European Forum on Patient Adherence to Medication

8th December 2011

European Parliament Building, Brussels, Belgium

Professor Dyfrig Hughes, Bangor University

Overall aim of the ABC project

"Produce evidence-based recommendations to inform the content of European policy relating to patient adherence to medicines, to achieve safer, and clinical and cost-effective use of medicines in Europe"

ABC policy recommendations should be:

- **Evidence-based ('what works')**
- **Have consensus**
- **Feasible**
- **Flexible for national/local adaptation**

Ascertaining Barriers for Compliance

SEVENTH FRAMEWORK PROGRAMME

WP1
European consensus on terminology used in the field of deviations from assigned treatment and relevant taxonomy

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Objective 6

Assessment of the cost-effectiveness of interventions that promote compliance

Objective 3

Development of a conceptual framework for the determinants of non-compliance

Objective 5

Identification and assessment of adherence-enhancing interventions

Objective 4

Exploring the current practices of compliance management by healthcare professionals and the pharmaceutical industry

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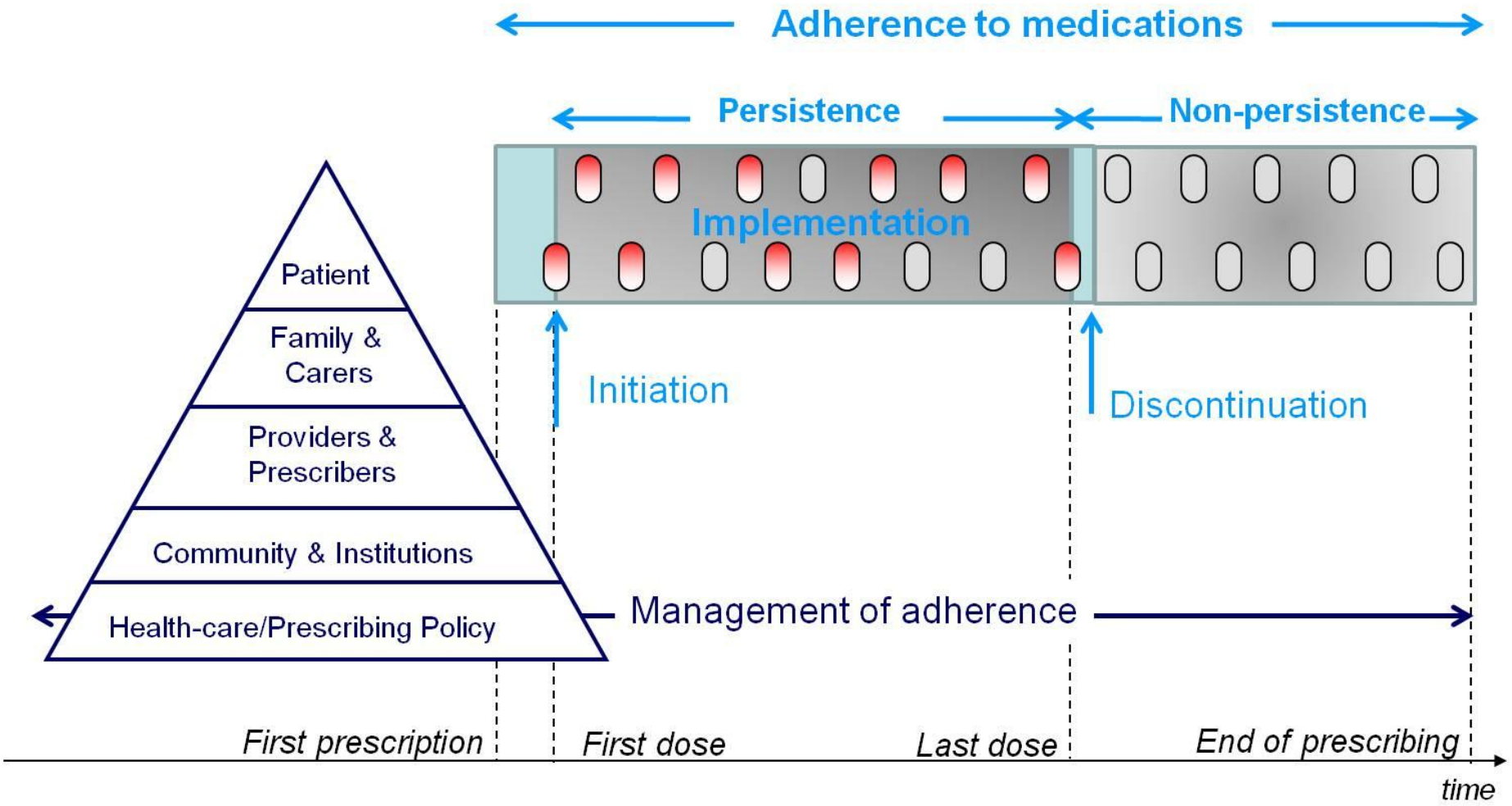
Work Package No. 1
Objectives

- To conduct a systematic literature review to identify the terminologies commonly used to describe deviations from prescribed treatment in ambulatory patients
- Propose a new, consolidated taxonomy and related terminology

Ascertaining Barriers for Compliance

Work Package No. 1
New taxonomy



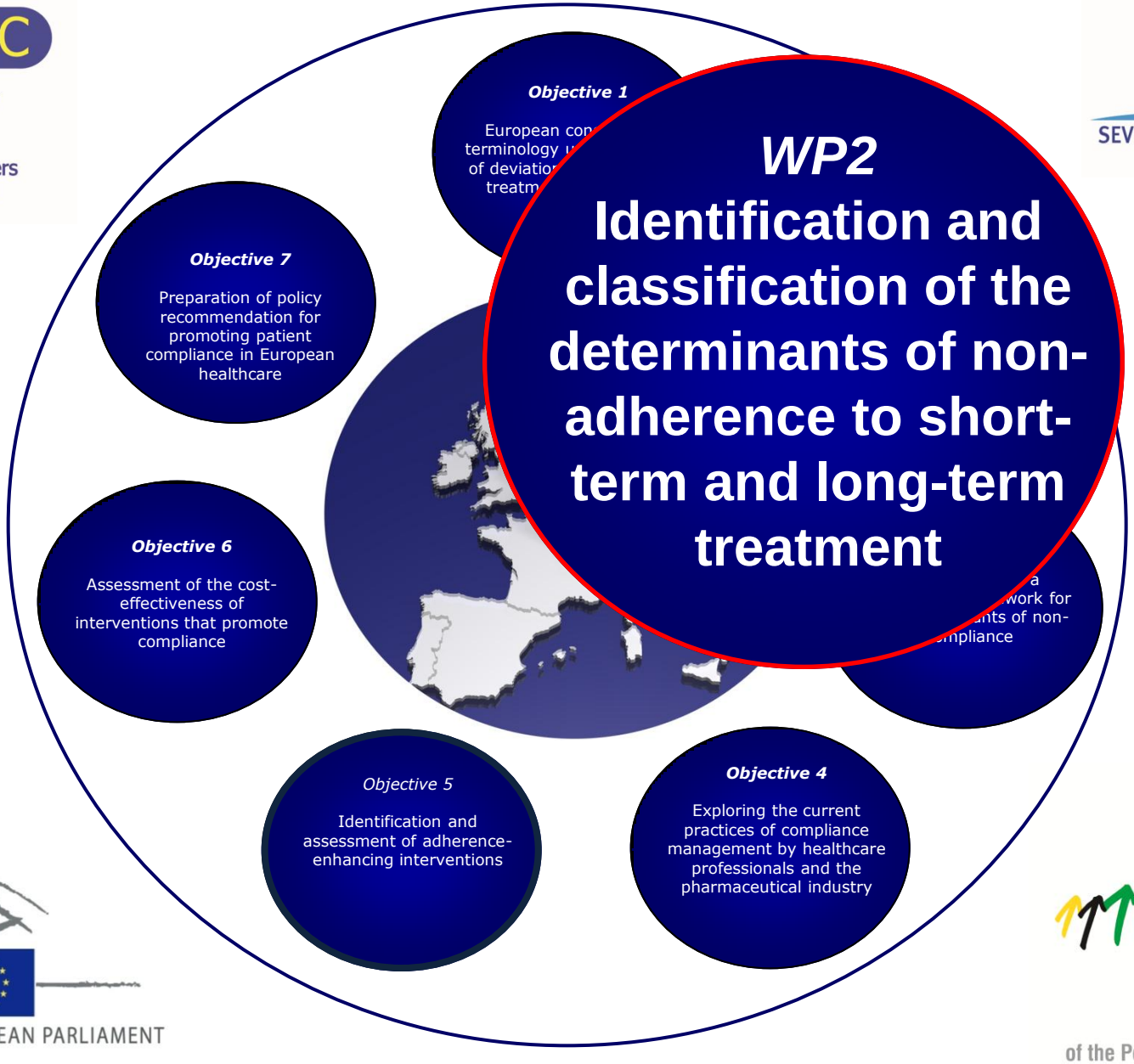
Vrijens et al, accepted in BJCP (2011)

Work Package No. 1
ABC policy recommendations

- **Any initiatives in respect to patient *adherence to medications* should address its 3 distinct elements:**
  - ***initiation – implementation – discontinuation***
- ***Management of adherence* derives benefit from a 'system-based' approach, wherein each stakeholder has a specific role to play:**
  - **the patient, their family & relatives, healthcare providers, institutions, and healthcare systems**

Ascertaining Barriers for Compliance

SEVENTH FRAMEWORK PROGRAMME



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Work Package No. 2
A 'review of reviews'

Findings

- Multiple patient-, therapy-, condition-, social- and healthcare-system-related factors determine adherence

Recommendations

- Interventions aimed at improving adherence have to acknowledge the complex nature of non-adherent behaviour

Work Package No. 2
Field survey

- **Multinational survey of adherence to medications, and determinants of non-adherence**
  - **Poland, Wales, England, Hungary, Netherlands, Germany, France, Belgium, Greece, Austria, Portugal**
- **Patients currently prescribed antihypertensive therapy**
- **Target recruitment of 323 per country**

Work Package No. 2
Extent of non-adherence

- **Percentage of patients classified as non-adherent to antihypertensive treatment, based on self-report:**

Country	Non-adherence
Wales	38.1%
England	41.5%
Poland	57.6%
Hungary	70.3%

- **There is no correlation between adherence to long-term, and short-term treatments**

Work Package No. 2
Determinants of non-adherence

Poland		England		Wales	
Morisky	*MARS*	*Morisky*	*MARS*	*Morisky*	*MARS*
		Employment			Gender
	Affordability	Number of items prescribed			
Concern about illness			Concern about illness		
			Treatment control		Intention
Barriers			Barriers	Barriers	Barriers
Self efficacy	Self efficacy	Self efficacy	Self efficacy	Self efficacy	Self efficacy

Work Package No. 2
ABC Policy recommendations

- Key targets
  - improvement in self-efficacy
  - reducing barriers to medication
- Determinants of adherence differ by country (and by the outcome measures used)
- Management of adherence in patients co-prescribed multiple medicines for chronic and acute conditions may require different approaches

Work Package No. 2
Discrete Choice Experiment

- **Drug attributes which influence patients' stated preferences to continue treatment:**
  - **Treatment benefit (positive)**
  - **Dose frequency (negative)**
  - **Mild adverse events (negative)**
  - **Potentially life-threatening but rare adverse events (negative)**

Work Package No. 2
Discrete Choice Experiment

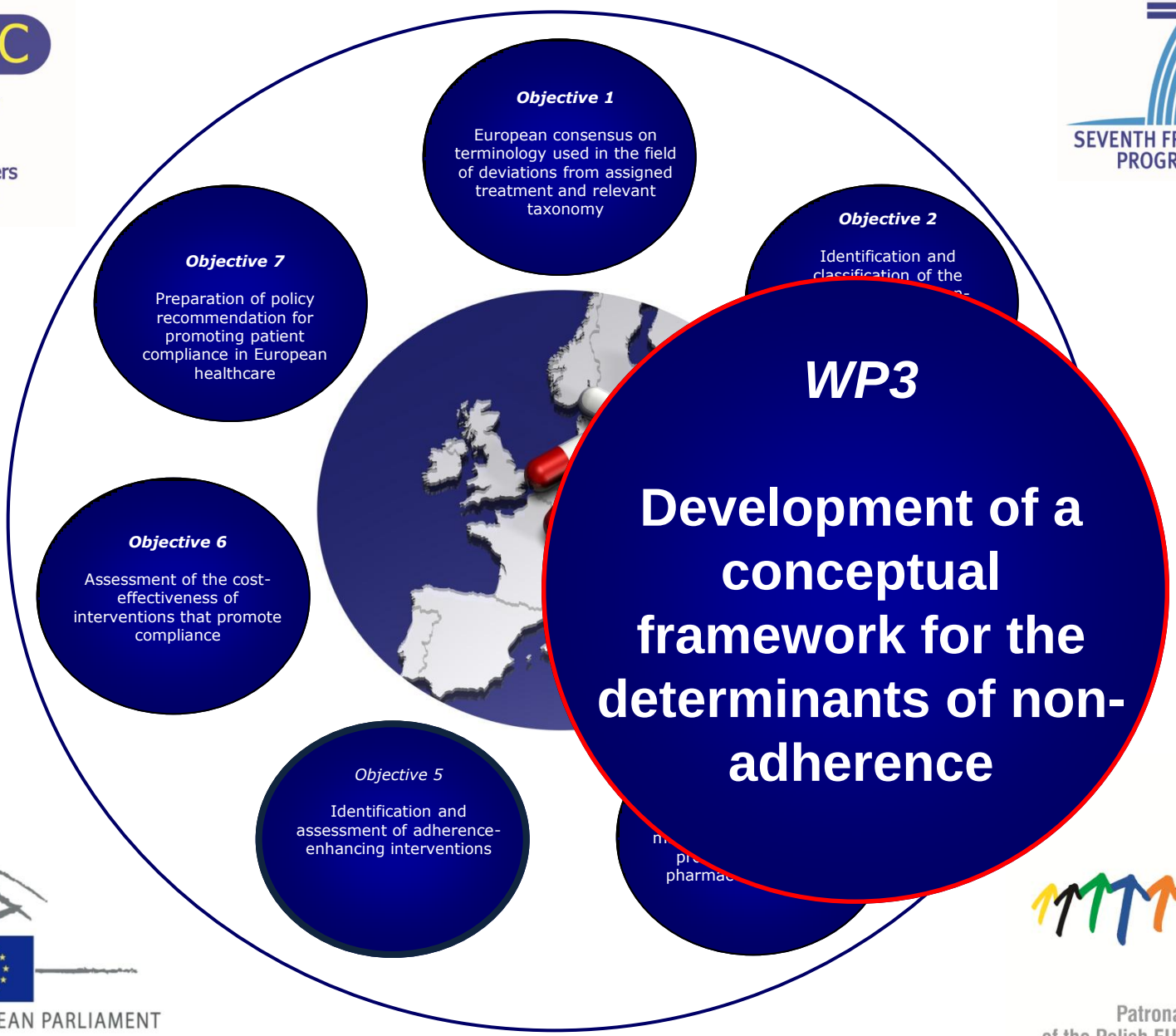
- To persist with treatment, patients are willing to accept the following trade-offs:
  - An increase in dosing frequency (OD, BD, QDS) if compensated by a 6% increase in treatment benefit
  - 24% increase risk of mild adverse events if compensated with a move from an 'uncommon' to 'very-rare' risk of life-threatening adverse events

Work Package No. 2
ABC Policy recommendation

- **Patients' preferences for drug attributes influence their decision to continue taking a medicine and should be considered when developing new medicines, formulations or interventions**

Ascertaining Barriers for Compliance

SEVENTH FRAMEWORK PROGRAMME



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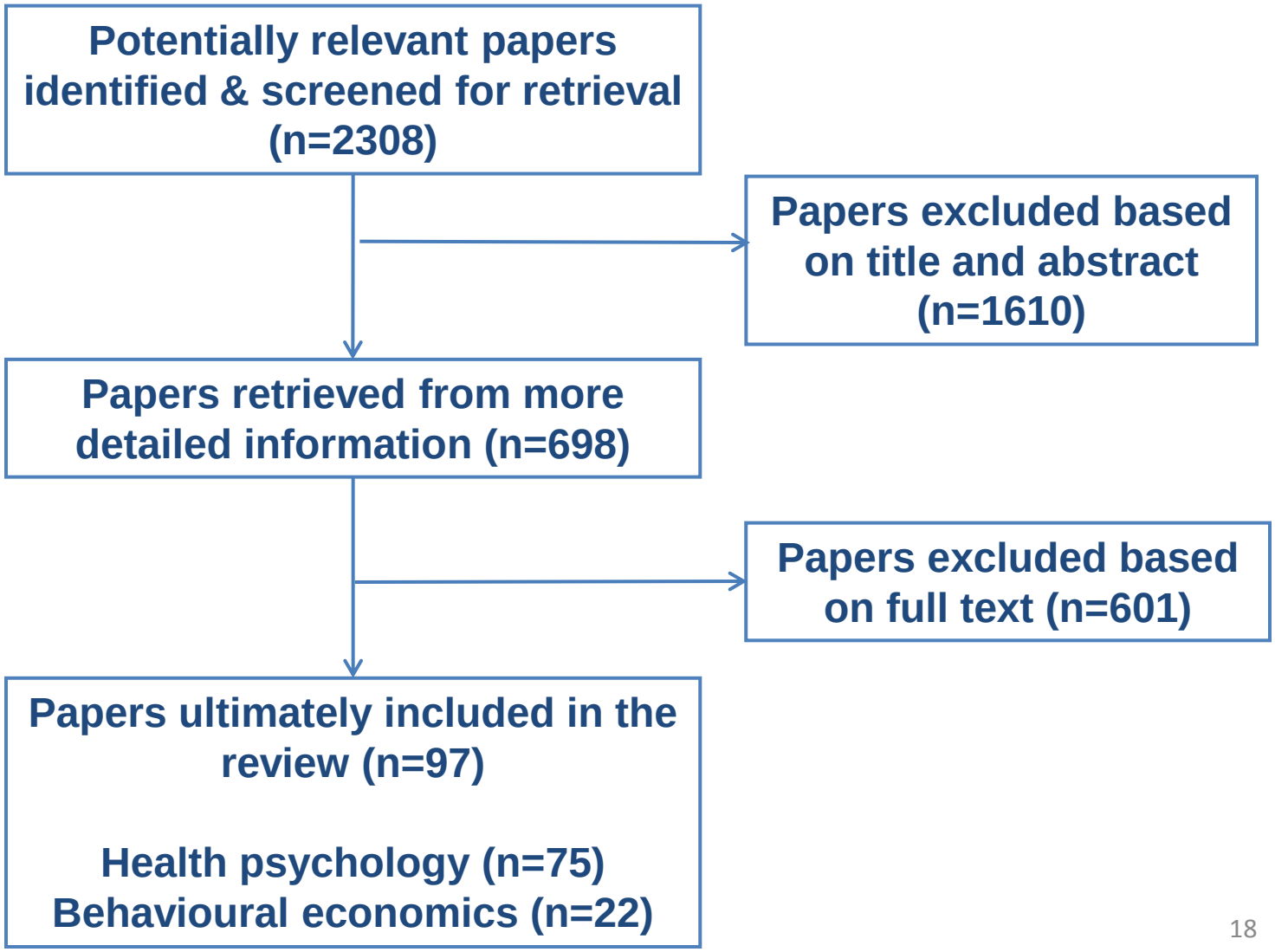
Work Package No. 3 Objectives

- To systematically review the health psychology and behavioural economics literatures to identify behavioural models that have been used to examine adherence to medication by adult patients
- To provide a theoretical basis for the development of adherence-enhancing interventions

Work Package No.3
Study selection



Work Package No. 3 Results

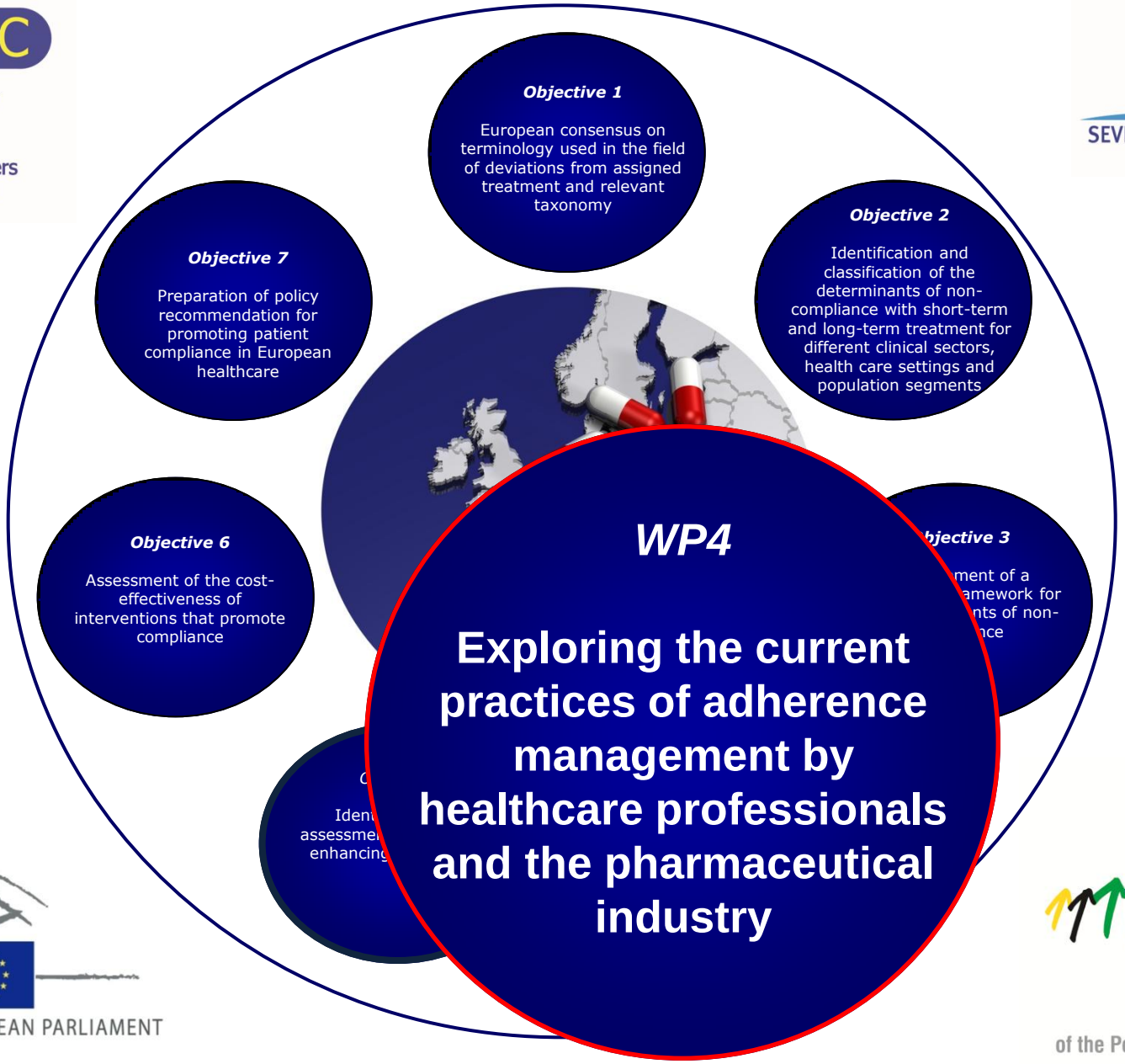
- Theories used to explain adherence behaviour:-
  - Social-cognition models (n=35)
  - Self regulation models (n=32)
  - Consumer demand theory (n=21)
  - Time preference (n=1)
- The extent to which individual components of behavioural models were tested varied
- Self-report was the most common measure of adherence (n=74)
- Studies were mainly cross-sectional (n=71)

Work Package No. 3
ABC policy recommendations

- Assessment of the theoretical basis of adherence behaviour should inform the development of adherence enhancing interventions
- Consolidation of behavioural models across disciplines will benefit the development of interventions that promote a more sustainable behaviour change

Ascertaining Barriers for Compliance

SEVENTH FRAMEWORK PROGRAMME



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Work Package No. 4
Healthcare professionals

- Key role in initiation and persistence with patient adherence to medication
- Skills mix – role of different healthcare professionals (doctors, nurses, pharmacists)
- Interventions to support medication adherence often provided or facilitated by healthcare professionals
- Gatekeeper/guide to adherence support

Work Package No. 4
Role of healthcare professionals

- Inventory of educational content of undergraduate teaching regarding medication adherence
- Survey of healthcare professionals across Europe
- Survey of pharma industry adherence initiatives
- Review of existing adherence guidelines
- New educational framework for healthcare professionals

Work Package No. 4
European survey

- On-line survey currently underway in 10 countries: Austria, Belgium, England, France, Germany, Hungary, Netherlands, Poland, Portugal, Switzerland
- What doctors, pharmacists and nurses think about patient medication adherence and what they do to support patients with medicine taking

Protocol published. Clyne W et al. BMJ Open 2011;1:e000355

Work Package No. 4
Inventory of programmes

- Sampled educational programs (medicine, nursing, pharmacy) across 16 European countries
- 201 programs invited (e-mail and phone contact to each program); 22 responded

Work Package No. 4
Inventory of programmes

- 71% of programmes report addressing adherence at some point in their curriculum
  - Amount of time devoted to adherence is often very little
  - Quality of adherence content is highly variable
- Most programs responding to the survey do not plan to start new adherence training initiatives in the next 12 months

Work Package No. 4
Survey of Pharmaceutical Industry

- Invited all members of EFPIA and EGA to participate; 9 completed the survey
- 4 reported inclusion of adherence to medications in strategic plans
- 2 have dedicated adherence staff
- Most report adherence initiatives targeting only adults at this time
- 5 report plans to start new medication adherence initiatives in the next year

Work Package No. 4
Adherence management guidelines

- Systematic review
  - Medical literature databases
  - Internet searches
  - Querying known adherence experts
- Identified 17 guidelines that specifically address adherence to medicines

Work Package No. 4
Adherence management guidelines

- Include algorithms to guide providers
- Assess adherence or change in symptoms
- Most common recommendations:
  - Provide medication education
  - Involve patients in decision-making
  - Modify home environments to improve adherence
- Nearly all guidelines developed based on expert opinion, rather than systematic research

New educational framework for European healthcare professionals

- 3 components:
  - Competency framework
  - Curriculum
  - Diagnostic tool for assessing competence
- All healthcare professionals but especially doctors, nurses, and pharmacists
- Europe-wide consultation and input from ABC team
- Framework can be accessed at: www.abcproject.eu/index.php?page=publications

Work Package No. 4
ABC policy recommendations

- Educational framework with 3 components:
  - Competency framework
  - Curriculum
  - Diagnostic tool for assessing competence
- Adherence should be included in curricula for all healthcare professionals, especially doctors, nurses, and pharmacists
- Specific, evidence-based practice guidelines are needed

Ascertaining Barriers for Compliance

SEVENTH FRAMEWORK PROGRAMME

Objective 1

European consensus on terminology used in the field of deviations from assigned treatment and relevant taxonomy

Objective 2

Identification and classification of the determinants of non-compliance with short-term and long-term treatment for different clinical sectors, health care settings and population segments

Objective 3

Development of a conceptual framework for the determinants of non-compliance

Objective 4

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Objective 7

Preparation of policy recommendation for promoting patient compliance in European healthcare

Objective

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WP5

Identification and assessment of adherence-enhancing interventions

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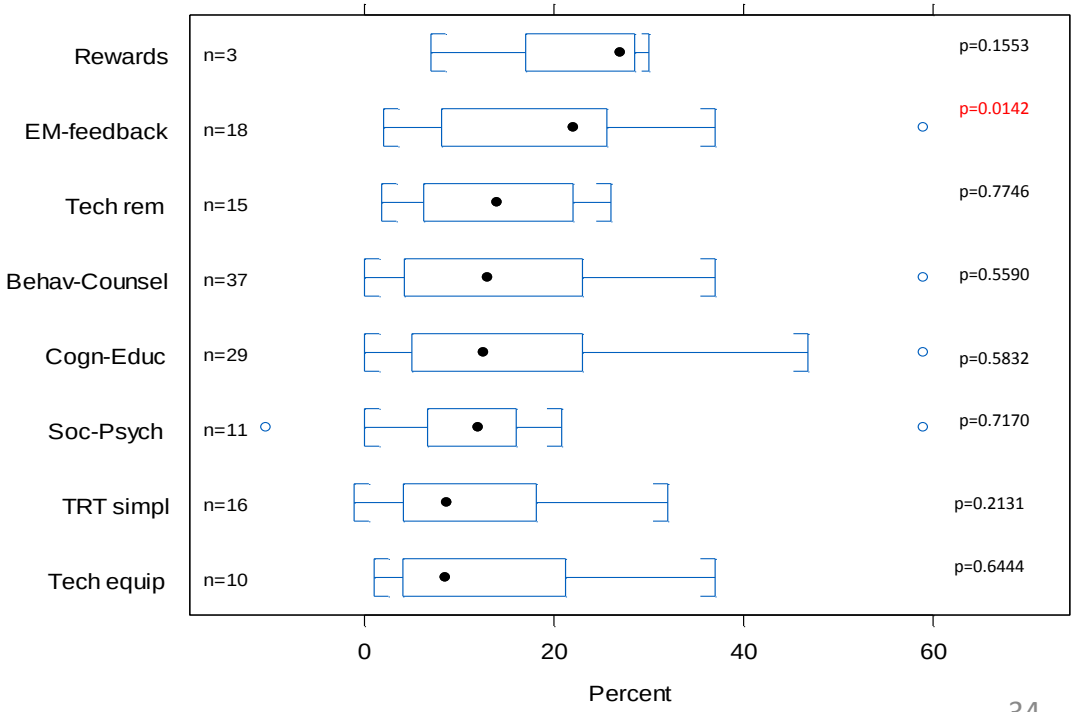
Work package No. 5
Objective

- To identify, through a systematic literature review, strategies for enhancing adherence and components thereof that successfully improve implementation of the prescribed drug dosing regimen and maintain long-term persistence

Work package No. 5 Results

- Large heterogeneity between studies despite a common measurement (EM)
- Effect of interventions on adherence decreases over time (p=0.022)
- EM-feedback showed a significant improvement in adherence outcomes (p=0.0142)



Demonceau et al, IAPAC, Miami 2011 (manuscript in preparation)

Work package No. 5
ABC policy recommendations

- Interventions intended to manage adherence should include, beside education, motivation and performance-based feedback to achieve measurable, pharmacologically sound goals
- The effects of interventions wane over time, calling for innovative approaches to achieve sustainable management, validated by long-term program evaluation

Ascertaining Barriers for Compliance

SEVENTH FRAMEWORK PROGRAMME

WP6

Assessment of the cost-effectiveness of interventions to promote adherence

Objective 1

European consensus on terminology used in the field of deviations from assigned treatment and relevant taxonomy

Objective 2

Identification and classification of the determinants of non-compliance with short-term and long-term treatment for different clinical sectors, health care settings and population segments

Objective 3

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Objective 4

Exploring the current practices of compliance management by healthcare professionals and the pharmaceutical industry

Objective 7

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Work Package No. 6 Objectives

- To generate economic evidence to inform policy and practice about adherence-enhancing interventions
- To review the literature associated with the cost-effectiveness of adherence-enhancing interventions
- To estimate the economic impact of adherence-enhancing interventions

Work Package No. 6 Findings

- Elliot et al (2005) identified 45 studies [1980-2004]
  - 9 carried out incremental economic analysis
  - 0 met all minimum requirements for an economic evaluation
- NICE (2009) identified 3 studies [2004-2009]
  - Pharmacy-based coaching programme (antidepressants)
    - ICER €149 per 1% improvement in adherence
  - Monitoring system and adherence training (antihypertensives)
    - ICER €15,667 per QALY gained
  - Long acting injection vs. oral (risperidone)
    - ICER US$821 per day of hospitalisation averted
- WP6 update (2010) found no additional studies

Work Package No. 6
Economic model

- Acute Upper Respiratory Tract Infections in Adults
- Systematic review
  - Identified two RCTs of informational interventions (written information / telephone back-up) significantly increased adherence with antibiotic treatment for acute sore throat
- Economic analysis
  - Based on the NICE clinical guideline for antibiotic prescribing for upper respiratory tract infections to estimate the cost-effectiveness of written information and telephone back-up

Ascertaining Barriers for Compliance

Work Package No. 6 Economic model findings

- Immediate dispensing of prescription
- Written information
  - Cost saving and clinically beneficial (dominant)
  - Sensitive to costs of intervention
    - i.e. increase of 1 minute of GP consultation time gives an ICER of £11,731
- Telephone back-up
  - More costly and less effective (dominated)
- Interventions targeted at acute conditions with small health benefit will need to have a low per patient cost to potentially be cost-effective

Work Package No. 6
ABC policy recommendations

- **Research recommendation – more quality evidence on the cost-effectiveness of adherence-enhancing interventions is necessary**

Conclusion

- **Through mixed methods research, the ABC project team have shortlisted a number of policy recommendations which, if implemented, could improve patients' adherence to medications in Europe**