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Announcements

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Welcome to today's session

SIGN 4 - Medicines use and quality

fip ADVANCING PHARMACY WORLDWIDE

DATE 13 October 2020 **TIME** 13.00 - 14.30 CEST

Paul Sinclair (Event Chair)
Chair of the Board of Pharmaceutical Practice
FIP (Australia)

Tamara Peiró Zorrilla
General Pharmaceutical Council of Spain
(Spain)

Jan Saevels
Scientific Director
Association of Pharmacists Belgium (APB)
(Belgium)

Jephney John Redford Jacquet
Haitian Pharmacy Students Association
(Haiti)

Speaker

Tamara Peiró Zorrilla
General Pharmaceutical Council of Spain

Presentation on
AdherenciaMED: adherence management service

Award winner of Pharmacy Practice Improvement Programme Award 2020

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ADVANCING PHARMACY WORLDWIDE

Background

- Lack of adherence to treatments is one of the **main challenges** for healthcare professionals and health care systems

World Health Organization

- **Approximately 50%** of patients with chronic diseases are non-adherent to their treatments[1]

- Non adherence is estimated to cause annual expenditure of **EUR 11,250 million in Spain[2]**

- Community pharmacists can improve medication non-adherence through patient tailored complex interventions.

1. Adherence to long-term therapies. Evidence for action. World Health Organization, Geneva, 2003.
2. Conthe P, Márquez Contreras E, Aliaga Pérez A, Barragán García B, Fernández de Cano MartínMN, González Jurado M, et al. Adherencia terapéutica en la enfermedad crónica: estado de la situación y perspectiva de futuro. Rev Clin Esp 2014;214:336-44

Background

WHAT IS AN **ADHERENCE MANAGEMENT SERVICE** IN SPAIN?

This is the professional service in which the pharmacist, through his or her intervention, **actively collaborates with the patient** so that, on a voluntary basis, he or she can follow the recommendations of the health professionals regarding the **appropriate process for the use of medicines** and healthcare products, the hygienic-dietary habits and/or the lifestyle, in order to achieve the expected results in the patient's health*.

**Forum PhC-CPh. Servicios Profesionales Farmacéuticos asistenciales; definiciones y clasificación. Panorama Actual del Medicamento 2016;40(395):709-711.*

Background

Led by:

Farmacéuticos
General Pharmaceutical Council of Spain

With scientific collaboration:

UNIVERSIDAD DE GRANADA

UTS
UNIVERSITY OF TECHNOLOGY, SYDNEY

Funded by:

cinfa

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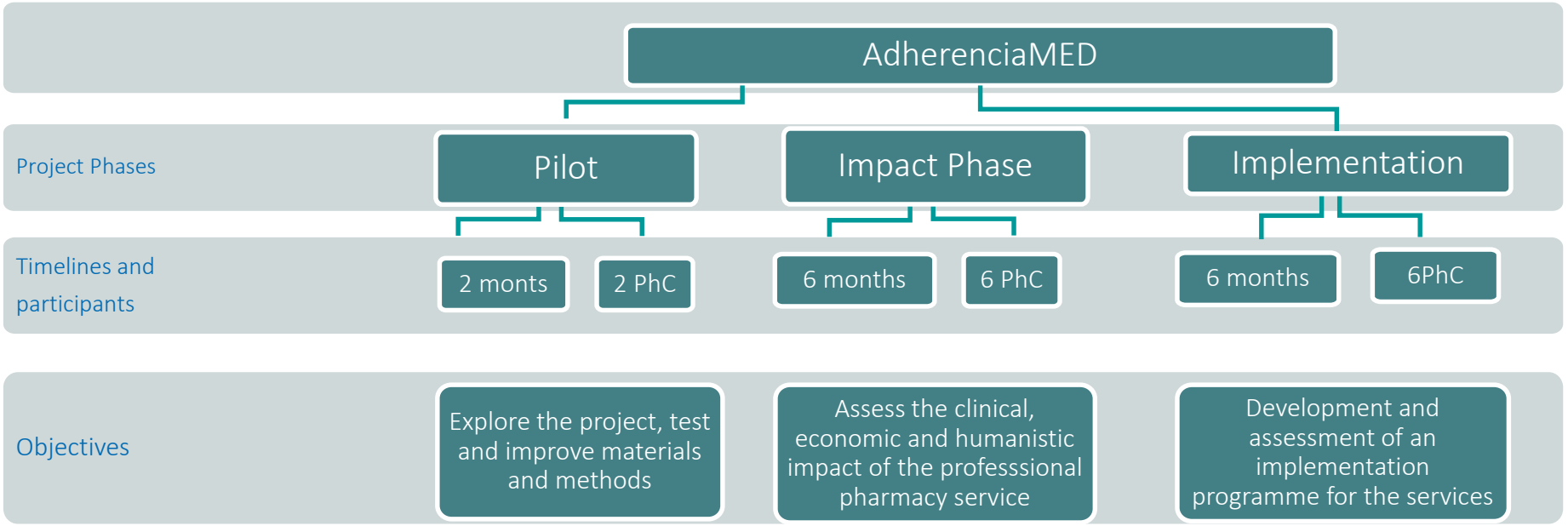
ADVANCING PHARMACY WORLDWIDE

AdherenciaMED
Adherence management service

Project Design



Impact Phase

138 pharmacists – 98 community pharmacies – 1.186 patients involved

Purpose

To evaluate the **clinical and humanistic impact** of a **community pharmacist-led adherence service** in patients with chronic conditions (Hypertension –HBP-, Asthma or Chronic Obstructive Pulmonary Disease -COPD-) **compared to usual care**.

Patients inclusion criteria

- ✓ > 18 years old
- ✓ Patients who are able to complete EuroQol-5D, Morisky, ACQ and CCQ questionnaires on their own
- ✓ Who signed an informed consent form
- ✓ In treatment for:
  - Hypertension
  - Asthma
  - COPD

Methods

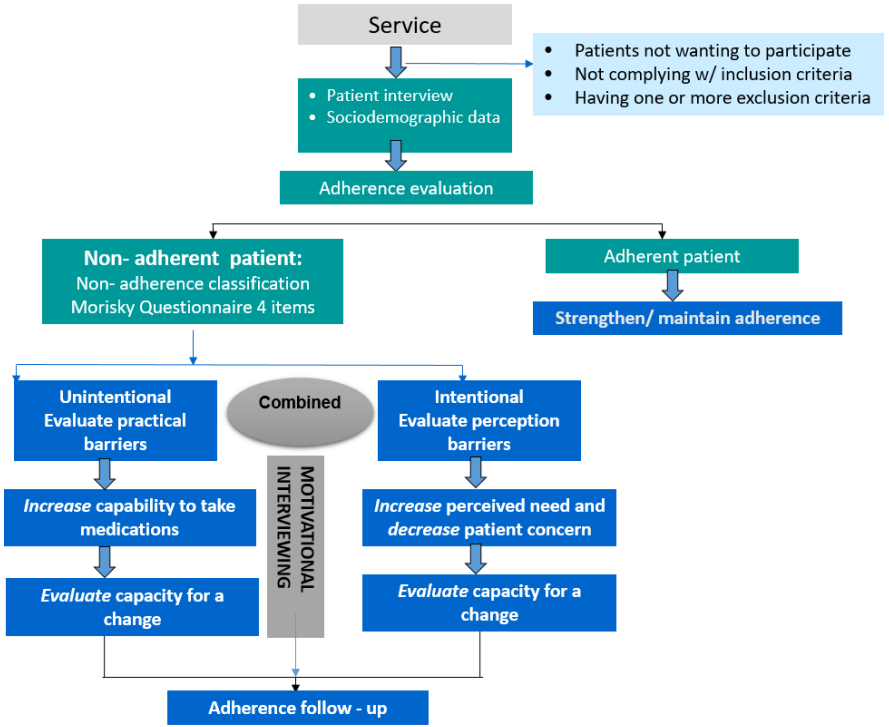
- A **cluster randomized controlled trial** was conducted in community pharmacies, divided in **two groups**, control and intervention group.

- Patients in **intervention group** received a tailored service aiming at identifying and addressing non-adherence, using **brief complex interventions** based on evidence-based **models for behavioural change**.

- Patients in the control group received the usual care.

- All patients received a **monthly follow-up** for six months.

Methods – Adherence Service Flowchart



AdherenciaMED
Adherence management service

1. Do you ever forget to take your medicine?	○ Yes	● No
2. Are you careless at times about taking your medicine?	● Yes	○ No
3. When you feel better, do you sometimes stop taking your medicine?	○ Yes	● No
4. Sometimes if you feel worse when you take the medicine, do you stop taking it?	○ Yes	● No

For intentional adherence:

- *Necessity and Concerns* Model [1]
- *Health Belief* Model [2]
- *Transtheoretical Model for Change* [4]
- Motivational Interview [5]

For unintentional adherence:

- Model Information - Motivation-Strategy [3]
- Transtheoretical Model for Change [4]
- Motivational Interview [5]
- Pharmacist Counselling
- Dose administration aids
- Education in inhalation technique

1. Horne R, Chapman SCE, Parham R, Freemantle N, Forbes A, Cooper V. Understanding patients' adherence-related beliefs about medicines prescribed for long-term conditions: a meta-analytic review of the Necessity-Concerns Framework. PLoS One 2013 ;8(12):e80633.
2. Carpenter JC. A meta-analysis of the effectiveness of health belief model variables in predicting behavior. Health Communication 2010; 25 (8): 661–669
3. DiMatteo MR, Haskard-Zolnierek KB, Martin LR. Improving patient adherence: a three-factor model to guide practice. Health Psychology Review 2012; 6(1): 74-91
4. Prochaska JO1, Velicer WF. The transtheoretical model of health behavior change. Am J Health Promot. 1997 Sep-Oct;12(1):38-48.
5. Miller WR. Motivational interviewing: research, practice, and puzzles. Addict Behav. 1996 Nov-Dec;21(6):835-42.
6. Easthall, C., Song, F., & Bhattacharya, D. (2013). A meta-analysis of cognitive-based behaviour change techniques as interventions to improve medication adherence. *BMJ Open*, *3*(8). doi:10.1136/bmjopen-2013-002749

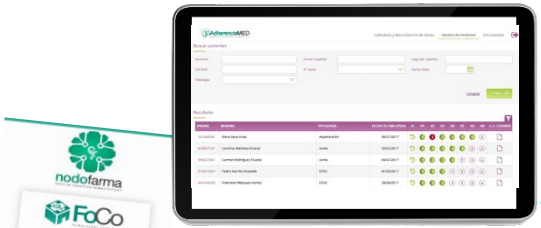
Outcomes

- **138** participating **pharmacists** working in **98 Community Pharmacies** from the 6 Provincial Pharmacists Chambers

- The study included **1,186 patients** (633 intervention group and 553 control group), of whom **42.3%** were patients with **HBP**, **32.5%** with **asthma** and **25.2%** with **COPD**

- Fieldwork lasted **6 months** and was facilitated by the Practice change Facilitator (FoCo)

- Data recorded in an Electronic Recording System

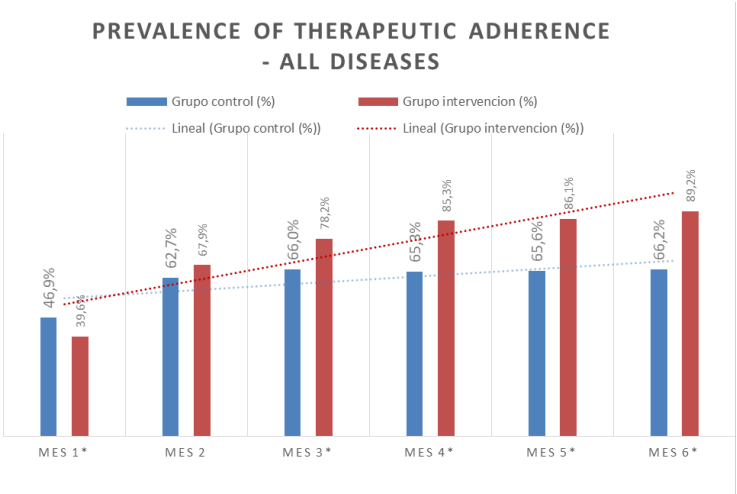


Outcomes

Effectiveness of service : prevalence of adherence

- ✓50% **increase of adherent** patients in the intervention group versus 20% increase of adherent patients in the control group.

- ✓At the end of the study, **the proportion of adherent patients in the intervention group was significantly higher** (89.2%) compared to the control group (66.2%)(p<0.0001).



Outcomes

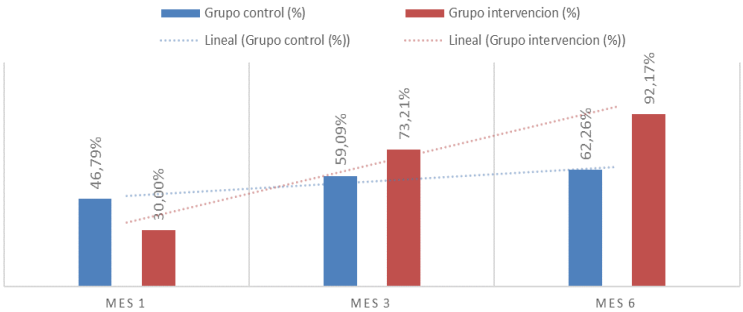
Effectiveness of service: Correct inhalation technique

✓ **Increase** of patients with **correct inhalation technique**:

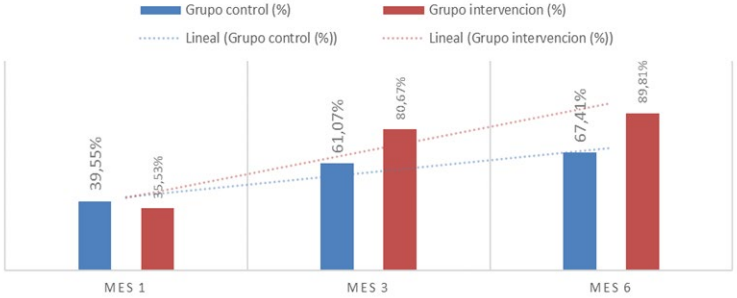
+ 40,7% for Asthma

+ 38,6% for COPD

Prevalence of correct inhalation technique - COPD



Prevalence of correct inhalation technique - Asthma



✓ At end of study **90% patients** had correct inhalation technique

Outcomes

Clinical impact - Health outcomes

Asthma control

Punctuation ACQ: decrease of 0,5 points in IG (p<0,0001)

Significant increase of **30% in patients controlled**

COPD control

Punctuation CCQ: decrease of 0,58 points in IG (p<0,0001)

Significant increase of **22% in patients controlled**

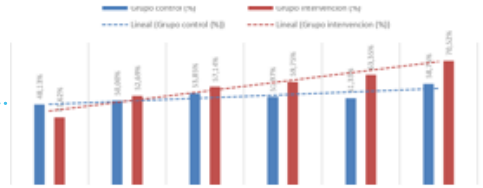
Hypertension Control

Decrease in diastolic levels

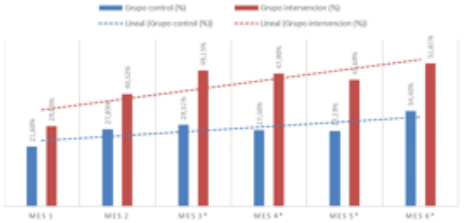
Increase of **13% in patients controlled**

Prevalence of controlled patients

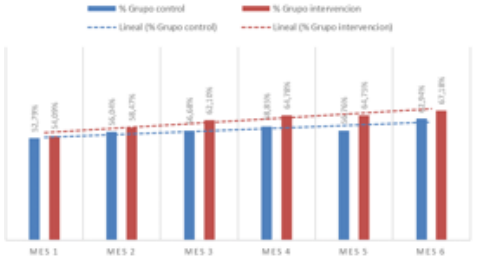
- Asthma



- COPD



- HBP

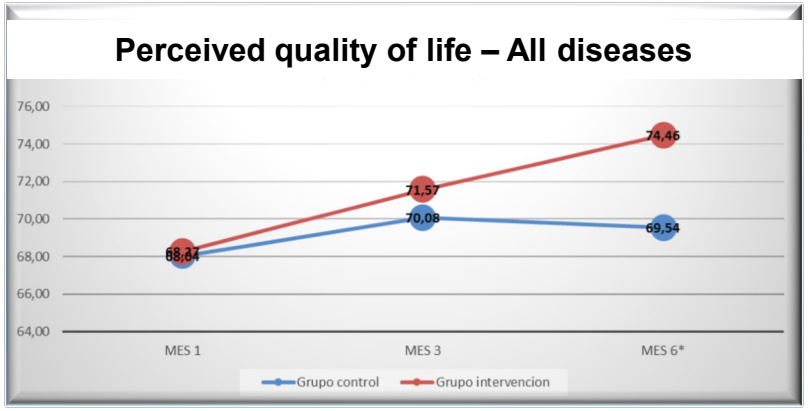


Outcomes

Humanistic impact – Quality of life

Humanistic impact was measured through medication adherence and health-related quality of life perceived by the patient (EuroQol)

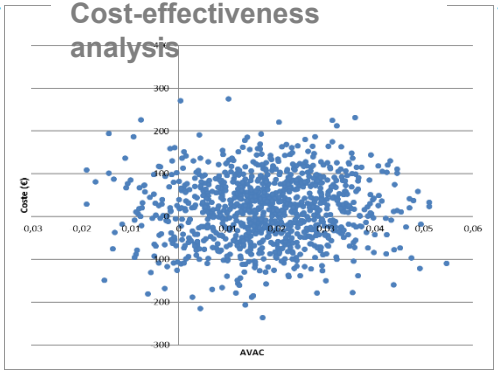
- ✓ *Almost **5 points of improvement using** Visual Analogic Scale (VAS) in the patient **perceived quality of life** between both study groups*
- ✓ *By pathologies:*
  - ✓ higher increase in asthma patients (8,94 points)
  - ✓ lower in COPD (3,97 points) and hypertensive patients (5,43 points)

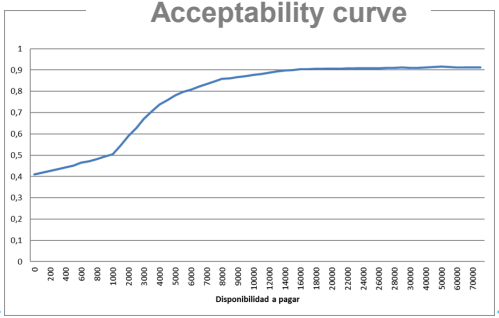


Outcomes

Economic impact – cost utility

- ✓ *Service proved to be cost effective with ICER of 753€/QALY.*
- ✓ *Cost associated 25,47€ per patient (6 months): 4,25€ patient / month.*
- ✓ ***Proposed remuneration of 5,5€ patient / month***





Implementation Phase

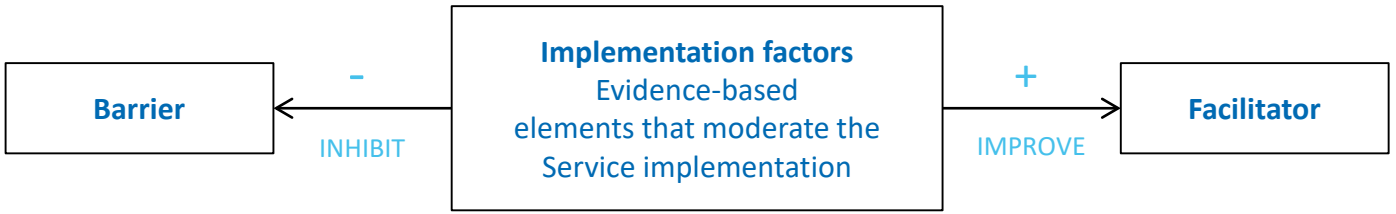
127 pharmacists – 90 community pharmacies – 850 patients involved

Why do we work on Implementation?

The implementation of a Professional Pharmaceutical Care Service is a complex and multifactorial process that requires a guided procedure to achieve it

The "Implementation Science", studies how to integrate the results in the daily practice

The implementation is determined by implementation factors, distributed along different domains, that interact with each other



Practice Change Facilitator

- External support
- Contribute in the practice changes
- Support and advisory work
- On-site visits to community pharmacies
- Individually designed strategies [1,2]

1. Van Hoof TJ, Grant RE, Campbell C, Colburn L, Davis D, Dorman T, et al. Society for Academic Continuing Medical Education Intervention Guideline Series: Guideline 2, Practice Facilitation. J Contin Educ Health Prof. 2015;35 Suppl 2:S55-9.
2. Taylor EF, Genevro J, Peikes D, Geonnotti K, Wang W, Meyers D. Building Quality Improvement Capacity in Primary Care: Supports and Resources. Rockville, MD: Agency for Healthcare Research and Quality; 2013.

What Practice Change Facilitator do?

- ✓ Periodic analysis of unmet needs
- ✓ Identification of barriers, facilitators and causes that influence the implementation.
- ✓ Situation analysis and FoCo interventions.
- ✓ Evaluation of the whole process for each pharmacy.
- ✓ Evaluation of the "Service Integration".
- ✓ Evaluation of the "Fidelity of pharmacists to the protocol".

Purpose

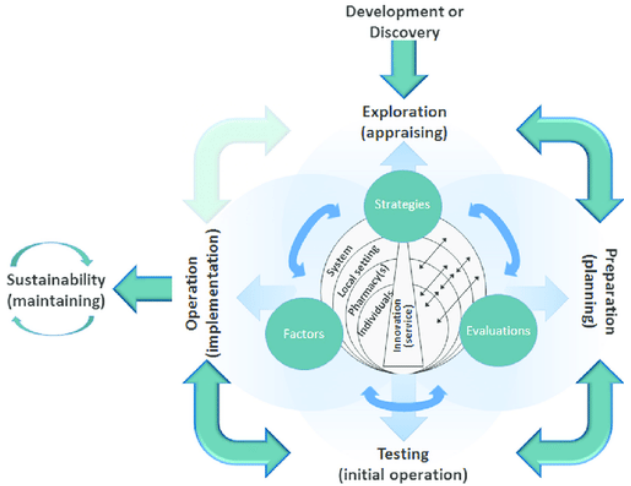
To develop and evaluate an implementation programme of a community pharmacist-led adherence service design before

Specific objectives

- ✓ To Evaluate the implementation of the Service through the different stages of the implementation model
- ✓ To evaluate the facilitation process for the implementation of the Service
- ✓ To evaluate the clinical and humanistic results of the Service during the Implementation phase and in contrast the results obtained during the Impact phase
- ✓ To evaluate the maintenance of the clinical and humanistic results obtained during the Impact phase

Methods

- Hybrid design effectiveness – implementation
- Theoretical framework FISpH (*Framework for the Implementation of Services in Pharmacy*)*



*Moullin JC, Sabater-Hernández D, Benrimoj SI. Model for the evaluation of implementation programs and professional pharmacy services. Res Social Adm Pharm. 2016 MayJun;12(3):515-22. Doi: 10.1016/j.sapharm.2015.08.003. Epub 2015 Aug 15

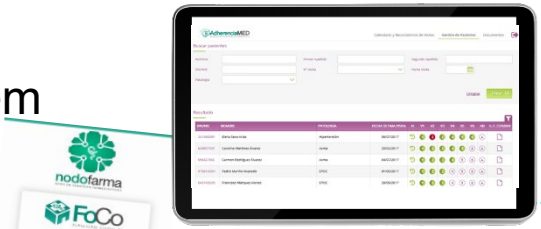
Outcomes

- **127** participating **pharmacists** working in **90 Community Pharmacies** from the same Provincial Pharmacists Chambers

- The study included **850 patients** of whom **51%** were patients with **HBP**, **27%** with **asthma** and **22%** with **COPD**

- Fieldwork lasted **6 months** and was facilitated by the Practice change Facilitator (FoCo)

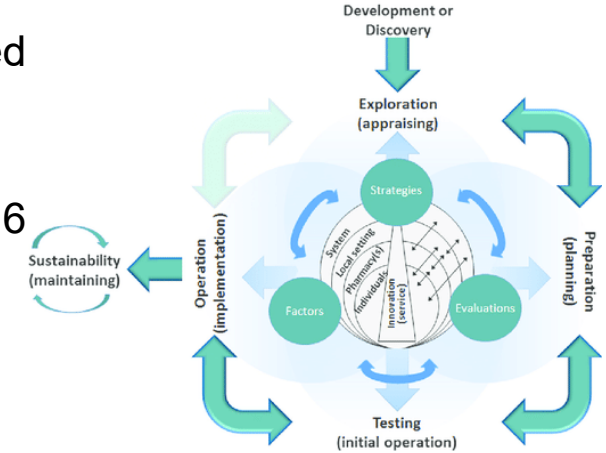
- Data recorded in an Electronic Recording System



Outcomes

Implementation outcomes – daily practice

- ✓76 community pharmacies from Impact phase agreed to continue during the Implementation phase
- ✓**75% pharmacies fully implement the service** at 6 months with >= 7 patients
- ✓ Only 6.7% pharmacies were lost during the study

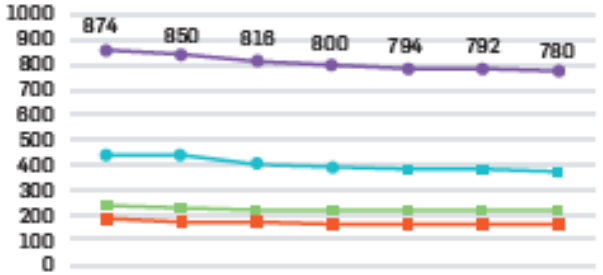


FISpH model Framework for the Implementation of Services in Pharmacy

Outcomes

Implementation outcomes – daily practice

- ✓850 patients recruited. 92% completed the study
- ✓High fidelity to the protocol (4,07/5)
- ✓Greater fidelity to the protocol in pharmacists from the Impact intervention group
- ✓Moderate Service integration in 6 months

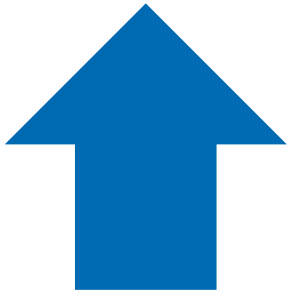


Patients per month

Outcomes

Implementation outcomes – Practice Change Facilitators

- **506 visits** in 6 months
- **1.096 implementation factors** identified:
  - ❖ 410 barriers → 307 solved (74,9%)
  - ❖ 686 facilitators → 598 used succesfully (87,2%)



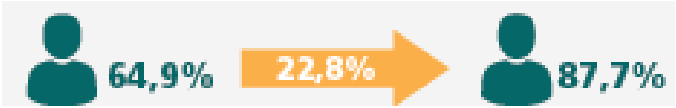
Facilitators:
- External support (30,2%)
- Personal characteristics (5%)
- Previous experience (5%)

Barriers:
- Service methodology (13,5%)
- Records (12%)
- Time (9,8%)

Outcomes

Effectiveness of service

At the beginning of this phase, **64.9%** of the patients included **were adherent** (the most adherent patients came from the intervention group of the previous phase who has been followed the previous 6 months)



After six months of follow-up, the number of adherent patients increased by **22.8%** (particularly the newly included patients in this phase)

The clinical and humanistic results of the Impact phase **were confirmed**, showing similar trends for all study variables

Conclusions

This study has shown a community pharmacist-led intervention **improves** medication adherence, clinical outcomes and health-related quality of life in patients with hypertension, asthma and COPD.

Success factors:

- ✓ Practice change Facilitators as facilitators of practice change
- ✓ A structured work protocol
- ✓ eRecording data

Difficulties were:

- ❑ Put theory into practice
- ❑ Promotion of behavioural changes are not incorporated in usual pharmacist training
- ❑ further adaption of electronic data collection to daily practice

AdherenciaMED
Adherence management service

Farmacéuticos
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GIAF-UGR

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Consejo General de Colegios Oficiales de Farmacéuticos

Thank you for your attention

tamarapeiro@redfarma.org

Farmacéuticos

General Pharmaceutical Council of Spain

Speaker

Jan Saevels, *PharmD, PhD*
Scientific Director - Association of Pharmacists Belgium (APB)

Presentation on
National quality improvement programme on compounded medicines

2020 Award Winner of Pharmacy Practice Improvement Programme Award

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National quality improvement programme on compounded medicines

APB – ASSOCIATION OF PHARMACISTS BELGIUM

- National federation of professional associations of independent community pharmacies
- Representing >95% of independent pharmacies and >85% of all community pharmacies in Belgium
- Our mission: *Support, develop and promote the community pharmacist ‘s added value to the benefit of the patients’ health*
- Staff : ~120 in Brussels
- Medicines Control Laboratory (post-marketing quality surveillance of medicines on the market)

National quality improvement programme on compounded medicines

Quality of compounded medicines

- *Council of Europe* Resolution CM/Res(2016)1 on *quality and safety assurance requirements for medicinal products prepared in pharmacies for the special needs of patients*
- National Legislation – Good Pharmacy Practice – Infrastructure – Equipment – Trained staff – National Formulary – Quality Manual - Protocols – Documentation – Controls – etc.
- Individual preparations for single patients – full (destructive) testing of end product is not possible
- 2017 : APB agrees with Federal Minister of Health to set up a new programme

National quality improvement programme on compounded medicines

Objective

- "A voluntary but systematic quality control of pharmacy preparations, and associated support for pharmacists with the aim to guarantee and improve (where necessary) the quality of pharmacy preparations"
- Available for all Belgian community and hospital pharmacies
- Free of charge for participating pharmacies
- Close collaboration with

The Federal Agency for Medicines and Health Products (FAMHP)

The Belgian Cooperative Pharmacies Office OPHACO

Hospital Pharmacists of Belgium BELGISCHE VERENIGING VAN ZIEKENHUISAPOTHEKERS
ASSOCIATION BELGE DES PHARMACIENS HOSPITALIERS

National quality improvement programme on compounded medicines

Methodology - general

- Simultaneous preparation of an predefined formula by about 100 voluntarily participating pharmacies (= 1 “cycle”)
- Inspection of
  - packaging and label
  - preparation report
  - analytical aspects
- Individual feedback to pharmacy + follow-up of non-conformities
- Publication of anonymised global results, with an important sensitizing and quality enhancing impact, also for non participating pharmacists

National quality improvement programme on compounded medicines

Methodology – details of a cycle

Registration → Selection → Preparation → Analysis → Feedback → Publication

National quality improvement programme on compounded medicines

Methodology – details of a cycle

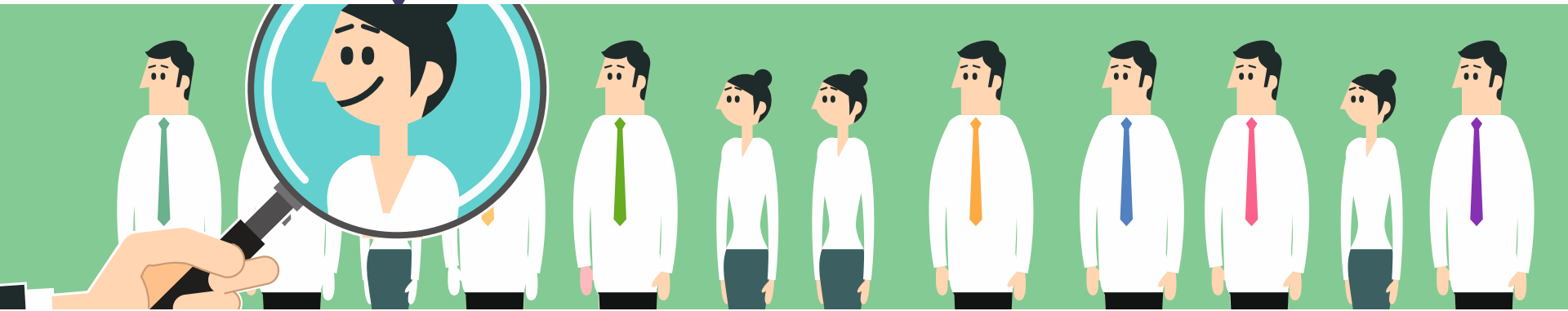
Registration → Selection → Preparation → Analysis → Feedback → Publication

Numéro	Titre
	Gouttes oculaires à 0,5% d'atropine
201810	Gélules à 0,5 mg de dexaméthasone
201801	Gélules à 50 mg de sulpiride FTM
201802	Crème hydrophile à 10% d'urée FTM
	Bain de bouche à l'hydrocortisone, lidocaïne chlorhydrate et nystatine FTM
201809	Suspension pédiatrique à 2 mg/ml d'oméprazole FTM

National quality improvement programme on compounded medicines

Methodology – details of a cycle

Registration › Selection › Preparation › Analysis › Feedback › Publication

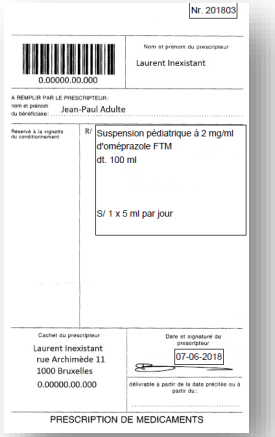


- Voluntary participation
- Preference for new participants
- Mix of community and hospital
- Notification www and e-mail
- Instructions by mail

National quality improvement programme on compounded medicines

Methodology – details of a cycle

Registration › Selection › **Preparation** › Analysis › Feedback › Publication


Nr. 201803

0.00000.00.000

Nom et prénom du prescripteur
Laurent Inexistant

A REMPLIR PAR LE PRESCRIPTEUR:
nom et prénom du bénéficiaire : Jean-Paul Adulte

Réservé à la vignette du conditionnement

Rp/
Suspension pédiatrique à 2 mg/ml
d'oméprazole FTM
dt. 100 ml

S/ 1 x 5 ml par jour

Cachet du prescripteur
Laurent Inexistant
rue Archimède 11
1000 Bruxelles
0.00000.00.000

Date et signature du prescripteur
07-06-2018

délivrable à partir de la date précitée ou à partir du :

PRESCRIPTION DE MEDICAMENTS

- Dummy prescription
- Usual preparation protocol
- Pharmacy raw materials
- Return preparation in the supplied packaging

National quality improvement programme on compounded medicines

Methodology – details of a cycle

Registration › Selection › Preparation › Analysis › Feedback › Publication

› Packaging and labeling

› Preparation report

› Laboratory analysis: identity, assay, mass uniformity, content uniformity, , homogeneity, microbilogy, sterility, etc.

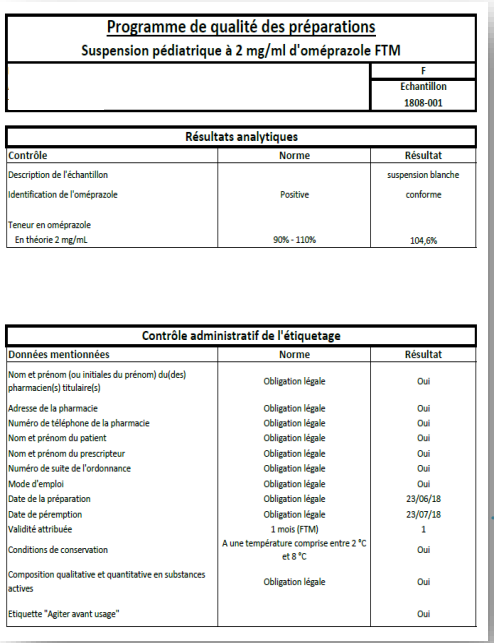
QUALITY MANAGEMENT SYSTEM
ISO 17025
ACCREDITED
LABORATORY

National quality improvement programme on compounded medicines

Methodology – details of a cycle

Registration › Selection › Preparation › Analysis › Feedback › Publication

- Personal report published
- Notification by e-mail
- Advice on non-conformities
- Document in Quality Manual



Programme de qualité des préparations

Suspension pédiatrique à 2 mg/ml d'oméprazole FTM

	F
	Echantillon 1808-001

Résultats analytiques

Contrôle	Norme	Résultat
Description de l'échantillon		suspension blanche
Identification de l'oméprazole	Positive	conforme
Teneur en oméprazole En théorie 2 mg/mL	90% - 110%	104,6%

Contrôle administratif de l'étiquetage

Données mentionnées	Norme	Résultat
Nom et prénom (ou initiales du prénom) du(des) pharmacien(s) titulaire(s)	Obligation légale	Oui
Adresse de la pharmacie	Obligation légale	Oui
Numéro de téléphone de la pharmacie	Obligation légale	Oui
Nom et prénom du patient	Obligation légale	Oui
Nom et prénom du prescripteur	Obligation légale	Oui
Numéro de suite de l'ordonnance	Obligation légale	Oui
Mode d'emploi	Obligation légale	Oui
Date de la préparation	Obligation légale	23/06/18
Date de péremption	Obligation légale	23/07/18
Validité attribuée	1 mois (FTM)	1
Conditions de conservation	A une température comprise entre 2 °C et 8 °C	Oui
Composition qualitative et quantitative en substances actives	Obligation légale	Oui
Etiquette "Agiter avant usage"		Oui

National quality improvement programme on compounded medicines

Methodology – details of a cycle

Registration › Selection › **Preparation** › Analysis › Feedback › Publication

- Always anonymised results
- Professional press articles
- Feedback to FAMHP (National Formulary)

Magistrale kwaliteit

Resultaten cyclus | Hydrocortison 20 mg gelules

Elke deelnemer aan een cyclus van het *Kwaliteitsprogramma bereidingen* krijgt achteraf via de applicatie *MyQualityControl* een individueel verslag met de resultaten van zijn bereiding. Aan het einde van iedere cyclus worden de globale geanonimiseerde resultaten van de bereiding in kwestie ook gecommuniceerd naar het ganse apothekerskorps om kwaliteitsbevordering te stimuleren. →

Deze rubriek in de *Korte Berichten* houdt je maandelijks op de hoogte van de resultaten van afgesloten cycli en/of van de evolutie van lopende cycli. Een van de cycli van het *Kwaliteitsprogramma bereidingen* die in 2017 werden gelanceerd betrof de bereiding Hydrocortison 20 mg gelules[1]. Hieronder vind je de belangrijkste resultaten van die cyclus terug.

Deelnemers

Van de 100 geselecteerde kandidaten ontvingen we uiteindelijk 94 bereidingen (periode 02/10/2017 tot 24/10/2017).

Resultaten

Analytische resultaten

- Identiteit hydrocortison: 93 bereidingen conform, 1 bereiding niet conform (bevatte hydrocortisonacetaat)
- Uniformiteit van massa: 91 bereidingen conform, slechts 3 bereidingen niet conform
- Gemiddelde gehalte: 90,5% (min.: 44,7% - max.: 136,1%) ⇒ 31 van de 93 bereidingen behaalden een onvoldoende. Het feit dat 1 op 3 een niet-conform resultaat heeft, wijst echt wel op een onderliggend probleem!
- Meest extreme resultaten: 44,7% (geen eenduidige verklaring), 136,1% (bereiding van gelules aan 30 mg).

Als we de spreiding van de resultaten bekijken merken we duidelijk een onderdosering bij quasi alle deelnemers.

Etikettering en bereidingsfiche

Voor deze bereiding kent het TMF een houdbaarheid van 2 maanden toe. Grafiek 2 geeft de bevindingen weer van de 94 ingestuurde bereidingen.

Conclusie

Gezien het zeer lage gemiddelde gehalte en het grote aantal niet-conforme bereidingen lijkt een bijsturing van het bereidingsprotocol in het TMF ons noodzakelijk. Mogelijke pistes zijn overdosering, gebreuk andere vulstof, enz.

De bevindingen van deze test werden alvast overgemaakt aan de TMF-commissie die dit verder zal analyseren. Na aanpassing van het TMF-protocol willen we alvast deze formule opnieuw opnemen in het kwaliteitsprogramma.

Hoewel het TMF afraadt gelules kleiner dan nr. 2 te gebruiken *(zie onder: Bereidingsvoorschriften ⇒ Kwaliteitswaarborging van bereidingen)*, gebruikt 48% van de deelnemers die toch (45 bereidingen).

Met betrekking tot de vervaldatum van de bereiding springen twee zaken in het oog:

- 23% van de deelnemers kent een houdbaarheid toe die langer is dan voorgeschreven door het TMF.
- 10% van de deelnemers vermeldt geen vervaldatum op de verpakking.

Grafiek 1: Dosering van de bereidingen

Grafiek 2: Conformiteit etikettering

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Variety in pharmaceutical forms

2017 & 2018

- Hydrocortisone acetate 1% hydrophilic cream
- Hydrocortisone 20 mg capsules
- Chlorhexidine 0,05% solution
- Sulpiride 50 mg capsules
- Urea 10% hydrophilic cream
- Omeprazole 2 mg/mL suspension
- Dexamethason 0,5 mg capsules
- Atropine 0,5% eye drops
- Hydrocortisone, lidocaine & nystatin mouth bath

2019 & 2020

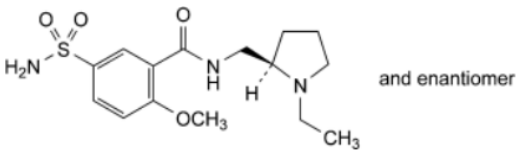
- Folic Acid 2% trituration
- Xylometazoline HCl 0,1% nasal drops
- Flufenamic acid 3% gel
- Cholecalciferol 800 IU capsules
- Erythromycine 4% solution
- Colloidal silver 150 mg suppositories
- Levocarnitine 200 mg/mL solution
- Nystatin 100,000 I.U./g hydrophilic cream
- Salicylic acid 20 % hydrophobic ointment
- Hydrocortisone 1% acid ear solution
- Nitrofurantoin 15 mg capsules
- etc.

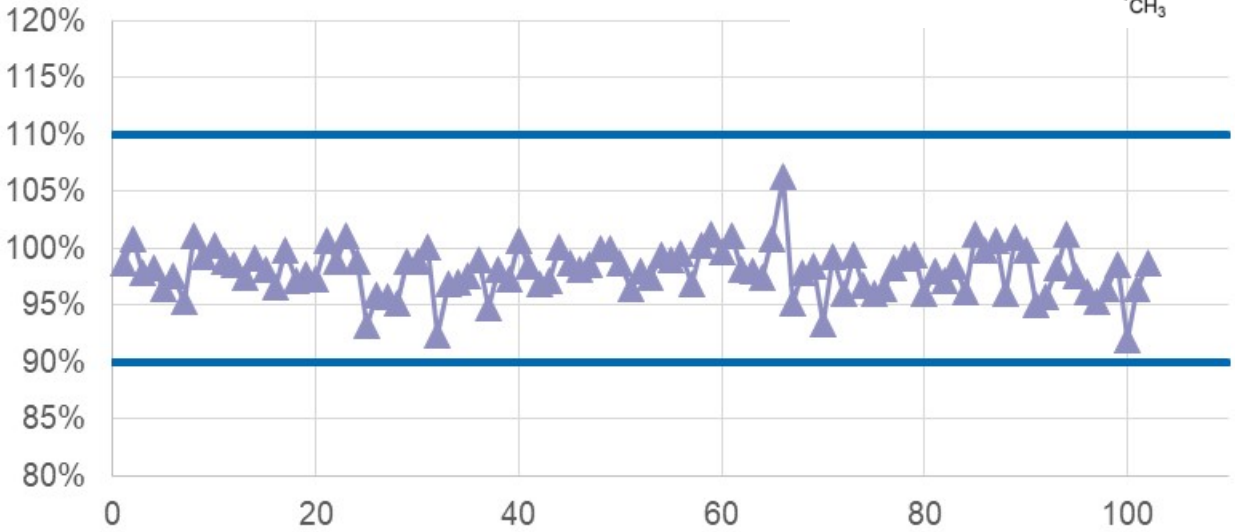
National quality improvement programme on compounded medicines

Sulpiride 50mg capsules

- **Samples :** 102
- **Identification :** 102 compliar
- **Assay :** 102 compliant

- Both lactose and mannitol based excipents are possib

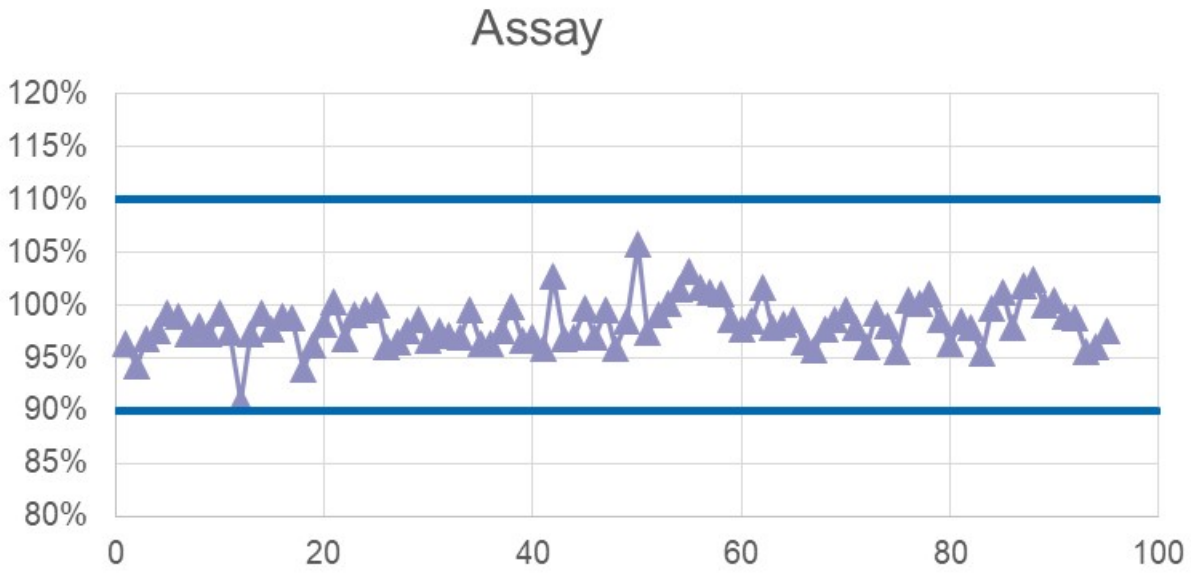




National quality improvement programme on compounded medicines

Hydrocortisone acetate 1% hydrophilic cream

- **Samples :** 95
- **Identification :** 95 compliant
- **Assay :** 95 compliant
- **Homogeneity** : 93 compliant
- **Microbiology** : 88 compliant
- TAMC 5 non-compliant
- TYMC 7 non-compliant
- No pathogens



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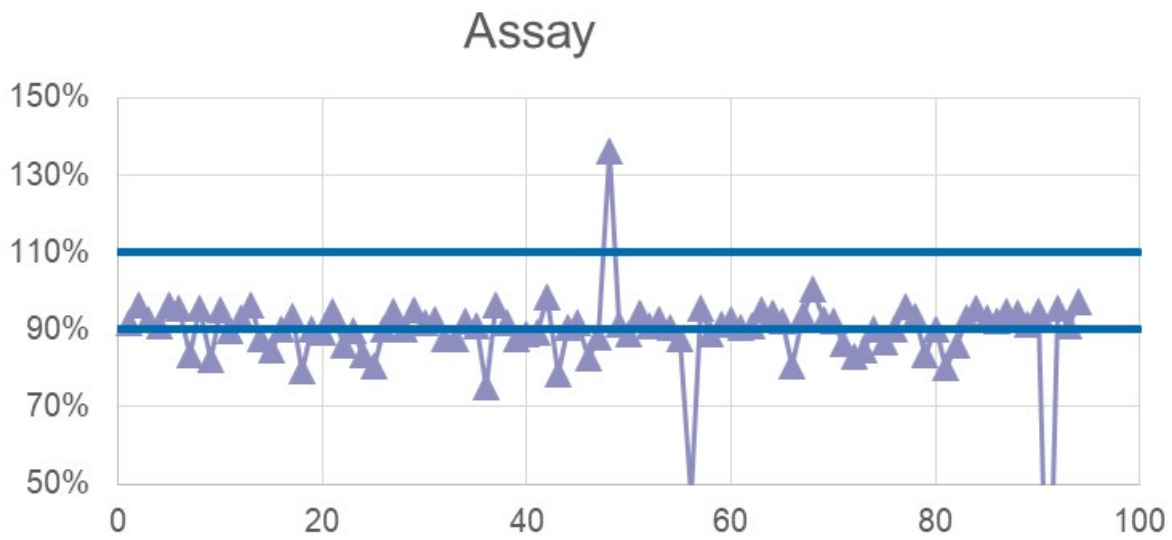
National quality improvement programme on compounded medicines

Hydrocortisone 20mg capsules (2017)

- **Samples :** 94
- **Identification :** 93 compliant
- **Assay :** 31 compliant
- Mean of assays : 90,5 %
- Systematic underdosage

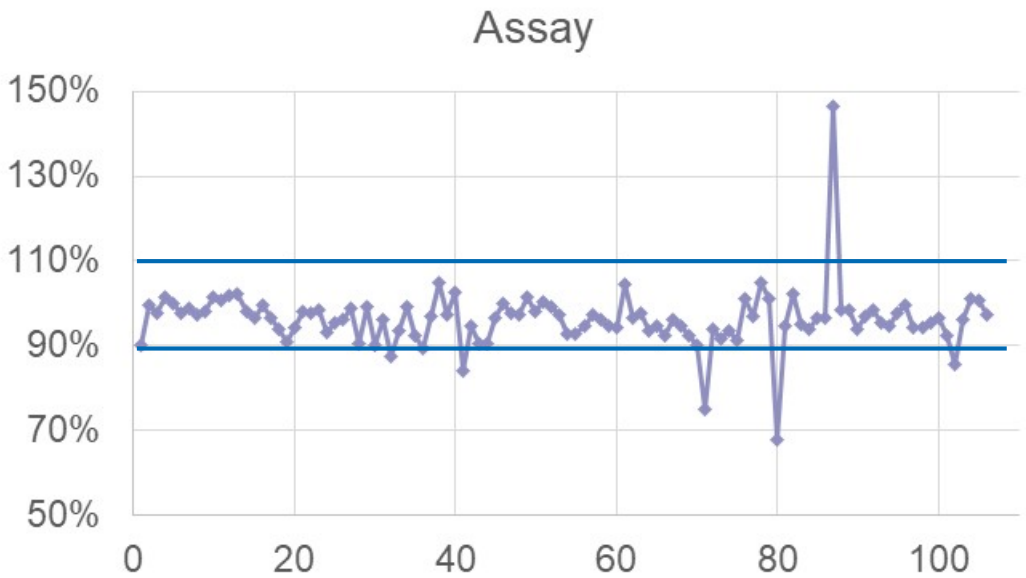


National quality improvement programme on compounded medicines

Hydrocortisone 20mg capsules (2019)

- **Samples :** 106
- **Identification :** 106 compliant
- **Assay :** 99 compliant

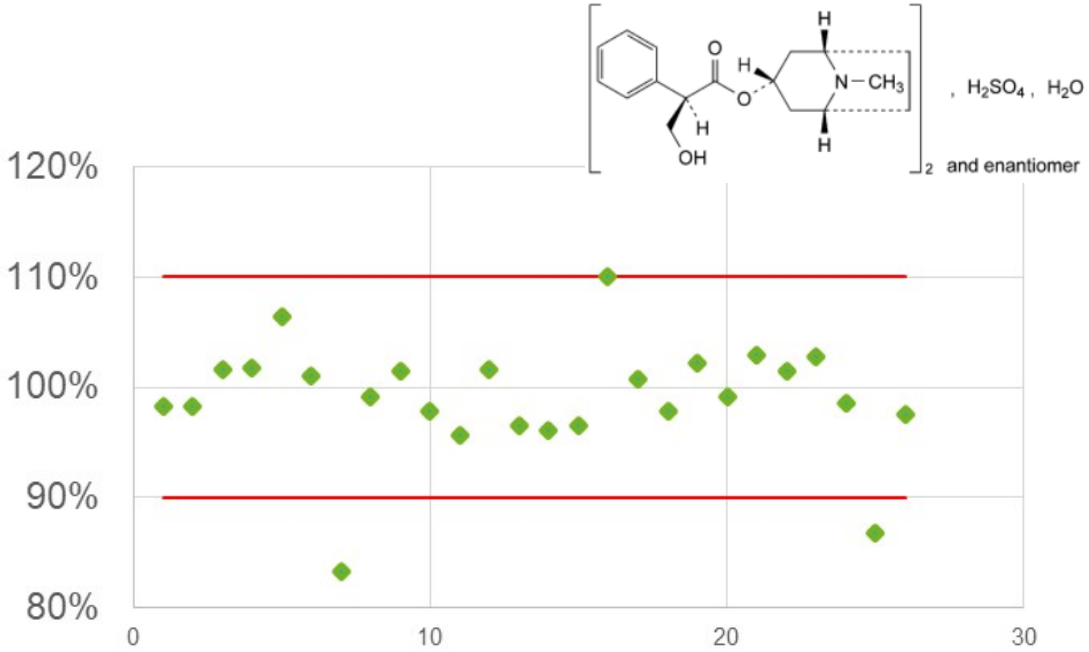
New preparation protocol
Compliance from 62% to 92%



National quality improvement programme on compounded medicines

Atropine 0,5 % eye drops

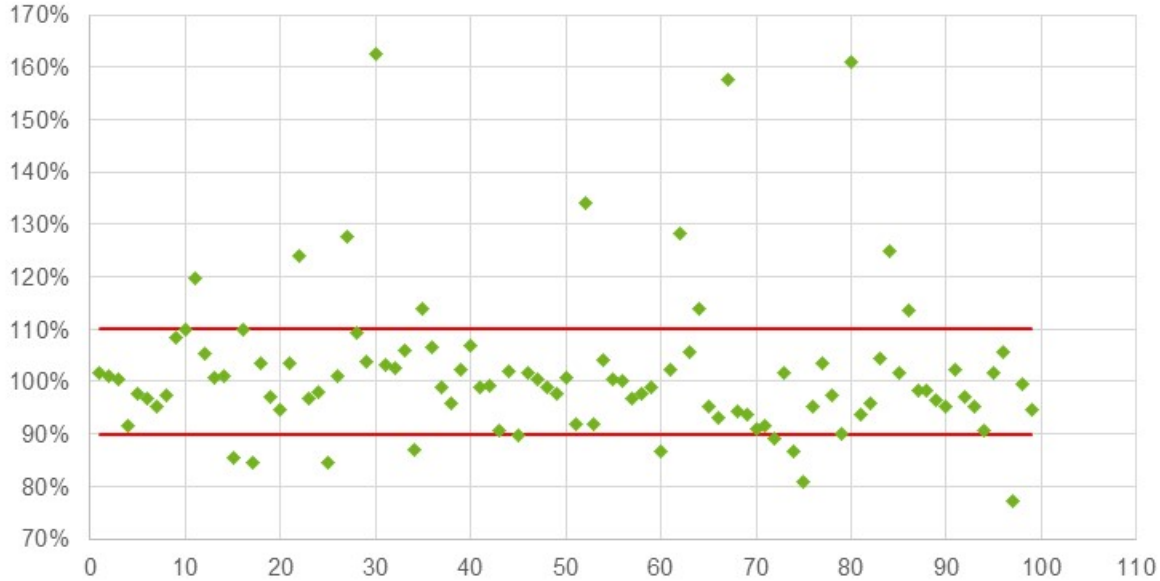
- **Samples :** 26
- **Identification :** 26 compliant
- **Assay :** 24 compliant
- **Sterility** : 26 compliant
- Sterile compounding in community pharmacy is possible!



National quality improvement programme on compounded medicines

Dexamethason 0,5 mg capsules

- **Samples :** 103
- **Identification :** 103 compliant
- **Assay :** 77 compliant
- **Content Uniformity** : 102 compliant
- Calculation errors!
- Use of intermediate dilution (trituration) adds variability in final result



National quality improvement programme on compounded medicines

Levocarnitine 200 mg/mL oral solution

- **Samples :** 20
- **Identification :** 20 compliant
- **Assay :** 20 compliant
- **Microbiology**: 18 compliant
- Use of preservatives

National quality improvement programme on compounded medicines

Conclusions

- Program started in 2017 – reached maturity in 2020
- 10 cycles per year
- 1 out of 5 pharmacies have already participated in a voluntary program
- Quality improvement on individual pharmacy level
- Quality improvement on macro-level with better preparation protocols
- Quality assurance of the production process IN the pharmacy, CLOSE to the patient is extremely relevant!
- The 2020 FIP Pharmacy Practice Improvement Award is a huge recognition of continuous efforts of a great team!

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« *Quality is not an option* »

National quality improvement programme on compounded medicines

https://www.youtube.com/watch?v=UEHJhU4-cTM

Thank you for your attention

Speaker

Jephney John Redford Jacquet
Haitian Pharmacy Students Association

Presentation on
Substandard Quality of the Antimicrobials Sold in the Street Markets in Haiti

On behalf of:
Théodule Jean-Baptiste, John Carpenter, Kevin Dahl, Wellington Derameau, Rosemela Veillard, Osselyn Pierre Ludens, John Redford Jacquet, Albert Figueras

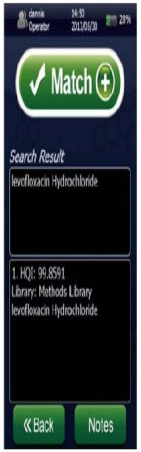
Introduction

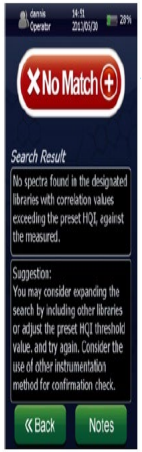
- According to the World Health Organization (WHO) Global Surveillance and Monitoring System, an estimated 1 in 10 medical products circulating in low- and middle-income countries are either substandard or counterfeit [1,2].

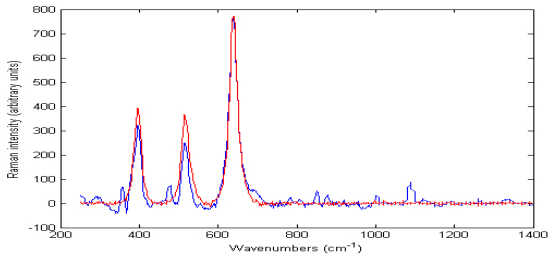
- One of the most important causes of AMR is an inappropriate use of antibiotics
- Antibiotics and antimalarials are the most commonly counterfeit medicines

- Selling medicines in street markets, Specifically antimicrobials, are common practice in Haiti. That's why we designed the present pilot study with the main purpose of analysing the quality of the antimicrobials sold in the street markets of Port-au- Prince.

Materials and Methods







- We identified and selected 28 frequented public markets in the eight communes of Port-au-Prince (Haiti) and Four research assistants bought different brands of antimicrobials products in them
- We analysed half of the content of pack, which was five units with An Handheld Raman Spectrometer
- ***Hit Quality Index*** a probabilistic approach expressed as a p-value or a correlation algorithm between the tested component and library reference spectra
- In our study, a HQI greater or equal to 90 was considered to be a “good spectral match” between the analysed units and their authentic counterpart

Street Markets List where we bought the samples

-Boisthor

-Brochette

-Gerald Bataille

-Carrefour Marassa

-Marche Bizoton

-Marche de Cazeau

-Marche d'Arcachon 32

-Marche de Croix des Missions

-Marche de Croix des Bouquets

-Marché de Damien

- Marche de Puits Blain
- Marche de Marin
- Marche de Tabarre
- Marche de Sarthe
- Marche Duvalier
- Marche en Fer
- Marche Salomon
- Marche Lalue
- Marche Telele
- Marche Se Radòt
- Poste Bon Repos
- Place Clercine
- Route de Delmas 32
- Rue des Miracles
- Source Corossol
- Marche de Kenscoff
- Gerit
- Lamantin 54

Results

A total of 258 packs of antimicrobials containing 21 generic medicine names labelled on the package were bought and 196 packs including 11 antimicrobials were analysed.

Generic name	Number of packs	Number of pills	Price range for a pack in US$*
Amoxicillin	58	290	0.5 – 0.76
Metronidazole	42	210	0.5 – 1.51
Cotrimoxazole	28	140	0.5 – 6.97
Tetracycline	21	105	0.5 – 0.61
Chloroquine	16	80	0.5 – 1.00
Ciprofloxacin	16	80	0.5 – 2.78
Erythromycine	7	35	0.76 – 1.82
Azithromycin	3	10	0.5 – 0.76
Cloxacillin	3	15	1.26 – 1.7
Amoxicillin / Clavulanic Acid	1	5	1.00
Clarithromycin	1	5	4.04

Results

- Origin Countries (presumed) of the antimicrobials

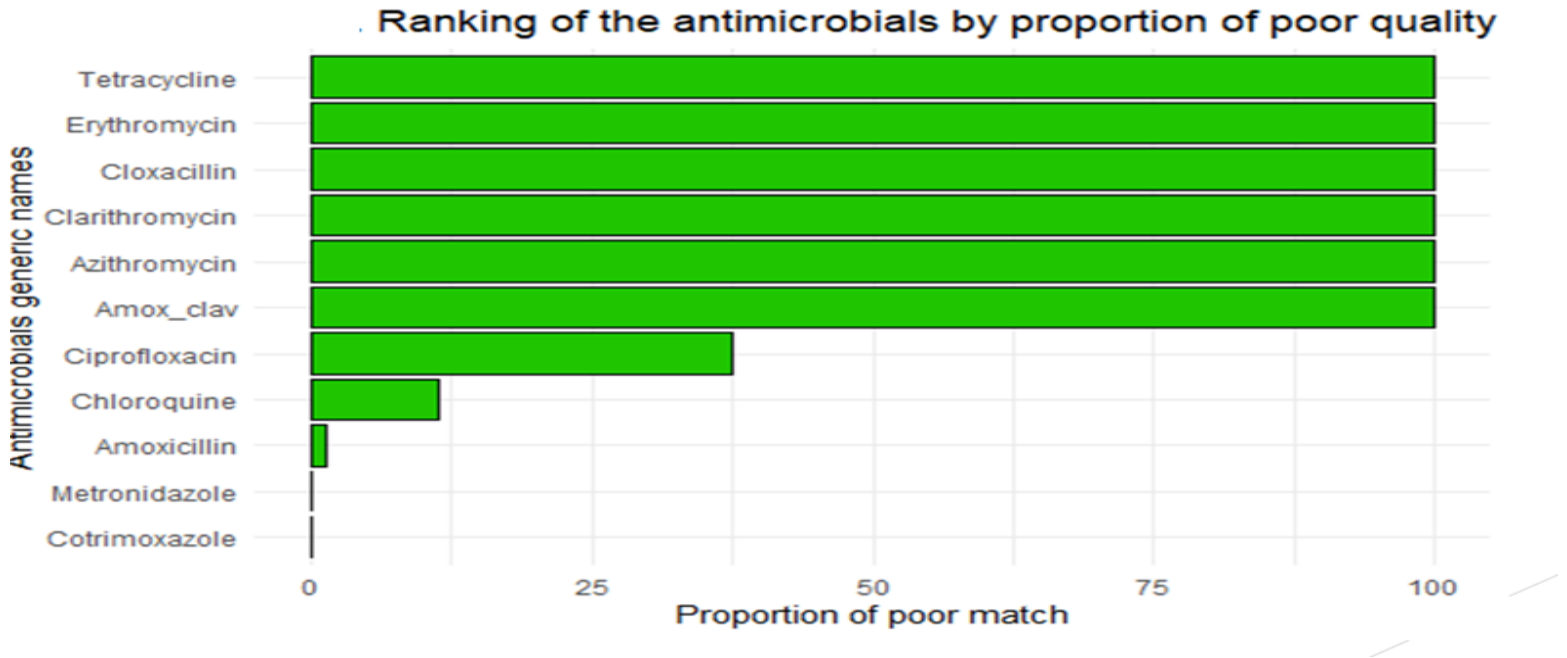
  - *India (75%), China (7%), Kenya(5%), USA (5%), Haiti, France, Canada, Honduras, Unknown*

Results -Spectrum Quality

Table 2. Description of the spectral match quality ("Good" or "Poor") of the analyzed sample of antimicrobials acquired in different street markets in Port-au-Prince (Haiti). The different medicines have been categorized according to the AWaRe classification (see Methods).

AWaRe Classification	Generic Name	Good Match	Poor Match	Total Samples
		n (%)	n (%)	n (%)
Access	Amoxicillin	286 (98.6)	4 (1.4)	290 (100)
	Amoxicillin/Clavulanic Acid	-	5 (100)	5 (100)
	Cloxacillin	-	15 (100)	15 (100)
	Cotrimoxazole	140 (100)	-	140 (100)
	Metronidazole	210 (100)	-	210 (100)
	Tetracycline	-	105 (100)	105 (100)
	Subtotal Access	636 (83.1)	129 (16.9)	765 (100)
Watch	Azithromycin	-	10 (100)	10 (100)
	Ciprofloxacin	50 (62.5)	30 (37.5)	80 (100)
	Clarithromycin	-	5 (100)	5 (100)
	Erythromycin	-	35 (100)	35 (100)
	Subtotal Watch	50 (38.4)	80 (61.5)	130 (100)
-	Chloroquine	71 (88.8)	9 (11.3)	80 (100)
	TOTAL	757 (77.6)	218 (22.4)	975 (100)

Results


Ranking of the antimicrobials by proportion of poor quality
Antimicrobials generic names
Tetracycline
Erythromycin
Cloxacillin
Clarithromycin
Azithromycin
Amox_clav
Ciprofloxacin
Chloroquine
Amoxicillin
Metronidazole
Cotrimoxazole
0
25
50
75
100
Proportion of poor match

Discussion / Conclusions

- Antimicrobials could be freely obtained without a prescription in Haiti and are available in street markets
- To our knowledge, this is the first study approaching the free sales of antimicrobials in Haiti using this technique
  - *new technology using a non-destructive and accurate approach to the detection of counterfeit pharmaceutical products*
  - *Can be extended to other types of drugs and new environments*
- Limitations
  - *Sampling process*
  - *HQI limits (the quality of the active ingredient, compounds present in counterfeit medicines, etc)*
- Conclusions
  - *Potential contributions of this problem in the actual Antimicrobial Resistance*
  - *Serious needs to Improve measurements on appropriate Use of Antimicrobials in Haiti*

Thanks to

- Faculté de Médecine et de Pharmacie of State University
  - *LABMES*
  - *Co-Dean Magalie Rosemond*
- PHARMINFOS Haïti

- Skaggs School of Pharmacy and Pharmaceutical Sciences, University of Colorado
- WHO Collaborating Centre for Research and Training in Pharmacoepidemiology (Barcelona, Spain)
- BWTEK (Dr Katherine Bakeev)
- Haitian Pharmacy Students Association

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THANK YOU

*Original Publication : Antibiotics **2020**, 9(7), 407; **https://doi.org/10.3390/antibiotics9070407***

Questions and Answers

SIGN 4 - Medicines use and quality

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Post your question via Q&A box

Paul Sinclair (Event Chair)
Chair of the Board of Pharmaceutical Practice
FIP (Australia)

Tamara Peiró Zorrilla
General Pharmaceutical Council of Spain
(Spain)

Jan Saevels
Scientific Director
Association of Pharmacists Belgium (APB)
(Belgium)

Jephney John Redford Jacquet
Haitian Pharmacy Students Association
(Haiti)

Thank you for your attention