WP1: Taxonomy

European consensus on taxonomy/terminology used in the field of deviations from recommended treatment in ambulatory pharmacotherapy

September 11, 2009
Bangor, UK

Ascertaining Barriers for Compliance

www.ABCproject.eu

Non- or Partial-Compliance/Adherence

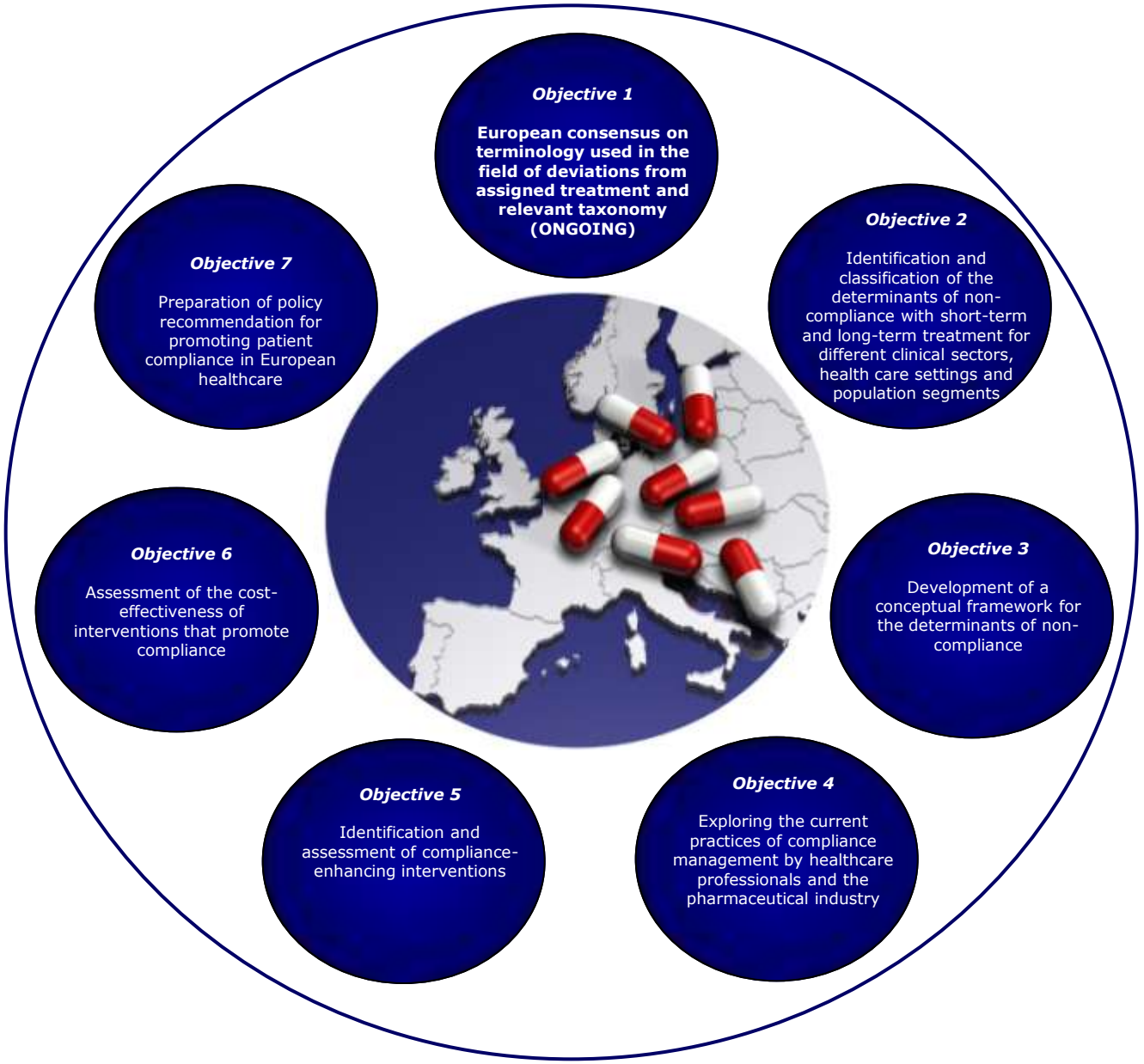
~

Any deviation from recommended treatment

There have been many attempts to be more formal

and the terms are used in many different ways…

AIM:
To produce evidence-based policy recommendations for European policymakers for improved patient compliance and subsequent better use of medication, in order to obtain safer, more effective and cost-effective use of medicines in Europe.



ABC
Ascertaining Barriers for Compliance

European consensus on taxonomy/terminology used in the field of deviations from recommended treatment

- ✓ To conduct a systematic review to identify across different fields of expertise – clinicians, statisticians, pharmacologists, health economists, patients, etc - the terminology commonly used to describe deviations from assigned treatment in ambulatory patients
- ✓ To compare formally the different taxonomic approaches, to support quantitative assessment of drug exposure and allow for benchmarking of treatment-enhancing strategies
- ✓ To take a system-wide view of the process of ambulatory pharmacotherapy
- ✓ To forge a consensus for a rigorous taxonomy that will support and inform the remaining tasks of the ABC project
- ✓ To communicate and defend the consensus taxonomy across European countries and abroad

WP1 timelines: JAN-DEC 2009

- JAN-JUN : review of the literature and informal discussions
- JUN : ABC internal consensus meeting
- JUN-AUG : adaptations following internal discussion
- SEP : interim external consensus meeting
- SEP-DEC : work out an acceptable proposal
- DEC : final document

1. Taxonomy is the practice and science of classification

2. Terminology is the study of terms and their use

- Data gathering: Retrieve, document and review systematically the literature on taxonomy and concepts describing deviations from assigned treatment.

- Searches for relevant papers were conducted in the following electronically available databases:

  - **MEDLINE (via Pubmed)**
  - **EMBASE**
  - **The Cochrane Library**
  - **Cinahl EBSCOhost**
  - **PsychINFO**

Search term	Number of hits
« Patient Compliance »	39186
« Patient Compliance » [MeSH]	36451
« Patient compliance » [Majr]	14298
« Patient Adherence »	1018
« Concordance »	16800
« Treatment Refusal » [MeSH]	9148
« Persistence »	42504
« Readiness »	5584

⇒ need for a more precise search strategy

⇒ use of MeSH terms

⇒ focus on taxonomy/terminology

- Search terms used to identify deviations from recommended treatment:

  "Patient compliance", "Treatment refusal", "Concordance", "Persistence", "Medication Possession Ratio", "Pharmionics", "Primary (non)-compliance", "Treatment acceptance", "Readiness"

- The afore-mentioned terms were used in conjunction with the following terms to restrict searches on taxonomy and terminology:

  "Classification", "Terminology as topic", "Concept formation", "Vocabulary Controlled", "Definition", "Taxonomy", "Meta-analysis"

- The search terms have been developed in MEDLINE and translated according to the indexing system specific to each database.

Term combinations used to search databases

1. **MEDLINE**

"Patient Compliance"[Majr] OR "Treatment Refusal"[Majr]

AND

"Classification "[Subheading] OR "Terminology as Topic"[MeSH] OR "Concept Formation"[MeSH] OR "Vocabulary, Controlled"[MeSH] OR "primary adherence"[All Fields] OR "primary non-adherence"[All Fields] OR "readiness"[All Fields] OR "pharmionics"[All Fields] OR "treatment acceptance"[All Fields] OR "concordance"[All Fields] OR "definition"[All Fields] OR "taxonomy"[All Fields] OR "terminology"[All Fields] OR "persistence"[All Fields] OR "medication possession ratio"[All Fields] OR "meta-analysis"[All Fields]

2. **EMBASE**

"Patient Compliance"/exp/mj

AND

"Primary compliance" OR "Primary non-compliance" OR "Readiness" OR "Pharmionics" OR "Treatment acceptance" OR "Concordance" OR "Persistence" OR "Meta-analysis"/exp OR "Definition" OR "'Taxonomy"/exp OR "Terminology"/exp OR "Concept"

3. **CINAHL**

"Compliance" OR "Adherence" OR "Concordance" OR "Noncompliance" OR "Non-compliance" OR "Nonadherence" OR "Non-adherence" OR "Concordance" OR "Persistence" OR "Treatment refusal"

AND

"Definition" OR "Taxonomy" OR "Classification" OR "Terminology"

4. **The Cochrane Library**

"Patient compliance" [MeSH term]

AND

"Primary compliance" $ [topic] OR "Primary non-compliance" [topic] OR "Readiness" [topic] OR "Pharmionics" [topic] OR "Treatment acceptance" [topic] OR "Meta-analysis" [topic] OR "Concordance" [topic] OR "Definition" [topic] OR "Taxonomy" [topic] OR "Concept" [topic] OR "Persistence" [topic] OR "Medication possession ratio" [topic]

5. PsycINFO

"Compliance" OR "Adherence" OR "Concordance" OR "Persistence" OR "Noncompliance" OR " Non-compliance OR "Nonadherence" OR "Non-adherence")

AND

"Classification" OR Taxonomy" OR "Definition" OR "Terminology"

Inclusion and exclusion criteria

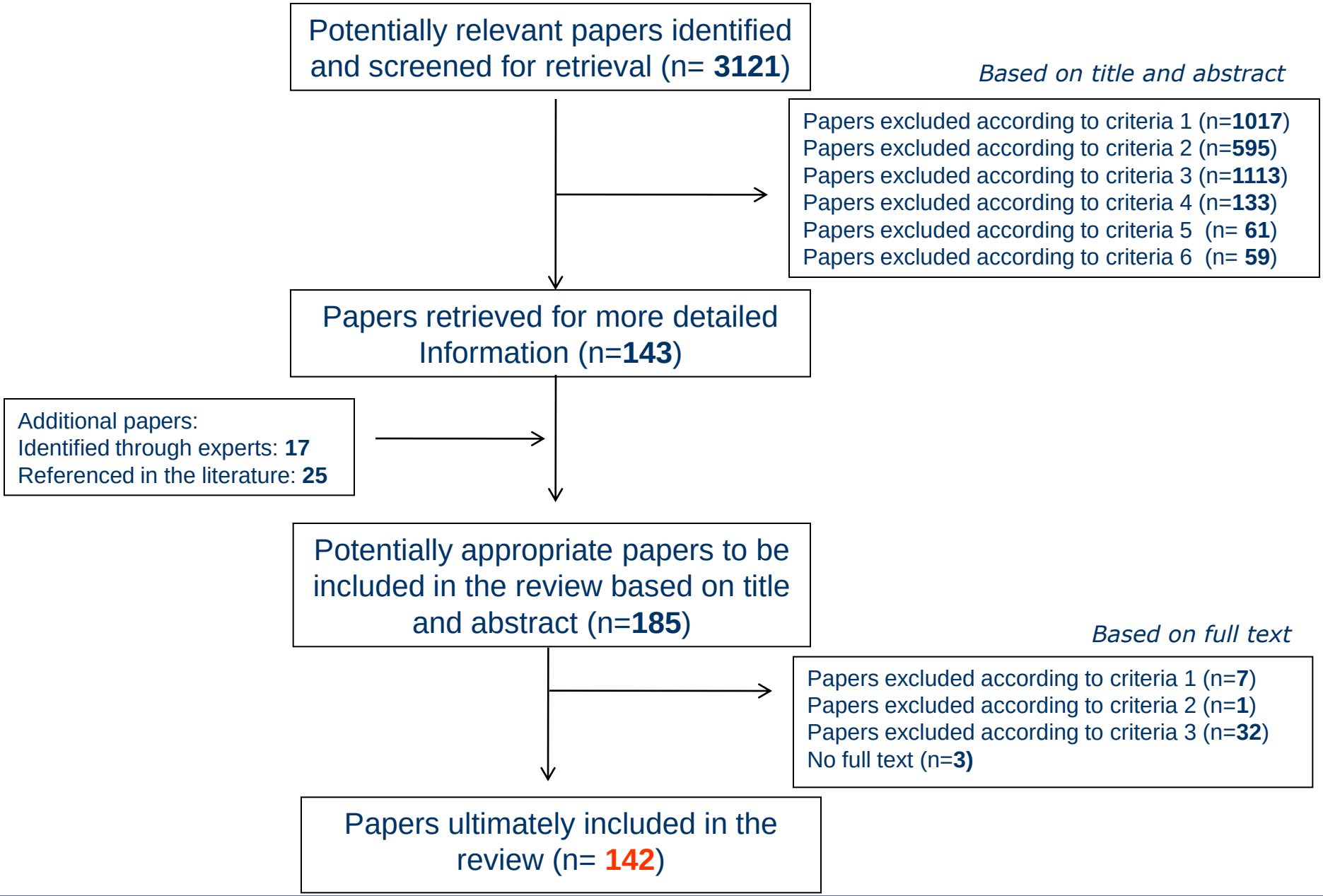
- ***Inclusion criteria:***

  - All papers focusing on the taxonomy used to describe deviations from recommended pharmacotherapeutic treatment in ambulatory patients. There was no restriction on the type of document. Editorials, book chapters and commentaries were included.
  - All papers were included until April 1st 2009. There was no other restriction on publication date.

- ***Exclusion criteria:***

  1. Papers that do not describe deviations from assigned treatment but describe refusal of specific medical practices or procedures other than pharmaceutical treatments.
  2. Papers that do not describe deviations from pharmaceutical treatment but for lifestyle changes / diet / exercise etc…
  3. Papers that do not specify the taxonomy used to describe the concept of deviations from assigned pharmaceutical treatment in ambulatory patients (e.g. clinical trials where adherence or compliance was estimated but where the underlying concept was not described)
  4. Papers for which only the title was available and seemed not to specify the taxonomy used to describe deviations from assigned pharmaceutical treatment
  5. Papers that are not in the English language
  6. Papers that are referenced in more than one database (double citations)

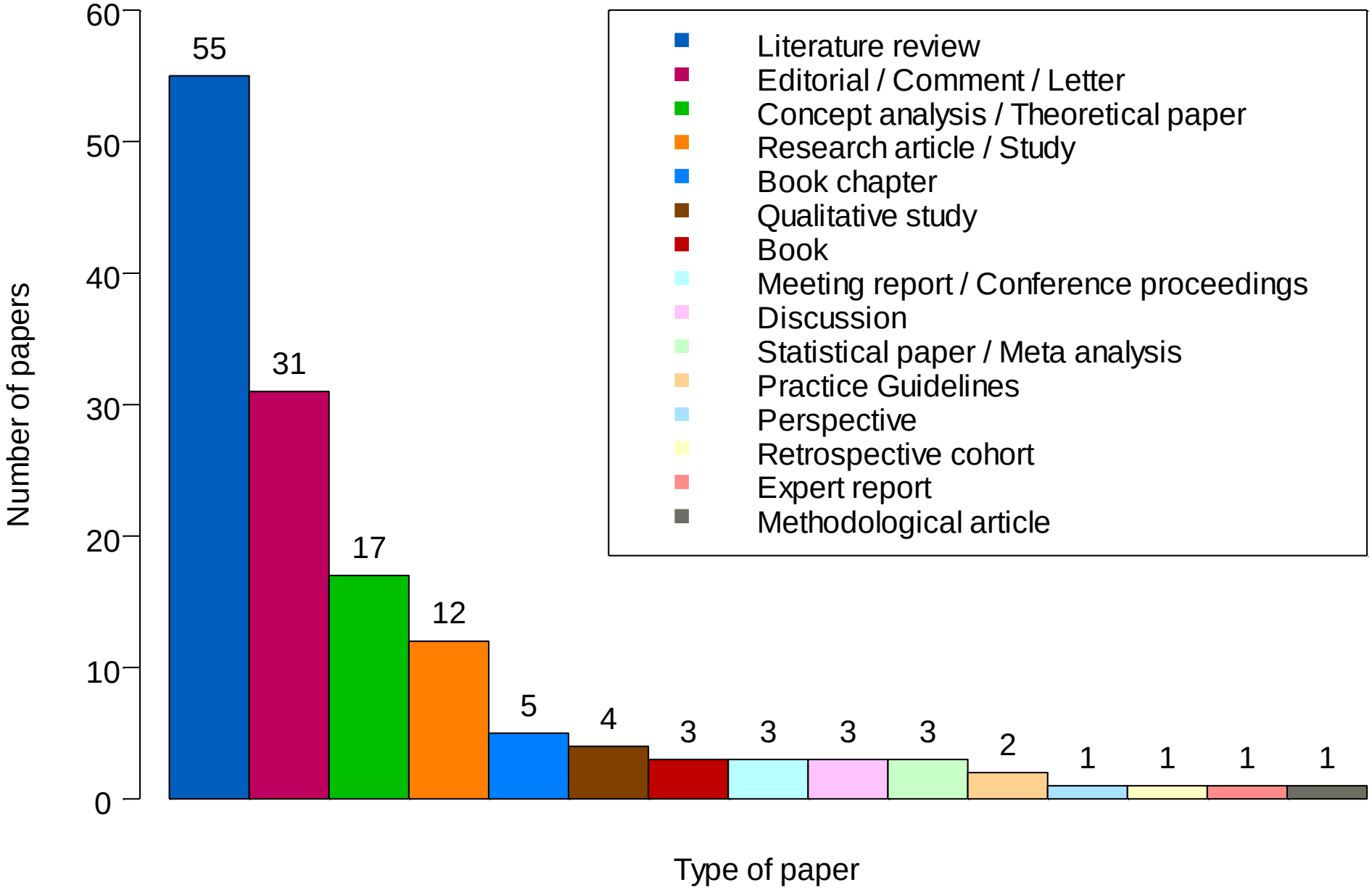
Search results



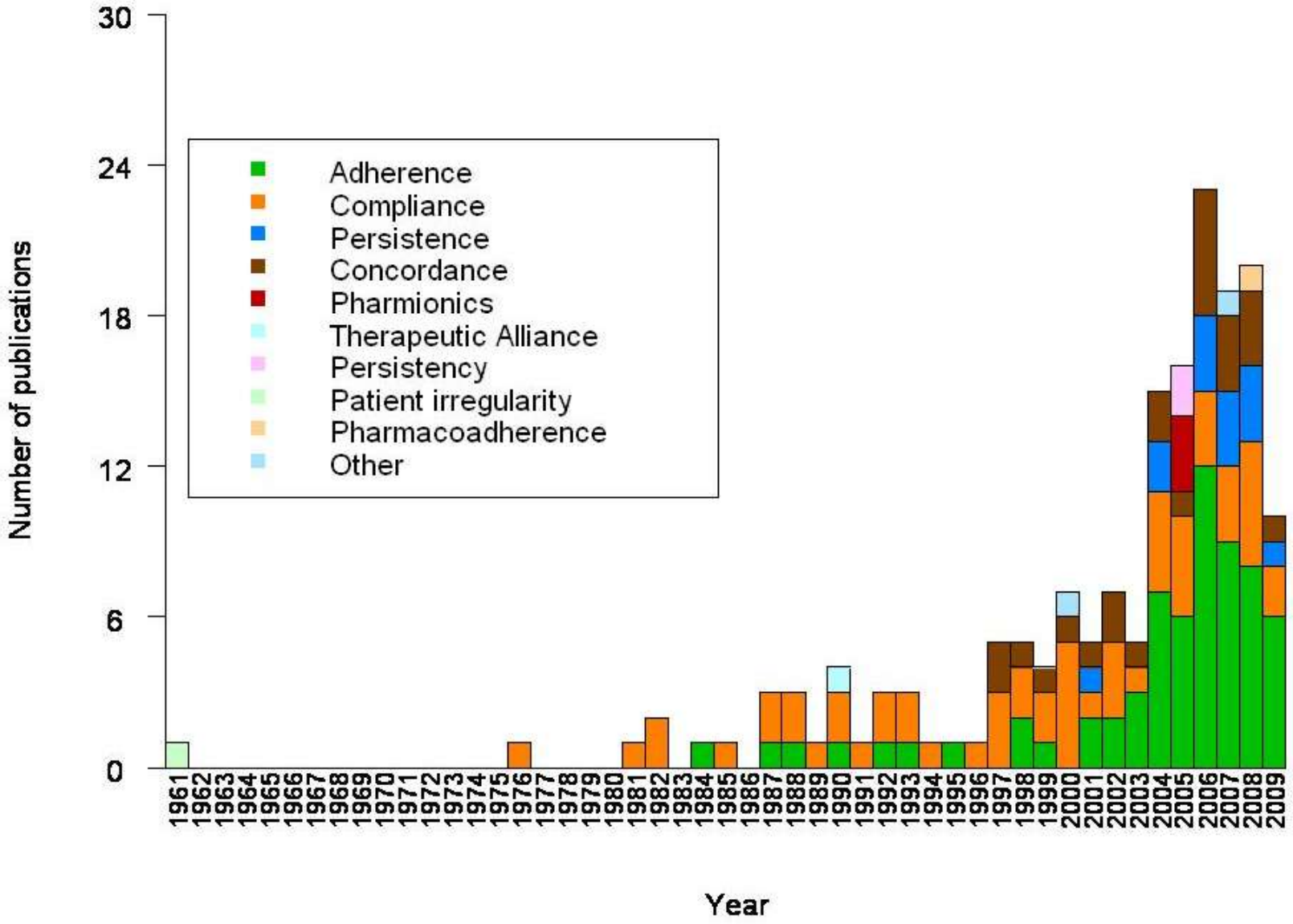
Information collected from the 142 identified papers

- Publication year
- Publication type
- Publication aim
- Author's preferred term
- Definition
- Reference to another paper
- Any additional comments

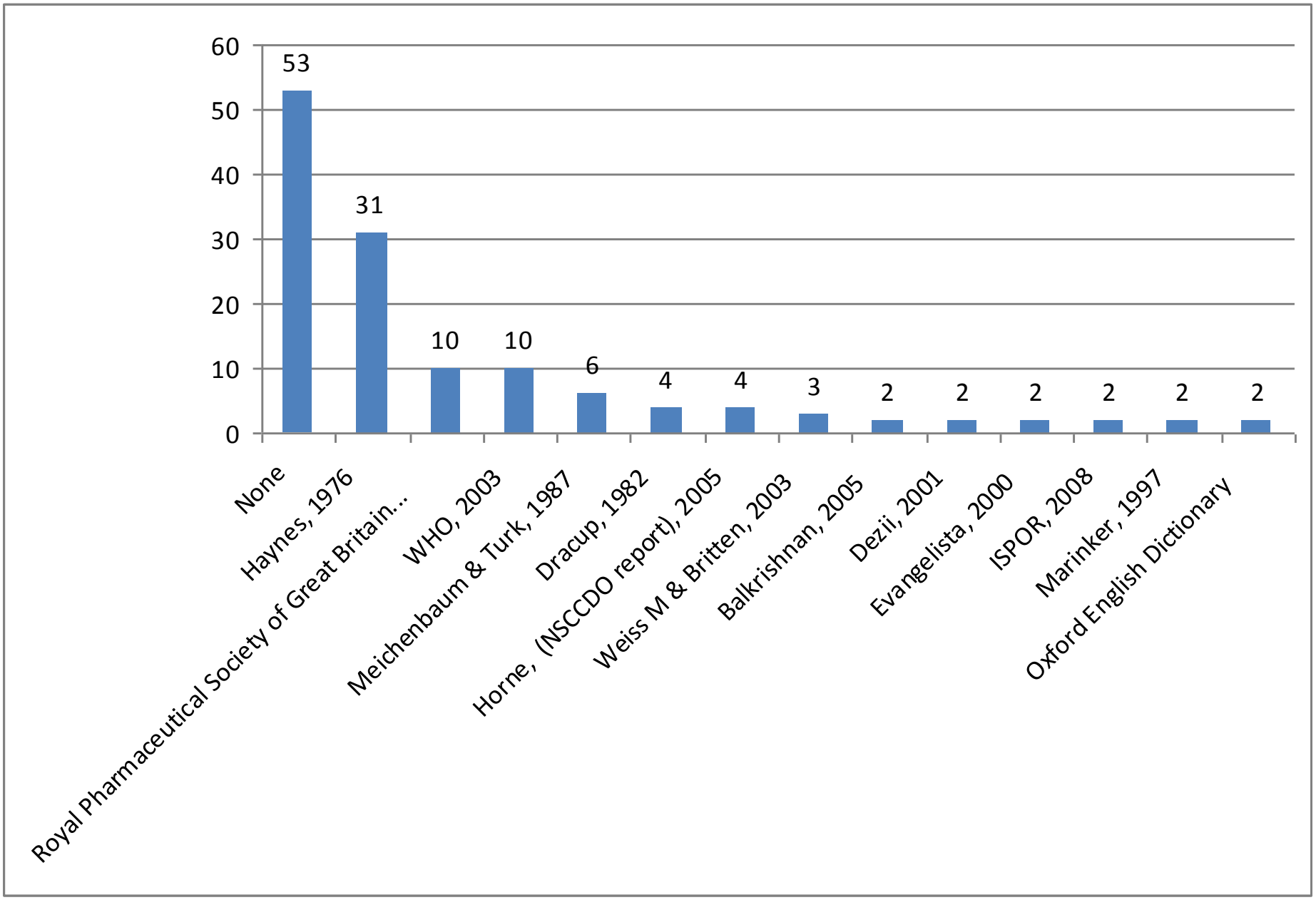
Publication type (142 selected papers)



Main terms used among the 142 selected papers



Main references cited among the 142 selected papers



Most often cited references for compliance or adherence

Definition	Authors - Year
Compliance is the extent to which the patient's behavior (in terms of taking medications, following diets or executing other lifestyle changes) coincides with the clinical prescription.	Sackett DL, Haynes BR; 1976
Compliance is the extent to which the patient's behavior coincides with the clinical prescription, regardless of how the latter was generated.	Sackett DL, Haynes BR; 1976
Compliance is the extent to which a person's behaviour (in terms of taking medication: following diets, or executing other lifestyle changes) coincides with medical or health advice	Haynes R.B., Taylor D.W. and Sackett D.L.; 1979
Compliance is the extent to which an individual chooses behaviours that coincide with a clinical prescription, the regimen must be consensual, that is, achieved through negotiations between the health professional and the patient.	Dracup K.A., Meleis, A.I.; 1982
Adherence is the degree to which a patient follows the instructions, proscriptions, and prescriptions of his or her doctor	Meichenbaum, D., Turk D.C.; 1987
Adherence is the extent to which a person's behavior - taking medication, following a diet, and/or executing lifestyle changes - corresponds with agreed recommendations from a health care provider	World Health Organization; 2003
Adherence is the extent to which a patient participates in a treatment regimen after he or she agrees to that regimen	Balkrishnan R.; 2005

Time sequence of terminology introduction

First recorded incident of human noncompliance… occured when Eve ate the apple in the Garden of Eden…

Hippocrates : « [The physician] should keep aware of the fact that patients often lie when they state that they have taken certain medicines

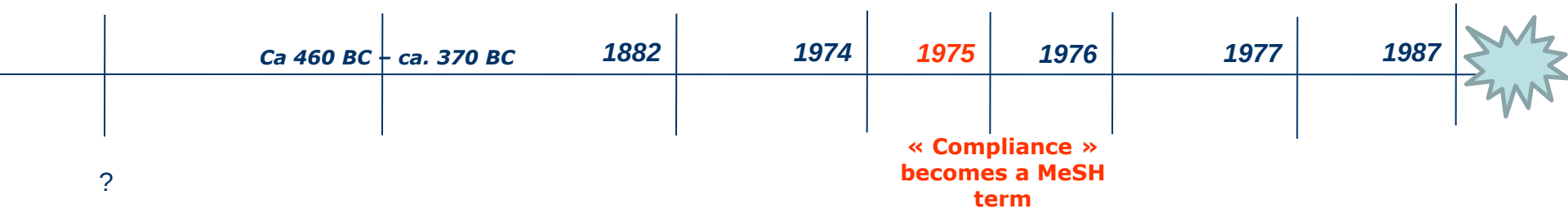
R. Koch stipulated that patients with TB were « vicious consumptives', 'careless' and/or 'irresponsible'

Mc Master workshop/symposium on Compliance with therapeutic regimens

Sackett introduced the term « compliance » into medicine

Mc Master workshop/symposium on Compliance with therapeutic regimens

The term « Pharmionics » is introduced by J. Urquhart



?

« Compliance » becomes a MeSH term

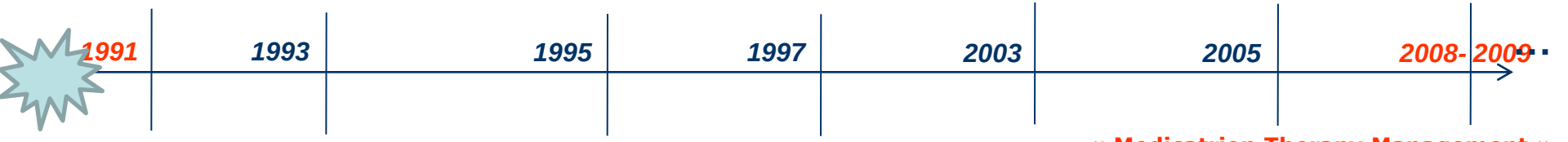
Leventhal has suggested that the conceptual shift from compliance to adherence represents an important step moving away from roles emphasising obedience to instructions (Myers 1998)…

Concordance is introduced by a joined working group of the Royal Pharmaceutical Society of Great Britain

AHA behavioral process influenced by the environement

WHO defintion on adherence

Intentional vs unintentional adherence (report NCCSDO=National Co-ordinating Centre for NHS Service and Delivery Organisation R&D)



« Treatment refusal » becomes a MeSH term

« Medicatrion Therapy Management »
« Medication adherence » become MeSH terms

Time sequence of terminology introduction

Biomedical perspecive
« Pharmacometric »

First recorded incident of human noncompliance… occured when Eve ate the apple in the Garden of Eden…

have taken certain medicines

and/or 'irresponsible'

therapeutic regimens

therapeutic regimens

The term « Pharmionics » is introduced by J. Urquhart

Ca 460 BC – ca. 370 BC | *1882* | *1974* | *1975* | *1976* | *1977* | *1987*

?

« Compliance » becomes a MeSH term

Psychological/Ecological perspective
« Behaviour »

Leventhal has suggested that the conc… from comp… adherence re… important st… away fro… emphasising obedience to instructions (Myers 1998)…

Britain

by the environement

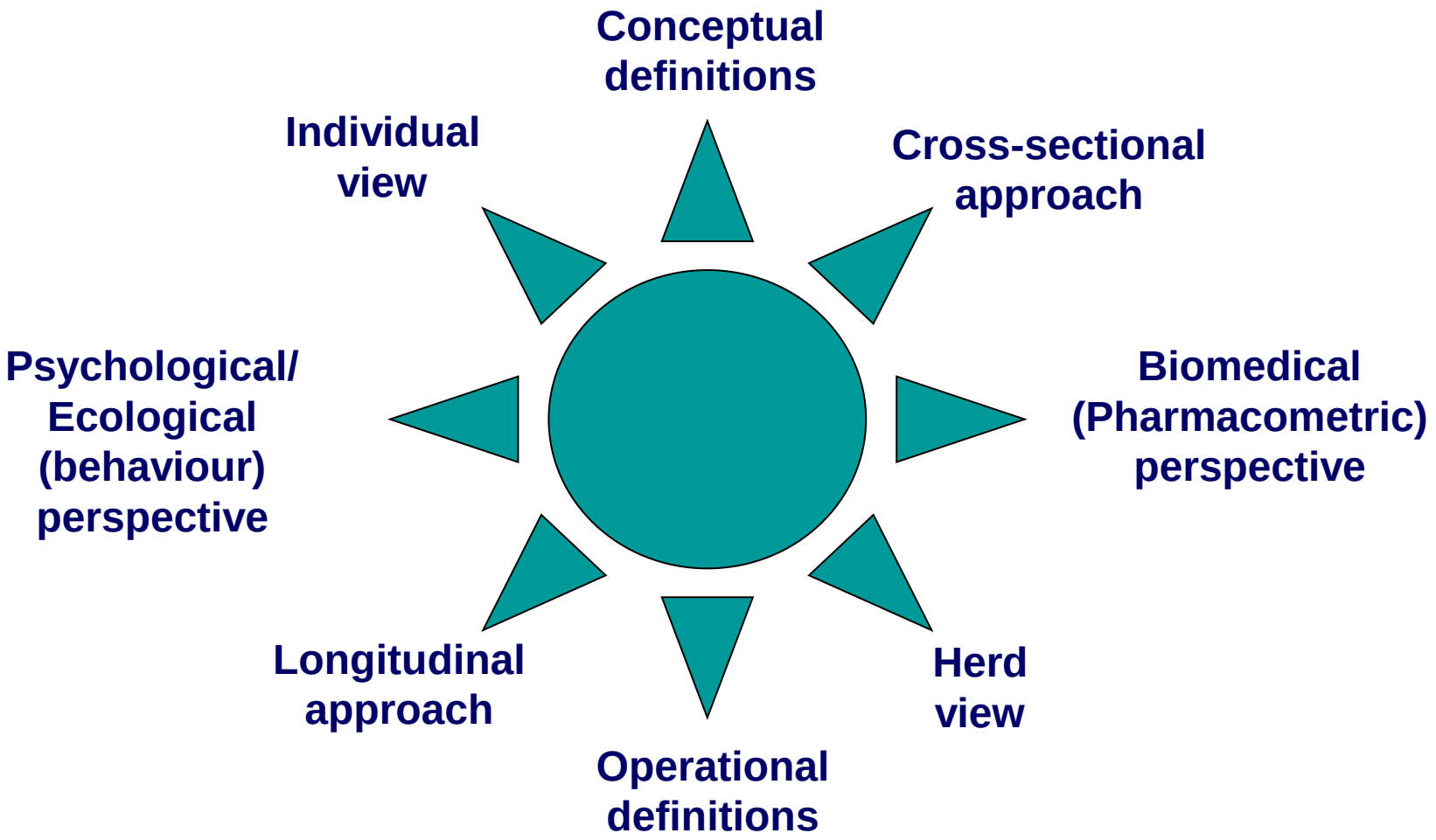
Intentional vs …dherence

…onal Co-…e for NHS …elivery Organisation R&D)

1991 | *1993* | *1995* | *1997* | *2003* | *2005* | *2008- 2009*

« Treatment refusal » becomes a MeSH term

« Medicatrion Therapy Management »
« Medication adherence » become MeSH terms


Conceptual definitions
Cross-sectional approach
Biomedical (Pharmacometric) perspective
Herd view
Operational definitions
Longitudinal approach
Psychological/ Ecological (behaviour) perspective
Individual view

Terminology commonly used: conclusion

- Terms are weak, vague, and inconsistent
- Terms are used to describe either a herd or an individual perspective
- Terms that become labels for patients are contentious
- Terms used without regard for the measurement problems they pose
- Terms ignore the reality that dosing histories are time-series data and cannot be reduced to a single number

- MeSH definition
- WHO definition
- ISPOR definition
- Definitions from the most often cited references

Medication Therapy Management (MTM)

- Assistance in managing and monitoring drug therapy for patients receiving treatment for cancer or chronic conditions such as asthma and diabetes,
- consulting with patients and their families on the proper use of medication;
- conducting wellness and disease prevention programs to improve public health;
- overseeing medication use in a variety of settings.

Year introduced: 2008

- **Patient compliance**: « Voluntary cooperation of the patient in following a prescribed regimen »

- **Medication adherence**: « Voluntary cooperation of the patient in taking drugs or medicine as prescribed. This includes timing, dosage, and frequency »

- **Patient compliance**:
  « Voluntary cooperation of the patient in following a prescribed regimen »

- **Medication adherence**:
  « Voluntary cooperation of the patient in taking drugs or medicine as prescribed. This includes timing, dosage, and frequency »

Definitions implicitely require the measurement of multidimentional variables highlighted in red but no metric is specified

Medication Compliance and Persistence Special Interest Group (MCP SIG)

Medication Compliance (Synonym: Adherence) is the extent to which a patient acts in accordance with the prescribed dosing regimen. The unit of measure is administered doses per defined period of time, reported as the proportion of prescribed doses taken in the prescribed time interval.

Medication Persistence is the accumulation of time from initiation to discontinuation of therapy, measured by time metric.

~ « Permissible gap » based on pharmacologic properties of the drug and the treatment situation

Definition is constrained by the inherent limitations of prescription refill data.

"The extent to which the patient's behaviour coincides with agreed recommendations from the prescriber" (WHO, 2003)

	Taking medication	Not taking medication
Agreement	Adherent	Non-adherent
No agreement	? "I don't agree with my Dr, but I guess he knows best so I still take them as he says I should"	? "I don't agree with my Dr, even if he says I should take these tablets, so I don't take them"

Illustration of the measurement problem they pose

To forge a consensus for a rigorous & robust taxonomy

Some Basic Considerations

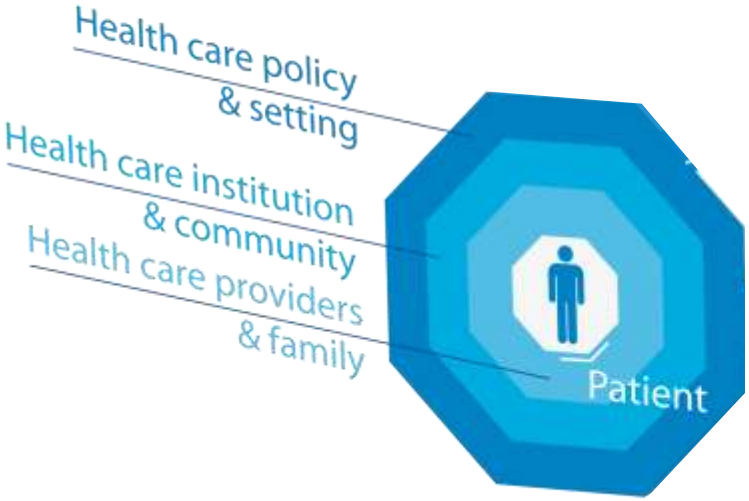
- Because of the breadth of the topic and the multiple behaviors subsumed under the topic, one cannot use a single term and definition to meet all needs of the field.

- There is a clear need to create a set of rules, agreed-upon, within which future activities should fit, if all are committed to fulfillment of the need for clear, concise, and adequate definitions and associated conceptual framework within which ongoing work can continue.

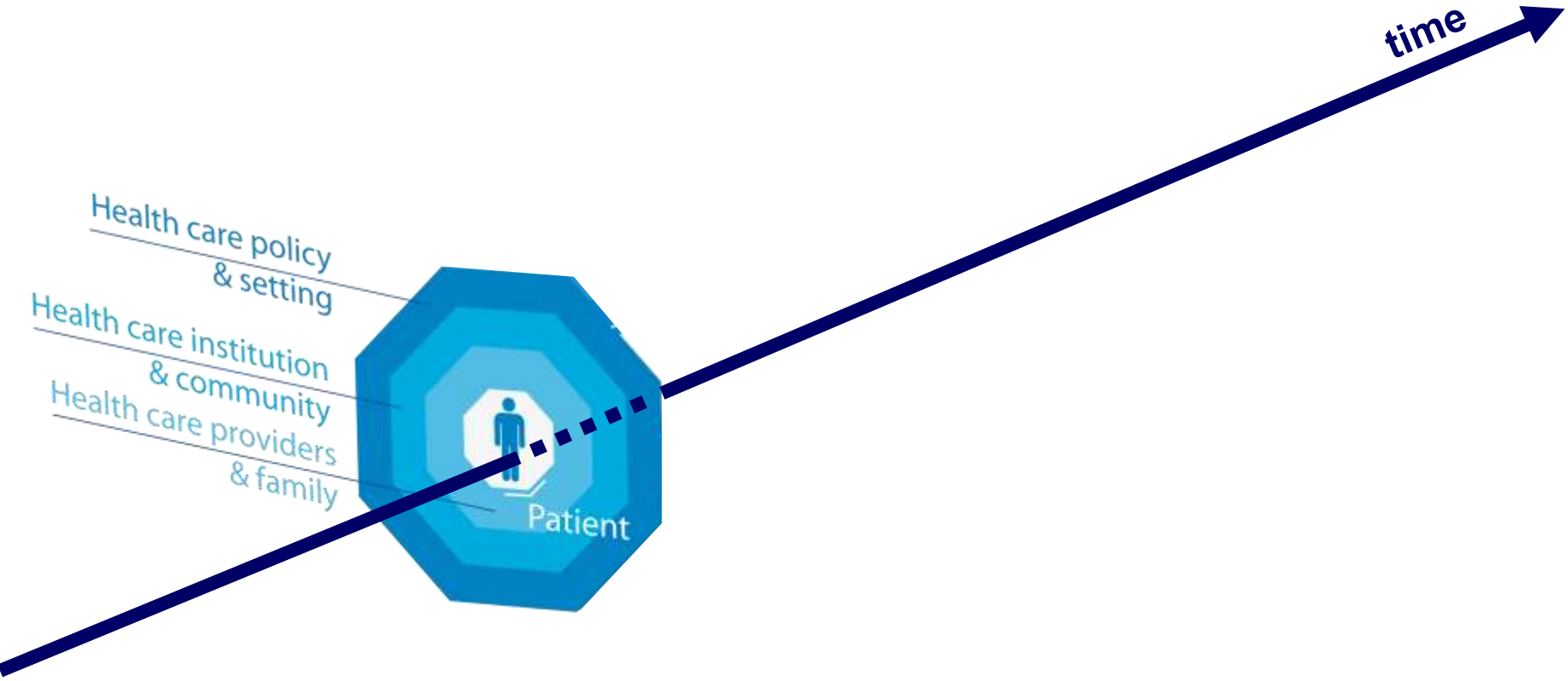
- New methods and new research findings may later force a fine-tuning or even a reshaping of the field's taxonomy.

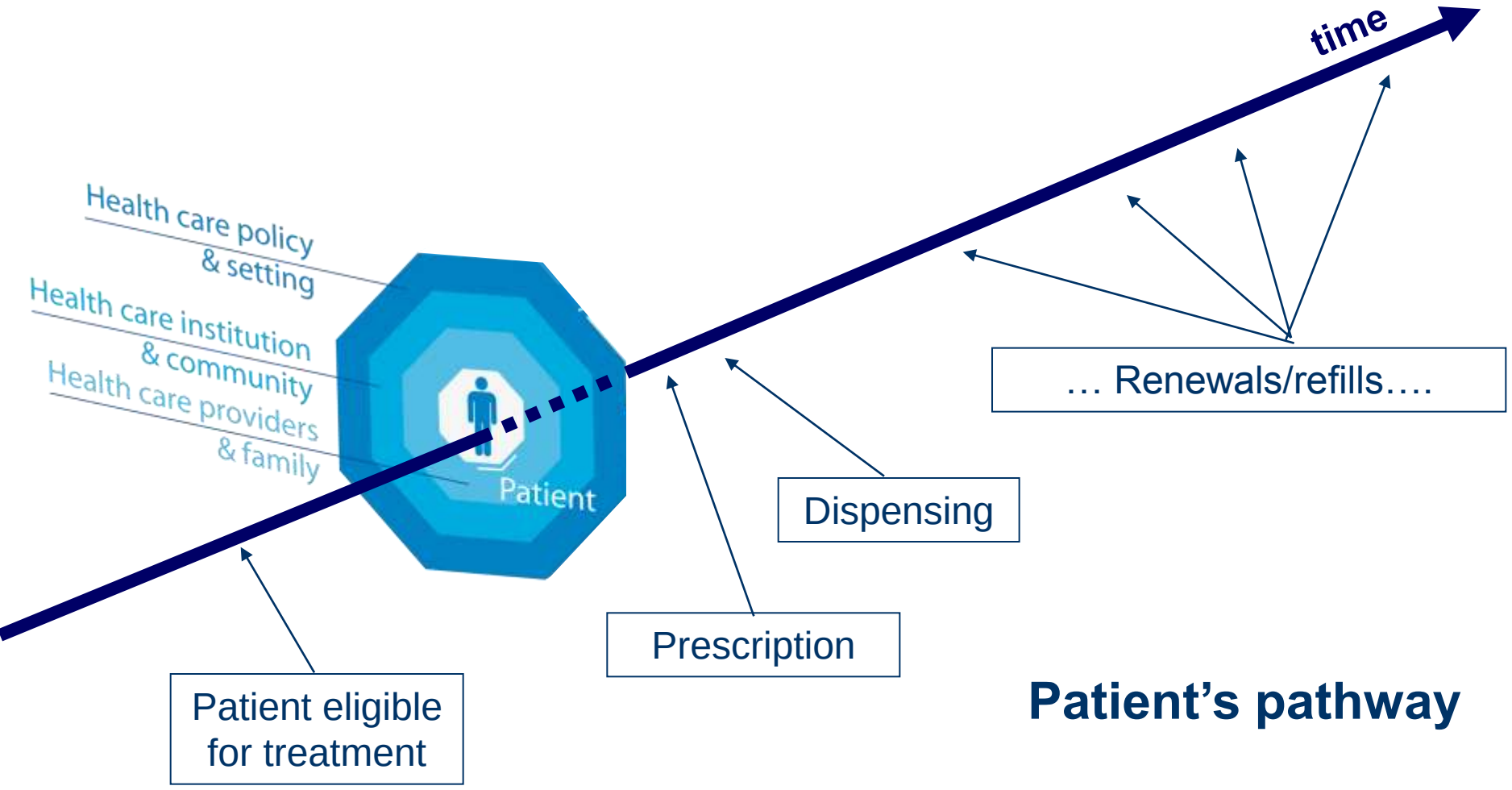
- Careful attention to the metrics for, and physical dimensions of, proposed terms or parameters is one of the pillars upon which a sound taxonomy should rest.

Building blocks (1/9)



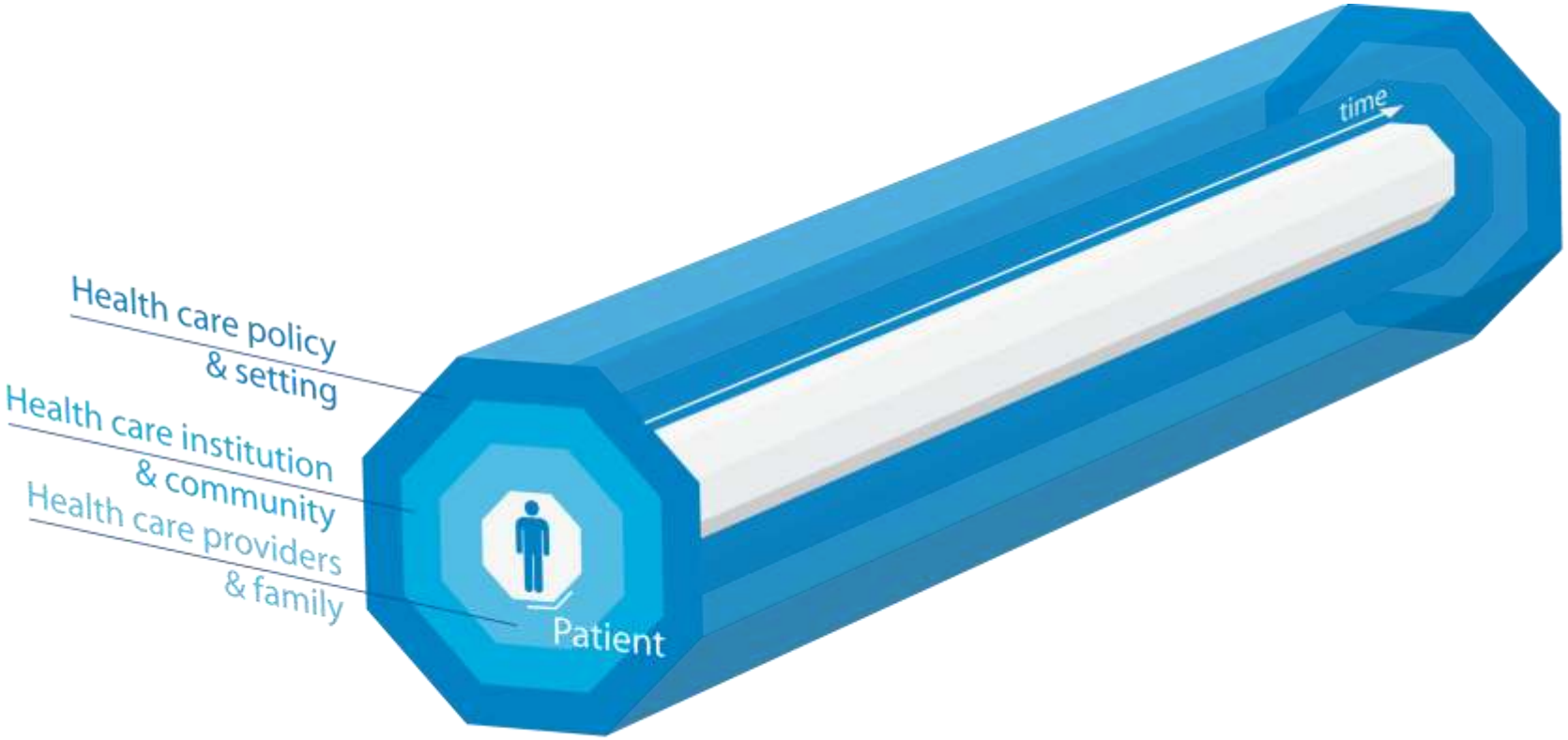
Building blocks (2/9)



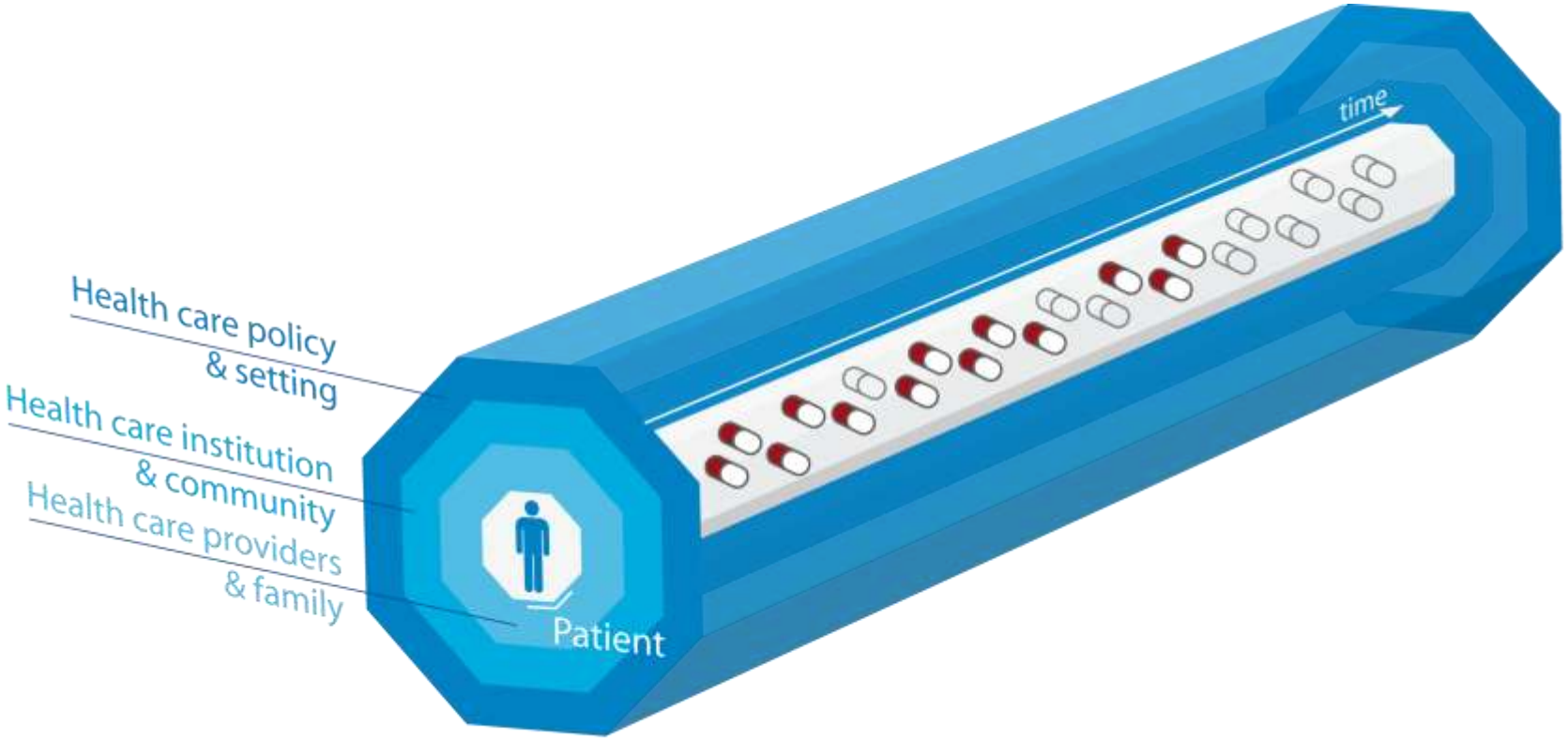


Patient's pathway

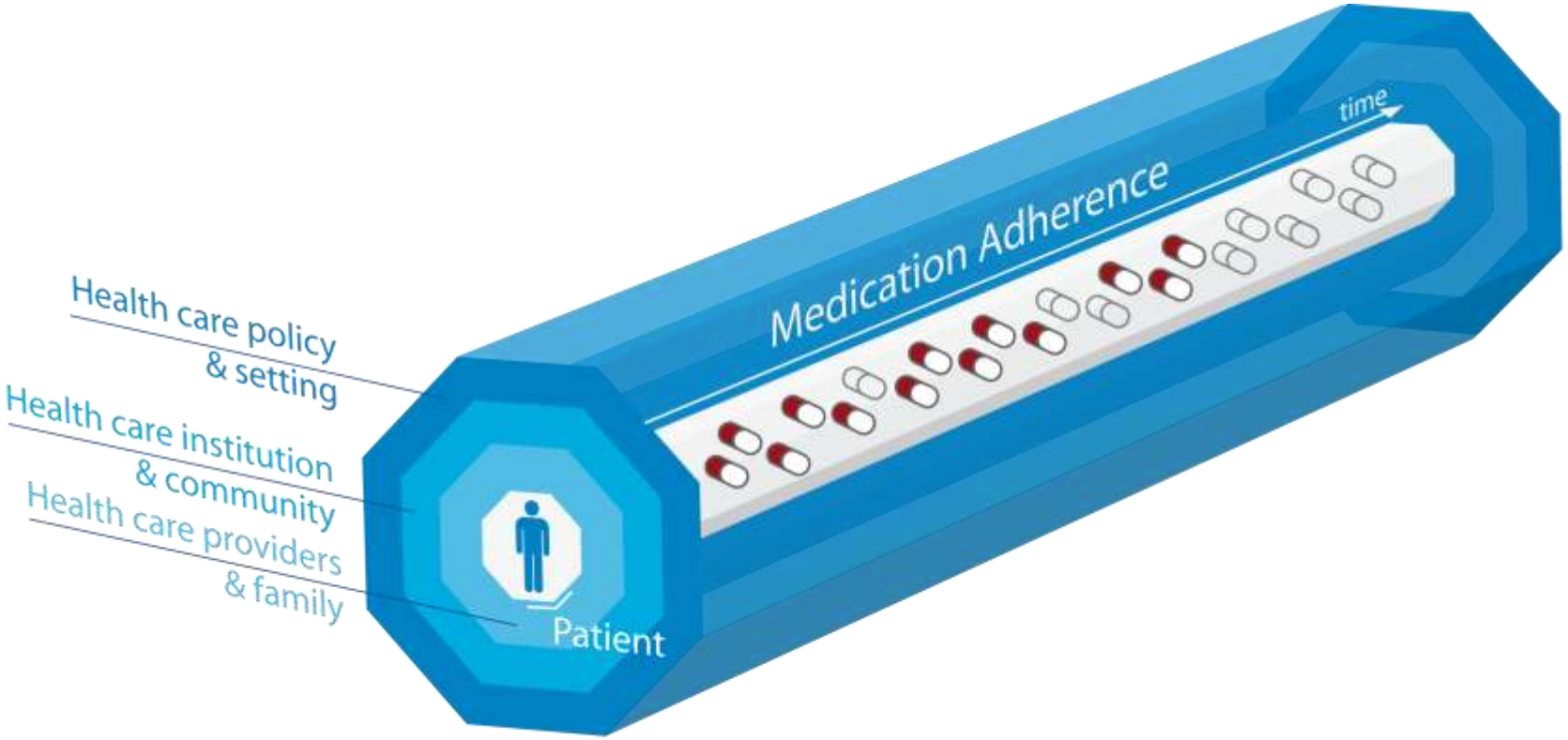
Building blocks (4/9)



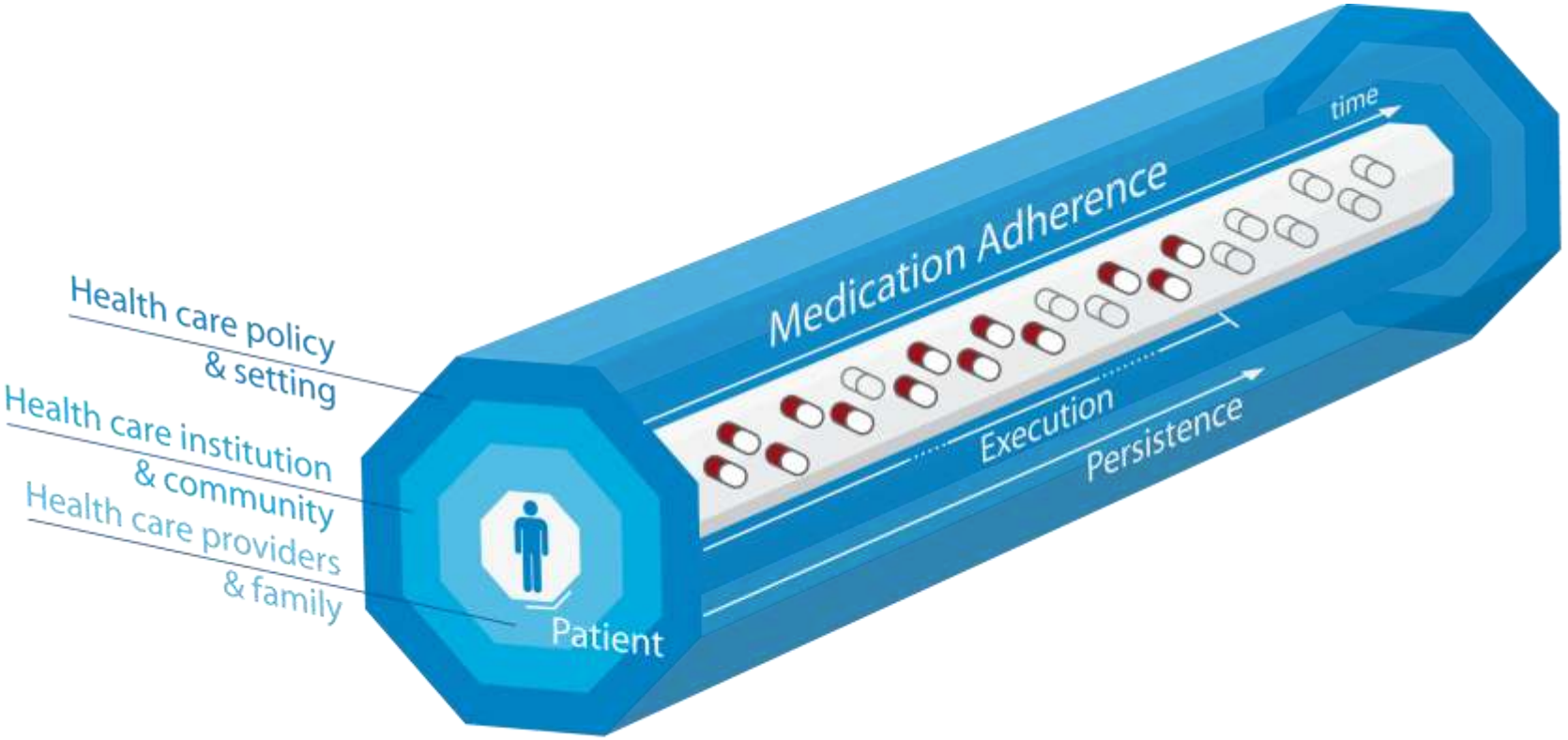
Building blocks (5/9)



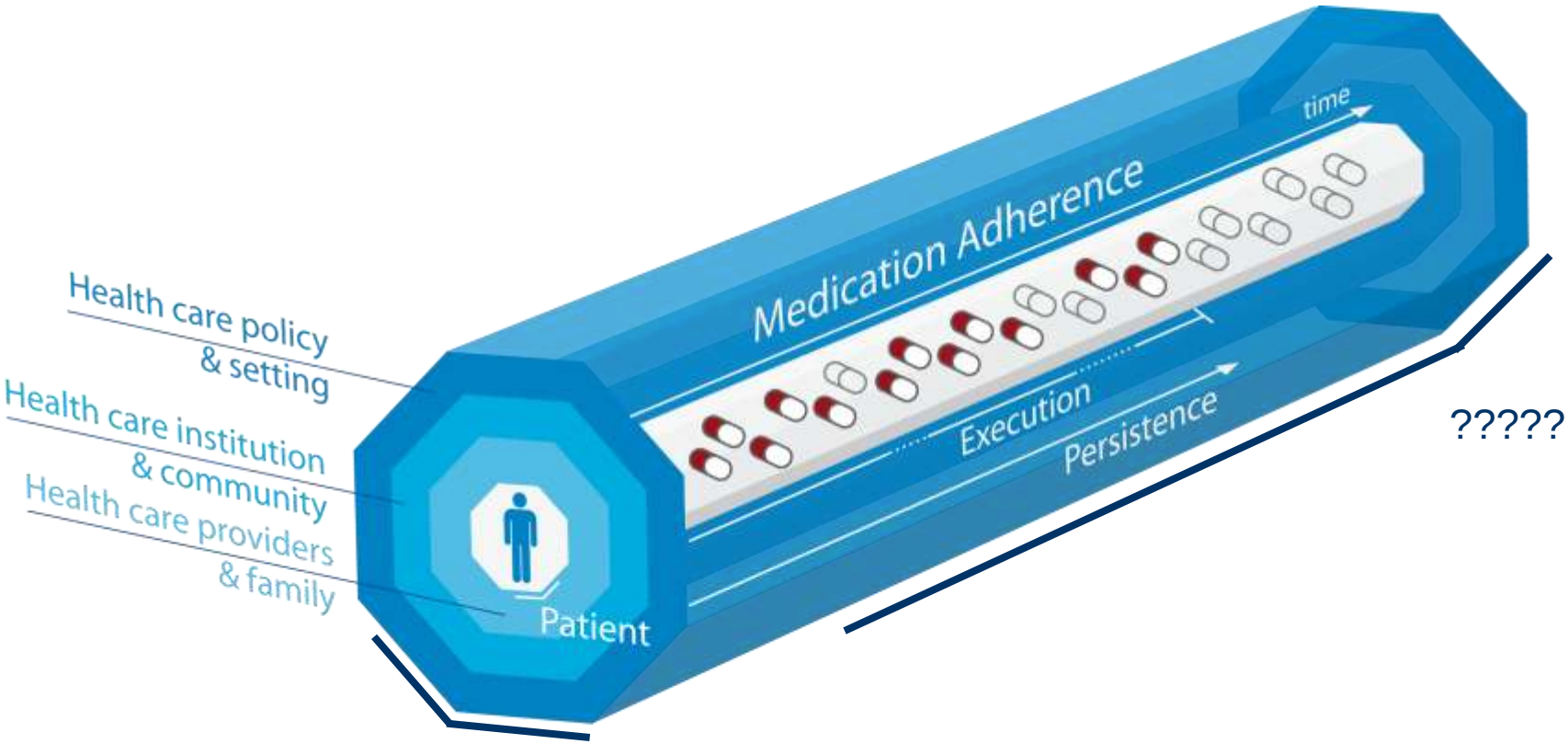
Building blocks (6/9)



Building blocks (7/9)

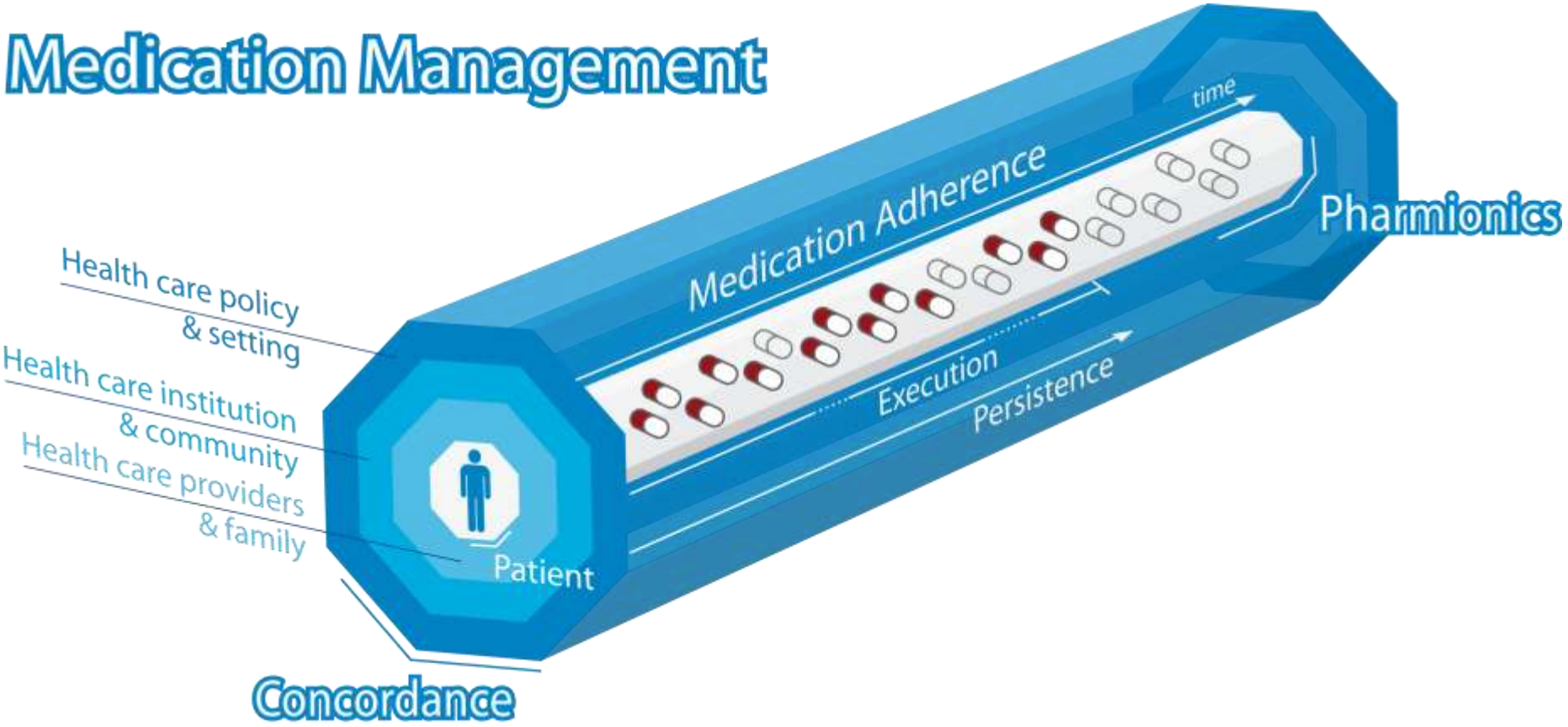


Building blocks (8/9)



Concordance
Agreement
Readiness
Cooperation
Therapeutic alliance

Proposed terminology (9/9)



- Compliance or more often non-compliance addresses deviations from the prescribed dosing regimen.
- Many see it as a pejorative term.
- It has a dozens of completely different meanings in many areas of biomedical practice and sciences.
- In consideration of the last two points it should be dropped
- It covers many different aspects of deviations from prescribed dosing regimen
  - Acceptance of the treatment
  - Execution of the dosing regimen
  - Discontinuation of treatment
- There is a need for a more formal construct

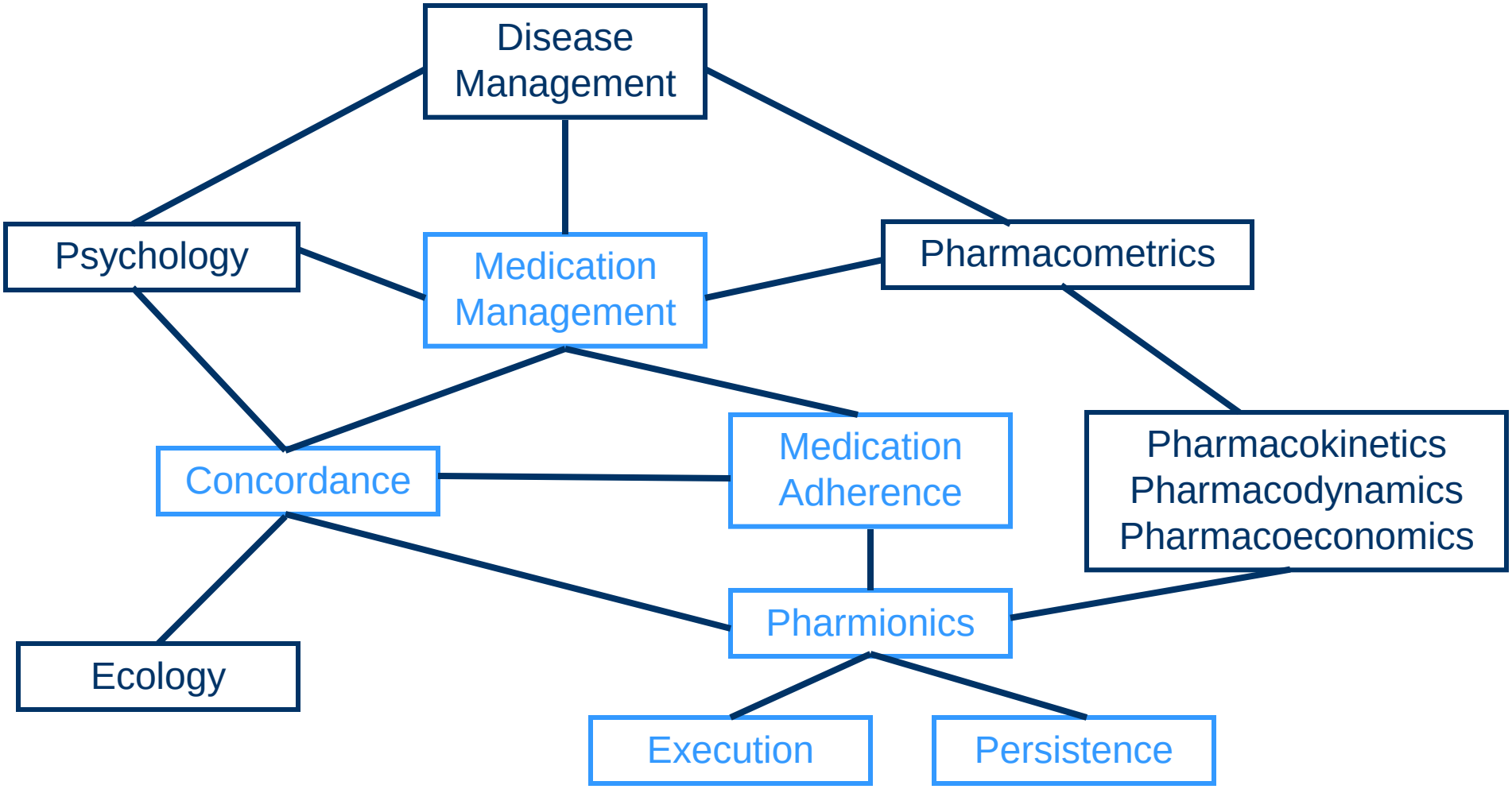
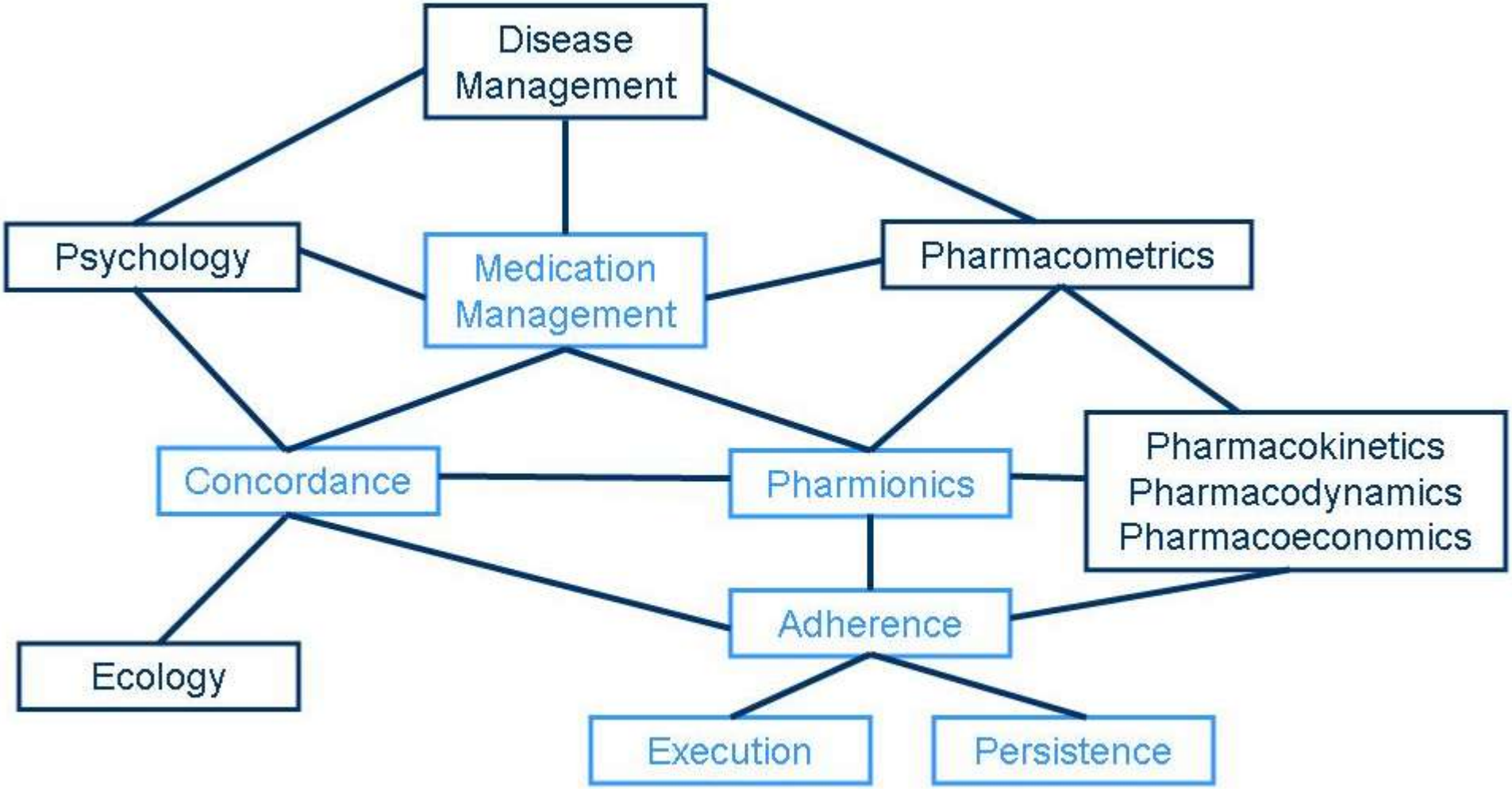
- Is an overaching construct useful for naming the field
- It clearly specifies that we are talking about pharmaceuticals
- It is a blanket term without any physical dimension
- It can thus not be measured or translated into numerical terms
- Removes the temptation to label a patient as adherent versus non adherent

- The process of discussion between healthcare professionals and patients to reach agreement about the treatment plan and the patient's use of prescribed medicines is named *concordance*. This process is particularly important at the initiation or change of treatment, but should, to a lesser degree of intensity, be maintained over the course of treatment. It has to be seen in a system-wide approach, where healthcare policies, organizations, and providers must work in agreement with individual patients and their families.

- *Pharmionics* is concerned with the study of how prescribed medications are used by ambulatory patients. Pharmionics (ion=to go) means "the *going* of the pharmaceutical(s)" and constitutes thus a link to the biomedical field as a natural input to pharmacokinetic and pharmacodynamic models for quantitative analysis of pharmacometric and economic consequences of dosing errors.

- The degree of correspondence between the dosing history and the prescribed drug dosing regimen defines *Medication Adherence* which can be broken into two main components:
  - *Persistence* is the length of time during which the medication is taken; and
  - *Execution* is the multidimensional outcome of the comparison of two time series: the prescribed drug dosing regimen and the patient's drug dosing history while he or she is still engaged with treatment.

Links with other concepts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