12

Incremental Cost Effectiveness: GEMINI III

Principal Failure to previous anti-TNF	Clinical Remision week 6	Placebo	np P>0.05	np	np
Subgroup General Population	Clinical Remision week 6	Placebo	14 (7 a 818)	10.398 €	145,572 € (72,786-8,505.564)
Subgroup Naive	Clinical Remision week 6	Placebo	5 (3 a 26)	10.398 €	51,990 € (31,194-270,348)

Estimation of the number of patients/ year candidates for treatment at the hospital, annual estimated cost and units of annual efficacy

Nº annual patients	Incremental Cost per patient	NNT	Economic annual Impact	Annual Units of efficacy
Vedolizumab 2nd line:**18-24**	27.728 €	6	499,104 € 665,472 €	3-4 Patients on clinical remission at week 52
Vedolizumab 3rd line:**18-37**	27.728 €	6	499,104 € 1,025.936 €	3-6 Patients on clinical remission at week 52

Estimation of the number of patients / year candidates for treatment at the National level, annual estimated cost and annual efficacy units

Nº annual patients	Incremental Cost per paciente	NNT	Economic annual Impact	Annual Units of efficacy
1.107-1.476 patients	27,728 €	6	30,694.896 €-40,926.528 €	184-246

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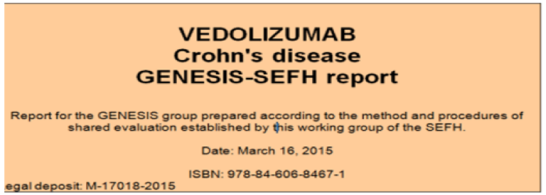
Grupo Genesis de la SEFH

- **Therapeutic aspects:**
  clinical benefit, subgroups of patients, safety, …

- **Cost aspects:**
  Cost, cost- efficacy and budget impact.

González Chávez J, Asensi Diez R, Tamayo Bermejo R, Alegre del Rey E, Martínez López de Castro N. Vedolizumab en enfermedad de Crohn. Marzo 2015. Informe compartido del Grupo GENESIS-SEFH (revisor). MADRID: SEFH (ed.), 2015. ISBN: 978-84-606-8467-1. [Fecha de la consulta].



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Sociedad Española de Farmacia Hospitalaria

GENESIS-SEFH		Versión:	4.0
	Programa MADRE versión 4.0	Fecha:	2014
	Informe Base	Página:	51

ANNEX 3: PRINTING OF ALLEGATIONS AND ALLEGATIONS TO THE PUBLIC DRAFT.
Tutor:

Allegations to the public draft (MAXIMO 3 PRINTED)		
1	**Allegation**	Tutor response

22 ALLEGATIONS FROM TAKEDA COMPANY: 50% minor changes at the report.

González Chávez J, Asensi Diez R, Tamayo Bermejo R, Alegre del Rey E, Martínez López de Castro N. Vedolizumab en enfermedad de Crohn. Marzo 2015. Informe compartido del Grupo GENESIS-SEFH (revisor). MADRID: SEFH (ed.), 2015. ISBN: 978-84-606-8467-1. [Fecha de la consulta].

GINF GUIDE "*Guide for the inclusion of new drugs*" :

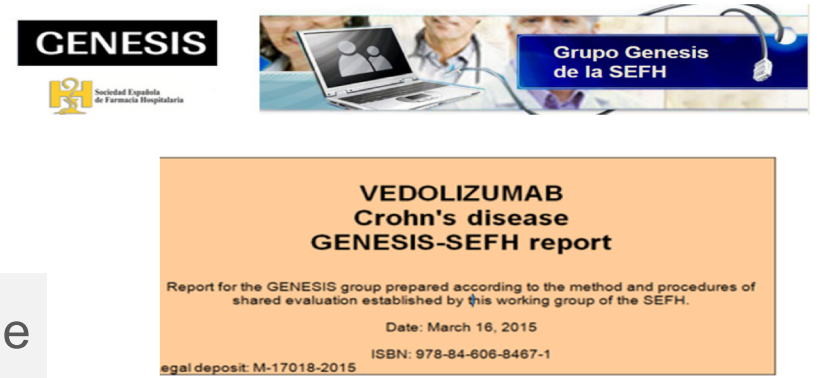
A: The drug is **NOT INCLUDED**: lack of some basic requirements. (A1/A2)

B: The drug is **NOT INCLUDED**: low ratio efficacy/ safety. (B1/B2)

C: The drug is **NOT INCLUDED**: low cost-effectiveness or considered therapeutic equivalent.

D: The drug is **INCLUDED** with recommendations.

E: The drug is **INCLUDED** without specific recommendations.



DECISION: **D:** The drug is **INCLUDED** with recommendations:

2nd or 3rd line of treatment of Crohn´s disease

González Chávez J, Asensi Diez R, Tamayo Bermejo R, Alegre del Rey E, Martínez López de Castro N. Vedolizumab en enfermedad de Crohn. Marzo 2015. Informe compartido del Grupo GENESIS-SEFH (revisor). MADRID: SEFH (ed.), 2015. ISBN: 978-84-606-8467-1. [Fecha de la consulta].

http://gruposdetrabajo.sefh.es/genesis/

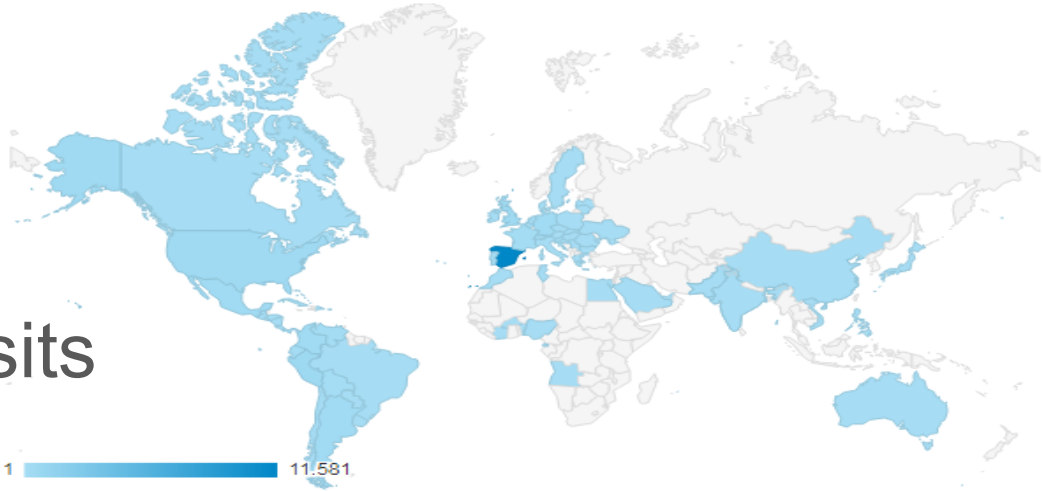
From January to December 2017

Usuarios	Usuarios nuevos	Sesiones
15.581	14.459	32.229

Número de sesiones por usuario	Número de visitas a páginas	Páginas/sesión
2,07	83.336	2,59

http://gruposdetrabajo.sefh.es/genesis/

15,581 users
14,459 new users
32,229 sessions
83,336 number of visits



Statement 2.2

Lead in developing, monitoring, reviewing and improving medicine use processes and the use of medicine related technologies.

- Infrastructure to analyse data.
- Experts to analyse data.
- Quality of the real world analysis.
- New ways of communication with patients.

Statement 2.2
Lead in developing, monitoring, reviewing and improving medicine use process and the use of medicine related technologies.

Original article

Content analysis of Twitter in relation to biological treatments for chronic inflammatory arthropathies: an exploratory study

Noemí Martínez-López De Castro,[1,2] Marisol Samartín- Ucha,[1,2] Alicia Martín-Vila,[1] Miriam Álvarez-Payero,[1,2] Guadalupe Piñeiro-Corrales,[1] José M Pego-Reigosa[2,3]

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[2]Group of Investigation in Rheumatology and Immune-Mediated Diseases, Instituto de Investigacion Sanitaria Galicia Sur, EOXI, Vigo, Spain
[3]Rheumatology, Department of Rheumatology, EOXI, Vigo, Spain

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Noemí Martínez-López
De Castro, Department

ABSTRACT

Objective To analyse the volume and content of tweets in relation to biological treatments for chronic inflammatory arthropathies.

Methods A Twitter analysis was carried out during one month using the following keywords: 'rheumatoid arthritis', 'ankylosing spondylitis', 'psoriatic arthritis' and their biological therapies: 'abatacept', 'adalimumab', 'certolizumab', 'etanercept', 'golimumab', 'infliximab' and 'tocilizumab'. Tweets were hand-coded and filtered for content.

Results 25 441 tweets contained at least one of the

welcome in clinical settings, particularly when relational aspects such as mutual trust, uncertainty and vulnerability are affected because of conflicting information and views that can be found on the internet.[4]

Rheumatoid arthritis (RA), ankylosing spondylitis (AS) and psoriatic arthritis (PA) are rheumatic diseases that globally affect as many as one in 100 people.[5] Many people with these conditions experience symptoms that worsen their quality of life. They must cope with these symptoms and also with other aspects related to these diseases or their treatments. Frequently, these patients with

Statement 2.3

Coordinate the development, maintenance and use of a medicines formulary system which may be in local, regional and/or national committees. The medicines formulary system should be linked to guidelines, protocols and treatment pathways based on the best available evidence including patient outcomes and pharmacoeconomic evaluations where these are available.

- Lack of homogeneity among committees and lack of teamwork among them.
- Agencies: new conditions of approval.
- Insufficient training of DTC members; Exorbitant drug prices.

Responsibilities of the pharmacist at the regional/ national DTC

1) DRUG EVALUATION:

Drug evaluation of recently approved drugs.

Drug evaluation for individual patients.

2) PHARMACOECONOMICS:

Analysis, budget impact, new ways of drug financing

3) PATIENT OUTCOMES:

To design and promote the use of health outcome indicators.

Responsibilities of the pharmacist at the local DTC

1) DRUG EVALUATION:

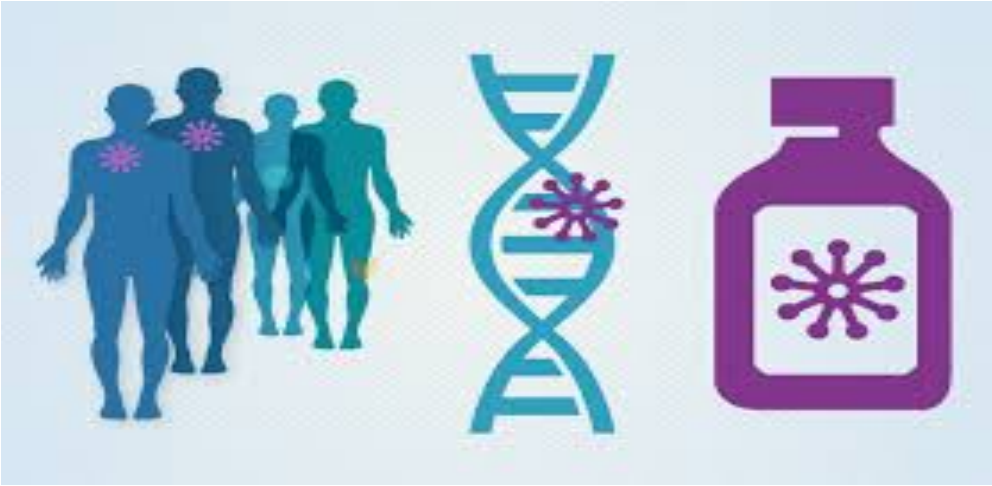
- Protocols and guidelines
- Biosimilar drugs
- Coordination of expert groups
- Evaluation of individual patient treatments
- Medication conciliation

2) PHARMACOECONOMICS: Efficiency and budget impact.

3) PATIENT OUTCOMES: Design and follow up

Statement 2.4

Procurement should be done according to the medicine formulary. A robust process to procure medicines not included in the formulary.



- Formal procedure for evaluation.
- Equity and transparency.
- Medical Direction.

for the pharmacist at the DTC

- Critical appraisal.
- Professional training: expert in new treatments.
- Aptitudes: ENGAGING.
- Communication.
- SHARING of information.
- Coordination of reconciliation activities.
- OUTCOMES: real world analysis.

My take home messages

1) DTC must contribute to the optimisation of drug evaluation, sharing information between expert groups. Efforts should be centred in drug positioning and establishment of efficient alternatives.

2) New challenges imply the DTC pharmacist must be an expert in: biological therapies, real world analysis, therapies for the elderly and pharmacoeconomics.

3) DTC decisions should be focused on the patient, irrespective of the health care setting.

THANK YOU!

http://gruposdetrabajo.sefh.es/genesis/

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23rd Congress of eahp

HOSPITAL PHARMACISTS - SHOW US WHAT YOU CAN DO!

21st - 23rd March 2018 | Gothenburg, Sweden

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