European wide Innovation Procurement in Health and Care

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Deliverable

D6.2: Functionalities and technical prescriptions

WP	**6**	Future PPI - Call writing
Task	**6.2**	Co-creation and technical prescriptions definition

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Deliverable abstract

After identifying the specific needs in both Rapid Diagnosis (*D4.2 Final procurement demands*) and Integrated Care (*D3.3. Draft of innovative solution requirement objectives for selected procurement demands and D3.4 Draft MEAT value-based procurement kit test cases fields)*, the present deliverable defines the functionalities and technical requirements that the future solutions must integrate in order to satisfy the identified and defined needs.

In order to proceed with the procurement process based on the MEAT Value Based framework, updated procurement kits with the latest information were collected after the open market consultation on both Rapid Diagnosis and Integrated Care. These outputs, combined with the unmet needs' definition, will be used as a basis to have a pre-tender dialogue or competitive dialogue as agreed within the memorandum of understanding.

This is considered a crucial point, as the only way in which solutions will meet their performance targets and expected outcome/impact is for them to be specified upfront, clearly, and unambiguously. It is a simple fact that if functions and performances are not a stated criterion of the solution requirements then the product/service designers will generally not consider (strictly) performance issues.

Deliverable Review

	Reviewer #1: Yves Verboven			Reviewer #2: NA		
	Answer	Comments	Type*	Answer	Comments	Type*
Is the deliverable in accordance with						
the Description of Action?	☒ Yes ☐ No		☐ M ☐ m ☐ a	☐ Yes ☐ No		☐ M ☐ m ☐ a
the international State of the Art?	☒ Yes ☐ No		☐ M ☐ m ☐ a	☐ Yes ☐ No		☐ M ☐ m ☐ a
Is the quality of the deliverable in a status						
that allows it to be sent to European Commission?	☒ Yes ☐ No		☐ M ☐ m ☐ a	☐ Yes ☐ No		☐ M ☐ m ☐ a
that needs improvement of the writing by the originator of the deliverable?	☐ Yes ☒ No		☐ M ☐ m ☐ a	☐ Yes ☐ No		☐ M ☐ m ☐ a
that needs further work by the Partners responsible for the deliverable?	☐ Yes ☒ No		☐ M ☐ m ☐ a	☐ Yes ☐ No		☐ M ☐ m ☐ a

* Type of comments: M = Major comment; m = minor comment; a = advice

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1. Introduction

The tasks undertaken in WP6 aims to encapsulate and clarifies the outputs generated in EURIPHI by the tasks conducted earlier and in parallel. In particular, it will take advantage of the knowledge capitalised in the EURIPHI Value Based Community of Practice and in support actions such as Cross Border PPI legal guidance. Innovative solutions have been identified in the fields of rapid diagnostic (RD) tools in infectious disease and in the most promising integrated care services (IC). The identification of specific demands and prioritization has been done by expert partners and through the establishment of the Health Regional Network including stakeholders. Following an open market consultation, case testing was performed in order to validate and refine the demands identified on both fields.

All this input will feed the different core activities for a suitable cross border Value-based PPI/PCP, which entails the redesign of clinical pathways having a strong focus on improved health outcomes, and more robust health outcomes measurement, consideration of additional benefit of value for health care actors and resulting in economic most advantageous, cost-efficient purchasing.

In the present deliverable D6.2, the rationale and the unmet needs will be translated into functionalities, which will become the core section of the technical specifications for future potential PCP/PPI. Although, unmet needs are already identified in earlier tasks, it is convenient to conduct a co-creation process involving the different stakeholders within each procuring entity, such as procurement professionals, clinicians from different care levels and patients' voice. This will ensure an internal validation and thus the mitigation of risks in the future implementation of innovative service.

Among the different procurement objectives defined in both rapid diagnostics and integrated care, the consortia decided to focus on one objective per field. For reasons that will be explained in the B*ackground* section, the selected procurement objectives are:

1. Rapid diagnosis tool for antibiotic stewardship of VAP; and
2. Integrated risk assessment tools on Stroke.

2. Background

The EURIPHI CSA fosters an acceleration in reforming procurement practices towards a value-based approach resulting in economic advantageous tendering. Common needs of health systems throughout Europe requires immediate changes in procurement practices, responding to the common needs of health systems throughout Europe. The objectives of EURIPHI project is to build a foundation for future EU cross-border Value Based PPI and PCP.

Innovative solutions were identified in the fields of rapid diagnostic (RD) tools in infectious disease and in the most promising integrated care services (IC). The identification of specific demands and prioritization was performed by expert partners and through the establishment of the Health Regional Network including stakeholders.

In the case of **rapid diagnostics (RD)**, the University of Antwerp led a work package (WP4) that aimed to analyse the current status of Antibiotic use at hospital and use – opportunities – barriers of Rapid Diagnostics test considering socio-economic consequences of AMR development and defining initial criteria.

To define the ideal and minimum acceptable product specifications for rapid diagnostic test solutions, two algorithms were considered: The first algorithm focuses on antibiotic stewardship of VAP by early detection of the presence of pathogens and their antibiotic resistance/susceptibility patterns. Such early detection might allow to alter treatment or de-escalation strategies and can thus impact on mortality and morbidity rates, the length of stay and overall costs and reduce the development of antibiotic resistance. The second algorithm considers a diagnostic test that would allow prevention strategies, reduce pathogen transmission, and avoid VAP infections.

When comparing the importance of the specification between the two algorithms, the second was scored with lower overall importance compared to the stewardship pathway. Given this fact, the present deliverable focuses the definition of functionalities and technical requirements of a solution on rapid diagnosis tool for antibiotic stewardship of VAP.

Two Open Market Consultations (OMCs) were performed on this topic. First, one took place in Paris in May 2019, engaging three interested companies. The second OMC, which took place in Brussels in January 2020 (PIN issued in November 2019), aimed to gather further feedback from the industry on the desired solution and broaden the scope form rapid diagnostics to rapid diagnoses (see attached chart) to which a broader set of solution by the industry was presented. As a result, seven companies showed interested, enabling EURIPHI to understand what is available on the market and what is the current state of the art on rapid diagnosis tools for antibiotic stewardship of VAP.

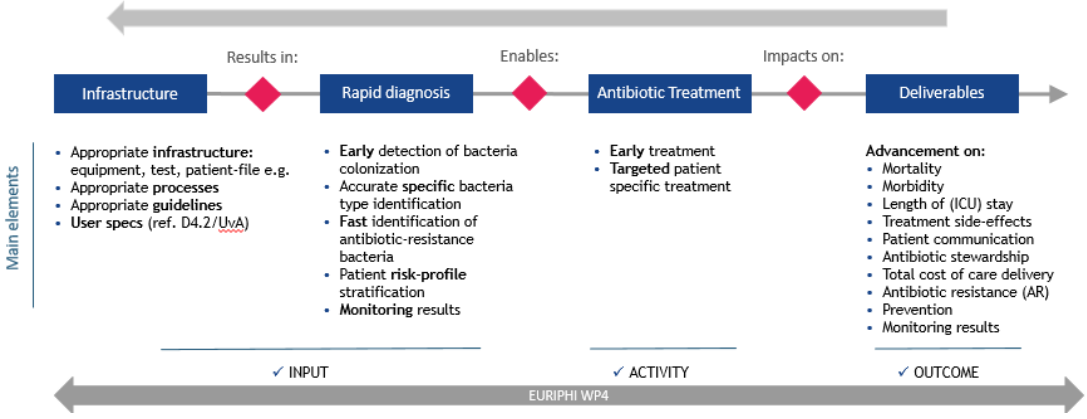

Figure 1. From a rapid diagnostic test on VAP towards management of hospital-acquired respiratory infections

The WP3, alternatively, undertook a series of preliminary **integrated care (IC)** focused networking activities on procuring innovative solutions, including engaging with the EURIPHI Health Regional Network and Value based community of practice to provide documentation for procurers across Europe. Led by International Foundation for Integrated Care (IFIC), the ultimate goal of this WP was to organise the demand side around a small set of Procurement Objectives to address the identified integrated care service delivery issues and to assist them in the related procurement processes.

In October 2019, an Open Market Consultation was performed to identify innovative solutions and to have 1:1 discussion on the value offered from different perspectives of the innovative solutions. It served as an input to defining the procurement demands on Integrated Care.

From the posterior test cases activities, three priority Integrated Care Procurement Objectives (ICPOs) were defined:

- ICPO1: Integrated risk assessment tools
- ICPO2: Integrated solutions to support information sharing and real-time communication within care provider organisations, among different care practitioners, people receiving care and their supporting community and social network.
- ICPO3: Integrated (remote) monitoring solutions for people living with complex needs.

Given the demand showed by the different public procurement organisations (PPOs) on ICPO1, Integrated risk assessment tools on Stroke was the selected field to define the functionalities and technical requirements of the solution.
Although procurement objectives have been defined on both rapid diagnosis and integrated care fields, it is said "*Before joint innovation procurement can be undertaken, first the cross-border cooperation between interested healthcare procurers must be established to counter fragmentation of delivering innovative solution in health care setting*". With this purpose, WP2 aimed to develop guidance conform legal requirements applicable in 12 selected countries to foster an effective cross-border procurement of innovation solutions through "MEAT Value based procurement framework".

The MEAT Value based procurement framework tool, which results in the economic most advantageous purchasing and a change in procurement practices, was adapted to both rapid diagnostic and integrated care and made available by the BCG and MEDTECH Europe in WP2 for use by the partners in the consortium, the EURIPHI Value Based Community of Practice (established in WP1) and for procurement organizations throughout Europe.

Ultimately, WP5 aimed, on first step, to identify the availability of innovative solutions to respond to the procurement demands identified through open market consultations (OMC). Once companies' feedback was gathered, test case learnings were then developed in order to answer to the following questions:

1. *Who is going to 'buy'?*
2. ***What are we going to 'buy' (subject of matter)?***
3. *How are we going to 'buy'? (procurement procedure & model of cooperation)*
4. *What matters to us? (outcome-based award criteria & award method)*

The work undertaken so far in the different Work Packages and the outputs resulted from the test case learnings (especially in Question 2) will serve as key input in the definition of the functionalities and technical prescriptions of the solutions on both integrated care and rapid diagnosis.

3. State of the Art and Preliminary Results

Rapid diagnosis tool for antibiotic stewardship of VAP

As stated in deliverable *D4.2 Final Procurement Demands*, appropriate antibiotic therapy needs to be based on the pharmacokinetics and -dynamics, adequate dosages with enough penetration in lung tissue and adapted to local antibiotic susceptibility profile [1]. It is also recommended that the de-escalation of therapy start as soon as the patient is stable and microbiology data are available. Both European and USA guidelines prefer to treat a patient for 7-8 days.

Each treatment of VAP patients starts with empiric treatment unless low clinical susceptibility or negative culture. This treatment should be based on the local pathogens presents, antibiotic resistance pattern, risk factors of the patient and the type of care.

Clinical decision tree

Based on the currently available guidelines UAntwerp defined two clinical decision trees, focusing on diagnosis and stewardship. In these trees, UAntwerp identified several needs, such as the presence of epidemiology data and the absence of useful prognostic biomarkers. Considering the clinical symptoms, there is a lack of specificity and sensitivity; and most likely, these symptoms alone are not enough for starting the antibiotic treatment. Microbiology should be an important step in these decision trees, although the current techniques are slow and different methods having similar outcomes are available. It is also important to assess how the diagnosis will guide stewardship, especially to avoid overuse of antibiotics.

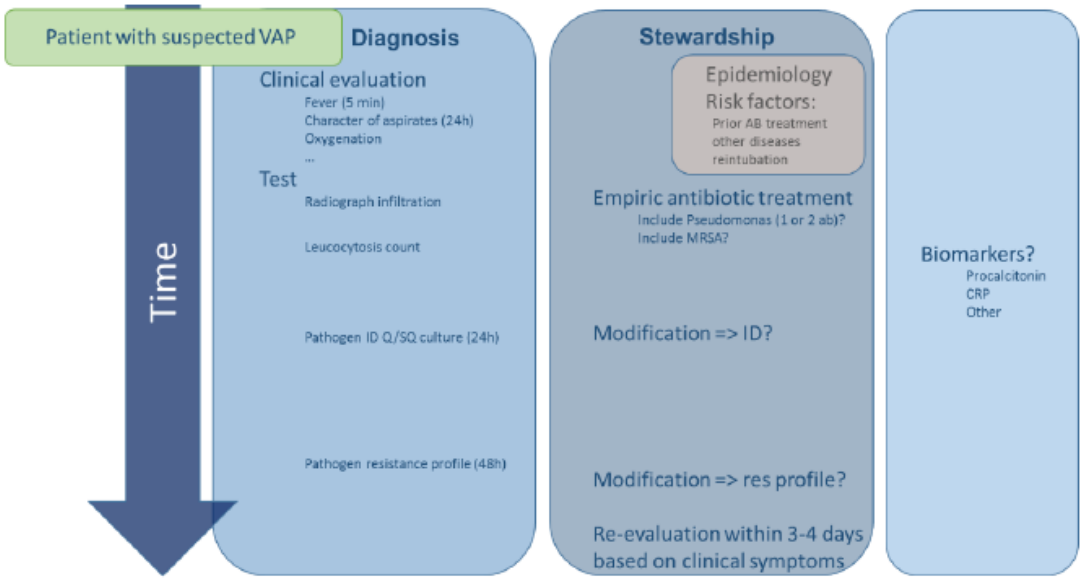

Figure 2. Current clinical decision tree for VAP

After the literature review, a new clinical decision tree has been defined, where a diagnostic test will improve the clinical diagnostic pathway of VAP (Figure 2). The diagnostic test will have an important impact on the decision tree where the pathogen identification and resistance profile will be determined sooner compared to the current clinical decision tree. This data was presented during a breakout session in the kick-off meeting in Brussels; all partners provided their input on this topic.

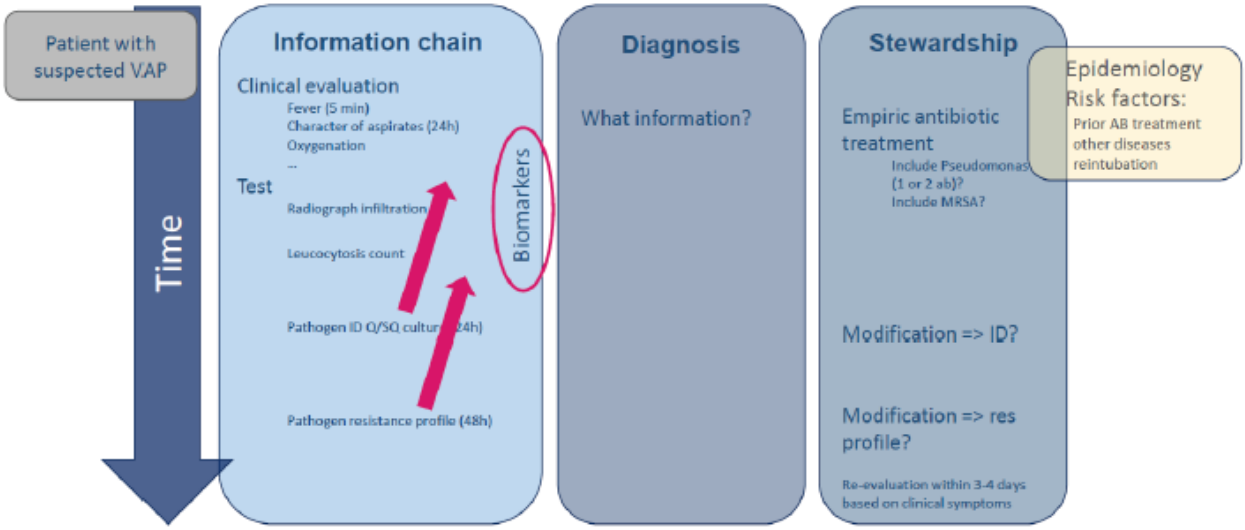

Figure 3. New clinical decision tree for VAP

To define the ideal and minimum acceptable product specifications for rapid diagnostic tests the two algorithms were being considered. The first algorithm focuses on antibiotic stewardship of VAP by early detection of the presence of pathogens and their antibiotic resistance/susceptibility patterns. Such early detection might allow to alter treatment or de-escalation strategies and can thus impact on mortality and morbidity rates, the length of stay and overall costs and reduce the development of antibiotic resistance. The second algorithm considers a diagnostic test that would allow prevention strategies, reduce pathogen transmission, and avoid VAP infections. These strategies were presented during a meeting in Antwerp with the WP4 partners (12/2/2019).

When comparing the importance of the specification between the two pathways, the detection of colonization was scored with lower importance compared to the stewardship pathway. Given this fact, **stewardship pathway was selected as the procurement objective in rapid diagnostics field.**

Stewardship pathway

It has been witnessed the emergence of new diagnostic tools over the last few years that might allow to promptly initial antibiotic therapy or rapid de-escalation after the initial dose. These diagnostic tools are capable of guiding antibiotic treatment, particularly in the case of broad-spectrum antibiotics in Intensive Care Units. Current recommendations for management of VAP in patients at risk of multi-drug resistant pathogens call for prompt broad-spectrum empirical treatment, including dual Gram-negative coverage. This recommendation is supported by consistent findings that delayed appropriate antibiotic therapy in multi-drug resistant pneumonia is associated with increased mortality. However, the definition of "patients at risk for multi-drug resistant pathogens" is very broad and results in massive overtreatment with broad-spectrum antibiotics. Kett et al showed that adherence to empirical treatment of these patients was associated with increased mortality [2]. A potential explanation for this increased mortality was the antibiotic-specific toxic effects of colistin, aminoglycosides and fluoroquinolones. ATS-IDSA guidelines recommend that the broad-spectrum empirical treatment is de-escalated when possible, based on clinical response and microbiological data. The goal of de-escalation is to limit the emergence of resistance and to reduce mortality.

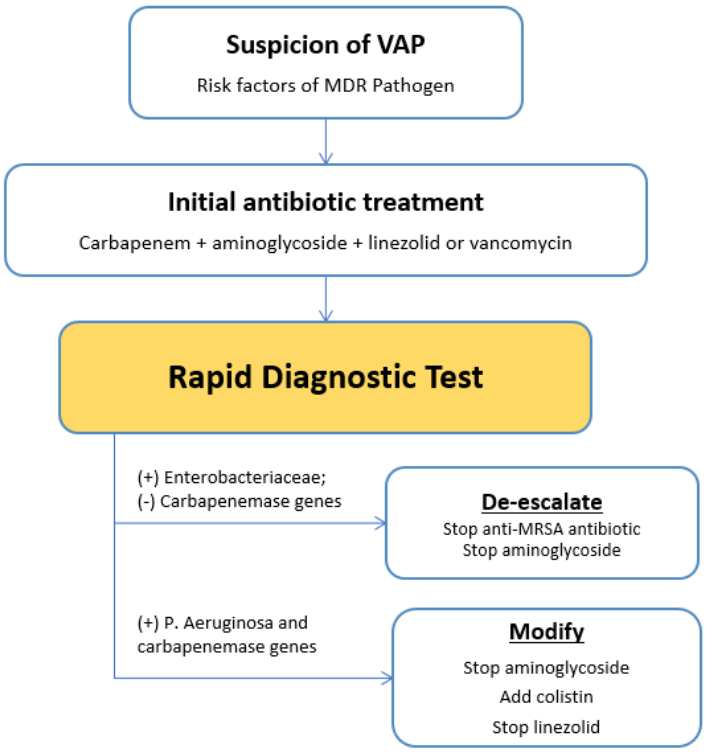

Figure 4. An example of an stewardship aproach algorithm

Preliminary results

UAntwerp partner developed a questionnaire with the aim to identify the technical specifications needed for a rapid diagnostic test for microbiological detection of pathogens causing VAP. Seven renowned VAP experts proposed by the European Respiratory Society (ERS), as well as three EURIPHI partners answered the questionnaire, which was focused on antibiotic stewardship of VAP by early detection of the presence of pathogens and their antibiotic resistance/susceptibility patterns. Such early detection allows to alter treatment or de-escalation strategies and can thus impact on mortality, morbidity, the length of stay, overall costs, and the development of antibiotic resistance. The technical specifications of the diagnostic test were identified by analysing the questionnaire results, allowing us to allocate weight factors to the various value associated outcomes and the underlying technical specifications, and bridging clinical significance to value. The goal of this questionnaire was to define (i) the importance of the technical specifications, and (ii) the ideal and minimum acceptable product specifications for rapid diagnostic tests that might fitting the algorithm. The technical specifications were split according to the different outcomes and levels. Details can be found in table 2 and attachment 1-2 from the D4.2.

Pathway	Stewardship
Number of questions	87
Minimum time to fill in	17 min
Average time to fill in	28 min
Maximum time to fill in	57 min
Program	Qualtrics

Table 1. Specifications of the questionnaire

Based on the descriptive analyses, the technical specifications at the patient level were scored as the most important (**Annex I** – also available on WP4 deliverables). The top 10 included 7 specs at the patient level, such as time to result, sensitivity, specificity, list of pathogens and resistance genes, type of sample and the culture method of the sample (Quantitative versus qualitative). All specs were having a score higher than 2.7/3, indicating the high importance ranked by the VAP experts. Also, the reduction of prescribing (global spec) and selective pressure (global spec), the reproducibility (device specs) and positive predicted value (PPV; device specs) were considered important (scores >2.7). On the other hand, the costs (hospital level) were scored as less important, of which the waste and footprint were the least important (score: 1.9).

For analysing the product specifications, experts on VAP were asked to identify the minimum and ideal product specifications. Global and individual results are reflected on D4.3 Final Procurement Demands.

A first Open Market Consultation (OMC) was performed on May 2019. At the EURIPHI OMC, procurement organizations, partners and members of EURIPHI, seek to obtain an overview of the latest information on innovative solutions available on the market or in development.

The industry had the opportunity to enter into dialogue with procurement organizations and experts through 1:1 dialogue session. The companies could present and discussed their innovation and value propositions. Value proposition which responded to the needs of patient and shortcoming of current care delivery but as well of expected interest of the actors in health care and society. The economic benefits and consequences were as well highlighted and possible interest in value-based contracting expressed.

Participating companies receive a description of identified awarding criteria and evaluation as a basis for discussion. These guided by user requirements and application of the MEAT Value Based Procurement Framework.

Given low number of companies, a second OMC was performed on February 2020. This time, the number of companies was higher (7) and better conclusions were obtained. As a result, EURIPHI got to understand the current state of the art on the rapid diagnosis tools on antibiotic stewardship on VAP and what is currently available on the market.

The results from both OMC confirmed the necessity to develop a solution, through a rapid diagnosis, might allow to promptly initial antibiotic therapy or rapid de-escalation after the initial dose. Given the « ambitious » minimal requirements identified by VAP experts, the OMC results determined that obligation of meeting them should be decided by each procurement organisation when publishing the Tender. If they consider these are too strict, then it would be considered as requirements that the solution would be NICE TO HAVE, instead of MUST HAVE.

Integrated risk assessment tools on Stroke

As stated in D3.3, population and chronic condition risk assessment tools need to be integrated into the care model to identify people at risk to enable appropriate care and support to be targeted at those who are most likely to benefit.

After the OMC consultations that took place on Integrated Care in October 2019, a Workshop was performed in November 2019, where most procurement organizations (12) defined an integrated care procurement objective on developing integrated risk assessment tools on Stroke.

Data from the integrated risk assessment tools are needed to inform primary and secondary prevention strategies at the individual and population levels which would impact positively in Population Health strategies and benefit strategies for Chronic Condition Management.

In the case of stroke, risk assessment online tools are largely limited to a single language domain, and not integrated with local health records or professional platforms and records. A survey of the state of the art in the market showed the use of pull media only and no interface with health systems either to draw risk parameters or to deliver assessment results back into the relevant systems.

The operation of current risk assessment models is imperfect: The ASCVD risk assessment, for example, was found to overestimate hypertension risk in adults, both for those without diabetes overall and across socio-demographic subgroups. Another tool, SCORE, can be used by health professionals to assess their patients, but it is not integrated into their own systems and relies on manual entry of patient parameters by the health professional. Further to this, these tools in most cases "tend to use 'snap-shot' measurements of risk factors taken at the time of assessment – such as cholesterol levels and blood pressure – to predict the patient's overall risk of cardiovascular disease. They do not account for a patient's medical history and how their risk factors have changed over time, nor do they differentiate the risk by specific heart and circulatory diseases, such as heart attacks, strokes, heart failure or abnormal heart rhythms." Another shortcoming of such score assessments is that they measure a 5 or 10-year risk for patients and thus under-estimate the life-time risk for younger patients, who are increasingly affected by a stroke.

People who have had a stroke or a Transient Ischemic Attack (TIA) are at increased risk of future stroke, especially in the first few months following a TIA or a stroke. Research shows that patients who suffer a recurrent stroke have poorer outcomes than those who suffer a first stroke. The risk for a recurrent stroke is six times greater than the first stroke, indicating the importance of secondary stroke prevention and timely secondary prevention has proven to be effective in reducing recurrent stroke in patients with stroke or a TIA.

As it is observed, lifestyle is influencing the risk of having a stroke and there is currently no device that can properly asses the risks of a stroke, taking into account all parameters. The issue is about (easy) integration of the different technologies/devices/apps rather than development of a new one.

The new IT device should be a (cross-institutional) *communication IT platform integrating different 'platforms or data sources' connecting the different stakeholders* (patient, social care, clinicians, other health care practitioners). It must bring both clinical and non-clinical data together and will provide data to both care practitioners and patients in order to manage stroke risk factors (e.g. blood testing, blood pressure, medication adherence) and to prevent from having a stroke.

The tool should:

- Use lifestyle data, patient tests and -data
- (Inter-) Connect the care practitioners' team to the high-risk stroke patient
- Monitoring stroke risk factors
- Analyse, assess, and predict the risk of a stroke appearance (based on an intelligent algorithms and weighting risk factors)
- Send out alarms, alerts and/or signals to patients and/or the care team

Preliminary results

As for D3.3, and taking into consideration the conclusions obtained on both the OMC in October 2019 and a workshop among partners in November 2019, a first set of functional requirements that the solution should meet was drafted:

Risk assessment tools should be able to detect individuals and subgroups of the population at risk to allocate resources to create specific prevention plans, screening programmes and design the adequate care pathway.

- individual risk assessment results need to be made available to care practitioners in order for them to case find, monitor and follow-up individuals (with appropriate consent)

Risk calculation and therapeutic recommendation tools should be personalised, addressing data sharing and infrastructure needs such as integrating highly heterogeneous multi-scale data sources. The provision of multiple channels to establish bi-directional communication of text, images, voices, and video should be addressed as well.

- integration functionalities towards EHRs or medical records (to draw risk parameters or to deliver assessment results back into the relevant systems)
- address limited accuracy of risk assessment tools (manual entries, only present "snap-shot" measurements of risk factors)
- more personalised risk calculation
- address lack of implemented standards for clinical and research data
- avoid algorithms that are not representative of real situations and do not allow flexibility

Risk assessment tools need to have a holistic approach beyond the disease-specific risk stratification tools. They should also include:

- variables relating to an individual's social connectedness
- capacity and capability of family carers to respond to the care burden
- cognitive and functional competencies
- self-awareness and self-management possibilities
- competencies in the use of digital solutions to communicate with care providers in case of an emergency or to design monitoring and self-management interventions and support

Risk assessment tools for secondary prevention need to assess people's situation in a more comprehensive way to foresee, plan and react in a proportionate way and avoid evitable relapses or reactivations, reduce the risk of unrecoverable disabilities or capacity reduction and avoid unnecessary hospitalisation. To do so they should be able to detect:

- the disease progression
- drug interaction risk
- changes in motivation and risk for mental health disorders
- treatment fatigue and the risk for treatment compliance reduction
- family and carers burnout and risk of social support reduction
- social isolation
- the risk of abuse and suspect possible abuse

4. Methodology and Results

Spend on global healthcare is estimated to rise from $7 trillion in 2015 to a staggering $8.7 trillion by 2020 as the world's major regions are predicting spend increases ranging from 2.4% to 7.5% (Deloitte, 2017). Despite its significance, professional procurement in the health industry is often immature and not strategically integrated (Nachtmann and Pohl, 2009). There is a recognition in the wider procurement literature of a conceptual shift from a narrow focus on prices paid to a wider value-based perspective encompassing innovation achieved through collaborative relationships (Corsten and Felde, 2005). Relationships and interactions stimulate the creation of value and improve organisational performance (Jaakkola and Hakanen, 2013), beyond price savings achieved only through iterative reductions in suppliers' profit margins. Accounting for value beyond suppliers' prices is essential (Anderson et al., 2000), as the single-faceted relentless pursuit of annual price-oriented savings in healthcare is not sustainable (Pritchard, 2012). For procurement, the longer-term value perspective is closely aligned to the concept of total cost of ownership (Wouters et al., 2005). Effective procurement practices are critical to an organisation's success, yet in the healthcare industry, procurement often overlooks contemporary views of value creation (Walker et al., 2008).[3]

The undertaken activities have been effective to ask key stakeholders to define their needs for innovation in terms of functional and performance requirements, without identifying a specific solution. This will encourage the market to the active generation of application ideas and technological choices, including divergent and alternative ones, though equivalent from the point of view of performance and expected outcome. The opportunity not to pre-define the technical solution and to be open to alternative technical ways to address the needs expressed in functional and performance-based requirements does not mean that needs definition should be short and very general.[4]

The MEAT Value based procurement[5] framework tool, which results in the economic most advantageous purchasing and a change in procurement practices, was adapted to both rapid diagnostic and integrated care. Doing this, identified holistic tender scope and requirements were defined along the layers of the MEAT VBP adapted frameworks, moving from a traditional to a VBP tender.

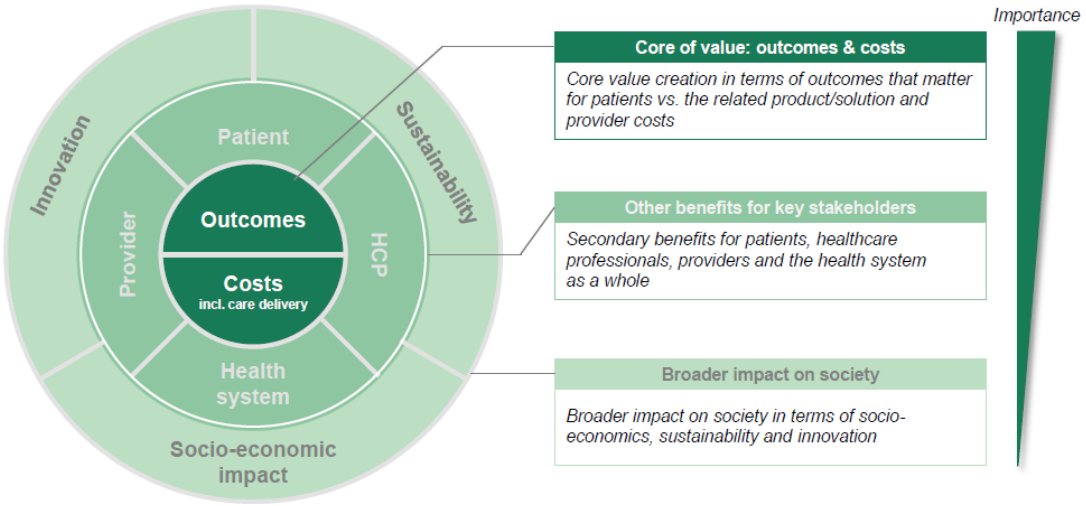

Figure 5. MEAT VBP framework - 3 layers

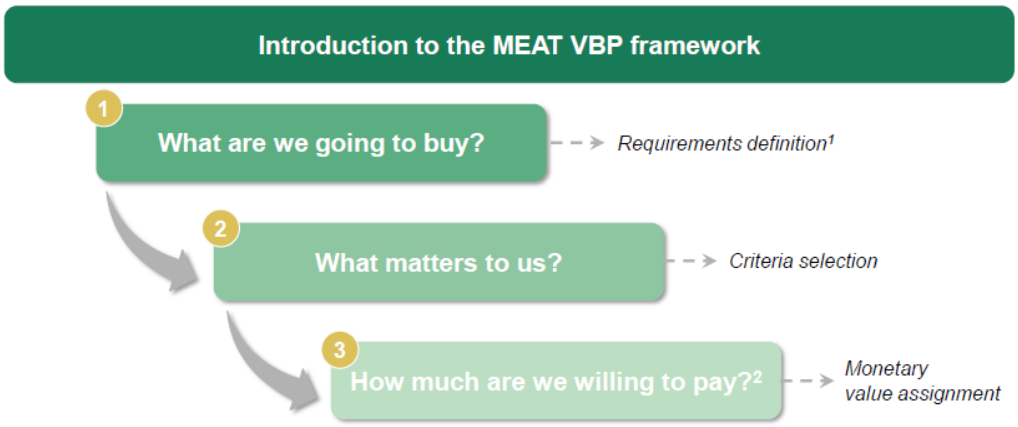

Figure 6. Questions to be answered by the Contracting authority

As mentioned in the *Introduction*, the present deliverable will focus on answering the first question – ***What are we going to buy?*** - by defining solution's minimal requirements on both a rapid diagnosis tool for antibiotic stewardship of VAP and Integrated risk assessment tools on Stroke.

Rapid diagnosis tool for antibiotic stewardship of VAP

Taking into account the conclusions from the deliverable D4.2 on WP4 and the two OMC conclusions, next steps were defined as follows:

The solution should comply with nine Rapid Diagnosis Key Functional Requirements (RDMFR) that will be described in a potential tender specification's sheet. As mentioned previously, procurement organisations will be responsible to determine whether these requirements end up being considered as key functional requirements that the solution MUST HAVE or would be NICE TO HAVE. In case first scenario is contemplated, the presented requirements will be considered as Knock-Out (KO) criteria, meaning that if any presented offer that does not respect all of them, will be automatically excluded.

In the second scenario (NICE TO HAVE), the fact that the solution does not meet the requirements will have an impact on the scoring, but not on the exclusion of the offer.

From the Adapted MEAT VBP Framework to Rapid Diagnosis, all defined RDMFR will have a direct impact on both patients and health care professionals (HCPs). However, they will also lead to outcomes that will have an effect at a hospital level as well as on the sustainability and at a socio-economic level. This is studied in more detail on *D6.3 Patient-centred assessment framework* deliverable.

Key Functional Requirement	1
Requirement Code	RDKFR1

Objective
The diagnostic test solution must provide **rapid results** in order to permit a quick response from the health care providers
Solution
The solution must provide a time-to-result inferior to 8 hours.

Key Functional Requirement	2
Requirement Code	RDKFR2

Objective

The diagnostic test must ensure a **high validity** associated to the proportion of actual **positive cases** that are correctly identified. It must correctly classify an individual as 'diseased'

Solution

The solution must ensure a sensitivity (also called true positive rate or probability of detection) of the assay greater than an 70% rate.

$$\text{Sensitivity}^{[6]} = a/(a+c)$$

Being a=true positive and c=false negative.

Key Functional Requirement	3
Requirement Code	RDKFR3

Objective

The diagnostic test must ensure a **high validity** associated to the proportion of actual **negative cases** that are correctly identified. It must correctly classify an individual as 'disease-free'

Solution

The solution must ensure a specificity (also called true negative rate) of the assay greater than an 70% rate.

$$\text{Specificity} = d/(b+d)$$

Being d=true negative and b=false positive.

Key Functional Requirement	4
Requirement Code	RDKFR4

Objective

The diagnostic test must ensure that **test positives are true positives**

Solution

The solution must ensure a positive predictive value (PPV) of the assay - percentage of patients with a positive test who actually have the disease - greater than an 90% rate.

$$PPV = a/(a+b)$$

Being a=true positive and b=false positive.

Key Functional Requirement	5
Requirement Code	RDKFR5

Objective

The diagnostic test must ensure that **test negatives are true negatives**

Solution

The solution must ensure a negative predictive value (NPV) of the assay - percentage of patients with a negative test who do not have the disease - greater than an 90% rate.

$$PPV = d/(c+d)$$

Being a=true positive and b=false positive.

Key Functional Requirement	6
Requirement Code	RDKFR6

Objective

The diagnostic test must be able to identify the existance of **main nosocomial pathogens**

Solution

The solution must ensure the identification of both *Staphylococcus aureus* and *Pseudomonas aeruginosa* pathogens

Ideally, the solution will identify all the ESKAPE pathogens:

Enterococcus faecium, Staphylococcus aureus, Klebsiella pneumoniae, Acinetobacter baumannii, Pseudomonas aeruginosa and Enterobacter

Key Functional Requirement	7
Requirement Code	RDKFR7

Objective

The diagnostic test must be able to identify **antibiotic resistant pathogens**

Solution

The solution must ensure the identification of at least two antibiotic resistant pathogens among:

- Carbapenem-Resistant Enterobacteriaceae
- Carbapenem-Resistant Acinetobacter baumannii
- Carbapenem-Resistant P. Aeruginosa
- Methicillin-resistant staphylococcus aureus

Key Functional Requirement	8
Requirement Code	RDKFR8

Objective
The diagnostic test must ensure high closeness between the **results of measurements** of the same measurand carried out under the **same conditions**
Solution
The solution must ensure a reproducibility of at least a 95%.

Integrated risk assessment tools on Stroke

The preliminary list of functional requirements was distributed among the twelve POs in order to refine them with experts on the field of Stroke.

1. **UNIHA**
2. **RESAH**
3. **APHP**
4. **NHSCS**
5. **NWSSP**
6. **AQUAS**
7. **FCRB**
8. **FPT**
9. **RSD**
10. **InnovaPuglia**
11. **SORESA**
12. **FDG**

The POs were asked to provide additional input or feedback regarding the subject of matter as well as the minimal functional requirements the solution should have.

In addition to this exercise, they were asked to indicate their 5 most important value-based award criteria relevant to the subject of matter indicating on what the product/solution should ultimately have an impact (what matters to us). Lastly, comments were also provided regarding the limitations of the Adapted VBP Framework on Integrated Care to the integrated risk assessment tools on stroke.

These answers contributed to the analysis and results from the *D6.3 Patient-Centred Assessment Framework*

Subject of matter

Lifestyle is impacting on the risk of having a stroke. There is currently no device that can properly assess the risks of a stroke, taking into account all parameters. The issue is about (easy) integration of the different technologies/devices/apps rather than development of a new one. The population scope are those persons with an identified high risk of stroke.

The new IT device should be a (cross-institutional) communication IT platform integrating different 'platforms or data sources' connecting the different stakeholders (patient, social care, clinicians, other health care practitioners). The tool must be an innovative technological solution empowering the patient.

It must bring both clinical and non-clinical data together and will provide data to both care practitioners and patients in order to manage stroke risk factors (e.g. blood testing, blood pressure, medication adherence) and to prevent from having a stroke. Also see (minimal) functional requirement listed below.

The tool should:

- Use lifestyle data, patient tests and data
- (Inter-) Connect the care practitioners' team to the high-risk stroke patient
- Assure equality in the use and to avoid age and gender discrimination
- Monitoring stroke risk factors

- Analyse, asses and predict the risk of a stroke appearance (based on an intelligent algorithms and weighting risk factors)
- Send out alarms, alerts, and signals to and from patients and care team (=patient push and clinical/care team pull PROM)

Regarding data attention should be given to:

- different data source(s)
- different data formats
- roles of data owner and -processor
- impact on GDPR and Information Governance
- current baseline data problems

Final key functional requirements

The solution should comply with the Integrated Care Minimal Functional Requirements (ICMFR) that will be described in a potential tender specification's sheet.

Despite the fact that the defined ICMFR will have a direct impact on both patients and health care professionals (HCPs), they will also lead to outcomes, in a greater or lesser extent, to all different categories of the Adapted MEAT VBP Framework to IC. In the same way as in rapid diagnosis, these is studied in more detail on *D6.3 Patient-centred assessment framework* deliverable.

Key Functional Requirement	1
Requirement Code	ICKFR1

Objective

Risk assessment tools should be **able to detect individuals and subgroups of the population at risk** to allocate resources to create specific prevention plans, screening programmes and design the adequate care pathway.

Solution

Individual risk assessment results need to be made available to care practitioners in order for them to case find, monitor and follow-up individuals (with appropriate consent).

Key Functional Requirement	2
Requirement Code	ICKFR2

Objective

Risk calculation and therapeutic recommendation tools should be **personalised, addressing data sharing and infrastructure** needs such as integrating highly heterogeneous multi-scale data sources.

Solution

The provision of multiple channels to establish bi-directional communication of text, images, voices, video should be addressed through:

- integration functionalities towards EHRs or medical records (to draw risk parameters or to deliver assessment results back into the relevant systems)
- address limited accuracy of risk assessment tools (manual entries, only present "snapshot" measurements of risk factors)
- more personalised risk calculation
- address lack of implemented standards for clinical and research data
- avoid algorithms that are not representative of real situations and do not allow flexibility

Key Functional Requirement	3
Requirement Code	ICKFR3

Objective

Risk assessment tools need to have a holistic approach beyond the **disease-specific risk stratification tools**

Solution

The solution should include:

- variables relating to an individual's social connectedness
- capacity and capability of family carers to respond to the care burden
- cognitive and functional competencies
- self-awareness and self-management possibilities
- competencies in the use of digital solutions to communicate with care providers in case of an emergency or to design monitoring and self-management interventions and support

Key Functional Requirement	4
Requirement Code	ICKFR4

Objective

Risk assessment tools for secondary prevention need to assess people's situation in a more comprehensive way to **foresee, plan and react in a proportionate way and avoid evitable relapses or reactivations, reduce the risk of unrecoverable disabilities or capacity reduction** and **avoid unnecessary hospitalisation**

Solution

The solution should be able to detect:

- the disease progression
- drug interaction risk
- changes in motivation and risk for mental health disorders
- treatment fatigue and the risk for treatment compliance reduction
- family and carers burnout and risk of social support reduction social isolation
- the risk of abuse and suspect possible abuses
- To be able to assess a secondary prevention, there is need to have access to the specific stroke etiologic information

Additional functional requirements that will be considered are outlined below:

Additional Functional Requirement	1
Requirement Code	ICAFR1

Objective
The solution should be easy to use.
Solution
The solution should ensure a quick and easy up taking, understanding and learning on how to use the technology for both users and professionals

Additional Functional Requirement	2
Requirement Code	ICAFR2

Objective
The solution should be easy to install.
Solution
The solution should ensure a quick and easy installation for both users and professionals.

Additional Functional Requirement	3
Requirement Code	ICAFR3

Objective
The solution should be easy to connect to different data sources.
Solution
The solution should ensure a easy and simplified ways to connect itself to other possible data sources.

Additional Functional Requirement	4
Requirement Code	ICAFR4

Objective
The solution should be interoperability.
Solution
The solution should ensure the ability to share information among professionals from different sectors (Social Services and Health Services) so this can be received, managed, and integrated into their systems.

Additional Functional Requirement	5
Requirement Code	ICAFR5

Objective
The solution should be secure and GDPR compliant.
Solution
The solution should ensure the compliance to the European General Data Protection Regulation (EGDP).

5. Conclusion

The present deliverable shows one of the main pillars from the work undertaken by the EURIPHI partners since the beginning of the project and it has enabled the definition of the functional requirements on both Rapid Diagnosis - focused on antibiotic stewardship - and integrated risk assessment tools on Stroke.

In the field of Rapid Diagnosis , the work undertaken in the different Work Packages (WP2 - to define among EURIPHI partners the Adapted VBP Framework on Rapid Diagnosis; WP4 - to identify a prior set of requirements by VAP experts; and WP5 - to understand the current state of the art within the market in order to compare and refine the identified requirements) lead to the definition of eight key functional requirements that the solution, in principle, SHOULD HAVE in order to achieve the expected goals. Given the feedback provided by the companies on both OMCs, each Procurement Organisation (PO) will be responsible, in the future tender, to consider these functional requirements either as knockout (KO) criteria or as subjective and valuable criteria that will be taken into consideration in the scoring.

The fact that the companies respect the defined key functionalities will lead to an impact at different stakeholder level. Outcomes such as the time to result reduction and diagnosis improvement will not only have an impact (short and long-term outcomes) on both patients and healthcare professionals, but also on healthcare systems, to the same services provider and at a socio-economic and environmental level.

On the other hand, in the field of integrated care, input was gathered from a great variety of innovation ecosystem agents in order to, through an iterative process; define the functional requirements on the integrated risk assessment tool. Defined requirements (key and additional) will enable both care practitioners and patients to manage stroke risk factors. The empowering of the patients is key and will enable the treatment compliance, as well as monitor the disease progression and assess a potential secondary prevention. In the same way, it will have an impact at a health and social care system, reducing visits and antibiotic consumption.

With the functional requirements defined, next steps will be focused on producing the rest of tools that will contribute to the successful preparation of a cross border value-based PCP and PPI.

i) A user-centred assessment framework with coherent awarding criteria that will be part of tender documentation, for both Rapid Diagnosis and Integrated care. The result will be published in the deliverable D6.3.

ii) A common challenge definition and business case, which will generate an impact analysis on the aimed model of care vision and will seek the one-time financial commitments needed to implement changes. This report will be published in D6.1.

iii) Last, but not least, the preparation of the guidelines on the definition of the model of governance for the buyer groups that will serve the tender preparation stage. This information will first fall under the Task 5.2 (memorandum of understanding signing for a cross-border procurement) and later on the Task 6.4, which will represent the form under which the procurement will be designed.

In order to respond to these aims, it will be necessary to involve key stakeholders within our organisations such as clinicians, managers, innovation staff, procurement officers and ICT, among others.

6. Annex I. Preliminary results on Rapid Diagnosis

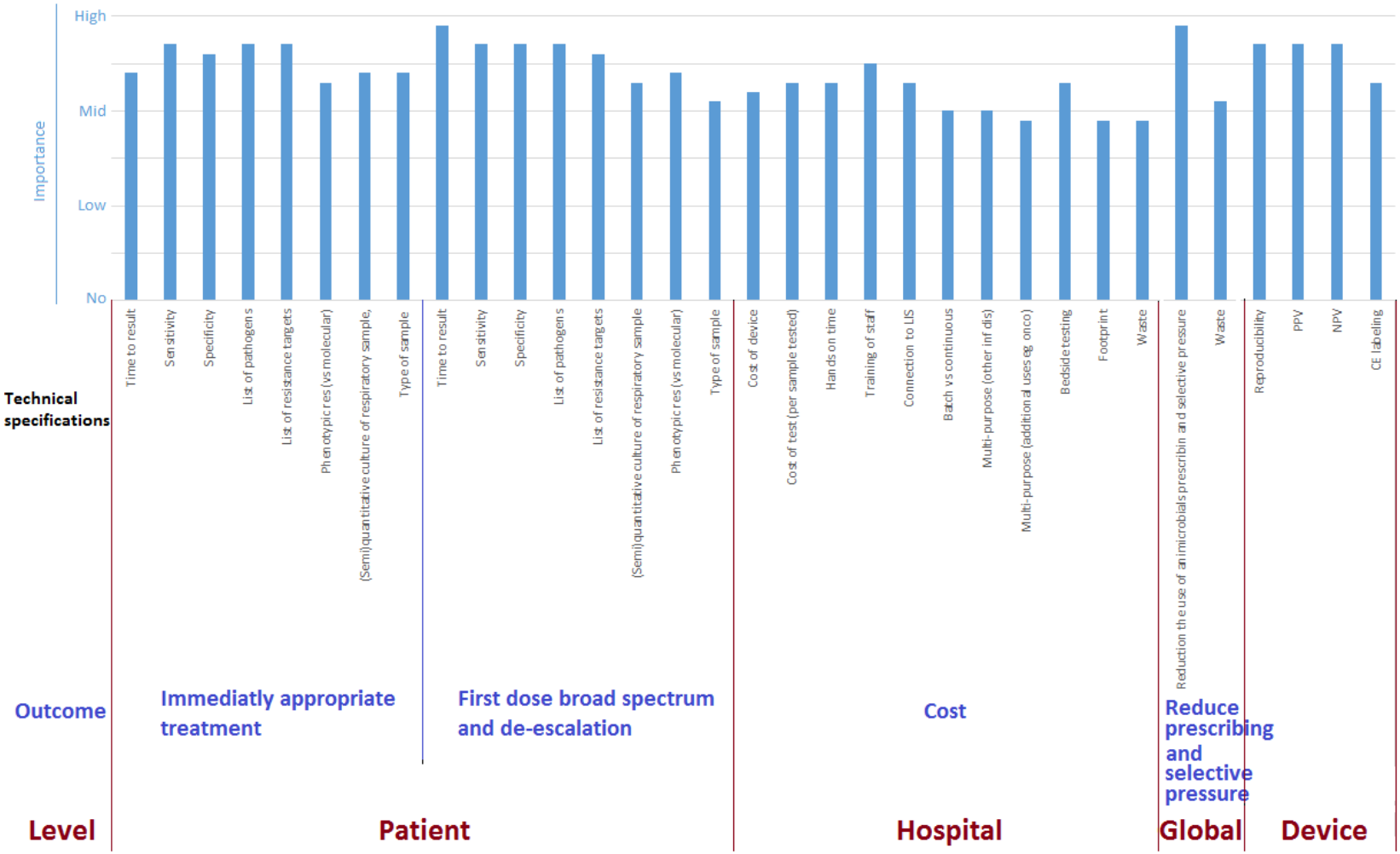

Figure 7. Importance of technical specification in the stewardship pathway (WP4)

7. References

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