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ABOUT THIS DOCUMENT

The ABC project

ABC (Ascertaining Barriers to Compliance) Project is a EU-funded 7th Framework Programme research initiative to improve patient adherence to medication in Europe, involving 5 research centres: Medical University of Lodz (Poland), Bangor University (UK), AARDEX Group Ltd. (Switzerland), NPC Plus, Keele University (UK), Katholieke Universiteit Leuven (Belgium). The strategic goal of this project is to produce evidence-based policy recommendations for improving patient adherence, and thus improve the effective use of medication by Europeans. This educational framework, as part of the ABC project, is funded by the European Commission Seventh Framework programme (FP7 Theme Health, 2007-3.1-5, grant agreement number 223477).

The Educational Framework Development Team

This document has been produced by members of the Keele University ABC team. They are:

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1. THE PURPOSE OF THIS DOCUMENT

With more patients taking medication than ever before, encouraging patients to get the most out of their medication is essential to avoid unnecessary ill health as well as reduce waste and unnecessary cost. Since the decision about whether to take medication or not ultimately lies with the patient it is crucial that health professionals and patients engage in a partnership approach to consultations to manage and support adherence to medication. This needs to be underpinned by appropriate education and development for health professionals. This document sets out an educational framework for appropriate education and development of health professionals in Europe on managing and supporting medication adherence with patients.

"Managing and supporting medication adherence needs to be underpinned by appropriate education and development for health professionals"

The educational framework presented is principally aimed at the professions of medication, pharmacy and nursing in Europe, but also applies to any health professional engaging in discussions with patients about their medications. The framework comprises several parts: a competency framework describing the skills, knowledge, attributes and behaviours of healthcare professionals that can support patients with medication; a curriculum for educational organisations to guide education and training for healthcare professionals in their work with patients and their medication; and a diagnostic tool that can be used both by healthcare professionals to reflect on their practice against specific criteria and by educational organisations to assess their curricula against the competencies that healthcare professionals need to support patients with medication and medication taking. The educational framework ends with a brief reading list for managing and supporting medication adherence. This document ends with a description of the development and consultation process that informed the educational framework.

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The framework can be used to:

- Help ensure that individuals and teams who engage with patients in managing and supporting adherence to medication possess all the relevant expertise

- Help individuals, and their employers / managers, identify gaps in knowledge and skills and therefore identify ongoing training and development needs

- Inform the commissioning, development, provision and accreditation of appropriate education and training programmes at all levels

- Support individual continuing education and professional development

- Support professionals / managers locally by informing the wider clinical governance framework

- Support managers locally by providing a framework to help recruitment and selection procedures and appraisal systems.

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2. A COMPETENCY FRAMEWORK

2.1 What is a competency framework?

Competence is the ability to carry out a job or task. A competency is a quality, characteristic or attribute of a person which is related to adequate, effective or superior performance. Competencies can be described as a combination of knowledge, skills, attitudes and values. Competencies help individuals (and their managers) look at how they do their jobs. Development of competencies should help individuals to continually improve their performance and to work more effectively.

"Competency frameworks are extremely flexible tools which can be used to support a wide range of activities"

A competency framework is a collection of those competencies thought to be central to effective performance. Competency frameworks are extremely flexible tools which can be used to support a wide range of activities. Typically they are used to help with:

- Education, training and professional development
- Performance review
- Recruitment

This section provides a framework of competencies which, if acquired and maintained, should help individuals and teams to effectively manage and support medication adherence with patients. The framework is best used as a starting point for discussion of competencies required by individuals or teams. The competency framework contains eight competencies (listening, communicating, context, knowledge, understanding, exploring, deciding, supporting). Each of the eight competencies has:

- An overarching statement which gives a general indication of what the competency is about
- A number of statements which are a guide to how individuals who have that competency will be behaving in practice

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"The framework is best used as a starting point for discussion of competencies required by individuals or teams"

For ease of reference these eight competencies have been grouped into two areas, as illustrated below.

2.2 Who can use this competency framework?

This framework was principally developed for the professions of medication, pharmacy and nursing, although it will also be of relevance to other health professions that are involved in medication adherence. Specifically, it can be used by:

Education and training providers

- In the initial education of health professionals and in competency-led postgraduate training programmes
- To provide training linked to service provision
- To provide the link between training and practice

Individual students and health professionals

- To assess own performance and identify gaps in knowledge and skills
- To identify education, training and professional development needs
- To demonstrate requirements for service delivery

Employers

- As an aid to appraisals and setting personal development plans
- To provide opportunities for employers to work collaboratively to deliver training for staff
- To support retention and recruitment

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Commissioners

- To set standards and monitor service delivery
- To provide a framework for accreditation of health professionals for service delivery
- To identify and remedy poor performance

2.3 How to use the framework

- The bullet pointed statements in each competency should be read one after another DOWN the list, NOT across competency boxes

- This framework can be used by ALL healthcare professionals involved in managing and supporting medication adherence with patients, regardless of professional background or employing organization

- Where this document refers to patients, it is important that the health professional also considers the role of family members, carers and advocates

- Some of the statements supporting the competencies will be more relevant in some consultations than others

- It should be recognized that the effects or consequences of medication non-adherence will vary according to the patient, the symptoms / illness and the medication

- The framework should be used as a starting point for discussion about the competencies required by healthcare professionals

- Initially, using this framework effectively will take time. How each of the statements supporting the competencies applies to an individual, or a team, must be considered

- When considering these statements, be aware that some are more complex than others. Expect to spend more time on the more complex statements

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A competency framework for managing and supporting medication adherence with patients - Overview

COMMUNICATING WITH PATIENTS ABOUT MEDICINES	
❶ **LISTENING** *Listens actively to patients*	❷ **COMMUNICATING** *Helps patients to interpret information in a way that is meaningful to them*
❸ **CONTEXT** *With the patient, defines and agrees the purpose of the consultation*	❹ **KNOWLEDGE** *Has up-to-date knowledge of area of practice and wider health and social services*
MANAGING AND SUPPORTING MEDICATION ADHERENCE	
❺ **UNDERSTANDING** *Recognises that the patient is an individual*	❻ **EXPLORING** *Discusses illness and treatment options, including no treatment*
❼ **DECIDING** *Decides with the patient the best management strategy*	❽ **SUPPORTING** *Supports the patient with medication-taking*

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2.4 The competency framework for managing and supporting medication adherence with patients

COMMUNICATING WITH PATIENTS ABOUT MEDICINES	
1. LISTENING ***Listens actively to the patient***	**2. COMMUNICATING** ***Helps patients to interpret information in a way that is meaningful to them***
1. Helps patients feel at ease and feel that you have time for them 2. Gives the patient the opportunity to express their views 3. Listens to the patient's views and discusses any concerns 4. Encourages the patient to ask questions about their condition 5. Allows time for questions 6. Treats the patient as an equal partner 7. Respects diversity 8. Expresses willingness to be flexible	1. Identifies barriers to communication and responds appropriately 2. Shares knowledge and information in a way that the patient understands 3. Explores and confirms the patient's understanding 4. Checks own understanding of the patient's viewpoint 5. Uses aids to help understanding (e.g. decision aids and question prompts) 6. Recognises the importance of non verbal communication and responds appropriately 7. Uses questions to elicit information 8. Maintains appropriate eye contact 9. Displays a non judgemental attitude
3. CONTEXT ***With the patient, defines and agrees the purpose of the consultation***	**4. KNOWLEDGE** ***Has up-to-date knowledge of area of practice and wider health and social services***
1. Reviews patient information prior to the consultation 2. Introduces and explains own role 3. Establishes how involved the patient wants to be in decisions about their treatment 4. Clarifies the timing, boundaries and expectations of the consultation 5. Ensures that the consultation takes place in an appropriate setting and minimises interruptions 6. Keeps focused on the agreed aims of the consultation	1. Knows own limitations 2. Maintains up-to-date professional knowledge and skills appropriate to own role 3. Knows when and how to seek further advice 4. Refers on to other health professionals and social services as required or as requested 5. Works in partnership with colleagues 6. Shares up-to-date information with patients about specialist support and community resources 7. Is aware of practical resources to help patients
▪ Managing and supporting medication adherence with patients may also involve others, e.g. family members, carers and advocates ▪ Health professionals clearly need a wide and variable range of competencies in their consultations with patients. This framework concentrates on the competencies that any health professional might need when engaging with patients in managing and supporting medication adherence and should be used in conjunction with other professional and organisational frameworks	

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MANAGING AND SUPPORTING MEDICATION ADHERENCE	
5. UNDERSTANDING ***Recognises that the patient is an individual***	**6. EXPLORING** ***Discusses illness and treatment options, including no treatment***
1. Seeks to understand the patient's current circumstances and previous experiences (including, for example, age, gender, disability, mental health, lifestyle, health literacy and socioeconomic status) that may impact on treatment 2. Is aware of whether the patient's cultural, religious or societal beliefs impact on treatment 3. Explores what the patient thinks about medication in general 4. Respects the patient's expertise and knowledge of their condition	1. Explores what the patient has been doing to deal with symptoms / illness and what the patient understands about their treatment 2. Discusses with the patient their expectations and concerns about their illness and treatment 3. Provides full, accurate and understandable information about the patient's symptoms / illness and the benefits, effects, risks (e.g. side effects) and uncertainty of all treatment options 4. Discusses prognosis and likely health outcomes 5. Establishes whether the health professional and the patient have similar or different views about the patient's symptoms / illness 6. Discusses any misunderstandings about illness or treatments 7. Encourages the patient to express positive and negative views about treatment and no treatment options
7. DECIDING ***Decides with the patient the best management strategy***	**8. SUPPORTING** ***Supports the patient with medication-taking***
1. Discusses the patient's preferred option for treatment, negotiates treatment goals and decisions, but accepts the patient's final decision 2. Gives the patient time to consider the information before making a decision, if appropriate 3. Maintains appropriate professional records about decisions that are made and their outcomes 4. Explores the patient's ability to undertake the agreed plan 5. Checks that the patient knows what medication they are taking and why 6. Discusses when treatment will be reviewed (and what this entails), changed or stopped 7. Ensures that the patient knows what to do if their symptoms change, do not improve, or if a problem arises (e.g. a side effect)	1. Recognises non-adherence (identifies patients at risk of non-adherence, assesses patients' adherence, for example by asking if they have missed any doses of their medication, and recognises the effects of non-adherence) 2. Identifies reasons for / causes of non-adherence, and barriers to future adherence 3. Manages adherence by providing effective practical support where the patient needs / wants help with adherence 4. Supports patients by providing ongoing information and feedback (including encouraging patients to come back with any questions), and monitors adherence
▪ Managing and supporting medication adherence with patients may also involve others, e.g. family members, carers and advocates ▪ Health professionals clearly need a wide and variable range of competencies in their consultations with patients. This framework concentrates on the competencies that any health professional might need when engaging with patients in managing and supporting medication adherence and should be used in conjunction with other professional and organisational frameworks	

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3. A COMMON CURRICULUM

3.1 What is a curriculum?

This curriculum is intended to guide education and training for healthcare professionals in their work with patients and their medication. It sets out a series of intended learning outcomes and associated educational content about medication adherence. The curriculum may be adapted for different levels of study and incorporated into existing education and training curricula for health professionals.

"It sets out a series of learning outcomes and associated educational content about medication adherence"

3.2 Who can use this curriculum?

This curriculum was principally developed for the professions of medication, pharmacy and nursing, although it will also be of relevance to other health professions that are involved in medication adherence. Specifically, it can be used by:

Education and training providers

- In the initial education of health professionals
- In postgraduate education and training programmes

Individual students and health professionals

- To assess own performance and identify gaps in knowledge and skills
- To identify education, training and professional development needs

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Regulatory and professional bodies

- To set standards
- To provide a framework for accreditation of health professionals
- To identify and remedy poor performance

3.3 How to use the curriculum

The educational content outlined in the curriculum may be incorporated into any of the following examples of learning and teaching activities that encourage active student participation:

- Interactive small group workshops
- Interaction with simulated patients and feedback on performance
- Case studies
- Directed and self-directed study
- Inter-professional learning activities
- Personal reflections on placement activity

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3.4 A common curriculum for managing and supporting medication adherence with patients

COMPETENCY AREA	LEARNING OUTCOMES	EDUCATIONAL CONTENT
Communicating with patients about medication	1. Listen actively to patients 2. Help patients to interpret information in a way that is meaningful to them	Theory, evidence, best practice and techniques on: ▪ Effective patient centred communication, including non-verbal communication, in relation to medication ▪ Reflecting on and developing communication skills
	3. Define and agree the purpose of consultations with patients 4. Demonstrate up-to-date knowledge of area of practice and wider health and social services	Theory, evidence, best practice and techniques on: ▪ How to effectively prepare for and manage consultations with patients ▪ Maintaining up-to-date professional knowledge and skills appropriate to own role ▪ Maintaining up-to-date knowledge of effective interventions and practical resources to support patients with medication adherence, and current terminology on adherence ▪ Evaluating and improving / developing broad strategies and policy aimed at managing and supporting adherence ▪ Working in partnership with colleagues and service providers to support patients with medication adherence
Managing and supporting medication adherence	5. Recognise that the patient is an individual 6. Discuss illness and treatment options, including no treatment 7. Decide with the patient the best management strategy 8. Support the patient with medication-taking	Theory, evidence, best practice and techniques on how to: ▪ Understand the patient's current circumstances and previous experiences and how these may impact on their beliefs and behaviour about their illness and its treatment. This includes recognising beliefs and behaviours found to be detrimental to adherence (e.g. low self-efficacy) ▪ Discuss with the patient their current symptom experience and management, and health outcomes related to treatment options, including no treatment. ▪ Discuss and agree with the patient their preferred option for treatment and the treatment decision ▪ Recognise non-adherence (i.e. identify patients at risk of non-adherence, assess patients' adherence and recognise the effects of non-adherence) ▪ Identify reasons for / causes of non-adherence, and barriers to future adherence ▪ Manage adherence by providing effective practical support where the patient needs / wants help with adherence ▪ Support patients by providing ongoing information and feedback (including encouraging patients to come back with any questions), and monitoring adherence

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4. A DIAGNOSTIC TOOL FOR ASSESSING COMPETENCE

4.1 What is a diagnostic tool for assessing competence?

A diagnostic tool for assessing competence is a standardised and reproducible means of examining an individual's performance in a particular competency or attribute (see section 2.1) and identifying whether that individual is currently demonstrating competence when measured on a pre-defined scale.

> *"Each of these competencies has a number of statements or attributes which indicate how individuals who have that competency may be behaving in practice"*

This diagnostic tool has been designed to assess the eight competencies in the competency framework (listening, communicating, context, knowledge, understanding, exploring, deciding, supporting). Each of these competencies has a number of statements or attributes which indicate how individuals who have that competency may be behaving in practice. A four-point rating scale (always, usually, sometimes, never) is provided to assess competence for each attribute.

4.2 Who can use this diagnostic tool?

This diagnostic tool was principally developed for the professions of medication, pharmacy and nursing, although it will also be of relevance to other health professions that are involved in medication adherence. Specifically, it can be used by:

Education and training providers

- In the initial education of health professionals
- In competency-led postgraduate training programmes
- To provide training linked to service provision

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Individual students and health professionals

- To assess own performance and identify gaps in knowledge and skills
- To identify education, training and professional development needs
- To demonstrate requirements for service delivery

Employers

- As an aid to appraisals and setting personal development plans
- To provide opportunities for employers to work collaboratively to deliver training for staff
- To support retention and recruitment

Commissioners

- To set standards and monitor service delivery
- To identify and remedy poor performance

4.3 How to use the diagnostic tool

In the context of managing and supporting medication adherence with patients, consider how you or the individual whose competence you are assessing demonstrates each attribute using the four-point rating scale of Always, Sometimes, Usually or Never. Definitions of these ratings should be determined in advance of the assessment. The following table gives example definitions for the assessment ratings:

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RATING	DEFINITION	PERCENTAGE EXPRESSION
Always	Demonstrates the expected standard of practice with occasional lapses	85-100
Usually	Demonstrates the expected standard of practice but with frequent lapses	50-84
Sometimes	Fails to demonstrate the expected standard of practice more often than the expected standard is demonstrated	16-49
Never	Only demonstrates the expected standard on occasions	0-15

It may be helpful to collate evidence of how these attributes are demonstrated in one or more of the following ways, which can form the basis of discussion about the individual's level of competence:

- Maintaining an activity log
- Self-reflection
- Critical incident analysis
- Day to day observations by another individual
- Specific consultations with patients observed by another individual
- Simulations or case studies

Once a decision has been reached, a tick should be placed in the appropriate box to indicate the chosen rating for each attribute.

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4.4 A diagnostic tool for assessing competence in managing and supporting medication adherence

COMMUNICATING WITH PATIENTS ABOUT MEDICATION					
	ATTRIBUTE	RATING (tick ONE box only for each attribute)			
		ALWAYS	USUALLY	SOMETIMES	NEVER
1. LISTENING	Helps patients feel at ease and feel that you have time for them				
	Gives the patient the opportunity to express their views				
	Listens to the patient's views and discusses any concerns				
	Encourages the patient to ask questions about their condition				
	Allows time for questions				
	Treats the patient as an equal partner				
	Respects diversity				
	Expresses willingness to be flexible				
2. COMMUNICATING	Identifies barriers to communication and responds appropriately				
	Shares knowledge and information in a way that the patient understands				
	Explores and confirms the patient's understanding				
	Checks own understanding of the patient's viewpoint				
	Uses aids to help understanding (e.g. decision aids and question prompts)				
	Recognises the importance of non verbal communication and responds appropriately				
	Uses questions to elicit information				
	Maintains appropriate eye contact				
	Displays a non judgemental attitude				

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	ATTRIBUTE	RATING (tick ONE box only for each attribute)			
		ALWAYS	USUALLY	SOMETIMES	NEVER
3. CONTEXT	Reviews patient information prior to the consultation				
	Introduces and explains own role				
	Establishes how involved the patient wants to be in decisions about their treatment				
	Clarifies the timing, boundaries and expectations of the consultation				
	Ensures that the consultation takes place in an appropriate setting and minimises interruptions				
	Keeps focused on the agreed aims of the consultation				
4. KNOWLEDGE	Knows own limitations				
	Maintains up-to-date professional knowledge and skills appropriate to own role				
	Knows when and how to seek further advice				
	Refers on to other health professionals and social services as required or as requested				
	Works in partnership with colleagues				
	Shares up-to-date information with patients about specialist support and community resources				
	Is aware of practical resources to help patients				

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MANAGING AND SUPPORTING MEDICATION ADHERENCE					
	ATTRIBUTE	RATING (tick ONE box only for each attribute)			
		ALWAYS	USUALLY	SOMETIMES	NEVER
5. UNDERSTANDING	Seeks to understand the patient's current circumstances and previous experiences (see list in section 2.5)that may impact on treatment				
	Is aware of whether the patient's cultural, religious or societal beliefs impact on treatment				
	Explores what the patient thinks about medication in general				
	Respects the patient's expertise and knowledge of their condition				
6. EXPLORING	Explores what the patient has been doing to deal with symptoms / illness and what the patient understands about their treatment				
	Discusses with the patient their expectations and concerns about their illness and treatment				
	Provides full, accurate and understandable information about the patient's symptoms / illness and the benefits, effects, risks (e.g. side effects) and uncertainty of all treatment options				
	Discusses prognosis and likely health outcomes				
	Establishes whether the health professional and the patient have similar or different views about the patient's symptoms / illness				
	Discusses any misunderstandings about illness or treatments				
	Encourages the patient to express positive and negative views about treatment and no treatment options				

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7. DECIDING	Discusses the patient's preferred option for treatment, negotiates treatment goals and decisions, but accepts the patient's final decision				
	Gives the patient time to consider the information before making a decision, if appropriate				
	Maintains appropriate professional records about decisions that are made and their outcomes				
	Explores the patient's ability to undertake the agreed plan				
	Checks that the patient knows what medication they are taking and why				
	Discusses when treatment will be reviewed (and what this entails), changed or stopped				
	Ensures that the patient knows what to do if their symptoms change, do not improve, or if a problem arises (e.g. a side effect)				
8. SUPPORTING	Recognises non-adherence (identifies patients at risk of non-adherence, assesses patients' adherence, for example by asking if they have missed any doses of their medication, and recognises the effects of non-adherence)				
	Identifies reasons for / causes of non-adherence, and barriers to future adherence				
	Manages adherence by providing effective practical support where the patient needs / wants help with adherence				
	Supports patients by providing ongoing information and feedback (including encouraging patients to come back with any questions), and monitors adherence				

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5. READING LIST

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APPENDIX 1

How the framework was produced

The purpose of this document is to describe an educational framework that healthcare professionals and healthcare professional education institutions can use to develop curricula and good clinical practice for engaging with patients to manage and support medication adherence. The starting point for the production of this framework was a competency framework for shared decision-making with patients for taking medication, produced in 2007, which is available at

http://www.npc.nhs.uk/non_medical/resources/competency_framework_2007.pdf

The document also details the methodology used to develop the educational framework. As part of the ABC project, this competency framework has been updated following a thorough review of the literature and a wide-ranging, formal process of consultation to form a new educational framework for health professionals in Europe on managing and supporting medication adherence, as detailed in the following three steps.

Step 1: Background research

Desk research was undertaken to identify new evidence published since the development of the 2007 competency framework. Literature searches of EMBASE, MEDLINE and the Cochrane Database were undertaken to identify the following publications in the English-language:

- Competency frameworks, curricula, guidance, standards or consensus statements on medication adherence, or the education and training of health professionals on medication adherence or aspects of managing and supporting medication adherence
- Systematic reviews and other high-quality evidence related to managing or supporting medication adherence

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Step 2: Wide-ranging consultation of stakeholders throughout Europe

In order to ensure that the competency framework is relevant to all current and future health professionals engaging with patients across Europe, a wide range of over 250 individuals and organisations in Europe were invited through a formal consultation process to comment on how the competency framework should be updated.

These individuals and organisations included: All national and European patient groups; All national and European organisations representing doctors, nurses, and pharmacists; A sample of 5 schools of medicine, 5 schools of nursing and 5 schools of pharmacy from each EU-member country and all European organisations representing schools of medicine, nursing and pharmacy.

Individual statements were identified in responses to the consultation and carefully considered by the educational framework development team. From these statements, the curriculum development team updated and adapted the framework (appendix 2). The team also mapped the competency framework to the common curriculum for managing and supporting medication adherence (section 3) and the diagnostic tool for assessing competence in managing and supporting medication adherence (section 4).

Step 3: Circulation for comment

This document in final draft was circulated to the ABC project partners for comment. Comments received were used to confirm the content and presentation of the final document.

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APPENDIX 2

Curriculum development consultation table

STAKEHOLDERS	COMMENTS		REPLY TO COMMENTS
The European Patients' Forum	*Competency areas*	We agree with the competency areas outlined, including their titles. We particularly welcome the reference to building a partnership and shared decision-making, which are in our view key components to improve adherence.	Thank you for your comment.
	Competencies	We generally support the competencies outlined: we welcome the idea to have "listening" and "communicating" as overarching competences, and we also agree with the competencies in area 3 as they outline the key steps of a consultation in a shared or collaborative decision-making model. For Competency 4 the overarching statement could be expanded to "has up to date knowledge of area of practice of wider health and social services". Integration of care between health and social services is fundamental to improve the quality of care for the patients, and could also be a factor in improving adherence. One competency that could be modified is "deciding": We would suggest "informing and deciding", as the process of informing the decision is a crucial part of the consultation, and this is well reflected in the content of this competence, but could be better highlighted in the title. Regarding competency "monitoring" it would be good to add some reference taking account of the new EU pharmacovigilance legislation, which when implemented will give options for patients everywhere to report adverse reactions directly to competent authorities in addition to health professionals. While in EPF's view the patient-health professional relationship should remain central, patients often cite a perceived lack of interest, or lack of listening, by health professionals as the reasons for	Thank you for your comments. We agree, this change has been made. We appreciate the point, but the process of informing the decision is already addressed in 'Communicating'. We appreciate the point and have amended the wording of attribute 1 in this competency area accordingly.

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		wanting to report directly. It is therefore important that a relationship of trust is established and patients are encouraged to turn to their health professional in the first instance concerning any suspected adverse reactions.	
	Listening	We agree with the attributes. Treating the patient as an equal partner, with valid and cogent health beliefs and expert knowledge of their own, is essential for shared decision-making. We welcome the recognition here of the changing role of the patient, from a passive recipient to an active participant in their own healthcare. We welcome particularly the idea to reassure the patient on timing, as time constraints for certain categories of healthcare professionals poses a significant practical problem and can undermine the building of a partnership for adherence. Furthermore, patients are often not aware of the possibility to request a longer than normal consultation even where such a possibility exists. We would also suggest possibly adding to the glossary the definitions for the terms “shared decision-making” and “concordance” (see final comments).	Thank you for your comments. We have now added a reading list that includes definitions for these terms.
	Communicating	The attributes outlined are a good basis towards establishing a shared understanding during the consultation. Improving the communication and interaction skills of healthcare professional is a key demand of patients. In our view, an essential counterpart to the informed and empowered patient is a health professional who welcomes this, and creates through their own behaviour an enabling environment for partnership and dialogue. Regarding the use of aids, we would like to highlight that many tools to enhance communication with the patients are available, including from patient organisations, such as decision aids, coaching and question prompts	Thank you for your comments. We agree and examples have been included.

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		which could be more widely shared and used. Possibly you are already aware of many such tools, but EPF would be happy to provide further information regarding this. Attribute 2 could be modified to: Shares knowledge and information in a way and a language the patient understands, throughout the consultation. It is important that healthcare professionals avoid using medical jargon and explain medical terms as far as possible, and maintain an appropriate communication at all time during the consultation; possibly this point could be further clarified.	We appreciate the point but have amended the text in 'Monitoring' rather than in 'Communicating' as this applies to all consultations.
	Context	EPF agrees with the attributes outlined. We think it is particularly important that patients' preferences as to their degree of involvement in the decision are taken into account. There are clearly differences between patients, but many patients particularly with chronic conditions, would welcome the opportunity to get more involved given the opportunity and environment to do so.	Thank you for your comment.
	Knowledge	EPF agrees with the attributes outlined as they address two key issues: updating the professional's knowledge on the one hand, and communication with other healthcare professionals in the team around the patient as necessary on the other hand**.** The attribute "shares up-to-date information on specialist support and community resources" is particularly pertinent: patients need and want information on many topics besides treatment, therapies and disease management: prevention, lifestyle, social and peer support, patient education and reimbursement options. Healthcare professionals, if they cannot provide such information themselves, should be able to point patients to other sources or contacts where they can ask for such information. These sources include relevant patient organisations.	Thank you for your comments. We appreciate the point and have included

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		Attribute 2 could be modified to "maintains an up to date knowledge appropriate to own role, including medical and technical knowledge, and soft skills." While updating medical and technical knowledge is essential, healthcare professionals should also develop and update "soft skills" such as communication with patients and carers. Attribute 4 could be modified to "refers to other healthcare professionals and social services as required or requested**".** As we mentioned in the question above, healthcare professionals should be able to point out relevant sources or contact for social support**.** A specific reference could also be made to communicating with the patient's care coordinator when necessary/requested.	professional skills. We agree, this change has been made.
	Understanding	We agree with the attributes as outlined. Point 4 is crucial for a genuine partnership. Point 1 is also fundamental, as many circumstances have to be taken into account. A more comprehensive list of examples could be developed and appended for more clarity on factors healthcare professionals may need to consider during the consultation, such as age, gender, psychological issues, mental health, social isolation, lifestyle issues, low health literacy, socio-economic/financial factors. All of these can have an influence on health and on adherence to treatment.	Thank you for your comments. We appreciate the point and have amended the wording in this competency area accordingly.
	Exploring	We welcome the attributes outlined. They take into account the perspective of the patient and provide a basis for a meaningful dialogue between the healthcare professional and the patient. Point 4 is very important as people's personal beliefs concerning medicines have been shown to be an important factor in adherence.	Thank you for your comments.
	Deciding	We agree with all points and they are all fundamentally important. Regarding point 2 we would reiterate that clear, accurate and	Thank you for your comments.

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		understandable information is key to improving patients' adherence to the agreed treatment plan, but the important thing is to have a genuine, two-way-exchange. Patients provide information that contribute to the shared decision-making process. It is a key role of the health professional to empower patients to convey their health beliefs, provide their perspective and participate actively in the consultation. This point therefore links very closely to the "Communication" area.	
		Attribute 2 could be further developed: "provide full, accurate and understandable information about the pros and cons of all treatment options including side effects and benefits, possible implications of long term use, and possible impacts on the patient's daily life.**"**	We appreciate the point, have included the word understandable and the phrase "benefits, effects and risks (e.g. side effects)…".
		The patient's understanding of the information should be checked. It is particularly important to convey information about the benefits of the treatment as well as risks, and reasons why the patient should not discontinue treatment without talking to their health professional.	We appreciate the point and have clarified this point in 'Exploring'.
		We would suggest amending attribute 6 to: "Discuss the patients preferred option for treatment": this formulation would make it clearer that patients' preference should also be taken into account at this stage, and that ultimately if the beliefs of both patients and healthcare professionals carry equal value, the most important choices are those made by the patients.	We agree, this change has been made.
		We would propose adding a last point: "Provides a clear written recap of the agreed plan or treatment, tailored to the needs of the individual patient." Providing written information can be essential for patients especially where time constraints prevent an extended discussion.	We appreciate the point, but feel that this is already embodied in the wording of attribute 7.
		Patients should furthermore always be encouraged to come back with questions arising after the consultation.	We agree, this has been added to 'Monitoring'.

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	Monitoring	This area includes the main attributes to ensure that patients have information regarding follow-up, when they should consider stopping their treatment or not, and when to consult a health professional again. Attribute 1 could be modified as follow: "Ensures that the patient knows what to do if their symptoms change, do not improve, or if a problem arises." Many patients are not aware that medicines do not work in every patient. They may feel more reluctant to tell their healthcare professional that the treatment is not having any effect at all, than to discuss adverse effects. An attribute which could be added is to monitor that patients' needs for information are met following the consultation. This would help in closing the gap between patients' need for more information and healthcare professionals' overestimation of the amount of information they provide[1]. [1] This gap is highlighted in several studies including: Coulter, A. et al (1998) Informing patients: an assessment of the quality of patient information materials. London: King's Fund; Coulter, A. et al (1999) 'Sharing decisions with patients: is the information good enough?'. British Medical Journal, 318: 318-322.	Thank you for your comments. We agree, this change has been made. We appreciate the point, and feel that this is embodied in 'provides ongoing information, support and feedback', which has been added to 'Monitoring'.
	Next steps	We would recommend considering inclusion of the concept of concordance[2] in the glossary, as in our view concordant consultation processes are more likely to result in higher adherence by patients and establish a therapeutic alliance. The definition of patient should be more inclusive: patients comprise human beings in need of or receiving health care services; and treatment can include not only medicines, but also medical devices and other forms of	Thank you for your comments. We have now added a reading list that includes a definition of concordance. We appreciate the point, but this framework is focused on adherence to medicines.

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		therapy. We welcome the explicit reference to family and carers' possible involvement in shared decision-making and we think this should be maintained, as they need adequate information and support from healthcare professionals to carry out their role. Dialogue between healthcare professionals and carers is also crucial, to take into account their needs and viewpoints. We feel that the title of the framework is somewhat negative. "Prevention and management of patient non-adherence to medications" implies that the non-adherent patient is a problem that needs to be managed. We propose that this should be worded in a more positive way, e.g. "management and support of patient adherence to therapies" (which incidentally also includes non-pharmacological therapies). As regards the dissemination and uptake of this competency framework, we would like to highlight that patient organisations can educate and train patients to be informed and empowered to participate in shared decision-making. They can also contribute to the design and delivery of communications training for health professionals. Many patient organisations have developed special tools for information and training of healthcare professionals, either on a specific condition or to develop a holistic approach to patient care. These can, for example, take the form of workshop formats with patient-doctor interaction, special presentations, films, and materials as well as structured patient dossiers for communicating with professionals. EPF and our members are happy to share experiences in this area. EPF would also be happy to support the effective dissemination of this	We agree, the title has been changed to managing and supporting medicines adherence.

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		competency framework to our European-wide membership (currently 51 member organisations, see our website. We see this framework as an important step in the recognition of the importance of patient involvement. Building partnership between patients' and healthcare professionals' organisations is necessary to share perspectives and understandings of the competencies and attributes outlined in this framework, and to develop initiatives to realise the principles outlined here in clinical practice. EPF works closely at EU level with organisations representing health professionals, such as pharmacists (PGEU), doctors (CPME), medical specialists (UEMS) and nurses (EFN). Some examples of how patients' and healthcare professionals' organisations can work together to put in place adherence interventions that work were presented at a recent event held at the European Parliament by EPF, CPME, PGEU and EFPIA (the pharmaceutical industry association) – please see EPF's website for more information. [2] EPF uses the terms as defined in Horne, R: "Compliance, adherence and concordance: implications for asthma treatment", *Chest*, 2006;130;65-72; and *Concordance, adherence and compliance in medicine taking. Report for the National Co-ordinating Centre for NHS Service Delivery and Organisation R&D*, December 2005.	
UK General Medical Council	Thank you for the opportunity to comment on the consultation document which describes the background to the development of the curriculum above. The key features of the proposed competency framework are very much akin to the generic expectations for undergraduate students in medical schools, particularly around communication, knowledge and working with patients. In the context of non-adherence to		Thank you for your comments.

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	medications, these are particularly important themes. The standards and outcomes which cover these and many other areas, are contained in our document *Tomorrow Doctors.* This was last revised in 2009 and can be accessed through the following link: http://www.gmc-uk.org/education/undergraduate/tomorrows_doctors.asp. The section, *Outcomes 2, The doctor as a practitioner*, paragraph 17(e), *Prescribe drugs safely, effectively and economically,* requires students to understand the principles of giving patients appropriate information about their medicines.		
Professor Karin Kjellgren, Professor of Nursing Science, University of Gothenburg and Linköping University, Sweden	*Competency areas*	They are well defined. Could sharing a decision be sharing a goal? Perhaps it would be of importance to have an area with the aim to improve or develop strategies for prevention and management	Thank you for your comment. We appreciate the point. The competency areas have been renamed and improving adherence strategies has been added to the curriculum.
	Competencies	In some way the competencies have an approach of paternalism by the words exploring, deciding. The words mastery and autonomy would be more appropriate from the patients point of view To include: Sharing?	Thank you for your comment. We have amended the wording of attributes to avoid creating any impression of paternalism. 'Exploring' is used because this is a framework for health professionals, but in 'Deciding' we have emphasised that the patient's decision should

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			be accepted.
	Listening	They are written from the perspective of providers. Is it possible to be more mutual?	Thank you for your comment. This is because it is a framework for health professionals rather than patients, but see the point about paternalism above.
	Communicating	They are written from the perspective of providers. Is it possible to be more mutual?	Thank you for your comment. This is because it is a framework for health professionals rather than patients, but see the point about paternalism above.
	Context	They are written from the perspective of providers. Is it possible to be more mutual?	Thank you for your comment. This is because it is a framework for health professionals rather than patients, but see the point about paternalism above.
	Knowledge	Perhaps it would be better to use the word understanding instead of knowledge in some sentences	Thank you for your comment. The word knowledge is only used once and in specific relation to maintaining a knowledge base.
	Understanding	This attributes are appropriate	Thank you for your comment.

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	Exploring	Could exploring be changed to sharing?	Thank you for your comment. 'Exploring' is used because this is a framework for health professionals
	Deciding	Could deciding be changed to set goals	Thank you for your comment. We appreciate the point, but feel that 'deciding' is a broader term.
	Monitoring	Monitoring to be able to master the health problem?	Thank you for your comment. We appreciate the point, but this is a framework for health professionals rather than patients.
	Next steps	A more condensed curriculum and less of checkpoints would lead to a better understanding and easier to get an overview of the scope of the competency framework.	Thank you for your comment. An overview of the scope of the competency framework is provided in figure 1.
Dr Ilse Hellermann-Geschwinder, Medical University of Graz, Austria	*Competency areas*	1 to 5 are basics; but: 6,7 and 8, do you really want to discuss that with all the professionals concerned (nurse, pharmacist AND physican?) Delete 6,7,8 - The more actors are involved, the less adherence you can expect	Thank you for your comment. This could be minimised by effective sharing of information between professionals
	Competencies	These are basics	Thank you for your comment.
	Listening	ok	Thank you for your comment.

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	Communicating	ok	Thank you for your comment.
	Context	ok	Thank you for your comment.
	Knowledge	1 is unlikely to be achieved, 2 to 7 are fine. Include legal aspects	Thank you for your comment. We appreciate the point, and have amended the text to take account of professional issues such as legal aspects
	Understanding	[no comments]	
	Exploring	[no comments]	
	Deciding	[no comments]	
	Monitoring	[no comments]	
	Next steps	[no comments]	
Dr. Siún O' Flynn, Head of Medical Education, School of Medicine University College Cork, Ireland	*Competency areas*	Broadly agree. Perhaps not an issue in the UK but cost is an issue elsewhere in compliance – perhaps this should feature in the exploration phase, Personally I also feel the risks of partial compliance have to be detailed in certain situations eg HIV ,TB ,Hep B where the consequences extend beyond the individual and have a population health impact. There are circumstances where unilateral decision is justifiable. Perhaps also duration of therapy should factor –ensure a patient and all other relevant parties understand why, when, how much does it cost, how long do I have to take it for, what happens if I don't take it at all, what happens if I sometimes take it /where can I find out more, what will be followed up, how will I know it is working – before a decision is reached to commence therapy or not .The punchier and shorter the presentation the better. In its current format I feel that many of my colleagues, other overburdened	Thank you for your comments. We appreciate the point. The wording of the points in 'Exploring' and 'Supporting' (formerly 'Monitoring') have been amended to take factors such as cost into account. Although an overview of the competency framework is provided

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		hospital doctors, might dispose of this document, laudable as it is, but are more likely to respond to something snappy and accessible presented along the lines of above. Delete any? No but I find that there is a somewhat artificial divide between 5 and 6	(figure 1), we intend to produce a separate short summary to facilitate this.
	Competencies	Broad and inclusive but possibly aspirational as opposed to practical. The simpler and snappier a framework is the more likely it is to be adopted and translated into practice – I suspect 8 steps with the need to read supporting documentation to identify what each step entails will secure participation ion those already interested in the area only	Thank you for your comment.
	Listening	Broadly agree	Thank you for your comment.
	Communicating	Broadly agree	Thank you for your comment.
	Context	Broadly agree	Thank you for your comment.
	Knowledge	Broadly agree	Thank you for your comment.
	Understanding	Cost is a significant factor in Ireland and elsewhere	Thank you for your comment. We appreciate the point, and have added other examples of factors.
	Exploring	I feel that outcomes of partial compliance need to be explored, and what can happen in the first few days or what you may notice…	Thank you for your comment. We appreciate the difference, and have added a point about this in section 2.4 (how to use this framework). We agree, and feel that

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			this is now embodied in the word "effects" in the new phrase "benefits, effects, risks and uncertainty".
	Deciding	Broadly agree	Thank you for your comment.
	Monitoring	Discusses what review entails – e.g. follow up bloods etc	Thank you for your comment. We agree, this has been added to attribute 2.
	Next steps	Make the framework very accessible to practice – some of the overarching headings require reading of the supporting text before they can really be understood– a sure way to ensure only the converted will read it. I would be very influenced by patient input also.	Thank you for your comment. The supporting text in the same box as the heading to facilitate ease of use.
Jeffrey Atkinson Executive Director of the PHARMINE project. Emeritus professor of pharmacology University of Nancy, France	*Competency areas*	I had some difficulty with the geographical scope "Europe-wide". Does the latter refer to the EU member states? If so, how does it fit in with the directive 2005/36/EC? Or does it refer to the EHEA? If so, how does it fit in with the Bologna declaration? How does it fit in with national frameworks in the EU e.g. that of the French Chamber of Pharmacists (http://www.ordre.pharmacien.fr/fr/bleu/index4.htm) Does it exclude other professions such as dentists and midwives that are also involved in patient compliance?	Thank you for your comments. These issues are dealt with in a new section 'Links to other frameworks and curricula' (section 1.3). It is principally aimed at doctors, nurses and pharmacists but is also of relevance to other health professionals (this point has been clarified in

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			section 2.3).
		The 8 competencies are split up into 3 competency areas, and yet they are numbered 1 through 8. The latter suggests some sort of chronology in application ("listening" to "monitoring") that is somewhat in conflict with the chronology of the competency areas ("building a partnership" to "sharing a decision"). I would prefer the "1 through 8" chronology.	We appreciate the point and have renamed the competency areas.
		I had a problem with the glossary and the definition of competency. The word has its origins in the French word "*compétent*" meaning "ability to perform" and the Latin "*competo-*" that introduces the notions of adequacy and attribute. The words "quality", "characteristic" and "performance" do not completely translate these aspects. This is important for those whose mother tongue is not English. In PHARMINE and at EAFP meetings we have had lively discussions with our UK partners as to what "competence/y" really means and to date the issue is not crystal clear. If we are to inculcate our pharmacy students with such notions then we had better be certain that we understand them.	This has been addressed in amended text in sections 1.2 and 1.3.
		Furthermore it is stated that "Competencies can be described as a combination of knowledge…" (page 6), then on page 7 knowledge is described as a competency *per se*. Again this may be confusing for those with a limited knowledge of English.	We appreciate the point and can clarify that the use of the word 'knowledge' in this framework relates to specific knowledge on managing and supporting adherence.
		Communicating is surely a competency that is important in all 3 areas not only "building a partnership"?	We appreciate the point. The competency areas have been renamed.

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		You could maybe include some notion of the specific patient-medicine interaction. Non-adherence to digitalis medication in an elderly patient with dementia will not be the same problem as non-adherence to antihypertensive treatment with a beta-blocker in a 40+ year old executive.	We appreciate the difference, and have added a point about this in section 2.4 (how to use this framework).
	Competencies	[no comments]	
	Listening	I wonder whether points 1 and 2 - that are very similar - could they not be grouped together. Point 8 raises the idea of "diversity" – of what exactly? Where is the "knowledge and skills framework" that is referred to in the lower box?	Thank you for your comment. We agree, this change has been made More detail has been included Reference to this has been removed
	Communicating	Point 5: "aids": could you give some examples?	Thank you for your comment. Examples have been added.
	Context	[no comments]	
	Knowledge	[no comments]	
	Understanding	[no comments]	
	Exploring	[no comments]	
	Deciding	Point 6: "negotiates"? Where is this going? How much leverage does the patient have?	Thank you for your comment. A reworded point 1 clarifies that ultimately the patient's decision should be accepted.
	Monitoring	The paradigm for monitoring extends to contact details but no further. Is there not a need to establish how monitoring will be performed?	Thank you for your comment. This has been

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			amended.
	Next steps	The FP7 theme health programme presumably is looking at concrete outcomes and namely how this project will actually improve the prevention and management of patient non-adherence to medicines. How do you propose to test this? What sort of evidence can you produce?	Thank you for your comments. This will be taken into consideration in the final report.

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APPENDIX 3

Acknowledgements

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- Dr Ilse Hellermann-Geschwinder - Medical University of Graz, Austria
- Kaisa Immonen-Charalambous - The European Patients' Forum
- Professor Karin Kjellgren - Professor of Nursing Science, University of Gothenburg and Linköping University, Sweden
- Dr. Siún O' Flynn - Head of Medical Education, School of Medicine, University College Cork, Ireland
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