INSPIRE case study

Lombardy hospital PCP pilot (or innovation procurement) in health-care sector

Roles involved:

- Direction for research of Lombardy Region: responsibility to coordinate and finance the PCP process
- General direction for Healthcare: responsibility to indicate the mid-to-long term political priorities for health-care services transformation and optimization
- Public Hospital Niguarda: responsibility in defining the innovation needs in terms of performance and functional requirements and running the technical activities like testing, comparing and evaluating of performance and functionality in real-life operational conditions
- Regional Purchasing Agency: adjudicating authority, entitled to define the (future) transition from PCP to PPI.
- Experts on innovation procurement: support to public sector to design and implement the entire end-to-end PCP process.

Status: on-going

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Key information

• Object: R&D services	y
• Demand side driven approach (need /challenge definition)	y
• Separation with the procurement of commercial volumes of end-product and no preferential treatment in the supply of the final product (re-opened competition)	y
• Absence of exclusive condition: the public purchaser does not reserve the R&D results exclusively for its own use	y
• Open and competitive procurement (no invitation-based or restricted procedure)	y
• Development in phases	y
• Multiple-sourcing contract	y
• Retaining at least two participating companies until the last phase to ensure a (future) competitive market	y
• Open, transparent, non-discriminatory selection procedure based on objective selection and award criteria specified in advance of the bidding procedure	y
• Contractual arrangements (including IPRs), rights and obligations allocation decided upfront and made available to all interested bidders in advance	y
• All potential bidders (including SMEs) have equal chances to bid against the same contractual condition	y
• Awarded criterion: MEAT (competition also on price)	y

1. Identification and assessment of unmet needs within (and starts from) the public bodies

The procurement process has started with a structured technological needs assessment, which has seen the involvement of end users (medical and nursing personnel, socio-health operators, clinical engineers, health managers) in a collective brainstorming and focus group.

The assessment step has led to the identification of 10 real needs, which were put in order of priority, on the basis of their expected impacts. In particular, a list of innovation needs has been ranked in term of relevance, considering a common set of criteria:

- (presumed) annual volume of expenditure for the purchase of the device (€)
- industrial applicability
- (potential) market volume for the device (€)
- (current) concentration level of the supply channel
- gap of quality perceived by end-users complexity and significance of technological need.

Only 3 of 10 needs has been confirmed and analysed in depth to understand whether no commercially stable solution exist or the market exhibit shortcomings which require new R&D.

The prior problem that it was decided to solve by a PCP initiative concerns the high rate of accidents and functional limitations of socio-health workers tasked with moving, via manual pushing and pulling, the hospital beds. At the present time moving hospital beds, be they gurneys or mechanical or electrical movement hospital beds, is carried out by pushing or pulling by at least 2 socio-health operators, with a high rate of accidents and long transport times. With reference to Niguarda Hospital, that has expressed the need, overall some ten accidents and collateral effects have been registered per year affecting nursing personnel and socio-health operators, which are generally below strength for the needs of Italian hospitals. Such accidents lead to 15-20% invalidity and/or functional limitation in those who carry out bed movements.

The desired innovative solution is a new and cost-effective automated universal medical device for moving hospital beds (and possibly also gurneys), that is easy to use and to manoeuvre for a single operator, equipped with all anti-collision and safety systems, reduced in size, which does not need tracks or guide lines and which can also be used on non rectilinear routes and in all hospital spaces (rooms, lifts, corridors and diagnostic ward spaces), which result in a significant advance in terms of technology and performance and, at the same time, cost reduction.

The aim is to improve patient comfort and safety when moved, but more than this to improve the efficiency of the overall service of beds movement in hospital, to avoid collateral and unwanted effect affecting nursing personnel and socio-health operators. Less personnel need, (significant) low rate of accidents and functional limitations in those who carry out bed movements and short transport times are expected. It has to be considered that actually socio-health operators are below strength for the general needs of Niguarda and Italian hospitals, the innovative solution will enable a more efficient resource allocation. The solution expected will contribute to enhance the service productivity and to reduce the negative impact on the cost of the public services offered. The expected savings will come from not only the reduction (at least 40%) in the cost of the solution as well as from the elimination of collateral effects, in the form of accidents and functional limitations affecting dedicated (public-engaged) personnel.

The multiplier effect of the impacts on efficiency for the regional procurer stem from the fact that the

number of hospital beds in Lombardy is roughly 40,000 units, of which around 70% are public beds, and it is estimated that 40% of beds could need a universal movement device.

2. Involvement of users in specification of requirements

The procurement process has started with a structured technological needs assessment, which has seen the involvement of end users (medical and nursing personnel, socio-health operators, clinical engineers, health managers).

The centrality of the user in the proposition, guide, co-creation and, subsequently, in the validation of the technological innovation was assured by the user-driven model adopted.

The final users and addressees of the innovation (medical and nursing personnel, socio-health operators, clinical engineers, health managers) were asked to define their needs for innovation in terms of functional and performance requirements, without identifying a specific solution, to encourage the active generation of application ideas and technological choices, including divergent and alternative ones, though equivalent from the point of view of performance.

3. SoA analysis via open technical dialogue and early market engagement

The required solution was identified following a structured state of the art investigation that brought to light the non-existence on the market of commercialised products complying with the requirements of universality, ease of use, safety and cost effectiveness.

A state of the art analysis has been carried out, by means of an open technical dialogue with the market (conducted through public hearings, advertised explorative calls for tender and an in-depth world-wide patents analysis) that had displayed the non-existence on the market of commercialised products complying with the requirements and shortcomings which require new R&D.
Technical dialogue has significantly reduced the information asymmetries (that constitute the basis of lock-in and hold-up mechanism) and enabled the purchaser to guide the R&D, to learn from (potential) suppliers' early feedback and to conduct independent and autonomous evaluation, becoming less dependent on third parties.

Furthermore, the market research undertaken prior to the procurement experiment highlighted a very concentrated supply market, giving rise to a high cost of solutions. The designed competitive procurement results in the most fit-for-purpose and cost-effective solution, avoiding single supplier lock-in.

4. Specification of functional / performance-based requirements

The tender does not pre-define the technical solution, but is open to alternative technical ways to address the needs expressed in functional and performance based requirements. The suppliers can therefore propose alternative and innovative technical solutions.

In total 32 (minimum) requirements have been formulated and classified according to the product life-cycle phases: production, delivery, installation, use, management, maintenance and disposal in order to ensure high long-term performance and (total life-cycle) costs as low as possible.
This has been a crucial point, as the only way in which solutions will meet their performance targets and expected behaviors 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 designers will generally not consider (strictly) performance issues.

5. Evaluation and Verification of innovative solutions (either within the tendering process or in pre-commercial phase)

In order to create a context that is favourable for the experimentation and evaluation of use modalities, the advantages and disadvantages of prototypes, with the active involvement final users (represented by a body of socio-health operators, medical personnel and clinical engineers), and in accordance with a "living lab" model, Lombardy Region and Niguarda Hospital has decided that the hospital rooms, corridors, lifts and diagnostic ward areas equipped for the preparation of patients constitute a real operational context, appropriately arranged and protected, for the experimentation, verification and validation of the effective functionalities and performances of the prototypes realised, i.e. their effective correspondence with innovation requirements.

6. Shared allocation of risks and benefit (including IPR management)

Coherently with COM (2007) 799, the public purchaser does not reserve the R&D results exclusively for its own use. Public authorities and industry share risks and benefits of the R&D needed to develop new innovative solutions that outperform those available on the market.

Because the "exclusiveness" of project results is not indispensable for public purchasers as the public purchaser is only one of many potential users of the developed solution and haven't a mandate to commercially exploit the research results, the contract assure the incentive for companies to invest in further commercialization and at the same time the right for public procurer participate in benefits and obtain a financial compensation related to the commercialisation and take up of the developed solutions. This provides an incentive to both parties to pursue standardisation and commercialization of R&D results.

Other contractual arrangement and a set of IPR related rights have been provided to ensure a future competitive supply chain to procurer:

- Licence free rights to use the developed solution (these rights represent the legal basis under which the contracting authority can use the information acquired with PCP to formulate the final supply demand),
- call-back option which ensure that IPRs ownership right returns back to the procurers in case that companies do not organize /succeed to exploit the IPRs themselves within a specific (beforehand defined) period.

7. Enable the participation of SMEs

To encourage the participation of SMEs and assure in its own right the possibility of purchasing the solutions arising from the R&S, despite the well-established practice, Lombardy Region has not used stringent qualification requirements as in procurements for large scale deployment (e.g. minimum

qualification requirements and financial guarantees proof, customer reference, provisional deposit…) but forward looking criteria which are objective and relevant in view of the subject-matter of the PCP and in particular a declaration of the ability to carry out all contractual activities and to have accounting and organizational structures to ensure the management, exploitation and / or transfer of IPRs arising from the research.

8. Enhance the competition during execution and facilitate innovation over the contract period (for PCP multiple sourcing and approach in phases, for PPI performance condition, lots….)

After confirmation - from the technical dialogue - of an innovation gap existence, an open, competitive and advertised pre-commercial public procurement has been run, coherently with COM (2007) 799, to de-risk the planned PPI.

The PCP implementation consists in a multiple-sourcing procurement of R&D services involving risk-benefit sharing with a competitive procedure in phases. The procurer will contract a number of competing suppliers, as they will develop R&D activities in parallel, with evaluations after each phase for selecting those that will continue to the next PCP phase for R&D services.

The on-going PCP contract results in three R&D phases (1. feasibility study, 2. technical design, 3. prototyping&testing&sperimentation), awarding parallel contract to a number of competing companies, keeping competition going between companies with evaluations of each company's performance after each project milestone, retaining at least 2 companies at the end, and assigning IPR ownership rights and leaving the opportunity to resell developed solutions to other markets afterwards to participating companies, in return for a financial compensation proportionated to sales.

9. Main lessons learnt

It’s necessary to involve and develop new specialized skills, with particular reference to economic and innovation management competences.

The effectiveness of PCP is determined by the goodness of the two preparatory phases: the user driven need assessment and the (advertised and open) technical dialogue with the market

The technical dialogue is not to be used to design the solution in a collaborative manner, but is finalized to obtain a better understanding of on-going industrial product developments in terms of solution availability and technological maturity. This process is fundamental to avoid opportunistic behavior from suppliers. It’s crucial to set aside the modus operandi that exceed regulatory requirements and to give up the practice of requiring stringent qualification and financial requirements

It’s crucial to provide an alignment between public and private objectives.