# ORIGINAL ARTICLE

# How primary care research can be improved in clinical practice? An Italian case study

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# ABSTRACT

BACKGROUND: Primary care is considered essential for the sustainability of the Health System, Practice-Based Research Networks (PBRN) play a strategic role in translation of primary care research into practice. Research Capacity Building in primary care requires a improvement and development strategy and well-developed research infrastructures to support physicians.

METHODS: We used the system development methodology referring to the Lean Thinking to create and support a research team in primary and pediatric care. In particular a "cascade" deployment model and the X-Matrix, a framework used in management studies to support strategy definition and management process.

RESULTS: A research unit in primary and pediatric care has been created, by sharing vision, mission, core values, long-

term strategies. The definition of a annual planning led to monitoring actions to guarantee the expected goals. CONCLUSIONS: Lean methodology is useful to adapt to various managerial and operational contexts, including healthcare. In our case it allowed team members to spread the culture of research, its importance and role to improve the health of patients, thank to the organizational support of a hospital IR, the Research and Innovation Department.

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KEY WORDS: Research; Primary health care; Public health infrastructure.

The World Health Organization considers the L primary care as a milestone of sustainable health systems.

In 2009 the World Organization of National Colleges, Academies and Academic Associations of General Practitioners/Family Physicians (WONCA) presented the Research Agenda for General Practice/Family Medicine and Primary Health Care in Europe, a reference for planning actions to fulfill evidence gaps and satisfy research needs. Research Agenda identified in research capacity building (RCB) the key development of quality, quantity, and impact of primary care research. RCB requires well-developed infrastructures to support good clinical practice with expert professionals, quality monitoring system, technological equipment and financial resources. 2-4

Practice-Based Research Networks (PBRN) play a strategic role in translation of primary care research into practice. PBRNs serve as instruments for improving research capacity building in primary care.

First PBRNs emerged in the 1960s in Netherlands, Canada, and Great Britain and later in the USA, where the number had grown substantially.<sup>5</sup> PBRNs primary aim was to improve outcomes for patients and practices, through a partnerships with experienced researchers engaged in asking clinical and organizational questions about primary healthcare and providing relevant and applicable evidence.<sup>6</sup>

Over the past 2 decades, PBRNs evolved into Health Improvement Networks by expanding their aims forward practice transformation, professional education, health care policy, quality improvement and engagement at numerous levels. Knowledge base and infrastructural support that currently exist to support primary care has not been everywhere adequate for the continuous challenges faced by health professionals.<sup>7,8</sup>

By evaluating publication UK researchers consistently placed among the best performers, compared to United States, Australia, Canada, Germany, and the Netherlands.<sup>9</sup>

Trends areas in primary care research publication between 2010 and 2020 were General Internal Medicine, Cardiology, Sociology, Psychiatry and Neurosciences/neurology. A systematic review, published in 2018, found that the most frequent health reasons to visit general practitioners (GPs), depending on the grade of countries developing, were respiratory tract infection, hypertension, routine health maintenance, arthritis, diabetes, depression or anxiety, pneumonia,

acute otitis media, back pain, and dermatitis.<sup>10</sup> That's the reason why it is mandatory to identify research needs in clinical practice in order to solve the gap between academic research and clinical care.<sup>11</sup>

Moreover the COVID-19 pandemic led to a heavy change in patient assistance at individual, organizational, interdisciplinary and social level. Por primary care, it has been an unprecedented wave of practice change, that motivated GPs to incorporate evidence-informed decision making and introduce technical upgraded instruments into everyday care practice. 8

In 2022 the WONCA reviewed the core values and principles of general practice and family medicine. Among the seven highlights, research in primary care represents a tool to increase medicine evidence and a start point to improve everyday practice. Foci are related to the relevant needs in GP care, performed with a constructive and academic approach.<sup>8</sup>

A recent work assessed the effectiveness of strategies to engage GPs in primary care research. Three different strategies, compensation/incentive, recruitment and support from a research network or an academic institution demonstrated a significant increase in participation rate.<sup>13</sup>

In this paper we present our work to create and support a research team in primary and pediatric care and how we tried to disseminate the culture of research, its importance and role to improve the health of patients.

This article focuses on the application of the logics, principles and tools of the Lean Strategy to the healthcare context, through the presentation and discussion of a case study developed with the action research methodology. The case relates to the Department of Research and Innovation, of the Public Hospital "SS Antonio e Biagio e Cesare Arrigo" of Alessandria (AO AL) in Piedmont region (Italy).

The European situation and the academic development in primary care is uneven, established in the National Health System or in the Universities, not always in both.

In Italy, universities have no primary care departments and general practice is not included in the undergraduate curriculum of Italian medical schools. The Regional Health System organizes a regional course to enable future GPs to practice. 14 Usually, private foundations conduct primary care research.<sup>15</sup> The Italian Society of General Medicine and Primary Care (SIMG), founded in 1982, promotes, enhances and supports the professional role of GP, in Italian, European and non-European healthcare organizations. It offers itself to public and private institutions as a scientific-professional referent of general medicine, with particular attention to training, research and continuous professional development activities. Many research projects are carried out in collaboration with national and international institutions (the Istituto Superiore Sanità, the Ministero della Salute, the Agenzia Italiana del Farmaco, the Centro Nazionale Ricerche, the World Health Organization). Scientific activities are organized into clinical areas, headed by a national area manager. The association also makes use of a research institute (Health Search) based in Florence, with the aim of developing epidemiological research and improving the quality of care. 16

From 1991 to 1993, some GPs carried out a National Cancer Registry by engaging hundreds of sentinel physicians active in 50 Italian provinces, who conducted a longitudinal observational study. These spontaneous groups attempted to carry out clinical research, but the lack of organizational and economic support prevented their continuation over time and their consolidation.

Primary care activities can really be recognized as a source of original knowledge. GPs and pediatricians play a key role in observational research and in clinical trials since the application of the Ministerial Decree of 2001. In the past two decades other groups of Italian GPs got involved in European academic organizations and networks to define and promote the active role of primary care in clinical research.

Currently the alarming lack of GPs concerns all Regions due to different reasons: lack of planning, early retirements, GPs with exorbitant numbers of patients and desertification in disadvantaged areas. This critical issue limits the opportunities for the development of primary care research, but a new possibility in structuring territorial assistance and a new hope for change comes from the Ministerial Decree n. 77 which provides for the reform of Territorial Medicine.

In the Piedmont Region, the function of supporting the governance of research and innovation activities of the Regional Health System was recently entrusted to the Research and Innovation Department (DAIRI), an inter-company department established between the Alessandria Hospital (AO AL) and the Local Health Authority (ASLAL), in collaboration with the University of Eastern Piedmont.<sup>17</sup> DAIRI has launched a research enhancement process in healthcare, the basis of a recognition as a Scientific Hospitalization and Care Institute.18 Scientific evidence attributes the main risk factor of many diseases to the environment, starting from the World Health Organization which indicates that around 24% of all diseases in the world are due to exposure to environmental factors<sup>19</sup> DAIRI started a research and clinical-assistance path to respond to the critical situation in the Alessandria territory, caused by the impact of environmental exposure to pollutants. DAIRI works to promote the consolidation of the research mission near to assistance. by having the main objective the improvement of the citizen's state of health. Through DAIRI, the collaboration with the University of Eastern Piedmont (UPO) has been strongly consolidated in the field of research, scientific activity, training, teaching and scientific consultancy.

DAIRI includes specific facilities (Clinical Trial Center, Grant Office, Biomedical Library, Biobank & Biorepository and Health Technology Assessment) that are essential to implement different types of research, such as:

- Preclinical Research (Research Laboratories);
- Clinical Research (Phase II-IV, Healthcare Profession research unit);
  - Translational Research (Disease Units);
- Population Research (Asbestos Health Center, Epidemiology, General Practitioners and Pediatricians research Unit);
- Managerial research (Health Management research group).

In particular, the Clinical Trial Center is a facility aimed at designing and conducting clinical trials by promoting efficiency in the activation, coordination, and management phase, according to the Good Clinical Practice (GCP) principles.

In line with the National Health Research

Program (PNRS),<sup>20</sup> DAIRI performed a Research Plan to define distinctive elements such as research governance, definition of priorities, assessment of the impact on citizens' health, dissemination of results and transfer of knowledge into clinical practice. The research lines of DAIRI are identified in the Plan, consistent with the national indications, regarding environmental pathologies, related asbestos pathologies and mesothelioma, pediatric gastrointestinal pathologies, non-Hodgkin's lymphoma, cardiac pathologies, perinatal pathologies, rehabilitation medicine, as well as possible areas of development in close collaboration with the University of Eastern Piedmont. The organizational and management strategy for the development of research and higher education provides for the creation of multidisciplinary research teams, named Disease Unit. The Disease Units represent a basic unit of translational medicine, the strategic tool to support and promote research, from bench to bed to community, in relation to the Scientific Institute for Research, Hospitalization and Healthcare (IRCCS) recognition process.

The General Strategy for the creation and development of the Disease Units refers to three fundamental pillars:

- 1. research: being a scientific reference for clinical, preclinical, epidemiological, and managerial research in healthcare, in network with other institutions;
- 2. internal processes: establishing interactions between company and inter-company structures, creating clinical-care pathways of excellence;
- 3. communication: ensure and promote the dissemination of activities and results to all the stakeholders.

Since 2019, eighteen Disease Units have been created.

In this paper we focus on the creation of a Disease Unit dedicated to research in primary care, composed by general practitioners, pediatricians, hospital specialists and researchers.

## Materials and methods

The approach known as Lean Thinking has undergone significant changes over time which today make it a real management philosophy.

Lean Strategy, also in health care context provides interested companies, with a complete and functional strategic management system aimed at creating a structured approach to managing corporate resources.<sup>21</sup>

To provide a systematic strategic planning approach and in order to manage the achievement of key objectives through a "cascade" deployment model, the Hoshin Karni method<sup>22, 23</sup> was chosen and applied, considered suitable in the creation phase of the Disease Units. Hoshin Karni is a systematic approach to define a strategy and management system that engages all people.

The system development methodology refers to Lean Thinking, a new way of organizing processes and activities in different scenarios, in order to eliminate waste, optimize resources and create more value for individuals.<sup>24, 25</sup>

Lean thinking encourages the practice of continuous improvement and it is based on the fundamental idea of people respect. The basis of performance management is the effective use of resources, the monitoring processes and results by the use of key performance indicators (KPIs).<sup>26,27</sup>

Lean approach was chosen to effectively involve the multidisciplinary team, with different experiences, all oriented towards a common goal with greater productivity and quality.

A annual planning has been defined to achieve the strategic objectives. Specific actions have been implemented by defining and involving dedicated people of the Unit. The objectives monitoring in line with national legislation and with the use of specific indicators, was carried out through a reporting system created ad hoc for the Unit.

The X-Matrix toll was chosen to align the general strategy to annual objectives, actions and results.

#### Results

Based on the framework shown in Figure 1, the process of defining the Unit development strategy was articulated according to the following steps:

- definition of vision, mission, core values and long-term strategies;
- strategic analysis of the context and determination of the strategic objectives;



Figure 1.—Lean Strategic Planning (Hoshin Kanri).

- definition of the annual objectives and actions that allow the achievement of the results;
  - implementation of the actions;
- control and monitoring in line with national legislation and with the use of specific indicators.

The core team was created by involving three GPs and one pediatrician, who in the past successfully carried out a research activity on primary care, several hospital clinicians (geriatrician, internist, pediatrician) and DAIRI staff.

They shared their own mission, reflecting on the deeper reasons on which the existence of a Unit dedicated to research in primary care into the DAIRI. The mission statement was the starting point for the subsequent phases of strategy development. It placed emphasis on the values creation process, implemented by the Unit and aimed at the main stakeholders: the patients, the community, the other colleagues, the Regional Health System. Core values, in fact, constitute the key principles inspiring the conduct of the team, to allow the explication of the corporate mission and, therefore, the achievement of the established strategic objectives. The core values represent the fundamental pillars on which everyone, within the organization, will direct their behaviors and actions and will establish partnerships with other entities.

Then the organization defined its future status, by becoming aware of the motivational drives that will guide the medium-long term development process of the Unit (Figure 2). The organizational commitment is one of the strongest, most predictable and direct positive effects of involving people around a convincing future state.

Once defined mission, vision and core values, the core team moved on to the next phase, represented by the strategic analysis of the competitive context of the Unit. A SWOT Analysis has been performed to focalize organization's internal strengths and weaknesses, opportunities to growth and improve and threats of external environment (Figure 3).

This phase ended up with the strategic goal to become a reference point for clinical and managerial research in primary care, focused on environmental disease, in the regional and national context. General Strategy applied to the Unit in primary and pediatric care research provides for these long-term objectives:

• understand why primary care research is useful for community health;

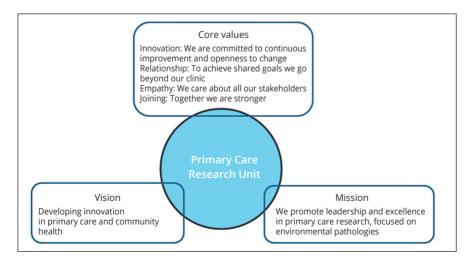
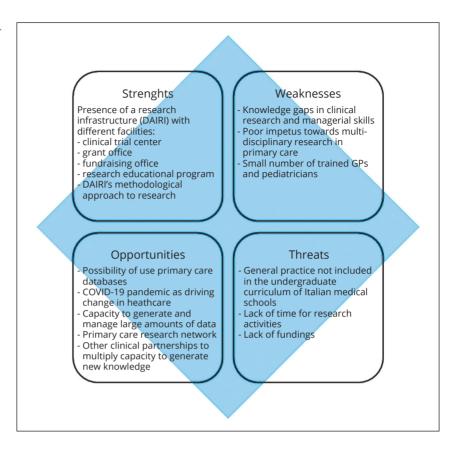


Figure 2.—Mission, vision e core values of the Unit.

Figure 3.—SWOT analysis.



- spread a culture of research among GPs and pediatricians;
- improve their research capacity building, communicative skills and establish relationships with other colleagues and other institutions.

In order to align the long-term strategy to daily activities, through the definition of a consensus X-Matrix, the core team developed a annual plan, in which operational objectives, actions and measurable indicators have been declined in different levels for the Unit improvement. Sharing and building the X-Matrix together allowed to provide a clear and concise vision of how long-term objectives can be declined into medium-term initiatives and how these can impact on main indicators (Figure 4).

Everyone activities have been considered vital to the project's successful execution, but few leaders had to be chosen for leading the completion of the activities, making them responsible for each operational objective.

To encourage the collaboration between the

team members and to share project progress, we organized dedicated meeting to carry out a gap analysis between the values of the measured metrics and the expected values. Ad hoc report has been created and updated each quarter to monitoring the progress of research activities.

## Discussion

For the achievement of a lean strategic planning and, above all, for the sustainability of its objectives over time, it is essential to leverage the following three key elements:

- · strategy sharing;
- · leadership;
- people engagement.

In this way, everyone becomes aware of an effective transformation and an actor in the change process which depends on own activity. GPs and pediatricians shared responsibilities across the Unit. Sharing represents a crucial aspect of the lean strategy conception and implementation process. All team members are respected and encour-

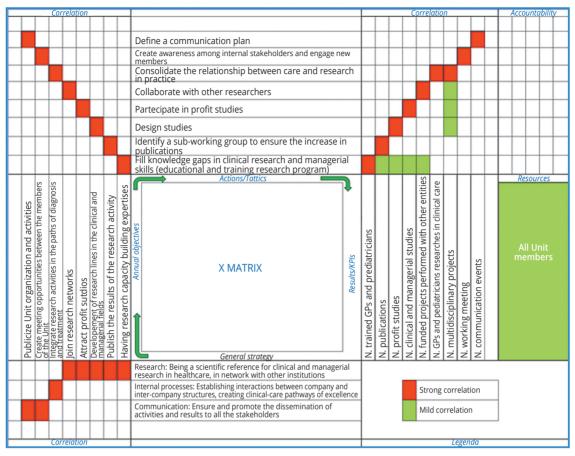


Figure 4.—X-Matrix.

aged to contribute ideas, and everyone is expected to continually improve and contribute to common goals. It requires a strong communicative effort, aimed at obtaining people's involvement and consent

The communication process does not end with the start of the scheduled activities. In fact, it is essential to communicate and keep all the members of the project team informed during the course of the activities. Monthly the core team met to evaluate critical issues and new opportunities to improve research capacity building. Effective communication made it possible to obtain true staff involvement.

Each leader has been chosen with the consensus of the core team, in relation on their own skills and interests, with the aim to guide working subgroups and obtain their confidence.

People engagement represents an advantage

tool to the growth and improvement of the organization through the integration of each contribution. An enthusiastic adhesion to innovation and the harmonization of different backgrounds, skills and ideas have been the main direct positive consequences. Teamwork has been a useful method for managing the Unit building process.

# Conclusions

Several considerations relating to case study have to be highlighted, on methodological point of view and reference context.

The first one concerns the choice made by DAIRI to adopt the strategy deployment of Lean principles to promote the Units increase, also in primary care. This methodology has been favorable to align the behaviors of the team, towards a common goal, by increasing awareness every-

one's contribution is fundamental to the achievement of corporate objectives.

The positive results of this intervention, and also of other Unit, could be of interest to other healthcare organizations engaged in similar process, thank to: clear goals, full team involvement, everyone's commitment in defining actions, constant monitoring and timely analysis, continuous alignment with the strategy. Lean methodology looks to be flexible and useful to adapt to various managerial and operational contexts.

In addition, referring to healthcare context, the team highlighted how essential is having a research infrastructure to promote, coordinate and support activities. A research infrastructure allows them to contribute new knowledge, to reduce the gap between hospital and territory thank to research, to improve the quality of care provided to patients.

In order to ensure progress in primary health care research, DAIRI offered solutions focused on the individual, team, and organizational levels. Applying lean methodology, DAIRI guaranteed a good functioning team, trained, stimulated and oriented to research.

Moreover, all the team members agreed the privileged position of GPs and pediatricians enable to care and follow a large number of patients, the ideal motivation to carry out scientific activity with relevance for clinical practice.

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## Conflicts of interest

The authors certify that there is no conflict of interest with any financial organization regarding the material discussed in the manuscript.

#### Authors' contributions

Conception and design: Annalisa Roveta, Guglielmo Pacileo, Mauro Cappelletti; project administration: Donatella Alesso, Alberto Bonissone, Lorenzo Fossati, Maria C. Giaccari, Fabio Maccapani, Camillo Milano, Nicolò Parodi, Federico Torregiani; supervision: Antonio G. Maconi, Luigi M. Castello; drafting the manuscript: Annalisa Roveta, Francesca Ugo; methodology: Francesca Ugo, Costanza Massarino. All authors read and approved the final version of the manuscript.

#### History

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